The SECURE Trial:
Update on Perforator Ablation
(Safety and Effectiveness Study: VenaCure Endovenous Laser Treatment (EVLT))

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Disclosures
• Angiodynamics

SVS Guidelines
• Recommended against selective treatment of perforating vein in patients with simple varicose veins (C2) GRADE 1B
• Recommended treatment of Pathologic Perforating Veins (reflux \(>500\) ms, vein diameter \(>3.5\) mm, located underneath healed or active ulcers, C5-C6). GRADE 2B.

What is the Best Method?
• Open subfascial ligation (Linton Procedure)
• Open suprafascial ligation
• Shearing devices
• Stripping and phlebectomy
• Endoscopic surgery (SEPS)
• Duplex Guided Sclerotherapy
• Duplex Guided RF Ablation

RF procedure and data
• One-year outcomes of radiofrequency ablation of incompetent perforator veins using the radiofrequency stylet device. Phlebology April 2010 25: 79-84
• 124 IPVs
• 14 month FU
• 82% closed
• 50% clinically improved

SAPS
Suprafascial Ablation of Perforator Surgery
Laser Perforator Procedure-Technique

400 um Laser Fiber Kit

Kit Components:
- 21 gauge Needle
- .018" x 40cm guidewire
- 4Fr x 10cm sheath with "stiff" dilator
- 400µm optical fiber with Compression clamp
SeCure Safety Study

- Multicenter study; a maximum of 7 investigational sites in the
- 86 Patients – 119-182 veins
- Primary Objective-IPV ablation at 10 days
- 3 month follow-up (CEAP, rVQSS, VeinsQoL, VAS)
- 12 months follow-up for publication
- CEAP Class 4b to Class 6 attributable to the IPV
- ENROLLING NOW
Enrollment Update

Total Enrolled: 70/86
Total IPVs: 100/119

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NYU Results

- Enrolled: 10
- IPVs: 10
- Mean Follow up: 6.5 months
- Ablation Rate: 8/10 (80%)
- Complications: None

Screen Failures

- BMI ≥ 40 kg/m²
- Anticoagulant therapy for Deep Vein Thrombosis or other conditions
- History of DVT within the last 6 months
- Thrombophilic state
- Prior venous procedures in the study limb (30 days)

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