Venclose

Multicenter Trial Design & Early Results

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Disclosures

Consultant: BD Bard, Boston Scientific, Cook, Cordis, Gore, Medtronic, Philips, Synervention,Veryn

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Venclose

- *Study Device*
- *Venclose™ RF ablation catheter*
  - 6F profile design for flexibility and to minimize invasiveness
  - Dual heating lengths to treat long and short segments with same catheter

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Study Design

- Post-market, multi-center, prospective interventional study
- Designed to provide clinical evidence to demonstrate reasonable assurance of safety and effectiveness of the Venclose system
- Up to 20 sites targeted for enrollment
- 274 subjects* to be enrolled
  - **100** in GSV/SSV cohort – **VENCLOSE Catheter**
  - **174** in ulcer IPV cohort (after GSV/SSV cohort enrolled) **MAVEN Catheter**

GSV – Great Saphenous Vein; SSV – Small or Short saphenous Vein; IPV – Incompetent Perforator Vein

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Study Design

- Clinic follow-up will be conducted at the following intervals:
  - 1-week; 1-month; 3-month; 6-month; 12-month
  - 24-Month follow-up will be conducted via telemedicine or clinic
- Independent Core Lab imaging analysis
- Lead Investigator/National PI: Erin Murphy, MD
- Medical Monitor: Lowell Kabnick, MD

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Study Inclusion Criteria

- CEAP C2 and higher
- Diagnosed refractory symptomatic disease attributable to the GSV/SSV to be treated
- GSC/SSV to be treated that has outward flow reflux ≥0.5 seconds immediately after release of manual distal compression with subject standing or in Reverse Trendelenburg
- GSV/SSV to be treated in leg that has a diameter ≥4.5 mm
- Subject is ≥ 18 years old; consented; able to comply with protocol

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Study Key Exclusion Criteria

- Previous treatment for venous insufficiency in same target vein
- Venous insufficiency secondary to venous obstruction cranial to intended treatment site
- Thrombus in vein segment to be treated
- Untreated critical limb ischemia from peripheral arterial disease
- Undergoing active anticoagulant therapy or has history of deep vein thrombosis within last 6 months
- ABI <0.8
- BMI > 40

ABI = ankle-brachial index; BMI = body mass index

Study Endpoints – GSV/SSV Cohort

- Primary Effectiveness Endpoint
  - *Rate of occlusion at 1-Month post procedure visit*
- Primary Safety Endpoint
  - *Cumulative incidence of device and procedural related deep vein thrombosis, and pulmonary embolism adverse events at 1-Month visit*

Study Secondary Endpoints – GSV/SSV Cohort

- Secondary endpoints: GSV / SSV Cohort
  - *Change in rVCSS score from Baseline to 1-week, 1-month, and 24 month visits*
  - *Change in CIVIQ-20 score from Baseline to 1-month and 24 month visits*

rVCSS – revised Venous Clinical Severity Score
CIVIQ-20 – Chronic Venous Insufficiency Questionnaire

Study Secondary Endpoints – GSV/SSV Cohort

- Secondary endpoints: GSV / SSV Cohort
  - **CIVIQ-20** at:
    - Baseline, 1-month, 3-month, 6-month, 12-month, and 24-month visits
  - **rVCSS, CEAP, VAS pain score** at the following intervals:
    - Baseline, 1-week, 1-month, 3-month, 6-month, 12-month, and 24-month visits
  - **Freedom from recanalization at**:
    - 1-month, 3-month, 6-month, and 12-month visits
  - **Duration Time of Index Procedure**
  - **Device and Procedural-related EHIT types 2 - 4** at 1-month visit

CEAP - Clinical Etiological Anatomical Pathophysiological
EHIT - Endovenous Heat Induced Thrombus

Study Timeline

Study timeline and early results

- *Active sites = 8*
- *Current enrolled subjects = 47*

Enrolled Location	Number enrolled
Michigan	1
Hawaii	11
New Jersey	20
North Carolina	2
Texas	1
Colorado	8

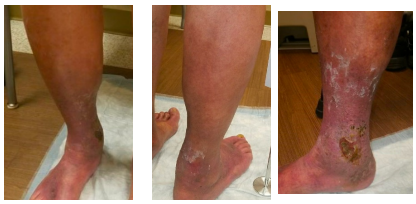
Return next year for study update during this session!

Case Study: Patient History

- *70M with:*
  - RLE ulceration > 2years with skin graft x 2 -> quick recurrence
  - Bilateral edema lower 1/3 legs
  - +paraestheisas
- *PMH/PSH:* + MVR on coumadin, stroke, prostate cancer s/p radiation
- *Venous History:* Bilateral GSV closures > 15 years ago

Case Study: Physical Exam

Exam: Severe right venous stasis changes with erythema, hyperpigmentation and LDS, right medial malleolar ulcer



CEAP: 6

VCSS: 23

Villalta: 22

Case Study: Imaging

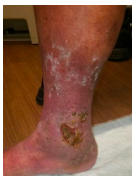
- *Right Reflux DVT:*
  - Deep Reflux (CFV, Femoral, Popliteal)
  - GSV: .91 Sec (Size 0.54– 0.93); SSV: 4 sec (size 0.45-0.7), Giacomini: 4.6 s (Size 0.8)
  - Incompetent perforator (1.2 sec, size 0.67)
- *Iliac US:*
  - No evidence of iliofemoral venous compression/stenosis/occlusion
- *CT:*
  - Evidence of right-sided heart failure
  - No compression/post-thrombotic disease

Case Study: Initial Plan

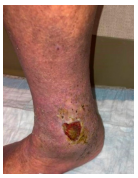
- *RFA of the GSV, SSV/Giacomini with Venclose system*
  - *Advantages:*
    - 10 cm treatment length
    - Curved tip to navigate recanalized venous segments
    - Ability to treat 2.5 cm segments and 10 cm segments with same catheter

- *US-guided Foam Sclerotherapy of Ulcer bed*

Pre-RFA/Sclero



2m s/p RFA/Sclero

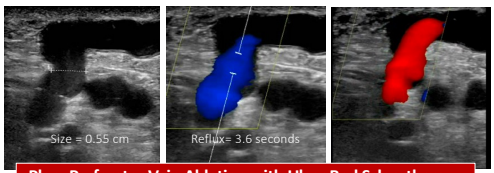


Pain Reduction, Skin Improvement, Ulcer healing progression

However wound improvement seemed halted

Case Study: Re-examination

- *Repeat RLE Reflux/DVT:*
  - Closed GSV/SSV/Giacomini
  - Persistent large (0.55) medial calf perforator feeding varices to Right ulcer



Plan: Perforator Vein Ablation with Ulcer Bed Sclerotherapy

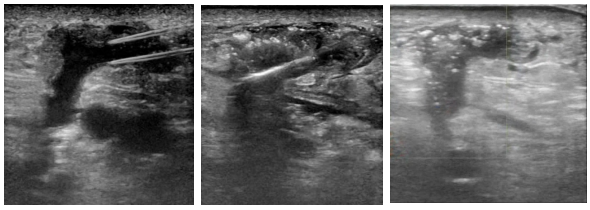
Maven Catheter Design

0.5 CM RESISTIVE HEATING COIL
- Provides circumferential resistive heating in one treatment cycle as compared to 4 treatment cycles required for bi-polar electrodes
- 130° C treatment temperature with 20 second cycles

6F PROFILE
- Small profile helps to minimize invasiveness
- Guidewire compatibility up to 0.025"

40 CM FLEXIBLE CATHETER SHAFT
- Helps facilitate more efficient treatment for varying vein lengths and anatomies

Perforator Ablation with Maven Catheter



- Perforator to edge of screen
- Access in Long
- Sheath Placement

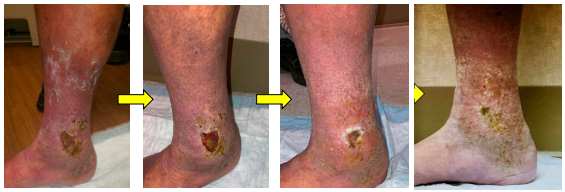
- Maven Catheter Placement
- Tumescent
- Treatment: 6 cycles ↓ @ ↑ fascia
- 0.5 cm segments

Closed Perforator

Case Study: Follow-up

- US and clinical follow-up at 2 days and at 30 days
- Perforator successfully closed
- No need for additional Sclerotherapy at this time
- Continue wound care / compression / cardiac management

Pre-RFA | 2m s/p RFA GSV/SSV | 2m s/p RFA-Perforator | 4m s/p RFA-Perforator



Now: No recurrence after 1.5 yrs

Conclusions

- Treatment of superficial venous reflux can significantly improve symptoms related to venous insufficiency
- Ablation of pathologic perforator veins is recommended in SVS-AVF VLU Guidelines for C4b, C5, and C6 disease*
- If treated properly, most venous leg ulcers heal in ~ 3 to 4 months
- In my practice, the Venclose and Maven catheters are effective treatment tools for these patients
- The Venclose trial will provide further clinical data on the safety and effectiveness of these tools

Thank you

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