Varithena®
(polidocanol injectable foam) 1%

**VIEW-VLU** | **VIEW-VLU Investigators**: Michael Y. Shao, MD, Stuart Harlin, MD, Beverly Chan, MD, KathyLee Santangelo, MD, Eri Fukaya, MD, Julianne Stoughton, MD, and Raghu Kolluri, MD, MS

# An observational study of the effect of Varithena on wound healing in the treatment of venous leg ulcers

## OBJECTIVE

To evaluate venous leg ulcer healing rate, recurrence rate and patient reported outcomes for Varithena

## Patients

*(n= 76; prospective, multicenter, open-label, 12-month phase 4 registry)*

### Patients eligible for treatment

- Classified CEAP 6 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

### Excluded patient criteria

- Concomitant disease (including significant arterial disease) that confounds ulcer healing
- Thermal ablation of index leg within 6 weeks prior to treatment with Varithena
- Belief that wound would close within 12 weeks without additional treatment

### Patient demographics & disease characteristics

- Obese to extremely obese (36.3 ± 10.2 BMI)
- Chronic ulcers (34.8 ± 51.8 weeks at first encounter)
- Severity of ulcers
  - 26.3% circumferential wound
  - 12.5% hospitalization for target ulcer
  - 27.5% previous treatment for target ulcer

**Study did not exclude patients based on wound size or wound age; these characteristics led to a challenging patient population**

| 76 Patients | |
|---|---|
| Age, years | 63.6 ± 13.7 |
| Male/Female | 60.5%/39.5% |
| BMI (kg/m2) | 36.3 ± 10.2 |
| **N=80 Ulcers** | |
| Circumferential Wound | 26.3% |
| Ulcer age at First Encounter, weeks | 34.8 ± 51.8 |
| Duration of Compression Therapy, weeks | 26.4 ± 35.9 |
| Compliance with Compression | 86.3% |
| Hospitalization for Target Ulcer | 12.5% |
| Previous Procedure/Treatment for Target Ulcer | 27.5% (22/80) |
| Previous Skin Graft for Target Ulcer | 22.7% (5/22) |
| Signs of Infection or Bioburden | 17.5% |
| GSV Incompetence | 96.3% |
| AASV Incompetence | 21.3% |
| Major Perforator Incompetence | 40% |
| Peripheral Arterial Disease | 3.8% |

## Methods

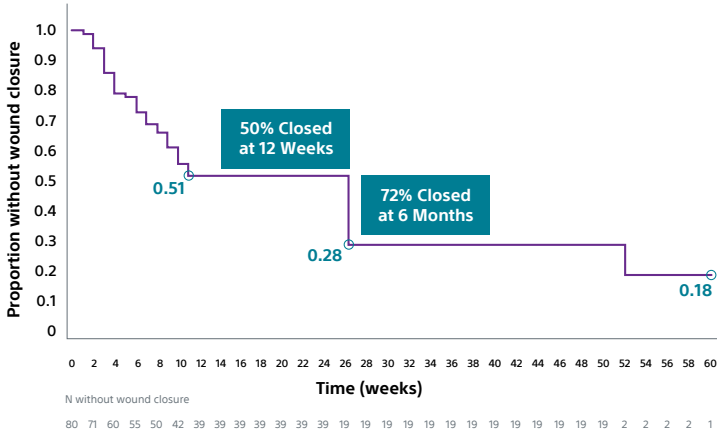
- Total injection sites 2.1 ± 1.6
- Varithena volume injected (mL):
  - 3.9 ± 5.7 above the knee
  - 9.4 ± 4.5 below the knee
- Patients photograph ulcer between visits using Tissue Analytics application, which automatically measures ulcers using machine learning
- Follow up visits at 1-week, 12-weeks, and 12-months; phone calls at 6-months post-treatment and 3-months post-wound closure

# Key Results

## Wound Closure

- **Procedure: 68%** of patients treated in a single session
- Ulcer healing / wound closure:
  - **53.8%** of ulcers healed (wounds closed) by 12 weeks
    - **88.9%** of wounds remained closed at 3 months post-closure
    - **27%** median perimeter reduction through rapid initial healing at 12 weeks

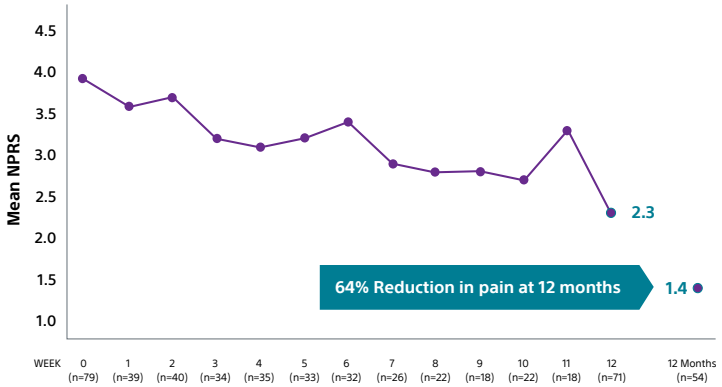
**Kaplan Meier Analysis** Ulcer Healing (Wound Closure) with Varithena




## Symptom Improvement

- **64%** mean reduction in pain at 12 months

**Patient Reported Pain** at Ulcer Location




## Safety Data

- Two SAEs reported as related to Varithena (asthenia and pain in extremity) in same patient, two days after index procedure

## Study Conclusion

Results show that patients treated with Varithena for venous leg ulcers had **rapid initial wound healing and sustained improvements in quality of life and pain**


1. Shao MY, Harlin S, Chan B, Santangelo K, FukayaE, Stoughton J, KolluriR; VIEW-VLU Investigators. VIEW-VLU observational study of the effect of Varithena on wound healing in the treatment of venous leg ulcers. J VascSurg Venous LymphatDisord. 2023 Mar 25:S2213-333X(23)00131-2. doi: 10.1016/j.jvsv.2023.01.011. Epubahead of print. PMID: 36972751


**Varithena (polidocanol injectable foam) 1%**
**INDICATIONS** Varithena (polidocanol injectable foam) is 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 improves the symptoms of superficial venous incompetence and the appearance of visible varicosities.

**IMPORTANT SAFETY INFORMATION** The use of Varithena is contraindicated in patients with known allergy to polidocanol and those with acute thromboembolic disease. Severe allergic reactions have been reported following administration of liquid polidocanol, including anaphylactic reactions, some of them fatal. Observe patients for at least 10 minutes following injection and be prepared to treat anaphylaxis appropriately. Intra-arterial injection or extravasation of polidocanol can cause severe necrosis, ischemia or gangrene. Patients with underlying arterial disease may be at increased risk for tissue ischemia. If intra- arterial injection of polidocanol occurs, consult a vascular surgeon immediately. Varithena can cause venous thrombosis. Follow administration instructions closely and monitor for signs of venous thrombosis after treatment. Patients with reduced mobility, history of deep vein thrombosis or pulmonary embolism, or recent (within 3 months) major surgery, prolonged hospitalization, or pregnancy are at increased risk for developing thrombosis. The most common adverse events observed were pain/discomfort in extremity, retained coagulum, injection site hematoma or pain, common femoral vein thrombus extension, superficial thrombophlebitis, and deep vein thrombosis. Physicians administering Varithena must be experienced with venous procedures, possess a detailed working knowledge of the use of the duplex ultrasound in venous disease and be trained in the administration of Varithena.

For Full Prescribing Information visit Varithena.com



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