Every month, 4-5 new patents for contact lens materials appear in the international chemical literature. However, rarely do more than one or two new materials reach the market during the year. In addition, almost all new materials are minor variations of the basic lens polymers that have been available for the last 10 to 15 years. The problem which keeps the new materials from entering the marketplace is not a lack of demand for improved materials, but that most of the potential polymers satisfy only one or two of the requirements for clinical success. This paper will discuss 20 aspects of lens polymers which must be considered by investigators hoping to bring their new polymer to the ophthalmic market.

INTRODUCTION

Contact lenses are a unique product in the biomedical arena. They are regulated by the Food and drug Administration (FDA) as Class III medical devices with all the testing detail required for such devices. However, they are often treated by dispensers as bulk commodities and loss-leaders and are often perceived by consumers as cosmetics. In fact, a good contact lens must be all of these things and more. It must also function as a safe and effective precision optical device.

The contact lens market is divided into hard lenses, rigid gas permeable (RGP) lenses, soft lenses, and hybrids. These lens categories are further divided into daily wear, provisional wear, extended wear, disposable, spherical, bifocal, toric, and cosmetically tinted lenses. The market is further complicated by an additional factor. Manufacturers cannot introduce materials which are incompatible with all the available solution regimens. This problem arises as a consequence of the potential for patient noncompliance with instructions for proper use. A safe lens product must be nearly foolproof.

To meet these demands, manufacturers must concern themselves with numerous characteristics of the polymers employed. Some aspects relate to manufacturability and cost, others relate to clinical function. Most relate to both.
MANUFACTURING METHODS

Manufacturing methods are diverse. Numerous manufacturing techniques have been tried, but three have surfaced as the best. These are lathe cutting, cast molding, and spin casting. The choice for a given product is related to material properties, cost, and functional quality requirements. A material not fitting one of these established techniques faces an uphill battle to the marketplace. The capital investment required to enter the market is enormous, and must be expended prior to FDA approval. At the present, the minimum time for a new material to reach the market is three years. A new process will extend the time by at least another year. In reality, from concept to market usually takes five years if any aspect of the development is novel. For a profitable entry, lens manufacturing costs must be less than $20 fully burdened, preferably less than $5. Some manufacturers claim less than $1. Low profit margins resulting from heavy competition keep R&D budgets lean.

IMPORTANT PROPERTIES

In this environment, in-depth screening of new products is mandatory before scarce R&D dollars are committed. The following aspects of new materials must be thoroughly investigated.

Hardness

This property is essential for a polymer to be manufactured by lathe cutting. Surface quality polishability, resistance to warpage during cutting, and scratch resistance are also dependent on hardness.

Modulus

The Young's modulus (hydrogels) and the flexural modulus (RGP) play a critical role in manufacturing and clinical performance. A lens with a low modulus will warp during lathe manufacture and flex during wear, yielding poor optical performance. To combat this problem, polymers with low modulus must be cut thick, reducing comfort and oxygen delivery to the cornea.

Oxygen Permeability

The human cornea derives most of its oxygen directly from the atmosphere. No Dk value is too high, but the higher Dks are often incompatible with other properties, and compromises must be made. The lenses should also pass CO2 easily since CO2 accumulation is also detrimental to corneal health.

Elongation

Elongation at break is one important measure of lens durability. Stretching often occurs during lens handling and cleaning and represents a significant challenge to lens integrity.