SPINE Volume 19, Number 5, pp 561–568


# A Randomized Controlled Trial of Transcutaneous Electrical Nerve Stimulation (CODETRON) to Determine Its Benefits in a Rehabilitation Program for Acute Occupational Low Back Pain

Edith Herman, PhD, PT,* Renee Williams, MSc, MHSc, PT,*
Paul Stratford, MSc, PT,* Angelica Fargas-Babjak, MD,† and Maria Trott, BSc

The authors report the results of a randomized controlled trial to examine the effectiveness of transcutaneous electrical nerve stimulation (TENS/CODETRON) when added to a standard exercise program for industrial workers with acute low back pain (LBP). Fifty-eight work-injured patients with LBP of 3–10 weeks duration were randomized into two groups that received actual or placebo stimulation in combination with the exercise regimen. The groups were compared on the primary outcome measures of disability, pain, and return to work. No significant differences between the experimental and placebo groups were discovered on any of the measured outcomes. Exercise alone, when continued over 4 weeks, reduced disability and pain scores significantly. Under the experimental conditions of this trial, no additional benefits of TENS/CODETRON were detected when added to an active exercise regimen. [Key words: industrial injury, low-back pain, randomized controlled trial, rehabilitation, transcutaneous electrical nerve stimulation]

Each year, at least 2% of the workforce sustain a compensable low-back injury.[17,18,37] Although 80%–90% of the injured workers return to work within 3 months,[13] the risk of chronic disablement increases disproportionally after 6 months off the job.[48] Early rehabilitation and a prompt return to work therefore is important for stemming the staggering economic drain that results from chronic disability. The development of cost-effective strategies for returning the patient to optimal levels of functioning as rapidly as possible has remained a therapeutic challenge.

The primary goal of rehabilitation is to decrease disability by reducing pain and increasing fitness, typically achieved by a progressive exercise regimen. There is evidence that intensive training, besides hastening functional rehabilitation and return to work,[25] also diminishes pain.[27]

To the extent that pain, or the fear of it,[21] interferes with the capacity to exercise, pain relief should enhance it. Among pain-relieving modalities with the strongest scientific support is electroanalgesia,[45] acupuncture being slightly superior to transcutaneous electrical stimulation (TENS) regarding the amount and duration of pain relief.[10,19] With the focus on pain relief, TENS is typically used in conjunction with rest; therefore, it may be counterproductive in attaining goals of physical and cardiovascular fitness and preventing deconditioning.

The rationale of using TENS in combination with exercise is based on neurophysiologic and behavioral features of exercise and electrical stimulation[43,49] that suggest common mechanisms of pain reduction. There is scientific evidence that exercise and TENS have neuroregulatory peripheral and central effects[11,15,47] and modulate pain transmission.[26,29] Both seem to be more effective with higher intensity,[23,24,28] plausibly explained by the activation of intrinsic pain-suppressive systems[40,41] and the concomitant release of opiate and nonopiate neuro-regulators.[1,7,11,12,32,39] However, although TENS is a "passive" modality (and may even condition dependency behavior), pain relief after exercise may be attributed to the patient's own efforts and thus be self-reinforcing.

Given the physiologic links between physical exercise and TENS, one would intuitively expect a synergistic action if they were used concurrently. The purpose of this investigation was to test this assumption by determining whether the addition of a pain-relieving modality (TENS/CODETRON),[6,33] given in combination with a standardized back rehabilitation program for recently injured workers, would help reduce disability and pain and enhance return to work. Conversely, if TENS failed to demonstrate significant benefits to the outcome measures, we may have to rethink its role within a rehabilitation program for patients with acute LBP. It should

From the *School of Occupational Therapy and Physiotherapy and the †Department of Anaesthesia, McMaster University, Hamilton, Ontario.
Accepted for publication February 2, 1993.

be clearly noted that this study's question does not primarily concern the efficacy of TENS in relieving pain, but its effects on disability when used with a back rehabilitation program.

## ■ Methods

**Subject Selection and Allocation.** Subjects were eligible for this study if they had sustained a work-related low-back injury of musculoskeletal or fibromyalgic origin of 3–10 weeks duration, were able to tolerate exercise and TENS/CODETRON, and provided informed consent. Subjects were excluded for the following reasons: 1) pregnancy; 2) objectively determined pathology of the spine; 3) previous spinal surgeries; 4) cardiac disease or cardiac pacemaker; 5) concurrent interventions (e.g., chiropractic or additional physical therapy); 6) toxification by narcotic analgesics; 7) psychiatric illness; 8) prior experience with TENS/CODETRON; or 9) contraindications to TENS.

Fifty-eight subjects were identified and randomly assigned to the two intervention groups: 1) active TENS/CODETRON plus exercise; or 2) placebo TENS/CODETRON plus exercise. Numerical randomization schedules were generated by computer in balanced block sizes of 10. Blindness of personnel and subjects to each subject's group allocation was maintained throughout the trial, except for the therapist who applied the TENS/CODETRON.

An *a priori* determination of the sample size required 46 patients (23 per group) for comparison of continuous variables, and accepted a statistical significance level of 5% (alpha = .05) and a power of 90% (beta = .10) for a one-tailed test (one-directional hypothesis); one standard deviation was considered clinically important. An expected drop-out rate of 20% was included in this calculation. The clinical difference for the return-to-work rate originally was based on a previously conducted follow-up of 98 patients who had completed the program (which did not include TENS). We decided that the return-to-work rate after TENS *plus* exercise would have to increase by 20% to be clinically significant.

**Setting.** The study was conducted between March 1990 and March 1992 within an existing Workers' Compensation Board back program at a teaching hospital in Hamilton, Ontario. The goals of this outpatient program are early rehabilitation of injured workers, early return to work, and reduced risk of reinjury. Patients were referred by a physician and attended the program 4 hours per day, 5 days per week.

**Intervention Protocols.** Subjects in both groups were instructed not to take their pain medication 4 hours before the application of electrical stimulation. The TENS device chosen for this trial was the CODETRON (EHM Rehabilitation Technologies, Inc., Downsview, Ontario, Canada) a type of TENS that has been shown to have scientific merits[33] and to have demonstrated good clinical results,[1,6] but that still lacks statistical validation of its clinical effectiveness. CODETRON differs from traditional TENS in that CODETRON randomly switches stimulation among six electrode sites every 10 seconds, preventing habituation to repetitive signals.

TENS/CODETRON was applied 30 minutes before the exercise regimen. Group A received TENS by an active CODETRON unit; the placebo TENS group received treatment

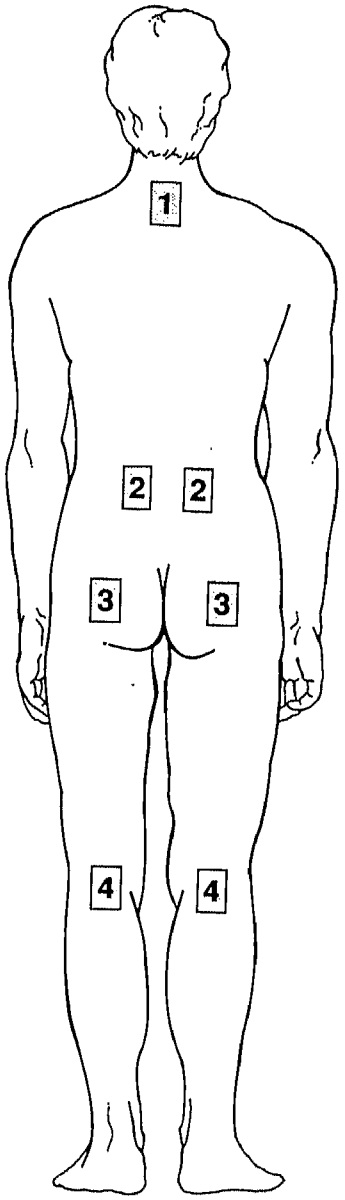


Figure 1. Electrode placement. 1. Below spinous process C7 (positive electrode); 2. Paravertebral L2–3; 3. Gluteal region/sciatic nerve; 4. Popliteal fossa/popliteal nerve.

with an identical unit that did not produce an output. The absence of sensation was explained with "subliminal" stimulation. One of the investigators (AFB) has extensive clinical experience with the device and trained the therapists in its proper use. Instructions to the patient and electrode placements[42] were standardized (Figure 1). The positive electrode was placed at C7 (corresponding to acupuncture point GV 14). The six negative electrodes were placed bilaterally in the following way: the first pair over the intervertebral foramina of L2–3, 2.5–3 cm from midline (B 23, 24); the second pair at the more tender point of where the sciatic nerve exits from the greater sciatic foramen (B 49) or over the sciatic nerve, one-third of the distance from the greater trochanter to the sacral hiatus (GB 30); and the third pair (distal placement) in the popliteal fossa at the bifurcation of the sciatic nerve (B 54).

The subjects in the experimental group first received 15

minutes of high frequency TENS/CODETRON (Code IV, 200 Hz)[5] with an intensity that produces a strong but comfortable tingling sensation but no muscle twitches, followed by 15 minutes of acupuncture-like TENS/CODETRON (Code III, 4 single pulses/sec), producing a very strong sensation and local muscle twitches. The subjects in the experimental group were encouraged to accept the highest intensity within limits of tolerance. Single pulses (Code III) were chosen over the more comfortable four short bursts of pulse trains with an internal frequency of 200 Hz because of the closer approximation to acupuncture stimulation and because of purported longer duration of pain relief.

**Exercise.** The back rehabilitation program was aimed at enhancing flexibility, muscle strength, and cardiovascular fitness. The regimen consisted of: hydrotherapy (principally stretching exercises); mobility exercises for spine and lower limbs; strengthening exercises for abdominals and trunk extensors, as well as for upper and lower limbs; and cardiovascular fitness training on a cycle ergometer. Each subject's training program was tailored to his or her ability.

**Outcome Measures.** The primary outcome measures were: disability; present pain perception; and return to work. Secondary measures included fitness, arm and leg strength, and lumbar mobility measurements.

The Roland-Morris disability questionnaire, an abbreviated adaptation of the Sickness Impact Profile, was used to assess disability.[35,36] Specifically designed for LBP, this self-administered questionnaire consists of 24 items and requires about 5 minutes to complete. Items are scored one point if checked, zero if unchecked. Thus, scores can vary from 24 (significant disability) to zero (no disability). This instrument has been shown to reliably and capably assess change over time in subjects with LBP. Our *a priori* estimate of a clinically important difference between groups was 2 points.

Perception of pain was measured three times each day (before TENS application [T1], following TENS application/before exercise [T2], and after exercise [T3]) using a 100 mm vertical visual analog scale (VAS).[38] The scale anchors were defined as "no pain" and "worst pain possible." After a standard explanation, subjects placed marks corresponding to their present pain perception on the line between the anchors. Apart from the ease of administration and its comprehensibility, this instrument's sensitivity and test-retest reliability ($r = 0.95$) have been established.[34] Our *a priori* estimate of a clinically important between-group difference was 10 mm.

Fitness was determined by a progressive incremental exercise test carried out on an electrically braked cycle ergometer (Elema 370; Siemens, Solna, Sweden) concomitantly with a 12-lead electrocardiographic monitor (1515-B Automatic Cardiograph; Hewlett Packard Inc., Fullerton, CA). Subjects exercised by pedalling at a rate of 60 revolutions per minute at an initial power output of 50 kilopond meters per minute (kpm/min) for the first minute, which then was increased by 50 kpm/min at the end of each minute. Because percentage of predicted peak work capacity provides an index of the integrated response of cardiovascular and respiratory systems,[16] this measure represented the dependent fitness variable.

Upper and lower extremity strengths were assessed using Hydrafitness equipment (Hydragym Industries, Belton, TX). This device quantifies the peak force generated. Upper extremity strength was assessed using the bilateral push-pull device, and lower extremity strength was estimated using the bilateral knee extension and flexion apparatus. Lumbar flexion was assessed using the modified Schoeber test.[22]

**Table 1. Subjects' Demographic Characteristics**

| | Group A* (n = 29) | Group B† (n = 29) |
|---|---|---|
| Sex | | |
| Male | 24 | 22 |
| Female | 5 | 7 |
| Mean (SD) age (yr) | 36.7 (11.5) | 41.7 (11.4) |
| Mean (SD) height (cm) | 171.6 (9.5) | 172.5 (9.8) |
| Mean (SD) percent of ideal weight | 119.9 (21.3) | 128.6 (19.2) |
| Married or equivalent | 21 | 24 |
| Job satisfaction (high) | 20 | 22 |
| Regular exercise | 8 | 11 |

* Active TENS/CODETRON.
† Placebo TENS/CODETRON.

The intended end-point for the outcome measures of disability, pain, fitness, and strength was 4 weeks after enrollment into the program. Because present pain perception was recorded at each treatment session, the subject's most recent visit before the defined end-point was used in the analysis in case a subject failed to complete the 4 week program. Return to work was formally assessed at 35 days (5 weeks) and 182 days (6 months) after the enrollment date. The 35th day was chosen for the return-to-work end-point (4 weeks plus one additional week for medical assessment and the necessary paper work). Our *a priori* definition of clinical significance was a 0.20 difference in the proportion of subjects returning to work.

**Statistical Methods.** A Fisher exact test was used to compare the number of subjects available in each group at follow-up. Intervention effectiveness for the variables disability and pain were assessed using a repeated measures analysis of variance (ANOVA). Because the rationale underlying the study was based on the premise that pain might interfere with exercise, a second pain analysis was performed that explored in more detail the daily VAS scores obtained before and after treatment and after exercise. The mean VAS data averaged over all days available per patient were subjected to a repeated measures ANOVA with the between-subjects factor of "treatment" (groups A and B) and repeated measures on the two within-subject factors of "time period" (three levels: T1, T2, T3) and "days of treatment" (20 levels). The incomplete database required a "regression-like" procedure provided by the BMDP package 5V,[4] which corrects for missing data and estimates the effects of various factors. Chi-squared tests were used to evaluate the proportion of subjects who resumed work at 5 weeks and 6 months. All subjects were included in the return-to-work analysis. The critical $P$ value for all statistical tests was set at 0.05. BMDP[4] statistical software (version PC 90; BMDP Statistical Software, Inc., Los Angeles, CA) was used to perform the analysis.

## ■ Results

Fifty-eight eligible subjects were entered into this trial. Table 1 provides a summary of their demographic char-

**Table 2. Reasons for Incomplete Data at Four Week Follow-up**

| Reason for Drop Out | Group A* | Group B† |
|---|---|---|
| Adverse effects | 2 | 2 |
| Protocol violation | | |
| Medication | 1 | — |
| Noncompliant with program | 3 | — |
| No post-test | | |
| Early return-to-work | 5 | — |
| No return-to-work | 3 | 1 |

* Active TENS/CODETRON.
† Placebo TENS/CODETRON.

acteristics according to treatment group. There were no significant differences between the two groups before they received the intervention. Although each group began the study with 29 subjects, complete data on all outcome measures were available for only 15 subjects (51.7%) in Group A and 26 subjects (89.7%) in Group B. The disproportionate attrition rate was statistically significant (Fisher exact test, $P = 0.0032$).

Table 2 summarizes the reasons for drop-out/non-completion that resulted in incomplete follow-up data. Two subjects in each group dropped out because of increased LBP. The mean baseline and 4 week follow-up values for the outcome measures of disability, pain, percentage of predicted peak work capacity, muscle strength, and lumbar flexion are presented in Table 3.

### *Disability*

The mean Roland-Morris scores at entry and at 4-week follow-up for each group, surrounded by 95% confidence intervals, are plotted in Figure 2. As can be seen, the groups had a similar decrease in Roland-Morris mean scores (approximately 4 points) between baseline and 4-week follow-up (Table 3). The repeated measures

**Table 3. Baseline and Four Week Follow-up Measures**

| | Baseline | | | 4-Week Follow-up | | |
|---|---|---|---|---|---|---|
| | Group | Mean | SD | N | Mean | SD |
| Roland Disability | A* | 12.5 | 5.1 | 19 | 8.9 | 5.0 |
| Score (items) | B† | 14.3 | 5.2 | 27 | 9.9 | 6.4 |
| Pain | A | 42.7 | 23.3 | 29 | 35.8 | 27.7 |
| VAS (mm) | B | 47.9 | 21.3 | 29 | 35.9 | 27.0 |
| Percent predicted | A | 75.6 | 22.6 | 15 | 90.0 | 19.3 |
| Peak work capacity | B | 79.3 | 21.1 | 26 | 90.6 | 20.8 |
| Upper extremity | A | 109.5 | 58.0 | 15 | 129.1 | 51.7 |
| Pull strength (lb) | B | 91.5 | 41.7 | 26 | 119.3 | 44.6 |
| Upper extremity | A | 138.5 | 65.9 | 15 | 154.9 | 60.8 |
| Push strength (lb) | B | 125.2 | 63.2 | 26 | 146.2 | 57.3 |
| Knee flexion | A | 55.8 | 49.5 | 15 | 69.4 | 36.4 |
| Strength (lb) | B | 50.2 | 27.4 | 25 | 59.7 | 26.3 |
| Knee extension | A | 101.5 | 62.7 | 15 | 117.3 | 56.2 |
| Strength (lb) | B | 95.8 | 48.6 | 25 | 106.4 | 50.1 |
| Lumbar flexion (mm) | A | 50.9 | 16.2 | 20 | 60.2 | 10.5 |
| | B | 44.8 | 15.9 | 29 | 61.7 | 13.9 |

* Active TENS/CODETRON.
† Placebo TENS/CODETRON.
VAS = visual analog scale.

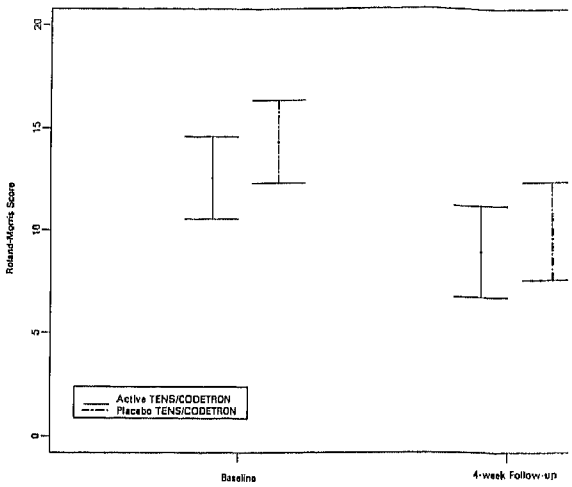


Figure 2. Mean Roland-Morris scores at baseline and follow-up. The points represent the mean Roland-Morris for active TENS/CODETRON group and placebo TENS/CO group at baseline and 4 week follow-up surrounded by 9 fidence intervals. Higher Roland-Morris scores indicate disability.

ANOVA showed a statistically significant differe tween the baseline and 4-week follow-up scores 25.81, $P < 0.0001$); however, no significant tre effect was noted (time × Treatment interaction 0.40, $P = 0.529$).

### *Pain*

Two repeated measures ANOVA were performed VAS scores. The first ANOVA, performed on th line and 4-week follow-up measurements, demon a significant decrease between entry and 4-we low-up scores ($X^2_1 = 7.85$, $P = 0.005$), and the no difference as a result of treatment (time × tre interaction $X^2_1 = 0.56$, $P = 0.455$; Figure 3).

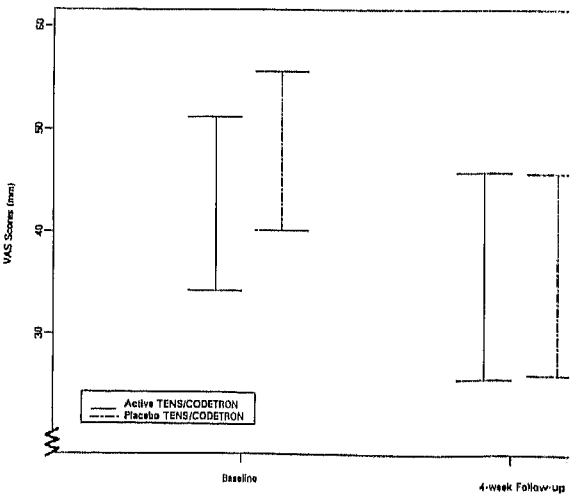


Figure 3. Mean visual analog scale (VAS) pain scores at and 4 week follow-up. The points represent the mean VA for active TENS/CODETRON group and placebo TENS/CO group surrounded by 95% confidence intervals.

Because the rationale underlying the study was based on the premise that pain might interfere with exercise, a second ANOVA was performed that explored in more detail the VAS scores before and after TENS (T1, T2) and before and after exercise (T2, T3; Figure 3). Significant effects were observed on each of the repeated measures factors. The significant effect of "day" ($X^2_{19}$ = 126.83, $P < 0.001$) reflects nonsystematic day-to-day variations in VAS scores over the time of study. The effect of "time" ($X^2_2$ = 49.05, $P < 0.001$) reflects a decrease in pain at T2 that does not appear to be sustained to T3. Of greater interest is the significant "treatment × time interaction" ($X^2_2$ = 14.44, $P$ = 0.001), which indicates that group A subjects show a greater pain reduction immediately after the application of TENS/CODETRON (T2) than group B subjects (Figure 4). This difference, however (less than 10 mm), does not meet our *a priori* definition for a clinically important change.

### *Percentage of Predicted Peak Work Capacity, Muscle Strengths, and Lumbar Flexion*

Concordant with the observations on disability and pain, these measurements showed significant differences between entry and 4 week follow-up measurements ($P < 0.001$), and no differences for the "treatment × time interactions" ($P > 0.05$).

### *Return to Work*

Seventy-two percent of the entire sample returned to work within 182 days of the enrollment date. The difference in return to work between the groups (66% of group A; 79% of group B) was not significant ($X^2_1$ = 1.38, $P$ = 0.24). The return to work curves, presented in Figure 5, show that eight subjects in the active TENS/CODETRON group and four subjects in the placebo group returned to work by the end of 35 days from the enrollment date. This difference is not statistically significant ($X^2_1$ = 1.68, $P$ = 0.19). It also is evident that the greatest rate of return to work occurred between the 35th day and the 70th day and that this rate was similar for both groups. The median interval from enrollment to return to work was 56 days for both groups.

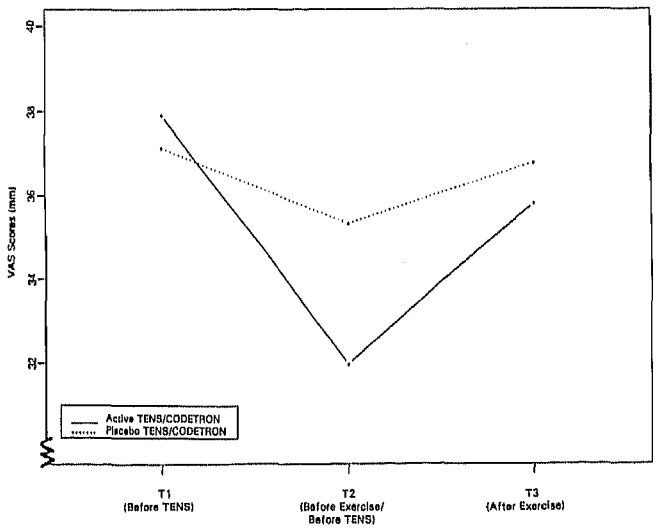


Figure 4. Mean visual analog scale pain scores across 20 days by treatment group. The measurements represent the pain levels at three time periods: T1, before TENS; T2, after TENS/before exercise; and T3, after exercise.

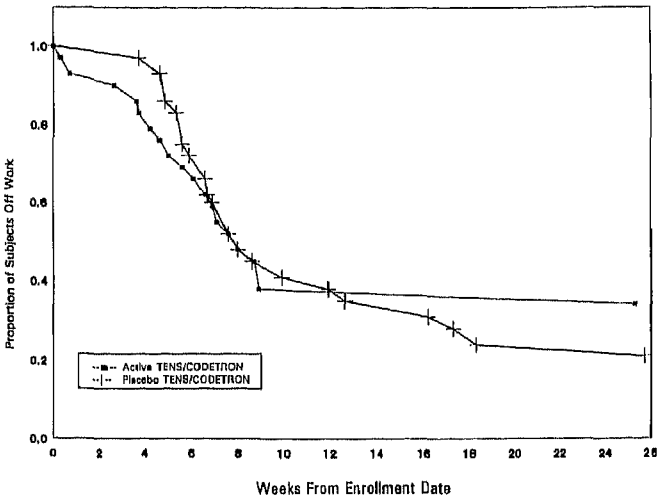


Figure 5. Return-to-work profile by treatment group.

Because the analyses did not detect a statistically significant difference between treatment groups, a post-hoc power analysis was performed on the three primary outcome measures.[8] The power values represent the probability of detecting a clinically significant difference between groups at a level specified *a priori* for each variable. These power analyses take into account the group differences on the outcome measures of interest observed in this study. The results of the power analyses (the ability to detect our stipulated between-group differences, given they truly exist) presented in Table 4 demonstrate high power values for the measures of disability (0.96) and pain (0.99), and a lower power (0.72) for return to work.

## ■ Discussion

The results of our study do not indicate that TENS/CODETRON treatments contributed to improved functional status, decrease in perceived pain, or earlier return to work in a homogeneous sample of Workers' Compensation Board workers with acute occupational LBP. Although both groups improved significantly during the program, no additional advantages accrued from TENS/CODETRON. No significant differences between the active TENS/CODETRON group and the placebo group were found on any of the outcome measures. The results of this study agree with previous reports that TENS, when added to exercises, did not result in better outcomes than exercise alone.[3,19]

The most obvious limitation of the study is the disproportionate drop-out rate among the subjects. As

**Table 4. Statistical Power for Primary Outcome Measures**

| Measure | *A priori* Estimate of CIBGD* | Difference Scores: Active TENS/CODETRON | Difference Scores: Placebo TENS/CODETRON | Error Variance | Power |
|---|---|---|---|---|---|
| Roland-Morris | 2.0 | 3.6 | 4.4 | 27.97 | 0.96 |
| Pain VAS | 10.0 | 6.9 | 12.0 | 683.41 | 0.99 |
| | | Actual return to work proportional at 5 weeks | | | |
| Return to work | 0.20 | 0.28 | 0.14 | 0.17 | 0.72 |

* Clinically important between-group difference.

pointed out, a significant proportion of patients in the experimental group did not complete the full regimen. Although this substantial attrition might have seriously compromised the statistical analysis, it is not clear how it affected the outcome, and it is unclear whether the results would have been different had the number of subjects in group A been maintained. A conservative evaluation of data on a variety of pre- and post-measures gave no indication of clinically important or statistically significant differences between the groups. The lack of group differences in acute LBP patients treated by slightly different methods is not unique to this study. Fordyce et al[9] found no group differences in activity measures taken immediately after a course of treatment. This observation may mean that improvement in the early stages occurs regardless of treatment methods used.

### *Disability*

The magnitude of change over the 4 week interval, approximately 4 points (or items) on the Roland-Morris scale, is similar to that reported by others.[2,36] Specifically, Roland and Morris[36] reported a 4-point change on the Roland-Morris scale over a 4 week period, and Deyo[2] found a 3-point change over a 3 week period. The significantly improved levels of functioning in both groups may have been expected because of a combination of factors such as exercise training, the passage of time, education, and the influence of the therapeutic milieu ("group spirit").

### *Pain*

Counter to previous reports,[31] in the present study acute LBP was not appreciably relieved by TENS/CODETRON, and the small changes were not sustained over time. Exercise alone, when carried out over an average of 20 supervised exercise sessions, reduced pain scores significantly. Exercises also may result in more enduring benefits. Previously presented evidence appears to support this contention.[13,24,25]

### *Fitness*

The greatest benefits derived from the program were reduced functional disability and pain and improved exercise capacity (increased peak work capacity, muscle strength, and lumbar mobility). Despite great individual variability, both groups improved considerably on a variety of fitness measures, confirming previous reports of the important benefits of activity-focused back rehabilitation programs.[3,19,20,25,27,44,46]

### *Return to Work*

Although 28% of the subjects in group A and only 14% of the subjects in group B returned to work within 5 weeks of enrollment in the study, this difference was not statistically significant. Expressed as proportions, the observed difference between treatment groups was 0.14. The power analysis suggests that, given our sample size, a difference of 0.20 would be detected 72% of the time. Clearly, this represents a power of marginal magnitude. If a smaller difference is considered clinically significant, the power would be lower than 0.72.

The overall return to work at six months was 72% in our sample. Although this rate is about 8% lower than that reported in other studies,[13,25,30] it may have been influenced by the prevailing economic situation (recession) at the time of this study. Some subjects were willing to return to work but were prevented from doing so because of changed working environments (no alternate jobs, plant closures, strikes, etc.). The finding of no difference in return to work between treatment groups is concordant with the other outcome measures.

Our results do not imply that selected patients do not benefit from TENS when it is judiciously applied after trial stimulation. It may be argued that in the present study TENS was not employed in its optimal manner. Although patients with typically poor response rates to TENS (multiple surgeries, opiate medication, psychopathology) had been excluded, TENS parameters were not adjusted to the patients' needs. Applying TENS with standardized, predetermined electrode placement is, in our experience, frequently not as effective as selecting optimal stimulation points that may differ not only from patient to patient but even vary from session to session. Parameters and modes of stimulation also were not individualized. The selected mode, although it most closely mimicked acupuncture, also has been described by some patients as being unpleasant.[14] Great individual differences in responsiveness to TENS complicate all group comparisons. Because randomized controlled trials are rather expensive in terms of time, money, and

people, single-case experimental designs (under rigorous experimental control and with systematic replications) may be a more appropriate method for determining the conditions under which TENS succeeds or fails. Flexible, relatively inexpensive, and easy to integrate in clinical practice, these designs would seem to reduce the threat to internal validity (e.g., disproportionate loss of subjects in the experimental group).

In conclusion, no additional benefits from standardized TENS/CODETRON treatments, when added to a back rehabilitation program, were observed in a sample of industrial workers with recent low-back injuries. As a pain-relieving modality, TENS may be a useful adjunct to a rehabilitation regimen for selected patients. When its efficacy is judged in terms of disability, however, its transient effect seems of little utility if the patient can (and does) perform the same level of activities without it.

## ■ Acknowledgments

This work was supported by a grant from National Health and Welfare Canada (#6606-4077-60). We gratefully acknowledge the loan of the CODETRON units, accessories, and technical support from Dr. N. Salansky and EHM Rehabilitation Technologies, Toronto, Ontario. We thank the research staff of the Henderson General Hospital, the biostatisticians Darryl Pahl and Kevin Thorpe, and the secretarial staff of McMaster University for their able assistance.

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*Address reprint requests to*

Paul Stratford
*McMaster University*
*School of Occupational Therapy and Physiotherapy*
*1200 Main St. West*
*Hamilton, Ontario 18N 3Z5*
*Canada*