Influence of capsular tension ring on posterior capsule opacification in myopic eyes

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Purpose: To determine the effect of a capsular tension ring (CTR) implantation in preventing posterior capsular opacification (PCO) after cataract surgery in patients with high myopia. Materials and Methods: In this prospective single-surgeon standardized-surgical-procedure fellow-eye comparison trial, 34 patients with high myopia had phacoemulsification surgery. Although one eye received an acrylic intraocular lens (IOL) and CTR, other eye received only an IOL as control. PCO, within the capsulorhexis overlap, was documented by standardized digital retroillumination images at least 2 years post-operatively, and the percentage area of PCO was scored (scale 0%-100%) using the POCOman software system. The PCO score and the incidence of neodymium-doped yttrium aluminum garnet (Nd: YAG) capsulotomy of groups, and correlations between PCO score and presence of CTR, age, phaco time, refraction, and axial length (AL) were determined. Results: The mean time interval from surgery to PCO measurement was 43.4 ± 11.2 months for the eyes with a CTR and 43.1 ± 11.6 months for the controls (P = 0.91). The PCO score of the eyes with a CTR was significantly lower than in the controls $(5.9 \pm 4.3 \text{ vs. } 22.3 \pm 12.2, \text{ respectively; } P < 0.001)$. There were statistically insignificant correlations between PCO score and pre-operative refraction (r = 0.02; P = 0.90), AL (r = 0.03; P = 0.80), phaco time (r = 0.11; P = 0.53), and patient's age (r = 0.23; P = 0.55). No patient with a CTR had a Nd: YAG laser capsulotomy, but it was six in controls (P = 0.025). Conclusions: CTR implantation seems to be effective in reducing the PCO and Nd: YAG laser capsulotomy rates in high myopic eyes.



Key words: Capsular tension ring, cataract, intraocular lens, myopia, phacoemulsification, posterior capsular opacification

Posterior capsule opacification (PCO) still remains a common complication of the modern cataract surgery, and develops from residual lens epithelial cells (LECs) that undergo proliferation, migration, metaplasia, differentiation, and opacification in the capsular bag after cataract surgery.^[1-3] Various mechanical,^[4-7] physical,^[8-11] and immunological^[12] methods have been described to prevent PCO; however, no method has been reported as practical, effective, and safe in clinical practice. Neodymium-doped yttrium aluminum garnet laser capsulotomy is the treatment of PCO. Nd: YAG capsulotomy may carry a risk of sight-threatening complications such as cystoid macular edema and retinal detachment (RD) especially in myopic eyes.^[13-14] Thus, it is of great importance to prevent PCO especially in myopic eyes.

Capsular tension rings (CTRs) are intraocular implantation devices introduced by Legler and Witschel,^[15] and Nagamoto *et al.*^[16] to maintain post-operative capsular bag integrity and mainly to stabilize the capsular bag by reinforcing zonules in eyes with a weak zonular apparatus such as high myopia.^[17,18] CTRs may stretch the posterior capsule and prevent collapse of capsular bag resulting in reduction of distance between intraocular lens (IOL) and posterior lens capsule. This may create a mechanical barrier together with the use of square-edged IOLs that prevents LECs migration. So, CTRs may have some influence on PCO formation. There are several

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reports describing the effectiveness of CTRs in PCO prevention after cataract surgery.^[18-20] The aim of this study is to determine the influence of CTRs on PCO development in high myopic eyes after phacoemulsification surgery with IOL insertion.

Materials and Methods

Sixty myopic patients meeting the below-mentioned eligibility criteria and who were scheduled to undergo phacoemulsification surgery in both eyes at our hospital between July 2004 and July 2007 were enrolled in this non-randomized, prospective, fellow-eye controlled study. The study followed the tenets of the Declaration of Helsinki and was approved by the local institutional ethical committee. All participants provided written informed consent.

Although a hydrophobic acrylic IOL and a CTR were implanted in one eye (ring group), the contralateral eye of each patient received only a hydrophobic acrylic IOL but no ring (controls; no-ring group). Those with the following features were not included in the study; (1) Myopia less than 6.00 diopter (D) or axial length (AL) less than 25.0 mm, (2) the history of previous ocular surgery or inflammation, (3) ocular and systemic pathologies such as diabetes mellitus and retinitis pigmentosa, (4) intraocular pressure (IOP) higher than 20 mm Hg, (5) pseudoexfoliation syndrome, (6) retinal pathologies other than myopia related, and (7) eyes with a pupillary diameter less than 6 mm after full dilatation.

Routine eye examination including visual acuity, IOP measurement, and fundus evaluation was performed. ALs were measured using partial coherence interferometry (IOL Master, Carl Zeiss Meditec Inc., Jena, Germany). Patients were evaluated by a retinal specialist, who decided whether to perform prophylactic laser cerclage.

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All cases were operated under topical anesthesia by the same surgeon (F.M.M.) using the same surgical technique in both groups. It consisted of a no-stitch 3.2 mm clear corneal incision, side-port paracentesis, and continuous curvilinear capsulorhexis (CCC) of about 5-5.5 mm in diameter. A hydrophobic acrylic IOL with 13.0 mm haptic (MA60BM or MA60MA Alcon Surgical Inc., Fort Worth, TX, USA) and a poly (methyl methacrylate) CTR with 13.0 mm diameter (Lucid Korea, Korea) were implanted. All IOLs were folded longitudinally with a folder and holder, and inserted into the capsular bag. Patients had sequential surgery and the maximum time interval between the two eyes was 7 days.

Post-operatively, all patients were treated with topical ofloxacin (0.3%) and prednisolone acetate (1%) eye drops four times daily for a month. Patients were evaluated on post-operative days 1, 7, 14, and 30 if there was no complaint. All IOLs were confirmed to be implanted in the capsular bag using slit lamp biomicroscopy after full mydriasis at post-operative day 7.

Patients were invited to their last control at least 2 years after operation by mail or telephone. Patients with a complicated intra-operative or post-operative course, any residual cortex or opacities on lens capsule after operation, CCC failed to totally overlap the optic, patients having less than 2 years follow-up and who did not come as controls were excluded from the study.

Digital retroillumination photographs of the posterior capsule using a digital camera (Nikon D-100, Tokyo, Japan) mounted on a zoom-photo slit lamp (Nikon FS-3V, Japan) with an external light and flash light source at a fixed illumination and magnification were used to evaluate PCO with maximal pupillary dilation. PCO was evaluated by POCOman software system, which is a semi-quantitative software that quantifies PCO using a computerized sectorial overlay of the digital retroillumination image. The percentage area of PCO within capsulorhexis overlap was determined for each eye and was expressed as a score from 0% to 100%.[21]

Nd:YAG laser capsulotomy was performed in circumstances such as presence of a decrease in visual acuity which was attributed to PCO or presence of a visually significant central PCO, and the PCO score (percentage area) before this procedure was used for analysis. The number of the cases needed Nd:YAG laser posterior capsulotomy was also determined for each group.

The statistical package for the social sciences (SPSS 11.5 for Windows; SPSS Inc, Chicago, IL, USA) was used for statistical analysis. Results are given as mean ± standard deviation, median (min-max), and percentage. Student t-test and Mann-Whitney U test were used to compare continuous variables of the groups. The Chi-square test and Fisher's exact tests were used to compare categorical variables. Linear associations between variables were calculated with Pearson correlation analysis.

Results

Of the initially enrolled patients, one had undergone cataract surgery without a CTR implantation due to CCC tearing, six had a CCC failed to totally overlap the optic and 19 lost follow-up or refused the last examination were excluded from the study. Thus, 34 patients (56.7%) were eligible for clinical analysis. Two patients had laser cerclage for retinal pathologies before surgery. The mean IOL power used was + 5.57 ± 4.1 diopters (D) (range: -5.0 to +12.0 D).

The characteristics of the patients are shown in Table 1. No statistically significant difference existed between the two groups in pre-operative characteristics except visual acuity because both the eyes of the same patient were included in the study. The mean time interval from surgery to PCO measurement was 43.4 ± 11.2 months (range: 25-60) for the ring group and 43.1 ± 11.6 months (range: 24-60) for controls (P = 0.91).

PCO scores of groups

Five eyes (14.7%) in the ring group had no PCO; all eyes in the control group developed some amount of PCO [Table 2]. Although the PCO score was $5.9 \pm 4.3\%$ (median = 5.5%, min = 0%, max = 13.2%) in ring group, it was $22.3 \pm 12.2\%$ (median = 20.2%, min = 6.0%, max = 44.5%) in controls (*P* < 0.001).

AL and refraction PCO score

There was no significant correlation between PCO score and the actual pre-operative spherical power (r = 0.10, P = 0.50) or AL (r = 0.03, P = 0.81) of the eyes.

Age and PCO score

There was no significant correlation between the patient age and PCO score (r = 0.23, P = 0.55). Although the correlation was slightly weaker in the ring group (r = 0.33, P = 0.054), it was slightly stronger in controls (r = 0.34, P = 0.046).

Table 1: Pre-operative characteristics of patients					
Characteristics	Ring group*	Controls**	Р		
No. of patients	34	34			
Age (years)					
Mean±SD	55.7±10.1				
Range	42-71				
Gender (<i>n</i>)					
Male	25				
Female	9				
Pre-operative refraction [§] (D)					
Mean	-16.9±4.2	-15.5±4.4	0.196†		
Range	[(-9.75)-(-24.20)]	[(-7.50)-(-23.60)]		
Axial length (mm)					
Mean	28.8±1.8	28.9±1.6	0.599†		
Range	25.7-32.6	25.8-31.8			
Pre-operative VA (LogMAR)					
Mean	0.7±0.3	0.6±0.3	<0.001‡		
Median (min-max)	0.7 (0.0-1.0)	0.5 (0.1-1.0)			
*Ring group: IOL and CTR (+), **Controls: IOL (+) and CTR (–), [§] Spherical equivalent, SD: Standard deviation, D: Diopter, [†] Independent <i>t</i> -test, [‡] Mann–Whitney <i>U</i> -test, CTR: Capsular tension ring, VA: Visual acuity					

Table 2: Posterior capsular opacification in groups

Characteristic (%)	Ring group*	Controls**	Р
Nd:YAG capsulotomy [n]	0 (0)	6 (17.6)	0.025 [†]
Presence of PCO [n]	29 (85.3)	34 (100)	0.053†
PCO score	5.9±4.3	22.3±12.2	<0.001‡

*Ring group: CTR (+), **Controls: CTR (-),†Fisher's exact test, ‡Chi-square test, CTR: Capsular tension ring, PCO: Posterior capsular opacification

Eyes in the ring group had longer phaco times $(1.63 \pm 0.54 \text{ min}; \text{median}, 1.75; \text{ range}, 0.9-2.6)$ than controls $(1.07 \pm 0.64 \text{ min}; \text{median}, 0.9; \text{ range}, 0.2-2.5)$, but the difference was statistically insignificant (*P* = 0.07). Also, there was no correlation between phaco time and PCO score (*r* = 0.11, *P* = 0.534).

Nd: YAG laser capsulotomy

No eye needed a Nd: YAG laser capsulotomy in ring group, but it was six (17.6%) in controls (P = 0.025). The mean time to Nd: YAG capsulotomy was 34.2 months (range, 25-48).

Complications other than PCO

Deepening of anterior chamber due to zonular weakness was the most common intra-operative difficulty. A CTR could not be implanted in one eye due to capsular tearing. Six eyes had a CCC failed to totally overlap the optic. No RD was observed throughout the study.

Discussion

One eye of each patient had implantation of both a CTR and an IOL during phacoemulsification surgery, and the other eye with only IOL implantation served as control in this study. There has been no study until now comparing the PCO development in myopic eyes with and without CTR implantation on the same patient. Surgical techniques of both groups were mainly the same except for CTR implantation, and all cases were operated by a single experienced surgeon. IOLs used in both groups were produced by the same manufacturer and had the same optic properties such as hydrophobic acrylic optic with sharp-edged design that causes less PCO than the other IOLs do. We also excluded the cases with incomplete overlap of the anterior capsulorhexis on the IOL optic edge in both groups because of its contributory effect in PCO development. The data relating to age, gender, pre-operative refraction, AL, and follow-up times of both groups were also similar [Table 1]. There was a statistically significant difference of pre-operative LogMAR visual acuity between groups in this study. This difference might have been due to existence of myopia-related retinal pathologies or cataractous lens changes. CTR implantation was preferred in eyes with worse visual acuity to prevent a probable CTR-related intra-operative complication on the better eyes. This also explains why the ring group had worse visual acuity than controls pre-operatively. By standardizing parameters such as the characteristics of patients, surgeon, cataract extraction technique, and IOL type, we prospectively aimed to determine the influence of CTR implantation on PCO in high myopias.

Our study demonstrates that there is a significant difference in the percentage area of PCO score between groups. The percentage area of PCO alone does not indicate the need for treatment because the development of central PCO is more important in terms of visual axis obscuration. Therefore, we decided to compare the Nd:YAG laser rates between groups. The PCO score $(5.9 \pm 4.3\%)$ and the rate of Nd:YAG capsulotomy (0%) in the ring group were significantly low. Although five eyes had no PCO and no eyes needed Nd:YAG capsulotomy in the ring group, six eyes in controls had Nd:YAG capsulotomy and all developed PCO [Table 2]. These may be related to the implantation of

CTR in this study. CTR may mechanically compress the capsule, reduce the distance between IOL and capsular bag, inhibit LECs migrations, and reduce the development of PCO. There are also some studies describing the reduced incidence of PCO with the use of CTR.^[19,20] To prevent LEC migration and to minimize the risk of PCO development, Nishi and coauthors modified the capsular ring with the added feature of a square-edged design and reported that the capsular bending ring has a significant potential of preventing PCO formation.[22,23] If we had used Nishi's capsular bending ring (not in the market in our country), the PCO scores and the Nd:YAG capsulotomy rates would have been lower in this study. Hara et al.^[24] reported favorable results with a closed silicone ring to prevent PCO, and Menapace et al.^[25] recommended that a sharp-edged and circumferential capsular ring has the potential of fully preventing PCO. Recently, Hara et al.^[26] confirmed that a square-edged, closed endocapsular equator ring (E-ring) prevented PCO in human eyes, and the PCO value of the eyes with an E-ring was significantly lower than in the control eyes without an E-ring and no eyes with an E-ring needed Nd:YAG laser capsulotomy 2 years post-operatively. However, the authors reported increased flare with no iritis lasting at least 1 month post-operatively and patients with an E-ring had oral steroid therapy. It was also reported that E-ring implantation is contraindicated in eyes with disorders in the posterior capsule or Zinn ligaments because of ring dislocation risk. We preferred CTR in myopic eyes because of zonular instability, and no patient was prescribed systemic steroid in this study. However, myopic eyes with CTR showed lower PCO values and no eyes with a CTR required Nd:YAG laser posterior capsulotomy post-operatively in our study. Hoffer's idea^[27] of positioning a barrier at the posterior optic to prevent PCO seems to be important, and developing square-edged, closed endocapsular equator ring (s) with good capsular and uveal biocompatibility will

In this study, no significant correlation was found between pre-operative spherical power or AL of the eyes and the PCO scores throughout the follow-up period. Hayashi et al.[28] compared PCO values between low, moderate, and high myopic patients after phacoemulsification surgery and IOL implantation, and found no significant difference between highly, moderately, and slightly myopic eyes throughout the 2-year follow-up period. Also there was no association between the AL and the degree of PCO. In Hayashi's study, the degree of PCO and the rate of Nd: YAG capsulotomy in eyes with myopia were relatively low when compared to previous reports in pseudophakic eyes without myopia.[29,30] This might be attributed to the implantation of low-power or minus-power IOLs, especially acrylic IOLs with sharp optic edge in these eyes. Posterior chamber IOL implantation in high myopic eyes may influence PCO formation in contrast to the eyes without IOL implantation.^[28-31]

probably prevent PCO development in the future.

Consistent with our findings, Vasavada *et al.*^[32] reported that axial myopia does not significantly increase the area or incidence of PCO in myopic eyes 4 years post-operatively. No correlation (r = 0.11, P = 0.53) between phaco time and PCO was found in this study, and this indicates that phaco time has no influence on PCO development.

This study has some limitations. First, the drop-out rate of patients is high (n = 19, 43.3%). Second, the follow-up is relatively short, even though longer than previous studies. Third, the patients were older and there was no significant correlation between the patient age and the PCO rate. If we had operated younger patients, the degree of PCO and the rate of Nd:YAG laser capsulotomy would possibly have been higher. Fourth, this study used a subjective method (Nd:YAG rate) and a semi-quantitative software for the percentage area of PCO analysis rather than objective quantification method of assessment. Fifth, this is a fellow-eye controlled study but not randomized. We preferred to implant a CTR in eyes with worse visual acuity due to probable complications of CTR.

In conclusion, CTR implantation significantly decreases the percentage area of PCO and Nd:YAG laser capsulotomy rate, but it is unable to fully prevent it. Further, comparative studies with long-term follow-up should be conducted in order to reduce PCO development in pseudophakic eyes with high myopia. Even though CTR implantation is not routine in cataract surgery, its implantation should be considered in high myopic patients who have zonular instability and retinal pathologies posing risk for Nd:YAG capsulotomy.

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