

Five-Year Incidence of Nd:YAG Capsulotomy After Cataract Surgery with Different Single-Piece Monofocal Intraocular Lenses: A Follow-Up Study of 3955 Eyes

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Purpose: To estimate the incidence of neodymium-doped yttrium aluminum garnet laser (Nd:YAG) capsulotomy up to five years after cataract surgery with different single-piece acrylic monofocal IOLs in a Spanish cohort.

Patients and Methods: Data were extracted from electronic medical records. Eligible participants were aged ≥ 65 , had cataract surgery with one of five different acrylic monofocal IOLs (Alcon AcrySof, AJL LLASY60, Medicontur Bi-flex, IOL Tech Stabibag and Zeiss Asphina), and more than six months baseline data. Participants were followed up to five years from surgery and up to six months from Nd:YAG. The incidence of Nd:YAG was compared between the IOLs and multivariate analyses were conducted to identify predictors of Nd:YAG incidence at five-years after cataract surgery.

Results: The initial cohort included 9545 patients with 14,519 eyes (53% female, average age 75 years). Of those, 3955 eyes were available for analysis five years after cataract surgery. Throughout the five years post-surgery, Nd:YAG incidence was consistently lower with Alcon AcrySof IOLs than the other IOLs. At five years the Nd:YAG incidence rate for Alcon AcrySof was 8.8%. In comparison, the incidence was 47.4% for AJL LLASY60 (OR = 9.54, 95% CI [6.57, 13.84]), 44.3% for Zeiss Asphina (OR = 8.35, 95% CI [5.85, 11.94]) and 44.0% for IOL Tech Stabibag (OR = 8.02, 95% CI [4.60, 13.84]).

Conclusion: Alcon AcrySof IOLs have a consistently lower risk of Nd:YAG incidence over a long follow-up period after cataract surgery, highlighting the importance of IOL choice for patients' long-term outcomes.

Keywords: Nd:YAG, long-term outcome, monofocal IOLs, real-world evidence

Introduction

Posterior Capsule Opacification (PCO) is the most common post-operative complication of cataract surgery.^{1,2} Neodymium-doped yttrium aluminum garnet (Nd:YAG) laser capsulotomy is a very effective surgical method to treat PCO. However, the procedure and possible associated complications can incur additional burden to patients and additional costs to the health care systems.^{3,4}

To develop effective strategies that reduce the incidence of PCO and the subsequent Nd:YAG capsulotomy, prior studies have examined the association of the potential related factors, such as IOLs material and design with the incidence rate of Nd:YAG capsulotomy.⁵ Our own recent work in a Spanish Cohort⁶ and previous real-world evidence (RWE) studies from Scandinavia and the UK demonstrated that IOL choice plays an important role in the incidence of Nd:YAG over shorter time frames up to four years.^{7–12} However, RWE on the incidence of Nd:YAG with a longer-term follow-up of over five years is still limited.^{13,14} This is crucial because prior evidence indicates that the incidence of Nd:YAG tends to increase over time post cataract surgery.¹⁴ Thus, further research is warranted to understand the long-term

incidence of Nd:YAG and related factors and to estimate the disease burden across different patient populations and healthcare systems.

Extending our previous three-year follow-up analysis of a large Spanish cohort,⁶ this study set out to investigate the incidence of Nd:YAG capsulotomy procedure rates over five years after cataract surgery for eyes implanted with different IOLs (Alcon AcrySof, AJL LLASY60, Medicontur Bi-flex, IOL Tech Stabibag and Zeiss Asphina) to evaluate predictors of the five-year Nd:YAG incidence.

Materials and Methods

Study Design and Data Source

Details about the design of this retrospective observational cohort study have previously been published elsewhere.⁶ The data were extracted from electronic medical records (EMR) of two regional hospitals captured in Ribera Salud's FLORENCE database. The EMRs for patients who had cataract surgery with five different IOLs included information on intra- and post- Nd:YAG capsulotomy procedure complications and were fully anonymised according to the Spanish data protection rules governing use of patient-level healthcare data (as defined by the EU General Data Protection Regulation of 25th May 2018). The study protocol has been approved by the Institutional Ethics Review Board of Ribera Salud, which at the time of study execution encompassed the Hospital Universitario de Torrevieja and Hospital Universitario del Vinalopó.

Study Population

Eye-level data of all eyes that had undergone cataract surgery recorded between November 2006 to June 2019 and that had detailed information about the utilized IOLs was included. The index period was defined between January 2007 to December 2017. The date of cataract surgery for each eye operated at the eye level during this time was defined as the index date. Here we report data of study participants who were followed up for five years from index to capture Nd:YAG capsulotomy events. Furthermore, they were also followed for up to six months to assess subsequent complications related to Nd:YAG capsulotomy event (for further details see Belda et al, 2021).⁶ In brief, included eyes had a cataract surgery within the study index period, with at least six months baseline data available before surgery, a record of in-the-bag IOL placement during surgery and recorded details of the IOL (manufacturer, material property) implanted in surgery and were aged ≥ 65 at cataract surgery. Exclusion criteria were any co-surgeries or Nd:YAG capsulotomy procedures within six months before or during cataract surgery, implant of any multi-piece or multi-focal IOLs, IOLs used in less than 100 surgeries in the initial cohort, any unknown eye laterality of the cataract surgery or Nd:YAG capsulotomy procedure, or a second or more cataract surgery on the same eye. Population selection and attrition for eyes is shown in [Figure 1](#). We completed the five-year follow-up for 3955 eyes (Alcon AcrySof = 396, AJL LLASY = 897, IOL Tech Stabibag = 84, and Zeiss Asphina = 2578).

Data Extraction

Variables gender, age at cataract surgery, number of eyes operated, year of cataract surgery, ocular co-pathologies (including glaucoma, diabetic retinopathy, high myopia, uveitis and retinal detachment), manufacturer/brand of IOL (for further details see Belda et al, 2021),⁶ Nd:YAG capsulotomy and intra-/post-Nd:YAG capsulotomy procedure complications were extracted. System wide Ribera Salud proprietary procedure codes, procedure descriptors and International Classification of Disease-10 diagnosis codes were used to code the data.¹⁵ Data for the Medicontur Bi-flex IOL was available until four years after cataract surgery.

Statistical Analysis

The analysis was conducted using SAS software version 9.4. We present the total number and percentage of eyes and patients included and report results stratified by IOL type. The incidence rate of eyes receiving Nd:YAG following cataract surgery at each follow-up year is reported by IOL type. Only for Medicontur there was no data available in the fifth year. Multivariate logistic regression was applied to compute adjusted odds ratios (OR) with 95% CIs to compare the

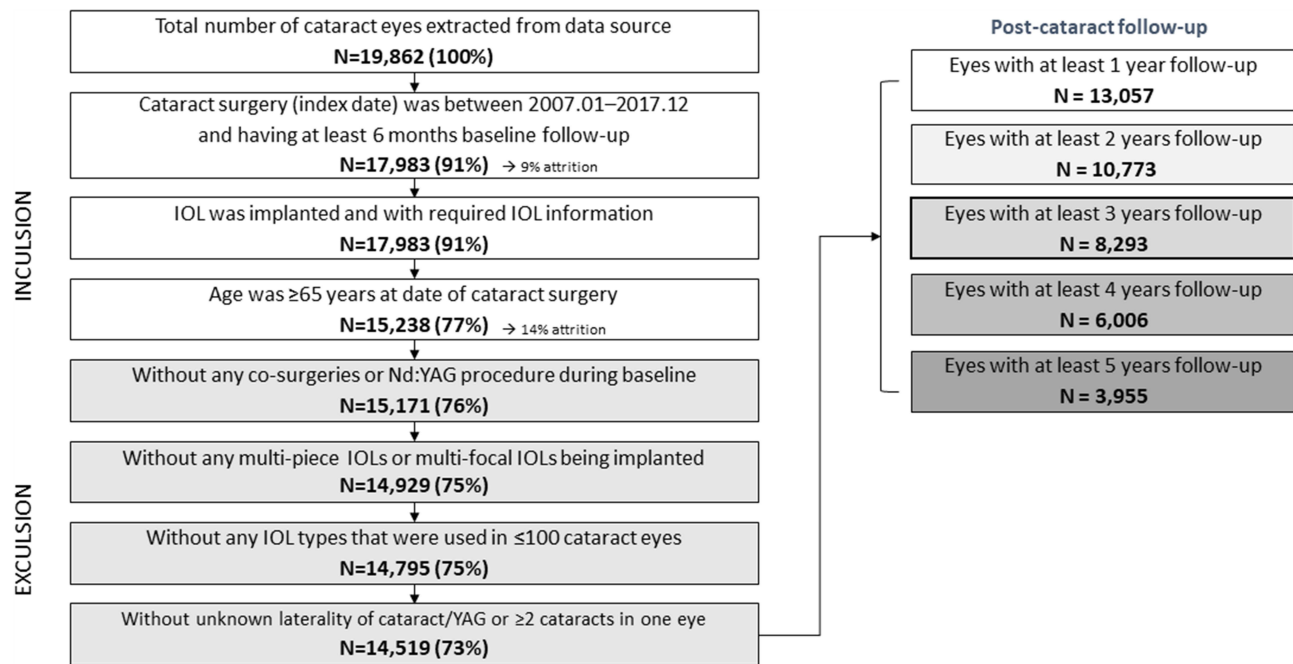


Figure 1 Population selection and attrition for eyes included in the study.

five-year incidence proportions of Nd:YAG procedures for the different IOLs (reference group: Alcon AcrySof). ORs were adjusted for gender, age at index, number of eyes operated, and relevant complications (eg, glaucoma, diabetic retinopathy, high myopia, uveitis, and retinal detachment). A significance level of 0.2 was required to allow a variable into the model, and a significance level of 0.1 was required for a variable to stay in the model.

Results

Baseline Demographic and Characteristic of Selected Population

The baseline characteristics have previously been described in detail.⁶ Initially, 9545 patients with 14,519 eyes were included. The mean age was 75 years \pm 5.9 and similar for the different IOL groups. The proportion of female patients was 53.0%. The proportion of patients with the surgery on a single eye was 48.0%, which was again similar for the different IOL groups, apart from the IOL Tech Stabibag, for which the proportion was 92.0%. Glaucoma was the most frequent co-pathology in the study population within six months before or during cataract surgery, affecting 3.9% of all eyes. The proportion of eyes with co-pathologies was similar for the different IOL groups.

5-Year Incidence of Nd:YAG Capsulotomy

The incidence proportion of Nd:YAG increased over the follow-up period of five years after cataract surgery, and it was consistently the lowest for Alcon AcrySof IOLs compared with the other IOLs. The incidence proportion of Nd:YAG was 8.8% for Alcon AcrySof, 44.0% for IOL Tech Stabibag, 44.3% for Zeiss Asphina, and 47.4% for AJL LLASY60 at five years after cataract surgery. Compared with the three-year Nd:YAG incidence rate (for details see Belda et al, 2021)⁶ the incidence rate for Alcon AcrySof remained relatively stable over time, while for the other lenses, marked increases were prevalent (Figure 2).

Adjusted Odd Ratios of Nd:YAG Capsulotomy

Table 1 shows odds ratios (OR) for Nd:YAG capsulotomy adjusted for age and gender. The OR of Nd:YAG capsulotomy at five years after cataract surgery was 8.02 when comparing patients receiving IOL Tech Stabibag with those receiving Alcon AcrySof IOLs (95% CI [4.60, 13.98], $p < 0.0001$). The adjusted OR was the highest for AJL LLASY60 IOLs: 9.54 (95% CI [6.57, 13.84], $p < 0.0001$) and 8.35 (95% CI [5.85, 11.94], $p < 0.0001$) for Zeiss Asphina compared with Alcon

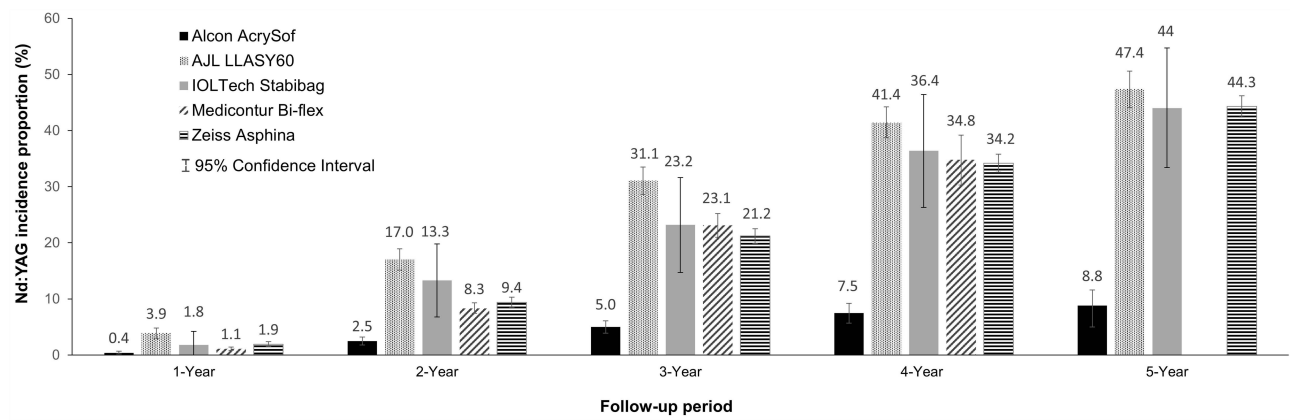


Figure 2 Nd:YAG procedure incidence proportions for different IOLs by year of follow-up.

AcrySof. Furthermore, characteristics such as younger age, female gender, and a diagnosis of diabetic retinopathy (Table 1) were significantly associated with a higher five-year incidence of Nd:YAG capsulotomy.

Discussion

This study reports Nd:YAG incidence rates after cataract surgery in a large Spanish cohort of 3955 eyes and over a follow-up period of five years. The study was an extension to our previous work on the three-year incidence of Nd:YAG after post-cataract surgery.⁶ The current results demonstrate that Nd:YAG incidence rates after cataract surgery are significantly lower for Alcon AcrySof monofocal IOLs compared to other acrylic monofocal IOLs (AJL LLASY60, MediconTur Bi- Flex, IOL Tech Stabibag and Zeiss Asphina) throughout the entire five-year follow-up period. While the Nd:YAG rates increased over the study duration, the incidence rate for the Alcon AcrySof IOL was consistently ~80%

Table 1 Multivariate Analysis Showing Adjusted ORs of Nd:YAG Capsulotomy at Five Years Post-Cataract Surgery

Covariate*	Sub-category	OR (95% CI)	P-value
Age at index (per 1 year increase)		0.98 (0.97, 0.99)	0.0003
Gender (Reference: Male)	Female	1.41 (1.24, 1.61)	<0.0001
Number of eyes operated (Reference: 1)	2	-	-
IOL brand (Reference: Alcon AcrySof)	AJL LLASY60	9.54 (6.57, 13.84)	<0.0001
	MediconTur Bi-flex**	NA	NA
	Zeiss Asphina	8.35 (5.85, 11.94)	<0.0001
	IOL Tech Stabibag	8.02 (4.60, 13.98)	<0.0001
Co-pathologies recorded prior to or on index date (Reference: No)			
Diabetic retinopathy	Yes	1.98 (0.95, 4.11)	0.0664
Glaucoma	Yes	-	-
Uveitis	Yes	-	-
High myopia	Yes	-	-
Retinal detachment	Yes	-	-

Notes: *A significance level of 0.2 was required to allow a variable into the model, and a significance level of 0.1 was required for a variable to stay in the model. **Data for the MediconTur Bi-flex IOL was unavailable at five years post cataract surgery.
Abbreviation: OR, odds ratio.

lower than that for other IOLs. Notably, the difference in Nd:YAG incidence between Alcon IOLs and the other IOLs increased over time as shown in Figure 2. The differences were still statistically significant after adjustment for key confounding factors. Our study findings based on the real-world health data from Spanish EMR corroborate similar positive findings related to the PCO protective properties of the AcrySof lens from other studies that were conducted in the UK, the US and other countries.^{8–11,14}

The good performance of AcrySof IOLs compared to the other lenses included in the study may be attributed to different design factors. Hydrophobic materials have been associated with lower PCO incidence and lower Nd:YAG laser capsulotomy rates compared to those of a hydrophilic composition. It has been suggested that this effect may be due to the close adherence of hydrophobic materials to collagen membranes through fibronectin.^{11,16}

As presented in detail in our previous work,⁶ the non-AcrySof lenses included in the study were either of a hydrophilic composition or in the case of Zeiss Asphina, hydrophilic with a hydrophobic surface. It has been commonly reported that hydrophilic acrylic IOLs are associated with a higher incidence of Nd:YAG capsulotomy compared to hydrophobic acrylic IOLs, attributed to a relatively higher water content and duller or less sharp edges of hydrophilic IOLs.^{17,18} The edge design of IOLs has shown to be an important factor with respect to the incidence of PCO,¹⁹ it is hypothesized that a square edge profile, exerts higher pressure on the posterior capsule, thus preventing lens epithelial cells from migrating onto the posterior capsule.²⁰ However, it is the case that some square edges are sharper than others. Indeed in Nanavatty et al, the authors report that the Zeiss Asphina lens has a “sharp edge but not a perfect square edge”, while also exhibiting a larger edge thickness and greater radius of curvature than that of the AcrySof lens,²¹ which may provide a rationale for its comparatively poorer PCO performance.

Consistent with our three-year analysis, this five-year study showed that diabetic retinopathy, younger age at cataract surgery and female gender are significantly associated with a higher risk for PCO, in line with findings previously reported by others.^{7,13,22} Although mixed results have been reported with respect to diabetic retinopathy being a risk factor,^{8,23} the exact reasons for the higher risk in females for PCO are not known, but previous research suggested that estrogen might play a role.²⁴ This could indicate that increased attention should be paid to female patients who are diagnosed with cataract to reduce their risk of developing PCO after surgery. However, others suggested differences in incidence rates might be accounted for by the fact that women are more likely to seek medical care.²⁵ While for younger individuals, specific attention in clinical practice to PCO risk may be warranted due to the increased risk owed to a tendency for proliferation of retained lens epithelial cells.²⁶

Our study is the first comprehensive, five-year analysis of real-world data on the incidence of Nd:YAG laser capsulotomies after cataract surgery by IOLs type in a large Spanish cohort of almost 4000 eyes. The large sample size allowed us to conduct multivariate analyses with sufficient statistical power on high quality EMR data. That is, the Ribera Salud hospitals that contributed data have fully adopted EMR and resource management systems and use the capitation model, which attracts patients to stay long within the care system and therefore accumulates more longitudinal and complete follow-up data. As such, the current findings contribute important insights to clinical decision making with respect to IOL choice, which may positively impact on patients' visual outcomes, disease burden and related economic costs.

However, the findings should be interpreted in the light of some methodological considerations. It is possible that severe patients were more likely to be observed in our study than those with mild PCO or those who responded well to the surgical treatment. There could also be variations between the study centers in terms of the frequency of patient monitoring and data recording. The data collected at each visit (eg, visual acuity, refraction) would reflect this and information on patients with severe conditions are expected to be better-populated. Thus, this could have led to an overestimation of complications. Further, there could be misclassifications of outcomes, especially for patients lost to follow-up, or those who were less frequently seen at the clinic, which typically occurs in observational database studies. Besides, the choice of IOLs might have depended on patient characteristics that were not included in this study. However, important factors such as age, sex and co-pathologies were accounted for in our analysis.

A limitation of the current analysis is that it is not possible to evaluate Nd:YAG capsulotomy-free rates using a Kaplan–Meier analysis. Consequently, insights into the timing of Nd:YAG capsulotomy occurrence post-cataract

surgery were not obtained. Future studies should expand on statistical analysis to explore the temporal effect of cataract surgery on PCO and the need for Nd:YAG capsulotomy, thereby providing a more comprehensive understanding of the associated risk factors.

Conclusion

In conclusion, this large Spanish cohort study shows that Alcon AcrySof IOLs are associated with a significantly lower long-term incidence of Nd:YAG laser treatment after cataract surgery than other types of IOLs. The choice of IOL at the time of cataract surgery may considerably influence the incidence of PCO following cataract surgery, which can impact on quality of life for the patients and healthcare costs. The current findings from routine clinical practice can inform clinical decision making and support clinical insights derived from randomized clinical trials. Further studies are needed to systematically investigate the relationship between specific IOL design characteristics and Nd:YAG capsulotomy rates, as well as the related clinical risks and economic costs over even longer follow-up periods.

What Was Known Before

- PCO is a significant complication in patients after cataract surgery.
- The risk of PCO estimated through the rate of Nd:YAG capsulotomy, has a tendency to increase over time.
- There are only limited data about Nd:YAG incidence rates over long follow-up periods.

What This Study Adds

- This study provides estimates of the incidence of Nd:YAG capsulotomy over five years after cataract surgery for different IOLs in a large Spanish population of 3955 eyes.
- Our study results suggest that IOL choice may be associated with significant differences in the risk of PCO in the five years after cataract surgery.

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Disclosure

There is no property or commercial interest in any material discussed in this article for all authors. Alcon provided financial support to IQVIA. DOB, XP, and CP are employees of Alcon. MZ, JY and SS are employees of IQVIA, the company contracted by Alcon to conduct the study. The authors report no other conflicts of interest in this work.

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