

**For Defense Council Journal of Medicine and the Law**  
**Daubert, Pain, Evidence and Inference in Temporomandibular Disorders**

The U.S. Supreme Court recently ruled on scientific evidence in the courtroom in the case of Daubert vs. Merrell Dow. In writing the majority opinion of the Court, Justice Henry Blackmun explained that subjective impressions are biased by the observer's model of the world, and thus can be misleading; and as such do not represent definitive scientific evidence or knowledge.

**PAIN AS SCIENTIFIC CRITERION**

· A patient presents to a dental office with pre-auricular pain. Examination reveals that the pain is referred from ipsilateral trigger points in sternocleidomastoid or trapezius muscles. Lidocaine injection over the TMJ results in no pain relief, but injecting the trigger point does relieve the pain. This is **referred pain**.

· A patient complains of orofacial pain in the upper right arch, but examination reveals that it is an abscessed tooth in the lower right arch. This is **poorly localized pain**.

· A patient is asked if palpation of a certain area hurts. They answer "**not really**". This non-definitive phrase doesn't say yes or no. We must recognize that **pain is vague** and **quantification is often unreliable**.

· If a doctor palpates the right side of a patient's face and they indicate tenderness on the left, it's an example of **psychosomatic pain**. It exists only in the patient's mind with no known neurological circuitry, but they perceive it as real.

· Lie detector tests are inadmissible as evidence in courts because they are unreliable, yet we know financial gain from **lying about pain** is sometimes a reality in accident cases.

So, one must logically ask, "Based on phenomena of referred pain, poorly localized pain, vagueness of pain, unreliability of quantification, variation in perception, presence of psychosomatic pain and people who lie about pain, how accurate can the patient's self-reports\_of pain be used as evidence or scientific criterion for the study of TMD?"

The ultimate test for separating science from non-science is the ability of science to pose testable hypotheses. Scientific hypotheses must be possible to refute. The patient's complaint of pain has **no observable, testable phenomenology**. The patient's subjective complaint of pain is a belief statement and as such is irrefutable, unfalsifiable and therefore unscientific as diagnostic or scientific criterion. Self-reports of a patient's pain are inherently untestable, obviously unreliable, and, therefore, decidedly unscientific.

The U.S. Congress has established Federal Rules of Evidence for use in the courts. Rule 702 states that the word "knowledge connotes more than just subjective belief or unsupported speculation." The ultimate test of scientific knowledge is whether it can be tested. Scientific methodology is based on generating hypotheses and testing them to see if they can be falsified. The criterion of refutability, testability or falsibility is what distinguishes science from pseudoscience.

## **EVIDENCE VS. INFERENCE**

Evidence has been defined variously as the means by which a fact is established; a body of facts on which proof is based; and facts that tend to clarify, support or prove a point in question. Inference is a probable conclusion, not based on deduction, but loose usage, experience or statistical correlation. Inference does not absolutely establish a premise but constitutes a demonstration of probability.

"Circumstantial Evidence" is events and occurrences which establish reasonable grounds by which a fact is substantiated. Circumstantial *evidence* is an example of inference. It is considered soft rather than hard evidence.

Epidemiology also exemplifies inference. Epidemiology is concerned with the incidence of a disease in populations. It addresses whether an agent can cause a disease, not whether it did cause any one patient's disease. Specific causation is beyond the domain of the science of epidemiology. Epidemiology is a soft science based on manipulation of statistics.

There is often confusion between correlation and causality when judgment is based on subjective experience. The vast majority of correlated sequences cannot be causally related. The study of temporomandibular disorders is overladen with experiential subjective beliefs.

Basing evaluation of treatment efficacy for any patient on reliance of statistics and results of double-blind controlled studies from the dental literature defines "INFERENCE" not "EVIDENCE." The United States Federal Judicial Center recently published "The Reference Manual on Scientific Evidence." It establishes that epidemiologic double blind studies *cannot* prove causation. Based not on individual case study, but on representative samplings, such studies cannot ascertain very small effects. They address whether an agent can cause a disease or a treatment might work, not whether it did cause a disease or will work for treatment. There is no logically rigorous definition of what a statement of probability means with reference to an individual instance. Interpretation and manipulation of epidemiologic statistics does not constitute scientific evidence or explanation; it is inference.

Epidemiology and double-blind controlled studies on temporomandibular

disorders (TMD's) are being challenged. Normal has never been definitely defined and there are not two well-delineated states such as diseased and disease-free relative to TMD's. TMD is not one disease entity but a grouping of many different conditions. In virtually all epidemiologic research, TMD's have been studied as a group, so the results are meaningless. Pain as a gold-standard is unscientific. It is irrefutable having no testable observable or measurable phenomenology. Psychometric testing based on the patient's self-report of pain has never been proven to be more appropriate than objective physiologic measurement for the study of TMD phenomenology. No double-blind study based on pain can possibly be considered hard scientific evidence.

Fortunately, hard scientific evidence is available to aid in documenting the physiologic status of our patients, advancing our understanding of temporomandibular disorders and guiding doctors toward better patient care. Intellectual learning is alive and well in TMD's.

COMPUTERIZED MANDIBULAR SCANNING electrically records mandibular incisor point movement in three dimensions in the field emanating from a magnet placed with adhesive in the inferior labial vestibule. The information is fed to a computer which digitizes the data into such frames of reference as sagittal/frontal, anterior/posterior, vertical, lateral and velocity of movement. Functional activity such as opening, closing, chewing and swallowing can be analyzed as to neuromuscular status, such as degree of relaxation or dysfunction, objectively, accurately, and non-invasively.

An ultra-low frequency transneural electrical stimulator (TNS) can also be utilized. Skin electrodes are placed on the face over the coronoid notch of the mandible and send impulses over the nerves beneath it which are then transmitted to all muscles innervated by them. The usual effect of this treatment is to cause relaxation of the musculature.

ELECTROMYOGRAPHIC TESTING is accomplished using silver chloride skin electrodes placed bilaterally over the mid-masseter, anterior temporalis, posterior temporalis and anterior digastric muscles. Muscle activity can be analyzed both in rest and function, before and after TNS therapy.

SONOGRAPHY utilizes computer based bilateral joint sound recorders. A pair of ultra-sensitive vibration transducers are held in place over the TM joints by a lightweight headset. Vibrations from each joint during opening and closing of the mandible are monitored by the transducers, amplified and input into a computer for processing, display and analysis.

Evidenced-based care is already being practiced by many clinicians. Using painless non-invasive, objective, electronic measurement such as electromyography, electrosonography and electrokinetic range of motion tracings, doctors are able to confirm the status of the musculoskeletal facial pain

patient before, during and after treatment. Thus one can accurately evaluate what was done to the patient to get the result. This is evidence.

The generally accepted biological principles on which such measurement is based are:

1. Muscles in rest position should be "relaxed" as demonstrated by low electrical activity measured by EMG.
2. Healthy musculature and joints should function smoothly and not dyskinetically.
3. Healthy oral musculature of both right and left sides should function in balance with high electrical activity in maximal clench as measured by EMG.
4. Healthy joints should function silently.
5. Healthy movement from rest position to closure in maximal intercusp contact should not have a distal component of movement.

Certainly when a patient presents to a doctor complaining of orofacial pain, the doctor must concern himself with their pain. If a doctor directs treatment solely at pain and the patient reports feeling better, one does not then know what really achieved that result. It is not scientific. Objective clinical data provides diagnostic validation and post-treatment outcome evaluation based on hard evidence. This is scientific dentistry.

Just as the legal standard of proof for tort cases is easier or "softer" than for criminal cases, which require "harder" standards, the judiciary recognizes soft and hard sciences. Sociological and psychological research data, which depend to a large part on statistical analysis of subjective self-reports by patients of their symptom status, are considered "soft data" or inference. The objective data obtained from chemical or electronic diagnostic technology in medicine are considered to be "hard data" or evidence.

Confusion and argument occur when "soft" social science research methodology is inappropriately applied as "hard data" to physiologic problems, and vice versa. An interpretive value judgement can never be as accurate as evidence from objective measurement corroborated by multiple electronic modalities.

Dr. Allen Moses has a dental practice in the Sears Tower, Chicago, IL (312) 993-0430. He is president-elect of the International College of Craniomandibular Orthopedics and on the clinical and teaching staff at Michael Reese Hospital. He has recently written a book, "Controversy in Temporomandibular Disorders: Clinicians' Guide to Critical Thinking," 1997 Futa Book Publishers, distributed by Myodata at (800) 553-2121, P.O. Box 803394, Dallas, TX 75380. Dr. Moses is a past contributor to "Of Medicine and the Law" and has written numerous articles in the dental literature.