

## Double-Blind Study of Pulsing Magnetic Field Effects on Multiple Sclerosis

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### ABSTRACT

We performed a double-blind study to measure the clinical and subclinical effects of an alternative medicine magnetic device on disease activity in multiple sclerosis (MS). The MS patients were exposed to a magnetic pulsing device (Enermed) where the frequency of the magnetic pulse was in the 4–13 Hz range (50–100 milliGauss). A total of 30 MS patients wore the device on preselected sites between 10 and 24 hours a day for 2 months. Half of the patients (15) randomly received an Enermed device that was magnetically inactive and the other half received an active device. Each MS patient received a set of tests to evaluate MS disease status before and after wearing the Enermed device. The tests included (1) a clinical rating (Kurtzke, EDSS), (2) patient-reported performance scales, and (3) quantitative electroencephalography (QEEG) during a language task. Although there was no significant change between pretreatment and posttreatment in the EDSS scale, there was a significant improvement in the performance scale (PS) combined rating for bladder control, cognitive function, fatigue level, mobility, spasticity, and vision (active group  $-3.83 \pm 1.08$ ,  $p < 0.005$ ; placebo group  $-0.17 \pm 1.07$ , change in PS scale). There was also a significant change between pretreatment and posttreatment in alpha EEG magnitude during the language task recorded at various electrode sites on the left side. In this double-blind, placebo-controlled study, we have demonstrated a statistically significant effect of the Enermed magnetic pulsing device on patient performance scales and on alpha EEG magnitude during a language task.

### INTRODUCTION

**M**ultiple sclerosis (MS) is a disease associated with central nervous system (CNS) dysfunction, with myelin sheath damage and nerve conduction slowing. Why would pulsing magnetic fields have an effect on MS? The brain is an electric organ. Some suggest that its major cellu-

lar components, the neurons, can be viewed as combinations of capacitors in parallel (Chandos B, Khan A, Lai H, personal communication). Statistically significant results have shown electromagnetic field (EMF) effects on CNS in the following areas: (1) altered calcium transport across cellular membranes (Walleczek and Liburdy, 1990; Frey, 1992; Walleczek, 1992), which may fa-

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ilitate axonal conduction in brain damage caused by demyelination, (2) normalization of visual evoked potentials in chronic progressive MS (Sandyk, 1994), (3) altered release of melatonin from the pineal gland (Reiter, 1993, 1994), and (4) altered immune function of lymphocytes (Beers, 1989; Frey, 1992). Guseo (1987) performed a double-blind study showing that pulsing electromagnetic field therapy of MS reduced spasticity, improved bladder control, and improved myoenergetic effects. His study showed a significant improvement in patients treated with pulsing EMF consisting of a 300-Hz sine wave lasting 6 msec with a 13-msec damped oscillation period (peak field strength of 5–7 mT).

Our study used a pulsing magnetic field device developed by Energy Medicine Developments Inc., which has been used primarily for treatment of migraine (Walpole, 1993). Walpole (1993) developed an electrode-free detection system for measuring bioelectrical signals, which was used in this study. The purpose of this study was to test the effects of low-level pulsing magnetic fields on the impact of MS symptoms on the quality of life, the Extended Disability Status Scale (EDSS), and brain electrical activity (electroencephalography, EEG). All subjects were assessed before and after exposure to the magnetic field in a double-blind manner.

## DESIGN AND METHODS

This was a placebo-controlled, double-blind study to measure the clinical and subclinical effects of a pulsed magnetic field device on disease-related symptoms in MS. Patients were included in our study only if their physician confirmed in writing that they had clinically definite MS [clinically definite MS diagnosis, Poser criteria (Poser et al., 1983)]. There were two patients desiring to be in our study who were excluded because they had been diagnosed with only probable MS. A total of 30 MS patients were recruited for this study, and all 30 remained in the study through its completion.

### *Treatment*

*Magnetic Pulsing Device.* The MS patients were exposed to a magnetic pulsing device [En-

ermed, Energy Medicine Developments (North America) Inc., Vancouver, Canada] where the frequency of the magnetic pulse was programmed individually to each patient in the 4–13 Hz range depending on each patient's bioelectric frequency readout using the Enermed detection system. Although this study used the Enermed magnetic pulsing device with its patient-specific frequencies, there are other companies that market magnetic pulsing devices. The Enermed is a watch-sized, programmable, magnetic pulsing device (powered by a 3 V battery) that produces a 1 millisecond magnetic pulse in the 50–100 milliGauss range. The magnetic pulse is entirely positive during the pulse on one side of the device and entirely negative on the other side and is generated by a unipolar square-wave input current source. The magnetic coil is encased in a plastic shell measuring 1.6 by 1.75 by 0.5 inches.

Thirty MS patients received the Enermed magnetic device and wore it taped with the negative magnetic polarity side against the body. The patients were instructed to place the device on one of three different acupuncture points located on the shoulder, back, or hip. The optimal placement of the three positions was determined empirically. The first group of 8 patients was told to wear the device 24 hours a day, but subsequent patients were told to start by wearing the device 4 hours the first day and then to gradually increase wearing time by 1 hour each day to avoid side effects. The patients were exposed to the device for 2 months. Half of the patients (15) randomly received an Enermed device that was magnetically inactive (placebo), and the other half received an identical but active device. The placebo device had a flashing light and programmable circuit the same as the active device, but the magnetic coil was disconnected from the programmable circuit. The devices were randomly distributed to the MS patients as they came in for their first appointment (each day an active device and a placebo device were handed out). The investigator distributing the devices did not know which patient was given the active device even during programming of the frequencies.

*Bioelectric Measurement.* As part of the treatment, the Enermed detector was placed on the top of the patient's head to detect weak bio-

electric fields that are naturally produced by the body (Walpole, 1993). This detector consists of a piezoelectric crystal mounted in a padded head frame (fitted with a photodiode and light source), which was connected to an amplifier and PC computer for analysis. The time-domain signal was Fourier transformed and displayed as a spectrum with a range of 1–25 Hertz. This spectrum was used to determine possible energy deficits (Walpole, 1993). The 16 frequencies displaying the lowest amplitude or power were identified, and the Enermed magnetic pulsing device was programmed to emit magnetic fields with four or five of these deficit (low signal intensity) frequencies.

#### *Patient measures*

Each MS patient received a set of tests to evaluate MS disease status before and after wearing the Enermed device for 2 months. The tests included (1) a clinical rating [Kurtzke, EDSS (Kurtzke, 1983)], (2) patient-reported performance scales, (3) quantitative electroencephalography (QEEG) during eyes-closed baseline and during a language activation task, and (4) bioelectric measurement with the Enermed detector.

*Performance Scales.* The performance scales are a set of patient-reported measures of neurologic impairment developed by Dr. Carolyn Schwartz and the Frontier Science & Technology Research Foundation (Schwartz et al., 1996). The patient rated eight symptoms (bladder control, cognitive level, fatigue level, hand function, mobility, sensation, spasticity, and vision) on a scale of 0–5, where 0 = normal, 1 = minimal disability, 2 = mild disability, 3 = moderate disability, 4 = severe disability, 5 = totally disabled. The survey given to each patient had simple explanations for each symptom and each symptom severity score to help the patients rate their symptoms based on their impact on daily activities.

*Quantitative Electroencephalography (QEEG).* Cortical potentials were measured using a standard 19 channel electrocap (International 10/20 placements) and a Lexicor-24 digital instrument equipped with software called NeuroSearch-24 for generating topographic brain maps and frequency analysis (power spectra)

of cortical signals (delta, theta, alpha, beta waves). To make good electrical contact with the scalp, a small blunt metal object was used to gently scratch the skin on the scalp, and all 19 electrodes were filled with conductive gel (ECI, electrogel) to achieve an impedance below 7 Kohms. The wires from the cap were connected to an amplifier and computer for display and analysis. The EEG signal was acquired at a sampling rate of 128 points per second during the following subject activities: (1) eyes open relaxed with no other activity, (2) eyes closed relaxed with no other activity, and (3) eyes closed during a language task where the patient was asked to silently generate a verb after hearing a noun. The EEG signal was recorded with the subject in a comfortable recliner inside a sound-insulated auditory booth.

#### *Statistical analysis*

The paired *t*-test was used to compare pre-treatment and posttreatment values (within subjects test) for EDSS, combined performance scales, and EEG alpha waves. The unpaired *t*-test was used to compare changes in the same parameters for the active and placebo groups (between-subjects test). This statistical analysis addressed the following questions. Was there a significant difference in the patient end points after exposure to the device compared with the patient's own baseline? Was there a difference in how the two groups of MS patients responded (active versus placebo)?

## RESULTS

The baseline characteristics of the two MS patient groups (active and placebo groups) were well matched and are shown in Table 1. Although there was no significant change between pretreatment and posttreatment in the EDSS scale (active group  $0.17 \pm SE 0.12$ , placebo group  $0.32 \pm 0.22$  change in EDSS scale), there was significant improvement in the performance scale combined rating and in individual symptom ratings of bladder control, cognitive level, fatigue, mobility, spasticity, and vision (Table 2). A scatter plot showing the change in performance scale combined score

TABLE 1. BASELINE CHARACTERISTICS OF MS PATIENTS

Parameter	Active group n = 15 mean (SD)	Placebo group n = 15 mean (SD)
EDSS average	5.13 (3.0)	4.98 (2.57)
EDSS range	0.0–9.0	0.0–8.5
Patient-reported performance scales		
Bladder control	3.0 (1.9)	2.2 (1.5)
Cognition	1.9 (1.3)	2.1 (1.3)
Fatigue	3.7 (0.7)	3.2 (1.2)
Hand function	2.7 (1.5)	1.9 (1.4)
Mobility	4.1 (1.9)	3.9 (1.9)
Sensation	2.5 (1.6)	2.4 (1.4)
Spasticity	3.4 (1.4)	2.6 (1.7)
Vision	1.9 (1.2)	1.6 (1.1)
Combined 8 symptoms	23.2 (8.1)	19.9 (8.0)
EEG electrode P3 alpha magnitude (microvolts)	52.9 (19.7)	46.6 (23.0)
Patients with exacerbating- remitting MS	7	5
Patients with progressive MS (primary or secondary)	8	10
No. of females	11	10

versus treatment group is shown in Figure 1. The type of MS disease (exacerbating-remitting versus progressive) had no influence on how the patient responded to the treatment.

Of the 19 EEG electrodes measured, there was a significant change between active device group and placebo group in alpha EEG magnitude during the language task for electrode P3 (Fig. 2 and Table 3). There was also a sig-

nificant change between pretreatment and posttreatment alpha EEG magnitude for the active device group in the following EEG electrode positions: C3, P3, T5, F7, T3, and PZ (Table 3). The adverse reactions for both MS groups are shown in Table 4. EEG topographic maps from one patient are shown in Figure 3. The alpha band maps (Fig. 3, second column of colored images) show a dramatic posttreatment change in signal intensity between the eyes closed state and the language task state.

## DISCUSSION

In this double-blind, placebo-controlled study, we have demonstrated a statistically significant effect of the Enermed magnetic pulsing device on patient-reported performance scales and on alpha EEG magnitude during a language task. The two groups studied had very similar baseline characteristics, and both groups had a wide range of physical disabilities (from a normal neurologic examination to an EDSS of 9.0). The EDSS was not significantly different after treatment between the two groups. However, EDSS is a gross scale mainly relating to mobility. Improvements in such symptoms as fatigue, bladder control, and spasticity have little affect on the EDSS. The combined 8 symptom measurement showed a robust improvement in the active group even

TABLE 2. PATIENT-REPORTED PERFORMANCE SCALE COMBINED MEASURE<sup>a</sup>

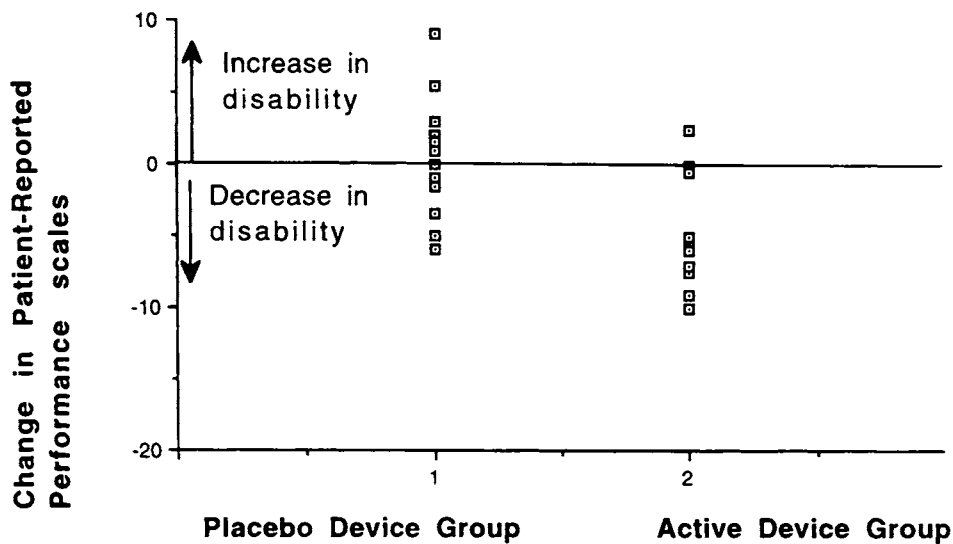
Functional scales disability	Average change active group	Average change placebo group	Comparison between groups
1. Bladder control	-0.50 (0.27)*	+0.07 (0.27)	NS
2. Cognition	-0.63 (0.37)*	-0.33 (0.21)*	NS
3. Fatigue level	-0.87 (0.40)*	-0.23 (0.18)	NS
4. Hand function	-0.20 (0.24)	+0.67 (0.21)*	$p < 0.02$
5. Mobility	-0.40 (0.27)*	-0.10 (0.34)	NS
6. Sensation	-0.20 (0.44)	-0.30 (0.34)*	NS
7. Spasticity	-0.80 (0.23)***	-0.17 (0.38)	NS
8. Vision	-0.23 (0.21)*	+0.23 (0.24)	NS
Total 1–8 (combined)	-3.83 (1.08)***	-0.17 (1.07)	$p < 0.05$

<sup>a</sup>Values are the average change (standard error in parenthesis) in quality of life measure (post-pre) with the scale as follows: 0 = normal, 1 = minimal disability, 2 = mild disability, 3 = moderate disability, 4 = severe disability, 5 = totally disabled. In other words, a negative change means less disability posttreatment, and a positive change means more disability posttreatment.

\*Significantly different between pretreatment and posttreatment ( $p < 0.05$ ) within the subject group (active/placebo).

\*\* $p < 0.01$ .

\*\*\* $p < 0.005$ .



**Fig. 1.** Scatter plot of change in performance scale (combined score from 8 symptoms) versus treatment group (active and placebo groups). The change score was calculated from the following subtraction:  $PS_{post} - PS_{pre}$ . A positive number means more disability, and a negative number means less disability.

though the patients had different MS symptoms.

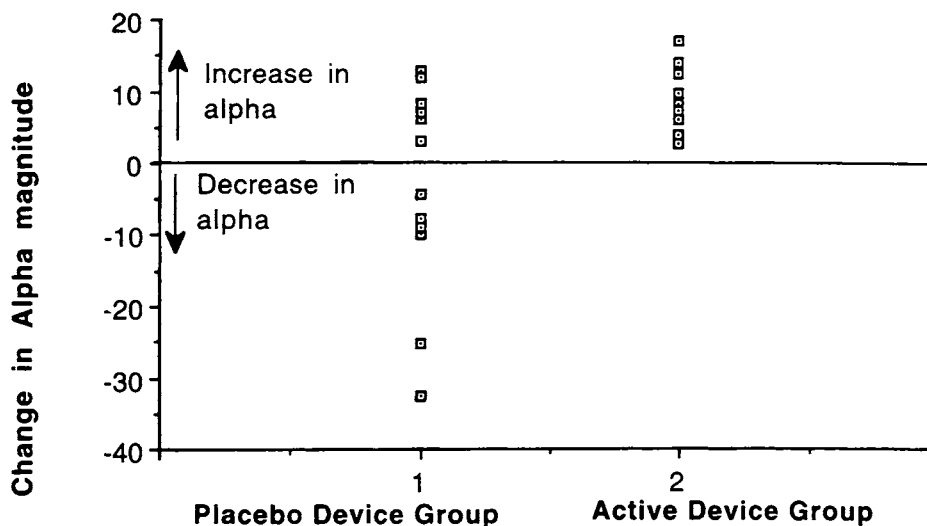
*Performance scales*

The PS developed by Schwartz et al. (1996) were chosen in our study as one of the main end points because we were interested in measuring the treatment effect on fatigue and other symptoms that are not assessed by the neurologic examination. Schwartz et al. (1996) performed a multicenter study where the PS and symptom inventory (SI) were validated in 300 patients with

MS and 300 healthy matched controls. Several other investigators have used quality of life measures as a tool to measure the impact of MS on patient function (Brunet et al., 1996; Cella et al., 1996; Hermann et al., 1996; Jonsson et al., 1996; Lankhorst et al., 1996; Malone and Lomaestro, 1996; Petajan et al., 1996).

*Quantitative EEG*

The increase in alpha EEG associated with the active pulsing magnetic field during a language task may be an indication of improve-



**FIG. 2.** Scatter plot of change in alpha EEG magnitude (8–12 Hz) versus treatment group (active and placebo groups). The change in alpha EEG was calculated from the following subtraction:  $EEG_{post} - EEG_{pre}$ . A positive number means more alpha EEG after treatment, and a negative number means less alpha EEG after treatment.

TABLE 3. EEG DATA: ALPHA EEG MAGNITUDE CHANGE (MICROVOLTS) DURING LANGUAGE TASK<sup>a</sup>

EEG scalp placement	Average change active group n = 12	Average change placebo group n = 14	Comparison between groups
Electrode C3	5.62 ± 1.6*	-0.60 ± 2.25	p < 0.05
Electrode P3	8.60 ± 1.3***	-2.97 ± 3.6	p < 0.01
Electrode T5	6.0 ± 1.9*	-1.96 ± 2.8	p < 0.05
Electrode F7	2.5 ± 0.8*	-0.88 ± 2.0	NS
Electrode T3	3.9 ± 0.8**	-0.43 ± 2.3	NS
Electrode PZ	7.79 ± 2.3*	-2.8 ± 3.9	p < 0.05

<sup>a</sup>Numbers were calculated from the alpha EEG magnitude signal during a language task and represent a change (posttreatment to pretreatment). A positive value means that the alpha wave increased posttreatment.

\*p < 0.01.

\*\*p < 0.005

\*\*\*p < 0.00001 comparing pretreatment and posttreatment within subject group.

ment in brain function. Alpha EEG waves are observed at 8–12 Hz (cycles per second) during a conscious relaxed brain state (Barlow, 1993). In normal brain activation, there is a decrease in alpha EEG, called alpha-blocking, in the area of brain that is aroused (Barlow, 1993). In the process of learning, the brain becomes more efficient during a task as the area of activated brain becomes smaller. Our hypothesis is that the decreased alpha EEG intensity during brain activation is a sign of local energy utilization. However, if noninvolved areas of brain can produce more alpha during the task, the brain is less activated. An individual who produces more alpha after treatment is, therefore, using less energy during the same task and has a more efficient brain (same concept as an automobile driving more miles per gallon of

gasoline). Brau and Ulrich (1990) observed an increase in alpha power during a visual tracking task that was higher in patients during an MS remission. In a study of normal volunteers, Lyskov et al. (1993) observed an increase in alpha EEG following exposure to 45 Hz magnetic fields (1.2 mT). Other investigators have shown an effect of magnetic fields on EEG activity in humans (Bell et al., 1992; Lebet et al., 1996) and on level of consciousness (Persinger et al., 1994; Tiller and Persinger, 1994).

### Blinding

Blinding in this study was easily achieved because both types of magnetic pulsing devices (active and placebo) had the same appearance and programmability. As evidence of true blinding, the first author was completely fooled by 3 patients in the placebo group. These 3 patients showed remarkable improvement after receiving the device.

TABLE 4. NUMBER OF MS PATIENTS WITH ADVERSE REACTIONS

Reaction	Active group	Placebo group
No adverse reactions	6	7
Increased headaches during first week	4	0
Increased depression or moodiness	0	4
Dizziness	2	0
Increased spasm during first week	2	0
Skin burning sensation and puffiness	2	1
Nausea	0	1
Major MS attack during treatment	1	2

### Remote Enermed effect

The Enermed device had an effect on brain EEG function even though the device was placed on the body at a site (acupuncture point) remote from the brain. We propose two hypotheses to explain this effect.

1. The frequency signal may be transmitted from the remote site to the brain via the sympathetic skin response (Watahiki et al., 1989). The sympathetic skin response (SSR) is usually

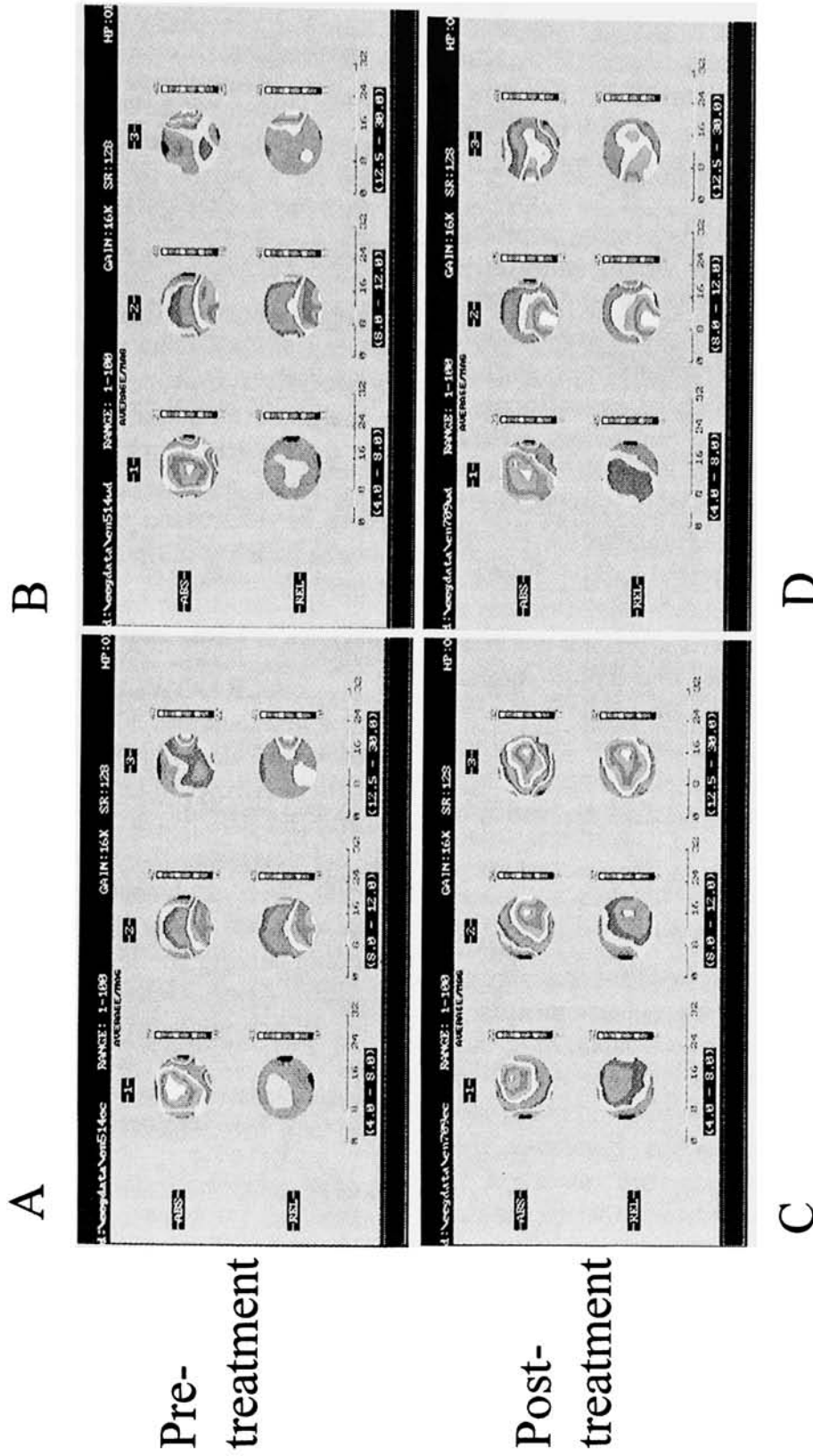


FIG. 3. EEG topographic maps from an MS patient during (A) eyes closed pretreatment, (B) during the language task pretreatment, (C) eyes closed posttreatment, (D) during the language task posttreatment. The maps are averaged over 100 epochs. Note the large increase in alpha EEG magnitude in the P3 electrode placement (D, posterior white area) during the language task compared with alpha shown in A, B, and C. P3 is located in the posterior right side above the occipital region. First column of images—delta waves (4–8 Hz); second column of images—alpha waves (8–12 Hz); third column of images—beta waves (12.5–30 Hz).

elicited by delivering electrical pulses (0.2 msec duration) to the median nerve at the wrist, and then a systemic response is recorded from electrodes placed on the ipsilateral hand (Watahiki et al., 1989). The stimulus affects the entire sympathetic nervous system even though only one small position along the median nerve is stimulated.

2. The frequency signal may be transmitted through the electric activity of the meridians (Sugano et al., 1994). In his study of acupuncture treatment of pain, Pomeranz theorizes that acupuncture stimulates peripheral nerves that send messages to the brain causing endorphin release, which blocks pain pathways in the brain (Horrigan, 1996). He also did experiments in which the acupuncture needles were inserted into nondecreased resistance points and showed that pain was not blocked. Pomeranz showed that specific kinds of nerves need to be stimulated within the meridians (such as the Hoku point) to activate endorphin release (Horrigan, 1996). Our treatment may not activate endorphins, but it may be important which types of nerves receive the magnetic signal in order to optimize the effect on multiple sclerosis.

#### *Adverse effects*

The adverse effects (Table 4) were different for the two treatment groups. For example, 4 of the patients in the active treatment group had increased headaches during the first week of treatment, but none of the placebo group noticed an increase in headaches. However, this increase in headaches was not observed in those active device patients who wore the device with a gradually increasing schedule compared with patients who were told to wear the device 24 hours a day from the beginning of treatment. Also, 4 of the patients in the placebo group had increased depression/moodiness that was not observed in the active group. The placebo device may not have been completely neutral because the patients were exposed to a small amount of energy from the flashing light and programmable circuitry. The patients who reported increased depression experienced a different type of depression during their expo-

sure to the placebo device compared with pre-treatment.

#### *Long-term effects*

In this study, we have shown a beneficial effect of pulsing magnetic fields on MS patients treated for a period of 2 months, which is far too short to assess its effects on the long-term progression of MS. To benefit MS patients over the long term, a treatment would need to be found that affects both the immune system and brain function. Do the pulsing magnetic fields provide only symptomatic relief? Could a pulsing magnetic frequency be found that would affect the defective immune system in MS patients? These are the types of questions that need to be addressed to determine the extent to which pulsing magnetic fields could benefit MS patients.

### ACKNOWLEDGMENTS

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