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**FREMS™: Scientific Principles**

Cells exchange information through a complex communication system based on the transduction of electrical signals and biochemical events by passing ions through channels in the cell membrane (fig.1).

![Cell membrane](image1)

fig. 1

Every cell and/or tissue has a certain resting membrane potential.

The ability to create a phasic depolarization event in a relatively short amount of time is called “excitability” and depends on the biological device that regulates transmembrane ions flux, by their type and density.

Generally the excitability of a cell/tissue is calculated in terms of an intensity/duration curve (fig.2) and the excitable cells have the ability to produce a recurring event, called “action potential” or “spike” that corresponds to an event which is always “identical”.

![Intensity/duration curve](image2)

fig. 2

There is always a refractory period after this spike during which the cell is not stimulated despite the fact that the same intensity is administered; it follows that there is a maximum characteristic frequency for every class of cell or tissue.

For example, the smooth muscle is immediately excited with stimuli below the perception threshold frequency of approximately 10 Hz, striated muscle at a frequency higher than 30 Hz, unmyelinated fibres at a frequency >150 Hz, etc.

The time that passes between one spike and another is a declaration of the ability of the membrane to repolarise itself after a depolarization event: this ability mainly comes from the inward flow of potassium from the outside of the cell (inward rectification).

The pathology disrupts the equilibrium of tissue and changes the excitability not only of the nerve cell, but also of other cell types, interconnected in various ways, such as muscle cells, gland cells, connective tissue, etc.

Another fundamental property of all biological tissues is adaptation: sequences of stimuli induce the modulation of the response threshold. The structural basis for this phenomenon also comes from the ionic properties of the membrane and especially from the types of ionic channels.

The most interesting element is that the adaptation reached by the functional unit (cell and/or tissue) is the final common pathway of all these interactions, regardless of the medium with which it has been reached.

It follows that electrical stimulation, because it has a direct effect on the transmembrane ionic channels, can induce functional changes to any cell/tissue system through the modulation of its response threshold.

The use of an electrical stimulation without any direct influence and neutral to analogue receptor signalling, allows the digital components of the intercellular information between connected systems be activated, provided that they are electrically active.

This can create manifestations and transformations in the innate potentials of the organism itself, bypassing hindrances that are interposed by the pathology in all its manifestations.
FREMS™: What is it?

Electricity is a sort of universal skeleton key for all biological functions. An electrical stimulation designed to pass through skin, with precise rhythms and sequences that vary in time and frequency is potentially capable of interacting with:

- Cutaneous receptors (touch, pressure, temperature, stabbing pain, and chemoreceptor) connected to fibres with high velocity conduction
- Free unmyelinated cutaneous nerve fibres (temperature, diffuse pain, inflammation and metabolism mediators)
- Smooth muscle fibres (blood vessels and myoepithelial cells of the glandular annexes)
- Striated muscle fibres below the dipole created by a pair of electrodes

FREMS™ (Frequency Rhythmic Electrical Modulation System), known also as “Lorenz”, which comes from the name of the manufacturer, involves the application of an electrical signal through small transcutaneous electrodes.

It is composed of sequences of electrical impulses (spikes), with a minimum amount of charge exchange, and a variable frequency and duration according to preset protocols.

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 then modulates the maximum amplitude based on the ionic balance of the tissue beneath the electrodes, keeping it in constant equilibrium (biofeedback).

The impulse is characterized by an active phase and a rest phase, which ensure the ionic balance for the tissue involved in the process.

The sequences of impulses are conceived on the basis of the characteristics of the tissues to be enrolled in the programmed action and are able to carry out synchronisms and rhythms in the excitable structures by activating a functional “rehabilitation” mechanism in the area being treated.

Due to its fundamental characteristics, FREMS™ can influence subcutaneous functional structures by producing determined and repetitive events such as vasomotion, intended as the rhythmic pulsation of the vessels, through the involvement of the pre-capillary sphincter muscles of the microcirculation.

FREMS™: The Target

FREMS™ is the result of a research dedicated to realize a non pharmacologic system able to treat vascular and neurological diseases such as diabetic neuropathy.

FREMS™ is an effective and innovative approach in the treatment of diseases and complications in the following systems:

- Peripheral nervous system
- Vascular system
- Locomotor system
- Integumentary system

During the studies that were conducted for the development of FREMS™, some actions of the endothelial and smooth muscle cells of vessels were studied, mainly regarding the effects of simultaneous depolarization, vasomotion (fig.4), the release of nitric oxide (NO) and the production of angio genetic growth factors (figures 5 and 6).

FREMS™ can activate a functional “rehabilitation” mechanism to the area affected by the disease through the following actions:

- Functional reactivation of degenerated biological tissue due to metabolic decompensation
- Deactivation of symptomatic neuro-muscular feedback processes
- Mobilisation of inflammatory and pro-inflammatory factors
- Acceleration in the repair of damaged tissue
**FREMS™: Action on the Biological Control Systems**

The healing effects of FREMS™ occur through a direct and indirect action on the biological control systems and especially in the autonomic system.

FREMS™ has the following specific effects:

**Vasomotor Action**

Vasomotion is the rhythmic pulsating action of the smooth muscles of the vessels that regulate the activity of the microcirculation.

Changes in the perfusion velocity in the microcirculation during FREMS™, measured by Laser Doppler Flowmeter, demonstrate an induced vasomotor activity (fig.4b).

These figures show the increases in blood flow and their direct relationship with the sequences performed during the stimulation.

The vasomotor profiles of the microcirculation demonstrate a close correlation with the aerobic respiratory status of the tissue treated with FREMS™ (fig.4a). It is clear how the adrenergic and non-adrenergic vasomotor components are differently modulated during the stimulation sequences.

**Release of VEGF and b-FGF**

Several experimental studies have shown the possibility of promoting the release and synthesis of VEGF (Vascular Endothelial Growth Factor) and other angiogenetic growth factors through the application of electrostimulation to smooth muscle cells, striated muscle cells and endothelial cells, in vitro or in vivo.

FREMS™ can greatly increase the release of plasmatic growth factors in human being, as shown in the studies conducted over the past few years by the Lorenz Research Centre at “Luigi Sacco” University Hospital in Milan.

**Analysis of systemic blood samples from healthy subjects, taken before, during and after FREMS™, showed a significant increase in the level of VEGF and b-FGF (basic-Fibroblast Growth Factor) (fig.5-6).**

**Anti-inflammatory Action**

The inflammatory response is often a physiological response to defend and protect
against agents that alter the biological and biochemical equilibrium of the body. The inflammatory response causes edema, pain and provokes dilation of the capillaries. The permeability of the capillary walls increases, allowing plasma to penetrate into the extracellular spaces. The liquid accumulates between the cells and causes swelling.

FREMS™ stimulates vasomotion, increases the drainage of the lymphatic system, reduces the swelling and triggers the immunological response to reduce the levels of pro-inflammatory cytokines. At the same time, it promotes the blood flow supplying oxygen and nutritional factors.

In diabetic patients with micro angiopathy, suffering from vessel endothelial inflammation, the high levels of circulating TNF-α and IL-2, significantly decrease after FREMS™ treatment (fig.7).

![Histogram showing TNF-alfa serum levels in diabetic patients with micro angiopathy](image)

**Modulation of Muscle Tone**

Thanks to its modulation action both from the reflex activity and the cortex excitability, FREMS™ is able to significantly intervene on the motor efferent nerve.

Modulation of the contraction processes can be obtained by means of this mechanism which may result from direct trauma to the locomotor or nervous system.

The ability to modulate the excitability of the motoneurons offers the possibility to treat pathologies such as dystonic disorders, spasticity or painful muscular syndromes.

**Pain Modulation**

FREMS™ can produce a functional ablation effect similar to that of analgesic electro stimulation. The application of electrodes to the skin is followed by a long lasting anaesthesia-analgésia effect. It can be compared to the effect due to the induction of a refractory period from the neurons of the spinal ganglion. FREMS™ is not just limited to short term excitability phenomena such as the induction of the refractory period, but it also induces the promotion of signal/noise filtering phenomena through a medium term conditioning of the excitability of the pain propagation systems.

In clinical terms, the same painful event, as a localized inflammatory process or a mechanical conflict on an algogenic structure, is more easily supported by a structure that has a large signal/noise extraction capability. Furthermore FREMS™ can also reduce the source of peripheral pain by means of the previously mentioned mechanisms.

**Tissue Repair**

FREMS™ encourages myocyte growth and the release of angiogenetic growth factors. The reduction of the haematatic effusion and the vascularization of the damaged muscle also reduce the state of ischemia; the tissue repair induced by FREMS™ will be more effective and prevent the formation of scar tissue the earlier the inflamed part are treated.

For muscular injuries, FREMS™ can be used immediately after the trauma when the bleeding has stopped.

For cutaneous ulcers, FREMS™ can be used to accelerate the repair of damaged tissue both through the supply of oxygen and nutritional factors induced by vasomotion and through the release of growth factors.
**Clinical Trials**

The San Raffaele Hospital in Milan and the University Monteluco Hospital in Perugia conducted a multicentric, randomized, double-blind clinical trial on painful diabetic neuropathy.

The results of the trial, published in the international journal “Diabetologia”, showed a significant recovery in the functionality of sensory and motor nerve fibres, monitored by means of electroneurography (figures 8b and 8c), monofilament and biotensiometry. There was also a notable result in the reduction of night pain (fig.8a) as well as an improvement in the microcirculation (fig.8d), measured by Laser Doppler Flowmeter.

Clinical tests performed at the L. Sacco University Hospital in Milan evaluated the efficacy of the FREMS™ system in a wide range of acute and chronic vascular, neurological and orthopaedic diseases. Moreover, it was shown a significant improvement in the microcirculation as well as a reduction in swelling and pain.

Other clinical trials are still in progress at Universities and Hospitals in the Neurological, Orthopaedic and Vascular fields which have shown the efficacy of FREMS™ in different clinical environments and in acute and chronic pathologies.

An open study conducted at the University of Udine concerning the treatment of diabetic peripheral arterial disease shows that FREMS™ achieves considerable effects on improvement of oxymetric values and pain free walking distance.

A double-blind study conducted at the University of Verona compared the application of FREMS™ in Myofascial Pain Syndrome with the application of TENS and showed that FREMS™ is more effective in the short term reduction of the pain and mostly in the medium term by supposing its intervention in the basic mechanism of the pain.

A multicentric study of the application of FREMS™ in the treatment of shoulder pain showed its effectiveness in improvement of symptoms.

Other studies on muscle injuries in athletes have demonstrated a better functional recovery of the treated area compared with conventional physical therapies, showing a substantial improvement in scarring after the injury without relapsing.

Some open studies on upper motoneurone syndrome have shown evidence of the reduction in spasticity and an improvement in the physiotherapeutical approach.

Ongoing clinical trials pertaining to the application of FREMS™ in ulcers and bedsores have demonstrated the efficacy of FREMS™ in tissue regeneration, even in the presence of serious metabolic pathologies such as diabetes mellitus.
FREMS™: Applications

FREMS™ activates a localized vasomotion system that mobilizes the inflammatory and pro-inflammatory cytokines located in the interested area.

Also by directly intervening on the small nerve fibres, it modulates the transmission of pain and the overall symptomatology. The supply of nutrients and the release of growth factors support tissue reconstruction and repair.

Some of the vascular pathologies that can be treated are:

- Peripheral Neuropathy
- Peripheral Angiopathies
- Ulcers
- Bedsores

FREMS™ modulates the activity of the peripheral nervous system by activating a biological-functional healing process.

It also allows a better physiotherapeutical approach and significantly reduces the localized pain.

Some of the neurological pathologies that can be treated are:

- Spasticity (as an aid in functional rehabilitation)
- Focal dystonias
- Myofascial Pain Syndrome
- Algodystrophies

FREMS™ acts both on the symptomatic level and on the related biological processes in different clinical areas and, depending on the specific pathology, can intervene with different effects both in the removal or reduction of the pathogenetic mechanism, and on the secondary symptoms of the pathology itself.

Some of the orthopaedic pathologies that can be treated are:

- Inflammation of the carpal tunnel
- Bursitis
- Perisynovitis
- Edematous states

FREMS™: How it is applied

FREMS™ consists in the application of an electrical signal that is transmitted through transcutaneous electrodes. These dedicated and specific FREMS™ electrodes must be positioned according to defined rules for every specific treatment and tested protocols for each application. The treatment involves a series of 30-minute daily sessions over a few weeks that can be performed both at hospital and at home.

FREMS™ is administrated through the device Aptiva™ which is equipped with two or four desynchronized and independent channels. According to the options and versions, Aptiva™ allows various applications such as the electro-myographic biofeedback and electro-neurographic analysis through the measuring of the nerve conduction and the F Wave and H Reflex.

The technology and the flexibility of these medical devices allow FREMS™ to be simply and safely applied by properly trained doctors and medical staff.

FREMS™ technology is developed and produced by Lorenz Biotech™ S.p.A., a company specialised in the development of Medical Devices dedicated to neuro-vascular and physical rehabilitation.

Lorenz Biotech™, its products and technologies are certified according to European and North American standards and are protected by European and international patents.
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