A novel approach to mechanical prophylaxis: Calf impulse technology mimics natural ambulation more effectively than sequential calf compression

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BACKGROUND: The risk of thrombosis can be reduced by mechanical compression, but the optimal device is unknown.

OBJECTIVES: To record the effect of natural ambulation on deep venous flow, providing a reference for evaluating the efficacy of mechanical compression systems, assuming that ambulation is the gold standard against which such systems should be compared; and to compare the hemodynamic effect of the A-V Impulse System CalfPad garment (A-VI) (Orthofix Vascular Novamedix, United Kingdom) with the SCD Express calf compression garment (SCD) (Covidien, USA).

METHODS: Twelve healthy volunteers were recruited and randomly assigned to either A-VI or SCD in a two-device, two-period crossover design. Peak femoral velocity (PFV) was calculated using custom ultrasound software and compared with baseline values. Ultrasound images were recorded.

RESULTS: A-VI augmented the mean ($\pm$ SD) PFV to 59.79 ± 29.07 cm/s compared with 22.86 ± 5.73 cm/s for SCD. The actual percentage increase from baseline was approximately five times greater for A-VI (mean increase $385\% \pm 260\%$) than SCD (mean increase $81\% \pm 53\%$). Using an analysis of covariance model, with baseline fitted as a covariate, a highly statistically significant difference in favour of A-VI was detected ($P=0.0002$). Least square (adjusted) means ($\pm 95\%$ CIs) were 37.24 cm/s (21.39 cm/s to 64.84 cm/s) for A-VI and 6.71 cm/s (3.86 cm/s to 11.69 cm/s) for SCD, representing more than fivefold greater improvement in PFV from rest with the A-VI device than with the SCD device.

CONCLUSION: Pulsatile impulse calf compression (A-VI) more closely mimics PFV of normal ambulation than slow-squeeze sequential compression (SCD). Pulsatile calf compression may provide superior protection against thrombosis in immobile patients.

Key Words: Calf compression; Deep vein thrombosis; Impulse compression; Mechanical; Thromboprophylaxis

Deep vein thrombosis (DVT) occurs in more than 20% of patients who undergo major surgery and more than 40% of patients who undergo major orthopedic surgery. Both physical and pharmacological methods have been shown to reduce the incidence of DVT and routine thromboprophylaxis is recommended for many groups of medical and surgical patients by all consensus groups (1-3).

Prophylaxis can be broadly categorized as mechanical or pharmaceutical (4). Mechanical compression protects against thrombosis formation by affecting all three aspects of Virchow's triad – not only enhancing venous flow but also modifying endothelial cell wall function and activating fibrinolysis (5). Unlike pharmacological prophylaxis, mechanical methods are not associated with bleeding complications. A systematic review (6) showed a risk reduction after surgery of approximately 50%. Therefore, mechanical compression has been recommended for patients undergoing a broad range of surgical procedures (orthopedic, gynecological, cardiac, thoracic, urological, neurosurgery, elective spinal, spinal cord injury,

vascular, multiple trauma, trauma and general surgery) (1-3). Mechanical devices can be used as an adjunct to chemical methods for those at particularly high risk of thrombosis, or as an alternative for those with a particularly high risk of bleeding (1,7). Limitations of mechanical devices include bulk, practical aspects of application, compliance, comfort and expense.

Intermittent compression devices promote venous return from the leg by compression, using bladders that inflate in sequence. Foot impulse technology was developed to closely mimic the normal process of ambulation, with evacuation of the venous plexus in the sole of the foot (8). Clinical trials have shown that foot impulse technology (A-V Impulse System, Orthofix Vascular Novamedix, United Kingdom) significantly reduces the frequency of both proximal and total DVT in hip arthroplasty and provides equivalent protection to low-molecular-weight heparin, but without the bleeding complications (9-15). A foot impulse device may be more practical in elective orthopedics than a calf or thigh compressor because of

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TABLE 1
Differences between devices

Company	Orthofix Vascular Novamedix, UK	Covidien, USA
Product name	A-V Impulse System CalfPad	SCD Express calf compression sleeve
Inflation pressure, mmHg	80	40
Time to reach pressure, s	0.4	8–11
Inflations/min	3	1

UK United Kingdom

the proximity of the wound. Patients tend to prefer foot pumps to calf or thigh compressors (16).

With the potential physiological advantages of impulse compression, but the widespread use and popularity of calf compression, a calf compression system based on impulse rather than sequential compression has been developed.

Assessing the clinical efficacy of a new mechanical device is challenging. While a randomized study would be the definitive way of comparing devices, the most appropriate or practical outcome measure is unclear. Demonstrating the likely small difference between (fairly rare) clinical outcomes would require a prohibitive sample size. Therefore, a surrogate for clinical efficacy such as venography or ultrasound may be considered. Research funding is unlikely to be financially feasible for the manufacturers, nor would it be a high priority for independent grant agencies. An alternative would be to compare the flow characteristics produced by each device. These devices vary in their inflation parameters (pressure delivered, time to reach inflation pressure and cycle time) (17) and also their location on the lower limb (foot, calf, or calf and thigh). Therefore, it is uncertain which flow parameter, peak or mean velocity should be used to evaluate the devices instead of a clinical trial (5,18,19).

It is logical to assume that the more closely a mechanical compression device mimics ambulation, the more beneficial the level of prophylaxis will be.

The purpose of the present study was twofold – first, to identify which device most closely mimicked the natural physiological process of ambulation and second, to compare the efficacy of the A-V Impulse System CalfPad device (A-VI) with the SCD Express sequential calf compression system (SCD) (Covidien, USA) in enhancing peak femoral velocity (PFV).

METHODS

Twelve healthy volunteers (two men, 10 women) with no history of venous disease or thromboembolism were recruited. Volunteers were excluded from the study if they had any contraindications for use of mechanical compression devices according to the manufacturer's recommendations. Informed consent was obtained from the volunteers before commencement of the study.

Measurement

Measurements were obtained using noninvasive colour flow duplex ultrasound performed by an experienced sonographer. The Doppler measurements were taken approximately 1 cm

TABLE 2
Baseline characteristics (n=12)

Statistic	Vein diameter (mm)
Mean ± SD	12.7±1.87
Median	13.0
Range	9.0–15
	Velocity of blood flow (cm/s)
Mean ± SD	13.25±3.60
Median	13.5
Range	9.0–20.0

proximal to the saphenofemoral junction in the common femoral vein. An HDI 5000 Sono computed tomography scanner (Philips Medical Systems, USA) was used. The probe used was the high frequency L10-5. The standard machine venous setup was used so that the same parameters were used in all patient studies.

Blood flow during normal ambulation

The common femoral venous flow was recorded with the patient applying weight to the foot. The patient was examined standing with the right foot slightly in front of the left foot. The ultrasound transducer was then held over the common femoral vein and the resting flow was recorded. The patient was then asked to rock forward on the right foot and raise the left heel and then place the left foot in front of the right, taking a step forward. The patient then placed the left foot back in the resting position behind the right leg, ready for the next step to be taken and recorded. Elevation of the foot and rocking forward (as in a step) contracted the calf muscles and to a lesser extent, the thigh muscles (as in the normal movement of walking). This procedure was repeated in each of the 12 volunteers.

Comparison of flow between devices

Subjects were measured to determine the appropriate size compression sleeve for each device; they were placed in the supine position in a normal hospital stretcher bed with the torso elevated 30°. The right leg was studied in each case. The room temperature was constant. The order of device placement was randomly assigned. The devices (Table 1) were applied following the published directions of the manufacturer. The measurements were taken with the gate of the Doppler opened to 70% of the width of the vein with the angle corrected to 60°. Due to the nature of the investigation, the sonographer was not blinded to the compression device applied. All sonography was completed by the same consultant radiologist to limit measurement error.

Baseline femoral venous scan and determination of PFV was recorded before application of the compression devices. Femoral velocity, along with volume flow readings, were obtained following initiation of pumping. PFV was recorded on a data sheet and all blood flow traces were recorded. Results from three consecutive cycles of the pump were obtained, recorded and averaged to minimize error. With the patient lying quietly and breathing gently, baseline femoral scans were recorded and the PFV was documented before application of the pressure devices. The measurements were taken with the Doppler gate open to 70% of the width of the vein and the

Figure 1) Typical flow in the femoral vein during normal ambulation. A Rest. Low velocity venous return with little turbulence behind vein valve cusps. B Walking. High velocity, turbulent venous return

TABLE 3

Actual baseline, postbaseline and change from baseline values and percentage change and percentage increase over baseline – peak femoral velocity (by treatment)

Treatment	Statistic	Actual baseline (resting) values (cm/s)	Actual postbaseline values (cm/s)	Actual change from baseline (cm/s)	Change from baseline (%)	Mean increase over baseline (%)*
A-VI (n=12)	Mean	13.25	59.79	46.54	385	485
	SD	3.60	29.07	29.89	260	260
	Median	13.5	43.18	33.60	353.0	453.0
	Minimum	9.0	24.57	11.57	76.0	176.0
	Maximum	20.0	106.9	92.9	828.0	928.0
SCD (n=12)	Mean	13.25	22.86	9.61	81	181
	SD	3.60	5.73	6.00	53.00	53.00
	Median	13.5	23.0	9.57	82.0	182.0
	Minimum	9.0	13.67	0.23	1.0	101.0
	Maximum	20.0	36.60	22.60	161.0	261.0

*Increase over baseline is the subject's postbaseline value minus the subject's baseline value. A-VI A-V Impulse System CalfPad (Orthofix Vascular Novamedix, United Kingdom); SCD SCD Express calf compression sleeve (Covidien, USA)

angle correction standardized at 60°. All of the vascular measurements were made by the same radiologist using the same equipment and standardized settings. Following application of the compression device, baseline femoral flow along with the PFV was recorded and results from three consecutive cycles of the pump were obtained. These were averaged to minimize error. The subjects rested for 5 min after completing testing of the first device and before initiating testing of the second device.

Analysis

The data were analyzed using SAS version 9.1.3 (SAS Inc, USA). To investigate the differences between the changes from baseline with the two devices, an analysis of covariance model was used with period and treatment as factors and the baseline PFV fitted as a covariate. The null hypothesis was that there was no difference between the A-VI and SCD devices and a two-tailed 5% significance level ($P < 0.05$) was used. Before analysis, model fitting assumptions of normality and constant variance were investigated and found to be satisfactory. No period effects were detected. The results of the analyses are presented as least square ('adjusted') mean point estimates and

95% CIs with F statistics and P values. To aid subsequent interpretation, the changes from baseline values were logged and the F statistics and P values were presented. The logged estimates were then back-transformed by exponentiating and presented as least square means and appropriate 95% CIs.

RESULTS

Baseline characteristics

Details of the subject's baseline characteristics are given in Table 2. The overall mean ($\pm$ SD) diameter of the common femoral vein was 12.7 ± 1.87 mm and the mean PFV at rest was 13.25 ± 3.60 cm/s.

Blood flow during normal ambulation

High-velocity, turbulent venous return was recorded in the common femoral vein as the foot was placed with the patient's weight to the floor (Figure 1). A similar pattern was found in each of the 12 volunteers.

Comparison of flow between devices

Summary statistics: Summary statistics of interest showing actual change from baseline and percentage change from

Figure 2) Comparison between normal ambulation, A-V Impulse System CalfPad (A-VI) (Orthofix Vascular Novamedix, United Kingdom) and SCD Express calf compression sleeve (SCD) (Covidien, USA). The CalfPad more closely resembles the pattern of normal ambulation. A Peak femoral velocity (PFV) is approximately 10 cm/s to 15 cm/s while resting. B SCD (sequential compression) PFV is 30cm/s. C A-VI PFV is 86 cm/s. D Normal ambulation PVF is 108 cm/s

TABLE 4
Change from baseline – statistical analysis

Model factors	Statistical analysis			
	Mean square	df	F statistic	P
Baseline	4.549	1	5.37	0.0313
Period	0.024	1	0.03	0.8690
Treatment	17.610	1	20.77	0.0002

The F value of 5.37 and the significant P value (P=0.0313) indicate that fitting the baseline value as a covariate was beneficial and improves the efficiency of the model used in the analysis. The lack of a period effect is confirmed (P=0.8690, period is not significant). The P value (P=0.0002) for the treatment effect indicates a highly statistically significant difference between the A-V Impulse System CalfPad (Orthofix Vascular Novamedix, United Kingdom) and the SCD Express calf compression sleeve (Covidien, USA). df Degrees of freedom

baseline values are presented by treatment in Table 3. Because the present study has a crossover design, the average resting peak velocity is necessarily the same in each group before activation of the devices (actual mean baseline PFV 13.25±3.60 cm/s). Following treatment with the A-VI device, the actual mean was 59.79±29.07 cm/s compared with 22.86±5.73 cm/s

TABLE 5
Back-transformed change from baseline values – estimates of treatment effect

Treatments	Least square	
	mean	95% CI
A-VI	37.24	21.39 to 64.84
SCD	6.71	3.86 to 11.69
A-VI/SCD	5.55	2.53 to 12.15

AV-I A-V Impulse System CalfPad (Orthofix Vascular Novamedix, United Kingdom); SCD SCD Express calf compression sleeve (Covidien, USA)

in the SCD group. This represents a 46.54±29.89 cm/s or 385%±260% change from baseline and 9.61±6.0 cm/s or 81%±53.0% change from baseline in the A-VI and SCD devices, respectively.

The mean percentage increase over baseline in PFV was 2.68 times greater for the A-VI than SCD devices (485%±260% versus 181%±53%).

Statistical analysis: The least square (‘adjusted’) mean change from baseline for the A-VI device was 37.24 cm/s (95% CI 21.39 cm/s to 64.84 cm/s) compared with 6.71 cm/s

(95% CI 3.86 cm/s to 11.69 cm/s) for the SCD device. This represents a highly significant ($P=0.0002$) improvement in the PFV of 5.55 times greater with the A-VI device when compared with the SCD device (95% CI 2.53 to 12.15) (Tables 4 and 5).

Matching of flow trace to normal ambulation

Subjective interpretation of the traces shows that the AVI matched the pattern of normal ambulation much more closely than SCD (Figure 2).

DISCUSSION

Intraoperatively and in the immediate postoperative period, patients are at increased risk of venous thromboembolism. Inability to perform the normal physiological process of ambulation to maintain pulsatile venous return leads to venous stasis and thrombus formation. This is potentiated by the hypercoagulable state that surgery provokes. Pneumatic compression devices should promote venous return when the patient is unable to ambulate; the closer these devices mimic the flow of normal ambulation, the more effective they are likely to be.

Before the development of impulse compression, no compression devices inflated rapidly enough to mimic the hyperemic effect of ambulation (8). It is known that a faster rate of inflation of mechanical compression devices correlates with a greater peak velocity (20). It is furthermore generally proposed (17,21,22), although not necessarily clinically validated, that peak velocity during compression is the most important hemodynamic performance indicator. Thus, it is a reasonable conclusion that a device with a higher peak velocity would have a better prophylactic effect.

Our study confirmed that pulsatile impulse compression of the calf in under 0.4 s compared with an inflation time of

approximately 10 s with the sequential compression device results in a higher PFV. Furthermore, our study showed that pulsatile impulse compression of the calf more closely mimics the pattern of femoral flow recorded during the normal physiological process of ambulation than a slow-squeeze sequential compression device. In the absence of a randomized clinical trial with venographic or, better still, symptomatic outcomes, one may surmise that the pulsatile calf device has a physiological advantage. Compliance (from patients and ward staff) is a limiting factor with compression devices (23); further study is needed to see if there is a practical advantage for one device over the other. Cost remains an important factor when health care systems decide between devices.

The CalPad is only available as a below-knee garment. Intermittent pneumatic compression devices are typically designed as below-knee or thigh-high garments. There is no clear physiological or clinical advantage to distinguish between the two (6,17). Guidelines do not recommend one over the other (1-3). Furthermore, the proximity to the surgical wound with lower-limb orthopedic procedures for above-knee stockings, greater expense and more difficulty in application all suggest that below-knee devices are adequate.

CONCLUSION

Pulsatile calf compression devices offer a physiological advantage over sequential calf compression devices, which may translate into improved clinical effectiveness, reducing postoperative stasis in the immobile patient and thus reducing venous thromboembolism.

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REFERENCES

- Geerts WH, Bergqvist D, Pineo GF, et al. Prevention of venous thromboembolism. American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). Chest 2008;133:381S-453S.
- National Institute for Health and Clinical Excellence. Venous thromboembolism. Reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in inpatients undergoing surgery. <<http://www.nice.org.uk/nicemedia/pdf/CG046NICEguideline.pdf>> (Version current at December 30, 2008).
- Cardiovascular Disease Educational and Research Trust; Cyprus Cardiovascular Disease Educational and Research Trust; European Venous Forum; International Surgical Thrombosis Forum; International Union of Angiology; Union Internationale de Phlébologie. Prevention and treatment of venous thromboembolism. International Consensus Statement (guidelines according to scientific evidence). Int Angiol 2006;25:101-61.
- Pellegrini VD Jr, Sharrock NE, Paiement GD, Morris R, Warwick DJ. Venous thromboembolic disease after total hip and knee arthroplasty: Current perspectives in a regulated environment. Instr Course Lect 2008;57:637-61.
- Morris RJ, Woodcock JP. Evidence-based compression. Prevention of stasis and deep vein thrombosis. Ann Surg 2004;239:162-71.
- Roderick P, Ferris G, Wilson K, et al. Towards evidence based guidelines for the prevention of venous thromboembolism: Systematic review of mechanical methods, oral anticoagulation, dextran and regional anaesthesia as thromboprophylaxis. Health Technol Assess 2005;9:iii-iv, ix-x, 1-78.
- Warwick DJ. New concepts in orthopaedic thromboprophylaxis. J Bone Joint Surg 2004;86B:788-92.
- Gardner AMN, Fox RH. The Venous System in Health and Disease, 3rd edn. Amsterdam: IOS Press, 2001.
- Warwick DJ, Harrison J, Glew D, Mitchelmore A, Peters T, Donovan J. Comparison of the use of a foot pump with the use of low molecular weight heparin for the prevention of deep vein thrombosis after total hip replacement. J Bone Joint Surg Am 1998;80-A:1158-66.
- Fordyce M, Ling R. A venous foot pump reduces thrombosis after total hip replacement. J Bone Joint Surg Br 1992;74-B:45-9.
- Stannard JP, Harris RM, Bucknell AL. Prophylaxis of deep venous thrombosis after total hip arthroplasty by using intermittent compression of the plantar venous plexus. Am J Orthop 1996;2:127-34.
- Santori ES, Vitullo A, Stopponi M, Santori N, Ghera S. Prophylaxis against deep vein thrombosis in total hip replacement. J Bone Joint Surg Br 1994;76-B:579-83.
- Bradley JG, Krugener GH, Jager HJ. The effectiveness of intermittent plantar venous compression in prevention of deep vein thrombosis after total hip arthroplasty. J Arthroplasty 1993;8:57-61.
- Stranks GJ, McKenzie NA, Grover ML, Fail T. The A-V Impulse System reduces deep vein thrombosis and swelling after hemiarthroplasty for hip fracture. J Bone Joint Surg Br 1992;74-B:775-8.
- Pitto RP. Mechanical prophylaxis of deep vein thrombosis after total hip replacement. J Bone Joint Surg Br 2004;86-B:639-42.
- Robertson KA, Bertot AJ, Wolfe MW, Barrack RL. Patient compliance and satisfaction with mechanical devices for preventing deep vein thrombosis after joint replacement. J South Orthop Assoc 2000;9:182-6.

17. Westrich GH, Specht LM, Sharrock NE, et al. Venous haemodynamics after total knee arthroplasty. Evaluation of active dorsal plantar flexion and several mechanical compression devices. *J Bone Joint Surg Br* 1998;80-B:1057-66.
 18. Labropoulos N, Oh DS. Improved venous return by elliptical, sequential and seamless air-cell compression. *Int Angiol* 2003;22:317-21.
 19. Whitelaw GP, Oladipo OJ. Evaluation of intermittent pneumatic compression devices. *Orthopedics* 2001;24:257-61.
 20. Flam E, Berry S, Coyle A, Dardik H, Raab L. Blood flow augmentation of intermittent pneumatic compression systems used for the prevention of deep vein thrombosis prior to surgery. *Am J Surg* 1996;171:312-5.
 21. Warwick DJ, Martin A, Glew D, Bannister GC. Measurement of femoral vein blood flow during total hip replacement. Duplex ultrasound with and without the use of a foot-pump. *J Bone Joint Surg* 1994;76-B:918-21.
 22. Warwick D, Pandit H, Shewale S, Sulkin K. Should stockings be used with the AV Impulse system? *J Arthroplasty* 2002;17:446-8.
 23. Comerota AJ, Katz ML, White JV. Why does prophylaxis with external pneumatic compression for deep vein thrombosis fail? *Am J Surg* 1992;164:265-8.
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