EFFECTS OF SCLERAL LANDING ZONE ON TEAR EXCHANGE

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Abstract page

Introduction: Scleral lenses are a form of contact the rests on the sclera of the eye completely vaulting the cornea. This form of correction is ideal for patients with severe ocular surface disease or irregular corneas because once inserted into the eye it becomes the new functional surface of the eye negating or significantly mitigating any anomalies behind that impact vision. This is achieved by the formation of a tear reservoir between the back surface of the contact lens and the front surface of the cornea. While the fitting of scleral lenses is a fantastic option to improve vision for patients with irregular corneas and ocular surface disease many will experience a phenomenon called tear exchange. Tear exchange is a process by which tears from outside the reservoir move under the lens bringing in debris which can reduce quality of vision by producing a "fog" over the patient's vision.

Methods: In this study we compared the Valley Custom Stable Elite scleral lens to an experimental Valley design called the Limbal Lite. The Limbal Lite features and enlarged scleral landing zone making a larger footprint in contact with the patient's sclera. It is this larger footprint we hypothesize that will reduce the amount of tear exchange under the lens improving quality of vision. To test this both lens designs were fitted to participants using anterior segment OCT and slit lamp observation. The lenses were then allowed to settle for one hour. After settling time the lenses were again observed behind a slit land and anterior segment OCT to evaluate tear exchange.

Conclusion: No conclusive data can be from this studying due to the limited sample size. The Limbal Lite lens did appear to be more effective at controlling for tear exchange when compared to the Custom Stable Elite but subjectively the patients felt the Custom Stable Elite was more comfortable.

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INTRODUCTION OF SCLERAL LENSES

A scleral contact lens is a category of lens that is supported completely by the sclera of the patient, vaulting the cornea entirely. This type of lens have been life-changing for those patients whose irregular corneas are not conducive to other lens types due to centration or comfort..[1] Scleral lenses host several advantages over their corneal counterparts, the primary being comfort.[1,2] This may seem counterintuitive due to their large size, 14mm to greater than 20mm in diameter.[1,2] However, this large size "minimizes movement and decreases lid interaction" in turn increasing patient comfort.[1] Another advantage of scleral lenses is that the need to achieve a closely aligned fit with the cornea is unnecessary due to the sclera bearing the weight of the lens, which increases the probability of achieving a good visual acuity in those patients with an irregular cornea.[1] Disadvantages of the scleral design include irritation to the patient secondary to the bulk of the lens, discouragement to trying the design due to its intimidating size, and difficulty in removal of the lens due to suction created by the lens-sclera interface.[1] Indications for fitting scleral lenses include any condition resulting in an irregular corneal surface such as keratoconus, pellucid marginal degeneration, and post operative penetrating keratoplasty. Because these lenses continuously bath the patient's cornea in a reservoir of tears patients suffering from severe ocular surface diseases such as dry eye, Sjogren's syndrome, or Stevens Johnson syndrome may also be of benefit.[2]

Scleral contact lenses constructed of PMMA were some of the first contact lenses to be introduced.[1] These early sclerals, however, presented a host of disadvantages. While PMMA is a robust and durable material its Dk of zero will result in corneal endothelial problems with chronic use of the lens. These early lenses were also fitted to patients by first creating a negative of their ocular surface using a dental mold and then molding a PMMA positive and carving in the back-surface curvatures.[1] This meant that only highly skilled practitioners were able to fit this lens modality resulting in few locations in the United States where they could actually be fit and at large expense of time and money.[1] Modern scleral lenses are composed of high-Dk materials that are not thermoplastic and therefore cannot be molded to the eye like PMMA materials.[1] Today's lenses are lathed into standard designs from high-Dk buttons and packaged as fitting sets which greatly increase the ease with which they can be fitted and ordered by practitioners.

Due to a current lack of research on the risk of various complications secondary to the use of scleral lenses they are typically not considered for first-line treatment of refractive error, corneal irregularities, or ocular surface disease.[1] The first step in fitting a scleral lens in selecting the appropriate patient. Factors to consider when selecting a patient for fitting include: "severity of the ocular condition, outcomes of previously attempted interventions, and event the patient's general mental and physical condition."[1] Practitioner should discuss what patients should expect from their scleral lenses to prevent any misunderstanding or disappointment. For example, patients with severe ocular surface disease will likely utilize sclerals as an additive therapy and not a cure-all, use of topical therapeutics may be reduced but will likely still be necessary.[1] Also optimal vision may not be achievable at all distances for the patient without the use of spectacles or not at all if the condition the lenses are being prescribed for is advanced enough or there exists a secondary condition reducing visual acuity.[1] The condition for which the lenses will be prescribed must then be fully understood when a thorough case history, try to elucidate previous therapies tried by the patient and their goals of scleral lens therapy as well as any history of other ocular conditions that may limit their best corrected visual acuity.[1] The next step in the fitting process is the ocular evaluation. Initially, consider patient factors like deeply inset eyes, which may make the insertion and removal of these lenses difficult, whereas more proptotic eyes may require a larger diameter lens to increase stability on eye.[1] Patients with taut lids may see a greater degree of settling on the eye creating the need for a lens with a higher vault to prevent any contact with the surface of the cornea.[1] Conditions such as meibomian gland dysfunction should be treated and controlled prior to the beginning of lens wear.[1]

Keratometry provides limited value when fitting a scleral lens due to the small area of the cornea being measured.[1] Also, while manufacturers of lenses refer to corneal topographic readings in their fitting guides for initial lens selection the predictive value of the performance on the eye is limited by the fact that a proper fitting lens will vault the entirety of the cornea and the conditions that necessitate a scleral lens may make accurate measurement of the corneal surface difficult.[1] Anterior segment OCT can be useful in the selection of a lens because it gives the practitioner the ability to precisely measure the anterior structures of the eye to find a starting sagittal depth for the trial lens. Should an anterior segment OCT not be available manufacturers guidelines based on patient keratometry or topography should be followed.[1] Once the desired lens is selected the reservoir should be filled with a sterile saline solution and dyed with sodium fluorescein strip if desired to better assess the relationship of the lens and cornea. Upon insertion the lens should be checked for the presence of large stationary air bubbles in the visual axis and if noted the lens removed and reinserted with fresh saline and sodium fluorescein.[1]

Once appropriate insertion is achieved the relation the fit of the lens can be observed through slit lamp examination. Though the lens is expected to settle with wear a too-shallow lens can immediately be observed and should this be the case the base curve of the lens should be steepened or the sagittal depth increased by increased lens diameter.[1] Vault of the cornea can be measured either by turning the slit lamp beam to a 45 degree angle and comparing the thickness of the reservoir to the known thickness of the lens or by anterior segment OCT scans with the lens on eye, an initial vault of 250 to 500 microns is generally considered acceptable.[1] When the desired central vault is achieved limbal clearance is then measured. To avoid damaging the limbal cells the lens should come into contact with conjunctival tissue 0.5 to 1 mm beyond the limbus, should this not be achieved initially a larger diameter lens may be needed.[1]

Once an ideal fit is identified the patient's over-refraction can be determined while the lens is allowed to settle. The refraction can be done in the phoropter and once complete the power need only be vertexed to the corneal plane and added to the power of the trial lens.[1] Final evaluation of the lens can then be completed after it has been on eye for 20-30 minutes.[1] Corneal clearance should be reassessed at this time and while a reduction in vault is expected it should be no less than 100-200 microns.[1] Edges of the lens should then be evaluated with even bearing of the lens on conjunctival tissue expected, be aware of any vessel impingement or congestion as well as conjunctival staining after lens removal as chronic impingement of the conjunctiva may lead to hypertrophy in the future.[1] Tear exchange under the lens can then be evaluated by applying sodium fluorescein to the front surface of the lens and then observing its flow through the slit lamp.[1] This tear exchange may lead to the accumulation of debris within the reservoir to the lens which will lead to a fogging of the patient's vision without a significant impact on visual acuity. Strategies to decrease this phenomenon include periodic removal and rinsing of the lens then reinsertion with fresh saline, reduction in vault of the lens thereby reducing the amount of debris to impact the quality of vision, and use of a more viscous fluid in the tear reservoir to decrease the mobility of such debris.[1] Newer strategies to reduce this occurrence include changes to the design of the lens itself, which is the focus of this study. This study aims to observe the amount of tear exchange in a novel scleral lens design that utilizes an increased footprint in the scleral landing zone to better reduce tear exchange and prevent the build up of debris within the tear reservoir and reduce fogging of patient vision.

Further complicating the fitting process of a scleral lens is the limited ability of the practitioner to accurately measure the topography of the sclera, which demonstrates and asphericity all its own. The physical characteristics that make up the corneoscleral junction lead to a less than ideal interaction with the edge of a contact lens.[3] To elucidate these values Tan et all used a commercial spectral domain OCT to capture an image of the corneoscleral junction in the nasal, temporal, superior, and inferior quadrants of their subjects. Their findings suggest that the flattest quadrant is the temporal followed by superior, inferior, and nasal quadrants.[3] Further, the mean difference between opposing corneoscleral junctions—superior-inferior and nasal-temporal—was much more pronounced in the horizontal meridian.[4] This plays an important role in the design of a scleral contact lens, for example a lens with a more spherical edge profile will likely lift more in the nasal quadrant contributing to greater tear exchange. This assessment favors a lens design, which is aspheric as well as quadrant specific.

Not only do topographic variables differ greatly within different areas of the eye these characteristics are also affected by differing populations. Hall et all studied corneoscleral profiles in the United Kingdom among Caucasians and “British Asians”, which included: Indian, Pakistani, and Bangladeshi descent, from a pediatric to geriatric age range. Significant differences were found between the Caucasian and British Asian populations such as horizontal corneal diameter, horizontal and vertical corneal sagittal height, and iris diameter.[4] However, Hall et al found that the factor that most greatly contributed to variance in corneoscleral profiles among all populations was age. Based on the principles in the studies above and many others Visser et al explored the prospects of a scleral lens that featured a bitangential design.

Bitangential is defined as a lens that is not rotationally symmetrical.[5] Visser et al found that with a bitangential design 97.7% of the eyes observed in their study showed a desirable amount of movement and positioning.

Like other contact lens modalities Scleral contact lenses present a host of complications the most concerning of which being ocular infection. The population of patients who are apt to wear scleral lenses are also likely more at risk for infection because many already have a compromised corneal surface.[6] However, the overall incidence of infection secondary to scleral lens use is low.[6] According to Walker et al this is due to several factors: the small population of patients who wear sclerals, that they are prescribed exclusively for daily wear, and that patients who are prescribed scleral lenses often exhibit more meticulous lens hygiene because of their underlying condition.

Of these complication one of the most common is midday fogging, which may lead to the accumulation of debris within the reservoir to the lens reducing visual acuity.[6] According to Walker et al this fogging effects 20-30% of wearers and can occur immediately after insertion of the lens or progress throughout the day. This fogging is more likely to be seen in those with dry eyes or inflammatory conditions.[6] While it is not yet certain where this fogging debris comes from it is know that there is a lipid component likely coming from the conjunctiva around the perilimbal area.[6] Strategies to decrease this phenomenon include periodic removal and rinsing of the lens then reinsertion with fresh saline, reduction in vault of the lens thereby reducing the amount of debris to impact the quality of vision, and use of a more viscous fluid ion containing fluid in the bowl of the lens.[1,6] Newer strategies to reduce this occurrence include changes to the design of the lens itself, which is the focus of this study. This study aims to observe the amount of tear exchange in a novel scleral lens design that utilizes an increased footprint in the scleral landing zone to better reduce tear exchange and prevent the build up of debris within the tear reservoir and reduce fogging of patient vision.

METHODS

Participants were first evaluated to ensure there ocular health is normal and healthy enough to proceed with the study. To do this, one of the principle investigators used a biomicroscope to evaluate the lids, lashes, conjunctiva, cornea, iris and anterior chamber. Once it was confirmed that these structures were healthy, the best corrected visual acuity (BCVA) was obtained. To do this, the principle investigators used a phoropter.

Once the participant was deemed healthy enough to continue with the study, an anterior segment optical coherence tomography was taken (AS-OCT). The AS-OCT scan was used to figure out the patients anterior segment depth. Once the depth was determined, three microns was added as the desired vault of the scleral lens. A traditional style toric scleral lens was selected from Valley Custom Stable Elites 15.8mm diameter lens that most closely matched the desired amount. A Valley Limbal Lite diameter 15.8 mm was also selected as the lens with the increased scleral landing zone. The Limbal Lite lens selected was most closely matched with the Custom Stable Elite lens.

After lenses were selected for the participants, the Custom Stable Elite lens was inserted into both eyes. The fit was determined by the investigators to be acceptable and an AS-OCT was taken to determine the vault of the lens. Once the fit was confirmed to be acceptable with proper vault, the participant wore the lenses for one hour to allow for settling and give tear exchange a chance to occur.

After the lenses have settled, the investigators instilled sodium fluorescein dye on top of the scleral lens. The biomicroscope was then used with the cobalt blue filter to determine if any areas of tear exchange were occuring. If tear exchange was observed, the investigators would determine which area the exchange was occuring. Another AS-OCT was then taken to determine if tear exchange could be seen in the imaging and how much the vault has changed. The lens was then removed and an ocular health exam was performed to ensure the eye health was unaffected. The investigators then checked the participant's BCVA to ensure it had not been affected. The participant then waited one hour or more with no contact lens to allow the eye to return to baseline. Baseline was determined by again checking the participant's BCVA and doing an ocular health evaluation to ensure ocular health was similar to when the study began.

After the participant had returned to baseline, the Limbal Lite was then inserted and the steps repeated. The investigators confirmed the fit to be acceptable, an AS-OCT was taken, and the participant wore the lenses for one hour. After the hour, sodium fluorescein was instilled on top of the scleral lens and the investigators looked for areas of tear exchange, an AS-OCT was taken, and lenses were removed. Investigators then performed ocular health examination and BCVA was checked.

RESULTS/CONCLUSION

(Table 1: Tear exchange of standard lens)

Custom Stable Elite	Sag	BC	Initial Vault	Vault after 1 hour	Tear exchange observed
Patient 1 OD	4.58mm	43.00D	450 um	550 um	Yes
Patient 1 OS	4.33mm	41.00D	200 um	180 um	Yes
Patient 2 OD	4.58mm	43.00D	330 um	270 um	Yes
Patient 2 OS	4.33mm	41.00D	120 um	80 um	Yes
Patient 3 OD	4.33mm	41.00D	310 um	310 um	Yes
Patient 3 OS	4.32mm	41.00D	370 um	270 um	Yes

After fitting a Custom Stable Elite lens on each patient's eyes, The initial vault was taken using the AS-OCT. All patients had an acceptable fit with at least 100 microns of clearance. The patients then wore the lens for one hour and were checked for tear exchange. All six eyes experienced some sort of tear exchange. Most common area for the tear exchange was the superior temporal quadrant, with two of the eyes experiencing tear exchange there. One patient had exchange nasally, another inferior, and the others had exchange but no specific area of exchange was observed.

(Table 2: Tear exchange of modified Limbal Lite lens)

Limbal Lite	Sag	BC	Initial Vault	Vault after 1 hour	Tear exchange observed
Patient 1 OD	4.59mm	43.00D	510 um	450 um	Yes
Patient 1 OS	4.33mm	41.00D	200 um	180 um	No
Patient 2 OD	4.59mm	43.00D	450 um	450 um	No
Patient 2 OS	4.33mm	41.00D	200 um	120 um	No
Patient 3 OD	4.33mm	41.00D	390 um	330 um	Yes
Patient 3 OS	4.33mm	41.00D	410 um	330 um	Yes

After fitting a Limbal Lite lens on each patient's eyes, The initial vault was taken using the AS-OCT. All patients had an acceptable fit with at least 100 microns of clearance. The patients then wore the lens for one hour and were checked for tear exchange. Only three eyes experienced tear exchange. Patient 2 no longer had any tear exchange. The remaining three eyes experiencing tear exchange no longer had a common area of tear exchange, each occurring in a different area.

(Table 3: Area in which tear exchange occurred)

	Tear exchange in Custom Stable Elite	Tear exchange in Limbal Lite
Patient 1 OD	Superior Temporal	Undefined area
Patient 1 OS	Undefined area	No
Patient 2 OD	Undefined area	No
Patient 2 OS	Nasal	No
Patient 3 OD	Superior Temporal	Superior Temporal
Patient 3 OS	Inferior	Undefined area

When comparing the tear exchange between the Custom Stable Elite and the Limbal Lite, the same area of exchange was only seen in one eye. Of the other five, tear exchange either no longer occurred or occurred in an undefined area.

A flaw of this study was that the rotation of the lenses were not measured. Rotation of the different lens designs should have been compared to ensure both designs were resting in similar positions. Without knowing the rotation, it is unclear whether the difference in tear exchange was caused due to a difference in the positioning of the toric curves or it was the difference in landing zone making the difference. In future studies it will be critical to pay attention to this component.

Due to the limited sample size of the study, more research is needed. Changing the size of the scleral landing zone does appear to improve tear exchange in some patients but no conclusive data can be drawn from this research.

In order to improve this study for future a few things can be done. The most obvious is to increase the size of the studying. One other way would be to increase the wear time of the lenses and check for tear exchange periodically. Multiple days of wear could also be evaluated to see if tear exchange improves or worsens as the lenses are worn more frequently.

DISCUSSION

According to the data collected the Limbal Lite scleral contact lens does appear to reduce tear exchange in compared to the Custom Stable Elite. As hypothesized the Limbal Lite, with its larger scleral landing zone footprint, reduced the number of eyes observed demonstrating tear exchange and thus fogging. An unexpected finding not the focus of this study was that the participants in the study reported that the original Custom Stable Elite lens was much more comfortable than the newer Limbal Lite designs. This may lead to patients choosing to wear a lens that may compromise quality of vision but is more comfortable for daily wear.

This is the first study of this type regarding tear exchange where the size of the scleral landing zone is the focus and due the size of the study more research is warranted. Scleral lenses are a wonderful option for patients with condition from severe ocular surface disease such as dry eye to corneal ectasias like keratoconus. However, no two patients are the same and finding what is best for the patient be it a scleral lens or another form of therapy is what is most important. The purpose of this study is to give clinicians another tool in their toolbox to better treat anterior segment conditions and better improve the already fantastic visual outcomes of scleral lens use.

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