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

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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 vasoconstriction, thus inhibiting the inflammatory response which may also reduce pain

Methods: Sport and Spine Rehab neck pain patients who agree to participate in the study and meet the inclusion and exclusion criteria of the study will be randomized into either a TENS group or a Biofreeze group. Application of the treatment will be given according to current standards. Pain scores will be provided immediately pre-application and 10 minutes after the initiation of treatment. No other treatment intervention will be performed prior to either the application of Biofreeze® or TENS. Statistical analysis will be performed to assess clinically and statistically significant changes in groups and between groups.

Hypothesis: Biofreeze® will reduce pain, fear avoidance scores, and disability scores greater than TENS that is both clinically and statistically significant.

Results: To date, there are 16 subjects enrolled in the trial. See tables below.

Conclusions: With 16 subjects entered into the study, we have four completed, four self discharges and eight still in data collection. Basic metrics have been presented in this abstract. It is still too early to determine the treatment group with the best outcome for pain, disability and fear avoidance. Larger data samples will be presented at TRAC. Based on projections for completion of care, data should be presented on approximately six to eight patients.

Study Characteristics - All	Value
Average Age	35.1
Males	12
Females	4
Average BMI	27.2
TENS Group	8
Biofreeze Group	8
Average Days Since Onset	153
Average Number of Treatments	6.75
Manipulation:Non Manipulation Ratio	12:4
Funhab® Progression	7.875
Self Discharges (All Biofreeze®)	4

Study Characteristics - Completed	Value
Average Age	45.75
Males	3
Females	1
Average BMI	29.75
TENS Group	4
Biofreeze Group	0
Average Days Since Onset	217
Average Number of Treatments	11.5
Manipulation:Non Manipulation Ratio	100:0
Funhab® Progression	8.75
Self Discharges (All Biofreeze®)	4

TENS GROUP (n=4)				
Initial Outcome	Score	Final Outcome	Score	Percent Change
Average Initial Oswestry	28	Average Final Oswestry	0.67	98%
Average Initial FABQ (W)	9	Average Final FABQ (W)	12.67	-41%
Average Initial FABQ (PA)	17.75	Average Final FABQ (PA)	11.67	34%
Average Initial VAS	6.25	Average Final VAS	0.5	92%