

Excimer laser recanalization of femoropopliteal lesions and 1-year patency: **results of the CELLO registry**

Operator and facility

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 $\geq 20\%$ 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 six 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 $34.7 \pm 17.8\%$ 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.

Devices

Atherectomy	• 8F Turbo-Booster (Philips) • 2.0 mm Turbo-Elite laser atherectomy catheter (Philips) • CVX-300 Excimer XeCl Laser System (Philips)
	• 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 six months. - $\geq 70\%$ stenosis by visual assessment. Reference vessel diameter ≥ 4.0 and ≤ 7.0 mm. - Combined lesion length of ≤ 15.0 cm, with at least one patent infrapopliteal runoff artery.
Procedural success	Defined as $\geq 20\%$ 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 six 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%.