# **Technical Committee Submission**

"Is Frequency Rhythmic Electrical Modulation System (FREMS) a modality that the College approves of? Further, is this form of treatment within the scope of a registered Chiropodist?"

Members:

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#### **Purpose:**

The College of Chiropodists of Ontario requested that the above question be researched by the members of the Technical committee, in order to respond to an inquiry submitted by a health insurance company.

#### What is FREMS?

FREMS (Frequency Rhythmic Electrical Modulation System), known also as Lorenz, the name of the manufacturer, involves "the application of an electrical signal through small transcutaneous electrodes. It is composed of sequences of electrical impulses, with a minimum amount of charge exchange, and a variable frequency and duration according to preset protocols. It is a form of transcutaneous electrotherapy using electrical stimulation that automatically varies in terms of pulse, frequency, duration, and voltage. The impulse amplitude is preset by the operator using a remote control at the maximum value according to the patient's sensitivity threshold of the stimulated tissue. The system modulates the maximum amplitude based on the ionic balance of the tissue beneath the electrodes, keeping it in constant equilibrium (biofeedback)". (1) The computer-controlled varied frequencies of electricity through the electrodes stimulate nerves and blood vessels to create the desired effect.

FREMS is a multifunctional transcutaneous electrical nerve stimulator (TENS) equipped with a surface electromyography and electroneurography. TENS units produce electric current in order to stimulate nerves for therapeutic purposes. TENS, by definition, covers the complete range of transcutaneously applied currents used for nerve excitation. Effectively, FREMS is a TENS unit that adjusts and modulates according to preset functions and biofeedback from the patient's tissue responses.

## What is FREMS indicated for?

There have been a few studies of the FREMS modality with the most common stated benefits of pain relief, anti-inflammatory effects, neuropathy symptom reduction, wound and ulcer healing, improved circulatory response, and enhancement of microvascular blood flow. The manufacture states that there is noted change in the perfusion velocity of the microcirculation during treatment with FREMS as measured by Laser Doppler Flowmeter. This demonstrated induced vasomotor activity. (1)(5) Another study demonstrated that FREMS is able to synchronize smooth cell activity, inducing and increasing 0.1Hz vasomotion, independently from the autonomic nervous system (2)

In a recent study of FREMS for the treatment of chronic painful leg ulcers the group of patients treated with FREMS and a topical treatment showed a greater reduction in pain and an improvement of epithelization of ulcers compared with the group treated with a topical treatment alone.(3)

In a study utilizing FREMS to treat painful diabetic neuropathy, the results indicated significant reduction in daytime and night-time pain score. Also noted was a significant increase in sensory tactile perception, as assessed by monofilament; a decrease in foot vibration perception threshold, as measured by a biothesiometer; and an increase in motor nerve conduction velocity. These results persisted over a four month period. (4)

## What is the treatment protocol?

The manufacture of the units, and the studies performed, recommend 30 minute daily application of FREMS for two to three weeks, for a total of 10 to 15 treatments. Two to four electrodes are placed in and around the area of the tissue or lesion to be treated, which for our purposes will be located around the foot and lower leg. All session are perform in the practitioner's office as the unit is large and bulky, unlike the small portable TENS units.

#### Is The Michener Institute teaching or utilizing the FREMS modality?

No, the Michener has not yet acquired a FREMS device specifically for teaching, training, or utilization within the clinic. The students at Michener are instructed on the principles, concepts, and utilization of transcutaneous electrical stimulation devices, such as TENS units, which are similar in functionality to the FREMS devices. At present, the only place to receive training in the use of the FREMS system is from the manufacturer, or its representatives.

# Is FREMS a medically accepted and utilized treatment for circulatory disorders of the feet?

We did not find any vascular medical group utilizing this modality over the course of our research, nor did we find any studies from vascular surgeons on the use of FREMS. Although there is some evidence from the current studies of FREMS suggesting that it does improve blood flow over a short period of time, we did not find any double blind studies, medical school studies, or university trials on the use of this modality in regards to vascular pathologies. We believe more independent short and long term studies need to be performed to assess the full effectiveness of FREMS for the treatment of vascular disorders. We do not know of any group regularly using this modality for the treatment of circulatory disorders. That does not mean it is not used, but if it was generally accepted we would expect to see it more widely used in practices treating vascular pathologies. So the question the College of Chiropody of Ontario may have to tackle is whether the use of FREMS for vascular improvement is ethical without more in-depth studies proving its effectiveness. As to whether the medical community will regularly accept this form of treatment for microvascular pathologies, only time, and more research, will tell. This should not preclude this modality from being utilized within our profession, as it has similar benefits to TENS therapy, as well as the other benefits discussed in the indication section above.

# Is FREMS within the scope of practice of our members?

According to Ontario regulation 107/96, within the Regulated Health Professions Act, 1991, neither frequency rhythmic electrical modulation, nor the similar modality of transcutaneous electrical nerve stimulation are listed under the electricity portion of forms of energy that are controlled acts. As such FREMS is a therapeutic modality that falls within the scope of a chiropodist and podiatry.

# **Conclusion:**

According to Ontario regulation 107/96, within the Regulated Health Professions Act, frequency rhythmic electrical modulation (FREMS) is a therapeutic modality that falls within the scope of a registered Chiropodist, and should be recommended college as a therapeutic modality under the same category as transcutaneous electrical nerve stimulator (TENS)

### References

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