Local and Remote Sustained Trigger Point Therapy for Exacerbations of Chronic Low Back Pain

A Randomized, Double-Blind, Controlled, Multicenter Trial

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Study Design. A randomized, double-blind, controlled, multicenter trial was conducted.

Objectives. To assess the efficacy of neuroreflexotherapy in the management of low back pain.

Summary and Background Data. Neuroreflexotherapy consists of temporary implantation of epidermal devices in trigger points in the back and referred tender points in the ear.

Methods. The rheumatology and rehabilitation departments of three teaching hospitals in Madrid recruited 78 patients with chronic low back pain. These patients were randomly assigned to the control group (37 patients) or to the treatment group (41 patients). Patients in the treatment group underwent one neuroreflexotherapeutic intervention. The control group received sham treatment consisting of placement of the same number of epidermal devices within a 5-cm radius of the target zones. Patients from both groups were allowed to continue drug treatment as previously prescribed. The use of medications during the trial was recorded.

Results. Patients underwent clinical evaluations on three occasions: within 5 minutes before intervention, within 5 minutes after intervention, and 45 days later. The preintervention assessment was carried out by the physician from each hospital department who included the patient in the study. Each of the two follow-up assessments were carried out independently by two of three physicians who had no connection with the research team. Patients in the treatment group showed immediate lessening of pain compared with the results in patients in the control group. This pain relief was clinically relevant and statistically significant, and it persisted up to the end of the trial.

Conclusions. Neuroreflexotherapy intervention seems to be a simple and effective treatment for rapid amelioration of pain episodes in patients with chronic low back pain. At this time, the duration of pain relief beyond 45 days has not been evaluated. [Key words: chronic low back pain, clinical trial, controlled, double-blind, multicenter, neuroreflexotherapy, randomized]
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Common low back pain is defined as pain in the lumbosacral region that may or may not be associated with referred pain, that is usually accompanied by painful limitation of motion, and that is a result of "mechanical" causes. This implies that backache is not related to underlying conditions, such as fractures, spondylitis, direct trauma, or neoplastic, infectious, vascular, metabolic, or endocrine-related processes.[10] Low back pain often is believed to be the result of degenerative disk syndrome, protrusion of intervertebral disks, strains, sprains, and other disorders associated with the position or movement of the spine, such as those caused by scoliosis or spondylolisthesis. In most cases, however, it is not possible to establish an organic cause.[10,44,52] Certain neural mechanisms, including depolarization of capsaicin-sensitive fibers, release of substance P and other neuropeptides, and stimulation of nociceptive neurons, have been implicated in the production and continuity of pain, inflammation, and muscle contracture.[3,9,15,17,32,46–48,50,51,55]

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Neuroreflexotherapy intervention is characterized by temporary implantation of epidermal devices in trigger points in the back at the site of dermatomes clinically involved in each case and in referred tender points in the ear.[18,19,25,26,29,40] Physical stimulation of dermal nerve endings related to the dermatomes involved could determine release of enkephalins.[7,35,58] Binding of enkephalins to receptors of capsaicin-sensitive fibers prevents the release of substance P, which deactivates nociceptive neurons and inhibits the mechanisms involved in the pathophysiology of low back pain.[8,12,20,24,35,51,58] In addition, structures in the thalamus and brainstem activated by stimuli applied far from the painful zone are capable of triggering pain-relieving effects.[2,5,21,54] In this respect, the ear may constitute a suitable territory for implantation because of the connections of its innervation-related nuclei.[6,54,56,57]

The efficacy attributed to intradermal injections and dry-needling in trigger points for managing chronic low back pain also might be explained by this hypothetical mechanism, which in turn would be similar to that argued for the effects of transcutaneous electrical stimulation (TENS), although the efficacy of this procedure is controversial.[11,16,19,34] Epidermal devices used in neuroreflexotherapy intervention remain in place as long as 90 days in the back and as long as 20 days in the ear, obtaining a more persistent stimulation than that achieved by TENS or intradermal injections. Neuroreflexotherapy interventions may be confused with acupuncture. Zones of the skin stimulated by neuroreflexotherapy are exclusively defined by their innervation, however, and they neither coincide with the points described in Chinese acupuncture texts nor with migration pathways of some radioactive tracers, as has been shown in the case of acupuncture points.[1,27,28,53] They also differ in their electrical characteristics and in the methods of stimulation used.[27,28,39]

The clinical experience derived from approximately 40,000 neuroreflexotherapy interventions performed at the Kovacs Foundation clinics (a nonprofit, private medical institution) between 1984 and 1993 on patients with low back pain, together with the results of a follow-up study in 2751 cases, indicate that this kind of intervention was potentially successful.[36] Efficacy of neuroreflexotherapy for chronic low back pain was demonstrated in a double-blind, controlled, clinical trial on patients referred to the Kovacs Foundation from primary health care facilities of the Spanish National Health System.[26] The present study reports the results of a double-blind, multicenter trial in which patients attending the outpatient clinics of acute-care teaching hospitals underwent neuroreflexotherapy intervention for chronic low back pain.

■ Methods

Study Population. The target population was defined as adults of 30–60 years of age with low back pain who were attending the outpatient clinics of three rheumatology departments and one rehabilitation unit of three different teaching hospitals from the Spanish National Health System in Madrid.

Inclusion criteria were as follows: presence of low back pain, with or without referred pain, that lasted for more than 3 years, during which time symptomatic periods prevailed over asymptomatic ones; a current episode of low back pain lasting longer than 12 weeks, during which period of time conventional treatment was unsuccessful in alleviating the symptoms and was accompanied by normal laboratory test results (sedimentation rate, hemogram, alkaline phosphatase, and serum calcium and phosphorus levels); and normal lumbosacral radiographs (posteroanterior and lateral views) or those with evidence of degeneration of intervertebral disks, spondyloarthrosis, scoliosis <50° Cobb, Schmorl nodes, spondylolisthesis grade I or II, dysmorphogenesis, transitional anomalies, or vertebral hyperostosis. Exclusion criteria consisted of: history of surgery in the dorsolumbosacral region, pain related to other conditions, use of pharmacologic treatment (nonsteroidal anti-inflammatory drugs (NSAID), steroids, analgesics, muscle relaxants, vitamins, and/or gangliosides) for other disorders, spondylolysis, spinal stenosis, marked emotional instability or poor social integration (grade 5 in the items of the COOP chart [developed by The Dartmouth Primary Care Cooperative Information Project]), infiltrations (extracellular accumulation within a tissue of any material that is not a normal component of that tissue) during the previous 6 weeks, alcoholism, drug addiction, uncontrolled metabolic disorders, systemic infections, neurologic degenerative disorders, malignancy, severe cardiovascular or pulmonary diseases, depression or treatment with psychoactive drugs, and dermatologic conditions that prevented neuroreflexotherapy intervention.[38]

Participants were recruited consecutively from January 15, 1992 to January 27, 1993. The selection of patients was assessed independently by one of the seven physicians from the four hospital departments who participated in the study, according to data obtained from a complete medical history, physical examination, and recent (no more than 8 weeks earlier) laboratory tests and posteroanterior and lateral roentgenograms of the lumbar region (when clinically indicated, roentgenograms of the hip and sacroiliac joints also were taken). After randomization and before the participating staff was told which group each patient was in, the records of all patients were reviewed jointly by these physicians.

Participants were informed verbally and in writing of the purposes and characteristics of the clinical trial. All patients gave their written consent to participate in the study. The study protocol was approved by the ethics committees of the participating hospitals. Medications for low back pain were not withdrawn. Patients were allowed to continue conventional treatments that had been prescribed previously, with the exception of calcitonin or rehabilitation sessions, which had to be discontinued 30 days before and during the patient's participation in the trial.

Neuroreflexotherapy Intervention. Randomization was carried out according to a table of random permutations.[37] Only the person responsible for randomizing patients to the treatment or control groups and the physician performing the intervention knew to which group each patient had been assigned. Neither had access to the patient's medical record, to

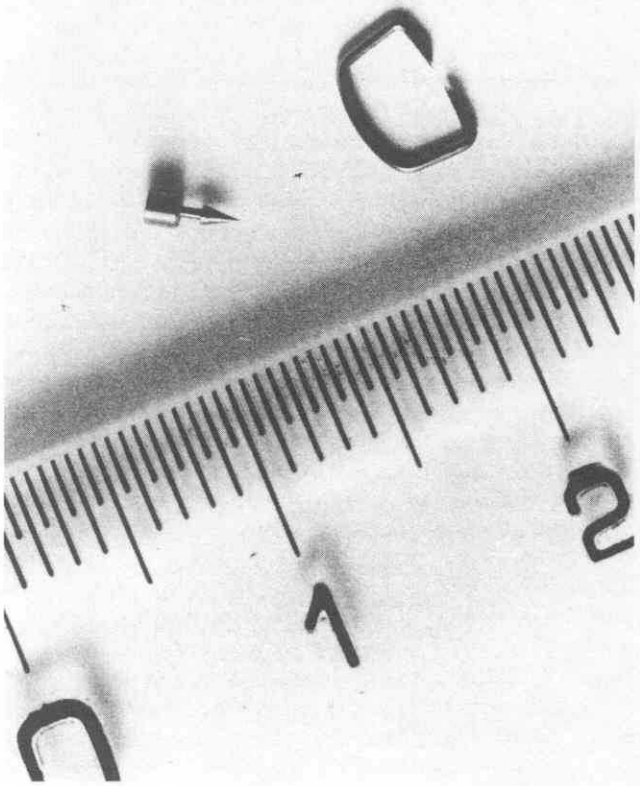

Figure 1. Epidermal devices: epidermal burin (left) and surgical staple (right).

information on the clinical evolution of the patient, or to data obtained throughout the trial.

A single physician (FMK) treated each patient once. Epidermal devices used for the neuroreflexotherapeutic procedure included surgical staples in the back and epidermal burins in the ear, as described in a previous study.[26] Surgical staples are commonly used in surgery for skin suture. Epidermal burins are small metallic punches placed less than 2 mm below the surface of the skin (Figure 1). Trigger points within the dermatomes involved in each particular case were sought. Trigger points were defined as either locations with local tenderness on palpation or the location where direct pressure evoked the patient's local or referred pain.[26,40] Auricular tender areas corresponding to the dermatomes involved in each particular case were identified according to specific anatomic references (available from the authors on request).[25,29] In patients assigned to the intervention group, epidermal devices were implanted into the skin directly over the identified trigger points and the auricular tender areas. Surgical closure staples were implanted before epidermal burins. Between nine and 53 staples and between four and 12 burins were inserted. In patients assigned to the control group, cutaneous territories were identified by the same procedure, and staples and burins were inserted in the same order. The same number of epidermal devices as that used in the previous patient assigned to the intervention group was implanted within a 5-cm radius of the target zones (Figures 2–7). The minimum limit was defined according to results of

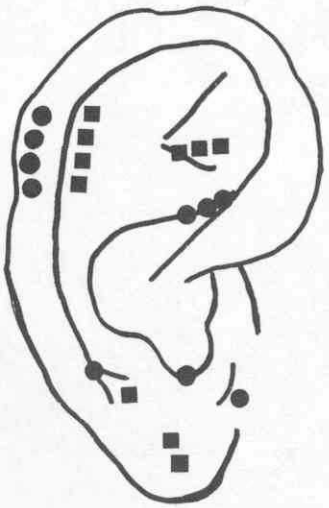

Figure 2. Auricular zones stimulated in the control group (■) and in the intervention group (●).

studies in which size of receptor fields of lumbar dermatomes has been defined.[13,49] These limits were established to ensure that patients could not tell if they were in the treatment group or in the control group.

Outcome Assessment. The clinical condition of each patient was evaluated during the 5 minutes immediately before intervention (preintervention assessment), during the 5 minutes immediately after intervention (first follow-up assessment), and 45 days later (second follow-up assessment).

The preintervention assessment was carried out by one of

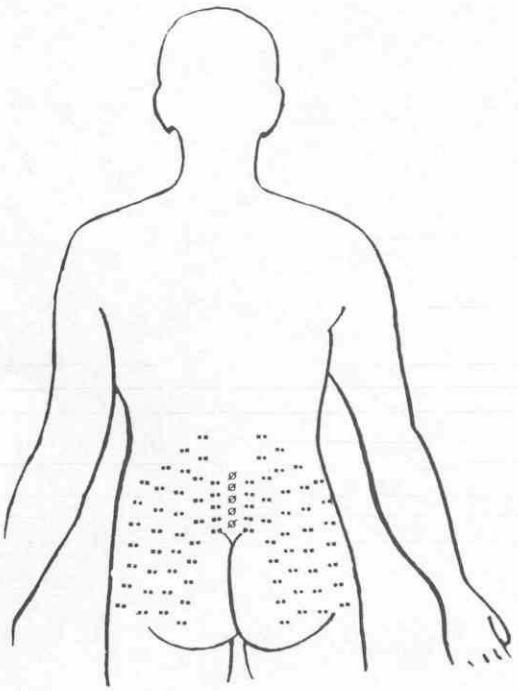

Figure 3. Dermatomic zones stimulated in the control group (■) and the intervention group (●), and zones stimulated in both groups (ϕ) in the control group, in nonindicated cases.

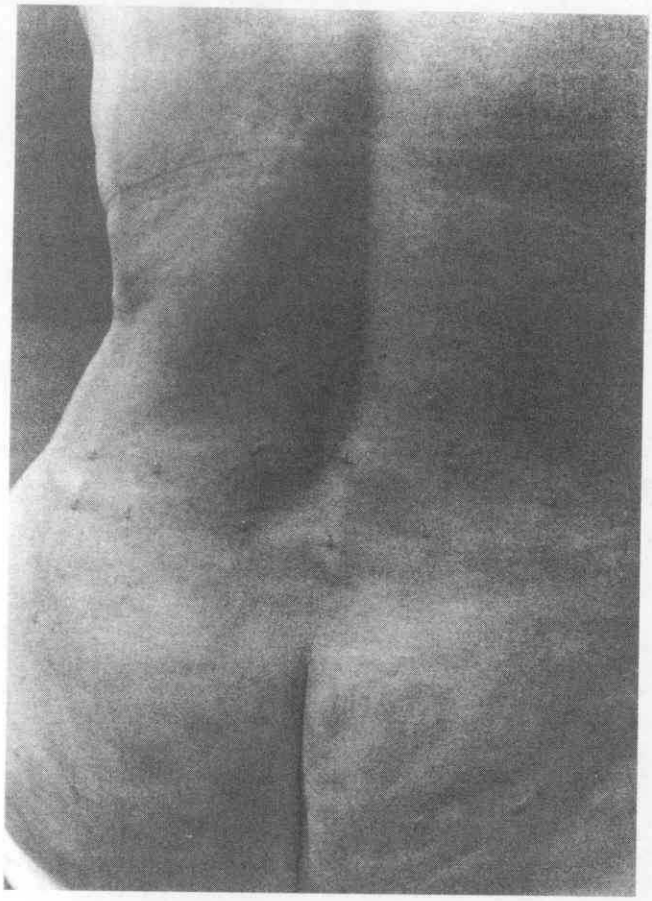

Figure 4. A patient in the treatment group.

the seven recruiting physicians, who did not see the patient again for the duration of the trial. The following variables were recorded: sex; age (expressed in years to one decimal); sociocultural level (scored as 1 = no studies, 2 = primary education, 3 = secondary education, 4 = higher education); job situation (classified as "unemployed," "total permanent disability," "temporary disability," "employed," "retired," and "others"); receiving disability compensation (yes/no); regular intense physical activity at work or during leisure time (yes/no); diameter of right wrist on right-handed individuals or left wrist on left-handed individuals (cm); height (cm); weight (kg); duration of symptoms (years); duration of the current episode of low back pain (weeks); intensity of spontaneous back pain (100-mm visual analog scale); intensity of referred pain (100 mm visual analog scale); intensity of pain on movement (anterior flexion, flexion to the left side and to the right side, assessed separately with 100 mm visual analog scale, and calculating the arithmetic mean for these three movements); distance (cm) from the tip of the fingers to the floor when standing upright and when bent forward (measurements were repeated three times and in each case the shortest distance was recorded); physician's suspicions of patient's simulation of symptoms (yes/no); pharmacologic treatment (NSAID, steroids, analgesics, muscle relaxants, vitamins) recorded as 1 = none, 2 = occasional, 3 = prescribed doses, 4 = greater than prescribed doses; and the effect of low back pain on the quality of life (scoring on a scale from 1 to 5, from best to worst, the items on the COOP chart: daily activities, social activities, pain during the past 6 weeks, change in condition, overall health, and quality of life).[22,38] The COOP chart items "impaired psychological state" and "social integration" were used to assess comparability between control and treatment groups as well as to exclude patients because of "marked emotional instability."

At each of the two follow-up assessments, patients in both groups underwent two separate evaluations. Each patient was examined separately by two of three physicians who were unaware of the participant's treatment status. The three physicians responsible for the follow-up assessments were fellows in the departments of rheumatology of the participating hospitals who agreed to participate in a trial on low back pain in which the efficacy of a procedure that involved the insertion of epidermal devices in the back and into the pinna was being evaluated. They had no connection with the research team and were not familiarized with the neuroreflexotherapy intervention at all. The rationale of the placement of burins and surgical staples was, therefore, completely unknown to them. All patients were evaluated with the torso covered. A skull cap was not used.

At the first follow-up assessment, the following variables were evaluated: intensity of spontaneous low back pain (100-mm visual analog scale), intensity of referred pain (100-mm visual analog scale), intensity of pain on movement (anterior flexion, flexion to the left side and to the right side, assessed separately with a 100-mm visual analog scale, and calculating the arithmetic mean for these three movements),

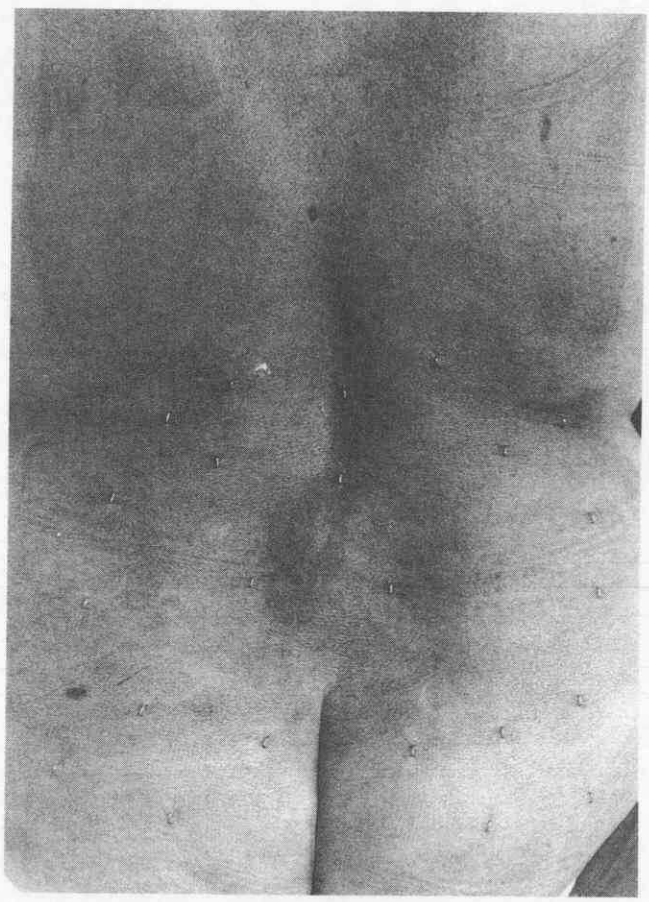

Figure 5. A patient in the placebo group.

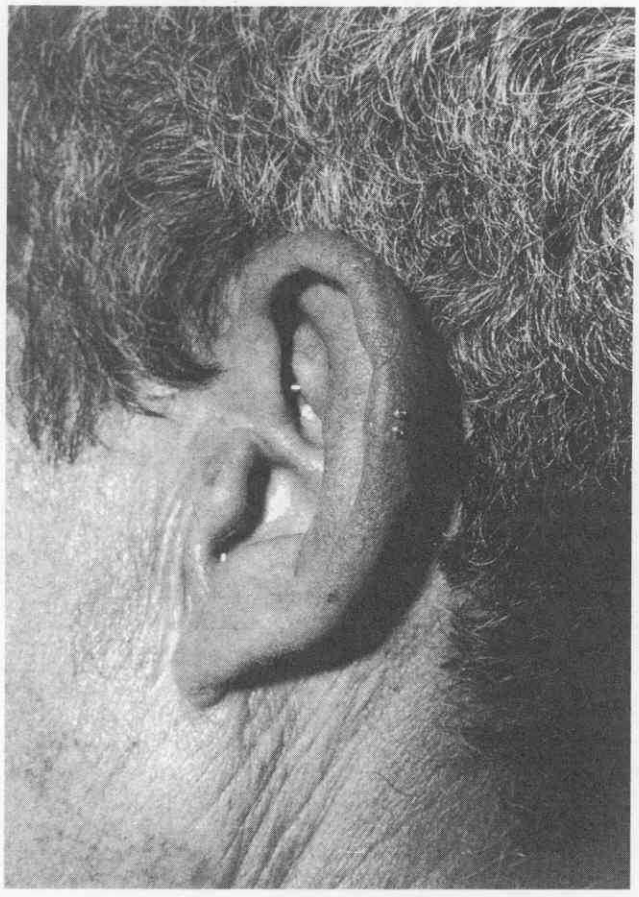

Figure 6. A patient in the treatment group.

and bending forward (distance [cm] from the tip of the fingers to the floor when standing upright minus distance from the tip of the fingers to the floor when bent forward with the arms in a vertical position; forward bending was repeated three times, and the shortest distance was recorded). In addition to these variables, changes in medication and the effect of back pain on the patient's quality of life were evaluated at the second follow-up assessment (45 days after treatment). Side-effects attributed to the intervention were solicited from the patient. Any incident reported during the execution of the trial also was recorded. All conversations between patients and staff were recorded and monitored by a physician independent to the study as an additional means of ensuring that patients did not know to which group they had been assigned.

Analysis. The size of the study population was established at 31 patients per group according to Machin and Campbell tables,[33] assuming a two-point difference in the visual analog scale in the improvement of pain-related variables between both groups and a variance of 12. A type I error of 0.05 and a type II error of 0.10 were accepted. The study population was increased to 78 participants to compensate for an anticipated 25% loss of patients for follow-up assessment.

Data were entered in a database that was inaccessible to all physicians involved in the study. Data were entered by assistants who were unaware of the patient's treatment status. Scores obtained at the follow-up assessments were subtracted from those at the preintervention evaluation. Raw analyses were carried out using the Student's t test, the chi-square (χ^2) test, and the Wilcoxon test. Multiple linear regression models were used to assess the association between the independent variable "group" (intervention/control) and the improvement of pain-related variables (low back pain, referred pain, and pain on movement), after adjusting for possible confounding variables.[23] An analysis of concordance between the two physicians who were responsible for the two follow-up assessments was carried out for the variables low back pain, referred pain, and pain on movement by means of the generalization of M coefficients for several observers with incomplete design using biquadratic weighted Kappa and standard errors estimated by the "jackknife" method.[14,30,45] Because M values corresponding to the first and second follow-up assessments carried out by different physicians were ≥ 0.80 for low back pain (0.93 ± 0.02 and 0.85 ± 0.06, respectively), referred pain (0.81 ± 0.07 and 0.80 ± 0.06, respectively), and pain on movement (0.92 ± 0.03 and 0.88 ± 0.004, respectively), the mean value for these variables was calculated.[31] Consequently, three linear regression models were obtained for each of the two follow-up assessments.

Variables with different values in the treatment and control groups at the preintervention evaluation were included in the models, as well as those that could exert a confounding effect on neuroreflexotherapy intervention, such as age; sex; fat coefficient (calculated from the diameter of the wrist of the dom-

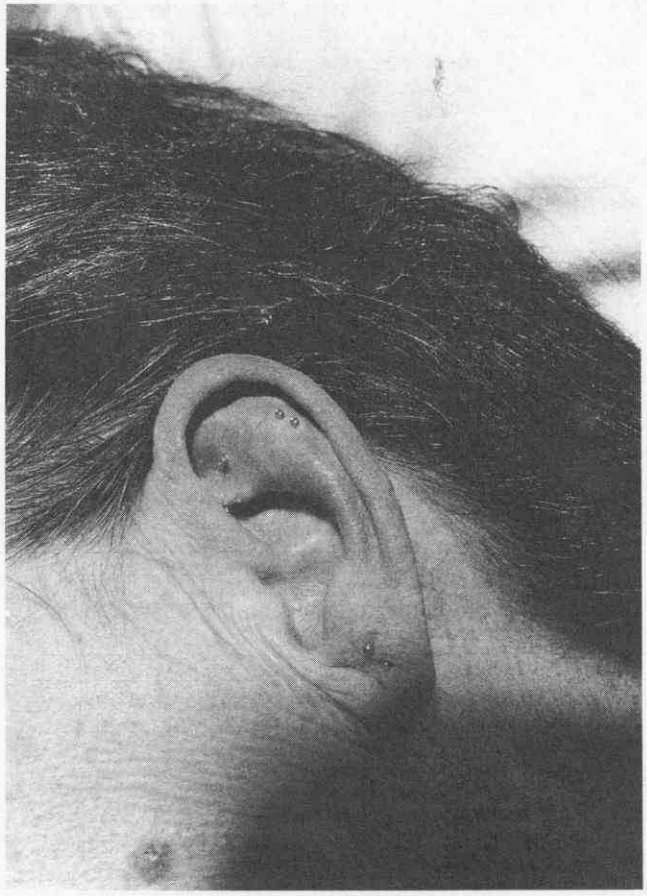

Figure 7. A patient in the placebo group.

Table 1. Distribution of Continuous Variables in Patients Assigned to the Intervention and Control Groups at the Preintervention Assessment

	No.	Control Group [mean ± SD (range)]	No.	Intervention Group [mean ± SD (range)]	*t* Test Value
Age (yr)	37	50.3 ± 8.7 (27 to 63)	41	51.7 ± 8.2 (34 to 65)	0.481
Duration of symptoms (yr)	37	8.9 ± 6.7 (3 to 40)	41	9.2 ± 5.5 (3 to 26)	0.827
Duration of current episode (wk)	36	62.9 ± 98.1 (4 to 480)	40	86.0 ± 122.5 (10 to 520)	0.370
Wrist diameter (cm)	35	16.7 ± 1.26 (13 to 20)	40	17.4 ± 1.28 (15 to 20)	0.008
Height (cm)	37	159.7 ± 8.5 (144 to 177)	38	161.0 ± 8.42 (145 to 177)	0.518
Weight (kg)	37	68.1 ± 10.2 (51 to 86)	40	72.1 ± 9.8 (55 to 96)	0.087
Low back pain*	37	5.6 ± 1.9 (0 to 9)	41	6.2 ± 1.7 (3 to 9)	0.175
Referred pain*	36	5.1 ± 2.9 (0 to 10)	41	5.3 ± 2.6 (0 to 10)	0.652
Pain on movement*	37	5.1 ± 2.6 (0 to 10)	41	5.5 ± 2.4 (1 to 10)	0.476
Anterior flexion	36	5.3 ± 3.0 (0 to 10)	41	5.7 ± 2.6 (1 to 10)	0.533
Flexion to the right	36	5.1 ± 3.0 (0 to 10)	41	5.4 ± 2.7 (0 to 10)	0.649
Flexion to the left	37	5.0 ± 2.7 (0 to 10)	41	5.5 ± 2.6 (1 to 10)	0.438
Forward bend (cm)	29	59.3 ± 14.8 (11 to 87)	27	61.3 ± 4.7 (48 to 68)	0.501
Physical condition†	37	3.6 ± 1.0 (1 to 5)	41	3.3 ± 1.0 (1 to 5)	0.279
Daily activities†	37	3.4 ± 1.1 (1 to 5)	41	3.5 ± 0.8 (1 to 5)	0.890
Social activities†	37	2.4 ± 1.3 (1 to 5)	41	2.5 ± 1.2 (1 to 5)	0.778
Pain during the past 6 weeks†	37	4.3 ± 0.6 (3 to 5)	41	4.3 ± 0.7 (2 to 5)	0.976
Change in condition†	37	3.1 ± 0.7 (2 to 5)	41	3.1 ± 0.6 (2 to 4)	0.689
Overall health†	37	3.9 ± 0.7 (3 to 5)	41	3.8 ± 0.7 (3 to 5)	0.551
Quality of life†	37	2.9 ± 0.8 (2 to 5)	41	2.7 ± 0.7 (2 to 5)	0.104

* 100 mm visual analog scale.
† COOP charts (scoring on a scale of 1 to 5).

inant laterality, height, weight, and sex); receiving disability compensation; regular intense physical activity; intensity of low back pain, referred pain, and pain on movement before intervention; duration of symptoms; duration of the current episode; pharmacologic treatment (recodified as yes/no); physical condition; psychological state; and quality of life.[41]

For each regression model, pain improvement (defined as scores before intervention minus scores in the corresponding assessment) was taken as the dependent variable. The collinearity of the maximal model was evaluated using the criteria proposed by Belsley.[4] A confounding variable was considered when its removal from the model caused a change in the coefficient of the variable "group" $\geq$ 10% of the value of this coefficient in the maximal model. A backward elimination strategy was used, so that the variable with the highest *P* value was excluded at each step.

The results presented in this report have been restricted to data analysis by treatment assigned to all 78 participants (analysis by intention to treat). Given that 16 patients who already had been randomized and treated were excluded later by consensus of recruiting physicians, a reanalysis without these patients also was performed (data not shown, commented on in the discussion).

■ Results

Of 141 preselected patients, 63 were excluded for the following reasons: refusal to take part in the study (24); marked emotional instability (12); no symptoms of back pain at the time of inclusion (8); symptoms of less than 3 years duration (7); pain attributable to other conditions under management with NSAID or analgesics (4); treatment with psychoactive drugs (3); age over 60 (1); spondylolysis (1); spinal stenosis confirmed by computed tomography (CT) scan (1); ischemic heart disease (1); and arrhythmia (1).

The study population consisted of 78 patients (30 men and 48 women), 41 of whom were assigned to the intervention group and 37 to the control group. Two patients, one from each group, failed to complete the trial. Mean data (± SD) for continuous and categorical variables at the preintervention evaluation in neuroreflexotherapy-treated patients and controls are shown in Tables 1 and 2. There were no statistically significant differences at preintervention assessment between patients in both groups except for wrist diameter and treatment with NSAID. In both evaluations carried out by different physicians at the first follow-up assessment (*i.e.*, 5 minutes postintervention), patients in the intervention group showed a statistically significant (Wilcoxon test, $P < 0.04$) improvement of all pain-related variables as compared with patients in the control group (Table 3). These improvements also were observed in both evaluations during the second follow-up assessment (Wilcoxon test, $P < 0.03$; Table 4). In addition, statistically significant differences (Wilcoxon test, $P < 0.03$) were found at the second evaluation in forward bending, pain during the last 6 weeks, and changes in quality of life. Regarding changes in medication, statistically significant differences between patients in the intervention groups and those in the control group were not found.

Results of the three regression models at each follow-up assessment are shown in Table 5. Collinearity was not present in maximal models. In this table, results range from −5, or maximum worsening possible, to 5, or

Table 2. Distribution of Categorical Variables in Patients Assigned to the Intervention and Control Groups at the Preintervention Assessment

	Control Group	Intervention Group	χ^2 p Value
Sex (F/M)	25/12	23/18	0.420
Sociocultural level (1–2/3–4)*	28/7	34/7	0.795
Job situation			
Unemployed	1	1	
Total permanent disability	4	3	0.550
Temporary disability	7	16	
Employed	17	15	
Retired	2	2	
Other	6	4	
Receiving disability compensation (yes/no)	25/12	20/21	0.148
Intense physical activity (yes/no)	15/19	20/15	0.400
Suspicion of simulation			
Yes	1	1	0.735
No	34	34	
Questionable	2	4	
Pharmacologic treatment			
Nonsteroidal anti-inflammatory drugs (1–2/3–4)†	25/12	37/4	0.028
Steroids (1–2/3–4)†	36/1	41/0	0.474
Analgesics (1–2/3–4)†	33/4	38/3	0.702
Muscle relaxants (1–2/3–4)†	32/5	40/1	0.096
Vitamins, gangliosides (1–2/3–4)†	35/2	41/0	0.222
Psychological condition (1–2/3–4)‡	16/21	26/15	0.119
Social integration (1–2/3–4)‡	33/4	35/6	0.740

* 1 = no studies; 2 = primary education; 3 = secondary education; 4 = higher education.
† 1 = none; 2 = occasional; 3 = prescribed doses; 4 = greater than prescribed doses.
‡ Points in the COOP chart.

maximum improvement possible (preintervention mean values for pain-related variables ranged between 5 and 6). Improvements in pain-related variables between 1.26 and 2.59, attributable to the effect of neuroreflexotherapy after adjusting for other factors, should be interpreted according to this range. This result indicates the extent of the effect exerted by neuroreflexotherapy on pain-related variables.

The same results were found after reanalyzing the data without the 16 patients excluded by recruiting phy-

Table 3. Results of Two Separate Assessments of Pain-Related Variables and Mobility at the First Follow-up Control During the 5 min Immediately After Intervention: Mean Differences Between Pretreatment and Posttreatment Measurements

Improvement of	No.	Control Group [mean ± SD (range)]	No.	Intervention Group [mean ± SD (range)]	p Value
Low back pain (VAS)					
FA	36	1.36 ± 2.65 (−4 to 6)	34	3.79 ± 2.41 (−2 to 9)	<0.001
SA	35	1.00 ± 2.88 (−4 to 7)	35	3.49 ± 2.50 (−2 to 9)	<0.001
Referred pain (VAS)					
FA	35	1.17 ± 3.98 (−9 to 8)	34	2.88 ± 2.43 (−2 to 8)	0.036
SA	35	0.54 ± 3.83 (−9 to 8)	35	2.34 ± 2.81 (−2 to 8)	0.028
Pain on movement (VAS)					
FA	37	0.81 ± 1.79 (−2 to 5)	40	2.30 ± 2.79 (−3 to 9)	<0.001
SA	37	0.41 ± 1.79 (−2 to 5)	40	3.10 ± 2.95 (−3 to 9)	<0.001
Anterior flexion (VAS)					
FA	36	1.00 ± 2.89 (−5 to 9)	34	2.68 ± 3.55 (−7 to 10)	0.033
SA	35	0.49 ± 2.93 (−4 to 9)	35	2.80 ± 3.25 (−3 to 10)	0.033
Flexion to the right (VAS)					
FA	36	0.78 ± 2.43 (−4 to 9)	34	2.85 ± 2.95 (−2 to 10)	0.002
SA	36	0.19 ± 1.79 (−4 to 5)	35	2.74 ± 2.91 (−3 to 10)	<0.001
Flexion to the left (VAS)					
FA	36	0.47 ± 1.93 (−3 to 7)	35	3.11 ± 2.72 (−2 to 9)	<0.001
SA	36	0.14 ± 2.30 (−7 to 7)	35	2.57 ± 3.08 (−4 to 9)	<0.001
Forward bend (cm)					
FA	37	−6.38 ± 9.10 (−25 to 10)	40	−3.28 ± 9.44 (−23 to 21)	0.147
SA	36	−8.33 ± 10.77 (−29 to 13)	40	−4.90 ± 11.98 (−31 to 22)	0.195

VAS = points in the visual analog scale; FA = first assessment; SA = second assessment.

Table 4. Results of Two Separate Assessments of Pain-Related Variables, Mobility, and Other Parameters at the Second Follow-up Control 45 Days After Intervention: Mean Differences Between Pretreatment and Posttreatment Measurements

Improvement of	No.	Control Group [mean ± SD (range)]	No.	Intervention Group [mean ± SD (range)]	p Value
Low back pain (VAS)					
FA	35	0.34 ± 2.98 (−6 to 5)	32	3.09 ± 2.56 (−2 to 9)	<0.001
SA	33	0.91 ± 3.23 (−5 to 6)	35	3.31 ± 2.62 (−1 to 9)	<0.001
Referred pain (VAS)					
FA	33	−0.61 ± 4.17 (−10 to 6)	34	2.03 ± 2.49 (−2 to 8)	0.003
SA	34	−0.65 ± 4.31 (−10 to 7)	33	2.00 ± 2.62 (−2. to 9)	0.004
Pain on movement (VAS)					
FA	36	0.03 ± 3.50 (−7 to 7)	38	2.87 ± 3.01 (−3 to 9)	<0.001
SA	36	0.44 ± 3.37 (−7 to 6)	38	2.95 ± 3.20 (−3 to 9)	0.002
Anterior flexion (VAS)					
FA	34	−0.09 ± 3.86 (−9 to 7)	34	2.53 ± 3.07 (−3 to 9)	0.033
SA	33	0.52 ± 3.35 (−9 to 6)	34	2.50 ± 3.48 (−6 to 9)	0.021
Flexion to the right (VAS)					
FA	35	−0.09 ± 4.16 (−10 to 8)	32	2.28 ± 3.20 (−2 to 8)	0.012
SA	35	0.06 ± 4.03 (−10 to 6)	35	2.51 ± 3.62 (−6 to 9)	0.009
Flexion to the left (VAS)					
FA	35	0.14 ± 3.76 (−10 to 7)	32	2.25 ± 2.79 (−3 to 9)	0.012
SA	34	0.38 ± 3.92 (−10 to 8)	32	2.53 ± 3.04 (−3 to 9)	0.016
Forward bend (cm)					
FA	34	−5.38 ± 12.42 (−44 to 14)	38	−0.82 ± 10.56 (−31 to 14)	0.096
SA	34	−9.88 ± 14.11 (−57 to 15)	38	−1.89 ± 13.54 (−45 to 36)	0.017
Physical condition (COOP)*					
FA	36	0.44 ± 1.23 (−3 to 3)	38	0.27 ± 1.26 (−2 to 3)	0.164
SA					
Daily activities (COOP)					
FA	36	0.61 ± 1.38 (−2 to 3)	37	0.81 ± 1.35 (−2 to 4)	0.534
SA	36	0.69 ± 1.26 (−2 to 3)	38	0.82 ± 1.27 (−2 to 4)	0.681
Social activities (COOP)					
FA	36	0.08 ± 1.50 (−3 to 3)	38	0.26 ± 1.39 (−3 to 4)	0.594
SA	36	0.11 ± 1.37 (−3 to 3)	38	0.42 ± 3.20 (−3 to 3)	0.307
Pain in the past 6 weeks (COOP)					
FA	36	0.56 ± 1.18 (−1 to 4)	38	1.13 ± 1.46 (−1 to 4)	0.067
SA	36	0.72 ± 1.11 (−1 to 4)	38	1.39 ± 1.39 (−2 to 4)	0.025
Change in quality of life (COOP)					
FA	36	2.83 ± 0.85 (1 to 5)	38	2.45 ± 1.11 (1 to 5)	0.095
SA	36	2.72 ± 0.91 (1 to 5)	38	2.21 ± 0.04 (1 to 5)	0.028
Overall health (COOP)					
FA	36	0.25 ± 0.87 (−1 to 2)	38	0.44 ± 0.89 (−1 to 3)	0.340
SA	36	0.36 ± 0.76 (−1 to 2)	38	0.61 ± 1.05 (−1 to 3)	0.256
Overall quality of life (COOP)					
FA	36	0.28 ± 0.85 (−2 to 2)	38	0.16 ± 0.97 (−2 to 2)	0.542
SA	36	0.17 ± 0.81 (−2 to 2)	38	0.18 ± 1.01 (−2 to 3)	0.935

* Points in the COOP chart items (scoring on a scale of 1 to 5).
FA = first assessment; SA = second assessment; VAS = points in the visual analog scale.

sicians, although the degree of statistical significance for the differences between treatment and control groups in the univariate analysis was even higher. Linear regression models also showed a higher pain improvement attributable to the effect of neuroreflexotherapy intervention. The majority of these patients (nine assigned to the intervention group and seven to the control group) were excluded because of questionable lumbar pain at the time of assessment, pain related to other conditions, and use of medications for other disorders.

No clinically relevant side-effects were observed after neuroreflexotherapy. Ten patients (four from the control group and six from the intervention group) reported transient cutaneous discomfort—itching, irritation, and redness—after insertion of surgical staples. Limited dermal infection at the site of some of the staples occurred in two patients (one from each group) and was treated successfully with an antibiotic cream in less than 48 hours. None of the patients required extraction of the staples before the last follow-up assessment.

■ Discussion

The present results demonstrate the efficacy of neuroreflexotherapy, compared with that of a sham procedure, to improve low back pain over a 6-week period in patients with chronic low back pain who were recruited from a hospital setting. A statistically significant and clinically noticeable improvement in back pain, referred

Table 5. Pain Improvement Estimated by the Regression Models

	Adjusted by	Pain Improvement* (95% CI)	p Variable	*F* Model
First follow-up control				
Back pain		2.47 (1.27 to 3.38)	0.00021	16.150
Referred pain	Impaired psychological state	1.78 (0.17 to 3.39)	0.03203	2.567
Pain on movement		2.59 (1.54 to 3.64)	0.00001	23.450
Second follow-up control				
Back pain	Initial pain Impact on physical condition	2.34 (1.09 to 3.59)	0.00061	14.432
Referred pain	Initial pain Nonsteroidal anti-inflammatory agents Impact on physical condition Duration of symptoms Duration of current episode Impaired psychological state	1.26 (0.14 to 2.38)	0.03056	12.408
Pain on movement	Initial pain	2.27 (1.05 to 3.50)	0.00063	24.950

* Mean differences between pretreatment and posttreatment measurements. Points in the visual analog scale range from −5 (maximum worsening possible) to 5 (maximum improvement possible).

pain, and pain on movement was experienced immediately after the intervention. This improvement persisted until the end of the trial, 45 days later. These results are in agreement with those previously reported.[26] Given that main outcome variables were those related to pain, the sample size was calculated according to those variables, and regression models were designed to assess pain improvement. The clinical evolution of forward bending, which is the most impaired movement in patients with low back pain, also was assessed in both groups.[42,43] In addition, COOP chart items were used to examine other potential general health changes after neuroreflexotherapy. Only the degree of pain experienced during the study period and the change noted in patients' quality of life compared with that of the period before treatment showed a statistically significant improvement in the treatment group at the follow-up assessment 45 days after intervention. Because the COOP chart is an instrument for evaluating general function and quality of life and has not been validated to assess the impact of low back pain, the absence of statistically significant differences in the other items between patients in the intervention group and control patients may be explained by the small sample size, by a lack of effect of neuroreflexotherapy on these items, or by an insufficient sensitivity of the chart to detect changes induced by the improvement of low back pain.[38]

At the first follow-up evaluation immediately after intervention, the degree of forward bending movement was reduced in both groups, although to a lesser extent in the intervention group. At the second follow-up control 45 days later, however, there was a partial restoration of this movement in both groups. The difference in the clinical course of this movement in both groups was statistically significant at the second assessment. Nevertheless, there was a significant reduction of pain when carrying out this movement in patients in the intervention group at both follow-up examinations. This would suggest that limitation of this movement could have occurred because the skin tightened after insertion of surgical staples, which would account for improvement in mobility at the last follow-up assessment.

No statistically significant differences were observed in either group concerning the consumption of pain-relieving drugs after intervention, probably because their use before intervention was not common among participants in the trial. This finding may reflect the tendency among patients experiencing chronic disorders to discontinue medication and the reluctance of Spanish specialists to prescribe multiple medications for chronic low back pain. This assumption may explain the statistically significant difference in the consumption of drugs observed in a previous study, in which patients who attended primary health care centers and received more medication before treatment were included.[26]

Control and treatment groups were homogeneous in all baseline variables studied except for two: the diameter of the wrist and the use of NSAIDs, although NSAIDs were prescribed to only 16 patients among the 78 participants in the study (Table 2). Results of multivariate analysis, however, showed that none of these factors had a confounding effect on the results of neuroreflexotherapy.

Although 16 patients who fulfilled exclusion criteria were identified, analysis by intention to treat revealed clinically relevant and statistically significant results. When these 16 patients were excluded, results continued to show the same effect for the same variables, although with a higher intensity and a greater degree of statistical significance.

The preservation of the blind design of the study is a key factor in ensuring the validity of results in a clinical trial. The present study was designed and conducted to prevent the eventual bias that would have resulted from the magnitude and the speed of the pain-relieving effect previously demonstrated through the use of neuroreflexotherapy.[22] This was the reason why physicians who assessed the patient's condition during the preinterven-

tion evaluation were different from the physicians who assessed the patient's condition during the two follow-up examinations. The high degree of concordance between both physicians evaluating pain-related variables at each assessment indicates the consistency of the visual analog scale and their objective interpretation of its results.[22]

Because an etiologic diagnosis is not possible in most patients with low back pain, the study population was defined largely on the basis of the patients' medical histories and clinical data. For this reason and because of feasibility, inclusion criteria were based on the diagnostic protocol used in the hospital departments participating in the trial and did not require the execution of specific diagnostic procedures, such as CT scan, magnetic resonance imaging, myelogram, or bone densitometry.[10,44,52] It is thus possible that patients with disorders that can only be documented using these diagnostic tools may have been unwittingly included in the study sample. Nevertheless, this fact does not affect the validity of results because randomization would have counteracted the potential confounding of factors not measured in this study.

At present, the duration of pain-relieving effects of neuroreflexotherapy beyond 45 days is unknown. The selection of time points for assessing the patients' condition was based on a previous clinical trial in which clinical evaluation was carried out immediately before and after neuroreflexotherapy and 30 days later.[26] It was considered appropriate to maintain the first two assessments, so that confirmation of the rapid appearance of the intervention-related effects would be useful to formulate a hypothesis on the mechanism of action of neuroreflexotherapy. To assess the persistence of pain improvement beyond 30 days, the last follow-up assessment was delayed to 45 days. Although the period of a month and a half is not sufficient for assessing the effect of neuroreflexotherapy on backache relapses, a 45-day interval was considered adequate for assessing the therapeutic effect of the intervention on the current episode.

Further studies are essential to confirm the present results in a larger sample size and to assess the duration of the effect after 45 days. Although some general health-related variables of the COOP chart did not change after treatment, the results of this study show that neuroreflexotherapy intervention can help to reduce the patient's disability associated with exacerbation and perpetuation of chronic low back pain. Neuroreflexotherapy appears to be a simple and effective treatment for rapid pain relief of the current episode in patients with chronic low back pain in whom medications are not effective.

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Point of View

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Kovacs et al showed in a prospective, randomized, controlled trial (RCT) that epidermal devices placed in specific points in the pinna of the ear and skin of the back resulted in a statistically significant reduction in low back pain (LBP) for a period of as long as 45 days. Although the study was reasonably well performed, I found the results difficult to believe. Such dramatic and sustained improvement with a single treatment is at odds with my clinical experience and at odds with the results of prior research on any treatment for patients with LBP. But the results showed a statistically significant difference in pain between the treatment group and control group.

Therein lies the dilemma. Statistics are numbers, not patients. Statistical probability is just that, probability. Statistical proof does not mean clinical truth.

Should a prestigious journal such as *Spine* publish an article that, although well done on paper, seems at odds with clinical experience and perhaps common sense? My answer is yes.

The study of the spine has lagged behind other medical disciplines. We have been lax in testing our hypotheses with RCT, and therefore the clinical study of the spine involves much controversy. We cannot penalize the authors because we have difficulty believing that their results will prove to be clinically useful or stand the test of further RCT. They did what we would ask, a RCT with adequate demographics and adequate description of methods so that others can retest the hypothesis. This is what scientific methodology is about.

If others retest the hypothesis and show that epidermal devices are not efficacious, these findings also need to be published. Perhaps researchers hesitate to prepare a manuscript with negative outcome. It takes a great deal of work. Why do it when studies with negative outcomes do not seem to get published or noticed? Journals must be willing to publish negative studies if these studies are done well.

Medical care changes. Some old treatments fall by the way side, but others remain. Some new and effective treatments appear, and others do not stand up under close scrutiny. That is the way of science and the way of change.

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