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A clinical comparison between the Boston Envision and a spherical tricurve RGP on moderately and highly toric corneas

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A clinical comparison between the Boston Envision and a spherical tricurve RGP on moderately and highly toric corneas

Abstract
A clinical comparison was made between the Boston Envision aspheric rigid gas permeable (RGP) lens and a spherical tricurve RGP lens on a population with moderately or highly toric corneas. Twenty subjects with greater than 1.00 D of corneal astigmatism wore a Boston Envision lens in one eye and a spherical Boston RXD tricurve lens in the other eye for one month. Each subject was administered a questionnaire asking for a rating of clarity of vision, consistency of vision and physical awareness of each lens. Forced choice comparisons were made between the two designs based on clarity of vision, comfort and overall preference at the dispense, one week and one month follow-up visits. Objective comparisons made were based on differences in corneal staining and changes in keratometry readings and corneal refraction. Subjectively, consistency of vision was found to be significantly better with the tricurve lens and a trend towards preference of the tricurve based on physical awareness of the lenses was seen. End of study responses of the forced choice comparisons revealed no significant difference between the two designs. Objectively, corneal flattening was significant in the steep meridians of both the spherical and aspherical design. Both lenses were found to be acceptable in this study and very few differences were observed that could be attributed to design.

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A CLINICAL COMPARISON BETWEEN THE
BOSTON ENVISION AND A SPHERICAL
TRICURVE RGP ON MODERATELY AND
HIGHLY TORIC CORNEAS

by

Daniel Hyduchak
Jennifer Kucala
Colleen Renchko

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Advisor:

Cristina M. Schnider, O.D.
A CLINICAL COMPARISON BETWEEN THE BOSTON ENVISION AND A SPHERICAL TRICURVE RGP ON MODERATELY AND HIGHLY TORIC CORNEAS

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Daniel Hyduchak was born and raised in Southern California, attended California Polytechnic State University, and received his BS in Biological Sciences in 1988. Daniel lives with his wife Sandy in Forest Grove, OR, and is presently attending Pacific University College of Optometry. Daniel plans to practice in the Pacific Northwest.

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Jennifer Kucala was raised in Kodiak, Alaska and lived in Anchorage for several years. She received her B.S. degree in 1990 from Pacific University in Forest Grove, Oregon where she is currently a fourth year optometry student. Upon graduation in May 1993 she anticipates completing a residency in contact lenses and then integrating a career in a private primary care optometry practice with clinical contact lens research.

COLLEEN RENCHKO

Colleen Renchko was born and raised in Calgary, Alberta, Canada. She graduated from the University of Calgary with a Bachelor of Science degree in Zoology in 1989. She will be receiving her Doctor of Optometry degree in May, 1993 from Pacific University in Forest Grove, Oregon. Upon graduation she plans to return to Canada to begin a career in primary care optometry with an emphasis on contact lens work.
ABSTRACT:

A clinical comparison was made between the Boston Envision aspheric rigid gas permeable (RGP) lens and a spherical tricurve RGP lens on a population with moderately or highly toric corneas. Twenty subjects with greater than 1.00 D of corneal astigmatism wore a Boston Envision lens in one eye and a spherical Boston RXD tricurve lens in the other eye for one month. Each subject was administered a questionnaire asking for a rating of clarity of vision, consistency of vision and physical awareness of each lens. Forced choice comparisons were made between the two designs based on clarity of vision, comfort and overall preference at the dispense, one week and one month follow-up visits. Objective comparisons made were based on differences in corneal staining and changes in keratometry readings and corneal refraction. Subjectively, consistency of vision was found to be significantly better with the tricurve lens and a trend towards preference of the tricurve based on physical awareness of the lenses was seen. End of study responses of the forced choice comparisons revealed no significant difference between the two designs. Objectively, corneal flattening was significant in the steep meridians of both the spherical and aspherical design. Both lenses were found to be acceptable in this study and very few differences were observed that could be attributed to design.

KEY WORDS:

Rigid Gas Permeable lens, contact lens, comfort, fitting, spherical, aspherical, Envision, RXD, astigmatism.
INTRODUCTION:

As far back as the mid 1800's, Helmholtz described the anterior corneal surface as non-spherical and most closely resembling the shape of an ellipse. The pioneers of corneal contact lens design recognized the cornea's flattening contour and sought to emulate the elliptical shape through a series of progressively flatter spherical peripheral curves. The progression of spherical rigid lenses from monocurve to bicurve to multicurve blended has been, at least in part, an attempt to match more closely the corneal topography. The development of aspheric lens geometries in the mid-1960's simply represented the next logical step in the evolution of rigid CL designs.

The designers of the Envision lens sought to create a junctionless posterior surface and increase the area of the posterior lens surface in alignment with the anterior cornea. The overall contour and edge were designed to lift the lens up under the lid, thus making the lens more comfortable. The broader aspheric/corneal alignment is said to more evenly distribute lid and tear adhesion forces. In clinical terms, this should translate into less decentration, enhanced movement characteristics, and greater stabilization. The broader alignment might also spread the pressure gradient of the lens over a wider area of the cornea to reduce mechanical trauma, and should decrease flare since there are no abrupt junction zones.

The ability of aspherics to correct high corneal cylinders is also a major benefit of their design. The usual progression of lens choice in clinical practice for the high astigmatic patient is usually soft torics (due to
ease of adaptation), spherical RGP lenses (which can flex and decenter), and then bitoric rigid lenses. Bitorics are usually a last option due to the perceived difficulty practitioners have in fitting these lenses. Aspheric lenses, however, are an option which can be placed between the spherical RGP lens and the bitoric lens in the fitting succession. Previous studies found that aspherics performed optically more consistently than did soft toric lenses, and patients found the comfort of aspherics to be almost equivalent to their soft toric lenses\textsuperscript{3,6,7}.

Studies have suggested that aspheric lenses also provide several advantages to practitioners and simplifies the trial fitting process\textsuperscript{4,7,8}. A preprogrammed back surface eliminates the need to specify optic zone and peripheral curve parameters\textsuperscript{4,7,8}. Ames et al have also demonstrated a given aspheric base curve will fit a wider range of corneal curvatures than a spherical base curve thereby reducing the number of base curves required in a fitting set by 50\%\textsuperscript{4,7,8}.

If these assumptions are true, one would expect the fitting characteristics and patient satisfaction of RGP lens wear to differ between an aspheric and a spherical base curve lens design. The purpose of this study was to compare the fitting characteristics, comfort, and consistency of vision of an aspheric and a spherical rigid lens design and provide a preliminary assessment of claims of performance differences.
METHODS AND MATERIALS:

Subjects

Twenty-three subjects were solicited via press releases, newspaper advertisements, and by reviewing current clinic patient records. Subject criteria included being pre-presbyopic and having corneal astigmatism greater than 1.00 D in each eye with less than 1.00 D corneal anisometropia. Each subject was given a comprehensive vision evaluation prior to the contact lens fitting exam to rule out systemic or ocular disease which would contraindicate contact lens wear.

Lens Design and Fitting

Polymer Technology Corporation (PTC) manufactures the Envision lens out of fluorosilicone acrylate RXD material (DK of 45). In order to keep as many of the study variables the same, the tricurve lens was also manufactured in RXD material. All lenses were manufactured by the Paracon Contact Lens Manufacturers of Portland, OR which is an authorized distributor of both RXD spherical RGP's and Boston Envision lenses.

The aspheric Envision lens has a biaspheric posterior surface composed of an elliptical central zone of approximately 7 mm surrounded by a hyperbolic zone which extends to the lens periphery. This posterior surface is characterized by the absence of a distinct junction between the central and peripheral zones of the lens which reduces points of lens-cornea bearing and greatly improves long term comfort. The tricurve lenses had an optic zone 1.4 mm smaller than the overall diameter. The peripheral curves were based on a local labs standard design and were calculated to achieve standard axial edge lift values between 80 and 120 mm. All lenses were lenticulated to approximate a -3.00 D lens edge.
The lens parameters used in this investigation included a diameter of 9.3 mm or a 9.6 mm. The requested center thicknesses ordered ranged from 0.12 to 0.20 mm with an average thickness of 0.15 mm for both lens designs and never varied more than 0.10 mm between designs on the same patient.

By random selection, each subject had a spherical tricurve lens assigned to one eye and an aspheric Boston Envision lens assigned to the other eye. The initial diagnostic lenses were selected according to the fitting guides provided by PTC. The fits were adjusted to achieve apical alignment with good edge lift, centration and movement for each design. An acceptable fit was one that geometrically centered over the pupil or slightly superior, with the upper portion of the lens tucked under the lid after blink, and moved 1.0-2.0 mm with each blink. Centration is important with aspheric lenses since decentered aspheric lenses may elicit a residual astigmatic over-refraction.

All twenty three subjects were initially dispensed Alcon Soclens Wetting and Soaking solution and Alcon Opti-Clean II Daily Cleaner. At study completion, one subject had switched to an alternate lens care system due to an allergic reaction to thimerosal. All subjects wore their lenses on a daily wear basis for a minimum of 8 hours a day. Those patients not previously adapted to RGP wear began wearing their lenses 4-6 hours the first day and increased wearing time each day. The subjects were encouraged to remove their lenses if they had any concerns about ocular trauma, red eyes, excessive discomfort with the lenses on, or any other concerns regarding their ocular health.
Clinical Procedures

The following variables were assessed at the dispense, one week, and one month follow up visits: over refraction, visual acuity, central and peripheral fluorescein pattern, slit lamp exam with and without the lenses, horizontal and vertical positioning, movement, corneal staining, comfort, lens off manifest refraction, and lens off keratometry. A subjective questionnaire assessing clarity of vision, consistency of vision and physical awareness of the lenses was filled out 15 minutes after lens insertion at dispensing, and at every follow up visit by the patient. At each visit the subjects were also asked to make forced choice comparisons between the two designs based on clarity of vision, comfort, and overall preference.

Data Analysis

Data were entered on a Macintosh computer and analyzed using the StatView statistical analysis package. Scaled data were analyzed using the Wilcoxon signed-rank method for two correlated or matched samples. Parametric data were analyzed with a two-tailed t-test for paired samples. Forced choice comparisons were analyzed using a one group Chi Square analysis (observed versus expected frequency), with a 50:50 chance level selected as expected. An alpha level of 0.05 was used to define statistical significance for all statistical procedures.

RESULTS:

Baseline Data

A total of twenty subjects completed the study. Of the original twenty-three that began, two dropped out due to disinterest and one subject could not adapt to the lenses due to ocular side effects of a seasonal allergy. The patients presented with a varied history of lens wear, as six
were presently wearing RGP lenses, eight wore daily wear soft contact lenses (DWSCL), and one wore polymethyl methacrylate (PMMA) lenses. The subject data is summarized in Table 1.

<table>
<thead>
<tr>
<th>Table 1. Patient Data and Refractive Error</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data</strong></td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Refractive Error-flat meridian</td>
</tr>
<tr>
<td>Refractive Error-steep meridian</td>
</tr>
<tr>
<td>Keratometry-flat meridian</td>
</tr>
<tr>
<td>Keratometry-steep meridian</td>
</tr>
</tbody>
</table>

| Cylinder Axis                             | 33 With the Rule |
| Gender                                    | 8 male, 12 female |

**Subjective Responses**

Subjectively, there was no statistical difference in clarity of vision between the two lens designs. Consistency of vision, however, was significantly better with the tricurve (p=.024) (Fig. 1 and Table 2).
Subjective Responses of Clarity and Consistency of Vision

![Bar graph showing clarity and consistency of vision results](image)

**Fig. 1** Graded on a scale of one through five, with one being the most favorable response.

<table>
<thead>
<tr>
<th>Question</th>
<th>Envision*</th>
<th>Tricurve*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarity</td>
<td>1.667</td>
<td>1.667</td>
</tr>
<tr>
<td>Standard Dev</td>
<td>.816</td>
<td>.795</td>
</tr>
<tr>
<td>Consistency</td>
<td>1.983</td>
<td>1.767</td>
</tr>
<tr>
<td>Standard Dev</td>
<td>.948</td>
<td>.890</td>
</tr>
</tbody>
</table>

* One is equal to the best response, and five is equal to the worst.

With regard to physical awareness of each lens, although a statistically significant difference was not found between the two designs, a trend toward preference of the tricurve (p=0.054) as being more comfortable was observed (Fig. 2 and Table 3).
Physical Awareness of RGPs

Fig. 2 Physical awareness is based on a scale of one through five, with five being the most comfortable.

Table 3 Physical Awareness of RGP Design (n=20).

<table>
<thead>
<tr>
<th>Question</th>
<th>Envision*</th>
<th>Tricurve*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awareness</td>
<td>Mean</td>
<td>3.367</td>
</tr>
<tr>
<td></td>
<td>Standard Dev</td>
<td>1.01</td>
</tr>
</tbody>
</table>

*One is equal to the worst response, and five is equal to the best.

When analyzing forced choice responses (clarity of vision, comfort, and overall preference) for all visits combined from each of the three questionnaires completed by each subject, the only significant difference between the two lenses was found in overall preference. The tricurve was preferred more often (p = .0469). See Fig. 3 and Table 4. However, analysis of end of study responses (1 month) separately showed no significant difference between the two designs for any of the three forced choice variables (Fig. 4 and Table 4).
Subjective Preference of RGP Design for All Visits

Fig. 3 Columns represent the gross number of preferences between the two designs.

Table 4 Envision/Tricurve Forced Choice Results*

<table>
<thead>
<tr>
<th>Question</th>
<th>Envision</th>
<th>Tricurve</th>
<th>Chi squared</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Responses</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clarity preference</td>
<td>23</td>
<td>27</td>
<td>.32</td>
<td>.5716</td>
</tr>
<tr>
<td>Comfort preference</td>
<td>21</td>
<td>35</td>
<td>3.5</td>
<td>.0614</td>
</tr>
<tr>
<td>Overall preference</td>
<td>21</td>
<td>36</td>
<td>3.947</td>
<td>.0469</td>
</tr>
<tr>
<td>Final Responses</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clarity preference</td>
<td>7</td>
<td>9</td>
<td>0.25</td>
<td>.6171</td>
</tr>
<tr>
<td>Comfort preference</td>
<td>6</td>
<td>13</td>
<td>2.579</td>
<td>.1083</td>
</tr>
<tr>
<td>Overall preference</td>
<td>5</td>
<td>13</td>
<td>3.556</td>
<td>.0593</td>
</tr>
</tbody>
</table>

*Note that deleted data is due to no preference between designs.
Subjective Preference of RGP Design at the Final Visit

Fig. 4 Columns represent the gross number of preferences between the two designs.

Objective Measurements and Observation

Keratometry readings were taken both initially and at the final visit. The Envision lens showed statistically significant flattening of both the steep \((p=0.0001)\) and flat meridians \((p=0.0105)\), thereby creating a decrease in corneal cylinder or "sphericalization" of the cornea (Figs. 5 and Table 5). The tricurve lens, however, only showed statistically significant flattening of the steep meridian \((p=0.0001)\).

Refractive error was also recorded at the first and final visit. There was no significant changes in the flat meridian with either the Envision lens or the tricurve lens. In regards to the steep meridian, both designs showed a statistically significant decrease in refractive cylinder (Fig. 6 and Table 5).
Average Change in K's for both Flat and Steep Meridians

Fig 5. Columns represent the average change of K's in diopters for both designs.

Table 5 Changes in Keratometry and Rx*(n=20).

<table>
<thead>
<tr>
<th>Change in K's flat</th>
<th>Average</th>
<th>p-value</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Envision</td>
<td>.228</td>
<td>.0105</td>
<td>-0.25 to 1.00</td>
</tr>
<tr>
<td>Tricurve</td>
<td>.143</td>
<td>.0704</td>
<td>-0.25 to 0.75</td>
</tr>
<tr>
<td>Change in K's steep</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Envision</td>
<td>1.006</td>
<td>.0001</td>
<td>-0.25 to 2.75</td>
</tr>
<tr>
<td>Tricurve</td>
<td>.697</td>
<td>.0001</td>
<td>-0.37 to 1.63</td>
</tr>
<tr>
<td>Change in Rx flat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Envision</td>
<td>-0.25</td>
<td>.0746</td>
<td>-0.37 to 1.50</td>
</tr>
<tr>
<td>Tricurve</td>
<td>-0.086</td>
<td>.2499</td>
<td>-0.37 to 0.75</td>
</tr>
<tr>
<td>Change in Rx steep</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Envision</td>
<td>-0.796</td>
<td>.001</td>
<td>pl to 3.00</td>
</tr>
<tr>
<td>Tricurve</td>
<td>-0.691</td>
<td>.0002</td>
<td>pl to 2.37</td>
</tr>
</tbody>
</table>

* Note that reductions in keratometry readings and reductions in minus lens power are positive values.
Average Change in Refractive Power in Both the Flat and Steep Meridians

In regards to corneal staining observations, once again, no significant difference was found between the two designs (Fig. 7 and Table 6).
Fig 7 Columns represent the average corneal staining, based on a grading scale of zero to four, with zero being no staining.

Table 6 Corneal Staining (n=20)

<table>
<thead>
<tr>
<th>Lens Design</th>
<th>Average*</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Envision</td>
<td>.488</td>
<td>.572</td>
</tr>
<tr>
<td>Tricurve</td>
<td>.457</td>
<td>.519</td>
</tr>
</tbody>
</table>

*Corneal staining was measured with zero being no staining, and 4 being epithelial loss.

Although fluorescein patterns were not quantitatively scaled and statistically analyzed, it was the general impression of each investigator that the Envision fluorescein patterns were consistently more uniform in appearance, without distinct transitions zones, and revealed less obvious horizontal corneal bearing and inferior pooling than did the tricurve lenses.
DISCUSSION:

The subjective responses from this study support findings reported previously in the literature\textsuperscript{10}. Vision was reported to be more variable with the Envision lens than the tricurve lens. This may be explained by considering that the smooth back surface of the aspheric may encourage more movement of the lens, causing the lens periphery to encroach upon the visual axis. Thus, distance visual acuity will suffer somewhat. It is assumed that flexure played a very minimal role when comparing consistency of vision between the two designs, as the average center thicknesses of the two designs were the same and did not vary more than 0.10 mm between designs on the same subject.

With regard to comfort, or physical awareness of the lenses, the results of this study found that the tricurve lens was subjectively more comfortable. However, the apheric Envisions compatibility with the corneal topography suggests that it would be more comfortable than a tricurve lens\textsuperscript{1,3,5,7,8,10}. Thus, this finding is opposite to what was expected based on previous research and clinical observations reported\textsuperscript{2,7,10}. However, one variable not assessed in this study was edge finish. As a result of the differences in the manufacturing and hand-finishing techniques, edge thickness and shape may have varied between lens designs. Although all in office modifications made to the edges of one lens were also made to the other lens at the same time, the procedure was done by hand and differences between the two lens edges may not have been eliminated entirely.

Comparison of the forced choice responses show that, even though there was an overall preference for the tricurve, the end of study responses alone revealed no subjective difference for any variable
between the two designs. It is possible that during adaptation a small difference in comfort could have caused a greater awareness of one lens over the other. As Ames and Erickson reported, once the patient adapts to the lenses, the awareness difference between lenses decreases. Therefore, at the end of the study, no significant differences were noted between the lenses.

Both the aspheric and spheric designs demonstrated a flattening of the cornea in both the flat and steep meridians, which was most likely a result of the fitting philosophy and large overall diameter. The aspheric lens showed a significant overall flattening in both meridians which was consistent with findings in previous studies. This would be expected since the aspherics lens to cornea fitting relationship aligns closely to the corneal surface and consequently flattens it. The spherical tricurve lens, however, attempts to make the cornea more spherical and therefore significantly flattened only the steep meridian. In addition, no corneal distortion was observed with either design during the course of this study.

In conclusion, the results of this study indicate that it is possible to successfully fit either a tricurve or an aspheric rigid contact lens on moderately and highly astigmatic corneas. However, a bitoric lens should also be considered to reduce the incidence and degree of corneal flattening and decrease in refractive cylinder (sphericalization). Both lenses were found to be acceptable in this study and there were very few differences observed that could be attributed to design. It is recommended that care be taken to ensure that lens manufacturing is consistent and of optimal quality.
ACKNOWLEDGMENTS:

Our sincere appreciation is given to Mr. Mike Wong and his staff at Paracon Contact Lens Manufacturers for manufacturing the lenses used in this study, and to the Polymer Technology Corporation for providing the lens buttons.
REFERENCES:


