Evaluation of Transcutaneous Electrical Nerve Stimulation (TENS) vs. Biofreeze® in the Treatment of Back Pain

Jay Greenstein, DC, CCSP, CGFI-L1, CKTP*; Barton N. Bishop, PT, DPT, CSCS, SCS, CGFI-L2, CKTP*; Robert Topp, PhD ^

*Sport and Spine Rehab Clinical Research Foundation, a 501-C3
^Marquette University, Department of Nursing

Introduction: TENS is a commonly used physical therapy modality for both in-office care and home care. The neurophysiological basis of the analgesic action of TENS remains under investigation, yet there are two popular theories to explain how TENS successfully decreases or eliminates pain. (1) The Endorphin Release Theory suggests that electrical impulses stimulate the production of endorphins and enkaphalins in the body. These natural, morphine-like substances block pain messages from reaching the brain, in a similar fashion to conventional drug therapy, but without the danger of dependence or other side effects. (2)The Gate Control Theory is the most commonly advanced explanation, suggesting that by electrically stimulating sensory nerve receptors, a gate mechanism is closed in a segment of the spinal cord, preventing pain-carrying messages from reaching the brain and blocking the perception of pain. Biofreeze®, a topical analgesic, is also thought to decrease pain through the Gate Control Theory. With the application of Biofreeze®, the menthol acts to stimulate specific temperature receptors in the skin. The neurologic mechanism of the "gate" is the same, but the sensory information is temperature input instead of electrical input. Further, the "cooling" affect has been shown to provide temporary vasoconstrictionand may inhibit the inflammatory response which may also reduce pain

Methods: Sport and Spine Rehab back pain patients who agree to participate in the study and meet the inclusion and exclusion criteria of the study are currently being randomized into either a Funhab® plus TENS group or a Funhab® plus Biofreeze group. The Funhab® protocol (Sports and Spine Rehab Holdings Inc., Fort Washington)is an evidenced-driven rehab protocol to maximize appropriate clinical tools inclusive of manual therapies, physiotherapies and rehabilitative functional exercises. This protocol consists of an exercise treatment and progression that addresses local, regional and global neuro-musculoskeletal dysfunction of the back by incorporating both the biomechanical (Range of Motion, joint mobility etc.) and neurological (proprioception, coordination etc.) components of rehabilitation. In addition to manual therapy and physiotherapies, the Funhab® protocol(Sports and Spine Rehab Holdings Inc., Fort Washington) takes the patient through postural, local, regional and then full body exercise progressions to maximize their overall level of function and correct muscular imbalances and dysfunctions. In addition to each group receiving Funhab® their specific group treatments are applied according to standard clinical guidelines. The TENS group applies their treatment once per day for 15 minutes to the area of pain. The Biofreeze applies their treatment three times daily to the area of pain. Variables concerning the patient's pain, fear avoidance scores, and disability are collected prior to and following a standard course of treatment. Statistical analysis will be performed to assess clinically and statistically significant changes in groups and between groups.

Hypothesis: Back pain patients who use Biofreeze® will report less pain, fear avoidance, and disability compared to back pain patients who use TENS .

Results: A total of 41 back pain patients have completed the trial, with 20 in the Biofreeze® group and 21 in the TENS group. There were 11 females who completed the trial, with seven in the Biofreeze® group and four in the TENS group. There were 30 males who completed the trial, with 13 in the Biofreeze® group and 17 in the TENS group. The following are the reported results:
There was a significant difference in the patients completing the clinical protocol ("completers") and patients who did not complete the clinical protocol ("self-discharges"). Seventy percent of the back pain patients who were assigned the Biofreeze® treatment self-discharged while only 23.8% of back pain patients receiving the TENS self-discharged. There was a similar gender distribution between completers and self-dischargers. The average number of visits for the completers was 12.23. The average number of visits for self-discharges was 4.06. Of the subgroup of back pain patients that completed care, the patients who received the TENS intervention reported a significant decline in their disability scores (Oswestry and FABQPA) while the

group receiving the Biofreeze did not statistically change either of these disability scores and were not statistically different on these disability scores compared to the TENS group following the trial. The group who received the Biofreeze® significantly decreased their disability (FABQPW) over the duration of the trial while the TENS group did not but not to a level which was significantly different than the TENS group at the end of the trial. Finally, both groups exhibited similar significant declines in their reported back pain over the duration of the trial.

COST DATA: Of the subjects who completed the trial, the patients who received the TENS attended an average of ~13% more visits than the Bio Freeze group. The average number of visits for the TENS group was 12. The average number of visits for Biofreeze® completers was 10.63. The average cost of the Funhab® usual care of $100, thus for this trial the average total cost for care was $1062 +15 = $1077 for the Biofreeze group and $1275 for the TENS group, representing a 18.3% higher cost for the TENS group as compared to the Biofreeze group.
Direct Cost Analysis: The cost of Biofreeze® in the trial was $15 per patient. The total cost in the TENS group was $75 per patient. Thus, the cost of Biofreeze is 1/5 the total cost of TENS to obtain similar clinical improvements in disability and reductions in pain.

Conclusions: 41 of a proposed number of subjects have entered into and completed the study. To this point, both Biofreeze and TENS groups had statistically similar outcomes for pain, disability and fear avoidance at completion of their care. Given the significant cost savings for Biofreeze®, it would seem to be a prudent choice to incorporate in patient care as an effective replacement of TENS.