Clinical Study of the Laser Sheath for Lead Extraction: The Total Experience in the United States

CHARLES L. BYRD,* BRUCE L. WILKOFF,† CHARLES J. LOVE,‡ T. DUNCAN SELLERS,§ and CHRISTOPHER REISER||

From *Broward General Medical Center, Fort Lauderdale, Florida, †the Cleveland Clinic Foundation, Cleveland, Ohio, ‡Ohio State University Medical Center, Columbus, Ohio, §Memorial Hospital, Colorado Springs, and ||Spectranetics, Colorado Springs, Colorado

BYRD, C.L., ET AL.: Clinical Study of the Laser Sheath for Lead Extraction: The Total Experience in the United States. The laser sheath uses optical fibers, delivering pulsed ultraviolet excimer laser light, to vaporize fibrotic tissue binding intravenous cardiac leads to the vein or heart wall during lead extraction from the implant vein. The total investigational experience with laser sheaths is reported. During the period from October 1995 to December 1999, 2,561 pacing and defibrillator leads were treated in 1,684 patients at 89 sites in the United States with three sizes of laser sheath. Endpoints were complete removal of the lead, partial removal (leaving the tip behind), or failure (abandoning the lead, onset of complications, change to transfemoral or transatrial approach). Minimal follow-up at 30 days was recorded. Of the leads, 90% were completely removed, 3% were partially removed, and the balance were failures. Major perioperative complications (tamponade, hemotorax, pulmonary embolism, lead migration, and death) were observed in 1.9% of patients with in hospital death in 13 (0.8%). Minor complications were seen in an additional 1.4% of patients. Multivariate analysis showed that implant duration was the only preoperative independent predictor of failure; female sex was the only multivariate predictor of complications. Success and complications were not dependent on laser sheath size. At follow-up, various extraction related complications were observed in 2% of patients. The learning curve showed a trend toward fewer complications with experience. Lead extraction with the laser sheath can be safely practiced with high success rates. Success is independent of laser sheath size. Major complications can be expected in < 2% of patients, and occur more often during an investigator’s early experience. (PACE 2002; 25:804–808)

pacing lead, defibrillator lead, lead removal, ultraviolet

Introduction

While a variety of tools have been used to implant transvenous pacing and defibrillator leads, specialized tools for lead removal are comparatively new. Telescoping sheaths, constructed from polymer extrusions or stainless steel tubes, aided lead extraction by providing a means to free the lead body from fibrotic tissue that grows over the lead.1–3 Locking stylets, which grip the lead near the tip, greatly facilitated lead removal from the implanted vein.4,5 Higher pulling forces, enabled by locking stylets and applied to dilate or tear the fibrotic tissue, may cause compromise or avulsion of the vascular wall with rapid exsanguination.6,7 Freeing the lead from intravascular scar tissue remains the most difficult part of intravascular lead extraction.

Recently, the initial results of clinical investigation of the laser sheath have been reported.8–12 While the results of a randomized trial9 and multicenter registries9,10 showed improved results over nonlaser tools, analysis of large experiences has been lacking. This report describes the total investigational experience of the laser sheath in the United States, including all cases performed under the US Food and Drug Administration (FDA) Investigational Device Exemption (IDE) protocol, and cases registered during a 1-year postmarket surveillance study.

Methods

The laser sheath (Model SLS, Spectranetics, Colorado Springs, CO, USA) was available in three sizes designated by their nominal outer diameters: 12 Fr, 14 Fr, and 16 Fr.9 Each laser sheath features a working section approximately 35 cm in length, with a hollow core that slides over the implanted pacing lead.12 An optical plug at the proximal end of the device inserts into a laser (Model CVX-300, Spectranetics), which generates pulses of ultraviolet light at 308 nm in a XeCl excimer laser engine.
at a repetition rate of 40 pulses per second. Each laser sheath was calibrated before use so that the fluence (laser energy delivered per square millimeter of fiber) attained 60 mJ/mm$^2$. For each laser sheath an appropriately sized bismuth-loaded polyethylene outer sheath was provided. The outer sheath was loaded onto the laser sheath, in telescoping fashion, prior to the procedure.

Included in the study were patients at least 18 years old presenting with a Class 1 (life-threatening) or Class 2 (generally accepted criteria) indication for lead removal with transvenous pacing or defibrillator lead(s) implanted for at least 1 year that were accessible from the generator pocket. Exclusion criteria included leads too large for the laser sheath, recent pulmonary embolus, unsuitability for emergent open-chest surgery, and unavailability of required equipment. Prior to commercial release of the laser sheath, patients gave informed consent before inclusion.

After preparation and draping, intravenous sedation or endotracheal anesthesia was administered at the preference of the investigator. The generator pocket was prepared for incision, as well as the sites for Seldinger-type access to the femoral vein and for emergent sternotomy. In pacemaker dependent patients, temporary pacing was established with a transvenous catheter or a temporary lead. The pulse generator pocket was then opened, debrided, and the generator disconnected from the leads.

Leads were prepared for extraction by cutting off the connector, dilating the inner coil with an expander and using gauge pins (Cook Vascular, Leechburg, PA, USA) to determine the lumen size of the inner coil. A properly sized locking stylet was inserted into the inner coil in a large majority of leads and locked as distally as possible. A length of suture typically ligated the proximal end of the lead body.

The laser sheath, with the outer sheath preloaded, was threaded over the locking stylet handle and then over the lead body. The moment of sheath application defined the beginning of the extraction procedure duration that continued until an endpoint was reached. Under fluoroscopic observation, the sheaths were advanced over the lead until a binding site was encountered. At this point, the tip of the laser sheath was pressed forward, into the binding tissue, while the laser was activated. As many bursts were administered as necessary to core through the binding site. The sheaths were then advanced carefully, using traction on the locking stylet and equal-but-opposite counter-pressure on the sheaths, until the next binding site was reached and vaporized. In this way the sheaths were advanced until the lead became free from the vasculature, or until the sheaths reached tip of the lead. If the tip remained attached to the heart, traction was applied to the stylet handle while counter-traction on the outer sheath was used to extract the tip from the heart wall. The lead and the laser sheath were then removed as a unit.

Radiographic outcomes were classified similarly to recommended definitions:

- **Complete Success**—Removal of all lead material from the vascular space.
- **Partial Success**—Removal of all but a small portion of the lead. This may be the electrode, ≤ 4 cm of conductor coil and/or insulation, or the latter two combined.
- **Failure**—Abandoning > 4 cm of lead after attempting to remove it from the implant vein, or changing the approach to transfemoral or transatrial.

The definition of complete or partial success used in this study added one criterion to the determination of radiographic outcomes: absence of complications. Secondary endpoints included acute complication and complications observed at 1 month.

From November 1995 to October 1996, subjects were enrolled at nine sites and allocated randomly to treatment with mechanical tools alone or treatment with the laser sheath plus mechanical tools in the Pacing Lead Extraction with the Excimer Sheath (PLEXES) trial. In this period, when only the 12 Fr laser sheath was available, crossover from the nonlaser group to the laser group was permitted after a failure endpoint was reached. An additional nonrandomized group was also treated with the laser to facilitate training new investigators. The 218 patients treated with the laser sheath in this period are included in this analysis.

From November 1996 to December 1998, the number of sites expanded to 59. During this period the 1-year implant duration criterion was abolished, and treatment of qualifying patients at participating sites with the laser was not mandatory. Data on all patients treated with any size laser sheath were tabulated in a prospective registry format. There are 1,261 patients in this group.

From December 1998 to December 1999, a limited postmarket surveillance (PMS) registry tracked the first ten patients treated with the laser sheath at 33 new sites only. These data, on 205 patients, are also included in this analysis, with sub-analyses on rates of success and complications.

Procedural data were recorded on paper forms and manually entered into a database (SAS/STAT, SAS Institute Inc., Cary, NC, USA) on a personal computer for analysis. Minimal data
were recorded at 1-month clinical or telephonic follow-up for patients enrolled prior to the PMS registry. Categorical variables were analyzed by frequency tables and compared via continuity adjusted chi-square probabilities. Continuous variables were reported as mean ± SD (range) and compared using the Student’s t-test. A P value of 0.05 was considered significant.

Multivariate logistic regression analysis was used to determine which variables were independent predictors of extraction failure and complications. Estimates of the coefficients of correlation and the corresponding standard errors were made for sex, age, tissue toughness (scored subjectively by the investigator on a scale of 1-4), lead manufacturer, lead location, fixation type, locking stylet usage, method of freeing the lead tip, and previous extraction attempt. A P value ≤ 0.05 determined which variables were predictive.

Results

The 1,684 patients treated had a mean age of 64 ± 18 (4-102) years; 64% were men. Lead descriptors are shown in Table I; more than one indication for extraction was noted for some leads. Enrollment per site varied from 1 to 346; 70% of patients were enrolled at 17% of the sites. Overall, 50% of the devices used were 12 Fr; the 14 and 16 Fr devices were used in 32% and 17% of cases, respectively. Mean procedural time was 15.7 ± 27 (0-300) minutes.

Radiographic outcomes are shown in Table II. Using the per protocol definition that observation of a complication forced the outcome to be listed as “failed,” 90% of procedures were completely successful, 3% achieved partial success, and 7% of the extractions failed from the implant vein. The reasons cited for failure, and other procedural results, are also shown in Table II.

Complications were analyzed according to the most serious adverse event observed during the intraoperative and perioperative periods and are noted in Table III. Major complications (hemopericardium with tamponade, hemothorax, pulmonary embolism, lead migration, death) were observed in 32 (1.9%) of 1,684 of patients. In-hospital death occurred in 13 (0.8%) patients. Death was secondary to a major complication in 10 instances: tamponade in 5 cases, hemothorax in 3, pulmonary embolus in 1, and rupture of an anomalous innominate arteriovenous fistula in 1. Other causes for death included renal failure in

---

**Table I.**

<table>
<thead>
<tr>
<th>Leads Descriptors</th>
<th>n = 2561</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean implant duration, months</td>
<td>76 ± 50 (0.8–365)</td>
</tr>
<tr>
<td>Location</td>
<td></td>
</tr>
<tr>
<td>Atrium</td>
<td>38.8%</td>
</tr>
<tr>
<td>Ventricle</td>
<td>59.8%</td>
</tr>
<tr>
<td>Coronary sinus</td>
<td>0.3%</td>
</tr>
<tr>
<td>Other/unknown</td>
<td>1.1%</td>
</tr>
<tr>
<td>Fixation</td>
<td></td>
</tr>
<tr>
<td>Active</td>
<td>31%</td>
</tr>
<tr>
<td>Passive</td>
<td>58%</td>
</tr>
<tr>
<td>Unknown/none</td>
<td>11%</td>
</tr>
<tr>
<td>Locking stylet used</td>
<td></td>
</tr>
<tr>
<td>88%</td>
<td></td>
</tr>
<tr>
<td>Indications for Extraction*</td>
<td></td>
</tr>
<tr>
<td>Class 1</td>
<td>14%</td>
</tr>
<tr>
<td>Class 2</td>
<td>96%</td>
</tr>
</tbody>
</table>

* > 1 indication for lead removal was possible.

**Table II.**

<table>
<thead>
<tr>
<th>Radiographic Outcomes</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete success</td>
<td>90%</td>
</tr>
<tr>
<td>Partial success</td>
<td>3%</td>
</tr>
<tr>
<td>Failure</td>
<td>7%</td>
</tr>
<tr>
<td>Mean treatment time, minutes</td>
<td>15.7 ± 26 (0–300)</td>
</tr>
<tr>
<td>Tip freed by</td>
<td></td>
</tr>
<tr>
<td>Traction</td>
<td>40%</td>
</tr>
<tr>
<td>Countertraction</td>
<td>46%</td>
</tr>
<tr>
<td>Other/unknown</td>
<td>14%</td>
</tr>
<tr>
<td>Reasons for failure</td>
<td></td>
</tr>
<tr>
<td>Lead breakage</td>
<td>17</td>
</tr>
<tr>
<td>Impassable lead</td>
<td>12</td>
</tr>
<tr>
<td>Impassable binding site</td>
<td>35</td>
</tr>
<tr>
<td>Complications</td>
<td>29</td>
</tr>
<tr>
<td>Change of approach</td>
<td>50</td>
</tr>
<tr>
<td>Other</td>
<td>24</td>
</tr>
</tbody>
</table>

**Table III.**

<table>
<thead>
<tr>
<th>In-Hospital Complications for 1,684 Patients</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tamponade</td>
<td>23</td>
<td>1.4</td>
</tr>
<tr>
<td>Hemothorax</td>
<td>6</td>
<td>0.4</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>2</td>
<td>0.1</td>
</tr>
<tr>
<td>Migrating lead fragments</td>
<td>1</td>
<td>0.06</td>
</tr>
<tr>
<td>Subtotal: major</td>
<td>32</td>
<td>1.9</td>
</tr>
<tr>
<td>Minor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perforation</td>
<td>5</td>
<td>0.3</td>
</tr>
<tr>
<td>Myocardial avulsion</td>
<td>2</td>
<td>0.1</td>
</tr>
<tr>
<td>Venous avulsion</td>
<td>1</td>
<td>0.06</td>
</tr>
<tr>
<td>Other</td>
<td>15</td>
<td>0.9</td>
</tr>
<tr>
<td>Subtotal: minor</td>
<td>23</td>
<td>1.4</td>
</tr>
<tr>
<td>Any complication</td>
<td>55</td>
<td>3.3</td>
</tr>
</tbody>
</table>
two cases, and arrhythmia at 12-hour postproce-
dure in one case. Minor complications were ob-
erved in 23 (1.4%) of 1,684 patients, including
laceration, avulsion of vein or myocardium, arm
swelling, pocket hematoma, and other observa-
tions.

Combined success (defined as complete suc-
cess or partial success) was observed in 93.5%, 93.4%,
and 93.4% of leads for the 12, 14, and 16
Fr devices, respectively (P = 0.99). Major compi-
lcations were observed in 1.7%, 2.6%, and 2.1% of
patients, respectively (P = 0.55).

Multivariate analysis showed that lead im-
plant duration > 10 years was a predictor of pro-
cedural failure. The presence of grade 4 tough tis-

tue also correlated with failures. Other variables
were not predictive at the 95% certainty level, in-
cluding lead fixation type, lead location, and laser
sheath size. Multivariate analysis of complica-
tions revealed that only female sex predicted com-
plications (P = 0.013) with an estimated odds ra-
tio of 2.5 (95% confidence interval: 1.4–4.4).

The learning curve effects were scrutinized by
plotting outcomes versus the number of laser
sheath procedures performed per site. Figure 1
shows a plot of the cumulative rate of combined
success versus the number of procedures per-
formed. The value near the x-axis origin gives the
success rate for all investigators after their first ten

![Figure 1](image.png)

Figure 1. The learning curve for cumulative combined
success (lower curve, left axis) shows a flat response with
experience. The postmarket surveillance data (diamond
point near x-axis origin) falls very close to the asymptotic
value of the curve. The learning curve for complications
(upper curve, right axis) shows a small decline over the
first 30 cases performed, and a slow decline thereafter.
The postmarket surveillance data (triangle point near x-
axis origin) falls close to the asymptotic value of the
curve.

<table>
<thead>
<tr>
<th>Table IV. Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up expected</td>
</tr>
<tr>
<td>Follow-up received</td>
</tr>
<tr>
<td>Of the follow-up received</td>
</tr>
<tr>
<td>Asymptomatic</td>
</tr>
<tr>
<td>Complications related to lead removal</td>
</tr>
<tr>
<td>Deceased (any cause)</td>
</tr>
<tr>
<td>Lost to follow-up</td>
</tr>
<tr>
<td>Data missing</td>
</tr>
</tbody>
</table>

procedures; the asymptote of this plot gives the
average cumulative value for investigators with a
large total experience. Also plotted as a single
point near x = 0 is the observed value for the PMS
group. A similar learning curve plot for observed
complications is also shown in Figure 1. The mul-
tivariate analysis of complications showed that
complication frequency trended downward with
increasing experience (P = 0.054).

Follow-up forms were recorded for 1,212
(80%) of the 1,507 patients in the IDE phase of the
study. Mean follow-up time was 69 ± 66 (1,510)
days. Of the follow-ups received, 2% reported a
complication related to lead extraction, 1% had
died, and 4% were lost to follow-up (Table IV). Com-
plexities at follow-up included arm
swelling, pleural effusions, pain at pacer site,
hematoma, small pulmonary embolus, and infec-
tion (in two patients who presented with infec-
tion).

Discussion

Tissue vaporization with pulsed excimer
laser light has been well studied in the context of
angioplasty.14,15 By a combination of photolytic
and photothermal mechanisms, cellular tissue in
contact with the device tip is reduced to subcellu-
lar debris. In the PLEXES randomized trial, the
coring action of the laser sheath made a significant
improvement in success rates versus the use of
mechanical tools alone. Success rates in this series
were nonsignificantly lower compared to the ran-
domized trial (P = 0.063), but the cumulative suc-
cess rates reported here are nearly identical to the
registry of early experience reported by Epstein et
al.9

Reports of perioperative major complications
include 2.5% for mechanical tools,5 2.5% in the
laser group of the PLEXES randomized trial,8
1.7% in the initial experience with larger laser
sheaths,8 and 2.0% in the initial European experi-
ence.10 Incidence of major complications or death
are nearly identical in this series, at 2.1%. The
trend toward the higher incidence of complications in women\textsuperscript{5} suggests that extreme care be taken in patients with small vessels.

Perioperative mortality of 0.8\% falls close to historical expectations. In the vast majority of cases, death resulted from a compromise of the vein or heart wall near the pericardial reflection. In the first year of investigation, perforations were observed during implant of a new lead through the outer sheath. This practice was discontinued in preference to the retained guidewire method, in which a floppy-tipped guidewire is inserted through the outer sheath, the outer sheath removed, and a standard introducer inserted over the guidewire prior to lead implantation. Cases in which the lead had eroded into the vein wall, or had been implanted with a circuitous route through veins and arteries, were especially troublesome; these conditions are nearly impossible to diagnose fluoroscopically and presage vascular wall opening when the lead and the scar tissue binding it are removed from the site.

Almost no learning curve was observed for success. In fact, the PMS success rate, achieved in the first ten usages of the laser sheath at sites with minimal lead extraction experience, matches the cumulative success rate of the entire data set. A shallow learning curve was observed for complications, which were 1.5 times as likely during the first ten cases as they were overall. The PMS data point once again matches the cumulative experience, and in this respect improves over the learning curve.

Observations at follow-up are consistent with expectations for pacer implants.\textsuperscript{16,17} Introduction of the laser sheath into the subclavian vein creates a vascular opening wider than the typical implant; this may correlate with the incidence of pocket hematomas observed at follow-up. Extra care should be taken to ensure hemostasis before final pocket closure in laser sheath cases.

**Study Limitations**

A number of the failed attempts at extracting leads from the implant vein were immediately followed by femoral extraction techniques, which successfully removed the leads in some cases. Since the outcomes of the femoral procedures were not recorded, a true estimate of final radiographic outcomes was not made. Since this study was conducted prior to the publication of consensus recommendations,\textsuperscript{13} clinical outcomes were also not recorded. Most of this study was conducted as a mandatory registry, without a control group; the PLEXES randomized trial remains the only prospective controlled study of lead extraction outcomes.

**Conclusions**

Lead extraction with the laser sheath can be safely practiced with radiographically successful results in at least 93\% of procedures. Major complications can be expected in approximately 2\% of patients, and occur more often during an investigator’s early experience, and more often in women. Success and complications are independent of laser sheath size. Radiographic failure can be expected more often in leads implanted for at least 10 years.

**Acknowledgments:** The authors thank M.A. Lloyd, M.D., for insightful comments on the manuscript.

**References**