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Objective clinical performance of 'comfort-enhanced' daily disposable soft contact lenses

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ABSTRACT

Purpose: To examine the objective clinical performance of 'comfort-enhanced' daily disposable contact lenses over a 16-h day.

Methods: Four contact lenses (Hilafilcon B, Etafilcon A Plus, Nelfilcon A and Nelfilcon A Plus) were evaluated in an investigator masked, open label trial at the end of a week's bilateral wear. Pre-lens non-invasive tear break-up time (PL-NITBUT), tear prism height, bulbar hyperaemia and ocular surface temperature (OST) were measured with the lens in situ at 8, 12 and 16 h of wear.

Results: There was no difference between how many hours the lenses types were worn each day ($F = 0.90$, $p = 0.44$). The PL-NITBUT decreased with the duration of daily lens wear ($F = 32.0$, $p < 0.001$) and was more stable with Nelfilcon A Plus ($F = 6.00$, $p = 0.002$) than with the other lenses evaluated. Bulbar blood vessels increased in coverage ($F = 11.5$, $p < 0.001$) but not overall redness ($F = 0.0$, $p = 0.99$) with the duration of daily lens wear, but there was no difference between the lenses ($p > 0.05$). The tear prism height decreased with the duration of daily wear ($F = 27.0$, $p < 0.001$) and differed between lenses ($F = 2.9$, $p = 0.04$). The OST decreased with the duration of lens wear ($F = 119.7$, $p < 0.001$) and was reduced by daily disposable lens wear ($F = 7.88$, $p < 0.001$), but did not differ between lenses ($F = 0.88$, $p = 0.45$).

Conclusions: Objective measures of tear film indicated a difference between the lenses evaluated for PL-NITBUT and tear prism height, but not for wearing time or bulbar conjunctival hyperaemia. Therefore clinical benefits of daily disposable 'comfort enhancing' contact lenses can be measured, but challenges remain in producing contact lenses that do not compromise anterior eye physiology over the whole day.

1. Introduction

Discomfort, particularly towards the end of the day, is a major cause of contact lens discontinuation [1]. Dry eye symptoms are the most common complaint [2,3], with over 70% of wearers reporting symptoms late in the day [4], and approximately one-third of these discontinue lens wear as a result [1].

The average duration of contact lens wear has been reported to be around 13–14 h a day [3–5]. Patients report finding their lenses comfortable for about 1–1.5 h less than their wearing time, and this seems to be the main limiting factor [3,5]. Approximately 25% of wearers report wearing their contact lenses for 16 h, with less than 10% wearing them 17 h a day or more [3]. However, only about half of these wearers report their contact lenses as still comfortable after 16 h of wear. The authors concluded "that for many patients, current soft contact lenses wear is not optimised" [3]. There have been a few studies published which examine contact lens wearers who had been wearing their lenses for an average of 12–18 h [2,7], but only our previous study on Nelfilcon A has performed a systematic assessment of lens performance after wearing times greater than 12 h [6].

Recent advances in daily disposable soft lenses have attempted to reduce the effects of end of day dryness. The SofLens one day (Bausch and Lomb) optimises comfort through its reduced thickness and mass design (creating smoother back surface transitions, reducing lens/lid interactions during blinking). In addition, the lens is formed from hilafilcon B high water content material and is packaged in a poloxamine containing lens storage solution that binds to the lens surface, being slowly released onto the lens surface. The 1-Day Acuvue Moist lens (Etafilcon A; Vistakon, Johnson and Johnson) uses LACREON™ Technology, permanently embedding polyvinyl pyrrolidone into their Etafilcon A material. The Focus DAILIES with Aquacomfort contact lens material Nelfilcon A contains approximately 1.5% polyvinyl alcohol (PVA) and is created by polymerising partially acetalized PVA with N-formylmethyl acrylamide. This polymer forms 31% of the

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finished contact lens and 'functionalised' PVA is bound in the matrix as part of the lens (70% water content). Incorporated non-functionalised PVA (extra, non-bound PVA making up 2% of the macromer formulation weight) remains free in the lens matrix after lens formation. This wetting agent, approximately 0.6% (w/v) of the finished lens, is then released slowly into the tear film (assisted by the mechanical effect of blinking) [6,8,9]. AquaRelease™ moisturising has been enhanced by the addition of hydroxypropylmethylcellulose and polyethylene glycol (which binds to PVA, prolonging its release) in DAILIES AquaComfort Plus contact lenses (Nelfilcon A Plus Ciba Vision).

To improve long-term contact lens wear, 'comfort enhancing' contact lenses such as those just described must provide good subjective comfort, but this is difficult to compare objectively in an open-label comparison due to the influence of brand awareness. However, clinical measures of tear film volume and stability and bulbar hyperaemia can be objectively assessed, all of which are related to a long-term healthy comfortable eye and the lubricating effects of the contact lens [10]. Therefore this study assessed these objective measures over 16 h of wear after a week of bilateral wear of each of the identified 'comfort enhancing' contact lenses.

2. Methods

Thirty-four subjects (average age 24.2 ± 5.8 years; 10 males) were enrolled on a bilateral prospective 1 week evaluation of each of Hilafilcon B, Etafilcon A Plus, Nelfilcon A and Nelfilcon A Plus daily disposable contact lenses (lens details in Table 1) worn in random order. The sample size was based on providing sufficient degrees of freedom to detect significant changes in analysis of variance testing (34 subjects × 4 contact lenses > 15 degrees of freedom recommended) [11]. None of the subjects were on ocular medication, had incurred ocular injury or surgery within the last 12 weeks, had pre-existing ocular irritation or displayed evidence of systemic or ocular abnormality, infection or disease likely to affect successful wear of contact lenses. The subjects were regular contact lens wearers. The investigators were masked throughout the study, but due to the loss of sterility that would result in re-packaging, the study was open label. Hence only objective data was collected except for hours of wear as a partial indicator of lens comfort [3]. Informed consent to take part in the study was received from all subjects. The study was approved by the Human Sciences Ethical Committee of Aston University and conformed to the Declaration of Helsinki.

At the end of a week's wear of each lens type, measures were taken at three time points throughout the day, at 8, 12 and 16 h after lens insertion. Measurements were taken in a systematic order, in case of anterior eye effects of the techniques themselves, by observers who were masked as to the lenses worn. Pre-Lens Non-Invasive Tear Break-Up Time (PL-NITBUT) was assessed using a modified CA-1000 topographer (Topcon, Newbury, UK), which projected circular mires onto the corneal surface, with the tear film reflection observed on a 30 in. flat panel monitor and the PL-NITBUT recorded at the first sign of mire distortion. An average of three measures was taken. Digital slit lamp images (JAI C-S2300 digital camera; resolution 767 × 569 pixels) of the bulbar conjunctiva and tear-meniscus height were captured. Objective image analysis grading was carried out on an area of approximately 3 mm × 3 mm on the bulbar conjunctiva using Labview software (National Instruments, Austin, USA) with validated edge detection and colour extraction techniques [12]. Vessel coverage assesses the length of blood vessel edges in the selected area which relates to the vessel contrast and extension. Red colouration relates to the intensity of red pixels in the selected area (relative to overall intensity) including both the blood vessels and the background hue. Labview programming was also used to measure average tear meniscus heights from the line of reflection along the top of the tear prism, to the edge of the eyelid. Repeatability of this technique has previously been shown to be high [6]. Ocular surface temperature (OST) was measured using a dynamic, non-contact, infrared thermography camera (Thermo-Tracer TH7102MX, NEC San-ei, Japan) [13]. OST is known to essentially be a measure of tear film quality and quantity with the tears spread by the blink action temporally raising the temperature of the central cornea [14]. The average OST (encompassing the wear of a contact lens) was taken at the centre of the cornea, at the temporal upper limbal area (6 mm from the central cornea) and over the central 5 mm^2 of the cornea, 2 s post-blink.

After each of the contact lenses had been worn and assessed, the same measurements were taken in all of the subjects after a week of no contact lens wear to assess baseline ocular surface characteristics. These measures were taken at the same time of day as the 8 h of wear assessed with the daily disposable contact lenses to allow comparison.

Repeated measures analysis of variance was used to assess differences between the lenses and with time of day for each of the objective tests.

3. Results

3.1. Diary

There was no difference between how many hours the lens types were worn each day ($F = 0.90$, $p = 0.44$) and there was no significant difference in wearing time during the week ($F = 2.19$, $p = 0.06$; Fig. 1).

3.2. Pre-lens tear break-up time

The PL-NITBUT decreased with the duration of lens wear (8 h: 16.1 ± 6.8 s; 12 h: 14.5 ± 6.0 s; 16 h: 13.2 ± 7.0 s; $F = 32.0$, $p < 0.001$; Fig. 2). Tear film was significantly more stable on the surface of Nelfilcon A Plus (16.7 ± 6.8 s; $F = 6.00$, $p = 0.002$; Chi-square 14.7, $p = 0.002$; Fig. 2) than with the Nelfilcon A (15.0 ± 6.6 s), Etafilcon A Plus (14.2 ± 7.0 s) and least stable with the Hilafilcon B (12.7 ± 4.3 s). Interestingly, the NITBUT on the ocular surface of subjects following a week of no contact lens wear was 14.2 ± 7.0 s. There was no

Table 1
Details of the daily disposable contact lenses trialled.

Contact lens	Hilafilcon B	Etafilcon A Plus	Nelfilcon A	Nelfilcon A Plus
Group	II	IV	II	II
Water content (%)	59	55	69	69
Base curve (mm)	8.6	8.5	8.7	8.6
Diameter (mm)	14.2	14.2	14.0	13.8
Hydrating agent(s)	None	PVP	PVA	PVA, HPMC, PEG
Centre thickness @-3D (mm)	0.09	0.08	0.10	0.10
Oxygen transmissibility @-3D (DK/t)	24	26	26	26
Storage solution	Poloxamine	Buffered Saline	Sterile citrate buffered saline	Sterile citrate buffered saline

Polyvinyl pyrrolidone (PVP); polyvinyl alcohol (PVA); hydroxypropylmethylcellulose (HPMC); polyethylene glycol (PEG).