VenaSeal™ Closure System: Long-Term Outcomes and Post-Procedure Care

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Faculty Disclosures

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Brand names are included in this presentation for participant clarification purposes only. No product promotion should be inferred.
VenaSeal™ Closure System

- Uses an advanced medical adhesive to safely and effectively close the diseased vein segment
- It is a non-thermal, non-tumescent, non-sclerosant (NTNTNS) therapy
  - No tumescent anesthesia
  - No risk of thermal injury
- Rapid return to normal activities
- No compression stockings*

*Some patients may benefit from the use of compression stockings post-procedure.
VeClose 5-Year Follow-Up Extension Study

To continue to assess the safety and efficacy of the VenaSeal closure system (VSCS) for the long-term effect on closure of the great saphenous vein (GSV) by conducting a follow-up visit at 5 years post-index procedure/enrollment in the study.
Cyanoacrylate Closure

Feasibility study

- Objective was to evaluate long-term safety and effectiveness of CAC of incompetent GSV
- Single-center, non-randomized
- 38 patients
- Treated with ultrasound guidance
- No tumescent anesthesia or post-procedure compression stockings
- 1, 3, 6, 12, 24, and 36-month follow-up

Cyanoacrylate Closure

Results

- 29/38 patients available at 36-month follow-up
- Recanalization of 2 patients at months 1 and 3
- Occlusion rate of 94.7% at 36 months
- VCSS improved from 6.1 to 2.2 at 36 months
- No serious adverse events
- CAC for insufficient GSV appears effective and safe for saphenous vein closure
- Occlusion rates comparable to thermal methods

eSCOPE Study

• Evaluate safety and efficacy
• European multicenter, prospective, non-randomized study
• N=70 (f-up to 12 mo)
• No sedation, tumescent anesthesia or compression stockings

• Inclusion
  – Symptomatic GSV incompetence
  – CEAP classification of C2, C3, or C4
  – GSV on standing US >3 mm and <10 mm

• Exclusion
  – Previous venous tx
  – Tortuous GSV that could limit catheter placement
  – Known sensitivity to cyanoacrylate adhesive

eSCOPE Study Results

- **Closure rates**
  - 92.9% at 12 months
  - 88.5% at 24 months
  - 88.5% at 36 months

- **VCSS** improved from 4.3 to 1.1 at 12 months

- **Phlebitis-like reaction** occurred in 8 cases

- **No serious adverse events**

VeClose Trial

- Demonstrate safety and effectiveness
- U.S. trial, prospective, randomized to VenaSeal or RFA (ClosureFast™ catheter)
- 222 patients symptomatic GSV incompetence
  - 108 VS, 114 RFA
- 3 day, 1, 3, 6, 12, 36 month follow-up
- Primary endpoint: Non-inferior to RFA in GSV closure
- Secondary endpoint: Superiority in reduction of post-procedural pain and bruising

VeClose Trial Results

- 1-month occlusion rate
  - 100% of VS
  - 87% of RFA
- 12-month complete occlusion rate
  - 97% in both groups
- 12-month freedom from recanalization was similar
- 36-month occlusion rate
  - 94.4% VS, 91.9% RFA
- Symptom and quality of life scores improved equally in both groups
- Similar adverse event rates

Phlebitis-Like Abnormal Reaction (PLAR)

- Defined as an unusual skin condition that develops over several days
  - Erythema, itching, swelling, pain/tenderness over treated vein
  - Tx with NSAIDS, oral antihistamines and IV dexamethasone
- More prevalent in suprafascial GSV
- 69/169 veins experienced PLAR (mean 13 days)
  - Mostly erythema
- Believed to be type IV hypersensitivity reaction (cell-mediated) due to foreign body

Post-Procedural Care

**PRE-OP INSTRUCTION:**
- Take 50 mg of Benadryl® 1 hour prior to procedure.

**POST VENASEAL INSTRUCTIONS:**
- **COMPRESSION:** compression stockings are not formally required but recommended. Follow instructions from your physician and nurses regarding compression hose. There might be some inflammation from the adhesive and support might make your legs feel more comfortable.

- **BATHING:** you may bathe 8 hours after the procedure. This gives time for the small incision to seal. Do not rub your incision directly.

- **PAIN & MEDICATIONS:** it is recommended and encouraged to take non-steroidal medication; such as aspirin 325 mg daily for 2 weeks post procedure. Some inflammation, tenderness and bruising is common. It is not uncommon to have slightly more tenderness during the second week after the procedure. Most discomfort can be relieved by NSAIDS and/or Tylenol. Warm moist compresses after 24 hours will help with local discomfort.

- **EXERCISE & ACTIVITY:** Walk every day after your VenaSeal procedure: at least 20 minutes per day, but preferable an hour a day. There is no set limit on activity after VenaSeal, but we recommend normal to vigorous activity for two weeks.
VenaSeal Checklist

**Indications**
- Inability to wear CS
- Superficial location of GSV
- Nerve damage in the past
- Resume exercise
- Less downtime

**Contraindications**
- Multiple allergies
- Implantable
- Patient preference
- Tape allergy?
- Allergy to glue - nails, eyelashes
Why should we offer Venaseal?
Why should we offer Venaseal?

Figure 1: Patient satisfaction

Very Satisfied

- 84.7%
- 79.1%
- 75.0%
- 78.4%

CAC | RFA

24 month* | 36 month

**New Protocol: VeClose Five Year Follow-up Extension Study**

<table>
<thead>
<tr>
<th><strong>Purpose</strong></th>
<th>To continue to assess the safety and efficacy of the VenaSeal Closure System (VSCS) for the long term effect on closure of the great saphenous vein (GSV) by conducting a follow-up visit at five years post index procedure/enrollment in the VeClose study.</th>
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</table>
| **Enrollment** | 89 subjects completed 60 month visit  
47 VSCS and 33 RFA (plus 9 roll-in VSCS subjects) |
| **Primary Endpoint** | Complete closure\(^1\) of the target vein at 5 years after index treatment |
| **Secondary Endpoints** | Change in Venous Clinical Severity Score (VCSS) at 5 years compared to baseline (BL)  
Change in Aberdeen Varicose Vein Questionnaire (AVVQ) at 5 years compared to BL  
Change in Quality of Life survey (EQ-5D) at 5 years as compared to Baseline  
Clinical, etiology, assessment and pathophysiology (CEAP classification)  
Satisfaction with Treatment  
Adverse Events related to target GSV  
Details of adjunctive procedures performed on the study limb |

\(^1\)Complete closure is defined as Doppler ultrasound examination showing closure along entire treated target vein segment with no discrete segments of patency exceeding 5 cm.
Primary Endpoint: Complete closure by Kaplan-meier analysis

RANDOMIZED ONLY

Closure rates were sustained long term with no new failures reported and non-inferiority demonstrated through 60 months.

<table>
<thead>
<tr>
<th>KM Estimates</th>
<th>Month 1</th>
<th>Month 3</th>
<th>Month 6</th>
<th>Month 12</th>
<th>Month 24</th>
<th>Month 36</th>
<th>Month 60</th>
</tr>
</thead>
<tbody>
<tr>
<td>VSCS</td>
<td>100.0%</td>
<td>99.0%</td>
<td>99.0%</td>
<td>97.0%</td>
<td>94.6%</td>
<td>91.4%</td>
<td>91.4%</td>
</tr>
<tr>
<td>RFA</td>
<td>94.6%</td>
<td>94.6%</td>
<td>91.7%</td>
<td>90.7%</td>
<td>89.5%</td>
<td>85.2%</td>
<td>85.2%</td>
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Secondary Endpoint: Satisfaction with Treatment

**RANDOMIZED ONLY**

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<thead>
<tr>
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<th>Month 60 Follow-up</th>
<th>Immediately following procedure</th>
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<tbody>
<tr>
<td>Very dissatisfied</td>
<td>0.0% (0/47)</td>
<td>0.0% (0/47)</td>
</tr>
<tr>
<td>Somewhat dissatisfied</td>
<td>0.0% (0/47)</td>
<td>2.1% (1/47)</td>
</tr>
<tr>
<td>Somewhat satisfied</td>
<td>8.5% (4/47)</td>
<td>6.4% (3/47)</td>
</tr>
<tr>
<td>Very satisfied</td>
<td>91.5% (43/47)</td>
<td>91.5% (43/47)</td>
</tr>
</tbody>
</table>

All 47 VSCS subjects were ‘somewhat or very satisfied’ with treatment at 60 month follow-up.

93.6% (44/47) said they would definitely choose VSCS again.
Summary

- Safe and effective treatment of truncal venous insufficiency
- Performed with only local lidocaine, no tumescent
- No post-procedure compression stockings
- Be aware of PLAR
- Good alternative for superficial/suprafascial saphenous veins
- Comparable occlusion rates to RFA (new data of 5 years)
- Similar adverse events as RFA
Thank You

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