5 years results: endovenous treatment of superficial vein reflux in an outpatient setting

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ENDOVENOUS TREATMENT: 5 YEARS RESULTS?

- EVLA (Endovenous laser ablation)

- RFA (Radiofrequency ablation)
  - Radiofrequency segmental thermal ablation
The RFA ClosureFast™ system delivers radiofrequency energy in a controlled fashion:
- segments of veins causing denaturation of the collagen
- contraction of the vessel
- no blood can flow through it
EVOLUTION OF CLOSUREFAST™ TECHNOLOGY

- VNUS Medical Technologies Founded: 1995
- FDA cleared Closure™ System: 1999
- Covidien acquires VNUS Medical Technologies: 2006
- FDA approval ClosureFast™ System (segmental ablation): 2009
- FDA cleared ClosureRFS™ Stylet: 2005
- Medtronic acquires Covidien: 2014
- FDA approval ClosureRFG™ Generator (RFG3): 2015

VNUS Medical Technologies

Medtronic
ClosureFAST study
Multicenter, prospective, 5 years f/u
Alan Dietzek. Veith Symposium New York City; November 19, 2013

Rassumussen study
Multicenter, randomized, 3 years f/u

Proebstle study
Multicenter, prospective, 5 years f/u
TM Proebstle, et al., BJS 2015 Feb;102(3):212-8
Study Features:

- International multi-center study (8 Europe, 5 US)
- Prospective, longitudinal, single arm
- 326 patients and 396 limbs treated
- 278 limbs followed to 5 years (70.2%)

Dietzek A. RF Segmental ablation: 5-year data. Annual VEITH Symposium
New York City ; November 19, 2013
Primary Endpoints
- Vein occlusion rate
- Absence of reflux rate

Secondary Endpoints
- Presence of complications and side effects
- Quality of life (QOL)
## Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Enrolled Subjects (N=326)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age mean (SD)</td>
<td>50.8 (13.3)</td>
</tr>
<tr>
<td>Age range</td>
<td>18 - 79 years</td>
</tr>
<tr>
<td>Gender</td>
<td>73.3% Female</td>
</tr>
<tr>
<td></td>
<td>26.7% Male</td>
</tr>
<tr>
<td>BMI mean (SD)</td>
<td>26.5 (5.6)</td>
</tr>
<tr>
<td>BMI range</td>
<td>16.2 - 48.5</td>
</tr>
</tbody>
</table>

BMI = Body mass index

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Dietzcek A. RF Segmental ablation: 5-year data. Annual VEITH Symposium New York City; November 19, 2013
OCCLUSION RATES AT 1 & 5 YEARS

96.6% success at 1 year

90.0% success at 5 years

Dietzek A. RF Segmental ablation: 5-year data. Annual VEITH Symposium New York City; November 19, 2013
### Occlusion & Reflux Free Rates

**Time** | **Occlusion Rates %** | **Std Error**
---|---|---
1 Year | 96.6% | 0.9%
2 Year | 94.3% | 1.2%
3 Year | 92.8% | 1.4%
4 Year | 91.1% | 1.5%
5 Year | **90.0%** | 1.7%

**Time** | **Reflux free Rates %** | **td Error**
---|---|---
1 Year | 98.9% | 0.5%
2 Year | 97.8% | 0.8%
3 Year | 95.7% | 1.1%
4 Year | 94.0% | 1.3%
5 Year | **93.7%** | 1.3%

*Product limit occlusion estimates.*

Dietzek A. RF Segmental ablation: 5-year data. Annual VEITH Symposium New York City; November 19, 2013
RASMUSSEN STUDY

Study Features:

- Randomized, prospective trial, two sites Denmark
- 500 subjects (580 legs)
- Patients assessed at 3, 30 and 1 & 3 years (intended 5 year follow-up)

Compared 4 treatments:

- EVLA (980 nm and 1470 nm) – 125(144)
- RFA ClosureFast™ catheter – 125(148)
- Ultrasound guided sclerotherapy (UGSF) – 125(144)
- Surgical stripping – 124(142)
Primary endpoint
- Closed or absent GSV
  (Refluxing segment 10cm or more considered failure)

Secondary endpoints
- Presence of varicose veins, reoperations, VCSS and QOL

Rasmussen LH et al., Randomized clinical trial comparing EVLA, RFA, FS, and stripping for GSV with 3 yr follow-up. J VS Venous Lymphat Disord 2013;349-356.
EVLA: Endovenous Laser Ablation 980-nm diode laser 17 legs & 1470nm diode laser 127 leg.; GSV, Great Saphenous Vein; RFA, Radiofrequency Ablations; USGS, Ultrasound-guided Foam Sclerotherapy.

Rasmussen LH et al., Randomized clinical trial comparing EVLA, RFA, FS, and stripping for GSV with 3 yr follow-up. J VS Venous Lymphat Disord 2013;349-356.
# Rasmussen Study Baseline Characteristics

: Rasmussen et al. 2013

<table>
<thead>
<tr>
<th></th>
<th>RFA</th>
<th>EVLA</th>
<th>UGFS</th>
<th>Stripping</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No. of patients</strong></td>
<td>125</td>
<td>125</td>
<td>125</td>
<td>124</td>
</tr>
<tr>
<td><strong>No. of legs</strong></td>
<td>148</td>
<td>144</td>
<td>144</td>
<td>142</td>
</tr>
<tr>
<td><strong>Bilateral</strong></td>
<td>23</td>
<td>19</td>
<td>19</td>
<td>18</td>
</tr>
<tr>
<td><strong>Age (range)</strong></td>
<td>51 (23-77)</td>
<td>52 (18-74)</td>
<td>51 (18-75)</td>
<td>50 (19-72)</td>
</tr>
<tr>
<td><strong>Female (%)</strong></td>
<td>70</td>
<td>72</td>
<td>76</td>
<td>77</td>
</tr>
<tr>
<td><strong>CEAP C2-C3 (%)</strong></td>
<td>92</td>
<td>95</td>
<td>96</td>
<td>97</td>
</tr>
<tr>
<td><strong>CEAP C4-C6 (%)</strong></td>
<td>8</td>
<td>5</td>
<td>4</td>
<td>3</td>
</tr>
</tbody>
</table>

EVLA: Endovenous Laser Ablation 980-nm diode laser 17 legs & 1470nm diode laser 127 legs; GSV, Great Saphenous Vein; RFA, Radiofrequency Ablations; USGS, Ultrasound-guided Foam Sclerotherapy.

Rasmussen LH et al., Randomized clinical trial comparing EVLA, RFA, FS, and stripping for GSV with 3 yr follow-up. *J VS Venous Lymphat Disord* 2013;349-356.
RASMUSSEN STUDY: Rasmussen et al. 2013

Kaplan-Meier (KM) plot of reoperations. The KM figures represent time to the event.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>RFA</td>
<td>8</td>
<td>7%</td>
</tr>
<tr>
<td>EVLA</td>
<td>8</td>
<td>6.8%</td>
</tr>
<tr>
<td>UGFS</td>
<td>31</td>
<td>26.4%</td>
</tr>
<tr>
<td>stripping</td>
<td>8</td>
<td>6.5%</td>
</tr>
</tbody>
</table>

EVLA: Endovenous Laser Ablation; GSV, Great Saphenous Vein; RFA, Radiofrequency Ablations; USGS, Ultrasound-guided Foam Sclerotherapy.

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▪ **VCSS (Venous Clinical Severity Score):**
Improved significantly in all groups (p<.0001), no significant difference between groups at any given point in time and continued throughout the 3 year follow-up.

▪ **AVVSS (Aberdeen Varicose Vein Symptom Severity Score)**
Improved significantly in all groups from day 3 through year 3 (p<.0001), no significant difference between groups throughout.

▪ **SF-36 Scores (Quality of Life)**
Significant improvements made over baseline in the following categories; physical, bodily pain, vitality, and social functioning, in addition to emotional and physical component summary in all groups at all times.

Rasmussen LH et al., Randomized clinical trial comparing EVLA, RFA, FS, and stripping for GSV with 3 yr follow-up. *JVS Venous Lymphat Disord* 2013;349-356.
Study Features:

- European multi-center (8 sites in Germany, France)
- Prospective, cohort study
- Between April 2006 ~ March 2007
- 225 patients and 295 limbs treated
- 177 patients and 236 limbs followed to 5 years (78.7%)
Primary endpoint: Vein occlusion
Absence of flow in the treated vein using distal augmentation

Secondary endpoints:
CEAP, VCSS, VAS for pain, complications etc.
Mean diameters of GSV 3cm distal to the SFJ

- Not visible in 53.4% at 5 years
- Fibrotic cord mean 2.0mm (preOP mean 5.8mm)
- GSV occlusion rate at 5 years: 91.9%

(complete occlusion with absence of any reflux up to 3cm below SFJ)
- **VCSS**
  
  Baseline mean 3.9(2.1)
  reaching 1.3(1.7) at 5 years

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Proebstle et al., 5 yr results from the prospective European multicenter cohort study in RF segmental thermal ablation for incompetent GSV. BJS 2015 Feb;102(3):212-8
RFA CLOSUREFAST™ CATHETER
: SUMMARY

- Occlusion rate:
  3-yr follow up 93% (Ramussen et al.)
  5-yr follow up 90% / 91.9% (Dietzek / Proebstle et al.)

- Significant improvements
  : VCSS, AVVSS, SF-36, pain VAS
My experience of RF segmental ablation (ClosureFast™)

- **1st case on 11 Nov 2014**

<table>
<thead>
<tr>
<th>Subjects (N=291)</th>
<th>No. patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age mean (SD)</strong></td>
<td><strong>More than 3 mo</strong></td>
</tr>
<tr>
<td>Age range</td>
<td>224</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>80.8% Female</td>
<td></td>
</tr>
<tr>
<td>19.2% Male</td>
<td></td>
</tr>
<tr>
<td><strong>BMI mean</strong></td>
<td></td>
</tr>
<tr>
<td>BMI range</td>
<td></td>
</tr>
<tr>
<td>23.5 (3.5)</td>
<td></td>
</tr>
<tr>
<td>15.8 - 42.7</td>
<td></td>
</tr>
</tbody>
</table>
My experience of RF segmental ablation (ClosureFast™)

- 50 patients reached up to 1 year of postop period
- 32/50 patients followed to 1 year (63.3%)
- 1 patient showed recanalization by perforators in lower thigh
- Occlusion rate 96.8% at 1 year

My procedures:
- EVLA 27%
- RFA 28%
- Stripping 45%
Thank you

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5 years results: endovenous treatment of superficial vein reflux in an outpatient setting

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