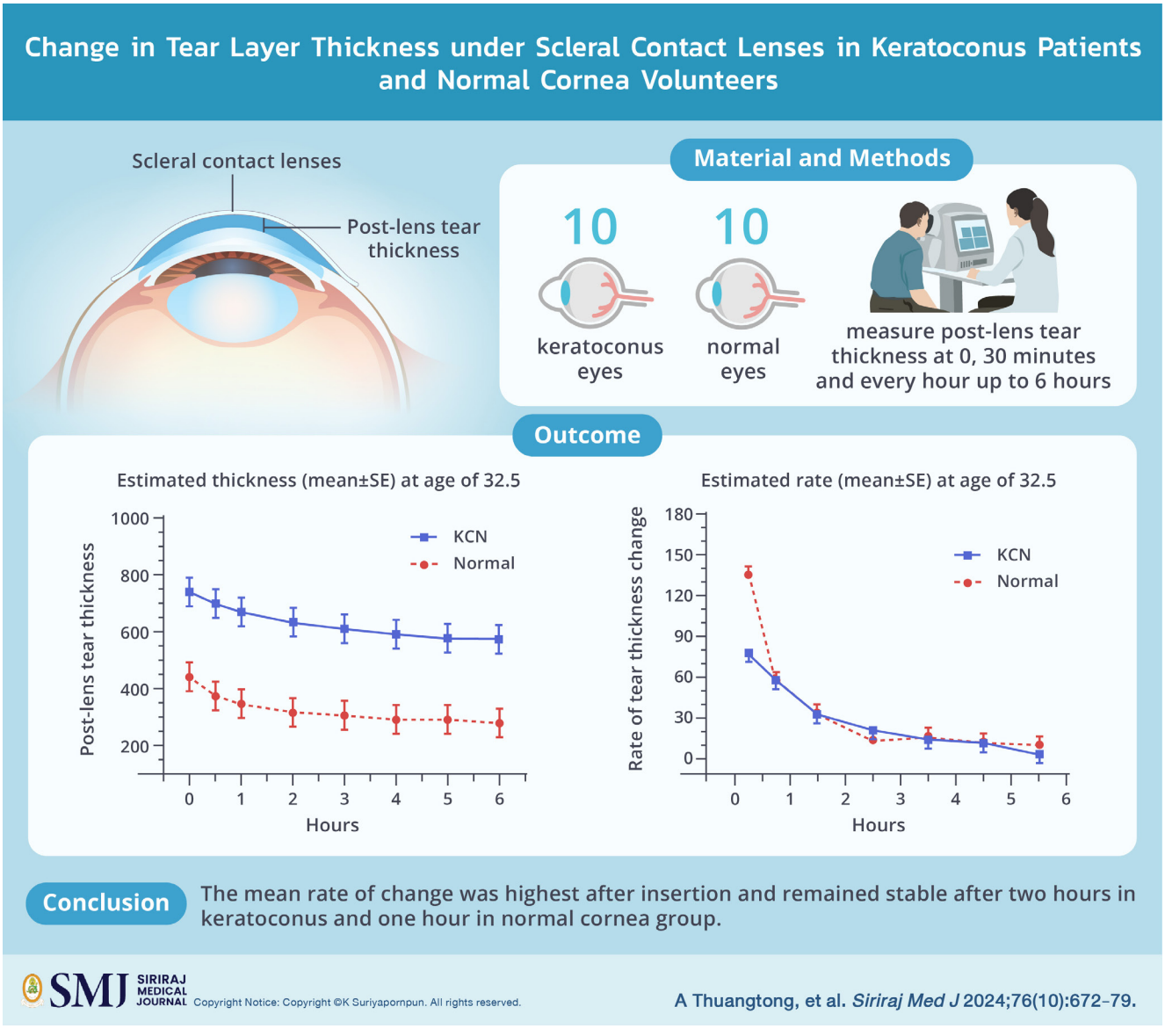
Change in Tear Layer Thickness under Scleral Contact Lenses in Keratoconus Patients and Normal Cornea Volunteers

Atiporn Thuangtong, M.D., Nuttacha Taetrongchit, M.D.*, Rung Kemahayung, MST

Department of Ophthalmology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand.



*Corresponding author: Nuttacha Taetrongchit
E-mail: girtnuttacha@gmail.com
Received 2 February 2024 Revised 20 May 2024 Accepted 29 May 2024
ORCID ID:http://orcid.org/0000-0003-0676-7272
https://doi.org/10.33192/smj.v76i10.267608

ABSTRACT

Objective: To quantify rate of post-lens tear thickness change under scleral contact lenses in keratoconus patients and normal cornea volunteers.

Materials and Methods: We conducted a prospective observational study where semi-scleral lenses were fitted to 20 eyes (5 subjects, 10 eyes in each group). After insertion, post-lens tear thickness was measured at 0, 30 minutes and every hour up to 6 hours using Anterior Segment OCT. To analyze post-lens tear thickness and its rate of change at each time point, both within and between groups, a linear mixed model was used.

Results: The initial mean post-lens tear thickness (μm) was 742 ± 50 and 440 ± 50 in keratoconus and normal cornea group, respectively. The mean rate of change (μm/hr) was highest in the first 30 minutes in both groups (80.8 ± 8.7, 132.2 ± 8.8 in keratoconus and normal cornea group). Following the first four hours in keratoconus and the first hour in normal cornea group, the reduction rate in post-lens tear thickness exhibited no statistically significant difference from the rate of change observed during the 5-6 hour period. The mean percentage of total change over 6 hours after lens insertion was higher in normal cornea compared to keratoconus group (36.6% vs 22.5%).

Conclusion: The reduction in post-lens tear thickness follows a nonlinear pattern. The mean rate of change was highest after insertion and remained stable after four hours in keratoconus and one hour in normal cornea group. The percent change over the 6-hour period was greater in normal cornea group.

Keywords: Keratoconus; scleral contact lenses; post-lens tear layer thickness; anterior segment OCT (Siriraj Med J 2024; 76: 672-679)

INTRODUCTION

Scleral contact lenses are becoming popular for treating diverse ocular surface diseases, particularly corneal ectasia, such as keratoconus.[1,2] Unlike traditional rigid gas permeable contact lenses, which make direct contact with the corneal surface, scleral contact lenses are uniquely designed to vault over the cornea and limbus and rest on the sclera instead. This creates a space between the corneal surface and the lens, forming a tear reservoir. This design has proven effective and stable in improving visual performance in individuals with corneal ectasia, especially keratoconus, due to its ability to cover the entire cornea and neutralize both regular and irregular corneal astigmatism. Additionally, the tear reservoir prevents direct contact between the lens and the apical corneal surface.[3,4]

Currently, there is a lack of consensus on the optimal amount of corneal clearance or post-lens tear thickness required to achieve an ideal fit for scleral contact lenses.[5] Recommendations for corneal clearance range between 100 and 400 μm, with variations depending on the lens design and diameter.[4,6-8] If the post-lens tear thickness is too low, there is a risk of mechanical damage to the corneal epithelium and consequent patient discomfort. This is particularly critical in cases of corneal ectasia like keratoconus where the progression of the condition can reduce post-lens tear thickness, which increases the likelihood of contact between the lens surface and the cornea. Conversely, excessive post-lens tear thickness can negatively impact optical quality and reduce oxygen transmission to the cornea.[4,6]

Due to the compressible nature of the conjunctival and tenon tissues, coupled with the pressure exerted by the eyelids, the clearance of scleral contact lenses decreases over time following the initial insertion.[4,7,9,10] The exact time it takes for a scleral lens to fully settle on the eye remains unknown. Factors like the lens diameter and the length of time it is worn are thought to affect the extent of settling of scleral lenses.

Fitting scleral contact lenses is a time-consuming process and requires practitioners to dedicate a significant amount of time to find ideal lens that provide optimal visual performance and comfort, while also being safe for the ocular surface, especially in the patients with advanced corneal ectasia. The sole type of design for scleral contact lenses utilized at Siriraj Hospital is the semi-scleral design (Onefit®). Previous studies have not reported on the settling of semi-scleral lenses and the rate at which post-lens tear thickness stabilizes in conditions of corneal ectasia compared to non-ectatic conditions.

This study aims to quantify the rate of change of post-lens tear thickness beneath scleral contact lenses (semi-scleral design) in keratoconus patients and normal cornea volunteers.

MATERIALS AND METHODS

In this pilot prospective observational study, we enrolled 10 subjects (20 eyes) aged over 18 years from the Department of Ophthalmology, Siriraj Hospital, between January 2022 and May 2023. The study included two groups: the keratoconus group comprising 10 eyes from 5 subjects previously diagnosed with keratoconus (Rabinowiz Criteria), and the normal cornea group, which consisted of 10 eyes from five volunteers with normal corneal curvature, as indicated by corneal topography (Oculus Pentacam). We excluded patients with active ocular disease and/or infections, those using eye drops during the study, and individuals for whom scleral contact lenses were contraindicated.

Prior to enrollment, all subjects gave their consent and signed an informed consent form. This study adhered to the principles outlined in the Declaration of Helsinki. The study protocol was reviewed and approved by the Siriraj Institutional Review Board (SIRB) at Siriraj Hospital, Mahidol University in Bangkok, Thailand, under IRB number 767/2022. The clinical trial was registered with the identifier TCTR20221208004 at www.clinicaltrial.gov.

All subjects were fitted with Onefit SC® semi-scleral lenses, each with a diameter of 14.7 mm (Blanchard Contact Lens, Inc) using non-preservative artificial tears (Tear Naturale Free®).

To measure post-lens tear thickness, we used anterior segment optical coherence tomography (CASIA2) at eight different time points after lens insertion: 0 minutes, 30 minutes, 1 hour, 2 hours, 3 hours, 4 hours, 5 hours, and 6 hours. A single researcher[5] conducted these evaluations to minimize interobserver variability. At each time point, three images were captured along both the steep and flat axes of the cornea. We utilized a software program to draw a line connecting the scleral spurs on either side of the anterior chamber angle. A perpendicular line was then drawn from the midpoint of this line, passing through the cornea and post-lens tear to the surface of the lens. The measurement of post-lens tear thickness was conducted manually on this perpendicular line as shown in Fig 1. The post-lens tear thickness measurements were conducted by a single researcher (NT) who calculated the average thickness at the center of both the steep and flat cornea from three images at each timepoint.

Statistical analysis

Quantitative data were summarized using means and standard deviations. Since post-lens tear thickness and the rate of its change were observed in both eyes for each subject and at eight different time points (0, 0.5, 1, 2, 3, 4, 5 and 6 hours after lens insertion), a multilevel linear mixed model was applied with level 1 of time, level 2 of eye and level 3 of subject. Subject and eye were random effects whereas time was repeated. Independent variables of group (KCN, normal), time (as a categorical variable), group*time interaction and age were fixed effects. Age was included in the mixed model due to a clinically significant higher mean age in the normal than KCN group and age might affect the outcome. Bayesian information criterion (BIC) was used to choose covariance structure and the best fitted model.

Data analysis was performed using IBM SPSS 30.0 (IBM Corp., Armonk, NY, USA). A p-value of less than 0.05 was considered statistically significant.

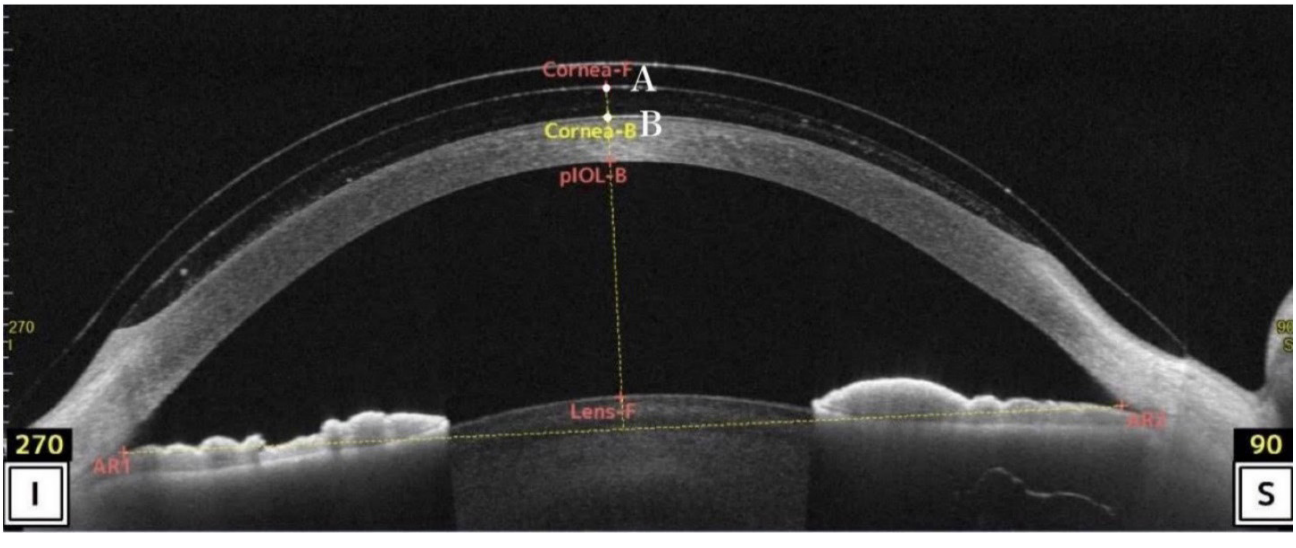


Fig 1. Measurement of post-lens tear thickness using the AS-OCT. Post-lens tear thickness is represented as distance from point A to point B.

RESULTS

In this study, a total of 20 eyes from 10 subjects (5 subjects in each group) were examined. In the keratoconus group, there was one female participant, while the normal cornea group consisted of five female subjects. Subjects in the normal cornea group were 8 years older than those in the keratoconus group, with a mean ± SD of 36.8 ± 8.0 and 28.6 ± 5.7 respectively (p=0.100). Due to only five subjects in each group, the difference in age of eight years was not statistically significant but clinically important. Among the 10 eyes diagnosed with keratoconus, the mean keratometry readings at the steepest and flattest axes were 54.26 ± 7.92D and 49.59 ± 6.95D respectively. In contrast, the 10 eyes in the normal cornea group showed mean keratometry readings of 43.93 ± 0.97D and 43.18 ± 0.96D, respectively. In keratoconus group, according to ABCD keratoconus grading system, 1 patient was grade 1, 4 patients were grade 2, 2 patients were grade 3 and 3 patients were grade 4 keratoconus.

Fig 2A illustrates the spaghetti plot of post-lens tear thickness against time for each subject's eye, by group (KCN, normal), while Fig 2B presents the observed mean ± SD by group and time. In the keratoconus group, the mean post-lens tear thickness (μm) at baseline and 6 hours post-lens insertion were 720 ± 166 and 553 ± 160, respectively, compared to 463 ± 91 and 303 ± 75 in the normal cornea group. The post-lens tear thickness was different in both groups. Over time, post-lens tear thickness in both groups decreased. Notably, at each time point, a post-lens tear thickness the keratoconus group was roughly 230-283 μm greater than that of the normal cornea group.

To account for correlated eyes and 8 repeated measures over time, a multilevel linear mixed model of post-lens tear thickness was applied. Based on the fitted mixed model, the post-lens tear thickness was estimated using the average age among 10 subjects. Mixed model reveals that the keratoconus group had consistently thicker post-lens tear than normal cornea group at every time point, with an average difference of 309 μm (Fig 2, Table 1). Within-group comparisons indicated that post-lens tear thickness decreases over time in both groups but stabilizes after 3 hours. In the keratoconus group, post-lens tear thickness decreased from 743 μm (0-30 minutes) to 614 μm (at 3 hours) and remained relatively stable at roughly 584 μm during the 4-6 hour period. Conversely, in the normal cornea group, it decreased from 441 μm (0-30 minutes) to 305 μm (3 hours) and was roughly stable at 287 μm after 3 hours. According to Table 1, the percentage change in post-

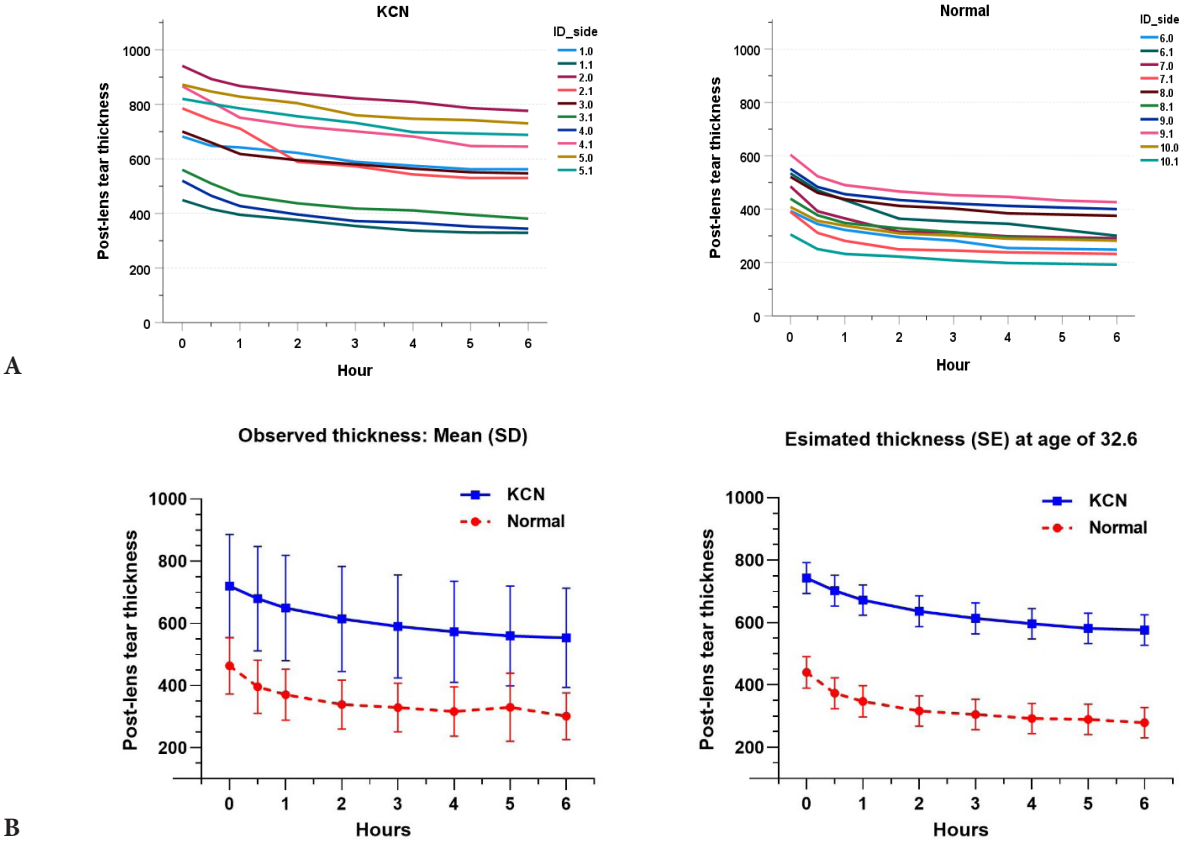


Fig 2. A spaghetti plot of the post-lens tear thickness in each eye over time by group (A), observed and predicted mean from mixed model (B).

TABLE 1. Estimated post-lens tear thickness (μm) at each time point in the keratoconus and normal cornea group.

	Post-lens tear thickness[#]: Mean ± SE		KCN – Normal:
	KCN	Normal	Mean difference (95% CI)
Time			
0 minute	**742 ± 50**	**440 ± 50**	302 (124 ,481)**
30 minutes	**702 ± 50**	**373 ± 50**	329 (150, 507)**
1 hour	**672 ± 49**	**347 ± 50**	325 (147, 503)**
2 hours	**636 ± 50**	**316 ± 49**	320 (143, 498)**
3 hours	**613 ± 50**	**305 ± 49**	307 (129, 485)**
4 hours	596 ± 49	292 ± 49	303 (126, 481)**
5 hours	581 ± 49	289 ± 49	293 (115, 471)**
6 hours	576 ± 49	279 ± 49	296 (118, 474)**
Comparison with 6 hours: Mean difference (95% CI)			
0 minute	166 (126, 207)***	160 (120, 201)***	
30 minutes	126 (93, 159)***	94 (61, 127)***	
1 hour	96 (67, 125)***	67 (39, 96)***	
2 hours	61 (48, 73)***	37 (24, 49)***	
3 hours	37 (25, 49)***	26 (14, 38)*	
4 hours	20 (7, 33)**	13 (-1, 26)	
5 hours	6 (-9, 20)	9 (-10, 28)	

[#] For subject aged 32.6 years

*** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$

lens tear thickness at 6 hours from baseline was greater in the in normal cornea group than in the keratoconus group (36.6% vs. 22.5%).

The mixed model of the rate of post-lens tear thickness change revealed that the highest rate occurred during the first 30 minutes, with an average of 81 and 132 μm/h in the keratoconus and normal cornea groups (Fig 3, Table 2) and significant difference of 51μm/h ($p < 0.01$). Within each group, the rate of change decreased over time. From 0-30 minutes to 1-2 hours, the rate reduced from 81 μm/h to 36 μm/h in the keratoconus group compared to a reduction from 132 μm/h to 31 μm/h in the normal cornea. After two hours, the rate of change was less than 24 μm/h in both groups. In the keratoconus group, there was no statistically significant difference in the rate of change after 4 hours, whereas in the normal cornea group, significant differences ceased after 1 hour (Table 2).

DISCUSSION

Our study focuses on the variation and rate of change in post-lens tear thickness beneath scleral lenses (14.7 mm in diameter) over a 6-hour period post-lens insertion in eyes with keratoconus and normal corneas. Consistent with previous studies, we observed a decrease in post-lens tear thickness over time in both the keratoconus and normal cornea group. The mean decrease in post-lens tear thickness after 6 hours was 166 ± 50 μm (22.5% from initial thickness) in the keratoconus group and 161± 50 μm (36.6% from initial thickness) in the normal cornea group. Although the reduction in tear thickness in microns was comparable between the two groups, the percentage change from initial to the 6-hour period was greater in the normal cornea group compared to the keratoconus group.

This is comparable to findings of *Caroline et al.*[10] who investigated the fitting of 16.5 mm diameter scleral contact lens in 15 healthy eyes. Their study reported an average decrease in apical corneal clearance of 96 μm (ranging from 70 to 180 μm) after 8 hours of lens wear. This highlights the significant variability in lens settling observed among different subjects.

Varsha M. Rathi et al.[4] conducted a study examining the changes in post-lens tear thickness during a 4-hour scleral lens wear in eyes with corneal ectasia and ocular surface disease. Their results showed a decrease in post-lens tear thickness in 90% of the eyes studied. They also observed a higher percentage of settling in the corneal

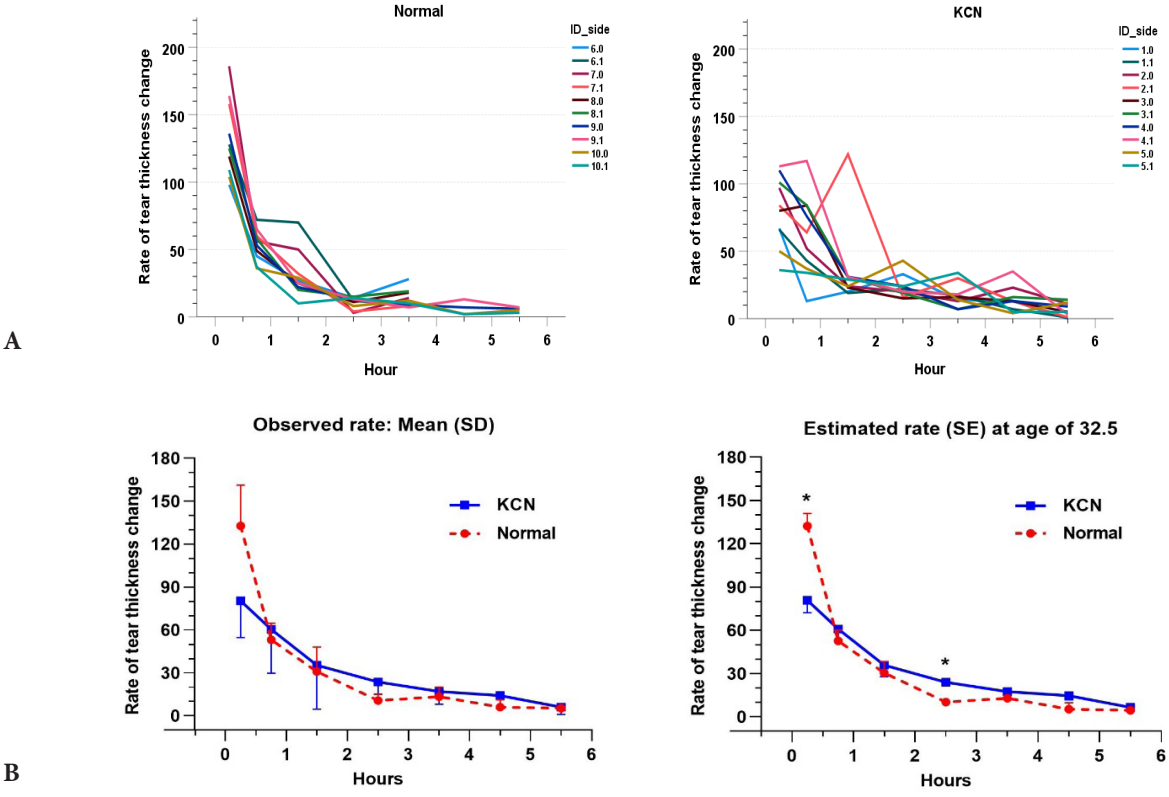


Fig 3. A spaghetti plot of the rate of tear thickness change in each eye over time by group (A), observed and predicted mean from mixed model (B).

TABLE 2. Estimated rate of post-lens tear thickness change (μm/h) at each time point in the keratoconus and normal cornea group.

	Rate of thickness change#: Mean ± SE		KCN – Normal:
	KCN	Normal	Mean difference (95% CI)
Time interval			
0 - 30 minutes	**80.8 ± 8.7**	**132.2 ± 8.8**	-51.4 (-77.4, -25.3)**
30 minutes - 1 hour	60.8 ± 7.4	52.6 ± 7.4	8.2 (-13.9, 30.3)
1 - 2 hours	35.8 ± 7.9	30.5 ± 7.9	5.3 (-18.3, 28.9)
2 - 3 hours	24.0 ± 2.1	10.2 ± 2.1	13.8 (7.4, 20.2)***
3 - 4 hours	17.4 ± 2.5	12.8 ± 2.5	4.6 (-2.9, 12.1)
4 - 5 hours	14.6 ± 2.8	5.3 ± 4.4	9.3 (-2.2, 20.9)
5 – 6 hours	6.5 ± 1.5	4.5 ± 2.4	2.0 (-4.4, 8.4)
Comparison with 5-6 hours: Mean difference (95% CI)			
0 – 30 minutes	74.3 (43.2, 105.4)***	127.7 (96.3, 159.1)***	
30 minutes – 1 hour	54.3 (27.9, 80.7)***	48.1 (21.3, 74.9)***	
1 – 2 hours	29.3 (1.1, 57.5)*	26.0 (-2.5, 54.5)	
2 – 3 hours	17.5 (9.2, 25.8)***	5.7 (-4.6, 16.0)	
3 – 4 hours	10.9 (1.4, 20.4)*	8.3 (-2.8, 19.4)	
4 – 5 hours	8.1 (-3.0, 19.2)	0.8 (-16.8, 18.3)	

For subject aged 32.6 years

*** p < 0.001, ** p < 0.01, * p < 0.05

ectasia group (17.25%) compared to the ocular surface disease group (13.9%). In their research, scleral lenses of various diameters, ranging from 16 mm to 18.5 mm, were used. The differences in settlings observed between the two types of corneal disease may have been influenced by the variations in lens design. In contrast, our study utilized a consistent semi-scleral lens design with a uniform diameter of 14.7 mm for all participants. Our results showed a decrease in post-lens tear thickness in all eyes across both groups, with a statistically significant difference in the percentage of settling between the two groups. Notably, the normal cornea group exhibited a significantly higher percentage of settling (36.6%) compared to the keratoconus group (22.5%).

Kauffman et al.[11] investigated the settling behavior of three different scleral lens designs (diameters of 14.3, 15.8, and 18.2 mm) in individuals with normal eyes. Their research, conducted over an 8-hour period, found variations in lens settling across these different designs. Additionally, they noted that 70% of total lens settling occurred within the first 2 hours following lens insertion. In our study, using 14.7 mm diameter scleral lenses, we noted a non-linear pattern in lens settling in both the normal cornea and keratoconus group. The most significant decrease in the average rate of post-lens tear thickness was observed in the first 30 minutes after lens insertion, followed by a gradual reduction noted over subsequent time periods in both groups. The reduction rate in post-lens tear thickness during the initial 30 minutes was statistically higher in the normal cornea group (132 μm/hr) compared to the keratoconus group (81 μm/hr). Consistent with the findings from *Kauffman's* study, our results in the normal corneal group indicated that 76.5% of the total lens settling over the 6-hour period occurred within the first 2 hours following lens insertion.

Previous studies have indicated that variations in scleral lens design and diameter impact settling behavior.[4,7,11] According to our results, using the same lens design and diameter (semi-scleral lens, diameter 14.7 mm), we observed that the degree and rate of settling vary between eyes with keratoconus and those without corneal ectasia. These findings underscore the importance of considering the settling behavior of scleral lenses in the context of different corneal diseases before finalizing lens orders.

A notable limitation of this pilot study is its relatively small sample size. Although we included both eyes of each participant in our analysis, we employed a linear mixed model with random intercept for both subject and eye. To the best of our knowledge, no prior study has examined the extent and settling rate of semi-scleral design contact lenses (specifically those with a diameter of 14.7 mm) and compared them between keratoconus and normal corneas. Therefore, further research with a larger sample size to assess the settling pattern in both ectatic and non-ectatic eyes is necessary to minimize scleral lenses fitting duration.

CONCLUSION

The degree and speed of post-lens tear change beneath a scleral lens varies among different corneal conditions. A decrease in post-lens tear thickness follows a non-linear trend. The most significant rate of change in tear thickness occurs within the first 30 minutes after lens insertion, followed by a gradual decrease over time. The rate of post-lens tear thickness reduction after four hours (in the keratoconus group) and after one hour (in the normal cornea group) exhibits no statistically significant difference from the rate observed between 5-6 hours. The overall percentage change in post-lens tear thickness over a 6-hour period is higher in the normal cornea group than in the keratoconus group.

ACKNOWLEDGEMENTS

The authors gratefully acknowledge contributors from Faculty of Medicine Siriraj Hospital, Mahidol University: Assist. Prof. Dr. Chulaluk Komontri (Research Department) for helping with statistical analysis and interpretation.

Author Contributions

A.T. designed and directed the project. R.K. performed the experiments. N.T. collect the data, analyzed of the results and wrote the manuscript in consultation with A.T.

DECLARATIONS

Conflicts of interest

None

Thai Clinical Trials Registry

TCTR20221208004

Funding

Siriraj Research Development Fund (Managed by Routine to Research: R2R), Faculty of Medicine Siriraj Hospital, Mahidol University (Grant Number (IO) R016635039).

REFERENCES

1. Romero-Jiménez M, Santodomingo-Rubido J, Flores-Rodríguez P, González-Méijome J-M. Short-term corneal changes with gas-permeable contact lens wear in keratoconus subjects: A comparison of two fitting approaches. J Optom. 2015;8(1):48-55.
2. Jacobs DS. Update on scleral lenses. Curr Opin Ophthalmol. 2008;19(4):298-301.
3. Gould HL. Therapeutic effect of flush fitting scleral lenses and hydrogel bandage lenses. Int Surg. 1973;58(7):469-72.
4. Rathi VM, Mandathara PS, Dumpati S, Sangwan VS. Change in vault during scleral lens trials assessed with anterior segment optical coherence tomography. Cont Lens Anterior Eye. 2017;40(3):157-61.
5. Segal O, Barkana Y, Hourovitz D, Behrman S, Kamun Y, Avni I, et al. Scleral contact lenses may help where other modalities fail. Cornea. 2003;22(4):308-10.
6. Michaud L, van der Worp E, Brazeau D, Warde R, Giasson CJ. Predicting estimates of oxygen transmissibility for scleral lenses. Cont Lens Anterior Eye. 2012;35(6):266-71.
7. Esen F, Toker E. Influence of Apical Clearance on Mini-Scleral Lens Settling, Clinical Performance, and Corneal Thickness Changes. Eye Contact Lens. 2017;43(4):230-5.
8. Otchere H, Jones LW, Sorbara L. Effect of Time on Scleral Lens Settling and Change in Corneal Clearance. Optom Vis Sci. 2017;94(9):908-13.
9. Schornack MM, Patel SV. Relationship between corneal topographic indices and scleral lens base curve. Eye Contact Lens. 2010;36(6):330-3.
10. Caroline PJ. Scleral Lens Settling. Contact Lens Spectrum. 2012;27:56.
11. Kauffman MJ, Gilmartin CA, Bennett ES, Bassi CJ. A comparison of the short-term settling of three scleral lens designs. Optom Vis Sci. 2014;91(12):1462-6.