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INTRAOCULAR LENS BIOMATERIALS FOR CATARACT SURGERY

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Abstract. The clouded lens is removed in standard cataract procedures, and the intraocular lens (IOL) is implanted. Different materials have been used in IOL that can be divided into rigid and soft materials. Polymethyl methacrylate (PMMA) is a rigid material, so the corneal incision has to be as big as the IOL to be inserted into the eye. While hydrophilic acrylic, silicone, and hydrophobic acrylic are softer and foldable materials, the IOLs can be implanted in tiny incisions. Hydrophobic acrylic IOLs are the most common lens in cataract surgery due to their foldability, biocompatibility, and lower posterior capsule opacification (PCO). Hydrophilic acrylic IOL suffers from calcification, while silicone IOL suffers from anterior and posterior capsule opacification. However, many modifications have yet to be made to the structure of the polymer or its surface to overcome this problem. The sharp-edge lens generally has a lower PCO than the round-edge lens. Continuous improvements in the material structure and surface and the surgery are needed to reduce the complications with the cataract procedure.

Keywords: Biomaterial, Intraocular lens, Opacification, Cataract surgery

1. Introduction

Cataract extraction and implantation of intraocular lenses (IOL) is the most common surgical procedure for people with cataracts. The natural lens consists of packed fiber cells with 65% water, and the rest is crystallin protein that gives the lens transparency with a high refractive index [1, 2]. The lens must maintain transparency throughout life to prevent visual impairment. Opacification of the natural lens (cataract) affects nearly 94 million worldwide according to the World Health Organization (WHO) [3]. The typical treatment for cataracts is the removal of the opacified lens and implanting an IOL [4]. Minimal invasive procedure with high-quality vision after the procedure is needed. All of this paved the way for different types of material to be used in IOL design in addition to modification. So there was an improvement in the characteristics and design of the material to enhance biocompatibility and visual quality and reduce surgical incisions.

The materials usually used to design the IOLs are poly(methyl methacrylate) (PMMA), hydrophobic acrylic, hydrophilic acrylic, and silicone. Hydrophobic acrylic, hydrophilic acrylic, and silicone biomaterials are used mainly in foldable IOLs which can be three pieces or one piece. PMMA IOL was first implanted in 1949 by Sir Harold Ridley in London [5]. Although foldable hydrophilic and silicone IOLs have started to replace the PMMA IOLs to minimize the incision during surgery, PMMA IOLs are commonly used, especially in developing countries. IOLs implantation is an effective procedure, but many complications have been reported with IOLs, such as opacification or discoloration of the IOLs, snowflake degeneration, and calcification. These processes will affect the optical properties of the IOLs, which result in light scattering and reduction of light transmittance [6]. Opacification of IOLs could be occurred due to calcification which is the precipitation of calcium, phosphate, and sodium on the IOLs, especially in the hydrophilic IOLs [7]. Hydrophobic IOLs usually do not suffer from opacification due to calcification, which implies that the structure of the IOL materials plays a role in the precipitation of the minerals. Opacification could also occur due to the slow degradation of the lens's biomaterial, called "snowflake degeneration,", especially in PMMA lenses [6]. Snowflake degeneration of the PMMA IOL results from ultraviolet exposure [8]. Snowflake degeneration could take up to 10-20 years to develop in PMMA IOls [8]. Posterior capsule opacification (PCO) is one of the main complications that usually happens after cataract surgery with an IOL [9]. PCO results from the proliferation of the remaining lenticular epithelial cells in the space between the posterior capsule and IOL, which could cloud the capsule and result in fibrosis formation [10].

The main IOL biomaterials that are usually used in cataract surgery are listed below with their physical properties (Table 1)

(i) Polymethyl methacrylate (PMMA)
(ii) Hydrophilic Acrylic _Poly(2-hydroxyethyl Methacrylate) PHEMA
(iii) Silicone
(iv) Hydrophobic Acrylic

Table 1 Physical properties of IOL material classes.

Material	**Refractive index**	**Contact angle**	**Water content%**	**Foldability**
Polymethylmethacrylate (PMMA)	1.49	65–71°	0.4–0.8	unfoldable
Hydrophilic Acrylic	1.41	20–70°	18-38	Foldable
silicone	1.41- 1.46	99°	0.38	Foldable
Hydrophobic Acrylic	1.44-1.55	73°	0.1-1.5	Foldable

2. Materials

2.1 Polymethyl methacrylate (PMMA)

Polymethyl methacrylate (PMMA) is a widely used material in IOL cataract surgery. PMMA group (Figure 1 a) is a nondegradable polyacrylate, an inert, hydrophobic, biocompatible, and inexpensive biomaterial [11, 12]. When fragments of Plexiglas were accidentally embedded in the eyes of World War II fighter pilots during aircraft crashes, its biocompatibility became evident [13]. It also has excellent light transmission properties with a refractive index of 1.49 [14]. The higher the refractive index the thinner the lenses. PMMA is rigid and non-foldable, so PMMA IOLs cannot pass through small incisions [14]. The corneal incision has to be 5-7 mm for PMMA IOL [15]. However, the PMMA IOL used in cataract surgery often induces posterior capsule opacification (PCO) [16]. These phenomena cause vision loss over time and disrupt IOL function, eventually causing the IOL implant to fail. Many methods were used to prevent the formation of the PCO, such as changing the materials or the design of the IOL or introducing drugs into the IOL. Findl et al. found that modification of the PMMA IOL design from a round-edge to a sharp-edge IOL results in less fibrotic PCO [17]. They discovered that IOLs with sharp optical edges had significantly less PCO one year, three years, and five years after surgery than IOLs with round edges. In another study, PMMA material was modified by forming a copolymer of methacrylisobutyl polyhedral oligomeric silsesquioxane-co-polymethyl methacrylate (MA POSS–PMMA) to enhance the material properties [18]. MA POSS-PMMA had a higher roughness and was more hydrophobic than PMMA. In addition, MA POSS-PMMA materials enhanced human lens epithelial cells' (HLECs') growth and spreading morphology compared with PMMA, indicating that this material would reduce PCO. Zhang et al. modified IOL materials by combining PMMA with heparin (Hp), with polyglycol (PEG), and with both Hp and PEG by using plasma treatment [12]. They found that, compared to PMMA, the modified PMMA lets less ultraviolet light through and has better antithrombogenicity. In another study, PMMA IOL was coated with polyvinyl alcohol (PVA), either with or without an adhesive layer (AL) [19]. They used AL to increase the adhesion bonding between the coating and the PMMA. The PMMA coated with PVA/AL did not change the transparency of the PMMA. The PMMA /AL /PVA had lower cell adhesion and inhibited the adsorption of proteins compared to the PMMA. In another study, the surface of PMMA was fluorinated with sulfur hexafluoride (SF6) plasma to make it less water-friendly [20]. Hydrophilic materials can form bonds with water, which could enhance the calcification and opacification processes, so reducing the hydrophilicity will hinder this process. The samples treated with plasma were less likely to hold water than those not treated, but this did not affect how the surface looked. Interestingly, the modified PMMA samples were clear to visible light but less in the ultraviolet range. Moreover, the deposition of inorganic compounds was less on the surface of the modified PMMA as compared with PMMA when immersed in simulated aqueous humor [20]. Hazra et al. studied the effect of different designs of PMMA on PCO prevention since the PCO treatment using ND: YAG laser is expensive [21]. They put IOL lenses in the eyes of white New Zealand rabbits. The lenses were either round-edged PMMA, square-edged PMMA, round-edged HEMA, or square-edged HEMA. PMMA is a rigid lens, while HEMA is foldable. The results showed that the round-edged lens has a higher PCO than the square-edged lens. There was no difference in PCO between rigid PMMA and HEMA IOLs. Round-edge IOLs are not commonly used in clinical nowadays [22].

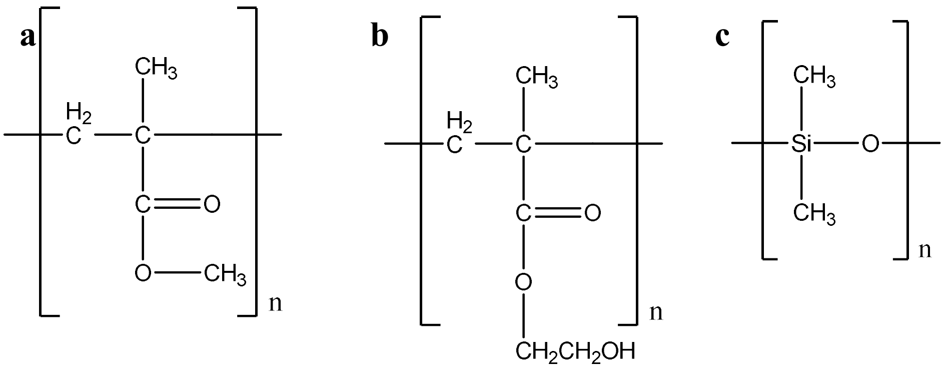


Figure (1): a. Polymethyl methacrylate (PMMA), b. Poly(2-hydroxyethyl Methacrylate)

PHEMA and c. polydimethylsiloxane (PDMS)

2.2 Hydrophilic Acrylic

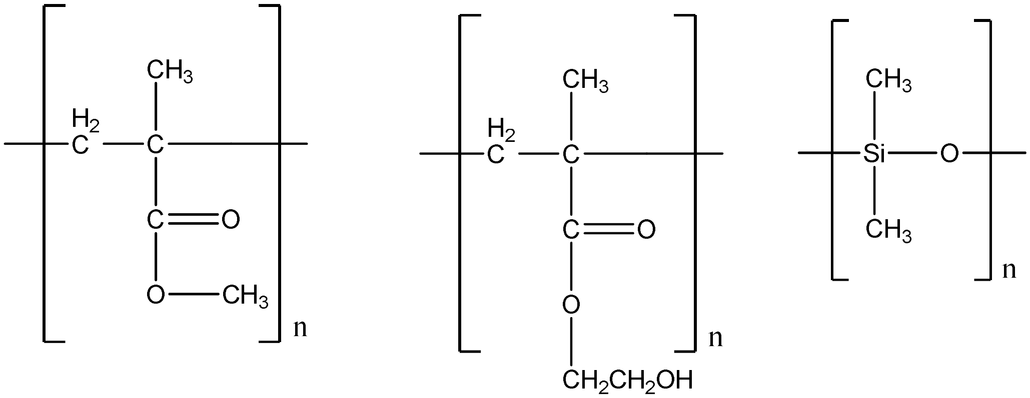
Poly (2-hydroxyethyl methacrylate), or PHEMA, is a hydrophilic foldable acrylic commonly used in soft contact lenses and flexible intraocular lenses [23]. Because of the hydroxyl group (Figure 1 b), the PHEMA gel has much water, which helps oxygen and solutes move through the gel [13]. The PHEMA materials are transparent, soft, biocompatible, non-degradable, and hydrophilic hydrogel [24]. They are usually used in foldable IOLs and can pass through small incisions smaller than 2 mm [25]. The glass transition temperature of PHEMA is around 116.6 °C [24]. When they are dry, PHEMA gels are hard and brittle, but when they absorb water, they become soft, transparent, and foldable [14, 26]. The PHEMA hydrogel has a transmittance of around 85% in the visible region (400–700 nm), which is close to the transmittance of the human corneas (99.7%–99.9%) [27]. The PHEMA hydrogel has a refractive index of about 1.41 [27], which means it is thicker than PMMA IOLs for the same refractive power. Hydrophilic PHEMA IOLs usually suffer from calcification due to the deposit of calcium phosphate crystals on the surface, while hydrophobic IOLs do not suffer calcification [28]. Richter-Mueksch et al. have studied the uveal and capsular biocompatibility of different types of IOLs in eyes with pseudoexfoliation syndrome (PEX), including hydrophilic acrylic, hydrophobic acrylic, and silicone [29]. Fewer signs of inflammation showed that the IOLs made of hydrophilic acrylic and silicone were the most compatible with the body. Compared to the other groups, lens epithelial cell outgrowth is lowest in hydrophilic acrylic, which shows that the capsule is biocompatible. Due to calcification and PCO formation, Grzybowski et al. urge that hydrophilic acrylic IOLs be avoided wherever possible, particularly in patients with vascular disorders. Additionally, it should be avoided in conjunction with endothelial keratoplasty or pars plana vitrectomy in cataract surgery [30]. Another retrospective cohort research at the National Eye Hospital of France indicated that all IOL calcification was associated with endothelial keratoplasty and that patients with endothelial problems should avoid hydrophilic IOLs [31]. Moreover,hydrophilic acrylic had insufficient uveal biocompatibility, as indicated by debris deposition on the surface of IOL [29]. Although the older generation of hydrophilic acrylic IOLs is connected to the calcification problem, the new generations of hydrophilic acrylic IOLs do not have this problem [32, 33].

2.3 Silicone

The first foldable silicone IOL was implanted in 1978 [34]. Silicone is a hydrophobic material with a contact angle of around 99° and a water content of up to 0.38% [14]. It has a refractive index of 1.41 to 1.46, so it is thicker than hydrophobic acrylic due to its lower refractive index [14]. Silicone IOLs are made of polydimethylsiloxane (PDMS) in addition to other silicone materials in which silicon-oxygen (Si-O) is the backbone of the structure. Ohnishi et al. have shown that the foreign body reaction was lower for silicone IOLs in monkey eyes than PMMA IOL. Furthermore, fewer cells were found to adhere to silicone IOLs than PMMA IOL [35]. However, silicone IOLs were reported to have more fibrotic tissue around the lens and enhance cellular activity, stimulating lens epithelial cell proliferation [36]. Fibrotic tissue formation could result in PCO and anterior capsule opacification, so it is not recommended to implant silicone IOLs in patients with a higher risk of a fibrotic reaction that may enhance the degree of anterior capsular fibrosis [36]. Pandey et al. have shown that plate-haptic silicone IOLs have a higher rate of anterior capsule opacification than acrylic IOLs [37]. Acrylic IOLs can be unfolded in a more controlled way than silicone IOLs [32]. The silicone IOLs can unfold suddenly after implantation, which may injure the posterior capsule [14]. In addition to that, silicone lenses adhere to silicone oil and intravitreal gases, which results in reducing the transparency of the lens [38]. Recently, silicone IOLs are not commonly used due to these limitations, especially in plate silicone designs [14]. However, a new design incorporating square optical edges to the silicone IOLs has been developed [32]. It has been shown that a sharp-edge silicone IOL has a lower PCO than a rounded-edge IOL [39, 40].

2.4 Hydrophobic Acrylic

IOLs made of hydrophobic acrylic can be folded and inserted through 2.2 mm minor cuts. The flexibility of the hydrophobic acrylic can be altered by changing the crosslinking degree or the side chain flexibility. Hydrophobic acrylic IOLs are the most common type of lenses used worldwide [41], with AcrySof (Alcon Laboratories, Inc.) being the most widely used hydrophobic acrylic IOL. The AcrySof IOLs are made from hydrophobic acrylic that includes phenylethyl acrylate (PEA) and phenylethyl acetate (PEMA) copolymers and are cross-linked by butanediol diacrylate (BDDA) (Figure 2) [33]. The AcrySof IOLs have square optical edges, a water content lower than 0.5%, and a contact angle of 73°. Square edge IOL design plays a role in reducing PCO [32]. AcrySof IOLs inhibit PCO due to the adhesion of IOLs to the posterior capsule [42]. For PCO prevention, the "Sandwich" theory states that the PCO is minimized by attaching a monolayer of LECs to the capsule and the hydrophobic acrylic IOL with a bioadhesive surface [43]. Without this attachment, the cells will proliferate behind the IOL, which results in PCO [43]. However, hydrophobic acrylic IOLs usually suffer from glare due to a high refractive index (1.44–1.55) [14]. Furthermore, hydrophobic acrylic is more likely to have glistening due to the formation of water pockets in the hydrophobic polymer [44] so increasing water content could reduce glistening in hydrophobic IOLs [33].



PEA **PEMA** **BDDA**

Figure 2 The AcrySof IOLs are made from a mix of phenylethyl acrylate (PEA) and phenylethyl Acrylate (PEMA) butanediol diacrylate (BDDA).

Recently, there has been a new type of hydrophobic acrylic lens with water contents ranging from 1.5% to approximately 4% while glistering-free [41]. For example, to improve the properties of hydrophobic IOLs, a new hydrophobic acrylic IOL with HEMA was made. Clareon IOLs are manufactured from hydrophobic acrylate–methacrylate copolymers containing hydroxyethyl methacrylate. Their water content is up to 1.5% and has a refractive index of 1.55. The Clareon IOL introduced an ultraviolet blocker to protect and give filtering for the ultraviolet and blue light range [45]. It was shown that Clareon IOLs reduce roughness and glistering compared to other types of IOLs [45, 46]. In addition, the rotational stability of the implanted Caleron IOLs is comparable to that of the AcrySof IOLs. [47]. Auffarth et al. have compared the removal of ophthalmic viscosurgical devices after cataract surgery in Clareon CNA0T0 and AcrySof SN60WF IOLs [48]. The ophthalmic viscosurgical device is usually used to aid cataract surgery, and it is vital to remove the whole device to avoid complications after surgery [49]. There was no significant difference in ophthalmic viscosurgical devices in both IOLS [48]. Interestingly, the interaction between cohesive ophthalmic viscosurgical devices and IOLs created from the new Caleron material was identical to that of IOLs built from AcrySof material.

An additional consequence of cataract surgery is anterior capsule contraction, which is intimately related to the substance of intraocular lenses (IOLs). [50]. The anterior capsule opening area contraction was studied for PMMA, silicone, and acrylic IOLs. It was found that the percentage of the anterior capsule opening area contraction was the highest in silicone IOLs [50]. Wang et al have compared the anterior capsule contraction after femtosecond laser-assisted cataract surgery (FLACS) of two kinds of hydrophilic acrylic IOLs (MI60, 509M) and hydrophobic acrylic IOLs (iSert250, ZCB00) [51]. Hydrophobic IOLs exhibited a lower rate of anterior capsule contraction than hydrophilic IOLs.

3. Conclusion

This article discusses the most popular IOL biomaterials used in cataract surgery, as well as their physical properties. Silicone, Polymethyl methacrylate (PMMA), Poly(2-hydroxyethyl Methacrylate) (PHEMA), and Hydrophilic Acrylic are the four different biomaterials that are used in IOL design. The majority of cataract patients opt to have their cataracts surgically removed and replaced with an intraocular lens (IOL). Although IOL implantation is generally effective, many complications have been reported. The physical characteristics of the most often used IOL biomaterials in cataract surgery are described here. PMMA is a biomaterial that is nondegradable, inexpensive, inert, hydrophobic, and biocompatible. It has excellent light transmittance and a high refractive index of 1.49. Human lens epithelial cells (HLECs) were found to proliferate more and adopt a more spreading shape when cultured on MA POSS-PMMA materials as opposed to PMMA. The concentration of PCO in the eye would drop if this chemical were used. Hydrophobic, foldable acrylic is widely used in soft contact and flexible intraocular lenses. In this article, different materials usually used in IOLs were discussed, along with the pros and cons of each material. The authors believe that as long as technology is dedicated to developing versatile biomaterials to mimic the functionality of the human lens, new materials and designs will be developed to minimize the drawbacks of existing IOLs.

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