

Local oxygen transmissibility of disposable contact lenses

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Abstract

Aim: Despite global standardisation in measurement of oxygen transmissibility (Dk/t), in our clinic we continue to see limbal vasculature changes in patients wearing some disposable lenses. The use of central Dk/t as a simple designator of a contact lens oxygen performance has clearly failed, it being acknowledged as often unrelated to the oxygen performance of the lens periphery. This study investigates a new criterion for contact lens oxygen transmissibility, the local Dk/t .

Method: The study measured 20 spherical disposable lens brands (power range: -15.00 to $+8.00$ D) and 8 toric lens brands (power range: -8.00 to $+4.00$ D sphere, with a -1.00 D/ -1.25 D \times 180). An electro-mechanical gauge (Heidenhain, Germany) was used to measure lens thickness (t) at different positions on the lens. Oxygen permeability (Dk) of each lens material was calculated from the equation $Dk = 1.67e^{(0.0397 \times \text{water content})}$ of Morgan and Efron [Contact Lens Anterior Eye 21 (1998) 3] who used ISO/ANSI standard methodologies. The local Dk/t value was calculated from the point of maximum thickness on the lens and compared to the criterion of 12 Fatt units set by Benjamin [Int. Contact Lens Clin. 23 (1996) 188], to provide corneal oxygenation greater than or comparable to that available in the normal closed eye.

Results: All lens types with a water content over 65% had a local Dk/t of 12 Fatt units or more for most or all lens powers: CIBAVision FocusDailies, Bausch & Lomb Soflens66, CooperVision Actifresh400, and CIBAVision PrecisionUV. In addition, some lenses in the 55–62% water content range had some lens powers with a local Dk/t in excess of 12: CooperVision Proclear, Johnson & Johnson Acuvue 1 and CIBAVision Focus 2 week. None of the disposable toric lenses had a minimum Dk/t of 12 or more. The silicone-hydrogels, Bausch & Lomb PureVision and CIBAVision Focus Night&Day, comfortably exceeded Dk/t of 50 for all lens powers.

Conclusion: Some current disposable soft lenses have local Dk/t values below physiological requirements. Contact lens manufacturers and international standards organisations should consider introducing the labelling of local Dk/t values on lens packaging so that clinicians can make informed prescribing decisions.

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1. Introduction

Disposable hydrogel lenses have rapidly grown in popularity. However, there is a lack of information on the overall oxygen performance of many contemporary disposable hydrogel lenses. Consequently, clinical practitioners do not know the oxygen transmissibility (Dk/t) of the lenses they are prescribing, despite a wide possible variation in the Dk/t of currently available lenses. Currently, there is no International Standards Organisation (ISO) standard for Dk/t requirements or labelling, and lens packages are not labelled with Dk/t .

Fatt [1] showed that the periphery of certain spherical disposable lenses could have a Dk/t as low as 3 Fatt units, in the case of a -6.00 D low water content lens. Another

study by Eghbali et al. [2] measured oxygen transmissibility (Dk/t) at various locations in hydrogel toric prism-ballasted contact lenses; however, these were conventional lens types. That study found the Dk/t of the inferior area of these lenses were frequently less than the Benjamin [3] criteria for “low” $Dk/t = 12$ Fatt units.

The consequences of a low Dk/t in contact lenses have been well established for many years [4]. Effects on epithelial metabolism, limbal vessel changes, stromal oedema and long-term endothelial effects have all been noted. Fig. 1 shows limbal vascular and corneal changes seen in our clinic with currently available disposable lenses. In the extreme and rare cases, corneal infection and blindness can result.

The contact lens industry has devoted millions of dollars and many years of research and development in alleviating hypoxia, initially with the move to mid- and high-water disposable lenses and then culminating more recently with the release of hyper Dk/t silicone-hydrogel lenses. However,

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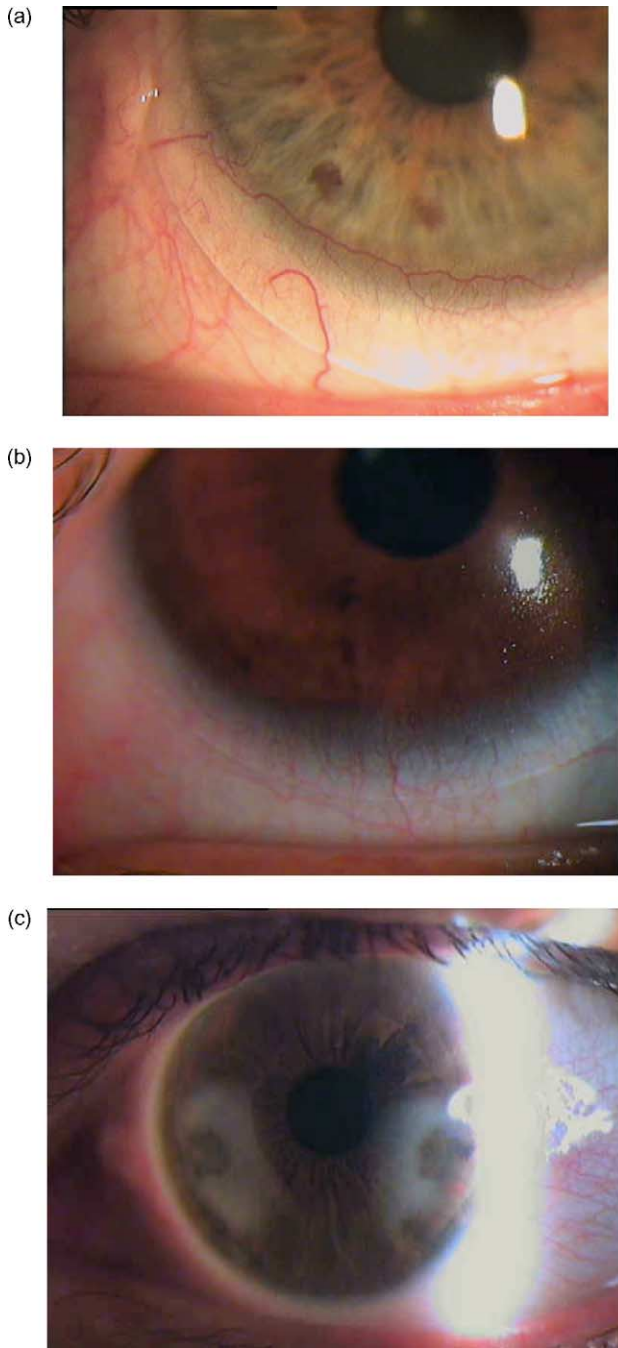


Fig. 1. Effects of a mid-water disposable lenses with a thick periphery on limbal vasculature: (a) circumferential limbal neovascularisation; (b) general limbal hyperaemia; (c) lipid keratopathy secondary to corneal neovascularisation.

there are still many lens types available which appear to cause hypoxic changes in ocular health, and there is a need to differentiate such lenses.

Dk/t values need to be related to the on-eye response. The earliest widely accepted critical Dk/t criterion is that of Holden and Mertz [5]. They found an ideal Dk/t value to be 24 Barrer/cm for daily wear and 87 Barrer/cm for extended wear, although clinically acceptable values were 15–20 and

34 Barrer/cm for daily wear and extended wear, respectively. The Holden–Mertz criterion has served the contact lens industry well for many years. It has served as a goal toward which enormous research and development activities have been devoted, culminating in the release of the high Dk silicone-hydrogel lenses in 1999. However, for clinical use, in evaluating and differentiating individual lenses, a different approach may now have more validity and benefit.

Papas [6] evaluated the effect on limbal vessel hyperaemia from open-eye wear of a range of soft lenses, with a peripheral Dk/t ranging from 5 to 71. He concluded that a peripheral lens Dk/t of at least 55 Barrer/cm was required to avoid limbal hyperaemia.

Benjamin [7] categorises the Dk/t of lenses in terms of the equivalent oxygen percentage received by the normal eye under various conditions:

- Low ($Dk/t < 12$): corneal oxygenation less than that available in the normal closed eye.
- Moderate ($Dk/t = 12–25$): corneal oxygenation similar to that in the normal closed eye.
- High ($Dk/t = 26–50$): corneal oxygenation significantly above that available in the normal closed eye, although can be significantly affected by lens design.
- Super ($Dk/t = 51–80$): corneal oxygenation significantly above that available in the normal closed eye, with lens design having reduced effect, but substantially below that received by the central cornea of the open eye.
- Hyper ($Dk/t > 80$): corneal oxygenation just below that received by the central cornea of the open eye, with minimal effect of lens design.

These criteria appear to be a useful clinical benchmark with which to compare measured Dk/t values. One of the impediments to agreement on the clinical application of Dk/t has been the need to agree on which thickness (t) value to use. In promotional material, the contact lens industry often use central thickness, being the thinnest value for a minus powered lens, but it is now accepted that central lens thickness may not relate to common clinical findings. Holden and Mertz [5] used average Dk/t in their research assessing central corneal oedema; however, this index also has limited use in predicting local epithelial hypoxia at different points on the cornea.

Most recently, Fatt [8] introduced ‘local Dk/t ’, terming it “a new physiological paradigm”. His concept was that local epithelial hypoxia is governed by the Dk/t of the lens directly above it. The benefits of measuring Dk/t across the entire lens surface are becoming increasingly recognised. There is experimental evidence to support this paradigm:

- Holden et al. [9] noted a limited lateral spread of stromal oedema in the eyes fitted with a (‘donut’) contact lens with a large central aperture.
- Efron and Fitzgerald [10] confirmed the presence of local variations in oxygenation across the surface of the cornea during soft contact lens wear.

- (c) Papas [6] showed limbal hyperaemia was dependent upon soft contact lens oxygen transmissibility in the peripheral (local) area of the lens.

In summary, this study assesses the lens thickness profile and oxygen transmissibility profile (Dk/t) of current spherical and toric disposable contact lenses. Results are compared to the Holden and Mertz [5] and the Benjamin [3,7] criteria for Dk/t . The null hypothesis is that no lens design or power would fail to allow sufficient oxygen to all areas of the cornea (as judged by the above criteria).

2. Methods

2.1. Material Dk

There is now agreement about the relationship between water content and oxygen permeability (Dk) of hydrogel materials. As shown in Fig. 2, the equations of Fatt et al. [11] and Morgan and Efron [12] are in reasonable agreement. They used methodologies consistent with the American and International standards [13]. Thus, the Dk of different materials can be readily compared using published data.

In the present study, lens material water content was taken from the nominal labelled water content, although it may vary slightly on eye, due to lens dehydration in vivo. For silicone-hydrogel lenses, the manufacturer nominal Dk was used.

2.2. Thickness measurements

An electro-mechanical thickness gauge (Heidenhain, Germany) was used to measure at different positions on the lens

(Fig. 3a). The instrument-measurement surface has a dome across which the lens was laid for measurement. To facilitate positioning of the lens, the lens was dotted with an indelible pen in each location. The lens was moved across the dome to measure peripheral locations.

Spherical lenses were measured twice, at the centre and at the periphery. Toric lenses were measured at seven locations as shown: one central, two superiorly, two inferiorly and two laterally. The positions measured are shown in Fig. 3b.

2.3. Calculation of Dk/t

The Dk/t was taken as the material Dk , divided by the local thickness (cm) [14,15]. The Dk unit Barrer is $(\text{cm}^2/\text{s})(\text{ml O}_2/(\text{ml mmHg})) \times 10^{-11}$ [16], also known as Fatt units.

2.4. Lenses

For each brand of spherical lens, the following powers were measured (if available): -15.00 , -12.00 , -10.00 , -8.00 , -6.00 , -5.00 , -4.00 , -3.00 , -2.00 , -1.00 , -0.50 , $+1.00$, $+2.00$, $+3.00$, $+4.00$, $+5.00$, $+6.00$, $+8.00$. Toric lenses were all in -1.00 or -1.25 D cyl at 180, and in spherical powers of -8.00 , -6.00 , -4.00 , -2.00 , plano, $+2.00$ and $+4.00$, if available. The brands of lenses assessed are listed in Table 1 and two lenses were measured for each brand and power. Up to 18 powers were assessed for each lens brand. Results were collected in two phases.

A second operator measured nine of the spherical lens brands on a separate occasion, in order to assess repeatability of both the lenses and measurement process. A separate

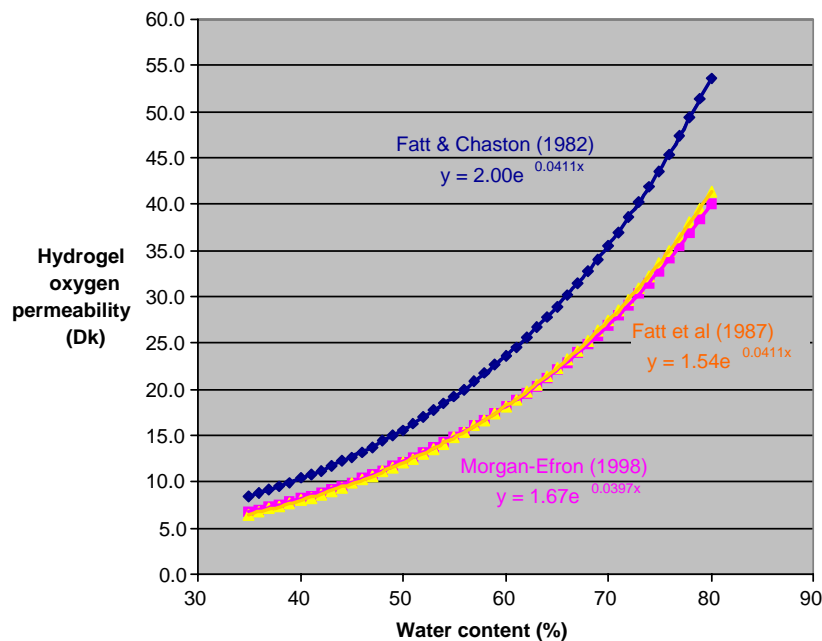


Fig. 2. Contact lens material water content and oxygen transmissibility (Dk/t) relationships found by various authors, differing from the original research [17]. The lower two curves are the more recent and show a high level of agreement.

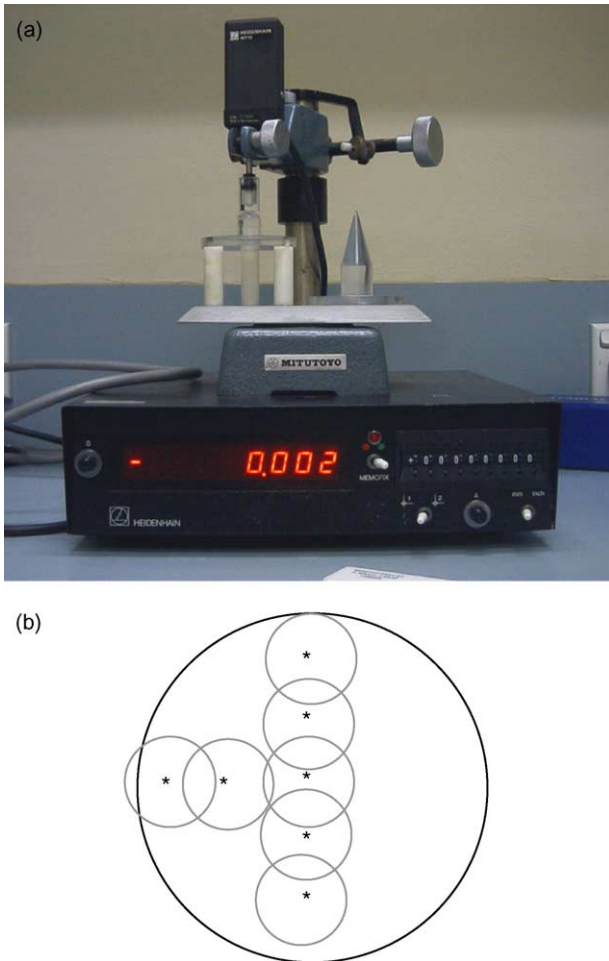


Fig. 3. (a) Heidenhain electro-mechanical thickness gauge used in assessment of lenses. (b) Location of thickness measurements on lenses. Spherical lenses were measured twice, centrally and peripherally. Toric lenses were assessed at all seven locations in order to assess the influence of prism or other thick zones.

series of lenses was ordered from the manufacturers for this assessment, with two lenses measured for each power. Results for the two series of lenses were compared with mean and standard deviation calculated (Table 2).

2.5. Analysis

For spherical lenses, the maximum thickness was recorded (minimum Dk/t). The point of maximum thickness was typically in the periphery for minus lenses and centre for plus lenses. Lens local oxygen transmissibility data was grouped using the criteria listed by Benjamin [7] and also compared to the Holden and Mertz [5] criteria. For toric lenses, the thickness profile at the seven locations was recorded and averaged for the lens powers measured, as there was relatively little variation in thickness with power.

3. Results

All lens types with a water content over 65% had a local Dk/t of 12 Fatt units or more for most or all lens powers: CIBAVision FocusDailies (69% water content), Bausch & Lomb Soflens66 (66%), CooperVision Actifresh400 (73%), and CIBAVision PrecisionUV (74%). In addition, some lenses in the 55–62% water content range had some lens powers with a local Dk/t in excess of 12: CooperVision Proclear (62%), Johnson & Johnson Acuvue 1 (58%) and CIBAVision Focus 2 week (55%).

All other hydrogel lenses were in the low Dk/t (<12) range. The lenses with all powers in the Dk/t less than 12 range all had water content less than 60%. Results are shown in Figs. 4 and 5.

All the toric disposable lenses, with the exception of the Acuvue Toric, were in the low Dk/t range for the inferior

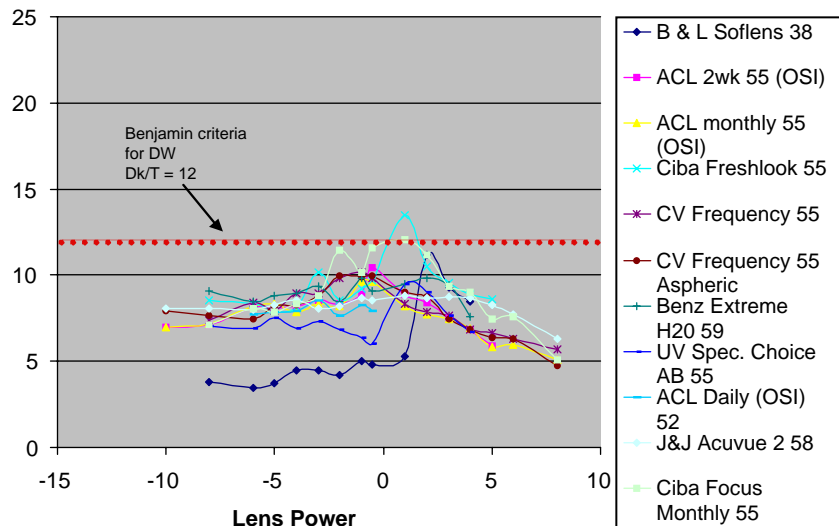


Fig. 4. Relationship between Dk/t and lens power for low (<12) Dk/t lenses.

Table 1

Manufacturer	Lens name	Water content	Dk
Spherical lenses			
Bausch & Lomb	Soflens38	38.6	7.7
Bausch & Lomb	PureVision	36	99.0
Bausch & Lomb	One-day	70	26.9
Bausch & Lomb	Soflens66	66	22.9
Benz Research & Dev	Extreme H ₂ O	59	17.4
CIBAVision	FocusDailies	69	25.9
CIBAVision	Focus monthly	55	14.8
CIBAVision	Focus 2 week	55	14.8
CIBAVision	Focus Night&Day	24	140.0
CIBAVision	Freshlook	55	14.8
CIBAVision	PrecisionUV	74	31.5
CooperVision	Frequency 55	55	14.8
CooperVision	Frequency 55 aspheric	55	14.8
CooperVision Biocompatibles-Hydrion	Actifresh400	73	30.3
CooperVision Biocompatibles-Hydrion	Proclear Compatibles	62	19.6
Johnson & Johnson	Acuvue	58	16.7
Johnson & Johnson	Acuvue 2	58	16.7
Ocular Sciences ^a	Biomedics 2-weekly	55	14.8
Ocular Sciences ^a	Biomedics monthly	55	14.8
Ocular Sciences ^a	Daily	55	14.8
Ultravision-Capricornia	Speciality Choice AB	55	14.8
Toric lenses			
Bausch & Lomb	Soflens66 Toric	66	22.9
Biocompatibles-Hydrion	ActiToric	73	30.3
CIBAVision	Focus Toric	55	14.8
CIBAVision	Freshlook Toric	55	14.8
CooperVision	Frequency 55 Excel Toric	55	14.8
Johnson & Johnson	Acuvue Toric	58	16.7
Ocular Sciences ^a	Biomedics Toric	55	14.8
Ultravision-Capricornia	Encore Toric	55	14.8

^aThe lenses measured were marketed in Australia under Australian Contact Lenses (Melbourne) own-brand labelling.

half of each lens due to the use of thick prism ballast designs (Fig. 6). The Acuvue Toric was the only toric lens tested to use lateral dynamic stabilisation zones which gave a vertical thickness profile more like that of a standard spherical lens.

The two silicone-hydrogel lens brands both comfortably exceeded Dk/t of 50 for all lens powers, although there was still a clear difference between the two. The CIBAVision Focus Night&Day was in the hyper (>80) Dk/t range for powers in the range of -6.00 to $+4.00$, whereas the Bausch

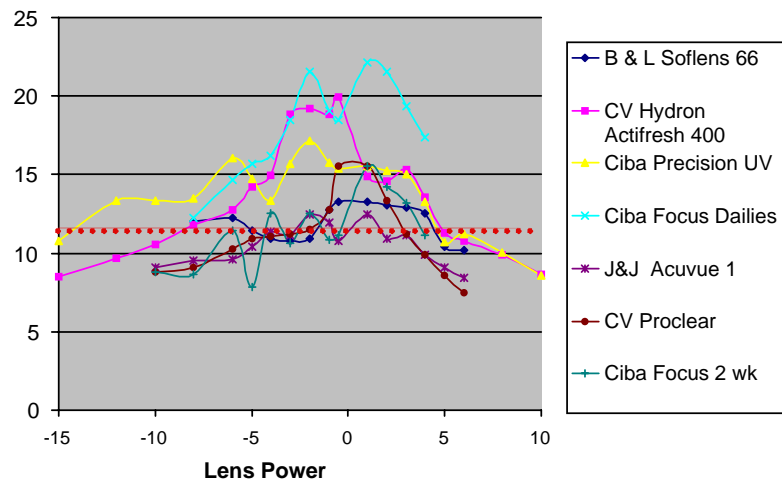


Fig. 5. Relationship between Dk/t and lens power for moderate (12–25) Dk/t lenses.

Table 2
Repeatability of lens Dk/t for lens brands ordered and measured on two occasions

	Number of lens powers tested	Mean Dk/t	Standard deviation
Actifresh400	13	14.8	1.1
Focus 2 week	13	10.9	1.9
Soflens66	11	12.5	1.5
Extreme H ₂ O	12	9.3	1.1
PrecisionUV	16	13.9	1.2
Proclear Compatible	11	12.0	1.7
Soflens38	12	5.1	1.9
Focus Night&Day	15	101.9	12.4
PureVision	8	53.8	2.4

& Lomb PureVision was in the super Dk/t (51–80) range for all lens powers, with the exception of the +1.00 lens (Fig. 7).

Repeatability of lens local Dk/t was good for the nine lens brands assessed, with the standard deviation (S.D.) being less than two for all the hydrogel lenses. The PureVision S.D. was also low; however, the Focus Night&Day S.D. was considerably higher at 12.4. Since the mean Dk for the Focus Night&Day is so high, the effect of any thickness variability in the lens would be magnified and the greater S.D. is unlikely to be of clinical significance.

4. Discussion and conclusions

All lens types with a water content over 65% had a local Dk/t of 12 Fatt units or more for most or all lens powers. In addition, some lenses in the 55–62% water content range had some lens powers with a local Dk/t in excess of 12 and the Acuvue Toric had most lens locations in excess of this level.

The results are in agreement with those of Fatt [1] who measured local Dk/t at the lens periphery for lenses with powers in the range –1.00 to –6.00D. He also found the Johnson & Johnson Acuvue 1 and CIBAVision Focus 2 week (NewVues) to have at least some lens powers in the medium Dk/t category, but that the Ocular Sciences Biomedics, CIBAVision Freshlook and Bausch & Lomb SeeSequence 2 (Soflens38) to have most or all lens powers in the low Dk/t category.

More than 15 years ago, Brennan and Carney [15] concluded, “minimum thickness lenses of water contents in the range of 65–70% are calculated to provide optimal oxygen transmissibility to the central corneal area for a wide range of powers”. The authors made their Dk/t calculations averaged over a 6 mm diameter central optical area, which is a different approach to the local Dk/t method used in the current study; however, there is agreement about the relative oxygen performance benefit of hydrogel materials with water content greater than 65%.

The results suggest that when 55 and 58% water content materials are used for disposable lenses, then there is no room for anything other than the thinnest lens designs—any increase in lens thickness for the purposes of improving patient handling, reducing spherical aberration or for any other reason will result in a low local Dk/t lens.

Toric lens designs were assessed by Eghbali et al. [2] who measured oxygen transmissibility (Dk/t) at various locations in conventional hydrogel toric contact lenses. Consistent with this study, Eghbali et al. [2] found the Dk/t of the inferior area of prism-ballasted lenses had a considerably lower Dk/t than the Benjamin [3] criteria for low Dk/t of 12 Fatt units.

The local Dk/t of the silicone-hydrogel lenses was in the super and hyper Dk/t ranges and this would seem suited to

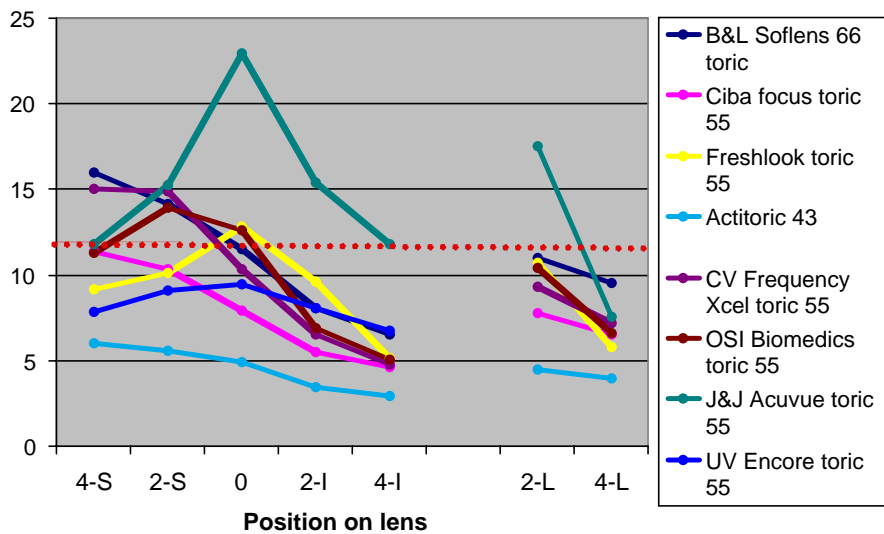


Fig. 6. Relationship between Dk/t and position on the lens for low (<12) and moderate (12–25) Dk/t toric lenses: 4-S = 4 mm superiorly; 2-S = 2 mm superiorly; 0 = centre of lens; 2-I = 2 mm inferiorly; 4-I = 4 mm inferiorly; 2-L = 2 mm laterally; 4-L = 4 mm laterally.

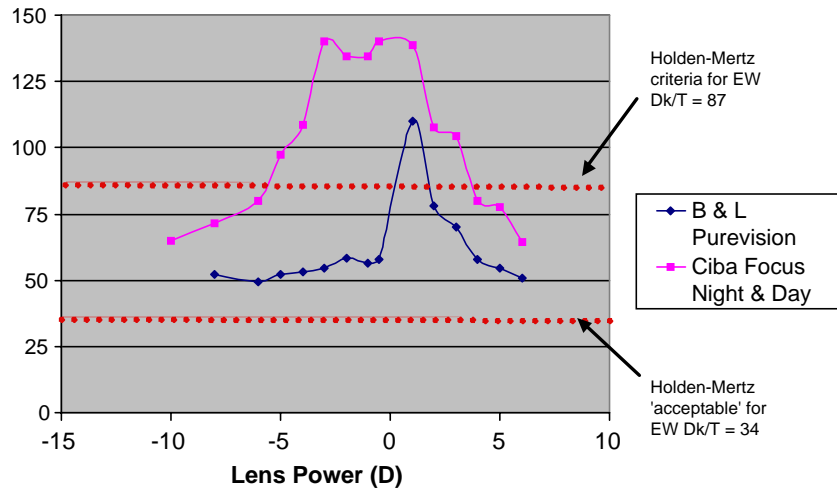


Fig. 7. Relationship between Dk/t and lens power for super (51–80) and hyper (>80) Dk/t lenses.

extended wear, but the results would not support the use of non-silicone-hydrogels in this modality.

This study has primarily used the criteria listed by Benjamin [7], who categorised the Dk/t of lenses into five groups: low (Dk/t < 12); moderate (Dk/t = 12–25); high (Dk/t = 26–50); super (Dk/t = 51–80) and hyper (Dk/t > 80). By having a number of groups, these criteria appeared to be more useful in the context of this study, although probably still consistent with the Dk/t criteria established almost 20 years ago by Holden and Mertz [5].

Since the original Holden and Mertz study there have been advances in methodology and understanding. Fatt [8] criticised the Holden–Mertz study because:

- Limited sample size ($N = 14$), considering contact lenses are worn by millions of people.
- No statistical analysis—no estimate of the standard deviation.
- Non-standard Dk values: Dk values were cited at room temperature (not 35 °C); and the Dk data is from 1977 to 1978, which predates measurement corrections for edge and boundary layer effects. However, these effects may cancel out to some extent.
- Dk/t values were based on the average thickness of the powered lenses. While this may be predictive of corneal stromal edema, it has limited use in predicting local epithelial hypoxia at different points on the cornea. The clinician may be concerned with the epithelial cell health under the thickest point of the lens.

While there are ISO standards on contact lens Dk/t measurement methodology, there is no ISO standard to say what is clinically acceptable, and no ISO standard on contact lens Dk/t labelling. This contributes to the lack of information at the clinical interface on the overall oxygen performance of contemporary disposable hydrogel lenses. Now that there is such a wide array of contact lenses available, including lenses in the low Dk/t through to hyper Dk/t categories, it

would be highly beneficial to both patients and practitioners if Dk/t labelling was introduced on lens packages. An example would be ‘low Dk/t lens may induce ocular health changes’. Practitioners would then be more able to make informed prescribing decisions.

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