



Clinical highs and lows of Dk/t

Part 1 – Has oxygen run out of puff?

In the first of a two-part series, **Professor Noel Brennan** and **Dr Philip Morgan** look at the latest terminology and theories about oxygenation of the cornea through silicone hydrogel lenses

Although silicone hydrogel (SiH) contact lenses have fallen short of their original goal, solving the continuous wear-infectious keratitis problem, they undeniably provide a superior environment than hydrogels by promoting normal corneal metabolic activity. While there is consensus on this benefit, it is less clear how high we have to go in terms of oxygen transmissibility (Dk/t) within the SiH category to achieve an optimal physiological result. (For simplicity, units of $10^{-9}(\text{cm}/\text{sec})(\text{mlO}_2/\text{ml}\cdot\text{mmHg})$ are omitted where Dk/t values are given in the text.) Theoretical modelling backed up by equivalent oxygen percentage (EOP)-based empirical data suggests that there will be little difference between any of the SiH lenses.¹⁻⁶ However, some authors argue that one should expect continuing benefits by increasing Dk/t within the SiH range.⁷⁻⁹

While the modelling and laboratory findings are important to contemplate, the ultimate test of these differences will be found in clinical performance. In this, the first of a two-part series, we address the clinical perspective to arrive at the conclusion that there is little to be gained in strict physiological terms by pushing Dk/t values beyond those provided at the low end of the SiH range. In part two, we will highlight important differences in performance within the SiH category that are not oxygen based and should be the real consideration for selecting between different lens brands.

The law of diminishing returns

The law of diminishing returns must apply when considering the relation between oxygen reaching the cornea and Dk/t. Let us suppose a contact lens with Dk/t equal to 100 leads to a partial pressure of oxygen at the front surface of the cornea of 100mmHg (from available data, this is most probably a conservative estimate). Under normal open eye wearing conditions, doubling the Dk/t to 200 will not lead to a partial pressure of 200mmHg. It cannot, because the partial pressure of

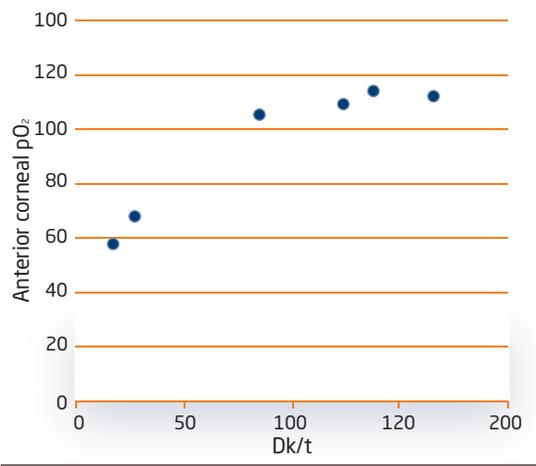


Figure 1 Open eye pO₂ estimates from a phosphorescent dye technique¹⁰

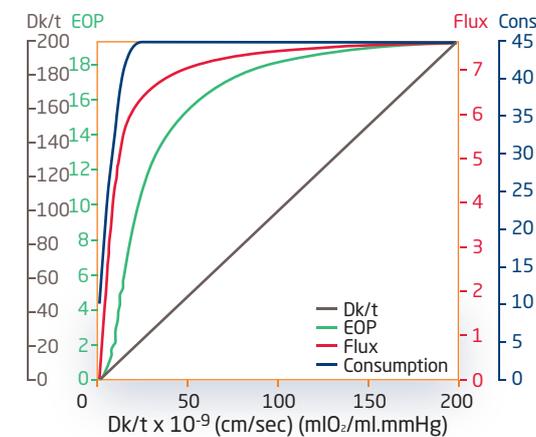


Figure 2 Combined graph showing Dk/t, EOP, anterior corneal oxygen flux (Flux; $\mu\text{l}/\text{cm}^2 \text{ hr}$) and Consumption (Cons; $\text{nl}/\text{cm}^3 \text{ sec}$) as a function of Dk/t for the open eye calculated according to Brennan.² Different y-axis scales are provided for each of these variables

atmospheric oxygen at sea level is about 159 mmHg (at STP) and the pO₂ at the corneal surface will never exceed this. We can keep doubling the Dk/t, but it will never lead to a pO₂ of greater than that in the atmosphere. Data from Bonanno *et al* in Figure 1 exemplify this by showing that pO₂ at the anterior surface increases only gradually above a Dk/t level of about 85.¹⁰

Figure 2 demonstrates that as the modelling of corneal oxygenation from Dk/t to EOP to flux to consumption

WHICH SCALE BEST DESCRIBES CORNEAL OXYGENATION?

When we talk about corneal oxygenation, what we really want to know is the amount of energy that the cornea is generating to carry out its normal functions.

Since oxygen flow is the rate-limiting step we know that this will be directly proportional to the rate of oxygen metabolism (or consumption) through the Krebs's TCA cycle and the electron transport chain. Before the advent of silicone-hydrogel lenses, soft lens Dk/t was limited to about 30. At this low level of oxygenation, Dk/t was a useful *de facto* index because the relationship between metabolism and Dk/t is essentially linear for this small section of the curve. But while Dk/t tells us exactly how much oxygen passes through a contact lens on the laboratory bench, that does not replicate the on-eye situation. Many people also used equivalent oxygen potential or percentage (EOP), which predicts the partial pressure of oxygen at the front surface of the cornea. However, the relation between partial pressure and metabolism is ultimately not linear as it follows a relation called Michaelis-Menten kinetics.

Fatt suggested using anterior corneal oxygen flux,¹¹ commonly referred to simply as 'flux', as this tells the volume of oxygen that enters the cornea. While this is a much-preferred index to EOP and Dk/t, it falls short of being a perfect index of metabolism because oxygen can also move across the posterior surface of the cornea. Ultimately, we want a means of determining the primary variable of interest and 'oxygen consumption' provides this; it is equivalent to the net flux, or the sum of the fluxes at front and back corneal surfaces. Currently, the best method available for assessing consumption is by using Fatt's method of diffusion equations.¹²

Figure 2 demonstrates how the law of diminishing returns becomes more apparent as we increase the degree of sophistication of the estimators from Dk/t to EOP to flux to consumption.

TABLE 1

Select SiH and hydrogel contact lens material properties. Maximum and minimum Dk/t values are derived from various sources including manufacturer data*, Bruce,¹³ Efron *et al*¹⁴ and our own unpublished measures†

Material	Brand name	Water content (%)	Modulus (MPa)	Maximum Dk/t *,13,14,†	Minimum Dk/t *,13,14,†	Surface modification	Other technology
Asmofilcon A	PremiO	40	1.07	161	70	Nanogloss plasma coating	Menisilk
Balafilcon A	PureVision	33	1.06	84	38	Plasma oxidation	
Comfilcon A	Biofinity	48	0.75	145	64	None	Aquaform Technology
Enfilcon A	Avaira	46	0.5	125	55	None	Aquaform Technology
Filcon II 3	Clariti	58	0.5	86	?	None	Aquagen Process
Galyfilcon A	Acuvue® Advance®	47	0.43	107	37	None	Hydraclear Technology
Iotafilcon A	Night & Day Aqua	24	1.5	203	68-140	Plasma-polymerisation	Aqua moisture system
Iotafilcon B	Air Optix Aqua	36	1.2	101	45	Plasma-polymerisation	Aqua moisture system
Narafilcon A	1-Day Acuvue® TruEye®	46	0.66	118	47	None	Hydraclear 1 Technology
Senofilcon A	Acuvue Oasys®	38	0.72	153	74	None	Hydraclear Plus Technology
Etafilcon A	Acuvue® 2®	58	0.3	26	8	None	
Omafilcon A	Proclear	62	0.49	29	11	None	

becomes more sophisticated, continuing to increase Dk/t shows increasingly marginal benefits (see panel). Hence, there is no question that the law of diminishing returns applies, the only real question is, at what point do increases in Dk/t cease to have real clinical benefit? Research on oxygen consumption and the clinical evidence presented below suggests that this level is below the lowest Dk/t value found in SiH lenses.

In analysing the implications of oxygen on corneal tissue, it is appropriate to refer to a set of lens parameter values. Such information is provided in Table 1. It should be remembered that the Dk/t value cited for most lenses applies to the centre of the lens alone. A lens with a central Dk/t of 20 may well have a peripheral Dk/t of 10 or less.¹³ Central and peripheral Dk/t values provided in Table 1 are estimates derived from various sources of permeability and thickness values, including manufacturer data, Bruce, Efron *et al* and our own unpublished measures.^{13,14} Maximal Dk/t data may vary from manufacturer stated values as these are commonly presented at -3.00D.

A common clinical interpretation is that power variations cause major changes in Dk/t; in truth, the manufacturers are skilled at keeping maximum thickness values below

about 0.30mm across a wide range of powers and this rule-of-thumb can be useful for estimating the worst case Dk/t on higher-powered lenses. For speciality lenses, such as torics, the same maximal thickness values will tend to apply, so the general conclusions made in this paper for spherical lenses will be generally applicable to speciality lenses.¹⁵ Dk/t values used in the discussion below will refer to central Dk/t unless otherwise stated. Acuvue® Advance® and PureVision exhibit minimum Dk/t data for SiH lenses generally recommended for daily wear (DW) and continuous wear (CW) respectively and these lenses will be referred to in this context below.

Known oxygen-related effects

Realistically, all hydrogel lenses induce corneal hypoxia. Short-term closed eye wear of hydrogel lenses leads to corneal oedema,^{16,17} limbal hyperaemia^{18,19} and endothelial blebs.²⁰ A period of hydrogel lens CW sees the development of microcysts and vacuoles,^{21,22} vascularisation of the cornea,^{18,21} stromal thinning,²³ endothelial polymegethism,²⁴ and myopic creep.²⁵

Open-eye wear of hydrogel lenses produces less effect than closed eye wear but evidence suggests that there is virtually always some degree of hypoxia somewhere in the cornea. Limbal hyperaemia is the most obvious

sign and occurs in most people during hydrogel lens wear.^{26,27} Long-term DW of hydrogel lenses has also been shown to cause endothelial polymegethism,²⁸ but it is unclear whether the extent is uniform across the oxygen transmissibility (Dk/t) range of hydrogels (about 0 to 30) as studies to date have only considered the various modalities by group. Lower Dk/t hydrogel lenses (less than about 20) are known to cause corneal swelling even with the eyes open.²⁹ Lenses at the low end of the Dk/t range (a peripheral Dk/t of less than about 10) may also lead to vascularisation.³⁰⁻³² It is therefore likely that lenses at the upper end of the Dk/t range (above a Dk/t of about 20) produce minimal change to the cornea aside from limbal hyperaemia. Since most contact lens wearers around the world use thin, medium-water content hydrogel lenses with a central Dk/t of 20 or thereabouts, it is reasonable to state that elimination of limbal hyperaemia constitutes the outstanding, if not only, reason for switching from DW hydrogels to SiH lenses.

Oedema, striae and endothelial folds

There is a strong link between the thickness of the cornea and its oxygen supply.^{33,34} During open-eye wear, the cornea will swell if the contact lens Dk/t is under about 20.³⁵ Hydrogels will therefore generally produce some



corneal swelling even when the eyes are open. If this amount is more than about 5 per cent, the clinician will also be able to see posterior stromal striae and when it swells by more than about 10 per cent, endothelial folds appear.³⁶ None of the SiH lenses would be expected to produce any corneal swelling while the eyes are open and there is evidence to support this contention.³⁷

During overnight eye closure, there will be some swelling of the cornea even without contact lens wear. The amount has been estimated to be between 0.7 and 5.5 per cent.³⁸ The amount varies with lens wearing experience; Cox *et al* found 3.8 per cent swelling in non-contact lens wearers, 2.0 per cent in subjects adapted to DW hydrogel lenses and 0.7 per cent in those adapted to CW hydrogel lenses.³⁹ All contact lenses will cause further swelling in the closed eye state above these baselines. Thin, medium-water content hydrogels will generally cause about 8 per cent further swelling and hydrogels with lower Dk/t than these will cause greater amounts.⁴⁰ SiH lenses cause much less oedema. The SiH lens with the lowest Dk/t that is approved for CW, PureVision, only causes about 2 per cent swelling additional to the baseline amount.⁴⁰ The SiH with the highest Dk/t, Focus Night & Day, causes about 1 per cent more swelling.⁴¹ It is unclear whether these small amounts of 1 to 2 per cent swelling seen with SiH lenses in addition to that which occurs without a contact lens in place are indicative of harmful hypoxic stress and whether the small differences between these lenses are important. In the absence of a known link between swelling and corneal pathology and given the large proportional difference between SiH and hydrogel lenses, we propose that the degree of swelling occurring with SiH lenses is of no consequence.

Microcysts

Holden *et al* stated that, of various compromises that CW of hydrogels may produce, 'the most easily observable condition indicative of epithelial compromise is microcysts'.⁴² Sweeney *et al* state that 'in clinical trials microcysts are used as the classic marker of hypoxia'. Hickson and Papas measured the incidence of microcysts in people who do not wear contact lenses to be 49 per cent, although none showed more than 5 microcysts per cornea.⁴³ DW of hydrogel lenses does not seem to influence this incidence;^{42,44} consequently DW of SiH lenses would not be expected to increase this prevalence, a premise based on



Figure 3 SiH contact lenses do not appear to induce vascularisation (shown here) at all

the default that no-one has deemed it worthy of measuring.

In contrast, the mean number of microcysts in subjects wearing hydrogel contact lenses after five years of CW has been reported as 17 ± 21 , with virtually all eyes showing at least one microcyst.²³ Microcyst numbers inversely correlate with Dk/t during closed eye wear, with the Dk/t level at which they fall to baseline numbers estimated at around 50.⁴⁵ Given that the central Dk/t of the PureVision is about 90, it is no surprise that microcysts are not generally reported as a problem with SiH lenses. Brennan *et al* reported on wear of 3 different type of SiH lenses and found an incidence of 30 to 59 per cent, which is consistent with the Hickson-Papas baseline but a higher incidence of 9 to 17 per cent with greater than 10 microcysts.⁴⁶ They studied the lenses with highest and lowest Dk/t values in the EW category for SiH but found no evidence of a relation between this most important marker of hypoxia and Dk/t within this group.

Vascularisation

Vascularisation is important because it is the only, serious, contact lens-related threat to vision other than microbial keratitis (Figure 3). It can occur with both DW and CW of hydrogels. Because it takes some time to develop and is non-acute in nature, incidence and relative risk data are very patchy. Lenses with even modest peripheral Dk/t values, say around 10 as is found in some thin high-water content lenses, may induce some minor sprouting of vessels but do not appear to induce significant vascularisation in DW. It is therefore most unlikely that any hypoxic related vascularisation would be found with SiH lenses in DW and we

are unaware of any such reports.

Dumbleton *et al* considered vascularisation over nine months of CW and found significant vascularisation in wearers of low Dk/t lenses (peripheral Dk/t about 10) and none in wearers of high Dk/t (peripheral Dk/t values in the region of 60 to 100) lenses,⁴⁷ confirming the general relation between vascularisation and Dk/t. However, there have been very few studies enabling assessment of the impact of Dk/t within the SiH category. Over a period of one year of CW, Brennan *et al* found near zero percent incidence of significant vascularisation in either eye among 212 subjects wearing PureVision and Acuvue® lenses contralaterally.⁴⁸

Further analysis of a one-year CW study of PureVision, Night & Day and Biofinity reported by Brennan *et al*⁴⁶ found that almost half of the subjects, who were from a mixed history of previous wear, were graded as having some degree of vascularisation on entry to the study. At subsequent visits, recorded vascularisation decreased considerably but more or less equally between the different lens types. At the final visit, 25 per cent of subjects wearing PureVision still showed some degree of vascularisation versus 21 per cent of subjects wearing Night & Day. Santodomingo *et al* do not even mention vascularisation in their 18-month comparison of PureVision and Night & Day, restricting comments entirely to hyperaemia.^{49,50}

In summary, SiH lenses seem to have eliminated hypoxically-induced vascularisation. Further, there is no evidence of differences within the SiH category with regard to propensity to induce vascularisation.

Limbal redness

As noted earlier, limbal redness is the primary hypoxic sign in DW of thin, medium water content, hydrogel lenses. Papas derived a critical peripheral lens Dk/t value of 125 to avoid limbal redness in open eye wear⁵¹ and this proposal is one of the main pillars for advocates of higher Dk/t. However, the methodology used to derive this criterion has shortcomings. In keeping with Holden and Mertz,³⁵ the mathematical approach seeks to identify an intercept between what is essentially an asymptotic curve and its asymptote, an inherently imprecise exercise. There are also serious doubts over the quality of the control used by Papas. The baseline was taken to be the eye without a contact lens. But mechanical effects and temperature during lens wear may confound limbal redness measures over

and above the influence of Dk/t.

To this end, we surveyed the literature for support to Papas' criterion of 125. Our search identified seven studies that compared differences between two different SiH lenses in the degree of induced limbal hyperaemia in both DW and CW.^{46,49,52-56} Since the peripheral Dk/t values of all the SiH lenses fall below 125 and no two values are the same, we would expect to find significant differences in the degree of limbal redness in all of these studies if Papas finding is clinically important. In none of these studies was there a difference reported. This suggests that, not only is the criterion of 125 of little relevance in the clinical world, but that a figure of 37, the minimum peripheral Dk/t found in DW silicone-hydrogel lenses, is adequate to avoid clinically important open-eye limbal redness.

Endothelial blebs

Within minutes of insertion of a contact lens, dark regions known as blebs appear in the specular reflection of the endothelium²⁰ (Figure 4). Although they are not regarded as being of pathological concern on their own, blebs constitute an immediate index of hypoxia with the area of the endothelium comprising blebs during wear of a contact lens being inversely proportional in general to the Dk/t of that lens.⁵⁷ However, we recently tested whether there were differences in bleb response within the SiH category. We examined bleb formation following 20 minutes wear of SiH lenses in East Asian eyes under open and closed eye conditions and were unable to demonstrate differences across Dk/t.⁵⁸

Endothelial polymegethism

Most studies agree that endothelial cell density is not affected by either daily or continuous contact lens wear; however, the distribution of cell sizes and shapes does change, effects known as polymegethism and pleomorphism respectively. Of the clinical markers that potentially indicate long-term physiological compromise to the cornea through chronic hypoxia, endothelial polymegethism would seem to be the most sensitive. Microcyst numbers tend to peak after several months of CW (not counting the rebound effect if this mode of wear is interrupted), stromal and epithelial thinning are generally modest in magnitude compared to population variance, vascularisation only arises in individual cases and usually requires severe hypoxia but polymegethism seems to continue to worsen linearly over time.^{28,59,60} It

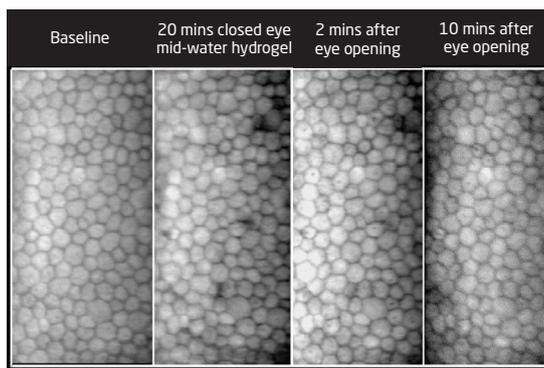


Figure 4 Endothelial photomicrographs showing a development and resolution of blebs with closed eye hydrogel lens wear at a single site (note matching cells between photographs). A new, interesting finding is the apparent increase in the number and clarity of central dots just after the stimulus is removed. SiH lenses cause minimal bleb response in the open or closed eye

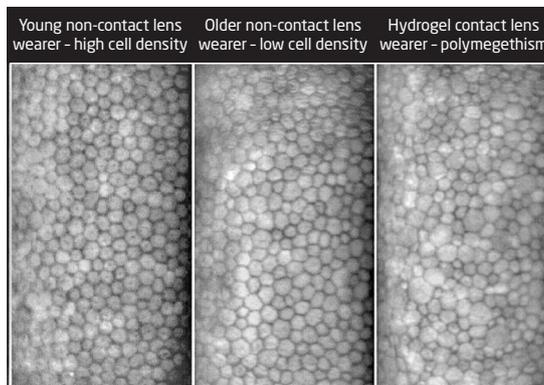


Figure 5 Endothelial photomicrographs showing normal cell density and high regularity in a six-year-old, lower cell density and increasing irregularity in a 49-year-old, and polymegethism in a 25-year-old veteran wearer of hydrogel contact lenses. We await the results of research to demonstrate whether SiH lenses cause endothelial polymegethism

also seems to increase with intensity of wear.⁵⁹ Figure 5 shows the endothelial appearance of a 25-year veteran hydrogel lens wearer compared to young and older non-wearers. The development of endothelial polymegethism appears to be related to the degree of hypoxia as there is considerable change in wearers of PMMA lenses, during CW of hydrogel lenses and to a lesser extent in DW of hydrogel lenses;^{24,61,62} however, there is minimal change in wearers of silicone elastomer lenses.⁶³ Yet, it is unclear at what Dk/t level polymegethism begins. It is also yet to be determined whether SiH lenses induce this phenomenon and also whether switching to these materials allows recovery from hydrogel lens induced endothelial polymegethism.

Corneal thinning

Both epithelial and stromal thinning may occur in response to CW of hydrogel

lenses²³ but an effect with DW is less obvious.^{64,65} It is uncertain how much of the thinning can be attributed to mechanical effects as opposed to hypoxic effects. Orthokeratology is known to thin the cornea centrally⁶⁶ and the majority of this effect is independent of Dk/t. There is no evidence that there is hypoxic related corneal thinning with SiH lenses.

Myopic creep

Small myopic shifts have been previously identified with DW and CW wear of hydrogel lenses and the degree to which these occur would seem to be greater than with spectacles.^{67,68} These changes are not apparent with wear of at least one brand of silicone-hydrogel lens.^{25,69} However, the degree to which myopic changes are attributable to hypoxia remains open to conjecture. There is no apparent increase in central corneal curvature associated with hydrogel lens-induced myopic shift.⁷⁰ It is theorised that peripheral retinal refraction is responsible for ocular growth.⁷¹ Wear of standard design contact lenses may change the aberration profile leading to a greater degree of optically stimulated myopic increase than if spectacles were worn. This effect may be counterbalanced in the case of wear of higher modulus silicone-hydrogel lenses, which will have a tendency to mechanically flatten the central cornea region.⁷²

Summary

There is little evidence of physiologically-based performance variation within the silicone-hydrogel lens category. That which is known to exist comprises small differences of unknown significance in the closed eye corneal swelling response between SiH lenses and laboratory differences in limbal hyperaemia that do not seem to manifest in clinical reports for either DW or CW. In part two of this series, we will consider those differences in lens performance between SiH brands which are important and show that these are related to material properties other than oxygen transmissibility. ●

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Clinical highs and lows of Dk/t

Part 2 – Modulus, design, surface - more than just fresh air

In the second part of a two-part series, **Professor Noel Brennan** and **Dr Philip Morgan** look at the clinical behaviour of silicone hydrogels based on characteristics other than oxygen performance

The first part of this two-part series considered differences between silicone-hydrogel (SiH) contact lenses in terms of their effect on ocular parameters known to be influenced by oxygen levels. Oxygen transmissibility (Dk/t) differences between lenses within this category appear to have little impact on such clinical outcomes. Here, we will consider clinical performance attributes that are known to vary between lens types and highlight the properties that are indeed important considerations in achieving an optimal clinical lens-wearing experience.

Non-oxygen related effects

The following is a list of adverse events that may occur with contact lens wear but either have been shown to be independent of oxygenation or have a converse relation with Dk/t in SiH lenses.

Infection

SiH contact lenses and their high oxygen delivery were introduced with the prospect of reducing the risk of severe keratitis, most commonly associated with microbial infection, to levels associated with daily wear (DW) of hydrogel lenses. Unfortunately the lenses did not deliver on the promise.¹⁻⁴ Recent epidemiological studies continue to find closed eye wear as the major risk factor for infection, with other identified risk factors including contact lens type, full-time wear, correction for hypermetropia or to alter eye colour, internet purchase of contact lenses, failure to wash hands before cleaning, poor storage case hygiene, younger age group, male gender, smoking, season, climatic conditions, less than six months' wear experience, and higher socioeconomic class.³⁻⁶ There is some suggestion that severity of the keratitis and the risk of vision loss is linked to Dk/t^{1-3,7} but certainly no evidence of an effect within the SiH category, even where differences between lens brands among different modalities were found.⁴

TABLE 1

Presence or absence of differences for the given performance attributes between different lens types

Performance attribute	Daily wear		Continuous wear	
	Hydrogel vs SiH	SiH vs SiH	Hydrogel vs SiH	SiH vs SiH
Oxygen related				
Microcysts	no	no	yes	no
Endothelial blebs	yes	no	yes	no
Polymegethism	yes	no	yes	no
Vascularisation	yes	no	yes	no
Limbal redness	yes	no	yes	no
Non-oxygen related				
Infection	no	no	no	no
Inflammation	yes	no	yes	no
Corneal staining	yes	yes	yes	yes
CLPC	yes	yes	yes	yes
Conjunctival splits	yes	yes	yes	yes
SEALS	yes	yes	yes	yes
Mucin balls	yes	yes	yes	yes
Comfort	yes	yes	yes	yes

Inflammation

Non-infectious infiltrative keratitis is an important inflammatory condition that can lead to discomfort, scarring and lens intolerance. There is no suggestion that increasing oxygen transmissibility leads to a reduction of risk of infiltrative keratitis; indeed, there is evidence to suggest that continuous wear (CW) of SiH lenses is associated with equal, if not greater risk, of infiltrates than hydrogels.^{1,8} This is unlikely to be related to Dk/t per se and may be more related to duration of contact lens wear, surface properties of the material or other aspects of the methodology of the study reporting this finding. The implication with respect to the topic of this article is that there are important material or additional predisposing factors other than Dk/t to take into consideration.

Corneal staining

Corneal staining occurs during wear of both hydrogel and SiH lenses. Recently there has been a keen interest in differential staining patterns with SiH lenses dependent on the contact lens care and storage solution.⁹ Links between staining and Dk/t are tenuous at best. Certainly six hours of anoxia does not lead to corneal staining.¹⁰

Papillary conjunctivitis

Contact lens related papillary conjunctivitis is a principal cause of contact lens intolerance, particularly in association with CW.^{11,12} Although the mechanism remains poorly understood, it is thought that the major factors involved are mechanical trauma of the upper palpebral conjunctiva and immunologic and inflammatory mechanisms.¹¹ As such, material

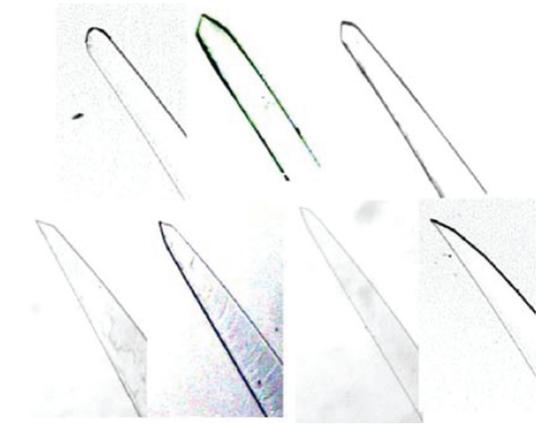


Figure 1 Series of photomicrographs of slivers of a range of commercially available lenses showing vastly different edge design philosophies

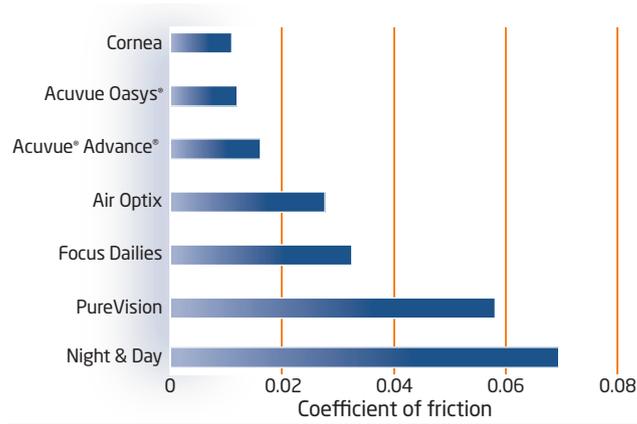


Figure 2 Coefficients of friction of select SiH and hydrogel lenses, redrawn from Ross *et al*²⁸

modulus, lens surface characteristics and lens design are implicated as the contact lens related causative factors.

Conjunctival splits

Lofstrom and Kruse recently identified a new finding arising from the use of SiH contact lenses.¹³ In certain patients, conjunctival splits and fringes have been observed near to where the edge of the contact lens sits. For the most part, the subjects appear to be symptomless and there do not appear to be serious ramifications. Mechanical effects are most likely the cause as CW causes a greater effect than DW.¹⁴ Material modulus and lens design are implicated as the lens related causative factors.

SEALs

Superior epithelial arcuate lesions (SEALs) are an infrequent occurrence of lens wear that give rise to concern as they present a consistent breach in the corneal epithelial surface. They may occur more commonly with SiH lenses. It is currently thought that SEALs are produced by mechanical chaffing as a result of inward pressure of the upper lid, in an area where the peripheral corneal topography and lens design, rigidity, and surface characteristics combine to create excessive 'frictional' pressure and abrasive shear force on the epithelial surface.¹⁵

Mucin balls

Mucin balls are small spheroidal structures that are visible beneath the surface of a contact lens and seem to occur with greater frequency with SiH lenses used for CW. While they are generally considered of limited clinical consequence, they can become inclusion bodies within the corneal epithelium.¹⁶ Aside from patient factors involved in their development, lens modulus,

design and surface properties appear to be key aetiological factors.¹⁷

Refractive error

Unwanted orthokeratology effects have been noticed during wear of SiH lenses, particularly those of high power.¹⁸ Lenses with higher modulus and a flatter back optic zone radius than the cornea are likely to lead to this effect by compressing and thus flattening the central cornea. This effect may act in the opposite manner to the myopic creep effect reported with hydrogel lenses.

Discomfort

Of the factors that govern success in contact lens wear, comfort is the most important.^{19,20} A number of articles have recently appeared suggesting the use of SiH lenses leads to greater comfort than is achieved with hydrogels.²¹⁻²⁴ Despite the apparent consistency between the studies, the position remains debatable. The typical design of these studies has been to switch hydrogel lens wearers to SiH lenses. However, the absence of a masked control group means that the reports of increased comfort may arise from a number of possible biases. Importantly, none of these papers makes a conclusive link to oxygen levels beneath a contact lens and such a link is most unlikely. In truth, there may be a false sense of comfort when oxygen levels are low, since hypoxia has been shown to induce corneal hypoesthesia.²⁵ Our research suggests that some hydrogel lenses are more comfortable than some SiH lenses.²⁶ Material modulus, lens design and surface properties such as lubricity are the principal determinants of comfort and there will be differences in comfort levels between SiH lenses as there are when comparing hydrogel lenses. Any possible relation between comfort and

oxygen levels is far outweighed by these other lens properties.

Negative effects of higher Dk/t

Table 1 compares differences between hydrogel and SiH lenses, and within the SiH group, across a range of oxygen and non-oxygen related performance attributes from clinical studies and current beliefs. In addition to the absence of effects within the SiH group in terms of oxygen related properties, there is a range of possible negative effects associated with higher Dk/t values. It is important to emphasise that these are not a direct effect of higher oxygenation but as a consequence of the material properties necessary to achieve high Dk.

Material Dk is generally a function of the proportions of silicone, water and oxygen-impermeable components. In turn the proportion of silicone will tend to be proportional to modulus of the material. While it was initially thought that a higher modulus might produce beneficial effects from greater tear exchange, it has become apparent that it is associated with numerous negative consequences. From the list above, it seems that through its association with higher lens modulus, higher Dk/t may be associated with increased frequency of CLPC, conjunctival splits, SEALs, mucin balls, refractive error changes and discomfort.

Important SiH lens brand differences unrelated to Dk/t

As demonstrated from the above discussion there are many lens parameters that will influence the clinical performance of a contact lens. Aside from modulus, lens design seems to play a key role in development of CLPC, conjunctival splits, SEALs, and discomfort. Figure 1 shows a set of



commercially available lens edge profiles. Thinner lens edges can lead to more comfortable lenses, but may also result in less movement and conjunctival staining. Chisel shape edges may be responsible in part with lens modulus for producing effects such as conjunctival splits and discomfort.¹³

Quality of the lens surface is also implicated in many adverse events with silicone-hydrogel lenses. Accumulation of material at the surface may lead to immunological and infective consequences.²⁷ A high coefficient of friction may be associated with discomfort and mechanical type effects such as papillary conjunctivitis and SEALs. Lens brands using Hydraclear technology seem to have the lowest coefficient of friction and this is thought to provide these lenses with a slippery feel and greater comfort (Figure 2).²⁸ Some authors report that this benefit may be short-term,²⁹ but when appropriate analytical methods are used, clinically and statistically significant end-of-day comfort benefits over the duration of wear are obvious.³⁰ Further examples of differences between lenses include water content, susceptibility to dehydration and incorporation of ultraviolet blocker.

Out in the great laboratory that is the real world, there appears to be practical recognition of the points raised in this article. First, the lens with the lowest Dk/t of available SiH materials is one of the largest selling SiH brands in the world. There are no reports of which we are aware that suggest that this lens produces hypoxic problems. Second, the first SiH lens introduced to the market remains the lens with the highest Dk/t; manufacturers have not seen fit to pursue lenses with greater Dk/t due presumably to a lack of hypoxic problems with lenses at lower Dk/t values and to avoid the unwanted, attendant problems arising from the higher silicone contents required.

Conclusion

Part one of this series demonstrated that there is no need to strive for the highest Dk/t possible when prescribing SiH lenses. In contrast, there is actually reason to select lower Dk materials within the SiH category, as material modulus, which is generally proportional to Dk/t, is thought to be associated with CLPC, conjunctival splits, comfort, unwanted orthokeratology, SEALs and mucin ball development. Other brand dependent lens properties that are largely unrelated to Dk/t, such as surface properties and lens design, will also affect corneal staining, CLPC, conjunctival splits, comfort, SEALs and mucin ball development. Theoretically, prescribing contact lenses with the highest possible Dk/t is a fine concept but only where other aspects of lens behaviour match. In reality, different lens brands behave quite differently. Practically the greatest clinical success with SiH lenses will be achieved by closely considering the range of parameters of available lenses and basing the selection on everything but Dk/t. ●

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