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Changes in pre- and post-contact lens tear film after wearing silicone hydrogel lenses and their correlation with visual perception

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Abstract

Purpose

To investigate tear film changes after wearing Verofilcon A silicone hydrogel soft contact lenses (SCL) and their correlation with visual perception.

Methods

A prospective observational study enrolled 34 myopic patients (68 eyes) who wore daily disposable Verofilcon A SCL continuously. Ocular surface parameters (NITBUT, TMH, LLT, blinking dynamics) were measured at baseline, 2 h, and 8 h after lens insertion using an IDRA Ocular Surface Analyzer; subjective evaluations were done via VAS and CLDEQ-8, with SPSS statistical analysis ($P < 0.05$).

Results

Pre-SCL LLT and TMH significantly decreased at 2 h and 8 h vs baseline (all $P < 0.001$), while pre-corneal LLT and TMH after lens removal showed no significant changes ($P = 0.424$, $P = 0.631$). Pre-SCL first NITBUT prolonged and persisted until 8 h, with no significant pre-corneal NITBUT change post-removal. CLDEQ-8 scores negatively correlated with pre-corneal NITBUT.

Conclusions

Wearing Verofilcon A SCL reduced pre-SCL LLT/TMH, prolonged pre-SCL first NITBUT, and maintained stable pre-corneal tear film. Shorter post-wear corneal NITBUT correlated with more severe dry eye symptoms.

1. Introduction

Owing to the high incidence of myopia, daily disposable contact lenses are prevalent because of their excellent hygiene and convenience [1, 2]. Hydrogel materials are one of the primary types of soft contact lenses (SCL), and their safety and comfort have been confirmed through years of clinical observations [3]. Silicone hydrogel (SiHy) materials have been developed rapidly, improving the oxygen permeability of SCL, maintaining normal corneal physiological function, and preserving physiological integrity under the lens. Silicone hydrogel SCL have become a crucial tool for correcting refractive errors owing to their high oxygen permeability [4]. As the first optical interface of the ocular surface, dynamic changes in the tear film is closely associated with visual perception [5]. Long-term wear of SCL may affect tear film stability, leading to dry eye symptoms and decreased visual quality [6, 7]. As Verofilcon A is a new type of silicone hydrogel material, its interaction with the ocular surface requires further investigation.

Based on the above background, this study, through a prospective observational clinical design, systematically evaluated changes in tear film parameters (including LLT, NITBUT, TMH, and blinking dynamics) after wearing Verofilcon A silicone hydrogel SCL, and analyzed the correlation between these parameters and subjective visual perception.

2. Methods

2.1 Study participants

This prospective observational clinical study was conducted at Eye and ENT Hospital of Fudan University between June and December, 2023. Study was designed according to the principles stated in the Declaration of Helsinki and approved by the hospital Ethics Committee (Ethics code: 2023112). Written informed consent was obtained from the patients included in this study. Thirty-four patients with myopic astigmatism (68 eyes) were enrolled. All subjects were fitted with and continuously wore Verofilcon A Sphere daily disposable contact lenses (PRECISION1, Alcon, Basic Curve 8.3 mm) for more than two weeks.

The inclusion criteria were as follows: age 20–40 years; Best Corrected Visual Acuity (BCVA, Snellen) > 20/25; and spherical refraction ranging from − 1.00 D to -10.00 D.

The exclusion criteria for this study were: ocular or systemic diseases, allergies, medications, other conditions contraindicating contact lens wear, history of ocular surgery, corneal distortion caused by rigid lens wear or keratoconus, pregnancy or lactation, diabetes mellitus, and corneal staining.

2.2 Study procedures

Baseline ocular surface parameters were measured in all participants without lenses. They were then instructed to wear the SCL continuously for two weeks, and the measurements were repeated at two key time points: 2 h and 8 h after lens insertion. Relevant parameters of the SCL surface during wear and corneal surface after lens removal were measured at each time point using an IDRA Ocular Surface Analyzer. The quantitative detection indicators at each time point were as follows:

- Noninvasive tear film break-up time (NITBUT, in s)
- Average noninvasive tear film break-up time (NITBUTav, in s)
- Blinking dynamics (as %)
- Tear film lipid layer thickness (LLT, in nm)
- Tear meniscus height (TMH, in mm)
- Bulbar redness

2.3 Subjective evaluation

After daily wearing of SCL for two consecutive weeks, the participants completed subjective questionnaires to assess the wearing experience. The VAS scores for evaluating comfort were categorized as follows: VAS scores for overall comfort (0-100 points), VAS scores for visual quality (0-100 points), and scores for operational convenience (0-100 points). For these scales, the subjects selected a value between 0 (extremely uncomfortable) and 100 (excellent) to describe their comfort. Wearing time/comfortable wearing time (h), visual acuity (logMAR), and lens fit (movement and positioning) were recorded. Additionally, an 8-item Contact Lens Dry Eye Questionnaire (CLDEQ-8) was completed.

2.4 Statistical analysis

Continuous variables were expressed as mean ± standard deviation. Depending on the type of data, paired t-tests or repeated-measures analysis of variance (ANOVA) was used to compare parameter data at different time points (baseline, 2 h after wearing, 8 h after wearing [on-lens], 8 h after wearing [post-lens removal]). Correlation analysis (Pearson or Spearman method) was used to examine the association between objective tear film parameters (e.g., NITBUT) and subjective questionnaire scores. Statistical significance was set at $P < 0.05$. significant. All analyses were performed using IBM SPSS statistical software (version 26.0; IBM Corporation).

3. Results

3.1 Baseline characteristics of study population

Among the 34 patients with myopic astigmatism (68 eyes), three were male (six eyes) and 31 were female (62 eyes). The average age was 26.71 ± 3.82 years (range: 20–39 years) (Table 1). All the participants completed the follow-up measurements without dropouts. No adverse events leading to visual impairments were observed during the study period. No corneal staining was observed in any eye at the final follow-up.

Table 1
Demographic characteristics and ocular description of the included participants

Factor	Mean ± SD	Range
Gender		
Female: N (%)	31 (91.18)	-
Male: N (%)	3 (8.82)	-
Age (years)	26.71 ± 3.82	(20, 39)
Corneal Curvature Radius (mm)		
Horizontal Corneal Curvature Radius	7.86 ± 0.25	(7.43, 8.49)
Vertical Corneal Curvature Radius	7.65 ± 0.24	(7.34, 8.23)
Average Corneal Curvature Radius	7.76 ± 0.24	(7.39, 8.36)
Refractive status (Diopter)		
Spherical Degree	-4.82 ±1.97	(-10.00, -1.25)
Cylindrical Degree	-0.57 ± 0.32	(-1.50, 0)
Spherical Equivalent Degree	-5.07 ± 2	(-10.25, -1.37)

3.2 Changes in tear film parameters

3.2.1 *Noninvasive Tear Film Break-Up Time (NITBUT)*

The pre-SCL first NITBUT was prolonged at 2 h after wearing compared with baseline and persisted until 8 h, with values of 7.77 ± 2.37 s, 8.13 ± 1.62 s, and 8.73 ± 2.06 s at baseline, 2 h, and 8 h after wearing, respectively (Table 2). There was no significant difference in the pre-corneal first NITBUT measuredafter 8 h lens wearing compared to baseline (7.94 ± 2.78 s) (Table 3).

Table 2
Ocular surface parameters before SCL wearing and after 2hours, 8hours wearing.

Baseline	NITBUT(S)	NITBUTav(S)	Completeness blink rate(%)	LLT(nm)	TMH(mm)	Bulbar redness
	7.77 ± 2.37	**11.65 ± 3.44**	**91.68 ± 10.65**	**66.03 ± 16.33**	**0.27 ± 0.10**	**34.43 ± 12.22**
Pre-SCL after 2hours wearing	8.13 ± 1.62 (0.363)	12.69 ± 2.51 (0.085)	93.08 ± 10.55 (0.370)	52.48 ± 15.90* (<0.001)	0.19 ± 0.06* (<0.001)	29.10 ± 9.33* (=0.006)
Pre-SCL after 8hours wearing	8.73 ± 2.06* (0.040)	12.01 ± 2.78 (0.547)	92.02 ± 11.42 (0.812)	51.80 ± 14.54* (<0.001)	0.20 ± 0.05* (<0.001)	30.74 ± 10.60* (=0.049)

NITBUT, non-invasive tear film break-up time; NITBUTav, non-invasive average tear film break-up time; LLT, liqid layer thickness; TMH, tear meniscus height.

*: with statistical significant difference compared with baseline ($p < 0.05$).

Table 3
Ocular surface parameters before SCL wearing and after 8H wearing.

Baseline	NITBUT(S)	NITBUTav(S)	Completeness blink rate(%)	LLT(nm)	TMH(mm)	Bulbar redness
	7.77 ± 2.37	**11.65 ± 3.44**	**91.68 ± 10.65**	**66.03 ± 16.33**	**0.27 ± 0.10**	**34.43 ± 12.22**
Pre-SCL after 8hours wearing	8.73 ± 2.06* (0.040)	12.01 ± 2.78 (0.547)	92.02 ± 11.42 (0.812)	51.80 ± 14.54* (<0.001)	0.20 ± 0.05* (<0.001)	30.74 ± 10.60* (=0.049)
Pre-corneal after 8hours wearing	7.94 ± 2.78 (0.705)	11.44 ± 3.87 (0.723)	92.01 ± 10.43 (0.724)	68.10 ± 17.91 (0.424)	0.26 ± 0.08 (0.631)	33.68 ± 11.99 (0.594)

NITBUT, non-invasive tear film break-up time; NITBUTav, non-invasive average tear film break-up time; LLT, liqid layer thickness; TMH, tear meniscus height.

*: with statistical significant difference compared with baseline ($p < 0.05$).

3.2.2 *Tear Film Lipid Layer Thickness (LLT)*

Pre-SCL LLT significantly decreased at 2 h after wearing compared to baseline and subsided until 8 h (baseline: 66.03 ± 16.33 nm; 2 h after wearing: 52.48 ± 15.90 nm, $P < 0.001$; 8 h after wearing: 51.80 ± 14.54 nm, $P < 0.001$) (Table 2). Pre-corneal LLT measured after 8 h lens wearing was 68.10 ± 17.91 nm, which was significantly higher than the simultaneous measurement on the lens surface and showed no significant change compared to baseline ($P = 0.424$) (Table 3).

3.2.3 *Tear Meniscus Height (TMH)*

The pre-SCL TMH decreased significantly after wearing the device. Baseline TMH was 0.27 ± 0.10 mm, which decreased to 0.19 ± 0.06 mm at 2 h after wearing ($P < 0.001$) and further to 0.20 ± 0.05 mm at 8 h after wearing ($P < 0.001$). Pre-corneal TMH measured after 8 h lens wearing was 0.26 ± 0.08 mm, which was significantly higher than the simultaneous measurement on the lens surface and showed no significant change compared to baseline ($P = 0.631$).

3.3 Blinking Analysis

Blink quality improved slightly after the SCL was worn. The baseline percentage of complete blinks before wearing was 91.68 ± 10.65 (%), which increased to 93.08 ± 10.55 (%) at 2 h after wearing ($P = 0.370$) and 92.02 ± 11.42 (%) at 8 h after wearing ($P = 0.812$).

3.4 Subjective evaluation results

The mean VAS score for comfort was 80.59 ± 15.94 points, and the mean VAS score for visual quality was 78.82 ± 17.71 points. A total of 23 participants (67.6%) reported wearing SCL for 8 h or longer, and 15 participants (44.1%) reported being able to wear SCL comfortably for 8 h or longer. The total CLDEQ-8 score was 10.15 ± 4.21 points (Fig. 1).

3.5 Correlation between tear film parameters and subjective perception

The correlation between pre-SCL tear film parameters and subjective perception after wearing the lens was weak. The pre-corneal first NITBUT measured after lens removal was significantly and negatively correlated with the CLDEQ-8 scores ($r = -0.296$, $P = 0.024$), and the average NITBUT also showed a significant negative correlation ($r = -0.320$, $P = 0.014$) (Fig. 2).

4. Discussion

By systematically evaluating changes in tear film parameters before and after wearing SCL, this study revealed an important association between lens surface tear film stability and subjective visual perception [8]. The results confirmed that wearing a disposable silicone hydrogel SCL daily led to decreased LLT and TMH on the lens surface and prolonged the first NITBUT. Additionally, no significant differences were found in pre-corneal tear film-related parameters measured after wearing 8 h compared to baseline, indicating that this lens material can maintain a relatively stable tear film environment on the corneal surface [9]. Furthermore, our study found that shorter the corneal surface tear film break-up time, the more severe were the subjective dry eye symptoms.

Changes in the lens surface tear film parameters showed that pre-SCL LLT and TMH were significantly lower than at baseline at 2 and 8 h after wearing. This finding is consistent with previous studies that reported accelerated tear film evaporation and altered tear distribution caused by contact lens wear [10, 11]. Notably, the first NITBUT was significantly prolonged after wearing, increasing from 7.2 s at baseline to 8.9 s at 8 h. This inverse trend suggests that Verofilcon A silicone hydrogel SCL may enhance tear film stability to a certain extent through their surface properties or moisture retention capacity [12]. The pre-corneal tear film parameters measured after lens removal (LLT: 68.10 nm, TMH: 0.26 mm, NITBUT-first, 7.94 s) showed no significant

differences from baseline, further confirming that the impact of the lens on the tear film is mainly concentrated on the lens surface.

Correlation analysis between subjective perception and objective parameters showed that NITBUT on the corneal surface measured after lens removal was negatively correlated with subjective dry eye scores (r = 0.42), indicating that patients with better corneal surface tear film stability reported higher subjective comfort [13]. Meanwhile, TMH was negatively correlated with total CLDEQ-8 scores (r = -0.296, -0.320), suggesting that corneal surface tear film stability is an important factor in determining subjective perception. These correlations were observed only in tear film-related parameters measured on the corneal surface and not on the lens surface, emphasizing the dominant influence of the corneal surface tear film status on subjective perception [14, 15].

To our knowledge, this is the first study to systematically compare changes in tear film parameters on the lens and corneal surfaces at different time points after wearing Verofilcon A lenses, and to establish associations between objective measurement indicators and various subjective evaluation tools. These results support the use of corneal surface tear film stability as an important indicator for assessing comfort in wearing contact lens and provide a scientific basis for optimizing clinical wearing protocols and lens material design.

This study has certain limitations: First, this is a single-center observational study with a relatively small sample size that limits the generalizability of the findings. Second, the wearing effect of a single-lens model for a short term was evaluated. Future studies should include different lens types, extend the observation period, and combine additional indicators such as the tear composition analysis to further deepen our understanding of the underlying mechanisms of tear film changes.

Conclusion

Wearing silicone hydrogel SCL resulted in decreased LLT and TMH on the lens surface and prolonged the first NITBUT. No significant changes were found in the pre-corneal tear film-related parameters measured 8 h after wearing compared to baseline. The SCL hydrogel exhibited appreciable corneal surface tear film stability. The shorter the pre-corneal tear film break-up time after wearing SCL, the more severe were the subjective dry eye symptoms. Corneal surface tear film stability is an important indicator of contact lens comfort.

Declarations

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Acknowledgements:

Conflicts of Interest:

None declared.

Declaration of Interest statement:

None declared.

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Author Contribution

Liu Liu, and Lin Jiang wrote the main manuscript text. Yanlan Ding and Lian Xu prepared figures 1-2. Chunyi Gui, Xingtao Zhou and Xiaoyu Zhang reviewed the manuscript

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Figures

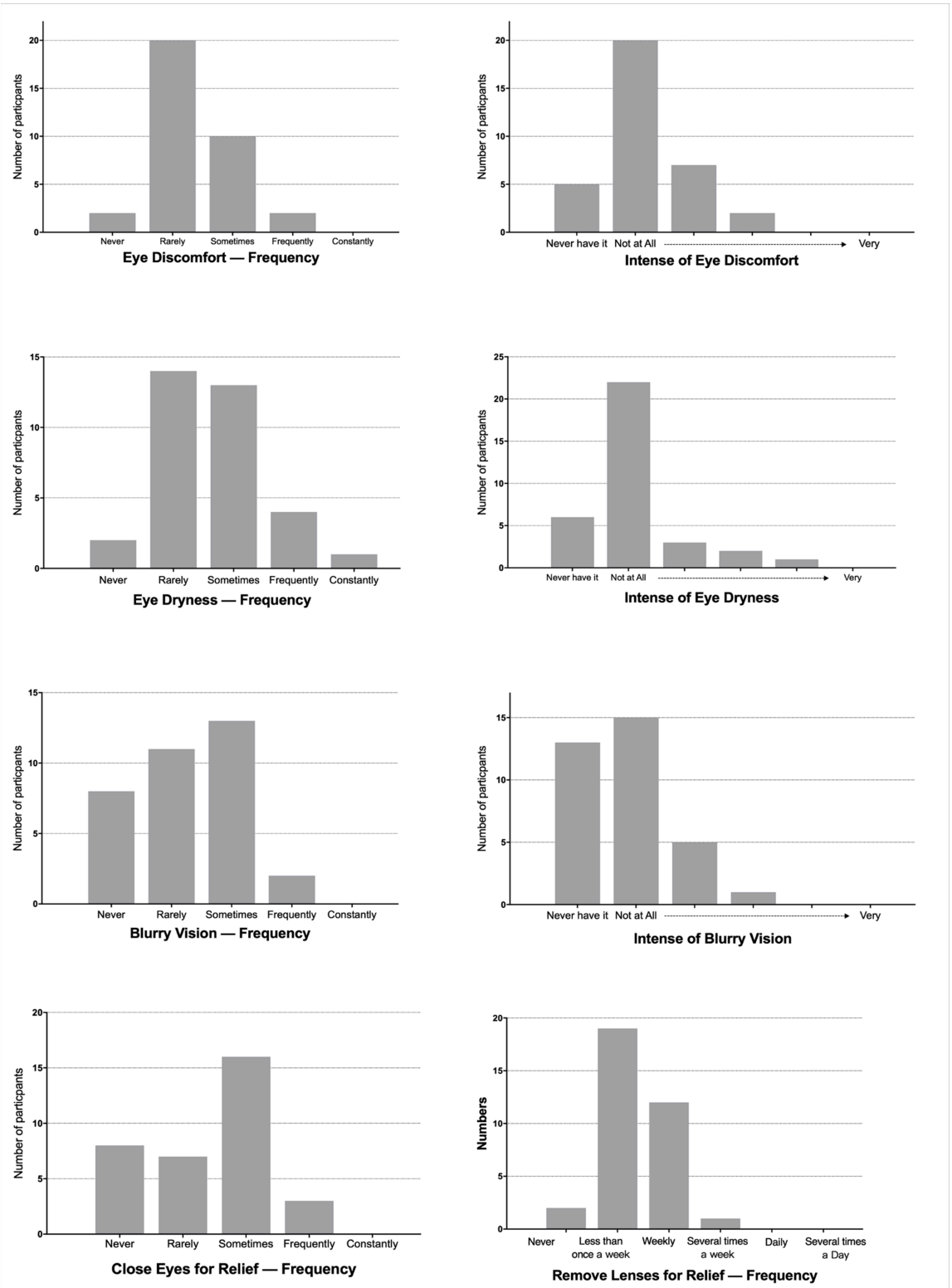


Figure 1

CLDEQ-8 results after PRECISION1 daily wearing

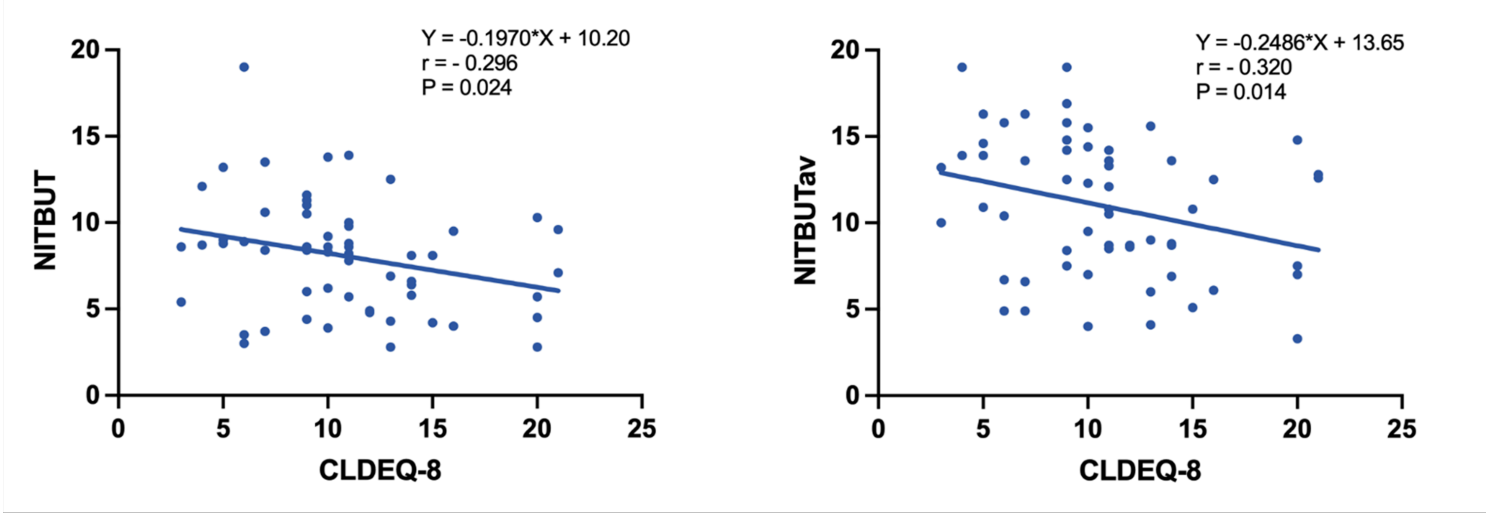


Figure 2

Correlation analysis between NIBUT and CLDEQ-8