INTRODUZIONE

Nell'ambito della terapia fisica, sono rare le tecnologie supportate da evidenze scientifiche. In questo spazio, abbiamo voluto concentrare diverse pubblicazioni che rendono la tecnologia FREMS™ unica, efficace ed efficiente. Ad esempio sono stati dimostrati e pubblicati alcuni studi riguardanti i meccanismi d'azione e gli effetti di base della neuro stimolazione FREMS™, che oggi la rendono la nuova alternativa che cura, per diverse patologie sia acute che croniche.

Med Eng Phys. 2010 Mar 5.
Recovery of 0.1Hz microvascular skin blood flow in dysautonomic diabetic (type 2) neuropathy by using Frequency Rhythmic Electrical Modulation System (FREMS).

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Synchronized oscillation of smooth muscle cells tension in arterioles is the main control system of microvascular skin blood flow. An important autogenic vasomotion activity is recognized in 0.1Hz oscillations through power spectrum analysis of laser Doppler flowmetry. Severe dysautonomia in diabetic neuropathy is correlated with loss of 0.1Hz vasomotor activity, hence with impaired blood microcirculation. FREMS is a novel transcutaneous electrotherapy characterized by sequences of electrical stimuli of high voltage and low pulse duration which vary both in frequency and duration. We have evaluated the changes in laser Doppler flow in the volar part of the forearm before, during and after FREMS. Normal controls (n=10, 6 females, age range 21-39 years) demonstrated significant 0.1Hz vasomotion power spectra at baseline conditions associated with large oscillations of adrenergic cutaneous sweat activity sampled from the hand; people with diabetes type 2 and severe dysautonomia (n=10, 5 females, age range 63-75 years) displayed a significant decrease of 0.1Hz vasomotion power spectra. During FREMS application we observed an increase ($p<0.05$) of 0.1Hz vasomotion power spectra only in the diabetic group, despite persistence of adrenergic cutaneous sweat activity suppression in this group. However, after the application of the stimuli, the relative energy values around the 0.1Hz peak remained significantly higher than preapplication values in the diabetic group ($p<0.05$). From these findings, we suggest that FREMS is able to synchronize smooth cell activity, inducing and increasing 0.1Hz vasomotion, independently from the autonomic nervous system.

J Diabetes Complications. 2009 Jan-Feb;23(1):46-8. Epub 2008 Apr 10.
Frequency-modulated electromagnetic neural stimulation enhances cutaneous microvascular flow in patients with diabetic neuropathy.

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AIM: The aim of this study was to investigate the effects of frequency modulated electromagnetic neural stimulation (FREMS), a recently developed safe and effective treatment of painful diabetic neuropathy, on cutaneous microvascular function. METHODS: Thirty-one patients with painful neuropathy were enrolled in a randomised, double-blind, crossover FREMS vs. placebo study; each received two series of 10 treatments of either FREMS or placebo in random sequence within no more than 3 weeks. Patients were

studied at baseline, end of FREMS and placebo series, and after 4 months of follow-up. Cutaneous blood flow was measured by laser doppler flowmetry and partial tissue tension of oxygen (TcPO2) and carbonic anhydride (TcPCO2) by oxymetry at the lower extremities in basal resting conditions and as incremental response after thermal stimulation. RESULTS: Crossover analysis showed no consistent differences between FREMS and placebo. After 4-month follow-up, a 52% increase of cutaneous blood flow was observed in resting conditions (P=.0086 vs. baseline), while no differences were observed as incremental flow after warming; compared with baseline, no significant differences were observed for TcPO2 and TcPCO2, both in resting conditions and as incremental response to warm. CONCLUSION: These results indicate that 10 treatments with FREMS may induce an enhancement of microvascular blood flow measurable at 4 months of follow-up. The findings of this study will need to be confirmed in a larger, adequately powered study (ClinicalTrial.gov Id: NCT00337324).

J Endocrinol Invest. 2007 Dec;30(11):944-7.

Induction of vascular endothelial growth factor release by transcutaneous frequency modulated neural stimulation in diabetic polyneuropathy.

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BACKGROUND: Pharmacological treatment for diabetic polyneuropathy (DP) has shown limited benefit; frequency-modulated electrical stimulation (FREMS) has shown positive results in pain control and nerve conduction velocity in DP. OBJECTIVE: To investigate the effects of FREMS vs transcutaneous electrical nerve stimulation (TENS) on the release of vascular endothelial growth factor (VEGF) in Type 2 diabetic and in non-diabetic subjects. METHODS: 10 non-diabetic [mean age 37+/-5 yr; females (F)/males (M): 6/4] and 10 Type 2 diabetic subjects (mean age 52+/-6 yr; F/M: 5/5) with DP underwent TENS (for 10 min) followed by 30 min interval without electrical stimulation, and then FREMS (for 10 min) over the forearm volar surface. Blood samples for VEGF measurements were obtained from the contra-lateral arm every 2 min during TENS/FREMS application and every 10 min during the intervals. RESULTS: We observed a significant rise in plasma VEGF during FREMS in both non-diabetic and diabetic subjects (maximal response 89.4+/-80.3 pg/ml and 48.5+/-18.3 pg/ml, respectively; $p<0.01$ vs basal) with a lower, but still significant response in diabetics. No changes in VEGF were observed during TENS application. CONCLUSION: VEGF release during FREMS may help explain the positive effects on nerve conduction velocity in DP, possibly mediated by favorable effects on vasa nervorum microangiopathy.

Eura Medicophys. 2007 Mar;43(1):37-47. Epub 2006 Dec 12.

Frequency rhythmic electrical modulation system (FREMS) on H-reflex amplitudes in healthy subjects.

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AIM: Changes in the amplitude of Hoffmann reflex (H-reflex) may reflect variations in the characteristics of the largely monosynaptic circuitry that is explored and are a possible target for diagnostic and physical therapeutic intervention. However, previous attempts to induce predictable changes in the H-reflex amplitude by transcutaneous electrical nervous stimulation (TENS) have generally failed. Previous workers applied fixed frequency in the low- (2-5 Hz) or in the high- (100 Hz) field, but they did not

attempt to vary frequency and/or impulse duration in time. METHODS: We evaluated the effect of a new type of painless electric stimulation, i.e. frequency rhythmic electrical modulation system (FREMS). FREMS is characterized by the use of transcutaneous electric pulses with sequentially modulated frequency (f: 1-39 Hz) and width (w: 10-40 micro s) at constant, perceptive threshold voltage (approximately 150 V). FREMS was applied at the abductor hallucis muscle (AHM), as conditioning stimulus of the H-reflex which was recorded ipsilaterally at the soleus muscle, according to the classic method, in 10 normal volunteers (age range 21-40 years). RESULTS: H-reflex amplitude was substantially decreased (-50%) during FREMS and H-reflex amplitude variations were influenced by w/f variation in time during FREMS subphase C in a predictable way ($r(2)=0.43$; $P<0.001$). Our results suggest an effective ability of FREMS to modulate H reflex amplitude. CONCLUSIONS: The ability to achieve large and predictable changes of the H-reflex amplitude simply by modulating both frequency and duration of a conditioning painless electrical stimulation offers new possibilities for the treatment of diseases characterized by motoneuron excitability abnormalities.

Eura Medicophys. 2004 Dec;40(4):293-301.

A randomized controlled study on the effect of two different treatments (FREMS AND TENS) in myofascial pain syndrome.

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AIM: Myofascial pain syndrome (MPS) is a frequent cause of chronic muscoloskeletal pain. Transcutaneous electrical nerve stimulation (TENS) is one of the most frequently employed treatments in MPS. The aim of this study is to compare the short and medium-term effects of frequency modulated neural stimulation (FREMS) to those of TENS in MPS. METHODS: Forty subjects with upper trapezius MPS were randomly allocated to 1 of 2 groups, treated with either FREMS (n=19) or TENS (n=21). Each treatment consisted in 10 sessions lasting 20 min each. Patients were evaluated before treatment, at 1 week, and at 1 and 3 months after the end of treatment. Clinical evaluation included parameters for measurement of pain levels using the neck pain and disability visual analogue scale (NPDVAS) and algometry, evaluation of myofascial trigger point characteristics and measurement of the range of cervical movement (range of motion, ROM). RESULTS: The FREMS group showed a significant improvement in the NPDVAS, algometry, in myofascial trigger point characteristics, and in the ROM (homolateral rotation, controlateral rotation, bending and extension) after the end of treatment and at 1 and 3 months follow-up evaluation. The TENS group showed significant improvement in the same outcome measures except for algometry and cervical extension, but these improvements were maintained only at the 1 month follow-up evaluation. However, were not observed statistically significant differences between FREMS of TENS in many of outcome measures. CONCLUSIONS: Both FREMS and TENS have positive short-term effects on MPS. But, medium-term effects were achieved only with FREMS