Five-Year Cumulative Incidence and Risk Factors of Nd:YAG Capsulotomy in 10 044 Hydrophobic Acrylic 1-Piece and 3-Piece Intraocular Lenses

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• PURPOSE: To evaluate the 5-year cumulative incidence and risk factors of Nd:YAG capsulotomy between hydrophobic acrylic intraocular lenses (IOLs).

• DESIGN: A retrospective cohort study.

• METHODS: A review of the registry of operations between the years 2007 and 2016 was carried out at the Ophthalmology Unit of Kymenlaakso Central Hospital, Kotka, Finland. A total of 10 044 eyes having cataract surgery and in-the-bag implantation of ZCB00 (Abbott Medical Optics Johnson & Johnson Vision, Inc, Abbott Park, Illinois, USA), SN60WF (Alcon Laboratories, Inc, Fort Worth, Texas, USA), or ZA9003 (Abbott Medical Optics Johnson & Johnson Vision, Inc) IOLs were included in the study. The cumulative incidence of Nd:YAG capsulotomy was estimated with competing risks methodology. Competing risks regression modeling was used to evaluate potential risk factors, including the patient's age, sex, type of IOL, dioptric power of IOL, and operating surgeon's seniority.

• RESULTS: The 5-year cumulative incidence of Nd:YAG capsulotomy after cataract surgery was 13.2% (95% confidence interval [CI] 12.5%-14.0%) for all eyes and 18.1% (16.5%-20.0%), 11.5% (10.5%-12.6%), and 9.6% (8.2%-11.4%) for ZCB00, SN60WF, and ZA9003 IOLs, respectively. Implantation of SN60WF and ZA9003 IOLs was associated with a 38% and 47% subhazard reduction (SHR), respectively, compared to ZCB00, after accounting for other predictors (SHR = 0.62; 95% CI 0.54-0.71; $P < .001$ and SHR = 0.53; 95% CI 0.43-0.64; $P < .001$). Increased risk of Nd:YAG capsulotomy was associated with eyes of patients aged younger than 60 years, female sex, and eyes implanted with an IOL of <22.5 diopters power.

• CONCLUSION: Real-world evidence suggests that the cumulative incidence of Nd:YAG capsulotomy is significantly lower in eyes receiving SN60WF or ZA9003 IOLs compared to ZCB00. (Am J Ophthalmol 2019;200:218–223. © 2019 Elsevier Inc. All rights reserved.)

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POSTERIOR CAPSULAR OPACIFICATION (PCO) remains the most common long-term complication of cataract surgery despite advancements in surgical techniques and intraocular lenses (IOLs). The development of PCO takes from months up to a few years and the reported incidences vary widely between 1% and 50%.[1,2] The variation of the reported incidence numbers can be attributed to different definitions and treatment indications for PCO, patient population characteristics, surgical techniques, IOL design and materials, and the length of follow-up. The incidence of Nd:YAG capsulotomy is often used as an indirect measure for PCO in the clinical setting. Estimating the real-world long-term incidence of capsulotomy in elderly cataract surgery patients with standard survival analysis methods is complicated by the competing risk of death, which precludes the occurrence of the event of interest.[3,4]

The risk factors for PCO can be generally classified as related to the systemic or eye diseases of the patient, the surgical techniques during the cataract operation, or the properties of the implanted IOL. Recently, growing interest has emerged in studying and improving IOL biomaterials and haptic design to prevent PCO. Knowledge of the effects of IOL design on PCO is inconclusive except for the evidence on reduced risk associated with sharp-edged vs round-edged IOLs.[5]

The Nd:YAG capsulotomy procedure is generally very safe, but it is associated with a risk of IOL damage or luxation, increased intraocular pressure, cystic macular edema, and retinal detachment.[6] Considering the risks of laser treatment, morbidity related to PCO, and its economic burden to health services and society, preventive measures reducing the incidence of PCO and subsequent Nd:YAG capsulotomy are essential.

The aim of this study was to evaluate the real-world long-term cumulative incidence of Nd:YAG capsulotomy with competing risks methodology, comparing the 5-year results between common hydrophobic acrylic monofocal intraocular lenses.

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TABLE 1. Intraocular Lens Characteristics

IOL Model	ZCB00[a]	SN60WF[b]	ZA9003[a]
Optic material	Hydrophobic acrylic	Hydrophobic acrylic	Hydrophobic acrylic
Haptic material	Hydrophobic acrylic	Hydrophobic acrylic	Polymethylmethacrylate
Haptic design	1-piece	1-piece	3-piece
Posterior edge design	360 sharp	non-360 sharp	360 sharp
Optic diameter (mm)	6.0	6.0	6.0
Overall diameter (mm)	13.0	13.0	13.0
Haptic angulation (degree)	0	0	5
Refractive index	1.47	1.55	1.47

[a]Abbott Medical Optics Johnson & Johnson Vision, Inc, Abbott Park, Illinois, USA.
[b]Alcon Laboratories, Inc, Fort Worth, Texas, USA.

TABLE 2. Baseline Demographic and Surgical Characteristics

Variables	All Eyes (N = 10 044)	ZCB00 (N = 3787)	SN60WF (N = 4882)	ZA9003 (N = 1375)	*P* Value
Age (years)	75.0 ± 9.1	72.3 ± 9.6	77.1 ± 8.0	75.0 ± 9.3	<.001*
≥60 years	9379 (93.4)	3415 (90.2)	4695 (96.2)	1269 (92.3)	<.001*
Sex (female)	6393 (62.7)	2195 (58.0)	3246 (66.5)	862 (62.7)	<.001*
IOL power (diopters)	22.1 ± 2.9	22.0 ± 3.1	22.1 ± 2.8	22.2 ± 2.6	.073
Surgeon seniority	n = 9986	n = 3755	n = 4862	n = 1369	
Specialist	9459 (94.7)	3599 (95.9)	4558 (93.8)	1302 (95.1)	<.001*

IOL = intraocular lens.
Data are presented as mean ± SD for continuous variables and absolute numbers (with proportions) for categorical variables. For multiple group comparisons, continuous and normally distributed data (age, IOL power) were analyzed with the 1-way ANOVA F test, and categorical data (number of patients ≥60 years of age, sex, surgeon seniority) with the Pearson χ^2 test.
P values ≤ .05 were considered significant (indicated by asterisk).

METHODS

THIS STUDY WAS CARRIED OUT AS A RETROSPECTIVE cohort study at the Ophthalmology Unit of Kymenlaakso Central Hospital, Kotka, Finland. The study was approved by the Research Director and Chief Medical Officer of the Kymenlaakso Central Hospital and the tenets of the Declaration of Helsinki were followed. We reviewed the registry of operations for phacoemulsification cataract surgeries and Nd:YAG laser posterior capsulotomies between September 3, 2007 and September 15, 2016. All eyes having phacoemulsification surgery and in-the-bag implantation of ZCB00 (Abbott Medical Optics Johnson & Johnson Vision, Inc, Abbott Park, Illinois, USA), SN60WF (Alcon Laboratories, Inc, Fort Worth, Texas, USA), or ZA9003 (Abbott Medical Optics Johnson & Johnson Vision, Inc) IOLs were included in the study (Table 1). Indications for Nd:YAG capsulotomy were decreased corrected distance visual acuity and decreased visual function caused by PCO.

The cumulative incidence of Nd:YAG laser posterior capsulotomy was estimated with competing risks survival analysis. The event of interest was a record of Nd:YAG capsulotomy procedure and death was treated as a competing event. The length of follow-up for each eye was until 5 years after cataract surgery or until the end of the study period. Competing risks regression modeling, according to the method of Fine and Gray,[3] was used to evaluate the potential risk factors, including the patient's age, sex, type of IOL, dioptric power of IOL, and the operating surgeon's seniority. Only the first eye of each patient having cataract surgery was selected for inclusion and in case of simultaneous bilateral surgeries, 1 eye was selected at random. Statistical analysis was performed using Stata software (version 13.0; StataCorp, College Station, Texas, USA). The significance level was set at 5%.

RESULTS

A TOTAL OF 17 691 EYES UNDERWENT CATARACT SURGERY and 1959 Nd:YAG capsulotomies were carried out between

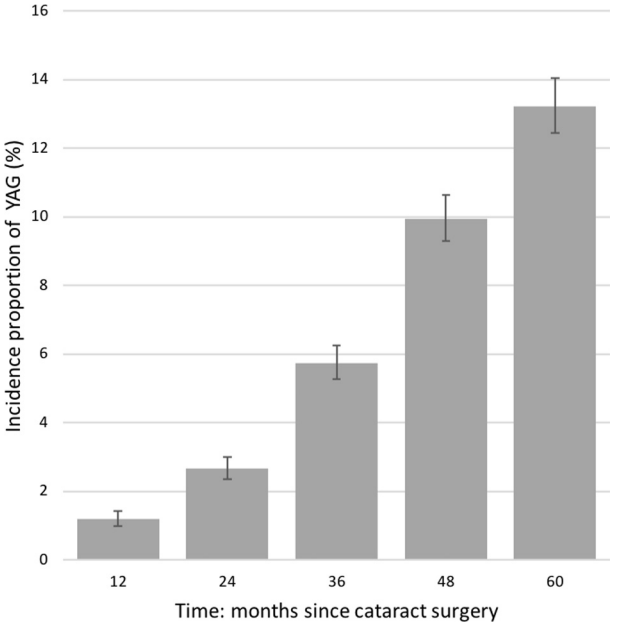

FIGURE 1. Cumulative incidence proportions of Nd:YAG capsulotomy after cataract surgery. The error bars indicate 95% confidence intervals of the estimates.

FIGURE 2. Cumulative incidence functions of Nd:YAG capsulotomy according to the type of implanted intraocular lens: ZCB00 (Abbott Medical Optics Johnson & Johnson Vision, Inc, Abbott Park, Illinois, USA), SN60WF (Alcon Laboratories, Inc, Fort Worth, Texas, USA), and ZA9003 (Abbott Medical Optics Johnson & Johnson Vision, Inc).

September 3, 2007 and September 15, 2016. In all, 10 044 eyes were included in the study according to the inclusion criteria and a total of 969 Nd:YAG laser posterior capsulotomies were performed on these eyes during the follow-up. Death as a competing event was recorded for 1753 eyes. The median duration of follow-up after surgery was 45 months. Baseline demographic and surgical characteristics for all eyes are listed in Table 2.

The overall cumulative incidence of Nd:YAG capsulotomy after cataract surgery was 1.2% (95% confidence interval [CI] 1.0%-1.4%) at 1 year, 2.7% (2.4%-3.0%) at 2 years, 5.7% (5.3%-6.3%) at 3 years, 10.0% (9.3%-10.6%) at 4 years, and 13.2% (12.5%-14.0%) at 5 years (Figure 1). The cumulative incidence functions according to the IOL types are shown in Figure 2. The incidence proportions of Nd:YAG capsulotomy at 1, 3, and 5 years were 1.8% (95% CI 1.4%-2.3%), 7.9% (95% CI 7.0%-8.9%), and 18.1% (95% CI 16.5%-20.0%) for ZCB00; 0.8% (95% CI 0.6%-1.1%), 4.8% (95% CI 4.1%-5.4%), and 11.5% (95% CI 10.5%-12.6%) for SN60WF and 1.0% (95% CI 0.6%-1.6%), 3.9% (95% CI 3.0%-5.1%), and 9.6% (95% CI 8.2%-11.4%) for ZA9003 (Supplemental Figure; Supplemental Material available at AJO.com).

Univariate and multivariate competing risks regression analysis of potential risk factors associated with Nd:YAG capsulotomy is shown in Table 3. Implantation of an SN60WF IOL was associated with a 38% reduction in the subhazard of Nd:YAG capsulotomy (subhazard reduction [SHR] = 0.62; 95% CI 0.54-0.71; $P < .001$) compared to ZCB00 after accounting for other predictors. Implantation of a ZA9003 IOL was associated with a 47% reduction in the subhazard of Nd:YAG capsulotomy (SHR = 0.53; 95% CI 0.43-0.64; $P < .001$) compared to ZCB00 after accounting for other predictors.

In subgroup analysis of patients aged ≥70 years (n = 7460), the implantation of SN60WF and ZA9003 IOLs was associated with a 36% and 50% subhazard reduction, respectively, compared to ZCB00 (SHR = 0.64; 95% CI 0.54-0.76; $P < .001$ and SHR = 0.50; 95% CI 0.39-0.65; $P < .001$). The mean ages of patients implanted with ZCB00, SN60WF, and ZA9003 IOLs in this subgroup were 78.5 ± 5.4, 79.7 ± 5.1, and 79.2 ± 5.1 years, respectively.

Increased risk of Nd:YAG capsulotomy was associated with patients younger than 60 years of age (SHR = 1.69; 95% CI 1.37-2.07; $P < .001$), female sex (SHR = 1.32; 95% CI 1.15-1.52; $P < .001$), and eyes implanted with an IOL of <22.5 diopters power (SHR = 1.19; 95% CI 1.05-1.35; $P = .007$). All risk factors that were statistically significant in the univariate analysis remained so also in the multivariate model.

DISCUSSION

THE RESULTS OF THE CURRENT STUDY SHOW A CONSISTENTLY increasing cumulative incidence of Nd:YAG capsulotomy within 5 years after cataract surgery. Our incidence numbers are considerably lower than those previously reported by Baratz and associates in 2001 (33% at 5 years),[7] Ando and associates in 2003 (32.7% at 5 years),[8] and

TABLE 3. Univariate and Multivariate Competing Risks Regression Analysis of Potential Risk Factors Associated With Nd:YAG Capsulotomy

	Univariate			Multivariate		
Risk Factor	SHR	95% CI	*P* Value	SHR	95% CI	*P* Value
Age (years)						
<60	1.73	1.41-2.12	<.001*	1.69	1.37-2.07	<.001*
≥60	Ref			Ref		
Sex						
Female	1.18	1.03-1.35	.016*	1.32	1.15-1.52	<.001*
Male	Ref			Ref		
IOL model						
SN60WF	0.62	0.54-0.71	<.001*	0.62	0.54-0.71	<.001*
ZA9003	0.53	0.43-0.65	<.001*	0.53	0.43-0.64	<.001*
ZCB00	Ref			Ref		
IOL power (diopters)						
<22.5	1.16	1.02-1.31	.023*	1.19	1.05-1.35	.007*
≥22.5	Ref			Ref		
Surgeon						
Specialist	1.22	0.87-1.70	.245			
Resident	Ref					

IOL = intraocular lens; Ref = reference category; SHR = subhazard ratio.

Significant variables on univariate analysis were included in the final multivariate model. *P* values ≤ .05 were considered significant (indicated by asterisk).

Elgohary and associates in 2006 (28.6% at 4 years),[9] reflecting the evolution of surgical techniques and IOLs. However, some previous studies may have overestimated the real-world incidence of Nd:YAG capsulotomy with standard survival analysis methods. Death as a competing event should be considered when evaluating long-term time-to-event outcomes in aging populations. A recent study assessing the incidence of Nd:YAG capsulotomy with different acrylic IOL materials, which excluded patients who died during their follow-up, reported a similar overall incidence of 6.4% at 3 years postoperatively.[10]

This study also demonstrated noticeable differences between common hydrophobic acrylic IOLs, which can be attributed to the effects of IOL design or biomaterial composition. The 1-piece IOLs with foldable haptics are currently the most popular lens design owing, for the most part, to the fact that they are easier to implant during surgery. Our results show significantly lower cumulative probability of Nd:YAG capsulotomy in eyes implanted with a 3-piece ZA9003 IOL compared to a 1-piece ZCB00 IOL. Both of these hydrophobic acrylic IOLs have a 360 squared posterior edge. A Cochrane meta-analysis of 66 prospective randomized controlled trials assessing the effect of different interventions on PCO found no difference between 1- and 3-piece IOLs.[5] Nevertheless, some studies have reported higher risk of PCO or Nd:YAG capsulotomy associated with 1-piece design.[11–13] The thin haptics of 3-piece IOLs may enable a more uniform fusion between the anterior and posterior capsules. The bulky size of the 1-piece lens haptic may prevent this "shrink wrap" effect.[14] It has also been suggested that the barrier effect to migration of lens epithelial cells (LEC) may be compromised in the region of the haptic-optic junction of 1-piece IOLs because the bulkier nonangulated haptic may prevent bending of the posterior capsule at this site.[15]

In addition to the design and haptics of hydrophobic acrylic IOLs, the differences between biomaterials can affect LECs migration and PCO rate. In this study we observed a significantly lower cumulative incidence of Nd:YAG capsulotomy in eyes implanted with an SN60WF IOL compared to a ZCB00 IOL. Both of these hydrophobic acrylic IOLs have 1-piece design. The posterior square edge of the SN60WF lens is interrupted at the haptic-optic junction, which may facilitate LEC migration and increase the PCO, but the opposite result of our study favoring SN60WF may support higher biocompatibility of the SN60WF lens material. The surface properties of the IOL biomaterial also affect its adhesion to the capsular bag through interactions with extracellular matrix proteins, especially with fibronectin.[16] The fibronectin binding properties of SN60WF were higher than other IOL materials tested in an in vitro study, but the difference was not statistically significant compared to ZCB00.[17] However, the favorable results of SN60WF compared to ZCB00 cannot be attributed only to biomaterial properties. Biomechanical behavior such as the lower haptic compression force to the capsular bag, which should enable better

maintenance of the capsular bag shape with less ovaling and stretching, may contribute to the lower risk associated with the SN60WF IOL.[18,19] The edge of the SN60WF lens optic is also slightly sharper compared to ZCB00 measured with scanning electron microscopy as a deviation from an ideal square.[20]

Regarding other potential risk factors associated with Nd:YAG capsulotomy, the eyes of younger patients, women, and those implanted with an IOL of <22.5 diopters power were at increased risk. Retained LECs after surgery appear more proliferative in the eyes of younger patients, which may explain their increased risk.[21] Younger patients may also have a greater need for sharp vision because of more demanding visual tasks such as driving. The mean age of the patients was highest among patients implanted with an SN60WF IOL, but this did not seem to confound the effect of IOL on risk of capsulotomy because the results were similar in the subgroup analysis of patients aged ≥70 years. The age of the patients was also one of the factors accounted for in the multivariate analysis. SN60WF IOLs may have been more commonly implanted for patients with age-related macular degeneration because of the blue light filtration properties of the IOL. The effect of this imbalance on capsulotomy rate is difficult to estimate because, on one hand, these patients may have lower visual demand in terms of central vision, but on the other hand they are probably more frequently monitored and capsulotomy also improves fundus imaging quality. The higher incidence among women has been explained by the differences between sex attitudes toward seeking medical care and concerning health problems.[8] The lower risk associated with lower-power IOLs could be explained with myopia and increased axial length of the eye, but controversy remains as to whether myopia is related to incidence of PCO.[22,23] However, the postoperative capsular adhesion has been found to be weaker in highly axially myopic eyes compared to emmetropic eyes because of relatively larger capsular bags and thinner implanted IOLs in myopic eyes, which may facilitate LEC migration and PCO formation.[24]

The present study has several strengths and limitations. The strengths of the study are the large sample size and the longitudinal design with a sufficient length of follow-up. Competing risks methodology should estimate the cumulative incidences more accurately than Kaplan-Meier estimates. The study included some of the most commonly used IOLs, several surgeons with varying degrees of experience, and the demographic characteristics of the study population correspond to the source population of cataract surgery patients in the hospital district. Thus, the results of this study offer real-world clinical practice evidence.

Some limitations should be considered when interpreting the findings. The retrospective design of the study sets limitations to the quality of data and allows potential for unknown confounding factors. The completeness of follow-up cannot be ascertained because individuals may have moved out of the region. Some cataract surgery patients may have received their subsequent Nd:YAG capsulotomy not at the hospital clinic but somewhere else, leading to small underestimation of the cumulative incidences. However, this number should not be significant, considering the national healthcare system financing, physician practice patterns, and the availability of medical services in the region. The single-center study design limits our ability to generalize our findings to other clinical and geographic settings, but avoids bias associated with the heterogeneity of the indications for Nd:YAG capsulotomy in multicenter studies. Nd:YAG capsulotomy is an indirect measure for PCO and, as such, an imprecise measure of the condition reflecting also local treatment practices and patient healthcare-seeking behavior, but nevertheless provides a functional indicator of morbidity related to PCO.

In conclusion, the results of this study showed significant differences in Nd:YAG capsulotomy incidence between common hydrophobic IOLs, which can be attributed to the effects of IOL design and biomaterial composition. The 5-year real-world results of this study provide evidence that the incidence of PCO and subsequent Nd:YAG capsulotomy is declining with advancements in modern cataract surgery.

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