

Study of Intraocular lenses (IOLs) specifications and biocompatibility

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Introduction

Intraocular lenses (IOLs) represent what is arguably the greatest single advance in ophthalmology, bringing visual rehabilitation to millions of people following cataract surgery. Their impact is nothing short of amazing, as is the story of their invention by Sir Harold Ridley. In the 1940s, he discovered that shards of acrylic cockpit canopies remained inert in the eyes of a British pilot who was blinded when his aircraft crashed during World War II. Ridley developed and implanted the first artificial lens in November, 1949, and reported on the first 27 cases in 1952. It was the first medical device implanted in a human being and generated considerable opposition from his peers.

Overview of IOL Specifications

The safety and efficacy of IOLs depend on their design and the properties of the material from which they are made. Material used must be biocompatible, optically clear, lightweight, durable, moldable, capable of being sterilized, resistant to forceps and folding marks, resilient to the stresses of implantation, able to withstand Nd:YAG laser capsulotomy, and inert in the eye through the rest of the patient's lifetime. The most common materials used today are foldable silicone and acrylic, as they can be implanted through a small incision. Polymethyl methacrylate (PMMA), less commonly used, is a rigid material suitable for rigid 1- and 3-piece IOL designs or for haptic materials.

Iol Materials

All currently used IOL materials may be subdivided into hydrophobic (hydrophobic acrylic, silicone, and PMMA) and hydrophilic categories. Hydrophobic materials contain less than 2% water, compared to 18%–38% for hydrophilic materials. Table 1 summarizes specific types of IOLs, including the refractive index of each.

Hydrophobic Iols. The strength of the polymer backbone of the optic material determines its flexibility. Acrylics have a hydrocarbon backbone with pendant ester groups. PMMA is a

homopolymer of methylmethacrylate. PMMA is the only nonfoldable optic material currently in use. PMMA has a refractive index of 1.49. The co- and terpolymer materials contain a cross-linking agent to improve their elongation, tensile/tear strength, and resiliency. The percent of elongation at breaking point and tensile strength in pounds per square inch are critical in establishing the insertion characteristics of the lens, and thus ease of use, foldability through a small incision, resiliency during unfolding, post-incision resolution recovery, and stability in the eye. Hydrophobic acrylic material has the unusual property of being tacky on the surface. Tackiness may help the lens adhere to the bag upon implantation but may cause it to stick to instruments or stick in the folded position for a prolonged period of time during implantation. The switch from folding forceps for IOL insertion to specifically designed inserters has alleviated many IOL insertion difficulties associated with hydrophobic acrylic materials.

Silicone material contains a polysiloxane backbone, methyl or phenyl alkyl groups and a cross-linker reinforcer. Silicone folds easily and springs open just as quickly. Acrylic material folds with greater resistance and unfolds slowly.

Hydrophilic Acrylic Iols. These IOLs demonstrate high differences in water content. Originally manufactured from pure poly(hydroxyethyl methacrylic) acid (polyHEMA) and having a water content of 38%, these lenses were too easily deformed and opacified (calcified), with a significant frequency. Current hydrophilic IOLs are copolymers of HEMA and PMMA, with water contents of 25%–26%, and are much more resistant to deformation and opacification. Hydrophilic acrylic IOLs are generally less expensive to manufacture. Given the range of water content, these lenses also comprise the most varied category of IOL materials.

Biocompatibility

IOL biocompatibility refers to the tolerance of the eye to the IOL; that is, it describes the interaction of the polymer with the host tissue and the mechanical impact of the IOL on the eye. Biocompatibility falls into two broad categories, uveal and capsular. Ophthalmologists are generally able to observe the macroscopic effects of the lens on ocular tissue, such as the fibrosis of the anterior capsule and cellular reaction in the anterior chamber. These findings are the cumulative result of the interaction of the IOL with either the lens epithelial cells

(LECs) or the immune system.

UVEAL BIOCOMPATIBILITY. This refers to the reaction of the iris, ciliary body, and anterior choroid to the IOL. It is measured in rough terms by the deposition of foreign-body giant cells on the exposed surface of the optic. Surgical irritation to the anterior uvea causes inflammation-related changes in the blood–aqueous barrier. Monocyte and macrophage migration through the uvea blood vessel walls create foreign-body giant cell deposits on the IOL. Factors such as incomplete polymerization of the primary optic material during manufacturing or extrinsic contamination of the optic may lead to a potentially toxic reaction. Fortunately, the current standards of manufacturing no longer make uveal biocompatibility an issue for most IOL materials. However, any IOL not placed in the capsule may have chafing due to continuous contact with the iris or ciliary body. This is particularly significant with square-edged single-piece acrylic IOLs. In 5-year studies involving uveitic patients, hydrophilic acrylic IOLs tend to be more uveal-biocompatible than hydrophobic acrylic or silicone IOLs.

Capsular Biocompatibility. Capsular biocompatibility refers to how the material interacts with the lens capsule. A specific material may be compatible with LEC survival and result in less capsule fibrosis but greater cellular proliferation. Or if it is less compatible with LEC survival, fibrous metaplasia may be induced. The clinical desire for precise optical function requires a hybrid between these two states, in which the LEC activity is kept in balance between fibrosis and proliferation and the posterior capsule remains clear. Compared to hydrophobic and silicone IOLs, hydrophilic acrylic materials have an increased tendency for lens epithelial cell outgrowth onto the IOL surface, posterior capsule opacification (PCO), and capsular contraction. Generally speaking, silicone IOLs are credited with a greater degree of fibrosis than hydrophilic or hydrophobic materials. Capsular contraction carries the risk of IOL decentration and axial shift and is of particular concern in patients with potential for compromised zonular support. Even if contraction of the anterior capsule opening does not impair visual acuity, the reduced opening can limit the examination of the peripheral retina and increase the difficulty of laser photocoagulation. The design of an IOL can significantly alter the response of LECs even within the same material class. The observation that sharp-edged hydrophobic acrylic IOLs inhibited LEC migration led to research into sharp-edged

optic designs intended to inhibit LEC migration. Studies comparing otherwise identical rounded-edged IOLs to sharp-edged IOLs show clear benefits to a sharp edge in reducing PCO, improved rotational stability, and reduced anterior capsule contraction. More recently, a specific rounded-edge silicone IOL (SI-40NB, Abbott Medical Optics [AMO], Santa Ana, CA) has been shown to reduce PCO more effectively than a sharp-edged hydrophobic acrylic IOL (MA60BM, Alcon, Fort Worth, TX) at 10 years after implantation. This suggests that the longest-term reduction in PCO is founded in mediating LEC activity through IOL material rather than IOL design alone.

IOL Design Single-Piece Versus 3-Piece Design



IOLs come in two major design varieties, single-piece and 3-piece. Single-piece IOLs are crafted from a single piece of material with the haptics intrinsically attached to the optic. Three-piece lenses have the optic manufactured separately from the haptics with the haptics then implanted into the optic material. Haptics may extend from the optic at various angles, usually between 0° – 10° of angulation. Haptics play a role in the position of the IOL after implantation. The first single-piece IOLs were the plate-haptic silicone lenses manufactured by Staar Surgical (Monrovia, CA). These lenses are relatively short in length at 10.8–11.2 mm in diameter. They are designed for in-the-bag placement only. More recent single-piece IOLs are crafted from hydrophobic or hydrophilic acrylic materials, and they superficially resemble their 3-piece counterparts. As the material has a high degree of compressibility, the outward force of the haptic on the capsular bag is negligible but serves to stabilize the optic in the desired capsular location during the process of capsule contraction. Given the relatively delicate nature of the acrylic material with regards to shearing, the haptics are generally bulky and demonstrate an excellent rotational stability. All current single-piece foldable IOLs have square posterior edges that also contribute substantially to the general lack of postoperative rotation.



Three-piece foldable IOLs have haptics of a much more rigid material, such as PMMA or polyamide. These haptics have considerable outward compression force

compared to that of single-piece foldable IOLs. The haptics are much thinner and are much better tolerated in the sulcus than the bulky, single-piece haptics. These haptics are much easier to damage during IOL insertion, and recent reports associate 3-piece IOLs with greater degrees of tilt as a result. 13 mm for 1-piece IOLs, but may be shorter in a 3-piece lens. In cases of capsule compromise in which the 3-piece IOL is to be placed in the sulcus without optic capture through the capsulorhexis, it is generally accepted that 13 mm is the minimum haptic length to achieve stable sulcus fixation. While it is generally considered that sulcus diameter will correlate to the white-to-white corneal diameter, this is not always the case and larger IOL length may be needed. In the United States, only the rounded-edge, silicone Staar AQ series IOLs have haptic lengths greater than 13 mm. Two clinical situations arising specifically as a complication of IOL placement are capsule phimosis and late within-the-bag IOL dislocation. These frequently occur together in the same eye, and many of the affected patients will demonstrate pseudoexfoliation. Each condition can occur even in the presence of a capsular tension ring, and aspects of IOL material and haptic design to reduce these problems continue to be an area of research. In general, if a patient is considered to be at risk of capsule phimosis or late IOL-bag dislocation, silicone lenses should be avoided. Consideration should be given for 3-piece lenses with the haptics in the sulcus and optic captured in the capsulorhexis. As mentioned previously, the sharp-edged haptics of a single-piece IOL can cause significant uveal chafing with concomitant pigment dispersion, uveitis, hyphema, and glaucoma.

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