

## ADJUSTABLE INTRAOCULAR LENS

This application is a divisional of application Ser. No. 08/592,845, now U.S. Pat. No. 5,728,155 filed on Jan. 22, 1996.

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

This invention relates to improved intraocular lenses which can be adjusted to correct both spherical and cylindrical refractive errors following implantation. The intraocular lens assemblies (IOL's) of this invention may be foldable to enable implantation with minimal trauma to the eye.

#### 2. Description of the Prior Art

The lens of a normal human eye is situated more or less centrally behind the pupil. A normal lens is substantially symmetrical, with opposed convex surfaces. Both the lens and cornea which protects it refract incoming light to focus it on the retina. The total refraction of the eye is approximately 60 diopters. The lens supplies approximately 20 diopters of correction, while the cornea provides about 40 diopters.

When a cataract forms, the lens becomes progressively opaque and eventually has to be surgically removed, typically through a horizontal incision on the sclera or the cornea itself. Removal of the lens, however, drastically changes the focal point of the light impinging on the retina, resulting in inability to focus a clear image. Correction of focus using eyeglasses and contact lenses, or a combination thereof, is often not fully satisfactory. Eyeglasses can lead to double vision, while contact lenses require periodic replacement which may be beyond the manual skills of elderly patients in whom cataracts most frequently appear.

Prior art intraocular lenses provide a partial solution to these problems. Such lenses in the past have comprised fixed focus devices made of rigid plastic or soft, foldable materials. They are implanted via the corneal or scleral incision through which the cataract was removed, by folding the IOL (in the case of foldable designs) and inserting it into the eye behind the pupil. The IOL may then unfold and is maneuvered into place through the incision. Typically, the fixed focus IOL comprises a central optic fitted with hook-shaped haptics which attach the IOL to the walls of the posterior chamber of the eye. (Placement of the IOL within the anterior chamber is also possible in some instances). The simplest optic surface is a spherical section. IOL's also may be made having optics with asymmetrical curvature designed to correct for astigmatism. This is accomplished by creating an optic in which the curvature is different along axes at 90° apart.

Since the shapes of individual eyes vary, fixed focus IOL's must be custom made for each patient. This requires pre-operative measurement of the axial length of the eye and the curvature of the cornea; prediction of the position of the IOL in the eye after implantation, and pre-operative calculation of the proper IOL power using available formulas. Such predictions, however, are not always accurate. The shape of the eye may be changed as a result of the surgical procedure and subsequent post-operative healing process. Moreover, in the case of asymmetrically curved optic surfaces that are designed to correct for astigmatism, the desired angular orientation of the IOL within the eye may not be perfectly achieved during implantation. In fact, the desired angular orientation can change during the post-operative healing period. So can the placement of the IOL along the optical axis of the eye, which changes the effective

focus of the optic. These factors are aggravated in pediatric patients, whose eyes are still changing shape as the patient grows.

Various techniques, both extracorporeal and inside the eye, have been suggested for post-operative adjustment of focus. Small adjustments of the angular orientation of the IOL may be made shortly after surgery using a needle inserted through the paracentesis incision at the corneoscleral limbus before the IOL has been fully fixated within the capsular bag via capsular fibrosis. But, the IOL may subsequently rotate away from the revised position and at this point in time the post-operative keratometric axis typically has not yet stabilized.

Eyeglasses or contact lenses can correct for residual spherical and/or cylindrical error, thereby allowing the post-operative cataract surgery patient to achieve optimal vision. In extreme cases invasive secondary surgical procedures such as radial, astigmatic or photorefractive keratotomy may be required. Sometimes, the IOL must be replaced, or secondary IOL's must be implanted.

The three types of post-operative adjustments of an IOL that may be desired are (1) changes of the axis of astigmatic correction, which is determined by the angular orientation of the IOL; (2) changes of the cylinder magnitude accompanying the astigmatism correction; and (3) changes of the spherical power due to imprecise prediction of the power of the IOL for a particular patient's eye. Adjustment of spherical power can be accomplished by movement of the optic along the axis of the eye; by changing the curvature of the optic, or by adjusting the index of refraction of the optic material.

Various techniques have been suggested for altering the spherocylindrical corrective power of IOL's. U.S. Pat. No. 5,443,506 (Garabet), for example, discloses an IOL comprising a fluid-filled lens whose focus can be changed by pumping fluids of differing refractive indices into and out of the central optic; pumping is effected by the response of various types of ionic fluids to electrical potentials generated when the ciliary body expands or contracts. U.S. Pat. No. 5,066,301 (Wiley) describes a variable focus intraocular lens comprising an envelope filled with a transparent gel in which are suspended a plurality of light-reflective particles. The orientation of the particles is said to be controllable by application of an electromagnetic or other force field, thus providing both variable spherical power and some post-operatively adjustable correction for astigmatism.

U.S. Pat. No. 4,787,903 (Grendahl) describes an IOL comprising a fresnel-type lens overlaid by a crystalline or other material that changes index of refraction when excited by electrical power or radiant energy, thus providing a post-operative adjustment function. In U.S. Pat. No. 4,816,031 (Pfoff), an IOL assembly comprising a hard PMMA (polymethyl methacrylate) optic overlain by a soft silicon optic is disclosed. The focal length of the optic assembly is adjustable by microfluid pumps that adjust the volume of clear fluid encapsulated between the PMMA optic and the silicon optic, thus changing the distance between the two optics and thereby altering the focus of the optic assembly.

U.S. Pat. No. 5,108,429 (Wiley) discloses a non-foldable IOL assembly in which a rigid hoop surrounds a fixed-focus optic. The hoop is fixed in the eye by means of external haptics; the optic is attached to the hoop by a plurality of micromotor devices illustrated as pistons which are said to be able to move the optic back and forth with respect to the hoop in response to computer-controlled electrical signals. U.S. Pat. No. 5,203,788 (Wiley) describes a non-foldable