Investigation of a rigid gas permeable contact lens for overnight corneal refractive therapy

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Investigation of a rigid gas permeable contact lens for overnight corneal refractive therapy

Abstract
Purpose This evaluation was conducted as part of a FDA study for the approval of Menicon Z™ (tisilfocon A) rigid gas permeable contact lenses for overnight corneal refractive therapy with the purpose of evaluating its safety and efficacy.

Methods Eleven subjects were enrolled in the study at Pacific University College of Optometry. The subjects presented wearing soft contact lenses or spectacles who wanted to try an alternative to their current modality. The participants slept in the lenses approximately 8 hours each night, over the course of 6 months, during which time their refractive errors were evaluated at fixed intervals. Each was fitted with a Menicon Z™ (tisilfocon A), reverse geometry lens exhibiting a DK permeability rating of 163. Upon a successful fit, subjects were evaluated at 24 hours, 2 weeks as well as 1, 2, and 3 months following their baseline visit. At the 3 month visit, the subjects were instructed to discontinue lens wear and return for scheduled visits at 8, 24, 48 and 72 hours post-removal to assess the reversal effects. They then resumed their wearing regimen for 3 more months before returning for a final assessment. Visits for any other reason were recorded as an unscheduled appointment.

Results Five of the eleven subjects completed the study with reportedly good subjective vision and comfort while four subjects withdrew from the study due to unsatisfied acuities and/or excessive lens awareness. Two subjects were discontinued by the investigators because one developed a corneal infiltrate and the other required a lens that was outside the fitting parameters of the protocol.

Conclusion This study suggests that the test lens works most favorably for spherical refractive errors below -3.00 diopters and negligible astigmatism. This lens is safe and effective for corneal refractive therapy, when fit and managed by a qualified practitioner.

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Thesis

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INVESTIGATION OF A RIGID GAS PERMEABLE CONTACT LENS FOR OVERNIGHT CORNEAL REFRACTIVE THERAPY

By:

MATTHEW LAMPA
HELEN KENDRA LEE
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A thesis submitted to the faculty of the College of Optometry at Pacific University Forest Grove, Oregon For the degree of

Doctor of Optometry
May 2006

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Patrick Caroline, COI, FAAO
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AN

ABSTRACT

OF THE

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Purpose

This evaluation was conducted as part of a FDA study for the approval of
Menicon Z™ (tisilfocon A) rigid gas permeable contact lenses for overnight
corneal refractive therapy with the purpose of evaluating its safety and
efficacy.

Methods

Eleven subjects were enrolled in the study at Pacific University College of
Optometry. The subjects presented wearing soft contact lenses or spectacles
who wanted to try an alternative to their current modality. The participants
slept in the lenses approximately 8 hours each night, over the course of 6
months, during which time their refractive errors were evaluated at fixed
intervals. Each was fitted with a Menicon Z™ (tisilfocon A), reverse geometry
lens exhibiting a DK permeability rating of 163. Upon a successful fit, subjects were evaluated at 24 hours, 2 weeks as well as 1, 2, and 3 months following their baseline visit. At the 3 month visit, the subjects were instructed to discontinue lens wear and return for scheduled visits at 8, 24, 48 and 72 hours post-removal, to assess the reversal effects. They then resumed their wearing regiment for 3 more months before returning for a final assessment. Visits for any other reason were recorded as an unscheduled appointment.

Results

Five of the eleven subjects completed the study with reportedly good subjective vision and comfort while four subjects withdrew from the study due to unsatisfied acuities and/or excessive lens awareness. Two subjects were discontinued by the investigators because one developed a corneal infiltrate and the other required a lens that was outside the fitting parameters of the protocol.

Conclusion

This study suggests that the test lens works most favorably for spherical refractive errors below -3.00 diopters and negligible astigmatism. This lens is safe and effective for corneal refractive therapy, when fit and managed by a qualified practitioner.
ACKNOWLEDGEMENTS:

We would like to give our heart felt gratitude to our dedicated advisors Jennifer Smythe, Peter Bergenske, and Patrick Caroline for their time, expertise, help, and support throughout the duration of this study. We would like to thank Paragon for their contributions of lenses, materials and financial support that made this study possible. We would also like to thank our subjects for their persistence and commitment to the study.
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OBJECTIVE

The objective of this FDA approval study is to assess the safety and efficacy of Menicon Z™ rigid gas permeable (RGP) contact lenses for overnight Corneal Refractive Therapy (CRT). The protocol includes a component that explores the reversal effects of lens removal on the cornea after three months of compliant therapy.

Background Information

Advancements in ocular science and technology have led to a greater understanding of corneal anatomy and physiology, which are making way for more innovative developments in contact lens design and materials.

This can be seen in the creation of the Menicon Z™ lens which provides more oxygen permeability than any other contact lens material available for commercial use that still provides structural stability and good wet ability (4).

The minimum oxygen transmissibility criterion to avoid overnight corneal edema to the level experienced without a contact lens in place was first determined by Holden and Mertz in 1984 to be a Dk/t value of 87 (1). In 1999 Harvitt and Bonanno took into account the pH and oxygen consumption rate (Qo2) of the cornea and determined the new minimum CL Dk/t for oxygen delivery to the basal epithelial cells to be 89 in the open eye condition (2). In the
closed eye environment, the required Dk/t to avoid anoxia in the corneal stroma is 125 (2). Menicon Z is unique in that it is the only material in existence that has an oxygen permeability (DK) value of 163 and provides enough oxygen permeability to allow a continuous wearing schedule without compromising ocular health and sacrificing mechanical strength, which has been a limiting factor with such materials in the past. Due to such unique properties, this material has been FDA approved for a continuous 30 day wearing schedule (3).

As contact lens designs have advanced through the use of computer lathe manufacturing and as corneal surface changes are better monitored through the use of computerized topography, accelerated orthokeratology or corneal refractive therapy (CRT) have seen great advances since its origin and provides a more predictable result (7). Corneal refractive therapy reshapes the cornea by applying a RGP lens on the eye while asleep for 6-10 hours. Once the lens is removed, the cornea generally maintains this shape for several hours to days later. The lens consists of a reverse curve design intended to reallocate the tear layer and induce a pulling force to redistribute the corneal epithelium, which should result in a reduction of corneal sagittal height and an ultimate correction in refractive error (16).

Paragon has incorporated these two technologies into a single lens design currently undergoing FDA clinical trials. This lens design surpasses previous
technologies in that it not only allows oxygen permeability but also incorporates
the benefits of not wearing contact lenses during the day and is an excellent
alternative to refractive surgery for those who are looking for a reversible, non-
permanent option. This modality is especially convenient for patients who are
prone to ocular dryness, athletes and people who do not want to wear correction
during the day (6). This study is one of the participants in the approval process
of FDA clinical trials.
EXPERIMENTAL DESIGN

METHODS:

The study is designed as a prospective multi-centered, concurrent cohort, controlled FDA clinical trial lasting six months using a total of 11 subjects enrolled at Pacific University, College of Optometry. All subjects underwent a standardized optometric examination at enrollment. Subjects were seen for a baseline fitting where a test lens was ordered, and returned for a subsequent dispense and 24 hour follow-up visit after one night of wear. Subjects were required to wear the test lenses in both eyes for up to 9 hours each night while asleep. As per study protocol, each subject was evaluated using subjective refraction, topography, logMAR acuities, keratometry, IOPs, biomicroscopy examination and sodium fluorescein staining.

The patients were then seen at 2 weeks, 1 month, 2 month and 3 month visits after their initial dispense. At the end of three months, the subjects were instructed to discontinue lens wear for the next 72 hours and were seen at 8, 24, 48 and 72 hours post-removal to assess reversal effects. Once this data was collected, the subjects resumed their wearing regiment for 3 more months at which time they returned for a final assessment. Visits for any other reason were recorded as unscheduled visits.
All test lenses used in the study were manually inspected for defects, damages and parameters. Lens cleaning and disinfection by the participants was to take place every morning upon lens removal with Unique pH contact lens care solution. The lenses were only replaced if damaged, lost or for cause. The patients were instructed to use Supraclens enzyme cleaner as needed to remove protein deposits that may form on the lenses.

**Inclusion Criteria:**

- Minimum of 12 years of age
- Refractive error between -0.50D to -4.00D with or without astigmatism less than 1.75D with acuity correctable to 20/20 in each eye
- Good general health
- Willing and able to follow all instruction and keep appointments

**Exclusion criteria:**

- Presence of ocular or systemic allergies or disease
- Use of medications that limit contact lens wear
- Must not have worn RGP contact lenses for a minimum of 1 month prior to the study
- History of corneal trauma or ocular surgery, infections, keratoconus, irregular cornea, recent trauma to the eyes
- Pregnant or lactating
- Diabetes, heart disease, immunological disease
- Participation in another clinical study within the past 30 days
MATERIALS:

- Paragon MeniconZ™ CRT lens
- Paragon CRT diagnostic dispensing lens set
- Humphrey Atlas Topographer
- Biomicroscope
- Manual Keratometer
- Bailey-Lovie LogMAR acuity chart
- Phoropter
- Humphrey Non-Contact Tonometer
- Sodium Fluorescein
- Projected Snellen Chart
- Peak Scope
- Nikon digital SLR camera for photographs

The CRT lens design consists of several parameters that can be adjusted for ideal fitting and treatment effects. The dispensing kit is composed of 100 lenses, with each lens having a lens diameter of 10.5mm.

The central treatment zone is 6.0mm across, with the back surface of this portion acting as the base curve. The base curve is flattened to increase myopia correction and steepened for hyperopia correction.

There are three additional parameters of the Paragon CRT system that can be modified to produce an optimal amount of centration and applanation as shown in Figure 1.
The Return Zone Depth (RZD) is the primary factor that can be increased or decreased to adjust the sagittal depth with the maximal effect. For each 0.025 increment of change in the RZD, there is a corresponding 12 microns of sagittal depth adjustment.

The Landing Zone Angle (LZA) can be modified to ensure tangential landing on mid-peripheral cornea, as well as finer adjustments to the sagittal depth. For every 1 degree increment of change in the LZA, there is a corresponding 7 microns of sagittal depth adjustment.

The last modifiable parameter is the overall lens diameter, which may not require any adjustments since the other three parameters allow sufficient control.
An ideal CRT fit includes a sodium fluorescein pattern that resembles a bulls eye with a central dark area of approximately 4mm or larger of touch, a zone of clearance or pooling cecocentrally, that corresponds to the return zone, as well as mid-peripheral touch with some peripheral edge lift controlled by the LZA. The lens should be centered on the pupil, with horizontal coordinates (X) of 0 and Vertical coordinates (Y) of 0. In the horizontal meridian, “+” represents millimeters of decentration nasally, while “−” indicates millimeters of decentration temporal. In the vertical meridian, “+” represents millimeters of misalignment in the superior direction, and “−” indicates millimeters of decentration inferiorly. Once proper alignment has been achieved, the lenses should be dispensed for overnight wear in order for corneal reshaping to occur over the prescribed time (16).
SAFETY AND EFFECTIVENESS ENDPOINTS:

The study protocol was approved by the Pacific University College of Optometry Institutional Review Board (IRB). As a requirement, each subject read and signed an informed consent outlining the nature of the study, the potential consequences and other applicable stipulations.

Patients were removed from the study if significant adverse events were identified or if subjects reported symptoms of discomfort or unacceptable acuity. Significant adverse events which justified removal from the study included significant visual acuity changes, positive slit lamp findings for corneal neovascularization, corneal infiltrates, corneal staining, edema, positive palpebral conjunctival findings and/or other adverse responses that may have compromised their visual system. We reserved the right to discontinue any participant who was unable to keep appointments or demonstrate compliance. Subjects were free to withdraw from the study for any reason, without consequence or prejudice.

A completed subject is defined as one having completed the entire 6 month extended wear period in accordance with the study protocol.
DEMOGRAPHIC DATA:

The source population primarily included students attending the university and friends or spouses of current optometric students due to the limited availability of participants.

The mean age of study participants was 25 years with a range of 21 to 33 years. Gender distribution was an approximate 4 to 1 ratio of females to males as outlined in Figure 2.

Figure 2: Gender Distribution
RESULTS

Baseline demographic, refractive and keratometric data for all eleven patients have been outlined in Table 1.

Table 1: Summary of Baseline Visit of all the patients

<table>
<thead>
<tr>
<th>Subject No.</th>
<th>Subject Name</th>
<th>Eye</th>
<th>Gender</th>
<th>Age (years)</th>
<th>Keratometry</th>
<th>LogMar BVA</th>
<th>Sphere</th>
<th>Cylinder</th>
<th>Perscription</th>
<th>CL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>MP</td>
<td>OD</td>
<td>M</td>
<td>25</td>
<td>43.00/43.25@090</td>
<td>51@20ft</td>
<td>-2.00</td>
<td>-0.50 x 140</td>
<td>Soft CL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OS</td>
<td></td>
<td></td>
<td>43.00/43.25@090</td>
<td>52@20ft</td>
<td>-2.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>PR</td>
<td>OD</td>
<td>M</td>
<td>25</td>
<td>43.87/45.75@100</td>
<td>50@20ft</td>
<td>-3.25</td>
<td>-0.25 x 110</td>
<td>Soft CL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OS</td>
<td></td>
<td></td>
<td>43.37/44.00@106</td>
<td>50@20ft</td>
<td>-3.00</td>
<td>-0.50 x 180</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>LF</td>
<td>OD</td>
<td>F</td>
<td>28</td>
<td>42.00/42.75@090</td>
<td>49@20ft</td>
<td>-2.25</td>
<td></td>
<td>DS</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OS</td>
<td></td>
<td></td>
<td>42.00/42.50@090</td>
<td>50@20ft</td>
<td>-2.25</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>NS</td>
<td>OD</td>
<td>F</td>
<td>21</td>
<td>42.87/43.50@060</td>
<td>50@20ft</td>
<td>-2.00</td>
<td></td>
<td>DS</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OS</td>
<td></td>
<td></td>
<td>44.12/44.62@158</td>
<td>50@20ft</td>
<td>-1.50</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>JP</td>
<td>OD</td>
<td>F</td>
<td>31</td>
<td>45.87/46.12@090</td>
<td>46@20ft</td>
<td>-3.75</td>
<td>-0.75 x 110</td>
<td>Soft CL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OS</td>
<td></td>
<td></td>
<td>46.37/46.50@090</td>
<td>45@20ft</td>
<td>-4.25</td>
<td>-0.50 x 086</td>
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<tr>
<td>6</td>
<td>CN</td>
<td>OD</td>
<td>F</td>
<td>27</td>
<td>44.00/45.00@90</td>
<td>48@20ft</td>
<td>-1.25</td>
<td></td>
<td>DS</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OS</td>
<td></td>
<td></td>
<td>44.00/45.00@90</td>
<td>45@20ft</td>
<td>-1.00</td>
<td></td>
<td></td>
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<tr>
<td>7</td>
<td>BJ</td>
<td>OD</td>
<td>M</td>
<td>24</td>
<td>42.12/42.87@162</td>
<td>50@20ft</td>
<td>-4.50</td>
<td>-0.75 x 150</td>
<td>Soft CL</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>OS</td>
<td></td>
<td></td>
<td>42.25/42.50@180</td>
<td>50@20ft</td>
<td>-4.25</td>
<td>-0.50 x 015</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>AD</td>
<td>OD</td>
<td>F</td>
<td>24</td>
<td>42.00/43.00@90</td>
<td>48@20ft</td>
<td>-4.75</td>
<td>-0.25 x 130</td>
<td>Soft CL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OS</td>
<td></td>
<td></td>
<td>42.00/43.50@80</td>
<td>45@20ft</td>
<td>-3.50</td>
<td>-1.25 x 163</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>TJ</td>
<td>OD</td>
<td>F</td>
<td>24</td>
<td>45.50/45.50@90</td>
<td>46@20ft</td>
<td>-3.25</td>
<td></td>
<td>DS</td>
<td></td>
</tr>
<tr>
<td></td>
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<td>OS</td>
<td></td>
<td></td>
<td>45.25/46.00@90</td>
<td>45@20ft</td>
<td>-4.00</td>
<td>-0.50 x 164</td>
<td></td>
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<tr>
<td>10</td>
<td>MB</td>
<td>OD</td>
<td>F</td>
<td>27</td>
<td>42.12/42.62@090</td>
<td>50@20ft</td>
<td>-0.50</td>
<td>-0.50 x 165</td>
<td>Soft CL</td>
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<tr>
<td></td>
<td></td>
<td>OS</td>
<td></td>
<td></td>
<td>41.87/42.50@070</td>
<td>51@20ft</td>
<td>-0.50</td>
<td>-0.75 x 010</td>
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<td></td>
</tr>
<tr>
<td>11</td>
<td>TB</td>
<td>OD</td>
<td>F</td>
<td>27</td>
<td>42.75/43.50@082</td>
<td>50@20ft</td>
<td>-2.00</td>
<td></td>
<td>DS</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>OS</td>
<td></td>
<td></td>
<td>43.12/43.75@085</td>
<td>46@20ft</td>
<td>-2.00</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The spherical refractive errors of subjects in this study ranged from -1.00 to -4.50 diopters with a mean power of -2.50 diopters. Astigmatism correction ranged from 0.00 to -1.50 diopters, with the most subjects exhibited "with the rule" astigmatism as shown in Figure 3.

**Figure 3: Distribution of Astigmatism**

![Diagram showing distribution of astigmatism](image)

The steepest cornea was 46.37 and flattest was 42.00. Mean value was 43.12.

The best visual acuity with habitual correction ranged from a logMar of 45@20ft to 52@20ft with an average acuity of 49@20ft. All eleven patients were previously successful soft contact lenses wearers.
CASE REPORTS:

Subject 1: MP

MP is a 25 year old white male who is an elementary school teacher. His initial baseline visit revealed a healthy anterior segment and a refraction of:

OD: -2.00 -0.50 x 140 51@20ft
OS: -2.00 DS 52@20ft

Based on this data and keratometric findings, the following lens was dispensed:

OD: 8.4 .525 -33
OS: 8.4 .525 -33

These lenses centered well and exhibited the following findings:

- Both Eyes X: 0, Y: 0
- Treatment zone: 5.0 mm
- Movement: 1.0 mm
- Best visual acuity: Right 51@20ft
  Left 49@20ft

In a 24 hour follow-up visit, the patient reported lens awareness and discomfort. LogMar acuity was 53@20ft and 54@20ft in the right and left eye respectively, with an over refraction of plano and +0.25D. Biomicroscopy revealed mild corneal staining and mild conjunctival staining and topography revealed well centered treatment zones in both eyes. Due to the acceptable fit, this was the final and only lens used on MP.

At his two week visit, MP complained of halos and variability of vision, at which time an over refraction revealed a quarter of a diopter overcorrection but a
well centered treatment zone. At his one-month follow-up visit, the halos became minimal and no longer a concern. We attributed these symptoms to the initial adjustment period of the lens.

After three months of wear as per the study protocol, the patient discontinued lens wear for 72 hours. The patient was seen at 8 hour, 24 hour, 48 hour and 72 hour post discontinuation of lens. Patient’s refractive error slowly returned to baseline as shown in Table 2. At 72 hours post removal, MP presented with the following refractive error and acuities:

OD: -1.00 -0.25 x 001 35@20ft
OS: -0.50 -0.75 x 001 46@20ft

Even though MP’s refractive error did not completely return to baseline after 72 hours of lens removal, we would have expected it to return to baseline had he been given more time to reverse.

Table 2: Baseline Results vs. 72 Hour Post Removal Results for MP

<table>
<thead>
<tr>
<th>Subject</th>
<th>Eye</th>
<th>Baseline LogMar VA</th>
<th>Baseline RX</th>
<th>72 hour post LogMar BVA</th>
<th>72 hour post-removal Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>LogMar VA</td>
<td>Sphere</td>
<td>Cylinder</td>
<td>Sphere</td>
</tr>
<tr>
<td>MP</td>
<td>OD</td>
<td>51@20ft</td>
<td>-2.00</td>
<td>-0.50 x 140</td>
<td>51@20ft</td>
</tr>
<tr>
<td></td>
<td>OS</td>
<td>52@20ft</td>
<td>-2.00</td>
<td>DS</td>
<td>53@20ft</td>
</tr>
</tbody>
</table>

The remainder of his visits produced an acceptable over refraction, negative slit lamp findings and acceptable central keratometric findings. The best and final visual acuity reported by MP was 54@20ft in both eyes, which is
slightly better than his baseline acuities. MP returned for the remaining
scheduled visits up to 6 months where he expressed his satisfaction with his
overall vision and comfort. This subject successfully completed the study and
has decided to continue with this modality.
Subject 2: PR

PR is a 25 year old white male who is currently a second year optometric student. His baseline visit revealed a healthy anterior segment and refraction of:

OD: -3.25D – 0.25 x 110  50@20ft  
OS: -3.00D – 0.50 x 180  50@20ft

Based on the CRT fitting guide, he was fit with the following test lenses:

OD: 8.4 .550 -34  
OS: 8.4 .550 -34

These lenses centered well and exhibited the following findings:

- Right Eye X: +0.50, Y: 0  
- Left Eye X: -0.50, Y: 0  
- Treatment zone: 4.0 mm  
- Movement: 0.75 mm  
- Best visual acuity: Right 45@20ft  
  Left 50@20ft

At the 24 hour follow-up visit, the lens off over-refraction was -1.00D and -0.25 -0.25 x 180 in his right and left eyes respectively, producing acuities of 44@20ft and 50@20ft. The slit lamp examination yielded grade 2 bulbar injection and the patient reported obvious lens awareness accordingly.

Based on these findings, we expected his acuities to improve at the next scheduled visit. At the two week visit his right and left eye unaided LogMar acuities were 40@20ft and 50@20ft respectively, at which point, PR expressed some concern about his consistently poorer acuity in his right eye, especially
noticed during the evenings. As a result, the landing zone angle in the right lens was increased to improve alignment.

At the one month visit the patient reported the same concern, with the addition of halos and increased fading vision towards the end of the day. The lens off subjective refraction was plano in both eyes with acuities of 45@20ft and 48@20ft in the right and left eye respectively.

After two months from the time of the dispensing visit the patient presented to the clinic not having worn lenses for the past month and wished to discontinue from the study. The patient reported unacceptable unaided visual acuity. Slit lamp exam was unremarkable and the patient reported no subjective symptoms at the time of the visit. The subjective refraction was:

OD -2.00 sph 
53@20ft 
OS -1.75 -0.25 x 010 
52@20ft 

As per the study protocol, PR returned for a one month post discontinuation visit which revealed grade 1 bulbar injection and a slow refractive reversal to base line as shown in Table 3.

Table 3: Baseline Results vs. 72 Hour Post Removal Results for PR

<table>
<thead>
<tr>
<th>Subject</th>
<th>Eye</th>
<th>Baseline LogMar VA</th>
<th>Baseline RX Sphere</th>
<th>Baseline RX Cylinder</th>
<th>72 hour post LogMar BVA Sphere</th>
<th>72 hour post-removal Rx Sphere</th>
<th>Baseline RX Cylinder</th>
<th>72 hour post-removal Rx Cylinder</th>
</tr>
</thead>
<tbody>
<tr>
<td>PR</td>
<td>OD</td>
<td>50@20ft</td>
<td>-3.25</td>
<td>-0.25 x 110</td>
<td>51@20ft</td>
<td>-3.25</td>
<td>DS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OS</td>
<td>50@20ft</td>
<td>-3.00</td>
<td>-0.50 x 180</td>
<td>53@20ft</td>
<td>-2.25</td>
<td>-1.00 x 002</td>
<td></td>
</tr>
</tbody>
</table>
Subject 3: LF

LF is a 28 year old Asian, self-employed female who was a highly motivated participant in the study because she “wanted freedom from her daily wear soft contact lenses.” LF plays softball on a regular basis, and reported symptoms of dry and itchiness with her current modality. Her ocular and systemic health was unremarkable and she reported negative ocular allergies.

Her initial baseline visit revealed a healthy anterior segment and a refraction of:

- OD: -2.25 DS  49@20ft
- OS: -2.25 DS  50@20ft

Based on the CRT fitting guide, LF was fit with the following test lenses:

- OD: 8.6 .475 -32
- OS: 8.6 .500 -31

These lenses centered well and exhibited the following findings:

- Both Eyes X: -0.50, Y: -0.50
- Treatment zone: 4.0 mm
- Movement: 1.50 mm
- Best visual acuity: Both Eyes 50@20ft

The patient reported initial lens discomfort while awake, but no lens awareness while asleep and adjusted to them quickly. Upon the 1 day follow up visit, LF reported that her acuity after removing the lenses was not as good as with her soft lenses. Her acuities were 41@20ft and 44@20ft in her right and left eye respective and over-refracted at -0.50D in both eyes. Biomicroscopy revealed
grade 1 conjunctival staining and injection OU. Her topographies revealed well centered lenses with a sufficient treatment zone. Due to the acceptable fit, this was the final and only lens used on LF.

The subject returned for her scheduled visits over the next 6 months where her acuities improved to 50@20ft in both eyes for the remainder of the study with unremarkable anterior findings. Before her 2 month visit, her right lens broke, and therefore restarted her soft contact lens wear in that eye during the interim, while a new lens was ordered. Once she re-started in the test lens, her acuity returned to 50@20 feet in that eye.

At her 3 month visit, LF experienced some difficulty with transient near blur, especially while reading. Initially, overcorrection was the suspected cause, however, upon an over refraction of plano in both eyes, we considered lens buildup was the real culprit as even small amounts of buildup can affect acuities. An additional cleaner was added to her lens care system, and her problem resolved.

LF’s best and final acuity achieved with these lenses was 50@20 feet in both eyes which was comparable to her baseline visual acuities.

As per protocol of the study, LF discontinued lenses wear after 3 months for 72 hours. We saw the patient at four different visits during the 72 hours
during which time the subject's refractive error showed a slow return towards baseline as outlined in Table 4.

Table 4: Baseline Results to 72 Hour Post Removal Results for LF

<table>
<thead>
<tr>
<th>Subject</th>
<th>Eye</th>
<th>Baseline LogMar VA</th>
<th>Baseline RX</th>
<th>72 hour post LogMar BVA</th>
<th>72 hour post-removal Sphere</th>
<th>Cylinder</th>
</tr>
</thead>
<tbody>
<tr>
<td>LF</td>
<td>OD</td>
<td>49@20ft</td>
<td>-2.25 DS</td>
<td>40@20 ft</td>
<td>-0.50 DS</td>
<td>DS</td>
</tr>
<tr>
<td></td>
<td>OS</td>
<td>50@20ft</td>
<td>-2.25 DS</td>
<td>35@20 ft</td>
<td>-0.75 DS</td>
<td>DS</td>
</tr>
</tbody>
</table>

LF made her satisfaction and enthusiasm for the test lenses apparent by making comments such as "I cannot imagine going back to wearing soft CL."

She reported excellent vision in both eyes, and reported no complaints. All ocular findings were within normal limits.

This subject successfully completed the study and has decided to continue with this modality.
Subject 4: BJ

BJ is a 24 year old white male, who presented at the baseline visit wearing spherical DW hydrogel lenses as his habitual distance correction. With his habitual correction, he was subjectively symptomatic for lens awareness, discomfort, dry and scratchiness, redness, and lens adhesion in both eyes.

His initial baseline visit revealed grade 1 corneal neovascularization and trace pigment on the corneal endothelium in both eyes. His refraction and acuities were:

<table>
<thead>
<tr>
<th>Eye</th>
<th>Sphere</th>
<th>Cylinder</th>
<th>Axis</th>
<th>Distance</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD</td>
<td>-4.50</td>
<td>-0.75</td>
<td>150</td>
<td>50@20ft</td>
</tr>
<tr>
<td>OS</td>
<td>-4.25</td>
<td>-0.50</td>
<td>015</td>
<td>50@20ft</td>
</tr>
</tbody>
</table>

Based on the CRT fitting guide, LF was fit with the following test lenses:

<table>
<thead>
<tr>
<th>Eye</th>
<th>Sphere</th>
<th>Cylinder</th>
<th>Axis</th>
<th>Distance</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD</td>
<td>9.10</td>
<td>.550</td>
<td>-32</td>
<td></td>
</tr>
<tr>
<td>OS</td>
<td>9.00</td>
<td>.550</td>
<td>-33</td>
<td></td>
</tr>
</tbody>
</table>

These lenses centered well and exhibited the following findings:

- Both Eyes X: 0, Y: 0
- Treatment zone: 5.0 mm
- Movement: 0.75 mm

At the first visit following overnight lens wear the SCOR was +0.25 D in both eyes with acuities of 53@20ft and 54@20ft in the right and left eye respectively. The lens off refraction revealed:

<table>
<thead>
<tr>
<th>Eye</th>
<th>Sphere</th>
<th>Cylinder</th>
<th>Axis</th>
<th>Distance</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD</td>
<td>-1.25</td>
<td>-0.25</td>
<td>090</td>
<td>38@20ft</td>
</tr>
<tr>
<td>OS</td>
<td>-1.00</td>
<td>DS</td>
<td></td>
<td>41@20ft</td>
</tr>
</tbody>
</table>
Grade 3 and grade 2 corneal staining was noted in the right and left eye respectively. The patient was instructed to discontinue lens wear for the next 24 hours before resuming with the study to allow the staining to resolve.

BJ reported at the two week visit that he "liked being able to see without contact lenses during the day," however, he was "never fully corrected and that made driving difficult." During this visit, we decided to increase the landing zone angle of the left lens to improve alignment.

Upon wearing the new lenses for the first night, BJ returned to clinic in the morning one hour after awakening, with lens adherence in the left eye, leaving an impression ring and dimple veil upon lens removal. The subjective refraction was plano with an acuity of 51@20ft. As the patient continued wearing with the test lens, the adhesion resolved and he was closely monitored for any further adhesions.

Two months after enrollment, the patient damaged his right lens, at which time, we decided to steepen the base curve slightly in an attempt to improve the refractive error in that eye. At this time, the left lens had developed a substantial amount of protein deposit and was therefore cleaned with Lobob Extra Strength Cleaner. The patient contacted the clinic within a few days to report a subjective improvement in acuities, overall comfort and treatment since the cleaning.
At two and a half months, BJ was seen for an unscheduled visit as he developed another lens adhesion in the left eye. Although the etiology of RGP lens binding is unclear, this problem can be solved by steepening the base curve and/or flattening the peripheral curve (9). BJ’s test lens was therefore steepened by increasing the return zone depth from .500 to .525 to ultimately increase the sagittal depth.

At 3 months, BJ discontinued lens wear in the left eye only, as dictated by the study at which time his left cornea demonstrated a slow return in refractive error toward baseline as expected at -2.75 -1.00 x 046 with an acuity of 38@20ft.

BJ started the new test lens after the 72 hour post-removal visit, in hopes that the corneal tissue would have returned more towards its original shape before trying to remold the cornea to the parameters of the new lens. Upon returning to clinic after the first night of wear the lens continued to adhere. A new lens was ordered once again, with an even steeper base curve to reduce the overcorrection and increase the sagittal depth.

The new lens was once again, sent home to be worn over night by the subject, and once again, lens adherence occurred upon awakening the next morning. The subject continued with this lens, and returned one week later for an evaluation, at this time, the right lens was determined to be a good fit,
however, the left lens was still adherent. The patient was closely monitored for further adherence symptoms.

Six months after enrollment into the study the patient returned to clinic with concerns of discomfort and lens awareness, blurred vision, redness, and lens adhesion in the right eye, and lens adhesion in the left eye. Slit lamp examination revealed grade 1 staining OU, grade 2 injection OD, and a 1mm peripheral infiltrate OD. This was assessed to be a moderate adverse event and proper paper work was completed to discontinue this subject from the study as outlined by the study protocol. It was decided not to culture the infiltrate because in the investigators opinion, the infiltrate appeared to be sterile and further manipulation it would only disrupt the epithelium. The prognosis was guarded and the subject was closely monitored. Upon returning to clinic the next day the peripheral infiltrate showed overlying staining, estimated to be 1 x 1.5mm. The patient was given Vigamox ophthalmic solution to instill in the right eye four times a day, prophylactically. Within two days, the peripheral infiltrate was noted to be minimal but the patient was instructed to continue the Vigamox another 24 hours before discontinuing. Upon a one week follow up, the adverse reaction had had completely resolved.
The reason for discontinuation was cited as a poor outcome with treatment or re-treatment lenses in addition to recurrent lens adherence in the left eye and poor visual outcome in the right eye.

There were a series of two post-discontinuation visits, each separated by one month, to ensure the patient had returned to baseline and all other ocular findings were within normal limits as shown by Table 5. These visits proved to show that the subject had returned to baseline and all other ocular findings were acceptable.

Table 5: Baseline Results vs. Discontinuation Results for BJ

<table>
<thead>
<tr>
<th>Subject</th>
<th>Eye</th>
<th>Baseline LogMar VA</th>
<th>Baseline RX</th>
<th>Post Discontinuation LogMar BVA</th>
<th>Post Discontinuation Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>BJ</td>
<td>OD</td>
<td>50@20ft</td>
<td>-4.50</td>
<td>53@20ft</td>
<td>-4.25</td>
</tr>
<tr>
<td></td>
<td>OS</td>
<td>50@20ft</td>
<td>-4.25</td>
<td>52@20ft</td>
<td>-4.00</td>
</tr>
</tbody>
</table>
Subject 5: CN

CN is a 26 year old white female librarian, who reports wearing her current soft contact lenses for 15-18 hours making her symptomatic for “very tired and dry eyes.”

Her ocular and systemic health was unremarkable with the exception of mild seasonal allergies.

Her initial baseline visit revealed a healthy anterior segment and a refraction of:

- OD: -1.25 DS 48@20ft
- OS: -1.00 DS 48@20ft

Based on the CRT fitting guide, LF was fit with the following test lenses:

- OD: 8.00 .525 -34
- OS: 7.90 .525 -34

These lenses centered well and exhibited the following findings:

- Both Eyes X: 0, Y: -0.50
- Treatment zone: 4.0 mm
- Movement: 0.75 mm
- Best visual acuity: right eye 51@20ft, left eye 47@20ft

The initial spherical over-refraction revealed +0.25D and plano in the right and left eye respectively. The subject reported some initial awareness with the test lenses but quickly adjusted to them after dispensing.

Upon her 24 hour follow-up visit, CN reported good lens comfort and vision. Her acuities were 45@20ft and 46@20ft in the right and left eye.
respectively, at which time she over-refracted at +0.25 and plano. Topography revealed that the lenses centered well at night and a good size treatment zone was also apparent with unremarkable biomicroscopy findings. Due to the acceptable fit, this was the final and only lens used on CN.

We saw CN on a continuous basis for the next 6 months. She reported having trouble getting the contact lenses in and out but otherwise was very happy with her vision throughout the day. The best visual acuity that CN achieved from this modality was 51@20ft and 53@20ft in the right and left eye respectively, indicating an improvement over her baseline acuities. CN’s acuities remained fairly stable at approximately 50@20ft for the duration of the study with consistently unremarkable slit lamp findings.

At the 3 month mark, CN to discontinue lens wear for 72 hours, at which time, her refractive error slowly returned toward baseline as demonstrated in Table 6.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Eye</th>
<th>Baseline LogMar VA</th>
<th>Baseline RX Sphere</th>
<th>Baseline RX Cylinder</th>
<th>72 hour post-removal LogMar BVA Sphere</th>
<th>72 hour post removal Rx Cylinder</th>
</tr>
</thead>
<tbody>
<tr>
<td>CN</td>
<td>OD</td>
<td>48@20ft</td>
<td>-1.25</td>
<td>DS</td>
<td>34@20 ft</td>
<td>-0.50</td>
</tr>
<tr>
<td>OS</td>
<td></td>
<td>48@20ft</td>
<td>-1.00</td>
<td>DS</td>
<td>34@20 ft</td>
<td>-0.50</td>
</tr>
</tbody>
</table>
CN completed the remainder of her visits and continued with good vision, unremarkable anterior segment findings and excellent comfort.

This subject successfully completed the study and has decided to continue with this modality.
Subject 6: AD

AD is a 24 year old white female optometry student who has been wearing soft contact lenses for since childhood. She reports good vision with her current soft contact lens prescription and her only concern is occasional dry and itchy eyes, especially at the end of the day. Her ocular and systemic health is unremarkable and she is currently not taking any medications.

Her initial baseline visit revealed a healthy anterior segment and a refraction of:

\[
\begin{align*}
\text{OD: } & -4.75 - 0.25 \times 130 & 48\text{@20ft} \\
\text{OS: } & -3.50 - 1.25 \times 163 & 48\text{@20ft}
\end{align*}
\]

Based on the CRT fitting guide, LF was fit with the following test lenses:

\[
\begin{align*}
\text{OD: } & 9.10 \ .525 \ -34 \\
\text{OS: } & 8.90 \ .525 \ -34
\end{align*}
\]

These lenses centered well and exhibited the following findings:

- Both Eyes X: +0.50, Y: +1.00
- Treatment zone: 4.0 mm
- Movement: 1.00 mm
- Best visual acuity: Both Eyes 50@20ft

The patient reported acute lens awareness and distress initially but slowly improved as the study progressed. The dispensed lenses produced a spherical over-refraction of +0.25D and +0.50D in her right and left eye respectively.
At her 24 hour follow-up visit, her acuities were 11@20ft and 36@20ft in the right and left eye respectively with an over refraction of -1.50 and -0.50. Biomicropscoy was unremarkable.

Considering AD was a moderate myope, we expected a longer duration for corneal reshaping to occur. Topography confirmed these expectations with a well centered, yet under corrected treatment zone. Based on this data, we expected AD’s vision to improve within the next few days as corneal molding pursued.

AD returned for her 2 week visit, at which time acuities were recoreded as 38@20ft and 25@20ft in the right and left eye respectively with an over refraction of -1.50DS and +1.50-1.00 x 174. Slit lamp findings were unremarkable; however the patient still reported some lens awareness and discomfort.

New test lenses that increased return zone depth and reduced edge lift were ordered with the following parameters.

OD: 9.00 .550 -34
OS: 8.90 .550 -34

Before theses lenses could be dispensed, the subject submitted a request to withdraw from the study, indicating poor lens tolerance, poor acuities and fluctuating vision as the main reasons for her discontinuation. AD was relying on her glasses to see, however due to her partially reshaped corneas, they were too strong and often elicited headaches. As dictated by the study guidelines, AD
returned for a discontinuation visit and a 1 month post-discontinuation visit to ensure that her vision had returned to baseline. Please refer to Table 7.

Table 7: Baseline Results vs. Discontinuation Results for AD

<table>
<thead>
<tr>
<th>Subject</th>
<th>Eye</th>
<th>Baseline LogMar VA</th>
<th>Baseline RX</th>
<th>1 month post discontinuation LogMar VA</th>
<th>1 month post discontinuation Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sphere</td>
<td>Cylinder</td>
<td>Sphere</td>
</tr>
<tr>
<td>AD</td>
<td>OD</td>
<td>48@20ft</td>
<td>-4.25</td>
<td>-0.25x130</td>
<td>49@20 ft</td>
</tr>
<tr>
<td></td>
<td>OS</td>
<td>48@20ft</td>
<td>-3.25</td>
<td>-1.25x163</td>
<td>46@20 ft</td>
</tr>
</tbody>
</table>
Subject 7: TJ

TJ is a 25 year old white female who is currently an optometry student and relies predominantly on glasses to correct her vision, however will use soft lenses when necessary. Her main complaint is that she cannot wear glasses to play soccer, and “they often get wet and fog up in the cold, rainy weather.”

Her ocular and systemic health was unremarkable and indicated no ocular allergies. Her initial baseline visit revealed a healthy anterior segment and a refraction of:

- OD: -3.25 DS
- OS: -4.00 - 0.50 x 164

Based on the CRT fitting guide, LF was fit with the following test lenses:

- OD: 8.20 .525 -34
- OS: 8.40 .550 -34

These lenses centered well and exhibited the following findings:

- Both Eyes X: 0, Y: +0.50
- Treatment zone: 4.0 mm
- Movement: 1.25 mm
- Best visual acuity: Right eye 50@20ft, left eye 49@20ft

The patient reported acute lens awareness and discomfort immediately upon lens insertion at the dispensing visit. The dispensed lenses produced a spherical over-refraction of plano in both eyes.
TJ did not return for her scheduled visits indicating that she was having trouble falling asleep with the lenses on her eyes, due to apparent lens awareness. After repeated attempts, TJ returned to the clinic after having successfully worn her lenses for 6 hours the night before. At the morning follow up visit, TJ presented with acuities of 22@20ft and 10@20ft in the right and left eye respectively, with an over refraction of -2.50D and -4.00D. Considering TJ was a moderate myope, we expected a longer duration for substantial corneal reshaping to occur. However, due to the highly uncomfortable properties of the lens, TJ withdrew from the study at this visit.

As indicated by the study guidelines, TJ returned for a 1 month post discontinuation visit to ensure that her vision had returned to normal within this time. Table 8 shows a comparison of her baseline refractive error to her 1 month post discontinuation visit. All biomicroscopy findings were within normal limits.

<table>
<thead>
<tr>
<th>Table 8: Baseline Results vs. Discontinuation Results for TJ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>TJ</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
Subject 8: NS

NS is a 21 year old white female, who is currently training within the armed forces to become a military negotiator. NS reported wearing her spherical hydrogel soft contact lenses for about 20 hours a day, seven days per week.

Her systemic health was unremarkable upon initial evaluation and she reported no allergies or conditions that would exclude her from the study. The subjects reported being a smoker and an occasional alcohol user.

Her initial baseline visit revealed grade 1 corneal neovascularization and grade 1 conjunctival injection in both eyes with a refraction of:

OD: -2.00 DS 50@20ft 19@5ft (unaided)
OS: -1.50 DS 50@20ft 25@5ft (unaided)

Based on the CRT fitting guide, LF was fit with the following test lenses:

OD: 8.40 .525 -33
OS: 8.00 .525 -33

These lenses centered slightly low and exhibited the following findings:

- Both Eyes X: 0, Y: -0.50
- Treatment zone: 4.0 mm
- Movement: 1.00 mm
- Best visual acuity: Right eye 44@20ft and left eye 38@20ft

These lenses were dispensed and produced a spherical over-refraction of +1.25D and plano OD and OS respectively. The subject reported initial discomfort of the lenses but slowly adjusted to them.
Upon her 24 hour follow-up visit, NS reported continued lens discomfort in both eyes upon awakening and presented with acuities of 50@20ft and 50@20ft in the right and left eye respectively with an over refraction of plano and -0.50D.

Slit lamp findings revealed slight conjunctival injection with no other abnormal findings from her initial visit. Her topographical maps revealed that the lenses centered quite well in the closed eye position and the treatment zone appeared to be sufficient.

At her two week visit, NS reported great vision in the distance, but decreased vision at near, having to bring reading material closer and having a harder time focusing on the computer. At this time, she presented with some central superficial punctuate keratitis and slight injection in both eyes but was encouraged to continue with the same lenses.

By her one month visit, the near complaints dissipated, lens comfort improved dramatically, and she reported no other problems. By her two month visit, her acuities improved to 52 and 50 in the right and left eye respectively at 20 ft.

Due to the satisfactory fit and vision, only one lens was used for NS, though a lost right lens was replaced for the subject on one occasion.

Table 9 shows NS’s results from the 72 hour post removal visit and reveals a slow return of refractive error to baseline.
Table 9: Baseline Results vs. 72 Hour Post Removal Results for NS

<table>
<thead>
<tr>
<th>Subject</th>
<th>Eye</th>
<th>Baseline LogMar VA</th>
<th>Baseline RX Sphere</th>
<th>72 hour post-removal LogMar BVA</th>
<th>72 hour post-removal Sphere</th>
<th>72 hour post-removal Cylinder</th>
</tr>
</thead>
<tbody>
<tr>
<td>NS</td>
<td>OD</td>
<td>50@20ft</td>
<td>-2.00 DS</td>
<td>35@20 ft</td>
<td>-1.25</td>
<td>DS</td>
</tr>
<tr>
<td></td>
<td>OS</td>
<td>50@20ft</td>
<td>-1.50 DS</td>
<td>45@20 ft</td>
<td>-0.75</td>
<td>DS</td>
</tr>
</tbody>
</table>

The patient reports overall satisfaction with the modality and appreciates the freedom from contact lens wear during the day. Because NS is now enrolled in boot camp, she is not permitted to continue with this modality, however, she has expressed great interest in continuing with this therapy after she completes her training requirements.

This subject successfully completed the study and has decided to continue with this modality.
Subject 9: MB

MB is a 27 year old white female who is a stay at home mom. She reports wearing her current hydrogel soft contact lenses for approximately 12 hours each day, seven days per week.

Her ocular and systemic health was unremarkable upon initial evaluation. Her initial baseline visit revealed a healthy anterior segment and a refraction of:

OD: -0.50 -0.50 x 165  50@20ft  39@5ft (unaided)
OS: -0.50 -0.75 x 010  51@20ft  34@5ft (unaided)

Based on the CRT fitting guide, LF was fit with the following test lenses:

OD: 8.20 .500 -33
OS: 8.30 .475 -32

These lenses centered slightly high and exhibited the following findings:

- Both Eyes X: 0, Y: +1.00
- Treatment zone: 4.0 mm
- Movement: 1.00 mm
- Best visual acuity: Right eye 45@20ft, left eye 47@20ft

These lenses were dispensed and produced a spherical over-refraction of plano in both eyes. The patient reported initial awareness of the lenses but quickly adjusted to them.

Upon her one day follow-up the next morning, MB reported good lens comfort in both eyes and presented with acuities of 47@20ft and 50@20ft in the right and left eye respectively with an over refraction of +0.25D in both eyes.
MB however did report symptoms of itching and burning on occasion, which was supported by slit lamp findings of grade 1 injection, mild central staining and grade 1 tarsal abnormalities. Her topographical maps revealed that the lenses centered well in the closed eye position and the treatment zone appeared to be sufficient.

At her one month visit, MB reported unequal lens awareness between the two eyes, with the left eye being more bothersome than the right. She experienced quick instances of sharp pain once in a while throughout the night in her left eye. Upon her slit lamp evaluation, we discovered some corneal staining and tarsal abnormalities, in her left eye.

After careful examination of MB’s left lens, we discovered that there were obvious lathe marks on the lens, indicating poor manufacturing. We re-ordered a left lens and refit MB, which resolved the problem upon lens insertion.

At her 3 month visit, MB withdrew from the study, indicating lens discomfort issues as the reason for discontinuation, even though she reported her appreciation for the crispness of vision. We saw MB for a one month post discontinuation visit to ensure her refractive error returned to baseline.
Subject 10: JP

JP is a 31 year old white female who is currently a naturopathic graduate student in Portland, Oregon. She reported wearing her current spherical hydrogel soft lenses for about 16 hours a day, seven days a week. Her ocular and systemic health was unremarkable and with no other conditions that excluded her from the study. Her initial baseline visit revealed a healthy anterior segment and a refraction of:

- OD: -3.75 -0.75 x110
- OS: -4.25 -0.50 x086

46@20ft 5@10ft (unaided)
45@20ft 5@10ft (Unaided)

Based on the CRT fitting guide, LF was fit with the following test lenses:

- OD: 8.20 .575 -34
- OS: 8.30 .575 -34

When placed on her eyes, these lenses were well centered but produced a treatment zone of 2mm in both eyes. As a result, we ordered a steeper fit of:

- OD: 8.30 .525 -36
- OS: 8.30 .525 -36

These lenses centered well in the right eye but centered poorly in the left with the following findings:

- Right eye X: 0, Y: 0, Left eye X: +1.00, Y: +1.00
- Treatment zone: right eye 5.0 mm, left eye 3.00 mm
- Movement: 0.50 mm
- Best visual acuity: Right eye 46@20ft, left eye 44@20ft
These lenses produced a spherical over-refraction of plano and +0.25D in the right and left eye respectively. Due to the poor fit in her left eye, we decided not to dispense these but rather reorder a new left lens before dispensing.

The following lenses were dispensed:

OD: 8.30 .525 -36  
OS: 8.30 .550 -37

Upon her one day follow-up evaluation, she exhibited marked inferior staining, potentially from either a suspected lagophthalmos or chronic blepharitis toxicity. As a result, we discontinued contact lens wear for one week and made adjustments to improve the fit. After two more attempts, the following lens was extrapolated as the best fit for JP’s very steep corneas.

OD: 8.30 .525 -38  
OS: 8.30 .525 -38

When this lens was ordered however, we discovered that the landing zone required for JP could not be made because the parameter was outside of the study protocol. As a result, we had to discontinue the subject from the study. We never managed to get any lenses on her for more than a one day follow-up because of the challenging fit. JP returned for her post-discontinuation visits to ensure her refractive error returned to baseline.
Subject 11: TB

TB is a 27 year old white female who is a spouse of an optometry student and is currently working as a bank manager. She reported wearing her current soft lenses for approximately 17 hours a day, seven days per week. She dislikes wearing soft contact lenses because of the inconvenience and dry eye symptoms that accompany this modality.

Her ocular and systemic health was unremarkable and she reported mild seasonal allergies. Her initial baseline visit revealed a healthy anterior segment and a refraction of:

\[
\begin{align*}
\text{OD:} & \quad -3.00 \text{ DS} \\
\text{OS:} & \quad -3.50 \text{ DS}
\end{align*}
\]

Based on the CRT fitting guide, LF was fit with the following test lenses:

\[
\begin{align*}
\text{OD:} & \quad 8.50 \ .550 \ -34 \\
\text{OS:} & \quad 8.50 \ .550 \ -34
\end{align*}
\]

These lenses centered slightly high and exhibited the following findings:

- Both Eyes X: 0, Y: +1.00
- Treatment zone: 5.0 mm
- Movement: 1.50 mm
- Best visual acuity: right eye 44@20ft, left eye 46@20ft

These lenses were dispensed and produced a spherical over-refraction of +0.75D and +1.00 in the right and left eye respectively. Patient reported initial awareness of the lenses but quickly adjusted to them.
On her one day follow-up visit, TB reported good lens comfort and lens off acuities of 17@20ft and 11@20ft with and an over refraction of 0.50 -1.25 x 012 OD and -0.25 -1.00 x 084 in the right and left eye respectively. Slit lamp findings revealed grade one central staining in both eyes and grade 1 conjunctival injection in both eyes. Her topographical maps revealed that the lenses centered well in the closed eye position. Treatment zone size appeared to be sufficient.

TB returned for her scheduled visits for the next 6 months at which time, four revisions were made to the lenses for each eye, either because of poor end acuity or a poor fit. Table 10 lists a summary of all the trialed lenses for TB:

Table 10: Summary of lenses fit on subject TB

<table>
<thead>
<tr>
<th></th>
<th>OD</th>
<th>OS</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD</td>
<td>8.50 .550 -34</td>
<td>8.50 .550 -34</td>
</tr>
<tr>
<td>OD</td>
<td>8.50 .525 -35</td>
<td>8.50 .575 -33</td>
</tr>
<tr>
<td>OD</td>
<td>8.50 .525 -34</td>
<td>8.40 .550 -35</td>
</tr>
<tr>
<td>OS</td>
<td>8.50 .525 -35</td>
<td>8.40 .550 -34</td>
</tr>
</tbody>
</table>

The final contact lenses we dispensed produced final unaided acuities of 45@20ft for both eyes and an over refraction of +0.75D and -0.25D in the right and left eye respectively.

Although TB was happy with the end outcome, and end acuities, fitting this subject was a challenge. For instance, during her second week of the study, TB experienced an episode of seasonal allergies whereby we prescribed Patanol
to be instilled twice a day and discontinued her from lens wear for a week until her episode subsided.

Then at the two month mark, TB experienced significant glare problems while driving at night. Her topographies revealed that even though in the open eye condition, the lenses clearly rode high, in the sleeping position; they actually rode low, which indicated a lens parameter change.

Table 11 shows TB's results from the 72 hour post removal period which showed a clear progression of her refractive error back toward baseline.

Table 11: Baseline Results vs. 72 Hour Post Removal Results for TB

<table>
<thead>
<tr>
<th>Subject</th>
<th>Eye</th>
<th>Baseline LogMar VA</th>
<th>Baseline RX</th>
<th>72 hour post-removal LogMar BVA</th>
<th>72 hour post-removal Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sphere</td>
<td>Cylinder</td>
<td>Sphere</td>
</tr>
<tr>
<td>TB</td>
<td>OD</td>
<td>50@20ft</td>
<td>-3.00</td>
<td>DS</td>
<td>9@20 ft</td>
</tr>
<tr>
<td></td>
<td>OS</td>
<td>46@20ft</td>
<td>-3.50</td>
<td>DS</td>
<td>9@20 ft</td>
</tr>
</tbody>
</table>

The patient reported overall satisfaction with the modality and appreciates the freedom from contact lens wear during the day. Though she reported that her visual acuities are not always stable, she did notice substantial improvement in her dry eye symptoms. This subject successfully completed the study and has decided to continue with this modality.
DISCUSSION / CONCLUSION

The Paragon-Z CRT contact lens unites two technologies into a single lens design that not only allows unrestricted oxygen entry to the cornea but also incorporates the benefits of not wearing contact lenses during the day. Of the eleven subjects, five subjects successfully completed the study and did very well with this modality. These five patients had little trouble adapting to the lenses and wearing schedule and often commented on the comfort and convenience over their previous correction during waking hours.

Four of the eleven patients withdrew from the study, citing significant lens discomfort or poor end acuities as the reason. One of the eleven subjects (JP) was discontinued because her corneal profile was outside of the fitting parameters of the study lenses. And one out of the eleven subjects experienced persistent lens adherence over the last five months of the study. Lens parameters were modified in an effort to eliminate this and still maintain sufficient corneal aplanation in the closed eye condition; however, all changes produced little resolution. Figure 4 shows a summary of how many subjects and their reasons for withdrawing from the study.
Rigid gas-permeable (RGP) lens adherence has been reported in both daily and extended wear, although it is considered to be more common with the latter (8,9). The mechanism for daily wear RGP lens adherence is likely similar to that of extended wear (9). An adhesive effect is thought to form between the cornea and the posterior lens surface by a thin, highly viscous retro-lens tear film (9). In 1989, Swarbrick and Holden proposed that lens binding is primarily a patient-dependent phenomenon rather than lens parameter-dependent (10). Swarbrick and Eiden found variable success in eliminating lens adherence by changing lens parameters (8,9). In some cases lens modifications helped eliminate or decrease lens adherence and in some cases no improvement was noted. We also found this to be the case with BJ. Some modifications in the lens parameters seemed to decrease the lens adherence; however it was never completely eliminated. We
think this is not due to the design or material of the lens but rather patient dependent. Additionally, it has been recommended to instill two to three drops of sterile, unpreserved saline on the eye before sleeping at night and upon wakening to decrease adherence (15). This is thought to initiate lens movement and flush debris from behind the lens (8, 15).

BJ presented with additional complications associated with RGP lens adherence including corneal indentation ring, distorted central cornea, peripheral and central corneal staining, and infiltrative keratitis. The earliest stages of contact lens peripheral ulcer (CLPU) and microbial keratitis (MK) are often difficult to differentiate (11). The key factors to monitor are discomfort, discharge, lesion size, an anterior chamber reaction, and the shape of the lesion (12). From the patient’s initial presentation until complete resolution, the signs and symptoms pointed toward a sterile infiltrate versus an infectious ulcer and the patient was managed accordingly. These complications are not thought to be associated with this lens design but rather a function of overnight lens wear and patient physiology.

In addition to the risk of lens adherence, other adverse effects are possible and expected with extended RGP lens wear, some of which include corneal edema, corneal staining, redness, tearing, irritation, and some distortion of vision. These are usually a temporary occurrence and generally resolve with
time. As expected, some of the study subjects experienced varying degrees of these side effects.

The results of this study suggest that a predictor of success with CRT may be an individual's baseline refractive error. This study found that for refractive errors greater than -3.00 diopters of spherical correction, CRT with the menicon Z lens, creates a greater challenge in the fitting process, as demonstrated by the increased number of lens changes and fitting attempts required by each subject with higher refractive errors and by the higher number of discontinuations for this refractive error group as shown in Figure 5 and Figure 6. In addition, these subjects presented with more reported adverse events throughout the duration of 6 months than the subjects with lower refractive errors.

Figure 5: Equivalent Sphere vs. Status in Study
The study also suggests that CRT with the lenses under investigation may be additionally successful if the subject has no astigmatic component in their correction as shown in Error! Reference source not found..
The subjects with baseline refractions below -3.00 diopters were observed to be the most satisfied and motivated to continue with this therapy. In fact, at the completion of the study, these five individuals indicated that they would continue using the study lenses as their primary form of refractive correction. Figure 8 shows the status of best visual acuity achieved by these subjects with CRT compared to their baseline acuities.

**Figure 8: Status of Acuities Achieved in the study**

![Bar chart showing status of final BVA compared to initial BVA.](chart)

This study also suggests that 72 hours of lens wear discontinuation is not enough time for remolded corneas to return to baseline; however all the subjects reached 100% recovery by the 1 month mark. And of the eleven subjects, one subject developed a corneal ulcer. In retrospect, we recognize that had we removed the subject from the study earlier, a corneal ulcer could have been prevented. The subject presented with early signs of being a poor candidate.
when he developed persistent lens adhesions and adverse reactions throughout most of the study, even with lens adjustments.

In conclusion, although all over night contact lens wear should be approached with caution by practitioners and patients alike, with careful clinical monitoring for adverse events, and appropriate recognition of a poor candidate, in our opinion, the CRT Menicon Z™ lens appears to be a safe and effective alternative to other lens modalities and refractive surgery.
REFERENCES


# APPENDIX

Table 12: Summary of Baseline Visit of all the patients

<table>
<thead>
<tr>
<th>Subject No.</th>
<th>Eye</th>
<th>Gender</th>
<th>Age</th>
<th>Keratometry</th>
<th>LogMar Perscipation</th>
<th>CL</th>
<th>Hx</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, MP OD</td>
<td>M</td>
<td>25</td>
<td>43.00/43.25@90</td>
<td>51@20ft -2.00 -0.50 x 140</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>1, OS</td>
<td>M</td>
<td>25</td>
<td>43.00/43.25@90</td>
<td>52@20ft -2.00 DS</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>2, PR OD</td>
<td>M</td>
<td>25</td>
<td>43.87/45.75@100</td>
<td>50@20ft -3.25 -0.25 x 110</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>2, OS</td>
<td>M</td>
<td>25</td>
<td>43.37/44.00@106</td>
<td>50@20ft -3.00 -0.50 x 180</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>3, LF OD</td>
<td>F</td>
<td>28</td>
<td>42.00/42.75@90</td>
<td>49@20ft -2.25 DS Soft CL</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>3, OS</td>
<td>F</td>
<td>28</td>
<td>42.00/42.50@90</td>
<td>50@20ft -2.25 DS</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>4, NS OD</td>
<td>F</td>
<td>21</td>
<td>42.87/43.50@90</td>
<td>50@20ft -2.00 DS</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>4, OS</td>
<td>F</td>
<td>21</td>
<td>44.12/44.62@158</td>
<td>50@20ft -1.50 DS</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>5, JP OD</td>
<td>F</td>
<td>31</td>
<td>45.87/46.12@90</td>
<td>46@20ft -3.75 -0.75 x 110</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>5, OS</td>
<td>F</td>
<td>31</td>
<td>46.37/46.50@90</td>
<td>45@20ft -4.25 -0.50 x 086</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>6, CN OD</td>
<td>F</td>
<td>27</td>
<td>44.00/45.00@90</td>
<td>48@20ft -1.25 DS</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>6, OS</td>
<td>F</td>
<td>27</td>
<td>44.00/45.00@90</td>
<td>48@20ft -1.00 DS</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>7, BJ OD</td>
<td>M</td>
<td>24</td>
<td>42.12/42.87@162</td>
<td>50@20ft -4.50 -0.75 x 150</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>7, OS</td>
<td>M</td>
<td>24</td>
<td>42.25/42.50@180</td>
<td>50@20ft -4.25 -0.50 x 015</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>8, AD OD</td>
<td>F</td>
<td>24</td>
<td>42.00/43.00@90</td>
<td>48@20ft -4.75 -0.25 x 130</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>8, OS</td>
<td>F</td>
<td>24</td>
<td>42.00/43.50@80</td>
<td>48@20ft -3.50 -1.25 x 163</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>9, TJ OD</td>
<td>F</td>
<td>24</td>
<td>45.50/45.50@90</td>
<td>46@20ft -3.25 DS</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>9, OS</td>
<td>F</td>
<td>24</td>
<td>45.25/46.00@90</td>
<td>45@20ft -4.00 -0.50 x 164</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>10, MB OD</td>
<td>F</td>
<td>27</td>
<td>42.12/42.62@090</td>
<td>50@20ft -0.50 -0.50 x 165</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>10, OS</td>
<td>F</td>
<td>27</td>
<td>41.87/42.50@070</td>
<td>51@20ft -0.50 -0.75 x 010</td>
<td>BVA</td>
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<td>Cylinder</td>
</tr>
<tr>
<td>11, TB OD</td>
<td>F</td>
<td>27</td>
<td>42.75/43.50@082</td>
<td>50@20ft -2.00 DS</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>11, OS</td>
<td>F</td>
<td>27</td>
<td>43.12/43.75@085</td>
<td>46@20ft -2.00 DS</td>
<td>BVA</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
</tbody>
</table>
BIOGRAPHY OF AUTHORS

Mathew Lampa
Academic Preparation
Pacific University College of Optometry, *Forest Grove, Oregon*, 2002-2006
- Doctorate of Optometry
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Scholarships
- Deans Scholarship, 2002
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- American Optometric Student Association, 2002-present
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  - Low Vision Rehabilitation Section
- Student Optometric Association, 2002-present
- Amigos Eye Care, 2002-present
  - 2003 Trip to Honduras Gift Coordinator
  - 2004 Trip to Guatemala Eye Glasses Coordinator
  - 2005 Trip to Ghana Co-Leader, Eye Glasses Coordinator
- Fellowship of Christian Optometrists, 2002-present
  - 2003-2004 President
  - 2004-2005 President

I plan to complete a residency in Cornea and Contact Lens immediately upon graduation. I then plan on transitioning into employment and partnership within a practice specializing in cornea, contact lens, and ocular disease.
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Amigos Eye Care, 2002-present
  • 2005 Trip to Vera Cruz, Oaxaca, Mexico

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  • 2004-present

Future Goals

Upon graduation, I hope to pursue a Contact Lens Residency before committing to a solo private practice or a partnership practice specializing in specialty contact lenses.
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- Pacific University College of Optometry, *Forest Grove, Oregon*, 2002-2006
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- Vancity Scholarship (1998)

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- American Optometric Student Association, 2002-present
  - Contact Lens and Cornea Section
- Member of California Optometric Association, 2002-present
- Member of Optometric Physicians of Washington (OPW), 2002-present
- Canadian National Institute for Blind (CNID), *Vancouver, BC, Canada* 2001-present
  - 2001 Trip to Punjab, India

After completing my OD degree, I plan on traveling through Europe, Africa and Asia for three months and then returning home to Vancouver, BC to work as an OD in a private practice setting for a year. I then plan on returning to the US for residency in Cornea and Contact Lens in 2007. I eventually hope to be in a partnership practice setting where I would fit completed cornea with contact lenses referred by other ODs or MDs in the area.
INVESTIGATION OF A RIGID GAS PERMEABLE CONTACT LENS FOR OVERNIGHT CORNEAL REFRACTIVE THERAPY

A thesis submitted to the faculty of the College of Optometry at Pacific University Forest Grove, Oregon For the degree of

Doctor of Optometry May 2006

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