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Original Reports

Electrical muscle stimulation as an adjunct to exercise therapy in the treatment of nonacute low back pain: A randomized trial

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Abstract

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A prospective, randomized, double-blind, placebo-controlled clinical trial was performed to investigate the efficacy of electrical muscle stimulation when combined with a therapist-guided, standardized exercise therapy program in the treatment of nonacute low back pain. Eighty patients with low back pain of at least 6 weeks' duration were randomized into the following 2 groups: standardized exercise therapy with functional electrical muscle stimulation or standardized exercise therapy with placebo electrical stimulation. Subjects were evaluated at baseline, 2 months, and 6 months with a standardized back pain questionnaire and objective measurements of lumbar spine function. Exercise therapy was continued for 6 months, but electrical stimulation was discontinued at the 2-month interval. Of the 80 patients initially enrolled, 42 discontinued or withdrew before completing the entire study protocol. At the 2-month follow-up interval, subjects in the treatment group had statistically significantly improved lumbar spine function compared with the control subjects. This effect continued during the last 4 months of the study after electrical stimulation had been discontinued. This suggests that electrical muscle stimulation can be an effective adjunctive treatment modality for nonacute low back pain. The effects of this combined therapy seem to last beyond the duration of electrical stimulation treatment. © 2001 by the American Pain Society

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Key words: [Low back pain](#), [electrical muscle stimulation](#), [exercise therapy](#), [randomized clinical trial](#)

Low back pain (LBP) continues to be a leading cause of disability, lost wages, physician visits, and health care expenditures in industrialized countries. Although a myriad of treatments have been described, it is currently widely accepted that trunk flexibility, paraspinal and abdominal muscle strength, and regular exercise play important roles in the conservative treatment and rehabilitation of subacute and chronic LBP.¹⁻⁵ There are numerous studies documenting the benefit of therapist-guided exercise and muscle conditioning to accomplish the aforementioned goals.^{5,6} Their benefit, however, is far from universal or complete. This may be due to a baseline pain level that will not allow patients to initiate exercise therapy and rehabilitation.

Various modalities are used to address this problem, including heat/cold therapy, ultrasound, and several types of electrical stimulation. One modality widely studied is transcutaneous electrical nerve stimulation (TENS). Effective for short-term pain relief,⁷⁻¹¹ the use of TENS has never been proved efficacious for long-term treatment of LBP. Indeed, several studies have shown TENS to be ineffective,¹²⁻¹⁴ and in 1 controlled study of patients with LBP, Deyo et al¹⁵ suggested the effects of TENS were insignificantly different than placebo.

Electrical muscle stimulation (EMS) for the treatment of mechanical LBP has not been well studied. EMS differs from TENS in that it activates myelinated motor neurons producing muscle contraction before activation of pain fibers.¹⁶ A recent study has shown EMS to be effective in improving range of motion, reducing muscle spasm, and reducing pain in patients with LBP.¹⁶ Moore and Shurman¹⁷ found EMS to be more effective when combined with TENS. EMS has the potential to be effective in the treatment of LBP for the following reasons: (1) it has been shown to be effective for both rehabilitation and pain control in the extremities; (2) we have found it is relatively easy to use, which should facilitate patient compliance; (3) in female patients it has been shown to increase the strength of the paraspinal muscles; and (4) pain reduction afforded by EMS may allow patients to begin a more effective exercise and rehabilitation program.² To see whether EMS as an adjunct to exercise therapy for the treatment of nonacute LBP was helpful, we designed a prospective, randomized, double-blind, placebo-controlled study. Our hypothesis was that EMS could provide additional benefit to a regimen of supervised exercise for patients with LBP.

Methods

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Patient enrollment

Before beginning the study, the described protocol was approved by the university's Institutional Review Board for Human Research. Study subjects were from several sources including (1) direct referral from the university hospital outpatient orthopaedic clinics, (2) identification of prospective subjects from the Department of Family Medicine patient database, and (3) advertisement for the study in the medical university campus newspaper.

Inclusion criteria were 18 to 80 years of age, LBP of at least 6 weeks' duration, ability to read and speak English, and willingness to comply with the study protocol. Radicular pain was not a contraindication to inclusion, but LBP had to be significantly greater than radicular pain.

Exclusion criteria included previous treatment with any kind of electrical stimulation, including TENS; pregnancy; morbid obesity; an identified nonspinal cause of LBP such as nephrolithiasis; and any end-stage or terminal medical problems including known cardiovascular disease.

Informed consent was obtained from patients meeting enrollment criteria, which included a verbal and oral explanation of the study protocol. Patients were advised of their right to withdraw at any time during the study. They were told that the purpose of the study was to examine the effect of electrical stimulation but were not told the differences between the study group and the control group.

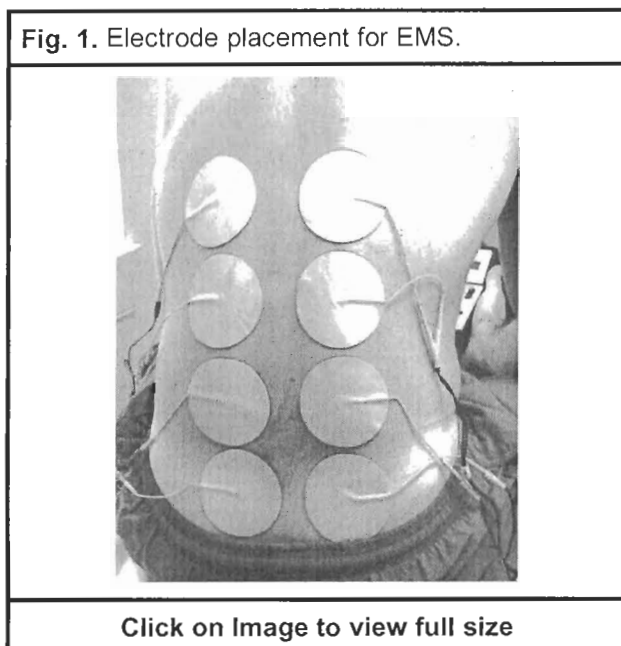
Study design

Consecutive patients meeting inclusion criteria were randomized into 1 of 2 groups. Subjects in the study group received exercise therapy and EMS treatment, whereas control subjects received the same exercise therapy and placebo electrical stimulation treatment. All subjects had initial evaluation including history and physical examination and all follow-up evaluations performed by one of the authors who was not involved with their care

(C.V.B.). Completed baseline outcome measurements are described later. Patients were issued electrical stimulation units and enrolled in the exercise therapy program. At 2- and 6-month follow-up intervals, patients were re-evaluated and had outcome measurement testing. Electrical stimulation was discontinued at the 2-month interval; home exercise therapy was continued for the duration of the study. After completion of the study and reduction of the data, the authors were "unblinded" to the group assignments, and differences between the groups were examined.

Electrical stimulation

Each subject was given either a study or placebo electrical stimulation unit, instructed in proper use of the unit (including a 15-minute videotape to standardize instruction), and advised to use it for 30 minutes twice daily. Subjects were instructed to use the highest possible intensity setting that was not painful or noxious. The study units were 4-channel, portable devices (RS-4M; RS Medical, Vancouver, WA). The unit was connected to the patient via cables attached to reusable, adhesive electrodes (Fig 1).



The placebo units were identical to the study units with the exception that they provided only very low dose, subthreshold cutaneous stimulation comparable with TENS. The units had been previously factory-programmed as either study or placebo, and the authors and subjects were all blinded to the status of the units throughout the duration of the study. A computer-generated list at the factory ensured unbiased random assignment of the units. Subjects were asked not to discuss their perceptions of the EMS treatments with other subjects in the group therapy sessions or with the study coordinator.

Exercise therapy

Exercise therapy included initial group instruction on trunk strength and flexibility exercises from a licensed physical therapist using a standardized protocol. Subjects attended 3 sessions (once weekly for the initial 3 weeks of the study) and were instructed to perform the home exercises daily for the duration of the study. Handouts with figures, photographs, and instructions were given to each subject to facilitate compliance.

Outcome measurements

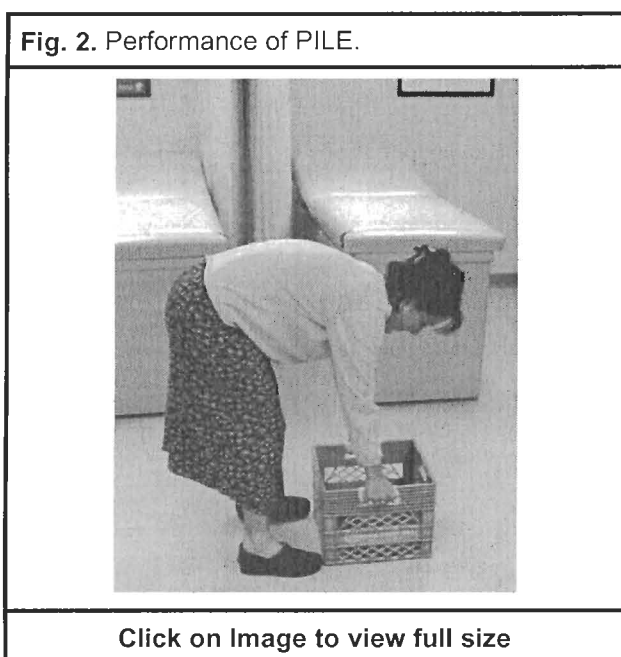
A set of subjective (patient-generated) and objective (performance-based) data were collected for each patient at baseline enrollment and at the 2- and 6-month follow-up intervals.

North American Spine Society Low Back Pain Outcome Instrument

The North American Spine Society Low Back Pain Outcome Instrument (LBPOI), as described by Daltroy et al,¹⁸ is a valid and reliable comprehensive back pain questionnaire. This instrument takes approximately 20 minutes to complete, is acceptable to most patients, and is designed to be applicable to a varied population of patients with back pain. The baseline raw data are reduced to 6 summative subscales based on 34 items: back pain, neurogenic symptoms, job exertion, job stress/satisfaction, expectations for treatment, and the Short Form 36 (SF36) mental health subscale. For the follow-up instrument, the "expectations for treatment" subscale is replaced by "expectations met for treatment" and a seventh subscale, "satisfaction with treatment," is added. Discrete, linear values are calculated for each subscale. The numeric range of response is 1 through 6. Details on the testing of this instrument can be found in the article by Daltroy et al.¹⁸

Progressive Isoinertial Lifting Evaluation

Lumbar spine function was evaluated by using the Progressive Isoinertial Lifting Evaluation (PILE). The PILE test, as described by Mayer et al,¹⁹ is a relatively simple, portable, and easily performed test of lifting capacity and trunk strength. The protocol involves repetitive lifting of a weighted plastic crate from the floor to waist level (Fig 2).



Weight is incrementally added until 1 of 3 described endpoints is reached. These endpoints are voluntary test termination, achievement of 85% of age-determined maximum heart rate, and achievement of 55% to 60% of body weight lifted. The test is male/female specific by using different beginning and incremental weights. Results are expressed in work (ft-lb), which lends the test suitable for uncomplicated statistical comparisons.

Statistics

Before beginning the study, a 1-tailed power analysis was performed with an assumption of a 30% increase in PILE scores, which yielded a sample size of 68 subjects needed to attain statistical significance. We therefore set 80 subjects as our enrollment goal, assuming there would be some subject discontinuation and withdrawal. Baseline mean LBPOI and PILE data for the 2 groups were compared by using *t* tests and Wilcoxon rank sum test as appropriate. Given that much of the data was not normally distributed, comparisons in the change in LBPOI and PILE scores for the 2 groups at 2- and 6-month follow-up were made by using nonparametric Wilcoxon rank sum tests. The primary analyses with the 2-month data were not restricted to patients completing the entire 6-month follow-up; however, we did perform secondary analyses in which analyses were restricted to

patients who were examined the entire study period. The number of subjects in each group who had improved PILE scores relative to baseline values was compared with Fisher exact test. For all comparisons, a *P* value of less than .05 was assigned for statistical significance, and for all 2- and 6-month comparisons between the 2 groups, 1-tailed significance tests were used.

Results

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Patient recruitment

Eighty patients (54 women and 26 men) were initially enrolled in the study. Twenty-five subjects discontinued or withdrew from the study during the first 2 months, leaving 55 total subjects at the first follow-up visit, 32 subjects in the study group and 23 in the placebo group. Seventeen more subjects dropped out between 2 and 6 months, leaving 38 (28 women and 10 men) who completed the study (21 study and 17 placebo). The dropout rate was not significantly different between the study (34%) and placebo groups (26%). There were numerous reasons for subject discontinuation and withdrawal from the study (Table 1).

Table 1. Reasons for Subject Discontinuation and Withdrawal

Reason for Discontinuation/Withdrawal	Study Group		Placebo Group	
	Before 2-Month Follow-Up	Between 2- and 6-Month Follow-Up	Before 2-Month Follow-Up	Between 2- and 6-Month Follow-Up
Inability to follow study protocol	2	3	7	0
Subject and/or coordinator became unblinded to study group	0	0	4	0
Inability to schedule group exercise therapy instruction	1	0	2	0
Lost to follow-up; unable to contact	0	4	2	3
Diagnosed with pathologic condition requiring surgical management or other care	1	0	1	0
Improved; no longer desired treatment	0	3	0	1
Worsened; sought medical care elsewhere	0	1	3	1
Became pregnant	1	0	0	0
Subject moved out of state	0	1	1	0

There were no significant ($P < .05$) differences between the study and the placebo patients at baseline with respect to age (study mean \pm standard deviation, 50.7 \pm 11.5 years; placebo, 53.0 \pm 14.0 years), sex (study, 38% male; placebo, 48% male), or race (study, 70% white; placebo, 68% white). In addition, dropout patterns observed in all age, race, and sex groups were not significantly different between study and placebo patients.

North American Spine Study LBPOI

Table 2 summarizes the scores for both the study and placebo groups at all 3 study intervals.

Table 2. Mean LBPOI Summative Scores at Baseline and 2- and 6-Month Follow-Up

Group (n)	Time	JE	JS	BP/D	NS	ET/EM	ST	SF36
1 (32)	Baseline	2.87 \pm	3.08 \pm		2.30 \pm			
		1.30	1.20	2.97 \pm 0.87*	1.10 [†]	3.57 \pm 0.82	—	67.8 \pm 20.6
		3.09 \pm	2.21 \pm					

2 (23)	Baseline	1.42	0.76	2.38 ± 0.67	1.76 ± 1.02	3.35 ± 0.98	—	74.1 ± 23.5
		2.69 ±	3.20 ±	2.36 ±	1.92 ±			
1 (32)	2-Month	1.21	1.00	0.65 [†]	0.95 [†]	2.84 ± 0.81	4.21 ± 0.82	70.2 ± 20.0
		2.83 ±	2.25 ±					
2 (23)	2-Month	1.12	0.83	2.13 ± 0.75	1.87 ± 1.15	2.74 ± 0.92	3.79 ± 0.93	80.0 ± 16.4
		2.74 ±	3.02 ±				4.02 ±	
1 (21)	6-Month	1.24	1.06	2.45 ± 0.77	2.17 ± 1.04	2.71 ± 0.77 [§]	0.94 [§]	67.9 ± 22.7
		2.89 ±	2.44 ±					
2 (17)	6-Month	1.37	0.96	2.30 ± 0.80	1.89 ± 1.22	2.56 ± 0.71	3.72 ± 0.88	76.2 ± 20.3

NOTE. Values are mean ± standard deviation. Group 1, study; group 2, placebo. Response range is 1-6 for all except SF 36.

Abbreviations: JE, job exertion; JS, job stress/satisfaction; BP/D, back pain/disability; NS, neurogenic symptoms; EM, expectations met for treatment; ST, satisfaction with treatment; SF36, mental health subscale.

**P* < .05 v group 2 at baseline.

†*P* < .01 v group 2 at baseline.

‡*P* < .001 v group 2 at 2 months.

§*P* < .05 v group 2 at 6 months.

The only significant baseline differences between the 2 groups was that the study group had higher scores for back pain/disability (2.97 v 2.38 for control, *P* < .05) and neurogenic symptoms (2.30 v 1.76 for control, *P* < .01) subscales. There were significantly greater declines in scores on the back pain/disability and neurogenic symptoms subscales in the study group at 2 months (*P* < .01). At 6 months there were higher values for the expectations met for treatment (2.71 v 2.56) and satisfaction with treatment (4.02 v 3.72) subscales in the study group, although these results were not statistically significant. Secondary analyses restricting the sample to those who completed 6 months of follow-up showed that changes in neurogenic symptoms at 2 months remained significant. Although the restricted secondary analyses failed to show statistically significant differences from the baseline in the 2-month back pain/disability scores because of a lack of statistical power, the trends were quite similar to those observed in the primary analyses regarding the mean 2-month scores, with the study group having lower scores on the back pain/disability subscale.

PILE

The results from the PILE scores are listed in Table 3.

Table 3. PILE Scores Among All Patients

Group	Baseline Median, Interquartile Range (n)	2-Month Median, Interquartile Range (n, Mean % Increase from Baseline)	6-Month Median, Interquartile Range (n, Mean % Increase from Baseline)
Study	277.5, 161.3-505.0 (n = 32)	390.0, 210.0-778.8 (n = 32, 80.9%)	390.0, 177.5-607.5 (n = 21, 62.9%)
Placebo	360.0, 187.5-900.0 (n = 23)	436.0, 245.0-982.5 (n = 23, 25.6%)	447.5, 210.0-900.0 (n = 17, 12.9%)

NOTE. Units are ft-lb.

There were no significant baseline PILE score differences between the 2 groups. Results of the PILE testing expressed as a percentage of baseline work performed for each group indicate an increase in work performed in both groups. At both the 2- and 6-month follow-up times, the increase in PILE scores was significantly greater (2-month, *P* = .0049; 6-month, *P* = .0341) among patients in the study group compared with the control group. When the 2-month data were restricted to those patients who completed the study, there remained a trend (*P* = .0633) suggesting greater improvement in PILE scores among the study group. At 2 months, 30 of 32 subjects in the

treatment group had equal or greater PILE scores than they did at baseline compared with 13 of 23 in the placebo group ($P = .0009$). This comparison remained significant when the analysis was restricted to patients who completed the study. In addition, at 6 months, 18 of 21 subjects in the treatment group had equal or greater PILE scores compared with baseline values versus 10 of 17 in the placebo group ($P = .0390$).

Discussion

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This study was a prospective, randomized, double-blind, placebo-controlled clinical trial designed to investigate the efficacy of EMS as an adjunct to exercise therapy for treatment of nonacute LBP. The central hypothesis of the study that EMS, when combined with exercise therapy, would decrease LBP and improve lumbar spine function was studied. We found that the addition of EMS to an exercise program did allow for improvement in lifting function in a greater percentage of patients when compared with exercise alone. The decrease in back pain was statistically significantly decreased in the study group at 2 months but never decreased below the level seen in the placebo group, so direct comparisons of the level of pain could not be made.

The study design attempted to address the difficulties associated with double-blind, placebo-controlled studies as outlined by Deyo et al.²⁰ The placebo units were identical to the study units except for the level of electrical stimulation delivered. Subjects who had any type of previous electrical stimulation treatment were excluded to reduce the likelihood of "unblinding." Instructions on use of the unit, including electrode placement and duration of treatments, were identical for all subjects. Follow-up visit frequency, duration of visits, and outcome measures were identical for all subjects. Finally, clear instructions were given to strictly avoid casual conversation with other subjects and the study coordinator regarding their EMS units and treatment intensity. To the best of our knowledge, these were adhered to.

There were several limitations of this study that must be considered in view of the findings. There was considerable dropout of subjects resulting in a relatively small sample size. This problem has been described in numerous other LBP studies. Of the 25 subjects who withdrew or discontinued during the first 2 months, 20 were in the placebo group. Conversely, 12 of the 17 subjects who withdrew or discontinued between the 2- and 6-month intervals were in the study group. The possibility of an "effective" selection bias during the first 2 months as a result of the differential dropout is a concern. The final study group of 38 subjects (20 study and 18 control) was balanced and had sufficient statistical power to generate statistically significant results. A majority of subjects were simply unable to comply with the study protocol, became unblinded, or were lost to follow-up (Table 1■). There were no statistically significant differences in reasons for discontinuation between the 2 groups. In addition, the reasons given for withdrawal from the study provide important insight into how that missing data may have affected the results. At 2 months, those patients in the placebo group who had withdrawn did so primarily for reasons related to their inability to follow the study protocol, not because their condition had improved. Similarly at 2 months, those patients in the treatment group who had withdrawn did not do so because of worsening of their condition. Thus, our findings are not likely to have been biased because of differences among the 2 groups with respect to reasons for withdrawal.

Although our original study design had called for 34 subjects in each group to achieve 80% power, our results were able to establish statistically significant differences in PILE scores at 6 months, 21 completers in the study group and 17 completers in the control group. Our initial power analyses had assumed normality in the change in PILE and LBPOI scores; however, it turned out that the changes in these scores were far from being normally distributed. Having to use nonparametric comparisons actually improved the statistical power in this case.

All subjects were enrolled in a standardized exercise therapy program led by licensed therapists, and each subject was required to attend 3 separate and progressive guided sessions. Subjects were withdrawn from the study if they did not complete all 3 of these sessions. No method of assessing subject compliance with the daily home-based protocol was established. Consequently, differential participation between the groups could have gone undetected and introduced bias.

Comparison of the raw PILE data between the 2 groups showed significant differences at both 2- and 6-month time intervals. However, when only the subjects who completed the study were included, the differences were not statistically significant. We believe the reason for this was the large range of work performed between individuals resulting in very high standard deviations, even when the data were normalized. Some subjects who could not

perform a single repetition in the PILE test at the beginning of the study could exponentially increase their work performed with only a single lift at follow-up. Conversely, subjects who started with normal or near-normal lumbar spine function had significantly less relative improvement in work performed despite the ability to perform many more repetitions. When the total number of subjects who showed no change or an improvement versus those who had worsened between follow-up intervals was considered, significant differences were appreciated at both time intervals. These differences remained even when restricted to only those subjects who completed the study. As expected, once the EMS was discontinued at the 2-month follow-up, there was a decrease in the overall PILE scores at the 6-month follow-up. Interestingly, however, the data suggest that there was less of a drop in the study group. This finding suggests that EMS has therapeutic effects lasting beyond the duration of treatment.

We are unsure of the exact mechanism of EMS that allows for this increased function. The 2 most likely mechanisms seem to be an increase in strength and/or a decrease in pain. We were unable to separate them in this study.

The results of the present study certainly cannot be generalized to all patients with LBP, and further investigation is needed. However, this combined therapeutic approach does seem to be helpful in this patient population and may offer patients with subacute and chronic back pain a more effective combined therapeutic rehabilitation protocol. We believe it is one more tool that can be used for this difficult group of patients.

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