Communications: SIF Congress 2023

Dehydration and surface friction of Kalifilcon A and Senofilcon A contact lenses

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received 10 April 2024

Summary. — In the context of contact lens (CL) wear, it is crucial to tailor the dehydration tendency and surface friction of CLs to ensure comfort. This becomes particularly significant when dealing with eyes with damaged or absent glycocalyx, leading to increased shear stress during blinking, as seen in cases of dry eye. Some manufacturers claim that the properties of their CLs are specifically crafted to retain hydration, ensuring comfort even for individuals experiencing CL discomfort and dry eve symptoms. This study focuses on evaluating and comparing the properties of two silicone hydrogel (SiHy) materials, Kalifilcon A and Senofilcon A. Three key aspects were examined: i) the hydration (WC_{wear}) of CLs after six hours of wear, compared to the CL equilibrium water content (EWC), ii) the *in-vitro* coefficient of friction of the CL surface at WC_{wear}, and iii) the *in-vitro* dehydration profile from EWC down to WC_{wear} , under conditions of temperature and humidity mimicking typical wear conditions. The results suggest that WC_{wear} is lower than EWC by a few percentage points for both materials, *in-vitro* friction is slightly higher for the SiHy Kalifilcon A than for the SiHy Senofilcon A, and the SiHy Kalifilcon A dehydration profile shows the typical behavior of hydrogels, in contrast to Senofilcon A, which shows the typical behavior of SiHys.

The interaction with water is a crucial property of soft contact lenses (CLs), influencing not only the lens material, its geometry and the tear film, but also impacting the corneal epithelium on the ocular surface [1]. Dehydration typically initiates when a CL is placed on the eye and continues throughout the wear period, influenced by factors such as material composition, physical properties, modifications during wear, CL thickness, environmental conditions, tear composition, and blink rate [1-4]. Dehydration is also expected to elevate friction, with its impact becoming more pronounced when the glycocalyx of the wearer is damaged or absent, intensifying shear stress during blinking. For certain types of CLs, manufacturers assert that the material composition is designed to retain hydration and maintain a smooth surface, aiming to meet the needs of CL wearers experiencing discomfort and dry eye symptoms. These symptoms have been linked to increased ocular inflammation, a key aspect of strong interest, given various studies concluding that CL wear is inherently inflammatory [5]. This study aims to assess and compare the *in vitro* dehydration kinetics of two CL materials, Kalifilcon A and Senofilcon A. The shape of the dehydration curves is discussed in relation to other available data in the literature. Additionally, the tribological properties (coefficient of friction, (CoF)) of the two materials were compared *in vitro* using a protocol developed to conduct measurements under slightly reduced hydration conditions, mimicking the CL environment in the eye during wear.

CLs with the same back vertex power (-0.50 diopters) of two different materials were studied (table I).

For each material, three CLs were rinsed for a few seconds in saline solution (preservative-free saline solution, Salisin, Schalcon, Italy). Fully dehydrated CLs were obtained by lyophilization (Scanvac, Analytical control De Mori, Milan, Italy) and their mass M_{deh} was measured using an analytical balance (Entris, Sartorius, Göttingen, Germany). The same balance was used to measure the mass M_{wear} of worn CLs immediately after removal from the eye without any rinsing. In this work, a single subject (female, 23 years old) wore all types of CLs for six hours, repeating the wearing of the same material three times using a new CL each time on three different non-consecutive days. The parameter WC_{wear} represents the water fraction corresponding to M_{wear} .

Tribological testing was performed using the nanotribometer Step 100-NTR3 (Anton Paar, Graz, Austria) equipped with linear reciprocating module and CL holder. CLs were rinsed as previously described. Once the M_{wear} was reached, the CL was transferred to the nanotribometer, which is equipped with an optical microscope, and a 8 μ L drop of saline solution was added with a micropipette on the apex of the CL. No other solution was added to the sample holder. Measurements were carried out by applying 5 mN normal load with 1 mm stroke length at a sliding speed of 0.063 cm/s for ten cycles. A 5-mm diameter glass disc (Menzel Gläser, Braunschweig, Germany) was used as counterpart to

| Material | Senofilcon | Kalifilcon |
|--------------------------------------|---|---|
| Brand | Acuvue Oasys | Infuse/Ultra One Day |
| Manufacturer | Johnson&Johnson | Bausch+Lomb |
| EWC (%) | 38 | 55 |
| Central thickness $@-3.00 D (\mu m)$ | 70 | 80 |
| Blister solution | Buffered saline with methyl ether cellulose | Phosphate buffered saline with potassium chloride, poloxamine, poloxamer 181, glycerin, and erythritol |

TABLE I. – List of the investigated CL materials and their parameters. EWC (equilibrium water content), central thickness, and blister solution composition are those provided by the manufacturers.

mimic the eyelid/CL sliding movement. The duration of an entire measurement on one sample was approximately 30 seconds to ensure negligible variations of the CL mass. In each half cycle, the CoF was calculated as the ratio between the tangential and normal forces in the central 0.5 mm of the path between the extremes of the stroke. For each material, the CoF measurement was repeated five times on five different CLs. The glass disc probe was replaced for each CL material and each condition.

To investigate the *in-vitro* dehydration kinetics, a protocol was identified to ensure consistency and improve reproducibility. Rinsed and unworn CLs were placed with the anterior surface exposed to air on a dynamic vapor sorption analyzer (Aquadyne DVS2, Anton Paar, Graz, Austria) by employing a plastic polydimethylsiloxane spherical holder (radius of curvature of 7.7 mm). CLs were dehydrated under controlled environmental conditions, mimicking typical wear conditions (temperature 34 °C, relative humidity 60%) (gravimetric method) [6]. The environmental conditions were kept constant throughout each experiment [7]. The CL mass was taken at intervals of 30 seconds with resolution 10^{-4} mg. The curves of the dehydration rate (DR) were obtained, DR being defined as $DR = \frac{M_{t(n)} - M_{t(n-1)}}{M_{t(n)}}$, where $M_{t(n)}$ is the sample weight at time n and $M_{t(n-1)}$ the sample weight at time (n-1) with intervals of 30 seconds.

Table II shows the mass values of fully dehydrated CLs after lyophilization (M_{deh}) , after 6 hour wear (M_{wear}) , and the corresponding hydration (WC_{wear}) .

The results suggest that WC_{wear} is lower than EWC by a few percentage points for both materials. Figure 1 shows the CoFs measured on the two CL materials after a brief rinse. Considering the specific conditions employed for these experiments, which are aimed to mimic the so-called boundary regime at relatively low sliding velocity, the comparison with the values measured in previous studies is not straightforward, as the results strongly depend on the measurement conditions, such as the counterpart material, the lubricant, the applied normal load, and the sliding speed [8,9].

The higher CoF was measured on Kalifilcon A. Nonetheless, the two SiHy CLs Senofilcon A and Kalifilcon A were found to show CoFs of the same order of magnitude. Figure 2 displays the DR mean values, obtained as a function of time on the two different CL materials. The starting point of the curve in each panel corresponds to the CL EWC, while the vertical line corresponds to WC_{wear}.

The three-phase pattern described in the literature by González-Méijome *et al.* [1] for hydrogel (Hy) CLs can be observed in fig. 2 only in the case of Kalifilcon A (panel (b)). These authors performed the analyses at 22.4 °C and 49.1% of relative humidity after blotting the CLs on filter paper. Although the analyses in this paper were conducted on different materials, at 34 °C and 60% of relative humidity with no blotting, a similar three-phase behavior was observed in the case of the SiHy Kalifilon A. Phase 1 (P1)

TABLE II. – Mass values of fully dehydrated CLs after lyophilization (M_{deh}) , after 6 hour wear (M_{wear}) , and the corresponding hydration (WC_{wear}) .

| Material (FDA group) | Senofilcon (V) | Kalifilcon(V) |
|---|--|---|
| M_{deh} (mg): Mean \pm SD M_{wear} (mg): Mean \pm SD WC_{wear} (%): Mean \pm SD | 18.2 ± 0.3 28.0 ± 0.0 35.0 ± 1.1 | $\begin{array}{c} 13.1 \pm 0.4 \\ 25.8 \pm 0.1 \\ 49.1 \pm 1.9 \end{array}$ |



Fig. 1. – Box chart of the CoF values measured for each CL material analysed in this study. CLs were subjected to a brief rinse in saline solution prior to tribology measurements, which were performed in the condition of hydration corresponding to WC_{wear} (table I).

ranges from the beginning of the experiment until the minimum DR. The length of P1 is expected to depend on the hydration of the CL at the beginning of the analysis. After reaching a minimum DR, the typical three-phase profile shows a rapid and progressive increase in the DR, which represents phase 2 (P2). Then, the CL approaches a DR value equal to zero, and this last part of the profile was defined as third phase (P3) although no distinct change can be defined between the phases [1].

An effect of the material composition on the dehydration profile was discussed by González-Méijome *et al.*, who highlighted that P1 is characteristic for Hy CLs and that there is a positive correlation between its duration and the equilibrium water content (EWC). These authors also underlined that this is not always true for SiHy CLs, in particular for siloxane-rich materials, which may even lack a P1. González-Méijome *et*



Fig. 2. – Curves of DR for Senofilcon A (panel (a)) and Kalifilcon A (panel (b)). The line represents the mean DR value calculated over independent experiments. The grey area shows the standard deviation range.

al. adopted the blotting procedure which is expected to eliminate the excess of water on the surface. Therefore, their starting point is expected to reasonably correspond to the condition at the EWC. Based on these considerations, the SiHy Kalifilcon A in this work is in good agreement with what reported by González-Méijome *et al.* for Hys because it shows a relatively long P1, while Senofilcon A does not show any P1. Kalifilcon A shows the P1 phase and, in this respect, it appears, as already mentioned, to behave as hydrogel CLs. It is made from a hydrophilic siloxane copolymer of 2-hydroxyethyl methacrylate (HEMA) and N-vinylpyrrolidone (NVP). Compared to other SiHy CLs, such as Senofilcon A, its EWC is relatively high, close to typical hydrogel CLs values [10].

Since CLs worn *in vivo* are expected to have slightly less hydration than the EWC, the position corresponding to WC_{wear} is also shown in fig. 2. This position does not correspond to the same phase for the two materials. For hydrogels, the value is expected to fall within P1 and it is far from the DR minimum [1]. On the contrary, for SiHys, it is expected to be close to the DR minimum. Interestingly, in the case of Kalifilcon A, which is a SiHy with a relatively high EWC, the value falls clearly within P1. Therefore, the *in-vitro* dehydration properties of Kalifilcon A seem to be more related to its water content, rather than to its SiHy composition.

This study delves into the crucial aspect of water interaction in soft CLs, recognizing its impact on lens material, geometry, tear film, and the corneal epithelium. The tendency of CLs to dehydrate is identified as a significant contributor to complaints of dryness and associated symptoms during wear, often linked to heightened ocular inflammation, emphasizing the intrinsic inflammatory nature of CL wear. Dehydration of CLs begins upon placement on the eye and persists throughout wear, influenced by multiple factors. Manufacturers claim that certain lens types are designed to retain hydration and maintain a smooth surface to address discomfort and dry eye symptoms. In this investigation, the properties of two CL materials, Kalifilcon A and Senofilcon A, were assessed and compared. The results indicate that the water content during wear (WC_{wear}) is slightly lower than the equilibrium water content (EWC) for both materials. The tribological properties, specifically the coefficient of friction (CoF), were measured, revealing a slightly higher CoF for Kalifilcon A, though both SiHy CLs exhibited CoFs of the same order of magnitude. It is important to point out that the tribology experiment was designed to mimic the so-called boundary regime at relatively low sliding velocity. Friction in this regime is expected to be critical when the glycocalyx is compromised, due to the absence of the expected brush-to-brush interaction. The choice of these specific experimental conditions prevents the direct comparison with the values measured in previous studies. The dehydration rate (DR) curves further illustrated distinctive patterns for each material. Kalifilcon A displayed a three-phase behavior reminiscent of hydrogels, while Senofilcon A did not exhibit a discernible Phase 1 (P1). The study aligns with prior research linking the duration of P1 to hydration levels, particularly in hydrogels, with Kalifilcon A, a SiHy material with a relatively high EWC, displaying a prolonged P1 phase. Interestingly, in this respect, despite being a SiHy CL, Kalifilcon A behaved more like a hydrogel, suggesting that its *in-vitro* dehydration properties may be more influenced by its water content than its SiHy composition. This work contributes valuable insights into the nuanced dehydration behavior of different CL materials, shedding light on potential correlations between hydration, material composition, and *in-vitro* dehydration profiles. Understanding these dynamics is crucial for optimizing CL design and addressing discomfort in wearers.

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