A novel intermittent mechanical compression device for stasis prevention in the lower limbs during limited mobility situations

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Received 7 December 2006; received in revised form 20 February 2007; accepted 28 February 2007
Available online 17 April 2007

Abstract

Introduction: Intermittent pneumatic mechanical compression is commonly applied to obviate venous stasis in patients with increased risk of thromboembolism. Aviafit is a small battery-operated intermittent compression device using a patented mechanical, non-pneumatic technology. Our objective was to examine its ability to prevent venous stasis.

Materials and methods: Doppler ultrasonography was used to determine venous hemodynamics of 22 healthy volunteers in both legs, before applying the Aviafit to one randomly selected leg, upon device activation and after 30 min. Each measurement provided values for peak flow velocity (PFV) and total volume flow (TVF).

Results: The PFV values were significantly higher in the treated leg upon activation of the Aviafit and at 30 min, compared to the baseline value and to the PFV of the untreated leg at the corresponding time points (p<0.001 for each). The TVF increased in the treated leg from baseline of 48 ml/min to 56 ml/min at T0, and then gradually decreased, similar to the untreated leg. At T30, 64% of the treated legs had a higher TVF than their untreated counterparts.

Conclusions: The lightweight, battery-operated and user-friendly Aviafit can provide the same hemodynamic benefits as larger conventional intermittent pneumatic compression devices. Its potential advantages for prophylaxis of thromboembolism and increased compliance in rehabilitation and homecare, and for use during long periods of immobility such as during flights, are evident.

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Introduction

Venous thromboembolism, e.g. deep vein thrombosis (DVT) and pulmonary embolism, afflicts approximately two million Americans [1], with approximately 200,000 new cases annually [2]. Its associated morbidity ranges from pain and swelling of the leg and irreversible damage to the venous valves to life-threatening pulmonary embolism. It was calculated to be the third most common cause of death in the US [2].

Venous stasis, vascular endothelial damage, and hypercogulability are the underlying pathological causes of venous thromboembolism. These are often encountered when mobility is restricted, such as in immobilized or postoperative patients, or during extended periods of confinement to restrictive seating, often encountered in mid-long range flights [3,4]. While in the latter condition even individuals in excellent physical health can be afflicted, several comorbidities are contributive to elevated risk of DVT elsewhere, and those include stroke and paralysis, malignancy and obesity, as well as pregnancy and the use of oral contraceptives [5,6].

Several prophylactic strategies have been adopted to prevent thromboembolism in individuals confined to bed. Chemical prophylaxis, primarily with low molecular weight heparin, but also with other anticoagulants such as aspirin, has many disadvantages, principally the increased risk of uncontrolled hemorrhage, especially intra-operatively [7,8]. Mechanical compression has been commonly applied to obviate venous stasis in patients with increased risk of thromboembolism. This is usually accomplished by applying intermittent pneumatic compression (IPC) devices. IPC devices comprise of inflatable leggings placed around the shin or the leg and apply pneumatic pressure to compress the lower extremity in cycles of compression and release [9,10]. Other devices used to prevent thromboembolism include foot compression devices that operate under higher pressures and which are used when the lower limb must remain accessible [11]. The external compression of the lower limb improves the venous hemodynamics, as evidenced by the increased peak flow velocity and total flow volume. Indeed, at pressures approximating 40 mm Hg, femoral vein flow velocities could be increased by 50–250%, even with calf compression alone [12–15]. There is evidence that such treatment also stimulates the fibrinolytic activity in the treated organ, by a mechanism still undefined, further lowering the risk of DVT [9,16].

However, such compression devices are usually cumbersome and expensive, and are only suitable for patients who are confined. These devices require external power source and their transport is inconvenient. Furthermore, in observational studies on the use of compression devices by non-ambulatory trauma patients, only 19% were fully compliant, and noncompliance was associated with a higher rate of DVT [17]. It was argued that patient compliance is one of the most important factors to consider when selecting a mechanical prophylactic system [18].

The objective of the present study was to examine the ability of a small battery-operated device that integrates a patented mechanical intermittent compression technology to prevent venous stasis and increase blood flow in the treated leg. This device is suitable for unassisted consumer and home use, and can be applied during mid-long flights or other situations of restricted mobility.

Materials and methods

Twenty-two healthy volunteers were enrolled in this pilot study. Excluded were individuals younger than 18 or older than 65 y, with body mass index > 30, and those suffering from acute life-threatening diseases, active pathological heart conditions, edema due to congestive heart failure, atrial fibrillation, evidence of DVT by compression ultrasonography, DVT in the 3 months preceding enrollment, revascularization or angioplasty of the target limb within the previous 6 months, ulcers or cellulitis in regions covered by the compression device, active phlebitis, muscular disorders, or compartment syndrome. Informed consent was obtained from all the participants.

The device tested (Aviafit™ by FlowMedic, Caesarea, Israel) is a battery-operated portable device placed on the shin and attached with a strap which is wrapped around the calf over or under the clothing (Fig. 1). It is compact and light (270 g),...
designed with a slight concave–convex surface for convenient placement.

Upon activation, the Aviafit pulls the straps periodically causing a tightening of the calf muscle, similar to the action that occurs during walking. Each contraction comprises a pull and release cycle of 7 s and 48 s, respectively. This applies intermittent controlled pressure (average 45 mm Hg) to the lower limb.

The device was applied to one randomly selected leg of each volunteer with the other leg serving as control. The tested individual was seated and rested for 30 minutes before measurements commenced. Venous hemodynamics was determined by Doppler ultrasonography (Philips HDI 5000 Sonocity) at the superficial femoral vein (SFV), with all measurements performed by a single ultrasound qualified technician. Measurements at each time point were the average of five repeated determinations of the peak flow velocity (PFV) and the total volume flow (TVF). Measurements were performed after 30 min rest with the device non-activated on the leg (baseline); immediately after the device was turned on (T0); and after 30 min of device activity (T30).

Statistical analyses were based on the lognormal transformation, because except for PFV in the untreated leg at T0, the distributions of the relevant variables were not significantly different from the lognormal distribution.

Results

The study group comprised 14 men and 8 women, of mean age of 39±8.2 y (range 27–54 y).

Fig. 2 depicts the values of the PFV in the treated leg and its contralateral control before the device was activated (baseline), at the onset of the compression (T0), and 30 min later (T30). The PFV values were significantly higher in the treated leg immediately upon activation of the Aviafit and at 30 min, compared to the baseline value and to the values obtained for the untreated leg at the corresponding time points (\( p < 0.001 \) for each). In the experimental legs the proportional change in velocity from baseline levels was highly significant (\( p < 0.001 \)) with an average increase of 5 fold. The effect of the device was instantaneous and there was no difference between these proportional changes between T0 and T30. No such effects were observed in the control leg.

The behavior of the TVF is illustrated in Fig. 3. In the untreated leg there was a gradual decrease of the total volume flow as the experiment progressed, from 51 ml at baseline to 40 ml at T30. This difference was significant (\( p < 0.01 \)). In the leg treated with the
device, the flow increased from baseline level of 48 ml/min to 56 ml/min at T0, and gradually decreased during the 30 min of treatment to 44 ml/ min, statistically similar to the untreated leg. Still, at T30, 64% of the treated legs had a higher TVF than their untreated counterparts, much more than the 50% observed at baseline (p=0.07).

It was noted by Doppler ultrasonography of the SFV that the device improves venous drainage with immediate recovery of the normal flow (Fig. 4). Within each cycle, venous flow was doubled during the compression phase as compared to the release phase, as detailed in Table 1. This ratio was maintained throughout the entire test (30 min).

**Discussion**

PFV measurements of the treated leg upon activation of the Aviafit showed an obvious and statistically significant fivefold increase, relative to baseline. This effect was maintained while the device was active throughout the session. This increase in PFV is consistent with increased peak flow velocity reported for intermittent pneumatic compression devices, and it fell within their reported range of flow velocity of 35–60 cm/s [12–15]. Since no significant difference in the prophylactic effect could be attributed to the site of compression on the lower limb, as delivered by different devices compressing the foot, foot and calf, calf, calf and thigh, and whole leg, the increased PFV is considered to be the mechanism of thrombosis prophylaxis. Hence, the increased PFV produced by the Aviafit through mechanical, non-pneumatic compression of the calf muscles may have an equivalent prophylactic effect. Therefore, the Aviafit device may have the potential to reduce the risk for DVT in the treated leg.

Measurements for venous flow were more ambiguous. Although a difference existed between the treated and the untreated leg, it was not statistically significant due to the large known variability in the resting blood flow. Not only are there inter-personal differences in venous flow [19], but they could also change over time in the same individual as a result of fluctuations in blood inflow [20]. Under our experimental conditions, the individual venous blood flow decreased during the monitoring period, probably due to in-flow changes resulting from the prolongation of the sitting. The behavior of venous flow was slightly affected by the Aviafit, and this was most pronounced when the device was just activated. While volume flow measurement at T30 was a poor indicator of the device’s effectiveness, due to individual and time variation, the increased proportion of treated legs with higher TVF suggests that the device produces a positive effect on the venous flow.

The doubling of the volume flow during the compression phase of the cycle compared to the released phase may indicate that increasing the compression frequency could substantially increase the TVF, above the equivocal behavior observed in this study. However, other compression devices were proven clinically effective in the prevention of DVT with their major effect being on the PFV rather than the TVF, similar to our device.

The effect of the device on blood circulation and prevention of stasis is evident, despite its relatively low-pressure (45 mm Hg) and non-sequential action. Previous studies have shown that pressures as low as 40 mm Hg provide clinically significant improvement in venous flow [21,22]. The abrupt action of the Aviafit improves venous drainage with immediate recovery of the normal flow. No strangulation of flow is observed as recognized from other IPC devices. The unique pressure profile of the device with its sharp pressure rise and fall affects the flow not only at the calf level, but actually increases the PFV also proximal to device location, at the superficial vein level as demonstrated in the superficial flow measurements.

In conclusion, this preliminary, pilot study indicates that the tested device may provide the same hemodynamic benefits as large conventional IPC devices. Its potential for prophylaxis in settings of rehabilitation and homecare, and for airline passengers on mid-long flights, is evident. Furthermore its simplicity, convenience and ease of use should increase patient compliance. Additional, large scale, controlled studies on the use of the Aviafit are required to fully appreciate its advantages and to provide evidence on its ability to prevent DVT.

**References**


