# A Double-Blind Comparative Study of
# Micro Stimulation and Placebo Effect
## In Short Term Treatment of the Chronic Back Pain Patient

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Reprinted from California Health Review
Vol 2 No. 1 August/September 1983


## ABSTRACT

Back pain is one of the most prevalent of all the psycho-physiological disabilities. It is estimated that more than 15% of all the industrial injuries and more than 20% of all compensation payments made in any given year are due to back pain and its associated anxiety (1). In general, these patients have been the domain of general practitioners or orthopedic surgeons. In some cases, pain relief may follow the administration of analgesic medication, chemopapain injections, facet rhizotomies and cordotomies. These often prove to be ineffective methods of long term pain relief (2, 3). As the facts are assembled, the chronic back pain patient appears to be highly refractory to rehabilitation of either conservative management or surgical methods.

The recent interest of physicians in managing chronic pain patients is evidenced by the growing number of pain centers, and devices for use by such patients. Significant advances have been made in computer technology, electronics and methods of applied electrostimulation over the past few years. The purpose of this study is to evaluate the effectiveness of pain management based on transcutaneous electrical nerve stimulation (TENS) utilizing a newly developed apparatus with non-invasive microcurrent characteristics.

Forty subjects with chronic back pain were divided into two groups—one received real stimulation, and the other placebo. The subjects in the real group experienced an average pain reduction of 37.26% greater than the placebo group. A two month follow-up showed a significant difference, 75.22% pain reduction in the real, and 6.30% pain reduction in the placebo group.


## INTRODUCTION

Pain is a subjective experience which we are only beginning to understand. An integrated pain mechanism would have to include biochemical, neurological, emotional, motivational and cognitive components. It is only useful as a "warning signal" when it is the symptom of an acute disorder or where it can be used for diagnostic purposes. Chronic pain of arthritis, myofasciitis, migraine headaches, etc. does not serve any useful purpose.

It has been estimated that chronic pain costs run the American people between $33 and $50 billion annually, with a three to fivefold increase during the past four years (4). Back injuries are the major industrial disabler affecting an estimated 6.5 million people daily (5).

It would be impossible to estimate the cost of the "ordinary" tension headache, but no one who has experienced one would debate that such pain decreases the sufferer's productivity, and enjoyment of life. Prescription drug abuse is another significant problem in patients with chronic pain. In many cases when medical and surgical efforts do not relieve the pain, patients still insist on increased doses of medication. A study at the Mayo Clinic of 144 patients with chronic pain showed 24% to be drug-dependent, and 41% to be drug abusers (6).

Transcutaneous Electrical Nerve Stimulation (TENS) has produced a great deal of interest in the past two decades, since publication of the Nobel Prize winning "Gate Control Theory" in 1965 (7). That theory suggests a convergence of different kinds of signals, afferent and efferent which monitor and regulate incoming afferents. Counterirritation by electrical stimulation, or other means, could then be understood to modulate our pain perception.

In more recent years, Becker has shown electrical stimulation to do more than simply "mask" the pain. In over 130 articles, he has postulated that control signals for regenerative healing may be due to bioelectrical activity (8).

TENS is rapidly proving itself to be an effective, cost efficient means of management for the chronic pain patient. This patient population, however, has been associated with significant psychopathology and the results of studies without controls may be misleading (9). This study involves a modified double-blind placebo methodology in that neither the therapists working directly with the subjects nor the subjects themselves knew which instrument was emitting real current characteristics.

## MATERIALS AND METHODS

We selected case-control (retrospective) research strategy as the most useful method to obtain cases of neuromusculoskeletal back pain syndromes. 201 cases of chronic neuromusculoskeletal back pain (12 months) were seen throughout the past year. The records were reviewed by significant underlying pathology and potential psychophysiological factors. Age, sex, education, marital status, employment, medical history, location of pain, and general compliance were also taken into account. 78 cases were determined to be potential subjects and were contacted for participation in the study. 40 were chosen (Table One) on the basis of the Chronic Pain Characteristic Profile (Table Two), Frequency (Figure A) and Severity (Figure B) Pain Charts, absence of unrelated significant complicating factors, and willingness to participate.

All patients had chronic, persistent (50 hours per week) neuromusculoskeletal back pain with few, if any remissions. Their ages ranged from 19 to 63 with an average of 38.3 years. 58% were female. 20 were on analgesic or other medications, and 18 had 1 or more previous surgeries. The majority 25 (63%) had low back pain, and 15 (37%) had neck, shoulder, or upper back pain (above the level of the seventh thoracic dermatome). 31 (78%) had headaches and 26 (65%) had extremity pain. All subjects provided statements of informed consent, completed an extensive history and were given a brief examination. The subjects were not offered any pay.

The 40 subjects were given an hourly pain evaluation chart to fill out daily for two weeks prior to the initiation of therapy (Figure C). They were asked to refrain from charting unrelated distant pains. The charts were computed for an hourly average per total waking hours in the following manner:

$$(1\times6) + (2\times4) + (3\times3) + (4\times3) + (5\times0) + 16 = 2.19$$

The average of 2.19 corresponding to the sample chart would indicate an extremely high level of painful activity with pain during each waking hour (16 total waking hours). At the end of each week, scores were calculated into a simple average of the seven daily scores for that subject. The first two weeks allowed for the establishment of a baseline of the level of pain. This was then used to divide the subjects into real and placebo groups.

These charts were used during the actual two week treatment period, two weeks after treatment, and again for an additional two weeks following a "washout" period of two months.

The ELECTRO-ACUSCOPE manufactured by Biomedical Design Instruments of Burbank, California, was used in measuring treatment sites and to actually administer the treatment. The ELECTRO-ACUSCOPE has two active probes which generate a biphasic (alternating) current of 25-500 microamperes (uA)* with variable frequency of 0.5 to 320 cycles per second (Hz) through solution saturated cotton tipped electrodes. The electrolyte solution allows for maximal conductance without any apparent irritation to the skin. Impedence values** of 0-3 volts (maximum) may be measured by the same probes when the instrument is on and the treatment cycle switch is not activated. Less than one microampere is used in measurement. A placebo probe was built into an identical second unit allowing impedence values to be read while eliminating the ability to transmit current.

The subject and therapist administering the treatment were both naive as to which unit was real in that the only physical difference was the manufacturer's serial numbers.

Measurements were taken of 16 low conductive points (eight bilaterally) between three and eight centimeters lateral to the posterior midline and on the extremities. In subjects with scoliosis, the palpable spinous processes were substituted for the midline. 14 points were used in the following manner; neurologic and orthopedic tests were used in conjunction with the subjects subjective appraisal to locate the involved dermatome(s). After isolating the primary area of involvement, measurements were taken for low impedence values three to eight centimeters bilateral at the level of involvement, three levels above, three levels below and one within the dermatome on the related extremity (Figure D). The sites were chosen on the basis of neuroanatomic distribution (dorsolateral fasciculus) and suggested standardized TENS placement sites (10).

The advantage of stimulating low impedence sites is based on the clinical experience and observations of the authors and laboratory evidence of differences in measurable skin impedence (11). It has been our observation that introducing a current into the areas where it is low is more beneficial than stimulating areas that already exhibit relatively high conductance.

The 16 sites were marked with a non-toxic violet skin marking pen. No stimulation was done during this time. After all sites were marked, the meter was covered with an opaque black cloth and the audio feedback was turned off. This eliminated the possibility of determination of post-stimulation impedence value changes allowing the subject or therapist to differentiate the placebo unit from the real unit.

The therapist then stimulated the subjects at the marked sites. Each site received two, six-second treatments with the instrument set at the maximum calibrated current and a frequency of 0.5 Hz. Since the feedback potential was eliminated and the waveform of the real ACUSCOPE is imperceivable at a conscious sensory level, there was no break in the double blind design. To further insure this, the therapist and subject were not permitted to converse about any immediatley noticeable improvement. The subjects were stimulated in this manner three times per week for two weeks.

## RESULTS

The results of the daily pain charts for each group were again averaged into four categories of two weeks each (Table Three).

The initial data analysis showed the differences in the responses of males with females and subjects experiencing upper or lower back pain were of neither statistical (P 0.05) or clinical significance.

The differences of the two groups averaged overall response was significant (Tables Three, Four and Graphs One and Two). The differences in the results confirmed the study of the placebo effect of TENS at the Mayo Clinic (12) and was consistent with double-blind studies where placebo medications were used (13).

The transient decrease of pain of the subjects in the placebo group was probably due to the expectations of the subjects as well as the attention given by the therapist.

In studying the placebo effect at Harvard, Benson & Epstein concluded that placebos, like other pain medications, can be powerful enough to modify physiological processes (14).

Another possible explanation for the temporary change in the placebo group could be the minute current (1uA) used in measurements.

The results were better than reported in previous studies using TENS in the management of chronic pain (15, 16). TENS units were originally designed with relatively crude components as testing devices for implantation surgery (17). During the time they developed into a therapeutic instrument, many advances were made in electronic instrumentation. The ELECTRO-ACUSCOPE is one of the more advanced TENS units available. The ability to measure and treat low impedence areas may account for the better results and we are currently comparing the effects of stimulation at high and low conductive sites.

The use of low frequency stimulation is another factor that may have influenced the results. We used one setting to eliminate a variable. 0.5 Hz was the recommended setting, but a future study using systematic variations of frequency may reveal more useful data.

This study clearly shows that utilizing a simple procedure, TENS can be of benefit for the chronic pain patient. It appears to be safe and efficacious enough for every physician or qualified paramedical personnel to employ in the primary care practitioner's office.

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Choose one word group which best describes the frequency or pattern of your pain:

_____ Continuous, Steady, Constant

_____ Rhythmic, Periodic, Intermittant

_____ Brief, Momentary, Transient

FIGURE A: Frequency Pain Chart

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The following words represent pain of increasing intensity.

1. Mild
2. Discomforting
3. Distressing
4. Horrible
5. Excruciating

Choose the number of the word which best describes:

_____ Your pain right now

_____ Your pain at its worst

_____ Your pain at its least

_____ The worst toothache you ever had

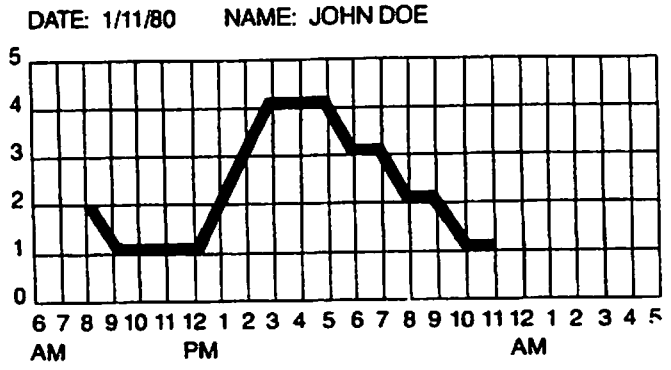
_____ The worst headache you ever had

_____ The worst stomachache you ever had

FIGURE B: Severity Pain Chart

*Non-resistive values

**Impedence is the measure of the resistance between probes




1-5 INDICATES THE INTENSITY OF PAIN BASED ON THE FOLLOWING CRITERIA

Line 5 excruciating pain, often debilitating

Line 4 intolerable pain, concentration difficult, able to perform certain tasks of an undemanding nature

Line 3 distressing pain, but able to continue tasks

Line 2 discomforting pain which may be ignored at times

Line 1 mild pain, only aware of it at times when attention is brought to it

Line 0 no pain

FIGURE C: Sample Graph of a hypothetical case (see text)

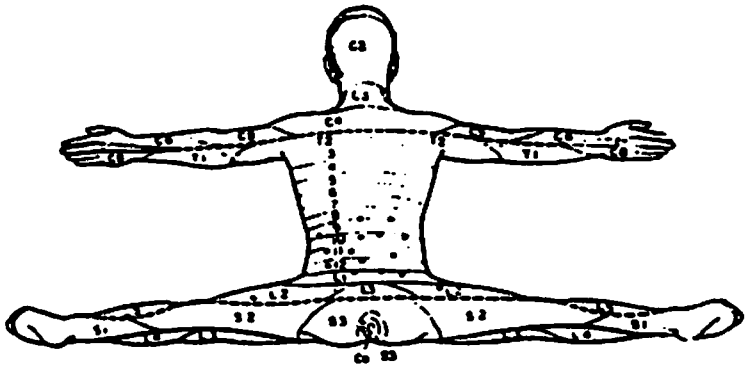
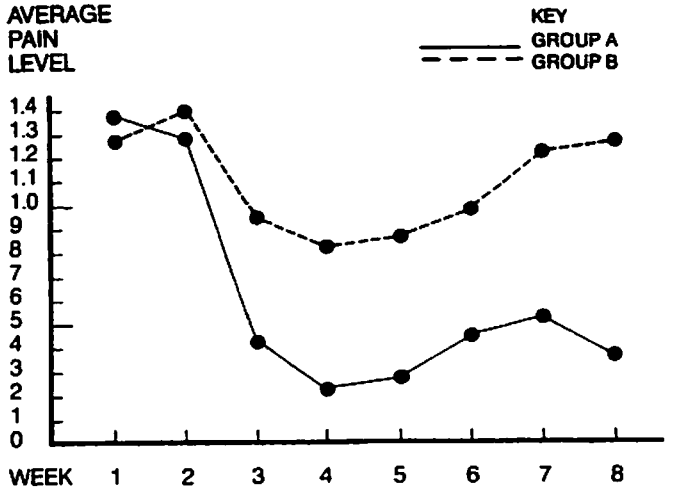
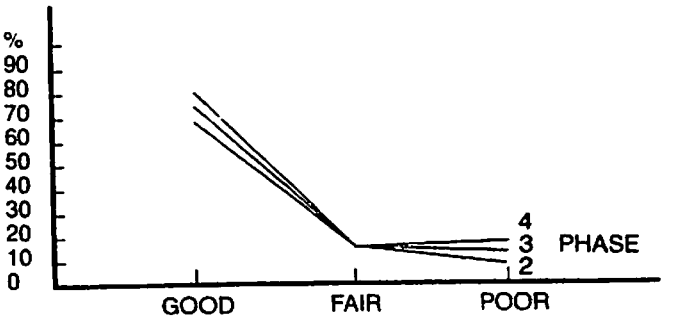
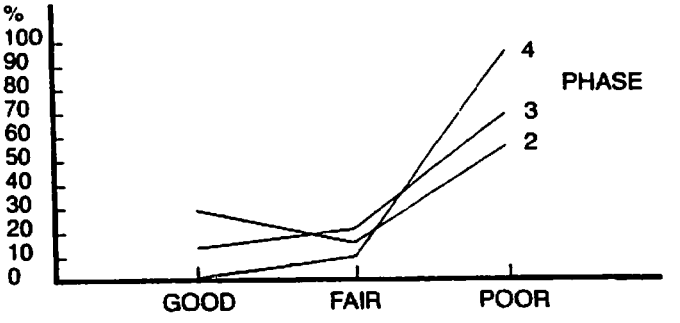


FIGURE D: Example of the 16 measured low impedence electrode placement sites in subject with low back pain.




GRAPH ONE: Average pain level over eight week period.
Group A = real, Group B = placebo
Key: week 1-2 = phase 1; week 3-4 = phase 2;
week 5-6 = phase 3; week 7-8 = phase 4.




GRAPH TWO: Percentage of pain decrease from baseline levels. Top = real; bottom = placebo. Good 70-100%; Fair 30-74.9%; Poor 0-49.9%. Key: phase 2) treatment phase; 3) post treatment phase; and 4) 2 month follow-up.

40 PATIENTS 1st 20—Real 2nd 20—Control

| | SEX | AGE | EDUCATION | MARITAL STATUS | UNEMPLOYED | NUMBER OF MEDS | OPERATIONS | LOCATION OF PAIN* |
|---|---|---|---|---|---|---|---|---|
| 1 | M | 19 | 12 | S | X | 1 | 1 | U |
| 2 | F | 26 | 08 | S | | 0 | 0 | U |
| 3 | F | 20 | 16 | M | | 0 | 2 | L |
| 4 | F | 40 | 20 | M | | 2 | 1 | L |
| 5 | M | 48 | 08 | M | | 3 | 0 | U |
| 6 | F | 50 | 12 | M | X | 2 | 0 | L |
| 7 | M | 62 | 12 | M | | 1 | 0 | L |
| 8 | F | 31 | 12 | M | X | 1 | 0 | L |
| 9 | F | 20 | 11 | S | | 0 | 1 | U |
| 10 | M | 26 | 14 | M | | 0 | 0 | L |
| 11 | F | 32 | 16 | M | X | 0 | 0 | U |
| 12 | F | 36 | 10 | M | X | 0 | 0 | L |
| 13 | F | 41 | 12 | M | | 1 | 2 | L |
| 14 | M | 40 | 13 | M | | 0 | 1 | U |
| 15 | M | 19 | 14 | M | | 2 | 0 | L |
| 16 | F | 28 | 16 | M | X | 4 | 0 | U |
| 17 | F | 50 | 20 | S | | 0 | 1 | L |
| 18 | M | 63 | 15 | M | | 3 | 0 | L |
| 19 | F | 35 | 12 | S | | 0 | 1 | L |
| 20 | M | 62 | 11 | M | X | 0 | 2 | L |
| 21 | M | 31 | 12 | M | | 1 | 0 | U |
| 22 | F | 28 | 16 | S | X | 0 | 0 | U |
| 23 | M | 40 | 18 | M | | 0 | 0 | U |
| 24 | F | 56 | 20 | M | X | 0 | 1 | L |
| 25 | M | 39 | 08 | M | | 1 | 0 | L |
| 26 | F | 60 | 08 | M | | 1 | 0 | L |
| 27 | F | 28 | 12 | S | X | 1 | 0 | L |
| 28 | F | 46 | 06 | M | | 2 | 0 | L |
| 29 | M | 31 | 12 | M | | 0 | 1 | U |
| 30 | M | 29 | 16 | M | | 5 | 1 | L |
| 31 | M | 19 | 14 | S | | 0 | 0 | L |
| 32 | F | 22 | 20 | M | | 2 | 2 | U |
| 33 | M | 50 | 24 | M | | 1 | 1 | L |
| 34 | F | 28 | 10 | M | X | 0 | 0 | U |
| 35 | F | 34 | 12 | M | | 0 | 1 | L |
| 36 | F | 39 | 12 | M | X | 3 | 1 | U |
| 37 | F | 43 | 14 | S | | 0 | 3 | L |
| 38 | M | 59 | 14 | M | | 0 | 0 | L |
| 39 | F | 61 | 08 | M | X | 0 | 0 | U |
| 40 | M | 40 | 11 | M | | 1 | 1 | L |

* U = Upper back (T-7)
L = Lower back (T-7)

TABLE ONE: Intake Date of the 40 Subjects

1. Persistent Pain
2. Sleep Problems
3. Change in appetite
4. Fatigue
5. Depressed mood (pessimism)
6. Chronic anxiety
7. Mypochondriasis
8. Loss of interest in social activities
9. Breakdown of family relationships
10. Multiple drug use or abuse
11. Reduction in physical activity
12. Increased time spent in bed or lying down
13. Reduction in sexual activity
14. Changes in normal recreational pursuits

TABLE TWO: Chronic Pain Characteristic Profile

(Modified from Feuerstein, M. and Akjel, E., Mastering Pain Bantam Books 1979)

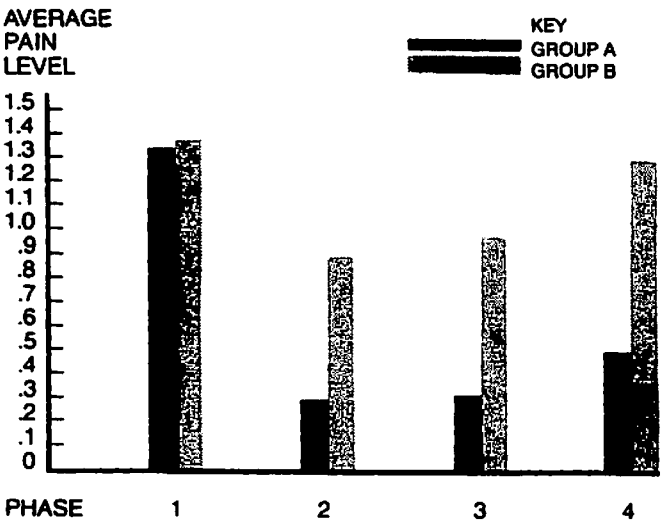



TABLE THREE: Pain scores averaged per two week period. Group A = real; B = placebo. Key: Phase 1) pre-treatment baseline; 2) treatment phase; 3) post treatment phase; and 4) 2 month follow-up.

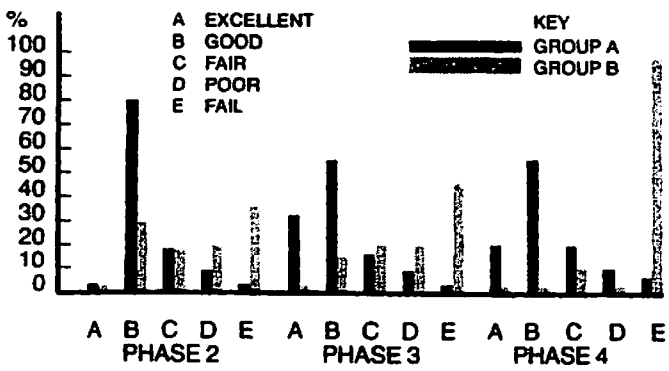



TABLE FOUR: Overall results calculated from baseline to show % failed and complete recovery. Group A = real; Group B = placebo. Excellent 100%; good 75-99.9%; fair 50-74.9%; poor 25-49.9%; and fail 0-24.9%. Key: Phase 2) treatment phase; 3) post treatment phase; and 4) 2 month follow-up.

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