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October 12, 2011

Dear CMS Administrators:

We are writing this letter on behalf of the Florida Society of Interventional Pain Physicians (FSIPP) in support of continued coverage of TENS therapy for chronic painful conditions. We have taken the liberty of modifying a report from Kathleen Slutka, PT, PhD (an academic Professor in Physical Therapy at the University of Iowa) to CMS, using information obtained by published peer-reviewed studies, and also are making comments based upon our Boards background and expertise in the subject of TENS. In this last section, it should be noted that FSIPP physicians, in the overwhelming majority, have no financial stake in dispensing TENS units but have developed belief in its efficacy in chronic musculoskeletal conditions after years of clinical practice.

TENS is the application of electrical current through the skin for pain control. As such there are numerous devices and methods of application of electrical current. Parameters commonly modulated and important for effectiveness include frequency, pulse width, and intensity of stimulation. Additionally, placement of electrodes can occur in many ways including at the site of pain, over a nerve trunk,

over acupoint sites, or in a dermatome. Further the outcome measure can be taken while the TENS unit is on, immediately after TENS is completed, or some time after the end of TENS treatment (1 week-6 months). All of these variables should be taken into account when designing a study, and when analyzing existing literature.

For low back pain there have been numerous trials that have tested the efficacy of TENS using a variety of different methodologies. Double-blind placebo-controlled trials, and trials comparing TENS to other treatments such as massage or acupuncture are generally reported. In recent years, it has become clear that intensity of TENS is critically important to obtaining a positive effect. Specifically, intensity of stimulation must be of sufficient strength to gain an analgesic response [1;18-20]. Overall, effectiveness of TENS for analgesia is intensity-dependent and must be given at adequate intensity. Two recent studies from our laboratory, in healthy controls, support this finding [18;19]. Specifically, we show that TENS delivered at a strong but comfortable intensity provided a significant analgesic effect while TENS delivered at or below sensory threshold is ineffective [18;19]. Thus, intensity must be increased to an adequate level to produce analgesia.

The recent systematic review by Dubinsky and Miyasaki [6] offers the following recommendation (page 175), "TENS is not recommended for the treatment of chronic low back pain due to lack of proven efficacy (Level A, Class I studies)." There are several critical factors to consider when deciding whether this recommendation is justified by the available evidence. We believe it is not. Upon review of the literature, it is apparent that there are 2 Level 1a, several Level 1b and several Level 2 studies that support the use of TENS for chronic low back pain (AMA criteria). Details will be presented below.

First, the recommendation by Dubinsky and Miyasaki [6] was based only on 2 studies. The authors defended this approach by limiting their recommendation to only include what they characterize as Class I studies (those with highest rigor). One of these studies was done in people with multiple sclerosis (MS) who had low back pain. Low back pain from MS is distinctly different from chronic low back pain commonly observed. The pain of MS is related to direct injury and permanent damage to the central nervous system [11]; while in

chronic musculoskeletal pain conditions the pain is generally due to modifiable 'plastic' changes in both the peripheral and central pain pathways (termed sensitization)[3;21;22]. The second study by Deyo and colleagues [5] compared TENS with and without exercise to sham TENS with and without exercise in patients with chronic low back pain. The subjects were given a period of high frequency TENS, switched to a period of low frequency TENS, and then chose their preferred treatment. Intensity was applied by having subjects set the amplitude to a pre-designated setting on the machine; what this setting means in terms of amplitude or patient response is unclear and thus we are unable to determine if adequate dosing of TENS was achieved.

Dubinsky and Miyasaki [6] reported that 2 Class II studies showed moderate benefit of TENS. There were no further attempts to pool the data from Class I and Class II studies (i.e. perform a meta-analysis) so limiting the clinical recommendation to Class I studies does not consider the Class II studies. The distinction between Class I and Class II is related to four criteria: 1) designate primary outcome, 2) clear exclusion and inclusion criteria, 3) adequate counting of dropouts, and 4) presentation of baseline characteristics to show similarity between groups. Otherwise both Class I and II are prospective, matched-group, cohort studies or a randomized controlled trial performed in a representative population with a masked outcome. Therefore, a Class II study could be missing one of four criteria listed above but still have strong results. The implication is that strong RCTs with significant effects could be disregarded by the analysis, and there could not be enough studies to do a meta-analysis to examine effectiveness.

As stated above, the time in which the outcome is measured is critically important. The effects of TENS do not last "forever" and has been reported to be greatest when the TENS unit is on, and occasionally may last up to 12-24h after TENS. Thus, measurement of TENS effectiveness 1 week to 6 months after removal of TENS is likely to show an insignificant to no effect. Appropriately designed studies on low back pain measure the effect of TENS on pain when the unit is on or immediately after termination of TENS, a time when maximal effectiveness is expected [14;16;17], and includes the Class II trials of Dubinsky and Miyasaki. In contrast, the Class I study in

Dubinsky and Miyasaki's review [5] on low back pain, pain was measured initially when the TENS was not on, and at some period of time after 4 weeks of treatment. This is not evidence of non-effectiveness: it is an entirely predictable and expected response.

Additionally, there are convincing data in the literature showing the benefit of TENS for chronic musculoskeletal pain, and includes those with low back pain. Most notably a rigorous meta-analysis from Johnson and Martinson [10] included data from 27 randomized trials. In a major difference from the Dubinsky and Miyasaki [6] approach, Johnson and Martinson [10] included patients with chronic (≥ 3 months) musculoskeletal pain from various anatomical locations (including back, neck, hip, and knee). Their rationale for a "more inclusive" approach was that TENS mechanisms for pain relief are not specific to anatomical region. Both the high and low frequency TENS activate central inhibitory mechanisms (PAG-RVM pathway) that can have widespread effects (my papers). Johnson and Martinson [10] performed a meta-analysis, so that the effects of all studies were considered in the conclusions. In contrast to the report from Dubinsky and Miyasaki [6], Johnson and Martinson [10] reported that TENS had a favorable pooled effect that was greater than placebo.

Machado and colleagues [15] also performed a meta-analysis of TENS effectiveness when compared to placebo for patients with low-back pain. In this meta-analysis, the data were restricted to people with non-specific low back pain. They included 4 trials and concluded that there was a favorable effect in reducing pain with the active TENS when compared to the placebo. This effect was considered moderate compared to placebo.

Khadilkar [12] performed a systematic review (Cochrane) and found 4 eligible trials: one showed a positive effect immediately after a 60 minute treatment [2] where intensity of stimulation was based on subject response and 3 times sensory threshold. The second trial by Deyo and colleagues [5] was ineffective-this is the same trial mentioned above in Dubinsky and Miyasaki's [6] systematic review which has unclear stimulation parameters and did not measure pain during or immediately after treatment. Mixed results are found in the study by Jarzem and colleagues [9] with no change in disability but

improvements in pain during activity when compared to a placebo. However, Jarzem and colleagues [9] did not report TENS parameters (frequency, intensity, pulse duration) making interpretation difficult. Topuz and colleagues [24] showed significant reductions in pain and improvements in quality of life with high frequency TENS when compared to placebo; low frequency TENS at tolerable intensity also improved pain and quality of life when compared to placebo in patients with chronic low back pain. Thus, three of the four studies in this review had significant improvement in pain and/or function after TENS.

In addition to the studies mentioned above, several randomized controlled trials support the use of TENS for low back pain. A recent trial examining the efficacy of low and high frequency TENS in patients who were opioid tolerant and compared to those who were not opioid tolerant showed a benefit of TENS in chronic pain [14]. The majority of the patient population (14/23) had spine pain. High frequency TENS reduced pain in both the opioid-tolerant and the non-opioid tolerant subjects while low frequency TENS only reduced pain in the non-opioid tolerant subjects. This study was based on pre-clinical data showing opioid-effects of TENS, and that low frequency produces its effects by acting on mu-opioid receptors [4]. This data shows a positive effect of TENS in chronic pain patients.

Similarly, Marchand and colleagues [16] (a Class II study reported by Dubinsky and Miyasaki), performed a double-blinded placebo controlled trial of TENS for chronic low back pain. In this trial they showed a 43% reduction in pain with active TENS which was significantly greater than the 17% reduction in pain provided by placebo TENS, and no significant changes in a control group that did not receive treatment. Using interferential current, a form of TENS, Zambito and colleagues [25;26] performed two randomized, double blind, placebo controlled clinical trials examining effects in older adults with vertebral column fractures (>50 years old) and in those with degenerative disk disease without radiculopathy. In both studies there was significant reduction in pain and in disability after treatment when compared to the placebo treatment.

In a study in elderly adults (> 60 years of age), Grant and colleagues [7] compared TENS to acupuncture and showed an approximately

50% reduction in pain, pain medication intake, and improvement in health (n=28) in subjects with chronic low back pain. Melzack and colleagues [17] compared the effects of TENS to that of massage in people with chronic low back pain. In this study, TENS was given at a strong tolerable level defined by turning the unit up until subjects considered the stimulation unpleasant and then turning down to a tolerable level. Melzack showed a significantly greater effect than massage with reduction of 70-80% in pain on the McGill pain questionnaire.

Recently, the laboratory of Dr. Slutka at the University of Iowa performed an initial trial in 41 subjects with back and neck pain from fibromyalgia. In this double-blinded, placebo controlled crossover trial, TENS was delivered at maximal tolerable intensity with electrodes placed on the spine. They demonstrated a significant reduction in pain during walking, increases in pressure pain thresholds of the lumbar and cervical spine, and improvements in function (walking distance increased during six minutes) (Dailey et al., 2011, CSM of APTA, abstract is presented after the Reference list at the end of this letter).

In order to present a balanced argument, several randomized controlled trials show negative effects [8;13;23]. This is true for virtually all forms of medical therapy. On careful inspection of parameters of design and application, Thompson and colleagues [23] did not report stimulation parameters, preventing us from interpreting the adequacy of stimulation parameters. Although Itoh and colleagues [8] used an appropriate intensity of 2-3x sensory threshold, they used a non-standard electrode placement technique. Lehmann et al. [13] used subthreshold TENS, an inadequate dose.

In summary, two meta-analysis (Level 1a evidence) support the use of TENS for chronic musculoskeletal pain including chronic low back pain. Four RCTs compared TENS against a placebo and showed positive results (Level 1b evidence) for active TENS in reductions in pain. Two RCTs compared TENS to another active treatment and showed significant effects for TENS when compared to measurements before TENS or an active treatment (Level 2). Results from a recent study in our laboratory, reported in abstract form (see abstract below), also show positive effects of TENS on pain and

function when compared to placebo or standard care when TENS was applied to the back in patients with fibromyalgia. Overall, when studies use adequate stimulation parameters, particularly intensity, there is strong evidence that TENS is more effective than placebo for chronic low-back pain. Thus, there is sufficient evidence to support continued Medicare coverage of TENS for chronic low back pain.

Sincerely,

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Abstract for CSM of the APTA in 2011

Title: Transcutaneous Electrical Nerve Stimulation (TENS) reduces pain and improves function in people with Fibromyalgia

Presentation Type: Poster

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ABSTRACT BODY

Purpose/Hypothesis: The primary objective of this study was to test the effect of Transcutaneous Electrical Nerve Stimulation (TENS) on pain, function and central excitability in people with fibromyalgia.

Background/Significance: The American College of Rheumatology (ACR) classifies Fibromyalgia as a clinical syndrome defined by chronic widespread muscular pain, fatigue and tenderness with hyperalgesia to pressure over tender points (Woolf et al., 1990). Pain in fibromyalgia is generally felt in the soft tissues of the body – muscles, tendons and ligaments. The cause of fibromyalgia is unknown, but it has been shown to demonstrate sensitization of the central nervous system pain pathways by demonstrating lower pain pressure thresholds and reduced diffuse noxious inhibitory controls. Pain associated with fibromyalgia can interfere with daily function, work, and social activities. Thus, one of the main treatments for patients with fibromyalgia must focus on pain relief to allow the person to function more independently both at home and at work. Research into the treatment of Fibromyalgia has demonstrated strong evidence that aerobic cardiovascular exercise improves symptoms of Fibromyalgia as well as improves quality of life (Busch, et al., 2007). However, exercise itself may be painful, and the pain may prevent a person from exercising (Vierck, et al., 2001). Thus, treatments aimed at decreasing pain will also improve a person's ability to exercise and participate in activities of daily living. Transcutaneous electrical nerve stimulation (TENS) is a modality utilized in physical medicine that delivers electrical stimulation through the skin and is used for both acute and chronic pain.

This pain treatment both increases central inhibition and decreases central excitability. Specifically, TENS activates descending inhibitory pathways from the midbrain and brainstem to inhibit excitability of nociceptive neurons in the spinal cord. (Sluka et al., 2001; DeSantana and Sluka, 2008 IASP; Kalra et al., 2001; Ma and Sluka) Although TENS has been shown to be effective for several pain conditions such as osteoarthritis, chronic musculoskeletal pain, and postoperative pain (Osiri, 2001; Johnson 2007; Bjordal 2003), its effectiveness in treatment of people with fibromyalgia is virtually unknown.

Subjects: 22 female subjects (29-73 year old, mean 49 ± 12.6 years) with diagnosis of Fibromyalgia completed informed consent and participated in 3 testing sessions.

Materials/Methods: The study used a double-blinded, placebo-controlled, crossover design of 22 patients with fibromyalgia with random assignment to three treatments: Active TENS (100 Hz, 200 μ s), Placebo TENS and No Treatment Control. TENS was applied for 30 minutes at the maximum tolerable intensity to either the upper or lower back, depending on primary pain location. All outcome assessments were measured before and after the 30 minutes of TENS intervention, with the TENS unit left on during the second assessment. Pain intensity was measured with a visual analog scale (VAS) at rest and after a six minute walk test (6MWT). Deep pain sensitivity was assessed with pressure pain thresholds (PPT) in the lumbar and cervical regions. Function was assessed with the 6MWT. To test descending inhibition(DNIC), the subject's foot was placed in an ice water bath (4°C) for up to two minutes (DNIC test) while PPTs were measured over the primary pain location. Data were analyzed using a repeated –measures ANOVA followed by post hoc paired t test.

Results: There was a significant decrease in pain with movement (6MWT) for Active TENS compared to Placebo TENS ($p \leq .05$) and No Treatment conditions ($p \leq .01$). However, there were no differences in pain at rest between conditions. Further there was a significant increase in distance walked by $1444 \text{ ft} \pm 139$ in the 6MWT during the Active TENS treatment when compared to the Placebo TENS condition ($p \leq .05$). Similarly, PPTs increased in either the cervical or lumbar regions during TENS for Active TENS when compared to Placebo TENS (Cervical $p \geq .12$, Lumbar $P \geq .14$) or No Treatment (Cervical $p \geq .13$, Lumbar $p \geq .13$). During Active TENS, DNIC was significantly stronger (higher PPT's) compared to Placebo TENS ($p \leq .01$) and No Treatment ($p \leq .05$).

Conclusions: The results of our study suggests that Active TENS restores descending inhibition (increased PPT 's during DNIC) increases deep tissue pressure pain (increased PPT's), decreases pain during movement to result in improved function during routine walking.

Funding Sources: Supported by the Orthopedic Section of the American Physical Therapy Association. TENS units donated by EMPI, Inc.

Key Words: Transcutaneous Electrical Nerve Stimulation, Fibromyalgia, Experimental Pain