Manuscript title

Development of Open-Capsule Intraocular Lens for Preventing Posterior Capsule Opacification

Short running title

PCO Prevention by Open-Capsule IOL.

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ABSTRACT

PURPOSE: To develop a single-piece, open-capsule intraocular lens (IOL) insertable through a small incision, which prevents posterior capsule opacification (PCO) by expanding the capsule and circulating aqueous humor into the capsular bag.

SETTING: Department of Ophthalmology, Dokkyo Medical University, Tochigi, Japan.

DESIGN: Experimental study.

METHOD: Using the same hydrophobic acrylic material as NY-60 (HOYA), we constructed a prototype Open-Capsule IOL (hereafter referred to as OC-IOL) consisting of a general optic and two haptics, with a spacer 2.8 mm in height and holes that allow circulation of the aqueous humor into the capsular bag by separating the anterior capsule from the posterior capsule and expanding the capsule. The OC-IOL or NY-60 (as control group) was inserted into rabbit eyes. PCO development was evaluated by measuring the thickness of cell layer at the center of the posterior capsule on histological specimens, and compared statistically between the OC-IOL group and control group.

RESULTS: The OC-IOL could be inserted through a corneal incision of 3.2 mm using a D cartridge (HOYA Injector System). The thickness of the cell layer at the center of the posterior capsule was 4.78 ± 2.61 μm in the OC-IOL group and 101.14 ± 25.19 μm in the control group, and was significantly smaller in the OC-IOL group.

CONCLUSIONS: We succeeded to construct a prototype single-piece IOL insertable through a small incision, which prevents PCO by expanding the lens capsule and circulating aqueous humor into the capsular bag.

Posterior capsule opacification (PCO), referred to as secondary cataract, is a common postoperative complication in eyes implanted with intraocular lens (IOL), and is reported to occur in up to 39% of the eyes within 5 years after cataract surgery.[1, 2] The formation of PCO is related to wound healing reaction accompanying lens removal, lens regeneration reaction, and foreign body reaction accompanying IOL insertion. Irregular cell proliferation between the lens posterior capsule and IOL as well as production of extracellular matrix have been implicated as the causes of PCO.[3-5]

A strategy to prevent PCO is to select the appropriate material or to modify the design of the IOL. One of the useful IOL designs for preventing PCO formation is an IOL with square-edged optic. Because of the square edge, the posterior capsule forms a sharp bend after insertion of the IOL, which probably impedes the lens epithelial cells (LECs) that proliferate at the equator of the capsule from migrating to the posterior subcapsular surface, thus preventing PCO formation.[6-17] Numerous cases demonstrating the efficacy of this design in preventing PCO formation have been reported, but there are also reports that the effect decreases in the long term.[18-20]

Another strategy to prevent PCO is to implant IOL with a separate device into the lens capsular bag. The endocapsular equator ring prevents migration of LECs to the posterior capsule by the squared edge[21-27] and suppresses opacification of the proliferative tissue at the equator based on contact inhibition mechanism.[28] In vivo observation of a capsular bag containing an endocapsular equator ring and IOL showed that proliferative tissue was blocked by the ring under the anterior capsule at the equator, and the posterior lens capsule remained clear.[26] On the other hand, the capsular bending ring[29-31] prevents PCO by bending the capsule. This device also has a squared edge, and by forming capsular bending at the equator, the ring inhibits migration of residual LECs to the posterior lens capsule. The capsular adhesion-preventing ring which is made of silicone aims to prevent PCO by

circulating aqueous humor into the capsular bag.[32] Since TGF-β2 in aqueous humor is known to induce apoptosis of LEC[33] and suppress cell proliferation,[34, 35] this device is thought to prevent PCO by expanding the capsule and circulating the aqueous humor into the capsular bag. This concept suggests that it may be possible to maintain the transparency of the entire capsule by circulating aqueous humor into the capsular bag sufficiently. Recently, an intraocular open capsule device[36] and a disk-shaped IOL,[37] which are made of hydrophilic acrylic material and used the above PCO prevention strategy (hereinafter referred to as open-capsule strategy), were evaluated and good results were reported.

In this study, we designed an IOL made of hydrophobic acrylic focusing on the open-capsule strategy of expanding the lens capsule and circulating aqueous humor into the capsular bag. The usefulness of hydrophobic acrylic as an IOL material has been proven from clinical experience, and the availability of this material facilitates IOL development. We confirmed the PCO preventing effect of this IOL in an animal study.

MATERIALS AND METHODS

Design of the Open-capsule IOL (OC-IOL)

The shape and size of the prototype IOL (Open-capsule IOL; hereinafter referred to as OC-IOL) are shown in Figure 1. The IOL made of the same hydrophobic acrylic material as NY-60 (HOYA Corp. Medical Division, Tokyo, Japan) has a single optic 6.0 mm in diameter and two haptics. A spacer (2.8 mm in height and 0.5 mm in thickness) is made perpendicular to the edge of the back surface of the optic for separation of the anterior capsule from the posterior capsule. The optic is perforated with eight holes (each 0.55 mm in diameter) along a circumference with a radius of 1.75 mm from the center of the optic for perfusion of aqueous humor into the capsular bag. Eight grooves connecting these holes are made in the direction of the edge on the front surface of the optic. The spacer is divided into four parts by four

notches (2.0 mm in height and 1.0 mm in width) and each part has a hole 0.55 mm diameter. This design of the IOL allows the aqueous humor to circulate uniformly in the space of the capsular bag including the equator region. In addition, this bulky IOL can be folded in half by folding two parts of the spacer inwards and straightening the other two outwards, and can be inserted through a small incision using an injector system (Figure 2). The OC-IOL weighs 45.6 mg in air.

Animal experiment

All animal experiments were conducted according to the National Institutes of Health Guidelines on the Care and Use of Laboratory Animals in Research and in compliance with the tenets of the ARVO Statement for the Use of Animals in Ophthalmic and Vision Research.

Twelve 10-week-old female Japanese white rabbits weighing approximately 2.3 to 2.5 kg were used in the experiment. Anesthesia, surgical preparation, and bilateral phacoemulsification with IOL implantation were performed as described in previous basic studies.[38] All surgeries were performed by the same surgeon (H. M.). In six left or right eyes, which were chosen randomly, after making a corneal incision of 3.2 mm, a 5.5-mm diameter continuous curvilinear capsulorhexis was prepared, and the lens was extracted by phacoemulsification and aspiration. BSS Plus® supplemented with betamethasone sodium phosphate and sodium heparin was used as irrigating solution to facilitate pupil dilation and control inflammation. Residual cortex was removed by the irrigation/aspiration (I/A) technique. An ophthalmic viscosurgical device (OVD) was used to expand the capsular bag. The OC-IOL was inserted using a D cartridge of the HOYA injector system (HOYA Corp. Medical Division) (OC-IOL group). In the remaining six eyes, a 2.2-mm corneal incision was made, the lens was extracted and the capsular bag was expanded by the same methods as for the OC-IOL group, and then a NY-60 IOL made of hydrophobic acrylic material (same

material as OC-IOL) was inserted using a N18 cartridge of the HOYA injector system (Control group). The shape change and degree of damage of the incision wound after IOL insertion were similar in the two groups. The wound was closed with 10-0 monofilament nylon suture after removal of OVD material by I/A, and a fradiomycin sulfate–methylprednisolone ointment was administered. Dexamethasone, tropicamide and phenylephrine hydrochloride ophthalmic solution, levofloxacin, and bromfenac sodium ophthalmic solutions were instilled twice a day for 2 weeks after surgery.

At 1, 2, 4 weeks postoperatively, observation by slit lamp microscopy (Righton RS-1000; RIGHT MFG Co., Ltd., Tokyo, Japan) was performed after anesthesia and mydriasis. Thereafter, the rabbit was euthanized by an overdose of sodium pentobarbital injected into the ear vein, and the eyeball was removed. The eyeball was fixed in 10% formalin in 0.2 M phosphate buffer, dehydrated as appropriate, embedded in paraffin, and cut into thin sections. The sections were stained with hematoxylin and eosin (HE) and observed with a biological microscope (BX-51; Olympus Co., Tokyo, Japan). The tissue thickness at five locations per eye at the center of the posterior capsule was measured. The OC-IOL group and control group were compared statistically using t-test with a significance level of 0.05.

RESULTS

Observation of the anterior ocular segment with a slit lamp microscope and histopathological examination of tissue sections were performed at 4 week after surgery. The wide angle pathological specimens of OC-IOL–implanted eye and control eye are shown in Fig. 3. In the OC-IOL–implanted eye, the lens capsule was expanded by the spacer, and a space was formed between the posterior surface of the IOL optic and the posterior capsule. No rupture of the zonules of Zinn was detected.

Retro-illuminated images of the anterior segment are shown in Figs. 4 and 5. In the

control group, cells extending to the posterior subcapsular surface was observed in all eyes, and the cells reached the center of the posterior capsule in some eyes (Fig. 4). In the OC-IOL group, cells extending to the posterior subcapsular surface was not observed in any of the eyes (Fig. 5).

Histopathological findings in the vicinity of the optic edge or the spacer and at the center of the posterior capsule are also shown in Figs. 4 and 5. In most eyes of the control group, the posterior capsule bend that should have been formed at the optic edge was not observed, and cells migrated toward the center of the posterior capsule (Fig. 4). In the OC-IOL group, however, the posterior capsule was bent due to the spacer, and cell migration to the posterior subcapsular surface was not observed (Fig. 5).

The thickness of the LEC layer formed at the center of the posterior capsule in each specimen is also shown in Figs. 4 and 5. The average thickness was 4.78 ± 2.61 μm in the OC-IOL group compared with 101.14 ± 25.19 μm in the control group, and was significantly larger in the control group ($P = 0.020$).

DISCUSSION

Recently, strategy of PCO prevention by expanding the lens capsule and circulating aqueous humor into the capsular bag is garnering attention. The OC-IOL designed based on this strategy aims to prevent PCO by utilizing the LEC proliferation inhibiting effect of aqueous humor. In the present animal study using rabbit eyes, this IOL was insertable through a small incision and cell proliferation on the posterior capsule did not develop even at the time when cell proliferation on the posterior capsule was evident in the control group, in which an IOL made of the same material but with a conventional shape was inserted. This result suggests that the OC-IOL is effective in preventing PCO.

We designed the spacer at the back surface of the IOL. This shape facilitates insertion

through a small incision, since the spacer can be folded inward together with IOL optic (Figure 2B). The spacer of the prototype OC-IOL in this study was 2.8 mm in height in order to fully expand the capsule and ensure smoothly perfusion of aqueous humor. However, sufficient effect was obtained even with a spacer 1.5 to 2.0 mm in height in previous reports.[22-26, 32, 37] In addition, it has been reported that LEC migration from the endocapsular equator region to the posterior capsule can be inhibited even by smaller spacers.[22, 27] Although not found in the present study, if the spacer is too high, the equator becomes flattened and the risk of rupturing the zonules of Zinn increases. It is necessary to study the optimum spacer height and define contraindications for these devices.

Past reports have shown that the diameter of the capsule expanding device is also important. An over-sized device cannot be inserted inside the capsule, while an under-sized device may rotate inside the capsule with a risk of causing iris inflammation.[24, 25, 27] A report showed that histological confirmation that the anterior capsule and posterior capsule were separated and the anterior capsule was in contact with aqueous humor.[22] However, the anterior capsule developed opacification. This cause was suggested that was mechanical irritation of the tissue due to the size mismatch of the capsule and the device.[24, 25, 27] With the OC-IOL, not only the spacer but also two haptics play the role of expanding the capsule. This structure is useful to confer optimal capsule dilation and prevent excessive expansion of the capsule.

In previous reports, the weight of the senile crystalline lens was 230 mg[39] and the total weight of the standard 9.5-mm endocapsular equator ring and IOL was 34.2 mg.[26] The weight of the OC-IOL is 45.6 mg and is much lighter compared with the senile crystalline lens.

The OC-IOL had multiple holes because it is possible that the efficiency of directing aqueous humor to the capsule chamber may decrease when the holes connecting the anterior chamber and the posterior capsule are blocked by cell growth in the anterior capsule or

surrounding tissues. Therefore, this structure may cause optical problems such as dysphotopsia in clinical applications. It is possible to suppress the influence on visual function by adjusting the size and position of the holes, since a phakic IOL with a central hole 1.0 mm in diameter in the optic showed modulation transfer function (MTF) similar to that of a non-perforated phakic IOL in a previous study.[40] Further studies are needed to investigate the influence of the holes on MTF, and to verify the appropriate position, shape and size of the holes.

Previous studies have shown that the capsular adhesion-preventing ring made of soft silicone[32] and the disk-shaped IOL made of hydrophilic acrylic[36, 37] prevent PCO by utilizing the ability of aqueous humor to inhibit LEC proliferation. In this study, we developed an OC-IOL made of hydrophobic acrylic and confirmed its PCO suppressing effect based on same strategy. Because the behavior of LECs on the lens material is associated with the formation and prevention of capsular opacification including PCO,[41-47] the choice of IOL material is important for designing conventional IOLs that do not utilize the LEC proliferation inhibitory effect of aqueous humor. In contrast, IOL design that directs aqueous humor into the capsular bag may realize inhibition of PCO development independent of IOL material. If IOL materials can be selected freely, this may accelerate further development of high-performance IOL.

WHAT WAS KNOWN

Wide area of the posterior capsule is retained clear with the use of several endocapsular rings. Also, it became clear that direct contact of the capsule and the aqueous humor is effective.

WHAT THIS PAPER ADDS

We developed a single-piece IOL made of hydrophobic acrylic focusing on expanding the

lens capsule and circulating aqueous humor into the capsular bag. Using this IOL, we reconfirmed the efficacy of the continuous aqueous humor circulation in maintaining the postoperative entire capsule transparent.

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Figure Legends

Fig. 1.

Shape and size of the Open-Capsule IOL (OC-IOL). (A) the front view, (B) the lateral view when viewed from the direction of Z, (C) oblique view when viewed from the direction of Z.

Fig. 2.

By folding a pair of the spacers inwards and straightening the other pair of the spacers outward, OC-IOL can be inserted into the capsular bag using a D cartridge of the HOYA injector system.

Fig. 3.

The wide angle pathological specimens of the Open-Capsule intraocular lens (OC-IOL)–implanted eye (A) and control eye (B). The lens capsule is indicated by arrow. In the OC-IOL–implanted eye, the lens capsule is expanded by the spacer that separates the anterior capsule from the posterior capsule, and a space is formed between the posterior surface of the IOL optic and the posterior capsule. No rupture of the zonules of Zinn is observed.

Fig. 4.

Retro-illuminated photographs, histopathological micrographs, and thicknesses of cell layer at the center of posterior capsule of 6 eyes (A to F) in the control group, at 4 weeks after implantation. The contact part between the optic edge and the posterior capsule is indicated by arrow.

Fig. 5.

Retro-illuminated photographs, histopathological micrographs, and thicknesses of cell layer at the center of posterior capsule of 6 eyes (A’ to F’) implanted with the Open-capsule intraocular lens (OC-IOL), at 4 weeks after implantation. The contact part between the spacer and the posterior capsule is indicated by arrow.