CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
JANUARY 21-23 2016
MARRIOTT RIVE GAUCHE & CONFERENCE CENTER
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3 Year Analysis of The European Cyanoacrylate Study (VenaSeal™)

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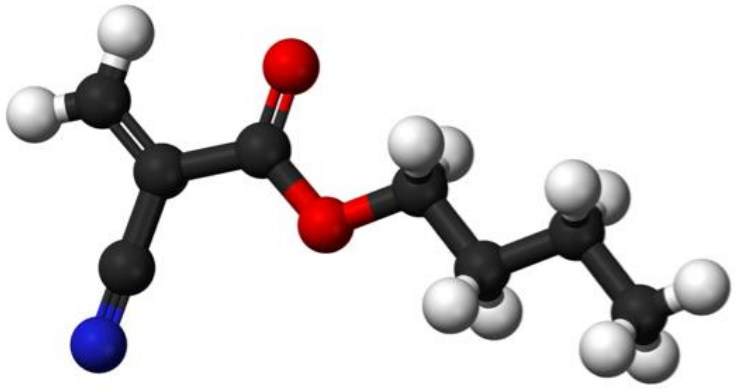
Disclosure

Thomas Proebstle

- ☐ I have the following potential conflicts of interest to report:
- ☐ Consulting
- ☐ Employment in industry
- ☐ Shareholder in a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)
- ☒ I do not have any potential conflict of interest

Objective



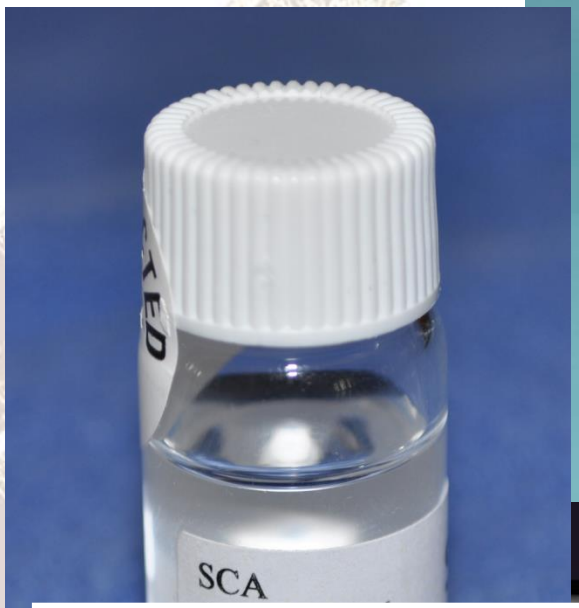
Occlusion of Refluxing GSVs

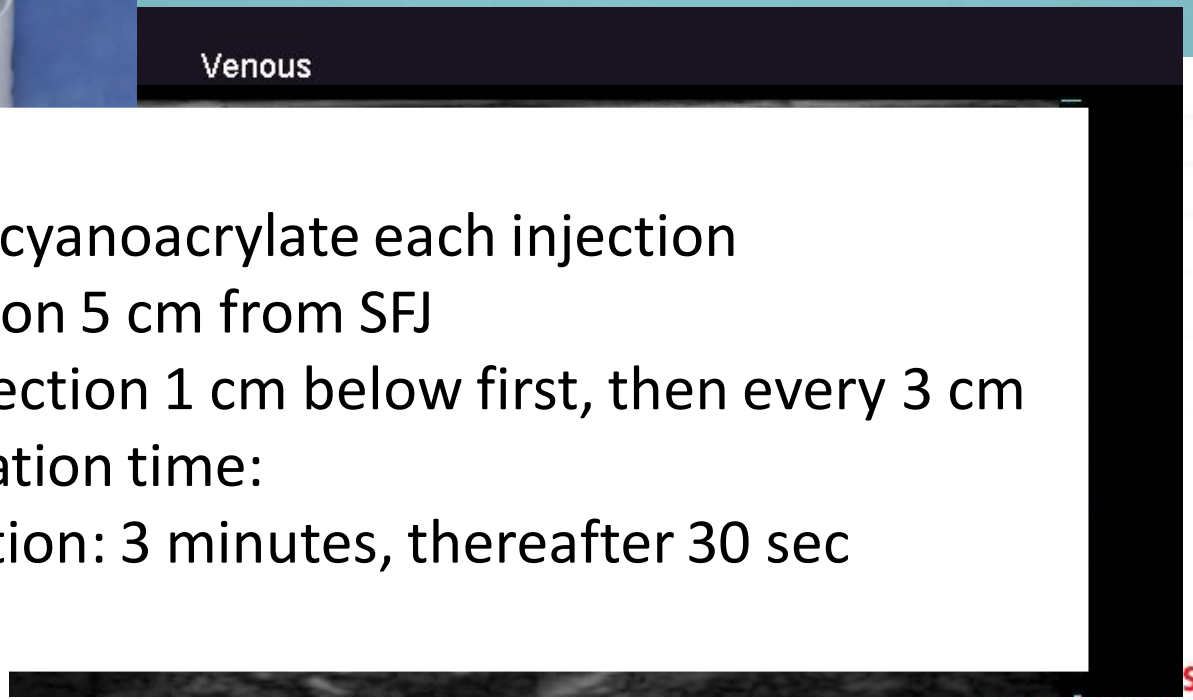
based on Cyanoacrylate Adhesive

Requiring

- no tumescent anesthesia
- no routine postinterventional compression
- causing no postprocedural paresthesia

Methods





- 0.09 ml of cyanoacrylate each injection
- first injection 5 cm from SFJ
- second injection 1 cm below first, then every 3 cm
- polymerization time:
  inital injection: 3 minutes, thereafter 30 sec

study charateristics

- Enrollment from Dec 2011 to Jul 2012
- 7 sites involved – total N=70 patients
  - Thomas Proebstle, Germany n = 20
  - Jens Alm, Germany n = 15
  - Sameh Dimitri, UK n = 11
  - Lars Rasmussen, Denmark n = 10
  - Mark Whiteley, UK n = 7
  - James Lawson, Netherlands n = 4
  - Alun Davis, UK n = 3

Adjunctive Procedures Performed (Phlebectomy and Sclerotherapy)

Procedure Performed	Number of Subjects	Number of Procedures
24-72 hours	0/70 (0%)	0
Day 30	0/70 (0%)	0
Month 3	2/70 (2.9%)	2
Month 6	23/70 (32.9%)	28
Month 12	13/68 (19.1%)	16
Month 24		
Month 36		

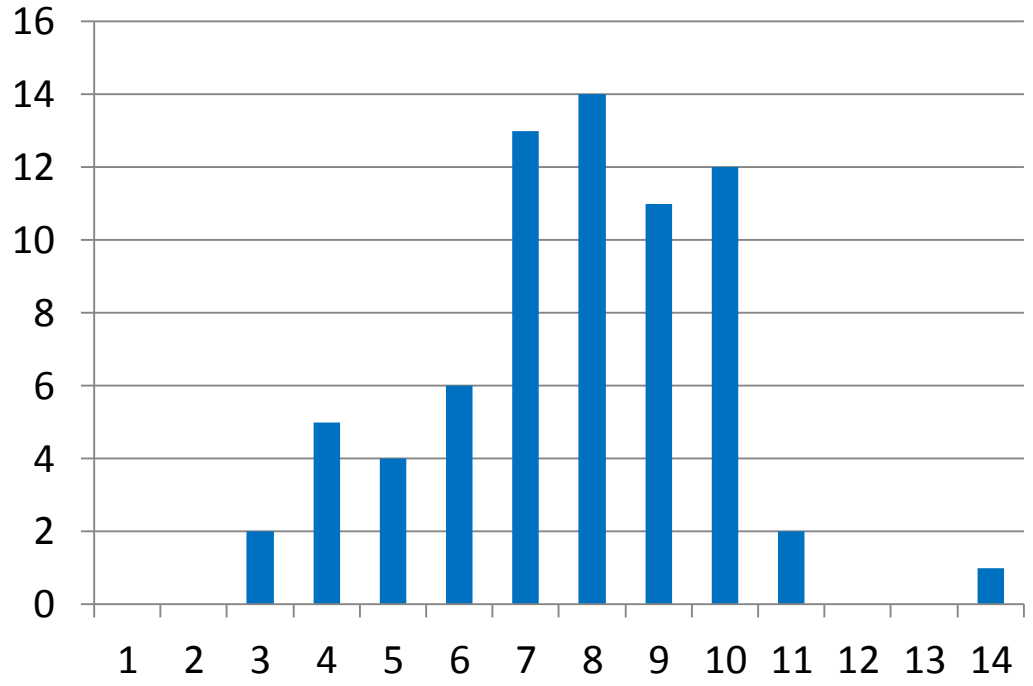
Notes: Includes procedures on either limb.
Data Source: eSCOPE Table 20.1 (April 24, 2014)

Protocol did not allow adjunctive procedures until after Month 3 visit.

patient characteristics

- age — median 48y [range 22 - 72]
- BMI — median 26.0 [range 18.9 – 39.0]

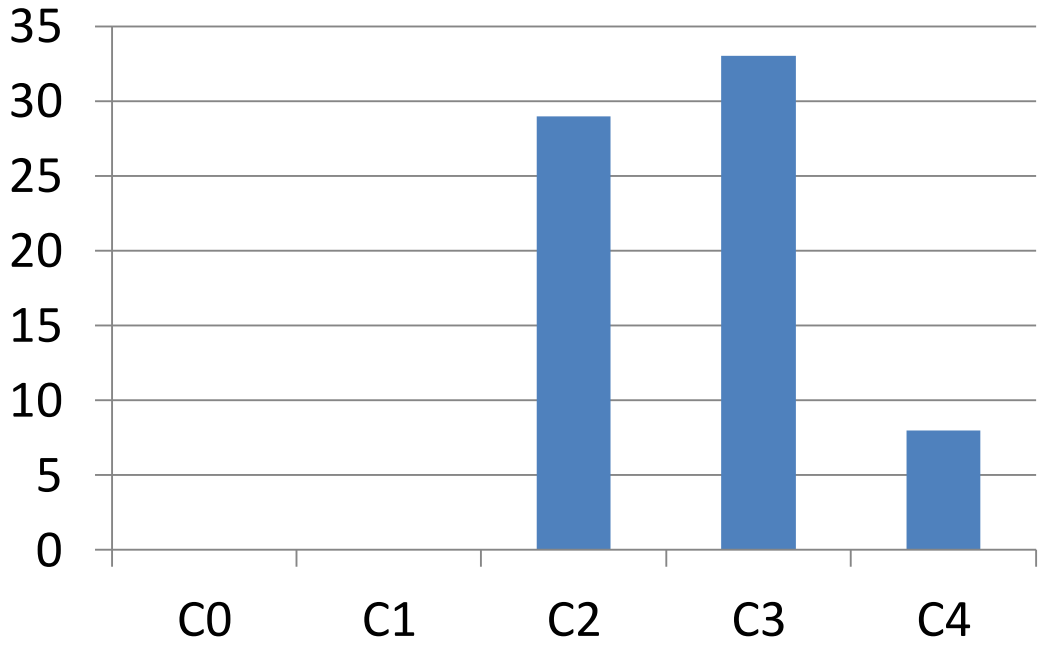
- Max GSV diameter
  median 8.0 mm
  [range 2.5 – 14]



patient characteristics

CEAP baseline

- C2 n = 29
- C3 n = 33
- C4 n = 8

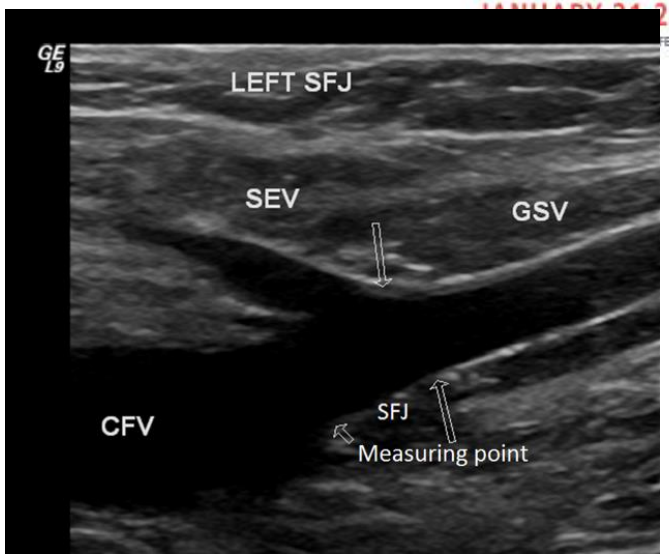


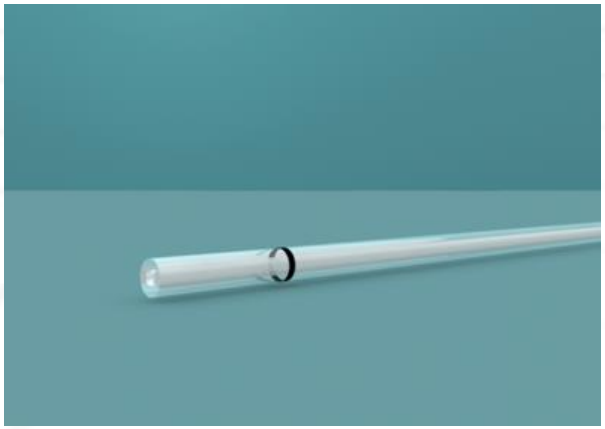
Results

Median GSV length treated
38 cm [range 7-72]

Median CA volume delivered
1.3 ml [range 0.4 - 2.2]

corresponding
to a median number of
injections of
N = 14 [range 4 - 24]





Results

All 70 patients treated technically successful (100%)

N = 64 patients (91%) were available for 36 months FU

N = 8 recanalizations - all partial, all originating from SFJ, apart from one distal recanalization

48h	n = 2
3 months	n = 2
6 months	n = 1
12months	n = 1
24months	n = 2

until 36 months follow-up stable,

no impact on clinical symptoms

Figure 1 Kaplan Meier Curve for Freedom from Recanalization

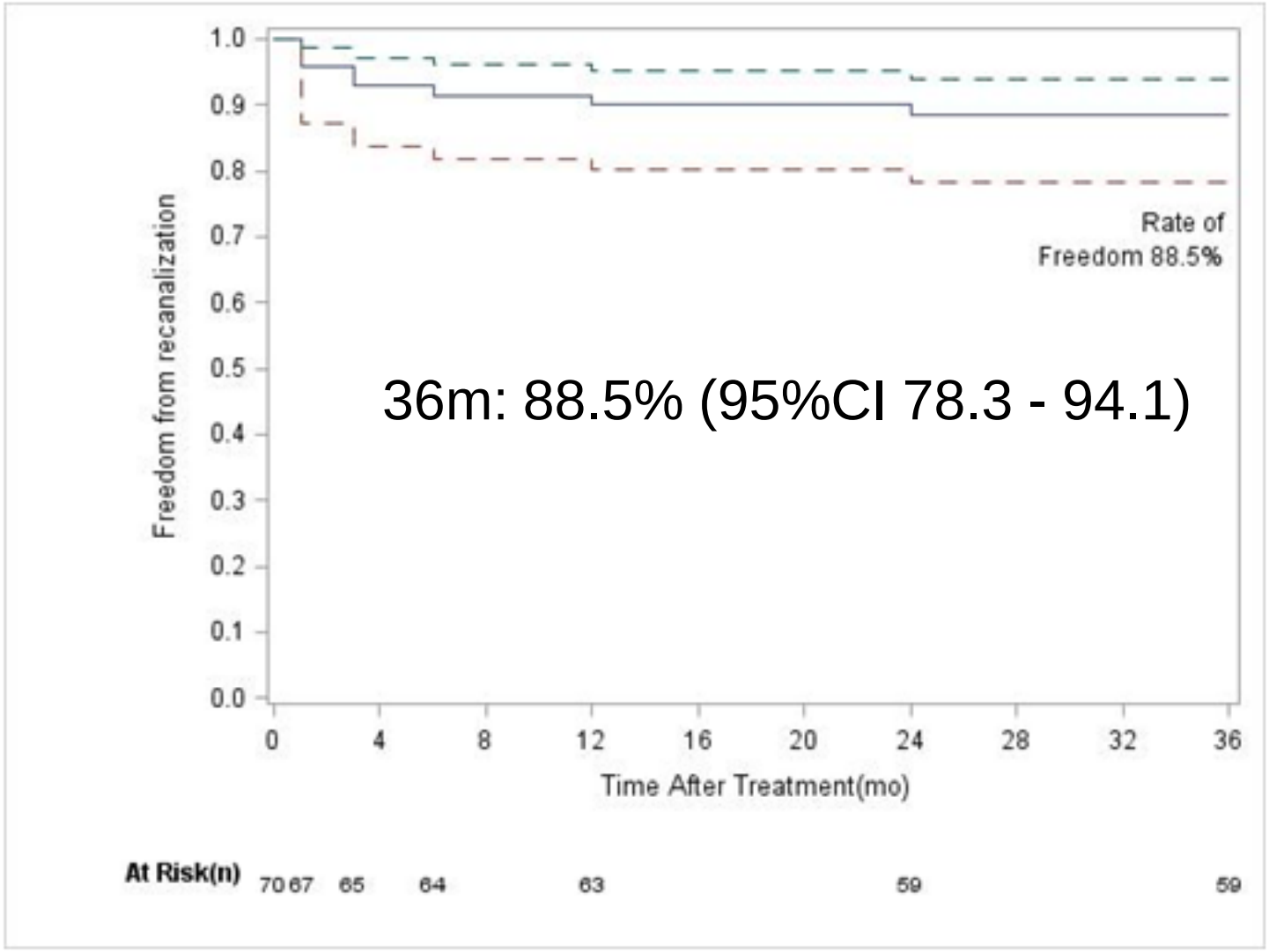


Figure 2 VCSS Score

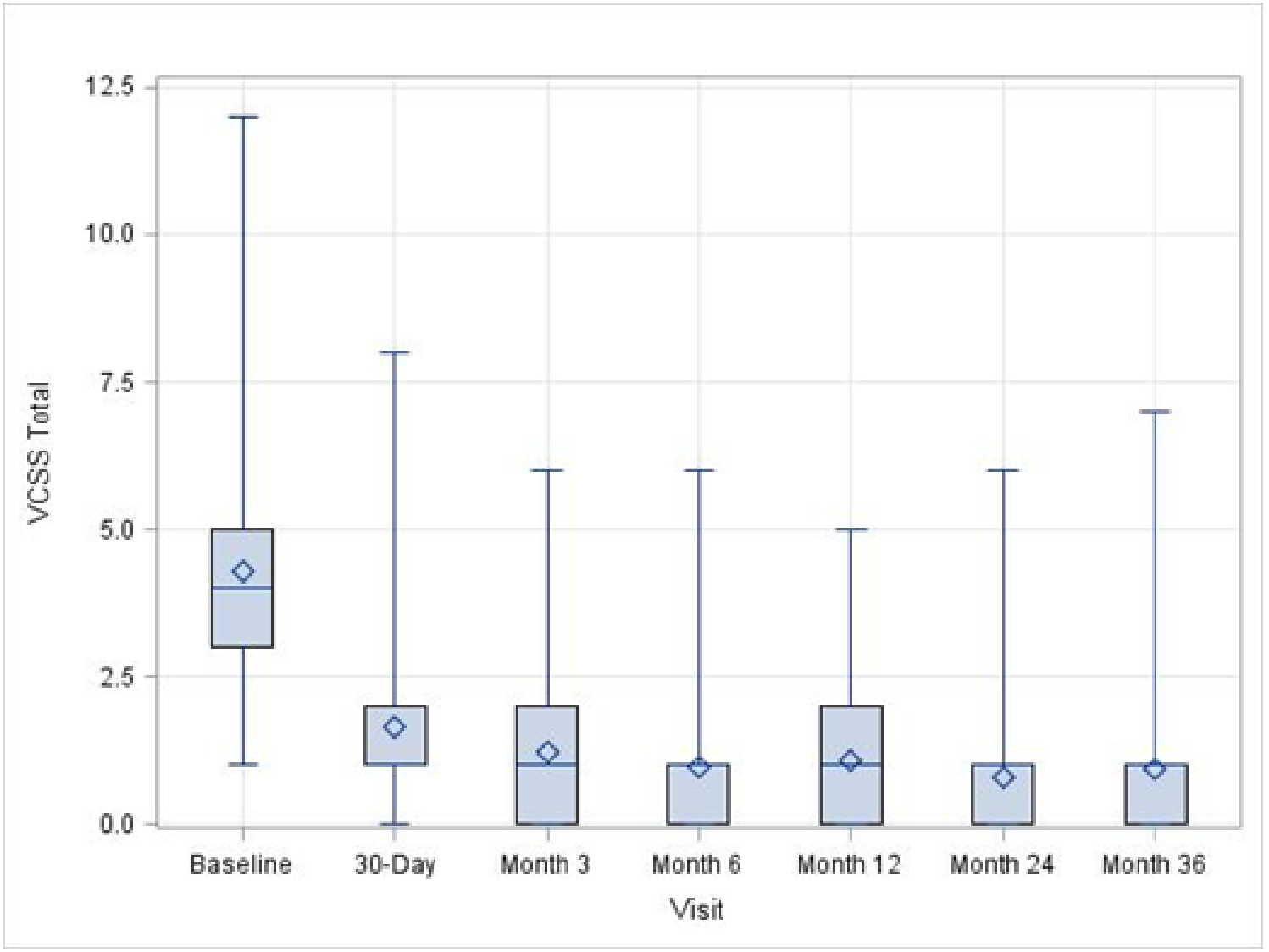
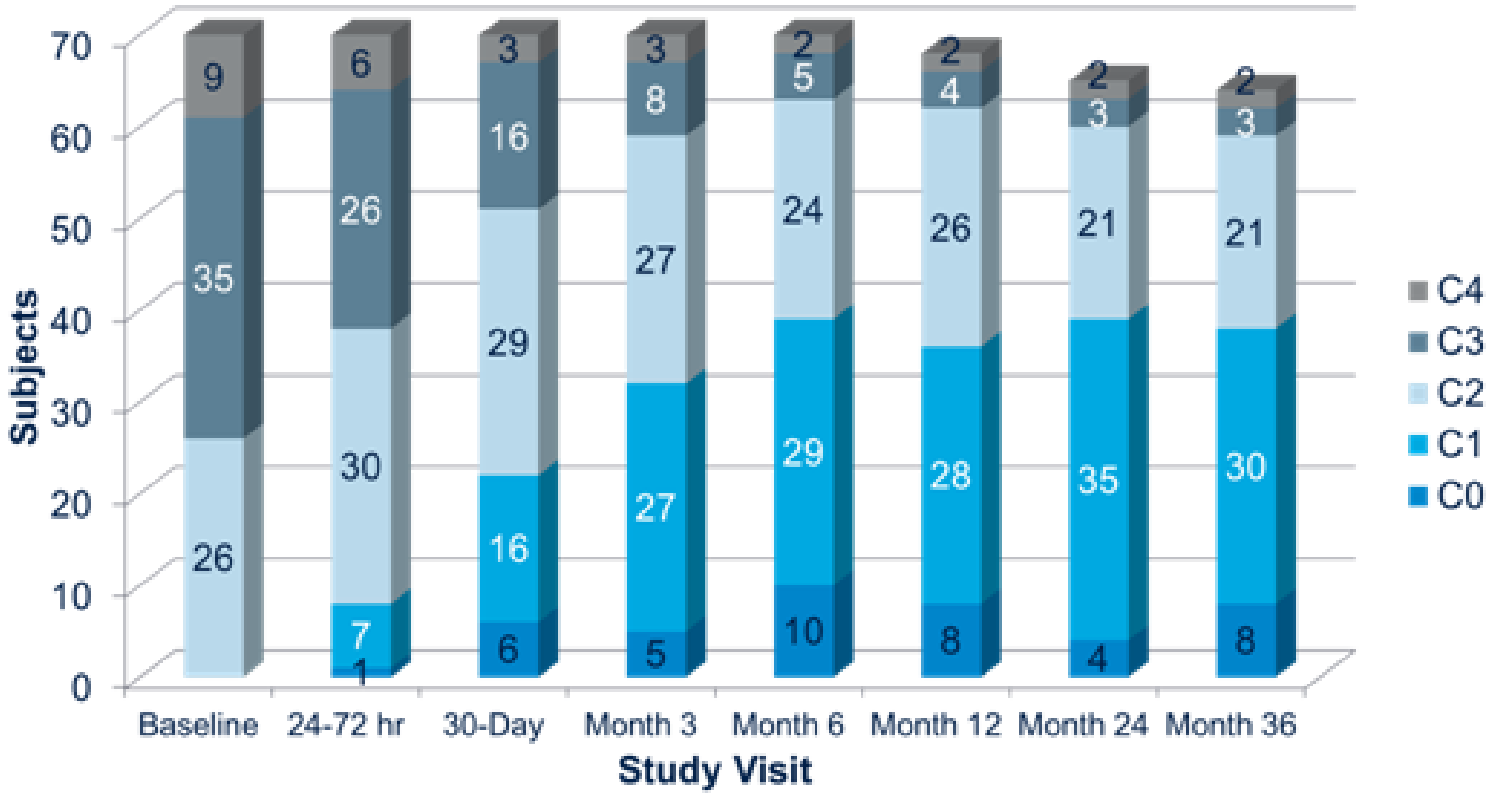


Figure 4 CEAP Scores



Adverse Events by Coding Dictionary

Coded Term	ALL
Number of Subjects	70
Access site infection	1 (1.4%)
Hyperpigmentation	0 (0%)
Other (not target limb/procedure associated)	7 (10.0%)
Paresthesia in the treatment zone	0 (0%)
Phlebitis in both treatment and non-treatment zones	9 (12.9%)

Journal of
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Venous and Lymphatic Disorders℠

CLINICAL RESEARCH STUDIES

From the American Venous Forum

The European multicenter cohort study on cyanoacrylate embolization of refluxing great saphenous veins

Thomas Michael Proebstle, MD,[a] Jens Alm, MD,[b] Sameh Dimitri, MD,[c] Lars Rasmussen, MD,[d] Mark Whiteley, MS, FRCS (Gen),[e] James Lawson, MD,[f] Daniel Cher, MD,[g] and Alun Davies, MA, DM, FRCS, FEBVS,[h] *Mainz and Hamburg, Germany; Chester, Guildford, and London, United Kingdom; Naestved, Denmark; Alkmaar, The Netherlands; and Palo Alto, Calif*

Objective: Cyanoacrylate (CA) embolization of refluxing great saphenous veins (GSVs) has been previously described. The outcomes from a multicenter study are still lacking.
Methods: A prospective multicenter study was conducted in seven centers in four European countries to abolish GSV reflux by endovenous CA embolization. Neither tumescent anesthesia nor postinterventional compression stockings were used. Varicose tributaries remained untreated until at least 3 months after the index treatment. Clinical examination, quality of life assessment, and duplex ultrasound evaluation were performed at 2 days and after 1, 3, 6, and 12 months.
Results: In 70 patients, of whom 68 (97.1%) were available for 12-month follow-up, 70 GSVs were treated. Two-day follow-up showed one proximal and one distal partial recanalization. Three additional proximal recanalizations were observed at 3-month (n = 2) and 6-month (n = 1) follow-up. Cumulative 12-month survival free from recanalization was 92.9% (95% confidence interval, 87.0%-99.1%). Mean (standard deviation) Venous Clinical Severity Score improved from 4.3 ± 2.3 at baseline to 1.1 ± 1.3 at 12 months. Aberdeen Varicose Vein Questionnaire score showed an improvement from 16.3 at baseline to 6.7 at 12 months ($P < .0001$). Side effects were generally mild; a phlebitic reaction occurred in eight cases (11.4%) with a median duration of 6.5 days (range, 2-12 days). Pain without a phlebitic reaction was observed in five patients (8.6%) for a median duration of 1 day (range, 0 - 12 days). No serious adverse event occurred. Paresthesia was not observed.
Conclusions: Endovenous CA embolization of refluxing GSVs is safe and effective without the use of tumescent anesthesia or compression stockings. (J Vasc Surg: Venous and Lym Dis 2015;3:2-7.)

Conclusion

Endovenous embolization with cyanoacrylate glue is an alternative treatment option for abolition of saphenous vein reflux with

- no anesthesia
- no compression stockings and
- no risk of paresthesia

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