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Effect of Neurofeedback on Variables of Attention in a Large Multi-Center Trial

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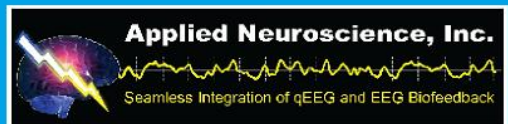
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Effect of Neurofeedback on Variables of Attention in a Large Multi-Center Trial

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ABSTRACT. *Background:* Neurofeedback studies have been criticized for including small numbers of subjects. The effect of SMR-beta neurofeedback training on the Test of Variables of Attention was evaluated in more than 1,000 subjects from thirty-two clinics.

Methods: 1089 subjects (726 children, 324 females, 186 with ADHD

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or ADD diagnoses) underwent twenty or more sessions of SMR-beta neurofeedback training for attentional and behavioral complaints at thirty-two clinical settings affiliated with EEG Spectrum, Inc. Subjects were evaluated prior to training and at training completion. One hundred and fifty-seven subjects who elected extensive training (forty sessions or more) were tested after both twenty and forty training sessions.

Results: Neurofeedback training produced significant improvement in attentiveness, impulse control, and response variability. Significant clinical improvement in one or more measures was seen in eighty-five percent of those subjects with moderate pre-training deficits.

Conclusions: Neurofeedback training is effective in remediating attentional dysfunction. Nevertheless, large-scale studies with greater control (e.g., wait-list designs) are sorely needed.

KEYWORDS. Neurofeedback, EEG biofeedback, attention, multi-center, outcome, TOVA

INTRODUCTION

Despite the fact that for more than twenty-five years neurofeedback training has improved cognitive and psychophysiological function in an increasing number of mental health and neurological conditions (Serman, Macdonald, & Stone, 1974; Lubar & Lubar, 1984; Tansey, 1991; Rozelle & Budzynski, 1995; James & Folen, 1996; Othmer, Othmer, & Kaiser, 1999), relatively few members of the psychiatric and neurological community are familiar with this effective supplement or alternative to pharmacological and surgical techniques. A lack of large contemporary, suitably controlled studies may limit general acceptance of this approach. Critics of neurofeedback call for double-blind designs to prove efficacy (e.g., Barkley, 1993), despite the fact that double-blind designs of behavioral-based treatments are often not feasible. Past attempts to maintain a treatment administrator's blind in neurofeedback studies failed as a result of the treatment's efficacy. Attempts at sham feedback, information presented to the subject unrelated to his or her psychophysiological state, were identified within minutes by subjects as being non-contingent (Serman, personal communication). The use of sham feedback was also judged to be unethical for studying efficacy of neurofeedback in ADHD populations

(University of California San Diego HSPC). Requiring a treatment modality to fit an inappropriate evaluation model is unscientific. Suitable controls for determining the efficacy of neurofeedback include wait-list control studies, outcome studies, effectiveness studies (i.e., comparison to a known effective treatment), and perhaps comparisons to active placebos (e.g., Linden, Habib, & Radojevic, 1996; Rossiter & La Vaque, 1995; Cartozzo, Jacobs, & Gevirtz, 1995).

Neurofeedback studies have been criticized for including small numbers of subjects (Barkley, 1998). In the present trial the effect of SMR-beta neurofeedback was evaluated in more than 1,000 subjects from thirty-two clinics across the United States. Given the large number of subjects, only a single measure was acquired systematically from all subjects: the Test of Variables of Attention (TOVA), a quantitative and reliable method of assessing attentional abilities. Fortunately, the lack of test-retest practice effects, the use of language-independent nonverbal stimuli, and an extended test length (22.5 minutes), all make this particular continuous performance task especially useful in evaluating treatment effects in an ADHD, learning disabled, or like populations (Greenberg, 1987). Attentional processes can be evaluated in response to treatment (pre and post) and/or in relation to a normative database. The TOVA provides an objective measure of effectiveness of SMR and beta biofeedback training for improving specific attentional properties such as impulse control and variability of response (Kaiser, 1998). For instance, improvement in TOVA performance was observed in ADHD children who reduced theta amplitudes in response to neurofeedback training (Lubar, Swartwood, Swartwood, & O'Donnell, 1995).

The purpose of the present trial is to evaluate the efficacy of SMR-beta neurofeedback for children and adults suffering from attentional problems. All four primary measures of the TOVA test are predicted to improve in response to training.

METHODS

Subjects. A total of 1089 subjects participated in this trial, consisting of 726 children and adolescents (age 5 to 16 years, mean 10.6) and 363 adults (17 to 67 years, mean 36.9). Females comprised one-fifth of the child group and nearly one-half of the adults (151 and 173, respectively). Subjects were obtained from thirty-two clinical settings

affiliated with EEG Spectrum, Inc. and were selected based on the availability of pre- and post-training data for the TOVA. None of these subjects were on any stimulant or antidepressant medications during the test administration. Although most subjects had attentional complaints, only 186 were formally diagnosed with ADHD or ADD. A handful were diagnosed with comorbid conditions of more severe behavioral disorders (Oppositional-Defiant Disorder and Conduct Disorder), Tourette's Syndrome, minor traumatic brain injury, epilepsy, anxiety disorders, and depression.

Materials. Neurofeedback training was performed on Neurocybernetics 2-Channel EEG systems. All subjects were evaluated with the TOVA. The TOVA test is a continuous Go/No-Go task. Subjects respond to targets by pressing a switch and do nothing when non-targets appear. Scores are presented in standard scores with one standard deviation presented as fifteen points above or below the mean. This test was administered on a personal computer and used a single micro switch for response generation. This test consists of only two non-verbal stimuli and requires a subject to pay attention for 22.5 min without prolonged rest. The subject responds to the target stimuli only. Presentation probabilities for target and distractor stimuli are mixed between blocks of time in order to evaluate high-likelihood and low-likelihood response conditions, and thereby provide measures of vigilance and of impulse control. Response time and consistency of response are also evaluated. Scores have been normed for single-year age groups and genders for ages 4 to 19 and ten-year age groups and genders for adults (Greenberg & Waldman, 1993).

Procedure. The training protocol consisted of rewarding enhanced EEG amplitudes in the 12-18 Hz frequency regime, while simultaneously inhibiting excessive amplitudes in the low frequency (4-7 Hz) and high-frequency (22-30 Hz) regimes, a protocol common in this field and developed from Serman's extensive research (Serman, 2000). Electrode placement included one electrode site on the sensorimotor strip (at either C3 or C4 in the standard 10-20 system) and possibly one electrode at either frontal, homologous central, or parietal placement. Training montage was either referential to the proximate ear or bipolar. Left-sided (C3) and right-sided (C4) training typically involved rewarding activity in the 15-18 Hz and 12-15 Hz, respectively. Occasionally, these two protocols were used in succession during a single training session with the respective duration (e.g.,

20 min Beta, 10 min SMR) of the two protocols titrated on the basis of changing symptomatology and TOVA results (Greenberg, 1987).

Training consisted of thirty minutes of visual and auditory feedback on the instrument, within a forty-five minute contact hour. Visual feedback was provided by a variety of averages that map the EEG amplitude in the reward and inhibit bands into the brightness, size, and/or velocity of objects on a computer monitor. When all reward conditions were satisfied for 0.5 seconds or longer, an auditory beep and visual incentive (e.g., highway stripe, star in sky) was provided as reinforcement. The visual feedback signal was occasionally complemented with direct tactile and auditory feedback of EEG amplitude in the reward band.

Subjects were evaluated prior to training and after twenty sessions. Those subjects who required further training (one-sixth of this group) were again retested after forty training sessions. A Huynh-Feldt correction for degrees of freedom was applied to all interactions to counter potential nonsphericity of dependent measures. The Bonferoni correction for multiple tests was applied appropriately.

RESULTS

A between-subject analysis of variance (ANOVA) was used to evaluate the presence of an ADD or ADHD diagnosis upon the TOVA score. As no interaction was found [$F(2,2010) = 1.434, p > .05$], both diagnosed and undiagnosed groups were collapsed into a single group. A within-subject ANOVA was then used to evaluate the effect of neurofeedback training on four dependent measures of the TOVA: percent omission (which reflects attentiveness), percent commission (which reflects impulse control), response time, and response variability (or consistency). TOVA raw scores were normalized relative to an age- and gender-based normative database into standard scores with a mean of 100 points and standard deviations of 15 points. Low scores were truncated at four standard deviations below normal as most behavioral tests, including TOVA, may be unreliable at such extreme deviations (here, $p < .0000317$). Pre- and post-training TOVA scores are presented in Table 1 for all subjects.

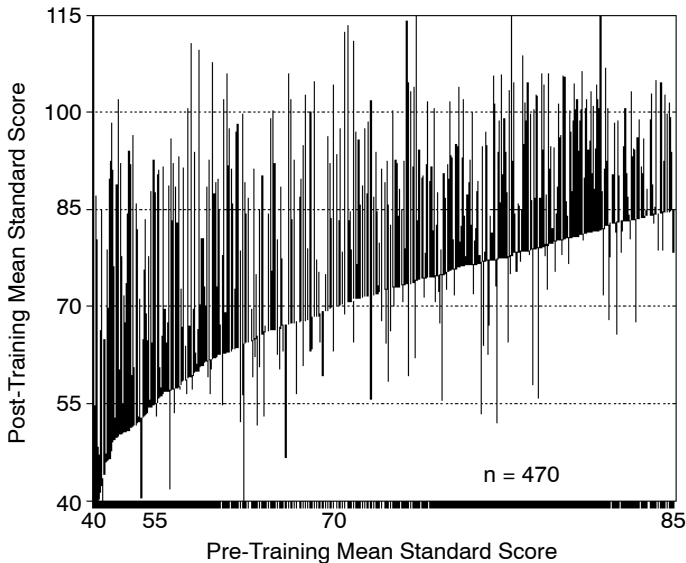
Neurofeedback training produced significant improvement in attentiveness scores; $F(1,1088) = 95.530, p < .001$; in impulse control scores, $F(1,1088) = 344.029, p < .001$; and in variability of response

time, $F(1,1088) = 127.725$, $p < .001$. Response time was *negatively* correlated with impulse control measures, $r = -.18$, $p < .05$. Results are even more dramatic when individual data are observed. In Figure 1, mean standard scores (average of the four measures) are presented for each subject who exhibited a moderate pre-training deficit TOVA

TABLE 1. Mean standard scores for TOVA measures before and after approximately 20 neurofeedback sessions for 1089 subjects.

	Pre-Training	Post-Training	Change
Attentiveness	83.5	90.6	+ 7.1
Impulse Control	88.6	99.1	+10.5
Response Time	92.2	92.3	+ 0.1
Response Consistency	80.5	87.9	+ 7.4

FIGURE 1. Pre- and post-training mean TOVA standard scores for 470 subjects with pre-training deficits. Each line segment represents a single subject's change from pre-training to post-training scores averaged across four dependent measures. Data are sorted by pre-training score. Improvement is indicated when the line segment rises above the pre-training value.



profile (one-standard deviation or more below the norm for at least one measure. Of 1089 subjects, a total of 470 subjects exhibited moderate deficits.

As can be seen in Figure 2, there is a systematic tendency toward improvement in test performance. Greater improvements occurred when pre-training scores were poor, especially for those very poor pre-training performers. Those subjects with moderately poor pre-training scores (i.e., greater than two standard deviations below the mean) improved nearly two standard deviations in attentiveness, $F(1,293) = 303.130$, $p < .001$; and in impulse control, $F(1,222) = 524.385$, $p < .001$ (see Figure 2). Improvement was less but still impressive in response time, 12 points (0.8 standard deviations), $F(1,180) = 58.330$, $p < .001$; and 20 points (1.3 standard deviations) in response variability, $F(1,347) = 260.029$, $p < .001$.

Of the 1089 total subjects, 157 continued training and were re-tested after forty or more neurofeedback sessions. As shown in Figure 3, additional neurofeedback sessions resulted in significant improvement in impulse control and response consistency ($p < .001$). Impulse con-

FIGURE 2. Pre- and post-training impulse control measures as organized by pre-training score in 676 subjects. * $p < .001$.

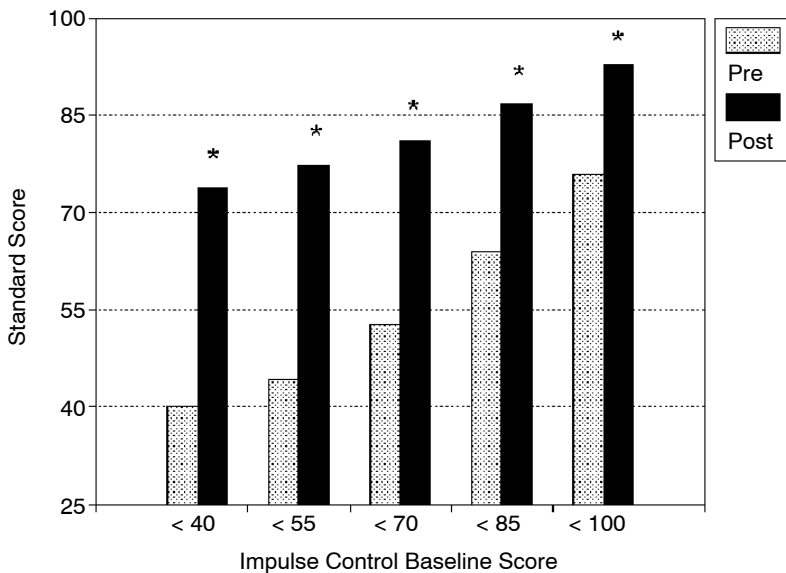
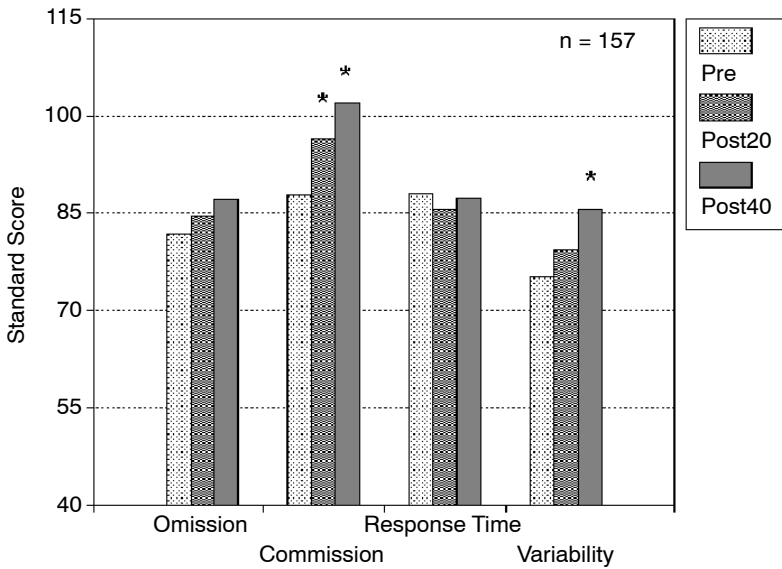


FIGURE 3. TOVA scores for 157 subjects at pre-training, after approximately 20 and 40 sessions in 157 subjects. * $p < .001$.



tol improved after twenty sessions and continued to improve after forty sessions (see Figure 3).

For those subjects in deficit prior to training, eighty-five percent exhibited significant clinical improvement in one or more measures, as defined by the test authors (7.5 points or greater; Greenberg & Dupuy, 1993; cf. Rossiter & La Vaque, 1995). Seventy-three percent of subjects showed one standard deviation or more improvement in one or more measures. Sixty-eight percent exhibited clinical improvement in two or more measures.

DISCUSSION

The present trial demonstrated the efficacy of SMR or beta neurofeedback in treating attentional deficiencies. Significant improvement was found for measures of attentiveness, impulse control, and consistency of response after twenty sessions of neurofeedback. When only those individuals with moderate pre-training deficits in a measure

were analyzed (i.e., two standard deviations below the mean), significant improvement was seen in all measures. Attentiveness and impulse control scores improved nearly two standard deviations in response to training. For those individuals who underwent forty or more training sessions, impulse control and response consistency continued to improve after twenty sessions. As this data was acquired from clinical settings, those individuals who pursued more than twenty sessions had attained only modest progress by session twenty. No correlation with presence or absence of an ADD or ADHD diagnosis was found.

This trial demonstrates the effectiveness of neurofeedback training for improving attentional function. Perhaps the strength of this trial lay with its population sample: a group drawn from thirty-two clinics, with varying degrees of severity and comorbidity—in other words, highly representative of the patient population neurofeedback clinicians encounter each day. In fact this trial might be viewed as a representative survey of the current practice of neurofeedback; an estimated one percent of all individuals who have ever undergone neurofeedback training are included. Prior to neurofeedback training many individuals in this group had already experienced numerous treatments for their condition, including stimulant medication, with little or no success. Some of the adults had suffered from their condition for twenty years. Success of the neurofeedback in the face of such client histories points to the robustness of this intervention in impacting attentional mechanisms. A recent review suggests that all psycho stimulants such as methylphenidate have about a seventy percent response rate (Cantwell, 1996). In this trial an eighty-five percent response rate was found for neurofeedback training, albeit on a single measure. Future research should focus on additional domains of functioning including psychophysiology, cognition, and behavior, as well the neurobiological mechanisms likely responsible for these promising results.

Malone, Kershner, and Swanson (1994) proposed a promising neurobiological model to explain the effectiveness of stimulant therapy for Attention Deficit Hyperactivity Disorder (ADHD). In this model, ADHD is argued to result from a failure in bihemispheric coordination of attentional processes, specifically due to lack of left hemisphere inhibitory control over the right hemisphere. Subsequently, stimulant medication is thought to restore neurotransmitter balance and alter the

hemispheric bias in favor of the left hemisphere and thereby restore bihemispheric collaboration of function. This model parallels the effects of different reward training in neurofeedback (Othmer et al., 1999). Beta training, which is usually performed on the left hemisphere, appears to resolve functions associated with the dopaminergic system, such as problems with sustained attention (Tucker & Williamson, 1984). Whereas SMR training, usually performed on the right hemisphere, addresses general arousal (i.e., noradrenergic) issues such as impulse control. Further analysis of the effect of reward frequency on left and right hemisphere tasks could bolster the usefulness of this model.

Although the application of neurofeedback for the remediation of ADHD/ADD symptoms has shown great promise in clinical practice, and despite documented observation of significant improvement in ADHD symptomatology following neurofeedback training (Lubar et al., 1995; Rossiter & La Vaque, 1995), the lack of large contemporary, suitably-controlled studies continues to limit the acceptance of neurofeedback within the larger psychological, psychiatric, and educational communities. The inclusion of 1089 subjects in this trial should help assuage this criticism. Future research should focus on converging measures of cognitive and behavioral performance, as well as on other mental health and neurological disorders. And it almost goes without saying that experimental designs that incorporate suitable controls, on the one hand, and yet respect ethical considerations on the other, are sorely needed.

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