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Prospective assessment of corneal biomechanical properties and intraocular pressure after scleral lens wear: A 12-month follow-up study

Rute J. Macedo-de-Araújo [a,b,*], Rita Maria Seco [a,b], José M. González-Méijome [a,b]

[a] Clinical & Experimental Optometry Research Lab (CEORLab), University of Minho, Braga, Portugal
[b] Physics Center of Minho and Porto Universities (CF-UM-UP), Braga, Portugal

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ABSTRACT

Purpose: To investigate the long-term influence of scleral lens (SL) wear on corneal biomechanical properties and intraocular pressure (IOP) in irregular and regular corneas. Secondary goal comprised evaluate the fluid reservoir (FR) thickness overtime and correlate it with the changes in corneal biomechanical parameters and IOP.
Methods: Seventy (70) eyes with irregular corneas (IC Group) and 21 eyes with regular corneas (RC Group) were fitted with 16.4 mm SL and wore the lenses for 12 months. Corrected IOP (IOPcc), Goldmann equivalent IOP (IOPg) and corneal biomechanical parameters (Corneal Hysteresis (CH) and Corneal Resistance Factor (CRF)) were measured with Ocular Response Analyzer. Slit lamp images were analyzed with ImageJ software to assess FR thickness overtime. Measurements were taken at lens dispensing visit prior lens wear (LDV1) and after 60 min of lens wear (LDV2) and at 1, 6 and 12-month follow-up visits. Measurements were done immediately after lens removal.
Results: There were no statistically significant differences on IOPcc, IOPg, CRF and CH over the follow-up visits in both groups. Mean IOPcc and IOPg fluctuations overtime were clinically insignificant and below 1 mmHg in both groups. IOPg, CH and CRF were significantly lower on IC Group ($p < 0.001$), although no statistically significant differences were found between groups for IOPcc. Regarding FR thickness, statistically significant differences were found over the follow-up on both groups, with a mean decrease of 186.29 μm on IC Group and 175.32 μm on RC Group ($p < 0.001$). Statistically significant moderate to high negative correlations between FR and IOPg, CRF and CH were found only in the RC Group.
Conclusions: Long-term SL wear was not associated to changes in corneal biomechanical parameters neither on IOP as measured after lens removal. Besides IOP measurement without SL removal, more studies are needed to investigate the potential relationship with SL fitting characteristics (namely FR thickness).

1. Introduction

Scleral lenses (SL) are known to be a satisfactory clinical option mainly for visual rehabilitation and therapeutic use in ocular surface diseases.[1–3] A total of 62 indications for SL wear were enumerated in previous studies.[4] Despite that, there are also some conditions considered as potential relative contraindications to its wear as overnight wear, patients with low corneal endothelial cell count and patients with glaucoma.[4] Patients with glaucoma need to be carefully evaluated before fitting because of the possible existence of drainage devices and blebs that need to be inspected and localized to alter the haptics of the scleral lens accordingly. Also, authors have hypothesized that SL may increase intraocular pressure (IOP) either because of resistance to aqueous humor outflow or, theoretically, because of increased subatmospheric pressure beneath SL.[4–6] IOP is maintained under normal values by a homeostatic process that accounts for the inflow and outflow of aqueous humor in the anterior segment. If somehow either the production or the drainage of aqueous humor from the anterior chamber is deregulated, an increase in the IOP can occur. If untreated, this deregulation could be implicated in the development of ocular pathologies including optic neuropathy and glaucoma. As SL haptics circumferentially land near the limbal area, which could potentially block the subconjunctival aqueous humor drainage pathway, different authors have suggested that SL wear may disrupt this balance and led to an

* Corresponding author at: Physics Center of Minho and Porto Universities – CF-UM-UP (Optometry), School of Science, University of Minho, Gualtar, Braga 4710-057, Portugal.
E-mail address: rjfmaraujo@fisica.uminho.pt (R.J. Macedo-de-Araújo).

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increase in the IOP due to blockage of Schlemm's channel.[7] Other authors have suggested that this can be further exaggerated by the subatmospheric suction force underneath a SL, and that it could be exacerbated with SL settling.[5] Based on these assumptions, several studies were carried out to investigate the influence of SL wear on IOP. The great limitation/challenge is that the vast majority of currently available methodologies to measure IOP require the removal of the SL for the measurement. This has direct implications on the understanding of the phenomena if the IOP is only elevated during lens wear. Devices previously used to measure IOP during and after SL wear comprised pneumatonometer, ocular response analyzer (ORA), iCare, improved Schiotz tonometer, Diaton transpalpebral tonometer and Goldmann applanation tonometry. [8] With the exception of Diaton transpalpebral tonometer and scleral pneumatonometer with which is possible to measure IOP with the lens on eye [7,9–11], all the other devices required the removal of the lens to perform the measurement. Another limitation of previous studies is that the great majority of them were done by evaluating the changes in IOP in healthy participants and SL (usually, diagnostic lenses) were worn only over short periods of time. [7,9,11–14].

An accurate IOP measurement is dependent on the biomechanical properties of the cornea. Corneal biomechanical properties are dependent on the distribution of collagen fibers in the stroma, and could be altered in different ocular conditions such as keratoconus,[15,16] after refractive surgery[17–20] and with overnight orthokeratology lens wear. [21,22] Other ocular conditions and treatments that could influence and alter those parameters comprise Fuchs endothelial dystrophy, diabetes, corneal cross-linking, intraestromal ring segment implantation, corneal edema and keratoplasty. [23] Therefore, corneal biomechanical outcomes could provide an important diagnostic tool to differentiate between normal and pathological corneas. The effect of contact lens wear on corneal biomechanics was also previously assessed. One study evaluated the influence of soft contact lens wear on corneal biomechanics and found a tendency for higher CRF values on myopic contact lens wearers whereas CH did not show a clear trend of change, suggesting that there may be some alterations on corneal microstructure and physiology following chronic CL wear (which may affect viscoelasticity). [24] In the same line, a study by Mukesh *et al* [25] aimed to evaluate the influence of SL wear on corneal biomechanics and IOP in patients with keratoconus and penetrating keratoplasty. In contrast with the results of the previous study in myopic contact lens wearers, the authors did not find significant changes in the outcomes in both groups. Montalt *el at* [26] also evaluated the influence of 1-year corneoscleral contact lenses wear in 27 eyes with irregular corneas after laser in situ keratomileusis (LASIK) surgery on corneal biomechanics and found a statistically significant increment in CRF (an increase from 7.57±087 to 7.68±0.84 mmHg). A difference of 0.21 mmHg in IOPcc was also found, but without statistically significant differences.

The main goal of the present work was to study the influence of SL wear on corneal biomechanics and intraocular pressure over a 12-month follow-up period, on irregular corneas and healthy corneas. Secondary goal was to evaluate the FR thickness overtime and assess potential associations of this parameter with the changes in corneal biomechanical parameters and IOP. As far as is known, this is the first study reporting IOP and corneal biomechanical follow-up data on patients wearing SL for one year.

2. Methods

2.1. Study design and subjects

This was a prospective clinical study involving patients with primary corneal ectasia, penetrating keratoplasty, postsurgical ectasia and regular corneas with moderate-to-high refractive errors (myopia >6.00 D, astigmatism >2.00 D, and/or hyperopia >4.00 D) that failed other forms of visual correction. Ninety-five patients were primarily recruited to be enrolled in the study and were divided into two groups: irregular corneas (IC Group: 134 eyes of 71 subjects) and regular corneas (RC Group: 46 eyes of 24 subjects). In the light of a previous publications that reported a success rate of 73 % during the 12-months of follow-up (77 % in IC Group and 58 % in RC Group), there were a total of 26 participants dropping out from multiple reasons (16 participants from IC Group and 10 participants from RC Group), so a total of 69 participants completed the 12-month follow-up period [27]. Regarding the variables in study in the present work, only participants that successfully completed the Baseline, Lens Dispensing Visit, 1-month, 6-month and 12-month visits and had valid measurements in each one of those visits were considered for the analysis of the present outcomes. Considering that, in the present work 70 eyes from 39 participants from IC Group and 21 eyes from 11 participants from RC Group were analyzed. Following the recommendations of the Declaration of Helsinki, all subjects received information from the study before accepting to participate and signed an informed consent form. The protocol of the study has been reviewed and approved by the Ethics Subcommittee for Life and Health Sciences of University of Minho (SECVS 171/2014).

2.2. Scleral lens used and follow-up appointments

All patients enrolled in the study were fitted with Senso Mini Sclera SL (Procornea, Eerbeek, the Netherlands) in Boston XO material (Dk 100 ISO/Fatt). Lenses were fitted following trial and error process with diagnostic fitting sets. [28] Technical characteristics are described in previous publications in the context of this 12-month follow-up clinical trial.[1,27–29] Patients were fitted with the first diagnostic lens following manufacturer recommendations based on the degree of severity of the corneal condition and slit lamp examination. Adjustments were therefore performed accordingly, considering the fluid reservoir thickness and haptic zone alignment. The goal of the fitting was a lens evenly landing on the bulbar conjunctiva and vault the entire corneal surface, including limbus, with a central fluid reservoir thickness between 150 and 300 μm after settlement. Data from the characteristics of the lenses of the patients that completed the follow-up could be found on previous study. [30].

All patients underwent the following follow-up visits: Baseline; Lens Dispensing Visit (LDV) which consisted of two visits at the same day: 10 min after lens insertion (LDV1) and after more than 60 min of lens wear (LDV2); 1-month visit (V1m); 3-month visit (V3m); 6-month visit (V6m); and 12-month visit (V12m). For the outcomes of the present work, only results from LDV1, LDV2, V1m, V6m and V12m were analyzed.

Habitual contact lens wearers were invited to not wear their habitual lenses for 3 days before baseline assessment and LDV. After LDV2, patients were fully instructed about the handling and hygiene procedures, were dispensed with care solutions and plungers and an information leaflet explaining all the procedures, including handling, care, wearing time and alert signs and symptoms. Lens care consisted of cleaning, wetting and disinfecting with standard RGP lens cleaner (Boston Advanced Cleaner) and multipurpose solution systems (Boston Simplus). Before lens insertion, patients were instructed to rinse the lenses with preservative-free saline solution and then fill the lens to the top with the same solution. After removal, patients were instructed to rub the lenses with cleaner, rinse them with saline solution and to store lenses on lens case filled with multipurpose solution. Patients were also instructed about lens case and plunger hygiene procedures.

2.3. Measurement of fluid reservoir thickness

The central fluid reservoir (FR) thickness – space between the anterior corneal surface and posterior lens surface – was measured with a previously described methodology. [31] Briefly, it comprised the measurement of tear reservoir thickness with an image processing software (ImageJ 1.52a – National Institutes of Health, Bethesda, Maryland,

USA). Pictures of the FR thickness were taken with slit lamp (CSL990 Elite 5x Digital Video, CSO, Italy) during SL fitting assessment at the different follow-up visits. Each picture was analyzed (in a random order) with ImageJ, after being coded with no information of the patient. The FR thickness measurement was measured with the built-in calipers considering the SL thickness (provided by the manufacturer for each lens). Six repeated measures of FR thickness for each image were done and the final value was the mean of those six values. As the observer knew in advance the lens thickness of each image, a simple conversion of the number of pixels corresponding to FR thickness to micrometers was done.

2.4. Measurement of intraocular pressure and mechanical properties of the cornea

The evaluation of intraocular pressure and corneal biomechanics was done with Ocular Response Analyzer (ORA, Reichert, Depew, NY). ORA is a noncontact tonometer that uses a rapid air pulse to indent the cornea to record corneal deformation.[32] It registers the dynamic flattening of the cornea to reach two peak pressures (P_1 and P_2), with P_1 corresponding to the first applanation while the cornea moves inward and P_2 corresponding to the second applanation recorded as the cornea moves outwards. From the measurement it is possible to record intraocular pressure equivalent to Goldmann applanation tonometry (IOPg) and the Corneal Compensated IOP (IOPcc) that is derived considering corneal hysteresis (CH) and corneal resistance factor (CRF). Both CH and CRF are corneal biomechanical metrics: CH is considered an indicator of corneal viscosity and reflects the corneal capacity to recover after an application of external force, and CRF is considered the indicator of overall resistance of the corneal tissue. [23,32] Measurements were done at LDV1 without lens and after a 3-day washout period for contact lens wearers. Then, measurements were repeated 5–10 min after SL removal at LDV2, V1m, V6m and V12m. Measurements at LDV2 were done after more than 60 min of lens wear (137±78 min: range 60 to 420 min). At the following appointments patients were asked to insert the lens at least 90 min prior the appointment: V1m (217±158 min: range 90 to 600 min), V6m (233±143 min: range 90 to 600 min), V12m (227 ±125 min: range 100 to 600 min). Follow-up appointments were scheduled within the same time as V1m, so subjects were observed within the same time window (±90 min) over time. Three repeated measurements were done and averaged.

2.5. Statistics

Statistical analysis was conducted using SPSS v.28.0 (SPSS. Inc. Chicago. Illinois. USA) to compare the different variables between groups and over time within the same group. Normality of data distribution was assessed using the Kolmogorov-Smirnoff or Shapiro-Wilk test in different groups of participants analyzed, according to the sample size of each group. Pairwise comparisons between groups (IC Group vs RC Group) were done using Independent Sample T-test for normally distributed data or Kruskal-Wallis for non-normally distributed data. Comparisons over time within the same group were done with one-way ANOVA or Friedman tests with Bonferroni post-hoc corrections/adjustments for pairwise comparisons. The level of statistical significance was set at $p < 0.05$.

3. Results

A total of 50 patients (90 eyes) were included in this analysis: 39 patients (70 eyes) with irregular corneas (IC Group) and 11 patients (21 eyes) with regular corneas (RC Group) and high refractive errors. Corneal irregularities presented in IC Group were: 49 eyes with keratoconus, 11 eyes with post-LASIK irregularities or ectasias, 9 eyes with penetrating keratoplasty and 1 eye with a corneal irregularity resulting from an ocular infection. [33] Mean age of the patients was 34.08±9.62 years (35.64±9.48 on IC Group and 28.55±7.92 on RC Group).

Table 1 summarizes the outcomes for the 12 month follow up period: FR thickness, IOPcc, IOPg and corneal biomechanics (CRF and CH) for both groups studied. Regarding fluid reservoir (FR) thickness, statistically significant differences were observed during follow-up in both groups ($p < 0.001$, ANOVA). Considering the group of irregular corneas (IC Group), post-hoc Bonferroni adjustments revealed a statistically significant decrease in the tear reservoir thickness on lens dispensing visit of 85 μm ($p < 0.001$), that continued to decrease overtime. The total decrease of FR thickness from LDV1 to V12m was of 186.26 μm ($p < 0.001$). Considering the group of regular/ healthy corneas (RC Group), a decrease of 76 μm was found at LDV but without statistically significant differences ($p = 0.346$). The decrease in FR thickness from LDV1 to V12m was 175.32 μm ($p < 0.001$). There were statistically significant differences between groups only for V1m and V6m ($p < 0.05$, Independent Sample T test).

Regarding the other outcomes, there were no statistically significant differences between visits for IOPcc, IOPg, CRF and CH ($p > 0.05$, ANOVA), for any of the groups studied. Regarding IC Group, the difference in IOPcc and IOPg from LDV1 (prior lens fitting) and after 12 months of lens wear was 0.04 mmHg and 0.01 mmHg, which is also clinically insignificant. Fluctuations during follow-up visits were also insignificant with a tendency to decrease both values during time (months) of lens wear. Regarding RC Group, differences without statistical or clinical significance in IOPcc and IOPg were 0.07 mmHg and 0.57 mmHg respectively. Results for corneal biomechanical outcomes were similarly unremarkable. On IC Group, differences in CRF and CH from LDV1 to V12m were 0.05 and 0.01, respectively. On RC Group, the differences were 0.22 and 0.09. There were statistically significant differences between groups for IOPg, CRF and CH at all visits, but only for V1m for IOPcc. IOPg revealed statistically significant higher values on RC Group compared to IC Group, which was not found on IOPcc (similar values between both groups). Regarding CRF and CH, values from RC Group patients revealed also higher values than IC Group ($p < 0.001$, Independent sample *t*-test).

Table 2 shows the correlations between FR thickness and the IOP and corneal biomechanical properties for all the follow-up visits in both groups. There were moderate-to-high negative and statistically significant correlations between IOP and corneal biomechanical properties in RC Group at all follow-up visit ($r = -0.511$ to $r = -0.736$), except for IOPcc (lower, non-significant correlations).

IC Group was further divided into three sub-groups: eyes with keratoconus (49 eyes), eyes with post-LASIK irregularities ($n = 11$ eyes) and eyes that underwent penetrating keratoplasty ($n = 9$) (Supplementary Table). From the outcomes, it is worth to highlight the tendency to an increase in IOPcc on post-keratoplasty group (increase of 1.97 μm from LDV1 to V12m), although without statistically significant differences.

4. Discussion

Investigating the role or the impact of SL wear on IOP is hampered by the lack of instrumentation to measure it during SL wear. Typically, studies regarding this topic are done over short-term (2 to 8 h of lens wear), on healthy subjects and the SL used are usually from the trial set which are not fully aligned with the peripheral conjunctiva of the patients. Considering the variables enumerated to be related to IOP elevation during SL wear, it is of paramount significance to have the SL haptics optimized to the ocular surface of each patient. In the present study, subjects with corneal irregularities and subjects with healthy corneas were fitted with 16.4 mm SL and wore the lenses for 12 months. Previous studies that evaluated IOP during medium to long term SL wear found minimal fluctuations on IOP overtime. [34–36] One of the studies prospectively fitted 74 eyes (29 healthy eyes, 20 eyes with intracorneal ring segments (ICRS) and 25 without) with corneoscleral lenses (12.6–13.5 mm) and evaluated IOP with ORA for 1 year of lens wear. Differences between baseline and 1 year for IOPcc were clinically and

Table 1
Changes in fluid reservoir thickness (FR), intraocular pressure (IOPcc and IOPg) and corneal biomechanics (CRF and CH) outcomes in patients with irregular corneas (IC Group) and regular corneas (RC Group) through the 12 months of follow-up.

	IC Group Mean ± SD [Min to Max]	RC Group Mean ± SD [Min to Max]	p*
FR_LDV1-10 min lens wear (μm)	429.09±103.96 [154.94 to 722.00]	454.82±106.82 [310.28 to 670.68]	*0.263*
FR_LDV2 (μm)	336.15±98.57 [127.80 to 583.26]	378.70±94.32 [204.20 to 582.71]	*0.131*
FR_V1m (μm)	265.15±84.29 [63.18 to 438.86]	316.23±103.42 [161.73 to 498.79]	***0.025***
FR_V6m (μm)	266.70±84.04 [99.18 to 503.43]	320.78±102.78 [153.98 to 497.73]	***0.037***
FR_V12m (μm)	242.80±90.02 [95.91 to 454.76]	279.50±92.62 [83.24 to 400.24]	*0.160*
Difference LDV1-V12m	−186.29	−175.32	–
p#	***<0.001*** LDV1 vs LDV2. V1m. V6m & V12m LDV2 vs V1m. V6m & V12m	**<0.001** LDV1 vs V1m. V6m & V12m LDV2 vs V12m	–
IOPcc_LDV1 (mmHg)	12.80±2.62 [7.80 to 20.60]	12.71±4.27 [4.10 to 20.50]	*0.914*
IOPcc_LDV2 (mmHg)	12.82±2.81 [8.40 to 23.00]	13.42±3.35 [8.40 to 19.50]	*0.421*
IOPcc_V1m (mmHg)	12.19±2.44 [5.00 to 17.30]	13.53±3.66 [8.10 to 21.70]	***0.029***
IOPcc_V6m (mmHg)	12.39±2.86 [3.30 to 21.00]	12.74±3.19 [7.90 to 20.20]	*0.639*
IOPcc_V12m (mmHg)	12.84±2.58 [7.80 to 19.40]	12.79±3.28 [5.80 to 17.80]	*0.941*
Difference LDV1-V12m	0.04	0.08	–
p#	*0.490*	*0.908*	–
IOPg_LDV1 (mmHg)	9.40±2.76 [3.40 to 16.40]	13.88±5.83 [7.80 to 25.70]	***<0.001***
IOPg_LDV2 (mmHg)	9.17±3.13 [3.80 to 17.30]	14.79±5.60 [7.70 to 26.60]	***<0.001***
IOPg_V1m (mmHg)	8.70±2.83 [3.40 to 17.50]	14.88±5.56 [6.20 to 28.60]	***<0.001***
IOPg_V6m (mmHg)	8.93±3.32 [2.50 to 20.00]	13.30±4.59 [7.20 to 24.50]	***<0.001***
IOPg_V12m (mmHg)	9.39±3.21 [2.80 to 17.20]	13.30±4.64 [3.50 to 22.40]	***<0.001***
Difference LDV1-V12m	−0.01	−0.58	–
p#	*0.602*	*0.908*	–
CRF_LDV1 (mmHg)	6.93±1.76 [3.00 to 12.50]	11.39±3.28 [7.50 to 18.10]	***<0.001***
CRF_LDV2 (mmHg)	6.76±1.63 [4.00 to 12.40]	11.85±3.41 [7.00 to 18.50]	***<0.001***
CRF_V1m (mmHg)	6.78±1.64 [3.50 to 11.80]	11.74±3.02 [7.40 to 18.70]	***<0.001***
CRF_V6m (mmHg)	6.81±1.78 [3.00 to 11.90]	11.08±3.02 [6.80 to 16.30]	***<0.001***
CRF_V12m (mmHg)	6.98±2.01 [4.00 to 13.50]	11.17±3.04 [6.80 to 15.90]	***<0.001***
Difference LDV1-V12m	0.05	−0.22	–
p#	*0.934*	*0.922*	–
CH_LDV1 (mmHg)	8.45±1.66 [4.80 to 13.70]	12.14±2.35 [9.20 to 16.20]	***<0.001***
CH_LDV2 (mmHg)	8.24±1.41 [4.80 to 12.20]	12.34±2.31 [8.00 to 16.10]	***<0.001***
CH_V1m (mmHg)	8.52±1.38 [5.80 to 11.40]	12.17±1.88 [8.80 to 15.70]	***<0.001***
CH_V6m (mmHg)	8.50±1.43 [6.10 to 13.20]	12.00±2.40 [8.00 to 17.40]	***<0.001***
CH_V12m (mmHg)	8.46±1.57 [5.80 to 13.70]	12.05±2.48 [8.40 to 17.40]	***<0.001***
Difference LDV1-V12m	0.01	−0.09	–
p#	*0.810*	*0.922*	–

LDV1: Lens dispensing visit – before lens wear (baseline); LDV2: Lens dispensing visit – more than 90 min of lens wear; V1m: 1 month appointment; V6m: 6 months appointment; V12m: 12 months appointment; IC: irregular cornea; RC: regular cornea.

ANOVA.

* Independent Sample T-test.

Table 2
Pearson correlation coefficients between fluid reservoir thickness and intraocular pressure (IOPcc and IOPg) and corneal biomechanical properties (CRF and CH) for both groups: Group1 – Irregular Corneas (IC Group); Group 2 – Regular Corneas (RC Group).

		Fluid Reservoir Thickness			
		LDV2	V1m	V6m	V12m
IOPcc	IC Group	0.027	0.01	−0.148	0.065
	RC Group	−0.392	−0.392	−0.319	−0.355
IOPg	IC Group	−0.025	0.098	−0.096	0.136
	RC Group	**−0.633****	**−0.633****	**−0.618****	**−0.673****
CRF	IC Group	−0.057	0.157	0.019	0.159
	RC Group	**−0.708****	**−0.708****	**−0.645****	**−0.670****
CH	IC Group	−0.088	0.144	0.105	0.131
	RC Group	**−0.675****	**−0.675****	**−0.514***	**−0.511***

LDV1: Lens dispensing visit – – before lens wear (baseline); LDV2: Lens dispensing visit – more than 90 min of lens wear; V1m: 1 month appointment; V6m: 6 months appointment; V12m: 12 months appointment; IC: irregular cornea; RC: regular cornea.

* The correlation is significant at 0.05 level.

** The correlation is significant at 0.001 level.

statistically insignificant (from a reduction of 0.51 on keratoconus eyes to an increment of 0.06 mmHg on control eyes).[36] Another study evaluated the IOP with Goldmann applanation tonometry in 32 SL wearers with irregular corneas before lens wear and after 1 and 6 months of lens wear and, similarly to the results of this work, the authors did not find statistically neither clinically significant differences (mean increase of 1 mmHg).[34].

Previous studies hypothesized that the intraocular pressure measured immediately after lens removal is probably underestimating the value with the lens on eye.[12] The major fact is that the influence of SL wear (and SL removal) on the outflow of aqueous humor is unknown. After SL removal, the eye is exposed to normal atmospheric pressure (which can be altered during lens wear, particularly under steep lenses) and thus, it will potentially influence the measurement. A study that measured the IOP with iCare in 9 eyes before SL wear and after 5 s of lens removal found an increase in the IOP after 8 h of lens wear (increase between 2.67 and 14.67 mmHg). [12] Other study that also measured the IOP immediately after lens removal (after 2 h of 15-mm SL wear) did not found an increase in IOP compared to the control eye.[7] In fact, several studies did not found any difference in IOP following SL wear [7,10,37], others did found an increase [9,11,12,14] and others found a reduction. [9,13].

As mentioned in previous studies, SL diameter could play an important role in this matter as large diameter lenses will have their bearing force distributed over a larger area (wide haptics) compared to small-diameter SL (14.0–16.5 mm). [7] Michaud *et al* [14] evaluated the influence of 15.8 mm and 18 mm SL on IOP over the short-term (4 to 5 h of lens wear) and found an increment of 4.3 mmHg and 5.2 mmHg in IOP, respectively. In the present study the lenses fitted had a diameter of 16.4 mm, which hypothetically should have led to a higher compression of the aforementioned structures responsible for aqueous humor outflow and consequently led to an increase in the IOP during lens wear. In the present study, it was not possible to measure IOP during SL wear (with the lens on eye), but immediately after lens removal the IOP remained unchanged compared to the baseline measure (LDV1, prior lens fitting). The fact that IOP was measured after lens removal is the great limitation of the present study and previous studies. From this work, it is possible

to conclude that if some compression of episcleral veins or Schlemm canal is present during lens wear and it increases the IOP, this effect is lost right after lens removal. Therefore, isolated IOP measurements following lens removal will not be sufficient to characterize the influence of SL wear on IOP and the potential impact on ocular hypertension and glaucoma. Diagnosis and management of glaucoma require other assessments. An analysis of the optic nerve head morphology during the 12 months of lens wear, as well as visual field assessment, would help to understand if there were some implications of the SL on the outflow of aqueous humor during lens wear with implications on glaucoma onset and/or progression. A short-term study evaluated the optic nerve head morphology during SL wear and did not found significant alterations, [11] however the long-term effect still need to be studied.

The results of the present work showed a statistically significant tendency for a decrease of IOPcc and IOPg in eyes with keratoconus and post-LASIK irregularities, which could be in accordance with the normal diurnal fluctuations of IOP (Supplementary Table). However, in the subgroup of penetrating keratoplasty patients an increase of more than 2 mmHg was found on the first hours of lens wear. After 12 months of lens wear, the value remained elevated compared to baseline, however these results were not powered enough to detect statistically significant changes as the number of eyes in this specific subgroup was 9. Despite that, a previous study did not found any changes on IOP or corneal biomechanics (measured with Corvis ST) after 8 h of SL wear in patients with keratoplasty. [25].

According to the pathogenesis of corneal ectasias, in which a weakening of the cornea is present, lower values of corneal biomechanical parameters (CRF and CH) should be expected in eyes with ectatic disorders. In agreement with that and with previous studies [36,38], corneal biomechanical properties were significantly lower in IC Group than RC Group in the present study. Also, given the amount of work that has been done regarding the influence of SL wear on IOP, it is important to assess the changes in corneal biomechanical properties overtime during SL wear, as changes in these properties might influence IOP measurement. Additionally, might help to investigate the potential effect of SL wear on structural corneal properties. A study evaluated the possible changes on corneal biomechanical properties following 1-year of corneoscleral lens (12.6–13.5 mm) wear in healthy eyes, eyes with keratoconus and eyes with keratoconus and ICRS. [36] The authors did not find clinically or statistically significant differences between baseline and after 1 year of lens wear on CRF (mean increment of 0.13 mmHg on healthy corneas, 0.26 mmHg on keratoconus and 0.22 mmHg in eyes with keratoconus and ICRS) and CH (mean increment of 0.23 mmHg on healthy corneas, and 0.27 on both keratoconus with and without ICRS). Despite the difference on the lens diameter used on that study and the lenses fitted on the present study, the results are similar. On the present study, a decrease of 0.22 mmHg and 0.09 mmHg on RC Group and an increase of 0.05 mmHg and 0.01 mmHg on IC Group were found on CRF and CH, respectively. By further analyze the IC Group, it was possible to conclude that the higher modifications were found on the eyes with penetrating keratoplasty (increment of 0.24 on CRF and decrease of 0.33 on CH) (Supplementary Table).

Regarding FR thickness, and similarly to previous studies[39–41], a short-term settling was found (LDV1 vs LDV2), followed by an overtime (12-month) decrease in the FR thickness in both groups. This overtime decrease in FR thickness was already previously documented[30] and emphasizes the reasonability to fit SL with more 100 μm (approximate difference between LDV2 – settled lens – and V12m in both groups) to account this overtime settling. It had been previously hypothesized that progressive SL settling would lead to a greater suction force that could increase IOP values [5]. That might anticipate a potential correlation between FR thickness and IOP or corneal biomechanical parameters which were investigated (Table 2). No significant correlations between FR thickness and CH and CRF on IC Group were found. However, when analyzing RC Group, consistent statistically significant negative moderate-to-high correlations were found between FR thickness and IOPg and corneal biomechanical properties. In clinical terms, this means that the shallower the FR thickness, the higher the IOPg measured. The same was found for CH and CRF parameters. Although a direct and precise causality effect cannot be attributed, mainly because difficulties in controlling all the variables that could potentially affect the outcomes, the consistency of this behavior over follow-up visits suggests the need to further study this potential relationship. It is important to mention that this possible relationship was only found in the group of regular corneas and not in the group of irregular corneas. The greater variability in the FR determination and in the structural properties of the irregular corneas limits the chance to find a statistically significant association. The FR thickness measurement was always made in the central area of the cornea, which in cases of irregular corneas will not represent the average FR thickness, because of regional differences (as FR thickness can vary substantially from one area to another). Another point to highlight is that IOPcc was the only parameters that did not significantly correlated with FR thickness in RC group. IOPcc is the *"corneal compensated"* IOP that considers the corneal biomechanical factors (CH and CRF) to correct the IOPg value. Therefore, for future studies, authors should consider the separated analysis of biomechanical properties, IOPg and IOPcc to assess these outcomes overtime.

5. Conclusions

Although further studies are needed to understand the exact influence of SL wear on aqueous humor outflow, the present study showed that long-term (12 months) SL wear did not cause significant alterations on corneal biomechanics neither on IOP, either in corneas with irregularities or healthy corneas with high refractive errors. Given the limitations in measuring IOP during SL wear using current methodologies, it is necessary to develop strategies to measure IOP with the SL in place and assess other variables such as visual field and optic nerve head morphology to understand the impact of SL wear on glaucoma onset and/or progression.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.clae.2023.102067.

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