Nd:YAG Laser Capsulotomy: Efficacy and Outcomes Performed by Optometrists

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SIGNIFICANCE: An increasing number of optometrists are performing Nd:YAG laser capsulotomy procedures; however, there is limited published information on the outcomes of these procedures.

PURPOSE: This study aimed to assess the efficacy and safety of capsulotomy procedures performed by optometrists.

METHODS: Subjects diagnosed with posterior capsule opacification causing reduced vision and subjective visual complaints were recruited for this study. A baseline examination was performed to ensure that the subjects met all the necessary criteria. The procedure was performed by a licensed doctor of optometry at six different clinics, and each subject was monitored for visual outcome and any potential complications.

RESULTS: Subjects' Snellen visual acuity improved from an average of 20/40 to 20/23 ($P < .001$) with no complications of increased intraocular pressure, inflammation, visually significant lens pitting, macular edema, or retinal detachment. Of 78 subjects who responded to a post-procedure survey, 77 (99%) reported subjective improvement in vision after capsulotomy.

CONCLUSIONS: Based on the outcomes of this study, YAG laser capsulotomies are effective treatments to improve patient vision that can be safely and effectively performed by optometrists.

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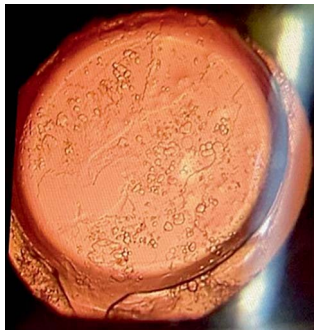

Optom Vis Sci 2023;100:665–669. doi:10.1097/OPX.0000000000002057

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Posterior capsule opacification, also called "secondary cataract," is the most common visually disabling complication after modern cataract surgery.[1–3] Formation has been shown to occur 18 to 50% of the time in adults within 5 years of surgery and up to 44% of the time in infants and juveniles.[1–3] Despite advances in surgical technology, the type of implanted lens and various unknown factors have led to the continued prevalence of posterior capsule opacification.[1–3] This opacification of the posterior capsule is caused by proliferation and migration of lens epithelial cells, which can lead to visual loss and a decreased quality of life. Vision loss typically results through either a regenerative or fibrotic component. A regeneratory posterior capsule opacification is more likely to produce vision loss due to the gradual formation of Elschnig pearls resulting in reduced central visual acuity, decreased contrast sensitivity, induced glare, or monocular diplopia.[4,5] Treatment is indicated in most symptomatic patients with posterior capsule opacification to improve vision and the quality of life.[4]

The neodymium-doped yttrium aluminum garnet (Nd:YAG) 1064-nm laser capsulotomy procedure has a long track record of improving visual acuity with low risk of complications.[4] Optometry's role in laser procedures has greatly increased over the last few decades beginning with the state of Oklahoma, where optometrists' scope of practice has included lasers since 1998. As of this writing, 10 states grant optometrists the right to perform capsulotomies and other anterior segment laser procedures. Although there have been no adverse events from optometry-performed lasers reported in the literature, likewise there has been no published study assessing the efficacy and safety of laser procedures, such as YAG capsulotomy, performed by optometrists.

The purpose of this clinical research was to assess the efficacy and safety of Nd:YAG capsulotomy procedures performed by optometrists.

Assessment was done by measuring visual acuity and subjective visual improvement along with rates of complications such as intraocular pressure spike, inflammation, intraocular lens pitting, post-operative cystoid macular edema, and retinal detachment. In addition, we compared the results from this study with previously published data from YAG capsulotomy studies.

METHODS

This research was reviewed by an independent ethical review board and conforms to the principles and applicable guidelines for the protection of human subjects in biomedical research. This study obtained approval from the Northeastern State University and Cherokee Nation Institutional Review Board (IRB) Committees. It consisted of procedures performed at Northeastern State University Oklahoma College of Optometry in Tahlequah, OK, as well as five private optometry locations throughout Oklahoma and Louisiana: Cockrell Eye Care Center in Stillwater, OK; Oklahoma Medical Eye Group in Tulsa, OK; Willis-Knighton Eye Institute in Shreveport, LA; Louisiana Family Eye Care in Covington, LA; and Bond-Wroten Eye Clinic in Hammond, LA. All procedures were carried out in states that permit optometrists to perform YAG capsulotomies, and all procedures were completed by optometrists who had completed the required training and obtained the required certification to perform therapeutic laser procedures.

This was a prospective study performed in primary care optometric settings. Subjects were identified from patients at the respective clinics who, upon routine examination, were found to have visually significant posterior capsule opacification with both reduced Snellen acuity and subjective visual complaints. The patients were then assessed to verify that they met the study criteria and consented to being part of this clinical research. The Cherokee Nation IRB provided the ethical review for the Native American subjects, and the Northeastern State University IRB provided review for the sites external to the Cherokee Nation. An informed consent was signed by each subject before undergoing the procedure.

Inclusion criteria included unilateral posterior capsule opacification with any of the following: decreased Snellen acuity of worse than 20/40, or caused significant effect on activities of daily living, or glare that reduced vision by two lines or more. Exclusion criteria included a history of severe nonproliferative diabetic retinopathy, diabetic or other macular edema, other underlying ocular disease other than mild dry macular degeneration, previous myopic refractive error greater than –6.00 D, complications after previous procedures (such as intraocular lens decentration), and any other previous ocular surgeries (except cataract surgery or uncomplicated refractive surgery). Incidental findings not affecting ocular health were not exclusionary. Mild or moderate nonproliferative diabetic retinopathy per Early Treatment Diabetic Retinopathy Study staging,[6] clinically defined by a few scattered microaneurysms, dot hemorrhages, or cotton wool spots, was not considered to be an exclusionary criterion for this study. Any subject who met these criteria and consented was placed in the study and had an Nd:YAG laser capsulotomy performed by an optometrist at the participating site.

The pre-operative protocol included recording corrected distance visual acuity, intraocular pressure, macular thickness, and central lens defects. Visual acuity was recorded using Snellen acuity values converted to logMAR values for calculation, intraocular pressure was measured with Goldmann applanation tonometry, and macular thickness was measured in micrometers with the macular cube setting using an optical coherence tomographer. Any subject with macular edema evident on the optical coherence tomography (OCT) scan was excluded from the study. Pupils were dilated with 0.5% tropicamide and 2.5% phenylephrine drops. All data were obtained and recorded by the optometrist who performed the YAG capsulotomy.

An Nd:YAG laser of various brands (depending on location) with a wavelength of 1064 nm was used to perform a posterior capsulotomy. To control potential subsequent intraocular pressure elevation, subjects also received one drop of brimonidine 5 to 10 minutes before the procedure. One drop of 1% proparacaine was used to anesthetize the eye before the procedure, and optionally, an Abraham capsulotomy contact lens with cushioning gel was placed on the subject's eye based on doctor preference. The initial energy level, number of pulses used, energy per pulse, and total laser energy were noted with each procedure. Immediately upon completion of the procedure, subjects received another drop of brimonidine to control for potential subsequent intraocular pressure elevation. In addition, the number of lens pits in the center of the intraocular lens was noted.

The post-operative medication regimen included topical 1.0% prednisolone acetate ophthalmic suspension four times a day for 1 week to help control inflammation. Ophthalmic brimonidine was prescribed to be used three times a day for 1 week if intraocular pressure was elevated by 5 mmHg or for more than 1 hour after the capsulotomy. After the 1-hour intraocular pressure check, the subject was scheduled for 1-week, 1-month, and 3-month follow-up appointments. In addition to baseline intraocular pressure, measurements were recorded for 1 hour and 1 week after the Nd:YAG capsulotomy. If intraocular pressure was elevated by 5 mmHg or for more than 1 hour after the procedure, an additional follow-up was performed 1 day after the capsulotomy. Inflammation was examined at each follow-up appointment using a standard cell and flare grading scale.[7] At each visit, the cornea was assessed for edema, and the vitreous was assessed for floaters. A macular cube/thickness OCT scan was done at the 1- and 3-month visits. On the final follow-up appointment, each subject was dilated, and the posterior pole and peripheral retina were examined for any retinal break or detachment. At the final follow-up visit, subjects were asked (yes/no) if they could appreciate a subjective improvement in vision.

RESULTS

Ninety-two eyes in 79 subjects completed through 1 month of follow-up, and 81 eyes in 69 subjects completed the study through the 3-month follow-up. For subjects completing through 1 month of follow-up, the mean pre-procedure visual acuity was 0.302 ± 0.208 logMAR (20/40 Snellen acuity) improving to 0.058 ± 0.07 logMAR (20/23 Snellen equivalent) post-capsulotomy ($P < .001$). The data for all subjects completing to the 3-month follow-up were similar: the mean pre-procedure visual acuity was 0.305 ± 0.214 logMAR (approximately 20/41 Snellen acuity) with an improvement to 0.054 ± 0.069 logMAR (20/23 mean Snellen acuity) after the capsulotomy ($P < .001$ with paired-samples t test). Data distribution showed few outliers and none in the post-operative measurements. Therefore, parametric statistics were used. See Table 1 for data summary. Average total energy used for each procedure was 69.6 mJ for all eyes completing at least 1 month of study and 73.7 mJ in the 3-month follow-up group. Four subjects were lost to follow-up after

TABLE 1. Data for subjects at 1-month follow-up (92 eyes in 79 subjects)

Measurement	Pre-procedure	Post-procedure	*P*
Visual acuity, mean	0.302 ± 0.208 logMAR (20/40 Snellen equivalent; median, 0.301 logMAR)	0.058 ± 0.07 (20/23 Snellen equivalent; median, 0 logMAR)	<.001
Intraocular pressure, mean	14.2 ± 3.05 mmHg (median, 15 mmHg)	14.4 ± 2.93 mmHg (median, 15 mmHg)	.36
OCT central macular thickness, mean	253 ± 23 μm (median, 252 μm)	253 ± 23 μm (median, 251 μm)	.59

OCT = optical coherence tomography.

1 week. All four of these subjects demonstrated improved acuity and no adverse events at the 1-week follow-up appointment.

Seventy-eight of 79 subjects (91 eyes) answered the post-procedure question: "Has your vision improved after the capsulotomy procedure?" Seventy-seven of 78 subjects (99%) who completed the post-procedure survey (89 of 91 eyes) reported a subjective improvement in vision. One subject reported no noticeable change in vision in both eyes, although Snellen acuity improved from 20/30 to 20/20 in the right eye and 20/25 to 20/20 in the left eye. Eighty-seven of 92 eyes (95%) demonstrated objective visual improvement of at least one line of Snellen acuity. Of the five subjects who did not improve at least one line of Snellen acuity, four maintained the same visual acuity (each subject having 20/25 pre- and post-procedure), and one subject went from $20/25^{-3}$ to 20/30. All five of these subjects did self-report an improvement in vision. Four subjects were lost to follow-up after the 1-week visit and did not complete the study. All four subjects showed improvement in Snellen visual acuity with no adverse events at the 1-week post-operative visit.

Average baseline intraocular pressure was 14.2 mmHg for all eyes, and the average 1-week post-procedure intraocular pressure was 14.4 mmHg ($P = .36$). Only four subjects had an intraocular pressure increase greater than 5 mmHg any time after the procedure. One subject's intraocular pressure was elevated by 6 mmHg at the 1-hour post-procedure check and returned to baseline at the 1-week follow-up. Another subject's intraocular pressure was elevated by 5 mmHg at the 1-week follow-up and returned to baseline at the 1-month visit. Two other subjects' intraocular pressure was within 5 mmHg of the initial reading until the final visit when the pressure was up 8 and 6 mmHg from the pre-procedure measurement, respectively.

Pre- and post-procedure macular OCTs were performed at the 1- and 3-month follow-up visits. Optical coherence tomographies were completed for 82 eyes in 69 subjects. The average pre-procedure central macular thickness was 252.9 μm, and the average post-capsulotomy thickness was 252.7 μm ($P = .59$), with only one eye showing more than an 8-μm change.

No eye experienced significant inflammation, an increase in vitreous floaters, corneal edema, cystoid macular edema, retinal detachment, or any permanent vision loss. No macular edema was evident on any OCT scan. Intraocular lens pitting within the central 3 mm was noted in 13 of 92 eyes (14%), although no patient reported visual symptoms such as glare or image degradation that would be consistent with visually significant intraocular lens pitting.

DISCUSSION

This study formally assessed objective and subjective visual improvement along with potential complications for laser capsulotomies performed by optometrists. The results of this study showed an average improvement in vision of almost three Snellen lines of acuity, and 99% of all subjects reported improved vision. There were negligible complications of increased intraocular pressure, macular edema, or inflammation. No serious complications such as retinal detachment or vision loss occurred. Overall, the number of eyes studied, the average amount of laser energy used, and the average final visual acuity were similar to many other YAG capsulotomy studies (Zepeda E. et al. IOVS 2016;57:ARVO E-Abstract 946).[8–22] This information is reflected in Table 2.

Opening a portion of the posterior lens capsule using an Nd:YAG laser capsulotomy is an effective and proven method of treatment for patients with decreased vision due to posterior capsule opacification.[4,23] The Nd:YAG laser capsulotomy was first offered in the 1980s as an effective alternative to surgical methods and prevented typical complications of endophthalmitis and vitreous loss. As opposed to surgical capsulotomies, YAG laser capsulotomy does not require an incision into the eye and yields immediate improvement.[24] Because decreased vision induced by posterior capsule opacification is correlated with more difficulty when performing daily activities, a YAG capsulotomy can immediately improve a patient's perception of the quality of life.[25,26] Best-corrected visual acuity and straylight values have both been reported to improve drastically after the Nd:YAG capsulotomy procedure. The straylight value indicates the amount of light scatter caused by the opacification, which leads to significant light glare and visual symptoms.[8] YAG capsulotomy may yield improvement in visual acuity without significantly affecting intraocular pressure, macular OCT, or endothelial cell assessment post-operatively.[9,13,26]

Prior studies show that YAG capsulotomy procedures can be learned very quickly. One study showed that ophthalmology residents performing Nd:YAG capsulotomy procedures early in their training had good outcomes with low complication rates that were comparable to outcomes in the literature. Years in residency did not correlate with post-capsulotomy best-corrected visual acuity or intraocular pressure. Within a single practice session, ophthalmology residents could perform an Nd:YAG laser capsulotomy with no damage to the intraocular lens.[27,28] Another study demonstrated quality outcomes with capsulotomies performed by nurse practitioners.[29] With minimal risk, a quick learning curve, and required slit-lamp skills already possessed by optometrists, laser procedures can be effectively used by optometrists to provide patients easier access to high-quality eye care.

With any ophthalmic laser procedure, complications may arise, and proper management must be undertaken. Such possible complications include intraocular pressure elevation, intraocular lens pitting, cystoid macular edema, uveitis, and retinal detachment. Although the risk of complications is very low, the rate of these complications is highly correlated with energy levels used during the procedure.[3] Studies suggest that keeping energy at or less than 50 to 70 mJ can help minimize the risk of complications.[10,13] The

TABLE 2. Comparable YAG capsulotomy studies and results

Study	No. eyes	Pre-YAG cap VA logMAR (Snellen)	Post-YAG cap VA logMAR (Snellen)	Average total energy used per YAG cap (mJ)
Van Bree et al.[8]	35	0.52 (20/63)	0.10 (20/25)	*
Karahan et al.[9]	46	0.61 ± 0.15 (20/80)	0.21 ± 0.16 (20/32)	57.9 ± 8.9
Karahan et al.,[9]†	32	0.66 ± 0.18 (20/90)	0.20 ± 0.12 (20/32)	61.0 ± 12.7
Bhargava et al.[10]	474	0.85 ± 0.22 (20/140)	0.21 ± 0.21 l (20/32)	51.93
Falavarjani et al.[11]	173	1.14 ± 0.25 (20/275)	0.51 ± 0.37 (20/64)	83.7
Falavarjani et al.[11]	131	1.15 ± 0.26 (20/280)	0.54 ± 0.39 (20/70)	*
Montenegro et al.[12]	53	0.298 (20/40)	0.078 (20/25)	*
Parajuli et al.[13]	56	0.68 ± 0.36 (20/95)	0.14 ± 0.13 (20/25-)	26.64 ± 12.92
Parajuli et al.,[13]‡	40	0.69 ± 0.36 (20/97)	0.17 ± 0.14 (20/30)	81.96 ± 32.10
Ozkurt et al.[14]	26	0.93 ± 0.23 (20/170)	0.38 ± 0.13 (20/50)	*
Magno et al.[15]	24	0.22 (20/32)	0.02 (20/20)	*
Levy et al.[16]	24	0.64 (20/87)	0.28 (20/40)	41.92
Choi et al.[17]	31	0.61 ± 0.36 (20/80)	0.19 ± 0.25 (20/32)	99.5 ± 36.1
Hayashi et al.[18]	41	0.30 (20/40)	0.018 (20/20)	*
Menon et al.[19]	60	0.34 (20/44)	0.16 (20/29)	*
De Senne et al.[20]	48	0.52 (20/63)	0.10 (20/25)	131.9
Oztas et al.[21]	30	0.50 ± 0.36 (20/63)	0.03 ± 0.06 (20/20)	*
Garcia Medina et al.[22]	26	0.38 (20/48)	0.08 (20/24)	*
Zepeda E. et al. (IOVS 2016;57: ARVO E-Abstract 946)	175	0.73 ± 0.54 (20/107)	0.51 ± 0.51 (20/64)	111.6 ± 91.0
This study	92	0.302 (20/40)	0.058 (20/23)	69.6

*Information not included in the study. †Same study with larger capsulotomy size (≥3.9 mm). ‡Same study, split into two groups based on total energy.

mean total energy for all eyes in this study was 69.6 mJ, which is comparable to other YAG capsulotomy studies (Table 2).

Intraocular pressure elevation is one of the most routinely listed complications after Nd:YAG capsulotomy. The probability of an intraocular pressure spike is variable, and even with prophylactic treatment, intraocular pressure elevation can occur 15 to 30% of the time.[24] The greatest chance for an intraocular pressure spike occurs 90 minutes to 4 hours after the procedure, but it likely returns to baseline levels within 24 hours.[30] Actions such as the use of topical brimonidine, apraclonidine, or timolol before and after the procedure as well as decreasing the size of the capsulotomy all help in controlling the amount of intraocular pressure elevation after the procedure.[9,31,32]

Beyond intraocular pressure elevation, 8 to 33% of capsulotomies result in pitting of the intraocular lens.[10,23,24] Shockwaves from the laser travel forward and can impact the intraocular lens, resulting in permanent pitting of the lens. One way to limit this complication is to retrofocus the laser beam throughout the procedure.[24] The intraocular lens pits recorded in this study did not result in any subjective vision complaints, and the rate of lens pitting was similar to, or less than, other YAG capsulotomy studies.[10,23,24]

Studies vary in the prevalence of cystoid macular edema after capsulotomy; however, this complication, as with many others, correlates greatly with energy used.[11,24] If macular edema does result, it typically arises 2 months after the procedure.[33] Uveitis can result after capsulotomy from freed capsular debris and acute inflammatory cells, but rates are very low.[23] There is up to a 10% chance of uveitis occurring 1 day after capsulotomy, but this is unlikely after the immediate post-operative period.[4,10] Although rare, retinal detachment is one of the most significant complications that can potentially result after capsulotomy. However, only patients with previous retinopathy, degeneration, breaks, or simply increased axial length are at greater risk of this complication after the laser procedure.[3,34] Previous studies have shown that a retinal detachment can happen a year or more after the procedure, and retinal detachment rates vary between 0 and 0.4% for 1 to 8 years post-capsulotomy.[10,23]

No subjects in this study reported floaters at the 1-week, 1-month, or 3-month follow-up. Although a temporary increase in floaters is common post-capsulotomy, these usually subside within a few days,[35] which explains why no floater symptoms were reported at the later follow-up visits.

Potential limitations of this study were the lack of masking/blinding when assessing pre-operative and post-operative visual acuity. Although subjects were asked about the quality of their vision post-procedure, a formal assessment of the quality of vision (e.g., contrast sensitivity, glare testing) was not done. The primary strength of this study was the prospective nature and the broad inclusion and limited exclusion criteria for subjects being seen in primary care optometric locations. The number of subjects was equal to or greater than many recently published YAG capsulotomy studies (Table 2). In addition, this is the first study to formally assess the efficacy and safety of optometrist-performed YAG capsulotomies.

CONCLUSIONS

Ninety-nine percent of subjects in this study who responded reported subjective improvement in vision, and 95% of subjects showed objective visual improvement, which allowed for a better quality of life. No significant adverse events were noted in any subject. This study demonstrates that capsulotomies can be effectively and safely performed by doctors of optometry with minimal risk to patients and significant benefit to visual function and provides evidence to support the use of YAG capsulotomy in optometric practice.

ARTICLE INFORMATION

Submitted: December 20, 2022

Accepted: June 28, 2023

Funding/Support: None of the authors have reported funding/support.

Conflict of Interest Disclosure: None of the authors have reported a financial conflict of interest.

Study Registration Information: Registration database: ClinicalTrials.gov, registration number: NCT04036214, registration date: July 18, 2019.

Author Contributions and Acknowledgments: Conceptualization: NL; Data Curation: NL, JMM; Formal Analysis: NL, JH, KH, BC, RS, BW, KW, DC, SL, CW, JA, JE, JMM; Investigation: NL, SJ, JH, KH, BC, RS, BW, KW, DC, CW, JA, JE; Methodology: NL, JH, KH, BC, BW, KW, DC, SL, CW, JA, JE, JMM; Project Administration: NL, SJ, RS, JMM; Resources: NL; Supervision: NL, SJ; Visualization: NL; Writing – Original Draft: NL, SJ, JH, KH, BC, RS, BW, KW, DC, SL, CW, JA, JE, JMM; Writing – Review & Editing: NL, SJ, JH, KH, BC, RS, BW, KW, DC, SL, CW, JA, JE, JMM.

The authors would like to thank Richard Hoenes, MA, for his assistance with the statistical analysis of this study.

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