

DEFORMABLE-ELASTIC INTRAOCULAR LENS

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

BACKGROUND OF THE INVENTION

The present invention relates generally to improvements in intraocular lenses (IOLs) designed for surgical implantation into the eye, for example, as a replacement for a cataractous or injured natural lens. More specifically, the invention relates to improvements in deformable IOLs which can be folded or rolled to a relatively low profile size to fit into the eye through a relatively small incision, and then within the eye naturally return to an internal nondeformed shape with predetermined optical properties.

IOLs are well known in the art for implantation into the eye as a replacement for a natural crystalline lens which has been surgically removed typically due to opacification, commonly referred to as a cataract condition. Such IOLs have been formed from a small disk of transparent glass or plastic material having appropriately shaped lens surfaces to achieve a desired set of optical properties. The IOL is implanted directly into the eye, typically after removal of the natural crystalline lens, via an incision formed in ocular tissue such as the sclera outside the normal line of sight. Many IOLs are designed for implantation into the so-called posterior chamber of the eye behind the iris and pupil, whereas other IOLs are adapted for placement into the anterior chamber in front of the iris and pupil. In most IOL designs, support structures are attached to or formed integrally with a central lens body or optic and project outwardly therefrom to contact eye tissue at the periphery of the posterior or anterior chamber, thereby retaining the lens body or optic in generally centered relation with the line of sight passing through the pupil.

In the past, most IOLs have been formed from polymethylmethacrylate (PMMA) which is relatively light in weight, possesses excellent optical properties, and is generally considered to be relatively inert when implanted into the eye, thereby avoiding adverse tissue reactions. However, PMMA comprises a plastic matrix which, when formed into the shape of a lens, possesses high rigidity and cannot be deformed by folding, rolling, compression, etc. Accordingly, the use of PMMA lenses requires a relatively large incision in the ocular tissue sufficient to accommodate the entire diametric size of the lens body; which is typically six millimeters or larger, together with the accompanying lens support structures. Although the resilient lens support structures such as polypropylene loops or haptics are commonly used and advantageously may be folded over the lens body during insertion, such resilient haptics are anchored into the periphery of the hard plastic lens body and thus tend to spring back to their initial unfolded shape with a rapid snap like action during IOL implantation, resulting in undesired trauma to sensitive eye tissues.

While IOLs with rigid PMMA lens bodies have gained widespread acceptance and use, it has been recognized that deformable IOLs have the potential of providing medical benefits well beyond those associated with current IOLs including rigid lens bodies. More particularly, an IOL including a deformable transparent lens body which may be folded or rolled into a reduced profile size may fit through a relatively small incision in ocular tissue and after insertion

and release within the eye return to its original size and shape by virtue of its natural resilience. The use of a smaller incision would beneficially result in a safer overall surgical procedure requiring fewer stitches and reduced likelihood of postoperative complications such as infections. In addition, a smaller incision would reduce the incidence of postoperative astigmatism and substantially reduce rehabilitation time. Second, it is anticipated that IOLs with deformable lens bodies may reduce the potential for complications secondary to contact or rubbing against delicate uveal tissues. Also, deformable IOLs may decrease the potential for pigmentary dispersion or pigmentary glaucoma. Finally, it is anticipated that the formable IOLs will provide an added margin of safety for patients with blood dyscrasias, coagulopathies and hematologic matogrant disease as well as those patients being given anti-coagulant therapy.

Accordingly, deformable IOLs formed of silicones and hydrogels have been proposed for implantation. For example, in 1983, Fyodorov reported on chemical testing of a silicone IOL (Fyodorov, S. W. et al "Initial Clinical Testing of a Silicone Intraocular Lens" Interzonal Scientific/Practical Conference of Ophthalmologists of Western and Eastern Siberia and the Far East, Conference Proceedings 4: 22-24, 1983, Vladivostock). Also in 1983, Mazzacco and Davidson presented initial data on the implantation of silicone IOLs with 6 mm optical zones through 3 mm incisions (Mazzacco, T. R. and Davidson, V. A. "6 mm Optic for a 3 mm Wound" presented at the A.I.O.I.S. United States Intraocular Lens Symposium, New Orleans, La., March 1983). Wichterle and his associates developed a hydrogel of hydrophilic polyacrylates for orbital and intracamerar implants in 1960 while Epstein implanted flexible IOLs comprised of poly(hydroxyethyl methacrylate) in 1976 and 1977. The condition of some patients implanted with such lens was followed until 1984 ("Insertion Techniques and Clinical Experience with HEMA Lenses" Soft Implant Lenses in Cataract Surgery T. R. Mazzacco, G. M. Rajacich, E. Epstein, published by Slack Inc., 1986, pp. 11).

Unfortunately, silicones and hydrogels have several well documented deficiencies which hinder their use as IOL materials. In particular, silicones cause complement activation leading to the production of C-4 proteins, a symptom of bio-incompatibility. Also, while silicones may be folded, when released they tend to snap back or regain their unfolded shape too rapidly, posing a threat to the integrity of the endothelial cell layer of the eye. In addition, the long term stability of UV-absorbing silicone formulations is uncertain. As for hydrogels, it has been found that hydrogel materials when hydrated vary in composition including water content from lot to lot. Such variability induces a corresponding variability in the refractive power of IOL lens bodies formed of hydrogel material. Therefore, hydrogel IOLs need to be hydrated in order to determine their refractive power in implanted state. Unfortunately, hydrated lenses cannot be safely stored in the wet state without losing sterilization. If they are dehydrated subsequently, the process of hydrothermal cycling reduces the tensile strength of the IOL material and may cause cracks or crazes to develop in the lens body.

Other deformable IOLs have been described in U.S. Pat. Nos. 4,573,998 and 4,608,049. More specifically, the '998 patent is directed to methods for implantation of deformable IOLs. The patent describes an IOL having an optical zone portion composed of materials such as polyurethane elastomers, silicone elastomers, hydrogel polymer collagen compounds, organic or synthetic gel compounds and combinations thereof. In practice, such materials possess the disadvantages previously attributed to silicone and hydrogen materials.