Prevention of Posterior Capsule Opacification by an Intracapsular Open Capsule Device

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Purpose. To investigate the ability of an open capsule device to prevent posterior capsule opacification.

Methods. A total of 40 eyes of 20 New Zealand white rabbits were randomly divided into six similar groups of 6 to 7 eyes each. After crystalline lens evacuation, one control group (group A) was implanted with a hydrophilic acrylic intraocular lens and no device, and another control group (group B) was implanted with a hydrophobic acrylic intraocular lens and no device. The study groups were implanted with a hydrophilic acrylic intraocular lens and a hydrophilic acrylic device (group C), a hydrophobic acrylic intraocular lens and a hydrophilic acrylic device (group D), a hydrophilic acrylic intraocular lens and a hydrophobic acrylic device (group E), and a hydrophobic acrylic intraocular lens and a hydrophobic acrylic device (group F). The rabbits were monitored for the ensuing 6 weeks and then killed. The enucleated eyes were evaluated using the Miyake-Apple view, Matlab software analysis, and histology.

Results. The posterior capsule opacification score was significantly reduced in the eyes that were implanted with the tested device compared with the control eyes (clinical evaluation: 69% reduction, $P = 0.001$; the Miyake-Apple view analysis: 77% reduction, $P = 0.000$; histology: 75% reduction, $P = 0.000$). Soemmering's ring area was significantly reduced in the eyes implanted with the tested device compared with the control eyes (Matlab analysis: 80% reduction, $P = 0.000$).

Conclusions. The tested devices were effective in reducing posterior capsule opacification and Soemmering's ring formation.

Keywords: posterior capsule, opacification, prevention

Cataract surgery has undergone significant improvement in terms of surgical technique, instrumentation, and the quality of intraocular lenses (IOLs) over the past decades. Although the rate of posterior capsular opacification (PCO) has decreased, it is still the most common complication following uneventful cataract surgery, with the rate of laser capsulotomy ranging from 10% to 37%.[1–5] Nd:YAG capsulotomy is a highly successful treatment, but it is not free of complications, such as IOL pitting or dislocation of the IOL, macular edema, and retinal detachment.[1] PCO also places an economic burden on the health care system.[6] The importance of PCO prevention has increased in recent years, due to the expanding popularity of premium IOLs. Patients implanted with a premium IOL usually have high demands with regard to outcome, and PCO also can have an earlier effect on the performance of a premium IOL (i.e., multifocal IOLs).[7]

Previous attempts to prevent PCO have included investigations of various IOL materials and designs, surgical techniques, and pharmacological materials.[1] Unexpectedly lower PCO rates were recently noticed in eyes that were implanted with a special type of IOL, for example, the Synchrony IOL (AMO, Santa Ana, CA, USA)[8–10] and the FluidVision IOL (PowerVision, Belmont, CA, USA).[11] It was hypothesized that the capsular bag stayed open due to the special design of these IOLs, and that this should reduce the PCO rate. Based on this concept, a special open capsule device was designed for intracapsular implantation in an attempt to maintain the capsular bag open and to reduce PCO rate. The purpose of this study was to investigate the ability of this device to prevent PCO in an animal model.

Methods

The study experiment included 40 eyes of 20 New Zealand white rabbits that weighed 2.5 to 3.1 kg. All of the animals were obtained from an approved vendor in accordance with the requirements of the Animal Welfare Act. They were housed and cared for in Harlan Biotech Israel, Ltd. (Reovot, Israel), in accordance with guidelines set by ARVO, the Animal Welfare Act and the "Guide for the Care and Use of Laboratory Animals." The animals were quarantined for 7 days before study initiation. The study was approved by the Israel National Council for Animal Experimentation.

Each animal was prepared for surgery by pupil dilation with 1% cyclopentolate hydrochloride (Cyclogyl; Bausch & Lomb, Rochester, NY, USA) and 2.5% phenylephrine drops (AK-Dilate; Akorn, Lake Forest, IL, USA). Anesthesia was provided by an intramuscular injection of ketamine hydrochloride 35 mg/kg (Ketalar; Pfizer, New York, NY, USA), and xylazine hydrochloride 7 mg/kg (Rompun; Bayer, Leverkusen, Germany) in a

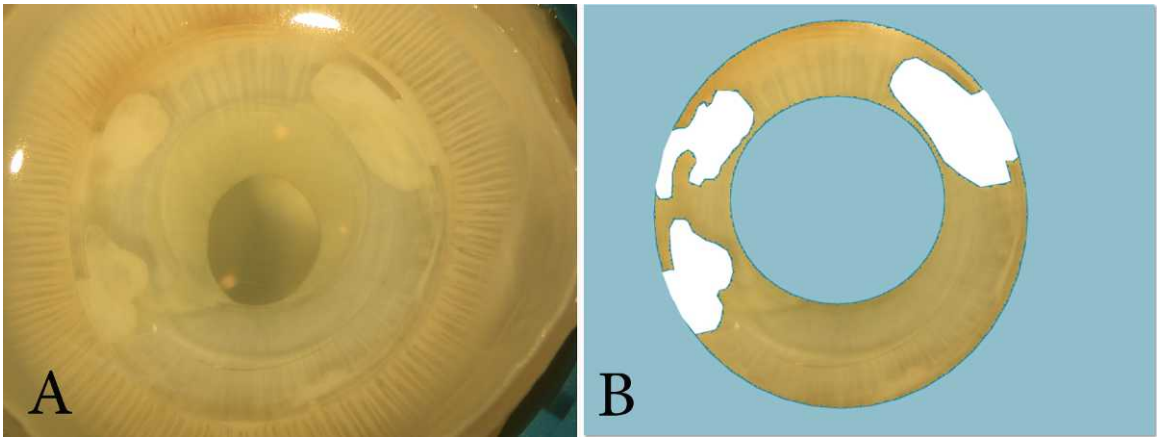

FIGURE 1. Example of manual marking of the Soemmering's ring area using the Matlab program (the central 6 mm is excluded). (**A**) Miyake-Apple posterior view. (**B**) Schematic illustration of manual marking corresponding to the Miyake-Apple posterior view.

mixture of 7:1, respectively. One drop of topical benoxinate hydrochloride anesthetic (Localin; Dr Fischer, Bnei-Brak, Israel) was applied to each eye before surgery. Eye movement and respiration were monitored intraoperatively, and supplemental anesthetics were given intramuscularly as needed.

After removal of the crystalline lens, the eyes were randomly divided into two control groups and four study groups. Group A (control) consisted of seven eyes implanted with a hydrophilic acrylic IOL (SeeLens AF; Hanita Lenses, Ltd., Hanita, Israel) and no device. Group B (control) consisted of seven eyes implanted with a hydrophobic acrylic IOL (Tecnis 1-piece IOLZCB00; AMO) and no device. Group C included six eyes implanted with a hydrophilic acrylic IOL and a hydrophilic acrylic device. Group D included six eyes implanted with a hydrophobic acrylic IOL and a hydrophilic acrylic device. Group E included seven eyes implanted with a hydrophilic acrylic IOL and a hydrophobic acrylic device. Group F included seven eyes implanted with a hydrophobic acrylic IOL and a hydrophobic acrylic device.

A combination of dexamethasone, neomycin sulphate, and polymyxin B sulphate eye drops (Maxitrol; Alcon, Fort Worth, TX, USA) was applied four times daily for the first 3 postoperative weeks. The postoperative follow-up included a weekly clinical slit-lamp examination of the anterior segment, including evaluation of the IOL, the device, and PCO scoring (PCO was graded between 0 and 4, where 0 = no PCO and 4 = severe PCO).

At the end of the study, the rabbits were given a 1.2 mL intramuscular injection of a 7:1 mixture of ketamine and xylazine, and euthanized with a 1 mL intravenous injection of pentobarbital sodium and phenytoin sodium (Euthasol Euthanasia solution; Virbac Animal Health, Inc., Ottawa, ON, Canada). The eyes were enucleated and placed first in Davidson's solution for 24 hours and then in 10% neutral buffered formalin for at least 48 hours. The eyes were bisected at the equator plane and photographed using the Miyake-Apple view for detecting visible abnormalities. They were analyzed for PCO scoring and underwent qualitative evaluation of Soemmering's ring formation by the Matlab program analysis (MatLab version R2013b; Mathworks, Natick, MA, USA). The area of Soemmering's ring in the Miyake-Apple view photograph was manually marked (the 6-mm central zone was excluded) and measured in mm^2, and the percentage of the posterior capsule that was covered with Soemmering's ring was determined (where 0% = no Soemmering's ring formation and 100% = the entire periphery of the capsule was covered with Soemmering's ring) (Fig. 1).

TABLE 1. Histologic Grading System for LEC Proliferation

Grade 0	No LECs on the posterior capsule
Grade 1	Minimal LEC proliferation in at least one location
Grade 2	Mild LEC proliferation in at least one location
Grade 3	Moderate LEC proliferation in at least one location
Grade 4	Ten or more layers of LEC in at least one location

Histology Evaluation

The bisected eyes were dehydrated, immersed in paraffin, sliced, and stained with hematoxylin and eosin (H&E). The histology evaluation was performed by a certified veterinarian pathologist for lens epithelial cell (LEC) proliferation (Table 1).

The Test Device

The test device (manufactured by Hanita Lenses, Hanita, Israel) was composed of a closed circular ring with a total diameter of 11 mm and a height of 1.5 mm, with windows in the ring's side wall. The edge of the ring was constructed according to a unique sharp-edge design (Fig. 2). The devices were manufactured from both hydrophilic and hydrophobic materials: the hydrophilic devices were implanted by means of an IOL injector (Softject 2.4-1P delivery system; Hanita Lenses), whereas the hydrophobic devices were implanted manually.

The IOLs

The two IOL designs used in this study were the SeeLens AF (Hanita Lenses) and the TECNIS one-piece IOLZCB00 (AMO). These IOLs share a similar design, with an overall diameter of 13 mm, an optic diameter of 6 mm, and a 360° square edge design, but SeeLens AF is made of acrylic hydrophilic material and TECNIS is made of acrylic hydrophobic material.

Statistical Analysis

The data are given as mean, SD, and median. Because the data were not normally distributed, we used the Mann-Whitney *U* nonparametric test for the evaluation of the study devices, as well as for comparison between the two control and four study groups. We used the Wilcoxon nonparametric test to evaluate the difference between the two IOLs (SeeLens AF and TECNIS) and the two devices (hydrophilic and hydrophobic). Fisher's

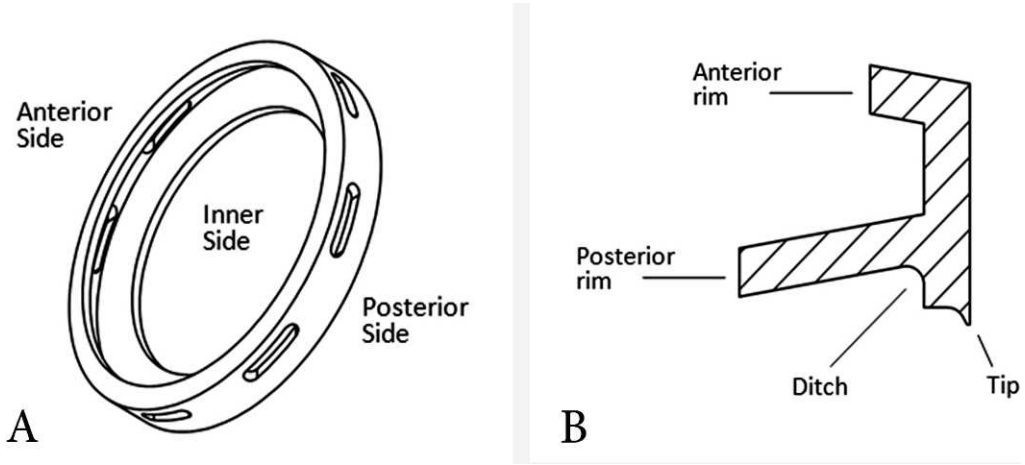

Figure 2. Schematic illustration of the test device structure. (**A**) Overview. (**B**) Side view.

exact test was used to evaluate the difference of the number of the "clear" capsules between the different groups. Differences were considered statistically significant when P was less than 0.05. All analyses were done with SPSS-21 software (IBM SPSS Statistics, IBM Corporation, Chicago, IL, USA).

Results

All the surgeries were uneventful except for one eye in group E in which excessive manipulation of the hydrophobic device during the implantation resulted in a suspected posterior capsule tear: the data on this rabbit were later excluded from analysis. The hydrophilic rings were easily implanted without any complications using the IOL injector. The implantation of the hydrophobic ring was found to be more difficult, because the side walls of the devices stuck to each other and required manipulation to open it.

All but three rabbits completed the follow-up time. One of them was killed at day 4 due to severe postoperative inflammation in one eye (right eye group B, left eye group A), another was killed at day 22 due to severe postoperative inflammation and corneal edema in both eyes (right eye group F, left eye group E), and the third was killed at day 29 due to weight loss (right eye group E, left eye group F). The data on those three rabbits were excluded from all the analyses. The final number of eyes that were available for all the analyses were six each in groups A to D (five eyes in group B were available for MatLab and histology analysis) and five each in groups E and F.

Slit-Lamp Evaluation

The capsular bags of 14 of 22 eyes in study groups C to F obtained an oval shape. The lens capsule was open in all the eyes implanted with the test device, in contrast to the eyes in the control groups in which the anterior capsule attached to

Table 2. Comparison of Clinical PCO Score at 6 Weeks After Surgery Between Control Eyes and Eyes That Were Implanted With the Intracapsular Open Capsule Device

Group	*n*	Mean	SD	Median	Range	*P* Value	PCO Decrease, %
Hydrophilic IOL							
A, control	6	2.8	1.3	3.25	0.5–4.0		
C, hydrophilic device	6	1.1	0.6	1.0	0.5–2.0	0.035	69
E, hydrophobic device	5	1.5	0.6	1.5	1.0–2.5	0.08	54
Hydrophobic IOL							
B, control	6	3.0	1.1	3.25	1.5–4.0		
D, hydrophilic device	6	0.8	0.5	0.75	0.0–1.5	0.005	77
F, hydrophobic device	5	1.2	0.4	1.0	1.0–2.0	0.011	69
Total							
A+B, 2 control groups	12	2.9	1.1	3.25	0.5–4.0		
C+D+E+F, 4 study groups	22	1.1	0.6	1.0	0.0–2.5	0.001	69

Table 3. Comparison of PCO Score of the Miyake-Apple View Evaluation Between Control Eyes and Eyes That Were Implanted With the Intracapsular Open Capsule Device

Group	*n*	Mean	SD	Median	Range	*P* Value	PCO Decrease, %
Hydrophilic IOL							
A, control	6	2.8	1.1	3.0	1.0–4.0		
C, hydrophilic device	6	0.6	0.6	0.5	0.0–1.5	0.008	83
E, hydrophobic device	5	0.7	0.7	1.0	0.0–1.5	0.016	67
Hydrophobic IOL							
B, control	6	3.1	1.2	3.5	1.0–4.0		
D, hydrophilic device	6	1.1	0.9	1.0	0.0–2.5	0.018	71
F, hydrophobic device	5	0.6	0.9	0.0	0.0–2.0	0.012	100
Total							
A+B, 2 control groups	12	2.9	1.1	3.25	1.0–4.0		
C+D+E+F, 4 study groups	22	0.8	0.7	0.75	0.0–2.5	0.000	77

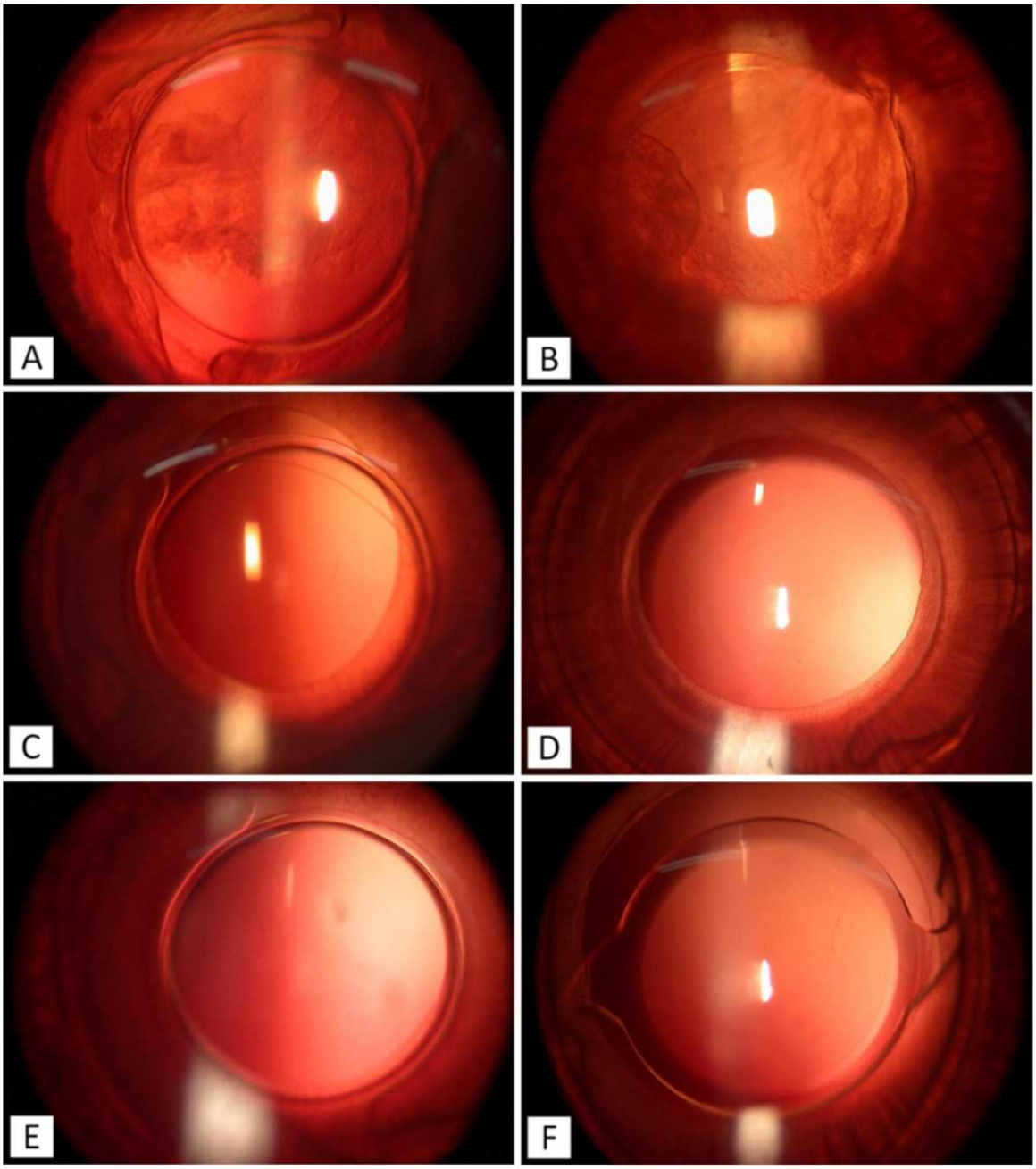

FIGURE 3. Clinical slit-lamp photograph of a sampled eye from each group at the 6-week follow-up examination demonstrating the difference between the posterior capsule opacification formation of the control eyes ([**A**]+[**B**]) and the study eyes ([**C**]+[**D**]+[**E**]+[**F**]). (**A**) Group A, (**B**) group B, (**C**) group C, (**D**) group D, (**E**) group E, and (**F**) group F.

the anterior aspect of the IOL optic. The PCO scoring in the four study groups at the final evaluation 6 weeks after the implantation was significantly lower than that of the two control groups (69% reduction of the PCO scoring, $P = 0.001$) (Table 2; Fig. 3). The difference in the PCO score between the two types of IOLs and the device materials was not significant.

Miyake-Apple View Evaluation

All The IOLs were well-centered in the capsular bag. The PCO scoring of the enucleated eyes demonstrated a significant reduction in PCO score in eyes that had been implanted with both types of the study devices and with both types of IOLs (a 77% reduction) compared with the control groups, $P = 0.000$ (Table 3; Fig. 4). The difference in the PCO score between the two types of IOLs and the device materials was not significant. The area of Soemmering's ring was smaller at the capsular bag periphery in the eyes of the study groups compared with the eyes of the control groups, and it was observed as being scattered in the study groups (Fig. 4).

Matlab Program Analysis

The coverage area of Soemmering's ring (both in mm^2 and in percentage of the area) in the four study groups' eyes was significantly lower than that of the two control groups (80% reduction in mm^2 and 81% reduction in percentage, $P = 0.000$ for both) (Table 4). The differences in the coverage area

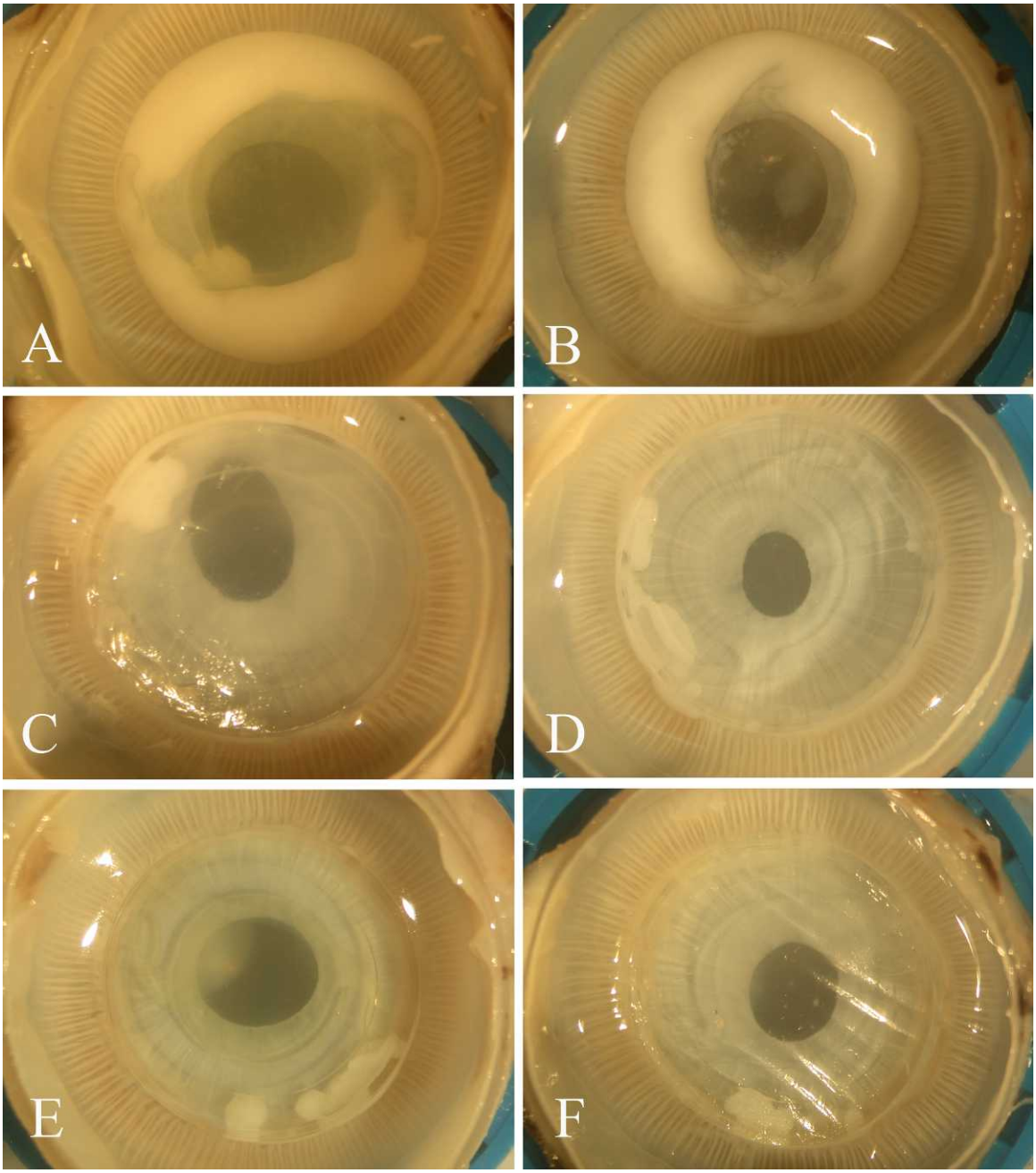

FIGURE 4. Miyake-Apple posterior view of a sampled eye from each group demonstrating the difference between the Soemmering's ring formation of the control eyes ([**A**]+[**B**]) and the study eyes ([**C**]+[**D**]+[**E**]+[**F**]). (**A**) Group A, (**B**) group B, (**C**) group C, (**D**) group D, (**E**) group E, (**F**) group F.

between the two types of IOLs and the device materials were not significant.

Histology Evaluation

The eyes in the four study groups demonstrated a total reduction of 75% of LEC proliferation score compared with the control groups, $P = 0.000$ (Table 5; Fig. 5). The difference in the LEC proliferation score between the two types of IOLs and the device materials was not significant.

Overall, there were significantly more eyes with "clear" capsules (graded 0 or 1) in the study groups' eyes than in the control groups' eyes both in the slit-lamp evaluation 6 weeks after the surgery and in the histology evaluation ($P = 0.001$ and $P < 0.0001$, respectively) (Table 6).

DISCUSSION

The results of our study suggest that implantation of an open capsule device has the potential to significantly reduce PCO formation after uneventful cataract surgery. The impact of these findings could be considerable because PCO is still a common event and one that constitutes a burden to the patient, the treating ophthalmologist, and the medical system, especially in the setting of premium IOLs. The many approaches that have been tried in the attempt to prevent PCO include pharmacological agents, such as catalin, metho-

Table 4. Comparison of Soemmering's Ring Area (in mm^2) and Percentage of Total Analyzed Area Using the Matlab Program Between Control Eyes and Eyes That Were Implanted With the Intracapsular Open Capsule Device

Group	*n*	Analysis	Mean	SD	Median	Range	*P* Value	Soemmering's Ring Decrease, %
Hydrophilic IOL								
A, control	6	mm^2	52.0	9.8	51.9	39.9–67.9		
		Percentage of area	91.7	6.2	91.5	84–100		
C, hydrophilic device	6	mm^2	10.1	6.5	10.5	0.95–18.6	0.004	80
		Percentage of area	17.8	11.6	20.5	2–34	0.004	78
E, hydrophobic device	5	mm^2	14.6	9.4	16.9	4.4–25.7	0.006	68
		Percentage of area	21.8	13.1	28.0	7–37	0.006	69
Hydrophobic IOL								
B, control	5	mm^2	51.9	8.0	50.5	45.1–64.3		
		Percentage of area	94.2	10.3	98.0	76–100		
D, hydrophilic device	6	mm^2	12.5	7.2	8.9	6.6–21.7	0.000	82
		Percentage of area	19.7	11.8	14.5	10–35	0.006	85
F, hydrophobic device	5	mm^2	11.0	10.7	6.9	0–24.3	0.006	86
		Percentage of area	15.0	13.4	11.0	0–30	0.006	89
Total								
A+B, 2 control groups	11	mm^2	52.0	8.6	50.5	39.9–67.9		
		Percentage of area	92.8	8.0	96.0	76–100		
C+D+E+F, 4 study groups	22	mm^2	12.0	8.0	9.9	0–25.7	0.000	80
		Percentage of area	18.6	11.8	18.0	0–37	0.000	81

trexate, and mitomycin; they were effective in preventing PCO, but they were toxic to the corneal endothelial cells, iris, ciliary body, and retina.[1,12,13] Maloof et al.[14] introduced a sealed capsule irrigation device (Perfect Capsule device; Milvella, Ltd., Sydney, Australia), which allows for a temporary seal of the capsulorrhexis after cataract extraction as well as selective irrigation of the capsular bag with a pharmacological agent, targeting only the residual LECs. Rabsilber et al.[15] investigated the device clinically using distilled water and demonstrated that the procedure is safe; however, long-term follow-up of the patients did not show significant PCO prevention. Hara et al.[16] were the first to suggest the concept of an intracapsular ring for preventing PCO. The authors hypothesized that the ring mechanically blocks the migration of the LECs that remained at the equator of the capsular bag. They also used a rabbit model and found that 70% of the eyes that were implanted with the ring had transparent posterior capsules after a mean follow-up of 3.5 months. They later reported a study with the equator ring in a monkey model in which they found that the ring maintained a circular capsule contour and posterior capsule transparency.[17] In 2007, the same group reported the results of the implantation of an endocapsular ring in a young human patient: They suggested that the ring retained capsular transparency throughout the 2-year postoperative follow-up.[18] In 2011, they published the results of a human clinical study using the equator ring, and demonstrated that the PCO score in the eyes that received the equator ring was significantly lower than that in the control eyes (4.4 vs. 11.4, respectively), and that no eyes that had been implanted with the equator ring required posterior capsulotomy compared with 45% of the control eyes.[19]

Table 5. Comparison of Histology Analysis Scoring of Lens Epithelial Cells Proliferation Between Control Eyes and Eyes That Were Implanted With the Intracapsular Open Capsule Device

Group	*n*	Mean	SD	Median	Range	*P* Value	PCO Decrease, %
Hydrophilic IOL							
A, control	6	2.2	0.4	2.0	2–3		
C, hydrophilic device	6	1.3	1.0	2.0	0–2	0.092	0
E, hydrophobic device	5	0.6	0.9	0.0	0–2	0.012	100
Hydrophobic IOL							
B, control	5	2.8	1.1	2.0	2–4		
D, hydrophilic device	6	0.7	1.0	0.0	0–2	0.018	100
F, hydrophobic device	5	0.6	0.6	1.0	0–1	0.007	50
Total							
A+B, 2 control groups	11	2.5	0.8	2.0	2–4		
C+D+E+F, 4 study groups	22	0.8	0.9	0.5	0–2	0.000	75

Nishi et al.[20,21] also developed a device for the prevention of PCO, which they termed the capsular bending ring. They implanted the ring in 60 human eyes and followed them for 2 years; the implantation of that ring resulted in a decrease in PCO formation (1.1 ± 0.3 in the control eyes versus 0.4 ± 0.25 in the tested eyes) and fibrosis of the anterior capsule (100% in the control eyes versus 30% in the tested eyes). Posterior capsulotomy was required in 4 of the tested eyes compared to 17 of the control eyes.[20,21]

Several reports regarding the Synchrony IOL (AMO) found a surprising low PCO rate.[8–10] It was suggested that the mechanism is related to the design of those IOLs, which creates a separation between the anterior and posterior capsules and expands the capsular bag.[22,23] These findings were later supported in a rabbit study using the FluidVision IOL (PowerVision)[11] and in studies using a new modified Zephyr IOL (Anew Optics, Inc., Newton, MA, USA).[22]

We developed an intracapsular device for the prevention of PCO. Our device is a ring that features several unique characteristics: a special square-edge design, a groove for IOL haptics fixation, "windows" that allow aqueous flow to the equator LECs, and a "roof" for anterior capsule lifting and support. Our study results yielded significant reduction in PCO

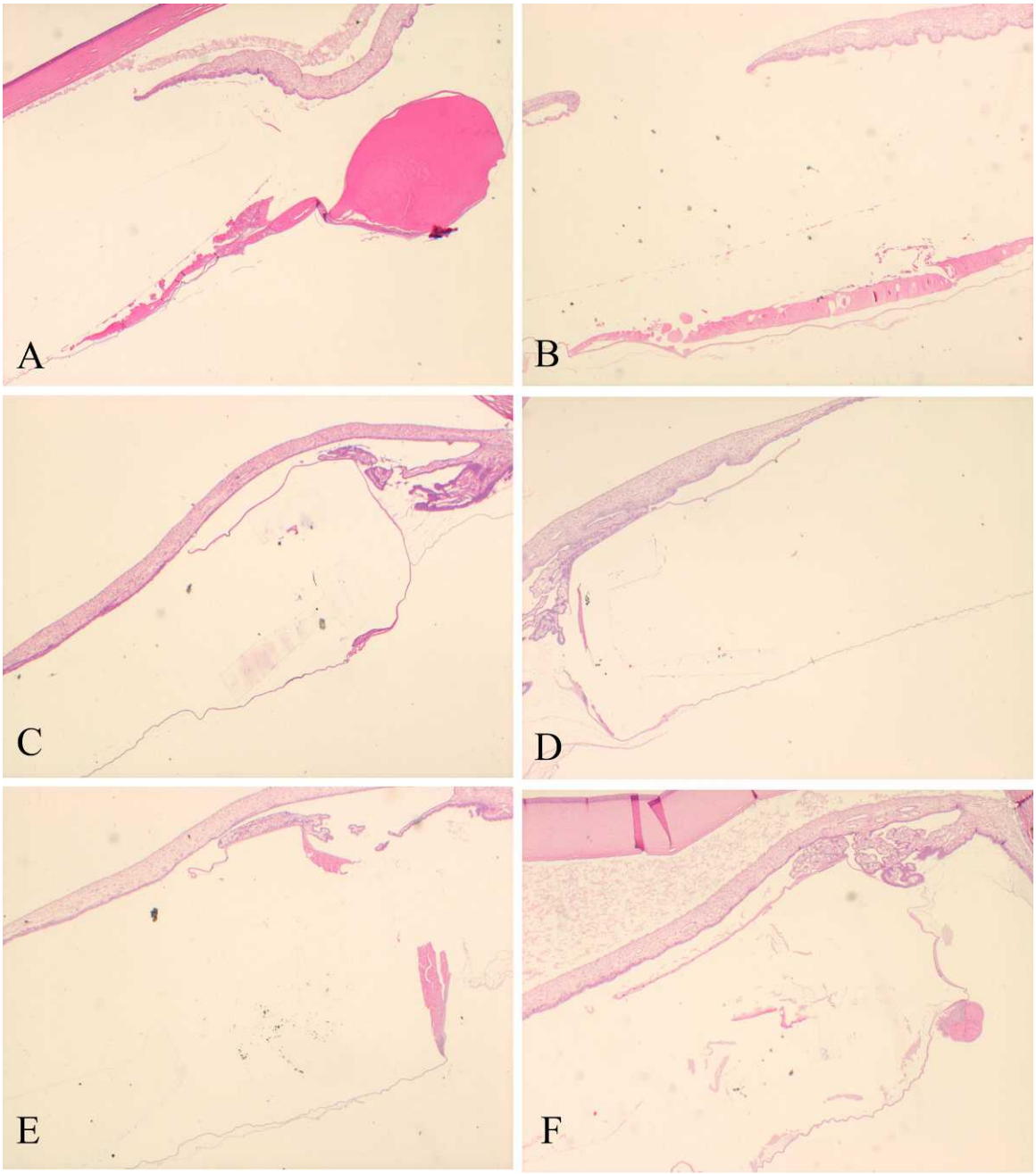

FIGURE 5. Light microscopy photographs of sampled eyes from each group demonstrating the difference of the lens epithelial cell proliferation of the control eyes ([A]+[B]) and the study eyes ([C]+[D]+[E]+[F]). (A) Group A, (B) group B, (C) group C, (D) group D, (E) group E, (F) group F (H&E stain, original magnification ×40).

scoring in all the tests that we conducted: specifically, clinical evaluation (69%), Miyake-Apple view analysis (77%), and histology (75%), and they were in agreement with each other.

The cells of Soemmering's ring are the precursors for PCO. The inhibition of Soemmering's ring formation (an 80% reduction), as demonstrated in the Miyake-Apple view and the Matlab analysis, suggests a primary prevention of PCO. The 360° unique square-edge design of the ring helps to keep the remaining epithelial cells at the equator area and serves as a second line of defense against PCO.

We tested devices that were manufactured from either hydrophilic acrylic or hydrophobic acrylic material with a combination of IOLs that were made of hydrophilic acrylic and hydrophobic acrylic materials to investigate the influence of different materials in the capsular bag. A low PCO score correlated only with the presence or lack of the device and not with a specific device or IOL material. One disadvantage of the hydrophobic device over the hydrophilic device was the manual manipulations required for its opening for proper location within the capsular bag.

The observation of the capsular bag's attaining an oval shape is probably a result of the device being too large (total diameter of 11 mm and height of 1.5 mm) for a rabbit's capsular bag.

The mechanism(s) by which PCO is prevented by our device is not clear. It is possible that it is linked to Hara et al.[16]

Table 6. Comparison of "Clear" Capsule Between the Control Eyes and the Eyes That Were Implanted With the Intracapsular Open Capsule Device ("Clear" Capsule Defined by PCO Grading of 0 to 1)

Group	Clinical Evaluation at 6 Weeks	*P* Value	Histology	*P* Value
Hydrophilic IOL				
A, control	1/6		0/6	
C, hydrophilic device	4/6	0.242	2/6	0.455
E, hydrophobic device	2/5	0.387	4/5	0.015
Hydrophobic IOL				
B, control	0/6		0/5	
D, hydrophilic device	5/6	0.015	4/6	0.061
F, hydrophobic device	4/5	0.015	5/5	0.008
Total				
A+B, 2 control groups	1/12		0/11	
C+D+E+F, 4 study groups	15/22	0.001	15/22	<0.0001

explanation of mechanical blockage or the explanation of the capsular bag's opening.[8–10,22,23] We suggest that our device's special design of having windows in its side walls also plays an important role. These windows allow aqueous humor flow to the equatorial LEC, thereby maintaining nutrition and oxygen supply to those cells. It is possible that the primary trigger for Soemmering's ring formation and the subsequent formation of PCO is a consequence of chronic ischemia and lack of nutrition of the equatorial LECs. Our hypothesis is supported by reports describing the prevention of LEC proliferation by $TGF\beta_2$, which is normally found in the aqueous humor.[1,24,25] Furthermore, Nishi et al.[26,27] reported that cytokines, such as IL-1, which are produced by LECs, stimulate processes such as mitosis and collagen synthesis by these cells. They suggested that constant irrigation by the aqueous humor may prevent certain cytokines involved in LEC's proliferation, such as IL-1, from reaching a threshold concentration level in the bag compartment.[28]

Kavoussi et al.[22] and Leishman et al.[23] recently reported their results of an experimental rabbit study of a new modified Zephyr IOL (Anew Optics, Inc.). This is a one-piece hydrophilic acrylic IOL suspended between two complete haptic rings connected by a pillar of the haptic material, which consists of haptic perforations between the peripheral rings. The design of this IOL also is able to keep the capsular bag in an open position. The 4-week PCO score was reported to be 0.0 in the study group and 1.75 in the control groups ($P = 0.005$).[23] In contrast to the modified zephyr IOL, our device allows the surgeon to implant any IOL while maintaining the PCO prevention features. A potential drawback of our device may be a risk for tilt or decentration of the IOL; this was not investigated in the current study and should be further explored. We recommend further research to investigate the mechanisms by which our device prevents PCO and to refine it for human use.

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