

## SUPPLEMENTARY INTRAOCULAR LENS SYSTEM

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### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

This invention relates generally to the field of intraocular lenses (IOLs) and, more particularly, to IOL's having changeable refractive correction after initial implantation into the eye.

#### 2. General Background

The human eye in its simplest terms functions to provide vision by transmitting an image through a clear outer portion called the cornea, and focusing the image by way of a lens onto a retina. The quality of the focused image depends on many factors including the size and shape of the eye, and the transparency of the cornea and lens.

When age or disease causes the lens to become less transparent, vision deteriorates because of the diminished light which can be transmitted to the retina. This deficiency in the lens of the eye is medically known as a cataract. An accepted treatment for this condition is surgical removal of the lens and replacement of the lens function by an artificial intraocular lens or IOL. Patients having such removal are referred to as aphakic patients.

Because removal of the lens leaves the eye with no ability to focus an image on the retina, aphakic patients require a substitute for the removed lens. Spectacles, contact lenses and surgical implantation of an intraocular lens or IOL are the three presently known techniques for providing this function. Surgically implanted IOLs are preferable to spectacles or contact lenses in that they provide a permanent replacement for the removed lens. However, because it is surgically implanted, the corrective power of the IOL cannot be as easily changed as the external spectacles or contact lens alternatives.

As presently practiced, cataract removal and the implantation of a replacement IOL is accomplished in a single surgical procedure through an incision in the cornea. The incision needed for cataract removal depends upon the method of cataract removal and ranges from 3.0 to 12.0 mm. A conventional hard lens can be inserted through an incision that is about 7 mm or larger. IOLs formed of soft or foldable materials can be inserted through smaller openings.

In addition, IOLs also include haptics or support loops for holding the IOL in place in the eye. The haptics are generally in the form of at least two relatively flexible, elongated, open-ended loops that project from the edge of an optic portion. These haptics may also require additional incision length, depending upon their length and configuration.

IOLs are available in a range of corrective refractive powers. Prior to surgery, the physician can take various measurements and use one of several proposed formulae

to determine IOL power to achieve the desired post-operative refraction needs of the patient. The physician then selects an intraocular lens nearest to the determined IOL power lens within a wide range of diopter powers.

However, this procedure which determines the post-operative refraction of the patient is difficult and inexact. Although there have been several formulae used for determining the approximate power of the lens for achieving desired refraction for a particular patient, they are not totally exact, and involve measurement of the axial length of the eye, corneal power measurement, and assume lack of post-operative induced astigmatism or spherical refractive changes in the cornea.

Examples of several formulae used for calculating IOL power needed for desired post-operative refractive requirements for aphakic patients are presented in an article by Scott C. Richards, et al, entitled "Clinical Evaluation Of Six Intraocular Lens Calculation Formulas" A. Intraocular Implant Soc. J., Vol. 11, March, 1985, pp. 153-158. Errors in measurement, inaccuracy of assumptions, and the difficulty of achieving precise placement of an IOL, make it unlikely that an IOL with an exact corrective power can be predicted. This in turn can lead to residual refractive errors and the need to correct the power of the IOL after initial surgery.

In addition to the inherent measurement problems, post-operative changes can occur which also change the refractive power needed for an IOL in a particular patient. Such post-operative change commonly occurs in very young aphakic patients because the size and shape of an eye changes with maturity. It can also occur as a result of differences in the manner in which the capsular bag shrinks, an IOL moves, or a cornea incision heals in different patients and even suturing techniques of different physicians.

Surgical implantation of an IOL involves inserting a lens through the cataract removal incision and then manipulating the lens into position in either the anterior or posterior chamber of the eye such that the support loops or haptics are properly placed. Proper placement and securing of the IOL requires manipulation of the lens in a way that could involve contact with the iris, cornea or other sensitive internal tissues. This manipulation adds to the trauma of the cataract surgical procedure.

Although the benefits to a patient of having a permanently implanted lens substitute far outweigh any risks involved in the trauma associated with cataract surgery, a second surgical procedure to remove an IOL and replace it with a properly powered one adds another undesirable level of trauma and risk. In addition, an IOL that has been in place for some time could have support loops that are encapsulated in the eye by tissue adhesions and may be difficult to remove. For these reasons, it would be desirable to be able to change the power of an IOL without removing the original implanted IOL.

Several patents relate to altering the refractive power of implanted IOL's, as follows: U.S. Pat. No. 4,685,922, issued to Peyman, describes one technique for altering the refractive power of an IOL by providing rupturable fluid-fill membrane sections in the implant. U.S. Pat. No. 4,685,921, issued to Peyman, describes another technique providing expandable chambers in the implant.

The techniques in both of these patents are limited by their design to correction of spherical refractive error as they can only provide changes along the axial length of