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Investigation of the influencing factors on subjective evaluation in initial and end-of-day silicone hydrogel contact lens wear

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Abstract

Background This study aimed to investigate the factors influencing subjective ratings of comfort, vision quality, dryness, and satisfaction at both initial and end-of-day wear among young Asian wearers of silicone hydrogel contact lenses.

Methods Participants aged 20 to 24 years who were satisfied wearers of silicone hydrogel daily disposable contact lenses were recruited. Each participant attended two scheduled visits. During the first visit (Day 1), ocular health, refractive error, visual acuity, first and average non-invasive tear break-up time (F-NITBUT and A-NITBUT), and subjective ratings were measured without lenses and 15 min after wearing Somofilcon A daily disposable lenses. On the second visit (Day 7), follow-up data were collected after seven consecutive days of lens wear.

Results A total of 59 healthy participants (mean age: 20.86 ± 1.29 years) participated in this study. Visual acuity demonstrated a significant negative correlation with comfort, vision quality, and satisfaction after 15 min of Somofilcon A lens wear on Day 1 and a positive correlation with dryness. Additionally, A-NITBUT was significantly positively correlated with vision quality. On Day 7, visual acuity was negatively correlated with overall vision quality after 8 h of wear. However, residual refraction and F-NITBUT showed no significant correlation with comfort, vision quality, dryness, or satisfaction after 15 min of wear on Day 1–8 h on Day 7.

Conclusions The results suggest that higher visual acuity at initial lens wear was strongly associated with improved subjective comfort, vision quality, and overall satisfaction, as well as reduced dryness. Furthermore, a longer average tear break-up time was associated with improved vision quality. For prolonged lens use, visual acuity was only associated with vision quality. Visual acuity plays a significant role in subjective ratings at the initial lens wear, while tear break-up time may serve as a predictor for subjective vision quality.

Keywords Subjective rating, Residual refraction, Visual acuity, Noninvasive tear break-up time

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Background

Dryness, discomfort, and vision disturbances are among the primary causes of dissatisfaction and discontinuation of soft contact lens wear [1, 2] Principal reasons for discontinuation include distance vision blur, poor near vision, discomfort, and handling difficulties [3, 4, 5]. Considering the contact-lens-wearing experience, initial and end-of-day comfort are critical for soft contact lens tolerance and sustained use or discontinuation [6]. Recent reviews have identified strategies for improving comfort and mitigating dryness, such as switching lens materials [7, 8] and changing wear modality, [9] separately or in combination. Adjustments to the refractive power of contact lenses and changes in lens types are recommended to enhance visual clarity. Subjective comfort questionnaires are commonly employed by contact lens practitioners to identify dissatisfied wearers [10]. Other subjective methods include specialised visual acuity tests, contrast sensitivity tests, and assessments of visual function. Objective methods include ocular wavefront aberration analysis and tear stability analysis. These assessments provide insights into vision clarity, subjective comfort, and overall satisfaction following contact lens wear.

Over-refraction is a clinical method used to confirm changes in optical refraction during contact lens examinations and fittings [11]. This procedure allows practitioners to rapidly assess both spherical and astigmatic components of residual refractive error. Residual refractive error can degrade retinal image quality and negatively impact the vision of contact lens wearers. The refractive index and water content of contact lenses are interrelated [12] Dehydration, which alters the refractive index, can diminish lens performance and visual acuity and exacerbate discomfort [13]. The refractive index is a physical parameter that reflects the optical and physiological properties of the contact lens material and its equilibrium water content. As contact lenses dehydrate, surface irregularities may develop, inducing changes in refractive error after prolonged wear.

Contact lens water content influences vision, comfort, and optical quality, although its effect may be less pronounced in silicone hydrogel lenses. Silicone hydrogels typically exhibit less dehydration than traditional hydrogels and do not compromise oxygen performance; the silicone component of the lens primarily facilitates oxygen permeability [14, 15]. Some studies have reported that contact lens dehydration is a factor contributing to lens wear discontinuation [2, 16]. Severe dehydration in silicone hydrogel lenses can disrupt the ionic and hydraulic permeability of the lens material, particularly affecting lens movement and reducing comfort [15]. Lens diameter, [17] fit, [18] and oxygen transmissibility [15] may be altered by dehydration, leading to decreased lens comfort. Soft lenses change proportions, to some extent, on the eye, which can alter optical properties during wear. Previous studies have found a significant negative correlation between the extent of dehydration and subjective comfort ratings after 12 h of soft contact lens wear [10]. The tear film affects ocular optical quality as it constitutes the first refracting surface of the eye. Dry eye can impair visual functions, such as reading, [19, 20] digital device use, and driving [21]. Studies indicate that dry eye affects contrast sensitivity performance [22] and is associated with irregular astigmatism and higher-order optical aberrations [23]. However, the factors influencing subjective ratings during initial and end-of-day wear of silicone hydrogel contact lenses remain unclear. Therefore, this study aimed to investigate the factors influencing comfort, vision quality, dryness, and satisfaction in both initial and end-of-day wear of silicone hydrogel contact lenses.

Methods

Participants

This prospective, open-label study recruited satisfied wearers of silicone hydrogel daily disposable contact lenses (Somofilcon A) from Chung Shan Medical University and Da-Yeh University. The study adhered to the principles of the Declaration of Helsinki and received approval from the Human Research Ethics Committee of Chung Shan Medical University Hospital (No: CS1-22177). Informed consent was obtained from all participants after they understood the experimental procedure.

All the eligible participants ($n = 59$) were myopic Asians (≥ -6.00 diopters [D]) aged 20 to 24, capable of achieving a monocular habitual visual acuity of at least 20/25 using spherical soft contact lenses in both eyes. The participants had either normal or mild eye dryness (Ocular Surface Disease Index [OSDI] scores < 22), [24] were free from any ocular or systemic health conditions, and were not taking any medications. Additionally, inclusion in the study required spending more than 4 h per day viewing visual display terminals.

Experimental procedure

This study comprised two scheduled visits. During the first visit, the ocular surface was evaluated using slit lamp biomicroscopy (Topcon SL-D2; Tokyo, Japan), and baseline data, including spherical equivalent (SE) and keratometry, were measured using an autorefractor (Shin-Nippon NVision-K 5001; Osaka, Japan), for the uncorrected eyes. First, non-invasive tear break-up time (F-NITBUT) and average non-invasive tear break-up time (A-NITBUT) were measured using a Keratograph 5 M (Oculus Optikgerate, Wetzlar, Germany). Participants then wore Somofilcon A lenses for 15 min, and data on residual refraction, visual acuity, F-NITBUT, and A-NITBUT were collected. Residual refraction was

measured using an autorefractor while participants wore the lenses. Visual acuity was measured at 6 m using a digital visual acuity chart system (VLC 1900-P, Seoul, Korea). Subjective ratings of comfort, vision quality, dryness, and satisfaction were assessed using a questionnaire after 15 min and 8 h of lens wear. Participants wore Somofilcon A lenses for 7 days, with daily lens replacements.

During the second visit, on the seventh day of Somofilcon A lens wear, participants underwent examinations for ocular surface health, residual refraction, visual acuity, F-NITBUT, and A-NITBUT after 8 h of lens wear. Subjective ratings of overall comfort, vision quality, lens dryness, and satisfaction were assessed using a questionnaire. Participants accessed the visual analogue scale (VAS) via an online platform during the study. All participants reported comfort scores ranging from 0 to 100, where 0 indicated "extremely uncomfortable" and 100 represented "extremely comfortable." A score of 0 represented "not at all dry," while 100 represented "extremely dry."

Statistical analysis

G*Power software (version 3.1; Düsseldorf, Germany) was used to calculate the sample size for this study. The calculation was performed with $\alpha = 0.05$ and included a 10% screening failure/dropout rate, resulting in a required minimum of 59 participants from two sites (Chung Shan Medical University and Da-Yeh University). Initially, 64 participants were recruited, but 5 were excluded for failing to meet the inclusion criteria. Ultimately, 59 eligible participants completed the study and were included in the analysis. All data were analysed using SPSS version 26 (IBM Corp, Armonk, NY). Only data from the right eye of each participant were included in the data analysis. The Friedman test was used to evaluate changes in residual refraction, visual acuity, F-NITBUT, and A-NITBUT while wearing Somofilcon A lenses. The Wilcoxon signed-rank test was used to compare subjective ratings after 15 min and 8 h of Somofilcon A lens wear. A linear regression model was used to assess the correlation of residual refraction between residual refraction subjective ratings of Somofilcon A lens wear and the correlation between residual refraction and visual acuity, F-NITBUT, and A-NITBUT. Data are expressed as median [interquartile range (IQR)], with a p-value of < 0.05 indicating statistical significance.

Results

Data collected from 59 participants (8 males and 51 females) were analysed, with a mean age of 20.86 ± 1.29 years (range: 20 to 24 years). The mean OSDI score was 6.93 ± 5.39, indicating that the participants did not exhibit dry eye symptoms. The mean spherical equivalent for the right eye was − 4.20 ± 1.65 D, and the mean keratometry was 43.57 ± 1.53 D. The mean of F-NITBUT and A-NITBUT were 12.14 ± 8.47 and 14.69 ± 7.33 s, respectively.

Table 1 presents the results of wearing Somofilcon A lenses. After 15 min of lens wear on Day 1, the mean residual refraction was 0.15 ± 0.45 D. This significantly decreased to 0.01 ± 0.36 D after 8 h of wear on Day 7 ($P = 0.01$). The F-NITBUT significantly increased from 8.56 ± 7.12 s after 15 min on Day 1 to 10.88 ± 8.21 s after 8 h on Day 7 ($P < 0.01$). Similarly, the A-NITBUT significantly increased from 13.12 ± 6.91 s to 16.48 ± 6.00 s after 15 min on Day 1 and 8 h of lens wear on Day 7 ($P = 0.03$). However, no significant difference in visual acuity was observed during Somofilcon A lens wear.

Table 2 presents subjective ratings of comfort, vision quality, dryness, and satisfaction at 15 min on Day 1 and after 8 h of wearing Somofilcon A lenses on Day 7. Comfort ratings significantly decreased from a median of 90.0 (IQR: 20.0) at 15 min to 89.0 (IQR: 10.0) after 8 h of wear ($P = 0.034$). Vision quality showed no statistically significant change. A significant increase in dryness was reported after 8 h, with median scores rising from 20.0 (IQR: 20.0) to 20.0 (IQR: 25.0; $P = 0.006$). Additionally, satisfaction ratings significantly decreased from a median of 90.0 (IQR: 15.0) at 15 min to 90.0 (IQR: 13.0) after 8 h of lens wear ($P = 0.014$).

Table 3 presents the correlation between residual refraction, visual acuity, F-NITBUT, A-NITBUT, and subjective ratings. Residual refraction and F-NITBUT did not show significant correlations with comfort, vision quality, dryness, or satisfaction after 15 min of Somofilcon A lens wear on Day 1 and 8 h on Day 7. However,

Table 1 The objective assessment of the participants after wearing Somofilcon A contact lenses

	Somofilcon A		
	With lens 15 min	**With lens 8 h**	**P-value**
Residual refraction (D)	0.15 ± 0.45	0.01 ± 0.36	**0.01***
Visual acuity (LogMAR)	-0.04 ± 0.07	-0.05 ± 0.07	0.21
F-NITBUT (s)	8.56 ± 7.12	10.88 ± 8.21	**0.03***
A-NITBUT (s)	13.12 ± 6.91	16.48 ± 6.00	**< 0.01****

P-value calculated using the Friedman test (analysis of variance), $^{**}P < 0.01$, $^{*}P < 0.05$

D, diopter; F-NITBUT, first noninvasive tear break-up time; A-NITBUT, average noninvasive tear break-up time; s, seconds

Table 2 Median subjective ratings (1–100 numerical rating scale, 1-point increments) for Somofilcon A contact lens wearers

		With lens 15 min		With lens 8 h		
		Median	**IQR**	**Median**	**IQR**	**P-value**
Somofilcon A	Comfort	90.00	20.00	89.00	10.00	0.034*
	Vision quality	90.00	15.00	90.00	16.00	0.504
	Dryness	20.00	20.00	20.00	25.00	0.006**
	Satisfaction	90.00	15.00	90.00	13.00	0.014*

P-value calculated using the Wilcoxon signed-rank test, $^{**}P < 0.01$, $^{*}P < 0.05$

IQR, interquartile range

Table 3 Linear regression model analysis to assess the correlation between residual refraction, visual acuity and subjective rating

Independent var.		**Residual refraction**		**Visual acuity**		**F-NITBUT**		**A-NITBUT**	
Dependent var.		*B*	95% CI	*B*	95% CI	*B*	95% CI	*B*	95% CI
With lens 15 min	Comfort	4.77	(-2.69 ~ 12.23)	**-59.97***	**(-107.63~-12.30)***	0.18	(-0.29 ~ 0.65)	0.42	(-0.07 ~ 0.90)
	Vision quality	3.16	(-3.01 ~ 9.34)	**-59.34****	**(-97.68~-21.15)****	0.30	(-0.78 ~ 0.68)	**0.42**	**(0.03 ~ 0.81)**
	Dryness	-3.71	(-11.94 ~ 4.51)	**55.05***	**(2.01 ~ 108.09)***	0.35	(-0.16 ~ 0.85)	0.32	(-0.21 ~ 0.87)
	Satisfaction	0.40	(-5.05 ~ 5.84)	**-47.43****	**(-81.34~-13.51)***	-0.12	(-0.35 ~ 0.32)	-0.03	(-0.39 ~ 0.33)
With lens 8 h	Overall comfort	-2.17	(-9.55 ~ 5.21)	-18.24	(-55.86 ~ 19.38)	0.09	(-0.23 ~ 0.41)	0.24	(-0.21 ~ 0.69)
	Overall vision quality	-1.10	(-8.23 ~ 6.05)	**-40.46***	**(-75.48~-5.44)***	-0.13	(-0.44 ~ 0.18)	-0.10	(-0.54 ~ 0.34)
	Overall lens dryness	10.81	(-1.98 ~ 23.60)	21.68	(-45.26 ~ 88.62)	0.21	(-0.36 ~ 0.77)	0.22	(-0.58 ~ 1.03)
	Overall satisfaction	-4.03	(-12.38 ~ 4.31)	-29.56	(-71.97 ~ 12.85)	-0.08	(-0.45 ~ 0.28)	-0.04	(-0.56 ~ 0.48)

B: regression coefficient; CI: confidence interval; F-NITBUT: first noninvasive tear break-up time; A-NITBUT: average noninvasive tear break-up time; *: $P < 0.05$

Fig. 1 illustrates that after 15 min of lens wear on Day 1, visual acuity was significantly negatively correlated with comfort (B = -59.97; 95% CI: -107.63 to -12.30), vision quality (B = -59.34; 95% CI: -97.68 to -21.15), and satisfaction (B = -47.43; 95% CI: -81.34 to -13.51), and significantly positively correlated with dryness (B = 55.05; 95% CI: 2.01 to 108.09). After 8 h of lens wear on Day 7, visual acuity was negatively correlated with overall vision quality (B = -40.46; 95% CI: -75.48 to -5.44). The A-NITBUT, after 15 min of Somofilcon A lens wear on Day 1, was significantly positively correlated with vision quality (B = 0.42; 95% CI: 0.03 to 0.81; Fig. 2).

Discussion

Silicone hydrogel daily disposable contact lenses are continuously optimised to improve tear film stability and reduce discomfort. Although contact lens materials have continuously improved over the past five decades, ocular discomfort remains a primary factor contributing to dropout among contact lens wearers [25]. Despite these advancements, discontinuation of lens wear remains a common challenge, primarily due to dry-eye symptoms and end-of-day ocular discomfort [26, 27, 28]. This study evaluated factors influencing comfort, such as over-refraction, NITBUT, and visual acuity, at the initial 15-min wear and a 1-week follow-up among young adults using silicone hydrogel contact lenses.

The results showed a more pronounced negative change in residual refraction after 8 h of wear compared to 15 min with Somofilcon A lenses (0.15 ± 0.45 D vs. 0.01 ± 0.36 D, $p = 0.01$). Contact lens wear can increase permeability due to epithelial thinning, [29, 30] formation of epithelial microcysts, [25] and reduced cell adhesion [31]. These changes in refractive error may be attributed to epithelial alterations caused by hypoxia, lens pressure, and modulation of epithelial homeostasis during soft lens wear [32]. High-water-content hydrogel lenses tend to dehydrate more, leading to physiological changes [33]. Lens dehydration plays a crucial role in corneal epithelium integrity and can negatively affect lens comfort [10]. The degree and timeframe of lens dehydration depend on factors such as the polymer's water content, lens thickness, temperature, humidity, and blink patterns [34, 35]. Reduced blinking while wearing high water content lenses is known to cause visual disturbances known as dehydration blur [36]. Additionally, decreased or incomplete blinking during prolonged digital screen use exacerbates tear film instability and increases visual aberrations [37, 38]. Dehydration-related alterations in the water content of contact lenses also change the refractive index, negatively affecting lens optics, visual acuity, and wearer comfort through refractive instability and visual degradation [13, 39].

In contrast, silicone hydrogel materials significantly improve oxygen permeability without increasing water content. Previous research demonstrated that in environments with 70% relative humidity and airflow, silicone hydrogel lenses experienced 10 – 20% dehydration.[33] The most significant changes in relative humidity occurred within the first 15 min of exposure. This dehydration may lead to diminished lens performance, including increased

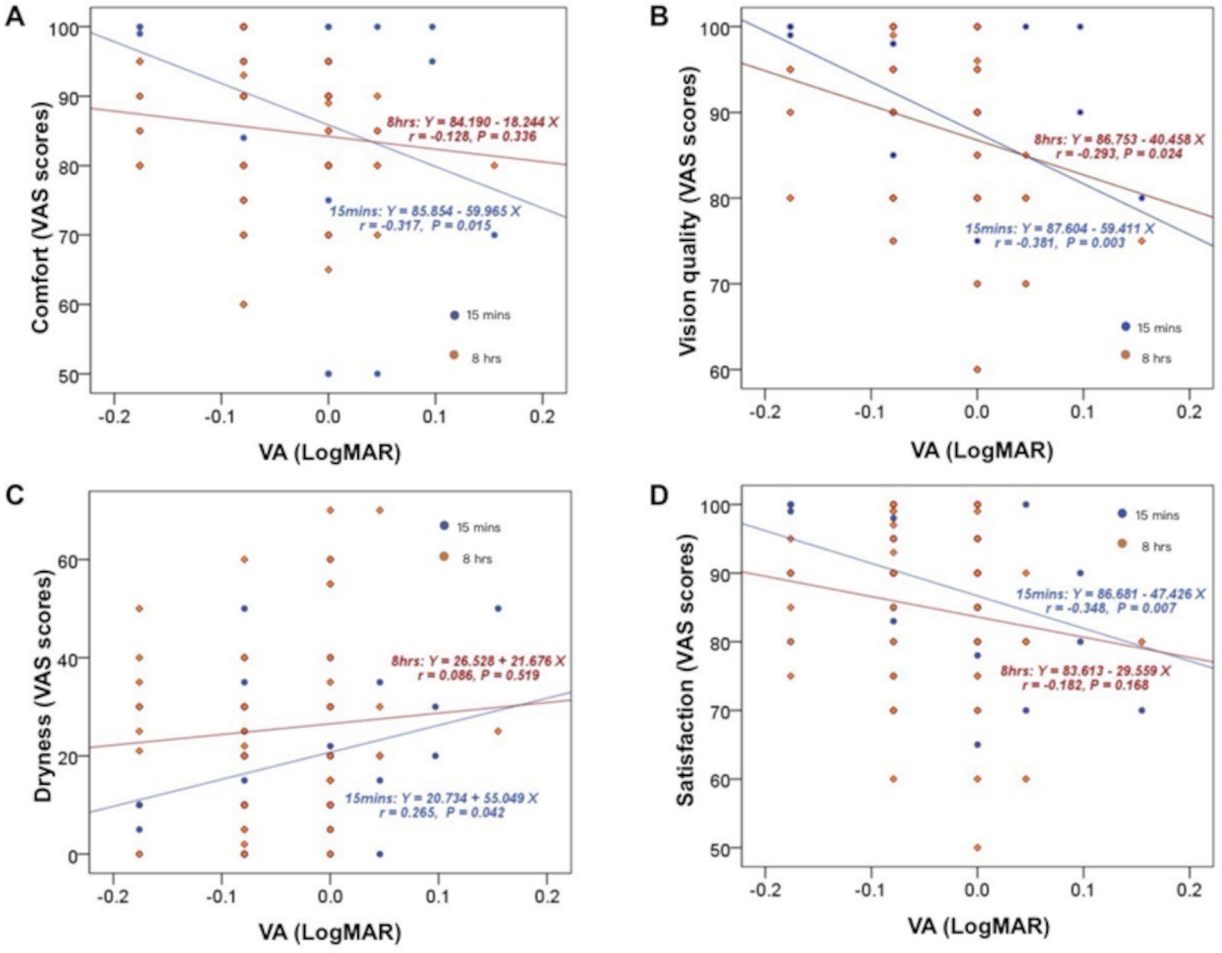

Fig. 1 Correlation between visual acuity (VA) and (**A**) comfort, (**B**) vision quality, (**C**) dryness, and (**D**) satisfaction after 15 min and 8 h of Somofilcon A lens wear

visual aberrations, reduced visual acuity, and greater deposition of tear film components [39, 40].

NITBUT is essential for maintaining visual clarity, particularly during prolonged digital device use [41]. If tear film stability is compromised, complications may arise [42, 43]. Colak et al. recruited 50 silicone hydrogel contact lens wearers and 50 non-wearers to evaluate the effects of silicone hydrogel lenses on ocular surface parameters. Their results demonstrated significantly shorter NITBUT values, along with higher corneal fluorescein staining, OSDI scores, and meiboscores in contact lens wearers compared to non-wearers [44]. Extended video display terminal use is a major risk factor for dry eye disease due to decreased blink rates and increased tear evaporation [45]. In the current study, both F-NITBUT and A-NITBUT significantly increased after 8 h of Somofilcon A lens wear compared to initial measurements at 15 min ($p = 0.03$ and $p < 0.01$, respectively). Although the F-NITBUT was ˂ 10 s during the initial 15 min of wear, it increased to ˃ 10 s after 8 h, suggesting the potential for sustained visual quality. These findings align with those of Varikooty et al., who investigated the clinical performance and physiological responses in silicone hydrogel contact lens wearers. Their study similarly reported stable tear break-up times after 8 h of silicone hydrogel daily disposable lens wear. Additionally, no significant differences were found between asymptomatic ($n = 51$) and symptomatic ($n = 53$) participants regarding pre-lens NITBUT, deposit rate, wettability, lens movement, bulbar or limbal redness, and corneal or conjunctival staining [46].

Several factors can influence ocular comfort, including environmental conditions, ocular health, and the material properties of contact lenses. In this study, subjective ratings of comfort, dryness, and overall satisfaction progressively decreased with longer wear times (Table 2), a finding consistent with other research showing a decline in comfort during extended soft lens usage [47, 48, 49]. However, a previous study indicated that a reduction in comfort was also observed in asymptomatic individuals

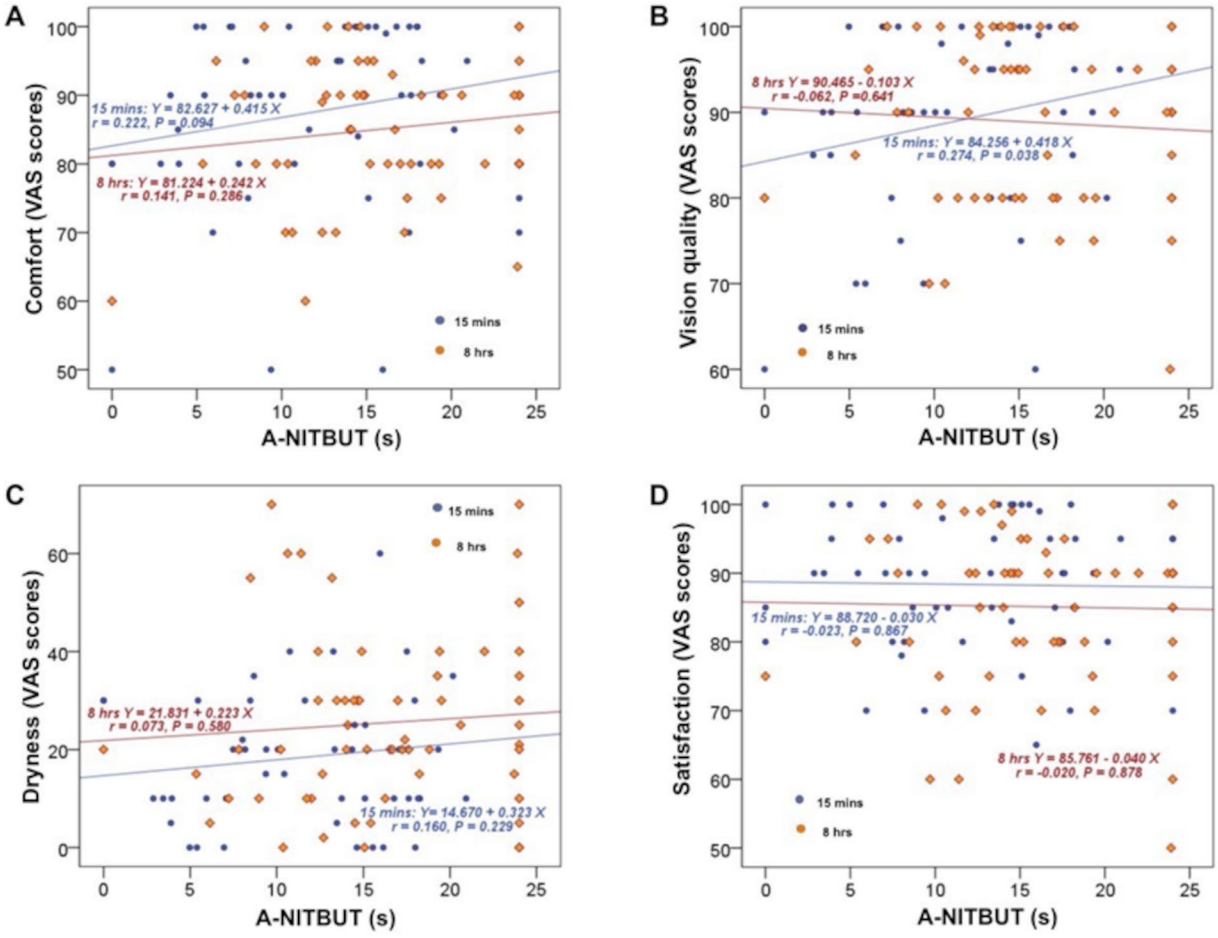

Fig. 2 Correlation between the average noninvasive tear break-up time (A-NITBUT) and (**A**) comfort, (**B**) vision quality, (**C**) dryness, and (**D**) satisfaction after 15 min and 8 h of Somofilcon A lens wear

not wearing contact lenses by the end of the day [50]. Contact lens materials can affect the tear film by increasing evaporation rates and reducing tear thinning time, [51] which may explain the significant increase in dryness observed after 8 h of wear in this study (Table 2). While evaporation can contribute to dryness, the sensory nerves on the ocular surface are stimulated to produce more tear fluid, resulting in increased tear production [52]. This may explain the significant increase in F-NITBUT and A-NITBUT after 8 h of wear (Table 1). Although dryness increased with prolonged wear, visual acuity did not decrease, which may be attributed to the stability of the tear film.

A key finding was that visual acuity significantly influenced subjective visual quality at the initial wear of the lenses and after 8 h of wear. The results indicated that better visual acuity was associated with lower levels of dryness and higher subjective comfort, vision quality, and satisfaction after the initial lens wear (Table 3). Additionally, a higher subjective vision quality level was significantly correlated with longer A-NITBUT at the initial wear. After 8 h, better visual acuity was significantly correlated only with a higher level of subjective visual quality. Previous studies suggest that better tear film quality improves vision quality. Another key finding was that the compensatory response to dryness might increase tear fluid production, which, in turn, extends tear break-up time and potentially helps to maintain vision quality. [53].

This study has some limitations. First, the participants recruited did not have dry eye disease, so the results only reflect subjective outcomes from individuals without dry eye conditions. Additionally, the duration of contact lens wear was 8 h, whereas extended wear typically exceeds 12 h.

Conclusions

Our findings demonstrated that visual acuity at initial lens wear was strongly associated with subjective comfort, vision quality, dryness, and overall satisfaction, while

average tear break-up time was correlated with vision quality. However, after 8 h of wear, visual acuity was only associated with vision quality. In summary, visual acuity is a key factor for subjective comfort at initial wear and tear break-up time and may serve as a predictor for subjective vision quality. These findings may aid eye care professionals in reducing contact lens discontinuation.

Abbreviations

F-NITBUT	First noninvasive tear break-up time
A-NITBUT	Average noninvasive tear break-up time
OSDI	Ocular Surface Disease Index
SE	Spherical equivalent
VAS	Visual analog scale
D	Diopter
IQR	Interquartile range
NITBUT	Noninvasive tear break-up time

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Author contributions
HS designed the study protocol and prepared the final manuscript. RY recruited the subjects and preformed the statistical analysis. YC conducted the study and prepared the final manuscript. All authors read and approved the final manuscript.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study adhered to the tenets of the Declaration of Helsinki and received ethical clearance from the Human Research Ethics Committee of Chung Shan Medical University Hospital (No: CS1-22177, approval date: January 18, 2023). Written informed consent was obtained from all subjects.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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