Comparative clinical evaluation of a traditional hydrogel soft contact lens and a silicone hydrogel soft contact lens

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Comparative clinical evaluation of a traditional hydrogel soft contact lens and a silicone hydrogel soft contact lens

Abstract
Purpose: Silicone hydrogel lenses were initially introduced due to the advantages of increased oxygen transmissibility for continuous wear. The introduction of newer silicone hydrogel lenses however is shifting this class of contact lenses toward daily wear. This study compared the daily wear clinical performance of a silicone hydrogel with a biomimetic hydrogel lens for comfortable wearing time, end-of-the-day and overall comfort.

Methods: This was a subject- masked, bilateral cross over investigation. 40 subjects wore the two test lenses in random succession and were evaluated after 2 and 4 weeks of wear.

Results: Mean comfort score on a 0-100 visual analogue scale was 79.0 for the traditional hydrogel (Lens A), and 68.8 for the silicone hydrogel (Lens B) (two-tailed P = 0.0046). Mean comfortable wear time for the Lens A was 11.83 hours and for the Lens B 10.75 (two-tailed P = 0.0563). There were no significant differences between lens types for dynamic and static lens fit, visual acuity or subjective ratings of visual quality. Slit lamp findings were similar between lens types except for Limbal Redness, which was better for Lens B at the 4 week point. Burning/Stinging and Dryness symptoms demonstrated a trend to lower frequency with Lens A. 68% preferred Lens A overall compared to 32% for Lens B 0% reporting no difference. For end-of-the-day comfort, 59% preferred Lens A as compared to 24% Lens B 17% indicating no preference.

Conclusion: Both lenses offer excellent overall clinical performance. These findings suggest that high Dklt alone is not sufficient for optimal contact lens wearing comfort and daily wear success.

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Degree Name
Master of Science in Vision Science

Committee Chair
Peter D. Bergenske

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daily wear, silicone hydrogel, hydrogel, comfort, contact lens, oxygen transmissibility

Subject Categories
Optometry

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Comparative Clinical Evaluation of a Traditional Hydrogel Soft Contact Lens and a Silicone Hydrogel Soft Contact Lens

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A thesis submitted to the faculty of the College of Optometry Pacific University, Forest Grove, Oregon for the degree of Doctor of Optometry, May 2007

Advisor
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BIographies

**Brian Jensen** grew up in Pocatello, Idaho. After high school, he studied biology at Idaho State University in Pocatello. After graduating from Pacific University, he would like to do a residency or join a group practice.

**Ryan Peine** graduated from Brigham Young University with a Bachelor of Science in Neuroscience. He is currently a third year optometry student at Pacific University. He has plans to do a residency after graduation and would like to practice in a co-management setting.

**Derri Sandberg** is originally from Fargo, North Dakota. She attended the University of North Dakota in Grand Forks and graduated with a Bachelor of Science in Biology. After graduation from Pacific University College of Optometry, she plans to complete a residency in primary care and eventually work in a private practice setting.

**Shannon Schaefer** grew up in Craig, Colorado and graduated from Moffat County High School in 1999. She went on to graduate from Western State College of Colorado in 2003. At Western, she double-majored in Human Biology and Organizational Communications with a minor in Chemistry. Upon completion of her optometric education, she plans to return to Colorado where she would like to begin her career as a family practice optometrist.
ABSTRACT

**Purpose:** Silicone hydrogel lenses were initially introduced due to the advantages of increased oxygen transmissibility for continuous wear. The introduction of newer silicone hydrogel lenses however is shifting this class of contact lenses toward daily wear. This study compared the daily wear clinical performance of a silicone hydrogel with a biomimetic hydrogel lens for comfortable wearing time, end-of-the-day and overall comfort.

**Methods:** This was a subject - masked, bilateral cross over investigation. 40 subjects wore the two test lenses in random succession and were evaluated after 2 and 4 weeks of wear.

**Results:** Mean comfort score on a 0-100 visual analogue scale was 79.0 for the traditional hydrogel (Lens A), and 68.8 for the silicone hydrogel (Lens B) (two-tailed P = 0.0046). Mean comfortable wear time for the Lens A was 11.83 hours and for the Lens B 10.75 (two-tailed P = 0.0563). There were no significant differences between lens types for dynamic and static lens fit, visual acuity or subjective ratings of visual quality. Slit lamp findings were similar between lens types except for Limbal Redness, which was better for Lens B at the 4 week point. Burning/Stinging and Dryness symptoms demonstrated a trend to lower frequency with Lens A. 68% preferred Lens A overall compared to 32% for Lens B and 0% reporting no difference. For end-of-the-day comfort, 59% preferred Lens A as compared to 24% Lens B and 17% indicating no preference.

**Conclusion:** Both lenses offer excellent overall clinical performance. These findings suggest that high Dk/t alone is not sufficient for optimal contact lens wearing comfort and daily wear success.

**Key Words:** daily wear, silicone hydrogel, hydrogel, comfort, contact lens, oxygen transmissibility, dryness.
ACKNOWLEDGEMENTS

The authors would like to thank Dr. Peter Bergenske, Dr. Jennifer Smythe, Dr. David Kading, and Pat Caroline for their assistance during contact lens fitting and follow up exams. We would like to give special thanks to our advisor, Dr. Peter Bergenske, for his insight, organization, and presentation of study results at the American Academy of Optometry annual meeting.

This research was presented by Dr. Peter Bergenske as a poster presentation at the American Academy of Optometry annual meeting in San Diego, California on December 8, 2005.
With the introduction of silicone hydrogel lenses in 1999, contact lens manufacturers and practitioners became interested in the physiologic benefits and wearability of silicone hydrogels as compared to their traditional hydrogel counterparts. Most research shows that silicone hydrogels allow for increased oxygen permeability and superior ocular health; however, their comfort has been questioned.

Oxygen transmission is important for ocular physiology; however, it is not the only factor that contributes to successful contact lens wear. Comfort is essential. According to Schlanger, 72% of failed contact lens wear is due to comfort related issues and not physiological concerns. This underscores the fact that high oxygen transmission does not always equate to successful lens wear. Comfort is crucial for satisfied contact lens wearers.

Comfort is a function of numerous lens properties including dehydration and lens modulus. On-eye lens dehydration often leads to dry eye symptoms. Discomfort secondary to dryness is implicated as a leading factor contributing to lens discontinuation. Previous studies have shown decreased dehydration with silicone hydrogel lenses in vitro; however, researchers question the predictability of these findings for on-eye performance and comfort. Additionally, research has suggested that first generation silicone hydrogels may have been poorly accepted by patients due to discomfort associated with the lenses' high modulus. Furthermore, the stiffness of early silicone hydrogels may have lead to increased corneal trauma including mucin balls, Contact Lens Induced Papillary Conjunctivitis, and Superior Epithelial Arcuate Lesions.

Today's silicone hydrogel manufacturers claim their lens's characteristics, namely low water content, result in less dehydration and therefore, increased lens comfort. Manufacturers also report less subjective dryness with silicone hydrogel lenses than with conventional hydrogel lenses; however, claims of decreased dryness are conflicting. The United States Food and Drug Administration (FDA) supports the notion that patients wearing silicone hydrogels are less symptomatic than those wearing conventional soft lenses; however, other investigations as well as anecdotal reports refute this claim. Regarding modulus, current lens designers are aware of its impact on comfort. Today's silicone hydrogels have lower moduli than their predecessors.

Traditional hydrogel lenses also have many qualities designed to increase patient comfort, in light of decreased oxygen transmission. For example, Proclear Compatibles® (Lake Forest, California) lenses by CooperVision are made of a biomimetic material, omafilcon A that binds tightly to water resulting in decreased dehydration in a high water content lens. In previous studies, Proclear lenses demonstrated good movement and centration as well as low on eye dehydration, all factors contributing to lens comfort.
Several studies have examined the short-term comfort of silicone hydrogels versus traditional hydrogel lenses; however, few studies have compared the comfort of these modalities over time. This paper investigates clinical aspects of contact lens wear for two readily available lenses, a hydrogel and a silicone hydrogel. The researchers explored subjective and objective findings relating to wearability, ocular health, and performance of the contrasting lenses.

**MATERIALS AND METHODS**

This was a two-month, 40-subject, randomized, two-part crossover study comparing traditional hydrogel lenses to silicone hydrogel lenses.

Prior to the outset of the study, approval was received from the Pacific University Institutional Review Board (IRB) regarding the protocol and methodology of the research. A copy of the document accompanies this report (Appendix 1).

**Study Population**

Forty subjects ranging in age from 19 to 52 years old were enrolled. The mean age was 25.6 with a standard deviation of 4.98 years. Sixteen subjects were males and 24 were females.

Prior to enrollment in the study, subjects were contacted by phone. During this conversation the purpose and timeline of the study were explained. Each participant was read the enrollment criteria and preliminary determination of their eligibility was decided by the researchers. At the initial visit, subjects were further screened regarding the following inclusion and exclusion criteria:

**Inclusion Criteria**

The subjects needed to meet the following criteria:

1. At least 18 years old
2. Signed the informed consent form
3. Refractive error ranging from -1.00D to -6.00D of myopic correction with less than or equal to 1.00D of astigmatism bilaterally
4. Best corrected distance visual acuity is 20/30 or better OU
5. Worn soft contact lenses at least 4 weeks prior to the start of the study in either bi-weekly or monthly replacement modality.
6. Can comfortably wear his or her soft contact lenses at least 10 hours or more each day
7. Healthy eyes as per the study protocol
8. Available during a two month period for biweekly appointments
Exclusion Criteria
The following criteria excluded subjects from the study:
1. Worn RPG or PMMA lenses within 4 weeks prior to the start of the study
2. A current O2 Optix or Proclear lens wearer
3. Pregnant, lactating, or planning pregnancy
4. Keratoconus
5. Currently wearing extended wear contact lens wearer
6. Taking ocular medications
7. Subject has a systemic condition and/or the medical treatment that affects the wear of contact lenses
8. Subject has had eye surgery 8 weeks prior to the start of the study
9. Subject has pre-existing ocular irritation that effects contact lens wear
10. Subject has abnormal lacrimal secretions

Lenses
The lenses compared in this study were a traditional hydrogel lens (Lens A) and a silicone hydrogel lens (Lens B). Lens A is a lathe-cut omafilcon A lens composed of 59% phosphorylcholine. It is an FDA Group 2 lens with a water content of 60% and a Dk of 34.0. There are BOZR’s available: 8.20mm and 8.60mm. Lens A has a diameter of 14.2mm. The lens is available in powers ranging from +4.00D to -6.00D in 0.25D increments. Lens A is designed for monthly replacement and is FDA approved to provide increased comfort for dry-eye sufferers. According to Tyler’s Quarterly,7 Lens B is a molded lotrafilcon B lens. It is an FDA Group 1 lens with a water content of 33% and a Dk of 110. The lens has an 8.5 mm BOZR with a diameter of 14.2mm. The lens is available in powers ranging from -1.00D to -6.00D in 0.25D increments. Lens B is FDA approved for up to six nights extended wear and is recommended as a two-week replacement modality.

Lens A, the control lens, was provided by the study’s sponsor. Lens B, the test lens, was purchased by the Contact Lens Institute at Pacific University College of Optometry.

Lens Care
Subjects were provided with Optifree Express (Alcon) contact lens disinfecting and storage solution at no cost for the duration of the study. Patients were instructed to follow the instructions found in the package insert. Optifree Express is a no-rub lens solution; however, in cases where excessive deposits were visible on the lenses subjects were instructed to incorporate a rubbing step into their care regimen.

Lenses were replaced on a monthly schedule. Lens A is recommended as a monthly replacement lens by the manufacturer; however, Lens B is suggested as a two week replacement modality. At the investigator’s discretion, a monthly replacement plan was implemented for both lenses unless loss or damage of the lens was evident; in which case replacement lenses were provided. It is important to note, the package insert for Lens B states “the eyecare practitioner is recommended to determine an appropriate lens replacement schedule based up on the response of the patient.”
Patients were instructed not to wear their lenses overnight as this study was evaluating the effects of daily wear conditions.

**Masking**

This study was a single-masked study in which the subjects were blinded to the lenses, manufacturers, and sponsors involved with the study. The investigators were not masked because the markings on Lens B were easily identifiable.

**Protocol**

Informed consent was obtained from each subject at the outset of the study. Each subject completed five visits over a two month period. During this time they wore a silicone hydrogel lens bilaterally (Lens B) for one month, and a traditional hydrogel lens (Lens A) bilaterally for one month.

Subjects were randomized into two groups using the website randomnumbergenerator.com. One group wore the silicone hydrogel lens first, while the other group wore the traditional hydrogel lens first. At the end of the first month the subjects returned their initial lenses and were fitted with the remaining lenses for the second phase of the study.

Each subject was assigned an identification number that consisted of a number representing the order in which they were enrolled in the study followed by their initials. In cases where subjects did not have a middle name an X was used.

The five visits were as follows:

**Baseline/Dispense Pair 1**

At this visit informed consent was obtained and study eligibility was confirmed. Additional information including gender, age, current lens brand, average daily wearing time with current contact lenses, and average comfortable daily wearing time with current contact lenses was obtained.

A spectacle refraction was performed to determine the subjects best vision sphere. The prescription was vertex corrected for those prescriptions greater than -4.00 DS. Baseline standard Snellen distance visual acuities were taken through the best vision sphere.

Keratometry was performed using a Marco manual keratometer.

An initial slit lamp examination was performed and the following observations were made: limbal and bulbar conjunctival hyperaemia; upper and lower palpebral conjunctival hyperaemia; presence, extent and location of corneal staining; presence, extent and location of conjunctival staining; other slit lamp findings. These characteristics were evaluated using the Cornea and Contact Lens Research Unit (CCLRU) standardized criteria (Appendix 2). Photographs were taken as outlined in a forthcoming description.
The first pair of lenses was fit and dispensed. Prior to dispensing standard Snellen distance visual acuity was assessed both with and without an over-refraction. Each subject was asked to subjectively rate the quality of their vision on a scale of 0-100% with 0% being worst and 100% being best. The fit was assessed by evaluation of lens centration, corneal coverage, post-blink movement, push-up test, and overall fit acceptance. Each criterion was graded using a standardized evaluation protocol (Appendix 3).

2 Week Follow-up, Pair 1 and 2 Week Follow-up, Pair 2
Upon follow-up patients were asked how long they had the lenses in that day as well as the number of days they had worn the lenses since their last visit. They were also questioned about the following symptoms/problems: discomfort, excess tearing, photophobia, haloes, itching, burning/stinging, blurred vision, variable vision, dryness, and redness. They were asked to evaluate each eye separately and to grade the symptoms/problems as none, mild, moderate, or severe.

Standard Snellen distance visual acuity was taken with the lenses in place. A best vision sphere over-refraction was performed and acuities were taken again if indicated. Subjects were asked to subjectively rate the quality of their vision on a scale of 0-100% with 0% being worst and 100% being best.

The researchers evaluated the fit of the lenses using the following criteria: lens centration, corneal coverage, post-blink movement, push-up test, and overall fit acceptance. Each criterion was graded using a standardized evaluation protocol.

The subject was then asked to remove their lenses and the following structures were examined with slit lamp evaluation: limbal and bulbar conjunctival hyperaemia; upper and lower palpebral conjunctival hyperaemia; presence, extent and location of corneal staining; presence, extent and location of conjunctival staining; other slit lamp findings. These characteristics were evaluated using the CCLRU standardized grading criteria (Appendix 2). Photographs were taken as outlined in the forthcoming description.

Finally, the subject was asked to complete a subjective questionnaire. On a scale of excellent, very good, good, fair or poor they were asked to rate the following characteristics: overall comfort, initial comfort, end of day comfort, dryness, vision, and comfortable wearing time. They were also asked to provide the number of hours per day they could comfortably wear the lenses. Lastly they were asked to indicate how comfortable their eyes felt on a subjective grading scale (Appendix 3).

4 Week Follow-up Pair 1/Dispense Pair 2
Subjects were asked how long they had the lenses in that day as well as the number of days they had worn the lenses since their last visit. They were also questioned about the following symptoms/problems: discomfort, excess tearing,
photophobia, haloes, itching, burning/stinging, blurred vision, variable vision, dryness, and redness. They were asked to evaluate each eye separately and to grade the symptoms/problems as none, mild, moderate, or severe.

Standard Snellen distance visual acuity was taken with the lenses in place. A best vision sphere over-refraction was performed and acuities were taken again as necessary. Subjects were asked to subjectively rate the quality of their vision on a scale of 0 to 100% with 0% being worst and 100% being best.

The researchers evaluated the fit of the lenses using the following criteria: lens centration, corneal coverage, post-blink movement, push-up test, and overall fit acceptance. Each criterion was graded using a standardized evaluation protocol.

The subject was then asked to remove their lenses and the following structures were examined with slit lamp evaluation: limbal and bulbar conjunctival hyperaemia; upper and lower palpebral conjunctival hyperaemia; presence, extent and location of corneal staining; presence, extent and location of conjunctival staining; other slit lamp findings. These characteristics were evaluated using the CCLRU standardized criteria (Appendix 2). Photographs were taken as outlined in the forthcoming description.

The second pair of lenses was fit and dispensed. Prior to dispensing standard Snellen distance visual acuity was assessed both with and without an over-refraction. Each subject was asked to subjectively rate the quality of their vision on a scale of 0-100% with 0% being worst and 100% being best. The fit was assessed by evaluation of lens centration, corneal coverage, post-blink movement, push-up test, and overall fit acceptance. Each criterion was graded using a standardized evaluation protocol.

The first pair of lenses was retrieved from the patient and placed in a storage case labeled with the subject’s ID number as well as the lens number (e.g. first lens). The discarded lenses were placed in refrigeration and sent to the sponsor’s laboratory for further evaluation upon completion of the study.

4 Week Follow-Up Pair 2/ Study Exit
At the second visit for each pair of lenses, subjects were asked how long they had the lenses in that day as well as the number of days they had worn the lenses since their last visit. They were also questioned about the following symptoms/problems: discomfort, excess tearing, photophobia, haloes, itching, burning/stinging, blurred vision, variable vision, dryness, and redness. They were asked to evaluate each eye separately and to grade the symptoms/problems as none, mild, moderate, or severe.
Standard Snellen distance visual acuity was taken with the lenses in place. A best vision sphere over-refraction was performed and acuities were taken again as necessary. Subjects were asked to subjectively rate the quality of their vision on a scale of 0-100% with 0% being worst and 100% being best.

The researchers evaluated the fit of the lenses using the following criteria: lens centration, corneal coverage, post-blink movement, push-up test, and overall fit acceptance. Each criterion was graded using a standardized evaluation protocol.

The subject was then asked to remove their lenses and the following structures were examined with slit lamp evaluation: limbal and bulbar conjunctival hyperaemia; upper and lower palpebral conjunctival hyperaemia; presence, extent and location of corneal staining; presence, extent and location of conjunctival staining; other slit lamp findings. These characteristics were evaluated using the CCLRU standardized criteria (Appendix 2). Photographs were taken as outlined in the forthcoming description.

Next, the subject was asked to complete a subjective questionnaire. On a scale of excellent, very good, good, fair or poor they were asked to rate the following characteristics: overall comfort, initial comfort, end of day comfort, dryness, vision, and comfortable wearing time. They were also asked to provide the number of hours per day they could comfortably wear the lenses. Then, they were asked to indicate how comfortable their eyes felt on a comfort visual analog scale (Appendix 3).

The second pair of lenses was retrieved from the subject and placed in a storage case labeled with the subject's ID number as well as the lens number (e.g. first lens). The discarded lenses were placed in refrigeration and sent to the sponsor's laboratory for further evaluation upon completion of the study.

In the event of an exit visit, a lens preference questionnaire was completed. Subjects were asked if they preferred the first or second pair of lenses, or if they had no preference for each of the following categories: overall comfort, initial comfort, end of day comfort, dryness, vision, and comfortable wearing time.

A final spectacle refraction and keratometric readings were obtained and the subject was exited from the study.

In cases where patients were unable to complete the study the main reason for discontinuation was cited. Options included poor visual acuity, unacceptable slit lamp findings, adverse reactions, unacceptable lens fit, patient discomfort, poor handling, loss to follow-up, disinterest, unable to attend appointments, unrelated medical problems, protocol deviation, inclusion/exclusion criteria, or “other.” The examiner also noted which eye(s) the problem related to and if the patient required a post-study follow-up visit.
**Slit Lamp Photography**
Photographs were taken at each visit using a Nikon slit lamp with a D100 Nikon anterior segment camera. Bulbar, limbal, and palpebral conjunctival hyperaemia were photographed for each eye. Each visit resulted in six photographs per subject. The photographs were labeled with the prefix 904 followed by the patients identification number. For example all photographs for subject 01 have the prefix 90401 followed by an L or R to indicate the eye, and a letter to identify the shot (e.g. C, Cornea; L, lower bulbar and tarsal conjunctiva; U Upper tarsal conjunctiva. The letter is then followed by a number one through five to represent the visit at which the photo was taken. An example of a photograph label would be 90401LC3, showing this was study number 904, subject number 01 and the photograph was of the left cornea at the third visit.

**Comfort Visual Analog Scale**
At each visit, the subjects were asked to complete a visual analog scale (Appendix 3). Using this method the subject placed marks on lines representing right and left eyes. Each line represented a scale of 0 to 100 with a mark placed closer to the top of the line representing a number closer to 100, and in turn a more comfortable lens. Each mark was measured and then used in statistical analysis.

**Retention Strategy**
The corporate sponsor of the study offered $75.00 to subjects who completed the study. Subjects who were unable to complete the study were provided with a proportionate compensation.

**RESULTS**

**Subjects**
Thirty-four of the forty subjects successfully completed the study. Reasons for discontinuation included unacceptable lens fit, unrelated illness, unacceptable lens comfort, and lost to follow-up.

There were four unscheduled visits. Three were related to comfort and became exit visits. One visit was to replace a torn lens.

One subject missed two consecutive visits and was dropped from the study. No other visits were missed.

There were several instances of unscheduled lens replacements. Eight replacement lenses for Lens A and six replacements for Lens B were dispensed as the result of lost or torn lenses.

There were no adverse events recorded for this study.
Photographs
Photographs were taken at each visit. They are available on CD from Dr. Peter Bergenske of the Pacific University Contact Lens Research Institute.

Data Analysis
The primary variables under investigation were: slit lamp findings, adverse events, symptoms, comfort, lens fit characteristics, visual acuity, subjective vision quality.

Slit Lamp Findings
Data were analyzed comparing right eye findings at each two week interval for each group. Analysis was performed using Friedman’s Repeated Measures ANOVA. Limbal redness was significantly less for subjects wearing Lens B than Lens A at the four-week point (p = 0.002, mean score for Lens A = 1.34, mean score for Lens B = 0.58).

Adverse Events
No adverse events were reported.

Symptoms
Data were analyzed comparing right eye findings at each interval for each group. Friedman’s Repeated Measures ANOVA was used. No significant differences were noted at either interval.

Of note is a trend showing worse scores for Lens B for burning/stinging and dryness evaluation. Figure 1 summarizes the responses for the two lenses at the two week intervals. Figure 2 shows the responses at the four week intervals.

Comfort
Data were analyzed comparing right eye findings at each interval for each group. Friedman’s Repeated measures ANOVA was used. No significant differences were noted.

Hours of Comfortable Wear
Combining all visits, mean wear time for Lens A was 11.83 hours and for Lens B was 10.75 hours. A paired t-test for normal data was used resulting in a two-tailed P value of 0.0563. This value is not statistically significant.

Comfort Visual Analog Scale
At the two week interval, the mean score for Lens A was 80.7. The mean score for Lens B was 78.5. A paired t-test for normal data was used to test for the significance of this difference. The two-tailed P value is 0.06322 is not significant.

Lens Fit Characteristics
No difference in lens fit characteristics was noted between the two lenses.
Visual Acuity
There was no difference noted in measured Snellen distance visual acuity, nor in the subject's subjective rating of visual quality.

Forced Choice Preference Questions
The breakdown of subject responses is summarized in the Fig. 3.

Table 1 gives the distribution by percentage. Fisher’s Exact Test was used to compute P values.

DISCUSSION

While many of the findings in this study were not statistically significant, there were some noteworthy trends.

Lens A performed better in the forced choice preference questions with 68% preferring Lens A overall, compared to 32% preferring Lens B.

Patients symptomatic for burning/stinging and dryness showed strong trends toward preferring Lens A for diminished symptoms. The statistical criteria for this analysis for this protocol were stringent; it may be of interest to design a study that looks at these issues in isolation.

Of interest to the authors, as well as to the contact lens community as a whole, is the issue of comfort with silicone hydrogel lenses. This study suggests silicone hydrogel lenses may be less comfortable than their traditional hydrogel counterparts for some patients. This is an aspect of silicone hydrogel research and development the industry will have to investigate and improve. From a patient’s prospective, it doesn’t matter how physiologically superior a lens is, it must be wearable.
REFERENCES


Table 1: Forced choice end-of-study percentages and P values

<table>
<thead>
<tr>
<th></th>
<th>Lens A</th>
<th>Lens B</th>
<th>No Preference</th>
<th>P Value&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>68%</td>
<td>32%</td>
<td>0</td>
<td>0.138</td>
</tr>
<tr>
<td>Initial</td>
<td>29%</td>
<td>50%</td>
<td>21%</td>
<td>0.362</td>
</tr>
<tr>
<td>End of day</td>
<td>59%</td>
<td>24%</td>
<td>17%</td>
<td>0.071</td>
</tr>
<tr>
<td>Dryness</td>
<td>35%</td>
<td>24%</td>
<td>41%</td>
<td>0.456</td>
</tr>
<tr>
<td>Vision</td>
<td>29%</td>
<td>18%</td>
<td>53%</td>
<td>0.416</td>
</tr>
<tr>
<td>Wear time</td>
<td>53%</td>
<td>29%</td>
<td>18%</td>
<td>0.261</td>
</tr>
</tbody>
</table>

<sup>a</sup>P Values computed from Fisher's Exact test method
Figure 1: Comparison of burning and stinging with Lens A versus Lens B at two-week wear time

Comparison at week 2
Figure 2: Comparison of burning and stinging with Lens A versus Lens B at four-week wear time

Comparison at week 4

- Lens A
- Lens B
Figure 3: End-of-study lens preference

Forced Choice Preference

- Lens A
- Lens B
- No Pref

Overall  Initial  End  Dry  Vision  Weartime
APPENDIX 1:

INSTITUTIONAL REVIEW BOARD (I.R.B.) APPROVAL
APPLICATION AND INFORMED CONSENT

Peter Bergenske, OD, FAAO

Pacific University College of Optometry
Forest Grove, Oregon
Project Title: Comparative clinical evaluation of a traditional hydrogel and a silicone hydrogel Soft Contact Lens

Abstract: This study will compare the clinical performance of two FDA approved frequent replacement soft contact lenses. Two common complaints of soft contact lens wearers are dryness and discomfort. Both study lenses have been reported to alleviate or decrease the frequency and severity of these symptoms. In this study clinical variables will be evaluated at 2 weeks and 4 weeks of daily wear of each lens type.

Project locations: The Pacific University Family Vision Center, Pacific at Birch, Forest Grove, OR 97116.

Project overview: Subjects will be solicited via email and verbal recruitment of current optometry students and their spouses. Eligible patients of the Pacific University Family Vision Center may also be invited to participate. All potential subjects must have had a complete optometric examination within the previous 12 months prior to consideration for the study.

The study will be a randomized single-blind contralateral design in which 20 subjects will simultaneously wear the two different soft contact lenses. Selection of the eye to wear each lens will be determined by a randomization table. To be eligible for study participation all potential subjects must:

* be free of ocular or systemic disease which would contraindicate contact lens wear
• not be current wearers of either study contact lens brand
• have a refractive error in the range of −1.00 to −6.00 with astigmatism ≤ 0.75 D in both eyes

Each lens type will be worn for a 4-week period during which the lenses will not be replaced unless required due to loss, damage or lens deposits.

The first visit will consist of a baseline exam including: a complete contact lens history, a refraction, complete slit lamp evaluation, corneal topography, diagnostic fitting of both study lens designs and over-refraction. Lenses will be dispensed, with appropriate lens care instruction, for wear following lens receipt. At the one week, two week and four week study visits the following will be assessed: distance visual acuity, lens fit assessment, over-refraction, ocular health and subjective evaluation of comfort, dryness and handling via questionnaire.

Following completion of the study, the data will be analyzed by parametric and non-parametric statistics, as indicated by the data format by an outside statistician.

Potential for conflict of interest: The study is sponsored by, the maker and distributor of the one of the test lenses. Subjects will be masked as to the lens types and will not be told that Cooper is the sponsor of the study. Payment for the study to Pacific University and to subjects is totally independent of study outcome.
Risks: All procedures performed in this study will be current, accepted clinical procedures for the fitting and management of contact lens patients. All lens materials, designs and care products have been approved for use by the US Food and Drug Administration (FDA). Small amounts of ocular redness may occur from lens wear, and there is a very small risk of ocular infection and/or loss of vision with the use of contact lenses. This risk increases with non-compliance to care and follow-up schedules. Subjects who do not comply with prescribed regimens will be discontinued from the study and will be required to forfeit their lenses. All subjects will sign an informed consent document. The IRB will be notified in the event that any subject is injured during the study.

Procedures to avoid risk: All optometric care will be carried out or directly supervised by a licensed optometrist. Subjects will be adequately instructed on the care and handling of their lenses, provided with written documentation of care and follow-up instructions, and given clinic and emergency phone numbers in case of problems.

VII. Signatures:

Peter Bergenske, OD, FAAO  
Principal Investigator  

Date
INFORMED CONSENT DOCUMENT

Institution:

<table>
<thead>
<tr>
<th>A. Title</th>
<th>Comparative clinical evaluation of two soft contact lenses</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Principal Investigator</td>
<td>Peter Bergenske, O.D.  (503) 352-2278</td>
</tr>
<tr>
<td>C. Locations</td>
<td>Pacific University Family Vision Center</td>
</tr>
<tr>
<td></td>
<td>Pacific at Birch</td>
</tr>
<tr>
<td></td>
<td>Forest Grove, OR  97116  (503) 357-5800</td>
</tr>
<tr>
<td>D. Dates of project:</td>
<td>February 2005 – April 2005</td>
</tr>
</tbody>
</table>

1. Description of project

The purpose of this study is to evaluate the clinical performance and patient preferences for two FDA approved planned replacement soft contact lenses. You will be one of thirty subjects who will wear each study lens brand on a daily wear basis for one month each. You will be monitored at the following intervals: enrollment visit, two weeks, and four weeks. At the four week visit you will be fit into the second lens type, which then be worn for four weeks, with visits at the two week and four week intervals. Interim visits will be scheduled as necessary to ensure appropriate eye care. At each study visit, lens fit, vision and eye health will be evaluated as well as subjective assessment of visual performance via questionnaires.

2. Description of risks:

All procedures performed in this study will be current, accepted clinical procedures for the fitting and management of contact lens patients. Small amounts of eye redness may occur from lens wear, and there is a very small risk of eye infection and/or loss of vision with the use of contact lenses. This risk increases with non-compliance to
care and follow-up schedules. If you do not comply with prescribed regimens you will be discontinued from the study and will be required to forfeit the lenses.

3. Description of benefits:

If you are accepted for study participation you will be supplied with products representing the newest technologies in contact lens care. Throughout the duration of the study, your lenses and lens care will be complimentary. If you attend all study visits you will be compensated $75 at the conclusion of the study.

4. Alternatives advantageous to subjects:

You may be better suited to other types of contact lenses or to spectacles. If the investigator feels you are not suited to the study protocol, the investigator will so advise you and endeavor to provide you with a prescription for your optimum form of vision correction. If you are not suited, you will not be enrolled in the study and not be eligible for compensation.

5. Confidentiality of records:

Records of this project will be maintained in a confidential manner and no name-identifiable information will be released. Records are maintained in a locked file cabinet to which only the investigator and his designees (study monitors or co-investigators) have access.

6. Compensation and medical care:

During your participation in this project you are not a Pacific University clinic patient or client, nor will you be receiving complete eye care as a result of your participation in the study. If you are injured during your participation in this study and it
is not the fault of Pacific University, the experimenters, or any organization associated with the experiment, you should not expect to receive compensation or medical care from Pacific University, the experimenters, or any organization associated with the experiment.

7. **Offer to answer any inquiries:**

   The investigators will be happy to answer any questions you may have at any time during the course of the study. Dr. Bergenske can be reached by phone at 503 352 2278 or by email at berg1101@pacificu.edu. If you are not satisfied with the answers you receive, please call the Institutional Review Board Chair, Dr. Karl Citek 503-352-2126 to discuss your questions or concerns further. Although Dr. Citek will ask your name, all complaints will be kept in confidence.

8. **Freedom to withdraw:**

   You are free to withdraw your consent and to discontinue participation in this project at any time without prejudice to you (see also section 4). If you withdraw prior to the completion of the study, data collected prior to your discontinuation may still be analyzed and reported. If you choose to withdraw prior to completion of the study, you will be compensated $10 for each visit completed.

9. **Potential conflict of interest:**

   The manufacturers of the two products being tested are competitors. The study is sponsored by one of the two companies, but for purposes of minimizing bias in the study, the sponsor identification is being withheld from subjects. At the conclusion of the study, subjects will be allowed to know the identification of the sponsor if they request this information.
I have read the above and understand its meaning. I am 18 years of age or over, or this form is signed for me by my parent or guardian.

Printed name ________________________________

Signed ________________________________ Date ______

(If subject is a minor, signature of parent or legal guardian)

Address ________________________________ Phone ____________

City ________________________________ State ______ Zip ________

Name and address of a person not living with you who will always know your address:
PATIENT COPY

INFORMED CONSENT DOCUMENT

Institution:

<table>
<thead>
<tr>
<th>A. Title</th>
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I have read the above and understand its meaning. I am 18 years of age or over, or this form is signed for me by my parent or guardian.

Printed name ____________________________ Signed ____________________________ Date ___________
(If subject is a minor, signature of parent or legal guardian)
Address ____________________________ Phone ____________________________
City ____________________________ State ______ Zip ______
Name and address of a person not living with you who will always know your address:

FILE COPY
APPENDIX 2:

CONTACT LENS GrADING CRITERIA
CONTACT LENS GRADING CRITERIA

The Cornea and Contact Lens Research Unit from the University Of New South Wales School Of Optometry scale was used in subjective grading of anterior segment responses to the contact lenses in the study. The grading scale displayed anterior segment photographs under categories with increasing severity. The categories of anterior segment responses and severity scale are listed below.

Categories:
1. Bulbar redness
2. Limbal redness
3. Upper palpebral conjunctiva redness
4. Lid roughness with white light
5. Lid roughness with fluorescein
6. Polymegethism
7. Corneal staining type
8. Corneal staining depth
9. Corneal staining extent
10. Conjunctival staining

Severity Scale:
1. Very slight (1+)
2. Slight (2+)
3. Moderate (3+)
4. Severe (4+)
APPENDIX 3:

STUDY FORMS

Recording Forms: Baseline Through Exit
Visual Analog Scales
Subjective Questionnaires
ID: [Blank] - [Blank]
Baseline: Visit 1

VISIT DATE: [Blank] [Blank] [Blank]
(MM/DD/YY)
Completed Informed Consent? Yes [ ] No [ ]
Current Lens Brand: [Blank]

Sex: M [ ] F [ ] Age: [Blank]
Average daily wearing time with current contact lenses: [Blank] (hours per day)
Average comfortable daily wearing time with current contact lenses: [Blank] (hours per day)

**Spectacle refraction**

<table>
<thead>
<tr>
<th></th>
<th>RE</th>
<th>LE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distance VA (with spec Rx)</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Best Vision Sphere</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Distance VA (with BVS)</td>
<td>20</td>
<td>20</td>
</tr>
</tbody>
</table>

**Keratometry**

<table>
<thead>
<tr>
<th></th>
<th>RE</th>
<th>LE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fl</td>
<td>[Blank]</td>
<td>[Blank]</td>
</tr>
<tr>
<td>St</td>
<td>[Blank]</td>
<td>[Blank]</td>
</tr>
</tbody>
</table>

**SLIT LAMP EXAMINATION**

**Bulbar Conjunctiva**
- Limbal Hyperaemia
- Bulbar Hyperaemia

**Palpebral Conjunctiva**
- Upper Palp. Hyperaemia
- Lower Palp. Hyperaemia

**Corneal Staining**
- Extent
- Region

**Conj. staining**
- Region

**Other Slit Lamp Findings**
(please grade & describe)

Comments on Baseline: [Blank]
**Insert Lenses according to Enrolment Log**

<table>
<thead>
<tr>
<th>Lens Type:</th>
<th>RE</th>
<th>LE</th>
</tr>
</thead>
<tbody>
<tr>
<td>O2 Optix / Proclear</td>
<td>O2 Optix / Proclear</td>
<td></td>
</tr>
<tr>
<td>Base Curve:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lot #:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Assess if lenses are suitable to dispense**

| Distance VA (with CLs) (Without over-refraction) | 20 | |
| BVS over-refraction | |
| Distance VA (with CLs) (With over-refraction) | 20 | |

**Vision quality**

**Centration:**

<table>
<thead>
<tr>
<th>Corneal Coverage</th>
<th>RE</th>
<th>LE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Post-Blink Movement**

<table>
<thead>
<tr>
<th>Push-up Test</th>
<th>RE</th>
<th>LE</th>
</tr>
</thead>
<tbody>
<tr>
<td>0  ½  1 ½  2 ½  3 ½  4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Fit Acceptance**

**Reason if ≤2**

**Lens OK to dispense**

**Reason if no**

*Please provide subject with Alcon Optifree Express lens care and schedule next visit*

Comments on dispensing:
<table>
<thead>
<tr>
<th>Sub ID:</th>
<th></th>
<th>Visit ID</th>
<th>Pair 1</th>
<th>Pair 2</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
<th>Visit 5</th>
<th>Unsched</th>
</tr>
</thead>
</table>

### Visit date (MM/DD/YY):
- [ ]
- [ ]
- [ ]

### Wearing time today:
- [ ]
- [ ]
- [ ]

### Number of days worn since last visit:
- [ ]
- [ ]
- [ ]

### Symptoms & Problems:

<table>
<thead>
<tr>
<th></th>
<th>RE</th>
<th>LE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discomfort</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excess tearing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Photophobia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haloes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Itching</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Burning/stinging</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blurred vision</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Variable vision</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dryness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Redness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (describe below)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Please ask subject to complete Comfort at Visit (10cm VAS)

#### Distance VA (with CLs) (Without over-refraction)
- 20 / [ ] [ ] [ ]

#### BVS over-refraction
- [ ] [ ] [ ] D

#### Distance VA (with CLs) (With over-refraction)
- 20 / [ ] [ ] [ ]

#### Vision quality (0 to 100)
- [ ] [ ] %

#### Centration:
- [ ] [ ] [ ] mm
- [ ] [ ] [ ] mm

#### Corneal Coverage
- Yes [ ] No [ ]

#### Post-Blink Movement
- [ ] mm

#### Push-up Test
- [ ] %

#### Fit Acceptance
- [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

#### Reason if <3

### Comments

Mktg0904
Please remove lenses and place in a lens case with saline. If this is Visit 3 or Visit 5, please ensure these lenses are labelled and stored in preparation for return.

### SLIT LAMP EXAMINATION

<table>
<thead>
<tr>
<th>Sub</th>
<th>Visit</th>
<th>Pair 1</th>
<th>Pair 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bulbar Conjunctiva</th>
<th>RE</th>
<th>LE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limbal Hyperaemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulbar Hyperaemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palpebral Conjunctiva</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper Palp. Hyperaemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower Palp. Hyperaemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corneal Staining Extent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Region</td>
<td>S</td>
<td>I</td>
</tr>
<tr>
<td>Conj. staining Region</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other SLF</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(please grade & describe)

### SUBJECTIVE QUESTIONNAIRE

Please ask the subject the following questions using the wording provided

'On a scale of 'Excellent', 'Very good', 'Good', 'Fair' & 'Poor', how would you rate the performance of the lenses you are currently wearing, for the following?'

<table>
<thead>
<tr>
<th>Overall comfort</th>
<th>Excellent</th>
<th>Very good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial comfort</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>End of day comfort</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dryness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vision</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comfortable wearing time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*What is your average comfortable daily wearing time? [ ] (hours per day)*

- If this is Visit 3 please continue to dispense the second pair of lenses on the Visit 3 Dispensing form.
- If this is Visit 5 please complete the Preference Questionnaire & Exit Form.

Comments:
Please indicate how comfortable your eyes feel:

**LEFT**
- Extremely comfortable,
- Lenses unnoticeable

**RIGHT**
- Extremely uncomfortable
- Impossible to wear the lenses
**PUCO Contact Lens Institute**

<table>
<thead>
<tr>
<th>Sub ID:</th>
<th>Visit ID</th>
<th>Pair 1</th>
<th>Pair 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 2</td>
<td>Visit 3</td>
<td>Visit 4</td>
<td>Visit 5</td>
</tr>
</tbody>
</table>

**Visit date (MM/DD/YY):**

**Wearing time today:**

**Number of days worn since last visit:**

**Symptoms & Problems:**
- **Discomfort:**
  - None
  - Mild
  - Moderate
  - Severe
- **Excess tearing:**
  - None
  - Mild
  - Moderate
  - Severe
- **Photophobia:**
  - None
  - Mild
  - Moderate
  - Severe
- **Haloes:**
  - None
  - Mild
  - Moderate
  - Severe
- **Itching:**
  - None
  - Mild
  - Moderate
  - Severe
- **Burning/stinging:**
  - None
  - Mild
  - Moderate
  - Severe
- **Blurred vision:**
  - None
  - Mild
  - Moderate
  - Severe
- **Variable vision:**
  - None
  - Mild
  - Moderate
  - Severe
- **Dryness:**
  - None
  - Mild
  - Moderate
  - Severe
- **Redness:**
  - None
  - Mild
  - Moderate
  - Severe
- **Other (describe below):**

---

**Please ask subject to complete Comfort at Visit (10cm VAS)**

<table>
<thead>
<tr>
<th>Distance VA (with CLs)</th>
<th>Distance VA (with CLs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20/</td>
<td>20/</td>
</tr>
<tr>
<td>(Without over-refraction)</td>
<td>(With over-refraction)</td>
</tr>
<tr>
<td>BVS over-refraction</td>
<td>D</td>
</tr>
<tr>
<td>BVS over-refraction</td>
<td>D</td>
</tr>
</tbody>
</table>

**Vision quality (0 to 100):**

**Centration:**
- **Horizontal:**
  - mm
- **Vertical:**
  - mm

**Corneal Coverage:**
- Yes
- No

**Post-Blink Movement:**
- mm

**Push-up Test:**
- %

**Fit Acceptance:**
- 0 ½ 1 ½ 2 ½ 3 ½ 4

**Reason if <3:**

**Comments**

Mktg0904
Please remove lenses and place in a lens case with saline. If this is Visit 3 or Visit 5, please ensure these lenses are labelled and stored in preparation for return.

### SLIT LAMP EXAMINATION

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<td></td>
<td></td>
</tr>
<tr>
<td>Limbal Hyperaemia</td>
<td>0 ½</td>
<td></td>
</tr>
<tr>
<td>Bulbar Hyperaemia</td>
<td>1 ½</td>
<td></td>
</tr>
<tr>
<td><strong>Palpebral Conjunctiva</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper Palp. Hyperaemia</td>
<td>2 ½</td>
<td></td>
</tr>
<tr>
<td>Lower Palp. Hyperaemia</td>
<td>3 ½</td>
<td></td>
</tr>
<tr>
<td><strong>Corneal Staining</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extent</td>
<td>4 ½</td>
<td></td>
</tr>
<tr>
<td>Region</td>
<td></td>
<td></td>
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<tr>
<td><strong>Conj. staining</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Region</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other SLF</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(please grade & describe)

### SUBJECTIVE QUESTIONNAIRE

Please ask the subject the following questions using the wording provided

'On a scale of 'Excellent', 'Very good', 'Good', 'Fair' & 'Poor', how would you rate the performance of the lenses you are currently wearing, for the following?'

- Overall comfort
- Initial comfort
- End of day comfort
- Dryness
- Vision
- Comfortable wearing time

'What is your average comfortable daily wearing time?'  

(hours per day)

If this is Visit 3 please continue to dispense the second pair of lenses on the Visit 3 Dispensing form.

If this is Visit 5 please complete the Preference Questionnaire & Exit Form

Comments:
Please indicate how comfortable your eyes feel:

**LEFT**
- Extremely comfortable, Lenses unnoticeable

**RIGHT**
- Extremely uncomfortable
- Impossible to wear the lenses
### Insert Lenses according to Enrolment Log

<table>
<thead>
<tr>
<th>Lens Type:</th>
<th>O₂ Optix / Proclear</th>
<th>O₂ Optix / Proclear</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base Curve:</td>
<td>[ ] mm</td>
<td>[ ] mm</td>
</tr>
<tr>
<td>Power</td>
<td>[ ] D</td>
<td>[ ] D</td>
</tr>
<tr>
<td>Lot #:</td>
<td>[ ] mm D</td>
<td>[ ] mm D</td>
</tr>
</tbody>
</table>

### Assess if lenses are suitable to dispense

<table>
<thead>
<tr>
<th>Distance VA (with CLs)</th>
<th>20 / [ ] .</th>
<th>20 / [ ] .</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Without over-refraction)</td>
<td>[ ] D</td>
<td>[ ] D</td>
</tr>
<tr>
<td>BVS over-refraction</td>
<td>[ ] D</td>
<td>[ ] D</td>
</tr>
<tr>
<td>Distance VA (with CLs)</td>
<td>20 / [ ] .</td>
<td>20 / [ ] .</td>
</tr>
<tr>
<td>(With over-refraction)</td>
<td>[ ] D</td>
<td>[ ] D</td>
</tr>
<tr>
<td>Vision quality</td>
<td>[ ] %</td>
<td>[ ] %</td>
</tr>
</tbody>
</table>

### Centration:

<table>
<thead>
<tr>
<th>Horizontal</th>
<th>Vertical</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] mm</td>
<td>[ ] mm</td>
</tr>
</tbody>
</table>

### Corneal Coverage

- Yes [ ]
- No [ ]

### Post-Blink Movement

<table>
<thead>
<tr>
<th>mm</th>
<th>mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

### Push-up Test

<table>
<thead>
<tr>
<th>%</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

### Fit Acceptance

<table>
<thead>
<tr>
<th>0</th>
<th>½</th>
<th>1</th>
<th>½</th>
<th>2</th>
<th>½</th>
<th>3</th>
<th>½</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

### Reason if ≤2

<table>
<thead>
<tr>
<th>Lens OK to dispense</th>
<th>Yes [ ]</th>
<th>No [ ]</th>
</tr>
</thead>
</table>

### Reason if no

<table>
<thead>
<tr>
<th>Lens OK to dispense</th>
<th>Yes [ ]</th>
<th>No [ ]</th>
</tr>
</thead>
</table>

---

*Please provide subject with Alcon Optifree Express lens care and schedule next visit*

Comments on dispensing:

---

Mktg0904
**PUCO Contact Lens Institute**

<table>
<thead>
<tr>
<th>Sub ID:</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit date (MM/DD/YY):</td>
<td>Wearing time today</td>
<td>Number of days worn since last visit:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Symptoms & Problems:

<table>
<thead>
<tr>
<th></th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discomfort</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excess tearing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Photophobia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haloes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Itching</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Burning/stinging</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blurred vision</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Variable vision</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dryness</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Redness</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (describe below)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Please ask subject to complete Comfort at Visit (10cm VAS)**

<table>
<thead>
<tr>
<th>Distance VA (with CLs)</th>
<th>20</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(Without over-refraction)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BVS over-refraction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distance VA (with CLs)</td>
<td>20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(With over-refraction)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vision quality (0 to 100)</td>
<td></td>
<td></td>
<td>%</td>
<td></td>
</tr>
</tbody>
</table>

**Centration:**

<table>
<thead>
<tr>
<th>Horizontal</th>
<th>Vertical</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>mm</td>
</tr>
<tr>
<td>mm</td>
<td>+</td>
</tr>
</tbody>
</table>

**Corneal Coverage:**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

**Post-Blink Movement:**

<table>
<thead>
<tr>
<th>mm</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>mm</td>
<td></td>
</tr>
</tbody>
</table>

**Push-up Test:**

<table>
<thead>
<tr>
<th>%</th>
<th></th>
</tr>
</thead>
</table>

| % | |

**Fit Acceptance:**

<table>
<thead>
<tr>
<th>0 1/2</th>
<th>1 1/2</th>
<th>2 1/2</th>
<th>3 1/2</th>
<th>4</th>
</tr>
</thead>
</table>

| 0 1/2 | 1 1/2 | 2 1/2 | 3 1/2 | 4 |

**Reason if <3:**

---

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**PUCO Contact Lens Institute**

**Visit**

**Pair 1** | **Pair 2**
---|---
Visit 2 | Visit 3 | Visit 4 | Visit 5 | Unsched

---

*Please remove lenses and place in a lens case with saline. If this is Visit 3 or Visit 5, please ensure these lenses are labelled and stored in preparation for return.*

---

**SLIT LAMP EXAMINATION**

<table>
<thead>
<tr>
<th>RE</th>
<th>LE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulbar Conjunctiva</td>
<td>Bulbar Conjunctiva</td>
</tr>
<tr>
<td>Limbal Hyperaemia</td>
<td>Limbal Hyperaemia</td>
</tr>
<tr>
<td>Bulbar Hyperaemia</td>
<td>Bulbar Hyperaemia</td>
</tr>
<tr>
<td>Palpebral Conjunctiva</td>
<td>Palpebral Conjunctiva</td>
</tr>
<tr>
<td>Upper Palp. Hyperaemia</td>
<td>Upper Palp. Hyperaemia</td>
</tr>
<tr>
<td>Lower Palp. Hyperaemia</td>
<td>Lower Palp. Hyperaemia</td>
</tr>
<tr>
<td>Corneal Staining</td>
<td>Corneal Staining</td>
</tr>
<tr>
<td>Extent</td>
<td>Extent</td>
</tr>
<tr>
<td>Region</td>
<td>Region</td>
</tr>
<tr>
<td>Conj. staining</td>
<td>Conj. staining</td>
</tr>
<tr>
<td>Region</td>
<td>Region</td>
</tr>
<tr>
<td>Other SLF</td>
<td>Other SLF</td>
</tr>
</tbody>
</table>

(please grade & describe)

---

**SUBJECTIVE QUESTIONNAIRE**

*Please ask the subject the following questions using the wording provided*

*On a scale of 'Excellent', 'Very good', 'Good', 'Fair' & 'Poor', how would you rate the performance of the lenses you are currently wearing, for the following?*

<table>
<thead>
<tr>
<th>Overall comfort</th>
<th>Excellent</th>
<th>Very good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial comfort</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>End of day comfort</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dryness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vision</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comfortable wearing time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*What is your average comfortable daily wearing time? [ ] (hours per day)*

*If this is Visit 3 please continue to dispense the second pair of lenses on the Visit 3 Dispensing form.*

*If this is Visit 5 please complete the Preference Questionnaire & Exit Form*

---

Comments:

---

Mktg0904
Please indicate how comfortable your eyes feel:

**LEFT**
Extremely comfortable, Lenses unnoticeable

**RIGHT**
Extremely uncomfortable
Impossible to wear the lenses
**PUCO Contact Lens Institute**

<table>
<thead>
<tr>
<th>Sub ID:</th>
<th></th>
<th>Visit ID</th>
<th>Pair 1</th>
<th>Pair 2</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
<th>Visit 5</th>
<th>Unshed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit date (MM/DD/YY):</td>
<td>Wearing time today</td>
<td>Number of days worn since last visit:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptoms &amp; Problems:</th>
<th>RE</th>
<th>LE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discomfort</td>
<td>None</td>
<td>Mild</td>
</tr>
<tr>
<td>Excess tearing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Photophobia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haloes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Itching</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Burning/stinging</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blurred vision</td>
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<td></td>
</tr>
<tr>
<td>Dryness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Redness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (describe below)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please ask subject to complete Comfort at Visit (10cm VAS)

<table>
<thead>
<tr>
<th>Distance VA (with CLs) 20/</th>
<th>RE</th>
<th>LE</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Without over-refraction)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BVS over-refraction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distance VA (with CLs) 20/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(With over-refraction)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vision quality (0 to 100)</td>
<td>%</td>
<td>%</td>
</tr>
</tbody>
</table>

Centration: | RE | LE |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Horizontal</td>
<td>mm</td>
<td>mm</td>
</tr>
<tr>
<td>Vertical</td>
<td>mm</td>
<td>mm</td>
</tr>
</tbody>
</table>

Corneal Coverage | Yes | No |
Post-Blink Movement | mm | mm |
Push-up Test | % | % |

Fit Acceptance | | |
Reason if <3 | | |

Comments

Mktg0904 14
Please remove lenses and place in a lens case with saline. If this is Visit 3 or Visit 5, please ensure these lenses are labelled and stored in preparation for return.

SLIT LAMP EXAMINATION

**Bulbar Conjunctiva**
- Limbal Hyperaemia
- Bulbar Hyperaemia

**Palpebral Conjunctiva**
- Upper Palp. Hyperaemia
- Lower Palp. Hyperaemia

**Corneal Staining**
- Extent
- Region

** Conj. staining Region**

**Other SLF**

(please grade & describe)

SUBJECTIVE QUESTIONNAIRE

Please ask the subject the following questions using the wording provided.

'On a scale of 'Excellent', 'Very good', 'Good', 'Fair' & 'Poor', how would you rate the performance of the lenses you are currently wearing, for the following?'

Overall comfort  
Initial comfort  
End of day comfort  
Dryness  
Vision  
Comfortable wearing time

'What is your average comfortable daily wearing time? [ ] (hours per day)'

If this is Visit 3 please continue to dispense the second pair of lenses on the Visit 3 Dispensing form.

If this is Visit 5 please complete the Preference Questionnaire & Exit Form.
<table>
<thead>
<tr>
<th>Sub ID:</th>
<th>Visit ID</th>
<th>Pair 1</th>
<th>Pair 2</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
<th>Visit 5</th>
<th>Unsched</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEFT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RIGHT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please indicate how comfortable your eyes feel:

**LEFT**
- Extremely comfortable, Lenses unnoticeable

**RIGHT**
- Extremely uncomfortable
- Impossible to wear the lenses
Did the subject wear both pairs of lenses? YES □ NO □

*If YES* please complete the Preference Questionnaire. *If NO* please go to section 3

**PREFERENCE QUESTIONNAIRE** (Please ask the subject the following questions using the wording provided)

'Did you prefer the first pair of lenses or the second pair of lenses, which you wore on this study, for the following? (you may choose no preference if this is the case).''

<table>
<thead>
<tr>
<th>Question</th>
<th>1st Pair</th>
<th>2nd Pair</th>
<th>No preference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall comfort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial comfort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>End of day comfort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dryness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vision</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comfortable wearing time</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Spectacle refraction**

<table>
<thead>
<tr>
<th>Distance VA (with spec Rx)</th>
<th>RE</th>
<th>LE</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 /</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Best Vision Sphere Distance VA (with BVS)</th>
<th>RE</th>
<th>LE</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 /</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4 Keratometry</th>
<th>RE</th>
<th>LE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>St</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5 Did the subject complete the study successfully? □ YES □ NO

*If YES* stop here. *If NO* continue below.

Please indicate the main reason for discontinuation (one reason only and indicate which eye, if applicable)

<table>
<thead>
<tr>
<th>Investigator Dissatisfied</th>
<th>Subject Dissatisfied</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual Acuity</td>
<td>Visual Acuity</td>
<td>Lost to Follow-up</td>
</tr>
<tr>
<td>Slit Lamp Findings</td>
<td>Discomfort</td>
<td>Disinterest</td>
</tr>
<tr>
<td>Adverse Reaction</td>
<td>Handling</td>
<td>Unable to Attend Appoints</td>
</tr>
<tr>
<td>Unacceptable Lens Fit</td>
<td></td>
<td>Unrelated Medical Problem</td>
</tr>
</tbody>
</table>

Which eye did this problem relate to? N/A □ Left □ Right □ Both □

Does subject require a post study follow-up visit? NO □ YES □

I have reviewed all data in THESE CASE REPORT FORMS and found THEM to be complete and accurate.

**Principal Investigator’s Signature**

**Date**