Clinical Optometry

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ORIGINAL RESEARCH

Subjective Comparison of Pre-Lens Tear Film Stability of Daily Disposable Contact Lenses Using Ring Mire Projection

This article was published in the following Dove Press journal:
Clinical Optometry

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Purpose: To subjectively evaluate the in vivo tear film stability of three daily disposable contact lenses (DDCLs) using placido ring reflection at lens wear times of 5 mins and 8 and 12 hrs.

Patients and Methods: This prospective, randomized, observer-masked, 3-way crossover study evaluated 28 subjects with good tear film stability. In vivo tear film stability was assessed for three DDCLs (nelfilcon A, etafilcon A, omafilcon A) on three different days over 12 hrs of lens wear. Time to first distortion by non-invasive keratography drying-up time (NIK-DUT_f) was assessed by reviewing the captured videos. Lens wettability was also graded subjectively by three investigators using a scale from 0 (no visible distortions) to 3 (distortions in more than one-third of the ring reflection zone). Medians were analyzed statistically.

Results: Mean $NIKDUT_f$ at 8 hrs was longer for nelfilcon A and shorter for etafilcon A and omafilcon A, but the differences were not significant. NIK-DUT_f did not differ significantly among nelfilcon A, etafilcon A and omafilcon A DDCLs at all visits (p=0.36). Subjective wettability grades after 5 mins, 8 hrs, and 12 hrs differed significantly for etafilcon A ($P < 0.01$) and omafilcon A ($p < 0.01$), but not for nelfilcon A ($p = 0.05$), DDCLs.

Conclusion: Grading was sufficiently sensitive to differentiate the wettability performances of the three lens materials. Nelfilcon A maintained wettability over the wearing period, whereas etafilcon A material showed faster dewetting at 8 and 12 hrs than at 5 mins after lens insertion.

Keywords: pre-lens tear film stability, wettability, NIK-DUT, drying-up time, daily disposable contact lenses, Keratograph 5M

Introduction

Surveys of contact lens wearers have found that the main reasons for discontinuation of lens wear include discomfort, dry eye symptoms, red eyes, reduced wearing times and visual problems.[1–3] These lens wear issues often result from insufficient wettability and stability of the tear film, which are essential for physiological compatibility.[4,5] Unstable tear film results in greater dehydration, friction, affinity for deposits, and discomfort, and reduces visual acuity.[6] In contrast, a stable tear film provides a smooth surface and enhances visual acuity, two major factors associated with lens wearer satisfaction and comfort.[6,7]

Pre-lens tear film stability can be assessed both in vitro and in vivo, although in vitro methods cannot evaluate all factors to which contact lens wearers are exposed throughout the day. In vivo wettability is frequently evaluated by slit-lamp microscopy

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DovePress
http://doi.org/10.2147/OPTO.S235167

with slit illumination, but this method only allows the observation of a small area of the lens, which may not be representative of the entire lens surface. Objective determination of tear film break-up time by video topography can assess the local drying of the ocular surface.[8] In addition, non-invasive keratograph break-up time (NIKBUT) was shown to have a greater discriminatory ability to detect dry eye than conventional fluorescein staining[9] and to be useful in fitting contact lenses.[10] Video topography has been shown to objectively and reproducibly assess the in vivo pre-corneal tear film and the in vitro drying of contact lens surfaces.[11–13] Video topography involves the projection of ring mires onto the pre-corneal tear film and contact lens surfaces and the simultaneous recording of reflected images.[12] These technological advances allow examination of a larger area, covering more than the optical zone of a contact lens, as well as allowing subjective assessments.

Several studies have reported that the use of visual display devices, including computer monitors, reduces blink frequency and increases interblink intervals in healthy normal subjects and in subjects with dry eye, with and without contact lenses.[14–18] Therefore, the present study evaluated the pre-lens dry-up time, as assessed by non-invasive keratography, in wearers of contact lenses over a 25-s post-blink period.

The purpose of this study was to subjectively compare the in vivo properties of three types of daily disposable contact lenses, nelfilcon A, etafilcon A and omafilcon A, after wearing of lenses for 5 mins, 8 hrs and 12 hrs. The primary objective of this study was to compare pre-lens non-invasive keratograph dry-up time to the first recognizable ring distortion (NIK-DUT$_f$) of the three lenses. The secondary objective was to evaluate the subjective in vivo wettability grade of the central 8–10 mm of each lens, the area covering the optical zone of the lens surface, over 25-s post-blink.

Materials and Methods

This study was conducted at a single site in Jena, Germany (JENVIS Research Institute). The study complied with the ethical principles outlined in the Declaration of Helsinki and was in accordance with Good Clinical Practice (GCP) guidelines. The study protocol was reviewed and approved by the local ethics committee of the Freidrich Schiller University Jena, Jena, Germany, and all participants provided written informed consent prior to any assessment.

Study Design

In this prospective, randomized, observer-masked, 3-way crossover study, eligible participants were randomly allocated (Visit 1) to one of the three types of daily disposable contact lenses: nelfilcon A, etafilcon A and omafilcon A (see Table 1 for specifications of the three test lenses). Each lens type was worn bilaterally for 12 hrs. Dewetting videos of the lens surfaces were taken at 5 mins (Visits 2, 5 & 8), 8 hrs (Visits 3, 6 & 9) and 12 hrs (Visits 4, 7 & 10) after lens insertion. The lenses were removed after the 12 hr visit. Following a washout period of at least one night, subjects were randomly allocated to the second type of lens, and then the third type. This protocol eliminated any possible carry-over effect, as only

Table 1 Specifications of Contact Lens Materials

Material	Lens Brand Name	H_2O Content [%]	Base Curve [mm]	Diameter [mm]	Specification	Wetting Agent in the Blister
Nelfilcon A (ALCON Vision Care Ltd.)	Dailies Aqua Comfort Plus®	69	8.7	14.0	PVA (polyvinyl alcohol) 31% incorporated into the lens matrix, blink-activated release throughout the day	PEG (polyethylene glycol) – to interact with PVA and prolong its presence in the lens HPMC (hydroxypropyl methylcellulose) – for insertion comfort
Etafilcon A (J&J Vision Care Inc.)	1-Day Acuvue Moist®	58	8.5 and 9.0	14.2	PVP (polyvinylpyrrolidone) - hydrophilic	None
Omafilcon A (Cooper Vision)	ProClear 1Day®	60	8.7	14.2	PC (phosphorylcholine) – hydrophilic, non-ionic	None

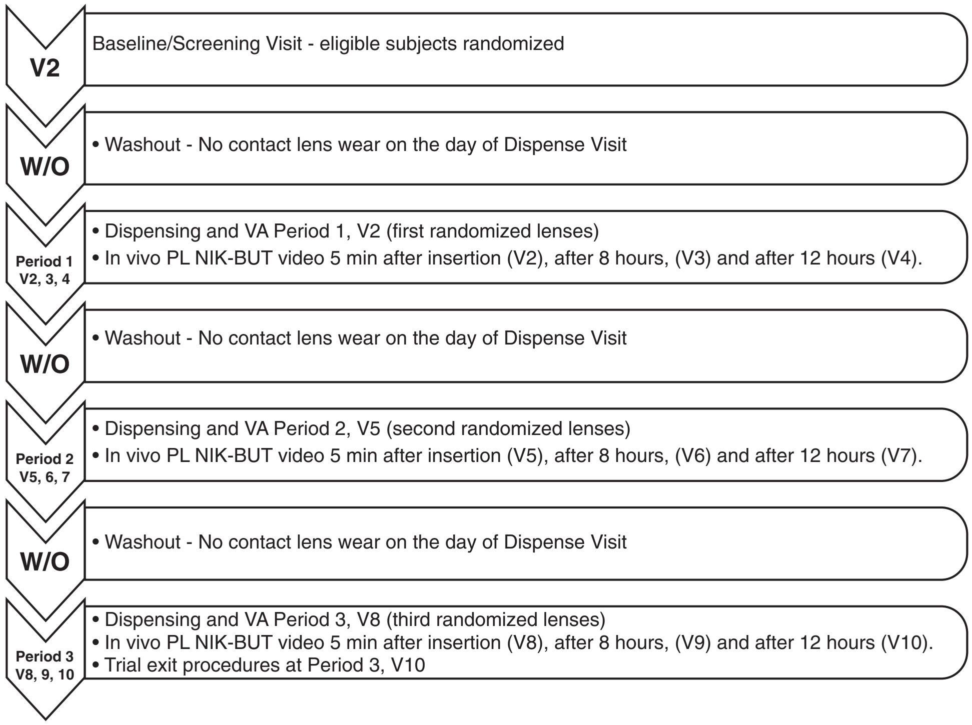

Figure 1 Study visit schedule.

lens surface wettability was analyzed. The complete study visit schedule is shown in Figure 1.

Study Population

The study enrolled adapted, current soft contact lens wearers aged 18–44 years with good tear film stability (NIK-BUT ≥ 13 s[19]), ametropia of +6.0 D to −10.0 D, astigmatism ≤ 1.0 D and visual acuity (VA) of 20/25 or better in each eye. Subjects were excluded if they had any ocular anterior segment disorder or contraindication to contact lens wear or the use of rewetting drops, if they had monocular vision or one-sided ametropia, had unstable tear film with a NIK-BUT <13 s in either eye without lenses, previous herpetic keratitis, ocular surgery or irregular cornea, were pregnant or had participated in another clinical study within the previous 30 days.

Assessment of NIK-DUT$_f$

Subjective NIK-DUT$_f$ was measured using a method based on the validated NIK-BUT technique that has been used to measure pre-corneal tear film stability in non-wearers of contact lenses.[11] This method is based on the principle that clearly reflected ring mires are present in eyes with stable tear film and that image quality will change over time when dewetting starts or progresses during the interblink period, with the reflected ring structure appearing distorted on dry areas of the lens surface.

At study Visits 2–10, dewetting videos were taken from the front surface of the right lens of each subject after wearing for 5 mins, 8 hrs and 12 hrs using an Oculus Imaging Keratograph 5M (Oculus Optikgeräte GmbH, Wetzlar, Germany). This device recorded videos for at least 25-s post-blink, with NIK-DUT$_f$ determined using the imaging-Modus software of the device. The video recordings were independently examined by three trained investigators masked to lens type. Each investigator recorded the time of the blink until the appearance of a first distortion of the placido ring system projected onto the lens surface by using a stopwatch. Additionally, the location of the first recognizable dewetting effect was recorded. The median of the results observed by the three graders was used for further analyses.

Assessment of in vivo Lens Wettability Grade

Overall wettability and wettability of five contact lens segments (central, superior, nasal, inferior and temporal) were graded subjectively at 5 mins, 8 hrs and 12 hrs after lens insertion using a scale of 0 to 3, where grade 0 is fully wettable, grade 1 represents mild hazing, grade 2 indicates clearly visible ring distortions within one-third of the ring reflection zone, and grade 3 indicates clearly visible ring distortions on more than one-third of the ring reflection zone (Figure 2).[20] The subjectively graded images at the five post-blink time points were generated from the NIK-

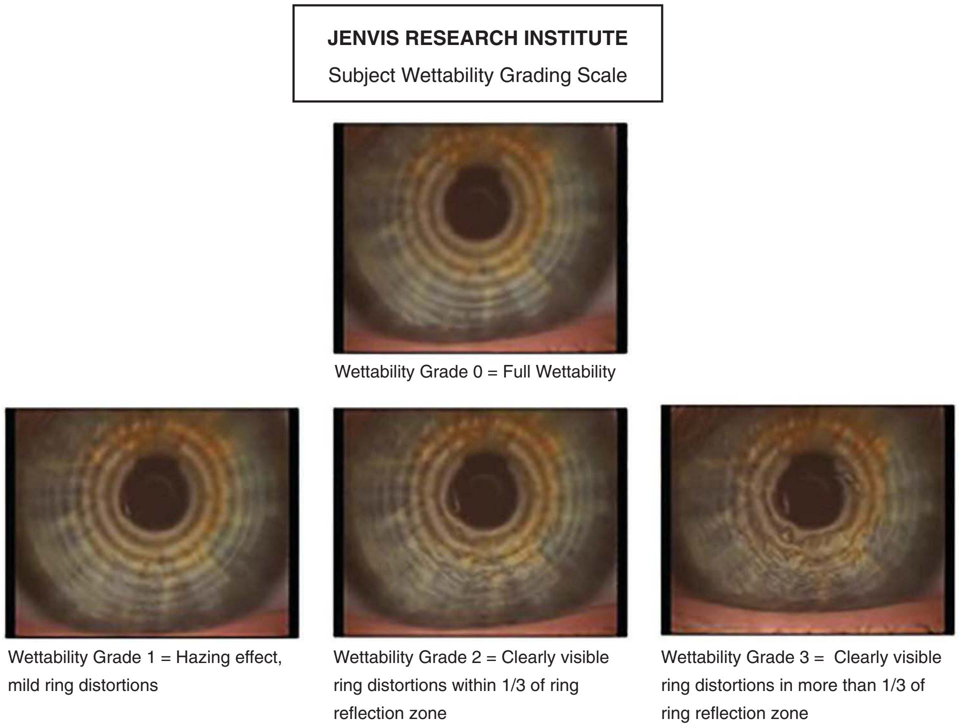

Figure 2 Subjective grading scale used to assess lens wettability.

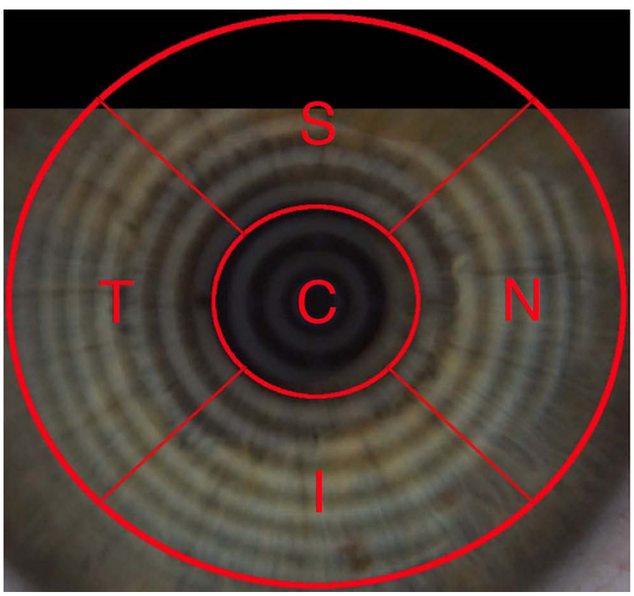

Figure 3 Fixed image of a right lens at one of five time points after blink covered with a lattice structure for grading of individual lens segments (C – central, S – superior, N – nasal, I – inferior and T – temporal).

DUT dewetting videos and overlaid with a lattice structure (Figure 3), which separated the lens surface into the five regions. The sizes of the segments resulted from the horizontal and vertical divisions of the grid into three equal parts and the diagonals of the circumference of the outermost ring.

Fifteen images (five-post blink times multiplied by three wear times) were obtained for each combination of subject and lens, 75 images for the five regions of each lens, and 2,100 images for all subjects for each lens. In some cases, the superior and/or nasal segments were shadowed by the eyelashes, eyebrows or nose; 74 such images (3.5%) could not be evaluated (15 from nelfilcon A, 19 from etafilcon A and 40 from omafilcon A contact lenses).

Safety

All subjects' eyes were examined at all visits by slit-lamp biomicroscopy under standards of professional eye care, with biomicroscopy findings classified using the validated JENVIS grading scale.[21] Safety was assessed in all 30 enrolled subjects.

Statistical Analysis

Sample size was calculated based on pilot data obtained for a study comparing nelfilcon A and stenfilcon A contact lenses for the time from first eye opening post blink to 10% and 20% distortion of the projected ring system. To calculate the sample size, a test time of 22 s was chosen. Based on a sample size of 28 persons per group and 32 events required and a test time of 22 s, a 0.050 level one-sided Log-rank test for equality of survival curves will have 80% power to detect a difference between a nelfilcon A proportion of 0.500 and a stenfilcon A proportion of 0.188.

Statistical analyses were performed using PASW Statistics Version 18 and SPPS software Version 21. Subjective assessments of NIK-DUT and lens wettability grade by the three examiners were summarized as medians. The normality of their distribution was analyzed using the Kolmogorov Smirnov test with Lilliefor's significance. Non-normally distributed results were compared by nonparametric tests, including the Kruskal–Wallis test (a = 0.05) for comparisons of the three lens types and the Friedman test (a = 0.05) for comparisons of lens wearing times. Post-hoc tests (α = 0.05) were performed if deviations were significant.

Results

Study Population

Of the 30 subjects with healthy eyes who were enrolled in the study, two discontinued after the baseline visit, one due to time conflicts and the other due to a sports accident with eye involvement. No lenses were dispensed to these subjects. The 28 subjects who completed the study included six men (21%) and 22 women (79%) and were of mean age 24.96 ± 3.54 years. No serious adverse events were reported during the study.

Analysis of NIK-DUT$_f$

The Friedman test showed that median NIK-DUT$_f$ of the three tested lenses did not differ significantly (X2 (2) = 2.05, P = 0.36) at all time points. Furthermore, dry-up times did not differ significantly for nelfilcon A (X2 (2, N = 26) = 2.07, P = 0.36), etafilcon A (X2 (2, N = 4.0), P =0.14) and omafilcon A (X2 (2, N = 0.48), P = 0.79) contact lenses. No dry-up spots could be detected on two nelfilcon A, four etafilcon A, and three omafilcon A contact lenses, indicating that wettability was stable for these lenses throughout the entire 25-s post-blink period.

The NIK-DUT$_f$ of the three lens types at 5 mins, 8 hrs and 12 hrs of wear are shown in Figure 4. Mean NIK-DUT for nelfilcon A lenses was longer at 8 hrs than at 5 mins and 12 hrs, whereas mean NIK-DUT$_f$ for etafilcon A and omafilcon A lenses was shorter at 8 hrs than at 5 mins and 12 hrs. Omafilcon A contact lenses had the longest mean NIK-DUT$_f$ at 5 mins and 12 hrs of wear, whereas nelfilcon A lenses had the longest NIK-DUT$_f$ after 8 hrs of wear. These differences, however, were not statistically significant. Mean tear film stability of wearers of the three lens types, as determined by the Kruskal Wallis test, did not differ significantly after 5 mins (X2 (2, N = 81) = 0.94, P = 0.63), 8 hrs (X2 (2, N = 80) = 2.46, P = 0.29) and 12 hrs (X2 (2, N = 82) = 0.98, P = 0.61).

Subjective NIK-DUT Grades

The Friedman test showed that subjective NIK-DUT grades did not differ significantly when wearing nelfilcon A contact lenses for 5 mins and for 8 and 12 hrs (X2 (2, N = 690) = 6.01, P = 0.05). By contrast, subjective NIK-DUT grades

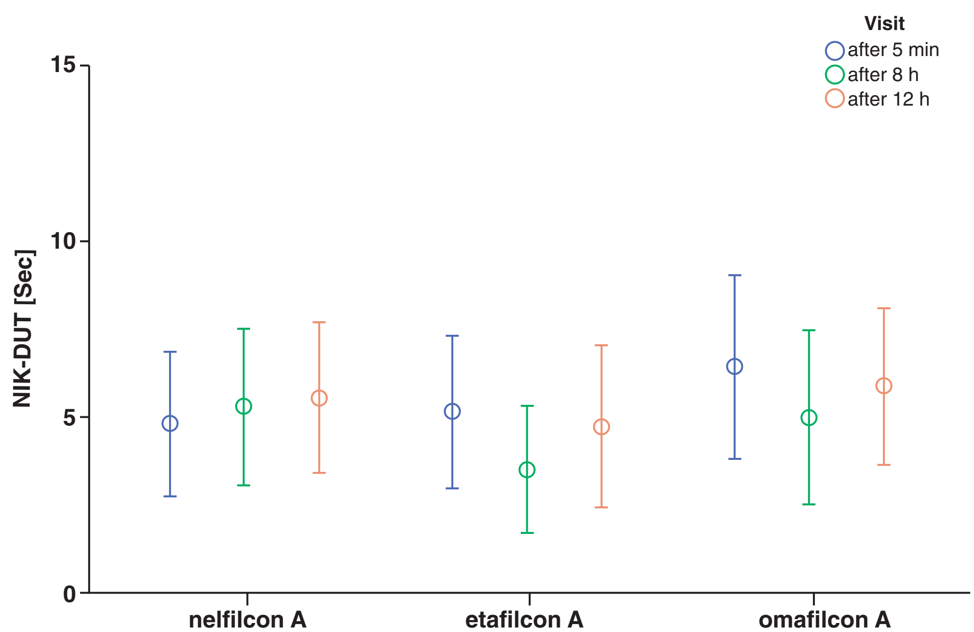

Figure 4 Mean NIK-DUTs for nelfilcon A, etafilcon A and omafilcon A contact lenses following wear for 5 mins, 8 hrs, and 12 hrs.

differed significantly for etafilcon A (X2 (2, N = 691) = 22.89, P <0.01) and omafilcon A (X2 (2, N = 680) = 69.34, $P < 0.01$) lenses. Post-hoc analysis showed significant differences in the grading of etafilcon A and omafilcon A contact lenses. Etafilcon A contact lenses had low grades immediately after insertion and were therefore rated better at 5 mins than after 8 and 12 hrs. The wettability of all three contact lenses was graded higher (less wettable) after 8 hrs than after 5 mins and 12 hrs. After 12 hrs, the wettability of the three lens types differed significantly ($P < 0.01$).

Each contact lens grade was based on five consecutive images, obtained 5, 10, 15, 20 and 25-s post-blink, which visualized changes in dewetting in the five lens segments. Each lens type showed significant differences in dewetting among the individual post-blink times ($P < 0.01$), indicating differences in the grading of the five lens segments. Lens wettability grading changed over time, with wettability grades being lower (better) within the first 5-s post-blink than at other times (Figure 5).

Time to First Distortion by Region

Assessment of the frequency distribution of the first detected drying per lens segment showed that the inferior segments of all three lens types were the first to show drying ($P < 0.01$ by both Cochran's Q and post hoc tests; Figure 6). About 50% each of the etafilcon A and omafilcon A contact lenses initially showed drying of the inferior segment. The percentages of contact lenses showing first break-up in the nasal, temporal, and superior regions ranged from 10.3% to 18.1%. First distortions in the central

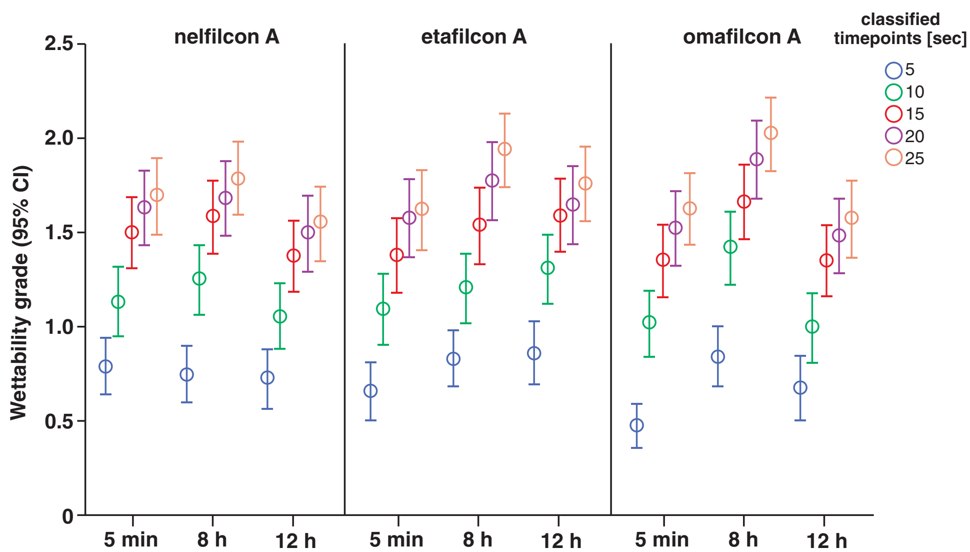

Figure 5 Mean (95% confidence intervals) overall subjective wettability grades of nelfilcon A, etafilcon A and omafilcon A contact lenses at post-blink times of 5, 10, 15, 20 and 25 s following wear of lenses for 5 mins, 8 hrs and 12 hrs.

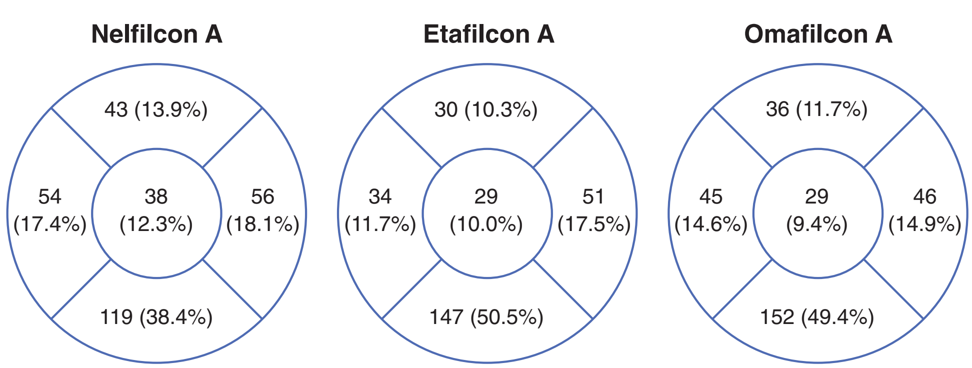

Figure 6 Distribution of the segments of nelfilcon A, etafilcon A and omafilcon A contact lenses on which the first dry spots were detected. Each lens was divided into five segments, as shown, and the first dry spots (n = 84 each) were assessed independently by three trained investigators. The number in each segment represents the number of dry spots and the percentage of the total number of dry spots.

area of the lenses were infrequent, ranging from 9.4% to 12.3%. Although drying of all lens types was significantly greater in the inferior region than in the other regions, wetting increased from 15 to 25-s post-blink, with no significant differences among these lens materials.

Discussion

Video topography can be used to subjectively monitor dewetting phenomena and changes in tear film on the anterior surface of contact lenses. Ring projection can be incorporated into the evaluation of the in vivo wettability of soft contact lenses. This study provides clues by which video topography can evaluate in vivo wettability.

Under real-world conditions, subjects insert contact lenses themselves. Despite washing and drying their hands, lipid-containing fingerprints may transfer onto contact lens surfaces, affecting the results obtained after 5 mins of lens wear. The present study, however, was intended to reflect normal lens handling by experienced contact lens wearers. Only one video image of each right lens was evaluated, thereby avoiding the effects of tear secretions during previous measurements. This factor may be circumvented by an interval of 5 mins between video recordings. Other difficulties experienced during the study were maintaining constant steady focus and motivating subjects not to blink during video recordings.

Tear film fluctuates throughout the day, with activity prior to examination having an effect on wetting.[22,23] Assessments of contact lens wearers' activities throughout the day may reveal possible causes of poor lens wetting. Moreover, wetting has been associated with lens comfort, suggesting the need for masked subject trials to evaluate the comfort of nelfilcon A, etafilcon A and omafilcon A contact lenses.

Despite differences in the properties of the three contact lens materials, their NIK-DUTs did not differ significantly at any time point. Omafilcon A contact lenses had the longest (5.72 s), whereas etafilcon A contact lenses had the shortest, (4.42 s) average NIKDUT$_f$, as well as the most unstable pre lens tear film, suggesting that polyvinylpyrrolidone (PVP) does not prolong dry-up times. Studies using the Tearscope have found that average break-up times were somewhat longer for etafilcon A lenses (5.8–7.3 s).[24–26] Studies of omafilcon A contact lenses have assessed the tendency to evaporate rather than the determination of dewetting times, suggesting that this material can reduce the drying up of pre lens tear film.[27–29] Nelfilcon A contact lenses were reported to have average dry-up times of 5.9–16.7 s,[25,30,31] with the shortest time, 5.9 s,[25] being for nelfilcon A lenses with no wetting substances in the blister solution. However, all comparisons with other studies are limited by their use of different methods and, in some, different measurement times. More than half the contact lenses tested in this study showed a first break-up below 5 s. Although the average time between two blinks in non-contact lens wearers has been reported to be 4.0–5.0 s,[32,33] the use of visual display devices, including computer monitors, increased interblink intervals in subjects with and without contact lenses.[14–18] Therefore, the present study evaluated the pre-lens dry-up time, as assessed by non-invasive keratography, over a 25-s post-blink period.

Despite being stable in all study subjects, tear film is subject to fluctuations and is more unstable during contact lens wear. Our results suggest that about 50% of contact lens wearers with a normal blink frequency may experience the disadvantages of contact lens drying. This is even more likely during concentrated work, when blink frequency is reduced.[34]

NIK-DUT$_f$ did not differ significantly among the three contact lens materials at each time point in this population of lens wearers with excellent tear film stability. The results obtained with nelfilcon A contact lenses were unexpected, in that average NIK-DUT$_f$ was higher at 12 hrs (5.50 ± 5.34 s) than at 5 mins (4.75 ± 5.35 s). Average NIK-DUT$_f$ of etafilcon A and omafilcon A contact lenses were 1.66- and 1.4-s lower, respectively, after 8 than after 12 hrs. A possible explanation is that, at 8 hrs, the subjects had worked extensively throughout the day, whereas from 8 to 12 hrs, they performed activities that required less attention, resulting in a higher blink frequency.

Studies assessing wettability using a NIBUT device (Tearscope, Keeler) have reported that PL NIBUT decreased 0.1 and 1.0 s after wearing nelfilcon A and etafilcon A contact lenses, respectively, for 6 hrs.[21] Moreover, NIBUT was found to be significantly lower, by 1.0 s[26] and 2.5 s,[35] after wearing etafilcon A contact lenses for 8 hrs. The dry-up times of nelfilcon A contact lenses obtained from blister pack solutions containing wetting agents increased slightly after 16 hrs of wear,[30] as did the dry-up times of etafilcon A contact lenses after 16 hrs.[31] Evaluation of NIK-DUT$_f$ showed that drying times did not decrease with wear time. The slight increase in tear film stability of nelfilcon A lens wearers may be due to the mobile portion of PVA, which is released by blinking over the entire wear period, as well as of the presence in blister solution of HPMC and PEG, which bind to PVA.[30,31] Nelfilcon A contact lenses showed the highest average NIK-DUT$_f$ after 8 hrs, followed by omafilcon A contact lenses, whereas etafilcon A contact lenses with bound PVP had the most unstable tear film on the front surface after 8 hrs of wear. The finding that contact lenses with additional wetting substances show longer NIK-DUT_f after 12 hrs of wear could not be confirmed by this method and with these materials in this cohort.

The subjective grading of dewetting pictures of the three contact lenses did not differ significantly over the entire wearing time. The NIK-DUT_f of the lenses paralleled their subjective classifications, with omafilcon A contact lenses showing the highest rate of grade 0 classification and the longest average dry-up time. In contrast, etafilcon A contact lenses showed the greatest reduction in wetting, the highest rate of grade 3 classification, and the shortest average NIK-DUT_f.

Lens materials containing the wetting substance PVA and the basic component PC performed significantly better after 12 hrs of wear (P<0.01 for nelfilcon A and omafilcon A compared with etafilcon A), suggesting that the PVA of nelfilcon A better moistens the surface than the PVP of etafilcon A. Moreover, the significant differences in lens classification indicate that direct examination of rewetting after a new blink may be a more sensitive measure of lens wetting than NIK-DUT_f.

Wetting of all contact lens materials was rated worse after 8 hrs than shortly after lens insertion. After 12 hrs, the lenses showed better grading scores than after 8 hrs. Although lens surface wetting is usually assessed subjectively, atypically by slit-lamp microscopy, the method utilized in this study can assess discrete regions of the front surface of the contact lens. Moreover, the classifications in previous studies differed in gradation and interpretation of wetting, precluding their comparison with the results of the present study. For example, topography has been utilized to objectively classify wetting, as well as tear film BUTs.[35] In that study, the total area of etafilcon A contact lenses was classified on a 5-point scale. Both drying time and contact lens wetting decreased with wearing time up to 8 hrs, a finding not confirmed in the present study.

As expected, the wettability grades of all lens materials were reduced over time, indicating a dynamic dewetting process with a longer interblink period, especially after 15 s. Poorer wetting of various regions of most contact lenses was observed at this time; these wetted areas may merge into each other and influence major parts of the surface in less time. The speed of drying of the three contact lens types did not differ significantly, precluding assessments of differences among wetting substances. However, the speed of drying of all three contact lens materials showed a greater increase before 8 hrs of lens wear, indicating a worsening of wetting and corresponding to the reduction in NIK-DUT_f at 8 hrs.

The wettability grades of the superior and inferior segments of the test lenses differed from those of the other segments. The superior segment had a lower grade, due to shading by eyelashes and eyebrows and covering by the upper eyelids, preventing the classification of the superior and/or nasal segment of 74 eyes (3.5%). The inferior segments of nelfilcon A and etafilcon A contact lenses had a higher grade, as shown by their significantly higher rates of the first break-up in this area, resulting in poorer wetting after the first few seconds. In contrast, the inferior and temporal regions of omafilcon A contact lenses, as well as the nasal and temporal regions, did not differ significantly. The nasal and temporal segments were classified as better than the inferior segment and worse than the superior segment, suggesting that the front surfaces of these contact lenses dry sequentially from the inferior to the superior region.

One limitation of this study was that the method used for subjective grading of the reflected placido ring pattern was limited to a 3-point scale. A finer grading scale may be better able to differentiate drying-up characteristics; however, these gradings may be subjectively more difficult to perform.

Conclusions

The subjective method described in this study is suitable for evaluating tear film stability with soft contact lenses on the eye. Using the projected ring mires, pre-lens dewetting could be detected. The subjective approach of grading the appearance of the reflected mires is time-consuming, especially for general contact lens practice. The method described in this study showed that omafilcon A and nelfilcon A contact lenses had more stable tear film and provided better on-eye lens wettability at 12 hrs than did etafilcon A contact lenses. Subjective dewetting grades differed significantly among these contact lenses. All three types showed a more unstable tear film after 8 hrs of wear than immediately after insertion, with better results after 12 than after 8 hrs. This study demonstrated that wettability changes during the day and may be influenced by the visual tasks performed by the subjects. Additional studies are required to assess the impact of blink frequency on wettability and vision.

Acknowledgments

The authors thank Daniela Oehring for statistical support and Thomas Harnisch, B.Sc. and Evgenia Karadineva for their involvement in grading. Editorial support was provided by BelMed Professional Resources, with funding by Alcon.

Disclosure

The authors report no conflicts of interest in this work.

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