LABORATORY SCIENCE

Long-term capsule clarity with a disk-shaped intraocular lens

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Purpose: To evaluate long-term capsular clarity with a modified disk-shaped 1-piece hydrophilic acrylic monofocal intraocular lens (IOL) (Zephyr) suspended between 2 complete haptic rings connected by a pillar of the haptic material.

Setting: John A. Moran Eye Center, University of Utah, Salt Lake City, Utah, USA.

Design: Experimental study.

Methods: Study and control (1-piece hydrophobic acrylic) IOLs were implanted into the right and left eyes, respectively, of 8 New Zealand rabbits. Eyes were examined at the slitlamp at set intervals for 6 months. At the end of the clinical follow-up, the globes were enucleated and capsular clarity was scored from the posterior view (Miyake-Apple technique). Then, all the eyes were processed for a complete histopathological evaluation.

Results: At 6 months, the slitlamp evaluation showed a posterior capsule opacification score of 0.28 ± 0.26 (SD) in the study group and 4 ± 0 in the control ($P < .0001$, paired t test). The anterior capsule was generally clear in the study group. This parameter was difficult to analyze in the control group because of synechiae formation and poor pupil dilation.

Conclusions: The degree of capsular bag clarity observed at 6 months postoperatively in the study eyes in this rabbit model was exceptional. It was likely because of the IOL design, keeping the capsular bag open and expanded, and minimizing contact between the IOL and the anterior capsule.

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Modern cataract surgery using phacoemulsification generates an intact capsular bag that remains in situ and serves to house a posterior chamber intraocular lens (IOLs) inserted through the capsulorhexis opening. However, residual lens epithelial cells (LECs) within the capsular bag recolonize within denuded areas of the anterior and posterior capsules and lead to anterior capsule opacification (ACO) and posterior capsule opacification (PCO). Capsule bag opacification is the most common complication of cataract surgery and can lead to significant secondary visual impairment.[1–3] However, several studies have demonstrated reduction in capsule bag opacification by improved IOL designs preserving the overall clarity of the capsular bag.[4–8,A]

Previously, we evaluated a modified 1-piece disk-shaped hydrophilic acrylic IOL versus a commercially available 1-piece hydrophobic acrylic IOL in the rabbit model for 5 and 4 weeks, respectively.[5,6] The aim of the current study was to evaluate, for the first time, the long-term (6 months) capsular bag clarity with this IOL design in the rabbit model.[B]

MATERIALS AND METHODS

A total of 8 New Zealand white rabbits weighing between 2.4 kg and 3.2 kg were acquired from approved vendors and treated in accordance with guidelines set forth by the Association for Research in Vision and Ophthalmology. Inclusion criteria included specific weight range, completion of a veterinary preoperative examination, and a preoperative gross examination of the eyes.

The Anew Optics study IOL, Zephyr, is a 1-piece hydrophilic acrylic monofocal IOL suspended between 2 complete haptic rings that are connected by a pillar of the haptic material (Figure 1). As such, the anterior ring rests against the anterior capsule at some distance from the capsule equator and the posterior ring rests against the posterior capsule, also at some distance from the

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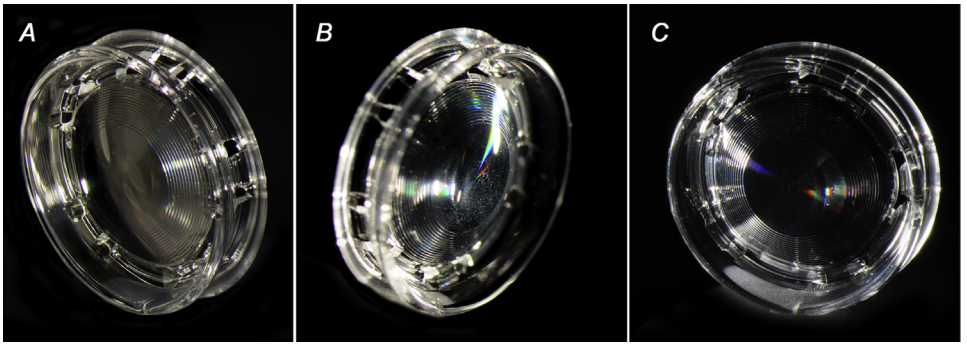

Figure 1. Gross photographs showing the disk-shaped IOL from an anterior-side view (*A*), a posterior-side view (*B*), and an anterior view (*C*) (IOL = intraocular lens).

capsule equator. The test IOL haptic rings are designed to fit the natural curvature of the capsule, and the space between the optic and the haptic rings is fenestrated with slits. The fenestrations facilitate circulation of the aqueous humor within the capsular bag. The test IOL optic is positioned to rest against the posterior capsule on the same plane as the posterior haptic ring. The IOL has an optic diameter of 5.8 mm; both the anterior haptic and posterior haptic diameters are 8.8 mm, and the distance between the anterior and posterior rings is 2.0 mm. Overall, the test IOL polar circumference measures 21.6 mm. The control IOL was the 1-piece hydrophobic acrylic Acrysof IOL, model SA60AT (Alcon, Laboratories, Inc.), which is commercially available in the United States. All IOLs used had the same optical power of +22.0 diopters. The test IOL was implanted in the right eye of each rabbit and the control IOL, in the contralateral (left) eye.

Anesthesia, surgical preparation, and bilateral phacoemulsification with IOL implantation were performed as described in previous foundation studies.[5–8] All surgeries were performed by the same surgeon (N.M.). Using aseptic techniques, a fornix-based conjunctival flap was created. A corneoscleral incision was then made using a crescent blade and the anterior chamber was entered with a 3.0 mm keratome. A capsulorhexis forceps was used to create a centered continuous curvilinear capsulorhexis (CCC) with a diameter of approximately 4.5 to 5.0 mm. After hydrodissection, the phacoemulsification handpiece (Infiniti, Alcon Laboratories, Inc.) was inserted into the posterior chamber for removal of lens nucleus and cortical material. One-half milliliter of epinephrine 1:1000 and 0.5 mL of heparin (10 000 USP units/mL) were added to each 500 mL of irrigation solution to facilitate pupil dilation and control inflammation. The endocapsular technique was used to fragment the nuclear and cortical material within the capsular bag. Residual cortex was removed with the irrigation/aspiration (I/A) handpiece. An ophthalmic viscosurgical device (OVD) was used to expand the capsular bag. Before implantation, the IOLs and OVD were warmed to body temperature to ease insertion in the injector and capsular bag. The IOLs were implanted in the capsular bag using the corresponding recommended injection system (Ophtec Dualtec Kit Acrylic 2.0 injector with LWS cartridge acrylic 2.8 cartridges for test IOLs, and Monarch II injector with B cartridges for control IOLs). The wound was closed with 10-0 monofilament nylon suture after removal of OVD material using I/A. Appropriate in-the-bag placement of the IOLs, IOL centration, and coverage of the IOL optic by the capsulorhexis were verified at the end of the procedure. Postoperative topical therapy included combination neomycin, polymyxin B sulfates, and dexamethasone ointment during the first postoperative week and prednisolone acetate drops during the second and third postoperative weeks.

Postoperative slitlamp evaluations were completed at 1, 2, 4, 6, and 8 weeks postoperatively and then at 3 and 6 months postoperatively. Both study and control eyes were dilated and evaluated for ocular inflammatory response and capsule bag opacification. Clinical color photographs of each eye at each timepoint were obtained with a digital camera attached to the slitlamp apparatus. A standard scoring method in 11 specific categories was used at each examination (conjunctival injection, conjunctival discharge, limbal vasculature, corneal opacity, extent of corneal opacity, aqueous cells, aqueous flare, iris vasculature, IOL centration, posterior synechia, inflammatory deposits on IOL surface). Retroillumination images with the pupil fully dilated were obtained for photographic documentation of CCC size, ACO, PCO, and capsule fibrosis.

After the final clinical examination at 6 months, the animals were anesthetized and then humanely killed with a 1 mL intravenous injection of pentobarbital sodium–phenytoin sodium. Their globes were enucleated and placed in 10% neutral buffered formalin. The globes were then bisected coronally just anterior to the equator. Gross examination and photographs from the posterior aspect (Miyake-Apple view) were performed to assess ACO and PCO development and IOL fixation. The extent and severity of ACO and PCO were scored according to previously described methods.[5–8] After gross examination and photographs, all globes were sectioned and the anterior segments including the capsular bags were processed for standard light microscopy and stained with hematoxylin–eosin.

RESULTS

All surgical procedures were uneventful. The study and control IOLs could generally be fully injected within the capsular bag. In all eyes (study and control), 100% coverage of the IOL optic periphery by the CCC was observed at the end of the surgical procedure.

Regarding the 11 specific categories evaluated under slitlamp evaluation, results described below summarize the positive findings. At the 1- and 2-week evaluations, the test eyes had a mild or moderate pupil dilation, whereas the control eyes had full pupil dilation. This resolved by the 3-week evaluation. The optic of the test IOL in the right eye of 1 rabbit was found to be protruding anteriorly rather than posteriorly. This remained unchanged throughout the study. The control eyes had fibrin formation, generally at the capsulorhexis edge or in front of the lens at the 1-week evaluation, which resolved by the 2-week evaluation. Trace PCO started to be observed in the eyes of both groups at the 2-week evaluation, with progressive increase throughout the study in the control eyes but remaining stable in the test eyes.

By the 8-week evaluation, the control eyes exhibited cortical proliferation and pearls in front of the IOLs, generally leading to posterior synechiae formation. Proliferation through the haptic fenestrations of the test IOLs could be observed in some test eyes, although generally without