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Diffusive contribution to permeation of hydrogel contact lenses: theoretical model and experimental evaluation by nuclear magnetic resonance techniques

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Abstract

The biocompatibility of contact lenses is closely related to their oxygen permeability. In hydrogel lenses, this characteristic can be attributed to the water permeability resulting from a combination of viscous and diffusive fluxes. Hydrogel lenses were studied by means of nuclear magnetic resonance (NMR) relaxation times, resulting in a mathematical model which evaluated the water self-diffusion coefficient as a quantification of the diffusive contribution to permeation. Comparing the results obtained with the data of permeability to oxygen as measured by other techniques, a reasonable agreement was shown for lenses with a higher water content (WC) with respect to lenses with a lower WC: this difference was accounted for by considering the different contribution to permeation. © 2001 Elsevier Science Ltd. All rights reserved.

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1. Introduction

Over the last few years, several studies have been performed on the chemical physical characterization of hydrogel materials. This has been expecially true for poly(2-hydroxyethyl methacrylate) (PHEMA), which has been extensively employed in biomedical applications, since its discovery in 1960 [1] due to its high biocompatibility. These studies have sought a better understanding of hydrogel structure, and have demonstrated the pivotal role of water in defining its properties.

Besides providing for plasticity, water confers biocompatibilty to materials, thereby favouring permeation by metabolites. The model most commonly used for describing water in hydrogels is the one proposed by Jhon and Andrade [2] (and confirmed by studies of nuclear magnetic resonance (NMR) [3], differential scanning calorimetry (DSC) [4,5], dielectric spectroscopy [6], and Fourier transform infrared (FT-IR) studies [7]). This model provides for three water classes: *bond* water, strongly associated to the hydrogel hydrophilic segments; *interfacial* water, less strongly associated due to the existing hydrophobic interactions; and the so called *bulk* water. To better understand the system and the experimental measurements performed on it, it is also necessary to consider the dynamical mechanisms attendant to water molecules as well as the appropriateness of the experimental methods used to classify the different states [3,8].

The biocompatibility of contact lenses is linked to their possible permeation by oxygen, since the cornea has no endogenous sources for it, but dependent solely on the atmosphere. In hydrogel contact lenses, this is attributable to the possibility that they can be permeated by water.

The phenomenon of membranes being permeated by water is due to the combination of viscous and diffusive fluxes. 'Viscous flux' is that occurring when the hydrostatic pressure gradient leads to a mass flux where molecules move as in a group; whereas 'diffusive flux' is that occurring when the chemical potential gradient leads to a flux characterized by the molecules moving individually through a random pathway [9,10].

The most commonly used method of measuring the permeability to oxygen of hydrogel contact lenses was first introduced by I. Fatt [11] and then officially adopted by the International Standard Organization (ISO) [12]. It is a polarographic method for direct measurement of oxygen

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flowing through the lens over time, with the lens being subjected to an oxygen pressure gradient between its surfaces. A number of recently published works bear evidence to the progressive interest in applying and improving the method [13].

Permeation of these materials by oxygen originates from a combination of the diffusive and the viscous fluxes, subject to the hypothesis that the oxygen molecules move within the hydrogel contact lens jointly with the water molecules in which they are dissolved.

The purpose of this work was to study with the aid of NMR techniques, the state of water in hydrogel contact lenses, thereby introducing an alternative model to that of direct measurement, to estimate the water self-diffusion coefficient within the lenses and quantify the diffusive contribution to permeation by the comparison of the results obtained from the values of oxygen permeability, as derived from polarographic measurements. To that end, the concepts used were those that have been developing over the last thirty years in the definition and validation of diffusion models [14,15].

2. Experimental

2.1. Sample protocol

A set of commercially available contact lens hydrogels was supplied by HYDRON Ltd UK, Ciba Vision Ophthalmics USA, Vistakon-Johnson and Johnson USA, Biocompatibles Ltd UK, Wesley–Jessen USA.

The materials used are shown in Table 1 with their equilibrium water content (EWC) and compositions.

The lenses used were taken out of the sealed container with silicon pliers and then cut by means of a steel tool to obtain samples of a diameter enabling them to fit snugly in a coaxial position into NMR tubes (9 mm diameter) without being deformed.

A known amount of physiologic solution was poured into the NMR tube together with the lens for an appropriate hydration of the material.

The NMR tube was then placed in the instrument sample holder and kept at a constant temperature of 35°C for 40 min, in order to perform measurements on adequately equilibrated samples.

2.2. Low resolution NMR measurements

A Minispec NMS 120 (Bruker Spectrospin S.r.l., Italy) pulse NMR spectrometer operating at 20 MHz was used for relaxation times and water self-diffusion coefficients measurements.

Measurements were performed at the temperature of 35 ± 1°C.

Transversal relaxation times, T_2, were measured by the Carr–Purcell–Meiboom–Gill (CPMG) sequence [16]: $90°_x - [(\tau - 180°_y - 2\tau - 180°_y - \tau)_k - \text{acquisition}]_n$ with $\tau = 250\ \mu\text{s}$ acquiring 1800 experimental points at 4τ intervals.

To obtain an increased signal/noise ratio, 128 experiments were accumulated in absence of signal saturation.

Relaxation curves were analyzed by Sigmaplot (SPSS Inc.), using for a Marquard algorithm to fit [17] the equation:

$$I(t) = \sum_i \left(I_{0i} \exp \frac{-t}{T_{2i}} \right) \qquad (1)$$

Where $I(t)$ is the amplitude of the signal as a function of time, I_{0i} is the amplitude of the equilibrium signal of the i-th component and T_{2i} is its transversal relaxation time.

3. Methods

3.1. Evaluation of water self-diffusion coefficient

Assuming that in contact lens, water diffusion is hindered by its polymeric network, and that the water molecules 'bound' to it do not efficiently participate in diffusion, the water self-diffusion coefficient (D_{eff}) may be expressed using a simple mathematical ratio:

$$D_{\text{eff}} = (1 - x_{\text{b}}) W D_{\text{H}_2\text{O}} + x_{\text{b}} D_{\text{p}} \qquad (2)$$

where x_{b} is the fraction of water molecules bound to the polymer network; $(1 - x_{\text{b}})$ is the fraction of 'free' (interfacial or/and bulk) water molecules within the lens; W is the obstructive coefficient typical of the single material; $D_{\text{H}_2\text{O}}$ is the water self-diffusion coefficient as measured at the same temperature (known from data in the literature [18]); and D_{p} is the polymer diffusion coefficient.

Table 1
Hydrogels used in this study

Gel name	Manufacturer	Material	Nominal EWC (%)
Zero 6	Hydron UK	PHEMA	38
NewVues	CibaVision Ophalmics USA	Vifilcon A	55
Acuvue	Johnson and Johnson USA	Etafilcon A	58
Proclear	Biocampatibles UK	Omafilcon A	62
Omniflex	Hydron UK	MMA/NVP	70
Precision UV	Wesley–Jessen USA	Vasurfilcon A	74

When considering D_p equal to zero, Eq. (2) is simplified to:

$$D_{eff} = (1 - x_b)WD_{H_2O} \tag{3}$$

Because of the microscopic homogeneity of hydrogels, it can be hypothesized that the obstruction coefficient (W) is equal to the portion of lens actually occupied by water in the swollen polymer, usually defined EWC and reported on the lens package. For instance, in the case of a lens consisting in 100% water, $W = 1$ and $D_{eff} = D_{H_2O}$; whereas for lenses at 38% water weight, $W = 0.38$.

Furthermore, when measuring relaxation time NMR T_2 and applying a multiexponential fitting for the data obtained, it is possible to determine x_b and hence, estimate D_{eff}.

This method represents an alternative to a direct evaluation of D_{eff} performed through NMR measurements which require more lenses for overlap, or the availability of 'buttons' of material, in order to make the signal of interest detectable [19,20].

3.2. Estimate of diffusive contribution to oxygen permeability in a lens

Permeability (P) is defined in a number of ways according to the operating context involved. In the case of oxygen flowing through lenses, P is defined as the product of a dynamic property, the diffusive coefficient (D), and a thermodynamic property (k), representing oxygen solubility in the water-swollen polymer:

$$P = Dk \tag{4}$$

Usually, permeability is given in barrers,

$$1 \text{ barrer} = 10^{-10} \frac{\text{cm}^3\text{O}_2(\text{STP})\text{cm}^2}{\text{cm}^3 \text{ of polymer s cmHg}}$$

In a hydrogel contact lens, it is evident that the polymeric structure takes a portion of its volume while another portion is taken by the water molecules. The amount of oxygen present in the lens can be quantified as equal to the amount of oxygen present in the portion of volume occupied by the water molecules and coherent with the tabulated solubility coefficient (k) [21]. Oxygen solubility in the swollen material (k_{eff}), then, will equal the product between the oxygen solubility coefficient in the water (k_{H_2O}) and W:

$$k_{eff} = Wk_{H_2O} \tag{5}$$

In the temperature range considered, the values reported in the literature for the oxygen diffusion coefficient in water [22] are very close to those reported for the water self-diffusion coefficient [18]. Therefore, we can hypothesize on the basis of qualitative conclusions of the Eyring Theory [23] and the Stokes–Einstein relation that the frictional forces for the dynamics of the oxygen molecules must be comparable to those of bulk water.

Starting from the model described in the previous section, we can formulate the hypothesis that the water self-diffusion coefficient is reduced by the presence of the polymer and by those water molecules interacting with it. Also, the oxygen accessible space is actually that available to water diffusing within the lens. In other words, we can assume that the product $(1 - x_b)$ W quantifies the integral proposed by Amsden [24] and adapted to our case in the formula:

$$\frac{D_{eff}}{D_{H_2O}} = \int_{r^*}^{\infty} g(r)\, dr \tag{6}$$

where $g(r)$ is the function describing the distribution of the radii of the openings between 'bound water hydrated' polymer chains, and r^* is the critical limiting radius required to permit oxygen (or water) diffusion.

Based on these hypotheses, we can calculate the diffusive contribution to oxygen permeability (P_{diff}) of the lens examined, using as the oxygen diffusion coefficient in water the value of the estimated water self-diffusion coefficient (D_{eff}):

$$P_{diff} = D_{eff}k_{eff} \tag{7}$$

4. Results

To validate our model, we have analyzed various hydrogel contact lenses having different hydration values (Table 1).

In Table 2, are reported the results of relaxation time NMR measurements which allowed for the evaluation of the contribution of both 'free' and 'bound' water, and the estimate of D_{eff} according to Eq. (3). An evaluated third component relative to external water (i.e. water surrounding the hydrogel) characterized by T_2 values close to those of pure water is not reported.

Table 2
Results of relaxation time (T_2) NMR measurements for different hydrogels at 35°C

Gel name	Material	T_2 bound (ms)	T_2 free (ms)	H_2O bound (%)	H_2O free (%)
Zero 6	PHEMA	10.1 ± 0.9	220 ± 10	57.5 ± 1.6	42.5 ± 1.6
NewVues	Vifilcon A	44 ± 1	237 ± 5	49.0 ± 0.7	51.0 ± 0.7
Acuvue	Etafilcon A	41 ± 3	290 ± 30	45.6 ± 1.8	54.4 ± 1.8
Proclear	Omafilcon A	40 ± 10	210 ± 20	24.5 ± 4.1	75.5 ± 4.1
Omniflex	MMA/NVP	11 ± 2	310 ± 10	23.2 ± 1.8	76.8 ± 1.8
Precision UV	Vasurfilcon A	9.5 ± 0.9	490 ± 20	22.7 ± 1.4	77.3 ± 1.4

Table 3
k_{eff}, D_{eff}, and P_{diff} values as compared with the permeability values (*DK*) supplied by the manufacturers and evaluated through the Fatt Method at 35°C

Gel name	Nominal EWC (%)	$K_{\mathrm{eff}} \times 10^{-4}$ (cm^{3}O$_2$(STP)/cm^3 of polym. cmHg)	$D_{\mathrm{eff}} \times 10^{-6}$ (cm^2 s^{-1})	P_{eff} (barrers)	Nominal *DK* (barrers)
Zero 6	38	1.23 ± 0.01	4.7 ± 0.2	5.8 ± 0.3	10
New Vues	55	1.79 ± 0.01	8.1 ± 0.1	14.5 ± 0.3	16
Acuvue	58	1.88 ± 0.01	9.1 ± 0.3	17.2 ± 0.6	21.4
Proclear	62	2.01 ± 0.01	13.6 ± 0.7	27.3 ± 1.6	25
Omniflex	70	2.27 ± 0.01	15.6 ± 0.4	35.4 ± 1.0	32
Precision UV	74	2.40 ± 0.01	16.6 ± 0.3	39.8 ± 0.9	38.9

k_{eff} values, instead, were obtained by relating the solubility values [21] to EWC as provided by the manufacturers according to Eq. (5).

In Table 3, we report k_{eff}, D_{eff}, and P_{diff} values as compared with the permeability values (*Dk*) supplied by the manufacturers and evaluated through the electrochemical method at 35°C (Fatt method).

In Table 4, we report D_{w} (defined as 'free' water diffusion coefficient) calculated by McConville and Pope (Table 3 in Ref. [20] for different hydrogels, compared with the data obtained, according to our model, as a product of the EWC measured, and the value of $D_{\mathrm{H_2O}}$ (2.02×10^{-9} m^2 s^{-1}, at 20°C [18]). In the same table are reported the fraction of water molecules specifically bound to the polymer (p_{wb}) (Table 3 in Ref. [20]) and the diffusion coefficient values (D_{app}) calculated according to the 'specific binding model' [20]:

$$D_{\mathrm{app}} = D_{\mathrm{w}}(1 - p_{\mathrm{wb}}) \tag{8}$$

In Table 5, we report the permeability values estimated at 35°C according to our model (P_{eff}), using $D_{\mathrm{H_2O}} = 2.90 \times 10^{-9}$ m^2 s^{-1} [18], EWC and p_{wb} values as reported by McConville and Pope for different hydrogels.

5. Discussion

There is considerable interest regarding the construction of models regarding NMR relaxation measurements of hydrogels, including models of systems and models of data. In terms of data models, often, sum-of-exponential functions are fitted. Unfortunately, these functions, even if they can describe completely the relaxation curves, by themselves, do not necessarily say anything about the hydration mechanism of hydrogels. As a result, they cannot be used, unlike in system modelling, with any degree of confidence for extrapolation or prediction purposes [25]. In spite of these intrinsic limits, models of the data are frequently used in practice to give a physical interpretation of the system, since sum-of-exponentials are a natural solution to NMR relaxation phenomena, and give a classification of water molecules that is in accordance with the model of data used for DSC (i.e. classes of freezing and non-freezing water).

The first step in modelling the system is the choice of a multicompartmental (multistate) model or of a noncompartmental model, to which measurements are referenced. Concomitantly, differential equations representing system dynamics are defined (in the case of multicompartmental models, the exchange between the compartments).

The possibility of classifying water in hydrogels through data models, motivated NMR scientists (because of knowledge of the chemical nature of the used polymer and their possible structure), often inadvertently, to choose a multicompartmental (multistate) model of the system, which consists in different states (compartments) of water, and another compartment constituted by exchangeable polymer protons. The structure of this model, to whom also we refer,

Table 4
D_{w} calculated by McConville and Pope for different hydrogels, compared with the data obtained, according to our model, as a product of EWC measured and the value of $D_{\mathrm{H_2O}}$; the fraction of water molecules specifically bound to the polymer (p_{wb}) and the diffusion coefficient values (D_{app}) calculated according to the 'specific binding model' [20], at 20°C. ($D_{\mathrm{H_2O}} = 2.02 \times 10^{-9}$ m^2 s^{-1}, at 20°C)

Gel name	Measured EWC (%)	EWC × $D_{\mathrm{H_2O}}$ (20°C) × 10^{-6} (cm^2 s^{-1})	$D_{\mathrm{w}} \times 10^{-6}$ (cm^2 s^{-1})	p_{wb} (%)	$D_{\mathrm{w}}(1 - p_{\mathrm{wb}}) = D_{\mathrm{app}} \times 10^{-6}$ (cm^2 s^{-1})
Benz 38	37.1 ± 0.3	7.5 ± 0.1	6.7 ± 1.1	57 ± 20	2.9 ± 1.8
Benz G-5X	58.4 ± 0.3	11.8 ± 0.1	12.5 ± 1.4	42 ± 6	7.3 ± 1.6
Benz 55	58.6 ± 0.3	11.8 ± 0.1	11.1 ± 0.8	47 ± 13	5.9 ± 1.9
Igel 58	57.1 ± 0.3	11.5 ± 0.1	12.4 ± 1.1	45 ± 8	6.8 ± 1.6
Igel 67	67.1 ± 0.3	13.6 ± 0.1	14.7 ± 3.7	41 ± 2	8.7 ± 2.5
Cibasoft	33.0 ± 2.3	6.7 ± 0.5	4.7 ± 1.0	56 ± 49	2.1 ± 2.7
SeeQuence2	33.8 ± 2.1	6.8 ± 0.4	6.9 ± 0.4	60 ± 96	2.8 ± 6.8
NewVues	52.7 ± 2.0	10.6 ± 0.4	9.1 ± 1.9	48 ± 13	4.7 ± 2.2
Acuvue	55.9 ± 2.1	11.3 ± 0.4	11.5 ± 5.3	44 ± 32	6.4 ± 6.6

Table 5
The permeability values estimated at 35°C according to our model (P_{eff}), EWC and p_{wb} values as reported by McConville and Pope [20] for different hydrogels. ($D_{\mathrm{H_2O}} = 2.90 \times 10^{-9}$ $\mathrm{m^2\ s^{-1}}$, at 35°C)

Gel name	Measured EWC (%)	$K_{\mathrm{eff}} \times 10^{-4}$ ($\mathrm{cm^3 O_2}$(STP)/$\mathrm{cm^3}$ of polym. cmHg)	$D_{\mathrm{eff}} \times 10^{-6}$ ($\mathrm{cm^2\ s^{-1}}$)	P_{eff} (barrers)
Benz 38	37.1 ± 0.3	1.20 ± 0.01	4.6 ± 0.2	5.6 ± 0.3
Benz G-5X	58.4 ± 0.3	1.90 ± 0.01	9.8 ± 0.1	18.6 ± 0.3
Benz 55	58.6 ± 0.3	1.90 ± 0.01	9.0 ± 0.2	17.1 ± 0.5
Igel 58	57.1 ± 0.3	1.85 ± 0.01	9.1 ± 0.1	16.9 ± 0.3
Igel 67	67.1 ± 0.3	2.18 ± 0.01	11.5 ± 0.1	25.0 ± 0.2
Cibasoft	33.0 ± 2.3	1.07 ± 0.01	4.2 ± 0.5	4.5 ± 0.6
SeeQuence2	33.8 ± 2.1	1.10 ± 0.01	3.9 ± 1.0	4.3 ± 1.1
NewVues	52.7 ± 2.0	1.71 ± 0.01	7.9 ± 0.2	13.6 ± 0.5
Acuvue	55.9 ± 2.1	1.81 ± 0.01	9.1 ± 0.6	16.5 ± 1.1

leave out of consideration ‘experimental visibility’ of all different compartments. Therefore, the purpose of many such studies is to determine the proportion between the size of different compartments and, eventually, measuring exchange constants. For hydrogels the exchange is defined as ‘chemical’ if it involves the compartment of exchangeable polymer protons and ‘diffusive’ if it occurs between different classes of water, including water molecules surrounding the hydrogels (external water).

In order to construct a *model of the system* it is necessary to have a precise definition of the matter to be modelled; i.e. the number of compartments that constitute the physical system, and the times that characterize it, so as to have in a correct appreciation of the dynamics of studied physical properties. For these reasons constraints emerge on the sampling rate, that are not necessary in the application of model of data.

In other words, using a model of data, the NMR measurements can be fitted to an exponential or sum-of-exponential function, but the assignment of physical significance to the determined parameters is not straightforward. Additionally, the results obtained using different sample protocols, different sampling rates, or different pulse spacing can be inconsistent. Thus, it is possible to make some compartments not NMR visible and/or obtain relaxation times and parameters that show different proportions between classes.

These concerns motivated our choice of studying commercial contact lenses, having standard chemico-physical characteristics, completely immersed in physiologic solution to guarantee the maximum degree of hydration, and of doing the experiments at a temperature close to eye temperature. Furthermore, we used measurement times that allow for visibility of all water components, even if our attention was only on water in the hydrogel.

In a recent paper by McConville and Pope [26], using measurement of transverse relaxation times (T_2) of water in hydrogel, some themes were addressed which have been previously discussed by Barbieri et al. [19] regarding chemical exchange, and confirmed the classification of water molecules into classes characterized by different mobility. Nevertheless, it is impossible to make a direct comparison of the results obtained with ours because, besides using a different sampling rate and different pulse spacing, the system studied by them has a completely altered hydration status (Table 1 in Ref. [26]). (This status was probably due to the temperature of hydration of 80°C and to further dehydration during measurements.) This hypothesis is confirmed through data that the same authors reported in another study [20]. These data show for the same polymers different values of p_{wb} and EWC — very near to those declared by manufacturers.

Our studies show new aspects of a diffusive exchange mechanism that increases the information about details of a developing model of hydrogel lenses. To justify our results, this model needs an effective mobility of water molecules in hydrogel limited by the molecules in major interaction ‘bound’ with the polymer. At the same time, the chemical exchange phenomena do not influence the dynamics of ‘free’ water molecules, but only determine the value of relaxation time of ‘bound’ water molecules. In fact, McConville and Pope [20], studying the behaviour of materials which contain exchangeable polymer protons and those that do not, have demonstrated from measurements of water self-diffusion coefficients obtained with NMR techniques, the relationship between water mobility and the ‘bound’ water content within the contact lens.

In this paper, we show that from relaxation time NMR measurements, it is possible to evaluate the percent of ‘bound’ water within a swollen polymer and estimate D_{eff} using a simple obstructive model.

In distinction from Pope’s model, our model introduces the obstructive term W, thereby supporting the obstruction model for diffusion within hydrogels as proposed by Yasuda et al. [27,28].

The use of relaxation data by applying a mathematical method to estimate the lens water self-diffusion coefficient instead of performing a direct NMR measurement as proposed by other scientists [19,20], has the advantage of allowing for a smaller sample, e.g. on a single lens. Actually, the techniques allowing a direct measurement, e.g. pulse filed gradient (PFG) spin-echo [29], use gradient pulses that dramatically attenuate the echo signal, even below a detectable threshold in the case of samples with a poor water content.

The data we obtained are, within the limits of the experimental error, consistent with the self-diffusion coefficient values as measured in lenses having the same hydration as that studied by McConville and Pope, as reported in Table 4.

For lenses having a higher hydration gradient, the application of our model using both the data from our measurements (Table 3) and those reported by McConville and Pope (Table 5), has yielded P_{diff} values at 35°C in agreement with those obtained by manufacturers through the electrochemical method. These results agree with the hypothesis that permeation of a contact lens having a high hydration degree may occur through mechanisms that are in principle diffusive.

For materials with lower water content, the calculated P_{diff} values are found to be lower than stated. This difference can be due to both the diffusive and the viscous fluxes contributing to permeation during the polarographic measurement.

The parameters that may influence the predominant type of flux are: 1) the size of the matrix pores; 2) the size of the molecules permeating the material; and 3) interactions occurring between the permeating agent and the material, that can be well characterized through T_2 relaxation time NMR measurements.

Lenses with a low hydration degree are found to be physiologically well tolerated, since the water inner diffusive characteristics do not substantially change. However, the different size of pores, characterizing the polymeric network, may explain the impossibility of permeation by other molecules; i.e. the so-called 'membrane phenomena'. If an osmotic phenomenon occurs, leading to a viscous flux toward the electrode of water and the oxygen diluted therein, it may exhibit a greater flux of oxygen through the lens than expected.

6. Conclusions

The obtained results demonstrate that it is possible to estimate the water self-diffusion coefficient in the materials examined through T_2 relaxation time NMR measurements, thereby enabling the evaluation of samples, of a relatively small size, and not particularly hydrated.

The proposed model allows for the evaluation of the diffusive contribution to permeation of lenses by oxygen and demonstrates that, for lenses with a high water content, it accounts for permeability as measured by electrochemical methods (Fatt method).

For materials with a lower water content, instead, it is necessary to hypothesize a further contribution to permeation, attributable to a viscous flux responsible for an increased oxygen flux during the measurements performed by the Fatt method.

This approach may be useful for evaluating the diffusive contribution in hydrogel lenses and for designing mathematical models that may help in understanding the complex function of these lenses in the eye.

Finally, the method proposed here is a useful tool for evaluating the best system to handle contact lenses, as well as for determining the most efficient methods for removing substances that may alter the material permeability, and for characterizing the best materials for contact lenses.

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