# Novel method of electrical nerve stimulation in the lower leg with the potential for DVT prophylaxis

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# Potential for DVT Prophylaxis

- geko® improves venous blood flow return
- geko® reduces venous blood stasis

*Since stasis is one of the three essential components of Virchow's Triad, reduction of stasis reduces the risk of developing thrombosis*

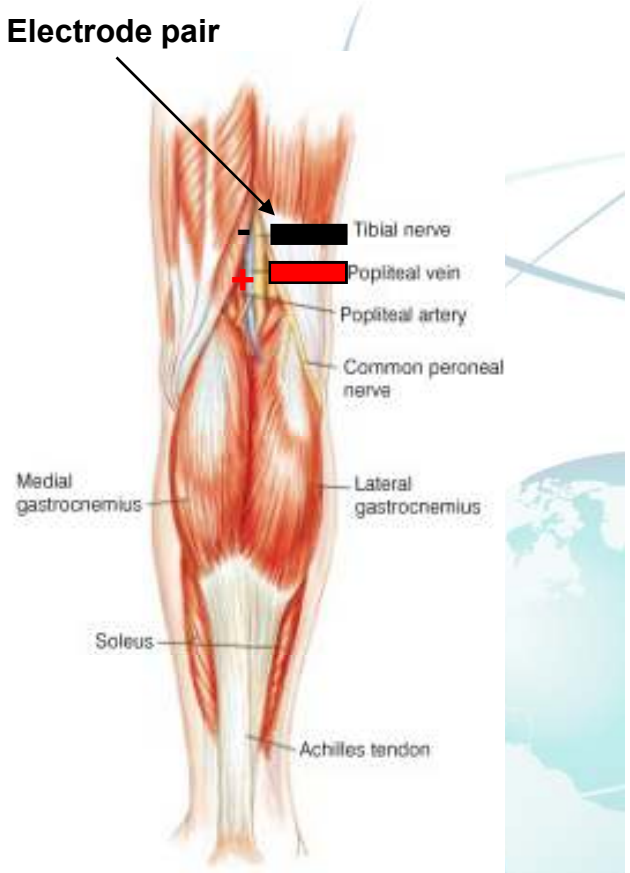
# OnPulse® Circulation Support Technology

- Simple and easy to use
- Small, light and comfortable
- Discreet
- Enables full freedom of movement
- Disposable
- One button control with LED


**geko's actual size**

# Mechanism of Action

- Electrodes are placed over the nerves located within the popliteal fossa
- Isometric activation of the venous muscle pumps of the lower leg (foot and calf pumps)
- Significant increase in lower limb blood flow



# Current DVT Prophylaxis

| Pharmacological treatment | Mechanical ( IPC / GEC) |
|---|---|

Disadvantages

IPC: Intermittent Pneumatic Compression
GEC: Graduated Elastic Compression stockings

| | |
|---|---|
| Active Bleeding | Discomfort/Pain |
| Allergic Reactions | Uncomfortable to wear |
| Risk of VTE persists for weeks or months after hospital discharge | Size |
| Drug interactions with several substances e.g. antibiotics, food | Weight |
| Clinical supervision | External power source necessity |
| | Poor Compliance |
| | Expense |

# THRIVE-1

**A study to determine the effects of a novel method for improving lower limb blood flow in Healthy Adult Subjects**

**Prof. Atholl Johnston, Dr. Arthur Tucker, Dr. Duncan Bain, Li-Hui Chen, Annelie Maass**

**Clinical Pharmacology, Barts & The London,**
**Queen Mary's School of Medicine and Dentistry**
**John Vane Science Centre**
**&**

**The Ernest Cooke**
**Microvascular Unit,**
**St. Bartholomew's Hospital**

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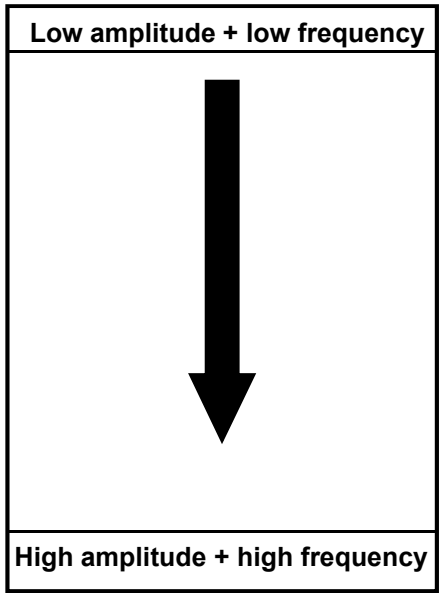
# Experimental Design

- 30 healthy volunteers, 2 visits per volunteer
- 15 different stimulations were applied as per table below

| Programme | Amplitude/mA | Frequency/Hz |
|---|---|---|
| 1 | 1 | 1 |
| 2 | 1 | 3 |
| 3 | 1 | 5 |
| 4 | 5 | 1 |
| 5 | 5 | 3 |
| 6 | 5 | 5 |
| 7 | 10 | 1 |
| 8 | 10 | 3 |
| 9 | 10 | 5 |
| 10 | 20 | 1 |
| 11 | 20 | 3 |
| 12 | 20 | 5 |
| 13 | 40 | 1 |
| 14 | 40 | 3 |
| 15 | 40 | 5 |




The stimulation programmes were applied to a randomly selected leg in a sitting position for 5 minutes, 5 further minutes of response recording followed by a 5-minute recovery

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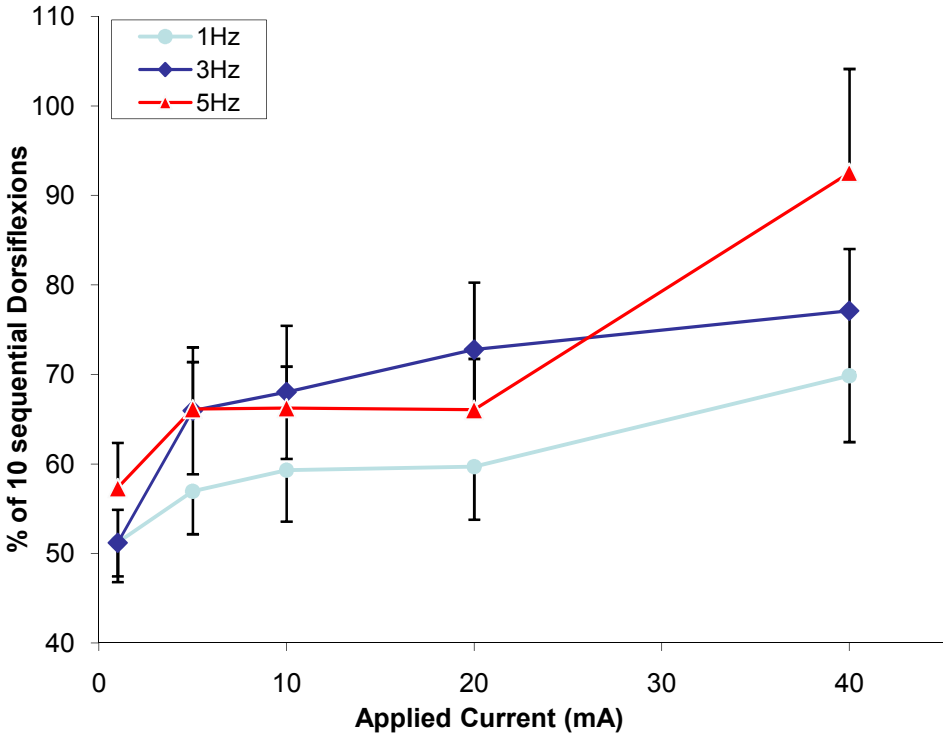
# Effect on Blood Flow




- Pulse oximeter was placed on dorsal foot veins
- Change in signal relates to dorsal foot venous emptying
- All PPG values were at least 50% of foot flexion value
- Potential to produce prolonged improved venous return from lower limbs

**Photoplethysmography (PPG) measurements showing venous emptying response versus stimulation current, by frequency, compared to 10 dorsiflexions with the heel on the ground which represented the theoretical maximum physiological response that can be obtained in the sitting position**

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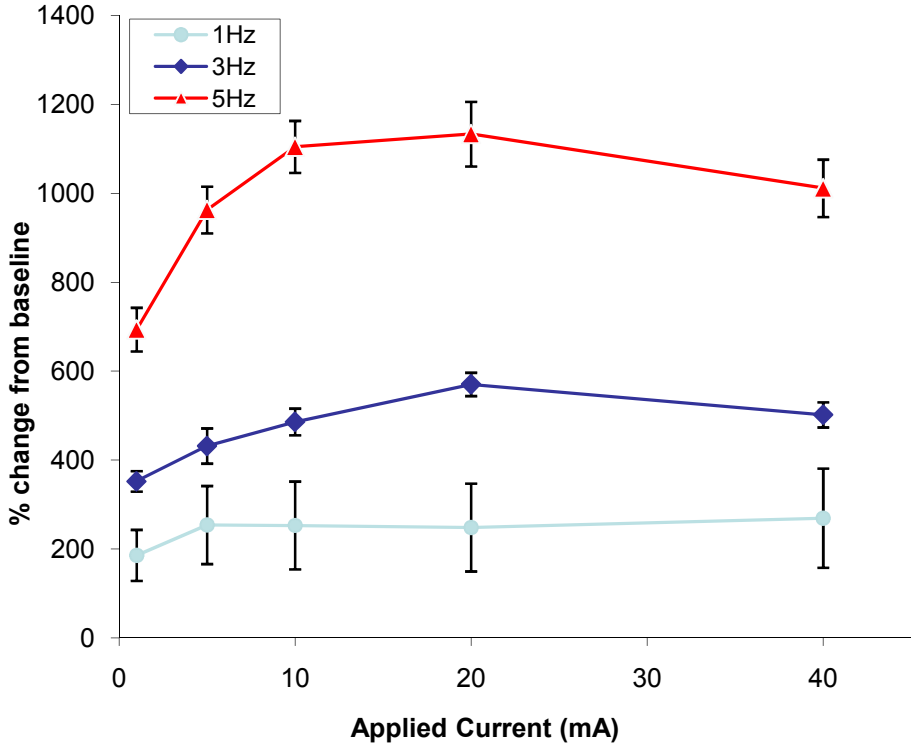
# Microcirculatory Blood Flow




- Measured on dorsum of foot
- At 1 Hz, at least a 2 fold increase in stimulated leg compared to resting baseline
- Significant increase in the temperature of the skin surface compared to unstimulated leg

**Laser Doppler Fluxmetry (LDF) measurements of microcirculatory flux (changes in capillary blood flow in the skin) on bilateral dorsum of foot, for each stimulation setting as a percentage of baseline**

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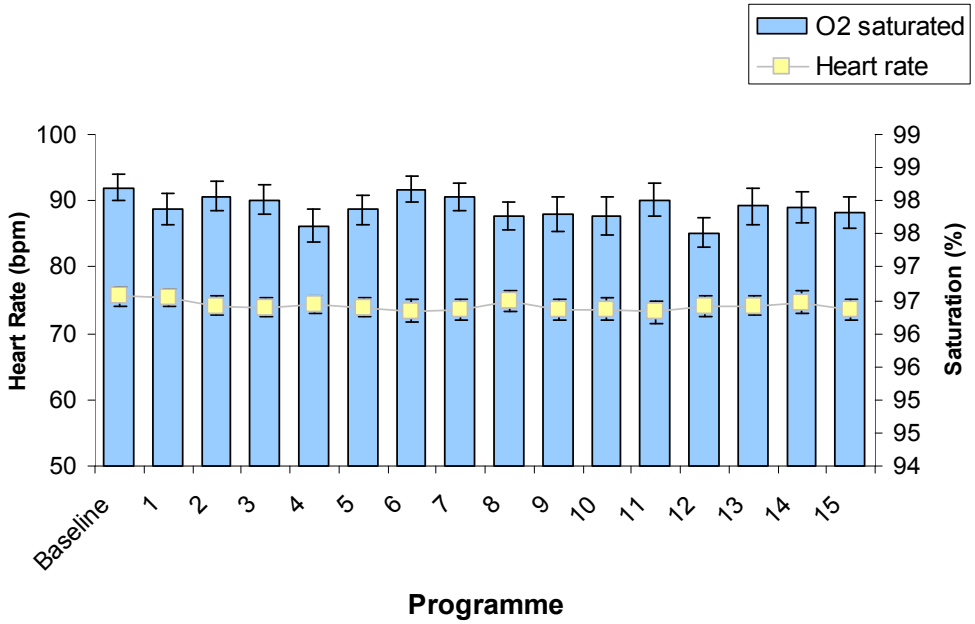
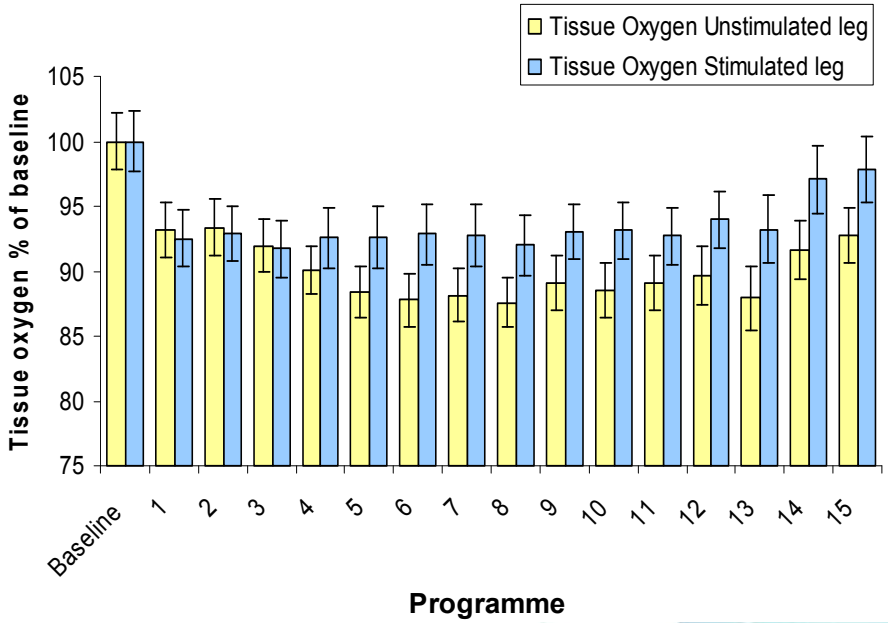
# Heart Rate and Tissue Oxygen

## Heart Rate & Oxygen saturation




Stable heart rate and no difference in mean oxygen saturation

## Tissue Oxygen




Tissue oxygen conserved by 6-7% at stimulations 5 -15

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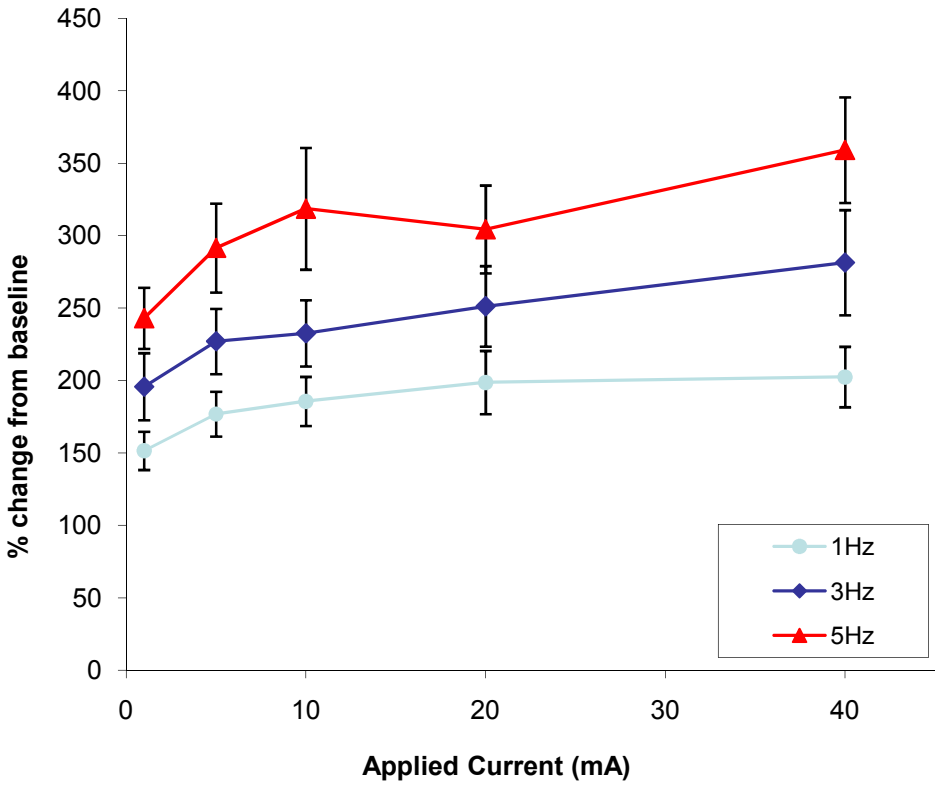
# Femoral Vein Velocity




**Ultrasound**

- Venous blood velocity increased significantly in the stimulated leg at all stimulations compared to baseline
- Responses were within normal physiological responses of dorsiflexion

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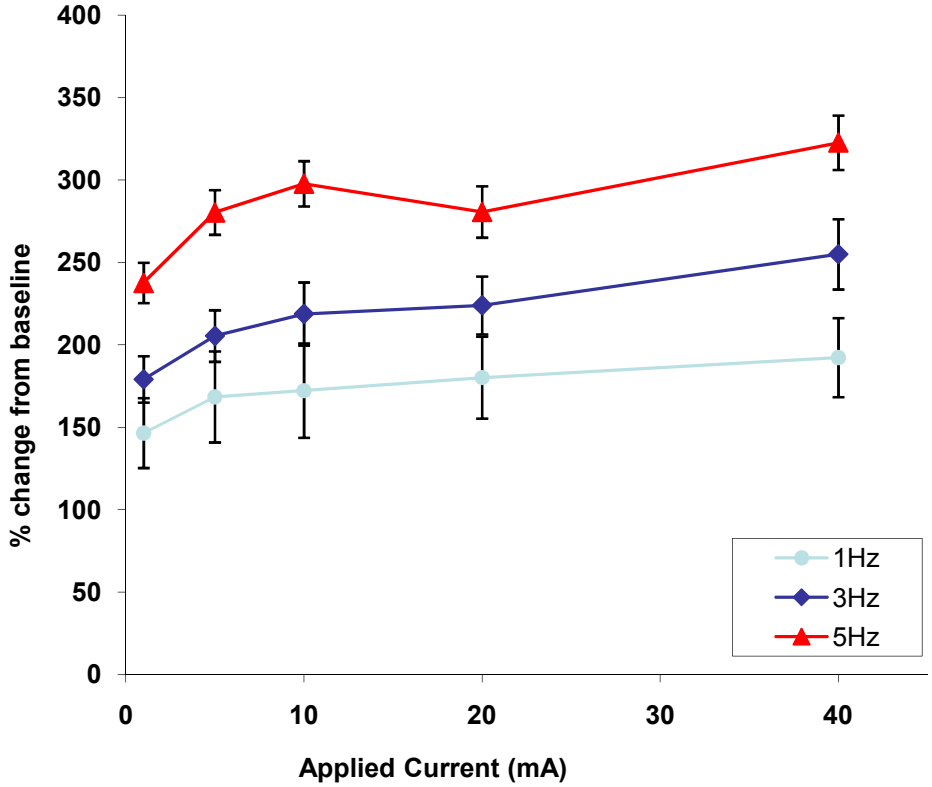
# Femoral Vein Volume Flow




**Ultrasound**

- Measured in the superficial femoral vein
- Increase in venous blood volume flow in the stimulated leg at all stimulations compared to baseline
- No significant change in mean vessel diameter throughout study

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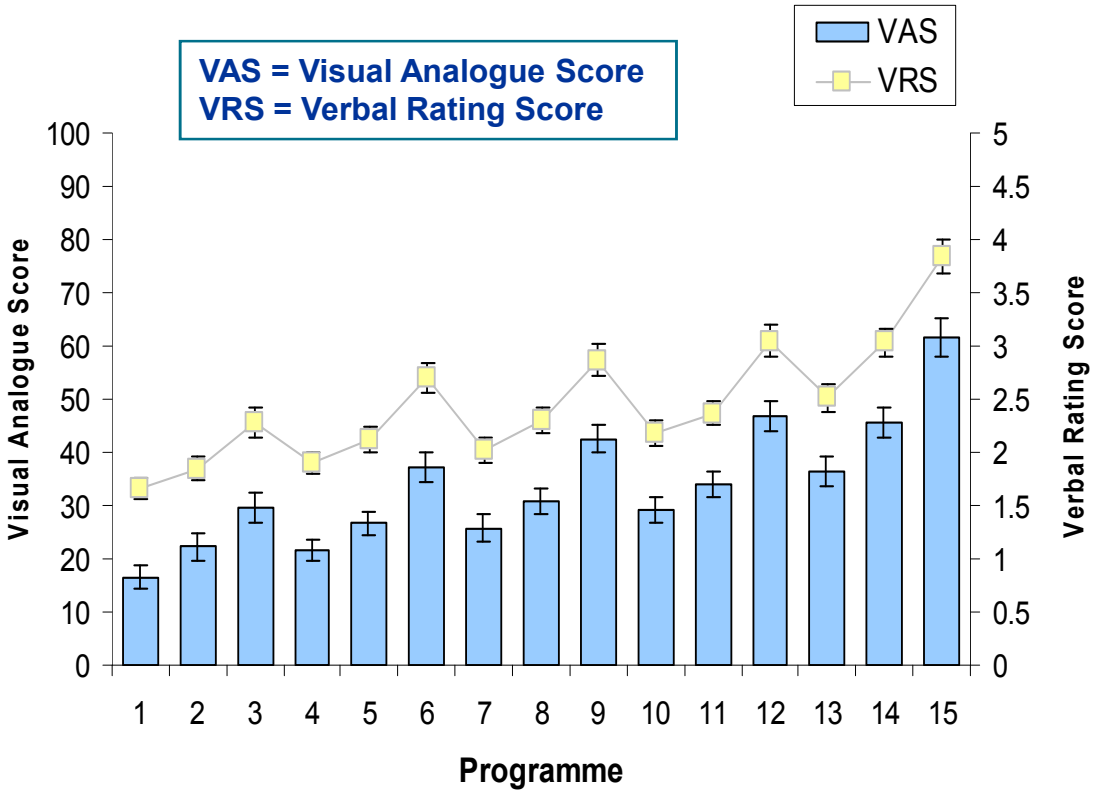
# Comfort and Tolerability

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| 10 | 20 | 1 |
| 11 | 20 | 3 |
| 12 | 20 | 5 |
| 13 | 40 | 1 |
| 14 | 40 | 3 |
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The device was well tolerated with both visual and verbal rating scores at "**minimal sensation**" for most settings

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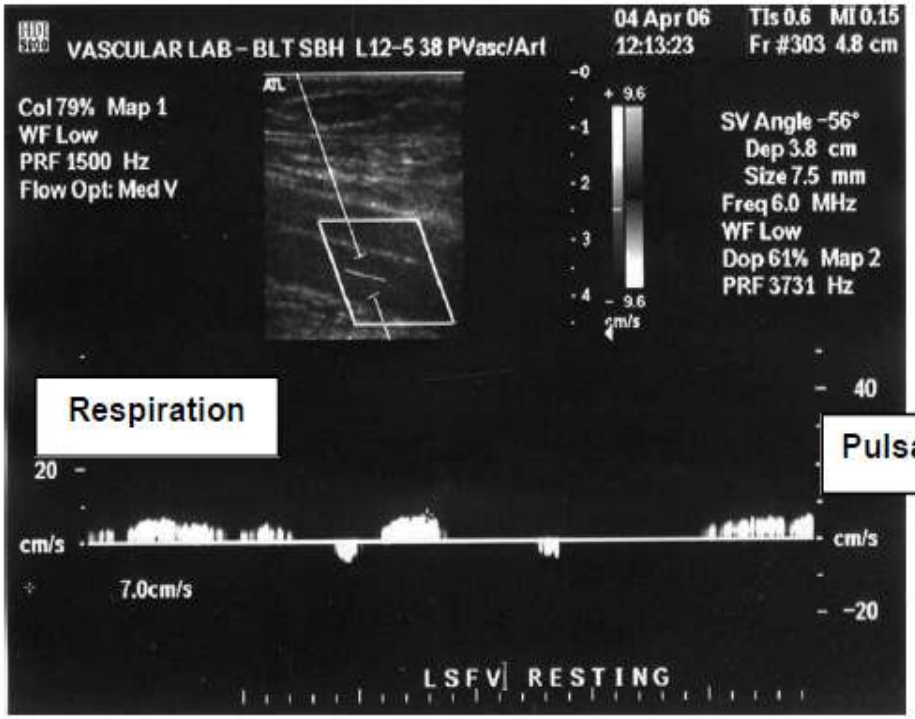
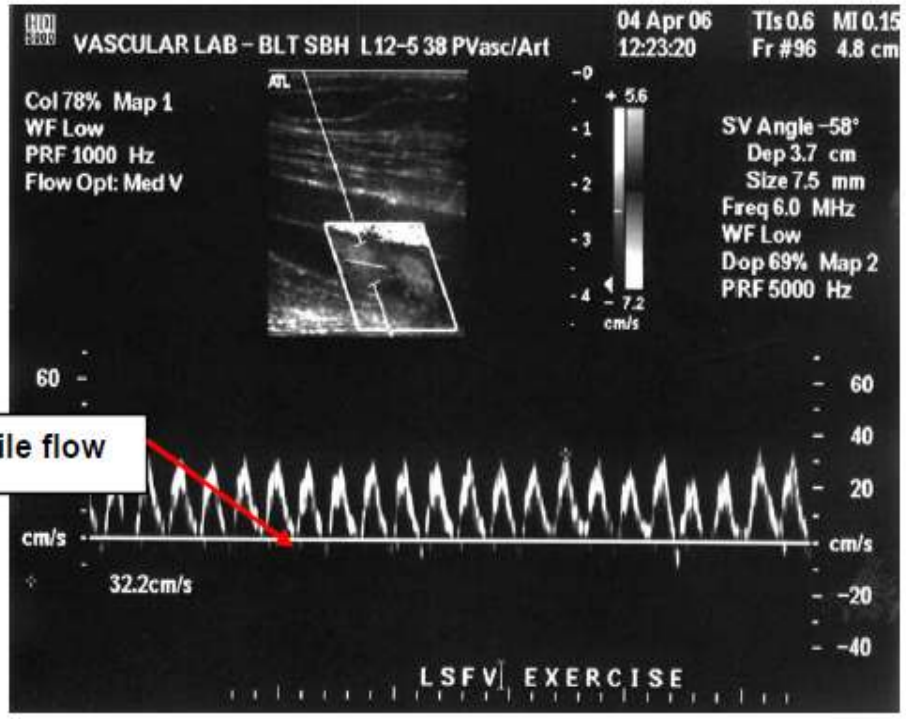
# Vascular Ultrasound Assessment

Visualization of increased blood flow volume, velocity and waveform




Superficial Femoral Vein: **At rest**




Superficial Femoral Vein: **Device active**

# Vascular Ultrasound Assessment

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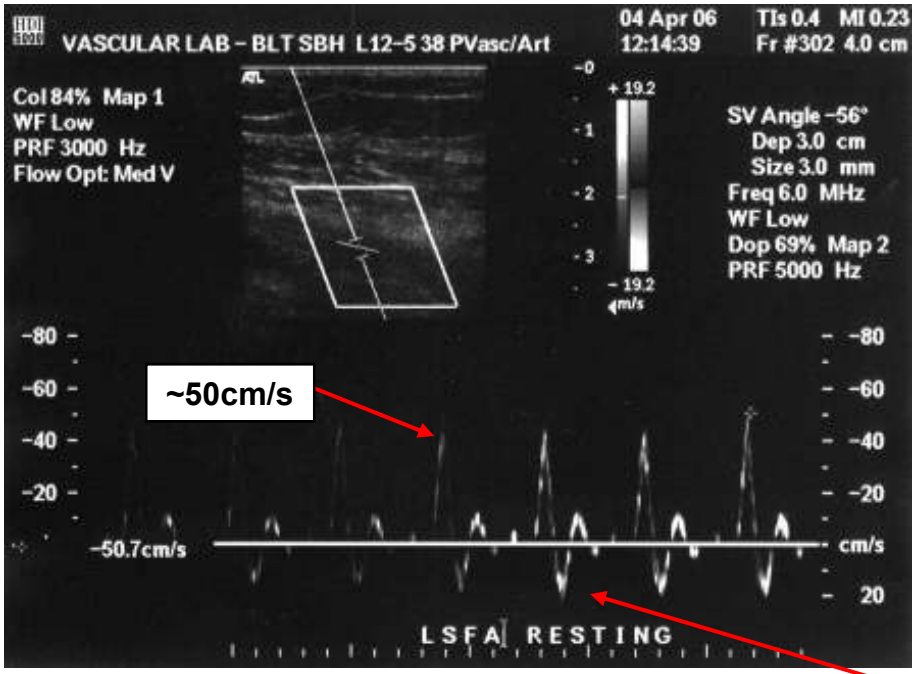


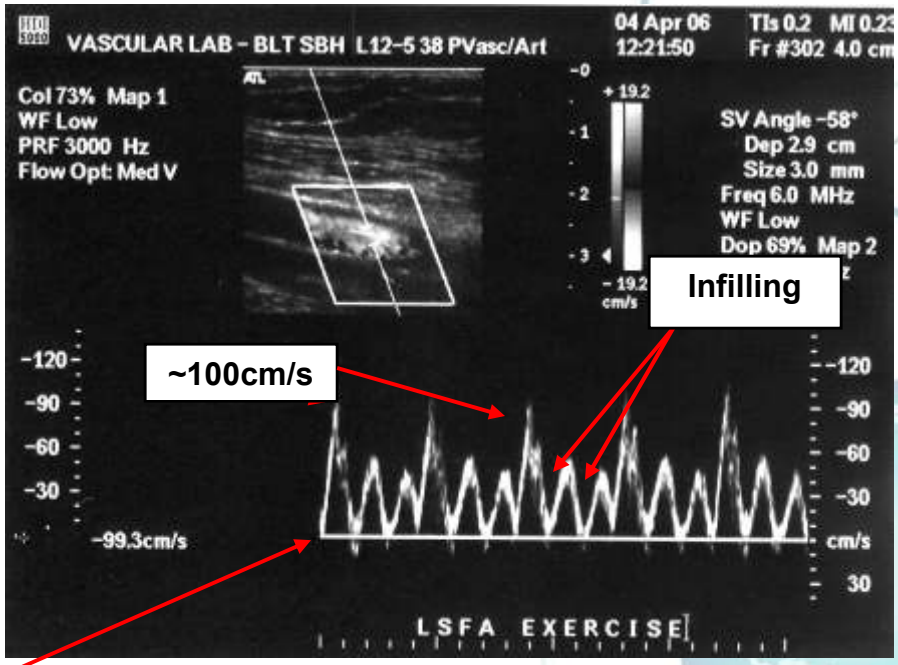


**Prevention of diastolic flow reversal**

Femoral Artery: **At rest**

Femoral Artery: **Device active**

# Summary of Results

- Up to ten fold increase in LDF (speed of blood flow) in stimulated leg compared to baseline*
- PPG values (blood volume change) were equivalent to at least 50% of foot flexions** - evidence of dorsal foot vein emptying
- Activation of the device results in less than 50% of the calf contraction of a foot flexion
- Skin temperature and tissue oxygen were preserved in the stimulated leg compared to the unstimulated leg indicating increased blood flow in the superficial layers of the skin

* Blood flow and velocity at rest

** 10 dorsiflexions (10 toe lifting movements) - the maximum venous emptying that can be obtained by foot and calf pump activation

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# Safety and Tolerability

- Stable heart rate and blood pressure throughout the study
- No significant change in mean vessel diameter
- Venous blood velocity increased significantly in the stimulated leg compared to baseline but stayed within normal physiological parameters
- The device was well tolerated with visual analogue and verbal rating scores at “minimal sensation”

# Device Comparison Study

**Principal Investigator Dr. Arthur Tucker & Dr Annelie Maass**

**The ERNEST COOKE Vascular & Microvascular Unit**
**4th Floor, Dominion House**
**Department of Clinical Physics**
**Clinical Support Services**
**St Bartholomew's Hospital**

The Royal Hospital of St. Bartholomew. The Royal London Hospital.
The London Chest Hospital. The Queen Elizabeth Children's Service

# Outline of the Study

- Conducted by St Bartholomew's Hospital
- Performed on 5 subjects
- Thrive box at 3Hz was compared against Kendall calf, Flowtron calf and Flowtron foot pumps
- Thrive box showed the most blood volume movement per minutes and peak max velocity in all subjects

# Device Comparison for Subject 2

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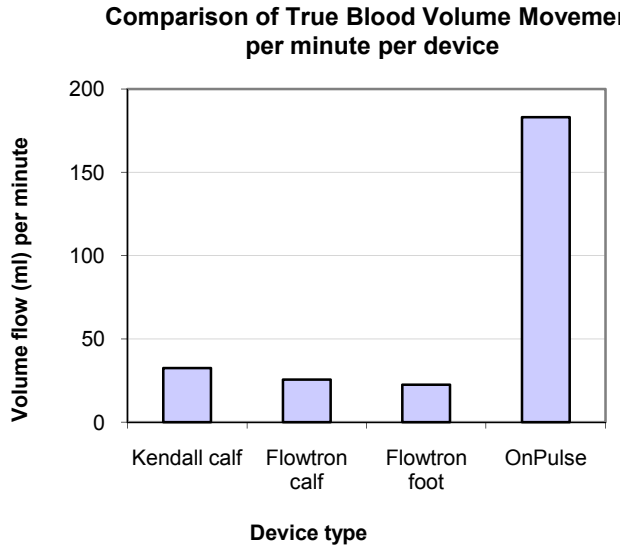
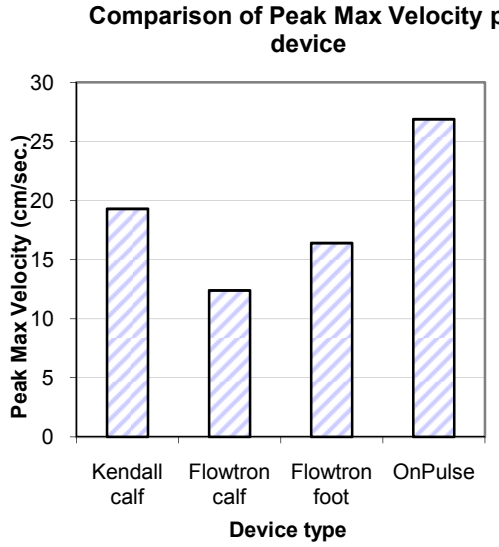
**Dynamic Device Comparison**




| Kendall Calf | Flowtron Calf | Flowtron Foot | geko® |
|---|---|---|---|
|  |  |  |  |

# Ease of Use

| Comparison Point | Compression stockings | IPC devices | geko® |
|---|---|---|---|
| Method of fitting | Patient measured for size<br>Correct size ordered from stores or custom made<br>Correctly size stockings fitted or often re-fitted as leg dimension may have changed<br>Frequently requires additional equipment to fit or can take up to 3 nurses with unconscious patients | Patient needs to be measured for sleeves<br>Pump needs to be located fixed, powered, tested and set<br>Sized sleeves tested with devices<br>Sized sleeves fitted to patient<br>Test again prior to use | Device attached and set by single care giver<br>Switched on |
| Mobility | Yes | No | Yes |
| Comfortable | No<br>May need to be cut off patient if ill fitted or caused swelling | No<br>Build up of sweat on legs<br>Can generate noise and skin irritation over a large area | Yes |
| Requires pre-fitting assessment and measurement | Yes | Yes | No |
| Measuring setting up and fitting time | 12 minutes – 4 hours | 8-15 minutes | 60 seconds |
| Requires equipment safety certificates and maintenance | No | Yes | No |
| Sizes needed for stock | Many | Many | One size fits all – each device has 7 settings |

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