

Open Studies

Newmark, Inc

Fibromyalgia - Open Study
Bradley Memorial Hospital
Southington, Connecticut

Therapeutic Results of Microcurrent Therapy using Newmark 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