Pros And Cons Of RF

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Current Approaches to CVI Treatment

Clinical efforts endovenous electrosurgical desiccation 1964 - 1994


1995 - VNUS Medical Technologies, Inc. is founded

RF Ablation

1997 - Closure Catheter

Preclinical testing
• Determine optimum temperature and time.
• Histology, mechanism of action

Multiple third-degree skin burns
20% saphenous nerve injury1-2

- Bipolar RF energy
- RF energy used to shrink veins
- Restore vein valves to competence
**RF Ablation**

1998
- First case: Bern, Switzerland
- Mathias Widmer, MD
  - Temperature-controlled at 85°C
  - General anesthetic
  - No tumescent anesthesia
  - High ligation of GSV on all patients
  - Pneumatic tourniquet on thigh

**Key Article**
- Lurie F
  - Prospective Randomized Study of Endovenous Radiofrequency Obliteration (Closure Procedure) versus Ligation and Stripping in Selected Patient Population (EVOLVeS Study).

**Closure (1st Generation)**
- Electodes transfer radiofrequency energy to vein wall
  - (EMR 300kHz – 1 MHz)
  - Atoms in vein wall excite and release thermal energy at 85°C (resistive heating)
  - Faster Recovery
  - Less post-op pain
  - Fewer adverse events
  - Superior QOL scores
GSV Treatment: ClosureFast™ Catheter* : 5-Year Data

- Prospective, multicenter single-arm study
- Purpose: To evaluate long-term effects of RF segmental ablation of GSV using the CLF catheter
- 326 patients (396 limbs) were treated with the ClosureFast™ catheter at 13 sites (8 Europe, 5 US).
- Follow-up: Patients were evaluated at 3, 6, 12, 24, 36, and 60 months post-procedure, 278 limbs followed to 5 years.

Primary Endpoints
- Vein occlusion and absence of reflux in the treated vein as determined by duplex ultrasound (DUS) imaging.
- Vein occlusion was defined as absence of any blood flow along the entire length of the treated vein segment assessed by DUS imaging.

Secondary Endpoints
- Presence of complications and side effects from the greater saphenous vein (GSV) intervention
- Quality of Life-Status of clinical signs and symptoms of lower limb venous disease.

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- Quality of Life-Status of clinical signs and symptoms of lower limb venous disease.
**Defined as bruising over greater than 25% of the treated surface area**

- **Speed**
- **Power setting**
- **Fiber tip**
- **Wave-lengths**

**RECOVERY Trial – Results**

**Pain score at follow-up visits**

- **ClosureFast Catheter**
- **Laser**

- Post-procedure ultrasound results:
  - **ClosureFast Catheter**
  - **Laser**

**RECOVERY Trial – Results**

**Quality of life (VCL-SI) scale 0 (good) to 10 (bad)**

- **ClosureFast Catheter**
- **Laser**

**Complication Rates**

<table>
<thead>
<tr>
<th>Complication</th>
<th>1 Week</th>
<th>1 Month</th>
<th>1 Year</th>
<th>5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paresthesia</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Erythema</td>
<td>1.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Infection</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Pain</td>
<td>1.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Panphlebitis</td>
<td>1.0%</td>
<td>2.0%</td>
<td>0.5%</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

**RECOVERY® Study**

- **Purpose**: Ablation for the treatment of Great Saphenous Vein reflux
- **Follow-up**: Patients were evaluated at 48 hours (24-72 hrs), 1 week, 2 weeks, and 1 month post-procedure
- **Primary**: Post-op pain, severity of bruising and adverse events
- **Secondary**: Vessel occlusion, VESS, reflux, tenderness, QoL

**Study Design**

- Prospective, multicenter, single-blinded, randomized
- 87 Veins in 69 Patients
- RFA VS. LASER

**NOTE**: Lower score reflects a better quality of life.
Rasmussen Study: Trial Comparing EVLA, RFA, Foam Sclerotherapy and Surgical Stripping for GSV

**Study Design**

- 500 patients (580 limbs) with GSV reflux were randomized to receive either
  - Endovenous laser ablation
  - Radiofrequency ablation
  - Ultrasound-guided foam sclerotherapy
  - Surgical Stripping

- Completion rate: 125 (25%)
- Ultrasound-guided foam sclerotherapy (126 patients)
- Surgical Stripping (124 patients)
- Duplex ultrasound imaging was done before and after the procedure

- Follow-up: Patients assessed at 3 days, 1 month, and 1 year post-intervention

**Primary endpoint**

- GSV closure expressed as vessel patency (treatment failure) one year post procedure

**Secondary endpoints**

- Pain scores post intervention-visual analog scale 0-10
- Scores of SF-36™/
- Scores of Aberdeen Varicose Vein Symptom severity Score (AVVSS)
- Venous Clinical Severity Score (VCSS)

- 500 patients (580 limbs) with GSV reflux were randomized to receive either
  - Radiofrequency ablation (n=125*)
  - Endovenous laser ablation (n=124*)
  - Vein Stripping (n=123*)
  - Ultrasound-Guided Foam Sclerotherapy (n=123*)

<table>
<thead>
<tr>
<th>Study</th>
<th>Efficacy at 1 year (reflux-free rate)</th>
<th>Post Intervention Pain Scores* (1 – 10)</th>
<th>Time to return to normal activities (days)</th>
<th>Time to resume work (days)</th>
<th>Indirect cost (€) Lost work</th>
<th>Total costs (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Ablation</td>
<td>95.2%</td>
<td>1.21 (p&lt;0.001)</td>
<td>2.9 (p&lt;0.001)</td>
<td>1120</td>
<td>560</td>
<td>1996</td>
</tr>
<tr>
<td>Endovenous Laser Ablation</td>
<td>94.2%</td>
<td>2.58 (p&lt;0.001)</td>
<td>4 (p&lt;0.001)</td>
<td>1120</td>
<td>840</td>
<td>2200</td>
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<tr>
<td>Vein Stripping</td>
<td>95.2%</td>
<td>2.25 (p&lt;0.001)</td>
<td>6.5 (p&lt;0.001)</td>
<td>1120</td>
<td>1120</td>
<td>2199</td>
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<tr>
<td>Ultrasound-Guided Foam Sclerotherapy</td>
<td>83.7%</td>
<td>1.60 (p&lt;0.001)</td>
<td>2 (p&lt;0.001)</td>
<td>1120</td>
<td>560</td>
<td>1559</td>
</tr>
</tbody>
</table>

*In the 10-day period post-procedure.

**Conclusion**

**Pros Of RF**

1. 15 years of data
2. Built-in reimbursement system
3. Radio frequency now more "commonplace term"
4. Quicker recovery than laser, more durable than foam.

**Cons Of RF**

1. Tumescent anesthesia required
2. Closes truncal vein, leaves varicosities
3. Catheters expensive

Thank You!