FOLDABLE INTRAOCULAR LENS SYSTEM

FIELD OF THE INVENTION

The present invention relates to foldable intracular lens systems and more particularly to bifocal foldable intraocular lenses and lens insertion devices which allow insertion of a lens into one of the chambers of the human eye through incisions sufficiently small so as not to require stitches.

BACKGROUND OF THE INVENTION

Many different types of intraocular lens (IOL) structures are presently in use. Such devices have been developed to satisfy the need for an artificial lens to be implanted into one of the chambers of the human eye once the eye's natural lens has been removed because it became useless due to the formation of a cataract.

While such IOLs and the procedures for inserting IOLs have proven to be very beneficial for patients afflicted with cataracts, there remains a need for improvement in several areas.

First, unlike the eye's natural lens, the artificial IOL lens is incapable of accommodation. Therefore, the patient will experience sharp vision for only one distance, usually chosen to be a far distance, for example 100 meters. Reading is therefore not possible unless the patient wears reading glasses. It is therefore desirable to provide a bifocal IOL, allowing the patient to switch between reading and distance vision instantly, thereby avoiding the need to remove or put on glasses each time a change in viewing is made.

Second, there is a need to reduce to a minimum trauma caused by the cataract operation, since people afflicted with this disease are typically of advanced age. It is highly desirable to keep the size of the incision, and therefore the size of the resulting tunnel into the eye, to a minimum. Typically, this incision should be on the order of 3.5 mm or less. Keeping within this size restriction allows the surgeon to forego suturing of the wound and provides for faster healing with a minimum of associated pain. Since the size of the body of typical IOLs is 6 mm or more, it is necessary to find ways to fold such IOLs so they can be passed through an approximately 3 mm tunnel.

Flexible and foldable IOLs and bifocal IOLs are known in the art. A flexible IOL is described by Mazzocco (U.S. Pat. No. 4,573,998). A flexible IOL holder is described by Keates (U.S. Pat. No. 4,619,657) and a foldable bifocal IOL is described by Bissonnette (U.S. Pat. No. 4,753,653). The Mazzocco patent teaches that the optically active areas of the IOL are manufactured from an elastic material displaying an elastic memory. Since the typical IOL is larger by a factor of about 2 than the desired incision, the Mazzocco patent teaches that the IOL is to be reduced in size by a factor of at least 2 and by as much as 80% by deforming the elastic material with mechanical forces. This requires not only a material compatible with the eye's tissue, but a highly elastic material as well.

Those familiar with elasticity theory will realize that, in accordance with Hooke's law, upon a certain limit of deformation the material will "flow," meaning upon release of the applied mechanical force the material will not return to its original shape. Material deformation to the extent required to roll a circular IOL disc into a cylindrical shape poses the danger that some of the material at certain locations on the IOL will be more deformed than the material at other locations. Therefore, some parts of the IOL may be stressed past their elastic limit and exhibit flow, while the material at other locations will stay below this limit and exhibit no flow. Consequently, prior art flexible and foldable IOLs present a danger for distortion of the optically active areas of the IOL, thereby severely influencing the performance of the IOL. Further, in part because of such flow problems, the number of materials suitable for use in forming IOLs is limited. One candidate material for such use is silicon. However, this material has lately shown adverse effects on human tissues, and in particular in connection with the use of silicon as breast implants, and it remains to be seen what the long term effects of this material will be to eye tissues.

Several attempts have been made to overcome these problems. For example, the Keates and Bissonette patents both describe a bifocal foldable IOL employing the widely tested material PMMA. Also, both patents refrain from distorting or deforming by mechanical forces the optically active areas of the IOL. The Keates patent describes a flexible lens holder, whereby relatively rigid PMMA lenses are inserted into pockets, thus allowing the lens/lens holder assembly to be folded and inserted into one of the chambers of the human eye through the above-described tunnel. Unfolding of the assembly inside the eye is accomplished by the lens holder. The Bissonette patent describes two half-moon shaped rigid IOLs that are connected by hinges. The two half moons are folded onto each other, thus reducing the size of the assembly by a factor of two. Upon insertion through the tunnel, the hinges facilitate unfolding inside the eye.

However, the technologies taught by Keates and Bissonette suffer from several common problems. First, if unfolding of a lens within the eye is not carried out to extreme precision, double images will result. In attempting to overcome this problem, Keates uses a rigid material endowed with memory and placed inside the peripheral ring of its lens holder, while Bissonette relies on the elastic properties of its hinges to insure proper unfolding. A problem with the Bissonette approach, however, is that the hinges provide little leverage, thus requiring additional externally applied force to unfold the lens. More specifically, since the edges of the lens will touch tissue upon partial unfolding, and since this tissue, or the IOL itself, has to be displaced to allow full unfolding, it is seen that significant forces are required to accomplish full unfolding. Such forces would have to be applied with the hinges being in a poorly leveraged position. Further, loose tissue particles picked up during the move through the tunnel can lodge in the area connecting the two lens halves, thus making total unfolding impossible.

Alternatively, to facilitate unfolding, Keates uses an elastic material in a better leveraged location than the Bissonette patent. However, this still may not provide the precision required to avoid double images. In an alternative embodiment, Keates has its elastic material inserted by the surgeon after partial unfolding has already taken place so as to insure full unfolding. However, this approach may not be popular with surgeons.

Another problem exhibited by prior art foldable IOLs such as those disclosed by Keates and Bissonette is that the area directly on the lens' optical axis cannot be used due to the split running through this area which is required to make folding possible. From an optical