EFFECT OF BIO-ELECTRICAL MUSCLE STIMULATION ON CHRONIC LOW BACK PAIN AND ABDOMINAL MUSCULAR ENDURANCE AND STRENGTH

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OBJECTIVE

Assess the safety and efficacy of treatment with the truSculpt® flex system on bio-electrical muscle stimulation for improvement of chronic low back pain and core muscular endurance and strength.

MATERIALS AND METHODS

Twenty-eight established patients at the Houston Spine and Rehabilitation Centers with chronic low back pain, unresponsive to physical therapy, chiropractic manipulations, and pain management injections, received six 45-minute bio-electrical muscle stimulation re-education treatments with the truSculpt flex system to the abdominal region (rectus abdominis, abdominal obliques, and transverse abdominis). Patients received a total of six treatments twice per week on each of the three settings: 1) Prep, 2) Tone, and 3) Sculpt. The patients were instructed to continue their normal daily routines and asked to refrain from any new activities. At baseline and 8 to 10 days post final treatment, the patients completed Roland-Morris and Oswestry Disability questionnaires and were functionally evaluated for lumbar flexion and muscular endurance and strength. Pain levels were recorded pre- and post-testing by questionnaire.

RESULTS

All patients completed all study visits. Pain levels were reduced in 23 of 28 patients (82%; 95% CI: 63%-94%; $p<0.001$) with an average pain reduction among responders of 2.8 ± 2.2 points (0-10 VAS). Clinically significant improvement in muscle endurance (≥ 5 second improvement in plank-test duration) was seen in 20 of 28 patients (71%; 95% CI: 51%-78%; $p<0.001$) with an average increase of 33 ± 22 seconds among responders; in muscle strength (≥10° improvement in straight-leg lowering test) was seen in 6 of 28 patients (21%; 95% CI: 8%-41%; $p<0.01$) with an average improvement of 12° ± 2° among responders; and in lumbar flexion (≥15° improvement) was seen in 11 of 16 patients (69%; 95% CI: 41%-89%) with <90° lumbar flexion at baseline (average improvement among all 16 patients: 26° ± 19° [$p<0.001$]). All treatments were well tolerated and there were no unexpected or serious treatment side effects.

CONCLUSION

Six treatment sessions, twice weekly for 3 weeks, with the truSculpt flex bio-electrical muscle stimulator demonstrated clinically and statistically significant improvement in chronic low back pain that was unresponsive to physical therapy, chiropractic manipulations and pain management injections, and clinically and statistically significant improvements in lumbar flexion and core muscular endurance and strength.

INTRODUCTION

Bio-Electrical Muscle Stimulation (BEMS) deploys a method to send electrical impulses to muscle nerves using an external source/stimulus. This stimulus causes the muscles to contract. BEMS can increase muscle strength, range of motion, and offset the effects of disuse. It is used to prevent muscle atrophy and to retrain or re-educate muscle function after surgery or periods of disuse.[1] BEMS targets the muscle itself, specifically through the motor nerves, and can improve both muscle structure and function by recruiting more muscle fibers, similar to that seen from volitional exercise.[2] In sports medicine, muscle stimulation is frequently used to improve muscular strength when training, warming up, or recovering from injury.[3]

MATERIALS AND METHODS

This was a physician-initiated, prospective single-center, open-label study conducted in accordance with the World Medical Association Declaration of Helsinki to evaluate the safety and efficacy of the truSculpt flex (Cutera, Inc. Brisbane, CA) bio-electrical muscle stimulation system for the treatment of chronic low back pain that was unresponsive to physical therapy, chiropractic manipulations, and pain management injections. Secondary endpoints were changes in core muscular endurance and strength, lumbar flexion, and Roland-Morris and Oswestry Disability scores between baseline and follow-up visits.

INVESTIGATIONAL DEVICE

The truSculpt flex is a device that administers multidirectional electrical currents to stimulate contractions in muscular groups. While the device can be used to stimulate up to 8 body areas simultaneously, within this study, treatments were limited to the abdominal region and specifically to the rectus abdominis, abdominal obliques, and transverse abdominis muscle groups. The device can be set to deliver current in sequence combinations of three operational modes (Prep, Tone, or Sculpt) with the intensity for each operational mode being independently adjustable for each output channel.

SUBJECTS

Twenty-eight established patients (Table 1), seen at the Houston Spine and Rehabilitation Centers for chronic low back pain, unresponsive to physical therapy, chiropractic manipulations, and pain management injections, were consented and enrolled. All patients were instructed to continue their normal daily routines and asked to refrain from any new activities.

Table 1. Subject Demographics

Subjects (n)	28	
Age ± SD (Median, Range)	47.3 ± 12.6 (43.5, 31-75)	
Females, n (%)	25	(89%)
Males, n (%)	3	(11%)
Race, n (%)		
White	26	(93%)
Black or African American	1	(3.5%)
White and African American	1	(3.5%)
Ethnicity, n (%)		
Hispanic or Latino	2	(7%)
Not Hispanic or Latino	26	(93%)

BASELINE AND FOLLOW-UP VISIT EVALUATIONS

Prior to the first treatment and 8 to 10 days after the final treatment, all patients were required to complete Roland-Morris and Oswestry Disability questionnaires and were functionally evaluated for lumbar flexion and core muscular endurance and strength using the testing methods described below. Pain levels, at best and at worst, were recorded pre- and post-testing by questionnaire.

Lumbar Flexion Test

Lumbar range of motion (ROM) measurements were taken with Goniometer with the patient in standing position bending forward with knees straight until an increase in low back pain was felt (higher angles indicate more ROM).

Muscular Endurance

Measured with a 3-Minute Plank Test with patients remaining in a pushup position and lifting limbs at specified times within the 3 minutes as follows: 60s Plank (1:00); 15s Left Arm Lift (1:15); 15s Right Arm Lift (1:30); 15s Left Leg Lift (1:45); 15s Right Arm Lift (2:00); 15s Left Arm and Right Leg Lift (2:15); 15s Right Arm and Left leg Lift (2:30); 30s Plank (3:00)

Muscular Strength

Measured with a Straight Leg Lowering Test as follows: A blood pressure cuff was placed under the patient's lower back just above the sacrum; the patient was then instructed to lift their legs toward the ceiling; while contracting abdominals to keep pressure on cuff at all times, lower their legs slowly; the hip angle was recorded with a goniometer when the pressure decreased by 50% from the pressure at 90° (lower angles indicate higher abdominal muscular strength).

TREATMENTS AND INVESTIGATIONAL DEVICE SETTINGS

Patients received a total of six treatment sessions with the investigational device set to the parameters shown in Table 2.

Table 2. Treatment Settings

			Median Intensity (%)						Start Intensity (%)		End Intensity (%)		Average
Week	Tx #	Mode	Start	5 min	10 min	20 min	30 min	End	Min.	Max	Min.	Max.	Intensity %
1	Tx 1	Prep	20	23	25	28	30	30	14	20	23	36	26.0
1	Tx 2	Prep	20	25	26	29	30	31.5	20	25	26	38	27.2
2	Tx 3	Tone	25	27.5	30	34	34	32	20	25	26	38	30.6
2	Tx 4	Tone	25	28	32	36	36	33	20	30	26	40	32.1
3	Tx 5	Sculpt	25	30	34	32	34	34	20	34	23	39	31.7
3	Tx 6	Sculpt	25	30	34	32	34	36	20	38	24	45	32.4

RESULTS

All patients completed all study visits. Pain levels were reduced in 23 of 28 patients (82%; Clopper-Pearson 95% CI: 63%-94%; paired-data two-tail Student's t-test: $p<0.001$) with an average reduction among responders of 2.8 ± 2.2 points (0-10 VAS). Clinically significant improvement in muscle endurance (≥ 5-sec improvement in plank-test duration) was seen in 20 of 28 patients (71%; 95% CI 51%-87%; $p<0.001$) with an average increase of 33 ± 22 sec among responders; in muscle strength (≥10° improvement in straight-leg lowering test) was seen in 6 of 28 patients (21%; 95% CI 8%-41%; $p<0.01$) with an average improvement of 12° ± 2° among responders; and in lumbar flexion (≥15° improvement or ≥90° follow-up visit ROM) was seen in 11 of the 16 patients (69%; 95% CI 41%-89%) with <90° lumbar flexion at baseline (average improvement among all 16 patients: 26° ± 19° [$p<0.001$]).

For all 28 patients, follow-up visit Roland-Morris Disability (RMD) scores (range: 0 – 24) showed a statistically significant improvement with respect to baseline scores ($p<0.001$, pair-data two-tail Student's t test). Stratford et al.[4] demonstrated that for baseline RMD scores of 4 or more, a reduction of 4 points showed a 90% probability, the improvement was not due to chance. Using this definition for clinically significant improvement, 12 of 18 patients (67%; 95% CI: 47%-90%) with a baseline RMD score of 4 or more had a clinically significant improvement. Similarly, for all patients, follow-up visit Oswestry Disability (OD) scores (range:

0 – 50) showed a statistically significant improvement with respect to baseline scores ($p<0.01$, pair-data two-tail Student's t-test). For patients with an OD score of 10 or more (moderately disabled by low back pain), a 5-point reduction or more (≥10%) is recognized to show clinically significant improvement.[5] Using this definition, for 7 of 16 patients (44%; 95% CI: 20%-70%) with a baseline OD score of 10 or more had clinically significant improvement.

TREATMENT DISCOMFORT AND EFFECTS

The study intent was for treatments to be given at the highest intensity setting for each treatment mode that could be tolerated with minimal to moderate discomfort. As shown in Table 2, the intensity was recorded at the start of each session, 5 min, 10 min, 20 min, and 30 min into each session, and at the end of the session. The intensity was adjusted whenever the patient indicated they could tolerate a higher intensity and lowered if the patient reported more than moderate discomfort. A small intensity percentage reduction significantly lowers treatment discomfort. During 55 of 56 (98%) "Prep" mode sessions (Tx's 1 and 2), the intensity was increased throughout each session; and all "Prep" mode sessions were comfortably tolerated. In 51 or 56 (91%) "Tone" mode sessions (Tx's 3 and 4), patients requested the intensity be lowered with the requests typically made during the final 15 minutes of the session, which is consistent with the treatment parameters. Similarly, for 31 of 56 (55%) "Sculpt" mode sessions (Tx's 5 and 6), patients requested the intensity be lowered, but 15 minutes into the session which is also consistent with the treatment parameters. No treatment sessions were ended prematurely due to excessive discomfort.

Other than transient erythema, self-resolving within several hours, there were no unexpected or serious treatment side effects.

DISCUSSION

Chronic low back pain affects up to 23% of the population worldwide, with 24% to 80% of patients having a recurrence at one year.[6, 7] Low back pain is among the most common complaints of patients seeking chiropractic care and physical therapy. For persistent or chronic low back pain, there are few effective long-term treatments. Nonsteroidal anti-inflammatory drugs (NSAIDs) are often used as first-line treatment and may provide short-term relief.[8] While NSAIDs are effective for short-term relief of chronic low back pain, there is no difference in effectiveness between different types of NSAIDs and between NSAIDs and other commonly used pharmacotherapies, including opioids and muscle relaxants, in those with chronic pain.[8] Physical therapy plays an integral role in the diagnosis and treatment of low back pain. Exercise therapy, in general, is as effective as other therapies for the treatment of chronic low back pain; and is also somewhat effective in reducing pain levels and improving the range of lumbar motion.[9] As seen in this study, the introduction of more effective bio-electrical muscle stimulation devices, which can effectively exercise muscular groups leading to improved core muscle endurance and strength and improved range of lumbar motion, offer the potential for improved outcomes from BEMS-based treatments for chronic low back pain, including for patients unable or unwilling to perform volitional core strengthening exercises due to low back pain.

CONCLUSION

Six treatment sessions, twice weekly for 3 weeks, with the truSculpt flex bio-electrical muscle stimulator, demonstrated clinically and statistically significant improvement in chronic low back pain that was unresponsive to physical therapy, chiropractic manipulations and pain management injections, and clinically and statistically significant improvements in lumbar flexion and core muscle endurance and strength.

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