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Cover Page Footnote

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The Effects of Deep Oscillation Therapy for Individuals with Lower-Leg Pain

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Purpose: Lower extremity (LE) pain accounts for 13-20% of injuries in the active population. LE pain has been contributed to inflexibility and fascial restrictions. Deep oscillation therapy (DOT) has been proposed to improve range of motion and reduce pain following musculoskeletal injuries. Therefore, our objective was to determine the effectiveness of DOT on ankle dorsiflexion range of motion (ROM) and pain in individuals with and without lower-leg pain. **Methods:** We used a single blind, pre-post experimental study in a research laboratory. Thirty-two active participants completed this study. Sixteen individuals reporting lower-leg pain and sixteen non-painful individuals completed the study. Participants received a single session of DOT performed by one researcher to their affected limb or matched limb. The intervention parameters included a 1:1 mode and 70-80% dosage. The intervention began by stimulating the lymphatic channels at the cisterna chyli, the inguinal lymph node, and the popliteal lymph node at a frequency of 150 Hz all for a minute each. Next, the researcher treated the triceps surae complex for 11 minutes at three different frequencies. Finally, the participant was treated distal to the popliteal lymph node at 25 Hz for 5 minutes. The main outcome measures included pain using the VAS and ankle dorsiflexion ROM with the weight-bearing lunge test (WBLT). Statistical analyses included descriptive statistics and F-test comparisons between and within groups. **Results:** The average WBLT measures for all participants increased 0.6 cm, which not to the minimal detectable change for passive ankle dorsiflexion ROM. Significant differences from pre-post measures were identified for pain on the VAS. **Conclusion:** While increases in ROM were identified, the difference was not clinically important. DOT was successful in decreasing lower-leg pain. **Keywords:** Hivamat, manual therapy, flexibility

INTRODUCTION

Lower-leg pain is a contributing factor to several pathologies that affect the physically active. While lower-leg pain itself is not a diagnosis, there are theoretical frameworks of how lower-leg pain may be an indicator for injuries such as medial tibial stress syndrome, stress fractures, and compartment syndrome. Two theoretical frameworks regarding the etiology of lower-leg pain include the fascial distortion model of the deep posterior compartment muscles pulling off the tibia during prolonged activities, or the inflexibility of the flexor digitorum longus, soleus, and tibialis posterior.¹⁻⁶ As these are considered the source of exercise-associated lower-leg pain, the treatment for the symptoms has been commonly approached through the paradigm of stretching and reduction of load.⁷ While these methods may be effective, there is

a need to explore the myofascial perspective related to the triceps surae (the gastrocnemius muscle and soleus muscle), specifically. As ankle dorsiflexion is limited by triceps surae tightness, there may be a link of this inflexibility with the associated signs and symptoms of lower-leg pain.^{8,9} When approaching interventions for lower-leg pain, clinicians should consider identifying the source of pain, rather than the site of pain itself. Many of these interventions focus on the management of the symptoms rather than the etiology of the condition. Common conservative interventions in treating lower-leg pain include neuromuscular control training and manual therapy targeted at increasing range of motion at the ankle.^{8,10,11}

Deep oscillation therapy (DOT) is a complementary therapeutic intervention that can be used for a variety of patient outcomes

including the promotion of tissue healing,¹² pain modulation,¹²⁻¹⁵ and anti-inflammatory effects.^{12-15,16} Previous research has also found that the use of DOT can increase muscular flexibility.^{13,17-20} Theoretically, DOT is thought to deliver various levels of frequency through an electrical circuit that is created by the modality and completed through the addition of two leads held by the patient and the clinician. The circuit created is referred to as the Johnsen-Rahbeck effect, where a magnetic force is created and a barrier is placed between two electrodes.²¹ From this effect, a vibration occurs that stimulates the flow of interstitial and lymphatic fluids, and has been theorized to decrease pain by causing alteration in fluid flow and micro-circulation of the interstitial connective tissue.^{18,21} The main difference between DOT and manual massage therapy is the reduction of pressure necessary from the clinician, which is advantageous for acute and painful conditions.

From the previous research completed on DOT and the benefits it has proposed, there is potential for the modality to aid in reduction of pain and increase muscular flexibility as it relates to lower-leg pain. Therefore, the purpose of this study is to determine the effectiveness of DOT in improving the flexibility of the triceps surae complex, as well as alleviate in the lower-leg. We hypothesized that participants would experience a decrease in lower-leg pain and an increase in ankle dorsiflexion following the DOT intervention.

METHODS

Design

We used a single blind, pre-post experimental study. The intervention used for this study was deep oscillation therapy. The independent variables were time (pre- and post-intervention) and group (non-painful and painful). The dependent variables were passive ankle dorsiflexion range of motion (cm) as measured using the weight-bearing lunge test (WBLT); self-reported pain as measured using the visual analogue scale

(VAS) in centimeters; and intervention perceptions assessed using the Global Rating of Change scale (GROC) measured in points.

Participants

An a priori sample size calculation identified a sample size of 32 participants for a power of 0.8. Thirty-two physically active individuals (males = 13, females = 19) participated in this study. Participants were recruited through flyers and word of mouth from a university campus. To be included in the study, participants had to be between 18 and 30 years of age and self-report at least 200 minutes of moderate or vigorous physical activity per week. Participants were excluded from the study if they did not meet the inclusion criteria or if they had any self-reported contraindication to DOT.²² After meeting inclusion criteria, the participants were designated to the non-painful group (n=16) or painful group (n=16) based on their self-reported lower-leg pain using a validated region-specific tool.²³ The tool used for group allocation consisted of items regarding the participant's lower-leg pain with rest and during activity. A score of one or greater on the tool qualified the participant for the painful group. Demographic data for all participants by group are presented in Table 1. Before the participants were recruited, Institutional Review Board approval was granted. All participants signed an informed consent and were made aware of any risks associated before partaking in the study.

Group	n	Male	Female	Age (years)	Height (cm)	Mass (kg)
Mean ± SD						
Non-Painful Group	16	8	8	23 ± 2	171.6± 8.7	79.6 ± 15.0
Painful Group	16	5	11	22 ± 3	169.5± 9.3	73.4 ± 11.1
All Subject	32	13	19	22 ± 2	170.5± 8.9	76.5 ± 13.4

Table 1. Participant Demographics

Procedures

Qualifying participants attended one data collection session in a university-based research laboratory. Two researchers were used to collect the study measures. Following informed consent, researcher A answered any questions related to completing the group allocation tool. After group allocation, participants completed the VAS. To collect baseline pre-measurements, researcher B was blinded to the group allocation. Researcher B collected WBLT pre-intervention measurements for both limbs. After pre-measurement data collection, researcher A administered the DOT intervention to the painful limb for the lower-limb pain group and to the matched limb for the non-painful group participants. Following the intervention, researcher A administered the post-intervention measures of VAS and the GRoC to participants. Once all the VAS and GRoC measurements had been recorded, researcher B collected post-intervention measurements. The total time spent participating in this study was approximately one hour.

Instrumentation and Measures

Deep Oscillation Therapy

For this study, we utilized a commercially available DOT modality (HIVAMAT® 200, Physiomed Elektromedizin AG; Schnaittach, Germany) that was calibrated prior to the start of data collection. Participants went through a three-phase, mobility-focused protocol produced by the manufacturer (Figure 1).²²

The research team was trained in proper application of the DOT modality from the manufacturer representatives. Prior to the intervention, the participant's area of treatment and hand that held the lead from the DOT modality were dried. The treatment was conducted on an examination table that had no direct contact with metal from the researcher or the participant.



Figure 1. Application of the DOT intervention to the lower-leg

A small amount of talcum powder was applied to the triceps surae complex to reduce friction from the vinyl gloves of the researcher to the skin of the participant. The spiral lead was connected to the connector sockets on the front panel of the DOT modality and an adhesive electrode was placed on the inside surface of the forearm of the researcher and secured using foam underwrap for the duration of the treatment. The second lead was given to the participant in the form of a neutral bar, which is made of titanium and held in their hand for the duration of the intervention. The researcher clearly articulated to the participant to maintain full contact with the conductor for the duration of the treatment to ensure the electrical field worked properly. The intervention began by activating the lymphatic system applying the DOT modality over designated areas using a circular motion with no pressure. The first area was treated for a one-minute intervention on the cisterna chyli (inferior to the xiphoid process of the sternum) at 150 Hz. Next, there was a one-minute intervention at the inguinal lymph node at 150 Hz, followed by a one-minute treatment at the popliteal lymph node at 150 Hz. After the initial phase of the protocol, the three-part flexibility-focused protocol began with the participant in a prone position. The gastrocnemius muscle

from the muscular heads to the calcaneal insertion was the target for the intervention. First, the researcher set the DOT modality to 120 Hz for four minutes. Next, the intervention consisted to 85 Hz for three minutes. The third part of the protocol treated the calf at 20 Hz for four minutes. All calf interventions utilized effleurage massage with no pressure starting inferior moving superior for lymph flow and venous return. After the third part of the protocol was finished, the DOT intervention was be completed with a five-minute stimulation of the popliteal lymph node of massage using circular motion with no pressure at 25 Hz.

Weight-Bearing Lunge Test

The WBLT is a test used to measure passive ankle dorsiflexion range of motion in the weight-bearing posture. The WBLT has strong test-retest reliability for participants with ankle dysfunction.^{24,25} Previous research has identified that WBLT minimal detectable change using the test was 1 cm for the affected limb and 1.5 cm for control limbs with no reported pathology.²⁵ Participant were provided verbal instructions and demonstration from the researcher on how to perform the test using the knee-to-wall method (Figure 2) used in previous research.²⁶⁻²⁸ Participants were placed in front of the designated doorframe where they were asked to place their testing foot on the tape measure 5 cm away from doorframe to start test and then informed to lunge towards the doorframe, and aim to hit their knee on the frame.²⁹ The participant was not allowed to lift their heel off the floor or move their foot closer to the doorframe. If the participant was able to complete this, then their foot was moved further back on the tape measure until they were no longer able to reach frame or lift their heel. At that time, the distance was recorded for the participant. These steps were repeated three times and averaged together to determine the mean WBLT measure per limb.



Figure 2. The Weight-Bearing Lunge Test

Visual Analogue Scale

The VAS was used to measure pain before and after the intervention session. The VAS is a single-item, unidimensional measure of pain intensity.³⁰ The participants were asked to mark their current pain on a ten-centimeter line with the left anchor representing zero or no pain and the right anchor representing ten or the most pain. After marking their current pain, the researcher used a tape measure to determine their pain by measuring the mark from the left anchor using centimeter scoring with millimeter designation. Previous literature has reported high test-retest reliability for the VAS.³¹ The minimum clinically significant difference has been estimated at between 1.0-1.4 cm on an eleven point scale.^{32,33}

Global Rating of Change

We utilized the GROC patient-reported outcome tool in order to analyze the participants' perceptions for change after DOT intervention. The single-question tool provided a Likert-scale of option ranging from -7 to 7 prompting the participant to rate their overall condition from the time they began the intervention to the time they were completing the tool.^{34,35} The GROC has excellent test-retest reliability.³⁵ The GROC provides a participant-reported outcome regarding the effectiveness of the DOT intervention.

Statistical Analysis

Data were collected and entered into a custom spreadsheet software (Microsoft Excel 2013, Microsoft Corp., Redwood, WA, USA). Descriptive and inferential statistics were completed. We completed multiple 2 x 2 (time x groups) repeated measures ANOVA on each of the dependent variables. We completed follow up dependent t-tests with Holms' sequential Bonferroni adjustments when appropriate. To analyze GROC scores, we utilized an independent sample t-test as data was only collected post-intervention. All data were analyzed using commercially available statistical analysis software (IBM Corp. IBM SPSS Statistics for Windows, Version 24.0).

RESULTS

Means and standard deviation for baseline and post-intervention for measures of WBLT, VAS, and GROC measurements are represented in Table 2. (Armonk, NY). Significance levels were set at $p \leq 0.05$ *a priori*. We identified a significant difference (95% CI: -0.83, -0.41, $p < 0.05$) between pre and post-intervention measures for ankle dorsiflexion ROM, yet no significant difference was found between the non-painful and painful groups. Additionally, we identified a significant difference between time and groups (Wilks' $\lambda = 0.61$, $F(30,1) = 18.95$, $p < 0.001$, $\eta^2 = 0.387$) for the self-reported measure of pain using the VAS. Finally, we identified no significant difference between the two groups following an intervention of DOT ($t(30) = -0.86$; $p = 0.40$;

mean difference = -0.44) for the measures of GROC.

Variable	Non-Painful	Painful	All Subjects
WBLT (cm)			
Baseline	13.1 ± 0.7	11.9 ± 0.7	12.5 ± 3.0
Post Intervention	13.6 ± 0.7	12.6 ± 0.7	13.0 ± 3.0
VAS (cm)			
Baseline	0.1 ± 0.5	2.4 ± 1.5	1.3 ± 1.6
Post Intervention	0.0 ± 0.0	0.9 ± 1.3	0.5 ± 1.0
GROC (points)			
Post Intervention	2.31 ± 1.40	2.75 ± 1.49	2.53 ± 1.51

Table 2. Mean and standard deviation data per outcome measure

DISCUSSION

The purpose of this study was to observe the effectiveness of DOT for improving flexibility of the triceps surae complex and perception of pain associated with lower-leg pain. We observed that a single session of DOT did improve passive ankle dorsiflexion ROM when looking at both the non-painful and painful participants, yet the improvements that we did identify did not meet the minimal detectable change for the WBLT. However, the DOT intervention did have significant alleviation of pain for the painful group. These findings are similar to previous research regarding DOT intervention to decrease pain and improve mobility and flexibility.^{13,15,17,18} While the outcomes are similar, it is important to note that the interventions methods differed in several of the previous studies that did not report clearing the lymphatic channel prior to intervention at the treatment site. Previous research has identified that a lack of ankle dorsiflexion ROM is a risk factor and contributor to lower-leg pain conditions such as MTSS.³⁶

Ankle Dorsiflexion Range of Motion

Common conservative interventions in treating lower-leg pain include neuromuscular control training and manual therapy targeted at increasing range of motion at the ankle.^{8,10,11} While these methods may be effective, there is a need to explore the

myofascial perspective related to the triceps surae. As ankle dorsiflexion is limited by triceps surae tightness, there may be a link of this inflexibility with the associated signs and symptoms of lower-leg pain.^{8,9} When approaching interventions for lower-leg pain, it is important that the clinicians identify the source of pain, rather than the site of pain itself. As previously described, one cause of the lower-leg pain can originate from fascial restrictions specific to the fascial distortion model.^{2,37} The methods described for fascial distortion mimic that of other pressure and manual therapies such as active release therapy and myofascial decompression. Additionally, the fascial distortion model seeks to replicate the model of deep lower-leg flexors tension created from overuse translated to the medial tibia at the site of attachment and the soleus.⁵ This is of interest to our study as the methods used focused on treatment to the posterior lower-leg, specifically the triceps surae. The treatment of the triceps surae has shown effects to improve ankle dorsiflexion with other interventions.³⁸ We believe the method of treating the origin of the musculature that inserts on the medial tibia may serve as treatment perspective worth exploring in further detail.

Multiple theories have been associated with positive outcomes of DOT. An emerging theory regarding DOT interventions is rooted in decreasing the excitability of the nerve to relax the nearby musculature.¹⁸ With a relaxation of the triceps surae complex, the proposed result would be greater ankle dorsiflexion. One method of assessing for greater ankle dorsiflexion is the WBLT. Previous research identified that the knee-to-wall method for the WBLT has a minimal detectable change of 1.9 cm for intra-clinician testing.²⁵ We observed that all participants from both groups had an increase in passive ankle dorsiflexion, yet the change did not meet the minimal detectable change as cited previously. The painful group improved more than the non-painful group on the test (painful group = 0.7cm; non-painful group = 0.5cm).

While these findings demonstrate some effectiveness in the DOT intervention, clinicians should be mindful that a single session of DOT may not produce a desirable outcome when seeking to improve the patient's ankle dorsiflexion. Soft-tissue mobilizations for the lower-leg muscle have similar range of motion changes as DOT. As manual therapy and instrument-assisted mobilizations can cause an increase of immediate pain,³⁹ clinicians should explore using DOT as the intervention is applied with minimal pressure with similar outcomes. Additionally, a prevention framework should be explored regarding the use of DOT to increase the range of motion for individuals identified with the risk factors for lower-leg pathologies such as MTSS. Future research should explore the role of DOT intervention in combination with therapeutic exercise to maintain the desired effects.

Pain

Pain levels for the painful group decreased by 1.5 cm following the intervention. The participants in our study reported a mean baseline pain level of 2.4 cm on the VAS. We believe the lower reporting at baseline may be due to the fact that we asked the participant to denote their current pain at rest rather than pain at activity. The literature for lower-leg pain states that activity and impact exacerbates painful signs along the tibia causing an increased perception of the pain.⁴⁰ Previous research on interventions for lower-leg pathologies such as periosteal pecking and extracorporeal shockwave therapy have provided symptom relief to the patients.⁴¹ The findings from this study support the reduction of painful symptoms through relaxation during the intervention. DOT is applied with minimal pressure and vibrating sensations causing a therapeutic effect that may have masked the painful signals associated with the participant's lower-leg pain. As such, we believe DOT may have value in treating patients that have acute or chronic lower-leg pain because of the analgesic effect it provides.

Rating of Change

The GROC, a patient-reported outcome tool, was used to identify participant perceptions regarding the effectiveness of the intervention. We found no significant difference between the non-painful group and the painful group on GROC scores. This may be due to the relatively large standard deviations among participants. Regardless of group assignment, participants reported feeling “a little better” to “somewhat better” (mean = 2.53 points) following the intervention. Our finding is similar to previous research that identified a GROC score of 3.17 points following a DOT intervention at the hamstring for healthy subjects.¹⁸ Patient-reported outcomes are a vital measure in the clinical assessment regarding the effectiveness of treatment interventions and functional status related to region-specific, disease-specific, or overall health status.⁴² In this study, the GROC was utilized as a health status tool specific to the participants’ lower-leg pain. We suggest that researchers integrate patient-reported outcomes into translational research studies⁴³, much like this study, as a means for clinicians to replicate this and future investigations with actual patients at the point-of-care.

LIMITATIONS

Our study had external validity limitations. First, we did not identify if the participants were clinical diagnosed with a lower-leg pathology. As such, the results of this study may not be generalizable to patients suffering from a range of lower-leg pathologies as inflexibility may not be a contributing factor for their condition. Additionally, the participant demographics were relatively young individuals (mean age = 22 ± 3 years). This variable limits the applicability of the findings to older, active adults. When measuring outcomes, we only tested the participants immediately after the intervention of DOT. The participants were not asked to complete any physical activity after the intervention. This resulted in short-term results with no measure of long-term

benefits. A secondary data collection following activity could be beneficial to identify any long-term effects of the intervention.

FUTURE RESEARCH

Future research should investigate the long-term changes in pain and flexibility measures following single and multiple sessions of a DOT intervention. This may include follow-up investigations regarding the sustained alleviation of pain after the participant has returned to physical activity. We also recommend an in-depth investigation regarding how DOT interventions when combined with therapeutic exercise and manual therapy affect flexibility and pain using validated, patient-reported outcomes.

CONCLUSION

While an intervention of DOT improved the weight-bearing ankle dorsiflexion ROM, the increase did not meet the minimal detectable change for the measure. Additionally, the DOT intervention decreased the pain for the painful group making it an option in the treatment of lower-leg pain conditions. Our study adds to the growing literature base regarding the effectiveness of muscular flexibility and mobility effects related to DOT interventions.

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