

## INTRAOCULAR LENS IMPLANT

This application is a continuation of application Ser. No. 06/824,833, filed Jan. 31, 1986, now abandoned, which in turn is a continuation-in-part of application Ser. No. 06/640,098, filed Aug. 13, 1984, now U.S. Pat. No. 4,664,666.

### FIELD OF THE INVENTION

This invention relates to improved intraocular lens implants, and more particularly to intraocular lens implants formed of a hydrogel.

### BACKGROUND

Various types of intraocular lens implants are known to the art. Most of the known implants, however, are constructed of a rigid material and designed for physical attachment to the iris. For example, U.S. Pat. Nos. 4,242,762, 4,254,509 and 4,261,065 to Tennant disclose intraocular lens constructions for placement in the eye. The device in 4,242,762 for posterior chamber placement is provided with a triangular base element with an optic element positioned therein and a pin extending from one corner and secured in place by a combination of tissue scarring within the capsular sac and clipping of the lens to the iris with a platinum pin. The lens construction comprises a polymethylmethacrylate or pHEMA haptic portion and an optic portion of either polymethylmethacrylate or pHEMA, but there is no disclosure of a lens constructed entirely of pHEMA. In U.S. Pat. No. 4,254,509, anterior chamber eye implant is disclosed which comprises a dumbbell-shaped optical lens having an anterior convex surface and a posterior planar surface and supported on diametrically opposed coplanar feet through two supporting members which form an arch. The lens may be formed of a rigid material such as polymethylmethacrylate or soft materials of the hydrophilic type such as 2-hydroxyethylmethacrylate referred to as pHEMA. In the preferred construction, the lens section is composed of a hard material while the haptics or arches are made of soft material. This embodiment is preferred in this patent so that if the soft haptics portion is moved, the rigid lens section will not be distorted. The anterior chamber device in 4,261,065 is for positioning in the anterior chamber on the scleral spur. The lens is made of PMMA.

U.S. Pat. No. 3,961,379 to Highgate discloses bioimplantable devices in general produced from crosslinked swollen hydrophilic polymers with suggested uses as prosthetic devices. The polymers include alkyl and hydroxyalkyl acrylates and methacrylate polymers. The polymers are modified by a swelling technique. No particular structures of prosthetic devices are disclosed.

U.S. Pat. Nos. 4,249,272, 4,257,521, 4,402,579 and 4,315,336 to Poler disclose intraocular lens structures to be used as implants in ophthalmological surgery and packaging means for intraocular lenses. The structures in 4,249,272 and 4,257,521 comprise a circular, optically finished lens element with a plurality of angularly spaced stabilizing feet formed integrally with the body of the structure. The device is designed to be placed within the posterior chamber. The implant disclosed in No. 4,249,272 appears to comprise two sections wherein the central focussing body or lens is of one material and the haptic section is of a different material. There does not appear to be any disclosure that the entire lens could be an integral piece of a single material. The disclosure

in 4,257,521 concerns a packaging device for implants of this type in general. The lenses are prepared from a plastic sheet as described in 4,402,579. Reference is made incorrectly to HEMA in columns 5 and 6 of 4,402,579 since the patentee is obviously referring to polymethylmethacrylate (PMMA). The device in 4,315,336 comprises a haptic element secured to a glass lens.

U.S. Pat. No. 4,449,257 discloses an intraocular lens of HEMA plastic in the form of a round lens with concentric grooves around the peripheral margins for frictional engagement with the rough interior walls of the posterior capsule. The lens is cut to a size that is small for placement but softens and expands to fill a posterior chamber capsule after it has been emptied of its natural contents. The softening and expanding of the lens is caused by aqueous humor uptake into one of the dry lenses from the capsule environment. The concentric grooves frictionally engage the rough interior walls of the capsule to position and retain the lens in place.

In a review article by Refojo, published in Technomic, Technomic Publishing Company, Inc., 1980, pages 171-185, entitled "Ophthalmic Hydrogels", there is a discussion of ophthalmic hydrogels and their use in ophthalmology. This review article is a general discussion of the benefits and disadvantages of hydrogel materials in general for such devices as corneal contact lenses, corneal prosthesis and intraocular lens implants. The discussion with respect to intraocular lens implants suggests that polymethylmethacrylate is very well tolerated by eye tissues and that some models of lenses have supporting loops or flanges of different materials. The article also discusses glaucoma drainage devices, scleral buckling and retinal detachment surgery and vitreous implants.

In a publication by Wichterle, Ceks Ophthalmol 16:154-159 (1960), there is disclosed in an English abstract the suggestion for use of tridimensional polymers with high water contents to obtain stability of shape in intracameral lenses. There is no specific discussion with regard to structure of such devices.

In two publications by Mehta et al, VIth Congress of the European Society of Ophthalmology, Royal Society of Medicine International Congress and Symposium Series No. 40, published jointly by the Academic Press Inc. (London) Ltd. and the Royal Society of Medicine, 1981, pages 859-863, and American Intra-Ocular Implant Society Journal, Vol. IV, October 1978, pages 200-205, there is publication of the considerable work by Mehta and associates in soft intraocular lens implants. These publications disclose the use of soft implant materials using the iris fixation technique with disclosure of various types of implants which have been tested, including a dumbbell-shaped optical lens and a series of other related structures. The publication in the American Intra-Ocular Implant Society Journal suggests that the choice of material for the implant is one which provides the highest degree of hydration consonant with a stable lens, the material must be machined or lathed easily, the material must be safely autoclaved repeatedly without distortion of lens parameters, should be able to withstand surgical handling and should not discolor or degrade in storage. A material identified as Soflex 44-R was selected as a preferred material. This Soflex 44-R is a commercial material comprising pHEMA. However, this publication suggests that a soft lens implant cannot be made self-supporting and a central support, i.e., iris fixation, must be used to ensure