

Lydia Gateri¹, Jun Zhang¹
¹Alcon Vision, LLC, Fort Worth, TX, USA

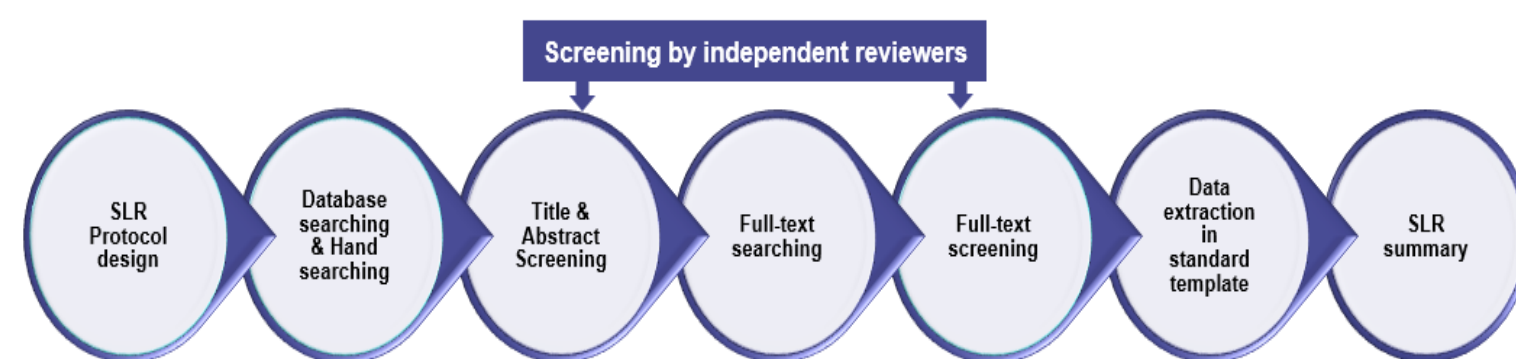
Background & Objective

- PCO is a common complication after cataract surgery, and the condition is treated by Nd:YAG laser capsulotomy^{1, 2}
- Although considered a safe procedure, Nd:YAG laser capsulotomy is associated with increased risks of complications and may be associated with additional costs to patients and health care providers³
- Intraocular lens (IOL) material and design has been shown to impact the incidence of PCO and Nd:YAG capsulotomy rates¹
- The purpose of this literature review was to collate and report Nd:YAG laser capsulotomy incidence in patients implanted with Clareon® IOL

Methods

- A literature search was conducted using PubMed, MEDLINE, Embase, Cochrane library, both the European and American Society for Cataract and Refractive Surgeons congress databases and an internal clinical trial database (Nov 2017 to Dec 2022).
- Incidence of PCO requiring Nd: YAG post Clareon® IOL implantation and the weighted average of Nd:YAG capsulotomy incidence was reported.
- All retrieved records were screened by two independent reviewers based on criteria described in Table 1. Incidence of PCO requiring Nd:YAG with Clareon® IOL was extracted and reported

Figure 1: Schematic overview of the SLR process



SLR = systematic literature review

Table 1: Selection criteria for studies

Category	Inclusion criteria	Exclusion criteria
Patient population	<ul style="list-style-type: none"> • Adult patients with age-related cataract 	<ul style="list-style-type: none"> • Patients with a history of ocular diseases other than cataract, such as glaucoma and uveitis • Patients with systemic disease, such as diabetes, requiring medical control
Intervention/Comparator	<ul style="list-style-type: none"> • Cataract surgery with Clareon IOLs 	<ul style="list-style-type: none"> • Cataract surgery with non-Clareon IOLs
Outcomes	<ul style="list-style-type: none"> • Number of eyes that underwent Nd:YAG laser capsulotomy 	<ul style="list-style-type: none"> • All other outcomes
Study Design	<ul style="list-style-type: none"> • Any clinical study with more than 12 months follow-up 	<ul style="list-style-type: none"> • Observational studies • Studies with follow-up <12 months

Results

Table 2: Key results from studies

Study	Follow-up duration (in months)	Number of Eyes	Nd:YAG events	Nd:YAG rate at end of study	Monthly YAG rate
Prospective observational study (Japan) 2020 ⁴	14	110	0	0.0%	0
Prospective observational study [Long-term] (Japan) ⁴	108	20	1	5.0%	0.0004
Prospective observational study (Spain) 2021 ⁵	12	60	0	0.0%	0
Prospective observational study (Australia) ⁶	36	40	0	0.0%	0
Prospective observational study – interim results (Europe) ⁷	12	1 st eye: 215 2 nd eye: 209	2 0	0.9% 0.0%	0.0007 0.0005
Prospective observational study – interim results (Europe) ⁷	24	1 st eye: 215 2 nd eye: 209	3 4	1.4% 1.9%	0.0007 0.0005
Prospective observational study – final results (Europe) ⁷	36	1 st eye: 215 2 nd eye: 209	7 14	3.3% 6.7%	0.0009 0.0005
Single arm trial (Korea) ⁸	12	1 st eye: 86 2 nd eye: 40	0 0	0.0% 0.0%	0 0
Single arm trial (India) ⁹	12	1 st eye: 111 2 nd eye: 40	0 0	0.0% 0.0%	0 0

Table 3: Weighted average* YAG capsulotomy incidence

Weighted average YAG capsulotomy incidence	12 months	24 months	36 months
Eight studies identified	0.74%	1.47%	2.20%

*Weighted averages of capsulotomy rates based on a recent systematic literature review of publications for various IOL models

Results

- A total of eight clinical studies reporting the incidence of Nd:YAG were identified in patients implanted with Clareon® IOL.
- The identified studies varied in follow-up duration (14-108 months) and sample size (N=20-215).
- The incidence of Nd:YAG among the included studies ranged from 0% at 12 months to 6.7% at 9 years (Table 2).
- The weighted average YAG capsulotomy incidence at 1 year was 0.74%, 2 years was 1.47%, and at three years was 2.20% (Table 3).

Conclusions

- Global clinical studies have demonstrated that Clareon® IOL biomaterial and its squared edge design protect against PCO with low incidence rates of Nd: YAG capsulotomy.

References

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