

Electrical Foot Stimulation and Implications for the Prevention of Venous Thromboembolic Disease

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Keywords

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Summary

Background: Venous stasis caused by immobility is an important risk factor for deep vein thrombosis following surgery and lower limb trauma, in bed-ridden medical patients, and in high-risk long distance air travelers. A safe and convenient method for reducing venous stasis would be useful in patients while in hospital and after discharge during their rehabilitation. *Subjects and Methods:* 49 healthy subjects aged 51-76 were seated for 4 hours during which they received mild electrical stimulation of the calf, or sole of the foot (plantar muscles). Popliteal and femoral venous blood flow velocities were measured via doppler ultrasound. The non-stimulated lower extremity served as the simultaneous control. Subjects completed a questionnaire regarding their acceptance and tolerance of the electrical stimulation. *Results:* There was a significant increase in venous femoral and popliteal blood flow for both calf ($p < 0.035$, $p < 0.003$), and plantar muscles ($p < 0.0001$, $p < 0.009$) on the stimulated side compared to the unstimulated side. The magnitude of the effect was similar for calf and plantar muscle stimulation. Subjects did not find the experience uncomfortable, and would use an electrical stimulator if told by their physician that they were at risk for developing blood clots. *Conclusions:* Mild electrical stimulation of the feet, as well as the calf, is a safe effective and convenient method for counteracting venous stasis and therefore has the potential to reduce the risk of deep vein thrombosis and pulmonary embolism for subjects who are immobilized.

Introduction

Venous thrombosis and pulmonary embolism or venous thromboembolism (VTE) are important complications of medical and surgical conditions that are associated with prolonged immobilization (1, 2). Immobilization is also a major contributor to the increased risk of VTE associated with prolonged air travel (3-5).

There is widespread under utilization of prophylaxis for VTE following major surgical procedures (6, 7) either by anticoagulation or physical methods. This practice continues despite good evidence that the risk of VTE continues for weeks after major orthopedic as well as other types of surgery. In certain specific situations there has been a marked improvement in proper prophylaxis, both directly post-surgical and out of hospital, such as following total hip arthroplasty (8). Over all, however, under prophylaxis continues to be a problem, particularly after hospital discharge, largely because there is no safe and convenient method for continuing prophylaxis in the convalescing patient. This applies not only to surgical patients, but also to other patients with immobilizing conditions including cerebral vascular accidents, and major head and neck trauma.

Increasing venous blood flow velocity is a well-established method of reducing stasis and thus has the potential to prevent thrombosis. A number of devices designed to increase venous blood flow velocity have been shown to reduce the incidence of post-surgical venous thrombosis. These devices include high intensity electrical calf stimulation during surgery, graduated compression stockings and external intermittent pneumatic compression.

All methods have limitations for out of hospital use. High intensity electrical calf muscle stimulation causes discomfort in the conscious patient and therefore can only be used during general anesthesia. External pneumatic compression can cause arterial ischemia (9), is cumbersome and can only be used while the patient is fully immobilized. Graduated compression stockings do not fit all leg shapes and improper application can cause complications. Thus, alternative convenient methods are needed which can be used both in the immobilized and partly mobile patient.

The aim of this study was to determine if mild electrical stimulation of the plantar foot muscles, or the calf muscles, significantly increases venous blood flow velocity in the femoral and popliteal veins of subjects seated for four hours.

Subjects and Methods

Forty-nine healthy subjects between the ages of 50 to 80 were recruited to participate in the study. IRB approval and informed consent was obtained. The subjects were seated for 4 h in chairs placed at a fixed distance apart. Subjects were constantly monitored throughout the study to ensure that they remained seated. Subjects were allowed to use a bathroom located several feet away only twice during the 4 h period. During the 4 h study period subjects were offered a maximum of 16 ounces of fluid and a normal lunch.

One lower limb was randomly selected for stimulation, with the other serving as a control. The study was performed in two parts. The first part involved calf stimulation and the second part foot stimulation. In the first group (calf stimulation), surface electrodes were placed over the medial and lateral gastrocnemius calf muscles. In the second group (foot stimulation), surface electrodes were placed on the sole of the foot over the plantar muscle group. The two groups were completely independent.

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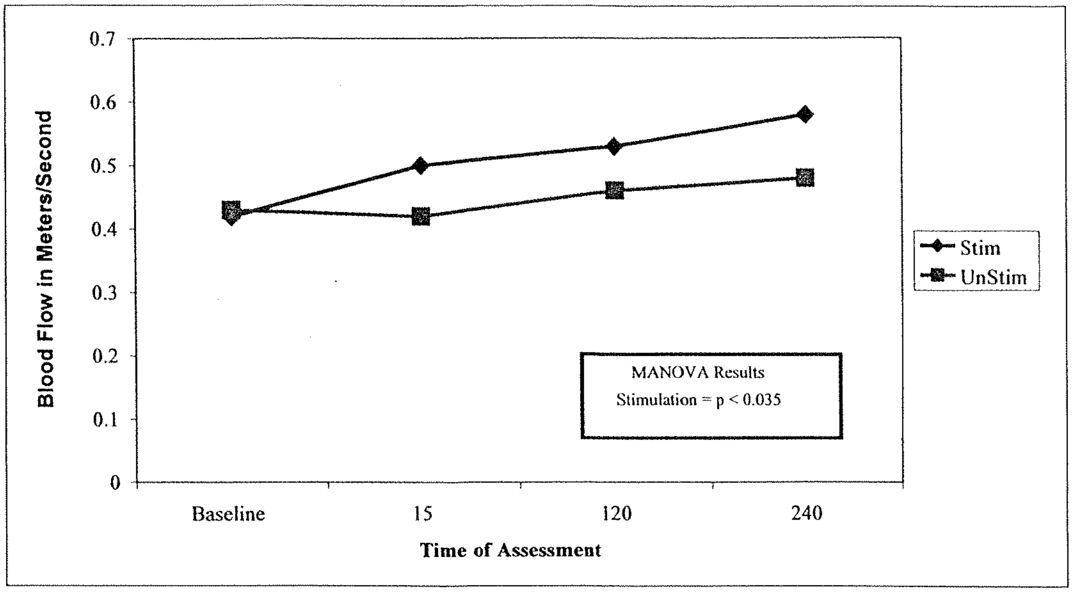

Fig. 1 Femoral venous blood flow stimulated versus unstimulated calf (N = 30)

In both groups, electrical stimulation was delivered by The Focus™ Neuromuscular Stimulation System, Empi, Inc., St. Paul, MN. The crucial stimulus parameters were: biphasic symmetrical square wave at 50 pulses per s, phase duration of 300 microseconds, a starting ramp up time of 2 s and a finishing ramp down time of 2 s per stimulation cycle, and a stimulation cycle of 12 s "on" and 48 s "off" per minute. Stimulation was increased to an intensity just sufficient to create a slight visible muscle twitch. This level of intensity caused no evident discomfort in any of the subjects at the onset of the 4 h study period. Subjects were continually monitored throughout for any indication of discomfort.

Popliteal and femoral venous blood flow velocities were measured bilaterally using a doppler ultrasound device at 0, 15, 120, and 240 min. The person evaluating the doppler ultrasound was blinded as to the limb stimulated. Immediately following completion of stimulation, subjects were asked to complete a brief questionnaire regarding their acceptance and tolerance of the electrical stimulation.

Statistical Analysis

The study followed a repeated measures design with two within-group factors: time of measurement, and stimulation (yes, no). Blood flow results were subjected to multivariate analyses of variance (MANOVA) with repeated measures using the General Linear Model (GLM) algorithm of SPSS® version 10.0 (10). Questionnaire results were evaluated using Chi-square statistics, again using SPSS®, version 10.0. P-values less than 0.05 were considered significant.

Results

Blood flow results for Group 1, the calf stimulation group, are displayed in Figs. 1 and 2. There was a significant increase in both femoral ($p < 0.035$) and popliteal ($p < 0.003$) blood flow associated with electrical stimulation.

[Repeated measures MANOVA disclosed a significant increase in femoral blood flow associated with electrical stimulation ($F(1,29) = 4.919$, $p < 0.035$). For the popliteal vein, there was also a significant increase in blood flow associated with electrical stimulation ($F(1,29) = 10.21$, $p < 0.003$)].

Blood flow results for Group 2, the foot stimulation group, are displayed in Figs. 3 and 4. Again, there was a significant increase in

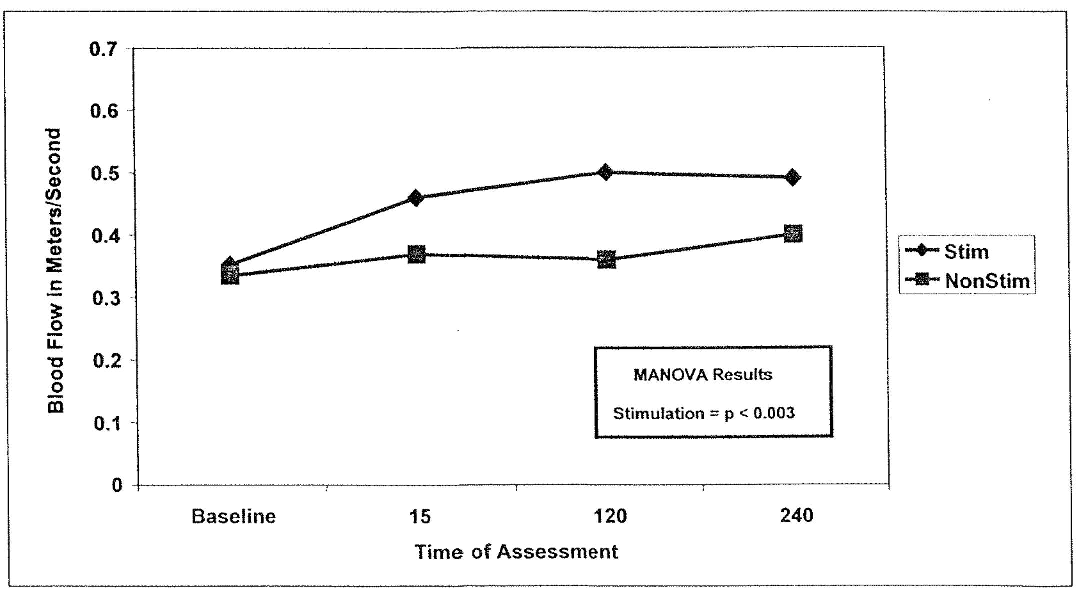

Fig. 2 Popliteal venous blood flow stimulated versus unstimulated calf (N = 30)

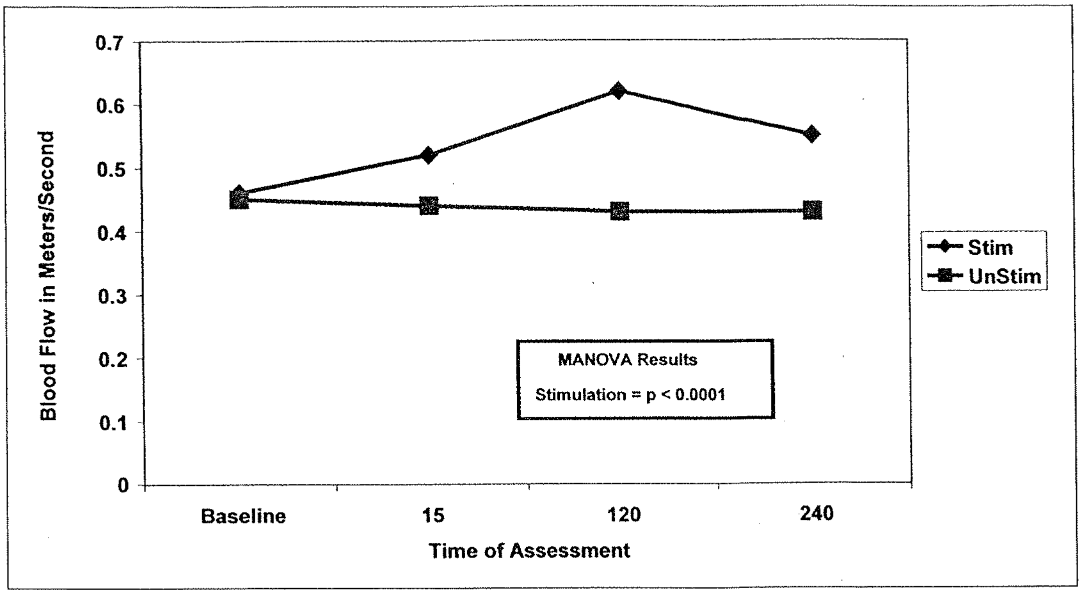

Fig. 3 Femoral venous blood flow stimulated versus unstimulated foot (N = 19)

both femoral ($p < 0.0001$) and popliteal ($p < 0.009$) blood flow associated with electrical stimulation.

[Repeated measures MANOVA disclosed a significant increase in femoral blood flow associated with electrical stimulation ($F(1,18) = 23.52$, $p < 0.0001$). For the popliteal vein, there was also a significant increase in blood flow associated with electrical stimulation ($F(1,18) = 8.66$, $p < 0.009$)].

Comparison of calf stimulation to foot stimulation by repeated measures MANOVAs indicated that there were no significant differences in the magnitude of the blood flow effects for either the femoral or popliteal blood flow data.

Following stimulation all subjects completed a questionnaire (N = 49, Group 1 -calf stimulation N = 30, Group 2 -foot stimulation N = 19). All subjects were queried about: 1. Whether the electrical stimulation was uncomfortable; 2. If they would consider using an electrical stimulation device if told by their doctor that they were at risk for blood clot formation; 3. Whether the stimulated leg felt better than the unstimulated leg after the study.

Chi square analyses revealed to a statistically significant degree the following (See Tables 1 and 2): 1. Both groups did not find the stimulation uncomfortable; 2. Both groups strongly felt that they would use an electrical stimulation device if told by their doctor that they were at risk for blood clot formation; 3. Both groups did not feel the stimulated leg felt better. However, more subjects in the foot stimulation group compared to the calf stimulation group felt that the stimulated limb felt better. Statistical significance was not reached, possibly due to the small sample size. In the comment section of the questionnaire, 2 subjects in the foot stimulation group indicated that the stimulation was pleasurable. No subjects in the calf stimulation group indicated that the stimulation was pleasurable.

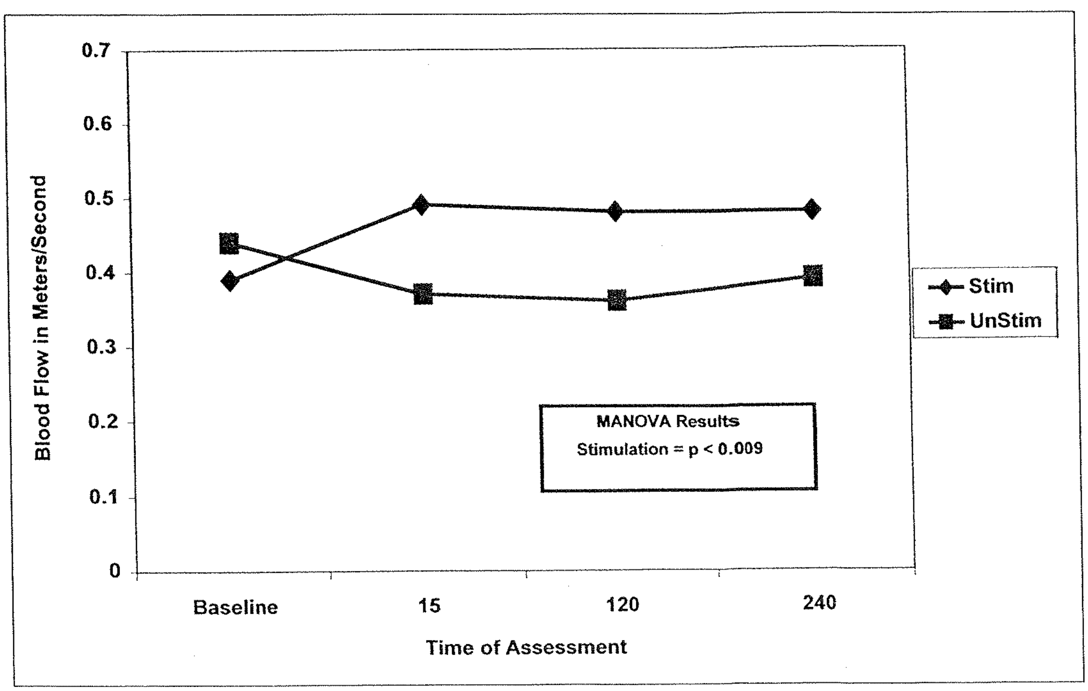

Fig. 4 Popliteal venous blood flow stimulated versus unstimulated foot (N = 19)

Table 1 Results of subject survey regarding acceptance of electrical calf stimulation (N = 30)

	Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree	Chi-Square (df)	p <
Question 1: *The electric stimulation was uncomfortable.*	2	2	1	15	10	25.7 (4)	0.001
Question 2: *If my doctor told me I was at risk of blood clot formation, I would consider using an electric stimulation device if I had to travel in a sitting position for a long time. (i.e. 4 hours)*	16	13	1	0	0	12.6 (4)	0.002
Question 3: *Compared to my unstimulated leg, my stimulated leg felt better after the study.*	6	5	14	4	1	15.7 (4)	0.004

Table 2 Results of subject survey regarding acceptance of electrical foot stimulation (N = 19)

	Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree	Chi-Square (df)	P <
Question 1: *The electric stimulation was uncomfortable.*	0	0	0	8	11	112.8 (4)	0.001
Question 2: *If my doctor told me I was at risk of blood clot formation, I would consider using an electric stimulation device if I had to travel in a sitting position for a long time. (i.e. 4 hours)*	11	8	0	0	0	112.8 (4)	0.001
Question 3: *Compared to my unstimulated leg, my stimulated leg felt better after the study.*	0	8	10	1	0	92.8 (4)	0.001

Discussion

Physical methods that increase blood flow in the leg veins are effective for reducing venous thrombosis in high-risk medical and surgical patients, and possibly in high-risk subjects exposed to long distance travel.

An illustrative clinical situation is total hip or knee arthroplasty. Recent studies have shown that the risk period for post-operative thrombosis after elective hip surgery extends for up to three months after the patient is discharged from hospital, and for approximately 30 days after major knee surgery (11, 12). Based on the prolonged duration of risk after hospital discharge, it is recommended that prophylaxis with either low molecular weight heparin (LMWH) or warfarin should be continued for up to 35 days following elective hip replacement. Both of these anticoagulants have limitations for out-of-hospital use. LMWH must be administered by subcutaneous injection and warfarin requires laboratory monitoring. Fondaparinux, a new synthetic factor Xa inhibitor, must also be given subcutaneously. Anticoagulants can also be expensive.

Physical devices have not been evaluated for out of hospital prevention of VTE, but based on their efficacy in the immobilized patient during the early post-operative period, they should be effective in preventing delayed thrombosis. The ideal device for out of hospital use should have the following characteristics: it should be safe, effective, portable, easy to use, inexpensive, and able to be worn while the patient is recumbent, sitting, standing or walking. Such requirements are necessary during convalescence from operation when the patient spends considerable periods of time in and out of bed before becoming fully mobile. They are also important requirements for thromboprophylaxis during prolonged travel.

Of the various physical methods available currently, compression stockings are the only type that can be used during recumbency and walking. Compression stockings, however, cannot be adapted to fit all legs, may be improperly applied and have a tendency to slip down the leg. Additionally compression stockings can cause edema of the legs and superficial thrombophlebitis (13, 14).

We have attempted to overcome the limitations of currently available physical devices by mild electrical stimulation of the plantar muscles of the feet. Each electrical discharge elicits a foot twitch that causes the intrinsic foot muscles to contract. This contraction compresses the plantar plexus of veins, and thereby increases venous velocity in the popliteal and femoral veins that is transmitted proximally up the leg veins. The observed increase in blood flow was comparable to that produced by the more traditional calf stimulation.

A plantar foot stimulation device can be inserted into a sock and can be battery operated. It has the potential to be worn while immobile, standing or walking with assistance, and would thus be suitable for use throughout convalescence after immobilization.

Thus, mild electrical stimulation of the feet provides a promising method to counteract venous stasis thereby preventing DVT and PE in a wide range of high-risk situations. Foot stimulation can be used alone or in conjunction with anticoagulation. Definitive proof of efficacy and safety requires formal investigation in appropriately designed clinical trials.

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