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Intraocular Pressure After 2 Hours of Small-Diameter Scleral Lens Wear

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Abstract

Objectives—Compression of episcleral veins or deformation of tissue in the Schlemm canal beneath the landing zone of scleral lenses could elevate intraocular pressure (IOP). We examined the effect of 2 hours of small-diameter scleral lens wear on IOP.

Methods—Twenty-nine participants, 29 ± 6 years old (mean $\pm$ SD) who had no history of eye disease or scleral lens wear were included in the study. Each participant was fitted with a 15-mm Jupiter scleral lens on 1 eye (study eye). IOP was measured in both eyes by pneumatonometry centrally on the cornea and peripherally on the sclera. The lens was then placed on 1 eye and was worn for 2 hours. IOP was remeasured immediately after lens placement, at 1 and 2 hours of lens wear, and immediately after lens removal. IOP after removal of the scleral lens was compared to IOP before placing the lens and to IOP in the control eye by using paired t-tests.

Results—Immediately after removing the scleral lens, mean central IOP in the study eye (13.9 ± 3.1 mm Hg) was not different from mean central IOP in the control eye (13.5 ± 2.2 mm Hg, $P=.4$) or in the same eye before lens wear (13.6 ± 1.9 mm Hg, $P=.6$). There were also no differences in IOP measured peripherally at 2 hours of lens wear ($P=.8$).

Conclusions—Neophyte scleral lens wear of a 15-mm scleral lens for 2 hours does not increase IOP in healthy eyes.

Keywords

episcleral veins; intraocular pressure; scleral lens

Scleral lenses have become increasingly popular during the past several years, not only for the management of severe ocular surface disorders, but also for correction of simple refractive errors. These large-diameter rigid gas permeable lenses were designed to rest on the conjunctival tissue overlying the sclera and to create a vault over the entire cornea and limbus. Unlike soft lenses, these lenses compress and settle into conjunctival tissue.^{1,2} During each blink, pressure from the lid may press the lens farther into the conjunctiva. Depending on the amount of force directed posteriorly, they may also compress deeper

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structures that produce resistance to aqueous humor flow out of the eye, such as collector channels and episcleral veins.³

In general, large-diameter scleral lenses (18.0 mm in diameter) have relatively wide haptics, or landing zones (up to 2 mm wide), which allow for broad distribution of the lens-bearing force on the eye. Furthermore, large-diameter scleral lenses contact the conjunctiva well beyond the limbus, so they may be less likely to compress any structures within or adjacent to the anterior chamber angle. However, small-diameter scleral lenses (14.0–16.5 mm in diameter) generally have limited haptic widths and diameters, and they contact the conjunctiva across a relatively small area closer to the limbus than do the larger lenses. Concentration of the bearing surface over a smaller area close to the limbus could conceivably compress not only conjunctival tissue, but also the Schlemm canal, the collector channels, or the episcleral veins, structures responsible for aqueous humor outflow. Compression of these structures could increase resistance to aqueous humor outflow and consequently increase intraocular pressure (IOP). Whereas compression of tissues that determine aqueous humor outflow resistance should be of concern when fitting scleral lenses, changes in IOP during scleral lens wear have not been previously studied. The purpose of this study was to assess whether IOP increases during the wearing of small-diameter scleral lenses.

Methods

All participants were examined before being included in the study and had a central IOP between 10 and 21 mm Hg in each eye. IOP was within 3 mm Hg between eyes. Twenty-nine healthy participants, aged 29 ± 6 years (mean $\pm$ SD; range, 22–44 years) were included (Table 1). None had a history of eye disease, eye surgery, or scleral lens wear. If participants wore soft contact lenses, they were asked not to wear their lenses on the day of the study visit. Completion of a scleral lens fitting was not expected for any participants. One eye (study eye) of each participant was randomly selected to be fitted with a 15-mm Jupiter scleral lens (Visionary Optics, Front Royal, Virginia) from a standard lens fitting set. All participants gave consent to participate after discussion of the study risks, and all gave written Health Insurance Portability and Accountability Act authorization. This study adhered to the tenets of the Declaration of Helsinki and was approved by the Mayo Clinic Institutional Review Board.

Lenses were fitted from a standard trial set (14 lenses) to provide 200 to 300 μ m clearance between the lens and central cornea, estimated with a slit-lamp examination. Lenses were not modified in any way. Contact between the peripheral lens edge and conjunctiva was assessed, but lens parameters were not changed to optimize the fit. At the initial fitting, none of the lenses produced complete circumferential peripheral blanching of blood vessels, although some produced moderate blanching in 1 or 2 quadrants.

IOP was measured by pneumatonometry (Model 30 Classic; Reichert, Inc; Buffalo, New York) with the sensor probe placed near the center of the cornea (central IOP) and with the probe placed on the temporal sclera approximately 2 mm temporal to the limbus (peripheral IOP), beyond the edge of the scleral lens (Figure 1). Peripheral IOP was measured regardless

of whether a scleral lens was in place, but central IOP was measured only when the scleral lens was not in place. Before each measurement, 1 drop of topical anesthetic (proparacaine, 0.5%) was instilled in each eye. During the measurements the participant was seated and looking straight ahead. In each position, IOP was measured 3 times and the average was recorded.

Central and peripheral IOP were measured in each eye at the screening examination and before lens placement (baseline). The scleral lens was then placed on the study eye, and peripheral IOP was measured in each eye immediately, at 1 hour, and at 2 hours. Central IOP was measured at the same time in only the control eye. The lens was then removed, and central IOP and peripheral IOP were measured immediately in the study eye.

Central IOP and peripheral IOP in the study eye were compared to the baseline IOP in the same eye and to the IOP in the control eye by using paired t-tests. The study had an 80% chance of finding a difference in IOP as small as 1.5 mm Hg if such a difference existed ($\alpha=.05$, $\beta=.2$, $N=29$).

Results

At baseline, before lens application, mean central IOP was not different in the study eye (13.6 ± 1.9 mm Hg) compared with the control eye (13.7 ± 2.2 mm Hg, $P=.8$; Figure 2). Mean peripheral IOP was also not different between the study eye (18.4 ± 3.0 mm Hg) and the control eye (18.4 ± 3.2 mm Hg, $P=.9$), but it was higher in both the study eye and the control eye compared to central IOP in each eye ($P<.001$).

Within 5 minutes after applying the scleral lens, there was no difference between mean peripheral IOP in the study eye (17.6 ± 3.9 mm Hg) and the control eye (18.3 ± 3.4 mm Hg, $P=.3$). After 1 hour of lens wear, there was no difference between mean peripheral IOP in the study eye (18.4 ± 4.5 mm Hg) and the control eye (18.0 ± 3.4 mm Hg, $P=.2$). At 2 hours of lens wear, mean peripheral IOP was still no different between the study eye (18.7 ± 3.9 mm Hg) and the control eye (18.1 ± 3.1 mm Hg, $P=.2$), and mean peripheral IOP in the study eye was not different from baseline measurements ($P=.8$; Figure 3). Immediately after removing the scleral lens, mean central IOP in the study eye (13.9 ± 3.1 mm Hg) was not different from mean central IOP in the control eye (13.5 ± 2.2 mm Hg, $P=.4$) or from mean baseline central IOP in the study eye ($P=.6$; Figure 4).

Discussion

Scleral lenses, which are supported by conjunctival tissue that overlies the sclera, tend to settle posteriorly with time.¹ Small-diameter scleral lenses have relatively narrow haptic zones and rest just posterior to the limbus. As the lenses settle, they could increase IOP by compressing the episcleral vasculature or deforming the trabecular meshwork or the Schlemm canal. Scleral lenses were originally reserved for managing severe ocular surface disease or corneal irregularity, and the possible risk of glaucomatous nerve damage from increased IOP during lens wear was easily outweighed by the protection of the ocular surface or the improvement in visual function that they provided. However, indications for scleral lens prescription are now expanding from management of eye disease to correction of

simple refractive error.⁴ As caregivers begin to prescribe these lenses for healthy eyes, concerns about negative effects of scleral lens wear on normal ocular structures must be considered. This study showed that wearing 15-mm scleral lenses for 2 hours does not increase peripherally measured IOP in normal eyes, even in the absence of an ideal peripheral fit in some eyes. This would suggest that the posteriorly directed force generated by the haptic is not sufficient to compromise aqueous outflow in normal eyes.

Studies that evaluated IOP during contact lens wear have primarily emphasized the accuracy of IOP measurement by use of various methods and instruments through hydrogel or silicone-hydrogel lenses of different powers.^{5–13} The ability to measure IOP through soft lenses can eliminate the need to remove bandage contact lenses from potentially fragile ocular surfaces. Previous studies were not designed to evaluate the effect of contact lens wear on IOP because it was assumed that hydrogel or silicone-hydrogel lenses simply drape over the cornea, limbus, and perilimbal conjunctiva and exert no appreciable posterior force on those tissues. During rigid gas permeable lens wear, measurement of IOP is not possible with any instrument that requires access to the cornea, but corneal rigid gas permeable lenses are not typically used as bandage lenses to manage severe ocular surface disease.

Scleral lenses are also made of rigid gas permeable materials, however, and these can be used to manage severe ocular surface disease. In these cases, it may be desirable to measure IOP without touching the fragile corneal surface. In this study, we measured IOP beyond the periphery of the lens by using a pneumotonometer. This method was not expected to measure IOP accurately, but previous studies have reported a strong correlation between central and peripheral pneumatonometry measurements in normal eyes.² As previously reported, our peripheral IOP measurements were higher than central IOP measurements.²

The process of applying and removing a soft contact lens may temporarily reduce IOP, presumably after a transient increase in IOP from manipulation of the eye, which can briefly increase aqueous humor outflow.⁸ Application and removal of scleral lenses requires a different technique than that used for soft lenses and may also force aqueous humor out of the eye and reduce pressure. Because it is impossible to measure central corneal IOP with a scleral lens in place, we measured pressure peripherally to identify any change in IOP induced by scleral lens insertion, wear, and removal. Peripheral IOP did not change immediately after lens application or removal, and peripheral IOP did not change during 2 hours of scleral lens wear. We also found no difference between IOP measured centrally immediately before and immediately after lens wear. The consistency of IOP measured both peripherally and centrally throughout the study provides reasonable confidence that IOP is not significantly affected by scleral lens application and removal or by 2 hours of wear.

We did not assess changes in IOP associated with scleral lens wear in patients with glaucoma; those patients may be more susceptible to lens wear because even slight obstructions to conventional outflow may have an increased effect on intraocular pressure. Consequently, these results may not be generalized to patients who have glaucoma. We cannot recommend prescribing scleral lenses for correction of simple refractive error in patients with glaucoma or ocular hypertension without first examining the pressure response in these patients. If scleral lenses are indicated for management of ocular surface disease or

corneal irregularity in a patient with glaucoma, a lens with a large-diameter design and a wider haptic may be preferred. These lenses land farther from the limbus and may reduce the likelihood of interference with aqueous outflow. However, there are no methods to measure IOP while a large diameter lens that extends beyond our peripheral measurement region is on the eye. In such patients, careful follow-up is strongly advised if scleral lenses are deemed necessary for management of anterior surface disease.

Several questions remain unanswered. All of our participants were relatively young, and none had worn scleral lenses before this study. Conjunctival thickness decreases with age,^{14–16} and it is possible that the thicker conjunctiva of our younger participants may distribute most of the posteriorly directed force generated by the scleral lens haptic over a wider area and that decreased conjunctival thickness in older patients may place them at greater risk for focal compression of the episcleral vasculature, collector channels, or the Schlemm canal. Long-term scleral lens wear could also lead to thinning or compression of conjunctival tissue beneath the haptic, and this could compromise aqueous drainage pathways, although this has not been studied. Scleral lens designs vary widely; lenses with different diameters, haptic designs, or corneal clearance may exert force onto conjunctival tissue differently. Thus, results obtained in this study may not be directly generalizable to all scleral lens designs. The extent to which larger-diameter scleral lenses (18–25 mm) cover the ocular surface may preclude peripheral measurement of IOP by pneumotonometry. Further study is clearly necessary to evaluate whether conjunctival thickness, age, scleral lens designs, or long-term scleral lens wear are associated with increased IOP. Despite remaining questions, however, the present study suggests that short-term wear of small-diameter scleral lenses does not significantly affect IOP.

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Abbreviation

IOP intraocular pressure

References

1. Kauffman MJ, Gilmartin CA, Bennett ES, et al. A comparison of the short-term settling of three scleral lens designs. *Optom Vis Sci*. 2014; 91:1462–1466. [PubMed: 25279781]
2. Kapamajian MA, de la Cruz J, Hallak JA, et al. Correlation between corneal and scleral pneumatonometry: an alternative method for intraocular pressure measurement. *Am J Ophthalmol*. 2013; 156:902–906.e1. Epub 2013 Aug 12. [PubMed: 23938125]
3. Roy Chowdhury U, Hann CR, Stamer WD, et al. Aqueous humor outflow: dynamics and disease. *Invest Ophthalmol Vis Sci*. 2015; 56:2993–3003. [PubMed: 26024085]
4. Michaud L. Beyond irregular: scleral lenses for everyday use [Internet]. June 1, 2015. *Contact Lens Spectrum*. 2015; 30:30–32. 34, 36. [Accessed September 11, 2015] Available at: <http://www.clspectrum.com/articleviewer.aspx?articleID=112909>.

5. Zeri F, Calcatelli P, Donini B, et al. The effect of hydrogel and silicone hydrogel contact lenses on the measurement of intraocular pressure with rebound tonometry. *Cont Lens Anterior Eye*. 2011; 34:260–265. Epub 2011 Jun 1. [PubMed: 21636312]
6. Anton A, Neuburger M, Bohringer D, et al. Comparative measurement of intraocular pressure by Icare tonometry and Airpuff tonometry in healthy subjects and patients wearing therapeutic soft contact lenses. *Graefes Arch Clin Exp Ophthalmol*. 2013; 251:1791–1795. Epub 2013 Mar 28. [PubMed: 23532453]
7. Schornack M, Rice M, Hodge D. Tonopen XL assessment of intraocular pressure through silicone hydrogel contact lenses. *Eye Contact Lens*. 2012; 38:270–273. [PubMed: 22810946]
8. Khan JA, LaGreca BA. Tono-Pen estimation of intraocular pressure through bandage contact lenses. *Am J Ophthalmol*. 1989; 108:422–425. [PubMed: 2801861]
9. Scibilia GD, Ehlers WH, Donshik PC. The effects of therapeutic contact lenses on intraocular pressure measurement. *CLAO J*. 1996; 22:262–265. [PubMed: 8906384]
10. Patel S, Stevenson G. Influence of lens material and intra-ocular pressure on the outcome of non-contact tonometry over soft contact lenses. *Cont Lens Anterior Eye*. 2009; 32:68–72. Epub 2009 Feb 4. [PubMed: 19195922]
11. Panek WC, Boothe WA, Lee DA, et al. Intraocular pressure measurement with the Tono-Pen through soft contact lenses. *Am J Ophthalmol*. 1990; 109:62–65. [PubMed: 2297033]
12. Liu YC, Huang JY, Wang IJ, et al. Intraocular pressure measurement with the noncontact tonometer through soft contact lenses. *J Glaucoma*. 2011; 20:179–182. [PubMed: 19593202]
13. Lim L, Ng TP, Tan DT. Accurate intraocular pressure measurement in contact lens wearers with normal pressures. *CLAO J*. 1997; 23:130–133. [PubMed: 9108980]
14. Zhang X, Li Q, Xiang M, et al. Bulbar conjunctival thickness measurements with optical coherence tomography in healthy Chinese subjects. *Invest Ophthalmol Vis Sci*. 2013; 54:4705–4709. [PubMed: 23744999]
15. Zhang XR, Zhang ZY, Hoffman MR. Conjunctival thickness measured by optical coherence tomography. *Ophthalmology*. 2013; 120:1305. [PubMed: 23732054]
16. Zhang XR, Zhang ZY, Hoffman MR, et al. The effect of age and conjunctivochalasis on conjunctival thickness. *Curr Eye Res*. 2013; 38:331–334. Epub 2012 Dec 18. [PubMed: 23249375]

Figure 1.
Intraocular pressure (IOP) measurement. Left, Central IOP. Right, Peripheral IOP.

Figure 2.

Intraocular pressure (IOP) before lens placement. Mean IOP was not different between the control eye and the study eye when measured centrally ($P=.8$) and when measured peripherally ($P=.9$). Circles indicate central IOP; diamonds, peripheral IOP; solid lines, mean central IOP; broken lines, mean peripheral IOP.

Figure 3.

Intraocular pressure (IOP) before and after 2 hours of lens wear. Mean IOP measured peripherally was not different after 2 hours of lens wear from mean IOP before lens wear ($P=.8$). The scleral lens was in place during measurements. Broken lines indicate mean peripheral IOP.

Figure 4.

Intraocular pressure (IOP) before and immediately after lens wear. Mean IOP measured centrally was not different immediately after scleral lens removal from before scleral lens placement ($P=.6$). Solid lines indicate mean central IOP.

Table 1

Study Population Characteristics

Characteristic	Value
Participants, number	29
Age, years	
Mean $\pm$ SD	29 $\pm$ 6
Range	22–24
Sex, number	
Female	19
Male	10
Screening IOP, mean $\pm$ SD, mm Hg	
Central, control eye	14.0 $\pm$ 1.7
Central, study eye	13.7 $\pm$ 1.9
Peripheral, control eye	18.8 $\pm$ 3.6
Peripheral, study eye	18.6 $\pm$ 3.1
Contact lens wearers, number	
Soft lens	17
No lens	12

Abbreviation: IOP, intraocular pressure.