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Efficacy of Biofeedback-Based Treatments for Temporomandibular Disorders

Andrew Crider,[1,4] Alan G. Glaros,[2] and Richard N. Gevirtz[3]

Bibliographic searches identified 14 controlled and uncontrolled outcome evaluations of biofeedback-based treatments for temporomandibular disorders published since 1978. This literature includes two randomized controlled trials (RCTs) of each 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). A detailed review of these six RCTs, supplemented with information from non-RCT findings, was conducted to determine the extent to which each type of intervention met treatment efficacy criteria promulgated by the Association for Applied Psychophysiology and Biofeedback (AAPB). 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.

KEY WORDS: temporomandibular disorders; biofeedback; electromyography; treatment efficacy.

Temporomandibular disorders (TMDs) are a heterogeneous group of problems characterized by orofacial pain typically located in the preauricular area, the muscles of mastication, or the temporomandibular joint (Glaros & Glass, 1993). However, patients may also report other facial pain, headache, and a variety of neck, shoulder, upper back, and lower back pain (McNeill, Mohl, Rugh, & Tanaka, 1990). In addition, TMD patients may present with a variety of jaw problems other than pain, including difficulty in maximal opening of the jaw, locking in the open or closed position, and clicking, popping, or grating sounds.

TMD involves the hard and soft tissues of the temporomandibular joint and the muscles of mastication. Many conditions can adversely affect the temporomandibular joint. Degenerative disorders can lead to erosion and flattening of the condyle or form undesirable growths called bone spurs. Both conditions may result in decreased function, pain, or both. Difficulty in opening or closing may be caused by an abnormal position of the articular disc. Temporary

[1]Department of Psychology, Williams College, Williamstown, Massachusetts.
[2]Kansas City University of Medicine and Biosciences, Kansas City, Missouri.
[3]California School of Professional Psychology, Alliant International University, San Diego, California.
[4]Address all correspondence to Andrew Crider, Department of Psychology, Williams College, Williamstown, Massachusetts; e-mail: acrider@williams.edu.

displacement of the disc from its normal position during movement can also cause clicking or popping noises. However, joint noises in the absence of pain, limitation of movement, or changes in opening pattern do not warrant treatment (Glaros & Glass 1993; Okeson, 1998).

Many cases of TMD involve pain in the muscles of mastication not involving any disturbance or pathological deformation of the temporomandibular joint (Fricton & Shiffman, 1995). The most important muscles for jaw function are the masseter, temporalis, and medial and lateral pterygoid muscles. The masseter and temporalis muscles elevate the mandible during mastication, and the temporalis muscles also help to position the mandible. The masseter and temporalis muscles can be palpated by placing the fingers directly above the angle of the mandible and on the temples, respectively, while the patient clenches. The lateral (external) pterygoid muscles protrude and depress the mandible, and aid lateral jaw movement. The medial (internal) pterygoids close the jaw, produce lateral movements to the opposite side, and aid in protrusion. Both of these muscles can be palpated intraorally, although distinguishing them may be difficult.

Dental and other health professionals recognize psychological and emotional factors as playing key roles in the etiology, maintenance, and treatment of TMD (Dworkin & LeResche, 1992). An emerging biopsychosocial approach (Greene & Laskin, 2000) creates a role for biofeedback clinicians as part of the treatment team for TMD. Contemporary standards of care for TMD emphasize conservative and reversible treatments such as patient education, medication, intraoral splints, and behavioral interventions. Among the latter, surface electromyographic (SEMG) biofeedback, relaxation training, and cognitive-behavioral techniques, alone or in combination, have been used to treat TMD for nearly three decades.

Crider and Glaros (1999) reviewed 13 controlled and uncontrolled outcome studies of biofeedback-based interventions for TMD, concluding that a variety of biofeedback interventions had collectively demonstrated treatment efficacy. Patients treated with biofeedback methods showed successful posttreatment outcomes in approximately 70% of cases, with no apparent deterioration at follow-up assessments. The present review differs from Crider and Glaros (1999) by distinguishing among three different biofeedback-based treatment protocols for TMD and by focusing primarily on randomized controlled trials (RCTs) as an evidential base. Our aim is to evaluate the treatment efficacy of the three protocols in terms of published standards for determining the methodological adequacy of biofeedback outcome studies (Efficacy Task Force, 2002).

REVIEW OF RANDOMIZED CONTROLLED TRIALS

Method

Database searches of MEDLINE for 1966 through 2004 and PsycINFO for 1990 through 2004 were conducted by crossing the terms *temporomandibular* and *TMD* with *biofeedback*. Bibliographies from the retrieved articles and from commentaries and reviews of behavioral interventions for TMD in the authors' possession were also searched. The search produced a total of six RCTs in which a biofeedback intervention was contrasted with a no-treatment, a sham treatment, or a plausible alternative treatment condition. By sham treatment we mean any placebo condition designed to control for nonspecifc treatment effects; by plausible alternative treatment we refer to a theoretically reasonable intervention that nevertheless lacks sufficient controlled evidence to be considered efficacious for TMD (e.g., TENS, ultrasound). The search also produced one nonrandomized controlled trial, four trials in which a biofeedback therapy was contrasted with an alternative active treatment (e.g., an intraoral splint), and three uncontrolled trials. Although the present review focuses on the methodologically superior RCTs, evidence using other designs is cited where appropriate.

All statements in the following summaries regarding the presence or absence of differences between experimental conditions reflect reports of statistical tests in the study under review. Any citation of a specific statistical test reflects the authors' post-hoc analysis of data presented in the original report.

Study Protocols

Each of the six retrieved RCTs was categorized into one of three forms of biofeedback-based treatment. These three procedures are not necessarily specific to the treatment of TMD but reflect more general biofeedback strategies in widespread use for a variety of medical and psychological conditions.

SEMG Biofeedback Training

This procedure attributes at least some TMD symptoms to dysfunctional activity of the masticatory muscles. The goal of SEMG biofeedback training is therefore to restore normal muscle function using a variety of techniques. Surface electrodes are typically placed over the masseter, in either unilateral or bilateral configurations. However, anterior temporalis or wide frontal placements have also been employed, alone or in combination with masseter placements. SEMG biofeedback training may include such techniques as muscle tension discrimination to increase proprioceptive awareness; shaping of increasingly lower levels of muscle tension to achieve maximal relaxation of the muscle; deactivation training to promote rapid recovery from contraction; and home practice of acquired skills to insure generalization to the everyday environment (Kasman, Cram, & Wolf, 1997).

SEMG Biofeedback Training with Adjunctive Cognitive-Behavioral Therapy

This approach combines SEMG training with cognitive-behavioral therapy (CBT) techniques. The assumption underlying this approach is that negative affective states secondary to impaired coping with stressful situations can cause or exacerbate TMD symptoms. Therefore, biofeedback training with adjunctive CBT considerably broadens both the conceptualization of and methods available for treating TMD. CBT may include various forms of relaxation training such a progressive muscle relaxation, autogenic training, and guided imagery, as well as different CBT techniques such as stressor identification, analysis of dysfunctional thoughts and beliefs, and the development of more effective cognitive and behavioral coping methods. CBT is not a standardized treatment protocol; rather it represents a general therapeutic orientation that draws on a variety of possible interventions as dictated by the goals of particular investigations.

Biofeedback-Assisted Relaxation Training

Unlike the foregoing procedures, biofeedback-assisted relaxation training (BART) does not involve targeted retraining of the masticatory muscles. Rather, the focus is on inculcating maximally effective systemic relaxation with the use of biofeedback monitoring. BART is a means of inculcating low arousal and is widely used in the treatment of stress-related disorders, of which TMD is assumed to be an example. In BART, physiological information is fed back to the patient as relaxation training progresses in order to monitor the depth of relaxation, as well as to identify maximally effective components of the training. SEMG feedback from facial sites, particularly from wide frontal or masseter placements, may be employed. However, indices of sympathetic nervous system activation, such as hand temperature or electrodermal activity, are also conventional modalities.

Study Summaries

SEMG Biofeedback Training

Dalen, Ellertsen, Espelid, and Gronningsaeter (1986). Nineteen TMD patients diagnosed with myofascial pain dysfunction syndrome were randomly assigned to biofeedback training (BFB; $n = 10$) or no treatment control ($n = 9$) groups. The referral source and patient population were not specified. BFB patients received SEMG feedback from unspecified frontalis and masseter muscle sites twice weekly for 13-min sessions over a 4-week period. The relationship between muscle contraction and SEMG activity was demonstrated to patients, followed by an instruction to reduce SEMG levels. By design, patients received no further instructions or training suggestions.

Assessments of TMJ function, pain duration on the previous day, and pain intensity during the previous hour were made at pretreatment, posttreatment, and at 3- and 6-month follow-ups. Both the BFB and the control group showed equivalent pre- to posttreatment decreases on all measures. The BFB group continued to show reductions on the two pain indices at 3 and 6 months, but between-group differences were not significant.

Comment: This study was designed to determine the efficacy of SEMG feedback for TMD unconfounded with adjunctive relaxation techniques. However, the procedure also failed to provide more than minimal guidance to patients on therapeutic strategies of muscle retraining. Other problems included lapses in reporting procedural details, very brief treatment sessions, and very limited sampling of pain reports.

Dohrmann and Laskin (1978). Twenty-four consecutive patients seen in a TMD research center with a diagnosis of myofascial pain dysfunction syndrome were randomly allocated to BFB training ($n = 16$) or sham treatment ($n = 8$) groups. The BFB intervention consisted of SEMG feedback from the most affected masseter with guided shaping of increasingly lower muscle tension. Sensors were also attached to the most affected masseter of the control patients, who were told the electrodes delivered a subliminal electrical current that operated to reduce masseter tension. Patients in both groups were instructed to avoid clenching or grinding of the teeth and to practice jaw relaxation between sessions. All patients were offered twice weekly 30-min treatment sessions over a 6-week period, although actual attendance varied between 9 and 12 sessions. Assessments of self-reported pain, pain on palpation of the masticatory muscles, occlusal opening, and joint sounds were made at the beginning of each session. Prior to and immediately following the end of treatment, each patient was also evaluated by a clinician, blind to treatment condition, who rated outcomes as either successful, partially successful, or failure.

Assessments at each patient's ninth session produced no differences between BFB and control groups in the proportion of patients with muscle palpation pain, joint sounds, or limitations of occlusal opening. However, a significantly larger proportion of BFB than control patients reported being pain free at the ninth session ($z = 2.00$, $p < .03$). In addition, the end of treatment clinical evaluation found that 100% of the BFB patients, compared with 50% of controls, achieved fully or partially successful outcomes ($z = 3.12$, $p < .01$).

Comment: This initial RCT of the efficacy of SEMG feedback training for TMD is notable for the use of a sham treatment control and a blind evaluation of global improvement. The measurement of more specific outcomes would have benefited from the greater use of continuous measures and associated parametric tests instead of the less sensitive dichotomous assessments typically employed. Nevertheless, the results clearly indicated that SEMG biofeedback training with minimal additional intervention was superior to a sham control for both self-reported pain and global improvement.

SEMG Biofeedback Training with Adjunctive Cognitive-Behavioral Therapy

Crockett, Foreman, Alden, and Blasberg (1986). Twenty-eight patients, 21 of whom completed treatment, were randomly allocated to biofeedback training with adjunctive relaxation training (BFB + RT)), intraoral splinting with physical therapy (IS + PT), or transcutaneous electrical nerve stimulation (TENS) groups. The participants were selected from consecutive patients seen in an oral medicine clinic who showed pain complaints of at least 6 months duration, pain on palpation of the masticatory muscles, and limitations of jaw movement. All groups received eight weekly 1-h treatment sessions combined with recommendations for 30 min of daily homework. The BFB + RT intervention consisted of feedback of bilateral masseter SEMG activity aimed at reduction of muscle tension both with and in the absence of feedback, with additional training in maintaining low tension under problem solving stress. Daily home practice of a tape-recorded progressive muscle relaxation program was also prescribed. The IS + PT intervention incorporated the use of an intraoral splint with weekly physical therapy sessions oriented to the masticatory system. Patients were also instructed to practice jaw exercises daily between treatment sessions. The TENS intervention employed weekly application of subthreshold electrical stimulation from electrodes placed bilaterally over the masseters and prescription of daily rest periods between sessions. The TENS intervention was conceptualized as a minimal treatment package to be contrasted with the more active BFB + RT and IS + PT interventions. Treatment was standardized for all three interventions by means of detailed treatment manuals.

Pre- and posttreatment assessments were made of limitations of opening and muscle palpation pain. Daily self-reports of pain intensity and pain frequency were averaged over a 3-week periods at the beginning and during the last 3 weeks of treatment. Results showed an overall pre- to posttreatment effect for palpation pain, but the change was not significant in the TENS group ($t = 1.10$). Treatment effects were also shown for pain intensity and pain frequency, with the BFB + RT group showing a greater reduction in pain intensity than the other two groups. Only the IS + PT group showed a significant reduction in pain frequency from pre- to posttreatment. However, the BFB + RT group reported less frequent pain at posttreatment than the TENS group ($t = 2.51$, $p < .05$). No treatment effects were found for opening limitations in any group. Finally, treatment credibility ratings revealed no differences among groups in expectations for success prior to treatment nor in therapist quality following treatment.

Comment: This well designed and executed study lacked statistical power to detect small differences among treatments. Nevertheless, the results differentiated BFB + RT from the TENS intervention on palpation pain and on self-reported pain intensity and frequency. The BFB + RT and IS + PT interventions showed no consistent differences across outcome measures. The TENS condition can be regarded as a plausible alternative treatment or a sham treatment. Under either definition, the results indicated that SEMG feedback training with adjunctive relaxation training was superior to this alternative intervention.

Turk, Zaki, and Rudy (1993). Eighty patients were randomly assigned to one of three conditions: SEMG biofeedback training with adjunctive CBT (BFB + CBT; $n = 30$), intraoral splint (IS; $n = 30$), or wait-list control ($n = 20$). The sample was selected from consecutive referrals to a TMD clinic who showed pain and tenderness of the muscles of mastication and limited mandibular movements of at least 2 months' duration. The BFB + CBT intervention consisted of six weekly 1-h sessions of bilateral masseter SEMG feedback aimed at reduction of muscle tension both with and in the absence of feedback. In addition, patients received training in cognitive methods for controlling pain, stress management counseling, and home relaxation practice. Patients in the IS group were instructed to wear a full-arch intraoral appliance at all times for the first 6 weeks of treatment, which also included weekly appliance monitoring and instruction in oral habits. All three groups were assessed at pre- and posttreatment on two depression measures, a measure of self-reported pain severity, a measure of palpation pain severity, and ratings of treatment credibility. Fifty-one patients were available for assessment at a 6-month follow-up.

Treatment effects were investigated by means of multivariate analyses that considered the two pain severity measures conjointly and the two depression measures conjointly. Both active treatments showed significant pre- to posttreatment reductions in pain severity, but the control group did not. An analysis of posttreatment to follow-up changes showed a significant continuing reduction in pain severity for the BFB + CBT group. The two active treatment groups showed equivalent levels of pain severity at follow-up. Both active treatment groups also showed significant reductions in depression from pre- to posttreatment, but the control patients did not. The BFB + CBT group maintained its reduction in depression at follow-up, but the IS group relapsed to pretreatment levels. Credibility ratings increased from pre- to posttreatment with no significant differences between the two active treatment groups.

Comment: This exemplary study found BFB + CBT to be superior to a wait-list control on pain reduction at posttreatment, with continuing improvement at 6-month follow-up. BFB + CBT was also superior to no treatment for the alleviation of depression. At follow-up, the BFB + CBT intervention did not differ from intraoral splinting for pain reduction but was more effective in reducing depression.

Biofeedback-Assisted Relaxation Training

Brooke and Stenn (1983). The study sample consisted of 190 patients selected from a facial pain clinic with a diagnosis of myofascial pain dysfunction syndrome of at least

2 month's duration. The patients were randomly allocated to one of four treatments conditions: ultrasound, intraoral splint (IS), BART, or relaxation training (RT) without biofeedback. The final *n*s in each condition at pretreatment, posttreatment, and at follow-up were not specified. Ultrasound was applied bilaterally to the right and left muscles of mastication for nine 10-min sessions over 3 weeks. Patients in the IS condition wore an appliance fitted to the upper teeth continuously for 10 days and thereafter only at night for a further 2 months. The BART condition combined RT with unilateral masseter SEMG feedback for seven weekly 1-h sessions. The RT alone condition was delivered on the same schedule. The type of RT and the manner of integration with SEMG feedback were not described. However, in an earlier study of TMD patients the authors employed continuous SEMG feedback from the masseter to monitor jaw relaxation during progressive muscle relaxation training (Stenn, Mothersill, & Brooke, 1979).

Patients were assessed for treatment success at the end of treatment and at 6-month follow-up by a clinician blind to patients' treatment condition. A successful outcome was recorded if the patient was symptom-free or showed minor symptomatology requiring no further treatment. At the posttreatment evaluation patients in the BART and RT groups showed higher proportions of successful outcome than did the IS and ultrasound groups. At follow-up, the combined BART, RT, and IS groups showed a significantly greater proportion of patients successfully treated compared to the ultrasound group. Specifically, 70% of the BART group, 71% of the RT group, and 60% of the IS group were successfully treated compared with 45% of the ultrasound group.

Comment: This brief report of an ambitious study lacks procedural and statistical detail. Nevertheless, the study demonstrated that BART produced clinically successful outcomes in 70% of patients. With regard to treatment efficacy, the ultrasound condition can be considered a plausible alternative treatment or a sham treatment. Under either definition, BART was superior to this alternative intervention. The proportion of patients improved in the BART group did not differ from that in either the IS or RT groups.

Mishra, Gatchel, and Gardea (2000); Gardea, Gatchel, and Mishra (2001). These are twin reports from the same study, the first analyzing immediate posttreatment outcomes and the second analyzing 1-year follow-up outcomes. We review here the follow-up report, which included a slightly larger number of subjects and produced larger effect sizes for pain outcomes than did the initial report.

Gardea et al. (2001) assigned 108 TMD patients, of whom 102 were available to follow-up, to BART, CBT, combined BART + CBT, or a no treatment control group. A semi-random assignment procedure was used to balance predetermined demographic and diagnostic variables among the four conditions. Patients were recruited from local dentists and by newspaper advertisement and were selected on the basis of Research Diagnostic Criteria for TMD of at least 6 months' duration. The active treatments were standardized by means of written manuals and administered for 12 sessions of 1 to 2-h duration over 8 weeks. BART consisted of relaxation training augmented by 15 min of skin temperature and frontal SEMG biofeedback in each session. The type of relaxation training and the manner of integration with biofeedback were not described. CBT consisted of a modified version of a program originally designed for the treatment of depression (Lewinsohn, Antonuccio, Steinmety, & Teri, 1984).

Pretreatment and follow-up assessments utilized self-report measures of pain, pain-related disability, and limitations of mandibular function. Analyses of pretreatment to follow-up difference scores revealed significant overall treatment effects for pain and mandibular limitation but not for disability. The BART and BART + CBT groups, but not the CBT group, showed greater reduction in pain than the no treatment controls. The CBT and the BART + CBT groups, but not the BART group, showed greater reductions in mandibular limitations than the no treatment controls. A credibility check found no difference among groups in treatment acceptance.

Comment: This well-conducted study found BART to be superior to no treatment for pain complaints but not for limitations of mandibular function. This differential result is consistent with the findings of Dohrmann and Laskin (1978), and Crockett et al. (1986) previously summarized. Although CBT alone did not differ from no treatment for pain, the addition of BART to CBT produced a significant treatment effect.

TREATMENT EFFICACY EVALUATIONS

The following discussion evaluates the foregoing review of RCTs against criteria established by the Association for Applied Psychophysiology and Biofeedback (AAPB) for determining the efficacy of biofeedback interventions from published outcome studies (Efficacy Task Force, 2002). The Task Force report specifies five levels of increasing evidence of efficacy, of which the final three can be summarized as follows.

Probably efficacious. Significant treatment effects have been demonstrated in multiple observational studies, clinical studies, or wait-list control studies.

Efficacious. At least two randomized controlled studies from independent research settings have demonstrated statistically significant superiority of the biofeedback intervention over no-treatment, sham treatment, or alternative treatment control groups. In addition, study participants were recruited from a problem-specific population and selected on the basis of explicit inclusion criteria; diagnostic and treatment procedures were sufficiently described to permit replication; valid and clearly specified outcome measures were used; and data were subjected to appropriate statistical analysis.

Efficacious and specific. In addition to the foregoing, the biofeedback intervention has been shown to be statistically superior to credible sham therapy, pill placebo, or alternative bona fide treatment.

SEMG Biofeedback Training: Probably Efficacious

One of the two RCTs in this category (Dohrmann & Laskin, 1978) demonstrated superiority of the biofeedback intervention over sham treatment for global clinical improvement and for self-reported pain. This study meets most of the AAPB criteria for demonstrating efficacy but is somewhat compromised by the incomplete statistical testing of results.

An additional controlled trial and several uncontrolled investigations have also reported positive evidence for SEMG biofeedback training. Hijzen, Slangen, and Van Houweligen (1986) used demographic and symptom information to match 48 patients into SEMG feedback training, intraoral splint, or no-treatment control groups. SEMG patients were taught to discriminate six different levels of masseter tension. At the end of 5 weeks of treatment, the SEMG feedback group showed greater reductions than the splint and no-treatment groups on an index of palpation pain and mandibular mobility, as well as on self-reports of masseter pain and ability to control and relax the jaw muscles. Uncontrolled investigations of SEMG feedback training have also reported improvements over the course of treatment among both previously unresponsive and treatment naive patients (e.g., Dahlstrom & Carlson, 1984; Dahlstrom, Carlson, Gale, & Jansson, 1984; Funch & Gale, 1984). In sum, SEMG biofeedback training fails to meet the criteria of two RCTs with positive results but does meet the criteria required for a probably efficacious intervention.

SEMG Biofeedback Training with Adjunctive Cognitive-Behavioral Therapy: Efficacious

The two RCTs in this category found this biofeedback intervention to be superior to no treatment (Turk et al., 1993) or to a plausible alternative intervention (Crockett et al., 1986) for both palpation pain and self-reported pain. These two studies fulfill all of the AAPB criteria required for designating an intervention as efficacious.

Biofeedback-Assisted Relaxation Training: Probably Efficacious

One of the two RCTs in this category (Brooke & Stenn, 1983) found BART to be superior to a plausible alternative intervention for clinical ratings of global improvement. The second study (Gardea et al., 2001) found BART to be superior to no treatment for pain. Unfortunately, neither study specified the type of relaxation training employed, nor the manner in which biofeedback was incorporated into the training. Although both studies demonstrated significant treatment effects in the context of randomized trials, the failure to provide procedural detail sufficient for replication requires a designation of probably efficacious.

OUTCOME RESEARCH RECOMMENDATIONS

Of the six RCTs thus far conducted by independent investigators, five have provided evidence for the efficacy of biofeedback-based treatments of TMD when compared to appropriate control conditions. By AAPB criteria, SEMG biofeedback training with adjunctive CBT is an efficacious treatment. SEMG biofeedback training as the sole intervention and BART are probably efficacious treatments. Further RCTs of SEMG biofeedback training and BART are warranted in order to establish higher levels of efficacy. In the case of SEMG biofeedback training we recommend the use of additional muscle training techniques, such as tension awareness and tension deactivation training, to complement the relaxation techniques typically employed (Kasman et al., 1997). The outcomes of SEMG biofeedback interventions should also be evaluated against stringent control conditions such as sham treatment or plausible alternative treatment (e.g., Dorhmann & Laskin, 1978; Crockett et al., 1986).

Further investigation is also indicated in order to clarify the interaction of SEMG biofeedback training and CBT approaches. The combination of the two approaches is eminently reasonable as well as efficacious. Preliminary research suggests that SEMG biofeedback training may potentiate the effects of CBT (Stenn et al., 1979) and vice versa (Olson & Malow, 1987). However, Crider and Glaros (1999) found no appreciable differences in pre- to posttreatment effect sizes when comparing SEMG biofeedback alone to SEMG biofeedback combined with various CBT techniques. More definitive answers will require trials contrasting SEMG biofeedback, CBT, and their combination.

A similar decomposition of BART is also warranted. Although BART is an efficacious intervention for TMD, relaxation training alone is also an effective treatment (Brooke & Stenn, 1983; Funch & Gale, 1984). Whether or not biofeedback monitoring enhances the effects of relaxation training can be determined by studies contrasting BART with relaxation training alone.

In addition to the foregoing recommendations, we offer the following guidelines for designing and reporting future outcome research on biofeedback interventions for TMD:

1. *Recruitment and description of participants*: The sources from which study participants are drawn should be clearly stated. Diagnosis should be based on professionally accepted standards, such as diagnostic manuals or research diagnostic criteria. Demographic, medical, and psychological criteria for both inclusion and exclusion of participants should be specified. Sample demographic information such as age and gender, as well as historical information such as duration of complaints and treatment history, should also be reported.
2. *Random assignment*: The random allocation of participants to treatment and control conditions is the gold standard for controlled investigations. Case controls, matching, and other nonrandom procedures should be avoided.
3. *Control groups*: No-treatment control groups provide an estimate of the degree of symptom change over time that can be expected among study participants due to such factors as normal recovery, self-initiated treatment, or altered life circumstances. No-treatment controls do not estimate the impact of nonspecific treatment factors such as patient expectations for improvement or mere professional attention. A credible sham treatment or plausible alternative treatment control group is therefore the more powerful method of demonstrating treatment specificity. Ethical issues arising from the use of such controls can be moderated by subsequently offering the experimental treatment to nonresponders. Steps should be taken to insure the equal credibility of sham, plausible alternative, and experimental treatments, including the use of pre- and posttreatment credibility measures.
4. *Statistical power and effect size*: The use of small samples poses the risk of failing to detect true differences among treatments or within the same treatment over time. Sample sizes should therefore be large enough to allow the rejection of null hypotheses that are in fact false. Given some prior knowledge of likely treatment effect sizes in TMD outcome research, investigators may consult power tables to determine the probability of rejecting the null hypothesis at different sample sizes.

   A difference between conditions may be statistically significant but clinically trivial. That is, a significant test of the null hypothesis speaks to the efficacy of an intervention but not to its magnitude. Therefore, a test of significance should be accompanied by a measure of the size of the effect. A variety of measures is available for this purpose (Cohen, 1988; Rosenthal, 1984).
5. *Biofeedback training procedures*: SEMG biofeedback training comprises many specific procedures, which should be specified. Specific muscle sites, the use of unilateral or bilateral feedback electrode placements, and the method of converting SEMG signals to biofeedback information should be described in detail. Specific training techniques, such as downtraining, tension discrimination, deactivation

training, and response generalization in the absence of biofeedback, should also be thoroughly described.

6. *Adjunctive cognitive-behavioral interventions*: Systematic relaxation disciplines and cognitive therapy strategies are often employed adjunctively with biofeedback training procedures. Because of the variety of such adjunctive techniques, they should be explicitly described when employed. It is also important to note whether these techniques are delivered by trained therapists during face-to-face training sessions, as homework prescriptions with limited professional involvement, or both.
7. *Treatment manuals*: Detailed written descriptions of treatment protocols are a means of standardizing treatment among patients, especially when multiple therapists are involved. They also provide more complete documentation of procedures than is usually available in published reports and thus can facilitate replication studies. Treatment manuals are particularly valuable when nonconventional or innovative therapeutic interventions are being evaluated.
8. *Outcome measures*: The controlled studies reviewed here indicate that biofeedback interventions are particularly efficacious for clinician judgments of global improvement and muscle palpation pain, as well as for patient ratings of pain frequency and intensity. Because different measures of these phenomena are not equally sensitive, due attention should be paid to issues of measurement validity and reliability. Validity can be ascertained through prior research reports of significant differences between treatment and control groups on measures of interest. The reliability of clinical judgments can be measured by tests of inter-rater agreement between two or more judges, whereas the reliability of patient ratings can be ascertained by repeated assessments over two or more occasions prior to treatment.

   A recent consensus report on outcome assessment in clinical trials of treatment for chronic pain recommends that expert and participant ratings of pain be supplemented with a broader array of assessments, including measures of functional impairment, affective state, adverse reactions, satisfaction with treatment, and adherence to treatment (Turk et al., 2003). A companion report suggests specific assessment methods and/or validated measures for each of these outcomes (Dworkin et al., 2005).
9. *Follow-up assessment*: Biofeedback interventions often produce continued posttreatment improvement, which may not be true of biomedical therapies when the treatment is withdrawn. Therefore, the outcomes of biofeedback interventions should be assessed both immediately posttreatment and several months following treatment.

CONCLUSIONS

Outcome evaluations of biofeedback alone or in combination with other conservative interventions have been conducted over several decades. Our analysis of two RCTs published to date plus information from other outcome studies suggests that SEMG biofeedback training of the masticatory muscles is probably an efficacious treatment. Two additional RCTs suggest that BART is also probably efficacious. Finally, two RCTs clearly demonstrate that SEMG biofeedback training combined with CBT methods is an efficacious treatment. Biofeedback-based treatments appear to be particularly effective for the management of TMD-related pain that is not secondary to another medical or dental condition. There is no evidence that biofeedback interventions are effective with patients who complain only of disc displacement or degenerative joint disease (Glaros & Lausten, 2003).

Recent research has favored the evaluation of treatment packages combining a variety of conservative biomedical and psychosocial interventions (e.g., Mishra et al., 2000; Turk, Rudy, Kubinski, Zaki, & Greco, 1996). Although this integrative approach appears to be quite effective (Syrop, 2002), it risks redundancy and the costs associated with unnecessary treatment. We therefore recommend further research designed to identify specific treatment combinations that act synergistically to enhance outcomes over the effects of their separate components. In the same vein, the development and evaluation of sequential or stepped care treatment protocols is also an important goal for future research. With stepped care, a cost-effective intervention can be routinely offered to all patients with similar presenting signs and symptoms, with additional treatments reserved for those showing incomplete recovery. In sum, a variety of biofeedback-based treatments for TMD are probably or clearly efficacious interventions. A challenge for the future will be to develop cost-effective treatment protocols that integrate biofeedback methods with other conservative biomedical and psychosocial approaches.

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