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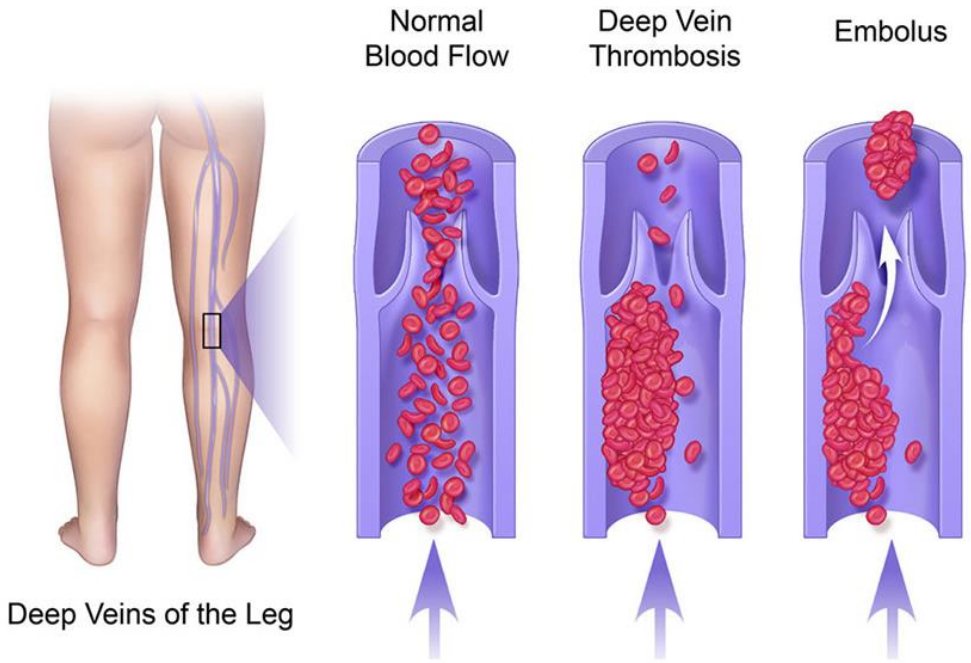
Simulation of Deep Vein Thrombosis in Healthy Subjects by Inducing Vein Stenosis via External Pressure

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Deep vein thrombosis

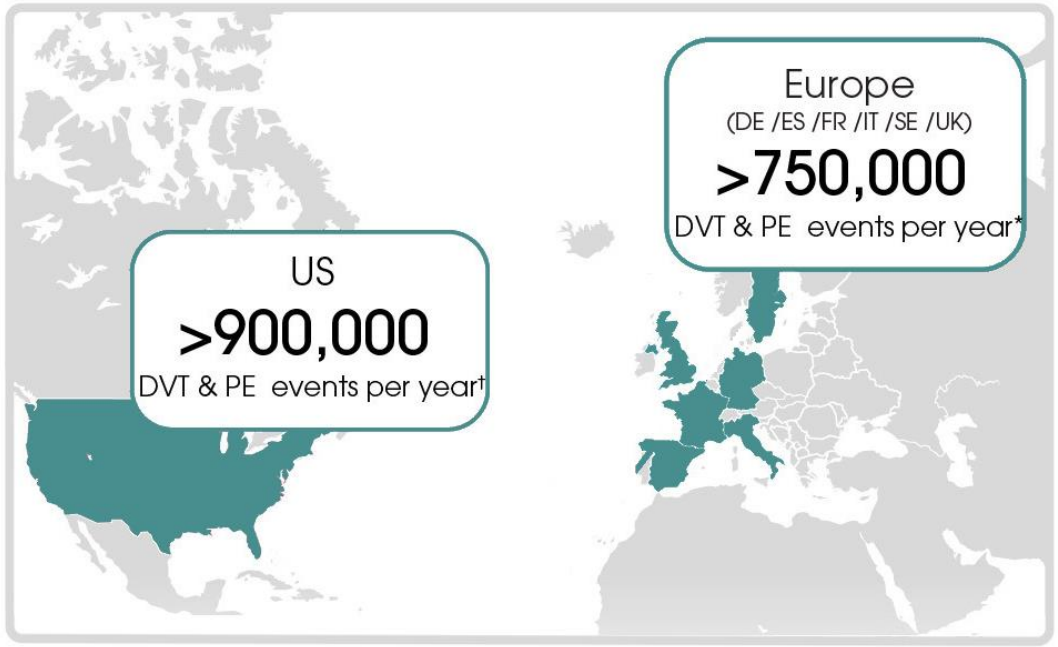
- The formation of venous thrombosis is understood to be influenced by **three key factors**: blood flow stasis, vein wall injury, and hypercoagulability;
- Up to **80% of blood clots** are formed in the deep veins of the legs;
- Deep vein thrombi can break away from the vein walls and reach the lungs with the bloodstream, causing **pulmonary embolism**.



Nicholson, M., Chan, N., Bhagirath, V., & Ginsberg, J. (2020). Prevention of venous thromboembolism in 2020 and beyond.

Incidence

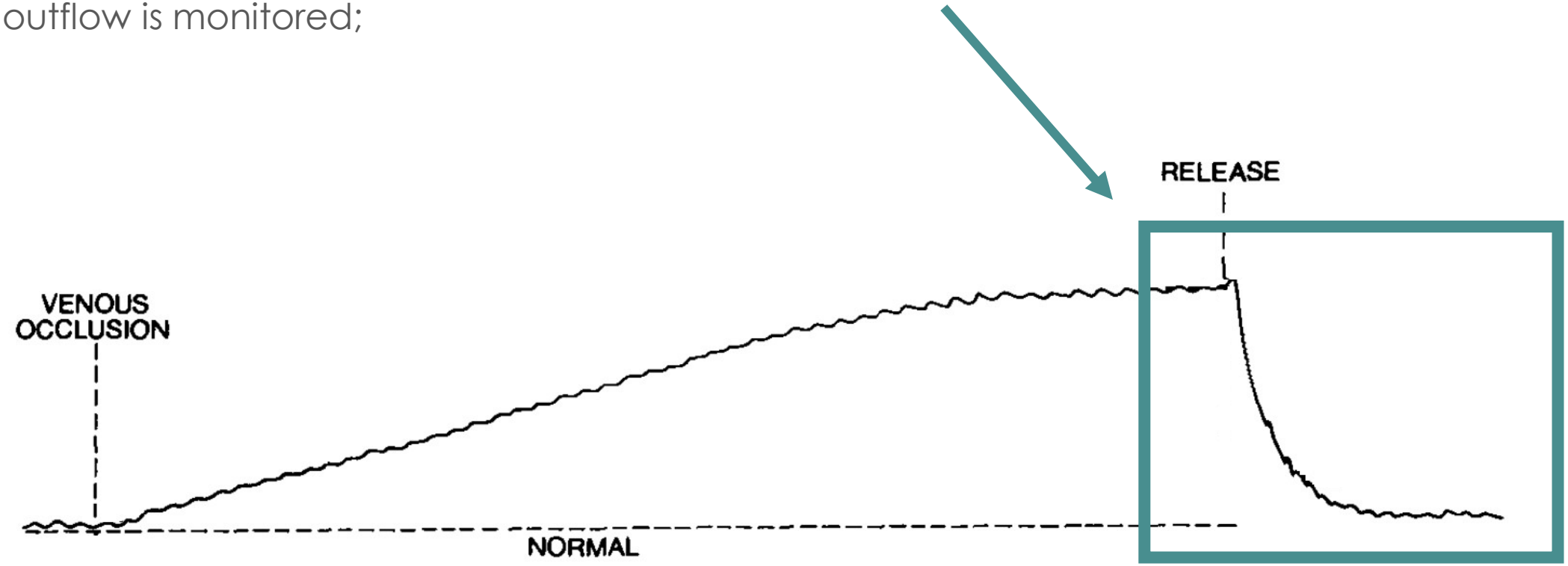
- Venous thromboembolism is the **third most common cause** of vascular mortality worldwide;
- The **incidence is steadily increasing** due to an aging population and comorbidities associated with venous thromboembolism, such as obesity, heart failure, cancer, etc.;
- The risk of DVT increases with age, **most often occurring over 40**.



Di Nisio, M., van Es, N., & Büller, H. R. (2016). Deep vein thrombosis and pulmonary embolism. In The Lancet (Vol. 388, Issue 10063, pp. 3060–3073).

Venous occlusion plethysmography (VOP)

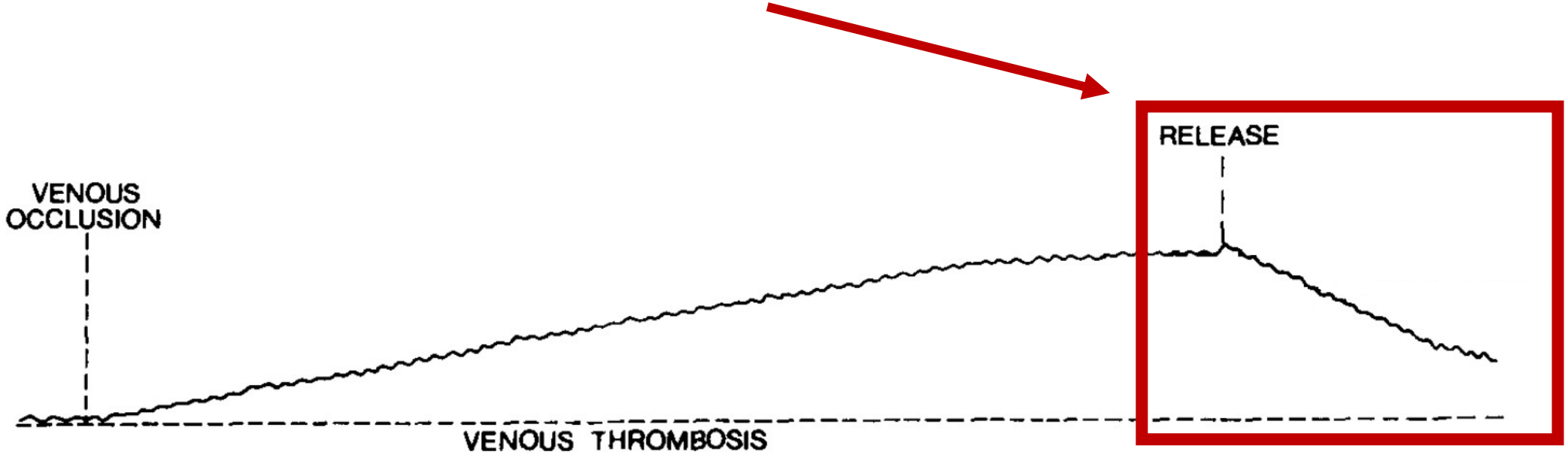
- The patient is placed **supine with the legs elevated** 20°–30° to enable venous drainage;
- The cuff is inflated to a pressure of up to 80 mmHg, **restricting venous outflow**;
- When the volume curve stops rising, the cuff is **rapidly released**, and the rate of venous blood outflow is monitored;



Anderson FA Jr. Impedance plethysmography in the diagnosis of arterial and venous disease. Ann Biomed Eng. 1984;12(1):79-102. doi: 10.1007/BF02410293.

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- The cuff is inflated to a pressure of up to 80 mmHg, **restricting venous outflow**;
- When the volume curve stops rising, the cuff is **rapidly released,** and the rate of venous blood outflow is monitored;
- In the presence of DVT, a **severely slowed venous blood outflow** is observed.



Anderson FA Jr. Impedance plethysmography in the diagnosis of arterial and venous disease. Ann Biomed Eng. 1984;12(1):79-102. doi: 10.1007/BF02410293.

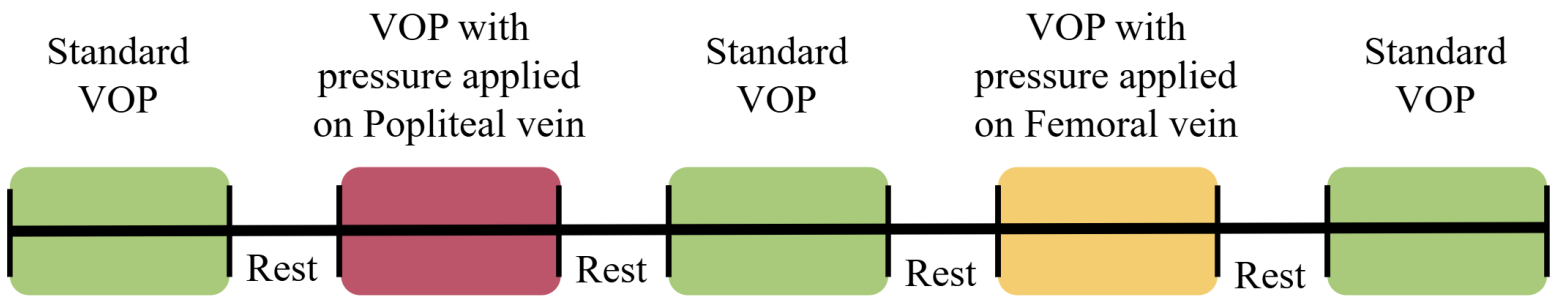
Problem definition

- Existing DVT screening methods require experienced sonographers or operators, making the whole process **time-consuming and cumbersome**;
- The development of new operator-less screening methods and experimentation with the patients can potentially increase the **risk of embolization**;
- Therefore, **simulation of DVT on healthy subjects is a safer option** for data collection and development;

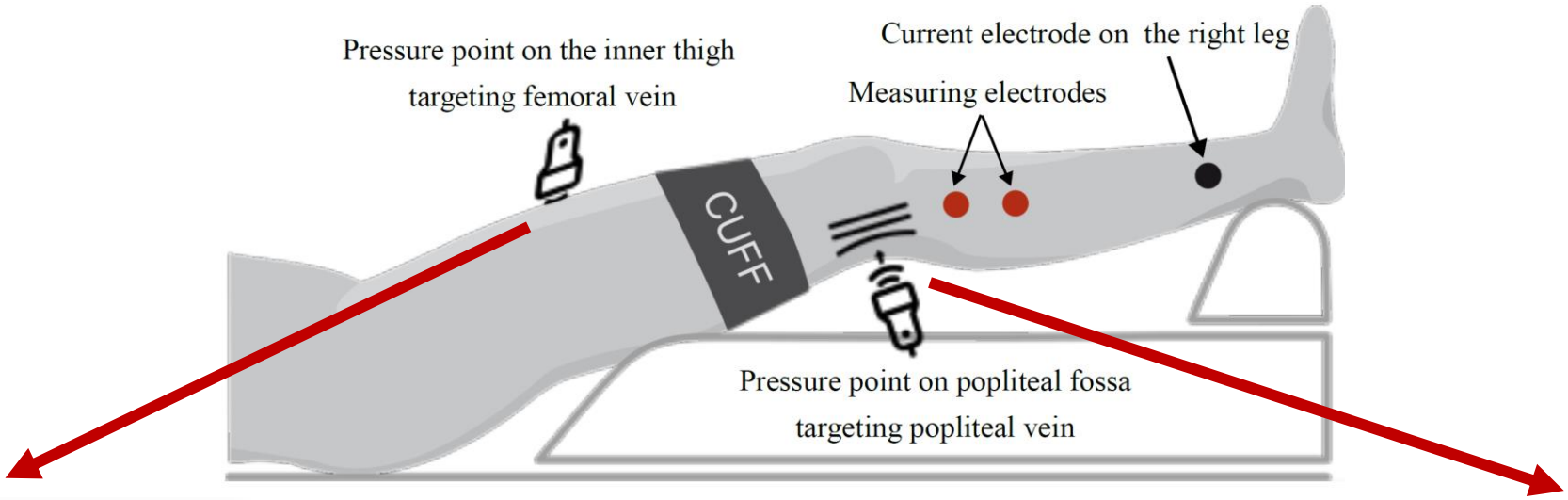
- This study aims to introduce **a method for simulating deep vein thrombosis in healthy individuals**, using localized pressure to create venous stenosis.

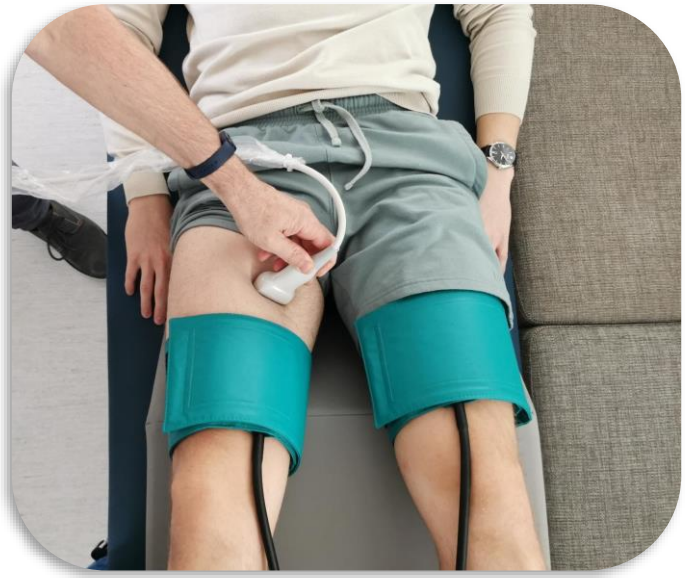
Study protocol

- A short **proof of concept** study with a sample size of 10 subjects;
- Two points of interest were chosen for **DVT simulation**:
  - The popliteal fossa region targeting the **Popliteal vein**;
  - The inner thigh targeting the **Femoral vein**;



Experimental setup





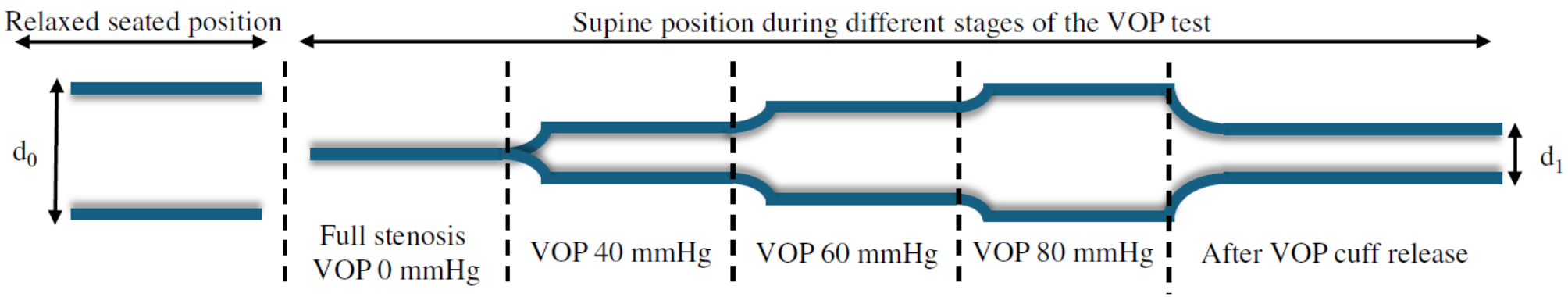
Used devices:

- VasoScreen4000/5000 (Medis)
- Ultrasound ArtUs (Telemed)
- Ultrasound SonixTouch (Ultrasonix)



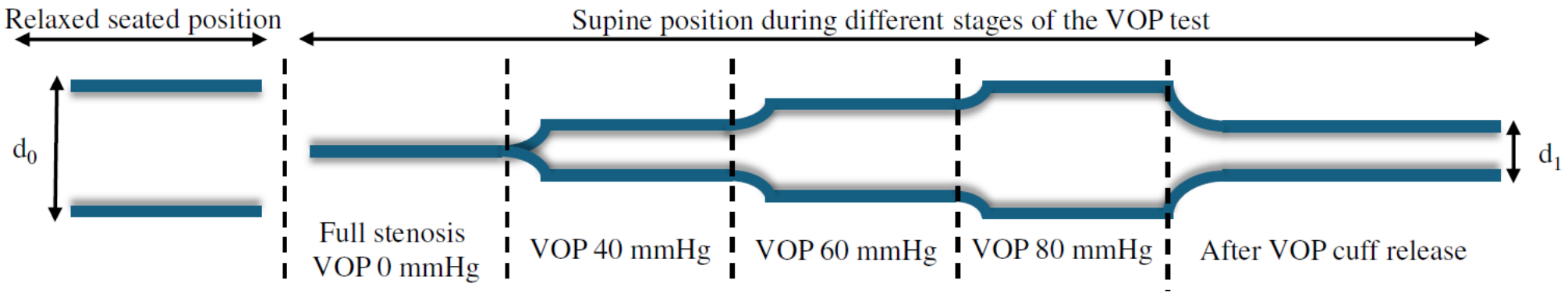
Challenges with the Popliteal vein

- The **biggest challenge** is the precise control of stenosis level, because of **high venous compliance**;
- The **schematical Popliteal vein M-Scan** shows how the vein lumen behaves during all phases of the VOP test with the pressure applied on the Popliteal vein;
- Even though the **Popliteal vein** is **occluded completely** with significant pressure, **it expands during the VOP test**.



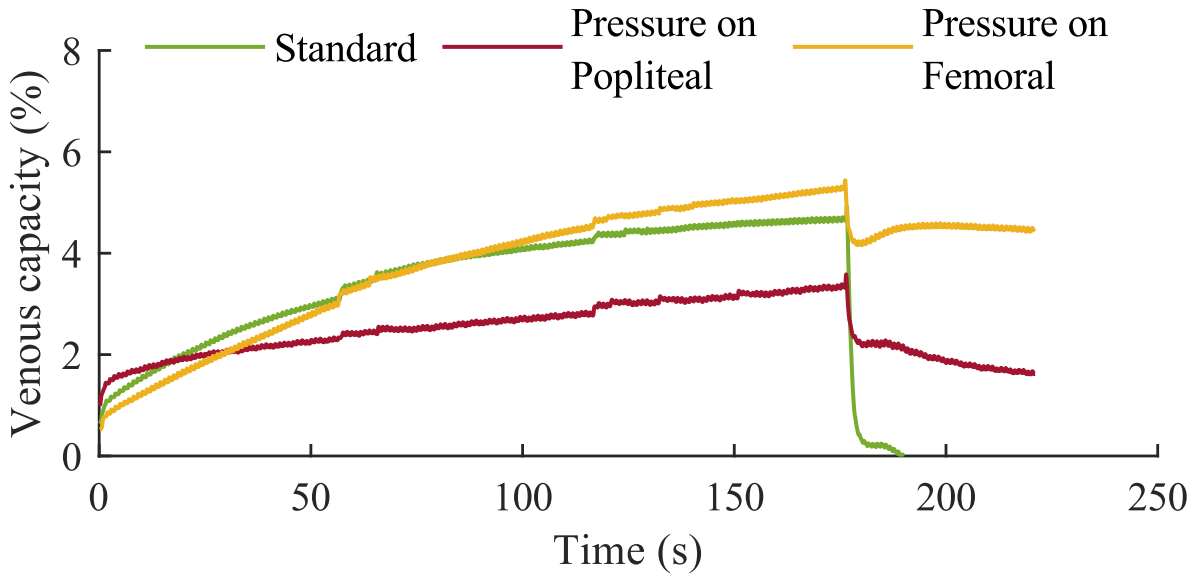
Challenges with the Popliteal vein

- The **pressure in the Popliteal vein** during the VOP test is rising and **potentially approaching arterial pressure**;
- To evaluate the effective stenosis level the initial vein lumen measurements were taken in a **relaxed seated position (d0)** and then compared to the vein lumen **right after the VOP cuff release (d1)** at the pressure point;
- For this study sample the **stenosis level** (d_{sten}) of the Popliteal vein reached 67.2% (σ=5.6%), and 95-100% for the Femoral vein.



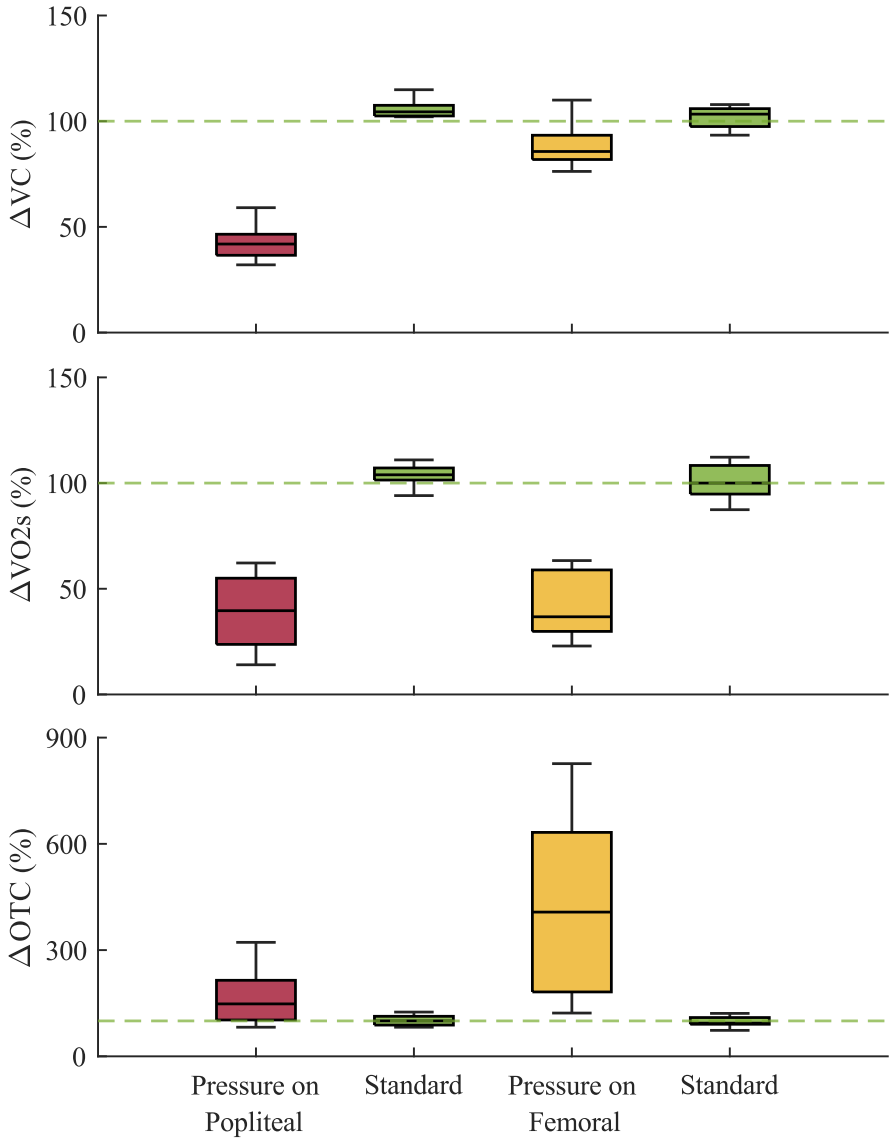
Example of VOP curves during different protocol stages

- During the **Popliteal vein** stenosis VOP curve indicates reduced venous capacity and a shallower outflow curve;
- During the **Femoral vein** stenosis, the vein capacity remains almost the same, but the outflow curve is shallower as well.



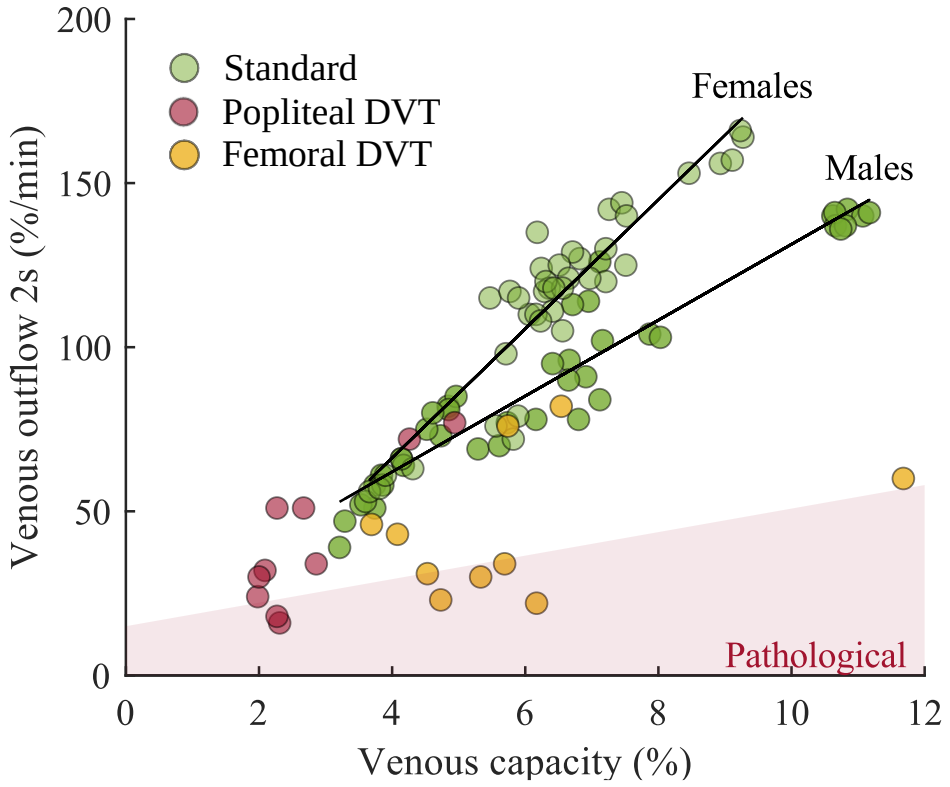
Results I

- Venous capacity (VC) was reduced to 41.9% for the Popliteal point and 85.6% for the Femoral point;
- Venous outflow 2s (VO2s) showed a highly reduced outflow rate for both points of interest, it was reduced to 39.6% and 36.7% respectively;
- Outflow time constant (OTC) increased strongly in both cases by 148% and 407%, respectively.



Results II

- Even though there are significant changes in outflow parameters, the VasoScreen device classified only 7 out of 20 cases (35%) as pathological;
- The threshold for pathological classification is proprietary, leaving it unclear on what studies it is based on;
- When applying a linear fit for the groups of males and females, the data suggest that there are differences between these groups.



Conclusions

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1. This experimental setup reached stenosis levels of 67.2% for the popliteal vein and 95-100% for the femoral vein, **resulting in 35% of the simulated DVT cases being classified as pathological**.

2. Obtained **VC and OTC results** with induced outflow restriction are similar to the VOP results from a study where DVT was confirmed by venography in 100 patients.

3. Despite the small sample size, **there is evidence of the feasibility of DVT simulation via external pressure**, allowing this method for further use in the development of DVT screening methods.

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