VEINOPLUS®

We stimulate your life

CLINICAL EVIDENCE SOURCE COMPILATION

Original publications and reports

Compiled for DynaPulse Medical LLC, Minnetonka, MN · HCP reference only

ABSTRACT

This compilation reproduces, in a single reference document, the original publications and reports that make up the VEINOPLUS® clinical evidence base. It brings together 19 sources across three areas of use of the VEINOPLUS® neuromuscular electrical stimulation device: venous (9), arterial (7), and deep vein thrombosis, or DVT (3). Each source is introduced by a divider page carrying its full citation, a verified link where one exists, and an evidence-quality label.

Within each section, sources are ordered from highest to lowest evidence value: independent peer-reviewed first, then manufacturer-supported peer-reviewed, then conference-only, then non-peer-reviewed surveys, case reports, and study reports.

This document is compiled for HCP reference.

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VENOUS STUDIES

01

Effects of electrostimulation (Veinoplus) on lower-limb venous insufficiency-related symptoms during pregnancy

Le Tohic A, et al. Gynecol Obstet Fertil. 2009;37(1):18-24 (French). PMID 19119049.

https://pubmed.ncbi.nlm.nih.gov/19119049/

INDEPENDENT PEER-REVIEWED

Published in: *Gynécologie Obstétrique & Fertilité 2009 Jan;37(1):18-24.*

EFFECTS OF ELECTROSTIMULATION (VEINOPLUS) ON LOWER LIMBS VENOUS INSUFFICIENCY-RELATED SYMPTOMS DURING PREGNANCY. PRELIMINARY STUDY

Also presented at *the European Venous Forum, Istanbul 2006*

A. Le Tohic[1], H. Bastian[1], M. Pujo[2], P. Beslot[3], R. Mollard[3], P. Madelenat[1]

1: Service de gynécologie-obstétrique, maternité Aline-de-Crépy, hôpital Bichat Claude-Bernard, AP–HP, 46, rue Henri-Huchard, 75018 Paris, France

2 : Cabinet de kinésithérapie, 22, rue des Cascades, 93160 Noisy-Le-Grand, France

3 : EA 4070, laboratoire d'anthropologie appliquée, université´ Paris Descartes, 45, rue des Saints-Pères, 75270 Paris cedex 06, France

Objective: To assess if electrostimulation of lower limbs relieves lower limbs venous insufficiency-related symptoms during pregnancy.

Patients and methods: A two-step study was conducted. First, a monocentric prospective preliminary study including 30 pregnant women was conducted to assess the effects of electrostimulation on foetal monitoring and uterine contractions. Then, a multicentric prospective non-randomised study including 58 pregnant women with a gestational age between 23 and 33 weeks of amenorrhoea was conducted to evaluate the electrostimulation treatment. This evaluation was based on a clinical examination performed pre- and post-treatment, a CIVIQ questionnaire filled out pre- and post-treatment and a daily diary filled out by the patient during treatment duration. Treatment duration was 21 days including two daily treatment sequences of 20 min. Three groups of patients were identified based on initial intensity of venous insufficiency-related symptoms (Group 1 minor symptoms, Group 2 moderate symptoms, Group 3 severe symptoms).

Results: Preliminary study showed no interference between electrostimulation and foetal cardiac rhythm, uterine contractions and maternal uterine and foetal umbilical arteries. Concerning the evaluation of the electro-stimulation: in Group 1, electro-stimulation significantly reduced heavy legs sensation ($p < 0{,}001$) and calves pain ($p = 0{,}02$) between the beginning and the end of the treatment. The four scores calculated with the CIVIQ questionnaire decreased after treatment and a significant reduction was noted for generalised pain feeling ($p = 0{,}04$) and psychological impact ($p = 0{,}03$). In group 2, a significant decrease was noted for tiredness ($p < 0{,}001$), heavy legs sensation ($p < 0{,}001$), calves pain ($p < 0{,}001$) and edema ($p = 0{,}02$) between the beginning and the end of the treatment. The four scores calculated with the CIVIQ questionnaires significantly decrease after 21 days of treatment. In group 3, a significant decrease of heavy legs sensation ($p = 0{,}03$) and calves and malleoli perimeters ($p < 0{,}05$) was noted. After 21 days of treatment, the four scores calculated with the CIVIQ questionnaire significantly decrease ($p < 0{,}05$). When comparing the three groups, beneficial effects of the treatment are most marked in group 2 regarding subjective symptoms, CIVIQ questionnaire scores and leg pain. According to the patients, effectiveness and tolerance of the treatment ranged from good to excellent in the three groups.

Discussion and conclusion:

Electrostimulation is an effective and well-tolerated treatment of lower limbs venous insufficiency-related symptoms in pregnant women. Its use during pregnancy did not show any effects on foetus and pregnancy.

VENOUS STUDIES

02

Electrical muscle stimulation with Veinoplus device in the treatment of venous ulcers

Bogachev VY, et al. Int Angiol. 2015;34(3):257-62. PMID 25719401.

https://pubmed.ncbi.nlm.nih.gov/25719401/

MANUFACTURER-SUPPORTED PEER-REVIEWED

VENOUS STUDIES

Published in *International Angiology 2015 Jun; 34(3):257-62.*

ELECTRICAL MUSCLE STIMULATION WITH VEINOPLUS® DEVICE IN THE TREATMENT OF VENOUS ULCERS

Presented at: *World Meeting of the International Union of Phlebology, Boston 2013*

Bogachev VY, Lobanov VN, Golovanova OV, Kuznetsov AN, Yershov PV.

Russian State Medical University, Department of angiology and vascular surgery, Moscow.

Objective: The aim of the study was to analyze the results of the electrical muscle stimulation (EMS) usage in patients with venous ulcers developed on top of a post-thrombotic syndrome (PTS).

Methods: Sixty patients (60 legs) with active venous ulcer (C6EsAsdpPr according to CEAP classification) were divided into two groups. In addition to the background therapy consisting of a standardized compression with ULCER X and intake of micronized purified flavonoid fraction (MPFF 1000 mg daily), all the patients in the main group underwent EMS with VEINOPLUS® V.I. for at least 3 times a day. Follow-up examinations were performed on days 30, 60 and 90. These included pain severity assessment with 100-mm Visual Analogue Scale (VAS), disease severity measurement with VCSS (Venous Clinical Severity Score) and ankle circumference above malleolus, as well as recording number of healed venous ulcers.

Results: At day 90 pain severity was reduced in both main and control groups. However, according to VAS pain reduction rates were significantly higher in patients of the main group (from 8.7 ± 0.6 to 1.9 ± 0.3 in the main group and 8.4 ± 0.6 to 3.9 ± 0.5 in the control group). At the end of the study, ankle circumference decreased from 270.9 ± 4.6 mm to 257.1 ± 4.2 mm in the main and from 269.7 ± 5.3 mm to 263.4 ± 5.2 in the control group. VCSS before treatment was 7.3 ± 0.6 in the main group and 6.8 ± 0.5 in the control group. By day 90 VCSS significantly decreased to 2.3 ± 0.4 and 4.6 ± 0.5 in the main and control groups respectively. Healing rates were significantly higher in the main group. On day 90, the number of open venous ulcers in the main group was 3 times lower than in the control group (4 vs. 12).

Conclusion:

EMS demonstrated high efficacy and good tolerability and provided significant reduction in pain severity, VCSS score and ankle edema, as well as a 3-fold increase in the number of healed venous ulcers.

VENOUS STUDIES

03

Electro-muscular stimulation with Veinoplus for the treatment of chronic venous edema

Bogachev VY, et al. Int Angiol. 2011;30(6):567-90. PMID 22233618.

https://pubmed.ncbi.nlm.nih.gov/22233618/

MANUFACTURER-SUPPORTED PEER-REVIEWED

Published in *International Angiology 2011 Dec;30(6):567-90.*

ELECTRO-MUSCULAR STIMULATION WITH VEINOPLUS® FOR THE TREATMENT OF CHRONIC VENOUS EDEMA

Also presented at: *European chapter of the International Union of Angiology, Paris 2010*
Russian Association of Phlebology, Moscow 2010
Mediterranean Congress of Venous Pathology, Nice 2010
DGP, Berlin 2010

Bogachev V. Y., Golovanova O.V., Kuznietzov A.H., Stchekoian A.O.

Russian State Medical University, Department of angiology and vascular surgery, Moscow

Objective: Electro-stimulation with VEINOPLUS® has recently emerged as a new technique to activate the calf muscle pump and improve symptoms of venous disease. The aim of this study was to determine in patients suffering from chronic edema of venous origin the efficacy of VEINOPLUS® treatment in terms of reduction of evening edema, diminution of pain, improvement of quality of life and also evaluate the durability of the treatment and its impact on venous hemodynamics.

Patients and methods: 30 patients (32 legs) aged 19-50 (mean 45.2 ±1.3) classified CEAP C3 with chronic evening venous edema were recruited (22 limbs: C3SEp and 10 limbs: C3EsPr). All patients were treated with CE-registered VEINOPLUS® neuromuscular stimulator during 30 days: 3 sessions per day (each session being 20 minutes) during 10 days, then 2 sessions per day during 10 days and one per day during the last 10 days. Main criteria was the circumference of the supramaleoal shin segment, measured with a tape in the evening, before treatment, daily and as control 5 days after treatment. As secondary criteria, patients were assessed on day 0 and 35 regarding pain on the Visual Analog Scale, Quality Of Life (QOL) according to CIVIQ questionnaire and venous Refilling Time (RT) measured by Photoplethysmography. Three months after the treatment, evaluation of symptoms was made again. No other means of treatment or prophylaxis were used.

Results: VEINOPLUS® treatment was well tolerated by patients. There was not drop out and patients did not change their lifestyle. After treatment, a total or partial reduction of evening edema was shown in 93.8% of limbs, the circumference of the supramalleolar shin diminished by 20,3mm ($p<0.001$), the number of painful legs reduced from 28 to 12 and the severity score was cut from 8.3 ±1.1 to 3.8 points ±0.9 ($p<0.001$), QOL was improved significantly as the score dropped from 34.5 ±7.8 to 17.2 points ±4.6 ($p<0.001$) and RT increased from 17.3 ±0.9 to 21.5 seconds ±1.1 ($p<0.001$).
Three months after VEINOPLUS® treatment a total remission of symptoms was observed in 50% of legs, despite absence of other treatment.

Discussion and conclusion:

VEINOPLUS® stimulation is an effective and well-tolerated therapeutic method for the treatment of chronic venous disease when it comes to treatment of chronic edema, for reducing pain and improving quality of life. VEINOPLUS® can be used as additional means in the treatment and the prevention of symptoms of chronic venous insufficiency.
This study also reveals that stimulation of calf muscles with VEINOPLUS® can improve venous hemodynamics leading to a remission of symptoms. This finding should be investigated and confirmed in further studies reduction in pain severity, VCSS score and ankle edema, as well as a 3-fold increase in the number of healed venous ulcers.

VENOUS STUDIES

04

Electrical calf muscle stimulation prevents recurrent DVT after cessation of anticoagulation in patients with residual venous obstruction

Lobastov K, et al. Int Angiol. 2018;37(5):400-10. DOI 10.23736/S0392-9590.18.03922-4.

https://www.minervamedica.it/en/journals/international-angiology/article.php?cod=R34Y2018N05A0400

MANUFACTURER-SUPPORTED PEER-REVIEWED

Electrical calf muscle stimulation prevents recurrent DVT after cessation of standard anticoagulation in patients with residual venous obstruction

Lobastov K, Ryzhkin V, Vorontsova A, Schastlivtsev I,
Barinov V, Laberko L, Boyarintsev V, Rodoman G

Pirogov's Russian National Research Medical University; Clinical Hospital no.24 of Moscow Healthcare Department; Ivanteevka Central City Hospital; Clinical Hospital no. 1 of the President's Administration of Russian Federation

Aim: To assess the efficacy of electrical calf muscle stimulation (EMS) in patients with post-thrombotic syndrome (PTS) and residual venous obstruction (RVO) after cessation of a standard anticoagulation.

Design: prospective comparative non-randomized clinical trial with masked outcome assessor.

Inclusion criteria: first episode of unprovoked femoro-popliteal DVT, completed a standard 6-month course of anticoagulation, signs of RVO in the affected veins, Villalta score of 5 and more, informed consent given (approved by RNRMU IRB).

Methods: 60 patients in the age of 40-86 years (mean - 58,5±11,4), 38 men and 22 women, divided into two groups (30+30). In both groups PTS was treated by active walking (at least 5,000 steps per day controlled by an individual pedometer), below-knee graduated compression stockings (23-32 mm Hg) and MPFF (2-month course 2/year). In the main group, EMS with «Veinoplus VI» device (3 procedures of 30 minutes every day) also was used.

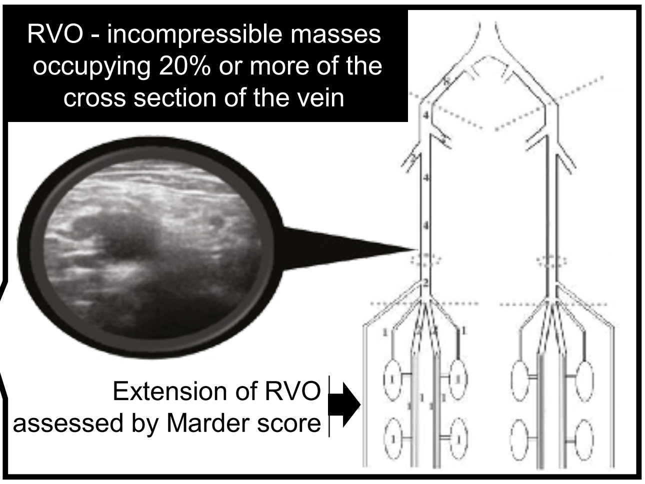
The primary endpoint: symptomatic or asymptomatic recurrent DVT confirmed by duplex ultrasound (DUS).

The secondary endpoint: changes in the degree of RVO.

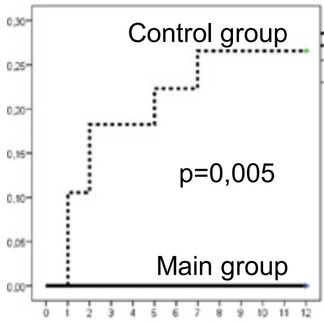
Follow up: 12 months with monthly DUS, aimed to reveal recurrent DVT, and 6-monthly DUS with evaluation of stenosis degree.

Results:

	Main (n=30)	Control (n=30)	p
Incidence of RVO in different veins (%)			
Common femoral	13,3	26,7	0,333
Superficial femoral	13,3	40,0	0,039
Popliteal			
Mean value of RVO in different veins (M±σ)			
Common femoral	47,2±14,3	48,3±14,9	0,903
Superficial femoral	54,8±23,6	52,5±21,5	0,862
Popliteal	60,8±17,5	49,6±21,4	0,030
Marder score	5,6±2,8	5,6±3,5	0,935



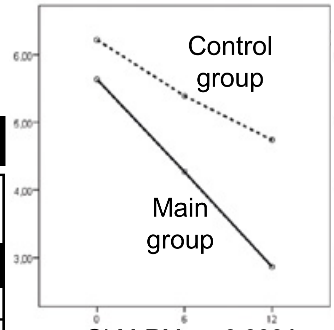
Cumulative incidence of DVT recurrence at 12m



EMS vs controls:
0% (95% CI: 0-11,4%)
vs
23,3% (95% CI: 11,8% 40,9%)

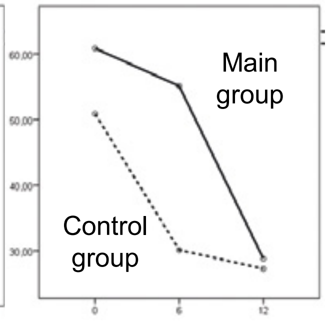
5 of 7 recurrent DVT - asymptomatic

Trends in Marder score



GLM-RM: **p<0,0001, p=0,048** , p<0,158

Trends in popliteal RVO



GLM-RM: **p<0,0001, p=0,004 , p<0,0001**

Conclusions: There is an ongoing process of deep veins recanalization during 12 months after cessation of anticoagulation in patients with RVO and PTS. Using of EMS in complex treatment of PTS allows to reduce the rate of recurrent DVT and increase the speed of recanalization.

Disclosure: Veinoplus devices and individual pedometers were provided by «BEHO+» ltd. The Company had no influence on the design of the study, data collection and their interpretation or preparing of this e-poster.

VENOUS STUDIES

05

Chronic (50-year) venous ulcer healing by electrostimulation

Zuccarelli F, et al. Angéiologie. 2006;58(4):32-3 (French).

MANUFACTURER-SUPPORTED PEER-REVIEWED

Published in: *Angéiologie 2006; 58 (4), 32-3.*

CHRONIC (50 YEARS) VENOUS ULCER HEALING BY ELECTROSTIMULATION

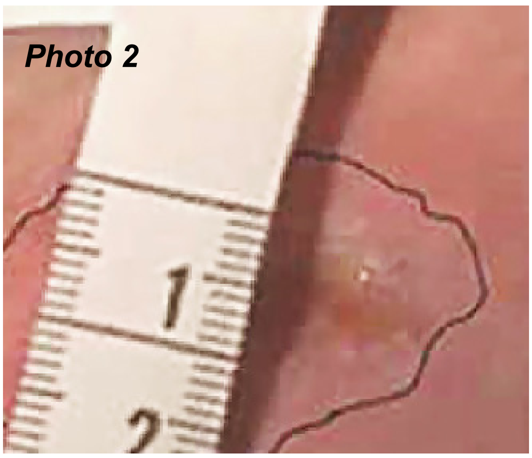
Also presented at: *American Venous Forum, San Diego 2007*

F. Zuccarelli[1], J. Le Magrex[1], M. Pujo[2], J.Cywinski[3]

1 : Phlebology Service, Hôpital Saint-Michel, 33 rue Olivier-de-Serres,F- 75015 Paris.
2 : INSEP, 11, avenue du Tremblay, F-75012 Paris.
3 : Institute of Medical Technology, C.P.17, CH-1937 Orsières, Switzerland.

Patient M.G. born in 1935, in January 1953 was diagnosed with thrombose of deep veins in the right leg. Bedridden for two months and treated with heparine and anti-vitamine K, developed thrombose also in the left leg and multiple hematomas. Released from hospital in March 1953, readmitted in August 1953 with an ulcer of 8 cm in length, above right ankle. Treated with topical application of placenta and IV Novocaine + antibiotic.. July 1954 after 1 year of in-hospital treatments was released for at-home care with non-healing bilateral ulcers. Readmitted to hospital at the end of 1954 received bilateral skin grafts. From 1957 till 2002, the ulcers alternatively reopened or partially healed. In May 2002 was admitted to Hospital St. Michel with post-thrombotic syndrome with bilateral nonhealed venous ulcers. Presented no problem with ambulation. The ulcers were located on interior sides of ankles with open cryptogenic aspect and atonic separating borders. Treated with multilayer contention + detergent the ulcer on the left leg closed, but on the right leg remained open in spite of antibiotic therapy and enzymatic cleaning of the ulcer opening. Since November 2004 M.G was treated at home with the Veinoplus stimulator for 20 min. daily. After 3 months the open right ulcer has diminished significantly (photo 1). After 6 months from the start of stimulation, the ulcer almost completely healed as shown on the Photo 2. Until May 2006 while continuing daily stimulations, no reoccurrence of active ulcers was observed. In May 2006 M.G. stopped the stimulation for personal reasons. In June 2006, the examining phlebologist observed reactivation and reopening of the ulcer. After one month, while reestablishing daily stimulations (20 minutes) with VEINOPLUS®, the ulcer healed completely again. In conclusion, the results of healing venous ulcers are encouraging and are warranting to enter into controlled clinical studies on this subject.

3 months after start of Veinoplus®



6 months after start of Veinoplus®

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VENOUS STUDIES

06

Efficacy and optimal use of a portable electrical muscle stimulator (Veinoplus) to improve symptoms of post-thrombotic syndrome

Soriano C, Moll S, Deal A. Poster, HTRS Scientific Symposium, Chicago, 2010.

CONFERENCE-ONLY (NOT PEER-REVIEWED)

EFFICACY AND OPTIMAL USE OF A PORTABLE ELECTRICAL MUSCLE STIMULATOR (VEINOPLUS®) TO IMPROVE SYMPTOMS OF POST-THROMBOTIC SYNDROME

Poster Presented At: *Scientific Symposium Of The Hemophilia & Thrombosis Research Society And North American Specialized Coagulation Laboratory Association Northwestern Memorial Hospital, Chicago 2010*

Catherine Soriano, Stephan Moll, Allsion Deal / University of North Carolina School of Medecine

Efficacy and Optimal Use of a Portable Electrical Muscle Stimulator (VeinoPlus®) to Improve Symptoms of Postthrombotic Syndrome

Catherine Soriano, Stephan Moll, Allison Deal
University of North Carolina School of Medicine

Introduction

An estimated 330,000 people in the United States have postthrombotic syndrome (PTS) [1]. Few studies have addressed the treatment of PTS [2]. A 2003 Cochrane Review examined available data regarding treatment of PTS with compression stockings or mechanical devices (intermittent pneumatic compression units) [3]. The authors report that there may be some benefit to the mechanical device at higher pressures in treating PTS though the trialwas too small and of too short a duration to draw strong conclusions. In regards to the ECS, the authors do not support, on basis of available evidence, treatment of PTS with ECS. Recently, a portable mechanical device has been shown to have a beneficial effect on the symptoms of PTS [2]. However, with only 32 patients enrolled, all of them with severe postthrombotic syndrome, and follow-up on treatment only having been 2 months, the study has been interpreted as too small, too short and too patient-selective to warrant advocating large-scale introduction of this device4. With few validated treatment options for PTS, further research and investigation is warranted given its significant morbidity.

Objectives

1. Estimate the *"clinical success"* of the device, defined by moderate improvement of symptoms, and an interest to continue using the device.
2. Estimate improvement in *quality of life* and objective findings of postthrombotic syndrome (villalta scale).
3. Estimate the *optimal electrical stimulation intensity* that has the largest benefit for relief of symptoms.
4. Compute information needed to power a future study.

Design & Methods

Patient Data Collection
Twelve subjects with postthrombotic syndrome were given a Veinoplusdevice to use for 2 months as they saw fit and record their experience.

Measurements
Villalta scale: : grades severity, from 0 to 3, of each of five symptoms (pain, cramps, heaviness, pruritus, paraesthesia) and six signs (edema, skin induration, hyperpigmentation, venous ectasia, redness, pain during calf compression)
VEINES-QOL/Sym questionnaire: specific for patients with deep vein thrombosis

Design & Methods

Statistical Analysis
Severity of condition was measured by the Villalta scale, where increased scores indicate increased severity. The questionnaire produced two summary scores based on venous symptoms and quality of life. The WilcoxonRank Sum test was used to compare intensity levels.

Device
The Veinoplus device electrically stimulates leg muscles via motor nerves, causing calf muscle contractions which facilitates venous blood return from the legs. The small battery operated device uses two electrode pads that deliver low quantities of electrical energy for 20 minutes per treatment with a user input, variable intensity.

Results

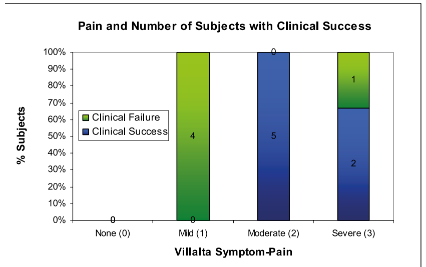
After using the device for eight weeks, 7 out of 12 patients (58%) had clinical success. Eighty-three percent (10) of subjects increased their QOL score, while 75% (9) increased their symptom specific score. The Villalta score improved in 67% of subjects, with a median decrease of two points.

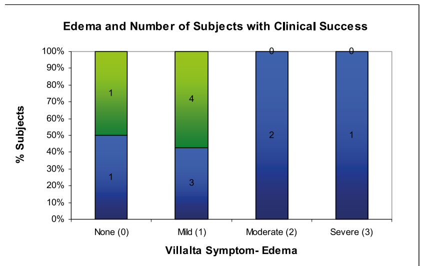
		Villalta Score		VEINES-SYM/QOL Questionnaire		
Subject ID	Clinical Success	Before	After	Before	After	Change
1	no	9	11	50.25	57.05	6.79
2	no	9	7	57.46	67.19	9.74
3	yes	22	15	45.76	50.23	4.47
4	no	14	12	49.66	62.01	12.35
5	no	9	10	51.42	42.5	-8.92
6	yes	14	13	54.1	42.13	-11.97
7	yes	14	15	31.11	32.74	1.63
8	yes	10	12	49.25	54.87	5.61
9	yes	17	14	36.86	47.78	10.92
10	no	15	13	42.49	45.21	2.72
11	yes	6	4	47.35	71.37	24.01
12	yes	12	8	47.31	63.9	16.58
Median		**12.58**	**11.17**	**46.92**	**53.08**	**6.16**

Results

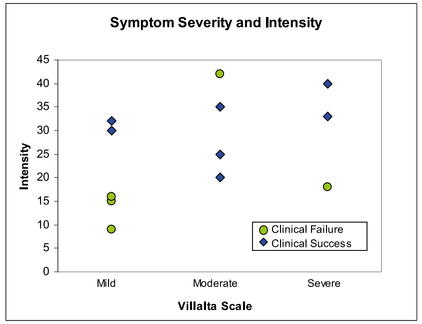
At the end of the study period 4 (33%) subjects had a decreased calf circumference. Optimal intensity was found to be a range, with most of the subjects who had clinical success using an average intensity of 20-40.

Of the five symptoms that make up the baseline Villalta score, only pain appeared to have a significant association with clinical success; all 5 subjects who reported moderate pain had a clinical success, along with 2 of the 3 patients who reported a severe pain level (p=0.02). All 3 subjects with moderate or severe edema had clinical success, along with 5 of 7 subjects with moderate to severe cramps. No significant associations with clinical success were found for other potential predictors of success (symptom severity, body mass index, and calf circumference). However, for all subjects symptom severity was found to be correlated with intensity (Rho=0.5, p=0.095) and calf circumference at baseline was strongly correlated with intensity (Rho=0.7, p=0.07).





Results



Conclusion

The VeinoPlus® electrical stimulation device appears to improve symptoms and QOL for patients with PTS. Although this study did not yield statistically significant results, given its small sample size, it provides the rationale and details needed for a larger trial. These initial findings are of clinical significance, as there are few treatments for patients with PTS. Veinoplus® is easy to use, small and portable, and had minimal disruptions in everyday life for most subjects. Elastic compression stockings and compression pumps could still be used in addition to using the Veinoplus®.

Futurs Directions

With the completion of this pilot study, we will be starting a phase 3 trial of the VeinoPlus® device. This study will have a sample size of 60 subjects. It will be a randomized, placebo controlled, and double-blinded trial. For more information, or if you are interested in becoming a study site, please contact smoll@med.unc.edu.

References

1. Heit JA, Cohen AT, Anderson FA. Estimated annual number of incident and recurrent, non-fatal and fatal venous thromboembolism (VTE) events in the US. Blood 2005; 106:267a.
2. O'Donnell MJ, McRae S, Kahn SR, et al. Evaluation of a venous-return assist device to treat severe post-thrombotic syndrome (VENOPTS). A randomized controlled trial. ThrombHaemost 2008; 99:623-9.
3. Kolbach DN, Sandbrink MW, Neumann HA, Prins MH. Compression therapy for treating stage I and II (Widmer) post-thrombotic syndrome. Cochrane Database SystRev 2003:CD004177.
4. Levi M. A long-awaited small step forward in the management of the post-thrombotic syndrome. ThrombHaemost2008; 99:463-4.

VEINOPLUS®

VENOUS STUDIES

07

Electric pulse muscle stimulation in treatment of low physical activity patients with venous stasis ulcers

Presented at EWMA Conference, Vienna, 2012.

CONFERENCE-ONLY (NOT PEER-REVIEWED)

ELECTRIC PULSE MUSCLE STIMULATION IN TREATMENT OF LOW PHYSICAL ACTIVITY PATIENTS WITH VENOUS STASIS ULCERS

Presented at *European Wound Management Association Conference, Vienna 2012*

Pulad Leval[1], Vyacheslav Nikitin[2], Vladimir Obolenskiy[1].

1: City Hospital #13 (Moscow, Russian Federation)
2: RSMU (Moscow, Russian Federation)

Aim: To assess effectiveness of joint use of long-term compression bandages (LTCB) and indirect electric pulse muscle stimulation (EPMS) in the context of conservative treatment of low physical activity patients with venous stasis ulcers (VSU) in the lower leg region.

Methods: A total of 17 low physical activity patients with VSU (C6, CEAP) with the following underlying somatic pathology: obesity, cerebrovascular accident after-effects, distorting osteoarthroses. Patients' average age was 74,7+13,6 years. Males amounted to 35,3%,
females – 64,7%. In the course of the study we employed a combination of EPMS and
LTCB approaches (primary zinc oxide saturated bandage and auxiliary 100% cotton bandage with 90% stretching property*). LTCB were applied for up to 7 days.
Prior to forming the bandage the skin at the back of lower leg was covered with self-attaching electrode with its terminal positioned outside the bandage. Having been briefed the patients used EPMS 3-10 times a day at their own discretion. Treatment efficiency was evaluated for four weeks.

Results: Hypostatic venous edemae of lower extremities were cut short within 3-10 days. In 23,5% of cases a full epithelialization of ulcerations was attained at the end of fourth week, in 47,1% of cases the area of ulcer size diminished in size by half and in 29,4% of cases the ulcers showed initial epithelialization stage.

Conclusion:

Combination of EPMS and LTCB are effective methodq of VSU improvement of healing for low physical activity patients.
Portability, safety and ease of use of the technology, as well as the rate of exchange of LTCB (once a week), make this method applicable for at-home-treatment.

* Veinoplus®, made in France.

VENOUS STUDIES

08

Activation of the calf muscle pump action by electro-stimulation with Veinoplus device

Zuccarelli F, et al. Angéiologie. 2005;57(2):48-54 (French).

CONFERENCE-ONLY (NOT PEER-REVIEWED)

Published in: *Angéiologie 2005;57(2), 48-54.*

ACTIVATION OF THE CALF MUSCLE PUMP ACTION BY ELECTRO-STIMULATION WITH VEINOPLUS DEVICE

Dr F. Zuccarelli[1], Dr J. Launay[1], Dr J. Le Magrex[1], Pr R. Mollard[1], P. Fargier, M. Pujo[3]

1 : Hôpital Saint-Michel, 33, rue Olivier-de-Serres, 75015 Paris.
2 : Laboratoire d'anthropologie appliquée, université René-Descartes, rue des Saints-Pères, 75270 Paris cedex 06.
3: INSEP, 11, avenue du Tremblay, Paris 12è

Purpose of the study: To study the effect of the electro-stimulation with the VEINOPLUS® device on the physiopathology and quality of life patients suffering from distal venous stasis and also from insufficiency of saphenous veins.

Material and methods: The study carried out was of non-randomized experimental type. The inclusion criteria for patients were to have pains of venous origin and venous insufficiency classified as C0S or C1S or C2S according to classification CEAP and saphenous incompetence. A duplex Doppler Ultrasound scan was performed at the initial examination, to evaluate the VEINOPLUS® physio-pathological effects on the reflux. Then each patient filled out a QOL CIVIQ-2 questionnaire. The patients used the VEINOPLUS® for 20 minutes daily during three weeks. During the last exam the questionnaire CIVIQ 2 was filled out.

Results: Physio-pathological effects were studied on 20 patients. The VEINOPLUS® electrostimulation restored physiological venous flow and drained the calf muscles of the blood accumulated there. The effect of VEINOPLUS® stimulation on the quality of life was studied on 40 patients and demonstrated significant improvement of the quality of life of these patients.

Conclusion:

VEINOPLUS® by the way of electro-stimulation of calf muscles is of significant interest for venous insufficiency treatment. It ensures distal venous draining and significantly improves the quality of life of patients.

09

Users of Veinoplus: Ad Rem Technology survey on symptoms, behaviour and satisfaction (2009)

Ad Rem Technology. Telephone survey, Q4 2009.

USER SURVEY

USERS OF VEINOPLUS: AD REM TECHNOLOGY SURVEY ON SYMPTOMS, BEHAVIOUR AND SATISFACTION (2009)

Objectives: The "VEINOPLUS® Users" study was conducted only among individual French clients in order to find out their symptoms and their behaviour. The results presented here cover the 4 principal questions of the study, namely:

1. What is the user profile (age, gender, activity…)?
2. For what condition(s) and symptom(s) do they use VEINOPLUS®?
3. What is the behaviour of the users with regard to VEINOPLUS®?
4. What is their degree of satisfaction?

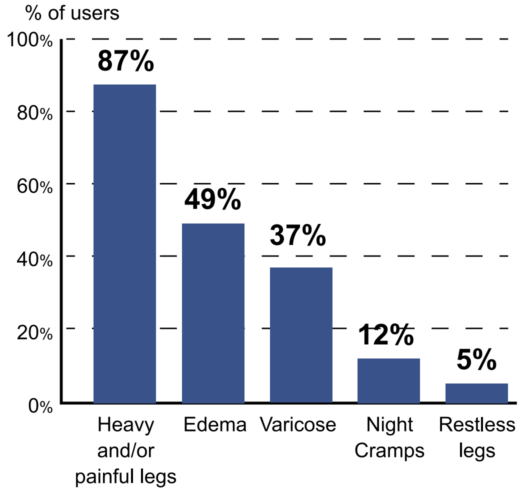
Methodology: The selected clientele gathers customers using VEINOPLUS® for more than 6 months and having repurchased electrodes from the company (whether or not the device had been purchased from the company). A questionnaire of 31 open and closed questions was submitted by telephone survey over a period of 8 weeks, in the 4th Quarter 2009. 100 individuals responded to the questionnaire, which is 32% of people called.

Results:

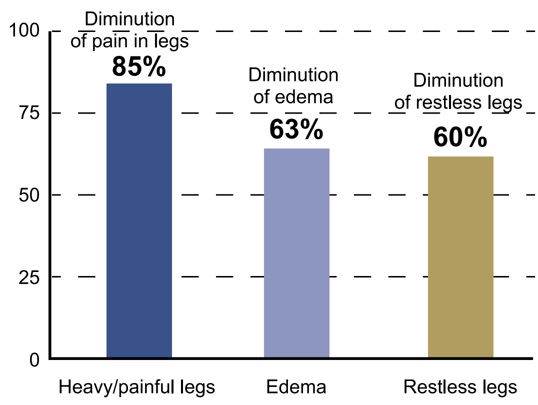
Over 3/4 of the VEINOPLUS® users questioned (78%) were working or of working age. The average age of the users was 52 for women (25-84) and 50 for men (31-90).
The vast majority of regular users of VEINOPLUS® suffer from heavy legs feelings and/or painful legs (fig 1), very often associated with other symptoms. Lower limb edema affected around 50% of the people questioned and came in 2nd place among the symptoms cited.
It should also be noted that a little over 1/5 of women use VEINOPLUS® according to the seasons, particularly during hot periods. Over 50% of women combine VEINOPLUS® with compression. The device acts very effectively on heavy and/or painful legs (fig 2).
The level of satisfaction of users is also very significant concerning the effect of VEINOPLUS® on oedema, and particularly the reduction of its volume. The vast majority of users confirm an instant effect upon use of VEINOPLUS®, particularly among women. In total, around 88% of VEINOPLUS® users consider VEINOPLUS® to be indispensable and/or useful. These figures therefore indicate a high level of satisfaction.

Developed in collaboration with Dr. F. Becker (Geneva University Hospital) and Dr. P. Blanchemaison (Professor at University of Medicine, Paris).

SYMPTOMS OF USERS



EFFECT OF VEINOPLUS®



ARTERIAL STUDIES

10

The use of transcutaneous electrical stimulation of the calf in patients undergoing infrainguinal bypass surgery

Mifsud M, Cassar KB. Ann Vasc Surg. 2015;29(8):1524-32. PMID 26318552.

https://pubmed.ncbi.nlm.nih.gov/26318552/

INDEPENDENT PEER-REVIEWED

THE USE OF TRANSCUTANEOUS ELECTRICAL STIMULATION OF THE CALF IN PATIENTS UNDERGOING INFRAINGUINAL BYPASS SURGERY

Presented at: *XVII Annual Meeting of the European Society of Surgery – Malta 2013*

Dr. Max Mifsud, Prof. Kevin Cassar

Department of Vascular Surgery, Mater Dei Hospital, Malta

Background: Infrainguinal bypass surgery is frequently associated with postoperative reperfusion edema of the limb. The etiology is thought to be multifactorial, and there is as yet no standardized treatment protocol for this problem. The primary aim of this study was to assess whether the use of intermittent electrical stimulation of the calf muscles after infrainguinal bypass surgery was effective in reducing the incidence of edema, and the secondary aims to determine the effect of calf muscle stimulation on arterial and venous flow in the operated leg.

Methods: Forty patients due to undergo infrainguinal bypass surgery for critical lower-limb ischemia (Fontaine grading IIIeIV or Rutherford grading IIeIII) were recruited prospectively and randomly divided into the control group, who received the current standard of care, and study group, who received electrical calf muscle stimulation for a 1 hour session twice daily for the first postoperative week. Preoperatively and postoperatively, the leg was measured at 3 predetermined points and a duplex ultrasound scan performed.

Results: The groups were well matched for all parameters. At 1 week, the below knee and calf girth were less in the study group (P ¼ 0.025 and P ¼ 0.043, respectively). Venous flow volumes at rest and on stimulation were higher in the study group (P ¼ 0.010 and P ¼ 0.029, respectively). At 6 weeks, the below knee girth and amount of pitting edema were less in the study group (P ¼ 0.011 and P ¼ 0.014, respectively).

Conclusions:

We conclude that transcutaneous electrical stimulation of the calf decreased lower-limb swelling at 1 and 6 weeks, and increased the venous flow volume at rest and on stimulation at 1 week in patients undergoing infrainguinal bypass surgery for critical ischemia regardless of patient factors or the type of bypass surgery performed or graft used.

ARTERIAL STUDIES

11

Increasing foot circulation with electrical stimulation in patients with diabetes mellitus

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INDEPENDENT PEER-REVIEWED

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ORIGINAL RESEARCH **ISSN: 2477-4073**

INCREASING FOOT CIRCULATION WITH ELECTRICAL STIMULATION IN PATIENTS WITH DIABETES MELLITUS

Iskandar[1*], Ridha Dharmajaya[2], Yesi Ariani[3]

[1]Master student, Faculty of Nursing, University of Sumatera Utara, Medan
[2]Faculty of Medicine,University of Sumatera Utara, Medan
[3]Department of Medical Surgical Nursing, Faculty of Nursing,University of Sumatera Utara, Medan

*Correspondence:
Iskandar
Master student, Faculty of Nursing, University of Sumatera Utara
Jl. Prof. Maas No. 3 Kampus USU 29155 Medan, Indonesia
Email: isnisam@yahoo.com

Abstract
Background: Peripheral arterial disorders in diabetes mellitus is a common complication that often occurs and can develop into diabetic foot ulcers. High blood sugar levels in people with diabetes mellitus can cause increased blood viscosity resulting in thickening of the capillary membrane, where erythrocytes, platelets and leucocytes are attached to the blood vessels. Electrical stimulation by placing electrodes in the calf muscle is one of the measures to increase foot blood flow that can reduce the poor foot circulation.
Objective: This study aims to determine the effect of electrical stimulation in improving blood flow of patients with diabetes mellitus.
Methods: The research use one-group pretest-posttest pre-experimental design. Sampling technique using pusposive sampling as many as 62 patients with diabetes mellitus. Electrical stimulation is done by attaching electrodes to left and right calf muscles for 20 minutes, frequency 3 times a week for 2 weeks. Before and after electrical stimulation performed foot circulation examination by ankle brachial index technique. Data analysis using Wilcoxon signed rank test.
Results: The results showed that before the stimulation was obtained the mean ankle brakhial index 0.82 mmHg and after stimulation 0.95 mmHg ($p = 0.000$), meaning there is an effect of electrical stimulation in increasing foot blood flow. A calf muscle contraction during stimulation leads to increased leg blood flow through the addition of vascular endothelial growth factor and increased nitric oxide as a vasodilator of blood vessels. Electrical stimulation can be applied in increasing the blood flow of the foot, thus preventing the occurrence of diabetic foot ulcers.
Conclusion: Stimulation is one therapy that can be done to prevent poor foot circulation of diabetes mellitus patients.

Keywords: electrical stimulation, foot circulation, diabetes mellitus

INTRODUCTION

Diabetes mellitus (DM) has a broad impact on the lives of patients, mainly due to the occurrence of prolonged complications. This disease is mentioned as one of the main causes of chronic disease and causes loss of limbs around the world (Hingorani et al., 2016). International Diabetes Federation (IDF) says that the prevalence of DM in the world in 2015 reached 7.3 billion people and is predicted to increase again in 2040 to 9 billion people. Indonesia is currently the seventh largest DM patient in the world with a total of 10 million people and is predicted to rise in sixth place by 2040 with a total of 16.2 million people. Based on the results of Basic Health Research (Riskesdas, 2013), an increase in DM prevalence in Indonesia from 1.1% in 2007 to 2.1% in 2013.

High blood glucose levels in DM patients can cause increased blood viscosity resulting in thickening of the capillary membrane, where erythrocytes, platelets and leucocytes are attached to the blood vessels. Narrowing of blood vessels due to membrane thickening resulted in reduced blood flow, resulting in various complications in patients with DM (Association, 2017).

Peripheral neuropathy is the most common complication of type 2 DM and occurs in the lower extremity of the limb which may affect the sensory, motor, and autonomic systems. The risk of peripheral neuropathy disorders 2 to 4 times higher in diabetics compared with non-diabetics, this disorder will increase with age and duration of diabetes (Beckman, Creager, & Libby, 2002).

One of the symptoms that appear in diabetic neuropathy is a leg injury. This is due to the disruption of blood vessels in the peripheral arteries and is a factor that contributes to the development of wounds in diabetic feet up to 50% of cases. Recommended interventions to reduce the continued effects of peripheral blood flow disruption such as regular exercise routine (walking, leg exercising, joint movement range) (Francia et al., 2015). Prevention to reduce the bad feet circulation in patients with diabetes mellitus is often done today, among others, regular exercise such as gymnastics fitness, walking exercise, range of motion on the feet. Some DM patients are found not to have enough time to exercise regularly because they are busy with other activities.

Electrical stimulation is one alternative therapy that can improve foot circulation to prevent potential foot injuries. Several studies have shown that commonly used electrical stimulation is to reduce pain, speed up wound healing and lower blood sugar levels. Research on electrical stimulation combined with walking for 50 minutes a day, 3 times a week for 4 weeks found an increase in foot circulation of DM patients compared to walking without electrical stimulation (Park, Son, Kim, Kim, & Oh, 2011). Previous study on electrical stimulation for 60 minutes, 3 times a week for 4 weeks found the perfect wound healing in the diabetic foot (Asadi, Torkaman, Mohajeri-Tehrani, & Hedayati, 2015). Previous research about electrical stimulation for 40 minutes a day, 3 times a week for 2 weeks on quadriceps femoris muscle with 50 Hz frequency was obtained before the average electrical stimulation of blood sugar 197.30 mg/dl and after stimulation in the last session an average of 148.10 mg/dl (Sharma, Shenoy, & Singh, 2010). Foot circulation is assessed using the ankle brachial index (ABI) method, which compares the systolic ankle and brachial systolic values. The purpose of this study was to determine differences in foot circulation of patients with diabetes mellitus before and after electrical stimulation of the calf muscles.

METHODS

Study Design

This study used one-group pretest-posttest pre-experimental design. The study was conducted at Public Health Center Muara Satu and Public Health Center Muara Dua of Kota Lhokseumawe from 5 July to 10 September 2017.

Research Subject

The sample size was 62 DM patients, using purposive sampling technique. The inclusion criteria established were (1) age over 40 years, (2) not diabetic foot ulcer, (3) blood sugar levels less than 500 mg/dl (4) did not suffer from respiratory diseases, (5) no cerebrovascular disorders. Exclusion criteria include DM patients with heart rhythm disturbances, experiencing respiratory complications (tachypnea/bradipnea).

Intervention

The electrical stimulation given in this study is using Veinoplus. Before the stimulation is done blood glucose examination and the measurement of ankle brachial index (ABI) as a pretest to determine foot circulation. Stimulate for 20 minutes by attaching electrodes to both left and right calf muscles in the sleeping patient position.. Treatment is given 3 times a week for 2 weeks. In the last session the treatment performed again measurement of blood sugar and ABI.

ABI is determined on the patient's supine position by inserting a sphygmomanometer cuff over the ankles (lateral malleolus), applying jelly to the artery tibial anterior, the vascular probe is placed in the artery tibial anterior of the until a pulse is heard, the cuff is then pumped until no pulse is heard. The cuff is released slowly to determine the ankle systolic. Similarly, to determine the brachial systolic in the patient's position to sleep on his back, then the cuff is mounted on the upper arm, the vascular probe is placed on the brachial artery. While blood glucose levels were assessed by taking blood samples on the patient's fingertips after being stabbed using a needle until blood came out about one drop, inserted into the Gluco-Dr.

Instrument

Instruments used include electrical stimulation with the brand VeinoPlus with battery type 9V (made in AD Rem Technology Paris, France). Vascular Doppler brand Bistos HI-dop (made in Model BT-200, 8 MHz ultrasound frequency, 1.5 V x 2 type battery (AA Type) (made in Bistos Co. Ltd., Seoul Korea). Furthermore, to support the implementation of vascular doppler is also used Sphygmomanometer Aneroid Type Tensi 200 brand OneMed (permit Depkes RI AKL 20501906481) to measure the systolic ankle and brachial pressure. Examination of blood glucose levels using Gluco-Dr (made in Alimedicus, Indonesia).

Ethical Consideration

This study has obtained ethical approval from the Ethics Committee of the Faculty of Nursing, University of Sumatera Utara with number 1236/VII/SP/2017. The researcher also confirmed that each respondent has gained approval for research.

Data Analysis

Data were analyzed using wilcoxon signed rank test

RESULTS

Table 1 shows that the mean age of DM patients in this study was 57.15 years (standard deviation = 6.44). The most dominant age was found by the 56-65 years old (62.90%). Minimum age 42 years, and makasimal 72 years. While the majority gender is female (64.50%).

Table 1 Characteristics of respondents

No	Characteristics	f	%	Average	Min-Max
1.	Age (years)			57.15	42-72
	36 – 45 years old	5	8.10		
	46 – 55years old	16	25.80		
	56 – 65years old	39	62.90		
	>65years old	2	3.20		
2.	Gender				
	Female	40	64.50		
	Male	22	35.50		
3.	Body Mass Index (BMI)			21.93	15.11-28.65
	<17 kg/m2	3	4.80		
	17 – 18.5 kg/m^2)	3	4.80		
	18.6–25kg/m^2)	48	77.40		
	25.1–27kg/m^2)	6	9.70		
	> 27 kg/m^2	2	3.20		
4.	During DM			9.63	2-22
	<10year	41	66.10		
	> 10 year	21	33.90		

Body mass index (BMI) averaged 21.98 kg/m^2 (standard deviation 2.87). Minimum BMI value 15.11 kg/m^2 and maximum 28.65 kg/m^2. Viewed from the long suffering DM average 9.63 years (standard deviation 5.05 years). The majority of patients less than 10 years (66.10%). At least suffer DM 2 years and 22 years old.

Table 2 shows that before the patient's blood sugar levels were stimulated in mild and moderate range (38.70%) and ABI in the mix arterial-venous category (50%). Meanwhile, after the stimulation of blood sugar levels in the normal category (58.10%) and ABI increased or normal (82.30%).

Table 2 Frequency distribution Blood sugar levels and ankle brachial index values

No	Blood Sugar Level and Ankle Brachial Index	Pre-test		Post-test	
		f	%	f	%
1.	Blood Sugar Level				
	Normal (<200 mg/dl)	4	6.50	36	58.10
	Mild (200-300 mg/dl)	24	38.70	20	32.3
	Moderate (301-400 mg/dl)	24	38.70	6	9.70
	Heavy (>400 mg/dl)	10	16.10		
2.	Ankle Brakhial Indeks				
	Mix arterial – venous	31	50	2	3.20
	Venous disorder	16	25.80	9	14.50
	Normal	15	24.20	51	82.30

Differences in blood sugar level and ABI values before and after the wilcoxon signed rank test were presented in table 3. The results showed that there was a significant difference in the decrease in blood sugar levels ($p = 0.000$, $p < 0.05$). The same is true of the patient's foot circulation before and after treatment ($p = 0.000$, $p < 0.05$).

Table 3 Differences in blood sugar levels and brachial ankle value index between pre-test and post-test of electrical stimulation

No	Blood Sugar Level and Ankle Brachial Index	Pre-test	Post-test	pvalue
1.	Blood Sugar Level			
	Mean	305.06	204.87	
	Standar deviasi	86.97	68.30	0.000
	Min – Max	114 - 425	90 - 375	
2.	Ankle Brachial Index			
	Mean	0.82	0.95	
	Standar deviasi	0.11	0.79	0.000
	Min – Max	0.62 – 1.17	0.77 – 1.17	

DISCUSSION

Blood Sugar Level Pre-test and Post-Test Electrical Stimulation

Increased blood sugar levels in DM patients due to pancreas do not produce enough insulin, or when the body cannot effectively use the insulin that has been produced (WHO, 2016). Hyperglycemia that occurs can cause increased blood viscosity so as to affect the blood flow is not good. Changes in blood sugar levels are influenced by multifactors, including age, body mass index, long DM, physical activity and tobacco use (Pamungkas, Limansyah, Sudarman, & Siokal, 2016).

Based on table 1 above can be seen there is a decrease in blood glucose levels before and after electrical stimulation. Mean pre-test blood sugar levels were 305.06 mg/dl and post-test 204.87 mg/dl ($p = 0.000$). Decreased blood sugar levels can occur due to muscle contraction by vibration of electrical stimulation in the calf muscles. Cells take glucose in the blood to convert into energy within the mitochondria. Furthermore, such energy causes contraction in the smooth muscles in the calf. A significant reduction in the study was also influenced by patient compliance in regular blood sugar control and oral therapy to lower blood sugar.

According to Asadi, Torkaman, Mohajeri-Tehrani, and Hedayati, explaining that the management of blood glucose levels of DM patients can be pursued by doing physical activity exercises so that glucose needs will increase compared to at rest. Regular electrical stimulation increases the absorption of glucose by the tissues during and after exercise, improves insulin sensitivity and improves the translocation of glucose transport. In addition to the stimulation provided, DM management also depends on lifestyle, pharmacological interventions with oral hypoglycemic or insulin preparations, blood glucose monitoring and early or continuous health education or counseling (Asadi et al., 2015).

The absorption of glucose that is transferred by muscle contraction is responsible for the decrease in blood glucose levels. Electrical stimulation can activate the absorption of glucose in the calf muscles by transporting GLUT-4 to the cell surface. However, the decrease in blood glucose after 2 weeks of stimulation in this study may be due to the accumulation of insulin-dependent effects of increased insulin sensitivity.

Differences in Foot Circulation Pre-test and Post-Test of Electrical Stimulation

Increased age in DM patients can cause endothelial vascular disorders. This disorder occurs from the early age of the elderly, causing the shrinkage of skeletal muscle cells progressively causing the disorder of protein cynthesis.

The adverse effects of circulation will damage the nerves. When interference on the autonomic nerves it will experience impaired function in the smooth muscles, glands and visceral organs. Changes in muscle tone can cause blood flow abnormalities (Petrofsky, 2011).

From the research results found the difference of foot circulation before and after electrical stimulation. The average ABI before the intervention was 0.82 (venous disorder) and the mean ABI after the intervention of 0.95, whereas after intervention there was an increase in the ABI value by an average of 0.13 or included in the normal ABI category. The result of test analysis of wilcoxon signed rank test to identify that 82.5% of respondents have increased circulation. The statistical results obtained p value = 0.000 means electrical stimulation has a significant effect on increasing the foot circulation of DM patients.

These results are consistent with the findings of Asadi et al. stimulation there was a change in peripheral skin temperature caused by increased blood flow (Asadi et al., 2015). Aldayel, Jubeau, Mcguigan, dan Nosaka reported that skin temperature in healthy individuals increased significantly within 10 minutes after induction of electrical stimulation in the quadriceps femoris muscle compared with the control group (Aldayel, Jubeau, McGuigan, & Nosaka, 2010). While Sandberg, Sandberg, and Dahl, induction of electrical stimulation of trapezius muscle in healthy individuals for 15 minutes can improve blood circulation in muscles (Sandberg, Sandberg, & Dahl, 2007).

Stimulation of the calf muscles causes increased blood flow in the leg area through the addition of endogenous blood vessel factors, which in turn will reduce the pain experienced by diabetic patients. Thakral et al. states that increased perfusion due to electrical stimulation is associated with increased vascular endothelial growth factor (VEGF) (Thakral et al., 2013). Where, VEGF is an angiogenic factor with selective endogenous cell mitogenic activity that plays an important role in vasculogenesis, the growth factor is highly specific to the function of vascular endothelial cells. The role of VEGF is very dominant in the process of formation of new blood vessels called angiogenesis. In addition, VEGF also plays a role in the permeability of blood vessels that cause extravasion of several other molecules.

VEGF determination after electrical stimulation occurs through RNA expression by oxygen exposure initiated by contraction of the smooth muscles that cause angiogenic formation of blood vessels. Angiogenic itself is a basic process in the formation of new blood vessels from the existing blood vessels. The angiogenic target here is arterial or venous capillaries in vascular endothelial cells and smooth muscle cells (Valiatti et al., 2011).

Asadi et al. increased blood flow in the wound area was associated with a vasodilation process caused by electrical stimulation. By releasing nitric oxide (NO), as a coronary vasodilator, or inhibiting sympathetic vasoconstriction. NO is a small atom, relatively unstable, free radicals and lipophilic molecules. NO works as an intermediary or regulates endothelium-dependent vasorelaxation, blood pressure, macrophage cytotoxicity, platelet aggregation. In addition, the role of NO serves to dilate blood vessels, phagocytosis process and inhibit platelet adhesion (Asadi et al., 2015).

The mechanism of improving blood circulation during electrical stimulation is due to the production of NO in vascular endothelial cells in response to electrical stimulation. Where, a calcium channel is called a transient receptor voltage vanilloid (TRPV) -4 that contains an open voltage to respond to electrical stimulation in the tissues. It further increases blood flow to the tissues through ENOS which is activated with calcium (Petrofsky, 2011). Ghosh, Sherpa, Bhutia, Pal, dan Dahal explains that increased superoxide concentration causes decreased endothelial nitric oxide synthase (eNOS) isoforms by triggering the final product of glycation and polymerization. NO is synthesized as a byproduct of the conversion of its L-arginine physiological precursor to L-citrulline. This reaction is catalyzed by an enzyme known as NO synthesis (NOS) (Ghosh, Sherpa, Yazum Bhutia, & Dahal, 2011).

Toda, Imamura, dan Okamura stated that NO is constitutively produced from endothelial cells and nerve fibers that contribute to the regulation of cardiovascular function (Toda & Morimoto, 2008). This substance is formed through endothelial NO synthesis that induces vasodilation, increased blood flow rate, thrombocyte aggregation and adhesion resistance, decreased smooth muscle proliferation and as other antioxidants. When a person has hypercholesterolemia, hyperglycemia and hypertension can cause endothelial cell disruption resulting in disruption of the NO release. In people who stimulated an electric current in a low-voltage category, it can cause NO release of vascular endothelial cells, which can lead to vasodilation associated with increased blood flow to tissues and the metabolism of glucose present in the blood.

The results showed after electrical stimulation performed on the calf muscles for 20 minutes with frequency 3 times a week for 2 weeks, showed an increase in circulation to the foot area. Significant increases in ABI after electrical stimulation are important to suggest that the form of passive exercise therapy has a therapeutic effect on diabetes mellitus.

Limitations of the study are no examination of nitric oxide levels to detect vascular endothelial changes that cause vasodilation of blood vessels, so there is no known good time sessions to increase the levels of NO.

CONCLUSION

The conclusion of the research is that there is an effect of electrical stimulation on the improvement of foot circulation of diabetes mellitus patients. Stimulation is one therapy that can be done to prevent bad foot circulation resulting from high levels of sugar in the blood so it can be used as management or prevention diabetic feet diabetic patients. Health workers, especially nurses, need to socialize the use of electrical stimulation to improve foot circulation or reduce pain in diabetes

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ARTERIAL STUDIES

12

Calf muscle stimulation with the Veinoplus device results in a significant increase in lower limb inflow without generating limb ischemia or pain in patients with peripheral artery disease

Abraham P, et al. J Vasc Surg. 2013;57(3):714-9. PMID 23312939. NCT01592812.

https://pubmed.ncbi.nlm.nih.gov/23312939/

MANUFACTURER-SUPPORTED PEER-REVIEWED

Calf muscle stimulation with the Veinoplus device results in a significant increase in lower limb inflow without generating limb ischemia or pain in patients with peripheral artery disease

Pierre Abraham, MD, PhD,[a,b] **Victor Mateus, MD,**[b] **Francois Bieuzen, PhD,**[c] **Nafi Ouedraogo, MD,**[b] **Fallou Cisse, MD, PhD,**[d] and **Georges Leftheriotis, MD, PhD,**[a,b] *Angers and Paris, France; and Dakar, Sénégal*

Objective: **Increase in arterial inflow to the lower limbs is important to obtain functional improvement in peripheral artery disease (PAD) patients with claudication. The aim of this study was to assess the effect of electrical stimulation of calf muscles on arterial inflow and tissue oxygen content in PAD in the area of stimulation.**

Methods: **Fifteen adult patients [mean (standard deviation) age, 62 (12) years; height, 165 (8) cm; weight, 76 (13) kg; lowest ankle-brachial index 0.66 (0.19)] with stable arterial claudication were recruited. All patients performed a treadmill test (3.2 km/h, 10% slope) associated with a transcutaneous oximetry test expressed as decrease from rest of oxygen pressure (DROP) index values (calf changes minus chest changes from rest) with a maximum walking distance (median [25th/75th percentiles]) of 295 [133-881] m. The DROP index on the symptomatic side was −25 [−18/−34] mm Hg. On another day the patients underwent electrical stimulation in the seated position on the leg that was the most symptomatic on the treadmill. After resting values were recorded, the gastrocnemius was stimulated for 20 minutes at increasing contraction rates at 5-minute steps of 60, 75, 86, and 100 bpm on the most symptomatic side. Arterial blood inflow with duplex Doppler ultrasound scanning of the femoral artery, DROP transcutaneous oxygen pressure value, and oxygen concentration (O_2Hb) from the near-infrared spectroscopic signal of the calf were recorded on both sides. Patients were instructed to report eventual contraction-induced pain in the stimulated calf. Results are given as mean (standard deviation) or median [25th/75th percentiles] according to distribution, and the level of statistical significance was set at $P < .05$ on two-tailed tests.**

Results: **Lower limb inflow (mL/min) was 64 [48/86] vs 63 [57/81] ($P > .05$) before stimulation, 123 [75/156] vs 57 [44/92] ($P < .01$) at 60 bpm, 127 [91/207] vs 49 [43/68] ($P < .01$) at 75 bpm, 140 [84/200] vs 57 [45/71] ($P < .01$) at 86 bpm, and 154 [86/185] vs 55 [46/94] ($P < .01$) at 100 bpm on the stimulated vs nonstimulated limb, respectively. No apparent decrease or significant leg difference was observed in DROP index or O_2Hb values. None of the patients reported contraction-induced pain in the leg.**

Conclusions: **Electrical stimulation of calf muscle with the Veinoplus device results in a significant increase of arterial inflow without measurable muscle ischemia or pain. Potential use of this device as an adjuvant treatment to improve walking capacity in PAD patients remains to be evaluated. (J Vasc Surg 2013;57:714-9.)**

Walking limitation is one of the first clinical complications of peripheral artery disease (PAD). Stimulating muscle contraction is the major method of increasing limb blood flow and improving walking capacity in patients with claudication resulting from PAD.[1] Regular walking has a beneficial effect,[2] but many events may preclude the adherence of patients to this recommendation,[3] including comorbid conditions, low motivation to exercise,[4] and bad weather conditions. As an adjuvant to walking or for patients who cannot walk, methods to induce passive increase of limb inflow, such as external intermittent compression or direct electrical muscle stimulation (EMS), have been proposed.[5-8]

The fact that EMS-induced contraction can improve blood flow and decrease muscle fatigue in the ischemic muscle has been previously suggested in animals[9] and humans.[5] Among commercially available devices, the Veinoplus (Ad Rem Technology, Paris, France) has been proposed to increase venous outflow for prevention of deep venous thrombosis.[10-12] Nevertheless, direct evidence of the tolerance of electrical-induced contractions in terms of EMS-induced ischemia and of the amplitude of inflow to the stimulated limb in PAD patients is lacking. Our primary hypothesis was that self-selected intensity of EMS with the Veinoplus system could induce a significant

From LUNAM, INSERM 1083 CNRS6214, Faculté de Médecine, Université d'Angers,[a] and the Laboratoire d'explorations Fonctionnelles Vasculaires, CHU d'Angers,[b] Angers; the Institut National du Sport, de l'Expertise et de la Performance, Service Recherche, Paris[c]; and the Laboratoire de Physiologie, Dakar.[d]

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Reprint requests: Pierre Abraham, MD, PhD, Laboratoire d'explorations Vasculaires Centre, Hospitalier Universitaire, 49033 Angers cedex 01, France (e-mail: piabraham@chu-angers.fr).

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increase in arterial inflow in PAD patients. Second, whether direct muscle stimulation results in calf ischemia comparable with that observed during walking has never been assessed.

The aim of this study was to confirm the tolerance and clinical effects of electrical stimulation of muscle in patients with PAD, that is, to determine whether self-selected EMS with the Veinoplus apparatus is feasible and safe in PAD patients.

METHODS

Study population. Adult patients were recruited among the patients referred for treadmill evaluation of arterial claudication at the exercise unit of the Department of Vascular and Exercise Investigations of the University Hospital in Angers.

Treadmill tests and exercise transcutaneous partial pressure of oxygen. The routine exercise procedure has been extensively described elsewhere.[13-15] In brief, we used a 10% slope and speed of 3.2 km/h for 15 minutes, followed by an incremental phase in case of nonlimiting claudication during the constant load phase. Exercise was stopped on patient request. For all transcutaneous partial pressure of oxygen ($tcPO_2$) tests, as a routine we used at least three transcutaneous oxygen pressure probes (TCM400 Radiometer, Copenhagen, Denmark), one on the chest and one on each calf. Each probe was carefully calibrated according to the manufacturer's recommendations. The $tcPO_2$ values were recorded for 2 minutes in the standing position before the treadmill was started, during the walking period, and for 10 minutes in the standing position after the end of the exercise test. The $tcPO_2$ values were automatically stored every 2 seconds by a homemade computer program and converted to decrease from rest of oxygen pressure (DROP) indices. The DROP index was calculated as $tcPO_2$ absolute changes from rest at the limb level corrected with the absolute value of the chest $tcPO_2$ changes, with chest changes subtracted (if increased from rest) or added (if decreased from rest) from the changes observed at the limb level. The DROP index has been shown to be a reliable and accurate index for exercise-induced regional blood flow impairment at the calf and buttock level because it is independent from absolute starting values.[13-15]

Patient selection and inclusion. Patients were eligible to the study if they had stable Fontaine stage 2 PAD for at least 1 month, an ankle-to-brachial systolic pressure index <0.90 on at least one side, a patent femoral artery on the mid-third of both thighs, and no femoropopliteal bypass. If proof of femoral patency was not available from the patient file, it was checked by ultrasound scanning before inclusion. The study was performed according to the recommendation of the Declaration of Helsinki and Register Number was NCT01592812 in the clinicaltrial.gov database. Patients provided written informed consent before inclusion in the study.

Investigations. Investigations were performed in the vascular unit of the department within two to 30 days of the treadmill test and the stimulation performed on the most symptomatic leg. The contralateral leg of each patient was not stimulated and thus was used as a control. Investigations were conducted in an air-conditioned room (22°C ± 2°C), with the patient comfortably seated on an armchair. A minimum period of 20 minutes in the seated position was allowed to avoid any possible influence of a previous walk over recordings. Thereafter, measurements were started at rest, performed throughout the 20-minute period of stimulation, and for 10 minutes after the end of the stimulation.

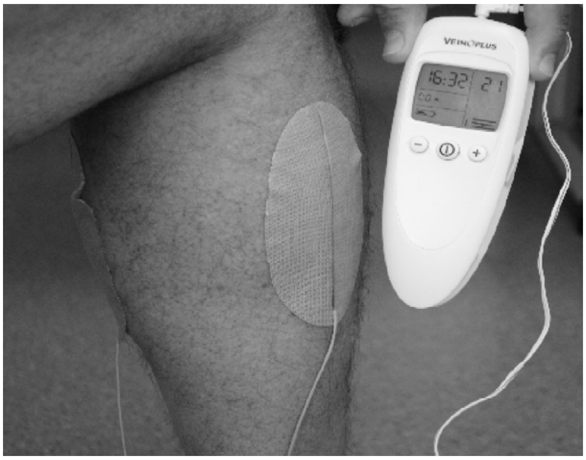

Fig 1. The Veinoplus device placed on a patient.

Electrical muscle stimulation. The stimulation from Veinoplus consists of a series of rectangular pulses of low energy (<25 μC), low voltage (50 V_{peak}), low frequency (1-250 Hz), and maximum duration of impulse 240 μs; intensity can be changed manually. The effective output voltage ranges from 0.1 to 5 V root mean square (RMS), with each intensity unit corresponding to approximately 0.1-V RMS increment. The shape of the current wave is biphasic, leading to nearly symmetric contractions of the muscles of the calf muscle in each leg. The device consists of a handheld central unit that works on a battery, connected to two ovoid skin adhesive electrodes. Each electrode is ∼8 cm wide and 13 cm long. The two electrodes of the device are positioned symmetrically on the medi-ocentral part of the calf (Fig 1). A switch on the central unit starts the preset EMS program, and, thereafter, the intensity of stimulation can be increased (or decreased) manually. There is a wide interindividual difference in the intensity required to reach muscle contraction as well as the intensity to reach stimulation-induced pain. When switched on, the device automatically delivers a stimulation of preset incremental rate, starting with 60 bursts of stimulation per minute (bpm) and changing to approximately 75, 86, and 100 bpm every 5 minutes. At the end of the 20 minutes of stimulation, the device stops automatically.

For the present study, the electrodes were positioned on the most symptomatic leg. Patients were instructed that the intensity of stimulation would slowly increase, that they should stop this increase before the feeling became uncomfortable, and that thereafter the intensity of stimulation would remain stable throughout the test. For the protocol, after 2 minutes of rest, the Veinoplus device was started and the intensity of stimulation was increased to reach the optimal intensity level within 1 minute. Thereafter, electrical stimulation could be stopped at the patient's request in case of ischemic pain or if the $tcPO_2$ in the calf of the stimulated leg (expressed as DROP index) fell by >5 mm Hg beyond the decline observed in the same calf during the walking test. A minimal level of intensity was required, corresponding to a visible contraction of the calf muscles with comfortable sensation. If the self-selected intensity did not result in visible contractions, the patient was excluded from the study.

Systemic hemodynamic parameters. Systemic and diastolic arterial pressures and heart rate were recorded every 2 minutes using Dynamap V100 (General Electric, Buc, France), before, during, and in the 10 minutes after EMS.

Ultrasound measurements. Arterial leg inflow was examined in the femoral artery with real-time gated Doppler sonography (Sequoia 512, 8-MHz linear array probe; Siemens SAS, Saint Denis, France). The sites to be measured on both sides were searched on the superficial femoral artery (SFA), 3 to 15 cm from the femoral bifurcation in order to avoid luminal irregularities, and marked with a permanent marker on the skin to allow repeated measurements on both sides. The diameter of the SFA was measured at rest on both sides before each protocol by viewing the artery longitudinally and by placing the tracker ball—guided calipers across the intimal—luminal interphases of the near and far walls. An average of five measurements was used to calculate cross-sectional area. This average value of cross-sectional area was used for calculating arterial inflow. Spectral velocity data were obtained at a maximum of 45° insonization angle with the sample volume gate encompassing the entire lumen of the vessel and the position of the probe marked on the skin to allow repeated measurements at the same place. Doppler waveforms were enveloped automatically using dedicated software for flow estimation. The mean integrated velocity (VTI) over three cardiac cycles (three peaks systolic velocity) was measured to calculate arterial inflow to the leg and performed as often as possible, changing the side of measurement for every three measurements of VTI. The goal was to average at least two, optimally three, measurements on each side and for each rate of stimulation in order to decrease measurement variability. Arterial inflow was calculated from VTI by the cross-sectional area of the femoral artery (L/min), before, during, and in the 10 minutes after EMS.

The $tcPO_2$ recording during EMS. The $tcPO_2$ was measured at the chest and on both calves close to the area where they were measured for the exercise treadmill test. Values were recorded manually every 2 minutes, before, during, and in the 10 minutes after EMS. Results are expressed as DROP values (mm Hg).

Near-infrared spectroscopy during EMS. Gastrocnemius muscle oxygenation was monitored by two pairs of continuous-wave near-infrared spectroscopy (NIRS) probes (Oxymon Mk III; Artinis Medical Systems, Zetten, The Netherlands). The NIRS light consisted of two wavelengths (780 and 850 nm). Oxygen content (O_2Hb) was calculated from the age-dependent differential path-length factors (range, 4.95-6.12). The theory, limitations, and reliability of measurement obtained with this device during exercise have been reported previously.[16,17] The probes consisted of one emitter and one detector (3.5 cm one from the other) housed in a black, plastic holder affixed over the belly of the gastrocnemius lateralis. A bandage covered and stabilized each probe holder in order to reduce the intrusion of external light and the loss of transmitted NIRS light from the measuring area. NIRS data were continually acquired at 5 Hz and transferred online from the Oxymon Mk III to a personal computer. Data were averaged over the last 30 seconds of each seven measurement periods. Results were analyzed before, during, and in the 10 minutes after EMS.

Table I. Demographic characteristics

Gender	12 males, 3 females
Age, years	62 (12)
Height, cm	165 (8)
Weight, kg	76 (13)
Systolic arterial pressure, mm Hg	139 (15)
Diastolic arterial pressure, mm Hg	81 (11)
Lowest ankle-brachial index	0.66 (0.19)
Maximal walking distance on treadmill, m	295 [133/881]
Heart rate before the walking test, bpm	75 (14)
Heart rate at peak exercise, bpm	120 (22)

Results are given mean (standard deviation) or median [25th/75th percentiles].

Calculation of the number of participants. From preliminary results we expected that the increase in arterial inflow to be at least 50% at the end of muscle stimulation compared with the contralateral limb (0%) with a variability of 15%, and that the decrease in the DROP index during EMS would remain smaller than the drop observed during treadmill for the same patient. Fifteen patients were included in order to assess the difference between the stimulated and control limb inflow, with $P < .01$ and power >80%.

Statistical analysis. Statistical calculations were performed using SPSS 16.0.1 (IBM, Bois-Colombes, France). Mean (standard deviation) values are presented for normal distributed variable and median [25/75 percentiles] for non-Gaussian distributions. Statistical tests for comparison of flow values between stimulated and nonstimulated limb were performed using Wilcoxon r-paired *t*-test as appropriate. For each test, the level of statistical significance was set at $P < .05$ on two-tailed test.

RESULTS

Characteristics of the patients are listed in Table I. All of the patients had PAD and claudication for 1 to 20 years, and five had undergone a lower limb revascularization. In brief, two patients had aortic stenosis, four had infrapopliteal lesions, five had bilateral iliofemoral lesions, and four

Table II. Decrease from rest of oxygen pressure index (median [25°/75° percentiles]) during treadmill test on the most symptomatic side (side of stimulation) and contralateral (control) side

	At minute 1	*At minute 2*	*Minimal value*
Side of stimulation, mm Hg	−5 [−3/−10]	−10 [−4/−15]	−25 [−18/−34]
Control side, mm Hg	−3 [−1/−5]	−5 [−3/−8]	−14 [−10/−25]

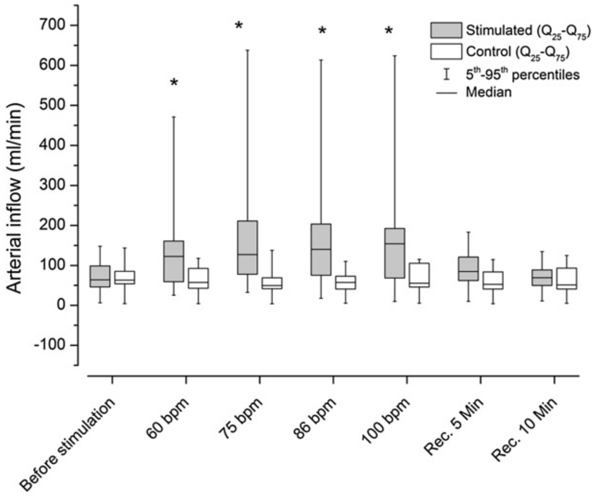

Fig 2. Median arterial inflow with 25-75 percentiles in the stimulated and control limb, at rest, during stimulation, and in the 10 minutes of recovery (*Rec*) after stimulation. Differences are significant between stimulated and control throughout the stimulated period. *$P < .05$.

unilateral iliofemoral lesions. In case of femoral lesions or occlusion, the femoral artery was always patent on both sides down to the lower third of the thigh. Three patients reported having type 2 diabetes, although only two were treated with antidiabetic drugs. All but one patient received antiplatelet agents. All but three patients were taking cholesterol-lowering drugs. Treadmill tests reproduced usual limb symptoms, and limitation was due to limb pain on the treadmill except in one patient. This patient had a self-reported maximal walking distance >1 km at usual walking speed. Although his symptoms were present while he was on the treadmill, he stopped the test because of exhaustion during the incremental phase of the treadmill (speed 4 km/h, slope 12%). As expected, the DROP index decreased progressively during exercise and tended to be lower in the most symptomatic side (the one used for muscle stimulation) than on the other side (Table II).

The stimulation was performed on the right side in eight patients and left side in seven patients. The level of stimulation reached ranged from 12 to 20 units (1.2-2 V RMS) for all patients on the device selector, allowing for visible calf muscle contraction in all cases. Calf EMS was well tolerated by all patients, and 20-minutes EMS could be completed in all cases without contraction-induced muscle ischemic pain, even for the seven patients with a maximal walking time on the treadmill <5 minutes.

No significant systemic hemodynamic changes were observed throughout the experiment, although systolic pressure tended to decrease moderately with time as a result of the patient being comfortably seated at rest for 30 minutes. Systolic and diastolic arterial pressures and heart rate were 139 (10) mm Hg, 76 (11) mm Hg, and 69 (13) bpm at rest, 136 (10) mm Hg, 75 (10) mm Hg, and 69 (14) bpm at 20 minutes of stimulation, and 134 (10) mm Hg, 76 (11) mm Hg, and 69 (12) bpm at the end of the experiments, respectively.

Stimulation induced a significant increase in arterial inflow in the stimulated limb, whereas the inflow remained stable on the control side (Fig 2). The coefficient of variation of repeated measurements during the test calculated in the nonstimulated leg was on average 18.3% (8.8%) for the 15 subjects. In the stimulated leg, we found a wide variability of inflow increase among subjects, ranging from 27% to >700% of resting values. The highest flow value increase was observed in a patient who had a severe stenosis at the origin of the profunda femoris artery with multiple but nonsignificant lesions on the SFA on the stimulated side. The lowest value was observed in a patient with distal occlusion of the SFA.

No relationship was found between the intensities of stimulation and flow ($r = 0.20$; $P > .05$). No difference in flow increase was found in perspective of treatments. Flow increase was 192% among the six patients who did not receive a vasodilating drug (nitrate, angiotensin-converting enzyme inhibitor, naftidrofuril, angiotensin-receptor antagonists) vs 181% in patients who did receive a treatment.

Although stimulation significantly increased arterial inflow, there was no apparent decrease in $tcPO_2$ (DROP index) during and in the 10 minutes after stimulation (Fig 3). Specifically, the lowest value observed during all sessions of 20 minutes of EMS was −10 mm Hg. This lowest value was found in a patient whose value after 6-minute walk on the treadmill (~300 m) was −25 mm Hg. Consistently, no significant difference was found on the NIRS signal between the right and left legs during and after EMS (Fig 4).

DISCUSSION

Muscle contraction induced by EMS seems to be well tolerated by PAD patients with claudication. EMS induced no pain due to the stimulation itself and no ischemic pain even though the total duration of EMS by far exceeded the duration of treadmill tests, limited by walking-induced pain in the same patients. This observation likely is a result of the moderate intensity of muscle contraction

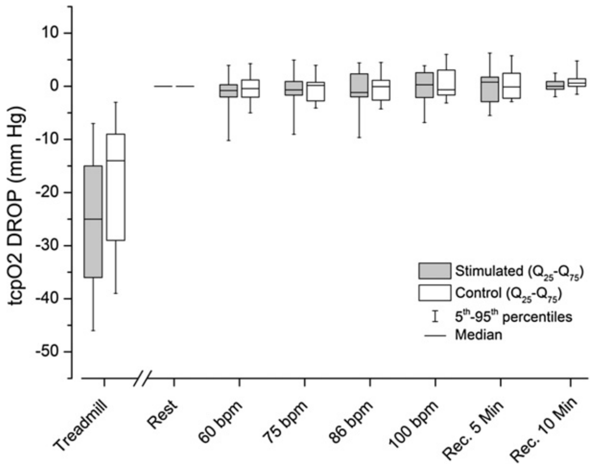

Fig 3. Median decrease from rest of the transcutaneous oxygen pressure (*tcPO₂*) decrease from rest of oxygen pressure (*DROP*) index with 25-75 percentiles observed during and in the 10 minutes of recovery (*Rec*) after stimulation. The minimum values observed on treadmill are shown as references.

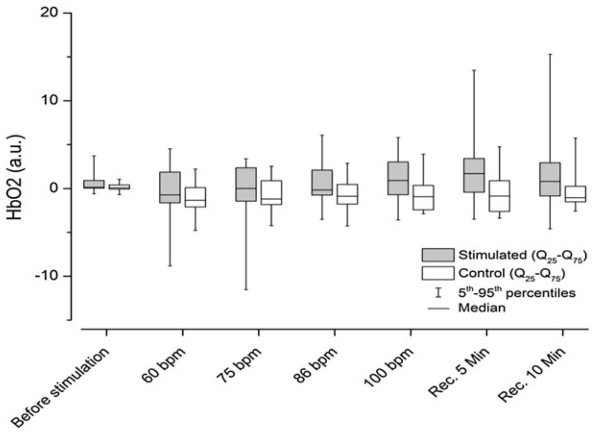

Fig 4. Near-infrared spectroscopy oxygen content (HbO_2) of the gastrocnemius lateralis muscle observed before, during, and in the 10 minutes of recovery (*Rec*) after stimulation.

and thus of oxygen demand. This hypothesis seems consistent with the absence of significant O_2Hb or $tcPO_2$ DROP index decrease on the stimulated leg compared with the nonstimulated leg. The NIRS changes during EMS were very small and extremely limited compared with the changes reported in the literature during walking tests.[18] Furthermore, $tcPO_2$ changes during EMS were much smaller than the changes observed during walking tests in the same patients. Consistently, the inflow increase found in this study remains moderate compared with the estimated limb flow increase observed during walking in healthy subjects. Indeed, blood flow to the anterior tibial compartment increased three- to fourfold during muscle contraction in healthy humans[19] and is dependent of age and exercise intensity.[20] The inflow values observed in the present study for the SFA were quite low compared with values in some previous reports.[8,20-22] It is likely that calculating limb inflow from the sole SFA underestimated the total leg inflow increase due to collateral circulation through the profunda femoris artery at the thigh level. The distribution of flow between the SFA and the profunda femoris artery is highly variable, and inflow in the SFA is decreased in the presence of lesions in this artery and is increased after angioplasty.[21,22] We believe that the inflow differences we observed likely resulted from the distribution of vessel lesions between the profunda femoris and the SFA. In the patient who showed the highest increase in inflow, we assume that all of the inflow increase was driven by the SFA, whereas in all other patients, the variable percentage of leg inflow was derived toward the profunda femoris artery. It is clear that total limb flow is, roughly, the sum of the inflow through the SFA and the profunda femoris arteries. The leg inflow that we measured likely was underestimated compared with the total flow of the limb. Thermodilution and xenon scintigraphy are invasive and not easily performed with patients in the seated position, and plethysmography results are influenced by the position of the limb from the heart.[23] It was not possible to measure both arteries on both sides with ultrasound in our experimental conditions. It could be suggested that measurement of arterial inflow at the level of the common femoral or popliteal arteries would have been preferable, but these arteries are difficult to access with patients in the seated position. Another point is that the absence of repeated diameter measurements may have interfered with our results, which could have underestimated arterial inflow changes.

There are other limitations to the present study. First, because the treadmill tests and EMS experiments were not performed in the same unit of the department, we could not record NIRS changes during exercise. Second, it is likely that greater changes could be attained if the intensity of stimulation, and the resulting force of muscle contraction, was increased. Nevertheless, the aim was to test the effect of tolerable (comfortable) use of the device in the setting of repetitive use "at home" without medical supervision, which we aim to study in the future. The intensity required to reach stimulation-induced muscle contraction was variable among subjects. Reasons for these differences (eg, electrode position, subcutaneous fat thickness, water content of the tissues) remain unknown. Third, the population studied showed relatively moderate severe claudication. This finding probably relies on the fact that we studied only patients with a patent SFA (at least of the first third) on both sides to allow ultrasound measurements. Clinical tolerance of EMS in patients with severe claudication or critical limb ischemia should be studied in another population. Finally, it could be suggested that the variability of flow increase resulted from the fact that arterial lesions were either proximal (aortoiliac) or distal. We believe this was not the case, but future experiments might be required to determine a difference in leg inflow between patients with suprainguinal and those with infrageniculate disease.

Clinical applications. Our results are important in view of potential use of EMS as an adjuvant treatment in PAD patients with claudication but remain to be evaluated. The absence of significant muscle ischemia on tissue saturation and DROP index is of major interest to prevent pain and for safety reasons if the device were to be used by the patient at home without medical supervision. Nevertheless, although the absence of pain and measurable ischemia during EMS may be beneficial from a compliance standpoint, it cannot be excluded that the oxidative stress of ischemia is as important as inducing increased arterial inflow in improving walking capacity, in which case, electrical stimulation would be less beneficial. We assume this is not the case because low-intensity treadmill walking exercise seems to be effective in improving maximum walking distance, even within a 6-week period for patients with intermittent claudication due to PAD.[24]

CONCLUSIONS

All study patients were able to self-select a level of intensity from the Veinoplus device that resulted in visible muscle contraction. The EMS of calf muscle resulted in a significant increase of arterial inflow in the SFA, without inducing ischemic pain in patients with PAD and a patent SFA. The decrease in $tcPO_2$ DROP index during and in the 10 minutes after EMS was extremely limited compared with the DROP index observed in the same leg and in the same patients during a treadmill walking test. Similarly, the NIRS O_2Hb values remained almost unchanged on the stimulated gastrocnemius muscle, suggesting that no measurable calf muscle ischemia occurred during or after EMS.

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AUTHOR CONTRIBUTIONS

Conception and design: PA, FB
Analysis and interpretation: VM, NO, FC, GL
Data collection: PA, VM, FB, FC
Writing the article: PA, FB
Critical revision of the article: VM, NO, FC, GL
Final approval of the article: PA, VM, FB, NO, FC, GL
Statistical analysis: PA, FB
Obtained funding: PA, FC
Overall responsibility: PA

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Extensive lower limb ulceration caused by iatrogenic arteriovenous fistula and peripheral arterial disease: use of Veinoplus calf muscle stimulation

Cassar K. Case report submitted to Ad Rem Technology, 2012; EWMA, Vienna, 2012.

CASE REPORT

Case report submitted to Ad Rem Technology (2012)

EXTENSIVE LOWER LIMB ULCERATION CAUSED BY IATROGENIC ARTERIOVENOUS FISTULA AND PERIPHERAL ARTERIAL DISEASE: USE OF VEINOPLUS CALF MUSCLE STIMULATION

By Prof. K. Cassar,

Mater Dei Hospital, La Valette, Malta

Abstract: We report the case of a gentleman with extensive arteriovenous ulceration of the right leg and foot secondary to an iatrogenic arteriovenous groin fistula in addition to occlusive disease at the level of the popliteal artery. The gentleman underwent an attempt at angioplasty of the popliteal artery which failed. He subsequently underwent surgical repair of the arteriovenous fistula as well as a popliteal to peroneal bypass graft using ipsilateral long saphenous vein. Postoperatively he was treated with Veinoplus electrical calf muscle stimulation twice a day for 20 days. The ulcer showed steady improvement and within 4 months had practically healed.

Case Report: An 84 year old gentleman presented with a 6 month history of extensive ulceration of the right leg and foot (Fig 1). The ulceration in the foot affected the dorsal aspect and measured about 8cm in diameter. The ulceration in the leg was almost circumferential and extended from just above the ankle to the mid leg with large amounts of necrotic fat and slough. The foot and leg were very markedly swollen compared to the contralateral limb. He also had a fissure at the base of the 2nd and 3rd toes. There was also ulceration over the lateral malleolus and over the Achilles tendon. The patient was diabetic on insulin and oral hypoglycaemics. He also suffered from hypertension, renal impairment secondary to diabetic nephropathy, hyperlipidaemia and ischaemic heart disease. Several years previously he had undergone percutaneous coronary intervention through the right groin. Clinical examination revealed palpable femoral pulses with a palpable thrill over the right groin. The popliteal pulse was palpable above the knee but no distal pulses were present. The waveforms at the ankle on the right were monophasic continuous. Ankle brachial pressure indices were not performed in view of the extensive ulceration over the leg. An ultrasound scan revealed the presence of an arteriovenous fistula between the profunda femoris artery and the common femoral vein with high flow through it. The duplex scan also showed that there was a short popliteal artery occlusion. The gentleman was referred for right popliteal artery angioplasty through an antegrade approach. Unfortunately it proved impossible to cross the lesion. In view of this the gentleman was taken to theatre where he underwent repair of the arteriovenous fistula between the profunda femoris artery and the common femoral vein. At the same procedure he also underwent right popliteal to peroneal artery bypass grafting using ipsilateral reversed long saphenous vein. The extensive ulceration of the right leg and foot was debrided (Fig 2).

Postoperatively he was treated with twice daily application of Veinoplus calf muscle electrical stimulation for 20 days. The ulcers made rapid progress and the marked swelling in the right lower limb improved dramatically (Fig 3). He was well enough to be discharged after 20 days (Fig 4). His bypass graft continued to be scanned at 1 week, 6 weeks and 3 months post operatively. At the 3 month scan a stenosis was identified in the bypass graft and the patient underwent bypass graft angioplasty with a good technical result (Fig 6). The patient continues to be followed up with bypass graft surveillance. At 4 months post op the ulcers are practically healed and the initial swelling in the limb has improved dramatically (fig 5).

Conclusion:

We report a case of extensive ulceration of the right lower limb secondary to arterial and venous disease treated successfully with bypass surgery, repair of an arteriovenous fistula and surgical debridement of the ulcers. VEINOPLUS® electrical calf muscle stimulation was used in the postoperative period to enhance healing and reduce swelling.

Fig 1: Extensive ulceration of the right leg and foot with necrotic fat and extensive skin loss

Fig 2: Right foot and leg ulcer immediately after surgical debridement

Fig 3: Right leg and foot 12 days after surgical intervention

Fig 4: Right leg and foot 20 days after surgical intervention

Fig 5: Right leg and foot 20 days after surgical intervention (full epithelialization

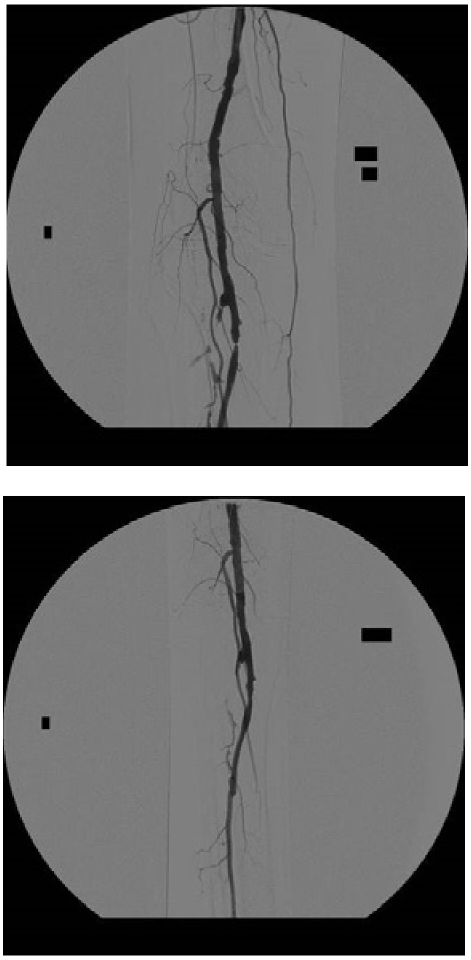

Fig 6: Right popliteal to peroneal vein bypass graft before and after angioplasty of graft stenosis

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Electric pulse calf muscle stimulation in treatment of patients with diabetic foot syndrome

Leval B, Obolenskiy V, Nikitin V. Study report, 2012; EWMA, Vienna, 2012.

STUDY REPORT

ELECTRIC PULSE CALF MUSCLE STIMULATION IN TREATMENT OF PATIENTS WITH DIABETIC FOOT SYNDROME

Presented at: *European Wound Management Association Conference, Vienna, 05/2012*

Bulad Leval[1], Vladimir Obolenskiy[1], Vyacheslav Nikitin[2].

1: City Hospital #13 (Moscow, Russian Federation)
2: RSMU (Moscow, Russian Federation)

Aim: to determine efficiency of indirect electric pulse muscle stimulation (EPMS) in treatment of patients with diabetic foot syndrome (DFS).

Methods: A total of 24 patients with different types of DFS presented an edema of the afflicted limb that developed in the wake of inflammatory alterations. Patients' average age was 56,1 years; men/women – 6/18.
All patients had the afflicted limb immobilized, their glycemia condition was corrected, the patients were administered antibiotics, antineuropathy, anti-angiopathy and metabolism-promotional medication. At the same time in the main group (14 patients) the afflicted limb also receive EPMT*) 2-5 times a day. DFS degree as per Wagner was presented in the main (control) group as follows: II – 1 (1), III – 4 (3), IV – 8 (6), V – 1 (0). Observation period was 4 weeks.

Results: On average in the main group edema subsided on the first day by 45%, on the third day it dropped down some 40% more and on the 5th day edema were cut short completely. 12 patients (86%) did not present an edema relapse. In control group edema subsided on the first day by 10%, on the third day it reduced some 30% more and on the 5th day it decreased 20% more and later on stayed at this level.

Conclusion:
The use of EPMS manifests in quick reduction of edema, positive changes in haemodynamics in afflicted areas which ultimately influences the general results of DFS treatment and reduces hospital stay.

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Electropulse muscle toning by the Veinoplus device as part of combination treatment of patients with obliterating atherosclerosis of lower limb arteries

Mikhailov IP, et al. Study report, 2012 (Sklifosovsky Research Institute, Moscow).

STUDY REPORT

Study report (2012)

ELECTROPULSE MUSCLE TONING BY THE VEINOPLUS DEVICE AS A PART OF COMBINATION TREATMENT OF PATIENTS WITH OBLITERATING ATHEROSCLEROSIS OF LOWER LIMBS ARTERIES

I.P.Mikhailov, Y.V.Kungurtsev, Y.A.Vinogradova, N.V.Sklifosovsky

Research Institute of Emergency Medicine, Moscow Healthcare Department, Russia

Aim of the study: This work contains a preliminary study of efficiency of Veinoplus portable apparatus in combination treatment of obliterating atherosclerosis for patients with chronic lower limbs ischemia. The received data indicate clinical efficiency of the device in combined therapy of chronic lower limbs ischemia.

Material and methods: 31 patients with different grades of chronic lower limbs ischemia received conservative vasodilating (Trental) infusion, and other pharmacological treatments. Hyperbaric oxygenation sessions were added for 17 patients. 13 patients underwent reconstructive operations on main arteries of lower limbs. Electropulse stimulation was also applied to the affected extremity muscles using the Veinoplus device in the treated group (21 people). The sessions were conducted during infusion vascular therapy (to improve perfusion of preparations in limbs tissue). The sessions were conducted 2 to 5 times a day.

Results: The results were estimated on the 1st, 5th, 10th day from the beginning of the therapy, then every 5 days (for patients after performing reconstructive surgery on the affected extremity arteries). In the treated group, on the 5th day, 14 patients (66.67%) reported abatement of the pain syndrome at rest and during minimum walking, increase of the painless walk distance by 100 meters on the average (versus 50 m in control group). On the 10th day, 19 patients (90.48%) reported a positive effect: absence of pain in the affected extremity at rest (for 8 patients, versus 3 patients in the control group), reduction of trophic disorders sizes (for 5 patients versus 1 patient in the control group). Regarding the increase of the painless walking distance, in the treated group it increased by by 300 meters (for 14 patients) and by up to 500 meters (for 5 patients). In the control group, it increased by 100 meters (for 6 patients); by up to 200 meters (for 3 patients) and by up to 300 meters (1 patient).
In the treated group, the edema of all 5 patients who underwent surgery decreased by 40% on the 1st day, by 50% on the 5th day, the edemas were eliminated on the 10th day and there were no recurrences of the edemas. In the control group, the edema was the same on the 1st day, decreased by 30% on the 5th day, 5 patients still had edema on the 10th day.

Conclusion:

The Veinoplus electropulse muscle toning apparatus is appropriate for combination treatment of patients with chronic ischemia of lower limbs, especially of patients with critical ischemia (grades III and IV according to Fontaine-Pokrovsky classification). Electric muscle toning by means of the Veinoplus apparatus during treatment of arterial pathology of patients with chronic ischemia intensifies the effect of traditional therapy methods (vasodilating infusion therapy, hyperbaric oxygenation) and facilitates fast formation of collaterals. Portability, simplicity and safety of the technology make it possible to use the Veinoplus device in the outpatient setting.

Keywords: obliterating atherosclerosis, fitness walking, electropulse muscle toning, Veinoplus device.

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Lower limb ulcer case report with severe arterial and chronic venous disease treated with electrostimulation (Veinoplus) and prostaglandins

Nicolaides AN, Georgiou N. Case report submitted to Ad Rem Technology, 2011; EVF Workshop, Vienna, 2011.

CASE REPORT

Case report submitted to Ad Rem Technology (2011)

LOWER LIMB ULCER CASE REPORT WITH SEVERE ARTERIAL AND CHRONIC VENOUS DISEASE TREATED WITH A COMBINATION OF ELECTROSTIMULATION (VEINOPLUS) AND PROSTAGLANDINS

Presented at: *European Venous Forum Workshop,Vienna 05/2011*

Prof. A. Nicolaides, N. Georgiou

Vascular Screening and Diagnostic Centre, Nicosia, Cyprus

Introduction: Ulcers with mixed venous and arterial components represent about 10% of cases and the more complicated the history of disease, the more difficult is the wound treatment. In affected patients, it is important to avoid compression, which is advised for pure venous ulcers. We report a case of ulcer on a complicated history of chronic venous and arterial disease treated with electrostimulation (EMS): VEINOPLUS and prostaglandins (PG).

Case presentation: We report here the case of a patient, Mr. MP, 56-years old. History: Deep venous thrombosis (DVT) in left leg 15 years ago followed by 5 further DVT; the last one 5 years ago. Every episode was treated by warfarin (1 month). In 2009 a left popliteal aneurysm was diagnosed and repaired with vein graft which closed 10 weeks later despite warfarin. Critical ischemia and intermittent claudication (IC) at 100m were managed by stenting a stenosis in left superficial femoral artery which resulted in symptoms relief.

Consultation in June 2011: Patient presented IC at 50m without rest pain and a left leg ulcer present for 2 months. He was able to sleep horizontal at night without any pain. His left Ankle Brachial Index (ABI) was 0.35.

Investigations and Treatment: The duplex scan showed an occluded popliteal vein and a partially recanalized femoral vein with marked reflux at the ilio-femoral segment. Angiography showed occluded lower femoral and popliteal arteries but with good collaterals across the knee.
Prescribed treatment was for outpatient management with PG E-1 daily infusion for 2 weeks, calf pump activation by EMS: VEINOPLUS in sitting position for 3-4 hours daily without warfarin discontinuation (INR 2.7).

Outcome: After 2 months (August 2011), swelling markedly reduced, ulcer healed and IC improved to 200m with no change in ABI.

Conclusion:

Management of mixed ulcers may not include compression as critical ischemia and limb loss may occur. It is therefore important to look for alternative ways of treatment. We describe the case of a mixed lower limb ulcer treated with electro-stimulation and PG that led to rapid healing of ulcer and improvement of IC. Possible contribution of EMS for treatment of leg wounds from both origins and the mechanisms underlying this action are worth further investigation.

Key words: mixed ulcer – electrostimulation
Published in Annals of Vascular Surgery 2015 (article in press)

DVT STUDIES

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The efficacy of a new stimulation technology to increase venous flow and prevent venous stasis

Griffin M, Nicolaides AN, Bond D, Geroulakos G, Kalodiki E. Eur J Vasc Endovasc Surg. 2010;40(6):766-71.

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MANUFACTURER-SUPPORTED PEER-REVIEWED

Eur J Vasc Endovasc Surg (2010) 40, 766–771

The Efficacy of a New Stimulation Technology to Increase Venous Flow and Prevent Venous Stasis☆

M. Griffin [a,*], A.N. Nicolaides [a,b,d], D. Bond [a], G. Geroulakos [b,c], E. Kalodiki [c]

[a] *The Vascular Noninvasive Screening and Diagnostic Centre, 30 Weymouth Street, London W1G 7BS, UK*
[b] *Department of Vascular Surgery, Imperial College, London, UK*
[c] *Ealing Hospital, Department of Vascular Surgery, London, UK*
[d] *Department of Biomedical Sciences, University of Cyprus, Nicosia, Cyprus*

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KEYWORDS
Deep vein thrombosis (DVT);
Venous stasis;
Ultrasonic venous imaging;
Thrombo-prophylaxis;
Calf muscle stimulation

Abstract *Objectives:* Electrical stimulation of calf muscles has been shown to be effective in prevention of DVT. The aim was to determine: (a) dependence of venous blood velocity and ejected volume on the rates of stimulated calf contractions: (b) clinical factors affecting efficacy in healthy individuals.
Methods: The maximum intensity stimulus tolerated was applied to calfs of 24 volunteers. In popliteal veins, Peak Systolic Velocities (PSV), ejected volume per individual stimulus (Stroke Volume SV) and ejected Total Volume Flow per minute (TVF) of expelled blood were determined using ultrasound. Stimulation rates from 2 to 120 Beats Per Minute (bpm) were applied.
Results: Mean baseline popliteal PSV was 10 cm/s. For stimulation rates between 2 and 8 bpm, the PSV was 10 times higher and reached 96–105 cm/s. Stroke volume (SV) per individual stimulus decreased in a similar fashion. With increasing rates of stimulation the TVF increased by a factor of 12 times (from 20 ml/min to 240 ml/min).
Conclusion: Electrical stimulation is an effective method of activating the calf muscle pump. Enhancements of popliteal blood velocity and volume flow are key factors in the prevention of venous stasis and DVT. Further studies are justified to determine the stimulation rates in those with a compromised venous system.

Introduction

Electrical stimulation has been used in the past to effectively activate the natural calf muscle pump. It significantly reduced the incidence of perioperative and postoperative deep venous thrombosis (DVT).[1–7] At that time, because of the pain associated with the stimulation its practical use was limited to anesthetized patients. Recently, an

☆ VEINOPLUS® is a registered trademark of Ad Rem Technology, Paris, France.
* Corresponding author. Tel.: +44 207 323 9477; fax: +44 207 436 3512.
E-mail address: maurabgriffin@googlemail.com (M. Griffin).

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electro-stimulator for calf muscles, the VEINOPLUS® (Ad Rem Technology, Paris, France) has been reported to improve quality of life.[8,9]

The aim of this pilot study was to determine the effect of VEINOPLUS® on: (a) popliteal vein blood velocity and (b) blood volume ejected from calf at broader rates of stimulation in a group of normal healthy volunteers. But also to determine the effect of age, gender, calf circumference, maximum stimulation intensity tolerated and popliteal vein diameter on (a) and (b).

Material and Methods

Stimulators

The VEINOPLUS® stimulator is a CE-certified and FDA-cleared, portable, battery (9V) powered device. It produces bursts of square-wave stimuli of 50 ms duration with adjustable voltage of 0–5 V_{RMS}, which result in safe, comfortable, painless calf muscle contractions. The maximum stimulation energy per phase delivered by the device is in the range of 3–24 micro-Coulombs (μC), which is 30% below international standard safety limits (AAMI/ANSI; NS4:1986/(R) 2002) and 250 times less than that used in the 1970s for the prevention of DVT.[4] The rates of calf contractions produced by the device quoted above[10,11] ranged from 60 to 100 per minute.

For the purpose of this study 12 rate-modified VEINOPLUS devices delivering rates from 2 to 120 bpm in 12 discrete steps were used.

Figure 1 Position of VEINOPLUS® electrode pads to the posterior aspect of the calf.

Participants and procedure

Twenty-four normal volunteers (12 females, 12 males) 8 from each of three age groups (18–30, 31–50, 51–61) were recruited to the study via information documents approved by the ethics committee for public display on 2 general hospital notice boards and a General Practitioner's waiting room. The potential volunteers were then screened during a telephone interview to confirm their suitability. The exclusions were small in number as the public notice was extremely detailed but over subscription to a particular age group namely the younger age group led to the some of these individuals being excluded. Clinical examination and duplex scanning were initially performed to ensure a normal venous system. Participants with superficial or deep venous disease, previous varicose vein surgery, congestive heart failure, patients with pacemaker, lower limb arterial disease (ABPI < 0.9) or active clinically suspected infection were excluded. Study protocols and informed consent were approved by the Regional Ethics Committee and the Medical Devices Committee. All participants gave written informed consent. After applying the pre-gelled stimulating electrodes (VeinoPack 5x13 by Ad Rem Technology, Paris France) to the posterior aspect of the calf (Fig. 1) each participant was placed in a semi-recumbent position and allowed to rest for 15 min. This was to ensure baseline equilibrium thereby reflecting more accurately the volunteer's true unaffected baseline venous flow. The intensity of the stimulus was gradually increased until the highest intensity comfortably tolerated by each participant was established. This particular intensity was then used for the rest of the examination. Different rates of stimulation were then applied ranging from 2 to 120 per minute in 12 steps (2, 3, 4, 5, 6, 8, 12, 15, 20, 30, 60, 120 bpm). Blood velocity in popliteal vein and volume flows were measured at rest before any stimulus was applied and during stimulation as described below. Only one leg per volunteer was tested. The side examined was determined randomly.

Ultrasound measurements

The popliteal vein was imaged in a longitudinal section using the IU22 ultrasonic scanner (Philips Medical, Seattle, WA) and a broad bandwidth L9-5 linear array transducer. Measurements were taken at popliteal fossa, just proximal to the confluence of the gastrocnemius veins. The Doppler sample gate was positioned across the entire vein diameter. Subsequently, peak systolic velocity (PSV) (cm/sec), diameter of the vein at the point of sampling and the duration of the Doppler spectral waveform produced by the calf muscle contraction were measured. The equipment's software was then able to calculate the cross-sectional area of the vein, the time averaged mean velocity (TAMV) and volume flow in ml/min (Fig. 2). These measurements were repeated using 12 different rates of stimulation as outlined above. Knowing that resting venous blood flow in a subject can change over

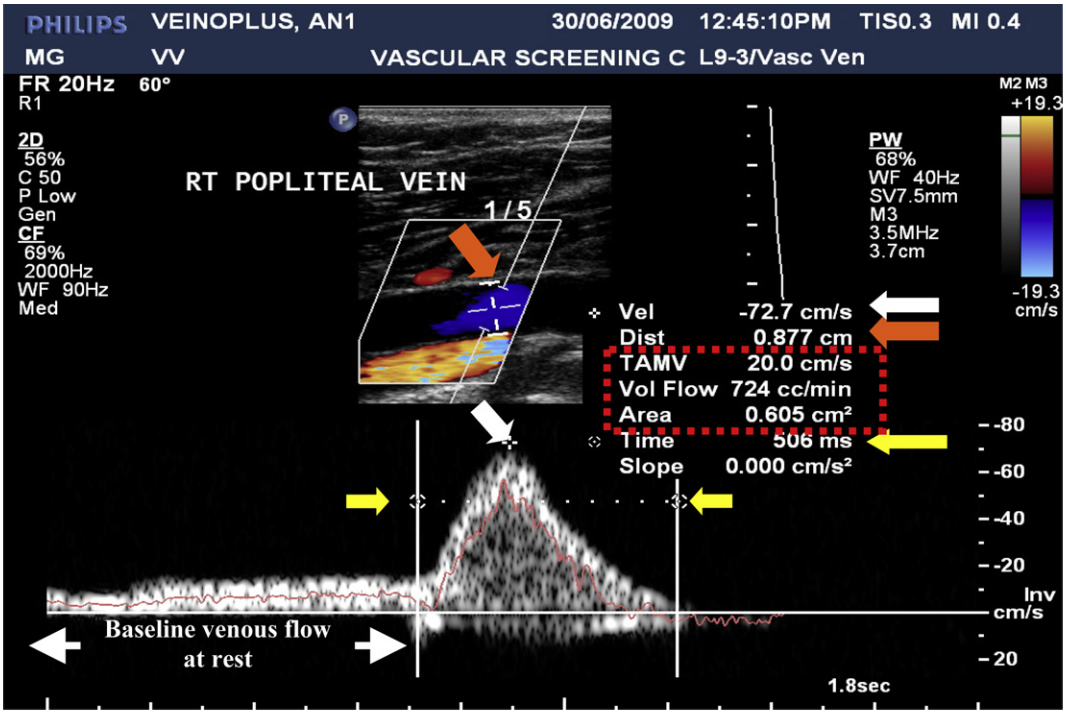

Figure 2 Typical Doppler waveform from one calf muscle stimulation. The orange coloured arrows highlight the popliteal vein diameter measured at the exact point where the sample volume "straddles" the whole vein. From these measurements the software then calculates the time averaged mean velocity (TAMV) and cross-sectional area to produce the volume flow, outlined by the red box. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article).

time[10] and patterns of flow will change according to breathing and the cardiac cycle[11] strict protocols were observed with the ultrasound measurements being repeated 3 times and the mean value taken. An interval of 3–5 min was allowed between different rates of stimulation to ensure return to baseline flow.

The volume expelled during a single stimulus and the volume expelled per minute as a result of the muscle contractions were calculated from the following equations:

$$\text{Volume expelled during single stimulus (ml)} = (\text{Volume Flow (ml/min)}/60) \times \text{Ejection Time (sec)}$$

$$\text{Volume Expelled per minute(ml/min)} = \text{Volume expelled during stimulus (ml)} \times \text{Number of stimuli/minute.}$$

Statistical analysis

The Kolmogorov–Smirnov test was used to test for normal distribution of the data. Age, calf circumference and popliteal vein diameter measurements were normally distributed; ultrasonic measurements were not. PSV, ejected volume per stimulus and ejected volume per minute were plotted against the stimulation rate. Kruskal–Wallis test was used for significance. Subsequently, PSV, ejected volume per stimulus and ejected volume per minute of subgroups of gender, calf circumference stimulus intensity tolerated, popliteal cross-sectional area and age were compared. Subgroups were based on median values of clinical features. Finally, logistic regression analysis was performed (a) with PSV and (b) volume ejected per minute as dependent variables with value above or below the median and clinical parameters as covariates. Because of nonlinear relationship of the odds ratio of covariates of calf circumference, stimulus intensity and vein area were converted into classes according to the median. Age was subgrouped as less than or more than 50 (lower 2 tertiles vs. upper tertile) because the odds ratio decreases markedly at this cut-off point. The statistical package SPSS for windows (version 18), Chicago, Illinois was used throughout. $P < 0.05$ was considered to be significant.

Reproducibility study

In 24 measurements repeated twice the intra-class correlation co-efficient and 95% CI for PSV and ejected volume per minute was = 0.952 (0.897–0.979) and 0.83 (0.606–0.926) respectively.

Results

The effect of the stimulation rate on PSV is shown in Fig. 3. Before stimulation was applied, during quiet breathing, mean popliteal PSV was 10 cm/s. For stimuli between 2 and 8 per minute PSV was 10 times higher at levels of 96–105 cm/s. As the stimuli increased further to the maximum of 120 per minute the peak velocity decreased rapidly to approximately 35 cm/s. Ejected volume per

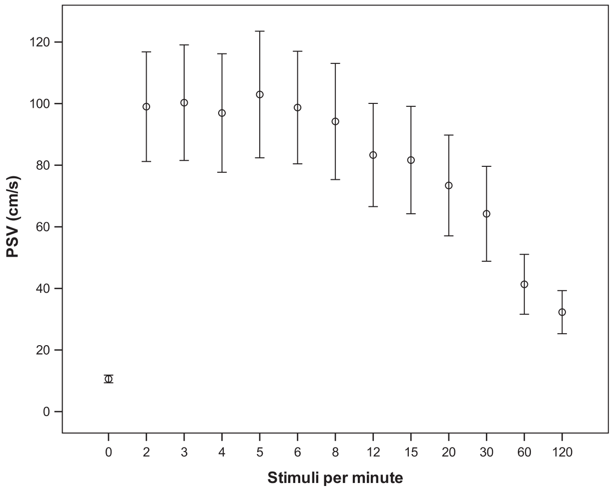

Figure 3 Peak systolic velocity (PSV) (mean and 95% CI) at different rates of stimulation. 0 indicated quiet breathing without any calf stimulation. Kruskal—Wallis test: $P < 0.001$.

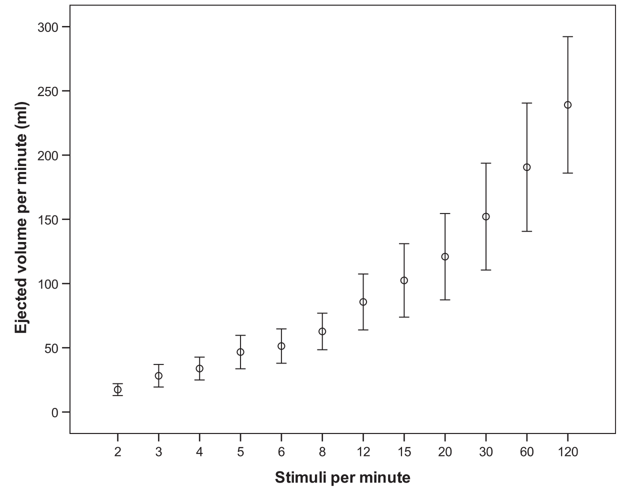

Figure 5 Ejected volume per minute (mean and 95% CI) at different rates of stimulation. Kruskal—Wallis test: $P < 0.001$.

individual stimulus decreased in a similar fashion (Fig. 4). There was a 19 fold higher ejected volume seen at 2 stimuli per minute compared to 120 stimuli per minute. However, with increasing rates of stimulation the ejected volume per minute increased 12 times from 20 ml/min to 240 ml/min (Fig. 5).

Male gender, increased calf circumference, high stimulus intensity, large popliteal cross-sectional area and increased age were associated with a higher PSV across all rates of stimulation (Table 1). However, only male gender, increased calf circumference, and a large popliteal cross-sectional area were associated with higher values of ejected volume per minute.

In a logistic regression analysis, only male gender, stimulus intensity, popliteal vein cross-sectional area and age greater than 50 were independently associated with PSV (Table 2). Using the same covariates only male gender, calf circumference and popliteal vein cross-sectional area were independently associated with ejected volume per minute (Table 3).

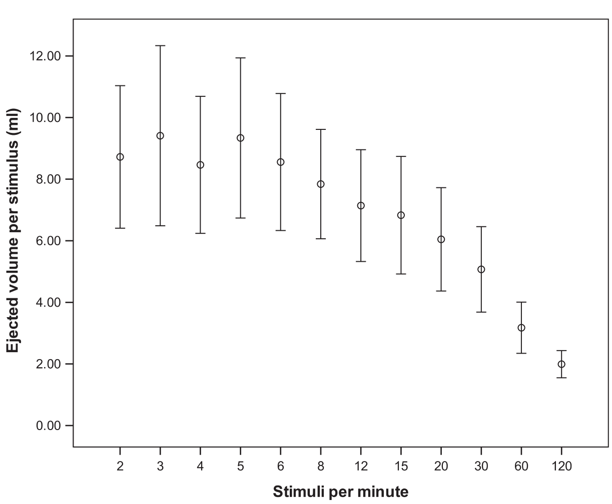

Figure 4 Ejected volume per stimulus (mean and 95% CI) at different rates of stimulation. Kruskal—Wallis test: $P < 0.001$.

Discussion

In this study on normal volunteers, we evaluated a calf muscle stimulator when using the maximum stimulus intensity that would produce a visible contraction of the calf muscles and can be tolerated comfortably by each individual. We demonstrated that this stimulus is effective in increasing both: peak velocity (PSV) and the total volume of flow in popliteal veins. It was noted that different rates of stimulation have a different effect on PSV and on volume flow. Low stimulation rates (from 2 to 8/min) are associated

Table 1 Median and (interquartile range) of peak systolic velocity (PSV) and median ejected volume per minute and (interquartile range) in subgroups of clinical features. Subgroups are created using median values. *P* value using Kruskal—Wallis test.

Feature	PSV(cm/s)	*P*	Ejected volume /min (ml)	*P*
Gender				
Female	50 (31; 84)		43 (23; 102)	
Male	88 (41; 137)	<0.001	100 (49; 194)	<0.001
Calf circumference (cm)				
<37	53 (32; 94)		48 (25; 104)	
≥37	82 (44; 126)	<0.001	102 (46; 194)	<0.001
Stimulus intensity				
<19	58 (35; 97)		67 (30; 140)	
≥19	75 (38; 126)	<0.044	65 (31; 142)	0.86
Popliteal vein cross-Sectional area (cm^2)				
<0.628	54 (32; 95)		45 (23; 104)	
≥0.628	81 (41; 124)	0.005	95 (45; 185)	<0.001
Age				
<39	65 (39; 134)		75 (33; 152)	
≥39	59 (36; 93)	0.012	60 (28; 121)	0.152

Table 2 Logistic regression with peak systolic velocity (PSV) < 70 or ≥ 70 cm/s (median) as the dependent variable and clinical features as covariates.

Feature	OR	95% CI	*P*
Gender (M/F)	2.01	1.21–3.35	0.007
Calf circumference (<37/≥37)	1.75	0.99–3.10	0.053
Stimulus intensity (<19/≥19)	3.06	1.77–5.29	<0.001
Popliteal vein cross-Sectional area (<0.628/≥0.628)	2.12	1.19–6.55	0.010
Age (<50/≥50)	3.54	1.92–6.55	<0.001

with high PSV and low total volume expelled per minute (TVF). In contrast, high stimulation rates are associated with lower PSV and higher TVF. This is probably due to the fact that at high stimulation rates; the interval between muscle contractions is too short to allow for venous refilling. The observation that PSV does not decrease until the rate of stimulation is greater than 8 per minute indicates that at least 7.5 s are required for the leg veins to refill in the semi-recumbent position. Higher rates of stimulation with shorter intervals between stimuli produce lower PSV but at the same time, substantially increase the TVF ejected from the calf per minute because of the higher number of muscle contractions. At the minimal rate of 2 contractions per minute the highest velocities were observed, yet during a period of 30 s between contractions, the blood stagnates. At the maximal rate of 120 contractions per minute the PSV was rather low, but the results showed a high total **TVF** ejected from the calf. In essence, the VEINOPLUS® Technology can provide either high velocities or high volumes. Therefore perhaps an optimal stimulus for DVT prevention might feature a rotation of different stimulation rates over a period of several minutes. This type of stimulation should provide a simultaneous combination of high velocities and high volumes of blood expelled.

It is not difficult to understand why men and individuals with bigger calfs and greater vein diameters have a higher PSV and higher volume flows. Perhaps future studies should normalise (adjust) velocity and volume measurements to calf circumference and popliteal vein cross-sectional area. Larger numbers are required to confirm the findings of the logistic regression analysis.

Based on the results of this study, this technology seems to have a number of potential applications not only for the prevention of DVT, for which more clinical studies should be encouraged. Reduction of edema, presumably by reducing venous pressure has already been demonstrated[8,9] and actions on the calf muscle pump could also improve venous hemodynamics in patients with chronic venous disease but this needs to be explored in more depth.

It must be remembered that this study has been conducted in a normal population and only in one position (semi-recumbent), so the results can hardly be extrapolated to patients with chronic venous disease or individuals in different life situations. We did not investigate the contribution of reactive hyperemia to the increased ejected volume at high rates of stimulation. Future studies to include popliteal artery flow measurements at different stimulation rates and in different positions are also needed. Such studies may involve the anaesthetized patient and there maybe concerns over the effect of diathermy on its application. However the VEINOPLUS electrode pads placed on the skin and connected to the device have a maximum current density below 0.1 mA/cm2 operating approximately 1000× less than quoted Standards. As it is a battery-powered it assures absolute isolation of the stimulating circuit from the ground and from the power lines of electrosurgical devices.

If efficacy of such a device in preventing DVT can be shown, the small size, its portability and most importantly simplicity of use may make this device an important therapeutic tool. Such assets could prove very useful in trying to improve the application and compliance[12–14] rates amongst a "patient" population thereby optimising thromboprophylaxis. Low application and compliance rates are often contributing factors to the reduced effectiveness of mechanical methods of prophylaxis.

In reference to one of the elements involved in Virchow's triad,[15] namely venous stasis, the VEINOPLUS® stimulation is an effective way of activating the calf muscle pump. The enhancements of popliteal blood velocity and volume flow, as shown by this study, are key factors in preventing venous stasis and such technology seems likely to become an additional method for prevention of venous thrombo-embolism.

Further studies are justified in order to determine the rates and configurations of stimulation, which would be applicable in the presence or absence of clinical factors and venous reflux, all of which influence calf pump output.

Table 3 Logistic regression with volume ejected per minute < 66 or ≥ 66 ml (median) as the dependent variable and clinical features as covariates.

Feature	OR	95% CI	P
Gender (M/F)	3.32	2.01–5.50	< 0.001
Calf circumference (<37/≥37)	1.88	1.07–3.30	0.028
Stimulus intensity (<19/≥19)	1.24	0.72–2.11	0.437
Popliteal vein cross-Sectional area (<0.628/≥0.628)	2.04	1.15–3.60	0.014
Age (<50/≥50)	1.66	0.91–3.03	0.100

Funding

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Conflict of Interest

No benefits in any form have been received or will be received from any commercial party relating to this article.

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Electrical calf muscle stimulation with Veinoplus device in postoperative venous thromboembolism prevention

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MANUFACTURER-SUPPORTED PEER-REVIEWED

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ELECTRICAL CALF MUSCLE STIMULATION WITH VEINOPLUS DEVICE IN POSTOPERATIVE VENOUS THROMBOEMBOLISM PREVENTION

Presented at: *European Venous Forum 2013 (Belgrade)*

Lobastov K.V.1, Barinov V.E.1, Boyarintsev V. et al.

Russian National Research Medical University named after N.I. Pirogov. Moscow, Russian Federation

Aim: The aim of this pilot study was to evaluate the potential effect of electrical calf muscle stimulation (EMS) in the prevention of postoperative deep vein thrombosis (DVT) in high risk patients and to assess efficacy and safety of EMS in patients with calf DVT.

Methods: This was a prospective non-randomized controlled study involving 80 patients over the age of 40 having major surgery (44 abdominal and 36 cranial or spinal surgery; duration more than 60 min under general anesthesia). Patients were divided into 2 comparable groups: main (N.=40) and control (N.=40). In both groups graduated middle stretch compression bandage with compression level 20-40 mmHg was applied and low dose unfractioned heparin (LDUH) injections (5000 U s.c. 3 t.i.d) were started on 1st or 2- 5th day after surgery and continued until discharge. The time of starting LDUH was comparable in both groups. In addition, electrical calf muscle stimulation (EMS) with Veinoplus device was performed for not less than 5 periods of 20 minutes per day (total >100 minutes) in the main group. Control of venous patency was performed with duplex ultrasound obligatory at baseline (first 24 h after surgery) and then every 3 days until discharge.

Results: The incidence of DVT was 2.5% in the main group and 25% in the control group (P=0.007). In patients without DVT at baseline it was 3% versus 21% (P=0.025). Patients with baseline thrombosis who underwent EMS did not have any new cases of DVT and PE, while in patients without EMS thrombosis progression was observed in 43% cases also without pulmonary embolism (not significant).

Conclusion:

EMS with Veinoplus device at >100 min per day (>5 sessions) can decrease the rate of postoperative DVT in high risk patients. Using of EMS in patients with calf DVT does not increase the rate of PE. These findings need to be confirmed in a randomized controlled trial.

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Efficacy of electrical muscle stimulation in the treatment of patients with shin bone fractures

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EFFICACY OF ELECTRICAL MUSCLE STIMULATION IN THE TREATMENT OF PATIENTS WITH SHIN BONE FRACTURES

V.N. Obolenskiy, A.V. Karpenko

SBHI City Hospital of Moscow Healthcare Department,
Russian National Research Medical University named Moscow, Russian Federation
Russian University of Friendship of Peoples, Moscow, Russian Federation

A prospective, randomized, controlled study was undertaken with the aim to evaluate the efficacy of calf electrical muscle stimulation (EMS) in the prevention of venous thromboembolism events (VTE) and reduction of treatment and rehabilitation times in patients with shin bone fractures. The authors analyzed the incidence of VTE, treatment and rehabilitation times, and changes in quality of life as assessed with the SF-36 questionnaire; they conclude that EMS is a valuable choice for recently hospitalized traumatology patients.