Abstract

Purpose: To measure the effect of scleral contact lens wear on tear osmolarity. Methods: A total of 31 healthy subjects were screened for inclusion in the study. All subjects have never worn scleral contact lenses. After discontinuing current contact lens wear for one week, baseline tear osmolarity measurements were taken with the TearLab Osmolarity System (TearLab Corp., San Diego, CA). Twenty-three subjects were fit with the Valley Custom Stable (Valley Contax, Springfield, OR) mini-scleral contact lens design. Once an acceptable fit was achieved, the contact lenses were dispensed for daily wear use only. At the one month follow-up visit, tear osmolarity was remeasured under the same baseline conditions. A total of 13 subjects completed the study. Results: We analyzed the data from twenty-six eyes of 13 subjects. The mean baseline tear osmolarity value was 293.58 +/- 8.49 mOsm/L. After 1 month of scleral contact lens wear, the tear osmolarity increased to 310.65 +/- 17.46 mOsm/L, which was statistically significant (p < 0.001). Conclusions: Results were consistent with similar studies involving other contact lens modalities. A statistically significant increase in tear osmolarity was noted at the one month visit. It is hypothesized that this increase is caused by the disruption of the natural tear layer and, potentially, decreased tear production.

Introduction

Scleral contact lenses are large diameter lenses that vault over the cornea and rest completely on the sclera. While scleral contact lenses are widely used today in the management of irregular corneas resulting from conditions such as keratoconus, pellucid marginal degeneration, and complications of post-corneal transplant/refractive surgery, they have an important role in the treatment of ocular surface disease (OSD). This is due to their unique ability to provide a constant fluid reservoir adjacent to the cornea. However, not much is known about the short and long term effects of this tear reservoir on the eye. Recently, it was discovered that after long term scleral contact lens wear, subjects with distorted corneas experienced a decrease in basal tear production and increased corneal sensation, while patients with OSD showed no changes in either parameters. The chronic inflammation in eyes with OSD is believed to be the cause of this difference.

While tear osmolarity has been studied for quite some time, only recently have we been able to use the TearLab Osmolarity System to quickly measure this value in office using a nanotechnology-based diagnostic instrument. Tear osmolarity is an objective marker of OSD that has been shown to be sensitive in the diagnosis and classification of dry eye. Tear hyperosmolarity is believed to cause an inflammatory cascade in epithelial cells, including goblet cells, leading to cell apoptosis and the cycle of chronic inflammation.

Dry eyes have long been associated with contact lens wear. Many studies have been conducted in search of the relationship between contact lens wear and tear osmolarity. Iskeleli et. al compared the changes in tear film osmolarity caused by daily wear soft and rigid gas-permeable contact lenses, finding a similar increase in tear osmolarity in patients wearing both types of lenses. Studies by Sarac et. al and Iskeleli et. al again found an increase in tear osmolarity with soft contact lens wear.
wear, but did not observe a difference between the types of soft contact lenses (hilafilcon B hydrogel vs. narafilcon A silicone hydrogel and first vs. second generation silicone hydrogel, respectively).8,10 It is theorized that soft and gas-permeable contact lenses, regardless of type, cause an unstable pre-lens tear film leading to greater evaporation rates and increased tear osmolarity.8

To our knowledge, there have been no studies measuring the effect of scleral contact lens wear on tear osmolarity. Though modern materials have improved considerably by providing high oxygen permeability to the eye, the scleral lens design inherently limits the amount of tear exchange compared to other contact lens modalities.11 One theory proposes that traditional contact lens wear reduces corneal sensitivity, subsequently reducing tear production and increasing tear osmolarity.12 However, a properly fit scleral contact lens avoids this effect by vaulting the cornea entirely. It is possible that the unique fluid reservoir from scleral contact lenses alters the tear physiology in a way that there is minimal change or even a decrease in tear osmolarity. Other theories suggest that scleral contact lens wear affects the chemical, mechanical, and thermal feedback mechanisms for normal tear production.2 But based on the observations from previous studies, we postulate that scleral contact lens wear increases tear osmolarity due to the disruption of the natural tear layer and potentially decreased tear production.

Methods
We recruited 31 subjects from the Illinois Eye Institute and Illinois College of Optometry using emails, flyers, and in-class announcements. Subjects included optometry students, faculty, and employees. To be included in the study, subjects must have had an eye examination within the past 12 months, must not be symptomatic for dry eyes based on the Ocular Surface Disease Index (12 or below), and must have normal tear osmolarities in both eyes (308 or below).13,14 In addition, subjects must not be taking any topical medications (including artificial tears) or have any significant ocular disease which can contribute to dry eyes. If currently wearing contact lenses, subjects needed to discontinue contact lens wear for one week before entering the study. All subjects were informed of the risks and benefits of the study. In addition, ethics approval was obtained from the Institutional Review Board of the Illinois College of Optometry.

At the initial visit, baseline tear osmolarity was measured using the TearLab Osmolarity System (TearLab, San Diego, CA) in a temperature-controlled room in the Cornea Center for Clinical Excellence in the Illinois Eye Institute. Measurements were taken from each subject’s inferior lateral tear meniscus. The examination included the subjects’ manifest refraction, topography (Carl Zeiss Atlas 9000 Corneal Topographer), manual keratometry, and horizontal visible iris diameter (HVID) used in the diagnostic fitting of the Valley Custom Stable scleral contact lens. The manufacturers donated all the lenses. Subjects were fit according to the manufacturer’s fitting guide while central clearance values were verified using the Visante Anterior Segment OCT (Carl Zeiss Meditec, Dublin, CA). An acceptable fit required the contact lens to have a “settled” central clearance value between 150 um to 250 um, adequate limbal clearance, and alignment in the scleral landing zone.15 All subjects were given the same instruction on proper contact lens application and removal, saline (0.9% sodium chloride solution), cleaning and storage (Boston Advance®), and wear schedule (a minimum of 8 hours per day, 5 days per week). Subjects were provided the appropriate lens care products at no cost. Follow up visits were scheduled every 2-3 weeks until the appropriate contact lens fit was achieved. Once the contact lens fit was finalized, the tear osmolarity was measured with the lens in situ, and the lenses were dispensed for full time wear. After one month of wear, tear osmolarity measurements were repeated with the lens in situ (after a minimum of 4 hours of wear). Follow-up measurements were made at the same general time of day as the baseline measurement (+/- 2 hours) to reduce any temporal effects. Central clearance OCT measurements with the Visante AS-OCT were repeated at this time. Statistical analysis using paired t-tests were used to compare changes in tear osmolarity (given as mean mOsm/L +/- standard deviation) with reference to the baseline values.

Results
In all, 31 subjects were screened for the study and 13 subjects completed the study through the one month period. The mean age of the patients who completed the study was 25.62 +/- 4.77. There were 8 (61.5%) females and 5 (38.5%) males. Of the subjects screened, 8 subjects did not pass the initial TearLab osmolarity screening criteria (tear osmolarity of 308 mOsm/L or below in both eyes), 7 subjects were unable to wear the scleral contact lenses for the duration of the study (due to poor comfort/fit or unacceptable midday fogging of the lenses), 2 subjects experienced solution sensitivity (diffuse superficial punctate keratitis), and 1 subject experienced unacceptable redness due to irritation of an existing pinguecula.

The Kolmogorov-Smirnov goodness-of-fit test determined that the data followed a normal distribution. The Pearson correlation p-value was not significant (p = 0.185), showing no correlation...
between the right and left eyes. We analyzed the data from twenty-six eyes of 13 subjects. The mean baseline tear osmolarity value was 293.58 +/- 8.49 mOsm/L. After 1 month of scleral contact lens wear, the tear osmolarity increased to 310.65 +/- 17.46 mOsm/L, which was statistically significant (p < 0.001).

**Discussion**

With regards to ocular surface disease, scleral contact lenses are mainly used to treat refractory cases such as graft vs. host disease, Sjogren’s Syndrome, and Stevens-Johnson Syndrome. Given the enormous growth of this lens modality in today’s market, our study may provide valuable quantitative evidence on the potential side effects of scleral contact lens wear. Scleral contact lenses are often indicated for patients with keratoconus, a condition known to have inflammatory comorbidities. Due to the link between tear osmolarity and inflammatory signals in the eye, this study may allow us to better understand and manage our patients’ long-term eye health.

All types of contact lens wear affect the characteristics of the tear film. Studies have found that contact lens wear may increase the rate of tear film evaporation. This may in turn increase tear osmolarity, a known biomarker of OSD. In diagnosing dry eye syndrome, Tomlinson et al. found tear film osmolarity to have a specificity of 94%, a sensitivity of 59%, and a positive predictive value of 89%. With advancements in technology, we are now able to use in-office diagnostic instruments such as the TearLab Osmolarity system to measure tear osmolarity in patients.

There is little research on the effect of scleral contact lens wear on the tear film and ocular surface. It is hypothesized that corneal gas-permeable and soft contact lenses reduce corneal sensitivity due to its direct contact with the cornea, causing a down-regulation of the lacrimal gland and subsequently reduced tear production. Unlike other contact lens modalities, scleral contact lenses completely vault the corneal surface and create a tear fluid environment. It is not fully known what effect this corneal environment may have on tear production.

All of the subjects in our study were first time scleral contact lens wearers. After one month of wear, the tear osmolarity measurements were found to increase at a statistically significant level. We believe the disruption of the tear film layer contributed to this increase in tear osmolarity. In addition, the constant fluid layer in front of the cornea may disrupt the normal pathways leading to tear production.

While the tear osmolarity measured with the TearLab in situ increased at a statistically significant level, it may be difficult to infer the true osmolarity affecting the eye at the corneal surface. Our study’s tear osmolarity measurements were taken from the inferior lateral lid margin. It could be argued that there are two related, but distinct, environments created by the scleral contact lenses: 1) the tear fluid layer directly in front of the cornea and 2) the tear layer outside of the scleral contact lens (where the tear osmolarity measurements were taken). Depending on the amount of tear exchange taking place, these values may be drastically different. Scleral contact lenses are known to have a reduced tear exchange rate in comparison to other contact lens modalities. We hope to gain a better understanding of these tear osmolarity measurements as more information on scleral contact lens tear exchange becomes available. In the meantime, future directions may seek to discover ways to directly measure the tear osmolarity of the tear fluid layer in front of the cornea. This may require alternative, perhaps more traditional, methods of tear sample collection.

One of the major limitations of the study was the high number of dropouts. While scleral contact lenses are being used frequently for corneal ectasias and OSD, our subject base consisted entirely of asymptomatic, non-pathological eyes. Without offering significant advantages over other lenses modalities, we believe the high number of dropouts resulted from the increased complexity of scleral contact lens fitting and maintenance. A major known complication of scleral contact lens wear is fogging of the post-lens tear layer after a couple hours of wear, even in a well-fitting lens. While this can normally be improved clinically by altering the contact lens cleaning solution or saline solution, the study parameters did not allow for these modifications. Variable levels of lens fogging may have had an unknown effect on tear osmolarity, in addition to causing dropout from the study. Furthermore, differences in central clearance values can also impact the degree of post-lens tear layer fogging, despite our restriction on the subjects’ range of acceptable tear layer clearances (150 um to 250 um).

Clinically, there is no definitive standard for central clearances; the final value is usually dependent on the shape of the cornea and the indications for scleral contact lens wear.

Our study did not seek to measure changes in dry eye symptoms. The Ocular Surface Disease Index (OSDI) was only used in the screening process for asymptomatic subjects. Future directions may explore the effects of scleral contact lens wear on subjects with ocular pathology including OSD. It may also be helpful to study changes in tear osmolarity as scleral contact lenses are worn throughout the day (i.e. after 4 and 8 hours of wear). Given the lack of dedicated scleral lens care products in the current market, we may want to test other solutions and saline alternatives to determine its effects on tear osmolarity, dry eye symptoms, and possible side effects.

At this time, there is much to learn about the effects of scleral contact lens wear on the ocular surface. Our study found a statistically significant increase in tear osmolarity after one month of scleral contact lens wear. However, scleral contact lenses are distinctly different compared to other contact lens modalities; a high tear osmolarity value in a scleral contact lens wearer may not have the same correlation to OSD as a high tear osmolarity value in a soft contact lens wearer. Further studies are needed to determine its true effects.
References

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