

# Limb Salvage Following Laser-Assisted Angioplasty for Critical Limb Ischemia: Results of the LACI Multi-center Trial

## Overview

Bypass surgery considered as the “gold standard” treatment is associated with significant morbidity and mortality. 37% of CLI patients may be considered poor surgical candidates and at high risk for limb loss. Advances in laser catheter design and refinement of recanalization techniques have resulted in improved results with laser-assisted angioplasty of complex peripheral arterial disease.

## Objective

To evaluate the effectiveness of laser-assisted angioplasty for patients with critical limb ischemia who were poor candidates for surgical revascularization.

## Methods

This multicenter prospective study was conducted from April 2001 to April 2002 included 145 patients enrolled at 11 US and 3 German centers.

The primary end point was limb salvage (avoidance of a major amputation above the level of the ankle) among surviving patients at 6 months. Minor amputation was defined as an amputation leaving an ambulatory foot, i.e. below the ankle.

## Results

145 patients with 155 critically ischemic limbs were enrolled. Median duration of CLI per patient was 13 weeks.

- Amongst 68 females and 77 males, the mean age was  $72 \pm 10$  years, occlusions were present in 92% of limbs.
- Procedural success was seen in 86% of limbs. Stents were implanted in 45% of limbs.
- Major complications occurred in 12% of limbs; major dissection in 4%, acute thrombus in 3%, distal embolization in 3% and perforation in 2% cases.
- At 6 month follow-up, limb salvage was achieved in 93% of surviving patients. Primary patency at 12 months was 75%.

## Conclusions

Laser angioplasty for CLI shows very good limb salvage rates in a very sick patient population who are unfit for traditional surgical revascularization.

## LACI 2006

### Prospective IDE Summary

#### Principle Investigator

- John Laird, MD

#### Device

- CVX-300 Excimer XeCl Laser System (Spectranetics®)

#### Study Overview

- Laser angioplasty for critical limb ischemia.
- Key Inclusion Criteria
  - At least one angiographically identifiable tibial arter
  - Poor candidates for surgical bypass due to absence of a suitable autologous vein, lack of undiseased distal vessel > 1mm in diameter, and/ or high risk of surgical mortality.
- Key Exclusion Criteria
  - Patients with necrosis necessitating immediate amputation
  - Life expectancy <6 months
  - Culprit lesions in a bypass graft, stents in culprit lesions
  - MI in the previous month, and renal insufficiency

#### Procedural Success

- Procedural success was defined as <50% residual stenosis in all lesions in the treated limb.

#### Conclusions

Results showed that laser angioplasty achieved very high limb salvage rates in surviving patients and is the highest reported for endovascular therapy of complex peripheral disease:

- Procedural success: 83%
- Limb salvage rates of 93% at 6months
- All patients received adjunctive balloon angioplasty, 45% of patients had a stent implantation.
- Major complication rates were 12%

## **Important Safety Information**

### **CVX-300**

The CVX-300 is an excimer laser system approved for use in minimally invasive interventional procedures within the cardiovascular system and for the removal of problematic pacemaker and defibrillator cardiac leads.

Potential adverse events associated with procedures used to treat PAD may include: a sudden, temporary or ongoing re-closure of the treated artery; blood clot or obstruction of the artery by plaque debris; a tear, rupture or damage to the artery (or nearby vein or nerve); minor bleeding or bruising at the entry site. Other complications may occur.

Potential adverse events associated with procedures used to treat coronary artery disease may include: a tear, rupture, damage to the artery; a sudden, temporary or ongoing re-closure of the treated artery; blood clot or obstruction of the artery by plaque debris. Other complications may occur.

Potential minor adverse events associated with lead extraction procedures that may or may not require medical or surgical treatment include: a tear or damage to the blood vessels, the heart or its structures; bleeding at the surgical site; or collapsed lung.

Rare but serious adverse events that require emergency medical or surgical procedures may include: a tear or damage to the blood vessels, the heart, lungs or their structures; blood clot or obstruction of the blood vessels or lungs by debris or lead fragments. Other serious complications may include: irregular heartbeat, weakened heart muscle, infection, respiratory failure or complications associated with anesthesia, stroke or death.

This information is not intended to replace a discussion with your healthcare provider on the benefits and risks of this procedure to you.

For important safety information, please visit [www.spnc.com/IFU](http://www.spnc.com/IFU).