Oxygen permeability measurements of contact lenses: a proposal for accuracy improvement

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Abstract— **Contact lens are a widespread medical device. In view of the importance of a proper oxygenation of the cornea, new materials are continuously being tested, with a high permeability to oxygen. Taking into account the limitations of the methods for testing soft contact lenses, as presented in the relevant international standards, this paper focuses on the polarographic method and on the approach of measuring oxygen permeability of stacked contact lenses. The effect of the interspersed saline solution layers on the measurable permeability of the stack is considered, using Fick's law of diffusive flux, and a proposal for accuracy improvement in oxygen permeability measurements is presented.**

I. INTRODUCTION

Soft contact lenses have marked a great advancement in the field of contact lenses with respect to traditional lenses, due to the higher comfort experienced by the user [1],[2]. Moreover, an increase in oxygen permeability was also allowed by these new lenses, which has a beneficial effect in the prevention of hypoxia-associated pathologies of the eye [3]-[5].

In the recent past, the emergence of hyperpermeable lenses (i.e., with a higher oxygen permeability than water) is being observed in the sector of soft contact lenses [2],[3].

According to the normative ISO 18369-1:2006/Amd 1:2009 (Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labeling specifications - Amendment 1), oxygen permeability Dk is defined as the oxygen flux, j, under specified conditions through contact lens material of unit thickness when subjected to unit pressure difference. Oxygen permeability Dk is expressed in units of 10^{-11} (cm^2/s) [ml O$_2$/(ml·hPa)]. With this convention, the units for Dk are referred to as "Dk units".

Due to the importance of oxygen permeability, it is essential to improve the methodologies adopted to measure such a quantity. It must be recalled that the latest international normative regarding contact lenses (ISO 18369-4: 2006 - Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials) poses some limitations about the samples whose permeability is to be measured: the first method (the polarographic method) is applicable to all types of materials, provided that the oxygen permeability is at most equal to 145 Dk units, whereas the second one (the coulometric method) is applicable only to non-hydrogel materials.

The polarographic method is applicable to the determination of the corrected oxygen permeability (Dk) of rigid and non-hydrogel flexible materials in the form of contact lenses, incorporating various refractive powers and rotationally symmetric lens geometries, and corrected oxygen permeability (Dk) of hydrogel and non-hydrogel, rigid and flexible contact lens materials in the form of standardized test samples. The polarographic method directly measures the number of oxygen molecules diffusing through a test material by electrochemically removing the molecules from solution as soon as they pass through the material. As a molecule of oxygen emerges from the sample material, it contacts the centre electrode (cathode) of the oxygen sensor, placed against the back surface of the sample, and is instantaneously converted to four hydroxyl ions. This production of ions constitutes the electric current which is quantified by the apparatus, and which is proportional to the number of molecules removed. The measured current is used to calculate the preliminary (uncorrected) oxygen transmissibility, Dk/T, where T is the thickness of the sample.

For high-permeability hydrogel lenses, the limitation of the polarographic method may be a problem, whereas the applicability of coulometric method is denied by the normative.

In order to overcome these limitations, Weissman and Fatt [6] proposed a modified polarographic method, involving the measurement of more than one lens, assembled in stacks. In this approach, measurements on stacks with different numbers of lenses are analyzed in order to extract a robust value of the permeability as obtained by the polarographic method.

A stack of lenses, though, can not be considered simply as the sum of its lenses: as demonstrated by Efron et al. [7], the total thickness of the stack is always higher than the sum of the thicknesses of the single lenses. This effect is attributed to the presence of thin layers of saline solution between the lenses constituting the stack.

In this paper, we propose a model for taking into account, in the determination of the lens permeability, the presence of these layers of saline solution, which tend to give an underestimation of the actual Dk value, in the case of high-permeability lenses.

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II. MATERIALS AND METHODS

Each contact lens composing the stack is hereby modelled as a planar sample, of thickness T_{lens}. In the space between two consecutive lenses it is assumed that a layer of saline solution of thickness T_w is present.

The permeability of the two phases is Dk_{lens} and $Dk_w = 80$ Dk units for the lens and the saline solution, respectively.

For the sake of simplicity, the thicknesses of the lenses and the layers of saline solution are assumed to be constant. The generalization to the case of unequal thicknesses can be readily obtained.
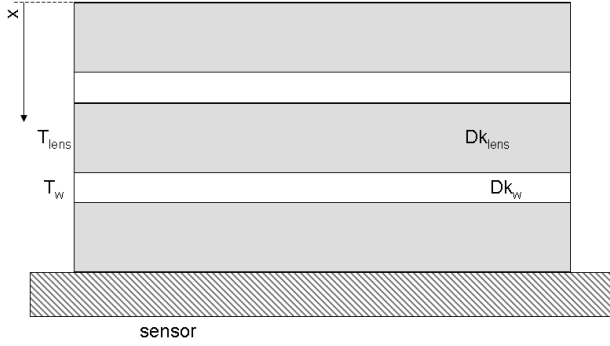

Fig. 1 – Model of the lens stack (in the example, N=3 lenses), lying on the polarographic sensor surface.

The flux of O_2 is related to the permeability as follows. Fick's first law relates the diffusive flux to the relevant species' concentration field, by postulating that the flux goes from regions of high concentration to regions of low concentration, with a magnitude that is proportional to the concentration gradient (spatial derivative). In one spatial dimension, this is described by the following:

$$J = Dk \frac{\partial \rho}{\partial x} \qquad (1)$$

Since the molecules of O_2 are immediately decomposed at the surface of the polarographic sensor, we can state that, on this surface, the concentration of O_2 is zero. Considering at first only a layer of given properties (Dk,T), the oxygen flow will be given by

$$J = Dk \frac{\partial \rho}{\partial x} = Dk\left(-\frac{n(0)}{T}\right), \qquad (2)$$

where $n(0)$ represents the oxygen concentration at the free surface of the layer, opposite to the sensor. The minus sign is due to the orientation of the x axis (Fig. 1).

Then, for every given value of the concentration of O_2 at some distance form the sensor, the current J is proportional to Dk/T.

If we consider a stack of layers at different values of Dk, the concentration gradient will be no more uniform.

Due to continuity of oxygen flow, at the two sides of an interface between different materials, located at the abscissa x, the following relation applies:

$$J|_{x^-} = J|_{x^+} . \qquad (3)$$

Hence,

$$\left.\frac{\partial \rho}{\partial x}\right|_{x^-} = \frac{Dk^+}{Dk^-}\left.\frac{\partial \rho}{\partial x}\right|_{x^+} \qquad (4)$$

At the generic abscissa x, the oxygen concentration is given by

$$n(x) = n(0) - \int_0^x \frac{\partial \rho}{\partial s} ds . \qquad (5)$$

In this formula, the values of x are assumed increasing from the value 0, at the free surface, towards the sensor.

The integral in Eq. (5) can be split in as many integrals as layers in the stack. For the case of 2 lenses and 1 layer of saline solution,

$$\int_0^T \frac{\partial \rho}{\partial s} ds = \int_0^{T_{lens,1}} \frac{\partial \rho}{\partial s} ds + \int_{T_{lens,1}}^{T_{lens,1}+T_{w,1}} \frac{\partial \rho}{\partial s} ds$$
$$+ \int_{T_{lens,1}+T_{w,1}}^{T_{lens,1}+T_{w,1}+T_{lens,2}} \frac{\partial \rho}{\partial s} ds \qquad (6)$$

$T = T_{lens,1} + T_{w,1} + T_{lens,2}$ being the total thickness of the stack.

Substituting the constant concentration gradient in each layer, using Eq. (4) and making the position $\beta_0 = \left.\frac{\partial \rho}{\partial s}\right|_{x=0}$,

$$\int_0^T \frac{\partial \rho}{\partial s} ds = \int_0^{T_{lens,1}} \beta_0 ds + \int_{T_{lens,1}}^{T_{lens,1}+T_{w,1}} \frac{Dk_{lens}}{Dk_w} \beta_0 ds$$
$$+ \int_{T_{lens,1}+T_{w,1}}^{T_{lens,1}+T_{w,1}+T_{lens,2}} \frac{Dk_w}{Dk_{lens}}\left(\frac{Dk_{lens}}{Dk_w} \beta_0\right) ds \qquad (7)$$

which can be simplified (we assume that the thicknesses of the lenses are the same, as well as the thicknesses of the saline solution layers) as

$$\int_0^T \frac{\partial \rho}{\partial s} ds = 2\int_0^{T_{lens}} \beta_0 ds + \int_0^{T_w} \frac{Dk_{lens}}{Dk_w} \beta_0 ds . \qquad (8)$$

Since

$$\int_0^T \frac{\partial \rho}{\partial s} ds = -n(0) \qquad (9)$$

we have from Eq. (8) that the oxygen concentration gradient at the free surface (and also in each lens of the stack) can be written as

$$\beta_0 = \left.\frac{\partial \rho}{\partial s}\right|_{x=0} = -\frac{n(0)}{2T_{lens} + \dfrac{Dk_{lens}}{Dk_w}T_w}, \qquad (10)$$

whereas the concentration gradient in each layer of saline solution is given by

$$\beta_w = \left.\frac{\partial \rho}{\partial s}\right|_{x=T_{lens,1}} = -\frac{Dk_{lens}}{Dk_w}\frac{n(0)}{2T_{lens} + \dfrac{Dk_{lens}}{Dk_w}T_w}. \qquad (11)$$

These formulas can be readily generalized for a stack of N lenses as follows:

$$\beta_0 = \left.\frac{\partial \rho}{\partial s}\right|_{x=0} = -\frac{n(0)}{NT_{lens} + (N-1)\dfrac{Dk_{lens}}{Dk_w}T_w} \qquad (12)$$

$$\beta_w = \left.\frac{\partial \rho}{\partial s}\right|_{x=T_{lens,1}} = -\frac{Dk_{lens}}{Dk_w}\frac{n(0)}{NT_{lens} + (N-1)\dfrac{Dk_{lens}}{Dk_w}T_w}. \qquad (13)$$

Figure 2 reports the oxygen concentration for stacks of different size (N=1, 2, 3 lenses). In this case, the parameters are relative to the Acuvue 1-day lens type (Dk=21.4, T_{lens} =111 μm), as reported in [7]. Accordingly, the decrease of oxygen concentration is less steep in the aqueous layers (where Dk=80).
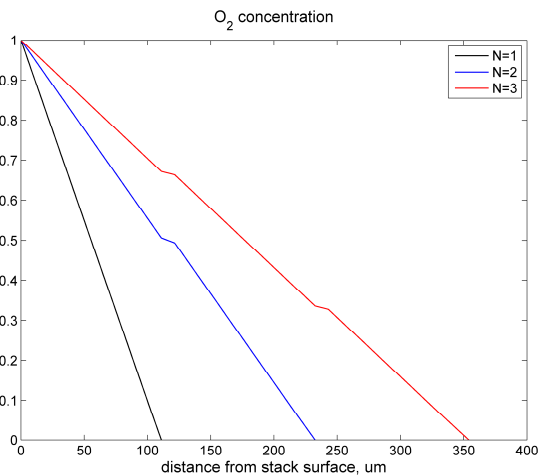

Fig. 2 – O$_2$ concentration as a function of the distance from the free surface of stack, for different compositions of the latter (N=1, 2 or 3 lenses)

The oxygen flux given by Eq. (12), after multiplication by Dk_{lens}, can be thought to be associated to a single layer of a suitable lens, having a thickness equal to T_{eq} and a diffusion coefficient Dk_{eq}, such that

$$J = Dk_{eq}\frac{\partial \rho}{\partial x} = Dk_{eq}\left(-\frac{n(0)}{T_{eq}}\right) \qquad (14)$$

Letting T_{eq} be equal to the sum of the thickness of the stack's lens, $T_{eq} = NT_{lens}$, we can write

$$Dk_{eq}\frac{n(0)}{T_{eq}} = Dk_{lens}|\beta_0| =$$

$$= Dk_{lens}\frac{n(0)}{NT_{lens} + (N-1)\dfrac{Dk_{lens}}{Dk_w}T_w}, \qquad (15)$$

whence

$$Dk_{eq} = \frac{T_{eq}\,Dk_{lens}}{NT_{lens} + (N-1)\dfrac{Dk_{lens}}{Dk_w}T_w} =$$

$$= \frac{Dk_{lens}}{1+\left(\dfrac{N-1}{N}\right)\dfrac{Dk_{lens}}{Dk_w}\dfrac{T_w}{T_{lens}}} \qquad (16)$$

Of course, when N=1, the formula (16) simply states that $Dk_{eq} = Dk_{lens}$.

From (16), since the denominator is always ≥ 1, it can be seen that the presence of the saline solution layers in the lens stack leads to an underestimation of the measured value of Dk (i.e., Dk_{eq}) with respect to the actual value Dk_{lens}, if one considers the thickness of the stack to be given by the sum of the thickness values of the lenses. The underestimation applies for both low- and high-permeability lens types.

In the calculation of the oxygen concentration curves of Fig. 2, use has been made of the least square fit of data relative to Acuvue 1-day reported in [7], according to the model herein presented: the thickness of the saline solution layer was 10.51 μm, whereas the mean lens thickness was 111 μm.

III. RESULTS

In order to assess the role of the aqueous layers between lenses, it is convenient to invert (16), whence the following formula applies:

$$Dk_{lens} = \frac{Dk_{eq}}{1-\left(\dfrac{N-1}{N}\right)\dfrac{Dk_{eq}}{Dk_w}\dfrac{T_w}{T_{lens}}}. \qquad (17)$$

Here Dk_{eq} represents the *measurable* value of oxygen permeability, considering the stack of lenses as a single lens of thickness equal to the sum of lenses, whereas Dk_{lens} is the corrected value, after taking into account the saline solution layers interspersed between the lenses.

From (17), we can calculate the effect of different values of lens thickness and Dk_{eq}.

Fig. 3 shows the relative difference (%) between Dk_{lens} and Dk_{eq}, having set T_w = 10 μm as a typical value, and N=2. The values of T_{lens} were allowed to vary between 50 and 150 μm. Values of measurable permeability were chosen in the range 20-180 Dk units.

Fig. 4 reports the same quantity as in Fig. 3, but with N=4. It is evident how the larger number of lenses in the stack entails higher differences between Dk_{lens} and Dk_{eq}. However, even at N=2 the difference can be quite large, up to 29% for Dk_{eq} =180 and T_{lens} =50 μm (Fig. 3).
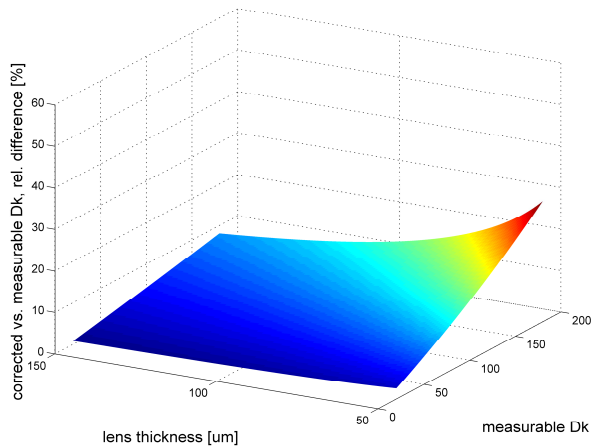

Fig. 3 – Relative difference between corrected and measurable O_2 permeability, as a function of lens thickness and measurable O_2 permeability (N=2 lenses)
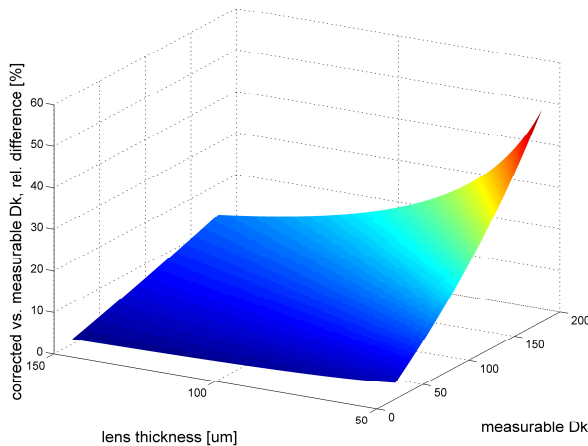

Fig. 4 – Relative difference between corrected and measurable O_2 permeability, as a function of lens thickness and measurable O_2 permeability (N=4 lenses)

The results of this study indicate that it is not possible to neglect the role of the aqueous layers in the modified polarographic method of lens stack measurement proposed by Weissman and Fatt [6]. Otherwise, a remarkable underestimation may be expected, especially for small lens thickness; moreover, hyperpermeable lenses give rise to such an underestimation, as well.

The deviation of the measurable permeability value from the corrected value should be judged referring to the relevant normatives. In the standard ISO 18369-4:2006 (Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials), it is requested that the repeatability of oxygen permeability measurements be 10% or less. As for the accuracy, no particular value is required, but it is suggested to determine the measuring accuracy over an appropriate range of measurement, the reference Dk of the materials used in such a determination being known to ±5%. As an example of commercial equipments, the technical data [8] of the Model 201T Permeometer (Createch, USA) report an accuracy for current measurements (directly proportional, through Eq. (2), to Dk/T) of 0.5% of reading.

These values confirm that neglecting the role of the finite width of aqueous layers in the lens stack may give an effect also larger in magnitude than the requirements for accuracy and repeatability stated by the relevant international normatives.

IV. CONCLUSION

A model was presented which enables to take into account the finite width of aqueous layers, when the oxygen permeability of ophthalmic lenses is measured by stacking them and performing polarographic measurements. The results suggest that a correction to measured Dk values should be made, since the role of the interspersed layers can not be neglected, especially with hyperpermeable lenses (i.e., those with Dk > 80 Dk units). The model can be used to improve the accuracy of lens permeability measurements, which are an important step in the assessment of the performance of such devices.

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