LABORATORY SCIENCE

Uveal and capsular biocompatibility of a new hydrophobic acrylic microincision intraocular lens

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Purpose: To evaluate uveal biocompatibility and capsular bag opacification of a new hydrophobic acrylic microincision intraocular lens (IOL) in comparison with a commercially available 1-piece hydrophobic acrylic IOL.

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

Design: Experimental study.

Methods: Eight New Zealand rabbits underwent bilateral phacoemulsification and implantation of the preloaded Nanex multi-Sert^{+} IOL in one eye and a commercially available preloaded lens (AcrySof IQ in UltraSert, model AU00T0) in the contralateral eye. A slitlamp examination was performed weekly for 4 weeks. The rabbits were then killed humanely and their globes enucleated. Capsular bag opacification was assessed from the Miyake-Apple view, and the eyes were subjected to histopathologic evaluation.

Results: Postoperative inflammatory reactions were similar between the test and control eyes in the 8 New Zealand rabbits. The mean postmortem central posterior capsule opacification (PCO) was 0.93 ± 0.73 in the test group and 1.19 ± 0.53 in the control group. The mean postmortem peripheral PCO was 1.75 ± 0.92 in the test group and 2.06 ± 0.77 in the control group. Central and peripheral PCO scores were not statistically different between the test and control groups (P = .41 and P = .35, respectively, 2-tailed t test: paired 2-sample for means).

Conclusions: A new 1-piece hydrophobic acrylic microincision IOL incorporating an ultraviolet–ozone treatment on the posterior surface performed similarly to a commercially available 1-piece hydrophobic acrylic IOL in terms of uveal and capsular biocompatibility in the rabbit model. To our knowledge, this is the first hydrophobic acrylic microincision IOL to demonstrate similar PCO performance when compared with a conventional, commercially available IOL.

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The evolution of cataract surgery over the past 30 years has been trending toward an ever-decreasing surgical incision size. This pursuit of incision size reduction has been driven by the benefits of quicker visual rehabilitation, reduced damage to the blood–aqueous barrier, fewer wound-related complications, and reduced iatrogenic astigmatism.[1] With the common use of foldable intraocular lens (IOL) materials, virtually all phacoemulsification cataract surgery is currently being performed through less than a 3.0 mm incision. Microincision cataract surgery (MICS) with further incision size reduction carries the advantages of shorter visual rehabilitation and little to no surgically induced astigmatism. However, the higher demands on the IOL have hindered the expansion of MICS into common practice in modern cataract surgery.[2]

Microincision IOLs must be compressible enough to fit through the smaller surgical incision. As a result, most of these IOLs have been made from hydrophilic acrylic polymers in variations on a plate-type platform design.[1,3–7] They must also be rigid enough to withstand the decentering and distorting effects of postoperative capsular fibrosis and shrinkage.[1] Furthermore, to be fully adopted into common use, these microincision IOLs must be at least equivalent to conventional IOL designs in terms of posterior capsule opacification (PCO) performance. PCO is the most common long-term complication of a cataract surgery, resulting in visual impairment and necessitating additional procedures.[8–10] Although the development of PCO is a multifactorial problem, lens design, especially the square posterior edge design, is thought to be the most critical factor for prevention of this complication.[11–13]

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The increased PCO noted with hydrophilic acrylic IOLs may be attributed to their rounder optic edge when compared with hydrophobic IOLs.[10,14] However, many studies comparing hydrophilic and hydrophobic microincision designs with conventional hydrophobic acrylic IOLs indicate higher rates of PCO with microincision IOLs.[3,4,15]

The IOL active oxygen–processing treatment (ultraviolet–ozone [UV–O_3]), such as the one seen in the Vivinex IOLs (HOYA Surgical Optics), has demonstrated predictable bioadhesion of the IOL to the capsule, thereby limiting PCO formation.[16–18] HOYA has recently developed a new preloaded hydrophobic microincision IOL, incorporating the UV–O_3 treatment on its posterior surface. The aim of this study was to compare the uveal and capsular biocompatibility of the new hydrophobic acrylic microincision IOL with a commercially available hydrophobic acrylic IOL in a rabbit model.

METHODS

Eight New Zealand white rabbits (4 males and 4 females) weighing between 2.4 kg and 3.2 kg were acquired from approved vendors and treated in accordance with the guidelines set forth by the Association for Research in Vision and Ophthalmology and the Animal Welfare Act regulations as well as the Guide for the Care and Use of Laboratory Animals. Each rabbit received the test IOL in the right eye and the control IOL in the left eye.

The test IOL (Nanex multiSert$^+$; HOYA Surgical Optics) is a 1-piece monofocal, aspheric hydrophobic acrylic IOL with 2 modified C-loops, which has a proprietary active oxygen–processing treatment on the posterior surface (Figure 1A). The hydrophobic acrylic material used in the manufacture of the Nanex is the same as that used in the manufacture of the AF-1 IOL (HOYA Surgical Optics), which has been commercially available in different markets for over 15 years.[19] The material is colorless, incorporating an UV filter. The IOL has an overall diameter of 13.0 mm from haptic to haptic and an optic diameter of 6.0 mm. It is preloaded in a disposable system, multiSert$^+$, designed for small incision surgery. The outer diameter of the injector tip is 1.62 mm, which is, to our knowledge, the smallest nozzle for a commercially available preloaded hydrophobic acrylic IOL with a C-loop or open loop. The injection system can be used either as a 1-handed push injector or as a 2-handed screw injector. The IOL can be delivered directly into the capsular bag or delivered through the incision tunnel with the aid of an insert shield incorporated into the injection system for a controllable injector depth. In this later case, the tip of the injector slightly enters the anterior chamber (Figure 1B).

The control IOL was the commercially available 1-piece monofocal, aspheric hydrophobic acrylic AcrySof IQ IOL in the UltraSert preloaded disposable delivery system (model AU00T0, minimal compatible incision size of 2.2 mm). The IOL has 2 modified L-loops, with an overall diameter of 13.0 mm and an optic diameter of 6.0 mm. The IOL material is yellow, incorporating a blue-light filter in addition to the UV filter.

The test and control IOLs have square optic edges, water content less than 1%, and a refractive index of 1.52 and 1.55, respectively. A dioptric power of +20.0 diopters (D) was used for the test and control IOLs. All surgeries were performed by the same surgeon (N.M.). The rabbit model was chosen because of its accelerated development of PCO, in which 1 month of implant time is approximately equivalent to 1 to 2 years in humans for PCO development.[20]

Anesthesia, surgical preparation, and bilateral phacoemulsification with IOL implantation were performed as described in a previous study.[18] Briefly, a fornix-based conjunctival flap was fashioned. A corneoscleral incision was then made using a crescent blade, and a 3.0 mm keratome was used to enter the anterior chamber. A capsulorhexis forceps was used to create a well-centered continuous curvilinear capsulorhexis with a diameter of approximately 5.0 mm. After hydrodissection, the phacoemulsification handpiece (Alcon Infiniti System) was inserted into the posterior chamber for removal of the lens nucleus and cortical material. To each 500 mL of irrigating solution, 1.5 mL of epinephrine 1:1000 and 0.5 mL of heparin (10 000 USP units/mL) were added to facilitate pupil dilation and control inflammation. The residual cortex was then removed with the irrigation/aspiration handpiece. Sodium hyaluronate 1.6% ophthalmic viscosurgical device was used to expand the capsular bag. The IOLs were then delivered into the capsular bag using the corresponding recommended preloaded injection systems. The wound was closed with a 10-0 monofilament nylon suture after removal of the ophthalmic viscosurgical device using irrigation/aspiration. Postoperative topical therapy included a combination of neomycin–polymyxin B sulfates–dexamethasone ointment during the first postoperative week and prednisolone acetate drops during the second postoperative week.

The eyes were dilated and evaluated by slitlamp examination for ocular inflammatory response 1, 2, 3, and 4 weeks (±2 days) postoperatively. Clinical color photographs of each eye at each timepoint were obtained with a digital camera attached to the slitlamp. A standard scoring method in 11 categories was used at each examination, including assessment of corneal edema and the presence of cells and flare in the anterior chamber according to the previously described methods.[18] Anterior capsule opacification (ACO) and PCO were also evaluated at each timepoint and scored from Grade 0 to Grade 4. Retroillumination images with a fully dilated pupil were obtained for a photographic documentation.

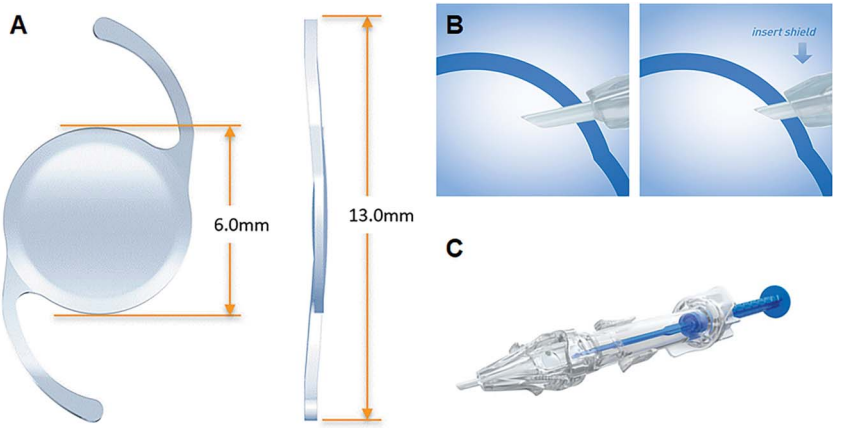

Figure 1. Schematic drawings. *A*: Design and dimensions of the 1-piece hydrophobic acrylic microincision IOL (Nanex, test IOL) used in this study. *B*: Position of the injector tip when the IOL is injected without using the insert shield (left) and with the insert shield (right). *C*: multiSert$^+$ disposable injection system (IOL = intraocular lens).

After the final clinical examination at 4 weeks, the animals were anesthetized and then killed humanely with a 1 mL intravenous injection of phenobarbital 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 the development of capsular bag opacification along with IOL fixation and centration. The extent and severity of capsular bag opacification were scored according to the methods established at the Intermountain Ocular Research Center, which include scoring of central and peripheral PCO and Soemmerring's ring formation.[18] 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

Overall, all surgical procedures were uneventful. All test and control IOLs could be fully injected within the bag or with a small maneuver with a collar button hook for complete in-the-bag fixation. All IOLs, test and control, were symmetrically fixated within the capsular bag and centered.

The slitlamp examination at 1 week postoperatively showed mild fibrin formation at the capsulorhexis edge or in front of the IOL in a majority of the test eyes and all of the control eyes, as well as a mild degree of aqueous cells in one of the control eyes. The above-mentioned findings essentially resolved by the week 2 examination. At this time point, mild amounts of PCO started to be observed in all test and control eyes. Starting at the 3 week examination, anterior proliferative pearl formation in front of the IOL optic in some eyes of both groups led to posterior synechia formation, without any statistically significant difference between the groups ($P = .35$ at week 4, 2-tailed t test: paired 2-sample for means). Mild giant-cell deposits started to be observed at the 3 week examination, without any statistically significant difference between test and control eyes until the end of the clinical follow-up ($P = .35$ at week 4).

PCO was scored as follows at the 4 week examination: 2.06 ± 0.97 in the test eyes and 2.25 ± 0.84 in the control eyes ($P = .47$) (Figure 2). It is noteworthy that the clinical assessment of PCO is limited to what can be observed behind the IOL optic, through the pupil. ACO was found to be mild in this study, scored 0 to 1. There was no statistically significant difference in ACO formation between test and control eyes at any time point.

Gross examination confirmed that all IOLs were symmetrically fixated within the capsular bag and centered. PCO formation was best assessed postmortem, through the posterior or Miyake-Apple view (Figure 3). The mean postmortem central PCO was 0.93 ± 0.73 in the test eyes and 1.19 ± 0.53 in the control eyes. When comparing central PCO between the 2 groups, the difference was not statistically significant ($P = .41$). The mean postmortem peripheral PCO was 1.75 ± 0.92 in the test group and 2.06 ± 0.77 in the control group, with no statistically significant difference in peripheral PCO between the 2 groups ($P = .35$). A power calculation of the postmortem central PCO was performed, with the parameters below:

1. Test group mean of central PCO score: 0.93;
2. Control group mean of central PCO score: 1.19;
3. Sample size of each group: 8 and 8;
4. Common standard deviation (SD) of the 2 groups (calculated based on each group's SD; test: 0.73; control: 0.53): = square root of ($[0.73^2 + 0.53^2]/2$) = 0.64;
5. Assumptions made: type 1 error, α: 0.05; 2-sided test.

The power was calculated using the web calculator (Rollin Brant, https://www.stat.ubc.ca/~rollin/stats/ssize/n2.html) was 0.13 for postmortem central PCO. Based on the same method, for peripheral PCO, the common SD was 0.85, and the calculated power was 0.11. There was a statistically higher degree of Soemmerring's ring formation ($P = .01$) in the control group.

Histopathologic evaluation did not show any substantial difference between the test and control eyes in terms of capsular bag opacification. There was no sign of untoward inflammation or toxicity in either group (Figure 4).

DISCUSSION

Despite the benefits of decreased surgical trauma and induced astigmatism, the development of MICS has been restricted by the challenges of creating an IOL that meets the demands of a small incision size without sacrificing the visual goals and PCO prevention achieved by standard IOLs.[1] The limits of IOL deformation and cartridge compressibility ultimately constrain the size of the incision.[2] Although microincision IOL designs have evolved from the hydrophilic acrylic plate-type styles to hydrophobic acrylic IOLs with open-loop haptics, higher PCO rates were demonstrated with these IOLs when compared with 3-piece and 1-piece standard hydrophobic acrylic IOLs.[3–7,15,21]

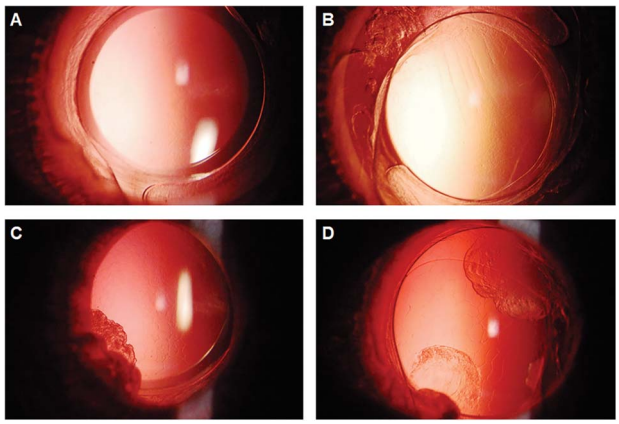

Figure 2. Clinical photographs of both eyes of 2 rabbits taken 3 weeks postoperatively. Right (*A*) and left (*B*) eyes of the same rabbit exhibiting overall a clear capsular bag. Right and left eyes of the same rabbit, with posterior capsule opacification starting at 1 optic–haptic junction in the test eye (*C*) and at both junctions in the control eye (*D*). Anterior proliferation of pearls can also be seen in both eyes.

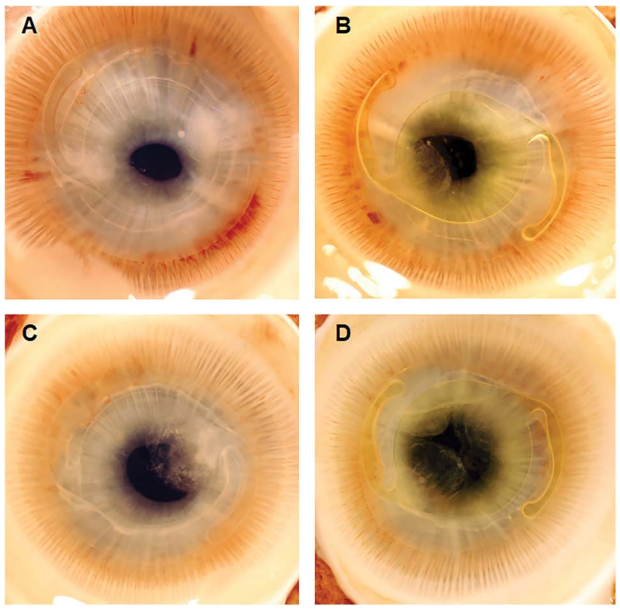

Figure 3. Postmortem Miyake-Apple view (4 weeks) of the anterior segment of test and control eyes from 2 rabbits. *A* and *C*: Right eyes with test IOLs. *B* and *D*: Left eyes with control IOLs. All 4 IOLs are centered and symmetrically fixated within the capsular bag. Posterior capsule opacification can be seen starting at the optic–haptic junctions (IOL = intraocular lens).

Preliminary studies demonstrated the effectiveness of an IOL surface modification with UV–O_3 or argon plasma treatment in preventing PCO formation.[17,18] These 2 techniques alter the adhesive property of the IOL with an increased adhesion of fibronectin and lens epithelial cells (LECs) to the treated surface, impeding further LEC migration and proliferation by increasing the attachment between the IOL and the capsular bag. However, argon plasma was found to be inferior to UV–O_3 treatment in preventing PCO and was associated with surface deterioration secondary to an etching effect.[17]

The possible mechanism of PCO prevention with UV–O_3 surface modification may be explained by the sandwich theory postulated by Linnola et al.[22–26] It states that a sandwich pattern of a bioadhesive IOL, LEC monolayer, and posterior capsule forms a seal that prevents further LEC proliferation. Fibronectin has been found to be the key player in the adhesion of a bioadhesive IOL to the capsular bag.[25,26] Active oxygen–processing treatment produces highly adhesive carboxyl groups on the IOL surface, thus improving its wettability and adhesion.[27–29] These carboxyl groups are particularly adhesive to fibronectin, likely allowing the formation of the sandwich pattern seal. Importantly, the UV-O_3–induced changes on the IOL surface do not compromise uveal biocompatibility or structural integrity.[17,18]

To our knowledge, this is the first study in which the active oxygen–processing treatment has been applied to the posterior surface of a preloaded hydrophobic acrylic microincision IOL. The overall design and dimensions of the Nanex multiSert^{+} are similar to those of conventional, open-looped 1-piece hydrophobic acrylic IOLs available in the market. However, the lens design with its material properties allows the lens to be compressed and injected through a cartridge with an outer tip diameter of 1.62 mm. The test IOL is manufactured from the same hydrophobic acrylic material of an IOL that has been commercially available for over 15 years (AF-1 IOL) but incorporating the posterior surface treatment. The eyes that received the test IOL exhibited comparable degrees of postoperative and postmortem PCO with the control eyes that received the commercially available IOL, AcrySof IQ.

A previous in vivo rabbit model study has already demonstrated that an UV-O_3–treated IOL significantly prevents PCO when compared with an identical untreated IOL.[18] The Vivinex IOL treatment platform used in that study is the predecessor to the Nanex microincision IOL investigated in this study. Another recent study with a graded culture human capsular bag model demonstrated that the Vivinex IOL (with UV–O_3 treatment on the posterior surface) had an overall better level of performance against postsurgical wound healing and PCO than the 1-piece AcrySof IOL.[30] We hypothesize that the enhanced adhesion of the test IOL in this study to protein, LECs, and the capsule was responsible to the comparable PCO performance of the microincision test IOL with the control conventional IOL, which is manufactured from a hydrophobic acrylic material with known adhesive properties.[25,26] Although attempts to improve the PCO performance of microincision IOLs through refinement of the square edged or implementation of open-loop haptics have been unable to meet the gold standard of the conventional IOLs, an UV-O_3–treated posterior surface appears to be the answer to the question of developing a hydrophobic acrylic microincision IOL with an equivalent PCO performance.[3,4,15]

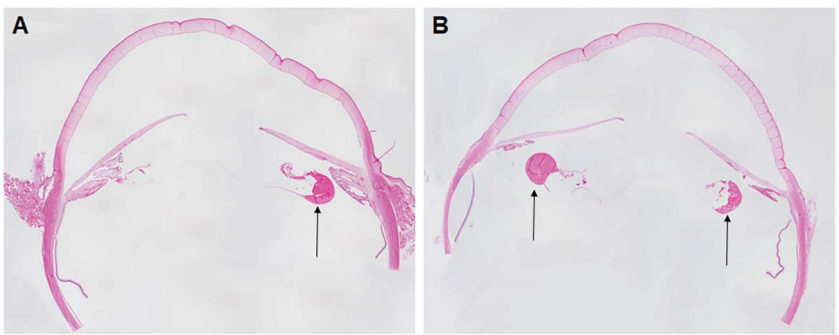

Figure 4. Light photomicrographs of histopathological sections cut from both eyes of the same rabbit. *A*: Right eye with the microincision IOL, showing cortical proliferation and Soemmerring's ring formation on 1 side of the section (*arrow*). *B*: Left eye with the control IOL showing cortical proliferation and Soemmerring's ring formation on both sides of the section (*arrows*). In both eyes, the central posterior capsule appears clear (*A* and *B*: composite light photomicrographs; hematoxylin–eosin staining; original magnification ×20) (IOL = intraocular lens).

Studies demonstrated that, when injector systems are used, the incision size for IOL implantation is largely determined by the outer diameter of the cartridge tip.[31–33] The test IOL in our study is preloaded in an injector, multiSert^{+}, with an outer tip diameter of 1.62 mm. Therefore, according to the manufacturer, the new preloaded system allows for the IOL insertion through an incision size as low as 1.8 mm (HOYA data on file). The preloaded system used in this study will likely allow surgeons to obtain small incisions using different insertion techniques, according to the preference of the surgeon.

Potential benefits associated with the use of preloaded injector systems include elimination of manual setting variability, avoidance of potential IOL loading errors and damages, shortened operation time, fewer surgical instruments, reduced surgical cost and complexity, and lower risk for instrument contamination with microorganisms as well as foreign bodies.[33] However, problems with injectors have also been described in the literature, including the need for intrawound manipulation, overriding of the plunger over the optic, and trauma to the IOL.[33,34] All incisions in this study were 3.0 mm incisions, and all IOL deliveries were done through a cartridge-insertion technique (Figure 1B, left). Incisions were not measured before and after IOL implantation, as evaluation of insertion techniques and incision size was not the objective of the study. However, all preloaded test IOLs could be delivered without any damage noted on their surfaces.

In summary, we have evaluated uveal biocompatibility and capsular bag opacification of a new hydrophobic acrylic microincision IOL in the rabbit eye for 4 weeks. The Nanex IOL, with a proprietary active oxygen–processing treatment on the posterior surface, showed noninferiority in prevention of postoperative capsular bag opacification when compared with a conventional, commercially available 1-piece hydrophobic acrylic IOL intended for a standard-sized incision. To our knowledge, this is the first in vivo study evaluating a hydrophobic acrylic microincision IOL and its ability to prevent postoperative capsular bag opacification in the rabbit model to show comparable PCO performance with a conventional posterior chamber IOL.

WHAT WAS KNOWN

- Despite its benefits, microincision cataract surgery has been limited because of higher rates of PCO with microincision intraocular lenses (IOLs), which have primarily been hydrophilic acrylic, plate-type IOLs.

WHAT THIS PAPER ADDS

- The new hydrophobic acrylic microincision IOL, Nanex, with an ultraviolet-ozone–treated posterior surface exhibited uveal and capsular biocompatibility similar to a commercially available conventional hydrophobic acrylic IOL in the rabbit model.

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