# Combined Neuromuscular Electrical Stimulation and Transcutaneous Electrical Nerve Stimulation for Treatment of Chronic Back Pain: A Double-Blind, Repeated Measures Comparison

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ABSTRACT. Moore SR, Shurman J. Combined neuromuscular electrical stimulation and transcutaneous electrical nerve stimulation for treatment of chronic back pain: a double-blind, repeated measures comparison. Arch Phys Med Rehabil 1997;78:55-60.

**Objectives:** A preliminary examination of NMES and combined NMES/TENS for the management of chronic back pain.

**Design:** Double-blind, placebo-controlled, randomized repeated measures.

**Subjects and Setting:** Consecutive sample of 24 chronic back pain patients (16 women and 8 men) attending an outpatient pain clinic (mean age 51.67 years, mean pain duration 3.83 years). All treatments were administered at home.

**Interventions:** Subjects self-administered NMES, combined NMES/TENS, TENS, and placebo treatments. Each treatment had a duration of 5 consecutive hours per day over 2 consecutive days, with a 2-day hiatus between treatments to minimize carryover effects.

**Main Outcome Measures:** Pain reduction was assessed through pretreatment to posttreatment differences on the Present Pain Intensity (PPI) scale, and a visual analogue scale of Pain Intensity (VAS-I). Posttreatment pain relief was assessed using a visual analogue scale of Pain Relief (VAS-R).

**Results:** Combined treatment, NMES, and TENS each produced significant pretreatment to posttreatment reductions in pain intensity as measured by both the PPI and VAS-I ($p < .05$). Combined treatment was superior to placebo on pain reduction ($p = .001$, $p = .016$) as well as pain relief ($p < .001$). Combined treatment was also superior to both TENS and NMES for pain reduction and pain relief ($p < .01$). NMES and TENS were superior only to placebo for pain relief ($p < .001$).

**Conclusions:** Combined NMES/TENS treatment consistently produced greater pain reduction and pain relief than placebo, TENS, or NMES. NMES alone, although less effective, did produce as much pain relief as TENS. Although preliminary, this pattern of results suggests that combined NMES/TENS may be a valuable adjunct in the management of chronic back pain. Further research investigating the effectiveness of both NMES and combined NMES/TENS seems warranted.



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CHRONIC BACK PAIN affects almost 1 million Americans each year and represents the leading cause of physical limitation and disability among persons of working age.[1,2] Numerous techniques are used to treat this condition including rest, exercise and physical therapy, biofeedback training, ultrasound, anti-inflammatory medications, nerve block injections, surgery, and manipulation.[3] Electrical stimulation is a noninvasive and relatively simple technique that has also been used for the treatment of chronic pain in general and chronic back pain in particular.

Transcutaneous electrical nerve stimulation (TENS) is the form of electrical stimulation most recommended for the treatment of chronic back pain. Two forms of TENS are widely utilized: conventional TENS, which produces high-frequency stimulation, and acupuncture-like TENS, which produces low-frequency, high-amplitude stimulation. Several mechanisms of action have been hypothesized to explain the effects associated with TENS. One theory suggests that TENS may inhibit the transmission of pain signals in a manner compatible with gate control.[4-6] Another suggests that TENS may stimulate the release of endogenous analgesic substances such as endorphins or enkephalins.[7,8] Most trials have concluded that TENS provides benefits in the treatment of chronic back pain,[9-12] although at least one study has suggested that TENS is no more effective than placebo.[13]

Anecdotal clinical evidence suggests that one other form of electrical stimulation, neuromuscular electrical stimulation (NMES), may also provide significant relief from chronic back pain. NMES utilizes high-intensity electrical stimulation to elicit intermittent contraction and relaxation of proximal muscle fibers; it is widely prescribed for physical rehabilitation and muscle strengthening following surgery and trauma. Research with animals suggests that NMES may reduce pain by stimulating the release of endogenous analgesics,[14,15] as well as vasoactive substances affecting blood flow and possibly temperature.[16] It is also possible that NMES reduces pain through muscle toning and the prevention of disuse atrophy and the muscle degeneration frequently associated with chronic myofascial pain.

To date, no controlled research has applied NMES to the management of chronic back pain, and this study was undertaken as a preliminary examination of its effectiveness in this role. In addition, we were interested in assessing the possible effectiveness of a combined regimen of NMES and TENS treatments for the reduction of chronic back pain. A double-blind, randomized repeated-measures design was used to compare the effects of NMES,conventional TENS, combined NMES/TENS, and placebo treatments on patient self-reports of pain reduction and pain relief. To approximate as closely as possible the conditions under which electrical stimulation is most often used, participants self-administered treatments according to protocol in an outpatient setting while maintaining their normal routine of daily activities.

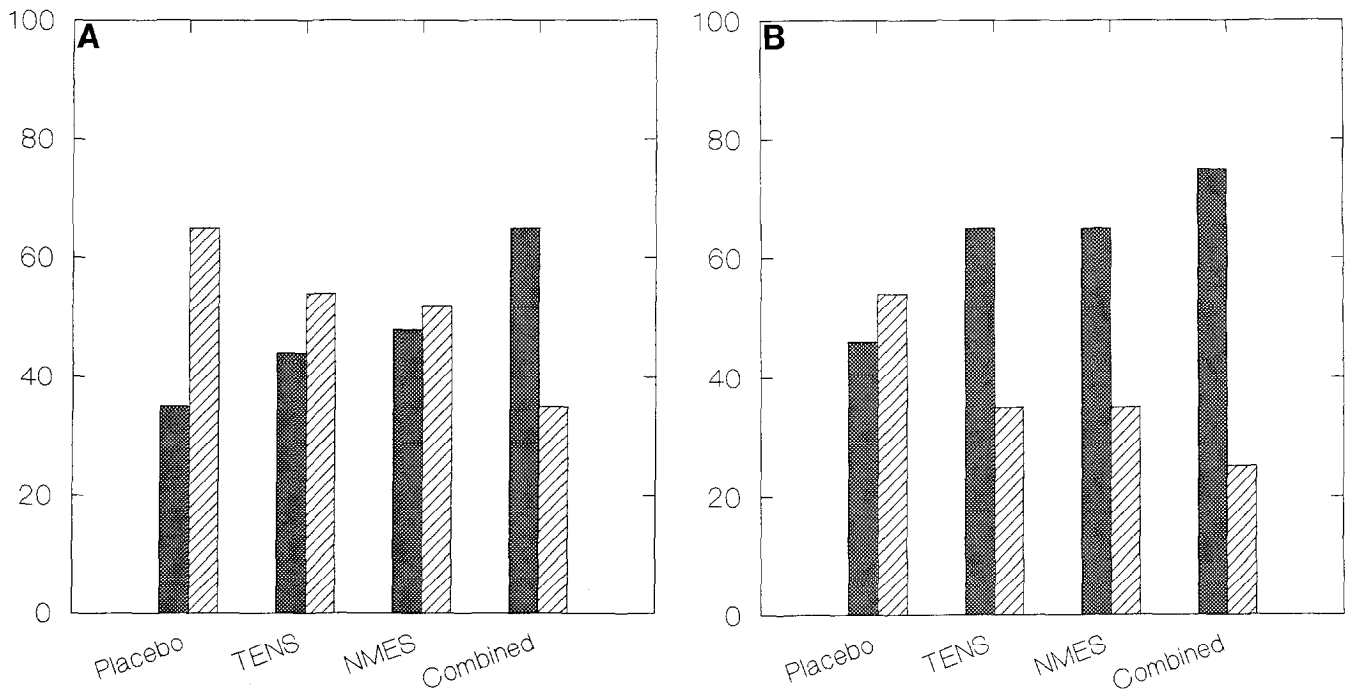


**Fig 1. Percentage of subject-days reporting pretreatment to posttreatment reductions in pain intensity as measured by (A) PPI and (B) VAS-I (■, improved; ▨, unimproved).**

## METHODS

### Subjects

Twenty-eight patients recruited from an outpatient Pain/Nerve Block Clinic in La Jolla, CA, fulfilled study criteria. The nature and purposes of the study were described in writing to all participants, and written informed consent was obtained. The criterion for inclusion was a diagnosis of back pain of at least 6 months' duration that had been largely unresponsive to previous treatments. Exclusion criteria included pregnancy, the use of a cardiac pacemaker, serious psychological disorder, and previous experience with either TENS or NMES. Four patients (all men) dropped out prior to completion of the study. The remaining 24 subjects (16 women, 8 men) who completed the study procedures ranged in age from 26 to 80 (mean age 51.67 years) and had a history of pain that varied from 2 to 10 years (mean duration 3.83 years). Nine subjects had a primary clinical diagnosis of bulging disc, 7 were diagnosed as postlaminectomy, 5 were diagnosed with spinal stenosis, and 1 had a diagnosis of spondylothesis. Subjects reported low back pain (15), middle back pain (3), upper back pain (4), and diffuse back pain (2).

### Pain Measurement

Subjects completed both the 5-point Present Pain Intensity (PPI) portion of the McGill Pain Questionnaire,[17] and a 10-centimeter visual analogue scale of Pain Intensity (VAS-I)[18] immediately before and immediately after each treatment. Subjects also completed a 10-centimeter visual analogue scale of Pain Relief (VAS-R) immediately after each treatment. After completion of the study, subjects were asked to indicate which treatment, if any, they would choose to continue if given the opportunity. Subjects were given instructions and practice in the use of all measures prior to their participation in experimental procedures.

### Materials

Conventional TENS treatment was delivered using a TENS unit producing an asymmetrical biphasic square pulse.[a] Pulse width was 100 microseconds with a frequency of 100Hz, and amplitude was adjustable within 0 to 60mA.

NMES treatment was delivered using a neuromuscular electrical stimulation unit producing a symmetrical biphasic square pulse.[a] Cycle on-time was preset at 5 seconds, and cycle off-time was preset at 15 seconds. Pulse width was 200 microseconds with a frequency of 70Hz, and amplitude was adjustable within 0 to 100mA.

Combined NMES/TENS treatment was delivered using a unit that combined both conventional NMES and TENS modes.[a] The TENS mode produced stimulation identical to that delivered by the TENS unit, while the NMES mode produced stimulation identical to that delivered by the neuromuscular electrical stimulation unit.

Placebo treatment was delivered using a modified TENS unit.[a] Although the power indicator light functioned in a manner identical to the unit employed in the TENS treatment condition, this unit was modified so that no actual stimulation was given. Subjects were told they would be unable to feel any stimulation because the unit delivered "imperceptible, subthreshold micro voltage." To increase the credibility of this manipulation, elaborate instructions were given for adjusting amplitude should "sensitization" cause the level of stimulation to exceed sensory threshold at any time during treatment.

All units were housed in identical $2\frac{1}{4} \times 3\frac{1}{2} \times 1$-inch unmarked plastic cases with dual output channels and dual on-off/amplitude controls. Two rectangular ($1\frac{3}{4} \times 1$ inch) reusable electrodes were used with each channel, for a total of four electrodes for each treatment.

### Procedure

All subjects self-administered NMES, TENS, combined NMES/TENS, and placebo control treatments, with order of

**Table 1: Pretreatment and Posttreatment Mean Pain Intensities and Standard Deviations, Percentage Decrease, *t* Scores, and Effect Sizes as Measured by PPI and VAS-R**

| Type of Treatment | Pretreatment Mean (SD) | Posttreatment Mean (SD) | Percentage Decrease | Paired *t* Test* | Effect Size |
|---|---|---|---|---|---|
| PPI | | | | | |
| Placebo | 2.79 (1.07) | 2.42 (1.15) | 13% | $t = 2.773$ ($p = .008$) | .375 |
| TENS | 2.58 (1.03) | 2.27 (1.13) | 12% | $t = 2.611$ ($p = .012$) | .356 |
| NMES | 2.67 (1.00) | 2.21 (.99) | 17% | $t = 3.974$ ($p < .001$) | .502 |
| Combined | 2.75 (1.14) | 1.94 (1.06) | 30% | $t = 5.864$ ($p < .001$) | .650 |
| VAS-R | | | | | |
| Placebo | 50.56 (29.13) | 44.81 (30.67) | 11% | $t = 1.88$ ($p = .066$) | .265 |
| TENS | 46.23 (26.88) | 40.58 (27.55) | 12% | $t = 2.49$ ($p = .017$) | .341 |
| NMES | 48.83 (27.66) | 39.67 (30.94) | 19% | $t = 3.24$ ($p = .002$) | .427 |
| Combined | 48.46 (28.81) | 36.33 (31.29) | 25% | $t = 4.11$ ($p < .001$) | .514 |

* $df = 1,47$ for all analyses.

treatments being completely randomized. Each treatment had a duration of 5 consecutive hours a day, for 2 consecutive days, with a 2-day hiatus between treatment conditions to minimize carry-over effects. Subjects were given the option of administering treatments during any 5-hour period of the day, with a requirement that all treatments must be administered at the same time each day throughout the entire study. Subjects were further instructed to continue their normal routine of daily activities during periods of treatment and to continue the use of all current pain medications as prescribed, but to begin no new regimen of pain medication, physical therapy, or other pain-related treatment during their study participation.

During both TENS and placebo control treatment phases subjects self-administered electrical stimulation (or sham stimulation) without interruption for 5 hours. During each 5 hours of NMES treatment subjects alternated three 10-minute periods of electrical stimulation with two 130-minute periods of no treatment. Treatment periods of 10 minutes were chosen because longer periods of repeated neuromuscular stimulation can cause muscle spasms in persons not accustomed to its use, and because this pattern of use is similar to that commonly prescribed. During each 5 hours of combined NMES/TENS treatment subjects alternated one 10-minute and one 20-minute period of NMES with 3 periods of TENS stimulation. Subjects were instructed to place the four electrodes from each unit directly over the area of the back where pain was typically most intense, and to use the same placement sites throughout the study. During TENS stimulation modes, subjects were instructed to adjust electrical output to an amplitude that produced a comfortable tingling sensation. During neuromuscular stimulation modes, subjects were instructed to adjust output to an amplitude that produced a strong and perceptible, but not painful, contraction of the muscles under each electrode. During placebo treatment subjects adjusted amplitude to a preset level. Subjects received both written and verbal instructions regarding procedures to be followed during each treatment phase. Subjects were given verbal instructions and practice in the use of all treatment devices by a research assistant who was blinded regarding the identity of the placebo. Subjects completed a daily record of medications and a daily checklist assessing adverse treatment effects and compliance with treatment protocol. After completion of their participation subjects were asked to indicate whether they had begun any new pain-related treatments during the course of the study.

### Statistical Procedures

McNemar's chi-square test ($\chi^2$) was conducted to test proportions of subjects in each treatment condition reporting pretreatment to posttreatment reductions in pain as measured by the PPI and VAS-I. Paired *t* tests (*t*) were used to examine pretreatment to posttreatment changes in pain intensity on both the PPI and VAS-I. Pretreatment to posttreatment difference scores were calculated for both the PPI and VAS-I, and along with VAS-R scores were tested using repeated measures analysis of variance (ANOVA) *F* statistics. The assumption of homogeneity of variance was verified using Levene's Test, and the assumption of homogeneity of covariance was satisfied. Although PPI difference scores, VAS-I difference scores, and VAS-R scores were nonnormally distributed, ANOVA is considered robust to violations of the assumption of normalcy of distribution.[19,20] Because homogeneity of variance was satisfied, the pooled error term was used to compute pairwise contrasts.[21,22] Contrasts between placebo and active treatments were handled as planned comparisons, while contrasts between active treatments were treated as post hoc (ie, unplanned). When the overall *F* was nonsignificant Bonferroni's correction was applied. Results were considered significant when $p < .05$.

## RESULTS

No adverse treatment effects were reported and no subject reported the addition of any new pain medication, physical therapy, or other pain-related treatment during the course of their study participation. Only subjects who complied with all experimental procedures were included in the data analysis. Results of a 4(Treatment) × 2(Day) repeated measures ANOVA indicated no main effect for day of treatment and no day-by-treatment interaction for any of the three primary dependent measures examined and, as a result, data for day 1 and day 2 were combined for all subsequent analyses.

### Dropouts

Of the 4 men who dropped out, 1 terminated due to reported frustration with treatment procedures, 1 failed to return for a follow-up appointment and could not be located, and 2 were eliminated because of noncompliance with experimental procedures. Dropouts differed from completers by sex ($\chi^2 = 3.80$, $df = 1$, $p = .05$), but not by age or duration of pain.

### Frequency Data

PPI measurements of pain intensity decreased on 31 subject-days (65%) following combined treatment, as opposed to 17 (35%) following placebo ($\chi^2 = 6.5$, $df = 1$, $p < .05$). A similar pattern emerged from analysis of the VAS-I, where decreased pain intensity following combined treatment was reported for 36 subject-days (75%), as compared to 22 (46%) following placebo ($\chi^2 = 6.4$, $df = 1$, $p < .05$) (fig 1).

After their participation, 9 subjects (38%) reported they would continue combined treatment if given the option, 5 (21%) chose NMES, 2 (8%) chose TENS, and 2 (8%) chose placebo. Six subjects (25%) reported they would choose none of the four treatments tested.

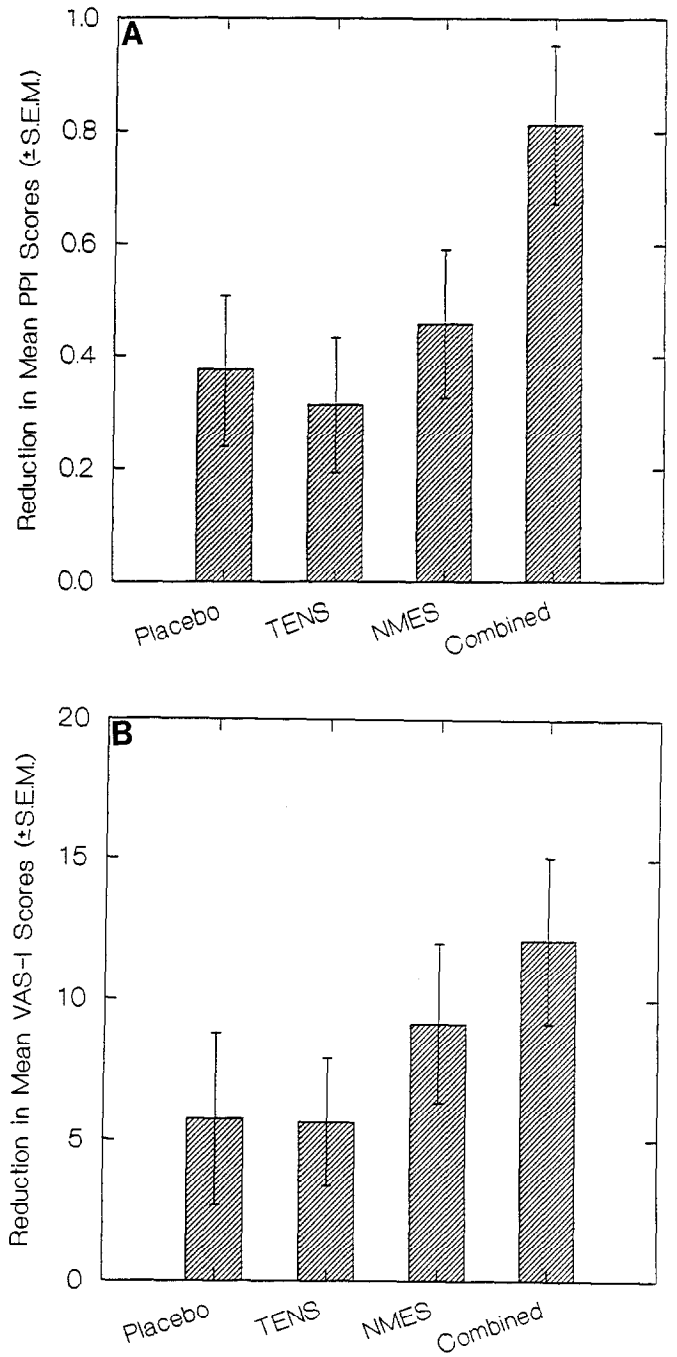


**Fig 2. Pretreatment to posttreatment reductions in mean pain intensity (and SEM) as measured by (A) PPI and (B) VAS-I.**

## Reduction in Pain Intensity

Subject's pretreatment ratings ranged from 1 (mild) to 4 (horrible) on the PPI and from 13 to 96 on the VAS-I, and did not differ significantly as a function of treatment condition. NMES, TENS, and combined NMES/TENS each produced significant pretreatment to posttreatment reductions in pain intensity as measured by both the PPI and VAS-I (table 1). Placebo produced a significant reduction on the PPI, but not the VAS-I.

Analysis of pretreatment to posttreatment difference scores indicated a significant overall treatment effect as measured by the PPI ($F(3,141) = 2.99$, $p = .033$), but not the VAS-I ($F(3,141) = 1.40$, $p = .246$). Combined treatment led to greater pretreatment to posttreatment reductions in pain intensity than placebo as measured by both the PPI ($F(1,141) = 11.48$, $p = .001$) and VAS-I ($F(1,141) = 5.91$, $p = .016$) (fig 2). Combined treatment also resulted in greater pain reduction than both TENS ($F(1,141) = 15.00$, $p < .001$) and NMES ($F(1,141) = 7.53$, $p = .007$) as measured by the PPI.

**Table 2: Mean Posttreatment Pain Relief and Standard Deviations as Measured by VAS-R**

| | Type of Treatment | | | |
|---|---|---|---|---|
| | Placebo | TENS | NMES | Combined |
| Mean | 32.167 | 47.167 | 48.479 | 59.313 |
| SD | 29.704 | 33.322 | 30.829 | 32.779 |

## Pain Relief

Overall effect of treatment on pain relief as measured by the VAS-R was highly significant ($F(3,141) = 9.95$, $p < .001$; (table 2). Combined treatment ($F(1,141) = 58.90$, $p < .001$), NMES ($F(1,141) = 21.27$, $p < .001$), and TENS ($F(1,147) = 17.98$, $p < .001$) each produced significantly more pain relief than placebo as measured by the VAS-R, and combined treatment produced significantly greater pain relief than either TENS ($F(1,141) = 11.79$, $p = .001$), or NMES ($F(1,141) = 9.380$, $p = .003$) (fig 3).

## DISCUSSION

Results indicate that a combined regimen of NMES and TENS treatments was significantly more effective than placebo on every measure of pain reduction and pain relief examined. Combined treatment was also significantly more effective than either TENS or NMES alone on a majority of the dependent measures assessed, with group trends in the direction of superior performance by combined treatment on every dependent measure. This pattern is similar to the results of two other studies[23,24] that reported that a combination of TENS and another treatment was more effective than TENS alone.

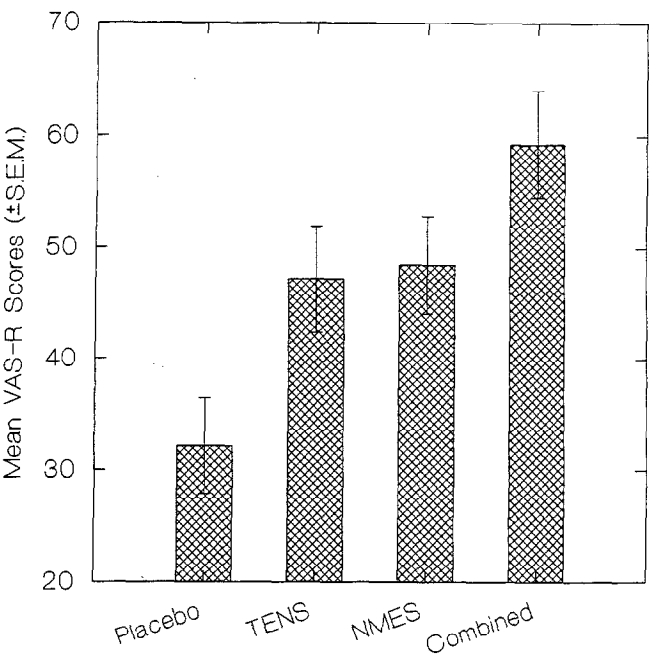


**Fig 3. Mean pain relief (and SEM) as measured by VAS-R.**

This study provides only qualified evidence for the effectiveness of either NMES or TENS alone. Both treatments did produce significantly more pain relief than placebo, but neither TENS nor NMES was significantly superior to placebo for pain reduction, and neither was significantly more effective when compared to any other active treatment examined. Group trends show that TENS was remarkably similar to placebo on every measure except the VAS-R, in addition to being inferior to both combined treatment and NMES on every measure. In contrast, trends for NMES were in the direction of greater effectiveness than both placebo and TENS on every dependent measure. The failure of TENS to demonstrate that it is more effective than placebo for reduction of back pain is in contrast to research suggesting that TENS may be efficacious in the management of a variety of pain conditions.[11] It is, however, consistent with the findings of the Quebec Task Force on Spinal Disorders, which concluded that convincing evidence for the efficacy of TENS in the treatment of chronic back pain is lacking.[3] The mixed pattern of results produced by NMES is similar to those reported in a clinical trial of subacute back pain in which NMES, chiropractic manipulation, corset, and massage treatments produced equal amounts of pain reduction.[25]

Several qualifications apply when considering the mixed pattern of results obtained for both NMES and TENS treatments. We used only conventional TENS, and it is possible that some subjects who did not respond to this treatment would have benefited from acupuncture-like TENS. In addition, it is also possible that instructing subjects to simply place electrodes over the spot where their pain was greatest reduced the effectiveness of TENS, and more rigorous placement selection might have produced a different outcome. Our own clinical experience, however, as well as that of others familiar with the use of TENS, suggests that patients frequently place electrodes in this manner despite other more specific instructions, and to the degree this is true our results are generalizable to actual patterns of use. In the case of NMES it is possible that a longer duration of treatment than the three 10-minute periods of stimulation spread across 5 hours used in our study might have produced significant results, especially if the effects achieved with NMES are cumulative.

The preliminary nature of this study necessarily dictated limitations in length of treatment, outcome measures, and follow-up. At the same time, the method employed does eliminate several possible sources of confounding that have flawed many previous studies examining TENS and electrical stimulation, including absent or inadequate double-blinding, a lack of quantitative outcome measures, and the absence of placebo control. Although we incorporated no formal check of our placebo manipulation, sham TENS did produce significant pretreatment to posttreatment reductions in pain intensity, as well as pain reductions similar to those achieved with actual TENS, and these results suggest that a significant placebo effect was achieved. In addition, several other clinical trials have also demonstrated that placebo TENS of the type used in this study is credible, and does create a reliable placebo effect.[13,26] Finally, by having subjects self-administer treatments in the course of their normal routine of daily activities the results of this study are directly generalizable to the unsupervised outpatient settings in which electrical stimulation is typically used.

Although preliminary in nature, our results suggest that a combined regimen of NMES and TENS may be a valuable adjunct in the management of chronic back pain. Table 1 shows that combined NMES/TENS produced pretreatment to posttreatment reductions of 25% on one measure of pain intensity and 30% on another, magnitudes of difference that are both clinically meaningful and twice as great as those achieved using TENS. Pain reductions associated with NMES alone were substantially smaller and of less certain clinical utility, although NMES did perform at least as well as TENS, the standard of effectiveness for electrical stimulation treatment. Several clinical trials have concluded that TENS demonstrates initial benefits that decline thereafter,[11] and it will be important that future research evaluating both NMES and combined NMES/TENS employ longer periods of treatment with follow-ups to determine if the effects of these methods also change significantly over time. Trials of longer duration are also needed to examine possible side effects associated with prolonged use of NMES for pain management, as are trials that measure a wider variety of important clinical outcome variables including pain, mood, and function.

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**Supplier**

a. Electrical stimulation units used in all treatment conditions were supplied by Vision Quest, Incorporated, Costa Mesa, CA 92626. TENS and placebo TENS treatments were delivered by a J.D. Medical, Incorporated, TENS unit, NMES was delivered using a J.D. Medical, Incorporated, Neuromuscular Stimulation unit, and combined NMES/TENS was delivered using a Vision Quest, Incorporated, Fast Start unit.