

ORIGINAL ARTICLE

Electrical Foot Stimulation: A Potential New Method of Deep Venous Thrombosis Prophylaxis

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The purpose of this study was to compare venous blood flow velocity of intermittent pneumatic compression to electrical stimulation of the foot. A prospective randomized controlled study of 40 healthy volunteers was conducted. Subjects were seated for 4 hours during which they received electrical stimulation of the sole of the foot or knee-high intermittent pneumatic compression. Popliteal and femoral venous blood flow velocities were measured via Doppler ultrasonography. Blood flow velocity in the nonstimulated or noncompressed lower extremity served as a simultaneous control. For both the femoral and popliteal veins, the electrical foot stimulation group exhibited a greater increase in blood flow velocity than the intermittent pneumatic compression group. Electrical foot stimulation was noninferior relative to standard intermittent pneumatic compression. Specifically, this result of a greater increase in blood flow velocity is achieved at time = 120 minutes for the femoral vein ($t = 2.70$; $p = .005$) and time = 120 ($t = 2.75$; $p = .004$) and 240 ($t = 2.27$; $p = .014$) minutes for the popliteal vein. Short-term electrical foot stimulation is at least as effective as knee-high intermittent pneumatic compression in increasing popliteal and femoral blood flow velocity. Electrical foot stimulation has the potential to be an effective method of deep venous thrombosis prophylaxis.

Key words: deep venous thrombosis prophylaxis, electrical foot stimulation, intermittent pneumatic compression, venous thromboembolic disease prevention

Venous thrombosis and pulmonary embolism or venous thromboembolism (VTE) are important complications of medical and surgical conditions that are associated with prolonged immobilization.¹ Immobilization is also a major contributor to the increased risk of VTE associated with prolonged air travel.^{2–4}

Despite good evidence that prophylaxis is effective, there is widespread underuse of prophylaxis for VTE following major surgical procedures as well as medical conditions that produce weakness or prolonged bed rest.^{1,5} There is also good evidence that the risk of VTE continues for weeks after major orthopedic and other types of surgery. It is now recognized that VTE occurring in the acute hospital setting, during rehabi-

litation, and after hospital discharge is a single entity⁶ and that extended prophylaxis with anticoagulants reduces the risk. A safe and more convenient method for reducing venous stasis would be particularly useful for preventing venous thrombosis in patients who require prolonged prophylaxis or cannot receive anticoagulation therapy.

Anticoagulant prophylaxis after hospital discharge,⁷ although indicated in certain high-risk groups, is inconvenient because the recommended methods, low-molecular-weight heparin and fondaparinux, must be administered by subcutaneous injection and warfarin requires laboratory monitoring. The oral anticoagulant rivaroxaban shows promise, but the risk of bleeding remains.

Physical methods that increase blood flow in the leg veins are effective for reducing venous thrombosis in high-risk hospitalized medical and surgical patients. These methods include high-intensity electrical calf stimulation during surgery, graduated compression stockings, and intermittent pneumatic compression (IPC) of the leg or foot. Of these, only graduated compression stockings, which are not very effective, can be used after hospital discharge. Graduated compression stockings, however,

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cannot be adapted to fit all leg shapes, may be improperly applied, have a tendency to slip down the leg, and are found to be uncomfortable by many patients. High-intensity electrical calf muscle stimulation is painful and can be used only during general anesthesia. AC-powered external pneumatic compression can be used only while the patient is fully immobilized. Thus, alternative convenient methods are needed that can be used in both the immobilized and the partly mobile patient, particularly after hospital discharge.

We attempted to overcome the limitations of currently available physical devices by using mild electrical stimulation of the plantar muscles of the feet. The efficacy of IPC foot pumps for deep venous thrombosis (DVT) prophylaxis has been well established.⁸⁻¹⁰ In our technique, transcutaneous electrical foot stimulation has been substituted for pneumatic foot compression. Each electrical discharge elicits a small foot twitch only in the plantar intrinsic foot muscles. This contraction compresses the plantar plexus of veins, thereby increasing venous velocity in the popliteal and femoral veins, which is transmitted proximally up the leg veins.

Our compact plantar foot stimulation device is powered by a 9-volt battery and small enough to be inserted into a sock. It has the potential to be worn while a

patient is immobile, standing, or walking and therefore is suitable for use both during the initial period of immobilization and throughout rehabilitation. This device allows patients to receive and participate in their rehabilitative therapy in an unencumbered manner. Activities of daily living can be addressed without interference from this technology (Figure 1).

In an earlier study, we reported that mild electrical stimulation of the plantar foot muscles caused an increase in blood flow comparable to that produced by direct calf stimulation.¹¹ The aim of this new study was to determine if, over a 4-hour period, mild electrical stimulation of the plantar foot muscles increases venous blood flow velocity to the same degree as IPC of the leg in both obese and nonobese subjects.

Methods

Institutional Review Board approval and informed consent were obtained from all subjects. Forty healthy subjects between the ages of 50 and 80 years participated in the study. Half of the subjects were nonobese with a body mass index (BMI) < 30. The other half of the subjects were obese with a BMI > 30. Exclusion criterion included a prior history of DVT or pulmonary embolism, the

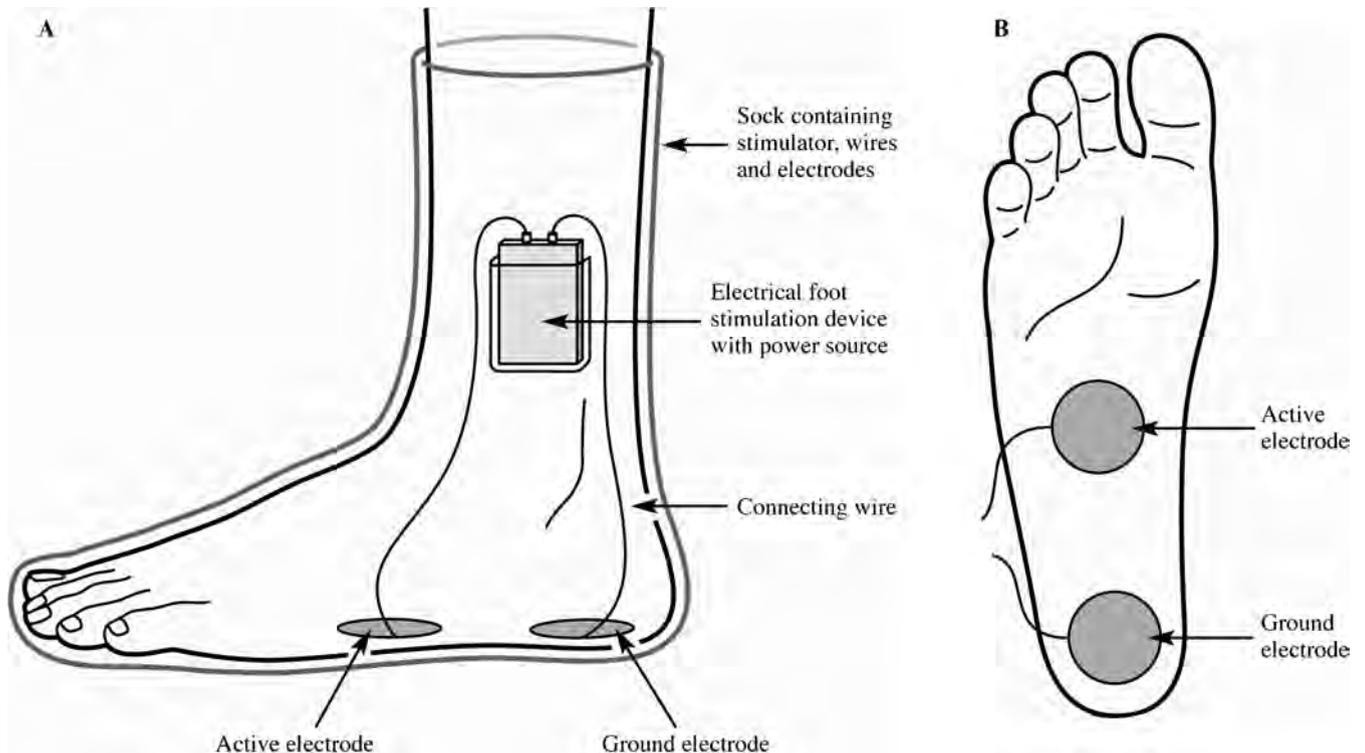


Figure 1. Electrical foot stimulation prototype device to enhance venous blood flow from the lower extremities (A, side view; B, sole view).

presence of a cardiac pacemaker, or any trauma or surgery involving any part of the lower extremities.

Subjects were studied over two sessions. At each session, subjects received either electrical foot stimulation or IPC of the calf of one leg. The other lower extremity served as a control. Subjects received one therapy at one session and the other therapy at a second session at least 48 hours later. The subjects were randomly assigned using a computer-generated protocol as to which leg would be treated and the order in which the type of therapy was to be given.

The study otherwise followed the protocol used in our initial study of electrical foot stimulation. Subjects were seated for 4 hours in chairs placed at a fixed distance apart. They 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-hour period. During the 4-hour study period, subjects were offered a maximum of 16 ounces of fluid and a normal lunch.

Electrical foot stimulation (see Figure 1) was produced by surface electrodes placed on the sole of the foot over the plantar muscle group. Electrical stimulation was delivered by the Focus Neuromuscular Stimulation System (Empi, Inc., St. Paul, MN). The crucial stimulus parameters were biphasic symmetric square wave at 50 pulses per second, phase duration of 300 microseconds, a starting ramp uptime of 2 seconds and a finishing ramp downtime of 2 seconds per stimulation cycle, and a stimulation cycle of 12 seconds “on” and 48 seconds “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 in our first study. Subjects were continually monitored throughout this study for any indication of discomfort.

IPC of the leg consisted of external IPC with a knee-high device. A Tyco Healthcare Kendall Novamedix A-V impulse system Model 6060 (Tyco Healthcare, Mansfield, MA) was used. Operating parameters were 130 mm Hg impulse pressure with 3-second impulse duration and “Program Preset 1” for DVT prophylaxis. The compression followed the approved standard patient protocol used at our institution detailed in *Utilization of Intermittent Pneumatic Compression (IPC) Stockings for DVT Prophylaxis*.^{12–14}

Popliteal and femoral venous peak blood flow velocities were measured bilaterally using a Doppler ultrasound device at 0, 15, 120, and 240 minutes. Measurements were taken at the midpoint of the “on cycle” for electrical foot

stimulation and pneumatic compression. The same ultrasound technician obtained all Doppler studies on all subjects throughout the study. All Doppler tracings were read by the same independent reader in a blinded fashion. Immediately following completion of each 4-hour session of electrical foot stimulation or IPC, subjects were asked to complete a brief questionnaire (Appendix) regarding their acceptance and tolerance of electrical stimulation or IPC.

This study was designed to compare venous blood flow velocity in the seated position with our device with IPC. The seated position was chosen because most patients who are discharged from the hospital will be sitting for a significant period of time during the day as they recover. Additionally, long-distance travelers, who are at risk for VTE, are also in the seated position.

Statistical Analysis

The primary objective of this clinical trial was to demonstrate the noninferiority of the experimental treatment (electrical foot stimulation) relative to standard accepted treatment (IPC). The noninferiority test was chosen because it matched the clinical goal to assess if the new device was similarly effective to compression. Noninferiority is a widely accepted standard when assessing new treatment modalities. This is particularly true of new treatment modalities that are safer, have fewer side effects, or offer greater compliance because of enhanced ease of use. IPC is presently used in the acute hospital setting as a means of mechanically increasing venous blood flow velocity. It has been demonstrated to reduce the risk of DVT for a number of conditions. In this way, the equivalence of electrical foot stimulation to IPC could be assessed. Owing to this, the statistical methods used in this study followed those recommended for reporting noninferiority trials.¹⁵

The study used a repeated measures design with two within-group factors: time from baseline and stimulation (stimulation, control). That is, all treatment comparisons were based on paired differences at each time point. Blood flow velocity measurements (at time = 120 and 240 minutes) were analyzed using two different approaches. A noninferiority index of 5.0 cm/s was chosen at the start of the study. The primary analysis was based on the use of paired *t*-tests after accounting for the noninferiority index. The secondary analysis accounted for baseline differences and made use of a mixed model. Specifically, change from baseline was modeled as a function of the fixed effects treatment group and baseline and a random subject effect. Tests corresponding to this model also were based on the

same noninferiority index (5.0 cm/s). The questionnaire results were analyzed using the Fisher exact test, and p values $< .05$ were considered to be statistically significant. All analyses were done with SAS 9.1 (SAS Institute, Cary, NC).

Results

By design, the sample was equally distributed in terms of gender (20 males, 20 females) and BMI (20 nonobese, BMI < 30 ; 20 obese, BMI > 30). The mean age of the sample was 62.6 years (SD 8.4 years). The mean BMI of the sample population was 30.6 (SD 5.6) (Table 1.) Two subjects dropped out of the study and were replaced. One subject developed a medical problem not related to the study, and the other subject did not return for the second session and could not be contacted by telephone.

For both the femoral and popliteal veins, at both time points (120 and 240 minutes), the electrical foot stimulation group exhibited a greater blood flow velocity measurement than the IPC group (Figure 2, Figure 3, Figure 4, and Figure 5).

The primary analysis indicates that the experimental treatment (electrical foot stimulation) is noninferior relative to standard treatment (IPC). Noninferiority was achieved at time = 120 minutes for the femoral vein ($t = 2.70$; $p = .005$), and time = 120 minutes ($t = 2.75$; $p = .004$) and time = 240 minutes ($t = 2.27$; $p = .014$) for the popliteal vein. Noninferiority was almost achieved at time = 240 minutes for the femoral vein ($t = 1.63$; $p = .055$).

After adjusting for baseline values using a mixed model, with baseline as a covariate, differences between therapy groups (electrical foot stimulation versus IPC) persisted. For the femoral vein, for time = 120 minutes, noninferiority was achieved ($F = 2.80$, $p = .008$). For the popliteal vein, for time = 120 and 240 minutes, noninferiority was

achieved ($F = 2.47$, $p = .018$; $F = 2.09$, $p = .043$). There were no statistical differences between blood flow velocity measurements in the control leg for electrical foot stimulation compared with the control leg for IPC. Both modalities, electrical foot stimulation and IPC, were equally effective regardless of BMI.

No subjects requested that the study be stopped once it was initiated at either session. No unacceptable discomfort or injury occurred to any subjects during or following this study.

In response to the questionnaire, a majority of subjects indicated that both treatments were uncomfortable, 92.5% (37 of 40) for IPC and 82.5% (33 of 40) for electrical foot stimulation. A majority of subjects, 62.5% (25 of 40), found the IPC treatment more comfortable than the electrical foot stimulation treatment. When told that the electrical foot stimulation treatment would allow them to walk while on therapy, a majority of subjects, 75.0% (30 of 40), indicated that this would increase their likelihood of using electrical foot stimulation therapy.

Discussion

The relative risk reduction of DVT of approximately 60% by IPC is well established.^{1,16–19} This includes a recent meta-analysis of over 2,200 postoperative patients in 15 studies.²⁰

Our study indicates that electrical foot stimulation is at least as effective as IPC in increasing venous blood flow velocity in the popliteal and femoral veins during the study period. The compact electrical foot stimulation device used in this study requires only a 9-volt battery power source and therefore does not interfere with ambulation and other activities of daily living. A rechargeable 9-volt lithium battery power source could be used for days at a time.

Table 1. Description of the Sample Population

Characteristic	Sequence 1 (Stimulation, Control)	Sequence 2 (Control, Stimulation)	Overall
Age (yr)	62.6 (8.8)	62.6 (8.3)	62.6 (8.4)
BMI	29.4 (5.3)	31.8 (5.9)	30.6 (5.6)
Nonobese (BMI ≤ 30)	13	7	20
Obese (BMI > 30)	7	13	20
Male	8	12	20
Female	12	8	20

BMI = body mass index.

Group 1 = stimulation, intermittent pneumatic compression (IPC); group 2 = IPC, stimulation.

Age and BMI are expressed as mean (SD).

Nonobese, obese, male, and female are expressed as frequencies.

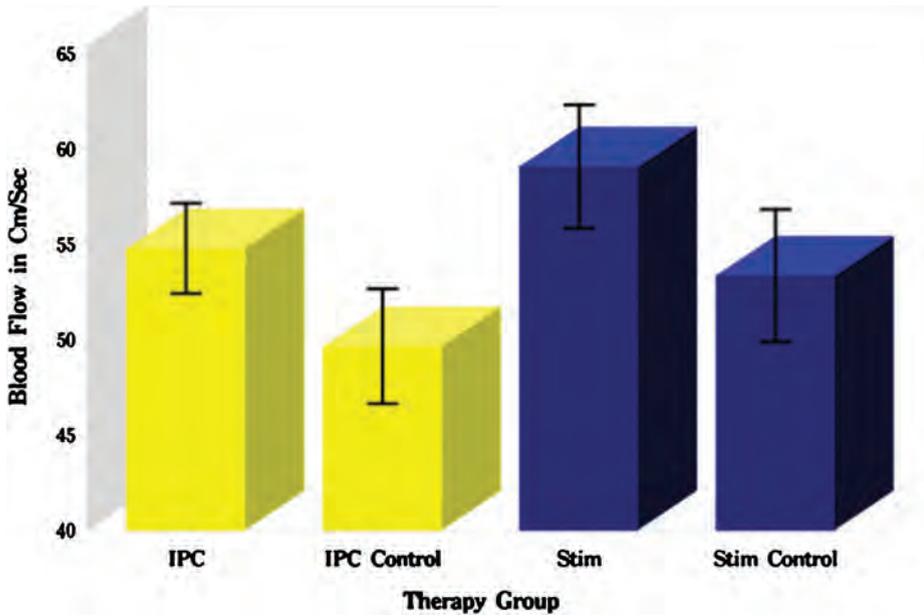


Figure 2. Femoral venous blood flow intermittent pneumatic compression (IPC) versus electrical stimulation. Time = 120 minutes (noninferiority: t value = 2.70 and p value = .005) (N = 40).

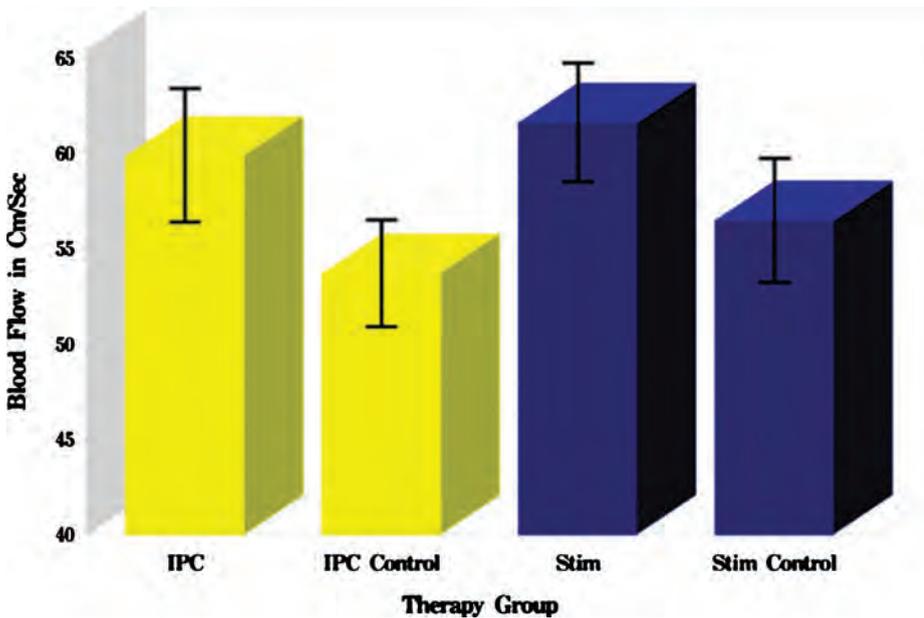


Figure 3. Femoral venous blood flow intermittent pneumatic compression (IPC) versus electrical stimulation. Time = 240 minutes (noninferiority: t value = 1.63 and p value = .055) (N = 40).

The electrical foot stimulation device has a mechanism of action similar to that of existing intermittent pneumatic pumps. Both increase flow velocity in the popliteal and femoral veins by rapidly discharging blood from the plantar venous plexus. Increased blood flow velocity reduces stasis in the venous sinuses and around the valve cusps. This is particularly important in the venous systems of the gastrocnemius and soleus muscles, where deep vein thromboses originate. The foot pump achieves this effect by intermittently compressing the veins in the plexus by external mechanical compression, whereas the electrical

foot stimulation device does so by stimulating the intrinsic foot muscles to contract and thus compress the plantar venous plexus. Given that the intermittent pneumatic foot pump has been shown to reduce the risk of venous thrombosis, it would be reasonable to expect that the electrical foot stimulation device would also be effective clinically, although a study comparing the two modalities in terms of actual VTE prevention is necessary.

Traditional intermittent leg or foot pneumatic compression devices require an AC power source, which tethers the patient and limits mobility. Portable battery-

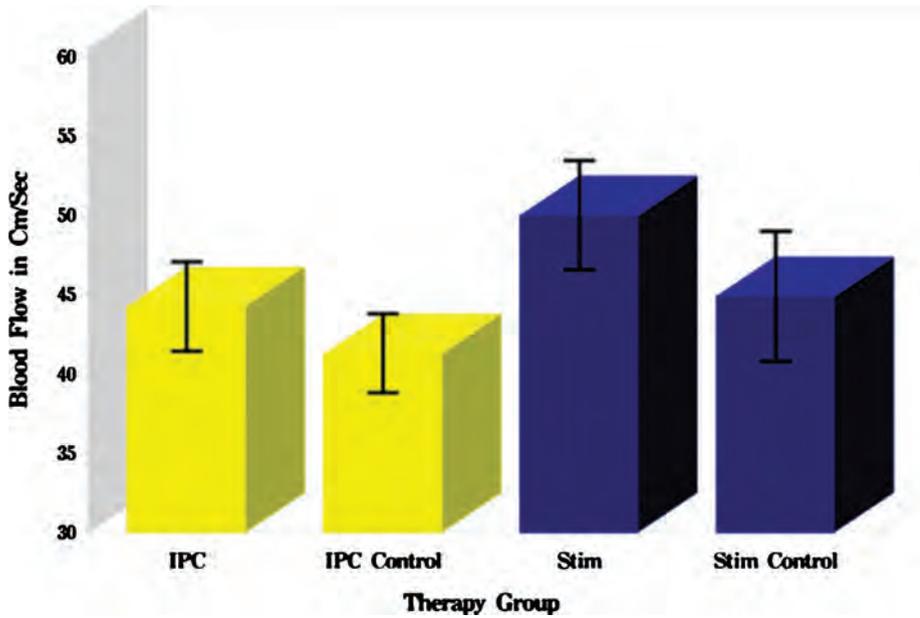


Figure 4. Popliteal venous blood flow intermittent pneumatic compression (IPC) versus electrical stimulation. Time = 120 minutes (noninferiority: t value = 2.75 and p value = .004) (N = 40).

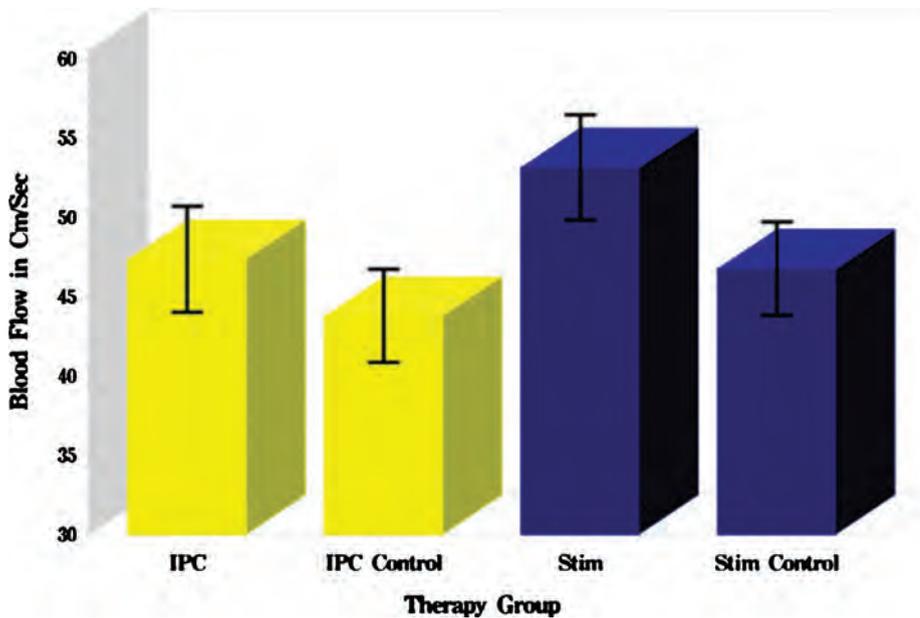


Figure 5. Popliteal venous blood flow intermittent pneumatic compression (IPC) versus electrical stimulation. Time = 240 minutes (noninferiority: t value = 2.27 and p value = .014) (N = 40).

powered IPC devices are now available.²¹ These devices are still cumbersome and allow a patient limited mobility and are therefore practical only in the acute hospital setting. Additionally, pneumatic compression devices are difficult to use correctly in a sustained fashion. In one study, only 23% of patients were correctly using a foot compression device on the fifth postoperative day following hip or knee arthroplasty.²²

Electrical foot stimulation has advantages over electrical calf stimulation. The anatomic variation of the sole of the foot is much less than that of the calf. The range of

voltage amplitude required is also less with foot stimulation compared with calf stimulation. This simplifies the design and use of the device.

Our device can be used as long as the plantar foot muscles are accessible to placement of the electrodes and a muscle contraction to the electrical stimulation can be obtained. The most important contraindication to electrical stimulation is the presence of a cardiac pacemaker. Skin lesions affecting the sole of the foot may also be a contraindication. Severe peripheral polyneuropathy, or trauma to the tibial nerve, which innervates the plantar

muscles, might prevent muscle contraction from occurring. Finally, pregnancy should be considered a contraindication.

The American College of Chest Physicians in July 2008 published the eighth edition of their evidence-based clinical practice guidelines for antithrombotic and thrombolytic therapy.²³ They recommend that mechanical methods of thromboprophylaxis be used in patients with a high risk of bleeding or as an adjunct to anticoagulant therapies. The guidelines emphasized that careful attention to the use of and optimal adherence to these methods are important. The new guidelines also recommend continued thromboprophylaxis after discharge for hip fracture and total hip and total knee replacement up to 35 days after surgery. Our device has the advantage of being portable and is therefore particularly well suited for prolonged DVT prophylaxis.

Long-term use of electrical foot stimulation will have to address the issue of comfort. The degree of discomfort noted by the subjects in this study should be analyzed in view of the fact that subjects sat continually for 4 hours in rather cramped conditions and that half of the subjects were obese. Furthermore, in our initial study, subjects did not find electrical foot stimulation uncomfortable and two subjects found foot stimulation pleasurable.¹¹

Electrical conductive fabrics presently exist that eliminate the need for adhesive electrodes such as those used in our study. Additionally, these soft electrodes, contained within the conductive sock fabric, would not cause increased friction or pressure on the skin surface. This should reduce discomfort, avoid skin breakdown, and enhance compliance.

Conclusions

Based on the favorable effects on venous blood flow velocity, this method of electrical foot stimulation has the potential to be an effective means of prophylaxis against venous thrombosis, particularly when patients are discharged after acute hospitalization. This compact device allows patients to simultaneously receive DVT prophylaxis as well as ambulate, perform various activities of daily living, and participate in physical and occupational therapy in an unencumbered manner. This device could also potentially be used in patients when anticoagulation is contraindicated or pneumatic compression is not feasible. Additionally, patients who require DVT prophylaxis on discharge from the acute hospital setting, as well as long-distance travelers, are potentially excellent candidates for

this method of DVT prevention. Further clinical evaluation of this modality is indicated.

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Financial disclosure of authors: James J. Czyrny, Robert E. Kaplan, and Jack Hirsh jointly hold a US patent for the electrical foot stimulation technology described in this article.

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Appendix: Subject Questionnaire

Intermittent Pneumatic Compression Questions

1. The compression was uncomfortable.
 - Strongly agree
 - Agree
 - Not sure
 - Disagree
 - Strongly disagree
2. Compared to my uncompressed leg, my compressed leg felt better after the study.
 - Strongly agree
 - Agree
 - Not sure
 - Disagree
 - Strongly disagree
3. If my doctor told me I was at risk for blood clot formation, I would consider using the foot compression device at home.
 - Strongly agree
 - Agree
 - Not sure
 - Disagree
 - Strongly disagree

Foot Electrical Stimulation Questions

4. The electrical stimulation was uncomfortable.
 - Strongly agree
 - Agree
 - Not sure
 - Disagree
 - Strongly disagree
5. Compared to my unstimulated leg, my stimulated leg felt better after the study.
 - Strongly agree
 - Agree
 - Not sure
 - Disagree
 - Strongly disagree
6. If my doctor told me I was at risk for blood clot formation, I would consider using the electrical foot stimulation device at home.
 - Strongly agree
 - Agree
 - Not sure
 - Disagree
 - Strongly disagree

Final Questions

7. Which device was more comfortable?
 - The foot compression device
 - The foot electrical stimulation device
 - Unsure
8. The compression device can only be used to walk a few steps. The electrical stimulation device does not limit your ability to walk. Do you think this would make you more likely to use the electrical stimulation device?
 - Yes
 - No
 - Unsure

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