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Review article

Mechanical properties of contact lenses: The contribution of measurement techniques and clinical feedback to 50 years of materials development

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Purpose: This review summarises the way in which mechanical property measurements combined with clinical perception have influenced the last half century of materials evolution in contact lens development.
Methods: Literature concerning the use of *in-vitro* testing in assessment of the mechanical behaviour of contact lenses, and the mutual deformation of the lens material and ocular tissue was examined. Tensile measurements of historic and available hydrogel lenses have been collected, in addition to manufacturer-generated figures for the moduli of commercial silicone hydrogel lenses.
Results: The three conventional modes of mechanical property testing; compression, tension and shear each represent different perspective in understanding the mutual interaction of the cornea and the contact lens. Tensile testing provides a measure of modulus, together with tensile strength and elongation to break, which all relate to handling and durability. Studies under compression also measure modulus and in particular indicate elastic response to eyelid load. Studies under shear conditions enable dynamic mechanical behaviour of the material to be assessed and the elastic and viscous components of modulus to be determined. These different methods of measurement have contributed to the interpretation of lens behaviour in the ocular environment. An amalgamated frequency distribution of tensile moduli for historic and currently available contact lens materials reveals the modal range to be 0.3–0.6 MPa.
Conclusion: Mechanical property measurements of lens materials have enabled calibration of an important aspect of their ocular interaction. This together with clinical feedback has influenced development of new lens materials and assisted clinical rationalisation of in-eye behaviour of different lenses.

Contents

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1. Introduction

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

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

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

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

2. The idealised lens development cycle

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

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

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

3. The developing need for mechanical property testing

The process of material development over time has not been characterised by regular steps; Fig. 2 summarises the evolution of

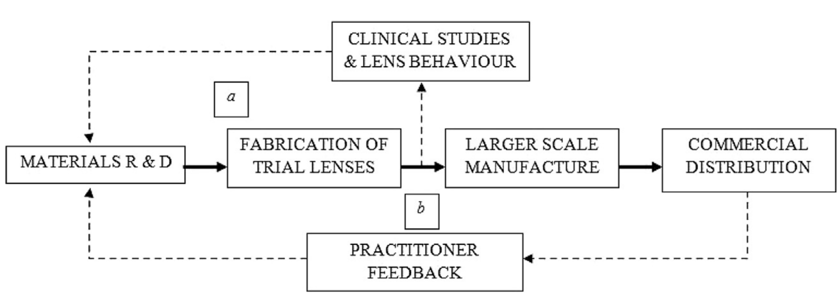

Fig. 1. Idealised schematic representation of the lens production and development cycle.

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