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## Self-reported remission, difficulty, and satisfaction with nonsurgical therapy used to treat anterior disc displacement without reduction

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**Objective.** The purpose of this study was to identify the appropriate treatment element for initial anterior disc displacement without reduction subjects.

**Study design.** Sixty-nine consecutive patients with temporomandibular joint disc displacement without reduction confirmed on magnetic resonance images were randomly divided into 3 experimental treatment groups. The treatment of group 1 consisted of short-term nonsteroidal anti-inflammatory drugs and self-care instructions (palliative care group); group 2, nonsteroidal anti-inflammatory drugs, self-care instructions, and occlusal appliance and mobilization therapy (physical medicine group); and group 3, no treatment (control group). Outcomes were assessed by means of a 5-item questionnaire that evaluated (1) symptom improvement, (2) difficulty of treatment, and (3) satisfaction with treatment during the 8-week observation period.

**Results.** Improvement scores in the palliative care group were significantly better than those in the physical medicine group or the no-treatment group. Satisfaction scores showed no significant difference among the 3 groups. Difficulty from treatment for the physical medicine group was significantly greater than that for other 2 groups.

**Conclusion.** These data suggest that palliative care would be more appropriate as the initial therapy to treat painful anterior disc displacement without reduction.

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The recent literature on temporomandibular disorders (TMDs) contains several well-considered randomized clinical trials.<sup>1-6</sup> However, only a few researchers have examined nonsurgical treatment for patients with temporomandibular joint (TMJ) disc displacement without reduction (DDwor).<sup>7-9</sup> Lundh et al<sup>7</sup> were the first to conduct a randomized clinical trial on 51 subjects with arthrogram-confirmed DDwor of the TMJ. They reported that several outcome variables for patients

(n = 25) using a nonrepositioning, flat occlusal appliance at night for 12 months were not as good as those for patients (n = 26) in a limited-treatment (ie, counseling and pain medications as needed) control group. Yuasa et al<sup>8</sup> also conducted a randomized clinical trial on 60 patients (2 groups of 30 patients each) with DDwor of the TMJ confirmed by means of magnetic resonance imaging (MRI). They reported that 1 group received a combination of a nonsteroidal anti-inflammatory drug (NSAID) plus instructions on how to stretch the jaws at home for 4 weeks, whereas the comparison group received only an explanation of the MRI findings. Furthermore, they noted significant group differences, with greater improvement in maximum mouth opening ( $P = .005$ ) and the interference-with-life score ( $P = .04$ ) seen in the NSAID plus self-stretching treatment group. Finally, Minakuchi et al<sup>9</sup> conducted a randomized clinical trial on patients with TMJ-DDwor confirmed through MRI. They set up 3 treatment groups: a control group (ie, receiving observation and education only), a palliative care group (ie, receiving education, an NSAID, and home care), and a physical medicine group (ie, receiving palliative care plus interocclusal appliances and active jaw mobilization therapy in the office). Patients in all 3 treatment groups demonstrated an equivalent mean gradual reduction of the signs and symptoms over the 8-week study period, but no statistically significant group differences in either visual analog scale (VAS) pain intensity levels or jaw mobility measurements were evident.

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Overall, these 3 randomized clinical trials suggest that no specific nonsurgical treatment element applied to patients with TMJ DDwor has consistently been shown to be critical to a positive outcome. Instead, it would be logical to conclude that simply the passage of time and the nonspecific effect of undergoing treatment are important. One aspect of treatment comparison studies that is often overlooked is the relative rate of complications from, satisfaction with, and the difficulty from various treatments. Such patient-oriented assessments are important because they reveal the quality of life during this difficult period. Moreover, information about the negative aspects and the financial toll of treatment is critical to any subsequent evidence-based decision process.<sup>10-12</sup> For all of these reasons, the current study was designed to document and present the patient-reported degree of symptom improvement, difficulty from, and satisfaction with treatment data collected through a self-administered questionnaire during an earlier randomized clinical trial.<sup>9</sup>

## PATIENTS AND METHODS

### Study population

The subjects were selected from a consecutive series of patients with DDwor of the TMJ (232 patients; male-to-female ratio, 55:177) who attended the TMD clinic at Okayama University Dental Hospital (Japan) from March 1997 to July 1998. This sample was a non-probability-based convenience sample with limited generalizability to a general population. Eligible subjects were those with painful DDwor who were selected according to the following inclusion criteria: (1) a report of pain with mouth opening or chewing difficulty, or both; (2) mouth-opening pain in the affected TMJ region at a level of more than 10/100 mm on the VAS of pain; (3) a positive diagnosis of DDwor of the TMJ on the affected side made by means of MRI according to the operational criterion (*IZ criterion*) described by Orsini et al.<sup>13</sup> The subjects were excluded if they presented with 1 or more of the following conditions: (1) were unwilling or unable to participate in the experiment and attend all planned follow-up evaluations for any reason; (2) were edentulous; (3) had serious systemic disease that would potentially compromise the experiment (eg, rheumatism, diabetes mellitus); or (4) had undergone or were undergoing treatments for their TMDs or tooth problems (eg, medication, intraoral appliance therapy, or dental restorative work) in other clinics. The appropriate committee to protect human subjects (an institutional review board) at the university approved the experimental protocol, and informed consent was obtained from each subject before the commencement of this study. All participants in this study were told that the most effective

therapeutic option for this disorder remains unknown and that this study was being conducted to clarify which therapeutic option is most practical and effective for relieving the symptoms of anterior DDwor.

### Randomization process

The disk displacement without reduction subjects were allocated randomly by a principal investigator (H.M.) to 1 of the 3 groups—ie, the control, palliative care, or physical medicine group—using a computer-generated false random-number method.

### Treatment groups

Patients in all 3 groups were shown the MRI images of their TMJs and provided an explanation of these findings with respect to the prevalence and prognosis of this disorder and the self-limiting nature of its signs and symptoms. The control group subjects received only the aforementioned explanation and advice regarding the prognosis. The palliative care group subjects were prescribed diclofenac sodium (Voltaren<sup>®</sup>; CIBA-GEIGY, Tokyo, Japan), an NSAID, to be taken 3 times/day in 25-mg doses, in addition to a gastroprotective agent (aldioxa, Isalon Granules<sup>®</sup>, Takeda, Osaka, Japan) to be taken 3 times/day in 600-mg doses. The subjects were also instructed in self-management, consisting of the use of a cold or hot pack, following a soft food diet, and performing gentle mouth-opening exercises. Those in the physical medicine group were treated with a flat occlusal appliance and active jaw mobilization therapy, in addition to the same therapies given to those in the palliative care group.

The findings, prevalence, prognosis, and medication and self-management procedures were discussed and the insertion and adjustment of all appliances were performed by the same trained dentist (H.M.); furthermore, this dentist had also been instructed not to discuss the relative merits of these treatments with any participant. All appliances were fabricated and adjusted to have maximal contacts in the centric occlusion and provided symmetric anterior contacts in a protrusive movement of the mandible and canine guidance in lateral jaw movement. The subjects were instructed to wear the appliances while sleeping and remove them during the day. The same trained dentist (H.M.) also performed manual jaw mobilization therapy at every follow-up examination (ie, 2, 4, and 8 weeks later), in the manner described by Farrar and McCarty.<sup>14</sup> This maneuver was accomplished by applying force downward with the thumb on the lower posterior teeth while pushing the patient's chin upward with the other hand (by firmly grasping the lower incisors and the lower border of the chin). The patient was instructed to relax the masticatory muscles for the procedure; also, during the first part of



**Table I.** The median and confidence interval of improvement scores among the 3 experimental groups

Experimental groups	Self-estimated improvement scores*		
	2 wk <sup>†</sup>	4 wk <sup>†</sup>	8 wk <sup>†</sup>
Physical medicine (n = 25)	3 (2.993-3.507) <sup>‡</sup>	3 (3.129-3.787)	3.5 (3.237-3.846)
Palliative care (n = 23)	4 (3.412-4.133)	4 (3.494-4.233) <sup>‡</sup>	4 (3.416-4.220) <sup>‡</sup>
Control (n = 21)	3 (2.881-3.500) <sup>‡</sup>	3 (2.586-3.224)	3 (2.812-3.474)
P value <sup>§</sup>	.04	<.01	.05

\*Median ( $\pm$ 95% confidence interval).<sup>†</sup>Follow-up time points after start of treatment.<sup>‡</sup>Statistically significant ( $P < .05$ ).<sup>§</sup>P values were calculated by using the Kruskal-Wallis test.**Table II.** The median and confidence interval of satisfaction scores among the 3 experimental groups

Experimental groups	Self-estimated satisfaction-with-treatment scores*		
	2 wk <sup>†</sup>	4 wk <sup>†</sup>	8 wk <sup>†</sup>
Physical medicine (n = 25)	3 (3.027-3.723)	3.5 (3.005-3.828)	3.5 (3.044-4.039)
Palliative care (n = 23)	3 (2.735-3.719)	4 (3.291-4.164)	4 (3.250-4.205)
Control (n = 21)	3 (2.711-3.384)	3 (2.754-3.531)	3 (3.202-3.940)
P value <sup>‡</sup>	.40	.11	.83

\*Median ( $\pm$ 95% confidence interval).<sup>†</sup>Follow-up time points after start of treatment.<sup>‡</sup>P values were calculated by using the Kruskal-Wallis test.

7:62; mean age,  $34.0 \pm 15.4$  years; unilateral-to-bilateral dysfunction ratio, 50:19).

### Group equality and the drop-out effect

Group equality was demonstrated in that no group differences were found among the 3 experimental treatment groups with regard to age, locking duration, the pretreatment daily activity limitation score,<sup>17</sup> or their VAS pain scores.<sup>9</sup>

During the observation period, 8 subjects discontinued the treatment without prior consent or any explanation being offered (1 woman at the 2-week follow-up and 7 women at the 4-week follow-up). Four of these subjects were assigned to the physical medicine group, and 2 subjects each were from the palliative care group and the control group. An additional 2 subjects were also excluded from the study because they required arthrocentesis. If these 10 dropout subjects were excluded, the experimental compliance rate of this study was 85.5% (59/69). An intention-to-treat analysis was conducted to evaluate the potential benefit to subjects enrolled in the treatment arm of the study, regardless of whether they completed the study. To evaluate the effect of the dropout on group equality, the age, daily activity limitation score, and the severity of the signs and symptoms at baseline were compared between the intended (including the dropout subjects) and the actual samples (not including the dropout subjects). No statistically significant differences were identified in the tested parameters.

### Group difference in improvement, satisfaction, and difficulty scores

With regard to the median improvement score, the patients receiving palliative care had the highest score ( $P = .04$ ,  $P < .01$ , and  $P = .05$  at the 2-week, 4-week, and 8-week observation points, respectively) among the 3 groups at every follow-up time point (Table I). No significant differences were found in satisfaction scores among the 3 experimental groups (Table II). On the difficulty scale (Table III), the physical medicine group had the highest score ( $P = .05$ ,  $P = .01$ , and  $P = .03$  at the 2-week, 4-week, and 8-week observation points, respectively).

### DISCUSSION

The protocol we labeled *palliative* (owing to the use of NSAIDs and a cold or hot pack, following a soft diet, and performing gentle mouth-opening exercises at home) was shown to produce a significantly higher degree of improvement than the control treatment at 2 months. The difficulty of treatment was reported as less in this group than in the physical medicine treatment group at 2 months. All treatments achieved an equivalent degree of patient satisfaction at 2 months.

In our earlier study yielding these data,<sup>9</sup> all the experimental treatment groups exhibited a similar significant change (ie, improvement) in mouth-opening dimension and VAS pain intensity over time. No significant group differences were disclosed during this experiment, and the only significant group difference

**Table III.** The median and confidence interval of difficulty scores among the 3 experimental groups

Experimental groups	Self-estimated difficulty of treatment scores*		
	2 wk <sup>†</sup>	4 wk <sup>†</sup>	8 wk <sup>†</sup>
Physical medicine (n = 25)	1 (1.652-5.681) <sup>‡</sup>	2.5 (2.150-7.017) <sup>‡</sup>	1.5 (1.335-5.748) <sup>‡</sup>
Palliative care (n = 23)	0 (0.048-2.225)	0 (0.124-2.058)	0 (-0.051-2.051)
Control (n = 21)	0 (0.035-2.727)	0 (0.228-3.677)	0 (-0.090-1.995)
P value <sup>§</sup>	.05	.01	.03

\*Median ( $\pm$ 95% confidence interval).

<sup>†</sup>Follow-up time points after start of treatment.

<sup>‡</sup>Statistically significant ( $P < .05$ ).

<sup>§</sup>P values were calculated by using the Kruskal-Wallis test.

observed was on a subjective 18-item questionnaire, in the category of daily activity limitation. This variable showed that the palliative care group (self-care/NSAID) had experienced significantly more change than the other 2 groups ( $P = .029$  at the 4-week observation point). These data plus the additional data reported in this article suggest that although occlusal appliances are not generally harmful, they might be inappropriate to treat patients with recently confirmed DDwor because of the cost and potential for harm (eg, bite changes). A more conservative approach of short-term NSAIDs and gentle self-applied stretching of the jaw at home is more logical. We believe that this conclusion is also supported by the other 2 randomized clinical trials conducted on subjects with a TMJ DDwor diagnosis.<sup>7,8</sup> Finally, a nonrandomized, retrospective analysis of treatment procedures, by Stiesch-Scholz et al,<sup>18</sup> also indicated that the treatment involving an NSAID and diazepam was better than an occlusal appliance alone or in combination with office-based jaw mobilization therapy for 72 patients with TMJ DDwor confirmed by means of MRI.

One well-known limitation of any self-estimate of change questionnaire is that the patient may not remember the original level of the variable being asked about (eg, pain).<sup>19</sup> In such cases, the estimate of change is potentially distorted. Moreover, this distortion is likely in a single direction—namely, they often report more change than actually was present. In this study we did collect VAS and millimeter ruler data on pain levels and mouth opening, in addition to the questionnaire data, in which more subjectivity is present. The data for both the objective measures (presented in our earlier article) and the subjective questionnaire-based responses (described in this article) are actually quite similar, with only minor exceptions. Because of this and the relative short period of the study (maximum of 4 weeks), we do feel that the data we report here are reasonably representative of the subjects' attitudes about the treatment they received and therefore worthwhile matter for study.

We performed power calculations on our 3 outcomes by using the existing sample size in hopes of assessing

whether our study has sufficient statistical power to certify a negative result. The power for the improvement score, satisfaction score, and difficulty score analyses were 0.83, 0.31, and 0.70, respectively. These levels suggest that a type-2 error was less likely for the improvement and difficulty scores, but that the satisfaction score outcome clearly has insufficient power. We found that it would be necessary to have 450 patients in each treatment group to achieve adequate power. This large sample size simply demonstrates that the group differences were extremely slight.

We recognize that these treatments still need to be compared in a randomized blinded clinical trial that includes intracapsular therapy with arthrocentesis to determine whether they offer equivalent improvement in a head-to-head comparison with this form of treatment. However, if arthrocentesis is not considered, the palliative protocol seems to offer the best approach, as this analysis proves.

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