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VENOUS STUDIES
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 (VENOPLUS) to Improve Symptoms of Post-Thrombotic Syndrome

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University of North Carolina School of Medicine

Introduction

Objectives

Design & Methods

Results

Conclusion

References
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.
OBJECTIVES OF VEINOPLUS® USERS: 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).
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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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 heparine and anti-vitamine 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 VenoPlus

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® 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.
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
Under press

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Aim of the study.
Increase in arterial inflow to the lower limb is important to obtain functional improvement in peripheral artery diseased (PAD) patients with claudication. The aim of this study was to assess the effects of electrical stimulation of calf muscles on arterial inflow and tissue oxygen content in PAD in the area of stimulation.

Methods
Fifteen adult patients (62±12 years old, 165± 8 cm, 76±13 kg, lowest ankle-brachial index 0.66±0.19 with stable arterial claudication were recruited. All patients have had a treadmill exercise (3.2km.h-1, 10% slope) transcutaneous oximetry expressed as DROP index values with a maximum walking distance of 295 [133/881] m. DROP on the symptomatic side was -25 [-18/-34] mmHg. After resting values were recorded, the gastrocnemius was stimulated for 20 minutes at increasing contraction rates with 5 min steps of 60 b.p.m. (beats-per-minute), 75 bpm, 86 bpm, and 100 bpm, on the most symptomatic side. We recorded on both sides: arterial blood inflow with Duplex Doppler ultrasound of the femoral artery, DROP transcutaneous oxygen pressure value and oxygen concentration (O2Hb) from the near infrared spectroscopic signal (NIRS) of the calf. Patients were instructed to report eventual contraction-induced pain in the stimulated calf. Results are mean±standard deviation (SD) or median [25/75 centiles] according to distribution and the level of statistical significance was set at P < 0.05 on two-tailed tests.

Results
Lower limb inflow (ml/min) was 64 [48/86] vs. 63 [57/81] (N.S) before stimulation and 123 [79/155] vs. 51 [44/92] at 60 bpm (p<0.01), then 127 [85/207] vs. 49 [43/73] (p<0.01) at 75 bpm, subsequently 140 [81/200] vs. 57 [45/74] (p<0.01) at 86 bpm, and 154 [85/185] vs. 55 [46/94] (p<0.01) at 100 bpm, on the stimulated vs. non stimulated 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.

Conclusion
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,
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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 5). 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.

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 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

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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.
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

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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
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.
NEW INSIGHTS ON EFFECTS OF ELECTRO-STIMULATION OF CALF-PUMP. A REVIEW OF PRELIMINARY FINDINGS USING VEINOPLUS* DEVICE AND THEIR IMPLICATIONS FOR TED AND PAD

Presented at Mayo Clinic Symposium, Paris, September 2011

Prof. J. Cywinski
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Aim
In cases of limited ambulation, the maintenance and improvement of circulation in legs can be done by external physical means. In addition to compression and IPC treatments, one of the practical choices is the activation of involuntary calf muscle contractions by electro-stimulation. This descriptive analysis is about applications of a pocket-size VEINOPLUS device intended for home use. The hemodynamic effects of such devices were reported by M. Griffin et al. in EJVES 2010.

Methods:
The Doppler study on 24 healthy volunteers showed that mean blood velocity in popliteal vein increased during stimulation by 10-fold. This means from 10 cm/s (no stimulation) to 95-105 cm/s at the stimulation rate of 8 bpm. The total flow volume increased from 20 ml/min to 230 ml/min at a higher rate of stimulation. Independently from the above, “in three patients with chronic venous insufficiency we have seen a reduction of venous pressure measured in a dorsal foot vein in all three cases.” (H.Partsch-personal communication).

Results:
A). Veinoplus treatments of pregnancy-related C3, (n=56) resulted in pain and edema reduction and in improvement of QOL (Cf.: 2009 Le Tohic et al.)
B). Reported treatments of patients with C0S-C2S (n=40) (Cf. 2005 Zuccarelli et al.) showed reductions of reflux and improved QOL.
C). Recently, the treatments of C5 & C6 VI resulted in total or partial venous ulcer healing in less than 3 month. One case report was published (2007 AVF poster) and as of this date 8 more case reports were received by the manufacturer of the device. The case reports were recently received (4) showed increased Absolute Claudication Distance (ACD), diminished acute hypoxia pain and lack of DMS in patients, who use Veinoplus up to 6 hours daily. These facts can be partially explained by results of study on healthy athletes at INSEP (n=10, publication in preparation) undergoing the Veinoplus stimulation. The Near Infrared Reflectance Spectroscopy (NIRS) of gastrocnemius muscle during post-exercise recovery, revealed that tissue O2 saturation (StO2) returns to 100% normal within less than 2 minutes. This means that the calf muscles, even when stimulated, use oxygen like they were in passive recovery and they do not fatigue. Yet at the same time, the blood flow measurements in popliteal vein (Cf.: 2010 Griffin et al.) and in popliteal artery (Nicolaides and Griffin-personal communication) show more then 4-fold increases. These facts demonstrate the potential for VEINOPLUS device application in IC and PAD. The case reports recently received (4) on increased Absolute Claudication Distance (ACD), diminished acute hypoxia pain and lack of DMS in patients, who use Veinoplus daily, just demonstrated this potential.

Conclusion: The calf-pump stimulation shows potential for non-invasive home-based treatments of TED and PAD and larger population clinical studies are now justified.
VENOUS DRAINAGE BY ELECTRICAL STIMULATION OF CALF MUSCLES TO PREVENT COMPLICATIONS OF VENOUS THROMBO-EMBOLISM

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Aim: The aim of this study was to assess electromyostimulation (EMS) effectiveness on venous drainage as part of comprehensive prevention of venous thromboembolism (VTE) in surgical patients.

Methods: Study carried out in hospitals n° 12 and 13, during 2011/2012 period.
Prospective study in patients admitted for general surgery and neurosurgery with a high risk of VTE. Inclusion criteria were: age over 40, surgical intervention, high risk of VTE in the postoperative period, agreed to participate to the study.
In total, the study included 60 patients aged from 40 to 85 years (mean age - 63.2 ± 12.1), which were randomly divided into two groups, numbering 30 people, matched by age and sex characteristics, type of disease, the transferred volume of surgical intervention, timing of treatment and observation.
Protocol for VTE prevention for the first (main) group included EMS with Veinoplus for more than 5 sessions a day and the imposition of a graduated compression bandage from the middle stretch (Putterbinde, Paul Hartmann- Fig 1) under the control of a portable gauge Kikuhime to the target pressure at point B1, corresponding to 20-40 mm Hg, anticoagulants administered in the absence of contraindications, which occurred in 73% of cases.
The second (control) group’s protocol consisted in the imposition of a graded compression bandage along with the administration of anticoagulants in 77% of cases. In order to diagnose VTE, ultrasonography angioscanning was performed before the study and then every 3-5 days of postoperative compression in order to detect signs of thrombosis. Lung perfusion scintigraphy and echo-cardiography were also performed to exclude pulmonary embolism.

Results: In the study group was registered a case of calf deep vein thrombosis (3.3%) without evidence of pulmonary embolism. In the control group occurred 10 cases of thrombotic occlusion in the inferior vena cava (33%) and 2 cases of pulmonary embolism (6.7%). The difference between study and control groups in the frequency of venous thrombosis is significant (p = 0.008, chi-square test with Yates correction). The relationship between the use of anticoagulation and the frequency of thrombosis in the control group was not revealed.

Conclusions: The inclusion of EMS techniques in the VTE prevention protocol in surgical patients at high risk can significantly reduce the incidence of postoperative venous thromboembolism.
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 ¼ .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
HIGH-INTENSITY PERFORMANCE IS RESTORED WITH SHORT-TERM BLOOD FLOW STIMULATION RECOVERY WITH VEINOPLUS®

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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 later al 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.