

Discomfort/Pain and Tissue Oxygenation at the Lower Limb During Circumferential Compression: Application to Soft Exoskeleton Design

Tjasa Kermavnar, Kevin J. O'Sullivan, Adam de Eyto, and Leonard W. O'Sullivan^{ID},
University of Limerick, Ireland

Objective: To establish the relationship between circumferential compression on the lower limb during simulated ramp and staircase profile loading, and the resultant relationship with discomfort/pain and tissue oxygenation.

Background: Excessive mechanical loading by exoskeletons on the body can lead to pressure-related soft tissue injury. Potential tissue damage is associated with objective oxygen deprivation and accompanied by subjective perception of pain and discomfort.

Method: Three widths of pneumatic cuffs were inflated at the dominant thigh and calf of healthy participants using two inflation patterns (ramp and staircase), using a computer-controlled pneumatic rig. Participants rated discomfort on an electronic visual analog scale and deep tissue oxygenation was monitored using near infrared spectroscopy.

Results: Circumferential compression with pneumatic cuffs triggered discomfort and pain at lower pressures at the thigh, with wider cuffs, and with a ramp inflation pattern. Staircase profile compression caused an increase in deep tissue oxygenation, whereas the ramp profile compression decreased it.

Conclusion: Discomfort and pain during circumferential compression at the lower limb is related to the width of pneumatic cuffs, the inflation pattern, and the volume of soft tissue at the assessment site. The occurrence of pain is also possibly related to the decrease in deep tissue oxygenation during compression.

Application: Our findings can be used to inform safe and comfortable design of soft exoskeletons to avoid discomfort and possible soft tissue injury.

Keywords: exosuit human interaction, tissue loading and comfort, wearable devices, assistive technologies, oxygenation, product design

INTRODUCTION

With the advent of robotics in recent years, exoskeletons have become increasingly topical in the medical field as assistive and rehabilitation devices. To date, the vast majority of exoskeletons are manufactured from hard materials that apply mechanical loads to the user's body via rigid components. Recently, attempts are being made to develop lighter, low-profile soft robotic devices, referred to as soft exoskeletons or exosuits (Asbeck et al., 2014), which help address usability issues with traditional hard robotics and hard exoskeletons.

Physical human-robot interfaces mediate the transfer of physical interaction between the user and the exoskeleton (De Santis et al., 2008). Soft exoskeletons/exosuits (hereafter mutually termed exosuits) exert external pressure on the limbs by means of circumferential compression, which results in mechanical loading of the tissues, mainly skin, adipose, and muscle tissues. Excessive mechanical loading can lead to soft tissue injury and cause pressure ulcers due to localized ischemia (Bouten et al., 2003; Reenalda et al., 2009; Stekelenburg et al., 2008), impaired lymphatic drainage (Bouten et al., 2003; Reenalda et al., 2009), elevation of local lactic acid levels (Stekelenburg et al., 2008), reperfusion injury, or sustained deformation of cells (Agam & Gefen, 2007; Bouten et al., 2003; Reenalda et al., 2009; Stekelenburg et al., 2008). Especially, pressure-related deep tissue injuries that are caused by sustained compression of the deep muscle layers over bony prominences can be potentially life threatening (Agam & Gefen, 2007; Bouten et al., 2003). The risk for soft tissue damage depends not only on the magnitude of external loading but also on its direction, distribution, duration, and

Address correspondence to Leonard W. O'Sullivan, School of Design and Health Research Institute, University of Limerick, Limerick V94 T9PX, Ireland; e-mail: leonard.osullivan@ul.ie

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loading cycle frequency (Bader, 1990; Mak et al., 2001). For example, the maximum safe inflation pressure for inflatable splints used in fractures is considered to be 30–40 mmHg (4–5.3 kPa) (Ashton, 1966), granted that they are only worn until appropriate medical care is available, that is, not more than a few hours.

As detailed in a previous review (Kermavnar et al., 2018a), attempts to establish safe thresholds for the external mechanical loading of soft tissues have been based mainly on interface pressures at load-bearing sites of the body. Previous studies, however, have shown that the relation between interface pressure and internal stress may not be linear (Reenalda et al., 2009), as internal stress is highly dependent on the nature of the intermediary soft tissues, for example, their thickness (Sangeorzan et al., 1989; Tamez-Duque et al., 2015), tone (Linder-Ganz & Gefen, 2009; Sangeorzan et al., 1989), mechanical stiffness (Oomens et al., 2010) and integrity (Sangeorzan et al., 1989), as well as the proximity of bony prominences (Agam & Gefen, 2007; Oomens et al., 2010; Sangeorzan et al., 1989; Tamez-Duque et al., 2015). Moreover, injury thresholds are reported to differ for skin, adipose, and muscle tissue, with the lowest threshold for muscle (Agam & Gefen, 2007). Thus, a safe threshold based solely on research of interface pressure is now considered limited (Agam & Gefen, 2007; Bouten et al., 2003; Oomens et al., 2010; Reenalda et al., 2009).

Pain and discomfort are direct responses of the human body to excessive external loads (Mak et al., 2001), and perceived pain is considered a good indicator of potential tissue damage (Pons, 2008). However, the relationship and distinction between discomfort and pain has not yet been universally agreed upon (Holtmann et al., 1998). Namely, some use the terms interchangeably, or consider discomfort to be a mild form of pain (Meyer & Radwin, 2007; Woodrow et al., 1972), while others define discomfort as a precursor to pain (Vanagaite et al., 1997; Xiong et al., 2010), or a negative feeling that is distinct from pain (Talley et al., 1999). Neumann proposes that discomfort, as opposed to pain, is a complex phenomenon that, among other factors, may include the expectation of

pain; therefore, pain is nearly always associated with discomfort, but discomfort is not necessarily associated with pain (Neumann, 2001). We define discomfort as an unpleasant sensation that occurs before pain, and increases with the increase of pain. Therefore, the intensity of discomfort ranges from barely perceivable (no pain) to unbearable (unbearable pain), and the detection of pain occurs at a certain point between the two extremes. As per definitions used in algometry, the pressure magnitude at which pain occurs is referred to as the pain detection threshold (PDT), and the pressure magnitude that causes unbearable pain, the pain tolerance threshold (PTT).

Previous studies have shown that PDT and PTT differ for different assessment sites at the lower limb and different patterns of pneumatic cuff inflation. Significantly higher PDT and PTT were recorded at cuff positions over smaller volumes of soft tissue, that is, at the calf compared with the thigh, and in the proximity of the knee and ankle joint compared with the widest part of the lower leg. Furthermore, staircase versus ramp pattern revealed higher PDT and PTT (Lindskou et al., 2017).

Considering user-centered design of exosuits, the focus needs to be on the elimination of discomfort, let alone pain. Hence, our aim was to gain insight into the prepain phase of discomfort. According to this, we have proposed in our previous review paper (Kermavnar et al., 2018b) that a modified version of the cuff algometer be used to assess discomfort rather than pain.

Pressure-related deep tissue injury has also been associated with oxygen deprivation due to localized ischemia (Bouten et al., 2003; Stekelenburg et al., 2008) and to reperfusion injury (Herrman et al., 1999; Peirce et al., 2000). Thus, identifying oxygen deprivation before irreversible damage occurs is proposedly useful in establishing safe thresholds for external mechanical loading of tissues. An effective, noninvasive method for assessing muscle tissue oxygenation in vivo is near infrared spectroscopy (NIRS); however, it has not yet been widely recognized in ergonomics and soft-tissue injury prevention. Instead, safe thresholds for the loading of soft tissues still tend to be based

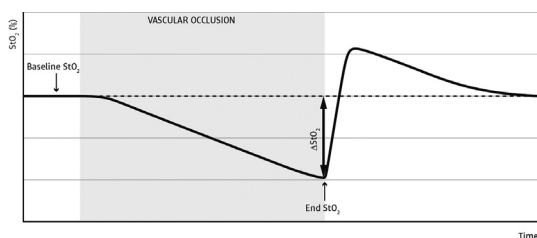


Figure 1. Tissue oxygenation change (ΔStO_2).

solely on interface pressures at load-bearing sites of the body, although researchers have deemed this approach to have many limitations (Agam & Gefen, 2007; Bouten et al., 2003; Oomens et al., 2010; Reenalda et al., 2009).

The aim of this experiment was to study the relationship between circumferential compression of the lower limb (as in exosuit use) and the development of discomfort/pain and tissue oxygenation, depending on (1) assessment site (calf vs. thigh), (2) pneumatic cuff width (5 vs. 12 vs. 22 cm), and (3) pneumatic cuff inflation pattern (ramp vs. staircase).

METHOD

Study Design

The experiment was a $2 \times 3 \times 2$ full factorial design. The independent variables were the assessment site (thigh and calf), pneumatic cuff width (5, 12, and 22 cm) and inflation pattern (ramp and staircase). The dependent variables were Pain Detection Threshold (PDT), discomfort detection threshold (DDT), and the rate of deep tissue deoxygenation ($\text{StO}_{2\text{ slope}}$).

We hypothesized that the magnitude of reduction in deep tissue oxygenation at PDT would influence discomfort and pain detection; therefore, we introduced a new metric, which we refer to as the tissue oxygenation change (ΔStO_2), and define as $\text{StO}_{2\text{ baseline}} - \text{StO}_{2\text{ minimum}}$ (Figure 1). Due to the dynamic effects of the staircase inflation pattern on deep tissue oxygenation, ΔStO_2 was only extracted for the ramp inflation pattern.

Testing was performed in a randomized order, with all cuff widths and inflation patterns used first at one of the assessment sites and then the other.

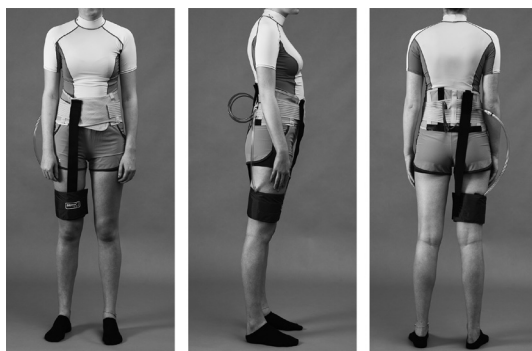


Figure 2. Pneumatic cuff mounting on the body, in this case on the thigh.

Participants

Healthy volunteers were recruited from the University of Limerick. Volunteers were excluded from the study if any of the following criteria were present: (1) BMI $\geq 30 \text{ kg/m}^2$; (2) skin fold at the assessment site $\geq 40 \text{ mm}$; (3) medical history of cardiovascular, respiratory, neurological, or endocrine disease; (4) current musculoskeletal injury or disorder, acute or chronic pain, local skin injury or disorder at the lower limb; (5) use of medications that could influence the cardiovascular, respiratory, or nervous system; (6) special diet or use of food supplements. Participants were required to abstain from caffeine, nicotine, alcohol, and food intake 8 hr prior to testing and were asked to avoid strenuous exercise 24 hr prior to testing.

This research complied with the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board at the University of Limerick (approval #2017_07_03_S&E). Informed consent was obtained from each participant to participate in this research, and for this research to be submitted for publication.

Equipment

Pneumatic cuffs. A Hokanson SC5 tourniquet cuff (width 5 cm), Hokanson Rapid deflate SC12D (width 12 cm), and Hokanson Contoured thigh cuff CC22 (width 22 cm) were used. The cuffs were positioned at the dominant thigh and calf, loosely wrapped with a nonelastic adhesive tape (Leukosilk, BSN medical GmbH, Hamburg, Germany) to ensure an even distribution of pressure, and secured in place with

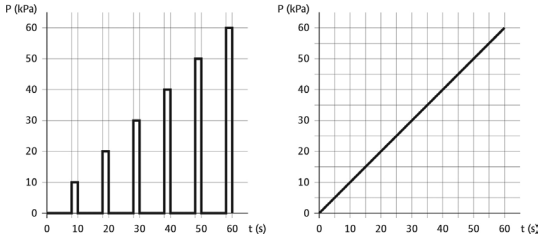


Figure 3. Staircase inflation pattern (left) and ramp inflation pattern (right).

Velcro™ straps attached to a waist belt (Thermoskin Adjustable back stabilizer, United Pacific Industries Pty Ltd, Kilsyth, Australia) at the front and back to prevent it from slipping down the leg (Figure 2).

Computerized cuff inflation apparatus. Cuffs were attached to a computer-controlled bespoke industrial pneumatic pressurized system (Design Pro, Rathkeale Co., Limerick, Ireland) which regulated the pressures as per the treatment conditions. The computerized system also had integrated data input to record the NIRS signals, and the discomfort scores via a handheld visual analog scale (VAS) slider (100 mm long) for continuous rating of perceived discomfort.

The computerized cuff inflation system was programmed in this instance to perform two inflation patterns: (1) staircase and (2) ramp. In the scientific literature, such staircase pressure profile is also termed “phasic” and ramp profile termed “tonic.” The staircase pattern involved an incremental rapid inflation and deflation to increasing target pressures (10, 20, 30, 40, 50, 60 kPa). The pressure pattern was 2 s of pressure, rapid deflation, and 8 s of no compression, followed by the next incremental pressure (Figure 3). The ramp pattern involved continuous inflation at 1 kPa/s (Figure 3) to a maximum of 60 kPa. No pressures were tested above 60 kPa on safety grounds. Based on previously reviewed algometry studies (Kermavnar et al., 2018a), it was expected that participants would terminate their treatments for PDT below this level of pressure.

Discomfort rating. During the experiments, the participants continuously rated their perception of discomfort on a 100 mm electronic VAS

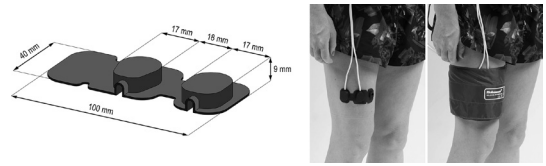


Figure 4. NIRS optode holder dimensions (left) and placement (right).

with values ranging from 0 (no discomfort) to 10 (unbearable discomfort). The scale was based on the VAS of pain intensity and the Borg CR10 scale that are used in algometry studies (Borg, 1998; Jensen et al., 2003; Löfgren et al., 2018), and according to which the perception of a certain attribute stretches from “nothing at all—0” to “the strongest one has ever experienced—10.” The participants were requested to terminate the inflation when the compression became painful rather than just uncomfortable by pressing the “stop” button. The participants’ discomfort was continuously sampled and monitored at 10 Hz. The inflation pressure at termination was recorded as PDT, and the inflation pressure at VAS > 0 as DDT.

Deep tissue oxygenation monitor. Deep tissue oxygenation during cuff inflation was monitored using a NIRS monitor (MoorVMS-NIRS, Moor Instruments, UK) and NIRS optodes (NP1, Moor Instruments, UK) with the interoptode distance 40 mm.

Procedure. The participants attended a single testing session. Prior to beginning the experiment, written informed consent was obtained and participants were asked about their health status to ensure that they did not have any of the conditions that would preclude them from taking part in the study. Next, the following information was recorded: participants’ age, sex, race, and engagement in sports. Anthropometric data in relation to NIRS were obtained based on a methodologic review of NIRS, including stature and body mass; thigh and calf length; thigh and calf width anterior-posteriorly and lateral-medially; thigh circumference and skin fold at two-thirds distance between greater trochanter and lateral epicondyle, over m. vastus lateralis;

TABLE 1: Male Participants’ Anthropometric Data

Male	Stature (mm)	Weight (kg)	BMI (kg/m ²)	Length (mm)		Circumference (mm)		Width ANT-POST (mm)		Width LAT-MED (mm)		Skin Fold (mm)	
				Thigh	Calf	Thigh	Calf	Thigh	Calf	Thigh	Calf	Thigh	Calf
Mean	1809.6	82.7	25.3	410.6	385.7	504.3	389.3	168.7	121.7	143.6	121.0	13.3	9.2
SD	72.0	10.0	3.0	19.2	28.6	18.4	20.7	9.1	6.9	7.5	8.6	4.2	2.9
Median	1779.0	83.6	25.9	414.0	403.0	505.0	395.0	169.0	123.0	145.0	119.0	12.0	8.5

Note. ANT-POST = antero-posterior; BMI = body mass index; LAT-MED = latero-medial; SD = standard deviation.

TABLE 2: Female Participants’ Anthropometric Data

Female	Stature (mm)	Weight (kg)	BMI (kg/m ²)	Length (mm)		Circumference (mm)		Width ANT-POST (mm)		Width LAT-MED (mm)		Skin Fold (mm)	
				Thigh	Calf	Thigh	Calf	Thigh	Calf	Thigh	Calf	Thigh	Calf
Mean	1674.8	61.4	21.9	383.5	356.3	471.7	355.8	155.7	112.2	135.0	108.0	24.8	19.7
SD	61.8	5.7	1.5	35.3	31.5	21.4	16.3	7.4	5.2	6.4	5.6	8.9	7.4
Median	1676.0	60.3	21.6	392.5	353.5	470.0	355.0	157.0	113.5	135.5	106.5	26.3	18.8

Note. ANT-POST = antero-posterior; BMI = body mass index; LAT-MED = latero-medial; SD = standard deviation.

and calf circumference and skin fold at the widest part of m. gastrocnemius (medial head). All lower limb measurements during compression were performed at the dominant limb. Ambient temperature and humidity were also recorded.

The NIRS optodes were attached to the participant’s dominant lower limb at one of the respective assessment sites. For the thigh, the optodes were positioned over m. vastus lateralis at two-thirds distance between greater trochanter and lateral epicondyle; and at the calf, over the medial head of m. gastrocnemius, at the site of largest circumference. The skin under the optodes was cleaned and shaven to optimize optode–skin coupling and signal quality. The optodes were covered with a manufacturer-supplied probe holder at an interoptode distance of 40 mm and attached to the skin with an adhesive pad. One of the pneumatic cuffs was mounted over the optodes and connected to the inflation device. The dimensions and placement of the optodes are presented in Figure 4.

The cuff was then inflated using one of the inflation patterns. During the inflation, the participants continuously rated their perception of discomfort on the handheld electronic VAS slider. Cuff inflation continued until the participant started feeling pain rather than just discomfort, at which point they terminated the inflation by

pressing the “stop” button. In case pain did not occur, the inflation was automatically terminated at 60 kPa.

After each treatment, the participants rested until their deep tissue oxygenation returned to baseline. They were then tested with the other inflation pattern for that experimental setup. When both patterns were tested, the procedure was repeated with the next cuff size. After testing all cuffs with both inflation patterns, the NIRS optodes and pneumatic cuff were moved to the other assessment site and the entire procedure was repeated.

All recordings were performed with the participants standing upright and standing still.

Data Analysis

All data were analyzed using IBM® SPSS Statistics software version 25, with significance set at $p < .05$. Three-way repeated measures ANOVA was performed with assessment site, cuff width, and inflation pattern as the independent variables, and DDT, PDT, the $StO_{2\text{ slope}}$, and ΔStO_2 as dependent variables. Within-subjects effects were assessed using an F -test with Mauchly’s test and Huynh–Feldt or Greenhouse–Geisser correction for violation of sphericity. Data are presented as mean

TABLE 3: Results of the Repeated Measures ANOVAs

Source	pDDT	pPDT	pStO _{2 Slope}	pΔStO ₂
Assessment site	.001 (F(1,12) = 16.95)	.001 (F(1,12) = 26.13)	p = .373 (F(1,12) = 0.86)	.141 (F(1,12) = 2.48)
Cuff width	.910 (F(2,24) = 0.09)	.001 F(1.32,15.80) = 24.82)	p = .069 (F(2,24) = 2.99)	.620 (F(1.33,15.98) = 0.36)
Inflation pattern	.001 (F(1,12) = 80.18)	.001 (F(1,12) = 20.39)	.001 (F(1,12) = 57.96)	N/A
Assessment site × Cuff width	.117 (F(2,24) = 2.35)	.001 (F(2,24) = 22.58)	p = .345 (F(2,24) = 1.11)	.733 (F(2,24) = 0.32)
Assessment site × Inflation pattern	.726 (F(1,12) = 0.13)	.001 (F(1,12) = 22.48)	p = .549 (F(1,12) = 0.38)	N/A
Cuff width × Inflation pattern	.691 (F(2,24) = 0.38)	.001 (F(1.34,16.11) = 26.38)	p = .372 (F(2,24) = 1.03)	N/A
Assessment site × Cuff width × Inflation pattern	.646 (F(2,24) = 0.45)	.003 (F(2,24) = 7.30)	p = .243 (F(2,24) = 1.50)	N/A

Note. DDT = discomfort detection threshold; PDT = pain detection threshold; StO_{2 slope} = deoxygenation rate; ΔStO₂ = fall in deep tissue oxygenation at PDT.

TABLE 4: Overall Values of Parameters Studied

Assessment Site	Cuff Width (cm)	Inflation Pattern	DDT (kPa)	PDT (kPa)	StO _{2 Slope} (%/s)	ΔStO ₂ (%)
Thigh	5	Ramp	16.7 (13.0)	56.4 (9.2)	−0.09 (0.09)	4.5 (3.9)
		Staircase	25.7 (15.0)	61.2 (0.1)	0.17 (0.11)	N/A
	12	Ramp	12.3 (7.3)	39.5 (14.8)	−0.10 (0.10)	3.8 (4.6)
		Staircase	23.4 (11.4)	59.5 (3.6)	0.21 (0.15)	N/A
	22	Ramp	12.0 (5.3)	35.8 (13.3)	−0.11 (0.11)	4.1 (4.9)
		Staircase	27.0 (14.1)	59.5 (4.2)	0.13 (0.11)	N/A
Calf	5	Ramp	19.3 (15.7)	57.2 (7.8)	−0.13 (0.09)	7.3 (4.8)
		Staircase	29.4 (15.5)	60.7 (1.9)	0.17 (0.11)	N/A
	12	Ramp	21.5 (13.7)	56.1 (8.7)	−0.13 (0.10)	7.1 (4.5)
		Staircase	31.7 (14.5)	61.2 (0.1)	0.16 (0.11)	N/A
	22	Ramp	20.8 (15.9)	53.5 (12.5)	−0.14 (0.10)	7.4 (5.8)
		Staircase	32.2 (17.3)	61.2 (0.0)	0.16 (0.13)	N/A

Note. DDT = discomfort detection threshold; PDT = pain detection threshold; StO_{2 slope} = deoxygenation rate; ΔStO₂ = fall in deep tissue oxygenation at PDT.

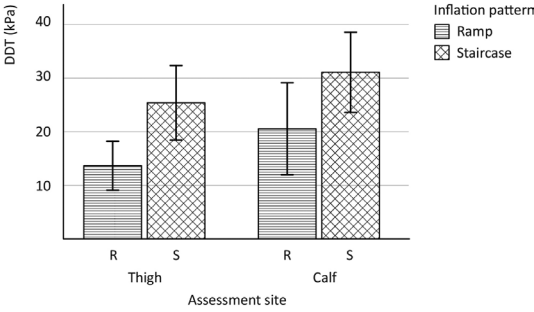


Figure 5. DDT for assessment site versus inflation pattern. Both the assessment site and the inflation pattern had a highly significant main effect on DDT ($p < .01$). The interaction between the assessment site and inflation pattern was statistically insignificant ($p = .726$).

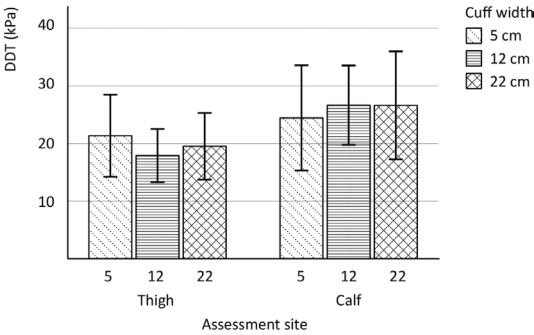


Figure 6. DDT for assessment site versus cuff width. The assessment site had a highly significant main effect on DDT ($p < .01$), whereas the cuff width did not ($p = .910$). The interaction between the assessment site and cuff width was statistically insignificant ($p = 0.117$).

and standard deviation (*SD*), and plots with the means and standard error (*SE*).

RESULTS

Participants and Environmental Details

This study included 13 healthy participants (6 female, 7 male) aged 22–57 years (median age 35 years), recruited from the University of Limerick. Twelve participants were Caucasian, one female was African. Two females and five males reported that they engaged in sports.

Participants’ anthropometric data are summarized in Tables 1 and 2. Ambient temperature and humidity during testing were $23.0 \pm 0.3^\circ\text{C}$ and $52.8 \pm 5.9\%$, respectively.

Repeated Measures ANOVAs

The results of the ANOVAs are presented in Table 3, and the associated mean and standard deviation values for the combinations of treatments are presented in Table 4.

Assessment site and inflation pattern had a highly significant effect on DDT ($p < .001$), but cuff width did not, nor were there any significant interactions between the variables. For PDT, assessment site, cuff width, and inflation pattern had a highly significant effect ($p < .001$), and there was a highly significant two-way interaction between all variables ($p < .001$). Regarding $\text{StO}_{2\text{ slope}}$, inflation pattern had a highly significant effect ($p < .001$), but cuff width did not ($p = .069$), as assessment site and the interactions did not ($p = .373$ and $p = .345, .549, .372, .243$, respectively). ΔStO_2 was analyzed only for the ramp condition (as it is affected by fluctuations for the staircase treatments). The values were not affected by assessment site ($p = .141$), cuff width ($p = .620$), or their two-way interaction ($p = .733$).

Discomfort Detection Threshold

The findings showed a highly significant main effect ($p < .001$) of assessment site and inflation pattern on DDT. At the thigh, discomfort was triggered at mean inflation pressures of 12.0–16.7 kPa with the ramp inflation pattern, and at 23.4–27.0 kPa with the staircase inflation pattern. At the calf, discomfort was triggered at mean inflation pressures of 19.3–21.5 kPa with the ramp inflation pattern, and at 29.4–32.2 kPa with the staircase inflation pattern, as presented in Figure 5.

The main effect of cuff width on DDT was not significant ($p = .910$), as presented in Figures 6 and 7. Discomfort was triggered at mean inflation pressures of 16.7–29.4 kPa for the narrowest cuff, 12.3–31.7 kPa for the medium cuff, and 12.0–32.2 kPa for the widest cuff. There were no significant two-way or

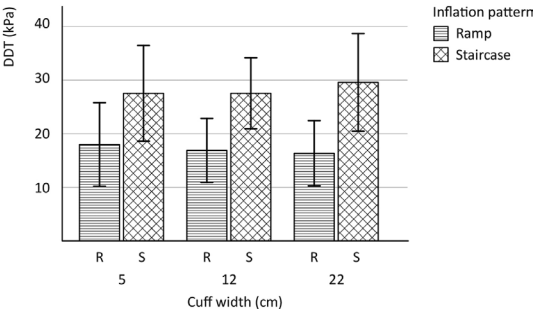


Figure 7. DDT for cuff width versus inflation pattern. The inflation pattern had a highly significant main effect on DDT ($p < .01$), whereas the cuff width did not ($p = .910$). The interaction between the assessment site and inflation pattern was statistically insignificant ($p = .691$).

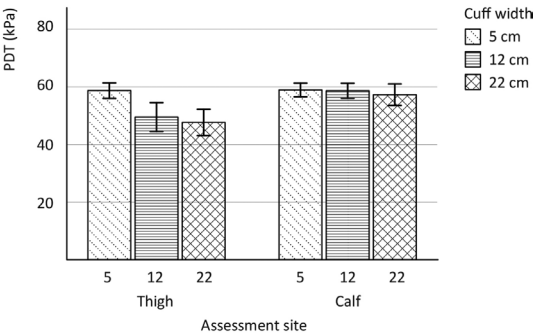


Figure 8. PDT for assessment site versus cuff width. Both the assessment site and cuff width had a highly significant main effect on PDT ($p < .01$). The interaction between the assessment site and cuff width was statistically highly significant ($p < .01$).

three-way interactions between assessment site, cuff width, and inflation pattern.

Pain Detection Threshold

The findings showed a highly significant main effect ($p < .001$) of all within-subject factors on PDT, as presented in Figures 8–10. At the thigh, pain was triggered at mean inflation pressures of 56.4–61.2 kPa for the narrowest cuff, 39.5–59.5 kPa for the medium cuff, and 35.8–59.5 kPa for the widest cuff. At the calf, pain was triggered at mean inflation pressures of 57.2–60.7 kPa with the narrowest cuff,

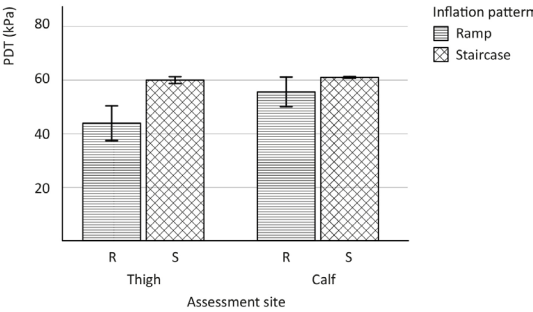


Figure 9. PDT for assessment site versus inflation pattern. Both the assessment site and the inflation pattern had a highly significant main effect on PDT ($p < .01$). The interaction between the assessment site and inflation pattern was statistically insignificant ($p = .726$). The interaction between the assessment site and inflation pattern was statistically highly significant ($p < .01$).

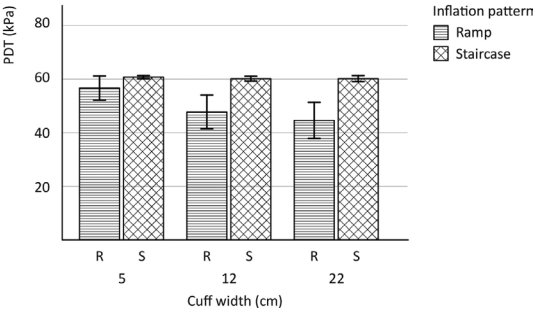


Figure 10. PDT for cuff width versus inflation pattern. Both the cuff width and the inflation pattern had a highly significant main effect on PDT ($p < .01$). The interaction between the cuff width and inflation pattern was statistically highly significant ($p < .01$).

56.1–61.2 kPa with the medium cuff, and 53.5–61.2 kPa with the widest cuff. PDT was reached at 35.8–57.2 kPa with the ramp inflation pattern and at 59.5–61.2 kPa with the staircase inflation pattern.

The two-way interactions between assessment site and cuff width, assessment site and inflation pattern, and cuff width and inflation pattern were highly significant ($p < .001$). The three-way interaction between them was also highly significant ($p < .001$).

TABLE 5: Discomfort Perception in Relation to Cuff Inflation Pressure at the Thigh and Calf

	Regression Equation	R^2	P_{Model}	P_{InfP}	P_{CW}	P_{ATT}
Thigh	$VAS = -31.138 + 1.469 \text{ InfP} + 1.477 \text{ CW} + 1.234 \text{ ATT}$.466	<.001	<.001	<.001	<.001
Calf	$VAS = -8.596 + 1.086 \text{ InfP} + 0.219 \text{ CW} + 0.276 \text{ ATT}$.349	<.001	<.001	<.001	<.001

Note. ATT = adipose tissue thickness (mm); CW = width of the pneumatic cuff (cm); InfP = cuff inflation pressure (kPa).

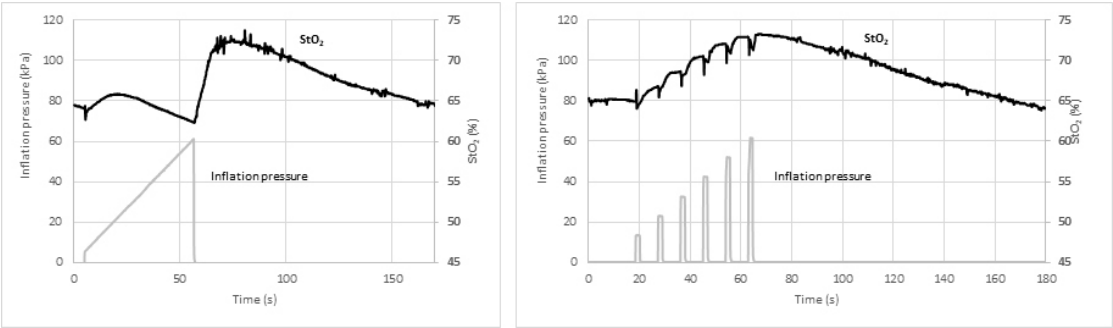


Figure 11. Typical pattern of ΔStO_2 during ramp inflation (left) and staircase inflation (right). Black curve, StO_2 ; gray curve, inflation pressure.

Post hoc analysis revealed highly significant differences between all three widths of pneumatic cuffs: 5 versus 12 cm ($p = .001$), 5 versus 22 cm ($p = .001$), 12 versus 22 cm ($p = .008$).

Discomfort Perception in Relation to Cuff Inflation Pressure

Regression analysis was performed to predict discomfort (VAS) based on cuff inflation pressure, adipose tissue thickness, and pneumatic cuff width (Table 5). When the equations are tested at the extremes of the independent variables, the equations predict some values just outside the VAS range sampled (0–100). This reflects the quality of fit obtained (R^2 values) for the equations.

The model for the thigh had an R^2 value of .46 and the model for the calf an R^2 value of .349. Both equations and the individual predictor variables were highly significant.

Deep Tissue Oxygenation

$\text{StO}_{2 \text{ slope}}$ Inflation pattern had a highly significant effect on $\text{StO}_{2 \text{ slope}}$ ($p < .001$). In fact, two distinctly different patterns of ΔStO_2 were

observed specific to each of the inflation patterns, as presented in Figure 11. During ramp inflation, StO_2 gradually decreased throughout the compression, rapidly increased above the baseline value after the release of the cuff, and slowly leveled off to baseline levels. With the staircase inflation pattern, StO_2 decreased during compression but tended to increase above the previous value after each release of the cuff.

Assessment site and cuff did not have a significant effect on $\text{StO}_{2 \text{ slope}}$, as also illustrated in mean data depicted in Figures 12 and 13. No statistically significant two-way or three-way interactions were identified.

ΔStO_2 At the occurrence of pain, the mean decrease in deep tissue oxygenation was considerably larger at the calf (7.1%–7.3%) than at the thigh (3.8%–4.5%). However, no significant main effects of the assessment site or cuff width on ΔStO_2 were identified ($p = .141$ and $.620$ respectively), as presented in Figure 14. There were no significant interactions between the two factors.

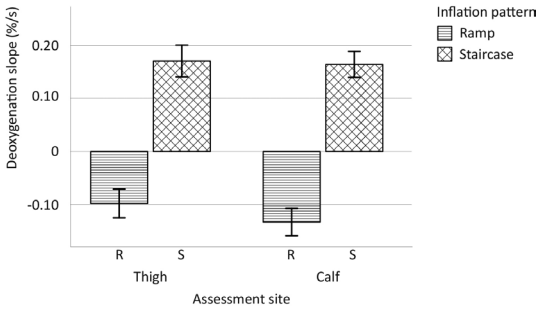


Figure 12. StO₂ slope for assessment site versus inflation pattern. The inflation pattern had a highly significant main effect on StO₂ slope ($p < .01$), whereas the assessment site did not ($p = .373$). The interaction between the assessment site and inflation pattern was not statistically significant ($p = .549$).

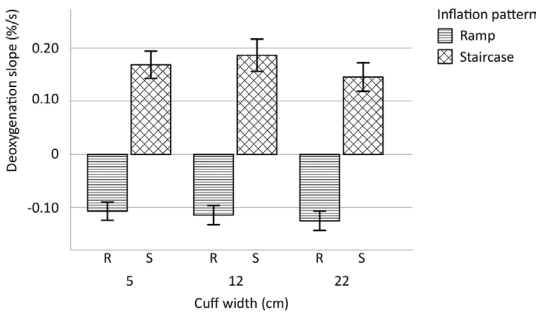


Figure 13. StO₂ slope for cuff width versus inflation pattern. The inflation pattern had a highly significant main effect on StO₂ slope ($p < .01$), whereas the effect of cuff width was prominent but not statistically significant ($p = .069$). The interaction between the cuff width and inflation pattern was not statistically significant ($p = .372$).

DISCUSSION

Overall DDT and PDT Values

The mean inflation pressures that caused discomfort ranged from 12.0 kPa for the ramp inflation of the widest cuff at the thigh to 32.2 kPa for the staircase inflation of the widest cuff at the calf. The mean inflation pressures that caused pain ranged from 35.8 kPa for the ramp inflation of the widest cuff at the thigh to 61.2 kPa for the staircase inflation of the widest cuff at the calf. The PDT values for the calf using a

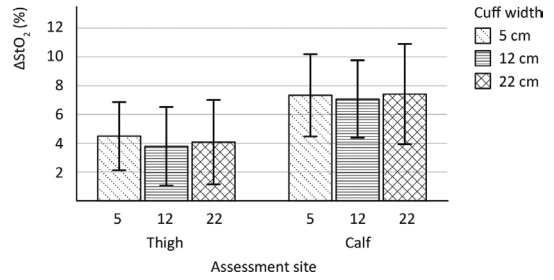


Figure 14. ΔStO₂ for assessment site versus cuff width at ramp inflation pattern. Neither the assessment site ($p = .141$), nor cuff width ($p = .620$) had any significant main effects on ΔStO₂. The interaction between the assessment site and cuff width at ramp inflation pattern was not statistically significant ($p = .733$).

12-cm wide cuff and ramp pattern are slightly higher than those reported in previous algometry studies with similar treatment (16.3 ± 11.2 to 34.1 ± 21.0 kPa; Kermavnavar et al., 2018a). The difference could be associated with the standing position of participants and their subjective interpretation of discomfort versus pain.

It is of note that the majority of research around human–robotics contacts has focused on interface pressure rather than cuff inflation pressures, as in the current research. Therefore, the following regression equations predicting interface pressures from inflation pressures were also developed in associated research:

Interface pressure at the thigh = $-11.128 + 1.379$ Inflation pressure + 0.518 Cuff width ($R^2 = .876, p < .001$)

Interface pressure at the calf = $-8.090 + 1.497$ Inflation pressure + 0.367 Cuff width -0.182 Adipose tissue thickness ($R^2 = .965, p < .001$)

According to these equations, the values above correspond to mean interface pressures of 16.8–46.9 kPa for discomfort and 49.6–90.3 kPa for pain.

The Influence of Assessment Site on the Perception of Discomfort and Pain

The results of this study suggest that discomfort is triggered at lower pressures at the thigh than at the calf, which is in agreement

with our expectations and previous studies that have found significantly higher PDTs at assessment sites with less soft tissue (Lindskou et al., 2017; Polianskis et al., 2002). Namely, as larger volumes of muscle tissue are compressed, compression becomes painful earlier due to spatial summation of pain. Our findings show that the same is also true for the development of discomfort. Thus, when designing wearable devices that apply circumferential compression to lower limbs, such as exosuit, it is preferable to interface them with body sites where smaller volumes of soft tissue are found.

The Influence of Pneumatic Cuff Width on the Perception of Discomfort and Pain

Although pneumatic cuff width did not significantly affect the initial detection of discomfort, wider cuffs caused pain at significantly lower inflation pressures than the narrower, which is in accordance with previous studies (Estebe et al., 2000; Lemming et al., 2017). Like above, the influence of cuff width on PDT can be explained by spatial summation of pain as well. Therefore, narrower exosuit cuffs that apply circumferential compression to lower limbs are preferred over wider cuffs in order to avoid discomfort and pain.

The Influence of Inflation Pattern on the Perception of Discomfort and Pain

The staircase inflation pattern was expected to be tolerated better than the ramp inflation pattern, as it allows for relief of discomfort and tissue reperfusion between individual compressions. Previous algometry studies have shown increased pain perception occurring when a painful stimulus of the same intensity is repeated with a frequency above 0.3 Hz (Anderson et al., 2013; Latremoliere & Woolf, 2009). However, we have no knowledge of studies confirming the same for the prepain discomfort, as the stimulation intensity as well as the first stimulation being painful is important for evoking temporal summation of pain (Finocchietti et al., 2012). In this study, we have not attempted to investigate whether temporal summation of discomfort exists; therefore, an 8 s duration of interstimuli interval was chosen in order to avoid a possible

influence of stimulation frequency. This finding suggests that ramp circumferential compression at the human–exosuit interface should be avoided and replaced with staircase profile compression whenever possible, to avoid the development of discomfort and pain.

Two- and Three-Way Interactions

Different combinations of assessment sites, cuff widths, and inflation patterns do not significantly affect the detection of discomfort, whereas pain varies with different combinations of assessment site and cuff width, assessment site and inflation pattern, and cuff width and inflation pattern, as well as the combination of all three.

The Influence of Assessment Site, Pneumatic Cuff Width, and Inflation Pattern on Deep Tissue Oxygenation

The findings of our study suggest that the staircase inflation pattern of the cuffs actually increases deep tissue oxygenation. A possible explanation for that would be that brief external compressions of the lower limb help promote venous blood toward the heart, but do not cause venous congestion, thus lowering the amount of HHb in the tissue. Simultaneously, short bouts of reactive hyperemia and hence the influx of O₂Hb are evoked due to previous arterial occlusion, the overall result being a rise in the O₂Hb–HHb ratio.

Ramp inflation, on the other hand, caused an expected fall in StO₂ during compression and reactive hyperemia after the release of the cuff, as has been previously reported. Overall, a larger mean decrease in oxygenation was found when pain was detected at the calf (7.1%–7.4%) than at the thigh (3.8%–4.5%), suggesting that lack of oxygen is tolerated better at the calf than at the thigh, possibly due to smaller volumes of muscle tissue. We have, however, found large interindividual variations; therefore, additional studies would be needed to confirm that hypothesis. This finding suggests that circumferential compression applied by wearable devices might be more appropriate at the calf than at the thigh in order to avoid discomfort. On the other hand, however, the fact that a larger decrease

in oxygenation is tolerated at the calf might expose deep tissues to noxiously low oxygen saturation without prior warning.

We have found no significant effects of cuff width on the decrease in deep tissue oxygenation at painful compression. Considering the fact that the degree of deoxygenation was similar at lower inflation pressures for wider than for narrower cuffs, the occurrence of pain might be connected to a certain fall in tissue oxygenation from baseline.

Limitations

This study focused on compression that the user would experience during standing while being assisted with maintaining balance by an exosuit. A separate study was conducted in dynamic conditions (walking on a treadmill), with the focus on loading experienced during assistance with movement. As our study aimed to investigate the connection between discomfort/pain and deep tissue oxygenation during circumferential tissue compression, the measurement of oxygenation was performed with the pneumatic cuff over the NIRS probe. This method had, to our knowledge, only been used in one previous study (Messere et al., 2017); therefore, the extent to which the compression of probes against the tissue might have influenced the NIRS readings is unknown. Furthermore, the actual inflation pressures for the staircase inflation pattern differed slightly from the target pressures, due to the rapid nature of inflation/deflation and the difference in cuff sizes. Whereas the target pressures were 10, 20, 30, 40, 50, and 60 kPa, the actual peak inflation pressures were 13.1, 22.7, 32.1, 42.1, 54.2, and 61.4 kPa, respectively. Moreover, the rate of deoxygenation might have been influenced by the relatively slow rate of cuff inflation during the ramp inflation pattern, possibly restricting venous blood influx before arterial. Despite a seemingly important difference in the mean decrease in oxygenation at the calf and thigh, we have found large interindividual variations; therefore, additional studies would be needed to confirm that assessment sites have an effect on the amount of tissue deoxygenation at painful compression. In our study, we have largely

focused on subjective assessment of the pre-pain discomfort that human-centered design aims to avoid. Despite detailed instructions, participants' ratings seemed to be considerably diverse, presumably due to the factors reported in previous studies (Buckle & Fernandes, 1998; Mukhopadhyay et al., 2007; Shen & Parsons, 1997). Finally, we also identify a potential for future studies to address monitoring of brain signals by means of NIRS or EEG in the context of discomfort/pain perception.

CONCLUSIONS

With this study, we aimed to simulate the use of continuous and intermittent mechanical loading that soft lower limb exoskeletons can exert on the wearer's body. We aimed to study the effect of circumferential compression at the thigh and calf on the development of discomfort and pain, and on tissue oxygenation.

Our findings show that both discomfort and pain are triggered at significantly lower pressures at the thigh than at the calf. Discomfort and pain also occur at significantly lower pressures during ramp compared with staircase compression. Moreover, pain occurs at lower pressures with wider compared with narrower pneumatic cuffs. According to these findings, it is preferable to interface exosuits with the user's body at anatomical sites with smaller volumes of soft tissue, and using narrow cuffs and staircase profile compression whenever possible.

Our investigation of changes in deep tissue oxygenation found that staircase profile compression tends to cause an increase in oxygenation, whereas ramp compression decreases it. A larger mean decrease in oxygenation was found when pain was detected at the calf than at the thigh. Cuff width did not have a significant effect on the decrease in oxygenation at painful compression, suggesting that the occurrence of pain could be connected to a certain fall in tissue oxygenation.

KEY POINTS

- Circumferential compression with pneumatic cuffs triggers discomfort and pain at significantly lower pressures at the thigh than at the calf, and

with ramp compared with a staircase profile inflation pattern.

- Circumferential compression with wider cuffs triggers pain at significantly lower inflation pressures than with the narrower.
- Staircase profile compression with pneumatic cuffs causes an increase in deep tissue oxygenation, whereas ramp profile compression decreases it.
- The fall in tissue oxygenation at the occurrence of pain is larger at the calf than at the thigh.

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ORCID iD

Leonard W. O'Sullivan  <https://orcid.org/0000-0002-0255-1979>

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Tjaša Kermavnar graduated in 2012 from medical faculty in Ljubljana, Slovenia and in 2013 from the Academy of Fine Arts and Design (Industrial Design) in Ljubljana, Slovenia. In 2016, she started her PhD research study in ergonomics aspects of human–exosuit interaction at the School of Design, University of Limerick, Ireland.

Kevin J. O'Sullivan graduated in 2010 with a BSc in product design and in 2016 with a master's degree in medical device design. He is currently a senior research fellow in the School of Design.

Adam de Eyto, head of School of Design, University of Limerick, Ireland, graduated from The National College of Art & Design, Dublin, Ireland, with a BDes (Industrial Design) in 1995 and with a PhD from Bournemouth University, UK, in 2009.

Leonard W. O'Sullivan is an associate professor in the School of Design. His research interests are in human factors of human robot interaction, to include exoskeleton interaction (hard and soft) and technology adoption aspects affecting users' experience of robotics.

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