Contact Lens and Anterior Eye 42 (2019) 386–391

Contents lists available at ScienceDirect

Contact Lens and Anterior Eye

journal homepage: www.elsevier.com/locate/clae

Quantification of contact lens wettability after prolonged visual device use under low humidity conditions

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ARTICLE INFO

Keywords:
Silicone hydrogel contact lenses
Relative humidity
Wettability
Tearscope

ABSTRACT

Purpose: Discomfort of silicone hydrogel (SiHy) contact lenses (CL) is associated with longer wearing time, demanding visual tasks, and dry environments. This study investigated the impact of challenging environmental conditions on thewettability of four daily disposable SiHy CL. Methods: Habitual wearers of delefilcon A (n = 32) and somofilcon A (n = 32) were tested with their habitual lenses and with stenfilcon A and narafilcon A lenses. Digital videos were captured using non-invasive Tearscope illumination after 3 hrs of conventional wear and 3 hrs of computer use at 20% relative humidity (RH). Masked investigators analysed non-invasive break up time (NIBUT), minimum protected area (MPA) ofthe lens surface by the tear film, and dehydration speed (DS) over the interblink period after exposure to 20% RH.Results: For habitual delefilcon A wearers, mean NIBUT was longer with delefilcon A (9.2 sec) than stenfilcon A (6.3 sec, $p = 0.052$) and narafilcon A (5.1 sec, $p = 0.006$); mean MPA was significantly higher with delefilcon A (95.4%)than stenfilcon A (84.4%, $p = 0.002$) and narafilcon A (82.9%, $p = 0.006$); mean DS was lower with delefilcon A (0.28 mm2/sec) than stenfilcon A (0.81 mm2/sec, $p = 0.002$) and narafilcon A (0.60 mm2/sec, $p = 0.056$). For habitual somofilcon A wearers, mean MPA was lower for narafilcon A (76.2%) than for somofilcon A (89.0%, $p < 0.001$) but not stenfilcon A (88.4%, $p = 0.748$) and mean DS was higher for narafilcon A (0.96 mm2/sec) than somofilcon A (0.60mm2/sec, $p = 0.029$) but not stenfilcon A (0.51 mm2/sec, $p = 0.701$). Conclusions: Delefilcon A CL performed betterthan stenfilcon A and narafilcon A after 6 hrs of wear including 3 hrs intensive visual tasks under challenging environmental conditions. Delefilcon A CL may be preferable for CL wearers with intensive computers and/or digital devices usage.

1. Introduction

Despite the increased use of silicone hydrogel daily disposable (SiHyDD) contact lenses and the development of new contact lens materials, discomfort remains the major cause of discontinuation of contact lens wear [1]. Contact lens wear has been shown to be a major cause of tear film instability, increased evaporation rate, and dry-eye symptoms, leading to increased end-of-day ocular discomfort and reduced wearing time [2–6]. This discomfort can be exacerbated by longer wearing time, demanding visual tasks, and by dry environments [7–9]. Low humidity conditions have been shown to significantly affect tear film stability in wearers of soft contact lenses, shortening non-invasive break-up time (NIBUT) and resulting in thinner tear film [8,9]. NIBUT is a measure of tear film stability and represents the length of time during the interblink period in which contact lens wettability is good and the tear film fully covers the contact lens surface. The percentages of areas exposed at the first break and at the following blink quantify the extent of tear film disturbances. Larger exposed areas are associated with poorer surface lubrication, leading to greater friction during the blink. The minimum protected area (MPA) is the opposite of this exposed area at blink. Dehydration speed (DS) is the time required for the contact lens surface to dry, beginning from the initial break in the tear film, and is therefore a measurement of the resistance of the contact lens surface to drying.

Factors associated with the wettability of SiHyDD contact lenses include the contact lens material, its packaging solution, and end-of-day fit [10–15]. However, the effects of challenging conditions on tear film kinetic (TFK) parameters have not yet been determined in wearers of SiHyDD contact lenses. This randomised, observer-masked, two-way crossover study evaluated the impact of a low humidity environment on

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https://doi.org/10.1016/j.clae.2019.03.004
Received 9 July 2018; Received in revised form 7 February 2019; Accepted 19 March 2019

SiHyDD contact lens performance following work on electronic displays. As part of this study, we measured the TFK parameters NIBUT, percent MPA, and DS using the Tearscope lighting system, a device that allows *in situ* determination of TFK, in SiHyDD contact lens wearers [3,16,17].

2. Methods

2.1. Study population

The study population consisted of habitual wearers of delefilcon A (DAILIES® TOTAL 1®, Alcon) and somofilcon A (clariti®1 day, CooperVision) soft SiHyDD contact lenses who were aged 18 years or older and adapted to their current contact lenses for at least 2 months. Subjects were required to have vision correctable to 6/7.5 or 0.1 logMAR or better in each eye at distance with study lenses at the time of screening and to be willing to wear lenses every day or at least for a minimum of 5 days per week for 6 h per day, every day if possible, and to discontinue artificial tears and rewetting drops usage on the days of study visits. Excluded were subjects with any ocular anterior segment infection, inflammation, abnormality, or disease or who used any systemic or ocular medications for which contact lens wear could be contraindicated. Subjects could not have participated in any clinical study within 30 days prior to enrolment in this study. The study protocol was approved by the Ethics Committees of all participating institutions, and all subjects provided written informed consent.

2.2. Study design

Each subject wore three types of contact lenses for 10 ± 3 days: their habitual lenses (delefilcon A or somofilcon A lenses) followed by stenfilcon A lenses (MyDay™, CooperVision) or narafilcon A lenses (1-DAY ACUVUE® TruEye®, Johnson & Johnson Vision Care), after which they were crossed over to the alternate lens. At the end each wearing period the participants attended the clinic for a follow-up visit, during which contact lens wettability was assessed twice using the Tearscope (Keeler, Windsor, UK), once after 3 h of wear and again after a further 3 h of wear while using a computer in a setting of 20% relative humidity (RH), representing a dry environment typical of an air-conditioned office.

2.3. Maintenance of 20% RH

The 20% RH was maintained using an environmental ocular goggle device designed and built by OCULAR TECHNOLOGY GROUP-*International* using modified welding googles, a portable conditioning environment that maintains relative humidity between 0% and 80%. The instrument is composed of an attaché briefcase containing the battery operated system that produces air flow at the required speed and humidity and a pair of goggles that creates the controlled environment around the eyes.

2.4. Tearscope analysis

TFK analysis was based on digital videos of the tear film over the total interblink period for each subject. The tear film was visualised using the Tearscope diffuse lighting system attached to a Topcon DC4 slit lamp (Topcon, Newbury, UK) set at ×20 magnification; recordings were obtained with the Topcon DV3 digital camera. The videos were masked and randomised prior to analysis by trained personnel. The parameters analysed included NIBUT, defined as the time elapsed (seconds) between eye opening after a blink and the appearance of the first dark spot (break in the lipid layer) within the tear film (Fig. 1A); % MPA, defined as the minimum percent (%) of the lens covered by the tear film immediately prior to the blink (Fig. 1B); and DS, defined as the speed of increase of uncovered area of the lens after the first break in the tear film (*i.e.*, the area in Fig. 1B minus the area in Fig. 1A) divided by time and reported as mm^2/s. NIBUT was measured for three successive interblink periods and the tear film kinetics analysed for the interblink period corresponding to the median NIBUT.

2.5. Statistical analyses

2.5.1. Calculation of sample size

Calculations showed that, when the sample size was 54, a two-sided 95% confidence interval for a single mean would extend 0.293 from the observed mean, based on a standard deviation of 1.1 and a confidence interval based on large sample z-statistics. Assuming a drop-out rate of 10%, a minimum of 60 subjects was required. The sample size was calculated to determine a certain level of variability associated with the data (95% confidence intervals of a certain width), not to determine P values or claim significance.

2.5.2. Outcome analyses

Data were analysed using SAS 9.2 statistical software (SAS Institute, Cary, NC). The intention-to-treat analysis set, which includes all randomised subjects, served as the primary analysis set of all efficacy evaluations. Data collected after subjects had worn their habitual contact lenses for 10 ± 3 days and had been exposed to 20% RH for 3 h were the reference data used to measure the effect of wearing other contact lenses. Data obtained after subjects had worn alternative contact lenses for 10 ± 3 days and had been exposed to 20% RH for 3 h were compared with reference data collected during habitual lens wear. Categorical data were reported as n (%), and continuous data as mean, standard deviation (SD), median, minimum, maximum and 95% confidence interval (CI). All statistical analyses were exploratory in nature and the data were not adjusted for multiplicity. Because of the exploratory nature of these analyses, the P values were ascertained for descriptive purposes only; thus, the manuscript focus is on the variables that were highly significant (p-value < 0.01) and less so on those that were of borderline significance. Therefore it is not appropriate to make adjustments for multiplicity in the data presented.

3. Results

3.1. Subject disposition

The study population consisted of 64 subjects, 32 habitual wearers of delefilcon A and 32 habitual wearers of somofilcon A SiHyDD contact lenses. Each habitual-wearer group was randomly assigned 1:1 to stenfilcon A followed by narafilcon A or to narafilcon A followed by stenfilcon A contact lenses. Demographic characteristics of the study population are shown in Table 1, and baseline ocular characteristics are shown in Table 2. Of the 64 subjects analysed, 19 were male and 45 were female, with a mean age of 33.8 ± 9.7 years (range 19–56 years). There were no significant differences between the two groups of habitual contact lens wearers.

3.2. NIBUT

After wearing their habitual lenses for 10 ± 3 days, the mean ± SD NIBUT following exposure to 20% RH for 3 h was 9.2 ± 11.1 s in habitual wearers of delefilcon A lenses and 6.2 ± 5.7 s in habitual wearers of somofilcon A lenses (Fig. 2A & B). Assessment of habitual wearers of delefilcon A lenses showed that NIBUT after 3 h of exposure to 20% RH was longer after wearing delefilcon A (9.2 ± 11.1 s) than after wearing stenfilcon A (6.3 ± 9.1 s; p = 0.0524) lenses and significantly longer after wearing delefilcon A (9.2 ± 11.1 s) lenses than after wearing narafilcon A (5.1 ± 5.7 s; p = 0.006) lenses (Fig. 2A). Assessment of habitual somofilcon A wearers showed that NIBUT after 3 h of wear at 20% RH did not differ significantly for somofilcon A (6.2 ± 5.7 s), stenfilcon A (6.4 ± 8.9 s p =

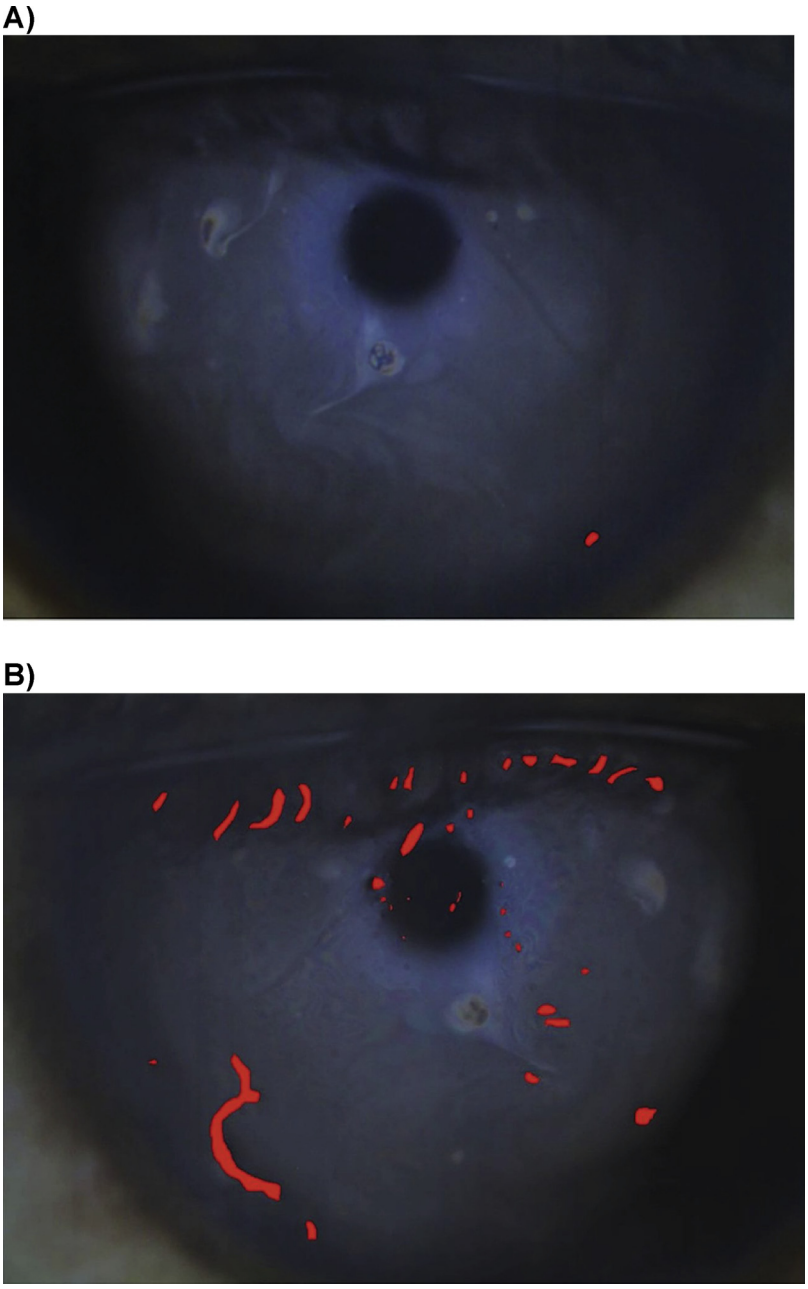

Fig. 1. Examples of exposed areas, as assessed by the Tearscope, (A) at first break and (B) immediately prior to the blink.

Table 1
Demographic characteristics of the intention-to-treat population.

	Delefilcon A Wearers	Somofilcon A Wearers	Total
Number	32	32	64
Age, yr			
Mean ± SD	34.3 ± 9.5	33.4 ± 10.1	33.8 ± 9.7
Median	32	32	32
Range	19, 56	20, 53	19, 56
Sex, n (%)			
Male	12 (37.5)	7 (21.9)	19 (29.7)
Female	20 (62.5)	25 (78.1)	45 (70.3)

0.8652 and narafilcon A (4.7 ± 3.6 s $p = 0.1489$) lenses (Fig. 2B).

3.3. MPA

After wearing their habitual lenses for 3 h at 20% RH, the mean ± SD% MPA was 95.4 ± 14.0% in habitual wearers of delefilcon A lenses and 89.0 ± 21.5% in habitual wearers of somofilcon A lenses (Fig. 3A & B). Comparisons in habitual wearers of delefilcon A lenses showed that, after exposure to 20% RH for 3 h, % MPA immediately prior to the blink was significantly greater while wearing delefilcon A (95.4 ± 14.0%) than while wearing stenfilcon A (84.4 ± 27.4%; $p = 0.002$) and narafilcon A (82.9 ± 33.8%; $p = 0.006$) lenses (Fig. 3A). In habitual wearers of somofilcon A lenses, % MPA after 3 h of exposure to RH was significantly higher for somofilcon A (89.0 ± 21.5%) than for narafilcon A (76.2 ± 32.9%; $p < 0.001$), but not for stenfilcon A (88.4 ± 22.7% $p = 0.7475$), lenses (Fig. 3B).

3.4. DS

Mean ± SD DS following exposure to 20% RH while wearing their habitual lenses was 0.28 ± 0.85 mm^2/s in habitual wearers of delefilcon A contact lenses and 0.60 ± 1.14 mm^2/s in habitual wearers of

Table 2
Baseline ocular characteristics of subjects in the intention-to-treat population.

	Stenfilcon A/ Narafilcon A	Narafilcon A/ Stenfilcon A	Total
Sphere (D)			
Number of eyes	64	64	128
Mean ± SD	–3.78 ± 1.59	–3.35 ± 1.72	–3.57 ± 1.66
Median (range)	–3.50 (–8.50, –0.75)	–3.00 (–7.75, –1.00)	–3.25 (–8.50, –0.75)
Cylinder (D)			
Number of eyes	64	64	128
Mean ± SD	–0.32 ± 0.25	–0.40 ± 0.26	–0.36 ± 0.26
Median (range)	–0.25 (–0.75, 0.00)	–0.50 (–0.75, 0.00)	–0.25 (–0.75, 0.00)
BCVA (Decimal) (OD & OS)			
Number of eyes	64	64	128
Mean ± SD	1.24 ± 0.21	1.28 ± 0.24	1.26 ± 0.22
Median (range)	1.25 (0.90, 1.60)	1.25 (0.90, 1.60)	1.25 (0.90, 1.60)

BCVA = best corrected visual acuity; OD = right eye; OS = left eye; SD = standard deviation.

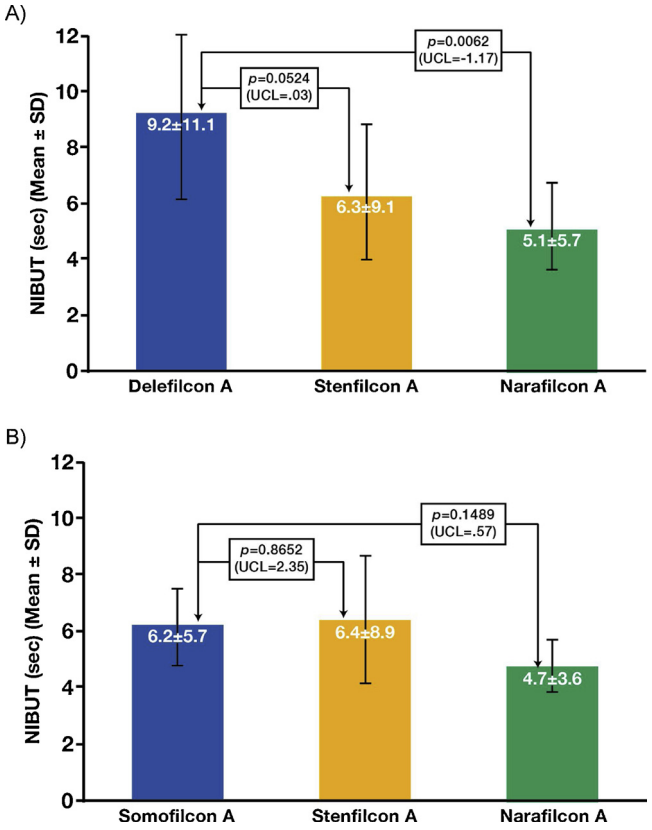

Fig. 2. Mean ± SD non-invasive break-up time (seconds) in habitual wearers of (A) delefilcon A and (B) somofilcon A lenses after exposure to 20% relative humidity while wearing habitual, stenfilcon A, and narafilcon A lenses.

somofilcon A lenses (Fig. 4A & B). Comparisons in habitual wearers of delefilcon A lenses showed that, after exposure to 20% RH for 3 h, DS was lower with delefilcon A (0.28 ± 0.85 mm^2/s) than with stenfilcon A (0.81 ± 1.42 mm^2/s; $p = 0.002$) or narafilcon A (0.60 ± 1.29 mm^2/s; $p = 0.0558$) lenses but not significantly with the latter. (Fig. 4A). In habitual wearers of somofilcon lenses, DS after exposure to 20% RH was lower while wearing somofilcon A (0.60 ± 1.14 mm^2/s) than while wearing narafilcon A lenses (0.96 ± 1.42 mm^2/s; $p = 0.0289$) but not when wearing stenfilcon A (0.51 ± 1.14 mm^2/s; $p = 0.7007$) lenses (Fig. 4B).

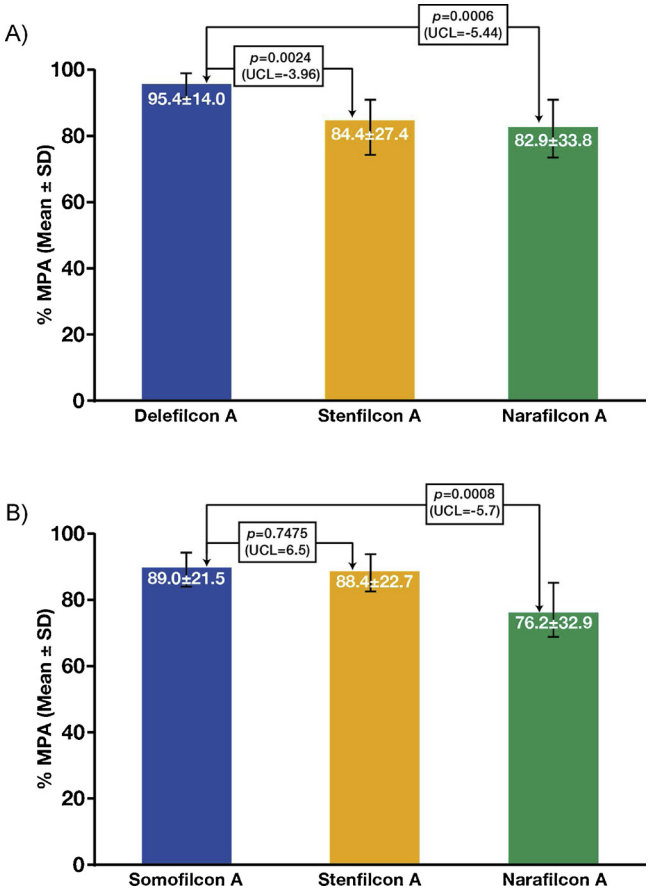

Fig. 3. Mean ± SD percent minimum protected area (%) in habitual wearers of A) delefilcon A and B) somofilcon A lenses after exposure to 20% relative humidity while wearing habitual, stenfilcon A, and narafilcon A lenses. The numbers within each bar represent the mean ± standard deviation (SD); the T-bars represent the 95% confidence intervals. MPA = minimum protected area, UCL = upper limit of the 95% confidence interval of the least square mean difference (Study CL-Habitual CL).

4. Discussion

The *in vivo* wettability of SiHyDD contact lenses is dependent on various factors, including lens material and design, lens surface wetting solution, environmental factors, and lens fitting characteristics [10–15]. In this study, all influencing factors were controlled, the only variable being the contact lens type. Analysis of TFK parameters in contact lens wearers allows for the quantification of tear film dynamics over the entire interblink period, including the period of time during which wettability is normal (NIBUT); the lens surface coverage at the time of the blink (MPA), when the eyelid interacts with the contact lens; and the speed at which the tear film destabilizes once the blink has occurred (DS), indicative of the surface resistance to dehydration *in vivo*, analogous to measuring the receding angle of the contact lens surface *in vivo*.

A previous three-way cross-over study assessed noninvasive tear breakup time (NITBUT) in 53 subjects who were symptomatic for dry eye and 51 asymptomatic subjects who were randomly selected to wear narafilcon A, somofilcon A and delefilcon A lenses for 3 days each under normal environmental conditions [18]. Although all three lens types performed well, mean NITBUT was significantly longer with delefilcon A than with the other two lens types ($p < 0.01$ each). In addition, the wettability of delefilcon A lenses was superior to that of the other two lens types ($p < 0.01$ each). There were no differences in NITBUT between symptomatic and asymptomatic study subjects.

This study utilized this methodology to evaluate contact lens

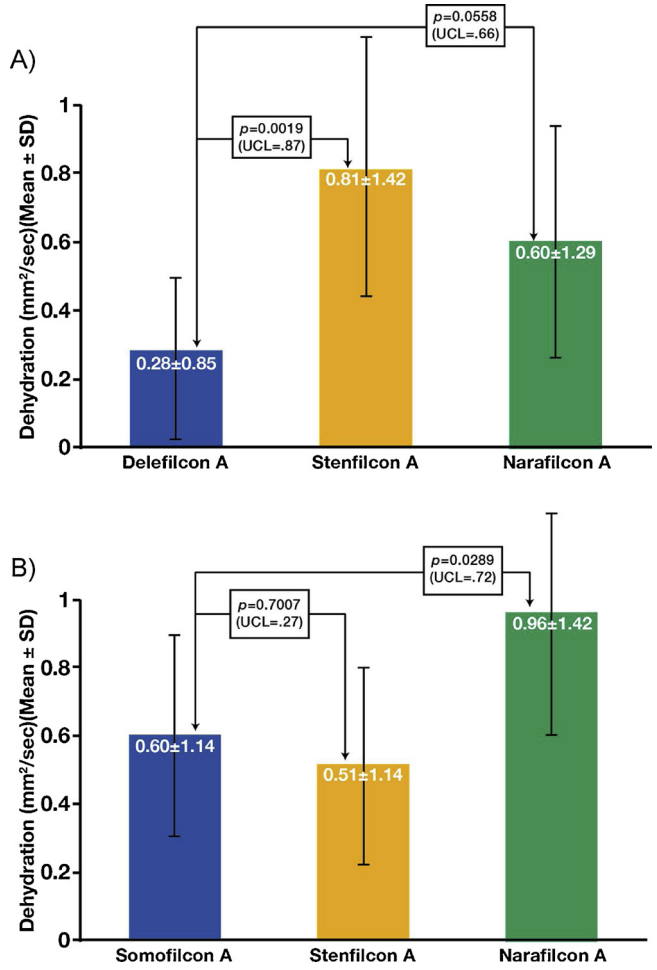

Fig. 4. Mean ± SD dehydration speed in habitual wearers of A) delefilcon A and B) somofilcon A lenses after exposure to 20% relative humidity while wearing habitual, stenfilcon A, and narafilcon A lenses. The numbers within each bar represent the mean ± standard deviation (SD); the T-bars represent the 95% confidence intervals. UCL = upper limit of the 95% confidence interval of the least square mean difference (Study CL-Habitual CL).

wearers following prolonged and intensive computer use under the controlled low-humidity conditions encountered in air conditioned offices. TFK parameters were assessed in subjects who wore their habitual lenses (delefilcon A or somofilcon A) and two alternative lens types (stenfilcon A and narafilcon A) for 10 ± 3 days as daily disposable lenses. All parameters were measured after 3 h of normal wear followed by 3 h of wear while using a computer in a setting of 20% RH.

Evaluation of habitual wearers of delefilcon A lenses showed that NIBUT was statistically different, clinically delefilcon A mean NIBUT was longer by 32% compared with stenfilcon A and 45% compared with narafilcon A. MPA was also statistically different between delefilcon A *versus* stenfilcon A and narafilcon A; clinically the mean coverage by the tear film being 2% and 13% respectively in favour of delefilcon A. DS was statistically different for delefilcon A than for stenfilcon A and narafilcon A lenses; clinically the differences corresponded to a highly significantly slower mean dehydration for delefilcon A by 189% and 114% respectively. Evaluation of habitual wearers of somofilcon A lenses showed that the only statistically significant differences were with narafilcon A for the 15% MPA for which the mean coverage was greater for somofilcon A and DS for which the mean speed of dehydration was slower for somofilcon A by 36%. No differences between somofilcon A and stenfilcon A lenses for MPA and DS and no differences in NIBUT were recorded among the three lens types.

Delefilcon A has been shown to have a lower coefficient of friction *in vitro* than both stenfilcon A and narafilcon A lenses [19]. Thus, a key question in this context is whether the superior *in vitro* findings are associated with superior clinical performance. Friction is highly dependent on the maintenance of a continuous liquid film between the surfaces in relative displacement (*e.g.*, eyelid and contact lens front surface). This study found that delefilcon A has superior on-eye wetting properties compared with the other two contact lenses, including longer time with full tear film coverage, greater resistance to dehydration once a break has occurred and greater surface coverage at the time of the blink, clinically corroborating the superiority of delefilcon A *in vitro*. It is important to note that this study was done after 3 h of normal wear followed by 3 h of wear while using a computer in a setting of 20% RH, hence total lens wear of 6 h. Results may be different under the same environment over a longer period (9–12 h).

A limitation of this study was that it did not include habitual wearers of stenfilcon A and narafilcon A lenses randomised to wearing of other lens types for 10 ± 3 days. Use of such control groups may better reveal the effects of lens material on *in vivo* wettability. Also, this was a short 6-h duration study and not the entire day.

In conclusion, delefilcon A contact lenses performed significantly better than stenfilcon A and narafilcon A lenses after 6 h of wear including 3 h under challenging environmental conditions while performing intensive visual tasks Delefilcon A contact lenses may be preferred for contact lens wearers involved in intensive usage of computers and/or digital devices.

Acknowledgments

This study was funded by Alcon Research, Ltd., Fort Worth, TX, USA. Editorial support was provided by BelMed Professional Resources, Inc., and was funded by Alcon.

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