

Dodick Photolysis for Cataract Surgery

Early Experience with the Q-switched Neodymium:YAG Laser in 100 Consecutive Patients

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Objective: To evaluate the safety and efficacy of a Q-switched neodymium:YAG (Nd:YAG) laser for removal of the human cataract.

Design: A multicenter, prospective, noncomparative study.

Participants: A total of 100 consecutive eyes undergoing cataract extraction with the Dodick Photolysis, Q-switched Nd:YAG laser.

Main Outcome Measure: Corneal endothelial cell loss, visual acuity improvement, intraocular pressure change, total intraocular energy used, and intraoperative and postoperative complications.

Results: The mean values were postoperative visual acuity improvement from 20/46.5 (0.43) to 20/26.6 (0.75), decrease in endothelial cell count of 177 cells/mm² (7.55%), and intraocular energy used of 6.7 J. Minor complications were encountered in three cases.

Conclusions: These data suggest that Dodick Photolysis may be a safe and effective new technology for cataract removal in human eyes. It appears to offer low intraocular energy and heat release, a clear-cornea incision less than 1.5 mm in size, and safe operation within the capsular bag. *Ophthalmology* 1999;106:2197-2202

Cataract surgery is not only the most common intraocular surgery but may well be the most common surgical procedure performed annually in the United States.¹ It is estimated that there are more than 2.3 million cataract extraction surgeries performed in the United States annually. Modern cataract surgery is relatively safe with a relatively low incidence of complications, considering the large overall number of procedures performed. The use of the neodymium:YAG (Nd:YAG) laser for cataract removal has evolved over the past decade. Since the first report of "phacolysis" of a human cataractous lens by an Nd:YAG laser,² the technology has gone through considerable development. We conducted a prospective study at the four initial investigative sites of the Dodick Photolysis system (A.R.C. Laser AG, Jona, Switzerland). This technology uses a pulsed Q-switched Nd:YAG laser that is transferred to the probe by a quartz fiber optic and is focused on a titanium target within the probe tip (Fig 1). Each pulse releases 12

mJ of laser energy of 14-nsec duration. The pulsing photic energy impacts the titanium target located at the probe tip, which in turn leads to optical breakdown and plasma formation. This creates a shock wave that emanates from the tip in a conelike fashion.³ These shock waves are used to disturb the substance of the cataract. The fragmented particles of the cataract are then aspirated out of the eye through the aspiration port, the lumen of which is also contained in the laser probe. Irrigation takes place through a second probe that is inserted through a separate 0.9-mm corneal incision.

Methods

A total of 100 consecutive patients were evaluated at 4 clinical sites: The Landersaugenlinik, Salzburg, Austria (EA); Klinik Dardenne, Bonn, Germany (PB); Manhattan Eye, Ear and Throat Hospital, New York, New York (JMD, AJK); and Hellenic Eye Center "ORASIS," Athens, Greece (AJK).

All patients were evaluated before surgery for the following parameters: age, operated eye, cataract density, best-corrected visual acuity, endothelial cell count, and intraocular pressure. The cataract density was rated before surgery on a +1 to +4 nuclear density scale by slit-lamp biomicroscopy after pupillary dilation. The number of laser pulses, and thus the total energy used within the eye, as well as the number of procedures that required conversion to standard phacoemulsification was recorded for all patients. After the completion of the cataract removal and intraocular lens (IOL) implantation, all patients were evaluated for the following postoperative parameters at 3 months' follow-up: visual acuity, endothelial cell count, intraocular pressure, and intraoperative and postoperative complications.

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Jack M. Dodick, MD, has a proprietary interest as the inventor and owner of the patent of the technology described. None of the other authors has any proprietary or financial interest in any product mentioned in this article.

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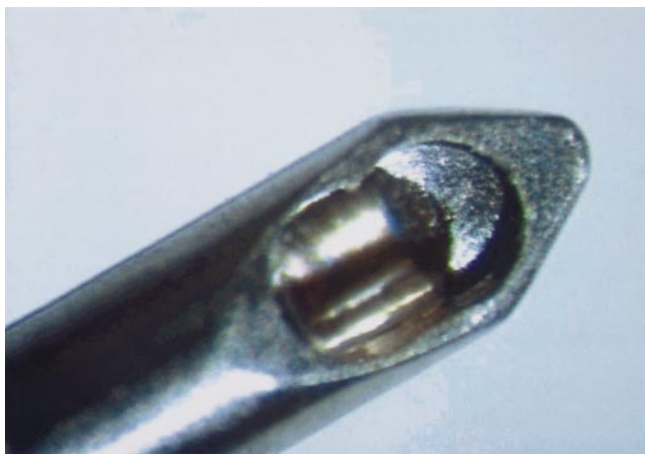


Figure 1. Magnified photograph of probe tip, demonstrating the probe opening and the titanium target on the right.

All patients were given preoperative informed consent for the photolysis cataract extraction procedure. European cases were performed after approval of this technology for human use by the European Commission (CE Mark) and in the United States as part of Investigational Device Exception issued by the Federal Food and Drug Administration.

Operative Technique

The use of this technology for cataract extraction in human eyes has been described previously.² The operative technique used in this study, however, has not been described previously. It is based on modern methods of bimanual cataract extraction performed with small-incision phacoemulsification. The basic steps included administration of topical or local anesthesia, capsulorrhexis, hydrodissection, cataract removal, cortical cleanup, and IOL implantation. Operative anesthesia for cataract surgery in these patients was either peribulbar block (EA, PB, JMD) or topical with intracameral injection (AJK).⁴

All surgeons used similar guidelines as to operative technique presented initially (by PB).⁵ A 1.4-mm clear-cornea incision was created between the 9- and 12-o'clock positions for insertion of the laser-aspiration probe. Similarly, a 0.9-mm clear cornea incision was placed between the 12- and 3-o'clock positions for insertion of the irrigation probe (Fig 2). All surgeons used Venturi-based vacuum systems with maximal intraoperative aspiration set between 250 and 300 mmHg. After routine curvilinear continuous capsulorrhexis using viscoelastic and a bent 25-gauge needle as a cystotome,⁶⁻⁸ hydrodissection was performed with balanced salt solution.⁹ Both probes were then passed through the two corneal incisions into the anterior chamber and the anterior central epinucleus and cortex is aspirated. The next step involved central epinuclear disassembly using pulsed laser fragmentation, directed by the surgeon via foot-pedal. Simultaneously, using a separate foot-pedal, the surgeon controlled irrigation/aspiration.

Intimate contact of the laser-aspiration probe with the lens material is necessary for effective fragmentation with this technique. "Purchase" of the lens material with the probe using vacuum, followed by application of the laser energy using the foot-pedal while contact is maintained, followed finally by brisk aspiration to remove the fragmented debris is performed. This clears the probe opening for the next sequence of touch-pulse-aspirate. The necessary probe position throughout the photolysis

sequence is with the opening facing posteriorly away from the corneal endothelium. This offers maximal fragmentation and minimal endothelial surface exposure to released energy. After removal of the nucleus, the residual epinucleus and cortex are removed either by "cracking" the residual cataract "bowl" with the use of the two probes in a bimanual fashion or by prechopping the residual cataract with two choppers, followed by photolysis of the residual cataract. On completion of nuclear and epinuclear removal, the residual cortical matter is removed via bimanual or unimanual technique. The number of pulses required for photolysis of the cataract varied significantly according to lens density, surgeon experience, and between surgeons (Table 1).

On completion of cataract removal and cortical cleanup, IOL implantation is performed by extending the initial laser probe incision to 2.8 to 3.2 mm into clear cornea, followed by viscoelastic expansion of the capsular bag. All surgeons preferred foldable IOLs. Some authors (EA, PB, and JMD) used Acrysoft (Alcon, Ft. Worth, TX), and some (EA and AJK) used the AMO SI40NB (Allergan, Irvine, CA).

None of the patients received postoperative antibiotic or corticosteroid injections. The postoperative care regimen included a topical fluoroquinolone used four times a day for 3 weeks and topical 1% prednisolone acetate used four times a day for 4 weeks as prophylaxis for postoperative inflammation and infection after clear cornea cataract extraction.¹⁰

Results

Of all 100 patients, only 8 procedures required conversion to standard phacoemulsification for removal of the cataract nucleus or cataract fragments. The mean preoperative visual acuity was 20/46.5 (0.43) and improved to the mean postoperative visual acuity of 20/26.6 (0.75). The mean preoperative intraocular pressure was 15.6 mmHg, and the postoperative intraocular pressure was 15 mmHg. The mean preoperative endothelial cell count was 2344.11 cells/mm², and the mean postoperative endothelial cell count was 2167.34 cells/mm², depicting a mean endothelial cell loss of 177 cells/mm², or 7.55% (Table 1).

The mean intraoperative number of laser pulses was 555. Each pulse releases 12 mJ of laser energy. Therefore, the average intraocular energy released was 6.7 J. Posterior capsule

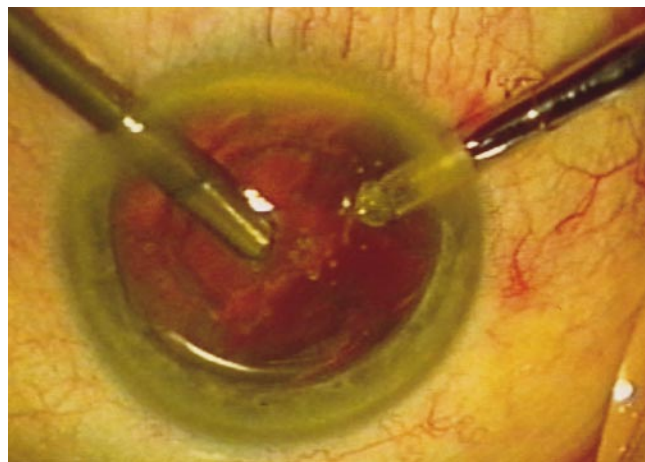


Figure 2. Intraoperative photograph demonstrating cataract debulking with the photolysis technology. On the left, the photolysis probe enters the eye through a 1.5 mm-incision. On the right, the irrigation probe, through a clear cornea incision, as well.

Table 1. Patient and Procedure Data, by Surgeon

Surgeon	Age (yrs)	Eye	Cat/Den	Pulses	PreVA	PostVa	PreECC	PostECC	PreIOP	PostIOP
EA	77	OS	1	292	0.3	0.5	1953	1235	16	16
EA	77	OD	2	1676	0.1	0.8	1972	1255	12	25
EA	75	OS	2	2856	0.2	0.4	2724	2135	15	11
EA	76	OD	1	258	0.4	0.5	2610	2134	12	10
EA	81	OS	3	2369	0.2	0.4	2463	2235	16	8
EA	79	OS	2	612	0.4	0.4	2624	2314	16	12
EA	74	OD	1	615	0.05	0.6	2793	2467	16	4
EA	83	OD	2	1455	0.25	1.0	2237	1980	17	13
EA	76	OS	2	1441	0.25	0.5	2347	2144	16	23
EA	79	OD	2	890	0.3	0.4	2012	1845	12	16
EA	79	OD	3	1398	0.4	0.5	2352	1950	15	16
EA	71	OS	1	141	0.4	0.6	1841	1567	14	16
EA	67	OD	1	75	0.25	1.0	2597	2145	16	13
EA	72	OD	2	196	0.4	0.6	2508	2450	20	12
EA	86	OS	3	954	0.01	0.6	2364	2103	10	8
EA	70	OS	1	284	0.3	0.6	2409	2255	10	8
EA	78	OD	2	604	0.25	0.6	2298	2345	14	10
EA	78	OD	2	791	0.2	0.6	2398	2110	17	14
EA	73	OD	2	962	0.4	0.6	2710	2545	19	10
EA	68	OS	1	141	0.4	1.0	2551	2350	13	8
EA	78	OD	2	532	0.4	0.6	1757	1655	10	10
EA	68	OD	1	303	0.3	0.3	2380	2311	14	12
EA	69	OS	2	545	0.25	0.8	2114	1980	12	17
EA	75	OS	1	40	0.4	1.0	2750	2545	12	10
EA	87	OD	1	117	0.25	1.0	1925	1755	17	11
JMD	63	OD	2	680	0.5	0.8	2900	2950	16	16
JMD	68	OS	2	1235	0.5	0.8	1950	1900	16	16
JMD	46	OD	1	1100	0.5	0.6	2250	2100	18	20
JMD	63	OD	2	1256	0.5	0.9	2650	2700	15	17
JMD	65	OS	2	680	0.5	1.0	2400	2350	15	14
JMD	74	OS	2	1135	0.4	0.8	2900	2800	17	17
JMD	72	OD	2	956	0.5	0.9	3200	2950	12	14
JMD	74	OD	2	876	0.55	0.9	2400	1500	16	12
JMD	71	OD	2	467	0.5	0.6	2550	2350	15	23
JMD	68	OS	2	673	0.5	0.8	2650	2345	20	10
JMD	65	OD	2	584	0.5	0.8	1800	1900	16	16
JMD	72	OS	2	655	0.5	0.9	2800	2900	15	12
JMD	84	OS	2	1350	0.5	0.5	2550	2300	16	17
JMD	48	OD	1	257	0.5	0.7	3100	2950	15	20
JMD	55	OS	1	541	0.4	0.7	2965	2690	19	10
JMD	61	OS	1	279	0.5	0.8	2500	2450	12	14
PB	78	OS	2	852	0.4	0.8	2438	1818	14	18
PB	76	OS	2	1123	0.4	0.5	1720	1555	16	12
PB	57	OD	1	172	0.5	0.2	2000	1937	16	16
PB	57	OS	1	214	0.5	0.7	2200	2100	16	16
PB	82	OD	3	1453	0.2	0.7	NA	NA	13	16
PB	70	OD	2	313	0.5	0.5	2004	2000	19	17
PB	57	OD	2	223	0.4	1	2200	2100	16	10
PB	69	OS	2	508	0.2	0.5	1950	1800	20	16
PB	67	OD	3	1320	0.3	0.7	2000	2000	15	12
PB	80	OD	3	NA	0.05	0.1	1965	NA	16	17
PB	53	OS	2	560	0.4	0.7	2200	2000	17	16
PB	48	OD	1	NA	0.1	0.6	2055	1810	18	15
PB	69	OD	1	433	0.5	1	1950	1800	18	20
PB	79	OS	3	524	0.5	NA	2500	2350	15	15
PB	41	OD	1	112	0.5	0.5	1858	1974	15	15
PB	41	OS	1	162	0.3	0.9	3150	3008	12	12
PB	79	OD	2	223	0.4	0.8	3150	2950	17	14
PB	84	OS	2	834	0.5	0.7	2100	1965	13	12
PB	87	OD	2	1415	0.3	NA	2100	1965	18	9
PB	75	OS	2	1374	0.6	0.5	1984	1755	15	10
AJK	52	OD	2	120	0.1	0.2	2450	2245	16	12
AJK	52	OS	2	141	0.1	0.2	2500	2375	15	16
AJK	43	OD	1	37	0.3	0.8	2765	2485	17	19
AJK	43	OS	1	42	0.4	1.0	2730	2605	16	18
AJK	53	OD	2	212	0.1	0.7	2275	2135	16	17
AJK	53	OS	2	240	0.2	0.7	2310	2225	16	14
AJK	21	OD	1	43	0.1	0.4	2795	2610	15	13

(continues)

Table 1 (continued).

Surgeon	Age (yrs)	Eye	Cat/Den	Pulses	PreVA	PostVa	PreECC	PostECC	PreIOP	PostIOP
AJK	21	OS	1	55	0.1	0.4	2890	2750	16	25
AJK	21	OS	1	32	0.3	0.7	3210	3240	13	10
AJK	18	OD	1	47	0.2	0.4	2950	2745	20	26
AJK	18	OS	1	23	0.5	0.6	3110	3050	10	16
AJK	21	OD	1	32	0.3	0.7	3450	3100	16	16
AJK	48	OS	1	46	0.1	1.0	2980	2955	18	15
AJK	37	OD	1	29	0.05	0.2	2355	2145	17	22
AJK	76	OD	3	456	0.05	0.7	1265	1110	17	12
AJK	43	OD	2	234	0.4	1.0	2450	2345	12	15
AJK	65	OD	2	257	0.4	1.0	1845	1655	16	20
AJK	65	OS	2	189	0.5	1.0	1945	1835	16	21
AJK	71	OD	2	267	0.3	0.8	1495	1350	18	18
AJK	71	OS	2	341	0.4	0.8	1460	1235	18	17
AJK	68	OS	3	657	0.2	0.7	NA	NA	14	13
AJK	80	OD	3	612	0.4	0.9	1245	1150	11	19
AJK	56	OD	2	322	0.2	0.7	2130	1950	21	15
AJK	64	OD	2	274	0.3	1.0	1355	1260	14	15
AJK	64	OS	2	192	0.4	1.0	1340	1265	15	17
AJK	75	OD	3	673	0.3	0.7	1530	1420	20	21
AJK	72	OS	4	511	0.4	0.5	1925	1550	18	17
AJK	45	OS	1	125	0.5	0.9	2950	2780	13	12
AJK	51	OD	2	435	0.4	1	2670	2475	15	16
AJK	51	OS	2	376	0.4	1	2650	2430	16	17
AJK	67	OD	2	674	0.2	0.6	2400	2435	19	20
AJK	36	OS	1	143	0.6	1	2950	2780	14	15
AJK	36	OD	1	112	0.6	1	2810	2650	13	13
AJK	72	OS	2	459	0.2	0.5	2200	2110	12	19
AJK	80	OS	2	671	0.4	1	1650	1350	17	15
AJK	45	OD	1	215	0.5	1	2350	2180	19	14
AJK	45	OS	1	196	0.6	0.9	2460	2250	17	19
AJK	64	OD	2	567	0.3	0.7	1950	1970	20	15
AJK	64	OS	1	235	0.5	0.8	2150	2200	18	15
Average	63.2		1.76	554.88	0.4278	0.7475	2344.112	2167.34	15.57	14.98

EA = Egon Alzner, MD; JMD = Jack M. Dodick, MD; PB = Peter Brauweiler, MD; AJK = Anastasios John Kanellopoulos, MD; Cat/Den = cataract density (+1- to +4); PreVa = preoperative visual acuity; PostVa = postoperative visual acuity; PreECC = preoperative cornea endothelial cell count; PostECC = postoperative cornea endothelial cell count; PreIOP = preoperative intraocular pressure; PostIOP = postoperative intraocular pressure; NA = data not available.

rupture was encountered in three patients. One was encountered during photolysis of the cataract. In this case, after removal of three fourths of the +3 nucleus with the laser, a residual fragment remained. Because this quadrant was engaged at the tip and the laser pulsed, poor simultaneous aspiration allowed the fragment to be "pushed" by the subsequent "burst" against the posterior capsule, resulting in a small posterior capsular perforation. The nucleus fragment remained in the capsular bag and was removed during the subsequent anterior vitrectomy that occurred.

The next case involved a patient after conversion to phacoemulsification. Specifically, the nucleus was rated as +4 nucleus sclerosis. Dodick Photolysis initially was used to remove part of the cataract. As a safety measure, the surgeon decided on conversion to phacoemulsification. Capsular rupture followed removal of the residual cataract by phacoemulsification. The last case with capsular rupture occurred after the completion of cataract removal with Dodick Photolysis. During IOL insertion in this case, posterior capsule rupture occurred. All three patients underwent uncomplicated anterior vitrectomy and posterior chamber IOL placement either within the residual capsular bag or by sulcus fixation.

Discussion

Over the past 30 years,¹¹ phacoemulsification has gone through a major evolution in technique and instrumentation. It has become the standard of care for patients undergoing cataract extraction in the United States and in many other parts of the industrialized world.¹²

Increased safety, faster visual rehabilitation, and increased patient comfort have been pivotal in the development of these contemporary techniques. Reduction of postoperative astigmatism has been a strong driving force for smaller incisions and the development and use of foldable IOL.¹³⁻¹⁹

Smaller incisions in modern cataract surgery incision have driven the evolution of smaller phacoemulsification tips and probes. A major limitation to making smaller phacoemulsification tips is the need for coaxial irrigation as a cooling mechanism to reduce the heat produced by ultrasonic energy within the ocular tissues. In pursuit of smaller instrumentation for cataract removal, laser energy has at-

tracted interest as a means for cataractous lens fragmentation.^{20–38}

The Dodick Photolysis system has also experienced significant evolution. The latest generation device used by four experienced phacoemulsification surgeons in this study appears to have created a safe, effective alternative to phacoemulsification.

Although all four participating surgeons were experienced in the use of phacoemulsification for cataract extraction, they were all “beginners” in the use of this technology. All surgeons participated in an extensive wet-lab with animal eyes to familiarize themselves with the instrumentation and techniques involved with the Dodick Photolysis system. Nevertheless, this group of patients comprises the “learning curve” with this technology and technique for all four surgeons. We found the operative technique and instrumentation to be extremely user-friendly. All procedures and, most important, the first several procedures for each surgeon required a very short learning curve to acquire considerable sense of safety and intraoperative control. These data therefore support our initial clinical experience, which is that this operative technique appears to be a relatively safe intraocular procedure. There were no clinical signs of corneal burn either at the completion of the procedures or during the postoperative period. This observation was supported by earlier laboratory studies, in which the intraocular use of the Dodick Photolysis probe was found to release no significant heat, either within the anterior chamber or intrastromally within the cornea.^{39,40}

Perhaps contributing to the safety of this technology is the low intraocular energy that is used. In this case series, the average energy used for each cataract extraction was 6.7 J. Surgical manipulation of the Dodick Photolysis probe within the anterior chamber of the eye appears to be relatively safe based on our initial clinical experience. The probe can even be inserted safely below the anterior capsule within the bag to photolyse the cataract material in situ. This is thought to be an advantage in comparison to the intraoperative handling of a phacoemulsification tip.

All cases of extracapsular cataract extraction were completed through an incision of approximately 1.4 mm. The smaller incision size used for the removal of cataracts is a significant advantage with this technique. This incision size can theoretically minimize postoperative astigmatic change, taken that an IOL can be inserted through it. This theoretical advantage was compromised to implant an IOL in these patients, because there were no IOLs available for insertion through an incision smaller than 2 mm. Perhaps the further evolution of IOL technology will enable implantation through incisions of 1.4 mm or smaller. Future development of an injectable material that could refill the capsular bag and act as an IOL with preservation of accommodation⁴¹ could dictate the use of this technology for a true endocapsular cataract removal through one or two minute incisions in the capsular bag. The use of a sub-1-mm diameter probe for Dodick Photolysis is one of the future goals of this technology.

From our initial experience with this technology, it is clear that effective operative technique requires tight fluids control for effective photolysis of the cataract to occur.

Again, this process is maximized if optimal approximation between the probe opening and the nuclear material is achieved between pulses. Unlike regular phacoemulsifiers, the photolysis probe is unable to “fire” when a piece of nontransparent nuclear fragment enters the lumen of the tip. In such cases, the laser pulsing results in no burst release due to blocking of the Nd:YAG beam along its path from the fiber-optic tip to the titanium target. A few seconds of brisk aspiration in such occasion is efficient in releasing the obstructing material and resuming the photolysis sequence.

Our initial clinical experience is that “softer” nuclei of +1 to +2 nuclear sclerosis were removed by the Dodick Photolysis technology in a timeframe comparable to that of phacoemulsification. Regarding more dense nuclei of +3, the operative time with this new technology was longer at this early stage. It appears from these limited data that the endothelial cell loss is comparable to that encountered after cataract extraction and IOL implantation with standard phacoemulsification at the follow-up time of 3 months. The number of intraocular and postoperative complications was also limited, considering that these were the initial cases for all investigators.

In conclusion, in this initial group of patients, we found the Dodick Photolysis to be a safe, effective technology for small-incision cataract removal in human eyes. It may involve less energy and heat release within the eye as well as a short and user-friendly learning curve for cataract surgeons. Evolution of IOL technology may allow the optimal utilization of the smaller incision involved with cataract extraction with Dodick Photolysis.

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