Original Article

The effect of different thickness scleral lens on corneal parameters in eyes with keratoconus

Asif Iqbal, Rinu Thomas, Rajeswari Mahadevan

Purpose: To investigate the impact of different-thickness scleral lenses (SLs) on corneal thickness, curvature, and fluid reservoir thickness in keratoconic eyes. **Methods:** Schiempflug imaging and AS-OCT was captured before and immediately following 6 h of SL wear. Different-thickness lenses were used while keeping the other parameters the same. The timing of the measurement for day 1 and day 2 was matched to allow for the control of the confounding influence of diurnal variation. **Results:** Immediately after 6 h of lens wear, no statistically significant difference ($P > 0.05$) was noted in corneal edema in any region and quadrants between thin- and thick-lens wearers. The calculated percentage of corneal edema was also within the range of overnight closed eye physiological swelling. Pentacam measured higher central corneal thickness compared to AS-OCT in both baselines and after 6 h of lens wear. The current investigation reported minimal but not statistically significant ($P > 0.05$) flattening in anterior and steepening in posterior curvature parameters in both thin and thick SLs. The mean reduction in the fluid reservoir thickness was 80.00 ± 3.99 and 79.36 ± 3.84 microns after 6 h of thin- and thick-lens wear, respectively, which was not statistically significant ($P > 0.05$). A statistically significant positive correlation (r = 0.67, $P = 0.02$) was found between lens thickness and change in anterior steep k with thick-lens wear. **Conclusion:** Central lens thickness of 200–400 μm did not cause any significant change in corneal curvature and fluid reservoir thickness and did not induce clinically significant corneal edema after short-term SL wear.

Key words: Corneal curvature, corneal edema, fluid reservoir thickness, keratoconus, lens thickness, scleral lens

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Ectatic corneal conditions such as keratoconus cause visual impairment due to irregular cornea and high astigmatism. In moderate to severe cases of keratoconus and patients intolerant to corneal gas permeable lenses, scleral lenses (SLs) offer a better solution. SLs are large-diameter gas permeable lenses that rest on the bulbar conjunctiva overlying the sclera and vault entirely over the cornea. The fluid reservoir between the posterior lens surface and anterior cornea can neutralize irregular astigmatism of the anterior surface. It is useful in dry eyes and can act as a bandage to provide protection to the ocular surface. These lenses can be made thicker than the traditional corneal gas permeable lenses to avoid the on-eye and handling flexure changes due to the inherent thickness of the lens.[1,2] Lens thickness plays a crucial role in prescribing SL as the lens moves very little to allow freshly oxygenated tears to replenish the post-lens-tear layer. Lens thickness acts as a barrier to atmospheric oxygen to fulfill the requirement of the cornea and can cause corneal swelling.[3,4] To overcome this issue, lenses should be made of highly oxygen-permeable materials with optimal thickness.

Corneal curvature alteration caused by SL wear should be considered important for patients with keratoconus, especially in progressive cases where collagen cross-linking is indicated. Curvature change can lead to over or underestimation of the level of keratoconus where progressive cases can be missed. Corneal curvature changes due to sub-atmospheric pressure behind the lens or by corneal swelling due to hypoxia following SL wear.[5] Reports on temporary curvature changes showed variable results with both steepening and flattening of anterior and posterior corneal curvature.[5-8]

The fluid reservoir thickness between the lens and cornea is also known as vault or corneal clearance. A reduction of 90–140 microns in fluid reservoir thickness has been reported by different researchers.[9,10] Practitioners should be careful while measuring fluid reservoir thickness after a certain period of SL wear as adequate fluid reservoir thickness is required to maintain the corneal and limbal integrity.

Few studies have assessed the impact of different-thickness SLs in corneal edema,[5] curvature,[5] and fluid reservoir thickness in patients with keratoconus. The thickness of an SL along with tear reservoir thickness and lens material permeability determines the amount of oxygen delivered to the

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cornea. The lens thickness should be considered carefully while fitting an SL. Therefore, the present study clinically analyzed the effect of SL thickness on corneal thickness, curvature, and central fluid reservoir thickness after 6 h of SL wear. Another objective of this study was to accurately measure and compare the central corneal thickness with anterior segment optical coherence tomography (AS-OCT) while the lens is on the eye to find out any rebound alteration in the exact amount of corneal edema.

Methods

A prospective comparative study was conducted in a specialty contact lens clinic. The study was approved by the institutional review board and ethics committee and was conducted in accordance with the Declaration of Helsinki. Participants with keratoconus, confirmed with Pentacam reports, and eligible for SL fitting with an endothelial cell count of above 2000 cell/mm^2 were included in this study. The severity of keratoconus was graded according to the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) criteria.[11] Pentacam keratometry values <45.00 D were graded as "mild" keratoconus, between 45.00 D and 52.00 D were graded as "moderate" keratoconus, and keratometry values >52.00 D were graded as "severe" keratoconus. Participants less than 18 years of age, presence of any ocular surface disorder, history of any eye injury, any other associated ocular pathology apart from keratoconus, any ocular surgery, and/or using topical ocular medications were excluded from this study. Informed consent was obtained from the subjects before performing the tests.

Scleral lens design

The patients were fitted with 16.0-mm diameter SLs (McAsfeer, Silverline, India) made from hexafocon B material (Boston XO_2) with oxygen permeability (Dk) =140 × 10 − ^{11} (cm^2/s) (mlo$_2$/mL × mmHg). The lenses were fitted according to the manufacturer's guidelines, and after obtaining adequate fit, spherical equivalent over-refraction was performed and visual acuity was recorded. If required, central and limbal fluid reservoir thickness modifications were done and the final lens was ordered. Two final lenses were ordered with different thicknesses with a thickness difference of approximately 150–200 microns by keeping the other parameters constant. A single increase in lens thickness was not possible due to manufacturing limitation. The mean central lens thickness was measured with lens gauge (Neitz Instruments Co., Ltd, Japan).

Experimental details

Corneal thickness, curvature, and fluid reservoir were measured at baseline and after 6 h of lens wear. The study was conducted on two separate days. Baseline measurements were performed in the morning (between 8.00 and 9.00 am) and then repeated after 6 h of lens wear (between 2 and 3 pm). The baseline measurements were done at least 2 h after awakening to minimize the influence of overnight swelling. The lenses were randomly selected and inserted by the examiner; the examiner was masked as to which of the two lenses was worn during measurements. The timing for days 1 and 2 were matched to control the confounding influence of diurnal variations. Participants were free to go for daily activities or allowed to sit in the clinic during those periods. Day 2 baseline measurements were taken at least 72 h after day 1 measurements to minimize the potential influence of day 1 lens fitting, and patients were advised not to wear any other lenses during those hours. All measurements were performed by a single observer to avoid interobserver variability. Both measurements were finished within 5 min to prevent artifacts induced by the restoration of corneal physiology. As soon as the cornea is exposed to the regular atmosphere after lens removal, it de-swells very rapidly;[12] to avoid this, the central corneal thickness was evaluated with AS-OCT during lens wear. The swelling response or percentage of corneal edema was calculated as follows:

Edema (%) = (Final corneal thickness – Baseline corneal thickness × 100)/(Baseline corneal thickness)

Measurement tools

Corneal thickness at different corneal locations (center, apex, and thinnest location) and different quadrants (superior, inferior, nasal, and temporal) and anterior (k flat, k steep, and k max), and posterior (k flat and k steep) corneal curvature was measured by Pentacam HR (OCULUS, Germany) system without the lens on the eye. Central corneal thickness and fluid reservoir thickness with the lens on the eye was measured immediately after 5 min of lens insertion and again after 6 h of lens wear before lens removal by using AS-OCT Casia SS-1000 (Tomey, Erlangen, Germany). The instrument uses a swept-laser source operating at a wavelength of 1310 nm; the image was considered optimally aligned when the specular reflex was observed. The inbuilt caliper of AS-OCT was used to measure the central fluid reservoir thickness (the distance between the posterior surface of the lens and anterior surface of the cornea) and central corneal thickness (the distance between the anterior and posterior-most border of the cornea). Three repeated measurements were taken with both instruments for every patient, and the mean value of the three measurements was used for analysis.

Statistical analysis

Using a significance level of 5%, power of 90%, and 0.50 effect size, the required sample size for the study was 34 eyes for both groups. Within the time period, it was possible to include only 22 eyes. With the effect size of 0.50 and sample size of 22 for both groups, the power of the study was 76.3%. Data entry was performed in Microsoft Excel 2010. Statistical analysis was performed using SPSS software version 20 (SPSS 17.0 for Windows evaluation version) and MedCalc (Version 10, free trial) software. The normality of the data was confirmed by the Shapiro–Wilk test of normality. Parametric tests such as independent *t* test and Pearson's correlation test were used for inferential analysis as the data was normally distributed. To assess the agreement between both instruments, Bland–Altman plots were created, and 95% limit of agreement (LoA) was calculated as mean ± 1.96 SD of the difference. P <0.05 was considered statistically significant.

Results

In this study, 22 eyes of 14 patients (eight male and six female) diagnosed with keratoconus with a mean age of 25.33 ± 4.50 years were included. The enrolled subjects in this study were seven eyes with mild keratoconus, seven eyes with moderate keratoconus, and eight eyes with severe keratoconus. The measured lens thicknesses for thin and thick lenses used in this study were 210.09 ± 41.34 and 360 ± 31.62 μm, respectively.

The overall mean keratometric values measured with Pentacam were K flat- 46.12 ± 5.26 D, mean K steep- 51.21 ± 5.72 D, and K max- 56.15 ± 7.32 D.

Corneal edema

No statistically significant difference was noted ($P > 0.05$) in calculated corneal edema in any region and quadrants of the cornea after 6 h of lens wear while comparing the thin and thick lenses [Table 1]. The higher magnitude of corneal edema noted in the superior quadrant was 2.82 ± 2.04% and 3.18 ± 1.17% for thin and thick lens wearers, respectively.

Agreement between instruments

There was a good correlation between the two methods while measuring central corneal thickness at baseline (r = 0.87, $P < 0.01$) and after 6 h of lens wear (r = 0.89, $P < 0.01$) as shown in Bland–Altman plots for agreement. Higher LoA values were found in both the baseline [Fig. 1] and after 6 h of lens wear [Fig. 2] measurement between both methods. The Bland–Altman plots show a tendency for the Pentacam method to yield thicker central corneal thickness measurement than the AS-OCT Casia in keratoconic eyes.

Corneal curvature

Fig. 3 shows the mean changes in the anterior and posterior corneal curvature after 6 h of SL wear. Minimal flattening (0.28–0.46 D) was noted in the anterior K flat, K steep, and K max. When comparing between thin and thick lenses, the present study found no statistically significant difference ($P > 0.05$) in any anterior curvature parameters. Posterior K flat and K steep showed minimal steepening (−0.03 to − 0.08 D) but showed no statistically significant difference between thin and thick lens wearers ($P > 0.05$).

Table 1: Mean±SD comparison of the percentage of corneal edema after 6 h of lens wear measured with Pentacam and AS-OCT

Locations	Thin lens	Thick lens	P*
	Calculated percentage of corneal edema after 6 h of lens wear (Pentacam)		
Corneal center	1.91±1.59	2.41±1.30	0.30
Corneal apex	2.18±1.17	2.73±1.20	0.26
Corneal thinnest location	1.73±1.42	2.36±1.03	0.24
Superior quadrant	2.82±2.04	3.18±1.17	0.61
Inferior quadrant	2.45±2.02	1.91±1.14	0.44
Nasal quadrant	1.45±1.29	1.64±1.20	0.73
Temporal quadrant	2.36±2.11	2.09±2.30	0.75
	Calculated percentage of corneal edema after 6 h of lens wear (AS-OCT)		
Corneal center	2.79±1.34	2.89±1.14	0.76

*Independent *t*-test

Fluid reservoir thickness

Table 2 shows the initial (after 5 min), final (after 6 h), and reduction in fluid reservoir thickness after 6 h for both thin and thick SL wear. The average reduction in the fluid reservoir thickness was 80 microns with thin-lens wearers and 79 microns with thick-lens wearers, respectively. The present investigation reported no statistically significant difference in the initial ($P = 0.35$), final ($P = 0.40$), and reduction in fluid reservoir thickness ($P = 0.80$) while comparing thin- and thick-lens wearers.

Correlation analysis

Association analysis revealed no statistically significant correlation between measured central lens thickness and corneal edema centrally (r < 0.40, $P > 0.05$). While correlating lens thickness and corneal curvature change, a statistically significant positive correlation (r = 0.67, $P = 0.02$) was observed only during thick-lens wear between thickness and anterior k steep [Fig. 4]. No statistically significant relationship was reported between lens thickness and initial, final, and reduction in the central fluid reservoir thickness (r < 0.40, $P > 0.05$) in both thin- and thick-lens wearers.

Discussion

Corneal hypoxic changes associated with SL wear have been reported as being due to lens thickness, oxygen permeability, fluid reservoir thickness, and other factors such as edge lift, lens compression, endothelial integrity, and duration of lens wear.[7,8,12] Researchers also reported the absence of chafing of the corneal epithelium by the eyelid during blinking as the SL vaults the cornea and allows the cornea to come back to its actual thickness.[13] The time taken between lens removal and completion of Pentacam measurement and the release of negative pressure and suction pressure behind the lens during SL removal also reported a slight underestimation in the exact corneal edema.[12] To avoid the influence of the abovementioned factors, the current study included keratoconus subjects with an endothelial cell count of above 2000 cell/mm^2; used lenses with the same design, diameter, and oxygen permeability; and measured the corneal thickness change without the lens (Pentacam) and with the lens on the eye (AS-OCT Casis). The present study observed a minimal and statistically insignificant difference in corneal swelling in different regions and quadrants of the cornea. The percentage of corneal edema noted with both thin and thick lenses were within the range of closed eye physiological corneal swelling, which was consistent with the results of previous studies.[12-15] The superior quadrant showed greater corneal edema than other quadrants, which might be due to the position of the upper eyelid acting as a barrier to atmospheric oxygen and consistent with the previous study.[12] The current study reported no association between lens thickness and central corneal edema for both thin and thick lenses. Bleshoy *et al.*[5] reported greater percentage of corneal

Table 2: Mean±SD comparison of central fluid reservoir thickness (μm) between thin- and thick-lens wearers

Parameters	Thin lens	Thick lens	P*
Initial fluid reservoir thickness after 5 min	448.36±43.02	452.91±42.05	0.35
Final fluid reservoir thickness after 6 h	368.36±39.03	373.55±38.20	0.40
Reduction in fluid reservoir thickness	80.00±3.99	79.36±3.84	0.80

*Independent *t*-test

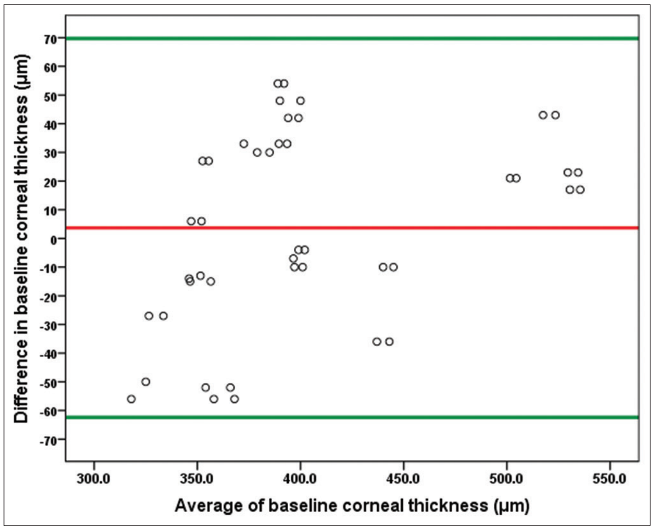

Figure 1: Bland–Altman plot showing agreement of baseline central corneal thickness measured by Pentacam and AS-OCT

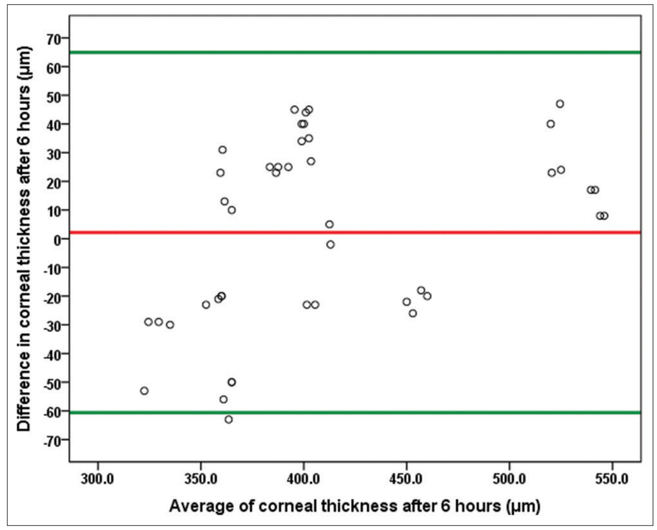

Figure 2: Bland–Altman plot showing agreement of central corneal thickness after 6 h of lens wear measured by Pentacam and AS-OCT

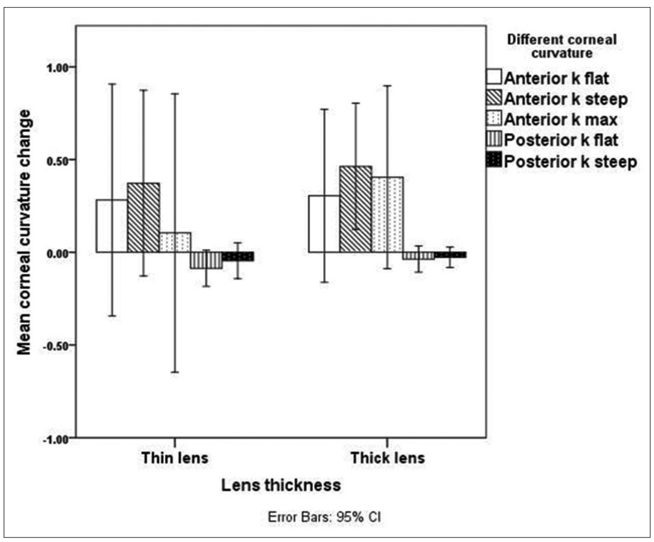

Figure 3: Bar graph showing the change in anterior and posterior corneal curvature after 6 h of lens wear between thin and thick lens wear

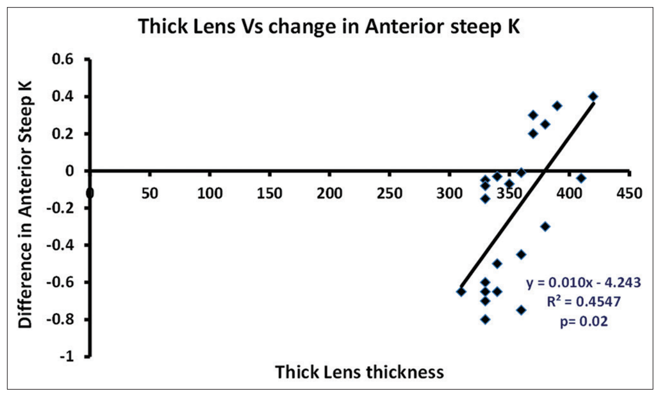

Figure 4: Scatter plot between lens thickness and change in anterior K steep in thick lens wearers after 6 h of lens wear

swelling than the present study; this could be due to high Dk lens material used in the present study (Dk = 140) than in their study (Dk = 24). Vincent *et al*.[12] found less percentage of corneal swelling than the present study, probably due to measuring in healthy corneas, whereas the present study was conducted in keratoconic eyes.

The present study measured the corneal thickness with the lens on the eye by using AS-OCT to avoid the rebound corneal thinning after lens removal. The measured central corneal thickness was higher with the Pentacam system compared with AS-OCT Casia in both baselines and after 6 h of lens wear. Though this investigation reported a good correlation between the two measurements, a clinically relevant difference and large disagreement was noted between both instruments. The average central corneal edema measured with Pentacam after lens removal was 1.91 ± 1.59% and 2.41 ± 1.30% in thin- and thick-lens wearers, respectively, and with AS-OCT Casia with lens on eye was 2.79 ± 1.34% and 2.89 ± 1.14% for thin- and thick-lens wearers, respectively, in the current study. The AS-OCT measured a higher percentage of corneal edema compared to Pentacam, thus proving that the time interval between lens removal and completion of Pentacam imaging results in thinning and slight underestimation in the actual amount of corneal edema. The same has been observed by Vincent *et al*.[12] and reported thinning of 0.66 ± 1.50% (3.72±9.17 μm thinning) between the first and fifth pentacam image obtained after lens removal. The above finding shows the restoration of corneal physiology after lens removal and recommends measuring the actual amount of corneal edema with the lens on the eye by using AS-OCT to avoid any underestimation.

Few studies have reported the change in corneal curvature after long hours of SL wear in keratoconus eyes. It is hypothesized that corneal curvature parameters are influenced by the eyelid pressure on the lens, the negative pressure created by the thicker fluid reservoir, corneal swelling, tissue compression near the limbus, and suction force created during lens removal. The current study reported a minimal flattening in anterior corneal curvature and steepening in posterior curvature in both thin- and thick-lens wearers. The present study results were consistent with some previous studies.[5,8-16] The current study observed a positive relationship only between lens thickness and anterior steep K in thick-lens wearers. This may infer that the thicker the lens, the greater the anterior steep K flattening due to the force generated by the tissue compression near the limbus. Another reason could be that the thicker the lens, the greater the mass, and the lens will land on the conjunctiva and episclera more closely, which may cause the tear layer to create more negative pressure over the cornea.

This study reported no strong association between the change in corneal curvatures and other factors such as corneal edema and reduction in fluid reservoir thickness. This confirms that minimal flattening observed in the present study could be because of negative pressure created by fluid within the sealed system or the effect of lid tone.[12] Vincent *et al*.[17] reported a 0.05-mm change in curvature, which equals a 0.37-D change in a 46–54-D (6.25–7.34 mm) cornea and a 0.50-D change in a cornea of 55 D (6.14 mm) or steeper. Serramito *et al*.[16] showed changes up to 0.20 mm, which is equivalent to 1 D after SL removal. Soeters *et al*.[8] reported steepening up to 0.50 D in Kflat, 0.70 D in Ksteep, and 1.1 D in Kmax in corneal curvature 1 week after SL removal in keratoconic eyes. Serramito *et al*.[16] found flattening up to 0.21 mm after 8 h of SL wear in keratoconus patients. The present investigation reported a mean change of 0.10–0.46 D in anterior corneal curvature after 6 h of lens wear. The above results showed the effect of the SL on corneal curvature in steeper corneas such as keratoconus and can give a negative impression on disease progression in subjects that use lenses for long hours (>12–16 h per day).

The current study found no significant difference between initial and final fluid reservoir thickness with different-thickness SLs. Previous studies hypothesized that the peripheral curve, central curvature, thickness, and overall diameter may be the reason behind the alteration in the central fluid reservoir. Several studies have reported less settling in the fluid reservoir with larger-diameter SLs compared to smaller-diameter lenses as the landing zone of large-diameter lenses covers a greater surface area and also depends on the type of bulbar conjunctiva.[10,18] This study hypothesized that the thicker the lens, the greater the mass, which along with lid pressure might cause the lens to land on bulbar conjunctiva and episclera more closely, which will impede the lens settling.[9] The current study observed no significant difference in reduction of fluid reservoir thickness between thin- and thick-lens wearers, and no association was observed between lens thickness and fluid reservoir thickness. This proves that the lens thickness to a certain range (200–400 μm) might not influence fluid reservoir thickness while using the same lens design and diameter.

Practitioners should be careful while measuring fluid reservoir thickness after settling of the lens as very little fluid reservoir thickness may result in the corneal and limbal bearing, which can affect the corneal and limbal integrity. Excessive fluid reservoir thickness can cause more turbidity in the tear reservoir and may reduce vision quality[19] and oxygen transmissibility to the cornea and limbus.[20] In the current study, the central fluid reservoir thickness ranging from 350 to 500 microns did not induce any clinically significant corneal edema after 6 h of lens wear. This result is consistent with the clinical report by Sonsino *et al*.,[21] who reported successful SL wear with a fluid reservoir of 380 ± 110 μm (up to 600 μm). There was no association found between central fluid reservoir thickness and central corneal edema, which suggests that the reported range of central fluid reservoir thickness with a material of 140 Dk may not cause significant corneal hypoxia in keratoconic eyes with adequate endothelial cell count.

Michaud *et al*.[20] concluded that to avoid central corneal edema, the ideal combination should be a maximum central lens thickness of 250 microns; fluid reservoir thickness should not be more than 200 microns with a lens of the highest DK available. Compan *et al*.[15] concluded a combination of at least 125 barrer of lens oxygen permeability, 200-micron lens thickness, and 150 microns of fluid reservoir thickness to avoid clinically significant edema. This study found that a combination of oxygen permeability of 140, lens thickness of 200–400 microns, and fluid reservoir thickness of 350–500 microns will not cause clinically significant corneal edema if worn for 6 h per day.

With disease progression, the fluid reservoir thickness may reduce, which again can cause contact between the lens and the cornea; hence, a marginally higher fluid reservoir can be considered in progressive keratoconus cases as a safety margin without compromising the visual quality, comfort, and oxygen transmissibility. A regular follow-up and measurements of corneal curvature are recommended to confirm the progression of the disease. Hence, practitioners need to be careful while measuring corneal parameters with corneal topography in SL users as the alteration of corneal curvature after lens removal may mask the disease progression or corneal steepening.

The limitations of the current study were that the lens settling was not measured at frequent time intervals as the purpose of the study was to evaluate the settling after 6 h of lens wear. The study was performed only on patients with keratoconus with adequate endothelial cell count; hence, the outcome of the study may not be implemented in any other corneal pathology and lens design. This warrants further studies on other corneal pathologies, post graft corneas, and ocular surface disorder conditions. The present study did not measure the magnitude of change in corneal curvature after a few days or weeks after lens removal. Though there was no significant difference in results between 6 h (present study) and 8 h[13] of lens wear, those using lenses for longer than 12–14 h continuously might have more effect and requires further studies.

Conclusion

In conclusion, alteration in lens thickness by keeping the other parameters same did not induce clinically significant corneal edema and was within the range of closed eye physiological corneal swelling after short-term SL wear. The central lens thickness of 200–400 microns caused a small and insignificant anterior corneal curvature flattening and posterior corneal curvature steepening. Lens settling or reduction in fluid reservoir did not change with lens thickness. Anterior segment OCT should be considered to measure the corneal thickness with the lens on the eye to avoid underestimation. An SL with a combination of high Dk material, 200–400-microns lens thickness, and 350–500-microns fluid reservoir can be used safely in patients with keratoconus having adequate endothelial health.

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Conflicts of interest

There are no conflicts of interest.

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