Scleral lens use has become increasingly widespread to correct vision and provide ocular surface protection for diseased eyes, with the benefits well established by the visual quality and comfort they provide. Although examples of visual success are acclaimed alongside these successes are accounts of adverse events and an increasing concern for potential adverse effects.10-16 Accordingly, there is an increasing interest in the effects of these custom devices on the ocular surface and adnexa.17,18 With evidence of adverse effects and considering the diseased eyes for which they are indicated,2,19 it is imperative to understand both the positive and negative ocular health impacts of scleral lenses.

The scleral lens fit is unique, vaulting over the cornea and landing on the conjunctival tissue adjacent to the limbus. The position of the lens on the eye is driven by a subatmospheric pressure beneath the lens, which forces the scleral lens against the conjunctiva and causes compression as great as approximately 50 μm. Beneath the conjunctiva lie the episcleral veins, and beneath that are the trabecular meshwork, canals, ducts, and channels of the aqueous humor outflow pathway. A disruption of aqueous dynamics could have an effect on intraocular pressure (IOP), a major risk factor for glaucoma. The landing of scleral lenses over these important structures has been a growing concern over the fact that scleral lens can create resistance to aqueous humor outflow and lead to increased IOP. Furthermore, greater amounts of scleral lens settling would in theory lead to greater suction force that could exacerbate an increase in IOP.

Measuring IOP during scleral lens wear presents a challenge because most clinical methods of measurement make direct contact with the cornea, which is covered by the scleral lens. To manage this challenge, investigators have measured IOP using several different techniques: (1) by measuring the pressure over the cornea immediately after lens removal, and a noncontact tonometer (TX-20P; Canon, Amstelveen, the Netherlands), respectively. Another more recent study by Aitsebaomo et al.31 used Icare (Icare Finland Oy, Vantaa, Finland) immediately after lens removal, and a noncontact tonometer (Diaton; DevelopAll Inc., Staten Island, NY) just before lens removal. Shahnazi et al.33 measured IOP after lens removal in patients with
ocular surface disease, using a Tono-Pen (Tono-Pen AVIA Tonometer; Reichert Technologies, Depew, NY). Each of these studies has variation in type of scleral lenses worn, sample size, hours of lens wear, and technique used to measure IOP, which creates a challenge when comparing results from one study to the next.

The optic nerve head is a relatively weak point in the otherwise rigid corneoscleral shell and, as a result, is particularly susceptible to the effects of IOP. F45 According to the response to acute IOP elevation with ophthalmodynamometry, changes in optic nerve head structure (e.g., pre-laminar tissue and neuroretinal rim thickness) can be detected. F36–39 Minimum rim width, quantified using optical coherence tomography, is a robust measure of the neuroretinal rim that has demonstrated excellent repeatability F40–43 and is sensitive for detecting subtle changes in the optic nerve head structure caused by IOP increase. Changes in IOP can result in thinning of the minimum rim width in as little as 5 minutes after IOP increase in primate models, although it takes approximately 2 hours to see the maximum change. F44 Although not typically measured during minimal (<10 mmHg) changes in IOP, the dose-dependent nature of minimum rim width thinning is suggestive that even with small increases in IOP (e.g., 5 mmHg) there would be changes to the minimum rim width after a prolonged increase. In this study, changes in the minimum rim width are measured to indirectly assess fluctuations in IOP during scleral lens wear.

The goals of the present study were to (1) assess changes in minimum rim width during 6 hours of scleral lens wear to indirectly determine whether scleral lens wear influences IOP and (2) compare two techniques (Diaton and Icare) for measuring IOP during scleral lens wear and determine their relationship to the minimum rim width findings.

METHODS

This study was done in compliance with the tenets of the Declaration of Helsinki and was approved by the institutional review board at the University of Houston College of Optometry. A total of 27 healthy scleral lens neophytes were recruited (26 completed), and all subjects signed an informed consent form before enrollment. Sample size was determined for ANOVA using a moderate effect size of \( f(0.3) \) with \( \alpha = 0.05 \) and power of 0.8. Potential subjects were excluded if they had a personal history of ocular hypertension or glaucoma, if their IOP measured greater than 20 mmHg in either eye on the day of enrollment, or if they had a history of ocular surgery (including refractive surgery such as laser in situ keratomileusis) that could affect IOP readings.

The first study visit determined eligibility and selected the lens to be used on the experimental day. IOP was measured using the Icare Finland Oy rebound tonometry. A scleral lens fitting set to be used on the experimental day. IOP was measured using the Icare rebound tonometer and the Diaton transpalpebral tonometer. Icare, which requires contact with the cornea, was used only before and after scleral lens wear on the test eyes (control eyes were measured at each time point) and was measured within 5 seconds of scleral lens removal when applicable. Measurements were repeated three times at each session and averaged for the final values. Diaton was used on both eyes at all time points while subjects laid in a supine position and were instructed to look at a target approximately 45° down toward their feet. The instrument probe was placed posterior to the eyelash margin just above where the scleral lens edge would land. Each instrument output represented a series of measurements analyzed and averaged by the instrument, and two measurements were obtained and averaged for each time point. The agreement of the two instruments was compared using a total of 100 matched measurements taken on the same eyes.

Minimum Rim Width Measurement

Optical coherence tomography (Spectralis OCT2; Heidelberg Engineering) was used to measure the change in minimum rim width during 6 hours of scleral lens wear. Global minimum rim width was measured in both eyes at baseline (pre- and post-lens application for test eyes), at the 2- and 6-hour time points, and again in the test eye after scleral lens removal. The Spectralis OCT system used for this study has a theoretical resolution of 7 μm. However, this axial resolution is for a single A-scan, and thickness measures are an average of several A-scans. Hence, with rigorous manual segmentation, it is possible to detect changes smaller than the theoretical axial resolution. Minimum rim width has demonstrated excellent repeatability with a within-subject standard deviation between approximately 1 to 2 μm. F45,46

To quantify minimum rim width, defined as the minimum distance from Bruch’s membrane opening to the internal limiting membrane, a 24-line (15°) radial scan centered on the optic nerve head was acquired, and Bruch’s membrane opening and the inner limiting membrane were automatically identified (Glaucoma Module Premium Edition, version 6.0; Heidelberg Engineering; Fig. 1). The software will occasionally fail to correctly locate Bruch’s membrane opening, which can then be manually reselected for the software to calculate rim width. Each scan was carefully inspected during this manual segmentation process and adjusted as needed by a single investigator (MKW) and then verified by a second investigator (NP). Manual correction of automated segmentation is an essential step in analysis to ensure accurate Bruch’s membrane opening detection; however, pre- and post-segmentation correction values for global minimum rim width still have excellent agreement as shown in other studies. F43,46 To minimize magnification effects with scleral lens wear, all scans subsequent to the initial pre-lens baseline were obtained using the AutoRescan feature.

Statistical Analysis

Normality of the data was tested using the D’Agostino-Pearson normality test. Mean IOP and minimum rim width were compared
between eyes before, during, and after scleral lens wear using repeated-measures ANOVA, paired t test, and the nonparametric equivalents when appropriate. Linear regression and Pearson correlation analyses were done to determine if there were associations between change in minimum rim width, change in IOP, and change in the fluid reservoir depth. To compare these variables of different scales, values were normalized by calculating them as their percent change from baseline.

To assess the performance of Icare and Diaton, a total of 100 IOP measurements taken on the same eyes with both instruments were compared using Bland-Altman analysis, linear regression, and Pearson correlation coefficient. In addition, repeatability was calculated for each instrument. All statistical analyses were completed using GraphPad Prism 7 (GraphPad Software, Inc., La Jolla, CA).

**RESULTS**

A total of 26 adults (81% female) between the ages of 23 and 33 years with normal ocular health and no history of scleral lens wear were included in this study. Mean central fluid reservoir depths were 221 μm (95% confidence interval, 192 to 251 μm) at initial application and 148 μm (95% confidence interval, 121 to 175 μm) after 6 hours of lens wear, settling an average of 73 μm (95% confidence interval, 56 to 91 μm). Before scleral lens application, mean central corneal thickness in the test eyes was 540 μm (95% confidence interval, 520 to 559 μm) and in the control eyes was 535 μm (95% confidence interval, 513 to 557 μm), showing no difference between the eyes (P = .18). After 6 hours of scleral lens wear and measured within 5 minutes of lens removal, mean corneal thicknesses were 537 μm (95% confidence interval, 517 to 557 μm) in the test eyes and 523 μm (95% confidence interval, 501 to 544 μm) in the control eyes, showing a significantly greater value in the test eyes (P = .0001) but reduced from baseline in both eyes. Anterior chamber depth remained unchanged in the test and control eyes throughout the experimental visit: 3.133 mm (95% confidence interval, 2.900 to 3.366 mm) in the test eyes and 3.039 mm (95% confidence interval, 2.937 to 3.141 mm) in the control eyes (P = .50) at baseline, and 3.062 mm (95% confidence interval, 2.953 to 3.172 mm) in the test eyes and 3.010 mm (95% confidence interval, 2.905 to 3.115 mm) in the control eyes (P = .24) after lens removal.

**Intraocular Pressure (IOP)**

Mean IOP (Icare) on the morning of the experimental visit was 14 mmHg (95% confidence interval, 12 to 15 mmHg) in both the test and control eyes. At the 2-hour, 6-hour, and post-lens time points, average IOP in the control eyes was 13 mmHg (95% CI at 6 hours, 12 to 14 mmHg), showing no significant change after 6 hours (P = .19). Mean IOP in the test eyes, only measured again after scleral lens removal, was 16 mmHg (95% confidence interval, 14 to 18 mmHg), showing a +2-mmHg (95% confidence interval, +1 to +3 mmHg) increase in IOP from baseline (P = .002; Fig. 2).

IOP measured with Diaton was 14 mmHg (95% confidence interval, 12 to 16 mmHg) in both the test and the control eyes before scleral lens application. After 6 hours of scleral lens wear (pre-removal), IOPs were 15 mmHg (95% confidence interval, 13 to 18 mmHg) in the test eyes and 14 mmHg (95% confidence interval, 12 to 16 mmHg) in the control eyes, not significantly different from each other (P = .35) or from their respective baseline measurements (P = .11 for the test eyes, P = .71 for the control eyes). After scleral lens removal, the mean test eye measurement returned to 14 mmHg (95% confidence interval, 12 to 16 mmHg). The mean IOP changes with Diaton were +0.3 mmHg (95% confidence interval, −0.9 to +3.2 mmHg) in the test eyes and +0.4 mmHg (95% confidence interval, −0.8 to +1.7 mmHg) in the control eyes, showing no difference between the two eyes (P = .90).

A comparison of means between Icare and Diaton for 100 IOP measurements showed no significant difference (Diaton, 15 mmHg [95% confidence interval, 13 to 15 mmHg]; Icare, 14 mmHg [95% confidence interval, 14 to 15 mmHg]; P = .35). The
within-subject standard deviation was calculated (square root of the variance) and then multiplied by 2.77 to determine repeatability. For Diaton, the repeatability was 8 mmHg versus Icare, which had a repeatability of 2 mmHg. The instruments were also compared using Bland-Altman analysis, which showed poor agreement and correlation of the instruments (regression slope = 0.22, \( R^2 = 0.03 \), Y intercept = 10.00, \( P = .07 \); Fig. 3).

**Minimum Rim Width**

The mean minimum rim widths at baseline, measured between 8 AM and 9 AM, were 351 \( \mu \)m (95% confidence interval, 330 to 372 \( \mu \)m) in the test eyes and 344 \( \mu \)m (95% confidence interval, 323 to 365 \( \mu \)m) in the control eyes. Intrasubject values were highly correlated with each other at baseline (\( R^2 = 0.76 \); \( P < .001 \)). After 6 hours and before scleral lens removal, minimum rim widths were 343 \( \mu \)m (95% confidence interval, 323 to 363 \( \mu \)m) in the test eyes and 338 \( \mu \)m (95% confidence interval, 318 to 358 \( \mu \)m) in the control eyes. This was a significant amount of minimum rim width change from baseline in both the test (−8 \( \mu \)m; 95% confidence interval, −11 to −6 \( \mu \)m) and the control eyes (−6 \( \mu \)m; 95% confidence interval, −9 to −3 \( \mu \)m; \( P < .01 \); Fig. 4). The difference in minimum rim width change between eyes, calculated by subtracting the control eye thinning from the test eye thinning for each subject, was on average −2 \( \mu \)m (95% confidence interval, −5 to 0 \( \mu \)m), indicating a slightly greater amount of thinning in the test eyes; however, this difference was not statistically significant (\( P = .09 \)). After scleral lens removal, minimum rim width was repeated in test eyes and did not change significantly from the pre-scleral lens removal measurements taken at 6 hours (\( P = .88 \); Fig. 4).

There was individual variation observed in these data. Although on average there was not a significant difference in the minimum

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**FIGURE 2.** Mean IOP and changes during 6 hours of scleral lens wear, measured using Icare and Diaton. The mean IOP of the test and that of control eyes are plotted as the mean with 95% confidence interval at each time point for Icare (A) and Diaton (C). The change in IOP (Δ IOP) from baseline is shown for Icare (B) and Diaton (D) measured after scleral lens removal for the test and control eyes. Positive values indicate pressure increased from baseline. A dotted line indicates minimal time passed between measurements. IOP measured with Icare was significantly increased in the test eye after 6 hours of scleral lens wear (\( P = .02 \)).
rim width with scleral lens wear, eight test eyes (31%) and seven control eyes (27%) had greater than 10 μm thinning during the 6-hour period. Most of the subjects with high amounts of thinning showed relatively symmetrical thinning between the eyes, although there was a trend of approximately 3- to 5-μm greater thinning in test eyes for several subjects (n = 10). Only two eyes, both test eyes, showed greater than 20-μm thinning during the test period, but both fellow control eyes also showed higher-than-average amounts of thinning.

Linear regression and correlation analyses were done to evaluate associations between changes in minimum rim width, IOP, and fluid reservoir depth. Change in minimum rim width was not correlated with change in IOP (regression slope = 0.01, \( R^2 = 0.02 \), \( Y \) intercept = −0.02, \( P = .50 \)) or change in fluid reservoir depth (regression slope = 0.002, \( R^2 = 0.0005 \), \( Y \) intercept = −0.02, \( P = .91 \)). In addition, there was no correlation between change in IOP (measured with Icare after lens removal) and change in fluid reservoir depth (regression slope = 0.31, \( R^2 = 0.11 \), \( Y \) intercept = 0.3, \( P = .10 \)).

**FIGURE 3.** Comparison graphs showing the Bland-Altman and correlation plots comparing Icare and Diaton. A total of 100 measurements, all taken with Icare and Diaton on eyes that were not wearing scleral lenses, were compared. (A) The Bland-Altman plot indicates a poor agreement between Diaton and Icare. (B) Each measurement was plotted against each other in the linear regression plot, which has a shallow slope that also shows poor agreement between the instruments. The 95% limits of agreement for each plot are shown by the dashed lines.

**FIGURE 4.** Mean MRW changes during 6 hours of scleral lens wear, measured with optical coherence tomography. Subjects wore a lens on one randomly selected eye for 6 hours, and the fellow eye acted as the control. (A) Mean change in MRW from baseline (ΔMRW) is plotted as the mean with 95% confidence interval at each time point for the test and control eyes (a dotted line for test group plot indicates minimal time passed between measurements). (B) The total change from baseline at 6 hours (before scleral lens removal) is also shown as a scatterplot of each test and control eye, with whiskers showing the 95% confidence interval for each group. Negative values indicate thinning of the MRW. Minimum rim width in the test eyes shows a slightly greater amount of thinning, although not representative of a significant difference (\( P = .09 \)). MRW = minimum rim width.
DISCUSSION

In this study, the effect of scleral lens wear on the optic nerve head minimum rim width and IOP were evaluated. Although there was a trend for increased thinning of the minimum rim width in test eyes, the change for the 6 hours of scleral lens wear was not statistically significant for these healthy eyes. However, there was a trend of greater thinning in the eyes wearing scleral lenses, which suggests certain individuals may be experiencing changes to the optic nerve head structure due to an increase in IOP. Individuals in this study with the greatest magnitude of minimum rim width thinning of the test or control eye were of greatest interest, as in theory they would be more likely to be sensitive to changes in IOP. However, in these individuals, the magnitude of minimum rim width thinning was similar between the eyes.

Almost all eyes showed minimum rim width thinning, regardless of scleral lens wear. The normal eye exhibits diurnal changes in minimum rim width throughout the day, on average showing approximately 8 μm of thinning between 7 AM and 7 PM in young, healthy individuals without contact lens wear. However, there is considerable individual variability over a 12-hour period (range, −31 to +1 μm). Therefore, this study used a control eye from the same individual to help reduce the effect of inter-subject variability. Ultimately, a normal eye appears to be quite capable of wearing a fitted scleral lens and maintaining a balance in IOP within limits that does not create significant mechanical stress at the optic nerve head.

It is not surprising that we do not see a significant difference in minimum rim width thinning between eyes, because normal individuals are quite capable of managing long-term IOP stress. The natural homeostasis of IOP is constantly tested by forces such as fluid intake, medications, body orientation, alcohol consumption, respiration, heart rate, exercise, and diurnal rhythms. In response, the trabecular meshwork is capable of sensing a transient increase in outflow resistance and will respond by increasing pulsatile flow or reducing upstream resistance to avoid prolonged increases that can create stress at the optic nerve head. However, glaucomatous eyes are often unable to self-regulate these stresses on IOP; therefore, it is essential that these experiments be repeated in that population. Furthermore, individuals with collagen diseases such as keratoconus, a population with a high incidence of scleral lens wear, may show a different response than seen with the normal eye.

IOP was measured using two different methods. Diaton, able to measure IOP as indicated during scleral lens wear, seemed desirable to use but exhibited questionable reliability. This was in agreement with other studies that showed poor comparability to the criterion-standard Goldmann applanation tonometry. Icare, a validated instrument that is reasonably comparable to Goldmann applanation tonometry, was in part used here to offer potential validation of Diaton. Our assessment of the instruments showed a large variability of Diaton, which had a repeatability of 8 mmHg. Conversely, Icare showed a better repeatability of 2 mmHg. There was also poor correlation between Icare and Diaton, suggesting poor accuracy of Icare, a conclusion that is in agreement with other studies. We propose that the inconsistencies of Diaton are in part due to variation in eyelid morphology between subjects, such as eyelid thickness, elasticity, and other mechanical tissue properties. The Diaton data in this study also did not agree with the study by Michaud et al., which showed an approximately 5-mmHg increase after several hours of lens wear. Ultimately, Diaton cannot be considered an accurate and reliable instrument for IOP assessment during scleral lens wear.

After removal of the scleral lenses, the Icare IOP was significantly greater in the test eyes than in the control eyes. This is in relative agreement with the study by Aitsebaomo et al., which also used Icare, although they saw an average increase about three times greater. However, the Icare data here do not agree with several studies that have used different methods of measuring IOP. Nau et al. found no increase using corneal pneumotonometry after 2 hours of scleral lens wear, Vincent et al. saw a slight reduction after several hours of lens wear when measuring with an ocular response analyzer and a noncontact tonometer, and Shahnazi et al. observed a slight decrease when measuring with Tono-Pen in ocular surface disease patients. The discrepancies in the studies may be due to the instruments used, the durations of scleral lens wear (which were 2, 3 to 8, and 1 to 8 hours, respectively, for the studies mentioned), or differences in the exact protocol for measuring IOP after scleral lens removal (i.e., how long after removal was IOP measured?). If an increase in IOP is true, either due to scleral lens wear or from the process of removing the lens itself, McMonnies and Boneham would predict that at removal the IOP would almost instantly return to baseline. This study measured IOP within 5 seconds of scleral lens removal, so it may have still been able to capture an increase during SL wear, although this is ultimately unknown. The remaining questions are whether the increased Icare measurements are true, and if so, are they caused by prolonged IOP increase during scleral lens wear or caused by the process of lens removal itself?

This study, although novel in technique, had several limitations that should be considered when designing similar studies. This study was short term and in normal subjects; long-term studies in diseased eyes may show different results, and this type of study should be repeated in individuals with glaucoma and keratoconus specifically. Another limitation is that normal diurnal changes in minimum rim width were not evaluated in the test eyes in the absence of a scleral lens. However, the test eyes would be expected to follow a similar diurnal pattern to that of the control eyes for a given individual, especially given the high correlation of minimum rim width between eyes at baseline. In addition, the duration of IOP increase measured with Icare after lens removal was not determined, and future studies should measure IOP for several minutes or longer after lens removal. Future studies may also benefit from careful biomicroscopic assessment of the anterior segment aqueous and episcleral veins beneath the scleral lens landing zone, which can sometimes be observed for pulsatile blood flow patterns. Lastly, a direct and accurate measure of IOP was still not obtained during scleral lens wear, although we are not aware of an instrument that can safely accomplish this task.

This is the first study, to our knowledge, that evaluates the sensitive optic nerve head tissue as an indirect measure of IOP during scleral lens wear. This study suggests that scleral lenses have a relatively small effect on IOP in the normal eye and that any impacts of pressure fluctuation on the optic nerve are likely not significant for young, healthy eyes. This conclusion is supported by the insignificant difference in optic nerve head minimum rim width change in scleral lens–wearing eyes. The long-term effects of scleral lenses on IOP and optic nerve head structure, especially in susceptible eyes, should be investigated.
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