

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

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28 **Abstract**

29 Purpose

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

33 Methods

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

39 Results

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

50 Conclusion

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

55

56 **Keywords**

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

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62 Introduction

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

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

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

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

106

107 **The Idealised Lens Development Cycle**

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

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

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

131

132 **The Developing Need for Mechanical Property Testing**

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

136 Historically, glass scleral lenses were primarily ground or blown [3]. Although PMMA could
137 not be fabricated by blowing, it was possible to fashion PMMA scleral lenses by thermo-
138 forming the polymer against an impression of the ocular surface and corneal lenses by using
139 lathe-based grinding and polishing techniques [1]. The latter approach was commonly used

140 for fabrication of precision optical (e.g. camera lenses). This is the foundation upon which the
141 design of materials for use in the lens fabrication techniques of the 1960s, 1970s, 1980s and
142 much of the 1990s were based.

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

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

153

- 154 • enhanced oxygen permeability
- 155 • susceptibility to reproducible fabrication
- 156 • the ability to maintain a coherent anterior and posterior tear film
- 157 • adequate mechanical durability
- 158 • dimensional stability

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

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

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

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

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

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

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

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

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

$$200 \quad 1 \text{ MPa} = 10^6 \text{ Nm}^{-2} = 145.04 \text{ psi} = 10^7 \text{ dynes cm}^{-2}$$

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

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

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

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

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

220

221 **Compression Behaviour of Hard and Soft Materials**

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

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

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

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

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

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

284 Of particular importance is the capability of the technique in illustrating the difference
285 between the deformational behaviour of rigid and soft materials. Rigid materials do not show
286 measurable deformation by this technique at loads below about 1.0 g (Fig 5). This illustrates
287 the point that the combination of eyelid load and a rigid lens material leads to deformation of
288 the cornea not the lens. This observation underpins the application of rigid lenses in
289 orthokeratology. The response of the cornea, which has a rigidity modulus of about 1.0 MPa
290 [48], is distinctly different for rigid and soft lenses but not recognisably so for two different
291 rigid lenses of the same design. Characterising and acknowledging the significance of the

292 difference in material properties between soft and hard materials, represented the first
293 milestone in contact lens development.

294 The study of material compressive behaviour in the contact lens field has predominantly
295 involved the use of micro- or more recently nano-indentation techniques. These methods
296 have however, been recognised to have limitations [49]. Several non-conventional techniques
297 have been developed to assess compressional behaviour, such as atomic force microscopy
298 [50-52], the falling dart method [53] and micro-shaft poking [49]. The improved
299 understanding of compression techniques has facilitated the development of mathematical
300 models to predict materials' behaviour [37, 49, 53-57]. Although the use of such models may
301 advance understanding, they are fundamentally reliant on assumptions based on experimental
302 observation. Because of the rapidly developing range of materials and consequent limited
303 range and volume of experimental work with each type, mathematical modelling is only in its
304 infancy in the comparative study of material properties.

305

306 **Tensile Testing and Soft Lens Development**

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

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

325 Tensile testing has been used for many years to measure the mechanical properties of textiles,
326 metals and plastics and has been adapted to the study of contact lens materials [58]. A
327 schematic of the technique and two examples of stress-strain curves obtained when handling
328 the small, fragile test pieces cut from lenses are shown in Fig 6. Note the distinctive
329 difference between the shapes of the stress-strain diagrams shown; Fig 6a displays a uniform
330 correlation between stress and strain, typical of a material with ideal elastic behaviour. Fig 6b
331 illustrates a somewhat exaggerated form of the stress-strain diagram frequently obtained with

332 soft lens samples, which are difficult to mount in a taut yet unstressed fashion, despite the
 333 mounting template (Fig 6c). As load is applied and the test sample is stretched, the slope of
 334 the curve changes at Fig 6b region b. Fig 6b region c displays a degree of material yield
 335 before failure occurs; this is not typical elastic behaviour but resembles that of plastic
 336 deformation.

337 A typical tensile test will provide three results:

- 338 • Tensile Modulus
- 339 • Tensile Strength
- 340 • Elongation to Break

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

347 Modulus = $\frac{\text{stress}}{\text{strain}}$ (MPa) *Equation 1*
 348

349 *where*

350 stress = $\frac{\text{load}}{\text{cross-sectional area}}$ *Equation 2*
 351

352 *and*

353 strain = $\frac{\text{extension of gauge length}}{\text{original gauge length}}$ *Equation 3*
 354

355 Young’s modulus in SI nomenclature is expressed in Pascals (1Pa = 1 Newton per square
 356 metre or 1Nm⁻²). In practical terms the prefix Mega (10⁶) or Giga (10⁹) is often used;
 357 alternative units for conversion have been stated previously. Compiled tables of material
 358 properties are readily accessible [59]. The value of Young’s modulus is typically around
 359 200.0 GPa for metals, 2.0 GPa for plastics such as PMMA and 0.5 MPa for hydrogels such as
 360 PHEMA.

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

367 In the case of stress-strain diagrams displaying perfect elastic behaviour (Fig 6a), the slope
 368 does not change and therefore modulus will be identical irrespective of the slope area chosen
 369 for calculation. With the experimental case (Fig 6b) the slope of the curve changes between

370 the origin and terminus of the diagram. To remove any ambiguity from the slope area used, it
371 is conventional for modulus to be derived from a tangent (dotted line) within the first 10%
372 extension range (shaded triangle).

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

385 *The “Correct” Modulus: Problems of Lens Non-planarity*

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

392 Table 1 contains tensile moduli data for both current and historic conventional hydrogel
393 lenses (data obtained by in-house laboratory assessment with the method illustrated in Fig
394 6c). The data set is based on the measured thickness of the lens at a “mid-point” between
395 centre and edge (MCZT) - measured with a 10 mm diameter probe. The measured thickness
396 cannot take into account the lens profile, even if the power of all lenses is maintained at -3.00
397 D. A similar problem arises when the calculated modulus is based on manufacturer’s quoted
398 centre thickness measurements – modulus values based on centre thickness are uniformly
399 higher but the relative magnitude of modulus values obtained for different lenses is similar.

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

407

408 *Problems of Material Variability and their Clinical Relevance*

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

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

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

435 *Designing Properties for Purpose*

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

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

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

461

462 **Shear-Induced Properties of Hydrogels: Dynamic Mechanical Property Measurement**

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

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

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

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

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

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

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

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

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

519 One important area of incomplete understanding is the uncertain link between *in-vitro*
520 techniques using well-lubricated, small contact areas that are used to determine coefficients
521 of friction, and the *in-vivo* behaviour of the lens itself. The relevance of coefficient of friction
522 data to the interaction between the lens and both the eyelid and cornea, which are coupled by
523 viscous drag effects, has yet to be quantified. Only recently has experimental data in this
524 important area of the elastic properties of the lens and the transfer of shear forces from eyelid
525 to cornea been reported [68]. Similarly, the significance of stick-slip phenomena in frictional
526 studies on substrates of similar mechanical properties to the eyelid and the effect of lipid
527 deposition on these interactions play no part in the low coefficient of friction measurements

528 reported for lenses. There are many aspects of the mechanical interaction of the lens with the
529 eye that are not yet understood and although mechanical property testing has become more
530 sophisticated in recent decades there is still much to be learned about this complex subject.

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

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

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

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

554

555 **Conclusion**

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

563 It is instructive to examine the distribution of lens moduli that have been used in common
564 clinically available contact lenses since the 1970s. Fig 9a shows a relative frequency
565 distribution of the moduli of a representative sample of all soft lens materials that have been
566 commercially available. The data are taken from Table 1 which shows a substantial selection

567 of conventional hydrogel materials, together with Table 2 which highlights the currently
568 available SiHys. It is important to reiterate the fact that because of the complex cross-section
569 of contact lens materials, these are relative rather than absolute values of tensile moduli. A
570 double-averaging technique has been used to provide the relative frequency distribution plot.
571 Fig 9b the inset diagram, shows how the moduli of SiHy lenses launched since 2000 has
572 changed over that time period.

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

580

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748 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

749 * [DAA; diacetone acrylamide, EEMA; ethoxyethyl methacrylate, HEMA; 2-hydroxyethyl methacrylate, MA;
750 methacrylic acid, MMA; methyl methacrylate, NFMA; N-(formylmethyl)acrylamide, NVP; N-vinylpyrrolidone,
751 PC; 2-methacryloylethyl phosphorylcholine, PVA; poly(vinyl alcohol), PVP; poly(vinylpyrrolidone)].
752 ‡ [MCZT; measured central zone thickness]. Measured with 10 mm diameter probe micrometer.
753 † 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
Manufacturer	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	somofilcon 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

755 ⁺ Now Alcon

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Figures

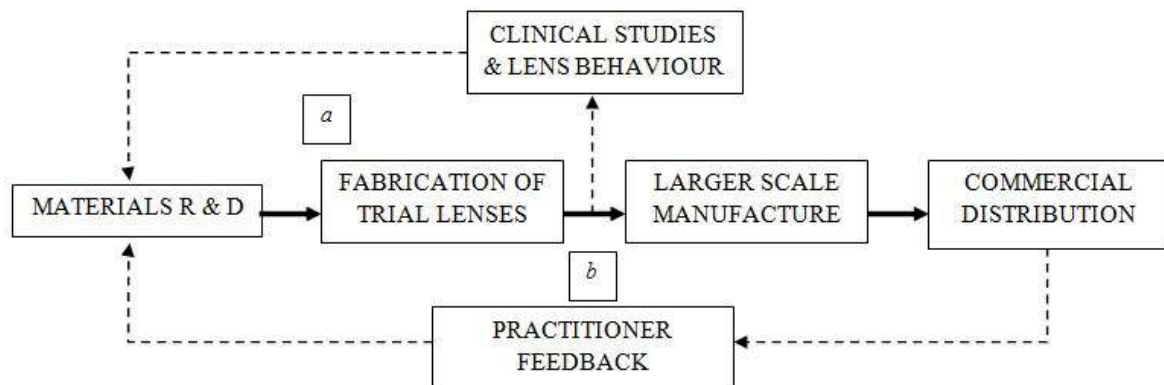


Fig 1 – Idealised schematic representation of the lens production and development cycle.

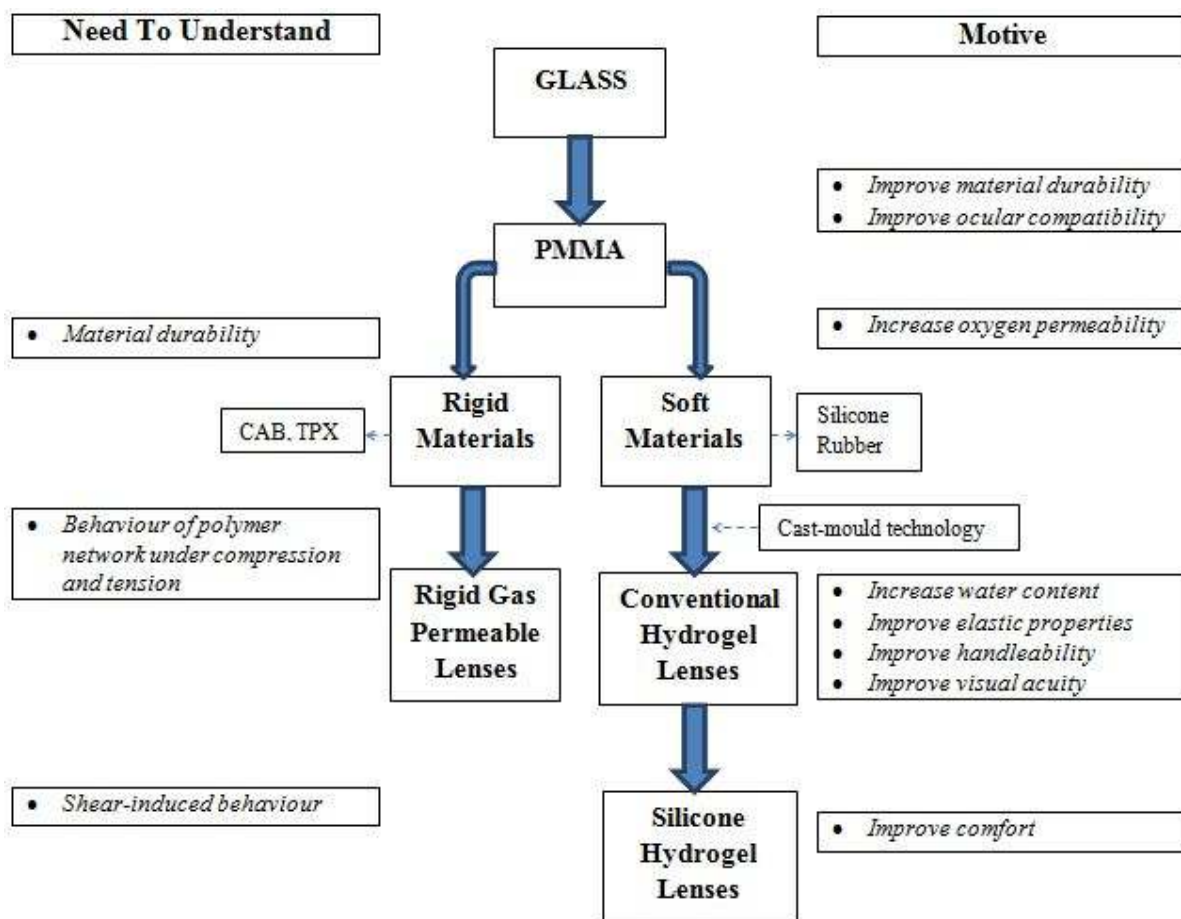


Fig 2 – Schematic representation of key aspects of contact lens material development.

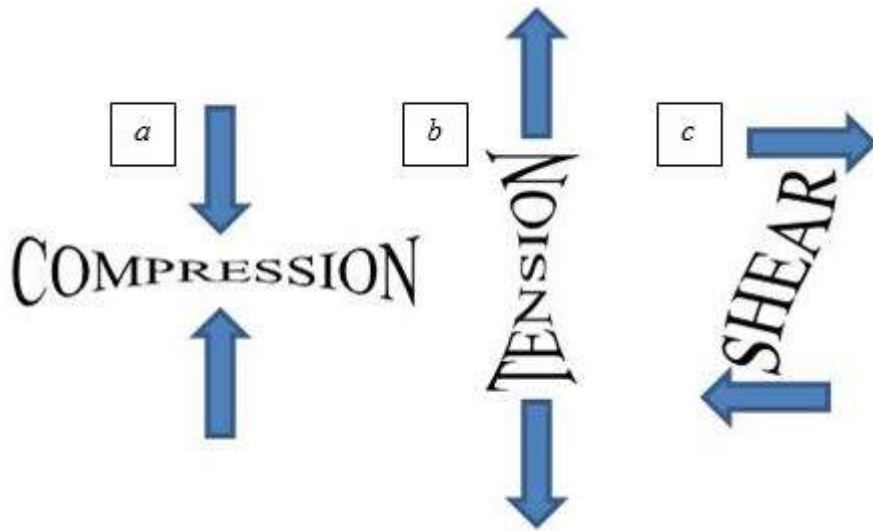


Fig 3 – Schematic illustrating mechanical property measurement methodologies.

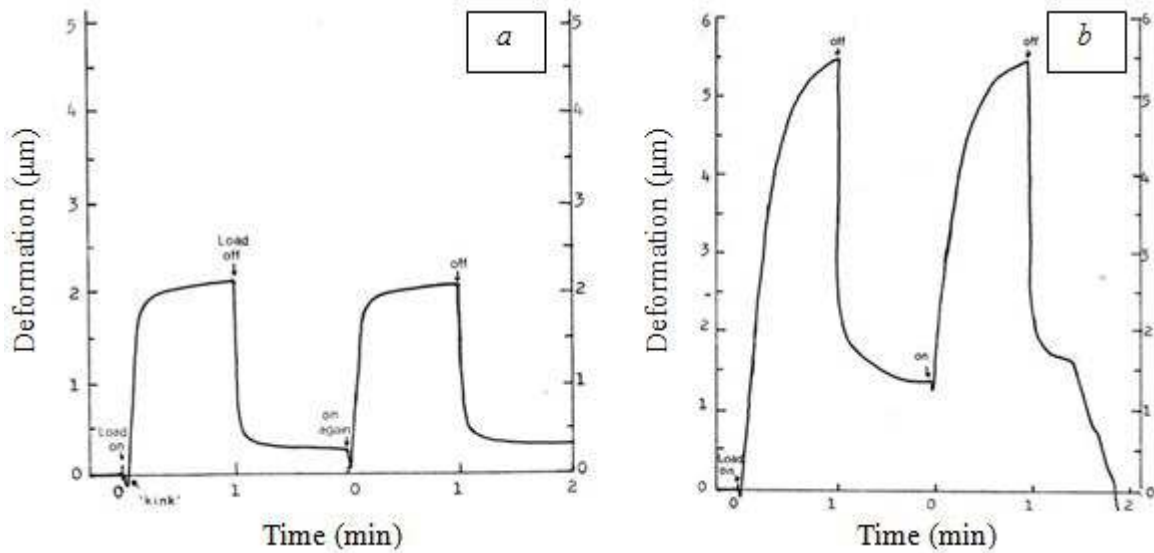
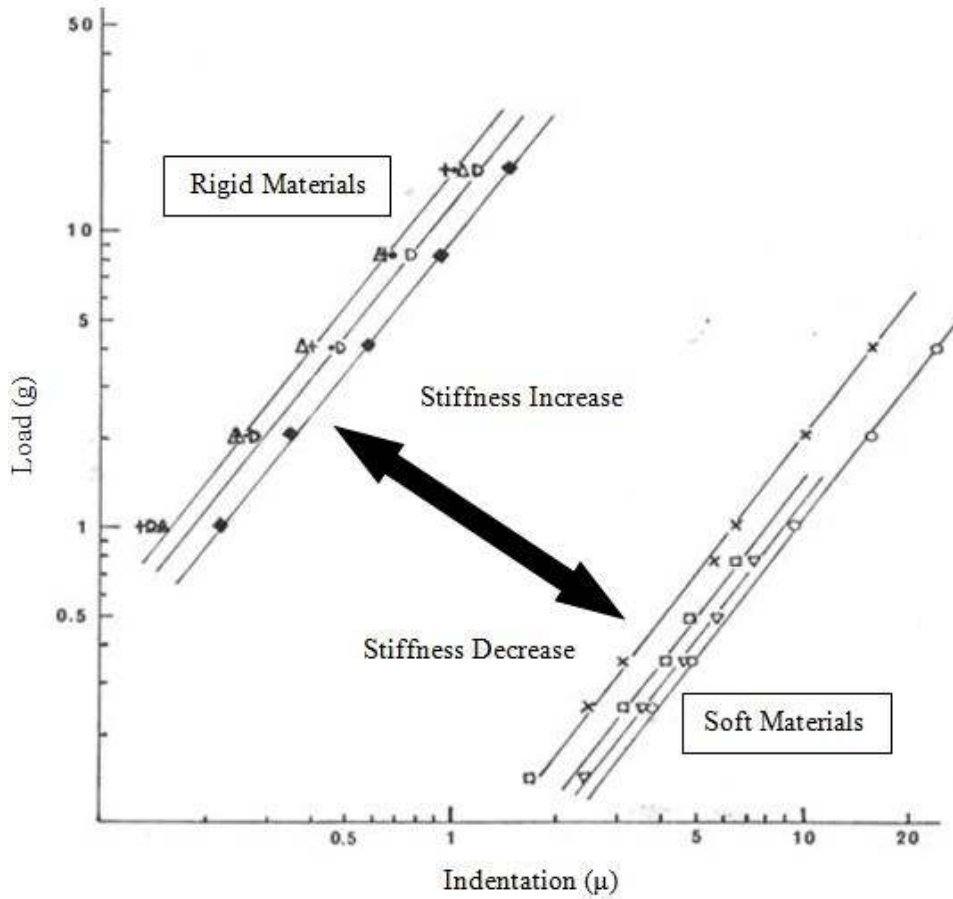


Fig 4 – Deformation and recovery of hydrogel materials under eye lid load [36]. Data obtained by compression (Fig 3a) testing of 100 µm samples of (a) PHEMA, and (b) PHPMA-co-NVP (20:80) with a flat-ended indenter (0.126 cm diameter). [PHEMA; poly(2-hydroxyethyl methacrylate), PHPMA; poly(2-hydroxypropyl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



Δ	PMMA	+	Dehydrated PHEMA	\circ	SBR
\mathbf{D}	Paraperm O2 RGP	\blacklozenge	CAB	∇	PHEMA hydrogel
\bullet	Boston II RGP	\times	Silicone Rubber	\square	HEMA-Styrene (90:10) hydrogel

Fig 5 – Compression (Fig 3a) 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].

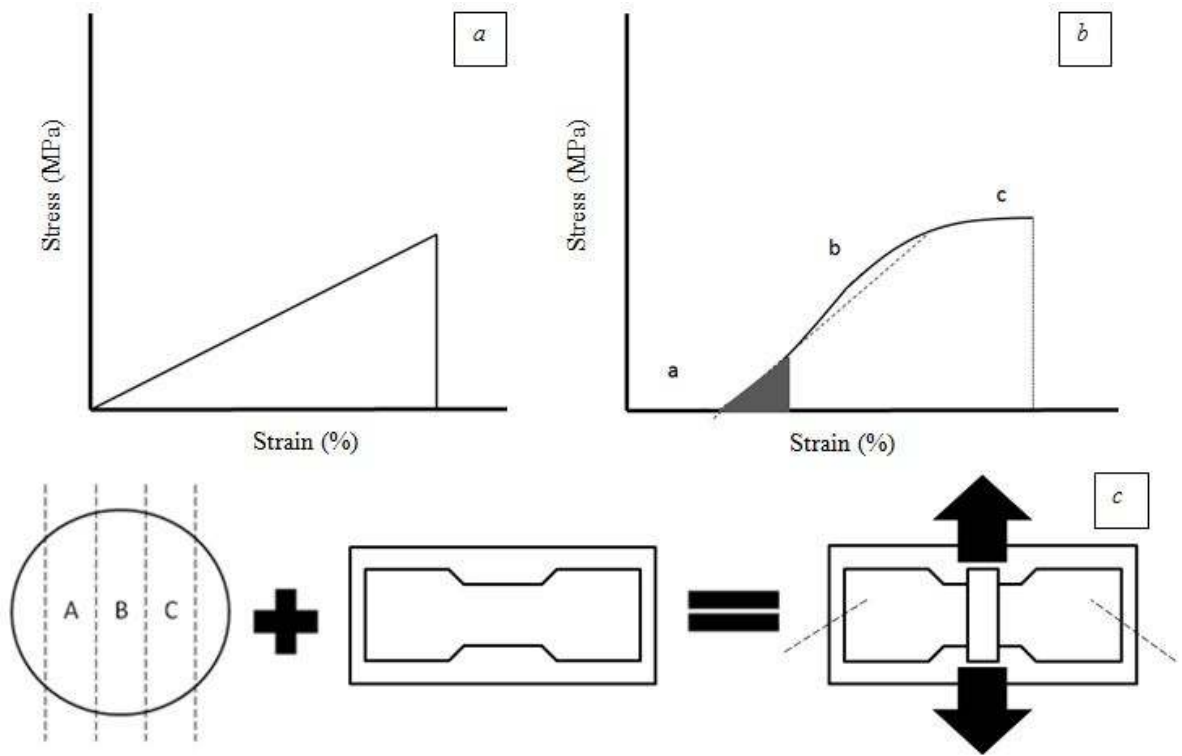


Fig 6 – Schematic representation of tensile stress-strain diagrams (Fig 3b); (a) ideal elastic behaviour, and (b) typical experimental lens data. Schematic representation of the template method employed at Aston University for tensile testing (c). Illustrations are author-generated.

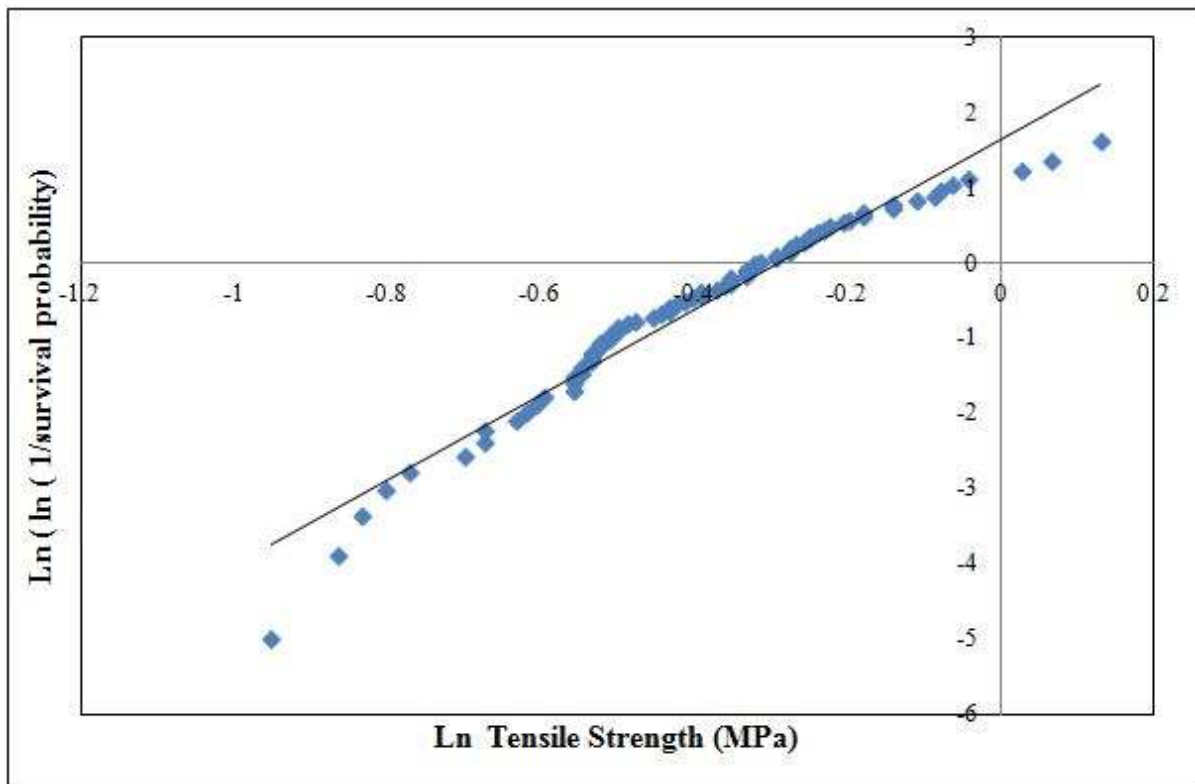


Fig 7 – Weibull Model plot of a lathe-cut lens batch (data derived from Trevett [65]).

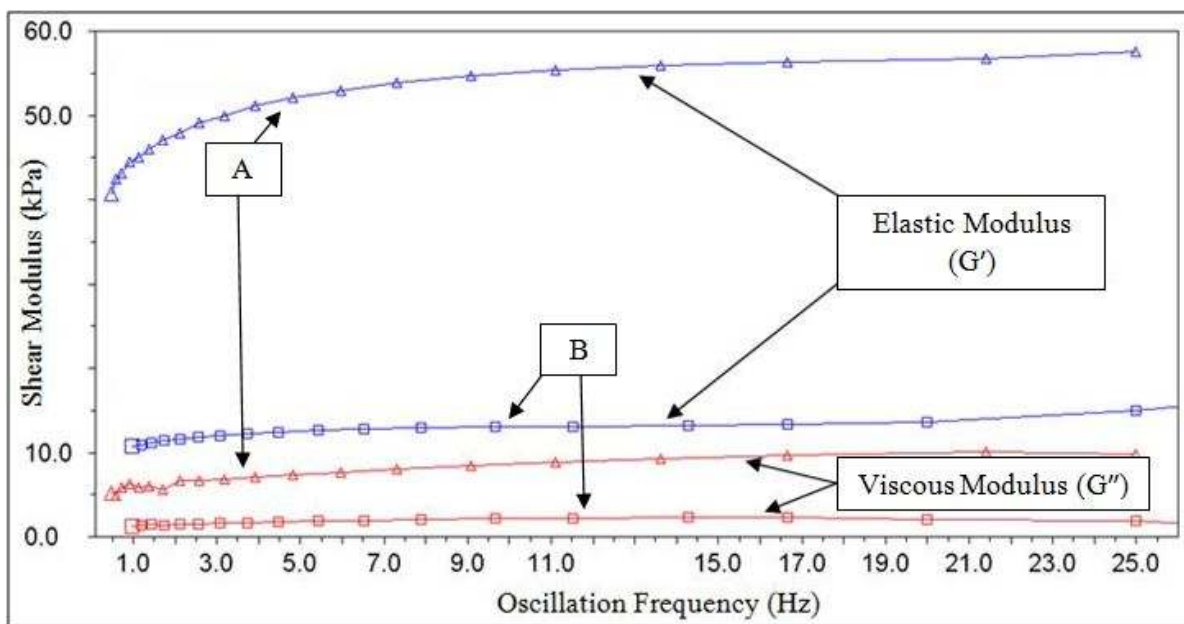


Fig 8 – Examples of shear-dependence (Fig 3c) of the elastic moduli of a typical silicone hydrogel (A) and a low modulus conventional hydrogel (B).

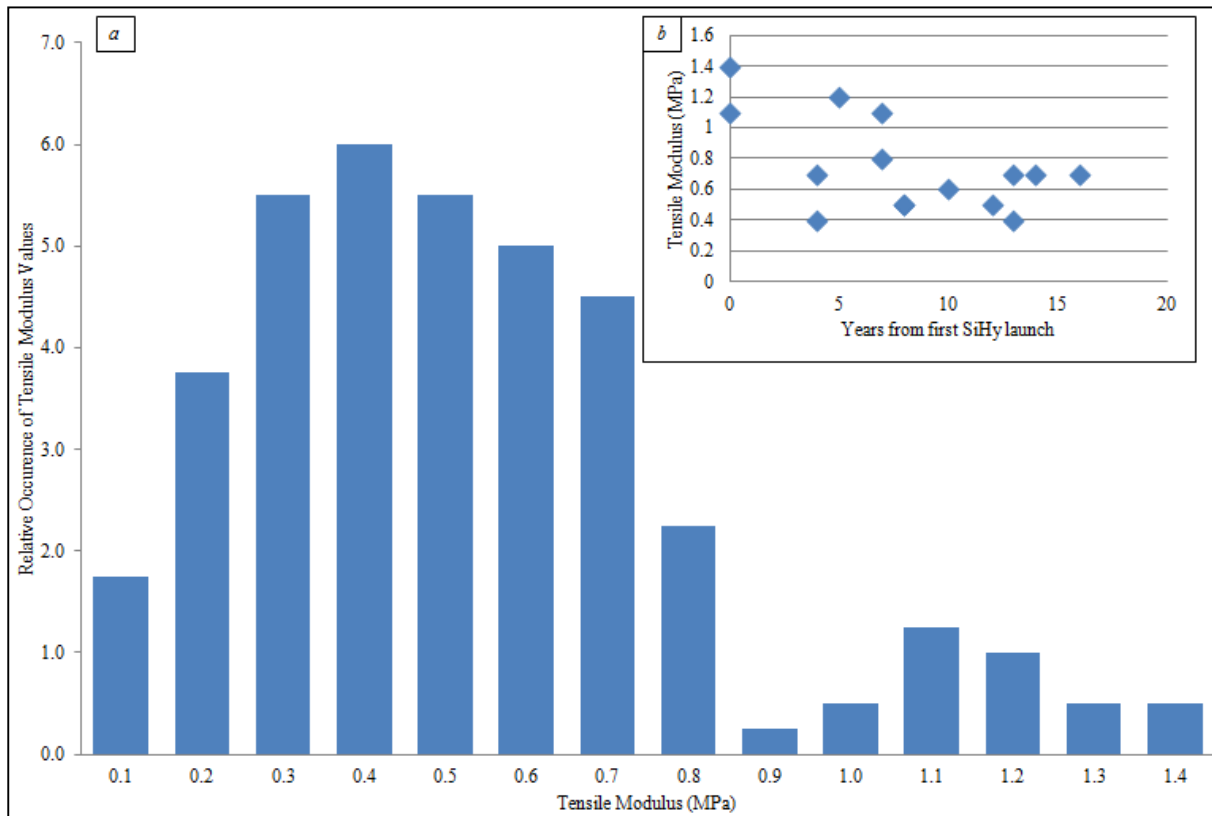


Fig 9a – Historical and current occurrence of particular values of tensile modulus for conventional* and silicone hydrogel (SiHy) contact lenses (data from Table 1 and 2). Fig 9b (inset) - Tensile moduli of newly launched SiHy lenses as a function of time since first SiHy availability in 2000.

* atlatilcon A has been omitted from the plot