Clinical Diagnosis of Orofacial Pain: Impact of Recent FDA Ruling on Electronic Devices

Every reader of this journal knows one thing for sure about orofacial pain: differential diagnosis can be quite difficult in many cases. Aside from the controversies about classification and taxonomy, the clinical challenge of figuring out what is going on with each individual patient remains. The traditional approach to this problem of diagnosis begins with a thorough history of everything the patient can remember about the onset, course, and previous treatment of his/her pain. Structured forms and protocols enable the clinician to cover all questions about precipitating, exacerbating, and alleviating factors, including any positive or negative responses to previous or current therapies. This anamnestic portion usually concludes with a current pain status report.

A thorough physical examination is then done to verify and augment what the patient is reporting. A symptom of clicking can be confirmed by palpation or auscultation, a complaint of limited jaw movement can be quantified by measurement of range of motion, a report of muscle pain may lead to findings of muscle tenderness and trigger points, and so forth. Of course, any nontemporomandibular disorder (TMD) sources of orofacial pain may mimic temporomandibular symptoms, but they usually can be sorted out during the examination. Therefore, it is important to identify specific examination characteristics that will discriminate one facial pain condition from another.

This combination of a history and a physical examination (HP), supplemented by appropriate imaging when indicated, has been referred to as the gold standard for the differential diagnosis of these kinds of pain problems. This designation implies that we have nothing better than the HP available as yet, and it also implies that new approaches must at least meet that standard (if not surpass it). Some members of our professional community have complained that this traditional approach is not much of a gold standard because it does not include the use of any 20th century diagnostic technology. Indeed, except for certain types of imaging machines, there currently is a lack of proven devices that can help in establishing a correct diagnosis for orofacial pain patients. (It should be mentioned at this point that we are no worse off in this regard than our medical colleagues who work with headache patients, fibromyalgia patients, or back pain patients.)

One response to this dilemma has been the adaptation of certain research technologies for use in clinical situations. Like most fields in medicine, we are not lacking in electronic and mechanical devices that can measure specific physical parameters. Electromyography (EMG) with surface and implanted electrodes has been used for nearly 50 years to study various aspects of jaw muscle function, including amplitude of postural activity and the dynamic activity of masticatory muscles during chewing and other movements. In addition, jaw functions such as voluntary opening and closing, chewing, and the full range of excursive movements have been studied with a variety of jaw-tracking instruments, including some that are interfaced with computers. Also, vibrations and noises from the temporomandibular joint, which were recorded years ago on simple tape recorders, can now be analyzed exhaustively by spectral analysis.

The developers and proponents of these devices have been arguing for nearly 20 years that these technologies are ready to be used in diagnosis and treatment planning for orofacial pain patients, as well as for establishing optimal jaw relations in various dental procedures. Indeed, they have been arguing that it is downright primitive *not* to use them. Analogies have been drawn to the practice of medical cardiology, in which it would be absurd not to use devices like electrocardiograms and ultrasound machines instead of merely ausculating or palpating the heart. This appeal to modernism has obvious attractive qualities, and as a result, many clinicians have bought into the neuromuscular dentistry concept of diagnosis and treatment, both philosophically and monetarily. Others, however, have resisted this trend on the basis that such devices have not yet been adequately proven to be suitable for clinical use.

The battle lines on this controversial issue became more sharply drawn in recent years as a combination of clinical researchers and basic scientists focused more attention on these matters. While the scientific basis for neuromuscular dentistry was under scrutiny from several neurophysiologists, the measurement accuracy of the devices themselves was under test in the laboratory. At the same time, clinical research was directed at the questions of diagnostic validity and accuracy, as well as the sensitivity and specificity of the tests done with each diagnostic device. It has no doubt been disappointing to the manufacturers that their devices failed most of the tests so badly; and in the end, the consensus of the scientific community was that these devices do not discriminate between healthy people and people with orofacial pain—nor do they help clinicians to do so. Furthermore, they concluded that what is being measured often has no relationship with disease processes—and even when it does, it often is measured inaccurately (for example, it is far more accurate to measure mouth opening with a millimeter ruler that costs a few cents than with a jaw tracking device that costs thousands of dollars). Finally, it was shown that some of the phenomena being measured are no longer regarded as important variables in TMD (eg, resting muscle activity, painless clicks), so it does not really matter whether they can be measured accurately or not.

While this controversy was raging in the dental and scientific literature, the American Dental Association compounded the problem by awarding these devices a Seal of Recognition (later suspended), followed by a Seal of Acceptance (later taken away, then granted again). The basis for awarding these seals was that the devices did what manufacturers said they could do, ie, they recorded physical phenomena. However, many members of the clinical and scientific community were outraged by this decision because it was clear that the evidence available did not support the clinical use of these devices.

This entire matter came to a head recently, when the Dental Products Panel of the US Federal Drug Administration (FDA) decided to take a hard look at these so-called TMD diagnostic devices. Some of them had previously been classified in the 510-K (grandfather clause) category, based on the fact that they were in use before 1976. However, on October 13, 1994, this FDA panel reviewed the supporting evidence submitted by the manufacturers, plus analysis of the scientific literature submitted by the authors of the present guest editorial. At the end of that session, the panel voted unanimously to recommend to the FDA that these instruments should be placed in the lowest category (Class III), requiring them to submit evidence within a specific time period that *(1)* the devices are reliable and effective in providing diagnostic information that leads to proper classification and treatment; and *(2)* the devices do not pose an unreasonable risk to patients (ie, misdiagnosis and improper treatment).*

Throughout this long debate, some people have tried to personalize the disagreements by claiming that certain researchers and clinicians were either prejudiced against them or, even worse, that they were intellectually incapable of recognizing real clinical progress. The true relationship between science and clinical practice always is much more complex than that; sometimes science leads the way, but at other times the observations of an astute clinician may open a new area of fruitful research. At certain moments, there may be tension between these parties because clinicians tend to want and to advocate new methods of diagnosis and treatment, while the traditional skepticism of researchers tends to hold them back until adequate proof has been demonstrated. The outcome of this natural tension between the two groups inevitably is some type of real progress, in which untenable concepts are rejected, unreliable methods of diagnosis are discarded, and ineffective (or even dangerous) treatments are abandoned, while valid new methods of diagnosis and treatment become accepted.

In conclusion, the authors of the present editorial believe that responsible clinicians in this field should be glad that this particular issue is on the way to being resolved by the action of the FDA panel.* Their decision reinforces the old but often forgotten maxim that a proper diagnosis can only be made by a well-informed and intelligent mind. While all of us in this field hope that some future technologies will be developed to assist us in the diagnostic process, it never will be possible to replace the mind of the skilled clinician with a machine—no matter how "space age" that device may appear to be.

Charles S. Greene, DDS
James P. Lund, BSD, PhD
Charles G. Widmer, DDS, MS
Subcommittee on TMD Devices
Neuroscience Group, IADR

**As this editorial goes to press, the FDA was scheduling a second hearing on this matter.*