OBSERVING LENS FLEXURE BY ALTERING VARIOUS SCLERAL LENS PARAMETERS

by

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This paper is submitted in partial fulfillment of the
requirements for the degree of

Doctor of Optometry

Ferris State University
Michigan College of Optometry
March 2016

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____ March 2016

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Faculty Advisor:

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Ferris State University
Doctor of Optometry Senior Paper
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Observing lens flexure by altering various scleral lens parameters

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ABSTRACT

Background: Scleral lenses have been used as far back as the 1800s as a treatment option for corneal irregularities. There have been many advancements in the design since then and through this study we hope to make another. The FDA approved gas permeable lens material will be modified to assess the flexure of the scleral lens. The modifications to the scleral lens will include modifying the central thickness, peripheral base curves, and landing zones. The ultimate goal is to create a lens design that has a thinner central thickness than current scleral lenses, thus allowing for better oxygen permeability to the cornea. *Methods:* The manufacturer, Valley Contax, will alter the lens parameters. The following procedures will be used to make the initial scleral lens fit: corneal biomicroscopy examination, corneal topography, and anterior segment optical coherence tomography (AS-OCT). Once all of the data is collected, a scleral lens with customized parameters will be fit on the patient's eye. Afterwards, lens flexure will be evaluated using corneal topography and AS-OCT. *Results:* The topographical data of lenses A, B, and C revealed that lens B had the lowest initial delta k, lowest final delta k, and lowest percent change from initial to final. Lens B also showed the most consistent settling across the different lens zones. Lastly, lens B was rated as the most comfortable by the subjects, proving that thinner lenses are not always more comfortable. *Conclusions:* The research showed that thicker scleral lenses flex less over time compared those of a thinner design. It also showed that thicker scleral lenses settle more consistently than thinner

lenses. Lastly, the research showed that thin peripheral curves are significantly less comfortable for patients.

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CHAPTER 1

INTRODUCTION

Leonardo da Vinci first proposed the concept of altering the optics of the cornea using a bowl to submerge the eye in 1508, in his book, Codex of the Eye: Manuscript D. It was four hundred years later that Adolf Fick designed the first contact lenses, which happened to be what we now call the scleral lens design. He had derived scleral glass casted molds from cadavers and used them to neutralize the optical distortions in patients with irregular astigmatism[1]. Since then there have been many improvements to the design of scleral lenses.

Despite the fact that scleral contact lenses have been around for centuries, only recently have they been recognized as an untapped resource in the optometric world[2]. It is understandable why providers were hesitant to fit the initial glass blown and PMMA lenses with Dk's of nearly zero in a lens that also provided minimal tear exchange. However, in more recent history, with the advent of oxygen permeable materials and reproducible manufacturing processes the scleral lens has become a valuable asset in the eye care provider's toolbox.

The different types of gas-permeable lenses are classified primarily based on where they rest on the eye, along with their diameter in millimeters. Full scleral lenses rest strictly on the sclera and range between 15-25 mm. Their large size comes with the

added benefit of remaining very stable on the eye. They are made up of three different regions called the optical zone, transitional zone, and haptic/landing zone[3].

The optical zone is the central area of the lens through which the patient gets their visual correction. The base curve, sphericity, and toricity of the optical zone can all be customized to provide the patient with optimal vision. Also, the use of wavefront technology can help provide correction in the optical zone for higher order aberrations[3]. The transitional zone may consist of multiple curves and can incorporate different designs to ensure complete clearance of the limbus, avoiding damage to the vital limbal-based stem cells[3]. The haptic or landing zone is where the lens rests on the ocular surface. This zone may also have multiple curves and typically increases in size with larger diameter lenses. This area of a scleral lens is crucial to its success and must be closely aligned to the shape of the sclera so that the weight of the lens can be dispersed evenly, without impinging blood vessels[3].

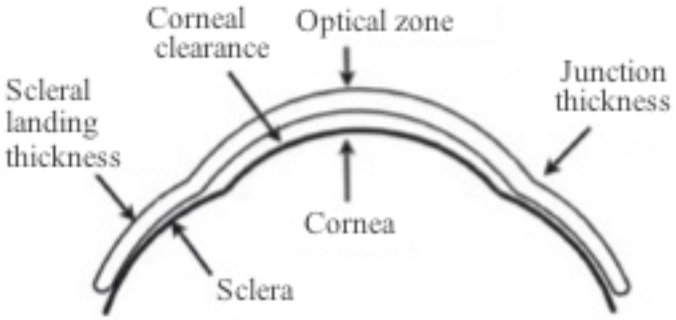

Figure 1. The different zones of a scleral lens

CHAPTER 2

BACKGROUND

The indicated uses for scleral lenses are very broad. They can be used for ametropia correction; ranging from myopia, hyperopia, corneal astigmatism, residual astigmatism, and even presbyopia. Scleral lenses are the not the first modality that come to mind when dealing with contact lenses, but they can provide the benefit of superior visual clarity that some other modalities might not be able to provide. For many patients, the fluid filled reservoir acts as a therapeutic bandage for ocular surface diseases. Recent studies have shown that patients with corneal diseases such as keratoconus, keratoconjunctivitis sicca, cicatrizing conjunctivitis, neurotrophic keratopathy, exposure keratopathy, limbal cell deficiency, and other corneal degenerations and dystrophies can benefit greatly from the use of scleral lenses[3,4]. The scleral lens acts a shield against the shearing force of the eyelid movement against the cornea while providing continuous hydration of the ocular surface[4]. In the study, Scleral Lenses in the Management of Ocular Surface Disease, it was found that visual acuity improved in many patients even though it was not a goal they were aiming for in their therapy. The study also showed that the most dramatic improvements in visual acuity were with the patients with significantly compromised corneas[4].

A critical factor that needs to be considered in the fitting process is how much oxygen the cornea receives with a scleral lens in place. Corneal diseases, like those

mentioned above, have a greater risk of progression when the corneal tissue is deprived of oxygen[3].

Currently there are a variety of different lens materials available that offer Dk's of greater than 100. However, most scleral lenses are manufactured at a thickness of 400 microns, which is four times greater than most gas permeable lenses. In addition to this increased thickness, there is very little tear exchange with scleral lenses which makes the cornea more susceptible to the effects of hypoxia[5]. The goal of our research has been to manipulate the thickness of different zones of scleral lenses to achieve maximum oxygen permeability without compromising the comfort, vision, and lens integrity.

CHAPTER 3

METHODS

There were two different sets of custom scleral lenses made: one with a sagittal depth of 41.00 and one with a sagittal depth of 43.00. Each set consisted of three lenses (A, B, & C) that were designed with varying thicknesses in three different zones. Their specific parameters are depicted in Table 1.

Lens	CT	JCT	SLT
A	150 µm	150 µm	150 µm
B	150 µm	400 µm	400 µm
C	150 µm	400 µm	150 µm

Table 1. Scleral lens parameters
CT = center thickness
JCT = junction thickness
SLT = scleral landing thickness

A baseline corneal biomicroscopy examination, corneal topography, and anterior segment optical coherence tomography (AS-OCT) were performed on each patient to determine which of the two sagittal depths would fit more optimally. Then the appropriate set of lenses was inserted onto the patient's eyes. A corneal topography and AS-OCT were performed immediately after insertion of each lens, and then these two tests were repeated after 20-30 minutes of settling. The corneal topographical data was used to determine lens flexure via a change in astigmatism (delta k). The AS-OCT data was used to compare central versus mid-peripheral settling.

CHAPTER 4

RESULTS

	Lens A	Lens B	Lens C
Average Initial Delta k	0.808 D	0.421 D	0.574 D
Average Final Delta k	0.912 D	0.442 D	0.905 D
Percent Change	+11.4%	+4.75%	+36.6%

Table 2. Topographical data of delta k for lenses A. B, and C

Table 2 summarizes the topographical data gathered regarding the delta k of each lens immediately after insertion (initial), after the 20-30 minutes of settling time (final), and what the percent change from initial to final was. The topographies were set using the tangential scale, which represents the true curve data[3]. Delta k refers to the difference in the curvature of the two principle meridians of the surface the topographer is measuring, or effectively the amount of astigmatism[6]. All of the lenses had spherical front surfaces, therefore, we can assume that any delta k greater than zero is secondary to flexure of the scleral lens. This is important to consider because increased astigmatism can poorly affect vision and comfort for the patient, which would directly negate any benefits from increased oxygen permeability that lens offers.

Percent Change	Lens A	Lens B	Lens C
Central Clearance	17.08%	15.12%	10.96%
Peripheral Curve 1 Clearance	10.98%	12.15%	11.02%
Peripheral Curve 2 Clearance	14.89%	13.25%	3.62%

Table 3. AS-OCT data of percent change in central clearance, peripheral curve 1, and peripheral curve 2 from initial to final scans (settling amount)

Table 3 summarizes the percentage of settling from initial to final in three different zones. Figure 1 depicts where these zones are located. This data does not provide any insight as to whether the lenses are flexing or not, but does allow us to observe if the different lenses are settling at a similar or dissimilar rate across the three points.

	Lens A	Lens B	Lens C
Average comfort rating	1.9	3.7	1.95

Table 4. Average comfort rating for lenses A, B, and C

Table 4 summarizes the overall comfort rating of each lens. Each subject was asked to rate the comfort of each lens on a scale of one to five. One representing significant discomfort and five representing ideal comfort.

CHAPTER 5

DISCUSSION

Our topographical data showed that lens B (CT:150 µm, JCT: 400 µm, and SLT: 400 µm) had the lowest initial delta k, lowest final delta k, and lowest percent change from initial to final. With the knowledge that it is more difficult to change the shape of thicker objects, this outcome is understandable. Both lenses A and C had nearly one diopter of astigmatism by the end of the settling time. These lenses on average are thinner than lens B, so it is also understandable that they showed a greater amount of flexure. Since we did not assess the visual acuity of subjects initially or after the setting time, it is difficult to say whether the greater amount of astigmatism seen with lenses A and C is clinically significant or not.

The AS-OCT data showed that lens B also had the most consistent rate of settling in different areas of the lens. Whereas lenses A and C showed much more inconsistency in the settling rate when comparing the change in central clearance to the change in the peripheral curve clearances. Again, without knowing the visual acuities before and after settling it is difficult to know if the abnormal settling of lenses A and C is clinically significant.

The comfort rating scale tells us that thinner does not necessarily mean greater comfort. Lens B was by far the most comfortable lens, with lenses A and C having very poor, and nearly identical comfort ratings. This, too, is something important to consider because even though lenses A and C can provide more oxygen permeability with their

thinner lens design, it will not help the patient at all if they are unwilling to wear the lens due to its lack of comfort.

CHAPTER 6

CONCLUSION

With scleral lenses becoming more and more popular, it is important that we consider the long-term effects they have on patient's eyes. With all types of contact lenses, a critical consideration is how much oxygen the cornea is receiving. Due to the fact that there is minimal tear exchange in a proper scleral lens fit, the majority of oxygen that reaches the cornea has to permeate through the lens. Since thinner lenses allow for greater oxygen transmission, our goal was to see if and how much these thinner lenses flex and whether or not the design would be clinically practical. The research showed that thicker scleral lenses flex less over time compared those of a thinner design. It also showed that thicker scleral lenses settle more consistently than thinner lenses. Lastly, the research showed that thin peripheral curves are significantly less comfortable for patients. This was a good pilot study, due to the fact that we have a better understanding of how scleral lenses act on the surface of the eye over time. However, we are unsure if the flexure and inconsistent settling would make clinically significant changes that the patient would notice or if they are insignificant. This would be a good area of focus for future research.

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APPENDIX A

IRB APPROVAL FORM

FERRIS STATE UNIVERSITY

Institutional Review Board for Human Subjects in Research

Office of Academic Research, 220 Ferris Drive, PHR 308 · Big Rapids, MI 49307

Date: May 21, 2015

To: Dr. Joshua Lotoczky, Neil Patel and Michael Ruthven
From: Dr. Stephanie Thomson, IRB Chair
Re: IRB Application #150304 *(Observing lens flexure by altering various scleral lens parameters)*

The Ferris State University Institutional Review Board (IRB) has reviewed your application for using human subjects in the study, "*Observing lens flexure by altering various scleral lens parameters"* (#150304) and determined that it meets Federal Regulations *Expedited-category 2A/2D*. This 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 May 21, 2016**. 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 (#150304), which you should refer to in future correspondence involving this same research procedure. 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 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,

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