
**NON-INVASIVE TREATMENT
OF
NERVE ENTRAPMENT SYNDROMES WITH
THE
SONOTRON
A PULSED RADIO FREQUENCY
THERAPEUTIC DEVICE**

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ABSTRACT

The objective of this clinical study was to determine the efficacy of the Sonotron, a pulsed wave radio frequency device, in the management of Carpal Tunnel and Tarsal Tunnel Syndromes. Fifty patient case studies were conducted. Each patient received a complete physical evaluation and EMG/NCV studies, before and after treatment with the Sonotron Device. Comparison of results yield evidence of objective improvement after a regimen of treatments with the Sonotron Device.

HISTORY

The Sonotron device is a non invasive device that employs modulated radio frequency (RF) energy in the form of a visible and audible corona discharge beam emanating from a discharge electrode. The design of the device is such that it assures that the electrode beams are delivered at a constant preset distance from the skin. It is employed as a therapeutic device that utilizes radio frequency energy transmitted through the air directly to the skin for treating various inflammatory joint conditions and nerve entrapment syndromes. A point of interest is the fact that the Sonotron device fits into the electromagnetic spectrum of other medical therapeutic modalities currently being used. On the upper end of the electromagnetic spectrum is ordinary diathermy and infrared therapy; while on the lower end of the spectrum is therapeutic ultrasound. The modulated RF energy of the Sonotron Device is in between these two modalities. Medical contraindications for the use of this device are similar to other electromagnetic modalities and include pacemaker patients, pregnant patients and use over open wounds or wet bandages.

Several studies have been performed in documenting both safety and efficacy of the Sonotron device including both animal and human models.¹ Animal model studies to date include rat studies performed at Long Island Jewish Medical Center and a horse study completed at the School of Veterinary Medicine of the University of Wisconsin.² Several human model studies have been and/or are presently being conducted. Blind placebo studies of the Sonotron therapy in osteoarthritis of the knee were performed at several different medical centers across the United States. Those studies were outpatient clinical studies focused on the treatment of joint inflammation and pain using the Sonotron device. As noted, initial studies have focused on inflammatory joint diseases. The study conducted at Orthopaedic and Sports Medical Institute of N.J. (OSMI-NJ), focusing mainly on nerve entrapment syndromes, has broadened the scope of application of the Sonotron Device. The OSMI-NJ study has focused mainly on the treatment of compressive neuropathies involving both of the Carpal and Tarsal Tunnels.

Classically, signs and symptoms of median nerve compression as it courses from the forearm to the hand is known as carpal tunnel syndrome.^{3,4} Similarly, compressive symptoms of the posterior tibial nerve, which gives rise to the medial and lateral plantar nerves of the foot, is known as tarsal tunnel syndrome.^{5,6}

Focusing on carpal tunnel syndrome, subjective symptoms include pain in the affected extremity. Pain is not necessarily limited to the hand. Numbness and weakness are usually elicited in the patient's history. Patients often report overall decreased function of the affected hand. Commonly these symptoms are worse at night.

Objective physical findings include decreased muscle power of the abductor pollicis brevis muscle. Grip and pinch strength measurements are taken with a standard dynamometer. Tinel's sign is usually positive. A Tinel's sign is elicited by tapping over the carpal ligament with a reflex hammer. A positive response is evident when the patient reports a radiating electrical type of sensation to the median nerve innervated fingers. Phalen's sign is another screening maneuver which is part of the complete examination. Phalen's sign is described as placing the wrist in a flexed position at 90 degrees and measuring the time frame involved to the reported symptoms. Visual inspection and palpation of hand muscles can yield evidence of atrophy of the affected hand.¹⁹

X-ray findings of the wrist may reveal evidence of sclerotic changes and/or anatomical narrowing of the carpal tunnel. These changes may be of a congenital origin, the result of cumulative occupational trauma, or post-traumatic in nature.

Electrodiagnostic testing yields objective data into the physiologic function of the affected nerves and muscles.^{7,8,18} Conducted in two separate areas, a comprehensive study includes both nerve conduction velocities and needle electromyographic examination. Findings and results of EMG/NCV studies are reproducible, when conducted by the same trained examiner on the same equipment. Pathologic nerve conduction values include prolonged distal latency values of the median nerve. The distal latency is considered the time it takes an induced impulse introduced above the wrist to traverse the carpal tunnel. Nerve conduction velocities are obtained for both motor and sensory components. Amplitudes of response are also measured on this part of the examination. In essence, this is the volume of the response. Normal values and techniques are referenced in the textbook, Laboratory References for Clinical Neurophysiology by Jay A. Liveson and Dong Ma.

Needle electromyographic exam yields a view of the physiologic activity within the affected muscle, both at rest and during activity. Pathologic findings on EMG exam include increased insertional activity of the muscle, abnormal wave forms of fibrillation, positive sharp waves and bizarre complex discharges. Any of these wave forms may be present to establish the diagnosis. Numerous other techniques and criteria exist for the electrodiagnosis of carpal tunnel.^{9,10} Any combination of the previously mentioned EMG/NCV findings may be present and consistent with criteria for the electrodiagnosis of carpal tunnel syndrome.^{18,20} Overall, the diagnosis is established after the comprehensive history and physical examination as well as supportive x-ray findings and EMG/NCV studies are performed.

The epidemiology of carpal tunnel syndrome traverses a wide range of patient types. It is more commonly noted in females than males. It has been recently linked to repetitive stress disorders and cumulative occupational trauma syndromes.

Findings in Tarsal Tunnel Syndrome include pain and decreased sensation in the foot, usually worse with weight bearing. Tinel's sign is usually positive over the Tarsal Tunnel. Pain can be

reproduced by palpating or compressing the laciniated ligament.¹⁹ Nerve conduction studies may not be electrodiagnostically conclusive for the syndrome to be present. NCV/EMG data focuses on the medial and lateral plantar nerves and their related innervated musculature.^{11,18,20}

Present treatments available include medications, which are usually limited to nonsteroidal anti-inflammatory compounds. Steroid injection is also an option but is usually poorly tolerated by patients.¹² Splinting has been gauged as effective but usually results in moderate limitations of function as reported by the patient. The limitation of functional use is the usual cause of the patient's noncompliance with a splinting regimen.¹³ Physical therapy is a useful adjunct in relieving symptoms and improving function. Modalities available to date include ultrasound, diathermy and paraffin.^{16,17,20} It is within this realm that the Sonotron device effectively uses pulsed wave radio frequency energy to optimize patient improvement. When conservative treatment fails, surgical decompression, open or endoscopically, is considered.¹⁴ The decision for surgery is influenced by a number of factors. Those factors include age and occupation of the patient, pain level, functional disability of the hand, and other co-existing medical conditions. The most important factor in considering surgery is the response to non-operative modalities.

MATERIALS & METHODS

In the OSMI-NJ study, patients were selected at random, in the normal course of medical practice. Upon selection, patients had to sign an informed consent to indicate their intention to participate in the study. The physician also signed the form certifying that he explained the treatment with the Sonotron Device. No preference was established for age, gender or occupation. All patients received a complete physical examination by a physician. Range of motion studies were performed with the use of a standard goniometer. Grip strength was measured with a Jamar dynamometer and a B & L pinch dynamometer was utilized for pinch strength of the affected hand. All pinch and grip values were compared to the opposite unaffected extremity. Sensory examination, including two point discrimination was conducted utilizing standard pinwheel and calipers.

Also observed was the functional use of the affected hand. Patient questionnaires of subjective symptoms and functional status were recorded.¹⁵ The OSMI-NJ study utilized the VAS (Visual Analog Scale) format to record results. X-rays of the wrist and hand were obtained. Electrodiagnostic studies were performed in accordance with the standards prescribed by the American Academy of Electrodiagnostic Medicine.¹⁸ Once the diagnosis of Carpal Tunnel or Tarsal Tunnel Syndrome was established, the patient was treated with a regimen of Sonotron treatments. The treatment unit of the Sonotron device is a 15 second emission period followed by an automatic 3 second shut-down. Three treatment units were applied on a once weekly basis over the Carpal Tunnel or the Tarsal Tunnel for four weeks. A total of 12 treatment units were applied over a four week period. After completing four weeks of treatment, the patients submit to repeat EMG/NCV studies and a repeat physical examination of the affected limb. Overall functioning ability is again reported by the patient on the VAS forms.

RESULTS

In a limited study of 50 patients, a total of 30 patients have completed the regimen of treatment for Carpal Tunnel as of November, 1996. Five patients have completed regimen of treatment for Tarsal Tunnel Syndrome. The remaining 15 patients are nearing completion of treatment for either disorder. The study has many more patients enrolled in the early stages of the regimen and treatment. Focusing on this limited number of 50 patients, 21 out of 30 completed patients yielded improvement in either nerve conduction velocity studies of latency values across the carpal tunnel or in the obtained amplitudes of response. Objective improvement in grip and pinch strength has also been recorded by dynamometer testing. More importantly, patients' subjective reports on the visual pain scale (VAS-Visual Analog Scale) showed improvement after Sonotron treatments. These improvements were reported as both decreased pain and improved function of the affected hand.

Regarding Tarsal Tunnel results, 3 out of 5 cases completed, report significant improvement in function and weight bearing potential as well as decreases in pain. The remaining 15 patients; although not fully completed, are yielding a trend towards improvement, in relief of symptoms and increased function of the affected hand or foot.

No complications have reported by patients and we have not experienced any adverse effects to date.

DISCUSSION

The OSMI-NJ study has observed and objectively documented improvement in nerve entrapment syndromes in a limited number of patients. The mechanism by which the Sonotron Device works has been hypothesized via high penetrance of soft tissue with low frequency sound waves. Sound wave energy can produce an effect on both hard and soft tissue. Although different ranges of the sound spectrum may be utilized, it is probable that the mechanism of action of the Sonotron is similar to ultrasound. Results indicate a clear pattern of efficacy, yielding an approximate 70% rate of improvement in Carpal Tunnel Syndromes and an approximate 60% improvement rate in Tarsal Tunnel Syndromes respectively. This progressive study continues to collect new objective data on an ongoing basis. Improved patient functioning, objective nerve conduction velocity improvement, and patients' subjective reports yield evidence of a significant positive trend in the efficacy of the Sonotron device.

CONCLUSION

Based upon the data collected in the OSMI-NJ study, it is evident that the Sonotron device is an effective non-invasive adjunctive modality in the conservative management and treatment of compressive neuropathies involving both the Carpal and Tarsal Tunnel.

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