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# Occlusal stabilization appliances

## Evidence of their efficacy

MARCELO KREINER, D.D.S.; EDWIN BETANCOR, D.D.S.; GLENN T. CLARK, D.D.S., M.S.

**A** 1997 review by Raphael and Marbach<sup>1</sup> suggested that decisions regarding treatment for a patient should be based on rules of evidence whenever possible. While this statement is true, it is easier said than done. For example, deciding when and how to treat patients with temporomandibular disorder, or TMD, according to the evidence actually is quite difficult. This difficulty stems from the fact that there is a large amount of literature available on the topic and interpreting it correctly is not always intuitive.

**Occlusal appliances do have sufficient evidence to support their use for the management of localized myalgia or arthralgia of the masticatory system.**

A search of the MEDLINE database from January 1995 to April 2001 using the search term “temporomandibular disorders” yields 1,633 published articles. This amount of information makes it difficult for experts to achieve consensus on the meaning of the data. For example, in 1996, the National Institutes of Health convened a technology assessment conference on the management of TMDs. After three days of presentations and a large amount of documentation was submitted by experts, this independent panel concluded that “the preponderance of the data do not support the superiority of any method

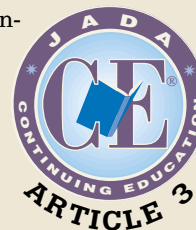
for initial management of most TMD problems. Moreover, their superiority to placebo controls or no treatment controls remains undetermined.”<sup>2</sup> The panel also concluded that “the efficacy of most treatment approaches for TMD is unknown, because most have not been adequately evaluated in long-term studies and virtually none in randomized controlled group trials.” One possible interpretation of this report is to conclude that until the more traditional forms of TMD therapy (for

**Background.** There is substantial controversy regarding the value of occlusal appliances for managing temporomandibular joint disorders. This article specifically assesses whether the evidence is sufficient to judge occlusal appliances as being efficacious for the management of localized masticatory myalgia, arthralgia or both. A major confounder is that few studies have measured or evaluated whether subjects had strong, ongoing parafunctional activity (such as clenching or grinding) and whether appliances influenced this behavior.

**Literature Reviewed.** The authors evaluated four placebo-controlled studies, several randomized wait-list controlled studies and several random-assignment treatment-comparison studies. Data from the wait-list condition studies vs. those from the occlusal appliance condition studies consistently suggested that the latter treatment’s effect on patient symptom level is far more than that of no treatment on a wait-list group’s condition. In contrast, the studies on placebo-controlled vs. occlusal appliance studies yielded a mix of data: two showed a positive benefit of occlusal vs. nonoccluding appliances, and two showed a null effect or no difference.

**Conclusions.** Considering all of the available data (pro and con), the authors conclude that the use of occlusal appliances in managing localized masticatory myalgia, arthralgia or both is sufficiently supported by evidence in the literature.

**Clinical Implications.** The mechanism of action by which occlusal appliances affect localized myalgia and arthralgia probably is behavioral modification of jaw clenching. However, if the behavior continues unabated, even the best splint will not work.



example, physical therapy and occlusal appliance therapy) are shown to be better than an inactive placebo condition, there is insufficient evidence to justify using them.

Raphael and Marbach<sup>1</sup> reviewed the research literature on occlusal appliances for TMD and explicitly stated that “most controlled studies conclude that appliances are not effective.” In 1998, a second review was published on occlusal appliance therapy, and it concluded that “the results of controlled clinical trials lend support to the effectiveness (that is, the patient’s appreciation of the positive changes that are perceived to have occurred during the trial) of the stabilization appliance in the control of myofascial pain.”<sup>3</sup> This conclusion appears to contradict the interpretation made by Raphael and Marbach,<sup>1</sup> with the latter concluding from essentially the same data that “occlusal appliances were not effective for treating patients with TMD.”

The intent of this article is to evaluate which conclusion is more logical with regard to one specific area of TMD treatment, namely occlusal appliances. We have selected this area because there have been multiple long-term treatment outcome studies (albeit uncontrolled) and several placebo-controlled or comparative-treatment studies published on this topic, and there still is substantial controversy regarding the efficacy of this method. We attempt to specifically address the question, “Do occlusal appliances have sufficient evidence to support or reject their use for the management of localized myalgia and/or arthralgia of the masticatory system?”

## UNDERSTANDING PLACEBO AND PLACEBO EFFECTS

Our review begins by first defining what a placebo is and what some of the important biopsychological mechanisms associated with placebos in the context of TMD therapy are. We believe these definitions have a big effect on the interpretation of the published evidence. In general, there is a wide scientific debate about these definitions; some authors have even proposed that the terms “placebo” and “placebo effects” should be abandoned.<sup>4(pp167-95)</sup>

“Placebo” usually is defined as “an intervention designed to simulate medical treatment, but it is not believed by the investigator to be a specific

therapy for the target condition.”<sup>4(pp167-95)</sup> It typically is used to control or reduce observer bias, as well as time-based effects (that is, regression to the mean) in clinical research studies. Controlling for time effect is important, as most patients with pain experience improve simply because they seek care during the flareup periods, and the pain level tends to go down to a mean level after this point.<sup>5</sup>

A “placebo effect” is when the placebo, which cannot on its own merit have any effect, does in fact have the same effect as the experimental substance or procedure. It has been reported that even when subjects are aware that one of the treatments is a placebo, one-third still will have a positive response.<sup>6</sup>

The percentage of subjects responding to placebo treatment actually is quite variable across studies.<sup>7</sup> When subjects are unaware they could be having a placebo response, the treatment success rate is higher than one-third. For example, one study reported that 64 percent of patients who underwent mock tooth-grinding as a treatment for myofascial pain had good improvement and symptoms remission.<sup>8</sup> Like active medications, placebos also are known to have side effects such as headaches, insomnia, nausea and drowsiness.<sup>9</sup> Moreover, the presentation characteristics of the placebo, or sham, therapy are themselves important to the response. For example, injected placebo medications will have larger effects than those administered orally,<sup>10</sup> and bigger capsules tend to be stronger placebos than small capsules.<sup>11</sup>

As these data indicate, the hypothesis that a placebo is an inactive, inert intervention without effect does not agree with the available data. Most likely, the effects produced by a placebo intervention are the result of the bio-behavioral effects that being in a study induces. For example, Pavlov was first to report that behavioral conditioning was a powerful intervention mediated by neural learning and association. Specifically, he described conditioned placebo effects in experimental dogs that showed a morphine-like response after simply being placed in the experimental site where they had previously received morphine. The results of several studies give support for the conditioning theory in ani-

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**A ‘placebo effect’ is when the placebo, which cannot on its own merit have any effect, does, in fact, have the same effect as the experimental substance or procedure.**  
 .....

mals<sup>4(pp288-305),4(pp306-23),12-14</sup> and in humans.<sup>15-21</sup>

Some authors believe that the patients' cognitive expectancy or belief that the treatment will be effective plays a vital role in the placebo response and is invoked in any study in which outcomes can be influenced by the investigator's behavior.<sup>22-23</sup> In fact, the effect of expectation fulfillment can be so powerful that it can override the active medication's true pharmacological effect.<sup>24-26</sup> This response would explain why knowing they might receive a placebo generates a placebo response in subjects only one-third of the time, but their being unaware of the placebo option produces a much higher placebo response rate. This concept is called the "Hawthorne effect" and is defined as the tendency for people to change their behavior in a predicted direction because they are the focus of a study.<sup>27</sup> This effect implies that study participation itself powerfully influences the outcome.<sup>28</sup> In several clinical studies, this phenomenon has been observed not only in subjects but also in care providers. One study's authors concluded—based on their data—that the phenomenon of altered behavior or performance occurred as a direct result of being a part of an experimental study.<sup>29</sup> Another study's authors concluded from their research that the Hawthorne effect can be induced without even requiring direct observation of the subject by the investigator.<sup>30</sup> They stated, however, that it does require a perceived demand for performance (that is, an expectation).

In summary, behavioral scientists consider a context-conditioned response to be a real physiological effect, mediated by our complex neurochemistry and not an inactive, inert intervention. For these reasons, it may be necessary to reconsider placebo therapy provided within a formal research study as an active behavioral intervention.

**OCCUSAL APPLIANCE THERAPY: ITS EVIDENCE**

Two unresolved issues associated with occlusal appliance treatment are identifying the mechanism of an occlusal appliance when used for myalgia and arthralgia problems in the jaw and determining its efficacy. While determining the occlusal appliance's mechanism will require new cleverly designed research studies, existing data

(Table) can approach the efficacy question.<sup>3,31-39</sup>

Traditionally, the strongest evidence for efficacy is considered to be controlled, randomized experimental research. There have been four placebo-controlled studies, several no-treatment or wait-list controlled studies and several random assignment treatment comparison studies evaluating occlusal appliances against alternative methods.

**Placebo appliance-controlled studies.** The first study in which a nonoccluding appliance was used as a control condition did not use a second (randomly assigned) treatment as a comparison.<sup>31</sup> Instead, the researchers used a sequential treatment design, providing the nonoccluding appliance as the first intervention (n = 71) for what they defined as a myofascial pain dysfunction, or MPD. Subjects with MPD were defined as those who had one or more of the following symptoms: facial pain;

It may be necessary to reconsider placebo therapy provided within a formal research study as an active behavioral intervention.

temporomandibular joint, or TMJ, clicking; deviation; and even limited opening. Symptoms did not include clinically evident osteoarthritis, or OA, problems. Except for excluding the subjects with OA, this group could best be described as an undifferentiated TMD clinic population. For the subjects who did not improve completely with the nonoccluding appliance, the researchers added additional acrylic to the appliance to

make it an anterior bite plane only (n = 60). Finally, researchers again modified the appliance to be a traditional full-arch occlusal appliance for those who did not improve completely (n = 44). The subjects did not know that the nonoccluding device was a placebo or minimally active intervention. Success—defined as complete, great or slight improvement—at the first stage of the study (nonoccluding appliance) was achieved in 28 of 71 subjects (39 percent). The next two phases of the study produced additional subjects who reported further improvement. The data showed that 30 of 60 subjects (50 percent) and 35 of 44 subjects (80 percent) showed improvement or success on the anterior plane and on the full-arch appliance, respectively. Comparative group statistical analysis was not performed. These data hint at the fact that the impact of the occlusal appliance is a combination of behavioral intervention (the nonoccluding appliance) and a mechanical effect produced by altering the occlusal rest position of the jaw.

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TABLE

A SUMMARY OF OCCLUSAL APPLIANCE STUDIES.						
STUDY	TYPE	DURATION*	OUTCOME MEASURES†	SUBJECTS‡	RESULTS§	GROUPS
Greene and Laskin <sup>31</sup>	Within-group, placebo-controlled, comparative-sequential	INP	Subjective symptom questionnaire	TMD minus OA	NOA = 40% improvement, ABP = 50% improvement, SOA = 80% improvement	NOA (n = 71), ABP (n = 60), SOA (n = 44)
Dahlstrom and colleagues <sup>32</sup>	Between-groups, randomized, comparative	One month	Clinical dysfunction index, subjective scales	TMD	SOA = BF	SOA (n = 15), BF (n = 15)
Okeson and colleagues <sup>33</sup>	Between-groups, randomized, comparative	Four to six-week follow-up	Muscle palpation score (0-3), ROM, others	TMD	SOA > SRT	SOA (n = 12), SRT (n = 12)
Rubinoff and colleagues <sup>34</sup>	Between-groups, randomized, placebo-controlled, double-blind	INP	Pain scales (0-5), muscle palpation score (0-3), others	TMD minus OA	SOA = NOA (no difference)	SOA (n = 15), NOA (n = 13)
Johansson and colleagues <sup>35</sup>	Randomized, comparative, wait-list controlled	12 weeks (treatment), eight weeks (control)	VAS, subjective dysfunction score (1-5)	TMD minus OA	SOA = ACUP (no difference); SOA + ACUP > WLC ( <i>P</i> < .01)	SOA (n = 15), ACUP (n = 15), WLC (n = 15)
List and colleagues <sup>36</sup>	Randomized, comparative, wait-list controlled	Six-eight weeks	VAS, others	TMD of muscular origin	ACUP > SOA ( <i>P</i> < .001); SOA + ACUP > WLC ( <i>P</i> < .01)	SOA (n = 40), ACUP (n = 40), WLC (n = 30)
Turk and colleagues <sup>37</sup>	Randomized, comparative, wait-list controlled	Six-month follow-up	Pain severity scale, muscle palpation (yes/no), others	TMD	SOA = BF/SM; SOA + BF/SM > WLC ( <i>P</i> > .001)	SOA (n = 28), BF/SM (n = 30), WLC (n = 30)
Dao and Lavigne <sup>3</sup>	Randomized, placebo-controlled double-blind	Eight weeks	VAS	Myofascial pain only	SOA = NOA = PC; time effect, <i>P</i> < .001; treatment effect, <i>P</i> = NS <sup>§**</sup>	PC (n = 19), NOA (n = 20), SOA (n = 22)
Wright and colleagues <sup>38</sup>	Randomized, comparative, controlled	Four-11 weeks	Subjective symptom index, ROM, muscle palpation	Masticatory muscle pain	SS > PT and WLC ( <i>P</i> < .05)	SS (n = 10), PT (n = 10), WLC (n = 10)
Ekberg and colleagues <sup>39</sup>	Randomized, placebo-controlled, double-blind	10 weeks	VAS, muscle palpation score (0-3), others	TMJ pain	SOA > NOA (daily pain, <i>P</i> = .02) (subjective symptoms, <i>P</i> = .006)	SOA (n = 30); NOA (n = 30)

\* INP: Information not provided.  
 † ROM: Range of motion; VAS: visual analog scale.  
 ‡ TMD minus OA: Temporomandibular disorder minus osteoarthritis; TMD: temporomandibular disorder; TMJ: temporomandibular joint.  
 § NOA: Nonoccluding appliance; ABP: anterior bite plane; SOA: stabilization occlusal appliance; BF: biofeedback; SRT: simplified relaxation therapy; ACUP: acupuncture; WLC: wait-list control; BF/SM: biofeedback/stress management; PC: passive control; SS: soft splint; PT: palliative therapy.  
 \*\* NS: Not significant.

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Another author team conducted the first random-assignment placebo-controlled study of occlusal appliances for MPD.<sup>34</sup> They used inclusion and exclusion criteria similar to the previously criteria<sup>31</sup> described. One subject group received traditional occlusal appliances (n = 15) and the others a nonoccluding placebo appliances (n = 13). The results of this study showed improvement in both groups and that there were no statistically significant pre- to- posttreatment differences between the two groups.

In partial agreement with these data is a 1994 study in which the researchers conducted a larger eight-week treatment study using three randomly assigned subject groups: full-arch occlusal coverage appliance (n = 22), nonoccluding palatal-only appliance (n = 20) and a full-arch occlusal coverage appliance that was worn only in the dental office at each of the five follow-up study visits (n = 20).<sup>40</sup> Unlike the two previous studies we discuss, in this study, the only subjects studied were ones who had frequent facial pain and jaw muscle tenderness on palpation. Researchers excluded patients with TMJ clicking, locking or OA symptoms. They did not describe or measure any parafunctional behaviors in their subjects nor did any of the other studies. The results of this study showed that there was a general reduction in the pain ratings during the treatment. No between-group difference was found at the end of the study, but there were statistically important differences at weeks three and five. The researchers concluded that occlusal appliances should be regarded as an adjunct to pain management rather than as a definitive treatment.

Another more recent study evaluated occlusal appliance therapy vs. a control nonoccluding appliance using a double-blind protocol in patients with TMD.<sup>39</sup> Patients were randomly assigned to one of the two equal groups of 30 subjects. These subjects were described as having a history of TMJ pain, which was verified by interview and clinical examination. In this study, as opposed to the three previous studies we discuss, improvement of overall subjective symptoms was reported significantly more often in the treatment group than in the control group ( $P = .006$ ). Moreover, there was a significant reduction in the frequency of daily or constant pain in the treatment

group ( $P = .02$ ) compared with the control group.

There are several caveats or confounders that must be considered when interpreting the data discussed in this section. First, the two studies that reported a positive result<sup>31,39</sup> used inclusion and exclusion criteria that were not very specific (excluding only OA). In contrast, the other two “no-difference” studies<sup>34,40</sup> used a more narrowly defined study population, with the former using only patients with myofascial pain and the latter using only subjects with confirmed capsulitis. These differences in inclusion criteria might be very important, as they could strongly affect the studies’ outcomes. For example, none of these four studies measured or evaluated whether their subjects had strong, ongoing, oral-parafunctional behaviors. Admittedly, such a determination is very difficult, as tooth wear is a poor marker of clenching and may not indicate current bruxism.

Nevertheless, this could be important if occlusal appliances work differently on clenching- or grinding-induced muscle pain vs. other types of muscle pain (for example, spontaneous daytime myofascial pain). In general, the use of disparate study samples, nonspecific definitions for study populations or both make it difficult to determine if occlusal appliance treatment would have a better result for one TMD subgroup

vs. another (for example, TMJ clicking with pain vs. myalgia with limitation of opening).

Another issue that needs to be addressed in future studies of occlusal appliance efficacy is how the appliance is designed and ultimately adjusted with regard to the position of the mandible/TMJ and to the number and distribution of occlusal contacts on the appliance. Such technical details need to be fully described, and some standard of performance needs to be met to ensure that occlusal appliance studies actually are comparable.

In spite of the previously described problems, two of the placebo-controlled studies<sup>34,40</sup> found that appliances had no efficacy above and beyond a placebo (nonoccluding appliance), while the other two studies<sup>31,39</sup> suggested that an occlusal appliance provides therapeutic benefit above and beyond that of the placebo appliance. Resolving this conflict clearly requires looking at the total picture painted by all of the available research evidence, not just placebo-controlled research studies.

While some would consider no-treatment control group results to be less powerful than placebo control data, the authors argue differently.

**Random-assignment, wait-list controlled studies.** While some would consider no-treatment control group results to be less powerful than placebo control data, we argue differently. A no-treatment control condition removes or reduces the expectation-fulfillment contamination from the outcome. Specifically, subjects in a no-treatment control group have no expectations of improvement, so any changes seen are the simple effect of time on the symptom level. Alternatively, subjects in a placebo-controlled study—especially when they are not informed that they will be getting a placebo—do have high expectations for improvement that induce very positive outcomes.

Although not placebo-controlled, one study of occlusal appliances used a no-treatment control condition with random subject assignment.<sup>35</sup> Johansson and colleagues<sup>35</sup> divided 45 subjects into three equal groups. They compared two active treatments (full-arch occlusal appliance, acupuncture) and a wait-list control (no-treatment) condition. The subjects were clinic patients with undifferentiated TMD (who did not have OA) similar to the MPD group defined by Greene and Laskin<sup>31</sup> in their 1972 study.

Johansson and colleagues<sup>35</sup> concluded that both the stabilization appliance and the acupuncture treatments clearly were superior to the results seen in the wait-list control group.

In another study, researchers performed a similar comparison but with a larger group of subjects ( $n = 110$ ) and a more rigorous protocol for outcome assessment that used pressure algometry.<sup>36</sup> Their groups also were wait-list control ( $n = 30$ ), occlusal appliance ( $n = 40$ ) and acupuncture ( $n = 40$ ). As before, subjects were clinic patients with undifferentiated TMD described as primarily having muscular pain and no OA. Researchers also concluded that the stabilization appliance and the acupuncture produced results that were superior to those seen in the wait-list control group.

A study in which researchers performed a three-group randomized, treatment comparison trial looked at a wait-list control ( $n = 30$ ), occlusal appliance therapy ( $n = 28$ ) and a biofeedback/stress management program ( $n = 30$ ) as the three treatment interventions.<sup>37</sup> The subjects were clinic patients with undifferentiated TMD who

did not have OA. Researchers concluded that the stabilization appliance and the behavioral intervention produced results that clearly were superior to those seen in the wait-list control group. The results comparing the appliance with the behavioral therapy suggest that the occlusal appliance treatment was more effective than the biofeedback/stress management program in reducing pain initially; however, at a six-month follow-up, the occlusal appliance group had relapsed significantly. This relapse was especially evident in those subjects who had been diagnosed with depression. In contrast, the biofeedback/stress-management program maintained improvement on both pain and depression. This study demonstrated that the combined treatment approach was more effective than either of the single treatments alone, particularly in pain reduction at the six-month follow-up.

Another study reported on a randomized clinical trial that compared a soft occlusal appliance group ( $n = 10$ ) with a palliative-treatment group ( $n = 10$ ) and a wait-list control condition ( $n = 10$ ) for masticatory muscle pain.<sup>38</sup> The results showed that after four to 11 weeks of treatment, subjects with soft occlusal appliance had statistically significant improvement ( $P < .01$ ), while the palliative-treatment group showed less improvement; the no-treatment group demonstrated no improvement.

Overall, these data consistently suggest that occlusal appliances

affect the patient symptom level far more than being in a wait-list group does. What they do not prove is whether this effect is strictly behavioral or if some other mechanism is being invoked.

**Random-assignment, treatment-comparison studies.** The final two studies we reviewed randomly assigned and compared two treatments but did not include a wait-list control or placebo-control condition. The first of these two studies looked at the clinical usefulness of biofeedback vs. appliance therapy in patients with mandibular dysfunction, or undifferentiated TMD.<sup>32</sup> Thirty female patients were divided randomly into two treatment groups. One group had full-coverage appliances, and the other group received biofeedback training. At the re-examinations at one and

The studies we reviewed suggest that occlusal appliances, when used for temporomandibular disorders, work as behavioral interventions and not as medical devices that produce effects via physical changes in the position of the mandible.

12 months after completion of therapy, the subjective and clinical symptoms were reduced significantly in both groups. No significant differences between the groups were found.

The second study randomly assigned 24 patients with undifferentiated TMD to receive either occlusal appliance therapy (n = 12) or simplified relaxation therapy (n = 12).<sup>33</sup> Researchers reported that the occlusal appliance group showed a significant decrease in total mean observable pain scores, maximum comfortable opening and maximum opening (even with pain), while the relaxation group did not. This study suggests that occlusal appliance therapy is a more effective treatment for the pain, tenderness and limited mandibular opening associated with TMDs than is simplified relaxation therapy.

## CONCLUSIONS

The studies we reviewed suggest that occlusal appliances, when used for TMDs, work as behavioral interventions and not as medical devices that produce effects via physical changes in the position of the mandible. Support for this view comes from the fact that occlusal appliances clearly work better than a wait-list control but not better than a credible placebo therapy, which is itself a nonspecific behavioral therapy. The behavioral effect of an occlusal appliance likely is the result of jaw function changes induced by both wearing a device and being in the study. In fact, when occlusal appliances were compared directly with a true behavior-modifying therapy, they were shown to be equal in efficacy.<sup>37</sup>

At the same time, however, it must be acknowledged that an occlusal appliance certainly can function as a physical device in that it obviously can protect teeth from attrition. Moreover, if the teeth do not contact in a stable manner, occlusal appliances can be used to provide a quick way to achieve a stable occlusal contact pattern until the teeth are restored. Occlusal appliances' assistance in protecting teeth that are wearing away as a result of excessive bruxism has not been contested in the literature. When such a clinical situation exists, the prescription of an occlusal appliance is both reasonable and rational. Logic suggests that occlusal appliances might work best in patients who have parafunction-associated muscle joint and tooth pain. Clearly, what is needed is additional information about which TMD subgroups, if any, most likely would benefit from an occlusal appliance.

Considering all of the available data both pro and con, we conclude that occlusal appliances do have sufficient evidence to support their use for the management of localized myalgia or arthralgia of the masticatory system. ■

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