SENSITIVITY/SPECIFICITY

STRAW MEN, RED HERRING & DENTAL POLITICS

The January 2011 Journal of Craniomandibular Practice editorial The Price of Freedom by Dr. David Miller chronicles the twenty five year efforts of Dr. Charles Greene and a small group of his anti-instrumentation academics and researchers to discredit the use of measurement devices that assist the clinician in diagnosis and treatment of temporomandibular disorders. ¹

In a larger sense, this argument and its proponents have repeatedly discredited the use of all treatment modalities that involve physical/functional/occlusal factors in TMD. This is why this issue is significant to all dentists who successfully treat patients suffering from craniomandibular/ temporomandibular disorders.

In 2010, publishing anti-instrumentation diatribes in the Journal of the American Dental Association (JADA) and Journal of Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontics (JOOOE) Greene again uses the specious and scientifically untenable sensitivity and specificity argument to summarily dismiss the scientific credibility of using computerized measurement instrumentation as aids in diagnosis and treatment of TMD.² ³

This inappropriate use of the sensitivity/specificity straw man argument was used by Greene in a Sept 2010 JADA article entitled: Managing the care of patients with temporomandibular disorders: A new guideline for care:

“However, the consensus of recent scientific literature about currently available technological diagnostic devices for TMDs is that, except for various imaging modalities, none of them shows the sensitivity and specificity required to separate normal subjects from TMD patients or to distinguish among TMD subgroups.” CS Greene

The straw man and red herring technique was used in 2012 by Manfredini et al in the same Journal of Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontics also used by Greene to disparage neuromuscular instrumentation. Again it appears the anti-instrumentation advocates have found a compliant peer review board to perpetuate the same positions that have failed to pass scientific scrutiny for 25 years.⁴

Sensitivity is a scientific term to determine whether a diagnostic test or device can predictably identify that a particular disease or dysfunction exists. It is expressed as the probability that the specific test will be positive when the pathology or dysfunction does exist. Specificity is the term that refers to whether a diagnostic test or device will not falsely
diagnose a disease of dysfunction that does not exist. This would result in a false positive finding.

While sensitivity and specificity are important in their application to determine the effectiveness of certain diagnostic procedures in clearly defined disease or dysfunction, they are not appropriate in evaluation of diagnostic and therapeutic procedures for ill-defined syndromes or groups of disorders such as TMD.

The dental clinician treating patients with temporomandibular disorders does not have the time or may not have the research inclination to understand the background or significance of this argument and how it is used by the anti-instrumentation group to deny optimal treatment for their TMD patients. Therefore the intent of this editorial is to bring a simple perspective and history to the use of the ‘straw man’ in the TMD debate.

This “straw man” and “red herring” argument has been used by a small group of anti-instrumentation individuals for twenty five years to further their anti-instrumentation and in a larger sense, their anti-occlusion agendas. A straw man is a specious type of argument that creates fallacies based upon misrepresentation of an opponent’s position. A “red herring” is a figurative expression referring to a logical fallacy in which a piece of information is designed to be misleading or distracting from the actual question. The sensitivity/specificity straw man argument has been the primary argument used by Drs. Greene, Mohl, Lund and Rugh since 1986 to discredit the use of measurement instrumentation that provide diagnostic information to assist in the diagnosis of temporomandibular disorders.5-7

While sensitivity and specificity are important criteria to determine the effectiveness of certain diagnostic and therapeutic procedure to identify and/or eliminate well defined diseases, they are not appropriate to evaluate diagnostic and therapeutic sensitivity and specificity for TMD devices. The multiple symptoms, multiple signs, widely variable intensity, chronicity and periodicity of TMD pain and dysfunction make it impossible for any single physical and/or psychometric test to distinguish TMD patients from non TMD patients. No single diagnostic device or test can be used to separate “normal subjects” from TMD patients or to distinguish among TMD subgroups. TMD is, indeed, a term used to describe a group of disorders or syndrome involving generic musculoskeletal pain and dysfunction of the cranial, masticatory and cervical muscles and the temporomandibular joints. The use of the sensitivity/specificity straw man/red herring argument demonstrates at best a lack of understanding of the subject or at worst self-serving agendas to discredit clinicians using these advanced instrumentations and procedures.

The distortion of sensitivity/specificity criteria began appearing after 1986 when the manufacturer of these instruments earned the American Dental Association (ADA) Council on
Scientific Affairs Seal of Recognition. The ADA Seal required extensive scientific scrutiny of these devices for ‘safety’ and ‘efficacy’ regarding all claims made by the manufacturer for these devices. In addition, the manufacturers had to undergo stringent Food & Drug Administration (FDA) regulatory protocols to receive 510k clearance showing that these devices, i.e. Myomonitor, Surface Electromyography (sEMG), Electrosonography (ESG) and Computerized Jaw Tracking (CMS) were ‘safe’ and ‘effective’ for all claims made by the manufacturer in their 510k application. The safety and efficacy of these devices was further validated in 2003 when the American Dental Association Council on Scientific Affairs again granted the ADA Seal of Acceptance for these devices. With irrefutable scientific evidence and a large body of literature supporting intended use of these devices the anti-instrumentation foes resort to the ‘straw man’ and ‘red herring’ strategy to defame the neuromuscular devices and serve their own agendas.

These devices are not intended to make a definitive diagnosis that identifies and categorizes the TMD patient from non-patients. The devices are designed to accurately record and display physiologic data that can assist the clinician during diagnostic and treatment protocols. There are three criteria or standards that the American Dental Association Council on Scientific Affairs and the U.S. Food & Drug Administration require when evaluating these devices. First, are there physiologic parameters relevant to TMD that can be measured? Second, do the measurement devices accurately record that data? Third, is the information relevant and helpful to the clinician in the clinical management of TMD? The above mentioned devices have been rigidly judged by these standards and have unfailingly been found to be safe and effective in assisting the clinician to diagnose and treat TMD.

Having failed in the scientific forum to prevent the acceptance of these devices by the American Dental Association and the U.S. Food & Drug Administration, the straw man and red herring strategy unfolded when the discredited 1988 Mohl ADA Draft Status Report on Devices for the Diagnosis and Treatment of Temporomandibular Disorders claimed all devices were useless in the diagnosis of TMD because they lacked diagnostic sensitivity and specificity. Subsequently, Drs. Greene, Mohl, Lund and Rugh published over 50 opinion articles, editorials and literature reviews proclaiming the devices had no scientific merit because they could not meet sensitivity and specificity standards to distinguish TMD patients from normal patients. The report was repeatedly used in articles, despite the rejection by the American Dental Association of the Mohl Draft Status Report that was clearly being marked “Draft Only, Not for Publication.”

Our profession must question why, after being implicated by the Office of Inspector General, Office of Investigations Report in 1997 for “rigging” a 1994 FDA Advisory Panel evaluating these devices Greene is allowed to revisit a familiar forum, The Journal of the American
Dental Association, JADA, to espouse again the same discredited sensitivity/specificity straw man used 20 years earlier.

The history of these failed attempts to influence the American Dental Association Council on Scientific Affairs and well documented corruption of the U.S. Food & Drug Administration regulatory process should be available to all patients seeking care for TMD so they are not denied the benefit and care possible.9-14

Most recently in 2013, two more publications utilized the spurious Sensitivity and Specificity argument to discredit the use of measurement devices and along with them, the entire TMD Neuromuscular Occlusion treatment protocol. One was published by the Canadian Agency for Drugs and Technologies in Health: Rapid Response Report which was republished on-line by the Canadian Dental Association15. The other, authored by Manfredini et al was published in JADA16.

Editors of dental journals should be aware of this history when approached by anti-instrumentation individuals such as Charles Greene, Daniele Manfredini and others so as not to propagate an already discredited straw man bias. This history should be known by every regulatory and professional organization considering the use and role of measurement instrumentation so their decisions can best serve the needs of the TMD patient. Straw men and red herrings have no place in legitimate scientific discussion if our profession is to best serve patient needs.

References:

2. Greene CS. Managing the care of patients with temporomandibular disorders: A new guideline for care. JADA 141 (9), Sept 2010

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