**Title**

A measurement array to assess prosthesis-limb interface pressures which avoid soft tissue damage

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**(498 words Total)**

**Introduction**

The soft tissues in an amputated residual limb form a critical interface with a prosthesis, transferring load during activities of daily living. This inevitably creates pressure and shear forces at the skin-device interface, which can result in recurring soft tissue discomfort and damage. There are critical relationships between tissue damage and the magnitude and duration of interface pressure and tissue strain[1], where critical vascular and lymphatic vessels can be occluded by external loads. The aim of this study was to develop a human *in-vivo* protocol for assessing the biomechanical and physiological response of lower limb soft tissues to loads representing prosthesis use.

**Methods**

Ten participants without amputation were recruited (6M:4F, 23-36yrs). A sphygmanomometer was applied to the right calf mimicking a total surface bearing prosthesis, containing a gel liner and indenters representative of socket rectification. The cuff was inflated from 20-60 mmHg in 10 mmHg increments every 10 minutes. An array of measurements was taken at three sites relevant to prosthetic load bearing, to assess biomechanical response and characterise tissue damage risk[2]:

- Interface pressures (Oxford Pressure Monitor II, Talley, UK);

- Transcutaneous oxygen tension ($T_cPO_2$) at all sites and carbon dioxide tension ($T_cPCO_2$) at one site, using skin mounted sensors (TCM4, Radiometer, Denmark);

- T1 Magnetic Resonance Imaging (MRI) at baseline, 20 mmHg and 60 mmHg to characterise direct tissue deformation.

**Results**

At 60 mmHg cuff pressure, interface pressures ranged from 55-90 mmHg, typically highest at the patellar tendon (61-90 mmHg) and lowest at the posterior calf (55-73 mmHg).

Exemplar transcutaneous data are presented portraying the two trends observed across participants; decreasing $T_cPO_2$ corresponding with an >25% increase in carbon dioxide above an apparent threshold pressure (Fig.1A) or with <25% increase in $T_cPCO_2$ (Fig.1B).

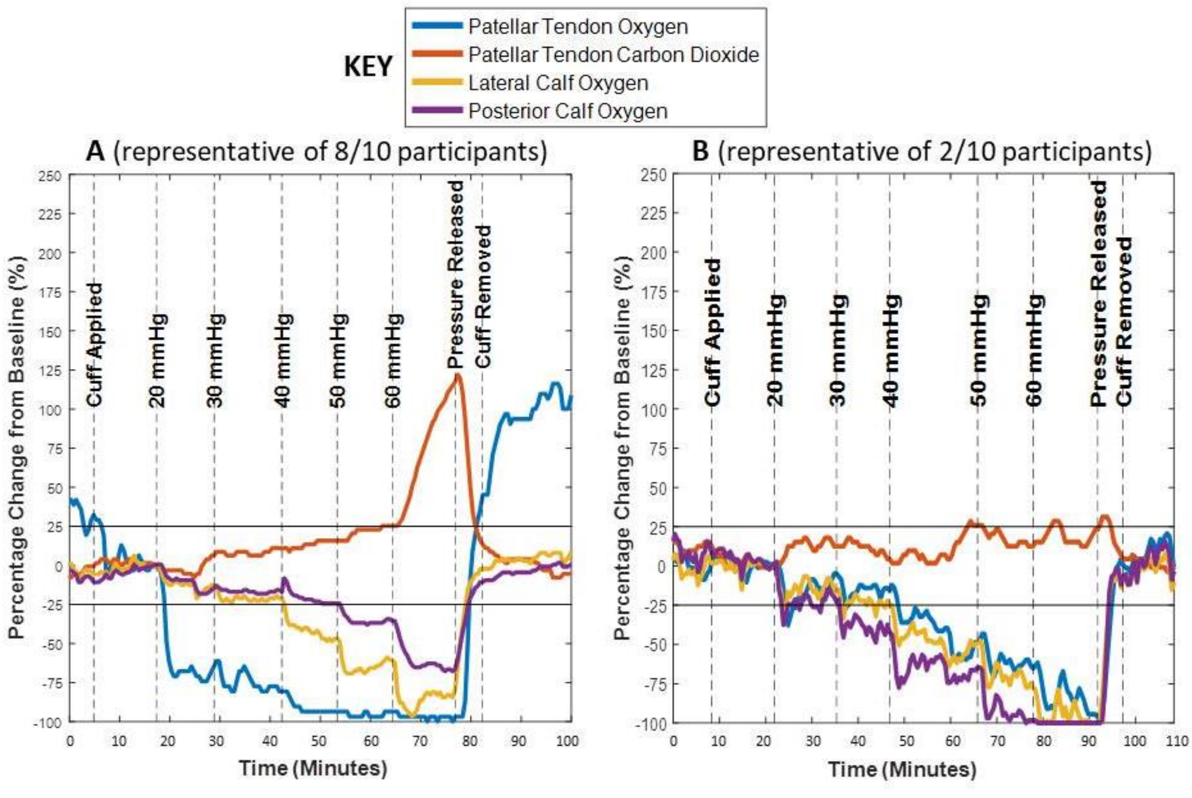


**Figure 1 Transcutaneous Oxygen and Carbon Dioxide pressure data for two participants' calves under incremental sphygmanomometer loading from 20-60 mmHg**

Decreased $T_cPO_2$ and increased $T_cPCO_2$, at the patellar tendon, were indicative of an ischaemic tissue response, observed in:

- 6/10 participants by 40 mmHg, at the patellar tendon;
- 7/10 participants by 50 mmHg, at the lateral calf;
- 5/10 participants by 50 mmHg, at the posterior calf; and
- 8/10 participants by 60 mmHg at all measurement sites.

Exemplar MRI data are presented for one participant (Fig.2).

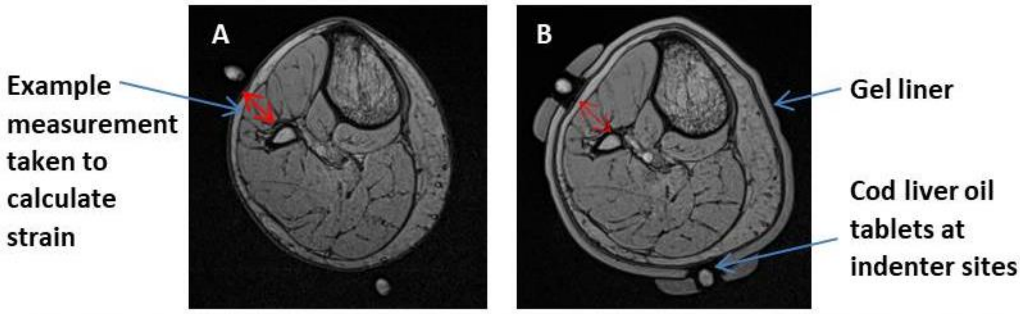


**Figure 2 Corresponding transverse section MR images displaying calf of one participant at (A) baseline and (B) loaded with 60 mmHg cuff pressure**

Gross strain at indenters ranged from ≈5-38% (mean≈16%) during 60 mmHg loading.

**Discussion**

The applied loads resulted in an ischaemic response of the skin tissues, represented by a decrease in $T_cPO_2$ and an increase in $T_cPCO_2$, precursors to tissue damage. MRI revealed gross tissue strains of ≈5-38% with most of the deformation occurring upon inflation to 20 mmHg. These preliminary tests involved participants with intact limbs, providing information relevant to early prosthetic rehabilitation using a temporary prosthesis. This array of measurement techniques will be translated for prosthesis users, to enhance knowledge of biomechanical adaptation and behaviour of soft tissues following lower limb amputation. In conjunction with interface sensors, this will provide evidence to inform socket design and gait rehabilitation.

**Acknowledgements**

Study ethics reference ERGO29696. The authors acknowledge funders EPSRC (EP/N509747/1, EP/N02723X/1), IfLS and RAEng (RF/130).

**References**

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