FIRSTtx

Introducing the FIRSTtx medical device

The First Choice in Pain Management and Treatment

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"We are inspired to transform healthcare through educating physicians and their patients about innovative products and services that personalize testing and treatments for each individual"

Introduction

The FIRSTtx™ medical device not only provides direct therapeutic effect, but also activates the natural defenses of the body[1] [2]. The effect is achieved through the stimulation of trigger points and acupuncture points on the skin surface.

Overall, the FIRSTtx device is an effective, non-invasive, advanced form of electrotherapy and may be effective in treating acute and chronic pain. By stimulating the body's inherent self-healing mechanisms, its direct effect is several times stronger than that of other physiotherapeutic devices, with no undesirable side effects[3] [4] [5] [6] [7] [8].

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Principles

Any living creature constantly regulates its internal processes in accordance with its own requirements and in response to environmental conditions. This self-regulation is dependent on a constant flow of information being delivered to the brain from the nervous, endocrine and circulatory systems. Of these systems the quickest is the nervous system which delivers its information via electric impulses. This vital biological system, its components and the way the

FIRSTtx is hypothesized to interact with it, are discussed next.

Biological Foundations of FIRSTtx Technology

The nervous system provides the principal function of a living organism and is composed of both central (brain and spinal cord) and peripheral components with the latter having both somatic and autonomic (parasympathetic and sympathetic) subdivisions.

The central nervous system's major function is to receive, process, and send out information. To accomplish this, the brain carefully coordinates all incoming and outgoing signals via a network of connections to various specialized regions of the brain. Any interruptions, no matter how minor, that occur in any part of this signaling system can disrupt certain functions or behaviors.

Although difficult to separate because of their overlapping effects, changes in the nervous system can be classified as:

Structural: these are changes affecting the structure of the nervous system such as the number of neurons or synapses;

Biochemical/metabolic: this includes changes in neurotransmitters affecting cerebral metabolism;

Functional: changes here can affect the electrical activity of the nerves or the motor, sensory and cognitive processes (Timiras, 1994).

The peripheral nervous system which links the brain with the skin, muscles and internal organs, via the spinal cord, orchestrates the processes that are not under conscious control. The central nervous system is either attenuated or stimulated via the parasympathetic and sympathetic subdivisions, respectively, depending upon the stimulus. This is carried out through the secretion of neuromodulators and hormones which act quickly to re-establish homeostasis or to shift the equilibrium point for adaptation to the new environmental conditions. In this way, the body is able to

constantly monitor changes within its environment enabling the body to survive and even resist disease and injury. Dysfunction that leads to disease and injury can occur when the body is placed under levels of duress from which it is not able to spontaneously recover.

The methodologies of many traditional healing practices such as acupuncture and acupressure are based on the fact that the skin and nervous system have the same embryological origin. The skin, which is a large sensory organ, remains linked throughout adulthood to the nervous system. It plays a unique role in providing a protective barrier to the body. Stimulating nerve endings within the skin at particular points is believed to effect changes in internal organs. Similarly, stimulating active points on the skin via electric impulses which follow the pattern of those of the central nervous system is hypothesized to stimulate and optimize the regulatory functions of the nervous system restoring health.

FIRSTtx therapy functions on two physiological principles: that the body has its own healing capabilities and that we can promote this ability to heal by stimulation of the areas of the brain responsible for regulation of the autonomic nervous system and homeostasis. FIRSTtx technology, which is a therapeutic electrotherapy delivered via the skin, is hypothesized to produce both local effects - by stimulating the skin, muscle and blood vessels - as well as a general influence - by an effect on nervous and endocrine systems. It is further hypothesized that the pattern of FIRSTtx impulses stimulates nervous pathways via active points in the skin in an effort to restore and to improve the regulation of the disease-affected organs and tissues. The FIRSTtx device function is aimed at stimulating the skin surface with specifically shaped impulses.

Constant measurement of electric skin parameters enables an intelligent feedback mechanism via a patented modulation algorithm. The FIRSTtx device is a small, hand-held device with a transdermal electroneurostimulator, with LED lights and audible indications. It delivers non-invasive, computermodulated therapeutic neurostimulation via a client's skin and involves high amplitude, short-duration waveforms with little discomfort to clients. These waveforms stimulate both the A delta fibers, responsible for the quick, shallow first pain, and the C fibers, known to maintain the state of hyper-excitability of the painful area and the spread of the hyperalgesic state to nearby neurons.

It has been shown that an electrical stimulus activates C fibers when an intensity higher than the threshold for A fibers is used. Due to the device's delivery of high amplitude oscillating waveforms in millisecond dosages, small unmyelinated C fibers can be stimulated to a higher degree than with other forms of electrotherapy. Stimulation of 'C' fibers has been shown to activate the right and left

anterior insula and the frontal operculum of the brain. The anterior insula are responsible for perception of pain and the maintenance of homeostasis within the body. [9]

When sufficiently stimulated, 'C' fibers also trigger local neuro- and regulative-peptide release with resultant pain relief and healing.

The FIRSTtx impulse is carried via afferent nerve fibers to regulatory centers in the brain which in turn responds via efferent nerve fibers. The FIRSTtx interprets this response and, via computer modulation, results in its next impulse being modified accordingly which further provides information back to the brain to either amplify or dampen the pathological signals initiating pain.

FIRSTtx technology relies on the body's mechanism of adaptation ensuring dynamic equilibrium or, homeostasis. This regulation is achieved through close connection and interaction of the nervous, endocrine and immune systems. These systems communicate through the release of biologically active chemical modulators called neuromediators. Peripheral electrical stimulation promotes the release of endogenous opioid peptides such as enkephalins, endorphins, and dynorphins [10] and sensory neuropeptides such as Substance P and Calcitonin Gene-Related Peptide. [11]

The main goal of FIRSTtx therapy is that a maximum number of C-fibers are activated to induce the secretion of a sufficient amount of neuropeptides. This is achieved by active feedback and bipolar electric impulse.

Active Feedback

The FIRSTtx is a system of monitoring and response. The most unique characteristic of the FIRSTtx is that it can locate, measure and treat with its biofeedback micro current. The FIRSTtx can induce changes in the parameters of its impulse automatically and in accordance with the body's response to the device. While conventional therapeutic devices are passive, the FIRSTtx involves active reflex biofeedback, which means that the FIRSTtx device communicates actively with the processes that are happening in the body.

The FIRSTtx device does this by monitoring the skin's impedance and then changing the electric impulse it is sending out in order to optimize the response at the epidermis. Therefore active reflex biofeedback means that maximal therapeutic effectiveness can be achieved with each individual.

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Bipolar Electric Impulses

The characteristics of the FIRSTtx impulse are such that the probability of excitation of the thin neuropeptide-secreting C-fibers is higher than conventional methods of electrotherapy [12] [13] [14].

The electrical signals generated by the FIRSTtx device are similar in form to the body's own endogenous neurological impulses. In this way the body does not recognize them as alien or invasive therefore negative side effects as a result of FIRSTtx therapy are few.

An important and unique characteristic of FIRSTtx is that it is independent of any other devices. It is physically controlled by a trained therapist who observes the therapy process and ensures the device's function. In this way the patient, the device and the therapist create a 'therapy triangle'. This therapy triangle is essential for *correcting* the disturbed function of the body and for *completing* the adaptive reactions of the body, resulting in the restoration of homeostasis.

FIRSTtx Therapy

The FIRSTtx device is small, portable, user-friendly, and is relatively low-cost. Patients may benefit from faster recovery times, versatility and fewer concurrent medication interactions. The FIRSTtx device can be used for pain relief regardless of the type of diagnosis and is therefore a non-specific approach. However depending on the complaint or ailment of the patient the therapist can choose the dosage of FIRSTtx or the direction in which FIRSTtx is applied. Clinical experience with the FIRSTtx device has further indicated that the optimal therapeutic effect is achieved when there is a maximal variability of the impulse during therapy [15] [16] [17]. The optimum therapeutic results are always dependent upon the patient's body response and therefore individual to each patient. As the FIRSTtx device monitors and evaluates therapy results it independently delivers the correct impulse without the possibility of overdosing and therefore reduces the risk of side effects.

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FIRSTtx therapy protocols include rating of pain, measurement of range of movement and testing of movement related to functional impairment.

Indications

The FIRSTtx is indicated for acute and chronic pain. Treatment areas can include where a patient is experiencing knee, shoulder, or other joint pain, neck and back pain, pre and post operative pain or plantar fasciitis pain.

Treatment can also include areas of the body where swelling or loss of sensation is evident. Other indications include areas with pain near wounds, rashes, ulcers, scars and areas of skin discoloration. Please take particular note of the contraindications. (Pg. 9)

Potential Side Effects

Side effects are rare, however some can occur within a few hours of therapy; These can include changes in skin colour (paler or increased redness), or an increase in pain, itching or loss of skin sensitivity. These effects can be observed in the area directly being treated or in other areas of the body, however they are generally short lived and normally subside within a few hours

Normal Device Characteristics

Individual characteristics can be observed emanating directly from the device, or as a result of contact with the patient, and can include the appearance (or disappearance) of a humming sound, the presence of ‘stickiness’ or indeed smoother movement of the electrode as it is being used, meaning that these zones may require a shorter therapy time.

Observed Clinical Treatment Responses to FIRSTtx therapy

- Pain Relief;
- Autonomic responses from the patient;
  - *Sympathetic* – in some cases patients may begin to perspire, heart beat and blood pressure increases slightly, and the patient feels warm ,
  - *Parasympathetic* – after 10 to 15 minutes of FIRSTtx therapy, most patients become relaxed, their heartbeat slightly decreases, and their blood pressure normalizes;
- Post FIRSTtx therapy– many patients report having prolonged deep sleep 'first time in years'
- Range of motion increases due to muscular relaxation;
- Microcirculation – increased – directly under the FIRSTtx electrode one can see erythema after a few minutes of application;
- Feelings of well-being, lightness, relaxed, sleepy or energized.

Contraindications

There are specific contraindications including: for patients who have any type of cardiac pacemaker, patients who are prone to seizures, (e.g. epileptic seizures), or intoxicated individuals.

In addition, placement of the FIRSTtx electrode over malignant tumors or open wounds is also contraindicated.

It is important to note however that FIRSTtx therapy is not contraindicated for patients who have metallic implants such as pins, plates, and screws nor is it contraindicated for clients who have had joint replacements.

Cautions

The FIRSTtx electrodes should not come in contact with wet skin, however natural body secretions such as sweat are acceptable. It is also recommended that jewelry be removed prior to application of the FIRSTtx.

Particular caution should be taken when FIRSTtx electrodes are placed over areas associated with phlebitis and thrombophlebitis as these conditions have increased chance of blood clot formation which could become dislodged during FIRSTtx therapy.

It is important to note that therapy sessions with the FIRSTtx should not exceed 45 minutes to any specific area of the body and that there should be a minimum of two hours between therapy sessions to avoid skin irritation.