

## 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<sup>1</sup>

### Overview

Paclitaxel drug-eluting balloons (DEB) have shown superior patency in de novo and ISR lesions of the SFA compared to PTA alone. However, the debulking of the occluded stent, especially in long complex ISR lesions, may potentially improve DEB results by reducing thickness of neointimal hyperplasia and increasing contact between the balloon surface and vessel wall.

### Objective

To compare the performance of laser + DEB vs. DEB-alone in patients affected by critical limb ischemia (CLI) and superficial femoral artery (SFA) chronic stent occlusion in a prospective randomized study.

### Methods and results

This was a single-center, prospective randomized study of 48 CLI patients with chronic SFA ISR who were poor candidates for bypass. The primary outcome measure was the primary stent patency at 12 months with a secondary outcome measure of TLR at 12 months. Patients were randomized to treatment with a laser + DEB [2.0 mm Turbo-Elite with three passes at settings of 40–60/60 followed PTA predilation + DEB (Freeway; Eurocor)] or DEB only [PTA predilation + DEB]. All patients had BTK lesion(s) which were treated with PTA to obtain best distal runoff and provide direct blood flow to foot ulcers.

### Conclusions

In this small initial experience, combined treatment with laser and drug-coated balloon is correlated with better outcomes in CLI patients with occluded SFA stents.

Key study results	Laser + DEB (N=24)	DEB alone (N=24)
Mean treated stent length (cm)	20	23
Technical success ( $\leq$ 30% residual stenosis)	100%	100%
Primary patency (six months)	91.7%	58.3%
Primary patency (12 months)	66.7%	37.5%
TLR (12 months)	16.7%	50%
Major amputation	2 (8%)	11 (46%)
Limb salvage (12 months)	91.7%	54.2%
Wound healing (12 months)	87.5%	62.5%
Distal embolization	1 (4%)	2 (8%)

### Study summary

#### Key points

- In this small single-center, prospective, randomized experience, patients treated with the combined approach of laser + DEB obtained higher patency rates at six and 12 months compared to DEB alone
- This is particularly important considering that all patients enrolled in this study were diabetic with CLI, conditions at high risk for reduced primary patency
- TLR was lower in patients treated with laser + DEB, which is reflected in the observed clinical outcomes: nearly 90% of patients treated with the combined approach had ulcer healing compared to 55% treated with DEB alone
- This data provides additional support for the use of the laser as a vessel prep method in ISR

#### Key limitations

- This is a small single-center experience and cannot substitute for level 1 clinical data
- These results cannot be used to draw any improved or equivalent safety or effectiveness claims for laser + DEB in ISR

Results from this case study are not predictive of future results.

1. Gandini R, Del Giudice C, Merolla S, Morosetti D, Pampana E and Simonetti G. 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. J Endovasc Ther. 2013; 20:805-14.