

# Electromuscular stimulation with VEINOPLUS® for the treatment of chronic venous edema

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**Aim.** Electromuscular Stimulation (EMS) with VEINOPLUS® has recently emerged as a new technique to activate the calf muscle pump, improving the symptoms of venous disease. The aim of the study was to evaluate efficacy of EMS and its impact on evening edema, venous pain, venous outflow and patients quality of life.

**Methods.** Thirty patients (32 legs) aged 19-50 (mean 45.2±1.3) classified CEAP C3 with chronic evening venous edema took part in the study (22 limbs: C3, S, Ep, Asp, Pr and 10 limbs: C3, S, Es, Aspd, Pr). All patients were treated with CE-registered VEINOPLUS® neuromuscular stimulator for 30 days. 3 sessions per day (each session lasted for 20 minutes) for the first 10 days, the next 10 days 2 sessions per day and one session per day for the last 10 days. The main evaluated criteria for venous edema was the circumference of the supramaleolal shin segment, measured twice with a tape measure; in the evening the day before and then 5 days after the treatment. All measurements were taken during the interval between 6 and 8 o'clock P.M. All the patients were asked to evaluate venous pain using the Visual Analog Scale, and to fill in a CIVIQ questionnaire (validated for Russian patients) for the Quality Of Life (QOL) measurement. Also venous refilling time (RT) was measured by digital PPG. That was also made twice – before the treatment and in 35 days after the treatment. No other treatments were used.

**Results.** The EMS treatment was well tolerated by patients. There were no drop outs and patients had no need to change their lifestyles. After the treatment, total or partial reduction of evening edema was shown in 93.8% of limbs, the circumference of the lower leg diminished by 20.3mm (P<0.001), the number of painful legs reduced from 28 to 12 and the severity score of venous pain was cut from 8.3 ±1.1 to 3.8 points ±0.9 (P<0.001), QOL improved significant-

ly 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, total remission of symptoms was observed in 50% of legs, despite there being no other treatments.

**Conclusion.** VEINOPLUS® stimulation is an effective and well-tolerated therapeutic method for the treatment of chronic venous disease. The introduced scheme of EMS application was shown to be useful for treatment of chronic edema, for reducing pain and improving quality of life. It can be used as an additional mean in treatment and to prevent symptoms of CVI. This study also reveals that stimulation of calf muscles with VEINOPLUS® can improve venous outflow and symptoms of CVI. This finding should be investigated and confirmed in further studies.

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Key words: Electric stimulation therapy - Venous insufficiency - Edema.

Improvement of the calf muscle-venous pump (MVP) function is one of the most important goals in chronic venous insufficiency (CVI) treatment. As a rule, compression therapy and various types of surgery are used to reduce the pathological venous capacity and increase the MVP efficiency. Meanwhile, an overwhelming majority of specialists disregard the necessity of stimulating another important “peripheral venous heart” component the calf muscles. Traditionally exercise therapy and so-called healthy sports (swimming, water aerobics, Scandinavian walking, etc.) are recommended. The patients are required to change their lifestyles drastically, but this is rarely achieved due to poor compliance. The optimum compression therapy schedule implies wearing bandages or compression stockings during physical activi-

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ties every day. This is only observed in less than 40% of patients.<sup>1</sup> More than a half of elderly patients, who suffer from severe CVI, have contraindications or are not able to apply compression treatment aids on their own.<sup>2</sup> Therefore, new methods of non-surgical treatment, designed to improve the performance of the MVP through stimulation of its muscular component and do not require permanent compression, attract great attention.

Today, in the European Union and the US, numerous research on Electromuscular Stimulation are carried out with the EMS procedure using VEINOPLUS® technology emerging as a new treatment of CVD- and CVI-related symptoms and syndromes. This technology can also be used to prevent venous thromboembolic complications.<sup>3-7</sup> In this study, we analyze outcomes of application of this method in patients with chronic venous edema.

### Materials and methods

The study carried out in May-August, 2009, engaged 30 patients (18 women and 12 men) at the age of 19-50 (mean age of  $45.2 \pm 1.3$  years) with CVD of 3<sup>rd</sup> clinical class by CEAP (chronic venous edema). In total, 32 lower extremities were studied. 22 lower extremities were referred to C3, S, Ep, Asp, Pr and 10 to C3, S, Es, Aspd, Pr. Patients were admitted to the study by the criterion of every-evening chronic venous edema of the ankle with the increase in circumference of its thinnest supramalleolar segment by 10 mm and more. Venous origin of the edema was revealed with the duplex ultrasound scan of blood vessels using SonoSite 180 Plus (ATL, USA) and digital photoplethysmography (PPG) using Dopplex Assist (Huntleigh Diagnostic, GB). All the patients reported pain of different intensity, related to venous disorders. All the patients reported pain of different intensity. Venous origin of the pain was confirmed by its intensification while in the sitting or standing position or by the end of day and weakening of the pain after elevation of the lower extremities. This kind of pain is called venous pain.

The EMS treatment using VEINOPLUS® (Ad Rem Technology, France, FS 2006/2208) was prescribed to all the patients on the following

schedule: days 1-10: 3 procedures (morning, afternoon, evening), days 11-20: 2 daily procedures (morning and evening), days 21-30: one daily procedure (evening). During the whole treatment period, the patients were not allowed to wear bandages or compression stockings and to take edema-curing medicines.

EMS was performed in the following way; when seated, the patient fixed electrodes onto the posterior surface of the lower leg along calf muscles. After the device was switched on, intensity of impulses (1 to 50) was adjusted by the patient him/herself so that there was no discomfort or sensation of pain felt or visible muscle activity. Whenever the range of muscular contractions decreased due to habitual effect in the course of EMS, the patient increased the impulse intensity him/herself. Effective EMS on average required the impulse intensity in the range of 20-30 ( $23.5 \pm 1.5$ ). Time of exposure to EMS was 20 minutes. On expiry of this period, the embedded timer stopped the device automatically.

Exclusion criteria were; heart rate disturbances, metal implants in lower extremities, pregnancy, serious traumatic brain injuries from a medical history, epilepsy and convulsive disorders. All patients signed a written consent to participate in the study and received a check list to record the time and the number of EMS procedures undertaken. The Protocol of the study was approved by The Ethics Committee of the Russian State Medical University.

Treatment results monitoring was carried out on the 35<sup>th</sup> day. It was made on the 35<sup>th</sup> day because 5 days were taken for the wash out period to see if the result continued after that interval. The following figures were accepted as estimation criteria: circumference of the thinnest (supramalleolar) segment measured with a tape measure during the fixed time of the day (6.00 p.m. – 8 p.m.), refilling time (RT), and other symptoms of the disease defined against the disease-specific questionnaire CIVIQ validated for Russian patients. The latter serves as a basis to determine the global index integral indicator of life quality, which describes all the four aspects.<sup>7</sup> Pain syndrome was estimated on the 10 cm visual analogue scale, where 0 points correspond to complete absence of pain, and 10 points to intolerable pain.

### Statistical analysis

Statistical analysis was carried out using Student's *t*-test, accepting  $P < 0.05$  as significant, after verification of the data with Mann-Whitney test. Mean values  $\pm$  standard deviation (SD) and 95% confidential interval (CI) are presented.

### Results

The recommended EMS schedule was fully observed by 22 patients. 8 respondents were regularly missing procedures in the afternoon due to their professional activities and due to the inconvenience of carrying out the procedure at work in the presence of other people. Nevertheless, the results of treatment were estimated with respect to all 30 patients (32 lower extremities).

Evening edema disappeared in 59.4% of cases (19 lower extremities), reduced in 34.4% of cases (11 lower extremities), and remained without changes in 6.2% cases (2 lower extremities). Before treatment, the group average circumference of the thinnest part of the ankle was  $276.5 \pm 1.1$  mm (95% CI 274.0 to 278.7); in 30 days of treatment, it was  $256.2 \pm 0.7$  mm (95% CI 253.0 to 259.14) ( $\Delta$ circumference = 20.3 mm,  $P < 0.001$ ; Figure 1). Venous pain was present in 87.5% of patients (28 lower extremities). The average severity score before the treatment was  $8.3 \pm 1.1$  points (95% CI 7.89 to 8.74) (Figure 2). On day 35, the venous pain remained in 34.5% patients (11 lower extremities), and its severity was reduced to  $3.8 \pm 0.9$  points (95% CI 1.90 to 5.59) ( $\Delta$ venous pain = 4.5 points;  $P < 0.001$ ). Initial RT value measured under the standard procedure using computer PPG constituted  $17.3 \pm 0.9$  s (95% CI 16.9 to 17.56) (Figure 3). On day 35, it grew to  $21.5 \pm 1.1$  (95% CI 21.07 to 21.87) sec ( $\Delta$ RT = 4.2 s;  $P < 0.001$ ). Before the treatment, the value of global life quality index was  $34.5 \pm 7.8$  (95% CI 30.95 to 38.05), and after the treatment, changed to  $17.2 \pm 4.6$  (95% CI 15.53 to 18.79). Dynamics of a global life quality index (reverse ratio) is presented in Figure 4. Integrally, life quality improved by 49.9% ( $P < 0.001$ ).

None of the participants refused to use EMS due to any adverse side effects. 18 patients (19 lower extremities), whose evening edema passed

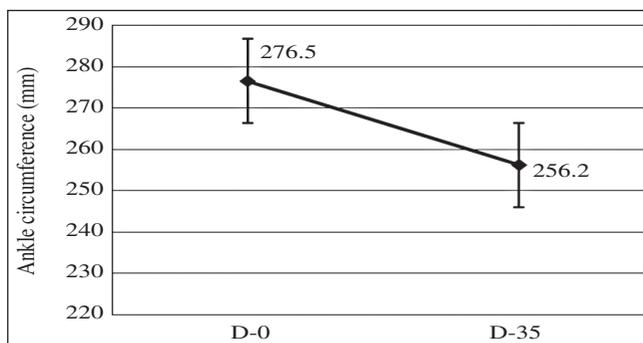


Figure 1.—Ankle circumference before and after treatment ( $p < 0.001$ ).

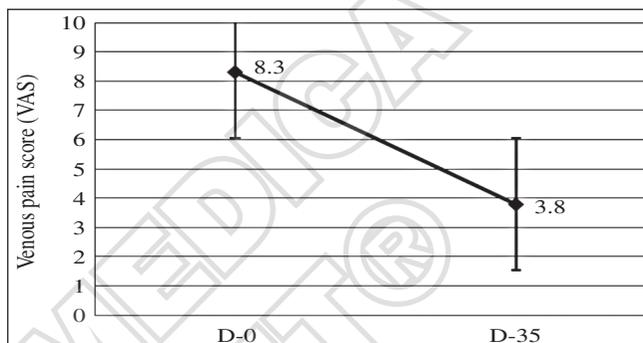


Figure 2.—Venous pain score before and after treatment ( $p < 0.001$ ).

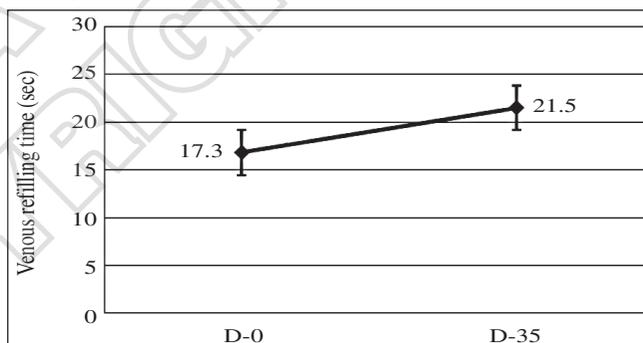


Figure 3.—Venous refilling time (RT) before and after treatment ( $p < 0.001$ ).

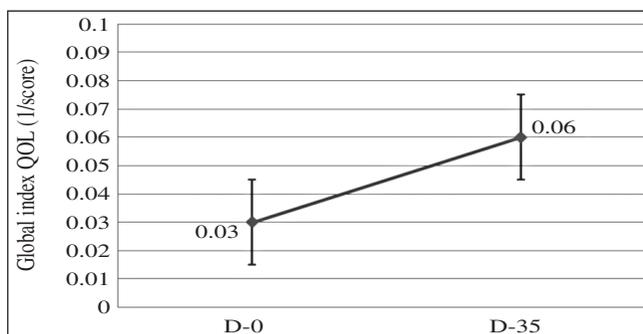


Figure 4.—Global index QOL (reverse ratio) before and after treatment ( $p < 0.001$ ).

after the EMS treatment, had CVD of class C3/Ep (varicose veins) and were preparing to have elective surgery. During the next 3 months without compression therapy and/or treatment with vein-active medicines, venous edema recurred in two cases only (3 lower extremities). In other patients, remission was observed.

### Discussion

EMS with VEINOPLUS® is shown to eliminate or significantly reduce manifestations of CVI C3, S, Eps, by CEAP in most patients within a relatively short period. Positive build-up of venous tone and reduction in blood backflow recorded during PPG provides evidence that the EMS procedure has pathogenic character. Compression therapy, pharmacotherapy and EMS use essentially different mechanisms to achieve curing effect, so their combined application may probably be more effective than separate use. In a number of cases (hot season, idiosyncratic reaction, necessity to observe the dress-code, ankylosis, chronic arterial insufficiency, sedentary lifestyle, etc.), EMS has higher priority than compression therapy.

Thus, EMS is a new pathogenic method for the treatment of CVD and CVI through stimulation of the muscle component of the calf MVP. Simplicity, safety and effectiveness of EMS with VEINOPLUS® technology allows extensive outpatient treatment of various chronic diseases of the venous system in lower extremities. Additional studies should be carried out in order to define the procedure for employment of EMS in the treatment of different forms and stages of CVD more exactly.

### Conclusions

VEINOPLUS® electromuscular stimulation is an efficacious and pathogenically based method of treatment of CVD chronic venous edema (C3 CEAP classification). The use of this technology during 30 days is well tolerated by patients, and renders positive clinical effect resulting in 3-month remission in 59.4% of cases. An overwhelming majority of patients observe the recommended schedule of EMS procedures without having to adjust their regular work activities.

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