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Request for Information Regarding the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008

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General Comment

I am a counseling psychologist who provides EEG biofeedback treatment to individuals with Attention Deficit Hyperactivity Disorder. I also utilize general, peripheral biofeedback modalities (EMG, skin temperature) for the treatment of anxiety related disorders. EEG biofeedback is an empirically validated and widely recognized effective non medication treatment for ADHD, as well as other conditions. There are over 50 studies evaluating the effectiveness of EEG biofeedback in the treatment of ADHD, Substance Use disorders and Autism. A recent review of this literature concluded “EEG biofeedback meets the American Academy of Child and Adolescent Psychiatry criteria for” Clinical Guidelines “for treatment of ADHD.” This means that EEG biofeedback meets the same criteria as to medication for treating ADHD, and that EEG biofeedback “should always be considered as an intervention for this disorder by the clinician”. In the case of general, peripheral methods of biofeedback, there is also compelling evidence published in peer reviewed journals indicating biofeedback to be effective in the treatment of generalized anxiety and related disorders. Despite a significant body of scientific literature supporting neurofeedback (EEG biofeedback) and general

biofeedback as equivalent in their efficacy in the treatment of these mental health diagnoses to the traditional methods of medication and psychotherapy, coverage for these services continues to be denied by many health insurance providers.
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This is limitation of an effective and validated treatment for a mental health problem. The reasons given by the insurance companies for this denial fell into two categories: 1) our company does not cover biofeedback for Mental Health problems or 2) there is not yet sufficient evidence for the efficacy of biofeedback. As such, they are using evidence-based criteria that are far more restrictive for mental health services than the criteria which are used for medical/surgical services. There are many routine medical and surgical procedures which have far fewer controlled studies about their efficacy than does EEG biofeedback. These medical and surgical procedures are generally not limited because of concerns about how many controlled studies have been performed about them.

We believe that the parity regulations, based on legal reviews of the parity statute, should require that employers and plans pay for the same range and scope of services for Behavioral Treatments as they do for Med Surg benefits and that a plan cannot be more restrictive in their managed care criteria and reviews for MH and SA disorders when compared to Med Surg. Today plans are being more restrictive in how they review evidenced based Mental Health and Substance Abuse Treatments when compared to Med Surg treatments. This violates both the intent and letter of the parity statue and we hope that the regulations will clarify that this can't continue.

Please include neurofeedback and biofeedback treatment of mental disorders as sevices that should be covered in parity with other Med Surg and mental health procedures.

Thank you.

Aubrey K. Ewing, Ph.D.
Immediate Past-President
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Attachments

EBSA-2009-0010-DRAFT-0252.1: Comment on FR Doc # E9-9629

Evidence-Based Practice in Biofeedback and Neurofeedback

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applied psychophysiology & biofeedback
aapb
an international society for mind-body research, health care, and education

Association for Applied Psychophysiology and Biofeedback (AAPB)

Founded in 1969, AAPB is the foremost international association for the study of biofeedback and applied psychophysiology. AAPB is an interdisciplinary organization representing the fields of psychology, psychiatry, medicine, dentistry, nursing, physical therapy, occupational therapy, social work, education, counseling, and others.

The mission of AAPB is to advance the development, dissemination, and utilization of knowledge about applied psychophysiology and biofeedback to improve health and the quality of life through research, education, and practice.

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Association of Applied Psychophysiology and Biofeedback	www.aapb.org
Biofeedback Certification Institute of America	www.bcia.org
Biofeedback Foundation of Europe	www.bfe.org
International Society for Neurofeedback and Research	www.isnr.org

Foreword:

Evidence-Based Practice in Biofeedback and Neurofeedback

Donald Moss, PhD, and Frank Andrasik PhD

Biofeedback and Neurofeedback

Biofeedback is a technique that enables an individual to learn how to change physiological activity for the purposes of improving health and performance (Gilbert & Moss, 2003; Schwartz & Andrasik, 2003; Shaffer & Moss, 2006).[1] Biofeedback instruments are used to feed back information about physiological processes, assisting the individual to increase awareness of these processes and to gain voluntary control over body and mind. Biofeedback instruments measure muscle activity, skin temperature, electrodermal activity (sweat gland activity), respiration, heart rate, heart rate variability, blood pressure, brain electrical activity, and blood flow. Research shows that biofeedback, alone and in combination with other behavioral therapies, is effective for treating a variety of medical and psychological disorders, ranging from headache to hypertension to temporomandibular to attentional disorders. The present publication surveys these applications and reviews relevant outcome research. Biofeedback is used by physicians, nurses, psychologists, counselors, physical therapists, occupational therapists, and others. Biofeedback therapies teach the individual to take a more active role in maintaining personal health and higher level mind-body health.

Neurofeedback is a specialty field within biofeedback, which is devoted to training people to gain control over electro-physiological processes in the human brain (Demos, 2005; Evans & Abarbanel, 1999; LaVaque, 2003; Thompson & Thompson, 2003). Neurofeedback uses information from the electroencephalogram (EEG) to show the trainee current patterns in his or her cortex. Many neurological and medical disorders are accompanied by abnormal patterns of cortical activity (Hammond, 2006). Neurofeedback assessment uses a baseline EEG, and sometimes a multi-site quantitative EEG (QEEG), to identify abnormal patterns (LaVaque, 2003). Clinical training with EEG feedback then enables the individual to modify those patterns, normalizing or optimizing brain activity. Neurofeedback practice is growing rapidly with the widest acceptance for applications for attention deficit hyperactivity disorder (ADHD), learning disabilities, seizures, depression, acquired brain injuries, substance abuse, and anxiety (Clinical EEG, 2000).

Complementary and Alternative Therapies

Biofeedback and neurofeedback are attractive approaches for individuals who are seeking complementary and alternative medicine (CAM) therapies (Lake & Moss, 2003). The public appears to seek out therapies that 1) give the individual a more active role in his or her own health care, 2) involve a holistic emphasis on body, mind, and spirit, 3) are noninvasive, and 4) elicit the body's own healing response (Jonas & Levin, 1999; Moss, 2003). James Gordon, the first chairman of the Federal Advisory Council of the NIH Office of Alternative Medicine, emphasizes that educating individuals in *self-care* must be at the center of this new medicine in order to deal with the changing picture of health problems today, especially the increasing incidence of chronic conditions (Gordon, 1996). Both biofeedback and neurofeedback are holistic therapies, based on the recognition that changes in the mind and emotions affect the body and changes in the body also influence the mind and emotions. Biofeedback and neurofeedback emphasize training individuals to self-regulate, gain awareness, increase control over their bodies, brains, and nervous systems, and improve flexibility in physiologic responding. The positive

[1] The Association for Applied Psychophysiology and Biofeedback and the International Society for Neurofeedback and Research are currently sponsoring a Task Force for Nomenclature, headed by Mark S. Schwartz, PhD, to develop an official definition of biofeedback. The present discussion draws on the Task Force language, but the Task Force has not yet reached final formulation.

effects of feedback training enhance health, learning, and performance. There are biofeedback protocols to address many of the disorders, including anxiety, depression, and chronic pain, for which the public is using CAM therapies in high numbers (Bassman & Uellendahl, 2003; Burke, 2003; Freeman, 2008; Kessler et al. 2001).

Evidence-Based Practice

Biofeedback and neurofeedback also provide the kind of *evidence-based practice* the health care establishment is demanding (Geyman, Devon, & Ramsey, 2000; Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000). Evidence-based practice is a process of using the best evidence, preferably research findings, to guide delivery of health services. Levels of evidence range from case reports and observational studies to randomized clinical trials. From the beginning, biofeedback developed as a research-based approach, emerging directly from laboratory research on psychophysiology and behavior therapy. The field of feedback therapies has maintained its close relationship with both pure and applied empirical research. Pure research takes place largely in laboratories and seeks new understandings of neurophysiological mechanisms underlying disorders such as panic disorder and hypertension. Better recognition of underlying mechanisms continues to inspire new biofeedback treatment approaches. One such line of research is using high resolution magnetic resonance imaging (fMRI) to learn more about pathophysiology of various conditions and to identify brain areas activated during biofeedback (Andrasik & Rime, 2007). In turn, many biofeedback applications have been tested and proven, both in research and practice.

Biofeedback and neurofeedback are also approaches that rely on well-developed professional standards and guidelines for competent practice. A national certification organization, the Biofeedback Certification Institute of America, has established a blueprint of necessary knowledge and skills and conducts examinations qualifying individuals for certification in general biofeedback, neurofeedback, and pelvic floor disorders such as urinary incontinence. (Information on certification standards is available at www.bcia.org.)

Efficacy and Effectiveness

The present volume fills a void in the biofeedback and neurofeedback practice world: the need for a standardized assessment of clinical efficacy and effectiveness for feedback-based therapies. “Efficacy” refers to the determination of a training or treatment effect derived from a systematic evaluation obtained in a controlled clinical trial (LaVaque et al. 2002). “Effectiveness” assesses how well a treatment works in actual clinical settings with more typical clinical populations. Everyday clinical practice includes more individuals who suffer with subsyndromal conditions and comorbid disorders and who are already participating in multiple treatments beyond the researcher’s control. It is rare for the average primary care physician or behavioral health practitioner to see a patient who has only one medical condition, who clearly meets diagnostic criteria, and who is not involved in other therapies.

Evidence-based practice must take into account both efficacy in controlled research settings and effectiveness in the real world of clinical practice. Neither the general public nor the novice biofeedback practitioner can always assess which applications are well documented and which remain more experimental. Attending biofeedback and neurofeedback conferences, one hears discussion of many promising new approaches, and Websites often claim “well-documented efficacy” for a variety of new approaches. Nevertheless, today’s research climate has higher standards for “efficacy” and “effectiveness” than were current during much of the time period in which biofeedback and neurofeedback evolved. The present publication applies current standards of research methodology to biofeedback and neurofeedback practice.

Efficacy Standards

In 2001, the two professional associations in this practice area, the Association for Applied Psychophysiology and Biofeedback (AAPB) and the International Society for Neuronal Regulation, now

known as the International Society for Neurofeedback and Research (ISNR), together commissioned a Task Force to develop official standards for research methodology, establishing what kinds of research are required for each of five levels of efficacy, ranging from the lowest level, "not empirically supported," to the highest level, "efficacious and specific." That Task Force report has been published along with a brief introduction describing the context and need for its development (LaVaque et al. 2002; Moss & Gunkelman, 2002). The efficacy guidelines themselves can be found, with criteria for each rating, on page 4 of the present document.

The Task Force has created rigorous standards, which are not easily applied to feedback therapies. There are inherent difficulties, for example, in creating a double-blind condition for a therapy that is founded on enhancing self-awareness of body and mind. For example, "sham feedback" (feedback that does not reflect the subject's actual physiological state) has been used as a control condition in biofeedback research. Yet, perceptive individuals quickly notice the sound or light feedback does not fit with their perceptions of their bodies; they are not blinded as the methodology requires. There are also ethical implications today, following the international Declaration of Helsinki, published by the World Medical Association (2000), in using placebos or sham therapies when the relative efficacy of one of the treatment conditions is already known (LaVaque et al. 2002).

In addition, most efficacy studies in the past have compared biofeedback alone to placebo or to currently accepted therapies. This approach attempts to isolate the specific therapeutic effects of biofeedback, which is important from a research standpoint. In clinical practice, however, biofeedback is often combined with a wide variety of adjunctive therapies, including relaxation training, visualization, behavior therapies, client education, and other strategies. James Gordon, director of the Center for Mind-Body Medicine, has advocated that future outcome research should compare integrative packages of alternative therapies, including biofeedback, to placebo alone or to accepted therapy packages (2003).

Nevertheless, it is critical to apply prevailing standards for outcome research in order to provide a credible rating of therapeutic interventions for today's evidence-based healthcare sector. Failing to do so exposes biofeedback and neurofeedback to the danger of being left by the wayside as irrelevant in today's best practices–focused treatment milieu.

Efficacy in Perspective

The present volume does not attempt exhaustive reviews of all research on each application. Rather, this volume reviews a sampling of the best available evidence and, in concise form, rates each application according to the official AAPB/ISNR efficacy guidelines.

A parallel series of white papers conducts a more comprehensive review. Seven white papers have been published to date, and the entire series will be published as a separate volume in 2009 – 2010 (Moss, LaVaque, & Hammond, in preparation). The white paper series reviews the efficacy of biofeedback for attention deficit disorders (Monastra, Lynn, Linden, Lubar, Gruzelier, & LaVaque, 2005), anorectal disorders (Palsson, Heymen, & Whitehead, 2004), anxiety disorders (Moss & Shaffer, in preparation), hypertension (Linden & Moseley, 2006), temporomandibular disorders (Crider, Glaros, & Gevirtz, 2005), tension and migraine headache (Nestoriuc, Martin, Rief, & Andrasik, in preparation), Raynaud's disease (Karavidas, Tsai, Yucha, McGrady, & Lehrer, 2006), substance abuse (Sokhadze, Cannon, & Trudeau, 2008), and urinary incontinence (Glazer & Laine, 2006).

A lower efficacy rating does not necessarily indicate an application is not helpful. In some cases a lower rating has been applied chiefly because the relevant research has not yet been conducted. In other cases, a lower rating means the application benefits some subjects and not others because of wide inter-subject variability. People are not all uniform. On a group comparison basis, these selective successes may not be statistically significant.

If a prospective client cannot tolerate the available medication therapies in traditional medicine, or if the individual is averse to staying with a medication, then "possibly efficacious" feedback therapies may be reasonable alternatives.

Many of today's well-accepted medical procedures have never been subjected to the rigorous efficacy standards adopted here. Many medications, in particular, are utilized off-label; that is, they are prescribed for specific medical conditions not indicated by the Food and Drug Administration and for which no rigorous clinical trials exist. Other medical therapies have been tested in randomized clinical trials and show reliable but relatively small effects. In a clinical drug trial with 10,000 subjects, even a small benefit will produce a statistically significant effect. At least one research report on antidepressants, for example, showed outcomes no better than placebo (Fava et al. 1998), yet these medications are among the most frequently prescribed in most primary care clinics. Similarly, many of the widely used educational methods for assisting students with learning disabilities have yet to be subjected to rigorous scrutiny. A "possibly efficacious" or "probably efficacious" biofeedback or neurofeedback application may still be relatively powerful compared to the mainstream alternatives available to an individual. The feedback therapies also provide a useful alternative for clients who show adverse effects to medications, those who fail to respond to mainstream therapies, and those who prefer more natural, self-regulation–oriented treatment.

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Introduction

Biofeedback and applied psychophysiology continues to be a vital, growing field. The Association for Applied Psychophysiology and Biofeedback (AAPB) originally created this efficacy series to summarize the current state of knowledge in the field. As you will see, there are a significant number of clinical problems for which biofeedback and applied psychophysiology are "efficacious" or "probably efficacious." Biofeedback is no longer an "alternative" treatment modality but a clear first choice for some conditions and an excellent adjunctive treatment for others.

This is the most comprehensive document of its kind on the efficacy of biofeedback and applied psychophysiology. The last edition of this work covered 37 areas; this one covers 41. The content of these areas has been updated to reflect current knowledge.

The work summarized in this volume represents the efforts of several individuals: the investigators who do the difficult task of organizing and running clinical trials and Doil Montgomery and Carolyn Yucha, who took time to carefully summarize the available evidence. To all: We thank you for your hard work and for your vision in moving the field forward.

Alan Glaros, PhD

AAPB President

Table of Contents

Overview of Biofeedback

Biofeedback therapies are nonpharmacologic treatments that use scientific instruments to measure, amplify, and feed back physiological information to the patient being monitored. The information assists the patient in gaining self-regulation of the physiological process being monitored. Psychophysiological self-regulation is a primary goal of biofeedback therapies, and feedback of information facilitates learned physiological control, just as feedback facilitates learning of any skill. For example, in the treatment of hypertension, surface electrodes are used to provide the patient with information about skin temperature and muscle tension. The feedback of information from the instrument guides the patient during training as he or she learns to warm the skin (by dilating blood vessels) and relax the muscles. This is generally accompanied by a reduction in blood pressure. In this example, the instrumentation provides physiological information that would otherwise be inaccessible to the patient. ***Biofeedback therapy always involves a therapist, a patient, and a monitoring instrument capable of providing accurate physiological information.***

Modalities of biofeedback are varied. Depending on the goal of the training, biofeedback clinicians may use sensors that detect such parameters as skin temperature, muscle activity, heart rate, respiration, skin conductance, or brainwave activity. This stream of information is then presented in some form that allows patients to perceive changes in their physiological activity in real time. Numerical or graphic displays are most common, but audio or vibratory feedback might also be used.

Biofeedback training requires that patients observe their physiological responses in detail and try to learn to alter them. This takes effort and time. For certain conditions, such as urinary incontinence, significant improvement may occur within a few sessions. In contrast, up to 50 sessions of neurotherapy (brainwave biofeedback) for attention deficit disorder may be needed before improvement is seen.

"Treatment" versus "Training"

"Treatment" implies a passive patient receiving something therapeutic from an active practitioner. The patient's automatic healing processes may be expected to operate, but beyond that, the patient is not asked to do much more than show up for procedures or swallow pills on schedule. "Treatment" is what insurance is traditionally designed to reimburse.

"Training," on the other hand, implies more active participation; people are trained to ride a horse, perform a job, ice-skate, etc. Learning is interactive, guided by instruction and information in order to develop a skill. Most biofeedback is done with this orientation, even though the action may be internal and visible only with the biofeedback instruments. Insurance policies often exclude procedures labeled "educational." The educational component in biofeedback, however, is more akin to speech therapy or rehabilitation than to a more abstract pursuit of knowledge.

A parallel can be drawn with physical therapy, which often directs a person to practice certain movements or exercises at home between sessions. This process requires active participation but is routinely considered treatment rather than training, even though therapeutic success may rest on the thoroughness of home practice. The patient must learn to do certain movements, carry out exercises, and avoid certain injurious activities and postures. Physical therapy and rehabilitation are considered reimbursable therapeutic procedures. Is this education, training, or treatment?

An insurer would not want to cover a course of biofeedback training done strictly for self-exploration, just as an insurer would not cover weekend courses in personal development or reading self-help books. But what if biofeedback is shown to be effective for a bona fide diagnosed disorder or if a self-control procedure is learned and then faithfully practiced? Is this now education, training, or treatment?

When biofeedback training is "prescribed" for a recognized disorder, the outcome usually depends on factors such as enhanced self-sensing, corrections in body use (changes in posture, breathing, muscle tension, or movement), relaxation, and managing emotions, all in conjunction with exposure to biofeedback signals and integrated into daily life via home practice. The biofeedback data serve as information only. The learner can use the information intelligently or not, and it is the use of the information, rather than exposure to it, that makes the difference.

Research Involving Behavioral Interventions

Much biofeedback research seems to assume a treatment model, as if biofeedback is a procedure "done to" an individual. This approach strives to standardize doses, techniques, and subject variables as much as possible. In biofeedback research, this would include items such as number of sessions, type of feedback display, and behavior of the trainer. Controlling all the factors surrounding the biofeedback process is very difficult. Pursuit of experimental control often makes the research protocol too limited and standardized to represent how biofeedback is used in clinical practice.

Double-blind research is generally held in high regard because subtle expectations on the part of both subjects and practitioners are supposedly eliminated. However, the double-blind, or even single-blind procedure, does not make sense in biofeedback because ongoing knowledge of changes in a physiological variable is central to the learning process. Eliminating expectations by double-blinding supposedly keeps things pure, but expectations may be the essence of the placebo effect, which is a very interesting self-healing phenomenon, not simply a confounding factor in experiments. In biofeedback, at least, such an effect is something to be maximized and mastered, not eliminated.

Tailoring the biofeedback learning process to the individual may be more effective clinically, but it introduces uncontrolled variability, the bane of research designs. Although keeping subjects passive and standardizing the protocol might keep things tidy for research purposes, it works against the success of biofeedback and other self-regulation methods.

Instead of considering biofeedback research as "inconclusive" because it does not follow the double-blind model of pharmaceutical research, a different model should be considered in which self-regulation is the active ingredient. The training model is most applicable to biofeedback applications. The training concept involves active participation and individualizing of the biofeedback situation to fit the individual learner. For instance, one person may learn best with continuous exposure to the feedback signal, while another person may learn best while using imagery with minimal feedback. The very factors that would introduce unwanted variability into most treatment research constitute the essence of active learning. Wait-list controls, controlled case studies, and other clinical research methods are more appropriate for studying biofeedback than standardized clinical trials.

"Training to criterion" refers to the subject/trainee/patient practicing a certain mode of control until a criterion, which represents meaningful change, is reached: for instance, a particular level of muscle tension or hand temperature. Without demonstrating the ability to alter one's physiologic responses, a subject in a biofeedback experiment cannot be said to be receiving the intended treatment. This would be comparable to a subject not taking the prescribed medication in a drug effectiveness study. Yet training to criterion is often ignored in biofeedback studies.

It follows that exposing someone to a course of biofeedback does not necessarily constitute an adequate intervention, any more than filling a prescription is adequate. Just as the pills must actually be swallowed, a person's active attention must be engaged. Even if the necessary control (blood pressure for instance) has been learned well in the laboratory, the application of that control in real life will vary. Adherence to the prescribed self-regulation regimen, including periodic relaxation, altered breathing, and cognitive changes, will be applied with varying degrees of diligence, depending on the amount of commitment, belief, suffering, and conflicting demands on attention and time. This variability is not

easily controlled and is comparable to drug research subjects taking the prescribed drugs in widely varying doses and concentrations at varying times from day to day and sometimes skipping days.

Understanding and applying the biofeedback information is certainly more complicated than swallowing a pill, but it constitutes the essence of the treatment and must be accommodated in the research design and accepted by those who evaluate biofeedback research. Bearing in mind these limitations, this monograph is a summary of the research findings over the past 20 years, examining the efficacy of biofeedback for various disorders.

Clinical Efficacy of Biofeedback Therapy: Explanation of Efficacy Levels

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, and

f. 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.

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Note: This document is also available online at www.aapb.org and www.isnr.org.

Conditions for which Biofeedback Has Been Used

The following review is not meant to be an exhaustive review of the literature, but rather an overview of the state of the evidence for biofeedback. The following process was used to select citations. First, a comprehensive literature search was done (PsychInfo and PubMed) with the help of librarians to find clinical research and systematic review articles mentioning biofeedback or neurofeedback between 1993 and the present. Publications addressing efficacy were published by AAPB in 1994 and 2003.

Reports studying only normal subjects were excluded. Remaining articles were sorted as to treatment condition, and the most pertinent ones were summarized briefly. Separate, more specific, literature searches were done on those conditions with few citations in order to expand the evidence, and these were incorporated into the document. This draft was sent to AAPB's board of directors and those listed in the acknowledgements for comments. These persons were asked to identify unlisted studies, if any, that might alter the efficacy levels. Certain classic studies were then added to the citations. It must again be emphasized that this book is NOT a comprehensive review of the field, and many important studies were not included. However, the authors feel confident that these studies would not alter the efficacy levels as reported here. Although this is not a comprehensive review of the field, the authors feel the studies reported represent the current status of research in the field.

Alcoholism / Substance Abuse

Level 3: Probably Efficacious

Researchers have used both biofeedback-assisted relaxation training and neurofeedback (alpha-theta brainwave feedback) to deal with alcoholism and its accompanying symptoms (e.g., depression). In comparison to a control group, thermal biofeedback increased drinking-related locus of control in a study of adolescent alcoholics (Sharp, Hurford, Allison, Sparks, & Cameron, 1997). Alpha-theta brainwave training was accompanied by significant decreases in certain factors measured using the Millon Clinical Multiaxial Inventory (schizoid, avoidant, passive-aggression, schizotypal, borderline, paranoid, anxiety, somatoform, dysthymia, alcohol abuse, psychotic thinking, psychotic depression, and psychotic delusional) in comparison to those receiving traditional medical treatment (Peniston & Kulkosky, 1990). Taub, Steiner, Weingarten, and Walton (1994) studied 118 chronic alcoholics randomly assigned to one of four treatment conditions: 1) routine treatment of Alcoholics Anonymous and counseling (RTT), 2) RTT plus transcendental meditation, 3) RTT plus EMG biofeedback, and 4) RTT plus neurotherapy. Self-report of abstinence for the four groups were 25%, 65%, 55%, and 28%, respectively. This study suggests the addition of meditation or EMG biofeedback enhances RTT while neurotherapy does not.

A number of case studies and uncontrolled studies show the benefit of neurofeedback for treating alcoholic depression (Kumano et al. 1996; Waldkoetter & Sanders, 1997). A few controlled neurofeedback studies (Peniston & Kulkosky, 1989; Saxby & Peniston, 1995) provided further evidence for this reduction in depression and reported sustained prevention of relapse at 21-month follow-up in alcoholics who had completed the training (Saxby & Peniston, 1995). Another showed that six of 10 alcohol-dependent males had not relapsed four months post self-regulation of slow cortical potentials (Schneider et al. 1993). These studies demonstrate promise in altering alcoholic behavior via alpha-theta brainwave feedback. Further, a very recent review concludes alpha-theta training — either alone, for alcoholism, or in combination with beta training, for stimulant and mixed substance abuse, and combined with residential treatment programs — is probably efficacious (Sokhadze, Cannon, & Trudeau, 2008).

Recent studies are beginning to provide evidence that EEG biofeedback improves treatment for cocaine addiction with improvements in length of stay (Burkett, Cummins, Dickson, & Skolnick, 2004)

and urinalysis, depression, and other self-report measures (Burkett, Cummins, Dickson, & Skolnick, 2005). A recent RCT comparing EEG biofeedback to control showed those in the treatment group remained in treatment longer than the control group, and 77% of those completing the protocol were abstinent at 12 months compared to 44% of the control group (Scott, Kaiser, Othmer, & Sideroff, 2005). Another RCT showed two sessions of motivational interviewing using EEG feedback led to a reduction in positive urine screens at 63%, compared to 85% in the control group (Stotts, Potts, Ingersoll, George, & Martin, 2006).

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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 mixed-exposure 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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Arthritis

Level 3: Probably Efficacious

Both thermal and EMG biofeedback have been used to teach relaxation techniques to adults with chronic arthritis. A recent meta-analysis of 25 randomized controlled studies demonstrated significant pooled effect sizes post-intervention for pain, functional disability, psychological status, coping, and self efficacy (Astin, Becker, Soeken, Hochberg, & Berman, 2002). Thermal biofeedback coupled with cognitive behavioral therapy decreased pain behaviors, self-reports of pain intensity, and rheumatoid factor titer (a measure of disease activity), in comparison to control subjects and those receiving social support only (Bradley, 1985; Bradley et al. 1987). This intervention was associated with a reduction in rheumatoid arthritis–related clinic visits and days hospitalized, thereby decreasing medical costs (Young, Bradley, & Turner, 1995). EMG biofeedback also reduced duration, intensity, and quality of pain in comparison to control groups (Flor, Haag, Turk, & Koehler, 1983), and these beneficial effects were maintained two and a half years later (Flor, Haag, & Turk, 1986). Finally, a small study of eight six- to 17-year-olds with juvenile rheumatoid arthritis were given relaxation training including EMG and thermal biofeedback; 50 to 62% of the children showed at least a 25% reduction in pain immediately after treatment, and 62 to 88% showed a 25% reduction by six-month follow up (Lavigne, Ross, Berry, & Hayford, 1992).

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Asthma

Level 2: Possibly Efficacious

A review of all randomized controlled research on relaxation techniques to affect asthma (Huntley, White, & Ernst, 2002) failed to find convincing evidence of efficacy as measured by pulmonary function testing or symptom change. Biofeedback studies were included, mostly using EMG. A second review of biofeedback interventions also showed little evidence biofeedback can substantially contribute to the treatment of asthma (Ritz, Dahme, & Roth, 2004). Finally, a Cochrane systematic review of 15 studies involving 687 participants led to the inability to draw firm conclusions for the role of psychological interventions in asthma, mainly because of the inadequate evidence base (Yorke, Fleming, & Shuldham, 2007). This review did report, however, a significant difference in forced expiratory volume (FEV_1) with biofeedback.

A study examining the effect of EMG feedback on immune system components found changes in neutrophils and basophils, suggestive of reduced inflammation, along with some improvement in asthma symptoms (Kern-Buell, McGrady, Conran, & Nelson, 2000). Respiratory sinus arrhythmia training (self-regulation of breathing for maximum heart rate variability) seems to produce beneficial changes in asthma symptoms and reductions in respiratory impedance (Lehrer, Carr, et al. 1997; Lehrer, Smetankin, & Potapova, 2000).

More recent work using heart rate variability biofeedback showed those in the treatment groups were prescribed less medication than those in the control groups and improved an average of one full level of asthma severity (Lehrer, Vaschillo, Vaschillo, et al. 2004). The decreases in the need for controller medication were independent of age (Lehrer, Vaschillo, Lu, et al. 2006). There is also some evidence that capnometry-assisted breathing training can raise end-tidal pCO_2, resulting in a decrease in respiratory rate and frequency and distress of symptoms of asthma (Meuret, Ritz, Wilhelm, & Roth, 2007).

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Attention Deficit Hyperactivity Disorder (ADHD)

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 for

children-revised (WISC-R) IQ, improved Test of Variables of Attention (TOVA), and Attention Deficit Disorders 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

authors state, correctly, the chosen single-case design elements control for the effects of internal validity, 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 self-controlled 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.

Orlando and Rivera (2004) selected a number of elementary students (n=28) with identified 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 frontal-central 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. Post-treatment 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, event-related 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

clinical outcome of these EEG biofeedback studies was positive for 18, inconclusive for one, and 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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Autism

Level 2: Possibly Efficacious

One case study of an eight-year-old boy with mild autism reported the effect of neurofeedback. After 31 sessions, the boy showed positive changes in all the diagnostic dimensions defining autism in the Mental Disorders-III-Revised (Sichel, Fehmi, & Goldstein, 1995).

More recently, a wait-list controlled study (Coben & Padolsky, 2007) provided assessment-guided EEG biofeedback over 20 sessions for 37 patients with autistic spectrum disorder. EEG biofeedback was determined for each treated subject based on locating the site of maximum hyperconnectivity. Once the treatment characteristics were determined, they stayed the same for the duration of the 20 treatment sessions. Improvement in symptoms was reported for 89% of the experimental group, significantly different than that reported in the control group. A 40% reduction in Autism Treatment Evaluation Checklist (ATEC) scores for the treatment group was noted as well as a 76% reduction in hyperconnectivity. A reduction in cerebral hyperactivity was associated with positive clinical outcome. This improvement was supported by neuropsychological tests in attention, visual perceptional functioning, executive function, and language skills.

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Bell's Palsy

Level 2: Possibly Efficacious

EMG biofeedback was shown to be more effective than kinesitherapy in a study of 74 persons with Bell's Palsy (Dalla Toffola et al. 2005). The first 32 patients were treated with therapeutic exercises performed by therapists and the latter 42 patients were treated using biofeedback/EMG methods with inhibition of synkinetic movement as the primary goal. Biofeedback patients showed better clinical recovery and minor synkinesis than kinesitherapy patients.

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Cerebral Palsy

Level 2: Possibly Efficacious

There are few studies examining the efficacy of EMG biofeedback to improve posture and walking in children with cerebral palsy. Biofeedback of the triceps surae muscle group in the leg improved gait symmetry in comparison to physical therapy alone (Colborne, Wright, & Naumann, 1994). Portable EMG units to help train ankle dorsiflexor recruitment improved ankle function as evaluated through tapping ability (Toner, Cook, & Elder, 1998). The addition of EMG biofeedback to conventional exercise programs has improved ankle movement and gait function (Bolek, 2003; Bolek, 2006; Dursun, Dursun, & Alican, 2004). Using surface EMG, two children were able to learn to contol their anterior tibialis and walk using this new gait pattern (Bolek, 2003). In a later study of 16 children, customized treatment plans using multiple surface EMG sites led to improved motor control during standing or sitting or in upper extremity or head control (Bolek, 2006). Dursun, Dursun, and Alican (2004) evaluated the effect of EMG biofeedback and conventional exercise in 21 children in comparison to 15 children who performed exercise alone. The biofeedback group showed significant improvements in tonus of the plantar flexor muscle and active range of motion of the ankle joints. While gait function improved in both groups, the improvement was greater in the biofeedback group.

One case study of adults with cerebral palsy showed biofeedback-assisted relaxation training decreased self-report of pain in two of three adults; however, these did not correspond with physiological changes (Engle, Jensen, & Schwartz, 2004).

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Chronic Obstructive Pulmonary Disease (COPD)

Level 2: Possibly Efficacious

A small, randomized study demonstrated those persons receiving breathing-pattern training had a 22% increase in forced expiratory volume (FEV_1) and a 19% increase in forced vital capacity (FVC) but no significant increases in the control group (Esteve, Blanc-Gras, Gallego, & Benchetrit, 1996). Another uncontrolled study showed five sessions of HRV biofeedback and walking with pulse oximetry feedback improved the distance walked in six minutes and quality of life in patients with COPD (Giardino, Chan, & Borson, 2004).

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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 $\geq 50\%$ 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 $\geq 50\%$ 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 biofeedback-assisted 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 post-discharge 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 biofeedback-assisted 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 time-series 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 EMG-biofeedback-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 biofeedback-assisted 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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Coronary Artery Disease

Level 2: Possibly Efficacious

Diminished heart rate variability (HRV) in patients with coronary artery disease is associated with increased cardiac morbidity and mortality. In patients with coronary artery disease, some HRV time-domain indices were improved in treatment versus control groups by EMG biofeedback (Wang, Zhang, Liu, & Lu, 2006) and HRV biofeedback (Nolan et al. 2005; Del Pozo, Gevirtz, Scher, & Guarneri, 2004).

Survivors of out-of-hospital ventricular fibrillation or asystole were randomized into two groups, a control group and a group receiving psychosocial therapy consisting of physiological relaxation with biofeedback focused on altering autonomic tone, cognitive behavioral therapy, and cardiovascular health education. Risk of cardiovascular death was significantly reduced by 86%, and all-cause mortality was reduced by 62% in those receiving psychosocial therapy (Cowan, Pike, & Budzynski, 2001).

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Cystic Fibrosis

Level 2: Possibly Efficacious

Respiratory muscle biofeedback coupled with breathing retraining produced significant improvement in forced expiratory volume (FEV_1) and forced vital capacity (FVC) in comparison to a control group that received biofeedback-assisted (hand warming) relaxation training (Delk, Gevirtz, Hicks, Carden, & Rucker, 1994). This single study was included in a Cochrane Review evaluating psychological interventions for cystic fibrosis (Glasscoe & Quittner, 2003). The Cochrane Review found high-quality efficacy trials for psychological interventions for cystic fibrosis are rare and was unable to conclude anything about biofeedback efficacy.

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Depressive Disorders

Level 2: Possibly Efficacious

Preliminary case studies (Kumano et al. 1996; Rosenfeld, 2000) and pilot studies (Waldkoetter & Sanders, 1997) show neurofeedback may decrease depressive symptoms. One study compared biofeedback-assisted relaxation to a wait-list control on depression in chronic pain patients and found improved scores on the Beck depression index (Corrado & Gottlieb, 1999).

Baehr, Rosenfeld, and Baehr (2001) presented a follow-up study of three of six patients who had completed an average of 27 EEG biofeedback sessions using a patented alpha asymmetry protocol for the treatment of depression. The follow-up data, from one to five years post-therapy, were derived from a single session re-test using the same alpha asymmetry protocol and the Beck Depression Inventory. The three patients originally diagnosed as having unipolar depression reached the training criteria for the nondepressed range by the end of their initial training, and they had maintained their normal scores for right hemisphere alpha asymmetry training over time. The follow-up Beck Depression Inventory scores were also within the normal range. While some patients reported mood changes with life's vicissitudes, none experienced clinical depression since they terminated therapy.

In a study conducted by Raymond, Varney, Parkinson, and Gruzelier (2005), 12 participants with high scores for withdrawal (as measured by the PSQ) were given either alpha/theta EEG biofeedback or mock feedback, and their personality and mood were assessed. Withdrawal scores on the PSQ-80 were not found to change in either group, but significant effects were found for the Profile of Mood States (POMS) with real feedback producing higher overall scores than mock feedback. Real feedback caused participants to feel significantly more energetic than did mock feedback. Sessions of real feedback made participants feel more composed, agreeable, elevated, and confident while sessions of mock feedback made participants feel more tired yet composed.

Fifty women between 42 and 74 years old with the diagnosis of knee osteoarthritis participated in a study by Durmus, Alayli, and Canturk (2005). The patients were randomized into two groups of biofeedback-assisted 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.

In a study by Karavidas et al. (2007) using Heart Rate Variability (HRV) as a treatment for major depressive disorder (MDD), all 11 participants received the 10 weekly treatments. Significant improvements were noted in the Hamilton Depression Scale (HAM-D) and the Beck Depression Inventory (BDI-II) by session four. Clinically and statistically significant improvement in depression persisted for the duration of the study.

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Diabetes Mellitus

Level 3: Probably Efficacious

Earlier studies showed biofeedback-assisted relaxation training had no effect on diabetic control as measured by glucose tolerance, fasting blood glucose, two-hour postprandial blood glucose, and fructosamine (Jablon, Naliboff, Gilmore, & Rosenthal, 1997) or on glycosylated hemoglobin (Lane, McCaskill, Ross, Feinglos, & Surwit, 1993). Mood (e.g., depression, anxiety) may impact this lack of response (McGrady & Horner, 1999). Later studies on those with noninsulin-dependent diabetes showed comprehensive intervention, including education and biofeedback, were associated with significant decreases in average blood glucose and HbA1C (McGinnis, McGrady, Cox, & Grower-Dowling, 2005).

On the other hand, thermal biofeedback to increase peripheral blood flow improved healing to foot ulcers in a randomized controlled study of 32 patients with chronic nonhealing ulcers; 87.5% of ulcers healed in the experimental group in contrast to 43.8% in the control group (Rice, Kalker, Schindler,

& Dixon, 2001). Another study supported the ability of those with diabetes mellitus to increase foot temperature despite mild-to-moderate neuropathy; 41% of the variance in foot warming was explained by lower-extremity sympathetic-autonomic and sensory nerve function tests (Fiero, Galper, Cox, Phillips, & Fryburg, 2003). Biofeedback of body center of gravity was shown to reduce the number of falls and force of the fall in elderly patients with diabetic sensory neuropathy in comparison to those who did not receive the biofeedback training (Wu, 1997). Finally, audio biofeedback on weight bearing of persons with transtibial amputation may help patients learn to ambulate correctly using a prosthesis (Chow & Cheng, 2000).

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Eating Disorders

Level 1: Not Empirically Supported

One study of 76 obese and 27 anorexic girls showed benefits of a multimodal program including biofeedback relaxation based on electrodermal response (EDR), with better results for anorectic girls (Pop Jordanova, 2000). This study also examined multimodal psychological assessment and manner of coping with stress and found anorexia nervosa and hyperphagia were associated with stress.

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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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Erectile Dysfunction

Level 2 Efficacy – Possibly Efficacious

Erectile dysfunction is a new area for biofeedback and is beginning to show some promise. Pelvic floor exercises, biofeedback, and electrical stimulation resulted in normal erection for almost half of those

treated; its effect was most favorable in those with venous-occlusive dysfunction (Van Kampen et al. 2003). An RCT of 55 men treated with pelvic floor exercises, biofeedback, and suggestions for lifestyle changes versus those treated with lifestyle changes alone (and later transferred to the active treatment) revealed those in the treatment group showed significant mean increases in anal pressure and digital anal grades (Dorey et al. 2004). After four months, 40% of participants had achieved normal erectile function, 35.5% had improved erectile function, and 24.5% failed to improve (Dorey, Speakman, Feneley, Swinkels, & Dunn, 2005).

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Fecal Disorders

Literature on biofeedback for fecal incontinence and constipation is difficult to interpret. Most studies include patients with a variety of conditions and lack control groups. A critical review of the literature concluded that biofeedback results in 67 – 74% success in treating fecal incontinence but states quality control is lacking in many of the studies reviewed (Heymen, Jones, Ringel, Scarlett, & Whitehead, 2001). A more recent efficacy review of 74 qualified studies showed a 67.2% success rate in those being treated for fecal incontinence and 62.4% success rate in those treated for constipation (Palsson, Heymen, & Whitehead, 2004); only 20% of studies were controlled outcome studies. In those with multiple sclerosis, biofeedback retraining appears to be an effective treatment for constipation and fecal incontinence (Wiesel et al. 2000). Biofeedback may be more useful in patients with milder disability and manometric alternations (Munteis et al. 2007).

Fecal Disorders in Children

Level 3: Probably Efficacious

Biofeedback has been used for fecal incontinence in children and for that occurring after surgery for anorectal malformations and results in clinical improvement in children with fecal incontinence (Iwai, Iwata, Kimura, & Yanagihara, 1997; van Ginkel et al. 2000; Hibi, Iwai, Kimura, Sasaki, & Tsuda, 2003; Leung et al. 2006). In contrast to numerous uncontrolled studies showing efficacy in children, a Cochrane Systematic Review (Brazzelli & Griffiths, 2006) concluded there is no evidence biofeedback training adds any benefit to conventional treatment.

Biofeedback has also improved constipation (encopresis) in 44 – 80% of children studied (Iwai et al. 1997; van Ginkel et al. 2000). The addition of home biofeedback does not enhance the effect of laboratory biofeedback (Croffie et al. 2005). A controlled study of biofeedback versus conventional therapy in 49 children with chronic idiopathic constipation (Sunic-Omejc et al. 2002) reported

biofeedback was an effective method of treatment for childhood constipation because rectal sensation threshold, critical volume, and recto-anal inhibitory reflex volume were significantly higher, and the prevalence of abnormal defecation dynamics was significantly lower after treatment in those receiving biofeedback training.

Fecal Incontinence: Adults

Level 3: Probably Efficacious

In adults, biofeedback has been used to treat chronic fecal incontinence and that following childbirth and anorectal surgery. It has resulted in improvement in fecal incontinence in 60 – 92% of those studied (Chiarioni et al. 2002; Ko et al. 1997; Ryn, Morren, Hallbook, & Sjodahl, 2000; Martinez-Puente, Pascual-Montero, & Garcia-Olmo, 2004; Beddy et al. 2004; Terra et al. 2006). In Solomon, Pager, Rex, Roberts, and Manning (2003), 120 randomly assigned patients in three biofeedback treatment groups — biofeedback with anal manometry, biofeedback with transanal ultrasound, and pelvic floor exercises with feedback from digital examination — showed a 70% improvement in continence with no difference between groups. The addition of cholestyramine to biofeedback treatment led to additional benefits in terms of stool frequency and consistency and the number of incontinent episodes (Remes-Troche, Ozturk, Philips, Stessman, & Rao, 2007). Another RCT compared biofeedback to standard care, standard care plus sphincter exercises, sphincter-pressure biofeedback, and biofeedback plus home EMG biofeedback in 171 patients with fecal incontinence; they reported biofeedback was no better than standard care (Norton, Chelvanayagam, Wilson-Barnett, Redfern, & Kamm, 2003).

Fecal incontinence was also improved with biofeedback after obstetric trauma (Fynes et al. 1999). Two RCTs comparing EMG biofeedback with EMG biofeedback and electrical stimulation after delivery showed conflicting results. Mahony et al. (2004) reported both groups had improved continence scores, and the addition of electrical stimulations did not enhance outcome. In contrast, Naimey et al. (2007) reported neither treatment showed improvement in continence scores. This contrast could be related to the type of fecal incontinence. Shafik, El Sibai, Shafik, and Shafik (2007) showed that while biofeedback was effective in 53% of patients with urge incontinence and 67% of patients with stress incontinence, it was not effective in mixed types.

Long-term efficacy of biofeedback for fecal incontinence has been demonstrated (Enck, Daublin, Lubke, & Strohmeyer, 1994; Guillomot et al. 1995; Ryn et al. 2000; Ozturk, Niazi, Stessman, & Rao, 2004). Despite all of these studies, a Cochrane Systematic Review concluded the limited number of controlled numbers together with their methodological weaknesses do not provide evidence of biofeedback enhancing the outcome of treatment for fecal incontinence compared to other conservative methods (Norton, Cody, & Hosker, 2006).

Biofeedback has also been used after anal sphincter repair (Davis, Kumar, & Poloniecki, 2004) and surgery/radiation for colorectal cancer (Allgayer, Dietrich, Rohde, Koch, & Tuschhoff, 2005). Neither of these studies found biofeedback to be effective in reducing post-treatment incontinence.

Two recent studies have attempted to identify those patients most likely to be successful in treating their incontinence with biofeedback. Predictors of positive response included older age and abnormal defecatory maneuver (Fernandez-Fraga, Azpiroz, Aparici, Casaus, & Malagelada, 2003; Byrne, Solomon, Young, Rex, & Merlino, 2007). Finally, comparison of clinic-based biofeedback with telephone-assisted biofeedback showed a 54% mean improvement in the patients' rating of incontinence with no significant differences in outcome between the groups (Byrne et al. 2005).

Constipation: 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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Fibromyalgia/Chronic Fatigue Syndrome

Level 2: Possibly Efficacious

This poorly understood disorder has often been the subject of clinical trials involving several simultaneous interventions. The rationale for this scattershot approach is usually that it is a multidimensional disorder and therefore calls for multiple approaches in combination. Biofeedback is often included as part of a treatment package including physical exercise and cognitive-behavioral therapy. EMG is the most common modality, but EEG feedback has been used also. Separate reviews (Hadhazy, Ezzo, Creamer, & Berman, 2000; Sim & Adams, 1999; Yousefi & Coffey, 2005; Sarzi-Puttini, Buskila, Carrabba, Doria, & Atzeni, 2007) of mind-body approaches to fibromyalgia, examining mostly randomized controlled studies, concluded there was no clear superiority of any mind-body approach including biofeedback but that collectively they seemed to help in conjunction with physical exercise. Berman and Swyers (1999) concluded, “The strongest data exist for the use of mind-body techniques (e.g., biofeedback, hypnosis, cognitive behavioural therapy), particularly when utilized as part of a multidisciplinary approach to treatment.” Several uncontrolled trials have shown improvement from EMG biofeedback alone (Mur, Drexler, Gruber, Hartig, & Gunther, 1999; Sarnoch, Adler, & Scholz, 1997). Improvement may include quality of sleep, self-efficacy, pain threshold, and emotional adjustment.

Donaldson, Sella, and Mueller (1998) included biofeedback with other therapies and found improvement in symptoms along with normalization of the EEG. Mueller, Donaldson, Nelson, and Layman (2001) improved fibromyalgia symptoms using EEG-driven stimulation; in contrast, Kravitz, Esty, Katz, and Fawcett (2006) did not observe an effect of EEG vs. sham feedback. EMG biofeedback showed some positive effects when used alone (Babu, Mathew, Danda, & Prakash, 2007) or in combination with cognitive behavioral therapy (Al-Haggar, Al-Naggar, & Abdel-Salam, 2006). A one-group study of HRV biofeedback, wherein 12 women were taught to breathe at their resonant frequency, showed decreases in depression and pain and improvement in functioning (Hassett et al. 2007).

Taken together, these studies do not show biofeedback efficacy in treating this challenging disorder, probably because the etiology remains unclear. Mitani et al. (2006) used physiological monitoring techniques to monitor differences between the right and left sides of the body. They found marked asymmetries of surface EMG, temperature, and skin conductance levels in those with fibromyalgia compared to healthy subjects and suggested these might be related to nervous system dysfunction.

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Hand Dystonia

Level 2: Possibly Efficacious

EMG biofeedback from the proximal large muscles of the hand was provided to 10 patients with hand dystonia (writer's cramp) (Deepak & Behari, 1999). Nine patients showed improvement from 37 to 93% in handwriting, alleviation of discomfort, and pain.

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Headache – Pediatric

Level 3: Probably Efficacious

Research support for migraine in children is stronger than that for mixed and tension-type headache. A recent review article (Hermann & Blanchard, 2002) summarized headache/biofeedback research to date in children and concluded thermal biofeedback is effective in alleviating headache activity in children; most studies showed more than two-thirds of the children had a 50% symptom reduction. Two recent meta-analyses examining psychological treatment of headache, and not specifically biofeedback, reported overall improvement with relaxation training in comparison to wait-list controls for children and adolescents with both migraine and tension-type headache (Trautmann, Lackschewitz, & Kroner-Herwig, 2006). A second meta-analysis, limited to tension-type headache, found no evidence for or against biofeedback effectiveness (Verhagen et al. 2005).

A minority of studies used EMG biofeedback from the frontal area instead of or in addition to hand-warming biofeedback. Most protocols used 10 sessions or fewer and included home practice; some involved the parents also. For example, five children with tension-type headaches (Arndorfer & Allen, 2001) participated in a multiple-baseline, time-lagged, within-subject design using thermal biofeedback. All learned the hand-warming technique and showed significant clinical improvement, and six months afterward, 80% were headache-free. Labbe (1995) compared thermal biofeedback-assisted autogenic training to autogenic training only with a wait-list control group in 30 migrainous children; 80% of the first group had significant improvement, 50% of the second group, and none in the third group. Finally, Damen et al. (2006) conducted a systematic review of 19 studies of nonpharmacological treatment in children; they reported biofeedback with relaxation was more effective than wait-list controls or placebo.

Headache – Adult

Level 4: Efficacious

Adult headache, whether tension, migraine, or mixed, has been the focus of much research. For example, Arena, Bruno, Hannah, and Meader (1995) compared biofeedback training from the forehead and trapezius muscles with a nonfeedback progressive muscle relaxation control group in 26 tension-headache patients; clinical improvement was strongest for the trapezius group. McGrady, Wauquier, McNeil, and Gerard (1994) and Vasudeva, Claggett, Tietjen, and McGrady (2003) found superior clinical results for biofeedback-assisted relaxation as compared to self-directed relaxation; this conclusion was supported by measurement of cerebral flood flow using transcranial Doppler monitoring. An RCT comparing temporal pulse amplitude biofeedback with cognitive behavioral therapy and wait list showed 68% headache reduction in the CBT group compared to 56% in the biofeedback group and 20% in the control group (Martin, Forsyth, & Reece, 2007). Thermal and EMG biofeedback coupled with relaxation training was found to be just as effective as propranolol in treating migraine headache but more effective during the first year post-treatment (Kaushik, Kaushik, Mahajan, & Rajesh, 2005).

Rokicki et al. (1997) found a significant drop in headaches following a six-session EMG biofeedback protocol compared with a control group that showed no improvement. Improvement correlated most with a greater sense of self-efficacy rather than with EMG levels. Later work by this same investigator suggests EMG variance, rather than just mean EMG level, may provide a more complete measure of physiological changes responsible for headache reduction following EMG biofeedback training (Rokicki et al. 2003).

Silberstein (2000) published a review of migraine treatment on behalf of the American Academy of Neurology – U.S. Consortium and concluded thermal and muscle biofeedback, in a general context of relaxation training, was generally effective and recommended as a treatment option. Isolating biofeedback as the active element from factors such as general relaxation, emotional improvement, and enhanced self-efficacy has not been very successful so far because most studies offer combined treatment approaches. But a very recent and specific meta-analysis of 55 studies examining the efficacy of biofeedback for migraine showed a medium effect size for all biofeedback interventions that was stable over 17 months; they also reported BVP biofeedback had higher effect sizes than thermal or EMG biofeedback (Nestoriuc & Martin, 2007). Andrasik (2007) reviewed meta-analyses and evidenced-based reviews of behavioral treatments for headaches in adults. After considering all meta-analyses to date, he concluded the effects of behavioral treatments are superior to various control conditions and similar to current medications for both migraine and tension-type headache. Combining behavioral and pharmacological treatments may increase effectiveness even further.

A recent study explored the effect of biofeedback on oxidative stress as measured by peroxides, nitric oxide, and superoxide dismutase in patients with migraine (Ciancarelli, Tozzi-Ciancarelli, Spacca, Di Massimo, & Carolei, 2007). They suggested the effect of biofeedback may be related to muscle relaxation associated with decreased oxidative stress.

Biofeedback is also effective for treatment of migraine in pregnancy and menstrually related headache. Conner and Rideout (2005) reported 72% of those receiving thermal biofeedback, relaxation training, and physical therapy exercise improved compared to 29% of the attention control group. In an uncontrolled study, Blanchard and Kim (2005) provided thermal biofeedback to women with menstrually related headache; those with vascular headache showed a reduction in headache and use of related medications while those with tension-type headache did not respond to training. Because many studies include a combination of treatments, it is not possible to separate out the specific effects of biofeedback.

Many patients are not able to access therapy sites. Therefore, Devineni and Blanchard (2005) tested an internet-based treatment for chronic headache composed of relaxation, limited biofeedback with autogenic training, and stress management versus a wait-list control. They found 39% of treated

participants improved post-treatment, and this rose to 47% two months post-treatment with a 35% reduction in medication usage.

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Hypertension

Level 4: Efficacious

A meta-analysis of 23 studies completed between 1975 and 1996 compared biofeedback-based training with active interventions (those thought to be effective, such as relaxation and meditation) and with inactive interventions (those representing a control group, such as clinic BP measurement or sham biofeedback). While both biofeedback and other active treatments resulted in a reduction in BP, there were no differences in the magnitude of the reduction in either systolic blood pressure (SBP) or diastolic blood pressure (DBP) when biofeedback was compared with active treatment. However, when biofeedback was compared to inactive control treatments, there was a significantly greater reduction in both SBP (6.7 mmHg) and DBP (4.8 mmHg) (Yucha et al. 2001).

A second meta-analysis of 22 randomized controlled studies (comprising a total of 905 essential hypertensive persons) published between 1966 and 2001 supported these findings (Nakao, Yano, Nomura, & Kuboki, 2003). In comparison with nonintervention controls, biofeedback resulted in significantly greater reductions in SBP (7.3 mmHg) and DBP (5.8 mmHg). Compared with other behavioral interventions, the net reductions in SBP and DBP were not statistically different. A very recent review of more than one hundred randomized controlled trials showed that behavioral treatments reduce BP to a modest degree (but as much as 14 mmHg for SBP and 11 mmHg for DBP), and this change is greater than that seen in wait-list or other inactive controls (Linden & Moseley, 2006).

Biofeedback appears to work just as well for those with white-coat hypertension as those with essential hypertension (Nakao, Nomura, Shimosawa, Fujita, & Kuboki, 2000) and for those with and without organ damage secondary to their hypertension (Nakao, Nomura, Shimosawa, Fujita, & Kuboki, 1999). Laboratory training followed by home training appears to be particularly effective (Henderson, Hart, Lal, & Hunyor, 1998), as do workplace stress reduction programs for hypertensive employees (McCraty, Atkinson, & Tomasino, 2003).

It is not clear exactly how biofeedback exerts its BP-lowering effect. Thermal biofeedback seems to work by helping patients to dilate peripheral blood vessels, thereby lowering total peripheral resistance. Because baroreceptor sensitivity is reduced in hypertension, two recent studies have shown that increasing baroreceptor sensitivity with baroreceptor feedback (Overhaus, Ruddel, Curio, Mussgay, & Scholz, 2003) or respiratory training (Reyes del Paso et al. 2006) may result in BP reduction.

Unfortunately, the degree of response to biofeedback training has varied widely for hypertension. This may be because of the starting level of BP (the higher the initial level, the better the response), the

variety of modalities used (thermal, EMG, heart rate, BP biofeedback), the length of the training (four to 20 sessions), and the ability of the subject to actually learn and incorporate the techniques into his or her lifestyle (Yucha, 2002; Linden & Moseley, 2006). Current literature shows thermal and EDR biofeedback are more effective than EMG or direct BP feedback (Linden & Moseley, 2006). While it is difficult to predict which hypertensives will be helped to reduce or even eliminate their antihypertensive medications with training, those with high resting sympathetic activity (low skin temperature, high heart rate, high BP) appear to benefit more with biofeedback-assisted relaxation training (Weaver & McGrady, 1995).

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Immune Function

Level 1: Not empirically supported

A small study (Gruber et al. 1993) of 13 stage-one breast cancer postmastectomy patients showed improvements in immune function (natural killer cell activity, mixed lymphocyte responsiveness,

cancavalin A responsiveness, and the number of peripheral blood lymphocytes). Another small study (n=10) examining the effects of relaxation training, including EMG biofeedback in HIV-positive men, showed significant improvement in anxiety, mood, self-esteem, and T-cell count in comparison to a control group (Taylor, 1995). A study of 42 HIV patients showed no treatment effects on immune function, but those treated with massage and biofeedback showed significant differences in quality of life assessment in health care utilization and health perceptions (Birk, McGrady, MacArthur, & Khuder, 2000).

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Insomnia

Level 3: Probably Efficacious

In 1996, an NIH Technology Assessment Panel examined existing research and concluded several nonpharmacological techniques, particularly relaxation and biofeedback, produced improvements in some aspects of sleep but questioned whether the magnitude of the improvement in sleep onset and total sleep time were clinically significant.

In 1998, the American Academy of Sleep Medicine recommended biofeedback along with progressive muscle relaxation for insomnia after reviewing the quality of research, using American Psychological Association research criteria. Biofeedback was rated “probably efficacious” along with sleep restriction and cognitive-behavioral therapy (Morin et al. 1998). (Progressive muscle relaxation, stimulus control, and paradoxical intent were rated even higher.)

The assignment of specific biofeedback procedures to particular subjects based on personal characteristics such as presence of tension and anxiety was examined by Hauri, Percy, Hellekson, Hartmann, and Russ (1982), using theta and SMR EEG. Nicassio, Boylan, and McCabe (1982) highlighted the importance of expectancy and found no correlation between achieved muscle relaxation and quality of sleep.

In an update by the American Sleep Disorders Association in 2006, a task force of content experts was appointed by the American Academy of Sleep Medicine to perform a comprehensive review of the scientific literature since 1999 and to grade the evidence regarding nonpharmacological treatments of insomnia (Morgenthaler et al. 2006). Recommendations were developed based on this review using evidence-based methods. Psychological and behavioral interventions are effective in the treatment of both chronic primary insomnia (standard) and secondary insomnia (guideline). Stimulus control therapy, relaxation training, and cognitive behavior therapy are individually effective therapies in the treatment of chronic insomnia (standard) and sleep-restriction therapy, multicomponent therapy (without cognitive therapy), biofeedback, and paradoxical intention are individually effective therapies in the treatment of chronic insomnia (guideline).

In a later but similar review by Morin, Jarvis, and Lynch (2007), therapeutic options for sleep-maintenance and sleep-onset insomnia published between January 1996 and January 2006 were evaluated. Nonpharmacologic options include stimulus control, sleep hygiene education, sleep restriction, paradoxical intention, relaxation therapy, biofeedback, and cognitive behavioral therapy. They concluded behavioral strategies, which often include biofeedback, have been demonstrated in numerous studies. These strategies are recommended when medications are not indicated, as an augmentation to medication, or as individual therapy in short-term mild insomnia.

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Irritable Bowel Syndrome

Level 2: Possibly Efficacious

Studies of biofeedback to reduce irritable bowel syndrome (IBS) symptomatology are mixed. Earlier studies showed benefits with effects lasting four years post-treatment (Schwarz, Taylor, Scharff, & Blanchard, 1990). Two controlled comparisons of a previously validated multicomponent (relaxation, thermal biofeedback, and cognitive therapy) treatment for IBS showed no difference in comparison to an attention-placebo control group or a symptom monitoring control group (Blanchard et al. 1992). A recent study tested the effect of computerized biofeedback games for teaching relaxation (monitored by electrodermal activity) to patients with IBS. Training reduced the global and bowel symptom score, and 50% of patients continued to use the technique to induce relaxation (Leahy, Clayman, Mason, Lloyd, & Epstein, 1998).

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Motion Sickness

Level 4: Efficacious

The rationale for biofeedback relies on an assumed correlation between ability to control the autonomic precursors of motion sickness (rise in skin conductance, drop in skin temperature, high heart rate) and resistance to sickness resulting from induced motion, such as a chair movable in three directions, as is done with NASA research.

Promethazine is commonly prescribed for motion sickness in astronauts with variable effectiveness. The strongest study on this application was by Cowings and Toscano (2000), where promethazine injections were compared to autogenic feedback training, including skin temperature and conductance with superior results for the latter. Control groups included a saline-placebo injection and no treatment. Four 30-minute sessions of autogenic training resulted in significantly more tolerance of the rotating chair in comparison with the two levels of intramuscular promethazine and placebo. Decreased variability of skin conductance plus lower HR was evident in the autogenic feedback groups.

Several studies were reviewed showing the impact of self-regulation training on motion sickness tolerance in virtually every motion sickness–inducing stimuli on the surface of a planet (Cowings, 1990), and research in space indicates this training is also effective in microgravity (Cowings et al. 1985; 1988; Toscano & Cowings, 1994). Scattered studies in the past 25 years have tried autogenic training assisted by biofeedback of temperature, skin conductance, and heart rate, sometimes including cognitive therapy.

Two studies with negative results investigated the correlation between physiological change and success in reducing symptoms of motion sickness (Graybiel & Lackner, 1980; Jozsvai & Pigeau, 1996). These showed little correlation. It was later demonstrated by Cowings that this finding was due to a procedural error. Graybiel manually measured heart rate, blood pressure, and temperature before the onset of the motion sickness stimulus and again when the stimulus ended. By continuously monitoring physiological changes on more than 140 people, Cowings et al. (1986) showed there are distinct patterns associated with motion sickness susceptibility. Subsequent studies further demonstrated there are individually specific response patterns that are stable over repeated exposures to a motion sickness stimulus (Cowings, Naifeh, & Toscano, 1990; Stout, Toscano, & Cowings, 1995).

Both NASA and military laboratories have demonstrated the effectiveness of training for control of airsickness in high performance aircraft (Levy, Jones, & Carlson, 1981; Jones et al. 1985; Cowings et al. 2001; Cowings et al. 2005). Desensitization in vivo has been the basic clinical model for intervention. Yet it is difficult to reproduce the conditions of a spaceship free of gravity. Also, the stimulus context of a chair spinning in three dimensions is more drastic than the usual context of a moving vehicle or boat. So generalizing from this experimental context to a more universal, nonastronaut situation is open to

question in spite of the study's design, so far unreplicated. The best approach, based on the research to date, seems to be training GSR control, first in isolation and then while exposed to a condition expected to induce motion sickness.

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Post-Traumatic Stress Disorder

Level 2: Possibly Efficacious

Several small studies incorporating biofeedback into multicomponent therapy, including eye movement desensitization and reprocessing (EMDR), reveal some improvement in self-report, psychometric, and standardized interview measures after therapy (Carlson, Chemtob, Rusnak, Hedlund, & Muraoka, 1998; Silver, Brooks, & Obenchain, 1995). A study of Vietnam veterans with combat-related post-traumatic stress disorder compared traditional medical treatment with 30 sessions of alpha-theta brainwave neurofeedback (Peniston & Kulkosky, 1991). Neurofeedback resulted in decreases in MMPI scores on clinical scales labeled hypochondriasis, depression, hysteria, psychopathic deviate, masculinity-femininity, paranoia, psychasthenia, schizophrenia, hypomania, and social introversion-extraversion in comparison to the traditional care group who showed decreases only on the scale labeled schizophrenia. A 30-month follow up showed all traditional-care patients had relapsed, in contrast to only three of 15 neurofeedback patients.

Pop-Jordanova and Zorcec (2004) selected a group of 10 children manifesting post-traumatic stress disorder (PTSD) diagnosed by ICD-10. The mean age of the patients was nine ± 3.05 years, from both sexes (girls three, boys seven). Mothers and children were examined by a battery of psychometric instruments (MMPI), CBCL, Eysenck (EPQ), and STAI. In addition to the classical psychotherapeutic methods (supportive, behavior, and play therapy), a multimodal computerized biofeedback technique was introduced for both assessment and therapy. The results showed a high level of anxiety and stress, somatization, and behavioral problems (aggressiveness, impulsivity, nonobedience, and nightmares), complemented by hypersensitive and depressive mothers and miss-attachment in the early period of infancy. The therapeutic results obtained with biofeedback techniques were very encouraging.

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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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Repetitive Strain Injury

Level 2: Possibly Efficacious

A randomized controlled study of 30 patients with upper extremity repetitive strain injury showed those receiving thermal biofeedback and autogenic relaxation had significantly higher reductions in pain in comparison to the waiting-list condition (Moore & Wiesner, 1996). Group training in ergonomic principles and psychophysiological awareness, coupled with EMG practice, may reduce body symptoms associated with computer work, thereby preventing injury (Peper, Gibney, & Wilson, 2004).

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Respiratory Failure: Mechanical Ventilation

Level 2: Possibly Efficacious

Relaxation training using EMG biofeedback and breathing retraining using tidal volume biofeedback may help patients to be weaned from mechanical ventilation (Jacovone & Young, 1998). Only one randomized trial showed those receiving biofeedback were weaned from their ventilator in 20.6 days in comparison to those in the control group who were weaned in 32.6 days (Holliday & Hyers,

1990). Respiratory relaxation feedback of expired CO_2 showed decreases in respiratory parameters reflecting neural respiratory drive (such as occlusion pressure, minute inspiratory volume, mean inspiratory flow, and selected EEG parameters) may contribute to the effectiveness of biofeedback in reducing weaning time (Holliday & Lippmann, 2003).

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Spinal Cord Injury

Level 1: Not Empirically Supported

There are limited studies on biofeedback post-spinal cord injury, and they involve different treatment protocols and outcome measures. However, there was a significant increase in triceps EMG activity in one hundred patients with long-term cervical spine injury after one biofeedback treatment, and further increases occurred after additional treatment sessions (Brucker & Bulaeva, 1996). A small study (n=10), studied patients in a daily therapy program lasting two months, including muscle strengthening and gait training. Half the subjects received biofeedback for 30 minutes a day; half used an ambulatory device to receive continuous biofeedback every time they walked. After two months, those undergoing clinical therapy showed a 50% reduction in hip drop; those using the home training device showed almost normal gait (Petrofsky, 2001).

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Stroke (Cardiovascular Accident)

Level 2: Possibly Efficacious

Four meta-analyses on the effect of biofeedback for rehabilitation after stroke show conflicting results. The first included eight studies (total of 192 patients) and examined functional outcome of EMG biofeedback. They found a significant effect size (0.81), concluding EMG biofeedback is useful for neuromuscular reeducation in the hemiplegic stroke patient (Schleenbaker & Mainous, 1993). The second meta-analysis compared the effects of EMG biofeedback and physical therapy on upper extremity function and found no significant differences (Moreland & Thomson, 1994). The third meta-analysis

included studies with an outcome of change in range of joint motion of a paretic limb. The results of pooling eight studies did not support the efficacy of biofeedback in restoring upper or lower extremity range of motion of hemiparetic joints (Glanz et al. 1995). The fourth meta-analysis examined the efficacy of EMG biofeedback compared with conventional physical therapy for improving lower extremity function. EMG biofeedback was superior to physical therapy for improving ankle dorsiflexion muscle strength but not for improving gait quality, ankle range of motion, ankle angle during gait, stride length, or gait speed (Moreland, Thomson, & Fuoco, 1998). Thus it appears that when functional measures related to lower extremity are the outcome, biofeedback is effective; when functional measures related to the upper extremity or change in range of joint motion is the outcome, biofeedback is not effective.

A more recent Cochrane Review (Woodford & Price, 2006) of 13 studies of 269 persons concluded, "Despite evidence from a small number of individual studies to suggest that EMG biofeedback plus standard physiotherapy produces improvements in motor power, functional recovery, and gait quality when compared to standard physiotherapy alone, combination of all the identified studies did not find a treatment benefit."

Finally, the use of biofeedback to treat urinary incontinence after stroke has not been sufficiently studied to demonstrate efficacy (Thomas et al. 2005).

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Syncope (Neurocardiogenic)

Level 1: Not Empirically Supported

Ten patients with neurocardiogenic syncope were treated with EMG and thermal biofeedback, coupled with progressive muscle relaxation; six showed a major decrease in symptoms (McGrady, Bush, & Grubb, 1997). A later controlled pilot study on 22 patients with neurocardiogenic syncope showed biofeedback-assisted relaxation training led to significant improvement in headache index and loss of consciousness in the treatment group (McGrady et al. 2003).

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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.

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Tinnitus

Level 2: Possibly Efficacious

EMG biofeedback and neurofeedback have been used in the treatment of tinnitus. Biofeedback appears to be of greatest benefit in reducing tinnitus for certain subgroups of patients (Erlandsson, Rubinstein, & Carlsson, 1991). For example, EMG biofeedback is most effective when muscle tension and mental distress accompany the tinnitus (Ogata, Sekitani, Moriya, & Watanabe, 1993). Another

showed tinnitus patients reported a greater amount of psychological stress than healthy controls but not physiological arousal (Heinecke, Weise, Schwarz, & Rief, 2008), supporting the need for relaxation training. Flor, Hoffmann, Struve, and Diesch (2007) showed patients (n=12) who engaged in regular auditory discrimination training as compared to those who practiced irregularly were significantly more successful in reducing tinnitus severity independent of the trained frequencies. One German study showed EEG biofeedback to upregulate the amplitude of alpha activity and downregulate the amplitude of beta-activity during muscle relaxation and acoustic orientation, which led to a significant reduction in the score on a tinnitus questionnaire in comparison to a control group that did not receive neurofeedback (Gosepath, Nafe, Ziegler, & Mann, 2001). A second German study comparing EEG-alpha and EEG-beta training showed both groups reported a significant reduction of subjective tinnitus annoyance (Schenk, Lamm, Gundel, & Ladwig, 2005). Finally, enhancing tau activity (oscillatory activity produced in perisylvian regions within the alpha frequency range (8-12 Hz) and concomitant reduction in delta power range (0.5-4 Hz) to alter the tau-to-delta ratio significantly reduces tinnitus intensity (Dohrmann, Weisz, et al. 2007). Comparison of neurofeedback-treated patients (n=21) with a group trained with a frequency discrimination task (n=27), showed the tinnitus relief in the neurofeedback group was significantly stronger (Dohrmann, Elbert, et al. 2007).

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Traumatic Brain Injury (TBI)

Level 3: Probably Efficacious

EEG biofeedback appears to improve memory in persons with brain injury (Thornton, 2000). It also improves attention and response accuracy of a performance task and decreases errors in a problem-solving task (Tinius & Tinius, 2000). Walker, Norman, and Weber (2002) found 88% of mild head injury patients showed more than 50% improvement in EEG coherence scores, and all patients who had been employed prior to injury reported being able to return to work following the treatment. One small controlled study (n=12) demonstrated EEG-based therapy results in improvement of some measures of

cognitive function as well as participants' reports of depression and fatigue (Schoenberger, Shif, Esty, Ochs, & Matheis, 2001). Another controlled study demonstrated significant improvement in attention deficits in those receiving feedback of beta activity in comparison with a matched control group (Keller, 2001).

In a review of the literature of EEG biofeedback treatment with TBI individuals, Thornton and Carmody (2005) provided a theoretical justification for EEG biofeedback based on a series of findings by several independent investigators (Miller, Tabano, Thatcher, Thornton, and Trudeau) that the EEG pattern is different between normals and TBIs. This difference is primarily the result of decreased posterior alpha, increased posterior beta, frontal connection abnormalities, and long cortico-cortico connection deviations. Recent results support the sensitivity of measures of coherence being approximately 90% when identifying TBI. The authors present a series of single case studies by other investigators and six of their own, demonstrating improvements in reading skills during and after EEG biofeedback. They also reviewed studies that used EEG amplitude feedback, coherence feedback, and audio/visual dominant frequency feedback. These studies employed minimal control conditions or none, but did demonstrate positive outcome on a variety of measures with follow-up assessment up to one year.

A recent study that used the low energy neurofeedback system (LENS) method with one hundred TBI patients (ages six to 80) with the outcome being assessed by session-by-session subjective symptom ratings reported average symptom ratings across 15 major problem areas (e.g., anxiety, mood disturbance, attentional problems, fatigue, pain, sleep problems, etc.) to show significant improvements (Larsen, Harrington, & Hicks, 2006). Equally significant was the drop in EEG amplitude at the highest amplitude electrode site (HAS) as well as a lesser but still significant decrease at Cz. In another article using the LENS technique, Hammond (2007) reported on a multiple case study with two individuals who suffered loss or reduction of olfactory acuity (anosmia) due to acceleration-deceleration traumatic brain injury (TBI). Both participants reported a complete reversal of long-term anosmia following neurofeedback treatment.

Hartelius, Theodoros, and Murdoch (2005) used electropalatography (EPG) as a biofeedback tool in a case study of a 30-year-old male with disordered articulation following TBI. Therapy was administered three times a week for five weeks. Results showed word and sentence intelligibility increased approximately 10%, and error patterns for lingual articulation indicated fricative errors decreased considerably. The authors concluded that as a part of an intervention program visual EPG biofeedback therapy appears to have a definite role in assisting dysarthric speakers exhibiting difficulties with lingual articulation in understanding their errors, learning how to exploit kinesthetic and acoustic sources of feedback, and how to make appropriate adjustments in tongue articulation to increase the level of speech intelligibility.

Based on these studies, it can be concluded the EEG biofeedback and the LENS technique are probably efficacious. Further research is needed, with appropriate controls and random assignment to conditions, to further clarify the applications of biofeedback with individuals who have suffered loss due to traumatic brain injury.

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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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Urinary Incontinence in Males

Level 3: Probably Efficacious

Most studies testing the effect of biofeedback on male incontinence have been done on males after prostatectomy. Two systematic reviews for urinary incontinence after prostatectomy show mixed results. MacDonald, Fink, Huckabay, Monga, and Wilt (2007) found men receiving biofeedback-enhanced pelvic floor training were more likely to achieve continence than those with no training. In contrast, Hunter, Glazener, and Moore (2007) concluded the value of pelvic floor muscle training with or without biofeedback remains uncertain, whether the training started pre-operatively or post-operatively. Two studies involved pre-operative biofeedback-enhanced pelvic floor training; both showed such training prior to radical prostatectomy hastens the recovery of urine control and decreases the severity of incontinence after surgery (Parekh et al. 2003; Burgio et al. 2006). One problem with past studies is that many of the men included were not incontinent; this decreases the ability to see an effect of treatment. For example, Wille, Sobottka, Heidenreich, and Hofmann (2003) showed the continence rate increased from 21.4% one day after catheter removal to 59.2% at three months and 85.9% at 12 months, but there was no difference among groups treated with instruction, biofeedback, or electrical stimulation. In studies including all prostatectomy patients, rather than those who were incontinent, biofeedback was not effective (Bales et al. 2000; Franke et al. 2000; Mathewson-Chapman, 1997). However, studies in men who were incontinent after prostatectomy demonstrate biofeedback was better than no treatment (control) (Van Kampen et al. 2000; Zhang, Strauss, & Siminoff, 2007) and equal to pelvic floor exercises (Floratos et al. 2002). It has also been shown to be effective for treatment post-micturition dribble in men with erectile dysfunction (Dorey et al. 2004).

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Urinary Incontinence in Children

Level 2: Possibly Efficacious

Studies of biofeedback efficacy in children who suffer from urinary incontinence lack control groups. In general, these studies show improvement in urinary incontinence in 60 to 90% of children treated (Combs, Glassberg, Gerdes, & Horowitz, 1998; Hoekx, Wyndaele, & Vermandel, 1998; McKenna, Herndon, Connery, & Ferrer, 1999; Barroso et al. 2006; Khen-Dunlop, Van Egroo, Bouteiller, Biserte, & Besson, 2006; Yagci et al. 2005; Shei Dei Yang & Wang, 2005). One five-year follow-up study of biofeedback for nocturnal enuresis showed 79% were still dry at night (Hoekx, Vermandel, & Wyndaele, 2003).

The lack of control groups is particularly problematic in this population because of the maturation factor. A systematic review of five studies concluded that no intervention tested in a trial has been shown to be of benefit (Sureshkumar, Bower, Craig, & Knight, 2003). A nonrandomized study comparing biofeedback to alpha blocker therapy showed comparable reduction in post-void residual urine volume

(Yucel et al. 2005). In two behavioral voiding programs delivered over 24 sessions, one with the addition of biofeedback, both led to improvement in urinary continence; those in the biofeedback group also showed a significant decrease in post-void residual urine (Vasconcelos et al. 2006).

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Vulvar Vestibulitis (Vulvodynia)

Level 3: Probably Efficacious

EMG biofeedback and pelvic floor exercises have been used to treat women with vulvar vestibulitis. A randomized study comparing biofeedback with cognitive behavioral therapy and with

vestibulectomy demonstrated that all three groups reported statistically significant reductions in pain and improvements in sexual function and psychological adjustment (Bergeron et al. 2001). Although the vestibulectomy group was more successful than the two other groups in regard to pain reduction, some patients assigned to this group refused the intervention. The benefit of EMG biofeedback and pelvic floor exercises has also been demonstrated in two uncontrolled studies with patients showing reductions in pain and approximately 70% able to resume sexual activity without discomfort (Glazer, Rodke, Swencionis, Hertz, & Young, 1995; McKay et al. 2001).

Intrapelvic sEMG biofeedback has also been demonstrated effective in treatment of the second subset of vulvodynia, dysesthetic vulvodynia (Glazer, 2000). Via chart review and patient follow up, 88% of patients responding stated they were pain free after EMG-assisted pelvic floor muscle rehabilitation (mean 39 months). Thus this treatment was shown to be an effective and long-term cure for dysesthetic vulvodynia.

Retrospectively, Jantos (2008) studied the psychophysiological profile of 529 women with vulvodynia. EMG data collected using a vaginal sensor were positively associated with pelvic muscle dysfunction and negatively associated with duration of pain. Patients practiced EMG-assisted pelvic muscle exercises and cognitive therapy for varying lengths of time until their pain decreased, and they were able to resume sexual activity. Compared to pre-training, EMG readings showed decreases in muscle resting baseline and instability and increases in phasic and tonic contraction amplitudes. Together these changes reflect more relaxed pelvic muscles and improved muscle tone.

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Emerging Applications

Level 1: Not Empirically Supported

Birbaumer, Hinterberger, Kubler, and Neumann (2003) utilized a thought-translation device (TTD) consisting of a training device and spelling program for the completely paralyzed using slow-cortical brain potentials (SCP). During the training phase, the self-regulation of SCPs is learned through visual-auditory feedback and positive reinforcement of SCPs; during the spelling phase, patients select letters or words with their SCPs. The neurophysiological and anatomical basis of SCP-regulation was

investigated by recording of BOLD-response in functional magnetic resonance imaging. The clinical outcome of 11 paralyzed patients using the TTD and quality of life of severely paralyzed patients were successful.

The results of a study by Block, Onslow, Roberts, and White (2004) on the control of stuttering with EMG feedback is reported. Participants were 12 children and adolescents. Two experienced clinicians and two student clinicians presented the treatment as outlined in the Craig manual for six hours per day over five consecutive days. Subjects showed a reduction of 48.9% of their stuttering during reading conditions after the treatment and a reduction of 36.7% of stuttering after the treatment during conversation. During the post-treatment period participants were speaking at a mean of 111 syllables per minute, which is around half the expected speech rate for Australians in this age group.

A study to evaluate the immediate, long-term, and carry-over effects of nasopharyngoscopic biofeedback therapy in patients with cleft palate who exhibit velopharyngeal dysfunction (VPD) was reported by Brunner, Stellzig-Eisenhauer, Proschel, Verres, and Komposch (2005). The study was completed at the Heidelberg University Hospital, Heidelberg, Germany. The participants were 11 patients with VPD who had received conventional speech therapy without showing significant improvement. The intervention was a four-stage feedback procedure. The patients watched and evaluated their velopharyngeal (VP) valving during speech by an endoscopic image displayed on a video monitor. Two feedback sessions took place for every target sound. Significant improvement and stability of VP closure was noted. Mean occurrence of VP closure was 5% before therapy, 91% after two biofeedback sessions, and 86% in the follow up after six months. Velopharyngeal dysfunction associated with compensatory articulation proved to be equally well trained as VPD on sounds with good articulatory placement. No significant difference was observed in the degree of improvement between phoneme-specific VPD and generalized VPD. The transfer to the level of words and sentences was successful and showed significant stability. The stability of VP closure for vowels was less than the stability for fricatives and stop sounds. Patients also gained improved auditory and kinesthetic self-perception of their articulation.

Earles, Kerr, and Kellar (2003) reported a study of the effects of EMG biofeedback for the treatment of vocal cord dysfunction (VCD), which is an obstructive upper airway syndrome that frequently mimics asthma and for which there is no empirical treatment of choice. Two military service members experiencing VCD were treated. Both cases were active-duty military members with VCD confirmed by laryngoscopy. They each received biofeedback self-regulation training to decrease tension in the extrinsic laryngeal musculature. Both patients responded to the treatment, denied the presence of dyspnea, and resumed military physical training.

An outcome study of laryngeal and velopharyngeal biofeedback treatment in children and young adults was reported by Lierde, Claeys, De Bodt, and Van Cauwenberge (2004). Four subjects were studied pretreatment (one week before LB or VB treatment) and posttreatment (one week after the LB or VB treatment). To measure and compare the effect of LB and VB, objective and subjective assessment techniques were used. Perceptual voice assessment included a perceptual rating of the voice using the GRBAS scale. Furthermore, the vocal quality in this population is modeled by means of the Dysphonia Severity Index. For the objective assessment of nasal resonance, the Nasometer and the Glatzel test were used. A perceptual evaluation of speech, the Gutzmann test, and the tests from Bzoch were used as subjective assessment techniques. Both patients selected for LB and VB treatment showed improvement of their performances. The resulting improvement, as measured by means of an objective approach, is in agreement with the perceived (auditory) improvement of voice and resonance.

A study to evaluate the effect of a six-session biofeedback intervention program on cognitive aspects of patients with somatoform disorders was reported by Moss et al. (2003). The treatment consisted of psychophysiological demonstrations of how mental processes can influence biological functions. Patients were assessed using a structured interview to diagnose somatization syndrome (SSI-8) and comorbidity according to DSM-IV criteria. Fifty patients were recruited and randomly assigned to

biofeedback treatment or control relaxation group. Participants completed a questionnaire battery assessing cognitive characteristics, causal attributions, and controllability before and after intervention. The results suggest biofeedback modified the patients' cognitive schemata: Patients with somatization syndrome of the biofeedback group showed a greater reduction of catastrophizing of somatic sensations and higher acceptance of psychosocial causal attributions than the control group. Both groups improved significantly in the conviction of self-efficacy.

In a study to improve cognitive functioning in the elderly using peak alpha frequency (PAF), which has been shown to correlate positively with cognitive performance and to correlate negatively with age after childhood, a new EEG biofeedback protocol was utilized (Angelakis et al. 2007). The study used a double-blind, controlled design to investigate whether training older individuals to increase PAF would result in improved cognitive performance. The results demonstrate PAF EEG biofeedback improved cognitive processing speed and executive function but had no clear effect on memory.

Becerra et al. (2006) reported a two-year follow up from a previous study describing positive behavioral changes and a spurt of EEG maturation with theta/alpha EEG biofeedback training in a group of learning disabled (LD) children. In a control-paired group treated with placebo, behavioral changes were not observed, and the smaller maturational EEG changes observed were easily explained by increased age. Two years later, the EEG maturational lag in the control group increased, reaching abnormally high theta Relative Power values; the absence of positive behavioral changes continued, and the neurological diagnosis remained. In contrast, after two years, EEG maturation did continue in children who belonged to the treatment group; this was accompanied by positive behavioral changes, which were reflected in remission of LD symptoms.

In a study of LD children, Fernandez et al. (2003) used 10 children with higher-than-normal ratios of theta to alpha absolute power (theta/alpha ratio). The children were divided into two groups in order to maintain similar IQ values. EEG biofeedback was applied in the region with the highest ratio, triggering a sound each time the ratio fell below a threshold value. Noncontingent reinforcement was given to the other group. Twenty twice-weekly half-hour sessions were provided. Before and after 20 sessions, TOVA, WISC, and EEG were obtained. There was significant improvement in performance on the outcome measures in the treatment group that was not observed in the noncontingent reinforcement group. EEG absolute power decreased in delta, theta, alpha, and beta bands in the treatment group. The noncontingent reinforcement group only showed a decrease in relative power in the delta band.

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Sample Protocols

General EMG Training

The principle of EMG training is normally to provide the learner with enhanced information about his or her muscle tension in a particular area, hoping this will facilitate learning control of the muscle. Relaxation of excess and inappropriate tension is the usual goal. Sensors are attached to the skin over the muscle being targeted for change. Muscles may be targeted anywhere on the body, including the forehead, neck, shoulders, back, jaws, arms, or legs. Insertable pelvic sensors are used to target pelvic muscles. Tiny electrical signals emitted by muscles, proportional to degree of contraction, are amplified and fed to a visual display or an audio signal. The visual display may be digits, polygraph-style lines, or changes in colors or patterns. The audio tone may indicate changes in muscle tension by a rising or falling tone, or by a change in frequency of a beep. Most biofeedback systems allow for recording average muscle tension over a specified time interval.

After some instruction, the learner is allowed quiet practice time during which he or she attempts to lower the measured muscle tension, using the biofeedback signal as an external guide. The trainer suggests various ways to relax, helps deal with obstacles to learning, keeps track of progress, and generally facilitates the learning process. Home practice is usually prescribed because the goal is to learn better control of the muscles without the aid of biofeedback monitoring. One or more criteria are usually set as goals of training: for instance, staying below two microvolts for the upper shoulder. Speed of recovery from contraction is another common criterion and also keeping muscle tension lower during movement.

Frequency of sessions varies, and may be twice per week or less often. The biofeedback is considered a temporary learning aid, and as the learner becomes more sensitive to internal sensations and learns to read his or her body better, the biofeedback becomes less necessary. The duration of this learning process varies from person to person but might typically take one to three months. Duration is best determined by achieving the criteria rather than by number of sessions. Symptoms are usually tracked with home diaries, and this helps the learner understand which activities and situations increase muscle tension. Self-regulation eventually begins to become habitual; goals such as keeping the shoulders low or the jaw loose require less and less conscious involvement.

Temperature Training

The goal of temperature training is to teach the learner to warm his or her peripheral extremities. While core temperature is 98.6^{o}F (37.0^{o}C), skin temperature is much lower, ranging from 75-95^{o}F. In order to raise skin temperature, one must relax skeletal muscles as well as the muscles within the walls of the blood vessels. This latter effect is believed to result in better blood flow to the skin and, therefore, a rise in skin temperature.

A thermal sensor, called a thermistor, is taped to the skin, usually on the palmar surface of one of the fingers. The temperature of the skin changes the resistance of the thermistor, thereby altering the electrical signal in proportion to the temperature. The signal is displayed visually and/or through a tone that changes in response to changes in temperature. The visual display may be digits, polygraph-style lines, or changes in colors or patterns. Commonly, the learner's skin temperature is displayed on a thermometer.

After some instruction, the learner is allowed quiet practice time during which he or she attempts to raise the skin temperature. The trainer suggests various ways to do this, using the biofeedback signal as a guide. For example, training in slow, deep breathing usually helps the learner to relax. The learner may repeat autogenic phrases, such as "My hands feel warm and heavy," or imagine lying on the beach feeling

the sun's warmth on the hands. Home practice is prescribed, and the learner may be given a simple, handheld thermometer to monitor progress. On subsequent training sessions, the thermistor may be moved from one hand to the other or to a foot. This helps the learner to generalize the skin temperature warming to areas beyond the hands. One or more criteria are set as goals of training. Typically learners are asked to raise hand temperature to 90 – 95^{o}F and foot temperature to 90^{o}F.

Thermal training sessions are typically held weekly. The biofeedback is considered a temporary learning aid, and as the learner becomes more sensitive to internal sensations of stress, the biofeedback becomes less necessary. The duration of this learning process varies from person to person but typically requires four to eight sessions accompanied by home practice.

Thermal training is typically combined with other biofeedback modalities to train learners in general relaxation. It is also used in a number of disorders such as Raynaud's disease, hypertension, migraine headaches, and anxiety. More recently, it has been used to increase blood flow to wounds, thereby promoting healing.

Skin Conductance Training

Skin conductance feedback provides information about sweat gland activity on the hand, which is closely correlated with sympathetic nervous system activity. This variable is called SCA (skin conductance activity), EDA (electrodermal activity), or the more classic term GSR (galvanic skin response). Sensors are attached to two fingers or two sites on the palm, and feedback is provided in various ways: a changing audio tone, changes in colors on a display, numerical change, meter deflection, or a moving line via video feedback. Response time is less than two seconds, making it very sensitive to transient changes in emotion.

Self-calming by physical or cognitive means tends to lower skin conductance, while negative emotions such as fear, worry, or anger usually raise it, as will a startle response. Any disorder that would benefit from emotional calming may respond to GSR biofeedback, provided the learner is able to generalize from the feedback situation to real life. For example, GSR feedback is often employed in treatment of phobias and anxiety attacks, and has been used as one element in modifying hypertension and bowel disorders, which are exacerbated by emotional upset.

In learning to reliably lower one's GSR, one learns to resist distractions, which disrupt attention, and to maintain a state of mind that is neutral or pleasant. Relaxation techniques such as slow breathing, imagery, or meditation can help keep the attention steady and the emotions calm. This tends to stabilize the autonomic nervous system. Time needed to learn the skill varies from days to months. Practice between biofeedback sessions facilitates mastery of the skill and is practical since home-trainer GSR devices are available for less than a hundred dollars.

EEG Training or Neurofeedback

The goal of neurofeedback is to teach learners to modify their EEG. There are many applications of EEG training. One of these includes teaching the learner to maintain a relaxed, alert, and focused mental state while carrying out cognitive tasks. Another application of EEG training includes teaching the learner to increase slower-frequency brainwaves to achieve deeper levels of psychophysiological relaxation or to access calmer mental states. Other applications use EEG training to treat such disorders as depression, anxiety, epilepsy, sleep disorders, fibromyalgia, pain, alcoholism, and other addictions. EEG training is also used in the rehabilitation of brain injury and stroke.

These applications are done by training learners to alter their brainwaves. Historically, there are four types of brainwaves identified according to their frequency or bandwidth. They are known as delta

(0.5-4 Hertz), theta (4-8 Hertz), alpha (8-12 Hertz), and beta (13-20^{+} Hertz), differing according to their frequency. Each person has an individual pattern of brainwave activity, but there are certain "signatures" of brainwave frequencies that are associated with specific symptoms or dysfunction. For example, people with Attention Deficit Disorder tend to have greater ratios of slower EEG activity (delta, theta, or even alpha) compared to faster beta activity. In this example, the goal of training for individuals with ADD is to decrease the amplitude of slow-wave activity (delta, theta, and/or alpha) while increasing the amplitude of faster wave activity (beta).

In neurofeedback training, surface sensors are placed on selected areas of the head and ears. The number and location of these sensors is determined by the specific application and goal of the EEG training. Typically, the number of sensors used varies between three and six. The EEG signal is displayed visually and/or through auditory tones that vary as the EEG changes. Brainwave changes in the desired direction are rewarded with visual and/or auditory feedback. The visual signal may be graphs, digits, waveforms, changes in colors or patterns, or even animations.

Neurofeedback training typically requires 40 or more 50-minute sessions, usually held twice or more weekly. EEG training may be accompanied by cognitive or other therapies. For example, those with ADD may receive coaching in learning strategies while those with alcoholism may receive coaching in alcohol avoidance.

Neurofeedback may be combined with other biofeedback modalities such as EMG, EDR, temperature, HRV, or other biofeedback modalities to train learners in general relaxation.

Heart Rate Variability

HRV stands for heart rate variability. The term RSA (Respiratory Sinus Arrhythmia) predates the term HRV, and refers to the rise and fall of heart rate synchronized with each breath (faster on the inhale, slower on the exhale). The magnitude of this systematic variability seems to reflect a healthy alternation between two autonomic influences on the heartbeat: sympathetic and parasympathetic. Lack of this variation reflects an imbalance between the two aspects of the ANS, most likely deficient parasympathetic influence, and is a sign of poor cardiovascular health. By calming one's emotional state and by making the breathing slower and more regular, the HRV can be increased, at least temporarily.

The biofeedback setup for HRV involves monitoring either heart rate alone or heart rate plus respiration. Heart rate may be detected from plethysmographic sensors on the finger or earlobe, or via EKG monitors. Most commonly, a trace reflecting cyclic variations in heart rate is displayed on a video screen. The mean heart rate per minute is not important; the variability of heart rate is the variable of interest. The trainee observes the trace (or a derived graphic display) and uses it as feedback for regulating the breath and/or the emotional state. The heartbeat variability is maximized at a particular "resonant frequency" (breathing rate per minute), and this rate, usually around six per minute, can be determined for each individual by observation and experimentation.

The time to achieve an improved HRV while assisted by biofeedback might average four to 10 sessions. Learning time varies as with any biofeedback procedure. Generalization to the everyday environment, away from the biofeedback monitoring, takes longer than achieving success within the biofeedback context. Practicing with HRV biofeedback provides a model for real-life self-regulation; the goal is to develop awareness of one's breathing and of one's emotional state, both of which interact and influence the autonomic balance. This balance, in turn, has been found to be helpful for several disorders involving chronic maladjustment of the autonomic nervous system.

Biofeedback Foundation of Europe

The Biofeedback Foundation of Europe (BFE) was founded to promote a greater awareness of biofeedback among European health professionals and, through training workshops, to educate clinicians in the use of biofeedback techniques and technology. BFE has compiled a series of clinical protocols developed by major contributors in the field of biofeedback and physical therapy in an effort to improve knowledge in the use of electromyography as an effective tool for physiotherapy. These describe assessment and biofeedback training technique. Protocols for the following conditions can be found on the Website (http://www.bfe.org/library.html, click on BFE protocols).

Patella Femoral Pain Syndrome

The Unstable Shoulder

Post Operative Knee

Urinary and Fecal Incontinence

Phantom Limb Pain

Oral Pharyngeal Dysphagia

Myofacial Pain and TMJ

Chronic Tension Headache

Repetitive Strain Injury

Effortless Diaphragmatic Breathing

Vulvovaginal Pain Disorders

Peak Performance Training with Electrodermal Biofeedback

Towards an Integrated Approach of sEMG Utilization: Quantitative Protocols of Assessment and Biofeedback

Protocol for use of EMG and Tactile Biofeedback in Treatment of Temporomandibular Disorders and Myofacial Pain

The Biofeedback Certification Institute of America

The Biofeedback Certification Institute of America (BCIA) is an autonomous nonprofit corporation that was created in January 1981 to establish and oversee standards for practitioners who use biofeedback, to certify those who meet these standards, and to progressively recertify those who advance their knowledge through continuing education. BCIA policies and procedures are set by an independent board of directors, which is comprised of a rotating group of distinguished biofeedback clinicians, researchers, and educators. Three certification programs are currently offered: 1) General Biofeedback (providing the basics of biofeedback, including GSR, EMG, HRV, thermal, and an introduction to EEG), 2) EEG Biofeedback (for those who wish to specialize in EEG biofeedback/neurofeedback), and 3) Pelvic Muscle Dysfunction Biofeedback (built specifically for licensed health care professionals who use biofeedback and behavioral interventions to treat incontinence and pelvic pain syndromes).

BCIA certification is the mark of distinction for providers of biofeedback services. Names of certified practitioners may be found in the "Find a Practitioner" area of our Website at www.bcia.org. A BCIA-certified practitioner must meet the following qualifications:

1. Prerequisite educational degree of a BA/BS or higher from a regionally accredited academic institution in a BCIA-accepted clinical health care field such as counseling, medicine, nursing, psychology, rehabilitation, or social work. Credentialed special education teachers and counselors may also become certified in EEG biofeedback to work in school environments.
2. Didactic training by completing a three semester-hour university course or its equivalent or completing a BCIA-accredited training program covering the relevant Blueprint of Knowledge statements specific to that certification program.
3. Evidence of a human anatomy, human physiology, or human biology course from a regionally accredited academic institution or from a BCIA-accredited program.
4. Practical training to teach the application of clinical skills provided by a BCIA-approved mentor using contact hours to review personal biofeedback, case conference, and patient/client treatment sessions.
5. Successful completion of a written certification exam covering all relevant blueprint areas.
6. Adherence to the BCIA Ethical Principles, including working within the scope of one's profession. When working with a medical or psychological disorder, BCIA certificants are required to carry a state-issued license (or other comparable credential), which allows independent practice in a BCIA-approved health care field or to work under legal supervision.

Though BCIA certification assures that an individual has met entry-level education and training requirements for the clinical practice of biofeedback, this certification is not a substitute for a state-sanctioned license or other credential to practice one's profession.

Please visit www.bcia.org, where the public or other interested professionals may read about certification requirements or search for a practitioner.

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Association for Applied Psychophysiology and Biofeedback (AAPB) Code of Ethics

Members of the Association for Applied Psychophysiology and Biofeedback are expected to comply with the organization's Ethical Principles. These principles cover such areas as responsibility, competence, standards, public statements, confidentiality, protection of client rights and welfare, professional relationships, and research with humans and animals. A copy of these can be found on the organization's Website at www.aapb.org.

Answers to Common Questions about Biofeedback Treatment

What is a normal amount of time for a visit? If it takes longer, is it customary to bill per quarter-hour increments, or is it usually one lump sum?

Biofeedback sessions commonly range from 45 to 90 minutes. Shorter or longer sessions may be justified under unusual situations (e.g., shorter for a brief, uncomplicated follow up or practice session; longer for EEG training for epilepsy or treatment of a multiplicity of symptoms). It is customary to bill either by length of session in quarter-hour increments or a fixed amount per session regardless of length, depending on the profession and setting or the person doing the therapy.

What are general guidelines for number of sessions for major diagnoses of migraine headaches, hypertension, tension headaches, Raynaud's disease, anxiety, or irritable bowel syndrome?

Eight to 20 sessions is a reasonable length of treatment for each of the disorders listed when there is good patient adherence and no other disorder is present. Follow-up interviews are advisable at three, six, and nine months after the end of treatment.

What are reasonable fees for biofeedback therapy?

Fees vary among professions (psychologist, physician, master's level counselor, nurse, social worker, physical or occupational therapist, etc.) and between geographical regions but are not dependent on the physiological system being addressed in biofeedback therapy. Fees range from $50 to $200 per hour for biofeedback therapy. There should be little difference in fees between modalities of biofeedback therapy except that EEG therapy will customarily be higher because further specialized training is required.

Is it customary to break down the psychotherapy bill separately?

Although some biofeedback providers bill separately for biofeedback therapy and psychotherapy in the same session, it may not be necessary to do so. In addition to the use of biofeedback instrumentation, the clinical protocols in biofeedback therapies customarily involve two or three modalities of biofeedback and a variety of therapeutic procedures. Examples are autogenic training, imagery, symptom charting, assessment of life stressors, cognitive behavior therapies, strategies for generalization from the clinic to everyday life and application of skills outside the therapy session, assignment and review of homework, and adherence management.

In some cases, biofeedback therapy may be considered a subcategory of psychotherapy, as is done by the World Health Organization in ICD-9CM. The factor that defines biofeedback therapy is the use of instrumentation for teaching physiological self-regulation. When biofeedback instrumentation is not part of assessment or treatment, the procedure is not biofeedback therapy and should not be billed as such.

In some states, biofeedback therapy is not considered a form of psychotherapy and is not billed as such. Biofeedback providers should check with the ethical codes of regulatory and professional agencies in their local region for the appropriate diagnostic code. Suggested CPT codes are provided on page 81.

For what diagnoses is biofeedback a treatment of choice?

Biofeedback therapy is a treatment of choice for certain types of fecal incontinence and urinary incontinence. It is a treatment of choice for tension-type headaches, migraine headaches, other chronic pain syndromes, irritable bowel syndrome, essential hypertension, asthma, Raynaud's disease/syndrome, and a variety of neuromuscular disorders, especially during rehabilitation. EEG biofeedback therapy is a treatment of choice for certain selected patients with epilepsy or attention deficit disorder.

What treatments should be tried prior to biofeedback?

We recommend a behavioral "step-care" approach to treatment prior to biofeedback therapy. This approach would include, for example, diet change, exercise, or environmental restructuring. If a disorder is life-threatening, it must be stabilized before biofeedback therapy is initiated. For example, the treatment of essential hypertension might include medication to bring blood pressure down and to maintain it at a safe level until the person develops self-regulation skills with biofeedback therapy. Also, when a person has psychological issues that interfere with learning self-regulation or with changing or eliminating a symptom, then psychotherapy may be needed before biofeedback therapy can be effective.

Please list any suggestions or ideas on why extended periods of time longer than 15 to 20 sessions might be necessary?

Many factors may contribute to an extended period of biofeedback therapy. Examples are the number and chronicity of symptoms, the number and type of additional medical or psychological diagnoses, the amount and type of medication and psychosocial factors such as motivation, multiplicity of life stressors, secondary gains, and intrafamily dynamics. Chronic pain of long duration, seizure disorders, and neuromuscular rehabilitation customarily take longer than 20 sessions.

Where can I get more information about biofeedback?

The Association for Applied Psychophysiology and Biofeedback has a Website with further up-to-date information at www.aapb.org.

Conclusion

The diversity of applications of biofeedback therapies reflects the commonality of underlying factors in many behavioral and psychophysiologic disorders such as emotional and cognitive stressors, the stress response, and failure to maintain healthy homeostasis. That biofeedback therapies are effective with a variety of symptoms is no mystery. Theoretically, any physiological process that responds to stress will respond to stress reduction. Biofeedback therapies incorporate a solid core of behavioral, cognitive, and physiological self-regulation techniques that are used by the patient to alleviate the underlying causes of the disorder. Biofeedback therapies have broad applications because they give the patient skills that facilitate the natural tendency of the body to return to healthy homeostasis as well as skills for enhanced well-being and prevention of disease.

Treatment Codes

(compiled by Robert P. Whitehouse, Ed.D., and Ronald L. Rosenthal, Ph.D.)

The treatment codes for biofeedback therapy used by practitioners and third party payors in the United States are established by the Current Procedural Treatment (CPT) Code committee of the American Medical Association.

Health and Behavior Assessment/Intervention: These codes describe services to patients who present with established illnesses or symptoms, who are not diagnosed with mental illnesses, and may benefit from evaluations that focus on the biopsychosocial factors related to the patient's physical health status.	
96150	Health & behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment
96151	Re-assessment
96152	Health & behavioral intervention, each 15 minutes, face-to-face; individual
96153	Health & behavioral intervention, each 15 minutes, face-to-face; group (2 or more patients)
96154	Health & behavioral intervention, each 15 minutes, face-to-face; family (with the patient present)
96155	Health & behavioral intervention, each 15 minutes, face-to-face; family (without the patient present)
Biofeedback	
90901	**Biofeedback training by any modality**
90911	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry
Psychiatric Therapeutic Procedures	
90875	Individual psychophysiology therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); approximately 20-30 minutes
90876	Individual psychophysiology therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); approximately 40-45 minutes
Other codes that might be useable, if approved by third party payors	
94010	Spirometry, including graphic record, total & timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation
94400	Breathing response to CO_2 (CO_2 response curve)
96002	Dynamic surface electromyography, during walking or other functional activities, 1-12 muscles
95957	Digital analysis of electroencephalogram (EEG) (e.g., for epileptic spike analysis)

90806	Individual psychotherapy. Insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 45-50 minutes, face-to-face with the patient
Neurofeedback Evaluation Codes	
95816	Digital EEG Recording
95957	Digital EEG Analysis
99090	Reference EEG database access
Alternative Codes for Biofeedback	
97112	Neuromuscular reeducation of movement, balance, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
97532	Development of cognitive skills to improve attention, memory, problem solving (includes compensatory training) (Formerly 97770)

ABC CAM Codes

Five character codes have been developed by the Alternative Link for more than 4,000 procedures "that describe the patient encounter with nursing, complementary and alternative medicine (CAM), and indigenous medicine services. Laws governing such providers differ by state and are available at 877-621-LINK.

CDAAP	Biofeedback, counseling, mental health services, practice specialties. Assisting the client to modify a body function using feedback from instrumentation.