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Lumbar Stimulation Belt for Therapy of Low-Back Pain

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Abstract: We developed the STIMBELT, an electrical stimulation system that comprises a lumbar belt with up to eight pairs of embedded electrodes and an eight-channel electronic stimulator. The STIMBELT is an assistive system for the treatment of low-back pain (LBP). We describe here technical details of the system and summarize the results of its application in individuals with subacute and chronic LBP. The direct goals of the treatment were to relieve pain, reduce muscle spasms, increase strength and range of motion, and educate individuals with LBP in reducing the chances of its reoccurrence. The outcome measures include: a Visual Analogue Scale (VAS), the Oswestry LBP Disability Questionnaire, the Short Form (SF)-12 health survey, and the Manual Muscle Test. The results indicate significant benefits for individuals who use the STIMBELT in addition to the conventional therapy as opposed to only the conventional therapy. **Key Words:** Electrical therapy—Low-back pain—Active lumbar belt.

A common problem resulting from sensory-motor deficiency due to lifestyle is pain in the lower back, termed low-back pain (LBP). LBP is the largest cause of workers' compensation in the USA and Canada and a major reason for visits to health-care professionals (1). A total of 60–90% of the adult population is at risk of developing LBP at some point in their lifetime (2–6). While the majority of episodes appear to resolve within 6 weeks, it is estimated that 10–20% of affected adults develop symptoms of chronic LBP, defined as persistent pain lasting longer than 3 months and occurring on at least 50% of days. Chronic LBP has a significant impact on functional status, restricting occupational activities with marked socioeconomic repercussions (7,8).

The management of LBP encompasses a range of different interventions including drug therapy, exercise, patient education, physiotherapy, cognitive–behavioral therapy, alternative therapies, and surgery (7–10). Medications are often used to treat acute and chronic LBP. Some authors, however, suggest bed rest (1–2 days at most) as an effective treatment (11,12). Another method is the use of traction which involves weights (after proper positioning) to gradually "pull" the skeletal structure into better alignment (13) and assist muscle relaxation. Spinal manipulation is literally a "hands-on" approach in which professionally licensed specialists use leverage and a series of exercises to adjust spinal structures and restore back mobility (14,15). Some individuals consider acupuncture, which involves the insertion of needles the width of a human hair along precise points throughout the body. Cold and heat have never been scientifically proven to quickly resolve low-back injury; yet, many individuals use them and claim positive effects. Ultrasound is a noninvasive therapy used to warm the body's internal tissues, which causes muscles to relax (16). Transcutaneous electrical nerve stimulation (TENS) primarily aims to provide a degree of pain relief (symptomatic) by specifically exciting sensory nerves and thereby stimulating either the pain gate mechanism and/or the opioid system (17–22). Exercise is likely the most effective way to speed recovery from LBP and help strengthen back and abdominal muscles (23). Maintaining and building muscle strength is particularly important for persons with

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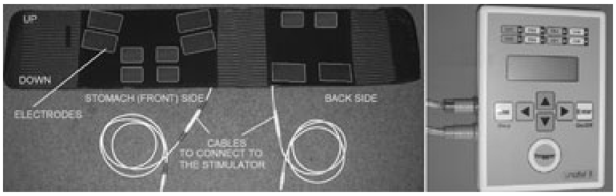

FIG. 1. The prototype version of the STIMBELT with six pairs of electrodes (left panel) and the eight-channel stimulator "UnaFET 8" are shown.

skeletal irregularities. A routine of back-healthy activities may include stretching exercises, swimming, walking, and movement therapy to improve coordination and develop proper posture and muscle balance. Finally, the use of wide elastic belts, although controversial, is used for the treatment of LBP (24–27).

STIMBELT: AN ASSISTIVE SYSTEM FOR TREATMENT OF LBP

The STIMBELT is an assistive system for treating LBP. It comprises an eight-channel programmable electronic stimulator (Fig. 1, right panel) and a lumbar belt embedded with up to eight pairs of electrodes (Fig. 1, left panel). Four pairs of electrodes on the front side stimulate muscles in the abdominal region, and two pairs of electrodes on the back side stimulate paraspinal muscles. The STIMBELT allows electrical activation of the muscles responsible for upper body posture; therefore, the biomechanical substrate could decrease the symptoms of LBP. The eight-channel stimulator used within the STIMBELT (right panel, Fig. 1) comprises control buttons for individual adjustment—or programming of the complete stimulation sequence—and the four-line display for feedback to the user. The stimulator communicates with a Windows-based host platform using a wireless link for down- and uploading the stimulation protocols.

The electronic stimulator used within the STIMBELT was developed from the UnaFET stimulator (Una Systems, Belgrade, Serbia), originally designed for functional electrical therapy (FET) of upper extremities (28,29). The modifications include the addition of four more channels and a new software to support the therapy of LBP.

We developed the UnaFET Studio software as a tool that offers user-friendly support for the process of LBP treatment. The UnaFET Studio integrates a database of stimulation protocols (SP) and a database of patient records (PR). The SP is a set of parameters defining the intensity and timing of stimulation for each of the stimulation channels. Figure 2 shows the graphic interface that is presented on the screen after starting the UnaFET Studio. This screen allows setting the onset, duration, and intensity of stimulation on all eight channels. By opening the "Channel View" and "Set Pulse Parameters" submenus, one opens the interface to set the frequency and rise and fall times. The SP can be saved for later use and can be downloaded into the stimulator by starting the infrared (IR) interface from the

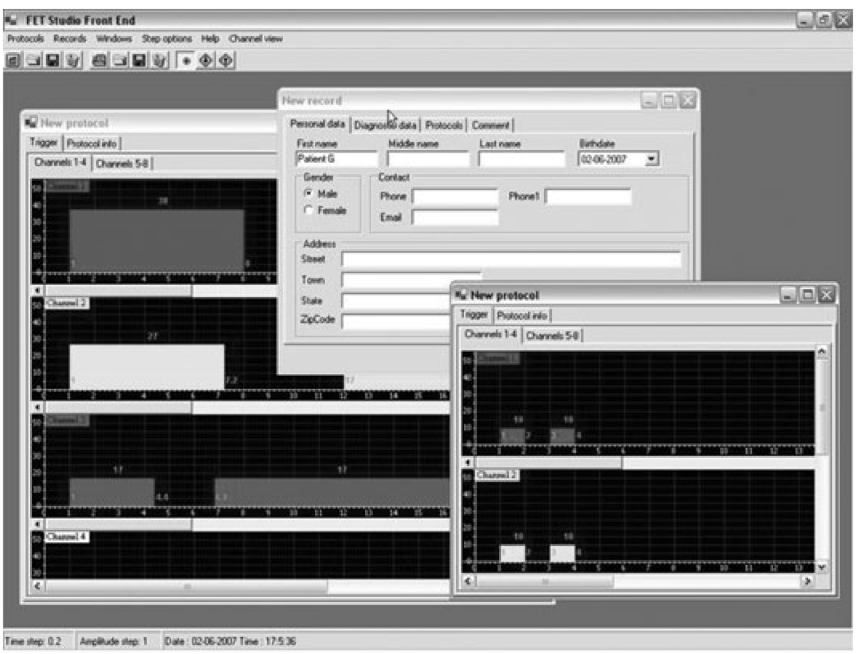

FIG. 2. The interface screen of the UnaFET Studio for setup of stimulation profiles for STIMBELT is shown.

FIG. 3. The use of STIMBELT for therapy. The left panel shows the exercise in the standing position (first phase of the STIMBELT therapy). The right panel shows the therapy during the third week of STIMBELT therapy.

submenu. The same IR link can be used to upload a protocol from the stimulator, and the uploaded program can be saved. The stimulator can store up to three protocols, which the user can select by using the push-button controls on the stimulator.

The PR comprises personal, diagnostic, and SP data used for patient therapy. Each PR could be associated with one or more SP from the SP database. The protocols associated (linked) with the PR can be opened directly from the PR.

THERAPEUTIC USE OF THE STIMBELT

Subjects

The study population comprised 90 inpatients or outpatients treated in the Rehabilitation Institute "Dr Miroslav Zotović" in Belgrade with verified lumbar disk herniation and LBP. All 90 subjects received conventional therapy consisting of hydro, physical, and exercise treatments. Of the subjects, 60 were in subacute stage of LBP, and 30 were in the chronic stage of LBP. Thirty subjects from the subacute group were randomly selected to form Group A and participate in the STIMBELT therapy. The remaining 30 subjects with subacute LBP were controls (Group B). Thirty subjects in chronic stage of LBP formed Group C and participated in the STIMBELT therapy. All subjects signed the informed consent form approved by the local ethics committee.

STIMBELT therapy

The daily therapeutic session lasted for 30 min. Two sizes of STIMBELT were used in the study in order to match the size of the patients. The electrodes were embedded in a manner that allows for small variations in their positions; hence, individual adjustments have been made to fit the individuals' body contours. The stimulation parameters were set at: $f = 50$ pulses per second, pulse duration $T = 500$ μs. The stimulation sequence was 5 s "rising" + 5 s "on" followed by 10 s off. The intensity was adjusted individually to a level that generated visible muscle contractions but at the level that, in most cases, was appreciated as pleasant. The typical intensity setting for the sessions was around $I = 30$ mA (pulse amplitude, monophasic, compensated current-controlled stimulation). The electrodes activated the following muscle groups: *Lumbosacral paravertebral bil. m.*, *Obliques Abdominis bil. m.*, and *m. Rectus Abdominis* (low portions). Stimulation was always triggered by the subject. The stimulation protocol was as follows: (i) 2 weeks—all muscles stimulated in parallel (muscle strengthening) in the standing position (left panel, Fig. 3); and (ii) 1 week—active contraction of *m. Rectus Abdominis* followed by stimulation of the other muscle groups in the horizontal position (right panel, Fig. 3).

Assessments of the therapeutic effects with STIMBELT

The assessment results presented in this article include the Oswestry LBP Disability Questionnaire, VAS, Short Form (SF)-12 survey, and Manual Muscle Test (MMT). These results were collected at the beginning and at the end of the therapy (3 weeks). More detailed results of the randomized clinical study will be presented at a later date in the appropriate clinical journal.

Oswestry Low Back Pain Scale is a measure of life limitations expressed in numbers from 0 (minimum) to 100 (maximum) divided in 10 sections (each ranging from 0 to 10), pain intensity, personal care (washing, dressing, etc.), lifting, walking, sitting, standing, sleeping, social life, traveling, and changing degree of pain.

A VAS is an instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. Operationally, a VAS is a 100-mm-long bar, anchored by word descriptors at each end ("no pain," "unbearable pain"). The patients mark, on the line, the point that they feel represents their perception of their current state. The VAS score is determined by measuring, in millimeters, the distance

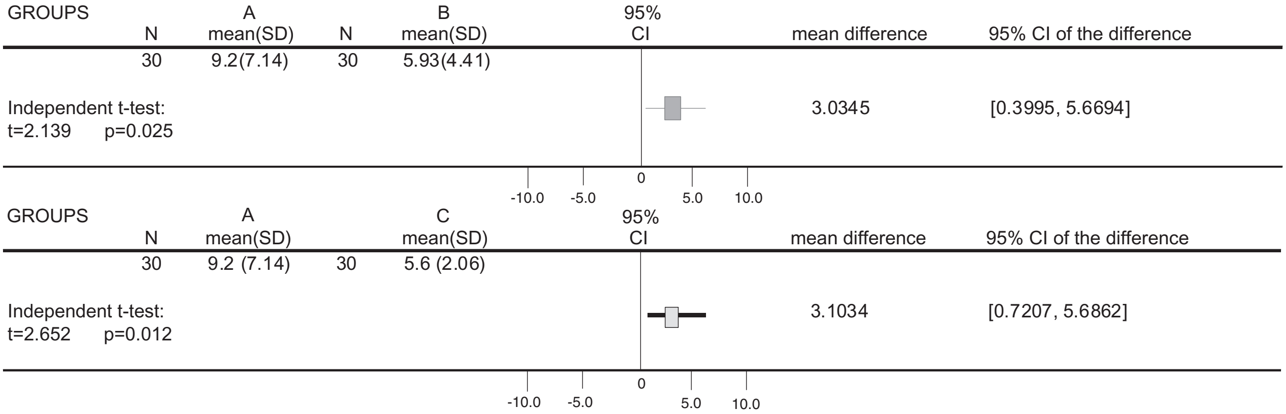

FIG. 4. Comparison of means in the Oswestry LBP Disability Questionnaire between Group A and Group B (top), and Group A and Group C (bottom).

from the left-hand end of the line to the point that the patient marks (0 "no pain"; 100 "maximum pain").

Manual Muscle Testing Scale is an instrument for rating the abilities for voluntary movements. The Manual Muscle Test Scale comprises grades from 5 (maximum) to 0 (minimum): 5—subject can hold the position against maximum resistance and through complete range of motion; 4—subject can hold the position against strong or moderate resistance and has full range of motion; 3—subject can tolerate no resistance but can perform the movement through the full range of motion; 2—subject has all or partial range of motion in the gravity eliminated position; 1—the muscle/muscles can be palpated while the patient is performing the action in the gravity-eliminated position; and 0—no contractile activity can be felt in the gravity-eliminated position.

The SF-12 is a multipurpose, short-form generic measure of health status. It was developed to be a more practical alternative to the SF-36, the 36-item instrument for measuring health status and outcomes from the patient's point of view. The 12 items in the SF-12 are a subset of those in the SF-36. It measures eight concepts commonly represented in widely used surveys: (i) limitations in physical activities because of health problems; (ii) limitations in usual role activities because of physical health problems; (iii) bodily pain; (iv) general health perceptions; (v) vitality (energy and fatigue); (vi) limitations in social activities because of physical or emotional problems; (vii) limitations in usual role activities because of emotional problems; and (viii) mental health (psychological distress and well-being).

Statistical analysis

Here, we present only two comparisons: (i) efficiency of STIMBELT versus controls (Group A vs. Group B), and efficiency of STIMBELT when applied in subacute or chronic LBP (Group A vs. Group C). Statistical analysis was done with SPSS 10.0 (Chicago, IL, USA); the results were expressed as mean ± SD. Statistical significance was tested using the paired *t*-test or Wilcoxon signed-ranks test for paired observations (comparison of mean values between the beginning and the end of the therapy) after the careful analysis of data. Statistically significant differences were tested using the independent *t*-test or Wilcoxon–Mann–Whitney rank-sum test for two independent groups. The Wilcoxon–Mann–Whitney test uses the ranks of data to test the hypothesis that two samples of sizes m and n might come from the same population. The procedure is as follows: (i) combine the data from both samples; (ii) rank each value; (iii) take the ranks for the first sample and sum them; and (iv) compare this sum of ranks to all the possible rank sums that could result from random rearrangements of the data into two samples. The level of statistical significance was set at a two-tailed P value of 0.05.

Comparison of mean values between the beginning and the end of the therapy

For all groups, we found statistically significant differences in all outcomes measured ($P < 0.001$), except for the results related to MMT in Group C.

The differences between Group A and Group B, and Group A and Group C in mean values of the Oswestry LBP Disability Questionnaire are in Fig. 4. In both cases, statistically significant differences were found. The $P = 0.025$ was found between Group A and Group B, and $P = 0.012$ between Group A and Group C.

The comparison of mean values between the Groups A, B, and C for the SF-12 health survey

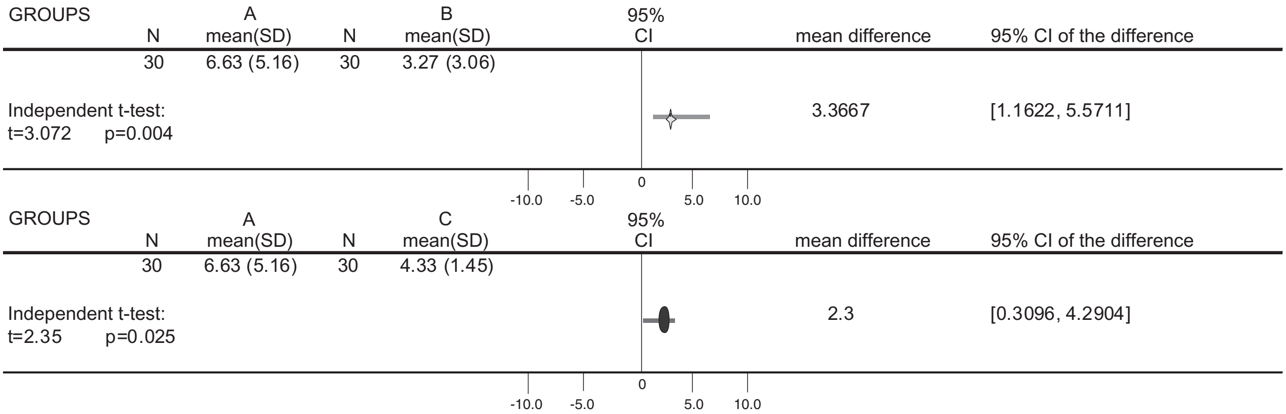

FIG. 5. Comparison of means in the SF-12 health survey between Group A and Group B (top), and Group A and Group C (bottom).

in Fig. 5 shows the comparison of Group A versus Group B, and Group A versus Group C. In both cases, statistically significant differences were found (A vs. B, $P = 0.004$; A vs. C, $P = 0.025$).

The differences of mean values between the groups, when using the VAS scores, are presented in Table 1 (A vs. B, A vs. C). In both cases, the Wilcoxon–Mann–Whitney test was used. Statistically significant differences were not found between Groups A and B ($P = 0.414$), but the difference was significant between Groups A and C ($P = 0.02$).

Comparison of mean values in the MMT of trunk muscles between Groups A and B, and Groups A and C is also presented in Table 1. In both cases, the Wilcoxon–Mann–Whitney test was used. Statistically significant differences were not found between Groups A and B ($P = 0.937$) but were found between Groups A and C ($P = 0.000$)

The reason for showing the comparison between Group A and Group B, and Group A and Group C was to demonstrate the therapeutic effects of STIMBELT in subacute and chronic populations. The results clearly indicate that the effects are better in subacute, compared with the chronic population but also that the STIMBELT has positive effects in both cases.

The size of the group was tested for power, and the finding was that a larger study is needed in order to fully support the indication that STIMBELT improves recovery when complemented to the conventional therapy of LBP.

An important finding from the study was that all subjects greatly appreciated and enjoyed using the STIMBELT as a tool to aid therapy (30,31).

When analyzing the results of this study, it is important to bear in mind the differences between the STIMBELT and TENS treatments.

TENS is a noninvasive therapeutic modality based on the "Gate Control Theory" (32). According to this theory, the stimulation of large-diameter (A-beta) primary sensory afferents activates inhibitory interneurons in the *substantia gelatinosa* of the spinal cord dorsal horn and thereby attenuates the transmission of nociceptive signals from small-diameter A-delta and C fibers. Several types of TENS applications, differing in frequency, amplitude, pulse width, and waveform, are used in clinical practice. The two most common application modes include (i) high-frequency or conventional TENS (40–150 pulses per second, 50–100 μs pulse duration, low intensity); and (ii) low-frequency or so-called acupuncturelike TENS (1–4 pulses per second, 100–400 μs pulse dura-

TABLE 1. *Comparison of mean values in the VAS and MMT of trunk muscles scores between Groups A and B, and Groups A and C*

Group	A	B	C
VAS score	2.98 ± 2.01	2.43 ± 1.1 $Z = -0.818$, $P = 0.414$	1.8 ± 0.43 $Z = 2.296$, $P = 0.02$
MMT score	1.16 ± 1.36	1.16 ± 1.31 $Z = 0.079$, $P = 0.937$	0.07 ± 0.25 $Z = -3.659$, $P = 0.000$

The numbers ± SD show the differences in scores at the beginning and the end of the treatment. Numbers Z and P in columns B and C relate to the differences A versus B, and A versus C, respectively tion, high intensity). Conventional TENS is associated with a faster onset and shorter duration of analgesia compared with acupuncturelike TENS. Three other standard modes of TENS include (i) brief-intense TENS (greater than 80 pulses per second, longer than 150 μs pulse duration, comfortable-tolerable intensity); (ii) burst TENS (bursts of pulses delivered at a low frequency of less than 10 pulses per second and at a comfortable intensity); and (iii) modulation TENS.

CONCLUSIONS

STIMBELT provides strong electrical stimulation of muscles in synchrony with the exercise. The stimulation parameters are $f = 50$ pulses per second, $T = 500$ μs, pulse amplitude $I \in$ 20–50 mA; hence, the amount of charge per pulse and per channel with the STIMBELT is on average one order of magnitude larger than that of TENS. The STIMBELT activates up to eight muscle groups in synchrony with the volitional movement of the trunk. Both muscle stimulation and volitional movement contribute to muscle strengthening. Stronger muscles contribute to better posture and provide a firm support for the optimal orientation and position of the spine while sitting, standing, and walking. Muscles that are exercised respond better to stretch; thereby, the sudden movement (rotation of the trunk with no rotations of the legs, or bending the back in order to reach an object on the floor) will be greatly attenuated and potentially prevent nonphysiological loading of the spine. In parallel, STIMBELT activates deep abdominal muscles that are rarely exercised by humans who are at risk for LBP.

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