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Effect of contact lens surface properties on comfort, tear stability and ocular physiology

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ABSTRACT

Aim: Retrospective analysis of different contact lens wearing groups suggests lens surface lubricity is the main factor influencing contact lens comfort. However, the examined commercially available contact lenses differ in material and design as well as surface properties. Hence this study isolates the contribution of lens surface properties using an ultra-thin coating technology.
Methods: Nineteen habitual contact lens wearers (21.6 ± 1.7years) wore formofilcon B soft monthly disposable contact lenses with and without coating technology modified surface properties for a month each in a randomised double-masked cross-over study.
Objective non-invasive: breakup time (NIKBUT), NIKBUT average and ocular redness (Jenvis grading scale) were evaluated (Keratograph 5M) after 1 week and 1 month of wear. Symptoms were assessed using the Contact Lens Dry Eye Questionnaire (CLDEQ-8); perceived vision quality and subjective lens comfort at insertion, mid-day and end of the day were rated with four Visual Analog Scales.
Results: Perceived visual quality ($F = 5.049, p = 0.037$), contact lens dry eye symptoms ($F = 14.408, p = 0.001$) and subjective lens comfort ($F = 28.447, p < 0.001$) were better for coated compared to uncoated lenses. The surface coating postponed the lens dewetting ($F = 8.518, p = 0.009$) and increased the pre-lens tear film stability ($F = 5.626, p = 0.029$), but bulbar ($F = 0.340, p = 0.567$) and limbal ($F = 0.110, p = 0.744$) redness were similar for both contact lenses. No parameter changed significantly between a weeks' and months' wear ($p > 0.05$). Lens surface wettability and ocular redness were not correlated to changes in symptoms ($p > 0.05$).
Conclusion: As previously hypothesised, enhancing the physical surface properties of a soft contact lens improves subjectively rated wearer comfort, which, in turn, should result in reduced contact lens discontinuation.

1. Introduction

The management of contact lens discomfort (CLD) remains a challenge in clinical practice [1]. There are more than 140 million contact lens wearers worldwide and about 50% of them report having adverse ocular sensations [1,2], generally described as ocular dryness [3,4].

The insertion of a contact lens into the eye induces various factors that may be related to CLD. Ocular dryness decreases after lens removal [5], and generally reduces during the afternoon and evening when wearing contact lenses [4–8]. Moreover, dry eye symptoms in contact lens wearers are more frequent and intensive than those of non-contact lens wearers [9,10]. Replacing the lens midway through the wearing period does not improve end of day comfort, suggesting that the physical presence of the lens and its interaction with the ocular surface causes a fatiguing effect on ocular tissues or stimulates nociceptors, rather than the decrease in comfort is due to changes occurring to the lenses during wear [11]. To diagnose CLD, the integrity of the tear film [12–15] and meibomian glands [16] as well as the ocular redness [17] and staining [18–20] are typically assessed. Nevertheless, the correlation between these signs and dry eye symptoms is generally poor [21].

Research into CLD aims to determine which contact lens properties (e.g. design and material) will improve contact lens adaptation. Hydrogels with lower water content have been shown to have greater lens hydration [22,23], providing a better lens comfort [24,25] than higher water content materials. Attempts to extend lens wear by increasing lens oxygen permeability have been addressed by adding silicone components to hydrogel materials [26]. However, silicone-containing monomers compromise lens wettability, giving rise to strategies to make silicone hydrogels more hydrophilic [26]. Current studies have suggested that the friction between lens surface and lid margin (termed

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Table 1
Contact lens characteristics with and without the coating technology (mean ± S.D.).

PARAMETER	MEASUREMENT	
	Uncoated lenses	Coated lenses
Modulus (MPa)	0.42 ± 0.19	0.45 ± 0.15
Sessile-drop contact angle (°)	42 ± 15	61 ± 11
Coefficient of friction	0.071 ± 0.005	0.004 ± 0.003
Water content (%)	50	
Dk/t (@ −3.00D) (barrer/mm)	140	
Diameter (mm)	14.2	
Base curve (mm)	8.6	
Center thickness (µm)	80	
UV filtration	Class 1 Blocking	
Coating (nm)	< 6–10	

lubricity) is the key contributor to lens comfort [26–29]; however, they use commercially available contact lenses which differ in material and design and are generally worn by different cohorts of patients, introducing potential confounding effects.

This study applied a nanometer thickness coating technology (without significantly altering lens design or core material properties) to monthly disposable silicone hydrogel lenses to determine whether surface properties alone affect lens comfort and wettability.

2. Method

Twenty habitual contact lens wearers were recruited for a randomised double-masked cross-over wear of formofilcon B monthly disposable soft contact lenses of the same design and modulus, with and without modifying the surface properties with a coating technology (Bettervision Pty, Keller, TX, USA; Table 1). A modified CSM nanoscratch tribometer was used to measure the dynamic coefficient of friction. Consent was obtained after explanation of the study and possible consequences of taking part. The study was approved by the ethical committee of Aston University, and conformed to the tenets of the Declaration of Helsinki. Participants were excluded from the study if they had astigmatism ≥0.75D, had a best corrected visual acuity of > 0.1 logMAR, had any ocular or systemic disease or surgery which might interfere with contact lens wear, were on medication with known ocular side effects, or were pregnant or breast feeding. Inclusion criteria included being ≥18 years of age and having a healthy ocular surface (Jenvis grades ≤2). All subjects expressed a desire to wear contact lenses full time and agreed to wear their lenses for a minimum of 7 h per day throughout the study. The subjects were masked to the prescribed contact lenses. They were provided with a supply of hydrogen peroxide solution and case (AOSept Plus, Alcon, Fort Worth, USA) and were talked through the cleaning regimen including neutralising, rubbing and rinsing. No additional solutions or eye drops could be use throughout the study. Moreover, contact lens fit was adequate and evaluated in each visit using a simplified recording scheme [30].

A clinical evaluation was conducted one week and one month after wearing each contact lens type, bilaterally in randomised order, each for one month. Objective non-invasive break up time (NIKBUT), the average time of all break up incidents (NIKBUT average), and nasal and temporal bulbar and limbal redness (Jenvis grading scale) were evaluated in both eyes after at least one hour of lens settling and with the Keratograph 5 M (OCULUS Optikgeraete GmbH, Wetzlar, Germany), previously shown to be repeatable [31]. Three consecutive NIKBUT and NIKBUT average readings were taken separated by at least 60 s and the mean was recorded. Contact lens dry eye symptoms were assessed using the 8-item Contact Lens Dry Eye Questionnaire (CLDEQ-8). Moreover, perceived vision quality and subjective lens comfort between visits were separately rated at insertion, mid-day and end of the day using four different Visual Analog Scales (VAS).

2.1. Statistical analysis

The data were continuous and normally distributed (confirmed using the Kolmogorov-Smirnov test) hence parametric statistics were utilised. Repeated measure analysis of variance (ANOVA) testing (with coating, duration of wear, eye and nasal and temporal quadrants as factors) was performed to establish whether a statistically significant difference ($p < 0.05$) existed between NIKBUT, NIKBUT average, comfort and ocular redness measured for coated and uncoated contact lenses. Mauchly's test was used to test the assumption of sphericity. In case of sphericity violation, Greenhouse-Geisser correction was applied. The association between subjective symptoms of ocular dryness and lens surface tear stability was assessed with a Pearson's correlation. Due to the repeated measures design, at least 15° of freedom is recommended [32], which was achieved with a sample size ≥15.

3. Results

Nineteen subjects (21.6 ± 1.7 years, 17 females) successfully finished the study. The drop out was due to the individual's scheduling issues. No adverse events occurred during the study. Perceived visual quality ($F = 5.049$, $p = 0.037$; Fig. 1), contact lens dry eye symptoms ($F = 14.408$, $p = 0.001$; Fig. 2) and subjective lens comfort ($F = 28.447$, $p < 0.001$; Fig. 3) were better for coated lenses compared to uncoated lenses, with no significant changes between a weeks' and months' wear ($F = 4.122$, $p = 0.057$; $F = 0.558$, $p = 0.465$; $F = 3.137$, $p = 0.72$, respectively). Tear film stability of the contact lens anterior surface and NIKBUT average were longer with coated lenses ($F = 5.626$, $p = 0.029$; $F = 8.518$, $p = 0.009$, respectively), were bilaterally similar ($F = 0.571$, $p = 0.460$; $F = 0.058$, $p = 0.820$, respectively) and were stable between one week and one month of lens wear ($F = 2.748$, $p = 0.115$; $F = 0.673$, $p = 0.423$, respectively; Table 2). Bulbar redness did not significantly differ with contact lens coating ($F = 0.340$, $p = 0.567$), between one week and one month of wear ($F = 0.057$, $p = 0.814$), right and left eyes ($F = 3.992$, $p = 0.615$) or nasal and temporal quadrants ($F = 0.049$, $p = 0.818$). This was also the case with limbal redness, with no significant differences with the contact lens coating ($F = 0.110$, $p = 0.744$), between one week and one month of wear ($F = 0.261$, $p = 0.615$) or between eyes ($F = 0.123$, $p = 0.730$), although the nasal limbus was significantly redder than the temporal limbus (0.25 ± 0.23 vs 0.18 ± 0.20; $F = 6.449$, $p = 0.021$). In addition, there was no interaction between factors when analysing differences between NIKBUT, NIKBUT average, comfort and ocular redness measured for coated and

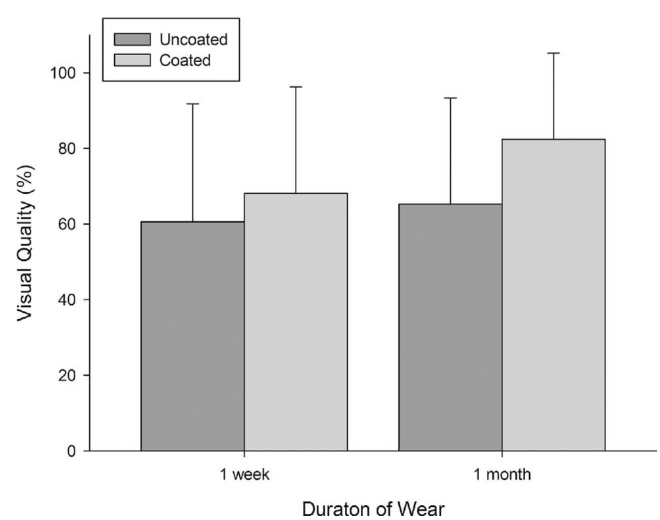

Fig. 1. Subjectively rated visual quality with and without contact lens coating with duration of wear. N = 19. Error bars = ± 1 S.D.