ZEISS Intraocular Lenses

• Advantages of Hydrophilic Acrylic Materials in Intraocular Lenses

• Advantages Specific to 3-Haptic Fenestrated IOLs
Advantages of Hydrophilic Acrylic Materials in Intraocular Lenses

Introduction

Cataract treatment has witnessed simultaneous advances in surgical procedures as well as the synthesis of intraocular lenses. Microsurgical techniques, phacoemulsification, and continuous curvilinear capsulorhexis have been accompanied by the development of foldable IOls that can be inserted through incisions as small as 2 or 3 mm, and which possess the several functional advantages that will be described below. These IOls are constituted of acrylate polymers, and/or copolymers with an abundance of hydrophilic groups. They are water-insoluble, super absorbent, and possess flexibility similar to human tissue. Their water content varies from 18% to 30%. These soft, flexible acrylic IOls fall into several groups. “Hydrogel acrylics” (“Hydrogels”) refer generally to implants made of poly-hydroxyethylmethacrylate (pHEMA), while “Acrylics” refer to non-hydrogel acrylics, and tend to have lower water content, and be less flexible. “Hybrid acrylics” usually incorporate HEMA into the chemical structure in order to improve flexibility.

Biocompatibility

Biocompatibility can be viewed as the relative ability of a material to interact favorably with a biological system, perform a specific application, and elicit an appropriate host response. The proliferation of lens epithelial cells on the surface of the IOL is an example of biocompatibility. This cell growth contributes to stability of the IOL in the capsular bag, but it can also result in the development of posterior capsular opacification (PCO), as well as anterior capsular opacification (ACO). An appropriate host response is usually characterized by the absence of inflammation, and the biocompatibility of an IOL is inversely related to the inflammation elicited by the IOL following implantation [1]. It is also related to the lens epithelial cell (LEC) reaction [2-9]. A postoperative foreign-body response and prolonged inflammation after cataract surgery are the clinical manifestations of an inappropriate host response and are associated with such complications as glaucoma, cystoid macular edema, and the formation of synechias and cyclitic membranes. In normal eyes, improved IOL design and better surgical techniques have reduced the incidence and severity of these complications, but they are still a significant problem in eyes with a damaged blood-aqueous barrier (BAB) from uveitis, glaucoma, diabetes, or other pre-existing ocular pathology [2].

The earliest IOls were made of polymethylmethacrylate (PMMA), and the biocompatibility of this material represents a benchmark against which subsequent materials have been compared. Later, a hydrogel IOL, made of poly-2-hydroxyethylmethacrylate (pHEMA), was developed, and offered the following advantages:

- Soft and flexible,
- Autoclavable,
- More Nd:YAG compatible,
- Foldable, and thus more suitable for small-incision surgery [10].

In order to document biocompatibility, several studies have been completed. In a 5-year study, Percival demonstrated that hydrophilic poly-hydroxyethylmethacrylate (pHEMA) could be introduced into acrylic material, improving flexibility and hydrophilic without compromising biocompatibility [10]. In this study, a lower incidence of precipitates on the anterior lens surface suggested superior biocompatibility of hydrogel over PMMA.

In a subsequent, 12-year study, Khan and Percival [11] demonstrated a statistically lower incidence of Nd:YAG capsulotomy in eyes implanted with pHEMA IOls when compared to PMMA IOls. This fact, as well as the remarkable clarity of capsules when intact, led them to conclude that pHEMA lenses had better biocompatibility than the PMMA lenses.

Cataract development is a common occurrence in patients who suffer from uveitis, due to chronic inflammation and treatment with steroids. Abela-Formanek and coworkers studied the biocompatibility of two types of acrylic IOls, as well as a silicone IOL, in the eyes of patients suffering from uveitis [1]. They found that hydrophobic acrylic IOls had better uveal but worse capsular compatibility, while hydrophilic acrylic IOls had better capsular but lower uveal biocompatibility. Uveal biocompatibility was evaluated by measuring the inflammatory response following implantation. This was done by measuring the grade of small round cells and the number of giant cells present during the postoperative period. Capsular biocompatibility was assessed by semiquantitative analysis of anterior and posterior capsule opacification up to and including six months following surgery. Despite the differences in IOL biocompatibility, all patients in this study benefited from cataract surgery. The development of anterior capsule opacification (ACO) is a potential and significant complication following cataract surgery, and the incidence of this complication is associated with the extent of the postoperative inflammatory response, as well as lens epithelial cell reaction. Tognetto [13] addressed the role that the biocompatibility of lens materials plays in the development of these complications by determining the postoperative cell reaction on the IOL surface, the ACO rate, and the presence of membrane growth over the anterior IOL surface. In this study of 73 consecutive cataract patients (73 eyes), she compared the behavior of 3 different hydrophilic IOls, the Storz Hydroview H60M, the Corneal ACR6D, and the ZEISS Stabibag, with 18%, 26%, and 28% water content, respectively. Clinically, the 3 hydrophilic IOls behaved differently, indicating different forms of biocompatibility. While the Stabibag group had a significantly higher grade of small inflammatory cell reaction initially, a significantly higher rate of ACO was observed in the ACR6D group. Also, the Hydroview and ACR6D groups both had a significantly higher percentage of membrane growth from the capsulorhexis edge onto the anterior IOL surface than the Stabibag group. In another comparative study, Percival and Yas evaluated the biocompatibility and relative safety of 3 foldable IOls: the Stabibag (ZEISS), a hydrophilic lens, the AcrySof (Alcon), a hydrophobic lens, and the Si30 (AMO), a silicone lens [14]. The results of this study showed that silicone was the least biocompatible due to a significant incidence of capsular fibrosis, capsular phimosis, and decentration, although none of these patients required posterior capsulotomy. Compared to the other lenses, the Stabibag, a hybrid acrylic, was the “cleanest”, as almost all the AcrySof and Silicone lenses showed evidence of pigment or debris deposits on the surface and a significant number showed vacuoles or specks in the lens substance. While all patients in this study experienced satisfactory improvement, those who had been implanted with the Stabibag IOL had the best results with 86% seeing 6/6 or better.

Optical clarity

Intralenticular glistenings are thought to result from accumulations of fluid in the microvoids of the optic [15], visible because of differences in the refractive index. Glistenings have been described as a phenomenon peculiar to hydrophobic acrylic IOls in general, but they were actually first reported in 1984 when they were described in a polymethylmethacrylate (PMMA) optic and have also been observed in silicone lenses, [15][16]. In 2002, Tognetto, in a study designed to evaluate the formation of gistenings in foldable intraocular lenses of various materials, documented the formation of gistenings in 7 different foldable IOls [17]. While the difference in postoperative BCVA among groups was not significant, the mean grade of glistenings was significantly higher in the AcrySof group than in the CeeOn 911 group at 180, 360, and 720 days, and than all the other IOL groups at 180, 360, and 720 days. In most groups, gistenings formation had stabilized by 180 days fol-
Following surgery, while in the AcrySof and CeeOn 911 groups, a continuous increase over time was observed. And while most IOLs had only trace glistenings, the AcrySof and CeeOn 911 groups were found to have the highest grade of glistenings at the last 3 examinations. Of the 7 IOL groups analyzed, the Sensar and Stabibag IOLs were the least susceptible to the glistening phenomenon. And while it was pointed out in this study that glistenings often occur as occasional phenomena, severe glistenings can impair visual acuity and contrast sensitivity.

Resistance to damage during insertion
It is well-known that silicone and hydrophobic acrylic IOLs are susceptible to damage, in the form of folding marks, as a result of the folding step prior to insertion in the injection cartridge. They are also susceptible to trauma from the forceps used during the surgical procedure. These potential complications have been reported in the literature [18-21]. Due to their water content, and, consequently their elasticity, hydrophilic acrylic materials are less susceptible to folding marks and trauma from forceps than silicone and hydrophobic acrylics. The recovery time, e.g., of a hydrophilic material is significantly reduced compared to that of a hydrophobic material. In 2001, a survey of the members of the American Society of Cataract and Refractive Surgery, the European Society of Cataract and Refractive Surgery, as well as ophthalmic surgeons worldwide looked at surgical complications of cataract surgery that resulted in explantation. What was significant in this survey was the absence of any instance of explantation due to damage of the IOL during insertion [18]. Kohnen and coworkers evaluated the surfaces of acrylate/methacrylate polymer IOLs with a scanning electron microscope after the folding process [20]. The hydrogel IOLs showed no signs of surface alterations, and the authors considered this was probably due to their high water content (which varied from 18% to 38% for the IOLs studied) which makes these lenses extremely soft and flexible. The two IOLs with a water content <1% evaluated in this study showed subtle scratching or tearing of the optic surface. According to the authors, the quality of foldable IOLs approaches in many instances meets the gold standard set by PMMA IOLs.

Tolerance to Nd:YAG laser therapy
Hydrophilic acrylic IOLs (including the ZEISS hydrophilic acrylic IOLs) were shown to have among the highest thresholds for damage when subjected to Nd:YAG laser therapy than hydrophobic or silicone IOLs in a study published in 2000 by Trinavarat and colleagues [22]. In this study, the damage threshold was defined as the laser energy level causing damage on the IOL surface 50% of the time. The threshold for the silicone lens (SF-40NB, AMO) was 0.37 ml, for the hydrophobic lens (MA60BM, Alcon) was 0.54 ml, and for the ZEISS IOL it was 0.58 ml.

Fewer dysphotopsias
For the fourth consecutive year, Mamalis conducted a survey of ophthalmic surgeons in an attempt to document the causes of IOL explantations [18]. In 2001, this survey was sent to surgeons worldwide, and 286 responses were obtained. The most common reason for explantations of all IOLs was incorrect lens power. While the author is careful to point out that this survey was not intended to suggest that one IOL type is preferable to another, there was a distinct difference between Hydrogel acrylic IOLs and hydrophobic acrylic IOLs when it came to the incidence of glare/optical aberrations. In the former group, 3% of respondents cited glare/optical aberrations as a reason for explantation, compared to 29% in the latter group.

Less susceptible to biocontamination
When bacterial endophthalmitis complicates cataract surgery, significant and permanent deterioration of visual acuity is the usual result. In most cases, it is felt that contamination of the IOL occurs prior to implantation as a result of contact with external ocular tissue. Consequently, the facility with which bacteria adhere to the IOL surface is considered to be an important factor in the development of this complication. In 2003, Schauersberger and colleagues studied the in vitro bacterial adherence to four types of rigid IOLs and five types of foldable IOLs [23]. They found that the higher the hydrophilicity of the IOL material, the lower the early adhesion and bacterial density on the IOL surface. They concluded that the use of hydrophilic IOLs in conjunction with the application of antibacterial and antimicrobial substances to the surface of the eye could reduce the incidence of endophthalmitis. Kodjikian and colleagues came to similar conclusions in a 2006 review of the literature on bacterial adhesion to intraocular lenses and endophthalmitis [24]. They concluded that while the ideal material that could prevent this complication has not yet been found, hydrophobic acrylic and hydrophilic materials were found to offer less adherence for bacteria than silicone or PMMA.
Stability in the capsular bag
The use of a 3-haptic architecture results in an ideal mechanical stability within the capsular bag, limiting posterior and anterior shifting, as well as decentration. This happens because the pressure of the haptics is symmetrically distributed around the equator of the capsular bag.
Ioltech, now Carl Zeiss Meditec SAS, was one of the first manufacturers of IOLs to commercialize a 3-haptic intraocular lens.

Lower incidence of PCO compared to other hydrophilic acrylic IOLs
In a study published in 2003, the rate of development of posterior capsule opacification in 370 eyes implanted with a ZEISS Stabibag IOL was evaluated by Strodhal and Drolsum [25]. They found the capsulotomy rate for these patients to be < 8% at 1.5 year. This compares very favorably to the findings of Scaramuzza [26] who reported Nd:YAG capsulotomy rates of over 50% when utilizing a hydrophilic acrylic IOL (with round edges). The 3-haptic design was felt to promote stability within the capsular bag, good centration, a lower incidence of capsular folds, and a tight wrapping of the capsular bag around the IOL. The sum of these factors was felt to have created an edge effect, thus limiting LEC migration.

In a not yet published study [27], the rate of PCO requiring capsulotomy in eyes implanted with the CT SPHERISM 203 (XL Stabi)* IOL was 9.09% at 21.4 ± 3.71 months (Doctor Lebrun, not published data). This finding demonstrates that the CT SPHERISM 203 (XL Stabi) platform results in very low rates of posterior capsule opacification when compared to other hydrophilic acrylic IOLs. This low rate of PCO is considered to be due to the design and geometry of the lens which result in a tight wrapping of the capsular bag around the IOL, which in turn has an inhibitory effect on lens epithelial cell migration [25].

Less anterior cell growth
Tognetto compared the local tissue response after implantation of 3 hydrophilic acrylic IOLs, the Storz Hydview, the Corneal ACR6D, and the ZEISS Stabibag [13]. She determined the postoperative cell reaction on the IOL surface, the anterior capsule opacification (ACO) rate, and the presence of membrane growth from the capsulorhexis edge over the IOL optic for each of the 3 IOLs. Membranous outgrowth was seen in more than 80% of the Hydview and ACR6D groups, while only 8% of the ZEISS Stabibag IOLs had LEC over the optic. Their opinion is that the more hydrophilic the IOL surface, the less adhesive and proliferative the cells. They also noted that although the ACR6D and ZEISS Stabibag IOLs have similar hydration, ACO was observed mainly on the ACR6D and not on the ZEISS Stabibag. Differences in hydration alone cannot explain the difference in clinical behavior, and that the chemical composition of the IOLs is at least as important.
Werner confirmed the observations of previous clinical studies that the rate of ACO is higher with plate-haptic silicone IOLs, and that the lowest rate was found with three-piece acrylic optic-PMMA haptic IOL, and that the IOL design and IOL material are both significant factors in the development of ACO [28].

A design that results in less ocular aberrations
In a comparative study by Rohart, tilt and higher-order aberrations were measured in patients who had been implanted with the hydrophobic MA60AC (Alcon) and the hydrophilic CT SPHERISM 203 (XL Stabi) (ZEISS) [29]. They found that the tilt and coma aberrations were significantly higher in the 3-piece hydrophobic acrylic group than in the 1-piece hydrophilic acrylic group.
Consequently, a combination of the CT SPHERISM 203 (XL Stabi) platform with an aspheric surface represents the best combination that could be offered to surgeons at this time to reduce the incidence of ocular aberrations. The CT SPHERISM 203 (XL Stabi) platform remains available with both a spherical as well as an aspheric design.

Injection of the lens
The CT SPHERISM 203P (XL Stabi Sky)* is implanted using the Skyjet system. This system enables the surgeon to inject the pre-loaded IOL through incisions as small as 2.8mm. The lenses are protected at all times, and do not require any manipulation, thus avoiding the risk of damage and contamination. This system affords a controlled injection, and improvement of injection quality. This device contributes to reduce the risk of inserting the IOL upside down, or placing the IOL in a de-centered position. Most importantly, this system results in a safer, more comfortable experience for the patient.

Advantages Specific to 3-Haptic Fenestrated IOLs

CT SPHERISM™ 203 (XL Stabi) platform

*Note:
CT SPHERISM™ 203 is the new name of the former XL Stabi.
CT SPHERISM™ 203P is the new name of the former XL Stabi Sky.
Please ask your local representative for the current product name used in your country.
The advantages of hydrophilic acrylic intraocular lenses are several, and have been well-documented in the scientific literature. These advantages include better bio-compatibility [1-9], improved optical clarity [17], greater resistance to damage during insertion [18,20], a lower incidence of posterior capsule opacification requiring laser therapy [22], fewer dysphotopsias [18], and a reduced susceptibility to biocontamination.

The ZEISS CT SPHERIS™ 203 (XL Stabi)*, is a one-piece hydrophilic IOL, made of 2-hydroxyethylmethacrylate/methylmethacrylate with 3 haptics, a total diameter of 10.5 mm, and an optic size of 6.0 mm. In addition to incorporating all the advantages of hydrophilic acrylic IOLs, this lens offers several additional advantages. With its 3-haptic architecture, it offers increased stability once implanted, and consequently a lower incidence of tilt and decentration [29]. As a result of an improved design and architecture, the incidence of PCO has been found to be low or delayed [27]. Also, the hydrophilic character of this lens, combined with its design, has been shown to result in a lower incidence of anterior cell growth and anterior capsule opacification [13].

To these attributes of the ZEISS IOL can be added the possibility of being able to choose a spherical or aspheric version, and the reassurance of knowing that these lenses come in a pre-loaded system that guarantees a safe and easy insertion of the IOL through a small incision.

Conclusion

The advantages of hydrophilic acrylic intraocular lenses are several, and have been well-documented in the scientific literature. These advantages include better bio-compatibility [1-9], improved optical clarity [17], greater resistance to damage during insertion [18,20], a lower incidence of posterior capsule opacification requiring laser therapy [22], fewer dysphotopsias [18], and a reduced susceptibility to biocontamination.

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Bibliography


