

## **Scientific Methodology in Temporomandibular Disorders: Part I, Epidemiology**

When scientific disagreements seem unresolvable by conventional means, it is often helpful to intellectually step back and evaluate arguments on the basis of the infrastructure of scientific theories and assumptions on which they are based.

Thomas Kuhn in his classic text "The Structure of Scientific Revolutions" popularized the word paradigm as an "accepted vehicle of current scientific theories constitutive of the common beliefs of a particular community of scientists." He further describes the concept of paradigm as a disciplinary matrix of scientific values which gives order and meaning to their observation, experimental design and communication. Paradigms function by telling scientists about the entities that nature does and does not contain and about the ways in which those entities behave. It provides the directions for making a scientific road map essential to observation and future research activity. Paradigms gain their status because they are more successful than their competitors in understanding and solving problems for that group of practitioners.

Scientific knowledge is embedded in theory and rules. Science is the collected body of facts, theories and methods. Science does not develop piecemeal by the cumulative stockpiling of individual discoveries and inventions that constitute scientific knowledge, but rather by trial and perpetuation of that which has been found most effective and discarding of the misfits.

Kuhn identifies normal science as the activity in which most scientists spend almost all their time. It is predicated on the assumption that the scientific community knows what the world is like. Its objective is to solve puzzles for whose existence the validity of the paradigm must be assumed, and thus extend knowledge. The purpose of scientific research is to increase precision or display a new application of the paradigm and eliminate ambiguities. Bringing a normal research problem to a conclusion is achieving the anticipated in a new way. Failure to achieve a solution discredits only the scientist and not the theory; the proverb applicable being, "It is a poor carpenter who blames his tools." If some glitch in the apparatus or vagueness in the theory prevents one from completing an experiment, colleagues may well conclude that the individual has measured nothing at all.<sup>1</sup>

Many of the puzzles characterizing normal science produce an incomplete and imperfect data-theory fit. Rarely does a puzzle solution ever validate a theory with which it is confronted by a perfect data fit. Anomalous experiences, however, do not constitute falsification. Insecurity is created by persistent failure of the results of normal scientific experiments to come out as they should. Awareness of anomaly is the prelude to a search for new rules. Persistence of anomalies deeply penetrating the validity of the paradigm, proliferation of varying versions of a theory, and insufficiency of methodological directives results in a

growing sense of crisis and may indicate that an occasion for scientific retooling has arrived.<sup>1</sup>

Scientific revolution begins with analytical thought experimentation which hopefully results in "a lightning flash", enabling the visionary to see the components of a paradigm in crisis in a new way, which for the first time elucidates a more rational theory. A new theory devised to resolve anomalies in the relation of an existing theory to nature, if successful, must permit predictions that are different from its predecessor. This substantive difference could not occur if the two were logically compatible. In the process of being assimilated, the second must displace the older incommensurable paradigm which is then declared "unscientific".

Paradigm changes do not come easily or smoothly. Scientists examine which of the two theories fit the facts better. Debate ensues based on persuasive and logical argument. The ultimate determination is based on which paradigm works better for the most members of the scientific community -- which paradigms make the most sense, which methodology is the most predictive of clinical reliability and experimental reproducibility, which answers the most questions.

It is in this "revolutionary" context that controversies and clinical disagreements in TMD will be discussed by this author regarding the use of objective electronic measurement devices (computerized mandibular scanning [CMS], electromyography [EMG], electrosonography [ESG], and use of ultra low frequency neural stimulation [ULFNS]).

The subjective literature articles opposing these devices take the following positions:

- 1) "Clinical testing of potential diagnostic aids such as EMG requires the use of a strict methodology that can provide non biased measurements from *homogeneous* samples of the population under study." It is these authors' position that a well designed clinical investigation should include the random assignment of subjects to test groups, appropriate controls, the use of placebos, double-blind evaluation techniques, and appropriate statistical analysis.
- 2) ALL studies involving "electrodiagnostic instrumentation" have lack of age and sex matched controls, an inadequate data base and statistical analysis, uncontrolled stimulus activity, uncontrolled biting force, no measurements not made by "blind" observers, and errors in the methodology.
- 3) Recent *epidemiologic* studies do not support the hypothesis that TM disorders are directly linked to occlusion.<sup>3</sup>
- 4) If electromyography is ever to be useful clinically, a better description of the "normal" population and its variability, the effects of age, sex, weight, and

skeletal types on EMG parameters must be known.<sup>3</sup>

Epidemiology is the science of the occurrence of diseases in human populations. There is a specific conceptual and theoretical framework which underlies the conduct and interpretation of epidemiological research. However, certain fundamental principles must remain for studies and experiments to be meaningful. There must be a clear concept of what constitutes the disease under consideration. Only must have well defined diagnostic criteria so as to not confuse or confound the study disease with other diseases. There must be two clearly defined states, "diseased" and "disease-free."

The objections all presuppose an epidemiologic methodology as the correct paradigm for the study of TMD. It is proposed by this author that epidemiology is not an appropriate paradigm for the study of TMD. This proposed "revolutionary restructuring" is based on at least seven major anomalies in which the epidemiological paradigm is flawed.

### **1) The extreme variation in the results of epidemiologic studies of TMD**

A review of epidemiological literature (Medline search 1979-1992) reveals a lack of reproducibility based on non-standardization of controls. Epidemiologic studies of "normal" populations for TMJ dysfunction ranged from 20-68%. Epidemiologic studies of prevalence of TMD signs in "normal" populations ranged from 43-88%. Epidemiologic studies of the prevalence of TMJ sounds ranged from 20-58% of the "normal" populations studied.

Comparable studies with such a wide range of variation in results cast doubts on the reproducibility and credibility of the diagnostic criteria, study, design or methodology. Any study based on statistical analysis of such non-reproducible biological data would have no value and might even impair future scientific progress.

### **2) Inability to establish proper controls in epidemiologic studies of TMD**

The concept of control is relatively easy to implement in studying infectious diseases. There is a narrow range of signs and symptoms. The patients either had the disease as identified by presence of the microorganism in laboratory studies or they did not, and the disease either went away or did not after treatment. The concept of "control" becomes more difficult when dealing with temporomandibular disorders (TMD).

There is a difference between normal and healthy. Normal is a statistical range in medical tests and refers to being within a standard deviation factor of the average or simply belonging to a group which is "not sick." Health is an optimal state of function in the absence of disease. Thus it may be normal to have a malocclusion<sup>4</sup>, but this does not necessarily imply health. It is possible to be

normal and not be healthy. Asymptomatic also does not imply healthy.

Comparisons with "normal" or "asymptomatic controls" in epidemiological studies are meaningless since they represent comparison of sick versus less sick and/or maybe not sick and/or maybe healthy and/or simply not complaining. The extreme difficulty in establishing a quality "control" must be seriously considered and may exclude the study of TMD from an epidemiologic methodology.<sup>4</sup>

Horal's paper is referred to repeatedly in TMD literature review articles in which 212 low back pain patients were matched with 212 controls free of back pain. History, physicals and radiographic exams revealed the two groups indistinguishable based on illness criteria. The distinguishable difference between the two groups was that control subjects did not consider themselves sick and did not seek treatment. Thus an epidemiological dilemma occurs. If the "standards for control" are set too high, one could conclude that there is an epidemic, but if one doesn't measure to health, the epidemiologic disease criteria becomes "you've got it if you say you've got it, and you don't if you say you don't." Therefore, it is essential that standards for control not be arbitrarily set.

For any TMD study or experiment using a "control" to be meaningful, healthy temporomandibular function must be confirmed based on consistent measurable parameters such as appropriate distance of maximum opening, opening and closing without deviation and without pain, appropriate lateral and protrusive movement, no missing teeth, nasal breathing, absence of malocclusion, deleterious oral habits, dysphagia, joint sounds and palpable muscle tenderness. In addition, health of the joint can and should be confirmed by noninvasive joint imaging, such as magnetic resonance imaging (MRI), to rule out any lanthanic<sup>4</sup> or subclinical joint and/or disk disease. Healthy control patients should also be screened to rule out presence of systemic, organic and psychological disorders which might otherwise lower their resistance to disease. If healthy controls are not used for epidemiologic studies and experiments results will not be reproducible (a sine qua non of scientific study).

### **3) Model of TMD as biopsychosocial disorder incompatible with epidemiologic study**

There are numerous authors and researchers who have advanced a biopsychosocial model for TMD. This proposes that many TMD are multicausal, whose etiology involves an interplay of biological, psychological, and sociologic factors as etiologic agents by themselves of a TMD or in combination with a physiologic cause. Validation of this theory would certainly present a serious epidemiologic dilemma since it would be virtually impossible to conduct a study well-controlled for this entire multitude of possible variables.

### **4) Concept of TMD as stress disorder is incompatible with epidemiological methodology**

Inclusion of TMD in the same epidemiologic context as chicken pox, tuberculosis or hepatitis, where presence of one specific virus or bacteria and the consequent symptoms determine the diagnosis and treatment. Whether TMD is a disease at all, in the epidemiologic sense, is subject to debate. There is disagreement among health scientists as to whether hypertension, hay fever and hemorrhoids are diseases in the true epidemiologic sense, or stress disorders - examples of maladaptation to the environment. Certainly many TMD would fit into this latter category.

The doctor, in dealing with diseases of maladaptation, does not cure the patient, as in infectious disease. Based on a thorough clinical workup and accurate diagnosis, the rationale by which dentists treat diseases of maladaptation is to strengthen the body's own defenses and decrease the amount of physiological stress in order to create an environment such that the body can heal itself. It is impossible, however, to predict in advance just how much stress must be eliminated in any given patient before the body will rid itself of pain.

The epidemiologist in attempting to study TMD as stress disorders has to contend with uncertainty over presence or absence of disease. Given individual variance, the effect of treatment is uncertain in any given patient. Shared neurological circuitry of the head and neck make etiology of the pain difficult to diagnose. Location of the pain may not be the site of the pathological lesion. Relations between signs and symptoms are not the same in every patient. These kinds of variables are so complex that design of epidemiologic studies of TMD as stress disorders becomes a virtual impossibility.

##### **5) Subjectivity of diagnostic criteria flaws epidemiological studies**

In order for dentists to scientifically study and treat TMD, it is essential that there be accurate reproducible identification of the disease. The treating dentist must have suitable diagnostic criteria to allow for identification of each TMD. If when converting clinical observation into anatomic inference, criteria are missing, undeveloped or excluded, each clinician develops his own mystique of diagnostic reasoning. Observations must be reported in objective terms or evidence for clinicians to establish criteria of diagnosis and treatment evaluation. Interpretations based on imprecise unstandardized information, interpreted without adequate criteria and in the absence of uniformity and/or consistency are severely impaired.

Assessing a patient's condition on the basis of subjective findings rather than on objective criteria is a widespread custom which leads to clinical disagreement. "Patient feels better," "patient is improved" or "pain has subsided" as the basis for reporting of therapeutic results in epidemiologic studies make no distinction between evidence and inference, criteria and conclusion.

There are no quantitative and nonsubjective methods of measuring the location, quality, quantity or other characteristics of different types of pain produced by toothaches, headaches, face pain, migraines, etc., associated with TMD. Duration can be measured but only for a pain that begins abruptly at a specific moment and not for pain which starts insidiously.

Pain on muscle palpation involves the subjective variables of amount of pressure applied, patient's subjective perception of pain and psychological desire to comply positively. Some doctors' only measure of success is relief of pain. Recognition of the subjectivity of pain and the psychological aspects of chronic pain leaves those doctors at the patient's mercy in terms of determining success and termination of treatment. Lacking other reliably measurable objective criteria, it is unreasonable to expect reproducibility in epidemiological studies of TMD and this has been demonstrated earlier.

#### **6) Accurate diagnosis is necessary for epidemiological study**

A defined purpose of epidemiology is identification of those patients likely to become ill and to identify the common features of susceptibility they share. This can only be established when a specific diagnosis is established. TMD is a generic diagnosis.

According to Welden Bell, "An accurate diagnosis is the first step in the treatment of any disorder and the process cannot be abridged. A diagnosis should do the following:

- 1) Identify and classify the disorder properly;
- 2) Establish the mechanism of dysfunction and the source of pain;
- 3) Determine the etiology if at all possible; and
- 4) Provide a basis for prognosis in the light of effective therapy."<sup>25</sup>

The TMJ is a complex of muscles, ligament, cartilaginous disk, joint capsule, bone, blood vessels and nerves. A proper diagnosis should be specific to the pathological or dysfunctional component such as arthritis, myositis, capsulitis, neuralgia, degenerative disk disease, avascular necrosis, etc. And the treatment should specifically and appropriately relate to the diagnosis. All TMD cannot logically be considered as having the same etiology nor the same epidemiologic basis.

#### **7) TMD refers to a group of diseases which cannot logically be combined for epidemiological study**

TMD refers to a group of problems related to the craniomandibular articulation, whose incidence is profoundly affected by emotional tension and which involve pain and/or dysfunction in the head, face and neck region.

A list of etiologies of those TMD involving pain should include trauma, neuralgia, neuritis, hyperalgesia, myalgia, myositis, myofascial pain syndrome, capsulitis, hypochondriasis, hysterical conversion, tension headache, cervicalgia, osteo and rheumatoid arthritis.

The origin of the many TMD involving dysfunction may be trauma, ankylosis, fibromyalgia, synovitis, disk-condyle adhesions, discitis, disk displacement (with or without reduction), odontalgia, muscle trismus, infectious disease, neoplasia, osteo and rheumatoid arthritis.

To suggest that all these disorders and dysfunctions have a common cause or a common treatment is beyond reason. Epidemiological studies of TMD which do not differentiate and specify the etiologic cause are of questionable value. Categorizing capsular fibrosis and myositis together as a common diagnosis of "TMD" in terms of epidemiologic evaluation of treatment modalities defies sound scientific methodology.

The effort to find a universal cause for TMD where there is none represents a serious flaw in an epidemiologic approach. To only consider the commonality of TMD symptomatology in epidemiologic studies is to ignore the differences on which an appropriate diagnosis can be made<sup>25</sup> and appropriate treatment instituted.

## **Discussion**

The argument that "recent epidemiological evidence does not support a direct link between TMD and malocclusion"<sup>3</sup> is perhaps the most universally difficult anomaly for clinical dentists to accept. Epidemiology is not the study of cause and effect. It is the study of the distribution of diseases in human populations. Virtually on a daily basis, clinical dentists treating TMD using neuromuscular instrumentation are adjusting occlusions and repeatedly not only getting symptomatic relief, but improvement of objectively measurable parameters. The dental literature is replete with retrospective studies which do demonstrate that correction of the occlusion (and "balancing muscles") relieves the symptoms of TM disorders of muscular origin." The causal factors are neither sufficient nor necessary. Epidemiologic studies disproving occlusion as sufficient cause of TMD are a waste of time. There is no scientific evidence against occlusion as a cause of TMD. To stop correcting occlusion on the basis of subjective literature searches is ludicrous. Opponents are incorrectly utilizing epidemiological methodology.

The morality and ethics of those who criticize instrumentation as being "dangerous and resulting in irreversible treatment of "healthy" people"<sup>3</sup> is also to be seriously questioned. It seems a reasonable assumption that there may possibly be incompetent professionals diagnosing and treating TMD (whose ranks include both users and nonusers of objective electronic measurement

devices). But when electronic instrumentation is utilized, there is no variation in the senses of the examiner, there is no tendency to record inference, and there is never entrapment by prior expectation. EMG, CMS, ULFNS and ESG are noninvasive and do no harm to the patient. They provide objective data. That this is in every situation superior and preferable to subjective data will be discussed in a subsequent paper.

Objective electronic measurement is not relied upon primarily to make a diagnosis. Hence the term *electrodiagnostics* is a misnomer applied to the CMS, EMG, ULFNS and ESG in certain dental literature.<sup>2,3</sup> The information provided by neuromuscular instrumentation is used to aid in treatment of patients diagnosed as having certain temporomandibular disorders. These devices can aid in determining treatment modality such as whether an orthotic is indicated or contraindicated (by virtue of insufficient freeway to accommodate one).<sup>21</sup> They are used to periodically measure treatment results. They can assist in determining prognosis such as by indicating whether an internal derangement has reduced or not.

Relative to the interrelated purposes for which diagnostic data may be sought as an aid in making a diagnosis<sup>33</sup> --

- 1) To judge the severity of the illness and strengthen the diagnostic hypothesis.
- 2) To predict the subsequent course and prognosis of the illness.
- 3) To estimate the likely responsiveness to therapy in the future.
- 4) To determine the response to therapy in the present.

-- objective electronic measurement devices meet all criteria.

## **Conclusion**

Epidemiologists concerned with the design and appraisal of therapy in treatment of TMD as stress disorders are impeded by the clinical complexity of TMD. The diverse patterns of symptomatology and etiology of TMD defy classification as a single disease for epidemiologic studies. Multiple legitimate diagnoses may coexist simultaneously in the same patient. Establishment of valid healthy controls have never been accomplished, and repeated epidemiologic studies of TMD signs and symptoms have not been consistent or reproducible.

The search for unifying principles applicable to the treatment of TMD is condemned by its clinical complexity and non-specificity of diagnosis. The diverse symptomatology of TMD is based on the fact that TMD is not a single disease. And because TMD are stress-related disorders, the patterns of appearance and of evolution vary so greatly in different hosts with the same pathologic state, no single course of natural history typifies the expectations in all individual patients. The human beings treated by dental clinicians are a heterogenous group. Epidemiology does not typify the way in which patients



select doctors nor the way doctors make diagnoses or select treatment.

Based on these considerable anomalies in the epidemiologic methodology, a reasonable scientist might conclude that epidemiology was inoperable as a paradigm for the study of TMD. Objections to use of objective electronic measurement, holding it to old demands based on an epidemiologic methodology would thus be invalid.

Concerning Kuhn's context of scientific revolution, the concept of clinical ethology has previously been suggested as presenting a more logical paradigm for the study of TMD. Within the disciplinary matrix of ethology, the use of instrumentation by clinicians for diagnoses of certain specific TMD and objective evaluation of treatment results becomes logical and appropriate.

In biologic treatment or investigation a constant reality check is required. Do the results of the experimentation seem reasonable based on one's experience? When the results disagree with the expectations one must evaluate:

- 1) Whether one's assumptions about methodology were correct.
- 2) Whether the experimental measurement was accurate.
- 3) Whether one's experience is adequate to have reasonable expectations about results.
- 4) Whether a new principle has been discovered.

In all other specialties of clinical medicine great strides have been made, and are being made daily, in treatment, diagnosis and establishment of etiology by studying and gaining greater understanding of the objective paraclinical measurements presented by electronic instrumentation. Noninvasive electronic measurement allows permanent recording and inferences to be made about a patient's health status at an accuracy level far beyond the powers of subjective observation. Thusly, can a doctor improve his or her clinical judgment. Assault by subjective literature search demanding nonscientific and inappropriate standards of validation is not part of the morals and humanistic principals of contemporary science should be rejected.