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Effect of different tinted soft contact lenses on the tear quality and ocular surface properties

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ABSTRACT

Different designs for contact lenses can result in insufficient oxygen permeability of the lenses. Moreover, the contact lens wearing schedule, replacement, lens care systems, and purchase methods are all important considerations for contact lens wearers. To evaluate the influence of tinted contact lenses with the pigment layer in different locations on the tear quality and ocular surface properties, as well as the subjective experience of the wearer. In this randomized double-blind study, 30 healthy subjects (60 eyes) were randomly assigned to two groups. The pigment layer of lenses in group I was embedded within the matrix, close to the front surface, while that in group II was located on the front surface of the lens. Subjects wore the contact lenses for 7 days, 8 h a day. In both groups, the frequency of blinking after lens wear increased significantly relative to that before lens wear. The tear-breakup time was significantly shorter in group II than in group I. Temporal bulbar conjunctiva, nasal bulbar conjunctiva, temporal limbal, nasal limbal, and eyelid redness levels in both groups, and corneal staining levels in group II, were significantly increased after 7-day lens wear. Nasal bulbar conjunctiva, temporal limbal, and nasal limbal redness; eyelid smoothness; and corneal staining levels were significantly higher in group II. There was no significant between-group difference in the subjective experience. Ocular surface properties deteriorated while the frequency of blinking increased after wear of both types of tinted contact lenses for 7 days. Both designs resulted in insufficient oxygen permeability of the contact lenses.

KEYWORDS

Tinted contact lens; tear quality; ocular surface properties; pigment layer; tear-breakup time

More than 140 million people worldwide wear contact lenses daily, and this number is increasing annually.^[1–4] In recent years, in addition to their use in vision correction, contact lenses are used to change the appearance of the eye through both complex lens designs and material applications. Additionally, tinted contact lens wear can also enlarge or increase the contrast of the limbal ring. Interestingly, Peshek et al. has shown that people with dark and distinct limbal rings are considered more attractive than identical faces with less distinct limbal rings.^[5]

Tinted contact lenses are typically produced by adding dyes to transparent contact lenses, and can visually change the diameter and the color of the iris, and are known as “cosmetic contact

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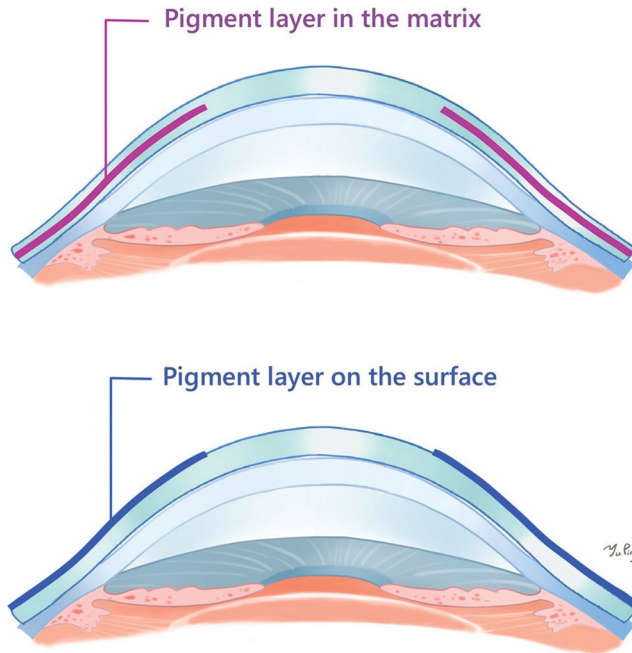


Figure 1. Schematic diaphragm of different designs of tinted contact lens. (A) Pigment layer within the lens matrix (group I). (B) Pigment layer on the surface (group II).

lenses” or “colored contact lenses.” The pigments used in these lenses must be non-toxic and safe for use in the eyes. Based on the distribution of the pigment layer, these lenses are roughly classified into three types: those with the pigment layer located on the front surface of the lens, which interacts frequently with the palpebral conjunctiva and the eyelids; those with the pigment layer located on the posterior surface of the lens and in direct contact with the cornea and conjunctiva; and those with the pigment layer located within the lens matrix itself (Figure 1). The third type, the so-called “sandwich design” should theoretically cause the least discomfort, as the pigment layer is not in direct contact with the eyelids, cornea, or conjunctiva, in contrast to the other designs.

Tinted contact lenses are particularly popular in Asian countries, such as Japan, Taiwan, Korea, Singapore, Hong Kong, and China.^[6–8] Most wearers of tinted soft contact lenses are teenagers and young adults, and are mainly female.^[9–12] In 2016, an international survey revealed that, overall, about 30% of contact lens wearers use tinted soft contact lenses, with the highest percentage (58%) from Taiwan.^[8] In Taiwan, contact lenses are considered second-level non-implantable medical devices, according to medical laws; thus, it is easy to acquire contact lenses in shopping centers, on the Internet, or at street markets, without professional guidance from ophthalmologists or optometrists. This phenomenon would lead to a significant increase in the incidence of contact lens infections, such as microbial keratitis.^[9,13–15]

Steffen and Barr found significant differences in comfort levels according to the position of the pigment layer on the lens surface of the same tinted contact lens.^[16] Lau et al. used a scanning electron microscope to determine the position and depth of pigment particles from the lens surface. They compared the coefficient of friction between the transparent region and the pigment layer of the lens, using a Basalt-MUST micro-friction tester, and detected surface roughness by using atomic force microscopy. They found that the coefficient of friction for the transparent area differed significantly from that for the area with surface pigmentation; however, it was not different from the coefficient for a pigment layer within the matrix.^[17] Another report used atomic force microscopy and

showed that the average surface roughness of transparent contact lenses was significantly different from that of the pigmented lenses, and suggested that increased surface roughness was an important physical factor for bacterial adhesion in tinted contact lenses.^[18]

Chan et al. shown that the pigment layer on the surface of the tinted contact lens was more prone to severe microbial adhesion than transparent contact lenses or lenses with the pigment layer within the matrix.^[7] Bakay and Paolat showed differences in *Acanthamoeba* adhesion to a different materials, which was not due to differences in moisture content; they stated that the chemical composition of tinted contact lenses seemed to be the main reason for the increased adhesion of *Acanthamoeba*.^[19] Lee et al. observed that *Acanthamoeba* showed stronger adhesion to tinted contact lenses than to transparent contact lenses, and that the rough pigment layer on the surface of tinted contact lenses was responsible for the increased adherence of *Acanthamoeba*.^[20]

Although microbial adhesion is a serious issue in contact lenses,^[7] oxygen permeability, the oxygen transmission rate, and water content in contact lenses are also important. In tinted lenses, these parameters are decreased, causing hypoxia in the eyes.^[21,22] Many studies have also observed that direct contact between the pigmented layer on the surface of tinted contact lenses and human tissue may cause eye irritation and even more serious complications.^[18,20,23–25] These complications can eventually lead to loss of vision, as well as requiring significant hospital resources and costs during treatment.^[12,26,27]

This study investigated the effects of tinted contact lenses with different designs on tear quality and ocular surface properties. Furthermore, a questionnaire survey was conducted to evaluate the subjective experiences of tinted contact lens wearers.

Methods

Subjects

Thirty healthy subjects (60 eyes; age: 23.58 ± 1.87 years; range 20–28 years) without a history of ocular surgery or ocular disease, or systemic disease affecting the ocular surface condition, were recruited. The study was approved by the relevant institutional review board (Number: CSMUH CS2-18065) and adhered to the tenets of the Declaration of Helsinki. Written consent was obtained from all subjects after they had been informed of the procedures, risks, and benefits of the study. All subjects were randomly assigned to wear one of two types of tinted contact lenses (group I and group II), with different locations of pigment, for 8 h a day, for 7 days.

Tinted soft contact lenses

Two brands of tinted soft contact lenses commercially available in Taiwan were included in the trial (1-DAY ACUVUE® DEFINE®, Johnson & Johnson Vision Care, Inc., Jacksonville, FL; MURIEL EYE Color Daily Disposable Soft Contact Lenses, PEGAVISION, Taoyuan, Taiwan) (Table 1). The color of the tinted soft contact lenses was limited to brown. The rub-off test, previously described by Chan et al.,^[2] was used to examine the position of the pigment layer of the two brands. The test involves applying a gentle rubbing of each lens surface 20 times using a wet cotton swab with weight of 110–230 g. Anterior segment Fourier-domain optical coherence tomography (TOMEY CASIA SS-1000, Tomey Corporation, Nagoya, Japan) was used to analyze the distribution of the pigment layer of the tinted soft contact lens on the human eye.

Evaluation of tear quality

Evaluations of tear quality included assessments of the tear breakup time and tear meniscus height by slit-lamp microscopy, non-invasive tear breakup time by keratometry, tear secretion by

Table 1. Properties of the tinted soft contact lens in group I and group II.

| | Group I | Group II |
|----------------------------------|--------------------|------------------------------------|
| Color | Vivid | Lush brown |
| Index of refraction (n) | 1.4 | 1.402 |
| Diameter (mm) | 14.2 | 14.2 |
| Graphic diameter (mm) | 12.8 | 13.6 |
| Base curve (mm) | 8.5 | 8.5 |
| Material | Etafilcon A | Etafilcon A + UV absorbing monomer |
| Water content (%) | 58 | 58 |
| Oxygen permeability (DK @ 35 °C) | 28 | 19.73 |
| Pigment layer position | In the lens matrix | On the lens surface |

the Schirmer II test, and observation of the blinking frequency for 1 minute, for a total of three times.

Evaluation of ocular surface properties

Slit-lamp examination was used to evaluate ocular surface properties using the Efron grading scale. Parameters included bulbar conjunctiva redness levels, limbal redness levels, eyelid redness levels, eyelid smoothness levels, and corneal staining levels assessed using a fluorescein sodium ophthalmic strip before and after lens wear for 7 days.

Rating questionnaire

After tinted contact lens wear for 7 days, subjects completed a questionnaire comprising 25 items to rate their subjective symptom perception. The questionnaire covered eight symptoms: foreign body sensation, tingling sensation, dryness, fatigue, itching, comfort, secretions, and visual satisfaction. For each symptom, the frequencies on day 1 and day 7, the intensity, and the degree to which it bothered the patient were assessed. For each question, the participants could provide ratings from 1 to 10. With regard to the frequency, 0 indicated “never” and 10 indicated “constantly.” With regard to the intensity, 0 indicated “nothing” and 10 indicated “very intensive.” With regard to the extent of trouble caused by the symptom, 0 indicated “nothing” and 10 indicated “a lot.”

Statistical analysis

Using IBM SPSS version 22.0 software (IBM SPSS, Chicago, IL, USA), we performed within-group and between-group comparisons of the tear quality and anterior surface assessment data before and after 7 days of tinted lens wear. The independent-sample *t*-test, one-sample *t*-test, and paired-sample *t*-test were used as appropriate. The results of the rating questionnaire are reported using descriptive statistics, and changes from day 1 to day 7 were assessed using the paired-sample *t*-test. A *p*-value of <.05 was considered statistically significant.

Results

Position of the pigment layer in the two tinted soft contact lens brands

The rub-off test was performed for both lens brands of lenses (Figure 2). Brand I passed the rub-off test, with no pigment particles removed from the front or back of the lenses. However, brand II failed the rub-off test, with pigment particles removed from the front surface of the lens by wiping with the wet cotton swab.

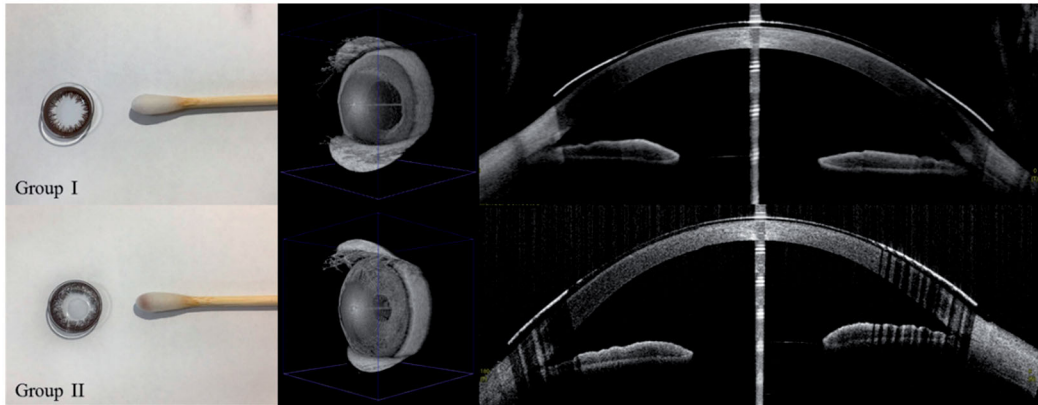


Figure 2. The results of the rub-off test and the anterior section optical coherence tomography of tinted soft contact lenses with the pigment layer within the matrix in group I and group II.

Table 2. Comparison of tear quality and ocular surface properties between baseline and day 7 of tinted contact lens wear.

| Measurement | Group I (n = 30) | | | Group II (n = 30) | | |
|------------------------------------|------------------|---------------|---------|-------------------|----------------|---------|
| | Baseline | 7-day visit | p-value | Baseline | 7-day visit | p-value |
| Tear quality | | | | | | |
| Non-invasive tear breakup time (s) | 7.144 ± 3.086 | 7.378 ± 2.650 | .679 | 6.744 ± 2.501 | 6.190 ± 2.306 | .280 |
| Tear breakup time (s) | 6.133 ± 2.561 | 6.601 ± 2.580 | .237 | 5.244 ± 1.350 | 5.067 ± 1.149 | .505 |
| Tear meniscus height (mm) | 0.143 ± 0.050 | 0.137 ± 0.049 | .537 | 0.150 ± 0.050 | 0.140 ± 0.0498 | .375 |
| Tear secretion (mm) | 14.37 ± 5.269 | 16.63 ± 6.749 | .045* | 14.60 ± 6.510 | 14.23 ± 8.207 | .797 |
| Blinking frequency (number/min) | 12.27 ± 3.667 | 15.87 ± 5.680 | <.001** | 13.20 ± 3.566 | 17.00 ± 7.066 | .006** |
| Ocular surface properties | | | | | | |
| Temporal | 0.43 ± 0.504 | 1.03 ± 0.809 | <.001** | 0.37 ± 0.490 | 1.10 ± 0.712 | <.001** |
| Nasal | 0.27 ± 0.450 | 0.77 ± 0.568 | <.001** | 0.50 ± 0.509 | 1.17 ± 0.699 | <.001** |
| Limbal redness levels (0–4) | | | | | | |
| Temporal | 0.13 ± 0.346 | 0.87 ± 0.730 | <.001** | 0.27 ± 0.450 | 1.23 ± 0.679 | <.001** |
| Nasal | 0.10 ± 0.305 | 0.80 ± 0.805 | <.001** | 0.43 ± 0.504 | 1.27 ± 0.640 | <.001** |
| Eyelid redness levels (0–4) | 0.80 ± 0.407 | 0.93 ± 0.365 | .043* | 0.77 ± 0.430 | 1.00 ± 0.525 | .006** |
| Eyelid smoothness levels (0–4) | 0.10 ± 0.305 | 0.17 ± 0.379 | .161 | 0.33 ± 0.479 | 0.43 ± 0.504 | .083 |
| Corneal staining levels (0–4) | 0.00 ± 0.000 | 0.07 ± 0.254 | .161 | 0.00 ± 0.000 | 0.57 ± 0.728 | <.001** |

* $p \leq 0.05$; ** $p \leq 0.01$.

Anterior segment Fourier-domain optical coherence tomography was performed on both lens brands (Figure 2). The pigmented layer reflective strip of brand I was located in the matrix, close to the front surface, and the surface of the tinted contact lens was smooth. In brand II, the pigmented layer reflective strip was located on the front surface, and the surface of the tinted contact lens was uneven.

Evaluation of tear quality and ocular surface properties

Tear quality

Relative to the baseline data, the blinking frequency (two-sample $t = 4.04$, $p < .0001$) and tear secretion (two-sample $t = 2.09$, $p = .045$) in group I showed a significant difference after tinted contact lens wear (Table 2). In group II, only the blinking frequency (two-sample $t = 2.95$, $p = .006$) was significantly different after tinted contact lens wear (Table 2).

In terms of tear quality, the non-invasive tear breakup time (two-sample $t = 1.85$, $p = .069$), tear meniscus height (two-sample $t = -0.26$, $p = .795$), tear secretion (two-sample $t = 1.24$, $p = .221$), and blinking frequency (two-sample $t = -0.69$, $p = .496$) after tinted contact lens wear

Table 3. Comparison of tear quality and ocular surface properties after tinted contact lens wear between group I and group II.

| Measurement | Group I (n = 30) Means ± SD | Group II (n = 30) Means ± SD | p-value |
|--|--------------------------------|---------------------------------|---------|
| Tear quality | | | |
| Non-invasive tear breakup time (s) | 7.3777 ± 2.65023 | 6.1900 ± 2.30588 | .069 |
| Tear breakup time (s) | 6.6010 ± 2.57985 | 5.0667 ± 1.14895 | .004** |
| Tear meniscus height (mm) | 0.137 ± 0.0490 | 0.140 ± 0.0498 | .795 |
| Tear secretion (mm) | 16.63 ± 6.749 | 14.23 ± 8.207 | .221 |
| Blinking frequency (number/min) | 15.87 ± 5.680 | 17.00 ± 7.066 | .496 |
| Ocular surface properties | | | |
| Bulbar conjunctiva redness levels (0–4) | | | |
| Temporal | 1.03 ± 0.809 | 1.10 ± 0.712 | .736 |
| Nasal | 0.77 ± 0.568 | 1.17 ± 0.699 | .018* |
| Limbal redness levels (0–4) | | | |
| Temporal | 0.87 ± 0.730 | 1.23 ± 0.679 | .049* |
| Nasal | 0.80 ± 0.805 | 1.27 ± 0.640 | .016* |
| Eyelid redness levels (0–4) | 0.93 ± 0.365 | 1.00 ± 0.525 | .570 |
| Eyelid smoothness levels (0–4) | 0.17 ± 0.379 | 0.43 ± 0.504 | .024* |
| Corneal staining levels (0–4) | 0.07 ± 0.254 | 0.57 ± 0.728 | .001** |

* $p < 0.05$; ** $p < 0.01$.

were not different between the two groups. However, the tear breakup time in group II was significantly shorter than that in group I (two-sample $t = 2.98$, $p = .004$; Table 3).

Ocular surface properties

Temporal and nasal bulbar conjunctiva redness levels (temporal: two-sample $t = -5.84$, $p < .0001$; nasal: two-sample $t = -4.79$, $p < .0001$), temporal and nasal limbal redness levels (temporal: two-sample $t = -5.81$, $p < .0001$; nasal: two-sample $t = -5.11$, $p < .0001$), and eyelid redness levels (two-sample $t = -2.11$, $p = .043$) showed significant changes after tinted contact lens wear in group I (Table 2). Similarly, temporal and nasal bulbar conjunctiva redness levels (temporal: two-sample $t = -5.81$, $p < .0001$; nasal: two-sample $t = -6.68$, $p < .0001$), temporal and nasal limbal redness levels (temporal: two-sample $t = -7.92$, $p < .0001$; nasal: two-sample $t = -7.71$, $p < .0001$), eyelid redness levels (two-sample $t = -2.97$, $p = .006$), and corneal staining levels (two-sample $t = -4.26$, $p < .0001$) showed significant changes after tinted contact lens wear in group II (Table 2). Moreover, temporal and nasal bulbar conjunctiva redness levels (temporal: two-sample $t = -0.339$, $p = .736$; nasal: two-sample $t = -2.43$, $p = .018$), temporal and nasal limbal redness levels (temporal: two-sample $t = -2.49$, $p = .016$; nasal: two-sample $t = -2.01$, $p = .049$), eyelid redness levels (two-sample $t = -0.57$, $p = .570$), eyelid smoothness levels (two-sample $t = -2.32$, $p = .024$), and corneal staining levels (two-sample $t = -3.55$, $p = .001$) indicated worse ocular surface properties in group II than in group I (Table 3).

Rating questionnaire

The rating questionnaire included subjective foreign body sensation, tingling sensation, dryness, fatigue, itching, comfort, secretions, and visual satisfaction for tinted contact lenses after lens wear for 7 days.

In the questionnaire, no statistically significant between-group differences were observed in the scores for foreign body sensation (two-sample $t = -1.45$, $p = .159$), tingling sensation (two-sample $t = -1.36$, $p = .893$), dryness (two-sample $t = -1.33$, $p = .196$), fatigue (two-sample $t = -0.50$, $p = .619$), itching (two-sample $t = 0.00$, $p > .99$), comfort (two-sample $t = -0.82$, $p = .417$), and secretions (two-sample $t = -0.10$, $p = .919$) after tinted contact lens just wear for 7 days (Table 4). However, there was a significant difference in the visual satisfaction score after

Table 4. Comparison of questionnaire ratings after tinted contact lens wear for 7 days between group I and group II.

| Subjective feelings | Group I (n = 30) | Group II (n = 30) | |
|------------------------|------------------|-------------------|---------|
| | Means \pm SD | Means \pm SD | p-value |
| Foreign body sensation | 2.60 \pm 3.01 | 2.06 \pm 2.54 | .160 |
| Tingling sensation | 1.06 \pm 2.12 | 0.73 \pm 2.21 | .893 |
| Dryness | 4.60 \pm 2.13 | 3.66 \pm 2.99 | .197 |
| Fatigue | 3.73 \pm 2.86 | 3.06 \pm 2.68 | .620 |
| Itching | 1.46 \pm 2.77 | 1.46 \pm 1.55 | >.999 |
| Comfort | -2.13 \pm 2.97 | -1.66 \pm 2.38 | .417 |
| Secretions | 1.26 \pm 1.38 | 0.73 \pm 1.22 | .919 |
| Visual satisfaction | -0.46 \pm 1.59 | -0.60 \pm 1.95 | .038* |

SD: standard deviation; * $p \leq 0.05$.

Table 5. Comparison of questionnaire ratings after tinted contact lens wear all day for 7 days between group I and group II.

| Subjective feelings | Group I | Group II | p-value |
|------------------------|-----------------|-----------------|---------|
| | Means \pm SD | Means \pm SD | |
| Foreign body sensation | 5.13 \pm 2.80 | 5.53 \pm 2.72 | .695 |
| Tingling sensation | 2.93 \pm 2.28 | 2.67 \pm 1.40 | .702 |
| Dryness | 6.73 \pm 2.12 | 6.80 \pm 2.37 | .936 |
| Fatigue | 6.13 \pm 2.17 | 5.80 \pm 2.76 | .716 |
| Itching | 3.53 \pm 2.42 | 3.53 \pm 2.03 | >.99 |
| Comfort | 3.67 \pm 1.72 | 4.87 \pm 2.10 | .098 |
| Secretions | 3.87 \pm 2.33 | 3.40 \pm 1.60 | .527 |
| Visual satisfaction | 5.60 \pm 2.41 | 7.20 \pm 2.24 | 0.070 |

tinted contact lens just wear for 7 days (two-sample $t = -2.19$, $p = .037$). There was no significant between-group difference in the subjective experience after tinted contact lens wear all day for 7 days (Table 5); this included foreign body sensation (two-sample $t = -0.40$, $p = .695$), tingling sensation (two-sample $t = 0.39$, $p = .702$), dryness (two-sample $t = -0.08$, $p = .936$), fatigue (two-sample $t = 0.37$, $p = .716$), itching (two-sample $t = 0.00$, $p > .99$), comfort (two-sample $t = -1.71$, $p = .098$), secretions (two-sample $t = 0.64$, $p = .527$), and visual satisfaction (two-sample $t = -1.88$, $p = .070$).

Discussion

In this study, we evaluated the influence of tinted contact lenses with the pigment layer in different locations on the tear quality and ocular surface properties, as well as the subjective experience of the wearer. We found that tinted contact lenses caused deterioration of ocular surface properties and tear quality, irrespective of where the pigment was located.

In a Contact Lens Spectrum journal survey, individuals between the ages of 18 and 39 years demonstrated the highest frequency of tinted contact lens wear (about 69%); thus, this study limited the age of participants to between 20 and 30 years.^[28] Up to 93.3% of the participants in this study were women, which was consistent with the fact that tinted contact lens wearers are predominantly female.^[1,29]

In the evaluation of tear quality, we found that tinted contact lenses with the pigment layer on the surface of the lens had a shorter tear breakup time than did those with the pigment layer embedded in the matrix. Nevertheless, there was no difference in subjective rating of experience of lens wear between the groups. It is possible that over the short term, contact lens wear may have changed eye physiology, as evidenced by our findings, but that the wearer may not be aware of these changes.

According to a study by Sterner et al., prolonged contact lens wear resulted in an increase in the friction coefficient.^[30] Tinted contact lenses with the pigment layer on the surface have a larger friction coefficient than lenses with the pigment layer embedded in the matrix.^[31] This was

in line with the results of our study, which found that tinted contact lenses with the pigment layer on the surface resulted in more marked changes in the ocular surface properties than lenses with the pigment layer in the matrix.

However, regardless of the position of the pigment layer in the contact lens, the ocular surface properties deteriorated after lens wear. Currently available tinted contact lenses are mainly made of hydrogel contact lenses, and their oxygen permeability is such that they are prone to causing oxygen deficiency in the eyes. By improving the oxygen transmission rate of these contact lenses, hypoxia can be significantly reduced.^[32]

However, there are marked limitations in our study. First, the case number was not large; further studies should include more cases. Second, this study involved short-term wear of tinted contact lenses; longer-term studies may yield different results. In future, tear quality and ocular surface properties should be investigated after tinted contact lens wear for a longer time. In addition, the tinted contact lenses used in this study were daily disposable lenses, but weekly, monthly, and annual disposable lenses should also be investigated. Moreover, changes in the ocular surface properties could also be related to the individual's cleaning and maintenance of the lenses; the influence of these steps should also be investigated.

In conclusion, the subjective experience of lens wear did not differ significantly between the two groups in this study. For subjects who wear tinted soft contact lens, the frequency of blinking after lens wear may significantly increase relative to the frequency before lens wear. The health of the anterior ocular region, such as the bulbar conjunctiva, may deteriorate while eyelid redness may increase after lens wear. Moreover, lens designs could result in insufficient oxygen permeability of the lenses. We suggest that individuals requiring lens should educate themselves regarding appropriate contact lens wear and care systems and avoid selecting different brands of contact lens or purchasing them on the internet. Proper disinfection, handling, insertion, and removal of soft contact lens are crucial for successful lens wear. These must be combined with appropriate hygiene, including thorough hand washing. New wearers and experienced wearers are not necessarily compliant wearers. In the global market, contact lens are perhaps one of the most commonly used medical devices, and the eye care community must do everything to maintain the ocular health of patients/lens wearers.

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