TRANSCUTANEOUS ELECTRICAL MUSCLE STIMULATION FOR THE TREATMENT OF PROGRESSIVE SCOLIOSIS AND KYPHOSIS.

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ABSTRACT

In the treatment of progressive, mild-to-moderate scoliosis and kyphosis, transcutaneous electrical neuromuscular stimulation is demonstrated to be a feasible alternative to bracing. At night, during the hours of sleep, the stimulation is applied by a portable pulse generator through surface electrodes to the trunk musculature on the convex side of the spinal curvature. The evoked muscle contractions result in biomechanical correction of the curve.

Treatment follow-up results of up to 4 years from 92 patients show the following rates of success in arresting or reversing the progression of the spinal deformity: (1) 88% for 65 idiopathic scoliotics with single major curves; (2) 78% for 9 idiopathic scoliotics with double major curves; (3) 90% for 10 neuromuscular scoliotics; (4) 100% for 8 kyphotics. If patient compliance and other reasons not related to the technique itself are deducted, the above rates improve to: (1) 97%; (2) 96%; (3) 100%; (4) 100%. Posttreatment observation of skeletally mature curves for up to 1 year in 3 patients reveals deformity stabilization with no curvature increase over time.

This treatment modality has many advantages over the brace. It lacks the emotional and physical problems often found with 23 hours of daily brace wearing. Unlike the brace, the stimulation therapy does not restrict many daytime activities, like competitive sports, and there are no year-long weaning period at the time of skeletal maturity.

INTRODUCTION

School screening to detect scoliosis and other spinal deformities in their early stages was the most significant advancement in scoliosis treatment in the 1970's. Early detection of small curves allows early treatment with a brace, thus greatly reducing the amount of surgical corrections. As a result, there has been a dramatic increase in the number of patients being fitted with either Milwaukee or low profile underarm braces. In addition to the increase in the frequency of brace application the length

of time of treatment has been extended. For a preadolescent pupil detected as having an abnormal spinal curvature, 2-6 years of brace wear could easily be required.

Unfortunately, the brace treatment often generates both emotional and physical side effects, and restricts certain daily activities, particularly competitive sports. An alternative treatment method not involving a restraining orthosis is therefore desirable.

Previous work done at Rancho Los Amigos Hospital showed that in straight cat spines, acute scoliotic curvatures of up to 50 degrees could be induced from electrical surface stimulation with electrode pads placed at an optimum position over the lateral trunk musculature [1]. In a clinical study of 40 scoliosis patients it was found that electrical surface stimulation could also be used to reduce existing curvature [2]. Due to the biomechanics of the spine, a lateral electrode placement (axillary line) with the advantage of the long lever arms of the ribs and ilium, was three times as efficient as a medial placement (paraspinal muscles) in reducing the scoliosis with stimulation applied. A striking side effect from stimulating the paraspinal musculature was a hyperextension of the spine, significantly reducing existing kyphosis. These clinical observations lead to the development and implementation of neuromuscular electrical surface stimulation for the treatment of scoliosis and kyphosis [3].

MATERIALS AND METHODS

Scoliosis

For the treatment of scoliosis the technique of Lateral Electrical Surface Stimulation (L.E.S.S.) has been developed. Two stimulation electrodes (discs, 5 cm in diameter) are placed around the apex of the major curve with a nominal distance of 10 cm between electrode centers. As a guideline for adolescent patients the electrode distance is 7-9 cm when the curve is short (< 5 segments) and 11-16 cm when the curve is long (> 7 segments). For juvenile patients with short trunks the electrodes are placed 1 to 2 cm closer together for all curve lengths. The distance between the outer rims of the electrodes is never longer than the distance between the neutral vertebrae of the stimulated curve to prevent stimulation carry-over into the concavity of the adjoining curves. In the thoracic area, the electrodes are placed symmetrically around the apical rib at its most lateral aspect, between the anterior and posterior axillary lines (see steps 1-4 in Figure 1). In the lumbar area the reference center for the electrodes is the apical vertebra itself. For thoracolumbar curves the two position rules are combined and carefully crosschecked by palpation of the contracting musculature and the moving spinal column.

The stimulation therapy is applied only at night during the hours of sleep. No additional daytime treatment or exercises are prescribed. To prevent muscle fatique the stimulator turns on and off in a cyclical fashion such that the muscles smoothly build up contraction over a period of 2 seconds, remain fully contracted for 4 seconds and relax for 6 seconds. The muscle stimulation is provided by a portable battery-operated stimulator which generates trains of rectangular constant-current pulses of 0.2 milliseconds duration at a repetition rate of 25 pulses per second. These pulses are of a balanced, asymmetrical, biphasic pattern to avoid electrode polari-

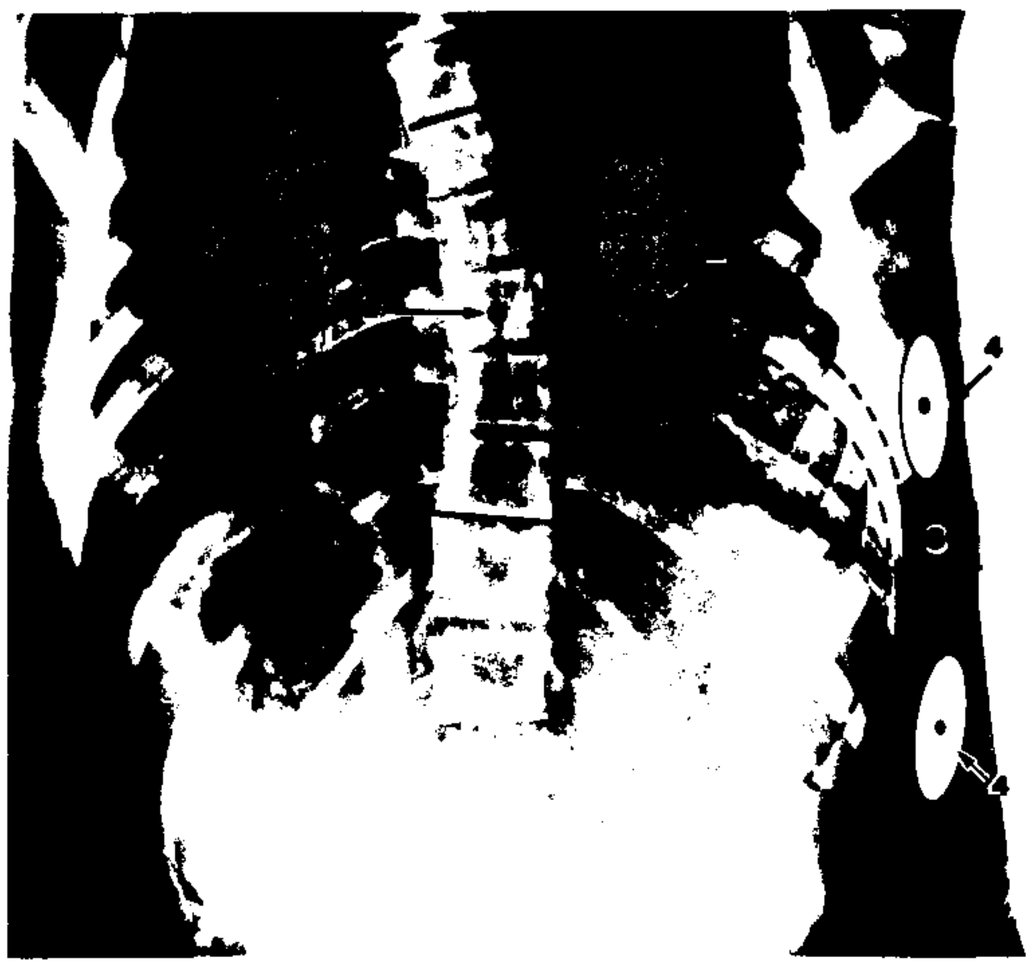

Figure 1 - Surface electrode placement technique for thoracic scoliosis.

zation, potentially causing skin irritation and electrode material deterioration. Patients with single major curves use the ScoliTron™ stimulator which is manufactured by Neoromedics, Inc. (previously MedGeneral, Inc.) to our specifications, while patients with double major curves make use of our own NME-201 dual-channel stimulator. The stimulator is connected to carbon-rubber electrodes which are interfaced to the skin via an electrically conductive, adhesive coupling medium (Figure 2). Several kinds of interface media are used due to skin sensitivity to certain materials. The following four alternatives are primarily used: (1) karaya pads (LecPads by LecTec, Inc.); (2) gel pads (T.E.N.S. Gel Pads by 3M, Inc.) and skin tape in rolls or patches (various brands); (3) gel (Spectra 360 by Parker Laboratories, Inc.) and skin tape; (4) polymer pads (TransCeptor Pads by MedGeneral, Inc.; production discontinued).

For evaluation of the efficiency of the L.E.S.S. treatment method, patients are selected according to the following criteria: (1) idiopathic scoliosis; (2) 20^{0} to 45^{0} of curvature; (3) at least 1 year of skeletal growth remaining; and (4) radiographic documentation of curve progression. The growth assurance criteria (3) more specifically requires: (a) prepuberty (female: no menarche; male: no voice change); (b) documented bone age of $\leq$ 13 years for girls (Greulich and Pyle Standards) and $\leq$ 14.5 years for boys; and (c) excursion of the iliac epihyses $\leq$ 50% (Risser sign $\leq$ 2). This criteria serves the double function of selecting patients whose curve progression is likely to continue and provides sufficient time for the treatment to function on non-mature, flexible curves. The curvature progression criteria (4) depends on the size of the curvature: (a) if the most recent x-ray shows a curve between 20^{0} and 24^{0}, at least 10^{0} of progression must be documented by 2 films 3 and 6 months earlier; (b) if the most recent x-ray shows a curve of 25^{0} to 29^{0}, at least 3^{0} of progression must be documented by the preceeding 3 month film; and (c) if the most recent x-ray show a curve of 30^{0} to 45^{0}, no documentation of progression is needed. Together with the growth assurance criteria this criteria is likely to prevent treatment of non-progressing scoliosis. Patients ful-

Figure 2 - Application of the L.E.S.S. surface etimulation method for scoliosis treatment at night time only.

filling the above four selection criteria are designated PROTOCOL patients. When one or more of the criteria are violated but progression seems eminent the patients are admitted as non-protocol patients. The follow-up results from the protocol and the non-protocol patients are treated statistically as separate groups.

All patients are given an equal choice between bracewear and electrical muscle stimulation. Only a small percent prefer the brace (Milwaukee or low profile) over L.E.S.S. treatment. When the L.E.S.S. treatment is initiated, the patients are given a full scoliosis-related physical examination, the placements of the electrodes are determined, stimulation is started, and the patients are familiarized with the equipment and its use at home.

After a 2-week adaptation phase, the scoliosis patients return for a check of the stimulation efficiency. Two prone x-rays are taken. The first is made without stimulation, to verify curve flexibility (change in degrees from standing to prone position) and location of the electrodes. If necessary, the electrode placement is adjusted. Another x-ray is taken with a stimulation level of 70 milliamperes. Correction of the major curve(s) and no worsening of the compensatory curve(s) must be seen, indicating that the proper muscles are being stimulated. The patients return to the clinic every three to six months for follow-up.

The treatment is usually terminated at skeletal maturity which is indicated when all vertebral ring apophyses are closed and two out of the following three criteria are fulfilled: (1) no change in standing height over the last 18 months; (2) complete fusion of the distal radius in the left wrist; and (3) risser sign 4+ or 5+. There are no weaning period after skeletal maturity, however, curves larger than 25^{0}, which exhibit a flexibility of more than 5^{0} from a standing to a prone position, are not considered safe from further progression and receive an additional year of post-maturity stimulation. Post-treatment x-ray observation at 6 month and annually thereafter is essential for determination of the curve behavior

after treatment termination.

The idiopathic patient population having at least 3 month of treatment follow-up consists of 67 girls and 7 boys for a total of 74 patients. Sixtyfive (65) patients have single major curves and 9 have double major curves. The average bone age at treatment initiation was 12 years and 5 months and the average risser sign was 1. Eleven (11) patients (or 15%) had a bone age of 10 years or less. Puberty on-set was found in 31 patients (or 42%) of the population. Thoracic hypokyphosis (kyphosis $< 20^0$) was observed in 23 patients with a population average of 24^0 kyphosis.

The neuromuscular population counts 6 boys and 4 girls, all pre-puberty with more than 1 year to the of estimated bone maturity.

Kyphosis

The treatment method and protocol for kyphosis patients are similar to that of the scoliosis patients except for the following basic differences: (1) curvature size; (2) electrode location; and (3) x-ray views. For patients with postural kyphosis the curvature must be at least 40^0 and for patients with Scheuermann's kyphosis the 3 most apical vertebrae must be wedged at least 5^0. Scheuermann's kyphosis often has associated scoliosis of 10^0-20^0, so by placing a single electrode pair on the paraspinal musculature unilaterally to the side of the scoliosis convexity, both correction of the kyphosis and the scoliosis is obtained. When no scoliosis exists, either bilateral stimulation of the paraspinal muscles by a dual-channel stimulator or alternating (every other day), unilateral stimulation by a single-channel stimulator is applied. To determine curvature size, lateral rather than Anterior-Posterior x-ray views, are taken. Figure 3b shows how the electrodes are places symmetrically around the curvature apex. The distance between electrode centers is generally 12-14 cm depending on curve extension. As with scoliosis, the spine movement reducing the kyphosis should be palpated with stimulation applied for selection of the optimum electrode distance. The natural, compensatory lumber lordosis must not be jeopardized by placing the lower electrode too close to the neutral vertebra.

The kyphosis population having treatment follow-up results consists of 6 Scheuermann's kyphotics and 2 postural kyphotics. All growth assurance and progression criteria have been fulfilled.

RESULTS

Scoliosis

As an example of results obtainable with the L.E.S.S. treatment for scoliosis, Figure 4 shows follow-up x-rays of a nine-year-old idiopathic protocol patient whose major curve progressed from 16^0 at 5 month prior to treatment to 25^0 at 1 month prior to treatment to 38^0 at treatment initiation. This translates into a monthly progression rate of 4.4 degrees. After 7 months of treatment the major curve had reduced 7^0 and the lumbar compensatory curve had reduced 2^0. Not shown in Figure 4 are the latest curvature degrees at the 2 year clinic visit: 25^0 (13^0 total reduction)

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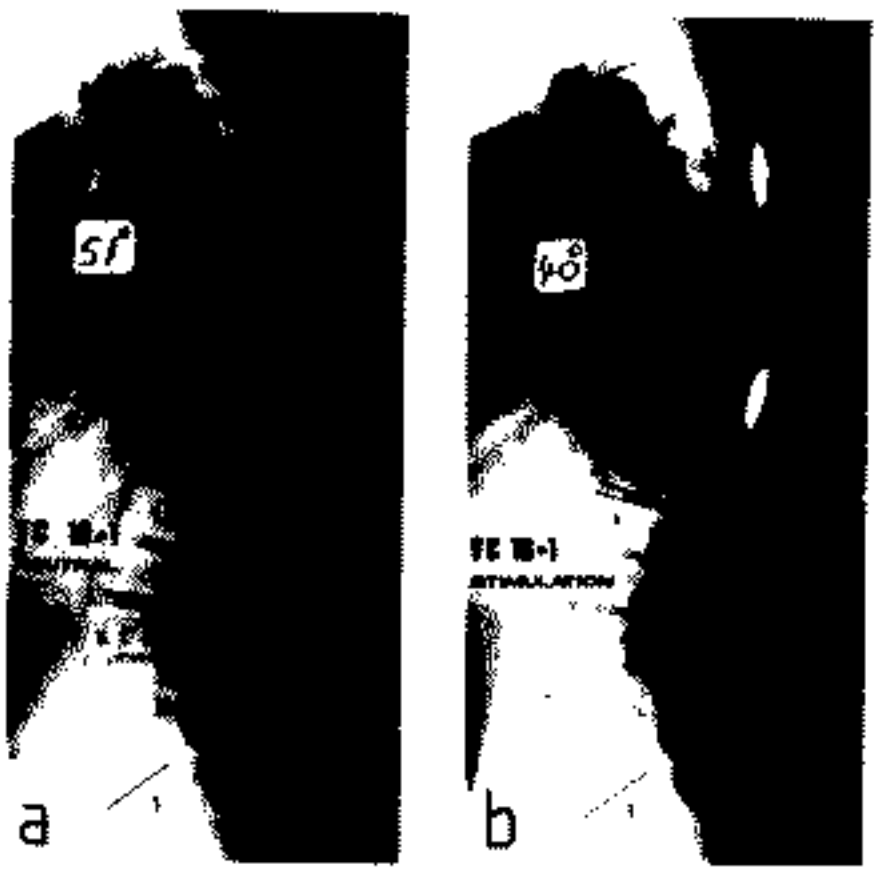

Figure 3 – Kyphosis patient in sidelying position at 2 week check. a) no stimulation: 51° kyphosis, 53° lordosis. b) stimulation (electrode placement indicated in white): 40° kyphosis, 49° lordosis.

for the major curve and 7° (9° total reduction) for the compensatory curve below.

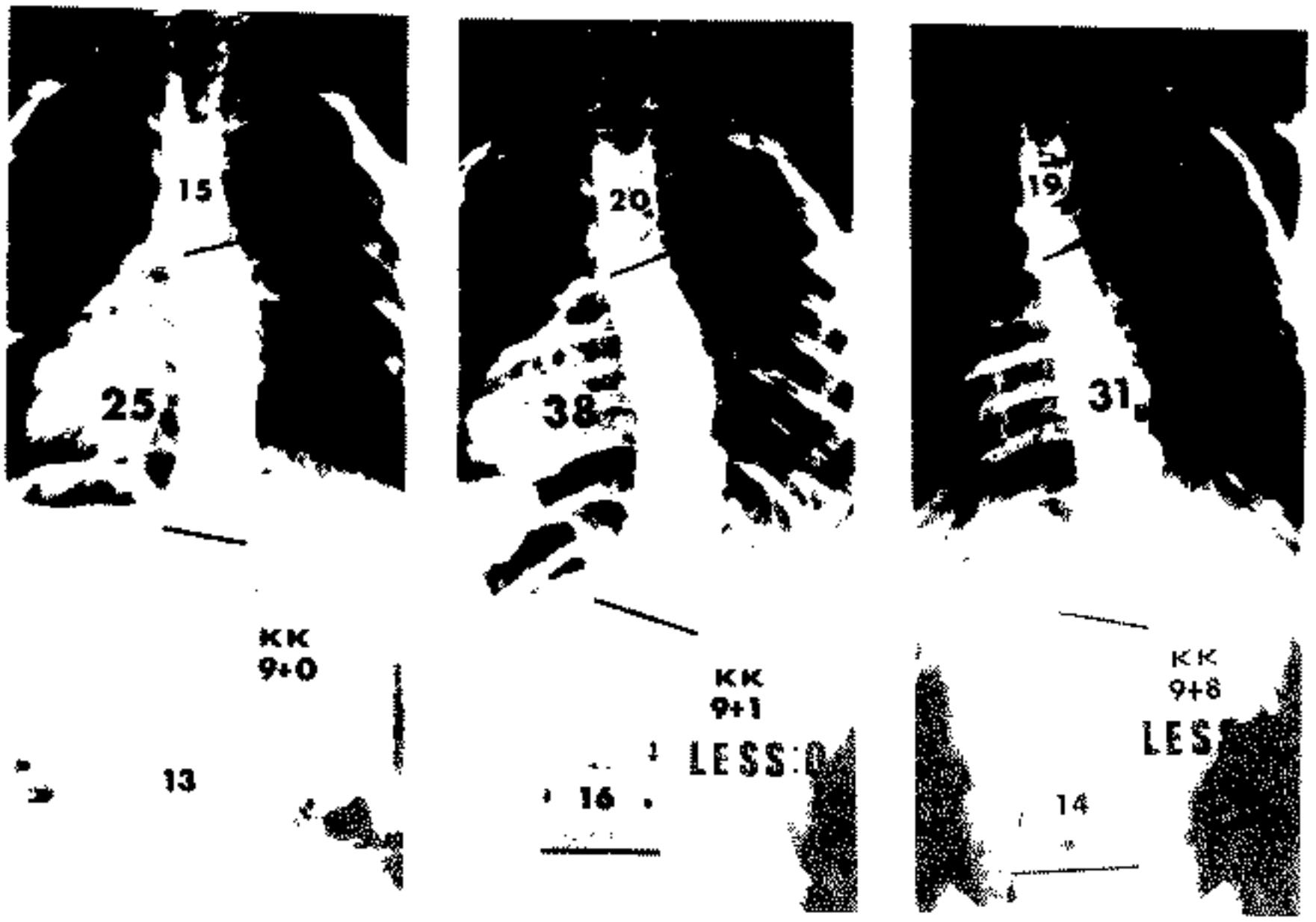

Figure 4 – Efficiency of the L.E.S.S. treatment. AP standing x-rays (no stimulation), left to right: 1 month prior to therapy initiation, start of treatment, 7 month of treatment.

Figure 5 displays a series of result graphs for up to 2 years of treatment of patients with idiopathic scoliosis.

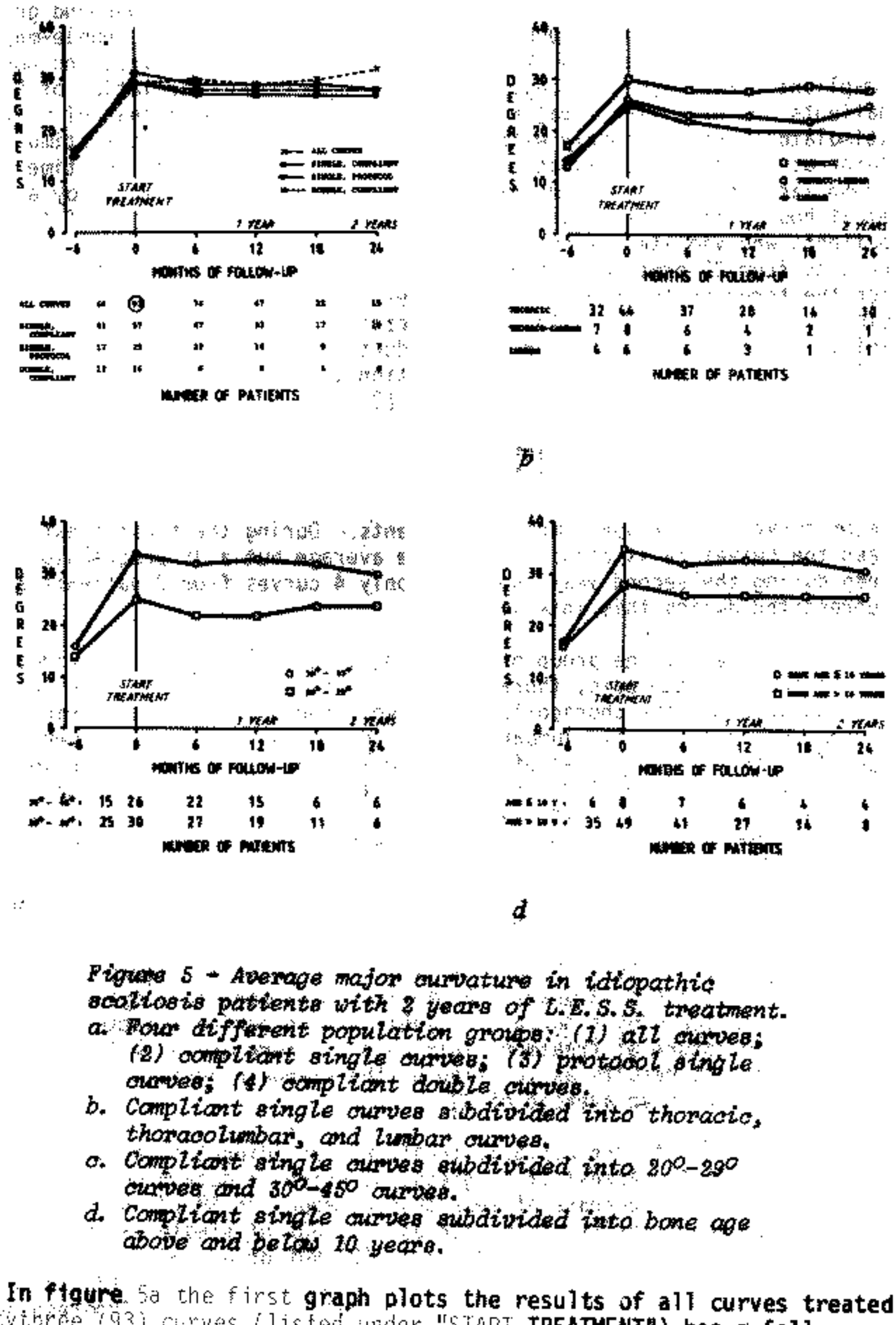

Figure 5 - Average major curvature in idiopathic scoliosis patients with 2 years of L.E.S.S. treatment.
a. Four different population groups: (1) all curves; (2) compliant single curves; (3) protocol single curves; (4) compliant double curves.
b. Compliant single curves subdivided into thoracic, thoracolumbar, and lumbar curves.
c. Compliant single curves subdivided into 20°-29° curves and 30°-45° curves.
d. Compliant single curves subdivided into bone age above and below 10 years.

In figure 5a the first **graph plots the results of all curves treated.** Ninetythree (93) curves (listed under "START **TREATMENT**") **has a follow-up of at least** 3 months (only 6 month intervals **are shown in the graphs). As for the** following graphs, **this graph is the sum of 8 individual graphs for each of** the decreasing patient **populations (the patients are started at different points in** time) **at each of the 3 month intervals from the 3 month follow-up to the 24 month follow-up.** While this method is not fully

correct statistically, the compound graph displays exactly the same information as all the individual graphs together. The second compound graph shows the results from a reduced curve population where all double-major curves,double-major curves initially treated as single curves, and non-compliant curves are excluded. Left is a homogeneous population of 57 patients who have single major curves treated with single-channel stimulators and who comply with the treatment program (use the stimulator at sufficient stimulatic levels) for at least half ot the time (compliance $\geq$ 50%). (The amount of stimulator usage is detected by a chemical hour meter installed in the units). A further exclusion of the patients who violate one or more of the growth assurance criteria leaves results from 25 protocol patients as plotted in the third graph. Common for the three graphs mentioned is a pre-treatment average monthly progression rate of 2.2^{o}-2.7^{o} followed by arrests of progression at treatment initiation and an average curvature reduction of 1^{o}-3^{o} over the 2 year follow-up period. The protocol population shows the best results with the highest pre-treatment progression rate (2.7^{o}) and the highest treatment curve reduction (3^{o}). Due to the similarity of the second graph, the bigger population of 57 compliant patients with only one treated curve is chosen over the protocol population as adequate for further statistics. The fourth graph in Figure 5a plots the results of treatment of double-major curves in therapy compliant patients. During the first treatment year the curvature is stabilized on the average but a 3^{o} progression is seen during the second year; however, only 4 curves from 2 patients are represented during this interval.

In figure 5b, the group of compliant single curves is subdivided into curves from the thoracic, thoraco-lumbar, and lumbar regions. While both the thoracic and the thoraco-lumbar curves show stabilization during the 2 years of follow-up the lumbar curves show a steady reduction over time. The compliant single curves of Figure 5c are subdivided into a group of 20^{o}-29^{o} curves and 30^{o}-45^{o} curves. The largest pre-treatment progression and treatment curvature reduction is seen in the big curves. For patients with bone age of 10 years or less at treatment initiation, Figure 5d, the treatment results are better than for the group with a bone age above 10 years.

The result graph for the compliant population of 57 patients with only one treated curve in Figure 5a is plotted again in Figure 6 in more detail for a period of 3 years. A pre-treatment monthly progression rate of 2.2^{o} is followed by a curvature stabilization during treatment at 2^{o} below the curvature at treatment initiation. There are no wild fluctuations in the treatment results as verified by the standard deviations ranging from 1^{o} to 4^{o} with an average of 3^{o}.

The response to the L.E.S.S. treatment for idiopathic scoliosis is listed in Table I. Arrest of progression, which is determined as a curvature increase or decrease of less than or equal to 5^{o} ($[-5^{o}, +5^{o}]$) accounts for the majority of the curves: (1) 80% of single major curves treated with single-channel stimulators; (2) 90% of one of the two double-major curves treated with single-channel stimulation; (3) 78% of double-major curves treated with dual-channel stimulators. Progression is seen in 13% of all curves including those with non-compliance and non-related problems. The reason for 93 curves in 74 patients are that 9 are double-curves and 10 curves initially treated as single curves have been converted into double-curves upon increase of more than 5^{o} in the non-treated major curve.

An indicator for the rotation of the spinal column and exterior deformity is the rib hump or lumbar prominence. The rib hump is measured initially, annually and at treatment termination. Figure 7 shows that on the average no change in the rib hump is observed after 1 year of treatment (33 patients measured) while an average reduction of 2 mm is measured at the 2 year visit (13 patients measured).

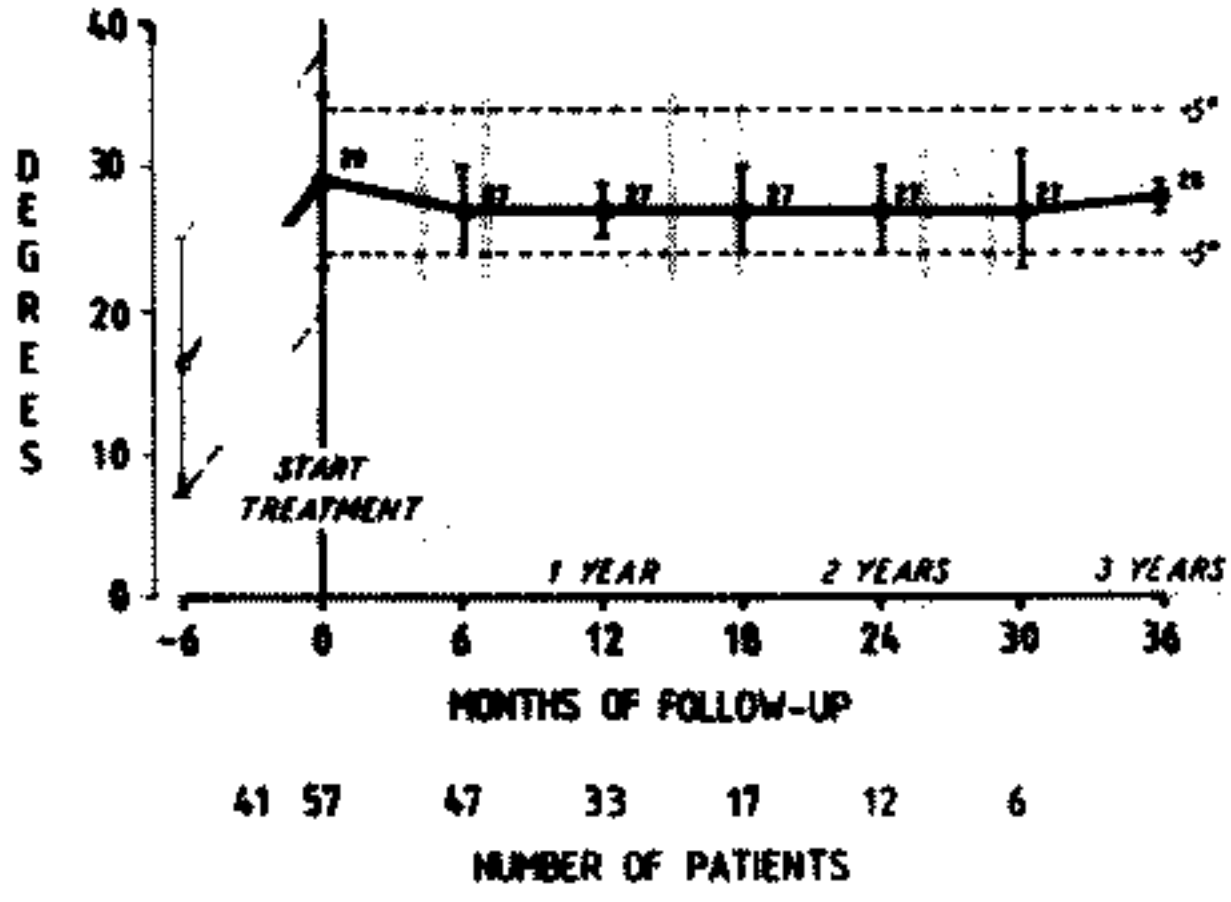

Figure 6 - 3 years of L.E.S.S. treatment follow-up for 57 compliant idiopathics with single treated curves.

TABLE I

Treatment status for idiopathic scoliosis

Response	Single curves	Single of double curves	Double Curves	All curves
Improvement	5 (8%)	1 (10%)	0 (0%)	6 (6%)
Arrest [-5°, +5°]	52 (80%)	9 (90%)	14 (78%)	75 (81%)
Progression	8 (12%)	0 (0%)	4 (22%)	12 (13%)
Number of curves	65 (100%)	10 (100%)	18 (100%)	93 (100%)
Number of patients	65	0	9	74

A total of 12 patientshave been discontinued prior to skeletal maturity of the various reasons listed in Table II. Three (3) additional patients not included in the table were dicontinued of reasons not related to the treatment. Non-compliance is the main offender being the reason for discontinuation in 58% of the cases. Skin rash has been the reason for discontinuation in only 2 patients (17%). Discontinuation due to treatment inefficciency has been required in 2 patients which is equivalent to

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a minute 3% of the total idiopathic patient population of 74.

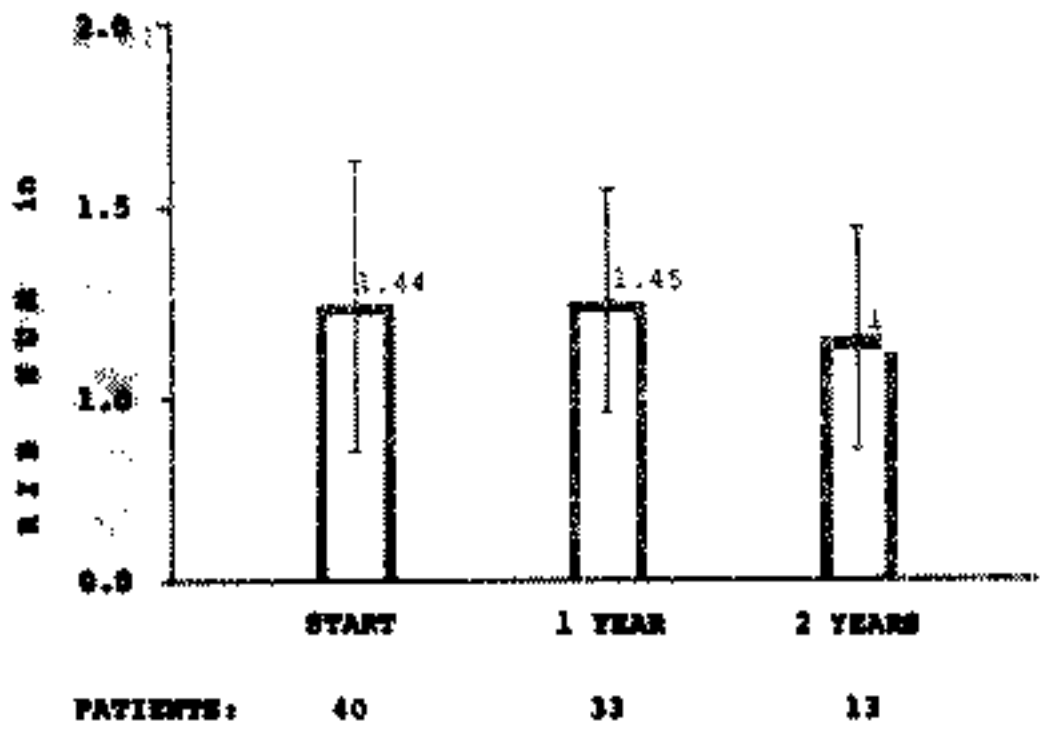

Figure 7 - Average rib hump for idiopathic L.E.S.S. patients.

A one year post-treatment observation of 3 idiopathic scoliotics with skeletally mature curves between 30^{0} and 32^{0} reveals stabilization of the deformity.

TABLE II

Discontinued Idiopathic Patients

Reasons	Single curves Progress	Single curves No Progress	Double curves Progress	Double curves No Progress
1. Non-compliance	3 (5%)	3 (5%)	1 (11%)	0
2. Electrode misplacement	0	0	0	0
3. Stimulation problems	1 (2%)	0	0	0
4. Skin rash	0	1 (2%)	1 (11%)	0
5. Treatment ineffective	2 (3%)	0	0	0
Patients discontinued	10 (15%)		2 (22%)	
Patients started	66		9	

In a supplementary treatment program, 10 patients with neuromuscular scoliosis are being treated with electrical surface stimulation during nighttime and body jackets for trunk stabilization during daytime. Nine (9) of the patients are neuropathic with 7 spinal cord injury patients and 2 patients with lower motor neuron deficiencies: myelomeningocoele and poliomyelitis. One (1) patient is myopathic with Duchenne's muscular dystrophy. Although fluctuations of $\pm 5^{0}$ are seen in a 2 year treatment follow-up, the overall trend is arrest or reversal of curvature progression as shown in Table III.

TABLE III

Treatment status in neuromuscular scoliosis

Improvement	3 (30%)
Arrest -5^{o}, $+5^{o}$	6 (60%)
Progression	1 (10%)
Number of curves	10 (100%)

Kyphosis

In the treatment of progressive kyphosis, a 2 year follow-up is available and depicted in Figure 8. Six (6) kyphosis patients with Scheuermann's disease has been treated with electrical surface stimulation of the paraspinal musculature. Over the 2 year treatment period the average curvature degrees are reduced from 44 degrees at initiation to 32 degrees at 2 years.

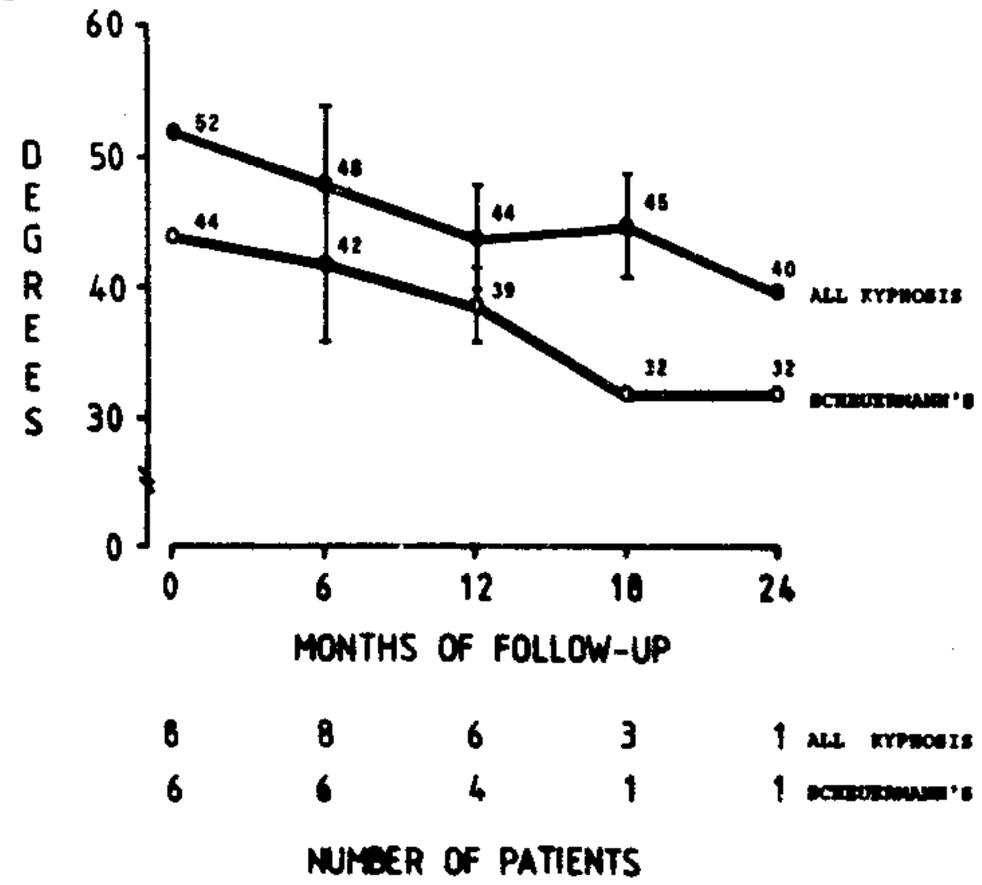

Figure 8 - Follow-up results of patients with progressive postural and Scheuermann's kyphosis being treated with electrical surface stimulation.

The reason why the degree numbers are not higher is due to the fact that two of the patients have severe but very small degree curves (21^{o}, 34^{o}) of only a few segments. From the steady downwards slope of the treatment follow-up graph an average monthly curvature improvement rate of 0.5^{o} is calculated. When 2 patients with postural kyphosis are included in the follow-up results, the new graph moves up 8^{o} but remains similar in shape and slope. All patients show correction of their kyphosis with either reduced or unchanged wedging of the apical vertebrae.

DISCUSSION

As opposed to the many psychological and physical problems with brace wearing, the only real problem encountered with electrical surface stimulation has been skin rash. Usually, the contact dermatitis is remedied by change of the electrode-skin coupling media to another of the 4 different types used. No patients have been discontinued due to persistant skin rash for the last two years. New electrode types are becomming available but still today no manufacturer has been able to produce an integrated electrode or coupling disc which has good adhesion properties, is comfortable to wear both with and without stimulation, causes no skin rash, is reusable for cost effectiveness, and can quickly be applied and removed. Of the 12 patients discontinued, 7 did not comply with the program. Although these patients could not give a specific reason for their non-compliance they all seemed irritated with the electrodes not being practical enough for the necessary every day use. It is believed that the arrival of a highly manageable electrode for quick application will decrease the non-compliance dramatically.

Beyond occational skin rash no other side effects has been observed. Further research needs to be done to optimize the stimulation parameters for stronger muscle contractions without associated excitation of the pain receptors. The stronger the muscle contraction, the better a biomechanical correction of the spinal curvature. With the stimulation parameters presently in use, the limiting factor for the muscle contraction force generated is the level of comfort of the individual patient.

In the treatment of scoliosis with L.E.S.S., the result graphs imply that the treatment method works equally well for all types of single curves. Many patients, who otherwise fulfilled the protocol selection criteria, were excluded from the protocol group due to menses onset. The "no menarche" protocol criteria seems very inaccurate in indicating time of skeletal maturity and should therefore be dropped. The treatment program has a success rate of 88% while the technique itself is able to prevent further progression in 97% of the cases treated. The L.E.S.S. treatment method produces extremely reliable results without wild unpredictable fluctuations as verified over 3 years by a flat horizontal result graph with an average standard deviation of only about 10% of the initial curvature (Figure 6). The few post-treatment observation results available show no further deformity progression upon treatment termination at the point of skeletal maturity. This means that a weaning period of several years as known from the brace is probably unnecessary.

In the treatment of kyphosis with neuromuscular electrical surface stimulation the results are even better than for scoliosis since a steady curvature reduction over time is seen. Also, the anormal vertebrae growth pattern found in the Scheuermann's disease patients has been partly corrected in several patients with an actual de-wedging of the apical vertebrae resulting from the treatment.

The most efficient electrode location is lateral for scoliosis and medial for kyphosis. In both cases the apical vertebra or apical rib is the center of the field of stimulation. If the paraspinal musculature is used as the stimulation target in scoliosis treatment, as other investigators do, only minimal advantage of the body mechanics is taken with an inherent risk of creating hypokyphotic or lordotic spines.

In conclusion, it is believed that neuromuscular electrical surface stimulation is an excellent alternative to brace treatment in the management of progressive mild-to-moderate scoliosis and kyphosis. Particularly, this treatment modality can be used as a preventive treatment of the many small but potentially progressive curves detected in the school screenings. Due to much higher patient acceptance of the stimulation treatment over brace treatment this method is likely to be prescribed more often and earlier than the brace. This is likely to result in fewer curves that progress to the stage of surgical correction.

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