Assessing the potential for pressure-sensing, connected-health technology to improve implementation of compression therapy.

Andrew Cameron PhD[1], Darren Burke PhD[1]

1. FeelTect Limited

eit Health
NDRC BEST PLACE TO START
NUI Galway OÉ Gaillimh
BIOINNOVATE IRELAND NEEDS DRIVEN OPPORTUNITY
ENTERPRISE IRELAND where innovation means business
European Union European Regional Development Fund
Health Innovation Hub Ireland

Disclosures

- Start-up company formed, FeelTect Ltd, with the aim of commercialising the Tight Alright technology.
- Patents #WO2020127610A1 & PCT/EP2021/086036
- FDA registration (Class I 510K Exempt): D485851
- Basic UDI-DI/EUDAMED DI Code: B-TightAlrightGK
- Not yet available for commercial sale

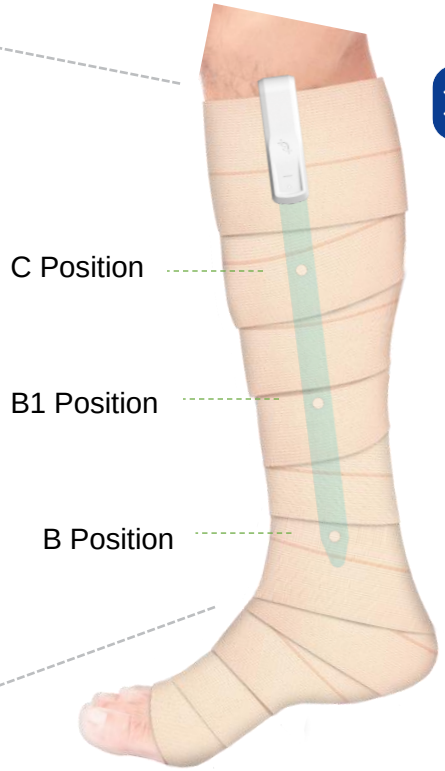
Technology Objectives

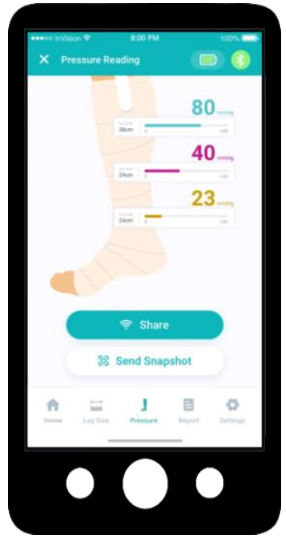
Product Type	Measurement	Accurate	Wearable	Remote Patient Management	Data Driven Optimisation
Traditional Compression	✗	✗	✓	✗	✗
Physical Indicators	✓	✗	✓	✗	✗
Handheld Pressure Sensors	✓	✓	✗	✗	✗
Wearable Pressure Sensing Device	✓	✓	✓	✗	✗
Wearable Pressure Sensing Device + Digital Platform	✓	✓	✓	✓	✓

Point-of-Care Solution

Electronics Clip

Sensing Arm



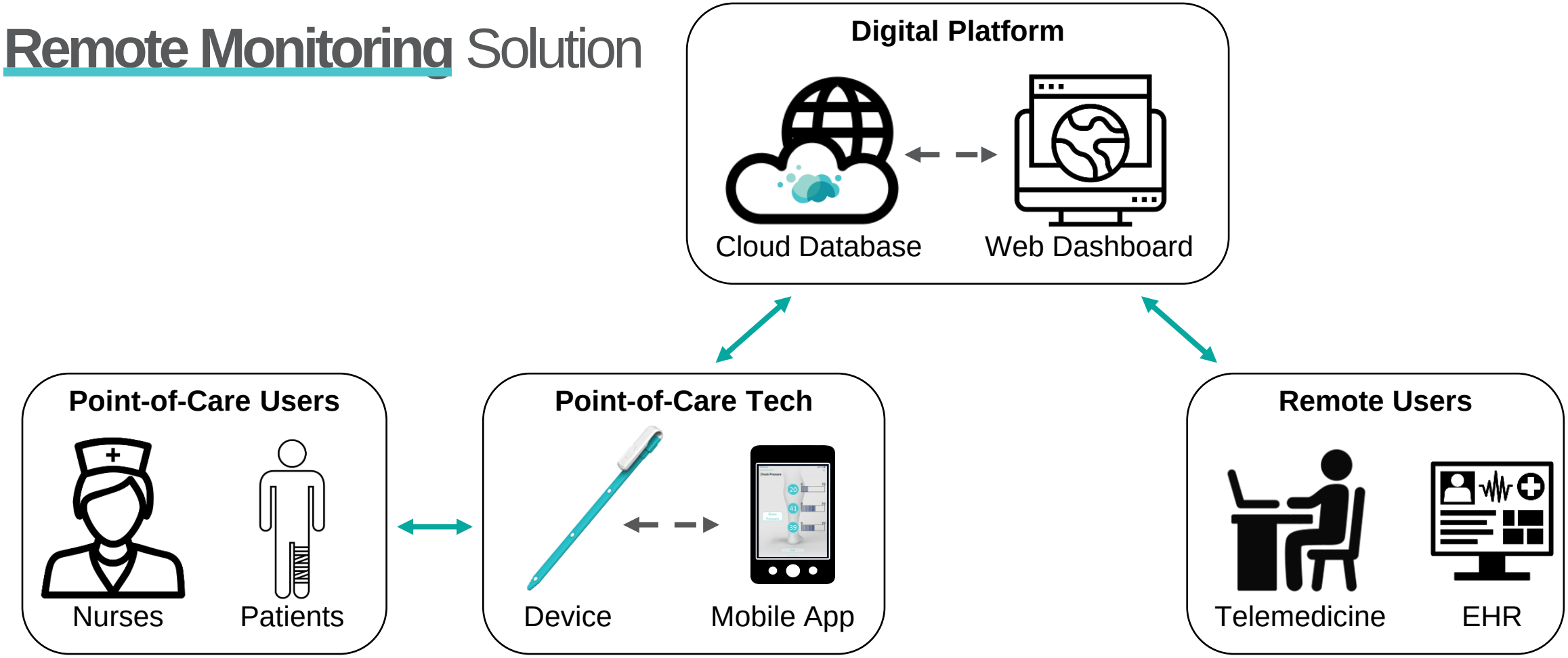


Mobile App

Clean Sheath

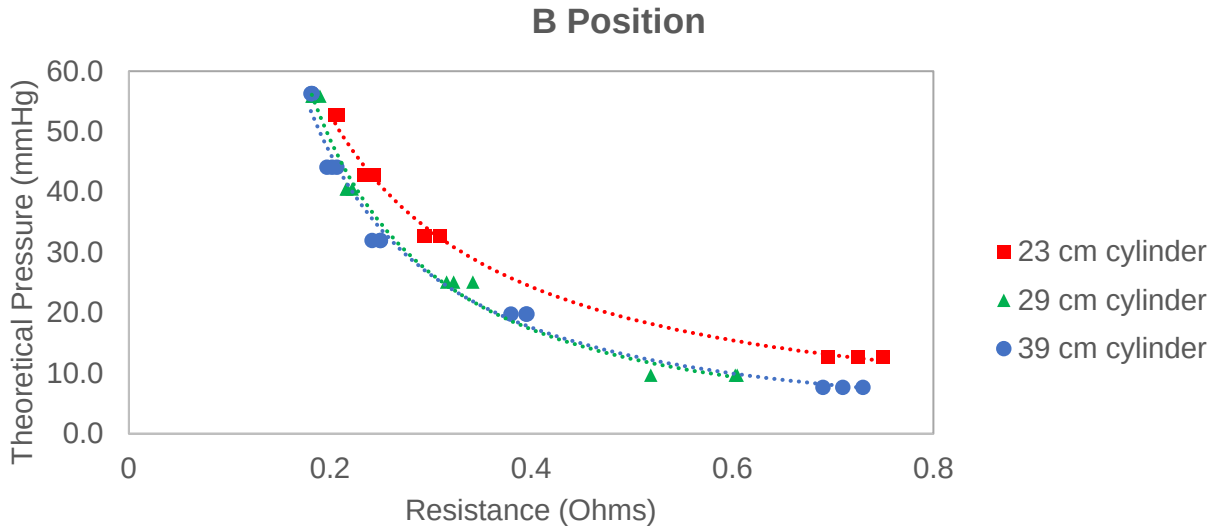
Guides consistent application of gold-standard treatment – **reducing healing times**.

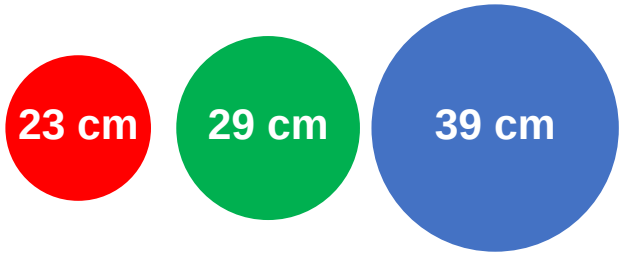
Remote Monitoring Solution

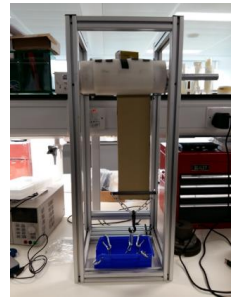


Enables remote monitoring, supported self-management, and data-driven optimisation – **reducing provider workload**.

Calibration Curves

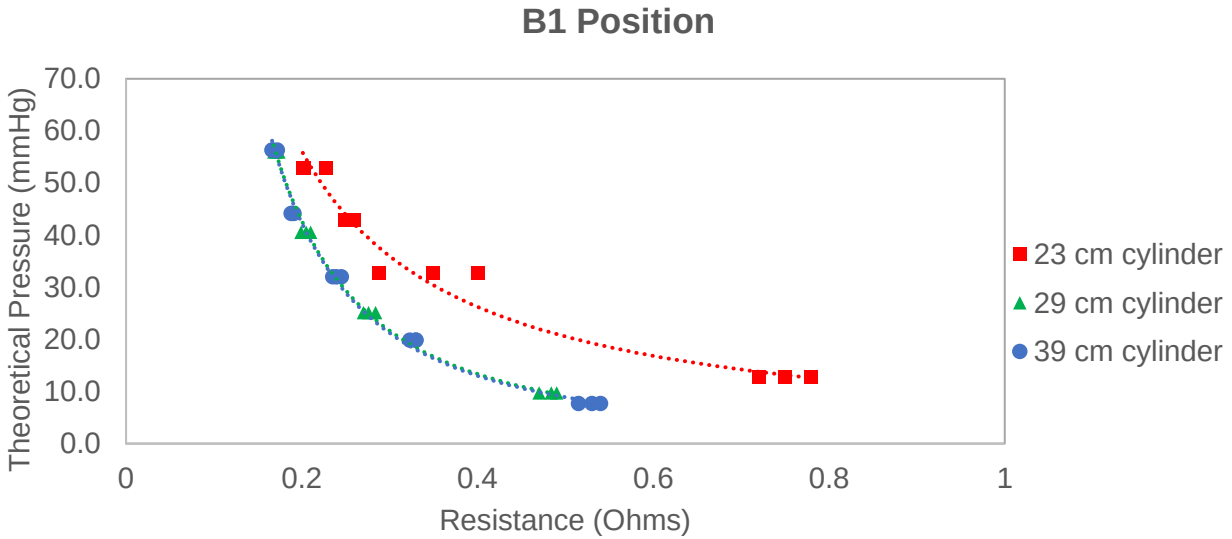


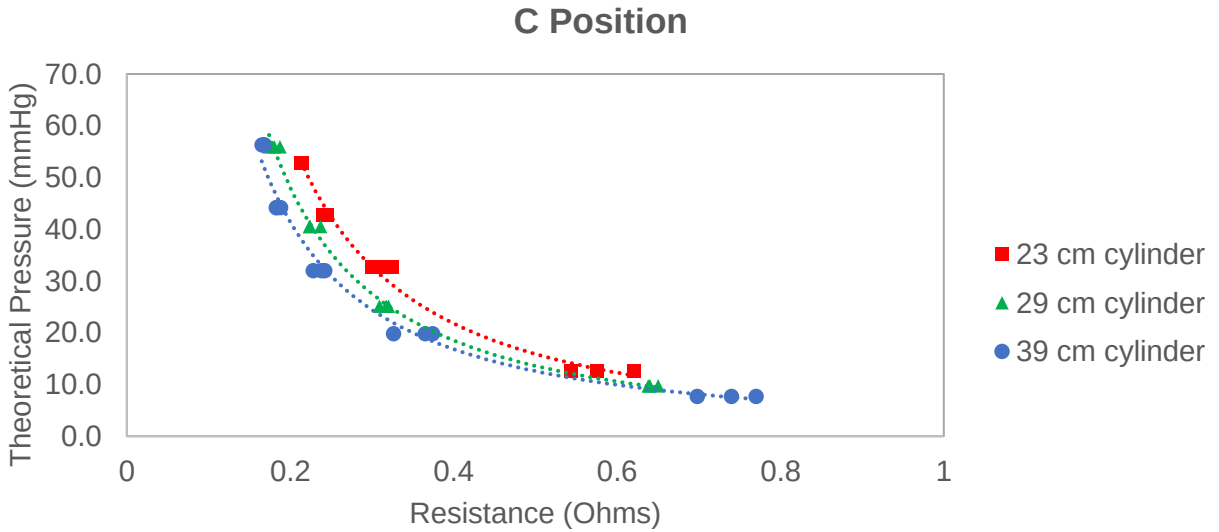




LaPlace's Law[1]:

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





Study Objectives

1. **Assess opportunities for impacting treatment regimens**
   - Can monitored pressure and targeted bandage changes be used to control/reduce impacts from swelling reduction?
   - Can foot positioning be used to influence sub-bandage pressure application?
2. **Assess opportunities for impacting self-management**
   - Can remotely-monitored pressure and self-managed compression be used to augment point-of-care clinical application?
3. **Assess opportunities for defining treatment metrics**
   - Is there a potential to process data to give meaningful metrics from large pressure monitoring data sets?

Treatment Regimen

Coban 2-Layer System by 3M (2LCS)

Treatment Regimen

Initial Application:
0 hrs

20 hours

Wear/monitor:
0-20 hrs

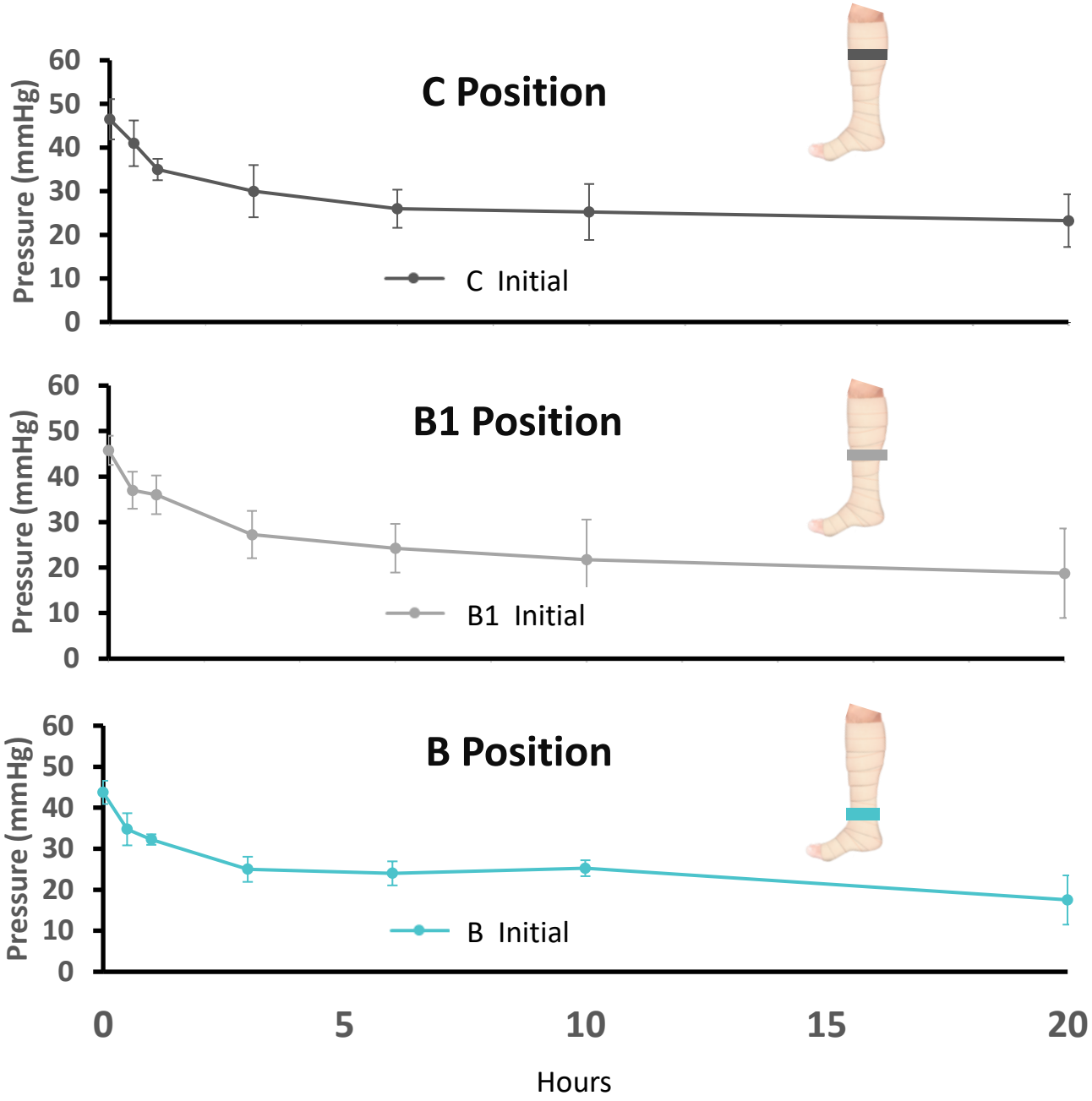
Reapplication:
20 hrs

6 hours

Wear/monitor:
20-26 hrs

Treatment Regimen

Position	0-6 hrs pressure loss	0-20 hrs pressure loss
C position (mmHg)	20.5 ± 4.8	23.3 ± 10.8
B1 position (mmHg)	21.5 ± 9	27 ± 11.5
B position (mmHg)	19.8 ± 4.8	26.5 ± 6.5



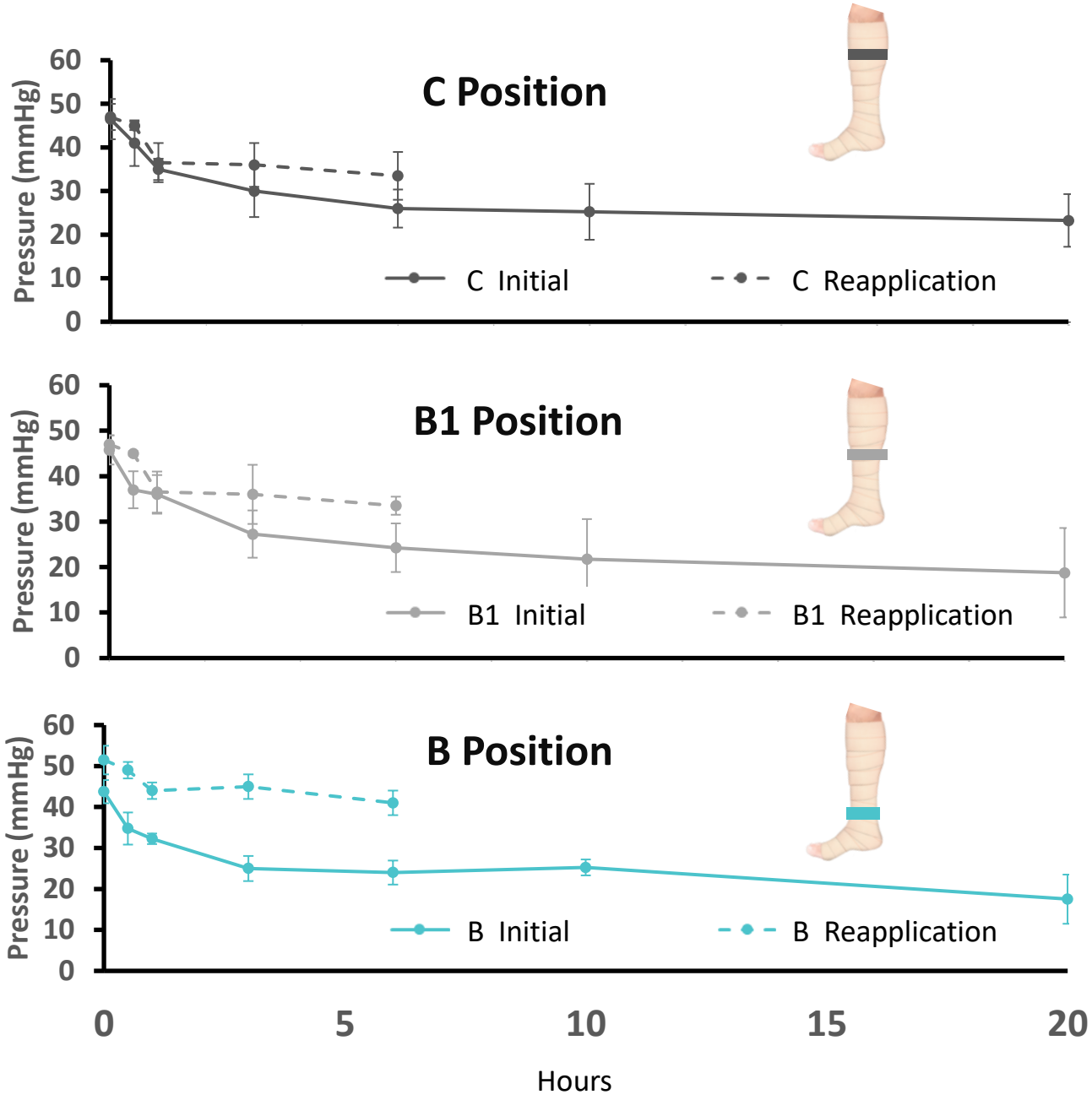
Treatment Regimen

Reapplication

Position	0-6 hrs pressure loss	0-20 hrs pressure loss	20-26 hrs pressure loss
C position (mmHg)	20.5 ± 4.8	23.3 ± 10.8	13.5 ± 3.5
B1 position (mmHg)	21.5 ± 9	27 ± 11.5	5 ± 5.6
B position (mmHg)	19.8 ± 4.8	26.5 ± 6.5	10.5 ± 0.7

Initial

Reapplication



Treatment Regimen

Reapplication

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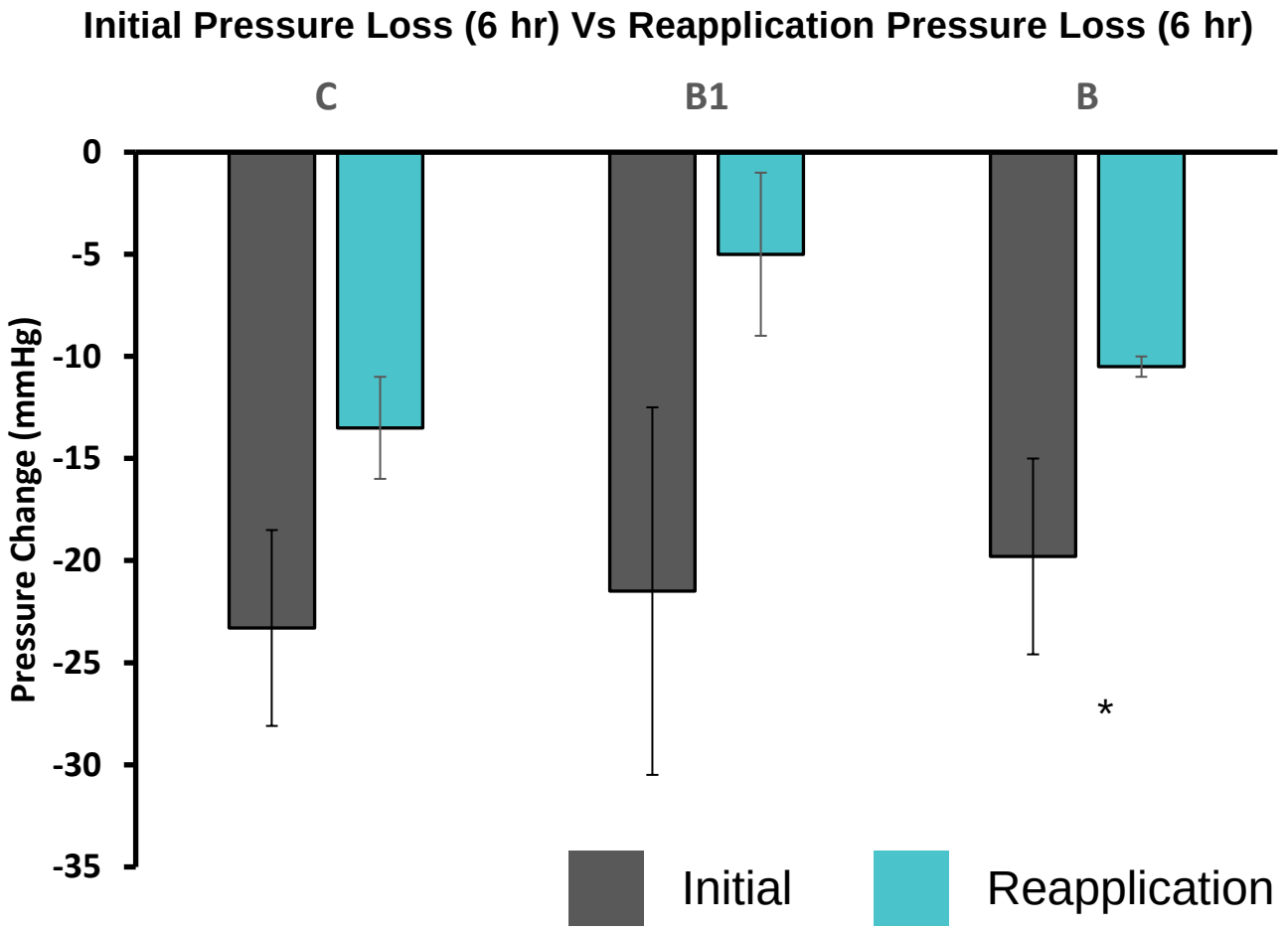
B1 position (mmHg)	21.5 ± 9	27 ± 11.5	5 ± 5.6
B position (mmHg)	19.8 ± 4.8	26.5 ± 6.5	10.5 ± 0.7

Initial Reapplication



** Statistically significant using T Test (P<0.05, n=4)*

Treatment Regimen

Neutral position during application

Dorsiflex during application

Journal of Wound Care, Vol. 32, No. 3 · Practice

Relative cost-effectiveness of three compression bandages in treating newly diagnosed venous leg ulcers in the UK

Julian F Guest, Graham W Fuller

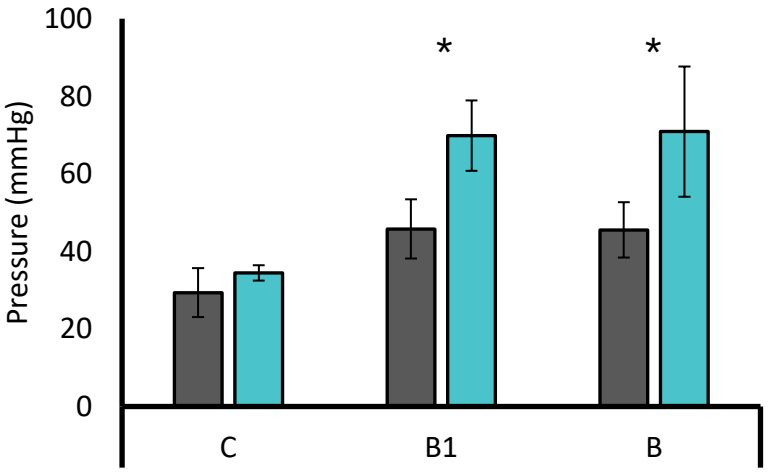
Published Online: 17 Mar 2023 | https://doi.org/10.12968/jowc.2023.32.3.146

- 3M Coban 2-Layer System
- L&R Actico with Cellona Padding
- UrgoKTwo

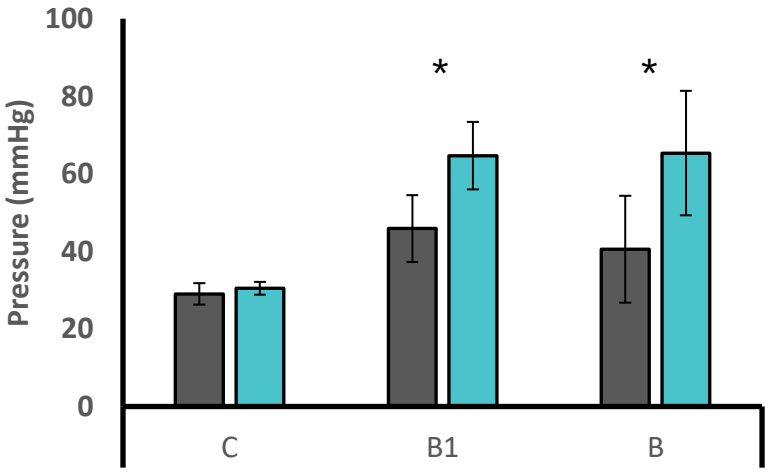
Treatment Regimen

Post-bandage Pressure in Dorsiflexion

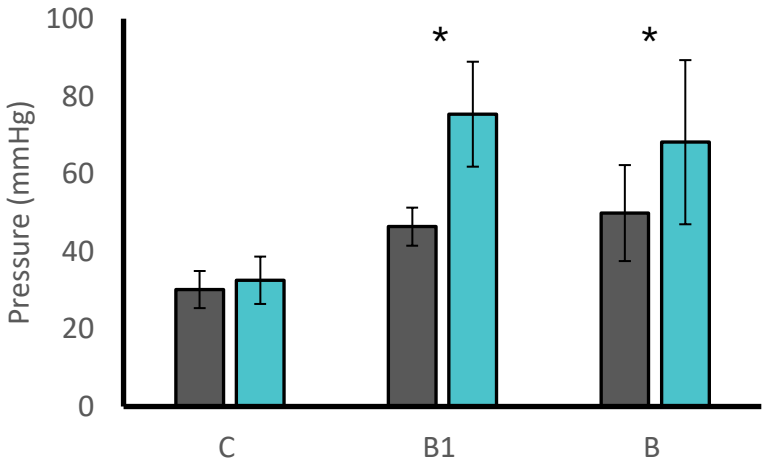
L&R Actico with Cellona Padding



3M Coban 2-Layer System



UrgoKTwo



Dorsiflex during application

Neutral position during application

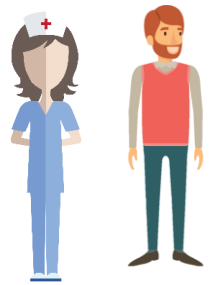
** Statistically significant using T Test (P<0.05, n=6)*

Self Management

Juxtacures Adjustable Velcro Wrap by medi (AVW)

Self Management

UNGUIDED COMPRESSION (2LCS)



GUIDED COMPRESSION (2LCS)

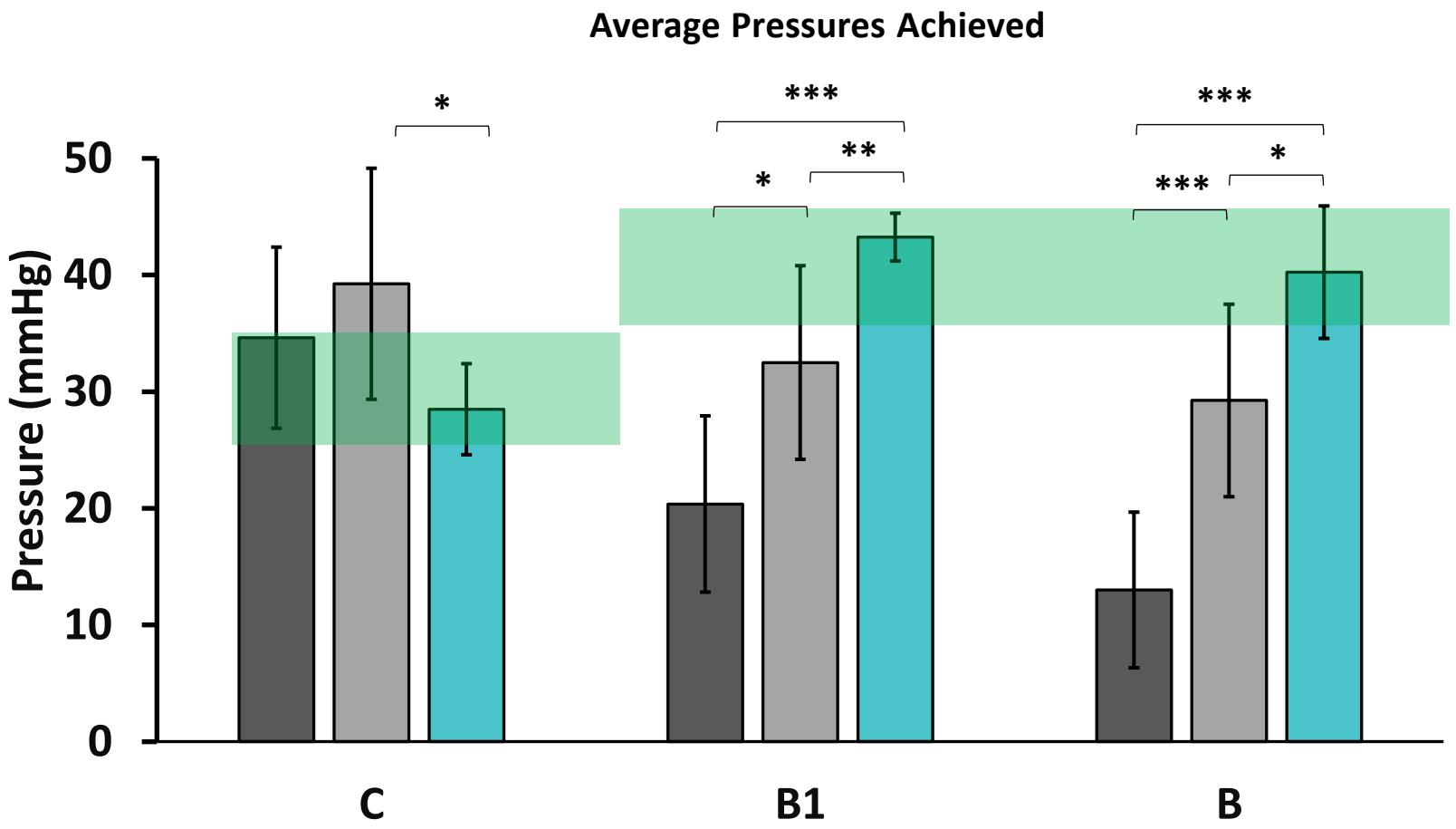
REMOTELY GUIDED COMPRESSION (AVW)

Self Management

Unguided 2LCS

Guided 2LCS

Remotely Guided AVW

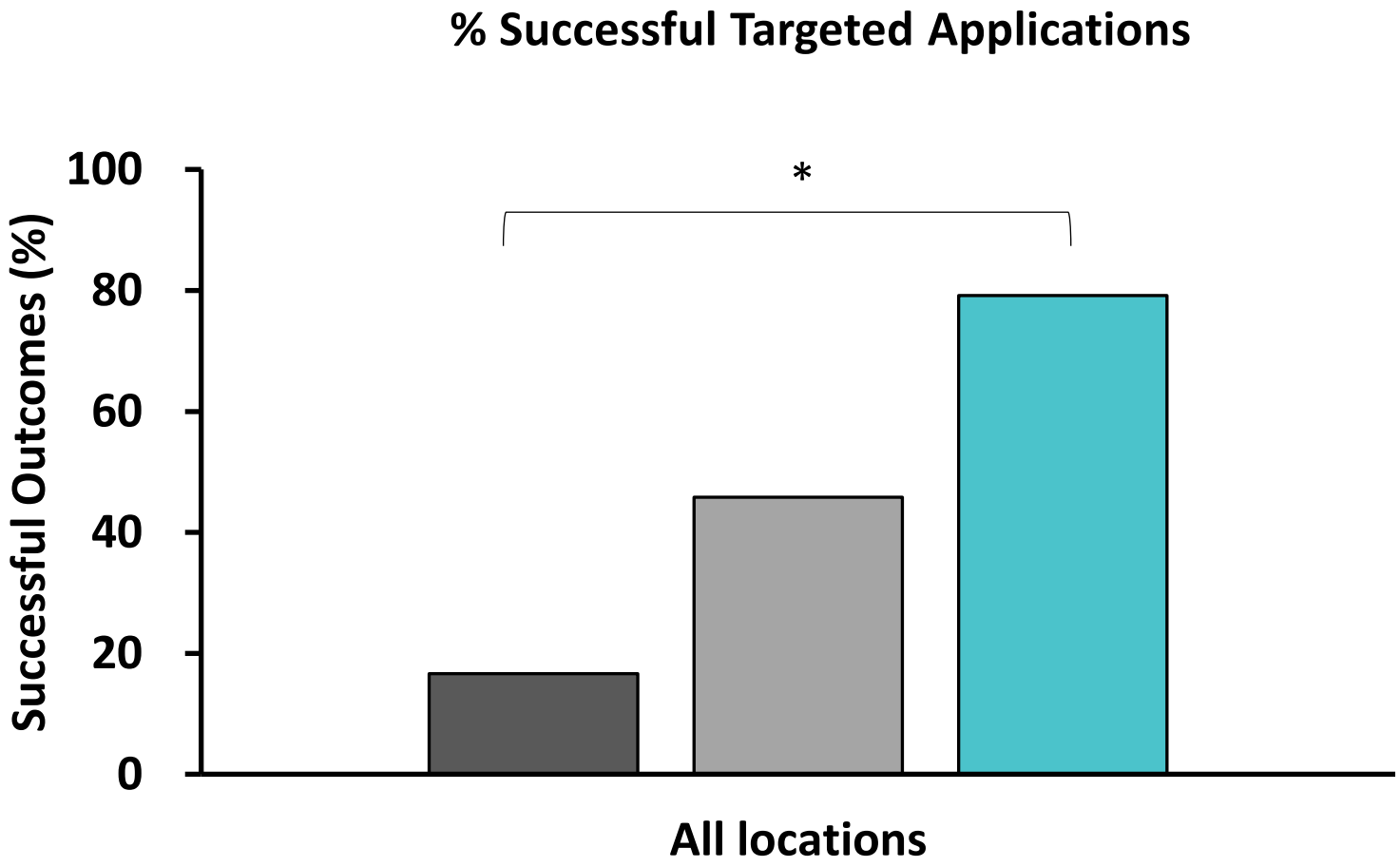


Self Management

Unguided 2LCS

Guided 2LCS

Remotely Guided AVW



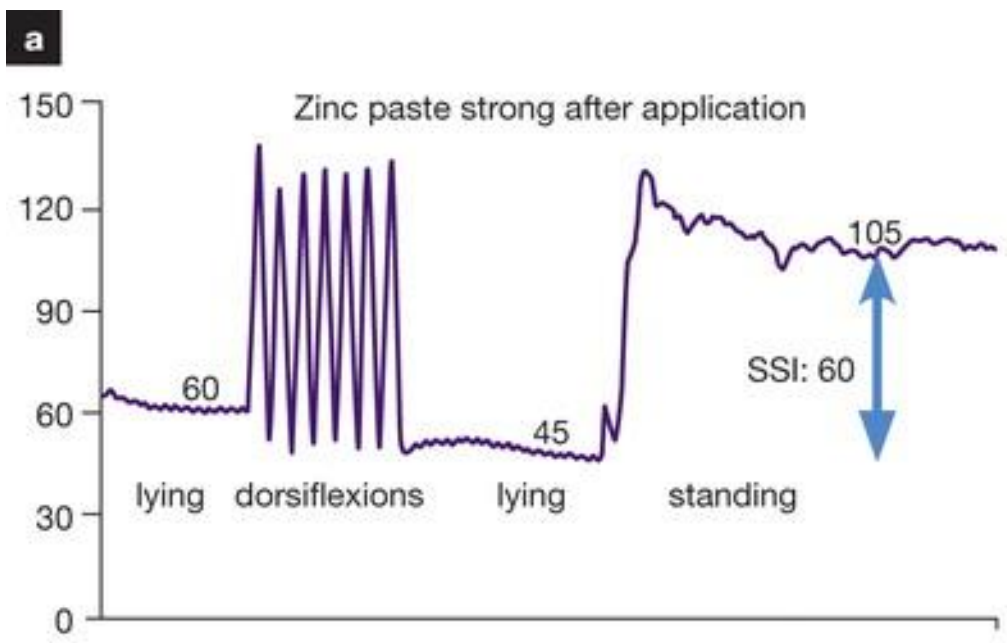
Performance Metrics

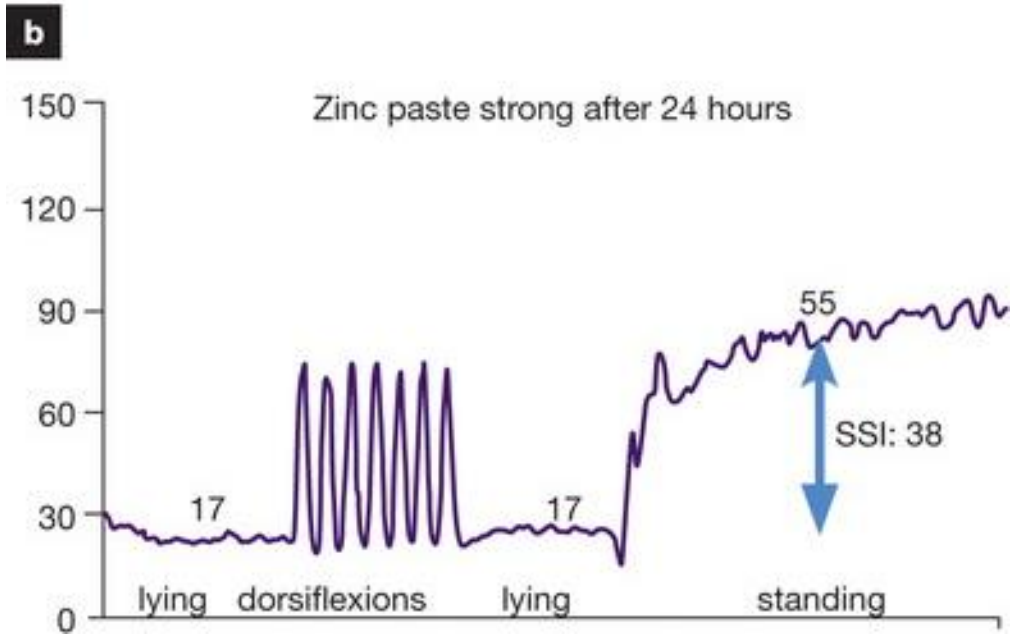
Journal of Wound Care, Vol. 25, No. Sup9 · Education

The Static Stiffness Index: an important parameter to characterise compression therapy *in vivo*

H. Partsch ✉, J. Schuren, G. Mosti, J.P Benigni

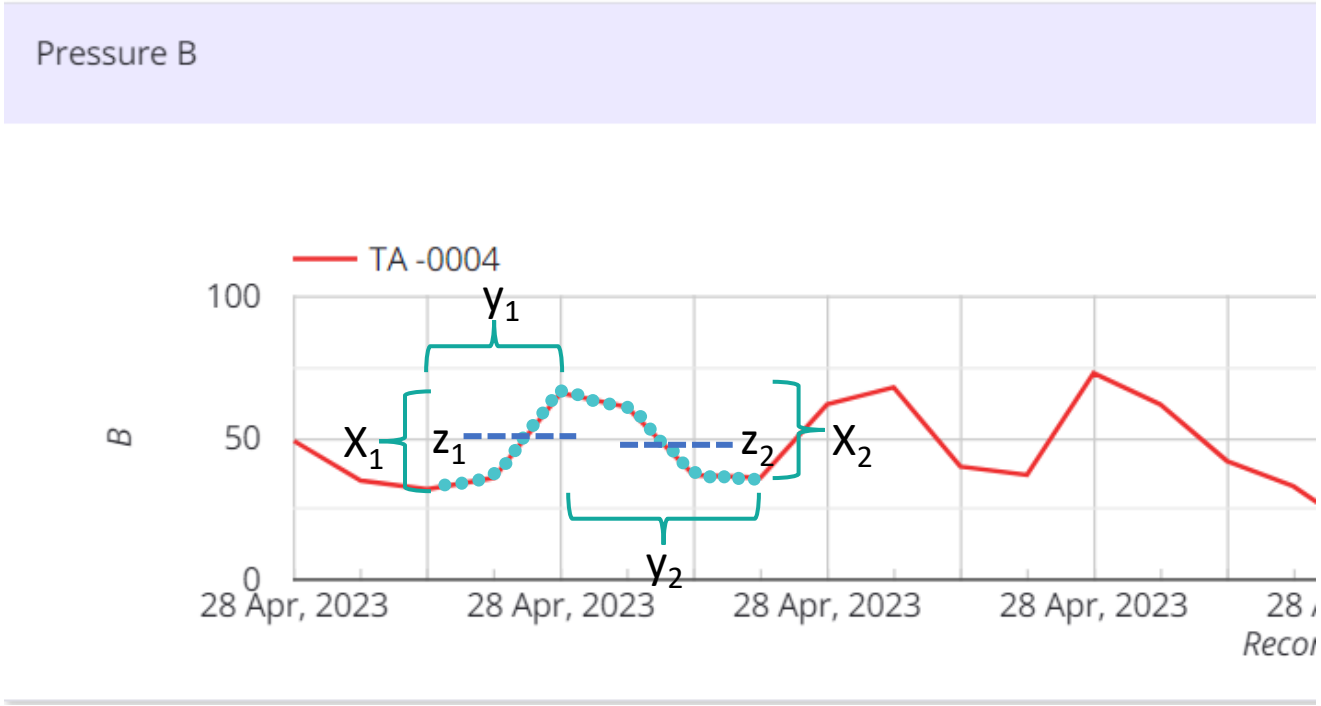
Published Online: 9 Sep 2016 | https://doi.org/10.12968/jowc.2016.25.Sup9.S4





Performance Metrics

$$Metric\ \#1 = \sum \left(\frac{X_i \times Z_i}{Y_i}\right)$$

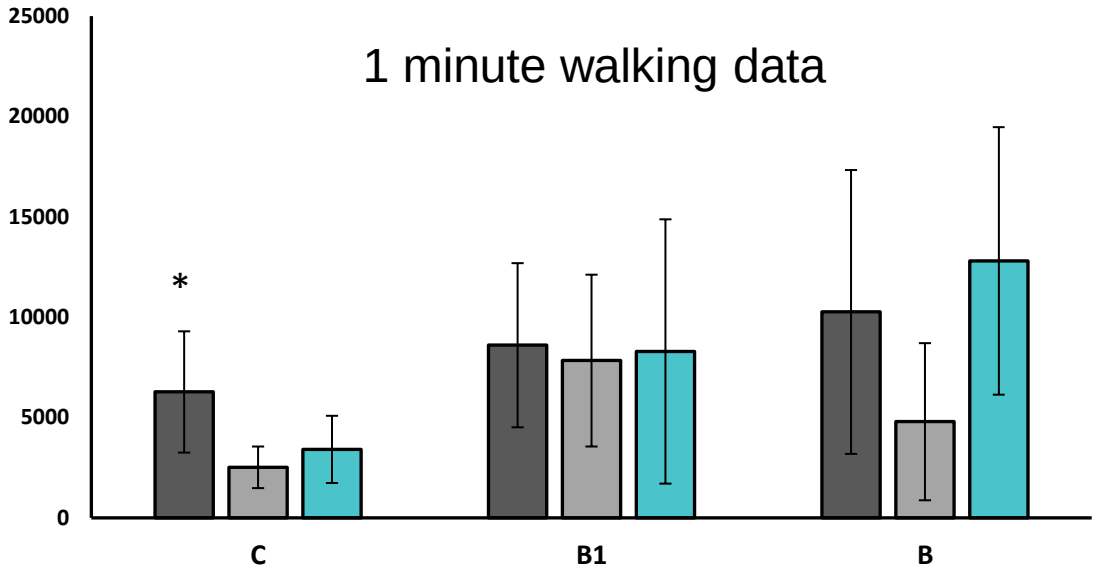


X_i = Individual amplitudes (SSI)
Y_i = Individual periods (rate)
Z_i = Individual average of amplitude values (magnitude)

L&R Actico with Cellona Padding

3M Coban 2-Layer System

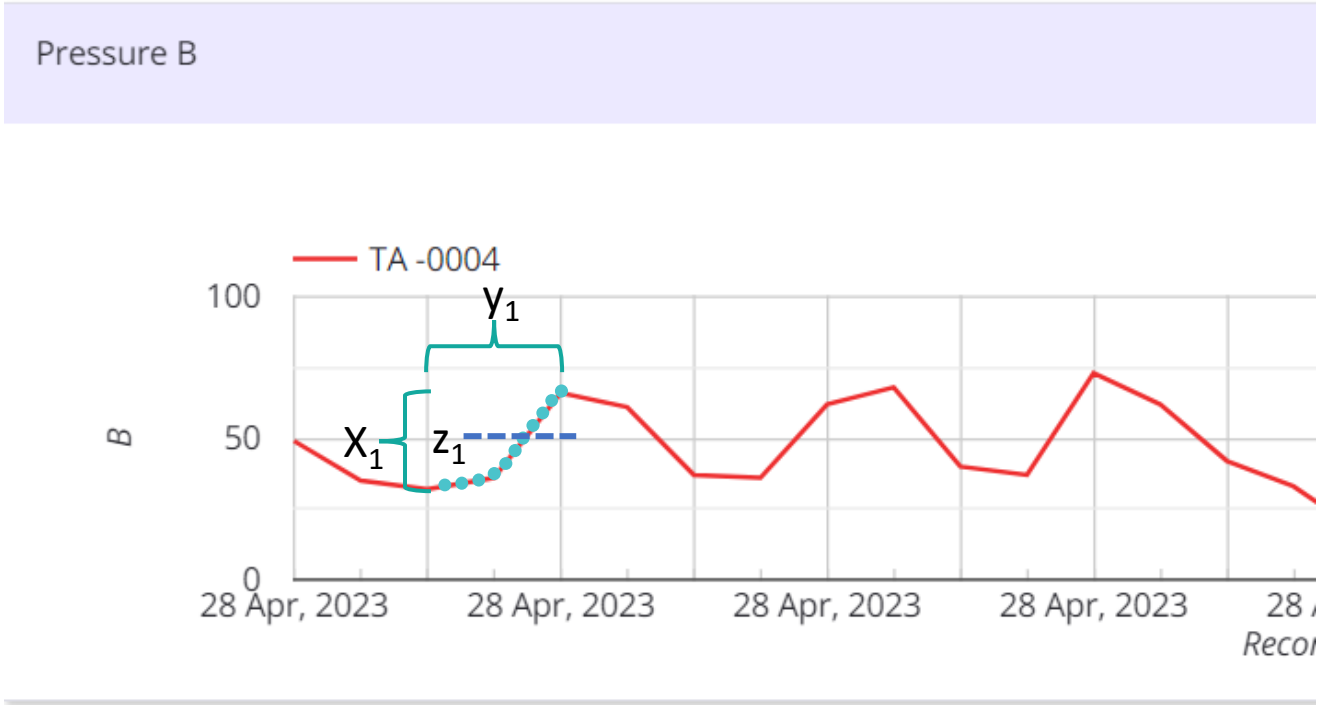
UrgoKTwo



** Statistically significant using T Test (P<0.05, n=6)*

Performance Metrics

$$Metric\ \#2 = \sum \left(\frac{X_i \times Z_i}{Y_i}\right)$$



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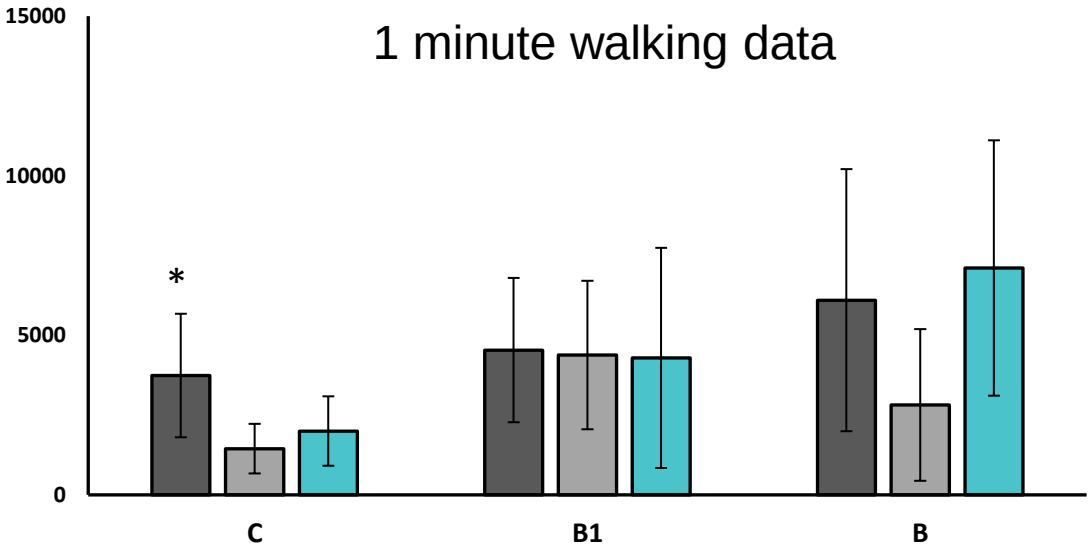
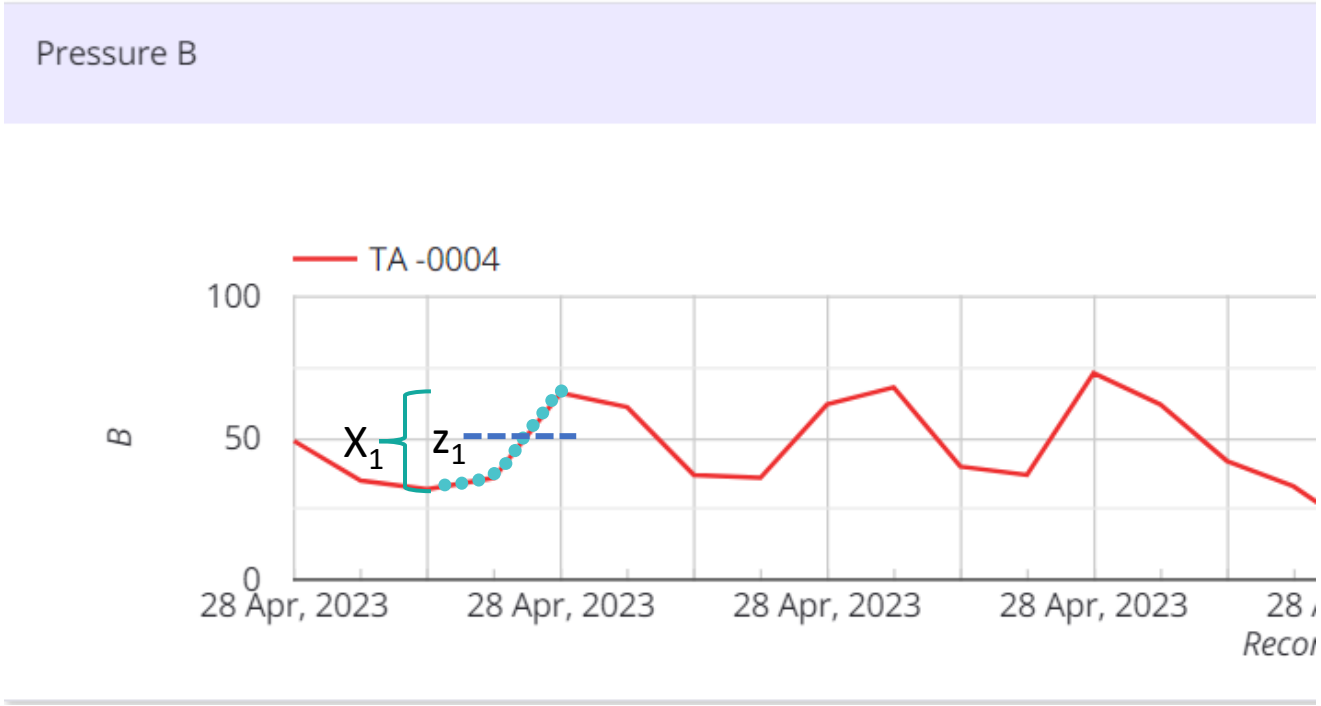


** Statistically significant using T Test (P<0.05, n=6)*

X_i = Individual amplitudes (inclining SSI)
Y_i = Individual periods (inclining rate)
Z_i = Individual average of amplitude values (inclining magnitude)

Performance Metrics

$$Metric\ \#3 = \sum X_i \times Z_i$$



X_i = Individual amplitudes (inclining SSI)
Z_i = Individual average of amplitude values (inclining magnitude)

L&R Actico with Cellona Padding

3M Coban 2-Layer System

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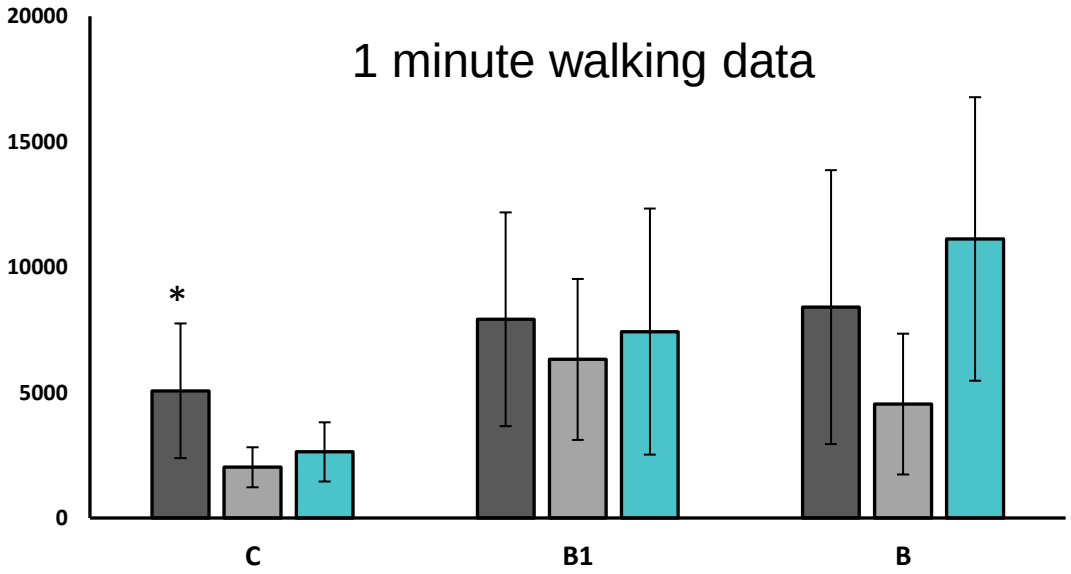

** Statistically significant using T Test (P<0.05, n=6)*

Project Summary

- **Limitations in current compression measurement options**
  - Measurement, accuracy, wearability, remote monitoring
- **Tight Alright**
  - Wearable device with electronics clip and sensing arm
  - Mobile app
  - Digital platform (cloud database/web dashboard)
- **Treatment Regimens**
  - Monitoring can identify timings for bandage changes
  - Pressure monitoring could help refine application techniques – improved consistency
- **Self Management**
  - Remotely transferred pressure readings open opportunities for supported self-management
  - Remotely guided volunteers had a 4-fold improvement in targeted pressure application
- **Performance Metrics**
  - Pressure amplitude, rate, and magnitude could demonstrate dynamic differences between products

Realise the Full Potential of

Compression Therapy,

Through **Safety**, **Efficacy**, and **Empowerment**

feeltect

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