CONJUNCTIVAL SETTLING OF SCLERAL CONTACT LENSES

by

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ABSTRACT

Background: Scleral contact lenses rest either exclusively on the bulbar conjunctiva or with minor touch at the limbus. It is well accepted across the contact lens community that scleral lenses settle into the conjunctiva with increased wear time. This study aims to determine the extent of settling with various wear time in six types of scleral lenses. This will allow for improvements in fitting of these lenses and provide patients with better care. Methods: Six patients will be fit in one of six scleral lenses. The initial visit will consist of visual acuity, biomicroscopy, corneal topography, anterior segment optical coherence tomography (AS-OCT), lens fitting, and insertion and removal training. Next the patient will return for the dispensing of the lenses. Visual acuity, over-refraction, biomicroscopy, and anterior segment OCT will be performed over the lenses immediately upon insertion and each hour thereafter for four hours. At the final visit the patient will present wearing their lenses for at least four hours and will have worn the lenses for the previous week. Biomicroscopy, visual acuity, and anterior segment OCT will be performed. Results: Limited data was available due to poor fit or patient loss to follow-up. Lenses settle into the conjunctiva on average 0.0467mm after one hour of wear and on s 0.0717mm after four hours of wear. The difference in settling between fellow eyes of one subject was on average 0.033mm after one hour of wear and 0.043mm after four hours of wear. Conclusions: While limited in size, this study appears to indicate that scleral contact lenses do settle into the conjunctiva. This settling should be accounted

for during fit of scleral lenses so as not to add bearing on the cornea after extended wear. This study is limited in size and, as such, warrants further research.

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CHAPTER 1:

INTRODUCTION

The ocular surface has always been known as a tough, resistant interface that allows for the maintenance of a healthy, comfortable eye and clear vision. People continually put their eyes through traumatic situations that, without such resilience, would result in severe damage and loss of sight. However, occasionally the trauma proves too much, and we as eye care professionals must do everything we can to save the ocular structure and vision. With today's ever evolving technology, we have been able to develop highly advanced treatment techniques, medications, and devices in order to help with a plethora of different conditions whether they are genetic, traumatic or infectious. This paper will focus on the technological advancements in the area of contact lenses, specifically, scleral contact lenses.

Contact lenses have been a treatment option since 1888 when they were manufactured from blown glass by a man named Adolf Fick.[1] As all eye care practitioners can attest, contact lenses have made large advancements in not only materials but also design since that time. One of the newest advances in the science of contact lenses is scleral contact lenses. These contact lenses are designed to be weight bearing on the sclera while vaulting the corneal surface along with the limbal zone. They are quickly becoming one of the most desirable fitting options in cases such as corneal irregularity from genetic disease, post-surgical corneas, corneal ectasias, and those who have below average vision with glasses or traditional contact lenses.

The following are some of the many uses for scleral contact lenses that traditional soft and gas permeable contact lenses have been unable to fill. First, these lenses can be fit comfortably on patients with severe dry eye such as Sjogren and non-Sjogren dry eye, Rosacea, Systemic Lupus Erythematous, and Rheumatic conditions. Patients with severe dry eye find great benefit from these lenses because the fluid chamber that the lens creates continually bathes the ocular surface providing relief from both the environment and eyelid movements. Irregular corneal surfaces from genetic diseases, trauma, and prior surgery also find benefit in these lenses because of the vault that the contact lens creates. By vaulting the ocular surface, the tear film is able to mask the corneal irregularities giving a smooth, regular refracting surface, thus helping improve otherwise poor vision. Finally, scleral lenses are beneficial in simply correcting refractive error. These lenses are known to be more comfortable, less drying, and have fewer aberrations than standard lenses, resulting in a more pleasant visual experience.

In the early years of these lenses, many set backs were encountered. The first major setback was the material with which the lenses could be made. Scleral contact lenses were historically made from oxygen impenetrable materials such as glass or polymethylmethacrylate (PMMA). Even with fenestrations, these lenses provided very little oxygen permeability and were rarely prescribed. It was not until many years later that the materials we use today such as fluorosilicone acrylate and Boston's XO_2 (hexafocon B) and EO (enflufocon B) were established as oxygen permeable products.

The second major hurdle to the popularity of these lenses was production. The original processes allowed for no repeatability due to a lack of technology. Today's manufacturers do not have that same difficulty thanks to advanced lathes and computer assisted manufacturing that has allowed for repeatability, accuracy, and speed in the process. Finally, fitting scleral lenses to the patient's eye has always been a challenge. Previously, molds were made of the front of the eye to try to get the best fit of the lens. This was labor intensive for the practitioner and very uncomfortable for the patient. Even though fitting these lenses is still a challenging endeavor, an increasing number of practitioners are taking on the challenge because of the enormous amount of resources that are now available such as corneal topography and anterior segment optical coherence tomography. However, challenges still exist. Some of these include creating an acceptable, comfortable and healthy fit, educating patients on proper insertion and removal, the high cost of specialty lenses and the long term side effects of wear. This study addresses one of these challenges - obtaining an appropriate fit. It is well known throughout the contact lens community that these large lenses settle into the conjunctiva over time, sometimes to the point where they begin to bear on the cornea and/or the limbus, which is unacceptable and may lead to complications. This study aims to determine the amount that these lenses settle over time to aide practitioners in more quickly and easily obtaining an acceptable fit.

CHAPTER 2:

METHODS

This study aims to evaluate the fitting and settling of scleral lenses in twelve eyes of six patients. These patients had at least three examinations. The initial visit included a visual acuity assessment, manifest refraction, biomicroscopy examination, baseline corneal topography using the Medmont Corneal Topographer, and baseline Anterior Segment Optical Coherence Topography (AS-OCT) with a Zeiss Visante AS-OCT. Based on the these parameters, the patients were fit with lenses from trial lens sets to determine an appropriate fit. An over-refraction was performed to determine the appropriate power of the lenses to be ordered. At this initial visit, the patients also received insertion and removal training for their scleral lenses. Lenses were ordered and to be available for the following visit.

Patients were fit with one of the following six lenses: MSD, Rose K 2XL, Maxim, OneFit, RevGeo, and Comfort SL. Each patient was fit with one lens design in the right eye and a different lens design in the left eye. Each lens design was used on one eye of two separate patients. The distribution of lenses as fit on the patients can be found in Table 1.

(TABLE 1: DISTRIBUTION OF SCLERAL LENSES)

Patient	Right Eye	Left Eye
Patient 1	MSD	OneFit
Patient 2	Rose K 2XL	RevGeo
Patient 3	Maxim	Comfort SL
Patient 4	Maxim	Comfort SL
Patient 5	OneFit	MSD
Patient 6	RevGeo	Rose K 2XL

The dispensing and follow-up visit began with lens insertion, biomicroscopy of the anterior segment to confirm an adequate fit, and immediate AS-OCT to determine corneal vault at insertion. Visual acuity and an over-refraction were performed to determine if any changes needed to be made to the lenses. In eyes with appropriate fits, AS-OCT was again performed at one, two, three, and four hours after insertion to determine corneal clearance. In eyes with an unacceptable fit lenses were reordered with new parameters, and the prior steps were repeated when appropriate lenses were available. Following the dispensing visit, patients were advised to wear their lenses every day for the next week and return for their final follow up.

At the final visit, the patient was instructed to arrive wearing the lenses and have had them in for at least four hours that day. Visual acuity was taken and biomicroscopy was performed in order to assess the health of the cornea and conjunctiva after one week of wear along with assessment of the lens itself. Finally, AS-OCT was again performed to determine corneal clearance.

CHAPTER 3:

RESULTS

(TABLE 2: CORNEAL CLEARANCE AT VARIOUS WEAR TIMES)

Patient: 1		Patient: 2		Patient: 3	
OD: 1	0.17mm	OD: 1	Unacceptable fit	OD: 1	0.18mm
OD: 2	0.10mm	OD: 2	Unacceptable fit	OD: 2	0.14mm
OD: 3	0.08mm	OD: 3	Unacceptable fit	OD: 3	0.11mm
OD: 4	0.09mm	OD: 4	Unacceptable fit	OD: 4	0.11mm
OD: 5	0.09mm	OD: 5	Unacceptable fit	OD: 5	0.10mm
OD: 6	Lost to follow-up	OD: 6	Unacceptable fit	OD: 6	0.12mm
OS: 1	0.24mm	OS: 1	0.26mm	OS: 1	0.11mm
OS: 2	0.17mm	OS: 2	0.18mm	OS: 2	0.08mm
OS: 3	0.14mm	OS: 3	0.17mm	OS: 3	0.07mm
OS: 4	0.13mm	OS: 4	0.17mm	OS: 4	0.06mm
OS: 5	0.12mm	OS: 5	0.15mm	OS: 5	0.08mm
OS: 6	Lost to follow-up	OS: 6	Lost to follow-up	OS: 6	0.06mm
Patient: 4		**Patient: 5**		**Patient: 6**	
OD: 1	Unacceptable fit	OD: 1	0.18mm	OD: 1	0.28mm
OD: 2	Unacceptable fit	OD: 2	0.17mm	OD: 2	0.23mm
OD: 3	Unacceptable fit	OD: 3	0.16mm	OD: 3	0.20mm
OD: 4	Unacceptable fit	OD: 4	0.16mm	OD: 4	0.19mm
OD: 5	Unacceptable fit	OD: 5	0.15mm	OD: 5	0.17mm
OD: 6	Unacceptable fit	OD: 6	0.14mm	OD: 6	0.19mm
OS: 1	Unacceptable fit	OS: 1	0.21mm	OS: 1	0.42mm
OS: 2	Unacceptable fit	OS: 2	0.13mm	OS: 2	0.36mm
OS: 3	Unacceptable fit	OS: 3	0.10mm	OS: 3	0.39mm
OS: 4	Unacceptable fit	OS: 4	0.09mm	OS: 4	0.38mm
OS: 5	Unacceptable fit	OS: 5	0.09mm	OS: 5	0.39mm
OS: 6	Unacceptable fit	OS: 6	0.08mm	OS: 6	0.37mm

Table 2 above depicts corneal clearance after various amounts of conjunctival settling due to wear time: 1: At insertion / 2: 1hr after insertion / 3: 2hrs after insertion / 4: 3hrs after insertion / 5: 4hrs after insertion / 6: 1 week after dispensing.

Acceptable fits and data collection through one week of wear were obtained in six of twelve eyes. In three eyes, no acceptable fit was obtained and no data was able to be gathered. In the remaining three eyes, acceptable fits were obtained and data through the initial four hours of wear collected, however the patients were lost to follow-up and no data following one week of wear was collected.

The above data suggests that scleral lenses do indeed settle into the conjunctiva with wear time. These numbers would lend research to the notion that the initial hour of wear time is when the majority of settling occurs, with an average amount of settling of 0.0467 mm. Whether or not the type of scleral lens used is relevant to the amount of settling expected is difficult to determine due to the size of this study. The RevGeo lens settled the most with an average of 0.070 mm of settling after one hour, whereas the RoseK lens settled the most with an average of 0.09mm after one week. While data for only one lens was available, the Comfort SL lens settled the least, with one hour of wear resulting in only 0.03 mm of settling and one week of wear resulting in 0.05 mm of settling. This data also shows that after the initial hour, little settling occurs. On average, settling after four hours of wear was 0.0717 mm and after one week 0.0617 mm. Due to the small number of participants in this study, conclusive data cannot be derived. It is also unclear whether this settling is more dependent on the type of contact lens or individual differences in patient anatomy. In patients where two successful fits were obtained (three patients, six eyes), the average difference in settling between the right and left eyes was 0.033 mm after one hour (that is, the lens in the right eye settled on average 0.033 mm more than the lens in the left eye, or vice-versa.) and an average difference of 0.043 after four hours of wear. No data is available for the difference in settling between the two eyes after one week of wear.

CHAPTER 4:

DISCUSSION

This study was conducted in order to assess the settling over time of scleral contact lenses into the conjunctiva. The largest concern with these lenses settling is when they become weight bearing on the cornea and limbal zone. The cornea is a group of complex tissues responsible for the majority of the refracting power of the eye along with protection from injury and infection. It is composed of five separate layers: the epithelium, Bowman's layer, the stroma, Descemet's membrane, and the endothelium. The epithelium is a layer of non-keratinized stratified cells with tight junctions in order to protect the eye as well as interact with the tear film. Posterior is Bowman's layer, a tough, trauma resistant layer that serves as a basement membrane for the epithelium. Bowman's layer lies anterior to the collagenous stroma which is lined with keratocytes. The innermost layers are Descemet's membrane which serves as a basement membrane for the single layer of cells known as the endothelium. The endothelium is vitally important in maintaining corneal transparency. It accomplishes this through pumps that transport nutrients from the anterior chamber to the stroma and water in the opposite direction. In order to maintain these five layers, a continual, self-renewing process of cell proliferation, differentiation, migration, and apoptosis must occur.[2] Maintenance is accomplished in the basal region of the corneo-scleral junction where the limbal epithelial stem cells are located. These cells begin their life cycle as undifferentiated cells which migrate toward the center of the cornea and then superficially. Throughout this migration, these cells differentiate until they reach their final stage in the epithelium where apoptosis occurs. The cells are then shed via the tear film with normal blinking. This cycle completes about every seven to ten days.[2] Without the clarity and protection that the cornea offers, people would struggle through life due to a lack of clear vision. Thus, due to the cornea's continual need for newly produced cells the limbus must always be an area of concern for eye care practitioners. Any compression or injury to these tissues can be detrimental to a patient's vision and daily function. This knowledge lends purpose to the notion that scleral lenses due in fact settle into the conjunctiva with wear time. It is hypothesized that this settling is due to the weight of the lens along with the loose, pliable nature of the conjunctival tissue. It is crucial when fitting scleral contact lenses to not only have an understanding of this principle, but to also account for it when fitting the patient and allowing for the appropriate vault clearance. The commonly accepted vault clearance of scleral contact lenses is roughly 100microns.[3, 4] Vault is measured as central corneal clearance, the distance between the anterior surface of the cornea and the posterior surface of the contact lens. This vault not only creates an environment free of abrasion, but is an area that continually moisturizes the cornea, as prior to lens insertion these lenses are commonly filled with a preservative free saline solution.

In this study there were no complications of scleral contact lens wear. No patient eyes that returned for one week follow-up exhibited hypoxia, edema, abrasion, or any other signs of harm due to the wear of scleral contact lenses. It is already well established that these lenses are a safe and viable modality, and this study is consistent with this principle.

CHAPTER 5:

CONCLUSION

Conjunctival settling is a real factor when fitting large diameter rigid gas permeable contact lenses, namely scleral lenses. Our data suggests that the original clearance value derived at the fitting is not the true measure that will occur as the patient continues to wear the contact lens. This is relevant to practitioners because when fitting the scleral contact lenses practitioners will have to allow for extra clearance to account for the settling with time. One way to ensure this clearance is to discuss with patients the importance of wearing their scleral lenses for at least one hour, preferably four hours, prior to follow-up after dispensing scleral lenses. If corneal clearance determine by an AS-OCT is a factor to be used by a practitioner in fitting these lenses, they should account for, on average, 0.075 mm of settling after initial lens insertion.

In order to improve this study for the future several things could be done. A larger sample size would aid in a more concrete estimate along with a longer duration of wear time extending out to at least a year. A larger sample size would allow comparisons between fellow eyes of a single patient as well as comparisons between types of lens. It would also be beneficial to follow these patients over the next 10 to 20 years to monitor for long term corneal and limbal changes that could possibly occur due to settling over time.

Unfortunately, due to constraints of study size and loss of patients to follow-up and unacceptable contact lens fit, the results of this study are inconclusive. While further investigation is needed, this study does lend credence to the notion that scleral contact lenses do settle after insertion, at an average of 0.054 mm after one hour of wear and 0.078 mm after four hours of wear. Furthermore, this study agrees that scleral contact lenses are a safe and viable modality for practitioners looking to improve their patient's visual experience and ocular health and comfort.

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Institutional Review Board (FSU - IRB)
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To: Dr. Josh Lotoczky, Dr. Craig Norman, Mr. Kevin Jameson and Ms. Krystal Michels
From: Dr. John Pole, Interim IRB Chair
Re: IRB Application #130406 (Title: Conjunctival Settling of Scleral Contact Lenses)
Date: May 10, 2013

The Ferris State University Institutional Review Board (IRB) has reviewed your application for using human subjects in the study, "Conjunctival Settling of Scleral Contact Lenses" (#130406) and determined it is expedited – 2D from full committee review. This approval has an expiration date of one year from the date of this letter. However, approval is based on the condition that your consent form is updated to include the alternative options to scleral contact lenses (eg, glasses, etc). Please provide the IRB a copy of the new consent form before you begin your study.

With this IRB approval, you may collect data according to procedures in your application until May 10, 2014. It is your obligation to inform the IRB of any changes in your research protocol that would substantially alter the methods and procedures reviewed and approved by the IRB in this application. Your application has been assigned a project number (#130406) which you should refer to in future applications involving the same research procedure.

We also wish to inform researchers that the IRB requires follow-up reports for all research protocols as mandated by Title 45 Code of Federal Regulations, Part 46 (45 CFR 46) for using human subjects in research. We will send a one-year reminder to complete the final report or note the continuation of this study. The final-report form is available on the IRB homepage. 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.