

INFLUENCE OF SCLERAL LENS ON INTRAOCULAR PRESSURE

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ABSTRACT

Purpose

Since Scleral Lenses (SL) rest entirely on the sclera and may affect underlying anatomical structures that may influence aqueous humour flow, it is important to determine the effect of SL wear on intraocular pressure (IOP).

Methods

Nine subjects with normal corneas were recruited for an Institutional Review Board-approved study. Best fit SL from a 15.8-mm diameter, 0.4-mm thick diagnostic-lens set was fitted on a randomly selected eye, with a silicone-hydrogel soft lens (soft lens) on the other eye. Three IOP measurements were taken with rebound iCare tonometer prior to lens application (baseline data measured at about 9:30 AM), and immediately after lens removal (final data measured at about 5:30 PM). Baseline and final lens vault were determined with anterior segment Zeiss optical coherence tomography (OCT). Mean baseline and final IOP for each eye was analyzed with a Student-t-test, 2-way repeated ANOVA, and the Bland-Altman plot.

Results

IOP was elevated with SL wear for all subjects. Soft lens eyes showed a slight elevation for some but decreased in others. Mean IOP change was 5.81 ± 1.62 mm Hg for SL and -0.62 ± 0.88 mm Hg for soft lens eyes. When mean IOP in SL eyes was compared to soft lens eyes, unpaired t-test showed a significant difference ($p < 0.05$) between the means. Bland-Altman bias was 6.43 (SD of bias 3.139). Repeated ANOVA also showed a significant difference between baseline and final IOP.

Conclusions

the results indicate that SL wear can elevate IOP. Eye care practitioners must consider this possible outcome in treating patients wearing SL. Additional studies are needed to determine the clinical implications of SL wear on IOP.

Key words: *Scleral Lenses, Glaucoma, Intraocular pressure, Scleral Lens Settling, Contact Lenses*

The notion that scleral lens (SL) wear can affect intraocular pressure (IOP) is not new. It dates to 1930 when it was suggested that IOP was lowered in eyes wearing SL for up to 8 hours daily during a 2–3-year period.¹ This suggestion was not studied until 1951 when data were collected on 33 subjects wearing a Zeiss brand glass SL for 25 minutes. In that study, the IOP was measured prior to lens application and immediately after the lens was removed using a Schiotz tonometer. For most of the subjects, IOP was elevated up to 30 mm HG.² However, a few subjects exhibited an IOP that either decreased or did not change. In a follow-up study using a similar method, IOP elevation was found to be more exacerbated in eyes with glaucoma when compared with normal eyes.³ As mentioned, this study did not measure IOP with SL on the eye.

Part of the problem with measuring IOP with SL on the eye is that most traditional tonometers, including Goldmann applanation tonometry (GAT), are designed to indirectly measure IOP through applanation of the cornea. The Diaton tonometer (Ryazan State Instrument-Making Enterprise) allows for transpalpebral IOP measurement and could be used to measure IOP with the lens in situ. However, because of the size of SL, it is very easy to run out of useful space for taking IOP measurements with the Diaton while the lens is on the eye. Care must also be taken to ensure that the lens is not impacted during IOP measurement. To overcome this problem, IOP can be measured with a corneal tonometer prior to lens application and immediately after the lens is removed. This method does not necessarily yield IOP with the lens in situ nor does it account for forces associated with SL removal on aqueous humour outflow. However, if measurements are taken within seconds of lens removal as in the current study, it might be possible to estimate IOP while the lens was on the eye.

RELEVANCE OF THIS STUDY AND CURRENT USE OF SCLERAL LENSES

Because SL wear is increasing worldwide,^{4–7} and the prediction is that the trend will continue, it is relevant to examine the effect of SL wear on IOP measurements.^{8–11} The increased popularity of SL may be due in part to advances in contact lens manufacturing technology and the wide availability of oxygen

permeable contact lens materials.^{7,12} Since SL vault the entire cornea, they create a tear lens that results in optical quality that may not be possible with conventional spectacles and soft lenses for people with irregular corneas. The tear lens makes SL one of the favourite modalities for the treatment of irregular cornea,^{13–16} severe dry eyes,¹⁷ and dry eyes associated with Graft-vs-Host Disease (GVHD).^{18–20}

This is not to imply that SL wear is the only option available for treating moderate to severe corneal ectasia. Corneal gas permeable lenses (GP) have traditionally been used to treat corneal ectasia. Corneal transplantation is also a viable option, but the long-term survival rate is low with rejection increasing over time,²¹ even with allogeneic transplants.²² Additionally, corneal surgery is invasive and can lead to or severely exacerbate existing ectasia.^{23–25} While residual cylinder from corneal grafts may be corrected with SL, it is important to note that any hypoxic stress from SL wear can have a negative effect on post graft patients, especially those with low endothelial cell counts. Given the growing number of conditions for which SL wear is being recommended, it is necessary to investigate any possible effects, specifically, whether SL interact with the ocular anatomy in such a way as to induce an elevation in IOP, as has been suggested.^{26–29}

POSSIBLE MECHANISM OF IOP ELEVATION WITH SCLERAL LENSES

The mechanism for possible IOP elevation with SL wear has not been well studied. It is reasonable to hypothesize that it may be linked to lens settling, the reduction of tear reservoir under SL.^{30,31} Lens settling in small diameter (16 mm or less diameter) SL is reported to be in the first 4 hours, with most of the settling occurring in the first 45 minutes to 2 hours.³² It is suggested that large diameter SL (over 16 mm diameter) may continue to settle with up to 8 hours of wear.³³ Lens settling may result in lens tightening and a sub-atmospheric pressure environment in the tear lens reservoir. Any pressure on the episcleral veins and/or Schlemm's canal,^{26,34} can potentially compromise aqueous humour outflow and ultimately cause IOP elevation. In a recent study, lens diameter (15.8 mm vs. 18.0 mm SL) did not appear to have any effect on the magnitude of IOP elevation.²⁹

Until recently, only a few studies have measured IOP while wearing SL. One study did not find an elevation in IOP after 2 hours of SL wear.³⁵ A study that used the Diatom tonometer started with 9 subjects but could only obtain reliable data on 2 subjects,³⁶ further demonstrating the difficulty with this method.

METHODS

Subjects between the ages of 18 and 35 that wore glasses or soft lenses and were correctable to 20/20 in each eye were solicited for the study. Extended lens wearers, as well as GP (including SL) wearers, were excluded. Subjects must not have been diagnosed with glaucoma or keratoconus prior to being enrolled in the study. Of the potential subjects that were screened, 9 third-year Optometry school students (3 males and 6 females) between the ages of 25 and 30 were recruited and consented for a University Human Subject Institutional Review Board-approved study. Recruited subjects were deemed free of corneal ectasia as well as glaucoma prior to being enrolled in the study. Two of the subjects previously ordered SL as part of a class exercise but were not currently wearing the lenses. Another 2 subjects had high baseline IOP (23 mm Hg and 26 mm Hg) on the day of the study but had not been diagnosed with glaucoma at the time.

The study required 2 visits: one for screening and SL fitting, and the other for data collection. Except for the 2 subjects that previously ordered SL as part of their class project, subjects were fitted with lenses from the clinic diagnostic-lens set. SL for all subjects (Boston XO, 15.8 mm diameter, 0.4 mm thick – inclusive of those that were previously ordered by 2 subjects) was fitted in one randomly selected eye, and the fellow eye was fitted with a soft lens of the subject's choosing. Seven subjects chose daily disposable soft with DK/t of 156 material, and the other 2 subjects chose a daily disposable with DK/t of 114 material. All lenses were fitted by the same investigator experienced in SL fitting and IOP measurements. Lens fits were judged as acceptable by the investigators. Soft lenses were centred, with a vertical movement of about 0.25 – 0.5 mm with each blink. SL fit did not demonstrate impingement or compression, but an initial ideal corneal vault of 220 – 300 μ m was not attained in some subjects because diagnostic lenses were used.

All equipment, including care solutions used in the study were located at the clinic where the study was conducted. IOP was measured with an iCare TA01i tonometer, a first-generation rebound tonometer from iCare. Measurements were taken in accordance with manufacturer guidelines. To ensure that measuring probes were not bent or otherwise rendered inadequate, a new iCare-sterilized probe was used for each subject during each session. The probe was gently lowered into the chamber of the tonometer and gently wiped with a pre-moistened alcohol pad before IOP measurements were taken. The tonometer displays the average of 6 consecutive measurements after a loud beep, accompanied by a letter "P" indicating confidence in the values. All readings showed high reliability. There was no reading with a low reliability, which would have been indicated with an "E" on the instrument and would not have been used in data analysis. The iCare was not calibrated as it has an internal calibration mechanism, and the manufacturer does not provide a way to manually calibrate it. iCare readings have been reported to be reproducible.³⁷ While some investigators found iCare to slightly underestimate GAT,³⁸ others have found that it slightly overestimates GAT by as much as 3 mm Hg. iCare has also been reported to have good agreement and correlation with GAT.^{39,40}

Corneal tomography, horizontal visible iris diameter, and pachymetry were measured with a Pentacam HR (Oculus, Germany) at the screening visit only. This allowed for a quick view of the anterior chamber depth, anterior chamber angle, and corneal thickness at various points on the cornea. SL vault was measured at the centre of the cornea, the nasal and temporal limbal zones, as well as at the nasal and temporal landing zones were assessed. These measurements were taken with an anterior segment OCT (Zeiss, Germany).

Recruited subjects who passed the screening visit were scheduled for data collection visits and asked not to wear contact lenses for at least 24 hours prior to data collections. During data collection, 3 baseline IOP readings, each comprising of 6 automatic IOP measurements, were taken in each eye in the morning at about 9:30 AM, prior to lens application. SL were cleaned with Boston Advance cleaning solution and rinsed with Biotrue multi-purpose solution (Bausch and Lomb). The SL bowl was filled with Addipak

preservative-free saline solution (Hudson RCI), and applied to the target eye by the principal investigator with the aid of a large suction cup (DMV). Fluorescein sodium was not added to the bowl, as this was not necessary for determining lens vault. After a soft lens in the subject’s prescription was applied to the other eye and the subject verbally confirmed that they felt comfortable in both lenses, a 5-line raster anterior segment OCT reading was taken on the SL eye at the centre, nasal, temporal, temporal/limbal, and nasal/limbal areas. All baseline measurements were taken between 5 to 7 minutes after SL was applied, ensuring that there was no lens settling. Lens fit in both eyes was further evaluated with a slit-lamp after lens application and prior to lens removal. This was to rule out any impingement and/or compression. Subjects were correctable to 20/20 in the soft lens eye and relied on that eye for functional vision for the next 8 hours. The acuity in the SL eyes ranged from 20/20 to 20/40. Subjects were required to return after 8 hours of lens wear, with instruction to return immediately to the clinic should one or both lenses became uncomfortable, or for any other reason. Subjects wore the lenses from 8–8.25 hours before the lenses were removed.

After the lenses were removed, a final OCT reading was taken at approximately the same location on the eye as during baseline data collection. Lens settling was calculated as the difference between baseline and final central cornea vault. Three final IOP measurements were taken within 5 seconds after lens removal in each eye. The time between lens removal and final IOP measurement was determined with a stop-watch and recorded for each eye. A mean change in IOP in the respective eyes was calculated as the difference between the mean baseline and mean final IOP for each eye.

RESULTS

Table 1 shows baseline and final IOP measurements, as well as baseline and final central vaults for the subjects. For IOP changes, a positive number indicates an elevation of IOP from baseline, while a negative number indicates a decrease in IOP from baseline. The range of IOP change for SL eye was 2.67 to 14.67 mm Hg, with a mean of 5.81 ± 1.62 mm Hg, and a range of -5.00 to 2.33 mm Hg and a mean of -0.62 ± 0.88 mm Hg for soft lens eyes. There was no significant difference between initial IOPs for the soft lens and SL eyes ($t = 1.62, p = 0.14$), suggesting

TABLE 1 Baseline and Final IOP for the SL and Soft Lens Eye for All Subjects. Positive “Change” Means the Final IOP Was Higher than Baseline IOP. Also Included is the Baseline Vault and Final Vault for The SL Eye.

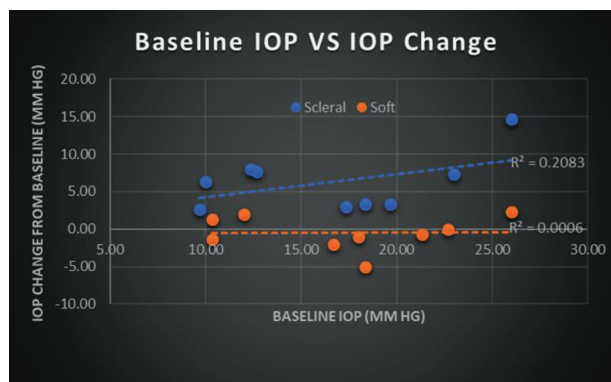
Sub. #	SL IOP (mm Hg)			Soft Lens IOP (mm Hg)			SL Central Vault (µm)		
	Baseline	Final	Change	Baseline	Final	Change	Baseline	Final	Settling
1	9.67	12.33	2.67	10.33	9.00	-1.33	364	300	64
2	23.00	30.33	7.33	22.67	22.67	0.00	420	220	200
3	17.33	20.33	3.00	18.00	17.00	-1.00	604	528	76
4	26.00	40.67	14.67	26.00	28.33	2.33	436	280	156
5	18.33	21.67	3.33	18.33	13.33	-5.00	564	396	168
6	19.67	23.00	3.33	21.33	20.67	-0.67	320	264	56
7	10.00	16.33	6.33	10.33	11.67	1.33	200	120	80
8	12.67	20.33	7.67	16.67	14.67	-2.00	460	364	96
9	12.33	20.33	8.00	12.00	14.00	2.00	220	148	72

that each eye of same subject can be treated as paired data points in a repeated-measure ANOVA.

A repeated ANOVA test shows an overall elevation of mean IOP between the initial and final IOP ($F[1,8]=9.66$, $p=.0145$) for all lenses. There is a significant difference in overall IOP change between the soft lens and SL ($F[1,8]=77.9$, $p<.0001$) eyes. The interaction between the lens type and the change in IOP was significant ($F[1,8]=47.4$, $p=.0001$); suggesting that the 2 lens types affected mean IOP differently. Looking at each lens type individually, SL shows a significant difference in mean IOP ($t[8]=-4.90$, $p=.001$); indicating that the final IOP was higher than the initial IOP. Therefore, with 95% confidence, it is estimated that the average elevation of IOP is at least 3.88 mm Hg, which is attributable to SL wear.

When data from the 2 subjects with high baseline IOP was eliminated (subjects 2 and 4), an unpaired t-test still showed a significant difference ($p<0.0005$) between initial IOP and final IOP in SL eyes, suggesting that the high baseline IOP did not unduly influence the results. SL settling ranged from 56 μm to 200 μm , with a mean of $104 \pm 53.62 \mu\text{m}$. The IOP change did not correlate with the baseline IOP ($P = 0.2175$) in the SL eye and in the soft lens ($P = 0.9525$) eye (Figure 1). Additionally, there was no correlation ($P = 0.2761$) between IOP change and SL settling (Figure 2).

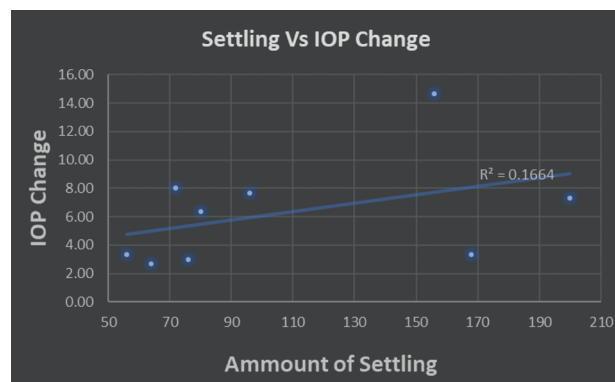
FIG. 1 Baseline and final IOP for the SL and Soft lens eye for all subjects. Positive “change” means the final IOP was higher than baseline IOP. Also include is the baseline vault and final vault for the SL eye.



DISCUSSION

IOP was measured on 9 subjects within 5 seconds of lens removal. It was hypothesized that the IOP measured immediately after lens removal approximates the IOP with the lens on the eye. However, the impact of SL removal on aqueous outflow is, to date, not known and is a possible limitation of the current study. IOP after lens removal is likely to underestimate IOP with the lens on the eye, since IOP is expected to return to baseline once the eye is exposed to normal atmospheric pressure. There are also other possible confounding elements in the experimental design of the study, such as the influence of contact lens-induced corneal edema^{41,42} on IOP measurements.^{43,44} Previous studies measured IOP while SL were on the eye and after lens removal. In some cases, there was no significant difference between IOP in SL eye and control. In the study where IOP was measured with the lens on the eye,³⁶ there was no significant difference between SL eye and control, but IOP was consistently higher in the SL eye when compared to control (mean IOP difference ranged from 2 to 6 mm Hg). The study started with 5 subjects, but reliable data was only obtained on 2. The small sample size in the study (2 subjects) may have contributed to the lack of a significant statistical difference. It also demonstrates the difficulty in attempting to measure the IOP while SL are on the eye. Since it is difficult to

FIG. 2 SL vs IOP Change. There is a small but not statistically significant correlation between lens settling and IOP change.



measure IOP with the lens on the eye, an alternative is to measure IOP after lens removal, and infer IOP with the lens on the eye.

Some studies suggest that iCare overestimates IOP,^{37,45,46} and others conclude that it is similar to GAT⁴⁷ when measurements are taken on edematous eyes. The degree to which iCare overestimates GAT measurements was not found to be statistically significant.⁴⁸ It is reasonable to assume therefore that iCare is a reliable and effective way to measure IOP prior to, and after contact lens wear.

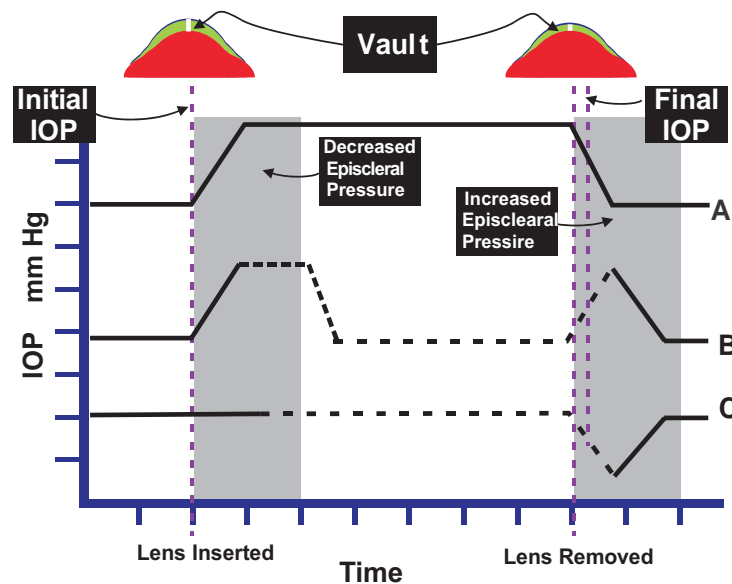
One underlying assumption in the discussion of possible reasons for an IOP elevation with SL wear is that SL may alter Episcleral Venous Pressure (EVP). It is pertinent to note that this study did not aim and was not powered to evaluate EVP. EVP has long been suggested to affect IOP.^{49,50} It has been postulated that a 0.83 mm Hg elevation of EVP results in approximately a 1 mm Hg^{51,52} rise in IOP. In fact, the GAT equation ($IOP = F/C + P_v$) where P_v is EVP, implies that changes in EVP affect IOP. It is not surprising therefore that EVP has also been implicated in the

development of glaucoma in patients with Sturge-Weber syndrome, where the extent of the hemangioma is said to correlate with the severity of glaucoma.⁵³

Regardless of the factors that promote IOP elevation during SL wear, it is important to determine the profile of IOP changes while the lens is on the eye. Figure 3 shows three possible models (A, B, and C) of IOP change with SL on the eye. For all 3 models, baseline IOP is shown on the left after lens insertion, followed by the predicted change in IOP as the lens settles, and after lens removal.

Model A depicts an elevation in IOP on lens application, which is sustained for the duration of lens wear. When the lens is removed, other factors and positive EVP are predicted to lower IOP to baseline. This model is consistent with the findings of studies that predict SL wear leads to an elevation of IOP. Model B also assumes that IOP is elevated with SL on the eye. The eye could compensate for the elevated IOP, thereby lowering IOP to baseline. If that were the case, final IOP is expected to be lower than baseline. When the lens is removed, the final IOP could be elevated if

FIG. 3 Possible Models of IOP change while wearing SL. Decreased Episcleral pressure (less than normal) represents a period when lens settling presumably is active, IOP might be elevated. Increased Episcleral pressure (greater than normal) occurs on lens removal and should lead to an elevation of IOP. Model A shows sustained high IOP during lens wear and only decreasing on lens removal. B and C show IOP at baseline during lens wear but with different prediction for final IOP on lens removal. Both models are not consistent with the finding of the study.



there were a spike in IOP as a result of removing the lens from the eye. While this is possible for studies where IOP was measured after the lens was removed, it does not explain the results of studies where IOP was measured with the lens on the eye. Finally, like model B, model C does not adequately account for results of all studies.

CONCLUSION

SL are a viable modality for the treatment of patients with moderate to severe corneal ectasia. The current study did not measure IOP with SL on the eye, but the results show a similar trend as studies that measured IOP with SL on the eye. If results from these studies are confirmed, eye care providers should be aware that SL wear can potentially lead to elevated IOP in their patients. The exact process of IOP elevation during SL wear is not yet understood and there is no evidence that the rise in IOP attributed to SL wear in these studies can lead to the development of glaucoma. While Additional studies on a larger population are needed to confirm these results, it is important to closely monitor IOP in SL wearers.

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COMPETING INTERESTS

None.

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