OXYGEN TRANSMISSIBILITY IN VARYING EXTENDED WEAR SOFT CONTACT LENS DESIGNS AND POWERS

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ABSTRACT

Background: The oxygen transmission (Dk/t) ratings of soft contact lenses are generally based on the center of a lens with a -3.00 diopter (D) profile. This study investigated if changes in prescription power caused a clinically significant decrease in the oxygen transmissibility at the thickest part of the lens. *Methods*: A volunteer was asked to wear several different powers of extended wear contact lenses from varying manufacturers. An anterior segment optical coherence tomographer (OCT) was used to assess the lens profile on the eye and to measure the central and/or thickest point of the lens. These values were then used to recalculate the Dk/t to compare them to the industry standards. *Results*: Oxygen transmissibility is variable depending on the profile of the lens. Minus powered lenses exhibited lower Dk/t in the peripheral aspects of the lens; the opposite was found to be true for plus powered lenses. *Conclusions*: Contact lens profiles vary based on the power of the lens, which can in turn affect the oxygen transmissibility and theoretically impact corneal health. Prescribing clinicians should be aware of the increased risks with extended wear contact lens use, especially in patients with high refractive error.

Key words: contact lenses, extended wear, oxygen transmissibility, cornea

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INTRODUCTION

Extended wear contact lenses offer patients the convenience of continued wear, day and night, for as long as 30 consecutive days. The ease of use with this modality has become increasingly popular with lens wearers and has challenged manufactures to develop safer and more effective designs. The largest hurdle to overcome has always been maintaining appropriate oxygen availability to allow healthy corneal metabolic activity to occur, especially during closed eye conditions.[1] This oxygen transmissibility (Dk/t) can be measured and varies primarily based on the composition and thickness of the lens material.[2,3]

Corneal hypoxia secondary to contact lens wear can lead to a number of pathological changes in otherwise normal corneal tissue.[4] The epithelium can develop neovascularization, surface defects, or microcystic changes. There can also be edema, thinning, or neovascularization of stromal tissue. Lastly, endothelial cell damage and loss can occur.[5,6,7] In order to preserve proper corneal function, researchers believe that the Dk/t must meet or exceed a specific threshold value.

The most widely accepted Dk/t rating to meet the healthy threshold in a closed eye is known as the Holden-Mertz criteria and has a value of 87 $\times 10^{-9}$ (cm/sec)(mlO_2/ml x mmHg), or more simply stated as 87.[6] This number is not without contention, and several studies have suggested the appropriate value should be closer to a Dk/t of 125.[5,8] However, for the purposes of the study, the Holden-Mertz criteria will be the reference point for further discussion.

The introduction of silicone hydrogel lenses have increased oxygen permeability (Dk) and have allowed manufactures to produce lenses with Dk/t values well above 87, thus making extended wear lenses viable options for patients.[1,4] Brands like PureVision 2 (Bausch + Lomb, Rochester NY), Acuvue Oasys (Johnson & Johnson Vision Care, Jacksonville, FL), Biofinity (CooperVision, Pleasonton, CA), and Air Optix Night & Day (Alcon, Fort Worth, TX) are among the industry leaders.[3,9] Oxygen transmissibility values for these lenses are widely published and available for both clinicians and consumers alike (see Table 1).[9] However, the standard value used is representative of the central Dk/t based on the profile of a -3.00 diopter (D) lens.[2,9] The profile of a lens design is subject to change based on the dioptric power of the lens, similar in principle to what is seen with spectacle lenses.[10] The purpose of this study is to evaluate whether a clinically significant reduction in Dk/t occurs when the power, and therefore the profile, of the lens deviates from the standard -3.00D.

Table 1: Oxygen Permeability (Dk) and Central Oxygen Transmissibility (Dk/t) for a -3.00D Lens

Brand (material)	Dk	Dk/t
PureVision 2 (balafilcon A)	91	130
Acuvue Oasys (senofilcon A)	103	147
Biofinity (comfilcon A)	128	160
Air Optix Night & Day (lotrafilcon A)	140	175

METHODS

One current soft contact lens wearing subject was asked to participate in this study. Informed consent was obtained and the minimal risks associated with normal handling, insertion, and removal of contact lenses was fully explained to the subject.

Trials of four of the industry's leading silicone hydrogel extended wear contact lenses were evaluated: PureVision 2, Acuvue Oasys, Biofinity, and Air Optix Night & Day. A standard base curvature of 8.4mm or 8.6mm was chosen depending on what was available in each design. Additionally, each design was ordered in 6 identical ranges of spherical powers: -10.00D, -6.00D, -3.00D, -0.50D, +3.00D, and +6.00D. The -3.00D lenses served as a known control value for the experiment to help reduce experimental error.

The subject was asked to briefly wear the various lenses in either eye while enhanced corneal hi-resolution scans were acquired with a Visante (Carl Zeiss, Oberkerchen, Germany) anterior segment optical coherence tomographer (OCT). The scan analyzed the lens profile along the 180 degree axis and this process was repeated until successful scans of all the lenses were obtained. These images were then used to identify and measure the central and/or thickest portion of each lens using the built in caliper tool. In instances where the center of the lens was not the thickest aspect (as was the case with all minus power designs) the thickest peripheral location was identified and measured using the experimenter's best judgment.

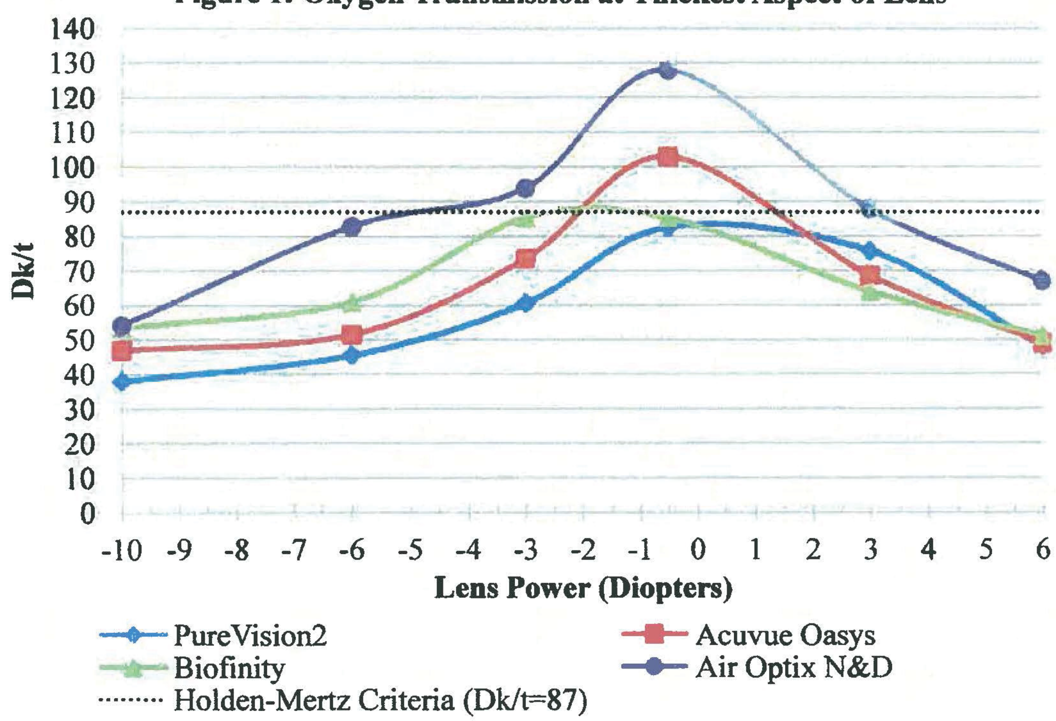
Dk/t was then recalculated by dividing the marketed Dk value of the lenses by the thickness at any specific point in the lens.

RESULTS

The measured thickness values were successfully obtained to the nearest one hundredth of a millimeter by the OCT. Nearly all minus powered lenses maintained a constant central thickness value consistent with their marketed figures. The greatest variance was seen in the mid-periphery of minus powered lenses and the central thickness of plus powered lenses. This holds true to the basic optic principles exhibited by both spectacle and contact lenses. An increase in refractive power correlated to further increased peripheral or central thicknesses in minus and plus powered lenses, respectively.

When factoring in the Dk/t corrected for the thickest portion of the lens, many lenses performed lower than the standard Holden-Mertz criteria. It is important to distinguish that these values are representative of the oxygen transmissibility at a single local area (or ring, if one assumes a consistent spherical design) of the lens. Figure 1 shows the relationship between the poorest performing points in each lens compared to the accepted normal criteria. A best fit curve line was applied to estimate the expected performance of lenses with powers not represented in the study.

Figure 1: Oxygen Transmission at Thickest Aspect of Lens



Air Optix Night & Day lenses maintained a Dk/t greater than 87 throughout the lenses in powers ranging from about -4.50D to +3.00D. Acuvue Oasys lenses in a narrow range of powers from roughly -2.00D to +1.50D that also remained above this threshold.

The only other lens projected at or above the Holden-Mertz line was the Biofinity lens of approximately -2.00D. Further analysis of how each brand faired individually follows.

PureVision 2

The PureVision 2 lens inherently has the lowest Dk (91) of the designs tested. It does, however, have the lowest central thickness (CT) in its minus lens design at 0.07mm, allowing its marketed -3.00D Dk/t value to be 130. Its aspheric design also produced the lowest plus lens central thickness values of the tested groups. When Dk/t was adjusted using the thickest point on the lens, none of the powers in this design were able to maintain a rating of greater than 87 throughout the lens. The measured values along with the calculated Dk/t at the thickest point are shown in Table 2.

Table 2: PureVision 2 Specifications (Dk 91)			
Power (D)	**CT (mm)**	**Thickest (mm)**	**Dk/t at Thickest**
-10.00	0.07	0.24	37.92
-6.00	0.07	0.20	45.50
-3.00	0.07	0.15	60.67
-0.50	0.07	0.11	82.73
+3.00	0.12	0.12	75.83
+6.00	0.19	0.19	47.89

Acuvue Oasys

The Oasys lens shares the thinnest CT with the PureVision 2, but has an improved material Dk of 103. The -3.00D design is marketed as a Dk/t of 147. Despite having the second lowest material Dk tested, it showed the second largest distribution of powers (approximately -2.00D to +1.50D) where Dk/t remained above 87 throughout the entire profile of the lens. The measured values along with the calculated Dk/t at the thickest point are shown in Table 3.

Table 3: Acuvue Oasys Specifications (Dk 103)			
Power (D)	**CT (mm)**	**Thickest (mm)**	**Dk/t at Thickest**
-10.00	0.07	0.22	46.82
-6.00	0.07	0.20	51.50
-3.00	0.07	0.14	73.57
-0.50	0.07	0.10	103.00
+3.00	0.15	0.15	66.67
+6.00	0.21	0.21	49.05

Biofinity

The Biofinity lens has a thicker CT than the previously mentioned designs (0.08mm) and was the only lens tested to show a slightly thicker CT with the -0.50D lens (0.11mm). The material Dk was the second highest tested at 128. Surprisingly, despite a marketed -3.00D Dk/t of 160, none of the powers tested were able to reach the Holden-Mertz criteria at its thickest point. However, the best fit curve shows a lens of approximately -2.00D may approach this threshold. The measured values along with the calculated Dk/t at the thickest point are shown in Table 4.

Table 4: Biofinity Specifications (Dk 128)			
Power (D)	**CT (mm)**	**Thickest (mm)**	**Dk/t at Thickest**
-10.00	0.08	0.24	53.33
-6.00	0.08	0.21	60.95
-3.00	0.08	0.15	85.33
-0.50	0.11	0.15	85.33
+3.00	0.20	0.20	64.00
+6.00	0.25	0.25	51.20

Air Optix Night & Day

Air Optix Night & Day lenses has the highest material Dk of all lenses tested (140) and the -3.00D standard lens has a Dk/t of 175. Because of this, they are the only one of the designs tested that is approved for 30 days of continuous wear (the others are approved for 7 days). With that advantage, Air Optix Night & Day lenses held above the Holden-Mertz criteria for powers between roughly -4.50D to +3.00D. The measured values along with the calculated Dk/t at the thickest point are shown in Table 5.

Table 5: Air Optix Night & Day Specifications (Dk 140)

Power (D)	CT (mm)	Thickest (mm)	Dk/t at Thickest
-10.00	0.08	0.26	53.85
-6.00	0.08	0.17	82.35
-3.00	0.08	0.15	93.33
-0.50	0.08	0.11	127.27
+3.00	0.16	0.16	87.50
+6.00	0.21	0.21	66.67

DISCUSSION

Contact lens designs approved for extended wear rely on a silicone hydrogel design to create a high material Dk. Though the central oxygen transmission across a standard lens power is well published, the results of this study show evidence that appropriate corneal oxygenation may not be consistent throughout the entire profile of varying lenses. A study by Bruce[10] resulted in a similar conclusion. Theoretically, this could lead to compromised corneal health, particularly in patients with highly myopic or hyperopic prescriptions.

Although this study does not specifically address the effects extended wear has on corneal health, several inferences can be proposed. As plus power increased, all designs tested showed a thickening at the center of the lens. A proportionate decrease in the Dk/t of the lens at that point caused many designs to fail to maintain an acceptable Dk/t rating. This, in theory, could lead to an increased likelihood of central corneal complications associated with corneal hypoxia (edema, microcysts, endothelial damage, etc.) A similar conjecture could be suggested for lenses with increasing minus power, where increases in mid-peripheral thickness could compromise the health of limbal cells and/or lead to more peripheral corneal complications.

There are some limitations to the study that can be addressed. Though every effort was made to obtain fair and accurate data, the determination of the thickest portion of a lens and its value with the OCT caliber tool was a highly subjective technique. However, published thickness values[9] of a +3.00D Acuvue Oasys (0.147mm) and Air Optix Night and Day (0.161mm) did compare favorably to the measured values in this study (0.15mm and 0.16mm respectively), suggesting the data collected was reasonably accurate.

Dk/t values would also vary across the entire profile of the lens, not just at its central or thickest point. It can also be inferred that toric and multifocal designs would present with their own unique thickness profiles. Therefore one would expect a gradient like change in Dk/t if every individual point was mapped. In these cases, the concern for corneal hypoxia would be highest at these focal areas of thickening. Further work would have to be done in order to obtain ratings at these individual points, or to calculate an average across the entire lens area.

The results of this study suggest that marketed Dk/t values may be misleading when the characteristics of varying lenses powers are accounted for. It would be premature to suggest that there is greater absolute risk to corneal health for patients fit with silicone hydrogel extended wear lenses. In fact, some research has shown the hypoxic effects on corneal tissue with continuous wear silicone hydrogel lenses to be negligible.[5] However; consideration should be given toward the potential for complications, especially in zones where lens thickness is greatest. Clinicians should make patients aware of risks with overnight wear and thoroughly evaluate these potential problem areas, especially in patients with high refractive error. Further research needs to be done to calculate an accurate assessment of how Dk/t throughout a lens varies, and whether or not this poses a clinically significant threat to corneal health.

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