

PROCESS FOR FABRICATING FULL SIZED EXPANSILE HYDROGEL INTRAOCULAR LENSES

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to intraocular lenses suitable for implantation using small incision surgical techniques. More particularly, the present invention involves hydrogel intraocular lenses and methods for their deformation in a dehydrated state to a size which is sufficiently reduced for their small incision implantation following cataract surgery. Subsequent to surgical implantation, the deformed lenses hydrate within the ocular environment to full sized lenses.

2. Description of Related Art

Since the early 1940's optical devices in the form of intraocular lenses have been utilized to replace the natural physiological crystalline ocular lens in humans and other mammals. Typically, the intraocular lens is implanted within the ocular environment immediately after surgically removing the natural lens which has become opaque or otherwise damaged by cataract formation or injury. For decades the most prevalently utilized materials for forming intraocular lenses were acrylates or methacrylates and particularly polymethylmethacrylate, a rigid, glassy polymer.

More recently developed surgical techniques and improved instrumentation have made it possible to remove the opaque or damaged natural lens through incision sizes as small as 2-3 mm. This contrasts sharply with earlier methods which involved forming incisions up to 9 or 10 mm in length in order to remove the natural lens and insert the intraocular lens. Because small incision surgery is much less traumatic for patients and decreases complications and healing time, this technique has become the method of choice for a large number of ophthalmic surgeons.

Since full-size intraocular lenses have diameters in the range of 8-13 mm, far exceeding the 2-3 mm incision size, the standard rigid polymethylmethacrylate lenses are not suitable for direct implantation through the reduced incision sizes. Thus, a number of different intraocular lens designs and materials have been developed for use in connection with small incision surgical techniques. One approach utilizes the concept of preparing lenses from elastomeric materials such as silicones and thermoplastic polymers. Prior to surgically inserting the elastomeric lens, the surgeon rolls or folds the lens so that it is reduced in size for passing into the eye through a smaller incision. Once placed within the eye, the lens unfolds or unrolls to its full size.

One problem associated with these elastomeric lenses is the possibility that permanent deformation or crease marks may occur when the lens is folded or rolled. This is especially a concern at the center of the lens optical zone where most of the rolling or folding deformation take place.

Another approach to providing a small incision intraocular lens is suggested in U.S. Pat. No. 4,731,079. This reference discloses an intraocular lens formed of a polymer having a softening (or glass transition) temperature less than 42° C. and preferably about body temperature. The lens can be heated to above its softening temperature and deformed by compression or elongation to reduce at least one dimension. Then, by cooling the lens at a temperature substantially below its softening tem-

perature, the lens will remain in the deformed configuration until it is warmed. Ophthalmic surgeons can implant the deformed lens and once the lens warms to body temperature it returns to its original configuration.

A major problem associated with these intraocular lenses is the restricted number of polymers available for preparing the lenses. Polymethylmethacrylate has a glass transition temperature above 100° C. and thus cannot be used to form these lenses. Most acrylates and methacrylates have similarly high glass transition temperatures. Through formulating the lenses with plasticizers will lower the glass transition temperature, the presence of plasticizers in intraocular lenses is generally unacceptable to most surgeons because of potential leaching problems. Alternatively, water is a suitable plasticizer, however, only small amounts of water, typically less than 10%, can be utilized in the polymers to place the glass transition in the appropriate range. Thus, typical hydrogels which have much higher amounts of water are not suitable for fabricating the deformable lenses.

An additional drawback with this suggested small incision intraocular lens is the added degree of surgical complexity required to deform the lens into its small incision configuration. The lenses are disclosed in U.S. Pat. No. 4,731,079 as being packaged in a form that requires the implanting surgeon to warm, deform, and cool the lens immediately prior to its implantation. This procedure is considerably more involved than traditional lens implantation techniques.

Another suggested approach for small incision lens implantation involves implanting hydrogel intraocular lenses in their smaller dehydrated state. Once the implanted dehydrated lens is secured within the eye it reportedly hydrates and swells in the aqueous ocular environment. A significant problem associated with this approach is the large amount of swelling required to produce an effective lens diameter. In order to fully swell the lens from a diameter of about 3 mm to about 6 mm the lens must swell 8 times by volume. This translates to a lens which is 85% water. For larger full sized intraocular lenses the swell volume is much higher. Since most hydrogels are structurally very weak at these high water contents, many surgeons are reluctant to implant them. Also, these high water content hydrogels have very low refractive indices of around 1.36 and in order to achieve suitable refractive powers the hydrogel lens must be thicker in the optic portion. As a result, a dehydrated hydrogel intraocular lens that will fit through a desirably small incision will not swell to a sufficiently large hydrated size to effectively function as an intraocular lens. This problem is compounded if larger, full size intraocular lenses are desired that have optic diameters greater than 6 mm. Alternatively, in order to produce a hydrated lens having a sufficient optic diameter the dehydrated hydrogel lens must be larger than desirable for a small incision implantation procedure.

Alternatively, U.S. Pat. No. 4,919,662 suggests rolling or folding hydrogel intraocular lenses in their elastic hydrated form, and then dehydrating the lenses at lower temperatures to fix the rolled or folded lens configuration at a size suitable for small incision implantation. Once implanted, these lenses hydrate and swell to the original lens configuration. Unfortunately, this method has the disadvantage of requiring the handling of fully hydrated lenses during the deforming process. Unfortu-