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Mechanical Properties of Contact Lenses: The Contribution of Measurement Techniques and Clinical Feedback to 50 Years of Materials Development

Abstract

Purpose

This review summarises the way in which mechanical property measurements combined with clinical perception have influenced the last half century of materials evolution in contact lens development.

Methods

Literature concerning the use of *in-vitro* testing in assessment of the mechanical behaviour of contact lenses, and the mutual deformation of the lens material and ocular tissue was examined. Tensile measurements of historic and available hydrogel lenses have been collected, in addition to manufacturer-generated figures for the moduli of commercial silicone hydrogel lenses.

Results

The three conventional modes of mechanical property testing; compression, tension and shear each represent different perspective in understanding the mutual interaction of the cornea and the contact lens. Tensile testing provides a measure of modulus, together with tensile strength and elongation to break, which all relate to handling and durability. Studies under compression also measure modulus and in particular indicate elastic response to eyelid load. Studies under shear conditions enable dynamic mechanical behaviour of the material to be assessed and the elastic and viscous components of modulus to be determined. These different methods of measurement have contributed to the interpretation of lens behaviour in the ocular environment. An amalgamated frequency distribution of tensile moduli for historic and currently available contact lens materials reveals the modal range to be 0.3-0.6 MPa.

Conclusion

Mechanical property measurements of lens materials have enabled calibration of an important aspect of their ocular interaction. This together with clinical feedback has influenced development of new lens materials and assisted clinical rationalisation of in-eye behaviour of different lenses.

Keywords

Contact lens, Mechanical Properties, Modulus, Compression, Tension, Shear

Introduction

The contributions that mechanical property measurements have made to the development of contact lenses and the understanding of the complexity of the ocular environment have increased progressively. The widely available techniques were, however, not designed for the contact lens format; even now there are no accepted dedicated standard technique or test conditions. In consequence most measurements have been made at room temperature on lenses taken from conventional packing solutions or phosphate buffered saline. The fact that on-eye conditions produce both higher temperature and some degree of progressive dehydration, is a complication that is still largely unaddressed. There is an undeniable need for a robust ISO standard for characterisation of the mechanical properties of contact lenses. In order to appreciate how mechanical properties and existing testing techniques have changed, it is important to briefly review the way in which materials have developed over time. Accounts of early attempts to improve vision by use of a lens contacting the eye are limited to a few isolated observations [1]; practical success was not realised until techniques for fabrication of lenses from glass were sufficiently developed [2]. Poly(methyl methacrylate) (PMMA) replaced glass in the late 1930s; the material was more durable, more readily fabricated and claimed by some to show better ocular compatibility [3]. During the same broad period there was also a change in emphasis from scleral to corneal contact lenses, which placed different demands on material design and development. The property considered to be of practical importance for contact lens manufacture at that time was refractive index [4]. Mechanical test procedures were not conventionally used.

The invention of soft hydrogel lenses [5] naturally led to an interest in the comparative mechanical properties of hard and soft materials. From this point, clinical observations related to the possible relationship between modulus and comfort could begin. It was immediately apparent that soft lenses provided better initial comfort than hard materials. Physically-related aspects of the contact lens such as lens design, surface imperfections, and particularly edge-related effects were, however, capable of providing even greater variability in patient response than the modulus itself. Early soft lenses were predominantly lathe-cut in the dry state and then hydrated, with a consequent change in dimensions and mechanical properties. The lenses were fragile when hydrated, were capable of deformation by eyelid movement and interacted with the tear film producing deposits and discolouration. An insightful review of the history of early soft lenses is provided by Pearson [6].

As the understanding of hydrogel chemistry improved, an increasing variety of soft lens compositions and water contents became available; much of this early learning is encapsulated in the patent literature [7-10]. In succeeding years, clinical evaluation of lens performance became a topic of detailed study involving effects of material structure [11], production techniques [12-14] and assessment of the biological response [15-17]. Despite the fact that the concept of "the ideal contact lens" has been regularly discussed, having been first raised by Kamath in the late 1960s [18], the ideal balance of mechanical, surface and transport properties is still an elusive concept.

This review examines the way in which mechanical property testing and lens materials have developed over the last fifty years. It is clear that clinical assessment and practitioner feedback have strongly influenced the optimisation of material mechanical properties during this period.

The Idealised Lens Development Cycle

The development of an increasing range of lens materials has inevitably stimulated increased interest in property measurement**.** As new lens materials began to supersede PMMA, increased understanding of lens characteristics required more detailed clinical studies and ultimately practitioner feedback. Fig 1 shows an idealised schematic view of the life cycle of the contact lens development process. This is clearly an over-simplification of the very diverse ways in which lens materials have emerged from different laboratories in the past, but it does illustrate the principles that underpin the interaction of laboratory data and clinical observations.

The initial feedback loop (Fig 1*a*) encompasses the early steps in lens development, involving the assessment of prototype and/or trial lenses. The scale of clinical studies conducted in such early stages is typically small, not necessarily representing the wider range of contact lens wearers and wear schedules in commercial usage. At this stage of evaluation, mechanical property testing can help to highlight problems of reproducibility in synthesis and fabrication, such as incomplete or non-optimised polymerisation. Incomplete polymerisation can lead to many problems, for example, dimensional instability and ocular leaching of unreacted monomer.

The secondary feedback loop (Fig 1*b*) represents large-scale commercial production. The purpose of mechanical testing at this stage is principally to ensure quality control, minimising inter-batch variation. Practitioner feedback will be based on a broader patient base involving a variety of ocular responses. An understanding of the fundamentals of polymerisation and biomaterials science are important to the optimisation of the network structure, physicochemical properties and consequent clinical performance of the lens material, which is related in many different ways to ocular health [15-17, 19].

The Developing Need for Mechanical Property Testing

The process of material development over time has not been characterised by regular steps; Fig 2 summarises the evolution of lens materials together with comments relating to the links between materials and clinical success.

Historically, glass scleral lenses were primarily ground or blown [3]. Although PMMA could not be fabricated by blowing, it was possible to fashion PMMA scleral lenses by thermo-forming the polymer against an impression of the ocular surface and corneal lenses by using lathe-based grinding and polishing techniques [1]. The latter approach was commonly used for fabrication of precision optical (e.g. camera lenses). This is the foundation upon which the design of materials for use in the lens fabrication techniques of the 1960s, 1970s, 1980s and much of the 1990s were based.

The temperature at which a material changes from a glassy to rubbery state, is referred to as its glass transition temperature (T_g). One great advantage of the first hydrogel material - poly(2-hydroxyethyl methacrylate) (PHEMA) – is that in the dehydrated (xerogel) state, it also has a T_g above 100^oC. The surface temperatures generated during lathing and polishing of lenses will depend upon the nature of the cutting tool and other detailed aspects of the process, but normally fall well below the T_g of PMMA and PHEMA.

The clinical recognition that PMMA lens wear induced corneal swelling stimulated the search for materials capable of producing lesser disturbance to the ocular environment. A set of complementary criteria emerged against which the desirable features of potential clinically successful candidate materials could be judged. These were:

• enhanced oxygen permeability
• susceptibility to reproducible fabrication
• the ability to maintain a coherent anterior and posterior tear film
• adequate mechanical durability
• dimensional stability

Although these were key properties for clinical and commercial success, for most of the serious candidate materials there was some trade-off of characteristics. CAB (cellulose acetate butyrate), silicone rubber and poly(4-methyl pent-1-ene) (TPX) all showed some properties that compared advantageously with those of PMMA, but none has proved to be commercially and clinically successful in the long-term [20-24].

By the 1980s, the use of siloxy methacrylates in combination with methyl methacrylate (MMA) had led to a new generation of contact lens materials – the so-called gas permeables. Many of the large number of emerging siloxymethacrylate gas permeable lenses suffered from poor surface hardness, which in turn led to surface scratches and in some cases a consequent build-up of film deposits.

The soft lenses developed initially by Wichterle were inevitably more fragile than rigid materials. As a strategy to increase the oxygen transmissibility of hydrogel lenses [25], lens thickness was reduced but not surprisingly, thin-high water content lenses lead to reported cases of high fragility [26]. Although experience of hydrogel chemistry was steadily improving at this time, driven mainly by the desire to achieve higher water contents, complete understanding of hydrogel network structures and their effect on mechanical durability took rather longer to achieve.

The fact that patients showed a more immediate acceptance of soft hydrogel lenses (whereas rigid lenses require an initial adaptation period) led to a growth rate of hydrogel lenses that was restricted by the much greater fragility of these new lenses [6]. At this time researchers and clinicians began to address the potential quantitative link between mechanical properties of the material and the clinical performance of the resultant lens.

Before discussing mechanical properties, it is first necessary to define two important characteristics:

- The strength of a material, which is conventionally defined as the force per unit area required to initiate failure.
- The modulus (stiffness) of a material is more relevant to in-eye contact lens behaviour. It is defined as the stress (force per unit area) required to induce a unit deformation or strain in the direction of deforming force.

There are various forms of modulus, depending upon how the sample is deformed (in tension or compression, for example) and whether the *initial* force/deformation or stress-strain slope is taken, or an *average* over the complete elongation range. In consequence, the terms tensile modulus and Young's modulus are typically quoted. Modulus and strength, although related in units of force per unit area, are not interchangeable.

Modulus is now widely used in relation to contact lens behaviour. Young's modulus, named after the 18th-century scientist Thomas Young, provides the initial description on elastic properties. It is important to note that this relates to tension or compression in only one direction. For the definition to be valid the deformed sample must return to its original length.

Several units have been used in the past to report mechanical properties; the SI unit is the Mega Pascal (MPa). It is relatively simple to convert between units, which all have the form of force per unit area:

$$1 \text{ MPa} = 10^6 \text{ Nm}^{-2} = 145.04 \text{ psi} = 10^7 \text{ dynes cm}^{-2}$$

The force can be applied in various modes, such as tensile, compression and shear. These are illustrated diagrammatically in Figure 3.

These different modes of deformation can provide useful and complementary types of information about the behaviour of contact lenses:

- Studies in tension provide a measured modulus, together with tensile strength and elongation to break, which all relate to handling and durability.
- Studies in compression can also be used to measure modulus and in principle indicate response to eyelid load.
- Studies in shear enable dynamic mechanical behaviour to be studied and the elastic and viscous components of modulus to be determined.

When a material under tension is elongated, its width is slightly diminished. The ratio of this transverse strain (deformation) to the longitudinal strain is called Poisson's ratio. The average value for Poisson's ratio for metals is ca 0.3, for PMMA 0.35-0.40, and for soft elastic materials such as hydrogels the value approaches 0.5. Poisson's ratio is important in characterising the relationship between the different types of moduli - e.g. bulk, shear and Young's moduli – that contribute to the complete characterisation of material deformability.

As materials have evolved, these different methods of mechanical property measurement have progressively informed understanding – as yet far from complete - of the effect of mechanical behaviour on clinical performance of different lens types.

Compression Behaviour of Hard and Soft Materials

Compression modulus testing is related to, but distinct from, the indentation techniques that were initially used to measure the relative hardness of materials, such as minerals and later extended to plastics and polymers. In the context of these softer organic materials, relative "hardness" was understood to be a measure of resistance to indentation. Commercially available hardness testers include: Vickers indenter, Rockwell hardness tester and Shore durometers. Hardness numbers are now quoted for rigid gas permeable (RGP) lens materials, but the absence of a standardised methodology and the existence of several different hardness scales increase the difficulty of a cross-material comparison. The properties evaluated by these methodologies include resistance to indentation and surface scratching and are generally strongly influenced by the hardness of the material surface [27, 28].

The use of compression testing to evaluate bulk, as distinct from surface properties stems back to the seminal work of Hertz. This approach typically uses spherical indentors and enables applied deforming force or load and the resultant indentation depth to be related to Young's modulus and Poisson's ratio of the indented material. Current understanding of modulus determination by spherical indentation and related techniques is underpinned by a huge amount of combined theoretical and experimental work [29]. The technique is extensively used in the characterisation of soft biomaterials and natural tissue [30, 31] using modifications of the Hertz equation that enable variables such as sample thickness to be taken into account.

Compression testing of soft contact lenses began by adapting the use of commercial instruments developed and used to study deformation of films, paints and coatings, which as a class exhibit a wide range of deformability. Compression modulus, as distinct from surface hardness, is an indicator of the amount of force (stress) necessary to compress (strain) the test-material by a given amount. The fact that there was considerable similarity between the deformability of soft contact lenses and that of elastomers such as silicone rubber, meant that the mathematical relationships derived for such materials were readily adaptable to the study of soft contact lens materials, by taking variations in Poisson's ratio into account. By observing the relative effect of an applied compressional force, comparable stiffness factors (moduli) of lens materials were derived [32, 33].

There was a considerable early interest in high water content contact lenses that both lay outside the scope of the intellectual property associated with PHEMA, and offered potential improvements on oxygen transmission. The mechanical behaviour – deformability and fragility of many of these early experimental lenses [34, 35] proved inferior to either PHEMA or current commercial lens-materials. The value of compression testing in understanding the deformational effect of the eyelid on the elastic recovery of the lens – and consequence for visual acuity during the blink cycle – underpinned the understanding of the importance of network structure in the development of commercially and clinically viable products. The mechanical behaviour of early lens materials can be illustrated by referring to the results of Ng [36], who modified a pneumatic hardness micro-indenter to study the deformational properties of soft lens materials. The scope of the technique could be extended by altering indenter shape [37, 38] and varying the load applied; in particular testing under eye-lid load (approximately 3-8 kPa [39]) which meant that correlations with clinical behaviour could be investigated. It is important to note from the work of Miller [40] and Shikura *et al* [41] that variability in eyelid load between subjects is large, even within one blink type and one measurement method.

Fig 4 illustrates the application of this technique and also compares the elastic behaviour of a lens with good visual acuity (Fig 4*a*) and one with poor visual acuity (Fig 4*b*) under eyelid load. Fig 4*a* displays ideal behaviour, with immediate deformation when load is applied and immediate recovery after load removal. Fig 4*b* illustrates a material with time-dependent elastic behaviour represented by incomplete recovery on repeated loading. The difference in visual performance between these two types of behaviour was quite marked; poor elastic recovery, characterised by Fig 4*b* is associated with lenses that show good comfort but vision which became unstable on blinking, a situation sometimes called "watery vision" [42]. Studies ascertaining the visual acuity of early soft lenses have been documented in the peer-reviewed literature [43-47].

The same technique carried out with a spherical indenter enables calculation of the rigidity modulus of materials to be determined, by use of modified versions of the Hertz equation developed for use with similar materials used in other fields [36]. The rigidity modulus can be defined as the force (stress) required to compress (strain) the material by a given value. Fig 5 illustrates results obtained with a range of early candidate contact lens materials. By plotting log (load) vs log (indentation) a series of lines of slope about 3/2 is obtained. Materials of increasing modulus lie higher up on the y-axis.

Of particular importance is the capability of the technique in illustrating the difference between the deformational behaviour of rigid and soft materials. Rigid materials do not show measurable deformation by this technique at loads below about 1.0 g (Fig 5). This illustrates the point that the combination of eyelid load and a rigid lens material leads to deformation of the cornea not the lens. This observation underpins the application of rigid lenses in orthokeratology. The response of the cornea, which has a rigidity modulus of about 1.0 MPa [48], is distinctly different for rigid and soft lenses but not recognisably so for two different rigid lenses of the same design. Characterising and acknowledging the significance of the difference in material properties between soft and hard materials, represented the first milestone in contact lens development.

The study of material compressive behaviour in the contact lens field has predominantly involved the use of micro- or more recently nano-indentation techniques. These methods have however, been recognised to have limitations [49]. Several non-conventional techniques have been developed to assess compressional behaviour, such as atomic force microscopy [50-52], the falling dart method [53] and micro-shaft poking [49]. The improved understanding of compression techniques has facilitated the development of mathematical models to predict materials' behaviour [37, 49, 53-57]**.** Although the use of such models may advance understanding, they are fundamentally reliant on assumptions based on experimental observation. Because of the rapidly developing range of materials and consequent limited range and volume of experimental work with each type, mathematical modelling is only in its infancy in the comparative study of material properties.

Tensile Testing and Soft Lens Development

When soft lenses were first introduced in the early 1970s, the study of mechanical properties as applied to contact lenses was regarded as a non-necessity. At this time soft lenses were in the majority lathe cut by many small laboratories, rather than the relatively few corporations operating today. Variations arising from lens material manufacture combined with lathing and polishing procedures, were capable of producing differences in dimensional stability, edge profile, surface quality and response to different care solutions. These factors alone produced an array of clinically observed lens behavioural problems that overshadowed, what are now understood to be small changes in material stiffness.

Lens manufacturers at the time (mid 1970s) were content in supplying practitioners their lenses to observe the ocular response of patients. The feedback provided to lens manufacturers would have been the general trend observed with the test lenses. It was, and still is, difficult to define a universally clinically successful lens applicable to a variety of patients whose ocular responses differ. As the number of soft material variants increased, empirical testing became an expensive method to assess clinical acceptability. Though compression modulus testing represented the first attempt to correlate clinical observation with material behaviour, it was limited by the difficulties of the technique e.g. edge effect of indenter and immobilisation of the lens on a rigid substrate. The difficulties associated with tensile testing of lens samples are significant but have proved easier to overcome.

Tensile testing has been used for many years to measure the mechanical properties of textiles, metals and plastics and has been adapted to the study of contact lens materials [58]. A schematic of the technique and two examples of stress-strain curves obtained when handling the small, fragile test pieces cut from lenses are shown in Fig 6. Note the distinctive difference between the shapes of the stress-strain diagrams shown; Fig 6*a* displays a uniform correlation between stress and strain, typical of a material with ideal elastic behaviour. Fig 6*b* illustrates a somewhat exaggerated form of the stress-strain diagram frequently obtained with soft lens samples, which are difficult to mount in a taut yet unstressed fashion, despite the mounting template (Fig 6*c*). As load is applied and the test sample is stretched, the slope of the curve changes at Fig 6*b region* **b**. Fig 6*b region* **c** displays a degree of material yield before failure occurs; this is not typical elastic behaviour but resembles that of plastic deformation.

A typical tensile test will provide three results:

- Tensile Modulus
- Tensile Strength
- Elongation to Break

Though a brief description of Young's modulus has been given when referring to Fig 3, it is important to define its relevance in particular to stress and strain. Young's modulus is equal to the longitudinal stress divided by the strain (Equation 1). Stress and strain can be described as the applied force across the cross-sectional area (per unit) of the test sample (Equation 2) and the change in length of the test sample when a particular force is applied (Equation 3) respectively.

$$\text{Modulus} = \frac{\text{stress}}{\text{strain}} \quad \text{(MPa)} \qquad \textit{Equation 1}$$

where

$$\text{stress} = \frac{\text{load}}{\text{cross-sectional area}} \qquad \textit{Equation 2}$$

and

$$\text{strain} = \frac{\text{extension of gauge length}}{\text{original gauge length}} \qquad \textit{Equation 3}$$

Young's modulus in SI nomenclature is expressed in Pascals (1Pa = 1 Newton per square metre or 1Nm^{-2}). In practical terms the prefix Mega (10^6) or Giga (10^9) is often used; alternative units for conversion have been stated previously. Compiled tables of material properties are readily accessible [59]. The value of Young's modulus is typically around 200.0 GPa for metals, 2.0 GPa for plastics such as PMMA and 0.5 MPa for hydrogels such as PHEMA.

Three mechanical property characteristics can be obtained from the stress/strain (load/elongation) curve produced in tensile testing. Tensile strength is the force per unit cross-section at the point of failure of the sample. Elongation to break is the length of the test-sample at the point of failure, expressed as a percentage of the original test-sample length. The tensile modulus however is derived from the slope of the stress-strain diagram using Equations 1,2 and 3.

In the case of stress-strain diagrams displaying perfect elastic behaviour (Fig 6*a*), the slope does not change and therefore modulus will be identical irrespective of the slope area chosen for calculation. With the experimental case (Fig 6*b*) the slope of the curve changes between the origin and terminus of the diagram. To remove any ambiguity from the slope area used, it is conventional for modulus to be derived from a tangent (dotted line) within the first 10% extension range (shaded triangle).

Tensile testing of contact lenses is now widely adopted, using conventional tensometers adapted for the relatively fragile nature of the samples. Tranoudis and Efron [60] made use of the Trevett [58] methodology, using tensile testing to characterise the behaviour of a series of non-commercial hydrogel lenses, which were then fitted to a group of subjects. They demonstrated that hydrogel materials with high stiffness and strength, display less tendency to change their geometric parameters. The basic technique can be modified to determine how modulus can be affected by external factors such as temperature [61] and the use of soft lens care products [62]. Different modulus related aspects of contact lens behaviour have been assessed by less conventional methods, such as lens eversion using a Vitrodyne Material Tester [63]. Similarly, the distribution of strain at low levels (10% extension) was observed visually using a BioTester system in conjunction with graphite particles sprinkled on the lens surface [64].

The "Correct" Modulus: Problems of Lens Non-planarity

An inherent problem that exists within the contact lens industry is attributing a "correct" modulus to any given lens material. Test strips cut from contact lenses are non-planar and coupled with the fact that the lens profile is not uniform, this inevitably suggests a measured thickness will vary depending upon the area of the test strip at which the measurement is taken. As the calculated modulus is a function of thickness (Equation 2), this calculated value will also vary.

Table 1 contains tensile moduli data for both current and historic conventional hydrogel lenses (data obtained by in-house laboratory assessment with the method illustrated in Fig 6*c*). The data set is based on the measured thickness of the lens at a "mid-point" between centre and edge (MCZT) - measured with a 10 mm diameter probe. The measured thickness cannot take into account the lens profile, even if the power of all lenses is maintained at -3.00 D. A similar problem arises when the calculated modulus is based on manufacturer's quoted centre thickness measurements – modulus values based on centre thickness are uniformly higher but the relative magnitude of modulus values obtained for different lenses is similar.

Because the lens is not a planar sample, the dynamics of lens extension, deformation and ultimately fracture are extremely complex. Tensile modulus values are conventionally averaged over a range of complex lens properties e.g. different thicknesses and extensions. In consequence the change in thickness as the sample elongates and the non-uniformity of the lens profile is not considered. In consequence quoted modulus values for lenses cannot be taken as absolute values of the constituent material and even the relative values for different materials will only be valid if the same assessment methodology has been used.

Problems of Material Variability and their Clinical Relevance

In assessment of mechanical properties it is conventional to average available data. This approach provides limited information relating to the extent of the variability displayed in material properties (either within a batch of a given material, or between different materials). Some early lathe-cut materials, for example Igel 67, a material that contained cyclohexyl methacrylate in addition to N-vinyl pyrrolidone and methyl methacrylate, tended to display a high level of brittle fracture in their failure (due to the stiff and bulky cyclohexyl methacrylate component) even though they were soft lenses. In analysing the behaviour of early thermally polymerised lathe-cut lenses, Trevett [65] demonstrated that survival probability assessed by the use of Weibull statistics, could be related to tensile strength measurements (Fig 7). The Weibull model is a classical weak link theory of failure usually associated with ceramics but with applicability to the fracture behaviour of soft lens materials.

Fig 7 illustrates the intra-batch variation in failure stress (tensile strength) of 74 early lathe-cut lenses based on the Igel 67 material. In this format, the data presentation is analogous to a Gaussian distribution or “bell curve”. Note the dense region in the middle of the distribution, where the majority of lenses will have a high probability of survival in clinical use. Test samples that lie in particular at the more negative end of the axes, will have a low probability of survival – particularly in handling. This is probably the result of a high level of network imperfections leading to brittle fracture. In addition it is important to note the complexity of the plot format – which involves plotting a reciprocal of survival probability and tensile strength on a logarithmic scale. The reason for this approach is firstly that it produces a near-linear presentation of the data distribution and secondly that it enables data points varying over several orders of magnitude to be plotted in a compact manner.

Although our understanding of hydrogel network theory and behaviour has advanced, with a consequent reduction in material durability concerns, there is always a degree of intra-batch variation inherent in mass production processes [66].

Designing Properties for Purpose

As soft lenses became more widely available, differences of opinion inevitably existed in relation to relative preference for the combinations of oxygen permeability, dimensional stability and mechanical durability offered by RGPs and soft lenses. Although soft lenses provided immediately perceived improvements in comfort, some time elapsed before the level and reproducibility of their mechanical properties and durability matched these advantages in initial comfort.

For lens-material manufacturers, it is possible, within certain limits, to modify the mechanical properties of the contact lens, to produce a desired clinical effect in handling or in eye. An effective method of customising mechanical properties for a given backbone position or assembly of monomers is to adjust the crosslink density. A cross-linked polymer network may conveniently be thought of as a wire-net fence; increasing the frequency of perpendicular wire-strands will inevitably make the fence stiffer.

The successful manufacture of ultra-thin and higher water content soft lenses with improved durability required more precise control of network perfection and cross-link density. Monomer selection and use of graft copolymer structures and interpenetrants enabled materials with enhanced stiffness levels to be produced. A notable example was atlafilcon A (Excelens). As can be seen from Table 1 this material had a significantly higher modulus than the generality of soft lenses and has not survived as a commercial product. The variability in material modulus as a result of modifying cross-link density and the modulus data for different historic PHEMA lenses is also shown in Table 1, which illustrates the moduli of a range of conventional hydrogel lenses, some currently available and some of historic interest only. Several of these lens materials were produced in button form and lathe-cut to specification in prescription houses. Some remain available in this form for specialist prescriptions whereas others, initially available as lathe cut buttons, made the transition to cast-moulded and spin cast lenses.

Shear-Induced Properties of Hydrogels: Dynamic Mechanical Property Measurement

In 1999 the introduction of silicone hydrogels (SiHys) increased the range of soft lenses, but in addition increased the incidence of a range of complications.

The first clinical observations that were interpreted in terms of ocular shear forces arose with the first generation SiHys. These lenses were much stiffer (higher modulus) than mid to high water content conventional hydrogels, that were in common clinical use at the time of their introduction. One of the early observations that distinguished the behaviour of SiHys from conventional hydrogels, was the observation of small particles of post-lens debris that became known as "mucin balls" [67]. Although the precise causative mechanism has not been experimentally proved, the clinical presumption that this phenomenon, which can be reduced by modification to the lens fit, is a shear-related effect is logical [67]. It is certainly consistent with the recent work on frictional and hydraulic drag effects [68]. Other behavioural characteristics are closely associated with the SiHy family. Lens involvement with the mucin layer, for example, can permit direct contact of lens and epithelium stimulating the formation of so-called superior epithelial arcuate lesions (SEALS) [69]. Documentation of the incidence of these clinical complications such as mucin balls, SEALS and contact lens-related papillary conjunctivitis (CLPC), highlights the very significant difference in incidence of the complications with SiHys compared to conventional hydrogel lenses and suggest generic shear-induced phenomena [70, 71].

In subsequent years the properties of the SiHy class of materials has evolved and the general trend has been to reduce the very high moduli of first generation materials to a level much closer to conventional hydrogel materials. It does appear that in doing this the level of complications encountered has diminished.

At the same time manufacturers have sought techniques to probe the differences in behaviour of conventional and silicone-containing hydrogels. One approach has been to use dynamic mechanical testing which by oscillating the sample – in shear or torsion for example (Fig 3*c*).

This reveals the fact that hydrogels, in common with most polymers, display both elastic and viscous flow characteristics. The elastic modulus (G′) describes the ability of the material to store energy reversibly, whereas the viscous modulus (G″) describes the dissipation of energy in the form of non-reversible molecular rearrangement.

Silicone rubber is highly oxygen permeable and displays ideal elastomeric behaviour; in the respect that its elastic attributes are dominant when the material recovers after deformation to any appreciable extent**.** In the case of SiHys, these lens-materials inherit both the oxygen transport properties and the inherent elasticity of their silicone rubber progenitor. Inclusion of silicone rubber "fragments" in SiHys enhances their elastic attributes in a much more marked manner than is found in conventional hydrogel lenses.

One way of characterising this behaviour is by adopting a dynamic rheological technique to assess the viscoelastic response of SiHy lenses. This is compared with that of conventional hydrogel lenses in Fig 8. The lens is substantially sealed from the atmosphere during testing and so does not undergo dehydration to any appreciable extent. The test protocol involves cutting 10 mm discs from lenses taken directly from packaging solution and mounting the sample between parallel plates, which then undergo oscillation at shear rates of 0.5-25 Hz at low amplitude. This range of shearing rates enables the assessment of the behaviour of the polymer network at higher frequencies in contrast to the slow deformation involved in tensile testing.

Fig 8 illustrates the effect of this increasing oscillatory shear rate (x-axis) on both G′ and G″ of two contact lens materials: material *A* (a first generation silicone hydrogel) and material *B* (a typical conventional hydrogel). It can be seen that for material *B*, neither the G′ nor G″ show any marked sensitivity to increasing shear rate (i.e. rate of eyelid movement). Material *A* behaves quite differently. Although there is a minor increment of G″ for material *A*, it remains relatively unaffected by increasing shear rate; G′ in comparison increases markedly as shear rate rises from 0.5 to 10 cycles per second [72].

The complexity of mechanical property effects in the anterior eye are not yet completely understood. Computer modelling techniques may appear to be sophisticated but they are reliant on data which are little different in validity from the summary in Duke-Elder's reference work [73]. Although understanding is now advancing it is far from complete and it is clear that subject-to-subject variability is extremely large [40, 41].

One important area of incomplete understanding is the uncertain link between *in-vitro* techniques using well-lubricated, small contact areas that are used to determine coefficients of friction, and the *in-vivo* behaviour of the lens itself. The relevance of coefficient of friction data to the interaction between the lens and both the eyelid and cornea, which are coupled by viscous drag effects, has yet to be quantified. Only recently has experimental data in this important area of the elastic properties of the lens and the transfer of shear forces from eyelid to cornea been reported [68]. Similarly, the significance of stick-slip phenomena in frictional studies on substrates of similar mechanical properties to the eyelid and the effect of lipid deposition on these interactions play no part in the low coefficient of friction measurements reported for lenses. There are many aspects of the mechanical interaction of the lens with the eye that are not yet understood and although mechanical property testing has become more sophisticated in recent decades there is still much to be learned about this complex subject.

The New Millennium: Growing Clinical Appreciation of the Significance of Modulus

The cycle of lens development shown in Fig 1, illustrates the importance of including practitioner feedback in the correlation of lens modulus and patient comfort. Just as patient preference for softer hydrogels over RGPs had increased their availability, so in the post SiHy era the growing appreciation of the correlation of mechanical properties and ocular response, has underpinned a reduction in tensile modulus of second and third generation SiHy materials.

By offsetting oxygen permeability in favour of lower modulus materials, lens manufacturers have directed their efforts towards expanding the variety of higher water content SiHy materials. The range of currently available commercial materials is shown in Table 2.

The current range of contact lens materials reflects the combined influence of clinical opinion and materials development technologies. The role of mechanical properties in optimising lens behaviour is now undisputed. With the development of mechanical property testing, a quantitative basis has been established which enables the influence of materials stiffness and related properties on the various aspects of clinical performance to be assessed. Despite all these developments we are still some distance from achieving the paradigm "ideal contact lens" discussed by Kamath in 1969 [18]. It is interesting to note that despite the commercial importance of the contact lens business and the range of clinical and technological expertise that has been brought to bear on the problem, *in-vitro* evaluation of contact lens performance still lags behind that of many other biomedical devices. The development of hip-joint prostheses, for example, which involves design in metals, ceramics and plastics materials, has for many years made use of *in-vitro* testing in a totally artificial hip-joint simulator. As yet, no equivalent device exists for the pre-clinical testing of contact lenses!

Conclusion

The last 50 years have shown a progressive development in the understanding of the clinical relevance of mechanical properties and in the availability to the practitioner of an ever-growing range of materials. Early contact lenses were fabricated with available materials for the objective of vision correction. As new materials were developed to improve wearer health and comfort, new mechanical characterisation techniques were needed. With the modification of available mechanical test instruments and techniques, it was possible to mechanically characterise the behaviour of the expanding range of contact lens materials.

It is instructive to examine the distribution of lens moduli that have been used in common clinically available contact lenses since the 1970s. Fig 9*a* shows a relative frequency distribution of the moduli of a representative sample of all soft lens materials that have been commercially available. The data are taken from Table 1 which shows a substantial selection of conventional hydrogel materials, together with Table 2 which highlights the currently available SiHys. It is important to reiterate the fact that because of the complex cross-section of contact lens materials, these are relative rather than absolute values of tensile moduli. A double-averaging technique has been used to provide the relative frequency distribution plot. Fig 9*b* the inset diagram, shows how the moduli of SiHy lenses launched since 2000 has changed over that time period.

Is there an ideal modulus for a contact lens? Any attempt to answer such a question is inevitably fraught with difficulties and reservations. The data reviewed here however, indicate that the range 0.3-0.6 MPa encompasses the greatest number of lens materials, both in terms of historical frequency and current commercial output. While this might be taken to suggest that a modulus around 0.4 MPa is statistically the most popular value for current contact lens materials, it should be noted that the distribution is in fact, bimodal, with a secondary peak at 1.1 MPa**.**

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Tables

Table 1 – Tensile moduli of current and historical conventional hydrogel lenses

Proprietary Name	Manufacturer	US Adopted Name	Principal Monomers[*]	EWC (%)	Tensile Modulus based on MCZT[‡] (MPa)
Soflens 03	Bausch & Lomb	polymacon A	HEMA	38	0.3
Durasoft	Ciba Vision[+]	phemefilcon A	HEMA-EEMA-MA	38	0.3
Optima 38	Bausch & Lomb	polymacon A	HEMA	38	0.5
Eurothin	Kelvin Lenses Ltd	polymacon A	HEMA	38	0.6
Z6	Cooper Vision	polymacon A	HEMA	38	0.6
Hydron Mini	Cooper Vision	polymacon A	HEMA	38	0.6
Cibasoft	Ciba Vision[+]	tefilcon A	HEMA	38	0.8
Hydron 04	Cooper Vision	polymacon A	HEMA	38	0.8
SeeQuence	Bausch & Lomb	polymacon A	HEMA	39	0.6
Aquaflex	Ciba Vision[+]	tetrafilcon A	HEMA-NVP-MMA	43	0.5
Classic	Cooper Vision	tetrafilcon A	HEMA-NVP-MMA	43	0.6
Focus Monthly	Ciba Vision[+]	vifilcon A	HEMA-PVP-MA	55	0.4
Hydrocurve 2	Ciba Vision[+]	bufilcon A	HEMA-DAA-MA	55	0.4
Acuvue	J & J Visioncare	etafilcon A	HEMA-MA	58	0.2
Surevue	J & J Visioncare	etafilcon A	HEMA-MA	58	0.3
B & L Soflens	Bausch & Lomb	hilafilcon B	HEMA-NVP	59	0.2
Proclear	CooperVision	omafilcon A	HEMA-PC	62	0.3
Excelens	Ciba Vision[+]	atlafilcon A	MMA-PVP	64	1.9
Medalist 66	Bausch & Lomb	alphafilcon A	HEMA-NVP	66	0.1
Focus Dailies	Ciba Vision[+]	nelfilcon A	PVA-NFMA	69	0.7
B & L Soflens	Bausch & Lomb	hilafilcon A	HEMA-NVP	70	0.2
Omniflex	Cooper Vision	lidofilcon A	MMA-NVP	70	0.3
B & L 70	Bausch & Lomb	lidofilcon A	MMA-NVP	70	0.6
Precision UV	Ciba Vision[+]	vasurfilcon A	MA-NVP	74	0.3
Permaflex	CooperVision	surfilcon A	MMA-NVP	74	0.3

* [DAA; diacetone acrylamide, EEMA; ethoxyethyl methacrylate, HEMA; 2-hydroxyethyl methacrylate, MA; methacrylic acid, MMA; methyl methacrylate, NFMA; N-(formylmethyl)acrylamide, NVP; N-vinylpyrrolidone, PC; 2-methacryloylethyl phosphorylcholine, PVA; poly(vinyl alcohol), PVP; poly(vinylpyrrolidone)].

‡ [**MCZT**; measured central zone thickness]. Measured with 10 mm diameter probe micrometer.

+ Now Alcon.

Table 2 – Tensile moduli of silicone hydrogel contact lenses from manufacturer literature

Proprietary Name	Focus Night & Day	O2 Optix	PureVision	Acuvue Oasys	Premi O	Avaira	Ultra	Acuvue Advance	Biofinity	Clariti	Dailies Total 1	Acuvue Oasys 1-Day	1 Day Acuvue TruEye	MyDay	Clariti 1 Day
Ianufacturer	CIBA Vision+	CIBA Vision+	Bausch & Lomb	J & J Visioncare	Menicon	Cooper Vision	Bausch & Lomb	J & J Visioncare	Cooper Vision	Sauflon	CIBA Vision+	J & J Visioncare	J & J Visioncare	Cooper Vision	Sauflon
US Adopted Name	lotrafilcon A	lotrafilcon B	balafilcon A	senofilcon A	asmofilcon A	enfilcon A	samfilcon A	galyfilcon A	comfilcon A	somofilcon A	delefilcon A	senofilcon A	narafilcon A	stenfilcon A	somofilco A
EWC (%)	24	33	36	38	40	46	46	47	48	56	33	38	46	54	56
Tensile Modulus (MPa)	1.4	1.2	1.1	0.7	1.1	0.5	0.7	0.4	0.8	0.5	0.7	0.7	0.6	0.4	0.5

+ Now Alcon

Figures

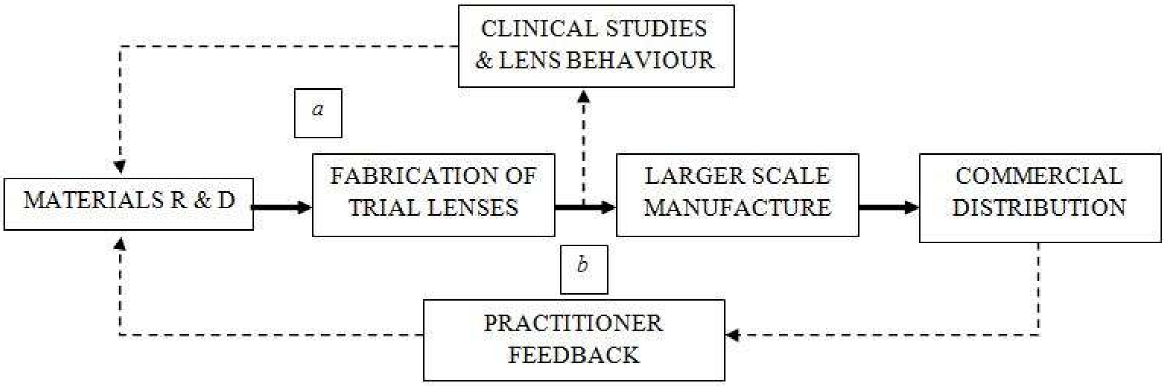


Fig 1 – Idealised schematic representation of the lens production and development cycle.

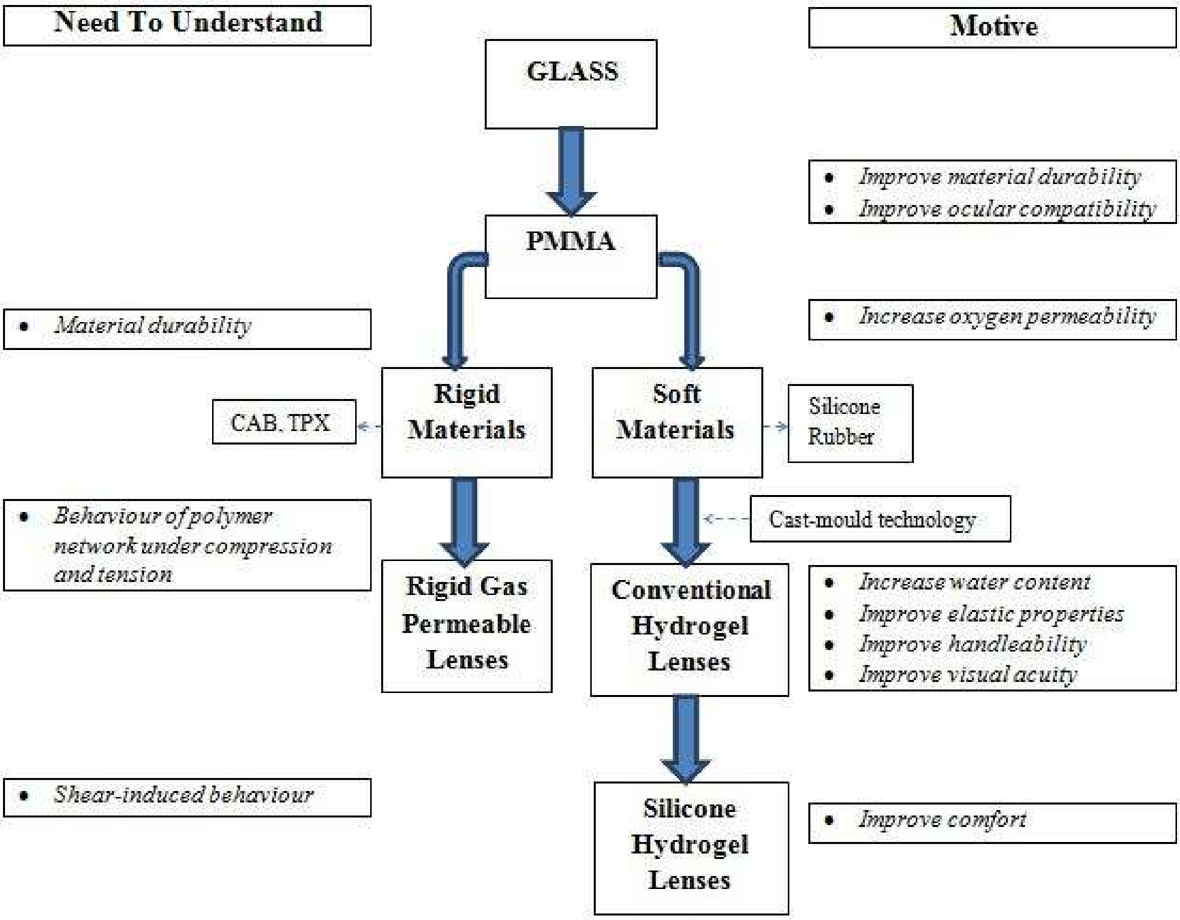


Fig 2 – Schematic representation of key aspects of contact lens material development.

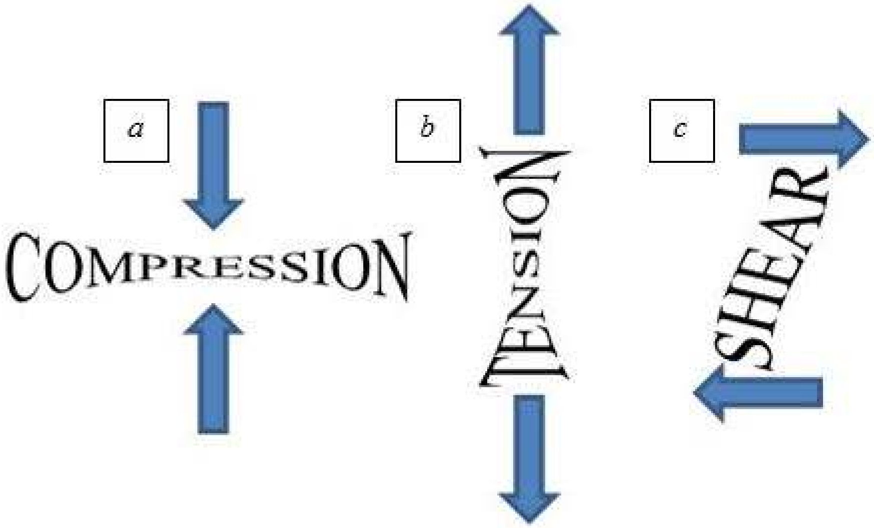


Fig 3 – Schematic illustrating mechanical property measurement methodologies.

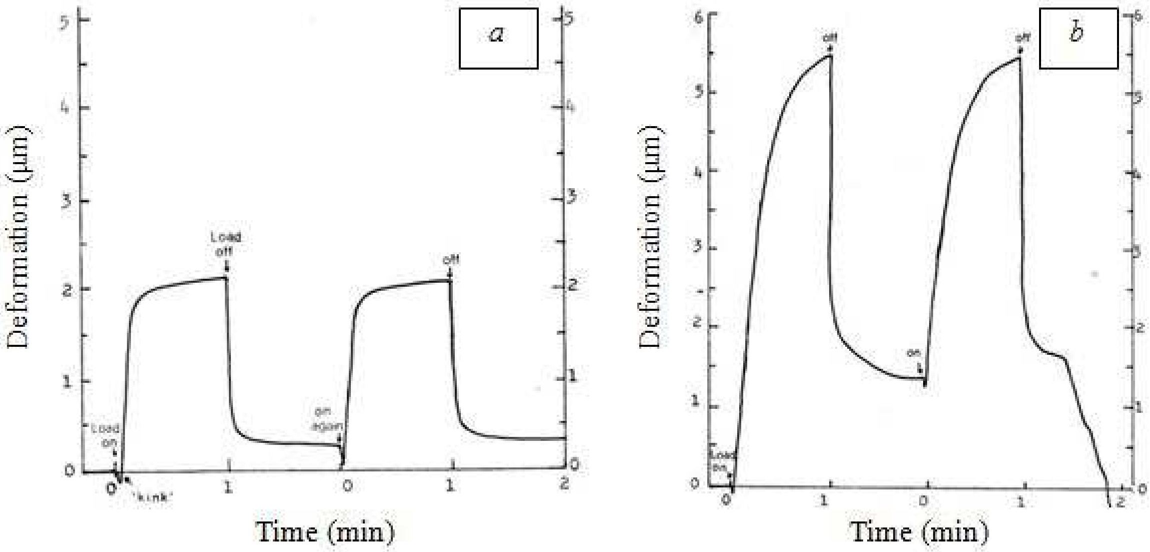
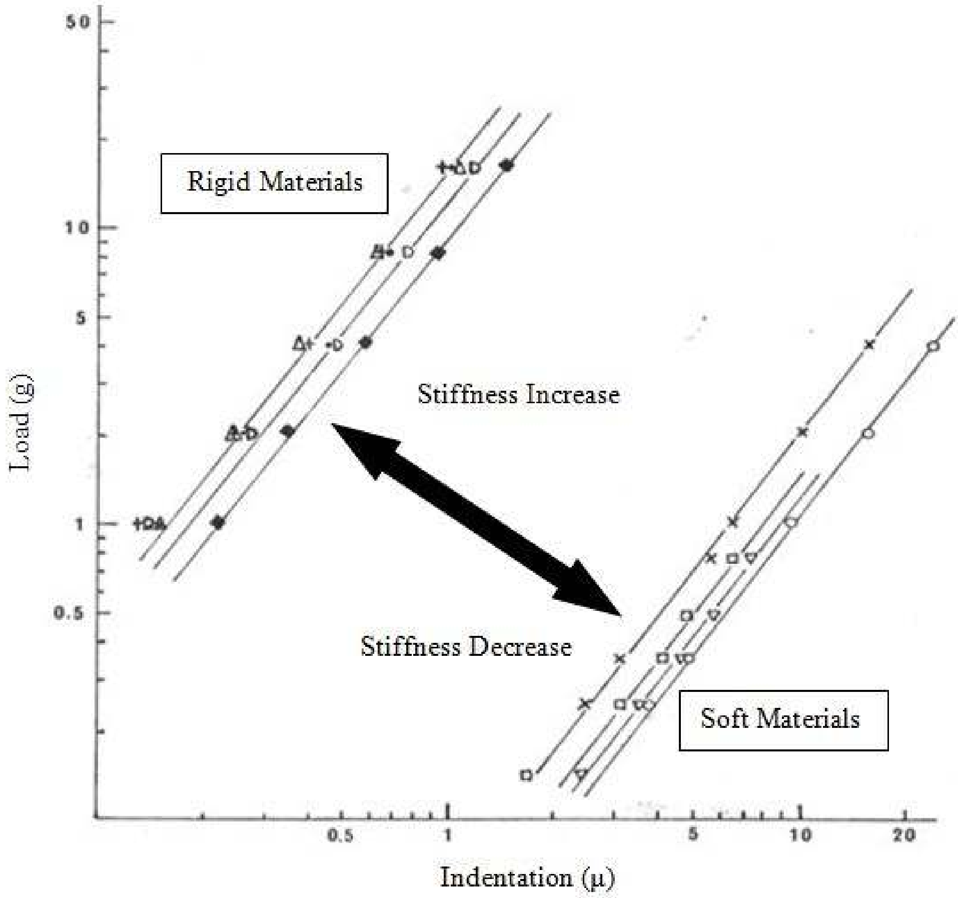


Fig 4 – Deformation and recovery of hydrogel materials under eye lid load [36]. Data obtained by compression (Fig 3*a*) testing of 100 µm samples of (*a*) PHEMA, and (*b*) PHPMA-co-NVP (20:80) with a flat-ended indenter (0.126 cm diameter). [PHEMA; poly(2-hydroxyethyl methacrylate), PHPMA; poly(2-hydroxypropyl methacrylate), NVP; *N*-vinylpyrrolidone].



Δ	PMMA	+	Dehydrated PHEMA	O	SBR
D	Paraperm O2 RGP	◆	CAB	∇	PHEMA hydrogel
•	Boston II RGP	X	Silicone Rubber	◘	HEMA-Styrene (90:10) hydrogel

Fig 5 – Compression (Fig 3*a*) data plotted for various materials in the form log (load) vs log (indentation) as a means of determining compression moduli [36]. [CAB; cellulose acetate butyrate, PHEMA; poly(2-hydroxyethyl methacrylate), PMMA; poly(methyl methacrylate), RGP; rigid gas-permeable, SBR; styrene-butadiene rubber].

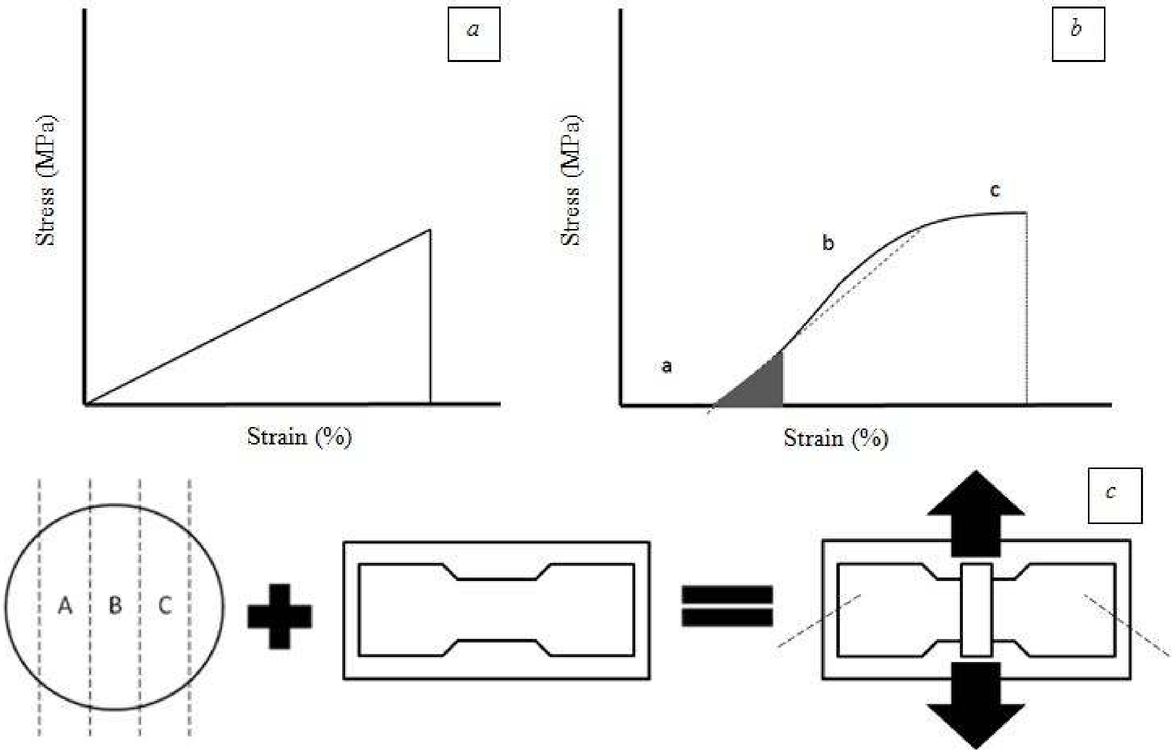


Fig 6 – Schematic representation of tensile stress-strain diagrams (Fig 3*b*); (*a*) ideal elastic behaviour, and (*b*) typical experimental lens data. Schematic representation of the template method employed at Aston University for tensile testing (*c*). Illustrations are author-generated.

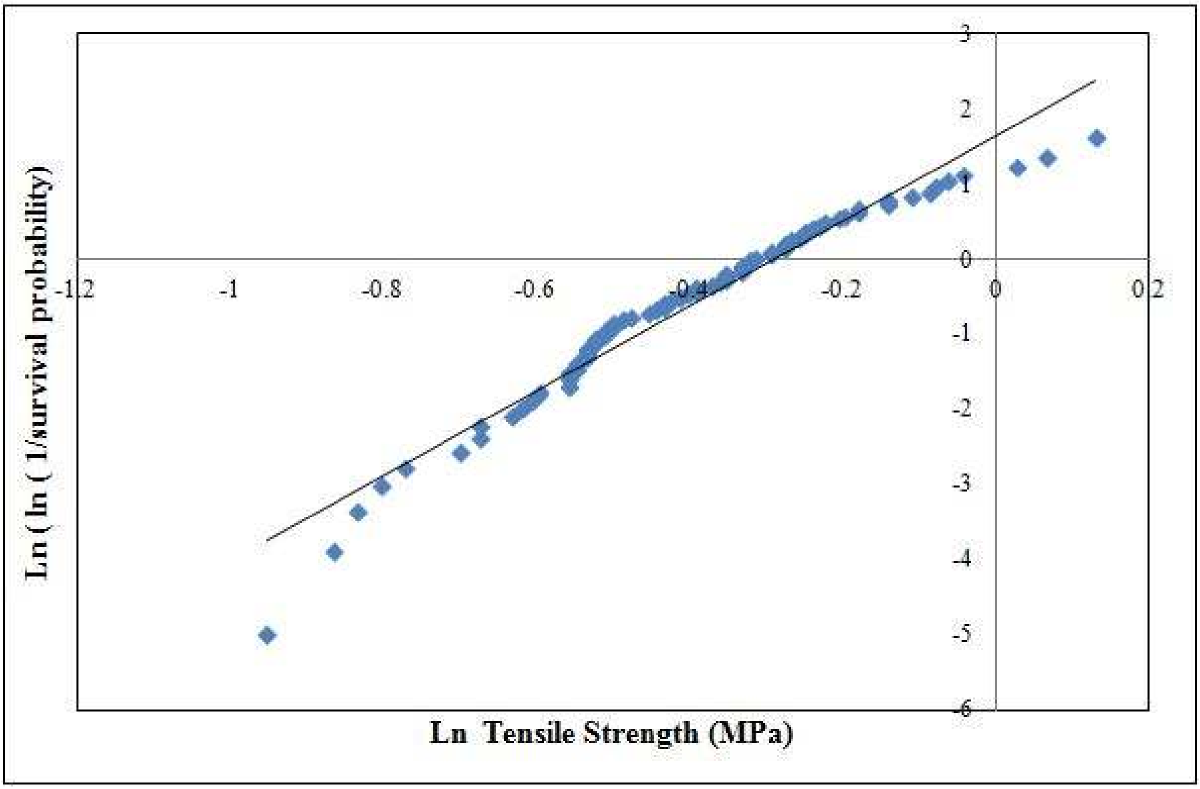


Fig 7 – Weibull Model plot of a lathe-cut lens batch (data derived from Trevett [65]).

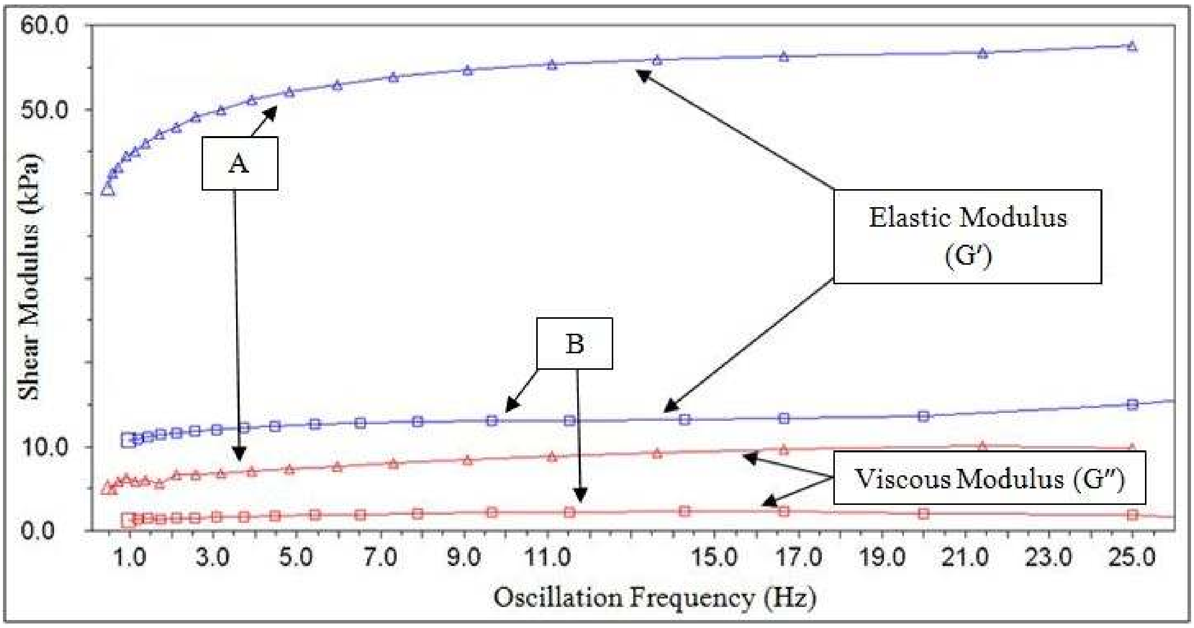


Fig 8 – Examples of shear-dependence (Fig 3*c*) of the elastic moduli of a typical silicone hydrogel (A) and a low modulus conventional hydrogel (B).

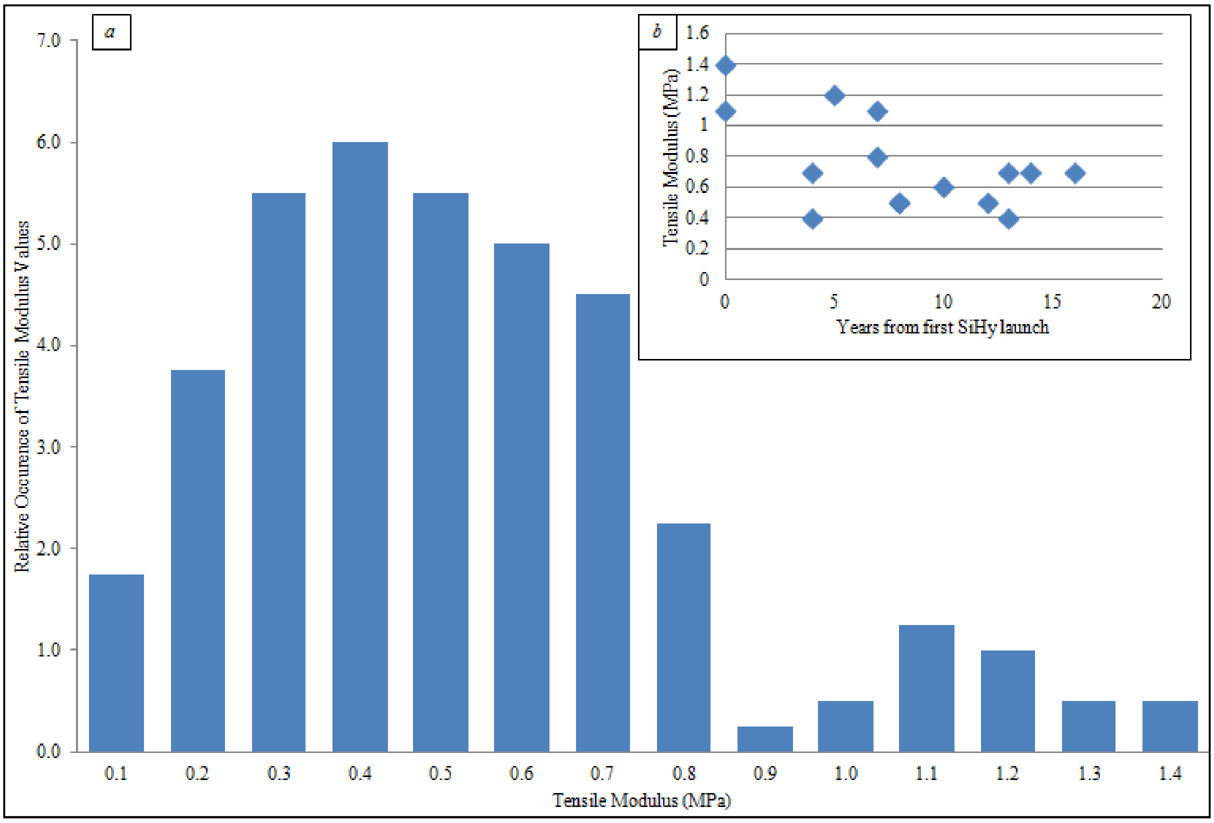


Fig 9*a* – Historical and current occurrence of particular values of tensile modulus for conventional* and silicone hydrogel (SiHy) contact lenses (data from Table 1 and 2). Fig 9*b* (inset) - Tensile moduli of newly launched SiHy lenses as a function of time since first SiHy availability in 2000.

* atlafilcon A has been omitted from the plot