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Neodymium:YAG Lasers

An FDA Report

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Abstract: Analysis of data from four neodymium:YAG laser manufacturers submitted to the Food and Drug Administration (FDA) on over 17,000 cases indicate the procedure is safe and effective for cutting opaque posterior lens capsules. A successful opening in the pupillary membrane was achieved in 98% of the cases, and vision improved in 84% of the cases. Clinically significant risks include: a rise in intraocular pressure two to four hours after treatment, damage to the intraocular lens, and rupture of the anterior hyaloid face. [Key words: cystoid macular edema, FDA, glaucoma, intraocular lens, neodymium:YAG laser, posterior capsule opacification.] Ophthalmology 92: 209–212, 1985

The neodymium:YAG (Nd:YAG) laser has been available for investigative use in the United States since July 1982. The initial investigative studies were designed by laser manufacturers and the Food and Drug Administration (FDA) to test the safety and effectiveness of the Nd:YAG laser in cutting the posterior capsule and noncapsular pupillary membranes and to determine the incidence of certain complications and adverse reactions associated with the procedure.

Early reports to the FDA indicated no significant clinical problems resulting from use of a Nd:YAG laser, and therefore suggested this to be a safe procedure. However, it became apparent to investigators using Nd:YAG lasers and to members of the Ophthalmic Device Section of the FDA that specific problems did occur and were significant enough to warrant further evaluation.[1,2] The purpose of this report is to present a summary of premarket approval (PMA) data submitted to the FDA from the four approved lasers regarding the safety and effectiveness of YAG lasers.

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MATERIALS AND METHODS

Results of all patients enrolled in the investigational study were reported to the manufacturer and then to the FDA. Patients were required to have follow-up visits at 24 hours, one week, one month, and six months after YAG laser treatment.

For FDA approval, a minimum of 500 patients must have completed all visits through six months. Those having completed visits through six months are termed "cohort cases." The remaining patients seen were followed for adverse reaction reporting and are termed "continuing cases." By October 1984, PMAs from four manufacturers have received a recommendation of approval from the Ophthalmic Device Committee (Table 1). Three units have received final FDA approval for distribution of an Nd:YAG laser. The number of "cohort cases" for each laser manufacturer ranged from 505 to 558. A total of 2110 "cohort cases" were available for analysis from the four manufacturers' studies. The number of "continuing patients" who had not completed six-month follow-up ranged from 1212 to 6303. The total number of cases evaluated for adverse reactions was 17,911.

Information recorded at the time of laser treatment included the number of laser shots, the energy used and complications such as intraocular lens (IOL) damage,

Table 1. Nd:YAG Lasers Recommended for Approval Prior to October 1984

Laser	Manufacturer
Coherent Systems 9900	Coherent, Inc.
Meditec Model OPL-3	Coburn Optical Industries, Inc.
AMO YAG-100	American Medical Optics
OPL-3	Medical Lasers, Inc.

rupture of the anterior hyaloid face, iris damage, corneal damage, bleeding, and retinal damage. Information obtained at the time of follow-up included visual acuity, intraocular pressure and recording of adverse reactions. Adverse reaction reporting was requested on the following complications: elevation of intraocular pressure, intraocular lens damage, cystoid macular edema, retinal detachment, corneal damage, postoperative inflammation, and bleeding.

After the studies were begun, it became apparent that intraocular pressure recordings immediately after the YAG laser treatment or 24 hours later were not adequate to document an acute rise in intraocular pressure. Therefore, additional studies regarding intraocular pressure were required for a specific number of patients during the first eight hours following Nd:YAG laser treatment.

RESULTS

The results presented in this paper are based on analysis of the 2110 "cohort cases" who had completed all follow-up visits. In the four studies, a succcessful opening in the posterior capsule was achieved in 98% of eyes. Final visual acuity was 20/40 or better postoperatively in 81% of the cases. Vision was improved in 84% of the cases; vision was unchanged in 12% of the cases, and vision was decreased in 4% of the cases (Table 2). On the average, the investigators used 50 pulses with a total energy of 140 mJ.

OPERATIVE COMPLICATIONS

The major operative complication was damage to the IOL. In the four studies this occurred in 20% of the cases with a range of from 15 to 30% (Table 3). Analysis of data showed that damage to the intraocular lens was more likely to occur if: (1) the lens was in the posterior chamber, (2) the posterior capsule was in close proximity to the lens, and (3) the membrane was thick. There appeared to be a direct correlation between IOL damage and the total laser power used, the number of laser pulses, and the number of pulse trains used.

Table 2. Nd:YAG Laser Studies: Results

Result	Mean of Studies	Range of Means
Successful opening	98%	96–99%
Improved vision	84%	75–88%
Unchanged vision	12%	6–24%
Decreased vision	4%	3–7%

Table 3. Nd:YAG Laser Studies: Major Operative Complications

Complication	Mean of Studies	Range of Means
Damage to IOL	20%	15–30%
Rupture of anterior hyaloid face	19%	15–22%
Corneal Edema	0.3%	0.2–0.3%
Bleeding	1%	0.2–3.4%
Iris Damage	0.4%	0.2–0.8%

The second most frequently reported operative complication was rupture of the anterior hyaloid face. This was more common in aphakia than pseudophakia and occurred in 19% of the cases. Other less frequently encountered operative complications included: corneal edema in 0.3% of the cases, bleeding in 1% of the cases, and iris damage in 0.4% of the cases (Table 3).

POSTOPERATIVE COMPLICATIONS

The major postoperative complication was elevation of intraocular pressure (IOP). In a subset of 213 "cohort cases" followed under the FDA eight hour protocol, 39% of the patients (range, 24–54%) had a 5 mmHg or more elevation of intraocular pressure above baseline within two to six hours after treatment (Table 4). In 28% of cases (range, 8–55%), the IOP was reported to rise to a level greater than 30 mmHg abolute pressure within two to six hours of treatment. Despite treatment with glaucoma medications, the IOP rose to a level greater than 60 mmHg in several of these patients.

The pressure rise following Nd:YAG laser treatment was delayed in onset. The maximum IOP increase occurred between 1.5 and 4 hours following treatment in the majority of the cases. In those cases where IOP was elevated to an absolute value above 30 mmHg, it occurred within two hours in 70% of the cases and within three hours in 85% of the cases. Within 24 hours after treatment, the pressure had dropped to less than 22 mmHg in over 60% of eyes and by one week in over 90% of eyes.

Between the third and sixth month after laser therapy, only 1% of the "cohort cases" had a persistent elevation in intraocular pressure to a level greater than 30 mmHg. Presumably, most of these patients were on therapy for elevated intraocular pressure.

Analysis of the intraocular pressure rise after Nd:YAG laser treatment revealed several risk factors. A rise in intraocular pressure to greater than 30 mmHg was associated with one or more of the following conditions: (1) a preoperative intraocular pressure of 20 mmHg or above, (2) patients with a diagnosis of glaucoma, (3) use of a high total energy level of the Nd:YAG laser, (4) use of cycloplegics, and (5) multiple Nd:YAG laser proce-

dures. One study showed a correlation of increased intraocular pressure with a posterior chamber lens in place; whereas, another manufacturer's studies indicated that postoperative rise in intraocular pressure was more likely to occur if no intraocular lens was in place.

Cystoid macular edema (CME) was detected at sometime during the six months following Nd:YAG laser treatment in 1.2% of the cases. Approximately 50% of the cases of cystoid macular edema were diagnosed within the first month after YAG laser treatment. Analysis of these cases demonstrated that cystoid macular edema was less likely to occur as the time between cataract surgery and YAG laser treatment increased. The cystoid macular edema in these cases may have been associated with the cataract surgery and not the YAG laser treatment.

Other postoperative complications occurring during the six months of the study included: retinal detachment in 0.5% of the cases, pupillary block in 0.1% of the cases, retinal hemorrhage in 0.4% of the cases, iritis in 0.6% of the cases, and vitritis in 0.3% of the cases (Table 4).

Table 4. Nd:YAG Laser Studies: Major Postoperative Complications

Complication	Mean of Studies	Range of Means
Elevation of IOP		
>5 mmHg	39%	24-54%
to >30 mmHg	28%	8-55%
Cystoid macular edema	1.2%	0.3-2.3%
Retinal detachment	0.5%	0.2-0.8%
Pupillary block glaucoma	0.1%	0.1-0.2%
Retinal hemmorhage	0.4%	0.2-0.4%
Iritis	0.6%	0.1-2.8%
Vitritis	0.3%	0.2-0.6%

IOP = intraocular pressure.

DISCUSSION

In these studies, the neodymium:YAG laser has been shown to be effective in opening opaque posterior capsules and pupillary membranes. In over 98% of the 17,911 cases treated, a satisfactory opening was achieved with 96% of the cases showing an improvement or no change in visual acuity. Only 4% of the cases had a reduction in visual acuity.

These studies have demonstrated that while the complications rate of the Nd:YAG laser are low, they may be clinically significant. Therefore, clinicians are recommended to exercise caution regarding the following potential sight-threatening complications:

Elevation of intraocular pressure. Elevation of IOP has been documented in a substantial number of patients following YAG laser treatment. Patients predisposed to a significant elevation of IOP are those with prexisting glaucoma and those that have received higher total amounts of energy or a higher number of laser pulses. Such patients should probably receive pretreatment with antiglaucoma medications; and when indicated, physicians should carefully monitor IOP for a minimum of two to four hours following treatment. Although IOP usually returns to pretreatment level within 24 hours, approximately 2 to 3% of the cases treated were reported to have a persistent elevation.

Damage to the intraocular lens. Pitting or marking of the intraocular lens has been noted in an average of 20% of the cases depending on the type of IOL and its proximity to the capsule. In an eye with a posterior chamber IOL where the capsule is close to the IOL, the chance of damage to the IOL is higher. In such cases, the surgeon should aim the laser slightly behind the capsule. This permits the anterior portion of the YAG laser explosion to disrupt the capsule without damage to the IOL. Patients should be warned that pits and cracks in the IOL can cause glare. Studies reported to the FDA to date have not shown a deleterious effect from damage to the IOL such as release of monomers or ultraviolet absorbing materials. However, with extreme damage to the IOL in the experimental situations, toxins may be released.[3,4] Posterior chamber glass IOLs have been cracked in patients' eyes; therefore, if the IOL is known to be made of glass, it is a relative contraindication to treat the eye with the YAG laser.

Bleeding. Bleeding may occur if vascularized tissue is hit. Bleeding is usually not persistent but may interfere with continuation of treatment.

Rupture of the anterior hyaloid face. Rupture of the anterior hyaloid occurs in a high percentage of aphakic cases in which no IOL is in place. Anterior movement of the vitreous may cause pupillary block and an increase in rate of cystoid macular edema, retinal detachment, and late-onset corneal edema. To avoid rupture of the anterior hyaloid face, when no IOL is present, it is recommended that the laser be focused slightly anterior to the posterior capsule and then moved posteriorly.

Pupillary-block glaucoma. Several cases of pupillary-block glaucoma have been reported in eyes after Nd:YAG laser treatment that had undergone extracapsular cataract extraction without an iridectomy. Such patients should be advised that if symptoms of pupillary block develop, they should contact their treating physician immediately.

Retinal damage. Changes in the retina such as retinal detachment and cystoid macular edema occur with or without laser capsulotomy. Less than 2% of the cases were noted to have these changes after Nd:YAG laser capsulotomy. It appears that the longer the interval between cataract surgery and capsulotomy, the less the risk for cystoid macular edema development. The data in this report are based on treatment of the posterior capsule. When undertaking treatment of posterior vitreous pathology, additional studies will be needed to determine how close one can treat to the retina without causing direct retinal damage. If optical breakdown and thus plasma shielding does not occur during treatment near the retina, the risk of retinal damage may be increased.

CONCLUSION

Analysis of aggregate data from four manufacturers who submitted premarked approval applications to the FDA indicate that the YAG laser can be safe and effective for cutting opaque posterior capsules and opaque pupillary membranes when used with the precautions enumerated above. Clinically significant risks include: a rise of IOP two to four hours after treatment, damage to the IOL, and rupture of the anterior hyaloid face. In addition, because of the complications from the procedure, patients with good visual acuity and minimal symptoms should be warned that there is approximately a 4% risk of reduced visual acuity from YAG laser capsulotomy.

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