

# Randomized Study Shows Superiority of Laser Debulking and DEB vs. DEB Alone for the Treatment of CLI Patients with SFA Stent Occlusion

*Study demonstrates potential value in combining laser debulking with drug-eluted balloon angioplasty.*

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## Overview

Treatment of Chronic SFA In-Stent Occlusion With Combined Laser Atherectomy and Drug-Eluting Balloon Angioplasty in Patients With Critical Limb Ischemia: A Single-Center, Prospective, Randomized Study\*.

## Purpose

To compare the safety and efficacy of laser debulking (LD) and drug-eluting balloon (DEB) angioplasty to treatment with DEB angioplasty alone in patients affected by critical limb ischemia (CLI) and superficial femoral artery (SFA) chronic stent occlusion in a prospective, randomized study.

## Methods

Among 448 CLI patients treated from December 2009 to March 2011, 48 patients (39 men; mean age 72.7±7.8 years) with chronic SFA in-stent occlusion were randomly assigned to treatment using LD+DEB (n=24) or DEB angioplasty alone (n=24).

Patency at 12 months was the primary outcome measure; secondary outcomes were target lesion revascularization (TLR) and clinical success at 12 months.

## Results

In the LD+DEB group, the patency rates at 6 and 12 months (91.7% and 66.7%, respectively) were significantly higher (p=0.01) than in the DEB only patients (58.3% and 37.5%, respectively). TLR at 12 months was 16.7% in the LD+DEB group and 50% in the DEB only group (p=0.01).

Two (8%) patients needed major amputations in the LD+DEB group vs. 11 (46%) in the DEB only group at 12 months (p=0.003).

## Conclusion

In this small initial experience, combined treatment with LD and DEB angioplasty is correlated with better outcomes in CLI patients with occluded SFA stents.

The authors declare no association with any individual, company, or organization having a vested interest in the subject matter/products mentioned in this article.

\*For distribution in the European Union only. Laser atherectomy using Turbo Elite and/or Turbo-Tandem is not FDA approved for treatment of in-stent restenosis in the United States.

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## CENTER

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## STUDY DESIGN

- Randomized comparison of Laser Debulking (LD) and DEB vs. DEB alone for the treatment of Fem-pop ISR total occlusions in patients with CLI.
- LD DEB (n=24); DEB (n=24)
- Comparison of demographics, procedural outcomes and 12 month patency/TLR

## FINDINGS SUMMARY

- TLR at 12 months, 16.7% vs 50%, LD DEB vs DEB (p=0.01)
- Patency at 6 months, 91.7% vs 58.3%, LD DEB vs DEB (p=0.01)
- Patency at 12 months, 66.7% vs 37.5%, LD DEB vs DEB (p=0.01)
- Limb salvage at 12 months, 91.7% vs 54.2%, LD DEB vs DEB (p=0.003)