A clinical evaluation of masking corneal astigmatism with Boston 2 gas-permeable contact lenses

Julie A. Ikeda
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A clinical evaluation of masking corneal astigmatism with Boston 2 gas-permeable contact lenses

Abstract
This study examined the flexure of the Boston II gas-permeable contact lens, while varying center thickness (.10mm, .14mm, .18mm) on with-the-rule corneas ranging from 1.12 to 1.11 D. All lenses were fit steeper than the flattest "K". It was found that contact lens with-the-rule flexure occurred on all the eyes studied, but it was seen to be less as center thickness was increased. The base curve-cornea fitting relationship and the amount of corneal toricity was found to significantly affect the amount of contact lens flexure.

Degree Type
Thesis

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A CLINICAL EVALUATION OF
MASKING CORNEAL ASTIGMATISM WITH
BOSTON II GAS-PERMEABLE CONTACT LENSES

INVESTIGATORS

Julie A. Ikeda
Dale E. Ogata
Kenneth T. Yamada

FACULTY ADVISOR

Don C. West, O.D.

Completed in Partial Fulfillment for the Degree
Doctor of Optometry

Pacific University College of Optometry
Forest Grove, Oregon

April 1984
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ACKNOWLEDGEMENTS

The completion of this study was facilitated by the assistance of many persons. We would like to extend our gratitude to our faculty advisor, Dr. Don C. West, for his many hours spent in guidance, consultation, and for furthering our knowledge in the field of contact lenses.

We would also like to express our thanks to Dr. Robert L. Yolton for imparting his insight into the data analysis, to the Pacific University College of Optometry clinical office staff for their assistance and cooperation in ordering lenses, and to Phi Theta Upsilon for providing a research grant that enabled greater flexibility in the project.

Finally, we extend our appreciation to Aquaflex for providing the Boston II gas-permeable contact lenses and solutions, and to Dr. Barry Kissack, Anne Frost, and Meg Coblio of Aquaflex, for their support and assistance throughout this study.
This study examined the flexure of the Boston II gas-permeable contact lens, while varying center thickness (.10mm, .14mm, .18mm) on with-the-rule corneas ranging from 1.12 to 3.31 D. All lenses were fit steeper than the flattest "K". It was found that contact lens with-the-rule flexure occurred on all the eyes studied, but was seen to be less as center thickness was increased. The base curve-cornea fitting relationship and the amount of corneal toricity was found to significantly affect the amount of contact lens flexure.
INTRODUCTION

There have been major advancements made regarding contact lens design within recent years. Improving various parameters such as wettability, stability, and oxygen transmissibility have been the major areas of concern.

The greatest single cause of failure with polymethyl methacrylate (PMMA) lenses has been corneal oxygen deprivation and the associated corneal physiological changes. With the advent of gas-permeable materials and thinner lens designs, oxygen transmissibility has been vastly increased. As a result, anoxia at the corneal surface has diminished.

The improvements in lens design have led to considerations regarding lens flexure and resulting residual astigmatism. Westerhout found very little correlation between hard contact lens flexure and corneal astigmatism. Bailey, Sarver, and Carter noted PMMA flexure in their respective studies on residual astigmatism. It is now generally accepted that flexure does occur under various conditions.

In the more recent literature, various studies have been conducted showing the effects of varying contact lens parameters on lens flexure. On spherical or near spherical corneas (ΔK < 0.50 D), PMMA lenses did not flex significantly or alter the residual astigmatism. However, significant flexure and changes in residual astigmatism were found on toric corneas. Lens flexure and residual astigmatism increased as center thickness decreased with lenses less than 0.13 mm thick. It is hypothesized that forces such as lid
pressure, adhesion, and surface tension have a greater influence on thin lenses. There was no significant lens flexure with thick lenses \((t > 0.13 \text{ mm})^{3,4,6}\).

Harris\(^3\) and Harris and Applequist\(^5\) studied the effects of lens diameter on lens flexure. They found that no correlation existed when contact lens diameter was varied with PMMA lenses.

Studies on corneal toricity and its effects on lens flexure have shown that they are positively correlated. As corneal toricity increases, lens flexure and residual astigmatism also increases\(^3,5,7,9\). Williams\(^9\) found that lens flexure in Polycons was 20-30% of the corneal toricity in with-the-rule astigmats up to 2.0 D of astigmatism. For higher degrees of with-the-rule astigmatism, the flexure for thinner lenses was most frequently 20% or less of the corneal toricity.

Using PMMA lenses, the base curve-cornea relationship was found to have no effect on lens flexure\(^8\). However, using Polycon lenses, the steeper the lens was fit, the greater was the lens flexure and with-the-rule astigmatism\(^7,9\). Fitting flatter than 'K' caused a decreased amount of flexure and an increase in against-the-rule astigmatism.

Harris and Applequist\(^5\) also studied the effects of the power of the contact lens on flexure. They found that with an increase in minus power, flexure and residual astigmatism decreased. They hypothesized that this was due to the increased edge thickness.

Previous studies have shown that neither overall diameter nor base curve have any significance with respect to lens flexure in PMMA lenses. The generalization of this statement to include gas-permeable contact lenses has been deemed premature until further
study has been conducted.6

It is the purpose of this study to evaluate the Boston II gas-permeable contact lens in masking corneal astigmatism. Contact lens parameters that will be varied include base curve, and center thickness.
A. Subject Selection

Twelve subjects were selected from a group of volunteers who desired to participate in a gas-permeable contact lens study. The usual screening for successful contact lens candidates was completed before fitting the lenses. This consisted of an eye examination including case history, keratometry, biomicroscopy, ophthalmoscopy, pachometry, and distance refraction findings. The criteria for subject selection was based upon:

1. Absence of ocular pathology
2. Availability for six months of study
3. Myopes or astigmats with .75 D or greater of corneal with-the-rule cylinder.
4. Previous hard or soft contact lens wearers who had not worn their lenses for the past six months and/or non-contact lens wearers.

B. Methodology

Data collection was performed at the Pacific University College of Optometry, Forest Grove clinic. Standard optometric equipment, including the phoropter, keratometer, and biomicroscope were used. Boston II lenses were supplied and manufactured by U.C.O. Optics, Inc.

The initial examination included all routine clinical tests. The base curve-cornea fitting relationship and the center thickness of the lens were the only parameters varied among patients. The lens overall diameter was 9.3 mm and of a bicurve design. The fit
of the lenses was evaluated by biomicroscopy, fluorescein pattern and lacrimal line:reference line ratio. After the appropriate base curve was selected, measurements were taken using lenses varying in center thickness only (.10 mm, .14 mm, .18 mm). Residual astigmatism was measured by an objective and subjective distance refraction. The residual refraction measured the amount of corneal cylinder masked by a given contact lens. Lens flexure was measured by the over contact lens keratometry readings. There were no modifications done on the lenses at any time during the data collecting period. Ten keratometer readings were taken and averaged, while four over-refraction measurements were performed per lens to evaluate stability of the lens on the eye. The same instrumentation and examiners were used to minimize experimental error.

A graphical analysis was completed on the collected data. This study was intended to evaluate the clinical performance of the Boston II gas-permeable contact lens in masking corneal cylinder of different magnitudes. This was determined by the amount of flexure of the lens on the toric corneas, and the resulting over-keratometry readings.
RESULTS

The findings of the study show that the amount of corneal astigmatism masked by the Boston II gas-permeable contact lens increased, as lens thickness increased. Additionally, the steeper the lens was fit, the greater the lens flexed as measured by keratometer readings over the contact lens.

The subjects' eyes were divided into groups according to how much steeper than the flattest "K" the contact lens was fit (Table 1):

<table>
<thead>
<tr>
<th>Group</th>
<th># of Eyes</th>
<th>Difference Between Flattest &quot;K&quot; and Base Curve of Lens (mm)</th>
<th>Average (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>10</td>
<td>.05 - .15</td>
<td>.127</td>
</tr>
<tr>
<td>II</td>
<td>8</td>
<td>.16 - .25</td>
<td>.200</td>
</tr>
<tr>
<td>III</td>
<td>2</td>
<td>.26 - .35</td>
<td>.295</td>
</tr>
<tr>
<td>IV</td>
<td>4</td>
<td>.36 - .45</td>
<td>.410</td>
</tr>
</tbody>
</table>

Figure 1 shows the relationship between the center thickness of the lens and the difference between "K" readings (Over-K) as measured over the three contact lenses (t=.10 mm, t=.14 mm, t=.18 mm). As indicated by the graph, in all four groups, the greater the lens thickness, the less was the residual corneal cylinder exhibited. This relationship was most prominent in Group IV, the most steeply fit group.
Figure 2 shows the relationship between 1) the fitting difference between the base curve and the flattest "K" (mm) of the subject's eye, and 2) the Over-K's measured for each of the three contact lens thicknesses. In all groups, as the contact lens thickness increased, the amount of flexure decreased. Also, the steeper the lens was fit, the greater the with-the-rule lens flexure.

For further analysis of the data, all eyes were categorized into five groups based on the amount of corneal cylinder present. They were as follows (Table 2):

**TABLE 2**

<table>
<thead>
<tr>
<th>Group</th>
<th>Amount of Corneal Cylinder (D)</th>
<th># of Eyes</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1.00 - 1.50</td>
<td>5</td>
</tr>
<tr>
<td>B</td>
<td>1.51 - 2.00</td>
<td>11</td>
</tr>
<tr>
<td>C</td>
<td>2.01 - 2.50</td>
<td>4</td>
</tr>
<tr>
<td>D</td>
<td>2.51 - 3.00</td>
<td>3</td>
</tr>
<tr>
<td>E</td>
<td>3.01 - 3.50</td>
<td>1</td>
</tr>
</tbody>
</table>

Figure 3 indicated that the greater the corneal toricity, the greater the lens flexed. As shown before, the amount of lens flexure decreased with increased lens center thickness. In all cases, the lenses flexed in the same direction as the steepest corneal meridian.
Center Thickness (mm)

FIGURE 1

Over ΔK x 180 (D)

1.20

1.00

0.80

0.60

0.40

0.20

0.10

0.14

0.18
Difference Between BC and Flattest K (mm)

FIGURE 2
FIGURE 3

Center Thickness (mm)

Over ΔK (D)

A
B
C
D
E
DISCUSSION

This study indicated that Boston II gas-permeable contact lens flexure is influenced by contact lens center thickness, on toric with-the-rule corneas. Thicker lenses appear to be more resistant to aforementioned forces such as lid pressure, adhesion, and surface tension, thereby decreasing the amount of residual astigmatism present as measured by Over-K's.

The base curve-cornea fitting relationship and the magnitude of corneal cylinder present, also affect the amount of lens flexure. The steeper a lens is fit, and the greater the corneal cylinder, the more a lens will flex. The base curve-cornea influence on lens flexure found in this study agrees with previous literature, as does the amount of corneal cylinder influence.

Previous studies on PMMA lens flexure on toric corneas have indicated that the parameters that influence the amount of residual astigmatism are center thickness, amount of corneal toricity, and power. Overall diameter and base curve have been shown to have no effect.

Studies on gas-permeable contact lens flexure on toric corneas have indicated that the amount of residual astigmatism is influenced by center thickness, the amount of corneal toricity, and the base curve-cornea relationship. It has been suggested that as a lens is fit steeper, less of the lens surface is in contact with the eyelid due to lower lens positioning on the cornea, resulting in less lid tension on the lens. This allows the lens to conform to the corneal surface in the direction of with-the-rule flexure on a with-the-rule cornea.
CONCLUSIONS

This study examined the flexure of contact lenses, while varying the center thickness on with-the-rule toric corneas. All subjects were fit steeper than the flattest "K", using a clinically acceptable fitting relationship. With the exception of center thickness, identical lens parameter Boston II gas-permeable contact lenses were utilized on eyes ranging from 1.12 to 3.31 D of corneal cylinder. The results of the study were:

1) The thinner the contact lens, the greater the flexure on toric with-the-rule corneas, which consequently resulted in greater amounts of residual astigmatism.

2) The use of Boston II contact lenses were found to mask significant amounts of with-the-rule corneal cylinder, showing greater masking ability as the thickness of the lens was increased.

3) Contact lens base curve-cornea fitting relationship and the amount of corneal cylinder significantly affect the amount of flexure of the contact lens. The effects increase as the contact lens center thickness decreases.

This study has shown that contact lens center thickness, the amount of corneal toricity, and the base curve-cornea relationship, all influence lens flexure on with-the-rule corneas.
It is therefore necessary to consider the effects of these parameters when fitting gas-permeable contact lenses. If the corneal toricity is of a large magnitude, it would be best to use a thicker lens and fit as flat as possible to insure maximum acuity for the patient. With less toric corneas, one can utilize increased lens thickness to offset a steeper fitting lens, in order to maintain an acceptable visual acuity level for the patient.
# APPENDIX A - SUBJECT DATA*

<table>
<thead>
<tr>
<th>NAME</th>
<th>FLAT K</th>
<th>t=.10 mm Over-K</th>
<th>t=.14 mm Over-K</th>
<th>t=.16 mm Over-K</th>
</tr>
</thead>
<tbody>
<tr>
<td>BH</td>
<td>1.937</td>
<td>1.463</td>
<td>0.901</td>
<td>0.323</td>
</tr>
<tr>
<td>BH</td>
<td>1.850</td>
<td>0.923</td>
<td>1.172</td>
<td>0.750</td>
</tr>
<tr>
<td>DF</td>
<td>2.424</td>
<td>1.086</td>
<td>1.224</td>
<td>0.948</td>
</tr>
<tr>
<td>LT</td>
<td>1.949</td>
<td>1.036</td>
<td>1.248</td>
<td>0.924</td>
</tr>
<tr>
<td>SST</td>
<td>1.499</td>
<td>0.850</td>
<td>0.590</td>
<td>0.336</td>
</tr>
<tr>
<td>SST</td>
<td>1.637</td>
<td>0.623</td>
<td>0.714</td>
<td>0.312</td>
</tr>
<tr>
<td>KS</td>
<td>1.862</td>
<td>0.861</td>
<td>0.922</td>
<td>0.454</td>
</tr>
<tr>
<td>NS</td>
<td>1.600</td>
<td>0.788</td>
<td>0.836</td>
<td>0.351</td>
</tr>
<tr>
<td>JH</td>
<td>1.122</td>
<td>1.023</td>
<td>0.623</td>
<td>0.385</td>
</tr>
<tr>
<td>JH</td>
<td>1.634</td>
<td>1.123</td>
<td>1.010</td>
<td>0.573</td>
</tr>
<tr>
<td>DM</td>
<td>1.826</td>
<td>1.204</td>
<td>0.623</td>
<td>0.348</td>
</tr>
<tr>
<td>DM</td>
<td>2.260</td>
<td>1.060</td>
<td>0.193</td>
<td>0.436</td>
</tr>
<tr>
<td>RHo</td>
<td>2.497</td>
<td>1.048</td>
<td>0.713</td>
<td>0.747</td>
</tr>
<tr>
<td>RHo</td>
<td>2.191</td>
<td>0.860</td>
<td>0.936</td>
<td>0.860</td>
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<tr>
<td>RHu</td>
<td>1.886</td>
<td>1.171</td>
<td>0.941</td>
<td>0.660</td>
</tr>
<tr>
<td>RHu</td>
<td>1.773</td>
<td>1.323</td>
<td>0.817</td>
<td>0.842</td>
</tr>
<tr>
<td>LG</td>
<td>1.315</td>
<td>1.250</td>
<td>0.895</td>
<td>0.396</td>
</tr>
<tr>
<td>LG</td>
<td>1.647</td>
<td>1.145</td>
<td>0.948</td>
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<tr>
<td>KH</td>
<td>2.511</td>
<td>2.215</td>
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<td>1.272</td>
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<td>KH</td>
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<td>2.674</td>
<td>1.922</td>
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<tr>
<td>SSA</td>
<td>2.964</td>
<td>1.787</td>
<td>1.736</td>
<td>0.737</td>
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<tr>
<td>PC</td>
<td>0.998</td>
<td>0.923</td>
<td>0.786</td>
<td>0.736</td>
</tr>
<tr>
<td>PC</td>
<td>1.013</td>
<td>0.513</td>
<td>0.573</td>
<td>0.579</td>
</tr>
</tbody>
</table>

* All data are an average of ten readings in diopters.
**APPENDIX A - SUBJECT DATA**

<table>
<thead>
<tr>
<th>NAME</th>
<th>SPHERE</th>
<th>CYLINDER</th>
<th>BASE CURVE-CORNEA DIFFERENCE STEEPER THAN FLATTEST &quot;K&quot; (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BH</td>
<td>-1.75</td>
<td>-0.75</td>
<td>0.15</td>
</tr>
<tr>
<td>BH</td>
<td>-1.50</td>
<td>-1.00</td>
<td>0.15</td>
</tr>
<tr>
<td>DF</td>
<td>-5.25</td>
<td>-1.50</td>
<td>0.29</td>
</tr>
<tr>
<td>DF</td>
<td>-6.75</td>
<td>-1.00</td>
<td>0.22</td>
</tr>
<tr>
<td>SS t</td>
<td>-8.00</td>
<td>-0.75</td>
<td>0.15</td>
</tr>
<tr>
<td>SS t</td>
<td>-6.25</td>
<td>-1.00</td>
<td>0.13</td>
</tr>
<tr>
<td>NS</td>
<td>-3.50</td>
<td>-1.25</td>
<td>0.09</td>
</tr>
<tr>
<td>NS</td>
<td>-3.25</td>
<td>-0.75</td>
<td>0.09</td>
</tr>
<tr>
<td>JH</td>
<td>-2.00</td>
<td>-0.50</td>
<td>0.20</td>
</tr>
<tr>
<td>JH</td>
<td>-1.25</td>
<td>-1.00</td>
<td>0.19</td>
</tr>
<tr>
<td>DM</td>
<td>-6.25</td>
<td>-1.00</td>
<td>0.14</td>
</tr>
<tr>
<td>DM</td>
<td>-5.50</td>
<td>-0.50</td>
<td>0.18</td>
</tr>
<tr>
<td>RHo</td>
<td>-0.50</td>
<td>-2.50</td>
<td>0.13</td>
</tr>
<tr>
<td>RHo</td>
<td>-1.25</td>
<td>-1.50</td>
<td>0.15</td>
</tr>
<tr>
<td>RHu</td>
<td>-3.75</td>
<td>-1.00</td>
<td>0.30</td>
</tr>
<tr>
<td>RHu</td>
<td>-3.00</td>
<td>-1.25</td>
<td>0.18</td>
</tr>
<tr>
<td>LG</td>
<td>Plano</td>
<td>-0.75</td>
<td>0.09</td>
</tr>
<tr>
<td>LG</td>
<td>Plano</td>
<td>-0.75</td>
<td>0.25</td>
</tr>
<tr>
<td>KH</td>
<td>-1.00</td>
<td>-0.50</td>
<td>0.45</td>
</tr>
<tr>
<td>KH</td>
<td>-0.50</td>
<td>-0.50</td>
<td>0.39</td>
</tr>
<tr>
<td>SSa</td>
<td>-5.00</td>
<td>-3.00</td>
<td>0.41</td>
</tr>
<tr>
<td>SSa</td>
<td>-5.00</td>
<td>-3.00</td>
<td>0.39</td>
</tr>
<tr>
<td>PC</td>
<td>-0.25</td>
<td>-1.00</td>
<td>0.19</td>
</tr>
<tr>
<td>PC</td>
<td>Plano</td>
<td>-1.00</td>
<td>0.25</td>
</tr>
</tbody>
</table>

* Sphere and Cylinder in diopeters.
PART A

1. **Institution**
   **Title of Project:** A Clinical Evaluation of Masking Corneal Astigmatism with Boston II Gas-Permeable Contact Lenses

   **Principal Investigators:** Julie A. Ikeda 357-3664
   Dale E. Ogata 357-8639
   Kenneth T. Yamada 357-8290

   **Advisor:** Don C. West, O.D. 357-6151 ext. 284

   **Location:** Pacific University College of Optometry
   Forest Grove, Oregon

   **Date:** 1983

2. **Description of Project**
   This study is designed to investigate a new gas-permeable contact lens (Boston II), with respect to measuring flexure (bending) of the contact lens on a non-spherical front eye (cornea) surface. Information obtained from this study shall contribute to approval by the Food and Drug Administration. Measurement of the curvature of the front surface of the eye will be done using two commonly used optometric instruments (keratometer and keratoscope). Front surface irregularities will be monitored by an instrument that measures front eye surface (cornea) thickness and also a microscopic lamp.

3. **Description of Patient Involvement**
   A) You must be available for progress examinations for a duration of six months, starting the day of dispensing of the contact lens.
   B) After the initial dispensing, examinations shall be conducted after thirty minutes, one week, one month and each month thereafter for six months.
   C) On the day of the examination, you must wear the contact lenses for at least four to six hours before the exam.
   D) A deposit of $30.00 will be required to become a subject of this experiment. Half of this ($15.00) will be refundable at the end of the experiment if all appointments are made and all instructions are followed as deemed possible by the investigators.

4. **Description of Risks**
   The possibilities of risks pertaining to the wearing of daily wear contact lenses and the use of new lens material are discussed on **PART B** of this release form. Please read and
understand that information before continuing.

A tear dye will be used as a precorneal (front surface eye) film dye to evaluate contact lens performance in the routine clinical manner. Subjects should be aware that practically no adverse effects have been associated with its use.

Allergic reactions have been seen to occur with the contact lens solutions. If this occurs, we will give you a different type of contact lens solution. If this problem still occurs, we will ask you to not continue with the experiment.

It is the responsibility of the subject to immediately report to the investigators any unusual or adverse symptoms as described in PART A. If vision is blurred, you are cautioned not to drive or participate in any activity requiring clear vision.

5. Compensation and Medical Care
If you are injured in this experiment it is possible that you will not receive compensation or medical care from Pacific University, the experimenters or any organization associated with the experiment. However, all reasonable care will be used to avoid injury.

6. Alternatives to Wearing Investigational Contact Lenses for Vision Correction
If for any reason the investigators decide that you are unable to participate in the study, you will be formally withdrawn from the project and fully refunded the deposit once the lenses are returned. You will then have the options of:
A) Using no visual correction.
B) Wearing spectacles.
C) Wearing another form of contact lenses.

All forms of these corrections shall be prescribed by your own practitioner or be referred to the Pacific University Optometry Clinic as a general patient, subject to all regular fees.

7. Benefits to Subjects
A) You will contribute in the advancement of clinical contact lens research.
B) A pair of contact lenses shall be received. You will pay thirty dollars as an initial deposit for your pair of lenses. At the completion of the study, half of your deposit will be refunded if there have been no extraneous costs incurred during the study (i.e. replacement of lost or damaged contact lenses).
C) All contact lens fitting and evaluation exam fees shall be waived in this research study.
D) All aspects of patient care will be provided for a period ending six months after the patient has received his contact lenses.
8. **Offer to Answer Any Inquiries**
The experimenters are willing to answer any questions or explain any procedures during the course of this study. They may be contacted through the Pacific University Optometry Clinic (Phone Number: 357-6151 ext. 208) or at home (Phone numbers are listed on first page of this form). If you are not satisfied with your communications with the experimenters, call Dr. James Peterson, at 357-0442.

9. **Lost or Damaged Lenses**
All efforts by the investigators shall be made to replace the contact lens without any cost to you. However, if this is not possible, paying for the new contact lens will be your obligation.

10. **Freedom to Withdraw**
You are free to withdraw your consent and to discontinue participation in this project at any time without prejudice to you. If you should decide to withdraw before the six month period, the amount of fifteen dollars shall be returned on receipt of the pair of undamaged investigational lenses and the remaining fifteen dollars of the original deposit will not be refunded. The experimenters are not held responsible for adverse effects from the lenses experienced by subjects who withdraw and fail to return the contact lenses. Consecutive failure to keep your appointed examinations will be considered as a withdrawal from the study.

I have read and understand the above. I am eighteen years of age or older.

Printed Name __________________________________________

Patient's Signature ____________________________________

Date __________________________________________________

Address _______________________________________________

Phone _________________________________________________

Name and address of a person not living with you who will always know your address __________________________________________________

_____________________________________________________

Don C. West, O.D.                                        Julie A. Ikeda

Dale E. Ogata                                            Kenneth T. Yamada

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INFORMED CONSENT AND AGREEMENT
EVALUATION OF CONTACT LENS AND SUPPORTING SOLUTIONS

To:

Name: ____________________________
Address: __________________________
City: ____________________________ State: ____________

From:

Investigator-Practitioner: ____________________________
Study Sponsor: ____________________________

Investigational Lens: THE BOSTON LENS® Contact Lens □ Clear □ Grey □ Blue □ Green
Investigational Solutions: THE BOSTON LENS® Conditioning Solution – THE BOSTON LENS® Cleaner

I understand that the purpose of these tests is to determine the safety and effectiveness of contact lenses and their supporting solutions. I understand that the contact lenses and solutions have been approved for human use testing by an Institutional Review Board but that such lenses and solutions are for investigational use only and have not been approved by the U.S. Food and Drug Administration for sale. Generally, I have been advised and understand that the Boston Lens® and its supporting solutions have been available to patients in Canada and other foreign countries for several years and that the lenses and solutions have not revealed any risks or hazards associated with their use that are any different than those associated with the contact lenses approved for sale in the United States. I understand as well that certain laboratory safety testing (toxicological testing and microbiological testing) of the Boston Lens® and its supporting solutions is now in progress.

I understand and agree that I will wear the contact lenses on a daily basis only in accordance with the written instructions attached hereto entitled Instructions For Patients Participating in the Investigation of The Boston Lens® Contact Lens and its supporting solutions. I also understand that I must return to see the investigator-practitioner for examination under a schedule that will be provided to me.

I understand that The Boston Lens® Contact Lens is intended for daily wear only. I understand that the potential risks associated with daily wear of Boston Lens® Contact Lenses and use of its supporting solutions are as follows:

- Abrasion of the eye and distortion of vision have been reported but are usually temporary and short-lived.
- In rare instances, corneal scarring, growth of blood vessels into the cornea, temporary decreased vision, and infections of the eye requiring treatment may occur.
- I understand that I have the choice of the following available alternatives to the use of the investigational Boston Lens® Contact Lens:
  - Wearing no visual correction.
  - Wearing U.S. Food and Drug Administration approved contact lenses.
  - Wearing conventional hard contact lenses and some other visual aid that my practitioner might prescribe.

I further understand that if any injury to me occurs during the course of this investigation, that neither the investigator-practitioner nor the sponsor will undertake to provide free medical care.

ITNESS WHEREFP, I have executed the foregoing this ______________ day of ____________________, 19________.

__________________________ ____________________________
ISS: PATIENT:

__________________________ ____________________________
SIGNATURE SIGNATURE

Address: ____________________________

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REFERENCES


