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Study of dehydration and water states in new and worn soft contact lens materials

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The purpose of this study was to examine the *in vitro* dehydration characteristics of new and worn conventional and silicone-hydrogel contact lenses. Four contact lens materials were investigated: three conventional hydrogels (etafilcon, nelfilcon, omafilcon) and one silicone-hydrogel (narafilcon). Gravimetric data were obtained with analytical balance with 1 min intervals. Quantitative parameters of water content and dehydration rate were calculated allowing quantitative description of dehydration process. Differential scanning calorimetry was used to monitor changes in water states in samples studied. As expected, dehydration behavior of each material is different in terms of mean dehydration rate values and phases of dehydration. Gravimetric data allowed us to distinguish three phases of dehydration. Interestingly, the effect of the osmolality of storing solutions on dehydration was found – lenses stored in hyperosmotic solutions needed more time to achieve equilibrium with the environment. Effect of wearing on dehydration patterns and water properties was confirmed. In worn samples, a decrease in water content was observed. Additionally, there was a change in water structure after 6 h of wearing in all lenses studied. This behavior may be ascribed to tear film components deposition and changes in surface wettability that appear during wearing.

Keywords: contact lenses, dehydration, hydrogel, silicone hydrogel.

1. Introduction

Any material designed to contact lens manufacturing needs to provide certain physicochemical characteristics to ensure its biocompatibility. Dehydration occurs immediately after the placement of lens on eye due to the tear film evaporation and continues until the equilibrium is reached. The extent of dehydration may be different depending on the material properties, lens thickness, environmental conditions, tear osmolality, *etc*. [1–4].

Soft contact lens materials can be divided into two groups: conventional hydrogels and silicone-hydrogels (Si-Hy). In general, hydrogels are materials capable of binding water molecules without dissolving. They resemble in their physical properties living tissues, especially with their high water content and soft rubbery consistency which minimize mechanical irritation to the surroundings. The expanded nature of hydrogel

structure allows small molecules to permeate through the material. This makes hydrogels suitable in many biomedical applications [5], particularly in the ophthalmology [6]. However, to maintain an adequate oxygen supply, conventional hydrogels should have high water content which negatively affects material strength. Silicone -hydrogels on the other hand are materials that do not need high hydration to maintain required oxygen permeability [7]. This was achieved by combining hydrophobic siloxane monomers with hydrogels [6]. Unfortunately, silicone-hydrogels have much higher Young's modulus than conventional hydrogels [6, 7] and poor wettability [8] which is important for stable vision and wearing comfort.

One of the most important lens characteristics is its water content. One believes that water in polymer may be divided into three thermodynamically different classes: free (bulk) water, loosely and tightly bound with the material [2]. Free water fraction decides on transport properties of the polymer [2, 9]. Thus, it will affect both diffusion and dehydration behavior.

Material hydration may differ during wearing due to water evaporation. This can induce changes in oxygen transmissibility, surface wettability or other lens parameters [8, 10] which may further affect lens fitting. When fully hydrated, all lens materials should have adequate wettability. A decrease in this parameter may lead to the excessive lids mechanical friction, enhanced dehydration and increased tear film components deposition [8, 11]. Dehydrated lens surface may scatter the light reducing visual acuity. The loss of water may also change lens fitting and its power (especially plus lenses) [10].

Tear evaporation seems to depend on many factors and contact lens wear clearly increases dehydration from the ocular surface [12]. Many patients complain about persistent dryness and discomfort which may lead to the contact lens drop outs [13, 14]. However, there is a little evidence that excessive dehydration produces contact lens induced dry eye [3, 15–17]. Thus, there is a need for better understanding of this issue. The aim of this study was to investigate changes in water content and its structure that may appear in lenses due to normal wear.

2. Materials and methods

2.1. Contact lenses

Four commercial one-day contact lenses were examined, including three conventional (etafilcon, nelfilcon, omafilcon) and one Si-Hy (narafilcon). This type was chosen because of the growth in the number of daily disposable lens wearers. The most important parameters of materials studied are summarized in Table 1.

2.2. Sample preparation

Our study consisted of two trials: new and worn lenses were measured. In each trial, 3–5 lenses of each material were used. Each sample was tested once.

T a b l e 1. Parameters and chemical composition of contact lenses studied.

	Material			
	Etafilcon	Omafilcon	Narafilcon	Nelfilcon
Trade name	Acuvue Moist	Proclear 1 Day	Acuvue TrueEye	Focus Dailies Aqua Comfort Plus
Water content	58%	62%	46%	69%
Diameter	14.2 mm	14.2 mm	14.2 mm	14.0 mm
Central thickness	0.084 mm	0.09 mm	0.085 mm	0.10 mm
Base curve	8.5	8.6	8.5	8.7
FDA group	IV	II	I	II
Chemical composition	HEMA, MAA, EGDMA, TMPTMA, PVP	HEMA, PC	HEMA, MPDMS, DMA, TEGDMA, siloxane monomer, PVP	PVA, N-formethyl acrylamide

FDA – Federal Drug Administration; HEMA – 2-hydroxyethyl methacrylate, MAA – methacrylic acid, EGDMA – ethylene glycol dimethacrylate, TMPTMA – trimethylolpropane trimethacrylate, PVP – polyvinylpyrrolidone, PC – phosphorylcholine, MPDMS – monofunctional polydimethylsiloxane, PVA – polyvinyl alcohol, DMA – N,N-dimethylacrylamide, TEGDMA – tetraethyleneglycol dimethacrylate.

We decided not to equilibrate both new and worn samples in any buffer solution. This allowed us to mimic typical on-eye conditions and to avoid leaching of contaminants from the worn samples. All studies performed earlier did not take into account the effect of storing solutions on dehydration. Usually all samples (new or worn) were measured after equilibration in saline solution while each lens material is stored in solution of different parameters [18] which may affect material behavior. To take it into account, osmolality of package solutions was examined.

2.3. Gravimetric measurement

New lenses were removed from the original package, gently dried with blotting paper and placed on a convex plastic holder. Its curvature was approximated to the lens radius to reproduce on-eye conditions where only the anterior surface is exposed to the air. The gravimetric measurement began after the holder was placed on the analytical balance (Radwag WPA 120/C/1). From this moment on the lens was continuously monitored by recording every minute its weight. Measurement was performed at room temperature (23 ± 1 °C) with the accuracy of 0.1 mg.

Three optometry students with no ocular symptoms were chosen to wear contact lenses. After approval of the procedure, their eyes were examined carefully in order to prescribe adequate lens powers and exclude any tear and ocular abnormalities. Then volunteers were fitted with lenses. After 6 hours of wearing, samples were collected for testing. Participants were staying in the laboratory for 6 hours to maintain the same environmental conditions. Samples were placed onto a holder immediately after removing from eyes. Each sample was tested once and the data obtained was averaged.

2.4. Differential scanning calorimetry (DSC)

Differential scanning calorimetry (DSC) was used to compare materials in terms of water structure and to monitor changes that may occur due to normal use of lenses. In this method, the difference in the amount of heat required to increase the temperature of a sample and reference is measured as a function of temperature. By measuring the difference in heat flow between the sample and reference, DSC reveals the amount of heat absorbed or released by the sample during phase transitions.

Different thermodynamic behavior of each water class is used in this method [2] – two peaks appearing on the calorimetric curve refer to free and loosely bound water (freezable water). Tightly bound water creates direct hydrogen bonds with polar groups or strongly interacts with polymer ionic residues. Therefore, it does not exhibit a phase transition in the DSC measurement (non-freezable water).

The study was conducted using DSC Q2000 (TA Instruments) in WLBS at the Adam Mickiewicz University, Faculty of Physics (Poznań, Poland). Samples were gently dried with blotting paper to remove excess water. They were cooled at a rate of 2.5 °C/min to –40 °C. Then, after 10 minutes of equilibration, samples were heated to a temperature of 20 °C at the same rate. Measurement was repeated twice and the data was averaged.

2.5. Osmolality examination

Osmolality and osmolarity are the terms that define the total concentration of the particles in solution. It might be expressed in Osm/kg (osmolality) or Osm/l (osmolarity). Osmolality of the storing solutions was determined with Marcel os 3000. Freezing point depression osmometer has been used, as osmotically active compounds depress the freezing point of fluids. For each lens type, 100 µl of the solution was probed from the storing container. Measurement was repeated five times and a new package was used for every single measurement. The results were averaged.

2.6. Quantitative description

From the results obtained, the quantitative parameters were calculated allowing the comparison with some previous studies [19–21]. Plots of these parameters in function of time reflect the process of dehydration.

Dehydration rate (DR) describes lens dehydration in reference to previous sampling. Thus, it represents the degree of dehydration at a certain point in time. It was calculated from the following equation:

$$\mathrm{DR} = \frac{m_t - m_{t-1}}{m_t} \times 100\% \tag{1}$$

where m_t is related to sample weight at time t and m_{t-1} represents sample weight at time $(t-1)$.

Water content (WC) was determined using the following equation:

$$\mathrm{WC} = \frac{m_h - m_d}{m_d} \times 100\% \tag{2}$$

where m_h is the weight of the fully hydrated and m_d – of the dehydrated lens.

Based on the DSC thermograms, it was possible to determine the amount of freezable free and loosely bound water F:

$$F = \frac{Q}{\Delta H} \tag{3}$$

where ΔH – heat of fusion of water (333.7 J/g), Q – heat of transition, reflected in the DSC curves as peaks. The amount of tightly bound water B was calculated as follows:

$$B = \mathrm{WC} - F \tag{4}$$

3. Results

Regression analysis (Paerson's procedure) was used to plot quantitative values against WC, Federal Drug Administration (FDA) group and osmolality to confirm if there are any statistically significant relationships. For all testing, the significance level $p < 0.05$ was considered significant. However, since the number of samples used for the purpose of this experiment is low, any firm conclusions cannot be drawn from this study.

From Eq. (1) DR values were calculated. In the experimentally determined time dependence of dehydration (Fig. 1), three ranges of time corresponding to a different rate of dehydration can be distinguished. The approximated end times of each phase are summarized in Table 2. Duration of each phase was deduced from the slope of DR graphs because it was not possible to calculate it as in the previous study [21]. Note that silicone-hydrogel narafilcon has a shorter phase I than conventional hydrogels.

T a b l e 2. Approximated phase duration times [min].

	Narafilcon		Nelfilcon		Omafilcon		Etafilcon	
	New	Worn	New	Worn	New	Worn	New	Worn
I	15	10	24	18	23	19	27	20
II	40	35	47	36	35	32	50	42
III	72	55	56	55	48	51	69	55

Mean DR value (average from the beginning to the end of measurement) was calculated to describe the mean rate of water loss. Mean DR is different in each phase of dehydration for all materials studied. Thus, DR values clearly depend on the material composition. Most lenses (except for PVA-based nelfilcon) exhibit an increase in

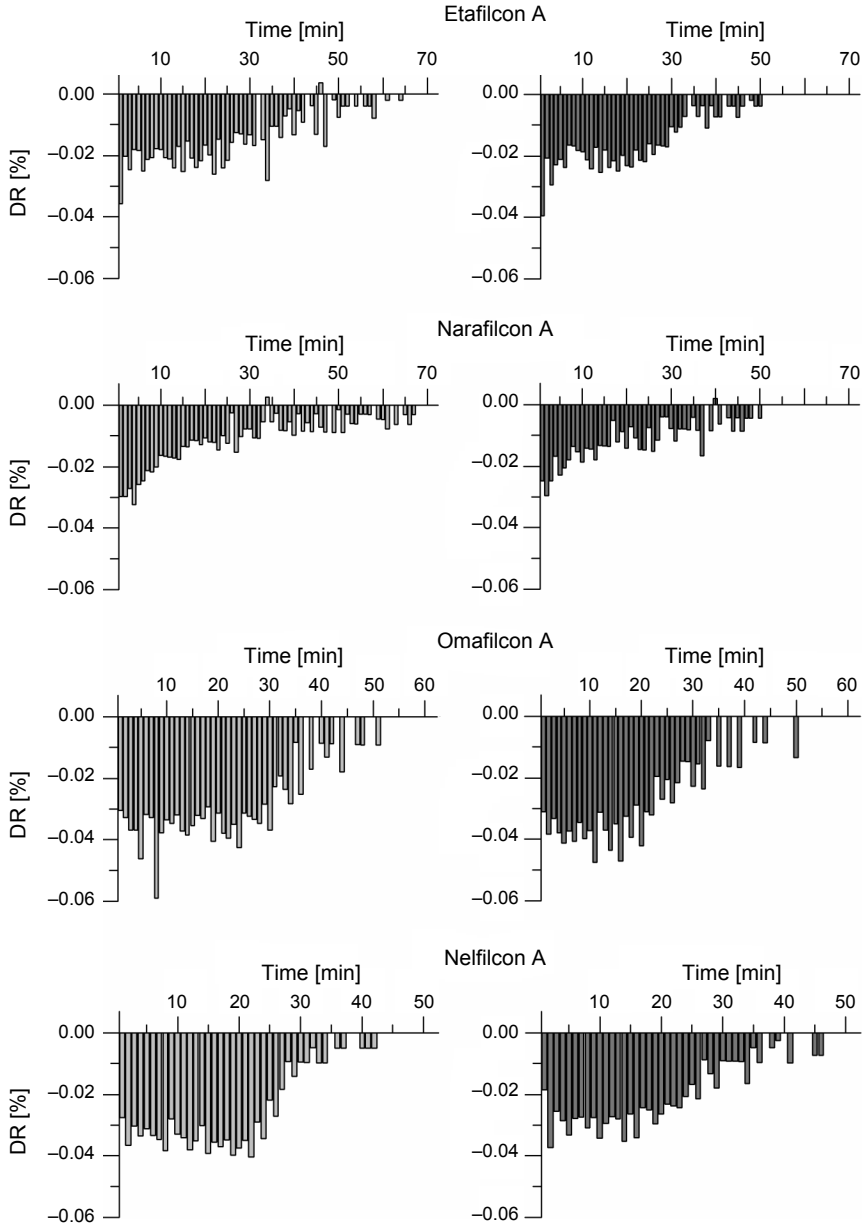

Fig. 1. Averaged DR values for new (left) and worn (right) samples (SE varies in the range of 0.01–0.03).

mean DR after 6 hours of wearing. Figure 2 shows the relationship between the mean DR and water content of the materials studied. There was a strong correlation ($R^2 = 0.95$, $p = 0.02$) in the new lenses group. In worn samples no correlation was found. There was no correlation between DR and FDA group. It means that water content and chem-

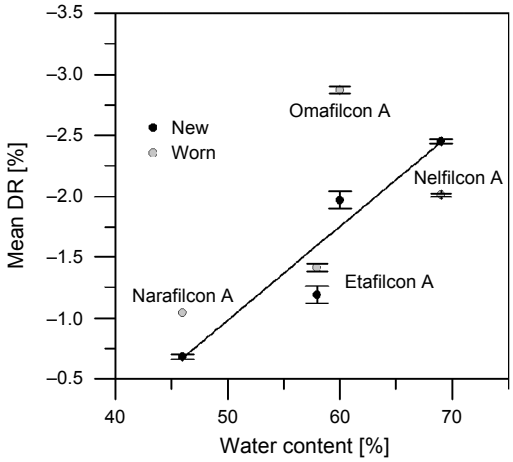

Fig. 2. Mean DR values plotted as a function of water content. Black line shows linear fit of data in new lenses.

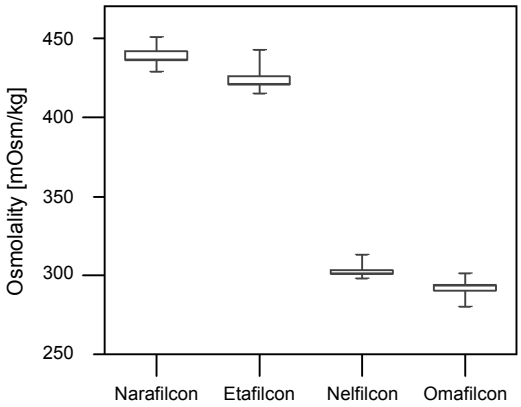

Fig. 3. Osmolality of package solution in which lenses are stored.

ical composition have a deciding influence on dehydration. The effect of its ionicity seems to be minor.

Measured osmolality values are shown graphically in Fig. 3. As seen, narafilcon and etafilcon lenses are stored in hyperosmotic solutions. We assumed osmolality of 310 mOsm/kg in worn samples (see Discussion). Interestingly, we found that with higher initial osmolality, the dehydration (indicated by phase III ending time) lasts significantly longer than in other samples ($R^2 = 0.93$, $p = 0.01$).

Calculated WC values are shown in Fig. 4. WC was smaller in worn samples. Regression analysis revealed that these changes were not statistically depending on the nominal WC given by the manufacturers nor on the ionicity of the material. Surprisingly, in silicone-hydrogel narafilcon lens hydration dropped by 7.5%. In hydrogel

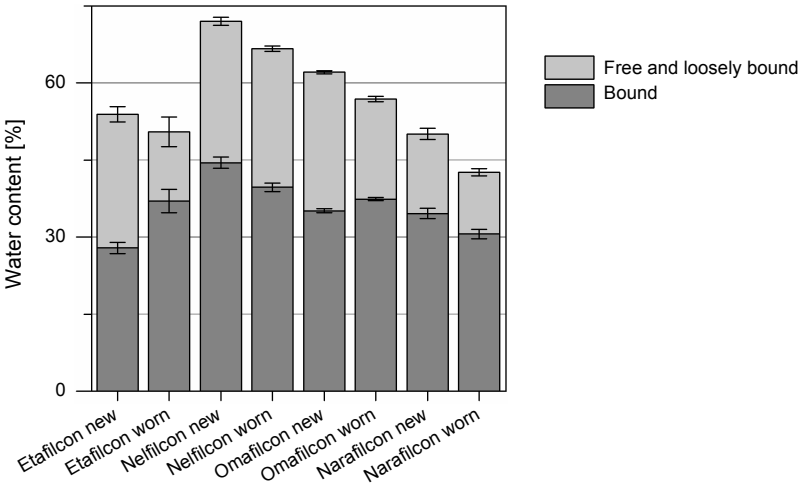

Fig. 4. Water content and water structure in new and worn samples.

samples it decreased by 3.4–5.3% while it is believed that hydrogel lenses dehydrate more than Si-Hy.

Some characteristic DSC results are shown in Fig. 5. Two peaks observed around –1 and –5 °C correspond to free and loosely bound water, respectively. Materials based on HEMA (etafilcon, narafilcon and omafilcon) shown similar DSC curves (Fig. 5**a**), while material that is based on PVA (nelfilcon) has a reversal free to loosely bound water ratio (Fig. 5**b**). The amount of freezable water was calculated from Eq. (3). Tightly bound water content was determined using Eq. (4). Changes in water states in relation to WC obtained from gravimetry are shown in Fig. 4. The only material that does not exhibit a change in freezable water content is nelfilcon (27.5% and 27.0% in

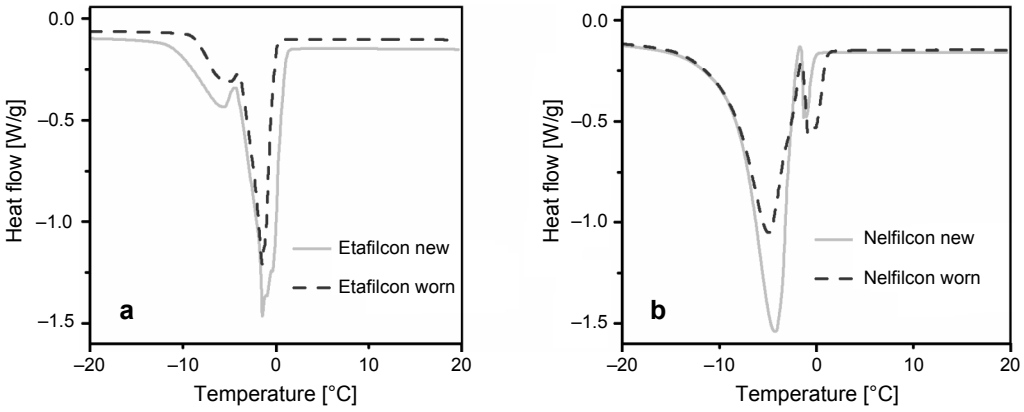

Fig. 5. Typical DSC thermograms – exemplary results.

new and worn samples, respectively). One can see that ionic etafilcon shows a substantial increase in freezable water content (from 27.9% to 37.0%). In other materials, the differences (rise or reduction) observed were much lower (up to 4.8%).

4. Discussion

From a clinical point of view, studying dehydration does not seem to tell us lot about comfort of wearing. Nevertheless, we can learn about material properties that affect lens performance.

As mentioned above, duration of each phase of dehydration was deduced from the DR plots. Unfortunately, we could not estimate any fixed values for the distinction of phases of dehydration. The reason of this is probably the fact that each material due to its different initial WC and chemical composition exhibits different dehydration behavior. Similarly to some other studies [22], we suppose that observed three-stage course of dehydration reflects water structure in the material which further affects its other parameters [2]. One can assume that in the phase I bulk water molecules evaporate. Because they do not interact with the material, dehydration proceeds rapidly. Then, in the phase II loosely bound water dehydrates. In the phase III material gains its equilibrium with the environment. Tightly bound water molecules produce strong bindings. Thus, they are unlikely to evaporate at room temperature.

Lira *et al*. [23] examined the effect of wearing on a refractive index of contact lens materials. They have demonstrated that Si-Hy have more capacity to retain initial hydration than conventional hydrogel etafilcon. The result for narafilcon is opposite to their findings. A possible explanation is the wrong model used to calculate water content in Si-Hy from refractive index, especially that gravimetry is confirmed to be an accurate method [21]. Additionally, in Si-Hy lenses surface modification may play some role in measurement [24].

In general, mean DR increased due to wearing (Fig. 2). Nelfilcon was the only one lens where DR drops due to wearing. We suppose that it may be linked to the fact that material contains some amount of non-crosslinked highly hydrophilic PVA molecules. It seems that with washing out, due to blinking, there is a decrease in water content. This may diminish lens dehydration. Nelfilcon is the first lens that delivers wetting agent from the polymer matrix [25]. It appears that this solution may be beneficial for contact lens wearers because of restricting lens dehydration despite its very high water content.

The change in mean DR may be related to the wettability of the material. In another study [26] authors suggest that thin glassy layer may be present at the lens surface exposed to air restricting further evaporation. However, dehydrated regions of the lens will accumulate deposits which in turn may reduce wettability and cause discomfort [8]. In ionic materials protein deposition is the highest [27, 28] and one can suppose that this is the reason why in etafilcon the largest increase in dehydration was observed.

Narafilcon has different surface properties from hydrogels [8]. It is well-known that Si-Hy need surface treatment or some other modification to enhance their wettability. However, with friction and water evaporation in on-eye conditions, hydrophobic silicone residues may be exposed to the surface [8, 11]. This secondary leads to increase in dehydration. Despite this, Si-Hy materials are often recommended for patients working in adverse environmental conditions (air conditioning, *etc*.) because it is believed that due to their low water content dehydration is lower [8, 29]. In our study, two hydrogels of high water content seem to perform better: omafilcon and nelfilcon. In both materials different approaches that may improve lens performance were used. Omafilcon contains highly hydrophilic biomimetic phosphorylcholine-modified HEMA which is confirmed to be less susceptible to dehydration [30]. In nelfilcon, controlled release of wetting agent was used [25].

Protein deposition may induce discomfort or eye complications in contact lens patients. High water content materials, especially ionic, are known to have the highest affinity to protein contamination [11, 28, 31]. LEVER *et al*. confirmed that in lenses from IV FDA group protein deposition was greater than in other groups [31]. However, there was no correlation between total protein deposition and patients comfort. Despite this, it may have some impact on dehydration and, in turn, affect safety of wearing. In hydrogel lenses, drop in water content is linked with a decrease in oxygen permeability. Corneal hypoxia may decrease its sensitivity so the patient does not complain on discomfort.

GONZÁLEZ-MÉIJOME *et al*. [19] performed a similar study. As expected, worn samples had different dehydration patterns than new ones. They ascribe it to tear film components deposition that produces surface changes. In our previous study [21] performed on the silicone-hydrogel senofilcon lenses, a significant decrease in both overall water content and freezable water content was found. The changes were greater with time, suggesting that progressive lens contamination and mechanical friction of lids change water properties of the material. Nevertheless, both GONZÁLEZ-MÉIJOME [19, 20] and other investigators [4] have washed out the original solution and equilibrated samples in buffer solution. We believe that differences in osmolality may have an influence on lens dehydration. Hydrophilic polymers may respond to changes in salt concentration by deswelling [32]. Hence, different dehydration behavior may be observed.

The normal value of tear osmolality is considered in the range from 302 to 334 mOsm/kg [33]. Enhanced concentration of elecrtolytes increases osmolality in patients with dryness symptoms. STAHL *et al*. [32] have studied the effect of hypoosmotic solutions on subjective dryness ratings and tear film stability. They have demonstrated that initial comfort does not change with osmolality of inserted lens (osmolality of the fluid in which it was stored). However, hypoosmotic lens reduces dryness symptoms and discomfort after 6 h of wearing. Surprisingly, some lens packaging are filled with hyperosmotic buffers (Fig. 3). This may influence patients comfort, especially since tear fluid of osmolarity higher than 310–320 mOsm/l is considered to be hyper-

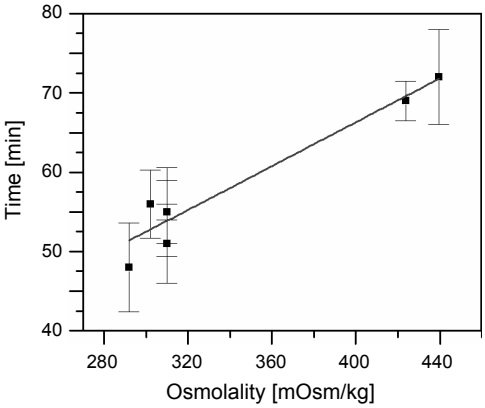

Fig. 6. The relationship between phase III time duration and osmolality.

osmotic [33] and is linked with dry eye sensations. We did not find correlations between change in WC or DR and packaging solution osmolality. However, the time of reaching equilibrium (phase III) was longer in lenses stored in hyperosmotic fluids. We assumed that osmolality of tears in worn samples was normal (310 mOsm/kg) and plotted duration times of phase III of dehydration against osmolality. Figure 6 reveals that increased time of reaching equilibrium is related to the osmolality of the fluid in which lens is inserted. As a result of the so-called salting-out, in conventional hydrogels elevated osmolality may lead to a decrease in WC. Amphoteric hydrogels (such as omafilcon) are less prone to this effect [34]. Based on this result, one can assume that elevated osmolality may lead to an excessive dehydration of some lens materials. This issue needs further investigation. Nevertheless, the right balance of electrolytes in tears together with physiological pH [34] seems to be especially important in case of ionic materials.

DSC curves show two peaks (one with the maximum around –1 °C and second around –5 °C) supporting the discreet model [2] of water states in hydrogels. Figure 5**b** shows an example of DSC curves obtained for PVA-based nelfilcon lens. The proportion of free and loosely bound water is opposite to the HEMA-based lens (Fig. 5**a**). It may result from the higher affinity of PVA hydroxyl groups to form hydrogen bonds with water molecules.

In worn samples, there is a change in free to bound water ratio (Fig. 4) that may be ascribed to the change in water content due to lens wear. This change seems to depend on the chemical composition of the material. MIREJOVSKY *et al*. [9] studied the effect of proteins on water and transport properties of contact lens hydrogels. They concluded that protein accumulation inside polymer matrix significantly reduces freezable water content. We have observed similar dependence. Only in nelfilcon a drop in bound water content was found. This is probably due to leaching of non-crosslinked PVA molecules from the material during wearing.

5. Conclusions

As follows from this study, contact lens wear may produce changes in the material that could further influence its on-eye behavior. It seems that within a relatively short time of wearing (6 h) some important changes in material may occur. Each lens performs different according to its chemical composition and water content. Introduction of new components, such as phosphorylcholine or non-crosslinked PVA changes material properties so that they are less prone to dehydration.

We have found an interesting dependence of the time of achieving equilibrium (phase III) and osmolality of the storing solution. Since we did not measure osmolality of the tears of volunteers that were wearing lenses, further investigation is needed. However, in the light of previous studies it appears that in order to increase the comfort of wearing during the day, iso- or hypoosmotic storing solutions should be recommended.

Some effect of wearing on dehydration and water states in lens materials was observed. There was a decrease in hydration in worn samples. As DSC measurements revealed, a change in water structure after 6 h of wearing in all lenses studied has been found. The changes observed may be due to protein deposition. Additionally, some changes in surface that affect lens dehydration may appear.

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