Tensile properties of soft contact lens materials

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Abstract

The strength of contact lens materials is an important consideration with respect to resistance to damage during lens handling and long term durability, and may govern some aspects of in-eye lens performance. The tensile properties of hydrogel contact lenses manufactured from eight different materials were examined in a series of clinical and laboratory experiments using the Instron 1122 Universal Testing Instrument. Lenses from the following eight materials (and nominal water contents) were used: HEMA/VP 40%, HEMA/VP 55%, HEMA/VP 70%, VP/MMA 55%, VP/MMA 70%, HEMA 40%, HEMA/MAA 55% and HEMA/MAA 70% (HEMA: 2-hydroxy-ethyl methacrylate, VP: vinyl pyrrolidone, MMA: methyl methacrylate, MAA: methacrylic acid). Tensile strength, elongation-at-break and Young's modulus were measured. A technique was devised that enables three parallel-sided specimens of identical width to be cut from a single contact lens with good accuracy. It was found that materials made from HEMA/MAA—although having a very low tensile strength and elongation-at-break— exhibit only a moderate Young's modulus. Materials made from HEMA/VP exhibit high-to-moderate tensile strength, high elongation-at-break and moderate-to-low Young's modulus. Materials made from VP/MMA exhibit high tensile strength and high-to-moderate elongation-at-break, but the Young's modulus is high for the 55% water content and low for the 70% water content materials. The HEMA 40% material exhibits a moderate tensile strength, a low elongation-at-break and a high Young's modulus. This experiment highlights the necessity of developing an accepted standard test methodology for contact lens material stiffness evaluation, in order to derive useful comparative information. Six subjects were fitted with the same lenses for one day. In vitro measurements of total diameter and back optic zone radius were taken at 35 °C before lens fitting and after 6 h of lens wear. Lens water content, the relative change in lens total diameter (%ΔTD) and relative change in lens back optic zone radius (%ΔBOZR) were calculated and correlated with the tensile properties of the eight hydrogel lens materials. It is concluded that hydrogel materials with high stiffness and strength display less tendency to change their geometric parameters and materials with a high water content do not necessarily have the weakest mechanical properties.
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Keywords: Tensile properties; Hydrogel contact lens materials; Tensile strength; Elongation-at-break; Young's modulus; Water content

1. Introduction

Mechanical properties are a significant consideration in the design and quality control of soft contact lens materials. Stresses in the lens materials imposed by repeated application, removal or eye movement can cause irreversible deformation or fracture, resulting in loss of optical performance, user discomfort or even complete disintegration.

An important characteristic of a contact lens material is its ability to maintain its physical dimensions, or return to its original shape after external forces have been applied. Many mechanical tests can be applied to a material to rate its performance, some of which have been reviewed by Efron [1]. He reported that in order to investigate the tensile properties of a contact lens it must be cut into a standard shape. A tensile stress, or load per unit area of minimum cross-section, can then be applied. On application of this stress, the material will immediately elongate, and the extent of this elongation is termed tensile strain. If a constant strain is applied over a long period of time, the material will continue to elongate slowly. This long term deformation is referred to as tensile creep, but it is of little significance in contact lens practice since lenses are usually not subjected to such long-term forces. If the strain is gradually increased the material will continue to elongate until a point is reached where there will be an increase in strain without a further increase in stress. This is known as the yield point. The tensile stress at yield point is a useful indicator of material

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strength as it indicates the degree of stress a material can withstand without being deformed permanently. The strain at yield point is also a useful indicator of the strength of a material. Further stress can be applied until breakage occurs. The tensile stress at this stage is commonly referred to as the tensile strength of the material. The stress divided by the strain gives the modulus of elasticity or Young's modulus. A higher modulus of elasticity indicates a harder material.

In conventional engineering tension tests, an engineering stress–strain curve is constructed from the load–elongation measurements made on the test specimen (Fig. 1). The engineering stress, *s*, used in this stress–strain curve is the average longitudinal stress in the tensile specimen. It is obtained by dividing the load, *P*, by the original area of the cross-section of the specimen, A_0, whereby:

$$s = \frac{P}{A_0}$$

The strain, *e*, used for the engineering stress–strain curve is the average linear strain, and is determined by dividing the elongation of the gauge length of the specimen, δ, by its original length, L_0, such that:

$$e = \frac{\delta}{L_0} = \frac{\Delta L}{L_0} = \frac{L - L_0}{L_0}$$

Because both the stress and the strain are obtained by dividing the load and elongation by constant factors, the load–elongation curve has the same shape as the engineering stress–strain curve. The two curves are often used interchangeably [2].

The shape of the load–extension curve is shown in Fig. 2. The initial strain is elastic, but beyond point *E*—the elastic limit—strain is plastic. Point U is the maximum load, and this value of load is used for the determination of the tensile

strength of the material. Point F marks the point of fracture. Although the applied load on the test-piece decreases beyond point U, the true stress acting on the test piece—taking into account the reducing cross-sectional area—continues to increase until fracture occurs. In the commercial testing of metals, it is the load–extension curve, rather than a true stress–strain curve, that is plotted and strengths are calculated on the basis of the original cross-sectional area of a test-piece. The following information is determined in a routine tensile test [3].

1.1. Tensile strength (TS) (formerly known as ultimate tensile strength)

This is based on the maximum load sustained by the test-piece, when the latter is tested to destruction, and corresponds to point U in Fig. 2. The numerical value of tensile strength is calculated as a nominal stress and is given by

$$TS = \frac{\text{maximum load applied}}{\text{original cross-sectional area}}$$

The units in which tensile strength is normally quoted are megapascals (MPa), meganewtons per square metre (MN/m^2) or Newtons per square millimetre (N/mm^2). Numerically these three values are equal [3]. In the construction industry, the units used generally are N/mm^2.

1.2. Modulus of elasticity (E) (also known as Young's modulus)

The modulus of elasticity may be calculated from the slope of the straight line portion of the load–extension
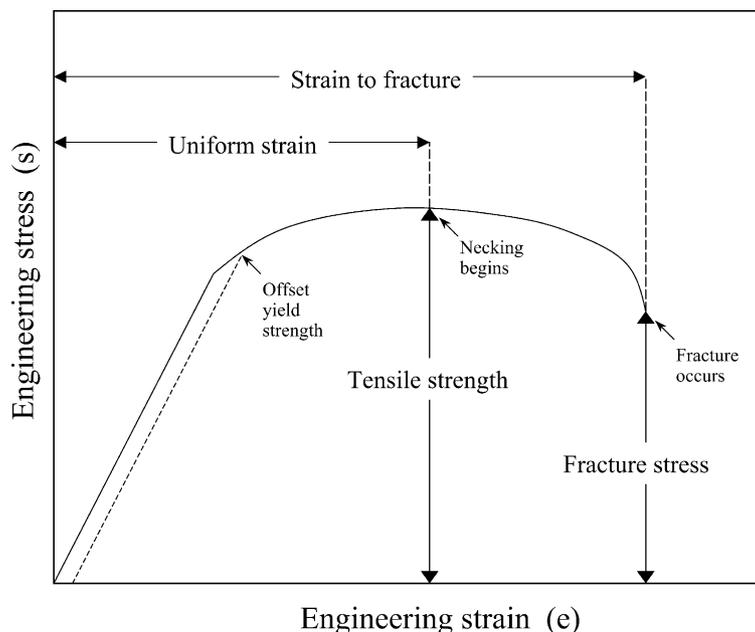

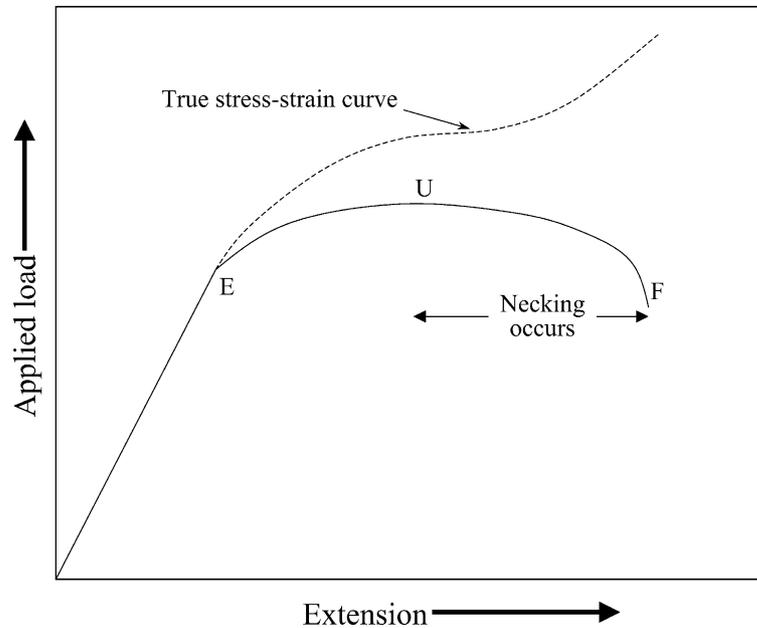Fig. 1. Engineering stress–strain curve (after Dieter[2]).

Fig. 2. Load–extension curve and its relation to a true stress–strain curve.

curve [3].

$$E = \left(\frac{\text{gauge length}}{\text{cross-sectional area}}\right) \times \text{slope}$$

The units in which E is quoted may be gigapascal (GPa), giganewton/square metre (GN/m^2) or kilonewton/square millimetre (kN/mm^2).

1.3. Percentage elongation

A definite length, the gauge length, is marked off on the test-piece before testing. After fracture, the two portions of the test-piece are placed together and the distance between gauge marks is re-measured [3]. The amount of extension, expressed as a percentage of the original gauge length, is then quoted as the elongation value, whereby:

$$\text{Percentage elongation on gauge length} = \left(\frac{L - L_0}{L_0}\right) \times 100$$

where L is the length between gauge marks after fracture and L_0 is the original gauge length. For an elongation value to have any validity, the fracture must occur in the central section of the gauge length and the gauge length must be specified, for example, in the form: 'the percentage elongation on 50 mm is 20%'. As the amount of plastic deformation of the test-piece is greatest at the point nearest to the site of fracture, the elongation value for any particular material will be much higher if measured over a short gauge length than if measured over a long gauge length. The percentage elongation value for a material will give a measure of its ductility.

Tighe [4] noted that before considering the relationship between mechanical properties and hydrogel polymer structure, it is first necessary to decide which property is of greatest clinical significance. Although tensile strength is relevant to the general durability and resistance to handling of a soft contact lens, the shear and compressive force due to eyelid motion produce a quite different type of deformation. The pressure produced by the eyelid during the blinking motion is of the order of 2.6×10^4 dynes/cm^2 and it has been found possible to reproduce this deforming force using a calibrated flat probe in conjunction with a microindentation apparatus designed for work on paint films. Hydrogels whose deformation behaviour is characterised by large (5 μm) and rapid initial deformation that does not reach equilibrium within one minute and shows poor recovery invariably give rise to lenses whose visual instability is unacceptable.

A soft hydrophilic material, particularly one with a high water content, may expel a small amount of water under pressure, and the degree to which such a polymer will return to its unstressed dimensions following deformation will critically affect its performance as a component in an optical system [4]. Tighe and Ng [5] used a modified pneumatic microindentation hardness apparatus to apply small constant loads, equivalent to eyelid pressure (approximately 2.6×10^4 dynes/cm^2) to various contact lens types and plotted lens deformation and recovery. These tests enabled the identification of materials that would be unstable under repeated eyelid pressure. Experiments such as these may lead the way to more clinically relevant methods of investigating the strength of new contact lens materials.

Where a material is too flexible, corneal toricity can encourage bending of the lens upon insertion due to the

capillary effects of the tears, and further bending during the blink due to the forces of the lids. Again, material design is of the utmost importance—more so than the modulus of elasticity of the material itself. Brennan [6] developed a theoretical model which showed that the degree to which a flat slab of material will distort is dependent upon the first power of the modulus, the third power of the thickness and the third power of the diameter. The modulus of elasticity varies only by a factor of two between the most flexible and the least flexible hydrogel materials available on the market today, and this difference can be easily accounted for by using a slightly thicker, larger lens. As an example, an increase of about 17% in thickness (from 0.15 to 0.17 mm) and 8% in diameter (from 9.0 to 9.7 mm) produces a 100% increase in the 'stiffness' of a lens [6].

Tighe and Trevett [7] explained how important it is for the materials manufacturer, for the contact lens practitioner wishing to use his existing experience in predicting the behaviour of new materials, and for the clinical researcher wishing to understand the effects of dehydration of lens materials on the eye, to each have access to reliable, reproducible mechanical property measurements made under controlled conditions. It is essential that any technique used should provide mechanical property measurements for the contact lens itself (not just the material). It is equally important that the technique should be related to measurements made on materials of all types under standard conditions. That is, it should be possible to relate the units and measurements made on contact lens materials to existing international standards for other biomaterials.

Little published work is available on the measurement of hydrogels used for contact lens production. Test methods for hydrogels are poorly defined mainly because the materials need to be in their hydrated state for results to be meaningful. Mizutani et al. [8] measured the mechanical properties of the tensile strength of soft contact lenses and considered factors regarding mechanical strength. They used seven kinds of soft contact lenses, each with characteristic mechanical properties. They found a range of approximate 50 g/mm^2 in elastic modulus at 100% strain, even for soft contact lenses with similar water contents. Soft contact lenses were strained to a maximum of 200%. When stress was released, the sample recovered within about 1 h, showing negligible permanent strain even after experiencing such deformation. When adding methacrylic acid alkyl esters for reinforcement, the mechanical properties of soft contact lenses depended on the molecular weight. The higher the molecular weight became, the more the elastic modulus increased. Generally, the elastic modulus of soft contact lenses decreased according to the increase in water content. The mechanical properties of soft contact lenses depended on temperature, whereby the elastic modulus decreased as temperature increased. This relationship suggests that care should be taken when handling soft contact lenses at high temperatures. Furthermore, careful consideration needs to be given to the kinds of mechanical properties appropriate

for clinical trials. Although the work by Mizutani et al. [8] provided interesting data, a study that could correlate this data with the behaviour of soft contact lens materials in clinical practice would be beneficial.

The mechanical properties of the hydrogel membrane of VP/MMA for the purpose of making soft contact lenses for extended wear were studied by Hosaka et al. [9]. They studied the dependence of tensile fracture energy, flexibility and recovery from deformation on the water content and thickness of the hydrogel membrane. A hydrogels disk of 10–12 mm diameter and 0.2–0.3 mm thick in swollen state was cut into strips of 2 mm width with a pair of razors that were fixed in parallel. Tensile tests were carried out in air at about 50% relative humidity or in water at 23 ± 1 °C using a tensometer. Both environments yielded similar results. This observation provides a sound basis for undertaking tensile tests of soft contact lenses in air. The hydrogel disks that were used by Hosaka et al. were rather thick (0.2–0.3 mm), so their data may not be applicable to the very thin hydrogel contact lenses used today.

Reducing the thickness of a lens was found to exert a more advantageous effect than increasing its water content on maximising the tensile fracture energy under the condition of an adequate supply of oxygen to the cornea through the contact lens. Hosaka et al. [9] suggested that as long as its water content is controlled between 63 and 78%, contact lens made of VP/MMA have flexibility of the same order as those of conventional soft contact lenses made of HEMA. The rate of recovery from deformation increases with water content, and the residual elongation is negligible in the range of water content over about 70%. Practical requirements for use of these contact lenses, determined by these three mechanical properties (tensile properties, flexibility and recovery from deformation), can be satisfied at the same time if the water content of the contact lens is greater than 70%.

Hosaka et al. [9] carried out clinical experiments on myopic and aphakic patients who continuously wore the VP/MMA lenses of 70% water content for 1–25 months. They presented data concerning the durability of the VP/MMA including the data of HEMA lenses for comparison. The breakage rate of the soft contact lenses of VP/MMA is lower than the breakage rate of HEMA lenses and low enough for practical use. Further, the adoption of extended wear resulted in a significant decrease in lens breakage rates. Although Hosaka et al. [9] did not give enough information about the design of the clinical study or statistically validate their findings, their study represents one of the few attempts to examine the relation between laboratory measurements and lens performance in clinical practice.

Kawabe et al. [10] constructed a tensile testing machine, with which tensile testing of various hydrogel contact lenses was successfully conducted. The tensile properties of various hydrogel lenses, including the effects of lens edge design, lens surface finish and lens peripheral finish, were compared using this apparatus. Unfortunately, the authors

did not provide numerical data from their experiments that would allow comparisons among other soft contact lens materials to be made.

The fracture toughness of three polymethacrylate contact lens materials was measured by Jackson [11]. He tested Snoflex S68−68% (Smith and Nephew Pharmaceuticals Ltd., London, UK), Igel 67–67% (Igel International Ltd., Beds, UK), and Hydron HX–65% (Hydron Europe Ltd., Hants, UK). Jackson [11] argued that for relatively brittle materials such as hydrogels, toughness is a more meaningful parameter than tensile strength because unlike the latter, it is theoretically independent of the size of flaws or defects present in the material. Toughness is an informative measure of mechanical failure since it includes the amount by which the material is strained as well as how much it is stressed in the calculation of the energy per unit area of fracture. In the measurement of fracture toughness, information is available about the mechanism of failure as well as how much energy has been used to cause the failure.

Jackson [11] found that the mean fracture energy per unit area (J_c) of Snoflex S68 was significantly greater than that of Igel 67 and that Igel 67, in turn, had a significantly larger J_c than Hydron HX. Thus, Snoflex S68 was the toughest of the three hydrogels, probably because it undergoes plastic deformations at high strains. His results also supported the notion that differences in toughness imply differences in the mechanical durability of contact lenses in normal use—an observation that can not be readily deduced from the results of tensile strength tests.

The method used in the experiments of Jackson [11] for the calculation of the toughness, was far more complicated than the simple tensile properties. In addition, the contact lens literature provides data of tensile strength, elongation-at-break and Young's modulus and not data of toughness. Continuing though the work of Jackson [11] and applying his theory to more contact lens materials could lead to very useful information. The mechanical testing of soft contact lens materials needs to be explored further as these results are important to the industry, the practitioner and to the successful wearing of contact lenses. Studies have also examined the mechanical properties of hydrogel membranes [12–14] and rigid contact lenses [15–21].

The aim of this experiment is to examine the mechanical properties of soft contact lenses; in particular, tensile strength, tensile modulus (Young's modulus) and percentage elongation-at-break. Relationships that exist among tensile properties, dimensional changes and water content of soft contact lens materials are also examined.

2. Methods

2.1. Lenses

The major materials used for commercialised soft contact lenses today are hydrogels. These are cross-linked hydro-philic (water-loving) polymers and can be made by polymerising suitable monomers with a cross-linking agent, or less commonly, by the post-treatment of non-crosslinked hydrophilic polymers. The monomer is the building block for these polymers. In general, the monomer unit contains a polymerizable vinyl group. The following are a few examples of monomers that are commonly used in the manufacture of hydrogel contact lenses:

- *2-Hydroxy-ethyl methacrylate* (HEMA) this monomer and its non-crosslinked low molecular weight polymer are water soluble. It is the primary monomer from which the first commercial soft contact lens was made.
- *Methacrylic acid* (MAA) is used to boost the water content in the hydrogel.
- *Methyl methacrylate* (MMA) is the monomer unit that makes up the PMMA (polymethyl methacrylate) lens. It is sometimes used to lower water content or to improve hardness and strength in some soft contact lenses.
- *Vinyl pyrrolidone* (VP) is an important monomer in addition to the methacrylates. Due to its hydrophilicity, it is commonly used to increase water content.

In order to be able to compare lenses made from different materials, non-commercial contact lenses were used throughout this study. The purpose of this study was to examine lenses with the following material compositions: HEMA/VP, VP/MMA and HEMA/MAA, each in low (40%), medium (55%) and high (70%) water contents.

The contact lens materials formulated specifically for the experiments described in this paper were supplied by a single contact lens material company (Vista Optics, Cheshire, UK). All lenses were manufactured (lathe-cut) by the same contact lens laboratory and had the same bicurve design with similar nominal parameters: total diameter (TD): 14.00 mm; back vertex power (BVP): −3.00 D, back optic zone radius (BOZR): 8.7 mm, and central thickness (t_c): 0.12 mm.

The aim was to obtain contact lenses that cover a wide range of contact lens groups according to the UK and FDA classifications. Two lenses of each of the types described in Table 1 were used. The measured parameters (BVP, BOZR, TD, t_c and WC) of the lenses used in these experiments can be found in Table 2.

2.2. Mechanical testing instrumentation

The Instron 1122 Testing Instrument (Instron Ltd., Buckinghamshire, UK) was used in the present study. This device comprises two cable connected assemblies; an electronic control console and a loading frame capable of testing loads up to 5 kN in tension, compression and flexure. The drive system operates as a closed loop servo system that applies a load to the specimen. The applied load is measured by a load cell and the resultant signal is amplified and applied to the chart pen recorder. Various accessory modules

Table 1
Soft contact lens materials used in the study

Copolymer type (WC)	Trade name	UK classification	FDA classification	Material composition wt.%	Cross-linker
HEMA/VP (40%)	Vistagel 42 HC	Filcon 3a	Group I	90/10	EGDMA[a]
HEMA/VP (55%)	Vistagel 55 H	Filcon 3a	Group II	70/30	EGDMA
HEMA/VP (70%)	Vistagel 75 H	Filcon 3a	Group II	45/55	EGDMA
VP/MMA (55%)	Vistagel 60	Filcon 4a	Group II	70/30	AMA[b]
VP/MMA (70%)	Vistagel 75	Filcon 4a	Group II	75/25	AMA
HEMA (40%)	Vistagel 38 R	Filcon 1a	Group I	Pure HEMA	EGDMA
HEMA/MAA (55%)	Vistagel 55 MA	Filcon 1b	Group IV	98/2	EGDMA
HEMA/MAA (70%)	Vistagel 70 MA	Filcon 1b	Group IV	96/4	EGDMA

[a] Ethylene glycol dimethacrylate.
[b] Alkyl methacrylate.

can be added to the control console to increase the versatility of the testing programmes. These additional accessories increase the height of the control console such that the upper module controls cannot be reached. In this case a secondary accessory console can be added to the system, into which the modules can be fitted to bring all controls into easy reach of the operator.

2.3. Experimental procedure

A technique was devised that enabled three parallel sided specimens of identical width (3 mm) to be cut from a single contact lens using a sharp utility knife (Fig. 3). Each soft contact lens was flattened between two thin plastic sheets. A simple device that employs a micrometer ('contact lens cutter') was constructed to allow parallel strips to be cut out

Table 2
Verification (@ 20°C) of lenses used for tensile testing

	Parameters (20°C)					
	Lens code	BVP (D)	t_c (mm)	TD (mm)	BOZR (mm)	WC (%)
HEMA/VP 40%	A3	−2.94	0.092	14.00	8.90	38
	A4	−2.94	0.100	13.90	9.10	38
HEMA/VP 55%	B2	−2.46	0.116	14.00	9.20	52
	B4	−2.58	0.083	13.90	9.40	47
HEMA/VP 70%	C1	−2.96	0.101	13.80	8.90	72
	C4	−2.64	0.080	13.90	9.10	72
VP/MMA 55%	E2	−2.80	0.135	14.10	9.30	60
	E4	−2.32	0.106	14.50	9.00	60
VP/MMA 70%	F3	−2.88	0.121	13.80	8.50	68
	F6	−2.98	0.145	14.00	8.70	68
HEMA 40%	G1	−2.72	0.080	14.00	9.10	38
	G5	−2.76	0.099	14.00	9.10	38
HEMA/MAA 55%	H2	−2.84	0.091	14.10	8.50	54
	H7	−3.18	0.129	14.00	8.60	55
HEMA/MAA 70%	I3	−3.26	0.127	14.30	8.50	65
	I4	−3.28	0.115	14.20	8.70	65
	Mean	−2.85	0.108	14.03	8.91	
	±S.D.	0.27	0.020	0.18	0.30	

of a single lens with good accuracy (Fig. 4). One of the problems with tensile strength testing of soft contact lenses is that if small flaws are accidentally introduced into the specimen during preparation and handling the test results are unreliable. A simple way of overcoming such problems was developed; this involved use of a 'plastic window frame' which enabled the specimen strips cut from the lens to be supported and safely handled whilst being transferred to the tensometer. Once mounted, the sides of the 'plastic window frame' support were snipped with a sharp pair of scissors. The test could then be conducted. In addition to providing mechanical support for the sample during handling, the 'plastic window frame' also enabled the so-called 'gauge length' to be set (10 mm). This defines the actual length of the sample being tested. Since the 'plastic window frame' was made of plastic it also provided a cushion for the specimen in the jaws of the tensometer. To avoid breakage of the specimen in the jaws, a minimum jaw pressure was used to hold the specimen (Fig. 5). This method is similar to that used for the tensile strength testing of plastic fibres and the jaws that are used are fibre jaws.

The specimens were immersed in saline before the tensile testing. Although it was possible to mount the specimen in the tensometer jaws and to then submerge the tensometer jaws in a bath of water to maintain the sample in its fully hydrated state during measurement, this was a relatively cumbersome process. In the time taken to carry out a test, the
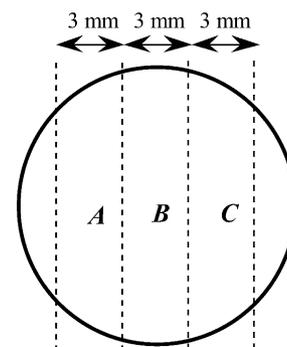

Fig. 3. Three parallel sided specimens of identical width cut from a single contact lens.
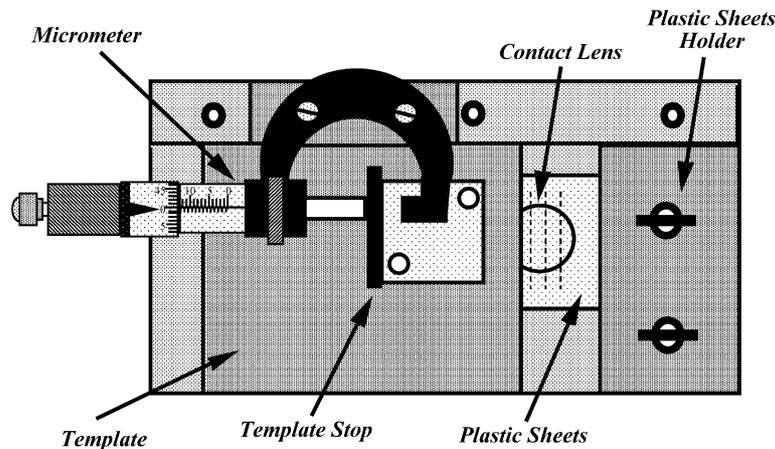
Fig. 4. Contact lens cutter.

film of water on the surface of the specimen remained intact, therefore, dehydration of the hydrogel was considered to be negligible [11]. A standard ambient temperature and humidity in the laboratory maintained and measured were adopted to avoid draughts whilst carrying out the test. The experiments were carried out in a room which was controlled for temperature (20 °C) and humidity (50%). The rate at which the sample was stretched was referred to as the 'strain rate' or 'extension rate' and ideally this should be fairly rapid. In the present experiment a strain rate of 200%/min was used. That is, the original length of the specimen is doubled in 30 s. This means that individual tests lasted less than 2 min, minimising the problem of dehydration. The full scale load was 0.2 N, the crosshead speed 20 mm/min (200%/min) and the chart recorder speed 100 mm/min. Two lenses per material (i.e., six specimens per material) were tested. Although plano lenses represent the ideal form of test sample, low minus (up to −3.00 D) lenses give excellent results [7]. In any standardised test protocol the power of the lens to be used should be specified. The tensile test experiment was conducted in a masked and randomised manner, in order to prevent experimental bias.

The following formulae were used for the tensile strength, elongation-at-break and Young's modulus calculations [3]:

$$\text{Tensile strength} \, (\text{kg/cm}^2) = \frac{\text{load}}{\text{cross-sectional area}}$$
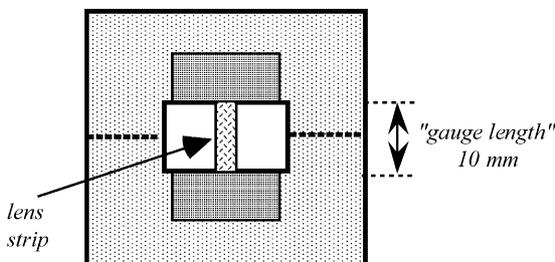

Fig. 5. Plastic window frame with the lens strip in position.

where cross-sectional area = width × thickness;

$$\text{Elongation-at-break} \, (\%) = \left(\frac{L - L_0}{L_0} \right) \times 100\%$$

where L = final length, L_0 = gauge length;

$$\text{Young's modulus} \, (\text{kg/cm}^2) = \left(\frac{\text{load}}{\text{extension}} \right) \times \left(\frac{\text{gauge length}}{\text{cross-section area}} \right)$$

To test the precision of measurement of this technique, measurements were made on 15 samples made from identical Acuvue lenses (Vistakon, Jacksonville, FL, USA). The means and standard deviations of these measurements were as follows: tensile strength: $6.43 \pm 1.88 \, \text{kg/cm}^2$; elongation-at-break: $71.93 \pm 15.91\%$; and Young's modulus: $11.46 \pm 2.07 \, \text{kg/cm}^2$.

2.4. Clinical study

Two lenses from each of the eight soft contact lens groups were used in experiments concerning the tensile properties of lenses during wear (Table 1). Six subjects were fitted with lenses for one day. In vitro measurements of TD and BOZR, were taken at 35 °C before lens fitting and after 6 h of lens wear.

In order to compare the difference of the parameters, before and after wear, among the eight different materials that were used in this study, the 'relative change in lens parameter' ($\%\Delta P$) was determined [22]. That is:

$$\%\Delta P = \left(\frac{P - P'}{P} \right) \times 100$$

where P is the lens parameter before wear and P' is the lens parameter after 6 h wear, giving the amount $\%\Delta P$ a positive value. The relative changes in lens total diameter ($\%\Delta \text{TD}$) and lens back optic zone radius ($\%\Delta \text{BOZR}$) were calculated. The results of this clinical study, which have been published previously [23], were used to examine the relationships that
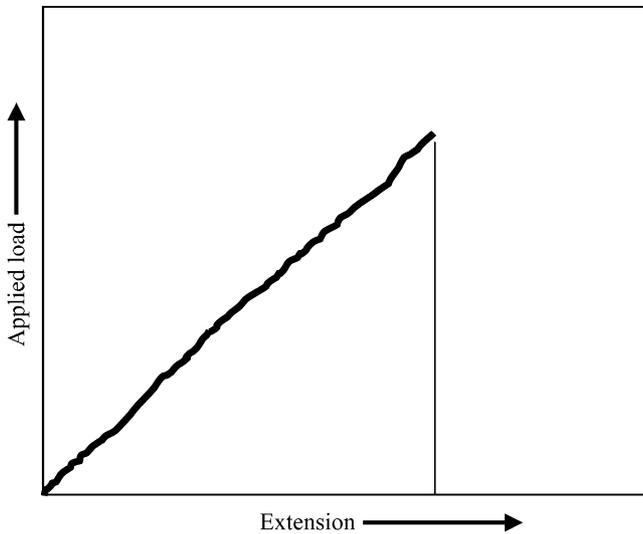
Fig. 6. Typical tensile test curve.

exist among the dimensional changes and the tensile properties of soft contact lens materials.

3. Results

The curve of a typical tensile test is shown in Fig. 6. The extent to which the material elongates or stretches on the horizontal axis is shown as a function of increasing load on the vertical axis. This load/elongation curve (such as is shown in Fig. 6) is generally called a stress/strain curve. The tensile strength is simply the load at which the material breaks and the curve suddenly drops down to the elongation or strain axis. The point at which it meets the strain axis is the amount by which the material has stretched or elongated when it breaks. The point reached on the stress axis or load axis when the curve suddenly drops down represents the load required to break the material. The breaking stress and the breaking strain then give the tensile strength of the material and the amount by which it stretches before it breaks.

The slope of the graph near to its origin, which is the point where strain and stress or load and elongation are both increasing from zero, gives the stiffness of the material. The steeper the slope the higher the stiffness or Young's modulus or initial modulus of the material. In terms of behaviour of a contact lens, this indicates the amount by which lenses of equivalent thickness will deform under a given stress.

Using the equations presented above, the tensile strength, elongation-at-break and Young's modulus for the eight different soft contact lens materials were calculated. Table 3 presents the results of these calculations. Four to six samples were used for each material and the mean values with standard deviations are shown in this table.

One-way analysis of variance was used to examine whether the differences in the tensile strength, elongation-at-break and Young's modulus values among the eight different

Table 3
Tensile properties (mean values ± S.D.) of the materials measured

Material	Tensile strength (kg/cm^2)	Elongation-at-break (%)	Young's modulus (kg/cm^2)
HEMA/VP 40%	2.59 ± 0.83	56.33 ± 15.04	7.01 ± 0.44
HEMA/VP 55%	1.81 ± 0.93	52.40 ± 27.91	3.72 ± 0.68
HEMA/VP 70%	4.01 ± 0.81	81.50 ± 23.74	5.87 ± 1.52
VP/MMA 55%	5.87 ± 2.48	43.33 ± 17.65	16.25 ± 1.18
VP/MMA 70%	3.40 ± 1.16	81.00 ± 31.41	5.04 ± 0.95
HEMA 40%	2.71 ± 1.27	43.00 ± 24.30	8.80 ± 0.49
HEMA/MAA 55%	1.23 ± 0.59	18.00 ± 5.16	5.92 ± 1.51
HEMA/MAA 70%	1.52 ± 0.47	21.60 ± 10.62	7.83 ± 1.10

soft contact lens materials are significant. These tests revealed the following results: tensile strength: $F = 7.17$, $p < 0.0001$; elongation-at-break: $F = 5.77$, $p < 0.0002$; and Young's modulus: $F = 80.94$, $p < 0.0001$. It can be concluded that there are statistically significant differences in the values of the material properties tested among the eight materials used in this study. The above results are presented graphically in Figs. 7–9. These figures show three bar charts of all the materials measured, the error bars being ±1 S.D. from the mean.

3.1. Elongation-at-break versus tensile strength

A significant relationship does not exist between elongation-at-break of the materials measured versus tensile strength ($r^2 = 0.23$, $p = 0.23$).

3.2. Young's modulus versus tensile strength

A significant positive correlation was found to exist between Young's modulus versus tensile strength (Fig. 10;
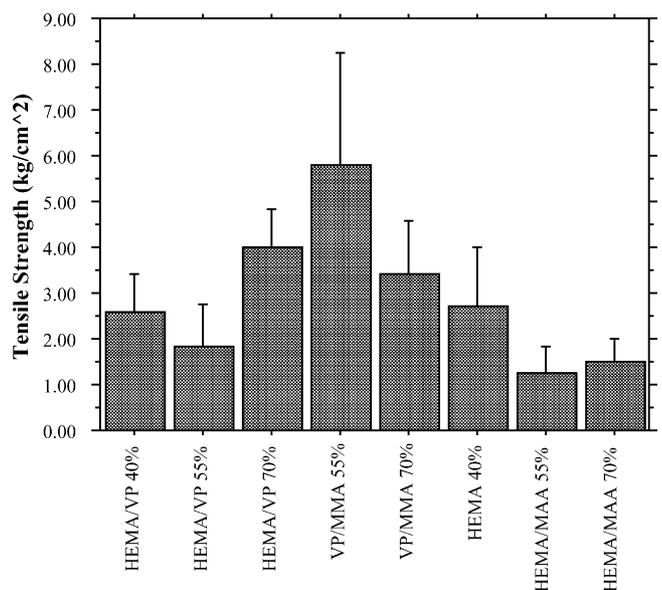

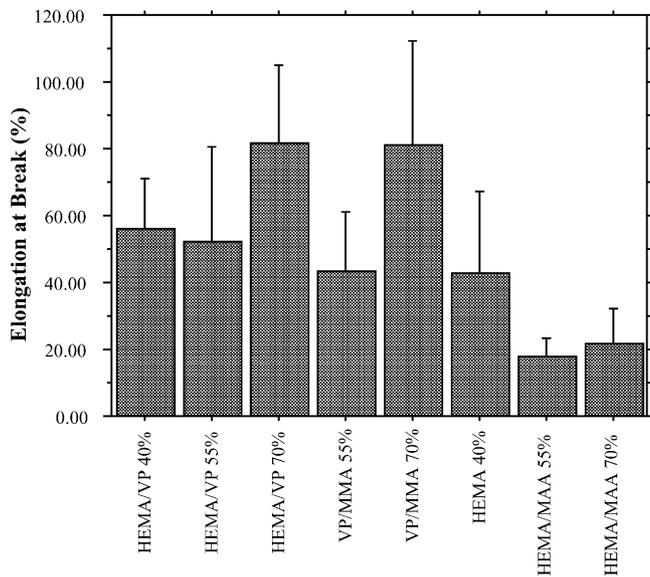Fig. 7. Tensile strength (kg/cm^2) of the eight materials (error bars represent ±1 S.D.).

Fig. 8. Elongation-at-break (%) of the eight materials (error bars represent ±1 S.D.).

$r^2 = 0.50$, $p = 0.05$). Thus, increasing tensile strength will result in an increase in Young's modulus.

3.3. Elongation-at-break versus Young's modulus

A significant relationship does not exist between elongation-at-break versus Young's modulus ($r^2 = 0.07$, $p = 0.53$).

3.4. %ΔBOZR versus %ΔTD

A significant relationship does not exist between back optic zone radius following wear versus relative change in total diameter following wear ($r^2 = 0.34$, $p = 0.13$).
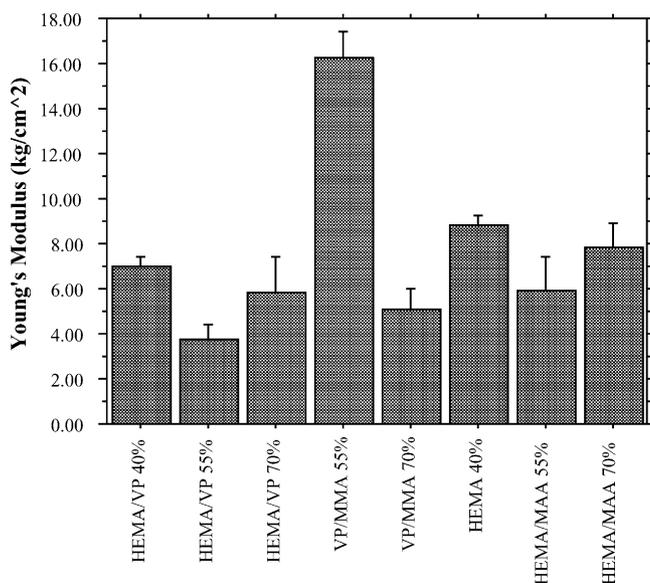

Fig. 9. Young's modulus (kg/cm²) of the eight materials (error bars represent ±1 S.D.).

3.5. %ΔTD versus tensile strength

A significant inverse correlation was found to exist between total diameter following wear versus tensile strength (Fig. 11; $r^2 = 0.68$, $p = 0.01$). Therefore, increasing tensile strength will reduce the relative change in total diameter following wear.

3.6. %ΔTD versus elongation-at-break

A significant inverse correlation was found to exist between total diameter following wear versus elongation-at-break (Fig. 12; $r^2 = 0.51$, $p = 0.05$). Thus, increasing elongation-at-break will decrease the relative change in total diameter following wear.

3.7. %ΔTD versus Young's modulus

A significant relationship does not exist between total diameter following wear versus Young's modulus ($r^2 = 0.13$, $p = 0.37$).

3.8. %ΔBOZR versus tensile strength

A significant relationship does not exist between back optic zone radius following wear versus tensile strength ($r^2 = 0.15$, $p = 0.35$).

3.9. %ΔBOZR versus elongation-at-break

A significant relationship does not exist between back optic zone radius following wear versus elongation-at-break ($r^2 = 0.16$, $p = 0.33$).

3.10. %ΔBOZR versus Young's modulus

A significant relationship does not exist between back optic zone radius following wear versus Young's modulus ($r^2 = 0.04$, $p = 0.66$).

3.11. Tensile strength versus water content

A significant relationship does not exist between tensile strength versus water content ($r^2 = 0.06$, $p = 0.55$).

3.12. Elongation-at-break versus water content

A significant relationship does not exist between elongation-at-break versus water content ($r^2 = 0.05$, $p = 0.59$).

3.13. Young's modulus versus water content

A significant relationship does not exist between Young's modulus versus water content ($r^2 = 0.00$, $p = 0.97$).
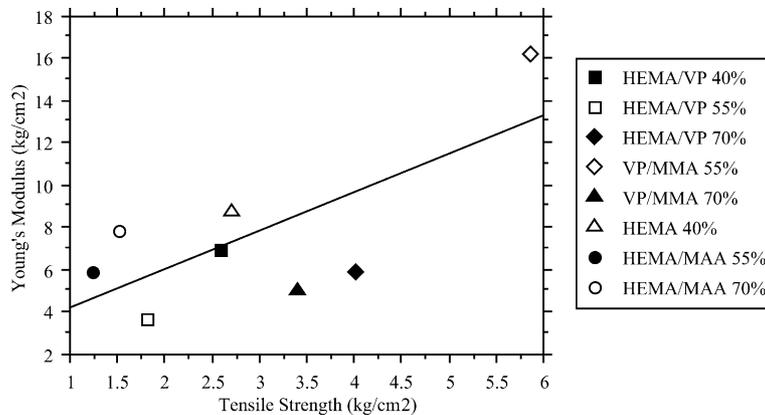
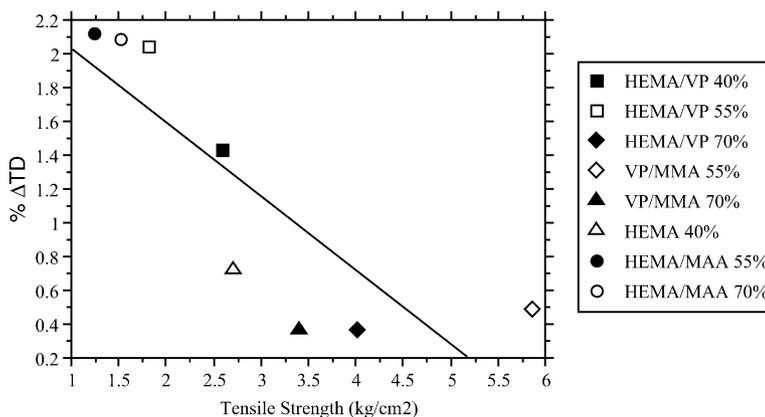Fig. 10. Relation between Young's modulus vs. tensile strength.

Fig. 11. Relation between %ΔTD vs. tensile strength.

4. Discussion

From the date presented in Table 3 and Figs. 7–9, it is possible to rank the soft contact lens materials investigated in this study according to their tensile strength, elongation-at-break and Young's modulus; these rankings are displayed in Tables 4–6, respectively.

The monomers used in contact lens polymers can be categorised into three classes: hydrophilic monomers containing portions which interact with water to form the basic hydrogel; hydrophobic monomers designed to add mechanical strength; and cross-linking agents which increase both mechanical strength and thermal stability [24]. Although both the hydrophobic monomers and the
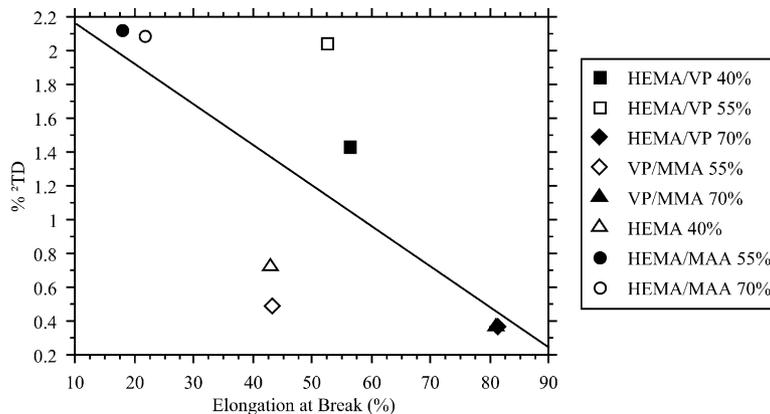

Fig. 12. Relation between %ΔTD vs. elongation-at-break.

Table 4
Rank order of the lenses (high–low) for tensile strength

VP/MMA 55%	HIGH
HEMA/VP 70%	
VP/MMA 70%	
HEMA 40%	
HEMA/VP 40%	**Tensile Strength**
HEMA/VP 55%	
HEMA/MAA 70%	
HEMA/MAA 55%	LOW

Table 6
Rank order of the lenses (high–low) for Young's modulus

HEMA/VP 70%	HIGH
VP/MMA 70%	
HEMA/VP 40%	
HEMA/VP 55%	**Elongation at Break**
VP/MMA 55%	
HEMA 40%	
HEMA/MAA 70%	
HEMA/MAA 55%	LOW

cross-linking agents serve to distinguish between individual lens materials in terms of durability, they do not provide the means to explain the varied performance difference found in actual use by contact lens wearers. In contrast, the hydrophilic monomers exemplify the basic nature of soft contact lenses. These molecules contain portions which provide the mechanism for the incorporation of water and also provide sites for interaction with the environment. The addition of hydrophobic monomers as well as increased cross-linking tend to decrease the water content of the non-ionic polymers while increasing polymer strength. This can be offset by the addition of MAA or a similar monomeric acid [24].

A high content of hydrogel groups is undesirable because this would result in weak mechanical strength and doubtful dimensional stability [25]. Increasing the content of hydrophilic monomers in a copolymer will increase lens water content and decrease lens modulus and elasticity. Likewise, increasing the content of hydrophobic monomers will decrease water content and increase modulus. Cross-linking monomers connect copolymer chains and increase modulus and elasticity and decrease soft contact lens water

Table 5
Rank order of the lenses (high–low) for elongation-at-break

VP/MMA 55%	HIGH
HEMA 40%	
HEMA/MAA 70%	
HEMA/VP 40%	
HEMA/MAA 55%	**Young's Modulus**
HEMA/VP 70%	
VP/MMA 70%	
HEMA/VP 55%	LOW

content [26]. Vinyl pyrrolidone has been added to HEMA-monomer to increase its swelling properties. The mechanical strength of this HEMA/VP copolymer is relatively poor [27]. In the present study the HEMA/VP materials exhibit high to moderate tensile strength, high elongation-at-break and moderate to low Young's modulus, which is probably due to the inclusion of the hydrophilic monomer VP.

Another copolymer examined in this work is VP/MMA. The MMA in the copolymer provides stability and mechanical strength and hardness and the VP component controls the water content of the copolymer. If one is aiming for a contact lens with a medium water content of 50–60% it is not possible simply to alter the relative amounts of MMA and VP in favour of MMA. If there is more than 50% MMA, the lens will be too stiff and hard [27]. According to Eggink and Pinckers [28], a disadvantage of VP/MMA contact lenses is their fragility. Tighe and Trevett [7] examined a range of materials that are VP/MMA copolymers at the same water content and found a wide range of stiffness. This can be explained by the fact that the VP/MMA copolymer is susceptible to polymerisation conditions as well as the nature of the cross-linking agent and the cross-linking density. They noticed a greater difference in the stiffness of the various VP/MMA copolymers. On a scale of relative stiffness that they produced (from 1 to 10), materials of the VP/MMA type at around 70% water content were found to have relative stiffness ranging from 3 to 10. In the present study the VP/MMA materials exhibit high tensile strength and high to moderate elongation-at-break. However, Young's modulus is high for the 55% material and low for the 70% material; this can be explained by the fact that the VP/MMA 55% material contains higher proportions of MMA compared with the VP/MMA 70%. This results in the 55% material being stiffer than the 70% material.

Tighe and Trevett [7] compared lathe-cut B&L 58 (Bausch and Lomb, Rochester, NY, USA) and cast polymerised Acuvue (Vistakon, Jacksonville, FL, USA) materials—which are HEMA/MAA copolymers—and found that the relative stiffness of these materials is

practically identical and falls at approximately two on the relative stiffness scale. It can be seen from Tables 4–6 that the HEMA/MAA materials—despite having very low tensile strength and elongation-at-break—are 'middle ranking' with respect to Young's modulus. This means that, although these materials exhibit a moderate stiffness, they are weak and can not be deformed much before fracture. This confirms the fact that the addition of hydrophilic monomers like MAA tends to increase the water content but is also responsible for weak mechanical strength.

Tighe and Trevett [7] examined HEMA lenses from two different manufacturers and found these to be different from each other. The HEMA material from one manufacturer had consistent stiffness of around 3 (on a relative scale from 1 to 10) and the HEMA material from the other manufacturer was appreciably stiffer but consistent in stiffness between 6 and 7. Tighe and Trevett [7] also found interesting differences between spin-cast and lathe-cut lenses in terms of strength and extensibility; this was thought to be related to differences in polymerisation condition. The 40% HEMA material in the present study exhibits a moderate tensile strength, a low elongation-at-break and a high Young's modulus, representing an 'average' overall mechanical behaviour.

In the present study, it was shown that strength (tensile strength) and stiffness (Young's modulus) are positively correlated; that is, the stronger the material the stiffer it is. On the other hand, significant correlations could not be demonstrated between elongation-at-break versus tensile strength and between elongation-at-break versus Young's modulus. These findings are in agreements with the observations of Billmeyer [29] who noticed that a polymer can be soft (low Young's modulus) and tough (high elongation-at-break) at the same time. A polymer can also be hard (high Young's modulus) but brittle (low elongation-at-break). Another possibility suggested by Billmeyer [29] is a polymer being both hard (high Young's modulus) and strong (high tensile strength); this combination of properties has been confirmed in the present study. In general, the properties of polymers are best determined from the characteristics of their stress–strain curves.

Although the water content plays a large part in controlling the mechanical properties of hydrogels, it is only one of several influencing factors. It is possible to produce very stable high (>70%) water content soft contact lenses because the elastic behaviour and rigidity of hydrogels is closely governed by polymer structure [5]. It must be emphasised, however, that the mechanical properties of a polymer depend on the conditions under which the test is made (e.g. temperature, rate of loading, type of stress).

The measurement of the mechanical properties of a contact lens material, in a way that enables an adequate correlation with clinical behaviour (both in terms of comfort and visual stability) presents two major problems. The first involves the choice of an appropriate mechanical property which will adequately reflect these two aspects of the behaviour of widely differing types of materials (i.e., from very soft gels to rigid thermoplastics). The second involves the choice or design of techniques to enable such measurements to be made of very fragile specimens (i.e., of similar thickness to contact lenses). This condition is necessary because it is desirable to choose testing methods which employ samples of similar dimensions to those of the materials used in practice [5].

The main source of experimental error (leading to the high standard deviations) arises from the way in which the test-pieces are held in the jaws of the testing machines. The pressure required to grip the sample can impart pre-stress in the sample, resulting in a non-uniform stress distribution. At the relatively small gauge length (10 mm) needed to test the hydrogel samples, the pre-stress near the ends could have a significant effect on the overall stiffness of the sample [11]. A second source of error is the different rate at which various materials dehydrate. However, Barnes et al. [30] noticed that the form of tensile stress–strain curves produced from measurements made in the appropriate aqueous medium do not show appreciable differences from measurements made in air, provided sufficient speed and care are taken to prevent premature dehydration of the sample. Another source of error is the small size of the samples available from contact lenses. This small size increases the error in determining the mechanical properties of contact lenses. Such experiments give a standard deviation which is substantially higher because the dimensions of the specimens are much less accurately known [17].

The mechanical properties of a contact lens material give useful insights into the way in which the polymer network is arranged. Thus, different samples of a polymer can have different amount of stiffness, strengths and elongations at break [7]. Greater amounts of cross-linking agents in a given type of polymer will result in a stiffer and less elastic material. If, however, two samples of the same polymer are similar in stiffness but one is much less extensible at break than the other, it is generally a sign that this network is less perfect (rather than an indication of the number of cross-links being about the same [7]).

Having shown that mechanical properties of contact lens hydrogels such as tensile strength, elongation-at-break and Young's modulus, can be measured and that differences can be detected, it now remains to relate these findings to the finished product. There is something to be said for having a lens which is brittle, because it could facilitate regular replacement. Certainly, lenses of very low mechanical strength could limit the life of a soft contact lens. A low modulus may result in increased comfort of soft lenses, but may also transfer any corneal astigmatism through the lens as a result of the 'wrap' factor [31]. The mechanical strength of a soft contact lens is controlled largely by its water content and overall thickness, although by manipulating the chemistry of the polymer it is claimed that higher water content materials can be produced with greater stability and tensile strength [32], such as silicone hydrogels.

Questions were raised regarding the quality of the edges of early-generation disposable hydrogel lenses [33]. As the manufacture of these lenses was based on a first-generation moulding technology, the possibility of damaged or wrinkled edges on removing the lens from the mould existed. Nevertheless, lenses can be damaged on removal from their sealed pack. If a long service life is required, then there is little doubt that a lens made from a tougher material would be the best choice; however, there is now little demand for such lenses. Rough handling of the lens which already contains small defects is not as likely to cause catastrophic fracture with a tough material as it is with a relatively brittle material. Of course, too much strain in a tough hydrogel could introduce irreversible deformation into the lens (with serious consequences for optical quality), but this is probably more desirable than to have a brittle hydrogel which would be destroyed altogether at much lower strains.

Production methods for soft lenses include lathe-cut, spin-cast, and cast-molding [34]. Successful high-yield lathe-cutting necessitates an appreciation the mechanical properties of materials. Low water content materials tend to be harder and therefore, more difficult to cut and polish whereas higher water content materials are softer and are easier to cut and polish. Literature from the manufacturers needs to be accessed in order to obtain information on the materials they use; however, details of manufacturing methodology are seldom disclosed because for proprietary reasons and any information that is made available typically lacks a standardised format.

This study has proposed a method for the tensile testing of soft contact lenses in air. The basic elements of this method are outlined in Appendix A. This methodology is advocated as a standard protocol for testing the tensile properties of hydrogel contact lenses. Practitioners may, from time to time, wish to consider the tensile properties of certain soft contact lens materials in order to reconcile such properties with clinical observations. We recommended that manufacturers determine these properties experimentally and publish such data. The test method should also be revealed and units of measurement relevant to contact lens materials should be adopted.

The mechanical properties of hydrogel polymers are not easy to measure. The very act of deformation involved in such testing procedures produces redistribution of the water in the specimen and the properties determined for hydrated polymers rarely reflect those of the material as used in the normal fashion. Nonetheless, such measurements can give useful comparative information. Information relating to material stiffness could be useful for clinicians, who could relate inherent material stiffness to the apparent stiffness of the total lens. However, it is not easy to clarify the relationship between the mechanical properties and the practical requirements of a soft contact lens. If a soft contact lens is too flexible, its insertion into an eye will be difficult and it will be unstable on the cornea because of excessive deformation brought about by blinking. On the contrary—if the resistance to deformation is too large, it will behave like a rigid contact lens, rather than a soft lens.

Although water content plays a large part in controlling mechanical properties, it is only one of several factors that practitioners should consider. For example, Tighe [4] demonstrated that cross-link density can modify the elastic behaviour of hydrogels of different water contents. As Tighe [4] noticed, the fact that such a great variety of structures is possible in this class of polymer—coupled with the fact that equilibrium water content, oxygen permeability, mechanical properties and surface characteristics are interrelated with structure in different ways—makes it possible to design hydrogels to fulfill a wide range of functions. It is possible to produce very stable, high (>70%) water content materials because the elastic behaviour and rigidity of hydrogels is closely governed by polymer structure.

In the present study, the relative change in total diameter following wear seems to be able to be predicted from tensile strength and elongation-at-break. Also, the stronger and stiffer a material, the more difficult it is for this material to change in dimensions.

Although there is a diverse array of procedures for testing specific aspects of the mechanical properties of materials, the application of results from these tests is often confusing. From the available data, a number of general conclusions may be drawn. The mechanical properties will very much determine the type of lens design that ultimately need to be used. According to Brennan [6], a material with a very low modulus of elasticity (a soft lens) will drape over the cornea and is often used with a large diameter design. These lenses cannot be made too thin or they will be fragile. On the other hand, a material with a high modulus of elasticity (a rigid lens) will be fitted according to fluorescein patterns, and usually in a small diameter design. Materials in between these extremes may have sufficient mechanical strength to produce a suction type effect on the cornea, as has been observed with silicone rubber lenses. Another important aspect of lens design with regard to material properties is the achievement of adequate tear exchange under the lens. For example, soft lenses must be fitted very flat to achieve a good exchange of tears for the removal of debris. Another example is the design of toric lenses, which must be different for rigid and soft materials [6]. Matching lens design to mechanical properties of a material is indeed a challenging aspect of achieving the optimal contact lens performance [35].

Perhaps surprisingly, a clear relation between water content and mechanical properties can not be demonstrated in this study. Stress–strain measurements produce interesting results. Tighe and Trevett [7] comparing Permaflex with Permalens (Pilkington Barnes-Hind, Southampton, UK)—which are lenses with similar water content—gave Permaflex a relative stiffness factor of 1 and Permalens 2.2. They also noticed that, taking a range of currently available materials of the same material type (i.e., VP/MMA copolymers) at the same water content, resulted in a wide range of material stiffness. Because the VP/MMA copoly-

mer is very susceptible to polymerisation conditions, the nature of the cross-linking agent and the cross-linking density, it is not surprising that differences between these materials are found. In general, the observations made by Tighe and Trevett [7] are confirmed in the present study.

In conclusion, a set of data is presented in this paper on a range of eight different soft contact lens materials, which has been derived using the same tensile testing method. This data can be valuable for the materials manufacturer, for the contact lens practitioner and for the clinical researcher in order to predict the behaviour of contact lenses on the eye and to compare the mechanical properties of a number of soft contact lens materials. A plea is made for the adoption of a standardised methodology when generating such data in the future.

Appendix A: proposed method of tensile testing of soft contact lenses in air

Soft contact lens parameters

BVP:	plano or up to -3.00 D	(mean value of $BVP_{present\ study}$ = -2.85 D)
t_c:	~ 0.10 mm	(Mean value of $t_{c\ present\ study}$ = 0.108 mm)
TD:	≥ 14.00 mm	(mean value of $TD_{present\ study}$ = 14.03 mm)
BOZR:	as flat as possible	(mean value of $BOZR_{present\ study}$ = 8.91 mm)

- At least two to three lenses from the same batch of contact lens material should be used.
- Lenses should be kept in normal saline solution prior to testing.
- Each lens should be flattened between two thin plastic sheets (overhead slides).
- Three parallel strips should be cut from a single lens, with good accuracy (this could be achieved by using a device that employs a micrometer, such as that used in this study.

Specimen (lens strip) dimensions

Width:	3 mm
Gauge length:	10 mm
Thickness:	~ 0.10 mm (centre thickness of the contact lens can be used for lenses up to -3.00 D)

- Three strips per contact lens should be tested.
- A 'plastic window frame' such as that used in this study, should be used to:
  - support and safely handle the strips while being transferred to the tensometer;
  - set the gauge length (10 mm);
  - provide a cushion for the specimen in the jaws of the tensometer.
- Fibre jaws should be used in the tensometer.
- The specimens should be kept in normal saline solution prior to testing.

Test conditions

The testing should be carried out in a temperature and humidity controlled environment, whereby:

- Temperature = 20 °C;
- Humidity = 50%;
- Crosshead speed = 20 mm/min (strain rate: 200%/min).

Formulae and units

$$\text{Tensile strength}\left(\frac{\text{kg}}{\text{cm}^2}\right) = \frac{\text{Load}}{\text{Cross-sectional area}}$$
(where cross-sectional area = width $\times$ thickness)

$$\text{Elongation-at-break}\ (\%) = \left[\frac{(L - L_0)}{L_0}\right] \times 100\%$$

(where L = final length, L_0 = gauge length)

$$\text{Young's modulus}\left(\frac{\text{kg}}{\text{cm}^2}\right) = \left(\frac{\text{load}}{\text{extension}}\right) \times \left(\frac{\text{gauge} - \text{length}}{\text{cross} - \text{sectional area}}\right)$$

Acknowledgement

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