

Clinical Studies

Clinical Trial of Galvanoplast Galvanic Electrode @ 10 μ A - Direct Current Circa 1997 Dr. Mario Bergner

Problem:

Direct currents are known to have effects on excitable structures. Their therapeutic use has lost significance on account of the electrolytic skin damage caused by the commonly applied 1 mA currents. The present study is concerned with the effect and innocuousness of direct currents of around 10 μ A applied throughout a treatment period of 48 hours.

Method:

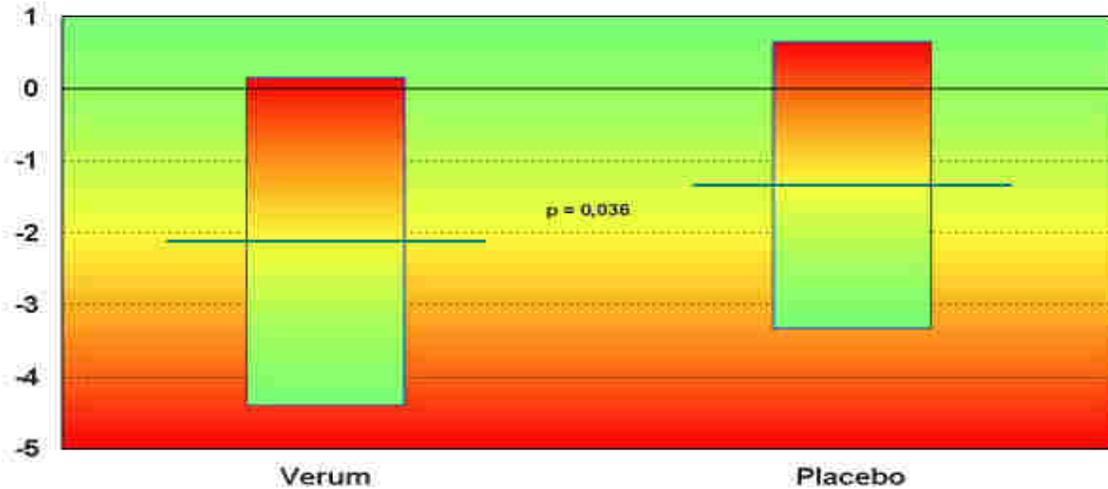
In a placebo controlled randomized double blind study, 135 patients with cervical spine syndrome were treated with an auto active "galvanic healing plaster" which was applied with one aluminum and one copper electrode to the trigger points of the descending part of the trapezius muscle. While the PLACEBO group was given a non-conductive connection cable, the VERUM Group did not perceive the current on account of its low intensity.

Results:

In the VERUM group, pain reduction as measured by the visual analogue scale (VAS) was significantly more pronounced ($p=0,036$). Significant differences with more favorable results for the VERUM group were also found in the subjective assessment of the reduction of the mobility impairment in the shoulder-neck area ($p=0,037$), the subjective assessment of effect by the investigating physician ($p=0,001$) and by the patient ($p=0,011$). Regardless of whether a current was present or not, the copper electrode was found to have a significantly more pronounced effect on the pressure sensitivity of the trigger points.

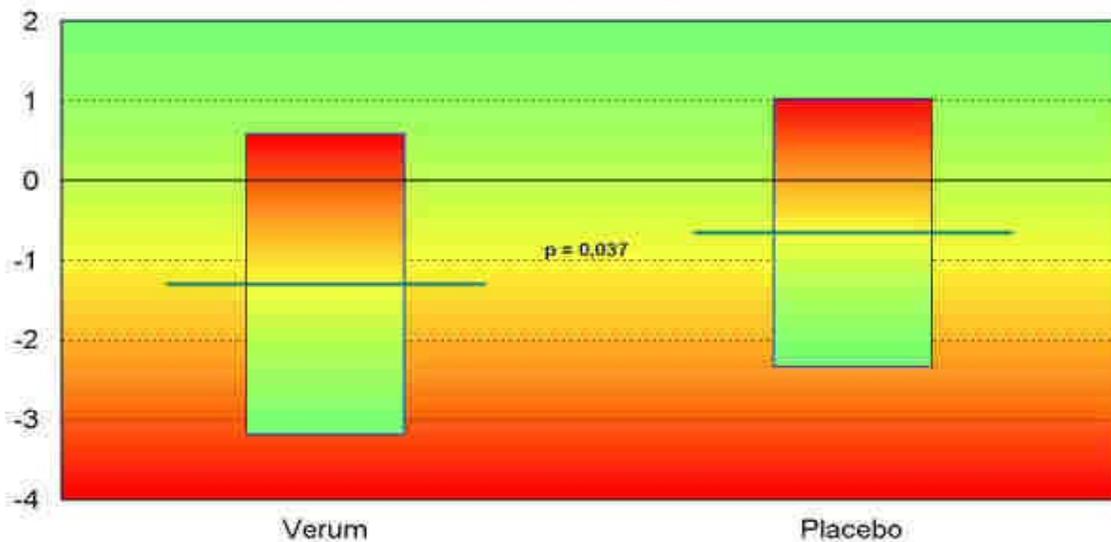
1. Change of pain from time before treatment and time after (on visual analog scale 0 to 10):

Placebo before - median: 5,240; Placebo after - median: 3,899; Placebo difference - median: -1,342
Verum before - median: 5,670; Verum after - median: 3,542; Verum difference - median: 2,128
p=0,036 (t-test) -> significant!



2. Make a better mobility of neck:

Placebo before - median: 4,866; Placebo after - median:4,209;
Placebo difference - median: - 0,657
Verum before - median: 4,971; Verum after - median: 3,667; Verum
difference - median: - 1,304
p=0,037 (t-test) -> significant

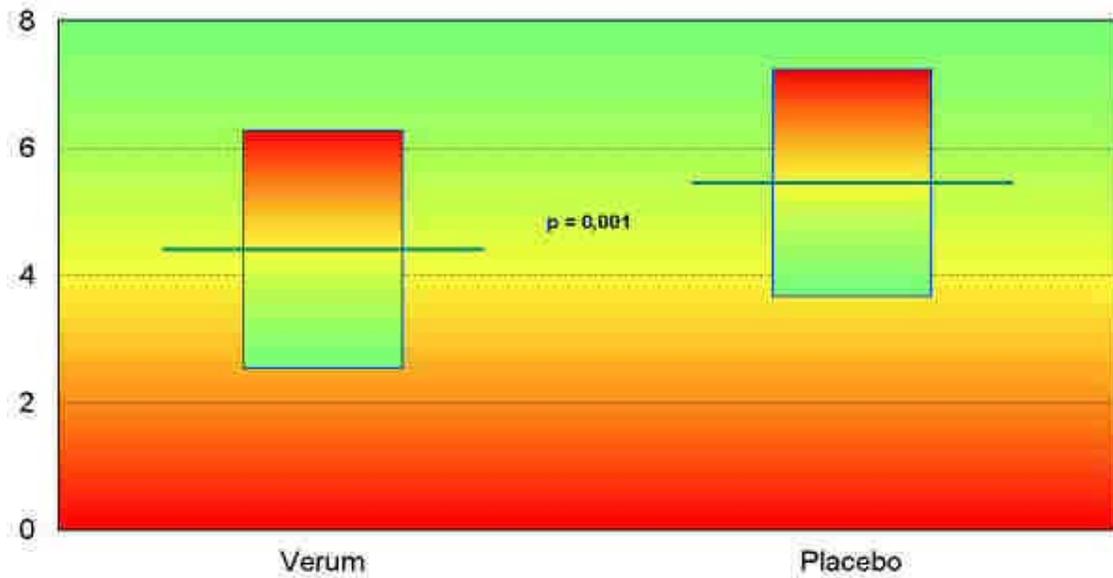


3. Effectiveness to doctors subjective estimation on scale from 1 (very good) to 7 (no effectiveness):

Placebo - median: 5,448

Verum - median: 4,406

p=0,001 (t-test) -> very high significant !

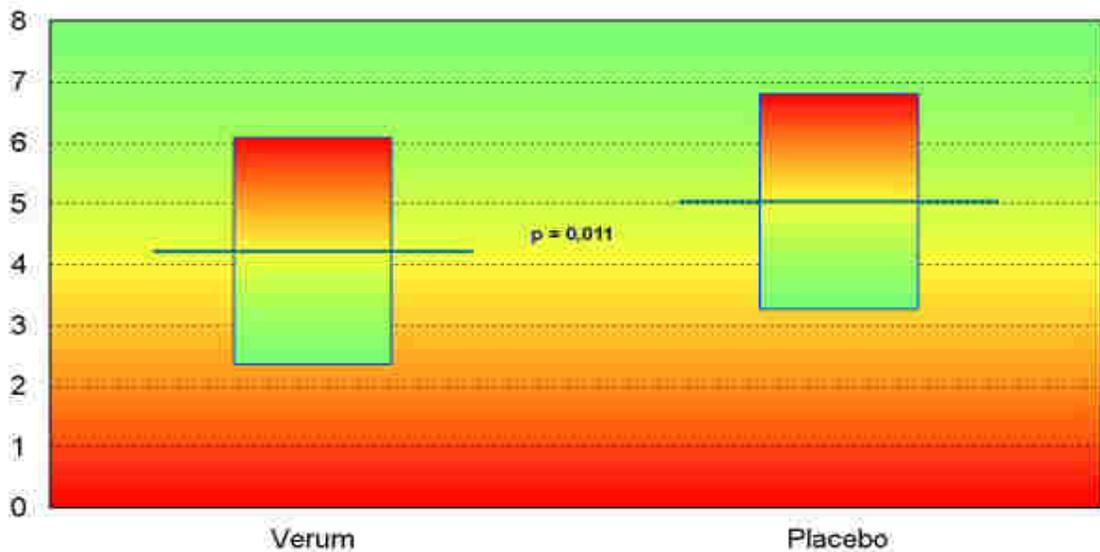


4. Effectiveness to patients subjective estimation on scale from 1 (very good) to 7 (no effectiveness):

Placebo - median: 5,030

Verum - median: 4,217

p=0,011 (t-test) -> high significant !



5. Meaning about the good practicability of this therapy:

Placebo: 92,5% !!!

Verum: 98,5%

Conclusions:

It was possible to demonstrate the effect of 10 μ A direct currents on painful muscle hardening for treatment periods of 48 hours. Further controlled studies should be carried out to demonstrate their effectiveness with other indications in orthopedics as well.

Case Studies

Newcare Products, LLC

MCT Patch Case Studies

Effectiveness with ailments of the Knee

Case 1.

A 70-year-old male suffering from severe pain from knee replacement surgery. Prior to treatment using Newcare MCT patches, treatments with anti-inflammatories provided temporary, short-term relief. Patient's treatment consisted of 24-hour treatment of 25 μ A of direct current utilizing Newcare MCT patches placed on the right and left side of knee. After 48 hours of continuous treatment patient experienced a 75% reduction of pain. Subsequent weekly treatments over three months have reduced the level of pain 90%.

Case 2.

A 65-year-old male suffering from chronic knee pain. Prior to treatment using Newcare MCT patches patient was using Celebrex, which gave some relief from the pain. During the four (4) weeks of treatment with Newcare MCT patches the patient discontinued the use of Celebrex and reported that the Newcare MCT offered an equal amount of pain relief, without the side effects associated with Celebrex. Treatment and patch placement was the same as case 1.

Case 3.

A 73-year-old male suffering from chronic knee pain. Prior to treatment using Newcare MCT patches patient was using over-the-counter pain relief medications with some success. Being an avid golfer, this individual seemed to suffer most pain during and immediately following exercise. Treatment consisted of application of Newcare MCT patches several hours prior to any exercise. Patient reported an immediate improvement in mobility and a complete reduction of pain during and after exercise.

Newcare case studies of effectiveness with Chronic Back Pain

Case 4.

A 64-year-old female (Ex-Wimbledon Champion) suffering from chronic back pain linked to years of strenuous exercise associated with tennis. Individual has been under several treatment protocols ranging from over-the-counter pain relievers to TENS treatment with very little success. Treatment consisted of continuous treatment at 25 μ A using the Newcare MCT patches periodically for one week and subsequent treatments

during and after strenuous exercise. Patches were placed in the small (dimple area) of the lower back. Patient reported a 65% reduction in pain after exercise and continues to improve with additional treatment. Treatment and use have been ongoing for five (5) months.

Case 5.

A 50-year-old female suffering from chronic lower back pain. Patient has had surgery to repair rupture and has suffered from post operative pain for the last five (5) years. Prescription pain relievers have offered only minor relief. Treatment consisted of application of Newcare MCT patches prior to sleep, allowing for treatment of up to eight (8) hours of continuous treatment with very little movement or strenuous activity. After four (4) nights of treatment patient has reported an 80% reduction in pain. After two (2) months of treatment consisting of approximately 36 hours of treatment per week patient reports a 90 to 95% reduction. Treatment has been ongoing for six (6) months. Patch placement was the same as case 4.

Newcare case studies of effectiveness with Chronic Neck Pain

Case 6.

A 35-year-old male suffering from chronic neck pain stemming from an automobile accident. Individual has suffered from chronic pain for five (5) years following the accident. Numerous treatment protocols have been used including Transcutaneous Nerve Stimulation (TENS), physical therapy and various prescription drugs commonly used for pain relief. Individual was treated on a continuous basis for two (2) weeks and subsequently every other day for an additional one (1) month. Early results showed a reduction of approximately 55% while long-term results are approaching 75%. MCT patches were placed on the lower neck area at the intersection of the shoulder and upper back. To date patient has been using Newcare MCT patches for eight (8) months and continues to improve. Recent results have allowed for a reduction of treatment to once or twice weekly for 24 hour periods.

Case 7.

A 60-year-old female suffering from chronic pain stemming from an automobile accident. Individual has been suffering from neck pain for approximately six months following injury. Traditional treatments of pain medication have been unsuccessful. Newcare MCT patches were applied to the lower neck area for 48 hours. Results showed a reduction in pain of 70%. After three (3) weeks of treatment individual reported a reduction of 85%.

Open Studies

Newcare Products, LLC

Fibromyalgia - Open Study
Bradley Memorial Hospital
Southington, Connecticut

Therapeutic Results of Microcurrent Therapy using Newcare Micro Current Therapy Patches with a current of 25 μ A.

Preface

A growing body of medical evidence is demonstrating that the passage of minute electrical current through body tissue (Micro Current Therapy) aids in the relief of muscular and joint pain. The MCT Patch provides a totally new physical treatment for electrotherapy via two self-adhesive electrode patches. The two patches are wired together and are activated when applied to the body, thus opening the electrical circuit and allowing the electrodes to emit 25 μ A of electricity into the body between the two electrode patches. This 25 μ A of current is 2.5% of the commonly used factor of 1mA for electrotherapy. However, the treatments can last 100 times longer than traditional treatment.

Ailment

Fibromyalgia Pain Syndrome is a painful muscle condition that was first identified in the early 1900's. Very little attention has been given to this disorder. In fact, until recently Fibromyalgia was dismissed by many health care practitioners as minor rheumatism. However, the pain and stiffness of Fibromyalgia affects an estimated five million Americans, and to date there is no known cause or cure.

The symptoms of Fibromyalgia generally first develop between the ages of 20 and 30 and may come and go in cycles. The sharp stabbing pains associated with this condition often appear in the neck, in the head and in the shoulder blades and arms. The pain may also be felt in the chest muscles and lower back, and sometimes in the jaw. Fibromyalgia may also result in dull aches in the thighs, hips and shoulder muscles.

Patients

A total number of forty five (45) members of the Bradley Memorial Hospital Fibromyalgia Support Group were studied. They suffered from various musculoskeletal and pain related ailments associated with Fibromyalgia. Of the forty five (45) participants in the study, forty one (41) were female and four (4) were male. Since Fibromyalgia tends to affect a greater number of females than males, this number is considered an acceptable ratio. The age of the participants ranged from 25 to 70. The average participant has suffered from Fibromyalgia and the accompanying pain for six (6) years.

Sample product was handed out to the participants in October 2000 along with survey forms. After four (4) weeks of use, the participants were called back for comment and gathering of survey material. At this time the study was extended to a larger group and we continue to gather information.

Results

The results of all 45 participants in the study are summarized and listed below in table 1. In twenty three (23) cases 51% reported a significant relief in pain. Of these twenty three (23) cases, ten (10) participants reported a decrease in pain greater than 60%, while two (2) reported a decrease of 83%. Ten (10) additional participants reported a decrease in pain greater than 30%. No one reported an increase in pain.

These results were achieved after an average use of 28 hours.

Pain

Location	Decrease in Pain						Total
	Significant	Good	Mild	Minor	None	Negative	
Lower back	6	4	1	5	1	0	17
Joint	3	1	0	2	0	0	6
Muscle	9	0	2	4	0	0	15
Knee	1	0	0	0	0	0	1
Headache	4	0	2	0	0	0	6
Total results	23	5	5	11	1	0	45

Legend	Significant	50%
	Good	40%
	Mild	30%
	Minor	Less than 30%
	None	No improvement
	Negative	Increased pain

Discussion

Fibromyalgia is considered one of the most difficult ailments to treat and these results are a significant advancement in the struggle to offer sufferers a treatment protocol that not only is effective, but also has none of the usual side effects of typical pain medication.

The results noted above are cumulative of the six months of testing and show a plateau effect of the long-term treatment, which resulted in lower overall results in the percentage of decrease in pain. This occurred because of the lowering of pain on a scale of 0-10, allowing the participants to re-evaluate their pain as they progressed through the study. A participant who had pain rated at nine (9) on the scale before using the MCT Patch, and a five (5) after initial treatment would have a new measurement point of five (5). This person's next report might only show a decrease from five (5) to four (4). When the results were tabulated, the overall average decrease in pain for this participant was lowered to the new average decrease.

Below are the results of additional information gathered during testing.

- **Side Effects** - No side effects were noted other than mild skin irritation from the adhesive material in nine (9) participants. A high number of Fibromyalgia sufferers have hypersensitive skin and these results were expected and are considered normal.
- **Adverse effects** – No short-term or long-term adverse effects were noted during the six (6) months of treatment.
- **Acceptance** – All participants were very acceptable to this type of treatment due to ease of use and lack of side effects associated with most prescription and over-the-counter drugs.
- **Recommendations** – All participants were asked if they would recommend this product to others, 100% responded positively.
- **Effectiveness** – All participants were asked to rate the effectiveness of the product, generating these results.
 - a. **Excellent** = 13
 - b. **Good** = 26
 - c. **Fair** = 6
 - d. **Poor** = 0