



MEET 2014
MULTIDISCIPLINARY EUROPEAN
ENDOVASCULAR THERAPY

Standardized microfoam for saphenous vein ablation

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■ Faculty disclosure



I, David Wright, disclose the following financial relationships:

Employee of BTG International Ltd

BTG is the developer of polidocanol endovenous microfoam, recently approved in the US by the FDA as Varithena™

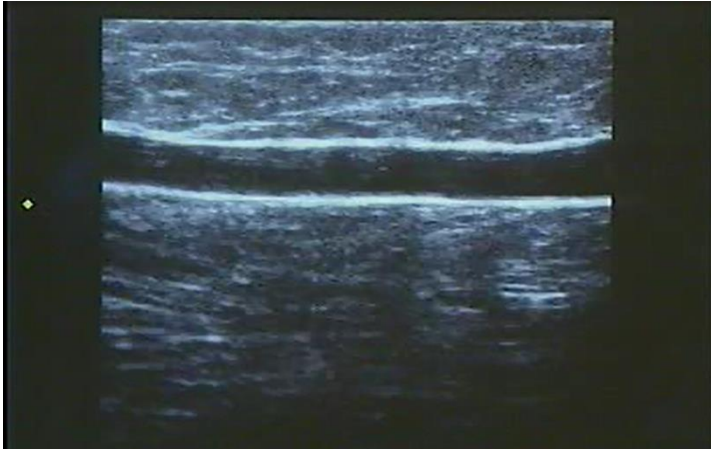
Principles of PEM treatment of the GSV

Diagnosis, consent and marking

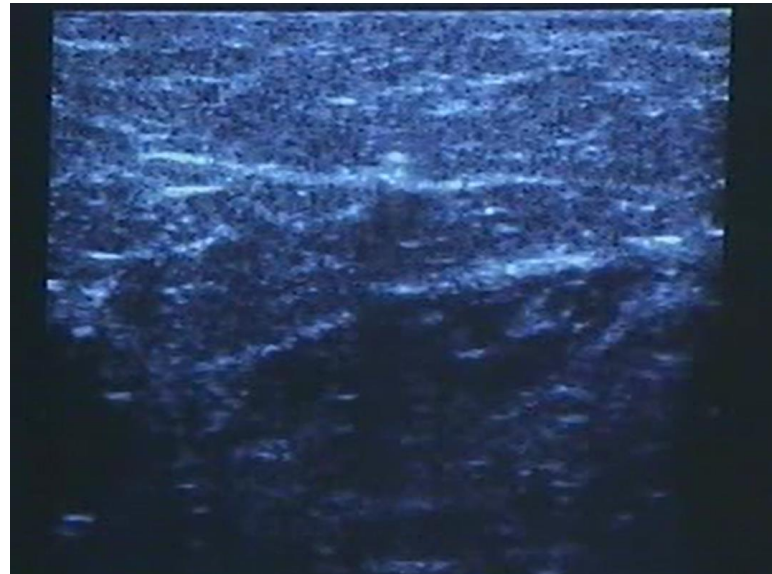


- Duplex ultrasound assessment
 - Deep and all superficial veins
- Plan
 - Agree the plan with the patient
- Pre-procedure
 - Marking to include all veins to be treated

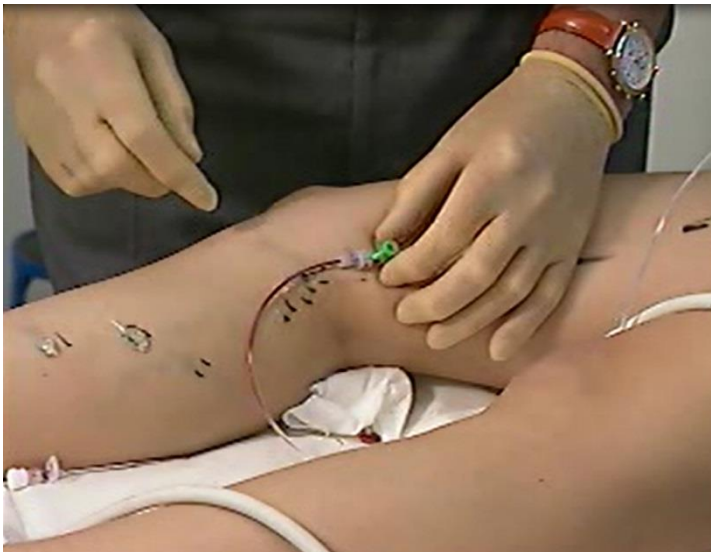
Obtain Venous Access



Choose your spot

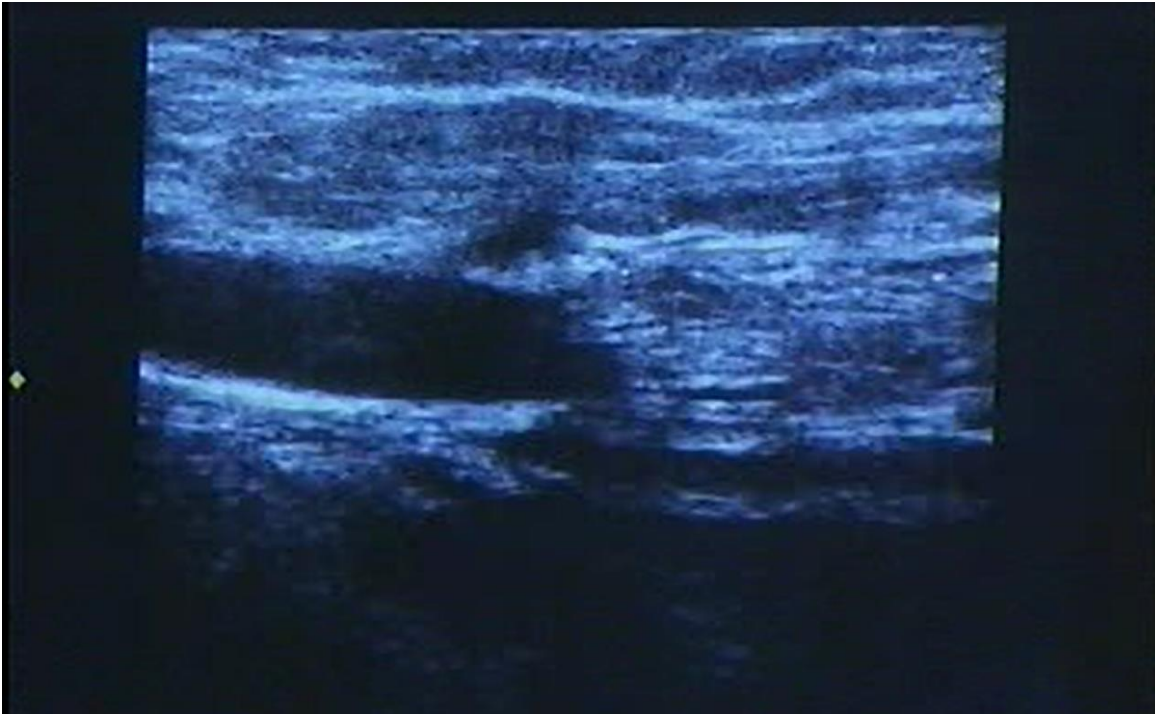


Accurate
vein
targeting



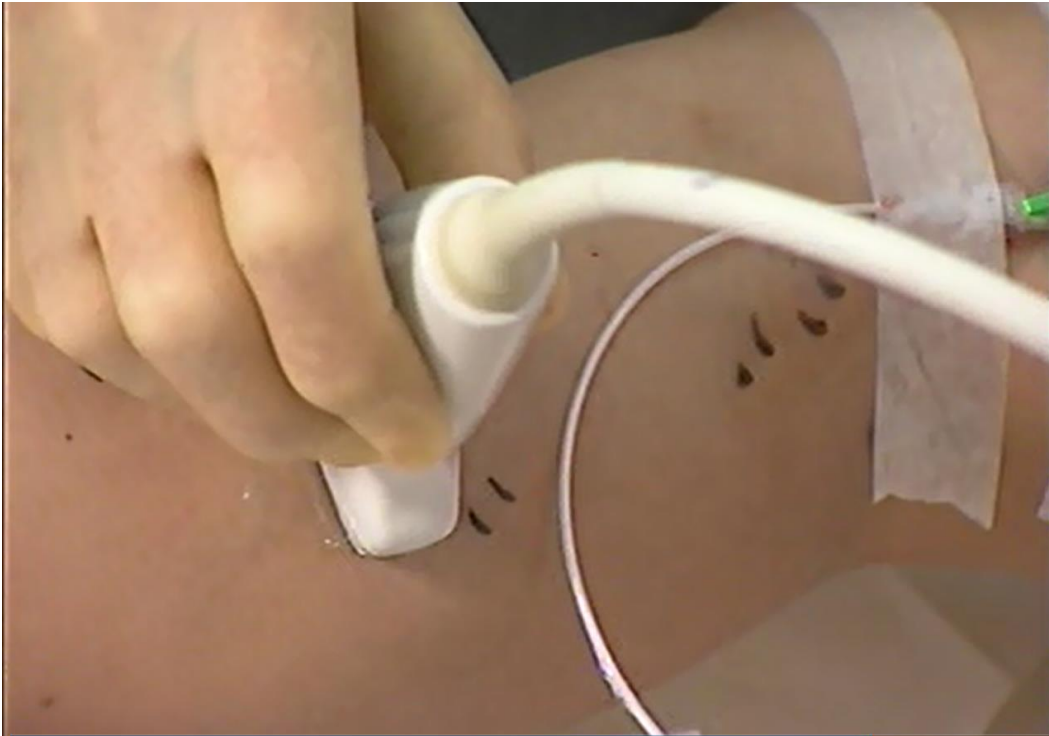
Prove venous access

Injection of Foam to Fill the Trunk Vein



- Fill the GSV or accessory vein towards the SFJ junction
- Stop 3-5 cm before the deep to superficial vein junction
- Compress the junction to stop flow of foam into the deep veins

Treatment of Superficial Varicosities



- From the trunk vein access
- Direct needle stick
- Butterfly needle

Post-Procedure Care



- First 48 hours, eccentric compression over treated superficial varices and trunk vein
- Limited stretch bandage
- Compression stockings
- Continue stockings - 2 weeks
- Avoid strenuous for first week

- Regular walking, 10 mins daily for 1 month
- Avoid inactivity, long car or plane journeys for one month
- Ultrasound check at 7 days
- Look for vein closure and thrombus
- Evacuate retained thrombus



Foams Are Not the Same

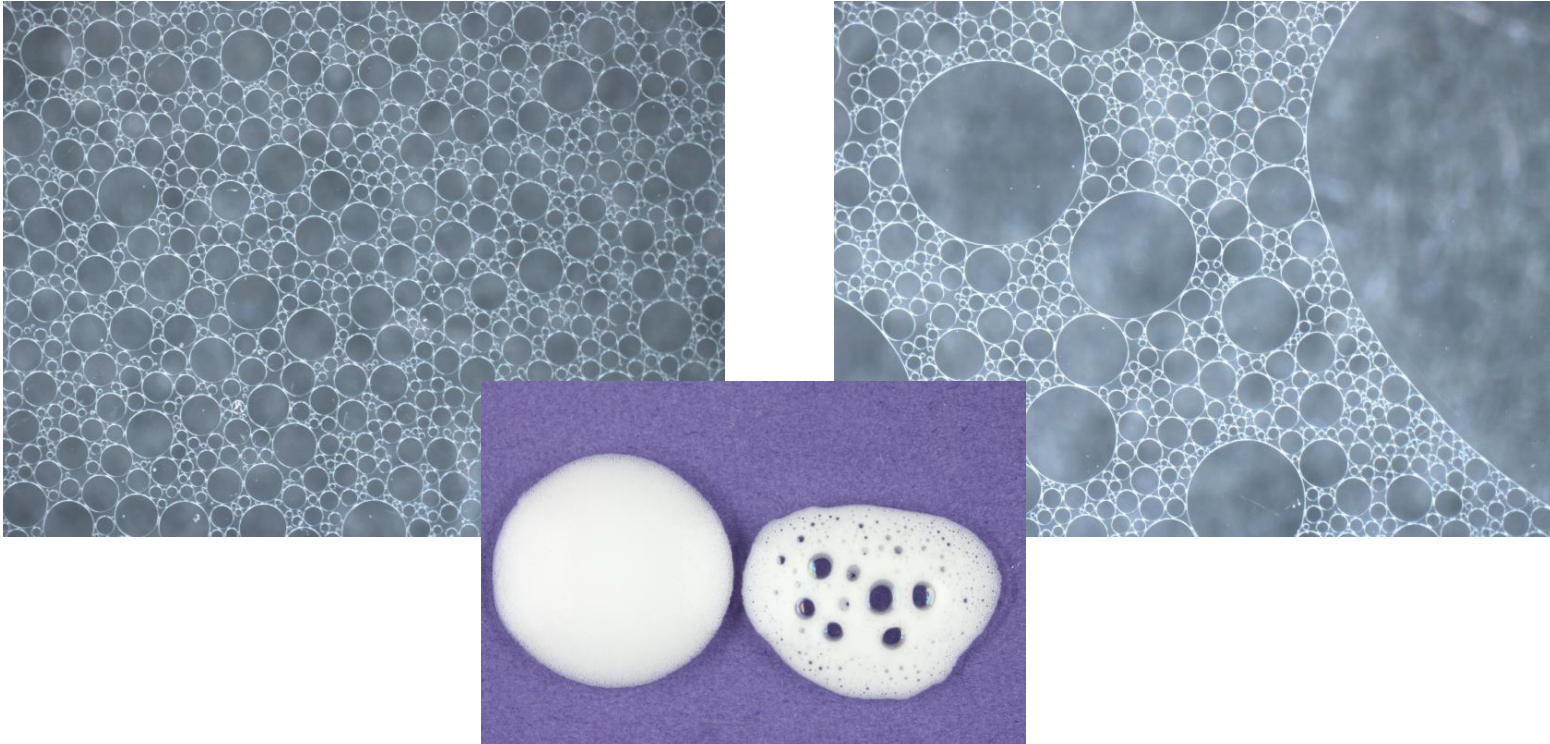


■ Polidocanol Endovenous Microfoam

- 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

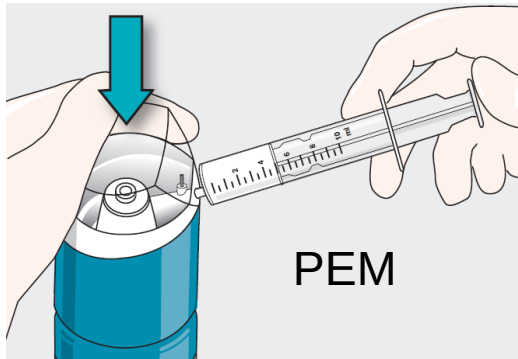


PEM vs. Physician-compounded Foam

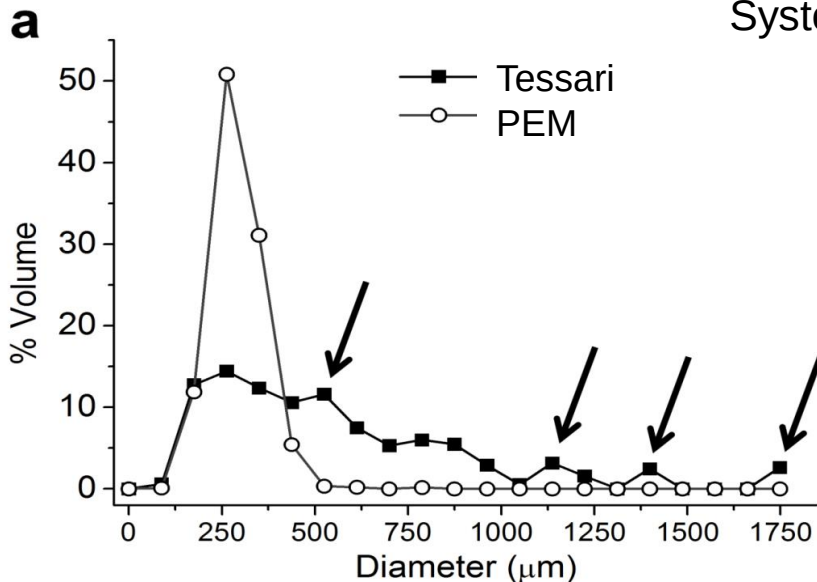


All images compare foams within approximately 10 seconds of creation. Photos of physician-compounded foam feature examples of manually created foam made 1:4 with 1% polidocanol solution and room air, Tessari technique. Because of conditions and techniques, properties of physician-compounded foams may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

Foam Bubble Size and Distribution at 40 seconds



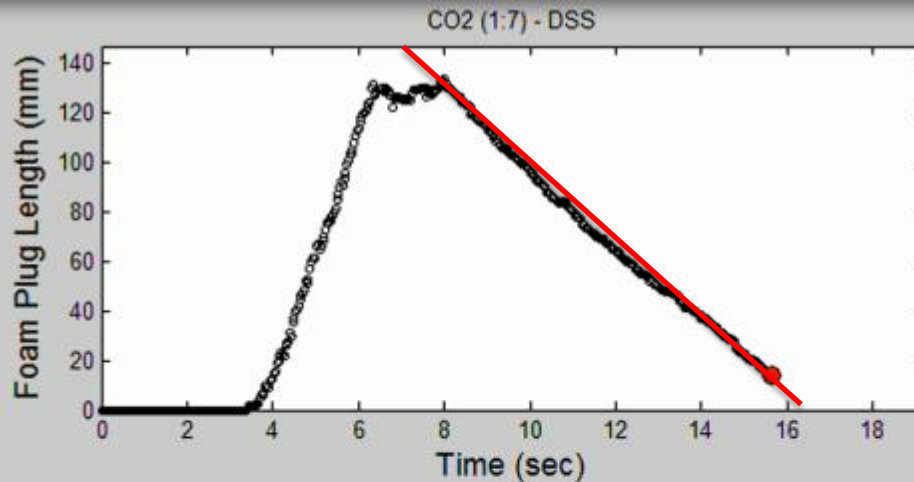
Tessari Syringe System



- PEM possesses a narrow bubble size distribution with no large bubbles
- PCFs made by Tessari have broader bubble size distributions and large bubbles, which has an impact on stability and safety

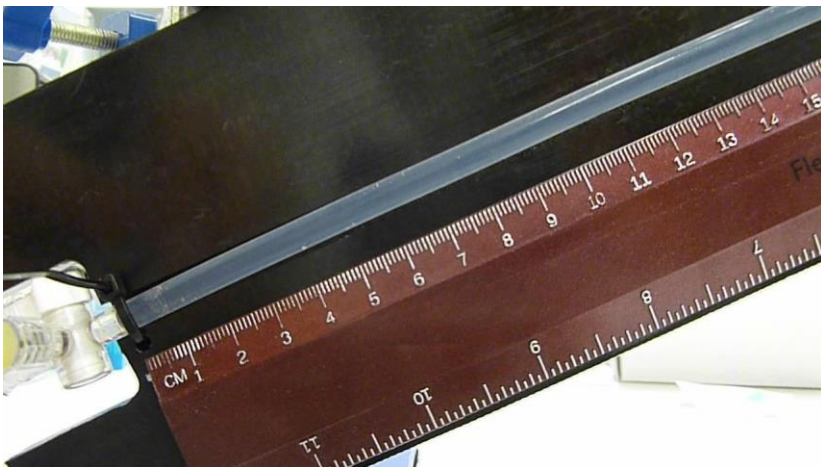
BTG data on file

Biomimetic Model: Degradation Rate

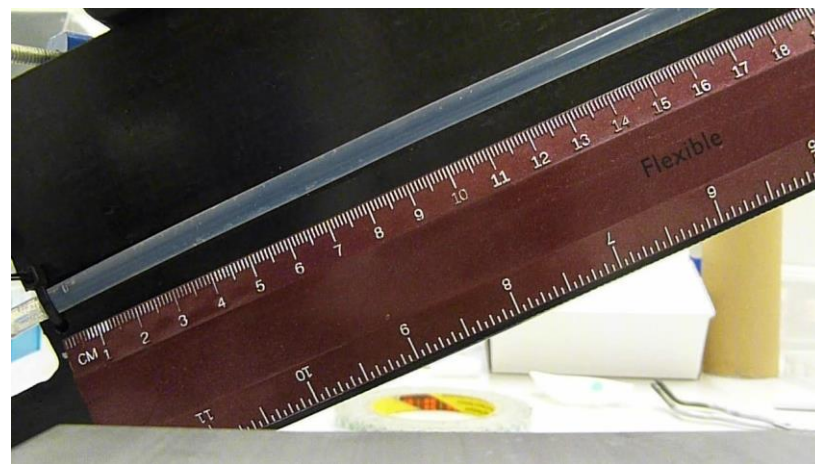


- Establish a foam plug
 - Observe the decay
 - Linear with time
 - Represents stability
- Speed of degradation inversely proportional to the contact time
- Slower degradation rate (DR) equals better foam

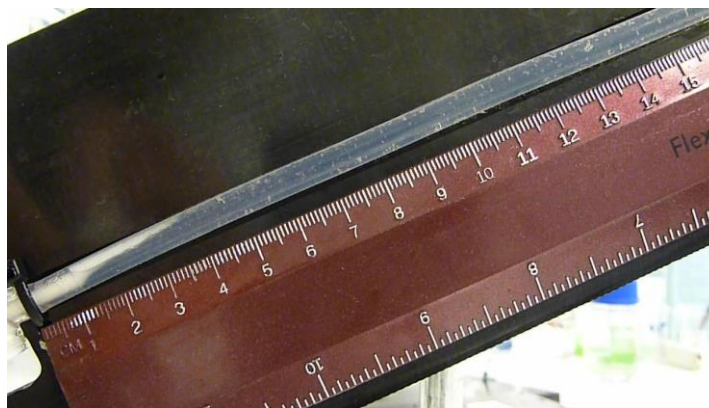
Biomimetic Model



100% CO₂

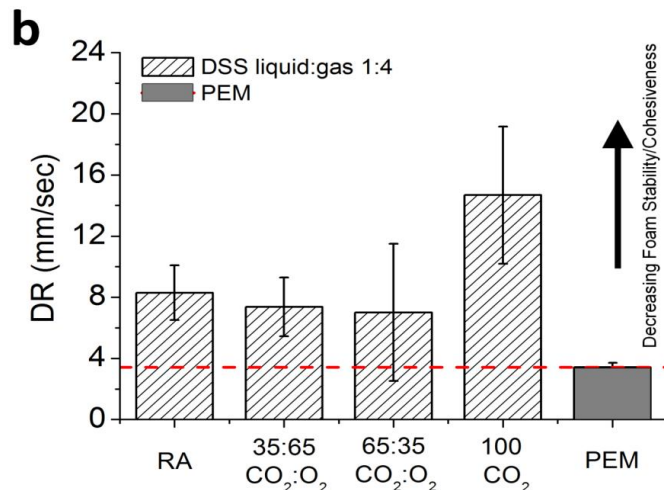
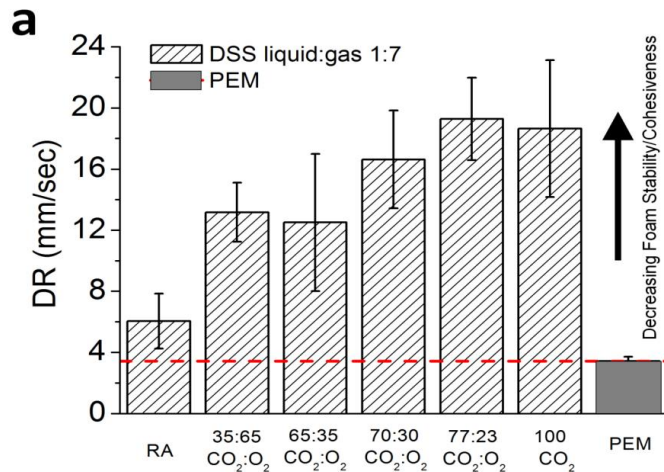


Room Air



PEM

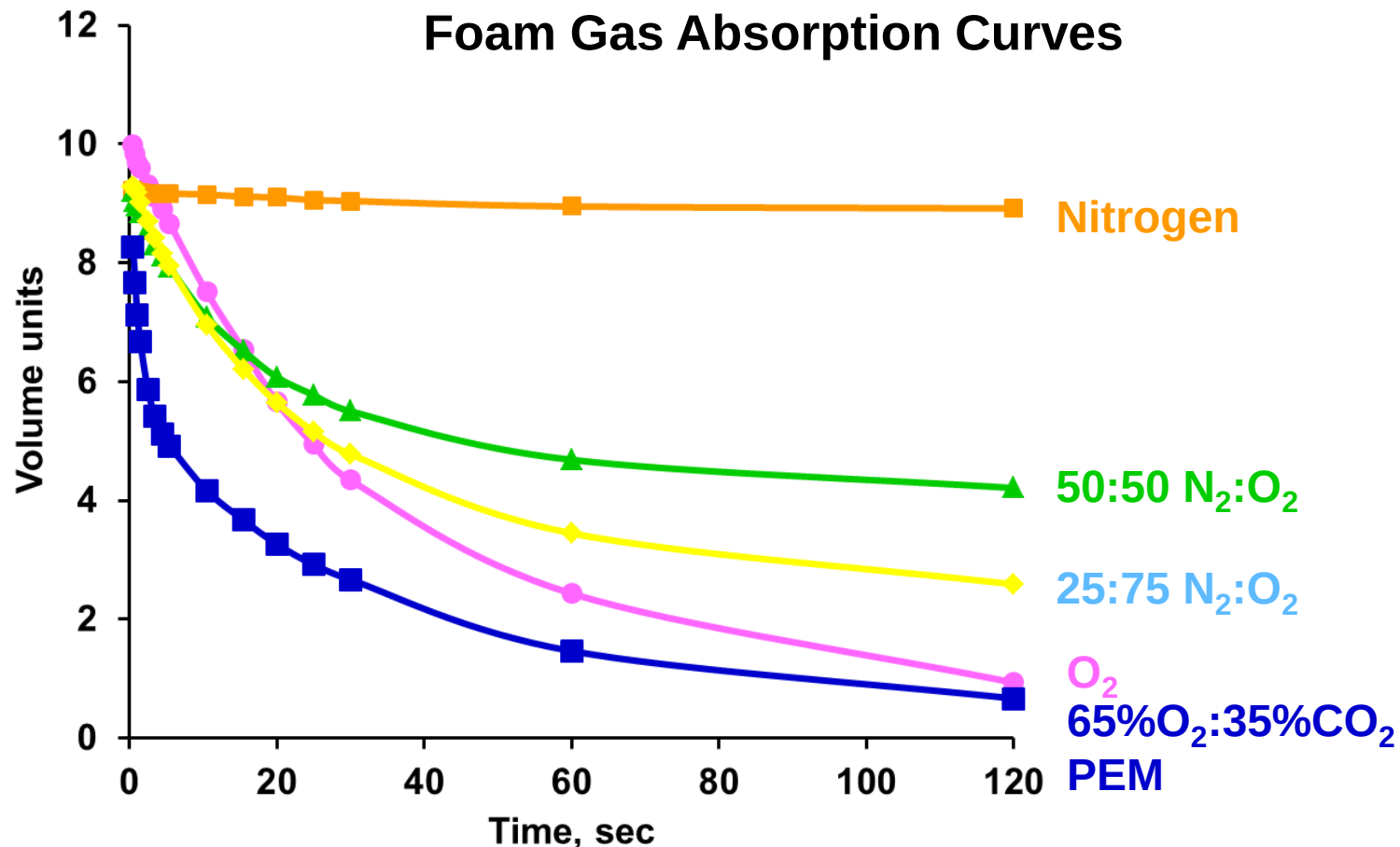
Biomimetic Model: Degradation Rates



- (a) PEM has the lowest DR compared to any PCFs, including foams made using room air (RA) ($p < 0.035$)
- (b) The same result was obtained at different liquid to gas ratios (1:4 and 1:7 liquid:gas)
- 100% CO₂ foams were least stable in all tests performed and different CO₂:O₂ mixtures had intermediate performance

DSS= Double syringe system

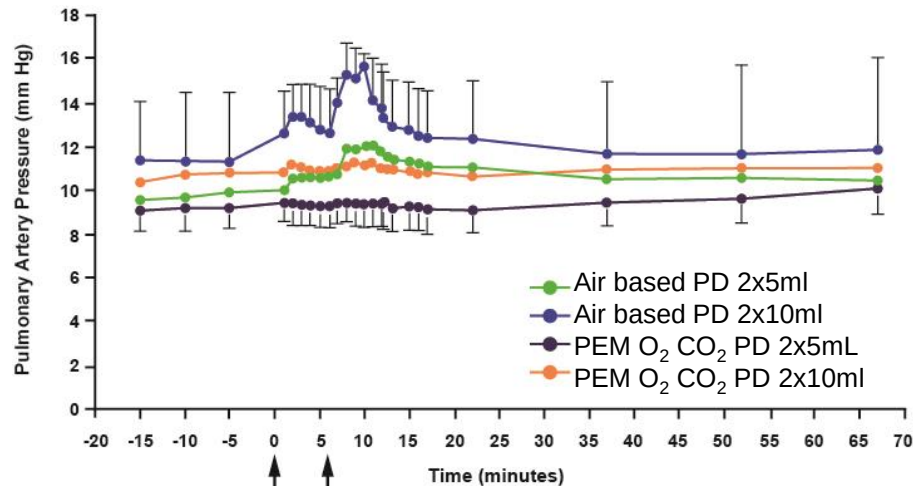
Impact of Nitrogen on Gas Absorption Rates



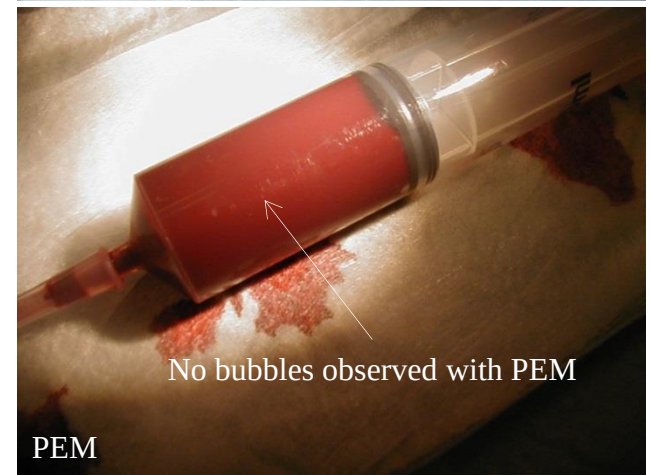
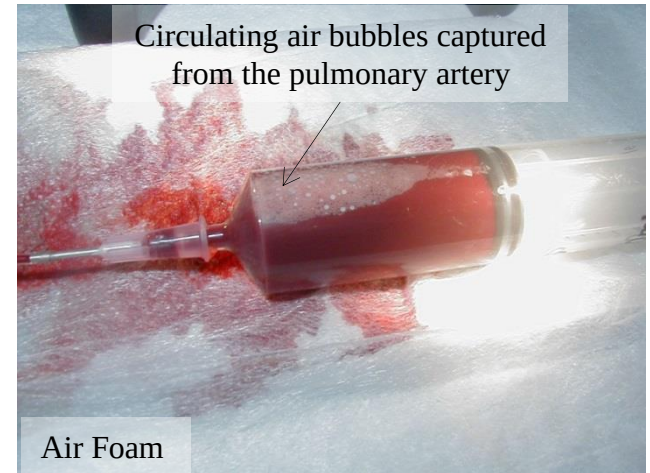
Air = More Stable Foam

Persistence of Bubbles = Reduced Safety

- Air foam or PEM, 2 injections into the saphenous vein of dog 5 mins apart
- 50% increase in pulmonary artery pressure with air foam
- Persistent bubbles in the pulmonary artery with air foam



Test agents infused at 0 start and 6 minutes (arrows). Values given as mean±SD. For clarity, SD not shown for air-based PD foam (2 x 5 ml) and Varithena™ (2 x 10 ml). PD signifies 1% polidocanol solution.



Butler dog studies. BTG, data on file

Conclusions

- Foams are not the same, impossible to compare clinical results unless 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 O₂:CO₂ low nitrogen gas composition and consistent foam generation is designed to optimize physical characteristics