BIOFEEDBACK AND ELECTROMEDICINE

Reduce the Cycle of Pain-Spasm-Pain in Low-Back Patients

STEPHEN I. ZIMMERMAN, R.P.T., Ph.D. and FRED N. LERNER, Ph.D.

This study investigated the relative efficacy of three treatment conditions/modalities, namely EMG biofeedback, microcurrent stimulation and the combined effect of the two, implemented for the purpose of alleviating and/or inhibiting chronic pain and associated muscle spasms, the two major components found within the "Vicious Cycle". Measures used to assess treatment outcome included Subjective Units of Disturbance (SUDS), trunk mobility evaluation, daily

pain record cards, microvoltage readings and pre- and post-treatment MMPI. Objective and subjective assessment and subsequent relative statistical analysis of findings demonstrated rehabilitative benefits in all treatment groups. The Biofeedback/Electrical Stimulation groups achieved, overall, greater therapeutic benefits than either modality used as a sole source of rehabilitation for the patient in the midst of the vicious cycle of pain and spasm.

The "vicious cycle of pain-spasm-pain" is a commonly occurring syndrome that is functionally inhibitive and relentlessly painful for patients with low-back involvement. A number of opinions concerning its etiology and treatment regime have been offered, some of which contradict and offset each other. The main purpose and most important aspect of this study is to establish and implement a treatment regime directed at countering this cycle's two main components—muscle spasm and associated pain.

Within the United States, low-back pain has been found to be second in frequency only to the common cold as a cause of disability in patients younger than 55. American industry loses 93 million work days per year because of low-back impairment. Further losses include medical consultations and expenses involved in disability payments.

The vast majority of low-back-pain patients have low-back strain/sprain. This may initially be considered a postural condition since pain from injury to ligaments and muscles precipitates reflex spasm within the muscles of the low-back region,

which, in turn, causes further pain as the muscles themselves fatigue and become sore from constant muscle contraction. Patients with this type of postural backache generally complain of diffuse, aching, nonradiating pain and back stiffness typically representative of muscle pain involvement. Within this situation, physical examination is likely to reveal little other than muscle spasm and laboratory workup is generally found to be negative.

These patients receive a variety of treatments inclusive of physical therapy modalities, psychological and behavior modification techniques, surgical procedures, pharmacology, relaxation exercises and massage, heat, cold and biofeedback training. The modalities used and treatment regimens applied are usually determined by the physician and/or health-care professional. Unfortunately, the chronic low-back patient has a tendency to remain particularly resistant to successful treatment. Reasons for treatment failure may be related to a poor understanding of the physical and/or psychological components underlying the process of chronic pain, in addition to the methods of treatment rendered.

MEDICAL ELECTRONICS

This study examines the effects of biofeedback, microcurrent electrical stimulation and their additive effects on lowback-pain patients.

THE "VICIOUS CYCLE" OF PAIN-SPASM-PAIN

The concept of a "vicious cycle" interrelationship of a muscle spasm and pain component seems to have had its origin with studies performed by Travell, Rinzler and Herman.¹ Their report describes the effective relief of upper extremity pain by infiltrating painful trigger points with procaine. From their findings, they hypothesized that if a muscle spasm causes pain, and pain reflexly causes the production of muscle spasm, a self-perpetuating, painproducing cycle might be created within a certain physiological environment. Several later studies supported this mechanism.²,3,4,5

Bonica stated that in certain individuals it is evident that emotional stress via psychophysiologic mechanisms produce skeletal muscle spasms, local vasoconstriction, visceral dysfunction, liberation of pain substances or a combination of these occurrences.6 Consequently, production of peripheral noxious stimulation evolves with reactive pain, reflex responses and affective reactions, all of which contribute to the initial state of emotional stress. In turn, provocation of additional psychophysiological impulses are produced, thus sustaining the vicious cycle of pain-spasmpain. Paris found that pain from dysfunction may prolong a present condition by causing voluntary muscle splinting.7 If this voluntary splinting continues, there is a tendency for the development of a more sustained involuntary splinting to occur which typically does not abate with rest and occurs as a consequence of the deficiency of the normal contract/relax cycle of muscle activity.

The Gate Theory, developed by Melzack and Wall, provided a neurophysiological mechanism to explain this system.⁸ Mannheimer and Lampe discussed this cycle as a form of self protection, by guarding, whether the inducing trauma is considered physical and/or psychological.⁹

Histochemically, the guarding or spasm produces an environment of increased muscle tension resulting in a deficiency of blood supply within the affected area, thus creating an ischemic state. There is an increase of metabolites as a by-product of muscle contraction in the area. Due to the lack of circulation from tonic contracture of the muscles, the accumulation and stagnation of metabolites compound the situation. Furthermore, the production and concentration of endogenous pain-producing substances such as bradykinin, histamine and prostaglandin E produce additional pain, discomfort and inactivity. This ischemic condition with retention of metabolites has the additive effect of perpetuating the pain-spasm-pain cycle on a histochemical level.

This study concentrated on the low-backpain patient. Lamb suggests that the majority of pain syndromes involving the lumbosacral region appear to be the direct result of mechanical dysfunction of the neuromuscular tissue. ¹⁰ Nigl reported that disorders of the low-back musculature may be in a state of hypercontraction for simultaneous reasons, inclusive of psychological and/or physiological factors. ¹¹

BIOFEEDBACK

Birk interprets biofeedback as a means of utilizing monitoring instrumentation for the purpose of detecting internal physiological processes within the human body so that these processes, which are ordinarily unavailable as information, are made available to the individual and, literally, fed back to him or her. 12 Upon continued exposure to this available information, in addition to ongoing practice relative to manipulation of the corresponding processes, there is evidence that one can learn how to bring under conscious control particular bodily functions that are not subject to conscious control, such as striated muscle tension.

Biofeedback involves the electronic measurement and subsequent amplification of physiological responses. These responses, in turn, are instantaneously fed back to the subject from whom the bioelectrical signals originated. It has been reported that, over a period of time, the person involved in biofeedback training will learn to control the physiological activity that has been fed back to him. Theoretically, this occurs as a result of utilizing internal cues or references that are correlated to the desired changes in the bioelectrical signal.

Although there are presently a variety of biofeedback instruments used for the treatment and rehabilitation of various conditions and disorders, the majority of clinical biofeedback techniques involve four primary types of bioelectronic measurements: electrothermal (skin temperature), electrodermal (EDR), electroencephalographic (EEG), and electromyographic (EMG).¹¹

In physical medicine and rehabilitation, EMG biofeedback has been found to be effective in volitional relaxation of excessive muscle activity and associated pain reduction, in improvement of mobility and strength, and in control of atrophied or paretic muscles or muscle groups. 11,13,14,15

Evidence found within the literature supports the contention that chronic low-back patients experience pain as well as exhibiting a hyperactive muscle tension component. 16,17 EMG biofeedback applications have been applied to low-back patients whose pain was believed to be present as a result of elevated muscle tensionin addition to the patient's inability to relax the muscles which were in spasm. The therapeutic goal is to teach patients, through physiological feedback, to voluntarily control the somatic mechanisms responsible for the production of and contribution to the involved pain. 18 Several studies have supported the efficacy of this therapy. 19,20,21,22

ELECTROMEDICINE

There has been a resurgence and metamorphosis of electrotherapeutic mechanisms and applications relative to the relief of pain and the enhancement of function. Upon reviewing the history and background of electrical stimulation pertaining to electroanalgesia and rehabilitation, one can see that the concept of electromedicine is not new and, although somewhat sluggish in development and acceptance, is gaining acceptance for both diagnostic and therapeutic purposes.23,24 One of the most common modern methods of treating chronic pain disorders is with transcutaneous electrical nerve stimulation (TENS) devices, first developed by Shealy. 25,26 Today more than 200 different models of TENS devices are in use, indicating a wide level of acceptance. Most produce a current in the milliampere range, and their success has been explained by the Gate Theory as well as by production of endorphins.27 They have been shown to be safe and can be used universally, subject to instruction and to the caution that they may not be used in cases of persistent pain without medical advice.

More recently, devices supplying current in the microampere range have been shown to have greater effectiveness than the more traditional TENS milliampere devices.28 These "microstimulators" deliver up to 500 microamps at frequencies as low as 0.5 Hertz. In 1981, a double-blind study with placebo group was conducted by Lerner and Kirsch using microampere stimulation on patients experiencing chronic low-back pain.29 Results showed that, after a twomonth follow-up, 75.22% pain reduction was experienced by the real (microstimulation) group and 6.3% reduction was experienced by the placebo group. Several other studies have shown a broad range of application of microstimulation with even fewer side effects than traditional TENS devices as summarized by Bauer.30 Studies included beneficial effects of microampere stimulation on head and neck cancer pain, low back pain, tennis elbow pain, sensorineural hearing loss and tinnitus, radiation therapy side-effects, and neurological disease.

MATERIALS AND METHODS

This study tested the following hypotheses:

Null Hypothesis: There will be no statistically significant difference between the group receiving biofeedback and electrical stimulation, the group receiving biofeedback alone, and the group receiving electrical stimulation alone, for the reduction of muscle spasms and relative pain experienced by the low-back patient.

Hypothesis #1: Electrical stimulation and biofeedback will be significantly more effective than biofeedback treatment alone for the reduction of muscle spasm and relative pain experienced by the low-back patient.

Hypothesis #2: Electrical stimulation and biofeedback will be significantly more effective than electrical stimulation treatment alone, for the reduction of muscle spasm and relative pain experienced by the low-back patient.

SUBJECTS

All subjects responded to public notices posted in several medical facilities in the New Hyde Park, Nassau County area of New York. They were non-paid volunteers and were required to have a physician's referral with low-back (erector spinae) spasms and associated pain. Subjects had to speak English and understand the Eng-

lish language. They could not be pregnant or have a history of heart disease, psychosis, diabetes, nor could they have a history of seizure disorders (epilepsy); nor could they be drug addicts or alcoholics, or be taking pain medication and, finally, they could not be undergoing other rehabilitative techniques during the time of this study.

Initially, 45 subjects were randomly divided into three treatment groups: a biofeedback/electrical stimulation group, a biofeedback group and an electrical stimulation group.

Subjects were introduced to, received and completed the Subjective Units of Disturbance (SUDS) form. All subjects received a trunk mobility evaluation. They were then asked to complete a Pre-Treatment Questionnaire/History form. All subjects were informed of the experimental procedures and were asked to read and sign an informed consent form prior to inclusion in the study. They were informed about the potential negative and positive effects of electrical stimulation and biofeedback, including the potential additive effects of these modalities. Subjects were then placed on the treatment table in a prone position, biofeedback electrodes were applied to the erector spinae muscle found to be in spasm and the biofeedback modality was implemented.

Microvoltage readings were taken after five minutes of modality application. At the conclusion of five minutes and documentation of microvoltage reading, the biofeedback machine was turned off and the subject and electrodes were properly cleansed and dried. Subjects were introduced to, received and completed the Minnesota Multiphasic Personality Inventory (MMPI). The biofeedback procedure was then repeated.

Introduction to and discussion of the Daily Pain Record ensued and sixty-one cards were given to each subject for home recording. Subjects once again completed the SUDS form. They were then given subsequent appointments following a question and answer period. One subject in the biofeedback group and two subjects in the electrical stimulation group failed to complete the study. Of the 42 subjects completing this study, 26 (61.9%) were females and 16 (38.1%) were males. The mean age of the subjects was 41.1 years, ranging from 23 to 62 years.

The Biofeedback/Electrical Stimulation group consisted of ten females and five males. The mean age of this group was 35.7 years, ranging from 23 to 62 years. The Biofeedback group consisted of eight females and six males. The mean age of this group was 44.6 years, ranging from 25 to 62 years. The Electrical Stimulation group consisted of eight females and five males. The mean age of this group was 43.5 years, ranging from 29 to 60 years.

All subjects had the opportunity for a question and answer period prior to and at the conclusion of the study.

INSTRUMENTATION

A. Electrical Stimulator: The source of electrical stimulation utilized in this study was the Alpha-Stim 350, manufactured by Electromedical Products, Inc. of Hawthorne, California. The Alpha-Stim 350 is a battery powered microampere stimulator with variable intensity, frequency and duration settings. It was designed to be used in conjunction with disposable, self-adhesive electrodes.

B. Electromyograph: The electromyograph used in this study was the EMG P-775, manufactured by the Biofeedback Instrument Company of New York City. It has three standard electrode inputs, allowing sequential monitoring of three separate areas of the body, and is battery powered. It utilizes fully shielded silver/silver-chloride electrodes attached to the skin with Dermilite II hypo-allergenic paper tape by Johnson & Johnson. Signa Creme Electrode Cream from Parker Laboratories, Inc. was used as an electrolyte.

The investigator, Stephen I. Zimmerman, a licensed, registered physical therapist and certified biofeedback practitioner with a Ph.D. in electromedical sciences, carried out all experimental procedures throughout all phases of this study.

The erector spinae, also called the sacrospinalis, was chosen for treatment in this study at a level between the third and fifth lumbar vertebrae. Patients were treated in a prone position on a standard cushioned treatment table. Pillows were placed under the patient from the pubic region to the upper chest region. The patient's forehead was resting on the treatment table and both arms were placed at the sides.

PROCEDURE

Electrical Stimulation/Biofeedback-Group I: Fifteen subjects received a total of twenty treatments. This group received electrical stimulation one time per week for thirty minutes, and biofeedback treatment one time per week for thirty minutes. Treatments were given three days apart as follows: each subject's skin was cleansed with 70% isopropyl alcohol. The electrodes were applied to the erector spinae musculature, unilaterally, in a vertical position at levels between the third and fifth lumbar vertebrae. The intensity of the electrical stimulation was initially set at 200 microamperes and was increased to 500 microamperes. The frequency used was 0.5 Hertz.

Biofeedback-Group II: Fourteen subjects received a total of twenty treatments. Subjects received biofeedback treatment two times per week for thirty minutes each. Treatments were given three days apart as follows: each subject's skin was cleansed with 70% isopropyl alcohol. Electrodes were placed on the erector spinae musculature, unilaterally, in a vertical position, at levels between the third and fifth lumbar vertebrae. The ground electrode was centered between the other two electrodes. The Meter Scale Selector was initially set at X4 (0 to 20 microvolts). If necessary this was changed to correspond to muscle fiber activity. The volume was regulated so that it was adequate and comfortable for each subject.

At this step, subjects were told that their level of muscle tension/spasm directly corresponds to the audio feedback mechanism, and that a decrease in muscle tension results in a slowing of the pulse rate burst (their goal), while an increase in muscle tension results in an increase in the pulse rate burst. The predetermined treatment time was 30 minutes.

Electrical Stimulation—Group III: Thirteen subjects received a total of twenty treatments. Subjects received electrical stimulation two times per week for thirty minutes each. Treatments were given three days apart. Electrical stimulation was performed in the same manner as the Group I subjects.

The following measures were taken during the fifth, tenth, fifteenth and twentieth sessions: Subjects completed a Subjective Units of Disturbance form and trunk mobility. The biofeedback modality was

implemented but no feedback was offered. After five minutes, microvoltage reading and subsequent documentation was made. Thirty minutes of prescribed treatment was given. The biofeedback modality was implemented but again, no feedback was offered. After five minutes, microvoltage reading and subsequent documentation was made. Subjects again completed the Subjective Units of Disturbance form.

During the twentieth treatment session, subjects received and completed the MMPI, followed by a question and answer session pertaining to this study.

RESULTS

The equivalence of the three treatment groups was examined for the background variables of sex, education levels attained, occupational level, injury site, socioeconomic class and age of the participant. No significant differences were found to exist between the treatment groups relative to sex distribution.

Subjects were grouped into seven educational levels based upon the work of Hollingshead and Redlich.31 No significant differences were found to exist. Subjects were also assigned to groups based upon occupational levels attained using the Hollingshead and Redlich criteria. No significant differences were found to exist. Injury sites were noted by each patient concerning left and right pain and spasm, and left and right buttock or groin pain or spasm. No assignment to treatment group effects were noted to exist for any of the injury sites. No significant differences were found to exist in assignment to treatment condition according to pain/spasm distribu-

The socioeconomic status of each subject was statistically calculated using their educational and occupational classification according to Hollingshead and Redlich. No significant differences were found to exist in terms of socioeconomic status distribution among each treatment condition.

The equivalence of the treatment groups was also examined for the age of the participants, with a result that a significant difference was found to exist between the Biofeedback/Electrical Stimulation group (mean age = 35.7 years) and the Biofeedback group (mean age = 44.6 years). This difference may have an effect on the outcome of the study and therefore can potentially be considered a limitation of this investigation.

The composition of the treatment groups was also evaluated relative to years of education attained by the participants and duration of the pain and spasm ("vicious cycle") for which treatment was rendered. No significant differences were found to exist among the treatment groups in terms of years of education completed and in terms of pain duration. Each treatment group started this study with an essentially equal relevant history of approximately 16.4 months.

TRUNK MOBILITY

The trunk mobility (measured in inches) for each subject was evaluated five times within the course of this study: during the pretreatment interview, 5th, 10th, 15th and 20th (final) treatment sessions. Trunk mobility was interpreted as an indicator of physical function, relative to pain and spasm associated with lumbosacral involvement. Statistical findings indicate that the three treatment groups did not differ in terms of overall mobility in the aggregate throughout the course of this investigation, with means of 2.9 inches (Biofeedback/Electrical Stimulation group), 4.0 inches (Biofeedback group), and 3.5 inches (Electrical Stimulation group) (see Fig. 1 and Table 1).

Ignoring group membership, analysis indicates that each trial significantly improved upon the degree of mobility of the subjects, over that which was seen from the prior treatment. All subjects improved over time. A net result was an increased trunk mobility to 2.31 inches at the conclusion of the program, across all individuals, from an initial rating of 4.40 inches (see Fig. 2 and Table 2).

Analysis indicates that all treatment groups did not change in the same manner throughout the course of this study. Several important outcome results were found:

1. The Biofeedback/Electrical Stimulation treatment group had significantly greater

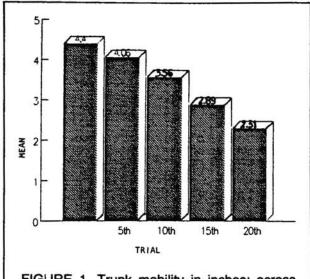


FIGURE 1. Trunk mobility in inches: across trials.

mobility at the conclusion of this investigation than the Biofeedback or Electrical Stimulation groups.

- 2. The Biofeedback/Electrical Stimulation treatment group improved significantly over their starting position.
- The Electrical Stimulation group had greater mobility at the end of the study than the Biofeedback group had during sessions one to fifteen, but did not differ significantly from the Biofeedback group at the end of the study.
- 4. The members of the Biofeedback group performed better at the end of treatment than they had during the first ten sessions of treatment, but did not differ significantly from the gains they had attained by the 15th session of therapy.

PATIENT PAIN CARDS

Subjective measures of perceived pain were obtained from each subject, on a daily basis, throughout the course of this study, until the 20th treatment session. A total of 20 pain indices, representing the daily pain cards, was created and, in turn,

TABLE 1. N	IEWMAN-KEULS	ON TRUNK MOBILITY	BA	IREAIMENI	IHIAL

#	Trial	Mean	1	2	3	4	5
1	Twentieth	2.31		0.58**	1.25**	1.75**	2.09**
2	Fifteenth	2.89			0.67**	1.17**	1.51**
3	Tenth	3.56				0.50**	0.84**
4	Fifth	4.06					0.34**
5	Initial	4.40					

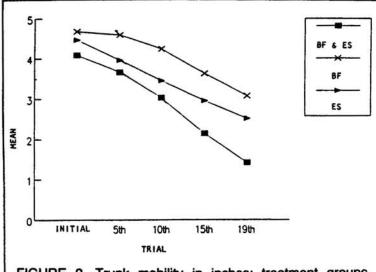


FIGURE 2. Trunk mobility in inches: treatment groups across trials.

was utilized as a measurement of experienced pain by each subject throughout this investigation.

A clear downward trend across the study by all three treatment groups was noted, with the Biofeedback/Electrical Stimulation group exhibiting a comparatively greater decline in perceived pain than the Biofeedback group. At the conclusion of the study it was evident that a greater reduction in perceived pain was noted by the Biofeedback/Electrical Stimulation and Electrical Stimulation groups than that exhibited by the Biofeedback group. The Biofeedback/Electrical Stimulation group exhibited

greater reductions in perceived pain than the Electrical Stimulation group, although parallel gains were made past midpoint of the investigation (see Fig. 3 and Table 3).

Concerning the variability in response to treatment, subjects receiving Biofeed-back/Electrical Stimulation treatment tended to improve on a regular basis with less variability of response, whereas subjects in the Biofeedback group improved on a more gradual basis with more consistency in variation of responses, and subjects among the Electrical Stimulation group demonstrated a greater degree of variation of response as the study progressed.

Relative to trials by treatment interaction, none of the three treatment groups differed significantly from each other during the course of the first nine treatment sessions, but did diverge significantly after this point. During the 14th session the Biofeedback/Electrical Stimulation group (means = 2.07) reported significantly less pain than either the Biofeedback group (means = 3.06) or Electrical Stimulation (means = 2.48), with the Electrical Stimulation group reporting significantly less pain than the Biofeedback group. This pattern of responses resumed and continued through to the conclusion of this study, with the Biofeedback/Electrical Stimulation group giving significantly lower pain reports than either the Electrical Stimulation or Biofeedback groups; and the Electrical Stimulation and Biofeedback groups also exhibiting significant differences (Fig. 3 and Table 3).

TABLE 2. NEWMAN-KEULS ON TRUNK MOBILITY FOR SIGNIFICANT TREATMENT X TRIALS EFFECT

,	GROUP &																NAME OF
_	INIAL	IRIAL MEAN 1 2			3 4			6	6 7		8 9		11	12	13	14	15
1	BFES-5	1.42		0.73**												3.17**	
2	BFES-4	2.15			0.38**											2.44**	
3	ES-5	2.523				0.44	0.50	0.55	0.93**	1.11**	1.14**					2.06**	
4	ES-4	2.961					0.06	0.12	0.49	0.67	0.70	1.00**	1.13**	1.27**	1.51**	1.62**	1.72**
5	BFES-3	3.03						0.05	0.43	0.60	0.63	0.94 **	1.06**	1.21**	1.44**	1.56**	1.65**
6	BF-5	3.08							0.38	0.55	0.58	0.88	1.01**	1.16**	1.39**	1.51**	1.60**
7	ES-3	3,453								0.18	0.21	0.51	0.63	0.78**	1.02**	1.13**	1.23**
8	BF-4	3.63									0.03	0.33	0.46	0.61	0.84**	0.96**	1.05**
9	BFES-2	3.66										0.30	0.33	0.58	0.81	0.92**	1.02**
10	ES-2	3.96											0.13	0.27	0.51	0.62	0.72
11	BFES-1	4.09												0.15	0.38	0.50	0.59
12	BF-3	4.24													0.23	0.35	0.44
13	ES-1	4.47														0.12	0.21
14	BF-2	4.59															0.09
15	BF-1	4.68			**p<.0	1											

SUBJECTIVE UNITS OF DISTURBANCE (SUDS)

All subjects within this study were requested to indicate the extent to which their physical symptoms resulted in psychological distress, and to estimate the degree of dysfunction along a continuum ranging from "0" (no disturbance) to "100" (extreme disturbance). This measure, referred to as Subjective Units of Disturbance (SUDS), was estimated by each subject during the initial and latter portion of their initial (pretreatment) interview, fifth, tenth, fifteenth and twentieth treatment sessions.

Examination of the means concerning the subject population in this study indicates that all groups had a tendency of reducing their pain levels throughout the course of treatment, with the Biofeedback/ Electrical Stimulation group demonstrating the greatest reductions in SUDS levels from an initial interview average of 89 points to the final treatment rating of 8.3 SUDS units. Over time, the Biofeedback/ Electrical Stimulation group became more homogeneous in responses, whereas the Biofeedback and Electrical Stimulation groups became more heterogeneous in their responses to treatment (see Fig. 4 and Table 4).

Progress was seen for all treatments across the duration of this study. Analysis of the means for each session demonstrated that the sample of individuals reported improvements in their SUDS ratings for each trial over their previous ratings.

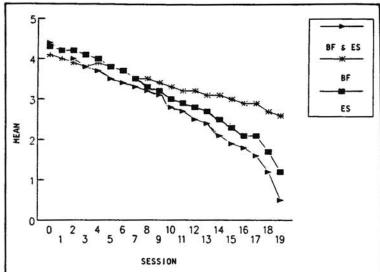


FIGURE 3. Pain ratings across experiment by treatment condition.

Significant group by session effects were demonstrated, although no significant differences existed between the treatment group at the onset of treatment, or at the fifth treatment session. Differences generally began to emerge at the 10th treatment session, such that at the conclusion of the study, the Biofeedback/Electrical Stimulation group expressed significantly less SUDS levels than either method used alone, and the Electrical Stimulation group reported significantly less SUDS levels than the Biofeedback group.

TABLE 3. MEANS AND STANDARD DEVIATIONS FOR DAILY PAIN CARD RATINGS BY TREATMENT CONDITION ACROSS STUDY PERIOD

Trial	B.F. &	E.S.	B.F	٠.	E.S.		Overall		
	Mean	S.D.	Mean	S.D.	Mean	S.D.	Mean	S.D	
Initial	4.4	0.6	4.1	0.7	4.3	0.4	4.3	0.6	
1	4.2	0.5	4.0	0.6	4.2	0.5	4.2	0.5	
2	4.0	0.6	3.9	0.6	4.2	0.5	4.0	0.6	
3	3.8	0.5	3.8	0.7	4.1	0.5	3.9	0.6	
4	3.7	0.5	3.9	0.7	4.0	0.5	3.9	0.6	
5	3.5	0.6	3.8	0.7	3.8	0.6	3.7	0.6	
	3.4	0.7	3.7	0.7	3.7	0.6	3.6	0.7	
6 7 8 9	3.3	0.6	3.5	0.6	3.5	0.5	3.5	0.6	
8	3.2	0.5	3.5	0.7	3.3	0.5	3.3	0.6	
9	3.1	0.7	3.4	0.6	3.2	0.6	3.2	0.6	
10	2.8	0.8	3.3	0.6	3.0	0.7	3.0	0.8	
11	2.7	0.9	3.2	0.6	2.9	0.7	2.9	0.8	
12	2.5	0.8	3.2	0.6	2.8	0.7	2.8	0.7	
13	2.4	0.8	3.1	0.6	2.7	0.7	2.7	0.8	
14	2.1	0.8	3.1	0.6	2.5	0.8	2.5	0.8	
15	1.9	0.8	3.0	0.6	2.3	0.9	2.4	0.9	
16	1.8	0.7	2.9	0.6	2.1	0.9	2.3	0.9	
17	1.6	0.7	2.9	0.7	2.1	1.0	2.1	1.0	
18	1.2	0.6	2.7	0.7	1.7	1.0	1.9	1.0	
19	0.5	0.4	2.6	0.7	1.2	1.0	1.4	1.1	

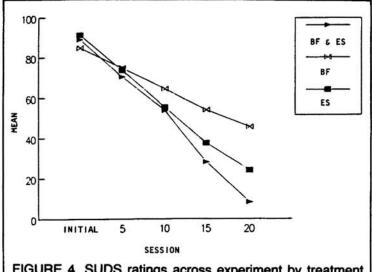


FIGURE 4. SUDS ratings across experiment by treatment condition.

The Biofeedback/Electrical Stimulation and Electrical Stimulation groups demonstrated significant reductions in perceived stress, evidenced across each trial. The Biofeedback group evidenced incremental changes such that significant improvements were noted between the initial intake and fifth session, but only between every other observation point following the fifth treatment session.

Relative to within-session changes, differences for the initial and final SUDS levels recorded by each subject were also noted to indicate that the subjects seen reported less disturbances following therapy than when first entering each session. The aggregate SUDS level for all groups was 58.6 for the initial report, compared to a final estimate of 54.5 points.

Significant within-session by groups effects for the aggregate across sessions indicate that average initial reports were significantly greater than final reports of disturbance for the Biofeedback/Electrical Stimulation and Electrical Stimulation conditions. The Biofeedback group also demonstrated improvements although increments of improvement were relatively slower.

The findings of significant trials by within-trials effects indicate that the within-session effects were not constant during each treatment period. Further analysis demonstrates that all subjects (regardless of group membership) left the initial interview with significantly greater distress than upon entrance into this study. During the course of treatment, subjects generally exhibited significant within-trial reductions in perceived distress, which was subsequently reduced to a significantly greater extent by the next measurement trial.

MICROVOLTAGE READINGS

Muscle spasm/tension, represented by microvoltage, was measured for each subject during the initial and latter portions of the pretreatment interview and the 5th, 10th, 15th and 20th treatment sessions. There were no significant microvoltage differences found between the three treatment groups when collapsed across the times they were seen. No significant differences were found between the three treatment groups across this investigation.

It was generally found that all subjects improved from one trial to the following trial, with significant reductions in microvoltage readings evident. The latter

TABLE 4. MEANS AND STANDARD DEVIATIONS FOR DAILY PAIN CARD RATINGS BY TREATMENT CONDITION FOR REPEATED MEASURES ANOVA ANALYSIS

	B.F. & E.S.		B.F.		E.S.		Overall	
Session	Mean	s.D.	Mean	S.D.	Mean	S.D.	Mean	S.D.
Initial	4.4	0.6	4.1	0.7	4.3	0.4	4.3	0.6
4th	3.7	0.5	3.9	0.7	4.0	0.5	3.9	0.6
9th	3.1	0.7	3.4	0.6	3.2	0.6	3.2	0.6
14th	2.1	0.8	3.1	0.6	2.5	0.8	2.5	0.8
19th	0.5	0.4	2.6	0.7	1.2	1.0	1.4	1.1
Overall	2.8		3.4		3.0		3.1	

116 MEDICAL ELECTRONICS

microvoltage readings for all subjects, for trials 5 through 20, were found to be significantly lower than the initial readings, although there was a reversal of this occurrence evidenced in the pretreatment interview session. Here, the latter microvoltage readings were found to actually be greater than the initial values. This finding was similar to the findings within the SUDS evaluations and may also be due to the increase in physical and/or psychological stress concerning the intensity and newness of the pretreatment interview atmosphere and/or the increased attention, sensitivity and awareness associated with the subject's involvement in the "vicious cycle" of pain and spasm (see Fig. 5 and Table 5).

Initial and final readings were found to significantly decrease across the span of the investigation, from each trial to the next. All groups were found to respond to treatment in a similar manner throughout the course of this study.

PERSONALITY ADJUSTMENT-MMPI

One of the most striking findings of the study was the decrease across treatment conditions in the degree of psychological distress experienced by the participants. Clinically significant decrements in impairment were found to exist on 13 of the 17 MMPI subscales which were examined (Lie, Faking Bad, Sophisticated Liar, Hypochondriasis, Depression, Hysteria, Psychopathic Deviate, Paranoid, Psychasthenia, Schizophrenia, Caudality, Low-Back Pain and Somatic Complaints). The findings denote a shift from individuals who present themselves, in the aggregate, as displaying clinically significant effects which connote persons who are overly sensitive towards others, with an increased emphasis upon their own symptomatology and decreased expectancy that others will be supportive and empathetic, while at the same time use physical complaints to focus attention upon themselves so as to manipulate others, towards more open and

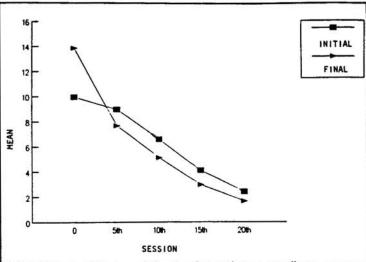


FIGURE 5. Initial and final microvoltage readings across treatment trial.

accepting individuals who experience less stressful and more adaptive patterns of functioning (see Figs. 6-12).

In terms of relative efficacy, the dual treatment condition experienced the greatest changes in adaptive functioning. experiencing significantly greater growth and stability than either single modality. Individuals receiving both treatments reported less depressive ideation, less concern with somatic complaint and bodily functions, greater trust in others and awareness of the impact of their behaviors upon the reactions of others, increased tolerance of ambiguity, increased attentiveness to their surroundings and effective behavior rather than ruminative obsessions and less focusing upon their back conditions. Although the electrical stimulation and biofeedback groups improved to a certain degree within each of these areas, the substantial differences which were observed indicate that maximal psychological benefit is to be expected from the combination of these approaches.

It is of interest to note that the changes noted in the MMPI profiles of the groups

TABLE 5. NEWMAN-KEULS ON SUDS RATINGS ACROSS TREATMENT SESSIONS

#	Session	Mean	1	2	3	4	5
_				15 (044	22 (0++	48.70**	64.20**
1	Twentieth	24.10		15.60**	33.60**		
2	Fifteenth	39.70			18.00**	33.10**	48.60**
2	Tenth	57.70				15.10**	30.60**
3	E-7777777					1	15.50**
4	Fifth	72.80					13.30
5	Initial	88.30					

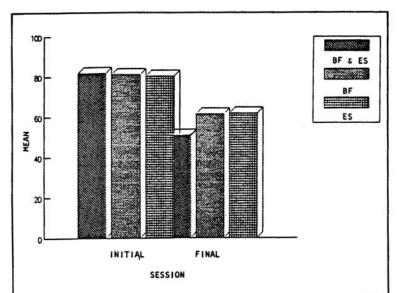


FIGURE 6. MMPI hypochondriasis scores for treatment X trials interaction.

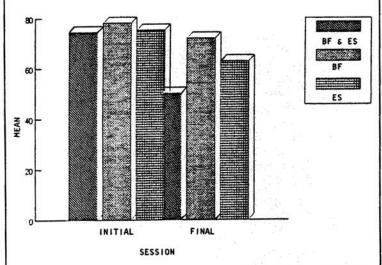


FIGURE 7. MMPI depression scores for treatment X trials interaction.

did not appear to be due to absolute differences in the degree of muscle tension reported. Hence, the adaptive functioning of the clients on a cognitive basis far outstripped actual physiological changes. Given these findings, one must question the extent to which the addition of a cognitive restructuring component to either the electrostimulation or biofeedback would enhance their effectiveness in terms of perceived pain reduction.³²

DISCUSSION

This investigation has been designed to provide information regarding the relative efficacy of three treatment modalities directed at the inhibition and/or alleviation of the "vicious cycle" of pain and spasm commonly experienced by the low-back patient. Upon reviewing the literature, there seems to be a limited amount of investigation considering the additive effects of two modalities such as Biofeedback and Electrical Stimulation for the modulation and inhibition of the vicious cycle of pain and spasm. Reports have been found wanting in both conceptual and methodological applications concerning this subject. Studies and investigations concerning the use of "dual" or additive treatments for a "multifaceted" condition have been found wanting in quality and quantity.

The results of this investigation suggest that, in the majority of the findings, the effects of each treatment modality were cumulative, or additive to the other mode of treatment, and more effective than each procedure used alone, with the exception of microvoltage reduction. Electromyographic biofeedback and electrical stimulation, each with their unique mechanisms, yet similar benefits, produced reductions in pain and muscular spasms and improvement in volitional mobility but, when used in an additive manner, the gains made were found to be predominantly more significant and increasingly beneficial.

The use of a single modality usually cannot adequately rehabilitate a patient found in the midst of the vicious cycle of pain and spasm. Even in the acute stages, treatment consisting of a unimodal procedure, regardless of the mode, frequently does not prevent chronicity. Specific modulation has been found to be beneficial in the alleviation or inhibition of pain and relative effects (i.e., muscle spasm) for intervals of time, but usually makes limited attempts at dealing with correction of the original etiology or fails to stress continuous, ongoing rehabilitation.

Biofeedback has exhibited an effective means of aborting or preventing the onset of pain and/or muscle spasm. Patients reporting pain and muscle contraction are given an increased "passive" awareness via biofeedback mechanisms without which there seems to be more of a potential for increased muscle tension, increased pain potential and immobilization. The use of biofeedback as a vehicle for teaching "target" muscle relaxation (i.e., erector spinae muscle group treated in this study) has been found to be an excellent means of pain relief.

A primary benefit of microcurrent application is demonstrated in this modality's ability to reduce symptomatic pain. Secondary benefits, such as producing a sedative effect and increases in tissue temperature are often reported. Although microcurrent stimulation has been found to be an excellent method of pain relief, it is suggested that we implement this mode of treatment as an adjunctive mechanism within the total rehabilitative process. It should also be noted that various benefits from therapeutic processes tend to be enhanced by the added effects of microcurrent stimulation.

It is suggested that enhanced pain/spasm reduction can be obtained by using microcurrent stimulation and/or biofeedback as an extension of the clinical facility, if used within the home and work place. This allows for a more sustained and continuous mode of rehabilitation, bridging the gap from clinical treatment to clinical treatment.

This study suggests that for improved rehabilitative processes and subsequent beneficial results, a synergistic approach of therapeutic procedures be utilized. This approach has been most beneficial in treating the low-back patient found within the vicious cycle of pain and spasm. This program demonstrates how one modality potentiates another modality's effects, and describes how the additive effects of each procedure is better than using each mode of treatment as a sole source of rehabilitation.

BIBLIOGRAPHY

- Travell, J., et al.: "Pain and Disability of the Shoulder and Arm," JAMA, 120:417-422.
- 2. Elliott, F.A.: "Tender Muscles in Sciatica," Lancet: 47-49, 1944.
- 3. Bonica, J.J.: "Management of Myofascial Pain Syndrome in General Practice," JAMA 164:732-738, 1957.
- 4. Fischer, A.: "General Principles for Treatment of Patients with Chronic Pain," in Asa P. Ruskin (ed.), Current Therapy in Physiatry, Philadelphia: W.B. Saunders Company 134-135.
- 5. Ruskin, Asa P.: "A Dynamic Approach to Pain Management," in Asa P. Ruskin (ed.), Current Therapy in Physiatry, Philadelphia: W.B. Saunders Company 146-149.
- 6. Bonica, J.J.: "Neurophysiologic and Pathologic Aspects of Acute and Chronic Pain," Arch. Surg. 112:750-761, 1977.
- 7. Paris, Stanley V.: "Mobilization of the Spine,"
- Phys. Ther. 59:988-995, August, 1979. 8. Melzack, R. & Wall, P.D.: "Pain Mechanisms: A New Theory," Science 150:971-979, Nov. 1965.
- 9. Mannheimer, J.S. & Lampe, G.N.: "Pain and TENS in Pain Management," in Clinical Transcutaneous Electrical Nerve Stimulation, Philadelphia: F.A. Davis Co., pp. 7-9, 1985.

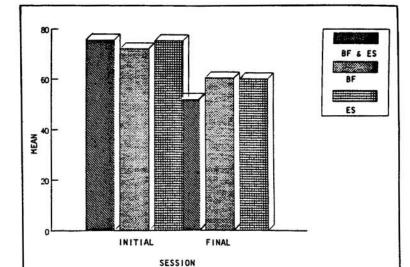


FIGURE 8. MMPI hysteria scores for treatment X trials interaction.

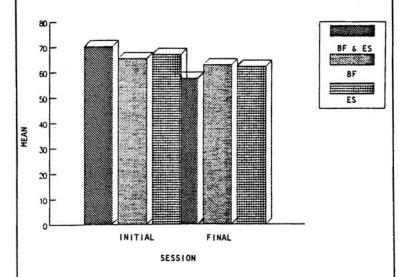


FIGURE 9. MMPI paranoia scores for treatment X trials interaction.

- 10. Lamb, David W.: "The Neurology of Spinal Pain," Phys. Ther. 59:971-973, August, 1979.
- 11. Nigl, Alfred J.: Biofeedback and Behavioral Strategies in Pain Treatment, Jamaica, New York, Spectrum Publications, Inc., pp. 6, 8-9, 119-126, 263-272, 273-291, 1984
- 12. Birk, Lee: Biofeedback: Behavioral Medicine, New York: Grune & Stratton, pp. 1-4, 145-165, 1973.
- 13. Finneran, Jane: "A Biofeedback Program for the Patient with Pain," Clinical Management in Physical Therapy, 5:6-9, 1985.
- 14. Middaugh, S.: "Biofeedback in Physical Medicine and Rehabilitation: An Overview and Bibliography," Paper written for the Dept. of Physical Medicine and Rehabilitation, Medical University of South Carolina.
- 15. Lee, N.H., et al.: "Myofeedback for Muscle Retraining in Hemiplegic Patients," Arch. Phys. Med. Rehab. 57:588-591, 1976.

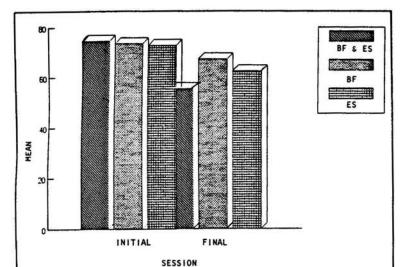


FIGURE 10. MMPI psychasthenia scores for treatment X trials interaction.

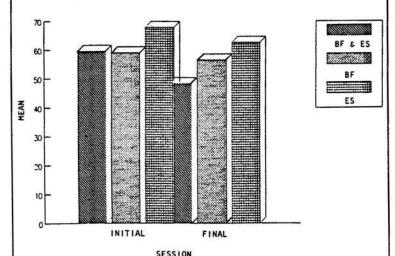


FIGURE 11. MMPI low-back pain scores for treatment X trials interaction.

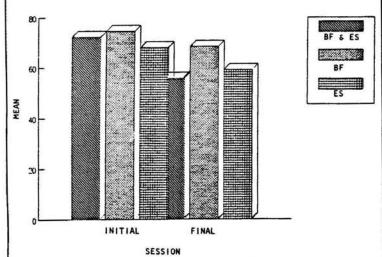


FIGURE 12. MMPI caudality scores for treatment X trials interaction.

- Holmes, T.H. & Wolff, H.G.: "Life Situations, Emotions and Backache," Psychosom. Med. 14:18-33, 1952.
- Grabel, J.A.: "Electromyographic Study of Low Back Muscle Tension in Subjects With and Without Chronic Low Back Pain," Dissert. Abs. Intl. 34(b):2929-B, 1973.
- Biederman, Heinz-Joachim: "Comments on the Reliability of Muscle Activity Comparisons in EMG Biofeedback Research and Back Pain Patients," Biofeedback and Self-Regulation 9, 1984.
- Gottlieb, H.: "An Innovative Program for the Restoration of Patients with Chronic Pain," Phys. Ther. 59:303-312, 1979.
- Nouwen, A. & Solinger, J.W.: "The Effectiveness of EMG Biofeedback Training in Low Back Pain," Biofeedback and Self-Regulation 4:103-111, 1979.
- Nigl, A. & Fischer-Williams, M.: "Treatment of Low Back Strain with Electromyographic Biofeedback and Relaxation," Psychosom. 21:495-499, 1980.
- Jones, A. & Wolff, S.: "Treating Chronic Low Back Pain," Phys. Ther. 60:58-63, 1980.
 Kornhauser, S.H. & Kirsch, D.L.: "A Brief Chro-
- Kornhauser, S.H. & Kirsch, D.L.: "A Brief Chronology on the History of Electromedicine," Am. J. of Electromedicine 1:4-6, 1985.
- Kornhauser, S.H.: "New Advanced in Electromedicine Signal A Need for Re-educating Today's Health Care Practitioners," Pod. Prod. Rpt. 42-44, 1986.
- Shealy, N., et al.: "Electrical Inhibition of Pain by Stimulation of the Dorsal Column: Preliminary Clinical Reports: Anesth. Analg. 45: 489, 1967
- Shealy, N.: "Transcutaneous Electrical Stimulation for Control of Pain," in R.H. Wilkins (ed.), Clinical Neurosurgery, Baltimore. Waverly Press, pp. 269-277, 1974.
 Hughes, G.S., et al.: "Response of Plasma Beta-
- Hughes, G.S., et al.: "Response of Plasma Beta-Endorphins to Transcutaneous Electrical Nerve Stimulation in Healthy Subjects," *Phys. Ther.* 64, No. 7:1062-1065, 1984.
- Bauer, W.: "Advances in Noninvasive Electrical Stimulation for Pain Control," Am. J. Electromedicine 1:6-8, 1985.
- Lerner, F.N. & Kirsch, D.L.: "A Double-Blind Comparative Study of Micro-Stimulation and Placebo Effect in Short Term Treatment of the Chronic Back Pain Patient," JACA Vol. 15, Nov., 1981
- Bauer, W.: "Neuroelectric Medicine," J. of Bioelectricity 2 (2 & 3): 159-180, 1983.
- Hollingshead, A.B. & Redlich, F.C., Social Class and Mental Illness, New York, 1958.
- Graham, J.R.: The MMPI, A Practical Guide, Oxford Univ. Press, New York, 1983.

ACKNOWLEDGEMENT

The authors wish to express their sincere appreciation to Dr. Louis J. Gallagher, Ph.D. for his guidance throughout this study, especially with respect to the biostatistical analysis.

STEPHEN I. ZIMMERMAN, R.P.T., Ph.D., can be reached at 700 Hillside Ave., New Hyde Park, NY 11040.

FRED N. LERNER, Ph.D., can be reached at 9201 Sunset Blvd., Suite 201, Los Angeles, CA 90069.