Silicone Hydrogels: Trends in Products and Properties

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INTRODUCTION

Although Silicone hydrogels resemble conventional hydrogels because of the water that they contain, the substantial presence of relatively hydrophobic silicone components leads to many differences in behaviour from that of simple mid to high water content hydrogel lenses. In six years since their launch, clinical experience has revealed a combination of characteristic benefits and complications (such as mucin balls and SEALS). The first two silicone hydrogels that became commercially available in the UK (balafilcon A marketed under the trade name PureVision by Bausch and Lomb and lotrafilcon A marketed as Focus Night & Day by Ciba Vision) had water contents of 36% and 24% respectively. Although both are classified as silicone hydrogels they are based on bulk and surface technologies that are significantly different from each other.

In 2004, a third silicone hydrogel (galyfilcon A, marketed as ACUVUE ADVANCE by Johnson & Johnson Vision Care) became available. The water content of this lens at 47% is appreciably greater than either of the two initial materials, as are its surface and bulk chemistries. The oxygen permeabilities of these materials are well publicised and as expected, fall with increasing water content. Despite this fact, there now appears to be a trend in silicone hydrogel development to sacrifice higher oxygen permeability in favour of increased water content. Evidence for this was initially found in the FDA website, information relating to new USAN names and new approval submissions, which revealed the development of two new silicone hydrogels, senofilcon A (Johnson & Johnson Vision Care) and lotrafilcon-B (CibaVision). These two materials have now been launched as ACUVUE OASYS and O_2OPTIX, respectively. This will increase the number of commercial silicone hydrogel lenses to five, covering Equilibrium Water Contents from 24% to 47% and oxygen permeabilities (Dk) from 60 Barrers to 140 Barrers. Further details of these materials are contained in Table 1.

This poster compares the dynamic mechanical properties, dynamic wettability, frictional properties and dehydration behaviour these five materials. Although conventional hydrogel behaviour provides one reference point, the human cornea provides another interesting comparator. It is interesting to ask the question: are silicone hydrogels becoming more like the cornea?

METHODOLOGY

Mechanical Properties (Tensile and Dynamic)

Mechanical properties are conventionally measured in tension, in compression or dynamically using an ascillating cyclic load. The dynamic method is more similar to deformation processes found in nature, such as flexing muscles or blinking. The mechanical behaviour of polymer-based tissues is not simple, they reflect the viscoelastic nature of these materials, and these are represented by an elastic and a viscous flow component. Valuable information on the mechanical properties of contact lenses is obtained by studying both tensile properties (initial modulus, elongation to break and tensile strength) and dynamic properties (storage and loss modulus as a function of frequency).

Tensile properties are measured on miniature dog bone parallel-sided specimens cut directly from contact lenses. The specimen is mounted in the jaws of a Hounsfield HK tensometer with a 10N load cell. Tensile tests are then carried out at a strain rate of 200%/min and ambient temperature. Spraying with a fine mister minimises dehydration during the test. The values obtained are initial modulus, elongation to break and tensile strength.

Dynamic mechanical properties are measured using a fully automated Bohlin CVO Rheometer coupled with a temperature-controlled unit interfaced to a microcomputer. The dynamic mechanical properties are measured in oscillation using a parallel plate set up with fritted surface to avoid sample slippage during oscillation. Samples are subjected to frequencies of 0.5Hz - 20 Hz and values of the complex modulus (G*) the elastic (storage) modulus (G′) and the viscous (loss) modulus (G″) are thus obtained.

Dynamic Vapour Sorbtion

The dehydration/rehydration dynamics of the samples were measured using an automated dynamic vapour sorption analyser (DVS). At the heart of the DVS system is an ultra-sensitive microbalance which monitors changes in sample mass over a sequence of typically 50-100 cycles in which the humidity is switched between upper and lower levels of 98 RH and 40 RH. Cycle times of forty minutes at 98 RH followed by two minutes at 40 RH provides an accelerated representation of front surface dehydration enabling both mass loss and regain to be observed and compared.

Dynamic Contact Angle

The dynamic contact angle is a way of measuring the wettability of the hydrogel. The lens is cut into three strips 3.3 mm wide, this strip is placed on a crocodile clip with a counter weight on the other end to keep the strip of lens straight. This strip is then lowered into, and raised out of, saline. This reflects the tear film break up in the eye and how the lens will adapt to dehydration following tear break-up.

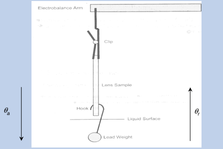


Figure 1: (above) Method used to hold lens strip for DCA analyses.

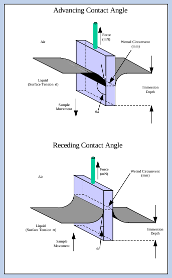


Figure 2:(right) Schematic of wettability measurements

Coefficient of Friction

Principles and Methodology
Friction is the resistance to the sliding of one solid body over or along another. The magnitude or "level" of friction can be expressed in terms of the coefficient of friction μ. A modified nano – scratch tester was used to measure the coefficient of friction μ as a contact lens is dragged over a substrate (μ = F/W, where the force F is required to produce sliding when a load W is pressing two solid bodies together). An important aspect of this is the difference between the situation where the surfaces first start to move (so-called start-up or static friction) and when they are in motion (known as steady state or dynamic friction).

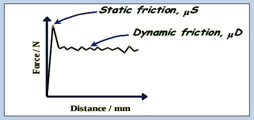


Figure 3

Figure 3 Shows a typical output (force vs distance) for a friction test and Figure 4 shows the way in which the apparatus was configured. A droplet of lubricating liquid forms a meniscus at the point of contact between lens and surface and simulates the way in which the upper tear meniscus moves with the eyelid over the lens surface. The contact lens is placed onto the curved support. 100 μl of the lubricating solution (saline with a trace of surfactant) is placed between the lens and the substrate (polyethylene terephthalate). The load applied to the contact lens is chosen to simulate *in vivo* eyelid – lens pressure.

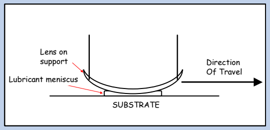


Figure 4

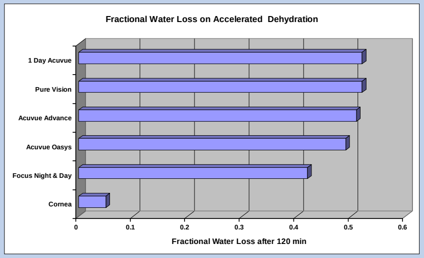
RESULTS

Table 1: Silicone-Hydrogel Lenses and Properties*

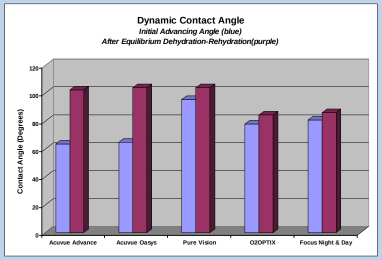
Proprietary Name	PureVision	Focus Night&Day	O_2OPTIX	ACUVUE ADVANCE	ACUVUE OASYS
United States Adopted Name	Balafilcon A	Lotrafilcon A	Lotrafilcon B	Galyfilcon A	Senofilcon A
Manufacturer	Bausch & Lomb	CIBA Vision	CIBA Vision	J&J Vision Care	J&J Vision Care
Water Content	36%	24%	33%	47%	38%
Oxygen permeability ($x\ 10^{-11}$)	99	140	110	60	103
Tensile Modulus (psi)	148	238	190	65	92
Initial Modulus (MPa)	1.1	1.4	1.2	0.4	0.6
Initial Advancing Contact Angle (°)	95	80	78	65	68
Relative Initial Dehydration Rate	1.9	1	1.5	2.4	1.8
Surface Treatment	Plasma oxidation, producing glassy islands	25nm plasma coating with high refractive index	25nm plasma coating with high refractive index	No surface treatment. Internal wetting agent (PVP)	No surface treatment. Internal wetting agent (PVP)

** Measured at Aston and collected from various sources*

Dynamic Vapour Sorption

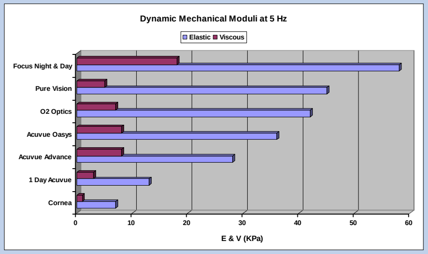


Dynamic Contact Angle

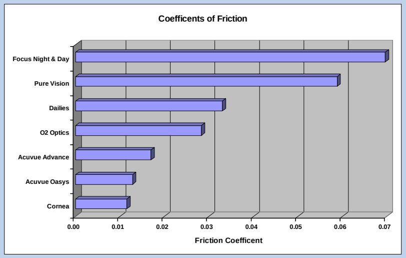


DCA measurements involve removal and reimmersion of a sample. The first immersion (initial) always gives a lower contact angle value than the following (equilibrium) immersions. This is an indication that the lenses have dehydrated to some extent after the first immersion and the relative magnitude of the surface change on dehydration is illustrated by the difference between initial and equilibrium values in the chart above.

Dynamic Mechanical Properties ("elastic stiffness")



Coefficient of Friction



CONCLUSIONS

- The relative behaviour of materials is illustrated by the order of ranking in bar charts. These are laboratory measurements not clinical indicators.
- The newly extended range of silicone hydrogels is moving closer to the cornea in physical properties although not in dehydration resistance.
- The trend to higher water contents has produced a dramatic reduction in stiffness both in simple tension tests and in dynamic studies.
- All lenses have relatively low coefficients of hydrated friction although differences in material surfaces produce different values.
- The inclusion of PVP in ACUVUE ADVANCE and ACUVUE OASYS lenses produces particularly low friction values – closely approaching that of human cornea.
- The PVP effect also produces low values of advancing contact angles while materials are fully hydrated, but does not improve dehydration resistance.
- The O_2OPTIX material is a higher water content version of Night&Day and has a similar plasma-coated surface. These lenses are less initially wettable than PVP-modified lenses but show less loss of wettability on dehydration.
- The extended range of water contents, wettabilities and stiffness values offered by the commercially available silicone hydrogels provides practitioners with a wide selection of significantly different clinical materials.
- The wettability and dehydration data presented here indicate that although the newer silicone hydrogels are in many ways similar to conventional hydrogels, lipid-related spoilation will pose greater problems for some patients than is the case with conventional hydrogels.
- The fact that current silicone hydrogels are significantly different from conventional hydrogels and also from each other highlights the need for standardised relevant *in-vitro* methods of assessment for these materials.