THE SCIENCE & VALIDITY BEHIND THE INSIGHT MILLENNIUM SUBLUXATION STATION

In the scientific community, there are generally three criteria that must be met to determine efficacy of an outcome assessment system, and the Insight meets them all:

1] Is the test approved for use by clinical guidelines accepted by the profession?

All three of the outcome assessment tests performed by the Insight sEMG, thermal scanning and digital inclinometry] are rated as "Established" by the Council on Chiropractic Practice's Clinical Guideline # 1: Vertebral Subluxation in Chiropractic Practice [Chapter 7, "Instrumentation and Imaging," Page 91- 97]. These guidelines are the only evidenced based chiropractic guidelines included in the Federal Government's National Guideline Clearinghouse. A complete copy of the guideline can be found on the CCP website http://www.ccp-guidelines.org/

2] Have the applications, indications, normatives and protocols for the test been published in a peer-reviewed chiropractic journal?

The Insight Subluxation Station meets this requirement. See references at the end of this document [1, 2] for more information.

3] Is the test taught at a CCE accredited chiropractic college?

The Insight Subluxation Station is now being taught and used in the clinics at Parker Chiropractic College, Northwestern, Bridgeport, Three Rivers in Quebec, and Life West Chiropractic College.

Has the test been admitted as evidence in court before? Yes, many times. One such case was documented in the Chiropractic Journal [November, 1999 isue, "Subluxation Evidence Helps Win Important Ohio Chiropractic Court Case]. This article can be emailed to you per your request.

INDEPENDENT STUDIES PROVING REPRODUCIBILITY AND ACCURACY OF SEMG:

Surface electrode paraspinal electromyography has been employed since 1948 to measure muscular activity.3

Cobb et al 4 concluded that "...muscle spasm (even when mild) is accompanied by muscular hyperactivity which can be evaluated by suitable electromyo-graphic techniques. Our data suggest that surface electrodes allow better sampling than teflon coated needles..." and that "...integration procedures (surface EMG) allow better quantification than does the visual evaluation of a (needle) EMG..."

Reliability is a measure of the ability to reproduce a measurement, which is expressed as a coefficient ranging from 0.00 to 1.00. Perfect reliability results in a coefficient of 1.00, while chance agreement would be 0.0. As presented below, research data indicates that the reliability of SEMG is clearly superior to palpation for muscle tension. Surface electrode electromyography with attached electrodes exhibits very good to excellent test-retest reliability.

Spector 5 reported a surface EMG study performed at New York Chiropractic College which yielded correlation coefficients ranging from 0.73 and 0.97.

Komi and Buskirk 6 compared the test-retest reliability of surface electrodes vs. needle electrodes in the deltoid muscle. The average test-retest reliability for surface electrodes was 0.88 compared to 0.62 for inserted electrodes.

Giroux and Lamontagne 7 compared the reliability of surface vs. intramuscular wire EMG of the trapezius and deltoid muscles during isometric and dynamic contractions. The statistical analysis on the integrated EMG was a factorial analysis model with repeated measures. They found that surface EMG was more reliable than inserted wire EMG on day-to-day investigations.

Andersson et al 8 compared the electrical activity in lumbar erector spinae muscles using inserted electrodes and surface electrodes. They found that the standard deviations and coefficients of variation for wire electrodes was greater than those for surface electrodes. They concluded, “Wire electrodes are more sensitive to electrode location and give estimates with less precision than surface electrodes.”

Thompson et al 9 found that the scanning electrode technique correlated well with the “gold standard” of attached electrode technique [The Insight sEMG has both static and attached electrode techniques].

Cram et al 10 evaluated the reliability of surface EMG scanning in 102 subjects in the sitting and standing positions. SEMG scans were performed on three occasions approximately one hour apart on the same day. The median correlation between hand-held and patch electrodes was high, with a correlation coefficient of 0.64. The authors concluded, “With adequate attention given to skin preparation, EMG sensors held in place by hand with a light pressure provide reliable results.”

A recent email from Chris Kent, DC, one of the chiropractic profession's leading researchers, sums up the issue on reliability of sEMG:

" Studies spanning decades consistently report high levels of reliability. Quite simply, no other procedure I am aware of in chiropractic, except measurements on x-rays, approach the reliability of SEMG. Studies from the Mayo Clinic to the NZ Chiropractic College have demonstrated this. NONE OF THESE STUDIES WERE PERFORMED OR FUNDED BY CLA."

Christopher Kent, DC, FCCI

INDEPENDENT LAB TESTS PERFORMED ON THE INSIGHT SUBLUXATION STATION:

An independent lab test was performed on the Insight Subluxation Station at the New Zealand Chiropractic College, which demonstrated that the Insight had "reliable" reproducibility results. 11

The Insight Millennium is the only one of it's kind to be registered with the FDA as a Class II Medical Device. The FDA 510(k) registration number for the Insight Millennium is K990778. You may verify our FDA registration (K990778) and the indications for the instrument online at the following address: http://www.fda.gov/cdrh/pdf/k990778.pdf You will need Adobe Acrobat Reader to access the file. It may be downloaded free of charge at the Adobe web site: http://www.adobe.com/products/acrobat/readstep.html

Other important safety factors that only the Insight technology has:

**The Insight is also the only system of it's kind to have received federal approval by Health Canada for sale as a class II device*
* An electrical power source that complies with international patient safety standards
* Anti-static circuitry
* sEMG scanners with computer circuitry that amplify the signal by 10,000 fold
* Shielded sEMG cable for better isolation and signal-to-noise ratio

Other medical specialties that use sEMG and thermal scanning

THERMOGRAPHY- Thermography has long been acknowledged in the scientific community as being an accurate and reproducible technology. In fact, there are over 3000 references to thermography on medline. Indications in the medical field include breast pathology, deep vein thrombosis, and muscle injury 11. The normative study used by the Insight is based on published scientific research done at Johns Hopkins University in 1988, in which a group of neurosurgens used thermal scanning technology to determine temperature asymmetry protocols and their relationship to sympathetic dysfunction. 2

SEMG - According to other sEMG manufacturers who market to the medical profession, the following medical specialties have utilized surface EMG since the late 1980's:

Urologists for diagnosis and treatment of urinary incontinence

Orthopedists for muscle rehab and training

Physiologists for anxiety, tension/migraine headaches, rehab

General practitioners for circulation problems, anxiety, desensitization, distonia [muscle tonus], incontinence, spasms, relaxation, psychosomatic symptoms

Family practitioners for circulation problems, anxiety, desensitization, distonia [muscle tonus], incontinence, spasms, relaxation, psychosomatic symptoms

Neurologists for anxiety, muscle training and rehab, spasms

Speech pathologists for anxiety, relaxation

Sports Medicine for muscle training and rehab

Corporate Medicine for muscle training and rehab

Psychiatrists and psychologists for anxiety, desensitization, psychosomatic symptoms, tortocollis, writer's cramp, phobias

Rehab centers for muscle training, relaxation, spasms, urinary incontinance

Occupational therapists for muscle training/rehab, relaxation, migraine headaches

Dentists for TMJ, anxiety, tension/migraine headaches

Since 1987, *chiropractors* have been using sEMG to measure paraspinal muscle activity.

References:

1 *Normative Data for Paraspinal Surface Electromyographic Scanning Using a 25–500 Hz Bandpass* Patrick Gentempo, Jr. D.C., Christopher Kent, D.C., Brett Hightower, D.C., Salvatore J. Minicozzi, D.C. Published in the Journal of Vertebral Subluxation Research, August 1996, Vol 1, No. 1

2 *Quantification of Thermal Asymmetry* Part 1: Normal Values and Reproducibility Sumio Eumatsu, M.D., David H. Edwin, PH.D., William R. Jankel, PH.D., Joseph Kozikowski, M.S.E.E., and Michael Trattner, R.T. Published in the Journal of Neurosurgery, October 1988

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11. *Medical indications for thermographic evaluation*, www.meditherm.com /therm_default.htm

12. *The Clinical Application of Surface Electromyography as an Objective Measure of Change in the Chiropractic Assessment of Patient Progress*: A Pilot Study Simon Kelly, W. R. Boone, Ph.D., D.C. Published in the JVSR, December 1998, Vol 2, No. 4