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Treatment of Migraine With Pulsing Electromagnetic Fields: A Double-Blind, Placebo-Controlled Study

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The effect of exposure to pulsing electromagnetic fields on migraine activity was evaluated by having 42 subjects (34 women and 8 men), who met the International Headache Society's criteria for migraine, participate in a double-blind, placebo-controlled study. Each subject kept a 1-month, pretreatment, baseline log of headache activity prior to being randomized to having either actual or placebo pulsing electromagnetic fields applied to their inner thighs for 1 hour per day, 5 days per week, for 2 weeks.

After exposure, all subjects kept the log for at least 1 follow-up month. During the first month of follow-up, 73% of those receiving actual exposure reported decreased headaches (45% good decrease, 14% excellent decrease) compared to half of those receiving the placebo (15% worse, 20% good, 0% excellent). Ten of the 22 subjects who had actual exposure received 2 additional weeks of actual exposure after their initial 1-month follow-up. All showed decreased headache activity (50% good, 38% excellent). Thirteen subjects from the actual exposure group elected not to receive additional exposure. Twelve of them showed decreased headache activity by the second month (29% good, 43% excellent). Eight of the subjects in the placebo group elected to receive 2 weeks of actual exposure after the initial 1-month follow-up with 75% showing decreased headache activity (38% good, 38% excellent).

In conclusion, exposure of the inner thighs to pulsing electromagnetic fields for at least 3 weeks is an effective, short-term intervention for migraine, but not tension headaches.

Key words: migraine, pulsing electromagnetic fields, treatment

Abbreviations: PEMFs pulsing electromagnetic fields

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Two pilot studies[1] have been conducted in which 23 chronic migraineurs were exposed to pulsing electromagnetic fields (PEMFs) over their inner thighs. In the open pilot study, 11 subjects kept a 2-week, pretreatment, baseline headache log before and after 2 to 3 weeks of exposure to PEMFs for 1 hour per day, 5 days per week. The number of headaches per week decreased from 4.03 during the baseline period to 0.43 during the initial 2-week follow-up and to 0.14 during the extended follow-up which averaged 8.1 months. In the double-blind pilot study, 9 subjects kept a 3-week log of headache activity and were then randomly assigned to receive 2 weeks of real or placebo PEMF exposures as described above. The 6 subjects exposed to the actual device first showed a change in headache activity from 3.32 per week to 0.58 per week. Three additional subjects in the blind study inadvertently received only half power and showed no change in headache activity. These results were sufficiently encouraging that undertaking a placebo-controlled study of the technique appeared to be worthwhile.

Pulsing electromagnetic fields have been in use as therapeutic modalities for at least 40 years. The PEMF units used in our studies (Diapulse, model D103, Diapulse, Inc of New York) are set to produce pulsed, high-frequency, high-peak power, electromagnetic energy at a frequency of 27.12 mHz in 65 microsecond bursts occurring in 600 pulse per second sequences at 975 peak

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watts. This is sufficient power to light a 60-watt bulb placed into the field. The field extends about 12 cm from the unit's head in a conical pattern. The unit's head is placed just above the area to be exposed and turned on for a set amount of time. The Diapulse device looks like a floor-mounted hair dryer from the 1950s, has a relatively loud fan, a ticking timer, and sufficient knobs, lights, meter, etc to be quite impressive.[1]

Exposure to PEMFs of the type described above appears to result in at least a temporary increase in peripheral blood flow. For example, Erdman[2] recorded peripheral blood flow from 20 normal subjects using both a temperature probe and volumetric measurements while they were being exposed to PEM-generated fields. He found a high correlation between the amount of energy produced by the device and peripheral blood flow, with increases beginning within about 8 minutes and reaching a plateau by 35 minutes. Pulse rate and rectal temperatures did not change. This relationship has been confirmed in basic studies of blood flow in rabbit ears.[3]

Freedman[4] has reviewed the effects of temperature biofeedback on peripheral blood flow. Numerous double-blind studies with 5- to 15-year follow-up have demonstrated that training patients with migraine to increase peripheral blood flow, through such techniques as temperature biofeedback from the finger, results in sustained decreases in all aspects of headache activity among a large percentage of those who successfully learn the techniques.[5] Thus, whatever other mechanisms come into play, a technique which is aimed solely at increasing peripheral blood flow frequently results in decreased headache activity when peripheral blood flow is successfully increased.

A placebo/nonspecific effects control group is vital to the study design because studies of headache usually find about a 30%, short-term response to inactive interventions. For example, Couch[6] reviewed 12 placebo-controlled headache studies and found a range of placebo response from 4% to 55% with most in the 30% range. While most studies, including those reviewed by Couch, used medicinal placebos, machines have also shown effective placebo responses.[7] The present study was especially likely to produce a placebo response because of the impressive nature of the device itself and the intense "treatment" regimen which required patients to make 10 visits to a major medical center. Nonspecific effects were also highly likely as all participants had to take time out of their normal routines to sit quietly in a comfortable room away from their daily stresses for 1 hour per day.

Subjects in headache studies usually keep a daily log of the frequency, duration, and intensity of headaches as well as use of headache-related medications before, during, and after the intervention period.[5] The efficacy of logs (sometimes called diaries or daily charts) for tracking headache activity is very high.[5,8]

Blanchard and Andrasik[5] reviewed the types of headache logs commonly in use and their validity and reliability. They found that subjects do not keep daily logs requiring several entries per day honestly. Rather, after a week or so, the subjects fill in events from memory. As numerous studies have shown that these memories for pain and related events are flawed to the point of uselessness, there is no point in asking people to keep detailed logs for several months. In one study, they found that only 72% of highly motivated staff members trying to test the validity of the type of log used in their clinic were able to keep a diary requiring four entries per day for 2 weeks. They found that the logs correlated well with reports from "significant others" about headache complaints and with global ratings of headache activity. Thus, the logs can be valid and reliable when in a useable format.

The type of log used in this study required the minimum possible subject compliance while gathering the most crucial data. It only required subjects to make one entry after each headache. The initial version required subjects to enter the date of occurrence, duration, worst and average intensity of the headache, and medications or other interventions utilized. The final version (used with most of the subjects) also required information about vomiting, description of the pain, and presence or absence of an aura. Andrasik[9] has recently endorsed this approach for the type of discontinuous headaches we evaluated and used it successfully in at least one study.[5] The minimum duration for an adequate evaluation of migraine activity has been established[10] and was exceeded by the month-long log utilized in this study.

METHODS

Design.–Subjects were diagnosed as having either migraine with aura or migraine without aura. All partici-

pants kept a 1-month, preexposure, baseline log. They were then randomized into real or placebo exposure groups with half the subjects receiving actual exposure to PEMFs and half receiving placebo exposure for 2 weeks. This was followed by a minimum of a 1-month follow-up during which subjects continued to keep the log every time they had a headache.

After the first month following exposure, patients were offered use of a working generator with the same exposure parameters as during the initial exposure period. Thus, patients failing to benefit from the initial exposure (sham or actual) were not denied access to actual exposure. Subjects kept logs for a minimum of 1 month after the second exposure.

Subjects.–Forty-eight subjects who met the International Headache Society's (IHS) criteria for migraine were recruited. Of these, 3 dropped out and 3 had only tension-type headaches during participation. The 42 subjects (8 men and 34 women) completing participation in this IRC-approved study were eligible for care at a large military medical center, had an average age of 45.6 years (SD 11.4, range 20 to 72, independent *t* between groups -1.26, *df* 20, *P*=.214), and had migraine (classical or common) for an average of 21.5 years (SD 15.9, range 3 to 70), with an average of 2.3 (SD 1.7) attacks per week. The demographic and headache characteristics of the participants are presented in Table 1. Headache diagnoses were made during an initial interview according to IHS classification.[11] Each subject had been diagnosed as having migraine by a physician as evidenced by entries in the medical records. No subjects with primarily medication rebound headaches, posttraumatic, sinus, cluster, tension, or other types of headaches participated. None of the women were or became pregnant during the study.

Three of the subjects who had migraine by history did not have any headaches which met the criteria for migraine during participation. Their headaches did meet the criteria for tension-type headaches, therefore, they were removed from the study and their data are reported separately.

Procedure.–Once subjects met the entrance criteria and consented to participate in the study, they were told to continue their current medications without significant change and were given a headache activity log (described in the introduction) to keep for 1 month. At the end of the month, they were randomized to be exposed to either actual or placebo PEMFs by a computer-generated algorithm which insured that the subjects would be evenly distributed after each 20 randomizations.

Evaluation of Headache Activity.– Subjects kept the log which listed headache frequency, duration, and intensity as well as use of headache-related medications throughout the entire period of participation. Pain intensity was rated on a visual analog scale, which has been shown to be highly reliable and effective.[12] Pain was rated on a scale of 0 (no pain) to 10 (so much pain that they would faint if they had to sustain it for 1 more second). The log we used is typical of those shown to be highly efficacious and required only one entry per headache.

Exposure to PEMFs or Placebo.–After keeping the initial baseline log for 1 month, subjects were exposed to PEMFs (real or placebo) on the thigh at a power/frequency setting of 6/600 for 1 hour per day, 5 days per week, for 2 weeks. The pilot results indicated that 2 weeks should have been sufficient for any effect likely to occur. The fields were directed to the thigh because it worked during the pilot study and the major blood vessels for the leg pass under that position. Neither the therapist exposing the subject nor the subject knew which group they were in. Only the therapist assigned to calibrate the devices knew which was which. The machines required calibration at least twice a week due to random loss of power every few weeks. Participants could not feel the machine working, so they could not tell which group they were in. However, each was asked whether they thought they were in the real or placebo group by having each rate how certain they were they had received the real treatment on a scale of 0 to 10, where 0 is not at all certain and 10 is sure they had received the real treatment.

The placebo machine was identical to the functioning machine both in looks (lights, dials, etc) and sounds (fan, timer noise, etc). The only difference was that several crucial tubes had been removed so it produced no field. As subjects could not sense the field, there was no way for them to know which machine was actually functioning.

Data Analysis and Presentation.–Changes in headache activity were determined solely from the log kept for a month before and after each intervention. Differences in proportion of subjects having headaches were analyzed using the *z* test for differences in proportions.

Changes in each subject's headache activity are pre-

Table 1.–Participant Characteristics

Subject	Age, y	Years of Migraine	Aura	Vomiting During Headache	Pain Pulses	Other Concurrent Headaches*
Placebo Exposure						
P1	60	40	Yes	?	?	None
P2	26	6	No	Yes	Yes	None
P3	62	60	Yes	Yes	Yes	None
P4	44	5	Yes	Yes	Yes	None
P5	26	9	Yes	?	?	None
P6	38	25	No	Yes	Yes	None
P7	37	7	No	Yes	?	None
P8	54	7	Yes	Yes	Yes	None
P9	54	4	Yes	Yes	Yes	None
P10	50	4	Yes	Yes	Yes	Mixed
P11	45	9	Yes	Yes	Yes	Mixed
P12	49	47	Yes	Yes	Yes	Mixed
P13	26	11	No	?	?	None
P14	38	10	?	?	?	Mixed
P15	37	17	Yes	Yes	Yes	Mixed
P16	48	8	Yes	Yes	Yes	Mixed
P17	43	3	Yes	No	Yes	Mixed + Sinus
P18	20	7	Yes	Yes	?	Mixed
P19	56	12	No	No	?	Mixed
P20	53	30	Yes	No	Yes	Mixed
Actual Exposure						
A1	52	15	No	Yes	Yes	Mixed
A2	39	20	Yes	Yes	?	Mixed
A3	36	18	Yes	Yes	?	None
A4	38	32	Yes	Used to	Yes	None
A5	37	24	Yes	Yes	No	None
A6	34	13	No	Yes	No	Mixed
A7	72	70	Yes	Yes	Yes	Mixed
A8	48	24	Yes	No	Yes	Mixed
A9	29	± 15	Yes	Once	Yes	Cluster, Mixed
A10	59	17	Yes	Yes	Yes	Mixed
A11	61	10	Yes	Yes	Yes	Mixed
A12	47	20	No	Yes	Yes	None
A13	49	20	Yes	Yes	No	Mixed
A14	47	32	Yes	Yes	Yes	None
A15	47	23	Yes	No	No	None
A16	53	13	Yes	Yes	No	None
A17	52	47	No	Yes	Yes	None
A18	60	41	No	Yes	Yes	Mixed
A19	50	43	Yes	Yes	Yes	Mixed
A20	52	25	Yes	Yes	No	None
A21	55	35	Yes	No	No	None
A22	33	29	Yes	?	?	Mixed

* Mixed indicates migraine and tension-type headache.

Table 2.–Migraine Activity of Subjects Exposed a Second Time to Pulsing Electromagnetic Fields

Subject	Preexposure Month: Frequency Intensity Duration	1 Month After Placebo Exposure: Frequency Intensity Duration	1 Month After Placebo Exposure: Overall Outcome*	1 Month After Placebo Exposure: Rate†	1 Month After Actual Exposure: Frequency Intensity Duration	1 Month After Actual Exposure: Overall Outcome*
Subjects were exposed to the actual device after the initial 1-month follow-up						
Placebo Exposure						
P2	1.5/4/4	3.5/5/4	W	1	1/5.3/3	NC
P3	1/7/9	0.5/8/11	M	5	0	E
P6	2.4/1/6	0.3/2/8	G	5	0.5/3/8	G
P8	1/4/4	1.5/5/5	NC	3	1/5/4	NC
P10	5.5/5/11	3.5/3/5	G	3	1/3/10	G
P11	1.5/5/15	2.5/5/22	NC	2	0.1/7/6	E
P12	3.3/4/23	3.5/3/24	NC	0	2/3/24	G
P16	2.3/4/8	1.3/4/13	NC	8	0.5/5/6	E

Subject	Preexposure Month: Frequency Intensity Duration	After Actual Exposure: Frequency Intensity Duration	After Actual Exposure: Overall Outcome*	After Actual Exposure: Rate†	After Second Actual Exposure: Frequency Intensity Duration	After Second Actual Exposure: Overall Outcome*
Subjects were exposed to the actual device a second time after the 1-month follow-up						
Actual Exposure						
A1	1/3/8	0.5/5/6	G	8	0	E
A2	2.8/5/20	1.3/6/24	G	5	0.4/?/24	G
A5	2.5/7/8	‡	NC	5	0	E
A7	1.8/3/3	1.3/4/1	M	0	0	E
A10	2.6/5/7	3/3/3	M	0	1.5/4/11	M
A15	2/5/8	3/6/6	NC	0	1/3/2	G
A18	5/4/11	6/4/12	G	1	6/3/8	G
A20	1/3/12	0.8/1/4	G	7	1/.5/2	G

Each exposure period consisted of daily, 1-hour exposures, five times per week, for 2 weeks.

Frequency indicates number of headaches per week, intensity of headache (on a scale of 0 to 10), duration of headache in hours.

* Overall outcome is the composite result of changes in frequency, duration, and intensity of headaches as well as amount of associated discomfort (eg, vomiting) and medication use over the course of participation: W indicates worse, more than a 10% increase in at least two variables with no decrease in others; NC no change, differences less than 10% of baseline activity on all variables; M minor decrease, decrease in headache activity of 10% to 19% on at least two variables; G good decrease, decrease of over 20% on at least two variables; E excellent decrease, headaches gone or nearly gone (less than one half hour in duration, pain intensity less than 2 on a 0 to 10 scale, frequency less than twice a month).

† Subject's rating of how certain they were they received actual exposure, on a scale of 0 to 10 with 10 being certain.

‡ Log was lost in transit, subject reported no change in headaches.

sented as a composite score derived from changes in frequency, duration, intensity, medication use, and ratings of associated discomfort (eg, vomiting). This method was chosen over presenting the individual measures in order to make the overall results easier to follow. The individual measures for each subject are reported in Tables appearing in the "Results" section. As can be seen from these tables, the overall change in group headache is obscured by the variety of idiosyncratic changes shown by the subjects comprising each group.

The composite scores were derived as follows: "worse" was defined as more than a 10% increase in at least two variables with no decrease in others; "no change" was defined as differences less than 10% of baseline activity on all variables; "minor decrease" was defined as a decrease in headache activity of 10% to 19% on at least two variables; a "good decrease" was defined as a decrease of over 20% on at least two variables; and an "excellent decrease" was when headaches were gone or nearly gone (less than 1/2 hour in duration, pain intensity less than 2 on 0 to 10 scale, frequency less than two per month).

RESULTS

Only one subject dropped out before completing the initial 2 weeks of exposure. However, three subjects dropped out of the study before sending in their 1-month follow-up logs. One of the dropouts received the placebo and two received actual exposure. No data were gathered for these subjects as they did not return their logs. Dropouts were replaced by the next subject joining the study.

Seventy-three percent of those receiving actual exposure initially showed decreased headaches (45% good, 14% excellent). Eight of these subjects received an additional 2 weeks of actual exposure after the initial follow-up month with all (100%) showing decreased headaches (50% good, 38% excellent). Twelve of the 13 subjects in the actual exposure group who did not receive additional exposure showed decreased headache activity by the second month (29% good, 43% excellent). Half of the placebo controls (10 of 20) showed at least minor decreases in headache activity (20% good, 0% excellent) while 15% got worse. Eight of the subjects initially receiving the placebo received 2 weeks of actual exposure after the 1-month follow-up with 75% showing decreased headache activity (38% good, 38% excellent). A z test for difference in proportions indicates that the actual exposure and placebo groups did not differ significantly after 2 weeks of exposure (z 1.53, P=.13) but did after 4 weeks of exposure (z 2.41, P=.016). As the group who received actual exposure for 2 weeks continued to improve after their first follow-up month, the overall rate of response to actual exposure at 2 months follow-up was 95% which is also significantly different from the placebo response (z 2.75, P=.006).

When only significant improvement (good and excellent responses) is considered, 4 of the 20 subjects receiving placebo showed good improvement and none showed excellent improvement (a 20% placebo response). Twenty of the 30 subjects given inadequate (2-week) actual exposure showed good to excellent improvement (a 67% response rate). These response rates are statistically different (z 2.7, P=.007).

Individual responses are detailed in Tables 2 and 3 and the results are summarized in Table 4.

The three subjects who only had tension-type headaches during the study period were not included in the overall analysis. All happened to be in the actual exposure group and none responded to exposure. One had chronic daily headaches at an average intensity of about 3 which did not respond to 2 weeks of actual exposure. The second subject had an average of one headache per week at an average intensity of 5, both before and after exposure to the actual device for 2 weeks during the blinded stage and to the active device for an additional 2 weeks. The third subject had headaches about 2 out of every 3 days at an average intensity of about 2, which did not respond to 2 weeks of actual exposure.

COMMENTS AND CONCLUSIONS

The crossover portion of the study's design was somewhat unusual. The investigators felt that it was crucial for those subjects in the placebo group who did not show improvement during the initial postexposure month to have an opportunity for actual exposure. After completing 2 weeks of exposure to either the actual or placebo device, all subjects were given the opportunity to volunteer for 2 weeks of actual exposure at the end of their initial 1-month follow-up period. Thus, most from the placebo group experiencing significantly decreased migraine activity due

Table 3.–Migraine Activity of Subjects Not Exposed a Second Time to Pulsing Electromagnetic Fields

Subject	Preexposure Month: Frequency Intensity Duration	1 Month After Placebo Exposure: Frequency Intensity Duration	Overall Outcome*	Rate†
Placebo Exposure				
P4	0.8/9/9	1.3/9/15	NC	0
P5	0.5/7/26	0.3/4/4	G	5
P7	2.3/3/8	1.8/5/6	NC	0
P9	3.5/2/14	1.3/1/25	M	–
P13	1.2/3/2	0.5/2/1	M	2
P14	2.3/4/7	1.8/4/4	M	2
P15	5.8/6/81	5.5/5/9	M	10
P17	3/5/4	0.5/4/6	G	8
P18	2/4/28	1/4/27	M	5
P19	0.7/6/26	1/7/96	W	6
P20	0.5/4/2	1/5/2	W	6

Subject	Preexposure Month: Frequency Intensity Duration	After Actual Exposure: Frequency Intensity Duration	Overall Outcome*	Rate†
Actual Exposure				
A4	0.7/3/5	1/3/5	NC	4
A6	0.9/5/11	0	E	10
A8	1.5/3/5	0.25/2/4	G	6
A9	1/3/7	1/5/7	NC	3
A11	2.5/5/6	0.5/4/6	G	4
A12	3.5/7/15	0.8/7/12	G	0
A13	0.6/5/2	0	E	9
A14	1.8/5/15	2.5/3/10	G	5
A16	3/6/18	1/5/7	G	4
A17	3.3/5/11	3.4/6/6	NC	3
A19	1/7/13	1/8/23	NC	–
A21	0.5/5/15	0.5/3/4	M	–
A22	0.3/6/6	0	E	5

Each exposure period consisted of daily, 1-hour exposures, five times per week, for 2 weeks.
Frequency indicates number of headaches per week, intensity of headache (on a scale of 0 to 10), duration of headache in hours.

* Overall outcome is the composite result of changes in frequency, duration, and intensity of headaches as well as amount of associated discomfort (eg, vomiting) and medication use over the course of participation: W indicates worse, more than a 10% increase in at least two variables with no decrease in others; NC no change, differences less than 10% of baseline activity on all variables; M minor decrease, decrease in headache activity of 10% to 19% on at least two variables; G good decrease, decrease of over 20% on at least two variables; E excellent decrease, headaches gone or nearly gone (less than one half hour in duration, pain intensity less than 2 on a 0 to 10 scale, frequency less than twice a month).

† Subject's rating of how certain they were they received actual exposure, on a scale of 0 to 10 with 10 being certain.

Table 4.–Summary of Results

Effect of Exposure on Headache*	No. (%) of Subjects				
	Actual Exposure First (n=20)		Placebo Exposure First (n=20)		
	Initial Month After Actual Exposure	Two Additional Weeks of Exposure After Initial Follow-up Month	Initial Month After Placebo Exposure	Two Weeks of Actual Exposure Following Initial Follow-up Month After Placebo Exposure	
Worse	0/22 (0)	0/8 (0)	3/20 (15)	0/8 (0)	
No change	5/22† (23)	0/8 (0)	7/20 (35)	2/8 (25)	
Minor decrease	3/22 (14)	1/8 (13)	6/20 (30)	0/8 (0)	
Good decrease	10/22 (45)	4/8 (50)	4/20 (20)	3/8 (38)	1 from no change
Excellent decrease	3/22 (14)	3/8 (38)	0/20 (0)	3/8 (38)	2 from no change
Total response ratio	16/22 (73)	8/8 (100)	10/20 (50)	6/8 (75)	

* Composite result of changes in frequency, duration, and intensity of headaches as well as amount of associated discomfort (eg, vomiting) and medication use over the course of participation: worse indicates more than a 10% increase in at least two variables with no decrease in others; no change, differences less than 10% of baseline activity on all variables; minor decrease, decrease in headache activity of 10% to 19% on at least two variables; good decrease, decrease of over 20% on at least two variables; excellent decrease, headaches gone or nearly gone (less than one half hour in duration, pain intensity less than 2 on a 0 to 10 scale, frequency less than twice a month).

† Nonresponse rate would have been 7/22 (32%) if reported tension headaches were included in the analysis.

to the placebo effect did not participate in this part. This enhanced our ability to differentiate placebo from actual effects. Subjects from both groups who did not show improvement were permitted to volunteer because the therapists did not know which was the actual exposure group. This complex process was required because our initial attempt at performing a standard crossover study[1] failed when subjects receiving actual exposure initially would not cross over to a placebo arm because their headaches had decreased significantly. A washout period was impractical because their headaches did not return for the entire follow-up period which averaged 8.1 months.

The decrements in headache activity during the open pilot study using this device[1] were far superior to those of the initial 2-week exposure to the actual device in this study. It is very likely that the difference is at least partially due to the exposure period of the open pilot being one third longer than provided by this study's initial exposure period. This possibility is validated by the increase in effectiveness from 73% to 100% upon an additional 2 weeks of exposure following the 1-month follow-up for those subjects requesting the second exposure. A second reason this study may have produced lower improvement rates may be that the subjects were more typical of average patients with migraine as they had headaches an average of 2.3 times per week which fits the accepted standards for migraine,[11] while the subjects in the open pilot were specifically selected as being "worst case" patients who had failed everything and had headaches an average of 4.3 times per week. A third possible reason for the difference was that subjects in the pilot study all ceased using preventive medications prior to initiation of exposure, while those in this study were not required to do so. During the double-blind portion of the study, the participants' rating of their belief that they received actual exposure was random with respect to whether they really received actual exposure. Thus, knowledge of which group the subject was in did not affect the results.

Neither migraine of traumatic origin nor tension headaches appear to respond to PEMFs. For four partici-

pants who had mixed headaches, it was possible to identify tension headaches in every log with a high degree of probability as they met all the criteria for tension-type headache and none for migraine. The rate of occurrence of these headaches remained approximately constant throughout participation while the rate of migraine dropped. When the data from these subjects were reevaluated eliminating the tension headaches, the subjects appeared to do much better than they did when the tension headaches were included. Thus, it is very likely that their migraines were decreasing while their tension headaches were holding steady.

Several of the subjects with mixed headaches reported that as the number of migraines decreased, they seemed to be getting more tension headaches. These "new" tension headaches occurred about as frequently as the migraines had been occurring. These individuals had usually indicated pain in the neck and shoulders along with symptoms of migraine during a "migraine." Thus, it is possible that concurrent tension headaches of which the subjects had not been previously aware were still occurring but were now noticed because the more intense migraines were no longer masking them.

The literature reviewed in the introduction indicates that the particular PEMF generator used in this study probably has some ability to increase peripheral blood flow. The same body of evidence does not seem to exist for the weaker battery-powered units, magnetic field generators which do not pulse, or permanent magnets. If the working hypothesis (that increased peripheral blood flow has resulted in decreased headache activity) is correct, then devices not capable of increasing peripheral blood flow to a similar extent may not be effective. This is supported by the three patients in the pilot study who received half the normal exposure, failing to show any change in headache activity.

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