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ORIGINAL RESEARCH

Evaluation of surface water characteristics of novel daily disposable contact lens materials, using refractive index shifts after wear

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Purpose: Contact lens wearers today spend much time using digital display devices. Contact lens manufacturers are challenged to develop products that account for longer periods of time where blink rate is reduced and tear-film evaporation rate is increased, affecting both visual acuity and comfort. Two manufacturers recently introduced novel daily disposable contact lenses with high surface water content. The objective of the present study was to compare surface water characteristics before and after initial wear of recently introduced nesofilcon A and delefilcon A high surface water lenses with those of etafilcon A lenses.

Patients and methods: Twenty healthy subjects wore each of the three lens types studied in a randomly determined order for 15 minutes. After each wearing, lenses were removed and the surface refractive index (RI) of each lens was immediately measured.

Results: The mean RI of the unworn delefilcon A lens was 1.34, consistent with water content in excess of 80%. After 15 minutes of wear, the surface RI shifted to 1.43, consistent with its reported 33% bulk water content. In contrast, the mean surface RI of the nesofilcon A lens was 1.38, both initially and after 15 minutes of wear, and that of the etafilcon A lens was 1.41 initially and 1.42 after 15 minutes of wear.

Conclusion: The surface of the delefilcon A lens behaves like a high water hydrogel upon insertion but quickly dehydrates to behave like its low-water silicone-hydrogel bulk material with respect to surface water content during wear, while both nesofilcon A and etafilcon A lenses maintain their water content during initial wear. The nesofilcon A lens appears unique among high water lenses in maintaining high surface and bulk water content during wear. This is important because changes in surface RI due to dehydration are reported to lead to visual aberration affecting user experience.

Keywords: contact lens dehydration, poloxamer, visual acuity, wetting

Introduction

The rapid development of new digital display devices over the past decade has changed the performance requirements of modern contact lenses. Where previously the lens-wearing population interfaced with primarily large, analog CRT screens and low-definition television monitors, current lens wearers increasingly use digital devices having smaller screen sizes in addition to high-definition digital computer monitors and televisions. In 2014, 55% of American adults owned a smartphone, 42% a tablet computer, and 32% an e-reader.[1] Our modern population spends over 10 hours daily using technology or electronic devices.[2] As smaller devices are used for viewing and reading at close range, the eyes must constantly refocus and reposition to process content.

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Decreased blink frequency, increased rate of tear evaporation, and decreased tear stability during video display terminal (VDT) use were first reported over 2 decades ago[3,4] after personal computers became commonplace, and other aspects such as reduced blink amplitude and tear-film disruption were reported over intervening years.[5,6] The blink rates of contact lens wearers during digital display use decrease on average from 15 to 5 blinks per minute, while the number of incomplete blinks increases.[5–11] This can be problematic for two reasons. First, tear-film disruption during longer interblink intervals leads to visual aberration due to changes in light refraction through the altered tear film. Second, lens dehydration per se perturbs lens geometry, which leads to further changes in light refraction and additional aberration. Contact lens wear during VDT use can be a contributor to computer vision syndrome, a combination of eye and vision problems associated with the use of computers.[11–13] New contact lens models should address the increased demands of wear while using digital display devices.[14]

Contact lens water characteristics play a key role in lens performance, vision, and comfort. Numerous in vitro and in vivo studies over several decades under a variety of conditions suggest that lens dehydration increases with lens water content.[15–21] As silicone hydrogels are inherently of low water content, they typically dehydrate less than traditional hydrogels do,[15,19,22] but not all lenses follow this trend. While most lenses of similar water content show only subtle differences in dehydration behavior,[18] omafilcon A lenses are reported to dehydrate on-eye less than do other high water lenses of similar water content.[23] This suggests that some hydrophilic wetting agents (such as phosphorylcholine in omafilcon A lenses) might attenuate lens dehydration.

Two novel daily disposable contact lenses with uncommon water characteristics were recently introduced to the contact lens market during the period of personal digital device use growth. Bausch & Lomb Incorporated (Rochester, NY, USA) launched Biotrue® ONEday (nesofilcon A, 78% water content), a US Food and Drug Administration (FDA) Group II (high water, nonionic) lens in 2012.[24] Ciba Vision (now Alcon, Fort Worth, TX, USA) launched Dailies Total1® (delefilcon A, ≥80% surface water content; 33% bulk water content), an FDA Group V (silicone hydrogel) lens in 2013.[25] Nesofilcon A is unique among commercial lenses as it has a water content the same as that of the human cornea (78%),[26] while delefilcon A is also unique in its water gradient structure.

Although lens surface hydration would seem desirable, lenses of higher water content are reported to dehydrate at a higher rate and to a greater extent than those of lower water content[15] and to be more susceptible to post-lens-tear-film depletion under dehydrating conditions.[22] Tear-film stability is a function of both rate and amount of water loss across the anterior surface of the lens;[27] thus, lenses that minimize water loss promote tear-film stability, a smooth and consistent optical surface, and greater visual stability. Further, lenses are exposed to air and tear components during wear that may change the surface properties of the polymers,[28,29] and lipid and protein deposition may reduce lens wettability, increase dehydration, and destabilize the pre-lens-tear film.[22] Because contact lens materials differ in their ability to resist dehydration, it is of interest to know if the unique engineering of nesofilcon A and delefilcon A lenses maintains lens surface water to promote a stable tear film.

Lens dehydration and visual acuity

In contact lens wear, the anterior surface becomes the first refracting surface. Maintaining a consistent optical surface is important in reducing light scatter and preventing optical aberrations.[30] While all soft lenses change dimensions to some extent on-eye, those that best maintain their physical properties provide the least change in visual acuity during wear. Hydrogel lenses dehydrate during interblink intervals, resulting in an irregular surface that scatters incoming light, thus reducing low-contrast retinal acuity and negatively affecting the vision of the wearer.[31] Suppression of blinking during high water content lens wear is reported to effect a major reduction in visual acuity first referred to as dehydration blur.[32] Additionally, decreased blink rates and incomplete blinks during digital display use lead to a disrupted tear film and additional visual aberration.[5,10] Changes in lens water content manifest as corresponding changes in refractive index (RI). Thus, dehydration that leads to changing RI can lead to suboptimal lens performance and vision, as well as increased discomfort.[33,34]

Because RI and water content are related, measurement of RI has been established as a means to assess lens water content.[35,36] While early attempts to develop a predictive model of dehydration based upon water content were unsuccessful,[37] later advances in interferometry measurement led to linear models for hydrogels, with good reliability within and between operators.[38] A similar linear model was also developed for silicone hydrogels.[39] Lenses with higher surface water content have a surface RI closer to that of water (1.33), while lenses with lower surface water content have a higher surface RI.[40] Thus, many researchers measured RI to follow changes in lens water content during wear or exposure to various environmental conditions. The RIs of many commercial lenses have been published.[16,38]

The objective of this study was to compare surface water characteristics of recently introduced nesofilcon A and delefilcon A high surface water lenses with those of 1-Day ACUVUE® MOIST (etafilcon A; Vistakon, Jacksonville, FL, USA; 58% water content) lenses before and after the initial 15 minutes of wear (Table 1).

Patients and methods

To determine water behavior when lenses were first placed on-eye, 20 healthy subjects wore each of the three lens types studied in a randomly determined order for 15 minutes. Each subject wore a lens of his or her prescribed power (ranging from –1.00 to –5.00 D). All comparator lenses were parameter-matched. After each wearing, lenses were removed and the surface RI of each lens was immediately measured with the Metricon M-2010 Prism Coupler (Pennington, NJ, USA) by a masked operator using sodium light (λ=589.3 nm). Lenses were not dabbed with a lint-free wipe to remove residual tear fluid so as not to artificially remove liquid from the lens surface, or not to deposit residue from the wipe to the lens that would interfere with the RI measurement. In contrast to the gravimetric method, RI is sensitive to changes in surface water that may not manifest as corresponding changes in weight depending upon the accuracy of the scale used and the systematic errors introduced by lens handling. For reference, ten unworn lenses of each type removed from their respective original packaging and shaken five times to remove excess fluid and surface RIs were then measured. Published values of RIs of various materials ranging from pure water (RI =1.33) to hydroxyethyl methacrylate (HEMA, RI =1.43) (Table 2) were compared with measured values to estimate water lost during early lens wear.

Statistical analysis

The differences in RI between lenses before and after 15 minutes of wear were tested for significance using Student's *t*-test. Differences were considered statistically significant if $P \leq 0.05$.

Results

The surface RIs of unworn and worn lenses are reported in Table 3. Lenses with high surface water content have a surface RI close to that of water (1.33), while lenses with low surface water content have a higher surface RI. The RI is typically 1.46–1.48 for a 20% water lens and 1.37–1.38 for a 75% water lens.[40] Differences between RI before and after wear were significant ($P<0.0001$) for all lenses due to the high accuracy of the Metricon instrument (routine RI accuracy of ±0.00054 and standard deviation from 0.0003 to 0.0056). Prior to wear, the delefilcon A lenses had a surface RI of 1.34 (Table 3), consistent with a lens having water content greater than 80% and almost as low as that of pure water (1.33) (Table 2). However, after only 15 minutes of wear, the RI increased to 1.43, consistent with a lens having water content closer to 33%. In comparison, the mean surface RI of nesofilcon A lenses changed relatively less after 15 minutes of wear, with mean values of 1.38 for both the unworn and worn lenses. Similarly, the mean surface RI of etafilcon A lenses also changed relatively less after 15 minutes of wear, with mean values of 1.41 for the unworn lenses and 1.42 for the worn lenses, respectively.

Although water loss and RI are linearly related, the relationship for HEMA-based hydrogels differs from that of silicone hydrogels. The relationships typically take the form % water = (RI – c_1)/c_2, where c_1 and c_2 are constants best determined experimentally by systematically varying and measuring water content by a different method (typically gravimetric), and comparing measured water loss to measured RI. This becomes problematic in the case of delefilcon A due to its different surface and core materials. Therefore, no attempt was made to determine the constants for the lenses in this study.

Discussion

Two daily disposable lenses recently introduced to the market propose novel ways to exploit water characteristics for enhanced lens performance. Biotrue ONEday (nesofilcon A) is a high water, traditional hydrogel lens that exploits the amphiphilic properties of Pluronic® F127 (BASF, Florham Park, NJ, USA), a polyethylene oxide (PEO)–polypropylene oxide (PPO)–PEO block copolymer surfactant, by incorporating it into a lens fabricated from HEMA and *N*-vinylpyrrolidone monomers.[24,41] Its relatively high water content is accomplished by creating a polymer with a high concentration of polyvinylpyrrolidone (the polymeric form

Table 1 Contact lenses evaluated

Material	Water content	FDA group	Brand name	Manufacturer
Delefilcon A	≥80% (surface) 33% (bulk)	V	Dailies Total1®	Alcon (Fort Worth, TX, USA)
Nesofilcon A	78%	II	Biotrue® ONEday	Bausch & Lomb Incorporated (Rochester, NY, USA)
Etafilcon A	58%	IV	ACUVUE® MOIST	Vistakon (Jacksonville, FL, USA)

Abbreviation: FDA, US Food and Drug Administration.

Table 2 Refractive indices of reference materials[40]

Material	Index of refraction (λ=589.3 nm)
Air	1
Water	1.33
HEMA	1.43
20% water hydrogel	1.46–1.48
75% water hydrogel	1.37–1.38
Human cornea	1.376

Notes: This table was originally published in the *Dictionary of Optometry and Visual Science*, 7th ed. Millodot M, Page No 167, Copyright © 2009 Butterworth-Heinemann Elsevier.[40] Copyright ©2013 Bausch and Lomb. Reproduced with permission, from Schafer J, Steffen RB. *Evaluation of surface water characteristics of novel daily disposable contact lenses using refractive index shifts after wear*. Poster presented at Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO); 5 May 2013; Seattle, WA, USA.[52]
Abbreviation: HEMA, hydroxyethyl methacrylate.

of *N*-vinylpyrrolidone), which is a humectant that is highly soluble in water, physiologically compatible, nontoxic, essentially chemically inert, temperature-resistant, pH-stable, nonionic, and colorless. The designers of this lens sought to mimic the lipid layer of the tear film to inhibit lens surface dehydration and maintain consistent optics while delivering virtually the same amount of oxygen as the open eye.[42] During polymerization, polyvinylpyrrolidone interacts with the Pluronic throughout the matrix, and the surface concentration of Pluronic increases due to its amphiphilic nature. The resultant lens has constant 78% water content throughout and a surface that retains water like the natural tear film by retarding water evaporation.

Although other commercial high water lenses are reportedly prone to dehydration and the associated loss of comfort and visual acuity,[16–21] the nesofilcon A lens maintained its water content over the first 15 minutes of wear as reflected by the minimal change in the surface RI (1.375±0.0008 before vs 1.381±0.0021 after). In comparison, the etafilcon A lens showed a slightly larger (yet still small) change in its water content after the first 15 minutes of wear (RI of 1.405±0.0013 before vs 1.417±0.0046 after). In a previous study, the etafilcon A lens lost greater than 5% of initial water after 4 hours of wear in a controlled, 6% relative humidity environment, while the nesofilcon A lens lost less than 2%.[43] In a different study of the two lenses, water loss was measured over 16 hours of wear in uncontrolled, ambient humidity.[44] While the etafilcon A lens continued to lose water over 16 hours of wear (>6%), the nesofilcon A lens water loss was consistently below 2% over the course of the day (Figure 1). Morgan and Efron[19] similarly reported that etafilcon A lenses lost 6.0% of their water after 2 weeks of wear.

Dailies Total1 (delefilcon A) is a low water, silicone-hydrogel lens with a surface treatment that results in extremely high surface water content for a silicone-hydrogel lens. The designers of this lens sought to maintain the high amount of oxygen permeability and lens-handling properties of silicone-hydrogel material while imparting the wettability, lubricity, and resistance to lipid fouling properties of high water, traditional hydrogel lenses.[45] This is accomplished by packaging molded lenses in a solution that includes copolymers of polyamidoamine and poly(acrylamide-acrylic acid) wetting agents and then initiating the surface modification reaction by bringing the packaged lenses to autoclave sterilization temperature.[25,46] This results in what the manufacturer describes as a water gradient across the lens, with a manufacturer-reported 90 μm hydrophobic core of 33% water content and 6 μm thick hydrophilic surface of 78.4%±5% water content on each side.[47] While the manufacturer did not measure the water content of the surface of the delefilcon A lens, the water content was estimated from a film of copolymer applied to a silicon wafer using neutron reflectometry.[48]

Although the RIs of other commercial silicone-hydrogel lenses are reported in excess of 1.40,[16] the average surface RI of the delefilcon A lens before insertion was 1.34, which is

Table 3 Surface refractive indices of contact lenses before and after 15 minutes of wear

Lens	Group	N	Minimum	Maximum	Mean	Standard deviation	Difference (worn–unworn)	*P*-value (*t*-test)
Nesofilcon A[24]	Unworn	10	1.374	1.376	1.375	0.0008	0.0064	<0.0001
	Worn	20	1.377	1.385	1.381 1.375[a]	0.0021		
Etafilcon A[51]	Unworn	10	1.403	1.407	1.405	0.0013	0.0123	<0.0001
	Worn	20	1.413	1.431	1.417 1.40[a]	0.0046		
Delefilcon A[25]	Unworn	10	1.336	1.338	1.337	0.0005	0.0932	<0.0001
	Worn	20	1.425	1.440	1.430 1.42[a]	0.0031		

Notes: The refractive index value for nesofilcon A reported in the table was determined by the test method used in this study, whereas those of etafilcon A and delefilcon A are as reported by their respective manufacturers in regulatory submissions using different test methods. [a]As reported in the respective FDA documents cited in the Lens column.

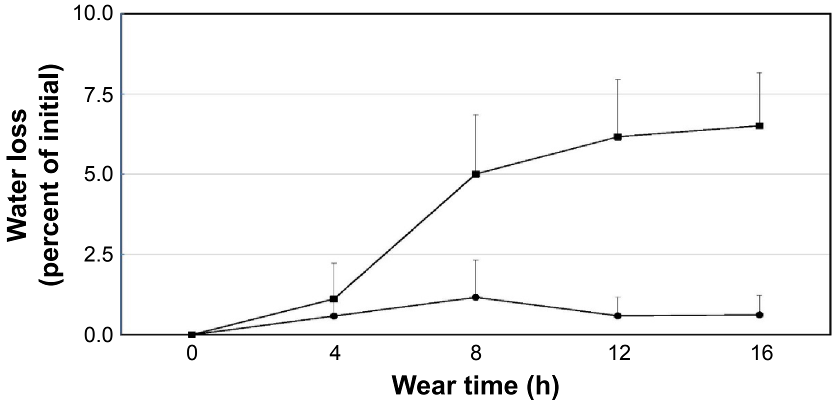

Figure 1 Water loss over the course of 1 wearing-day.
Notes: Circle, nesofilcon A; square, etafilcon A. Mean + standard deviation. Lower error bar omitted for clarity (Steffen and Schafer, unpublished data 2013).

closer to that of pure water (1.33) than those of other silicone-hydrogel materials (>1.40), the nesofilcon A lens (1.37), or the etafilcon A lens (1.40). This suggests a surface water content in excess of 80%. However, the delefilcon A lens did not maintain its high surface water content over the first 15 minutes of wear as reflected by a large change in surface RI (1.337±0.0005 before vs 1.430±0.0031 after).

While the delefilcon A lens quickly loses its surface water to exhibit water behavior similar to that of other silicone hydrogels, the nesofilcon A lens maintains its water over the first 15 minutes of wear and dehydrates less than 2% over 16 hours of wear;[44] although the etafilcon A lens did not lose substantial surface water over the first 15 minutes of wear in this study, it loses in excess of 6% of its water content over an extended period of wear.[19,43] Dehydration of the delefilcon A lens surface previously reported suggests that the mechanism may be collapse of the hydrophilic surface moieties that attract water once in contact with the eye and the associated tear fluid under the shear of normal blinking.[49]

The effect of dehydration upon lens shape and image stability of nesofilcon A versus etafilcon A lenses was recently studied. Using an in vitro method that quantitates a predicted logMAR score based upon optical image quality as lenses dehydrate, researchers demonstrated a consistent and slower reduction in predicted retinal image quality over time of nesofilcon A compared to etafilcon A lenses.[50] Although the loss of water with the delefilcon A lens was not evaluated in this study, dehydration may manifest as decreased lens performance, including visual aberration and decreased acuity,[31] and increased deposition of tear-film components.[21] Additional research regarding the changes in surface water and the relationship to symptoms among contact lens wearers that use digital devices will be valuable.

Conclusion

Two recently introduced daily disposable lenses with unique water characteristics behave differently on-eye. The surface of delefilcon A, a novel silicone-hydrogel lens with 80% or greater initial (prewear) surface water content and 33% bulk water content, behaves like a high water hydrogel upon insertion but quickly dehydrates to behave like its low-water silicone-hydrogel bulk material with respect to water content during wear, while both nesofilcon A and etafilcon A lenses maintain their water content during initial wear. In contrast, both nesofilcon A, a novel hydrogel lens with 78% water content, and etafilcon A, a traditional hydrogel lens developed some 4 decades ago, maintain their water content during initial wear. The nesofilcon A lens appears unique among high water lenses in maintaining high surface and bulk water content during wear. Because surface dehydration is reported to lead to visual aberration due to tear-film disruption and changes in lens geometry, additional studies of the effects of surface water loss from delefilcon A and nesofilcon A on visual performance are warranted.

Disclosure

Schafer, Steffen, and Reindel are direct employees of Bausch & Lomb Incorporated. Chinn is a paid consultant to Bausch & Lomb Incorporated. The authors report no conflicts of interest in this work.

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