Periodic leg movements (PLMs) are repetitive movements characterized by rapid partial dorsiflexion of the ankle, extension of the great toe, and partial flexion of the knee and hip that occur during non-REM sleep. Abnormal PLMs occur in most patients with restless leg syndrome and are associated with an increased risk of hypertension and cardiovascular disease. Elevated PLMs in subjects with chronic pain compared to non-pain controls has been reported. Although the neurologic generator for PLMs is unknown, evidence points to enhanced spinal cord excitability and deficient descending inhibition.

Transcutaneous electrical nerve stimulation (TENS) is a non-invasive treatment for chronic pain without significant side effects. TENS is believed to improve chronic pain by decreasing central sensitization and enhancing descending inhibition through opioidergic pathways.

We hypothesized that subjects experiencing a reduction in chronic pain following 10-weeks of TENS use would also demonstrate a reduction in PLMs.

**METHODS**

This retrospective, observational study evaluated users of a TENS device (Quell®, NeuroMetrix, Waltham, MA) to treat chronic pain over a 10-week period. The device is always placed on the upper calf (see Figure 1) and is comprised of a one-channel electrical stimulator, a stretchable band to secure the stimulator to the leg, and an electrode array. The electrode array is comprised of 4 hydrogel pads, each approximately 15 cm², configured as two 30 cm² electrodes. When placed on the upper calf, the electrode array wraps around the leg overlapping sensory dermatomes S2 through L4. These dermatomes are typically targeted when tending foot, leg and low back pain with TENS.

The device and companion app collect utilization data, demographics, pain characteristics, pain ratings, and adverse events derived from asynchronous data that are stored in a cloud database. The pain ratings included pain intensity and the three pain interference values.

**RESULTS**

There were 304 responders and 351 non-responders. Table 1 compares baseline demographics and pain characteristics between the two groups. Both groups had long duration, multi-site pain and several painful conditions. Essentially all participants had lower extremity or low back pain, and most had extra-segmental (i.e., segments unrelated to nerve stimulation) pain. There were few statistically significant differences between the groups: responders were older and had greater pain interference with sleep and activity at baseline.

Table 2 compares sleep measures at baseline. There were no statistically significant differences. Table 3 compares TENS adherence parameters in the two groups. The two groups had generally similar adherence, with the responders having slightly higher device use that is likely not clinically meaningful.

The median relative change in PLMI from weeks 1-2 to weeks 9-10, over the entire study population, was -5.0% (95% CI -10.5, 0.0). Figure 2 shows the distribution of PLMI changes stratified by responder status. Responders exhibited a median -9.8% (95% CI -18.2, -3.9) change in PLMI compared to a median 0% (95% CI -8.0, 9.5) change in non-responders (p = 0.023). This result was further confirmed by the two-sample Kolmogorov-Smirnov test (p = 0.020).

We hypothesize that TENS reduces both pain and PLMs through an overlapping reduction of central excitation and/or enhancement of central inhibition.

This study also demonstrates that TENS improves both patient reported and objective outcomes, further supporting the clinical utility of this non-invasive chronic pain treatment.

**CONCLUSIONS**

The key finding from this study is that TENS users who reported at least a minimum clinically important reduction in composite pain, also experienced a statistically significant reduction in PLMI. We hypothesize that TENS reduces both pain and PLMs through an overlapping reduction of central excitation and/or enhancement of central inhibition.

**REFERENCES**