Do Scleral Lenses Provide Adequate Oxygen Permeability for Overnight Lens Wear?

Paul Nefedov
nefe6310@pacificu.edu

Recommended Citation
https://commons.pacificu.edu/opt/20

This Thesis is brought to you for free and open access by the Theses, Dissertations and Capstone Projects at CommonKnowledge. It has been accepted for inclusion in College of Optometry by an authorized administrator of CommonKnowledge. For more information, please contact CommonKnowledge@pacificu.edu.
Do Scleral Lenses Provide Adequate Oxygen Permeability for Overnight Lens Wear?

Abstract

Purpose: The purpose of this study was to evaluate corneal hypoxic edema after overnight (closed eye) wear of scleral lenses. Hypoxia of the cornea leads to accumulation of lactic acid in the corneal stroma, and subsequent corneal edema.

Methods: Eleven healthy subjects were selected and pre-screened for any ocular pathology or ocular surface/corneal abnormalities. The study was performed in two phases: on the first night subjects slept without contact lenses on. Corneal thickness was measured immediately before sleep, and then again immediately upon awakening to establish baseline nocturnal swelling. During the second night subjects wore had a scleral contact lens (Boson XO2 material with Dk 141) on the right eye. Both corneas were evaluated again immediately upon wakening. Corneal pachymetry was performed using measured with the Zeiss Visante OCT and a sonographic pachymeter.

Results: The average amount of overnight corneal swelling in the right eyes following the overnight wear of a scleral lens was 8.54% when measurement variability was considered, and an average physiological swelling was 2.5% using anterior segment OCT measurement. All subjects reported some degree of visual haze in the scleral lens-wearing eye upon awakening and average visual acuity loss was 1 line of Snellen chart that lasted up to 2 hours.

Conclusion: The results of this study appear to indicate that therapeutic, overnight wear of scleral lenses needs to be approached with caution. This study highlights the need for higher Dk lens materials (for overnight lens wear) and/or lens solutions that contain oxygen soluble particles (i.e. fluorocarbons) that can provide additional oxygen to the ocular surface in the closed eye environment. In patients requiring the therapeutic, overnight use of scleral lenses a risk to benefit should always be considered.

Degree Type
Thesis

Degree Name
Master of Science in Vision Science

Committee Chair
Pat Caroline, FAAO

Second Advisor
Matthew Lampa, OD, FAAO

Third Advisor
John Hayes, PhD

Keywords
scleral lenses, corneal edema, corneal hypoxia, contact lenses, hard lenses, pachymetry

This thesis is available at CommonKnowledge: https://commons.pacificu.edu/opt/20
PACIFIC UNIVERSITY OREGON
COLLEGE OF OPTOMETRY VISION SCIENCE GRADUATE COMMITTEE

This thesis of Paul Nefedov, titled “Do Scleral Lenses Provide Adequate Oxygen Permeability for Overnight Lens Wear?” is approved for acceptance in partial fulfillment of the requirements of the degree of Master of Science.

Accepted Date

Signatures:

Thesis Advisor: Pat Caroline, FAAO.
Pacific University College of Optometry

Thesis Co-Advisor: Dr. Matthew Lampa, O.D., FAAO.
Pacific University College of Optometry

Thesis Committee: Dr. John Hayes, PhD.
Pacific University College of Optometry
ABSTRACT

Do Scleral Lenses Provide Adequate Oxygen Permeability for Overnight Lens Wear?

by

Paul Nefedov

Master of Science in Vision Science
College of Optometry
Pacific University Oregon, 2016

Purpose: The purpose of this study was to evaluate corneal hypoxic edema after overnight (closed eye) wear of scleral lenses. Hypoxia of the cornea leads to accumulation of lactic acid in the corneal stroma, and subsequent corneal edema.

Methods: Eleven healthy subjects were selected and pre-screened for any ocular pathology or ocular surface/corneal abnormalities. The study was performed in two phases: on the first night subjects slept without contact lenses on. Corneal thickness was measured immediately before sleep, and then again immediately upon awakening to establish baseline nocturnal swelling. During the second night subjects had a scleral contact lens (Boson XO2 material with Dk 141) on the right eye. Both corneas were evaluated again immediately upon wakening. Corneal pachymetry was measured with Zeiss Visante OCT and a sonographic pachymeter.

Results: The average amount of overnight corneal swelling in the right eyes following the overnight wear of a scleral lens was 8.54% when measurement variability was considered, and an average physiological swelling was 2.5% using anterior segment OCT measurement. All subjects reported some degree of visual haze in the scleral lens-wearing eye upon awakening and average visual acuity loss was 1 line of Snellen chart that lasted up to 2 hours.

Conclusion: The results of this study appear to indicate that therapeutic, overnight wear of scleral lenses needs to be approached with caution. This study highlights the need for higher Dk lens materials (for overnight lens wear) and/or lens solutions that contain oxygen soluble particles (i.e. fluorocarbons) that can provide additional oxygen to the ocular surface in the closed eye environment. In patients requiring the therapeutic, overnight use of scleral lenses a risk to benefit should always be considered.
ACKNOWLEDGEMENT

First of all, I would like to thank my thesis advisor, Pat Caroline, associate professor at Pacific University College of Optometry for his great help and guidance in this project. He consistently allowed this project be my own work but at the same time guided me in the right direction whenever I needed it. His passion for contact lenses inspired me to pursue this topic and, hopefully, conduct more studies in the field of contact lenses in my future.

Also, I would like to thank my thesis committee – Matthew Lampa, O.D., and John Hayes, PhD, for their support and great ideas on how to organize and make this project more sophisticated. Special thanks also go to my dear friend and great doctor Sheila Morrison who supported me throughout my project and was a huge help with data collection.

This study would not have happened without great support and care from our contact lens faculty of Pacific University College of Optometry!
## TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>SECTION</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSTRACT</td>
<td>IV</td>
</tr>
<tr>
<td>ACKNOWLEDGMENTS</td>
<td>V</td>
</tr>
<tr>
<td>LIST OF FIGURES</td>
<td>VII</td>
</tr>
<tr>
<td>LIST OF TABLES</td>
<td>VIII</td>
</tr>
<tr>
<td>INTRODUCTION</td>
<td>1</td>
</tr>
<tr>
<td>METHODS</td>
<td>4</td>
</tr>
<tr>
<td>RESULTS</td>
<td>6</td>
</tr>
<tr>
<td>DISCUSSION</td>
<td>22</td>
</tr>
<tr>
<td>CONCLUSION</td>
<td>24</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>25</td>
</tr>
</tbody>
</table>
**LIST OF FIGURES**

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Difference between pachymetry readings OU measured by ultrasonic and OCT in the morning</td>
<td>7</td>
</tr>
<tr>
<td>2</td>
<td>Ultrasonic and OCT measurement difference between R/L eyes taken in the evening as baseline measurement.</td>
<td>9</td>
</tr>
<tr>
<td>3</td>
<td>Ultrasonic and OCT measurement difference between R/L eye taken in the morning after scleral lens wearing in the right eye.</td>
<td>11</td>
</tr>
<tr>
<td>4</td>
<td>Correlation between ultrasonic pachymetry measurement and apical clearance (initial fitting sagittal depth of scleral contact lens)</td>
<td>18</td>
</tr>
<tr>
<td>5</td>
<td>Correlation between OCT pachymetry measurement and apical clearance (initial fitting sagittal depth of scleral contact lens)</td>
<td>19</td>
</tr>
</tbody>
</table>
LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1</td>
<td>Variability analysis of ultrasonic pachymetry method</td>
<td>13</td>
</tr>
<tr>
<td>Table 2</td>
<td>Amount of average physiological swelling measured by Ultrasonic and OCT method when adjusted for baseline</td>
<td>15</td>
</tr>
<tr>
<td>Table 3</td>
<td>Corneal swelling in the right eye measured by OCT after scleral lens wear compared to the left eye (eye without the lens).</td>
<td>15</td>
</tr>
<tr>
<td>Table 4</td>
<td>Corneal swelling in the right eye measured by ultrasonic method after scleral lens wear compared to the left eye (eye without the lens)</td>
<td>16</td>
</tr>
<tr>
<td>Table 5</td>
<td>Mean visual acuity (in logMAR units) in the morning after scleral lens wear</td>
<td>21</td>
</tr>
<tr>
<td>Table 6</td>
<td>Pairwise comparison: Mean visual acuity loss compared to baseline in logMAR units</td>
<td>21</td>
</tr>
</tbody>
</table>
INTRODUCTION

Within the last decade the contact lens world was re-introduced to scleral contact lens modality that has not been employed for many years. Newest technologies in gas permeable plastic contact lens material allowed to re-visit the idea of having a contact lens that would rest on the sclera rather than on the cornea. This idea of a lens that has no contact point on the cornea is very beneficial and, at times, crucial to many patients suffering from variety of corneal abnormalities.

Scleral lenses have wide variety of visual and comfort benefits to the patient. First of all, scleral lenses improve quality of vision in patients with irregular corneas. Cornea with its tear film plays a major role in refraction of incoming light [2]. In order to achieve great vision with minimal amount of optical aberrations cornea has to maintain proper shape – right amount of curvature, asphericity, and smooth surface with stable tear film. Many ocular conditions result in corneal warpage, irregularity of the surface, and corneal thinning. Most common examples of that would be disorders involving corneal ectasia such as keratoconus, pellucid marginal degeneration, and keratoglobus. Patients suffering from such conditions experience tremendous amounts of high and low optical aberrations that may not be easily corrected with the glasses of classic design contact lenses [6]. In fact, any corneal contact lens may exacerbate the condition by putting extra mechanical stress on the affected cornea and cause corneal scarring and progressive thinning. Benefit of scleral lens design is that scleral lenses do not rest on the corneal surface, they completely vault the cornea eliminating low and some of the higher order aberrations.

Secondly, scleral contact lenses are very promising in therapeutic uses for anterior surface eye diseases and degenerations [4], [11]. Vaulting the entire cornea eliminates mechanical stress on the corneal surface that is being exerted by the eyelids. Many ocular surface conditions have chronic nature simply due to constant interaction between the eyelid and the cornea. Example of that would be epithelium basement membrane dystrophy. Normally, corneal epithelium is being attached to the Bowman’s layer and anterior stroma by hemi-desmosomes that run through the epithelial basement membrane. In case of EBMD (senile, acquired, or inherited) corneal epithelium loses its attachments due to thickened/irregular basement membrane. When that happens, upper eyelid disturbs and displaces weakly attached epithelium causing great deal of pain and discomfort, as well as blurry and unstable vision. Scleral lenses prevent that from happening. They vault the cornea allowing more time for epithelium to get re-attached to its underlying Bowman’s and stroma [4].

Not only scleral lenses prevent eyelids from rubbing against the corneal surface, they also create a moisture chamber in which re-epithelization happens way smoother. Chronic dry eye syndrome is a great example of the condition when lack of stable tear film results in epithelial defects [4]. These defects lead to fluctuation in visual acuity, burning and itching sensation, and excessive
watering. Scleral lenses could be successfully used on patients suffering from dry eye syndrome to help with the symptoms and promote healing of the corneal symptoms.

As scleral lenses are currently being employed to help with above mentioned conditions during the day time, it is sometimes needed to protect the corneal surface during the sleep hours also. Patients who have severe cases of dry eyes may not have enough moisture on the ocular surface during the night which will lead to epithelial defects in the morning and persistent symptoms throughout the day. Also, patients with nocturnal lagophthalmos expose their corneal surface to the air would benefit greatly with an overnight wear of scleral lenses [15]. Patients with Steven’s Johnsons Syndrome and Ocular cicatricial pemphigoid have pathological changes on the ocular surface and pseudomembrane formation that happen during the night time that could be prevented with an overnight wear of scleral contact lenses.

Ocular diseases aside, overnight use of scleral lenses could be employed for an ortho-K purposes. Given a great stability of these lenses on patient’s eye it is possible to create good ortho-K designs that will flatten the corneas of myopic patients in the very precise optical zone creating optimal change in refractive error.

Although overnight wear of scleral lenses has a great deal of applications that may be quite useful in therapeutic and refractive treatments, it has to be approached with caution because of its negative side effects, main of which is a corneal hypoxia and consequent edema.

In the open eye corneal cells receive most of its oxygen from the tear film that contains atmosphere oxygen dissolved in it [8]. Oxygen molecules penetrate corneal epithelium, stroma, and reach all the way to the endothelium cell layer. Atmosphere oxygen enters electron transport chain in glycolysis of all corneal cell layers.

In the closed eye condition, partial pressure of atmospheric oxygen drops significantly which becomes insufficient for corneal tissues. Now, corneal epithelium and anterior stroma receives oxygen from the vasculature of upper palpebral conjunctiva that is in direct contact with the tear film when the eye is closed. Some oxygen comes from perilimbal blood vessels to provide for peripheral cornea and endothelium receives its oxygen from the aqueous humor. This system allows aerobic respiration to continue but at the much smaller ratio compare to anaerobic. By-product of anaerobic respiration is lactic acid that slowly starts to build up in the corneal stroma as glycolysis ratio shifts towards anaerobic respiration. Lactic acid is very hydrophilic draws water into the tissue. That results in stromal edema [3], [5].

As water content of the stroma increases, distance between stromal fibers increase, and some light waves create constructive interference resulting in overall haze of the stroma and light scatter. Small amounts of corneal edema during the sleep happens every night and it is called
physiological swelling which is completely normal and does not exceed 3-5% [14]. This type of edema resolves almost instantly as the eye gets exposed to the atmosphere oxygen when the eyelids open. Healthy endothelium as well as epithelium get rid of the extra water from the stroma and cornea returns to its normal thickness.

When scleral lens is put on the eye it creates a barrier between palpebral conjunctiva and cornea. When the eye is closed, amount of available oxygen is already decreased, but contact lens makes it even harder for the oxygen to get to the epithelium [13]. Even though some scleral lenses may have very high oxygen transmissibility (Dk of 140), they still create very significant barrier for the oxygen. Besides that fact that in the closed eye oxygen has to travel through the scleral lens, it is also has to pass through a tear chamber under the lens that could be 200-400 microns thick. As a consequence cornea becomes significantly deprived of oxygen and anaerobic shift in glycolysis takes place. Greater amounts of lactic acid build up leads to greater water retention and subjectively noticeable corneal edema [8].

Purpose of the study:

Overnight use of scleral contact lenses has many great applications but enough studies has to be done to define the risks and consequences. It is necessary to know how much stroma expends and how much it influences subject’s visual acuity. This study was conducted to determine amount of corneal change due to hypoxic environment after 8 hours of sleeping in scleral lenses. Results of this study will help to understand better how to weigh risks and benefits of overnight scleral lens wear and which factors contribute the most to the corneal changes.
METHODS

Presented study received an approval from Institutional Review Boards, it met all their criteria and was designed according to their rules and regulations for safety of the participating subjects. Eleven subjects were recruited from Pacific University College of Optometry to participate in this study with average age of 26.27 years old, 7 females and 4 males. Age of all subjects ranged from 25 to 29 years old. Subjects were pre-screen for any ocular pathology and amblyopia. Exclusion criteria for the study was any ocular pathology including degenerations, infections, history of ocular surgeries including refractive surgeries, benign findings such as pingueculas, and any other ocular conditions that would affect scleral lens fitting. Acceptable best corrected visual acuity was 0.00 logMAR units or better (20/20 Snellen equivalent or better).

Eleven subjects (22 eyes that have been tested) was more than sufficient to detect a one standard deviation difference between eyes with an r=0.7 correlation between eyes with a power of .90 and an alpha = 0.05.

Instruments and materials employed in the study:

Visual acuity: electronic Clear Chart with logMAR units

Contact lenses and ocular health evaluation: Reichert slit lamp

Contact lenses sagittal depth and OCT pachymetry: anterior segment OCT Visante by Karl Zeiss

Sonographic corneal pachymetry: Tomey SP 100 ultrasonic pachymeter.

Scleral lens material used in the study: Boston XO₂ material with Dk 141 with the diameter of 16.5 mm.

Contact lenses fitting process:

A single examiner fit the lenses for all subjects. An individual lens design was determined by an on-eye evaluation of diagnostic scleral lenses with known parameters. Anterior segment OCT image was taken and based on the height from corneal surface to the 15 mm chord initial trial lens with given sag depth was selected. Corneal clearance was evaluated by anterior segment OCT to establish the optimal sagittal height of each lens which varied from 180 to 713 microns. Secondary and peripheral zones of individual lenses were determined by observing the vascular compression patterns of the bulbar conjunctiva to prevent any ischemia to the anterior surface of the eye.

Subjects spent two consecutive nights at the school with the eyes being closed during the night time for at least 8 hours. Subjects’ sleeping area was set up prior to experiment. As soon as all
measurements were taken in the evening subjects were instructed to close their eyes and educated to keep their eyes closed throughout the whole night. Subjects were told not to open their eyes in the morning as they wake up until all the instruments are ready to take the measurements. One researcher stayed with the subjects both nights of the experiment to ensure that subjects are compliant with the rules of the experiment. First night was used to collect baseline data in regards to physiological corneal changes. First night experiment: all subjects’ eyes were dropped with one drop of Fluorox (Benoxinate/fluorescein ophthalmic) to evaluate corneal surface for any defects with the slit lamp (using cobalt filter) and to anesthetize the eyes for sonographic pachymeter use. Pachymetry of both eyes was measured using two different instruments. First it was measured with anterior segment OCT Visante by Zeiss and then corneal pachymetry was measured with Tomey SP 100 ultrasonic pachymeter. After all measurements were taken subjects were instructed to close their eyes, they went to sleep and it was ensured that the eyes remained closed throughout 8 hours. In the morning, subjects’ eyes stayed closed until they were told to open them. Once everything was set up, subjects were dropped with 1 drop of Fluorox in each eye again and a quick corneal evaluation was done with the slit lamp to check for any epithelial defects present. Pachymetry map utilizing anterior segment OCT was performed immediately after the slit lamp examination and then corneal central thickness was measured again with ultrasonic pachymeter. All pachymetric measurements were performed in the right eye first with both methods OCT and ultrasonic.

Second night experiment: upon arrival to school building best corrected visual acuities were measured by using electronic standard logMAR chart (Clear Chart). All subjects were examined with the slit lamp at this point to ensure that there are no corneal epithelial defects are present (1 drop of Fluorox ophthalmic solution was instilled in each eye). Due to a temporary OCT Visante software problem corneal pachymetries were measured only with ultrasonic pachymeter. Scleral lens was applied on the right eye and apical clearance was determined by anterior OCT (cross section picture is taken and OCT software caliper is used to measure the thickness of tear lens in microns). After that subjects went to sleep and it was ensured that no one opens their eyes for the next 8 hours. In the morning, immediately after opening the eyes scleral lenses were removed, 1 drop of Fluorox was instilled in each eye to check epithelial defects using the slit lamp, and then central corneal thickness was measured with OCT and ultrasonic pachymeters. Once again, right eye was always measured first. Next, BCVA was measured (subjects had their glasses on for this measurement). All subjects were warned to return to clinic if any visual discomfort or haziness persisted for longer than 2 hours. By the end of 2 hours there were no visual concerns or symptoms present in any of the subjects.

Corneal thickness was measured in microns and visual acuity was measured in logMAR units. Data analysis was done using SPSS computer program.
RESULTS

Since corneal pachymetry was measured employing two different methods it was worth noting the difference between Sonographic instrument (Tomey SP 100 ultrasonic pachymeter) and anterior segment OCT pachymetry software. Using the average readings for OCT and ultrasonic pachymeters in the first baseline measurements in the evening of the first day and then comparing that to the readings obtained in the next morning Bland-Altman plot was constructed to indicate the difference between those two methods. As Figure 1 shows, difference between those two methods is quite significant and increases as corneal swelling increases. These comparisons are made on the average readings between both eyes.
Figure 1: Difference between pachymetry readings OU measured by ultrasonic and OCT in the morning
If the right and the left eyes are analyzed separately (since the contact lens was applied on the right eye only therefore that eye underwent greater swelling) then the difference between two pachymetry methods becomes even more evident. Figure 2 shows the difference between two eyes and two methods in the first evening baseline measurement.
Figure 2: Ultrasonic and OCT measurement difference between R/L eyes taken in the evening as baseline measurement.
Whereas figure 3 represents the difference between both eyes and two different methods in the morning after wearing scleral contact lens on the right eye for eight hours with the eye closed.
Figure 3: Ultrasonic and OCT measurement difference between R/L eye taken in the morning after scleral lens wearing in the right eye.
It was determined that the greater the corneal thickness the greater the difference and variability between OCT and Ultrasonic methods of pachymetry. After performing the one-way ANOVA test results show that variability of Tomey 100 SP instrument is almost five times greater than anterior segment OCT (table 1)
<table>
<thead>
<tr>
<th></th>
<th>Estimates of variance</th>
<th>t-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasonic pachymetry</td>
<td>521.509091</td>
<td>22.83657</td>
</tr>
<tr>
<td>OCT</td>
<td>105.009091</td>
<td>10.24739</td>
</tr>
</tbody>
</table>

**Table 1:** Variability analysis of ultrasonic and OCT pachymetry methods
Main outcome variable of this study was amount of corneal swelling measured in microns and percentage of swelling was calculated. During the first night subjects were not wearing any contact lenses on their eyes. Corneal thickness was measured in the evening before bed and in the morning immediately upon awakening. This measurement showed normal physiological corneal swelling. Ultrasonic method of corneal pachymetry showed 3.96% swelling on average for right and left eyes (OD 4.40% and OS 3.52%). Anterior OCT method showed 2.43% of physiological swelling (OD 2.62% and OS 2.24%).

During the second night all participants were wearing scleral contact lens on the right eye for 8 hours with the eye completely closed. Same set of measurements were taken in the morning using both pachymetry methods. Ultrasonic pachymeter measurements showed 9.96% swelling on average for both eyes (OD 15.37% and OS 4.56%) and anterior OCT showed average of 6.27% swelling for both eyes (OD 10.60% and OS 1.95%). Sonographic percent swelling ranges for right eye in the morning were from 9.35% to 26.34%, whereas OCT percent swelling ranged from 7.24% to 14.13%.

Simple comparison of initial and final corneal thickness does not take into consideration the variability of the instrument readings. As shown above, OCT and ultrasonic pachymeters have certain degree of variability when it comes to the measurements of corneal thicknesses and this variability greatly increases as corneal thickness increases.

When percent of corneal swelling was adjusted for the baseline (compared to the left eye that was not wearing any lens), following results are obtained: physiological swelling of the corneas during the first night using ultrasound pachymeter was 4.01%; using anterior OCT was 2.50%. Corneal swelling as a result of the contact lens wear during the night time – ultrasonic method showed 10.17% swelling and anterior OCT showed 8.54% swelling (tables 2, 3, and 5).
Paired Samples Statistics

<table>
<thead>
<tr>
<th>Day</th>
<th>Pair</th>
<th>Method (Baseline PM)</th>
<th>Mean</th>
<th>N</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>Mean</th>
<th>Std. Error Mean</th>
<th>Relative phys swelling</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pair 1</td>
<td>Pachy sono</td>
<td>540.636</td>
<td>22</td>
<td>48.316</td>
<td>10.301</td>
<td>1.040105</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(No lens AM)</td>
<td>562.318</td>
<td>22</td>
<td>53.6997</td>
<td>11.4488</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pair 2</td>
<td>Pachy OCT</td>
<td>530.364</td>
<td>22</td>
<td>42.1771</td>
<td>8.9922</td>
<td>1.025024</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Baseline PM)</td>
<td>543.636</td>
<td>22</td>
<td>48.7994</td>
<td>10.4041</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 2:** Amount of average physiological swelling measured by Ultrasonic and OCT method when adjusted for baseline

<table>
<thead>
<tr>
<th>eye</th>
<th>Mean</th>
<th>Std. Error</th>
<th>df</th>
<th>95% Confidence Interval</th>
<th>Relative percent swelling</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>OD - Contact</td>
<td>587.058</td>
<td>2.855</td>
<td>18.909</td>
<td>581.081</td>
<td>593.034</td>
</tr>
<tr>
<td>OS - No Contact</td>
<td>540.852</td>
<td>2.855</td>
<td>18.909</td>
<td>534.875</td>
<td>546.828</td>
</tr>
</tbody>
</table>

**Effect size: 16.1642**

a Dependent Variable: Pachy OCT (Lens OD AM).

b Covariates appearing in the model are evaluated at the following values: Pachy OCT (Baseline PM) = 530.36 microns

**Table 3:** Corneal swelling in the right eye measured by OCT after scleral lens wear compared to the left eye (eye without the lens).
<table>
<thead>
<tr>
<th>eye</th>
<th>Mean</th>
<th>Std. Error</th>
<th>df</th>
<th>95% Confidence Interval</th>
<th>Relative percent swelling</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lower Bound</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Upper Bound</td>
<td></td>
</tr>
<tr>
<td>OD - Contact</td>
<td>627.27</td>
<td>6.998</td>
<td>18.839</td>
<td>612.614</td>
<td>641.926</td>
</tr>
<tr>
<td>OS - No Contact</td>
<td>569.366</td>
<td>6.998</td>
<td>18.839</td>
<td>554.711</td>
<td>584.022</td>
</tr>
</tbody>
</table>

**Effect size: 8.2744**

a Dependent Variable: Pachy sono (Lens OD AM).

b Covariates appearing in the model are evaluated at the following values: Pachy sono (Baseline PM) = 540.64 microns

**Table 4:** Corneal swelling in the right eye measured by ultrasonic method after scleral lens wear compared to the left eye (eye without the lens)
Another question needs to be answered is whether initial scleral contact lens sagittal depth correlates with amount of corneal swelling. Saline solution and tear layer between the corneal surface and back surface of the contact lens slows down the oxygen transfer to the cornea. Not only lens itself but also the tear lens vaulted by the scleral lens acts as a barrier to the oxygen from palpebral conjunctiva of the upper lid to the cornea.

Coefficient of determination (r squared) between corneal swelling measured by ultrasonic pachymeter and sagittal depth of the contact lens is relatively low (0.1595). Coefficient of determination (r squared) between corneal swelling measured with anterior segment OCT and sagittal depth is fairly high (0.4161) which makes the correlation to be 0.6451. Figure 4 and 5
Figure 4: Correlation between ultrasonic pachymetry measurement and apical clearance (initial fitting sagittal depth of scleral contact lens)
Figure 5: Correlation between OCT pachymetry measurement and apical clearance (initial fitting sagittal depth of scleral contact lens)

\[ y = 0.0556x + 30.913 \]

\[ R^2 = 0.4161 \]
In terms of visual acuity, right eye (eye that had contact lens on) experienced some loss of visual resolution. On average visual acuity loss was 4.65 letters (approximately 1 line of acuity chart). Average visual acuity at baseline was -0.058 LogMAR which corresponds to 20/15-2 of Snellen notation. Average visual acuity of the right eye after having a scleral lens over night was 0.035 LogMAR which corresponds to 20/25+2 of Snellen notation (table 6 and 7)
<table>
<thead>
<tr>
<th>eye</th>
<th>Mean</th>
<th>Std. Error</th>
<th>df</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD - Contact</td>
<td>-.035b</td>
<td>0.030</td>
<td>18.187</td>
</tr>
<tr>
<td>OS - No Contact</td>
<td>.058b</td>
<td>0.030</td>
<td>18.187</td>
</tr>
</tbody>
</table>

Based on estimated marginal means. *. The mean difference is significant at the .05 level.

a. Dependent Variable: Acuity (Snellen) AM after wearing lens.
b. Covariates appearing in the model are evaluated at the following values: Baseline VA/logMAR = .0909.

d. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).

Table 5: Mean visual acuity (in logMAR units) in the morning after scleral lens wear

<table>
<thead>
<tr>
<th>(l) eye</th>
<th>Mean Difference (I-J)</th>
<th>Std. Error</th>
<th>df</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD - Contact</td>
<td>OS - No Contact</td>
<td>-.093*</td>
<td>0.039</td>
<td>10</td>
</tr>
</tbody>
</table>

Table 6: Pairwise comparison: Mean visual acuity loss compared to baseline in logMAR units
DISCUSSION

Main purpose of this experiment was to determine the changes that the cornea undergoes in terms of hypoxic swelling while wearing the scleral contact lens for at least 8 hours with the eye closed. Also, another goal was to determine whether initial sagittal depth of the scleral contact lens plays a big role in amount of corneal swelling.

As results of the study suggest, cornea does undergo significant hypoxic stress which leads to swelling, increasing in corneal water content, and causing notable temporary visual acuity loss. On average, visual acuity loss was noted in the eye wearing the lens in amount of approximately 1 line of Snellen acuity chart. This acuity loss was temporary and resolved within 1 hour after removal of scleral contact lens. Some subjects also noted transient light sensitivity that got resolved within first hour without the contact lens.

For normal healthy individuals such corneal swelling of 8.54% measured with OCT may not be a great concern since corneas return to its normal thickness within couple of hours. On the other hand, patients suffering from corneal diseases and degenerations, or other inflammatory conditions may not recover from hypoxic swelling so rapidly and may suffer significantly greater visual acuity loss that will last longer. In addition, due to ocular surface problems it is possible they will produce greater corneal edema over night with the contact lenses on.

In terms of pachymetry measurement methods, anterior segment OCT proved to be five times more consistent from one measurement to the other in comparison to the ultrasonic Tomey SP 100 model. Sonographic pachymeters are very sensitive where the probe is placed on the cornea. Since experimenter approximates the location of the corneal center – results vary significantly. Given the fact that corneal thickness varies depending on the location (center is the thinnest and periphery is the thickest) [8], it is very difficult to keep measurements consistent. Therefore, for further investigations involving corneal pachymetry anterior segment OCT should be employed. In addition, ultrasonic pachymeters require instillation of topical anesthetic drops that potentially may weaken corneal epithelium and introduce inaccuracy in readings [8].

This study was a good start to determine the changes that corneas go through in regards to hypoxic swelling over one night of scleral lens wear. There are many other questions that need to be answered though.

First of all, one of the flaws of the study was lack of randomization of the eyes. In this study only the right eyes were wearing scleral lenses. There could be a greater variability in the results if eyes would be selected randomly for contact lens wear. In addition, great bias was introduced into the study since the right eye was always measured first. The moment participating individuals were opening their eyes to get measured their corneas were exposed to the oxygen in the air leading to a
reverse of corneal hypoxia. It was a time sensitive process. Since right eye was always measured first, left eye had greater chance to reveal less swelling. To improve the quality of the experiment, eyes should have been measured in randomized sequence.

There was appropriate number of participants to evaluate amount of corneal swelling but not quite enough to determine the correlation between initial sagittal depth of the contact and amount of corneal swelling. Question still remains whether it is safer to fit smaller vault scleral contacts to reduce amount of swelling. Another factor that could also correlate with amount of swelling is central thickness of the contact lenses that also was not measured and not taken into account in this study.

Also, this study needed to include a survey that participants would fill out in the morning after removal of the contact lens. This survey would include questions regarding visual comfort, pain, irritation, sensitivity to light, presence/absence of haloes around the lights, and any other subjective comments.

Finally, this study did not measure the pace at which corneal thickness returned to its original measurement. After initial measurement in the morning, it would be good to know how fast corneas dehydrate. It would take another set of measurements every 30 min, for example, until corneal thickness returns back to its original value.

For the next step in the study of hypoxic corneal swelling it would be necessary to determine the correlation between the number of endothelial cells and amount of corneal swelling. Endothelial cells play a very crucial role in regulating corneal thickness by using their ionic water pumps. Healthy endothelial layer ensures proper regulation of water content in the corneal stroma.

Finally, since the optics of scleral lenses are not the most important factor in therapeutic use it is needed to be studied whether creating fenestrations in the scleral lenses will allow more oxygen to permeate into the corneal layers and prevent development of acute hypoxia to corneal tissues. If scleral lenses physical modifications will not prove its effectivity there is an idea of using higher oxygen content solutions that may be used with scleral lenses instead of sterile saline solution.
CONCLUSION

This study in fact confirmed that overnight wear of scleral lenses creates hypoxic environment for the corneal layers and leads to stromal swelling. Amount of swelling exceeds physiological nocturnal corneal expansion almost two folds. This means that usage of scleral lenses overnight should be limited and approached with great caution. While young and healthy corneas may recover quite rapidly during the following day in the open eye condition, compromised corneas may take longer to restore stromal pH balance and return to original thickness. Further studies are needed to determine the main factors of scleral lens fitting that influence amount of swelling such as sagittal depth (thickness of tear reservoir), dK of contact lens material, central thickness, and usage of different saline solutions for contact lens application. Also, further studies are necessary to evaluate long term effect of overnight scleral lens wear on the corneal physiology. It needs to be studied whether corneas may respond with certain adaptations to regular nocturnal hypoxic conditions caused by scleral lenses.

As of right now, based on all current research about scleral lens wear and corneal swelling, usage of overnight scleral lenses should be approached with the great caution. Individuals wearing scleral lenses overnight should be watched closely by eye care professional to monitor for corneal changes on the daily basis.
REFERENCES
