THE COMPARISON BETWEEN SPHERICAL SCLERAL CONTACT LENSES AND SOFT TORIC LENSES FIT ON EYES WITH ASTIGMATISM

by

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Has been approved

April 27, 2018

APPROVED:

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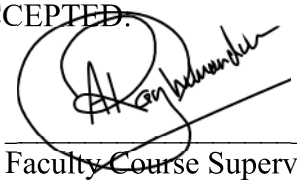
ACCEPTED:



Faculty Course Supervisor

Ferris State University
Doctor of Optometry Senior Paper
Library Approval and Release

THE COMPARISON BETWEEN SPHERICAL SCLERAL CONTACT LENSES AND SOFT TORIC LENSES FIT ON EYES WITH ASTIGMATISM

We, _ Brian Hochstetler & Stephen Herman_ hereby release this Paper as described above to Ferris State University with the understanding that it will be accessible to the general public. This release is required under the provisions of the Federal Privacy Act.

Doctoral Candidate: Stephen A Herman

Doctoral Candidate : Brian Hochstetler

3/16/18
Date

ABSTRACT

Background: Soft contact lenses are a common option offered by eye care providers to correct refractive error. A less frequently used method of correcting refractive error is scleral contact lenses. The visual performance of scleral and soft contact lenses have been compared in several recent studies.[1, 2, 3, 4] Many studies, though, were limited by the amount of time the lens was on the eye and the wear schedule of each lens.[1, 2, 3] These studies also did not take into account the performance of each lens outside of the clinical setting, and minimal data was collected regarding the subjective evaluation of each lens. *Purpose*: This study was conducted to investigate the visual performance and overall patient satisfaction of scleral contact lenses as compared to soft toric contact lenses over the period of one week. *Methods*: Subjects were required to wear each lens modality for one week to evaluate the visual performance and overall satisfaction with each lens modality. Performance measures included visual acuity, contrast sensitivity, and glare. Subject satisfaction with each modality was recorded through a survey that focused on visual performance during different activities of daily living, the physical handling of the lenses, and the comfort of the lenses. Each individual was fit with one pair of Art Optical Ampleye scleral contact lenses and one pair of CooperVision Biofinity toric contact lenses. After each fit, the subject wore the lenses for one week and reported the visual performance and comfort under different activities of daily living. *Results*: All subjects reported that they preferred insertion of the soft toric contact lenses compared to the scleral lenses. No other statistically significant conclusions could be gathered from the data collected. A larger sample size is needed to further study this subject with statistical relevance.

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CHAPTER 1

INTRODUCTION

Soft contact lenses are a common option offered by eye care providers to correct refractive error. A less frequently used method of correcting refractive error is scleral contact lenses. Scleral contact lenses are made of a rigid gas permeable material that fully rests on the sclera while completely vaulting the cornea. Because of the way they rest on the eye, scleral lenses tend to be used with patients who cannot be successfully fit in traditional contact lens modalities.

In regards to fitting contact lenses, successfully correcting astigmatic refractive error can be a challenge for practitioners. To best correct corneal induced astigmatic refractive error, the contact lenses with the best optics are made from rigid gas permeable material.[1] Rigid gas permeable contact lenses include spherical, back-toric, front-toric, and bi-toric lens designs, as well as the scleral lens modality. The popularity of rigid gas permeable lenses is limited, though, because of increased time required for a practitioner to fit these lenses, as well as decreased patient motivation due to comfort and adaptation issues.[2] For scleral lenses, it has been suggested in a recent study that comfortable wear is achieved after one month of continued wear at an average of ten hours per day.[3] This same study also reports that patients who are intolerant to scleral contact lenses are limited to wearing them for an average of five hours at a time.[3]

Commonly, soft lenses are the first contact lens of choice for correcting refractive errors because of patient comfort and the ease of fitting these lenses. However, traditional soft toric contact lenses often have parameter limitations and, at times, require additional time to fit.[4]

Within the last few years, several contact lens companies have made strides in producing expanded parameters for soft toric contact lenses.[4,5] For this study, the lens type used for traditional soft toric contact lenses was CooperVision Biofinity because of its expanded parameters, monthly replacement schedule, breathable lens material, and overall affordability to the average consumer. The scleral lens type used in this study was the Art Optical Ampleye, who sponsored this study by providing the lenses and consultation services during the fitting process.

CHAPTER 2

METHODS

This study was reviewed and approved by the Ferris State University Institutional Review Board, on October 27th, 2017 (Appendix A). All subjects were given a copy of the Research Subject Letter (Appendix D) prior to signing the Research Subject Consent Form (Appendix E).

Six participants from the Michigan College of Optometry student body and staff volunteered to participate in the study. In order to be eligible to participate, the subjects were required to wear spectacle correction and have at least 0.75 diopters of cylinder in their prescription. The subjects were not compensated for their participation, but they were allowed to keep their respective trial contact lenses at the conclusion of the study. All subjects were previous or current contact lens wearers.

Subjects were fit in Art Optical Ampleye scleral lenses and CooperVision Biofinity soft toric lenses. The Ampleye parameter ranges for this study included the following: power range of -5.25 to +5.75 diopters, sagittal depth of 3,800 to 4,200 micrometers, base curve of 8.04 to 8.44 millimeters, and diameter of 16.5 millimeters. The CooperVision Biofinity parameter ranges for this study included the following: sphere power of -7.00 to +4.75 diopters, cylinder power of -0.75 to -2.25 diopters, cylinder axes from 0 to 90 degrees, base curve of 8.7 millimeters, and diameter of 14.5 millimeters.

Corneal topography was measured with the Medmont E300 corneal topographer, and best-corrected visual acuity was obtained by subjective refraction prior to fitting the contact lenses. The most appropriate trial lens from the scleral set was allowed to settle

on each eye for 30 minutes before performing a spherical over-refraction. The fit was then re-evaluated and documented. The lenses were ordered over the phone by consulting with an Art Optical contact lens consultant.

Based on the subjective refraction, the proper soft toric contact lenses were chosen and fit on each eye of each subject. Fit was evaluated and over-refraction was performed when necessary. New lenses were then ordered for each subject based on the initial fit and over refraction.

The final scleral lenses were dispensed at a follow-up visit. Each scleral lens was allowed to settle for 30 minutes before evaluating the fit. If the fit was adequate, vision was recorded using monocular Snellen distance acuity. Brightness acuity testing was then performed and the vision was recorded. After the subjects were given ample time to recover from the brightness acuity testing, binocular contrast sensitivity was conducted using the Pelli-Robson contrast sensitivity chart. If applicable, the subjects were then taught insertion and removal of the scleral lenses until they felt comfortable performing it by themselves.

The soft toric lenses were then inserted and allowed to stabilize. Since the lens fit was approved at the initial visit, vision was recorded using monocular Snellen distance acuity. Brightness acuity testing was then performed and the vision was recorded. After the subjects were given ample time to recover from the brightness acuity testing, binocular contrast sensitivity was conducted using the Pelli-Robson contrast sensitivity chart.

For all subjects, all lenses were dispensed only if the fit was approved and if the visual acuity measured 20/25 or better. Subjects were given samples of ClearCare with

Hydraglide to disinfect both lens modalities at night. Additionally, Boston Simplus was given to soak the scleral lenses during the day if they needed to be removed. Purilens Plus preservative free saline was used to fill the bowl of the scleral lenses prior to insertion. Optifree PureMoist was given to soak the soft toric lenses during the day if they needed to be removed.

Subjects were instructed to wear the soft toric lenses for seven consecutive days for approximately 8 hours per day. At the conclusion of the seven days, the subjects filled out a survey pertaining to various aspects of wearing the soft toric lens. The subjects were instructed to wait at least 24 hours before beginning the trial of the scleral lenses. The subjects were instructed to wear the scleral lenses for seven consecutive days for approximately eight hours per day. At the conclusion of the seven days, the subjects filled out a survey pertaining to various aspects of wearing the scleral lens and comparisons between the scleral and soft toric lenses.

CHAPTER 3

RESULTS

There were three different aspects of vision measured in clinic during the study: Snellen visual acuity, brightness acuity testing (BAT), and contrast sensitivity. BAT testing measured change in acuity as a result of glare. Contrast sensitivity testing measured for contrast differences between a visual target and its background.

For the 12 eyes tested, the mean Snellen visual acuity with the scleral contact lenses was $20/20^{+1}$ (-0.02 logMAR). The mean Snellen visual acuity for the soft toric contact lenses was $20/20^{+1}$ (-0.02 logMAR). Based on these findings, each lens modality performed equally in regards to Snellen visual acuity.

For the 12 eyes tested, the mean brightness acuity testing (BAT) for the scleral lenses was $20/20^{+3}$ (-0.06 logMAR). The mean BAT for the soft toric lenses was $20/20^{-1}$ (0.02 log Mar). Although there is a difference in BAT results between the lenses, no statistically significant difference was found.

The contrast sensitivity results while wearing the scleral lenses measured 1.982 log units with a standard deviation of 0.078 log units. The contrast sensitivity results with both eyes while wearing the soft toric lenses was 1.95 log units with a standard deviation of 0.0 log units. Although there is a difference in contrast sensitivity results between the lenses, no statistically significant difference was found.

There was only one statistically significant value recorded from the subjective survey. With respect to lens insertion, test subjects reported that they were comfortable inserting the soft toric lenses earlier in the study than for the scleral lenses. It was determined that subjects were completely comfortable inserting the soft toric lenses 3.2

days before they were completely comfortable inserting the scleral lenses (95% confidence interval; p-value 0.01).

All other survey findings showed a preference for one lens modality over the other; however, no statistical conclusions of lens modality superiority could be drawn. Given the raw data, on average, test subjects felt more comfortable and confident removing scleral contact lenses earlier in the study (day 2.8) as compared to the soft toric lenses (day 3.2). Based on a 10-point scaled survey, test subjects reported that soft toric lenses (mean 8.3/10) were slightly more comfortable than scleral lenses (mean 7.5/10). Test subjects also preferred the overall vision through the soft toric lenses (mean 8.5/10 vs. 7.7/10). However, the scleral lenses out-performed the soft toric lenses for specific tasks, including computer work, exercising, and driving. The mean comfort score while wearing scleral lenses during computer work was recorded at 8.2/10 compared to the soft toric mean of 7.5/10. The mean vision performance score of the scleral lenses during computer work was 7.5/10 compared to the soft toric mean of 7.3/10. The mean score of visual performance and comfort of the scleral lenses during physical activity was 7.7/10 compared to the soft toric mean of 8.5/10. The mean visual performance score of the scleral lenses while driving was 6.5/10 compared to the soft toric mean of 6.2/10.

Two of the subjects in this study reported that they suffered from dry eye symptoms. Both subjects were using over-the-counter artificial tears as therapy for their dry eye symptoms prior to study participation. Subjectively, both subjects reported that the scleral contact lenses provided relief from dry eye symptoms, whereas the soft toric lenses exacerbated their symptoms. No additional information was gathered in regards to the topic of dryness.

The survey included several free-response questions that further asked about feedback in regards to each contact lens modality. With respect to scleral lens insertion, two patients reported that it was difficult to open their eyes wide enough to successfully insert the lenses. Two other subjects reported difficulty inserting the scleral contact lenses without having bubbles under the lens post-insertion. One test subject reported an apparent fear of scratching the cornea during scleral lens insertion. Most subjects reported wearing the scleral lenses for up to 12 hours, which was up to four hours over the recommended wear time for this study.

Several of the test subjects reported having prior experience inserting soft toric contact lenses. One subject reported a preference for daily disposables compared to the monthly replacement lenses. Each test subject was able to wear the soft contact lens for at least eight hours. Some subjects reported wearing them for up to 14 hours, which was up to six hours over the recommended wear time for this study.

CHAPTER 4

DISCUSSION

There were several measurements taken during this study. However, most of the results gathered from these measurements have no statistical significance. Though no significant quantitative conclusions could be drawn from the results, qualitative information based on observation and patient responses allowed some informal conclusions to be drawn.

The BAT measurements did not show any statistically significant differences between the two contact lens modalities. The subjects who performed noticeably poorer with the BAT results while wearing the scleral lenses, though, also reported some clouding of the lenses during the day. It is very possible that excessive tear exchange occurred with these subjects, leading to a decrease in vision as a result of glare. Had none of the subjects experienced improper tear exchange while wearing the scleral lenses, it is hypothesized that the results of the BAT with the scleral lenses may have shown statistical superiority.

The Snellen visual acuity and contrast sensitivity measurements also displayed no statistical significance between the two lens modalities. With both modalities, patients had normal visual acuity. One test subject recorded a contrast sensitivity of 2.14 log units while wearing scleral lenses. This measurement showed higher sensitivity than the 1.95 log units of contrast sensitivity that were recorded by the other subjects in either soft toric or scleral lenses. Furthermore, this subject also reported qualitatively that scleral lenses provided the “best vision” they had ever experienced.

Though data analysis did not show any statistical significance, visual performance and comfort during specific tasks were reported to be better with scleral lenses than soft toric lenses. These specific tasks included computer work, driving, and physical exercise. It is hypothesized that the enhanced clarity of vision occurs due to lack of rotation of a scleral lens while blinking in comparison to a soft toric lens. The increased comfort of a scleral lens might correspond to less edge awareness with blinking as well as the constant fluid layer between the cornea and contact lens throughout the day. In comparison, soft toric contact lenses maintain less fluid between the cornea and contact lens and are, by design, expected to move on the eye while blinking, which can cause enhanced lens awareness.

For many practitioners, scleral contact lenses are not considered as a first option for a patient who is a good candidate for soft contact lenses. This may be due to the perceived difficulty of fitting scleral lenses and the increased chair time and multiple follow-ups that may required to fit scleral lenses. While performing this study, it was determined that fitting a spherical scleral lens does not necessarily require more time than fitting a soft toric lens. As long as the trial lens from the fitting set required minimal parameter adjustments, the fitting process was relatively quick. From the limited number of scleral lens fits performed during this study, it was determined that the biggest factors that required more time to successfully fit the patient with lenses were lenses with excessive movement or moderate lens decentration and those subjects that demonstrated better visual acuity with a sphero-cylindrical over-refraction. These subjects tended to prefer soft toric lenses over scleral lenses.

CHAPTER 5

CONCLUSION

The strength of this study is centered upon the subjective feedback received about the contact lenses during daily activities away from the clinical setting. It is the believed that the subjects were best able to appreciate the visual performance of each lens modality by wearing the lenses outside of the clinic. Previous studies had only measured the visual performance and comfort of each lens modality within a clinical setting.

It is hypothesized that patients who demonstrate a relatively good scleral fit in-office with trial lenses and those who achieve 20/20 acuity with a spherical over-refraction will require minimal follow-up appointments and be highly satisfied with their scleral lens performance. Should additional research confirm this hypothesis, optometrists may begin to offer scleral lenses as an option to the average contact lens wearing patient. This could help to improve patient satisfaction and patient loyalty to a practitioner. Additional information must be obtained to determine which patients will be good candidates for quick and successful scleral lens fits. It is possible that specific factors such as certain corneal curvature ranges, certain prescription ranges, or a combination of both could be the key to predetermining who may be a quick and successful fit in scleral lenses. To the best of our knowledge, the exact factors that can predict a successful scleral lens fit have not been determined.

Potential weaknesses of this study include a small sample size and limited age demographic. Increasing the sample size and the patient demographic would allow more useful information to be gained from this study. Another improvement could involve recruiting habitual soft toric contact lens wearers to wear spherical scleral lenses for a

trial period. This approach could further help to identify factors that can predict a successful scleral lens fit.

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APPENDIX A
IRB APPROVAL LETTER

FERRIS STATE UNIVERSITY

Date: Oct 27, 2017

To: Joshua Lotoczky
From: Gregory Wellman, R.Ph, Ph.D, IRB Chair
Re: IRB Application *IRB-FY17-18-3 The Comparison between Scleral Contact Lenses and Custom Soft Contact Lenses Fit on Toric Corneas*

The Ferris State University Institutional Review Board (IRB) has reviewed your application for using human subjects in the study, " *The Comparison between Scleral Contact Lenses and Custom Soft Contact Lenses Fit on Toric Corneas" (IRB-FY17-18-3)* and Approved this project under Federal Regulations Expedited Review Categories:
1b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.

Approval has an expiration date of one year from the date of this letter **. As such, you may collect data according to the procedures outlined in your application until Oct 27, 2018 .** Should additional time be needed to conduct your approved study, a request for extension must be submitted to the IRB a month prior to its expiration.

Your protocol has been assigned project number IRB-FY17-18-3. Approval mandates that you follow all University policy and procedures, in addition to applicable governmental regulations. Approval applies only to the activities described in the protocol submission; should revisions need to be made, all materials must be reviewed and approved by the IRB prior to initiation. In addition, the IRB must be made aware of any serious and unexpected and/or unanticipated adverse events as well as complaints and non-compliance issues.

Understand that informed consent is a process beginning with a description of the study and participant rights with assurance of participant understanding, followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document and investigators maintain consent records for a minimum of three years.

As mandated by Title 45 Code of Federal Regulations, Part 46 (45 CFR 46) the IRB requires submission of annual reviews during the life of the research project and a Final Report Form upon study completion. Thank you for your compliance with these guidelines and best wishes for a successful research endeavor. Please let us know if the IRB can be of any future assistance.

Regards,

Gregory Wellman, R.Ph, Ph.D, IRB Chair
Ferris State University Institutional Review Board
Office of Research and Sponsored Programs

APPENDIX B
SAMPLE SOFT TORIC CONTACT LENS SURVEY FORM

Contact lenses survey form

The following questions include yes/no response, free response and scaled questions; with 1 representing the lowest satisfactory score and 10 representing the highest satisfaction.

Questions for SOFT TORIC contact lenses.

1. Did you find it difficult to insert the contact lens at first?
   (Yes) (No)
2. On what day did you find it easiest to insert the contact lenses?
   (1 2 3 4 5 6 7)
3. On what day were you completely comfortable and confident with inserting the contact lenses?
   (1 2 3 4 5 6 7) or (still not confident)
4. If there was any difficulty, what was the most difficult part of inserting the contact lens?
   _____
   _____
   _____
5. What was the difficulty level for insertion of the contact lenses during the training period?
   (1 2 3 4 5 6 7 8 9 10)
6. How satisfied were you with the insertion of the contact lenses at the end of the wearing period? (1 2 3 4 5 6 7 8 9 10)
7. Please list any additional comments about the insertion of the lenses.
   _____
   _____
   _____
8. Did you find it difficult to remove the contact lens at first?
   (Yes) (No)
9. On what day did you find it easier to remove the contact lenses?
   (1 2 3 4 5 6 7)
10. On what day were you completely comfortable and confident with removing the contact lenses?
    (1 2 3 4 5 6 7)
11. If there was any difficulty, what was the most difficult part of removing the contact lens?
    _____
    _____
    _____
12. How satisfied were you with the removal of the contact lenses at the end of the wearing period?

(1 2 3 4 5 6 7 8 9 10)

13. How satisfied were you with the removal of the contact lens?
    (1 2 3 4 5 6 7 8 9 10)
14. Please list any comments you would like to leave about the removal of the lenses.

    _____
    _____
    _____

15. How many hours did your wear your contact lenses during a single wear period?

    _____
    _____
    _____

16. Did your tolerance for wearing the contact lenses improve during the study?
    (Yes)/(No)
17. Did you ever have to remove your lenses throughout the day?
    (Yes/No)
18. Why did you remove your contact lenses throughout the day?

    _____
    _____
    _____

19. Did you ever accidently or intentionally fall asleep in your contact lenses?
    (Yes) (No)
20. What cleaning system did you use for cleaning your contact lenses?

    _____
    _____
    _____

21. Did you rub your contact lenses before or after the cleaning process?
    (Yes) (No)
22. What types of solutions or drops did you use with your contact lenses?

    _____
    _____
    _____

23. Did the solution or drops help with comfort and wear time of your contact lenses?
    (Yes) (No)
24. Did you wear your contact lenses while reading for more than 30 minutes?
    (Yes) (No)
25. How comfortable were your eyes after reading for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
26. How was your vision during /after reading for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
27. Did you wear your contact lenses while watching TV for more than 30 minutes?
    (Yes) (No)

28. How comfortable were your eyes after watching TV for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
29. How was your vision during /after watching TV for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
30. Did you wear your contact lenses while working on the computer for more than 30 minutes?
    (Yes) (No)
31. How comfortable were your eyes after working on the computer for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
32. How was your vision during /after working on the computer for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
33. Did you wear your contact lenses while being physically active for more than 30 minutes?
    (Yes) (No)
34. How was your vision during your physical activity?
    (1 2 3 4 5 6 7 8 9 10)
35. How comfortable were your eyes during your physical activity?
    (1 2 3 4 5 6 7 8 9 10)
36. Do you feel that contact lenses improved your performance during your activity?
    (Yes) (No)
37. Did you wear your contact lenses while driving for more than 30 minutes?
    (Yes) (No)
38. How comfortable were your eyes after driving for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
39. How was your vision during /after driving for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
40. Were there any other activities in which you wore your contact lenses in which you would like to report?
    _____
    _____
    _____
41. For the above mentioned activity, how comfortable were your eyes during/after?
    (1 2 3 4 5 6 7 8 9 10)
42. For the above mentioned activity, how was your vision?
    (1 2 3 4 5 6 7 8 9 10)

Dry eye questions

43. Do you have dry eyes?
    (Yes) (No)
44. If you have dry eyes how do you treat the dry eyes?

_____
_____
_____

45. Did the contact lenses improve or make the dry eyes worse?
(Improved) (Worsened) (No Change)

APPENDIX C
SAMPLE SCLERAL CONTACT LENS SURVEY FORM

Contact lenses survey form

The following questions include yes/no response, free response and scaled questions; with 1 representing the lowest satisfactory score and 10 representing the highest satisfaction.

Questions for SCLERAL contact lenses.

1. Did you find it difficult to insert the contact lens at first?
   (Yes) (No)
2. On what day did you find it easiest to insert the contact lenses?
   (1 2 3 4 5 6 7)
3. On what day were you completely comfortable and confident with inserting the contact lenses?
   (1 2 3 4 5 6 7) or (still not confident)
4. If there was any difficulty, what was the most difficult part of inserting the contact lens?
   _____
   _____
   _____
5. What was the difficulty level for insertion of the contact lenses during the training period?
   (1 2 3 4 5 6 7 8 9 10)
6. How satisfied were you with the insertion of the contact lenses at the end of the wearing period? (1 2 3 4 5 6 7 8 9 10)
7. Please list any additional comments about the insertion of the lenses.
   _____
   _____
   _____
8. Did you find it difficult to remove the contact lens at first?
   (Yes) (No)
9. On what day did you find it easier to remove the contact lenses?
   (1 2 3 4 5 6 7)
10. On what day were you completely comfortable and confident with removing the contact lenses?
    (1 2 3 4 5 6 7)
11. If there was any difficulty, what was the most difficult part of removing the contact lens?
    _____
    _____
    _____
12. How satisfied were you with the removal of the contact lenses at the end of the wearing period?

(1 2 3 4 5 6 7 8 9 10)

13. How satisfied were you with the removal of the contact lens?
    (1 2 3 4 5 6 7 8 9 10)
14. Please list any comments you would like to leave about the removal of the lenses.

    _____
    _____
    _____

15. How many hours did your wear your contact lenses during a single wear period?

    _____
    _____
    _____

16. Did your tolerance for wearing the contact lenses improve during the study?
    (Yes)/(No)
17. Did you ever have to remove your lenses throughout the day?
    (Yes/No)
18. Why did you remove your contact lenses throughout the day?

    _____
    _____
    _____

19. Did you ever accidently or intentionally fall asleep in your contact lenses?
    (Yes) (No)
20. What cleaning system did you use for cleaning your contact lenses?

    _____
    _____
    _____

21. Did you rub your contact lenses before or after the cleaning process?
    (Yes) (No)
22. What types of solutions or drops did you use with your contact lenses?

    _____
    _____
    _____

23. Did the solution or drops help with comfort and wear time of your contact lenses?
    (Yes) (No)
24. Did you wear your contact lenses while reading for more than 30 minutes?
    (Yes) (No)
25. How comfortable were your eyes after reading for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
26. How was your vision during /after reading for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
27. Did you wear your contact lenses while watching TV for more than 30 minutes?
    (Yes) (No)

28. How comfortable were your eyes after watching TV for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
29. How was your vision during /after watching TV for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
30. Did you wear your contact lenses while working on the computer for more than 30 minutes?
    (Yes) (No)
31. How comfortable were your eyes after working on the computer for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
32. How was your vision during /after working on the computer for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
33. Did you wear your contact lenses while being physically active for more than 30 minutes?
    (Yes) (No)
34. How was your vision during your physical activity?
    (1 2 3 4 5 6 7 8 9 10)
35. How comfortable were your eyes during your physical activity?
    (1 2 3 4 5 6 7 8 9 10)
36. Do you feel that contact lenses improved your performance during your activity?
    (Yes) (No)
37. Did you wear your contact lenses while driving for more than 30 minutes?
    (Yes) (No)
38. How comfortable were your eyes after driving for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
39. How was your vision during /after driving for more than 30 minutes?
    (1 2 3 4 5 6 7 8 9 10)
40. Were there any other activities in which you wore your contact lenses in which you would like to report?
    _____
    _____
    _____
41. For the above mentioned activity, how comfortable were your eyes during/after?
    (1 2 3 4 5 6 7 8 9 10)
42. For the above mentioned activity, how was your vision?
    (1 2 3 4 5 6 7 8 9 10)

Dry eye questions

43. Do you have dry eyes?
    (Yes) (No)
44. If you have dry eyes how do you treat the dry eyes?

_____
_____
_____

45. Did the contact lenses improve or make the dry eyes worse?
    (Improved) (Worsened) (No change)

Comparison Questions

46. Which contact lens did you prefer to insert?
    (Scleral/ Soft Toric/ Neither/No difference)
47. Which contact lens did you prefer to remove?
    (Scleral/ Soft Toric/ Neither/No difference)
48. Which contact lens did you feel you saw the best in?
    (Scleral/ Soft Toric/ Neither/No difference)
49. Which contact lens was the most comfortable to wear at the beginning of the study?
    (Scleral/ Soft Toric/ Neither/No difference)
50. Which contact lens was the most comfortable to wear at the end of the study?
    (Scleral/ Soft Toric/ Neither/No difference)
51. At the conclusion of the study would you prefer to wear your:
    (Spectacle correction) (scleral contact lens) OR (soft toric contact lens)?
52. Why did you select the previous choice?

    _____
    _____
    _____

APPENDIX D
SAMPLE RESEARCH SUBJECT LETTER

Dear Research Subject,

The research team would like to thank you for your cooperation and dedication to this research topic. This study may require a reasonable time commitment for all subjects involved. We, the research team, appreciate your sacrifice for the betterment of contact lenses wearers. The information gathered from this study will help eye care professionals better develop specialty contact lenses. Throughout this study you will be fit with scleral contact lenses and custom soft toric contact lenses. The fitting process might require several visits to the research center before a proper fit can be determined. After the lenses have been fit properly, each research subject will be required to wear each pair of contact lenses for a predetermined amount of time. At the end of each wear schedule the subject will be asked to fill out a survey for each pair of contact lenses. Some the of the question topics include, but are not limited to, ease of insertion and removal, dryness issues, vision quality during activities of daily living (ADLs) and lens care. While not required for this study, a journal for each lens modality might be helpful for specific comments for the researchers.

Thank you for your time.

Respectfully,

Research team

APPENDIX E
RESEARCH SUBJECT CONSENT FORM

FERRIS STATE UNIVERSITY

BIOMEDICAL RESEARCH STUDY INFORMED CONSENT

RESEARCHER INFORMATION

Project Title: The Comparison between Scleral Contact Lenses and Custom Soft Contact Lenses fit on Toric Corneas
Principal Investigator/Faculty Advisor: Joshua Lotoczky O.D.
Email: joshlotoczky@ferris.edu Phone: (231) 591-2192
Co-Investigators: Brian Hochstetler, Stephen Herman, and Austin Schipper O.D
Email: hochstb@ferris.edu Phone: (419) 296-5125
Email: hermans4@ferris.edu Phone: (906) 399-9635
Email: schippa3@ferris.edu Phone: (231) 591-3762

STUDY PURPOSE

You are invited to participate in a research study involving Scleral Contact Lenses and Custom Soft Contact Lenses. Researchers are interested in looking at the difference in patient experience between wearing scleral contact lenses and wearing custom soft contact lenses fit for toric corneas.

PARTICIPATION

Taking part in this study is completely voluntary. You do not have to participate in this study if you don't want to and you may leave at any time without consequence.

You are eligible to participate in this study because you are 18 years of age or older, a student, faculty, or staff at Ferris State University, and not pregnant. Your refractive error (eye glasses prescription) and toric cornea (shape of the front curvature of your eye) have all been considered prior to this study. A toric cornea means that curvature to the front of your eye is not completely round and that you may have corrective lenses to minimize your astigmatism. For this study a toric cornea measures between 0.75 D to 3.00 D of astigmatism. For this study you are not required to be a current contact lens wearer. During this study you will be provided information on the proper care, handling and complications of contact lens wear. You will be provided the standard written material given to any University Eye Center patient. If you have never used contact lenses you will be given instructions about the proper care and wear of contact lenses.

If you agree to be part of this study, you will be asked to wear scleral and custom soft contact lenses for a period of time and then sit for an anterior evaluation of your eye along with subjective vision testing following each wear.
The study will take approximately 30-60 minutes for each meeting, following the initial fit. Daily wear of both the custom fit scleral contact lenses and custom soft lenses will be required during

this study.

During this investigation you will be asked to fill out several survey forms about the comfort and visual performance of each lens. All information gathered is voluntary. The information collected from these forms will be used to further evaluate the performance of the lenses.

Your active participation in this study will conclude when both scleral lenses and custom soft lenses have been properly fit, worn for the required time, required measurements have been obtained and the appropriate survey forms have been completed.

POTENTIAL RISKS/DISCOMFORTS

Researchers have taken steps to minimize the risks of this study. However, you may still experience some risks related to your participation, even when the researchers are careful to avoid them.

The known or expected risks when wearing ANY contact lens include:

- Allergic reaction- a reaction to the lens material, solution or environmental factors that may make wearing the contact lenses difficult
- Corneal Abrasion- a painful scratch to the front of the eye. Most likely caused from finger nails or improperly removing contact lenses. These usually heal within a few days if proper care is sought.
- Corneal Infiltrate- irritation of the eye that may or may not indicate some form of infection
- Corneal swelling-increased fluid build up in the corneal tissue that may cause reduced vision
- Corneal ulcers- an infection of the eye caused by bacteria, fungus and/or other microbial agents. Usually acquired from improper contact lenses wear, improper cleaning/disinfecting procedures and or exposure to adverse wearing conditions.
- Chemical Burn- usually experienced after an agent, such as hydrogen peroxide, is accidently instilled in the eye. It is often painful and requires medical attention.
- Discomfort/tearing- any feeling related to contact lens wear that may cause an increased awareness or discomfort to the subjects eye. Increased watering of the eye due to contact lens wear.
- Dryness- the feeling of itching, gritting and/or burning of eyes due to contact lens wear
- Giant Papillary Conjunctivitis- large bumps that may appear underneath the eyelid due to improper care or wear of contact lenses.
- Neovascularization- increased blood vessel growth. Usually due to over wear or improper wear of contact lenses. This may cause the eyes to look more read than normal.
- Loss of vision- vision loss that may affect the subject if proper care is not taken during the care and wear of contact lenses.
- Redness/ irritation- also known as CLARE (Contact Lens Induced Acute Red Eye. An increased level of redness of the eyes due to improper fit, over wear or sleeping in contact lenses.

Please be aware to any changes with your eyes. These include the above mentioned conditions as well as worsening pain around the eyes. Light sensitivity, sudden blurry vision, unusually

watering eyes and/or discharge. If you believe any of the above conditions have occurred do not hesitate, immediately contact one of the investigators of this study.

You will be provided written material about the proper care and handling of these materials to further ensure your safety. Please review any manufacture written material from solutions or other contact lens related materials. The investigators will be available for any questions or concerns about lens wear and complications.

The lenses in this study are FDA approved for daily wear and should not pose additional risks over standard lenses.

You should NOT take part in more than one study at a time without approval from the researchers involved in each study. Being in more than one research study at the same time may increase risks and/or affect study results.

ANTICIPATED BENEFITS

Although you may not receive any direct benefits by participating in this study, others may benefit from your participation because the information gathered will help advance scientific knowledge on contact lens fitting.

MEDICAL TREATMENT

Experimental study procedures, drugs, or devices include fitting scleral contact lenses and custom soft lenses, and using Anterior Segment Optical Coherence Tomography to assess the fit. In case of complications, such as injuries, side effects, or other problems that you may experience during this study, contact one of the researchers listed in the "Contact Information" section below.

PARTICIPANT RIGHTS

You are free to leave the study at any time. If you leave before the study is finished, you will not lose any benefits to which you may otherwise be entitled. If you are an employee/student at FSU, your employment status/academic standing at FSU will NOT be affected whether or not you decide to participate in this study. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in the *"Contact Information"* section below.

If you decide to leave the study before it is finished, there will be no harm to you.

Researchers could take you out of the study, even if you want to continue to participate. There are many reasons why the researchers may need to end your participation in the study. Examples include:

- The researcher believes that it is not in your best interest to stay in the study
- You become ineligible to participate
- Your condition changes and you need treatment that is not allowed while you are taking part in the study
- The study is suspended or cancelled

Researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the

study, it is possible that you may be asked to sign a new consent form that includes new information.

CONFIDENTIALITY

Your participation in this research study will remain completely anonymous. As required by federal regulations and university policy, study records will be maintained for 3 years and kept confidential and securely stored on the password-protected, HIPAA-compliant, electronic medical records at the University Eye Center. Should the results of this study be published on any report, publication or at any scientific meeting, your identity will not be revealed.

Use of photographs/video images:
Your initials _____ indicate your permission to photograph/video record during this study. Your photograph/ video recording may be used in presentations related to this study. If your photograph/ video recording is used for presentations of any kind, names or other identifying information will not be associated with it.

Signing this form is required in order for you to take part in the study and gives the researchers your permission to obtain, use and share information about you for this study. The results of this study could be published in an article, but would not include any information that would identify you. There are some reasons why people other than the researchers may need to see the information you provided as part of the study. This includes organizations responsible for making sure the research is done safely and properly, including Ferris State University, government officials. The researchers certify that the use of medical records in this study complies with the Health Insurance Portability and Accountability Act (HIPAA) and/or the Family Educational Rights and Privacy Act (FERPA).

CONTACT INFORMATION

The main researchers conducting this study are Brian Hochstetler and Stephen Herman, graduate students at Ferris State University. **Please ask any questions you have now.** If you have questions later, you may contact Brian Hochstetler, at hochstb@ferris.edu, or by phone (419) 296-5124, or contact Stephen Herman at hermans4@ferris.edu, or by phone (906) 399-9635.

If further questions need to be addressed you may contact the principal investigator/faculty advisor, Joshua Lotoczky O.D., at the following:
Email: joshlotoczky@ferris.edu Phone: (231) 591-2192.

If you have questions or concerns about your rights as a subject in this study, please contact:
Ferris State University Institutional Review Board (IRB) for Human Participants
220 Ferris Drive, PHR 308, Big Rapids, MI 49307; (231) 591-2553 or IRB@ferris.edu

SIGNATURES

Research Subject: I understand the information printed on this form. I have discussed this study, its risks, potential benefits and other alternatives. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in the

"Contact Information" section. I understand that I will receive a copy of this form at the time I sign it. I understand that if my ability to consent for myself changes, either my legal representative or I may be asked to re-consent prior to my continued participation.

Signature of Subject: _____

Printed Name:_____

Date of Signature:_____

Principal Investigator (or Designee): I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Printed Name:_____

Title:_____

Signature:_____

Date of Signature:_____