HIGH REFRACTIVE INDEX POLYMERIC COMPOSITIONS SUITABLE FOR USE AS EXPANSILE HYDROGEL INTRAOCULAR LENSES

This is a Continuation-in-Part of my copending application entitled HIGH REFRACTIVE INDEX POLYMERIC COMPOSITIONS SUITABLE FOR USE AS EXPANSILE HYDROGEL INTRAOCULAR LENSES filed Dec. 22, 1989, Ser. No. 07/455,087 now abandoned, which in turn is a Continuation of my prior application entitled HIGH REFRACTIVE INDEX POLYMERIC COMPOSITIONS SUITABLE FOR USE AS EXPANSILE HYDROGEL INTRAOCULAR LENSES, filed Oct.9, 1987, Ser. No. 07/107,281 now abandoned.

FIELD OF THE INVENTION

This invention relates to improved expansile hydrogel intraocular lenses suitable for small incision cataract surgery and their preparation from certain chemicals. More specifically, this invention relates to flexible, biocompatible, optically clear, castable, moldable or machinable hydrogels having refractive indices in the dehydrated state of at least 1.53 and at least 1.40 in a swollen state.

BACKGROUND OF THE INVENTION

Cataract surgery is among the most common major surgical procedures performed in the United States today. In fact, it is the most common surgical procedure performed in Medicare beneficiaries who are 65 years or older. With steadily increasing frequency in appropriately selected patients, cataract surgery is combined with intraocular lens implantation. While much work has been done since the first intraocular lens was implanted in the human eyes in 1949, there remains a substantial need for an improved expansile hydrogel intraocular lens which will enhance the safety and efficiency of cataract surgery.

This need is fully described in U.S. Pat. No. 4,556,998, issued Dec. 10, 1985 in the name of Steven B. Siepser and entitled ARTIFICIAL INTRAOCULAR LENSES AND METHOD FOR THEIR SURGICAL IMPLANTATION. The entire disclosure of this Siepser Patent is hereby being incorporated herein by reference.

The presently used materials, i.e. copolymers of 2-hydroxyethyl methacrylate with vinyl pyrrolidone or ethylenedimethacrylate with their sufficient 170% swell characteristics, have refractive indices that are too low when fully hydrated. It seems that the ideal highest power small incision lens that can be made with the most modern technology is about 21 diopters. Even such an advanced lens would exclude a considerable portion of the "cataract" market.

It is well known that the refractive index of lens material affect the base curves, diameter, edge and certain thickness relative to any fixed dioptic power. For example, the optical properties of high refractive index glass permit use of a relatively shallow base curve, thus avoiding excess edge thickness in glasses for patients with extreme myopia. In preparing and designing an expansile hydrogel intraocular lens one must keep in mind that the refractive index of all hydrogels usually decrease in linear proportion to the amount of hydration. In these applications maximum expansion is

needed, i.e. the higher the expansion, the higher the water uptake. Inherently, the expansion ratio of a material is limited by the water uptake which reduces its refractive power beyond acceptable limits.

The refractive (diopter) power of a lens is a function of its refractive index and the radii of curvature of its optical surfaces. To obtain a lens of given power with a reduced refractive index, the lens designer must use a smaller radius, i.e. tighter curve, for one or both optical surfaces. For a given diameter lens, this will result in a lens that is thicker along the optical axis. Because of the relatively low refractive indices of most conventional hydrogels, a larger cross sectional diameter at the equator are called for. This increase is not conducive to small incision cataract surgery.

As has been pointed out in U.S. Pat. No. 4,556,998, hydrophilic (hydrogel) intraocular lenses offer many advantages compared to present hydrophobic lenses as typified by poly (methyl methacrylate) and polypropylene. Not only does the use of hydrogels permit smaller incision cataract surgery with resultant decrease in wound healing time, but it also protects the corneal endothelium and leads to less mechanical and immunologic intraocular inflammation. Nevertheless, widespread use of hydrogel compositions as expansile intraocular lenses to date continues to be limited by the unavailability of materials which are biologically and chemically inert, flexible, displaying refractive indices above 1.40 in the swollen state, and at least 1.53 in the dehydrated state and capable of fabrication to desired forms.

To obtain corrective powers much greater than 25D with a 6 mm optic, researchers have found that hydrated polymers, i.e. polymeric hydrogels, must have refractive indices of at least 1.40 because the refractive index of the hydrogel lens is reduced by loss of the air/lens interface and the hydrated lens' high water content. To obtain this high a refractive index in the fully swollen state, it is necessary that the polymers in their dry state (prior to hydration) have a refractive index of at least 1.525 (1.53). None of the commercially available expansile intraocular lenses possess this level of refractive index today. Nor has there been any appreciation to date of just how critical each fractional increase in refractive index is in expansile concept intraocular lens.

In previous technology involved in the development of hydrogels the refractive index of the material was not important. These materials were most often used in refractive use as a contact lens and the refractive index of air being 1.0 and in water 1.33, the difference between water and the lens being less than 0.1 was not really significant. In current application these lenses are placed in the eye thereby making their refractive index far more critical. The refractive index of the media inside the eye is 1.33 and any increase in the hundredths in refractive indexes results in a very significant decrease in the thickness and contours of the lens needed to refract the light.

The importance of every hundredths of increase in refractive index can not be overemphasized for each hundredth results in a significant decrease in the thickness of the lens. In small incisions cataract surgery there is a need for surgeons to reduce the size of the opening in the eye to do cataract surgery. The importance of this is that intraocular lenses must be designed so that they are quite small and can fit through these smaller openings. The technology presently available is in silicone