

EVALUATION OF COMFORT SL IN PATIENTS WITH REGULAR CORNEAS

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## ABSTRACT

*Background* This study investigates the quality of vision and comfort attained through the wear of Comfort SL, a gas-permeable scleral contact lens, on regular corneas. In general, scleral gas-permeable contact lenses are used on irregular corneas and play a little role in correcting refractive error in people with regular corneas. This study was performed to determine if patients with regular corneas are satisfied with the comfort, vision and acceptance of a hard scleral contact lens. The Comfort SL averages 16.2 millimeters in diameter and is specially designed for non-distorted corneas based on K readings, corneal diameter, and refractive error by Accu Lens Laboratories. This study was designed to determine patient's level of comfort and clarity of vision while wearing the Comfort SL lens on students and faculty of the Michigan College of Optometry over a three month timeframe. *Methods* The previous were evaluated though the patient's reported maximum wear time, comfort level, corneal health, Snellen acuity, and overall patient acceptance of the lens. *Results* It was found that the majority of patients had good comfort while wearing these lenses and equivalent if not better quality of vision once optimally corrected. Patients were happy with their quality of vision, comfort, and wear time. *Conclusions* Though follow up visits are necessary, patients with regular corneas, are satisfied with vision and comfort of gas permeable scleral contact lenses.

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## RESEARCH PAPER

### INTRODUCTION

Historically, scleral contact lenses were the first contact lenses used.<sup>1,2</sup> Although the record of who was the first to develop a scleral contact lens is not well-documented, it is believed that from 1886 to 1888 the first designs were being created.<sup>1,3</sup>

Friedrich Anton Muller-Uri and Albert Carl Muller-Uri used blown glasses to create their first lens as a protective shell to shield and guard the eye. During this same time period, Adolf Fick fit irregular corneas with blown glass lenses. Eugene Kalt was noted using glass shells in an effort to correct keratoconus by applying central touch as an attempt to hinder the progression of the cone. Finally, August Muller worked to develop a lens that would correct his own highly myopic refractive error. Fick, Kalt, and Muller had sophisticated ideas requiring lenses made to meet their specifications. These glass lenses suffered from many of the same drawbacks of the glass eye, including corrosion by a patient's tears.<sup>1</sup>



Contact lens design took a leap forward with the progression of materials; lenses strayed away from glass to polymethyl methacrylate in 1934.<sup>4</sup> The PMMA lenses were documented to be sixty percent lighter than equivalent glass lenses.<sup>1</sup> The PMMA material was unaffected by the patient's tears and proved to be much more durable with increased wear time.<sup>1</sup> Materials continued to evolve and gas-permeable scleral contact lenses were described by Don Ezekiel in 1983.<sup>1</sup> Currently, scleral contact lenses are able to be lathe-cut from high dK materials such as Boston XO, Boston XO 2, and HDS 100.<sup>4</sup>

Today, scleral lenses are often utilized with patients where conventional rigid contact lenses or soft contact lenses are able to provide an acceptable fit or vision. Scleral lenses are most commonly fit in cases of corneal irregularity due to keratoconus, corneal transplants, trauma; high refractive errors; iris encapsulation; and therapeutic needs due to severe dry eye, corneal abrasion, or poor lid closure.<sup>2</sup> Scleral lenses often thrive by their ability to span the entire cornea and their unique fluid reservoir.<sup>2</sup>

The Comfort SL is a lens specially designed for non-distorted corneas based on K readings, corneal diameter, and refractive error by Accu Lens Laboratories.<sup>5</sup> These lenses average 16.2 millimeters and are lathe-cut from Boston XO 2. This study was designed to determine patient's level of comfort and clarity of vision ranks highly with the Comfort SL lens on students and faculty of the Michigan College of Optometry over a three month timeframe. This will be evaluated through the patient's reported maximum

wear time, comfort level, corneal health, Snellen acuity, and overall patient acceptance of the lens. It is anticipated that clarity of vision ranks highly without sacrificing comfort.

## METHODS

Once the patients were gathered from the Michigan College of Optometry they were all seen for an initial visit. During the patient's initial visit we obtained a health history, explained the project, obtained a signed informed consent, assessed the corneal health, completed topography and gathered each patient's refractive correction. From the information we obtained, we ordered the Comfort SL lenses from Accu Lens Laboratories using the patient's manifest refraction and the average K readings and corneal diameter that was obtained using a Medmont Corneal Topographer.

Once the lenses were received, each patient returned to the clinic and the lenses were inserted into the patient's eyes for an initial lens evaluation. The ordered lenses were evaluated based on the patient's fluorescein patterns. Fit was assessed by estimating the amount of tear film present between the anterior corneal surface and the back surface of the scleral contact lens using an optic section on the slit lamp. The thickness of the tear film was compared to the overall thickness of the cornea and was estimated based on an average corneal thickness of 550 microns. If the cornea was completely vaulted and there was no apparent touch between the posterior surface of the lens and the anterior corneal surface, then the lenses were deemed safe for the patient. Visual acuity measures using a Snellen visual acuity chart were taken and an over refraction was

performed to determine if the lenses were acceptable for the patients. If the fit and/or acuity measures were not acceptable, new lenses were ordered based on these findings obtained. If the over-refraction and fit of the lens was deemed good, then the patient was able to leave with lenses. Before taking the lenses home, the patients were instructed on proper insertion and removal with the assistance of a plunger and the use of the Boston Advanced cleaning system.

After wearing the lenses for seven days, patients returned to the clinic for a one week evaluation of vision. During this visit patients were asked to rank their level of comfort, wear time, vision, and overall opinion of the lenses on a scale of 0 (extremely poor) to 10 (extremely good). The fit was evaluated, visual acuity measured, and corneal health assessed. The patients were then re-evaluated in the same manner at the 1 month and 2 month visits. Evaluation forms are included in the appendixes.

## RESULTS

At the conclusion of the study and after all of the data had been gathered it was determined that there was an overall high acceptance of the Comfort SL lenses based on comfort and visual acuity.

Patient comfort ranked highly with an average of  $8.55 \pm 1.27$  out of 10 at the 8 week follow up. These rankings fall on the 0 (extremely poor) to 10 (extremely good) scale in the good range. Figure 1 illustrates individual patient ranks for each of the follow up

visits: 1 week, 4 weeks, and 8 weeks. The patients did not experience a clinically significant change in comfort after the fit was finalized.

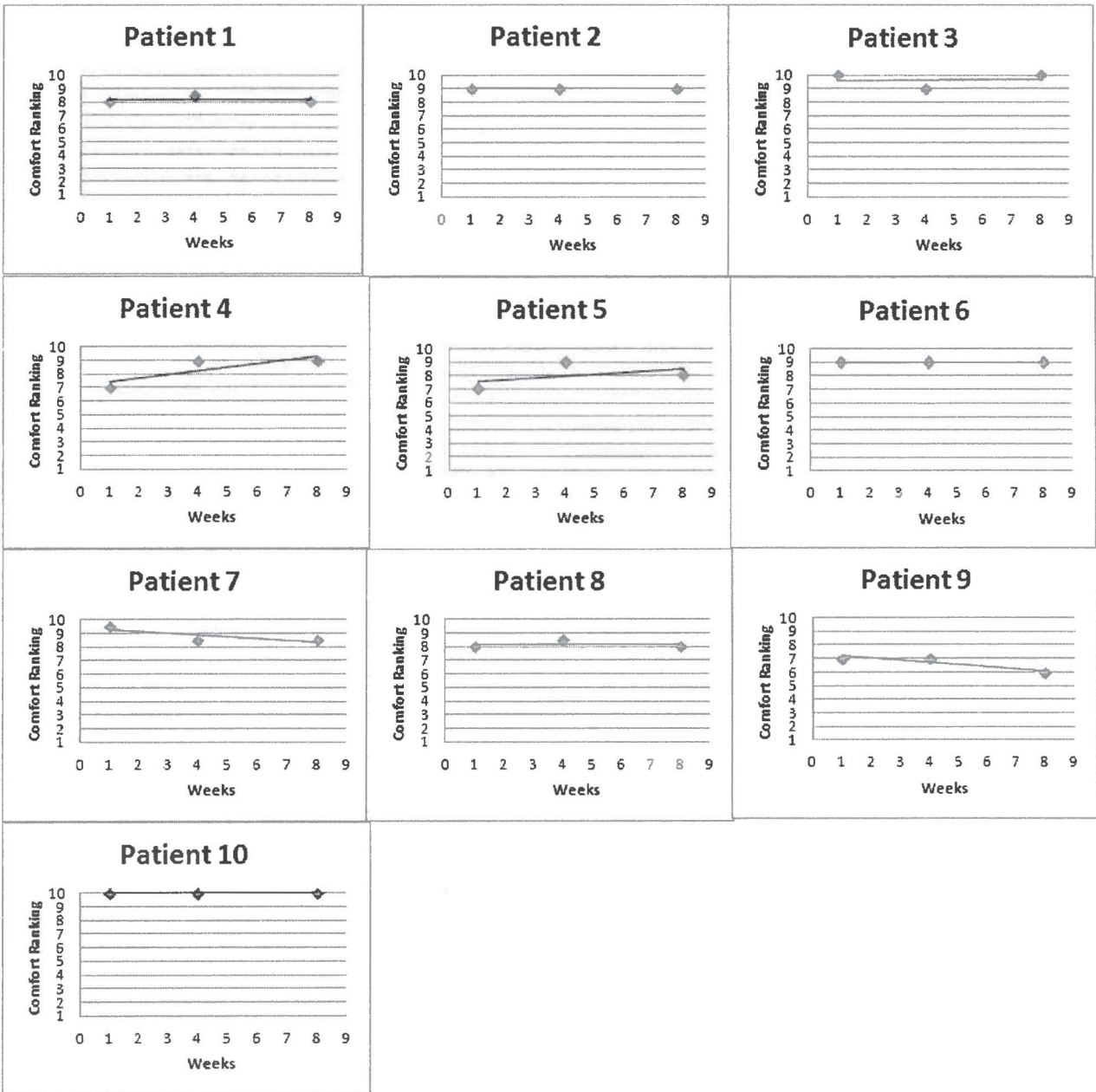


Figure 1. Comfort ranking recorded at the 1 week, 4 week, and 8 week follow up appointments for each of the 10 patients.

Average wear time was assessed on a scale of 0 (extremely poor) to 10 (extremely good).

The patients' averages during the follow up periods are illustrated in Table 1. Patients

found wear time to average 8.4 out of 10 after 1 week of wear. One month after the patient's fitting, the patient similarly found the lenses to rank 8.5 out of 10 on the wear time scale. At the final visit 2 months after the initial fitting, patients on average ranked wear time 8 out of 10. According to these results, patients found the wear time to fall in a good range. The variance standardizes the scores and shows there is no statistical variation over the follow up period.

	Average Wear Time Ranking
1 week	8.4 ± 1.2
4 weeks	8.5 ± 1.4
8 weeks	8.0 ± 1.7

Table 1. Average wear time rankings from 1-10 at the follow up appointments.

	Average Overall Opinion
1 week	8.45 ± 1.5
4 weeks	8.4 ± 1.0
8 weeks	7.9 ± 1.5

Table 2. Average patient's overall opinion of the lenses on a scale of 1-10 at each of the follow up periods.

Overall opinion was also assessed on a scale of 0 (extremely poor) to 10 (extremely good). Table 2 shows the patients' averages at 1 week, 4 weeks, and 8 weeks. Patients' average overall opinion of the lenses after 1 week of wear was 8.45 out of 10. The overall opinion was similar at the one month follow up ranking 8.4 out of 10. At the final 2 month follow up visit, patients on average ranked their overall opinion 7.9 out of 10 falling in the good range. When taking into consideration the variance among the candidates, the overall opinion throughout the study is consistent.

When evaluating opinions on vision, vision received similar averages at the 1 week, 4 week, and 8 week follow ups. Table 3 illustrates these values are all statistically stable throughout the study. At week 1 follow up, the average of the patients' opinion on vision was 8.8 out of 10. Week 4 follow up had an average of 8.7 out of 10. The average of the

patients' opinion of vision was 8.8 at the final 8 week follow up. Patients' opinions on vision were good and didn't change through the study once the standard deviation was taken into account.

	Average Vision Ranking
1 week	8.8 ± 1.8
4 weeks	8.7 ± 1.0

8 weeks	8.8 ± 1.3
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Table 3. Average vision ranks on 0-10 scale during follow up visits.

During the study, none of the patients showed any clinical signs of central or peripheral corneal staining, corneal edema, or conjunctival injection.

## DISCUSSION

Scleral lenses have their niche in treating irregular corneas and corneal surface diseases by providing optical correction, mechanical protection, relief of symptoms, and facilitate healing.<sup>6,7</sup> This study has also shown that patients with regular corneas also value the comfort, vision, wear time, and overall opinion of scleral lenses.

Romero-Rangel et al found that scleral contact lenses provide rehabilitation to patients that have debilitating ocular surface disease by decreasing pain, increasing vision, and therefore increasing quality of life.<sup>8</sup> A study complete by Jacobs and Rosenthal found that a scleral lens are an effective treatment for patients with severe dry eye due to chronic graft versus host disease.<sup>9</sup> This study analyzed the symptoms of 33 patients with chronic graft versus host disease who have previously attempted punctal occlusion, topical cyclosporine, steroids, and partial tarsorrhaphy.<sup>9</sup> After being fit with scleral

contact lenses, patients reported a reduction in eye pain, improvement in photophobia, and an increase in quality of life.<sup>9</sup>

Scleral lenses are a well-known option in keratoconus due to the fact that sclerals are able to vault the entire cornea and avoid the cone which causes corneal contact lenses to decenter. Schornack and Patel completed found on average an improvement in best-corrected visual acuity from 20/40 to 20/20 after fitting keratoconic patients with scleral lenses. Patients of this study not only appreciated their visual acuity but the scleral lenses provided good comfort as well.<sup>3</sup>

This study shows that after initial an ideal fit is found with the scleral lenses, patients did not experience variations in their quality of vision, comfort, and wear time. Though follow up visits are necessary, patients with regular corneas, are satisfied with vision and comfort of gas permeable scleral contact lenses.

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APPENDIX A

STATEMENT OF INFORMED CONSENT



APPENDIX B

INITIAL VISIT FORM

**COMFORT SL Study Form**

**Initial Visit / Fitting / Order Form**

**Subject Name:** \_\_\_\_\_ **Date of Birth:** \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**Investigator:** \_\_\_\_\_ **Date:** \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**Project Explanation and Informed Consent Completed:**      YES      NO

**History:**

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**Manifest Refraction:**

OD: \_\_\_\_\_ VA: \_\_\_\_\_

OS: \_\_\_\_\_ VA: \_\_\_\_\_

**Corneal Topography Performed:**      YES      NO

**Keratometry:**

OD: \_\_\_\_\_ @ \_\_\_\_\_ ; \_\_\_\_\_ @ \_\_\_\_\_

OS: \_\_\_\_\_ @ \_\_\_\_\_ ; \_\_\_\_\_ @ \_\_\_\_\_

**Corneal Diameter:**

OD: \_\_\_\_\_

OS: \_\_\_\_\_

**Slit Lamp Examination:**

	OD	OS
<b>Ocular Adnexa</b>		
<b>Tear Film</b>		
<b>Conjunctiva</b>		
<b>Cornea</b>		
<b>Anterior Chamber</b>		
<b>Iris</b>		

**Comfort SL Contact Lens Parameters**

OD: BC \_\_\_\_\_ Power \_\_\_\_\_ Diameter \_\_\_\_\_ SAG \_\_\_\_\_

OS: BC \_\_\_\_\_ Power \_\_\_\_\_ Diameter \_\_\_\_\_ SAG \_\_\_\_\_

APPENDIX C

STUDY FORM- OTHER VISITS

**COMFORT SL Study Form**

Visit Type (circle one):      Dispense      1 Week      1 Month      2 Months

Subject Name: \_\_\_\_\_ Date of Birth: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

Investigator: \_\_\_\_\_ Date: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**History:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Visual Acuity:**

	Distance	Near
OD		
OS		

**Over-Refraction:**

	Distance
OD	
OS	

**Subjective Quote:**

\_\_\_\_\_

\_\_\_\_\_

**Subjective Responses:**

*\* Ask the subject to rate the following items based on the scales as shown and circle the appropriate response (0=extremely poor; 10=extremely good)*

**Vision:**

OD -    1    2    3    4    5    6    7    8    9    10  
OS -    1    2    3    4    5    6    7    8    9    10

**Comfort:**

OD -    1    2    3    4    5    6    7    8    9    10  
OS -    1    2    3    4    5    6    7    8    9    10

**Maximum Wear Time:**

OD -    1    2    3    4    5    6    7    8    9    10

OS -      1      2      3      4      5      6      7      8      9      10

**Overall Opinion:**

OD -      1      2      3      4      5      6      7      8      9      10

OS -      1      2      3      4      5      6      7      8      9      10

**Subjective Symptoms:**

\* Ask the subject to rate the presence/severity of the following symptoms and then write in the appropriate response for each eye on the line provided

**Irritation (i.e. dryness, burning, scratching, grittiness, stinging, itching)**

0 = absence  
1 = minimal      OD \_\_\_\_\_  
2 = mild  
3 = moderate      OS \_\_\_\_\_  
4 = severe

**Awareness**  
0 = absence  
1 = minimal      OD \_\_\_\_\_  
2 = mild  
3 = moderate      OS \_\_\_\_\_  
4 = severe

**Redness**  
0 = absence  
1 = minimal      OD \_\_\_\_\_  
2 = mild  
3 = moderate      OS \_\_\_\_\_  
4 = severe

**Cloudy/Variable VA**  
0 = absence  
1 = minimal      OD \_\_\_\_\_  
2 = mild  
3 = moderate      OS \_\_\_\_\_  
4 = severe

**Light Sensitivity/Halos**  
0 = absence  
1 = minimal      OD \_\_\_\_\_  
2 = mild  
3 = moderate      OS \_\_\_\_\_  
4 = severe

**Slit Lamp Examination:**

	OD	OS
<b>Ocular Adnexa</b>		
<b>Tear Film</b>		
<b>Conjunctiva</b>		
<b>Cornea</b>		
<b>Anterior Chamber</b>		
<b>Iris</b>		

**Injection**

0 = absence of signs  
 1 = minimal amount      **OD** \_\_\_\_\_  
 2 = mild amount  
 3 = moderate amount      **OS** \_\_\_\_\_  
 4 = severe amount

**Central Staining**

0 = absence of signs  
 1 = minimal amount      **OD** \_\_\_\_\_  
 2 = mild amount  
 3 = moderate amount      **OS** \_\_\_\_\_  
 4 = severe amount

**Peripheral Staining**

0 = absence of signs  
 1 = minimal amount      **OD** \_\_\_\_\_  
 2 = mild amount  
 3 = moderate amount      **OS** \_\_\_\_\_  
 4 = severe amount

**Corneal Edema**

0 = absence of signs  
 1 = minimal amount      **OD** \_\_\_\_\_  
 2 = mild amount  
 3 = moderate amount      **OS** \_\_\_\_\_  
 4 = severe amount

**Other** \_\_\_\_\_

0 = absence of signs  
 1 = minimal amount      **OD** \_\_\_\_\_  
 2 = mild amount  
 3 = moderate amount      **OS** \_\_\_\_\_  
 4 = severe amount

**Other** \_\_\_\_\_

0 = absence of signs  
 1 = minimal amount      **OD** \_\_\_\_\_  
 2 = mild amount  
 3 = moderate amount      **OS** \_\_\_\_\_  
 4 = severe amount

**Lens Fitting Rating Scales:****Centration**

-2 = extreme temporal decentration, clinically unacceptable  
 -1 = temporal decentration, clinically acceptable      **OD** \_\_\_\_\_  
 0 = optimal centration  
 +1 = nasal decentration, clinically acceptable      **OS** \_\_\_\_\_  
 +2 = extreme nasal decentration, clinically unacceptable

**Fluorescein Pattern Interpretation/Sagittal Depth**

-2 = central bearing and/or limbal bubbles, clinically unacceptable  
 -1 = light bearing, clinically acceptable      **OD** \_\_\_\_\_  
 0 = alignment  
 +1 = slightly steep, clinically acceptable      **OS** \_\_\_\_\_  
 +2 = deep pooling and/or central bubbles, clinically unacceptable

**Edge/Periphery**

-2 = excessive lift off sclera, clinically unacceptable  
 -1 = slight lift off sclera, clinically acceptable      **OD** \_\_\_\_\_  
 0 = ideal scleral fit  
 +1 = slightly steep (no blanching), clinically acceptable      **OS** \_\_\_\_\_  
 +2 = excessive impingement, clinically unacceptable

**Tear Film Assessment**

**OD** \_\_\_\_\_ microns  
**OS** \_\_\_\_\_ microns