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Effect of Scleral Contact Lens Size and Duration of Wear on Intraocular Pressure

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Abstract

Objective: To evaluate the effects of scleral lens size and the duration of wear on intraocular pressure (IOP) during lens wear.

Methods: Healthy adults were recruited for this prospective and randomized study. IOP measurements were performed using a pneumotonometer. A block randomization was used to assign the order of scleral lens diameter of either 15.6mm or 18.0mm for 5-hour bilateral wear over a course of two visits. Scleral IOP (sIOP) was measured during the pre-determined intervals, 1.25-hour (hr) apart, during the 5-hour scleral lens wear. Corneal IOP (cIOP) was measured before and after the scleral lens wear. The primary outcome measure was the mean change in sIOP from pre-lens insertion baseline.

Results: cIOP unchanged after scleral lens removal compared to the baseline measurements (p=0.878). Smaller and larger lenses introduced significantly higher sIOP at 2.5 hours post-lens insertion) with the mean [95% CI] increase of 1.16 [0.54, 1.78] mmHg and 1.37 [0.76, 1.99] mmHg, respectively. There was no difference in IOP change between the smaller and larger diameter lenses (p=0.590).

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T. Litvin was involved in conceptualizing and designing the study, data collection, and manuscript preparation. V. Tse was involved in data collection, study management, and manuscript preparation. L. Chung was involved in research subject recruitment and data management. Y. Zhou was involved in data analysis and manuscript preparation. B. Tan was involved in data collection. Ying Han was involved in study design and manuscript preparation. M.C. Lin was involved in study design, data collection, and manuscript preparation.

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Conclusions: Well-fitted scleral lenses do not result in clinically significant changes in intraocular pressure during 5-hr lens wear in young and healthy individuals.

Background

The use of scleral lenses in the management of complex corneal and ocular surface conditions has gained popularity in recent years. The possibility of an increase in intraocular pressure (IOP) with the use of scleral lenses has been raised and explored.[1–8] While the results of these studies are conflicting, it is apparent that an increase in eye pressure does occur with scleral lens use in some individuals under certain fitting conditions. The individual susceptibility to an increase in eye pressure with scleral lens wear may correlate with overall susceptibility to the development of glaucoma. It is, therefore, imperative to identify and evaluate factors that may lead to an increase in intraocular pressure during scleral lens wear. Episcleral vein compression or deformation of tissue in Schlemm's canal beneath the landing zone of scleral lenses has been proposed as a potential contributing factor to an increase in resistance to aqueous outflow, which consequently may lead to intraocular pressure elevation during scleral lens wear.[3,4] It has been shown that most scleral lens settling on the ocular surface occurs during the first four to five hours of wear. It has been speculated that the incremental post-lens tear loss during lens settling leads to increased lens tightness, which in turn forms negative pressure beneath the lens.[9–11] Another proposed mechanism for IOP elevation during scleral lens wear is the displacement of intraocular fluid due to applanation and indentation of the ocular surface.[3]

An increase in IOP during short-term wear of a glass scleral lens was reported as early as 1951.[1] More recently, Vincent et al. suggested that mini-scleral lens wear resulted in a minimal drop of IOP after 3 and 8 hours of wear.[12] However, the method of IOP measurement in this study was not well characterized. Non-contact pneumotonometry was used, implying that IOP was not measured with the scleral lens in situ. Nau et al. also observed no significant change in IOP, on average, after 2 hours of small-diameter (15 mm) scleral lens wear using corneal and scleral pneumotonometry.[4] Fogt et al. examined the effect of a 15.2 mm and an 18.0 mm scleral lens diameter on intraocular pressure during one hour of scleral lens wear. The IOP was measured using pneumotonometry and transpalpebral tonometry. Mean IOP was not significantly different from baseline when measured using pneumotonometry while transpalpebral IOP was significantly different.[13] Aitsebaomo et. al. did find an average increase in cIOP of 5.8±1.62 mmHg after 8 hours of scleral lens wear using the iCare rebound tonometer;[7] however, these measurements were not made with the scleral lens on the eye, but rather after lens removal. Michaud et al. found an average 5 mmHg increase in transpalpebral IOP after 4.3 hours of wear with both small diameter (15.8 mm) and large diameter (18 mm) scleral lenses.[3] However, this study employed a transpalpebral tonometry method, which is known to have a high level of variability, and has relatively poor agreement with the clinical gold standard Goldman tonometry.[14,15] Obinwanne et. al. evaluated the anterior chamber angle (ACA) and sIOP changes during and after scleral contact lens wear in black African population using Schiotz tonometer and anterior segment optical coherence tomography (OCT). They found no significant impact of scleral lens wear on ACA or IOP during and after 4 hours of scleral lens wear.[2] Other authors found no effect of scleral lens wear on cIOP in patients with and without ocular

disease over an extended follow up time,[5,6] although the IOP measurements in those studies were not taken with the scleral lens on the eye.

Methodology to study the effect of scleral lenses on the IOP differed widely in the cited studies making the direct comparison of the study results difficult. Current literature suggests that the duration of scleral lens wear and, possibly, the size of the scleral lens may play a role in its effect on intraocular pressure. The data, however, are conflicting, due in part, to significant methodological differences among the published studies. Additionally, no data is available on the effect of small and large scleral lens wear on IOP after 4–5 hours of wear using a reliable and validated tonometry method. Normal healthy patients are increasingly turning to scleral lenses for improved wearing comfort. Patients with dry eye symptoms are finding relief due to the “bandage effect” of wearing scleral lenses that vault the cornea. Many glaucoma patients suffer from dry eye symptoms; therefore, gaining an understanding of how scleral lens wear affects ocular symptoms and IOP is critical for these patients.

Pneumotonometry has been shown to correlate well with manometry (true eye pressure) in both cadaveric and living eyes for both children and adults. [16] Change in scleral pneumotonometry was shown to have nearly 1:1 linear correlation with change in corneal pneumotonometry, with scleral pneumotonometry averaging 9.0 mmHg higher than corneal pneumotonometry.[17] This makes scleral pneumotonometry suitable for assessing the change in IOP over time. This study was designed to evaluate the effects of scleral contact lens size and the duration of wear on intraocular pressure in healthy scleral lens neophytes using scleral pneumotonometry before, after, and during the scleral lens wear, as well as using corneal pneumotonometry before and after lens wear.

Methods

This was a prospective, randomized study, which adhered to the tenets of the Declaration of Helsinki and was approved by UC Berkeley and UC San Francisco Institutional Review Boards. Non-pregnant and non-nursing adults without the diagnosis of glaucoma or other pathology that may be exacerbated by the increase in intraocular pressure were recruited. Soft contact lens wearers were eligible for recruitment if they were willing to tolerate all the testing procedures, including insertion and removal of scleral lenses. Exclusion criteria were best-corrected visual acuity worse than 20/40, baseline IOP at or above 22 mmHg, history of any ocular surgery, presence of systemic conditions that may affect a study outcome. All participants signed a written informed consent form. Scleral Lens fitting was performed and diurnal variation of IOP was established on two separate visits. Subjects were instructed to discontinue the use of habitual soft contact lenses three days prior to the first study visit and for the duration of their participation in the study. All IOP measurements were performed using pneumotonometer (Model 30™, Reichert Technologies, Inc., Buffalo, New York) and standard Goldmann applanation tonometer.

During the initial study visit, best-corrected visual acuity, anterior segment biomicroscopy, scleral lens fittings of two lens diameters (15.6mm and 18.0mm), and baseline Goldmann IOP measurements were performed. At the second study visit, diurnal IOP measurements

were performed using a pneumotonometer at both cornea and superotemporal sclera at baseline (t_0), and several times within a 5-hr session (1.25-hr (t_2), 2.5-hr (t_3), 3.75-hours (t_4), and 5-hr (t_5)) to parallel with the lens wear period. A block randomization was used to assign the order of scleral lens diameter of either 15.6mm or 18.0mm for 5-hr bilateral wear at the 3rd and 4th visits. Pneumotonometry was used to measure corneal IOP prior to scleral lens insertion (t_0), immediately after the lens removal at the end of a 5-hr period (t_6), and 1-hr post lens removal (t_7). Scleral IOP (sIOP) was measured at the same time points as those at the 2nd visit and immediately after lens insertion (t_1). All pneumotonometry measurements were repeated 3 times and averaged. IOP measurements performed during study visits 2, 3, and 4 were in general scheduled at the same time of the day with similar awake times in the morning of each study visit. Scleral lens fit and surface assessment were performed 20 minutes and 5 hours after lens insertion. If major conjunctival impingement or blanching were observed, study measurements were discontinued for that day, lenses were removed, and adjustments were made to the scleral lens parameters to achieve optimal fit. Subjects were then invited to resume their study visit sequence. Post-lens tear thickness (PoLTT) measurements were performed using high-resolution spectral domain optical coherence tomography (ENVISU 2300; Bioptigen Inc, Durham, North Carolina). Post-lens tear thickness (PoLTT) was used to track scleral lens settling. Figure 1 provides a summary of the study protocol.

The primary outcome measure was the mean change in sIOP from pre-lens insertion baseline at four predetermined time intervals: 1) immediately after lens insertion, 2) 1.25-hr after lens insertion, 3) 2.5-hr post lens insertion, 4) 3.75-hr after lens insertion, 5) 5-hr post lens insertion, and 4) immediately after lens removal, for each lens diameter.

Data Analysis

Power analysis for repeated-measure designs was performed to obtain a sample size estimation. The correlation between the repeated measures was referenced from the empirical data of pneumotonometer measurements of IOP. The minimum detectable mean IOP difference of 2 mmHg was based on clinical relevance and the previously published data.[18,19] Sample size estimation indicated that a sample size of 11 subjects would give a power of at least 0.8 to detect a minimum IOP difference of 2 mmHg with standard deviation of 3 mmHg and correlation of 0.75 at 0.05 significance level. A sample size of 30 subjects was determined to be sufficient to detect clinically significant change in IOP.

A linear mixed effect model using PROC MIXED procedure in SAS© was utilized for analysis. The linear mixed effect model was flexible to adequately address between-subject and within-subject variances, where within-subject correlations from repeated measurements and fellow eyes were specified as random effect. The p-values from mixed effect model were adjusted for multiple comparisons.

Results

Thirty healthy participants with no active ocular disease and no history of scleral contact lens wear were recruited at UC Berkeley School of Optometry, Clinical Research Center between March of 2021 and November of 2021. The demographic variables of the sample

are summarized in Table 1. Mean (Standard Deviation, SD) age of the group was 28 (9.8) years old. Females represented 73% of the sample. Asian/Pacific Islanders, Caucasians and Hispanics accounted for 60%, 20%, and 13% of this sample, respectively. There was no diurnal change in IOP without scleral lenses on the eye during 5-hr observational period at the central cornea (Table 2) or superotemporal sclera (Table 3 and Figure 2). On average, pneumotonometry measurements were performed approximately at the same time intervals after research subjects woke up in the morning (awake time), Table 4, and at the pre-specified time intervals after lens insertion, Table 5. Corneal IOP was unchanged after scleral lens removal when compared to the baseline measurements prior to scleral lens insertion (p=0.878). Figure 3 shows both small and large lenses introduced significantly higher sIOP at 2.5-hr post lens insertion (small lenses: p=0.031; large lenses p=0.002) with the mean [95% CI] increase of 1.16 [0.54, 1.78] mmHg and 1.37 [0.76, 1.99] mmHg, respectively (Figure 4). There was no difference in IOP change between the smaller and larger diameter lenses (p=0.590). IOP restored to the baseline at 3.75-hr lens wear and remained stable thereafter. Scleral lens settling, measured by the change in PoLTT, occurred most rapidly during the first two hours after lens insertion and reached plateau at 4-hr post lens insertion (Figure 5). PoLTT was significantly greater with large lenses compared with small lenses. The rate of PoLTT change was not statistically different between lens diameters (p=0.462).

Discussion.

The thick tear reservoir between the cornea and the posterior surface of the scleral lens is useful in optical treatment of irregular astigmatism and in providing ocular hydration for managing ocular surface disease. The landing zone of scleral lenses is beyond the limbus, which makes them more comfortable than traditional small-sized corneal gas permeable lenses. These properties of scleral lenses allow clinicians to treat a range of disorders, which not only include patients with irregular cornea but also those with moderate-to-severe dry eye disease.[20] It has been proposed that as the scleral lenses settle on the eye, compression of episcleral veins or deformation of the trabecular meshwork and Schlemm's canal may lead to increase in IOP due to the location of the lens landing zone on the sclera.[4]

The combination of the rate of scleral lens settling and the presumed increase in the pressure exerted by the lens on the bulbar conjunctiva, has been speculated to occur primarily during the first four hours of scleral lens wear, following non-linear time-settling relationship, with most rapid lens settling occurring during the first 1.5 – 2 hours.[20] If the proposed mechanism of IOP elevation is true, it is reasonable to expect the maximum rise in IOP to occur at some point after most of the scleral lens settling has occurred, as shown by our data. In this study, there is a small, statistically significant but not clinically significant increase in sIOP during the scleral lens wear. Scleral IOP was observed to peak at 2.5 hours after lens insertion, which coincides with the time of most rapid lens settling, with both small and large diameter lenses. This finding of statistically but not clinically significant increase in sIOP in the present study cannot be compared with the results reported by Nau et al.[4] and Fogt et al.,[13]as both studies only measured sIOP within 2 hours of lens wear.

In our study, sIOP restored to the baseline after 3.75 hours of scleral lens wear with both diameters. Scleral lens diameter did not have an impact on IOP during lens wear over a 5-hr period. The observed increase in sIOP of slightly above 1 mmHg at 2.5 hours after lens insertion is unlikely to be clinically significant in normal eyes without the diagnosis of or significant risks for glaucoma. It should be noted that six out of thirty subjects showed an increase in sIOP between 5 mm Hg and 7 mmHg at least at one point during the scleral lens wear. In each subject, sIOP restored to the baseline on subsequent measurements. In the ad-hoc analysis, 10 mm Hg increase in sIOP corresponds to 3 mmHg in cIOP when sIOP falls in the mid-20s range. We therefore reason that the pressure exerted by a well-fitting scleral lens on the bulbar conjunctiva of a young and healthy eye is not sufficient to overwhelm regulatory mechanisms that exist to maintain equilibrium between the rate of aqueous production and drainage to maintain clinically acceptable levels of intraocular pressure. However, given the evidence that scleral lens wear does result in some degree of alteration in intraocular pressure at 2.5-hr post lens insertion, further studies are needed to investigate the capacity of glaucomatous patients to adapt to the scleral-lens-induced changes for maintaining clinically acceptable levels of IOP.

It is important to note that in this study IOP was assessed only after an optimal scleral lens fit was achieved and confirmed by using standardized scleral lens fit and ocular-surface evaluation approach. Other strengths of this study include ability to reliably measure IOP with the scleral lenses on and off the eye using a validated method of scleral pneumotonometry; measuring IOP beyond the time that it takes for scleral lenses to settle on the eye; consistent time points for IOP measurements; establishment of baseline diurnal curve during the same time intervals; and the ability to assess the effect of scleral lens size on IOP.

This study has some limitations. It is not possible to measure corneal IOP during scleral lens wear and thus we must rely on the less frequently used method for measuring IOP – scleral pneumotonometry. We also did not evaluate IOP during the prolonged scleral lens wear of several days or months. In addition, our sample was not well-balanced with respect to the male-female sex. The generalization of the results of this study is limited to young healthy individuals.

Conclusions

Well-fitted scleral lenses of 15.6 mm and 18 mm diameter do not result in clinically significant changes in intraocular pressure measured by scleral pneumotonometry during the period of 5 hours in young and healthy individuals. There is evidence of adaptation to the changes introduced by scleral lens wear with respect to regulation of intraocular pressure. These results, in combination with previously published data, favor the conclusion that properly fitted scleral lenses are likely safe, with respect to changes in intraocular pressure, in young adults without glaucoma. At the same time, additional studies are necessary to evaluate the ability of eyes affected by glaucoma to respond to potential biomechanical changes introduced by scleral lens wear to maintain safe levels of intraocular pressure during lens wear.

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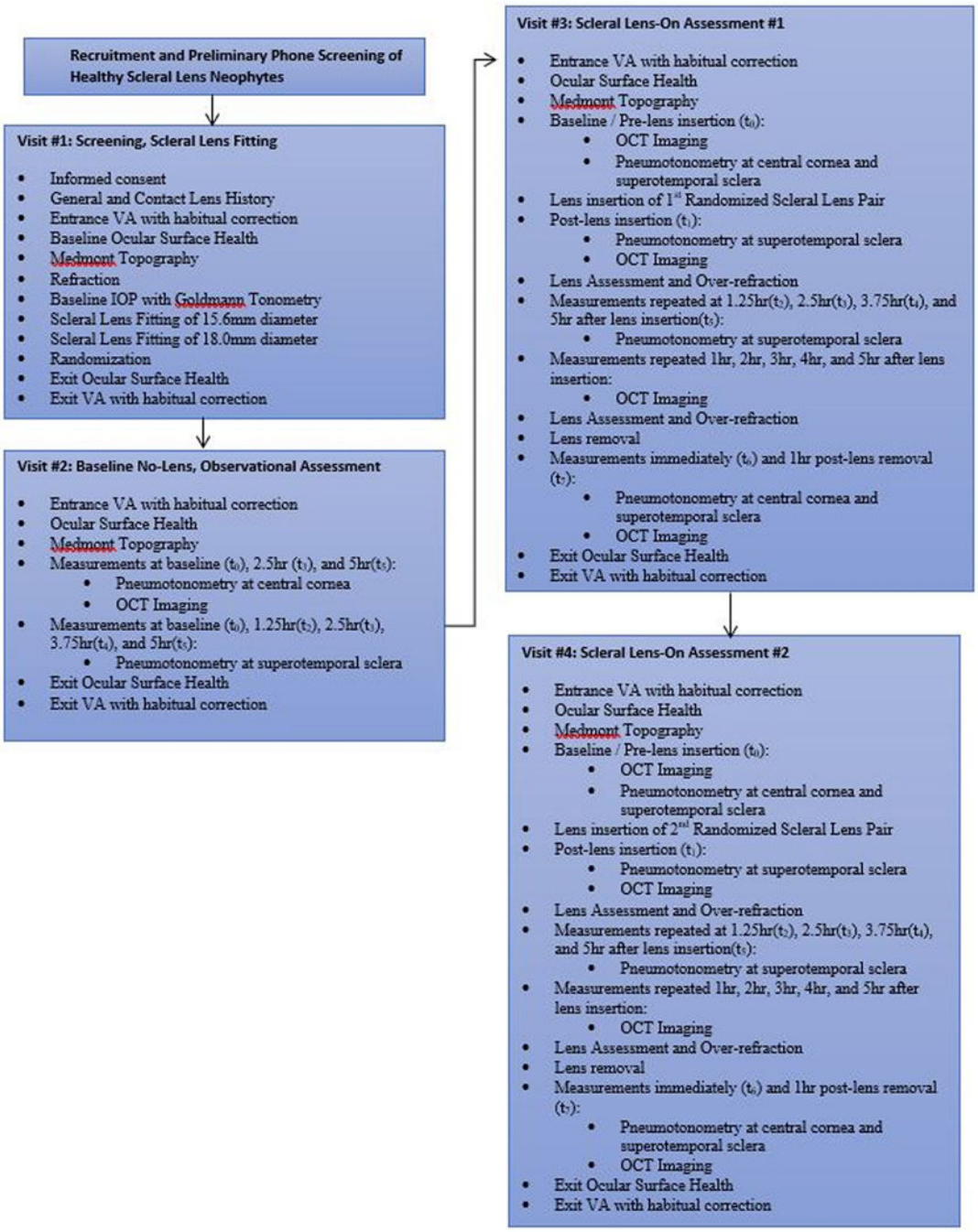

Figure 1.
Patient Flow Chart

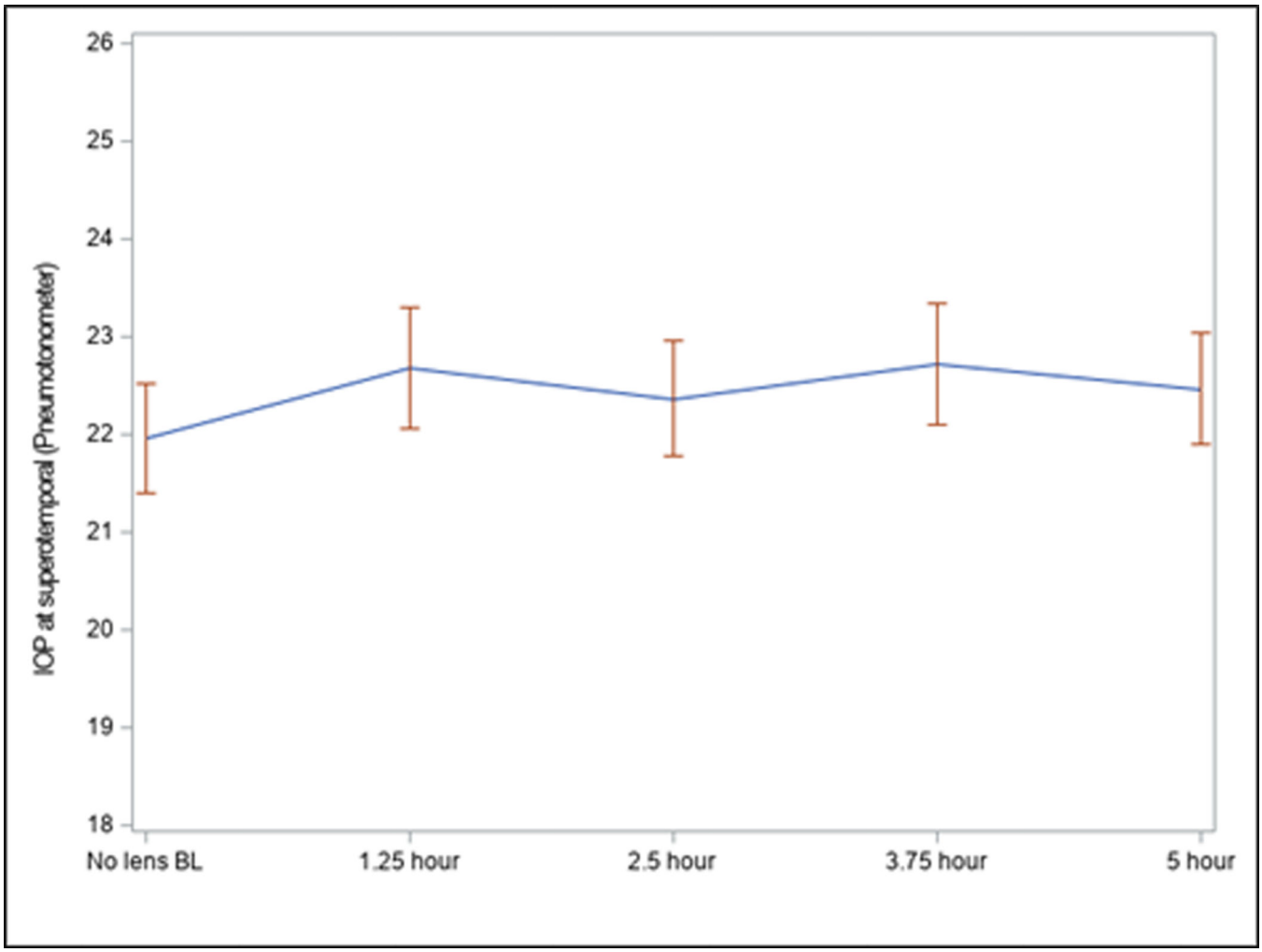

Figure 2.
Superotemporal scleral IOP variation over a 5-hour period without scleral lenses.

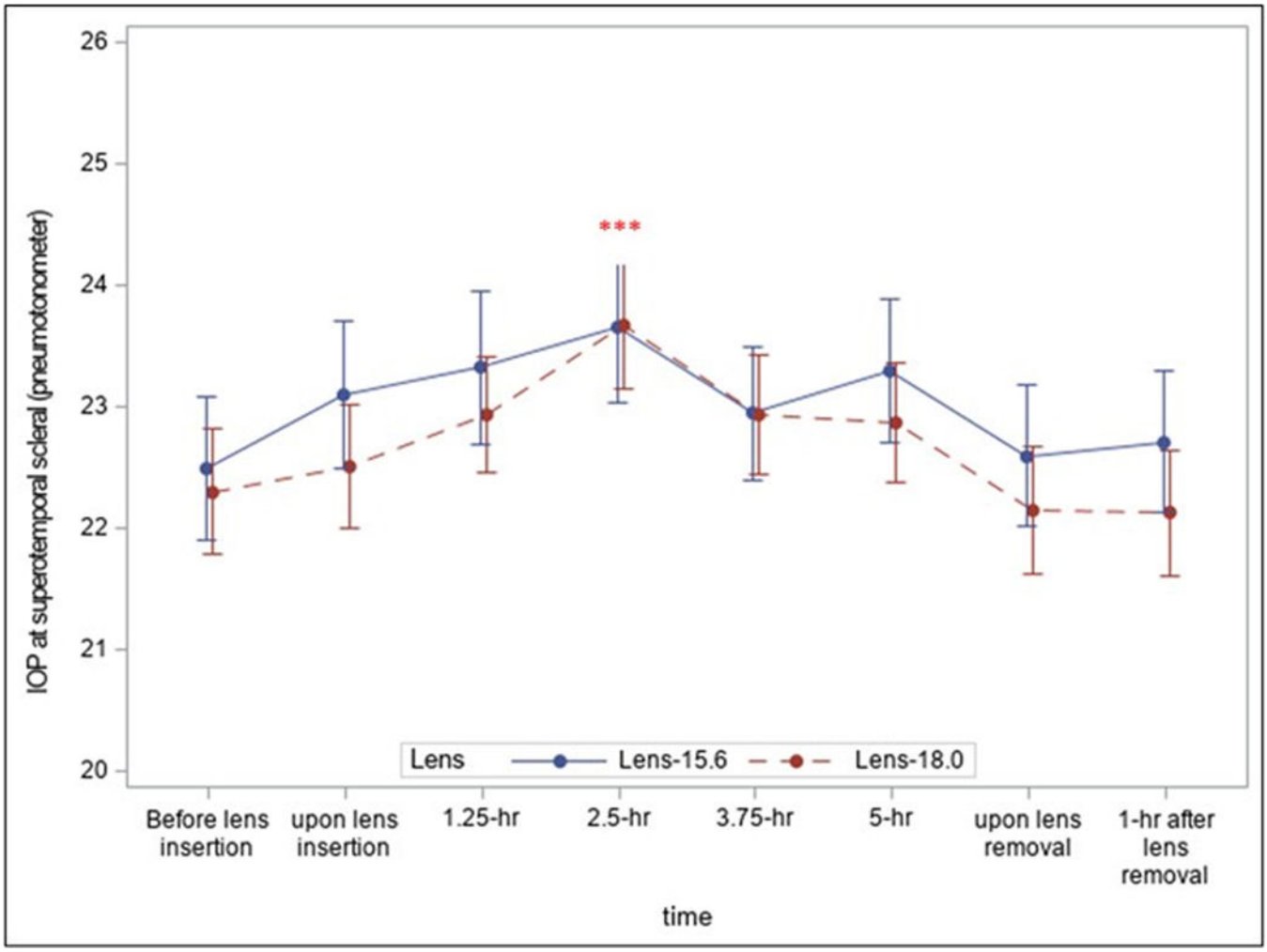

Figure 3.

Scleral IOP fluctuations with small and large scleral lenses on the eye. *** indicates statistically significant change from baseline for both small and large diameter lenses.

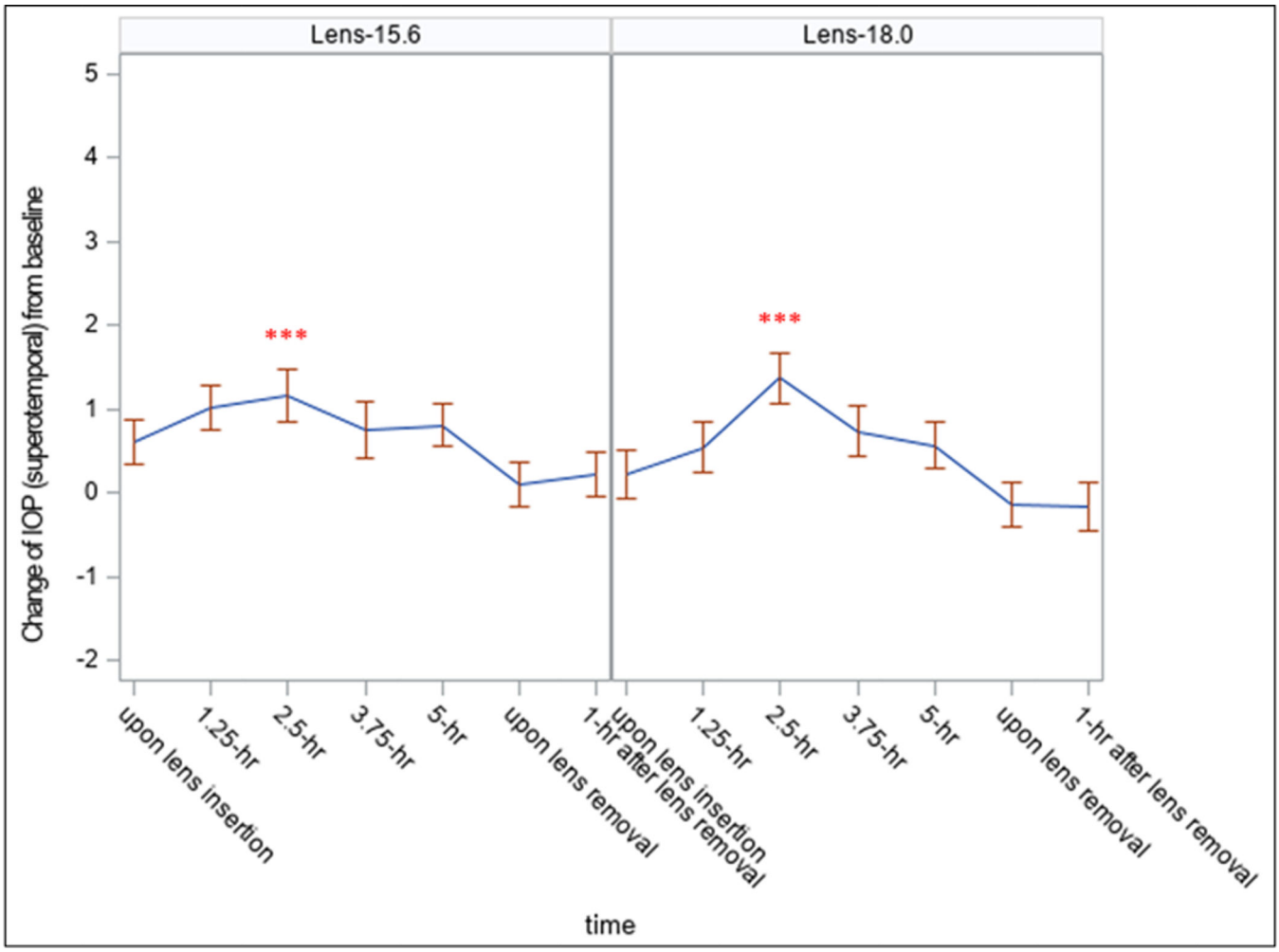

Figure 4.
Change in IOP from baseline with small and large scleral lenses on the eye

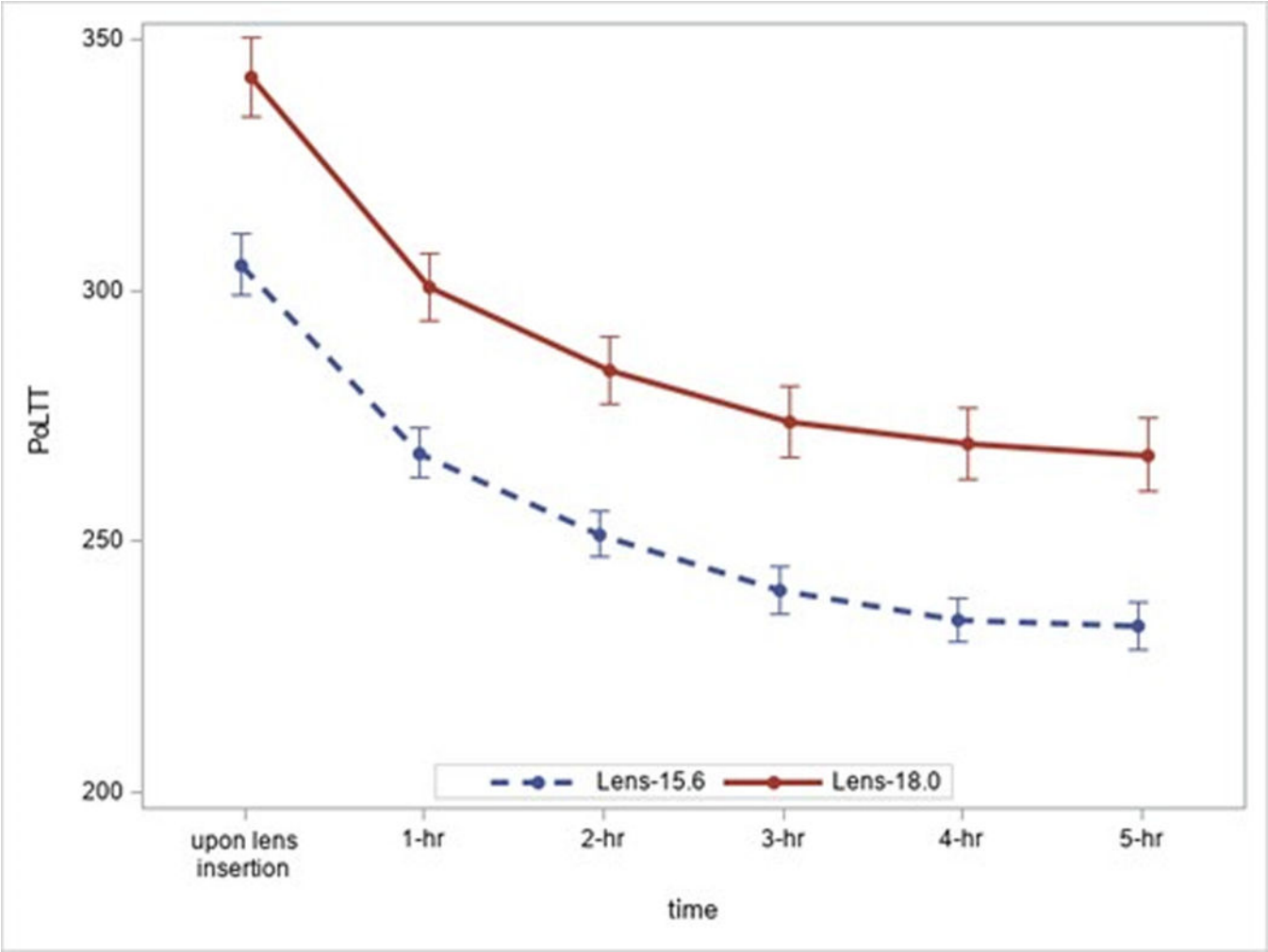

Figure 5.
Scleral lens settling shown as a measure of change in post lens tear thickness (PoLTT).

Table 1.

Age and Demographic distribution in the study sample

Age				
N	**Mean**	**SD**	**Min**	**Max**
30	28	9.8	18	53

Ethnicity	
Asian/Pacific Islander	18
Caucasian	6
Hispanic	4
Other (50% Asian/Pacific Islander, 50% Caucasian)	1
Other (50% Caucasian, 50% Hispanic)	1
Sex	
Female	22
Male	8

Table 2.

Central corneal IOP variation over a 5-hour period without scleral lenses. No changes in IOP were observed in this sample during the 5-hour period.

Pneumotonometry IOP (Central cornea)					
Visit	**N**	**Mean [95% CL]**	**Min**	**Max**	**Adj. *P*-value (ref=Baseline)**
Baseline	60	17.53 [16.93, 18.12]	12.83	22.17	-
2.5-hour	60	17.46 [16.88, 18.05]	12.17	21.00	0.939
5-hour	60	17.31 [16.83, 17.79]	12.00	20.00	0.510

Table 3.

Superotemporal scleral IOP variation over a 5-hour period without scleral lenses. No changes in IOP were observed in this sample during the 5-hour period. Note: Subject #1, 3, 4, 5, 6, 7, 8, 10 did not have IOP measured at 1.25-hr and 3.75hr

Pneumotonometry IOP (Superotemporal)					
Visit	**N**	**Mean [95% CL]**	**Min**	**Max**	**Adj. *P*-value (ref=Baseline)**
Baseline	60	21.96 [20.85, 23.08]	13.33	32.17	--
1.25-hour	44	22.68 [21.42, 23.93]	15.83	34.83	0.921
2.5-hour	60	22.37 [21.18, 23.55]	13.33	33.33	0.986
3.75-hour	44	22.72 [21.46, 23.97]	12.67	34.67	0.906
5-hour	60	22.47 [21.33, 23.61]	15.17	34.17	0.969

Table 4.

Pneumotonometry measurement times from the awake time (hours)

Time	Mean	Std Dev	Min	Max
Before lens insertion	3.1	0.7	2.4	5.1
Upon lens insertion	3.1	0.7	2.2	5.2
At 1.25 hrs after lens insertion	4.4	0.8	3.5	6.4
At 2.5 hrs after lens insertion	5.6	0.7	4.6	7.7
At 3.75 hrs after lens insertion	6.9	0.8	5.9	9.0
At 5 hrs after lens insertion	8.2	0.8	7.2	10.4
Upon lens removal	8.5	0.7	7.7	10.5
At 1 hr after lens removal	9.5	0.7	8.6	11.5

Table 5.

Pneumotonometry measurement times from lens insertion (hours)

Time	Mean	Std Dev	Minimum	Maximum
t1 (upon lens insertion)	0.02	0.01	0.00	0.05
t2 (1.25 hr)	1.24	0.04	1.13	1.38
t3 (2.5 hr)	2.50	0.04	2.33	2.67
t4 (3.75 hr)	3.74	0.05	3.58	3.88
t5 (5 hr)	5.12	0.07	4.95	5.42