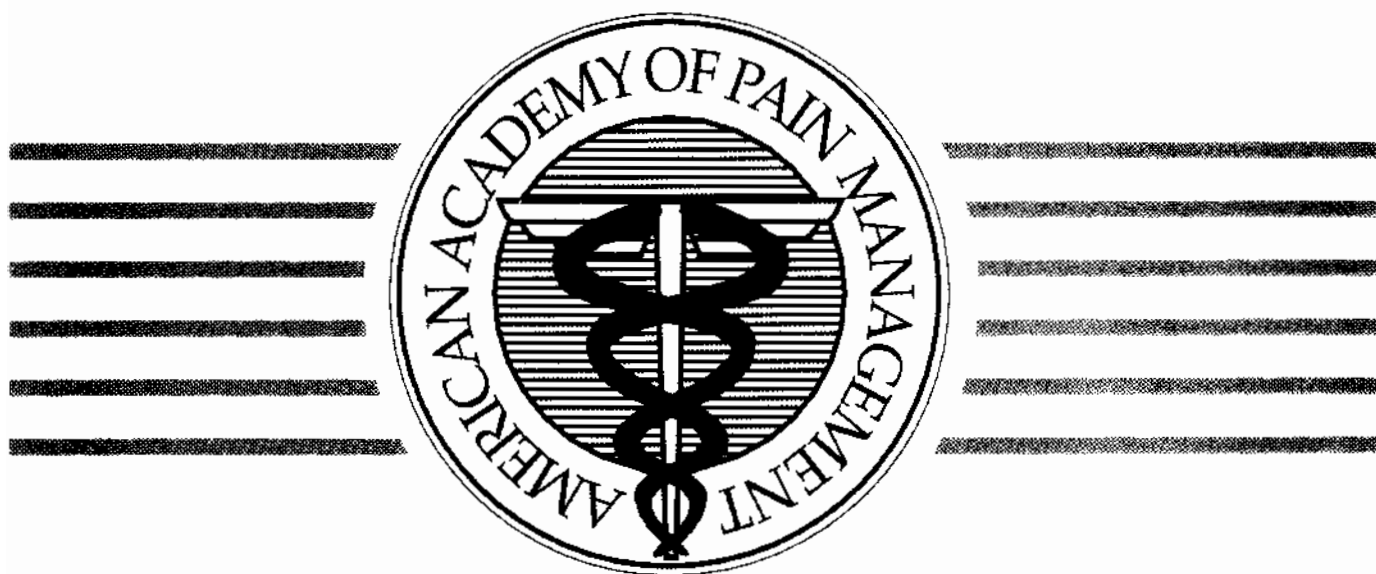


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IS MICROCURRENT STIMULATION EFFECTIVE IN PAIN MANAGEMENT? AN ADDITIONAL PERSPECTIVE

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Abstract. *In the 1990s, the effectiveness of transcutaneous electrical nerve stimulation in pain management was called into question by a double-blind study that found it to be no more effective in a group of pain patients than sham treatment. More recently, the effectiveness of microcurrent electrical therapy (MET) in pain management has come into question. An analysis of 2500 consecutive warranty cards submitted by patients who had been prescribed the Alpha-Stim MET device was undertaken in the present study. The results of an analysis of 1,949 of these patients who listed pain as their primary symptom and had used the device for a minimum of 3 weeks prior to mailing in the card are presented. With these self-reports of pain patients, the investigator determined that 93.02% claimed significant pain reduction, ranging from a low of 81.82% in chronic regional pain syndrome patients to a high of 98.31% and 100% in those suffering from migraine headaches and carpal tunnel syndrome, respectively.*

Descriptors. *electrotherapy, MET, microcurrent, pain*

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Electrotherapeutic devices are widely used in modern pain treatment programs. These can include such treatments as interferential current, transcutaneous electrical nerve stimulation (TENS), iontophoresis, and short wave therapy, among others (1). Microcurrent electrical therapy (MET) also has proponents (2), as does electroacupuncture (3).

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In 1990, the use of TENS received a major setback when a double-blind study found it to be no more effective than sham treatment in treating pain (4). Sales of TENS units were said to plummet in the wake of that study (5), in spite of rebuttal that subsequently appeared in the literature (6). More recently, MET received a similar negative evaluation in a double-blind study (7). Yet another double-blind, placebo-controlled study completed about the same time reported positive results among 30 fibromyalgia patients (8); so the reviews have been mixed and additional, clarifying information seems indicated.

In a different type of approach to the measurement of effectiveness, physicians were recently asked to evalu-

ate the results of MET treatment of their pain patients. In their evaluations of 500 patient outcomes, physicians rated MET significantly effective (25% or greater improvement) in 90.91% of those patients (9).

More recently, it became apparent that another important source of data was available – patients' self-reports. When physicians prescribe MET units for their patients' use, warranty cards can be submitted by the patients in which they are given the option of describing their perception of the outcome of their treatment with the device. The present study involved an analysis of such warranty card data.

METHODOLOGY

Two-thousand five-hundred consecutive warranty cards for the Alpha-Stim MET device, which were sent in as of July, 2000, on which optional diagnosis and treatment outcome parameters were entered, were analyzed. Separated out of the main analysis were those cards on which the patient indicated that the device had been used for less than three weeks at the time of submittal. The rationale for that is that many of the pain patients also listed depression among their clinical symptoms, and earlier studies have shown that 21 days of daily treatment are often necessary for depression to subside with electrotherapy stimulation (10,11). Also over 300 of the cards listed fibromyalgia, and the fibromyalgia study cited above involved daily, one-hour MET treatment for 21 days. Since the MET device is a recognized treatment for depression, anxiety, and insomnia in addition to pain, the present results are for only those cards in which patients listed pain as their primary symptom.

Types of pain, such as arachnoiditis, lupus, and coccygeal pain, were not represented in sufficient numbers to warrant analysis.

SUBJECTS

A total of 1,949 of the cards, or 77.96% of the total, listed pain as the primary diagnosis. One-thousand four-hundred eleven (72.4%) of the patients were female. The ages ranged from 15 to 92 years with a mean of 50.07

years. The age at the first quartile was 42 and at the third quartile was 57, indicating a curve with a relatively sharp peak of middle-aged users. The length of use ranged from the predetermined 3-week cutoff period up to 5 years (2 cases). The average period of use reported was 14.68 weeks, or just over three and one-half months.

FINDINGS

The most frequently listed types of pain were back pain (N = 403), fibromyalgia (N = 363), cervical pain (N = 265), and arthritis (both rheumatoid and osteoarthritis, N = 188). The warranty cards provided the patients with categories of treatment response or improvement to check-off. These were *Slight Improvement (0-24%)*, *Fair Improvement (25-49%)*, *Moderate Improvement (50-74%)*, *Marked Improvement (75-100%)*. The results for the total pain group are shown in Table I, where it can be seen that the most frequently marked improvement category was *Moderate Improvement (50-74%)*, with 93.02% (N = 1,813) reporting significant improvement of 25% or greater.

Table I. Patient evaluation of treatment outcome for all types of pain combined.

Condition	Number of Patients	Amount of Improvement Reported				
		Slight 0-24%	Fair 25-49%	Moderate 50-74%	Marked 75-100%	Significant 25%+
All Pain	1,949	6.97%	31.97%	38.02%	23.04%	93.03%

Table II shows the breakdown of those reporting neuromusculoskeletal pain. It can be seen that while the most frequently checked improvement category among patients suffering lumbar, cervical, and shoulder/arm/hand pain was *Moderate 50-74%*, those suffering from

hip/leg/foot pain were more likely to check the *Marked 75-100%* category. That group also reported a higher percent of significant improvement, followed by the back pain patients, the cervical pain patients, and the shoulder/arm/hand pain patients, reporting 96.25%, 95.04%, 93.21%, and 91.33%, significant improvement, respectively.

Table II. Patient evaluation of treatment outcome for neuromusculoskeletal pain.

Pain Area	Number of Patients	Amount of Improvement Reported				
		Slight 0-24%	Fair 25-49%	Moderate 50-74%	Marked 75-100%	Significant 25%+
Back	403	4.96%	27.05%	38.96%	29.03%	95.04%
Cervical	265	6.79%	26.04%	47.17%	20.00%	93.21%
Hip/Leg/Foot	160	3.75%	26.87%	33.13%	36.25%	96.25%
Shoulder/Arm/Hand	150	8.67%	27.33%	42.00%	22.00%	91.33%

Table III shows other pain areas that had strong representation in the sample. It can be seen that among this group, the migraine sufferers responded more significantly overall (98.31%), followed by those with degenerative bone/joint pain (94.74%), arthritis (94.15%), fibromyalgia (90.91%), myofascial pain (90.32%), TMJ pain (89.24%), headaches other than migraine (82.14%), and finally by only 81.81% of the reflex sympathetic dystrophy patients.

It is interesting that while only 1.69% of the migraine sufferers reported as little as 0-24% improvement, 17.86% of the patients in the "all other headache" category did. On the other hand, the single most frequently selected category of the migraine patients was *Fair 25-49%*, while the single most frequently selected category of the other headache patients was *Marked 75-100%*. That suggests that while the various, non-migraine type

headaches are most difficult to treat, and many do not respond within the time limit set for this analysis, those who do respond do so to a greater extent than do migraine patients. Similarly, it can be seen that apart from the headache patients, the most frequently checked improvement category for all pain patients was *Moderate 50-74%*.

Table III. Treatment outcome evaluations of patients for additional types of pain.

Type of Pain	Number of Patients	Amount of Improvement Reported				
		Slight 0-24%	Fair 25-49%	Moderate 50-74%	Marked 75-100%	Significant 25%+
Fibromyalgia	363	9.09%	36.09%	41.87%	12.95%	90.91%
Arthritis ^a	188	5.84%	27.13%	46.82%	20.21%	94.16%
TMJ	158	10.77%	37.97%	37.97%	13.29%	89.23%
Migraine	118	1.69%	41.53%	25.42%	31.36%	98.31%
Headaches: All Other	112	17.85%	26.79%	21.43%	33.93%	82.15%
Myofascial	62	9.68%	29.03%	29.03%	32.26%	90.32%
Degenerative Bone/Joint ^b	65	5.26%	21.05%	47.37%	26.32%	94.74%
RSD ^c	55	18.18%	29.09%	34.55%	18.18%	81.82%

^aIncludes both osteoarthritis and rheumatoid arthritis. The two were not different upon analysis.
^b83% (N = 54) listed disk or spine, the rest listed arthritic.
^cReflex sympathetic dystrophy, usually reported as "whole body".

DISCUSSION

There are major weaknesses inherent in this kind of data analysis, but there is also major information to be gained.

Among the weaknesses are the many unknowns, such as how often and for what length of time for each treatment the patients used the device and which of three different types of electrodes that are available with the device were used by the patients during treatment (probes, self-adhesive electrodes, ear clip electrodes). Other unknowns were the quantity and quality of training provided the patient by the prescribing physician, what kind of treatment follow up was provided, and what other treatment or medications were being used simultaneously. Additionally, it might be assumed that patients unhelped by the modality may not have returned their warranty cards. On the positive side, with the large number of patients involved in this analysis, most of this potential error variance would be expected to randomize out (12).

Further complicating the picture is that many patients probably do not choose to submit their warranty cards (exact percentage is unknown, since that information is commercial proprietary information), and among those, only about half of them choose to fill in the optional information regarding their diagnosis and treatment outcome. That makes it impossible to generalize directly to the population at large in terms of specific treatment outcomes to be expected, which is the same problem faced by many double-blind studies, some of which have involved as few as 11 patients (7).

On the confirming side, the device manufacturer does have a 30-day free use period after which any patient who does not believe the treatment is being effective can return the device for full refund. Less than 1% of units are returned this way, though that figure rose to 1.9% in 1999. Since the device can be relatively expensive, there would surely be a great temptation for most patients to return the unit if they didn't feel that it was being helpful.

An additional factor in the low return rate, as well as the relatively high apparent success rate in using the device for the treatment of pain, is the toll-free hotline on which patients can call the company for clinical assistance in their use of the device. Following this kind of additional clinical support, many patients who were not responding to treatment with the device report that they then do. On the other hand, company records show that

fewer than 0.01% of purchasers call for this kind of assistance.

All other considerations aside, it is an important finding that when 1,949 patients themselves were asked if MET is of therapeutic benefit, all but 136 of those, reporting across all pain categories, and who had at least three weeks of experience with the device, stated that it had helped them significantly.

While we await the evidence of additional double-blind, placebo-controlled experimental research studies, this kind of data, plus that given by the physician ratings cited earlier (our figures were only 2.11% off of those, the patients giving slightly higher ratings overall), can offer an increased measure of confidence to those practitioners who are now prescribing MET devices, or who contemplate using MET technology for their pain patients in the future.

Disclosure. Dr. Ray B. Smith is an employee of Electromedical Products International, Incorporated, the manufacturer of Alpha-Stim, the microcurrent electrical therapy device evaluated in this study.

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