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Comment on the Treatment of Fibromyalgia Syndrome Using Low-Intensity Neurofeedback with the Flexyx Neurotherapy System: A Randomized Controlled Clinical Trial, or How to Go Crazy Over Nearly Nothing

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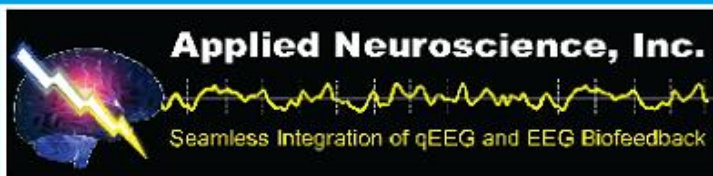
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Comment on the Treatment of Fibromyalgia Syndrome Using Low-Intensity Neurofeedback with the Flexyx Neurotherapy System: A Randomized Controlled Clinical Trial, or How to Go Crazy Over Nearly Nothing

Len Ochs, PhD

SUMMARY. This commentary to the Kravitz, Esty, Katz, and Fawcett (2006) study reports a significant flaw in the hardware used in the study. This hardware problem was not known at the time of the study and was only revealed later in technical analyses of the equipment. The difference in outcome between the Kravitz et al. study versus other studies using low energy electromagnetic feedback stimulation may be explained by this analysis. doi:10.1300/J184v10n02_04

KEYWORDS. Neurotherapy, Flexyx Neurotherapy System, fibromyalgia, controlled clinical trial, treatment, neurofeedback

An element missing in the Kravitz, Esty, Katz and Fawcett (2006) study is a discussion of the equipment used in formal and informal studies preceding that study, as well as in the Kravitz study, from the perspective of the underlying mechanism of the properties of the carrier medium that was used for the feedback stimulation. The Kravitz report treats all versions of the neurofeedback that were used as one undifferentiated type. Furthermore, there was no discussion of electromagnetic characteristics of the different EEG preamplifiers. In

fact, from what we now know, it is probable that the configuration of the I-330 C2 accounts for both the negative results and the side effects seen in the current study. The stimulation characteristics, electromagnetic characteristics or light of equipment used in previous studies are shown in Table 1.

First, a word about the lights embedded in the glasses that were worn for light feedback in the past and in the Kravitz et al. study. Long experience with the older I-400 preamplifier systems had led us to exclusively use lights that were

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TABLE 1. Comparison of Electromagnetic Fields in Equipment in Previous Studies.

Author	EEG Model	EM-characteristics	Feedback Carrier	Observations
Schoenberger et al.	I-400	None	Light	Positive outcome
Mueller et al.	I-400	None	Light	Positive outcome
Donaldson et al.	I-400	None	Light	Positive outcome
Kravitz et al.	I-330 C2	Strong	EMF+Light	Negative

taped over with up to 60 layers of black vinyl electrical tape. In fact, at times the layers of tape were so thick that they pressed upon the eyes of the patients wearing the glasses. Some of the therapists joked about the possibility that one or two photons per week might pass through the tape to the eyes. No light was ever visible under this condition, even though the results of the supposed visual feedback seemed satisfactory.

When the new I-330 C2 preamplifier was introduced, however, the strength of the stimulation seemed to be much greater than from the previous I-400. J&J Engineering worked with us to reduce current flow to the lights until any further reduction in light intensity would reduce the coded feedback information to a level lower than the thermal noise of the electrons passing through the wire to the lights in the glasses.

Because one fibromyalgia patient fell asleep for at least 45 minutes after each I-330 C2 session, I was asked to assess the problem and to see if I could further reduce the intensity of the feedback. At the start of the session I removed the glasses from the patient and moved them as far away from her face as the cable from the I-330 C2 would allow me—approximately four feet. I pressed a graphic button on the screen four times as I pulled the glasses further and further away, delivering what I thought was four seconds of feedback from the lights in the glasses. Each time I pressed the button I could see her EEG respond to the feedback impulse. For the first time since this patient began using the system, she was energized enough that she was able to take a reasonably long walk after the session, and she was both free from fibromyalgia pain and from mental fog. As we will see, what really happened is that there was one less

cable—the cable to the glasses—draped over the patient.

Early clinical use of the I-330 C2 EEG showed the same kinds of untoward effects as reported in the study. The presence of these effects impelled us to reduce the strength of the radio frequencies. Radio frequency interference filters were used to reduce the intensity of the electromagnetic field. This field was conducted by the EEG leads down to the patient's head. This made the EEG leads bidirectional conductors, carrying the EEG signal to the EEG preamplifier in one direction, and the electromagnetic field with the feedback signal, to the head in the other direction.

Again, the therapists using what was then called the Flexyx Neurofeedback System (FNS) system joked that I was soon going to have them moving the glasses into the next room. Our perplexity about the implausibility of such stimulation doing anything at all led us to feel the need to have the feedback signals analyzed, which led to a private grant to have the system evaluated by Lawrence Livermore Labs (LLNL) in Livermore, California.

Data from an unpublished LLNL (Bland, 2000) analysis of both the I-400 and the I-330 C2, which only became available after the commencement of Kravitz study, showed that the earlier I-400 models of the EEG had no discernable electromagnetic field around it, making the LEDs in the glasses the source of the feedback stimulation in the older system (Bland, 2000). However the I-330 C2 generated two different levels of electromagnetic field in addition to the light feedback stimulation.

The lowest level of electromagnetic field had strength of 10^{-21} watts/cm². This is the strength of the electromagnetic field while the unit is simply recording data, but not providing feedback—an emission for baseline operation, if you will. The second type of electromagnetic field has strength of 10^{-18} watts/cm².

The generator for these fields was considered by the author of the LLNL (Bland, 2000) study to be the crystal clock in the I-330 C2 that generates the timing signals for the on-board digital signal processor. The digital signal processor provides the capability of much faster analysis of signals than did the desktop computer based analysis in the older I-400 system. The I-400 system had no such on-board micro-

processor, and was, therefore, electromagnetically much quieter. Furthermore, Lawrence Livermore Labs said that the glasses, masked as such by the black tape, played no part in the stimulation feedback; in fact, they said that the effects from the system came from the radio frequency carrier wave for the feedback frequencies. All wires attached to the EEG were said by the LLNL staff to be antennas; that is, the EEG leads (active, reference, and ground), the cable from the EEG to the computer, and the cable to the glasses were all, in fact, antennas conducting the electromagnetic field.

Even with the field strength reduced by the radio frequency filters, it still proved somewhat tricky to conduct treatment with very sensitive patients. With the field strength lowered, I began to be bothered by what still seemed to be feedback stimulation that was too intense.

Because I could not remove the radio frequencies which were part and parcel of how the EEG system now operated, in desperation and holding my breath, I disconnected the glasses from the EEG by unplugging the glasses cable. Surprisingly, the system still worked—and worked better. The EEG leads remained the effective source of the radio frequencies once the cable to the glasses was removed. This, then, is the configuration we finally settled on with the I-330 C2, and used in treatment until still newer generations of equipment were produced by J&J with 3,000 to 4,000 times less electromagnetic field strength. In fact, we no longer needed the heavy electromagnetic field filters with the newer equipment. We have found, however, that we still need to continue the process of giving only seconds of feedback in any one session. By the time we discovered that we needed to eliminate the glasses, however, the Kravitz study, with the greater intensity electromagnetic field, was either well under way or had completed the running of participants.

In summary, the EEG preamplifier used in the Kravitz study emitted a hitherto unknown radio frequency stimulus that was strong enough to reduce the efficacy of the feedback system. This caused temporary side effects such as fatigue and interfered with the reduction of symptoms. This stimulation was not present in the previous generations of equipment, and is vastly reduced in intensity in the current models—reduced enough to not be a problem as long as we keep the feedback exposure short with most of the clinical conditions with which we now work. In conclusion, while there may be other factors that encumbered the efficacy of FNS in the study, it seems to me that the electromagnetic field, in general, but particularly from the glasses cable, was the primary reason that the Kravitz study did not succeed. This seems supported by our clinical experiences where we found the need to avoid using the cable and glasses in working with patients.

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