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Effect of Electrical Stimulation on Lumbar Paraspinal Muscles

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Forty healthy, sedentary, premenopausal women were entered into a randomized, single-blind, controlled study to determine the effects of capacitively coupled electrical stimulation on the strength of the lumbar paraspinal muscles and the bone mineral in the lumbar spine. All were between 35 and 45 years of age and had normal physiologic estrogen. The study group received electrical stimulation over the lower lumbar paraspinal muscles for 30 minutes twice a day. Isometric strength of the lumbar paraspinal muscles was assessed with a strain-gauge dynamometer at entry and again after 3, 6, 9, and 12 months. Bone mineral was measured in the lumbar spine by dual-energy x-ray absorptiometry at entry and at 6 and 12 months. After 3 months, the median increase in isometric strength was 8.1% in the study group and 1.6% in the control group ($P < 0.03$). This initial difference was maintained during the remainder of the study. No further changes were seen between the two groups at 6, 9, and 12 months. It was concluded that capacitively coupled electrical muscle stimulation can, throughout a 1-year period, improve and maintain isometric strength of the lumbar paraspinal muscles independent of exercise, but it has no measurable effect on bone mass in the lumbar spine. [Key words: electrical stimulation, isometric strength, lumbar paraspinal muscles, premenopausal]

A major component of nearly all rehabilitation programs aimed at comprehensive treatment of the patient with low-back pain is some form of therapy designed to improve body mechanics, which includes strengthening trunk muscles. Active exercises to increase trunk strength are usually neither feasible nor tolerable, depending on the abnormality, particularly early during the acute and subacute periods of pain. A desirable addition to these programs would be a passive strengthening method that would prevent further deconditioning and allow strengthening to begin earlier during the recovery period and thereby shorten the expensive but necessary rehabilitation process.

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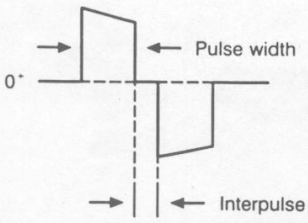
Percutaneous electrical stimulation has been successful as a passive isometric strengthening method in muscles of the lower extremities in animals,[19] humans with spinal cord injuries,[18] and healthy humans.[8–11,20] Previous studies of the effect of electrical muscle stimulation on trunk muscles were nonrandomized, uncontrolled, lacked sufficient numbers, or isolated entirely to an attempt to correct the curves of scoliotic spines[1–4,14,23] or were of controversial efficacy.[5,7]

A randomized, controlled study of the effect of electrical stimulation on the strength of the lumbar paraspinal muscles was recently conducted by Kahanovitz et al, however.[12,17] They found that low-frequency percutaneous electrical stimulation significantly increased slow-speed isokinetic extensor strength in the absence of exercise when compared with a similar control group. Of interest, a similar difference was not found with isometric strength tests. Their results were noted after only 20 30-minute sessions (30 minutes per day, 5 days per week for 4 weeks). They were encouraged by their results, suggesting that as a passive method of muscle strengthening, electrical stimulation may be better tolerated than exercise, particularly in acute or subacute low-back pain.

This prospective study was based on the hypothesis that isometric back extensor strength should be augmented by electrical stimulation in a manner similar to that in previous studies of electrical stimulation involving the muscles of the lower extremities, namely, the quadriceps muscles. Therefore, the study was designed to focus on isometric strength changes in lumbar paraspinal muscles in which both the frequency of stimulation sessions and the duration of the study (that is, the number of total sessions) were increased beyond the protocol used by Kahanovitz et al.[12,17]

Research studies[21] have shown that muscle strength and bone mass are correlated and that bone mass as well as muscle mass can be increased with exercise or lost with inactivity. We have, therefore, included measurements of bone mineral by absorptiometry at the skeletal site where muscle stimulation was effected to evaluate whether electrical stimulation has a measurable effect on bone mass, perhaps through electrically induced muscle contractions.



Parameter	Nominal specifications--using 500 Ω load
Pulse amplitude	Adjustable, 0-100 mA
Pulse rate	Fixed at 35 pulses/second
Pulse width	Fixed at 300 microseconds
Interpulse width	Fixed at 25 microseconds
Rise time	Fixed at 2 seconds
Fall time	Fixed at 1.0 second
Cycle "on" time	25 seconds
Cycle "off" time	8 seconds

Figure 1. Specifications of electrical muscle stimulator used for lumbar paraspinal muscles.

■ Material and Methods

Recruitment and Randomization. After review and approval of the research protocol by the Mayo Institutional Review Board, white women aged 35–45 years were solicited by public notice in local and medical center newspapers to participate in a year-long study on the effects of electrical muscle stimulation on the strength of the lumbar paraspinal muscles. All women who responded were screened to exclude those who smoked, reported regular exercise regimens, used any prescription medication, reported previous low-back problems of any kind, had an implanted cardiac pacemaker, were pregnant or desired future pregnancy, or had undergone an operation to remove one or both ovaries (that is, had the potential for nonphysiologic estrogen regulation). All women passing the initial screening then met with the same examiner (M.T.M.) and underwent a complete physical examination and were rescreened according to the above-listed criteria. Those who were selected were then assessed against a standardized activity scale,[22] and the first 40 women whose total score was < 8 were enrolled in the study.

Each subject had to give informed consent before involvement in the study.

Randomization was achieved as the women were enrolled in the study by their sequential assignment to one of two groups of subjects based on a predetermined, blinded (to examiners) assignment sequence. One of these groups was arbitrarily assigned as the study group, and the other group served as controls.

Strength Measurement. All subjects had the strength of their back extensor muscles measured at baseline and at 3, 6, 9, and 12 months. The same examiner (L.D.S.) evaluated all subjects to eliminate interexaminer variation. The isometric strength of the back extensor muscles was measured with a strain-gauge dynamometer, which converted force into a digital readout in pounds. This technique has been previously described.[13,21,22]

Measurement of Bone Mineral Density. Bone density was measured in the lumbar spine (L2–4) with dual-energy x-ray absorptiometry using a Hologic, Inc., bone mineral analyzer. Data were expressed in units of area density (gram of bone ash equivalent per unit of area scanned [cm]). All patients were scanned twice at the beginning of the study, at 6 months, and at the end of the study. The same blinded approach as described above was used. A seasonal effect on bone mass[6] was excluded by evaluating the subjects at the same season 1 year apart.

Electrical Stimulation. The 20 subjects in the study group were instructed in the operation and self-application of a portable electrical muscle stimulator (Respond TM Quadriflex Model 3109, Medtronic, Minneapolis, Minnesota). The electrical parameters of the device are shown in Figure 1. Two electrodes (Neuroaid 3.5 TM Model 7790) were placed symmetrically over the erector spinae muscle bulk at the L2–4 level. The subjects were instructed to set the intensity of stimulation at the maximal level that was comfortably tolerable for a 20-minute period. They were also instructed to allow a 5-minute warm-up period and cool-down period at lower intensities. The total stimulation period was therefore 30 minutes. The subjects were asked to perform two separate stimulations per day, 5 days a week, for a maximum of 10 sessions per week. The subjects were free to go about their normal activities during the stimulation periods. The maximal stimulation intensity was recorded for each session on logs that were examined at 3-month intervals. A factor called stimulator use index, defined as the product of the average maximal stimulator intensity per session multiplied by the average number of stimulation sessions per week, was calculated for each study patient for each 3-month interval.

Compliance was assessed by recording the number of 30-minute sessions of stimulator use per week and by recording the intensity of stimulator use on a scale of 0–10. The control group was not provided with a sham device, and therefore the subjects were not blinded as to their assignment within the study.

Follow-up. All subjects were encouraged to continue in their current nonathletic lifestyles. Physical activity scores were assessed at 6 months by telephone and again at 12 months by face-to-face interview.

Statistical Methods. The two groups were evaluated at baseline with two-sample or Wilcoxon rank-sum tests for all factors studied, including morphometric and strength variables. Because strength changes after a given intervention are a function of the initial strength of an individual (baseline), the analysis focused on individual relative strength changes (percentage change) after an intervention or over time. Specifically, strength changes were determined by dividing a given difference in strength measurement by its baseline value for a particular individual. Mean relative change then was computed for each group for each 3-month interval. Student t test or a rank-sum test with a one-sided type-one error rate of 5% was used to determine the significance of any differences between the groups. The associations between various measurements were assessed with linear correlation.

■ Results

Baseline and quarterly cross-sectional comparisons of independent variables between the study and control

Table 1. Average Back Extensor Strength in Subjects With and Without Electrical Stimulation

	Stimulation			No Stimulation			
Time of Measurement	Mean	SD	Median	Mean	SD	Median	*P* Value
Baseline strength (lb)	65.7	15.9 (n = 20)	69.5	69.8	14.5 (n = 20)	74.5	0.40* 2-sided
3 Months strength (lb)	71.9	14.8 (n = 18)	72.5	70.7	16.4 (n = 20)	72.5	0.40* 1-sided
% Change	15.3	23.3	8.1	2.2	18.3	1.6	<0.05†
6 Months strength (lb)	76.8	15.2 (n = 17)	76.0	74.5	12.0 (n = 19)	74.0	0.30* 1-sided
% Change	26.5	45.8	23.7	9.8	23.4	14.1	0.12*
9 Months strength (lb)	87.8	20.0 (n = 18)	84.0	85.0	16.5 (n = 18)	81.5	0.34* 1-sided
% Change	45.1	63.0	33.0	25.5	28.1	31.6	0.17†
12 Months strength (lb)	94.2	14.3 (n = 17)	94.0	91.0	15.1 (n = 18)	88.0	0.26*
% Change	60.7	58.0	49.1	31.8	25.0	30.3	<0.03†

*Two-sample *t*-test.
†Wilcoxon's rank-sum test.

Table 2. Physical Activity Score in Subjects With and Without Electrical Stimulation

	Score						
	Stimulation			No stimulation			
Time of Measurement	Mean	SD	Median	Mean	SD	Median	*P* value
Baseline	5.1	1.7 (n = 20)	5.0	5.6	1.2 (n = 20)	6.0	0.51* 2-sided
6 Months	5.4	1.6 (n = 17)	5.0	4.7	1.4 (n = 19)	5.0	0.12* 1-sided
12 Months	5.2	1.6 (n = 17)	5.5	5.8	1.4 (n = 18)	6.0	0.17* 1-sided

*Two-sample *t*-test.

groups are shown in Tables 1 and 2. The study group was significantly heavier (66 kg) than the control group (59 kg) ($P < 0.002$, two-sided, two-sample t test). There was no significant difference between the two groups in regard to average activity level (5.1 versus 5.6) (Table 2) or average extensor strength (66 versus 70) at baseline (Table 1).

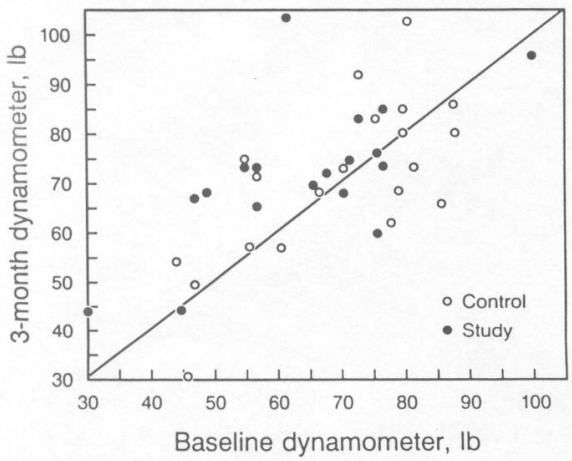


Figure 2. Back extensor strength at baseline plotted against strength at 3 months in subjects with electrical stimulation (study group) and without stimulation (controls).

When the baseline dynamometer force was plotted against the 3-month dynamometer force for both groups (Figure 2), the study group had more relative increase than the control group. Similar plots (not shown) for the values at 3 months versus 6 months, 6 months versus 9 months, and 9 months versus 12 months did not disclose any obvious differences between the two groups in terms of their relative change from study period to study period.

At the time of the 3-month evaluation, the average strength of the stimulation group had significantly increased ($P < 0.03$, two-sided paired t test), but there was no significant increase in the control group ($P = 0.74$). The actual strength at 3 months was not significantly different in the two groups, but the median percentage change in strength was greater in the stimulation group (8.1%) than in the control group (1.6%) ($P < 0.05$, one-sided Wilcoxon rank-sum test).

At the 6-month evaluation, there was still no significant difference in average physical activity score (5.4 versus 4.7). In the stimulation group the average strength continued to be significantly increased from baseline ($P < 0.1$, two-sided paired t test), but the control group still had no significant increase in average strength.

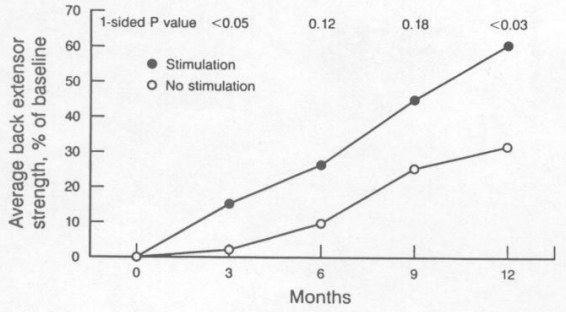


Figure 3. Mean percentage change in back extensor strength in subjects with and without electrical stimulation.

Neither the average strength nor the median percentage change in strength was significantly different between the two groups at 6 months.

At the 9-month evaluation, the average strength was significantly increased from baseline in both the stimulation group ($P < 0.001$) and the control group ($P < 0.01$, two-sided paired t test). Neither the average strength nor the median percentage change in strength was significantly different between the two groups at 9 months.

By the 12-month evaluation there was still no significant difference in average physical activity score (5.2 versus 5.8). The average strength remained significantly increased from baseline at 12 months in both the stimulation group ($P < 0.001$) and the control group ($P < 0.001$). The average strength was not significantly different between the two groups, but the median percentage change from baseline was significantly greater in the stimulation group than in the control group ($P < 0.03$, one-sided Wilcoxon rank-sum test).

When the mean percentage change in back extensor strength (relative to baseline) plotted over time was evaluated (Figure 3), both the study and the control groups showed relative increases in back extensor strength. The most obvious difference in the curves occurred during the first 3 months of the study, in which the increase in strength in the study group was significantly greater than that in the control group. This difference was preserved throughout the remainder of the study, but the changes between the groups were not significant beyond the 3-month evaluation.

In terms of compliance, there were no significant differences between the periods of the study in either the median number of 30-minute sessions per week or in the median intensity of the sessions (Wilcoxon signed rank tests). The median number of sessions was 9.8 at 3 months, 9.7 at 6 months, 8.7 at 9 months, and 8.7 at 12 months. The median intensity of sessions was 4.0 at 3 months, 5.2 at 6 months, 4.8 at 9 months, and 5.0 at 12 months.

When the stimulator use index was plotted against the relative strength change at 3 months (Figure 4) for the individuals remaining in the stimulation group, the percentage change in strength at 3 months was positively correlated (with borderline significance) with the stimulator use index ($P = 0.07$, Spearman's rank correlation coefficient).

There were no significant differences in bone density, change in bone density, or percentage change in bone density between the group with electrical stimulation and the control group at either 6 months or 12 months (Table 3). Precision of the measurements was calculated from dual measurements made at baseline. The range of absolute bone mineral density values of the difference expressed as percentage of the mean value was 0 to 4.4%, the mean difference was 0.9%, and the median difference was 0.7%.

■ Discussion

The results suggest that electrical stimulation can independently increase the isometric strength of the back extensor muscles. Further, the resulting strength change due to the stimulation occurred within the first 3 months and was maintained but not improved on with continued stimulation during the next 9 months.

Of interest, despite the difference in baseline mass (weight) between the two groups, there was no difference in baseline back extensor strength. Possibly, individuals with large mass may be more susceptible to changing strength given the same level of physical activity. We are not aware of any studies to this end. We would agree that this study specifically requested that the subjects not alter their level of physical activity and therefore, aside from electrical stimulation intervention on the study group, we would not expect any change in back extensor strength given no change in daily routine.

We did notice a change in the strength of the control group toward the end of the study. Because the study followed them over a 1-year period, seasonal trends, if any, should be eliminated. It is possible that the groups became better at demonstrating strength on the dyna-

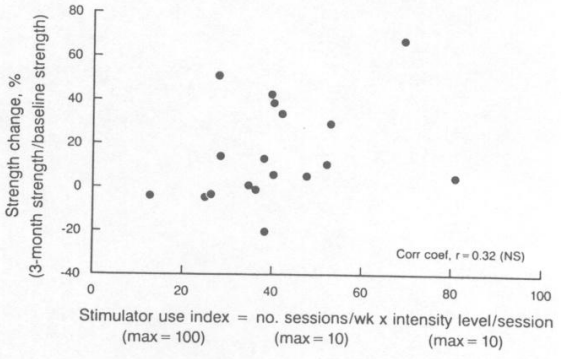


Figure 4. Stimulator use index plotted against percentage change in back extensor strength at 3 months in 18 subjects who used electrical stimulation. Corr coef, correlation coefficient; NS, not significant.

Table 3. Bone Mineral Density in Subjects With and Without Electrical Stimulation

	Stimulation			No Stimulation			
Time of Measurement	Mean	SD	Median	Mean	SD	Median	*P* Value*
Baseline BMD (g/cm^2)	1.11	0.12 (n = 20)	1.13	1.10	0.13 (n = 19)	1.08	0.76
6 Months BMD (g/cm^2)	1.10	0.11 (n = 18)	1.12	1.09	0.13 (n = 19)	1.08	0.40
Change from baseline	−0.003	0.013	−0.002	−0.10	0.019	−0.006	0.10
% Change	−0.27	1.24	−0.14	−0.89	1.68	−0.46	0.11
12 Months BMD (g/cm^2)	1.10	0.12 (n = 18)	1.12	1.10	0.13 (n = 19)	1.09	0.48
Change from baseline	−0.002	0.022	0.006	−0.002	0.022	−0.010	0.47
% Change	−0.25	2.00	0.49	−0.07	2.07	−0.83	0.39

*Two-sample *t*-test, two-sided for baseline test and one-sided for all other tests.
BMD, bone mineral density.

mometer (that is, learned) and that this improvement appears more obvious in the control group because there was no other "change" in strength. Indeed, if the difference in strength between the study and control groups is graphed, this learning trend is eliminated from the resultant curve (which clearly shows a net positive change in strength in the study group during the first 3-month period, which is not reduced or improved on throughout the remainder of the study).

The use of a sham device was considered by the investigators of this study. Because we thought that it would be obvious to the control subjects that they were not receiving electrical stimulation (that is, lack of cutaneous stimulation or irritation), we elected to proceed with the study without any sham device for the control group. Therefore, the possibility of a placebo effect of the stimulator device on the study subjects has not been eliminated. Because the increase in strength noted in the study subjects occurred during the first 3 months and was maintained but not improved on throughout the duration of the study, we believe that the result is likely due to the electrical stimulation and not a placebo effect. Future studies with a sham device could be considered, however, to rule out a possible placebo effect.

The entire study population was purposely biased to nonathletic but otherwise healthy premenopausal women. The belief was that they would have back extensor muscles with a potential for the greatest strength change given any level of electrical stimulus. This fact should be taken into account in any extrapolation of the data to other patient populations.

Apart from the population selection bias, this study was designed to repeat a portion of a previous study by Kahanovitz et al[12,17] with some particular modifications. The previous study found no significant improvement in isometric back extensor strength over controls after providing the study group with 20 total stimulation sessions (once per day, for 5 days a week for 4 weeks) at a similar location, duration, and intensity. Our study group received two sessions per day for 5 days a week for 3 months before isometric strength significantly changed compared with controls. The stimulator factors were identical. Presumably, the choice of population, the increased number of daily sessions, or simply the increased total number of sessions was necessary or sufficient to result in a significant increase in strength.

Another difference between our study and that by Kahanovitz et al[12,17] was that our study used stimulators in a self-application, self-monitored setting. Patient compliance is the most important factor in any treatment regimen. Although compliance may be increased by requiring a patient to receive the electrical stimulation under the guidance of a therapist, this approach may not be absolutely necessary or cost-effective. Although not intentionally addressed in this study, it is encouraging that study compliance was surprisingly high throughout the entire 1-year period.

Anecdotally, several women in the study group reported that the device was easy to use and did not interfere with their daily routine. Some even reported that the stimulation sessions were relaxing. This comment immediately suggests that at least some portion of the women were likely not operating the stimulator at the maximal intensity that was tolerable.

Finally, the results were obtained with specific stimulation waveform factors. Given the differences in impedance of skin, fat, muscle, and nerve, modification and experimentation with both the modulation and the carrier frequencies of the stimulator may eventually result in the ability to direct more electrical energy to the motor nerves and less energy to the (painful) cutaneous nerves and thus improve both efficacy and compliance.[15,16]

Despite the increase in strength of the back extensor muscles, there was no measurable effect on bone mass in the lumbar spine. This finding supports our previous study of postmenopausal women who underwent a low-level exercise program, which resulted in a measurable increase in strength of the back extensor muscles but also did not show changes in bone mineral density.[21,22] Apparently more vigorous or different types of exercise are needed to affect bone mass.

■ Conclusion

The effect of electrical stimulation on back extensor muscles has been investigated previously, but no significant change in isometric strength was found. Our study suggests that with low-frequency electrical stimulation, isometric back extensor strength may be significantly increased and this increase can be maintained with continued stimulation for up to 1 year. It remains to be shown whether the strength changes are in any way protective for low-back pain or potentially effective for strengthening in a person with acute or subacute back pain. There was no effect on bone density at the lumbar spine.

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