

# The effect of lens wear on refractive index of conventional hydrogel and silicone-hydrogel contact lenses: A comparative study

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## Abstract

**Purpose:** The purpose of this work was to evaluate the ability of four silicone-hydrogel contact lenses (galyfilcon A, balafilcon A, lotrafilcon A and lotrafilcon B) to retain their equilibrium water content before and after wear, through measurements of refractive index and compare with that of a conventional disposable hydrogel contact lens (etafilcon A).

**Methods:** The refractive indices of 115 contact lenses were measured using an automated refractometer (CLR 12-70, Index Instruments, Cambridge, U.K.) before and after a schedule of daily wear by 58 patients for 30 days in the case of silicone-hydrogel lenses and 15 days for the conventional contact lenses.

**Results:** In the silicone-hydrogel contact lenses the changes on the refractive indices were not statistically significant, however after being worn the refractive index of the conventional etafilcon A hydrogel contact lens increased significantly ( $p < 0.001$ ).

**Conclusion:** The results presented here show that after being worn the silicone-hydrogel contact lenses, show more capacity to retain or to reach their initial equilibrium water content than conventional hydrogel contact lenses. This suggests that the silicone-hydrogel contact lenses are less susceptible to spoilation over time maintaining its biocompatibility and contributing to the clinical success of lens performance.

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**Keywords:** Refractive index; Automated refractometer CLR 12-70; Silicone-hydrogel contact lenses; Conventional hydrogel contact lens; Equilibrium water content

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## 1. Introduction

Refractive index is a physical parameter that reflects the polymers composition of the contact lenses and also their equilibrium water content (EWC), and so it is an important parameter for the optical and physiological perspective. The EWC represents the ability of the hydrogel materials to bind water and it is an important property for clinical behaviour of the contact lenses.

Water plays a key role in the functionality of hydrogel contact lens materials because it has an important effect on the ion and gaseous permeability [1], mechanical and

surface properties [2], and also on the biocompatibility of the contact lenses. It has been shown that an increase in refractive index compared to the “true” refractive index is a surrogate outcome for lens dehydration [3]. Lens dehydration can cause changes in contact lenses parameters leading to a decrease in their clinical performance [4–6]. It has also been shown that environmental conditions can significantly affect contact lenses dehydration [4,7–9]. Many studies link contact lens wear discontinuation results to dehydration of the ocular surface, which is one of the main factors restricting the growth of the contact lenses market [10,11].

Although, the evidence is inconclusive that the loss of lens water content occurring during contact lens wear is responsible for dryness symptoms [12–14], the lens materials capacity to maintain its EWC during wear may be an important factor to consider for the clinical success of contact lenses. In fact, clinical and experimental

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observations made in conventional hydrogel contact lenses with higher water content show that these lenses tend to dehydrate on the eye faster and by a greater amount [12,13,15] and some lenses exhibit an irreversible loss of water over time [12].

Patients using frequent replacement lenses complain less of dryness than wearers of other lens types [16,17]. This may be due to increased wettability [18], reduction deposition [19] or reduced dehydration [20]. In addition, wearers of silicone-hydrogel contact lenses are also less aware of lens-induced dryness, particularly at the end of the day [20].

The water content of conventional hydrogel contact lenses is usually above 38%, which contributes to the softness and comfort of these lenses. However, the oxygen permeability is limited by the water phase restricting their wearing schedule. The silicone-hydrogel contact lenses were developed in order to increase the oxygen transmissibility to the cornea, and thus preventing complications due to corneal anoxia observed with the use of conventional hydrogel contact lenses.

Silicone-hydrogel contact lenses are slightly stiffer and have relatively lower water content than the conventional hydrogel materials. The silicone components combined with conventional hydrogel monomers in contact lens materials, increases oxygen permeability but decreases its hydrophilicity [21] making lens surface more hydrophobic and so more prone to deposits adhesion. This has been already established in *in vitro* studies [22–25].

A surface treatment of silicone-hydrogel contact lenses is needed to make them hydrophilic and tolerable on the eye and is an important factor for the clinical performance of these contact lenses. Significant differences exist between the silicone-hydrogels materials [2,26]. Balafilcon A, lotrafilcon A and lotrafilcon B are treated using gas plasma techniques, but balafilcon A undergoes plasma oxidation which transforms the silicone components into glassy islands on the surface. Lotrafilcon lenses are treated with hydrocarbon plasma that reacts with air to create continuous hydrophilic surfaces [2,26]. On the other hand, galyfilcon A

has no surface treatment but incorporates an internal wetting agent that apparently leaches to the lens surface.

Refractive index and EWC are closely linked in conventional soft hydrophilic materials [27,28]. In a previous study was also reported a similar, but independent relationship to that of the conventional hydrogels, between refractive index and EWC for the four silicone-hydrogel contact lenses used in this work [29].

Recently, the automated refractometer CLR 12-70 designed to measure the refractive index of hydrogel lenses has become available. Nichols and Berntsen used this instrument and found it easy to use and it is a reliable and valid technique to determine the refractive index of soft contact lenses [3]. These authors found good reliability within and between operators in the measurements of the refractive index using this refractometer and also demonstrated that this instrument had excellent within-operator reliability. We consider these factors as an advantage of measuring hydrogel refractive index rather than measuring water content directly.

As the refractive index reflects changes in the EWC of the contact lens materials, changes on refractive index, allows the evaluation of the ability of the contact lenses to reach or to maintain their EWC after being worn.

The purpose of this work was to evaluate the ability of four silicone-hydrogel contact lenses (galyfilcon A, balafilcon A, lotrafilcon A and lotrafilcon B) to reach or retain their EWC, through measurements of refractive index, and compare with those occurred on a conventional disposable hydrogel contact lens (etafilcon A).

## 2. Material and methods

A total of 115 commercial lenses were measured: 22 Acuvue<sup>®</sup> Advance<sup>™</sup>, 20 Purevision<sup>™</sup>, 24 Focus<sup>®</sup> Night&Day<sup>™</sup>, 19 O<sub>2</sub>Optix<sup>™</sup>, and 30 Acuvue<sup>®</sup>. The properties of the contact lens used in this study are detailed in Table 1.

Table 1  
Conventional and silicone-hydrogel contact lenses used in this study

Brand	Acuvue <sup>®</sup> Advance <sup>™</sup>	Purevision <sup>™</sup>	Focus <sup>®</sup> Night&Day <sup>™</sup>	O <sub>2</sub> Optix <sup>™</sup>	Acuvue <sup>®</sup>
Manufacturer	Johnson & Johnson	Bausch & Lomb	CIBA Vision	CIBA Vision	Johnson & Johnson
USAN	Galyfilcon A	Balafilcon A	Lotrafilcon A	Lotrafilcon B	Etafilcon A
FDA group	I	III	I	I	IV
Water content (%)	47	36	24	33	58
Surface treatment	No surface treatment	Gas plasma oxidation	Plasma coating	Plasma coating	No surface treatment
RI	1.4055 <sup>a</sup>	1.426 <sup>a</sup>	1.43 <sup>a</sup>	1.42 <sup>a</sup>	1.4055 <sup>a</sup>
Principal monomers	mPDMS + DMA + EGDMA + HEMA + siloxane macromer + PVP + visibility tint + UV blocker	NVP + TPVC + NCVE + PBVC	DMA + TRIS + siloxane macromer	DMA + TRIS + siloxane macromer + visibility tint	HEMA + MA

USAN, United States Adopted Names.

<sup>a</sup> Obtained from Food and Drug Administration, DMA *N,N*-dimethylacrylamide; PDMS, polydimethylsiloxane; EGDMA, ethylene glycol dimethacrylate; HEMA, poly-2-hydroxyethylmethacrylate; MA, methacrylic acid; NVP, *N*-vinyl pyrrolidone; TPVC, tris-(trimethylsilyloxy) propylvinyl carbamate; NCVE, *N*-carboxyvinyl ester; PBVC, poly[*dimethylsiloxy*] di(*silylbutanol*) bis[*vinyl carbamate*].

The lenses were worn by 58 patients in a daily wear schedule (12–14 h a day) for 30 days in the case of silicone-hydrogel. Due to safety reasons, the wearing period of the conventional hydrogel was only 15 days. According to the manufacturer's instructions, galyfilcon A should only be worn for a 15-day period. However, in this study, patients wore this type of lens for 30 days, in order to make possible the comparison with the other silicone-hydrogel contact lenses tested. The average age of patients was  $23.3 \pm 6.1$  years (range 16–47 years). The subjects were informed of the proposed procedure and signed a consent form in accordance with the Helsinki Declaration. The criteria for excluding patients from this study were symptoms of dry eye, active ocular illness, systemic disease and any surgery of anterior segment of the eye. All patients used the same multipurpose solution, Renu Multi-Plus™ (Bausch & Lomb) to store the lenses overnight. After the trial period, lenses were removed from the patient's eyes and placed in a preservative-free saline solution (0.9% NaCl prepared in distilled water) at least 48 h before being measured in order to equilibrate and allow the contact lenses to reach their initial EWC.

The samples were measured at a room temperature of  $21 \text{ }^\circ\text{C} (\pm 2 \text{ }^\circ\text{C})$  and relative humidity of  $52 (\pm 2\%)$ . It must be stressed that the solutions used to equilibrate the lenses before measurements do not affect the refractive index values. This was supported by assessing the refractive index in lenses equilibrated in saline solution (0.9% NaCl prepared in distilled water) and the solution contained in the blisters packs (data not shown). The refractive index considered for each lens was the average of five consecutive measurements and each lens was equilibrated and re-hydrated between each consecutive measurement by immersion in saline (0.9% NaCl prepared in distilled water).

The refractive indices of all contact lenses were measured via refractometry, then worn, removed, equilibrated and then measured again. The initial value of the lenses refractive index was the value measured after removal from the original pack.

The CLR 12-70 digital automated refractometer (Index Instruments, Cambridge, UK) was used to directly measure the refractive index of all contact lens. This instrument measures refractive index by back reflection at 589 nm and provides direct refractive index reading with minimal influence of operators subjectivity displaying accurate and reproducible values of refractive index of contact lenses [3,29]. The instrument was programmed to use a "continuous scan", and its zero setting was checked before each initial use. The values of refractive index were taken immediately when stability was reached.

The EWC of all contact lenses was obtained using a polynomial relationship between refractive index, obtained directly from CLR 12-70 automated refractometer) [30]

$$\text{EWC} = 952.85x\text{RI}^2 - 3193.9x\text{RI} + 2664 \quad (1)$$

Using this equation we have the advantage of being able to obtain water content values (clinically important) from refractive index of the lenses obtained using the accurate, rapid, and objective automatic CLR 12-70 refractometer. Without such equation we only can compare refractive index values which are more difficult to interpret in clinical terms. Very small changes in refractive index are able to have significant effects in relative percentage of water content information on the contact lens material.

The change in lens water content of a contact lens can be obtained through the following equation based on Brennan et al. definitions [31]

$$\% \Delta \text{EWC} = \frac{\text{EWC}_w - \text{EWC}_{un}}{\text{EWC}_{un}} \times 100 \quad (2)$$

$\text{EWC}_{un}$  and  $\text{EWC}_w$  are the equilibrium water content of the contact lenses before and after wear obtained using Eq. (1).

### 2.1. Statistical analyses

All data were analysed using Statistical Package for Social Sciences, SPSS Version 11.

The differences between refractive index for unworn and worn contact lenses were compared using the paired sample *T*-test for parametric data. For all hypotheses testing,  $p \leq 0.05$  was considered statistically significant.

## 3. Results

Table 2 shows the minimum, maximum and average value of the refractive index measured on unworn and worn contact lens.

The values of the refractive index of unworn lenses, determined by automated refractometer, were slightly lower than the nominal values given by Food and Drug Administration (FDA) for the etafilcon A and balafilcon A lenses and almost the same for galyfilcon A, lotrafilcon A and lotrafilcon B.

The refractive index of worn silicone-hydrogel contact lenses was not significantly different from that of unworn contact lenses. However, the conventional hydrogel exhibited a significant increase ( $p < 0.001$ ), in the refractive index after being worn (Fig. 1).

Using Eq. (1), we were able to calculate the EWC for each lens used in this work, before and after being worn, and obtain information about the change in EWC of the contact lenses by using Eq. (2). Etafilcon A showed a change in EWC of 10%, and lotrafilcon A of 3%. For galyfilcon A, balafilcon A and lotrafilcon B, the changes in EWC are, respectively 0.9, 1 and 0%. The conventional hydrogel presents higher changes than the silicone-hydrogel contact lens.

Table 2

Results from refractive index measured in unworn and worn contact lenses

		No.	Minimum	Maximum	Mean $\pm$ S.D.	Significance ( <i>p</i> )
Etafilcon A	u	30	1.361	1.405	1.398 $\pm$ 0.008	0.000
	w	30	1.405	1.413	1.410 $\pm$ 0.002	
Galyfilcon A	u	22	1.405	1.414	1.408 $\pm$ 0.002	0.127
	w	22	1.405	1.413	1.409 $\pm$ 0.002	
Balafilcon A	u	20	1.417	1.424	1.421 $\pm$ 0.002	0.467
	w	20	1.418	1.425	1.422 $\pm$ 0.002	
Lotrafilcon A	u	24	1.425	1.428	1.426 $\pm$ 0.001	0.319
	w	24	1.425	1.487	1.429 $\pm$ 0.124	
Lotrafilcon B	u	19	1.421	1.423	1.422 $\pm$ 0.008	0.500
	w	19	1.419	1.423	1.421 $\pm$ 0.001	

u: unworn CL; w: worn CL.

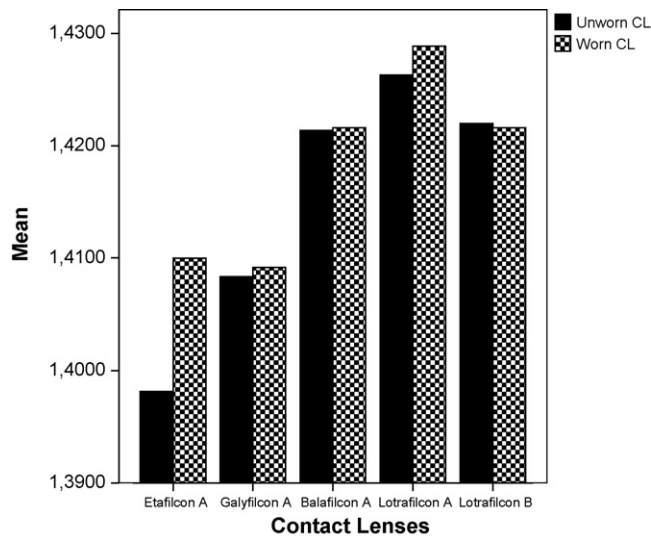


Fig. 1. Mean refractive index for unworn and worn contact lenses.

#### 4. Discussion

Water content can be obtained by several methods which include gravimetry [32,33], nuclear magnetic resonance imaging and refractometry. Although the gravimetric technique is more accurate, it is a time-consuming method. In previous work, it has been shown that the values of water content could be obtained from the refractive index using polynomial relationships and the water content and refractive index of conventional hydrogel contact lenses obtained with manual and automated refractometry were comparable [30].

Hand held refractometers are often used in the food and wine industry for measurement of sugar concentration using the Brix scale. This scale represents the grams of sucrose in 100 g of sucrose solution. Brennan [27] describes the utility of this instrument in measuring refractive indices of contact lenses. However, because the Brix scale is based on a sucrose–water relation, it can induce errors for hydrogel materials that do not have the same water and refractive

index relation as sucrose and water [34]. Due to the lower refractive index of siloxane monomer compared to the monomers used in conventional hydrogels, silicone-hydrogel lenses do not fit to the Brix scales. Refractometers calibrated for such scales give a systematic overestimation of contact lens hydration [3,29].

The refractive index can be obtained more accurately with automated refractometry for silicone-hydrogels thus displaying an excellent/positive agreement with nominal data [29]. However, when the refractive index is converted to water content using the Brix scale, the difference between the nominal and the measured value is statistically significant [3,29]. This can be explained by the difference in the refractive index of silicone-hydrogels materials and sucrose. However, if the refractive index is measured before and after contact lenses wear, and these values converted to water content using the Brix scales, it is possible to establish comparisons with a good level of accuracy. For silicone-hydrogel lenses we are expecting to obtain higher water content values than they actually have. Despite this

limitation, the values obtained in this study using the same procedure for initial and final measurements of contact lenses will be comparable against each other using Eq. (1).

In hydrogels, the polymer network has free and bound water and the free water molecules can easily evaporate. In the present study, lenses were allowed to reach their EWC in a saline solution after being worn and before being measured. This procedure allows the replacement of lens free water content and enables the evaluation of the ability of the contact lens material to restore the same level of initial water content.

It has been demonstrated that the Acuvue<sup>®</sup> disposable contact lenses loses significant water content during open-eye wear [9]. This loss was considerably greater than that found in other contact lenses, apparently because the polymers are ionic. Several studies have demonstrated that hydrogel contact lenses can suffer *in vivo* dehydration [35,36] causing a modification in oxygen permeability [33]. It seems that the lens material undergoes chemical changes which can result in variations in the components of the lenses [31]. The fact that silicone-hydrogel contact lenses suffer less dehydration has already been established by *in vitro* studies [37]. However, because only one side of the lens is exposed to the atmosphere *in vivo* and because the lipid layer of the tear film may limit lens dehydration, *in vitro* studies do not exactly mimic real conditions. This makes *in vivo* studies essential. The capacity of water to diffuse through an hydrogel and to be lost at the lens surface has been suggested to be related to the proportion of relatively loosely bound water, which is greater in a higher water content lens [38]. Evaporative water loss at the anterior lens surface is a potential cause for contact lens dehydration and surface treatment must be considered. The degree and rate of dehydration is related to the material of the lenses and may affect oxygen transmissibility in hydrogel contact lenses [39]. A solution-diffusion water transport model has been developed, which predicts that a soft contact lens on the eye loses water fast until it reaches a steady state [40] and this is consistent with available measurements of contact lens dehydration.

*In vitro* dehydration studies of conventional and silicone-hydrogel contact lenses indicate that evaporation rates from materials are mainly related with water content [41]. Even for lenses belonging to the same FDA group, dehydration behaves differently due to the different material properties [42].

Lens dehydration can have serious implications in lens performance. According to Tranoudis and Efron [43], lens parameters and their properties alter with changes in hydration, and consequently have a decrease in comfort associated to dehydration [44]. So, the ability to contact lens material reach their EWC is a very important fact to consider for the point of view of clinical performance of the contact lens. Morgan and Efron [45] find that some changes occur in water content on hydrogel lenses as a result of ageing and can be related to lens spoilage over time. Also, in another study Morgan and Efron [33] attributed the loss of water content to

displacement of water by deposits such as proteins and lipids. Additional related experiments were also conducted to help explain the mechanisms that can lead to contact lens surface damage and formation of deposits [46] and it was proved that silicone-hydrogel contact lenses adsorb a lower amount of proteins than the conventional hydrogel lens [46]. Based on these studies, this can be one possible explanation for the findings presented in the present study.

The present results show that although the different composition, different nominal equilibrium water content ( $EWC_{nom}$ ) and the different surface properties of the four silicone-hydrogel contact lenses used in this work, the changes in refractive index and the EWCs, before and after being worn, are not statistically significant. These materials appeared to maintain a constant level beyond which its equilibrium water content would not fall.

## 5. Conclusions

The results presented here show that after being worn the silicone-hydrogel contact lens, show more capacity to retain or to reach their initial EWC than conventional hydrogel contact lenses. Since the refractive index is function of water content, the results of this study suggest that the presence of the hydrophobic organosilicon moieties in the silicone-hydrogels, their lower EWC and the lower levels of proteins exhibited [46], compared to the conventional hydrogel lens, are the cause of apparent better water retention.

This also suggests that the silicone-hydrogel contact lenses are less susceptible to spoilage over time maintaining its biocompatibility and contributing to the clinical success of lens performance.

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