## instruments/techniques

# Stacking Samples While Measuring Oxygen Transmissibility of Hydrogel Contact Lenses

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#### **ABSTRACT**

It is necessary to measure several samples with different thicknesses of the same material to be able to determine a value for the oxygen permeability (Dk incm² mi  $O_2$ /s ml mm Hg) of that material. Some current contact lens materials are not available in multiple thicknesses, but it might be possible to "stack" several samples of the same thickness as an alternative procedure. This study demonstrates that measurements of Dk for one particular midwater-content hydrogel (Methafilcon, a nominally 55% water-content ionic material) give statistically indistinguishable results whether single samples of various thicknesses (Dk =  $20.52 \times 10^{-11}$ ) or thinner stacked samples to attain similar thicknesses (Dk =  $20.05 \times 10^{-11}$ ) are used in this measurement.

Key Words: oxygen transmissibility and permeability, contact lenses

The oxygen transmissibility (Dk/L) of contact lenses and the permeability of their materials (Dk) have been measured by the polarographic method of Fatt and St Helen<sup>1, 2</sup> for the past 20 years. This method was a modification of earlier work of Aiba and his colleagues.<sup>3</sup> The introduction of high permeability hydrogel contact lenses has brought about the need for improvements in the original methodology.

As the oxygen permeability of a sample increases toward the permeability of water (about  $80 \times 10^{-11}$ ),<sup>2</sup> any water layer(s) on either surface of the sample begin to participate in the resistance to oxygen flux detected by the polarographic cathode. Under these conditions, the problem becomes one of resistance in series. This was recognized by Fatt

and St Helen¹ but was not significant in their study because the transmissibilities of their samples were relatively low. Such water layers may also become significant when the sample is measured with both surfaces in fluid⁴ or when there is a thicker layer of water held between the sample and the cathode.

Fatt and Chaston's solution to this problem was to measure the oxygen transmissibility of several samples of different thicknesses, and then plot the reciprocal of oxygen transmissibility (L/Dk in s ml mm Hg/cm ml O<sub>2</sub>)<sup>a</sup> vs. sample thickness (L in cm) (Refojo et al.6 described a similar technique somewhat earlier). The data then appear linear in form. and the slope of the linear regression of data points should be 1/Dk. Also it is worthwhile to note that the intercept of the linear regression on the L/Dk axis is the diffusional resistances of all boundary layers. More recently, both Fatt et al. and Brennan et al.8 have recognized an additional "edge effect." They suggest that Dk and Dk/L will be overestimated when measured in the polarographic cell due to the finite size of the cathode. This is due to the ability of the cathode to collect diffusing oxygen from an area in the sample somewhat greater than its own diameter. Fatt et al.7 proposed a simple correction factor for the edge effect with hydrogels: flux ratio = 1.00 + 4.72 L for a cathode which has a diameter of 4 mm. They later extended their treatment to all cathode diameters.9

Therefore, use of the one-chamber polarographic method of Fatt and St Helen¹ to determine the Dk of a hydrogel material currently dictates measurement of Dk/L for several samples of the same plastic with different thicknesses as well as correction for the edge effect at each measurement. Unfortunately, several modern contact lens materials are not available in substantially different thicknesses; for one example, recently introduced collagen shields are molded in only one thickness (about

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<sup>\*</sup>Note that these units will be used throughout this paper.

0.15 mm).10 When multiple thicknesses are not available, it is difficult to measure Dk with sufficient precision. Direct multiplication of the Dk/L determined in the polarographic cell from one or more samples by the average thickness (L) of the sample(s) has been shown to be improper, except when transmissibility is very low.5 Alternative methods of obtaining a value for Dk of a hydrogel material include: (1) estimation based on water content of the material from a formula<sup>5</sup> presented by Fatt and Chaston, and (2) it is proposed here that it may be possible to stack several thin samples in the polarographic cell to simulate use of at least four different thicknesses of material. The linear regression method as described above, corrected for both boundary and edge effects, may then be used for measurement of Dk.

Stacking samples may introduce errors—for example if air or fluids are trapped between the layers, or if each boundary acts in other ways to increase the resistance to oxygen. This study therefore investigates the feasibility of using stacked samples in the polarographic oxygen cell in the measurement of Dk of a hydrogel contact lens.

#### MATERIALS AND METHODS

Seven samples of a hydrogel contact lens material were made available by Coastvision of Huntington Beach, California for measurement in this study. All samples were specially manufactured concentric surfaced spherical shells<sup>11</sup> of Hydrosoft (Methafilcon A, a nominally 55% water, ionic hydrogel material). This material was selected because it is a midwater-content hydrogel and results might also be applicable to both lower and higher water-content materials. Because they were not to be used on eyes, peripheral curve systems were not applied to these shells. Four samples were ordered with nominal thicknesses of 0.10 mm, and one each was

ordered at 0.20, 0.30, and 0.40 mm, respectively (concentric surfaced shells should have parallel surfaces and therefore constant thicknesses). These samples were supplied, hydrated in 0.9% saline, in shipping vials. The laboratory also provided electronically measured thicknesses (see Table 1) for the shells which differed only slightly from ordered values.

The same basic methodology described by Fatt and his co-workers<sup>1, 2, 5</sup> to measure the oxygen transmissibility of hydrogel materials was used here, with the same assumptions and precautions. A polarographic oxygen sensor (Roche no. 8396), consisting of a 4-mm diameter gold cathode and silver-silver chloride ring anode, was mounted on a specially constructed plastic holder. This was connected to a Schema Versatae 920A amplifier (previously calibrated with three known resistors), which maintained voltage between the anode and cathode at a constant 0.7 V and both amplified and measured the resultant current, which was then recorded on a linear strip chart recorder.

Dk/L is temperature-dependent, so the entire apparatus was maintained at 35°C by using a surrounding styrofoam box and an enclosed 60 W light bulb controlled by an Oven Industries 5C5-335 thermostat. Paper towels saturated in hospital grade sterile irrigation water were placed on the floor of the box to maintain high humidity so that samples would not change in hydration during the course of measurement. Four hours were allowed for temperature and humidity equilibration within the box before any measurement of samples. The contact lenses and a container of the unpreserved saline were also kept within the styrofoam box for thermal equilibration during this 4-h period.

The Dk/L values of all the single samples of various thicknesses were measured one time each, and then two 0.10-mm thick samples, three 0.10-mm thick samples, and all four 0.10-mm thick

Table 1. Measurements of sample thickness (electronic thickness gauge), water content (hand refractometer), and oxygen transmissibility (as measured on the polarographic cell at 35°C) for seven samples of Hydrosoft (Methafilcon A); data corrected for the edge effect (L/Dk<sub>e</sub>) is shown as well.

Lens No.4	L (cm)*	L <sub>m</sub> (cm)⁵	% H₂O°	Dk/L × 10 <sup>-98</sup>	L/Dk × 107°	$L/Dk_e \times 10^{7d}$
Single samples						
1	0.010	0.011	57	15.3	6.52	6.86
2	0.011	0.010	57	13.6	7.33	7.68
3	0.010	0.010	58	13.6	7.33	7.68
4	0.010	0.010	57	14.3	6.98	7.31
5	0.021	0.022	59	8.5	11.73	12.95
6	0.030	0.030	59	6.8	14.67	16.74
7	0.041	0.043	59	5.1	19.56	23.52
		Sum of				
Stacked samples		thicknesses				
1 + 2		0.021		8.2	12.22	13.43
2 + 3 + 4		0.030		7.2	13.97	15.95
1 + 2 + 3 + 4		0.041		5.1	19.56	23.34

<sup>\*</sup> As indicated by manufacturer.

<sup>&</sup>lt;sup>b</sup> Measured values.

<sup>&</sup>lt;sup>c</sup> Uncorrected.

With edge effect correction.

samples were measured in stacks. All samples were allowed at least 10 min to rehydrate in their vials in 0.9% saline at 35°C between trials. Before measurement, a single drop of preheated unpreserved 0.9% saline (Bausch & Lomb Hypoclear) was placed on the electrode surface. Each single contact lens sample was removed from its shipping vial, its surfaces dabbed dry with a single sheet of lint-free tissue, and then placed flat (concave side upward) onto the electrode. The sample was held in place by a plastic tube covered by a small piece of nylon mesh. For measurement of multiple samples, they were stacked carefully, concave side down, in known order, on the nylon mesh of the plastic holding tube. Any observed bubbles between samples were manually removed, and then the tube inverted and inserted into the holder so that the samples were held flat, now concave side upward on the electrode surface. Any residual fluid was removed before measurement with a cotton-tip applicator.

When the cell was turned on with the sample(s) in place, it took between 1 and 5 min for the tracing on the chart recorder to reach an asymptote. Previous work has shown that current is related directly to Dk/L of the sample<sup>1,2</sup> at this steady-state condition. Current was measured by the described and calibrated device, and Dk/L was then calculated as described previously.<sup>2,5</sup> (Dark current of our device was measured immediately before sample measurement, and was found to be too small to make any contribution to these calculations.)

After rehydration for an additional 5 to 10 min in fresh 0.9% saline at 35°C, an electronic thickness gauge was used to remeasure thicknesses (L in cm) of all samples, 12 and then after another 5 to 10 min of rehydration a hand refractometer (Fisher Brix 28–62%) was used to measure the water content of each sample. 13

The reciprocal of each Dk/L value was taken and plotted against thickness. The values for thickness actually measured were used both for single samples and summed for stacked groups of samples. Each L/Dk value was then multiplied by  $[1 + (4.72 \times L)]$  as described by Fatt et al. to correct for the edge effect. This value (L/Dk<sub>e</sub>) was then plotted on the same graph. A linear regression was taken for each

**TABLE 2.** Linear regression parameters for graphical data where y = slope x + intercept, or:

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- /1/DE

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	Uncorrected	Data Corrected for Edge Effect			
	Data	Single samples	Stacked samples		
Intercept	$3.15 \times 10^{7}$	$2.35 \times 10^{7}$	$2.27 \times 10^{7}$		
Slope	$3.83 \times 10^{9}$	$4.87 \times 10^{9}$	$4.98 \times 10^{9}$		
1/slope (pre- dicted Dk <sub>material</sub> )	26.12 × 10 <sup>-11</sup>	20.52 × 10 <sup>-11</sup>	20.05 × 10 <sup>-11</sup>		
Correlation coefficient (r)	0.9967	0.9974	0.9921		

of these data sets. See Table 2 for the parameters of the linear regressions of this information.

#### **RESULTS**

Measured values of both L and Dk/L for each sample are shown in Table 1. Measured water content, noted to be slightly higher than the nominal 55% for this material, is also shown on the table.

Simple multiplication of Dk/L by L for each sample gives a value for Dk of this material ranging

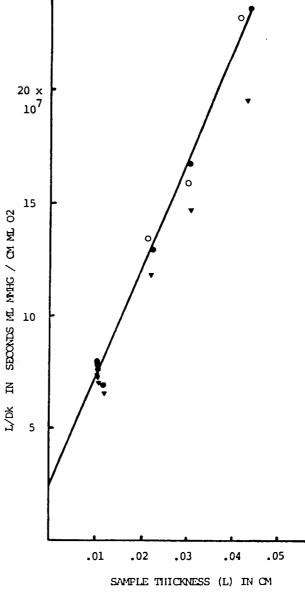


Figure 1. Reciprocal of oxygen transmissibility (L/Dk, in s ml mm Hg/cm ml  $O_2$ ) is graphed against sample thickness (L in cm). Inverted filled triangles indicate uncorrected data points for single samples of different thicknesses as indicated. Filled circles represent the same points after the edge correction has been made as noted in the text; solid oblique line is linear regression of these data. Open circles represent data points for stacked samples of summed thicknesses as indicated. See Table 2 for linear regression parameters for all data.

from 13.60 to 21.93  $\times$  10<sup>-11</sup> cm ml O<sub>2</sub>/s ml mm Hg, with a mean of 17.05  $\times$  10<sup>-11</sup> (SD of 3.40  $\times$  10<sup>-11</sup>).

A graph was prepared for L/Dk vs. L (see Fig. 1). Using the values for L/Dk uncorrected for edge effects on this graph leads to a linear regression which calculates a Dk for this material of  $26.12 \times 10^{-11}$ . However, correction for the edge effect using the several single samples of differing thickness gives  $Dk/L_e$  and from this a Dk of  $20.52 \times 10^{-11}$  is derived. Substituting the stacked samples for the thicker single samples suggests a calculated Dk of  $20.05 \times 10^{-11}$  (see Table 2).

#### DISCUSSION

These latter two values appear very similar, and inspection of the figure suggests that the linear regressions cannot be greatly different. Following a method described earlier by Fatt, 14 statistics were used to give a 95% confidence interval for the edge effect-corrected value of Dk determined by use of the single samples of various thicknesses, and this was determined to be  $\pm 3.14 \times 10^{-11}$ , meaning that any values of Dk between  $17.38 \times 10^{-11}$  and 23.66 $\times$  10<sup>-11</sup> should be statistically indistinguishable. This calculation therefore agrees with inspection and suggests that the values for Dk determined with either single samples of various thicknesses or stacked samples of similar thickness are statistically similar. However, the values for Dk suggested by either direct multiplication or use of the linear regression of values uncorrected for edge effects both fall outside of this confidence interval.

We therefore conclude that the Dk measured by use of the stacked samples is equivalent to that measured with a series of samples of different thickness. Alternatively it appears quite reasonable to alternatively use stacked samples for measurement of oxygen permeability whenever a series of samples of different thicknesses are unavailable.

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