

Development of a pressure sensing device for use in compression therapy of venous leg ulcers

*By Dr Andrew Cameron
ICC Meeting 2019*



European Union
European Regional
Development Fund

**Health
Innovation
Hub Ireland**

Disclosures

- Aiming to form a start-up
- Patent #EP18214871
- Non-FDA and Non-CE Mark use



NUI Galway
OÉ Gaillimh



European Union
European Regional
Development Fund

Health
Innovation
Hub Ireland

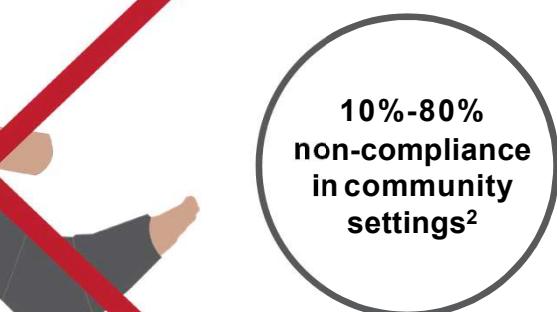
Clinical Problems



Too Loose
= Ineffective



Too Tight
= Dangerous



Standardised Pressure

Non-Compliance

1. Protz et al. JDDG. 2014;12:794-801.

2. Moffatt et al. International Wound Journal. 2009;6:386-93

Design Inputs

TABLE 1. Characteristics of an "Ideal Sensor"

- Size-insensitive to force concentrations
- Flexibility-insensitive to bending, but not distensible
- Durability
- Reliability
- Overload tolerance
- Electronic simplicity
- Low cost
- Low hysteresis
- Little creep
- Insensitive to temperature and humidity changes
- Continuous output
- Linear response to applied pressure
- High sampling rate-locomotion studies
- Operating range consistent with biological parameters
- Accuracy
- Resolution (time <0.1 sec, amplitude <0.1 mmHg)
- Thin
- Variable sensor sizes

Partsch et al.. Dermatologic Surgery. 2006;32:224-33.

- Accurate pressure measurement
- Versatile positioning
- Unobtrusive
- Safe/comfortable
- Easy insertion
- Compatible with existing bandages
- Secure attachment
- Clear user interface
- Low cost

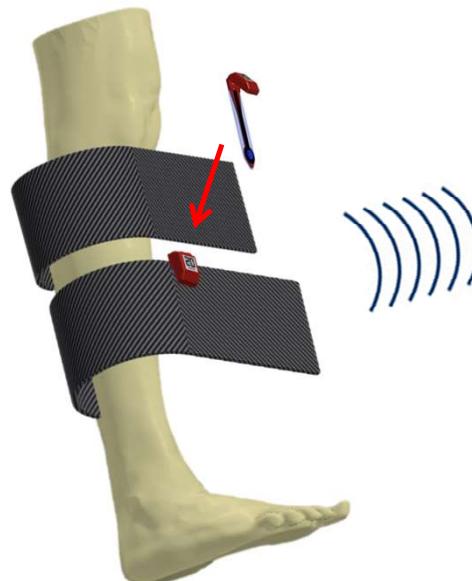
Our Solution

Design Inputs

- Accurate pressure measurement
- Versatile positioning
- Unobtrusive
- Safe/comfortable
- Compatible with existing bandages
- Secure attachment
- Easy insertion
- Clear user interface



Pressure Sensing Device



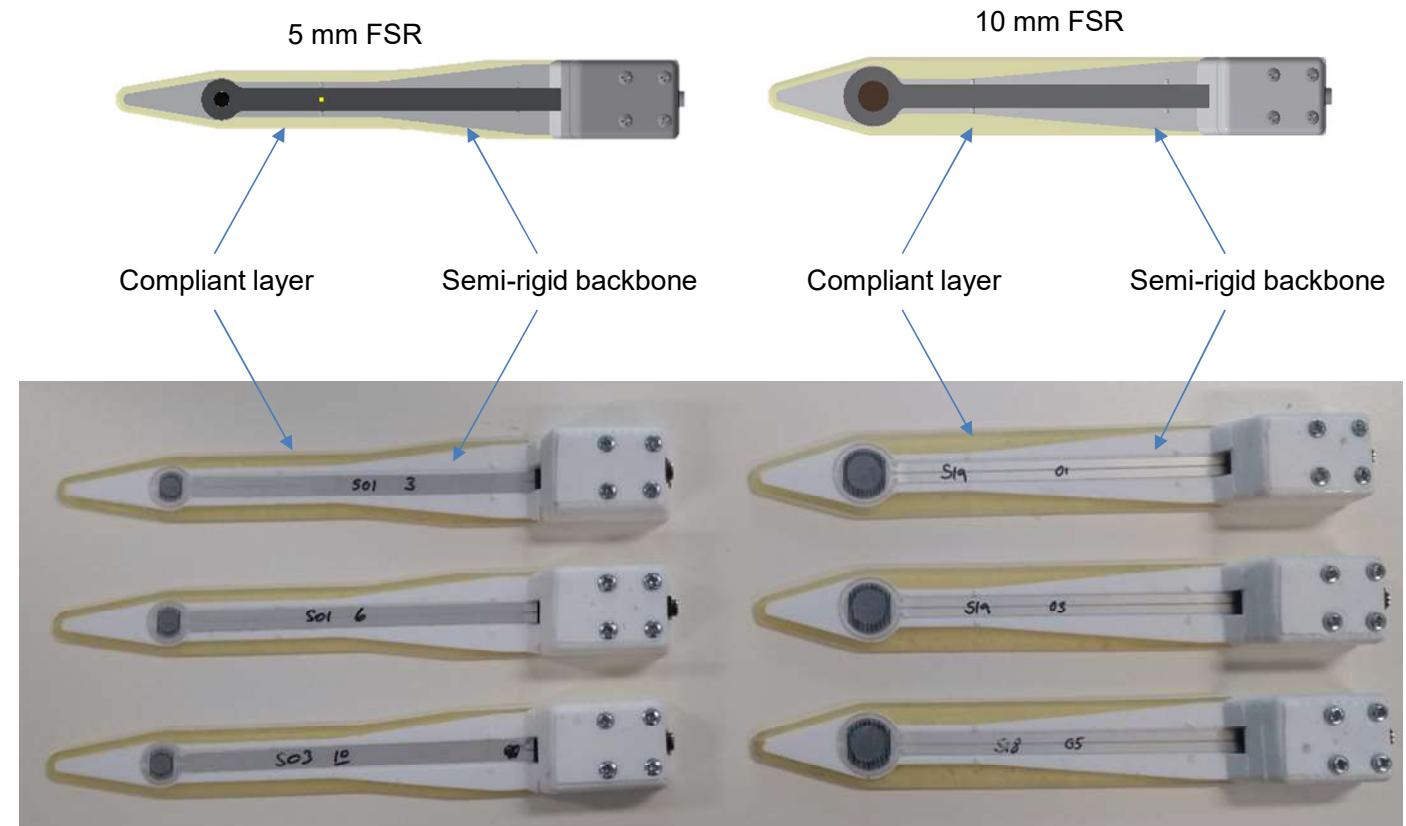
Compression Bandage



Digital Interface

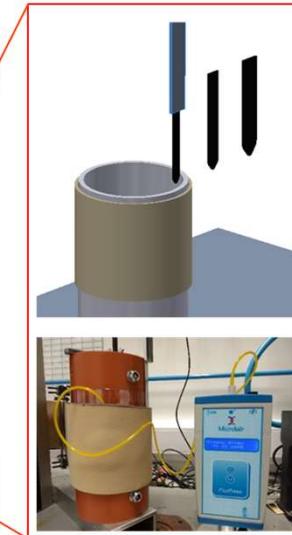
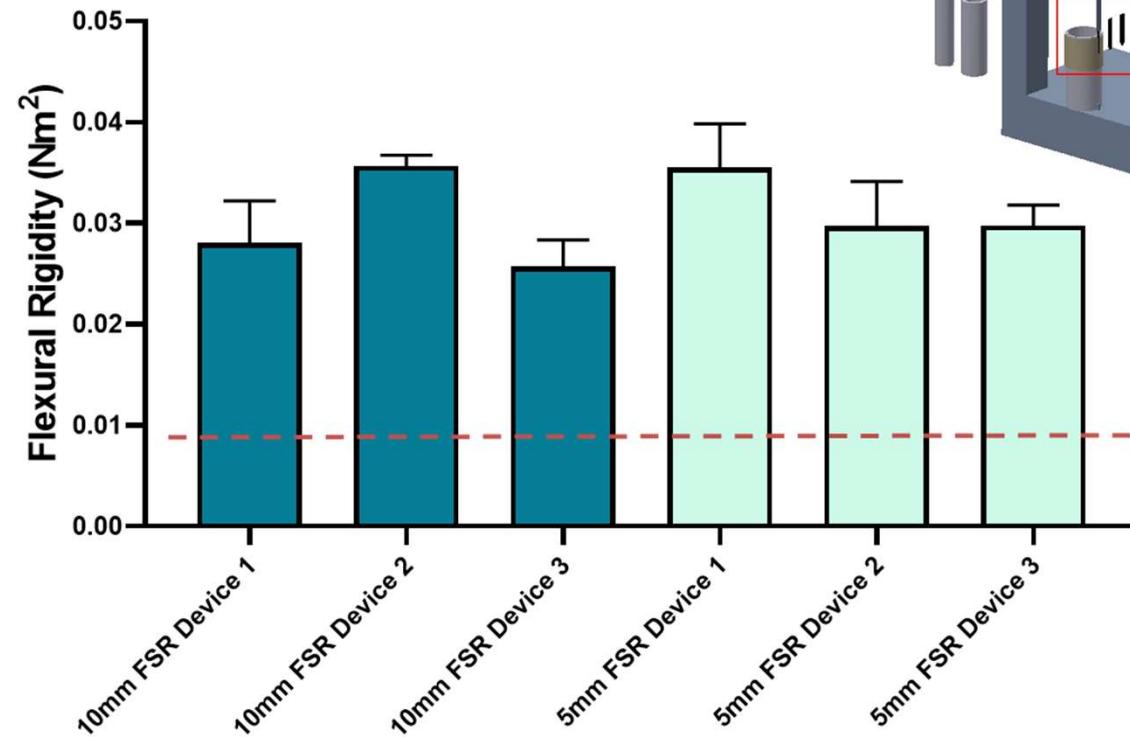
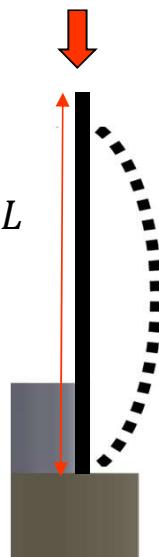
1. Parmar et al. Sensors. 2017;17:1923.
2. Khodasevych et al. Sensors. 2017;17:2399.

Device Assembly



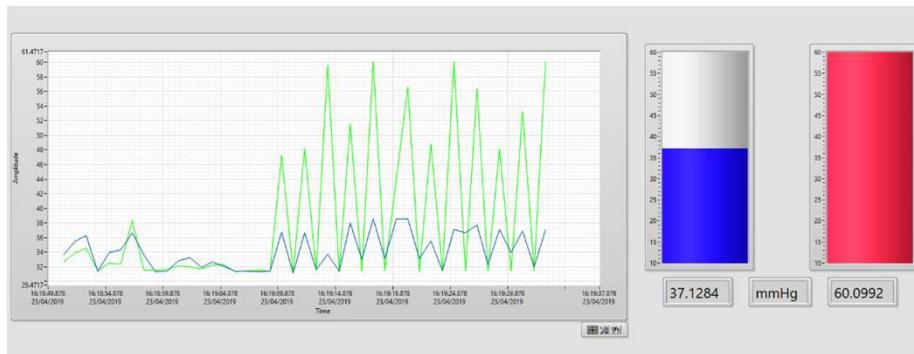
Flexural Rigidity

Critical load (P_c): maximum load before bending



Calculated
minimum

Device Testing



Software Interface

1. Thomas S. Journal of Wound Care. 2014;23:234-46.

LaPlace's Law¹

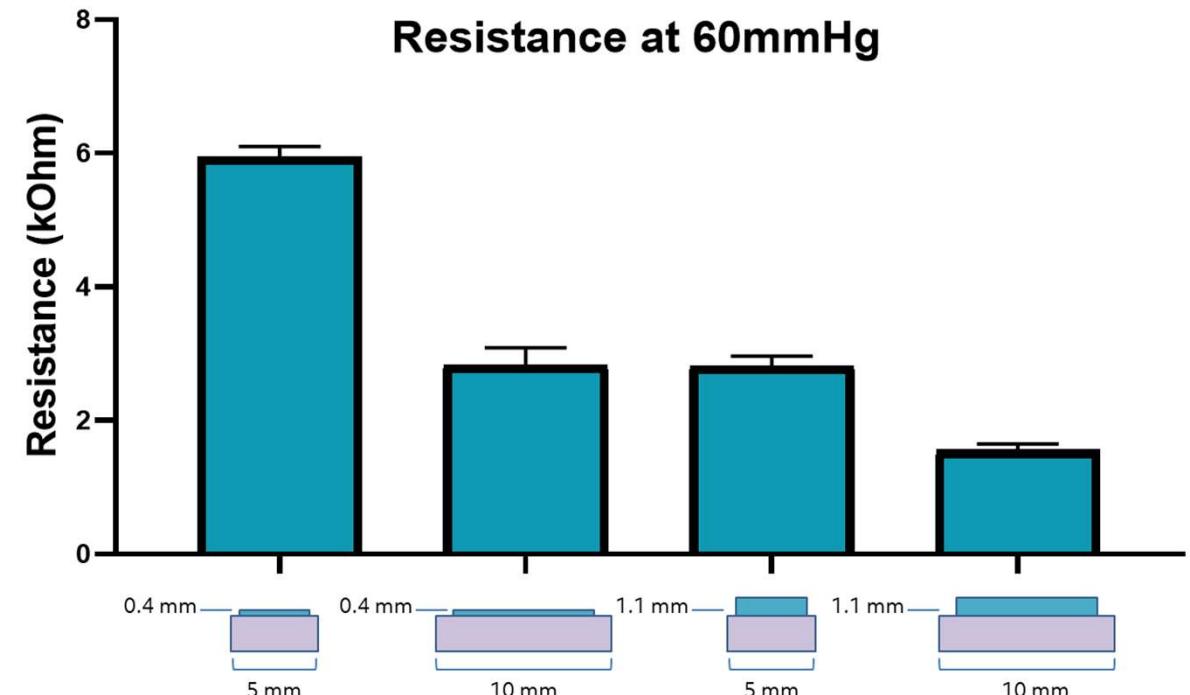
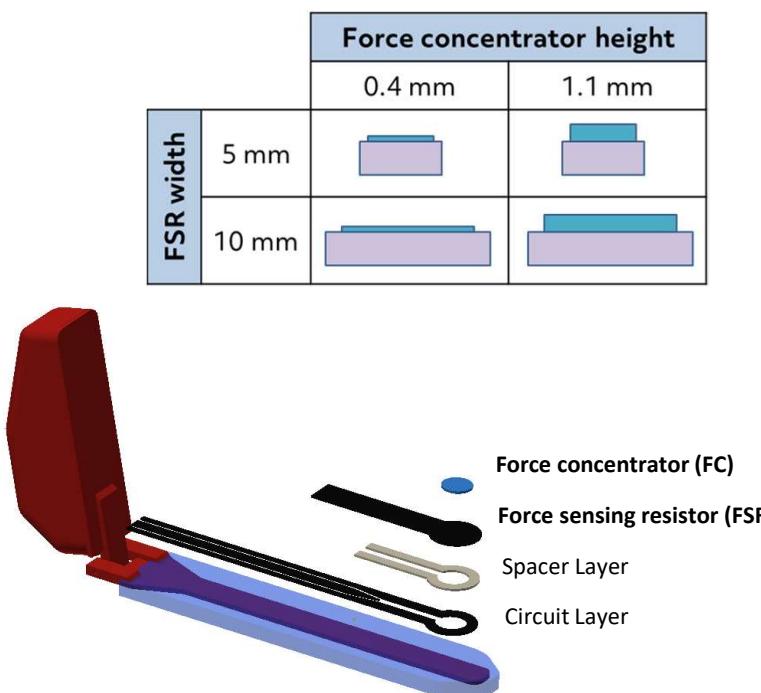
$$\text{Pressure (mmHg)} = \frac{\text{Tension (Kfg)} \times n \times 4620}{\text{Circumference (cm)} \times \text{Bandage width (cm)}}$$



4 weights X 3 cylinders = 12 pressures tested

Pressure Testing Rig

Force Concentrator

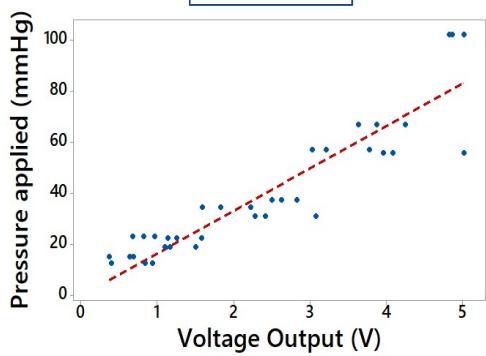


Device Calibration



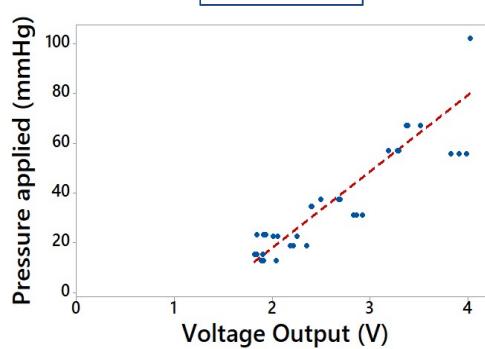
0.4 mm
5 mm

$$R^2 = 0.84$$



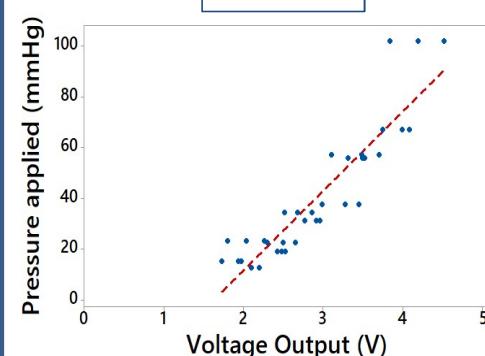
0.4 mm
10 mm

$$R^2 = 0.83$$



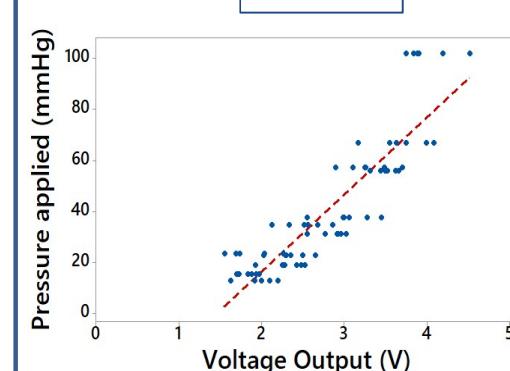
1.1 mm
5 mm

$$R^2 = 0.83$$



1.1 mm
10 mm

$$R^2 = 0.78$$



NUI Galway
OÉ Gaillimh



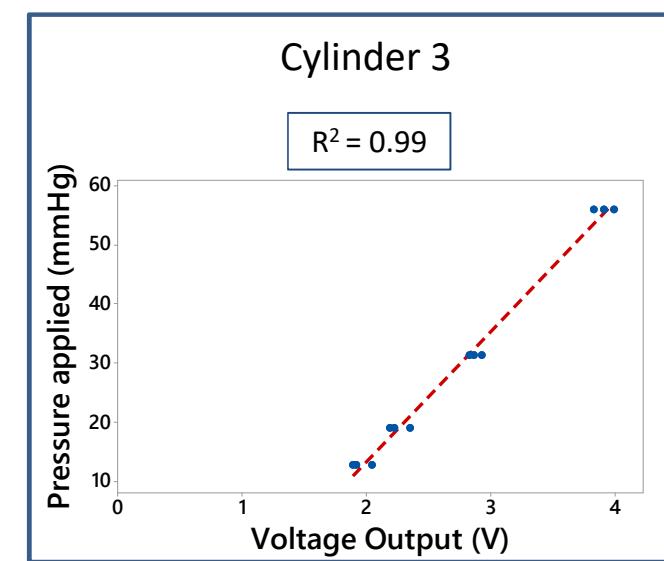
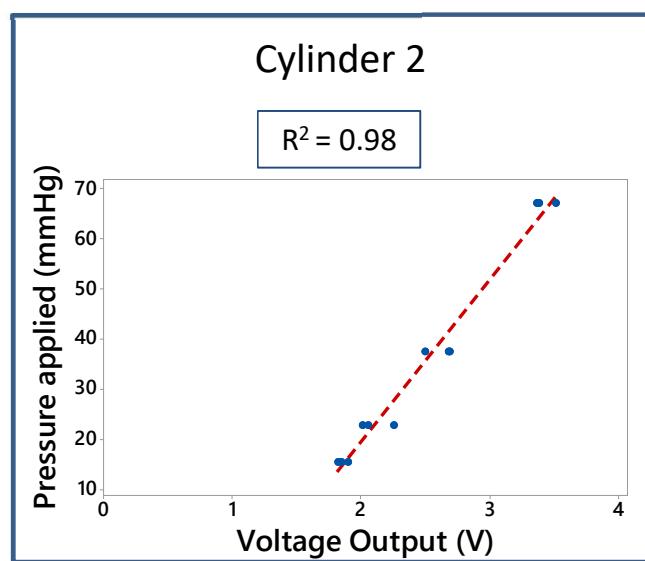
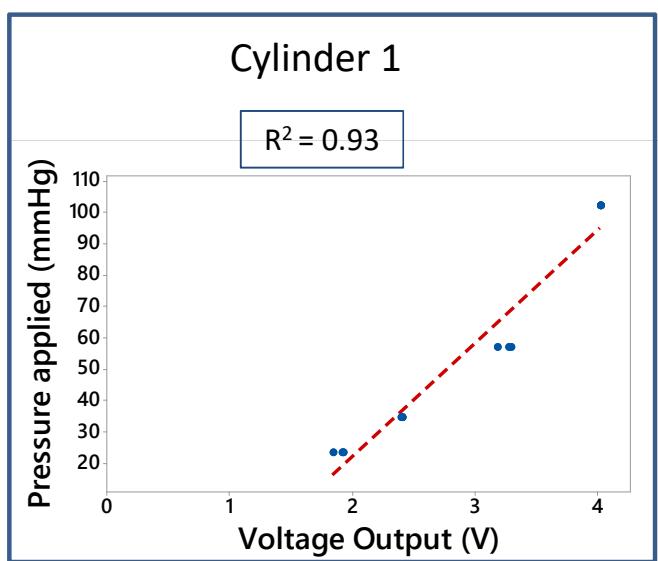
ENTERPRISE
IRELAND
where innovation means business



European Union
European Regional
Development Fund



Device Calibration



NUI Galway
OÉ Gaillimh



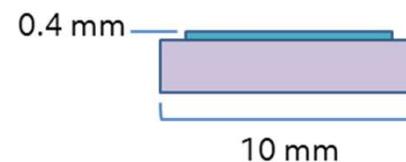
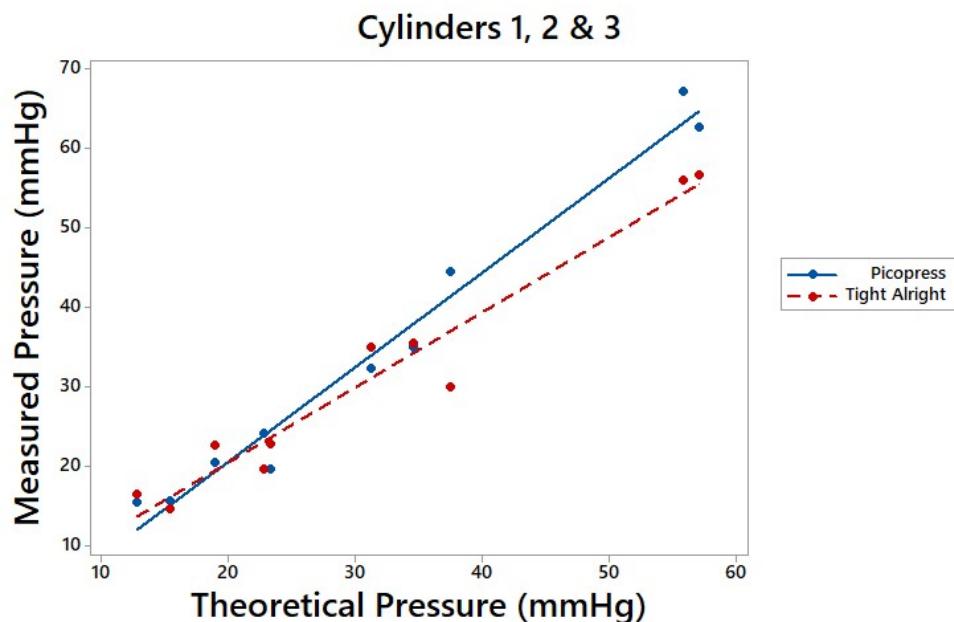
ENTERPRISE
IRELAND
where innovation means business



European Union
European Regional
Development Fund

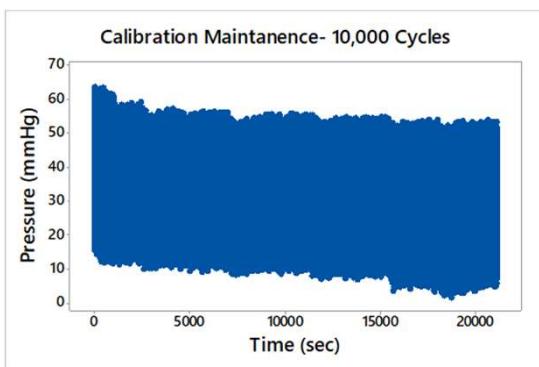
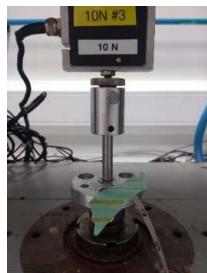


Device Comparison

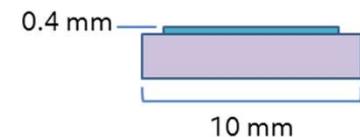
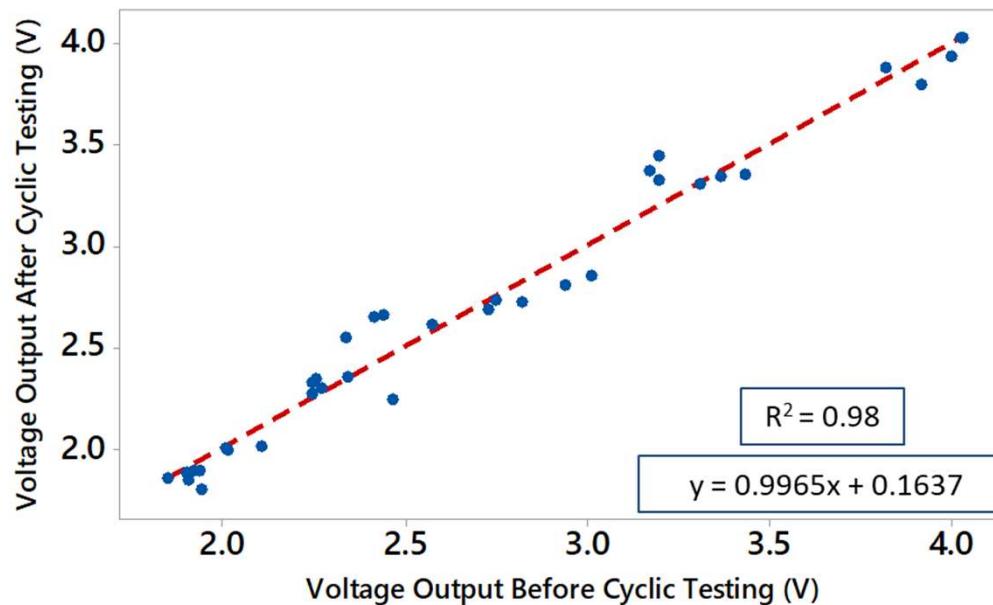


Measurement Device	Pearson Coefficient	Regression Equation
PicoPress	0.958	$y = 1.19x - 3.01$
Tight Alright	0.975	$y = 0.94x + 1.74$

Calibration Maintenance



Tight Alright Voltage Output Before & After Cyclic Testing

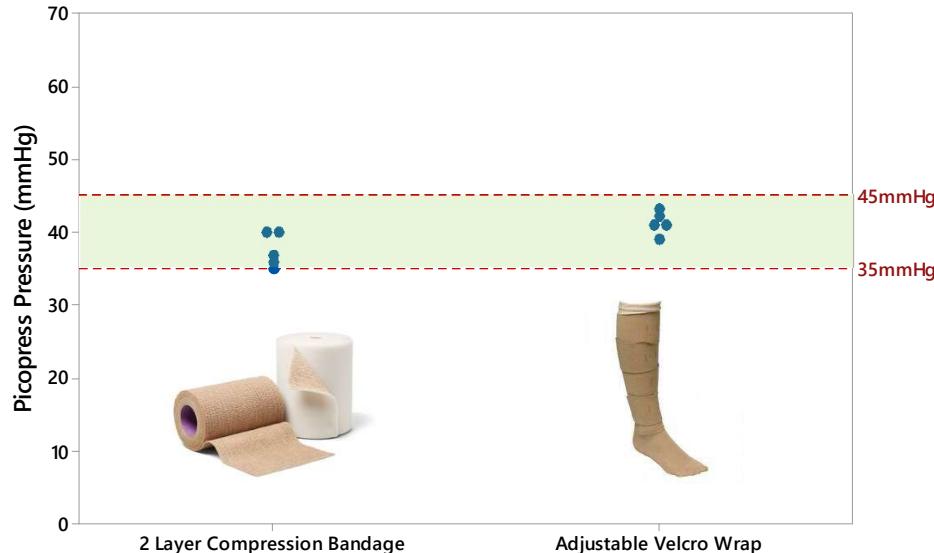


Prototype Demonstration

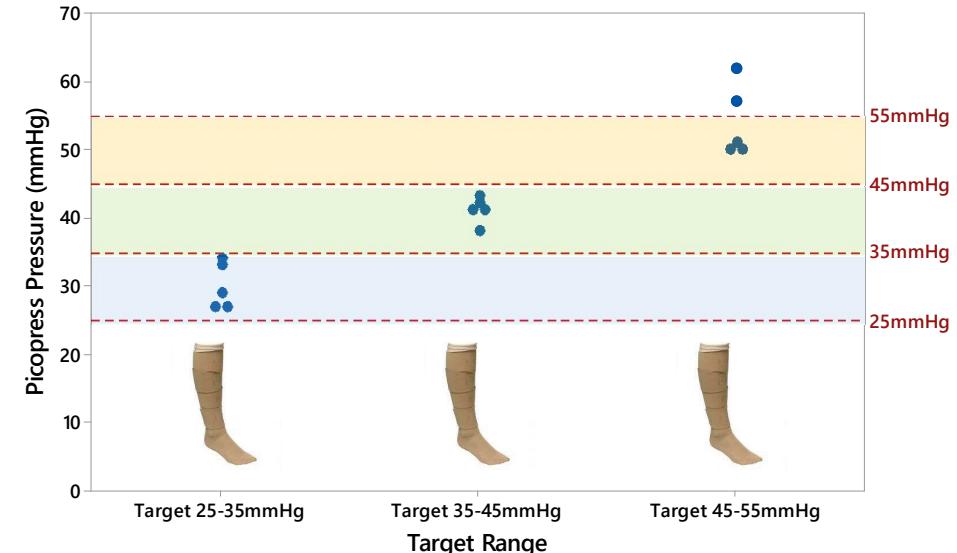


Guided Compression

Tight Alright Guided Compression using Multiple Bandage Types



Tight Alright Guided Compression at Various Ranges (AVW application)



NUI Galway
OÉ Gaillimh



BIOINNOVATE
IRELAND

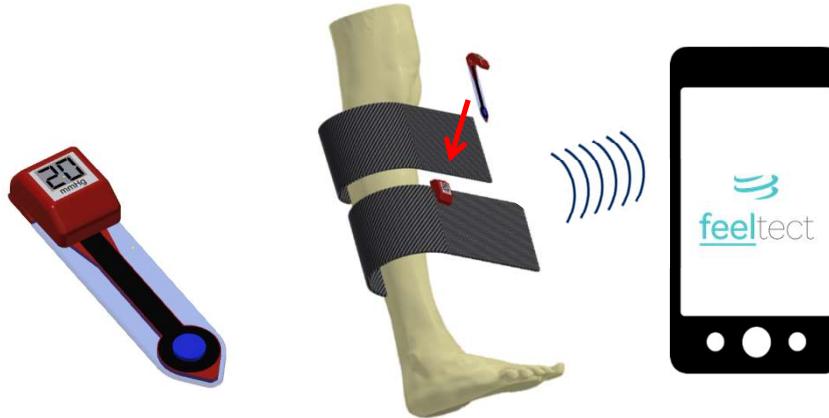
ENTERPRISE
IRELAND
where innovation means business



European Union
European Regional
Development Fund

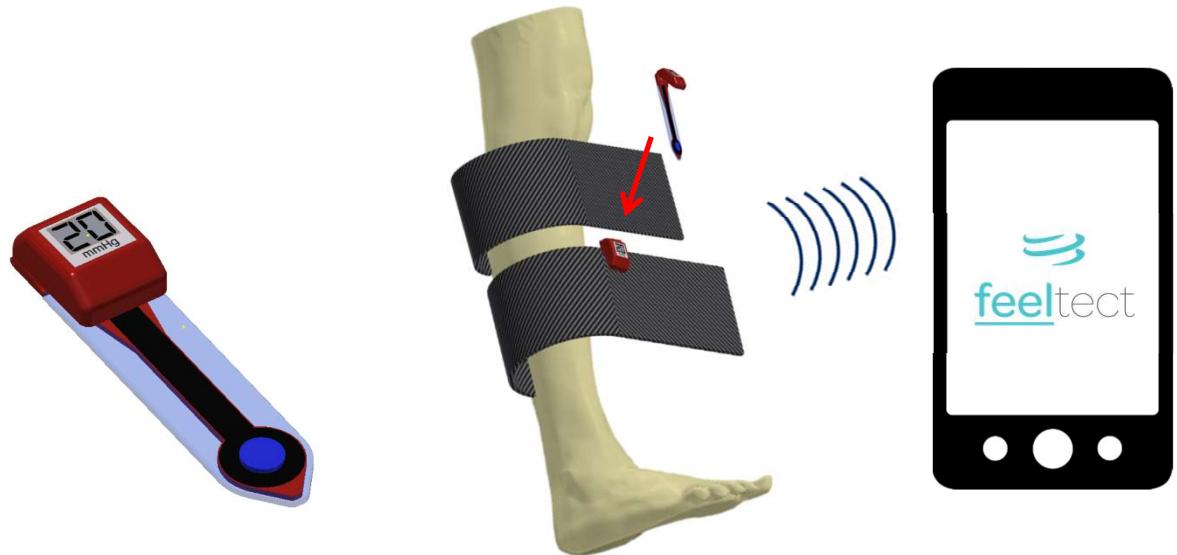


Summary Points



- **Device design:** Hinged arms, unobtrusive, tailored dimensions, selected materials.
- **Flexural rigidity:** Meets the rigidity required for inserting in an applied bandage.
- **Enhanced sensitivity:** Force concentrator can heighten response to pressure.
- **Calibration:** Linearity dependent on radius of curvature.
- **Device comparison:** Comparative performance to gold standard device.
- **Calibration maintenance:** Calibration maintained after 10,000 cycles.
- **Pressure guidance:** Application of targeted sub-bandage pressure using different compression systems.

Future Directions



- **Outer arm:** Develop wireless, miniaturised electronics.
- **Bandage integration:** Understanding interaction between device placement and bandage application.
- **Clinical validation:** Usability/functionality studies with VLU patients as the basis for efficacy studies.

The Team



Dr Andrew Cameron
Project Lead



Dr Darren Burke
Technical Lead



Dr Georgina Gethin
Clinical Collaborator (Nursing)



Dr Myles Mc Garrigle
**Manufacturing and
Design Engineer**



Dr Adnan Elahi
Advisor (Technical)



Prof. Mary-Paula Colgan
**Clinical Collaborator (Vascular
Medicine)**



Prof. Garry Duffy
Innovation Strategist



Dr Scott Robinson
**Clinical Collaborator (Vascular
Surgery)**



Mr Rafael Mazuz
Advisor (Wound Care Market)

Development of a pressure sensing device for use in compression therapy of venous leg ulcers

Dr Andrew Cameron
andrew.cameron@bioinnovate.ie
+353 87 184 0912
www.feeltect.com

*Room 1001, Human Biology Building, NUI Galway
University Rd, Galway, Ireland*



European Union
European Regional
Development Fund

**Health
Innovation
Hub Ireland**