Physical Self-Regulation Training for the Management of Temporomandibular Disorders

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Aims: *To evaluate the long-term effectiveness of a brief skills training program for the management of chronic facial muscle pain. This program of physical self-regulation (PSR) involved primarily training in breathing, postural relaxation, and proprioceptive re-education.* **Methods:** *Physical self-regulation training was presented by a dentist during two 50-minute sessions spaced at 3-week intervals and was compared to a standard dental care (SDC) program that included a flat-plane intraoral appliance and self-care instructions provided by a dentist. Participants (n = 44) were initially evaluated by a dentist experienced in the diagnosis and management of orofacial pain and were determined to have myofascial pain (Type 1a and 1b diagnoses per the Research Diagnostic Criteria) prior to random assignment to either the PSR or SDC conditions. Posttreatment evaluations 6 weeks and 26 weeks after treatment had begun were conducted by a dentist who was not aware of which treatment the participants received.* **Results:** *Initial results indicated that pain severity and life interference from pain were reduced in both groups (*$P < 0.001$*), while perception of control was increased (*$P < 0.001$*), as was incisal opening without pain (*$P < 0.05$*). At the 26-week follow-up, the PSR group reported less pain (*$P < 0.04$*) and greater incisal opening, both with (*$P < 0.04$*) and without (*$P < 0.01$*) pain, than the SDC group. There were also significant decreases (*$P < 0.05$*) in affective distress, somatization, obsessive-compulsive symptoms, tender point sensitivity, awareness of tooth contact, and sleep dysfunction for both groups over time.* **Conclusion:** *The findings support the use of PSR for the short- and long-term management of muscle pain in the facial region. These results are discussed in terms of the potential mechanisms by which self-regulation treatment strategies are effective for the management of these pain disorders.*

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Temporomandibular disorders (TMD) include a broad array of conditions associated with pain and dysfunction in the head and neck region. These conditions are common within the general population and, in some instances, may lead to debilitating and refractory chronic pain syndromes.[1] Recently, Dworkin[2] suggested that chronic TMD represent a recurrent pain condition analogous to back pain and headache. Since persons with TMD, compared to persons with back pain and headache, reflect a similar degree of disruption in psychosocial functioning and treatment-seeking for pain relief, he proposed that treatment

of TMD should be guided by a biobehavioral model similar to that used in successful multidisciplinary treatment centers for back pain and headache.

Several research groups have reported that depression, fatigue, and anxiety characterize the psychologic domain of persons with TMD.[3,4] Physiologically, it has been shown that these individuals "over-respond" to environmental stimuli with excessive cardiovascular activity and altered breathing rates.[5] It has also been demonstrated that persons with TMD report significantly more life stressors than do individuals who are pain-free.[6] Taken together, these findings suggest that factors associated with the level of emotional and physical activation may contribute to the chronicity of TMD.

While increased autonomic activation is a normal adaptive mechanism for managing life stressors, heightened emotional and physical responsivity is also characteristic of a chronic defense reaction in the presence of relentless stressors.[7,8] Prolonged stimulation from nociception, for example, is known to be one of the most significant activators of the sympathetic nervous system and can be viewed as an important endogenous stressor itself.[9] Recent evidence has shown that when primary nociceptors are stimulated by tissue damage, activity by collateral non-nociceptive peripheral neurons further increases the rate of activity from those nociceptors.[10,11] Even in non-painful situations, anxiety-induced autonomic activity that alters carbon dioxide levels may cause ectopic impulses to be generated from dense receptive fields within the trigeminal region.[12] Under conditions promoting central sensitization, sympathetic activity from a variety of stimuli may have significant effects on nociceptive transmission or subsequent pain reports.[13] Therefore, management of sympathetic activity can be regarded as an important treatment goal for persons with pain disorders, even though it may not be clear as to whether it is a causative factor or a consequence of the pain experience.[14]

Previous work has indicated that masticatory muscle pain (MMP) patients are more sensitive to pressure stimulation[3] and to upper-arm vascular compression than normal pain-free individuals.[15] It has also been noted that MMP patients have altered breathing parameters and report more fatigue, depression, and sleep disruptions than do normal controls.[3] These findings indicate that factors affecting pain sensitivity, which include perfusion, breathing pattern, fatigue, mood, and sleep dysfunction, may be appropriate treatment targets, in addition to the pain itself.

Several studies have examined the efficacy of biobehavioral strategies for the management of the behaviors and physiologic processes thought to be associated with TMD.[16,17] These biobehavioral programs have focused on information about the disorder (eg, self-limiting, varying intensity), skills training in self-control strategies to modify pain perception (eg, relaxation training), and cognitive restructuring techniques to alter dysfunctional belief systems. The biobehavioral approaches have been compared to conventional intraoral appliance therapy to evaluate overall outcomes. The findings of Dworkin et al,[16] for example, have generally revealed lowered pain levels and life interference from the pain for both occlusal appliance therapy and biobehavioral therapy initially, but at long-term follow-up, the biobehavioral strategies have been shown to be more efficacious in reducing pain.

Rugh and Dahlstrom reviewed evidence from experimental studies of psychologically based treatments of TMD and concluded that such treatments generally produced results equivalent to standard dental therapies.[18] However, they suggested that these results may be due more to non-specific treatment factors, such as a relationship with a caring health provider, rather than to changes in physiologic processes related to the disorders themselves. Additionally, Dao et al[19] have noted that dental splint therapy may also be effective because of non-specific factors that may be associated with the administration of any treatment by a health professional. These include placebo effects, spontaneous remission, natural fluctuations or the progression of a condition, and the therapeutic relationship between the provider and the patient. Therefore, it would be important to employ a research strategy to control for non-specific therapeutic effects in any evaluation of TMD treatments, but especially those examining the role of biobehavioral strategies.

The present project was designed to explore the effectiveness of a self-regulation approach that targeted the modification of pain-related symptoms observed in TMD patients who were experiencing muscle pain. The self-regulation program developed for use in this study is distinguished from other published reports of psychologically based strategies in several respects. The protocol emphasized to patients that the treatment rationale was based on available data describing the altered physiology accompanying pain. Second, it employed very brief interventions/training that addressed controlling the altered physiologic functions associated with pain. Based on the literature reviewed above, several hypotheses were tested in

the present study. It was expected that immediately following completion of the treatment regimen, participants in the self-regulation program would display a significant reduction in pain, life interference, somatization, sleep dysfunction, and fatigue that would be equivalent to traditional dental therapy with intraoral splints. It also was expected that there would be an increase in incisal opening for both treatments. Consistent with the work of Dworkin et al,[16] however, it was predicted that at long-term follow-up, participants in the self-regulation program would have greater reductions in pain, life interference, somatization, sleep dysfunction, and fatigue than participants who received standard dental care, as well as greater incisal opening than those who received standard dental care.

Materials and Methods

Participants

During the period of the study, 71 patients met the criteria for inclusion and were initially invited to participate in this project, which was conducted in the outpatient Orofacial Pain Service, Department of Oral and Maxillofacial Surgery, National Naval Medical Center (NNMC), Bethesda, Maryland. The study was approved by the institutional review board for the protection of human subjects at the NNMC. Fifteen of the patients who initially met the criteria for the study failed to complete the 2-week baseline evaluation before random assignment to treatment protocols. This 2-week baseline period was used to ensure stability of participants' pain symptoms in light of the possibility of regression to the mean.[20] The characteristics of those individuals who did not complete the baseline evaluation are the subject of another report. Twelve other patients who did complete the 2-week baseline period were unable to finish the study, and complete follow-up data were not collected from them, so that an intention-to-treat analysis could not be performed. Three of these individuals became pregnant. Two others had worsening symptoms that required additional treatment beyond the guidelines of the protocols. One required a tooth extraction and another was discovered to have a tear of the teres minor muscle. Four participants in the standard dental care (SDC) protocol and 3 participants in the physical self-regulation (PSR) protocol withdrew from the study for personal reasons (eg, transportation difficulties, changes in residence) prior to outcomes assessment. Subsequent data analyses of the initial physical and psychologic characteristics of those who dropped out of the study versus those who completed the study did not reveal any significant differences between the 2 groups on measured variables obtained at the beginning of the study.

Overall, 44 participants met the inclusion criteria (34 women and 10 men) and completed the treatment protocol. The average age of this sample was 34.6 years, average duration of pain was 52.3 months, and average pain intensity on a 100-mm visual analog scale (VAS) was 44.1 mm. All participants were either active-duty or retired military personnel (Navy, Marine, Air Force, or Army) or family members of active-duty or retired military members. To be included in the study, participants had to have a primary diagnosis of myofascial pain in the masticatory muscles that was based on guidelines from the Research Diagnostic Criteria for Type 1a and Type 1b disorders[21] and included a chief complaint originating from the masticatory muscles, pain complaint that had been present for longer than 1 month, and report of pain in response to palpation of 3 or more standard muscle sites. All participants were maintained on medications that they were taking prior to the initial evaluation, and initial medication usage was not altered by the treating dentists during the course of the study. Twenty-one participants reported medication usage during the initial consultation; these included nonsteroidal anti-inflammatory drugs (NSAIDs) (13 of 21 participants reporting usage), selective serotonin reuptake inhibitors (3 of 21 participants), muscle relaxants (4 of 21 participants), and beta-blockers (1 of 21 participants). In the majority of cases, these medications were being taken for the management of the presenting pain complaints.

Design

Participants were randomly assigned to either the SDC (n = 21) or PSR (n = 23) conditions. Random assignment was accomplished by the use of a table of random numbers. Thirteen participants in the PSR group and 8 participants in the SDC group reported taking medication. Dependent measures were collected at baseline and at 6 and 26 weeks after the initial treatment session. A board-certified dentist with postdoctoral training in orofacial pain who was not aware of the treatment protocol to which each participant was assigned performed all initial dental evaluations and administered the self-report measures after the dental evaluations. A maxillary dental impression was made for each participant at the time of the initial evaluation.

The SDC was provided by a dentist experienced in the treatment of orofacial pain and consisted of 2 visits separated by a 3-week interval. At the first treatment visit, the dentist reviewed the initial examination findings with the patient. The dentist then fabricated and delivered a flat-plane intraoral appliance according to the methods described by Okeson.[22] Patients were instructed to wear the splint at night and were provided with general information regarding etiology and self-care strategies for managing myofascial pain (eg, eat soft foods, relax the jaws during the day). This program was consistent with the dental management/self-care strategies presented by Clark et al.[23] Participants were then scheduled for a follow-up appointment in 3 weeks for splint adjustment and reinforcement of the pain management procedures. Participants were also reminded about how to seek further care if they felt that the present protocol was not meeting their needs. At the second visit, any needed adjustments were made on the appliance, questions were answered, and the participant was reminded of the management strategies presented in the first treatment session. Each of the sessions was approximately 50 minutes in length.

The PSR protocol was provided by another dentist experienced in the treatment of orofacial pain. At the first treatment visit, the dentist reviewed the initial examination findings with the patient and explained the physiologic dimensions of these findings. The dentist not only provided information concerning the role of pain and possible etiologic mechanisms, but also offered specific physical self-regulation strategies for the management of the presenting pain complaints. The self-regulation strategies targeted 7 specific domains: monitoring and reducing muscle parafunction in the head and neck region, proprioceptive awareness training to improve symmetric head and neck posture, instructions for improving sleep onset, position-oriented relaxation training, physical activity, nutrition/fluid management, and training in diaphragmatic breathing. The strategies were presented in the sequence outlined above during two 50-minute sessions separated by a 3-week interval. During the first appointment, the first 6 domains were presented. At the second session, these domains were reviewed and diaphragmatic breathing training was performed. This involved ensuring diaphragmatic function during inspiration, while the accessory muscles of inspiration remained quiet. An additional criterion was breathing at a pace of 5 to 7 respirations during practice sessions. The entire protocol was summarized on a 1-page handout and explained in a detailed treatment manual provided to participants.[24] Participants in this experimental group were also reminded about how to seek further care if they felt that the PSR protocol was not meeting their needs. In both experimental groups, none of those who completed the study requested additional treatment during the period of the study.

Dependent Measures

Self-reports of pain severity, life interference from pain, and perception of life control were made by the participants on those subscales from the Multidimensional Pain Inventory (MPI).[25] The scales have coefficient alphas ranging from 0.72 to 0.90. The test-retest reliabilities for the subscales range from 0.68 to 0.86. Participants also completed a pain diary in which they recorded overall pain ratings on a 100-mm VAS (anchored with "no pain" at the left side and "worst possible pain" at the right side) at 3 time periods each day (morning, afternoon, and evening). An average pain score was computed for each day, and daily averages were summed and averaged over the period of data collection (2-week initial baseline and after the second treatment appointment).

The orofacial pain evaluations were carried out by a dentist not aware of the protocols to which the participants were assigned. The standard examination for each patient included the measurement of comfortable interincisal opening without increasing pain and of maximum interincisal opening. A millimeter ruler was used to record the measurements (from the incisal edge of the mandibular incisor to the edge of the maxillary incisor) as described by Okeson.[22] Seventeen bilateral muscle palpations in the cervical and orofacial region (eg, trapezius, sternocleidomastoid, masseter, temporalis) were obtained and rated on a scale of 0 to 3, where 0 represented "non-painful," 1 represented "tender," 2 represented "painful," and 3 represented "pain with withdrawal." A muscle pain index was obtained by summing the scores across all sites for each participant. During the course of the examination, individuals were also asked to estimate how long their teeth touched for any reason during a 24-hour period. The number of minutes each participant self-reported this estimate constituted the measure of awareness of tooth contact.

Measures of psychologic status included the somatization, depression, anxiety, and obsessive-compulsive scales of the Revised Symptom Checklist-90 (SCL-90-R).[26] Average scores for each scale were obtained according to instructions

outlined in the scoring manual. The coefficient alphas for these scales range from 0.85 to 0.90, and the test-retest reliability of these scales ranges from 0.80 to 0.86. Overall affective distress was measured by the affective distress scale from the MPI. The coefficient alpha of this scale is 0.73, and the test-retest reliability is 0.69.[25] Fatigue was assessed on a Likert format scale of 0 to 10 (where 0 represented "no fatigue" and 10 represented "a great deal of fatigue") for participants to assess the degree of fatigue that they currently experienced.[27] Sleep quality was measured by the Pittsburgh Sleep Quality Index.[28] The overall test-retest reliability for the sleep dysfunction scale was 0.85, with a coefficient alpha of 0.83.

Procedure

Upon presentation to the clinic, participants underwent a thorough diagnostic evaluation, including a panoramic radiograph. The examination followed a standardized format and the results were recorded on a standard form. This physical examination, which included sequential muscle palpation, was the same for each of the assessments in the study. Following the determination by the dentist that the patient met the criteria for inclusion in the study, the patients were asked whether or not they were interested in participating in the research project; no financial incentives were offered for participation in the project. Those willing to participate completed the informed consent as well as the series of standardized questionnaires. After completing the questionnaires, subjects were given a set of self-monitoring forms and instructed to record their pain ratings 3 times daily (morning, noon, evening) for the next 14 days to establish a baseline pain profile. An appointment was then set for them to return to the clinic in 2 weeks to be re-evaluated.

After 2 weeks, the self-monitoring forms were collected, a brief clinical evaluation was completed to ensure the continued presence of symptoms, and, depending on the random assignment outcome, participants were referred to either the dentist offering SDC or to the dentist offering PSR treatment. Participants returned to the clinic 3 weeks later for a follow-up visit with the treating dentist. At this visit, they were given the self-monitoring forms and asked to complete them daily and bring them back for the posttreatment follow-up evaluation that was then scheduled for 3 weeks later.

At the posttreatment follow-up evaluation (8 weeks since first visit), the dentist who conducted the initial evaluations completed another examination, asked participants to complete the standardized questionnaires, and collected the self-monitoring forms. Participants were asked to return to the clinic at 26 weeks after initial presentation to undergo the same physical examination and complete the same series of questionnaires. Nineteen participants in the PSR condition and 13 participants in the SDC condition returned for this evaluation. At the conclusion of the 26-week follow-up evaluation, participants again had the opportunity to receive additional treatment, if they so desired. A flowchart of the protocol is presented in Fig 1.

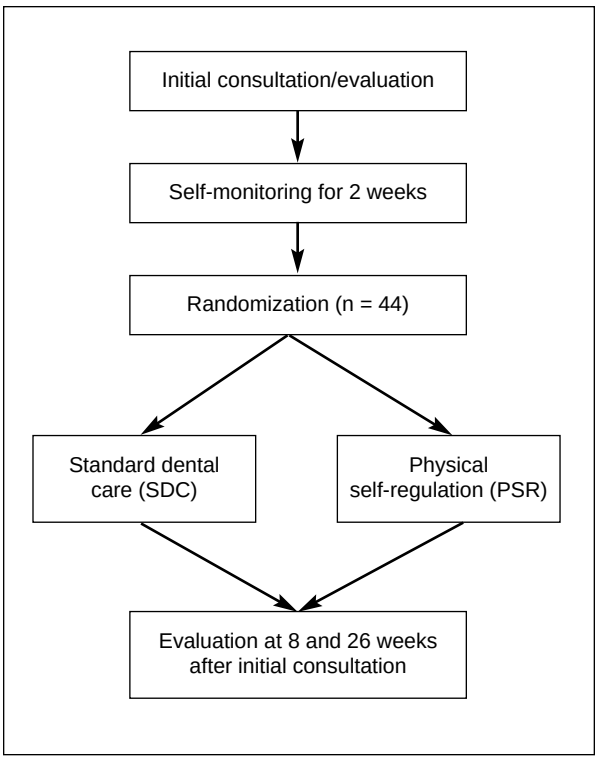

Fig 1 Flowchart of study protocol.

Data Analyses

Based on the a priori hypotheses, it was expected that both groups would initially report treatment gains. Therefore, a 2 × 3 (SDC versus PSR; and baseline versus 6 weeks versus 26 weeks) repeated-measures analysis of variance would be an appropriate analytic strategy to account for pretreatment scores. A priori hypotheses were evaluated with focused contrasts to assess expected between-group differences. The alpha level was set at $P < 0.05$. The Statistical Package for the Social Sciences (Version 10, SPSS Inc) was used for all analyses.

Table 1 Initial Treatment Outcomes

Measure	PSR (mean and SD)			SDC (mean and SD)			F(2,66)	*P*	Effect size
	Baseline	6 weeks	26 weeks	Baseline	6 weeks	26 weeks			
Pain measures									
Daily self-monitor (mm)	35 (23)	24 (28)	—	35 (23)	26 (24)	—	11.93*	0.002	0.57
Pain severity (0 to 6)	3.2 (1.1)	1.6 (1.3)	1.2 (1.5)	3.2 (1.4)	2.4 (1.9)	2.0 (1.5)	26.75	0.000	0.67†
Life interference	1.8 (1.5)	1.0 (1.1)	0.8 (1.1)	2.0 (1.6)	1.5 (1.7)	1.0 (1.6)	16.05	0.000	0.57
Life control	3.5 (1.0)	4.2 (1.3)	4.6 (0.8)	3.7 (1.1)	4.0 (1.0)	4.1 (1.1)	7.36	0.001	0.43
Physical examination									
Opening w/o pain (mm)	35.0 (8.5)	41.6 (8.3)	41.8 (8.5)	34.4 (11.1)	36.2 (8.6)	39.3 (8.4)	8.09	0.001	0.45†
Opening with pain (mm)	46.3 (8.5)	48.7 (8.0)	49.5 (9.3)	46.4 (10.6)	44.5 (9.8)	46.4 (7.5)	4.02‡	0.02	0.33†
Muscle pain index	18.3 (13.4)	11.2 (12.1)	9.3 (10.5)	19.8 (16.4)	19.3 (22.4)	12.8 (13.2)	8.26	0.001	0.44
Awareness of tooth contact (minutes)	666 (441)	83 (91)	118 (198)	486 (390)	240 (346)	41 (67)	27.46	0.000	0.72
Psychologic variables									
Affective distress	2.9 (1.1)	2.3 (1.4)	2.0 (1.3)	2.9 (1.5)	2.6 (1.5)	2.3 (1.7)	5.91	0.04	0.39
Somatization	0.60 (0.53)	0.35 (0.36)	0.30 (0.28)	0.72 (0.64)	0.58 (0.51)	0.60 (0.64)	4.04	0.02	0.33
Depression	0.46 (0.38)	0.28 (0.31)	0.30 (0.41)	0.52 (0.59)	0.40 (0.36)	0.35 (0.43)	2.67	0.08	0.28
Anxiety	0.31 (0.29)	0.20 (0.23)	0.18 (0.22)	0.36 (0.52)	0.28 (0.31)	0.24 (0.33)	2.82	0.07	0.28
Obsessive/compulsive	0.53 (0.55)	0.28 (0.32)	0.30 (0.36)	0.67 (0.86)	0.44 (0.53)	0.45 (0.52)	4.99	0.01	0.37
Fatigue	2.7 (2.8)	2.1 (2.2)	1.6 (2.0)	2.0 (2.4)	2.9 (3.2)	2.1 (2.8)	0.49	0.62	0.12
Overall sleep dysfunction	6.81 (2.72)	5.50 (2.50)	5.26 (2.88)	6.57 (3.02)	5.61 (3.68)	6.08 (3.77)	3.83	0.03	0.32

*Degrees of freedom (1,25).
†Focused a priori contrast $P < 0.05$ at 26 weeks.
‡Significant 2-way interaction.
PSR = physical self-regulation; SDC = standard dental care.

Results

Pain Measures

The primary measures of interest in this study were whether or not the SDC or PSR treatments resulted in significant relief of pain for the participants. Daily VAS self-ratings of pain indicated that both experimental groups experienced a significant reduction in pain during the initial 6-week treatment period ($F[1,25] = 11.93$, $P < 0.002$). Furthermore, results indicated that both the SDC and the PSR interventions resulted in significant decreases in pain severity, as measured on the MPI ($F[2,66] = 26.75$, $P = 0.000$). At the 26-week follow-up, however, the PSR group reported significantly less pain than the SDC group ($F[1,66] = 4.46$, $P < 0.04$). The results also revealed that both the SDC and the PSR interventions resulted in significant decreases in life interference from pain ($P = 0.000$). Finally, both groups had significant increases in their perception of control over their pain ($P < 0.001$). There were no differences between groups at 26 weeks for either life interference or perception of control ($P > 0.05$). Results are presented in Table 1.

Physical Examination Variables

The maximum interincisal opening without pain increased significantly for both groups over the course of the assessment ($P < 0.001$). At the follow-up period, the PSR group had a greater maximum opening without pain than did the SDC group ($F[1,65] = 4.62$, $P < 0.04$). The PSR group also displayed an increase in the maximum interincisal opening with pain over the course of evaluation, but the SDC group did not ($P < 0.02$), with the focused contrast at the 26-week evaluation revealing that the PSR group had a significantly greater opening with pain than the SDC group ($F[1,65] = 10.52$, $P < 0.002$). The muscle pain index indicated a significant change for both groups ($P < 0.001$) over the course of the evaluation period. Finally, participants' awareness of tooth contact showed a significant reduction over the course of the evaluation period ($P < 0.001$). Detailed results are presented in Table 1.

Psychologic Variables

Participants' overall affective distress as indexed on the MPI showed a significant reduction over the assessment period for both groups ($P < 0.04$). Somatization scores on the SCL-90-R also showed

a significant decrease over time for both groups ($P < 0.02$). Levels of depression ($P < 0.08$) and anxiety ($P < 0.07$) were not significantly changed over the assessment period. Obsessive-compulsive symptoms, however, did change significantly over time for both groups ($P < 0.01$). Results for self-reports of fatigue level indicated that fatigue was not changed for participants in either group ($P > 0.62$). Finally, self-ratings of sleep dysfunction showed a significant decrease in both groups over the evaluation period ($P < 0.03$). However, there were no differences in measured psychologic variables between groups at the 26-week follow-up (all $P > 0.05$). These results are presented in Table 1. The overall combined effect size for the treatment programs was an r of 0.42 with a range from 0.12 to 0.72 for all the measured dependent variables. The overall combined effect size was computed by converting the r values to z scores, obtaining the average of these scores, and then converting back to r values.

Discussion

As expected, the overall results immediately after treatment indicated that both treatments provided improvements in pain severity, life interference from pain, perception of control, mouth opening without pain, affective distress, somatization, and overall sleep quality. At the 26-week follow-up, however, participants in the PSR condition demonstrated less severe pain and greater incisal opening with and without pain than those participants assigned to the SDC condition. The data, therefore, support the continued exploration and use of PSR as an effective short-term and long-term management approach for chronic muscle pain that is as effective as standard dental therapy in the short term but provides improved pain reduction and range of motion over a 6-month period.

The pathogenesis of muscle pain disorders is not well understood at the present time. The PSR program, however, addressed multiple components (eg, proprioceptive training, progressive relaxation, diaphragmatic breathing training, sleep hygiene, and control of parafunctional activities) that are commonly described as factors in the onset and perpetuation of muscle dysfunction.[22,29] While the PSR program may improve fundamental pathophysiologic disturbances, it also may be operating to improve participants' self-efficacy.[30] It is known that perceptions about one's ability to manage a problem (self-efficacy) can influence one's general health outcomes,[31] as well as basic physiologic processes. Future research concerning the factors associated with the effectiveness of the PSR approach should examine how self-efficacy contributes to positive health outcomes in chronic pain patients. Finally, given the availability of data suggesting that the efficacy of splint therapy could be caused by any one or a combination of factors, including a placebo effect, spontaneous remission, the natural fluctuations or progression of a condition, and the therapeutic alliance between the provider and the patient,[19] the effectiveness of the PSR protocol for reducing pain severity and improving incisal opening suggests a therapeutic effect beyond that obtained with current practice standards. Our hypothesis is that the PSR protocol improves physiologic functioning so that both sensory experience and observable functioning are altered in a manner that is detectable beyond whatever factors may be operating during the standard treatment program.

The present sample represented individuals with substantial and long-standing pain complaints. We observed that 13 participants in the PSR condition and 8 participants in the SDC condition were taking medications that were not altered during the period of the study. While there is the potential that the ongoing medication use may have influenced the outcomes of the study, we would suggest that the chronic nature and stability of the symptoms established prior to random assignment minimize this interpretation. It is worthwhile to note that both protocols resulted in an initial 50% reduction in pain severity, regardless of the means by which the results were obtained. At 26 weeks, pain severity was reduced by over 60% for the PSR group. Jacobson and Truax[32] have defined a clinically significant effect as a movement of greater than 1 standard deviation in the direction of better health outcomes. The PSR protocol satisfies this criterion and offers a reasonable immediate and long-term treatment alternative to practitioners providing care to patients with a lengthy history of musculoskeletal pain in the temporomandibular region.

One factor to consider in evaluating the PSR program involves a cost-benefit analysis. Since the costs for evaluations were equivalent between the 2 treatment conditions, the cost of care provided to the participants in the PSR protocol essentially equaled the costs associated with two 50-minute sessions with a skilled dentist. If such sessions were billed at $119 per session (CPT code 99215), as is the current fee schedule for the Orofacial Pain Center at the University of Kentucky, then the total treatment costs for PSR would be $238.

Standard dental splint care (CPT code 99002) varies in cost, but a conservative estimate based on current billing practices at the Kentucky clinic would be $450. If these data are applied to the current sample, there is an immediate 47% cost savings from the use of the PSR strategy, as compared to the use of SDC, with the same clinical outcome initially and greater pain reduction and incisal opening at the 26-week follow-up examination. Such outcomes, however, require further evaluation and confirmation through other controlled clinical trials involving a broader spectrum of patients and health providers.

For the present study, we used a single dental practitioner to deliver the treatment protocols to each patient group. With restricted resources to conduct the project, the use of additional dentists within each treatment condition was not feasible. It is not known, therefore, if the present findings are a result of non-specific practitioner effects or of the quality of the interventions themselves. Future research at multiple sites and with multiple practitioners is necessary to address this issue. Moreover, the current design did not specifically address the measurement of compliance with either regimen, so it is not known with the present data whether or not there may be a relationship between treatment outcomes and day-to-day application of the respective protocols.

We also expected that the perception of fatigue would be an important treatment target addressed by the PSR protocol. However, the results indicated that there were no differences across time or between groups. These results may represent the resistance of perceived fatigue to clinical interventions over an extended period, or they may represent measurement problems associated with the construct of fatigue itself, as is suggested by the rather substantial standard deviations obtained in the present sample. While the perception of fatigue has been shown to characterize the clinical presentation of myofascial pain patients,[3] it is not known whether the perception of fatigue[27] reflects the same construct that is associated with the increased myoelectric frequency shifts demonstrated in muscle pain patients[33,34] and whether or not this may be malleable to clinical intervention. If the Piper Fatigue Scale[27] measures, for example, delineate fatigue more as a trait psychologic measure rather than a state physiologic measure, the scales may not be sensitive to significant changes in the physiologic aspects of fatigue over time. Since fatigue is one of the more common symptoms reported by muscle pain patients,[3] clinical differentiation between the physiology and the psychology of fatigue is an important direction for future research.

One of the diagnostic dilemmas associated with headache and facial muscle pain is the lack of visible tissue damage. The role of both perceived and physiologic fatigue could explain pain complaints in such clinical presentations. Future work should include dependent measures of both perceived and physiologic fatigue to explore these issues and to determine the linkages between perceived fatigue and physiologic fatigue. Establishment of selective measures that better define the intricacies of fatigue could also provide clinically relevant data for muscle pain management.

An interesting feature of the current data set is the relatively low level of psychologic symptomatology, as indexed by the scores on the somatization, depression, and anxiety scales of the SCL-90-R, as compared to other non-military clinical samples.[35] There may be social constraints about admitting depression or anxiety in a military environment as compared to general society. On the other hand, the military population may truly have a lower level of psychologic dysfunction. Research concerning the role that social environment plays in the onset, intensity, and consequences of muscle pain would be most useful for interpreting the present results. Nonetheless, it would be important to apply the PSR principles to patients from other muscle pain populations, where substantial psychologic dysfunction is known to be present.[3,4] In more disturbed populations, the psychologic effects of an effective pain management strategy may emerge more clearly.

The current data represent an initial study of the effectiveness of a physical self-regulation protocol for the management of a common and debilitating muscle pain condition. The present data set provides an example of a randomized, controlled clinical trial addressing the effectiveness of a biobehavioral intervention for myofascial pain in the temporomandibular region. The results indicate that a focus on the regulation of physiologic processes has merit for those individuals in pain. Rugh and Dahlstrom[18] have noted that most TMD are self-limiting and that conservative, reversible therapies should be the first choice of treatment. Our data suggest that the PSR strategy should be considered in the initial treatment options presented to patients because it represents an inexpensive and effective means of managing pain in the short term as well as over a 6-month period.

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