THE IMPORTANCE OF SCLERAL LENS EDGE PROFILE

By

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THE IMPORTANCE OF SCLERAL LENS EDGE PROFILE

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March 11, 2019

ABSTRACT

Background: In the world of specialty contact lenses, the number of practitioners fitting patients in scleral lenses has greatly increased, due to the ability of these lenses to fully vault over the cornea and treat corneal diseases from keratoconus to keratoconjunctivitis sicca. Each manufacturer offers their own fitting guide and all have a unique edge design, which can make fitting these lenses especially difficult if practitioners are unfamiliar with each and every manufacturer. *Methods:* We used an anterior segment optical coherence tomography to create cross sectional images of each manufacturer's lens to determine how they fit and had the subject grade the lenses according to subjective comfort. We focused on and measured the central vault, edge profile, lens thickness, limbal clearance, and weight distribution in relation to lens awareness. *Results*: Our study suggests that the scleral lens contact length, edge thickness, and weight distribution were all factors in predicting lens awareness and comfort for the patient. *Conclusions:* We hope that this study not only shows the intricacies of each scleral lens used, but parlays how the edge profiles are important determinants in predicting patient comfort while wearing the lens.
Keywords: scleral lens, contact lens, edge profile, lens awareness, lens comfort, edge thickness

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1

INTRODUCTION OF THE IMPORTANCE OF SCLERAL LENS EDGE PROFILE

With the popularity of scleral lenses on the rise, several manufacturers have produced their own unique versions to be released into the market. In the past, scleral lenses were mainly used for eyes with ocular pathology such as keratoconus, corneal scarring, etc. but in recent years they have also become popular for patients with dry eye syndrome and moderate to high corneal astigmatism.[1] In addition to different pathologies, each patient may present with different corneal and scleral anatomy which can make the fitting process difficult. In a broad sense, scleral lenses are designed to vault over any corneal pathology with the purpose of using a tear prism to correct for any irregular astigmatism. Irregular astigmatism can cause patients to have reduced visual acuity that is uncorrectable through spectacles and sometimes even traditional rigid gas permeable lenses.[2]

Although scleral lenses may allow for better visual acuity, long term comfort for the patient is just as important when determining which lens should be used. During the fitting process, central clearance is often focused upon to ensure that a proper amount of tears bathes the cornea whereas the edge profile may be overlooked. We believe that a proper fit requires an ideal edge profile to allow for minimal lens awareness. The measurements from this study will give doctors quantifiable data of the lens' edge profile that can help determine what makes a scleral lens comfortable or uncomfortable for the patient.

The ideal edge of scleral lenses prevents the lens from pinching in on the conjunctiva which leads to impingement and blanching, distributes the weight of the lens evenly across the surface of the conjunctiva, and has a rounded edge shape as opposed to a blunt edge shape.[3] These characteristics allow for a scleral lens to be both comfortable and healthy for the patient during long periods of wear. Our study will be looking at the differences between the edges and overall fit of each manufacturer's scleral lenses and how it affects comfort. By taking thickness measurements at different points from the lens edge and the length of contact between the scleral lens and the patient's conjunctiva, we hope to find trends and compare these findings to patient reported comfort at time of insertion and after 45 minutes of wear time.

CHAPTER 2

METHODS

The subject was first screened with an eye examination to rule out any anterior segment pathology through a biomicroscopic examination. We then proceeded to perform a corneal topography to ensure the patient had an averaged shaped cornea (43D-45D in both of the principal meridians) and to confirm the absence of any anterior segment pathology.[4] By choosing a patient with average corneal values, we hoped our results would be representative of the majority of the population and allow for inferences about the ideal edge profile to be made.

The parameters of each scleral lens we used were chosen only by following the manufacturer's fitting guide for each lens design without making any further alterations. The lenses and fitting guides used in this study were Ampleye® by Art Optical, Custom Stable Elite® by Valley Contax, Zenlens® by Alden Optical, TruScleral® by TruForm Optics, OneFit® by Blanchard Contact Lenses, and Maxim® by AccuLens. We inserted a scleral lens into each eye and allowed the lens to settle for 45 minutes. An anterior segment optical coherence tomography was used to take images of the lenses in the center, superior, inferior, temporal and nasal quadrants. These scans were taken both moments after insertion and then repeated after 45 minutes of wear time to allow the lens to settle. We then took note of the edge shape, measured lens thicknesses at 100 and 700 micrometers from the edge, amount of limbal clearance, length of contact area between inner landing zone and edge of the lens, amount of central vault, and subjective patient comfort of each lens out of a score of 10, with 10 being most comfortable and least lens awareness. After the measurements were taken, each scleral lens was taken out for the patient by the examiner. We then waited approximately 20 minutes to allow the cornea and conjunctiva to assume its normal shape before repeating this process for all six different lenses.

Chapter 3

RESULTS

For each lens design, the data collected suggests that length of lens contact showed correlation to patient comfort. The patient reported that the Zenlens®, Custom Stable®, and Ampleye® lenses were considerably more comfortable than the Onefit®, Maxim®, and TruScleral® lenses, reporting comfort level scores of 9, 8, and 7 out of 10 for the first three lenses and levels of 5, 4, and 3 out of 10 for the last three lenses respectively. The patient did not report any significant increase in comfort after 45 minutes of wear for any of the lens designs.

The Zenlens®, Custom Stable®, and Ampleye® lenses all had a length of lens contact between 1,000 and 2,000 microns with approximately equal lens to conjunctival contact in all four quadrants. The amount of lens to conjunctival contact generally increased in contact length after 45 minutes of wear time.

All lens designs except the Maxim® lens showed proper central lens clearance, while the Onefit® and TruScleral® lenses both showed no limbal clearance in all quadrants. Although the Zenlens® showed no limbal clearance in all quadrants upon insertion, it did after 45 minutes of wear. Our data does not suggest that having more limbal clearance or limbal touch in a specific quadrant is indicative of patient comfort.

These results demonstrate the multitude of factors across the lens from the center of the lens to the edge that could be influencing patient comfort and lens awareness. We will further investigate how the data works to quantify the ideal edge profile to further maximize patient comfort in our practices when fitting scleral lenses.

All of the lens measurements we took during this study are organized in the following tables below.

Ampleye® (at insertion)	Center	Nasal edge	Temporal edge	Superior edge	Inferior edge
Central clearance	206				
Thickness in center	300				
Thickness 100 microns from edge		223	217	240	231
Thickness 700 microns from edge		365	369	391	396
Limbal clearance		72	102	311	280
Length of lens contact		1082	1244	1267	1013

Table 1a. Central clearance, lens thicknesses at the center, 100 microns and 700 microns from the edge, limbal clearance in all quadrants, and length of lens to conjunctival contact in all quadrants for Ampleye® at time of insertion as measured using SPECTRALIS anterior segment optical coherence tomography.

Ampleye® (after 45 mins)	Center	Nasal edge	Temporal edge	Superior edge	Inferior edge
Central clearance	184				
Thickness in center	300				
Thickness 100 microns from edge		145	161	190	207
Thickness 700 microns from edge		372	372	393	393
Limbal clearance		289	231	231	405
Length of lens contact		1172	1180	1355	1563

Table 1b. Central clearance, lens thicknesses at the center, 100 microns and 700 microns from the edge, limbal clearance in all quadrants, and length of lens to conjunctival contact in all quadrants for Ampleye® after 45 minutes of wear time as measured using SPECTRALIS anterior segment optical coherence tomography.

Zenlens® (at insertion)	Center	Nasal edge	Temporal edge	Superior edge	Inferior edge
Central clearance	192				
Thickness in center	358				
Thickness 100 microns from edge		196	195	186	183
Thickness 700 microns from edge		268	275	270	277
Limbal clearance		0	0	29	159
Length of lens contact		2283	2263	1959	1765

Table 2a. Central clearance, lens thicknesses at the center, 100 microns and 700 microns from the edge, limbal clearance in all quadrants, and length of lens to conjunctival contact in all quadrants for Zenlens® at time of insertion as measured using SPECTRALIS anterior segment optical coherence tomography.

Zenlens® (after 45 mins)	Center	Nasal edge	Temporal edge	Superior edge	Inferior edge
Central clearance	206				
Thickness in center	354				
Thickness 100 microns from edge		145	181	177	181
Thickness 700 microns from edge		275	272	291	258
Limbal clearance		37	29	36	130
Length of lens contact		1846	2162	1968	2128

Table 2b. Central clearance, lens thicknesses at the center, 100 microns and 700 microns from the edge, limbal clearance in all quadrants, and length of lens to conjunctival contact in all quadrants for Zenlens® after 45 minutes of wear time as measured using SPECTRALIS anterior segment optical coherence tomography.

Custom Stable Elite ® (at insertion)	Center	Nasal edge	Temporal edge	Superior edge	Inferior edge
Central clearance	354				
Thickness in center	344				
Thickness 100 microns from edge		195	260	239	225
Thickness 700 microns from edge		381	391	412	391
Limbal clearance		11	9	65	130
Length of lens contact		1542	1735	1279	1456

Table 3a. Central clearance, lens thicknesses at the center, 100 microns and 700 microns from the edge, limbal clearance in all quadrants, and length of lens to conjunctival contact in all quadrants for Custom Stable Elite® at time of insertion as measured using SPECTRALIS anterior segment optical coherence tomography.

Custom Stable Elite ® (after 45 mins)	Center	Nasal edge	Temporal edge	Superior edge	Inferior edge
Central clearance	333				
Thickness in center	351				
Thickness 100 microns from edge		216	239	247	230
Thickness 700 microns from edge		362	391	396	419
Limbal clearance		5	4	109	179
Length of lens contact		1612	1793	1150	1399

Table 3b. Central clearance, lens thicknesses at the center, 100 microns and 700 microns from the edge, limbal clearance in all quadrants, and length of lens to conjunctival contact in all quadrants for Custom Stable Elite® after 45 minutes of wear time as measured using SPECTRALIS anterior segment optical coherence tomography.

Onefit® (at insertion)	Center	Nasal edge	Temporal edge	Superior edge	Inferior edge
Central clearance	192				
Thickness in center	282				
Thickness 100 microns from edge		94	184	126	111
Thickness 700 microns from edge		203	275	263	240
Limbal clearance		0	0	0	0
Length of lens contact		2439	2739	3239	2811

Table 4a. Central clearance, lens thicknesses at the center, 100 microns and 700 microns from the edge, limbal clearance in all quadrants, and length of lens to conjunctival contact in all quadrants for Onefit® at time of insertion as measured using SPECTRALIS anterior segment optical coherence tomography.

Onefit® (after 45 mins)	Center	Nasal edge	Temporal edge	Superior edge	Inferior edge
Central clearance	145				
Thickness in center	297				
Thickness 100 microns from edge		95	145	158	98
Thickness 700 microns from edge		217	283	272	235
Limbal clearance		0	0	0	0
Length of lens contact		2738	3065	3617	2958

Table 4b. Central clearance, lens thicknesses at the center, 100 microns and 700 microns from the edge, limbal clearance in all quadrants, and length of lens to conjunctival contact in all quadrants for Onefit® after 45 minutes of wear time as measured using SPECTRALIS anterior segment optical coherence tomography.

TruScleral ® (at insertion)	Center	Nasal edge	Temporal edge	Superior edge	Inferior edge
Central clearance	372				
Thickness in center	184				
Thickness 100 microns from edge		326	320	300	328
Thickness 700 microns from edge		420	379	437	414
Limbal clearance		268	203	481	492
Length of lens contact		2284	1967	2417	2001

Table 5a. Central clearance, lens thicknesses at the center, 100 microns and 700 microns from the edge, limbal clearance in all quadrants, and length of lens to conjunctival contact in all quadrants for TruScleral® at time of insertion as measured using SPECTRALIS anterior segment optical coherence tomography.

TruScleral ® (after 45 mins)	Center	Nasal edge	Temporal edge	Superior edge	Inferior edge
Central clearance	282				
Thickness in center	174				
Thickness 100 microns from edge		311	321	351	316
Thickness 700 microns from edge		412	414	421	417
Limbal clearance		0	0	0	0
Length of lens contact		3016	2855	4224	3536

Table 5b. Central clearance, lens thicknesses at the center, 100 microns and 700 microns from the edge, limbal clearance in all quadrants, and length of lens to conjunctival contact in all quadrants for TruScleral® after 45 minutes of wear time as measured using SPECTRALIS anterior segment optical coherence tomography.

Maxim® (at insertion)	Center	Nasal edge	Temporal edge	Superior edge	Inferior edge
Central clearance	36				
Thickness in center	275				
Thickness 100 microns from edge		145	197	169	261
Thickness 700 microns from edge		420	458	393	477
Limbal clearance		87	29	109	181
Length of lens contact		1540	1399	1419	1467

Table 6a. Central clearance, lens thicknesses at the center, 100 microns and 700 microns from the edge, limbal clearance in all quadrants, and length of lens to conjunctival contact in all quadrants for Maxim® at time of insertion as measured using SPECTRALIS anterior segment optical coherence tomography.

Maxim® (after 45 mins)	Center	Nasal edge	Temporal edge	Superior edge	Inferior edge
Central clearance	0				
Thickness in center	298				
Thickness 100 microns from edge		260	206	231	204
Thickness 700 microns from edge		485	384	423	426
Limbal clearance		18	0	37	152
Length of lens contact		2704	2581	1596	1659

Table 4b. Central clearance, lens thicknesses at the center, 100 microns and 700 microns from the edge, limbal clearance in all quadrants, and length of lens to conjunctival contact in all quadrants for Maxim® after 45 minutes of wear time as measured using SPECTRALIS anterior segment optical coherence tomography.

CHAPTER 4

DISCUSSION

The findings of this study suggest that the comfort of a scleral lens is based upon a multitude of factors. Typically, fitting a scleral lens involves obtaining a corneal topography of the front curvature of the cornea, finding a lens most optimal to begin with according to the respective manufacturer's fitting guides, and making adjustments based on slit lamp biomicroscopy findings such as conjunctival impingement, vessel blanching, excessive vault, insufficient vault, or limbal touch.[5] However, with the scans and measurements obtained across multiple scleral lenses using the anterior segment optical coherence tomography, we were able to take many measurements and determine how they correlated to patient reported comfort.

Our patient reported their level of comfort on a scale from 1 to 10, with 10 being most comfortable, at time of insertion and after 45 minutes of wear time. The order of lens comfort did not change after the 45 minutes of wear time. According to our subject, the lenses in order from most comfortable to least comfortable were: Zenlens®, Custom Stable Elite®, Ampleye®, Onefit®, Maxim®, and TruScleral®. In an attempt to control for fitting variability and customizability of each lens, we fit the patient only according to the lens in the sample fitting set correlating to their corneal curvature or sagittal height found via the fitting guide without any subsequent modifications.[6,7,8,9,10,11]

The subject determined that the Zenlens®, Custom Stable Elite®, and Ampleye® were much more comfortable when compared to the other three lenses. Although no trend was found between the amount of limbal clearance and how it relates to comfort, we did find that the amount of the lens that is resting on the conjunctiva does appear to correlate to the patient's reported comfortability. Our subject did not find that lenses showing no limbal clearance were indicative of poor comfort, but studies show that a lens resting on the limbus long term can lead to severe corneal complications such as limbal edema, neovascularization, or keratitis.[12] So even though limbal touch did not affect lens comfort, lenses that rest on the limbus should be modified to ensure proper long term ocular health.

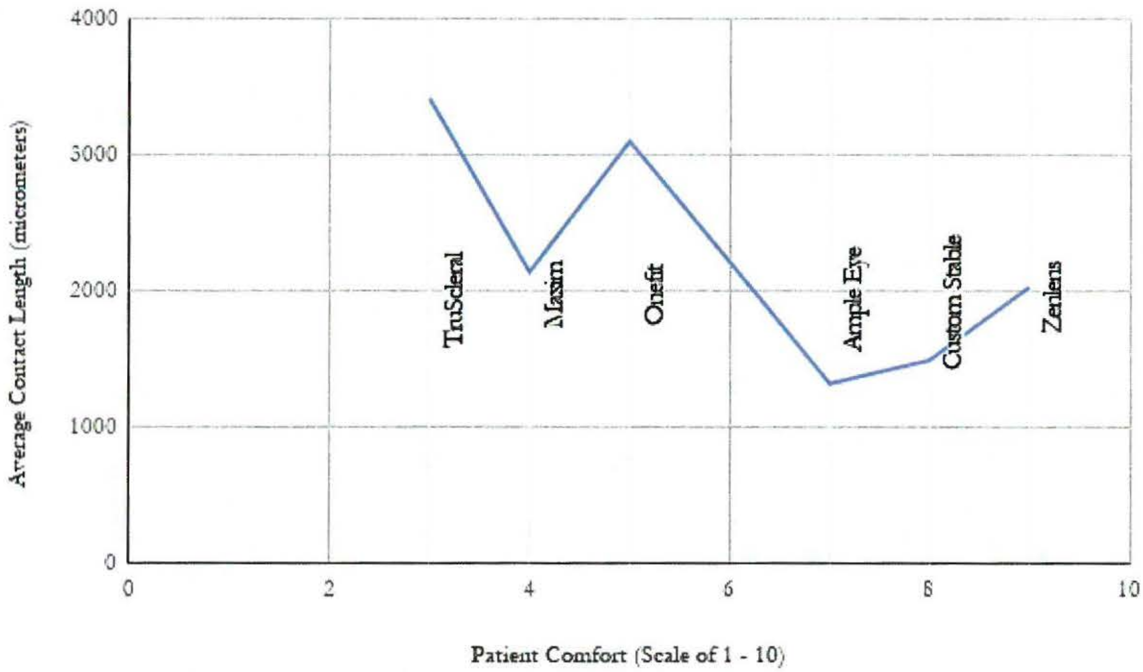

Fig 1. Higher subjective patient comfort showing the ideal average contact length to fall between 1,000 to 2,000 microns of peripheral lens bearing on the conjunctiva.

The contact length was measured from the edge of the lens to where the lens first lifts off the globe, and we also measured the edge thickness values at 100 and 700 microns from the edge of the lens. We found the ideal lens contact length to be approximately 1,000 - 2,000 microns and the ideal edge thicknesses at 100 and 700 microns from the lens edge to be 150 - 250 microns and 300 - 400 microns thick respectively depicted by Fig 2,3, and 4.

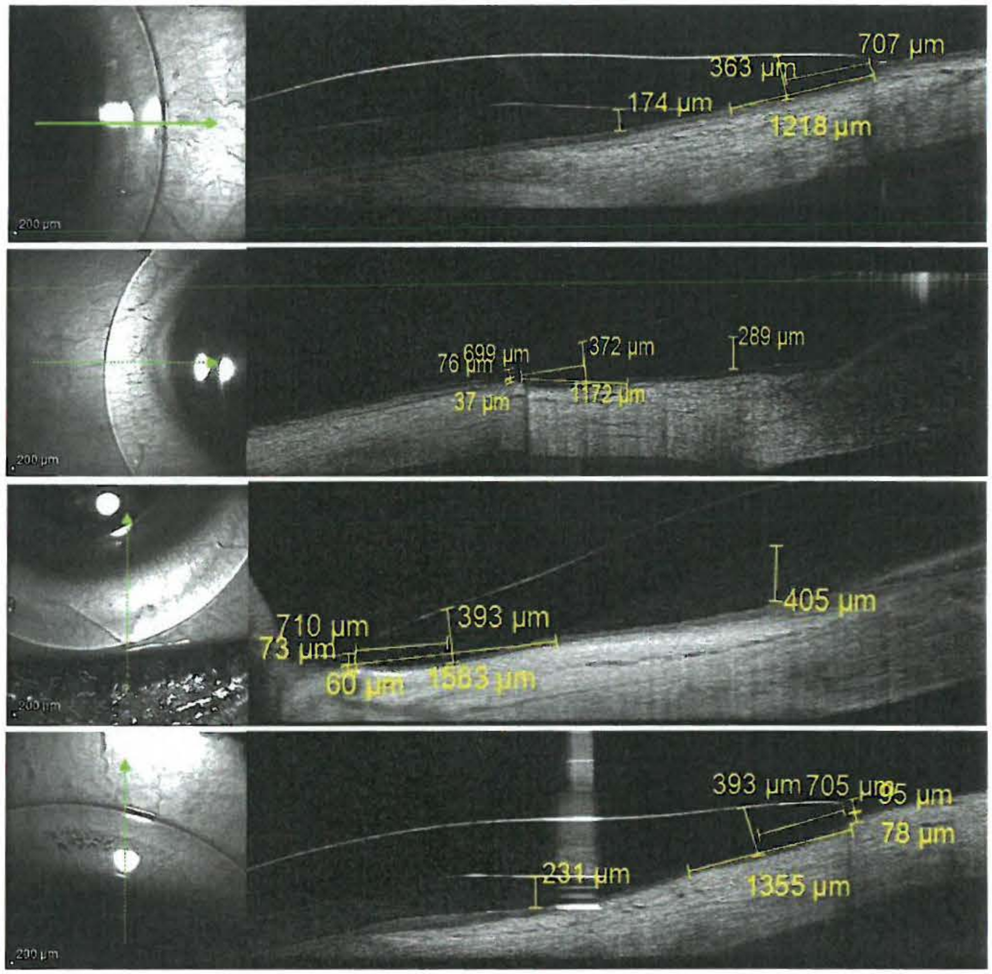

Fig 2. Contact length and lens thickness at 100 and 700 microns between Ampleyes® lens and patient's conjunctiva in the nasal, temporal, inferior, and superior quadrants respectively.

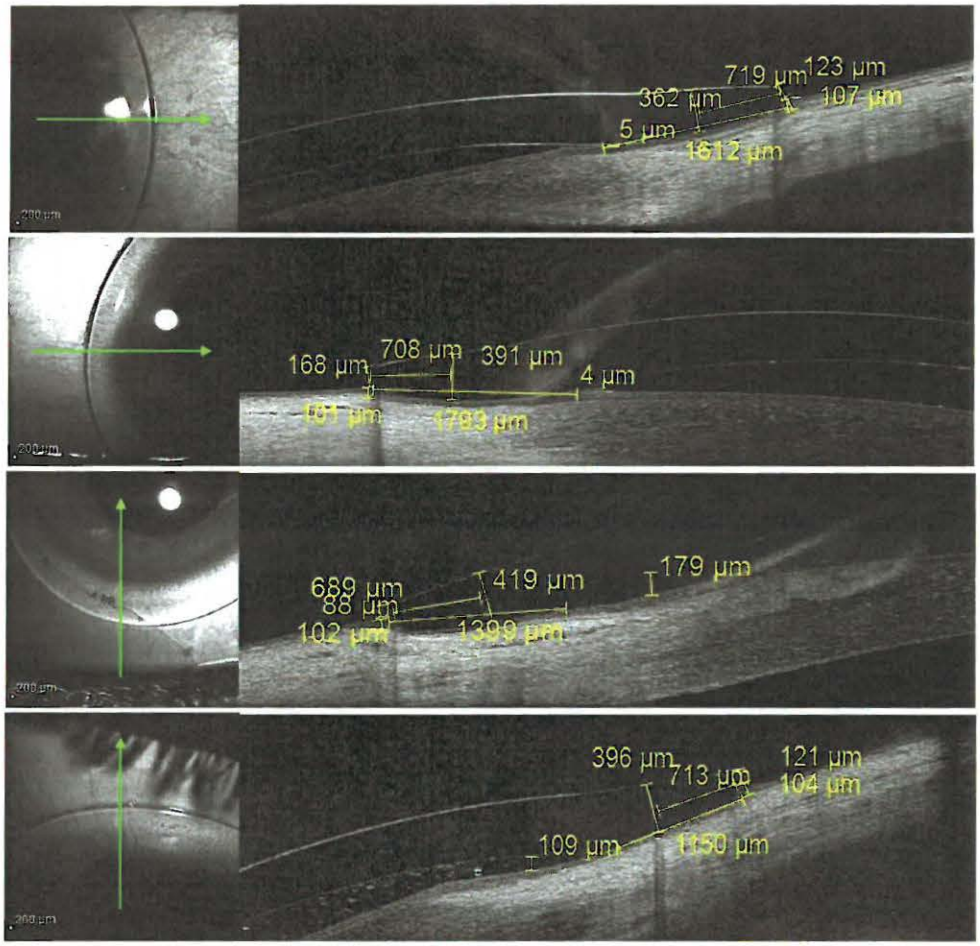

Fig 3. Contact length and lens thickness at 100 and 700 microns between Custom Stable Elite® lens and patient's conjunctiva in the nasal, temporal, inferior, and superior quadrants respectively.

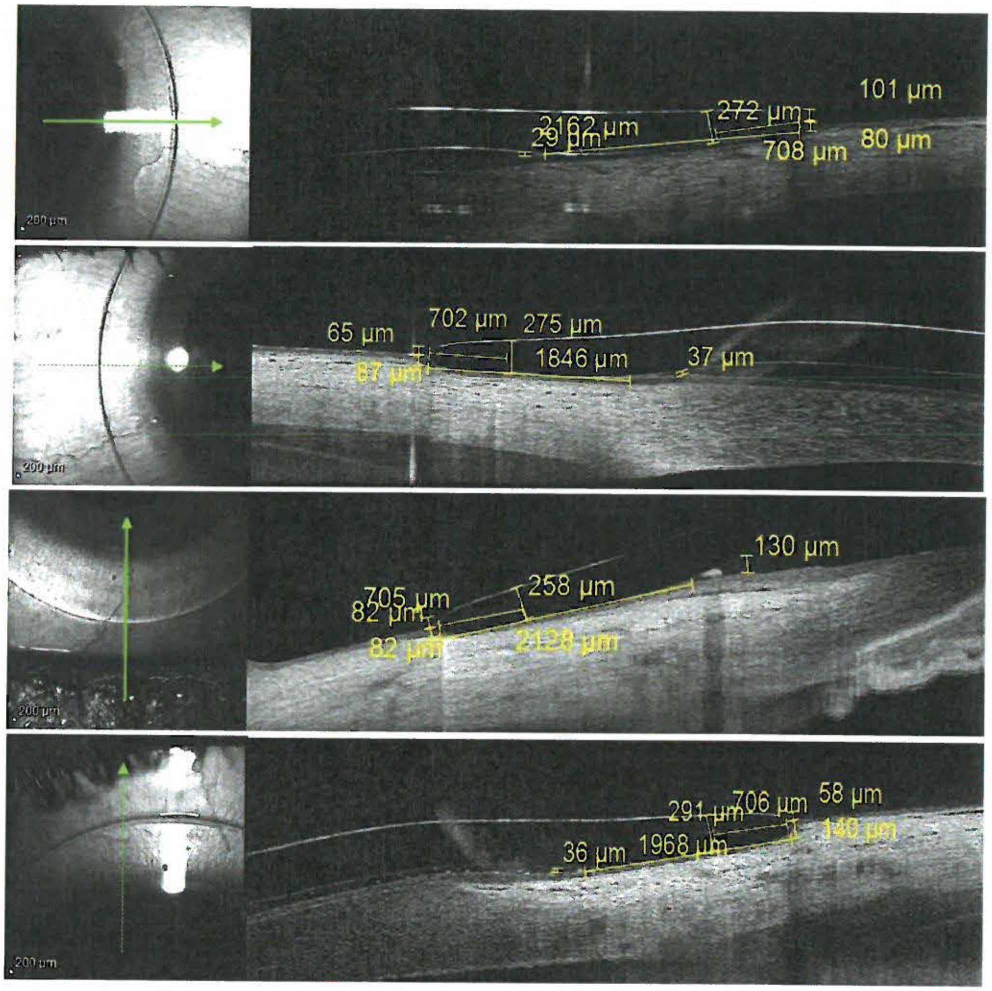

Fig 4. Contact length and lens thickness at 100 and 700 microns between Zenlens® and patient's conjunctiva in the nasal, temporal, inferior, and superior quadrants respectively.

Our study also indicated that the more similar the contact area is in all four quadrants, the more comfortable the lens is perceived to be. In the three most comfortable lenses all quadrants were within approximately 500 microns of contact area, while the Onefit® and TruScleral® lenses, which were both reported as uncomfortable lenses, had contact areas that varied by up to 1,500 microns between quadrants. It is important to note that although the Maxim® lens showed contact symmetry of approximately 1,000 microns in all four quadrants, it is likely that the lens was perceived as uncomfortable due to the lack of central vault (0 microns) leading to corneal touch. Other than corneal touch causing the lens to be uncomfortable, there was no relationship shown between central vault height and comfort in any of the other lenses.

We expected that the larger the contact zone of the lens the more comfortable it would be due to a more spaced out distribution of the weight, but this was not the case in our study. Our data suggests that any more than approximately 2,500 microns of landing zone contact on the conjunctiva appears to actually decrease comfort and increase lens awareness for the patient. This can be shown by the TruScleral® and Onefit® lenses, both showing up to 3,500 - 4,000 microns of contact, which is well above what we found to be the ideal contact length. We do not have any data to suggest that less than 1,000 microns of contact would increase lens awareness for the patient, but we suspect that at a certain value, too little contact between the lens and the conjunctiva would mimic a sharp landing zone, make for poor weight distribution, and pinch the conjunctiva causing patient discomfort.

All three lenses that the patient reported being comfortable showed round edges, which is consistent with a study showed that the ideal lens edge profile is round, but not blunt, in shape.[3] Two of the three uncomfortable lenses, the Maxim® and TruScleral® lens, had edges that appeared to settle deep into the patient's conjunctiva and caused the most conjunctival disruption at the landing zone. We attribute this to the patient's increased lens awareness. Another study reported needing a landing zone that is parallel to the patient's conjunctiva for proper weight distribution of the lens.[4] All but one quadrant of the uncomfortable Maxim® lens showed an obtuse and angular landing zone, instead of the recommended parallel landing zone.

Fitting a patient with a scleral lens is for the most part systematic and straight forward according to the manufacturer's fitting guide. Our study shows that there are still many factors in play when a patient reports lens awareness. When practitioners think of scleral lens awareness, they often begin by ruling out corneal touch which can be measured by approximating the amount of fluorescein via biomicroscopy. Our intentions of this study is not to undermine the importance of central clearance, but to make practitioners attune to the importance of the scleral lens edge profile. We found that the conjunctival contact zone, weight distribution, edge shape, and contact profile of the lens to all be important determinants of patient comfort, decreased lens awareness, and contributors to healthy contact lens wear.

While we were able to visualize trends in the measurements we took and how comfortable the lens was reported, this study does contain a few limitations. One major limitation is that only one subject was used to draw all of our inferences. Even though we chose a subject with average corneal values, it is very possible that the lenses could have settled quite differently on different eyes, and that other subjects may have ranked the lenses differently as comfort was reported subjectively. Using subjects with corneal values outside of the normal range (steeper than average, flatter than average, high astigmatism, with ocular pathology, etc.) may also have showed a variation in the results. Another limitation to our study is that we were not able to map out our subject's bulbar conjunctiva. If we were able to map out this area on our subject, we may have had a better idea of how well our findings would translate to the overall population. During our study we mapped the thickness of lens center, 100 microns in from the edge, and 700 microns from the edge, but taking measurements at more locations on the lens may provide for a more accurate scleral lens to conjunctival contact volume giving better insight on the edge design and how it relates to comfort.

REFERENCES

1. DeNaeyer, Greg OD. Who's a Candidate for Scleral Lenses? Review of Contact Lenses, January 2015. Available at http://www.reviewofcontactlenses.com/article/whos-a-candidate-for-scleral-lenses. Accessed Feb 11, 2019.
2. Schein OD, Rosenthal P, Ducharme C. A gas-permeable scleral contact lens for visual rehabilitation. Am J Ophthalmology. 1990;109(3):318-22.
3. Brujic, Mile OD, Miller, Jason OD, MBA. Stick the Landing. Review of Contact Lenses, April 2014. Available at http://www.reviewofcontactlenses.com/article/stick-the-landing. Accessed Feb 11, 2019.
4. Merrim, J.C., Zheng, L. The Relationship of Corneal Curvature and Axial Length in Adults. The Association for Research in Vision and Ophthalmology, May 2005. Available at https://iovs.arvojournals.org/article.aspx?articleid=2400600. Accessed Feb 11, 2019.
5. DeNaeyer, Greg OD. The Scleral Lens Vault. Contact Lens Spectrum, January 2015. Available at https://www.clspectrum.com/issues/2015/january-2015/the-scleral-lens-vault Accessed Feb 11, 2019.
6. Art Optical. Ampleye Professional Fitting Instructions, 2016. Available at https://www.artoptical.com/storage/docs/Ampleye_Fitting_Booklet.pdf. Accessed Feb 11, 2019
7. Alden Optical. Zenlens Fitting Guide, 2016. Available at http://www.aldenoptical.com/docs/zenlens/Zenlens-brochure.pdf. Accessed Feb 11, 2019.

8. Valley Contax. Custom Stable Fitting Guide, 2017. Available at https://www.valleycontax.com/files/custom-stable-fitting-guide.pdf. Accessed Feb 11, 2019.

9. Blanchard Lab. Onefit Scleral Lens Fitting Guide, Aug 2018. Available at http://blanchardlab.com/wp-content/uploads/2018/09/Onefit-Fittingguide-08-13-18-Web.pdf. Accessed Feb 11, 2019.

10. Acculens. Maxim Clinical Guide for Scleral Lens Success, 2018. Available at http://www.acculens.com/pdf/clinical-guide-success.pdf. Accessed Feb 11, 2019.

11. TruForm Optics. TruForm Fitting Guide for TruScleral, 2016. Available at http://www.tfoptics.com/presbyopic/documents/FSAFIT.pdf. Accessed Feb 11, 2019.

12. Carrasquillo, Karen OD PhD, Byrnes, Steve OD. Corneal Edema and Scleral Lenses. Contact Lens Spectrum, Nov 2018. Available at https://www.clspectrum.com/issues/2018/november-2018/corneal-edema-and-scleral-lenses. Accessed Feb 11, 2019.

APPENDIX A

FERRIS STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECT RESEARCH
1010 Campus Drive FLITE 410 Big Rapids, MI 49307 | (231) 591-2553 | www.ferris.edu/irb

Date: January 24, 2019

To: Joshua Lotoczky
From: Gregory Wellman, R.Ph, Ph.D, IRB Chair
Re: IRB Application *IRB-FY18-19-44 Importance of Scleral Lens Edge Profile*

The Ferris State University Institutional Review Board (IRB) has reviewed your application for using human subjects in the study, " *Importance of Scleral Lens Edge Profile" (IRB-FY18-19-44)* and Approved this project under pre-2018 Common Rule Federal Regulations Expedited Review 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.)

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 January 24, 2020 .** 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-FY18-19-44. 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