Magnetic mattress pad use in patients with fibromyalgia: a randomized double-blind pilot study

Agatha P. Colbert[a,*], Marko S. Markov[b], Mandira Banerji[c] and Arthur A. Pilla[d]
[a]*Dept. of Physical Medicine and Rehabilitation, Tufts University School of Medicine, Boston, MA 02111, USA*
[b]*Department of Orthopedics, Mount Sinai School of Medicine, New York, USA*
[c]*Litterst & Associates, Newton, MA, USA*
[d]*Dept. of Orthopedics, Mount Sinai School of Medicine, New York, and Dept. of Biomedical Engineering, Columbia University, New York, USA*

Objective: To determine if the chronic pain and sleep disturbances experienced by patients with fibromyalgia can be improved by sleeping on a magnetic mattress pad.

Design: A double-blind randomized controlled trial.

Setting: Patients' homes and the private practice office of the principal investigator.

Patients: Thirty-five female subjects diagnosed with fibromyalgia syndrome were recruited. Thirty met inclusion/exclusion criteria and entered the study. Twenty-five completed it. One was lost to follow-up. Three were withdrawn for protocol violations and one because of an intercurrent hospitalization.

Intervention: Sleeping on an experimental (magnetized at a magnet surface field strength of 1100 $\pm$ 50 Gauss and delivering 200–600 Gauss to the skin surface or a sham (non-magnetized) mattress pad over a 16 week period.

Main Outcome Measures: Visual Analog Scales (VAS) for global wellbeing, pain, sleep, fatigue and tiredness on awakening; Total Myalgic Score; Pain Distribution Drawings; and a modified Fibromyalgia Impact Questionnaire.

Results: Subjects sleeping on the experimental mattress pad experienced a significant decrease in pain ($p < .05$), fatigue ($p < .006$), total myalgic score ($p < .03$), and pain distribution drawing ($p < .02$). Additionally, these subjects showed significant improvement in reported sleep ($p < .01$) and physical functioning as evidenced from the modified Fibromyalgia Impact Questionnaire ($p < .04$). Subjects sleeping on the sham mattress pad experienced no significant change in these same outcome measures. Subjects in both the control and experimental groups showed improvement in tiredness on wakening, demonstrating a placebo effect in this parameter. Neither group showed any effect on global wellbeing.

Conclusions: Sleeping on a magnetic mattress pad, with a magnet surface field strength of 1100 $\pm$ 50 Gauss, delivering 200–600 Gauss at the skin surface provides statistically significant and clinically relevant pain relief and sleep improvement in subjects with fibromyalgia. No adverse reactions were noted during the 16-week trial period.

1. Introduction

Fibromyalgia (FM), characterized by chronic, widespread, musculoskeletal pain and stiffness, disturbed sleep and fatigue, is a common, well-recognized clinical syndrome. Prevalence rates for women are estimated at 3.4%, and for the general population, 2% [1] with an even higher rate among military personnel, ranking second in the list of most frequently self-reported symptoms among Gulf War veterans (19.2%) [2]. The etiology and pathophysiology of this disorder remains uncertain. Current management strategies, both pharmaceutical and non-pharmaceutical, provide limited symptomatic relief. Medications such as the tricyclic antidepressants, benzodiazepines, anti-inflammatory agents, and other CNS active medications have produced meaningful improvement in 30–50% of patients [3], with unwanted side effects experienced by up to 98% [4]. Non-medicinal treatments including aerobic exercise and stress management [5], electroacupuncture [6], hypnotherapy [7], electromyography-biofeedback [8], and cognitive behavioral therapy [9] provide significant benefit, and

*Correspondence to: Agatha P.Colbert, M.D., 25 Grant Street, Suite 4, Waltham, MA 02453., USA. E-mail: apcolbert@mediaone.net.

Journal of Back and Musculoskeletal Rehabilitation 13 (1999) 19–31
ISSN 1053-8127 / $8.00

have minimal adverse effects, compared with medications, but require active compliance on the part of the patients for lasting relief.

Low frequency pulsing electromagnetic fields (EMF), first approved by the Food and Drug Administration (FDA) in 1979, are commonly used to treat recalcitrant bone fractures and soft tissue injuries [10,11]. Therapeutic permanent magnets are gaining worldwide popularity for self-administered pain control. The standard physical unit of measure for magnetic field strength is Tesla (T). One Tesla is equal to 10,000 Gauss (G). For comparison, the earth's magnetic field is approximately 0.5 G, while a standard MRI instrument utilizes magnetic fields in the range of 1.5–2.5 T (15,000–25,000 G). Gauss will be used to characterize the magnetic field level employed in this study. Therapeutic devices utilizing permanent magnets are not yet regulated in the United States.

A Medline search of the relevant literature in English revealed only three reports of controlled trials in which the therapeutic efficacy of permanent magnets was assessed. A 1982 study of a magnetic necklace for neck and shoulder pain found no difference in therapeutic benefit between groups wearing the sham or the magnetized necklaces [12]. A more recent double-blind pilot study documented approximately 70% pain reduction in patients with post-polio syndrome, after permanent magnet (surface field strength of 300–500 G) application to painful trigger points for a 45-minute period [13]. Neuropathic pain from diabetic neuropathy is also reportedly diminished as a result of wearing magnetic insoles [14].

A double-blind study at San-Ikukai Hospital in Japan [15] demonstrated effective pain control in over 70% of 375 individuals who used static magnetic mattress pads for a variety of musculoskeletal pain complaints. The permanent magnets embedded in the mattress pads had a surface field strength of 750–950 G. In Japan, these devices are regulated for therapeutic efficacy at a minimum surface field strength of 500 G. No adverse effects related to the use of static magnets were reported in any of these studies.

In general, permanent magnets used for therapeutic purposes are of two structural types: flexible (made of plastilloy) or hard (ceramic or metal based). Manufacturers characterize their magnetic products by the term "gauss rating", which describes the magnetization energy at the core of the magnet. This designation however, does not specify the therapeutic importance or dosimetry of a magnet as it gives no information about the magnetic field at the magnet's surface or the amount of magnetic energy delivered to the target tissue. The magnetic field strength (flux density) of a permanent magnet is measured with a magnetometer or Gauss meter, usually with a Hall effect probe. The flux density decreases exponentially with distance from the magnet's surface. The actual dosage of magnetic energy delivered to the target tissue(s) depends upon the relative size of the magnet and target and the distance the area to be treated is from the magnet. Since the magnetic field penetrates all tissues in exactly the same manner as in air dosimetry can be estimated, based on magnetic field measurements in air.

The magnetic field strength of mattress pads containing magnets is a function of the magnetization energy, the size, the volume and the shape of a particular magnet, as well as the configuration in which the magnets are placed in a given mattress pad. In addition, when an individual is lying on a foam mattress pad in which ceramic magnets are embedded, other factors, such as the individual's weight, the compressibility of the mattress foam, or whether the patient is in a side-lying, prone or supine position influence the magnetic dosage delivered to specific areas of the body. All layers of human tissue are equally penetrated by a magnetic field. The only factors that affect the actual magnetic field "seen" by the tissue are its distance from the surface of the magnet and its orientation with respect to that surface.

Although, to date, the clinical literature on therapy using permanent magnets is sparse, there is compelling evidence that both electromagnetic and static magnetic fields have physiologically relevant biological effects on the human organism [16–25].

In light of this background information on therapeutic magnets, and the fact that pharmaceutical management strategies for treating patients with fibromyalgia have limited success and a high incidence of associated adverse effects, this study was designed to investigate the potential benefits of a magnetic mattress pad for reducing pain and improving sleep in this patient population.

2. Subjects and methods

2.1. Subjects

Thirty-five female subjects with fibromyalgia were recruited from three sources: the principal investigator's clinical practice, a referring physical therapy group and a local fibromyalgia support group. Thirty subjects met the inclusion/exclusion criteria and were

Table 1
Baseline demographic characteristics by treatment group

	Experimental	Control
Age (yrs)	51.15 ± 13.50	48.17 ± 11.09
Weight (lbs)*	152.69 ± 37.19	178.33 ± 38.00
Months since diagnosis	34.62 ± 30.81	40.00 ± 12.00
Marital status		
Single	2	3
Married	3	4
Other	3	0
Employment status		
Working	10	6
Not working	3	6
On Medical Disability	1	3

*Weight was the only significant variable ($p = .005$).

accepted for participation in the study. Five subjects did not complete the study: one withdrew on her own, one was withdrawn because of an intercurrent psychiatric hospitalization, three others were withdrawn because of protocol violations. (See the Results section for more detail). The average age of the 25 subjects who completed the study was 49.7 years, ranging from 25 to 78 years. The average weight was 166 lbs., ranging from 115 to 216 lbs. Chronic diffuse pain symptoms were present for a minimum of two years in all subjects. Ten subjects were married; 5 were single; 7 divorced; and 3 were unmarried, but living with a partner. Sixteen were employed outside the home. Four were receiving medical disability benefits (see Table 1).

2.2. *Inclusion/exclusion criteria*

Subjects were enrolled in the study if they met the American College of Rheumatology's diagnostic criteria for fibromyalgia syndrome [26]. Patients had to have a history of pain for greater than three months, present on both the right and left sides of the body, and above and below the waist. Subjects had to agree to start no new pain medications, or additional pain management modalities during the 16-week trial period. Study participants were allowed to continue taking current medications or maintain therapies such as physical therapy, acupuncture, chiropractic or myofascial release, if they had been taking the medications or engaged in the specific therapeutic modality for a minimum of four previous weeks. The medications and therapeutic modalities being used by both patient groups are given in Tables 2 and 3 respectively. There was no significant difference in the number of subjects in both groups who maintained other therapies ($p = .40$) or continued to use prescribed medications ($p = .087$) during this study. It was anticipated that, if the magnetic mattress pad was to be effective, a significant improvement above and beyond that derived from a maintenance pain control program would be evident.

Table 2
Number of subjects in each group using FM related prescribed medications

Medication	Experimental	Control
Antidepressant	5	7
Anti-inflammatory	5	5
Anti-psychotic	0	1
Anxiolytic	1	6
Bladder	0	1
Gastrointestinal	2	5
Migraine	1	0
Muscle relaxant	1	3
Narcotic (mild)	0	4
Sleep aid	2	2
Other		
Guafenesin	0	1

Table 3
Number of subjects in each group using other therapeutic interventions

Therapy	Experimental	Control
Acupuncture	5	6
Alexander technique	1	0
Chiropractic	3	3
Craniosacral	4	0
Exercise (home program)	4	3
Massage	1	2
Myofascial release	2	1
Myotherapy	2	0
Osteopathy	0	1
Psychotherapy	1	1
Ultrasound	1	0

Two of the recruited candidates excluded themselves from the study because they had previously experienced a temporary worsening of symptoms while wearing 800 G neodymium magnets on acupuncture points. The other three recruits were excluded because they anticipated prolonged travel or the possibility of starting a new pain medication within the time period of the therapeutic trial.

The study was approved by the Tufts University School of Medicine Investigational Review Board through the Department of Physical Medicine and Rehabilitation. All subjects gave written informed consent.

2.3. *Research design*

This was a randomized double-blind pilot study, performed at the patient's home and at the principal investigator's private practice office. Subjects were randomly assigned to either the experimental or control

group. The mattress pads were shipped directly to the subject's home. The code was kept by the manufacturer until all data was entered into the computer system, at which time it was sent to the biostatistician who had no contact with the subjects. Neither the principal investigator nor her research assistant saw any of the mattress pads, and both remained blinded observers throughout the clinical assessments and data analysis phases. There was no contact between the code-keeper (manufacturer), the patient, anyone who had contact with the patient or the biostatistician, during the course of this study.

At baseline all subjects underwent an initial clinical examination by the principal investigator to confirm the diagnosis of fibromyalgia according to the criteria of the American College of Rheumatology [26]. Subjects were also seen for two follow-up visits: after 2 weeks of mattress use and again for a final evaluation at the end of the trial period. All evaluations were performed by the principal investigator to avoid problems with interrater reliability. Each subject mailed in completed weekly visual analog scales for global wellbeing, pain, sleep disturbance, fatigue and tiredness on wakening. Subjects were seen for a final visit after 16 weeks of sleeping on the mattress pad. The research assistant and principal investigator were available by telephone at all times during the study period and the majority of subjects were in weekly communication. Subjects were advised not to discuss issues related to the study if they happened to meet another participant in the study.

2.4. Therapeutic intervention

Subjects were asked to sleep nightly on either a magnetized mattress pad (experimental) or on a non-magnetized pad (sham) for a 16 week period. Subjects were told to use the mattress pad at night only and not to rest on it during the day. There were no visible or textural differences between the experimental and the sham mattress pads.

Both the experimental and sham mattress pads were provided by Magnetherapy, Inc*. Each pad (experimental and sham) contained 270 domino shaped ceramic pieces, measuring $2.0 \times 4.5 \times 1$ cm. The ceramic pieces were placed 4 cm apart and arranged in a pattern of 15 rows across and 18 rows down. All ceramic pieces were encased in the bottom layer of two layers of hospital grade foam, which were glued together. The entire pad was covered by a quilted cotton case. The total thickness of the mattress pad was 4 cm. The ceramic pieces in the mattress pads of the experimental group were magnetized with a surface field strength of 1100 ± 50 G. With this surface field strength and the positioning of magnets in the pad, it is estimated that between 200–600 G is delivered to the skin surface at various anatomical sites. This magnetic field level is well within that reported to achieve clinically meaningful therapeutic effects [13–15]. Magnets were placed such that the field direction facing the body attracted a north seeking compass needle. The sham ceramic pieces were identical in every way to those in the experimental magnets, but were not magnetized. All mattress pads were shipped directly by the manufacturer to each subject's home. Subjects were asked not to try to determine whether they had the experimental or sham pad. They were instructed to place the pad on their bed according to directions, as soon as it was delivered. When placed in its proper position, the thickest foam layer of the pad faced upwards, making it difficult to detect magnetization with lightweight items such as paperclips.

2.5. Outcome measures

The primary outcome measures were related to pain and sleep. Eight variables were studied: five Visual Analog Scales (VAS) i.e., global well-being, pain, sleep disturbance, fatigue and tiredness on wakening; Total Myalgic Score; a Body Pain Distribution Drawing; and a physical functioning score derived from the Fibromyalgia Impact Questionnaire (FIQ) [27].

2.6. Visual Analog Scales (VAS)

Subjects were requested to complete five VAS for global well-being, pain, sleep, fatigue and tiredness on wakening, on a weekly basis, during the 16-week study period. Visual Analog Scales are frequently used to assess these parameters in clinical trials of patients who have fibromyalgia [4,7,9,28,29]. Each VAS consisted of a 10 cm horizontal line anchored at both ends with "0" = no symptoms and "10" = worst possible symptoms. Subjects were asked to place a mark at the point on the scale, which represented their symptom level that day. In an attempt to adjust for the wide fluctuation in day to day symptoms experienced by patients with fibromyalgia, subjects were instructed to complete the VAS on Wednsedays at approximately 10 a.m.. They were specifically requested not to complete the VAS on the weekend. The completed VAS was mailed weekly, in a self-addressed stamped envelope, to the principal investigator's office.

2.7. Total myalgic score

The American College of Rheumatology requires that pain be reported by the patient in at least 11 of 18 tender points, when the examiner uses 4 kg of digital pressure (the point at which the thumbnail begins to blanch) [26] for a confirmed diagnosis of fibromyalgia. A baseline tender point evaluation, by palpation, was performed on the 18 predesignated anatomic regions by the principal investigator. This examination was done in accordance with the general procedures recommended for the standardized Manual Tender Point Survey [30] and scored on a three point scale. The intensity of tender point pain was scored as "2" for intense pain, "1" for moderate pain and "0" for no pain at these points. The total possible myalgic score was 36 if all the tested tender points were described as "intensely painful". Total myalgic scores were obtained by the principal investigator at the beginning and end of the trial period.

2.8. Body pain drawing

On a body drawing with anterior, posterior and lateral views, subjects were instructed to color, with either red (severe pain) or green (moderate pain), all painful areas. No coloring meant no pain. These drawings were quantified by superimposing a template of 316 contiguous circles, and counting the number of colored circles for a total score. The template was developed by the research assistant and principal investigator. Red circles were scored as "2" and green circles as "1". The baseline drawing score was compared to the endpoint drawing score. The worst possible score, i.e., if every circle has red coloration, is 632. To establish interrater reliability, subsets of data were scored independently by the principal investigator and research assistant. Interrater reliability was computed at $r = .72$.

2.9. Physical functioning

The FIQ [27] was developed and validated to assess current health status of women with FM. Item 1, a 10 part question, was used in this study to assess physical functioning in tasks of daily living. The best possible score for this item is 0, meaning that subjects are always able to do the 10 specified tasks of daily living. The worst possible score is 30, meaning they are never able to perform any of the tasks. Subjects were asked to complete the modified FIQ at the beginning and end of the trial period.

2.10. Daily diary

In addition to completing their weekly VAS, subjects were requested to keep a daily diary in which to document any unusual or adverse reactions. Exact number of hours of sleep or hours spent on the mattress pad was not documented.

2.11. Statistical analysis

All primary outcome measures were compared at the start of the study and at end of the 16th week for all subjects in the treated and sham groups. All outcome data were analyzed using a paired Student's t test. The analysis of variance F test confirmed there was no significant difference in the variances for all comparisons. The Kolgomorov-Smirnov test confirmed all data sets were normally distributed. Significance was accepted for $p \leqslant 0.05$.

3. Results

Thirty female subjects met the inclusion/exclusion criteria and were enrolled in the study, which began in March 1997 and was completed in December 1997. Five subjects did not complete the study. One from the sham group was lost to follow-up; a second also from the control group had an interim psychiatric hospitalization. Three others were withdrawn because of protocol violations. One subject from the experimental group added a new medication for pain control; another from the experimental group was discovered to have been taking morphine from the onset; one subject from the control group was found to be enrolled in an active pain management program. The final number of test subjects who completed the protocol and slept on the mattress pad for 16 weeks was 25; 13 in the experimental and 12 in the control group. Table 1 shows the demographics of the study participants. There was no significant difference in age, sex, employment, marital status, or months since onset of symptoms, between the experimental and control groups. The only significant variable was weight; the sham subjects were heavier than the real treatment subjects ($p = .005$). As will be seen, this had no effect on the outcome since the magnetic field level would have been within the 200–600 G range for the sham group had they been treated with active magnets.

The means of all outcome data for the control and experimental groups were compared at the start (base-

line) and end of treatment at week 16 (endpoint) using the paired Student's t test. The baseline and endpoint means and standard errors of these data are summarized in Table 4 and presented in Figs 1–4 for all VAS measures except for global wellbeing since there was no significant difference in this clinical outcome for either group at any time point (see Table 4). With the exception of wellbeing in which there was a significant difference between the two groups at the start of the study, there was no significant difference between the mean values at baseline for the experimental and control groups.

In order to assess the time course of response to treatment with static magnets, outcome data for pain, sleep, tiredness and fatigue were compared at monthly intervals by averaging the weekly means for the experimental and sham groups for each 4-week period in the study. These comparisons are shown in Figs 5–8. As shown in Fig. 5, by the 4th week subjects in the experimental group demonstrated a significant reduction in pain ($p < .05$) and this continued to decrease through week 12, with no significant further improvement by week 16. In contrast, there was no significant change in pain for the control group over the entire 16-week period. Figure 6 indicates a significant sleep improvement ($p < .03$) in the experimental group by week 12, with still further improvement at week 16 ($p < .01$). No significant sleep improvement was observed throughout the 16-week study period in the control group. Figure 7 shows a significant improvement in fatigue in the experimental group by week 8, with no further improvement by week 16. The control group showed no significant improvement in fatigue throughout the study period. Tiredness upon awakening improved significantly in both control and experimental groups by week 12, demonstrating a placebo effect of the magnetic field on this outcome parameter. Tiredness in the experimental group further improved by week 16, whereas there was no further improvement in the control group (Fig. 8).

In addition to the five VAS measures taken weekly, three dependent variables were scored at baseline and endpoint only: Total Myalgic Score, modified FIQ, and Body Pain Drawings. These data were analyzed for significance using the Student's paired t test and are summarized in Table 4. The Total Myalgic Score in the control group showed no significant change over the 16-week period while the subjects in the experimental group improved significantly from a mean $= 30.3 \pm 0.99$ to a mean $= 26.8 \pm 1.5$ ($p < .05$). The measure of daily functioning (FIQ) also remained constant for the control subjects across the 16 weeks, while the experimental group improved significantly from mean $= 7.6 \pm 1.8$ to a mean $= 5.3 \pm 1.7$ ($p < .05$). The results for the Pain Drawing data were similar to the FIQ. Although Body Pain Drawing Scores for the control subjects dropped somewhat over time, from mean $= 134 \pm 26$ to mean $= 109 \pm 23$, this was not significant ($p = .19$). The experimental group improved significantly over time ($p < .05$) and by endpoint had less reported pain than the sham treatment subjects. As with several of the VAS variables, there was a tendency for subjects in the experimental group to have better scores at the time of group assignment on both the FIQ and Pain Drawing. However, neither difference approached significance ($p = .21$ and .57 respectively). The correlations of these variables with patient weight were also not significant ($r = .32, p = .11; r = .13, p = .52$).

Review of the daily diaries and discussion with the subjects revealed that there had been no adverse effects related to the use of the magnetic mattress pad during the trial period. Three of the experimental subjects reported an intensification of their usual FM symptoms, i.e., aches, pains and fatigue, which subsided after the first 7 to 10 days of mattress pad use. One of the sham users noted increased anxiety during the first 2 weeks of use.

4. Discussion

This pilot study was undertaken to determine whether any clinical improvements could be documented in patients with FM as a result of sleeping on a magnetic mattress pad. The results demonstrate that subjects with FM who slept on mattress pads containing permanent magnets delivering 200–600 G to the skin surface, for a 16-week period, when compared to sham controls, experienced statistically significant and clinically relevant pain reduction and sleep improvement. This was evidenced by the self reported improved VAS for pain, sleep, and fatigue, a reduction in the total myalgic score and the subject's own assessment of her body pain distribution. The diminished pain and enhanced sleep also correlated with improvement in the subject's functional abilities for performing tasks of daily living as measured by the modified FIQ. These results are especially salient when compared with drug trials in patients with FM. Major clinical improvement in pain and/or sleep occurs in only 25% of subjects taking tricyclic medications and certain other central nervous system active medications [4,28]. The efficacy of

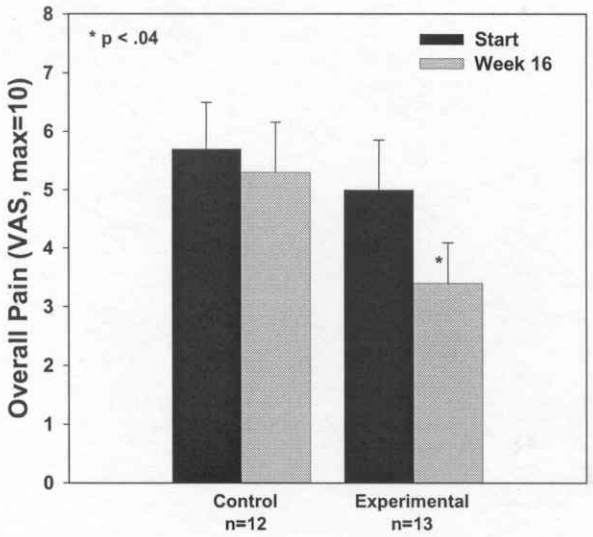

Fig. 1. Effect on pain of sleeping nightly on a mattress pad delivering 200–600 G static magnetic field to female patients with fibromyalgia. Use of a visual analog scale (VAS) showed mean overall pain decreased significantly by 32% for patients in the experimental group. The mean pain decrease of 7% for the sham treated patients was not significant.

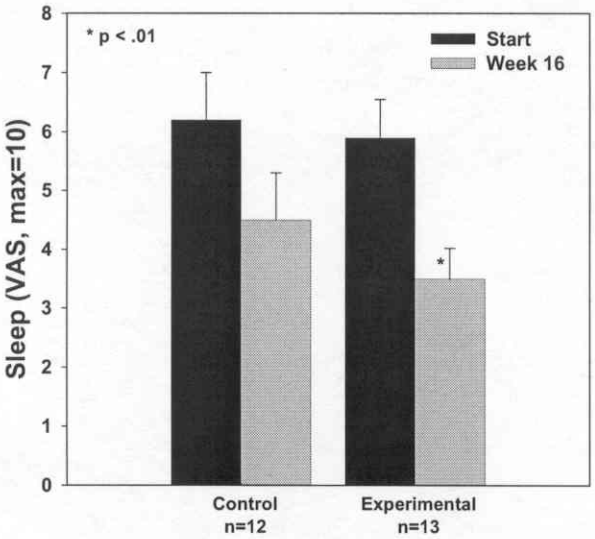

Fig. 2. Effect on sleep of sleeping nightly on a mattress pad delivering 200–600 G static magnetic field to female patients with fibromyalgia. Use of a visual analog scale (VAS) showed sleep was significantly improved by 40% for patients in the experimental group. The 27% change for the sham treated patients was not significant.

these medications lessens with time and the incidence of adverse effects is up to 98% [3]. The placebo effect seen in this study has been reported in other clinical trials of patients with FM [29,31,32]. Of interest here was the apparent beneficial effect of the firm mattress pad itself. Subjects in both groups reported continued comfort with the hardness of the mattress pad over the first half of the study period correlating with improvement in fatigue on the VAS in both groups. However, this placebo effect leveled off by week 8 in the control subjects, while the experimental group continued to improve over the entire 16-week trial (see Fig. 6). Seven of eight outcome measures showed statistically significant improvement in the experimental group, whereas

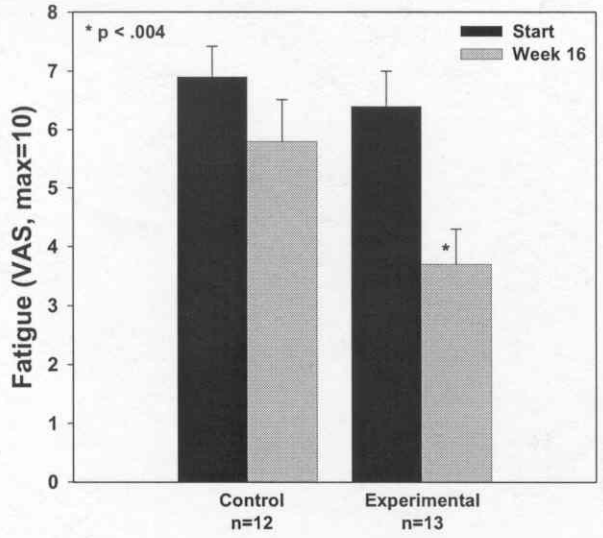

Fig. 3. Effect on fatigue of sleeping nightly on a mattress pad delivering 200–600 G static magnetic field to female patients with fibromyalgia. Use of a visual analog scale (VAS) showed fatigue was significantly decreased by 42% for patients in the experimental group. The 16% change for the sham treated patients was not significant.

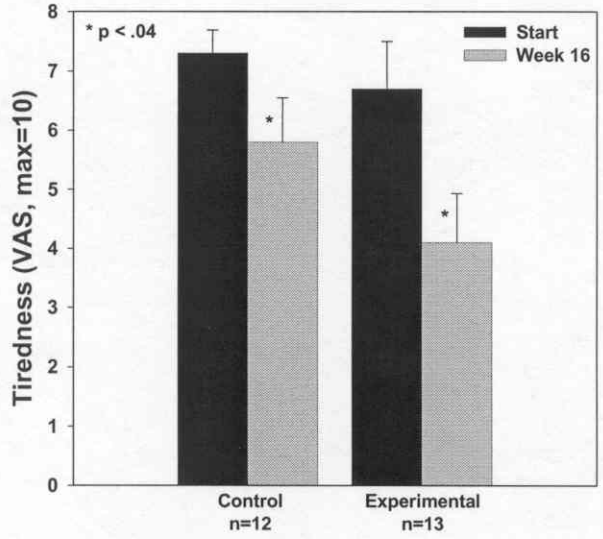

Fig. 4. Effect on tiredness upon awakening of sleeping nightly on a mattress pad delivering 200–600 G static magnetic field to female patients with fibromyalgia. Use of a visual analog scale (VAS) showed tiredness upon awakening decreased by 39% for patients in the experimental group and by 21% for the sham treated patients. These changes were significant in both groups, demonstrating a placebo effect of the magnetic field in this outcome measure, possibly reflecting the added comfort of the mattress pad.

only one of these eight measures improved significantly in the sham subjects. The only difference between the two groups was the addition of a static magnetic field, suggesting this therapeutic modality was effective for the experimental subjects in this study.

There is no longer any doubt that weak electromagnetic and static magnetic fields can modulate biochemical processes in biological tissue in a physiologically meaningful manner. Electromagnetic fields in current orthopedic clinical practice have been employed to treat delayed and non-union fractures [19,33–36], rotator cuff tendinitis [37], spinal fusions [38] and

Table 4
Overall results from five Visual Analog Scales, Total Myalgic Score, Body Pain Distribution Drawing, and Modified Fibromyalgia Impact Questionnaire by treatment group. Values reported are means ± SEM

	Experimental ($n = 13$)			Control ($n = 12$)		
	Start	Week 16	P value	Start	Week 16	P value
Pain	5.0 ± 0.45	3.4 ± 0.69	.04	5.7 ± 0.79	5.3 ± 0.85	.62
Sleep	5.9 ± 0.65	3.5 ± 0.52	.01	6.2 ± 0.80	4.5 ± 0.80	.149
Fatigue	6.4 ± 0.60	3.7 ± 0.58	.006	6.9 ± 0.52	5.8 ± 0.71	.176
Wellbeing	3.3 ± 0.68	2.6 ± 0.53	.438	5.4 ± 0.73	4.8 ± 0.88	.640
Tiredness	6.7 ± 0.80	4.1 ± 0.83	.019	7.3 ± 0.39	5.8 ± 0.75	.043
Myalgic Score	30.3 ± 0.99	26.8 ± 1.5	.025	30.6 ± 1.1	30.8 ± 0.61	.821
Pain Drawing	116 ± 20	62 ± 12	.015	134 ± 26	109 ± 23	.193
FIQ 1	7.6 ± 1.8	5.3 ± 1.7	.033	11.3 ± 2.2	11.6 ± 1.9	.845

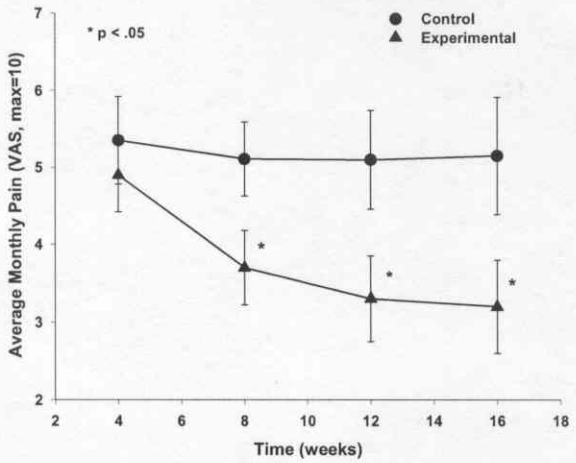

Fig. 5. Time course of effect of static magnetic field therapy (200–600 G) from mattress pads on pain in fibromyalgia. Each time point represents the mean value for this outcome measure averaged over the prior four-week period. Pain decreased significantly by week 8, with further decreases by week 16 in the experimental group. In contrast there was no significant decrease in pain throughout the 16-week trial period in the control group.

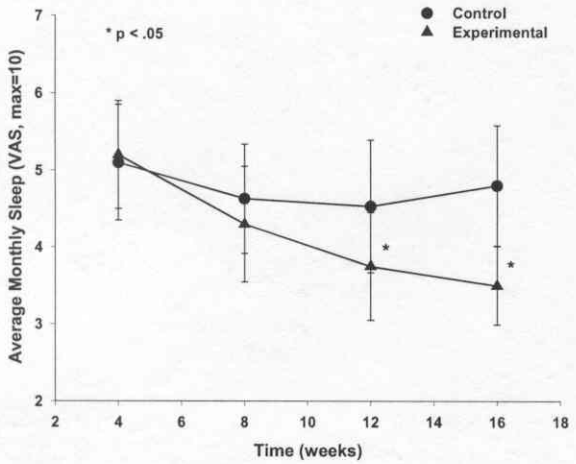

Fig. 6. Time course of effect of static magnetic field therapy (200–600 G) from mattress pads on sleep in fibromyalgia. Each time point represents the mean value for this outcome measure averaged over the prior four-week period. Sleep improved significantly by week 16 in the experimental group compared to no change in this outcome measure in the control group throughout the 16-week trial period.

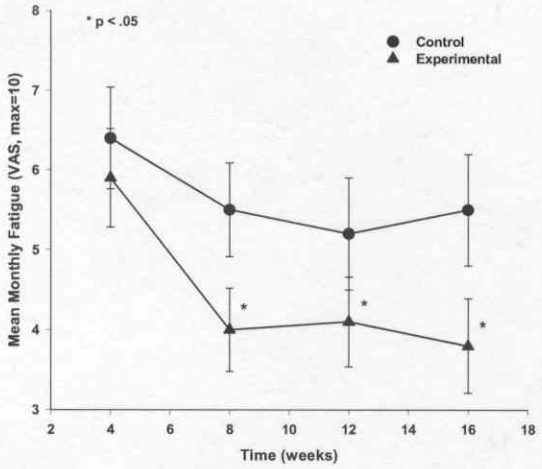

Fig. 7. Time course of effect of static magnetic field therapy (200–600 G) from mattress pads on fatigue in fibromyalgia. Each time point represents the mean value for this outcome measure averaged over the prior four-week period. Fatigue was significantly less in the experimental group by week 8 and was maintained through week 16. In contrast there was no change in this outcome measure in the control group throughout the 16-week trial period.

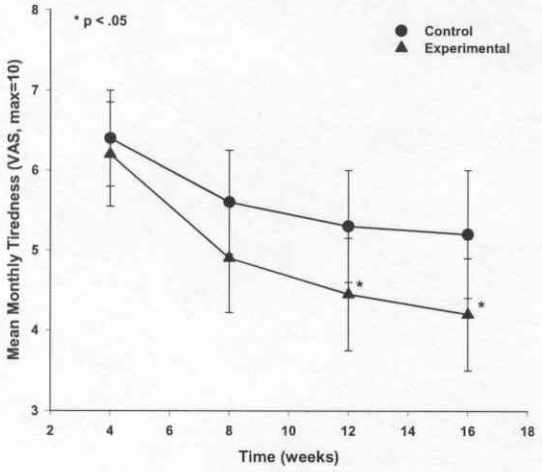

Fig. 8. Time course of effect of static magnetic field therapy (200–600 G) from mattress pads on tiredness upon awakening in fibromyalgia. Each time point represents the mean value for this outcome measure averaged over the prior four-week period. This measure significantly decreased in both control and experimental groups by week 8. In addition, both groups continued to decrease significantly, at different rates, through week 16. A placebo effect of magnetic field treatment was demonstrated for this outcome measure.

avascular necrosis [39] and were originally employed for the treatment of infections in the pre-antibiotic era [40]. Successful double blind clinical studies using non-thermal pulsed radio frequency signals have been reported for chronic wound repair [41], acute ankle sprains [42], and acute whiplash injuries [43,44]. These signals were also shown to increase skin microcirculation in diabetic patients [45].

There are numerous studies suggesting the mechanism of action of EMF involves ion/ligand binding at regulatory molecules and the increased release of cytokines and even neurotransmitters [46–49]. At the clinical level EMF are known to reduce edema [42] and increase peripheral blood flow [45], both of which might be factors in the pain reduction from permanent magnets reported here. However, the exact mechanisms of interaction which result in the pain reduction and sleep improvement observed in this study are still unknown [16–25,46,47]. The particular magnets used in this study have a surface field strength of approxi-

mately 1100 ± 50 G with a dose of about 200–600 G being delivered to the subject [23–25]. This dosage is within the range of reported bioeffects and takes into account the individual's weight, how much of the body surface contacted the mattress pad and whether the individual was prone, side-lying or supine. The duration of magnetic exposure for any given pain site can not be controlled in such a study. However, it is commonly accepted that magnetic therapy acts as a trigger for a physiologically relevant biochemical pathway, e.g., peripheral blood circulation and cytokine release since the magnetic field delivered to tissue is too weak to supply the energy for such processes.

Three experimental subjects documented an intensification of their FM symptoms during the first 1 to 2 weeks of mattress pad use. This type of "therapeutic exacerbation", a phenomenon observed by osteopathic physicians, chiropractors, physical therapists and other body workers, is characterized by a temporary worsening of symptoms during the initial weeks of treatment. We are postulating that the small perturbations in the body's bioelectromagnetic field caused by magnet placement may be evoking the same type of self limited "therapeutic exacerbation". The two recruits who initially excluded themselves from the study had previously experienced an exacerbation of symptoms while using permanent magnets on certain acupuncture points. They reported increased pain, nausea and dizziness while wearing the magnets, but obtained almost immediate relief of the symptoms when the magnets were removed. There are other reports of certain individuals who are particularly sensitive to electromagnetic fields [50]. This appears to be a subset of the population who should be identified and studied further.

The limitations in this exploratory study suggest recommendations for future studies. Stricter selection criteria should be implemented to exclude: subjects who are on morphine-like drugs; subjects who are involved in significant life changes such as marriage or divorce; anyone in the process of settling a medical disability claim; and subjects in whom a psychiatric disorder is a dominant feature. A certain range of weight should also be a selection criterion in order to assure minimal baseline differences between the groups. Subjects should have baseline VAS scores of at least 4 so as to eliminate a floor effect, i.e., when patient entry scores show low levels of impairment or discomfort, there is little room for measurable improvement. In addition, a lead-in assessment time for the two-week period prior to actually using the mattress pads would provide a more reliable baseline. Actual duration of time spent on the mattress pads and usual sleeping position should be more precisely documented.

5. Conclusions

The results of this pilot study demonstrate that sleeping for an average of 8 hours per night (prone, supine, or side-lying) on a mattress pad (containing 270 domino shaped ceramic magnets, measuring 2.0 × 4.5 × 1 cm, 4 cm apart and arranged in a pattern of 15 rows across and 18 rows down) which delivers a 200–600 G static magnetic field, for 16 weeks, provides significant pain relief and sleep improvement in women with FM. Because pharmaceutical agents are associated with a high rate of adverse effects and offer only minimum relief for the majority of patients, we recommend a trial of magnet therapy, as a non-invasive, painless, low risk adjunct to standard medical and physiatric interventions. Further controlled investigation of devices which incorporate permanent magnets for the treatment of chronic and acute musculoskeletal pain is definitely warranted. A minimum study period of 2 years is recommended to document long-term efficacy, assess the possibility for habituation, and determine optimal dosimetry, including strength of magnetic fields, exposure time and pole orientation. In this manner the efficacy of this promising simple, non-invasive treatment for FM may be properly established.

Acknowledgements

Partial support for the project was provided by Magnetherapy, Inc. and by the Horace W. Goldsmith Foundation.

The authors wish to honour the late William Roper, whose encouragement and support made this project possible.

Material in this manuscript was presented at the 4th annual meeting of the North American Academy of Magnetic Therapy on January 24, 1998 in Los Angeles, CA and at the 20th annual meeting of the Bioelectromagnetics Society on June 11, 1998 in St. Pete's Beach, FL, USA.

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