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Review

# Lead extraction using a laser system: Techniques, efficacy, and limitations

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ABSTRACT

Transvenous lead extraction is becoming popular in Japan since the approval of laser extraction system in 2010. The laser system seems to be the standard method used by most physicians, owing to its efficacy and ease of handling. The efficacy and safety of this technology has been well proven in many studies and the data suggest that it can be used for Japanese patients safely. However, lead extraction can cause serious complications. Thus, it is important to learn the limitations as well as the basic techniques and efficacy of this procedure.



**Contents**



## 1. Introduction

Laser-assisted lead extraction was approved in Japan in 2010. The system itself has been in use in western countries for many years and its effectiveness as well as safety has been proven in many studies. Various methods are used for a transvenous lead extraction. However, the laser-assisted system seems to be the standard method used by most physicians, owing to its efficacy and ease of handling. Needless to say, any lead extraction method has limitations and a risk of major adverse events (MAEs). It is important, not only for the physicians but also for the medical staff involved in this procedure, to understand the benefits and limitations of this system.

## 2. History

An excimer laser system for the extraction of permanent pacemaker lead has been developed by Spectranetics Inc. (Colorado Springs, CO) and the first extraction was performed by Dr. Charles L. Byrd in 1994. In 1998 [1], Dr. Kennergren reported their experiences to use an excimer laser. The initial model of laser sheath (SLS I) was modified and a second-generation laser sheath (SLS II) was launched in the market in 2002. The major improvements included a more flexible distal of the laser sheath up to

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10 cm and a slight bevel of the tip, as much as 15° (Fig. 1). The efficacy and safety of this laser sheath has been proven in many articles throughout the literature. SLS II was approved in Japan in 2010.

## 3. How it works

The laser sheath fiber-optically delivers the laser energy to the distal end of the sheath, releasing the lead from the encapsulating fibrotic tissue. The sheath is constructed using 82 optical fibers, each with a core diameter of 100 μm, around an inner lumen. The CVX 300 (Fig. 2, Spectranetics, Colorado Springs, CO) emits an excimer laser beam utilizing xenon chloride, with an output of 308 nm, which falls in the ultraviolet region, not visible for humans. This cool cutting laser has an absorption depth of 0.05 mm, the energy being absorbed by proteins and lipids. These parameters are well suited for lead extraction, allowing cutting of the tissue without damaging the veins or insulation of lead.

## 4. How to use

The SLS II laser sheath comes in three different sizes; 12 French (F), 14 F, or 16 F (Fig. 2), according to the diameter of extracting lead. Each sheath permits removal of lead with a maximum outer diameter of 7.5 F, 9.5 F, and 11.5 F, correspondingly. The SLS II laser sheath was positioned over the targeted lead and adhesions were lysed using the laser when required (Fig. 3). The beveled edge of the sheath was kept on the inside when approaching the brachiocephalic curve. The lead tip was freed by performing "counter traction", applying adequate traction to the lead while retaining

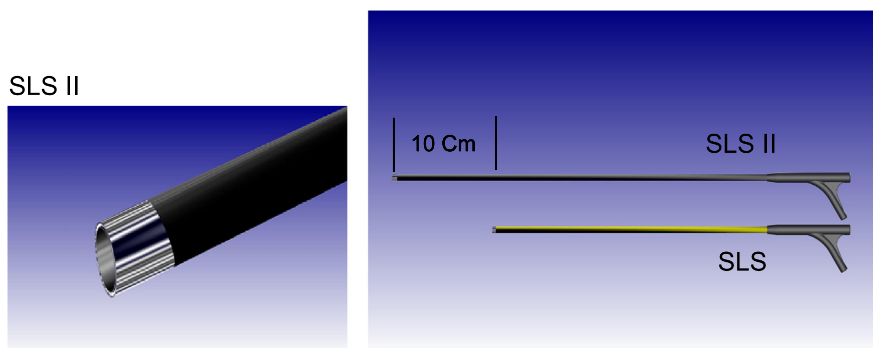


**Fig. 1.** SLS II, the second-generation laser sheath. The tip of the sheath has a slight bevel of about 15° (left panel). The distal part, up to 10 cm, is more flexible than the original laser sheath (right panel).

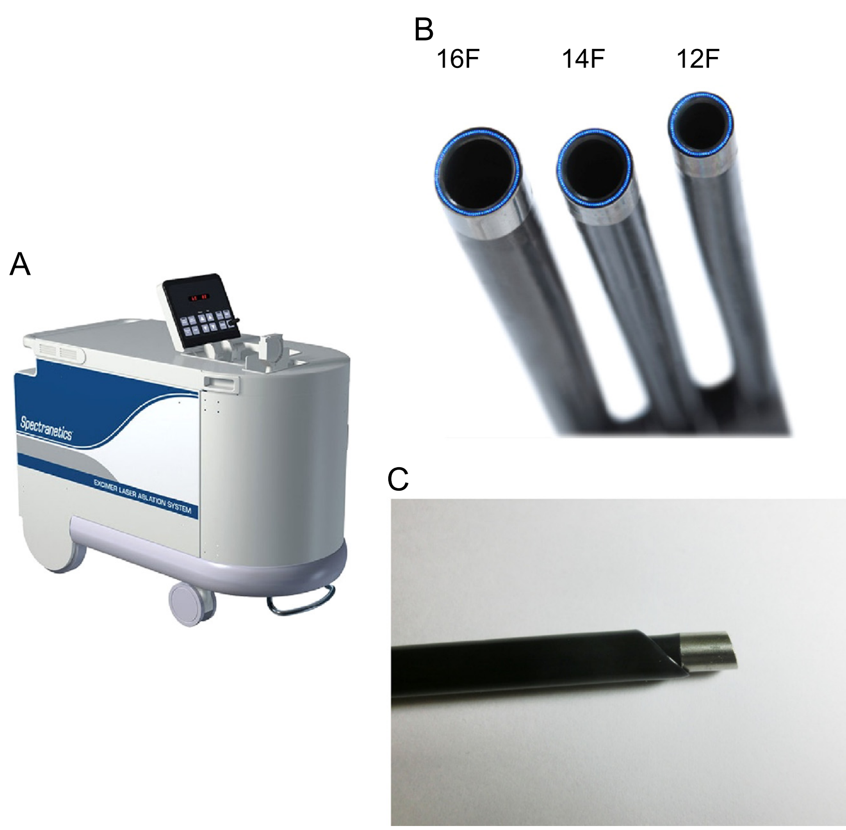


**Fig. 2.** (A) CVX 300 (Spectranetics, Colorado Springs, CO), the generator that emits an excimer laser utilizing xenon chloride with an output of 308 nm. (B) SLS II laser sheath with a line up of three sizes. The sheath is constructed using 82 optical fibers, each with a core diameter of 100 μm, around an inner lumen. (C) Mechanical outer sheath over the inner laser sheath.

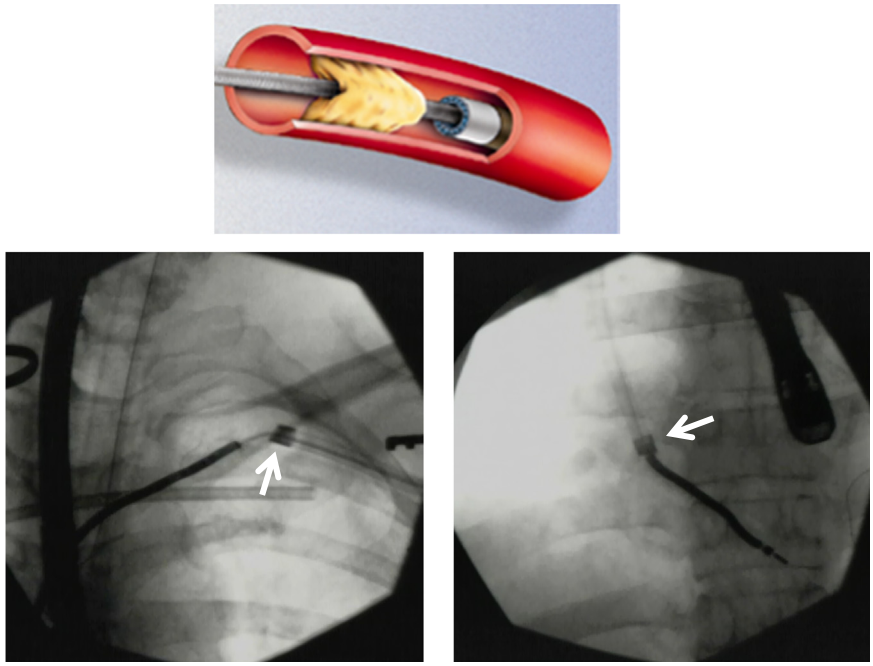

**Fig. 3.** (Upper panel) Illustration of the working of the laser sheath. It is positioned over the targeted lead and adhesions are lysed using the laser when required. (Lower panel) Fluoroscopic image when the laser sheath is positioned over the lead. White arrow shows the distal tip of the laser sheath. Note that the beveled edge of the sheath is kept on the inside.

the sheath in a position close to the atrial or ventricular endothelium. To maintain a certain amount of tension in the lead, a specific locking stylet is employed in most cases. When the laser sheath cannot advance on its own, probably due to calcified adhesions, a mechanical outer sheath made of polytetrafluoroethylene (Fig. 2) can be applied. In addition, when the subclavian approach does not work well, a femoral approach using a snare catheter is helpful.

## 5. Efficacy and safety

The PLEXES trial [2] was a randomized prospective clinical trial, comparing the first 12 F laser sheath to a non-laser cohort in 301 subjects, with 465 chronic pacemaker leads. Complete lead removal rate was 94% in the laser group and 64% in the non-laser group ($p=0.001$). 88% of the time, the failed non-laser extraction was completed using laser tools. The mean time to achieve a successful lead extraction was also significantly reduced using laser tools, as compared to non-laser techniques ($p<0.04$). None of the non-laser techniques led to any potentially life-threatening complications. However, such complications arose in three of the laser patients, including one death ($p=$NS).

Subsequently, in 2002, Byrd et al. [3] reported the laser lead extraction of 2561 pacing and defibrillator leads from 1684 patients at 89 sites in the United States. The procedural success rate was 90%, with a major complication rate of 1.9% and an in-hospital death rate of 0.8%.

Bordachar et al. [4] reported a prospective study comparing the safety and effectiveness of laser sheaths to that of femoral snare extractions. They showed that laser extraction was not only as safe as the femoral approach but also reduces the procedure time and the fluoroscopic time.

The LExICon trial [5] was a retrospective multicenter study using an SLS II laser sheath with a large number of patients (2405 leads from 1449 patients). In this study, leads were completely removed 96.5% of the time, with a 97.7% clinical success rate. Thus, clinical goals associated with the indication for lead removal were achieved in most cases. The major adverse events seen in 20 patients, including 4 deaths (0.28%), were directly related to the procedure (1.4%). This study showed an extremely high rate of success and a low rate of adverse events. On the other hand, it showed that failure to achieve clinical success was associated with body mass index (BMI) $<25$ kg/m$^2$ and low extraction volume centers. Furthermore, major adverse effects were associated with patients with a BMI $<25$ kg/m$^2$.

## 6. Evidence from Japan

Okamura et al. [6] reported their first experience of 40 cases with laser sheath. The median duration of lead implantation was 87 months, which was comparable to the 82 months observed in the LExICon trial [5]. The mean BMI value was 21.8 kg/m$^2$ in their patients. Based on the LExICon trial data, patients in their study, including many low BMI patients and those having leads implanted for many years, appeared to be at a higher risk for procedure-related MAEs. However, the success rate of complete removal was 97.1%, without any major complication.

Also, we can find interesting case reports from Japanese centers as well. Ohmori et al. [7] reported a case of thoracoscopy-guided lead extraction with an excimer laser sheath and Okada et al. [8] reported a case of transjugular extraction using a snare technique.

The data from Japan is limited but the number of cases of laser-assisted lead extraction has been increasing dramatically year by year. As of December 2014, it is performed in more than 30 centers in Japan. It is thus important to accumulate data from experiences in Japan and evaluate it properly. Accordingly, a case registration system, led by Japanese Heart Rhythm Society is under consideration.

## 7. Complications

MAEs can happen even if the extraction is performed without any powered tool [9]. According to previous reports [3,10–15], the

MAE can happen in 1–3% of the cases. An especially serious complication involves a tear of superior vena cava and a perforation of atrial or ventricular wall, which results in massive bleeding, requiring emergent thoracotomy which can be fatal.

The deaths and cardiovascular injuries due to device-assisted lead extraction have been reported by Hauser et al. [16]. They searched the US Food and Drug Administration's (FDA) Manufacturers and User Defined Experience (MAUDE) database from 1995 to 2008 and found 57 deaths and 48 serious cardiovascular injuries associated with device-assisted lead extraction. The majority of deaths and injuries involved ICD leads, and most were caused by lacerations of the right atrium, superior vena cava, or innominate vein. Overall, 62 patients underwent emergency surgical repair of myocardial perforations and venous lacerations and 35 (56%) of them survived.

Once the complication requiring thoracotomy occurs, the in-hospital mortality is reported to be 36% [17]. To minimize this, skilled standby cardiothoracic surgery is essential. Also, the indications for transvenous lead extraction should be fully discussed and decided based on the Heart Rhythm Society (HRS)/ American Heart Association (AHA) 2009 consensus document [18].

## 8. Future device

Previous published results of laser lead extraction procedures were obtained using laser sheaths delivering 40 pulses per second. The 80-Hz GlideLight laser sheath, a new extraction tool delivering double the number of pulses per second, has been approved in the US in 2012. Hakmi et al. [19] have reported the first experience of using this new tool. A total of 76 leads were treated in 38 patients using 80-Hz laser sheaths. The mean procedural time was 68.3 min and 94.8% of the leads were completely removed with a clinical success rate of 97.4%. MAE of superior vena cava perforation occurred in one case (2.6%), but no death was recorded. The current 40-Hz laser sheath has enough efficacy and safety and hence, it is premature to mention the superiority of this new 80-Hz laser sheath. However, the 80-Hz laser sheath may reduce the need for mechanical force, thereby preventing intraoperative adverse events. Thus, we need to carefully observe future results comparing these two laser sheaths.

## 9. Summary

Lead extraction using a laser sheath is an established method with abundant positive evidence. Its efficacy and safety have been well proven, but complications can happen with a certain probability. It is thus important to accumulate our experience and spread this therapy prudently for the patients who require lead extraction.

## Conflict of interest

H. Okamura plays the role of a trainer in the educational program of laser-assisted lead extraction.

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