ABSTRACT

Aim: Intermittent pneumatic compression (IPC) is an alternative method of compression treatment designed to compress the leg and mimic ambulatory pump action to actively promote venous return. This study explores the efficacy of a new portable IPC device on tissue oxygenation (StO_2) in two sitting positions.

Methods: Twenty-nine participants were screened and recruited using (PAR-Q, CA). All data conformed to the Declaration of Helsinki and ethical principles. Participants attended two separate one-hour sessions to evaluate StO_2 in a chair-sitting and long-sitting position. StO_2 was recorded for 20-minutes pre-, during and post- a 20-minute intervention of the IPC unit (Venapro™, DJO Global, CA).

Results: A significant difference was seen between the two seating positions ($p=0.003$) with long-sitting showing a 12% higher StO_2 level than chair-sitting post intervention. A similar effect was seen in both seating positions when analysing data over three, time points ($p=0.000$). Post-hoc pairwise comparisons showed that significant improvements in StO_2 ($p \leq 0.000$) were seen from baseline, throughout the intervention, continuing up to 15 minutes post intervention, indicating a continued effect of the device after a short intervention.

Conclusion: Post-operative care poses huge demands and cost to health services worldwide, so promotion of portable rehabilitation tools that facilitate community rehabilitation affords immense potential. Increasing StO_2 through short-intervention sessions with this portable device within various health and sports-based practices, improving tissue health, potentially reducing post-operative DVT risk or inflammation. Such devices lend themselves to wide self-management implementation.

Key words: Venous thromboembolism, Intermittent Pneumatic Compression, tissue oxygenation, self-management, lymphoedema

INTRODUCTION

Compression systems such as bandaging, compression stockings and Intermittent Pneumatic Compression (IPC) devices aim to correct the body's venous insufficiencies by counteracting the force of gravity, increasing cutaneous pressure[1,2]. This in turn helps to increase blood flow and skin tissue oxygenation to promote healthy tissue[1, 3-7] significantly reducing the volume of fluid within the compression area and clearing toxins, improving mobility and clinical outcome[7-10]. IPC devices offer a method of compression treatment designed to compress the leg, stimulating the thigh, calf and foot to mimic ambulatory pump action, actively promoting venous flow and formation of tissue channels as pathways for lymphatic drainage[6, 11-12]. Therapeutic effects of IPC therapy have been seen in the management of venous leg ulcers, lymphoedema and peri- or post-operative management of venous thromboembolisms (VTE) among others[12-15]. Whilst both the advantages and limitations of IPC therapy have been noted in previous literature, currently IPC is an underused tool requiring further research and support in its use[16].

External pressure on the lower extremity has been used to improve blood circulation, to promote healing in wounds such as venous leg ulcers since the 1800's, utilising both compression and suction to improve healing rates[7,13,17-19]. The majority of venous ulcers are as a result of vascular disease (venous, arterial, lymphatic)[20]. Correctly applied compression therapy is key to preventative and therapeutic care of venous disease[21]. Venous ulcers have been shown to heal quicker with rapid IPC therapy compared to slow[17] and patients with advanced venous disease have been shown to be more responsive to combined compression garment and IPC therapy[11]. Similarly, for patients with advanced lower limb lymphoedema where oedema may reach the perimuscular fascia, a combined compression garment and IPC therapy is recommended[22]. Non-compliance to mechanical compression therapy in non-intensive care patients is poorly understood[23-24]. Recent development of mobile IPC devices have attempted to overcome barriers associated with their implementation, including restricted mobility due to the bulky nature of the device, cost, hygiene and attached power supply[25-27].

Venous Thromboembolism (VTE) refers to a venous blood clot formation due to hypercoagulability, blood stasis within the vessel or injury to the endothelium. VTE is one of the leading consequences of vascular disease after myocardial infarction and cerebral vascular accident, with 10 million cases occurring globally every year[27]. Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) are manifestations of VTE, with DVT occurring predominantly in the legs. Early mobilisation of patients is recommended, particularly post orthopaedic surgery where there may be a significantly increased (88%) risk of DVT [28-30]. Where pharmacological prophylaxis is contraindicated, IPC therapy is recommended until patients are mobile[31]. Therefore, compression therapy that affords easy early mobilisation is not only key, but paramount for patient compliance.

Venous stasis has been shown to be a risk factor in the formation of blood clots and low blood flow volume can lead to tissue damage causing significant health risks[32]. Despite being common, VTE is a potentially preventable cause of morbidity and mortality in hospitalised patients[33-34]. There is limited consensus regarding which patients should be in receipt of thromboprophylaxis with inconsistency in the use of DVT prophylaxis noted[30]. Recent European guidelines for the management of VTE prophylaxis recommends the use of Pharmocological prophylaxis alongside IPC for patients at very high risk, as non-dynamic compression garments have been shown to be less effective post stroke[14,35-36]. Stroke survivors are reported to be at especially high risk of VTE having been detected in up to 42% of patients[14].

The NHS England's *Five Year Forward View*, suggests it is necessary to empower and educate patients in self-management[37]. It is essential that consideration is given to compression therapy that is mapped to patient need whether that be in critical care, peri or post-operative rehabilitation or simply to optimise self-management and or assist in early mobilisation[38-39]. Previous studies have shown the importance of positioning on optimising blood flow or skin tissue oxygenation (StO_2)[3,40]. Non-dynamic compression garments have been shown to significantly increase tissue oxygenation in long sitting and chair sitting[3]. Whilst the need for mobile IPC therapy to promote self-management has been acknowledged[26], it is unknown whether IPC is effective at increasing StO_2 in both chair sitting and long sitting. Improvement in StO_2, through the use of portable IPC therapy that affords easy application and mobilisation has key implications for multiple patient groups with key consequences for patient compliance. This study explores the efficacy of a new portable IPC and device on tissue oxygenation in long sitting and upright chair sitting in healthy adults.

METHODS

Participants

A convenience sample of healthy individuals were recruited through staff and students of the University as well as through the snowballing effects of the study. All volunteers to the study were screened using the Physical Activity Readiness Questionnaire (PAR-Q+)[41] health screening form to check eligibility. Any participant not passing the screening assessment, with suspected, active or untreated deep vein thrombosis, skin vascular disease, severe atherosclerosis, pulmonary oedema, severe congestive heart failure, thrombophlebitis, an active infection, vein ligation, gangrene, dermatitis, open wounds, recent skin grafts, massive oedema or extreme deformity of the lower leg was not eligible for the study. All data collection conformed to the Declaration of Helsinki and data protection regulations, with volunteers giving written informed consent prior to participation. Participants were requested not to consume any caffeine or wear any tight fitting or compression garments on the day of testing. Full ethical approval was granted by the University Ethics Committee (STEMH#566v1).

Procedure

The device

The portable IPC device (Venapro™, DJO Global, CA; Figure 1) was designed to enhance blood circulation and skin tissue oxygenation to aid in the clinical management of venous stasis ulcers, arterial leg ulcers, deep vein thrombosis or lymphoedema. IPC devices are often bulky, require extended hospital stays and external cabling connecting to pump. The device was a compact two-chamber rapid IPC unit, which inflated from the distal to proximal chamber at a pre-set pressure of 50 mmHg once/minute, holding pressure for 4.5 seconds. As a lightweight IPC unit, this device affords easy application and self-management; key factors in the optimisation of self-care regimens.

The intervention

All participants visited the university testing facilities for two separate one-hour sessions a minimum of two days apart. All individuals were evaluated in two separate sitting positions (chair-sitting and long-sitting) in randomised order (www.randomisation.com). At the first session for each participant, baseline measures were taken (height, weight, BMI, "dominant leg" calf circumference) to ensure all participants fit within the recommended fitting guidelines.

For the long-siting position, participants sat on a standard height adjustable plinth. Once participants were seated comfortably, the IPC device was fitted in line with manufacturer guidelines. Following this a mobile Near Infra-Red Spectroscopy monitor (MoXY Monitor, MN, USA) was set and attached to the participants calf, approximately over the fibular artery with hypoallergenic tape and a blackout strap (Figure 1). A lightweight cloth covered the area to ensure environmental light interference was minimal. Participants were required to sit in the standardised positions for 15 minutes with the device off to allow for acclimatisation and baseline readings to be taken. The IPC device was then switched on for a period of 20 minutes with continual recording of StO_2, followed by a further 15 minutes with the device switched off to allow post intervention change to be monitored[3]. The second condition involved the same test set up as the long-sitting condition but seated on a standard height chair with knees flexed at approximately 90 degrees.

Data Analysis

All data was exported and analysed in Microsoft Excel. Skin tissue oxygenation (StO_2) values were averaged over 15 minutes pre and post the intervention and for the 20 minutes during the intervention (IPC on). All data were entered into SPSS 25 for Windows (IBM, NY, USA) for analysis. A repeated measures analyses of variance (ANOVA) was performed for the two sitting conditions (Long-sitting and chair-sitting) and three-time points (pre-, during, post- intervention), followed by post-hoc pairwise comparisons with Bonferroni correction (significance level α=0.05). Violations of Mauchly's sphericity assumption were accounted for using the Greenhouse-Geiser correction where required to avoid a type one error.

RESULTS

Twenty-nine healthy participants (age: 33 ± 11 years; height 175 ± 8cm; weight: 82.6 ± 14.5kg), were included in this study. Demographic and anthropometric data for this study are presented in Table 1 for the individuals (n=29).

A significant difference was seen between the two seating positions (p=0.003; Figure 2, Table 2). When chair-sitting, participants had the lowest baseline StO_2 levels (12.87% lower than long-sitting), significantly increasing during the intervention (p=0.000; 5.55%↑) compared to baseline. This effect continued 15 minutes post intervention (p=0.000; 5.29% ↑). Chair-sitting yielded a total 11.14% increase when comparing post-intervention tissue oxygenation to baseline levels. When long-sitting, tissue oxygenation increased significantly (p=0.000; 4.59%) during the intervention, with this effect continuing up to 15 minutes post intervention. A total 8% increase in tissue oxygenation was seen in the long-sitting position, compared to baseline. Overall tissue oxygenation levels in long-sitting were significantly ($p=0.000$; 10.35%) higher than chair-sitting post intervention.

DISCUSSION

This study explored the effects of a new IPC device on skin tissue oxygenation (StO_2) in a group of healthy adults.

The longer term gravitational effects of chair sitting have been suggested to have a negative impact on tissue oxygenation in individuals with vascular compromise[33], yet previous research has shown that upright chair sitting may produce the highest oxygenation saturation levels[40]. In agreement with suggestions that patients should be asked to lie down[43] recent research on the impact of a compression garment has suggested supine and long sitting affording higher overall StO_2 levels post intervention[3]. However, this recent study, suggested that whilst the baseline StO_2 was lower for chair sitting, the highest overall increase occurred in this position following a short compression garment intervention. In agreement with this recent work[3] the present study suggests that the use of this portable, wireless IPC device, affords higher StO_2 levels when long sitting compared to Chair sitting post intervention, however a higher overall percentage increase in StO_2 when chair sitting[3]. Such findings have direct implications for patients who are unable to sleep in a bed and have to resort to chair sleeping, potentially superseding the need for limb elevation[44] through the use of such mechanical prophylaxis.

It has been suggested that the impact of compression systems on StO_2 should be analysed in both sedentary and dynamic activities in order to identify a potential ladder of intervention and to understand further the relationship between mobilisation and compression[3]. During the sedentary positions involved in previous and present studies it is clear that there are distinct differences in the way StO_2 increases are attained when comparing an IPC unit and compression garment. Results from previous research suggest that in a chair seated position, individuals will initially benefit significantly through the use of static compression, however this is not sustained immediately following compression garment use[3], likely due to gravitational impacts on venous pooling. In long-sitting, there was no real change in tissue oxygenation between baseline and application of the compression garment however, there was a significant improvement post intervention[3]. In contrast, the results of the present study suggest the impact of mechanical compression differs to previously studied garments in that regardless of position there is an initial increase in StO_2 during compression, followed by a continued impact post compression. Further research is needed to truly understand both the implications for sedentary patient groups or those with mobility restrictions compared to potential benefits for those adopting early mobilisation during post-operative rehabilitation[31].

The results of the present study give an initial indication as to the baseline and post intervention effects of position and use of this IPC unit, in two key seating positions previously shown to have a significant influence on tissue oxygenation. However, in order to truly understand the impact such a device may have on the management of VTE, lymphoedema, management of venous leg ulcers or other conditions, further studies with relevant clinical presentations are needed. The use of such a device for the management of lymphoedema or venous ulcer may be limited by the stage of the condition, skin damage, size of calf and involvement of the foot. However, as is suggested in the clinical guidance for these conditions[33,42], a combination of graduated compression and this mechanical compression may be needed. It is suggested for these patient groups additional measures are also necessary for both tissue oxygenation and limb volume proximal and distal to the device, in order to understand it's efficacy as a self-management therapy.

It has been suggested that an increase in StO_2 may also have positive implications for recovery times following intensive sports activities[45-47]. In light of the results in the present study, IPC units such as this may afford a potential adjunct to post match recovery during post-match travel. This however would require further research to determine baseline and true post intervention impacts possible.

Although economic benefits were not a primary consideration for this study, the use of IPC devices that can be self-managed and portable have reduce nursing time, encourage better function and mobility, encouraging patients to engage and continue with activities of daily living. The engagement in better self management regimens has the potential to improve outcomes by reducing the risk of falls, cellulitis, sepsis and tissue degradation associated hospital admissions.

LIMITATIONS

This is a pragmatic study to establish the effects of this device on healthy adults, in order to evaluate it's potential to impact the clinical self-management of conditions such as VTE, Lymphoedema or venous ulcers amongst other conditions. Currently limited evidence supports the use of portable IPC devices, in these patient groups, therefore it is suggested that studying the true impact of different compression regimens compared to pharmacological prophylaxis alone, may help to better inform clinical decision making. It is also important that future studies consider the potential barriers to the wider implementation of such devices for different clinical presentations and the potential influence of tissue type and other confounding factors on the effectiveness of treatment regimens.

CONCLUSION

In conclusion, this study explored the use of a mobile IPC device and its potential for use in various patient groups. Results suggest this device increases tissue oxygenation saturation levels in both chair sitting and long sitting positions. With the rising cost of post-operative care and wound management, coupled with a drive to promote self-management of conditions, the results of this study have potential implications for the use of mechanical prophylaxis for self-management in individuals with venous disease or compromise, lymphoedema, or simply reduced mobility post-surgery.

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Table 1: Participant demographics and anthropometrics

DEMOGRAPHICS	MEAN (SD)	RANGE
AGE (YEARS)	33.2 (10.6)	20-58
HEIGHT (M)	1.75 (0.08)	1.63-1.88
WEIGHT (KG)	82.6 (14.5)	64.4-130
BMI (KG/M^2)	27.2 (4.9)	21.3-42.2
GENDER	17 Males/12 Females	
CALF CIRCUMFERENCE (CM)	39.5 (3.0)	35-46.2

Table 2: Tissue oxygenation (StO_2) and temperature data:

	CHAIR	LONG-SITTING
TOTAL HAEMOGLOBIN (THb)		
	12.36 (0.32)	12.25 (0.39)
RAW DATA (StO_2)		
OVERALL (BASELINE-POST)	66.97 (14.49) [A]	76.97 (10.00) [A]
DURING INTERVENTION (20 MINUTES)	70.69 (14.50) [A]	80.39 (9.27) [A]
POST-INTERVENTION (15 MINUTES)	74.43 (13.84) [A]	83.03 (8.59) [A]
PERCENTAGE CHANGE IN StO_2 (%)		
BASELINE - DURING	5.55	4.59
DURING – POST	5.29	3.28
OVERALL (BASELINE-POST)	11.14	8.02

Figure 1: The Intermittent Pneumatic Compression device (VenaPro™; DJO Global, USA)

Figure 2: Tissue oxygenation in the two sitting positions.