CONTROVERSIES & UPDATES IN VASCULAR SURGERY
JANUARY 22-24 2015
MARRIOTT RIVE GAUCHE & CONFERENCE CENTER PARIS, FRANCE

Standardized microfoam for saphenous vein ablation

David Wright MB FRCS
VP Medical Affairs
BTG International Ltd

Disclosure

Speaker name: David Wright

☒ 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

Foams Are Not the Same

Polidocanol Injectable Foam (PEM)*

Engineered microfoam with consistent physical characteristics and performance

- Homogeneous
- Stable
- Coherent
- Echogenic

Safety

- Median size < 100 µm
- No bubbles > 500 µm

Gas mixture

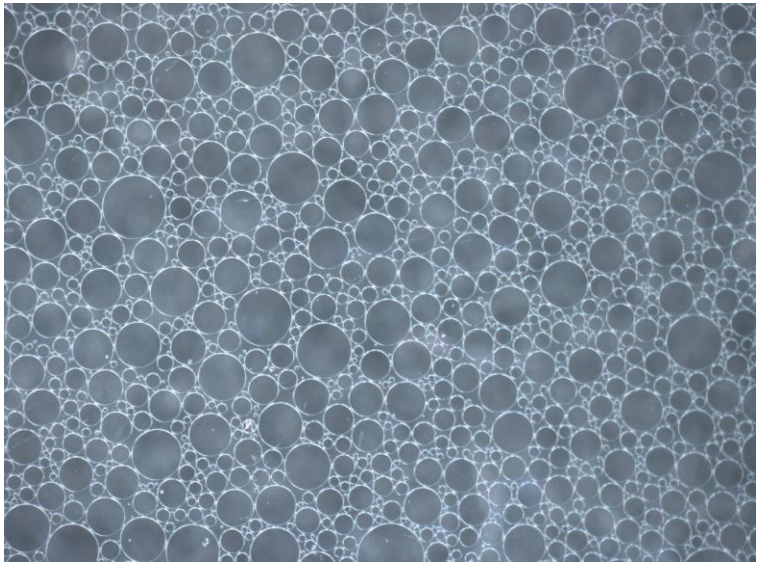
- 65% oxygen/35% carbon dioxide
- Low nitrogen content less than 0.8%

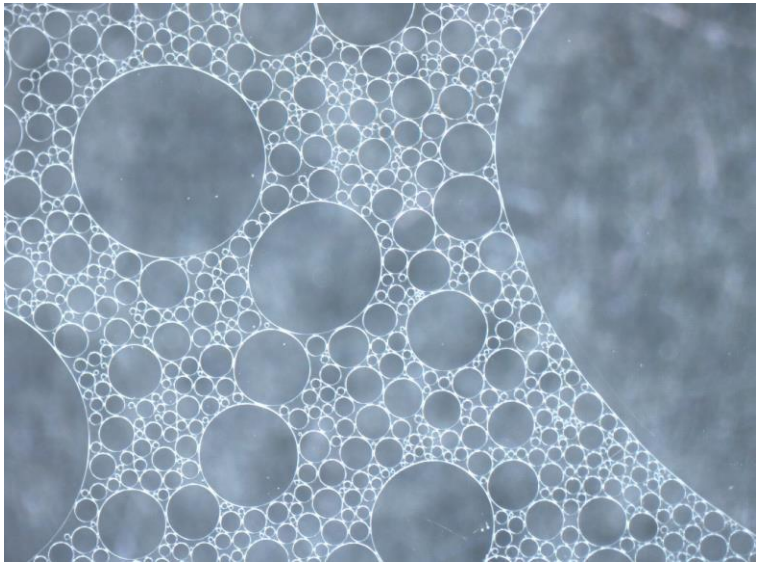
Liquid: gas ratio

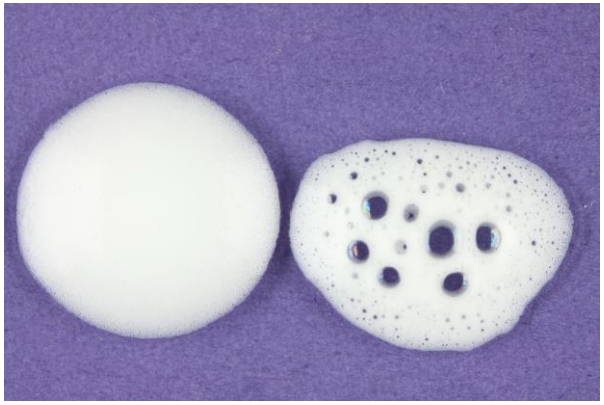
- Defined microfoam density 0.13g/mL

*Polidocanol injectable foam 1% is the generic name of Varithena® formerly known as PEM and Varisolve™. It is not approved for use in Europe.

PEM vs. Physician Compounded Foam(PCF)

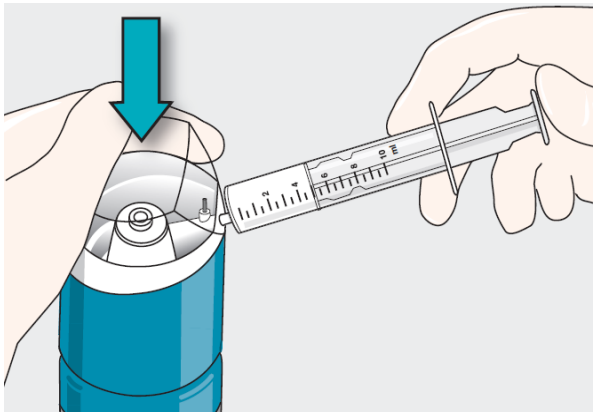




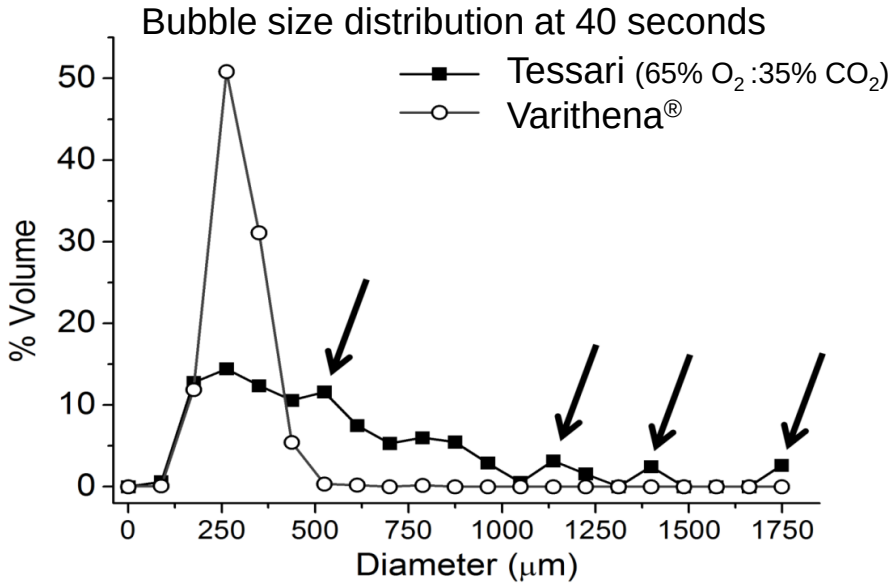


All images compare foams within approximately 10 seconds of creation. Photos of physician-compounded foam feature examples of manually created foam made 1:4 with 1% polidocanol solution and room air, Tessari technique. Because of conditions and techniques, properties of physician-compounded foams may vary. RSSL 2014

Foam bubble size and distribution



Tessari Syringe System



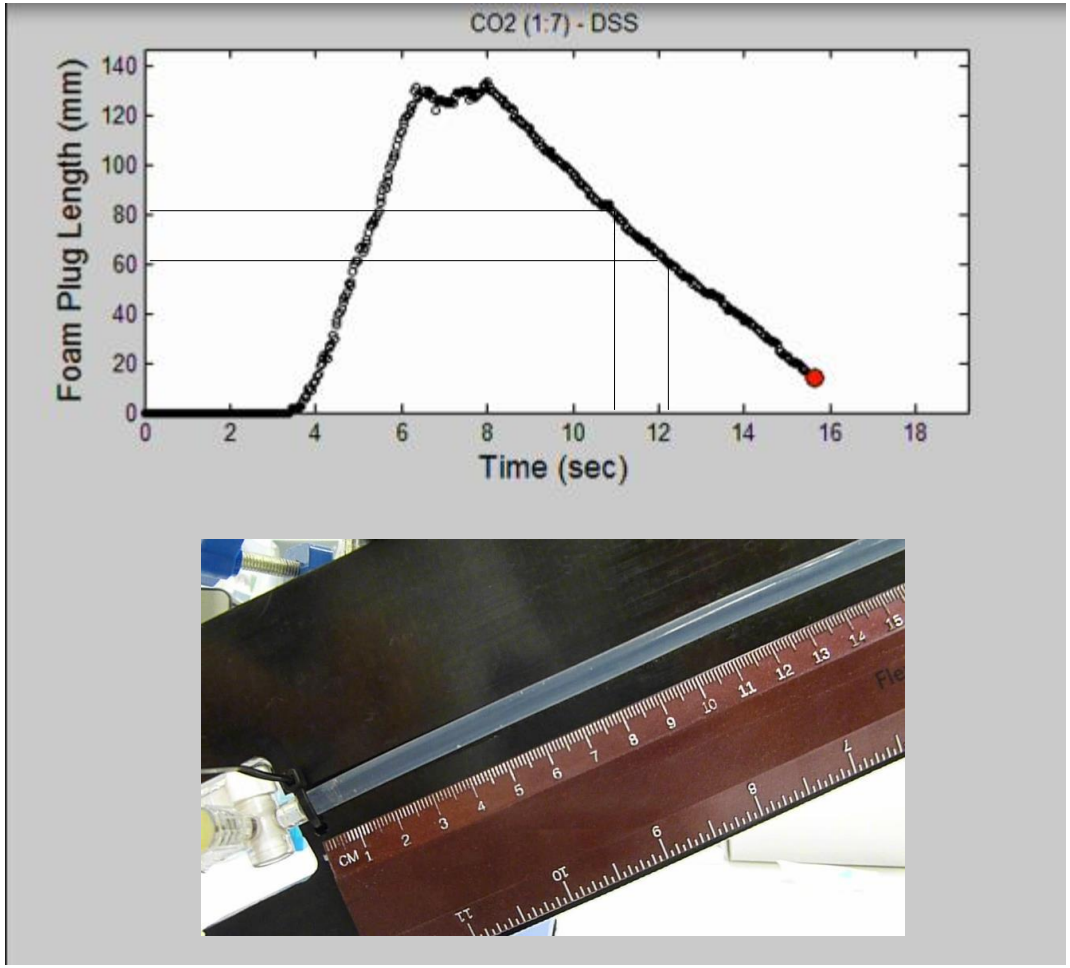
Varithena® possesses a narrow bubble size distribution with no large bubbles

PCFs made by Tessari method have broader bubble size distributions and large bubbles, which has an impact on stability and safety

– *Tessari L et al. Dermatol Surg.* ***2001*** *Jan;27(1):58-60*

BTG data on file submitted for publication
PCF = physician-compounded foam

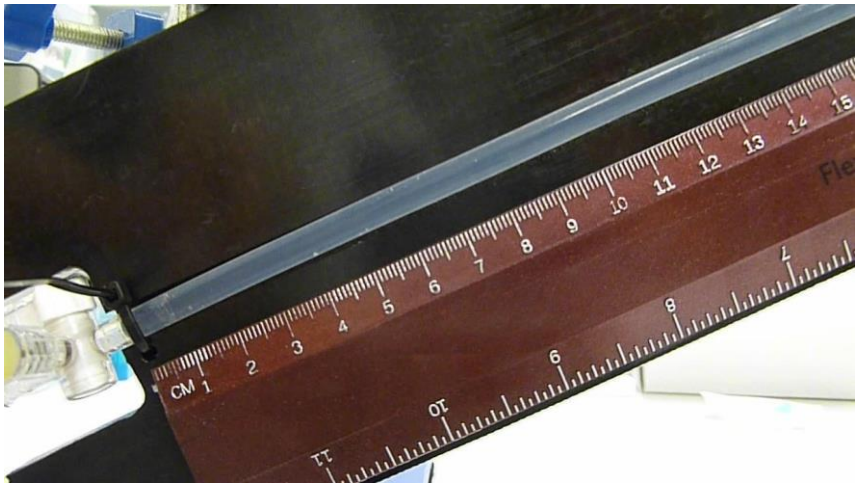
Biomimetic Model: Degradation Rate or Dwell Time



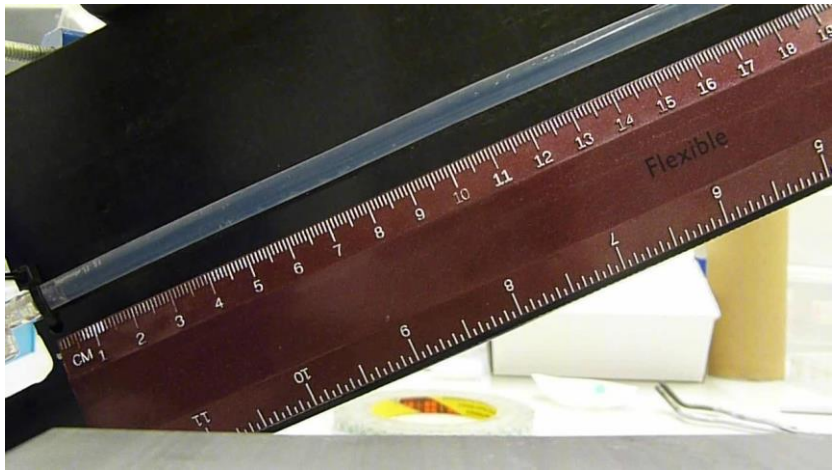
- Establish a foam plug
  - Observe the decay
  - Linear with time
  - Represents stability
- Speed of degradation inversely proportional to the contact time expressed as dwell time
- Slower degradation rate (DR) or longer dwell time, results in longer endothelial contact time

Carugo D. J Mater Sci: Mater Med,2013;24:1417-1423

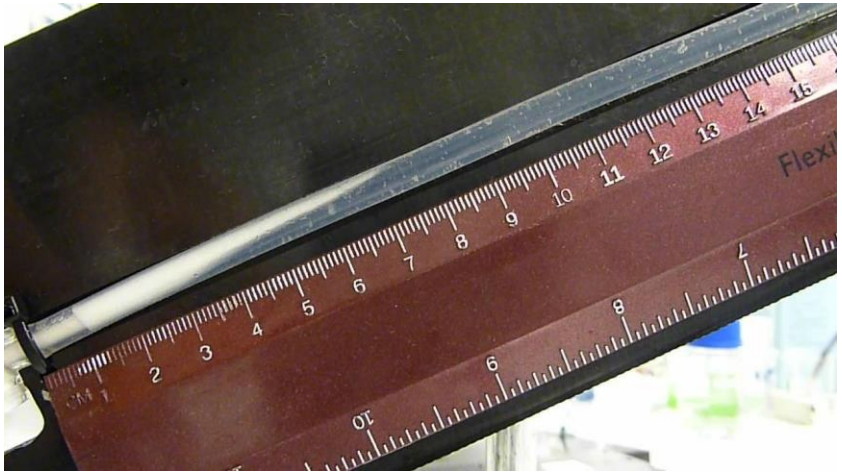
Biomimetic Model



100% CO_2

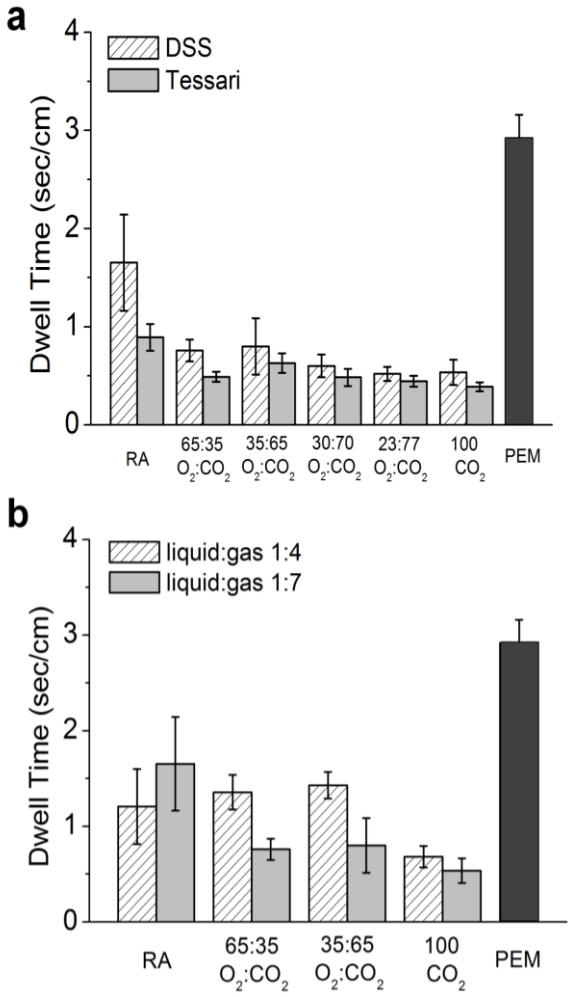


Room Air



PEM

Biomimetic Model: Dwell Time



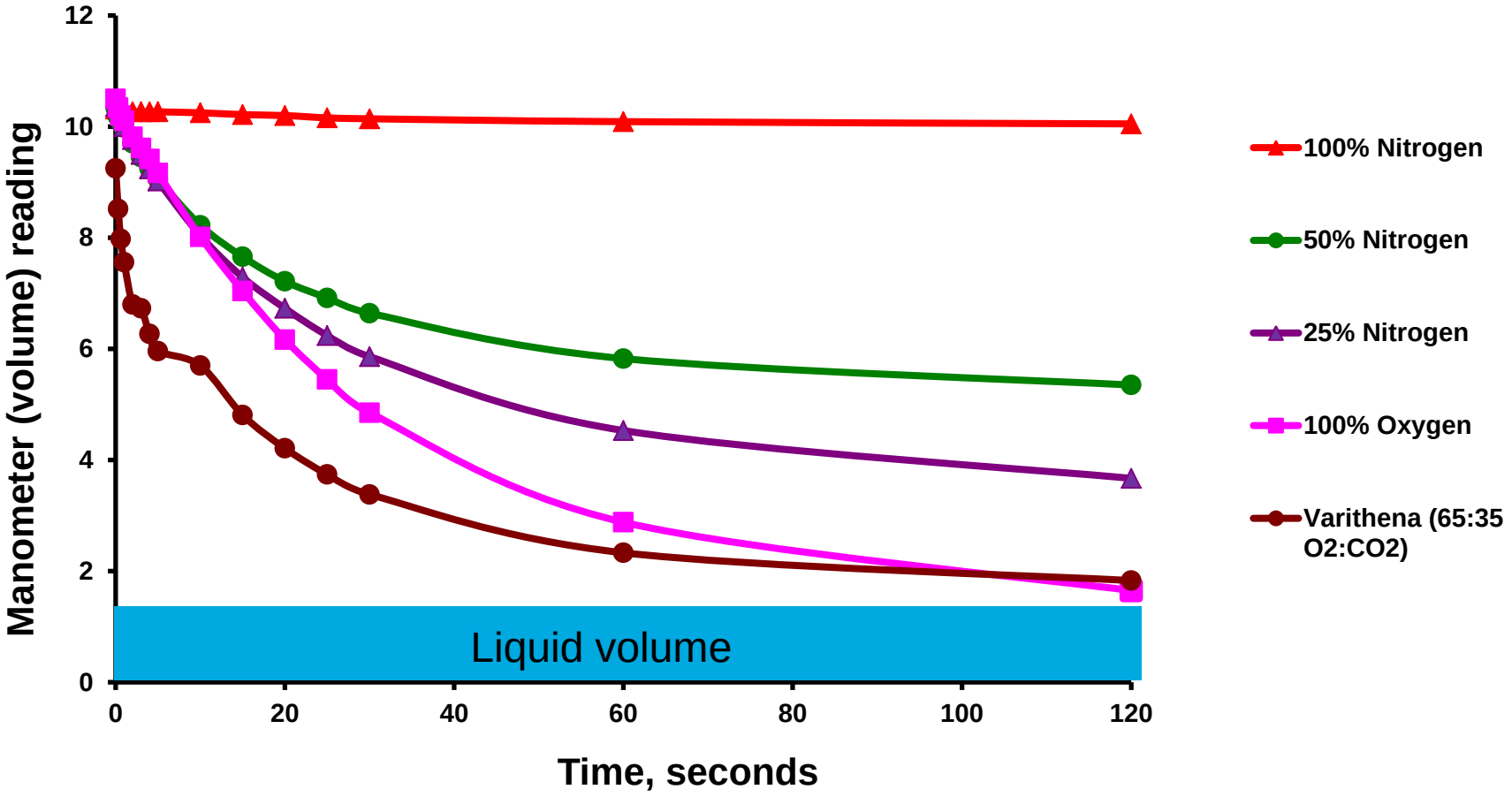
(a) PEM has the longest dwell time compared to any PCFs, including foams made using room air (RA)

(b) The same result was obtained at different liquid to gas ratios (1:4 and 1:7 liquid:gas)

100% CO_2 foams were least stable in all tests performed and different O_2:CO_2 mixtures had intermediate performance

BTG data on file submitted for publication

Impact of Nitrogen on Gas Absorption



Conclusions

- Foams are not the same, impossible to compare clinical results, unless foam characteristics are known and reproducible
- Air foams have good performance but have associated risks with persistent bubbles in the circulation
- Small bubbles and narrow bubble distribution, with slow drainage and separation times, improves foam performance by enhancing stability
- PEM O_2:CO_2 low nitrogen gas composition and consistent foam generation is designed to optimize physical characteristics