A DOUBLE-BLIND EEG-RESPONSE TEST FOR A SUPPOSED ELECTROMAGNETIC FIELD-NEUTRALIZING DEVICE, PART I: VIA THE CLINICIAN EXPERTISE PROCEDURE

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Introduction

Brain potential mapping procedures are becoming increasingly more credible probes for revealing cerebral dysfunction. This method of assessment has been determined to be a valuable tool for distinguishing "normal" and "abnormal" states[1] and power spectral analyses of such time-domain data have been used for investigating psychological disorders[2]. Statistical significance probability mapping has been recently used as an adjunct to visual interpretation in a study of migraine with aura[3] while computerized electroencephalographic (EEG) asymmetries in depressed individuals have been reported in several studies[4-6]. One of us, Dr. Norman Shealy, has also noted that these patients do not follow photostimulation and/or respond with same or lower frequencies and, more importantly, have a worsening of their EEG asymmetry when a simple electric clock is placed within six inches of the crown of the head[6]. It has also been noted that many individuals who do not exhibit abnormalities by this particular electromagnetic (EM) stressor, do produce EEG asymmetry in response to a computer printer. Recommended EMF safety levels range from 0.5 milligauss (mG) to 2.5 mG as the maximum exposure with 1.0 mG as the preferred U.S. standard. In contrast, at approximately four inches from the device, a computer generates 4 to 20 mG, a coffee maker 6 to 29 mG, and a blender 50 to 220 mG.

On a much simpler organism scale, very recent experiments with (a) purified water samples[7], (b) in vitro liver enzyme (alkaline phosphatase) samples[8], and (c) in vivo fruit fly larvae (D melanogaster) samples[9], all showed a statistically significant difference ($p < 0.001$) between two unique treatments of these samples: (a) samples placed in a small electrically grounded Faraday cage with the cage placed on a shelf inside an incubator and (b) physically identical samples placed in an unshielded condition on the shelf immediately adjacent to the cage inside the incubator. These experiments were run simultaneously and they dramatically showed the effect of electromagnetic shielding from ambient EMF's inside the incubator on these three distinct types of samples.

A little earlier, it was found that water exhibits a type of EM memory characteristic via both (a) EM treatment of water held inside a solenoidal coil or outside a toroidal coil, provided the field intensities which were weak were above critical threshold levels[10] and (b) via studies of the hypersensitivity of some humans to

relatively weak EMF's at precise and patient specific frequencies that had been imprinted into a vial of water using a solenoidal coil[10]. The existence of this latter human phenomenon has been confirmed through double-blind clinical trials[11] and seems to manifest in most cases via spastic muscle groups, or greatly weakened muscle groups, in particular limbs or parts of the body for the affected person. Since the brain must be directly involved in such manifestations, this work brings us back to the possible use of EEG studies as a vehicle for studying some EMF effects on humans.

Because of societal concerns about EM pollution, various commercial products have appeared on the market, purportedly designed to neutralize harmful effects of environmental EMF's and increase human performance in such environments. The available evidence to support the efficacy of such devices for their designated purpose is, at present, largely anecdotal based on a variety of testimonials. However, this is such an important consideration for human welfare that we decided to test such claims using one of these products called the QLink[12]. We were able to obtain a supply of physically identical pendants from the supplier in the following two conditions: (a) The pre-treatment state before their master processor involvement and (b) The post- treatment state after use of this master processor. Thus, we were able to design a relatively clean double-blind type of experiment. The data arising from this experiment has been analyzed in several ways. This paper utilizes the standard professional expert opinion type of procedure which is essentially a qualitative "eye-balling" of the EEG data by an experienced practitioner. The second paper of this series looks at quantitative changes in the total power distributed over five sites on the head in the delta, theta, alpha and beta- bands of the brain waves. For both procedures, we find statistically supportive evidence of significant amelioration of the brain wave changes induced by the EM stressor.

Experimental Methods

Participant Pool: Recruiting for this study was done by way of radio announcement and general announcement at a local psychology graduate school. Those individuals with either a diagnosis of epilepsy or currently taking any prescription medications or under the age of eighteen were excluded. Of the 30 participants initiating the study, 18 were female and 12 were male with a mean age for the group of

36 years and a range from 18 to 61. Over the entire course of the study, one male and two females dropped out resulting in a final data base of 27 participants.

Testing Protocol: Each of the participants first presented themselves for a screening interview. At this time, they were further informed about the nature of the study, asked to fill out a Symptom Index and asked to sign an indication of informed consent.

There were initially 60 pendants prepared for this study: (1) 20 pre-master processor treated, (2) 20 post-master processor treated and (3) 20 sham units which did not have the metal pattern deposited on the plastic substrate of the commercial unit (see Fig 1). A code A, B, C was randomly assigned to these three groups of pendants and each had a small sticker with this labelling placed on it. The groups of 20, which had been labelled and stored in separate electrically grounded Faraday cages in California were shipped, one group at a time, by Federal Express on separate days, to Dr. Shealy in Missouri. On arrival, each group was placed in its own electrically grounded Faraday cage in remotely separated rooms of the Shealy Wellness Center (about 50 feet apart) until the actual experiment was ready to begin. No one in the clinic environment knew the relationship between the A, B, C coding on the pendants and the three specific natures of the devices, although there was a visible difference between the sham units and the other two.

The study followed a double-blind, cross-over design with two treatments for each participant. Each participant was randomly assigned an A, B, or C pendant at the beginning of each of the two treatments through a coding procedure that was not influenced by the initial interviewer. While attempts at true randomization were pursued, each participant was guaranteed to receive one of the commercial looking pendants (see Fig. 1) while many received a blank pendant for one of their treatments.

Each treatment was of one-month duration, initiated and concluded with an EEG session. Each of these sessions was of approximately one-hour duration with the EEG being taken with a Lexicore Neurosearch 24-channel system. Only the power spectra for the FP1, FP2, CZ, O1 and O2 contact points were displayed in the print-outs, along with the average power in the delta, theta, alpha and beta-bands.

In preparation for their EEG, each participant was given ear plugs, blindfolded and placed on an exam table. At this time, a folded towel was placed on their chest to

insure their inability to detect the presence of a pendant carefully placed on the towel at an appropriate time during the EEG session. Each EEG session consisted of (1) a 20 minute baseline (4-5 min sequence), (2) a 5 minute exposure to an electromagnetic stressor (a large digital clock), (3) a 5 minute exposure to one of the pendants alone, (4) a 10 minute exposure (two 5 minute sequences) to both the EM stressor and the pendant simultaneously, (5) a 10 minute exposure (two 5 minute sequences) without either the EM-stressor or the pendant, (6) after this pre-treatment EEG session, the participant was given this same pendant and instructed to wear it for one month excluding bathing and periods of sleep, (7) at the end of one month, the participants were measured again via the (1) through (5) steps of the original EEG session with the same pendant that they wore for a month, (8) participants were then instructed to avoid wearing their pendant for one week and then to return for a third EEG session at the end of the week and (9) at this time, the entire process was repeated with a new pendant of a different type (A, B, or C). At the conclusion of this second treatment phase, the original code was broken and each participant was informed as to the types of pendants they had been wearing. In addition, they were also given an active, commercial pendant for their personal use.

Results

Table 1 provides the overall EEG assessment results regarding the protective effects of the Clarus QLink pendant vs. the plastic pendant. Considering just the two pre treatment results with the placebo pendant, 6 of 18 testing occasions yielded positive effects on the EEG profiles; that is, the proportion of these testing sessions in which there were reduced EEG abnormalities with the placebo device was 0.33. Considering just the two post treatment results for the placebo pendant, this type of result jumps to 11/18 = 0.61. Thus, wearing the placebo for a month seemed to condition it in a very positive way.

Among the participants assigned to the Figure 1 – Type Pendant Group (A and C), we could not meaningfully discriminate between A and C so we combined them, presuming that they had somehow communicated with each other and transferred the key processing information. Thus, together, 44 of 77 sessions showed beneficial effects on EEG testing, yielding a proportion of 0.57. This ratio was the same for just pre treatment and just post treatment.

The most appropriate statistical test for significant differences between the proportions showing benefit is the Z-test for equality of proportions. One of the assumptions of this test is violated in the present study in that one sample size falls below 30 (the placebo group); however, the test is fairly robust in this regard and so was judged to be an acceptable analytic method. Results for this test indicated that the proportion of testing sessions demonstrating benefit from the active pendant was significantly larger than the proportion showing benefit from the sham device (0.57 vs. 0.33, $Z = 2.3$, $p < 0.01$).

The EEG data for a typical subject is provided in Figs. 2 and 3, with Fig. 2 relating to the first treatment and Fig. 3 relating to the second treatment. In both cases, the first two baseline readings have been excluded. The written professional assessment from the actual brain maps after the first treatment was "There is quite striking strong delta and theta activity, especially in the frontoparietal and central areas, with somewhat greater activity in the right frontoparietal than the left and in the right occipital than the left. Delta activity increases quite strikingly further with application of the Clarus, and all activity is attenuated with the application of the clock. With the clock plus the Clarus in the second run, it's essentially back to baseline, but in the post phase there is the best symmetry we've seen, with much more delta activity and now a striking 10-12 Hz activity bilaterally in the occipital region." The written professional assessment a month later after the second treatment was "Baseline shows a great deal of delta activity especially in frontoparietal and central areas and increasing amounts of theta especially centrally. With the Clarus there is initially a striking increase in delta activity in all leads. With the clock this becomes even more pronounced. With the Clarus plus the clock, it increases further. This is moderate quieting, back even almost below the baseline, in the first post period, but in the second post period much closer to baseline."

Discussion

In this type of study, two important factors deserve serious future consideration. The first is the interaction and information transfer between the A and C groups of patients. Whether this occurred in California before shipping or in Springfield prior to the first treatment experiment or during the month when the subjects were walking around Springfield wearing the pendants, is not known. Most likely, all three

possibilities played a part. The second is the interesting conditioning result found by wearing the placebo pendant while walking around Springfield as part of this larger group of simultaneous active pendant wearers. At this point in time, we can do no more than highlight this anomalous behavior.

In general, there are many patients clinically present with symptoms and EEG findings compatible with electromagnetic dysthymia as mentioned in the introduction. At present, there is no known conventional treatment for these patients who present with greater than average sensitivity and failure to respond to antidepressants. Thus, any simple, safe technique which moderates their exaggerated response to ordinary electrical devices may help prevent or diminish such anomalous electrical activity in the brain. The current device tested, the QLink pendant, is the first we have found which demonstrates meaningful potential for regulating this disorder.

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TABLE I

PROTECTIVE EFFECTS OF THE QLINK PENDANT VS. PLASTIC PENDANT

		POSITIVE	NEGATIVE
1.	PRE TREATMENT		
	A	7	3
	B (PLACEBO)	4	6
	C	5	5
2.	FIRST POST TREATMENT		
	A	3	6
	B (PLACEBO)	7	2
	C	5	5
3.	SECOND PRE TREATMENT		
	A	5	5
	B (PLACEBO)	2	6
	C	6	4
4.	SECOND POST TREATMENT		
	A	7	2
	B (PLACEBO)	4	5
	C	6	3