Extract of Clinical Evaluation

CyberScan & CyberScan-Software

AussiMed Ltd.

1 Purpose

The purpose of this clinical evaluation is to assess safety and effectiveness of the CyberScan as a biofeedback system as required by the European Directive 93/42/EEC (Annex X, section 1.1c) and the German Medical Device Act (Paragraph 19). The assessment of the clinical data has been carried out following the guidance documents MedDev 2.7.1. "Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies".

2 Device Description

Aussimed's CyberScan is an electronic system providing visual and auditory signals corresponding to the patient's physiological status. It detects changes in physiological functions that are outside of normal awareness, amplifies these signals and provides this as feedback to the patient with the intention of promoting the healing process. Examples of use are pain reduction, muscle relaxation, stress reduction and reduction of allergic reactions

3 Intended Use

Aussimed's CyberScan in intended to be used as a biofeedback system.

4 Clinical Data

Generally the benefit of a medical technology can be evaluated by conducting an evidence based technology assessment of its safety, effectiveness and clinical benefit. Such an assessment involves a comprehensive search and review of relevant, published, peer-reviewed literature and / or clinical investigations.

Accessories for a biofeedback system does not require a clinical study to establish data on performance and safety or side effects as these products have been established for a number of years.

4.1 Literature Search

For this report a comprehensive literature search has been conducted by using the following database:

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xxxx comprises more than 20 million citations for biomedical literature from MEDLINE, life science journals, and online books. PubMed citations and abstracts include the fields of medicine, nursing, dentistry, veterinary medicine, the health care system, and preclinical sciences. PubMed also provides access to additional relevant Web sites and links to the other NCBI molecular biology resources.

xxxx is a free resource that is developed and maintained by the National Center for Biotechnology Information (NCBI), at the U.S. National Library of Medicine (NLM), located at the National Institutes of Health (NIH).

Relevant literature was identified from multiple searches between July 25 and August 15, 2011.

The following search query has been applied:

"Biofeedback, Psychology"[MAJR] AND Meta-Analysis[ptyp]

A total of 32 citations were found.

4.2 Results of the Literature Search

The literature (abstracts) has been screened with the aim to identify articles / reports addressing safety and / or clinical benefit as well as side effects.

Author	Journal	Title	Evaluation
Angoules, Antonios G.; Balakatounis, Konstantine C.; Panagiotopoulou, Kalomoira A.; Mavrogenis, Andreas F.; Mitsiokapa, Evanthia A.; Papagelopoulos, Panayiotis J.	Orthopedics (Orthopedics)	Effectiveness of electromyographic biofeedback in the treatment of musculoskeletal pain	Electromyographic biofeedback is a therapeutic modality used along with other interventions in the treatment of pain. Electromyographic biofeedback is comparable to cognitive behavioral treatment and relaxation techniques. When added to an exercise program in patients with patellofemoral pain or acute sciatic pain, no further pain reduction is achieved. Electromyographic biofeedback promotes active participation and thus may motivate patients to adopt an active role in establishing and reaching goals in rehabilitation. Further research is required to investigate its effect on musculoskeletal pain.
Arns, Martijn; Ridder, Sabine de; Strehl, Ute; Breteler, Marinus; Coenen, Anton	Clin EEG Neurosci (Clinical EEG and neuroscience : official journal of the EEG and Clinical Neuroscience Society (ENCS))	Efficacy of neurofeedback treatment in ADHD: the effects on inattention, impulsivity and hyperactivity: a meta-analysis	We conclude that neurofeedback treatment for ADHD can be considered "Efficacious and Specific" (Level 5) with a large ES for inattention and impulsivity and a medium ES for hyperactivity.
Astin, John A.; Beckner, William; Soeken, Karen; Hochberg, Marc C.; Berman, Brian	Arthritis Rheum (Arthritis and rheumatism)	Psychological interventions for rheumatoid arthritis: a meta-analysis of randomized controlled trials	Despite some methodologic flaws in the literature, psychological interventions may be important adjunctive therapies in the medical management of rheumatoid arthritis.
Barclay-Goddard, R.; Stevenson, T.; Poluha, W.; Moffatt, M. E. K.; Taback, S. P.	Cochrane Database Syst Rev (Cochrane database of systematic reviews (Online))	Force platform feedback for standing balance training after stroke	Force platform feedback (visual or auditory) improved stance symmetry but not sway in standing, clinical balance outcomes or measures of independence.
Bize, R.; Burnand, B.; Mueller, Y.; Cornuz, J.	Cochrane Database Syst Rev (Cochrane database of systematic reviews (Online))	Biomedical risk assessment as an aid for smoking cessation	Due to the scarcity of evidence of sufficient quality, we can make no definitive statements about the effectiveness of biomedical risk assessment as an aid for smoking cessation.
Bize, Raphaël; Burnand, Bernard; Mueller, Yolanda; Rège Walther, Myriam; Cornuz, Jacques	Cochrane Database Syst Rev (Cochrane database of systematic reviews (Online))	Biomedical risk assessment as an aid for smoking cessation	There is little evidence about the effects of most types of biomedical tests for risk assessment. Spirometry combined with an interpretation of the results in terms of 'lung age' had a significant effect in a single good quality trial. Mixed quality evidence does not support the hypothesis that other types of biomedical risk assessment increase smoking cessation in comparison to standard treatment. Only two pairs of studies were similar enough in term of recruitment, setting, and intervention to allow meta-analysis.
Coulter, Ian D.; Favreau, Joya T.; Hardy, Mary L.; Morton, Sally C.; Roth, Elizabeth A.; Shekelle, Paul	Altern Ther Health Med (Alternative therapies in health and medicine)	Biofeedback interventions for gastrointestinal conditions: a systematic review	The evidence is insufficient to support the efficacy of biofeedback for these gastrointestinal conditions.

Author	Journal	Title	Evaluation
Crider, A. B.; Glaros, A. G.	J Orofac Pain (Journal of orofacial pain)	A meta-analysis of EMG biofeedback treatment of temporomandibular disorders	Although limited in extent, the available data support the efficacy of EMG biofeedback treatments for TMD.
Crider, Andrew; Glaros, Alan G.; Gevirtz, Richard N.	Appl Psychophysiol Biofeedback (Applied psychophysiology and biofeedback)	Efficacy of biofeedback-based treatments for temporomandibular disorders	We conclude that SEMG training with adjunctive CBT is an efficacious treatment for temporomandibular disorders and that both SEMG training as the sole intervention and BART are probably efficacious treatments. We discuss guidelines for designing and reporting research in this area and suggest possible directions for future studies.
Fahrion, S. L.	Prim. Care (Primary care)	Hypertension and biofeedback	Treatments may be appropriate both in early hypertension and in instances of more advanced disease process. Current national policy stipulates that, after hypertension is controlled by medication for 1 year, medications should be gradually withdrawn and an attempt made to control blood pressure through nonpharmacologic means.
Glanz, M.; Klawansky, S.; Stason, W.; Berkey, C.; Shah, N.; Phan, H.; Chalmers, T. C.	Arch Phys Med Rehabil (Archives of physical medicine and rehabilitation)	Biofeedback therapy in poststroke rehabilitation: a meta-analysis of the randomized controlled trials	Results of pooling available randomized control trials do not support the efficacy of biofeedback in restoring the range of motion of hemiparetic joints.
Herderschee, Roselien; Hay-Smith, E. Jean C.; Herbison, G. Peter; Roovers, Jan Paul; Heineman, Maas Jan	Cochrane Database Syst Rev (Cochrane database of systematic reviews (Online))	Feedback or biofeedback to augment pelvic floor muscle training for urinary incontinence in women	Feedback or biofeedback may provide benefit in addition to pelvic floor muscle training in women with urinary incontinence. However, further research is needed to differentiate whether it is the feedback or biofeedback that causes the beneficial effect or some other difference between the trial arms (such as more contact with health professionals).
Heymen, S.; Jones, K. R.; Ringel, Y.; Scarlett, Y.; Whitehead, W. E.	Dis. Colon Rectum (Diseases of the colon and rectum)	Biofeedback treatment of fecal incontinence: a critical review	Although most studies report positive results using biofeedback to treat fecal incontinence, quality research is lacking. Recommendations are made for future investigations to 1) improve experimental design, 2) include long term follow-up data, and 3) to use an adequate sample size that allows for meaningful analysis.
Heymen, Steve; Jones, Kenneth R.; Scarlett, Yolanda; Whitehead, William E.	Dis. Colon Rectum (Diseases of the colon and rectum)	Biofeedback treatment of constipation: a critical review	Most studies report positive results using biofeedback to treat constipation, quality research is lacking.
Hollands, Gareth J.; Hankins, Matthew; Marteau, Theresa M.	Cochrane Database Syst Rev (Cochrane database of systematic reviews (Online))	Visual feedback of individuals' medical imaging results for changing health behaviour	Due to the limited nature of the available evidence and the mixed results that were found, no strong statements can be made about the effectiveness of communicating medical imaging results to change health behaviour. We suggest,

Author	Journal	Title	Evaluation
			however, that targeted interventions using medical imaging technologies may be effective in certain contexts, or as applied to certain behaviours, but that this should be considered on an intervention by intervention basis, and not assumed as a general principle.
Holroyd, K. A.; Penzien, D. B.	Pain (Pain)	Pharmacological versus non-pharmacological prophylaxis of recurrent migraine headache: a meta-analytic review of clinical trials	Meta-analysis revealed substantial empirical support for the effectiveness of both propranolol and relaxation/biofeedback training, but revealed no support for the contention that the two treatments differ in effectiveness. These results suggest that greater attention should be paid to determining the relative costs and benefits of widely used pharmacological and non-pharmacological treatments.
MacDonald, Ewen N.; Purcell, David W.; Munhall, Kevin G.	J. Acoust. Soc. Am (The Journal of the Acoustical Society of America)	Probing the independence of formant control using altered auditory feedback	Two auditory feedback perturbation experiments were conducted to examine the nature of control of the first two formants in vowels. A moderate correlation was found between individual compensations suggesting that the control is processed in a common manner at some level. While a wide range of individual compensation magnitudes were observed, no significant correlations were found between individuals' compensations and vowel space differences.
Monastra, Vincent J.; Lynn, Steven; Linden, Michael; Lubar, Joel F.; Gruzelier, John; LaVaque, Theodore J.	Appl Psychophysiol Biofeedback (Applied psychophysiology and biofeedback)	Electroencephalographic biofeedback in the treatment of attention-deficit/hyperactivity disorder	Although significant clinical improvement was reported in approximately 75% of the patients in each of the published research studies, additional randomized, controlled group studies are needed in order to provide a better estimate of the percentage of patients with ADHD who will demonstrate such gains in clinical practice.
Moreland, J.; Thomson, M. A.	Phys Ther (Physical therapy)	Efficacy of electromyographic biofeedback compared with conventional physical therapy for upper-extremity function in patients following stroke: a research overview and meta-analysis	The results do not conclusively indicate superiority of either form of therapy. Although there is a chance of Type II error, the estimated size of the effect is small. Given this estimate of little or no difference, therapists need to consider cost, ease of application, and patient preference when selecting these therapies.
Moreland, J. D.; Thomson, M. A.; Fuoco, A. R.	Arch Phys Med Rehabil (Archives of physical medicine and rehabilitation)	Electromyographic biofeedback to improve lower extremity function after stroke: a meta-analysis	The results indicate that EMG biofeedback is superior to conventional therapy alone for improving ankle dorsiflexion muscle strength.

Author	Journal	Title	Evaluation
Nakao, Mutsuhiro; Yano, Eiji; Nomura, Shinobu; Kuboki, Tomifusa	Hypertens. Res (Hypertension research : official journal of the Japanese Society of Hypertension)	Blood pressure-lowering effects of biofeedback treatment in hypertension: a meta-analysis of randomized controlled trials	The results suggested that biofeedback was more effective in reducing blood pressure in patients with essential hypertension than no intervention. However, the treatment was only found to be superior to sham or non-specific behavioral intervention when combined with other relaxation techniques. Further studies will be needed to determine whether biofeedback itself has an antihypertensive effect beyond the general relaxation response.
Nestoriuc, Yvonne; Martin, Alexandra	Pain (Pain)	Efficacy of biofeedback for migraine: a meta-analysis	Biofeedback (BFB) was more effective than control conditions. Frequency of migraine attacks and perceived self-efficacy demonstrated the strongest improvements. Blood-volume-pulse feedback yielded higher effect sizes than peripheral skin temperature feedback and electromyography feedback. Moderator analyses revealed BFB in combination with home training to be more effective than therapies without home training.
Nestoriuc, Yvonne; Martin, Alexandra; Rief, Winfried; Andrasik, Frank	Appl Psychophysiol Biofeedback (Applied psychophysiology and biofeedback)	Biofeedback treatment for headache disorders: a comprehensive efficacy review	Biofeedback was more effective than waiting list and headache monitoring conditions in all cases, while electromyographic feedback for tension-type headache showed additional significant effects over placebo and relaxation therapies. Levels of efficacy (migraine: efficacious, level 4; tension-type headache: efficacious and specific, level 5) and recommendations for future research are provided.
Nestoriuc, Yvonne; Rief, Winfried; Martin, Alexandra	J Consult Clin Psychol (Journal of consulting and clinical psychology)	Meta-analysis of biofeedback for tension-type headache: efficacy, specificity, and treatment moderators	Biofeedback was more effective than headache monitoring, placebo, and relaxation therapies. The strongest improvements resulted for frequency of headache episodes. Further significant effects were observed for muscle tension, self-efficacy, symptoms of anxiety, depression, and analgesic medication. Moderator analyses revealed biofeedback in combination with relaxation to be the most effective treatment modality; effects were particularly large in children and adolescents. In intention-to-treat and publication-bias analyses, the consistency of these findings was demonstrated. It is concluded that biofeedback constitutes an evidence-based treatment option for tension-type headache.

Author	Journal	Title	Evaluation
Pollock, A.; Baer, G.; Pomeroy, V.; Langhorne, P.	Cochrane Database Syst Rev (Cochrane database of systematic reviews (Online))	Physiotherapy treatment approaches for the recovery of postural control and lower limb function following stroke	There is evidence that physiotherapy intervention, using a mix of components from different approaches, is significantly more effective than no treatment or placebo control in the recovery of functional independence following stroke. There is insufficient evidence to conclude that any one physiotherapy approach is more effective in promoting recovery of lower limb function or postural control following stroke than any other approach. We recommend that future research should concentrate on investigating the effectiveness of clearly described individual techniques and task-specific treatments, regardless of their historical or philsophical origin.
Sarafino, E. P.; Goehring, P.	Ann Behav Med (Annals of behavioral medicine : a publication of the Society of Behavioral Medicine)	Age comparisons in acquiring biofeedback control and success in reducing headache pain	Results showed that both children and adults reported substantial improvements in headache activity with TBF and EMG biofeedback treatment (Ms ranged from 34% to 81%), but children showed significantly greater improvement than adults. No age differences were found in the acquisition of biofeedback control. Further analyses revealed two additional findings. First, biofeedback control and headache improvement were strongly correlated. Second, headache activity continued to decrease in the weeks following treatment, and this decrease was significantly greater for children than adults.
Schleenbaker, R. E.; Mainous, A. G.	Arch Phys Med Rehabil (Archives of physical medicine and rehabilitation)	Electromyographic biofeedback for neuromuscular reeducation in the hemiplegic stroke patient: a meta-analysis	These results indicate that EMG-BF is an effective tool for neuromuscular reeducation in the hemiplegic stroke patient.
Stevens, Sean E.; Hynan, Michael T.; Allen, Mike; Braun, Michelle M.; McCart, Michael R.	Psychol Rep (Psychological reports)	Are complex psychotherapies more effective than biofeedback, progressive muscle relaxation, or both? A meta-analysis	Consistent with hypotheses, more complex treatments provided a small, significant improvement over biofeedback and progressive muscle relaxation. A subset of the more complex behavioral treatments accounted for most of this small incremental effectiveness of more complex treatments.
Tan, Gabriel; Thornby, John; Hammond, D. Corydon; Strehl, Ute; Canady, Brittany; Arnemann, Kelly; Kaiser, David A.	Clin EEG Neurosci (Clinical EEG and neuroscience : official journal of the EEG and Clinical Neuroscience Society (ENCS))	Meta-analysis of EEG biofeedback in treating epilepsy	Based on this meta-analysis, EEG operant conditioning was found to produce a significant reduction on seizure frequency. This finding is especially noteworthy given the patient group, individuals who had been unable to control their seizures with medical treatment.

Author	Journal	Title	Evaluation
Weatherall, M.	BJU Int (BJU international)	Biofeedback or pelvic floor muscle exercises for female genuine stress incontinence: a meta-analysis of trials identified in a systematic review	Biofeedback may be an important adjunct to pelvic floor muscle exercises alone in the treatment of female genuine stress urinary incontinence. A quantitative statistical analysis of the studies identified leads to different conclusions from those in the systematic review.
Woodford, H.; Price, C.	Cochrane Database Syst Rev (Cochrane database of systematic reviews (Online))	EMG biofeedback for the recovery of motor function after stroke	Despite evidence from a small number of individual studies to suggest that EMG-BFB 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. Overall the results are limited because the trials were small, generally poorly designed and utilised varying outcome measures.
Yucha, C. B.; Clark, L.; Smith, M.; Uris, P.; LaFleur, B.; Duval, S.	Appl Nurs Res (Applied nursing research : ANR)	The effect of biofeedback in hypertension	Biofeedback (with related cognitive therapy and relaxation training) showed a significantly greater reduction in both systolic blood pressure (6.7 mm Hg) and diastolic blood pressure (4.8 mm Hg) when compared with inactive control treatments.

The retrieved literature confirms the benefit of biofeedback and the use of biofeedback systems like Aussimed's CyberScan.

The Association for Applied Psychophysiology and Biofeedback (AAPB) created an efficacy series to summarize the current state of knowledge in the field of biofeedback. Hereafter an extract of this report will be presented.

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.

4.2.1 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).

4.2.2 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 (autonomie 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.

4.2.3 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).

4.2.4 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-1 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 AB AB 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 Autonomie 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 Autonomie 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 collègues 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 (IV A). 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 TO VA 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 TO VA 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 S MR (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 opérant 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.

4.2.5 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 opérant conditioning-only treatment. Newton-John, Spence, and Schotte (1995) compared cognitive therapy with EMG biofeedback in chronic back patients and obtained similar beneficial effects with both as compared to a wait-list control group. Effects persisted at a six-month follow up. Humphreys and Gevirtz (2000) reported a study of recurrent abdominal pain in 64 children and teenagers that used thermal biofeedback alone or in combination with cognitive-behavioral treatment. Results for pain relief were significantly above an inactive treatment (fiber-only) control group.

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

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

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

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

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

A series of articles reported on the treatment of 52 consecutive patients with chronic myofascial pain who had failed to respond to physical, chiropractic, medical, surgical, and pharmacologie 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.

Böhm-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.

4.2.6 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.

4.2.7 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).

4.2.8 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 étal. 2006).

4.2.9 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.

4.2.10 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, Lai, & 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).

4.2.11 Motion Sickness Level 4: Efficacious

The rationale for biofeedback relies on an assumed correlation between ability to control the autonomie 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.

4.2.12 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.

4.2.13 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 & Glares, 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, Glares, 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.

4.2.14 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 (Bo, 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).

4.2.15 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).

4.2.16 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.

5 Risk-Benefit Evaluation

The intended use for Aussimed's CyberScan was reviewed on the basis of available literature.

On the basis of the technical documentation and the available scientific literature reviewed in course of this clinical evaluation, it can be concluded that the CyberScan is a state-of-the-art product and intended intended to be used as a biofeedback system.

It can be concluded that the benefits that obtained by the patient through the use of the CyberScan biofeedback system outweigh the risks associated with its use.

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