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The effect of daily wearing time on oxygen permeability of Opus III and Boston II contact lenses

Abstract
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Degree Type
Thesis

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THE EFFECT OF DAILY WEARING TIME ON OXYGEN PERMEABILITY OF OPUS III AND BOSTON II CONTACT LENSES

Scott Saki
Gary Stremcha
Brian Sullivan
Norman Wong

A Thesis submitted to the
Pacific University College of Optometry
in partial fulfillment of the requirements for the degree of Doctor of Optometry

Donald C. West O.D.
Advisor

March 15, 1985
Abstract

Ten subjects were fit with a Boston II and an Opus III gas permeable rigid contact lens, one on each eye. Oxygen permeability measurements were made on the new lenses and at each progress evaluation with a polarographic cell developed by Fatt and St. Helens. The data gathered was analyzed by multiple regression using dummy variables. The statistical analyse showed a decrease in permeability (Dk) that could be explained by surface deposits as a function of patient wearing time.
Introduction

Current trends in the contact lens field point to rigid gas permeable contact lenses as the lenses of the future, combining the optical quality of PMMA lenses and the oxygen transmissibility of hydrophillic lenses. Because the design of these lenses is similar to that of PMMA lenses, they provide a tear pumping mechanism which actively pumps oxygenated tears in, and waste debris out from under the lens. Many contact lens manufacturers have spent a great deal of time and money developing new materials that provide greater oxygen permeability, in fact high permeability is a major selling ploy in today’s market. Transmissibility (DK/L) appears to increase with every new gas permeable material developed. Some lens materials are even approaching transmissibility values high enough to be considered for extended wear. (14)

Several researchers have been studying the effects of surface and matrix contamination on the oxygen permeability of hydrophillic lenses. Fatt et. al. (11) found that calcium phosphate deposits, developed during wear, significantly reduced permeability in high water content soft contact lenses. Three articles by Fatt and Morris (10), Fatt et. al. (11), Refojo et. al. (27) found that protein deposits did not
reduce permeability significantly. Another study by Huth, Lannom, and Lannom (17) showed that in vivo and in vitro protein deposits did not reduce the oxygen permeability of polyHema lenses. However, studies by Benjamin and Hill (2) and Hill and Going (15) showed that in vitro developed protein films reduced oxygen permeability in Hema lenses. With hydrogel contact lenses the effect of lipid deposits has never been addressed in the literature.

It is known that silicone-acrylate lenses have poorer wetting properties than PMMA. (29) Another characteristic of silicone-containing materials is their affinity for deposits, a problem compounded by their poor wettability which makes the surface more susceptible to deposits. (29) Two other factors compounding the problem are the poor blinking habits of refit PMMA wearers and the fact that silicone-containing materials scratch easier than PMMA which causes increased deposit buildup. (29) In an article by Seidner and Sharp (29) they state that the major deposit component in rigid gas permeable lenses is lipid, with calcium and protein also being found. As seen in studies done on hydrogel lenses, (10, 11) calcium deposits have a significant negative effect on oxygen permeability and protein, most likely, does not produce any significant effect. Because lipids are the major deposits found on silicone-acrylate lenses, (29) it is
the purpose of this study to monitor the effect of surface
deposits, on the oxygen permeability of Boston II and Opus
III lenses as a function of a average daily wearing time over
a three month time period.

Materials and Methods

Thirteen subjects were selected on the basis of their
ocular health and refractive error; that is, myopes with
refractive astigmatism of 1.00 D or less, a spherical
component within the limits of stock lenses produced by the
manufacturers, and less than 1.50 D of with-the-rule corneal
toricity. Each was fit with a Boston II lens on one eye and
an Opus III lens on the other eye. The Boston II lenses were
provided through Columbia Bifocal of Portland, Oregon by
Polymer Technology and the Opus III lenses were provided by
Precision-Cosmet of Minneapolis, Minnesota. A study by Fatt
(6) found the permeability (Dk) of the Boston II lens to be
9.8 x 10^-11 ml Oz cm²/sec m1 mm Hg at 20 degrees celsius.
Precision-Cosmet (24) claims a Dk of 11.0 x 10^-11 ml Oz cm²/
sec m1 mm Hg at 21 degrees celsius for the Opus III lens.

Prior to dispensing, each lens was verified and its
permeability was measured using a polarographic cell
developed by Fatt and St. Helens. The cell was composed of a
4.05 mm diameter 24 karat gold cathode and a hollow silver cylinder for an anode with a thermistor bead in its wall to monitor cell temperature. Both were cast concentrically in an epoxy cylinder. The polarographic current was then amplified by a Createch polarographic amplifier. Cigarette paper saturated with saline solution having an average Dk/L of $3.95 \times 10^{-12}$ was placed between the cell and the lens, thereby keeping the lens surface wet. By multiplying the microampere reading of the amplifier by the calculated cell constant of $2.91 \times 10^{-9}$, microamps were converted to Dk/L. The Dk/L of the lens is obtained by subtracting L/Dk of the paper from the L/Dk of the lens plus the paper and then inverting the result. Permeability (Dk) is then obtained by multiplying Dk/L by the center thickness of the lens. Cell temperature was recorded with each transmissibility measurement.

Subject progress evaluations were scheduled each week for a month, at two months from dispense, and at three months from dispense. Each progress evaluation consisted of contact lens permeability measurement, overrefraction, biomicroscopy with and without the lenses, and post-removal keratometry and refraction.

Subjects are instructed to follow a strict care regimen of daily cleaning with Boston II cleaning solution, for the
Boston II lenses, and Allergan LC65, for the Opus III lenses, Nightly soaking in Boston II conditioning solution and Allergan Wet and Soak, for the Boston II and Opus III lenses respectively, was followed by each subject. One subject’s lens became excessively coated with some form of deposit between two evaluations. He was instructed to enzymatically clean the Boston II and the Opus III with Allergan Weekly Enzymatic Cleaner. There were no further coating problems following the weekly enzyme treatments.

Three subjects were eliminated due to poor adaptation and/or poor compliance with conditions set forth. Ten subjects achieved full-time wear thereby providing ten lenses of each brand for evaluation for the duration of the study.

At the end of the study the subjects were given the choice of keeping the lenses they were wearing or being refit with the brand of lens they preferred, providing them with a matching pair. Two subjects were refit from Opus III to Boston II.

A summary of the data collected appears in Appendix 1. This study is not intended to measure the absolute permeability of these lenses. Rather, it is intended to monitor any change in permeability of each lens; therefore, our permeability measurements may differ from the manufacturer’s and previous experimental findings.
Results

Of the lenses used in this study, two Opus III and three Boston II lenses had permeability measurements at all six intervals of the design; six Opus III and five Boston II lenses had five out of six measurements; one Opus and four Boston lenses had four out of six measurements; and one Opus and one Boston had three out of six measurements. The reason for the missing data stated above is that two subjects had to drive a considerable distance, week 8 progress evaluation fell on Christmas break, these problems account for thirteen of the twenty-two missing data sets. The remaining nine were the result of broken or lost lenses.

A multiple regression analysis was chosen to statistically evaluate the data due to the fact that three variables were interacting to effect the results: permeability, time, and temperature. Time and temperature are the independent variables and permeability is the dependent variable. The reason for two independent variables is that temperature was not controlled for. By using dummy variables for time and subjects in the regression equation the errors resulting from individual subjects or unequal time intervals were eliminated. This method also eliminates any
error resulting from the missing data sets. The following are results of the regression:

<table>
<thead>
<tr>
<th>variable</th>
<th>mean</th>
<th>s.d.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dk</td>
<td>9.71</td>
<td>2.10</td>
</tr>
<tr>
<td>Temp</td>
<td>17.12</td>
<td>0.87</td>
</tr>
<tr>
<td>Week</td>
<td>3.91</td>
<td>4.28</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>variable</th>
<th>b</th>
<th>significance</th>
<th>beta</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temp</td>
<td>0.266</td>
<td>0.336</td>
<td>0.111</td>
</tr>
<tr>
<td>Lens</td>
<td>-0.808</td>
<td>0.016</td>
<td>-0.193</td>
</tr>
<tr>
<td>P1</td>
<td>-0.477</td>
<td>0.510</td>
<td>-0.075</td>
</tr>
<tr>
<td>W12</td>
<td>-2.205</td>
<td>0.001</td>
<td>-0.391</td>
</tr>
<tr>
<td>P7</td>
<td>-1.135</td>
<td>0.134</td>
<td>-0.165</td>
</tr>
<tr>
<td>P8</td>
<td>1.876</td>
<td>0.060</td>
<td>0.193</td>
</tr>
<tr>
<td>P5</td>
<td>0.327</td>
<td>0.857</td>
<td>0.049</td>
</tr>
<tr>
<td>W2</td>
<td>-1.521</td>
<td>0.008</td>
<td>-0.263</td>
</tr>
<tr>
<td>P4</td>
<td>0.107</td>
<td>0.989</td>
<td>0.001</td>
</tr>
<tr>
<td>P3</td>
<td>0.342</td>
<td>0.661</td>
<td>0.048</td>
</tr>
<tr>
<td>W3</td>
<td>-1.272</td>
<td>0.027</td>
<td>-0.231</td>
</tr>
<tr>
<td>P6</td>
<td>-2.885</td>
<td>0.001</td>
<td>-0.419</td>
</tr>
<tr>
<td>P9</td>
<td>0.764</td>
<td>0.325</td>
<td>0.111</td>
</tr>
<tr>
<td>W1</td>
<td>-0.317</td>
<td>0.587</td>
<td>-0.059</td>
</tr>
<tr>
<td>P2</td>
<td>0.232</td>
<td>0.748</td>
<td>0.036</td>
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</table>
When interpreting these results one variable is analyzed and the others are controlled in regard to their predictability of Dk. The variables P6 and W12, with slopes (b) of -2.885 and -2.205 respectively, predict a decrease in Dk significant at the .001 level. At the .01 level W2 with slope of -1.521 significantly predicts a decrease in Dk and at the .05 level W3 with a slope of -1.272 significantly predicts a decrease. None of the other variables used in the equation for the regression significantly explained a decrease in Dk.

Another multiple regression was run, this time only using a dummy variable for subjects and time as an interval measurement. The following is a result of this regression:

<table>
<thead>
<tr>
<th>variable</th>
<th>b</th>
<th>significance</th>
<th>beta</th>
</tr>
</thead>
<tbody>
<tr>
<td>temp.</td>
<td>.245</td>
<td>.245</td>
<td>.102</td>
</tr>
<tr>
<td>lens</td>
<td>-.203</td>
<td>.019</td>
<td>-.193</td>
</tr>
<tr>
<td>P1</td>
<td>-.364</td>
<td>.618</td>
<td>-.057</td>
</tr>
<tr>
<td>P8</td>
<td>.190</td>
<td>.033</td>
<td>.219</td>
</tr>
<tr>
<td>P7</td>
<td>-1.104</td>
<td>.105</td>
<td>-.161</td>
</tr>
</tbody>
</table>
Interpreting the results of this regression is done in the same manner as the above regression. The variables Week and P6, with slopes of $-0.149$ and $-2.730$ respectively, predict a decrease in Dk significant at the .001 level.

From the regression equation the estimated Dk's of the two lenses can be compared. The estimated Dk for Boston equals .808 times the estimated Dk of Opus for the regression using the two dummy variables. From the regression using time as an interval measurement and subjects as a dummy variable, the estimated Dk for Boston equals .805 times the estimated Dk of Opus.

The Durbin-Watson test was used to determine if there was any correlation between independent variables. The first regression showed a value of 2.06 and the second regression
showed a value of 1.97. These values indicate that there is no auto-correlation.

Discussion

The statistical analyses run on the data collected throughout the course of this research indicate that oxygen permeability does decrease with patient wear over time. It also indicates that patient hygiene plays a role in permeability as demonstrated by the fact that patient six, who in the opinion of the experimentors had poor personal hygiene, showed a significant decrease in Dk. This patient’s Opus lens began with a Dk of 7.62 x 10^{-11} at 19.5 degrees celsius and ended with a Dk at week twelve of 4.51 x 10^{-11} at 18.7 degrees celsius. This study indicates, from the data collected, that a decrease in oxygen permeability with gas permeable rigid contact lenses can be expected with patient wear.

Several areas that could have been improved on in this study were: more precise temperature control, taking the Dk readings at a temperature of 35 degrees, and stricter patient compliance. More precise temperature control would have eliminated temperature as a third variable thereby making the statistics much simpler. Taking the Dk readings at a
temperature of 35 degrees celsius would more closely approximate in vivo conditions. Lastly, stricter patient compliance, progress attendance and lens hygiene, would provide a more complete, less variable data sets.

One feature of the regression equation that was not pursued was the ability to forecast estimated Dk. The second regression equation could be used to estimate Dk at anytime in the future. A larger number of data points and stricter patient compliance would be required to supply better data to analyze. The resulting regression equation would have higher Multiple R and R Square values. These higher values would state that the estimated Dk's are closer to the anticipated real Dk then we would be able to predict with an R Square of .460.

Acknowledgements

We would like to thank Dr. Donald C. West, Dr. Eileen Brennan, Kenneth Pike, and the University of Washington for their valuable assistance. We would also like to thank Precision-Cosmet and Polymer Technology for providing the contact lenses used in this study.
References


### APPENDIX I

<table>
<thead>
<tr>
<th>Lens</th>
<th>New Lens</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 8</th>
<th>Week 12</th>
</tr>
</thead>
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<tr>
<td>1</td>
<td>9.50/20.4</td>
<td>8.98/20.0</td>
<td>9.45/18.9</td>
<td>9.17/18.5</td>
<td>8.40/17.7</td>
<td>9.50/19.5</td>
</tr>
<tr>
<td>3</td>
<td>9.47/20.3</td>
<td>10.52/19.6</td>
<td>9.65/19.0</td>
<td>9.10/18.0</td>
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<td></td>
</tr>
<tr>
<td>4</td>
<td>9.38/19.6</td>
<td>9.79/19.3</td>
<td>8.28/19.6</td>
<td></td>
<td></td>
<td>8.72/19.4</td>
</tr>
<tr>
<td>5</td>
<td>9.99/19.6</td>
<td>10.78/19.7</td>
<td>9.93/19.2</td>
<td>9.46/19.0</td>
<td>9.93/18.5</td>
<td>10.24/18.8</td>
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<td>6</td>
<td>7.62/19.5</td>
<td>8.74/20.4</td>
<td>7.67/19.4</td>
<td>5.77/19.7</td>
<td></td>
<td>4.51/19.7</td>
</tr>
<tr>
<td>7</td>
<td>7.24/18.8</td>
<td>7.15/19.2</td>
<td>7.28/19.4</td>
<td>7.98/18.4</td>
<td></td>
<td>8.40/19.0</td>
</tr>
<tr>
<td>8</td>
<td>15.17/19.0</td>
<td>9.65/19.2</td>
<td></td>
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<td>11.58/19.3</td>
<td>10.04/19.6</td>
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<td>8.75/19.5</td>
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<td>9.59/17.5</td>
<td>10.93/18.1</td>
<td>9.63/19.5</td>
</tr>
</tbody>
</table>

### Opus III Dk / Temp.

<table>
<thead>
<tr>
<th>Lens</th>
<th>New Lens</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 8</th>
<th>Week 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>13.04/18.8</td>
<td>9.82/19.4</td>
<td>8.95/19.2</td>
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