

Nd:YAG Capsulotomy Rates With Two Trifocal Intraocular Lenses

Rafael Bilbao-Calabuig, MD; Fernando Llovet-Osuna, MD, PhD; Felix González-López, MD; Jaime Beltrán, MD

ABSTRACT

PURPOSE: To compare Nd:YAG capsulotomy rates following implantation of two diffractive trifocal intraocular lenses (IOLs).

METHODS: This multi-center retrospective analysis included patients who underwent uncomplicated lens phacoemulsification and were implanted with a diffractive trifocal IOL: FineVision MicroF (PhysIOL, Liège, Belgium) or AT Lisa tri 839MP (Carl Zeiss Meditec, Jena, Germany). All surgeries were performed during the same period. The postoperative follow-up period was at least 1 year. Chi-square and Kaplan–Meier tests analyzed non-parametric estimates for survival/failure functions. The Wilcoxon (Breslow) test compared Nd:YAG capsulotomy rates between the two groups.

RESULTS: Of 5,130 eyes included, 3,387 were implanted with the FineVision MicroF IOL and 1,743 with the AT Lisa tri 839MP IOL. There were no statistical differences in age, axial length, or IOL power between groups. Nd:YAG capsulotomies were necessary in 330 eyes (9%) in the FineVision group and 408 eyes (23%) in the AT Lisa tri group ($P < .001$). The probability of having Nd:YAG capsulotomy up to 9 months postoperatively was equal for both lenses. Beyond 9 months, the Nd:YAG capsulotomy rate increased significantly more in the AT Lisa tri group, reaching a probability of 35% for eyes with a follow-up of 34 to 44 months, whereas in the FineVision group the probability was 14% after a follow-up of 37 to 47 months. The differences in survival (without Nd:YAG capsulotomy)/failure (with Nd:YAG capsulotomy) functions were significant ($P < .001$).

CONCLUSIONS: Eyes implanted with the FineVision MicroF IOL required significantly fewer Nd:YAG laser capsulotomies than those with the AT Lisa tri 839MP IOL during the first years after implantation. The design of the IOL platforms could account for these differences.

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The most prevalent complication after cataract surgery is posterior capsular opacification, which can lead to significant visual disability, particularly in patients implanted with a multifocal IOL. Posterior capsular opacification can be successfully treated with Nd:YAG capsulotomy, which, although accepted as a standard noninvasive and safe treatment, carries the risk of complications and a financial cost burden.¹

Trifocal IOLs, a new type of multifocal IOL, are reported to obtain high spectacle independence, providing better intermediate vision than bifocal IOLs.²⁻⁴ They have been commercially available since 2010 and have been used extensively by our group since 2011. Although several published studies describe visual performance following trifocal IOL implantation, there is a paucity of data describing the incidence of posterior capsular opacification with these lenses. Consequently, and after a previous extensive clinical experience, we undertook a retrospective analysis to assess and compare the incidence of Nd:YAG capsulotomy rates following the implantation of two different models of diffractive trifocal IOLs.

PATIENTS AND METHODS

STUDY DESIGN AND PATIENTS

In this multi-center, multi-surgeon study, data were collected from patients who underwent uncomplicated clear lens or cataract surgery and implantation with one of the two trifocal IOLs: the FineVision MicroF (PhysIOL, Liège, Belgium) or the AT Lisa tri 839MP (Carl Zeiss Meditec, Jena, Germany). Institutional review board approval was obtained

From Clinica Baviera Madrid, Instituto Oftalmológico Europeo, Madrid, Spain.

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Correspondence: Rafael Bilbao-Calabuig, MD, Clinica Baviera Madrid, Instituto Oftalmológico Europeo, Paseo Castellana 20, 28046 Madrid, Spain. E-mail: rbilbao@clinicabaviera.com

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from the Clinica Baviera medico-legal committee prior to study commencement.

Patients underwent surgery in any of the 24 surgical centers from Clinica Baviera, Spain, by 47 experienced surgeons, using the same surgical protocol, instruments, and devices. Each surgical center implanted one or both types of trifocal IOLs. Preoperatively, patients received detailed information regarding the surgical procedure and vision concerns after trifocal IOL implantation, and provided written consent. All surgeries were undertaken between October 2011 and August 2014, and only patients with at least 1 year of follow-up were included in the analysis. Eyes with capsular tension ring insertion or any significant intraoperative or postoperative complication (other than cystoid macular edema) were excluded from the analysis. Data were recorded from the central computerized medical file system from Clinica Baviera. The system contains all of the medical records and surgical data from all of the patients evaluated in Clinica Baviera.

CLINICAL ASSESSMENTS/ENDPOINTS

All patients underwent full ophthalmic examination before and after lens surgery and trifocal IOL implantation. Patients were observed for at least 3 months after lens surgery. If required, a laser corneal refractive enhancement procedure was performed after this period. Patients were discharged at least 3 months from any surgical intervention and were asked to return for routine follow-up visits every year thereafter. The incidence of Nd:YAG laser capsulotomy during the extended follow-up period and the timing of this treatment after surgery were recorded. The indication for YAG capsulotomy was determined individually in every case by the surgeon according to the amount of posterior capsular opacification present, the decrease in corrected distance visual acuity, and patients' visual complaints that could be attributed to the posterior capsular opacification. Clinically significant cystoid macular edema cases were also recorded (comprising postoperative secondary macular edema detected in the follow-up examinations that required specific treatment).

IOL DESCRIPTION

The FineVision MicroF is a single-piece, foldable, tetraloop hydrophilic acrylic IOL with a water content of 25% and an overall diameter of 10.75 mm. The 6.15-mm optic of the IOL has a diffractive anterior surface that is entirely convoluted and a posterior surface with a spherical aberration of $-0.11 \mu\text{m}$. By varying the height of the diffractive step, the amount of light distributed to the near, intermediate, and distant foci is adjusted according to the aperture of the pupil.

The AT Lisa tri 839MP is a preloaded plate-haptic IOL with a single-piece diffractive multifocal design. It has a 6-mm biconvex optic and an overall length of 11 mm. It is a foldable hydrophilic acrylate IOL with a water content of 25% and hydrophobic surface properties. The IOL optic consists of a central 4.34-mm trifocal zone and a peripheral bifocal zone from 4.34 to 6 mm with diffractive rings covering the entire optic diameter. The aspheric optic corrects spherical aberrations of the typical cornea; the asphericity of the IOL is $-0.18 \mu\text{m}$.

SURGICAL PROCEDURE

Surgeons performed all cataract surgeries using a standardized technique without sutures. The technique included a 2.75-mm incision in the temporal or steepest meridian according to the eye keratometric cylinder, a capsulorrhexis diameter of approximately 5 mm, hydrodissection, phacoemulsification, irrigation/aspiration of cortical remnants, IOL implantation in the capsular bag, and intracameral injection of cefuroxime. The side ports were hydrated in all cases; the main incisions were hydrated only if necessary. Postoperatively, topical therapy included a combination of antibiotic and steroidal agents for 1 month. Phacoemulsification and trifocal IOL implantation of the second eye were performed within 2 weeks of the initial (first eye) procedure.

STATISTICAL ANALYSIS

A Kolmogorov–Smirnov test was used to determine whether the data were normally distributed. An unpaired *t* test was used to compare outcomes between groups; however, a non-parametric Mann–Whitney test was used for non-normally distributed data. A chi-square test was performed to compare odds ratios. Due to the disparity in the follow-up times of the patients, a survival curve to Nd:YAG capsulotomy was performed. The Wilcoxon (Breslow) test was used for equality testing of survival functions between groups. Statistical significance was set at a *P* value of .05 or less across all endpoints/tests.

RESULTS

The analysis included 2,860 patients; 1,830 patients were implanted with the FineVision MicroF IOL and 1,015 patients were implanted with the AT Lisa tri 839MP IOL. In total, 3,387 eyes were implanted with the FineVision MicroF IOL and 1,743 eyes were implanted with the AT Lisa tri 839MP IOL. Group characteristics (ie, age, IOL power, and eye axial length) were compared and showed no statistical difference (**Table A**, available in the online version of this article).

The time to Nd:YAG capsulotomy and mean follow-up times are described in **Table B** (available in the online version of this article). The time between cataract surgery

TABLE 1
Rates of Nd:YAG Capsulotomy and Irvine–Gass Syndrome

Variable	FineVision MicroF		AT Lisa tri 839MP		P ^a
YAG	9%	320 of 3,387	23%	408 of 1,743	< .001
Irvine–Gass syndrome	2%	53 of 3,387	2%	30 of 1,743	.674

^aChi-square test.

The FineVision MicroF is manufactured by PhysiOL, Liège, Belgium, and the AT Lisa tri 839MP is manufactured by Carl Zeiss Meditec, Jena, Germany.

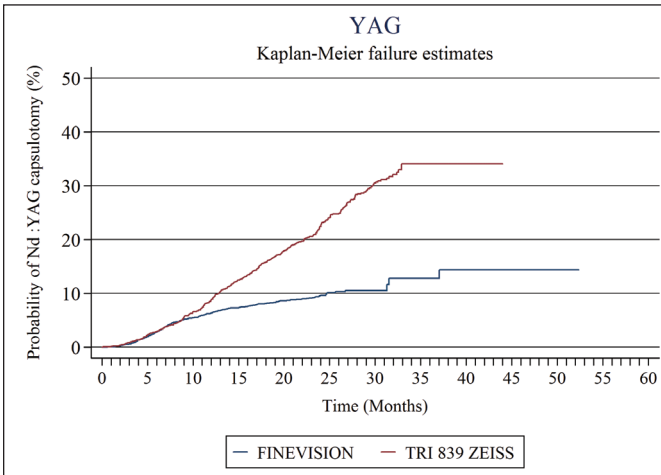


Figure 1. Survival analysis curves and failure distribution functions to Nd:YAG capsulotomy. Failure function, $F(t) = 1 - S(t)$, gives the probability of having Nd:YAG capsulotomy up to the time point t .

and Nd:YAG capsulotomy was significantly shorter in the FineVision group than in the AT Lisa tri group (ie, 310 ± 195 vs 458 ± 230 days; $P < .001$). The mean follow-up was significantly longer with the FineVision MicroF IOL than with the AT Lisa tri 839MP IOL (38 days), but was not clinically significant.

The rates of Nd:YAG capsulotomy are compared in **Table 1**. Overall, 9% of Nd:YAG capsulotomies were observed in the FineVision group and 23% in the AT Lisa tri group. The rates of Nd:YAG capsulotomy per year confirm these outcomes. The survival analysis curves and failure distribution functions to Nd:YAG capsulotomy showed a similar trend for both groups during the first 9 postoperative months (**Figure 1**). Beyond 9 months, the Nd:YAG capsulotomy rate increased in the AT Lisa tri group, reaching a probability of 35% for eyes with a follow-up of 34 to 44 months. In contrast, the probability of having Nd:YAG capsulotomy in eyes implanted with the FineVision MicroF IOL only reached 14%, with a follow-up of 37 to 47 months. The Wilcoxon (Breslow) test for equality of survivor functions showed a statistically significant difference between the FineVision group and the AT Lisa tri group ($P < .001$) (**Figure 2**).

The incidence of Irvine–Gass syndrome was similar with both lenses, with no statistical significance noted between groups ($P = .674$) (**Table 1**).

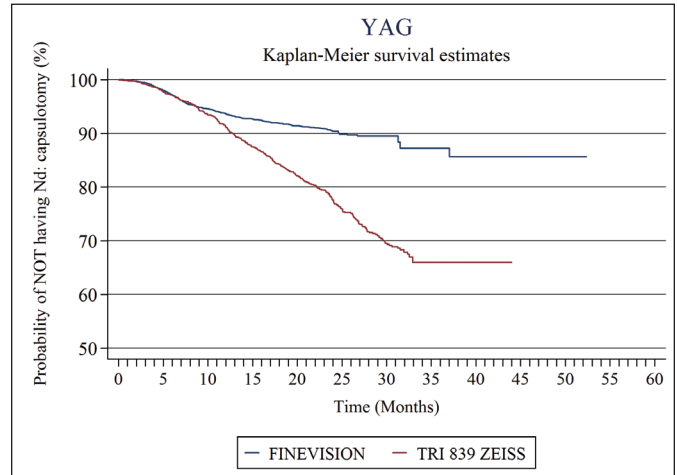


Figure 2. Wilcoxon (Breslow) test for equality of survivor functions ($P < .001$). Survival function, $S(t) = 1 - F(t)$, displays probability of not having Nd:YAG capsulotomy at time point t conditional on not having Nd:YAG capsulotomy up to the time point t .

DISCUSSION

The aim of this study was to assess and compare the incidence of Nd:YAG capsulotomy rates following the implantation of two different models of diffractive trifocal IOLs. Because this was a retrospective study and there was a disparity in follow-up times, we employed a survival analysis using the same protocol as Leysen et al.,⁵ with additional representation such as Kaplan–Meier failure estimates.

Our findings showed that 9% versus 23% of Nd:YAG capsulotomies were observed in the FineVision group and the AT Lisa tri group, respectively. The time to Nd:YAG capsulotomy was shorter with the FineVision MicroF IOL than with the AT Lisa tri 839MP IOL. However, it is important to note that the survival analysis curves and failure distribution functions to Nd:YAG capsulotomy showed that the probability of having Nd:YAG capsulotomy up to 9 months postoperatively was equal for both lenses. Beyond 9 months, the Nd:YAG capsulotomy rate increased more in the AT Lisa tri group. After the first 9 postoperative months, fewer capsulotomies were needed in the FineVision group. This explains the mean shorter lapse between surgery and Nd:YAG capsulotomy in eyes implanted with the FineVision MicroF IOL.

The design of both IOL platforms, specifically the differences in the flexibility between the tetraloop design (FineVision MicroF IOL) and the plate-haptic design (AT Lisa tri 839MP) and differences in the haptic–optic junction (the route via which lens epithelial cells migrate behind the IOL optic), could explain the large difference found in Nd:YAG capsulotomy rates between the two IOLs.

Previous studies have shown that the plate-haptic IOL design provides good refractive predictability and intraocular optical quality, an excellent rotational stability, and similar results concerning posterior capsular opacification rates when compared with other similar IOLs with open-loop haptic designs.^{6–8} In contrast, other studies have pointed out that the plate-haptic design may be associated with a greater posterior capsular opacification formation and higher risk of Nd:YAG capsulotomy.^{9,10}

In our study, the FineVision MicroF IOL with its tetraloop design demonstrated better posterior capsular opacification performance, possibly creating a greater capsular tension and getting a better apposition of the posterior capsule with the IOL optic.

Interestingly, although both IOLs are manufactured with a similar material (hydrophilic acrylate with a water content of 25%), the hydrophobic coating of the AT Lisa tri 839MP IOL, which in theory would minimize posterior capsular opacification occurrence, did not seem to provide any major protection against posterior capsular opacification.

With a hydrophilic platform, the FineVision MicroF IOL demonstrated Nd:YAG capsulotomy rates at 4 years similar to those published with hydrophobic IOL benchmarks (26.1% with the Tecnis ZCB00 and 21.7% with the AcrySof SA60AT at 3 years,¹¹ and 35.6% with the iMics1 NY-60 and 16.7% with the AcrySof SN60WF at 3 years¹²). Although the AcrySof SA60AT and SenSAR capsulotomy rates were 10% and 22% at 5 years,¹³ 809C, SI-40NB and AcrySof MA60BM16 rates were 29%, 54%, and 8%, respectively, at 5 years. We found different outcomes from those presented by Schrieffl et al.¹⁴ They showed a large confidence interval at 4 years, although the study was limited to a small cohort with a large number of dropouts. However, we found similar outcomes with the plate-haptics to Nanavaty et al.'s study¹⁵ with the Acri.smart 36A IOL.

Both IOLs demonstrated similar rates of cystoid macular edema. Clinically significant cystoid macular edema with visual loss and metamorphopsia appears in only 1% to 2% of patients^{16–18} with a peak incidence occurring, on average, 6 weeks after surgery. Subclinical cystoid macular edema (without visual impact) is found in nearly 30% of patients

when screened with angiography and in 11% to 41% of patients on optical coherence tomography screening despite preventive treatment.^{17,18} The results for the FineVision MicroF and AT Lisa tri IOLs in the current study are in the upper part of the score. This could indicate that the threshold of clinically significant cystoid macular edema is higher with multifocal IOLs than with monofocal IOLs, possibly related to the reduction in contrast sensitivity. A similar effect of multifocal IOLs has been previously described regarding the clinical tolerance of patients to posterior capsular opacification; patients implanted with multifocal IOLs required more frequent Nd:YAG laser capsulotomies than patients with monofocal IOLs and a similar lens design. The reasons for these findings may include the increased visual demands of patients with multifocal IOLs and complex visual phenomena associated with the interaction of multifocal optics and posterior capsular opacification.¹⁹

The current study clearly has limitations. First, it is retrospective and was restricted to an analysis of available cases. However, we included a survival analysis to provide confidence intervals that demonstrate the precision of the study; this approach has been used previously in other surveys assessing posterior capsular opacification and Nd:YAG laser rates.^{20,21} This study also includes data gathered from multiple surgical centers (n = 24) with different surgeons (n = 47). However, surgeons followed the same surgical protocol and a large number of cases were included in this analysis, which should (to some degree) compensate for these variations. Additionally, although patients are normally scheduled for yearly follow-up visits, the follow-up rates of patients included were variable.

Another weakness of the study is the lack of a clearly defined indication prompting YAG laser capsulotomy and the absence of an objectivized posterior capsular opacification scoring system. However, this is common in many posterior capsular opacification and YAG capsulotomy rates reported in publications. Moreover, the main goal of the study was to evaluate the clinical behavior of these two IOL models regarding YAG capsulotomy incidence rather than objectively quantify posterior capsular opacification. This was a multi-center/multi-surgeon trial and the precise indication for YAG capsulotomy was determined individually in every case by the surgeon; this may have led to some variability in the results. However, all of the procedures followed the same protocol and similar clinical criteria and, under these circumstances (and with such a large sample size), many of these possibly confounding factors may be compensated for.

Marques and Ferreira²² published data showing that the FineVision MicroF IOL led to slightly better uncorrected intermediate and near visual acuity than the AT Lisa tri 839MP IOL. They could not determine any difference in distance vision. They also showed that there was no significant difference in contrast sensitivity or dysphotopic phenomena between groups. The current study shows a significant and important difference in the Nd:YAG capsulotomy rate in favor of the FineVision MicroF IOL but equivalence of the two IOLs in the incidence of cystoid macular edema.

This study demonstrated that the FineVision MicroF IOL shows a lower Nd:YAG capsulotomy rate (14% at 4 years vs 35% for eyes in the AT Lisa tri group) with a follow-up of 34 to 44 months. Both IOLs had similar cystoid macular edema scores. This study of complications in a large patient cohort showed that trifocality is safe with a low rate of postoperative complications.

AUTHOR CONTRIBUTIONS

Study concept and design (RB-C, FL-O, FG-L, JB); data collection (RB-C, FL-O, FG-L, JB); analysis and interpretation of data (RB-C); writing the manuscript (RB-C); critical revision of the manuscript (RB-C, FL-O, FG-L, JB)

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TABLE A
Demographics and Baseline Characteristics

Variable	FineVision MicroF				AT Lisa tri 839MP				P
	No.	Range (Min/Max)	Mean ± SD	Median (Q25/Q75)	No.	Range (Min/Max)	Mean ± SD	Median (Q25/Q75)	
Age, y	1,830	22/88	58 ± 8	58 (53/63)	1,015	28/81	58 ± 8	58 (53/63)	.970 ^a
ALX	3,387	19.44/29.41	23.00 ± 1.22	22.88 (22.25/23.63)	1,743	15.00/30.40	23.07 ± 1.50	22.89 (22.20/23.67)	.552 ^a
Lens power	3,387	10.00/35.00	22.81 ± 3.76	23.00 (21.00/25.00)	1,743	3.00/32.00	22.44 ± 4.26	23.00 (20.50/25.00)	.156 ^a

SD = standard deviation; ALX = axial length

^aData non-normally distributed. Non-parametric Mann-Whitney test used.

The FineVision MicroF is manufactured by PhysiOL, Liège, Belgium, and the AT Lisa tri 839MP is manufactured by Carl Zeiss Meditec, Jena, Germany.

TABLE B
Time to Nd:YAG Capsulotomy

Variable	FineVision MicroF				AT Lisa tri 839MP				P
	No.	Range (Min/Max)	Mean ± SD	Median (Q25/Q75)	No.	Range (Min/Max)	Mean ± SD	Median (Q25/Q75)	
Days from surgery to YAG	320	61/1,130	310 ± 195	255 (167/417)	408	62/1,004	458 ± 230	435 (283/604)	< .001 ^a
Days from surgery to September 30, 2015 (final follow-up)	3,387	579/1,597	718 ± 121	692 (643/758)	1,743	579/1,342	756 ± 181	649 (607/939)	< .001 ^a

SD = standard deviation

^aData non-normally distributed. Non-parametric Mann-Whitney test used.

The FineVision MicroF is manufactured by PhysiOL, Liège, Belgium, and the AT Lisa tri 839MP is manufactured by Carl Zeiss Meditec, Jena, Germany.