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### CONTACT LENS PART 1

# Current materials and care regimes – implications for clinical practice

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Choosing the most appropriate lens type and care regime for your patient is crucial to minimise patient dropout. But even the most enthusiastic contact lens practitioner can feel daunted by the large number of both lens options and care products available to them for recommendation, and of course, the situation is a dynamic one. This first article in the series aims to highlight the most pertinent developments, whilst also taking the opportunity to revise important principles about the classification and chemistry of lens materials and care regimes.

### Classification of contact lens materials

It is important to understand generic names as they relate directly to a material's properties and care regime. Since the introduction of EN ISO 11539: 1999, there is an internationally recognised method for the classification of contact lens materials. Every Federal Drug Administration (FDA)-approved material is classified by a six-part code (Table 1). An example of this would be lotrafilcon B I 5 – “lotra-” is the USAN; “-filcon” indicates a soft lens, “B” indicates it is a second formulation, “I” indicates <50% water content, non-

ionic, and “5” indicates that the Dk is in the range 101 to 150 ISO Dk units.

It should be remembered that many custom-made lenses in the UK are made from materials that are not FDA approved, and may still be classified according to the old system (e.g. filcon 1a) – see the ACLM Year Book for more details.

### Material characteristics and lens performance

Contact lens materials continue to develop; the last 10 years have seen enormous developments in silicone hydrogel lenses alone. So, one may ask, “Which characteristics are particularly

important to the eye care practitioner to predict the clinical performance of current contact lenses?” Most of us would include in our response that oxygen transmissibility, comfort, wettability, deposit resistance, reducing infection risk, and avoiding solution interactions, are all important factors. But how do current lens materials and care regimes address these issues? One of the most important aspects of contact lens wear is comfort. Indeed, at least 30% of hydrogel lens wearers cite discomfort as the primary reason for discontinuation.<sup>1-3</sup> But which characteristics particularly influence comfort?

### Lens stiffness and elasticity

When the first silicone hydrogel contact lenses were launched in the late 1990s, much focus was placed on the inherent ‘stiffness’ of the first generation materials, and it may seem that this is a relatively recent topic. However, the manufacture and stability of a lens as well as its fit, handling, durability and potential tear exchange has always related to some measure of the lens’ reaction to an external force. Polymers are viscoelastic substances and their responses under mechanical stress can vary considerably: this is usually described in terms of modulus. Modulus is a way of describing the behaviour of a material before it reaches breaking (failing) point, or in engineering terms, the stress/strain ratio. There are several types of modulus measures that can be described by manufacturers; these are shown in Table 2.

Manufacturers provide us with the product information to compare the modulus between materials (although caution should be applied as different methods can be used), but understanding the clinical implications is more difficult.

Table 3 shows some representative values for some currently available hydrogel lenses with the proviso that some of this data is taken from manufacturers’ websites. Increased modulus in a soft lens can certainly aid handling, but it has been suggested

that perhaps increased modulus is of aetiological significance in the pathogenesis of contact lens-related infection in silicone hydrogel lens wearers.<sup>4</sup> It certainly appears that a greater proportion of silicone hydrogel lens patients develop a localised form of contact lens-associated papillary conjunctivitis (CLPC),<sup>5</sup> even though recent studies indicate a lower incidence of CLPC with the lower modulus lens formulations and the option of a second steeper base curve.<sup>6</sup>

Reductions in comfort from mechanical complications, such as superior epithelial arcuate lesions (SEALs; Figure 1), did appear to occur more frequently with silicone hydrogel lenses in their early days when only lenses with high modulus of elasticity (and limited parameters) were available.<sup>6,7</sup> Such mechanical complications are also more common with overnight wear. Fluting of the lens edge occurs when a relatively stiff lens is poorly aligned with the limbus, causing discomfort and staining.

All this evidence may lead the practitioner to assume a rather negative view of higher modulus values, but it should be remembered that gas permeable lenses possess a very high level of stiffness but are associated with relatively low levels of microbial keratitis.<sup>8</sup> It is important to understand that modulus is a property of the material itself, whereas stiffness depends on the design and thickness of the lens profile, which will determine how it behaves on the eye. It is better to consider that as modulus increases, the philosophy of some disposable lenses that 'one base curve will do' is more prone to falling short of expectations. At the present time, only certain silicone hydrogel lenses are offered in more than one base curve, and no stock lenses are offered in alternative diameters. This may reflect the idea that manufacturers are comfortable with the notion that acceptable fits can be achieved most of the time within their current portfolio of products. Given

<b>Prefix</b>	USAN (US adopted name). E.g. eta, oma	
<b>Stem</b>	filcon for soft lenses focon for rigid lenses	
<b>Series suffix</b>	capital letter used if there has been revision of original chemical version (e.g. -filcon A, -filcon B)	
<b>Group suffix</b>	<b>Rigid lenses</b>	<b>Soft lenses</b>
	<b>I</b>	<50% water content, non-ionic
	<b>II</b>	≥50% water content, non-ionic
	<b>III</b>	<50% water content, ionic
	<b>IV</b>	<50% water content, ionic
<b>Dk range</b>	Numerical code to indicate RANGE of permeability in ISO units (currently 0-7)	
<b>Modification code</b>	'm' indicating surface modification of the lens	

**Table 1**

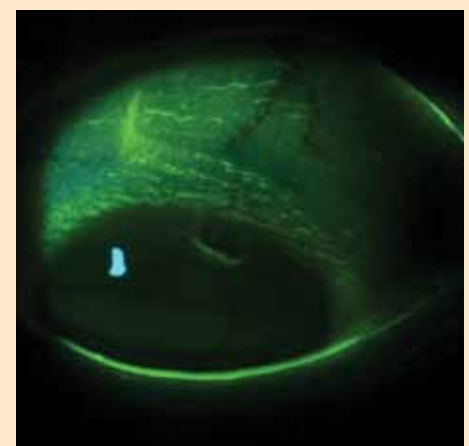
Classification of lens materials according to EN ISO 11539: 1999 (adapted from the *ACLM Contact Lens Year Book 2009*, Ed. C Kerr and D. Ruston)

that many silicone hydrogel lenses fall within standard hydrogel modulus ranges (Figure 2), practitioners should perhaps consider that concerns with modulus (and therefore optimal fitting) are more pertinent to the first generation materials such as lotrafilcon A and balafilcon A. Of recent interest is the use of lathe-cut high water content silicone hydrogels such as UltraVision's lathe-cut KeraSoft 3 and Kerasoft IC lenses to mask distortion on highly irregular corneas.

**Wettability, biocompatibility, biotribology and biomimesis**

The material and surface characteristics of a contact lens determine how the lens will interact with the tear film (see the next article of this series), and manufacturers and practitioners alike are always striving to provide lenses that mimic the natural ability of the cornea to remain moist for 25-30 seconds. The clinical performance

of any contact lens is governed by its wettability, as this will affect its ability to form a stable pre- and post-lens tear film. Fundamentally, a contact lens must have good wetting to permit good vision and comfort, to resist deposition



**Figure 1**

Superior epithelial arcuate lesion (SEAL) stained with sodium fluorescein

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Modulus measure	Description	Units
Tensile modulus	Measured by pulling or stretching	ocon for rigid
Initial modulus	Measured during the first few % of the deformation process (like the typical deformation from handling)	MPa (MegaPascal = 106 Pascal = newtons/mm <sup>2</sup> )
Elastic modulus	Measured during small rapid deformation and recovery (like the typical force of a blink)	@5Khz; given in kPa

**Table 2**

Different expressions of modulus measures, relevant to contact lens materials

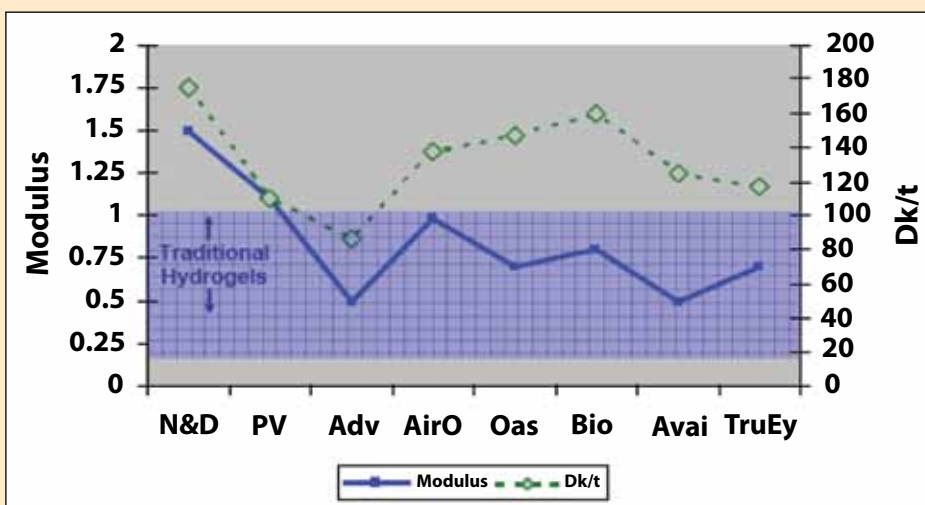
and to be truly compatible with the eye.

Traditionally, wettability is described using the results from techniques in the laboratory using contact angles, captive bubble and sessile drop techniques.<sup>10</sup> The lower the contact angle of a material, the more wettable is its surface. Contact angles traditionally measured on lenses *in vitro* can vary depending on whether they come straight from the pack, have been soaked overnight in care solutions, and whether they ‘mask’ their inherent hydrophobicity via bulk properties or surface-treatments (see Table 3). The relationships between measures of *ex*

*in vivo* wettability and the usual clinical signs and symptoms are unclear from the literature, but this may reflect differences in the methods used between studies. Measuring wettability *in vivo* is usually a semi-qualitative assessment at best, using the slit lamp biomicroscope or the Tearscope (Keeler, UK). Researchers in Manchester have recently developed a novel technique for measuring contact angles *in vivo* which looks promising (poster observed at ARVO, 2009), and may give us more insight into the relationship between manufacturer descriptions and ‘on eye’ performance.

Gas permeable lenses frequently contain silicone to impart superior oxygen permeability but this decreases wettability of the material surface due to the hydrophobic properties imparted by the silicone. Copolymerisation with fluorine atoms or hydrophilic monomers such as methacrylic acid improves surface wettability and *in vivo* tear film stability for these lenses. Some manufacturers coat the gas permeable lens with hydroxyl groups or employ plasma treatments to further enhance wetting of the lens surface. Plasma treatment in this way is not a coating – it is more of a cleaning method as it removes the entire manufacturing residue.<sup>9</sup> Lenses are placed in a vacuum chamber, and an electrically charged cold gas is drawn over the lens to react with the contaminants on the lens, freeing them from the surface. The plasma and contaminants are then drawn out leaving an extremely clean lens surface. This process results in a more hydrophilic surface with lower wetting angles on delivery, which should improve initial comfort for patients, but will wear off over time.

With soft lenses, even the hydrophilic groups in the polymer have the ability to rotate away from the surface when they encounter the lipids of the tear film, so it is a continuous challenge to extend the period where the surface of the lens remains lubricious. One of the first lens types to address this issue was omafilcon A (Proclear,



**Figure 2**

Modulus and oxygen transmissibility (Dk/t) values for current contact lenses. (N&D = Night & Day, CIBA Vision; PV = PureVision, Bausch & Lomb; Adv = ACUVUE ADVANCE, Johnson & Johnson Vision Care; AirO = Air Optix, CIBA Vision; Oas = ACUVUE OASYS, Johnson & Johnson Vision Care; Bio = Biofinity, CooperVision; Avai = Avaira, CooperVision; TruEy = 1-Day ACUVUE TruEye, Johnson & Johnson Vision Care). Reproduced by kind permission of CIBA Vision (UK)

Manufacturer	DAILIES Aqua Comfort Plus	1-DAY ACUVUE MOIST	Proclear 1 day	Soflens Daily Disposable	AIR OPTIX Aqua	ACUVUE OASYS	Pure Vision	1-DAY ACUVUE TruEye	Clariti 1 day	Avaira	Biofinity	PremIO	Saphir (toric lens)
	CIBA Vision	Johnson & Johnson Vision Care	CooperVision	Bausch & Lomb	CIBA Vision	Johnson & Johnson Vision Care	Bausch & Lomb	Johnson & Johnson Vision Care	Sauflon	Cooper Vision	CooperVision	Menicon	Mark' Enovy
Polymer	nelficon A II 2	etafilcon A IV 2	omafilcon A II 2	hilafilcon B II 2	lotrafilcon B I 5	senofilcon A I 5	balafilcon A III 4M	narafilcon A I 4	filcon II 3	enfilcon A I 4	comfilcon A I 5	asmofilcon A I	filcon V 3
Water content	69%	58%	60%	59%	33%	38%	36%	46%	56%	46%	48%	40%	75%
Oxygen permeability (Dkx10 <sup>-11</sup> )	26	28	25	22	110	103	91	100	60	100	128	129	60
Modulus (elastic; Mpa)			0.2		1.0	0.6	1.06	0.66	0.5	0.5	0.75	0.9	0.27
Special features of polymer	Cross linked with both functional and non-functional PVA	Lacreon technology: incorporating high molecular weight PVP into matrix	PC Technology: fully incorporating a phospholipid (phosphorylcholine)		Permanent plasma surface treatment	Hydraclear Plus technology: incorporating high molecular weight PVP	AquaGen process to decrease wetting angle	Hydraclear 1 technology: incorporating high molecular weight PVP into matrix		Aquaform (Property of the bulk material)	Aquaform (Property of the bulk material)	Menisilk with Nanogloss	Low dehydration rate
Additive(s) that enhance wettability or biomimesis	HPMC, PEG & dual molecular weight PVA sustained release	PVP in lens matrix		Comfort Moist Poloxamine in packaging solution	PVP in packaging solution	PVP in lens matrix		PVP in lens matrix					

**Table 3**

Main characteristics of current soft contact lenses (adapted from available manufacturer and published data)

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	Mode of action	Examples
<b>Packaging additives</b>	Surfactants, lubricants Cushioning effect upon insertion Lower contact angle at time of insertion Washes away over first day	HPMC, PVP
<b>Bound to lens matrix</b>	Lubricants, wetting agents Maintain surface wetting and lens dehydration	PVP, PEG
<b>Release from lens matrix</b>	Lubricants, wetting agents 'Time release'; 'blink-activated'	PVA

**Table 4**

The search for biomimesis: current approaches to improving wettability of hydrogel contact lenses

CooperVision) – it contains a synthetic analogue of a naturally occurring phospholipid (phosphorylcholine) which encourages the material to retain moisture,<sup>11</sup> and is now available as both a monthly and daily disposable lens product. These lenses were the first to be given FDA approval for use for patients with mild to moderate dry eye symptoms during contact lens wear, and they have demonstrated biocompatibility with the ocular environment in a number of studies.<sup>12,13</sup>

Silicone hydrogel lenses all have to adopt a method of overcoming the natural hydrophobic tendencies of their silicone content and maintain wettability of the lens surface. To avoid patent disputes it is necessary for manufacturers to seek to achieve this in different ways – this may take the

form of permanent surface treatments, plasma oxidation, and more recently the use of internal wetting agents and intrinsic increases in hydrogen bonding to attract water molecules (see Table 3). Several manufacturers adopt a trademark for their approach to this problem, with examples including Aquaform, AquaGen, and Hydraclear. The names Menisilk and Nanogloss used by Menicon (Japan) describe a novel polymer and a plasma treatment, which combines the benefits of both plasma coating and oxidation.

More recently the terms biocompatible and biomimesis are enjoying renewed popularity in the contact lens field as manufacturers take an even more proactive approach to improving wettability during lens wear. *Biocompatibility* implies that a contact lens will be in harmony with the eye and have little or no adverse effects; in fact, all contact lenses have to become biocompatible quite quickly once on the eye to be tolerated and this response mostly depends on the patient.<sup>14</sup>

*Biomimesis* describes the construction of artificial biomaterials that mimic natural forms and effects, and is a term used in relation to contact lens products/approaches that try to recreate the smooth, stable and moist optical surface naturally found on the cornea. *Biotribology* is the study of friction and can provide useful measures about the

relative performance of contact lenses and materials as they are subjected to blinking – this is an important factor in creating a biomimetic contact lens.<sup>15</sup>

So, what are the latest proactive approaches to the biomimetic challenge?

Much of the recent activity has surrounded daily disposable products, as the effects have only to last one day, but we are now seeing specific methods entering the monthly lens category (e.g. Air Optix Aqua, CIBA Vision). There are three approaches currently being used (Table 4).

The packaging additives are known surfactants or lubricants, which cushion the lens upon insertion as well as lower the contact angle at the time of insertion. Even though the additive will wash away during the first day, there is evidence that a lens that is more comfortable on insertion remains more comfortable during the day. An example of this approach is Bausch & Lomb's Soflens Daily Disposable (hilafilcon B), which has a surfactant in its packaging solution.

A second approach is to bind lubricants or wetting agents to the polymer itself to maintain the surface wetting or lens hydration, or to reduce friction. With the 1-day Acuvue Moist lens (Johnson & Johnson Vision Care) polyvinylpyrrolidone (PVP) is embedded into the matrix of the polymer (etafilcon A) to enhance wettability and comfort (termed 'Lacreon technology').<sup>16</sup> PVP is a humectant (it readily binds to water) and it is this property that helps the contact lens to retain moisture. In the Safegel 1day lens (Safilens, Italy), hylauronic acid (HA) is added as a wetting agent with the added benefit of reducing protein adsorption.<sup>17</sup>

The third approach is incorporating lubricants or wetting agents that are intended to leach out of the polymer slowly over the life of the lens. This is easiest to accomplish in daily disposable lenses but also can be effective in monthly/weekly lenses. Practitioners will encounter the terms "time release" or "blink activated" where the wetting agent is wiped from the surface with



**Figure 3**

Lipid deposits on a silicone hydrogel contact lens surface

the blink to then be replaced with more wetting agent from the internal hydrogel structure. The daily disposable products from CIBA Vision demonstrate this sort of evolution of approach to the wettability problem. The original lens is made from nelfilcon A (cross-linked with polyvinyl alcohol (PVA)), further improved by the addition of non-functional PVA that can be released gradually into the tear film to serve as a wetting agent.<sup>18</sup>

The latest formulation of this lens product (Dailies AquaComfort Plus) also has hydroxypropylmethyl cellulose (HPMC) and polyethylene glycol (PEG) added; the HPMC adds comfort on insertion, and the PEG adds to the PVA in the lens matrix that will be released via blinking. A clinical trial has shown that the sustained release of PVA from nelfilcon A appears to enhance comfort compared to oculifcon B lenses over long wearing times, despite clinical appearances being similar,<sup>19</sup> and this is consistent with *ex vivo* studies.<sup>20</sup>

### Deposition and electrical charge

Lens deposits can reduce vision and comfort so the tendency of a lens material to attract deposits remains a concern for contact lens practitioners despite frequent replacement modalities being the most popular in the UK.<sup>21</sup> Lens material can carry electrical charge or be neutral. Ionic materials (mostly negatively charged) tend to attract the deposits that are positively charged, such as lysozyme (a protein found in the tear film), and protein attraction increases with water content and/or ionicity. The term 'zwitterionic' is also sometimes used to describe materials that carry a total net charge of zero, (thus electrically neutral) but carry formal positive and negative charges on different atoms in the monomers.

For gas permeable contact lenses, the charge on the surfactant cleaner and the wetting and soaking solutions are usually formulated to attract and repel deposits respectively. Traditionally, group IV lens materials tend to deposit lysozyme and group II lens materials (particularly if

THE IER MATRIX STUDY: CORNEAL STAINING				
Solution-Induced Corneal Staining per month with the combination*				
Lens / Solution	CLEAR CARE®	AQuify®	OPTI-FREE Express®	OPTI-FREE Replenish®
ACUVUE® ADVANCE™	0.0%	0.9%	0.0%	0.0% (2W)
ACUVUE® OASYS™	0.9% (2W)	2.6% (2W)	6.2%	7.1% (2W)
O <sub>2</sub> OPTIX™	0.5%	3.2%	5.9%	6.7%
PureVision®	0.9%	23.2%	11.3%	14.2%
NIGHT & DAY™	1.7%	0.9%	7.2%	6.7%

Legend: Lower quartile (Green), Inner two quartiles (Yellow), Upper quartile (Orange)

Figure 4a

IER Matrix Study (<http://www.ier.org.au/news/0408/news1.asp> accessed on 27/10/09)

		Lens and solution combinations percentage of average corneal staining area at 2 hours							
		Unisol Saline	Clear Care	Opti-free Express	Opti-free Replenish	Renu Multiplus	Renu Multipurpose	Complete MPS Easy Rub	Aquify
Hydrogel	Acuvue 2	1%	1%	2%	5%	1%	1%	1%	1%
	Proclear	1%	1%	1%	2%	57%	23%	6%	12%
	Soflens 66	1%	1%	1%	1%	73%	32%	17%	8%
Silicone Hydrogel	Acuvue Advance	1%	1%	1%	1%	13%	4%	12%	2%
	Acuvue Oasys	2%	1%	3%	5%	9%	5%	4%	3%
	Biofinity	2%	2%	3%	2%	4%	2%	2%	2%
	Purevision	2%	1%	4%	7%	73%	43%	15%	21%
	O2 Optix	2%	1%	2%	5%	24%	7%	3%	3%
	Night & Day	2%	1%	2%	3%	24%	11%	1%	3%

Updated: August 25, 2008

Staining colour codes: Green= under 10% Yellow= 10-20% Red= over 20%

Figure 4b

Andrasko & Ryen Staining Grid showing average corneal staining at two hours

they contain vinyl pyrrolidone) have a tendency to deposit lipid.<sup>22</sup> This is an area that has received fresh interest since silicone hydrogels were introduced, and a recent review<sup>23</sup> highlighted the major findings of the previous eight years. A recent study by Boone et al.<sup>24</sup> showed that silicone hydrogel lenses deposit low levels of protein, but the amount and percentage of denatured (inactive) lysozyme can be relatively high, depending on the overall surface charge of the material and absence or type of

surface treatment. Where lenses are surface treated, protein is unable to enter the lens matrix and tends to stay on the surface where it may become denatured.<sup>25</sup>

Lipid deposits have been reported on silicone hydrogel lenses<sup>26</sup> (Figure 3), which can decrease comfort and vision over time due to poor wettability, although there are some suggestions that a very small amount of lipid can improve initial wettability with some silicone hydrogel materials.<sup>23</sup> Both protein and lipid deposits on silicone hydrogels

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Factors affecting measurable dehydration of a contact lens
Water content
Water bound to polymer
Material composition/surface properties
Environment
Lens thickness
Wearing period
Patient
Tear film quality
Methods of measurement

**Table 5**

Important factors that influence measured contact lens dehydration

are reduced by the use of a ‘rub and rinse’ regime and/or a multipurpose solution that contains a surfactant.

The durability of silicone hydrogel lenses beyond three-month replacement is really unknown, although it has been shown with gas permeable lenses that Dk appears to have a detrimental effect on lens life.<sup>27</sup> With high Dk soft lenses now available as affordable daily disposables, soft lens deposits may be less relevant in everyday practice, and lipid deposition on silicone hydrogels may become more manageable for affected patients, but it is interesting that there are still many practitioners who do not recommend frequent replacement of high Dk gas permeable lenses as a strategy to combat deposit-related problems.

### Lens dehydration

There is frequently a reduction in perceived comfort during the wearing period with all hydrogel lenses, often described as ‘dryness’, of which

lens dehydration is part of the story. Dehydration is affected by many factors (Table 5). For example, soft lens materials with a significant amount of bound water, such as hioxifilcon and omafilcon A, are very useful to minimise dehydration and alleviate contact lens dryness.<sup>28</sup> The relationship between wearing comfort and lens dehydration is unclear from the literature but this is probably a reflection of the difficulty in assessing *ex vivo* hydration. Another incentive to minimise on-eye dehydration is that the lens material would sustain higher oxygen transmissibility throughout the day.<sup>13</sup> Research has shown that silicone hydrogels dehydrate at a slower rate than conventional hydrogels, and also to a lesser extent.<sup>29,30</sup> Using silicone hydrogels, patients have reported their lenses to feel ‘less dry’ at the end of the day, with the result that they have longer lasting comfort.<sup>31,32</sup> One study found that 75% of subjects who experienced reduced wearing times due to the feeling of uncomfortable dryness, had increased wearing times and improved comfort after two weeks of silicone hydrogel wear.<sup>33</sup> Not only are silicone hydrogels said to improve the comfort of lens wear throughout the day, they have also been suggested to perform much better in challenging environments. Studies have found that they provide improved comfort compared to conventional hydrogels in air-conditioned work places, with computer screen use and in heated rooms.<sup>34</sup>

### UV protection and contact lenses

All contact lens materials block ultraviolet (UV) radiation to some extent (approximately 10% of UV-A radiation and 30% of UV-B radiation), but it is limited to the area of ocular surface covered and is certainly not a substitute for wrap-around sunglass protection. Several products (including Acuvue, and Precision UV) have an additional monomer purposefully added prior to manufacture to significantly increase this property. As patients become increasingly aware of the added value

of such benefits, practitioners should be careful to stress that this approach should be seen as complimentary to other forms of facial UV protection.

### Drug delivery and antimicrobial lenses

There has been much patent activity in the area of drug delivery via contact lenses and anti-microbial properties of contact lenses. Several studies have shown promising ability to deliver antibiotics in a controlled manner.<sup>35-39</sup> It is an exciting prospect that perhaps infection risk during contact lens wear may be reduced by the use of anti-microbial contact lenses, in the not too distant future.

### Interactions between silicone hydrogel lens materials and care solutions

Corneal staining noted with certain combinations of silicone hydrogel materials and solutions has generated a plethora of research. It is beyond the scope of this article to offer a comprehensive review and the reader is referred to the excellent resource [www.siliconehydrogels.org](http://www.siliconehydrogels.org). To summarise, recent studies show that certain care regimens can result in abnormally high levels of relatively asymptomatic corneal staining with silicone hydrogels,<sup>40</sup> sometimes appearing after two to four hours<sup>41</sup> either in a typical diffuse punctuate pattern across the entire cornea or in a ring like pattern around the corneal periphery. Following these reports, both Andrasko & Ryen<sup>42</sup> and the Institute for Eye Research (IER)<sup>43</sup> have produced grids demonstrating that other multipurpose solution/silicone hydrogel combinations can cause similar staining (Figures 4a and 4b).

The difficulty in comparing information from the IER Matrix Study and the Andrasko Staining Grid is that the latter reports a mean area of the cornea affected after two hours exposure while the IER data is incidence during a clinical study over three months. Much criticism has been levelled at the Andrasko & Ryen grid,<sup>43</sup> but both studies agree that least interaction is seen with hydrogen peroxide systems

and silicone hydrogels. Interestingly, the Sauflon product Synergi (with Oxipol), which utilises a very different approach, has shown similar staining levels to peroxide systems elsewhere. It uses a small amount of hydrogen peroxide (to stabilise the solution) in combination with sodium chlorite, and its active ingredients decompose into oxygen, salts and water outside the lens case.

How much should we be concerned about solution-induced staining? Carnt et al.<sup>44</sup> reported that asymptomatic corneal infiltrates were associated with solution related staining; subjects presenting with such staining were three to six times more likely to have had corneal infiltrates. Bacterial invasion of the cornea is opportunistic but it is unlikely that even high levels of the type of staining caused by such adverse lens/solution combinations causes enough corneal insult or damage to predispose to infection. More research is needed to examine any such proposed relationship, but with over 93% of all lens care systems prescribed being multipurpose,<sup>45</sup> even without this proof, practitioners should still strive to eliminate this staining.

We have seen the marketing of some lens products aimed at silicone hydrogels in particular. It is interesting to note that in January 2009, the FDA organised a workshop to discuss the issue of incorporating acanthamoeba

testing into the requirement for licensing multipurpose solutions. This is not currently a requirement but recent outbreaks of acanthamoeba keratitis<sup>46</sup> have contributed to a drive to introduce change. It has been shown that some silicone hydrogels with a surface treatment have a greater affinity for attachment of acanthamoeba.<sup>47</sup> Once consensus is achieved about the standards, we are likely to see a new generation of care products emerging in the coming years.

#### Oxygen performance of current lens materials

The need for oxygen permeability is well documented. Of more current interest is the debate about how we judge materials and lenses in this respect. Whilst the manufacturers will always feature the Dk (permeability; property of the material) and Dk/t (transmissibility; property of the lens and dependent on thickness) values in their marketing material, it has become more difficult for practitioners to make a judgement about what this means for our patients. This difficulty comes in two parts. Firstly, the ideas about ‘how much oxygen is enough’ have shifted somewhat in recent years, and are influenced by the mode of measurement. Secondly, even when a minimum level of oxygen permeability is agreed

upon, the research hasn’t always shown us satisfying improvements with the lenses that we hoped for, indicating that ocular health and patient satisfaction are multi-factorial challenges.

Traditionally, oxygen penetration through a lens is described using Dk or Dk/t values (Table 6; using Fatt or barrer units) and these are often quoted for product comparison, although we should all really be adopting new ISO units of hectoPascals (hPa); “old” values need to be divided by 1.333, e.g. Fatt Dk 100 becomes ISO Dk 75. These measures indicate the ease with which oxygen can pass through a material, and a contact lens of certain thickness, respectively. There is no current technique to measure the oxygen beneath a lens directly so to gain insight into oxygen concentration of the cornea under the lens, indirect methods such as Equivalent Oxygen Percentage (EOP) are used. Uptake rates for a particular contact lens are compared to uptake rates obtained after the cornea has been exposed to reduced concentrations of oxygen (maximum 21%). It has been argued that oxygen flux is a more useful measure for contact lenses – it takes into account not only the transmissibility of the lens but also the partial pressures at both sides of the lens. There is a positive relationship between the magnitude of the difference between the surfaces

Term	Definition	Physical Unit
Oxygen flux j	Volume of oxygen reaching an area of the cornea through a specified area of a contact lens over a set amount of time	µl O <sub>2</sub> (cm <sup>2</sup> sec)
Oxygen permeability Dk	Amount of oxygen passing through a contact lens material over a set amount of time and pressure difference	10-11 (cm <sup>3</sup> O <sub>2</sub> cm)/(cm <sup>3</sup> sec mmHg) OR 1 Barrer
Oxygen transmissibility Dk/t	Amount of oxygen passing through a contact lens of specified thickness in vitro, over a set amount of time and pressure difference	10-9 (cm ml O <sub>2</sub> )/(ml sec mmHg)

**Table 6**

Commonly used measures of oxygen performance

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Dk/t	Modality	Criterion	Author	Year
24	Open eye	0% oedema	Holden/ Mertz	1984
87	Closed eye	4.0% oedema	Holden/Mertz	1984
35	Open eye	No corneal anoxia	Harvitt & Bonanno	1999
125	Closed eye	No corneal anoxia	Harvitt & Bonanno	1999
125	Closed eye	3.2% oedema	Sweeney/Holden	2004

**Table 7**  
Critical oxygen values obtained for various physiological indicators

and the movement of oxygen through the lens. There will be a maximum reached where the oxygen tensions either side are equal: at higher values of Dk/t the improvement in oxygen flux reduces. It is important to note that a simple relationship between increasing water content and permeability exists for standard hydrogels, unlike with silicone hydrogels where there is a bit of a paradigm between these features apart from the newer materials which provide higher water contents and Dk values (see Table 3). This is where oxygen flux is a particularly useful measure for oxygen performance.<sup>48</sup> But how much oxygen is enough? The answer depends on what you choose as your clinical criterion. Holden & Mertz were the first to define safe limits of oxygen performance based on corneal swelling,<sup>49</sup> followed by Harvitt & Bonanno.<sup>50</sup> Table 7 shows the criteria they and other landmark studies have defined. The values seem to vary widely, but they utilise Dk/t – it has been shown that if you utilise the oxygen flux model then there is little further benefit beyond the values of the Holden & Mertz criterion.<sup>51</sup> For the time-being, most manufacturers continue to present Dk/t values until clear criteria using oxygen flux performance are established and adopted across the industry.

Published evidence does not really support the idea that dryness discomfort is directly related to oxygen

performance, but we know that there are many physiological benefits to be gained – decreased hypoxic responses such as microcysts, oedema, hyperaemia, and neovascularisation. When silicone hydrogels were launched there was clear expectation that infection risk would be reduced but the major studies have shown that the reality is a little disappointing. Two papers from Australia presented an absence of difference in the incidence of microbial keratitis between those who wore silicone hydrogel lenses on an extended wear basis versus those who wore conventional hydrogel lenses on an extended wear basis.<sup>52,53</sup> From Manchester came several studies<sup>54-56</sup> that demonstrated increased incidence but significantly reduced severity of keratitis in those wearing silicone hydrogel lenses versus those using hydrogel lenses for overnight wear. It should be remembered that incidence rates will vary according to the definitions used for the diagnosis, and much of this data was collected when only the first generation silicone hydrogel materials were in use; as we learn more about incidence rates with newer materials, a new picture may emerge. Perhaps one of the most significant findings presented is a meta-analysis of published evidence that concluded there is approximately a two-fold higher risk for corneal inflammatory events in silicone hydrogel lens wearers when worn for up to 30 days extended

wear when compared with low Dk extended wear lenses worn for seven days extended wear.<sup>57</sup> The clinical implication is that it may be better to consider six nights wear as opposed to 30 nights', but there remains conflicting evidence.

It is clear that infection risk is not all about oxygen performance and there are more modifiable risks, such as smoking, sleeping in contact lenses, compliance with care regimes, swimming and internet purchase, etc.

**Conclusion**

This article has presented a broad review of the main characteristics of contact lens materials and care regimes that are most pertinent to modern contact lens practice. In the next article of this series, the interaction between contact lenses and the tear film will be discussed.

**About the author**

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**References**

See [www.optometry.co.uk/references](http://www.optometry.co.uk/references)

## Module questions

Course code- C-12756

**1. The contact lens material known as balafilcon A III 4M has what properties?**

- a. It is an ionic hydrogel lens with water content greater than 50%
- b. It is a non-ionic rigid lens with low water content with surface modification
- c. It is an ionic hydrogel lens with water content less than 50%
- d. It is a non-ionic, hydrogel lens with water content less than 50%

**2. Which of the following approaches does NOT enhance wettability when lenses are worn?**

- a. Incorporation of phosphorylcholine into lens material
- b. Lipid deposition
- c. Plasma treatment of the surface
- d. Increasing the stability of the tear film

**3. Which of the following is likely to improve comfort and wettability of a hydrogel contact lens on insertion?**

- a. Hydroxypropylmethyl cellulose (HPMC) added to the packaging saline
- b. Hyaluronic Acid (HA) added to the packaging saline
- c. Polyvinylpyrrolidone (PVP) added to the packaging saline
- d. All of the above

**4. Which of the following is NOT likely to improve long-term wettability of a contact lens surface?**

- a. Utilising a 'no rub' approach to lens care
- b. Continuous wear of a standard hydrogel contact lens
- c. The addition of high molecular weight polymer to the lens matrix
- d. Plasma treatment of a gas permeable lens

**5. Which measure of modulus is closest to simulating the deformation force on a contact lens from blinking?**

- a. Elastic modulus
- b. Tensile modulus
- c. Stiffness
- d. Initial modulus

**6. Which of the following is a typical mechanical complication of hydrogel contact lens wear?**

- a. Superior epithelial arcuate lesion
- b. 3 and 9 staining
- c. Chalazion
- d. Pingueculae

**7. The science of tribology is the study of what?**

- a. Biocompatibility between two membranes
- b. Friction in bioscience
- c. Organisms that colonise biocompatible surfaces
- d. How bacteria group together on a contact lens surface

**8. How is wettability achieved with the Daily AquaComfort Plus (CIBA Vision) lens during wear?**

- a. Extra PVA that is released from the lens during wear
- b. HPMC added to packaging
- c. PEG added to packaging solution to combine with the PVA
- d. All of the above

**9. Which of these tear film constituents carries a positive charge?**

- a. Albumin
- b. Chloride
- c. Lysozyme
- d. Hydroxide

**10. Which of the following statements about silicon hydrogel lenses is CORRECT?**

- a. They tend to have less denatured protein than standard hydrogels
- b. They tend to attract less lipid but more 'active' protein
- c. They tend to attract lipid only
- d. They tend to attract less protein but more lipid

**11. Which pattern of staining is characteristic of a solution compatibility problem between silicone hydrogels and multipurpose care solution?**

- a. Central punctate staining appearing immediately after lens insertion
- b. Peripheral punctate staining appearing immediately after lens insertion
- c. Peripheral punctate staining appearing 2-4 hours after lens insertion
- d. Central punctate staining appearing 2-4 hours after lens insertion

**12. Which of the following would reduce hydrogel lens transmissibility?**

- a. Reducing centre thickness
- b. Increasing water content
- c. Incorporating a wetting agent in the polymer
- d. Lens dehydration

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