Behavior of a Multicomponent Dual Component System (DCS)* Bandage in a Hot Environment: results on Hospital Staff Volunteers with a Pitting Edema

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INTRODUCTION

Bandaging and compression wraps are highly recommended for edema reduction in all individuals with edema. But compliance is low, a major reason being sense of excess heat in the lower limb, and a feeling of constriction particularly in hot and humid weather conditions. Also, bandages slip, and can and there can be loss of the critical factor, the "Static Stiffness Index" or SSI which measures the ability of the bandage to offer adequate pressure on the limb during walking/ambulation. The SSI maintenance is critical for bandage to remain effective over time. Some bandages which are poorly designed slip too quickly post any edema reduction. This causes patient discomfort leading to non compliance in bandage wearing. This study reports observations on the Dual Compression System (DCS) DCS includes BOTH a short and a long stretch bandage. Study was done in a very hot and humid climate.

OBJECTIVES

To evaluate effects of DCS after 4 hours of wear and a treadmill test on 20 subjects in a hot climate:

-Leg volume

-Static Stiffness index (interface pressure measured in standing position minus interface pressure measured in a lying postion)

-Interface **pressures at various stages of the study**

METHODS

Subjects: 20 hospital staff volunteers seen in 4 days (5 subjects assessed per day) under hot and humid conditions (39-40° C, 102.2-104° F) in Cairo, Egypt.

Baseline leg volume measurements were performed after those subjects were working and standing after few hours. This leads to confirmable edema as measured by a pitting edema detector (Figure 1). After baseline 3 D Laser scanning based leg volume measurements, the DCS bandage was applied using visual indicators. After 4 hours of wearing the compression system (subjects remained immobile/supine for these 4 hours), measurements were made (pressure, bandage slippage). The subjects then walked on a treadmill (15 min, slope 8%, speed 4 km/h), and measurements were made again. (pressure, leg volume with Laser scanning, bandage slippage). Specifically, interface pressures (i.e pressure on the limb with the bandage) and calculation of SSI were documented after application of bandage, and then after 4 hours of wearing the K2 and just before the treadmill test and just after 1 km walk (average distance walk by an elderly person with venous leg ulcer).

Key Conditions:

-No air conditioning. Only fans.

-**Selection visit** between 9:30AM to 11:30AM with evaluation of **pitting edema at end of work session.**

-**Inclusion visit and initiation of bandaging** between 11:30AM to 2:00PM

-**Evaluation post bandaging, rest, and treadmill,** between 3:45PM to 6:15PM

INSTRUMENTS

Pitting edema confirming device used on subjects post work stress on limbs before bandaging.

PicoPress ®: Measures interface pressure.

HandyScan ® 3D (Peel 2 version, Creaform): used for the leg volume calculation.

Computers with special software linked to Handyscan
A computerized 3D mesh model and segmentation of the leg was performed to calculate leg volume via laser device. (the leg volume excludes foot volume)

DEMOGRAPHICS

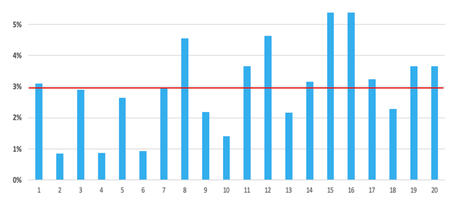
N	20 F 8, M 12
Age (years: mean - SD)	36 (8.2)
Height in cm (mean-SD)	167.8 (7.5)
Weight in kg (mean-SD)	75.3 (11.2)
BMI (mean- SD)	26.7 (3.5)
Ankle circumference in cm (mean- SD)	22,4 (1.4)
CEAP classification C0a, COs	15
CEAP classification C1a, C1s	5
Pitting ruler in mm (selection visit)	4.7 (1.3)

STUDY MANAGEMENT SCHEDULE SCHEMATIC

	Selection visit (T-2h)	Inclusion visit (TO)	T+4h	After Treadmill test
Patient information and consent	X			
Validation of selection criteria	X			
Pitting Edema + ruler > 3 mm	X			
ABPI and Echo-Doppler	X			
Volumetry by HandyScan		X		
Bandage application		X		X
Interface pressure (picopress)		X	X	X
Slippage				X
Comfort (VAS)				X

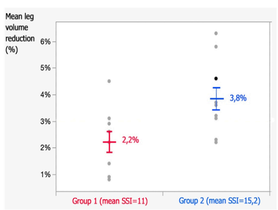
RESULTS

Volume reduction per study subject (No. 1- 20)



Mean reduction of 2.9% of leg volume, 81 ± 42 ml

Correlation between leg volume reduction & SSI



Assessment of interface pressures and stiffness (Static Stiffness Index)

	Resting Pressure			Staff stiffness index**		
in mmHg	Inclusion T0	T4	After Treadmill test	Inclusion T0	T4	After Treadmill test
Mean	**45.4***	**30***	**30.4**	13.0**	15.8**	15.1
SD	**1.3**	**3.6**	**3.5**	4.8	4.9	4.9
Median	45.4	30.4	30.3	15.5	15.5	16.2
	Resting pressure T0 vs T4. p< 0.001			**Static Stiffness Index (SSI) T0 vs T4 NS**		

RESULTS

Among the 20 patients, there are two groups: one with a low SSI (mean value 11) and one with a high SSI (mean value 15). The greater the stiffness (SSI) of the bandage before the treadmill test, the greater the reduction in volume after the test (SSI=11 mmHg for 2.8% volume reduction vs. SSI=15.2 mmHg for 3.8 %). That means that high SSI is more effective in reducing existing edema.

COMFORT AND SLIPPAGE

Comfort Level (Visual Analong Scale, VAS): 8 ± 1.6 (Shows high degree of comfort).

Slippage: T+4 hours: 6 ± 0.3 mm **After treadmill test: 7 ± 0.4 mm**

This level of slippage is deemed minimal from a clinical perspective, even after vigorous treadmill exercise.

CONCLUSION

Significant leg volume reduction of 81 +/- 42 ml, representing 2.9% of leg volume. The Static Stiffness Indes (SSI), the single most major criterion of bandage efficiency remains constant over time even after vigorous exercise. Stiffness has critical hemodynamic impacts via the massaging effect it provides. The DCS compression system is effective in leg volume reduction and improving venous hemodynamics, even in a hot and humid environment without air conditioning, so the results are expected to be even better in temperate or sub tropical climates. No adverse events. Even in high temperatures, high comfort is noted without slippage after a 4 hour period and a vigorous treadmill session. Longer term studies will be useful in this specific hot environment on patients presenting lower limb edema and/or venous leg ulcers.

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