Evaluation of the feasibility of 3D scanning to provide individualized compression therapies among healthy volunteer subjects

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Introduction

The management of venous and mixed aetiology leg ulcers often involves the use of compression therapies both to improve leg ulcer healing rates and prevent leg ulcer recurrence.[1,2] Challenges exist that limit clinicians' ability to apply compression[3] including maintaining a constant tension during application and the impact of variations in leg shape upon ensuring a good fit with no application of excessive pressures that may themselves cause skin damage. Compression stockings are commercially available in a wide range of sizes which are *matched* to the patient's leg using a range of leg length and circumference measurements; this process of leg measurement can be time consuming. This study compared the pressures applied when *off-the-shelf* compression stockings were worn or when a knitted stocking was worn that had been created following a 3D scan of the lower leg.

Materials and Methods

Participants were invited to place a foot upon the footplate of a portable 3D scanner (Orbbec Astra, Orbbec USA, Figure 1). Each scan of the lower leg from knee to foot took approximately 10 seconds to complete. The data file containing the scan was provided to the study sponsor (Advanced Therapeutic Materials) to enable a stocking to be knitted to the dimensions of the scanned leg. Standard leg measurements were manually collected to enable selection of an appropriate below-knee commercially available compression stocking (all comparison stockings were drawn from the Class II Sigvaris range, Sigvaris Britain Ltd, UK).

At a second visit participants were invited to wear the 3D scanned stocking while a non-invasive pressure sensor (Kikuhime, TTMeditrade, Denmark) was placed first at the lowest point on the calf, the B1 position[4] with sub-stocking pressures measured and repeated three times and then the sensor was moved to the C position (maximum width of the calf) and pressure measurements repeated. The 3D scanned stocking was then removed and replaced with an appropriate sized Sigvaris stocking on the same leg. All volunteers then had pressure measurements repeated at B1 and C positions with the Sigvaris stocking *in situ*. All pressure measurements were completed within one hour. Permission for the study to be conducted was provided by the School of Medicine Research Ethics committee of Cardiff University. All statistical tests were conducted using paired t-tests using the SPSS V24 statistical software package (SPSS Inc., USA).

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Results

Twenty-five adult volunteers participated in the study with five subjects having both left and right legs scanned and allocated 3D scanned and Sigvaris stockings so giving a total of 30 limbs with pressure measurements made at the calf and ankle. Table 1 details the characteristics of the 25 subjects.

Of the twenty-five subjects 5 were male and 20 were female. In 15 cases the stockings were applied to the left leg with 15 applied to the right leg (5 subjects had stockings applied to both the right and left leg). Twenty-three subjects used standard Sigvaris compression stockings; two required made to measure stockings.

Table 2 shows the mean sub-stocking pressures recorded at the ankle and calf while subjects wore either the 3D scanned stocking or a Sigvaris compression stocking. The sub stocking pressures were higher at both the calf and ankle when a Sigvaris or made-to-measure stocking was applied compared with the stocking knitted to the dimensions of the leg (ankle; t= –11.2, df=29, P=0.000: calf; t= –6.1, df=29, P=0.000). The standard deviations around the mean sub stocking pressures were wider when the Sigvaris or made-to-measure stockings were applied suggesting greater variability in sub stocking pressure. The class II stockings used in this study should have applied between 23 and 32 mmHg at the ankle, this level of compression was

Table 1. Characteristics of the subjects recruited to the study.

	Mean (standard deviation)	Range
Age (years)	49.2 (12.2)	29-71
Body mass index	27.1 (6.3)	19.8-51.1
Ankle circumference (cm)	22.3 (2.1)	18.5-28.5
Calf circumference (cm)	38.0 (4.4)	29.5-50.1
Lower leg length (cm)	40.6 (3.1)	34.5-46.0

Table 2. Sub-stocking pressures applied at the ankle and calf by two compression stockings.

Stocking	Sub-stocking pressure		
	Mean (mmHg)	Standard deviation (mmHg)	Range (mmHg)
3D scanned			
Ankle	26.5	6.7	14.7-49.0
Calf	20.1	3.7	14.0-28.0
Sigvaris or Made to Measure			
Ankle	43.2	9.3	24.0-67.7
Calf	25.6	4.7	18.0-40.0

Figure 1. Scanning of the lower leg to gather leg dimensions.

seen in 4/30 legs wearing Sigvaris stockings and in 20/30 legs wearing the 3D scanned stocking.

Conclusions

This study set out to determine whether 3D scanning of the lower leg could help produce below knee compression stockings that applied therapeutic levels of compression more consistently than did commercially available compression stockings fitted to the leg using leg length and circumference measurements. The results suggest that: i) the 3D scanned stockings applied lower pressures than did the Sigvaris stockings; ii) the 3D scanned stockings applied more consistent sub stocking pressures as shown by the narrower standard deviations around the mean pressure measurements; iii) the 3D scanned stockings were more likely to apply compression anticipated by a class II stocking.

References

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