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The Gait-dependent Intermittent Pneumatic Compression Ambulatory Boot Device: Preliminary Reports on Calf Pressure and Venous Hemodynamics

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Rationale: Compression therapy has been demonstrated to be beneficial in a number of vascular conditions including chronic arterial ischemia, venous insufficiency and primary and secondary lymphedema. Its effectivity however is limited and questioned by the nature of the treatment procedure which requires that the patient be in a sitting or recumbent position while it is being administered.
Methods: The author describes the development of a boot device which provides gait-dependent intermittent compression to the ankle and calf.
Results: In volunteer studies, the device produced a cycle of pressure changes from 15-40 mmHg at the interface. Simulated calf compression resulted in augmentation of venous flow recorded by duplex sonography at the superficial femoral vein area, indicating an improvement in venous hemodynamics with the use of the device.
Conclusion: These findings demonstrate the potential for an attractive ambulatory alternative to the commonly employed non-ambulant therapies for venous insufficiency.

Keywords: hemodynamics, compression therapy, venous insufficiency, femoral vein

Compression therapy has been shown to be of benefit in a number of vascular conditions[1,2,3] and is a mainstay of treatment for chronic venous insufficiency and primary and secondary lymphedema.[4] However, inherent limitations of present strategies and devices preclude complete compliance by the patient and thus limit their effectivity. Intermittent compression devices are most effective in reducing and maintaining reduction of limb volume but require the patient to be immobile and confined to bed while the treatment is going on, and thus limits therapy to only short periods every day. Continuous compression strategies such as elastic stockings and elastic bandages, on the other hand, allow the patient to ambulate; however, the high compression pressures needed for them to be effective make them difficult for the patients to put on, and the continuous pressures may reduce skin capillary perfusion with resultant impairment of wound healing.[5]

The ideal compression device is that which maintains continuous function in order to ensure continuous treatment. For this to occur, the device must necessarily be easy to put on and activate, promote mobility, and provide intermittent compression in order to avoid skin capillary perfusion impairment, while being able to maintain therapeutic compression levels despite changes in limb volume. This paper describes the development of a gait-dependent intermittent compression boot which encourages instead of prevent ambulation while fulfilling the requirements of the ideal compression device mentioned previously.

Methods

A prototype compression boot was constructed which consisted of a system of connected inflation cuff bladders incorporated into an elastic neoprene boot (Figure 1). Two pediatric-sized inflation bladders were installed at the plantar area, one at the proximal heel pressure point, and the other at the distal metatarsal pressure point. The proximal heel bladder was connected by a rubber hose to an ankle adult-sized cuff inflation bladder, while the distal metatarsal bladder was connected to another adult-sized inflation calf bladder. The constraining material consisted of an elastic neoprene boot, which can easily be applied by the use of Velcro fasteners. The elastic neoprene boot was secured with Velcro straps around the lower limb from just distal to the metatarsal heads up to around the infrapopliteal gastrocnemius muscle. Alternatively, two rolls of six-inch wide elastic bandages served as the constraining material around the air bladders. Calibration of the boot was done by inflating the calf bladder to a pressure of 40 mmHg while on weight bearing (stance phase). Intermittent compression to the ankle and calf was produced upon ambulation when the heel strike and toe push sequentially inflate the ankle and calf bladders, respectively (gait phase).

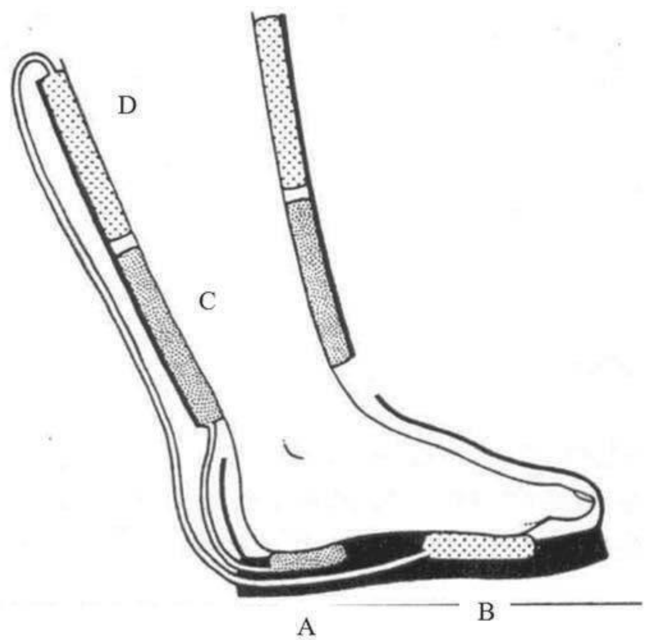

Figure 1. Diagram of ambulatory pneumatic compression boot. Two pediatric size air bladders (A and B) are positioned under the heel and the metatarsal heads connected by the rubber tubes to the calf air bladders (C and D). (*illustration used with permission, Hamzeh MA, et al. A new device producing ambulatory intermittent pneumatic compression suitable for the treatment of lower limb oedema: a preliminary report. J Med Eng Technol 1993 17(3):110-3.*)

The boot was tested on six healthy volunteers and five volunteers with documented chronic venous insufficiency. In each subject, the compression exerted by the inflation bladders upon ambulation on an exercise treadmill were recorded by continuous measurement on a polygraph of the bladder pressure by means of a pressure transducer attached to an outflow hose (Figure 2).

Venous flow was determined by duplex ultrasonography (Acuson, USA). A 5MHz linear vascular Doppler probe was applied over the ipsilateral superficial femoral vein of each standing subject while the compression bladders were sequentially inflated to the pressures generated during ambulation. Doppler spectral waveforms were recorded on a video cassette recorder (Panasonic, Japan) and offline review of the data was done during playback.

Results

Stance pressures generated by the elastic neoprene boot and the inflated bladders were easily calibrated to 40mmHg. The stance phase allowed the calf bladders to be inflated to the given compression pressure while the plantar bladders are compressed by the weight of the subject (Figure 2). This ensured that the maximum compression pressure of 40mmHg can be transmitted to the calf compartment.

Gait pressures recorded during ambulation are shown in Table 1. During the lift phase, both plantar bladders were inflated, and resting pressures on the calf compartment were due to the elastic compression of the constraining material. At the heel strike phase, the heel bladder was compressed, which channeled air through the tubes to inflate the lower ankle bladder. As the weight shifted to the metatarsals, the metatarsal bladder became compressed, which sequentially compressed the upper gastrocnemius bladder. The toe-push phase continued to generate higher pressures in the upper calf, while the succeeding lift phase returned the resting pressures to baseline (Figure 3).

The pressures recorded using neoprene as constraining material were uniformly lower than those recorded using the less compliant snugly wound elastic bandage (Table 2).

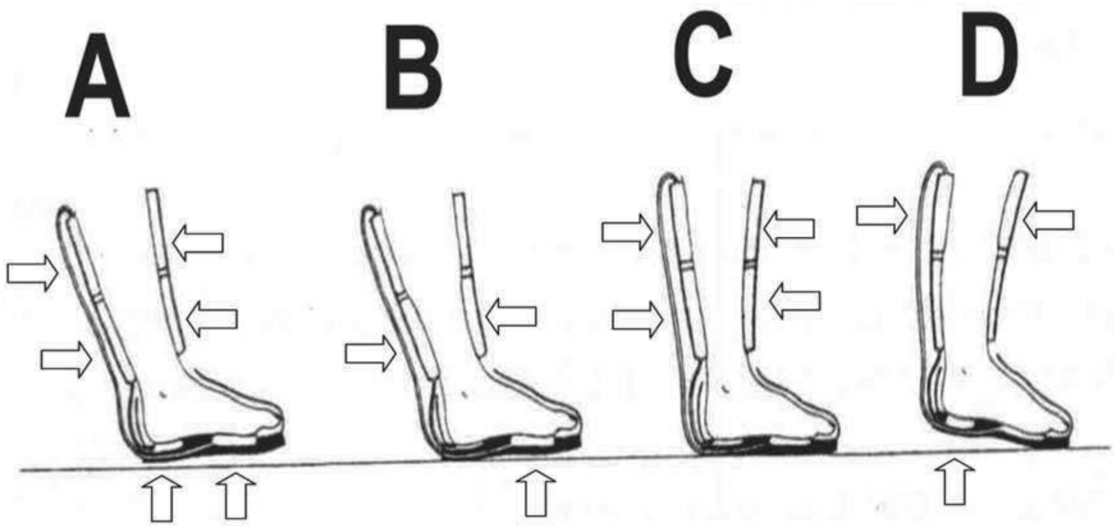

Figure 2. Diagrams showing air bladder inflation changes during gait cycle. Arrows point to inflated cuffs. A. lift phase, all air bladders inflated at equilibrium; B. heel strike, compressed heel bladder inflates lower calf bladder; C. stance phase, both insole air bladders compressed, sequential inflation of upper calf bladder while maintaining inflation of lower calf bladder; D. toe push, heel bladder regains inflation, while continued compression of metatarsal bladder maintains inflation of upper calf bladder. (*illustration used with permission, Hamzeh MA, et al. A new device producing ambulatory intermittent pneumatic compression suitable for the treatment of lower limb oedema: a preliminary report. J Med Eng Technol 1993 17(3):110-3.*)

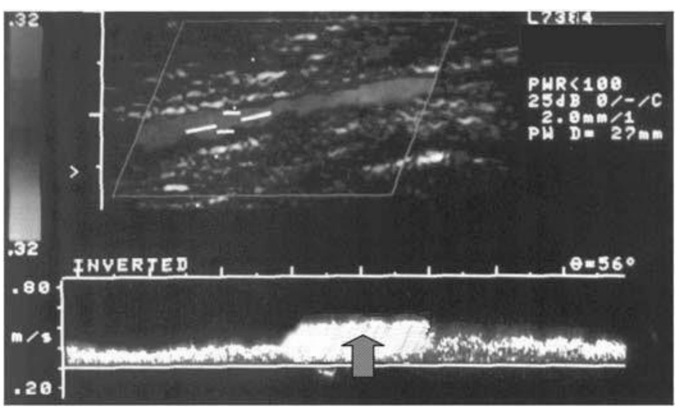

Figure 3. Duplex ultrasound image of the proximal third of the superficial femoral vein showing increase in venous flow velocity (arrow) on distal compression of calf compartment.

Table 1. Calf pressure measurements during the gait cycle. Values obtained from ambulatory boot constructed from neoprene. (Values expressed as mean ± SEM, p>0.05). CVI, chronic venous insufficiency.

	Calf Pressures (in mmHg)			
	Normal Volunteers		Volunteers with CVI	
	Lower Calf	Upper Calf	Lower Calf	Upper Calf
Lift Phase	12 ± 3	8 ± 1	10 ± 4	9 ± 3
Heel Strike	38 ± 4	13 ± 5	39 ± 6	14 ± 4
Stance	42 ± 2	36 ± 7	39 ± 5	34 ± 6
Toe Push	11 ± 5	42 ± 4	13 ± 4	39 ± 6

Table 2. Calf pressure measurements during the gait cycle. Values obtained from ambulatory boot constructed from elastic bandage. (Values expressed as mean ± SEM, p>0.05). CVI, chronic venous insufficiency.

	Calf Pressures (in mmHg)			
	Normal Volunteers		Volunteers with CVI	
	Lower Calf	Upper Calf	Lower Calf	Upper Calf
Lift Phase	15 ± 5	10 ± 4	15 ± 3	14 ± 3
Heel Strike	42 ± 4	17 ± 4	39 ± 3	20 ± 5
Stance	40 ± 2	42 ± 2	41 ± 2	40 ± 4
Toe Push	16 ± 2	42 ± 2	19 ± 2	41 ± 3

Venous flow at the superficial femoral veins of both healthy and diagnosed venous insufficiency volunteers exhibited compression-augmentation patterns during sequential bladder inflation (Figure 3). Venous flow velocities were higher than those obtained from tiptoe maneuvers (Table 3).

Discussion

Chronic venous insufficiency and lower limb lymphedema share a common hemodynamic etiopathology for their sequelae of complications: failure of the outflow mechanism to provide continuous flow for the washout of metabolic wastes and other degradative substances. Traditionally, these two conditions were managed conservatively by prolonged bed rest and limb elevation, which facilitated venous return and decreased intravascular pressures, thereby avoiding tissue extravasation of the metabolic waste products.

Compression therapies are part of the mainstay of treatment for chronic venous insufficiency and lymphedema.[3] External compression has been shown to increase venous flow by mechanisms analogous to and augmenting the pumping action of the calf muscles during walking.[7] External compression raises tissue pressure briefly, evacuates the underlying veins, and transiently reduces venous pressure.[8] Venous stasis is avoided ,[9,11] and thrombogenesis as well as microcapillary injury secondary to fibrin deposition is reduced.[10]

Aside from the mechanical hemodynamic effects, external compression may also mediate the release of endothelial and humoral factors having local and systemic effects.[11] Compression has been shown to promote release of prostaglandin I_2 (PGI_2) from endothelial cells as a result of the changes in shear stress and blood flow. PGI_2 is a vasodilator and a potent inhibitor of platelet aggregation that is mainly responsible for microcirculatory injury. Studies have also demonstrated an enhancement of fibrinolytic activity with external compression that

Table 3. Peak venous velocities as measured by duplex ultrasound at the superficial femoral vein. (Values expressed as mean ± SEM). CVI, chronic venous insufficiency.

	Peak venous velocities (cm/sec)		
	Normal Volunteers	Volunteers with CVI	p
Compression	40 ± 6	38 ± 2	> 0.05
Tiptoe	32 ± 2	26 ± 4	> 0.05
p	< 0.05*	< 0.05*	

may be beneficial in the prevention of deep vein thrombosis and improve wound-healing capabilities.[9,10]

Present approaches for delivering compression therapies may be divided into two main strategies: constant compression and intermittent compression therapies. Constant compression therapies make use of elastic stockings or bandages which apply a constant pressure ranging from 18 to 20 mmHg and can be worn for extended periods.[3] The chief advantage is that they allow the patient to be mobile and ambulant. However, the inherent weakness is that the pressures are generally too low for adequate compression of the superficial venous system and thus does not completely prevent reflux or stasis in the superficial venous system. Those stockings and bandages that do provide sufficient compression are too difficult to put on, and are too uncomfortable to wear for extended periods, and may reduce skin capillary perfusion and hence, impair wound healing.

Intermittent compression therapies on the other hand are able to deliver the higher compression pressures of up to 200 mmHg necessary to not only prevent reflux into the superficial venous system, but also provide a positive pressure push for a more rapid emptying of the venous system.[3] These devices are also generally more effective in reducing and maintaining the reduction in limb volume. In addition to improving venous hemodynamics, intermittent compression has been shown to promote release of endothelial factors mentioned earlier. The main disadvantage of present intermittent compression devices, however, is that they universally require the patient to be immobilized during the therapy, and is limited to short periods of treatment each day.

The gait-dependent intermittent pneumatic compression boot combines the advantages of intermittent compression with the mobility and ease of application of constant compression. The device is easily applied and is light enough to be mobile; it also has the added advantage of encouraging and promoting ambulation in order to deliver the required compression cycles. The pressures delivered are higher than those generated by constant compression strategies. Furthermore, the boot can be calibrated to a level of pressure that is not excessively high as to be uncomfortable to the patient and detrimental to skin capillary flow. The plantar-calf bladder system may be adaptable to a variety of constraining materials either elastic or non-elastic. Whatever constraining material is used, the calibration procedure can assure that the pressures delivered during the gait cycle are adequate to maintain increased tissue pressure and superficial venous compression.

The boot may potentially be applied for the conservative treatment of chronic venous insufficiency and lower limb lymphedema, and may demonstrate some utility in the non-surgical management of chronic arterial ischemia.[13,14] Further clinical trials are warranted in order to document its efficacy in these vascular conditions.

Conclusion

The gait-dependent intermittent pneumatic compression boot offers an attractive ambulatory alternative to the traditional non-ambulant method of treatment for chronic venous insufficiency and lower limb lymphedema. Clinical trials are recommended in order to establish its efficacy in various vascular disorders.

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