Biomechanical and optical properties of 2 new hydrophobic platforms for intraocular lenses

Dimitriya Bozukova, PhD, Christophe Pagnoulle, PhD, Christine Jérôme, PhD

PURPOSE: To compare the biomechanical and optical properties of 2 new hydrophobic platforms and a series of commercially available foldable intraocular lenses (IOLs).

SETTING: Center for Education and Research on Macromolecules, University of Liège, Liège, Belgium.

DESIGN: Experimental study.

METHODS: Eleven benchmark foldable IOLs (iPure, Podeye, Acrysof SN60WF, Envista MX60, Sensar AR40e, Tecnis ZCB00, Isert 251, AF-1 YA-60BB, Finevision, Acri.Tec 366D, and Ioflex) were tested by standard analytical methods for biomechanical, rheological, and optical investigations under identical conditions.

RESULTS: With 1 exception, IOLs equilibrated in aqueous medium had a lower glass-transition temperature, higher deformability, lower injection forces, and complete recovery of their initial optical properties after injection. Typical hydrophobic acrylic dry-packaged IOLs required higher injection forces with high residual deformation and lost part of their initial optical quality after injection. Hydrophobic acrylic C-loop, double C-loop, and closed quadripod haptics applied optimum compression forces to the capsular bag with negligible optic axial displacement and tilt compared with plate haptics and poly(methyl methacrylate) haptics.

CONCLUSIONS: The combination of the C-loop haptic and the bioadhesive glistening-free material, which absorbs a predetermined amount of water, allowed for a biomechanically stable IOL. The same material used in association with a double C-loop haptic design facilitated the perioperative manipulation and placement of the IOL in a smaller capsular bag without impairing the other biomechanical properties of a single C-loop design.

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Recently, the trends in cataract and refractive surgery are toward diminishing corneoscleral incisions to lower the risk for postsurgical complications.[1] Therefore, foldable intraocular lenses (IOLs) of acrylic or silicone polymers are preferred for replacement of the opacified cataractous natural lens.

An IOL is considered to be compatible with minimally invasive cataract surgery when it (1) is injectable via a sub-3.0 mm incision, (2) does not permanently change its optical and mechanical properties as a result of IOL folding and compression during injection, (3) preserves its biocompatibility, (4) does not induce higher posterior capsule opacification (PCO) rates, and (5) provides sufficient refractive stability.[1]

Sharp-edged IOL platforms have proved their efficiency in PCO prevention,[2,3] although some authors state that sharp-edge is not able to prevent PCO alone.[4] In that aspect, the materials' properties,[5–7] the IOL design,[5,7] and the haptic shape, material, and strength[6–8] remain important factors. Previous studies report higher biocompatibility with a reduced risk for PCO formation,[9,10] better biomechanical stability,[7] and better refractive and rotational stability[8] of hydrophobic acrylic IOLs compared with their silicone plate-haptic counterparts.

For 1-piece IOLs, the material should be able to provide the IOL with excellent optical properties as well as sufficient rotational and mechanical stability, which is usually obtained by selecting the proper haptic design. It has been thought that haptics that apply stronger compression force to the capsular bag provide the IOL with better biomechanical stability.[11] However, in

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experimental studies, Lane et al.[7] and Pandey et al.[6] found that the risk for posterior capsule striae, capsule stretch, and capsulorhexis ovaling was higher when silicone or hydrophilic acrylic IOLs with poly(methyl methacrylate) (PMMA), polypropylene, or plate haptics were implanted than when hydrophobic acrylic 1-piece IOLs were used. Such deformations of ocular tissue may result in an increased risk for PCO, fibrosis, IOL decentration, and IOL tilt and may cause zonular stress in a direction parallel to the IOL haptics.[6]

Meanwhile, the mechanical resistance of the material of a typical hydrophobic acrylic IOL is an important advantage but may also be a major limitation. Such material is usually slow to fold and unfold, which may cause it to become damaged during injection and lead to loss of optical quality after implantation as a result of IOL deformation.[1] The presence of a low, but controlled, quantity (<5 wt%) of small molecules with a plasticizing effect, such as water, may significantly improve this aspect.[12] It imparts the hydrophobic acrylic IOL with shape memory properties, improved foldability, and controlled unfolding while preserving its mechanical stability and biocompatibily.[13]

The purpose of this study was to experimentally evaluate the biomechanical and rheological properties of 11 benchmark IOLs of hydrophobic and hydrophilic acrylic materials with different optic designs (refractive, diffractive) and haptic designs (C-loop, double-C-loop, plate, PMMA, closed quadripod). The results in this study should be considered in relation to results in clinical trials.

MATERIALS AND METHODS

Tested Intraocular Lenses

The iPure (C-loop) and Podeye (double C-loop) IOLs (Physiol S.A.) are of a proprietary, patented hydrophobic acrylic glistening-free material (GF)[14] and have obtained Conformité Européenne certification. The other tested benchmark IOLs were as follows: Finevision (Physiol S.A.), Acri.Tec 366D (Carl Zeiss Meditec AG), Ioflex (Mediphacos Ltda.), Acrysof SN60WF (Alcon Laboratories, Inc.), Envista MX60 (Bausch&Lomb, Inc.), Tecnis ZCB00 and Sensar AR40e (Abbott Medical Optics, Inc.), and Isert 251 and AF-1 YA-60BB (Hoya Surgical Optics GmbH) (Table 1). Systematically, new IOLs were used for each test. When appropriate, method validation was performed with a series of 5 samples of the Podeye IOL and the corresponding and similar variation in the measured value was used for all tested IOL models.

Water Uptake

The quantity of water present in a material influences its rigidity, opacity, sterilization ability, and biocompatibility. For determining the water uptake, IOLs (1 per IOL model) were incubated in water for 24 hours at 65°C to reach their equilibrium water content. Their surface was then dried by a short air flush to eliminate water droplets, and the IOLs were weighed with a laboratory microbalance to obtain their weight in the hydrated state (Wh). They were then dried at 65°C for 24 hours and their weight in the dry state (Wd) was measured. The water uptake was determined according to the following equation:

$$\mathrm{WU\,wt\%} = [(\mathrm{Wh} - \mathrm{Wd}) \times 100]/\mathrm{Wd}$$

The measurements were performed with a balance with precision of 0.0001 g, which can induce 0.45% variation in the measured value.

Glass-Transition Temperature

Glass-transition temperature (Tg) is the temperature at which an amorphous material passes from its rigid glassy state to its soft rubbery state.[15] It is particularly important in the case of IOLs because it determines their ability to fold upon implantation in the eye. Hence, the lower the glass-transition temperature (Tg) of the material, the more foldable the IOL. This parameter was determined for all test IOLs in their original packaging state with a differential scanning calorimeter (Perkin-Elmer series 7, operating with Pyris version 8 software). Specimens were hermetically sealed in aluminum capsules, placed in the equipment, cooled to −60°C and then heated from −60°C to 100°C with a heating speed of 15°C/min. One measurement was performed per IOL model. The method was validated with a series of 5 samples of the Podeye IOL, and a value variation coefficient of 10.7% was established.

Haptic Compression Force

The force applied by the haptics to the capsular bag is important for IOL rotational and refractive stability and may have some effect on its resistance to PCO. The force was determined with a compression force tester (MFC-1385-IOL, Applied Micro Circuits Corp.); the possible value variation was less than 0.2%. Before the measurement, the equipment was calibrated according to the standard manufacturer's procedure. Intraocular lenses in their original packaging state (1 per IOL model) were placed between the 2 jaws, and the compression force, in milligrams force, was measured for well diameters of 11.0 mm, 10.5 mm, 10.0 mm, and 9.5 mm, corresponding to various sizes of the capsular bag. In all cases, measurements were taken

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Corresponding author: Dimitriya Bozukova, PhD, Liège Science Park, Allée des Noisetiers, 4, B-4031 Liège, Belgium. E-mail: d.bozukova@physiol.be.