

## INTRAOCULAR LENS AND IMPLANTATION METHOD

This invention relates to an improved method of removing a cataract or an otherwise diseased natural lens from the eye and to the replacement thereof with a novel intraocular lens structure.

The surgical procedures for removal of a cataract and the replacement of the clouded lens with a synthetic intraocular lens have been in use for many years. In the most common surgical procedure, a small incision is made at the top of the eye in the region of the limbus where the cornea meets the sclera. An intracapsular extraction, i.e., a procedure in which the entire lens and capsule is removed, or extracapsular extraction, i.e., a procedure in which the capsule is only partially removed, is then performed by extracting the lens, normally through the pupil with special forceps or a cryoprobe. Thereafter, the synthetic lens assembly is inserted through the incision and physically manipulated into place in either the anterior or posterior chamber by utilizing a suitable surgical instrument.

A large variety of intraocular lens structures are known in the art. A typical lens structure consists of a central optic section and one or more peripheral stabilizing feet or haptics as illustrated, for example, by Poler U.S. Pat. Nos. 4,122,556 and 4,249,271; the Kelman Anterior Chamber Intraocular Lens; or the Lindstrom Centrex Posterior Chamber Lens. Alternately, the haptics may be in the form of iris clips as illustrated in Richards U.S. Pat. Nos. 3,925,825 or 3,975,779. Irrespective of the particular structure or configuration, the lens assembly, as a unit, is inserted through the incision after removal of the cataract and physically manipulated so that the lens is centered over the pupil area. For an anterior chamber lens, the haptics rest against and are stabilized by the anterior angle, i.e., the angle formed by the cornea and the plane of the iris. Because the lens structure is not normally sutured or otherwise permanently anchored to the iris, except by the growth of tissue adjacent to the haptics, the size and arrangement of the haptics is crucially important in ensuring that the lens remains immobile after implantation. Accordingly, the use of structures having three feet spaced apart so as to define a stable plane is one popular overall haptic structure. It is also important that the overall diameter of the lens assembly closely approximate the diameter of the chamber or adjust to the diameter of the chamber in which the lens is implanted so as to minimize the opportunity for movement in any direction.

While the foregoing surgical method and lens implantation technique has been generally successful, it entails certain risks. More specifically, as a result of the surgical procedures which are required to remove the cataract, the eye loses some of its structural integrity and rigidity; the vitreous humor is exposed; and the aqueous humor flows into the void left by the removal of the lens. Since cataract surgery is commonly performed on elderly people who may have a weaker vitreous membrane and a more watery vitreous humor, a risk exists that the vitreous will be punctured either by the lens assembly or the lens insertion instrument when the lens assembly is physically manipulated into position, thereby permanently impairing the patient's vision. Further, because the iris is soft and floppy after the lens extraction, it may adhere to the intraocular lens assembly during the manipulations required to position the

lens, thereby causing folds or tucks to develop in the iris which will distort the pupil.

It is an object of the present invention to provide a novel surgical procedure for cataract removal and lens implantation which reduces the risk of surgical injury to the eye.

Another object of the invention is to provide a novel intraocular lens structure which is easier to insert and position in the eye and which reduces the possibility of surgical injury during implantation.

It has now been discovered that intraocular lens implantation can be simplified and improved by employing a novel method and lens assembly which together permit all or a substantial portion of the lens assembly to be pre-positioned in the anterior chamber of the eye prior to removal of the cataract. More specifically, in the novel method of the invention, the surgical procedure commences with a normal incision, but thereafter, and prior to the removal of the cataract, at least a portion of a lens assembly is inserted through the incision and physically manipulated so that at least one and as many as all of the stabilizing feet or haptics associated with the lens assembly are pre-positioned in the anterior chamber of the eye at substantially the location which they will permanently occupy when the surgical procedure is completed and the lens assembly is functioning as a replacement for the surgically removed cataract. The cataract is then surgically removed in accordance with any of the prior art surgical techniques. Surgical removal is possible without interference from the pre-positioned lens assembly because the optic or lens portion thereof is either not placed in its final position or is temporarily movable therefrom and, accordingly, will not interfere with the normal physical manipulations which occur during the step of surgically removing the cataract. Following extraction of the cataract, the optic section of the lens assembly is either placed in or, by virtue of its resilient structure, automatically moves into its final position with respect to the pre-positioned portion of the lens assembly, and the incision is sutured to complete the operation.

The novel method of the invention is made possible by employing novel intraocular lens structures. In one embodiment, such lens structure comprises a two-piece assembly consisting of a frame section and an optic section. The frame section is adapted to receive the optic section and includes one or more peripheral stabilizing feet or haptics. The separate optic section is adapted to clip on to or otherwise mate with the frame section and includes a lens and one or more additional peripheral stabilizing feet or haptics. When this embodiment of the invention is employed, only the frame section of the two-piece lens assembly is inserted through the incision and physically manipulated so that the haptics associated therewith are placed into their respective proper final locations in the anterior chamber of the eye prior to surgical removal of the cataract. The optic section of the lens assembly is inserted through the incision and slipped into mating engagement with the pre-positioned frame section after surgical removal of the cataract.

In an alternative embodiment of the invention, the lens assembly consists of integral frame and optic sections, but the lens assembly is so constructed that it may be partially or totally rotated, folded, or otherwise moved to a position which will not interfere with the surgical removal procedure and thereafter readily moved into its final position. In this embodiment, the