Contact Lens and Anterior Eye 42 (2019) 104–110

Contents lists available at ScienceDirect

Contact Lens and Anterior Eye

journal homepage: www.elsevier.com/locate/clae

Intra-ocular pressure variation associated with the wear of scleral lenses of different diameters

Langis Michaud[a,*], Dan Samaha[a], Claude J. Giasson[a,b]

[a] École d'optométrie, Université de Montréal, 3744 Jean-Brillant, Suite 270, Montreal H3T 1P1, Canada
[b] Centre de Recherche en Organogénèse Expérimentale de l'Université Laval/LOEX et le Centre Hospitalier Universitaire de Québec, Hôpital du Saint-Sacrement, Québec, Canada

ARTICLE INFO

Keywords:
Scleral lenses
Intra-ocular pressure
Transpalpebral tonometry
Glaucoma

ABSTRACT

Purpose: To evaluate the variation of intra-ocular pressure during scleral lens wear, and the influence of the lens diameter on the results.
Methods: This is a prospective, randomized study performed on Caucasian subjects (16 F; 5 M), aged 24.7 + 4.1 y.o. A diurnal variation pattern (IOPg) was established, then, transpalpebral IOP (IOPt) was taken before and during SL wear. One eye, randomly fitted with a 15.8 diameter SL (L1), was compared to the fellow eye, fitted with an 18 mm SL of the same design, thickness and material (L2). Anterior segment tomography was taken pre-and after lens removal.
Results: Baseline IOPg (L1:15.2 + 3.1 mm HG; L2: 15.1 +/− 2.8 mm) did not reveal significant diurnal variations. Wearing L1, IOPt rose from 10.1 + 1.9 mm HG to 14.4 + 5.5 mm HG after 4.5 + 0.3 hrs, while with L2, it rose from 9.2 + 2.1 mm HG to 14.4 + 4.8 mm Hg. This difference is statistically significant based on time but not on lenses. Anterior segment parameters did not vary except for the anterior chamber volume (L1: −1.53 + 7.61 mm^3; L2: −3.47 + 6.4 mm^3), and for the corneal thickness (+2.1% with L1 and L2).
Conclusion: These results suggest that, as evaluated with a non-standard transpalpebral methodology, IOP during scleral lens wear may be increased in average by 5 mm Hg, regardless of the lens diameter. More work is needed to confirm if practitioners should be warned when using SL on populations at risk for glaucoma.

1. Introduction

The benefits of scleral lenses have been extensively described [1], but there remain some unanswered questions about their long-term safety and outcomes. For instance, the possibility of scleral lenses elevating intraocular pressure (IOP), has been raised [2]. One hypothesis is that, because of their mass and size, scleral lenses may compress episcleral veins, and reduce aqueous drainage facility in susceptible individuals [3]. Another possibility is that lens bearing zones may applanate and/or indent the ocular surface and displace intraocular fluid so that IOP becomes elevated. In this respect, the area and depth of indentation in lens bearing areas appears likely to be determined by the degree of fitting tightness [2]. To the extent that a less rigid sclera is easier to applanate and/or indent in scleral lens bearing zones, a thin sclera is also considered a risk factor [4]. Validation of one or more of these hypotheses would suggest an increased risk factor to be considered when fitting scleral lenses for glaucoma patients or glaucoma suspects [3], especially those with narrow irido-corneal angles (ICA) or with less rigid sclerae.

Contradictory clinical results have been reported. IOP variation, following the short-term wear (25 min) of a scleral lens made of glass, was reported as early as in 1951 [5]. This study was made on 33 subjects and pressure was evaluated with Schiötz tonometer shortly after glass lens removal. A vast majority (25/33) of the subjects showed variable IOP increase (+2 mm HG up to + 30 mmHg), while others were stable (2/33) or had a decrease compared to baseline IOP (5/33). Author associated IOP rise to compression of aqueous veins by a scleral lens with "narrow haptics" (not defined) and reported a rapid recession of the pressure when the lens was removed. Using modern gas permeable scleral lenses, in another study, IOP measured from the sclera with pneumotonometry was found to be, on average, not significantly different from baseline, although an IOP elevation was recorded for a small minority of subjects [3]. Another study found a reduced IOP, measured with an air-puff tonometer, after 3 to 8 h of scleral lens wear [6]. However, depending on aqueous humor drainage facility, elevated IOP could increase aqueous humor outflow during lens wear and

* Corresponding author.
E-mail address: langis.michaud@umontreal.ca (L. Michaud).

https://doi.org/10.1016/j.clae.2018.07.004
Received 23 May 2018; Received in revised form 13 July 2018; Accepted 19 July 2018

explain lower IOP recorded on lens removal [2]. The use of Honan balloon [7], ocular massage before cataract surgery [8] and tonographic assessments [9] illustrate how elevated IOP can be reduced over time by accelerating aqueous outflow from the eye. According to this hypothesis the facility of aqueous outflow and the level of any IOP elevation during scleral lens wear would help determine post-wear IOP and thus explain the lower IOP measurement for subjects with normal outflow facility which is unrestricted by the lens. On the other hand, this implies that outflow facility may be less efficient in subjects who do not have lowered IOP after scleral lens wear. Finally, elevations in IOP were recorded for two of five subjects while wearing scleral lenses of 16.5 mm of diameter, a variation which persisted 4 to 8 h later [10]. More recently, a study made on 9 patients, wearing a 15.8 mm scleral lens on one eye for 8 h, confirmed a similar IOP increase of 5.81 ± 1.62 mm Hg as measured in the central cornea with iCare tonometer just after lens removal. However, this value does not take corneal central thickness in account [11]. Apart from restricted aqueous outflow, any rise in IOP is at least partly due to the degree to which intraocular fluid is displaced by 'tangential applanation' of the sclera according to its depth and area of indentation. It has been suggested that such an increase of IOP could be more severe if smaller scleral lenses were used, on the basis that the distribution of bearing zones are reduced for smaller diameter lenses with reduced scleral portions [3]. According to this hypothesis, and based on the new definition of the corneo-limbal diameter (14 mm vs 11.8) recently suggested by Bergmanson [12], a larger lens would have wider distribution of contact with the ocular surface and induce less indentation into it, in a manner similar to a snowshoe supporting a heavy weight on snow. This echoes to another study made with goggles, which showed that the area of compression and the level of pressure applied, and not the scleral rigidity by itself, are the factors to consider to explain scleral lens induced effect on IOP [13].

Hence, it is possible that greater conjunctival compression and increased applied pressure, may be associated with tighter lenses, and greater risk of IOP elevation. A scleral lens, designed with spherical haptics, fitted on an astigmatic sclera may cause greater total indentation along the flattest meridian. It may then be preferable to fit toric peripheral curves whenever conjunctival toricity becomes clinically significant. However, the peripheral toric lens may cause other issues, such as induced greater sub-atmospheric pressure under the lens since post-lens tear circulation may be restricted by closer alignment of the lens-with the sclera.

Another element to consider is that scleral lens stabilization and settling has been measured by evaluating the fluid loss [14–16] or by degree of conjunctival compression [16]. In this study, conjunctival and episcleral tissues remained compressed for a few hours after scleral lens wear. This may influence the IOP measurement made shortly after lens removal. Open-eye and blink-related lid forces can also be expected to exert a significant influence on lens compression forces. For example, Alonso-Caneiro and co-authors [16] reported greater conjunctival compression in the superior quadrant with scleral lens wear.

Considering all of these factors, and the fact that contradictory results are still debated, this study aims to examine the influence of scleral lens wear on IOP by assessing IOP during wear of lenses of different diameters while variation of anterior segment parameters (irido-corneal angle, anterior chamber volume, corneal front and back central curvatures) are monitored.

2. Methods

This is a prospective, randomized, controlled study, conducted in adherence to the tenets of the Declaration of Helsinki. It was approved by the Université de Montreal (UM) review board for experimentation on humans. Participants were recruited at the UM-Clinique Universitaire de la Vision, via posters and social networks. Written consent was obtained from the 21 subjects recruited, after they had been fully informed of the goals and procedures of the study. Subjects were at least 18 years old and found to be free of any systemic or ocular diseases. Specifically, they were not known as being at risk for glaucoma and had no known familial history for this pathology. In addition, these subjects reported no previous eye surgery and their corneas were found to be normal under topography and past slit lamp exams. Five participants had been wearing silicone hydrogel disposable contact lenses on a regular basis (> 4 days/week; > 8 h00 /day). They were asked to stop contact lens wear 72 h before the beginning of the study. All participants were required to be available for three consecutive days, during which testing sessions started between 8:30 am and 10:00 am. The first session (day 1) was necessary to establish inclusion criteria and to determine the pattern of individual IOP diurnal variation over this time interval, using Golmann tonometry (IOPg), to guarantee the validity of this result.

The second session (day 2) involved scleral lens fitting. The third session (day 3) was dedicated to lens application and IOP assessment with lenses in situ at baseline, then taken again during a forth session 5h00 later. The only technology relatively available allowing IOP measurement during scleral lens wear is transpalpebral technology tonometer (Diaton, Bicom Ophtalmics, USA). This instrument measures the resistance of the eyelid, the conjunctiva and sclera and coverts it to an estimate of intraocular pressure. It was found that this type of measurement offers a fair agreement [17] with IOPg results, on normal corneas, although with higher variability [18]. On the other hand, Wisse and coauthors found poor agreement between IOPt and IOPg results for irregular cornea patients [19]. A recent review published article summarized the findings about this technology, proving that it may be used with efficacy as a screening device, and to evaluate IOP when other methods cannot be applied, which is the case when scleral lenses are worn. Especially, transpalpebral Diaton tonometry (DT) is recommended for screening in young (20–50 y.o.) and healthy subjects [20]. However, authors caution to do not use it to establish a glaucoma diagnosis [21], precluding it from being considered as equivalent to Goldmann tonometer [22]. To make things perfectly in perspective, Diaton was used here because this study is concerned with any change in IOP with lenses in situ, using the same tonometer, pre and during lens wear, when no other reliable methods can be used, rather than to compare Diaton to any instrumentations or to diagnose ocular pathology related to scleral lens wear.

To perform this type of testing, there is no need to use anesthetic drops for DT. Subject are reclined in an exam chair with their head supported to achieve a close to supine orientation and their gaze on an index finger to achieve primary gaze fixation. The observer then uses a finger to position the upper lid margin about 1 mm above the visible iris periphery by gently pulling the skin over the supraorbital margin so that finger or extra lid pressure on the globe is either avoided or limited to a minimum. The tip of the tonometer is then placed vertically over the tarsus. The operator makes sure that the tonometer is not in contact with the lens edge. The DT emits a warning beep sound if the position is not vertical as it is lowered toward the lid. A measurement beep is heard before there is any pressure on the lid. The tonometer is tilted back from vertical to reset the scale for each of the two following measurements after which the average of the three measurements is displayed. Not knowing each value, it is impossible to report variability within these measurements. In this study, all DT measures were made by the same experienced observer to reduce the variability in the measurement process.

A 15.8 mm diameter scleral lens (L1), plano power, in Boston XO material (Laboratoires Blanchard, Canada) was fitted on one randomly selected eye. The fellow eye was fitted with the same lens but with an 18.0 mm diameter (L2). Both lenses were designed with spherical haptics and none carried fenestrations. Each lens type was fitted with an intended initial central clearance of 300 µm (at insertion) according to the manufacturer's recommendations. The central clearance and the absence of contact on any part of the cornea or the limbus were

determined by anterior segment ocular coherence tomography (OCT) (OptoVue, Clarion, USA) after 30 min of lens stabilization. Slit lamp examination was also conducted to ensure that there was no obvious conjunctival compression associated with the final experimental lens chosen during the fitting sequence. Baseline lens in situ IOPt was recorded as were, prior to lens application, baseline findings for anterior central and posterior corneal curvatures, corneal pachymetry, irido-corneal angle, as well as anterior chamber depth and volume, using different maps taken with Scheimpflug technology tomography (Pentacam, Oculus, USA). Three measurements were made for each eye and the results were averaged. Auto-refraction indicated an appropriate spherical over-correction and a high DK thin silicone daily disposable soft contact lens (senofilcon A, 0.085 mm @ -3.00D, Johnson & Johnson Vision Care, USA) was inserted on top of the scleral lens to allow the patient to remain functional (at least 20/30 visual acuity) during regular daily activities. Subjects were asked to come back 4–5 h later. Instructions were given to refrain from consumption of caffeine or any other stimulant that might have the potential to increase IOP, as well as to refrain from any form of strenuous physical activity because exercise-related Valsalva maneuvers and strenuous muscular efforts are known to have the potential to elevate intra-ocular pressure [23]

Subjects were again examined after having worn the scleral lenses for 4–5 hours when IOPt measurements were repeated. The scleral lens was then carefully removed by a member of the research team, using a small plunger to avoid inducing excessive pressure on the ocular surface during the process [24]. Ocular tomography was immediately performed followed by a final slit lamp examination to assess ocular health. The procedure was repeated for the fellow eye. In the absence of any significant adverse slit lamp findings, the subject was then discharged.

3. Statistical analysis

Differences between the IOPg obtained in the morning and 5 h later were tested for statistical significance with a two-way repeated measures analysis of variance A two-way repeated measures analysis of variance was also used to test the effect of time (pre-post wear) and lens on IOP. Similar repeated measures ANOVAs were used, on a smaller set of data because of unreliable/unreadable Scheimpflug maps, to test the effect of time and lens on values of 1) front and 2) back surface flat and steep curvatures of the cornea, 3) corneal thickness, 4) the volume and 5) depth of the anterior chamber and 6) the irido-corneal angle to the corresponding measurements acquired after lens removal. In order to keep these ANOVAs as simple as possible, differences between the right and left eyes were not included in the model so that results obtained in either eye were considered as repeated-measures on the same subject. These analyses were conducted with the SPSS software (IBM Corp, Armonk, NY) or with the statistical shareware Jeffreys's Amazing Statistics Program, (JASP) (Version 0.8.6) for Windows (https://jasp-stats.org/).

4. Results

The mean age for the subjects (16 females and 5 males), was 24.7 ± 4.1 years. Table 1 summarizes the profile of the lenses fitted.

Table 1
Paramters of the lenses tested.

	L1	L2
Lens Diameter	15.8	18.0
Average sag (um)	4 100 ± 125	4 400 ± 160
# lenses to reach optiomal fit	1.2 ± 0.5	1.4 ± 0.6
Lens thicknesses (um)	315.1 ± 0.7	309.5 ± 1.3
Central clearance (um)	329.7 ± 34.7	324.5 ± 32.3

4.1. Diurnal IOP variation

The initial IOPg was for the right and left eyes 15.2 ± 3.1 and 15.1 ± 2.8 mm HG in the morning, respectively. Corresponding values of IOPg measured 4.5 ± 0.3 h later were 15.1 ± 2.1 mm and 14.8 ± 2.5 mm Hg. There was no interaction between time and side and neither the effect of time ($p = 0.593$) or side ($p = 0.255$) was significant. Considering that there is no difference between the two eyes, randomization for the lens wear is not affected by subject's initial IOP.

4.2. IOP variation induced by lens wear

For the eye wearing a smaller scleral lens (L1) mean initial IOPt was 10.1 ± 1.9 mm Hg, rising to 14.4 ± 5.1 mm Hg, 4.5 ± 0.3 h later. For the larger lens (L2) initial IOPt was 9.24 ± 2.1 mm Hg rising to 14.4 ± 4.8 mm Hg. (see Fig. 1) Because there is no significant interaction between the main parameters (lens diameter and time), it is possible to evaluate their separate effects on IOP. Time exerted a statistically significant effect on IOPt ($F = 35.186$; $p = 0.000$) but not lens diameter (L1 vs L2), with an average increase of 4.4 ± 5.0 mm Hg and 5.2 ± 4.1 mm Hg respectively ($F = 0.694$; $p = 0.415$). As expected, there is a high inter-subject variability. Four subjects (19%) showed no difference or lower IOPt post-wear, with L1, compared to only one eye (4%) wearing a larger lens(L2). Four eyes (19%) had their IOP raised by 10 mm Hg and more with L1, compared to 3 eyes (14%) fitted with L2. The highest IOPt increase observed for each lens were +15 mm Hg (L1) and +17 mm Hg (L2) from baseline.

These results indicate that scleral lenses can induce a statistically significant IOPt increase for a majority of subjects after 4 h of wear. This variation was similar, considering two different lens diameters but was highly variable among subjects.

4.3. Corneal and anterior segment parameters

Average corneal diameter was 11.6 ± 0.3 mm (L1) and 11.5 ± 0.4 mm (L2), not showing any statistical difference ($p = 0.408$). There was also no significant variation in corneal curvature (see Figs. 2 and 3), to the exception of a slight but significant flattening of the steep curvature on the anterior surface ($F = 15{,}352$; $p = 0.001$), as it was already reported after scleral lens wear [25,26].

The effect of time on corneal thickness was significant ($F = 17.788$; $p = 0.002$): both lenses induced central corneal swelling after 4.3 h of wear, - see Fig. 4 (L1: 2.2 ± 0.8%; L2: 2.1 ± 0.6%). Neither the effect of time nor the one of lens on the irido-corneal angle were significant, despite that on average, the irido-corneal angle increased by 0.15° with L1, varying from 42.72° to 42.87°, but decreased by 0.18° with L2, from 42.35° to 42.17°. There was no significant effect of time or lens on the anterior chamber depth or volume. The volume of the anterior chamber was found to be reduced with both lenses (L1: -1,53 ± 7.61 mm^3; L2: -3.47 ± 6.4 mm^3) For this parameter, there was also a high variability in subjects response.

5. Discussion

The results presented here confirm that IOPt, taken with non-standard transpalpebral technique, rises by an average of 5 mm Hg if we compare pre-lens insertion values and those taken after 4.3 h of wear. This finding seems to confirm what was already established 50 years ago. In fact, by examining the force required to remove scleral lenses Miller and Carroll demonstrated that lens tightness could generate a sub-atmospheric pressure of 5–18 mm [27], in the reservoir anterior to the cornea. Similarly, it has been shown that IOP can be increased by applying a suction cup to the bulbar conjunctiva [28].

Scleral lenses may take up to 8 h to complete the stabilization process [15,29,30], time being influenced by factors such as lens design, conjunctival anatomy, lid forces on the lens, the force used to

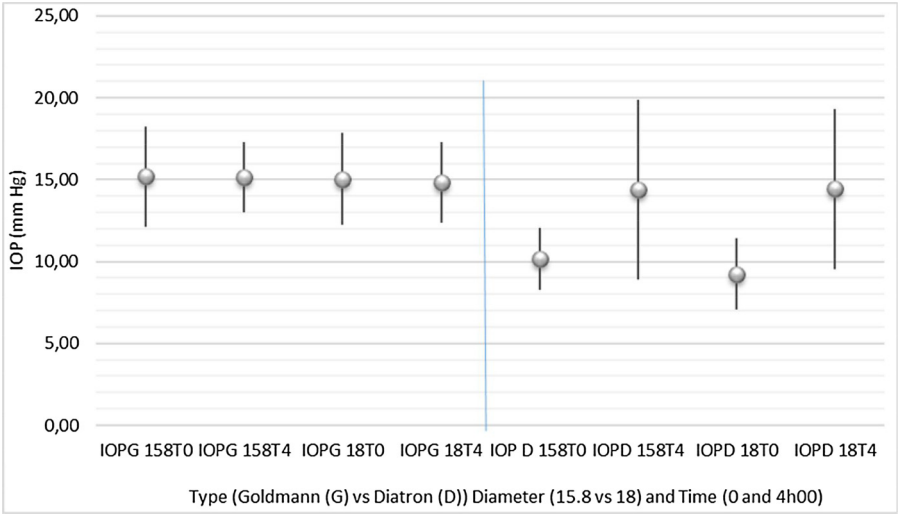

Fig. 1. IOP vs time and lens diameter.

apply the lens, etc. However, for the lens design used in this study, it is recognized that nearly 90% of the settling is completed after 4h00 of wear [31], which leads us to speculate that our results might be representative of responses to habitual wear with the lenses used in this study or with a similar design.

As explained earlier, there are two ways to increase ocular pressure: by restricting the aqueous outflow or by displacing the intraocular fluid by tangential applanation of the sclera. Compression of the conjunctiva is higher when scleral lenses are fitted tighter. Tightening of the lens occurs while the scleral lens sinks in the conjunctiva. Some patients present a smoother conjunctival tissue, allowing for more lens sinking and then more compression, explaining the inter-subject variability seen in this study.

5.1. Influencing factors

Although baseline IOPt values were lower than baseline IOPg values, which is expected [21], results presented here are unlikely to be affected by IOP diurnal variation, as demonstrated by the diurnal tension curve performed during the same 4 h of the day when lenses were not yet being worn.

The absence of difference based on the lens diameter seems to contradict the previous hypothesis, as smaller lenses were thought to land very close to the newly defined average corneo-limbal area [12], potentially penalizing the aqueous outflow facility [2] and possibly extending their compression up to Schlemm's canal. It is important to remember that one factor to consider here is the primary functional diameter (PFD) of the lens, which is defined by the chord where the lens lands on the conjunctiva, and not the overall lens diameter. In this study, PFD is relatively similar in both lenses: 13.8 mm for the 15.8 mm lens and 14.4 mm for the 18 mm for L2. Consequently, because of the fact that PFD is almost the same for the two lenses, similar results can be expected.

Neither the scleral thickness, tissue compression, the episcleral vein network, nor Schlemm's canal were directly evaluated during our experimentation. It is not possible, therefore, to comment on the validity of this theory. However, one may think that both lenses were supported by a sclera that is, in general, stiffer closer to the limbus and softer toward the posterior pole [32], limiting the perceived benefit of a larger diameter lens. In fact, this study brings indication about the absence of the overall lens diameter as a factor that may influence IOP. Based on the results, it is possible to suggest that the net tightening effect seems to be the same, regardless of the lens size. This may imply that the "snowshoe" effect is non-existing for most patients, becauce the landing of the lens, determined by the primary functional diameter (and not the overall one), always occurs near the limbus (as newly defined), no matter if the lens is 15.8 or 18 mm in diameter. Obviously, such conclusion is not definitive and will have to be correlated with other

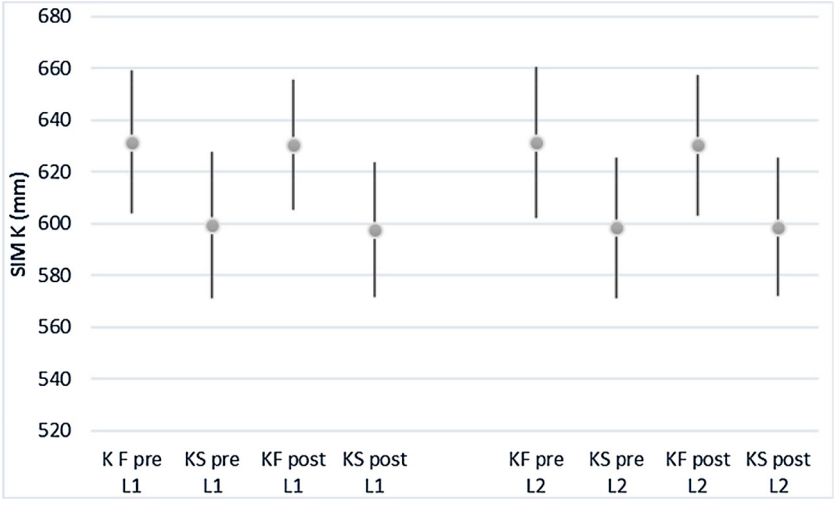

Fig. 2. Back central corneal curvatures Pre and Post lens wear.

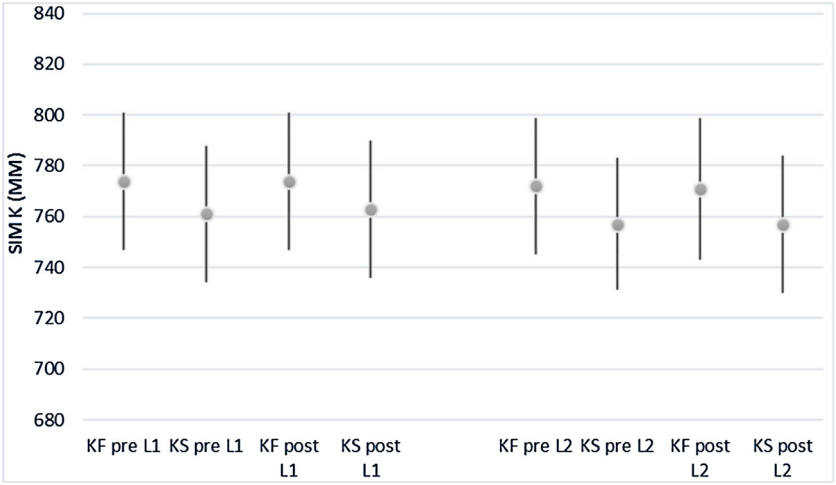

Fig. 3. Front central corneal curvatures Pre and Post lens wear.

studies in which the ideal protocol would imply to fit the 18 mm diameter lens to the same eye that wore the 15.8 mm diameter, but on a separate day, in a randomised order.

A second possibility is that the number of enrolled subjects was too low to detect such a difference. Nonetheless, the data are quite clearly demonstrating the absence of difference between larger and smaller lenses, and consequently the non existence of snowshoe effect in scleral lenses.

5.2. Corneal changes

Corneal shape changes under transient elevated IOP are not expected. This was confirmed in this study. There were almost no significant tomography changes detected for corneal posterior and anterior central curvatures, ICA, and anterior chamber depth (ACD), except for a minimal variation of the anterior chamber volume (ACV). This factor did not influence our results, assuming that IOP variation is not related to ACD and ACV modifications, but more likely to an opening of the irido-corneal angle [33], a factor that remained stable among study subjects.

Another significant difference was found in pachymetry, likely due to corneal edema. Despite data missing for a few subjects, our analysis proved that, with both lenses used, the cornea showed a statistically significant swelling of 2.1–2.2% (L1 and L2). Such increased pachymetry is expected, based on theoretical models [34,35], because average thick scleral contact lenses (> 300ɥm), fitted with a larger tear fluid layer (> 300 ɥm of clearance), were used as a representation of the average recommended lenses from the manufacturers. This type of combination does not meet the minimal requirements to alleviate hypoxia [36], as corneal epithelial pO_2 beneath scleral lenses fitted with a clearance of 200 ɥm, has been recently shown to be below those required to avoid hypoxia [37]. What is a new finding here is the possibility that edema may be favored also as a consequence of pressure variation [38].

In addition, the use of a soft lens on top of the scleral one contributed to reducing slightly the DK/t of the overall system. Based on the fact that the soft lens (85 um for the lens thickness; with a DK/t of 103), the scleral lens (see Table 1), and the tear layer can be considered reservoir in series, L1 generated a DK/t of 12.3 Fatt units and L2 of 12.5 Fatt units, compared to 13.7 and 14.0 Fatt units respectively, without the piggy back system. Both do not meet minimal criteria to alleviate hypoxia. The level of corneal swelling measured here is similar to those published [39] when similar scleral lenses are used alone.

Considering this hypoxic stress (2.1%) benign and as similar to physiological edema [40] is misleading, because it is constant during all wearing hours, and the cornea is never able to reach a new steady state of hydration. Interestingly, hypoxia cannot be minimized by tear exchange, which remains minimal under scleral lenses [41] except if the lens is designed with channels or is ventilated [42].

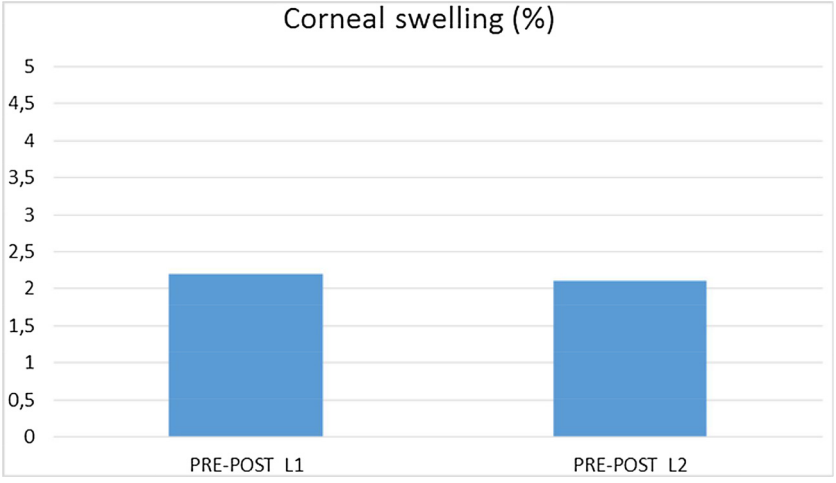

Fig. 4. Central corneal thickness over time.

5.3. Clinical implications

The fitting of the scleral lenses was performed with diagnostic lenses and was not entirely optimized, especially for the landing zone. There was no compression seen under slit lamp exams and OCT evaluation, but the results may be different with the use of fully customized, quadrant specific designs before making IOP comparisons. A recent clinical tendency is to closely align the lens peripheral curves to the conjunctival shape [43]. It is possible to make the hypothesis that such a closed alignment may increase lens tightening and can infuence IOP in consequence.

Elevated IOP is a positive risk factor for the development of glaucomatous optic nerve damage and visual field loss [44]. Lowering IOP slows the rate of progression of glaucomatous optic nerve damage, regardless of the state of the disease [45] and avoiding chronic ocular hypertension may be equally important [46].

Scleral lenses are being fitted for many ocular conditions and increasingly on normal corneas, and any associated IOP elevation may represent a significant risk, at least for glaucoma patients and glaucoma suspects. For example, think of African American [47], Latinos with African American ancestry [48] any patient with positive familial history for glaucoma, patients with thin corneas [49] and those under systemic medication known to increase IOP.

It was also demonstrated that a keratoconus cornea shows an abnormal response to increased IOP [50]. Normal-tension glaucoma prevalence is reported higher in this clinical population, as a consequence of the altered bio-mechanical properties of the lamina cribosa [51]. Risk factors in keratoconus patients also include sleep apnea as a strong association between sleep apnea, glaucoma and keratoconus has been demonstrated [52].

This does not imply that scleral lens fitting of the products used here (or of similar designs) should be considered a total contra-indication on these at risk populations, but their use should however be based on a low risk/high benefit ratio [53]. These patients should be monitored closely to track subtle early glaucomatous signs or changes. In such cases, scleral lens design should be modified to favor tear exchange and release compression on the conjunctival tissue. Switching to other lens modalities may be also considered.

This study may be biased by the relatively low number of patients involved and by the fact that the instrument used to assess IOP is not widely recognized as a standard of care. Limitations about this technology are mostly related to the manipulations made to acquire IOP readings. First, the eyelid is manipulated to obtain a reading and therefore the device may not be applied at the same position of the eyelid pre and post lens wear. Second, pressure is applied to the eyelid and globe during the procedure and this may potentially increase or decrease the IOP estimate. The amount of external pressure may be difficult to control across two different time points. Third, the measurement is also influenced by the position of the device upon the sclera. This could also be difficult to control at two different time points. Importantly, the thickness of the sclera adjacent to the lens edge changes during scleral lens wear which may also influence the estimate of IOP. Despite all precautions made to minimize these impacts, and the fact that the same technician reproduced the same procedure for all patients, it is not possible to totally exclude that this methodology generated a transient increase in IOP during manipulation of the eye, which can briefly increase aqueous humor outflow. It may be possible to relate higher measurements to a partial touch of the lens edge during the procedure. Moreover, IOP was not monitored just after lens insertion, to evaluate whether the increase in IOP seen after 4 h of wear could occur immediately after lens insertion. The results should then be interpreted considering these significant limitations, acknowledging that it is the only clinically available technology to evaluate IOP during scleral lens wear. However, to do not report such findings, with the potential clinical consequences implied, is certainly not optimal as well, if not non ethical. Further studies, monitoring the intraocular pressure with a more ideal technology, at several intervals could be useful. As Pearsons suggested [54], longitudinal studies may also be required.

Finally, our clinical population was young and moderately myopic, with very limited risk factors for glaucoma. Consequently, conclusions only apply to a similar group of patients, not excluding that other groups may show comparable outcomes.

6. Conclusion

The results of this study suggest that scleral lens wear may be associated with increased ocular pressure by up to 5 mm Hg, after 4 h of wear, as measured with a screening device (Diaton tonometer) on a regular cornea population. Scleral lens diameter does not seem influence this outcome. More clinical work is needed to confirm if practitioners should be warned to take precautions and to follow more closely patients when using scleral lenses on populations at risk for glaucoma.

Aknowledgements

Authors are grateful to Pr. Charles McMonnies for providing theoretical background during interesting exchanges about this study and its implications.

Authors want to thank Laboratoires Blanchard (Sherbrooke, Canada) for providing the lenses used in this study.

Finally, we want to recognize the contribution of Gabrielle Julien, Michael Morasse, Christopher Tambasco, undergraduate students, who participated in the data collection for this study.

References

[1] M.M. Schornack, Scleral lenses: a literature review, Eye Contact Lens 41 (1) (2015) 3–11.
[2] C.W. McMonnies, A hypothesis that scleral contact lenses could elevate intraocular pressure, Clin Exp Optom 99 (6) (2016) 594–596.
[3] C.B. Nau, M.M. Schornack, J.W. McLaren, A.J. Sit, Intraocular pressure after 2 hours of small-diameter scleral Lens Wear, Eye Contact Lens 42 (6) (2016) 350–353.
[4] C.W. McMonnies, Response to Re: a hypothesis that scleral contact lenses could elevate intraocular pressure, Clin Exp Optom 100 (1) (2017) 104.
[5] A. Hugert, Increase of the intraocular pressure when using contact glasses, Acta Ophthalmol (Copenh) 29 (4) (1951) 475–481.
[6] S.J. Vincent, D. Alonso-Caneiro, M.J. Collins, Evidence on scleral contact lenses and intraocular pressure, Clin Exp Optom 100 (1) (2017) 87–88.
[7] P.J. McDonnell, H.A. Quigley, A.E. Maumenee, W.J. Stark, G.M. Hutchins, The Honan intraocular pressure reducer. An experimental study, Arch Ophthalmol 103 (3) (1985) 422–425.
[8] J.T. Ernest, T.K. Goldstick, M.A. Stein, J.D. Zheutlin, Ocular massage before cataract surgery, Trans Am Ophthalmol Soc 83 (1985) 205–217.
[9] J.H. Eriksen, T. Odberg, Experimental tonography on enucleated human eyes. II. The loss of intraocular fluid caused by tonography, Invest Ophthalmol 14 (12) (1975) 944–947.
[10] E. Korszen, P. Caroline, B. Kinoshita, M. Lampa, Does scleral lens wear influence intraocular pressure? Poster- GSLS (2017).
[11] A.P. Aitseabomo, J. Wong-Powell, W. Miller, A. Farshid, Effect of scleral Lens Wear on intraocular pressure, Available from: (2018) https://ep70.eventpilot.us/web/page.php?nav=false&page=IntHtml&project=ARVO18&id=2923528.
[12] J.P. Bergmanson, J.G. Martinez, Size does matter: what is the corneo-limbal diameter? Clin Exp Optom 100 (5) (2017) 522–528.
[13] A.P. Paula, J.S. Paula, M.J. Silva, E.M. Rocha, C.G. De Moraes, M.L. Rodrigues, Effects of swimming goggles wearing on intraocular pressure, ocular perfusion pressure, and ocular pulse amplitude, J Glaucoma 25 (10) (2016) 860–864.
[14] F. Esen, E. Toker, Influence of apical clearance on mini-scleral lens settling, clinical performance, and corneal thickness changes, Eye Contact Lens 43 (4) (2017) 230–235.
[15] S.J. Vincent, D. Alonso-Caneiro, M.J. Collins, The temporal dynamics of miniscleral contact lenses: central corneal clearance and centration, Cont Lens Anterior Eye 41 (2) (2018) 162–168.
[16] D. Alonso-Caneiro, S.J. Vincent, M.J. Collins, Morphological changes in the conjunctiva, episclera and sclera following short-term miniscleral contact lens wear in rigid lens neophytes, Cont Lens Anterior Eye 39 (1) (2016) 53–61.
[17] S. Nadeem, B.A. Naeem, R. Tahira, S. Khalid, A. Hannan, Comparison of Goldmann Applanation, diaton transpalpebral and air puff tonometers, Pak J Ophthalmol 31 (1) (2015) 33–39.
[18] J.A. Cook, A.P. Botello, A. Elders, A. Fathi Ali, A. Azuara-Blanco, C. Fraser, et al., Systematic review of the agreement of tonometers with Goldmann applanation tonometry, Ophthalmology 119 (8) (2012) 1552–1557.
[19] R.P. Wisse, N. Peeters, S.M. Imhof, A. van der Lelij, Comparison of Diaton

transpalpebral tonometer with applanation tonometry in keratoconus, Int J Ophthalmol 9 (3) (2016) 395–398.
[20] Y. Li, J. Shi, X. Duan, F. Fan, Transpalpebral measurement of intraocular pressure using the Diaton tonometer versus standard Goldmann applanation tonometry, Graefes Arch Clin Exp Ophthalmol 248 (12) (2010) 1765–1770.
[21] A.K. Chakraborty, M. Maumder, S. Sen, Comparison of transpalpebral tonometer with Goldman aplanation tonometer, Taiwan J Ophthalmol 4 (2014) 110–115.
[22] M.D. Doherty, Z.I. Carrim, D.P. O'Neill, Diaton tonometry: an assessment of validity and preference against Goldmann tonometry, Graefes Arch Clin Exp Ophthalmol 40 (4) (2012) e171–e175.
[23] C.W. McMonnies, Intraocular pressure and glaucoma: is physical exercise beneficial or a risk? J Optom 9 (3) (2016) 139–147.
[24] J.A. Khan, B.A. LaGreca, Tono-Pen estimation of intraocular pressure through bandage contact lenses, Am J Ophthalmol 108 (4) (1989) 422–425.
[25] S.J. Vincent, D. Alonso-Caneiro, M.J. Collins, Miniscleral lens wear influences corneal curvature and optics, Ophthalmic Physiol Opt 36 (2) (2016) 100–111.
[26] S.J. Vincent, D. Alonso-Caneiro, M.J. Collins, Corneal changes following short-term miniscleral contact lens wear, Cont Lens Anterior Eye 37 (6) (2014) 461–468.
[27] D. Miller, J.M. Carroll, Corneal edema and scleral lenses, Int Ophthalmol Clin 8 (3) (1968) 623–635.
[28] G. Garhofer, H. Resch, G. Weigert, S. Lung, C. Simader, L. Schmetterer, Short-term increase of intraocular pressure does not alter the response of retinal and optic nerve head blood flow to flicker stimulation, Invest Ophthalmol Vis Sci 46 (5) (2005) 1721–1725.
[29] M.J. Kauffman, C.A. Gilmartin, E.S. Bennett, C.J. Bassi, A comparison of the short-term settling of three scleral lens designs, Optom Vis Sci 91 (12) (2014) 1462–1464.
[30] C. Bray, S. Britton, D. Yeung, L. Haines, L. Sorbara, Change in over-refraction after scleral lens settling on average corneas, Ophthalmic Physiol Opt 37 (4) (2017) 467–472.
[31] C. Courey, L. Michaud, Variation of clearance considering viscosity of the solution used in the reservoir and following scleral lens wear over time, Cont Lens Anterior Eye 40 (4) (2017) 260–266.
[32] A. Elsheikh, B. Geraghty, D. Alhasso, J. Knappett, M. Campanelli, P. Rama, Regional variation in the biomechanical properties of the human sclera, Exp Eye Res 90 (5) (2010) 624–633.
[33] W. Lee, H.W. Bae, C.Y. Kim, G.J. Seong, The change of anterior segment parameters after cataract surgery in normal-tension glaucoma, Int J Ophthalmol 10 (8) (2017) 1239–1245.
[34] L. Michaud, E. van der Worp, D. Brazeau, R. Warde, C.J. Giasson, Predicting estimates of oxygen transmissibility for scleral lenses, Cont Lens Anterior Eye 35 (6) (2012) 266–271.
[35] V. Compan, M. Aguilella-Arzo, T.B. Edrington, B.A. Weissman, Modeling corneal oxygen with scleral gas permeable Lens Wear, Optom Vis Sci 93 (11) (2016) 1339–1348.
[36] D.M. Harvitt, J.A. Bonanno, Re-evaluation of the oxygen diffusion model for predicting minimum contact lens Dk/t values needed to avoid corneal anoxia, Optom Vis Sci 76 (10) (1999) 712–719.
[37] C.J. Giasson, J. Morency, M. Melillo, L. Michaud, Oxygen tension beneath scleral lenses of different clearances, Optom Vis Sci 94 (4) (2017) 466–475.
[38] A. Elsheikh, C.W. McMonnies, C. Whitford, G.C. Boneham, In vivo study of corneal responses to increased intraocular pressure loading, Eye Vis (Lond) 2 (2015) 20.
[39] B. Tan, Y. Zhou, T.L. Yuen, K. Lin, L. Michaud, M.C. Lin, Effects of scleral-lens tear clearance on corneal edema and post-lens tear dynamics: a pilot study, Optom Vis Sci 95 (6) (2018) 481–490.
[40] J.P. Bergmanson, D.F. Ezekiel, E. van der Worp, Scleral contact lenses and hypoxia: theory versus practice, Cont Lens Anterior Eye 38 (3) (2015) 145–147.
[41] J.R. Paugh, E. Chen, C. Heinrich, H. Miller, T. Gates, A.L. Nguyen, et al., Silicone hydrogel and rigid gas-permeable scleral Lens tear exchange, Eye Contact Lens (2018).
[42] T. Tanhehco, D.S. Jacobs, Technological advances shaping scleral lenses: the Boston ocular surface prosthesis in patients with glaucoma tubes and trabeculectomies, Semin Ophthalmol 25 (5-6) (2010) 233–238.
[43] E.S. Visser, R. Visser, H.J. Van Lier, Advantages of toric scleral lenses, Optom Vis Sci 83 (4) (2006) 233–236.
[44] A.L. Coleman, G. Kodjebacheva, Risk factors for glaucoma needing more attention, Open Ophthalmol J 3 (2009) 38–42.
[45] R.N. Weinreb, P.L. Kaufman, The glaucoma research community and FDA look to the future: a report from the NEI/FDA CDER Glaucoma Clinical Trial Design and Endpoints Symposium, Invest Ophthalmol Vis Sci 50 (4) (2009) 1497–1505.
[46] M.A. Kass, D.K. Heuer, E.J. Higginbotham, C.A. Johnson, J.L. Keltner, J.P. Miller, et al., The Ocular Hypertension Treatment Study: a randomized trial determines that topical ocular hypotensive medication delays or prevents the onset of primary open-angle glaucoma, Arch Ophthalmol 120 (6) (2002) 701–713 discussion 829-30.
[47] P.A. Sample, C.A. Girkin, L.M. Zangwill, S. Jain, L. Racette, L.M. Becerra, et al., The african descent and Glaucoma evaluation study (ADAGES): design and baseline data, Arch Ophthalmol 127 (9) (2009) 1136–1145.
[48] D. Nannini, M. Torres, Y.D. Chen, K.D. Taylor, J.I. Rotter, R. Varma, et al., African ancestry is associated with higher intraocular pressure in latinos, Ophthalmology 123 (1) (2016) 102–108.
[49] G.W. Belovay, I. Goldberg, The thick and thin of the central corneal thickness in glaucoma, Eye (Lond) (2018).
[50] C.W. McMonnies, G.C. Boneham, Corneal responses to intraocular pressure elevations in keratoconus, Cornea 29 (7) (2010) 764–770.
[51] S. Akkaya, B. Kucuk, Lamina cribrosa thickness in patients with keratoconus, Cornea 36 (12) (2017) 1509–1513.
[52] S.D. West, C. Turnbull, Eye disorders associated with obstructive sleep apnoea, Curr Opin Pulm Med 22 (6) (2016) 595–601.
[53] L. Michaud, Beyond irregular: scleral lenses for everyday use, CL Spectrum 30 (June) (2015) 30–36.
[54] R.M. Pearson, Re: a hypothesis that scleral contact lenses could elevate intraocular pressure, Clin Exp Optom 100 (1) (2017) 103–104.