

VEINOPUS®

We stimulate your life



BOOK OF ABSTRACTS



VENOUS STUDIES	2
• Electrical muscle stimulation with veinoplus device in the treatment of venous ulcers.....	3
• Electro- muscular stimulation with Veinoplus for the treatment of chronic venous edema.....	4
• Efficacy and optimal use of a portable electrical muscle stimulator (Veinoplus) to improve symptoms of post-thrombotic syndrome.....	5
• Effects of electrostimulation (Veinoplus) on lower limbs venous insufficiency-related symptoms during pregnancy. preliminary study.....	6
• Users of Veinoplus: ad rem technology survey on symptoms, behaviour and satisfaction (2009).....	7
• Electric pulse muscle stimulation in treatment of low physical activity patients with venous stasis ulcers.....	8
• Chronic (50 years) venous ulcer healing by electrostimulation.....	9
• Activation of the calf muscle pump action by electro-stimulation with Veinoplus device.....	10
• Electrical calf muscle stimulation prevents recurrent DVT after cessation of standard anticoagulation in patients with residual venous obstruction.....	11
• Electrical calf muscle stimulation increases deep vein recanalization and reduces the incidence of recurrent deep vein thrombosis in patients with post-thrombotique syndrome and residual venous obstruction after completed 6 month of anticoagulation therapy.....	12
ARTERIAL STUDIES	14
• 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.....	15
• Extensive lower limb ulceration caused by Iatrogenic Arteriovenous fistula and Peripheral arterial disease: use of Veinoplus calf muscle stimulation.....	16
• Electric pulse calf muscle stimulation in treatment of patients with diabetic foot syndrome.....	18
• Electropulse Muscle Toning by the Veinoplus device as a Part of Combination Treatment of Patients with Obliterating Atherosclerosis of Lower Limbs Arteries.....	19
• Lower limb ulcer case report with severe arterial and chronic venous disease treated with a combination of electrostimulation (Veinoplus) and prostaglandins.....	20
• The use of transcutaneous electrical stimulation of the calf in patients undergoing infrainguinal bypass surgery.....	21
• Acute effects of calf neuromuscular electrostimulation (Veinoplus arterial) on the microcirculation in patients with peripheric arterial disease at the stage of permanent ischemia.....	22
• The Effectiveness of Calf Muscle Electrostimulation on Vascular Perfusion and Walking Capacity in Patients Living With Type 2 Diabetes Mellitus and Peripheral Artery Disease.....	24
DVT STUDIES	27
• The efficacy of a new stimulation technology to increase venous flow and prevent venous stasis.....	28
• Electrical calf muscle stimulation with veinoplus device in postoperative venous thromboembolism prevention.....	29
• Efficacy of electrical muscle stimulation in the treatment of patients with shin bone fractures.....	30
SPORTS STUDIES	31
• Recovery After High-Intensity Intermittent Exercise in Elite Soccer Players Using Veinoplus Sport Technology for Blood-Flow Stimulation.....	32
• Positive effects of low-frequency electrical stimulation during short-term recovery on subsequent high intensity exercise.....	33
• Influence of post-exercise limb blood flow stimulation on performance recovery.....	34
• Low-frequency electrical stimulation combined with a cooling vest improves recovery of elite kayakers following a simulated 1000-m race in a hot environment.....	35
• The effects of a calf pump device on second half performance of a simulated soccer match in competitive youth players S. béliard, J. Cassirame, G. Ennequin, G. Coratella and N. Tordi.....	36
BACK STUDIES	37
• 2018 Veinoplus Back users survey.....	38



VENOUS STUDIES

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

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

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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.

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

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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 supramalleolar 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.

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

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

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Introduction

An estimated 330,000 people in the United States have postthrombotic syndrome (PTS)¹. Few studies have addressed the treatment of PTS^{2,3}. A 2003 Cochrane Review examined available data regarding treatment of PTS with compression stockings or mechanical devices (intermittent pneumatic compression units)². The authors report that there may be some benefit to the mechanical device at higher pressures in treating PTS though the trial was 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 PTS⁴. 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.

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 Wilcoxon Rank Sum test was used to compare intensity levels.

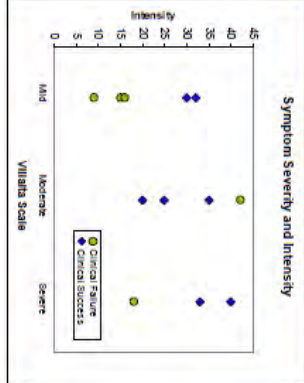
Results

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.



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).



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®.

Future 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

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Objectives

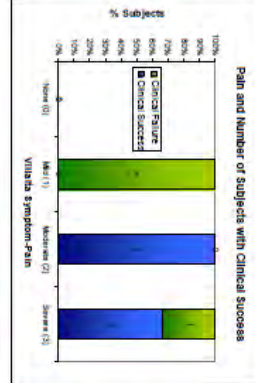
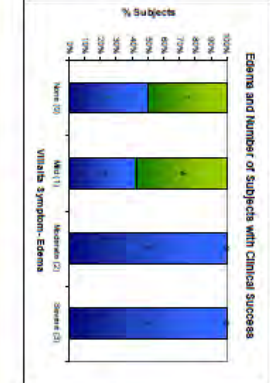
1. Estimate the 'clinical success' of the device, defined by moderate improvement of symptoms, and an interest to continue using the device.
2. Estimate improvement in quality of life and objective findings of postthrombotic syndrome (Villalta scale).
3. Estimate the optimal electrical stimulation intensity 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 Veinoplus device 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

Subject ID	Villalta Score		VEINES-SYM/QOL Questionnaire		Change	
	Before	After	Before	After		
1	no	9	50.25	57.05	6.74	
2	no	9	57.45	67.19	9.74	
3	yes	22	45.75	50.23	4.47	
4	no	14	49.55	62.01	12.35	
5	no	9	51.42	42.5	-8.92	
6	yes	14	54.1	42.13	-11.97	
7	yes	14	51.11	32.74	18.37	
8	yes	10	49.25	54.87	5.61	
9	yes	17	35.95	47.79	11.84	
10	no	15	42.45	45.21	2.76	
11	yes	5	47.25	71.37	24.12	
12	yes	12	47.21	53.9	6.69	
Median		12.58	11.17	45.92	53.08	6.16



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

Also presented at the European Venous Forum, Istanbul 2006

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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.

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.

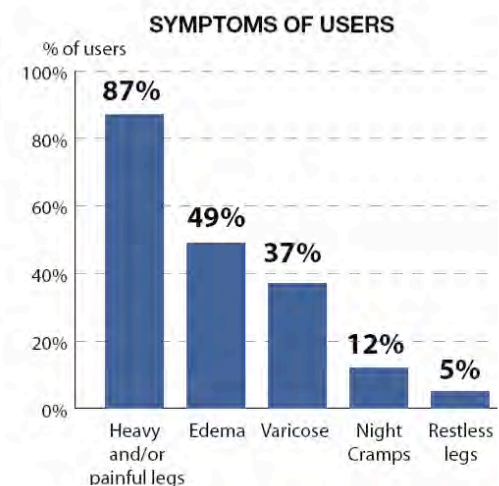


Fig. 1

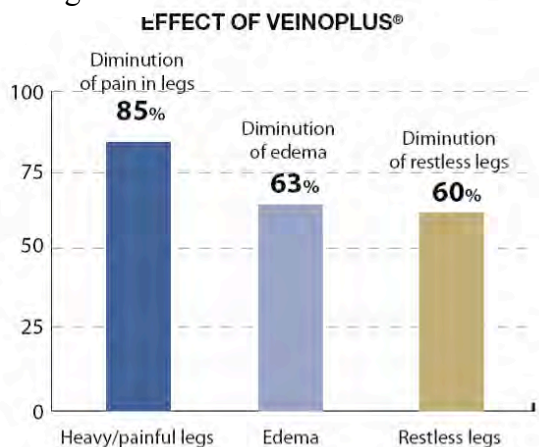


Fig. 2

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

ELECTRIC PULSE MUSCLE STIMULATION IN TREATMENT OF LOW PHYSICAL ACTIVITY PATIENTS WITH VENOUS STASIS ULCERS
Presented at European Wound Management Association Conference, Vienna 2012

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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 method 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, Varolast®, Putterbinde®, made in Germany

CHRONIC (50 YEARS) VENOUS ULCER HEALING BY ELECTROSTIMULATION

Also presented at: American Venous Forum, San Diego 2007

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3 : Institute of Medical Technology, C.P.17, CH-1937 Orsières, Switzerland.

Patient M.G. born in 1935, in January 1953 was diagnosed with thrombosis of deep veins in the right leg. Bedridden for two months and treated with heparin and anti-vitamin K, developed thrombosis 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.

Photo 1: 3 months after start of VeinOplus



Photo 2: 6 months after start of VeinOplus



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

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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[®] physiopathological effects on the reflux. Then each patient filled out a QOL CIVIQ-2 questionnaire. The patients used the VeinoPlusT[®] 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.



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

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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.

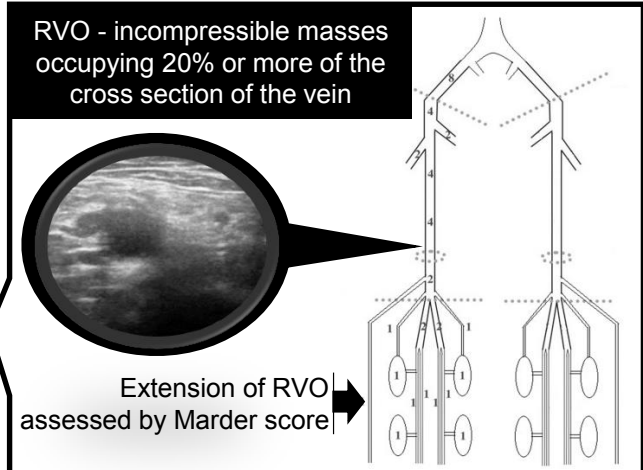
The primary endpoint: symptomatic or asymptomatic recurrent DVT confirmed by duplex ultrasound (DUS).

The secondary endpoint: changes in the degree of RVO.

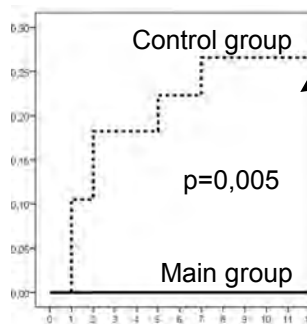
Follow up: 12 months with monthly DUS, aimed to reveal recurrent DVT, and 6-monthly DUS with evaluation of stenosis degree.

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	100,0	100,0	-
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



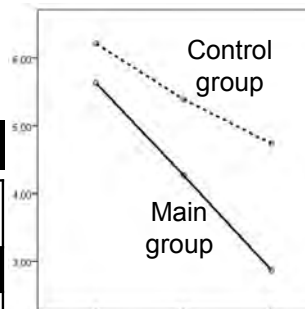
Cumulative incidence of DVT recurrence at 12m



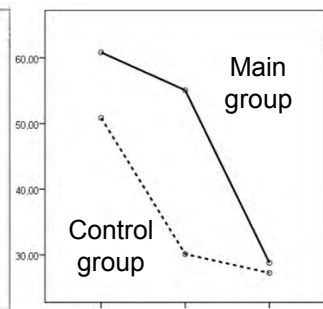
EMS vs controls:
0% (95% CI: 0-11,4%)
vs
23,3% (95% CI: 11,8-40,9%)

5 of 7 recurrent DVT - asymptomatic

Trends in Marder score



Trends in popliteal RVO



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.

Electrical calf muscle stimulation increases deep vein recanalization and reduces the incidence of recurrent deep vein thrombosis in patients with post-thrombotic syndrome and residual venous obstruction after completed 6 month of anticoagulation therapy

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Ilya SCHASTLIVTSEV, Victor BARINOV, Leonid LABERKO, Grigory RODOMAN

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ABSTRACT

BACKGROUND: the aim of this study was to assess the impact of electrical calf muscle stimulation (EMS) on clinical and ultrasound outcomes in patients with post-thrombotic syndrome (PTS) and residual venous obstruction (RVO).

METHODS: This was a prospective, comparative, non-randomized clinical trial involving patients who had completed a standard 6-month course of anticoagulation therapy for a first episode of unprovoked femoro-popliteal DVT and had signs of RVO in the affected veins and PTS as shown by a Villalta score of >5. A blinded outcome assessor performed the ultrasound evaluations.

A total of 60 patients in the age range from 40 to 86 years (mean 58.5±11.4) consisting of 38 men and 22 women were enrolled. They were divided into two groups of 30 participants each. Both groups (experimental and control) were treated by active walking, below-knee

graduated compression stockings, and micronized purified flavonoid fraction. In the experimental group, EMS with «Veinoplus VI» device (three applications for 30 min every day) was also used. The patients were followed for 12 months with monthly DUS to reveal recurrent DVT and changes in RVO. The clinical criteria for treatment efficacy included changes in Villalta, VCSS and CIVIQ-20 scores.

RESULTS: Recurrent DVT was found in seven of 30 patients in the control group and in zero of 30 patients in the experimental group (23.3% versus 0%, $p=0.01$). Through the follow-up period the degree of RVO decreased in all affected veins in both groups ($p < 0.01$). The most significant changes were found in the popliteal vein; 60.8% decreased to 28.8% in the experimental group and 50.9% to 27.3% in the control group ($p < 0.01$) with significant differences between the groups ($p < 0.01$). VCSS, Villalta and CIVIQ-20 scores also significantly decreased in both groups ($p < 0.01$). In the group with EMS, changes in the current parameters were more intensive ($p < 0.01$).

CONCLUSIONS: There is an ongoing process of deep vein recanalization during the 12 months after anticoagulant therapy cessation. Use of EMS in PTS treatment allows for reduction of recurrent DVT rates, increase the speed of deep vein recanalization and leads to additional improvement in the clinical PTS outcomes.

Keywords: postthrombotic syndrome, electrical calf muscle stimulation, vein recanalization, treatment, prophylaxis

ARTERIAL STUDIES

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.

Presented at XXV World Congress of the International Union of Angiology 2012

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3 : Institut National du Sport et de Education Physique; Paris
4 : Laboratoire de physiologie, 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 20minutes at increasing contraction rates at 5-minute steps of 60, 75, 86, and 100bpm 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 (O₂Hb) 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 60bpm, 127 [91/207] vs 49 [43/68] (P < .01) at 75bpm, 140 [84/200] vs 57 [45/71] (P < .01) at 86bpm, and 154 [86/185] vs 55 [46/94] (P < .01) at 100bpm on the stimulated vs nonstimulated limb, respectively. No apparent decrease or significant leg difference was observed in DROP index or O₂Hb 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.

KEY WORDS: Transcutaneous oxygen pressure, Claudication, Arterial disease, Near infra-red spectroscopy, NIRS, Electrical muscle stimulation, EMS.

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

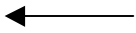
By Prof. K. Cassar,
Mater Dei Hospital, La Valette, Malta

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 4: Right leg and foot 20 days after surgical intervention



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



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



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

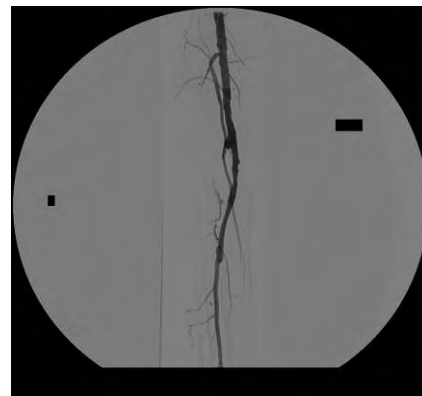
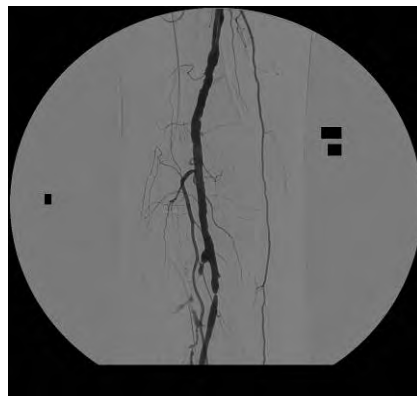


Fig 6: Right popliteal to peroneal vein bypass graft before and after angioplasty of graft stenosis

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

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

Bulad Leval¹, Vladimir Obolenskiy¹, Vyacheslav Nikitin².

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.

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 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.

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. Nicolaidis, 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)

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 ($P = 0.025$ and $P = 0.043$, respectively). Venous flow volumes at rest and on stimulation were higher in the study group ($P = 0.010$ and $P = 0.029$, respectively). At 6 weeks, the below knee girth and amount of pitting edema were less in the study group ($P = 0.011$ and $P = 0.014$, 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.



Acute effects of calf neuromuscular electrostimulation (Veinoplus Arterial®) on the microcirculation in patients with peripheral arterial disease at the stage of permanent ischemia

THOMAS H¹., TERRIAT B²., BELIARD S³.

Peripheral arterial disease and calf neuromuscular electrostimulation

- **Acute effects :**
 - Increased arterial inflow
 - Increased venous outflow
- **Chronic effects :**
 - Increased walking distance without pain
 - Increased ABI

Pilot Study

- **Prospective, mono-centric study**
- **N=6 (average age = 74,3 ± 10,7)**
- **Criteria for inclusion: patients with chronic permanent ischemia**
 - $TCPO_2^4 < 35$ mm Hg
 - Toe Pressure ⁵< 50 mm Hg

Study design



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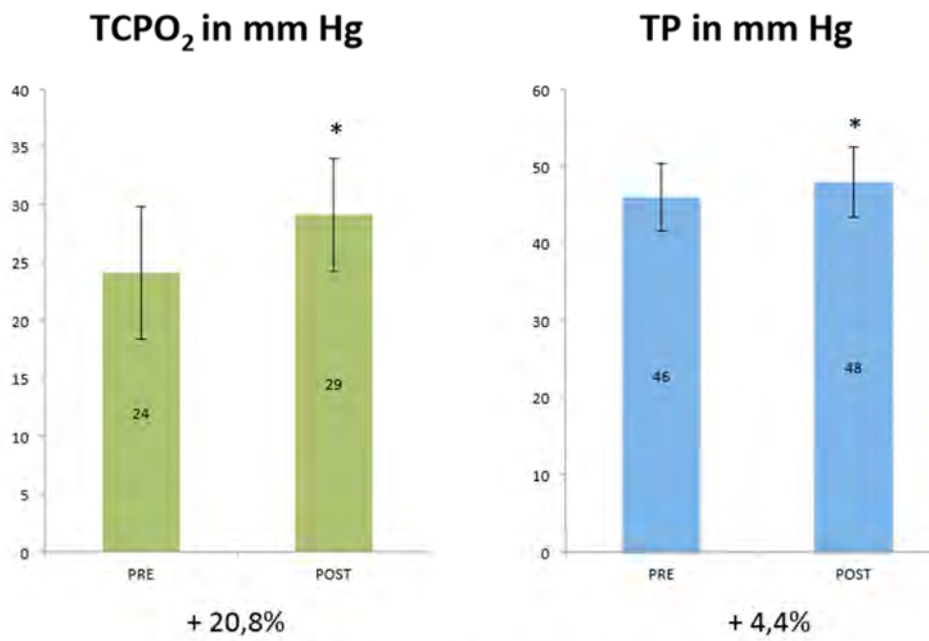
³ PEPITE EA4267, Exercice Performance Santé Innovation (EPSI), Université Bourgogne Franche-Comté, 25000 Besançon, France.

⁴ TCPO₂ 20 min after

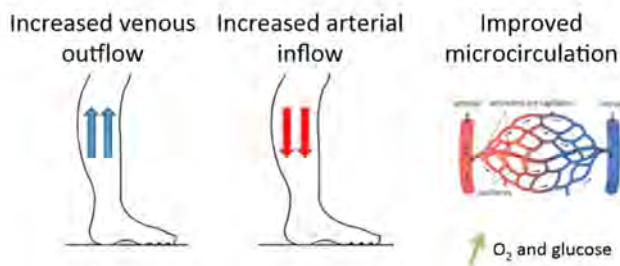
⁵ TP : 5 min after



Results



Physiological hypothesis




Arterio-venous continuum

CONCLUSION

- Good tolerance, easy to use
- Improved perfusion
- Arterio-venous pressure gradient
- Chronic muscle / vascular effects

The Effectiveness of Calf Muscle Electrostimulation on Vascular Perfusion and Walking Capacity in Patients Living With Type 2 Diabetes Mellitus and Peripheral Artery Disease

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Extremity Wounds
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Christian Ellul, MSc¹, Cynthia Formosa, PhD¹, Alfred Gatt, PhD¹, Auon Abbas Hamadani, MD², and David G. Armstrong, DPM, MD, PhD²

Abstract The aim of the study was to explore calf muscle electrostimulation on arterial inflow and walking capacity in claudicants with peripheral artery disease and diabetes mellitus. A prospective, 1-group, pretest-posttest study design was used on 40 high-risk participants (n = 40) who exhibited bilateral limb ischemia (ankle brachial pressure index [ABPI] <0.90), diabetes mellitus, and calf muscle claudication. A program of calf muscle electrical stimulation with varying frequency (1-250 Hz) was prescribed for 1 hour per day for 12 weeks. Spectral waveforms analysis, ABPI, absolute claudication distance (ACD), and thermographic temperature patterns across 4 specified regions of interest (hallux, medial forefoot, lateral forefoot, heel) at rest and after exercise, were recorded at baseline and following intervention to evaluate for therapeutic outcomes. A significant improvement in ACD and ABPI was registered following the intervention (P = .000 and P = .001, respectively). Resting foot temperatures increased significantly (P = .000) while the post exercise temperature drops were halved across all regions at follow-up, with hallux (P = .005) and lateral forefoot (P = .038) reaching statistical significance. Spectral Doppler waveforms were comparable (P = .304) between both serial assessments. Electrical stimulation of varying frequency for 1 hour per day for 12 consecutive weeks registered statistically significant improvement in outcome measures that assess arterial inflow and walking capacity in claudicants with diabetes mellitus. These results favor the use of electrostimulation as a therapeutic measure in this high-risk population.

Keywords electrical stimulation, diabetes mellitus, peripheral artery disease, intermittent claudication

Exercise has been the cornerstone of noninvasive management of peripheral arterial disease (PAD) for the past 40 years¹. Indeed, several collaborative authorities, including the Trans-Atlantic Inter-Society Consensus (TASC) II

PAD management working group², the American Heart Association/American College of Cardiology,³ and the Society of Vascular Surgery,¹ recommend exercise as a first-line therapy in claudicants. Despite the known efficacy of exercise in patients living with PAD, not all patients can follow a prescribed exercise regime. A number of physical and psychosocial factors may preclude adherence of patients to any form of exercise program.¹ Comorbid conditions like osteoarthritis, musculoskeletal problems, foot/limb pain, foot ulcers, and other factors like bad weather, age, and lack of motivation may all discourage any form of cardiovascular exercise.⁴ Another significant

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barrier to exercise is intermittent claudication, which is experienced by 25% to 35% of patients with PAD.

Furthermore, in the context of diabetes, a cross-sectional study⁵ on a multigender cohort of 460 patients with PAD (147 with diabetes) aged 55 years and older with medical histories consistent of PAD (ankle brachial pressure index [ABPI] <0.90) demonstrated that patients with diabetes and PAD have poorer lower extremity functions than patients presenting with PAD only. All these factors preclude adherence to exercise therapy creating a lacuna for the effective management of this vulnerable population. In this context, electrical stimulation (ES) targeted on ischemic muscles has been proposed as a potential passive alternative to exercise training. However, to date, only a few studies have evaluated the sustained effectiveness of this therapeutic modality on patients living with diabetes and PAD.^{6,7} Moreover, those studies that provide evidence on the effects of intermittent ES have been conducted on laboratory ischemic animal models⁸⁻¹¹ while those including PAD patients had methodological limitations, including poor sample sizes, fixed low frequency of stimulation, and short duration of intervention.^{6,7} Therefore, the aim of this study was to explore the efficacy of longer term variable frequency (1-250 Hz) calf muscle ES on arterial inflow and walking capacity in claudicants with PAD and diabetes mellitus.

Results

Out of a total of 71 prospective participants, 40 participants (30 males; 10 females) with a mean age of 70.83 years (SD 7); mean body mass index 28.88 kg/m² (SD 3.7); mean diabetes duration 15 years (SD 6); mean HbA1c 8.2% (SD 1.56) (66 mmol/mol), were included in the study. Thirty-one participants were excluded during screening due to elevated ABPI readings or because they did not reach claudication distance within the maximal walking distance or timeframe stipulated in the protocol. The Veinoplus Arterial device (Ad Rem Technologies, France) was used for a consecutive mean duration of 91.68 days (SD 6.23) as quantified through the patient log-sheets. Seventy-five percent of participants were on aspirin, 10% on clopidogrel, and 22.5% on dipyridamole.

Arterial Flow

The ABPIs of 80 limbs were recorded with each limb scored separately for each participant at baseline (mean 0.702, SD 0.12) and follow-up (0.743, SD 0.16). Following intervention, a statistically significant increase in ABPI was detected (paired sample t test, $P = .001$; 95% CI, 0.02-0.07). Figure 2 presents the mean baseline and follow-up ABPI scores. Qualitative spectral waveforms of the posterior tibial and dorsalis pedis arteries of both limbs ($N = 80$) were also evaluated. Table 1 illustrates the waveform classification for each artery. Spectral waveform changes at follow-up relative to baseline are comparable (McNemar test, posterior tibial, $P = .304$; dorsalis pedis, $P = .117$).

Walking Capacity

The mean ACD at baseline was 333.71 m (SD, 208.44), which increased to 470.73 m (SD, 278.75) at 12-week follow-up. This translated to a mean walking capacity that was 41% better at follow-up relative to baseline. This mean improvement (137 m, SD = 136) in ACD was found to be statistically significant (Wilcoxon signed rank test, $P = .000$). The post hoc power analysis of the ABPI and ACD result was 90% and 94%, respectively, exceeding the minimum level of power required of 80%.

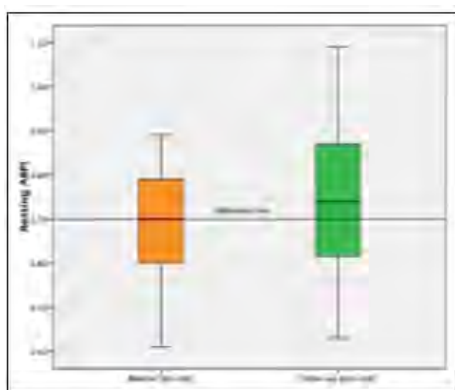


Figure 2. Baseline versus follow-up resting ankle brachial pressure index (ABPI) with means (N = 80). Reference lines indicate baseline and follow-up means.

Table 1. Comparison of Spectral Doppler Waveforms at Preintervention and Postintervention.

Anatomical Artery	Waveform Type	Baseline n (% Frequency)	Follow-up n (% Frequency)
Posterior tibial	Monophasic continuous	15 (18.8)	16 (20)
	Monophasic	60 (75)	59 (73.8)
	Biphasic	5 (6.3)	5 (6.3)
Dorsalis pedis	Monophasic continuous	26 (32.5)	24 (30)
	Monophasic	49 (61.3)	52 (65)
	Biphasic	5 (6.3)	4 (5.1)

Resting Temperature and Post exercise Temperature Change

The resting temperatures and eTC derived from the regions of interest at baseline and follow-up are presented in Table 2. In both measures, the mean resting temperature was lowest in the hallux ROI and highest in the medial forefoot ROI; however, these differences were not found to be statistically significant (baseline, $P = .451$; follow-up, $P = .259$, one-way analysis of variance).

Table 2. Comparison of Infrared Thermal Temperatures at Baseline and at 12 Weeks Following Intervention.

Description	Region of Interest	Baseline (N = 80), °C		Follow-up (N = 80), °C	
		Mean	SD	Mean	SD
Resting temperatures	Hallux	27.71	3.19	30.14 ^a	2.45
	Medial	28.38	2.59	30.74 ^a	2.07
	Lateral	28.19	2.58	30.66 ^a	2.04
	Heel	28.06	2.21	30.43 ^a	1.75
Exercise temperature change (eTC)	Hallux	-0.82	1.35	-0.41 ^a	1.22
	Medial	-0.50	1.38	-0.25	1.16
	Lateral	-0.57	1.42	-0.29 ^a	1.08
	Heel	-0.30	1.26	-0.11	1.05

^a $P < .05$, relative to baseline.

At the follow-up, a statistically significant increase (paired-sample t test) in resting temperature of around 2°C was recorded across all ROIs for the hallux ($P = .000$, 95% CI, 1.86-2.99), medial ($P = .000$, 95% CI = 1.89-2.84), lateral ($P = .000$, 95% CI, 2.00-2.95), and heel ROI ($P = .000$, 95% CI 1.93-2.82). Following exercise, drops in temperatures were registered across all ROIs at both baseline and follow-up as presented in Table 2. The reduction in temperature drops following the 12-week intervention was approximately halved in all regions and found to be statistically significant in the hallux ($P = .005$, 95% CI, -0.10 to -0.72) and lateral forefoot ($P = .038$, 95% CI, 0.03 to -0.58) ROI. In the medial ($P = .063$, 95% CI, 0.07 to -0.56) and heel ($P = .091$, 95% CI, 0.09 to -0.47), no statistical significance was found

DVT STUDIES

**THE EFFICACY OF A NEW STIMULATION TECHNOLOGY TO INCREASE
VENOUS FLOW AND PREVENT VENOUS STASIS**

Also presented at American Venous Forum, Amelia Island 2010

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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 calves 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.

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

Presented at European Venous Forum 2013 (Belgrade)

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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 unfractionated 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.

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

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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.

SPORTS STUDIES

RECOVERY AFTER HIGH-INTENSITY INTERMITTENT EXERCISE IN ELITE SOCCER PLAYERS USING VEINOPLUS SPORT TECHNOLOGY FOR BLOOD-FLOW STIMULATION

Also presented at: XXIXth National Congress of French Sports Medicine Society, Biarritz 2009

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Context: Electric muscle stimulation has been suggested to enhance recovery after exhaustive exercise by inducing an increase in blood flow to the stimulated area. Previous studies have failed to support this hypothesis. We hypothesized that the lack of effect shown in previous studies could be attributed to the technique or device used.

Objective: To investigate the effectiveness of a recovery intervention using an electric blood-flow stimulator on anaerobic performance and muscle damage in professional soccer players after intermittent, exhaustive exercise.

Design: Randomized controlled clinical trial. Setting: National Institute of Sport, Expertise, and Performance (INSEP).

Patients or Other Participants: Twenty-six healthy professional male soccer players.

Intervention(s): The athletes performed an intermittent fatiguing exercise followed by a 1-hour recovery period, either passive or using an electric blood-flow stimulator (VEINOPLUS).

Participants were randomly assigned to a group before the experiment started.

Main Outcome Measures(s): Performances during a 30-second all-out exercise test, maximal vertical countermovement jump, and maximal voluntary contraction of the knee extensor muscles were measured at rest, immediately after the exercise, and 1 hour and 24 hours later. Muscle enzymes indicating muscle damage (creatine kinase, lactate dehydrogenase) and hematologic profiles were analyzed before and 1 hour and 24 hours after the intermittent fatigue exercise.

Results:

The electric-stimulation group had better 30-second all-out performances at 1 hour after exercise ($P = .03$) in comparison with the passive-recovery group. However, no differences were observed in muscle damage markers, maximal vertical countermovement jump, or maximal voluntary contraction between groups ($P = .05$).

Conclusions: Compared with passive recovery, electric stimulation using this blood-flow stimulator improved anaerobic performance at 1 hour postintervention. No changes in muscle damage markers or maximal voluntary contraction were detected. These responses may be considered beneficial for athletes engaged in sports with successive rounds interspersed with short, passive recovery periods.

Key Words: quadriceps muscle, fatigue, athletes

POSITIVE EFFECTS OF LOW-FREQUENCY ELECTRICAL STIMULATION DURING SHORT-TERM RECOVERY ON SUBSEQUENT HIGH INTENSITY EXERCISE

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Purpose:

The aim of this study was to compare the effectiveness of blood flow stimulation (BFSTIM) with VEINOPLUS© device to active and passive recovery methods during a short-term recovery period between two exhausting exercises of short duration.

Methods:

Fourteen highly trained female handball players completed two successive ‘Yo-Yo intermittent recovery’ tests (level 2; YYIR2) elapsed by a 15 min recovery period during which they used one of the three recovery modalities presented in a random order (Active, BFSTIM or Passive). Performances (i.e. distance achieved) were measured at the end of each YYIR2 test. Blood lactate, pH and bicarbonates ions concentrations were measured or calculated before and immediately after the first YYIR2 test and every three minutes during the recovery. Heart rate, respiratory gas exchange and tissue saturation index (%TSI) of the lateral gastrocnemius were continuously recorded during the recovery phase.

Results:

In comparison to passive recovery, we observed a beneficial effect with BFSTIM (+13.0% ± 7.8%; ± 90% confidence limits) and a “possible” beneficial effect with active recovery (+4.0% ± 9.0%) on performance during the second YYIR2. BFSTIM and active recoveries versus passive recovery clearly showed a significantly faster return to baseline value of blood lactate, pH and bicarbonates ions concentrations during the recovery period ($P < .05$). Whereas %TSI was continuously lower, heart rate and oxygen uptake were higher with active recovery in comparison to the two others modalities.

Conclusion:

The results suggested that blood flow stimulation with VEINOPLUS© and, to a lesser extent, active recovery are effective interventions to improve recovery during short time periods and could be useful during half-time.

INFLUENCE OF POST-EXERCISE LIMB BLOOD FLOW STIMULATION ON PERFORMANCE RECOVERY

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Introduction: Elite sport requires athletes to complete multiple bouts of high-intensity exercise with limited rest periods that are not sufficient for full recovery. To facilitate the performance recovery, recovery therapies like active,¹ immersion² or neuroelectromyostimulation³ (NEMS) have achieved very good results. It has been hypothesized that the increase of blood flow with these strategies could accelerate the supply of oxygen rich blood, increase the flush of waste products and help reduce H⁺ levels associated with lactic acid build-up. Consequently, the assumption of a strong relationship between blood flow and high intensity performance recovery is often cited although never tested. Therefore, the aim of this study was to test this hypothesis by stimulating the blood flow at three different levels during a 30-min recovery intervention period between two sessions of multiple sprint interval (three 30-s WanT) exercise.

Methods : Thirty-seven trained athletes participated in a randomized controlled trial. Each session consisted of performing 3 x 30 WanT (bouts 1–3) followed by a randomly assigned 30-min recovery intervention of either: high blood flow (Veinoplus Sport®)(HBF), low blood flow (Cefar-Compex Theta 500®)(LBF); sham NEMS device (SHAM; that does not stimulate the blood flow) and passive recovery (PAS). A 30-s WanT was then repeated (bouts 4) and compared to bout 1 for peak power and mean power. Measures of blood flow, blood lactate and heart rate were recorded every 3 min throughout the recovery intervention period to monitor physiological responses.

Results: Blood flow was significantly higher in HBF group compared to PAS, SHAM and LBF groups. Examination of heart rate and blood lactate revealed no recovery effect. The recovery of mean power was likely beneficial in the HBF group compared with the SHAM group and very likely beneficial compared with the PAS group and the LBF group. The recovery of peak power in the HBF group was likely beneficial and very likely beneficial compared with the LBF group and the PAS group, respectively.

Conclusion: Stimulate total blood flow at a high velocity is a mean of preserving performance when repeating acute exhausting exercise interspaced by short recovery period. However this positive effect is not accompanied by a greater lactate removal.

Key words: Recovery, Blood flow, NEMS

LOW-FREQUENCY ELECTRICAL STIMULATION COMBINED WITH A COOLING VEST IMPROVES RECOVERY OF ELITE KAYAKERS FOLLOWING A SIMULATED 1000-M RACE IN A HOT ENVIRONMENT

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This study compared the effects of a low-frequency electrical stimulation (LFES; Veinoplus® Sport, Ad Rem Technology, Paris, France), a low-frequency electrical stimulation combined with a cooling vest (LFESCR) and an active recovery combined with a cooling vest (ACTCR) as recovery strategies on performance (racing time and pacing strategies), physiologic and perceptual responses between two sprint kayak simulated races, in a hot environment (~32 wet-bulb-globe temperature). Eight elite male kayakers performed two successive 1000-m kayak time trials (TT1 and TT2), separated by a short-term recovery period, including a 30-min of the respective recovery intervention protocol, in a randomized crossover design. Racing time, power output, and stroke rate were recorded for each time trial. Blood lactate concentration, pH, core, skin and body temperatures were measured before and after both TT1 and TT2 and at mid- and post-recovery intervention. Perceptual ratings of thermal sensation were also collected. LFESCR was associated with a very likely effect in performance restoration compared with ACTCR (99/0/1%) and LFES conditions (98/0/2%). LFESCR induced a significant decrease in body temperature and thermal sensation at post-recovery intervention, which is not observed in ACTCR condition.

Conclusion: the combination of LFES and wearing a cooling vest (LFESCR) improves performance restoration between two 1000-m kayak time trials achieved by elite athletes, in the heat.



The effects of a calf pump device on second half performance of a simulated soccer match in competitive youth players S. Béliard, J. Cassirame, G. Ennequin, G. Coratella and N. Tordi

ARTICLE HISTORY

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ABSTRACT

During soccer matches, performance decrements have been reported that relate to both physical abilities and technical skills. To investigate the effects of low-frequency electrical stimulation LFES (VeinoplusSport®, Ad Rem Technology, France) administered during half-time recovery on performance alterations during the second half. Twenty-two highly trained young players undertook a soccer-match simulation (SAFT⁹⁰). During half-time, they were randomly assigned to LFES group or Placebo group. Each half was split into 3 bouts of 12 minutes. Following each bout, maximal strike speed (MSS), sprint test (ST), maximal sprint accelerations (MA) and metabolic power (MP) were determined in both groups. Arterial (AF) and venous flows (VF) were measured at rest and at the end of half-time. LFES group exhibited beneficial effects on performance compared to the Placebo group with a likely effect for MSS, ST, MA, and a possible effect for MP. AF and VF increased statistically more in LFES group compared to Placebo group. The use of specific calf-pump LFES during half-time of a youth simulated soccer match attenuated the decrease in performance during the second half compared to Placebo group. This effect is most marked at the beginning of the second half with regards to explosive parameters.

Conclusions and practical applications

The use of calf LFES during half-time in youth soccer players during a simulated soccer match attenuates the reduction in performance within the second half. This effect is mainly apparent at the beginning of the second period in relation to explosive tasks such as sprinting capabilities, strike or metabolic power. We emphasized that these kinds of capabilities are very important for soccer players because they can lead to a difference in performance over an opponent and may improve chances of scoring. Given at the elite level teams are well matched and scoring chances are limited any small

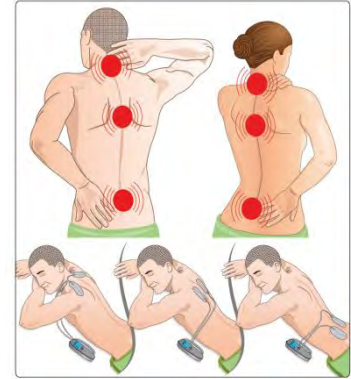
advantage through more thorough recovery during half-time period may be important. The present study was design as close as possible to a youth soccer match. Our investigation highlighted benefits of calf LFES. In order to use this recovery method during competition, we recommend familiarity with this process to create routines that avoid time loss and permit recover whilst also managing tactical feedback provided by coaches.

BACK STUDIES

2018 VEINOPLUS BACK Survey

Main criterias and results :

- 94% of pain relief feeling
- 96% of product satisfaction
- 96% of positive recommandation



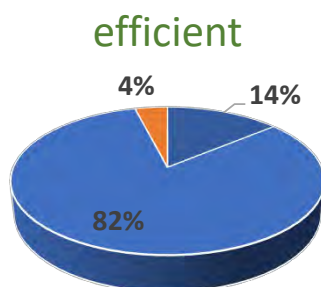
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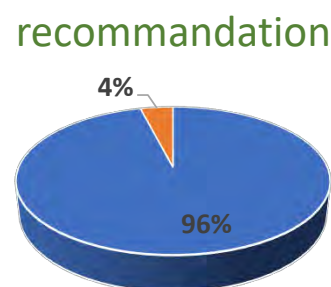
■ very Satisfied ■ Satisfied ■ not Satisfied



■ YES ■ NO



■ very effective ■ effective ■ not effective



■ YES ■ NO

VEINOPLUS® back

Independent Usage survey made on 50 people in Hong Kong in 2018. 50 Veinoplus Back users, 29 Women / 21 men. 86% of the users have tried the product over 3 months. 50% of the users were between 40 & 60 years old / 32% over 60.

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