

## METHOD FOR RAPID IMPLANTATION OF SHAPE TRANSFORMABLE OPTICAL LENSES

This is a divisional application of U.S. patent application Ser. No. 08/194,079 filed on Feb. 9, 1994, now abandoned.

### FIELD OF THE INVENTION

The present invention generally relates to methods and associated apparatus for the insertion and placement of medical implants, particularly intraocular lenses. More particularly, the present invention is directed to methods for the surgical implantation of rapidly shape transformable implants, through an ejector apparatus having a very small diameter, elongate, tubular outlet suitable for very small incision implantation techniques. The elastomeric or gelatinous, highly extensible implants possess lasting memories enabling them to recover their original conformational shapes immediately upon passage through the ejection apparatus allowing for their rapid implantation and positioning.

### BACKGROUND OF THE INVENTION

The replacement or augmentation of natural body parts with medical implants is a mature technology having a wide variety of well-developed applications and techniques. Many surgically implanted medical devices perform useful and often essential functions based upon a variety of mechanical properties, including strength and flexibility. Common examples of such widely known medical implants include replacement heart valves and artificial joints. However, another class of medical implants performs useful and desirable functions by virtue of the physical shape of the implant rather than its structural or mechanical properties. Representative examples of this class of medical implants include cosmetic devices designed to augment or replace missing tissue or, more importantly, artificial optical lenses designed to replace or augment the natural lens of the eye. With respect to optical implants, it is the shape of the lens itself that, in conjunction with the refractive index of the lens material, provides the useful light-focussing function. Other minor structural features may be present to assist in the placement or retention of these devices following implantation.

Recent trends in implantation surgery have been directed toward the reduction of patient trauma, discomfort, healing time, and the associated complications that may occur through the utilization of reduced size or small incision surgical implantation techniques. The relatively rapid development of arthroscopic and microsurgery techniques and instruments has greatly facilitated the ability of the implanting surgeon to confine the physical impact of the surgical procedure to the desired target location which is accessed through a small, often remote incision. In this manner, the implanting surgeon is able to avoid trauma and damage to intervening tissues that would normally be cut and moved aside to provide surgical access using conventional large incision surgical techniques.

Unfortunately, the development of small incision techniques has not been particularly successful in conjunction with the implantation of medical devices. The principal impediments to the development of small incision techniques for use in conjunction with medical implants are the volume, the size and rigidity of the implants themselves. For example, the typical intraocular lens implant includes an optical lens portion having a minimum diameter on the order

of 6 mm. Current trends in the posterior chamber implantation of intraocular lens utilize what are known as "full-sized" optics having lens diameters of 9 mm or more. As a result, the intraocular lens implantation procedure must utilize a surgical incision at least as large as the minimum dimension of the optical implant.

This is a particularly frustrating circumstance for many ocular surgeons in that the current procedures for removal of damaged or cataractous lenses require surgical incisions of only 3 to 4 mm. Thus, the implanting surgeon is required to enlarge a relatively small opening in order to implant the intraocular lens. In the ocular environment, these lengthened incisions have the additional drawback of possibly inducing postoperative astigmatism or corneal distortions in addition to the risks of increased complications and healing time.

Contemporary efforts at developing "small incision" intraocular lenses (commonly defined as capable of implantation through an incision of 4 mm in length or less) have been focussed in several different directions. For example, foldable lenses having optical portions formed of silicone have been proposed that may enable the diameter of the lens optic to be reduced by half through the folding or rolling of the lens prior to insertion. Alternatively, expansile lenses made of materials such as hydrogels may be desiccated prior to insertion to reduce the overall volume and dimensional characteristics of the lens. Following implantation, the hydrogel material hydrates and expands to its desired size. More speculative proposals include balloon lenses which may be inserted in the deflated state and then filled with a highly refractive material to form the final lens configuration. Similarly, injectable lenses have been proposed wherein a liquid polymer is injected into the naturally occurring lens capsule where the polymer cures into its final, hopefully lens shaped, form.

Though theoretically capable of small incision implantation, each of these proposals has significant drawbacks making them difficult, if not impossible, to use. While folding a silicone lens will reduce one dimension, it necessarily doubles the folded over dimension and leaves the third dimension unchanged so that the potential for small incision implantation may not be achieved. Further, folding the lenses may produce permanent deformation in the optic portion, rendering them ineffectual as an optical lens following implantation. Conversely, while it is possible to significantly reduce the dimensions of hydrogel lenses, the current state of the art requires a 3-to-24 hour hydration period following implantation. At present, this is unacceptable to the implanting surgeon who is unable to determine if the lens is properly positioned prior to complete hydration. As a result, implanting surgeons are reluctant to close the implantation incision until they are certain that access to the interior of the eye is no longer necessary. Balloon lenses have their own problems in that it is difficult to inflate the balloon with any degree of accuracy or control following implantation. Thus, the actual refractive characteristics of the lens is difficult to control. Moreover, complete removal of air bubbles from the balloon remains a significant problem. Similarly, injectable lenses cannot produce predictable optical power and resolution because the natural capsular bag will not consistently produce the necessary or desired lens shape.

Accordingly, one of the primary objects of the present invention is to provide a method for the rapid implantation of an optical lens into an eye through a minimally traumatic surgical procedure.

It is an additional object of the present invention to provide a general implantation methodology that will allow