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**Comparison of Higher Order Aberrations between On- and Off- Eye Scleral Lenses in Dry
Eye and Ocular Surface Disease Patients**

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COMPARISON OF HIGHER ORDER ABERRATIONS BETWEEN ON- AND OFF-
EYE SCLERAL LENSES IN DRY EYE AND OCULAR SURFACE DISEASE
PATIENTS

by

Tyler Skiba
Kevin Liberman

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

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May, 2016

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Has been approved

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ABSTRACT

Background: The pilot study measured and compared higher order optical aberrations (HOA) with scleral contact lenses on-eye and off-eye in a group of subjects with confirmed Dry Eye Syndrome (DES). It has been confirmed that the corneal surface and tear film irregularities associated with DES increase the amount of HOA in the optical system of the eye, leading to the detrimental visual symptoms of glare, halos and decreased contrast sensitivity. *Methods:* A sample of subjects, N=8, with a confirmed diagnosis of DES, had an initial fluorescein tear break-up time (TBUT) performed on them. Subjects with a TBUT of <10 seconds were included. All subjects were fit in scleral lenses OU. Two measurements of total HOA and total aberrations were performed on each eye; i) scleral lens off-eye (SCL or naked eye) and ii) scleral lens on eye – using the Nidek OPD – Scan III. *Results:* Root Mean Square (RMS) values of the total HOA and total aberrations (higher order + lower order) were obtained and analyzed. Dry eye subjects showed a statistically insignificant reduction of 0.02 RMS in total HOA with scleral lenses on-eye vs. off eye, $t=1.89$; $p<0.35$. Subjects showed a statistically significant increase of 0.21 RMS in total aberrations (H+L) with scleral lenses on-eye vs. off-eye, $t=2.36$; $p<0.03$. *Conclusions:* By vaulting the cornea and filling in any corneal irregularities with the tear reservoir, a scleral lens theoretically creates a new, regular anterior refracting surface for the eye and a continuous optical system. There was no statistically significant reduction in total HOA with scleral lenses for dry eye patients. This study showed no significant evidence that scleral lens technology reduces HOA in dry eye patients, compared to SCL's or naked eye, to resolve function vision problems such as glare, halos, and reduced contrast sensitivity.

TABLE OF CONTENTS

	Page
LIST OF TABLES.....	vi
CHAPTER	
1 INTRODUCTION TO OCULAR SURFACE DISEASE, DRY EYE DISEASE, AND SCLERAL LENSES	1
2 METHODOLOGY OF MEASURING HOA IN DRY EYE PATIENTS WITH SCLERAL LENSES	4
3 RESULTS OF TOTAL HOA AND TOTAL ABERRATIONS IN DRY EYE PATIENTS WITH SCLERAL LENSES	11
4 DISCUSSION OF PILOT STUDY: HOA IN DRY EYE PATIENTS WITH SCLERAL LENSES	14
REFERENCES	16
APPENDIX	
A. IRB APPROVAL FORM	19

LIST OF TABLES

Table		Page
1	Raw RMS values: Total HOA and Total Aberrations (H+L) with Scleral Lenses On-Eye vs. Off-Eye	12
2	RMS Analysis and Statistical Significance: Total HOA with Scleral Lenses On-Eye vs. Off-Eye	13
3	RMS2 Analysis and Statistical Significance: Total Aberrations (H+L) with Scleral Lenses On-Eye vs. Off-Eye	13

CHAPTER 1

INTRODUCTION TO OCULAR SURFACE DISEASE, DRY EYE DISEASE, AND SCLERAL LENSES

Dry Eye is a multifactorial disorder causing alterations in the volume, composition, and/or distribution of the tear film¹. In DES, there are insufficient tears to lubricate and nourish the ocular surface, the cornea². People with dry eyes typically either do not produce enough tears (lacrimon deficient DES), have a poor quality of tears (lipid deficient DES), or do not blink completely or frequently enough². With each blink of the eyelids, tears are spread across the front surface of the eye, the cornea². Tears provide lubrication, reduce the risk of infection, wash away foreign matter in the eye, and keep the surface of the eyes smooth and clear². The corneal surface itself, the epithelium, is inherently rough and irregular – relatively speaking. The tear film is distributed over the corneal surface and serves to fill in or mask any corneal irregularities and create a smooth anterior refractive surface for the eye³. A smooth anterior (outer) ocular surface is essential for good vision³.

In DES, the front surface of the eye is examined using vital stains, fluorescein and lissamine green⁴. Fluorescein stains both the pre-corneal tear film and corneal epithelial erosions (missing corneal epithelial cells)⁴. Lissamine green stains or highlight dead, devitalized, and superficially damaged cells⁴. The tear break-up time (TBUT) describes the stability of the tear film⁴. The normal ranges lies between 20-30 seconds, less than 10 seconds are considered definitely pathological for DES⁴.

Without a sufficient tear film to create a smooth anterior refractive surface for the eye, not only do patients with DES suffer from physical discomfort, but DES also impairs

functional vision. Eyes of dry eye patients have showed greater optical aberrations compared with normal control eyes, more specifically an increase in higher order aberrations, attributable to tear film irregularities and consequentially ocular surface irregularities⁵. Contrast sensitivity has been shown to be significantly reduced in dry eye patients compared to control subjects⁶. Symptoms of glare may also manifest as a result of the irregular surface of a dry cornea⁷. DES especially impairs functional vision in reading, computer work, and when driving⁴. Reading speed can be significantly reduced and correlates with disease severity⁴. Tests in driving simulators have shown significantly reduced reaction time⁴. Reduced quality of life in everyday activities and leisure pursuits are reported by a significant portion of patients suffering from DES, as is reduced efficiency at work⁴.

Traditionally, scleral contact lenses are reserved for corneas with irregular astigmatism; however, the superior tear chamber offered by the modality can be taken advantage of to help manage certain corneal problems – including many forms of dry eye⁸. A scleral lens vaults over the cornea in its entirety, and lands and rests on the sclera. The bowl of the scleral lens is filled with non-preserved saline and then placed on the eye⁸. Upon successful insertion, a tear reservoir rests between the anterior corneal surface and the posterior surface of the contact lens⁸. This liquid “cushion” acts as a liquid bandage that continuously bathes the anterior corneal surface, keeping it moisturized and rejuvenating the ocular surface⁹. Additionally, the rigid lens material – now essentially the new anterior corneal surface – creates a smooth anterior refracting surface for the eye, which is often absent in a severely compromised cornea¹⁰. The tear reservoir masks any

irregularities in the compromised corneal surface and creates a smooth, continual optical system behind the new smooth anterior refracting surface, all the way to the retina⁹. With an appropriate prescription, a scleral lens may provide the patient with refractive correction, free of debilitating glare, halos, and decreased contrast sensitivity that is common in patients with DES – all while rehabilitating the ocular surface¹⁰.

CHAPTER 2

METHODOLOGY OF MEASURING HOA IN DRY EYE PATIENTS WITH SCLERAL LENSES

Subjects – A sample of subjects (N=8) were recruited from the Michigan College of Optometry (MCO) student, staff, and faculty body, as well as the University Eye Center (UEC) patient body at MCO. All of the subjects were patients suffering from Ocular Surface Disease (OSD) including aqueous-deficient Dry Eye Disease (DED), both Sjogren's and non-Sjogren's varieties, Evaporative DED, meibomian gland dysfunction (MGD), and other lid-related DED¹. The test used to screen for OSD in prospective subjects was a Fluorescein Tear Break-Up Time (TBUT). The criterion to qualify as possessing significant OSD was a TBUT of less than 10 seconds (sensitivity 72%; specificity 62%)¹¹. Subjects may also have had subjective symptoms related to OSD including, but not limited to: glare, halos, burning, foreign body sensation, redness, and/or itching. Subjects may have been hyperopic, myopic, astigmatic, or emmetropic, but all participating subjects were required to have vision correctable to 20/20 and clear, healthy ocular media. An email explaining the criterion for participation and the data collection process was distributed to the MCO faculty, staff, and student body. Faculty, staff and students were urged to participate in the study if they had ever been told they suffered from OSD/DED or, they believed they were currently experiencing symptoms related to OSD/DED. The email also requested that faculty and student interns inquire about participating in the study, with any patient they believed might meet the necessary criteria as having OSD/DED. A consent form approved by the Ferris State University, Institutional Review Board was presented to the prospective subjects either prior to or

upon the initial office visit. Subjects were required to sign the consent form prior to any data collection.

Procedures – To ensure that the subjects' vision was correctable to 20/20 and to ensure the clarity and health of the ocular media, the examiners measured the subject's visual acuity using the high contrast Snellen letter acuity chart and conducted a basic slit lamp biomicroscopy examination. This study required subjects to be fit in scleral contact lenses and possibly silicone hydrogel contact lenses as well, if the subject possessed a clinically significant degree of ametropia, $> \pm 0.50$ D. Spherical refractive error and astigmatism are lower order aberrations; correcting ametropias with a soft contact lens isolated higher order aberrations for measurement for the purpose of this study. To ensure that the subjects indeed possessed some form of OSD, the examiners performed a TBUT on the subject, including in the trial subjects with a TBUT < 10 seconds, and excluding subjects with a TBUT > 10 seconds. The TBUT is a diagnostic test to assess the stability of the pre-corneal tear film¹². The time interval between a complete blink and the first appearance of a dry spot (a dark spot) in the tear film after fluorescein instillation is measured in seconds¹². An unstable tear film and accelerated evaporation of the tear film is one of the most common findings in patients with OSD¹². The visibility of the fluorescein tear film is enhanced by the use of a yellow barrier filter in conjunction with the slit lamp biomicroscope¹¹. The biomicroscope is an instrument that is used to examine the health of the anterior and posterior segments of the eye. It is also indispensable in the evaluation of contact lenses. Assuming the subject qualified for the trial based on the aforementioned measures, the

examiners then fit the initial trial lens on each subject based upon central corneal curvature (CCC) readings and the corneal diameter – i.e. the sagittal depth of the cornea. The CCC measurement was made using the corneal

topographer or keratometer. The corneal topographer is an instrument that maps the curvature of the broad expanse of the anterior surface of the cornea non-invasively. A keratometer is a device that measures the curvature of the central 3 mm of the cornea using reflections from the front corneal surface. The corneal diameter and sagittal depth measurement were made using anterior segment – optical coherence tomography (AS-OCT). The AS-OCT is an instrument that uses low-coherence interferometry to produce a high-resolution cross-sectional image of the cornea, as well as the iris and crystalline lens. The non-invasive instrument provides a histological view of living tissue without biopsy. Corneal topography, keratometry, AS-OCT, and slit lamp biomicroscopy all require subjects to place their chin on the chin rest of the instrument and keep their fixation steady while measurements/observations are made.

Scleral and Silicone Hydrogel (SiHy) Contact Lens Design – Scleral Contact Lens: The examiners used the Custom Stable (Valley Contax) Full Scleral lens design with an overall lens diameter of 15.8 mm. A corneal clearance/vault of 250-400 microns is anticipated with this lens design. Corneal vault creates a reservoir of tear film between the posterior lens and anterior corneal surface, and can be altered by manipulating the sagittal height of the lens relative to the sagittal depth of the cornea.

Silicone Hydrogel Lens: Unless the subject was emmetropic ($< \pm 0.50$ D), the examiners fit the subject in a SiHy soft contact lens to simulate a naked cornea

(i.e. no tear reservoir). Free of any lower order aberrations. The SiHy lens of choice was the CooperVision Biofinity (comfilcon 48%). The SiHy lens parameters were determined based upon the measurement of the subjects' corneal diameter, CCC, corneal astigmatism, and corneal refractive error.

Scleral and SiHy Lens Fit & Assessment – Both the scleral and SiHy lenses were fit according to the manufacturer's fitting and reference guidelines. Prior to insertion, the examiners thoroughly cleaned and rinsed the lens with solution compatible with the lens of interest. To insert the scleral lens, the bowl of the lens was first be filled $\frac{3}{4}$ of the way full with preservative-free saline solution (which helps to form the fluid reservoir between the posterior lens and anterior corneal surfaces) and sodium fluorescein dye was put into the saline solution to enhance the visibility and assessment of the fit. The scleral lens was inserted into the subject's eye with his or her face parallel to the table/floor. The examiners then performed a preliminary evaluation of the fit, inspecting for air bubbles beneath the lens and looking for optimal corneal vault/clearance. If the initial fit appeared satisfactory, the patient was required to wear the lens for approximately 20-30 minutes in order to allow the lens to settle. The fit was then evaluated again for optimal corneal vault and alignment using the slit lamp biomicroscope and the AS-OCT. The OCT captures high-resolution cross-sectional images of the contact lens on the eye, allowing easy and accurate assessment of the contact lens fit. To insert the SiHy lens the examiners held the subjects upper lid up and the lower lid down, with the soft lens placed on the index finger of the hand. The subject was required to fixate upward slightly and the lens was gently

placed on the inferior conjunctiva of the subject's eye. The subject was then required to fixate straight ahead, which slid the contact lens onto the central cornea. The SiHy lens was allowed to settle on the eye for approximately 5 minutes, following which the fit of the lens was assessed for centration, limbal coverage, and movement using the slit lamp biomicroscope. Following the fit assessment for both the scleral and SiHy contact lenses, an over-refraction was performed to determine the best corrected visual acuity (BCVA). The necessary alterations were made to both the scleral and SiHy lens parameters by the examiner to obtain an optimal fit and optimal visual acuity. Once an optimal fit and BCVA were achieved with both the scleral and SiHy lenses, measurement of higher order wavefront aberrations (described below) were done with scleral lens on-eye and off-eye, for each of the subject's eyes, using the Nidek OPD –Scan III.

Wavefront Aberration Measurement & Instrumentation – Total Higher Order Aberrations (HOA) and total aberrations (lower order + higher order) were measured with the Nidek OPD-Scan III which is a multifunctional ophthalmic device. The Nidek OPD is one of many commercially available devices currently available that can be used to measure wavefront aberrations. It uses the principle of a time-based slit laser interferometry. In this procedure a slit of light scans the eye in various meridians. Photodetectors within the instrument then measure the time it takes for the light to reflect from the back of the retina. This information, along with the scan rate, is then used to construct the wavefront and thereby the aberrations.

The machine was first prepared by cleaning the forehead and chinrest with alcohol swabs. Subjects were required to place their chin as deeply as possible in the chinrest,

rest their heads gently against the forehead rest and fixate on a target presented by the instrument while it takes the measurements. The height of the chinrest was adjusted so that the subjects' eyes were aligned with the eye alignment marker. Although the OPD scan III uses infrared technology, the potency of the infrared rays is very weak and as such poses no threat to the ocular system. OPD scans were taken both while the subject was wearing a scleral lens and also either wearing a SiHy lens or over their naked cornea, for both eyes.

Sequence of Visits for Data Collection –

1. The patient presented to clinic wearing their habitual contact lens or spectacle correction. At the baseline visit, the examiners conducted entrance tests – namely a TBUT and a slit lamp biomicroscopy examination of the anterior segment – to ensure that the subject met the criteria for inclusion in the study (as described above). Assuming a subject met the inclusion criteria, the appropriate measurements were taken and each eye was fit in a SiHy contact lens (or this step will be omitted if the subject is emmetropic). An OPD scan was taken over the SiHy lens or the subject's naked cornea (scleral lens off-eye) to measure “off-eye” HOA, for each eye. Each eye was then measured and fit in a scleral lens (as described above). Following adjustment and finalization of the fit and prescription, the scleral lenses were ordered (the lenses took approximately 10 days to arrive at the UEC). Patients were educated that the process of finalizing the scleral lens fit and performing the necessary data collection could take up to 2 additional visits.

2. Again, the patient presented to clinic for the second visit wearing their habitual contact lens or spectacle correction. At the second visit the scleral lens was inserted into

the eye, evaluated, and allowed to settle for 30 minutes. After 30 minutes of wear time, the scleral lens was evaluated for corneal vault and alignment (as described above) and visual acuity was tested. Assuming an acceptable scleral lens fit and acceptable acuities, HOA was measured in each eye via an OPD scan, with the scleral lens on-eye.

3. In the event that the fit of the scleral lens was deemed unacceptable by the examiners at the second visit, the parameters of the scleral lens were adjusted accordingly and the lens was reordered. The subject then returned to the clinic approximately 10 days later for a third visit. The new scleral lens was inserted into the eye, the fit was evaluated, visual acuity was tested and, assuming an acceptable fit and acuities, HOA aberrations were then measured with the scleral lens on-eye, for both eyes.

Data Analysis – Root Mean Square (RMS) values of the total HOA as well as the RMS values of the total aberrations (higher order + lower order) were obtained for each condition – scleral lens on-eye and off-eye. The RMS value is an index that is used as a measure of the magnitude or severity of aberrations present in the eye. **A two factor analysis of variance (ANOVA) was run of the RMS data. The two factors were the type of contact lens (Scleral or Hydrogel) and the class of aberration. Additionally,** a paired two tailed t-test was used to compare RMS values obtained with scleral lenses on- and off-eye. Excel 2013 and SPSS Statistics software packages were used for data analysis purposes.

CHAPTER 3

RESULTS OF TOTAL HOA AND TOTAL
ABERRATIONS IN DRY EYE PATIENTS WITH
SCLERAL LENSES

Root Mean Square (RMS) values of the total HOA and total aberrations (higher order + lower order) were obtained and analyzed. Of 8 total eyes, 5 eyes exhibited a measurable decrease in total HOA with scleral lenses on-eye, compared to off-eye (naked eye or SCL); two of the 5 eyes showed > 50% reduction in total HOA (52% and 62% reduction respectively), while a 3rd showed 35% reduction in total HOA. Three of 8 eyes exhibited a measurable increase in total HOA with scleral lenses on-eye vs. off-eye. Eight out of 8 eyes exhibited a measurable increase in total aberrations (H+L) with scleral lenses on-eye, compared to sclerals off-eye.

Table 1: Raw RMS values: Total HOA and Total Aberrations (H+L)

with Scleral Lenses On-Eye vs. Off-Eye

Patient	JS OD	JS OS	BS OD	BS OS	CS OD	CS OS	DH OD	DH OS
Age	24	24	24	24	23	23	26	26
Sex	F	F	M	M	F	F	M	M
Refractive Error	-3.75 DS	-3.25 DS	-3.75 -0.50x172	-3.00 -1.00x163	+1.75 -0.50x180	+1.75 -0.50x180	-0.25 -2.25x105	-1.00 -1.75x067
TBUT	9s	4s	3s	3s	5s	4s	8s	8s
NAKED EYE	DW SCL	DW SCL	DW SCL	DW SCL	DW SCL	DW SCL	DW SCL	DW SCL
Total (H+L)	0.237	0.359	0.409	0.578	0.431	0.143	0.347	0.38
Tilt	0.157 @25	0.211 @163	0.118 @175	0.060 @069	0.116 @142	0.088 @212	0.082 @119	0.124 @151
HOA Total	0.143	0.124	0.085	0.148	0.187	0.093	0.084	0.195
Coma	0.045	0.086	0.05	0.053	0.003	0.01	0.055	0.024
Trefoil	0.134	0.072	0.063	0.126	0.133	0.05	0.056	0.165
Spherical	0.003	0.042	0.003	0.019	0.091	0.062	0.016	0.06
SCLERAL								
Total (H+L)	0.333	0.443	0.513	0.601	0.65	0.795	0.394	0.837
Tilt	0.120 @15	0.138 @120	0.099 @139	0.143 @145	0.487 @255	0.373 @306	0.234 @226	0.204 @293
HOA Total	0.093	0.13	0.081	0.071	0.185	0.157	0.103	0.074
Coma	0.052	0.069	0.025	0.051	0.139	0.128	0.075	0.067
Trefoil	0.06	0.09	0.048	0.046	0.119	0.071	0.065	0.024
Spherical	0.02	0.029	0.003	0.006	0.006	0.02	0.015	0.006

A paired two tailed t-test was run on the sample of 8 dry eyes to compare the obtained RMS values and determine if there was a statistically significant mean difference between total HOA and/or total aberrations (H+L) with scleral lenses on-eye vs. off-eye. The mean (N=8) RMS for total HOA with scleral lenses off-eye was 0.132; the mean RMS for total HOA scleral lenses on-eye was 0.112. Subjects showed a statistically non-significant reduction of 0.02 in total HOA with scleral lenses on-eye vs. off eye, $t=1.89$; $p<0.35$.

A comparison of the HOA with the Scleral and Hydrogel contact lenses made with the two factor ANOVA fell just short of statistical significance ($F(1,79) = 3.66$; $p = 0.059$).

Table 2: RMS Analysis and Statistical Significance: Total HOA
with Scleral Lenses On-Eye vs. Off-Eye

	Mean	N	t	Sig. (2-tailed)
Total HOA Off-Eye	0.132	8	1.89	0.35
Total HOA Scleral On-Eye	0.112			

The mean RMS for total aberrations (H+L) with scleral lenses off-eye was 0.361; the mean RMS for total aberrations (H+L) scleral lenses on-eye was 0.571. Subjects showed a statistically significant increase of 0.21 in total aberrations (H+L) with scleral lenses on-eye vs. off-eye, $t=2.36$; $p<0.03$.

Table 3: RMS Analysis and Statistical Significance: Total Aberrations
(H+L) with Scleral Lenses On-Eye vs. Off-Eye

	Mean	N	t	Sig. (2-tailed)

Total Aberrations (H+L) Off-Eye	0.361	8	2.36	0.03
Total Aberrations (H+L) Scleral On-Eye	0.571			

CHAPTER 4

DISCUSSION OF PILOT STUDY: HOA IN DRY EYE

PATIENTS WITH SCLERAL LENSES

The study showed no statistically significant reduction in total HOA in the eyes of dry eye patients, when wearing scleral lenses rather than SCL's or naked eye. The study did show a statistically significant increase in total aberrations (H+L) in the eyes of dry eye patients, when wearing scleral lenses, compared to SCL's or naked eye. Being that the study was unable to prove a significant reduction in HOA in dry eye patients with scleral lens wear, the study was unable to prove the benefit of scleral lenses in solving functional visual problems of glare, halos, and decreased contrast sensitivity in dry eye patients.

The study was a pilot study consisting of a relatively small sample size of 4 patients, 8 eyes total. Future research should strive to employ more subjects to test a larger sample size. The study also used all relatively young subjects with subjectively mild cases of DES. Future studies should use more strict criteria in qualifying subjects as having DES or OSD to include them in the trial. More strict, or stringent criteria would include older individuals with more inherent DES, faster TBUT's, and more objective signs of moderate to severe DES/OSD. Keeping in mind that there was in fact a measureable reduction in total HOA with scleral lenses on-eye, albeit a statistically insignificant one, it is possible that with more severe cases of DES, the reduction in HOA would be more dramatic and possibly

statistically significant. The therapeutic effects of scleral lenses in reducing glare, halos, etc. could potentially be much greater and worthwhile for patients with severe DES, compared to mild DES.

Another potential source of error within the study was poor scleral lens fits, resulting in uncorrected ametropia present when taking aberration measurements on the OPD scan. For the off-eye measurement, if the patient possessed $> \pm 0.50$ D of ametropia, it was required that they be fit in an SCL to be worn for the OPD scan. This was an effort to neutralize lower order aberrations – i.e. refractive error – and isolate HOA for the trial's purpose. Two out of 8 eyes, 25%, had manifest over-refractions $> \pm 0.50$ D with scleral lenses on, meaning significant, excessive, and unwanted lower order aberrations were present for the on-eye scan. This could have potentially skewed the data and is worth considering, seeing that 8 out of 8 eyes showed an increase in total aberrations – a measure of both higher order + lower order aberrations – with scleral lenses on-eye.

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APPENDIX A
IRB APPROVAL FORM