Protocol Title

Impact of direct current neuromuscular electrical stimulation on physical therapy treatment of lumbosacral radiculopathy

Abstract

This study will compare two methods of electrical stimulation (alternating current and direct current) as an adjunctive therapy to treating lumbosacral radiculopathy. Both types of electrical stimulation have been used in clinical practice for physical therapy, however direct current stimulation is much less common and there is less known about its impact on physical therapy outcomes. The aim of this project is to show the efficacy of a novel device, the Neubie direct current device, compared to traditional TENS unit in clinical physical therapy treatment of radiculopathy. Outcomes measured will include: pain intensity, functional status, neurological status, electrophysiological changes and patient satisfaction.

Investigators

Hands On Diagnostics: Dimitrios Kostopoulos, DPT, MD, PhD, DSc, ECS
NeuFit: Ramona von Leden, PhD

Setting of the Research

To determine the efficacy of direct current electrical stimulation (the Neubie device) on long-term symptoms and severity of lumbosacral and thoracic radiculopathy, participants will enroll in a 6-week treatment regimen at one of 9 Hands-On Physical Therapy associated clinic sites listed included in application. The first session will consist of an intake evaluation session that will include: Visual Analogue Scale (VAS) for pain, Oswestry Disability Index questionnaire to assess functional disability, Straight Leg Raise Test to address nerve root irritation or compression, and Electrophysiological evaluation to determine the nerve function. These tests will serve as baseline (and a within subject control) for the intervention.

Participants will then undergo a specialized radiculopathy protocol that includes traditional PT therapy as well as treatment with the Neubie (or traditional electrical stimulation) both during PT exercises and as additional treatment after sessions. Subjects receive an evaluation session that includes Visual Analogue Scale (VAS) for pain, Oswestry Disability Index questionnaire to assess functional disability, Straight Leg Raise Test to address nerve root irritation or compression, and Electrophysiological evaluation to determine the nerve function.

The experimental group subjects follow with 12 sessions of physical therapy over a 6-week period which include 30 min of various physical therapy exercises with the Neubie.

The control group subjects follow with 12 sessions of physical therapy over a 6-week period which include: a 30-min of various physical therapy exercises with TENS application.

At the end of the 12 sessions of treatment, subjects receive a final evaluation session that includes Visual Analogue Scale (VAS) for pain, Oswestry Disability Index questionnaire to assess functional disability, Straight Leg Raise Test to address nerve root irritation or compression, Electrophysiological evaluation to determine the nerve function, and a patient satisfaction questionnaire to assess patient satisfaction with the treatment. Participants will

receive 12 treatments over 6 weeks. Measurement of these variables will provide both quantitative and qualitative data on the severity of radiculopathy symptoms (see “Tools for data collection” below).

Clinic Sites

Hands-On Physical Therapy
32-44 31st Street
Astoria, NY 11106

Hands-On Physical Therapy of Queens Village
220-01 Jamaica Ave
Queens Village, NY 11428

Hands on Physical Therapy
3867 E Tremont Avenue
Bronx, NY, 10465

APEX Physical Therapy
15751 San Carlos Boulevard
Suite #4
Fort Myers, FL 33908

APEX Physical Therapy
900 SW Pine Island Rd
Suite 112
Cape Coral, FL 33991

WellHealth Physical Therapy
1848 Deer Park Ave
Deer Park, NY 11729

WellHealth Physical Therapy
265 N Broadway, Hicksville, NY 11801

Courcier Clinic
14017 N Eastern Ave
Edmond, OK 73013

Catalyst Physical Therapy
1206 Court Street
Clearwater, FL 33756

NCEPT Physical Therapy
457 North Elm Street

Escondido, CA 92025

Spine & Rehab Specialists
6358 Edgemere Blvd
El Paso, Texas 79925

Spine & Rehab Specialists
11855 Physicians Drive
El Paso, Texas 79936

KORT Shepherdsville
431 Adam Shepherd Pkwy
Suite 1
Shepherdsville, KY 40165

KORT Bardstown
875 Pennsylvania Ave
Suite A
Bardstown, KY 40004

Kinetix - Haile Plantation Location
2839 SW 87th Dr. Ste 10
Gainesville, FL 32608

Kinetix - Arbor Greens - Jonesville Location
13559 NW 1st Ln.
Newberry, FL 32669

Adams Physical Therapy Services
111 W North St.
Portland, IN 47371

Research Purpose and Hypothesis

Radiculopathy is one of the most common complaints evaluated by a spine surgeon. Its prevalence has been estimated to be 3%-5% of the population, affecting both men and women. Age is a primary risk factor, as it occurs secondary to the degenerative process within the spinal column[1]. Commonly referred to as a pinched nerve, radiculopathy is injury or damage to nerve roots in the area where they leave the spine[1]. Lumbrosacral and thoracic radiculopathy is the most common form of radiculopathy. It occurs in the mid to lower region of the spine and is associated with tinging, numbness, and sciatica pain in the front and lower limbs of the body[1,2]. This condition can affect anyone and can be the result disc degeneration, disc herniation or other trauma[2]. Radiculopathy occurs often with aging. As the body starts to age, the discs in the spine start to degenerate and begin to bulge or can begin to dry out and stiffen[1,2]. Common symptoms associated with radiculopathy are tingling, numbness,

weakness, pain, and decreased motor function in the lower half of the front of the body and legs[1,2]. Traditionally, non-surgical treatment for radiculopathy has focused mainly on physical therapy combined with steroid injections or non-steroidal anti-inflammatory drugs, which are temporary solutions and are associated with multiple side effects including pain at the injection site, fever, and occasionally infection[3,4]. In severe or chronic cases, invasive surgical treatments are used, including spinal decompression (discectomy) or fusion and disc replacement, which are associated with surgical risks (infection, poor wound healing, blood clots), and do not guarantee resolution of symptoms[5,6].

One non-invasive therapy for radiculopathy that has shown promise is the use of electrical stimulation (e-stim), a non-invasive therapeutic modality where nerves are stimulated with electrical current via surface electrodes to stimulate muscular contraction to improve strength and physical performance[7]. This method has been widely used for the management of nonacute low back pain[8]. It is plausible this method has potential to reduce pain in patients with low back pain by strengthening trunk muscles, similar to exercise. E-stim has few side effects and contraindications, and no known drug interactions[9]. E-stim is performed through the use of a device to send gentle electrical pulses through the skin into muscles, joints, bones, and nerves. E-stim has also been used successfully to increase cutaneous perfusion and circulation[10,11], and was found to be efficacious for postoperative pain, pain after trauma[9,12,13].

The literature on the use of e-stim for treating radiculopathy symptoms demonstrates the capability of the modality to alter nerve injury. Additionally, in conditions with similar symptoms, like neuropathy, there is growing evidence for it's use to improve nerve function. Cutaneous circulation is significantly increased with the application of e-stim, but in addition, there is evidence of increased vascular endothelial growth factor (a primary angiogenic factor)[14,15]. This increase suggests that e-stim may increase angiogenesis, which in turn may improve microcirculation associated with neuropathy, leading to reduced symptoms and improved nerve function[14,15]. Further, the application of e-stim stimulates cutaneous afferent fibers, which may contribute to the reported analgesic effect[16]. Pre-clinical studies suggest that e-stim inhibits nociception at the presynaptic level in the dorsal horn, effectively reducing pain by limiting the transmission of pain signals[16].

There are a limited number of clinical studies that have investigated using e-stim for radiculopathy symptoms. Many have used transcutaneous e-stim (TENS), which employs low frequency alternating currents (AC), and have seen some effectiveness for pain associated with neuropathy, but has limited impact on other symptoms[16]. There is evidence that e-stim has been shown to improve outcomes in foot drop secondary to lumbar radiculopathy when paired with exercise-based PT, with an increase in strength in lower limbs after each session[17]. However, the efficacy of AC current on radiculopathy is unclear, as one review of the literature found very little difference in TENS vs sham when treating cervical radiculopathy symptoms[18]. In contrast, clinical studies have found that direct current (DC) neuromuscular e-e-stim at higher frequencies is significantly more effective than TENS at ameliorating symptoms like motor function and numbness[19-22]. Further, one review compared the effectiveness of TENS versus higher-frequency e-stim devices in clinical studies of neuropathy and found a significantly increased percentage of patients with improvements in symptoms when using higher frequency e-stim compared to those using TENS[16]. A more specific

illustration of this was a study that investigated the use of at high frequency home plantar e-stim for management of neuropathy related motor-function and sensory impairments[16]. Balance, gait, stride time and length, and cadence, vascular function, and plantar sensation were measured at baseline, and after six weeks of plantar stimulation, all showed improvements. This difference in efficacy between high frequency e-stim and TENS may be in part due to the use of higher frequency DC as opposed to AC. The unidirectional flow of DC fields is more useful for rehabilitation work as it is able to achieve more input stimulation to sensory afferent signaling compared to the bidirectional flow of AC, which can cause a co-contraction that suggests both input and output stimulation to the nervous system. In contrast, DC allows for more specific contractile movement at higher amplitudes, making it more useful and efficient for training and rehabilitation[23]. Further, activation of denervated muscles requires a longer pulse length, achievable with DC but not with AC[24].

Though limited, the current evidence suggests that high frequency direct current e-stim may be an effective therapeutic avenue for improvement and management of radiculopathy symptoms, and should be investigated further. Accordingly, the purpose of the proposed study is to evaluate the immediate and long-term effectiveness of repeated treatments with a high-frequency direct current electrical stimulation device for treatment of lumbosacral radiculopathy. The Neubie Direct Current Electrical Stimulation Device offered by Neurological Fitness Equipment and Education LLC (NeuFit) is a neuromuscular electrical stimulation device that uses direct current electrical stimulation to stimulate muscle activation, blood flow, and various aspects of the nervous system. Historically, DC current has been less useful in the clinical setting, as the continuous unidirectional flow of ions leads to a buildup of charge that can cause skin irritation. The Neubie device uses a direct current frequency via conductive pads placed at the targeted areas and counters the issue of irritation with an additional waveform to eliminate skin irritation by dissipating heat and any charge buildup caused by the direct current stimulation. The Neubie device is FDA cleared for the following indications: 1) Maintaining or increasing range of motion, 2) Increasing local blood circulation, 3) Neuromuscular re-education, 4) Preventing atrophy, 5) Reducing spasms, 6) Preventing venous thrombosis after surgery, 7) Management or relief of chronic pain, and 8) Management of post-surgical and post-traumatic acute pain. The only two contraindications are: 1) The presence of a cardiac pacemaker and 2) Pregnancy. For DPN, the Neubie would be uniquely suited to be used for increasing range of motion, increasing local blood circulation, preventing atrophy, neuromuscular re-education, reducing spasms, and management or relief of chronic pain.

We hypothesize that treatment with the NEUBIE device twice a week for 6 weeks will result in improvement Visual Analogue Scale (VAS) score, Oswestry Disability Index questionnaire score, Straight Leg Raise Test degrees of movement, improved outcomes in Electrophysiological findings of Tibial H-Reflex and presence of degree of spontaneous electrical activity such as fibrillation potentials and positive sharp waves, and improvement in a patient satisfaction questionnaire score. The results of this study could impact future recovery protocols not just for radiculopathy, but any condition that results in nerve damage, muscle weakness, and chronic pain.

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Research Design and Methodology

To determine the efficacy of direct current electrical stimulation (the Neubie device) on long-term symptoms and severity of lumbosacral and thoracic radiculopathy, participants will enroll in a 6-week treatment regimen at one of 9 Hands-On Physical Therapy locations. The first session will consist of an intake evaluation session that will include: Visual Analogue Scale (VAS) for pain, Oswestry Disability Index questionnaire to assess functional disability, Straight Leg Raise Test to address nerve root irritation or compression, and Electrophysiological evaluation to determine the nerve function. These tests will serve as baseline (and a within subject control) for the intervention.

Patients will be assigned to either the control group (TENS unit) or the experimental group (Neubie) through a randomization process: All subjects will be assigned a number as they are cleared through the screening process. We will use a randomization schedule to assign these numbers, created with the Graphpad randomization calculator web application (https://www.graphpad.com/quickcalcs/index.cfm). We will use the block randomization method to build two groups of equal size, with a block size of 4. This method will satisfy our need for two equal groups sizes, control and experimental.

Participants will then undergo a specialized radiculopathy protocol that includes traditional PT therapy with the Neubie (experimental group) or TENS unit (control group) being used during PT exercises. Both the experimental and control group subjects will undergo 12 30-minute sessions of physical therapy over a 6-week period which include pre-set physical therapy exercises. We hypothesize that treatment with the NEUBIE device twice a week for 6 weeks will result in improvement Visual Analogue Scale (VAS) score, Oswestry Disability Index questionnaire score, Straight Leg Raise Test degrees of movement, improved outcomes in Electrophysiological findings of Tibial H-Reflex, and presence of degree of spontaneous electrical activity such as fibrillation potentials and positive sharp waves of muscles innervated

by L4, L5, and S1 nerve roots, and improvement in a patient satisfaction questionnaire score. These variables will provide both quantitative and qualitative data on the severity of radiculopathy symptoms (see “Tools for data collection” below).

Sample size: A power analysis was performed to determine appropriate minimum sample size for recruitment. Based on a power analysis using G*Power, we will analyze our data using a repeated measures ANOVA for within-subject factors (baseline vs post treatment). A sample size of 64 subjects per group (TENS unit or Neubie device) is sufficient to detect a clinically important difference between timepoints assuming an effect size of 0.5 between means with 80% power and a 5% level of significance. Considering a dropout rate of 10%, the sample size required will be a minimum of 141.

Data Collection Methods

Data will be collected via observational measurements taken by staff trained specifically on EMG/NCS at Hands on Diagnostics clinic sites. Consent forms and data will be stored in a locked cabinet. Data will be kept for a period of 5 years after the final report has been produced. Thereafter, the data will be destroyed. Detailed description of these measurements is included in the methodology section. Data Analysis and manuscript preparation based on findings will be performed by Dimitrios Kostopoulos, DPT, MD, PhD, DSc, ECS (co-PI) and Ramona von Leden, PhD (Director of Research at NeuFit).

Participant data will be analyzed to test for an intervention main effect and symptoms at beginning and end of treatment completion (time x intervention). Measurements at the final treatment session will be compared to baseline with an ANOVA (significant changes in EMG/NCS – baseline vs session #) as a within-subject factor.

Tools for Data Collection

Time commitment for participants: 12 hours over 6 weeks (1-hour sessions, frequency detailed below).

Materials Needed:

NEUBIE device

Electrodes

Carbon Fiber Pad

AMBU Nerve Conduction Study disposable skin electrodes

AMBU EMG needle electrodes

Alcohol wipes

Cadwell Summit EMG device

Needle Disposal Receptacle

Intervention/Treatment Protocol

Neurostimulation pads (either rectangular or circular carbon fiber) are linked to electrodes (designated red and black) for paired placement on the skin. Pad colors determine polarity of electrical current (Red = positive, Black = negative; typical direction of electron current flow is Black to Red).

Standardized pad placement: Rectangular electrodes attached to the red leads will be placed on the myotome of affected nerve (as determined by EMG). To address distal denervation, the rectangular electrodes attached to the black leads will be placed on the Tibialis Anterior muscle for cases of L4 radiculopathy, Extensor Digitorum Brevis muscle (EDB) on the dorsum of the foot for cases of L5 radiculopathy and the Soleus muscle for cases of S1 radiculopathy, as indicated by EMG findings. When multiple levels involved, then the most distal muscle will be selected.

Standardized training frequencies: Electrical frequencies used are standardized via NeuFit's protocols. The pulses per second (PPS) determine the type of stimulation being provided. Frequencies on the Neubie range from 1-500 PPS. The PPS designated here (500 PPS) causes a smoother stimulation (rather than intermittent contractions) that results in relaxation to support increased range of motion, nerve conduction, and stimulation of blood flow.

Training intensity: Participants will be asked to undergo e-stim with the Neubie at their "treatment threshold". Treatment threshold will be described as "uncomfortable," but not "painful" (a 5-7 out of 10 on a perceived intensity scale). While being stimulated, participants will be asked to undergo a variety of PT exercises to mobilize their hips, legs, feet and ankles.

Duration of sessions: Roughly 45-60 minutes per session – 30 minutes of stimulation (either Neubie OR TENS application) + physical therapy exercises + time for clinical measurements/outcome measures.

At the end of the 12 sessions of treatment, subjects receive a final evaluation session that includes a Visual Analogue Scale (VAS) score, Oswestry Disability Index questionnaire score, Straight Leg Raise Test degrees of movement, Electrophysiological findings of Tibial H-Reflex, and presence of degree of spontaneous electrical activity such as fibrillation potentials and positive sharp waves of muscles innervated by L4, L5, and S1 nerve roots, and a patient satisfaction questionnaire score.

Outcome Measures

Pre and post treatment paradigm (at baseline and at 6 weeks), the following variables will be evaluated: Visual Analogue Scale (VAS) score, Oswestry Disability Index questionnaire score, Straight Leg Raise Test degrees of movement, Electrophysiological findings of Tibial H-Reflex, and presence of degree of spontaneous electrical activity such as fibrillation potentials and positive sharp waves of muscles innervated by L4, L5, and S1 nerve roots, and a patient satisfaction questionnaire score.

Procedures and Risks

Risks associated with participation in this study are minimal and no greater than those experienced during a routine physical therapy intervention. Both AC and DC stimulation has been employed in physical therapy practice for over 15 years. Risks associated with electrical stimulation include mild discomfort caused by the sensation of the electrical stimulation (buzzing, tingling), and possible delayed onset muscle soreness (DOMS) after sessions.

This therapy is non-invasive, and stimulation intensity is governed by the participant. The patient will be asked to tolerate some discomfort with a perceived intensity level of 5 out of 10 but will never be asked to tolerate intensity that causes pain. Further, they will be monitored for the duration of the sessions by their practitioner and will never be left alone while being stimulated.

Potential Benefits

Participants will receive electrical stimulation treatments specifically in the lower back and leg regions. This 12-session course of treatments may decrease symptoms associated with radiculopathy, including nerve damage related weakness, numbness, and pain. Such improvements in pain could significantly benefit participants quality of life and physical mobility.

Benefit to Society The use of a non-invasive medical device like the Neubie for treatment of peripheral neuropathy could have several major benefits. Most substantially, it could validate a treatment that could be used in both a clinic setting, or with proper training, at home by patients, to keep radiculopathy related symptoms from worsening or reoccurring. It could also help in understanding the use of electrical stimulation in rehabilitation from neurological disease, nerve damage, and neuropathic pain.

Data Safety Monitoring

The study does not have a data and safety monitoring board, but the researchers have an internal plan for data and safety monitoring. Safety information will be collected by staff at Neufit and Hands On Diagnostics. All personnel involved with patient interactions will have completed necessary HIPAA training.

Safety data collection will start from recruitment and will be collected at each treatment session. The data, specifically patient health and response to treatment, will be reviewed by the PIs monthly. Research will be suspended if there is any indication of injury or increased pain to participants. Patients will be withdrawn early from the study if there is an indication that they are unable to comply with the protocol or there are any safety concerns related to side effects of the e-stim. If withdrawn early due to safety concerns, clinical evaluation by a physician may be necessary to evaluate for additional health issues.

Population and Sample

Inclusion criteria:

1. Must show evidence of lumbo-sacral radiculopathy as determined by EMG and straight leg raise test.

2. Must be able to attend weekly sessions for the 6-week period of the study (no extended travel)

3. Must be at least 18 years old.

Exclusion criteria:

1. Currently pregnant
2. Cardiac pacemaker
3. Active or recent cancer
4. Active or recent blood clots
5. History of epilepsy
6. Open wounds
7. Spinal fusion surgery

Participant Recruitment

Participants will be recruited from existing clinic patient population who seek treatment for radiculopathy. Any patient meeting the criteria who contacts any of the study sites will be told about the study and will be provided with a copy of the informed consent to review. Clinic Managers will handle enrollment at their respective sites. During phone or in person consultation, patients who are interested in joining the study will be required to enroll and submit the signed informed consent form prior to their evaluation visit.

No incentive will be offered or provided for the study beyond treatment outcomes.

Privacy and Confidentiality

Initial recruitment may occur over the phone, but all additional consent processes and procedures will occur behind closed doors in private treatment rooms with only staff involved in conducting the study present to minimize the risks of privacy.

Results of this study may be used in publications and presentations. The study data will be handled as confidentially as possible. Individual names and personal identification information will not be collected at any point. Data may be shared for use in future studies or with other researchers. In this case, any personal identifying information of participants will not be

included.
Participant data will be stored without any identifiers or codes for three years or longer.