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Effect of lens care system on silicone hydrogel contact lens wettability

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ABSTRACT

Purpose: The purpose was to compare the effect of the repeated usage of two care systems (one hydrogen peroxide cleaning and disinfecting system and one polyaminopropyl biguanide (PHMB) containing multi-purpose system) with silicone hydrogel contact lenses worn for three months on a daily wear modality. A specific aspect of interest was of the effect of the care systems on contact lens wettability.
Methods: Seventy-four symptomatic contact lens wearers, habitually wearing either ACUVUE® OASYS® ($n = 37$) or PureVision™ ($n = 37$), constituted the study population. The study was a two-arm prospective, investigator-masked, bilateral study of three-month duration to evaluate the effects of CLEAR CARE® compared with renu® fresh™. The subjects were randomized to one of the two lens care systems. Contact lens wettability and surface cleanliness were assessed with the Tearscope and reported in terms of pre-lens non-invasive break-up time (PL-NIBUT) and visible deposits. Baseline assessments at enrollment were with the subjects' own contact lenses worn for at least 6 h when using their habitual PHMB-preserved care system and at the dispensing visit with new contact lenses. At the follow-up visits, the contact lenses were worn for at least 6 h, and were at least 11 days old for ACUVUE® OASYS® and 25 days old for PureVision™.
Results: The results obtained showed that: (i) with CLEAR CARE®, a significant improvement in contact lens wettability was recorded compared with the habitual care system at the three-month follow-up visit (mean median PL-NIBUT 5.8 *vs.* 4.0 s, $p < 0.001$). Further, with this same lens care system a significant increase in wettability was observed at the three-month follow-up visit compared with dispensing (mean median PL-NIBUT 5.8 *vs.* 4.5 s, $p = 0.022$). (ii) Whereas no difference in contact lens wettability was observed at dispensing between the two lens care groups (mean PL-NIBUT: 4.5 *vs.* 4.2 s, $p = 0.518$), a significantly more stable pre-lens tear film was observed with CLEAR CARE® than with renu® fresh™ at both the two-month (mean PL-NIBUT: 4.6 *vs.* 3.7 s, $p = 0.005$) and three-month (mean PL-NIBUT: 5.8 *vs.* 4.2 s, $p = 0.028$) visits. iii. With renu® fresh™, no significant differences were observed at the end of three months of use compared with either the habitual care system or the new contact lens solution (mean PL-NIBUT: 3 M 4.2 *vs.* Disp 4.2 s ($p = 0.420$) *vs.* enrolment habitual care solution 5.1 s ($p = 0.734$)). iv. With CLEAR CARE® significant increases in the incidence of surfaces free of both mucus (3 month 95%. *vs.* habitual solution 82% enrolment; $p = 0.005$) and lipid (3 month 87% *vs.* habitual solution 72% enrolment; $p = 0.009$) were observed.
Conclusion: Significantly better contact lens wettability and surface cleanliness were achieved for ACUVUE® OASYS® and PureVision™ with CLEAR CARE® than with renu® fresh™ at the end of three months of use.

1. Introduction

The introduction of silicone hydrogel contact lenses has created challenges for contact lens care systems beyond disinfection and good compatibility with lens materials. Additional challenges are, in particular, the efficient removal of deposits, mainly from tear film lipids, and the lubrication of contact lens materials containing hydrophobic silicone based components. Consequently, a large number of studies have examined the influence of lens care systems on the performance of silicone hydrogel contact lenses. However, whereas most studies have assessed the effect of lens care on comfort [1–5], very few studies have quantified the effect of lens care on lipid deposits or on-eye contact lens wettability,

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which are other relevant clinical endpoints [6–8]. Nichols studied the effect of four lens care systems on lipid deposition with galyfilcon A silicone hydrogel contact lenses and concluded that whereas small differences between lens care systems existed, the main factor that affected lipid deposits was the incorporation of a digital rub in the lens care regimen [7]. Young et al., assessed a PHMB-preserved and a polyquad-preserved lens care system on the wettability of group IV hydrogel and silicone hydrogel contact lenses and were able to detect a difference in subjective classification of wettability between the two lens care systems in combination with the hydrogel contact lenses, but not the silicone hydrogel contact lenses [8]. Lorentz et al., analysed the effect of *in vitro* lipid doping on lens wettability of conventional hydrogel and silicone hydrogel contact lenses using sessile drop contact angle measurement and determined that exposure to lipids may improve the wettability of certain contact lens materials, especially silicone hydrogel materials that are surface treated [6].

Among the various lens care systems, those utilizing a hydrogen peroxide disinfectant seem to perform well with silicone hydrogel contact lenses. In particular the hydrogen peroxide systems have been associated with a very low level of corneal staining, (significantly lower than PHMB-containing MPS) [9,10]. Additionally, palpebral changes have been observed with the use of some PHMB systems [8,11]. Clear Care®, a hydrogen peroxide system, has also been reported to provide effective cleaning [12,13]. As such, it may favorably impact the interaction between silicone hydrogel contact lenses and the eyelid tissue, [12,14,15] and contribute to better cleaning and wetting of the contact lens surface by the tear film.

The purpose of this study was to evaluate the effect on eye of two different lens care systems (one hydrogen peroxide system and one PHMB multi-purpose system) on contact lens wettability and cleanliness of silicone hydrogel contact lenses worn on a daily wear basis for three months.

2. Materials and methods

2.1. Study products

The test product was CLEAR CARE® (AOSept® Plus in the UK) hydrogen peroxide cleaning and disinfecting solution (Alcon Laboratories, Inc., Fort Worth, TX, USA). The control product was renu® fresh™ (Renu® MultiPlus Fresh™ in the UK) multi-purpose solution (Bausch & Lomb Inc., Rochester, NY, USA). Both products were used according to the manufacturers instructions (*i.e.* the multi-purpose users were instructed to rub and rinse their lenses after removal and the hydrogen peroxide users were instructed to rinse their lenses while on the domed lens holders of the case).

The subjects were also issued Minims® unpreserved single dose saline (Laboratories Chauvin) to use as needed as a contact lens re-wetting drop. No recommended use schedule was imposed, but the re-wetting drop usage was monitored and recorded at the follow-up visits.

2.2. Study population

The study was carried out at a single site (OCULAR TECHNOLOGY GROUP—International). The target population was symptomatic daily wear silicone hydrogel contact lens wearers, wearing either ACUVUE® OASYS® (senofilcon A) replaced every two weeks or PureVision™ (balafilcon A) replaced monthly, and caring for their contact lenses with a PHMB-preserved lens care system.

To identify a symptomatic contact lens wearing population, only participants who reported wearing their contact lenses less than 10 h a day or experiencing at least 2 h of uncomfortable wearing were enrolled. This inclusion criteria was assessed towards the end of their contact lens wearing period. The end of the wear period was taken as contact lenses 11–17 days old for the two week replacement contact lenses and 25–35 days old for the monthly replacement contact lenses.

2.3. Experimental method

This was a two-arm, prospective, interventional, bilateral, investigator-masked study. Upon enrolment, the subjects were randomly allocated (1:1 randomization) to use one of the two lens care systems for the three month duration of the study (Fig. 1). Each lens care system was assessed for the change between the data collected at enrolment (recorded for the subjects' habitual lens care system) and the data recorded at the follow-up visits. The data recorded at the follow-up visits was also compared to that recorded at the dispensing visit (with new contact lenses inserted from the blister pack).

The experimental protocol was reviewed and approved by an independent ethics committee in the UK. The study complied with

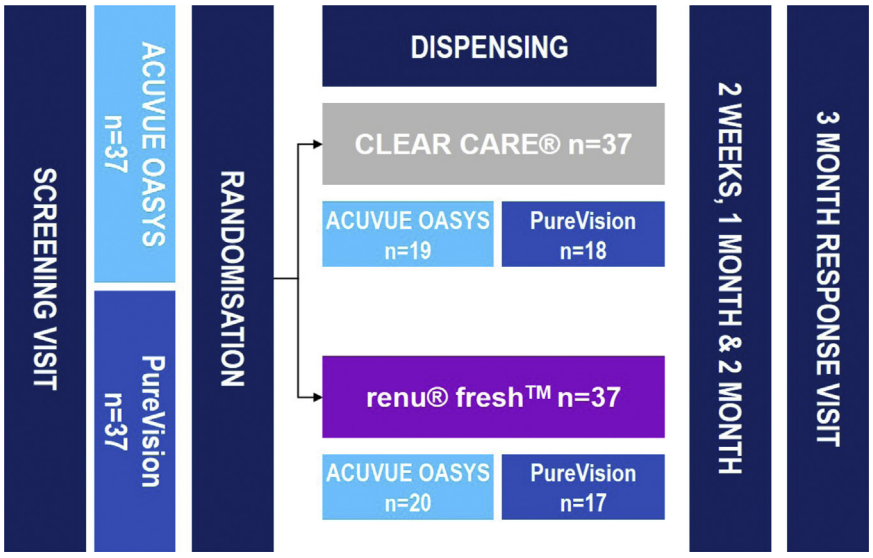

Fig. 1. Summary of study design and study visits.