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The Physical and Clinical Characteristics of Silicone Hydrogel Lenses: How They Work?

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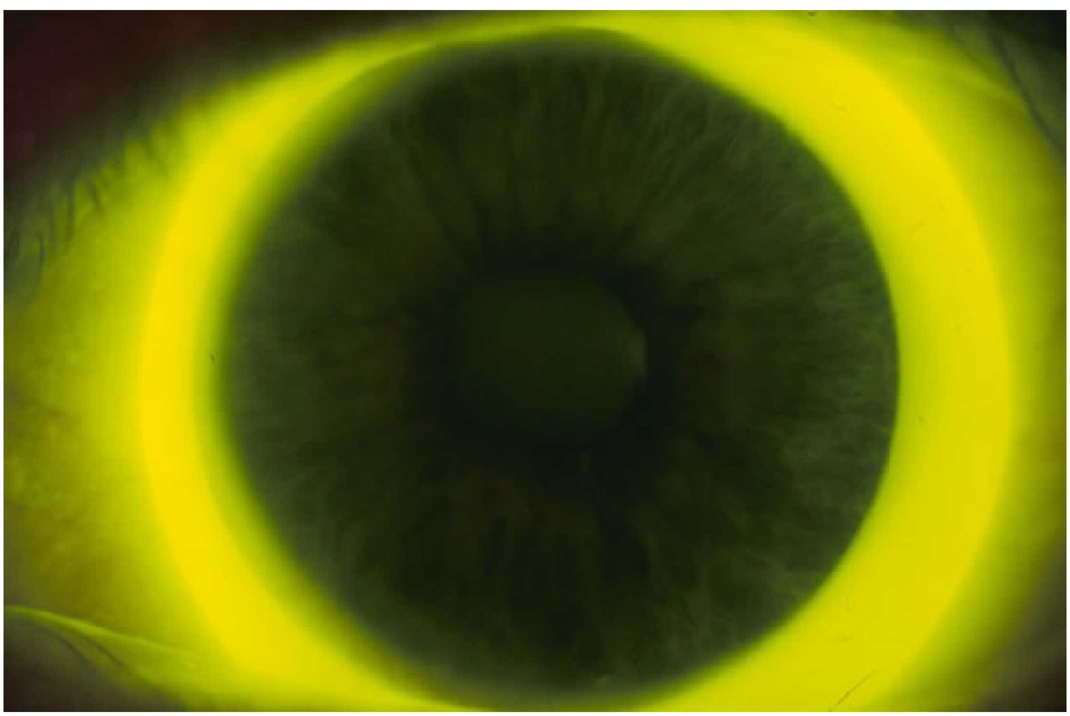
Introduction

Silicone hydrogel lenses are a made from an innovative group of extremely oxygen permeable contact lens materials. The development of these materials arose from the desire to eliminate the hypoxic responses known to occur as a result of wearing conventional hydrogel materials on an extended wear basis.

It was proposed that combining the properties of silicone and hydrogel materials would offer many advantages including the comfort and wettability of hydrogels and the high oxygen transmissibility of silicone. TOP

Silicone hydrogel materials differ considerably from the silicone rubber (elastomer) lenses used for therapeutic or paediatric applications. Although silicone-elastomeric lenses offered exceptional oxygen transmission and durability, a number of major limitations are associated with their use in clinical practice. As fluid is unable to flow through the lens and the lens surfaces are hydrophobic, binding to the ocular surface is very likely.



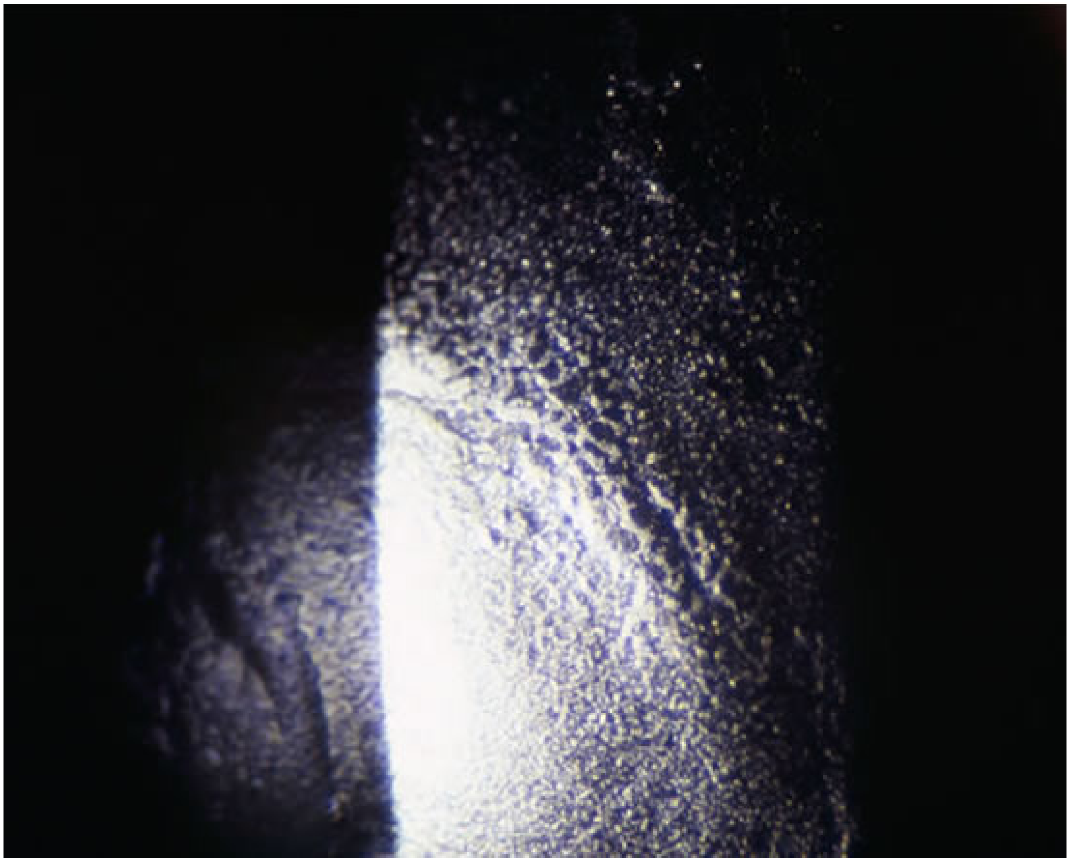
Binding of a silicone rubber (elastomer) lens

Materials

All contact lens materials are polymers. The constituent monomers which comprise the polymers determine the physical and chemical properties of the materials. Repeating chains of monomers are arranged in patterns with cross-linking between the polymer chains to afford strength and further govern the characteristics of the lens materials. The monomers commonly employed in contact lens materials include N-vinyl pyrrolidone (NVP), methacrylic acid (MA) and poly-2-hydroxyethyl methacrylate (pHEMA). These polymers allow the lens materials to absorb and bind water. TOP

In silicone hydrogel materials, silicone rubber is combined with conventional hydrogel monomers. The silicone component of these lens materials provides extremely high oxygen permeability, while the hydrogel component facilitates fluid transport and thus lens movement. Unfortunately, this process or combination is not without difficulty and it has therefore taken some considerable time for these materials and designs to come to fruition. The process of combining these monomers has been likened to efforts of combining oil with water, while maintaining optical clarity[1].

An additional impediment to the development of these contact lens materials relates to the decreased wettability, increased lipid interaction and accentuated lens binding inherent in silicone based materials. Therefore a technology referred to as "gas plasma surfacing" is employed in order to render the surfaces hydrophilic[2].



Poor wetting of a silicone rubber (elastomer) lens

How they work

Detailed explanations of the development of silicone hydrogel materials for contact lenses[1,3] and their polymer chemistry[4] have been described previously. The following account is intended to provide a brief, simplified overview for practitioners.

Contact lens materials must permit the transmission of both oxygen and ions. One approach which may be used to achieve this goal involves the incorporation of two "phases" into the materials. Phase separation occurs when the interconnections between the chemically similar molecules in the material are stronger than the adhesive connections between them and the different molecules. This approach to material development was historically avoided because it usually resulted in an opaque material which would be unsuitable for contact lenses. However, techniques have been developed in which the phase separation is limited, such that the phase size is far shorter than the wavelength of light, resulting in optically clear materials[4].

CIBA Vision's Focus Night and Day? material, lotrafilcon A, employs such a biphasic or two channel molecular structure. The fluorosiloxane phase facilitates the storage and transmission of oxygen and the hydrogel phase transmits water and oxygen, allowing good lens movement. The two phases work concurrently to allow the co-continuous transmission of oxygen and ions. Lotrafilcon A is comprised of a fluoroether macromer co-polymerised with the monomer trimethyl-siloxy silane (TRIS - used in the preparation of RGP materials) and the solvent N,N-dimethyl acrylamide (DMA) in the presence of a diluent. The resultant silicone hydrogel material has a water content of 24% and an oxygen permeability (Dk) of 140 barrers. Lenses are manufactured from lotrafilcon A using a standard industry molding process and then the surfaces are permanently modified in a gas plasma reactive chamber to create a permanent, ultrathin (25nm) continuous hydrophilic surface. TOP

Bausch and Lomb's PureVision? material, balafilcon A, is a homogeneous combination of the silicone containing monomer Polymethylsiloxane (a vinyl carbamate derivative of TRIS) co-polymerized with the hydrophilic hydrogel monomer N-vinyl pyrrolidone (NVP). This silicone hydrogel material has a water content of 36% and a Dk of 110 barrers. Cast molded balafilcon A lenses are surface treated in a gas plasma reactive chamber[2] which transforms the silicone components on the surface of the lenses into hydrophilic silicate compounds. Glassy silicate "islands" result and the hydrophilicity of these areas "bridges" over the underlying hydrophobic balafilcon material.

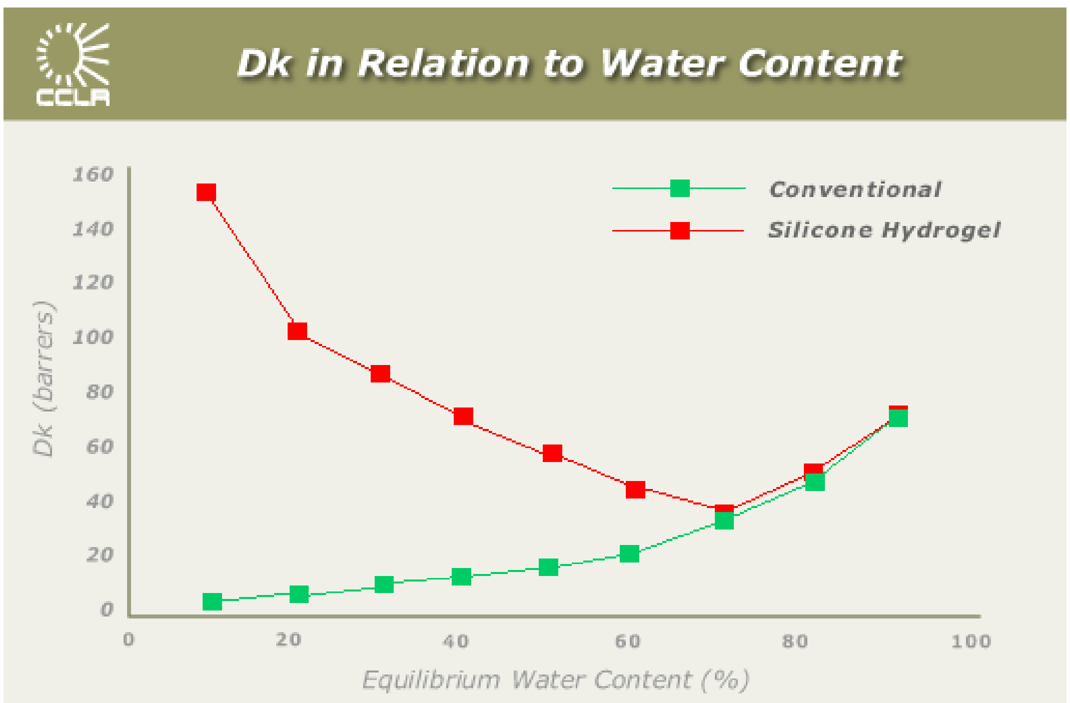
The flow of oxygen and fluids through the lenses is not impeded by these surface modifications. Both surface treatments are an integral part of the lens and are not surface coatings that can be easily "stripped" away from the base material. Silicone hydrogel lenses have also been reported to have extremely low protein deposition[5]. TOP

Oxygen Transmissability and Corneal Health

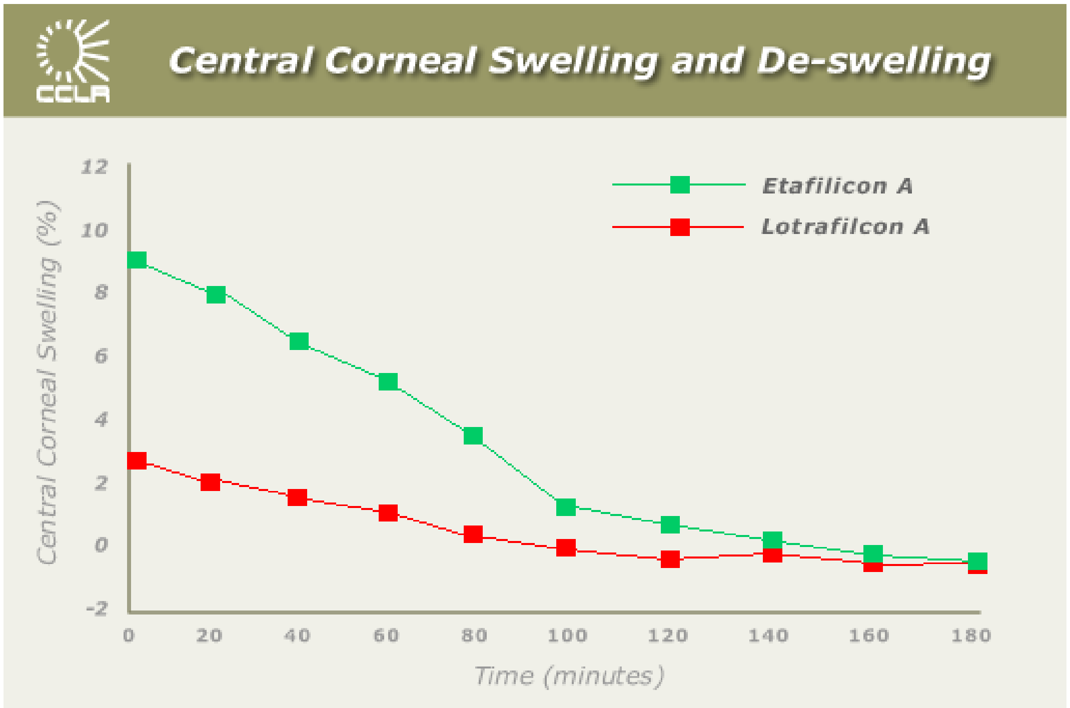
A sufficient oxygen supply is required in order to maintain corneal integrity and to provide defence against infection. The minimum requirements for oxygen transmissibility (Dk/t) of extended wear contact lenses in order to prevent overnight hypoxia-induced edema was estimated to be 87 x 10-9 (cm x ml O2)/(s x ml x mmHg) by Holden and Mertz in 19846.More recently a level of 125 x 10-9 (cm x ml O2)/(s x ml x mmHg) has been reported as a requirement to prevent stromal anoxia[7].

Traditional contact lenses have relied on water to carry the oxygen through the lens. This has been a limiting factor, since 100% water has a Dk of only about 80 barrers. As a result, conventional hydrogel lens materials do not deliver sufficient oxygen during extended wear and a number of clinical signs of chronic hypoxia may occur. Conventional high-water lenses needed to be made thicker than their low water counterparts resulting in relatively low Dk/t values. Consequently, thicker high-water content lenses and thinner low-water content lenses deliver approximately the same amount of oxygen to the central cornea. It is the close relationship between water content and oxygen permeability that has impeded hydrogel lens material development for extended wear for more than 20 years. TOP

In silicone hydrogel materials the oxygen is transmitted through the silicone component of the lens material, resulting in a dramatic increase in the oxygen permeability. Pure silicone rubber has a Dk of 400 to 600 barrers and this provides silicone hydrogel materials with Dk/t values of 110 to 175, which is 6 times more permeable than conventional hydrogel contact lenses. Figure 1 is redrawn from Brian Tighe's chapter in Silicone Hydrogels[1] and demonstrates the Dk of these materials compared with conventional materials, in which the Dk is directly related to the water content of the lens material.



As a result of the increased oxygen availability, studies conducted at the CCLR have found overnight edema levels with the new generation materials to be similar to the levels seen with no lens wear and to be far lower than those measured with commercially available disposable soft lenses[8]. Figure 2 demonstrates the degree of central corneal swelling upon eye opening for eyes wearing etafilcon A (Acuvue?) and lotrafilcon A (Focus Night and Day?) lenses. TOP



Central corneal swelling induced by an etafilcon A lens on eye opening was significantly higher than with a lotrafilcon A lens (8.7 ± 2.8% vs. 2.7 ± 1.9%, $p<0.00001$). The de-swelling profiles following lens removal were much quicker for the lotrafilcon A induced corneal swelling (100 minutes) than for etafilcon A induced swelling, which took almost twice as long to return to baseline levels.

In a similar study, the overnight central corneal swelling induced by balafilcon A lenses (PureVision?) was found to be 2.8 ± 2.0% compared to 8.7 ± 2.7% with a 70% water content lens (Dk/t = 22)9. TOP

Ionic and Hydraulic Permeability and Lens Movement

The transport of fluid and ions through contact lenses is crucial for the provision of essential nutrients and removal of waste products and debris. The flow of water through the lens is also necessary for on-eye lens movement, comfort and wettability. It is the hydrogel component of lens materials that is responsible for these processes.

In homogenous silicone hydrogel materials such as balafilcon A, while the oxygen permeability increases, the hydraulic permeability decreases with decreasing water content. This is because fluids and ions are transported through the hydrogel component of the lens material. A minimum sodium ion and hydraulic permeability of 0.2 x 10-6 cm2sec-1 has been reported to be required for lens movement1. A balance therefore has to be reached between maximising oxygen transmission while still allowing sufficient hydraulic flow to prevent hydrophobic binding of the lens to the cornea.

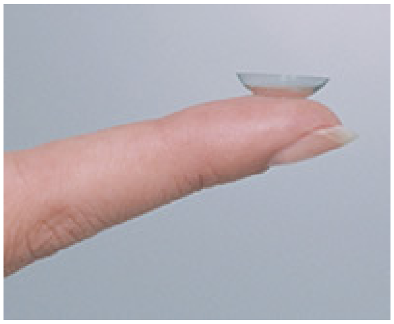
In biphasic co-continuous silicone hydrogel materials such as lotrafilcon A, the oxygen and fluid permeability are "uncoupled" allowing a much greater level of hydraulic and ionic permeability than would be available through a polyHEMA with an equivalent water content. As a result, lenses made from this material display adequate lens movement while still benefiting from the additional oxygen permeability afforded with a water content of 24%. In the case of the balafilcon A material, a water content of 36% provides a hydraulic permeability which actually corresponds with that normally offered by a 40% water content lens. This suggests that there may also be some degree of phase separation of the material. TOP

Mechanical Properties and Lens Stiffness

Lens adhesion is also a factor of material elasticity. Pure silicone materials are extremely elastic and tend to adhere to the cornea with a "suction effect". The material elasticity of the currently marketed silicone hydrogel lenses is much less and fortunately approaches that of HEMA. This further helps to prevent lens adhesion and promote movement and tear flow beneath the lens.

Silicone hydrogel lenses are however much "stiffer" than their conventional hydrogel counterparts. It is this property that gives the lenses their excellent handling characteristics. The modulus, stiffness or rigidity of the materials is 110 - 120 g/mm2 (1.1 - 1.2 MPa)1 which is over twice that of polyHEMA and nearly four times greater than the HEMA-methacrylic acid components of the etafilcon A material (Acuvue?). As a consequence, the "stiffer" material does not drape over the cornea as easily. When silicone hydrogel lenses are too loose, the result is often a lens that exhibits edge lift or slight fluting that causes foreign-body like discomfort to the patient10. 8.2% of post- dispensing discontinuations with Focus Night and Day? lenses have been attributed to poor fit[11]. Following the introduction of a further steeper base curve for this lens type, a recent study has shown that for trial fitting assessment and subjective comfort, 98% of the patients in the trial could be satisfactorily fitted with a choice of an 8.4 or 8.6 mm base curve[12]. TOP

Fluting of a silicone hydrogel lens as seen in a small percentage of potential wearers



Handling properties of silicone hydrogel materials are excellent

The increased stiffness likely contributes to the formation of mucin balls beneath the lenses with overnight wear[13]. It may also be a factor in the formation of superior epithelial arcuate lesions (SEALs) in some patients. SEALs have been reported to occur more frequently with silicone hydrogel materials than conventional hydrogel lenses[14,15]

Summary

Table 1 summarises the differences between the two commercially available silicone hydrogel materials and compares them with the Acuvue? lens material. TOP

Table 1: Characteristics of Novel and Conventional Lens Materials

Proprietary Name	***PureVision™***	***Focus Night & Day™***	***Acuvue™***
Manufacturer	Bausch and Lomb	CIBA-Vision	Vistakon
Ct (@ -3.00D)mm	0.09	0.08	0.07
Water Content	36%	24%	58%
Dk	99	140	22
Dk/tx10-9@ 35oC	110	175	31
Surface Charge	Surface slightly ionic	Surface slightly ionic	Surface highly ionic
Surface Treatment	Plasma oxidation, producing glassy islands	25nm plasma coating with high refractive index	No treatment
"Stiffness" (g/mm2)	110	120	35
FDA Group	III	I	IV
Monomers	NVP + TRIS-VC	DMA + TRIS + siloxane macromer	HEMA + MA
USAN	balafilcon A	lotrafilcon A	etafilcon A

DMA (N,N-dimethylacrylamide); HEMA (poly-2-hydroxyethylene methacrylate); MA (methacrylic acid); NVP (N-vinyl pyrrolidone); TRIS-VC (tris-(trimethylsiloxysilyl) propylvinyl carbamate).

New silicone hydrogel materials are currently being developed and modifications made to those currently available. Future designs may benefit from decreases in modulus (and consequently stiffness) and changes to the manufacturing process in order to increase the rate of production at a lower cost. These changes will offer the practitioner and patient a wider choice of lens materials and designs in order to achieve successful continuous wear. TOP

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