# The validity and utility of disease detection methods and of occlusal therapy for temporomandibular disorders

Glenn T. Clark, DDS, MS,<sup>a</sup> Yoshihiro Tsukiyama, DDS, PhD,<sup>b</sup>

Kazuyoshi Baba, DDS, PhD,<sup>c</sup> and Michael Simmons, DMD,<sup>d</sup> Los Angeles, Calif. SECTION OF DIAGNOSTIC SCIENCES AND OROFACIAL PAIN, UCLA SCHOOL OF DENTISTRY

Our evaluation of the clinical usefulness of devices for the diagnosis or treatment of temporomandibular disorders (TMD) led to the conclusion that the only current gold standard for TMD is a global clinical examination, because none of the instruments can be said to provide more than ancillary documentation and none have proven diagnostic validity or utility. Regarding the therapeutic efficacy of occlusal adjustment, we could find no comparative studies that test the efficacy of occlusal adjustment in preventing TMD. The studies we reviewed on the relationship of occlusion to TMD are not convincing, powerful, or practical enough to make any recommendations about a causal association. (Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1997;83:101-6)

In evaluating the clinical usefulness of devices for the diagnosis or treatment of temporomandibular disorders (TMD), we examined more than 500 articles and reviewed 193 articles in detail. Because of the extensive volume of material involved in this evaluation, our full review will be published elsewhere. In this article we present 10 generalizations garnered from our review.

## DOCUMENTATION DEVICES MUST BE BOTH ACCURATE AND FEASIBLE

The need for an instrument or device to be accurate goes without saying, but the feasibility or utility of an instrument is not as easy to evaluate or understand. An example of the criteria we used is as follows: a documentation device was considered to be of low utility when its sole purpose was to document information that, while it was above and beyond the information gathered in a thorough interview and comprehensive examination, did not have an impact on the clinical decision being made. If an instrument was an efficient substitute for the clinical examination and its cost to the patient was thus neutral, it was considered to be a device of neutral utility. If a device provided crit-

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<sup>a</sup>Professor and Chairman.

<sup>b</sup>Visiting Scholar from Department of Prosthetic Dentistry II, Faculty of Dentistry, Kyushu University, Fukuoka, Japan.

<sup>e</sup>Visiting Scholar from The First Department of Prosthodontics, Faculty of Dentistry, Tokyo Medical and Dental University, Tokyo, Japan.

<sup>d</sup>Lecturer.

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ical information that could not be determined from a clinical examination and if that information was critical to the clinical decision being made, it was considered to be a high-utility device.

Far too many instruments and devices gather data that is not of value in making clinical decisions. For example, jaw motion tracking, sonography of the temporomandibular joint (TMJ), occlusal contact recordings, and electromyographic recordings of the jaw muscles are examples of devices that provide documentation. It may be nice to have this information in the patient's file, but the central issue to consider before using any device is whether it will generate critical information that will influence treatment decisions. If the device doesn't generate such information, the cost-benefit ratio of the procedure is very low. We strongly suggest that all devices, methods, or instruments proposed to supplement the standard clinical examination and history process be tested sufficiently to prove to the community of users (clinicians, health care insurers, and scientists) that the device has a reasonable cost-benefit ratio and has undergone rigorous, test-retest precision evaluation by independent investigators before it is accepted as a useful ancillary documentation device.

#### DOCUMENTATION IS NOT DIAGNOSIS

A claim that an instrument provides diagnostic data of value for disease detection and, subsequently, clinical decision making needs to be proved, whether the claim was made by the manufacturer or the instrument's advocates. We suggest that the standard diagnostic matrix testing process is applicable to all putative diagnostic instruments. This testing needs to be done whether the device measures occlusal contact patterns, surface electromyography levels, mandibular motion, or any other physiologic or behavioral re-

#### Table I. A suggested process for proving diagnostic efficacy

- Identify a group of at least 30 consecutive patients who are reporting to an Orofacial Pain and TMJ clinic for treatment but are not yet in treatment and who have a specific subtype of a TMD (e.g., myalgia without derangement, disk-condyle locking of less than 4 weeks duration without arthritis, or disk-condyle clicking without limitation of opening or arthritis). At least 30 patients are needed for each subtype to be studied. Patients who have unusual signs or symptoms or do not have a TMD should be excluded.
  - a. Train and calibrate at least two examiners to a high level of precision.
  - b. Document their signs and symptoms with a routine clinical examination of the head, neck, and oral structures (teeth and tissues).
  - c. Conduct interviews and carefully note the patients' complaints and history.
  - d. Administer several standardized questionnaires and pain scales.
- 2. Independently validate that these subjects are indeed suitable subjects for the agreed upon subtype of TMD patients by having at least three independent experts review the collected clinical examination and questionnaire data.
- 3. Identify group of 30 or more non-TMD subjects matched for age, gender, and educational level.
- a. Document the absence of clinical signs and symptoms with a routine clinical examination of the head, neck, and oral structures (teeth and tissues).
- b. Document the absence of TMD-like complaints with use of the same interview and standardized questionnaires.
- 4. Independently validate that these subjects are indeed non-TMD subjects by having at least three independent experts review the collected clinical examination and questionnaire data.
- 5. Collect the putative diagnostic information (e.g., surface electromyography, sonography, occlusal contact pattern, and jaw tracking) for the two groups of subjects in a fashion completely blind to subject status.
- 6. Score the resulting electromyography, sonography, and jaw tracking data for abnormality in a fashion completely blind to subject status. This scoring has to be based on prestated criteria of abnormality.\*
- 7. Submit the resulting data to sensitivity analysis (percentage of correctly diagnosed patients) and specificity analysis (percentage of correctly diagnosed normals) and then calculate the positive and negative predictive value of the various devices.
- 8. Repeat this process with patients with TMD versus patients with other diseases that might be confused with TMD problems (e.g., migraine headaches or tension-type headaches).

sponse. Table I suggests an approach for how this testing should be done. To date, none of the instruments mentioned thus far have been submitted to such research scrutiny, as reported in some previous reviews.<sup>1-5</sup>

#### NONINVASIVE, "SAFE" INSTRUMENTS THAT LEAD TO BAD DECISIONS ARE NOT HARMLESS

When safely acquired data result in a recommendation for therapy that a patient does not need to prevent a condition he or she may not get, issues of iatrogenic disease and overtreatment become of substantial concern. Widmer et al.<sup>4</sup> stated in their review that no papers in the literature calculated the sensitivity and specificity of instruments (Table II), and that until well-controlled clinical trials with appropriately defined control groups demonstrate that diagnostic tests performed with these or similar devices have high sensitivity and specificity, it is incumbent on all clinicians who use them to be cautious and to recognize that the main danger is unnecessary and sometimes irreversible treatment of healthy people.

#### **VERTICAL DIMENSION IS NOT A DISEASE**

A claim frequently made by advocates of the electromyography, jaw tracking and muscle stimulator system is that they can discover an abnormal vertical dimension.<sup>6-8</sup> Dentists have been making this obser-

vation for years and without use of any devices in cases of multiple missing teeth or severely worn teeth, in which the dimension between the ridges or teeth are inadequate to allow a prosthesis or fixed restoration to be correctly made. Most of the time, loss of tooth structure is an aesthetic or restorative feasibility issue, not a disease that needs to be eradicated. In recent times a muscle stimulator has been used in combination with a jaw tracking and electromyography recording device to assess the vertical dimension of a patient. It is known that the muscle stimulator induces a reduction in jaw closer muscle tone. However, when the jaw loses all postural muscle activation, it assumes a wider open position. This situation can be compared to a person who loses all postural tone in his or her back and legs and falls down. It would be foolish to state that this acquired position on the floor is the position in which the body should be maintained because it is the position of lowest muscle activity. To evaluate this concept, Rugh and Drago<sup>9</sup> measured the vertical dimension where electromyographic activity was least. They studied 10 subjects with natural teeth and no symptoms of TMD and discovered that this position was 6 to 18 mm open and varied greatly with the small posture changes of the head. On the basis of these facts, the claim is not acceptable that the vertical dimension is abnormal if there is more than 2 mm tooth separation after muscle stimulation.<sup>6-8</sup>

## THE POSITION OF THE MANDIBLE WHEN NO POSTURAL TONE EXISTS IS NOT THE SAME AS THE "CLINICAL REST POSITION"

The clinical rest position is often used by dentists to determine the vertical dimension in the edentulous. Nevertheless, muscle stimulator advocates believe that a poststimulation freeway space of more than 2 mm is an indication of occlusal overclosure (too large a freeway space). Advocates of the muscle stimulator suggest that it be used in combination with the jaw tracking device to show how the jaw is clearly out of position and that the vertical dimension of occlusion is incorrect and thus needs alteration. As previously mentioned, it is suggested that electromyographic null position is not the same as clinical rest position.<sup>9</sup> Furthermore, Manns et al.<sup>10</sup> reported that the position at which the various jaw closer muscles activity levels would achieve the lowest activity varied depending on the muscles, and thus it is not possible to establish a single standard vertical dimension at which all muscles are minimally active. On the basis of these facts, their claims appear to be entirely unfounded by the research evidence. It appears that these devices allow clinicians to document a transient increased jaw opening position induced by a postural tone ablation process produced by a jaw muscle stimulator.

A study by Cooper and Rabuzzi<sup>6</sup> demonstrates the problems with the way these data are interpreted by advocates of the muscle stimulator. In this study, the diagnostic value of a jaw tracking, electromyography system in combination with an electrical jaw muscle stimulation method to determine the putative correct jaw position and vertical relationship was evaluated with use of a group of 26 asymptomatic subjects. The major flaw of the study was that the data set of control subjects was a convenience sample and not a probability sample. In addition, no patients with problems were studied. Studying a group of patients with problems might have helped to define an appropriate cutoff point for the diagnostic categories used in the study. No repeated measures were made on the same subject to assess repeatability or precision. Furthermore, no calibration data were provided to see if the specific instruments they used were accurate in their ability to actually measure jaw movement or electromyography levels. It is clear that the examiner was never blind to subject status, and the selection of which tracing to use and which time period of muscle activity to measure were in the control of the examiner. Such a situation lends itself to the possibility of great systematic bias. Finally, even if the results were duplicated in another group of asymptomatic control subjects, the conclusion of the authors that the

Test result	Disease status	
	Present	Absent
Positive	True-positive	False-positive
Negative	False-negative	True-negative
	True-positive + false-negative	False-positive + true-negative

Table II. Determining sensitivity and specificity

Sensitivity equals true-positive/(true-positive + false-negative). Specificity equals true-negative/(false-positive + true-negative).

jaw tracking-electromyography-muscle stimulator method used in this study is a valuable diagnostic instrument that discovered disease in 21 of the 26 asymptomatic subjects who were not yet aware of the disease is not warranted. These findings are in fact quite illustrative of the danger of setting up artificial nonvalid criteria of disease.

# SUMMARY: CLINICAL UTILITY OF DIAGNOSTIC DEVICES FOR TMD

Clearly, additional research on all examination methods is needed. However, this is especially true for all ancillary documentation procedures, instruments, and devices that might theoretically be used to supplement the clinical examination and history database. This research should be directed toward identifying the test-retest precision of these methods and instruments. In addition, the devices that have a substantial cost associated with their use require a costbenefit analysis assessment. When advocates of an instrument put forth a claim that a specific device has diagnostic potential, a rigorous research protocol that tests these claims must be followed. In spite of its shortcomings, the only current gold standard for TMD is a global clinical examination and thorough history performed/obtained by an expert examiner. For the time being, none of the instruments (tooth contact detection devices, surface electromyographic monitoring of the jaw muscles, jaw motion tracking, or vibratory analysis of the joint for sound on movement) can be said to provide more than ancillary documentation, and none have proven diagnostic validity or utility.

## OCCLUSAL AND TEMPOROMANDIBULAR DISORDERS ARE NOT THE SAME THING

We now turn to our review of the role of occlusal therapy in the management of TMD. If you read most modern textbooks on TMD, it will be apparent that most contemporary descriptions of TMD do not include the problems that might be described as occlusal disorders.<sup>11, 12</sup> This has not always been the



Fig. 1. Evolving disease concepts.

case. Before TMD became well defined, occlusal and temporomandibular abnormalities, dysfunction, and disease were considered synonymous. The exclusion of occlusal disorders from TMD evolved during the past 30 years and occurred as a result of new research into underlying mechanisms of TMJ or masticatory muscle dysfunction. At the same time, alternative etiologic theories that feature psychologic,<sup>13-15</sup> neurologic, and immunologic<sup>16, 17</sup> factors, external trauma, and repetitive microtraumatic events<sup>18-20</sup> have gained prominence<sup>11, 12</sup> (Fig. 1).

How do we respond to the following question: "Because modern definitions of temporomandibular disorders do not include occlusal disorders any more, why link the occlusal therapy to TMD?" This linkage is largely historic and exists because the original, somewhat undefined concepts of "TMJ syndrome" and "Costen's syndrome," which were put forth earlier in this century, relied heavily on abnormalities of the occlusion as the etiologic theory.<sup>21</sup> Such an idea was actually quite plausible, especially in the early part of this century, given the level of dental disease (e.g., multiple teeth missing and the great need for restorative and prosthetic care in most patients) in the period from 1900 to 1950. The probable intent of this theory was to encourage the proper restoration of poor occlusion to a more ideal biomechanical situation in patients who were having dental work done anyway. The level of dental disease seen in the first half of this century no longer exists in the United States today.

### NO ONE ACCEPTED JAW POSITION OR EXCURSIVE GUIDANCE SCHEME HAS BEEN DEMONSTRATED AS CORRECT

Many persons developed theories about where the jaw and teeth belong.<sup>22-28</sup> When these theories are studied carefully, it is clear that they are not based on carefully collected data and are actually quite vague

about the ''disease'' that would result if the stated ideal occlusion was not present. Nevertheless, these theories have dictated the approach and method of occlusal therapy that is advocated when a patient has an occlusal abnormality. Of course, the choice of occlusal position to which the patient is to be restored is highly dependent on the theory that is believed. For example, centric relation,<sup>24</sup> condyle concentricity,<sup>28</sup> and the masseter muscle stimulator-induced position (myocentric) are all different positions. Belief systems often have devoted followers, and ''clinical success'' with a patient is generally all the proof that the believer needs; any research that contradicts the belief is largely anathema to the believer.

#### SEEING IT IS NECESSARY FOR BELIEF IN IT

The need to see something to believe in it is best demonstrated by the fact that although the microbiologic theory of periodontal disease was put forth in the late nineteenth century, it was not fully accepted until the middle of the twentieth century. With regard to occlusion and TMD, it is much easier for a dentist to treat an occlusal abnormality with available methods than to try to alter a patient's stress level or change his or her motor patterns while sleeping. The concept of an ideal occlusion is easy to grasp and to explain to patients, and the dentist has the skills to "fix" these problems. However, regardless of how easy it is to convince patients, it must also be the right thing to do.

## A LARGE INTERFERENCE IN CENTRIC WILL CHANGE THINGS, BUT THESE CHANGES ARE NOT TMD

The published experimental occlusal interference data are very limited in number and qualitative in large part; in addition, the magnitude of the interferences are very large (250 to 500 µm) and should not be considered natural.<sup>29-34</sup> Nevertheless, for the experimentally introduced occlusal interferences in centric occlusion, the data suggest that if the contact scheme is altered substantially, it will cause transient mandibular muscle coordination changes,<sup>29-33</sup> sore teeth,<sup>35</sup> sometimes even cause the jaw to tip slightly,<sup>36</sup> and make sore jaw muscles and temporomandibular joint dysfunction.<sup>33</sup> The relationship of these motor patterns, accommodative behaviors, and transient symptoms to any chronic disease state is unknown at present. All future research on the clinical effects of experimentally placed occlusal interferences and occlusal therapy should include control groups and improved methodology and long-term monitoring of effects.

# THE REASONS WHY THINGS WORK ARE NOT ALWAYS THE SAME AS WE THINK

Many persons investigating treatment methods get the results they expect because the study was not well designed, well controlled, or well conducted.<sup>37-41</sup> One can be confident that a causal inference exists between two variables only after all possible spurious associations have been ruled out. One type of spurious association to be considered is chance. Chance can be combated by increasing the sample size and by ensuring that the data analysis strategy is sound. Another major spurious association to combat is that resulting from bias. Bias can be dealt with by making sure that the design is as strong as possible (e.g., through use of blinding, probability sampling, repeatable measurement methods, predefined criteria of outcome, and elimination of confounders).

Confounders introduce the issue of alternate explanations (other than cause-effect). There are two types of alternate explanations for these relationships: effect-cause and effect-effect relationships. Effectcause relationships can be dealt with by assessing the association between the predictor variable and the outcome variable at several time points. Such data will allow one to see the disease develop as would be expected. Effect-effect relationships are difficult to prevent; the only way to do so is to gather information about all possible known confounders and then test for association in the analysis.

The rules of science dictate that sufficient evidence for causality requires data consistency, strength of association, the presence of a dose-response relationship, and biologic plausibility, as well as impeccable methodology and bias control methods. The research we reviewed on how occlusal adjustment compares with a placebo adjustment does not meet these criteria.<sup>37-41</sup> In most cases the methodology was by no means impeccable and the bias control procedures were poor. For example, the examiner and subject were often not blinded to the treatment, or if it was claimed that they were blinded, either no method was described for how the blinding was conducted or no ongoing blinding maintenance checks were performed. The subject groups were typically not probability based and the specifications for the subjects were not determined a priori and often were very vague or even not stated. The group randomization process was usually absent or, if it was claimed to be present, it was not described. None of the studies dealt with the issue of dropouts in an appropriate manner, and none of the analyses that we reviewed examined the dropouts for a systematic confounding effect on the analysis conducted. Often the statistical analyses being performed on the data were simplistic and inappropriate and the power of the results was not stated or tested.

The conclusion of the studies that occlusal interferences could have a causal role (factor) in TMD causation seems unwarranted because of the design and analysis flaws previously mentioned.<sup>37-41</sup> In general, neither the data, the logic of the study samples, nor the disease definitions used in the various studies we reviewed are convincing or powerful enough to make any recommendations about this relationship. Logically, if only 5% of the population have significant temporomandibular joint problems at any time in their lives,<sup>42-44</sup> why treat 100% of a population multiple times in a preventive fashion for a non–lifethreatening, low morbidity dysfunction?

# SUMMARY: TREATMENT OF TMDs WITH OCCLUSAL THERAPY

Unfortunately, no comparative studies have been performed that test the efficacy of one occlusal adjustment approach over another for preventing TMD. The studies we reviewed on the relationship of occlusion to TMD are not convincing, powerful, or practical enough to make any recommendations about a causal association. Therefore, performing occlusal therapy in young adults or children as a TMD preventative method is not appropriate. No reliable evidence has been presented to demonstrate that occlusal interferences can cause nocturnal bruxism or stop it if the interferences are removed. At present, no matter how much we wish it to be so, none of the various theories put forth about the relationship of occlusal abnormality and TMD can be proved with existing data.

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Reprint requests: Glenn T. Clark, DDS, MS Section of Diagnostic Sciences and Orofacial Pain UCLA School of Dentistry Box 951668, Rm 43-009 CHS 10833 Le Conte Avenue Los Angeles, CA 90095-1668 e-mail: glennc@DENTnet.dent.ucla.edu