DO SCLERAL LENSES SUCK?

by

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Faculty Course Supervisor

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DO SCLERAL LENSES SUCK?

We, Jacquelyn Cosgrove and Felicia Slate, 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.

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5/2/2017

Date

ABSTRACT

Background: It is widely accepted that scleral lenses "settle" onto the eye. This is a group of investigative studies that further analyzes the structures that are responsible for this change as the lens settles, and further determines if there are any suction-like forces that are created by the loss of the tear lens that may be affecting the anterior structures. Modifications to FDA approved scleral lenses were made by having a laboratory lathe a hole into lenses in order to eliminate possible suction forces. *Methods:* The investigator placed optimally fit lenses to multiple eyes and took various measurements at different chord lengths. The investigator also placed an identical test lens containing a lathed fenestration and corresponding measurements were taken. All measurements were taken using anterior segment optical coherence tomography. *Results:* Measurements of central clearance and anterior chamber depth at various locations and time intervals were taken for the standard lens and lathed lenses. The measurements were compared for each individual eye to determine if there was a significant difference between the standard lens and the lathed lenses. Conjunctival settling only accounts for a portion of change in lens clearance. The majority of the change in vault is actually due to the cornea moving anteriorly. *Conclusion:* The change in central clearance for the standard and fenestrated lenses were do to an increase in anterior chamber depth over time and not solely as a result of lens "settling". However, this does not appear to be due to lens suction forces but more likely due to a mechanical force being applied to the eye causing elongation of the eye

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CHAPTER 1

INTRODUCTION

Over the recent years, much research and attention has been given to how scleral lenses affect the eyes. Practitioners fitting these types of lenses realize that there is an amount of tear vault exhibited between a lens and a cornea, and that this vault decreases throughout the day. Historically, this has been attributed to the lens "settling" into the conjunctiva. A question then arises, "What happens to the volume and fluid underneath the lens as it settles and is conjunctival settling the whole picture?"

According to Merriam Webster Dictionary, suction is the act or process of removing air, water, etc., from a space in order to pull something into that space *also*: the force with which the air, water, etc., in a space is removed.[1] Suction is the force that holds a scleral lens to the eye and allows it to stay aligned.[2] This study was based on the hypothesis that a suction-like force is created between the posterior lens surface and the cornea. It is postulated that this suction is a result from the loss of tear volume which ultimately creates space for the cornea to be pulled anteriorly. If fluid from the tear lens is lost, this may create a suction force that could affect the structure and physiology of the cornea and the anterior chamber.

With this series of pilot studies, we plan to first prove that conjunctival settling is not all that is occurring as central vault is decreased, and that the majority of change in the vault is actually due to the cornea moving anteriorly. This study will be broken down into peripheral, mid-peripheral, and central analyses.

CHAPTER 2

METHODS

For these pilot studies, all testing was conducted at the University Eye Center at the Michigan College of Optometry. This sample population was also limited to the faculty and student population of the Michigan College of Optometry. We placed scleral lenses of various diameters on multiple patients' eyes and measured a variety of changes over a specific amount of time. Optical Coherence Tomography (OCT) images were taken using both the Zeiss Visante and Heidelberg Spectralis instruments. Images were taken of the entire anterior segment as well as specific peripheral, mid-peripheral, and central portions of multiple lenses.

In the first set of data that was collected for the peripheral analysis portion of this study, a patient was optimally fit in a standard size scleral lens. Anterior segment OCT photos were taken at the peripheral zone of the lens over an 8 hour increment to demonstrate the change in relationship between the landing zone of the scleral lens and the conjunctiva over time. An overlapping image was then created to measure a change in microns.

In the second set of images that were analyzed as the mid-peripheral analysis portion of this study, a patient was also optimally fit in a standard size scleral lens. Anterior segment OCT photos were taken to illustrate the mid-peripheral and landing zones of the scleral lens after 4 hours of wear time. Then the lens was removed and immediately reinserted on the eye and additional images of the mid- peripheral and landing zones were taken again for comparison. Various measurements using calipers in microns were taken. For the remaining and majority of the data collected as the central and anterior chamber analyses portion of this study, the investigators optimally fit six eyes in various diameter scleral lenses. These lenses were ordered exactly as fit, and a duplicate lens with identical parameters was also ordered that contained a single 1.0 mm lathed fenestration.

The fenestration was designed in an attempt to eliminate possible suction forces that may be created by the loss of tear volume during scleral lens wear. However, this produced bubbles under the lens almost immediately after insertion. To minimize the harmful effects that bubbles trapped under a lens may have on the cornea, a soft lens was additionally placed over the fenestrated scleral lenses. (Figure 1) The investigator then placed the standard, optimally fit, control lens, onto each eye and took various measurements including central clearance and anterior chamber depth at various chord lengths over a 2 hour interval. On a separate day, the investigator also placed the identical, test lens, containing the lathed fenestration onto each eye and collected the corresponding measurements. Calipers were then used to accurately measure central clearance which was measured from the posterior surface of the scleral lens to the anterior surface of the cornea. Calipers were also used to measure the anterior chamber depths (ACD) at various chord lengths ranging from 8mm up to 15mm in length. The ACD includes the corneal thickness. (Figure 2)

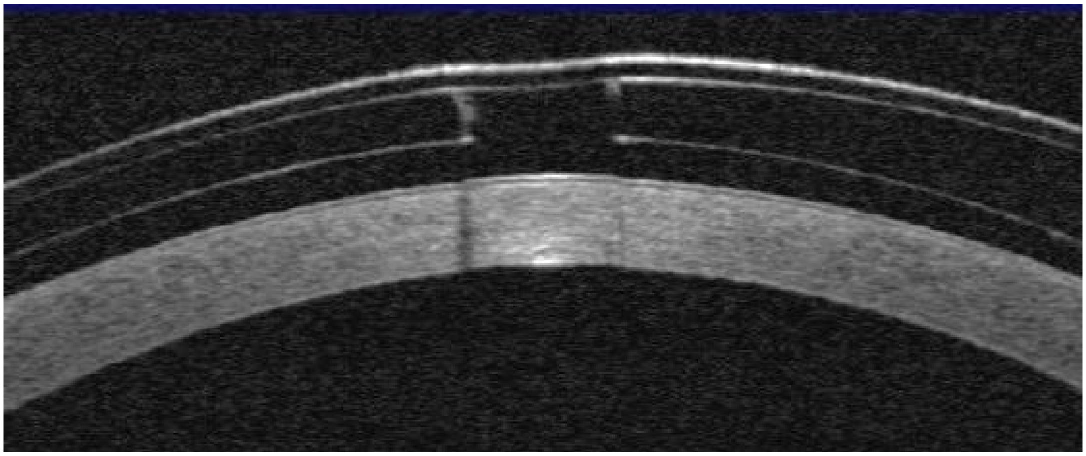

Figure 1. Superiorly, a soft CL was placed over a scleral lens containing a 1.0 mm central fenestration.

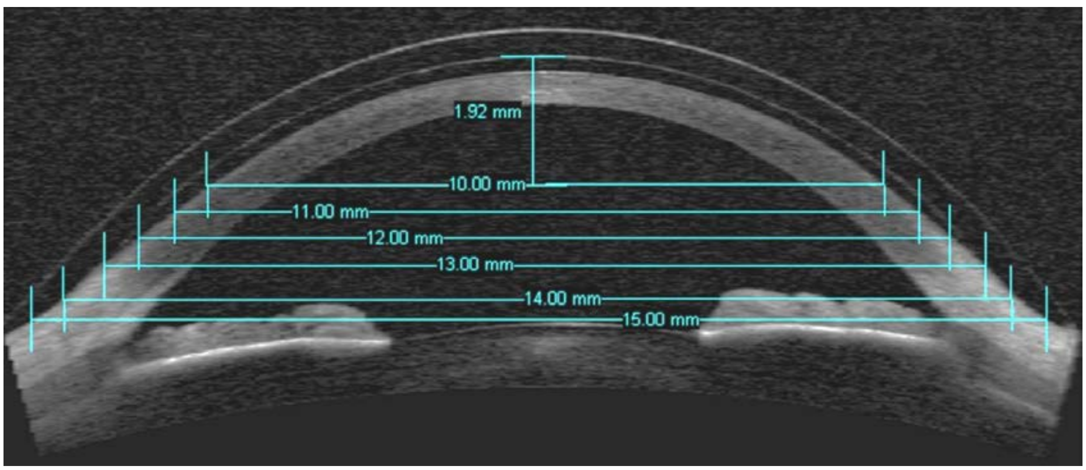

Figure 2. Measurements were taken from various chord lengths to assess central clearance and anterior chamber depth changes.

CHAPTER 3

RESULTS/DISCUSSION

It is widely accepted that the central vault or clearance between the cornea and posterior lens decreases over time. Research has already been compiled to determine the average change in central clearance for scleral lenses over normal wear time. This has historically been referred to as lens settling and *Kauffman* reported that lenses of similar diameter to those used in this study (14.8mm, 15.8mm, and 16.8mm), settle around 133.7 microns.[3] Other similar studies have found that lenses settle around 141 microns.[4] The overall general acceptance among fitters is between 100-150 microns of change over the course of a day. [5]

So what accounts for this 100-150 microns of clearance change? It is unlikely that there is one reason alone to correspond to this amount of change in central vault. Therefore, we will discuss some of our findings beginning in the periphery and then work our way towards the anterior portion of the lens.

Peripheral Analysis: Some theories postulate that the lens is settling onto the conjunctiva in the periphery and therefore the entire lens vault is decreasing. *Alonso-Caneiro et al.* studied the impact scleral lens wear had on the conjunctiva, episclera, and sclera.[6] They found that a majority of tissue compression occurs in the conjunctiva and episclera, which accounted for approximately 70% of the total tissue compression.[6] A majority of this compression occurs in the landing zone where the lens sits on the conjunctiva.[6] After a three hour recovery period following lens removal, the thickness values did not return to baseline values, which shows that lenses can alter the anterior segment structure even after removal.[6] A further investigation of this theory was done to measure a possible settling value of a scleral lens onto the conjunctiva after 8 hours of wear time. Figure 3c is an anterior segment OCT photo that illustrates the peripheral relationship between a scleral lens and the conjunctiva on a patient over 8 hours of wear time. This shows that only 53 microns, or less than half of the change in clearance, can be accounted for when assessing the settling of the conjunctiva alone.

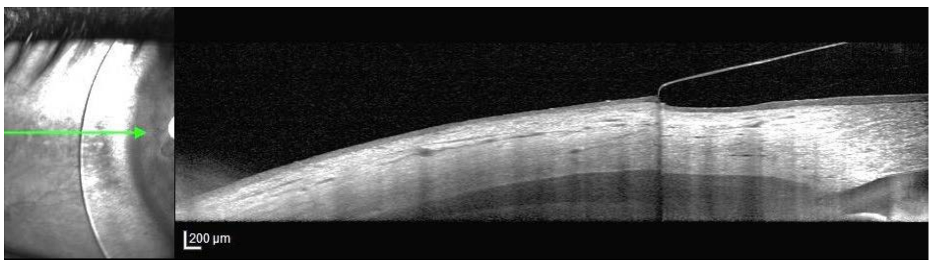

Figure 3a. Lens after insertion.

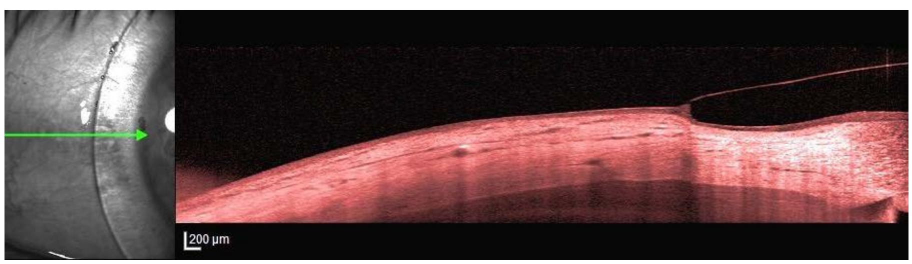

Figure 3b. Lens after 8 hours of wear time.

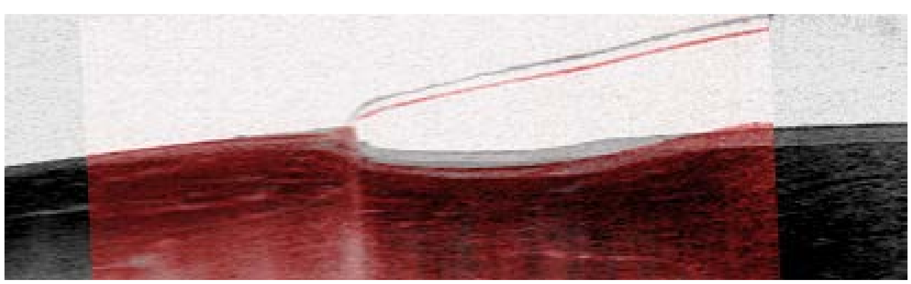
Figure 3c. Comparison illustrating a 53 micron change.

This establishes that the central change in lens clearance does not correlate explicitly to the amount of change measured in the periphery. The central clearance decreases by approximately 140 microns and the peripheral lens settles into the conjunctiva by approximately 50 microns. So what is accounting for this remaining ~90 microns in change?

Mid- peripheral analysis: We will now move anteriorly and assess the lens/conjunctiva interaction at the mid-peripheral zone of the lens. A comparison of Figure 4a to Figure 4b demonstrates what happens to the mid-periphery clearance when a lens is removed and immediately put back on an eye.

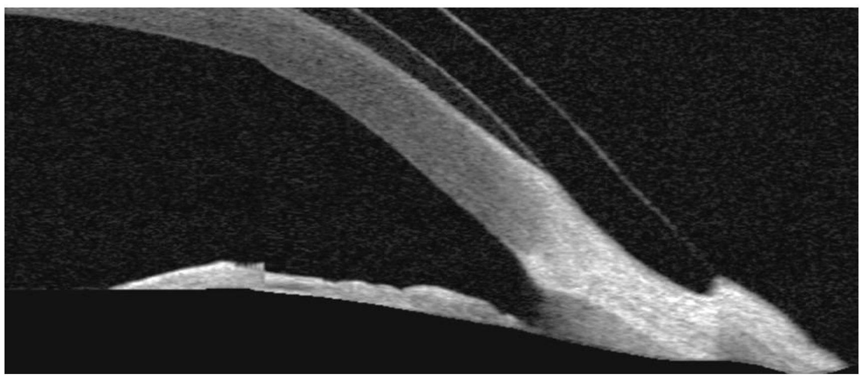

Figure 4a. Lens after 4 hours of wear.

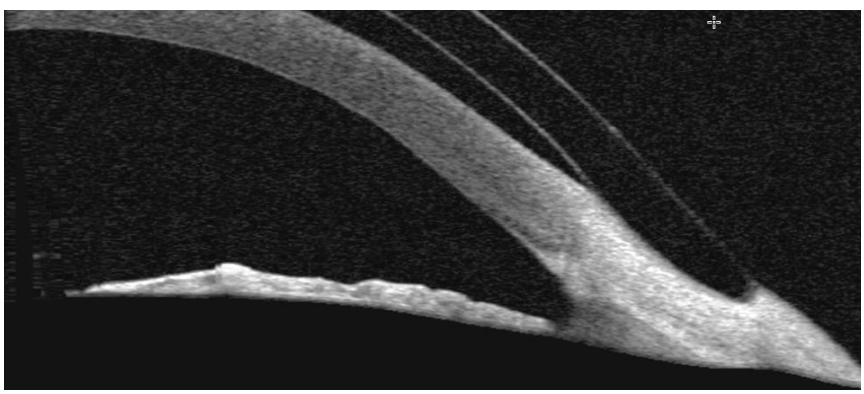

Figure 4b. Lens immediately after reinsertion.

By immediately reinserting the lens the conjunctiva remains compressed yet the central and peripheral clearances are different. Note, that the peripheral landing portion of the lens is nearly identical suggesting that the change in the measured central clearance is likely the result of changes taking place within the cornea and the anterior chamber structures rather than the periphery.

Central analysis: This study was based on the hypothesis that a suction-like force was created between the posterior lens surface and the cornea. Therefore, this suction would result in a loss of tear volume in order to create space for the cornea to be pulled anteriorly. The fenestrated lenses discussed were made with the intention to eliminate any suction force that could be created by the loss of tear volume during scleral lens wear. Unfortunately, this produced bubbles under the lens almost immediately upon lens insertion. To minimize this and prevent causing harm to the ocular surface, a soft contact lens was placed over the top of the scleral lens while conducting the measurements over a 2 hour increment. By placing the soft contact lens over the fenestration it is unclear whether or not suction forces were reestablished.

First, central vault was measured on two different diameters of lenses for both the standard and fenestrated lenses at 0 and 2 hours of wear time. The fenestrated lenses showed a lower average central clearance initially which may seem as though the fenestration may have broken some form of tension or suction force. However, the fenestrated lenses showed a lower average central clearance after 2 hours as well: A central clearance of 300 microns was measured for the 15.8mm control lens and 230 microns initially for the 15.8mm fenestrated lens. After 2 hours there were 200 microns compared to 100 microns, respectively. A similar comparison was made for the 14.8mm lenses. (Table 1) This demonstrates that an overall change in central clearance for the control lenses was similar to that of the fenestrated lenses, and that suction was unlikely broken with the creation of the fenestration. However, this does not disprove that the cornea may still be under suction forces or that the anterior structures of the eye are not moving, and thus further investigation to account for the additional changes in central clearance was conducted to determine if the lens is settling into the conjunctiva or if the cornea is being pulled anteriorly.

	Control Lens Average Vault			
	Central 0 hrs	Peripheral 0 hrs	Central + 2hrs	Peripheral + 2hrs
15.8 mm	0.30	0.31	0.20	0.23
14.8 mm	0.42	0.51	0.22	0.37
	Test Lens Average Vault			
	Central 0 hrs	Peripheral 0 hrs	Central + 2hrs	Peripheral + 2hrs
15.8 mm	0.23	0.25	0.10	0.16
14.8 mm	0.24	0.23	0.06	0.17

Table 1. A comparison of central vault between control and test lenses at 0 and 2 hours.

Although suction was unlikely broken from the fenestrations alone this study also used calipers to measure the resulting changes to the anterior chamber depths (ACD) at various chord lengths to determine if a change in anterior chamber depth occurred. Anterior chamber depth consistently showed an increase over a 2 hour period of wear time for the various diameters of lenses. The anterior chamber depth also increased in both the standard lenses without fenestration and the lenses that did have a fenestration. (Figures 5-7) Regardless of suction's role, this data does provide evidence that scleral lenses are not just "settling" onto the eye but that there is another underlying mechanical force causing the anterior chamber to expand and displace anteriorly.

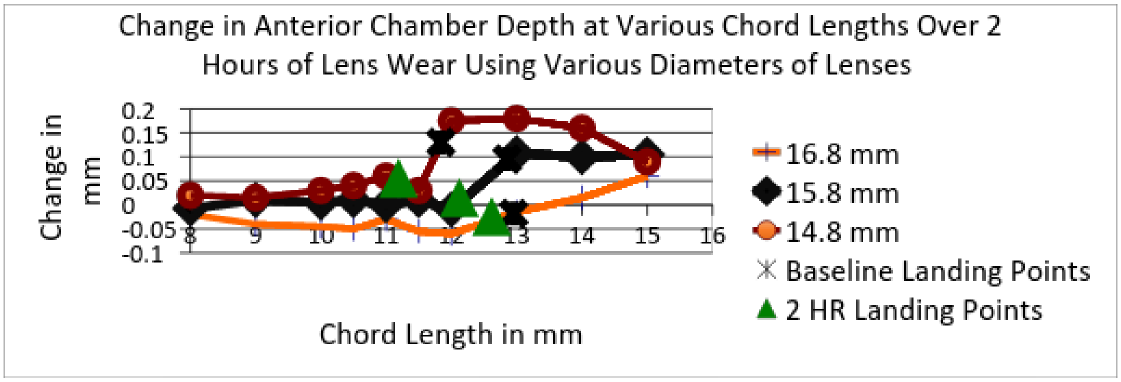

Figure 5.

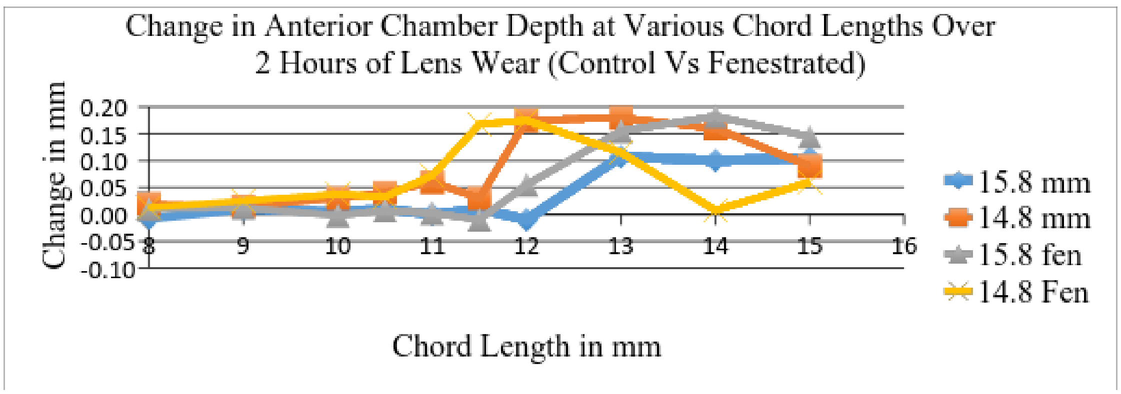

Figure 6.

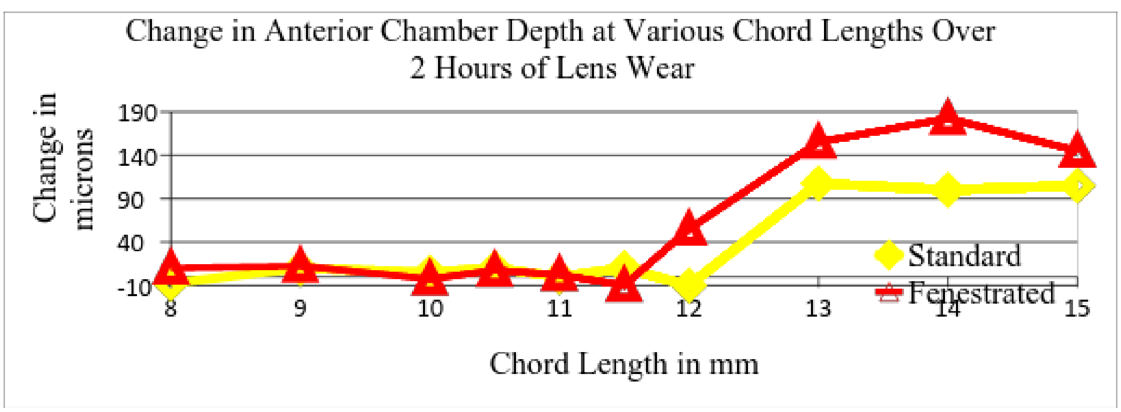

Figure 7.

When analyzing the data further there is a significant increase in the amount of anterior chamber depth that occurs from baseline to a 2 hour period which begins near the landing points on the various diameter lenses. This can be seen when looking at Figure 8 and noticing that there is a larger gap between corresponding lines at 0 hour and 2 hours in the longer chord lengths (12-15mm) versus the shorter chord lengths (8-11mm). A closer comparison can be made when looking at Figure 9 and comparing the solid lines (0 hours) to the corresponding dotted color line (2 hours) as the chords depicted here are only the 12-15mm chord lengths. This increase in ACD most accurately accounts for the remaining ~90 microns change seen in traditionally termed "lens settling". This combined with the ~50 microns of conjunctival compression in Figure 3c gives us the 133-140 microns often reported for 15.0-18.0 mm lenses. [3-5]

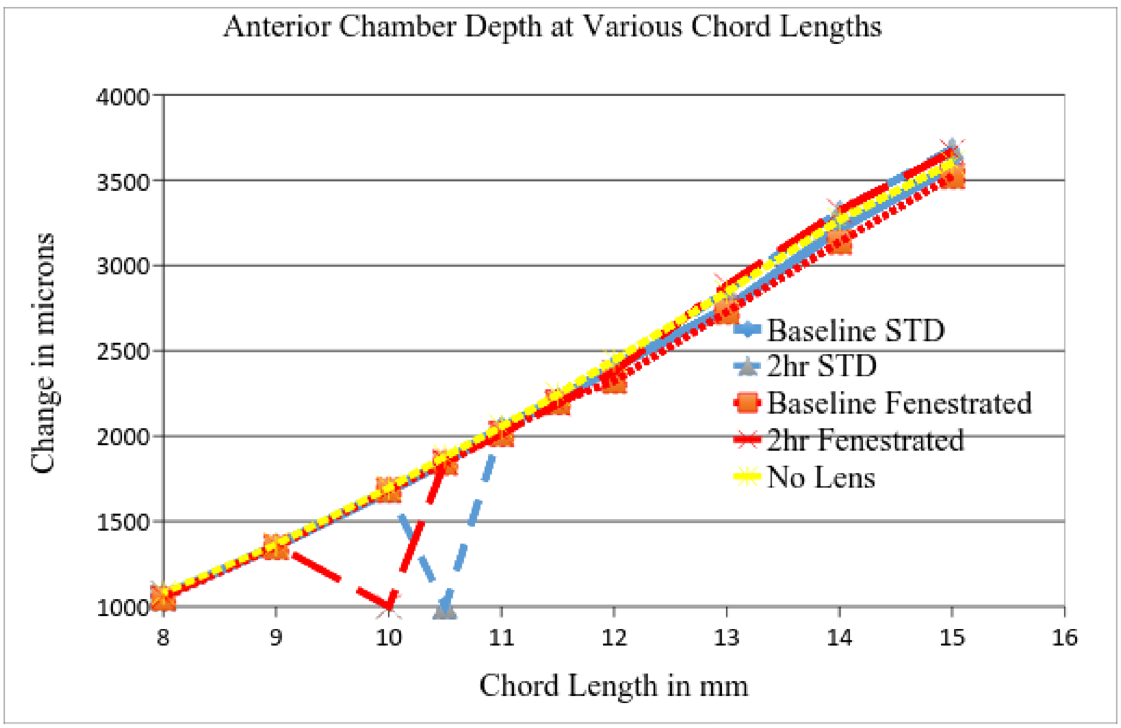

Figure 8.

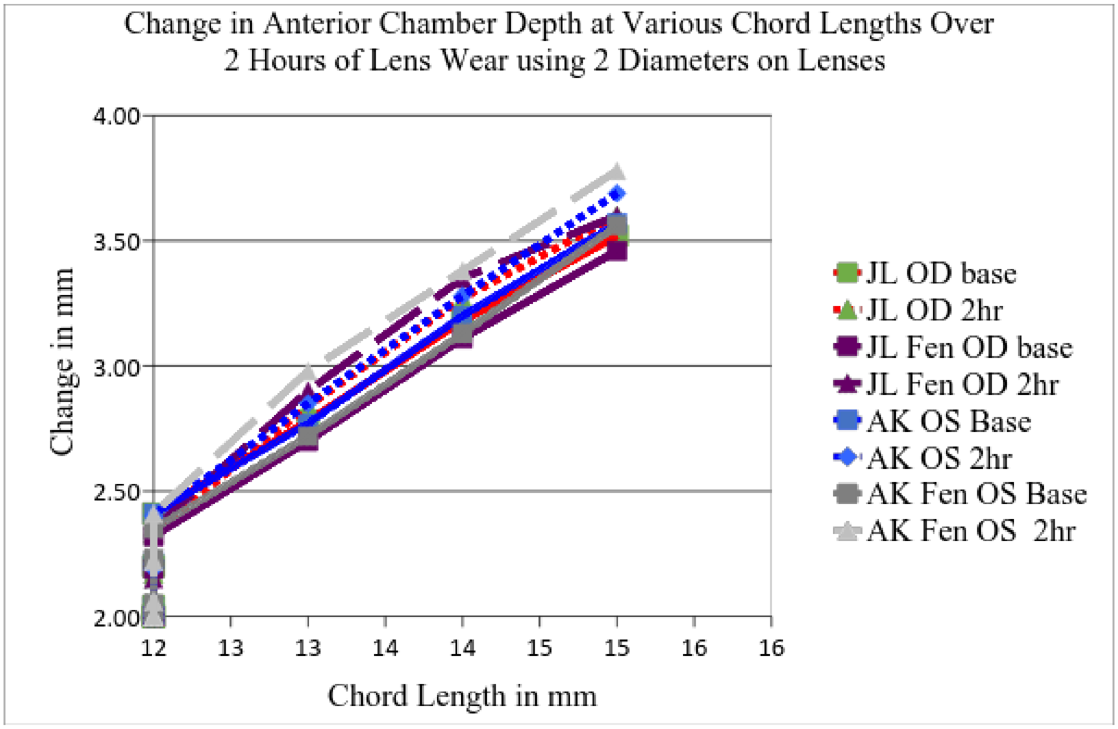

Figure 9.

Now that we have had a chance to assess multiple angles at the cornea to scleral lens interface, it is apparent that there is not one simple mechanism at work when determining as to why and how scleral lenses "settle" onto the eye. We know that the peripheral landing zone of the lens partially settles onto the conjunctiva accounting for some change in central vault change. The anterior chamber depth increases with length of time of lens wear especially in the periphery indicating that the majority of change in the vault is actually due to the peripheral cornea moving anteriorly. It could be postulated that the cornea may not be moving anteriorly due to suction forces but rather from another mechanical force causing elongation of the cornea similar to how a scleral buckle would elongate the retina. Understanding what effects scleral lenses are having on the anterior surface of the eye, especially the cornea, is imperative to the long term success and safety of habitual scleral lens wear. A change in the anterior chamber depth can influence the movement and centration of scleral lenses.[7]

This study is mostly limited based on its small size of data collection, ability to perform repeatable and accurate measurements using the optical coherence tomography technology and calibration systems, and the short duration of time that was measured for comparison. Further studies should be done in the future that continue to monitor the changes over longer intervals of time with a larger population size and advances in technology that make measuring microns more accurate. Additional theoretical calculations could also be beneficial to determine if it is possible that suction-like forces have a role in the process of lens settling. Further investigation should be placed on the manipulation that is occurring on the anterior structures of the globe.

REFERENCES

1. Hacker. Merriam-Webster.com. (2017.) https://www.merriam-webster.com/dictionary/suction.
2. Aldridge C. What Causes Settling in Scleral Contact Lenses? Contact Lens Spectrum, 30 (2015), pp. 44-47.
3. Kauffman MJ, Gilmartin CA, Bennett ES, Bassi CJ. A comparison of the short-term settling of three scleral lens designs. Optom Vis Sci 2014;91:12.
4. Bauer A, Lotoczky J. Let's Settle This Once and For All: A Comparison of Scleral Lens Settling. Poster 2016 Global Specialty Lens Symposium.
5. Ensley R, Miller H. (March 2016) Springtime for Sclerals. Review of Cornea & Contact Lens. Retrieved from http://reviewofcontactlenses.com/.
6. Alonso-Caneiro D, Vincent SJ, Collins MJ. Morphological changes in the conjunctiva, episclera and sclera following short-term mini scleral contact lens wear in rigid lens neophytes. Contact Lens Ant Eye, 39 (2016), pp. 53–61.
7. Montani, G. Biometry of Anterior Segment of Normal Eyes. Presentation 2016 Global Specialty Lens Symposium.

APPENDIX

APPENDIX A

IRB APPROVAL FOR

FERRIS STATE UNIVERSITY

Institutional Review Board for Human Subjects in Research

Office of Research & Sponsored Programs, 220 Ferris Drive, PHR 308 - Big Rapids, MI 49307

Date: January 8, 2016

To: Nicholas Gidosh, Josh Lotoczky, Jacquelyn Cosgrove and Felicia Slate
From: Dr. Gregory Wellman, IRB Chair
Re: IRB Application #151107 *(Scleral Lenses Suck)*

The Ferris State University Institutional Review Board (IRB) has reviewed your application for using human subjects in the study, *"Scleral Lenses Suck"* (#151107) and determined that it meets Federal Regulations *Expedited-category 2A/2D.* This approval has an expiration of one year from the date of this letter. As such, you may collect data according to the procedures outlined in your application until January 8, 2017. 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 (#151107), 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,

Ferris State University Institutional Review Board
Office of Research and Sponsored Programs

Version 1.2015