Efficacy Determinations for Highly Effective Biofeedback Interventions

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This is an internal teaching document used in the Psychophysiology Doctoral Concentration within the Department of HC Psychology at Saybrook University. Nearly all of the material is quoted from other documents.

This document has three parts:

1. Methods for determining a treatment's effectiveness / efficacy
2. Efficacy determinations for several highly efficacious biofeedback based interventions.
3. Cost effectiveness

If you are already familiar with how effect sizes are calculated and how efficacy evaluations of psychological / behavioral interventions are generally performed, you may wish to skim or skip the first portion of this document.

A. Methods for determining effectiveness of a treatment

This section contains two major parts:

(1) reviews vs. meta-analysis and effect size and

(2) formal evaluation methodology for establishing effectiveness

The key questions addressed here are: How do we figure out how effective a treatment (such as EMG biofeedback to prevent tension headaches) actually is? How do we objectively compare the efficacy of several different treatments (e.g. Temp BFB vs. Propranalol to prevent migraines)?

1. Old style literature reviews vs. meta-analysis based effect size determinations

We all used to review the literature and take a best guess.
Now, we perform statistics as part of doing a "meta-analysis" to produce results phrased using such terms as "effect size".

When we used to review the literature on some topic (such as my old review of biofeedback for low back pain), we would find every article we could on the topic and essentially make a big table listing how many subjects there were, what the treatment was, how many folk got how much better, follow-up duration, etc. We tried to synthesize the information into a "best guess" about how well the treatment worked by informally factoring in study quality (clear diagnosis, controls, well defined Rx, meaningful / objective outcome measures, etc.) and trying to match designs as well as we could.
Our conclusions were always rough and open to considerable bias.

First off – what is a **Meta-Analysis**?
The limitations of reviews are somewhat compensated for by including "meta-analytic" techniques.
The idea seems great: Use statistics to combine a bunch of small, relatively weak studies into one big, relatively strong study with sufficient patients to be more certain of how efficacious the outcome is.

We begin by finding all the studies on the topic (e.g. BFB for back pain).

Then we do some quality control by eliminating all the studies which are very weak (e.g. no clear Dx, can't tell what the Rx really was, no decent outcome measures, etc.).

Next, we combine the data from studies with similar designs which use similar treatments and similar objective outcome measures.

This eliminates most of the studies but leaves us with relatively strong, comparable studies.

After doing magic statistics (which most of us need help from a professional statistician to perform correctly), we come up with numbers showing how effective the treatment probably really is and how certain we are of that judgment.

The most relevant to us is "effect size".

Effect Size - For most of us, the term "effect size" brings to mind something about how effective treatments are judged to be after a meta-analysis.
Just how Effect Size is calculated, what it is to do with a meta-analysis, and how it relates to the more familiar "significance values" tends to be pretty cloudy.
The key concept to remember is that Effect Size is how effective the treatment actually is. This means we can:

a. objectively determine the effectiveness of a treatment and use it to predict how well patients are likely to do and

b. directly compare the effectiveness of two treatments

The following is Modified from "Research Rundowns" web site Sept 13
"What is Effect Size?
The simple definition of effect size is the magnitude, or size, of an effect. Statistical significance (*e.g., p* < .05) tells us there was a difference between two groups or more based on some treatment or sorting variable. What this fails to tell us is the magnitude of the difference. In other words, *how much more effective* was (treatment one than treatment two)?

To answer this question, we standardize the difference and compare it to 0 – no effect."
"One type of effect size, the standardized mean effect, expresses the mean difference between two groups in standard deviation units."
Typically, you'll see this reported as Cohen's *d*, or simply referred to as *"d*."

"How can effect sizes be interpreted?
One feature of an effect size is that it can be directly converted into statements about the overlap between the two samples in terms of a comparison of percentiles.
An effect size is exactly equivalent to a 'Z-score' of a standard Normal distribution.
For example, an effect size of 0.8 means that the score of the average person in the experimental group is 0.8 standard deviations above the average person in the control group, and hence exceeds the scores of 79% of the control group."
(From: It's the Effect Size, Stupid What effect size is and why it is important. Robert Coe
School of Education, University of Durham, email r.j.coe@dur.ac.uk
Paper presented at the Annual Conference of the British Educational Research Association, University of Exeter, England, 12-14 September 2002)

For us, the effect size is stating the objective the difference between the means & standard deviations for two treatments or a treatment vs. placebo. It tells us how much difference in outcome we can expect between a person in the control group and the treatment group.

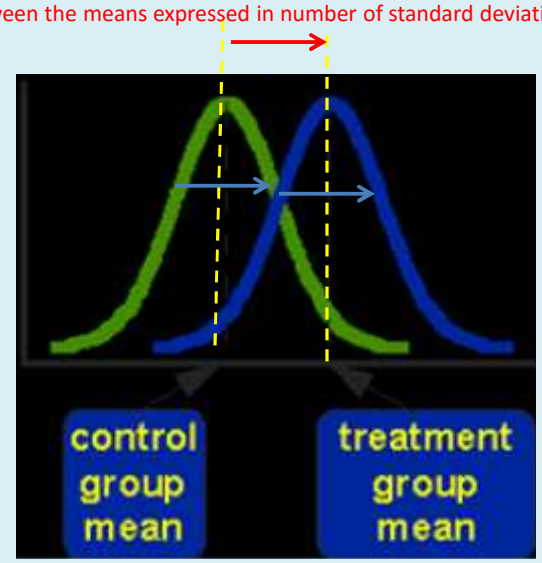
The values calculated for effect size are generally in the range of 0 to 3.0
The meaning of effect size varies by context, but the standard interpretation offered by Cohen (1988) is:
.8 = large (8/10 of a standard deviation unit)
.5 = moderate (1/2 of a standard deviation)
.2 = small (1/5 of a standard deviation)"

Biofeedback based interventions usually show effect sizes in the range of 0.4 to 0.8. If biofeedback treatments are effective, why are the effect sizes so small? Shouldn't they be at least 2 instead of a pitiful 0.4 to 0.8? Not really. An Effect size of 2 means that an average of 98% if the placebo controls can be differentiated from the real treatment group. Biofeedback based interventions help about 60 to 80 percent of patients to show improvements of about 80% in various measures of headache activity such as frequency, duration, intensity, debilitation, and drug use. Good HA placebos get the same results for about 30 percent of matched patients. (I once got a placebo response among 50% of patients showing at least minor improvements for at least six months). Thus, our effect sizes are realistic.

The following slide (Sherman 2013) explains how effect size is related to the distance between the means of two groups in number of standard deviations.

Effect size relative to standard deviations

Distance between the means expressed in number of standard deviations.



1 SD around the mean contains about 68% of the population if the curve is normally distributed

In behavioral treatments, the distance between the means is usually less than 1 SD. If the distance between the means is 0.8 of an SD, the effect size would be 0.8.

Effect Size	Percentage of control group who would be below the average person in the experimental group
0.0	50%
0.1	54%
0.2	58%
0.3	62%
0.4	66%
0.5	69%
0.6	73%
0.7	76%
0.8	79%
0.9	82%
1.0	84%
1.2	88%
1.4	92%
1.6	95%
1.8	96%
2.0	98%
2.5	99%
3.0	99.9%

2. Method of rating treatment efficacy established by AAPB and ISNR:

a. Efficacy vs. Clinical Effectiveness:

Efficacy is determined by evaluating formal studies done on each disorder. When a study is done, the treatment is very carefully standardized, the people doing the interventions should have great expertise in the treatment and the disorder, and patients are very carefully selected. In the real clinical environment, the patients may have many problems in addition to the one they are being treated for (which would affect the chances of the treatment doing well), may be given many overlapping treatments at once (so you can't tell how much help any one treatment was), and the therapist may not be as experienced as the people running the research study. Thus, a treatment's efficacy may be greater or lesser than its effectiveness in the real clinical world.

b. Establishment of Rating Criteria:

The Association for Applied Psychophysiology has developed the following criteria for setting the level of evidence for efficacy (Moss and Gunkelman 2002, LaVaque et al 2002):
It is very similar to the rating schemes developed by other organizations such as the American Psychological Association. Please note that the efficacy ratings made based on these criteria are from formal studies. Please see these citations for an explanation of how the ratings were arrived at and a discussion of the weaknesses of double blind studies for several of the techniques evaluated.

LaVaque, T., Hammond, D., Trudeau, D., Monastra, V., Perry, J., Lehrer, P., Matheson, D., & Sherman, R. (2002). Template for developing guidelines for the evaluation of the clinical efficacy of psychophysiological evaluations. *Applied Psychophysiology and Biofeedback*, 27(4), 273–281. Co-published in *Journal of Neurotherapy,* 6, 11–23.

Moss, D. & Gunkelman, J. (2002). Task force report on methodology and empirically supported treatments: Introduction. *Applied Psychophysiology and Biofeedback,* 27, 261–262.

c. Criteria:

(Quoted directly from Yucha and Montgomery's Evidence-Based Practice in Biofeedback and Neurofeedback, 2008)

"Biofeedback therapy has matured over the last 30 years, and today there are myriad disorders for which biofeedback therapy has been used. Large research grants have funded prospective studies on biofeedback therapy for a variety of disorders, such as headache (migraine, mixed, and tension), essential hypertension, and urinary incontinence. These studies consistently report positive results.

On the other hand, several reports of unsuccessful biofeedback training have appeared in the research literature since the inception of biofeedback training three decades ago. Many of the unsuccessful studies conducted in the early development of the field reflect failure to thoroughly train patients. For example, some unsuccessful studies provided only minimal training with the biofeedback instrumentation (often one to four sessions of short duration), provided little coaching, involved no home practice, and failed to train to clinical criteria.

In 2001, a Task Force of the Association for Applied Psychophysiology and Biofeedback and the Society for Neuronal Regulation developed guidelines for the evaluation of the clinical efficacy of psychophysiological interventions (Moss & Gunkelman, 2002). The board of directors of both organizations subsequently approved these guidelines.
These Criteria for Levels of Evidence of Efficacy, described below, were used to assign efficacy levels for the vast number of conditions for which biofeedback has been used.

Level 1: Not Empirically Supported
Supported only by anecdotal reports and/or case studies in nonpeer-reviewed venues. Not empirically supported.

Level 2: Possibly Efficacious
At least one study of sufficient statistical power with well-identified outcome measures but lacking randomized assignment to a control condition internal to the study.

Level 3: Probably Efficacious
Multiple observational studies, clinical studies, wait-list controlled studies, and within-subject and intrasubject replication studies that demonstrate efficacy.

Level 4: Efficacious
a. In a comparison with a no-treatment control group, alternative treatment group, or sham (placebo) control utilizing randomized assignment, the investigational treatment is shown to be statistically significantly superior to the control condition, or the investigational treatment is equivalent to a treatment of established efficacy in a study with sufficient power to detect moderate differences, and
b. The studies have been conducted with a population treated for a specific problem, for whom inclusion criteria are delineated in a reliable, operationally defined manner, and
c. The study used valid and clearly specified outcome measures related to the problem being treated, and
d. The data are subjected to appropriate data analysis, and
e. The diagnostic and treatment variables and procedures are clearly defined in a manner that permits replication of the study by independent researchers, andf. The superiority or equivalence of the investigational treatment has been shown in at least two
independent research settings.

Level 5: Efficacious and Specific
Evidence for Level 5 efficacy meets all of the criteria for Level 4. In addition, the investigational treatment has been shown to be statistically superior to credible sham therapy, pill, or alternative bona fide treatment in at least two independent research settings.

In this particular update, we asked a professional librarian (Eva Stowers, University of Nevada, Las Vegas) to provide a comprehensive literature search of biofeedback and neurofeedback articles.
Criteria used included being published in a peer-reviewed journal between 2003 – 2007. When there were numerous higher level research studies available, case studies were not added to this version. Abstracts and articles in languages other than English were not included. This

monograph is not meant to be an inclusive review of all literature published on every possible disorder, but rather is meant to provide rationale for efficacy ratings of biofeedback.

References

Moss, D., & Gunkelman, J. (2002). Task force report on methodology and empirically supported treatments: Introduction and summary. *Biofeedback*, *30*(2), 19-20.
Moss, D., & Gunkelman, J. (2002). Task force report on methodology and empirically supported treatments: Introduction and summary. *Applied Psychophysiology and Biofeedback*, *27*(4), 261-262."

SECTION B

Efficacy determinations for Highly efficacious biofeedback based interventions.

This section contains detailed evaluations of the efficacy of biofeedback based interventions for (1) prevention of tension headaches and migraine headaches of non-traumatic origin, (2) jaw area pain due to muscle problems (TMD), (3) ADHD among children, (4) Anxiety, (5) Rayndauds syndrome, (6) Urinary incontinence among adult women due to muscle tension problems, (7) Chronic Pain, (8) Epilepsy, and (9) Functional constipation.

1. Headache Pain Emphasizing Temperature and Muscle Tension Biofeedback for Prevention of Tension Headaches (including jaw area musculoskeletal pain) and Migraine Headaches of Non-Traumatic Origin

(Much of the following material is summarized from Sherman 2013 and Andrasik 2012.)

Temperature and Muscle Tension Biofeedback for Prevention of Tension Headaches (including jaw area musculoskeletal pain) and Migraine Headaches of Non-Traumatic Origin have been shown to be superior or equal to preventive medications for prevention of (non-traumatic origin) migraine and tension headaches in overall effectiveness, lack of side effects, and duration of effect.
Here is a summary of the effectiveness of muscle tension and temperature feedback for treating non-traumatic origin migraine and tension headache:

15 year follow-ups – if it works, patients stick with it.
Not true for medications.
Controlled studies with over 3,500 participants
Large groups
Comparative effectiveness studies
7 Medical groups including American College of Neurology now recommend biofeedback to be first line of treatment for children with headaches.

The following material is from a presentation Frank Andrasik did at AAPB's 2012 Portland (Oregon) meeting which summarized the crucial data on this topic.
He has been kind enough to permit me to use modified versions of his slides for this portion of the paper.

Evidence Base for determining efficacy:
Efficacy Reviews
1. • Qualitative
   • Panel of experts
   • Rigorous design criteria
   • Consensus reached
2. Meta-Analytic Reviews
3. Quantitative/Statistical review

Efficacy Panels
• National Institutes of Health (US)
• Diagnostic & Therapeutic Technology Assessment (JAMA)
• Canadian Headache Society
• Clinical Psychology Division of APA
• US Headache Consortium
• 7 Physician Societies
• Society of Pediatric Psychology
• Association for Applied Psychophysiology & Biofeedback
• Cochrane Collaboration

US Headache Consortium recommendations:
Relaxation training, thermal biofeedback combined with relaxation training, EMG biofeedback, and cognitive-behavioral therapy may be considered as treatment options for prevention of migraine (Grade A Evidence)
• Behavioral therapy may be combined with preventive drug therapy to achieve additional clinical improvement for migraine (Grade B Evidence)
• Evidence-based treatment recommendations are not yet possible regarding the use of hypnosis, acupuncture, TENS, cervical manipulation, occlusal adjustments, hyperbaric oxygen (Grade C Evidence)

Interpreting the results of meta-analyses of migraine treatments:
Effect Sizes for treatment of Migraines
Small effect – effect size of .2 - .5
Moderate effect – effect size of .5 - .8

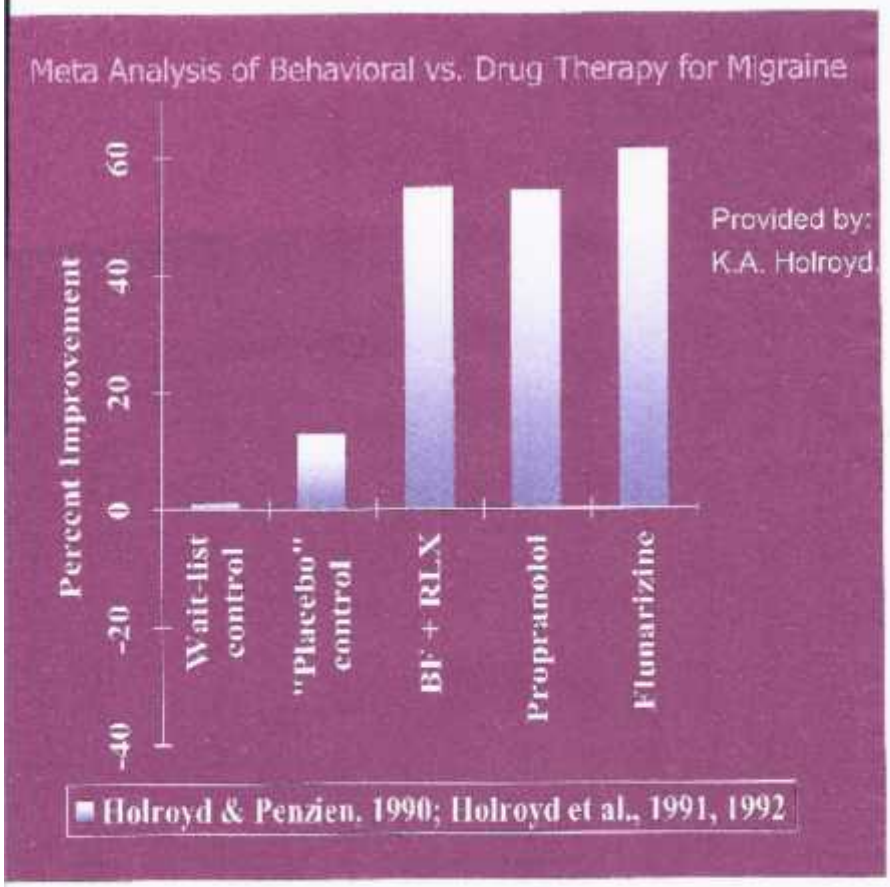
Large effect – effect size greater than .8.

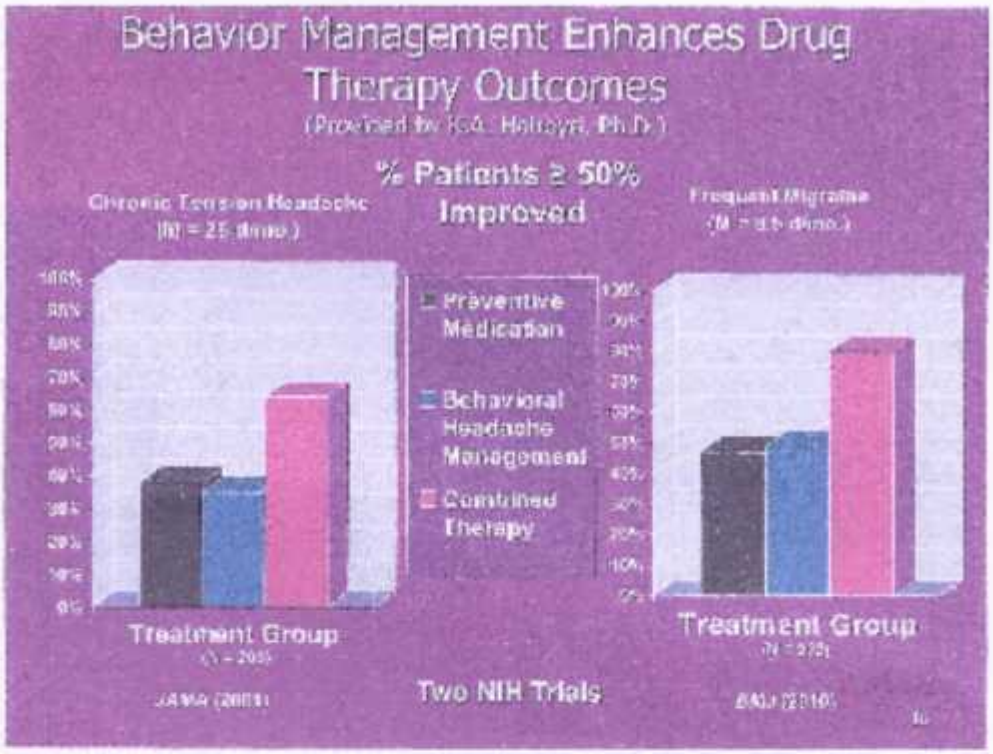
From: Nestoriuc Y, Martin A, Rief W, Andrasik F. (2008). Biofeedback treatment for headache disorders: A comprehensive efficacy review. *Applied Psychophysiology and Biofeedback, 33, 125-140.*

Data on efficacy of BFB for HA compiled from:
94 Studies, 3,500 Patients
• 56 Migraine, Mean 40 Patients per study
• 45 TTH, Mean 29 Patients per study
• 7 Both HA types
• Results same for Intention To Treat Analyses (LOCF)
• Results held at FUP, Mean 14 months
• "Fail Safe Analyses"/Bias Potential
• >4,000 studies with 0 effects to reduce mean effect score to 0.00
• 148 migraine studies with 0 effects to reduce mean effect score to small (0.20)
• 168 TTH studies with 0 effects to reduce mean effect score to small (0.20)

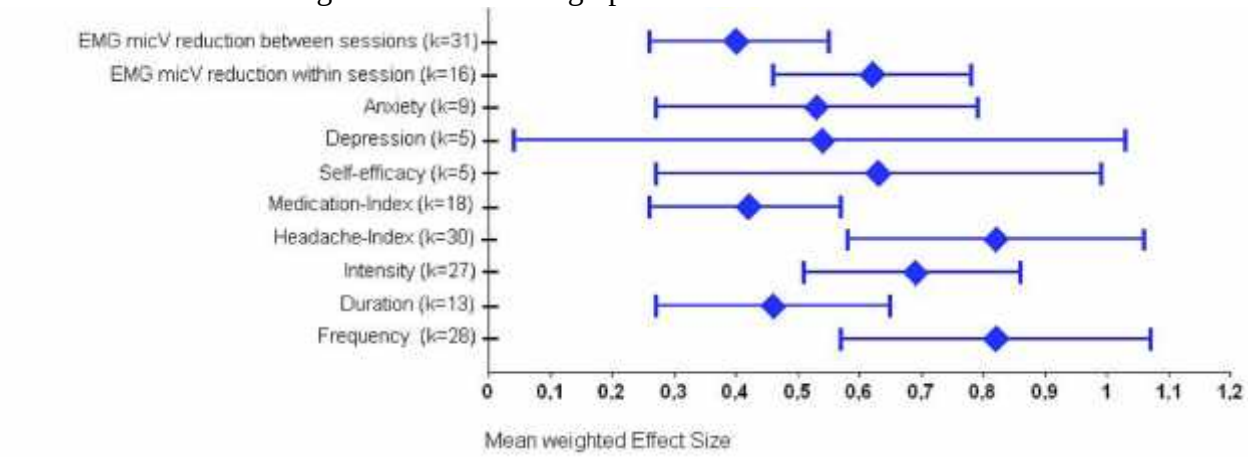
Meta-Analyses for efficacy of BFB for Migraine HA
Blanchard, Andrasik et al. (1980)
• Holroyd et al. (1984)
• Blanchard & Andrasik (1987)
• Holroyd & Penzien (1990)
• Haddock, Rowan, Andrasik et al. (1997)
• Goslin et al. (1999)
• Eccleston et al. (2002)
• Nestoriuc & Martin (2007)
• Nestoriuc et al. (2008)
Goslin et al., Tech Rev 2.2, AHCPR, 1999.
McCrory et al. 2001
Eccleston et al. *Pain 2002.*
Nestoriuc & Martin. *Pain 2007.*
Nestoriuc et al. *Appl Psycho Biof, 2008.*
Effect sizes for tension headaches
Nestoriuc Y, Martin A, Rief W, Andrasik F. (2008). Biofeedback treatment for headache disorders:
A comprehensive efficacy review. *Applied Psychophysiology and Biofeedback, 33, 125-140.*

ES Values for Nonpharmacological (n=17) & Pharmacological (n=24) Treatment


Meta Analysis of Behavioral vs. Drug Therapy for Migraine
Provided by:
K.A. Holroyd
Percent Improvement
60
40
20
0
-20
-40
Wait-list control
"Placebo" control
BF + RLX
Propranolol
Flunarizine
Holroyd & Penzien, 1990; Holroyd et al., 1991, 1992


Behavior Management Enhances Drug Therapy Outcomes
% Patients ≥ 50% Improved
Chronic Tension Headache
Frequent Migraine
Preventive Medication
Behavioral Headache Management
Combined Therapy
Treatment Group
Treatment Group
Two NIH Trials

The following graph summarizes the results of meta-analyses indicating changes in various symptoms related to tension headaches. The effect sizes plus and minus one standard deviation are shown along the bottom of the graph.



Meta-Analyses for efficacy of BFB for Tension HA
Tension-Type Headache
• Blanchard, Andrasik et al. (1980)
• Holroyd & Penzien (1986)
• Bogaards & ter Kuile (1994)
• Haddock, Rowan, Andrasik et al. (1997)
• McCrory et al. (2001)
• Eccleston et al. (2002)
• Nestoriuc et al. (2008)
Blanchard, Andrasik et al. *Beh Ther 1980.*
Holroyd et al., paper, AASH, 1984.
Holroyd, Penzien. *J Behav Med 1986.*
Blanchard, Andrasik. In *Biofeedback: Studies in clinical efficacy. 1987.*
Holroyd, Penzien. *Pain 1990.*
Bogaards, ter Kuile. *Clin J Pain 1994.*
Haddock, Rowan, Andrasik et al. Cephal 1997
(From RS: This is a crucial slide as it shows how effective behavioral treatments are for migraine HA relative to (especially preventive) medications.

(end of Andrasik's material)

What about EEG and HRV feedback for HA?

While other biofeedback interventions for headache, especially HRV and EEG BFB, show great potential, there is as yet insufficient evidence to recommend applying them as initial treatments for well diagnosed tension and non-traumatic origin headaches. You certainly should not charge for them.

The studies showing efficacy at levels required by the current ethical and legal environment simply have not been done yet.

What about biofeedback for other types of headaches? Many biofeedback interventions show great potential for treating many types of headaches but the studies showing efficacy at levels required by the current ethical and legal environment simply have not been done yet.

There is no good evidence that behavioral interventions help cluster headaches, trigeminal headaches, TMJ (the joint problem), etc.

2. Temporomandibular Disorder (TMD)

Level 4: Efficacious

Used alone, biofeedback improves pain, pain-related disability, and mandibular functioning (Gardea, Gatchel, & Mishara, 2001). When used in combination with other treatments, such as intraoral applications (Turk, Zaki, & Rudy, 1993), and in cognitive-behavioral skills training (Gardea et al. 2001), the effect is enhanced (Turk, Rudy, Kubinski, Zaki, & Greco, 1996). A meta-analysis of 13 studies of EMG biofeedback treatment showed biofeedback was superior to no treatment or psychological placebo control for patient pain reports, clinical exam findings, and/or ratings of global improvement (Crider & Glaros, 1999).

Gatchel, Stowell, Wildenstein, Riggs, and Ellis (2006) conducted a randomized clinical trial to evaluate the efficacy of a biopsychosocial intervention for patients who were at high risk (HR) of progressing from acute to chronic TMD-related pain. The authors assessed pain and psychosocial measures at intake and at one-year follow up. Two conditions were studied: standard care and standard care plus CBT and biofeedback comprised of frontal EMG and finger temperature training. Of 101 subjects who started the study, 98 completed the one-year follow-up study. Subjects' self-reported pain levels were measured on an analog scale and as a response to palpation. At one year, the treatment group subjects had significantly lower levels of self-reported pain and depression. The normal treatment group subjects had utilized more health care for jaw-related pain. The normal treatment group subjects were 12.5 times as likely to have a somatoform disorder, more than seven times as likely to have an anxiety disorder, and 2.7 times more likely to have an affective disorder at one year compared with treatment group subjects.

In a recent review of the literature, Crider, Glaros, and Gevirtz (2005) report on 14 controlled and uncontrolled outcome evaluations of biofeedback-based treatments for TMD published since 1978. This literature includes RCTs of three types of biofeedback treatment: 1) surface electromyographic (SEMG) training of the masticatory muscles, 2) SEMG training combined with adjunctive cognitive-behavioral therapy (CBT) techniques, and 3) biofeedback-assisted relaxation training (BART). Based on a detailed review of RCTs supplemented with information from nonRCT findings, the authors concluded SEMG training with adjunctive CBT is an efficacious treatment for TMD, and both SEMG training as the sole intervention and BART are probably efficacious treatments.

Medlicott and Harris (2006) reported the results of a systematic review of the effectiveness of exercise, manual therapy, electrotherapy, relaxation training, and biofeedback in the management of TMD. Thirty studies met four criteria: 1) subjects were from one of three groups identified in the first axis of the Research Diagnostic Criteria for TMD, 2) the intervention was within the realm of physical therapy practice, 3) an experimental design was used, and 4) outcome measures assessed one or more primary presenting symptoms were found. Among other recommendations, the authors state combinations of active exercises, manual therapy, postural correction, and relaxation techniques often combined with biofeedback may be effective.

In another recent systematic review, Turp et al. (2007) found 11 RCTs that met the criteria of at

least four weeks of interventions where simple therapy was compared to multimodal interventions. Their conclusions were that with patients with no psychological disturbances simple treatment is effective, but for those with comorbid conditions a multimodal program is needed.

Myers (2007) reported on a systematic review to TMD treatments and, based on a collection of previously reviewed studies and yet-to-be-reviewed studies, concludes biofeedback has been shown to be consistently superior to placebo or no-treatment controls. However, when compared to other treatments, biofeedback had mixed results: sometimes superior, sometimes equivalent, and sometimes less effective.

References

Crider, A.B., & Glaros, A.G. (1999). A meta-analysis of EMG biofeedback treatment of temporomandibular disorders. *Journal of Orofacial Pain*, *13*(1), 29-37.

Crider, A., Glaros, A.G., & Gevirtz, R.N. (2005). Efficacy of biofeedback-based treatments for temporomandibular disorders. *Applied Psychophysiology and Biofeedback*, *30*(4), 333-345.

Gardea, M.A., Gatchel, R.J., Mishra, K.D. (2001). Long-term efficacy of biobehavioral treatment of temporomandibular disorders. *Journal of Behavioral Medicine*, *24*(4), 341-59.

Gatchel, R.J., Stowell, A.W., Wildenstein, L., Riggs, R., & Ellis, E., 3rd. (2006). Efficacy of an early intervention for patients with acute temporomandibular disorder-related pain: A one-year outcome study. *Journal of the American Dental Association, (1939)*, *137*(3), 339-347.

Medlicott, M.S., & Harris, S.R. (2006). A systematic review of the effectiveness of exercise, manual therapy, electrotherapy, relaxation training, and biofeedback in the management of temporomandibular disorder. *Physical Therapy*, *86*(7), 955-973.

Myers, C.D. (2007). Complementary and alternative medicine for persistent facial pain. *Dental Clinics North America*, *51*(1), 263-274.

Turk, D.C., Rudy, T.E., Kubinski, J.A., Zaki, H.S., & Greco, C.M. (1996). Dysfunctional patients with temporomandibular disorders: Evaluating the efficacy of a tailored treatment protocol. *Journal of Consulting Clinical Psychology*, *64*(1), 139-46.

Turk, D.C., Zaki, H.S., & Rudy, T.E. (1993). Effects of intraoral appliance and biofeedback/stress management alone and in combination in treating pain and depression in patients with temporomandibular disorders. *Journal of Prosthetic Dentistry*, *70*(2), 158-64.

Turp, J.C., Jokstad, A., Motschall, E., Schindler, H.J., Windecker-Getaz, I., Ettlin, D.A. (2007). Is there a superiority of multimodal as opposed to simple therapy in patients with temporomandibular disorders? A qualitive systematic review of the literature. *Clinical Oral Implications Research*, *18*(Suppl. 3), 138-150.

3. EEG Biofeedback for Attention Deficit Hyperactivity Disorder (ADHD) in children

The following material is largely based on (a) “Evidence-Based Practice in Biofeedback” by Yucha, C and Montgomery, D. AAPB, 2008 and (b) Arms, M et al “Efficacy of Neurofeedback Treatment in ADHD: The Effects on Inattention, Impulsivity, and Hyeractivity: A Meta-Analysis. Clinical EEG and Neuroscience 40: 180, 2009. The following figure is from the Arms article referenced above. It provides an excellent summary of the effect sizes generated by both controlled and pre-post studies. The effect sizes are well within the range anticipated for good treatments.

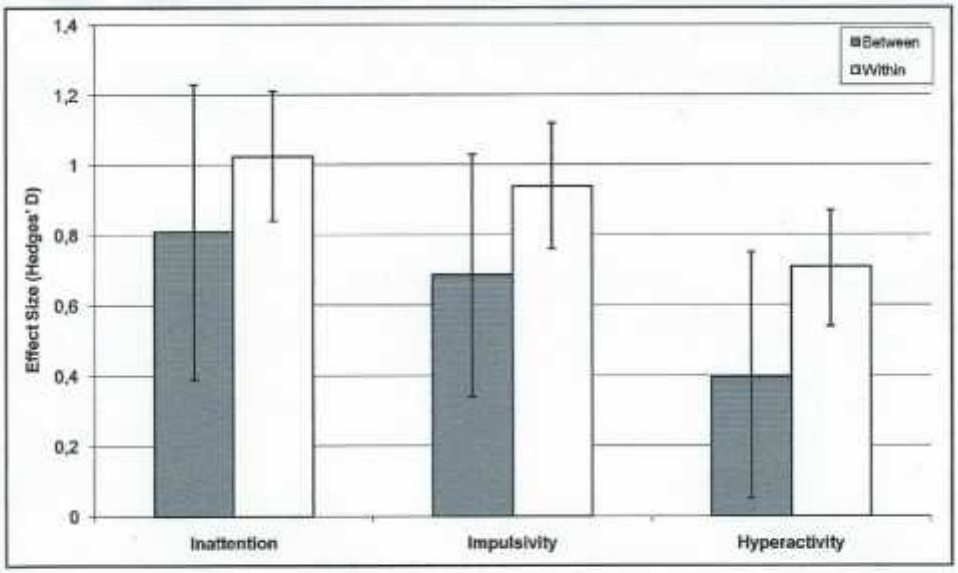


Figure 3.
This figure shows the grand mean ES for the controlled studies compared to the within-subject effect sizes for all studies for all 3 core symptoms. Note that the ES for the controlled studies are slightly smaller, which could be due to the fact that many controlled studies used a "semi-active" control group. Furthermore, given the 95% confidence intervals the ES for inattention, hyperactivity and impulsivity are significant for both comparisons.

From Yucha, et al, 2008: Level 4: Efficacious

A variety of techniques such as slow cortical potentials, hemoencephalographic feedback, and cranial electrotherapy for treatment of ADHD have recently been reported. However, the majority of biofeedback studies have utilized EEG biofeedback; therefore, this technique will be the only one used to evaluate the efficacy for this disorder. The other techniques will be briefly presented at the end of this section.Even studies using EEG biofeedback to treat ADHD are difficult to summarize because they use a variety of training protocols and a variety of outcome measures. However, because the majority of studies used protocols that were directed toward reducing the abundance of slow frequencies while increasing the abundance of fast frequencies, some generalizations across studies are warranted. Numerous case studies; a multitude of treatment-only studies; some treatment compared to wait-list or no-treatment controls; and a few random-assignment, treatment-comparison groups have been reported. There are also a few review articles. These review articles should be evaluated with caution as they tend to have many of the same studies incorporated within their results. While the majority of the review articles conclude EEG biofeedback is effective when compared to no treatment, a placebo, or another treatment group, some of the reviews find fault with either the methodologies or outcome measurements of some studies.

Earlier uncontrolled studies using neurofeedback (NF) contingent on decreasing slow wave activity and increasing fast wave activity show persons with ADHD improved in symptoms, intelligence score, and academic performance (Grin'-Yatsenko et al. 2001; Lubar, Swartwood, Swartwood, & O'Donnell, 1995; Thompson & Thompson, 1998). In one study, only those individuals who significantly reduced theta over the training sessions showed a 12-point increase in Wisconsin Intelligent scale forDisorders Evaluation Scale (ADDES) rating score (Lubar et al. 1995). One large multicenter study (1,089 participants, aged five to 67 years) showed sensorimotor-beta EEG biofeedback training led to significant improvement in attentiveness, impulse control, and response variability as measured on the TOVA (Kaiser & Othmer, 2000) in those with moderate pretraining deficits.

A few early controlled studies compared EEG biofeedback to other treatments. The first of these was a study with four hyperkinetic children under six conditions: 1) no drug, 2) drug only, 3) drug and sensory motor rhythm (SMR) training, 4) drug and SMR reversal training, 5) drug and SMR training II, and 6) no drug and SMR training (Shouse & Lubar, 1979). Combining medication and SMR training resulted in substantial improvements in behavioral indices that exceeded the effects of drugs alone and

were sustained with SMR training after medication was withdrawn. These changes were absent in the one highly distractible child who failed to acquire the SMR task.

In a study of 16 elementary-age children who were randomly assigned to conditions comparing EEG biofeedback to a waiting-list control, Carmody, Radvanski, Wadhwani, Sabo, and Vergara (2001) reported conflicting outcomes as measured by the TOVA and teacher reports. They found improvements in the reduction of errors of commission, anticipation, and attention, but no improvements in impulsivity or hyperactivity. Another small (n=18) controlled study showed increased intelligence scores and reduced inattentive behaviors as rated by parents in comparison to the waiting-list control (Linden, Habib, & Radojevic, 1996). Another study by Rossiter and La Vaque (1995) comparing EEG biofeedback to stimulant medication demonstrated both groups improved on measures of inattention, impulsivity, information processing, and variability as measured by the TOVA. Since 2002, a number of studies on the effectiveness of EEG biofeedback have been published, and they are presented briefly below. Some are outcome studies, and where available, the methodologies and outcome measures are presented while others are reviews. Some studies were not based on slow-wave reduction and fast-wave enhancement, so their techniques need to be considered separately from the typical EEG biofeedback protocol.

In a study of EEG biofeedback and stimulant medication effects, Fuchs, Birbaumer, Lutzenberger, Gruzelier, and Kaiser (2003) compared the effects of a three-month EEG biofeedback program providing reinforcement contingent on the production of cortical SMR (12-15 Hz) and beta-l activity (15-18 Hz) with stimulant medication. Participants were aged eight to 12 years; 22 were assigned to the EEG biofeedback group and 12 to the methylphenidate group according to their parents' preference. Both EEG biofeedback and methylphenidate were associated with improvements on all subscales of the TOVA and on the speed and accuracy measures of the d2 Attention Endurance Test. Furthermore, behaviors related to the disorder were rated as significantly reduced in both groups by both teachers and parents on the IOWA-Conners Behavior Rating Scale. Another study relating stimulant medication to EEG biofeedback training reported 16 of 24 patients taking medications were able to lower their dose or discontinue medication totally after 30 sessions of EEG biofeedback (Alhambra, Fowler, & Alhambra, 1995). Finally, Monastra, Monastra, and George (2002) studied one hundred children with ADHD receiving Ritalin, parent counseling, and academic support at school. Based on parent preference, 50 children also received EEG biofeedback. While children improved on the TOVA and an ADHD evaluation scale while taking Ritalin, only those who had EEG biofeedback sustained these improvements without Ritalin.

In a multiple case study (n=7), five participants completed an ABAB reversal methodology designed to alter the SMR/theta ratio in ADHD children (Heywood & Beale, 2003). Two participants failed to complete all training sessions, and the effects of training on behavior were analyzed both including and excluding these noncompleters. During alternate periods, they were trained using a placebo protocol identical to the treatment protocol except the association between EEG patterns and feedback was random. When all participants were included in analyses that controlled for overall trend, EEG biofeedback was found to be no more effective than the placebo control condition involving noncontingent feedback, and neither procedure resulted in improvements relative to baseline levels. The such as maturation, history, and treatment order, but it does not control for carry-over from a treatment that has sustained effects, which EEG biofeedback has been shown to have in numerous studies. Because of a small number in the control group (n=2), possible carry-over effects, and a limited number of treatments (eight to 11), the reported lack of difference is tenuous at best.

Pryjmachuk (2003) presented a review of randomized controlled trials (RCTs) evaluating treatment for ≥ 12 weeks in children with ADHD. Articles were selected if they were full reports published in any language in peer-reviewed journals. Fourteen RCTs (1,379 participants, 42% in one RCT) met the selection criteria. The findings relevant to EEG biofeedback state EEG biofeedback was superior to no treatment (one RCT), and treatment with EEG biofeedback led to better results on an intelligence test than did a waiting-list control (one RCT).

In a replication of a previous study (Rossiter & La Vaque, 1995), Rossiter (2004) reports on a study with a larger sample, expanded age range, and improved statistical analysis. Thirty-one ADHD

patients who chose stimulant drug treatment were matched with 31 patients who chose an EEG biofeedback treatment program. EEG biofeedback patients received either office (n = 14) or home (n = 17) EEG biofeedback. Stimulants for medication patients were titrated using the (TOVA). Both groups showed statistically and clinically significant improvement on the TOVA measures of attention, impulse control, processing speed, and variability in attention. The EEG biofeedback group demonstrated statistically and clinically significant improvement on behavioral measures (Behavior Assessment System for Children and Brown Attention Deficit Disorder Scales). The TOVA Confidence interval and nonequivalence null hypothesis testing confirmed the EEG biofeedback program produced outcomes equivalent to those obtained with stimulant drugs.

To explore the effectiveness of EEG biofeedback on children with ADHD, a randomized selfcontrolled study with assessment taken before and after treatment was conducted (Chen et al. 2004). A total of 30 ADHD children were selected for the study from the Children's Mental Health Clinic of Nanjing Brain Hospital. Children were treated with EEG biofeedback. The Integrated Visual and Auditory continuous performance test (IVA) was used to evaluate before treatment and after 20 and 40 treatments. Main outcome measures were the control quotient and attention quotient of the IVA. After 20 treatments, the control quotients significantly increased and continued to significantly increase after 40 treatments. Cho et al. (2004) reported a study on the effectiveness of EEG biofeedback, along with virtual reality (VR), in reducing the level of inattention and impulsiveness. Twenty-eight male adolescents with social problems took part in this study. They were separated into three groups: a control group, a VR group, and a nonVR group. Both the VR and nonVR groups underwent eight sessions of EEG biofeedback training while the control group just waited during the same period. All participants performed a continuous performance task (CPT) before and after the complete training session. The results showed both the VR and nonVR groups (both also received EEG biofeedback training) achieved better scores in the CPT after training while the control group showed no significant difference.

Eisenberg, Ben-Daniel, Mei-Tal, and Wertman (2004) reported a study to determine the effect of a new noninvasive technique of noncognitive biofeedback called Autonomic Nervous System Biofeedback Modality on the behavioral and attention parameters of a sample of children with attention deficit hyperactivity disorder. Nineteen subjects who met DSM-IV criteria for ADHD received four sessions of Autonomic Nervous System Biofeedback Modality treatment. The heart rate variability was measured before and after the treatment, as were measures of efficacy, including Conners Teacher Questionnaires (28 items), the Child Behavior Check List for parents and teachers, and Continuous Performance Test. Positive treatment effect was observed in all the subjects. A positive correlation between heart rate variability changes and improvement of symptoms of attention deficit hyperactivity disorder was found.

learning problems for EEG biofeedback. Pre- and post-test reading and cognitive assessments were administered to sixth-, seventh-, and eighth-graders. Control and experimental groups were chosen at random. EEG biofeedback training was provided to the participants of the experimental group only. The control group had no treatment, just normal school-related activities. Seventeen students were assigned to each group. For various reasons, 12 finished treatment, and 14 were available for post measures in the control group. EEG biofeedback training lasted approximately 30 to 45 minutes and was conducted weekly for seven months. Some students received more sessions than others because of absences, field trips, testing, and other natural rhythms of home and school life. The average number of sessions per student was 28. EEG biofeedback was significantly more effective in improving scores on reading tests than no EEG biofeedback training. There were significant interactions between EEG biofeedback and time on basic reading, and EEG biofeedback training was more effective in improving both the verbal and full-scale IQ scores than no EEG biofeedback training. There was a significant interaction between EEG biofeedback and time on verbal IQ and on full-scale IQ. There was a trend interaction for EEG biofeedback and performance IQ, but it was not significant. The results support the hypothesis that biofeedback training is effective in improving reading quotients and IQ in LD children.

In a study by Hanslmayr, Sauseng, Doppelmayr, Schabus, and Klimesch (2005), increasing upper

alpha power while lowering theta in eight sessions improved cognitive functioning as measured by a mental rotation task performed before and after training. Only those subjects who were able to increase their upper alpha power performed better. Training success (extent of EEG biofeedback training–induced increase in upper alpha power) was positively correlated with the improvement in cognitive performance and significant increase in reference upper alpha power.

Fleischman and Othmer (2005) reported a case study of mildly developmentally delayed twins. They observed improvements in IQ scores and maintenance of the gains following EEG biofeedback. Full-scale IQ scores increased 22 and 23 points after treatment and were maintained at three follow-up retests over a 52-month period. ADHD symptom checklists completed by their mother showed a similar pattern of improvement and maintenance of gains.

Jacobs (2005) describes the application of EEG biofeedback with two children who manifested multiple diagnoses, including learning disabilities (LD), ADHD, social deficits, mood disorders, and pervasive developmental disorder (PDD). Both boys had adjusted poorly to school, family, and peers. They received individualized protocols based on their symptoms and functional impairments. They were administered semiweekly 20-minute sessions of one-channel EEG biofeedback training for approximately six months. In both cases, symptoms were identified and tracked with a parent rating scale and one case with the Symptom Assessment-45 questionnaire (SA-45) also. Each boy improved in all tracked symptoms without adverse effects.

In a study (Kropotov et al. 2005) of the effects of EEG biofeedback on Evoked Response Potentials (ERP)s in 86 ADHD children (ages nine to 14), ERPs were recorded in an auditory Go/No Go task before and after 15 to 22 sessions of EEG biofeedback. Each session consisted of 20 minutes of enhancing the ratio of the EEG power in the 15-18 Hz band compared to the EEG power in the rest of spectrum and seven to 10 minutes of enhancing the ratio of the EEG power in 12-15 Hz to the EEG power in the rest of spectrum. On the basis of quality of performance during training sessions, the patients were divided into two groups: good performers and bad performers. ERPs of good performers to Go and No Go cues gained positive components evoked within 180-420 ms latency. At the same time, no statistically significant differences between pre- and post-training ERPs were observed for bad performers. The ERP differences between post- and pre-treatment conditions for good performers were distributed over frontalcentral areas and appear to reflect an activation of frontal cortical areas associated with beta training. A series of three studies by Li and collegues are reported below: Li, Wu, & Chang, (2003) investigated the therapeutic effect of EEG biofeedback for ADHD. Sixty children aged six to 10 years were selected (30 children with attention deficit associated with hyperkinetic syndrome in the experimental group; 30 healthy children in the control group). The EEG recorded from the experiment group was significantly different from the control group. There was no significant difference in EEG between male and female children. Ten children received EEG biofeedback training and showed brain function was improved. In a second study by Li and Yu-Feng (2005), ADHD children with comorbid tic disorder (n=14) received EEG biofeedback treatment (average 34 sessions). The outcome was evaluated with a variety of outcome measures before and after treatment. Significant reductions in multiple symptoms were reported. Tic symptoms were greatly reduced in all but two children who also had Tourette's syndrome. In the third study (Li, Tang, et al. 2005), 113 outpatient children (88 male and 25 female, mean age of 10 ± three years) from the Psychology Hyperactivity Department of the Central Hospital of Anshan City were selected. Inclusion criteria were from six to 14 years of age. Exclusion criteria were nervous system organic diseases, pervasive developmental disorder (PDD), mental retardation, epilepsy, psychotic disorder, and acoustical and visual abnormalities. ADHD children were diagnosed, and then the EEG diagnostic accuracy was calculated. The diagnostic sensitivity of EEG on ADHD was 83.58%, the specificity was 82.61%, and misdiagnosis was 16.4%. These results compare favorably with the diagnostic accuracy of the Intermediate Visual and Auditory test (IVA). The EEG biofeedback system was also used for EEG biofeedback with 27 ADHD children. Conners Parent Symptom Questionnaire was used to assess pre- and post-hyperactivity levels. There was a significant difference between the EEG values before and after treatment, and the hyperactivity index scores were significantly declined from pre-treatment to post-treatment.

A study by Pop-Jordanova, Markovska-Simoska and Zorcec (2005) comprised 12 children of both sexes diagnosed as ADHD with the mean age of nine and a half years (seven to 13 years old). Each participated in a five-month program of EEG biofeedback training performed twice weekly. Posttreatment results showed improved EEG patterns expressed in increased 16-20 Hz (beta) activity and decreased 4-8 Hz (theta) activity. In parallel, higher scores on WISC-R, better school notes, and improved social adaptability and self-esteem were obtained.

A report by Putman, Othmer, Othmer, and Pollock (2005) that used the TOVA as the outcome measure was divided into three categories: a) primarily attentional deficits (n=12), b) primarily psychological complaints (n=20), and c) both (n=12). Participants were 44 males and females, six to 62 years old, who underwent treatment for a variety of clinical complaints. The TOVA was administered prior to EEG biofeedback training and 20 to 25 sessions thereafter. After EEG biofeedback training, significant improvements on omission, commission, and variability were observed. There was no change in reaction time. Reaction time was predominantly in the normal range for this population and remained unchanged following training.

Functional magnetic resonance imaging (fMRI) was used by Beauregard and Levesque (2006) to measure the effect of EEG biofeedback training in ADHD children. Twenty unmedicated ADHD children participated. Fifteen children were randomly assigned to the group trained to enhance the amplitude of the SMR (12-15 Hz) and beta 1 activity (15-18 Hz) and to decrease the amplitude of theta activity (4-7 Hz); whereas, the other five children were randomly assigned to the no-treatment group. Both groups were scanned one week before the beginning of EEG biofeedback and one week after the end of EEG biofeedback while they performed a “Counting Stroop” task and a Go/No Go task. Changes were noted in several subcortical areas after biofeedback treatment in the EEG biofeedback group but not in the control group. These results suggest EEG biofeedback has the capacity to functionally normalize the brain systems mediating selective attention and response inhibition in ADHD children.

A study reported by Zhang, Zhang, and Jin (2006) compared EEG biofeedback with methylphenidate in ADHD children who were treated at the Department of Child Health Care, Xinhua Hospital. Participants were randomly assigned to groups. The EEG biofeedback group received treatments of reinforcing 16-20 Hz and suppressing 4-8 Hz; EEG biofeedback treatment was provided three to five times per week continuously for three months, totaling 35 to 40 sessions. The children in the medication group were treated with methylphenidate every morning. The dose started at 5 mg and increased gradually with the patients’ conditions until the effects were satisfied without any adverse effect. The Conners Parent Rating Scale was utilized to assess the behavioral changes. The children in the EEG biofeedback group and medication group were evaluated at pre-treatment, post-treatment and one, three, and six months of follow ups. Forty children who received EEG biofeedback and 16 who received medication were involved in the result analysis. Half the children who received EEG biofeedback were those who did not respond to medication after at least three months, so EEG biofeedback was provided. After treatment, the EEG biofeedback group demonstrated significant decreases in scores on all factors of the Conners Parent Rating Scale compared to those at pretreatment and remained stable during a six month follow up. The medication group also showed significant decreases in scores of all factors except psychosomatic disorder and anxiety compared with those at pretreatment. The scores of psychosomatic disorder and anxiety were significantly lower in the EEG biofeedback group than in the medication group at post-treatment.

In a controlled study of effectiveness of EEG biofeedback training on children with ADHD, Zhong-Gui, Hai-Qing, and Shu-Hua (2006) reported EEG biofeedback training was applied for 30 minutes, two times per week for 40 sessions. The IVA was adopted to evaluate the effectiveness of EEG biofeedback training. The results from 60 children indicated the overall indexes of IVA were significantly improved.

In a study by Kropotov et al. (2007), it was reported that changes in EEG spectrograms, eventrelated potentials, and event-related desynchronisation were induced by relative beta training in ADHD children. EEG, ERPs, and event-related synchronization/desynchronization (ERD/ERS) were recorded and computed in an auditory Go/No Go task before and after 15 to 22 sessions of EEG biofeedback.

Eighty-six ADHD children participated in the study. Each session consisted of 30 minutes of relative beta training. The patients were divided into two groups (good performers and poor performers) depending on their ability to elevate beta activity during sessions. Amplitude of late positive components of evoked potentials in response to No Go stimuli increased, and event-related synchronization in alpha frequency band measured at central areas decreased in the group of good performers but did not change for the poor performers group. Evoked potential differences between post- and pre-treatment conditions for good performers were distributed over frontal-central areas, reflecting activation of frontal cortical areas associated with beta training. This activation likely indicates recovery of normal functioning of the executive system, but unfortunately, no clinical outcome measures were reported.

This study (Leins et al. 2007) compared EEG biofeedback training of theta-beta frequencies and training of slow cortical potentials (SCPs). SCP participants were trained to produce positive and negative SCP shifts while the theta/beta participants were trained to suppress theta while increasing beta. Participants were blind to group assignment. Each group comprised 19 children with ADHD (aged eight to 13 years). Both groups were able to intentionally regulate cortical activity and improved in attention and IQ. Parents and teachers reported significant behavioral and cognitive improvements. Clinical effects for both groups remained stable six months after treatment. Groups did not differ in behavioral or cognitive outcome.

A summary of recently published review articles is presented below. Most of the review articles include many of the same original studies; therefore, caution needs to be exercised in their interpretation. Eighty-three studies were reviewed by Riccio and French (2004) to determine the status of treatments for ADHD. The studies were reviewed and categorized by the type of trial, whether or not the study included a control group, and the nature of the control group. The methodology of each study was then rated and assigned to one of four categories (commendable, acceptable, marginal, and seriously flawed). The results were then categorized into three categories (positive, negative, and inconclusive). Twenty studies were identified for treatment of ADHD with EEG biofeedback, and of those, seven were determined to have acceptable methodologies while 13 had marginal methodologies. The negative for one.

In another review, Fox, Tharp, and Fox (2005) reported that, in the last 30 years, multiple studies have consistently shown differences between ADHD children and nonADHD children in that the ADHD children have a surplus of slow-wave activity, mostly in the delta and theta bands, and deficiencies in the alpha and beta bands. They state that 70 to 80% of ADHD children respond favorably to stimulant medication, 35% respond favorably to placebo, and 25 to 40% do not respond favorably to medication. However, multiple studies have shown when stimulant medication is withdrawn, the improvements seen during medication usage in the medication responders are no longer maintained. In a summary of five EEG biofeedback outcome studies, they reported consistent improvements in behavior, IQ, and rating scales comparable to medication usage, and only those trained in biofeedback maintained their improvements when the treatment was withdrawn.

In a review, Loo and Barkley (2005) report EEG measures have been used to study brain processes in children with ADHD for more than 30 years, and this research supports the EEG differences between ADHD and nonADHD children. The differences are primarily in the frontal and central areas with theta activity being more abundant and beta activity less abundant; therefore, the theta-beta ratio is consistently and diagnostically larger in ADHD than nonADHD children. They report evidence of a possible percentage of ADHD subtypes for which the EEG activity described above does not fit, and a number of these individuals seem to be between 10 and 20% of all ADHD children. Thompson and Thompson (2005) report these subtypes show distinctively different EEG patterns with an abundance of high-frequency beta. The reviewers report that, more recently, EEG has been used, not only in research to describe and quantify underlying neurophysiology of ADHD but also clinically in the assessment, diagnosis, and treatment of ADHD. For the treatment of ADHD with EEG biofeedback, they reported mixed results based on one study from an unpublished presentation at the American Psychological Association meeting in 1994 (so methodology and outcome assessment techniques cannot be determined) and three controlled studies. Of these three studies, one had a single-case design that was inappropriate

for a treatment such as EEG biofeedback, which has a demonstrated carry-over effect. The two others demonstrated positive outcomes but were dismissed on what were viewed as weak methodical grounds because the studies did not use methodologies typically associated with pharmaceutical studies but used procedures usually associated with acceptable behavioral outcome studies.

In a series of review articles (Monastra, 2005; Monastra et al. 2005; Monastra et al. 2006), the authors report, in the past three decades, EEG biofeedback has emerged as a nonpharmacologic treatment for ADHD. These articles present imaging and EEG findings that support the theory of cortical hypoarousal, especially in the central and frontal regions of the cortex and that this intervention was derived from operant conditioning studies. These conditioning studies have demonstrated the capacity for neurophysiologic training in both humans and other mammals and targets atypical patterns of cortical activation that have been identified consistently in neuroimaging and quantitative EEG studies. The research findings published to date from case studies and controlled clinical outcome studies have reported increased cortical activation on quantitative electroencephalographic examination, improved attention and behavioral control, gains on tests of intelligence, improvement on self- and other rating scales, improved CPTs, and academic achievement. Three standard protocols of SMR enhancement and beta reduction, theta enhancement and beta reduction, and SMR enhancement and beta reduction are also presented.

A number of biofeedback articles based on techniques other than EEG biofeedback are presented below. These articles are presented in this section rather than the Emerging Applications section because they are treating individuals diagnosed with ADHD.

The effect of ROSHI protocol and cranial electrotherapy stimulation on a nine-year-old anxious, dyslexic male with attention deficit disorder was studied by Overcash (2005). Psychological testing was administered, and QEEGs were recorded before and after treatment intervention. The patient was treated using the ROSHI Complex Adaptive Protocol, Cranial Electrotherapy Stimulation, and the Project Read Reading Program. This multimodal treatment lasted six months with follow-up testing administered 15 months after initial diagnostic testing. Before and after, objective psychological test results and QEEG changes indicate significant improvement in reading, math, and spelling achievement and significant reduction in anxiety and ADD symptoms.

Mize (2004) reported a single case study of hemoencephalography (HEG) with a 12-year-old male who had a well-established diagnosis of ADHD. He was performing well in school on Concerta 36 mg at 7am and Ritalin 5 mg at 4pm. Off medication, he had significant abnormalities on IVA testing (attention quotient or AQ = 78) and in the QEEG. IVA and clinical status measurements were made before and after 10 sessions. Following the 10 sessions, the participant was tested off medication and showed a normal QEEG with improved Z scores for relative power and a normal IVA (AQ = 99.75). These results persisted in an 18-month follow up. His medication was lowered to Focalin 2.5 mg twice daily.

In a study designed to test the effectiveness of self-regulation of slow cortical potentials in children with ADHD (Strehl et al. 2006), 23 children with ADHD aged between eight and 13 years received 30 sessions of self-regulation training of slow cortical potentials in three phases of 10 sessions each. Feedback was provided while increasing and decreasing slow cortical potentials at central brain regions. Measurement before and after the trials showed that children with ADHD learned to regulate negative slow cortical potentials. After training, significant improvement in behavior, attention, and IQ score were observed. All changes proved to be stable at six months' follow up after the end of training. Clinical outcome was predicted by the ability to produce negative potential shifts in transfer sessions without feedback. In summary, based on these studies and the reviews, EEG biofeedback has typically been shown to be superior to control conditions and equivalent to other treatments such as stimulant medication.

The utilization of EEG measures to facilitate diagnostic determination and protocol determination is strongly supported. Because the EEG protocols vary widely in specific bandwidths and thresholds selection, it is prudent for the practioner to know the literature to determine which specific settings to use for each client. In addition to the EEG assessment, multiple assessments, including psychological, family,

and medical history; a clinical interview; and standardized assessments, such as a continuous performance test and ratings scales, should be used to formulate a comprehensive treatment plan. EEG biofeedback techniques other than those focused on EEG patterns are also under development. Further studies are needed to examine long-term effects of training sessions and whether or not refresher sessions are needed to maintain the effects.

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4. ANXIETY

Much of the information provided here is from Carolyn Yucca's 2008 book "Evidence Based Practice in Biofeedback & Neurofeedback" AAPB, Wheat Ridge, CO.

Overview & Efficacy: Everybody gets anxious. Treatment is called for if the amount of anxiety is out of proportion to the problem or lasts too long. Many methods for helping people reduce and control their anxiety have been shown to be effective. Behavioral techniques include relaxation training, cognitive restructuring, and biofeedback. Any form of biofeedback which helps people become aware of their physiological responses as they become anxious and which helps people learn to relax is apparently at least as effective as any other behavioral technique.

This therapy is rated as efficacious (level 4 on a scale of 1 – 5 with 5 being the best).

Why biofeedback would help this problem: There are several different underlying problems which cause abnormal levels of anxiety. Biofeedback helps each for different reasons.

a. Breathing problems which cause anxiety: Half or more of people who habitually breathe too rapidly with shallow breaths are anxious because of the effects of their breathing on their brains' chemistry. Most of these people are not aware they have incorrect breathing patterns. These incorrect patterns are easily detected using psychophysiological assessments and are corrected using several types of biofeedback related to helping people normalize their breathing patterns. When the breathing is normalized, the anxiety goes away.

b. When a person experiences greater levels of anxiety or the anxiety lingers far longer than it should, the body's normal responses to an emergency situation don't shut down. This can cause the

body to wear out while thinking and memory patterns change. The physiological reactions to anxiety are accurately assessed using psychophysiological recording techniques so both the patient and therapist always know when any therapy is helping and how much. Biofeedback treatments show the patient the abnormal physiological response levels. Patients use this knowledge to recognize when they are becoming abnormally anxious and to control their anxiety.

Brief summary of evidence supporting the efficacy of biofeedback for abnormal levels of anxiety:

Anxiety

Level 4: Efficacious

Multiple case studies have demonstrated clinically significant outcomes with carefully screened and thoroughly assessed participants for various forms of anxiety-related disorders. There are also several treatment-only group studies with moderate sample sizes, demonstrating positive results of various forms of biofeedback that were often combined with other behavioral interventions. A few well-controlled, randomized studies have shown biofeedback to be equivalent to other relaxation and self-control methods for reducing anxiety while it is occasionally shown to be superior to another intervention. Most show biofeedback (EMG, GSR, thermal, or neurofeedback) to be roughly equivalent to progressive relaxation or meditation.

Lehrer, Carr, Sargunaraj, and Woolfolk (1994) evaluated the hypothesis that biofeedback is most effective when applied in the same modality as the disorder (autonomic feedback for ANS disorders, EMG feedback for muscular disorders, etc.). Other researchers have asserted self-relaxation techniques have in common the process of using conscious intent to calm oneself, and for anxiety reduction, it may matter little which modality is used because the central component is the cognitively based conscious intent. Clarification of this issue must await further clinical outcome studies.

Two studies showed biofeedback's efficacy in reducing anxiety without making comparisons with other relaxation techniques. Hurley and Meminger (1992) used frontal EMG biofeedback with 40 subjects trained to criterion and assessed anxiety over time using the State-Trait Anxiety Inventory (STAI). State anxiety improved more than trait anxiety. Wenck, Leu, and D'Amato (1996) trained 150 seventh- and eighth-graders with thermal and EMG feedback and found significant reduction in state and trait anxiety.

Roome and Romney (1985) compared progressive muscle relaxation to EMG biofeedback training with 30 children and found an advantage for biofeedback; however, Scandrett, Bean, Breeden, and Powell (1986) found some advantage of progressive muscle relaxation over EMG biofeedback in reducing anxiety in adult psychiatric inpatients and outpatients.

Rice, Blanchard, and Purcell (1993) studied reduction in generalized anxiety by comparing groups given EMG frontal feedback, EEG alpha-increase feedback, and EEG alpha-decrease feedback to two control conditions (a pseudo-meditation condition and a wait-list control). All treatment groups had comparable and significant decreases in the STAI and drops in the Psychosomatic Symptom Checklist. The alpha-increasing biofeedback condition produced one effect not found with the other treatment conditions: a reduction in heart-rate reactivity to stressors. Similar results were obtained by Sarkar, Rathee, and Neera (1999), who compared the generalized anxiety disorder response to pharmacotherapy and to biofeedback; the two treatments had similar effects on symptom reduction. Hawkins, Doell, Lindseth, Jeffers, and Skaggs (1980) concluded, from a study with 40 hospitalized schizophrenics, that thermal biofeedback and relaxation instructions had an equivalent effect on anxiety reduction. However, Fehring (1983) found adding GSR biofeedback to a Benson-type relaxation technique reduced anxiety symptoms more than relaxation alone.

Vanathy, Sharma, and Kumar (1998), applying EEG biofeedback to generalized anxiety disorder, compared increased alpha with increased theta. The two procedures were both effective in decreasing symptoms. In a recent case study, Hammond (2003) reported on two cases using EEG biofeedback for OCD. Clinically significant improvements for both participants were reported. In a single case study (Goodwin & Montgomery, 2006) of a 39-year-old male with panic disorder and agoraphobia,

electrodermal biofeedback was combined with CBT, graded exposure. They reported a complete cessation of panic attacks, a remission of agoraphobia, and a clinically significant reduction in depression. In a study by Gordon, Staples, Blyta, and Bytyqi (2004) a total of 139 PTSD postwar high school students were provided a six-week program of biofeedback, meditation, drawings, autogenics, guided imagery, genograms, and breathing techniques. No control group was used, but they reported a significant reduction immediately after treatment and at follow up. In a two-treatment group comparison study (n=50) of anxiety in individuals with chronic pain, Corrado, Gottlieb, and Abdelhamid (2003) reported a significant improvement in anxiety and somatic complaints in the group that received biofeedback of finger temperature increase and muscle tension reduction when compared to a pain education group. In an RCT study of 87 participants, Bont, Castilla, and Maranon (2004) presented the outcome of three intervention programs applied to fear of flying: a reattributional training-based program, a mixedexposure
procedure, and finally a biofeedback training program in order to change psychophysiological responses. A fourth group of wait-list controls were also assessed. They found a significant reduction in anxiety for the treatment groups when compared to the control group of no treatment. In another RCT study of imipramine and imipramine plus biofeedback, Coy, Cardenas, Cabrera, Zirot, and Claros (2005) found the biofeedback group plus medication (n=18) was significantly improved compared to the medication-only group (n=14).

From a group of 312 high school students in Shanghai, Dong and Bao (2005) recruited 70 students who met criteria for high levels of anxiety and assigned 35 students to a group who were treated with biofeedback and 35 to a group of no-treatment controls. They reported a significant improvement in anxiety, somatization, and depression in the treatment group when compared to the controls.

In conclusion, biofeedback of various modalities is effective for anxiety reduction. It is often found to compare favorably with other behavioral techniques and occasionally found to be superior to those and medication alone.

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5. Raynaud's Disease

Level 4: Efficacious

There were several brief, relatively uncontrolled studies published in the 1970s that confirmed the rationale underlying temperature biofeedback (TBF) treatment of primary Raynaud's disease (RP). Peterson and Vorhies (1983) studied thermal biofeedback-trained Raynaud's patients, observing the speed of hand temperature return to baseline after hand immersion in ice water, which was six to seven times as fast after biofeedback training (six minutes average after training versus 40 minutes before). Jobe, Sampson, Roberts, and Kelly (1986) compared hand temperature responses to whole-body chilling before and after biofeedback training and found it to be effective. When Guglielmi, Roberts, and Patterson (1982) compared thermal biofeedback with EMG biofeedback and controls with a double-blind procedure, all three groups had comparable improvements, suggesting a role of nonspecific factors. The results of this study have limited generalization to clinical practice because the participants could not have adequate instructions about how to perform the physiological changes, when and how to utilize the training, and any motivational guidelines for incorporating the training daily to enhance the clinical training. Keefe, Surwit, and Pilon (1980) found similar results, in which other behavioral control methods performed as well as thermal biofeedback. However, Freedman et al. (1988) compared simple thermal biofeedback with autogenic training and found the former to be more effective.

The largest study to date of Raynaud's involving biofeedback compared use of a calcium-channel blocker (nifedipine) with thermal biofeedback, EMG feedback, and a placebo (Raynaud's Treatment Study Investigators, 2000). In this study of 313 subjects with primary Raynaud's disease, nifedipine seemed to be the superior agent for reducing symptoms. Problems with training the thermal biofeedback subjects to an adequate level of skill, however, mitigated the final results (Middaugh et al. 2001).
A recent review of finger temperature training in primary Raynaud's phenomenon that focused on whether subjects were adequately trained to increase finger temperature found eight RCT, one nonRCT, and two follow-up studies (Karavidas, Tsai, Yucha, McGrady, & Lehrer, 2006). The authors concluded the level of evidence for TBF efficacy is categorized as Level IV: efficacious. The rationale was based on three randomized controlled trials conducted in independent laboratories that demonstrated "superiority or equivalence" of treatments that include TBF.

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6. Urinary Incontinence in Females

Level 5: Efficacious and Specific

Numerous within-subject studies have demonstrated biofeedback efficacy at the lower levels of efficacy (Dannecker, Wolf, Raab, Hepp, & Anthuber, 2005; Rett et al. 2007); all of these have not been reported here. Rather, only RCTs and systematic reviews are included that show levels four and five efficacy of biofeedback for urinary incontinence in females. It is better than no treatment (i.e., control) (Burgio et al. 1998; Burns et al. 1993; Dougherty et al. 2002; McDowell et al. 1999), better than or equal to other behavioral treatments (e.g., pelvic floor exercises, bladder training) (Burns et al. 1993; Glavind, Nohr, & Walter, 1996; Sherman, Davis, & Wong, 1997; Sung, Hong, Choi, Baik, & Yoon, 2000; Weatherall, 1999; Wyman, Fantl, McClish, & Bump, 1998; Wallace, Roe, Williams, & Palmer, 2004), as effective as pelvic floor electrical stimulation (Goode et al. 2003; Wang, Wang, & Chen, 2004) and vaginal cone (Seo, Yoon, & Kim, 2004), and better than drug (i.e., oxybutynin chloride) treatment (Burgio et al. 1998; Goode, 2004). The benefit of biofeedback over drug therapy was supported by a systematic review (Teunissen, de Jonge, van Weel, & Lagro-Janssen, 2004). Combining drug and behavioral therapy in a stepped program can produce added benefit for those not satisfied with the outcome of single treatment (Burgio, Locher, & Goode, 2000).
Biofeedback is also effective for reducing urinary incontinence in older women (Tadic et al. 2007). In comparison to drug treatment with oxybutynin, biofeedback reduced incontinence (Goode, 2004) and nocturia in older women (Johnson, Burgio, Redden, Wright, & Goode, 2005). Exploring the effect of pelvic floor muscle exercises on urinary incontinence following childbirth is more complicated. Studies where it is administered prenatally include women who are both continent and incontinent postnatally; this diminishes the results, and the effect is not different from that seen in control groups. However, in studies in which this training is provided to only those who are incontinent after childbirth, there is a significant effect on reducing or resolving urinary incontinence (Haddow, Watts, & Robertson, 2005). In those with multiple sclerosis, EMG biofeedback for lower urinary tract dysfunction, especially in combination with neuromuscular electrical stimulation, decreased incontinence episodes (McClurg, Ashe, & Lowe-Strong, 2007).

A number of systematic reviews are now available reporting efficacy for pelvic floor muscle training (Bø, 2003; Neumann, Grimmer, & Deenadayalan, 2006; Hay-Smith & Dumoulin, 2006). In a Cochrane Review, Alhasso, McKinlay, Patrick, and Stewart (2006) found symptomatic improvement was more common among those on anticholinergic drugs compared with bladder training (with and without biofeedback). In contrast, a more specific review of pelvic floor muscle biofeedback reported the overall mean treatment improvement was 72.6% and that in 60% of paired comparisons, biofeedback demonstrated superior symptomatic outcome to control or alternate treatment groups, including oxubutynin (Glazer & Laine, 2006).

Recent studies have explored variations in biofeedback therapy. Home biofeedback for 12 weeks resulted in an increase in pelvic floor muscle activity and a decrease in leakage index (Aukee et al. 2004). A telemedicine continence program (including biofeedback-assisted pelvic floor training) was as effective as a clinic-based program (Hui, Lee, & Woo, 2006). Position during training (supine vs supine and upright) does not differentially affect treatment outcomes (France, Zyczynski, Downey, Rause, & Wister, 2006).

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7. Chronic Pain

Level 4: Efficacious

Chronic pain can arise from just one or two sites, or it can be pervasive and widespread. Most research studies focus on pain from a particular site, but because chronic pain, regardless of its source, may involve nonspecific factors such as neural sensitization, altered neurotransmitter levels, inflammation, and muscle guarding, there is some logic to also treating chronic pain as a unitary condition regardless of its site and supposed generating mechanism. This section on Chronic Pain excludes specific categories that are presented in other sections for that disorder (e.g., headaches). Because some specific disorders have clearly demonstrated biofeedback effectiveness while others have only case studies and mixed results for the efficacy of specific disorders, it is necessary to generalize across various specific pain disorders. For specific disorders, review other sections of this document and other related, more detailed publications such as AAPB's White Paper on chronic pain (Clinical Efficacy of Psychophysiological Assessments and Biofeedback Interventions for Chronic Pain Disorders Other Than Head-Area Pain, 2006). Most studies of biofeedback treatment are from studies where biofeedback is a

part of a multiple modality program, so it is not possible at this time to ascertain the unique contributions biofeedback may provide for chronic pain patients. However, the studies presented below clearly demonstrate treatment programs that include biofeedback are as effective as standard (single treatment or medication alone) and more effective than no-control conditions. Flor and Birbaumer (1993) studied both EMG biofeedback and cognitive therapy for both back
pain and temporomandibular joint pain. In this study, biofeedback had the strongest effect on many aspects of pain, and the effects were still present at a 24-month follow up. Vlaeyen, Haazen, Schuerman, Kole-Snijders, and van Eek (1995) studied the response to EMG biofeedback training in 71 chronic back pain patients in comparison with a cognitive-training group. The groups had comparable positive outcomes as compared to wait-list control and an operant conditioning–only treatment. Newton-John, Spence, and Schotte (1995) compared cognitive therapy with EMG biofeedback in chronic back patients and obtained similar beneficial effects with both as compared to a wait-list control group. Effects persisted at a six-month follow up. Humphreys and Gevirtz (2000) reported a study of recurrent abdominal pain in 64 children and teenagers that used thermal biofeedback alone or in combination with cognitive-behavioral treatment. Results for pain relief were significantly above an inactive treatment (fiber-only) control group.

A comprehensive literature review of biopsychosocial approaches to chronic pain published in 2001 (Nielson & Weir, 2001) examined many single and combined treatments and found EMG biofeedback had at least moderate support as a separate treatment. The bulk of the studies and the three systematic reviews covered mostly back pain, the most common focus for research at that time.

Fifty chronic pain patients were evaluated pre- and post-treatment using the Wahler Physical Symptoms Checklist and the IPAT Anxiety Scale (Corrado, Gottlieb, & Abdelhamid, 2003). Participants were randomly assigned to a biofeedback-plus-relaxation-training group or a pain-education group. The biofeedback-plus-relaxation-training group reported significantly improved symptoms of anxiety and significantly reduced somatic complaints in comparison with the pain-education group.

Hawkins and Hart (2003) used thermal biofeedback in the treatment of pain associated with endometriosis. A multiple case study design ($n = 5$) was employed. Four participants were able to demonstrate mastery over hand temperature through thermal biofeedback. Of those four participants, significant reductions in various aspects of pain were observed. Pulliam and Gatchel (2003) examined the literature with respect to biofeedback and chronic pain and summarized the current indications of this treatment modality for various disorders.

Conditions reviewed included headaches, temporomandibular disorders, low back pain, fibromyalgia, irritable bowel syndrome, and Raynaud's disease. The authors concluded biofeedback represents a useful adjunctive treatment technique for most chronic pain conditions. Its addition to standard treatment provides significant incremental validity for many disorders.

A review article by Stinson (2003) reported only RCT trials comparing a clearly defined psychological treatment with a control condition (wait-list and self-monitoring) for chronic pain in children or adolescents. The main outcome was pain experience denoted as a Pain Index. A reduction in the Pain Index of ≥ 50% from baseline was equivalent to a clinically significant improvement with subsequent classification of the outcome as improved or unimproved. Thirteen of 18 RCTs that met the selection criteria were included in the meta-analysis. The 25 psychological treatments studied in these RCTs included relaxation (11 RCTs), relaxation with biofeedback (four RCTs), cognitive behavioral therapy (nine RCTs), and cognitive behavioral family intervention (one RCT). Twelve RCTs took place in clinic settings and six in school settings. More patients in the treatment group than in the control group had a ≥ 50% reduction in the Pain Index from baseline.

A series of articles reported on the treatment of 52 consecutive patients with chronic myofascial pain who had failed to respond to physical, chiropractic, medical, surgical, and pharmacologic treatment with physical therapy combined with EMG biofeedback, counseling, medications, and trigger point injections (Sorrell & Flanagan, 2003; Sorrell, Flanagan, & McCall, 2003). They compared groups with clinically defined anxiety and depression or both with the group having neither. All patients with anxiety took anxiolytic medication during the study, and all but one with depression took antidepressants. Results

were that anxiety alone had no effect on outcomes while depressed patients were less likely to improve. Engel, Jensen, and Schwartz (2004) studied three adults with cerebral palsy, using biofeedbackassisted relaxation training on self-reported pain and muscle tension. Two of three participants reported decreases in their pain experiences post-treatment. Their subjective reports, however, did not correspond with physiological changes.

Ninety-two systemic lupus erythematosus (SLE) patients were assigned randomly to receive either biofeedback-assisted cognitive-behavioral treatment (biofeedback/CBT), a symptom-monitoring support (SMS) intervention, or usual medical care (UC) alone (Greco, Rudy, & Manzi, 2004). Biofeedback/CBT participants had significantly greater reductions in pain and psychological dysfunction compared with the SMS group and the UC group. Biofeedback/CBT had significantly greater improvement in perceived physical function compared with UC and improvement relative to SMS was marginally significant. At a nine-month follow-up evaluation, biofeedback/CBT continued to exhibit relative benefit compared with UC in psychological functioning.

In a study of Complex Regional Pain Syndrome (CRPS), the effects of a multidisciplinary day treatment program were examined by McMenamy, Ralph, Auen, and Nelson (2004). Participants included 11 adults with a history of CPRS of six months or longer. Multidisciplinary treatments used included physical therapy; occupational therapy; stress management; biofeedback; goal-oriented cognitively based individual, group, and family counseling; sympathetic blocks; medication management; behavioral modification; pain management; nutritional education; and case management. Variables assessed at admission and discharge included physical and occupational therapy ratings, thermal biofeedback levels, self-reported pain levels, depression and somatic distress levels, narcotic use, and vocation status. At postdischarge

follow up, which ranged from six to 30 months, pain levels, vocational status, and narcotic use were assessed. Results support the hypothesis that multidisciplinary treatment of CPRS is effective in the improvement of symptomatology.

Fifty women between 42 and 74 years old with the diagnosis of knee osteoarthritis participated in a study (Durmus, Alayli, & Canturk, 2005). Patients were randomized into two groups of biofeedbackassisted

isometric exercise or electrical stimulation. For both groups, 20 minutes of therapy was applied five days a week for four weeks. Patients were evaluated before and after therapy. Both treatment groups showed significant improvements in pain and physical function scores and demonstrated significant improvements in anxiety and depression scores.

Phantom limb pain (PLP) was studied in nine individuals (Harden et al. 2005). They received up to seven thermal/autogenic biofeedback sessions over the course of four to six weeks. Interrupted timeseries

analytical models were created for each of the participants, allowing biofeedback sessions to be modeled as discrete interventions. Analyses revealed a 20% pain reduction was seen in five of the nine patients in the weeks after session four and at least a 30% pain reduction (range: 25 to 66%) was seen in six of the seven patients in the weeks following session six.

In an illustrative case study, Masters (2006) describes how, after three years of various medical interventions, including exploratory surgery, an individual was referred for biofeedback training. After a course of seven sessions over five months that variously included heart rate variability and skin temperature feedback along with extensive home practice of paced breathing and hand warming, the patient achieved significant symptom reduction and improved coping abilities.

A study of 50 chronic pain patients aged 18 to 65 who suffered for at least six months (23 patients with pain in the lumbar region and 27 patients with pain in the cervical and dorsal regions) was reported by Ferrari, Fipaldini, and Birbaumer (2006). The patients were assigned randomly to one of two treatment conditions: 12 sessions of 60 minutes of EMG biofeedback with the electrodes placed in the region of pain and 12 sessions of 80 minutes in a small group. At the end of both treatments, a reduction in the quantity of analgesics consumed, the subjective pain intensity, and the self-evaluations of pain were

observed. These improvements continued at the one-month and the six-month follow ups. In a study by Qi and Ng (2007), an eight-week home program provided patellofemoral pain syndrome patients with a treatment with and without EMG biofeedback of the vastus medialis obliquus and vastus lateralis. Twenty-six subjects were randomly allocated into exercise-only or EMGbiofeedback-plus-exercise groups. Both groups performed the same exercise program lasting eight weeks. The intensity of the knee pain was recorded. The results reveal the incorporation of EMG biofeedback into a home exercise program significantly facilitated the activation of the vastus medialis obliquus muscle and the reduction of pain.

In a study by Tsai, Chen, Lai, Lee, and Lin (2007), the effects of frontal EMG biofeedbackassisted relaxation on pain in patients with advanced cancer in a palliative care unit was assessed. Participants were randomly assigned to conditions. The experimental group (n = 12) received six EMG biofeedback-assisted relaxation sessions over a four-week period; whereas, the control group (n = 12) received conventional care. The primary efficacy measure was the level of pain, measured by the Brief Pain Inventory. Findings from this study showed frontal EMG biofeedback is effective in reducing cancer-related pain in advanced cancer patients.

Voerman, Vollenbroek-Hutten, and Hermens (2006) studied changes in pain, disability, and muscle activation patterns in chronic whiplash (WAD) patients after four weeks of ambulant myofeedback training. Eleven WAD patients received ambulatory myofeedback training, during which upper trapezius muscle activation and relaxation were continuously recorded and processed for four weeks. Feedback was provided when muscle relaxation was insufficient. Pain in neck, shoulders, and upper back (Visual Analogue Scale), disability (Neck Disability Index), and muscle activation patterns during rest, typing, and stress tasks (surface electromyography) were assessed before and after the four weeks of training. Pain intensity decreased after training. Clinically relevant changes were found with regard to pain in the neck and upper back region and right and left shoulder. A trend for decreased disability was found that was clinically relevant in 36% of the patients. A remarkable reduction was found in the Neck Disability Index items concerning headache and lifting weights.

In a review of studies that evaluated treatments for recurrent abdominal pain (RAP), Weydert, Ball, and Davis (2003) located 10 studies that met the inclusion criteria that the study involve children aged five to 18 years with a diagnosis of RAP, and subjects were randomly assigned to treatment or control groups. Studies that evaluated famotidine, pizotifen, cognitive-behavioral therapy, biofeedback, and peppermint oil enteric-coated capsules showed a decrease in measured pain compared to control groups. The studies that evaluated dietary interventions had conflicting results, in the case of fiber, or showed no efficacy, in the case of lactose avoidance.

In a review of treatment of chronic pain, Singh (2005) reported the therapeutic response of pharmacotherapy in chronic pain at the present time remains unsatisfactory and refractory at best. Multidisciplinary pain management has not only brought new hope but has also increased the therapeutic response in general. The multidisciplinary management allows patient access to a complete armamentarium of pain therapies and includes relaxation therapy, physiotherapy, transcutaneous electrical nerve stimulation, exercise, biofeedback techniques, acupuncture, behavior modification, hypnosis, sympathetic nerve block, desensitization, and cognition therapy as well as the therapeutic benefit of pharmacotherapy. Multidisciplinary management of chronic pain syndrome has become the key for enhanced success and the route of holistic management.

In a review of mind-body interventions for chronic pain in older adults, Morone and Greco (2007) reported on 20 trials. There was some support for the efficacy of progressive muscle relaxation plus guided imagery for osteoarthritis pain with limited support for meditation and tai chi for improving function or coping in older adults with low back pain or osteoarthritis. In an uncontrolled biofeedback trial that stratified by age group, both older and younger adults had significant reductions in pain following the intervention. Bohm-Starke, Brodda-Jansen, Linder, and Danielsson (2007) provided 35 women with provoked vestibulodynia four months of treatment with either EMG biofeedback (n=17) or topical lidocaine (n=18). Assignment to conditions was randomized. Vestibular and general pressure pain thresholds (PPTs) were

measured and the health survey Short Form-36 (SF-36) was filled out before treatment and at a six-month follow up. Subjective treatment outcome and bodily pain were analyzed. Thirty healthy women of the same age served as controls for general PPTs and SF-36. Three patients reported total cure, and 25 were improved.

The results of a comprehensive review by the National Institutes of Health Technology Panel are summarized by Lebovits (2007). He reports cognitive-behavioral approaches include hypnosis, relaxation (including guided imagery, progressive muscular relaxation, meditation, and music therapy), biofeedback, coping skills training, cognitive restructuring, supportive and group therapy, and stress-management techniques. The panel concluded the evidence is "strong" (its highest rating) for the effectiveness of relaxation in reducing chronic pain. Specific relaxation strategies that have been shown to reduce levels of pain include guided imagery, progressive muscle relaxation, and meditation. Yet despite the generally accepted efficacy of these methods with pain patients, their relative ease of implementation, and their very low side-effect profile, barriers still exist with the integration of psychological therapies into standard medical care.

In a recent study utilizing EEG biofeedback for Complex Regional Pain Syndrome Type 1 (CRPS-1), Jensen, Grierson, Tracy-Smith, Bacigalupi, and Othmer (2007) reported the results from 18 participants. Pain was measured before and after each 30-minute EEG biofeedback treatment. The EEG biofeedback varied for each participant and across sessions. The authors report a substantial and significant reduction in pain from pre- to post-treatments with 50% reporting clinically meaningful reduction in pain.

In summary, the category of Chronic Pain is a diffuse collection of pain-related, specific disorders, and their treatment with biofeedback techniques has a range of efficacy associated with them. For many chronic conditions, biofeedback has been shown to be effective in treating pain, especially when included in a multiple modality program. Therefore, the general conclusion is that biofeedback is efficacious in treating chronic pain, but its utilization for specific disorders needs to be determined from an in-depth review of the literature for that specific condition.

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8. Epilepsy

Level 4: Efficacious

Early studies testing EEG biofeedback for epilepsy showed promise in reducing seizure activity,

utilizing some form of the technique to increase the abundance of SMR (typically defined at 12-15 Hz) and often to simultaneously decrease the EEG in the typical low-frequency range of 4-8 Hz. In the first case study published in 1972, Sterman demonstrated a complete cessation of seizures in a woman who had a seven-year history of medically uncontrolled generalized tonic-clonic seizures. After becoming seizure-free, she was issued a state driver's license. This research was an extension of studies with animals that demonstrated they could be operant-conditioned to increase SMR, and this increase was associated with an increase in seizure threshold.

Recent studies built on these findings demonstrate self-regulation of slow cortical potentials using EEG feedback decreases seizure activity in drug-resistant epilepsy when compared to pre-training (Kotchoubey, Schneider, et al. 1996; Kotchoubey et al. 1999; Sterman, 1986; Swingle, 1998). This effect was sustained for at least six months after therapy (Kotchoubey, Blankenhorn, Froscher, Strehl, & Birbaumer, 1997). A five consecutive–day neurobehavioral treatment protocol resulted in 79% of patients being able to achieve seizure control (Joy Andrews, Reiter, Schonfeld, Kastl, & Denning, 2000). Kotchoubey et al. (2001) studied patients with refractory epilepsy in a controlled clinical trial comparing an anticonvulsive drug plus psychosocial counseling (drug), a group that learned to control breathing (control), and a group learning self-regulation of slow cortical potentials (experimental). The experimental and drug groups showed a significant decrease of seizure frequency, but the control group did not.

In a review of the EEG biofeedback treatment for seizures, Sterman (2000) reviewed 18 studies published between 1981 and 1996 in peer-reviewed journals. Most studies used pre-treatment baselines for comparisons, but 10 used appropriate controls such as another biofeedback modality or noncontingent feedback. These trials treated 174 patients with 142 of them (82%) showing clinically significant improvements and 115 of them (66%) demonstrating significant increases in SMR activity. There were no reports of increased seizure activity in those treated with biofeedback. Unfortunately, because none of the studies were designed to be RCTs, this led a Cochrane Database Systematic Review to conclude there is no reliable evidence to support the use of EEG biofeedback in the treatment of epilepsy because of methodological deficiencies and limited number of patients studied (Ramaratnam, Baker, & Goldstein, 2005). However, because most of the subjects were refractory seizure victims, in spite of medication usage, and the biofeedback was shown to clinically reduce the seizure, this technique appears to be effective and safe.

In a recent review by Marson and Ramaratnam (2003), which looked at only RCT studies, one controlled trial was found, and that trial reported significant reductions in median seizure activity. Another review of biofeedback treatment of seizures (Sheth, Stafstrom, & Hsu, 2005) reported a review from 16 studies. Subjects in all studies were designated as having refractory epilepsy. Sample size for most studies was relatively small (n = 1 – 8), but one larger sample size study was found (n = 83). When all studies were combined, 82% of those treated with biofeedback showed clinical improvement. This review also presented studies with two other biofeedback techniques, and these are Contingent Negative Variation (CNV) or Slow Cortical Potential (SCP) and Galvanic Skin Response (GSR). Both techniques had positive outcomes with reduction in seizure activity being clinically significant.

Pop-Jordanova, Zorcec, and Demerdzieva (2005) report a case study of biofeedback treatment of a 13-year-old girl with psychogenic nonepileptic seizures (PNS). The treatment was electrodermal (EDR) biofeedback combined with cognitive-behavioral therapy. After 10 sessions of 45 minutes per day, they observed cessation of attacks, stabilization of neurotic tendencies, progression of the maturational process, and good academic results. In conclusion, based on more than 30 years of clinical trials with EEG biofeedback based on EEG

waveform characteristics for the treatment of seizures, several independent investigators have demonstrated EEG biofeedback is effective in reducing seizure activity, often in refractory patients. There is no evidence this treatment has been linked to an increase in seizures. Other biofeedback techniques (SCP and GSR) have been tried with some success.

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9. Constipation in Adults

Level 4: Efficacious

A critical review of 38 studies of biofeedback treatment for constipation reported most studies report positive results (Heymen, Jones, Scarlett, & Whitehead, 2003). Success rate for pressure biofeedback (78%) was greater than for EMG biofeedback (70%), but there was no difference in outcome using intra-anal or perianal EMG sensors. These findings are consistent with another review showing a 62.4% success rate in those treated for constipation (Palsson et al. 2004).

Biofeedback has led to significant improvement in those with constipation (Heymen et al. 1999; Ko et al. 1997; Pucciani et al. 1998). A number of controlled trials have shown EMG biofeedback and manometry biofeedback had similar effects (Wang, Luo, Qi, & Dong, 2003), biofeedback and electrical stimulation were comparable (Chang et al. 2003), EMG biofeedback was better than medical treatment with diazepam or a placebo (Heymen et al. 2007), EMG biofeedback was better than sham biofeedback or standard care (Rao et al. 2007), and biofeedback was better than laxatives (Chiarioni, Whitehead, Pezza, Morelli, & Bassotti, 2006). It appears to be more effective for those with pelvic floor dyssynergia than for those with slow-transit constipation (Bassotti et al. 2004; Battaglia et al. 2004; Chiarioni, Salandini, & Whitehead, 2005).

Biofeedback has also been used after surgery for rectal disorders. In uncontrolled studies, biofeedback was shown to be of benefit after surgery (Kairaluoma et al. 2004; Hwang et al. 2005; Hwang et al. 2006).

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SECTION C

Cost Effectiveness

The above sections demonstrate that many biofeedback based interventions are highly efficacious and that some have been shown to work as well or better than drugs. In addition, they don't have any side effects.

A common assumption is that behavioral interventions must cost far more than taking medications as ten or more sessions of biofeedback (perhaps as many as 40 for some EEG based interventions) are needed to achieve lasting effectiveness and each session costs a minimum of $150 (frequently $300 or more) in private pay situations. Biofeedback based interventions have been shown to help only an average of 80% of patients at all with the average amount of help also being about 80% control of symptoms. Thus, at least 20% of patients will need to get other types of therapy and the third party payer or the patient is out the cost of the biofeedback therapy.

However, medications for the conditions discussed above seldom help any more patients any better than biofeedback. So, the same situation holds for medications as for biofeedback.

In the mid 1980s experts such as Carol Schneider* began trying to figure out the relative cost of biofeedback vs. medications when all the factors were taken into account.

*Biofeedback Self Regul. 1987 Jun;12(2):71-92. Cost effectiveness of biofeedback and behavioral medicine treatments: a review of the literature. Schneider CJ.

Carol and many others since then have come up with the same basic conclusion: Biofeedback – even when augmented with relaxation training and / or cognitive restructuring actually costs less in the long run than medicine based treatments.

Here are some of the key factors:

1. Medications can be incredibly expensive and insurance frequently doesn't cover much or all of the cost of sufficient numbers of pills.
2. It is very rare that the correct medication is picked the first time a patient sees a primary care provider and doses need to be tinkered with ad infinitum.
3. Many – if not most – patients wind up making multiple visits to incredibly expensive sub-specialists such as neurologists.
4. The visits never stop because the drugs usually have to be changed and doses titrated as the drugs lose effectiveness over time.
5. Side effects are frequently expensive to treat.
6. Sometimes drug effects require hospitalization and rehospitalization.
7. Drugs have a poor record of long term relief from the disability related to chronic pain. This disability (e.g. days of work lost) costs the patient and society a fortune.
8. Reviews such as Schneider's consistently indicate that "that multicomponent behavioral medicine treatments are cost-effective on all dimensions reviewed.
9. Cost/benefit ratios range between 1:2 and 1:5, with a median of 1:4."
10. Often, there may not be any really effective drugs for some conditions such as IBS.
11. Many patients do not respond to any medications for their conditions or respond minimally.
12. Patients frequently won't take potentially effective medications due to significant side effects.

Herman PM, Craig BM, Caspi O. BMC Complement Altern Med. 2005 Jun 2;5:11.
Is complementary and alternative medicine (CAM) cost-effective? A systematic review.

Insurance coverage:

For current information on insurance coverage for biofeedback, see Ron Rosenthal's article "New Guidelines for Third Party Reimbursement for Biofeedback" at www.aapb.org.

Summary of reasons to refer patients for bfb

1. Biofeedback is not magic. Rather, muscle tension biofeedback helps patients learn to recognize incorrect patterns of muscle tension proven to cause headaches and to correct those patterns. Same idea for temperature.
2. Biofeedback is not "experimental" when used for headache control. Rather, biofeedback for prevention of tension headaches and migraine headaches of non-traumatic origin has about as much solid research supporting its efficacy as that available for most preventive headache medications.
3. Biofeedback has been shown to have effect sizes proving it to be as efficacious as popular preventive medications.

It helps at least the same percent of patients to about the same extent as medications (about 80% of patients get 80% better).

4. Biofeedback has no side effects.
5. It lasts for up to 15 years.
6. It is cost effective.

Modified from Andrasik's slides 2013 – used with his permission.
For those practitioners who prefer to prescribe medications rather than send patients for behavioral interventions:
When to choose behavioral treatments over medications

- Patient prefers a non-drug approach

• Drug treatment cannot be tolerated or is medically contraindicated
• Response to drug treatment is absent or minimal
• Patient is pregnant, has plans to become pregnant, or is nursing
• History of frequent or excessive use of analgesic or other acute medications
• Significant life stress or deficient stress-coping skills