# Predicting the Outcome of a Physical Medicine Treatment for Temporomandibular Disorder Patients

## Glenn T. Clark, DDS, MS

Professor and Director Center for Orofacial Pain and Oral Medicine Division of Diagnostic Sciences School of Dentistry University of Southern California Los Angeles, California

### Kazuyoshi Baba, DDS, PhD

Professor and Chair Department of Prosthodontics School of Dentistry Showa University Tokyo, Japan

## Charles P. McCreary, PhD

Professor Neuropsychiatric Institute Department of Biobehavioral Sciences University of California, Los Angeles Los Angeles, California

# Correspondence to:

Dr Kazuyoshi Baba Department of Prosthodontics School of Dentistry Showa University 2-1-1, Kitasenzoku, Ohta-ku Tokyo 145-8515 JAPAN Email: kazuyoshi@dent.showa-u.ac.jp Aims: To investigate whether any of the pretreatment physical signs, symptoms, and responses on psychological questionnaires would predict treatment outcomes after a standardized temporomandibular disorder (TMD) treatment program. Methods: The care provided to 157 TMD patients was a short course of physical therapy, an occlusal appliance, and over-the-counter nonsteroidal anti-inflammatory drugs (OTC NSAIDs). A multidimensional outcome assessment was performed using six variables. Follow-up data were available on 81.5% of enrolled subjects and elapsed time from initial visit to the two follow-up points was  $13 \pm 4.7$ and  $33.6 \pm 9.8$  months, respectively. Multiple regression analyses were conducted to assess the relationship between 18 predictor variables and the six outcome variables. Results: The results showed that the combination of a higher initial visual analog scale (VAS) pain score plus a lower jaw function interference score was significantly associated with a reduction of VAS pain after treatment (P < .05; adjusted  $R^2 = 0.54$ ). Moreover, the combination of a higher initial activity limitation score plus a lower jaw function interference score was associated with a greater reduction of the activity limitation score after treatment (P < .05; adjusted  $R^2 =$ 0.36). None of the other outcomes were found to relate to any of the pretreatment variables. It must be noted that no single variable was a strong predictor and the odds ratios between the above three variables and the predicted outcomes were not robust. **Conclusion:** The corollary of these results suggests that if a high degree of jaw function interference is present (eg, clicking, locking), then the prognosis of improvement with brief self-directed physical therapy, an occlusal appliance, and OTC NSAID is lower, at least within the time frame of this study. J OROFAC PAIN 2009;23:221-229

Key words: multiple logistic regression analysis, physical medicine treatment, predictors, temporomandibular disorders, treatment outcome

The collective term temporomandibular disorders (TMD) refers to a number of clinical problems that involve pain and dysfunction of the masticatory musculature and/or the temporomandibular joints (TMJs).<sup>1-4</sup> Although these disorders are frequently separated into prototypical subgroups, the common approach for the majority of TMD can be described as a general physical medicine treatment, which consists of physical therapy, occlusal appliances, and nonsteroidal anti-inflammatory drugs (NSAIDs). In most studies, this method has yielded a positive response in approximately 75% of patients.<sup>5-8</sup> What is not known

is whether the 25% who do not respond positively are because of inaccurate diagnosis, ongoing causative factors, or ineffective and possibly even inappropriate treatment. It would be valuable if the success or failure of this treatment approach could be predicted by some unique set of pretreatment features in the patient's physical signs or symptoms or by their psychological profile. If there are reliable predictors of success or failure of a general nonspecific physical medicine treatment approach, then these patients might be targeted for other interventions (eg, behavioral or pharmacological therapy) or for a more intense or more specific program of therapy (eg, intracapsular procedures) than is usually provided.

Several studies have been published on how psychosocial features might be useful as predictors of TMD treatment outcome.<sup>9-14</sup> In fact, a recent review suggested that pychosocial dysfunction is prevalent among patients with chronic orofacial pain and TMD.<sup>15</sup> This review suggested that the potential predictors of outcome would include high levels of disability, psychological disorders, and prolonged or excessive use of opiates, benzodiazepines, alcohol, or other drugs. They also suggested dentists can improve the quality of care for patients with chronic orofacial pain by screening for psychosocial risk factors and by referring patients with them for psychological or psychiatric assessment and treatment. Unfortunately, one major problem with the psychological inventories is that they are often not used routinely in a primary care setting by dentists. While it could easily be argued that psychological inventories should be used more frequently, if any of the routine physical examination or history variables collected more routinuely were found to relate to treatment outcome, this would also be valuable. To date, there are no data in the literature which suggest that any of the pretreatment symptoms or signs can be predictors of treatment outcome for TMD. Moreover, regardless of which type of predictor is being looked at, the prior research has been lacking in many aspects. For example, in many of the treatment outcome studies, patients were not receiving a standardized course of treatment, or the pretreatment signs and symptoms were not gathered in a systematic fashion by calibrated examiners or with the use of standardized questionnaires. Many of the published studies involved retrospective analysis of charts, and the case selection criteria were often not clear and the dropout rate not determinable. In addition, most of the studies were limited by using only a single measure of general outcome while outcome is usually multidimensional. Finally,

previous studies have not considered the possibility that differences in pretreatment levels of pain may account for the relationship between pretreatment distress levels and posttreatment pain levels.

For all of these reasons, the aim of this study was to investigate whether any of the pretreatment physical signs, symptoms, and responses on psychological questionnaires would predict treatment outcomes after a standardized TMD treatment program. The study also collected personality profiles by using an indepth psychological inventory before treatment; the indepth personality inventory descriptor data will be analyzed and reported in another manuscript. The study's null hypothesis was that pretreatment pain, dysfunction, and psychosocial depression and anxiety measured with three short mood and pain assessment tests would not be related to a response to standard physical medicine care for TMD patients.

# **Materials and Methods**

## Subjects

A total of 245 consecutive new patients who attended the University-based faculty TMJ Pain Clinic over a 3-year period were solicited as potential subjects in this study. In general, patients came to the clinic because of jaw pain and/or dysfunction. The main requirements of the study were that subjects had to agree to complete a 3-hour battery of psychosocial tests. Of the potential 245 patients examined, 157 patients agreed to complete the pretreatment psychosocial testing (Minnesota Multiphasic Personality Inventory [MMPI]) required and return the forms within 2 weeks and therefore qualified for the study. Regarding the 88 subjects who were solicited to participate in the project but elected not to join, each declining subject was asked the reason for their refusal; this inquiry was made at the end of the first visit or if they did not decline initially, but did not elect to fill out the MMPI, the inquiry was made by the research assistant over the phone. Generally, this group often volunteered that they were only at the clinic for a consultation and could not return to the clinic because of difficulty obtaining time off from work or the long travel distance required. Of these 88 subjects, only 38 actually sought treatment at the clinic. For the 157 enrolled subjects, follow-up office visits were conducted at two time points (recall 1 = 1 year after treatment and recall 2 = 3 years after treatment). Although the strategy for these recalls was to invite all subjects to the

clinic and conduct a clinical examination (no charge for the examination), this was not always possible. A second strategy for subjects who could be contacted but could not attend the clinic was to have them complete a set of follow-up questionnaire forms on their current symptom level and treatment satisfaction. Inclusion criteria involved (1) the willingness to seek treatment for their TMD at the university-based faculty treatment facility only, (2) completion of all of the pretreatment pencil and paper test instruments required, (3) a willingness to return for several follow-up examinations after treatment was completed, (4) a positive complaint of jaw pain and/or functional impairment which was of a protracted nature (greater than 3 months), (5) pain localized by the patient to the masticatory muscles and joints, and (6) no active treatment being undertaken for their TMD at another clinic. Exclusion criteria involved (1) pain which was paroxysmal, brief electrical, or cutaneous pain in nature; (2) pain due to dental hard tissue disease, periodontal or mucosal pain or disease; (3) more than one of the following migraine-like symptoms: photophobia, nausea, an aura, visual scintillating scotoma, or a severe throbbing sensation; (4) a positive history of treatment for a migraine disorder within the past 3 years; (5) a prior TMJ surgical intervention; or (6) use of any prescription medication for their pain. Before beginning the study, all qualified subjects signed the "consent to act as a research subject" form which was approved by the Human Subjects Protection Committee of UCLA.

## Symptom-Based Questionnaire Data

Patients self-assessed their orofacial pain on a standard 100-mm-long visual analog scale (VAS) by placing a single mark that indicated the amount of their usual pain during the previous week. The VAS line was anchored on the left with the words "no pain" and on the right with the words "most intense pain imaginable." Jaw function interference was also rated using an 11-point scale which ranged from 0 = no abnormal jaw function to 10 =the most severe or abnormal jaw function imaginable. In an attempt to cross-validate the patients' orofacial pain and abnormal jaw function scores, a 13-item jaw pain/function questionnaire was employed.<sup>16</sup> Its questions allowed the patient to choose a category which rated their pain frequency and severity in different areas of the jaw and at different times of the day, and a single summary score was calculated. The McGill Pain Questionnaire was used to assess qualitative aspects of the

patients' pain, and three scores were obtained by summing the scale values for the sensory, affective, and evaluative categories.<sup>17</sup> Finally, the subjects also filled out the activity limitation scale, which is an 18-item form that assesses how much the subject's daily activities caused pain.<sup>18</sup> A single summary score was calculated.

# Psychological Questionnaire Data

Three additional predictor variables were derived from responses to two self-report psychological tests. These instruments were the Beck Depression Inventory<sup>19</sup> and the Spielberger State-Trait Anxiety inventory.<sup>20</sup> The Beck Depression Inventory is a 21-item self-rating measure of depression and provides a single summary score. The Spielberger State-Trait Anxiety inventory scale contains two subtests of 20 items each, measuring either state or trait anxiety.

## **Clinical Examination Data**

Clinical examinations were performed on every patient by one of two trained and calibrated examiners. First, jaw movement variables under study were pain-free opening, active mouth opening, and passive mouth opening. The opening movements were all performed with a millimeter ruler placed interincisally at the right central incisors. Incisal overbite measured in a position of maximum intercuspation was then added to the interincisal measurement for each movement. Second, the vibrations associated with TMJ noises were assessed by light digital palpation of the lateral capsule of the TMJ during opening and closing jaw movements. Click-like or crepitation-like joint sounds were noted as being absent or present in each joint (no = 0, present = 1). The joint noise examination  $\frac{1}{2}$ involved achieving agreement between both the patient and the examiners before a positive finding was recorded. Intermittent clicking which was not present at the time of the examination and all disagreements between the patient and examiner, were recorded as a no. Third, muscle and joint tenderness was assessed by direct finger pressure palpation. The finger pressure palpation involved compression of the superficial masseter, deep masseter, anterior temporalis, middle temporalis, lateral TMJ capsule, and dorsal TMJ capsule on each side of the face. Details of palpation sites have been described.<sup>21</sup> These palpations were performed in a sequential fashion on the right and left sides by using a 2-second constant force application with the examiners' index finger. The force level

Table 1 Subject Demographics								
Group	Number	Mean age ± SD	Gender ratio (females to males)					
All subjects	157	33.64 ± 12.48	6.85:1					
Males only	20	$34.05 \pm 12.84$						
Females only	137	33.58 ± 12.47						
Recall 1 group	107	33.90 ± 13.34	6.64:1					
Males only	14	$36.57 \pm 14.14$						
Females only	93	33.49 ± 13.25						
Recall 2 group	94	33.74 ± 13.80	7.55:1					
Males only	11	34.64 ± 12.72						
Females only	83	33.63 ± 14.01						
Declined participation	า 88	$31.37 \pm 10.24$	4.5:1					
Males only	16	$31.31 \pm 7.54$						
Females only	72	31.39 ± 10.81						

used during the palpation examination was established by calibration to be  $1.8 \pm 0.2$  kgf for muscle and  $0.8 \pm 0.2$  kgf for the joint sites. The patient was asked to score the elicited tenderness on a four-point scale: 0 = none, 1 = mild, 2 = moderate, or 3 = severe. Joint and muscle tenderness scores were derived by adding the scores obtained at the four muscle sites and two joint sites (on the same side).

## **Calibration of Examiners**

The two examiners were calibrated before the onset of the study and recalibrated periodically throughout the study by using the methods specified previously.<sup>22</sup> This calibration involved training on how to deliver the two finger pressure levels during the muscle and joint palpation examination and to reproducibly locate the specified muscle and joint sites. The examiners were tested periodically regarding their ability to perform these two tasks. Overall, the examiners achieved the mean performance level of 89.5% on testing with the target pressure range plus or minus 0.5 kg and were able to select the palpation sites within 7 mm with repeated testing.

### Treatment Protocol

The treatment protocol involved (1) occlusal appliances, (2) physical therapy procedures, and (3) over-the-counter (OTC) NSAIDs (the recommended NSAID was Ibuprofen) on an as needed basis. Specifically there were two visits associated with the initial insertion (visit 1) and second adjustment (visit 2) of a full arch acrylic occlusal appliance. All subjects received occlusal appliances and were instructed to use them for 24 hours a day, except during eating, for the first 2 weeks. After this they could reduce their use to nighttime only. In addition, each subject underwent from one to five additional visits which involved physical therapy treatment and instruction in a homebased exercise program which consisted of jaw and neck muscle stretching and jaw positional awareness exercises to be performed daily at home. Finally, every subject who tolerated these drugs was encouraged to use as needed OTC Ibuprofen (200 mg/day up to 1,000 mg/day) for a 6-week treatment period.

# **Outcome Variables**

In order to evaluate the treatment outcomes, four additional questions (two binary scores and two continuous scores) were given to the patients at the follow-up visit only. The first and second questions asked patients whether they felt the necessity of additional treatment and whether they actually did seek it. Those who answered "No" were assigned to the improvement group for each question. The third question asked patients to report their satisfaction level by scoring the 0 to 10 scale, where 0 = not satisfied at all, 10 = completely satisfied. The fourth question estimated the improvement of pain level by letting the patients mark a single mark on a VAS anchored on the left with the words "no pain improvement" and the right with "complete relief of pain". Those who rated their satisfaction as > 4/10 or those who rated their pain relief as > 49/100 were assigned to the improvement group. The last two outcome variables were derived from two of the pretreatment variables, which were repeated at recall. Again the change in the patient's current VAS pain and their activity limitation scale score as compared to these same scores before treatment was used as the continuous variable. As with the above four variables, improvement was defined as any reduction in the score that was < 49% of their initial score.

### **Statistical Analyses**

Multiple regression analyses were performed on the data set with the second recall exclusively since longer term results were considered more important. Multiple Logistic Regression analyses were performed using the 18 predictor variables against two binary outcome variables (necessity of additional treatment and seeking additional treatment). Multiple linear regression analyses were performed using the 18 predictor variables against four other continuous data outcome variables (P < .05). All

(Iviedian ± QD)				
Predictor	Declined group (n = 88)	Dropout group (n = 63)	Recall 2 group (n = 94)	Statistics
Pain-free mouth opening	37 ± 6	37 ± 7.5	40 ± 9	ns
Active mouth opening	47 ± 5.1	$46 \pm 5.8$	47 ± 7.3	ns
Passive mouth opening	$50 \pm 4$	$50 \pm 5.3$	49 ± 6	ns
Clicking	0 ± 0.5	$0 \pm 0.5$	$0 \pm 0.5$	ns
Sum of muscle palpation score (right)	6 ± 2.3	5 ± 1.8	5 ± 2	ns
Sum of muscle palpation score (left)	6 ± 2.5	$5 \pm 2.5$	$5 \pm 2.5$	ns
Sum of condyle palpation score (right)	2 ± 1	2 ± 1.5	1 ± 1.5	ns
Sum of condyle palpation score (left)	2 ± 1.5	$1 \pm 0.75$	1 ± 1	ns
VAS pain previous week	46 ± 25	44 ± 23	40 ± 22	ns
Jaw function interference	6 ± 2.5	$5 \pm 2.3$	7 ± 2	ns
Jaw pain questionnaire	NA	21 ± 7	18 ± 6.4	ns
McGill Pain Questionnaire (sensory)	NA	6 ± 5	$6.5 \pm 3.5$	ns
McGill Pain Questionnaire (affective)	NA	2 ± 1	2 ± 1	ns
McGill Pain Questionnaire (evaluative)	NA	$1 \pm 0.5$	$1 \pm 0.5$	ns
Activity limitation score	NA	11.5 ± 8	9 ± 5.5	ns
Beck Depression Inventory	NA	9 ± 5.5	6 ± 4.5	ns
Spielberger State-Trait Anxiety Inventory (state)	NA	$68 \pm 28.5$	56 ± 25.5	ns
Spielberger State-Trait Anxiety Inventory (trait)	NA	65 ± 33	63 ± 31.5	ns

Table 2	Pretreatment Data for Subjects who Declined to Participate, Dropout Subjects, and Recall 2 Subject
	(Median ± QD)

 $QD = quartile deviation, Q3 = quartile 3, Q1 = quartile 1, QD = \frac{1}{2}(Q3 - Q1).$ 

Statistics: Kruskal-Wallis test; NA = data not available; ns = not statistically significant.

these analyses were performed using the forward stepwise variable selection (*P*-in = .10, *P*-out = .05) by JMP5.11J (SAS Institute).

# Results

### **Dropouts and Follow-ups**

Eighty-two percent of the 157 enrolled subjects returned for an examination or sent in their questionnaire for at least one of the recall visits. Specifically, more than 87% of those subjects seen at the first recall had examination data but only 66% of those seen at the second recall had examination data. Actual data (either clinical examination and questionnaires or questionnaires only) were available on 107 subjects at recall 1 and 94 subjects at recall 2 (68% and 60% respectively, Table 1). The mean time from the first visit to the first follow-up was 13 months  $\pm$  4.7 and the second time point was 33.6 months ± 9.8. ANOVA comparisons contrasting the predictor variables between those subjects who declined to participate in the study, subjects who did not return for the second follow-up visit, and subjects who had data available at the second posttreatment follow-up visit revealed that there were no differences in their initial examination profile of signs and symptoms on any of the 18-predictor variables (Table 2).

### **Predictor and Outcome Variables**

The median ( $\pm$  quartile deviations; QD) scores for the 18-predictor variables recorded in this study before and at the two recall appointments after treatment are shown in Table 3. Two pretreatment columns are included since the number of subjects at each follow-up time point was different. The numbers of subjects who were scored "Yes" or "No" on the dichotomized outcome variables at the first and second recall visits after treatment are shown in Table 4. A Spearman's correlation matrix of the six outcomes showed no correlation above .595 with most being well below this level.

## **Multiple Regression Analyses**

The result of regression analyses showed that three of these 18 predictors were significantly associated with two of the six outcome variables, namely improvement in VAS pain and activity limitation score (which is an analog of pain). Specifically, a combination of initial VAS pain (positive correlation) and jaw function interference (negative correlation) was significantly associated with the change in VAS pain (Adjusted  $R^2 = 0.54$ , Initial VAS pain: estimate = 0.864, P < .0001; Initial jaw function interference: estimate = -0.660, P = .0070, Table 5) and a combination of initial activity limitation

Table 3 Pretreatment versus Post-Treatment Data for the Recalled Subjects (Median ± QD) Post-Subjects Subjects									
	Recall 1 group				Recall 2 group				
Predictors	Pretreatment	Posttreatment	n	Р	Pretreatment	Posttreatment	t n	Р	
Mouth opening									
Pain-free	$39 \pm 9.0$	46 ± 5.5	93	**	$40 \pm 9.0$	$46 \pm 5.8$	62	**	
Active	$45 \pm 7.0$	$49 \pm 4.5$	93	**	$47 \pm 7.3$	$49 \pm 5.0$	62	**	
Passive	$48 \pm 6.0$	$51 \pm 4.0$	93	**	$49 \pm 6.0$	$51.5 \pm 3.5$	62	**	
Clicking	$0 \pm 0.5$	$0 \pm 0.5$	93	ns	$0 \pm 0.5$	0 ± 0.5	62	ns	
Sum of muscle palpation score									
Right	5 ± 1.8	3 ± 2.5	93	**	$5 \pm 2.0$	3 ± 2.5	62	ns	
Left	4 ± 2.0	3 ± 1.5	93	**	$5 \pm 2.5$	$3.5 \pm 2.5$	62	*	
Sum of condyle palpation score									
Right	1 ± 1.5	0 ± 1.0	92	**	1 ± 1.5	0 ± 1.0	62	**	
Left	1 ± 1.0	$0 \pm 0.5$	92	**	1 ± 1.0	$0 \pm 0.5$	62	**	
VAS pain previous week	40 ± 25.0	$12 \pm 12.0$	97	**	40 ± 22.3	$15 \pm 15.0$	93	**	
Jaw pain questionnaire	$18 \pm 6.0$	$11 \pm 5.0$	98	**	$18 \pm 6.4$	$11 \pm 4.5$	82	**	
Jaw function interference	7 ± 2.0	2 ± 2.0	97	**	7 ± 2.0	2 ± 2.0	93	**	
McGill Pain Questionnaire									
Sensory	6 ± 4.0	$3 \pm 3.0$	99	**	$6.5 \pm 3.5$	$2.5 \pm 3.5$	92	**	
Affective	2 ± 1.0	0 ± 1.0	99	**	2 ± 1.0	0 ± 1.0	91	**	
Evaluative	$1 \pm 0.5$	$1 \pm 0.5$	99	**	$1 \pm 0.5$	$0 \pm 0.5$	91	**	
Activity limitation score	$10 \pm 5.9$	3 ± 2.3	98	**	9 ± 5.5	3 ± 3.0	92	**	
Beck Depression Inventory	$7 \pm 5.0$	4 ± 3.3	98	**	$6 \pm 4.5$	3 ± 3.0	90	**	
Spielberger State-Trait Anxiety Inventory	/								
State	62 ± 25.0	$56 \pm 28.0$	98	**	$56 \pm 25.5$	49 ± 30.0	92	**	
Trait	65 ± 31.5	47 ± 29.0	98	**	63 ± 31.5	59 ± 27.0	92	**	

Statistics: Wilcoxon test.

\**P* < .05; \*\**P* < .01.

Table 4 Outcome Variables								
	Recall 1 group				Recall 2 group			
Outcomes	Total no.	Improvement	No improvement	Success rate (%)	Total no.	Improvement	No improvement	Success rate (%)
No need for additional treatment	97	80	17	82.5	91	71	20	78.0
Did not seek additional treatment	97	89	8	91.8	93	85	8	91.4
Satisfaction with treatment (> 4/10)	98	79	19	80.6	92	74	18	80.4
Pain relief (> 49/100)	97	66	31	68.0	92	61	31	66.3
Reduction in VAS pain level* (> 49%)	77	51	26	66.2	78	41	37	52.6
Reduction in activity limitation score* (> 49%)	80	52	28	65.0	74	47	27	63.5

\* = as compared to this score before treatment began.

score (positive correlation) and jaw function interference (negative correlation) was associated with a change in the activity limitation score (Adjusted  $R^2 = 0.32$ , Initial activity limitation score: estimate = 0.681, P < .0001; Initial jaw function interference: estimate = -0.322, P = .0009, Table 5). No significant correlations were seen for any of the other physical examination data or for the two short psychological inventory data.

## Discussion

This study should clearly be considered an exploratory investigation of whether physical signs, questionnaire-based symptoms, and two short psychosocial inventories were related to response to treatment. Confirmatory studies would be done only after several studies such as this find and suggest a predictor-outcome relationship.

Table 5 Significant Models by Multiple Regression Analyses								
Outcome variable	Estimate	F-ratio	Probability					
Change in VAS pain*								
Intercept	-3.883	0.000	1.0000					
Initial VAS pain	0.864	109.427	< .0001					
Initial jaw function interference	-0.660	7.617	.0070					
Change in activity limitation score <sup>†</sup>								
Intercept	3.419	0.000	1.0000					
Initial activity limitation score	0.681	44.092	< .0001					
Initial jaw function interference	-0.322	11.900	.0009					
Adjusted $B^2 = 0.54 (P < .0001)$ .								

<sup>+</sup>Adjusted  $R^2 = 0.32 (P < .0001)$ .

Given this general cautionary note, based on the data collected, it is possible to reject the null hypothesis that pretreatment pain, dysfunction, and psychosocial depression and anxiety would not be related to a response to standard physical medicine care for TMD patients. However, it should be noted that only three variables of 18 possible predictors were found to be statistically associated with treatment outcome. These three variables were self-reported VAS pain, activity limitation score, and jaw function interference type data. Moreover, none of the pretreatment examination-based data nor the brief psychological inventory score data were able to predict the treatment outcomes. This fact raises the question of whether it is worthwhile for clinicians to bother collecting extensive pretreatment data, above and beyond that which is necessary for differential diagnosis. In other words, this lack of a relationship between the pretreatment data and these outcomes suggest that while the "more objective" physical examination data might be important for determining the specific features of the patients' TMD, they are not critical to any prediction of success or failure with the type of treatment provided in this study.

The treatment outcome data in this study were generally positive, with a large percentage of patients reporting good satisfaction with treatment and almost two thirds showing a 50% improvement in their VAS score at the first follow-up. However, this study was designed to analyze if any variable could predict this outcome, and was not designed as a treatment comparison study. The significant associations with outcome found in this study are interesting and if the corollary to these positive associations is also true, then those patients with lower initial pain (as measured by VAS or its analog, the activity limitation score) but with a higher initial jaw function interference score were less likely to have a substantial reduction in pain level with the treatment. These associations are reasonably predictive and indicate that such subjects with moderate jaw function interference as their primary problem should be under closer scrutiny and may have a worse prognosis with a standardized treatment program including insertion and adjustment of a full arch occlusal appliance, one to five visits of physical therapy including instruction in self-exercise methods to use at home daily, and as needed OTC Ibuprofen (200 mg/day up to 1,000 mg/day) for a 6-week treatment period.

The present overall outcome results are consistent with other such reports in the literature. For example, the percentages of patients requiring further treatment have varied but are always between 14% and 34%.<sup>5-8,23,24</sup> Although the treatments being used are somewhat different with each study, these prior studies generally always used a physical medicine model for their TMD treatment program. In the present study, only 8.6% of the follow-up subjects reported actually having sought additional care, but it seems likely that the rate of outside treatment-seeking would have been higher if all subjects enrolled had participated in the follow-up. These data are not unexpected since many of the clinical problems with TMD are not "cured" but instead "managed" by a general physical medicine program.

It is well known that TMD treatment outcomes are influenced by the natural course of the condition. For example, Kamisaka et al, who investigated a nonpatient population reported that more than half of the subjects who had reported TMJ and neck pain at the initial survey no longer reported these symptoms at the second survey that was conducted 4 years later, whereas TMJ noise and shoulder stiffness remained in more than 70% of the subjects.<sup>25</sup> As illustrated in Table 3, pretreatment conditions in the present study were consistently improved at both first and second follow-up periods except for joint clicking and muscle pain score on the right side at the second follow-up, but unfortunately there were no data on how much of these improvements could have been the result of the treatment protocol rather than the natural course of the patients' condition. Since this was not a study about the efficacy of a treatment protocol, such research questions should be addressed in future studies.

Regarding the limitations of this study, information was not collected on how well the patients adhered to the treatment protocol. Since the majority of the patients' symptoms were successfully managed by the initial treatment, it can be speculated that most of them stopped using the appliances and NSAIDs but, unfortunately, accurate data on the adherence are not available. In addition, while it would have been better to gather more data from more subjects, the present study should clearly be considered an exploratory investigation for predictors of TMD treatment outcome as stated above, and the proof of any predictor's utility should be determined in subsequent studies. The combination of multiple studies recommending the same predictor is where power is determined. No single report of a predictor or set of predictors can achieve this goal, but the beginning of the process starts with a single study suggesting items that might be predictive.

The strengths of the current study are that it employed a multiple dimensional method to assess outcome and utilized a calibrated clinical examination, a longer recall period, and actual examinationbased follow-up data. Moreover, the current study had far more consistency in treatment protocol than the authors' earlier TMD treatment outcome study<sup>15</sup> since it was conducted by a private practice with only one treating doctor and one physical therapist rather than in a combined graduate student/faculty clinic setting as was done in the prior study. Finally, because of the authors' prior experience with TMD outcome studies,<sup>8,15</sup> they were aware that dropouts would be a problem with any recall point beyond 1 year. To minimize the problem, it was necessary to exclude noncomplaint subjects at enrollment. This was done by requiring that all enrolled subjects complete the 3-hour long battery of psychosocial tests prior and be willing to

and agree to seek their treatment at the clinic before enrollment. While these selection criteria and the dropouts make the resultant study sample less generalizable to all patients, it would be impossible to harvest a higher follow-up rate in a large urban center without a larger monetary incentive to participate. The specific mitigating factors that dictate noncompliance to treatment have been reported.<sup>26,27</sup> Unfortunately the present study did not collect systematic information from the dropouts but, based on the discussions with these patients, it can be speculated that some simply had an objection to taking psychological content tests in a repeated fashion or lacked the resources to continue treatment. The study's approach yielded a 68% and 60% follow-up rate at the two recall points, respectively. It could be argued that these missing data weaken any conclusions drawn from this study, but the data are true prospective data and dropouts are an unfortunate part of any such study. Over the time period involved in this study, the recall rate is reasonably good for an urban environment such as Los Angeles. Secondly, the fact that as the study progressed a larger percent of subjects were missing physical examination data (mailed questionnaires only) does not appear to be of great consequence to most of the treatment outcomes. Specifically it can be seen that more than 87% of those subjects seen at the first recall had examination data but only 66% of those seen at the second recall had examination data (Table 3), yet the physical findings and symptom findings at these two time points (which were available for all recalled subjects) were consistent. This consistency argues that the missing physical examination data do not remarkably bias the outcome of the study. For all these reasons and within the above-stated limitations, the data reported herein should be generalizable to most patients in a limited to TMD and orofacial pain-based private practice.

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