Varithena® VLU Registry: The Effects Of Polidocanol Endovenous Microfoam On Wound Healing And Recurrence

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Disclosures

- **Consultant/Advisor/ DSMB/ CEC -**
  - **Abbott, Auxetics, Boston Scientific, Diachii Sankyo, Koya Medical, Medtronic, Penumbra, Philips, Surmodics, USA**
- **Board of Trustee**
  - **The VIVA Foundation**
  - **Intersocietal Accreditation Council | Vascular Testing**
- **President**
  - **Syntropic Core Lab**

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Varithena™

(polidocanol injectable foam) 1%

- Nonthermal, nontumescent treatment for venous insufficiency
- Varithena is FDA approved and indicated for the treatment of incompetent great saphenous veins, accessory saphenous veins and visible varicosities of the great saphenous vein (GSV) system above and below the knee
- Varithena produces cohesive, low-nitrogen microfoam with O_2:CO_2 (65:35) gas mixture with <0.8% nitrogen.[1]

1. Eckmann DM. Polidocanol for endovenous microfoam sclerosant therapy. Expert Opin Investig Drugs. 2009;18(12):1919-1927

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VIEW-VLU observational study of the effect of Varithena on wound healing in the treatment of venous leg ulcers

Michael Y. Shao, MD,[1] Stuart Harlin, MD,[2] Beverly Chan, MD,[3] KathyLee Santangelo, MD,[4] Eri Fukaya, MD,[4] Julianne Stoughton, MD,[5] and Raghu Kolluri, MD, MS,[6] for the VIEW-VLU Investigators, *Chicago, IL; Houston, TX; Oklahoma City, OK; Palo Alto, CA; Boston, MA; Columbus, OH; and Oakville, Ontario, Canada*

Objective	Evaluate VLU healing rate, recurrence rate, and patient reported outcomes for Varithena
Study Design	• Prospective, multicenter • Open label • 12-month phase 4 registry
Primary Endpoints	• Rate of epithelial migration (mm/week) measured by wound perimeter on photograph • Ulcer healing at 12 weeks (±1wk) post treatment • Time from initial treatment with Varithena to ulcer healing
Patients	• Patients classified C6 with active VLU • N=80
Investigational Centers	USA and Canada

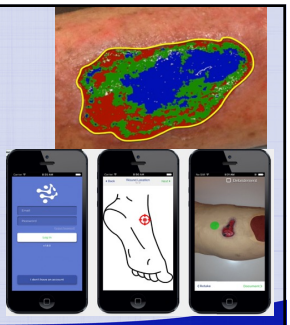
- ***Follow-up visits at 1 week, 12 weeks, and 12 months; phone calls at 6 months post treatment and 3 months post-wound closure***
- ***Patients photograph ulcer between visits using app***
- ***Study terminated early by the sponsor***

OhioHealth J Vasc Surg Venous Lymphat Disord. 2023 Jul;11(4):692-699.e1

Tissue Analytics:

Automatic Wound Measurement Application

- Ulcer perimeter and epithelial migration measured by photograph using Tissue Analytics® application on tablets provided to patients
- Automatically measures ulcers using machine learning
- Data submitted to Tissue Analytics for independent physician analysis



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VIEW-VLU

Key Inclusion and Exclusion Criteria

Inclusion Criteria

- Age ≥18
- CEAP C6 with chronic (≥ 3 months) VLU resulting from GSV and/or AASV incompetence
- Reflux >500ms on duplex ultrasound
- **Ulcer can be visualized in one plane,** or if wound is circumferential, subject must be able to capture entire wound using multiple photographs

Exclusion Criteria

- Concomitant disease that confounds ulcer healing
- Thermal ablation of index leg within 6 weeks prior to treatment with Varithena
- Significant arterial disease or ABI≤0.8
- In the opinion of the investigator, wound would close within 12 weeks without additional treatment

Study did not exclude patients based on wound age

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VIEW-VLU
Demographics

Characteristics	
Patients	**(n = 76)**
Age, years	63.6 ± 13.7
Male	46 (60.5)
Female	30 (39.5)
BMI (kg/m^2)	36.3 ± 10.2
BMI category	
18.5 to <25.0	12 (15.8)
25.0 to <30.0	13 (17.1)
≥30.0	51 (67.1)
Target wound leg	
Right	32 (42.1)
Left	40 (52.6)
Both	4 (5.3)

Wounds	(n = 80)
Circumferential	21 (26.3)
Ulcer age at first encounter, weeks	34.8 ± 51.8
Median (IQR), weeks	24.0 (11.5-40.0)
Hospitalization for target ulcer	10 (12.5)
Previous procedure/treatment for target ulcer	22 (27.5)
Previous skin graft for target ulcer	5 (6.3)
Compliance with compression	69 (86.3)
Duration of compression, weeks	26.4 ± 35.9
Signs of infection or bioburden	14 (17.5)
CSV incompetence	77 (96.3)
AASV incompetence	18 (22.5)
Major perforator incompetence	32 (40)
SSV incompetence	25 (31.3)
Baseline VCSS (target leg)	18.6 ± 4.7

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Table II. Key VIEW-VLU and EVRA[9] patient characteristics at trial enrollment

	VIEW-VLU	EVRA
Mean BMI, kg/m^2	36.3	30.1
Median ulcer size, cm^2	6.4	2.7
Mean ulcer age, months	8.7	3.1
Median VCSS	18.5	16
Mean EQ-5D-5L index	0.65	0.73

BMI, Body mass index; *EQ-5D-5L*, EuroQol Five Dimension Five-level Questionnaire; *VCSS*, Venous Clinical Severity Score.

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VIEW-VLU
Varithena Procedure

68% of patients treated in a single session

Varithena Treatment by Ulcer	N=80 Ulcers
Total Injection Sites	2.1 ± 1.6
Volume Injected Above the Knee (mL)	3.9 ± 5.7
Volume Injected Below the Knee (mL)	9.4 ± 4.5
Number of Patients with Additional Varithena Treatment*	31.6% (24/76)

**Additional Varithena treatments could not occur until at least 5 days post index procedure*

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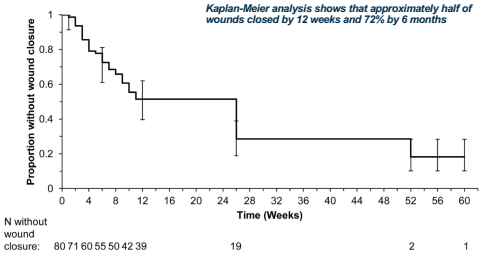
Kaplan-Meier analysis shows that approximately half of wounds closed by 12 weeks and 72% by 6 months



Median time to ulcer closure (range)	73 (2-461) days
Wounds remaining closed 3 months post-closure	87% (47/54)

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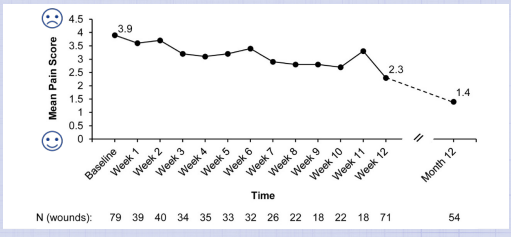
VIEW-VLU
Pain and QOL

64% Mean Reduction in Pain at 12 Months



**Patient reported pain at ulcer location on scale from 0-10*

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VIEW-VLU

Safety: Polidocanol-related SAEs

- **2 SAEs reported**
- **Both in same patient**
- **2 days after index procedure**

Assessment

- **Asthenia (n = 1)**
  - **Investigator assessed: related to the device**
  - **Sponsor pharmacovigilance assessed: unlikely associated with the device**
- **Pain in extremity (n = 1)**
  - **Investigator assessed: possibly associated with the device**
  - **Sponsor pharmacovigilance assessed: possibly associated with the device**

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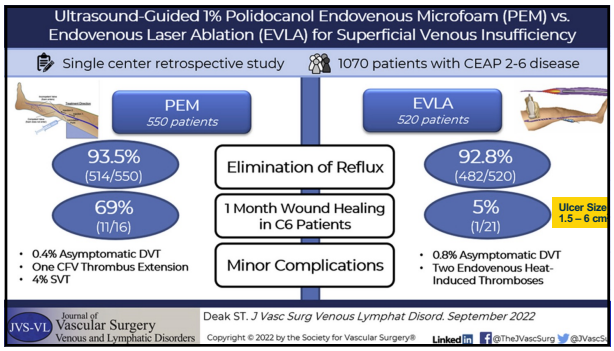
Ultrasound-Guided 1% Polidocanol Endovenous Microfoam (PEM) vs. Endovenous Laser Ablation (EVLA) for Superficial Venous Insufficiency
Single center retrospective study
1070 patients with CEAP 2-6 disease
PEM
550 patients
EVLA
520 patients
93.5% (514/550)
69% (11/16)
Elimination of Reflux
1 Month Wound Healing in C6 Patients
Minor Complications
92.8% (482/520)
5% (1/21)
Ulcer Size 1.5 – 6 cm
0.4% Asymptomatic DVT
One CFV Thrombus Extension
4% SVT
0.8% Asymptomatic DVT
Two Endovenous Heat-Induced Thromboses
JVS-VL Journal of Vascular Surgery Venous and Lymphatic Disorders
Deak ST. J Vasc Surg Venous Lymphat Disord. September 2022
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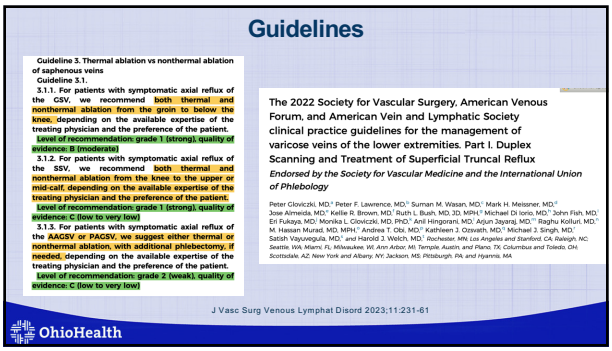
Guidelines
Guideline 3. Thermal ablation vs nonthermal ablation of saphenous veins
Guideline 3.1.
3.1.1. For patients with symptomatic axial reflux of the GSV, we recommend both thermal and nonthermal ablation from the groin to below the knee, depending on the available expertise of the treating physician and the preference of the patient.
Level of recommendation: grade 1 (strong), quality of evidence: B (moderate)
3.1.2. For patients with symptomatic axial reflux of the SSV, we recommend both thermal and nonthermal ablation from the knee to the upper or mid-calf, depending on the available expertise of the treating physician and the preference of the patient.
Level of recommendation: grade 1 (strong), quality of evidence: C (low to very low)
3.1.3. For patients with symptomatic axial reflux of the AAGSV or PACSV, we suggest either thermal or nonthermal ablation, with additional phlebectomy, if needed, depending on the available expertise of the treating physician and the preference of the patient.
Level of recommendation: grade 2 (weak), quality of evidence: C (low to very low)
The 2022 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society clinical practice guidelines for the management of varicose veins of the lower extremities. Part I. Duplex Scanning and Treatment of Superficial Truncal Reflux
Endorsed by the Society for Vascular Medicine and the International Union of Phlebology
J Vasc Surg Venous Lymphat Disord 2023;11:231-61
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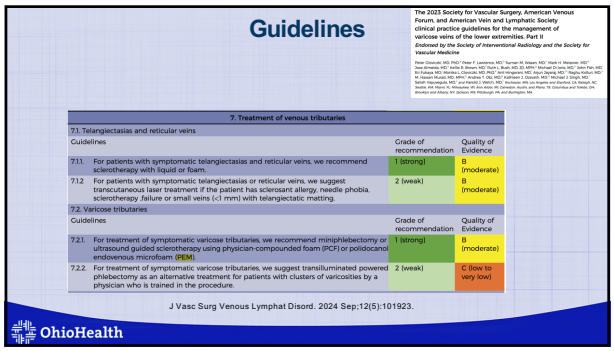
Guidelines
The 2023 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society clinical practice guidelines for the management of varicose veins of the lower extremities. Part II
Endorsed by the Society of Interventional Radiology and the Society for Vascular Medicine
7. Treatment of venous tributaries
7.1. Telangiectasias and reticular veins
Guidelines
Grade of recommendation
Quality of Evidence
7.1.1. For patients with symptomatic telangiectasias and reticular veins, we recommend sclerotherapy with liquid or foam.
1 (strong)
B (moderate)
7.1.2. For patients with symptomatic telangiectasias or reticular veins, we suggest transcutaneous laser treatment if the patient has sclerosant allergy, needle phobia, sclerotherapy failure or small veins (<1 mm) with telangiectatic matting.
2 (weak)
B (moderate)
7.2. Varicose tributaries
Guidelines
Grade of recommendation
Quality of Evidence
7.2.1. For treatment of symptomatic varicose tributaries, we recommend miniphlebectomy or ultrasound guided sclerotherapy using physician-compounded foam (PCF) or polidocanol endovenous microfoam (PEM).
1 (strong)
B (moderate)
7.2.2. For treatment of symptomatic varicose tributaries, we suggest transilluminated powered phlebectomy as an alternative treatment for patients with clusters of varicosities by a physician who is trained in the procedure.
2 (weak)
C (low to very low)
J Vasc Surg Venous Lymphat Disord. 2024 Sep;12(5):101923.
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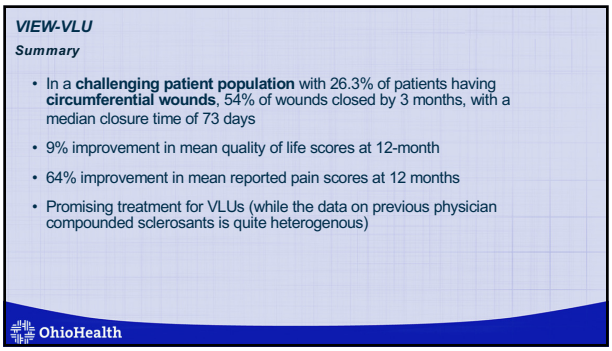
VIEW-VLU
Summary
In a challenging patient population with 26.3% of patients having circumferential wounds, 54% of wounds closed by 3 months, with a median closure time of 73 days
9% improvement in mean quality of life scores at 12-month
64% improvement in mean reported pain scores at 12 months
Promising treatment for VLUs (while the data on previous physician compounded sclerosants is quite heterogenous)
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