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Effect of the osmolarity change in multipurpose solutions induced by an improper contact lens case cleaning procedure

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ABSTRACT

Purpose: To determine whether variations in multipurpose disinfecting solution (MPDS) storage osmolarity from inappropriate contact lens (CL) case cleaning affect ocular surface integrity and wearer comfort.
Methods: There were twenty contact lens cases (study CLCs) in the study group. Ten were filled with ReNu Multiplus® and 10 with SoloCare Aqua™ (MPDS-1 and -2, respectively) and kept closed for 8 h; the cases were then emptied and kept open for air-drying for 16 h. This procedure was carried out every day for two months. Storage solution osmolarity was measured on days 0, 15, 30, 45 and 60.
Ten subjects were then fitted with both month-old lenses stored in the study CLCs and with new lenses stored in new cases with fresh solution for 24 h (control CLCs). Symptoms, tear osmolarity and percentage of subjects whose conjunctival hyperaemia and ocular surface staining scores changed were determined after 1 h of wear.
Results: Study CLC osmolarity increased in both solutions after two months ($p < 0.05$). For MPDS-1 there were differences in stinging between study CLCs and control CLCs after 10 min of CL wear ($p = 0.04$), and in comfort after 10 ($p = 0.035$) and 60 min wear ($p = 0.042$). Significant ($p < 0.05$) differences between study CLC and control CLC groups were also found for MPDS-2 in limbal hyperaemia (study: 50% change; control: 0% change) and bulbar and corneal staining (study: 80% change; control: 20% change).
Conclusion: The stored-MPDS osmolarity increase caused by air-drying the CLCs could affect the ocular surface. This increase might reduce lens wear comfort.

1. Introduction

Wearing contact lenses (CLs) has several advantages over other forms of correction of refractive errors. However, CL wearers need to maintain certain hygiene and care standards for success. Lenses, care solutions and CL cases (CLC) have to be handled and managed properly to avoid contamination and minimise the risks of adverse reactions to wearing CLs. The accessories most usually contaminated are CLCs [1–3]. A possible association between inadequate CLC hygiene and ocular surface complications has been demonstrated [4,5], but wearers might not always rub and rinse their cases correctly [6]. One reason may be the lack of standardised CLC hygiene procedures [7,8]. The few well established protocols or guidelines in the scientific literature uphold this hypothesis [9].

When choosing a lens care solution, more than its safety and CLC cleaning efficacy against bacteria and biofilm formation have to be considered; subject comfort related to chemical and physical solution properties is also important [10]. Osmolarity, a physical parameter of CL solutions that shows the total concentration of dissolved particles, can affect wearer comfort [11]. An osmolarity increase has been found in daily and extended CL wear [12,13]. Moreover, dry eye status has been linked to elevated tear film osmolarity in habitual CL wearers [14].

An in vitro study has established that the osmolarity of the multipurpose disinfecting solution (MPDS) stored in the CLC depends on how the case is cleaned every day [15]. The aim of this study was double: to examine MPDS osmolarity variation from improper CLC cleaning procedure in real conditions with a CL in the CLC and, second, to determine how this variation affected the ocular surface and wearer comfort when a lens stored in that solution was fitted onto the eye.

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2. Materials and methods

2.1. Phase I: in-vitro study

Twenty standard flat-well CLCs made of acrylonitrile butadiene styrene (Avizor, Madrid, Spain) (study CLCs) were used in this part of the study. Both compartments of 10 of these cases were filled with 2 mL of MPDS-1 (ReNu Multiplus®; Bausch & Lomb Inc., Rochester, NY, USA). Likewise, both compartments of the other 10CLCs were filled with 2 mL of MPDS-2 (SoloCare Aqua™; Alcon Laboratories Inc., Fort Worth, Texas, USA). The MPDS compositions are detailed in Table 1.

Next, an Air Optix® Aqua contact lens (Lotrafilcon B, 33% water content, 8.6 mm base curve, 14.2 mm total diameter, 0.0 D power; Alcon Laboratories Inc., Fort Worth, Texas, USA) was placed in each compartment of each study CLC. These cases were then closed and kept at controlled room temperature (21 °C) for 8 h. After that, the CLs were removed from the study cases with sterilised tweezers and placed in new cases (wear-simulation CLCs) filled with 2 mL of saline solution (Saline, Avizor); these cases were kept closed for 16 h to simulate daily lens wear. Meanwhile, the solutions were discarded from the study CLCs, which were left open to air dry for 16 h (cases and caps were left facing up to let residual solution evaporate) [15]. After the 16-h wear simulation time, each lens was returned to its corresponding study CLC, which was refilled with fresh solution (MPDS-1 or MPDS-2). The saline solution was discarded from each wear-simulation CLC, which was dried with a lint-free tissue. These CLCs used to simulate CL wear were replaced every week.

This 24-h procedure (lens storage and lens wear simulation) was performed every day for 2 months. The 20 study CLCs were always the same, while the lenses were discarded and replaced on day 30 to simulate monthly replacement. At the end of Phase 1 the solutions were not discarded and the lenses were kept in these solutions until CL fitting in Phase 2.

In order to determine the osmolarity of the study CLC solutions, a 20-μL sample was collected from each compartment of the study cases on day 0 just after CLC filling with new MPDS. Likewise, samples were collected at the end of the 8-h storage period on days 0, 15, 30, 45 and 60. These samples were kept at 4 °C no more than 2 h until their processing. Osmolarity was determined using a Fiske 210 Micro-Sample Osmometer (Advanced Instruments, Norwood, MA, USA). The instrument was calibrated before every measurement session using the manufacturer's control solution.

2.2. Phase II: in-vivo study

Ten healthy emmetrope subjects, with no history of CL wear, were included in this randomized, double-blind crossover study. The protocol was approved by the University of Valladolid Ethics Committee (Valladolid, Spain) and informed consent was obtained from all subjects after explaining the study protocol.

The inclusion criteria were an ocular surface disease index (OSDI) score <12, tear film break up time (TBUT) ≥ 10 s [16], phenol red thread test ≥ 20 mm in 15 s [17] and corneal fluorescein staining $\leq$grade 1 (0–4, Efron scale). These criteria were selected in order to avoid including subjects with ocular surface alterations that could introduce bias in the determination of possible ocular surface changes induced by the differently treated lenses used in the study. Subjects under treatment with any oral or topical eye drug, having active ocular or systemic diseases, and/or having history of ocular surgery were excluded from the study.

At the screening visit (V0), an ocular surface evaluation was performed to confirm that subjects complied with the inclusion criteria. After that, new plano CL (Air Optix®; Aqua Alcon Laboratories Inc.) were inserted in both eyes to assess CL fit after 1-h wear. All participants showed an acceptable fit.

Subjects then made 4 study visits (V1–V4) on 4 different days separated by 48 h, where they were randomly fitted bilaterally with the 1-month old lenses (Lotrafilcon B) from the study CLCs (MPDS-1 and -2) or with similar fresh lenses (Lotrafilcon B, plano CL). All the lenses were fitted within the first 10 days after the end of Phase I; therefore, a slight osmolarity difference was to be expected between day 60 of Phase I and the insertion day. As our main study goal was to perform the maintenance process as closely to real life as possible in order to determine the real impact of improper CLC maintenance, it was necessary to use the lenses from Phase I (1 month old) as study lenses. The new lenses were immersed in fresh solution (MPDS-1 and -2) for 24 h in new cases (control CLCs) before insertion. Consequently, we had four lens-wearing scenarios: a) MPDS-1 study CLC, b) MPDS-2 study CLC, c) MPDS-1 control CLC and d) MPDS-2 control CLC.

2.3. Tests performed

Clinical examinations were performed in the following sequence:

2.3.1. Ocular symptoms

Participants rated itchiness, dryness, stinging and comfort of both eyes together. Subjects were asked to rate each symptom using a visual analogue scale (VAS), which consisted of a 100-mm horizontal line divided into 10 equal unit steps [18]. At the left end of the line, the number "0" indicated the absence of symptoms for itchiness, dryness and stinging, while for comfort, it indicated the minimum possible comfort. At the right end, the number "100" indicated maximum severity of symptoms for itchiness, dryness and stinging, while for comfort, it indicated the maximum possible comfort. Symptoms were evaluated after 10 min and after 1 h of wear.

2.3.2. Bulbar and limbal conjunctival hyperaemia

To determine bulbar hyperaemia, the conjunctiva was divided into two zones (nasal and temporal). To determine limbal hyperaemia, the conjunctiva was divided into four zones (upper, lower, nasal and temporal). In both cases each zone was evaluated with a slit lamp biomicroscope (SL-8Z; TOPCON Corporation, Tokyo, Japan) and graded according to a modified Efron scale [19], using a 0.5 decimal scale ranging from 0 to 4. The final score for bulbar hyperaemia was the average of the 2 zones, while the final score for limbal hyperaemia was the average of the 4 zones. The

Table 1
Compositions of the multipurpose disinfecting solutions used in the study.

Brand	Manufacturer	Components		
		Buffers	Preservatives	Surfactant
ReNu Multiplus®	Bausch & Lomb Inc	Boric acid, sodium borate	Polyaminopropyl biguanide 0.0001% (DYMED®), EDTA	Poloxamine (Tetronic 1107)
SoloCare Aqua™	Alcon Laboratories Inc.	Sodium dihydrogen phosphate	Polyhexamethylene biguanide 0.0001%, EDTA	Pluronic F127 (poloxamer 407)