

An Evaluation of a Novel Compression Device on Popliteal Venous Blood Flow

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Abstract

The authors evaluate a novel compression device for the treatment of lower extremity vascular disorders. Subjects were treated with a Sequential Contraction Compression Device and Popliteal Vein blood flow was measured. As a comparator, patients blood flow was also measured during passive plantarflexion/ dorsiflexion of the foot, and also during Electric Muscle Stimulation of the calf. The Popliteal blood flow was significantly elevated with use of the SCCD as compared to EMS, and was not significantly less than with passive range of motion which is the gold standard.

Keywords: Deep vein thrombosis; Lymphedema; Vascular disease

Introduction

Deep Vein Thrombosis (DVT) is a potentially life threatening event among people with prolonged lower extremity immobility including long distance travelers, post-operative patients, and obstetric patients [1]. As early as the 1800s, physicians have experimented with the concept of improving blood circulation by exerting external pressure on the legs [2]. Intermittent pneumatic compression (IPC) devices are used in the prevention of deep venous thrombosis (DVT), the treatment of venous ulcers, lymphedema, venous insufficiency, arterial occlusive disease, prevention of hematomas [3-6]. The sudden application of a uniform external pressure on the lower extremity imposes a physiological change in the structure and hemodynamics of the lower extremity [7].

Electric Muscle Stimulation (EMS) devices are primarily used in Rehabilitation Medicine for reduction of pain, and strengthening of atrophic muscles as well as muscle retraining [8,9]. There has also been an indication for the use of EMS in treating vascular disease [10,11]. EMS devices work by sending an electric impulse to the neuromuscular junction causing a muscular contraction. By directing the current to some specific loci, a targeted muscle can be stimulated to contract in a pattern or sequence of the practitioners choice.

The authors evaluate the effect of Flow Aid FA 100 Sequential Contraction Compression Device (Flow aid Technologies Corp. New York, USA) on lower limb venous hemodynamics. The SCCD stimulates the muscles via an electric stimulus to the neuromuscular junction much in the same way as a traditional EMS, however, the pattern of contractions generated is more similar to that of an IPC.

Materials and Methods

The study set out to compare flow rates and velocities in volunteers during passive activity in the sitting position as compared to induced

active dorsi-plantar flexion of the foot and Electric Muscle stimulation (EMS) of the calf to that of stimulation with the Flowaid FA100 SCCD.

22 lower limbs of 11 volunteers between the age of 25 and 45 without symptoms or risk factors of peripheral vascular disease (PVD) were recruited for this study. The subjects were nonsmokers, with no history of DVT and no current or past diagnosis of Peripheral Arterial Disease or Chronic Venous Insufficiency. IRB approval was given and prior to participation patients gave their informed consent. Subjects were brought to the examination room and asked to sit with their legs in a dependant position of at least 60 degrees. They were asked to rest for 15 minutes so that a baseline bloodflow could be established and not be affected by previous ambulation. Doppler Ultrasonography was used to evaluate Popliteal Venous Blood flow which was measured for two consecutive periods of 30 seconds. The 2nd thirty second period was used as the primary comparator.

Measurements were recorded for each subject as follows:

- Both legs in passive, dependent position.
- Active Dorsi/plantar flexion of the foot at 2 second intervals.
- Both legs in passive dependent position with application of the FlowAid FA 100 SCCD. The SCCD's intensity was raised until contraction of the gastrocnemius muscles was observed.
- Both legs in passive dependent position with application of a two electrode EMS (Empire Bio Medical, New York, USA).

The intensity of the EMS device was raised until contraction of the gastrocnemius muscle was observed.

Between each evaluation patients were rested for 5 minutes to allow the circulation to return to baseline.

The doppler examination was performed using a vascular doppler (Huntleigh Diagnostics) with a 4 MHz array transducer. Peak and averaged mean velocities, and volume flow were calculated. Evaluation was performed by a single observer.

Results

Table 1 represents the comparison of the Popliteal Vein blood flow velocity with comparison to the passive resting sitting position: A 317% increase was seen when the FlowAid FA 100 SCCD was utilized. A 415% increase was found in active dorsi-plantar flexion of the foot. A 166% increase was seen when operating the Electro muscle stimulation (EMS).

Popliteal venous flow TAMV - time averaged mean velocity (cm/sec)				
Patient #	Passive Sitting	E.M.S.	FlowAid 100	FA Dorsi-plantar flexion
1	1.28	3.78	9.3	4.82
2	1.39	1.17	1.93	4.06
3	1.28	3.43	2.86	4
4	1.09	1.61	6.04	3.57
5	1.06	2.29	4.82	5.12
6	1.36	1.25	2.94	7.7
7	0.87	0.74	2.94	5.85
8	0.82	1.33	2.1	6.4
9	1.91	4.68	3.59	5.06
10	1.33	2	4.1	6.29
11	1.69	1.06	3.97	5.53
Mean	1.28	2.12	4.05	5.31

Table 1: Popliteal Venous Flow Velocity among Volunteers

Figure 1 represents the comparison of Popliteal Vein blood flow rate in comparison to the passive resting sitting position: A 330% increase was seen when operating the FlowAid FA 100 SCCD. A 437% increase was found in active dorsi-plantar flexion of the foot. A 172% increase was seen when operating the Electro muscle stimulation (EMS). Although the sample size was too small for statistical analysis for significance, this flow increase is well above variation measurement.

Discussion

SCCD was developed as a result of the need to address the inherent problems with IPC, in particular patient compliance [12]. The design for the contraction sequence in the SCCD was based on findings that a sequentially applied wavelike compression provides the most efficient method of venous emptying, suggesting that a sequential compression device may more effective in preventing DVT [13]. The increase in the A-V pressure gradient and subsequent increase in arterial flow caused by IPC has been postulated as a possible mechanism by which IPC improved patients with claudication [5]. Because SCCD causes a similar change in the A-V gradient, by increasing the venous outflow side of the equation, it can likewise be thought, that SCCD would be useful in therapy of claudication as well.

The results of this study compare favorably with other studies evaluating devices that affect venous return. Nicolaidis et al. found that if the pressure is applied sequentially, the accelerated blood flow could increase the peak flow velocity by over 200% within the lumen

[14]. Supervised and unsupervised exercise protocols are the gold standard for treatment of many vascular conditions of the lower extremity [15]. Induced passive Dorsiflexion- Plantarflexion mimics this therapy [16].

The SCCD transmits stimulation to the underlying calf muscle groups through electrodes placed on the skin. While this is comparable in action to a traditional EMS, this stimulation induces a unique sequence of contractions in a peristaltic-type wave form, along the calf muscles from distal to proximal. Blood vessels are compressed, which improves circulatory blood flow. As a result, flow of deoxygenated blood via the venous system improves and an increase in flow of oxygenated blood is delivered to the extremities.

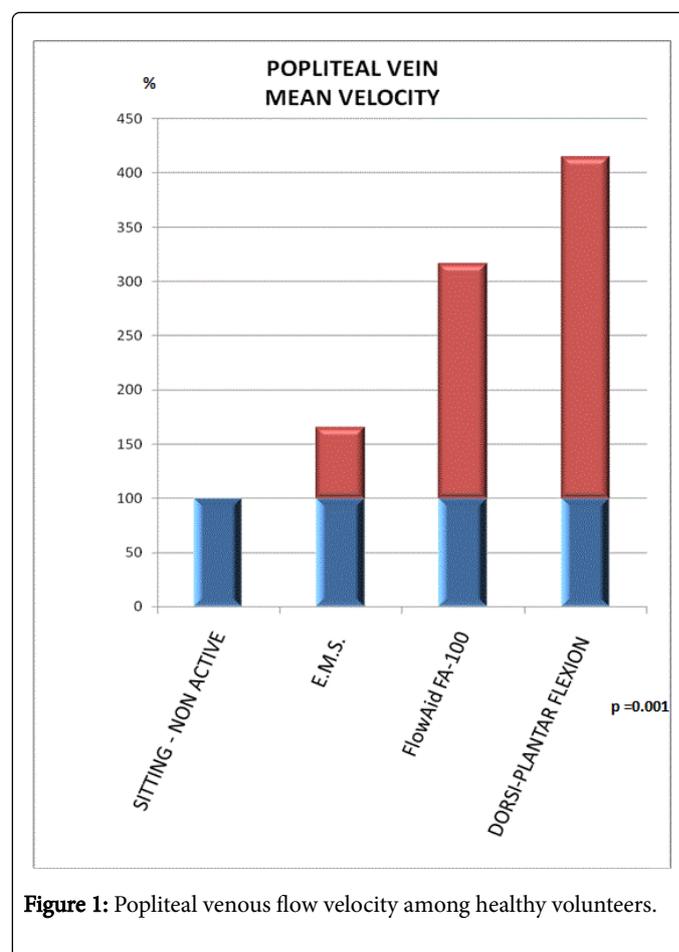


Figure 1: Popliteal venous flow velocity among healthy volunteers.

Conclusion

The application of FlowAid FA 100 SCCD enhances venous flow rate and velocity in the Popliteal Vein. While this is a small study on healthy subjects, and an RCT on specific patient populations is warranted, our findings may explain the beneficial effects of this SCCD on lower limb venous and arterial disease, its benefits in accelerating wound recovery, reducing pain, increasing walking distance in patients with Peripheral vascular disease and reducing lymphedema. Increased venous flow velocity when using the FlowAid FA 100 SCCD may also prove beneficial as a prophylactic device to prevent DVT.

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