ENGLEWOOD HEALTH

Clinical Feasibility and Safety Study of a Novel Device for the Treatment of Chronic Venous Insufficiency of the Lower Limb

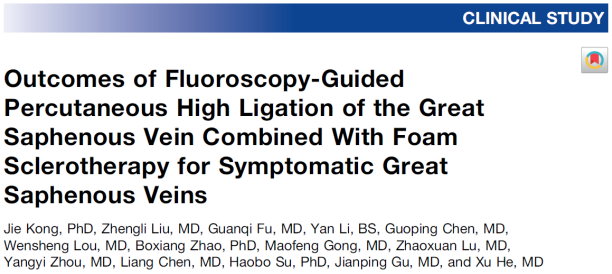
Steve Elias

DISCLOSURES

BD	Consultant
Boston Scientific	Advisory Board
Elastimed	Consultant/Stock options
Enveno	Stock options
Gore	Consultant
Medtronic Inc.	Advisory Board
Methapharm Inc	Consultant
Philips	Advisory Board
Sun Scientific	Advisory Board
Tactile Medical	Advisory Board
Theraclion	Consultant
Thrombolex	Consultant
Verge Medical	Consultant
USA Therm	Advisory Board/Stock
VVT Medical	Advisory Board/Stock
VB Devices	Advisory Board/Stock

Background

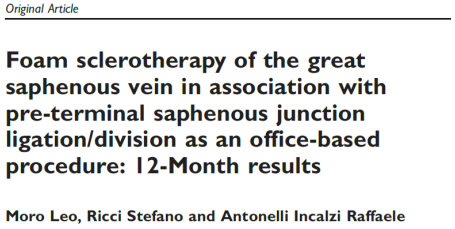
- Combining **high ligation** and **foam sclerotherapy** for treating Great Saphenous Vein (GSV) incompetence offers several notable advantages.
- Simultaneously addressing the proximal source of reflux and the incompetent saphenous trunk or tributaries may lead to **lower recurrence rates** and enhanced **long-term vein occlusion**.



CLINICAL STUDY

Outcomes of Fluoroscopy-Guided Percutaneous High Ligation of the Great Saphenous Vein Combined With Foam Sclerotherapy for Symptomatic Great Saphenous Veins

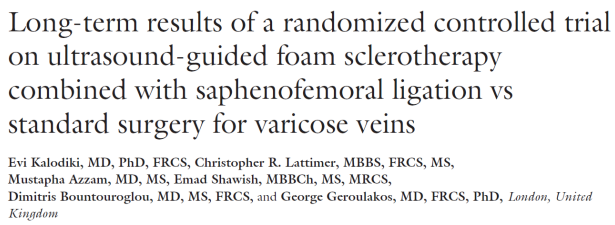
Jie Kong, PhD, Zhengli Liu, MD, Guanqi Fu, MD, Yan Li, BS, Guoping Chen, MD, Wensheng Lou, MD, Boxiang Zhao, PhD, Maofeng Gong, MD, Zhaoxuan Lu, MD, Yangyi Zhou, MD, Liang Chen, MD, Haobo Su, PhD, Jianping Gu, MD, and Xu He, MD



Original Article

Foam sclerotherapy of the great saphenous vein in association with pre-terminal saphenous junction ligation/division as an office-based procedure: 12-Month results

Moro Leo, Ricci Stefano and Antonelli Incalzi Raffaele



Long-term results of a randomized controlled trial on ultrasound-guided foam sclerotherapy combined with saphenofemoral ligation vs standard surgery for varicose veins

Evi Kalodiki, MD, PhD, FRCS, Christopher R. Lattimer, MBBS, FRCS, MS, Mustapha Azzam, MD, MS, Emad Shawish, MBBCh, MS, MRCS, Dimitris Bountouroglou, MD, MS, FRCS, and George Geroulakos, MD, FRCS, PhD, *London, United Kingdom*

Li X. et al., Ann Vasc Surg. 2018

Kong J. et al., J Vasc Interv Radiol., 2022

Moro L. et al., Phleb. 2018

Klodiki E. et., J Vasc Surg. 2012

Purpose

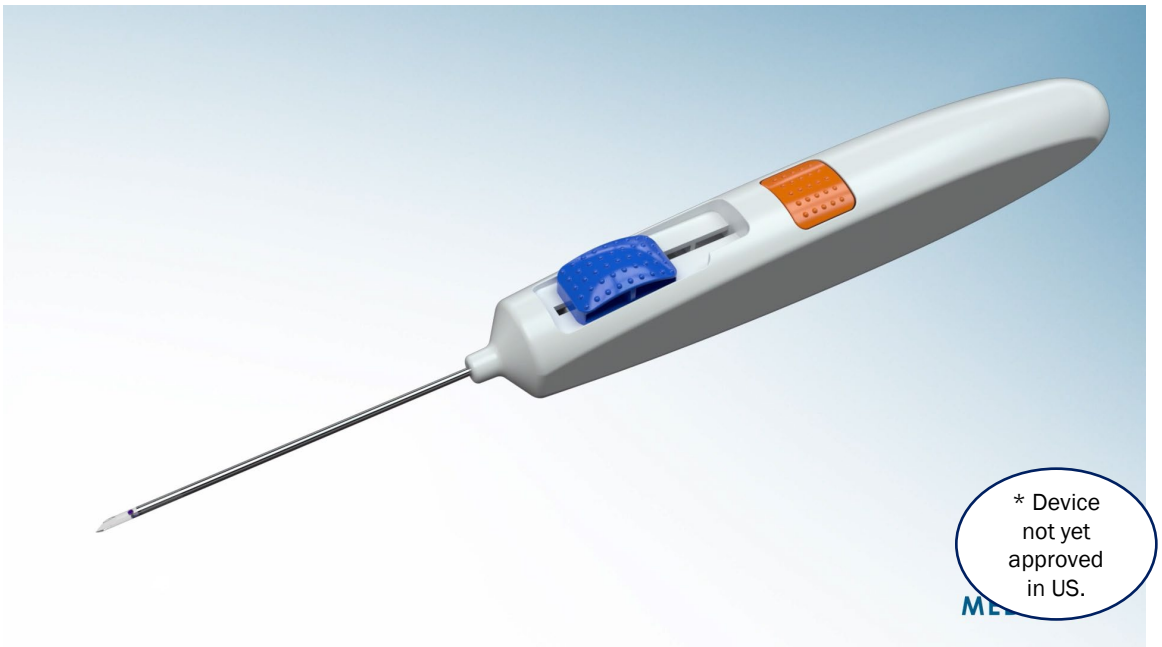
We report the 12-month safety and efficacy of a **novel device** for **percutaneous occlusion** of **Great Saphenous Vein, Small Saphenous Vein** and **perforating veins**, used in association with **foam sclerotherapy** in a first in human study.

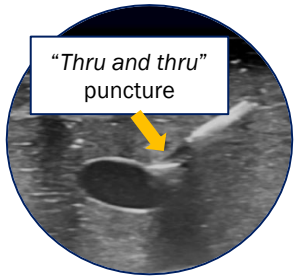


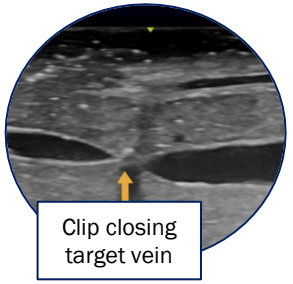
Vein closure device on 17G cannula

2 resorbable clips connected with a suture, loaded into a metal 17G cannula.

Percutaneous insertion with a "***thru and thru***" puncture of the walls of the target vein **under US guidance** in transverse view.







Study Design

Study Site

Single center (Salus Spitali) in Tirana, Albania

Patient population

28 patients

Principal Investigator

Gastone Bergamaschi, MD, Vascular Surgeon

Co-Investigator:

Steven Kum, MD, Vascular Surgeon

Primary endpoint

The feasibility and safety of the GSV occlusion procedure with the novel device, in combination with ultrasound-guided foam sclerotherapy (UGFS)

Safety

Any serious adverse events (SAEs) related the device, to be evaluated within the 30 days after the procedure

Feasibility

GSV occlusion at the end of the procedure, ultrasound, as absence of any flow inside the vessel

Study Design

Secondary endpoints

- **6-month and 1-year occlusion rate of the GSV, assessed by DUS**
- Rate of procedure-related complications assessed at the clinical examinations at discharge, 1 week, 1-month, 6 months, and 12 months
- Assessment of pain, at discharge and at 1 week, assessed by the patient on a visual analog scale
- Change in disease-specific QoL according to the Aberdeen Varicose Vein Severity Score (AVVSS) at 6 and 12 months
- Change in CEAP class at 6 and 12 months

Study Design – usual criteria

Inclusion criteria

- Presence of reflux at the level of the saphenous-femoral valve and/or along the course of the great saphenous vein, diagnosed by US with the patient in the upright position (incompetence was defined as reflux greater than 0.5 seconds)
- CEAP clinical grade ≥ 2
- No previous treatment for varicose veins
- Deep vein patency and continence
- Age 18–70 years
- Only one leg per patient included in the study; in patients with bilateral varicose veins, the most severely affected limb was considered

Exclusion criteria

- Clinical state not suitable for surgery
- Malignancy
- Pregnancy
- BMI exceeding 40 kg/m^2
- Allergy to the sclerosant or lidocaine; allergy to iodinated X-ray contrast medium or contraindication to foam sclerosant treatment
- Peripheral arterial disease
- Lymphoedema
- History of deep venous thrombosis (DVT)
- Coagulation disorder

Demographics and Baseline

Characteristic	Mean ± SD (range) or number (frequency)
N limbs	28
Ethnicity Caucasian	28 (100%)
Mean BMI (kg/m^2)	27.14±3.55
Gender (Female)	19 (68%)
Age, years	48±12.8
CEAP clinical class	
C2	8 (29%)
C3	8 (29%)
C4a/b	11 (39%)
C5/6	1 (4%)
Follow-up (months)[1]	13.8±3.8

Demographics and Baseline

Vessel	# treated vessels	Diameter mean ± SD (range)
Mean Prox Thigh GSV Diameter	27	9.22±2.76 (6-16)

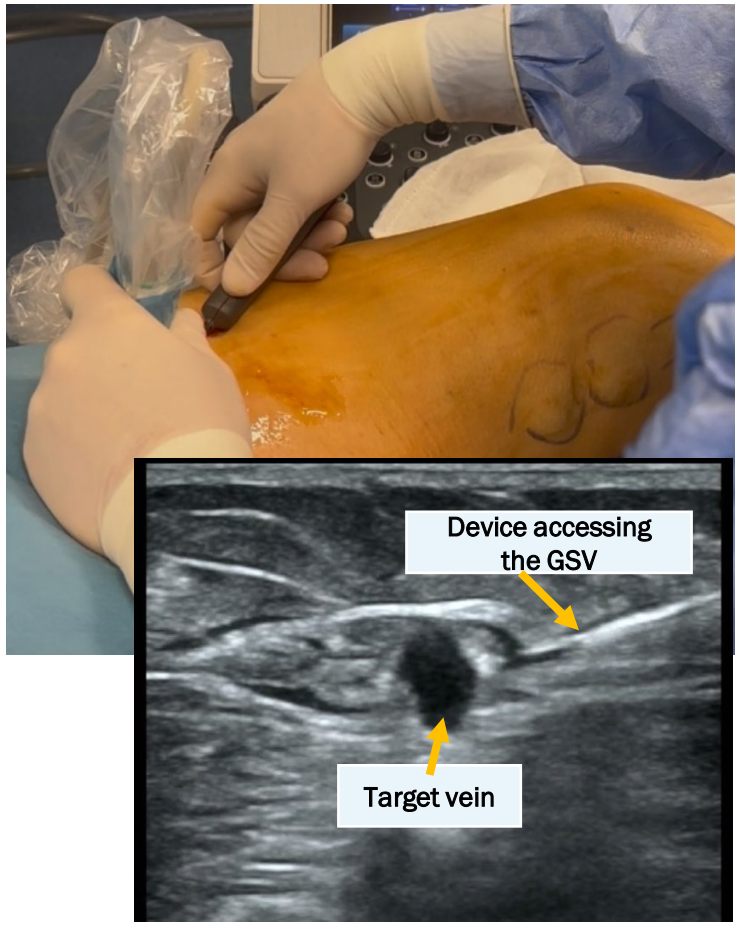
Additional vessels treated

Vessel	# treated vessels	Diameter (range)
Small saphenous vein (SSV) Diameter	2	6-8
Perforator veins	20	3.5-5

One patient with only SSV reflux was included in the study.
One patient with both GSV and SSV reflux was included in the study.

The procedure

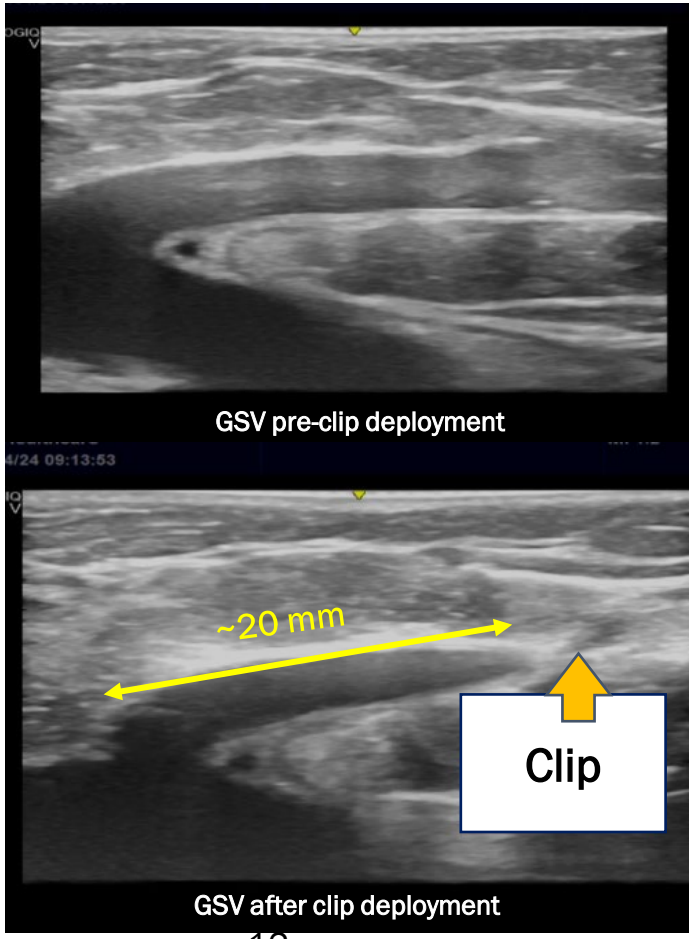
1. Device percutaneously inserted with a “thru and thru” puncture of the walls of the target vein under US guidance in transverse view



The procedure

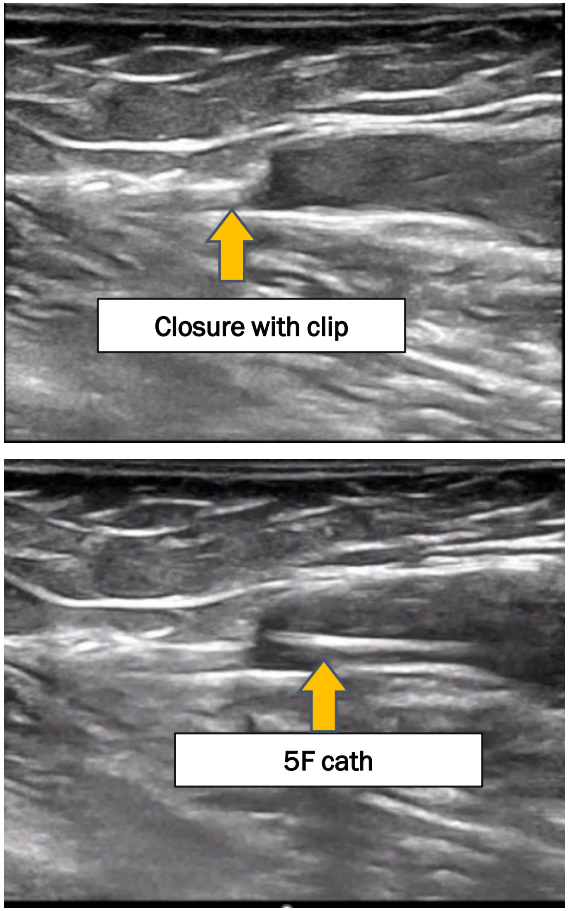
1. Device percutaneously inserted with a “thru and thru” puncture of the walls of the target vein under US guidance in transverse view

2. **Vessel closure achieved ~2 cm from the saphenofemoral junction (SFJ) in the case of GSV**



The procedure

1. “thru and thru” puncture of the walls of the target vein under US guidance in transverse view
2. vessel closure achieved ~2 cm from the saphenofemoral junction (SFJ) in the case of GSV
3. time taken to deploy the clip less than **3 min**
4. clip deployment followed by **delivery of polidocanol 3%** foam infused through a pull-back of a 5F catheter introduced from the lower GSV[1]
5. no tumescent anesthesia was required



[1] In selected cases, direct foam injection with needle was performed.

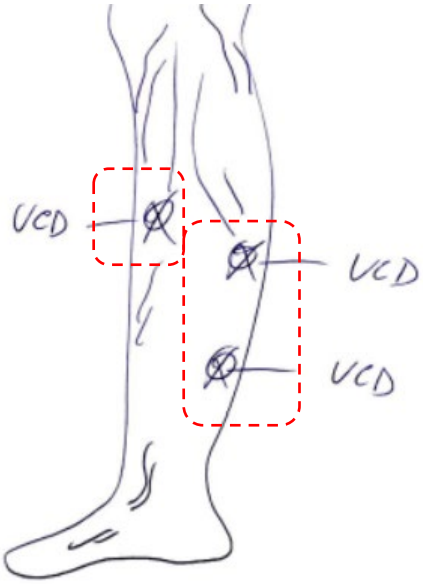
The procedure

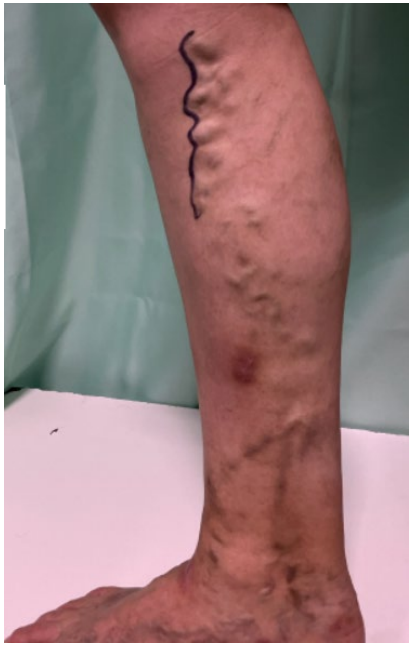
GSV closure



The procedure

Perforator vein closure

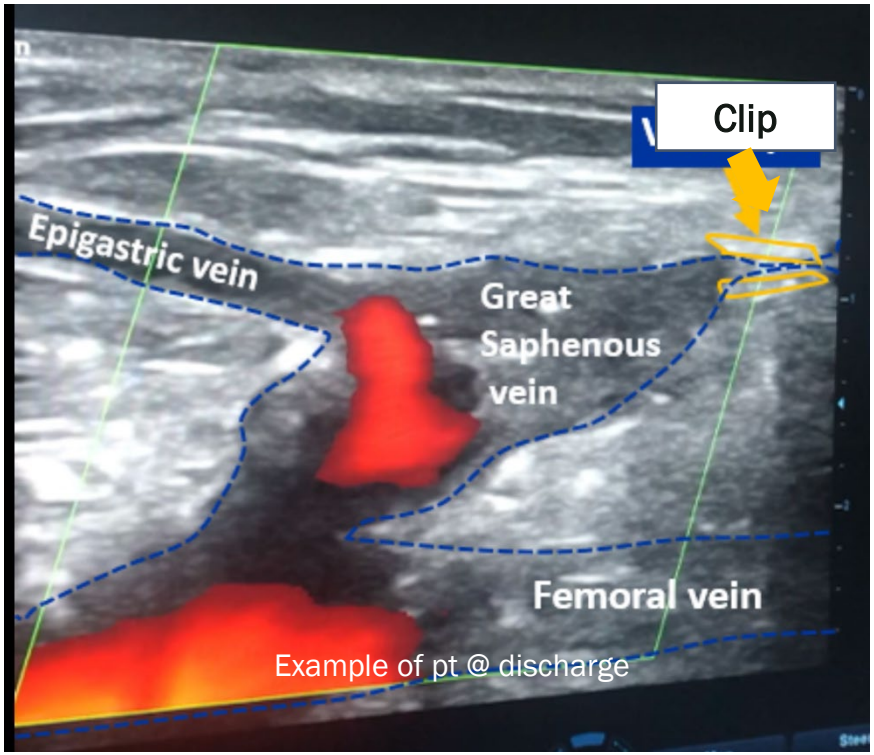




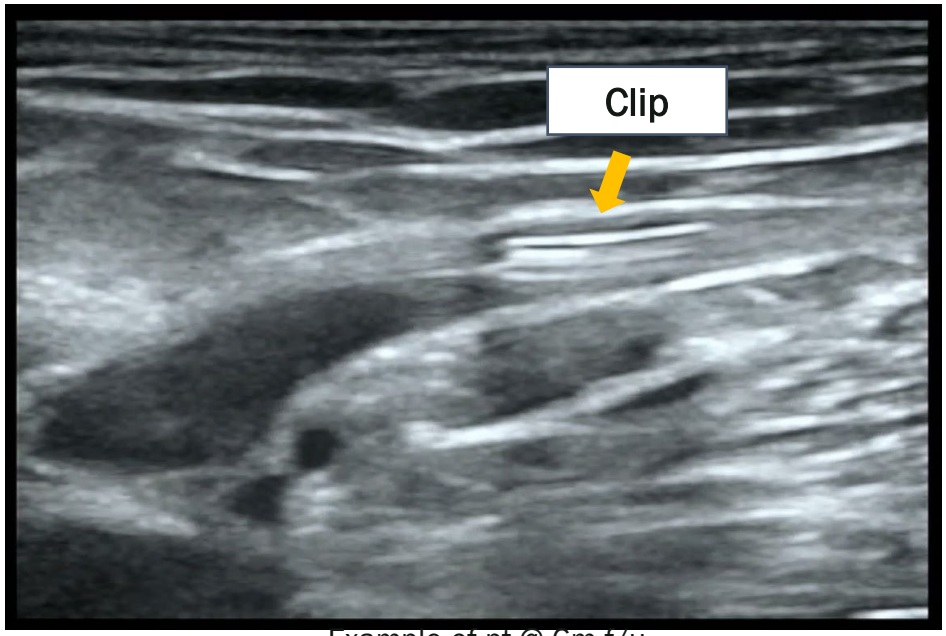


Results

Control at patient discharge and @6 months f/u (GSV)



Example of pt @ discharge



Example of pt @ 6m f/u

Results

Pre and post treatment



Pre-treatment



Post-treatment



Pre-treatment



Post-treatment

Clinical Results

Great Saphenous Vein and Small Saphenous Vein results

Treated vessel diameters up to 16 mm

Number of treated vessel	N closed / N controlled @1m (%)	N closed / N controlled @6m (%)	N closed / N controlled @12m (%)
29[(1)]	29 / 29 **(100%)**	24 / 26 **(92.3%)**	20 / 21 **(95.2%)**

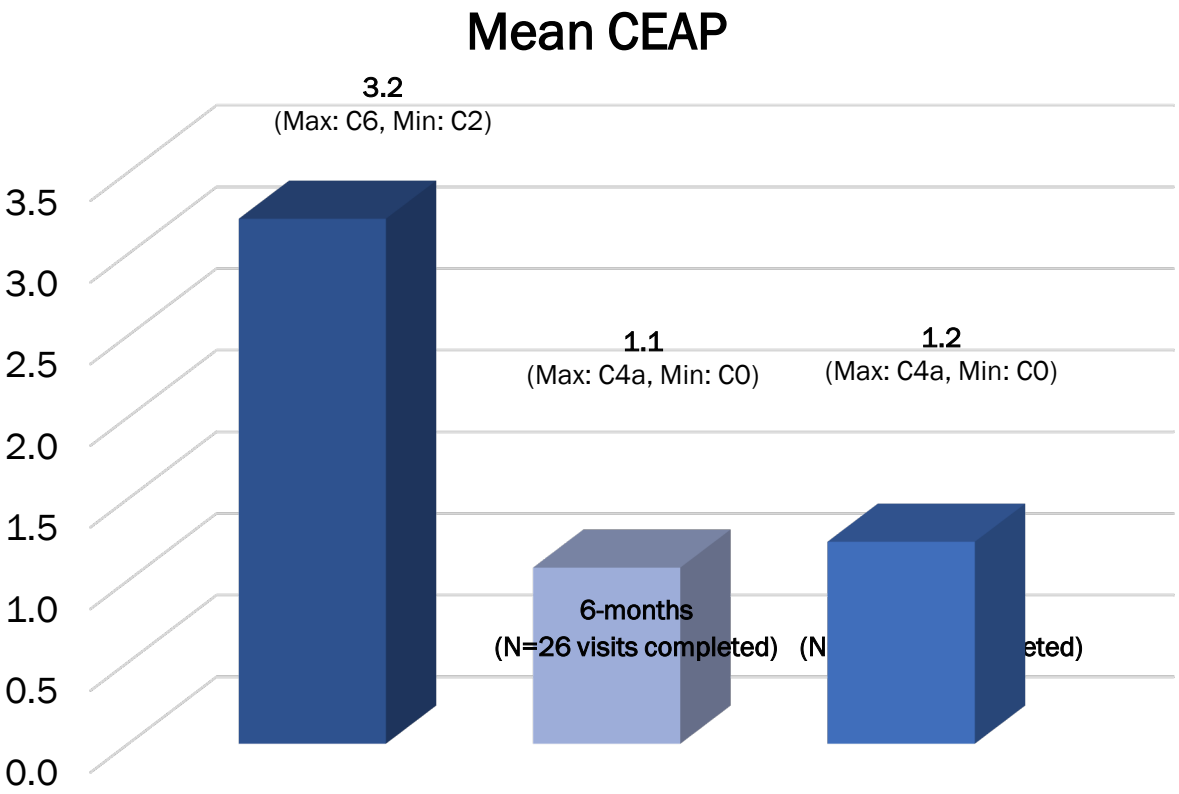
[(1)] Cumulative data of 27 GSV+ 2 SSV

Perforator veins results

Number of treated vessel	N closed / N controlled @1m (%)	N closed / N controlled @6m (%)	N closed / N controlled @12m (%)
20	20 / 20 **(100%)**	16 / 19 **(84%)**	12 / 13 **(92.3%)**

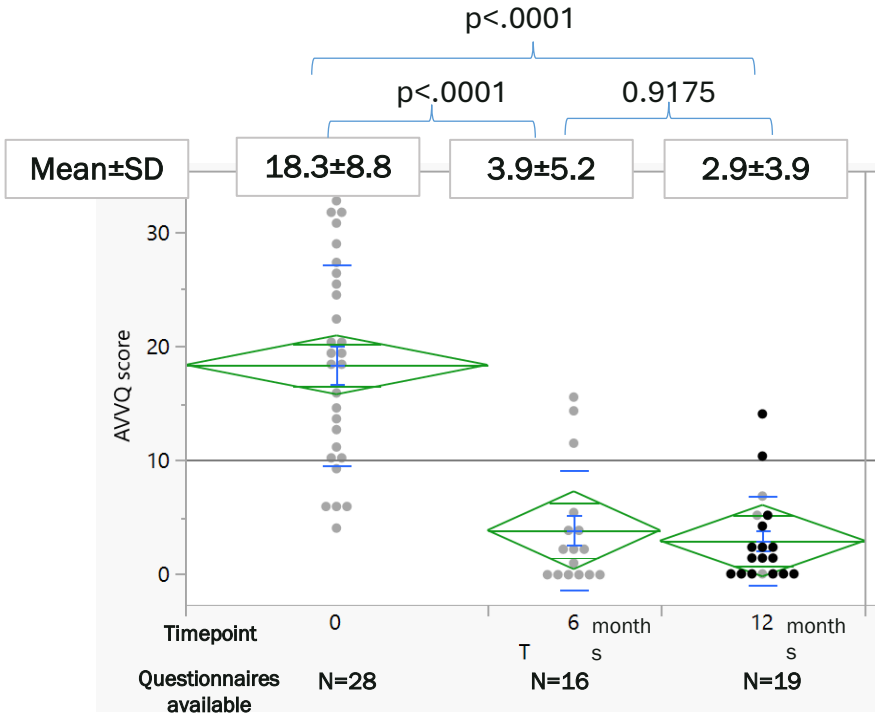
Results: QoL

CEAP



Results: QoL

AVVQ[1]



[1] Kiss G. et al., Int. J. Environ. Res. Public Health 2022

Summary of results

- ✓ 100% technical success with deployment under US
- ✓ The procedure to occlude the vessel was well tolerated
- ✓ All target vessels evaluated with duplex US were occluded at the end of the procedure
- ✓ Perforator veins were successfully treated
- ✓ Primary safety and feasibility endpoint met, with no device-related adverse events
- ✓ No serious adverse events
- ✓ One subfascial venous thrombosis of the calf was found in one patient at 1 week FU and resolved with prolonged heparin treatment after 10 days
- ✓ Significant improvement in QoL

Conclusions

- The data confirms the **safety and feasibility** of this new device for the percutaneous occlusion of superficial veins in combination with foam sclerotherapy
- Average time to deploy the device was **3 min**, with an average overall procedure time comparable to the current modalities
- **Effectiveness of this treatment in the GSV, with results comparable to thermal ablation**
- **Encouraging closure results** are also seen in the **perforators**
- The use of an **ultrasound guided percutaneous device** for **junctional occlusion** of the GSV in combination with foam sclerotherapy can be a **viable alternative to existing thermal and non-thermal methods**
- Further studies with a next generation device and comparative studies are planned
- **ASV, CHIVA, GSV, SSV PPV**