THE FUNDAMENTALS OF ...
TENS Units

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About the Author

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One can find peripheral nerve stimulators, in one form or another, throughout today's healthcare facility. Small bipolar peripheral nerve stimulators are used by anesthesiologists and anesthetists to assess the level of patient consciousness. These units have no wave shaping, amplitude, or pulse width controls, but instead have a single momentary push button switch and generate their output via simple ball electrodes at the end of a pair of one-inch long metal probes. The opposite end of the spectrum includes the built-in nerve stimulator employed in electromyography. However, probably the most common peripheral nerve stimulator used in healthcare is the transcutaneous electrical nerve stimulation (TENS) unit. The TENS unit is used either with analgesics or alone to relieve both acute and chronic pain associated with a number of conditions, including surgery and trauma.

In 1965, Ronald Melzack and Patrick D. Wall, both MDs, proposed the gate control theory to explain the action of a TENS unit. The gate control theory states that the number of impulses along the small-diameter, pain-carrying nerve fibers is equal to the number of impulses along the large-diameter sensory fibers that converge at the transmission cell in the dorsal horn of the spinal cord. They hypothesized that when the number of impulses through each fiber is equal, pain does not reach the brain. Further, when the number of impulses through the pain-carrying nerve fibers increases, a "gate" opens allowing the impulses to reach the brain and triggering the perception of pain. The doctors further believed that increasing the number of impulses stimulating the large-diameter sensory fibers would restore the balance, close the gate, and stop the perception of pain. They provided this stimulation with a modified pulse generator.

A relatively more recent and simpler theory explaining why a TENS unit relieves pain is the endorphin/enkephalin theory. This theory is based upon the proven fact that endorphins (endogenous morphine-like peptides) and enkephalins (opioid neurotransmitters) control pain perception and endorphins are often considered the body's natural painkillers.

The endorphin/enkephalin theory is based upon the belief that a TENS unit aggravates tissue, thus causing the release of endorphins and enkephalins. (Capsaicin-based analgesic creams rely on this same principle, except that they chemically irritate surface tissue, causing the subsequent release of endorphins and enkephalins, and relieving pain in the area of application. Capsaicin is the component of hot peppers that causes the "heat.") These, in turn, inhibit the release of the chemical neurotransmitter that allows pain impulses to be carried to the brain.

Although both theories are plausible, neither has been definitively proven nor dispelled. No one knows exactly why TENS units relieve pain because they do not always relieve the same

pain (chronic lower back pain, for example) in all patients. For some reason, TENS units relieve some pains for some people, but not for others. The primary advantage of using a TENS unit is that it is cost-effective, free of side effects, and non-addictive—unlike opioid-based pain killers. The downside to using a TENS unit is that the analgesic effect occurs only while the device is used. There is no residual pain relief once the unit is turned off or disconnected.

Current Technology

The typical TENS unit is handheld, portable, battery-powered, and is usually worn by the user either in a pocket or on their belt. It is roughly the shape and size of a cellular telephone and provides its output to either one or two channels, corresponding to either two or four electrodes connected to the patient's skin. Commensurate with their small size, the batteries used in TENS units range from the common 1.5 volt AA-size or 9 volt alkaline battery to their rechargeable nickel-cadmium (ni-cad) equivalents, to 3.6 volt lithium-ion (Li-Ion), and even 3 volt button cells. Depending on the design of the TENS unit, its operating settings, and the particular battery selection used, their operating time varies from three to 180 hours on a single battery or charge.

The output can be either monophasic (positive or negative) or biphasic (both), with the majority of units being biphasic. Most biphasic units produce a relatively brief positive pulse, followed immediately by a negative pulse with a slow decay. This sequence is repeated based upon the device's settings, which includes adjustments for pulse rate, width, and amplitude. Some units, depending on the manufacturer, provide variations of this waveform sequence, such as modified square wave and asymmetric biphasic outputs. The amount of power supplied is minimal, typically 10 to 130 milliamperes (mA) through 50 ohms (Ω), with pulse widths from 10 microseconds (μs) to 1 millisecond (ms) and frequency (of repetition) from 40 to 150 times per second (Hz).

The electrodes are either reusable or disposable, based upon individual preference. The most common reusable electrodes are composed of solid carbon-impregnated silicone rubber and require gelling prior to application. Other reusable electrodes include the foam-and-sponge type, which must be moistened with water before use, karaya (or sterculia) gum, or one of a various number of conductive adhesive synthetic polymers. Disposable electrodes are generally self-adhesive and require little or no preparation before application. Reusable electrodes are cheaper to use, but are less convenient since they require both pre-use preparation and post-use cleaning. Conversely, disposable electrodes are more costly, but also more convenient since they come ready to use and are simply discarded after use.

The electrodes are placed as directed by the prescriber, typically near or on either side of the painful area. Depending on the type and location of the pain, the electrodes are sometimes located either side of the spine, on acupuncture sites, in peripheral nerve areas, and at other trigger points on the body. In addition to electrode placement, the prescriber will also indicate the frequency, current, and pulse amplitude. The initial treatment with a TENS unit usually occurs in a clinical setting with the prescriber closely monitoring the patient to determine the optimum electrode placement and control settings, while assessing

A transcutaneous electrical nerve stimulation (TENS) unit is used to relieve both acute and chronic pain..

the patient's response to the stimulus. Once treatment efficacy has been determined, the prescriber gives the patient instructions for home use and they jointly establish a treatment schedule. The prescriber continues to monitor the patient and adjust treatment parameters as necessary.

How to Manage the Device

Since the cost of TENS units ranges from under $100 to several hundred dollars and very limited maintenance is possible, the device should be managed as other low-cost, non-critical medical equipment. That is, it may be managed as a durable item, only requiring preventive maintenance in conjunction with remedial maintenance, or it may be managed as a nonrepairable, virtually disposable item.

Upon receipt as a new item, performance should be benchmarked using a resistor decade box, oscilloscope, and camera or hardcopy printer. The TENS unit should be connected to the decade box as a dummy load (set for about 500 Ω), the controls set for biphase mode with analog settings approximately midrange, and the resultant waveform recorded with the camera or hardcopy printer. The key device identification information (locally assigned tracking number, manufacturer, model, and serial number) as well as the control settings should be documented on the back of the photograph. The photograph should be maintained as long as the item is in the equipment inventory and used for later comparison during performance of preventive maintenance and if required for litigation. After the initial benchmarking, minimal maintenance is necessary.

Regulations

TENs units are regulated by the Food and Drug Agency (FDA) as Class 2 medical devices. There is one standard promulgated by the Association for the Advancement of Medical Instrumentation, AAMI NS4:1986/2002, which establishes safety standard for TENS units. Among other things, the standard specifies minimum and maximum outputs for effective treatment and requires TENS units to contain circuitry to prevent life-threatening arrhythmias such as out-of-sequence heart beats, and ventricular fibrillation.

Risk Management Issues

Although no major hazards are associated with the use of TENS units, there are a number of precautions that must be observed. For example, high-output units must not be used across the chest since they can interfere with sinus rhythm. Some manufacturers also discourage TENS use over carotid nerves, especially around the laryngeal area because there is some evidence they could cause larynx spasms strong enough to occlude the airway. Likewise, TENS units must not be used over a pregnant uterus because their output, although low and does not harm the mother, may interfere with cardiac and fetal monitoring. There is always the chance of skin irritation at the electrode site caused by the gel, adhesive or perspiration. Shifting the electrodes to a different site every 24-hours usually helps to avoid the irritation. Additionally, users must ensure the correct type of battery is used. For example, one should never install a alkaline battery in place of a ni-cad, then attempt to use the charger supplied with the unit. Lastly, to avoid an unexpected user shock, many units employ circuitry which turns detects a high-impedance loop between the electrodes (which can be caused by the gel or sponge drying out or even the accidental disconnection of the electrode wire) and temporarily turns off the output.

Troubleshooting

Other than documenting the performance of the unit upon receipt, then referring back to the benchmarked data during future preventive maintenance sessions, there is very little the biomedical electronics technician can do with a TENS unit. The most common repairable "failures" are caused by worn and broken electrode wires or when the unit self-limits the output due to poor electrode contact. A dummy load and oscilloscope will quickly reveal whether there is anything wrong with the TENS unit. Typically they only break after suffering a severe fall, which causes one or more microscopic cracks on the printed circuit board (PCB), damages an integrated circuit (IC), or both. Most of the time, the labor cost of the time spent trying to locate and repair the crack without shorting other runs on the board approaches the point at which repair is not economical. Therefore, some shops have imposed a time limit on troubleshooting TENS units, at which time a new one should be purchased. Compounding their lack of reparability is the reluctance of TENS manufacturers to provide schematic diagrams and parts lists; often, only cosmetic (case) parts are available to the biomed.

Training and Equipment

Since schematic diagrams and internal repair lists are seldom available, and owing to their relatively low cost, only minimal service may be performed beyond benchmarking operation and replacing external components. Therefore, basic electronics training, sufficient to understand the basic operating principal of a TENS unit, and the skill to operate the required test equipment is all that is required to perform most of the necessary maintenance. That basic test equipment is a multimeter (for testing electrode leads), an oscilloscope, and either a camera that mounts to the oscilloscope or a hard-copy printer capable of preserving the waveform and its values.

Future Development

Although the basic design of the TENS unit has not changed since its inception, several safety features have been added, such as output limits and unanticipated shock protection, and this is now considered mature technology.

Origin and Evolution

By several accounts, the first recorded use of electrical stimulation for pain control was around 63 A.D., when Scribonius Largus reported that pain was relieved by standing on an electrical fish at the seashore. While one may debate whether this was the first true use of electrical stimulation to relieve pain, one will find that at various times throughout history, especially after the 16th century, numerous electrostatic devices were used to control pain and treat cancer. Probably because the Faradic Electrifier and the Oscilloclast—both devices claiming to cure a wide variety of unrelated ailments, even cancer—and many other devices like it are bogus, little serious research into the true value of electricity on the human body was performed until about 75 years ago.

Emerging from the plethora of medical device manufacturers prosecuted after the passage of the Food, Drug, and Cosmetic Act in 1938, the manufacturer of the Electreat was forced to limit its claims only to the relief of pain. No doubt, noteworthy users of the device, such as neurosurgeon C. Norman Shealy, continued using this device in private practice. Based upon his experience and that of others, Shealy approached Medtronic and persuaded them to begin developing solid-state TENS devices. They obtained their first of many patents on TENS units in 1974. Thereafter, they and competitors in the marketplace developed smaller and more sophisticated units as advances in electronics would permit.

Early TENS units were barely able to be worn and were comprised of discreet components assembled using conventional single-layer PCBs. However, as technology increased, individual components not only became smaller, but entire portions of a circuit were replaced by a single integrated circuit (IC). Modern TENS units are either composed of several custom ICs soldered to a multilayer PCB or are microprocessor-controlled devices. In either case, their continued evolution will be dependent upon advances in the general electronics field. ■

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