LATERAL ELECTRICAL SURFACE STIMULATION FOR THE TREATMENT OF PROGRESSIVE SCOLIOSIS

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ABSTRACT

A screening procedure of 27 scoliosis patients has indicated that transcutaneous electrical muscle stimulation is effective in acute correction of scoliosis curves. When the electrodes were moved from the medial paraspinal musculature to the lateral trunk muscles a significant increase in curvature correction was seen.

Based on a series of animal experiments and the screening results, Lateral Electrical Surface Stimulation (LESS) treatment of patients with progressive, mild-to-moderate scoliosis has been initiated. The stimulation therapy is applied during the hours of sleep only. A portable stimulator is connected to carbon-rubber surface electrodes. Skin problems or stimulation intolerance have been negligible. A six (6) months follow-up of seven (7) patients with curves of 20 to 38 degrees and an average monthly progression rate of 2.3 degrees revealed arrest of progression in five (5) and improvement in two (2).

Encouraged by these results, a multicenter clinical investigation is being launched. Several hundred patients will enter a strict protocol for controlled evaluation of the efficiency and feasibility of the LESS-treatment method, which is seen as an alternative to bracing. Presently 15 patients have entered the program.

INTRODUCTION

In the treatment of progressive, mild-to-moderate scoliosis, an external orthosis, in particular the Milwaukee brace, is normally fitted to the patient. Acceptance, however, is a major problem for the psychologically sensitive adolescent patient. The brace is non-cosmetic in appearance, highly restrictive in physical activities, and must be worn twenty-three hours a day. Therefore, the young patient is often reluctant to wear the brace faithfully and as a result, the curvature may increase to the point where surgical correction is necessary.

A promising alternative to bracing is the use of electrical muscle stimulation. The trunk musculature on the convex side of the scoliotic curve is electrically stimulated into contraction which, in turn, creates corrective forces acting on the spinal column. Until now, electrical muscle stimulation for treatment purposes has only been applied to the paraspinal musculature adjacent to the midline. One technique, the Electro-Spinal Instrumentation

System (ESI), supplies electrical stimulation by an implanted "Spinal Pacemaker" via corkscrew electrodes inserted into the paraspinal musculature around the apex of the curve.[1] Transcutaneous stimulation of the same muscle group has also been attempted.[2,3]

At Rancho Los Amigos Hospital an animal study showed attainment of a better curve correction when stimulating electrodes were moved from the paraspinal musculature to the more lateral trunk muscles.[4] A screening of a series of patients confirmed this.[5] When we started to experience lead failures in the ESI implants in 1977, this stimulation mode was replaced by Lateral Electrical Surface Stimulation (LESS). The treatment results were so gratifying that LESS, which is the subject of this paper, became our new treatment option. This Lateral Electrical Surface Stimulation method is non-invasive and lacks the brace objections.

METHODS

ESS Screening

To evaluate if a particular scoliosis patient is a candidate for Electrical Surface Stimulation (ESS), the patient is carefully screened for stimulation tolerance and acute correction efficacy. ESS is applied through carbon impregnated silicone-rubber pads (3.6 x 4.8 cm), coated with electrolytic electrode gel. A constant-current generator supplies square wave pulses of 0 to 100 mA in amplitude, 0.2 msec duration and at a rate of 30 pps. Two surface

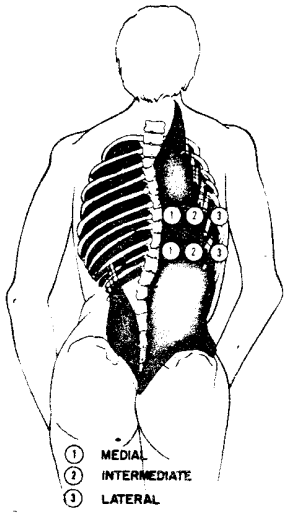

Figure 1. Electrode placements in ESS-screening

electrodes, attached to an adjustable electrode holder, are placed on the skin on the convex side of the primary curvature, symmetrically around the apex, (as determined by the standing AP X-ray), with a distance between electrode centers of 6 to 14 cm. Seventy (70) milliamperes is selected as the current amplitude because this usually is the maximum level the patient can tolerate without discomfort; at the same time, this amplitude is sufficient to produce a strong contraction of normal, healthy trunk musculature. The electrode spacing giving the best palpated muscle contraction and visible correction of the curve is selected. This procedure is repeated with the electrodes placed in three (3) different locations across the back, (Figure 1).

In the medial location (1), the electrode pads are placed on top of the paraspinal musculature 3 cm lateral to the spinous processes. In the lateral location (3), the electrodes are placed on the axillary line while the intermediate location (2) is halfway between the two. With the patient in the prone position, four 36" radiograms are taken. One without stimulation, and one with stimulation in each of the selected electrode locations. The stimulation current remains constant at 70 mA for about 4 seconds while the individual X-ray is taken.

A patient is considered a candidate for treatment by electrical muscle stimulation if the stimulation current is tolerated well, and the major curve corrects at least 5^{o} with the best electrode location without increasing the compensatory curve(s) (or second major curve).

LESS-Treatment

In addition to the ESS-screening criteria, the patient must pass the following selection criteria for inclusion in the LESS-treatment program: (1) Indications of at least one year of bone growth remaining, (2) 15^{o} to 40^{o} of curvature, and (3) radiological documentation of curve progression.

When treatment is initiated, bending films for spine flexibility, a wrist film for bone age, and standing anterior-posterior and lateral views for curve measurements are taken for radiological reference. Using the same parameters as in the screening, a portable battery-operated stimulator supplies constant-current pulses through carbon-rubber electrodes taped onto the skin, (Figure 2).

For each patient the stimulation amplitude is set to a comfortable level, (typically 60 mA), which causes a strong muscle contraction for unbending of the spinal column. To prevent muscle fatigue the stimulator functions in a cyclical mode with on/off times of 1/5. The stimulation is only employed 8 to 10 hours during sleep, adding to the convenience of this treatment method.

The patient returns to clinic each third month for follow-up including a standing AP radiogram. At a supplementary visit 1½ months into the program the electrode positions are adjusted if necessary. Upon bone maturity the therapy will be extended one (1) year. Bending films, and standing AP and lateral films are acquired for final reference.

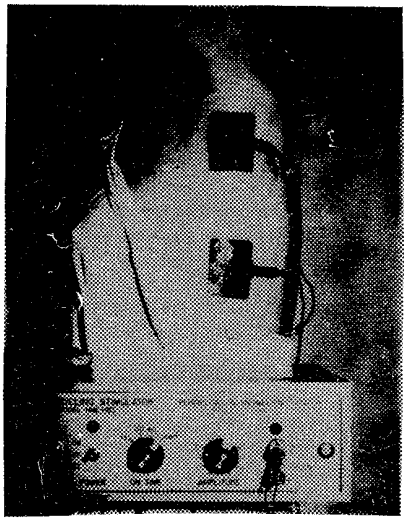

Figure 2. Stimulator and Electrodes Applied in LESS-Treatment

RESULTS

ESS-Screening

To date, 21 idiopathic scoliotics and six (6) spinal cord injury patients with scoliosis have been evaluated in the ESS-screening, (Figure 3).

In the idiopathic population, the average prone major curve measures 17 degrees, (6 to 28 degree range), and the average minor curve measures 14 degrees, (6 to 30 degree range). With medial stimulation of the major curve, it corrects 2 degrees on the average, (12% decrease; -9 to 13 degree range), while the non-stimulated minor curve worsens 2 degrees, (14% increase; -15 to 9 degree range). In the intermediate configuration the major stimulated curve corrects 7 degrees, (41% decrease; 2 to 14 degree range), and the minor curve 5 degrees, (36% decrease; 1 to 15 degree range). For the lateral electrode location, the major curve corrects 8 degrees, (47% decrease; 1 to 20 degree range), while the minor curve improves 5 degrees, (36% decrease; 0 to 10 degree range). The spinal cord injury population shows the same pattern. Correction of the major curve is 3 degrees in medial, 4 degrees in intermediate, and 8 degrees in lateral. For the non-stimulated minor curve, 4 degrees worsening is seen in medial, no change in intermediate, and 2 degrees improvement in lateral.

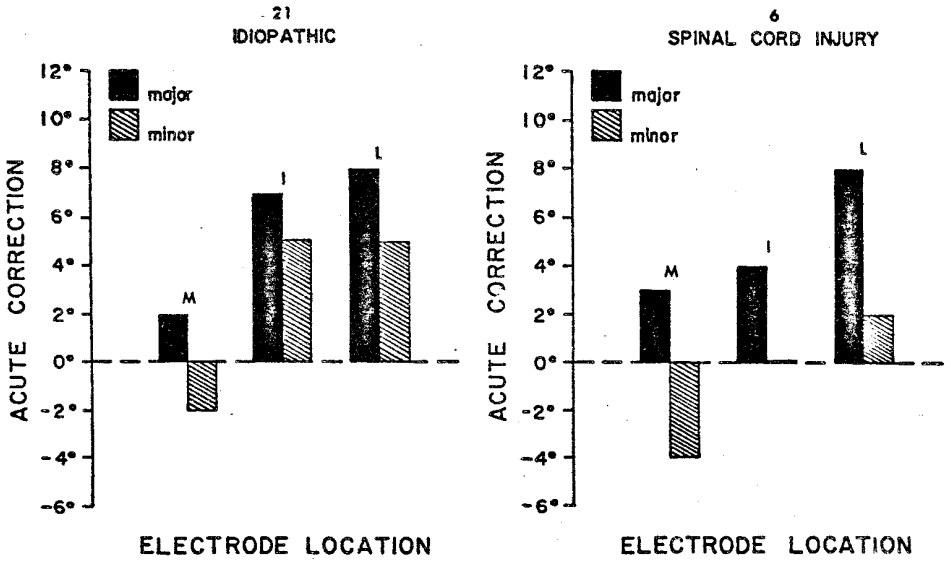

Figure 3. Results From ESS-Screening

A subgrouping of the screening results into a thoracic, a thoracolumbar, and a lumbar region combined with degree ranges, (0 to 9 degrees, 10 to 19 degrees, 20 to 29 degrees, 30 to 39 degrees), does not change the overall findings.

Visual evaluation of curve correction in the ESS-screening reveals that medial stimulation always gives rise to hyperextension of the spine, and a mechanical downwards spread of contraction which impairs the lumbar compensatory curve, if present. The intermediate stimulation sometimes moves the scapular although it does not seem to bother the patients. No side-effects are seen with lateral stimulation.

In all screened patients medial stimulation is outperformed by intermediate and lateral stimulation. (Both intermediate and lateral are actually lateral with respect to medial.) One third of the patients have a correction in the intermediate configuration which is marginally better than the lateral. Knowing that muscle stimulation will strengthen the treated muscles and the fact that the patients themselves can apply the electrodes in the lateral location causes us always to select lateral stimulation over intermediate. Besides, this way we retain a consistent treatment modality from patient to patient.

LESS-Treatment

So far, 13 idiopathics and 2 spinal cord injury patients have been accepted into the Lateral Electrical Surface Stimulation (LESS) program.

Follow-up data is available from 11 idiopathics and the two (2) SCI patients. (Figure 4). The average number of years left until bone maturity is estimated at three (3) years, (Range: 1 to 6 years). Twenty (20) to 38 degrees of curvature is measured at the start of LESS-treatment. Accounting for different time periods, the normalized average progression in 6 months is 14 degrees, (Range: 4 to 34 degrees), equivalent to a rate of progression of 2.3 degrees per month.

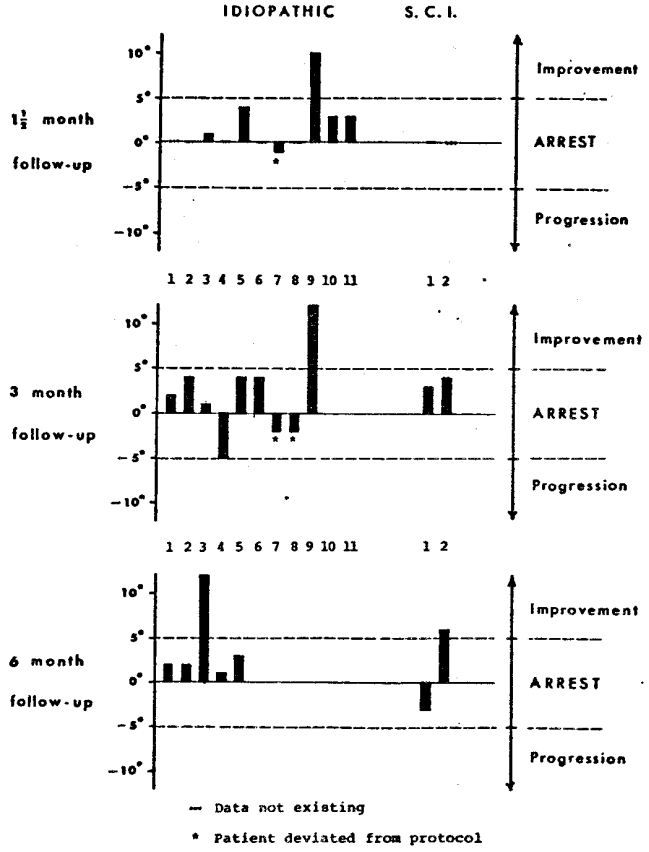

Figure 4. Results From LESS-Treatment

For the follow-up data of standing X-rays, (no stimulation, major curve), a classification criteria is selected as follows: 1) Improvement: more than 5 degrees correction, 2) Progression: more than 5 degrees of curve increase, and 3) Arrest: change of 5 degrees or less. The 1½-month follow-up consists of 11 idiopathics and 2 spinal cord injury patients. One idiopathic curve (I9) exhibits improvement, (10 degrees), while progression of the rest of the curves has been arrested. The 3-month follow-up displays the results from 9 idiopathics and the 2 SCI patients; arrest in 10 patients and the same patient, (I9), as before shows improvement, (now 12 degrees). At the 6-month follow-up the patient population is down to 5 idiopathics and 2 paralytics.

One (1) idiopathic patient (I3) has improved, (12 degrees), one (1) paralytic patient (P2) has corrected, (6 degrees), the rest remain unchanged.

In summary: Of 13 patients currently having follow-up data of 1½ to 6 months, three (3) patients have improved their curvature and the rest have stopped progression. The minor compensatory curves display the same trend as the major structural curves.

DISCUSSION

ESS-Screening

The overall results from the ESS-screening show that lateral stimulation of the major curve in the prone position produces acute correction of the idiopathic spinal curve that is four (4) times better than in the medial stimulation configuration. Similarly, in the paralytic patients, lateral stimulation corrects the curvature three (3) times better than the medial. The minor non-stimulated curve gets worse in the medial configuration while lateral stimulation always corrects this curve. Lateral stimulation of the major curve indirectly corrects any compensatory curve or even a second structural curve.

The reason for better correction of the major curve in the lateral mode is based on the simplified biomechanical consideration that the moments and the pushing forces exerted by the long lever arms of the ribs, or the ribs and pelvis, overcomes that of the short vertebral articulations and ribs in the medial mode. The stronger paraspinal musculature does not counterbalance this mechanical advantage of the weaker lateral trunk muscles.

The worsening of the lumbar compensatory curve during medial stimulation of the paraspinal musculature seems to be caused by an additional contraction of the longissimus thoracis muscle which inserts into the lumbar spine and pelvic area. On the other hand, correction of the major curve during lateral stimulation always improves the compensatory curve. The reason for this is probably simplest explained biomechanically by the fact that a flexible beam shaped into an S-form and fixed in one end with free movement in the longitudinal direction will correct both curves if only one curve is corrected by exterior forces. This may apply to this situation with the spinal column having a certain stiffness and the pelvis being relatively immobile in the prone position.

Of major concern is the hyperlordosis experienced with medial stimulation, which is used in other scoliosis treatment programs based on electrical stimulation.[1-3] The worsening of the compensatory curve(s) may indirectly reduce the maximally possible treatment improvement of the major curve. Lateral stimulation shows no visible side-effects, and moreover, electrode application is easy for the patient.

LESS-Treatment

The treatment results strongly indicate that the LESS-method is capable of arrest and even improvement of highly progressive, mild-to-moderate scoliosis. With a pre-treatment progression rate of 14 degrees per 6 months,

we have seen improvement in three (3) patients and arrest of curvature progression in 10 during a relatively short treatment period (6 months).

Given an equal choice between a brace and the LESS-treatment, only one (1) out of the 16 patients asked, preferred the brace. Only two (2) patients have had difficulties adhering to the treatment protocol. Skin irritation and pinching by the adhesive tape when the muscles contract were the causes. A new semi-solid disc, (2 mm thick), for electrode-skin interface alleviates these problems by elimination of tape and gel. This new adhesive interface material, (Ceptor-Pad TM), conforms well to the body, even when the skin folds upon muscle contraction. Moreover, it prevents "hot-spots" under the electrodes where the gel could be missing or dried out.

As an additional outcome of the ESS-screening it has become obvious that other spinal deformities like kyphosis or lordosis may be treated with Electrical Surface Stimulation (ESS) by selection of the proper muscle groups. To investigate this possibility, we have screened one (1) lordotic, (lordo-scoliosis), and one (1) kyphotic patient, (Scheuermann's Disease). They both corrected in the screening and were concurrently started on a special treatment program. The patient with kyphosis shows no change, (+1 degree), after 1½ months of treatment. A six (6) months follow-up on the lordotic patient demonstrates a curve improvement of 35 degrees.

Encouraged by the scoliosis treatment results using the LESS-method, an international multi-center clinical investigation sponsored by MedGeneral, a medical equipment manufacturer, is being launched. Several hundred patients will enter a strict protocol for controlled evaluation of the efficiency and feasibility of this treatment method, which is seen as an alternative to bracing.

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