# Excimer Laser Recanalization of Femoropopliteal Lesions and 1-Year Patency: Results of the CELLO Registry

## Overview

Turbo-Booster was designed to allow rotational orientation of laser catheter in an offset or biased plane during photoablation. This sequential directional ablation can create a larger lumen diameter than achievable using the standard non-biased photoablation technique.

## Objective

To evaluate the safety and efficacy of Turbo-Booster with Turbo-Elite for treatment of superior femoral artery and proximal popliteal artery lesions.

## Methods

CliRpath Excimer Laser System to Enlarge Lumen Openings (CELLO) was an IDE multicenter, prospective, non-randomized single arm study. Enrollment between July 2006 and March 2007 at 17 US sites included 65 patients.

The primary efficacy end point was defined as a ≥20% mean reduction in the % diameter stenosis following photoablation. The primary safety endpoint was the occurrence of major adverse events, or death at the time of procedure, prior to discharge, at 30 days, or 6 months post procedure.

## Results

Sixty-five patients with intermittent claudication, stenotic lesions > 70% by visual assessment were included in the study. 20% were total occlusions, 62% lesions had moderate to severe calcium. Sixty-five de novo lesions (5.6±4.7 cm) in 13 occluded and 52 stenotic arteries were treated with laser-assisted recanalization with optional balloon angioplasty (BA) or BA + stenting.

- Mean age of patients was 68.3 ± 10.1 years; 60% were male, and 40% were diabetic.
- Primary efficacy endpoint was achieved with a mean % diameter stenosis reduction to 34.7±17.8% following laser. A 43% reduction in stenosis was achieved following laser treatment, 21% with any adjunctive therapy (PTA, stent). 23% patients received a bailout stent.
- IVUS demonstrated increased lumen area and decreased plaque volume following laser treatment.
- There were no major adverse events.
- The target vessel revascularization was 23% at 12 months and primary patency rate of 54%.

## Conclusions

Study demonstrated safety and efficacy of Turbo-Booster and Turbo-Elite, and vessel compliance changes with high clinical success rate and target vessel revascularization.

# CELLO 2009

## Prospective IDE Summary

### Principle Investigator

- Rajesh Dave, MD

### Atherectomy Devices

- 8Fr Turbo-Booster (Spectranetics®)
- 2.0 Turbo-Elite (Spectranetics®)
- CVX-300 Excimer XeCl Laser System (Spectranetics®)

### Study Overview

- Safety and efficacy study of Turbo-Booster with Turbo-Elite.
- Key Inclusion Criteria:
  - Angiographic confirmation of stenotic or occlusive atherosclerotic disease within the SFA or the proximal popliteal artery within 6 months.
  - ≥ 70% stenosis by visual assessment. Reference vessel diameter ≥ 4.0 and ≤ 7.0 mm.
  - Combined lesion length of ≤15.0 cm, with atleast 1 patent infrapopliteal runoff artery.

### Procedural Success

- Defined as ≥20% mean reduction in the % diameter stenosis following laser therapy, and no occurrence of major adverse events or death at the time of procedure, prior to discharge, at 30 days, or 6 months post procedure.

### Conclusions

- Results showed great safety profile and efficacy with Turbo-Booster and Turbo Elite, and used qualitative and quantitative angiographic core lab:
  - 35% reduction in % diameter stenosis following laser.
  - No major adverse events.
  - Target vessel revascularization was 23% at 12 months and primary patency rate of 54%.

## Important Safety Information

**Turbo-Elite**

The Turbo-Elite Laser Catheter devices are indicated for use in the treatment of infrainguinal stenosis and occlusions. When used in conjunction with the Turbo-Booster and/or as an accessory to the Turbo-Tandem System, the devices are indicated for atherectomy of infrainguinal arteries.
The 0.014" and 0.018" Over-the-wire (OTW) Turbo-Elite laser catheters are also indicated for use as an accessory to the use of the Turbo-Tandem System in the treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, when used in conjunction with Percutaneous Transluminal Angioplasty (PTA).

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.

Rare but serious potential adverse events include: the need for urgent additional procedures or surgery due to bleeding, vascular damage, loss of blood flow or other complications; decrease or loss of kidney function due to contrast exposure; the need for amputation due to inability to restore blood flow; and infection, stroke, irregular heartbeat, heart attack 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.

**Turbo-Booster**

The Turbo-Booster Guiding Catheter, when used in conjunction with the Turbo Elite Laser Catheter, is indicated for the treatment of peripheral arterial disease (PAD) located in the legs.

Rare but serious potential adverse events include: spasm, major dissection, thrombus, distal embolization, perforation, death, reintervention, acute limb ischemia, major amputation, bypass surgery, hematoma with surgery, re-occlusion, pseudoaneurysm, renal failure bleeding, nerve injury, AV fistula formation, endarterectomy, infection, stroke, myocardial infarction and arrhythmia.

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.





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