

Pacemaker Lead Extraction With the Laser Sheath: Results of the Pacing Lead Extraction With the Excimer Sheath (PLEXES) Trial

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- OBJECTIVES** The purpose of this study was to evaluate the safety and effectiveness of pacemaker lead extraction with the excimer sheath in comparison to nonlaser lead extraction.
- BACKGROUND** Fibrotic attachments that develop between chronically implanted pacemaker leads and to the venous, valvular and cardiac structures are the major obstacles to safe and consistent lead extraction. Locking stylets and telescoping sheaths produce a technically demanding but effective technique of mechanically disrupting the fibrosis. However, ultraviolet excimer laser light dissolves instead of tearing the tissue attachments.
- METHODS** A randomized trial of lead extraction was conducted in 301 patients with 465 chronically implanted pacemaker leads. The laser group patients had the leads removed with identical tools as the nonlaser group with the exception that the inner telescoping sheath was replaced with the 12-F excimer laser sheath. Success for both groups was defined as complete lead removal with the randomized therapy without complications.
- RESULTS** Complete lead removal rate was 94% in the laser group and 64% in the nonlaser group ($p = 0.001$). Failed nonlaser extraction was completed with the laser tools 88% of the time. The mean time to achieve a successful lead extraction was significantly reduced for patients randomized to the laser tools, 10.1 ± 11.5 min compared with 12.9 ± 19.2 min for patients randomized to nonlaser techniques ($p < 0.04$). Potentially life-threatening complications occurred in none of the nonlaser and three of the laser patients, including one death ($p = \text{NS}$).
- CONCLUSIONS** Laser-assisted pacemaker lead extraction has significant clinical advantages over extraction without laser tools and is associated with significant risks. (J Am Coll Cardiol 1999;33:1671-6) © 1999 by the American College of Cardiology

Tools and techniques for the transvenous removal of cardiac pacemaker leads have been demonstrated to be effective, but are associated with a small but significant risk to the patient (1). Fibrotic tissue develops over time and entraps the implanted lead in the veins and in the cardiac chambers (2,3). The existing extraction sheaths (Cook Vascular Incorporated, Leechburg, Pennsylvania) are advanced over leads to tear and peel away the encapsulating tissue. Excimer

laser generators produce pulsed ultraviolet light capable of dissolving human tissue, a technique that has found application in angioplasty (4). The excimer laser has also been applied to pacemaker lead removal (5). The laser sheath (The Spectranetics Corporation, Colorado Springs, Colorado) fiberoptically delivers the laser energy to the distal end of the sheath to release the lead from the encapsulating fibrotic tissue, permitting the advancement of the sheath without excess force or tearing of the tissues. To test the safety and efficacy of the laser sheath, the Pacemaker Lead Extraction with the Excimer Sheath (PLEXES) Trial was conducted at multiple centers in the USA.

METHODS

The laser sheath, shown in Figure 1, replaces the inner sheath of the Teflon telescoping sheath set. The 35-cm long sheath consists of thin inner and outer polymer walls

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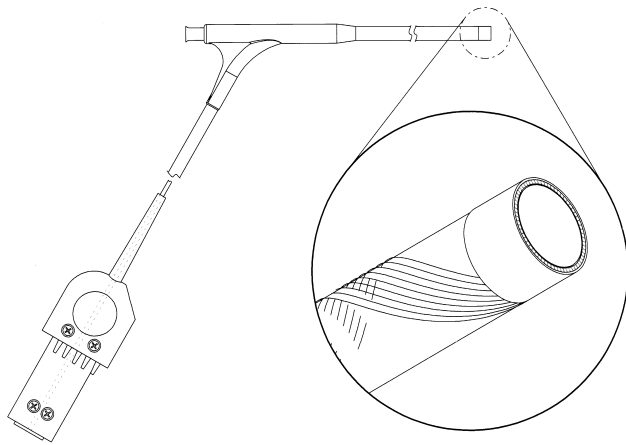


Figure 1. The laser sheath is the tubular structure that passes over the pacemaker lead. The inset demonstrates the wrapping of the optical fibers that conduct pulsed ultraviolet light to the distal tip as a ring of light. Also pictured is the modular connector, which attaches to the excimer laser generator and transmits the light to the tubular or working section of the sheath.

between which a single layer of optical fibers has been spirally wrapped (6). At the distal tip of the sheath the fibers present a single circumferential ring of light sandwiched between the inner and outer walls of the tip. At the proximal end of the sheath the fibers pass through a connecting cable to the laser generator. The 12-F laser sheath has an inner diameter of 8.4 F (2.8 mm) and an outer diameter of 12.4 F (4.1 mm).

The CVX-300 Excimer XeCl Laser System (Spectranetics Corporation, Colorado Springs, Colorado) emits 135-ns pulses (308 nm wavelength) at a repetition rate of 25 to 40 Hz. The fluence (output energy per unit area of fiber) at the distal tip of the device can be set to values between 30 and 60 mJ/mm².

Extensive research has been reported on laser-tissue interaction with this laser system (7-10). A combination of photochemolysis and photothermal ablation causes the layer of tissue immediately in contact with the device tip to disintegrate into particles no larger than 5 μm in diameter. Since the penetration depth of 308-nm light in vascular tissue is approximately 100 μm, the laser light is completely absorbed by the tissue immediately in front of the tip. This produces a controlled and precise removal of only that encapsulating fibrous tissue directly surrounding the lead body (11).

Statistical methods. Case data were recorded on paper forms, forwarded to the data coordination center and keyed into a computer database (SAS/STAT, SAS Institute Inc, Cary, North Carolina). Data from all centers were pooled before analysis. Means of continuous variables were compared by Student *t* test at 95% confidence. Differences in dichotomous categorical variables were deemed significant if the chi-square test yielded *p* < 0.05. Multivariate predictors of nonlaser failure were selected from the list of univariate

predictors if the coefficients for a predictor were significant at *p* < 0.05 in a multivariate logistic regression model built using the model-building strategies of Hosmer and Lemeshow (12).

Trial protocol. Overall, 301 patients with 465 pacemaker leads were prospectively randomized into the laser and nonlaser groups after granting written informed consent. Nine institutions in the U.S. contributed patients during the period from November 1995 to October 1996, after human ethics committee approval was received at each site.

Investigators were selected by their prior experience with lead extraction and were required to visit an active site to observe laser-assisted pacemaker lead removal. In addition, the first two laser procedures at each new site were proctored and not entered into the randomization. The training protocol was an attempt to reduce the bias related to the learning curve. Thereafter all patients who met the trial criteria were randomized at each institution.

Patient inclusion criteria for the PLEXES study required a lead with at least one year of implantation duration, accessibility of the lead from the subclavian, internal or external jugular or cephalic veins, informed consent, mandatory or necessary indications for lead removal and availability of all necessary extraction equipment (13). Exclusion criteria included the inability to use fluoroscopy, unavailability of surgical backup, and a lead too large for the laser sheath. A registry of the excluded patients was not maintained; however, failure to enroll an eligible patient was rare.

For both groups, the primary end point was complete removal of the lead by the randomized therapy without the development of a complication. The secondary end point added subtotal lead removal by the randomized therapy leaving behind only the electrode with or without a short segment (<4 cm) of conductor coil.

A second analysis determined the clinical success rate per patient instead of per lead; this "intention-to-treat" analysis required complete or subtotal extraction of all targeted leads by all techniques, laser, nonlaser and femoral tools, without complications. The time required to remove each lead and to remove all the targeted leads from each patient was recorded. These definitions were chosen to conform to published terminology (1).

Procedural failure for both the laser and nonlaser groups was defined as: 1) failure to gain venous entry; 2) failure to pass through a binding site, as evidenced by partial lead deformation or destruction of the plastic or laser sheath; 3) change to the transfemoral or transatrial or thoracotomy approach; 4) failure to extract the lead, or 5) occurrence of a complication. In the nonlaser group, the leads were removed by standard lead extraction counterpressure and countertraction techniques from the subclavian, jugular or cephalic veins (14), under fluoroscopic guidance. This approach was used until the procedure yielded lead removal or an objective measure of failure. If there was failure of the

Table 1. Patient Demographics and Extraction Indications

	Nonlaser	Laser	p Value
Number of patients	148	153	
Age (yr)	66 ± 18	65 ± 18	0.32
Female (%)	38%	33%	0.49
Mandatory indications	16 (11%)	19 (12%)	0.80
Septicemia	12 (8%)	15 (10%)	0.75
Endocarditis	4 (3%)	7 (5%)	0.58
Lead migration	0	1 (1%)	0.99
Device interference	3 (2%)	0	0.23
No usable veins	1 (1%)	2 (1%)	0.98
Necessary indications	140 (95%)	147 (96%)	0.74
Pocket infection	38 (26%)	37 (24%)	0.87
Chronic draining sinus	9 (6%)	11 (7%)	0.88
Erosion	14 (9%)	12 (8%)	0.77
Vein thrombosis	5 (3%)	8 (5%)	0.61
Lead migration	2 (1%)	2 (1%)	0.64
Potential device interference	26 (18%)	13 (8%)	0.03
Tricuspid insufficiency	3 (2%)	4 (3%)	0.96
Lead replacement not Accufix	44 (30%)	53 (35%)	0.43
Lead replacement (Accufix)	57 (39%)	57 (37%)	0.92

nonlaser approach, the investigator was free to choose any alternative modality to complete the extraction procedure.

In the laser group, standard lead extraction techniques were used with the exception that the laser sheath replaced the inner telescoping extraction sheath. In a typical procedure, a locking stylet was placed in the lead. A Teflon outer sheath was preloaded over the laser sheath before the stylet and lead were threaded through the assembly. The laser sheath and outer sheath were passed over the lead body until the first binding site was reached. Five-second bursts of excimer laser energy combined with gentle advancement pressure on the laser sheath and withdrawal traction on the locking stylet ablated the tissue and enabled the sheaths to advance to the next binding site. The CVX-300 was adjusted to the maximal setting of fluence of 60 mJ/mm² and a repetition rate of 40 pulses per second. The sheath assembly was advanced over the lead until it was freed from its attachments or until the sheath tip reached a point a few millimeters from the heart wall. At this point, the outer sheath was advanced, and countertraction was applied to remove the lead.

Table 1 shows demographic information on the 301 patients enrolled in the randomized trial. No significant differences were seen between the two groups in age, gender, lead implantation duration or the lead's characteristics such as manufacturer, chamber location, insulation type or polarity. Following the classification of Byrd et al. (13), the indications for extraction were classified into two categories: Mandatory or Necessary. Only 11.6% of patients presented with Mandatory indications, primarily infection. Table 1 shows that the most frequent Necessary indications were lead replacement and pocket infection. Many patients

Table 2. Lead Demographics

	Nonlaser	Laser	p Value
Randomized leads	221	244	
Leads/patient	1.49 ± 0.69	1.59 ± 0.67	0.10
Atrial	119 (54%)	125 (51%)	0.63
Ventricular	101 (46%)	118 (48%)	0.63
Coronary sinus	1	1	0.52
Fixation			
Active	99 (45%)	106 (43%)	0.84
Passive	117 (53%)	134 (55%)	0.74
Other/unknown	5 (2%)	4 (2%)	0.88
Lead age (mo)	69 ± 46	65 ± 42	0.16

presented with more than one lead and several and overlapping indications for removal.

A summary of the lead information shows that 1.54 ± 0.68 leads were extracted per patient (Table 2). Slightly more atrial leads were removed in a ratio of 1.1:1 compared with ventricular leads. By far the most common lead model extracted was the Teletronics (Teletronics Inc., Englewood, Colorado) 330-801 Accufix atrial lead, which accounted for 25% of all leads targeted for explantation in this study. The leads were implanted for 67 ± 44 months. There were no statistically significant demographic differences between the groups.

RESULTS

Extraction efficacy was significantly higher in patients randomized to laser-assisted removal (p = 0.001) (Table 3). Complete or partial success was achieved for 97% of leads randomized to laser versus 66% of leads in the nonlaser group. Because the protocol allowed crossover to the laser if deformation or partial destruction of the lead occurred, very few procedures in the nonlaser group proceeded to the secondary end point of partial extraction. Investigators preferentially attempted to remove the entire lead with laser

Table 3. Extraction Outcomes and Reasons for Failure

	Nonlaser	Laser	p Value
Leads (n)	221	244	
Complete extraction*	142 (64%)	230 (94%)	< 0.001
Partial extraction	4 (1.8%)	6 (2.5%)	0.87
Failure*	75 (34%)	8 (3.3%)	< 0.001
Failed venous entry	14 (6%)	0	< 0.001
Binding site impasse	42 (19%)	3 (1.2%)	< 0.001
Lead disruption	14 (6%)	2 (0.8%)	0.003
Lead diameter	3 (1.4%)	0	0.21
Acute complication†	0	3 (1.2%)	0.28
Crossover to 12-F laser	72 (33%)	—	—
Crossover to 16-F laser	1 (0.5%)	—	—
Crossover to femoral	2 (0.9%)	5 (2.0%)	0.53
Clinical success of procedure (patients)	142 of 148 (95.9%)	145 of 153 (94.8%)	0.83

*p = 0.001. †p = NS.

Table 4. Total Extraction Time: Intention to Treat Analysis

Extraction	Randomized Nonlaser		Randomized Laser			Crossover to Laser	
	min	n	min	n	p	min	n
Complete	12.9 ± 19.2	202	10.1 ± 11.5	225	0.04	14.1 ± 15.1	62
Partial	51.9 ± 45.9	7	15.2 ± 9.4	6	0.03	32.3 ± 24.0	3
Failed	27.2 ± 33.6	8	43.7 ± 35.1	7	0.19	23.9 ± 16.1	5
All leads	14.7 ± 22.1	217	11.2 ± 13.9	238	0.02	15.6 ± 15.9	70

assistance rather than leave a lead fragment behind. Of 72 leads crossed over to complete the extraction, 63 (88%) were completely and three (4%) partially removed with the laser.

Multivariate predictors of failed extraction with the nonlaser tools are: 1) lead manufacturer, 2) decreased patient age, and 3) the extraction center. With respect to the first predictor, the Telectronics 330-801 Accufix atrial lead accounted for 57 (26%) of the nonlaser and 57 (23%) of laser leads. This lead frequently met the failure criteria of deformation or destruction of the lead, because the lead body tends to pull apart between its electrodes during explantation with the increased traction force required with the nonlaser technique (14-16). Because the outer insulation protects the patient from lacerations from the J wire, partial destruction of the integrity of the lead was a contributor to failed nonlaser attempts to remove these leads. Of the 57 Accufix leads randomized to the nonlaser approach, only 27 (47%) were removed successfully compared with 96% of the laser randomized cases. In total, 86 of 87 (99%) Accufix leads treated with laser techniques as the randomized or rescue technique were successfully removed. In addition, all Accufix leads crossed over were completely removed with the addition of laser tools.

Binding sites and dense fibrous tissue were found at all locations from the venous entry site to the atrial or ventric-

ular destination. For successful laser cases a mean of 50 of laser application (2,000 laser pulses) was used.

The elapsed time from the first application of sheaths to the moment of explantation or failure is represented in Table 4. The mean procedure duration for all randomized and all successfully extracted cases was significantly shorter for the laser group patients. However, a portion of the nonlaser group patients (64%) had complete lead removal in an average time of removal of 8.1 ± 9.3 min. The other third of the nonlaser patients required a second procedure, and the total complete extraction time was 23.7 ± 29.0 min. In contrast, 94% of the laser group lead removals were completely successful in 10.1 ± 11.5 min. This increased likelihood of success and shorter duration of the extraction procedure was achieved despite the imposition of a 5-s maximum laser burst length and a 10-s rest period between laser bursts. Because the average case required 50 s of laser treatment time, this produced 100 s of enforced rest periods during an average laser-assisted lead removal.

Although there were no complications directly related to the application of laser energy, there were significant complications in five patients randomized to laser use and in two patients randomized to nonlaser (p = NS). Three of these patients, all randomized to laser, required procedural intervention; one died after a cardiac tamponade. In the latter patient, severe calcification was noted, which is a recognized

Table 5. Complications

Complication	Randomization	Result	Description
Tamponade	Laser	Thoracotomy, death	Laceration of the lateral right atrial wall produced cardiac tamponade and consequent death. The atrial lead was tightly bound by densely calcified scar tissue observed on chest radiography and fluoroscopy.
Tamponade	Laser	Thoracotomy	Laser removal of another lead was complete. Occurred during femoral tool removal of a lead not eligible for randomization due to preoperative retraction into the brachiocephalic vein.
Hemothorax	Laser	Chest tube	Laser sheaths had been advanced to the distal electrode and had been withdrawn. Polymer sheath advancement lacerated the SVC due to inadequate tension on the lead during counterpressure.
Valve damage	Laser	Medical treatment	Peripheral edema and severe tricuspid insufficiency were noted after a difficult and failed extraction with the laser and other tools.
Thrombosis	Nonlaser	Anticoagulation	SVC occlusion.
Thrombosis	Laser	Anticoagulation	Arm edema.
Thrombosis	Nonlaser	Observation	Arm edema.

SVC = superior vena cava.

risk factor for lead extraction. In follow-up, two other patients died from causes unrelated to the extraction procedure (Table 5).

DISCUSSION

The PLEXES study shows that the addition of the laser sheath significantly improves the efficiency of transvenous lead extraction. Telescoping stainless steel and polymer sheaths require mechanical force to pass them over the leads through dense fibrous tissue, allowing passage to a point near the endocardial surface. With the laser sheath, the pulsed ultraviolet light ablates the tissue, greatly reducing the magnitude of force applied. Ideally, the laser sheath minimizes the use of counterpressure. We attribute the difference in success rates to the cutting action of the laser sheath, a feature that has been absent in other explanation tools.

Comparison with historical expectation. Extraction failure was defined differently in this trial than in previous reports to highlight the impact of the laser sheaths on extraction. Previously reported success rates of up to 95% included the use of tools from the subclavian veins, femoral veins and transatrial routes. The analogous rate of extraction without the laser tools in prior studies (69% to 88%) would include only those leads removed without the femoral and transatrial techniques (1,14,17). In this study, success was broadly defined as the inability to remove the lead from the subclavian or cephalic vein approach even if the lead was subsequently removed with femoral or transatrial tools. The increased failure rate of 34% in the nonlaser group and consequent crossover rate in this study suggest that there are additional issues. In many cases, patients referred to the PLEXES sites were preselected by their referring physician because extraction was expected to be difficult. It should be noted that only leads implanted >1 year were included in the PLEXES study, whereas previous reports did not impose this restriction.

The PLEXES study design allowed investigators to declare failure in a nonlaser case when the lead began to stretch or fall apart. Crossover to the 12-F laser sheath was used in all but three of these patients. Crossover in the opposite direction was meaningless, because the laser technique included the nonlaser tools and requires increased traction forces on the leads. Most (88%) of these leads were completely removed without changing to the femoral approach. Defining lead disruption as a failure end point distinguishes this study from previous reports (1). Before this experience, partial removal of a lead with nonlaser tools was an acceptable outcome, occurring in over 7% of the patients with implantation durations similar to the patients in this study. It seems likely that in many of the crossover cases partial success would have ensued with the nonlaser approach. The complete success rate in either primary or rescue laser-treated leads combined with the ease of removal with this technique raised the expectations of the investigators and biased toward earlier crossover. This bias was

further magnified by the higher incidence of fractured or fragile leads, such as the Teletronics "Accufix" 330-801 atrial lead, in the PLEXES study vis-à-vis the historical database.

Another motivation for using the laser tool relates to the predictability of the procedure. Not only were 94% of the leads completely removed with this technique, the mean procedure duration was 10.1 min. When the initial approach was nonlaser with the willingness to crossover to the laser techniques, 95.9% of these patients achieved a clinical success with an additional mean extraction time of 14.1 min. When the nonlaser technique was used 34% of the leads required this additional intervention, which made the total extraction time an average of 23.7 ± 29.0 min. The frequently time-consuming use of femoral extraction tools was uncommon (<1% of leads) in the trial. The combination of improved complete success rates and reduced extraction times makes the laser approach attractive.

Management of complications. In this study, relatively few patients presented with a "mandatory" indication for lead removal. Lead replacement was the largest indication by far, including replacement of leads under recall. Teletronics 330-801 Accufix J leads contributed 114 of 211 (54%) of these leads. This implies that both patients and their physicians believe that the benefits of extraction presently outweigh the risks of leaving these leads in place. Although complications occurred and were life-threatening, the incidence of complications in the laser group remained below 2%, comparable to previously published values (1). Although statistically not significant, the larger number of complications in laser group patients emphasizes the need for extreme caution with this and all extraction approaches. Further consideration of the risk versus benefit ratio will require a much larger registration of cases as the tools and level of experience improves.

One would anticipate that complications such as vascular laceration, perforation, hemothorax, tamponade and death might be present regardless of the percutaneous means of extracting leads (1,14-16). Of the complications observed with the laser-assisted technique, none was judged to be secondary to the use of laser energy. However, experience with the laser sheath indicates that additional precautions should be taken. In some cases, the outer telescoping sheath was retained in the vasculature when the laser sheath and lead were removed together. If this technique is used, the outer sheath should be positioned in the right atrium or pulled back into the subclavian vein to avoid inadvertent damage to the distal superior vena cava. Alternatively, the extraction sheath should be removed after the introduction of a J-tipped guide wire, and a long peel away introducer that reaches the right atrial chamber should be used to implant the replacement lead. These two techniques minimize the possibility that the introduction of the new lead would perforate the potentially extraction-weakened superior vena cava. This one potentially new, avoidable and

life-threatening complication underscores the previously identified need for aggressive monitoring and prompt and competent surgical management.

Study limitations. As in any randomized trial with crossover, the mere existence of a crossover option raises the question of bias. The protocol attempted to minimize bias against the nonlaser group by providing “objective” measures of failure. However, even these measures contain some degree of variability and subjectivity. For instance, each investigator determined individually and in each patient’s case how much force could be safely applied to a lead without damaging it, thereby reaching a failure criterion. This clearly was a source of site-to-site variability.

The lack of a crossover option would make the data more convincing, but this trial without crossover may not have served the best interests of the patients. Because most crossover leads were extracted successfully by laser, it would be difficult to argue that a femoral or transthoracic approach would have served the patients better. Total study enrollment was powered to show significance if laser achieved 94% success and nonlaser achieved 83% success, the best-case historical benchmark. Thus, if crossover bias had not been present and if nonlaser success had equaled the literature value, laser would still have been shown to be significantly more successful. It would certainly be true that the mean nonlaser procedure time would have been even longer.

Crossover from the laser group to a nonlaser modality was specifically not included in the protocol. Because nearly all standard extraction tools must be used in a laser case, crossover to a nonlaser modality was practically indistinguishable from the laser modality. During the trial, it was noted in some instances that the laser sheath did not traverse the lead all the way to the tip, but the lead was removed using polymer sheaths from the furthest advancement of the laser sheath onward. Such an instance counted as a laser group success, wherein the laser sheath and polymer sheaths performed mutually adjunctive functions.

Conclusions. The results of the PLEXES Trial show that the addition of the laser sheath to the standard tool set provides an improved approach for completely removing chronically implanted pacing leads. Although the possibility for serious complications still exists in lead extraction, no new safety issues were linked with the use of the device; observed complications were not directly related to the laser. Because the risks of lead extraction must always be weighed against its benefits, the apparent effectiveness of the laser sheath will certainly affect the standards used to evaluate patients for lead extraction.

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