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FINAL REPORT
PILOT TRIAL: ELECTROTHERAPY WITH GAENESY ALG 400 IN THE TREATMENT OF CHRONIC PAIN
• CHRONIC LUMBAGO
• CHRONIC CERVICAL PAIN
• MUSCULOTENSIVE HEADACHE

1. INCLUSION AND EXCLUSION CRITERIA

The patients taken into consideration for this trial were selected after specialist assessment (orthopaedic, physiotherapy, neurological), in order to make a correct nosological diagnosis.

Adult patients were included. Excluded were patients with cancer, those with pacemakers, pregnant women and patients with psychoses or those in any way unable to complete the questionnaires correctly.

In accordance with current regulations, all patients included gave their informed consent in writing to the treatment, after receiving appropriate information, as stipulated by the protocol referred to. The patients also signed the personal data processing consent form for research purposes.

Specific inclusion criteria:

a. chronic lumbago: chronic lumbar pain (> 12 weeks) with no radicular element, pharmacological washout for at least 24 hours.
b. chronic cervical pain: chronic cervical pain (> weeks) with no radicular element, therapeutic washout for at least 24 hours.
c. musculotensive headache: verified according to IHS (International Headache Society) criteria.

2. TRIAL PLAN AND METHOD

This is a perspective observational trial on the results of treatment with microcurrents, comprising also a non-randomised control group on conventional pharmacological treatment.
Patients who, in the observation period (12 months), attended the aforesaid hospital (pain treatment centre, E.O. Ospedali Galliera) were invited to take part in the Gaenesy trial (please refer to the individual protocols attached). Although the initial protocol envisaged randomisation, it was decided to change the protocol, while it was in progress, into a non-randomised perspective observational one, because often the patients who came to the pain treatment centre had previous experiences of pharmacological treatment without apparent results and therefore refused any further pharmacological proposal. Each individual protocol envisaged a minimum enrolment of 30 patients, divided into 2 GROUPS.

The assessment protocols per individual trial are summarised below:

1. Chronic Lumbago:

- on admission:
    a. completion of the pain form showing the area concerned, completion of the case history form with particular regard to the specific pharmacological treatment and any physiotherapy treatment.
    b. completion of visual analogue scale (VAS) indicating the 4 standard pain parameters: What is your pain now? What is your pain on average? What is your minimum pain level? What is your maximum pain level?
    c. Completion of a questionnaire to assess the level of disability (Roland Morris questionnaire).

- during treatment: a monitoring form was completed based on the VAS system and its main disability indices (effect of pain on sleep and normal activities (see annex).
- at the end of treatment a summary form was completed indicating the current pain level (VAS scale): the percentage of improvement in the level of disability, the degree of satisfaction with the treatment received, any complications and side effects.

2. Chronic Cervical Pain:

- on admission:
    a. completion of the pain form showing the area concerned, completion of the case history form with particular regard to the specific pharmacological treatment and any physiotherapy treatment.
    b. completion of visual analogue scale (VAS) indicating the 4 standard pain parameters: What is your pain now? What is your pain on average? What is your minimum pain level? What is your maximum pain level?
    c. Completion of a questionnaire to assess the level of disability (Neck disability index).

- during treatment: a monitoring form was completed based on the VAS system and its main disability indices (effect of pain on sleep and normal activities (see annex).
- at the end of treatment a summary form was completed indicating the current pain level (VAS scale): the percentage of improvement in the level of disability, the degree of satisfaction with the treatment received, any complications and side effects.

3. Musculotensive Headache:

- on admission:
    a. completion of the pain form showing the area concerned, completion of the case history form with particular regard to the specific pharmacological treatment and any physiotherapy treatment.
    b. completion of visual analogue scale (VAS) indicating the 4 standard pain parameters: What is your pain now? What is your pain on average? What is your minimum pain level? What is your maximum pain level?
    c. Completion of a questionnaire to assess the level of disability (Headache disability index).

- during treatment: a monitoring form was completed (headache diary) based on the VAS system and its main disability indices (effect of pain on sleep and normal activities (see annex).

- at the end of treatment a summary form was completed indicating the current pain level (VAS scale): the percentage of improvement in the level of disability, the degree of satisfaction with the treatment received, any complications and side effects.

NB: in all the protocols a form was completed showing the positioning of the electrodes, the intensity of the pain before treatment, the intensity of the pain at the end of treatment; length of the treatment.

- Protocol of treatment with GAENESY ALG 400

The treatment protocol was standardised as follows: (1) the patient was asked, before starting treatment, to indicate the site of the pain; (2) then he/she was asked to quantify the pain by means of the VAS scale; (3) when the patient reports pain in several sites, the site of maximum painfulness is assessed; (4) the patient then undergoes a quick objective examination, with particular regard to joint motility in the area concerned; (5) the rods/electrodes are then positioned in such a way as to make the point of maximum painfulness pass along an imaginary line, that unites the two rods; (6) since the human body is three-dimensional and the current passage inside it is related to tissue impedance, the maniples are moved on the three planes; (7) the patient is reassessed when the correction parameters indicated by the machine show a significant improvement (> 75%); (8) the patient is treated with the aim of obtaining a reduction in the pain symptom of at least 50%; (9) the patient is considered not to respond unless a significant reduction (> 25%) in the pain after eight treatment cycles is obtained.

- Standard treatment protocol

1. Lumbago and chronic cervical pain: the patients were prescribed TRAMADOL, in prolonged-release tablet form, at full doses (100 mg every 12 hours). If the pain relief was insufficient, the patient was allowed to increase the dose to 200 mg twice a day.
The patients who did not respond underwent peridural analgesic treatment (after having been removed from the trial) or another treatment at the discretion of the specialist in question.
2. Musculotensive headache: treatment was carried out with TRAMADOL, by administration of prolonged-release tablets at full doses (100 mg every 12 hours). If the pain relief was insufficient, the patient was permitted to increase the dose to 200 mg twice a day. This protocol envisaged the drug to be taken every 12 hours for 15 days, regardless of the headache episode. During the trial period, no other complementary drugs were administered (antidepressants, tranquillisers, muscle-relaxants).

- Definition of outcome

In order to assess the results, the patients were divided into 3 groups according to the NPIS - score, carried out at the time of completion of the end-of-trial form:

a. VAS 0-2: COMPLETE RESPONSE
b. VAS 3-4: MODERATE PAIN CONTROL
c. VAS 5-10: POOR PAIN CONTROL

CHRONIC LUMBAGO: electrotherapy group										
Initials	Sex	Age	VAS start	VAS end	Roland start	Roland end	Degree Satisfy.	Outcome VAS	Side effects	No. sesssions
M.L.	Fem.	58	5	0	13	1	M.S.	C.C.	headache	8
V.V.	Fem.	53	10	1	10	4	M.S.	C.C	no	10
V.M.	Fem.	73	4	0	20	4	M.S.	C.C	no	7
D.G.	Male	63	6	5	5	5	N.S.	S.C.	no	8
S.C.	Fem.	68	8	6	15	15	N.S.	S.C.	no	6
M.F.	Male	64	5	5	13	13	N.S.	S.C.	no	8
A.C.	Male	32	5	5	3	3			drop out	2
A.P.	Fem.	66	7	7	11	11	N.S.	S.C.	no	6
T.F.	Fem.	72	8	6	22	19	S.	S.C	no	12
B.F.	Fem.	64	5	5	9	9	N.S.	S.C.	no	7
V.G.	Male	62	3	0	18	2	S.	C.C	no	4
L.M.	Fem.	50	6	3	13	10	S.	C.M	no	9
R.G.	Fem.	68	8	2	12	4	S.	C.C	no	8
C.M.	Fem.	64	5	1	9	3	M.S.	C.C	no	10
G.M.	Fem.	63	8	4	18	12	S.	C.M.	no	8
B.M.	Fem.	71	5	1	13	6	S.	C.C.	no	6
L.C.	Fem.	61	5	2	8	5	S.	C.C.	no	6
C.D.	Fem.	34	8	4	12	9	S.	C.M	no	9
C.F.	Male	64	4	0	4	0	M.S.	C.C.	no	4
M.M.	Male	63	10	1	12	4	M.S.	C.C.	no	8
C.A.	Fem.	62	5	0	5	0	M.S.	C.C.	no	5
M.M.	Fem.	58	9	1	11	0	M.S.	C.C.	no	8
L.A.	Fem.	65	6	3	7	0	M.S.	C.M.	pain	6
F.C.	Fem.	32	7	1	3	1	M.S.	C.C.	no	4
D.M.	Male	54	7	2	14	4	S.	C.C	no	8
F.R.	Fem.	61	5	0	3	0	M.S.	C.C	no	6
M.L.	Fem.	73	7	4	11	8	S.	C.M.	no	6
I.D.	Fem.	64	4	4	9	9	N.S	S.C	no	8
A.L.	Fem.	59	6	3	8	7	N.S.	S.C.	no	8
C.E.	Fem.	71	8	2	7	3	S.	C.C.	no	8
B.A.	Fem.	78	6	2	9	4	M.S.	C.C.	no	8
T.C.	Fem.	61	5	2	10	3	M.S.	C.C.	no	6

Key: M.S. = very satisfied; S = satisfied; N.S. = dissatisfied; C.C. = complete pain control; C.M. = moderate control; S.C. = poor control.
Summary chart: no. of patients recruited 32, 1 patient dropped out
Degree of satisfaction:

- very satisfied: 13/31 42%
- satisfied: 11/31 35.5%
- dissatisfied: 7/31 22.5%

OUTCOME:

- Complete pain control: 18/31 58.1%
- Moderate control: 5/31 16.1%
- Poor control: 8/31 25.8%

Comparative analysis with the multicentre observational trial (preliminary report):
no. of patients 110

1. complete pain control 30%
2. moderate control 33.6%
3. poor control 36.4%

Comparative analysis with control group: standard treatment										
Initials	Sex	Age	VAS start	VAS end	Roland start	Roland end	Degree satisf.	Outcome VAS	Side effects	Drug
V.O.	Fem.	52	8	4	13	5	S.	C.M.	no	Tramadol
S.P.		44	7	4	11	6	S.	C.M.	no	Tramadol
P.V.	Fem.	30	8	3	16	6	S.	C.M.	no	Tramadol
V.G.	Fem.	82	8	3	19	8	S.	C.M.	nausea	Tramadol
P.M.	Male	43	8	7	16	16	N.S.	S.C.	no	Tramadol
R.M.	Male	71	7	3	13	7	S.	C.M.	no	Tramadol
C.G.	Fem.	70	7	7	21	21	N.S.	S.C.	nausea	Tramadol
T.L.	Fem.	58	9	8	20	20	N.S.	S.C.	discomfort	Tramadol
B.B.	Fem.	69	9	9	19	18	N.S.	S.C.	nausea	Tramadol
F.M.	Fem.	68	9	2	18	4	M.S	C.C.	no	Tramadol
F.D.	Male	36	8	8	14	14	N.S.	S.C.	no	Tramadol
D.B.	Male	70	10	8	21	19	N.S.	S.C.	no	Tramadol
C.T.	Male	74	8	4	8	3	S.	C.M	Reduc. cognit. capacity	Tramadol
B.A.	Male	81	8	3	13	6	S.	C.M.	no	Tramadol
T.E.	Fem.	98	7	2	22	15	M.S.	C.C.	no	Tramadol
S.C.	Male	43	6	1	12	0	M.S.	C.C.	no	Tramadol
D.C.	Fem.	49	5	2	7	2	M.S.	C.C.	no	Tramadol
L.M.	Fem.	29	8		16				drop out	Tramadol

Results

19 patients enrolled, 2 dropped out (one psychiatric patient and one patient with poor motivation). 17 patients analysed.

Degree of satisfaction:

- Very satisfied : 4/17 23.5%
- Satisfied : 7/17 41.2%
- Dissatisfied : 6/17 35.3%

Outcome : Complete pain control: 4/17
Moderate control: 7/17
Poor control: 6/17

RESULTS OF CHRONIC CERVICAL PAIN TRIAL										
TABLE: ELECTROTHERAPY GROUP										
Initials	Sex	Age	VAS		Disab. Index		Degree satisf.	Outcome VAS	Side effects	No. of sessions
			start	end	start	end				
N.O.	Fem.	48	4	4	10	10	N.S.	S.C.	Asthenia	2
G.G.	Fem.	69	7	2	13	5	M.S.	C.C.	no	8
B.A.	Male	78	4	1	9	2	M.S.	C.C.	no	5
B.M.	Fem.	73	6	3	12	10	S.	M.C.	no	8
D.N.	Fem.	68	5	2	12	6	M.S.	C.C	no	8
D.L.	Fem.	51	7	2	12	3	M.S.	C.C	no	7
P.G.	Male	73	9	8	15	15	N.S.	S.C.	no	7
R.R.	Fem.	71	4	1	4	2	M.S.	C.C	no	3
A.V.	Fem.	69	6	2	10	4	M.S.	C.C	no	7
C.A.	Fem.	73	7	2	14	5	M.S.	C.C	no	8
L.M.	Fem.	63	3	1	9	2	M.S.	C.C	no	5
O.N:	Fem.	78	5	3	6	6	S.	M.C.	no	8
D.M.	Fem.	74	6	2	8	4	S.	C.C.	no	8
G.O.	Fem.	69	8	6	11	10	N.S.	S.C.	no	8
M.L.	Fem.	61	6	3	9	5	S.	M.C.	no	8

Key: M.S. = very satisfied; S = satisfied; N.S. = dissatisfied; C.C. = complete pain control; C.M. = moderate control; S.C. = poor control.

Summary chart: no. of patients recruited 15

Degree of satisfaction:	very satisfied:	8/15	53.4%
	satisfied:	4/15	26.6%
	dissatisfied:	3/15	20%

OUTCOME :	Complete pain control:	9/15	60%
	Moderate control:	3/15	20%
	Poor control:	6/15	20%

Comparative analysis with the multicentre observational trial (preliminary report):
no. of patients 92
complete pain control 32.6%
moderate control 40.2%
poor control 27.2%

TABLE: PHARMACOLOGICAL TREATMENT GROUP										
Initials	Sex	Age	VAS		Disab. Index		Degree satisf.	Outcome VAS	Side effects	Drug
			start	end	start	end				
B.G.	Male	44	5	2	7	3	M.S.	C.C.	no	Tramadol
P.F.	Male	67	7	6	12	12	N.S.	S.C.	nausea	Tramadol
D.G.	Fem.	61	4	2	9	5	S.	C.C.	no	Tramadol
V.M.	Fem.	50	7	3	10	2	M.S.	C.C.	nausea	Tramadol
V.A.	Male	71	6	3	11	6	S.	M.C.	no	Tramadol
N.A.	Fem.	58	6	5	13	13	N.S.	S.C.	nausea	Tramadol
C.E.	Fem.	78	6	3	8	4	S.	M.C.	no	Tramadol
M.R.	Male	70	5	2	7	2	M.S.	C.C.	no	Tramadol
A.E.	Fem.	67	4	2	6	2	M.S.	C.C.	no	Tramadol
M.G.	Male	73	7	4	12	8	S.	M.C.	no	Tramadol
M.P.	Fem.	47	8	5	10	9	N.S.	S.C.	Discomfort	Tramadol
F.S.	Fem.	76	5	3	12	10	S.	M.C.	Discomfort	Tramadol
B.C.	Male	58	4	1	5	1	M.S.	C.C.	no	Tramadol
A.A.	Male	65	3	1	6	2	M.S.	C.C.	no	Tramadol
L.M.	Fem.	77	8	7	14	13	N.S.	S.C.	Cognit. defic.	Tramadol

Summary chart: no. of patients recruited 15

Degree of satisfaction: very satisfied: 6/15 40%
satisfied: 4/15 33.3%
dissatisfied: 4/15 26.7%

OUTCOME : Complete pain control: 7/15 46.6%
Moderate control: 4/15 26.7%
Poor control: 4/15 26.7%

RESULTS OF MUSCULOTENSIVE HEADACHE TRIAL											
Table: electrotherapy group											
Initials	Age	Sex	Grad. headache	No. attacks/wk		Disab. Index		Outcome	Side effects	No. sessions	Degree satisf.
				pre	post	pre	post				
G.M.	62	Fem.	S.	Const.	3	7	6	C.M.	NO	8	S.
S.C.	42	Fem.	M.	1	0	4	0	C.C.	Reacut.	6	M.S.
T.G.	61	Fem.	S.	7	7	13	13	S.C.	NO	8	N.S.
P.T.	51	Fem.	S.	1	0	15	0	C.C.	NO	7	M.S.
P.P.	41	Fem.	S.	3	0	5	0	C.C.	NO	8	M.S.
T.A.	55	Fem.	M.	7	1	8	0	C.C.	NO	6	M.S.
F.P.	46	Fem.	S	3	0	10	0	C.C.	NO	6	M.S.
F.C.	66	Male	M.	7	2	6	2	C.M.	NO	8	S.
D.P.	54	Fem.	M.	2	0,05	6	1	C.M.	NO	8	S.
M.U.	64	Male	S.	3	0	5	0	C.C.	NO	7	M.S.
M.S.	32	Fem.	M.	2	0,05	4	2	C.M.	NO	8	S.
P.S.	44	Fem.	M.	3	2	6	6	S.C.	Dizz.	8	N.S.
D.C.	63	Fem.	M.	2	0,05	4	2	C.M.	NO	8	S.
C.S.	51	Male	S.	6	6	12	12	S.C.	Discomf.	8	N.S.
B.L.	57	Fem.	M.	3	1	7	2	C.M.	NO	8	S.
A.P.	44	Fem.	S.	6		14			Drop out		

Key: Grading: S: SEVERE, M: MODERATE, L=SLIGHT; OUTCOME: CC=COMPLETE CONTROL, CM=MODERATE CONTROL; Satisfaction grading: M.S. = VERY SATISFIED; S = SATISFIED; N.S. = DISSATISFIED;

Summary chart: no. of patients recruited 16. 1 patient dropped out;
no. of patients studied 15.

Outcome: Complete headache control : 6/15 40%
Moderate headache control : 6/15 40%
Poor headache control: 3/15 20%

Degree of satisfaction: very satisfied 6/15 40%
satisfied 6/15 40%
dissatisfied 3/15 20%

Since musculotensive headache is often associated with pericranial muscle disorders, anxiety state and depressive syndrome, a polygraph (visual energy tester - elemaya) was used for the patients included in the trial. This analysed the variability of the heart rate, skin resistance, musculoskeletal tone and synchronisation of the Electroencephalogram. The main aim of this analysis was to study the relationship between the psychological states and the physiological processes in excitation condition. Excessive activation was considered to be the main cause of stress-related psychosomatic conditions. In fact, a state of non-adaptive hyperactivation would be created, with a resulting pathological condition suffered by the body.
The objective was to assess in which subgroup of patients CRANIAL ELECTROSTIMULATION (CES) is indicated, possibly administered through the home-care system, in addition to treatment carried out in the outpatients' department.

As far as could be assessed, most of the patients displayed an anxiety state, with moderate predominance of the sympathetic system (zone 8).

Table: pharmacological treatment group										
Initials	Age	Sex	Grad. headache	No. attacks/wk		Disab. Index		Outcome	Side effects	No. sessions	Degree satisf.
				pre	post	pre	post				
T.A.	49	Fem.	S.	5	4	8	6	S.C.	Discomf.	2	N.S.
C.M.	65	Fem.	M.	2	0	4	2	C.M.	NO	2	S.
D.G.	62	Male	S.	5	2	11	8	C.M.	NO	2	S.
B.M:	53	Fem.	M.	2	2	7	6	S.C.	NO	2	N.S.
B.P.	71	Fem.	S.	6	4	14	10	C.M.	NO	2	S.
T.F.	51	Fem.	M.	2	0	5	0	C.C.	NO	2	M.S.
M.A.	56	Fem.	M.	2	1	7	3	C.M.	nausea	2	S.
G.G.	49	Fem.	S.	5	3	8	4	C.M.	NO	2	S.
L.F.	55	Male	M.	1	0	4	1	C.C.	NO	1	M.S.
R.G.	62	Male	M	2	1	6	3	C.M.	NO	2	N.S.
M.M.	49	Fem.	S.	5	4	13	4	C.M.	NO	2	N.S.

Key: Grading: S: SEVERE, M: MODERATE, L=SLIGHT; OUTCOME: CC=COMPLETE CONTROL, CM=MODERATE CONTROL; Satisfaction grading: M.S. = VERY SATISFIED; S = SATISFIED; N.S. = DISSATISFIED

Results: 11 patients analysed

Degree of satisfaction:
Very satisfied: 2/11 18.2%
Satisfied: 6/15 54.5%
Dissatisfied: 3/15 27.3%

Outcome: Complete control: 2/11 18.2%
Moderate control: 7/11 63.6%
Poor control: 2/11 18.2%

PILOT TRIAL FINAL REPORT: ELECTROTHERAPY WITH ALG 400
IN THE TREATMENT OF CHRONIC PAIN

- ANKLE SPRAIN

1. INCLUSION CRITERIA:

- Under 60 years of age
- Sprain < 72 h from date of inclusion in the trial
- Suspension of pharmacological treatment 24 h before

2. EXCLUSION CRITERIA:

- Pregnancy
- Pacemakers
- Comorbidity associated with Karnovsky's disability index < 50

Sample definition
30 patients

Type of trial
Perspective randomised in parallel groups
Standard treatment vs electrotherapy

PRETREATMENT ASSESSMENT PARAMETERS

- Time elapsed between injury and start of cure
- Previous treatment

START OF TREATMENT ASSESSMENT PARAMETERS

- Extent of pain by means of VAS scale
- Extent of functional limitation

END OF TREATMENT ASSESSMENT PARAMETERS

- VARIATION OF PAIN (PRIMARY)
- VARIATION OF OEDEMA (SECONDARY)
- RECOVERY TIME: ability to walk 20 metres without limping (SECONDARY)

OUTCOME ASSESSMENT
In order to assess the results, the patients were divided into 3 groups according to the NPIS - score, made at the time the end of trial form was completed:

d. VAS 0-2: COMPLETE RESPONSE
e. VAS 3-4: MODERATE PAIN CONTROL
f. VAS 5-10: POOR PAIN CONTROL

TREATMENT PROTOCOL
The treatment that is the subject of assessment corresponds to phase 1 of the American College of Foot and Ankle Surgeons, whose aims are to reduce the pain, oedema and to promote ligament recovery

1. electrotherapy protocol
   - rest for the first 24 h

- protective device
- electrotherapy: 1 session/day according to ALG 400 protocol for a maximum of five sessions/week
- the number of sessions is decided according to the medical response
- the treatment is suspended when the medical targets are reached: VAS < 2 and ability to walk 20 metres without limping
- a Poor medical response is considered to be a VAS score variation < 25% after six sessions

2. standard treatment
   - rest for the first 24 h
   - ice: 4 applications per day for the first 72 h
   - protective device or elastic bandage for the first 72 h
   - painkillers when needed

Initials	Spr. type	Grad.	Time	VAS		No. sessions	Outcome	Recov. time	Degree satisf.
				start	end				
A.P.	L	2	<24h	7	2	5	C.C.	5 days	M.S.
F.F.	L	1	<3 days	3	1	3	C.C.	3 days	M.S.
G.G.	L	2	<3 days	6	2	4	C.C.	4 days	M.S.
C.G.	L.	2	<3 days	8	4	8	C.M.	10 days	S.
M.M.	L.	2	<24h	4	1	3	C.C.	3 days	M.S.
M.B.	L	2	<24 h	8	2	3	C.C.	3 days	M.S.
C.A.	L	2	<24 h	6	2	3	C.C.	3 days	M.S.
S.F.	L	2	<24 h	7	2	3	C.C.	3 days	M.S.
P.S.	L	2	<3 days	6			Drop out		
P.C.	L	2	<3 days	5	1	3	C.C.	3 days	M.S.
F.A.	L	3	<24 h	8	3	8	C.M.	10 days	S.
G.A.	L.	2	<24 h	7	2	4	C.C.	4 days	M.S.
A.F.	L	1	<24 h	5	1	3	C.C.	3 days	M.S.
F.M.	L	2	<3 days	7	6	8	S.C.	10 days	N.S.
G.M.	L.	2	<3 days	6	2	4	C.C.	4 days	M.S.

Key: M.S. = very satisfied; S = satisfied; N.S. = dissatisfied; C.C. = complete pain control; C.M. = moderate control; S.C. = Poor control.

Analysis of results

15 patients were recruited; one patient dropped out of the treatment protocol because of taking painkillers during the trial period

The results relating to the 14 patients eligible for the trial are:

outcome : Complete pain control: 11/14 78.6%
Moderate pain control: 2/14 14.3%
Poor pain control: 1/14 7.1%

Degree of satisfaction: very satisfied: 11/14 78.6%
satisfied: 2/14 14.3%
dissatisfied: 1/14 7.1%

Mean recovery time (understood as VAS < 2 and/or possibility of walking 20 metres without limping) : 4.8 days (range 3-10). By analysing only the patients with complete response, it is found, however, that the mean recovery time is approximately 3 days.

TABLE: STANDARD TREATMENT

Initials	Spr.type	Grad.	Time	VAS		Outcome	Recov. time	Degree satisf.
				start	end			
G.M.	L	2	<24 h	6	2	C.C.	6 days	S
A.A.	L	2	<24 h	5	1	C.C.	4 days	M.S.
B.A.	L	2	<3 days	5	2	C.C.	6 days	S.
F.M.	L	2	<3 days	7	3	C.M.	9 days	S.
B.M.	L	3	<24 h	9	4	C.M.	14 days	S.
P.E.	L	2	<24 h	7	2	C.C.	7 days	M.S.
P.M.	L	2	<3 days	6	3	C.M.	6 days	S.
S.C.	L	1	<24 h	5	1	C.C.	5 days	S.
P.S.	L	2	<3 days	6	3	C.M.	6 days	S.
M.Z.	L	1	<3 days	7	1	C.C.	5 days	M.S.
M.A.	L	2	<24 h	9	2	C.C.	9 days	S.
P.G.	L	2	<24 h	10	5	S.C.	10 days	N.S.
A.F.	L	3	<24 h	7			Drop out	
K.F.	L	2	<3 days	7			Drop out	
A.A.	L	2	<3 days	7	2	C.C.	5 days	M.S.

Key: M.S. = very satisfied; S = satisfied; N.S. = dissatisfied; C.C. = complete pain control; C.M. = moderate control; S.C. = poor control.

Analysis of results

15 patients were recruited; two patients dropped out of the treatment protocol due to poor motivation towards the protocol method

The results relating to the 13 eligible patients:

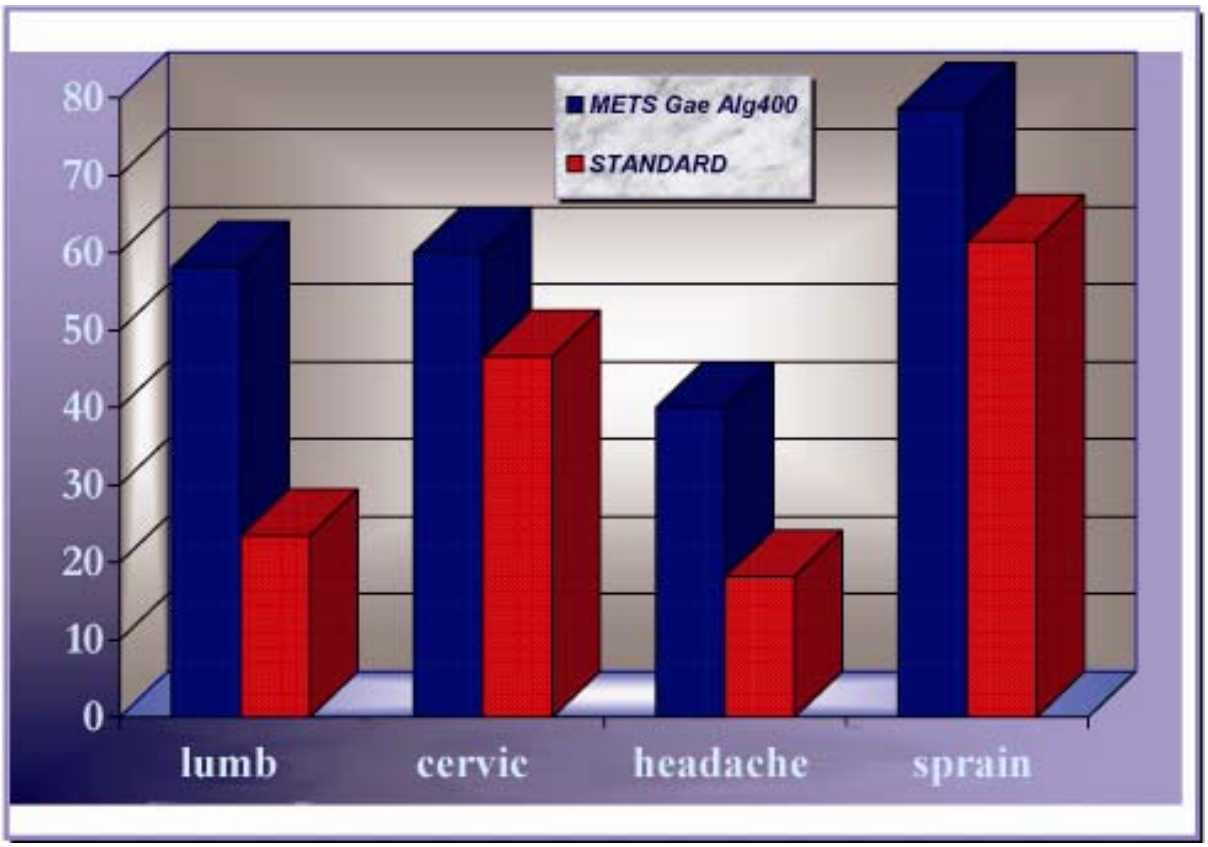
outcome: Complete pain control: 8/13 61.5%

	Moderate pain control:	4/13	30.8%
	Poor pain control:	1/13	7.7%

Degree of satisfaction:	very satisfied:	4/13	30.8%
	satisfied:	8/13	61.5%
	dissatisfied:	1/13	7.7%

Mean recovery time (understood as VAS < 2 and/or possibility of walking 20 metres without limping): 7 days (range 4-10).

GRAPH COMPARING PATIENTS WITH COMPLETE PAIN CONTROL BETWEEN ELECTROTHERAPY AND STANDARD TREATMENT



CONCLUSIONS

The above-mentioned trials were conducted using state-of-the-art equipment that supplies microcurrents (Gaenesy ALG 400 - Gaenesy srl).
The instrument uses a direct digital modulation code multiphase synthesis to obtain an accurate analysis of the bioimpedance of the tissue to be treated and a comparison with the healthy tissue, under the constant supervision of a controlled computer-type process.

The literature already provides a considerable amount of evidence that the healing process is mediated by the flow of endogenous current (defined by Becker as “lesion current”). However, the electrical impedance in the tissues where the lesion is located is considerable, particularly at the site of chronic lesioning; what Nordenstrom has defined as a process of separation from the lesioned tissue is created. The final result will be reduced circulation, a lower supply of oxygen, and an impaired metabolism as a result, with persistent inflammation and a resulting vicious circle of pain.
The ALG 400 system corrects the electrical imbalances at the site of the lesion and thus speeds up cell metabolism and consequently the recovery of the inflammatory process.
Patients treated with ALG 400 have shown a significantly greater improvement than the control group with standard treatment, for all the main efficacy variables.