PHILIPS

Laser atherectomy

# EXCITE clinical trial

## EXCImer laser randomized controlled study for the treatment of femoropopliTEal in-stent restenosis

### Overview

Femoropopliteal stenting has shown superiority to percutaneous transluminal angioplasty (PTA) for lifestyle-limiting claudication and critical limb ischemia, though treating post-stenting artery re-obstruction, or in-stent restenosis (ISR), remains challenging.

### Objective

To evaluate safety and efficacy of excimer laser atherectomy with adjunctive PTA (ELA + PTA) versus PTA alone for treating chronic PAD patients with femoropopliteal bare nitinol ISR.

### Methods[1,2,3]

The multicenter, prospective, randomized controlled EXCITE ISR trial was conducted across 40 United States centers. Patients with Rutherford Class 1 to 4 and lesions of target lesion length ≥ 4 cm, vessel diameter ≥ 5 mm were enrolled and randomly divided into ELA + PTA and PTA groups by 2:1 ratio.

The primary efficacy endpoint was target lesion revascularization (TLR) at six-month follow up. The primary safety endpoint was major adverse event (MAE, death, amputation or TLR) at 30 days post-procedure. Patients were treated using Turbo-Tandem and, if a 2 mm pilot channel did not exist prior to treatment, a Turbo-Elite catheter was used to create a pilot channel as an accessory to Turbo-Tandem.

### Results[1,2,3]

Study enrollment was stopped at 250 patients due to early efficacy demonstrated at a prospectively specified interim analysis.

- A total of 169 ELA + PTA subjects (62.7% male; mean age 68.5 ± 9.8 y) and 81 PTA patients (61.7% male; mean age 67.8 ± 10.3 y) were enrolled.
- Mean lesion length was (19.6 ± 12.0 cm vs. 19.3 ± 11.9 cm) and (30.5% vs. 36.8%) patients exhibited total occlusion.
- ELA + PTA subjects demonstrated superior procedural success.
- (93.5% vs. 82.7%) with significantly fewer procedural complications.
- ELA + PTA and PTA subject six-month freedom from TLR was 73.5% vs. 51.8% and 30-day MAE rates were 5.8% vs. 20.5% ($p < 0.0007$), respectively.[4]

### Conclusions

The EXCITE ISR trial is the first of its kind, a large prospective randomized atherectomy clinical trial. Excimer laser atherectomy with adjunctive balloon angioplasty results in significantly better acute and midterm efficacy and safety outcomes for treatment of peripheral femoropopliteal ISR compared to conventional PTA alone in all lesion types examined in this research.

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

### Clinical trial summary[1,2,3]

#### Principal investigators

- Eric J. Dippel, MD
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#### Atherectomy devices

- Turbo-Tandem laser guide catheter with laser atherectomy catheter
- Turbo-Elite laser atherectomy catheter

#### Study overview

- Key inclusion criteria
  - ISR lesion ≥ 4 cm
  - RCC 1-4
  - RVD ≥ 5.0 mm
  - ≥ 1 patent tibial artery
- Key exclusion criteria
  - Target lesion extends > 3 cm beyond stent margin
  - Untreated inflow lesion
  - Grade 4 or 5 stent fracture
- Follow-up
  - Discharge, 30 days, six-months and one year post-procedure

#### Procedural success

- ELA + PTA demonstrated superior procedural success (93.5% vs. 82.7%; $p = 0.01$)

#### Conclusions

Initial results show ELA with adjunctive PTA is superior to PTA alone for the treatment of femoropopliteal ISR:

- Complicated lesions averaging 19 cm in length
- Significantly higher procedural success rate: ELA + PTA 93.5% vs. PTA alone 82.7%, $p = 0.01$
- Superior safety vs. PTA alone: MAE at 30 days ELA +PTA 5.8% vs. PTA alone 20.5%, $p < 0.001$
- Significantly higher rate of freedom from TLR (at six months): ELA + PTA 73.5% vs. PTA alone 51.8%, $p < 0.005$

1. Turbo-Tandem Instructions for Use, http://www.spectranetics.com/resources/ifu-library/.
2. EXCITE Trial Clinical Study Report, Philips data on file, July 2014.
3. Dippel NCVH 2014, New Orleans, LA. http://www.ncvh.org/ncvh-2014-live-cases.html.
4. Major adverse events are defined as all cause death, major amputation in the target limb, or target lesion revascularization (TLR) (surgical or interventional) from procedure to 30 days (+ 7 days).



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