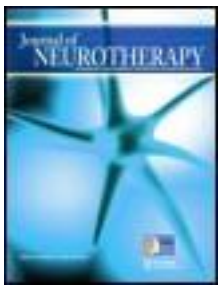

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The LENS (Low Energy Neurofeedback System): A Clinical Outcomes Study on One Hundred Patients at Stone Mountain Center, New York

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The LENS (Low Energy Neurofeedback System): A Clinical Outcomes Study on One Hundred Patients at Stone Mountain Center, New York

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SUMMARY. *Introduction*. The Low Energy Neurofeedback System (LENS) developed by Dr. Len Ochs (2006a) uses feedback in the form of a radio frequency carrier wave, administered at a positive *offset* frequency from the person's own dominant EEG frequency. Although it is an unusual biofeedback procedure, the feedback being invisible and the subject passive, clinical evidence supports the efficacy of the LENS across a spectrum of conditions. Published research studies (Schoenberger, Shifflet, Esty, Ochs, & Matheis, 2001; Donaldson, Sella, & Mueller, 1998; Mueller, Donaldson, Nelson, & Layman, 2001) have shown the effectiveness of the LENS method with traumatic brain injury (TBI) and with fibromyalgia. No study to date has evaluated LENS treatment across the spectrum of disorders and with a significantly large sample. This study was devised to address these issues. The study hypotheses were that the LENS treatment would be effective in reducing both systematic symptom ratings and measurements of EEG amplitudes, and that the therapeutic effect would produce the most rapid improvements in early sessions of treatment.

Method. "Blinded" research associates selected the first 100 patients from approximately 300 case files that met the following inclusion criteria: the person had received at least 10 treatment sessions, completed an initial CNS questionnaire, and that session-by-session subjective symptom ratings (SSRF) had been obtained. Patients ranged from 6 to 80 years old, almost evenly divided between male and female, with a wide range of symptoms and comorbid DSM-IV diagnoses.

Results. Data were statistically analyzed for significance and corelational variables. Average symptom ratings across 15 major problem areas (e.g., anxiety, mood disturbance, attentional problems, fatigue, pain, sleep problems, etc.) showed significant improvements ($p < .0001$) from beginning to end of treatment. After an average of only 20 treatments the mean average of patient symptom ratings (0-10) declined from 7.92 to 3.96, a 50% improvement. Equally significant was the drop in EEG amplitude at the highest amplitude electrode site (HAS; $p < .0001$) as well as a lesser but still significant decrease at Cz ($p < .002$). A final analysis of the average symptom score with the HAS score showed them to be highly correlated. All hypotheses were confirmed.

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Conclusions. LENS treatment appears to be very efficient and effective in rapidly reducing a wide range of symptoms. It particularly produces rapid improvements in the first five to six sessions. Recommendations for future research are provided. doi:10.1300/J184v10n02_06

KEYWORDS. Neurofeedback, EEG biofeedback, LENS, Low Energy Neurofeedback System

INTRODUCTION

The LENS

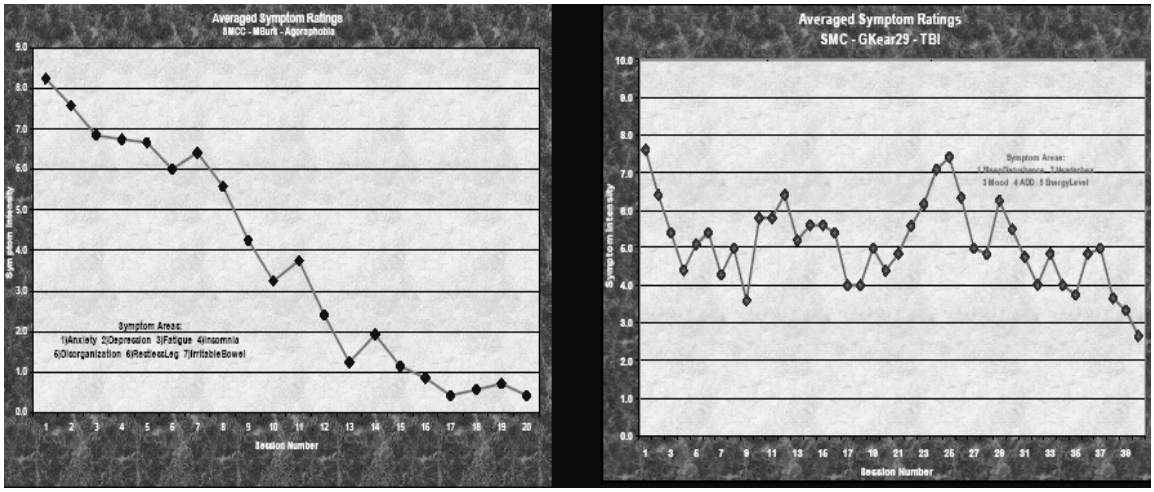
The Low Energy Neurofeedback System (LENS), devised by Dr. Len Ochs and tested by him and clinicians he has trained, has evolved continuously for 16 years (Ochs, 2006a). This neurofeedback system provides the patient with instantaneous electromagnetic field feedback that is "offset" by 5, 10, 15, or 20 Hz faster than the patient's dominant brainwave frequency to avoid any possibility of seizures being triggered by the procedure. While treatment relied on flashing lights in the past, a technical laboratory examination of the equipment showed the effective mechanism of treatment to be carried on radio frequency waves of extremely low intensity (Ochs, 2006b) and at 15-100m Hz frequency range.

Len Ochs (1994) had claimed to often obtain very significant improvements with many patients in less than ten sessions. This sometimes raised eyebrows and skepticism among colleagues in the field of neurofeedback. Nonetheless anecdotal experiences by trained LENS practitioners, including the authors, had confirmed the tenor of his claims. In addition, a growing body of published literature (Donaldson, Sella, & Mueller, 1998; Larsen, 2006; Mueller, Donaldson, Nelson, & Layman, 2001; Schoenberger, Shiflett, Esty, Ochs, & Matheis, 2001) had shown that the LENS was effective in ameliorating a variety of conditions associated with CNS dysfunction. What seemed unanswered was whether the LENS procedure produced more effective results early in treatment compared with later? Did all problems respond equally well, or some problems respond better and some worse than others? Therefore, the authors decided to gather data on the effects of LENS treatment in clinical office cases. This paper reports our findings.

The authors began several years ago to systematically collect assessment and outcome data on clinical cases that we treated. In each case, during the intake interview, patients completed the CNS Questionnaire (see Appendix) developed by Ochs (1996, 2006a). After completing the questionnaire patient were asked: "Of these reported symptoms/problem areas, which most impair your quality of life?" The problems of greatest concern were then listed first on our Subjective Symptom Reporting Scale (SSRS), followed by others, until five or more symptoms were elicited and entered. Each was rated by the patient on a 0 to 10 scale. They were told, "Ten (10) means the worst possible interference with your freedom, creativity, and ability to enjoy life; Zero (0) means the problem has disappeared or become unnoticeable." The therapist and the patient agreed to work collaboratively to track these numbers and their ratings were obtained at the beginning of every session. If the patient was a child, a parent or guardian was asked to help with the evaluation ratings. If a spouse or partner attended the treatment session, they were asked to help confirm the veracity of the answer–a "second opinion." Sometimes a symptom might have fluctuated over the week. For example, insomnia may have varied from 2 (a pretty good night) to a 6 (a much worse night's sleep) as reported on the SSRS rating form. In such cases, an average number for the period since the last session (e.g., the number 4, in our example) would to be entered for that period.

This study consists of a retrospective analysis of the five most serious symptoms reported by patients from the beginning to completion of treatment. Figure 1 displays examples of average symptom ratings that were obtained over

FIGURE 1. Progress of an "Easy" Care and a Difficult Case



the course of treatment with a relatively "easy" case that responded rapidly, and with a more difficult case that responded to treatment more gradually.

METHOD

Sample

As indicated, our subjects were not specially selected experimental subjects. They were patients who came for treatment between 2001 and 2005 at our offices in New Paltz, New York City, Long Island, and Kingston, New York. Approximately half of the patients were physician-referred. The sample ranged in age from age 6 to age 80 (see the distribution in Figure 2), with the majority of the sample between age 11 and 60 and fairly evenly divided between male and female. The majority of patients received LENS treatment on a weekly basis, but a few were treated twice weekly at the beginning, and then toward the end of treatment most patients were weaned off treatment with semi-weekly or monthly sessions.

Sampling Procedure

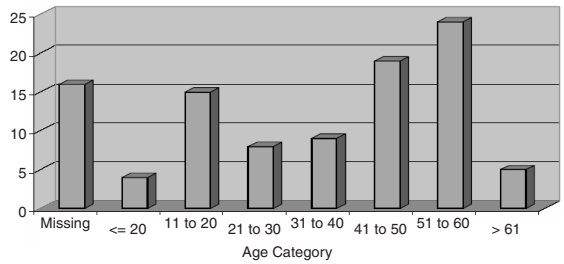
From a sample of about three hundred patient files, 100 cases were randomly selected for retrospective examination by blinded research associates who knew nothing about the patients personally. The research associates signed a form agreeing to protect patient privacy and the actual names were masked and a code name assigned to each file. No attempt was made to select "good responders" or "poor responders" to treatment. Simply the first 100 cases that met the following criteria were chosen for study. The file qualified for inclusion in the study if it had:

1. An initial LENS topographic brain map. Once selected, from these maps the microvolt amplitudes were obtained for the highest amplitude site (HAS) and for the Cz electrode site.
2. The patient had received 10 or more clinical treatment sessions with the LENS.
3. An intake CNS Questionnaire and initial symptom ratings had been completed for at least five symptoms, and symptom rating data had been gathered for at least 10 sessions.
4. Measurements of the overall EEG amplitudes at Cz and the HAS had been completed at the final treatment session.

Hypotheses

The following hypotheses were examined to explore how observations by Len Ochs and others clinicians would stand up to systematic assessment across a variety of symptom areas.

FIGURE 2. Distribution of Clients by Age



- Lens treatment (independent variable) will improve quality of life (dependent variable) across a variety of CNS-related symptom areas as reflected in the Subjective Symptom Rating Scale (Larsen, 2001).
- There will be a steady improvement in symptoms throughout treatment, but improvement will be most noticeable in the early sessions.
- There will be a decrease in overall EEG amplitudes over treatment at the highest amplitude site (HAS) and at the vertex (Cz) as measured on a LENS topographic map.
- There will be a correlation between subjective ratings of symptom improvement and an objective physiological measure of EEG amplitude as measured in microvolt levels.

In relation to the third hypothesis, it should be noted that Ochs (2006a) has suggested that cortical EEG amplitudes are highest where the cortex is functioning most poorly in inhibiting subcortical activity. The topographic map used in LENS practice, with its accompanying histogram (see Ochs, 2006a for an example) quantifies measures taken at 19 or more electrode sites. Based on our clinical experience, we predicted the HAS would decrease in amplitude as treatment rendered the cortex more functional.

Measures and Symptomatic Complaints

As indicated, ratings were examined on the Subjective Symptom Rating Scale (SSRS) and EEG amplitude measures were obtained. On the SSRS we used the patient's own descriptive terms such as "fatigue," "moodiness," "mental cloudiness," etc. Many patients were tracked on as many as eight to ten symptoms, but for the purposes of this study we selected only the five most significant symptoms.

After examination of the data 15 categories were developed to which all of the symptoms reported in the study could be assigned: Addiction (alcohol, drugs, food, sex), Anxiety Problem (generalized anxiety disorder, panic attacks, phobias, hypervigilance), Attention Problem (ADD/ADHD, problems concentrating), Cognitive Problem (cloudiness, cognitive deficit, memory problems, confusion), Dissociation (dissociated, detached, withdrawn), Disorganization (disorganized, procrastination), Problem in Executive Function (impaired planning, sequencing, impulsiveness), Pain, Fatigue (lack of energy, chronic fatigue, fibromyalgia), Flexibility Problem (rigidity or obsessive-compulsive disorder), Mood Disturbance (dysthymia, depression, bipolar disorder, irritability, explosiveness), Sleep Disturbance (insomnia, early morning awakening, restless legs), and a Miscellaneous category for less frequently encountered symptoms (tics, seizures, psychotic symptoms). The distribution of symptoms by category in our sample may be seen in Figure 3. It can be observed that the mostly highly represented problem areas were mood disturbance, followed by problems with cognition, pain, disorganization, sleep, anxiety, attention, and fatigue. Although most patients qualified for multiple diagnoses, the complexity of problems in the patient sample may be seen in Figure 4.

Equipment

All treatment was rendered on J&J I-330 C2 or mini-C2 EEG processors with a sampling rate of 1,028 samples per second, using the electromagnetic emissions of their crystal clock, offset at a faster frequency from the dominant brainwave frequency. All treatment used Ochs Labs proprietary versions of J&J's USE 2 or USE 3 software to administer the stimulations. Maps and offset assessments were processed on Ochs Labs proprietary Report Generator.

All treatment followed an initial brain map at 19 or 21 sites, mapping each site individually and processing the map and histogram for delta, theta, alpha and beta frequency bands, along

with a measure of total amplitude and dominant frequency maps and histograms. Where it was possible to do an Offset assessment (meaning the patient was *not too* neurologically sensitive) this was done. If an Offset assessment could not be obtained because the patient seemed too hyper-reactive, the default of a +20Hz offset was used. The hardier patients were exposed to somewhere from 1 to 21 seconds of stimulation (10^{-18} watts/sq. cm^2) per session, while patients who were judged to be too sensitive/reactive early in treatment were simply exposed (at least initially) to the background energy level of the system without stimulation, which has been found in laboratory analyses to be only 10^{-21} watts/sq. cm^2 in intensity. The number of treatment sites and seconds of exposure were based on the sensitivity/reactivity of the patient as discussed in Ochs (2006a).

Confounding Factors

About half of our patients come to us on medication prescribed by their physician. Most were informed that they should tell their doctor that they were receiving neurofeedback and releases were signed so that clinicians from our facility could talk to their physicians, neurologists, or psychiatrists. They were advised that during our treatment they might find themselves needing less medication to achieve the same effect, and should they wish to reduce medications, they should do so under the care of their prescribing physician.

Although neurofeedback was, in our estimate, the main therapeutic modality, a proportion of the patients were also treated with photonic stimulation (an infrared stimulation device) for peripheral pain and fatigue syndromes. Several were given instructions in HeartMath (heart rate variability biofeedback). Some took supplements such as B vitamins, glyconutritionals, SAM-e and Rhodiola Rosea. During treatment, patients did in fact often *decrease their prescription medications*. (This measure, in fact, could be a pivotal one to examine in future studies.) We did not control for any of these variables, nor did it seem possible to do so. The only thing that all 100 patients had in common was that they received the LENS treatment for over 10 sessions, and most patients had 20 sessions of LENS treatment (see Figure 5). The mean number of treatment sessions was 19.43 (SD = 5.51). As clinicians, our initial and primary intent in working with these patients was in helping them improve their quality of life and functioning, not conducting a controlled study.

FIGURE 3. Frequency of Complaint by Category

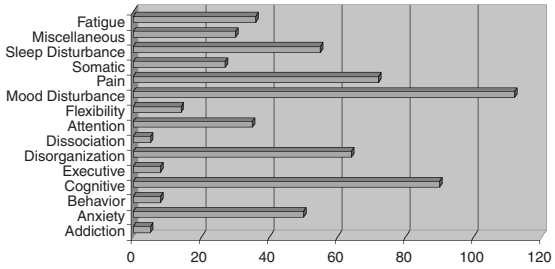
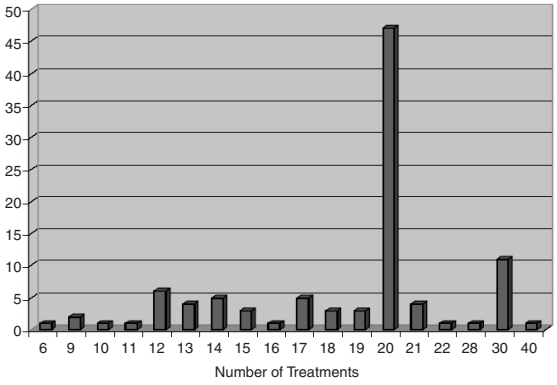


FIGURE 4

DSM IV-r Related Diagnostic Categories Represented in Study

- ADD, ADHD, attentional problems of all sorts, Learning Disabilities
- Affective Disorders including Monopolar and Bipolar Depression, Dysthymia
- Autistic Spectrum Disorders, including Aspergers Syndrome
- Anorexia and Bulimia
- Dissociation
- Epilepsy and Seizure disorder
- Explosive Personality Disorder, Oppositional-Defiance
- Fibromyalgia, Chronic Fatigue, Lyme Disease, Epstein-Barr syndrome
- High Blood Pressure
- Headaches (Cluster, Tension and Migraine)
- Irritable Bowel, Ulcerative Collitis
- Obsessive Compulsive Disorder
- Pain, both Acute and Chronic or both, Muscle Spasms, Dystonia
- Paranoia and Schizophrenia
- Post Traumatic Stress Disorder (PTSD)
- Tourettes, and Tic Disorders
- Traumatic Brain and Spinal Injury (TBI)

FIGURE 5. Distribution of Number of Treatments



Data Analysis

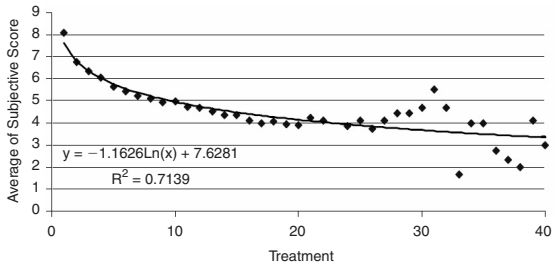
After gathering and entering data into spreadsheets, the data was compiled and sent to an independent statistician for analysis. Two sample paired t-tests were run on EEG amplitude changes at the HAS and at Cz pre- and post-treatment, and on the average symptom ratings pre- and post-treatment. Logarithmic regressions were then computed on each symptom category to test if the patients were reporting a reduction in symptoms and if that decline was rapid in early treatment sessions.

RESULTS

The results confirmed all hypotheses and the outcomes were found to be highly statistically significant. Every symptom category not only decreased over the course of treatment, demonstrating that LENS treatment was clinically effective in ameliorating widely diverse CNS-related problems, but the second hypothesis was confirmed as well. The decline in the average ratings of symptom categories was found to be greater in early sessions of treatment, with further improvements occurring at a more gradual pace over time, as the experience of Ochs (1994) had suggested. This finding may be seen in Figure 6. It was noted, however, that there was still a definite ongoing continuum of improvement up to 20 sessions and beyond.

In relation to this finding, clinical observations have encouraged us to urge that patients not discontinue LENS treatment after the initial rapid improvements, sometimes called "the honeymoon phase" of treatment because the nervous system continues to gradually reorganize itself. Further treatments beyond the first 10 to 20 sessions may be necessary to consolidate and promote maintenance of the changes achieved early in treatment. Determination of the maintenance of changes over time will require a study with a post-treatment follow-up period.

FIGURE 6. Plot of Average Score by Treatment All Categories



When each of the 15 symptom categories was plotted by treatment time, it was found that on average the rate of improvement followed a logarithmic curve, with most of the improvements occurring early in treatment, with smaller but steady gains being made thereafter. Although each category appeared slightly different, they all showed the same pattern of rapid improvement with the exception of addiction problems, which was the only symptom category that did not appear responsive to LENS treatment in this study. Figure 7 shows linear regression lines for four sample symptom areas, illustrating what was seen across symptom categories. The r-squared values in rank order of improvement for symptom categories were: Disorganization, .985; Cognitive Problems, .983; Attention, .956; Fatigue, .955; Mood Disturbances, .954; Pain, .941; Anxiety, .928; Executive Function, .903; Miscellaneous Problems, .894; Sleep Disturbances, .891; Somatic Complaints, .874; Flexibility, .864; Behavioral Problems, .857; Dissociation, .715; and Addictions, .0003.

It is evident as seen in Figure 8 that as the length of treatment progresses, particularly beyond 20 sessions (at which point most subjects had completed treatment), the number of observed occurrences of symptoms decreases. Thus beyond 20 sessions and with symptoms that were less frequently represented in the sample, the findings become less reliable as seen in Figure 9. This did not, however, affect the confirmation of the hypotheses of the study which were primarily based on the effect of the first 20 sessions of treatment.

As indicated, the first hypothesis was confirmed by our findings. Figure 10 displays the change during LENS treatment of the mean symptom ratings which, interestingly at post-treatment (3.92) were exactly half of the pre-treatment symptom levels (7.92), a finding that was highly significant ($p < .0001$).

The third and fourth hypotheses are also confirmed. The overall EEG amplitudes were

FIGURE 7. Regression Lines for Sample Symptom Categories

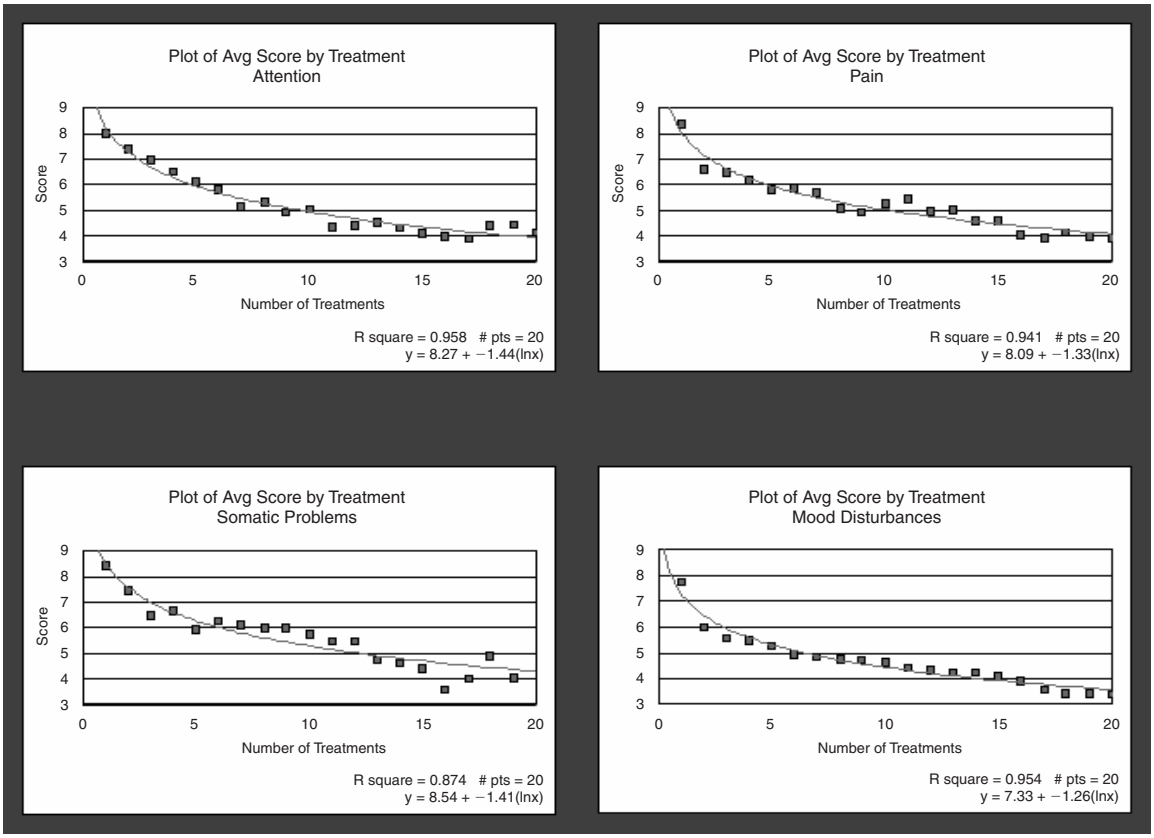


FIGURE 8. Number of Observations per Treatment Period

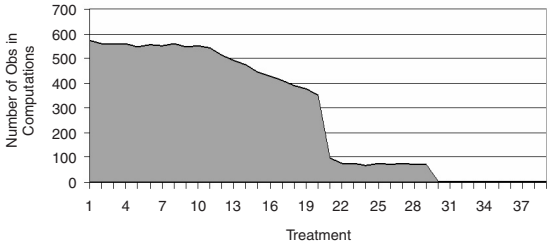
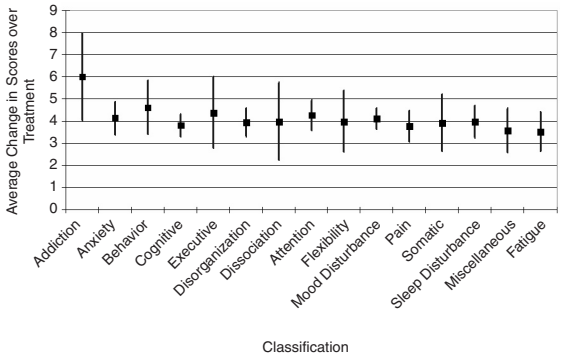


FIGURE 9. 95% Confidence Interval for Change in Scores by Category



found to significantly ($p < .0001$) decline over the course of treatments at the highest amplitude site (HAS), as seen in Figure 11. In addition, confirming the fourth hypothesis, this EEG improvement was also highly correlated (r-square = 0.869) with improvements in symptom ratings (as seen in Figure 12). This finding adds validity to the accuracy of the improvements noted in patient self-ratings of their symptoms. Thus, each of the two separate measures, subjective well-being (symptom ratings) and EEG amplitudes, both respond to the independent variable (the LENS treatment).

A significant reduction ($p < .0022$) in the overall EEG amplitude at Cz was also found, decreasing from 10.67μv to 9.62μv. Since the LENS treatment involved feedback stimula-

FIGURE 10. Average Score Pre- and Post-Treatment

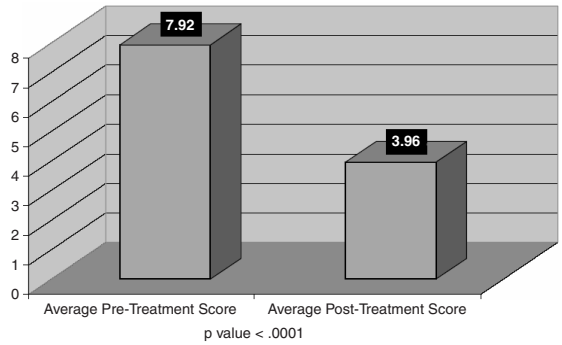


FIGURE 11. Reduction in Highest Amplitude Size (HAS)

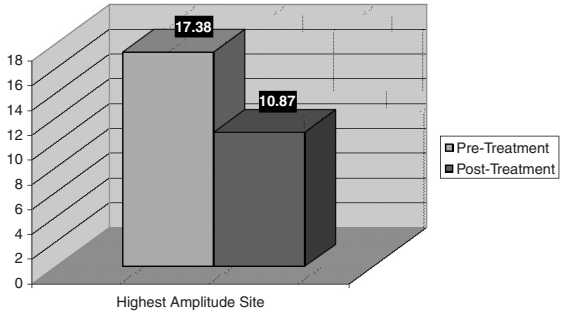
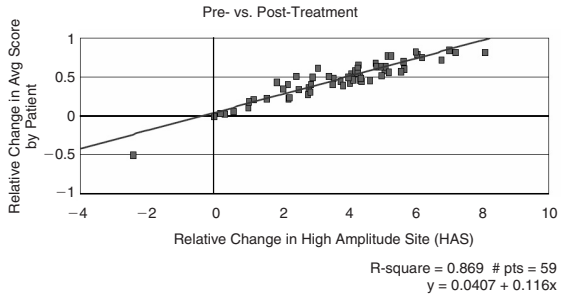


FIGURE 12. Plot of Relative Change in Qualitative Score vs. HAS



tion being received at one or more different electrode sites in each session, we had no reason to suspect that activity at CZ would be "treated" more than any other site since, on average, work at Cz occurred only once in about every four to five sessions. However, Cz has often been considered an important site in traditional neurofeedback (Tansey, 1990; Lubar, 1995).

The changes in EEG amplitude at the HAS provides confirmation of LENS theory (as well as effectiveness). Ochs (2006a) does not believe that LENS treatment will be effective by simply concentrating the treatment in the area of the brain with the highest EEG amplitudes. Interestingly, research (Fernandez et al., 2003) with traditional neurofeedback applied to learning disability children found that the greatest reductions in EEG amplitude often did not occur at the site where neurofeedback treatment was focused. Ochs (2006a) has theorized that by having treatment proceed from locations where there are lower amplitudes toward electrode sites where there are higher amplitudes (which reflect less efficient cortical inhibitory processes) the functioning of the entire cortex will be positively influenced and the amplitudes at the highest amplitude sites will decrease. Such changes had been previously observed in clinical work by Larsen (2001). Though in our current study the HAS would not have received any more treatment emphasis than was received at Cz (as described above) there was found to be an average decrease in amplitudes of 6.51μv at the HAS (see Figure 11). The mean amplitude at the HAS decreased from 17.38μv to 10.84μv, representing a 37% decline.

DISCUSSION

By basing our study on subjective symptoms as described in the patient's own words, we have tried to make this study relevant to people's *quality of life* in a very immediate and practical way. It is true that this type of classification of problems may have made this study superficially seem less technical or professional than a study simply based on strict DSM-IV criteria. However, symptoms are what people suffer with and are the fundamental components that make up diagnostic categories. Whereas many studies through the years have shown limited reliability in assigning diagnostic categories (e.g., Klein, 1982), we believe that symptoms are not only "where people live," but also are more reliably identified in comparison with over-arching diagnoses.

The rationale for tracking five or more symptoms rather than a single one stemmed from the fact that rarely do symptoms exist in isolation. It

has also been our clinical observation that improvement is often *a non-linear process*. Thus an individual's presenting complaints may have been anxiety attacks and migraine headaches, but he or she may also complain of problems with fatigue, insomnia, and photophobia. In our clinical work we have noticed in cases like this that the target symptoms of anxiety and migraines may remain approximately the same for a while, while sleep improves and the patient becomes less light-sensitive. These are good signs that seem to indicate that some deeper neurological re-balancing is underway and bodes well for the treatment. Suddenly one day, the patient reports that her schedule is filling up, social anxiety is dwindling, and the migraines are shorter in duration. This is, in fact, not an atypical course of treatment.

Although it would have been ideal in our study to use psychological tests with established validity and reliability because most of our patients had a large number of symptomatic complaints, we made the decision in our office to use symptom ratings at the beginning of each session for accountability. One of the important reasons for this decision was our desire to track session-by-session changes in patient symptoms, in which case it would be impractical to require patients to complete a lengthy psychological test (or multiple tests) once or twice weekly. Therefore, we believed that subjective ratings, particularly when combined with objective physiological (EEG) data, would allow frequent and systematic verification of symptomatic changes. Our results support these decisions.

This study represents an uncontrolled case series. Nonetheless, we believe that the topographic brain map documentation of EEG amplitude changes, and the correlation between these changes and symptom ratings, demonstrate the great likelihood that the changes in our patients did not simply stem from a desire to please a therapist or placebo effects. Therapy was also conducted by four separate therapists.

We should note, in contrast to our present findings, that sometimes in treatment we have found that there may be a rise in EEG amplitudes associated with symptomatic improvements, particularly when the patient has a low voltage EEG at the beginning of treatment. Such a pattern often seems to be associated with fatigue, depression, lack of motivation, and alcoholism. As the person improves subjectively in such cases, amplitudes go up. Our theory is that in many of these cases, a kind of cortical over-suppression might have been at work, and the therapy restores energy to areas of the brain.

In the kind of clinical cases seen in our study sample, we will also sometimes see the HAS decrease in magnitude, while the lowest amplitude sites come up in microvolts. The net effect is to produce a more balanced looking brain map (site sort), without the bright colors associated with high amplitude activity. Future studies can explore some of these variables.

The rapid improvements found in this study following early LENS treatment sessions has mirrored our clinical experience. We commonly see a rapid decrease in symptoms which then continue to diminish more gradually as treatment progresses through about 20 sessions. It has been our clinical experience that sometimes shortly after patients have received 20 treatment sessions, and leading up to and after 30 sessions, there can sometimes be a surge of symptoms temporarily worsening, followed after about session 33 with the lowest symptom ratings attained. From a clinical perspective, these symptom fluctuations have particularly seemed to be associated with more "chronic" patients whose symptoms are more longstanding and where we believe there is a strong genetic component to the main problem areas (e.g., an affective disorder, or familial ADD). This clinical experience has suggested the hypothesis that continued treatment may possibly be gradually addressing increasing "layers" of CNS dysfunction that did not immediately present themselves or respond readily to initial treatments. These clinical observations support the idea that improvements can continue to occur after a larger number of sessions than was usually administered in this study, perhaps as more "endogenous" factors associated with even deeper levels of CNS functioning are gradually calmed and normalized.

In summary, this study provides further objective evidence for the positive therapeutic outcomes reported by Dr. Len Ochs in previous studies. The results represented therapy conducted by four separate clinicians, following training procedures articulated by Drs. Ochs and Larsen in the training conducted for profes-

sionals, providing evidence that the outcomes are not associated with simply a charismatic therapist. It is concluded that LENS provides a very encouraging therapeutic option to traditional neurofeedback for the treatment of a wide range of clinical, brain-related conditions, particularly because LENS requires minimal cooperation and allows the patient to remain passive. It is recommended that future studies employ randomized assignment to LENS treatment in comparison with wait-list control groups, with medication treatment, and that placebo-controlled double-blind studies be done.

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