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Does the osteopathic pedal pump reduce lower limb volume in healthy subjects?

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Abstract

Context: Lymphatic treatments are gentle and passive techniques believed to enhance movement of lymph back into the central circulatory system. Animal studies provide supportive evidence, yet there are few studies in humans.
Objectives: The aim of this study is to investigate whether the osteopathic pedal pump protocol reduces volume in the lower limbs of healthy subjects.
Methods: A total of 30 first- and second-year medical students were recruited. Subjects were excluded from participating if they had acute asthma, chronic obstructive pulmonary disease (COPD), congestive heart failure, active infections, fractures of the lower extremities, or metastatic cancer. A within-subjects study design with pre- and posttreatment measurement of lower limb volume was utilized. Pretreatment lower limb volume measurements were obtained utilizing a volumetric water gauge prior to myofascial thoracic inlet release and a 5 min pedal lymphatic pump protocol treatment. Posttreatment lower limb measurements were taken immediately following the protocol treatment. A telephone interview was conducted 2–3 days after the treatment to assess the participants' experience of the treatment and whether the treatment elicited a subjective change from baseline. A paired t test was utilized to determine the statistical significance of volume displacement posttreatment.
Results: The mean change of pretreatment to posttreatment lower limb volume was −45.63 mL with a standard deviation of 37.65 mL. The change between the pretreatment and posttreatment volume measurements was statistically significant ($p<0.001$). The minimum displacement was +19 mL, and the maximum displacement was −167 mL. The majority of participants perceived the treatment as effective and enjoyable, were likely to recommend it to others, and were willing to have it performed on them at routine office visits if there was a need.
Conclusions: The osteopathic pedal pump technique, when utilized on those without leg lymphedema, reduces lower limb volume as measured by the volumetric water gauge. Further studies are warranted, especially in persons with excess lower-extremity edema, lymphedema or venous stasis.

Keywords: edema; lymphatic pump; lymphedema; osteopathic; pedal pump.

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The osteopathic profession has traditionally stressed the importance of the lymphatic system in the treatment of disease and maintenance of health. In 1898, Andrew Taylor Still, MD, DO, wrote, "Thus we strike at the source of life and death when we go to the lymphatics." Early osteopaths wrote extensively about lymphatic anatomy and how to utilize manual treatments to unblock restrictions to lymphatic circulation [1]. In the 1920s, Miller [2–4] developed a new class of manual techniques designed to enhance the movement of lymph and coined the term "lymphatic pump." Today, lymphatic pump techniques are taught in all osteopathic medical schools. These are gentle, passive techniques purported to be useful for treating conditions related to excess interstitial fluid (edema, lymphedema, and venous stasis) and for enhancing the immune response to infections by enhancing the movement of lymph to the central circulatory system [5].

Animal models provide evidence that lymphatic pump techniques enhance both immune function and the transport of lymph. Dery et al. [6] showed that intermittent pulsation pressure applied to the ventral thorax of rats enhances uptake into the lymphatic circulation from the potential space near the rat's hip between the two heads of the rectus femoris muscle. In five dogs surgically fitted with a transducer to measure flow through the thoracic duct, lymphatic pump techniques increased lymph flow through the thoracic lymphatic duct [7]. Further animal models show that lymphatic pump techniques increase flux of white blood cells and the movement of inflammatory cytokines through the lymphatic duct [8–10]. In rats, lymphatic pump techniques inhibit the growth of *Streptococcus pneumoniae* bacteria in the lungs and enhance the effectiveness of antibiotics for clearing *S. pneumoniae* from the lungs [11, 12]. In a multicenter clinical trial, a combination of thoracolumbar soft tissue, rib raising, doming of the diaphragm, myofascial release, cervical soft tissue, suboccipital decompression, thoracic inlet myofascial release, thoracic lymphatic pump, and pedal lymphatic pump were utilized to treat pneumonia in 387 elderly individuals. This protocol reduced the hospital length of stay by 2.9 days (p=0.006) and reduced mortality (2% mortality in group that received OMT vs. 3% mortality in those who received light touch vs. 13% mortality in those who received conventional care only, p=0.05) [13–15].

Unfortunately, evidence that lymphatic pump techniques remove excess interstitial fluid volume in clinical disorders relating to edema, lymphedema, or venous stasis remains mostly anecdotal. One small clinical trial found that the pedal lymphatic pump reduced lower-extremity edema and wound size by 4.9 cm^2/week in five out of eight subjects [16]. Edema is palpable swelling caused by an increase in interstitial fluid volume with stagnant fluid, whereas lymphedema is more chronic and is associated with the accumulation of proteins and cytokines leading to fibrosis of the tissues [17]. Lower-extremity edema, lymphedema, and venous stasis are common disorders contributing to cellulitis, poor wound healing, venous stasis ulcers, and other morbidities [18, 19]. Both edema and lymphedema have many causes including venous insufficiency, lymphatic dysfunction, pulmonary hypertension, heart failure, certain medications, and obesity [20].

To our knowledge, no published studies have evaluated the effectiveness of the pedal lymphatic pump technique for removing excess fluid volume from the lower extremities. The present feasibility study was designed to determine if the use of the pedal pump technique following the opening of the thoracic inlet with the myofascial release technique is able to move volume out of the lower extremities in normal adults without comorbidities or lower-extremity edema. This study was preliminary to evaluating the efficacy of this same protocol in seniors with chronic edema or lymphedema in the lower extremities. Water volume displacement volumetry was chosen to assess changes in lower-extremity volume because it is practical, accurate, and considered a gold-standard method of lower-extremity volume measurement [21].

Methods

This study was reviewed and approved by the Institutional Review Board of Rowan University School of Osteopathic Medicine (PRO-2020-72) and registered at ClinicalTrials.gov (No. NCT05119517). The study was funded by the Osteopathic Heritage Foundation for Primary Care Research. Informed consent was obtained from each participant utilizing paper forms by J.A., S.P., and B.G. prior to taking part in the study. Each participant received a $10.00 gift card for completing the study.

Participant recruitment

First- and second-year medical students were recruited to participate in the study utilizing either the online application GroupMe or by word of mouth. The recruitment materials included a description of the study design, treatment procedure, and acknowledgment of a $10 TD Bank gift card for completion of the study. Subjects interested in participating in the study were then instructed to input their name, phone number, and email address with their study appointment date preference on the electronic survey tool, Qualtrics. The subjects were scheduled for half hour appointments with the study team on Friday afternoons over the course of one month ranging from Apr 6, 2021 to May 7, 2021. At each of the subject's appointments, the subject was brought into the room, the procedure was explained, and the subject's eligibility to take part in the study was confirmed. To be included in the study, participants had to be currently enrolled as medical students at Rowan-Virtua School of Osteopathic Medicine. Subjects were excluded from the study if they had acute asthma, chronic obstructive pulmonary disease (COPD), congestive heart failure, active infections or fractures of the lower extremities, or metastatic cancer. Once eligibility was confirmed, written informed consent was obtained, and demographic information was collected. Demographic information consisted of age, height, weight, and sex. Data on the demographics of each participant was collected via self-report utilizing an open-ended question to describe the study sample.

Procedures

The initial water displacement of one lower extremity was measured utilizing a Baseline® Volumetric Edema Gauge from Fabrication Enterprises, Inc. (Elmsford, New York), dimensions 6 × 13 × 24 inches. The volumetric gauge was placed on a compact moving dolly to facilitate easy positioning under the limb to be measured. The volumetric gauge was filled with water until a meniscus formed at the edge of its spout. The student was instructed to sit on the examination table behind the volumetric gauge, and to remove his or her shoes and socks. The examination table was elevated to facilitate positioning of the limb to be lowered into the volumetric gauge. The student's leg was guided into the volumetric gauge and lowered until the sole of the foot rested on the bottom. The distance between the bottom of the volumetric gauge on the edge of the spout opening was 34 cm. This was the portion of the lower extremity measured for volume displacement. The water was generally level with the mid-calf and in no case did it go above the knee. The displaced water was caught utilizing a 5-gallon plastic bucket. The limb was kept in the volumetric gauge until all water had stopped coming out of the spout. The medical student's foot was then slowly lifted out of the bucket and dried. Water from the bucket was transferred into a 1000 mL plastic beaker and then into a 1000 mL plastic graduated cylinder for measurements. A 100 mL glass graduated cylinder was utilized to measure the remainder of the volume to the nearest mL and recorded. After the baseline measurement was completed, the subject received a 10 min protocol treatment consisting of myofascial release to the thoracic inlet and the osteopathic pedal pump. The myofascial release was performed by J.A. on all patients, and the pedal pump technique was performed by either J.A. or B.G. following training with D.N. The thoracic inlet was treated first utilizing direct and indirect myofascial release technique. The subject lay supine on the examination table, and the operator placed both hands over the thoracic inlet and engaged the myofascial tissue assessing motion in three planes (X-axis [cephalocaudad], Y-axis [left to right], and rotation around a Z-axis [clockwise and counterclockwise]). The patient was instructed to take deep breaths for the use of respiratory assist in the myofascial release. First, the operator moved the tissues away from the restriction (moved to a point of ease) for 30 s or until a release was palpated, then the tissues were taken directly into the barrier for a release. The pedal pump was then performed by either J.A. or B.G. for 5 min while the student remained supine. The operator stood at the foot of the table, placed hands on the balls of both feet and then induced a rhythmical cephalo-caudad motion by dorsiflexing the feet, causing the whole body to move superiorly, and then rebound back toward neutral. Once back to neutral, the feet are dorsiflexed again to set up a cephalo-caudad body rhythmic motion, at approximately 110–130 cycles per minute. This motion causes a flexing and relaxing motion in the tissues of the lower extremities and induces the abdominal contents to move up and down against the abdominal diaphragm.

Immediately following the treatment protocol, the posttreatment volume displacement measurement was taken utilizing the same limb and method as the pretreatment measurement. The posttreatment volume displaced was recorded, and the difference in volumes was calculated.

Follow-up was completed 2–3 days after the procedure via telephone call. The follow-up form included six questions, including four 5-point Likert scale multiple-choice questions and two open-ended questions. The purpose was to collect data regarding patient satisfaction and to rule out side effects of the treatment. All 30 subjects completed the follow-up survey.

Statistical analysis

To analyze the data, IBM's Statistical Package for the Social Sciences (SPSS) was utilized. A paired t test was utilized to determine the statistical significance of volume displacement posttreatment. Measures of central tendency were also utilized in addition to frequency distribution for demographic information.

Results

A total of 30 normal, healthy subjects without lymphedema of the lower extremities completed the study. The average age of subjects in the study was 24.53 years (range, 22–30 years). Fifteen subjects were male (50%), and 15 were female (50%). The mean body mass index (BMI) of all subjects was 24.56 kg/m^2. All subjects reported no comorbidities and self-reported that they were healthy. The demographics of the study cohort are summarized in Table 1.

The mean distal 34 cm of one lower limb pretreatment volume was 2,303.6 mL (SD, 435.27 mL) with a range of 1,534–3,760 mL. The posttreatment mean volume was 2,257.7 mL (SD, 435.95), with a range of 1,510–3,779 mL. The mean change in volume of the distal 34 cm of one lower limb was −45.63 mL (SD, 37.65 mL), with a range of +19 to −167 mL. The change between the pretreatment and posttreatment volume measurements was statistically significant ($p<0.001$). The pretreatment-to-posttreatment change in volume displacement for subjects ranged from a +19 mL to a −167 mL. The individual with a gain in volume likely reflects a measurement error due to a small amount of water being spilt during measurement. Table 2 summaries the water volume displacement measurements.

In a post-hoc analysis, no other recorded variable (age, BMI) accounted for statistically significant changes in water displacement. It was observed that the two individuals with the greatest decrease in limb volume (−114 mL and −167 mL) were females undergoing menses at the time of the study.

There were two open-ended posttreatment survey questions, one questioning the length of the treatment effects, if any, and the other questioning if there were any noted side effects. All 30 subjects reported only transient effects of the procedure, with the overwhelming majority reporting less than 24 h of posttreatment effects. Two subjects thought the effects may have lasted 2 or 3 days. The posttreatment side effects included the need to urinate following delivery of the pedal pump. Two subjects reported unique effects that they ultimately attributed to their diet and not the technique itself. One of those subjects reported a headache but believes it was caused by "crash dieting," and the other one reported a feeling of "wooziness" but believes that it was attributed to their

Table 1: Self-reported demographics of 30 subjects who completed the osteopathic pedal pump protocol.

Age, years	
Mean	24.53
Range	22–30
Gender	
Male	15
Female	15
Mean body mass index (BMI), kg/m^2	24.56

Table 2: Changes in volume of the distal 34 cm of one lower limb in 30 normal subjects who received the osteopathic pedal pump protocol treatment.

Volume measurement	Mean volume	Standard deviation
Pretreatment volume	2,303.6 mL	435.27
Posttreatment volume	2,257.7 mL	435.95
Change in posttreatment volume	−45.63 mL	37.65
Volume change range	Maximal gain +19 mL	Maximal loss −167 mL

copious ingestion of fluids pretreatment. Otherwise, no notable side effects were reported.

The posttreatment surveys were also promising, with the majority of subjects endorsing that the treatment elicited a perceived physiologic change from baseline, that it was enjoyable, that they would recommend it to others, and that they would opt to receive the treatment at routine office visits (Table 3).

Discussion

Osteopathic medical schools routinely teach application of myofascial release to the thoracic inlet in conjunction with the pedal pump to remove excess fluids out of the lower extremities [5]. Having a mechanical means to remove excess fluid volume in the lower extremities may be useful for treating peripheral edema, venous stasis, lymphedema, and leg wounds, and possibly for boosting the immune response to infection. This study is the first to provide objective evidence that these two techniques utilized together in a standardized protocol do indeed reduce fluid volume in the lower extremities. The mean volume reduction for the distal 34 cm of one lower extremity was 45.63 mL with a p value of $p<0.001$. It is remarkable that volume reduction occurs in normal individuals with no apparent leg edema and that the effect appears to be robust. However, an identified limitation of this study is that there was no control group. A sham group could have been implemented to further support the efficacy of the pedal pump by nullifying the potential confounder of decreasing lower leg volume via supine positioning and/or leg elevation. Presumably, an equal amount of volume is removed from the other limb, and even more volume is likely moved above the measured 34 cm mark. Thus, the total volume moved back to the central circulatory system is likely much more than 45.63 mL. It is reasonable to believe the protocol will also work in persons with disorders relating to edema, lymphedema, or venous stasis.

A secondary goal of this feasibility study was for the student researchers to gain experience with the treatment protocol and measurement techniques before utilizing them in adults with edema, lymphedema, or venous stasis. The student researchers refined their skills to ensure that the techniques and measurements were standardized throughout the patient populations. When one early participant moved the limb too quickly, triggering a small amount of water spillage, adjustments in the measurement technique prevented this from happening again. This study demonstrates the utility of utilizing the volume displacement method for measuring the effectiveness of osteopathic techniques for reducing volume in the lower extremity. The volumetric device was easy to utilize and the measurements sensitive enough to measure changes in volume. The equipment is relatively affordable. It was purchased from a medical supply store for $282.00.

The study has a few limitations. A small amount of unmeasurable water clings to the skin, cylinder, and bucket

Table 3: Posttreatment survey. The percentage of responses from the 30 subjects who completed the study protocol.

How effective was the treatment?	Not effective	Somewhat not effective	Neutral	Somewhat effective	Very effective
	6.7	0.0	23.3	40.0	9.0
Would you recommend the treatment to others?	Strongly not likely	Not likely	Neutral	Likely	Very likely
	0.0	0.0	3.3	40.0	56.7
How much did you enjoy the treatment?	Strongly not a lot	Not a lot	Neutral	Somewhat	Very much
	3.3	3.3	16.7	33.3	43.3
Would you be willing to receive this treatment routinely?	Never again	Maybe never	Neutral	Sometimes	All the time
	0.0	0.0	10.0	43.3	46.7

surfaces during measurement. This amount is believed to represent only a few milliliters and is a consistent error from subject to subject. Measurement error was reduced by keeping the subject very still and by waiting the several minutes for all water to fully stop dripping out of the measurement container spout. A small amount of water was spilled during measurement for only one subject due to noncompliance secondary to body habitus; after this, if this occurred with any other subjects, the volumeter gauge was refilled and the measurement repeated. This happened only twice during the remainder of the study. The height of the volumetric gauge from the base to the lower lip of the spout was 34 cm. As such, this limits the measurement to the distal 34 cm of one lower limb. A taller volumetric gauge could be utilized; however, a taller unit is mechanically harder to lower a limb into without spilling water, and some lower limbs affected by lymphedema are too wide for the taller volumetric gauge available to us.

Future research could incorporate the methods utilized in this study to explore the best protocol for moving volume out of the lower extremities. For example, a study testing a lymphatic pump protocol with and without myofascial release to the thoracic inlet technique could clarify the usefulness of opening up the thoracic inlet before utilizing a lymphatic pump technique. Future projects could explore the best duration of pedal lymphatic pumping or if the thoracic lymphatic pump also reduces lower-extremity volume. In at least one animal study, lymphatic pumping at a remote body area did enhance lymph uptake at a distal body area [6]. The long-term effects of this protocol in adults with disorders related to edema, lymphedema, or venous stasis could also be explored. The greatest volumes of displacement occurred in two females. Interestingly, when discussing the amount of volume displaced with those two female subjects, each one volunteered the information that they were currently menstruating. Unfortunately, this was not a foreseen confounder, and no other females who participated in the study were questioned on their menstrual cycle. Further studies could be performed to better understand how the use of the pedal lymphatic pump reduces menstrual cycle bloating and related symptoms. The ultimate intention was to perform the technique in a geriatric population that suffers from chronic lower limb edema because there remain few reliable treatment modalities. Fortunately, the healthy subjects did appear to enjoy the treatment and endorsed that it elicited a perceived physiologic change from baseline, supporting future attempts to try it in the geriatric population.

Conclusions

The administration of the pedal lymphatic pump protocol reduces lower limb volume in healthy subjects. This volume reduction supports the premise that the pedal pump treatment protocol enhances the uptake of excess interstitial fluid into the lymphatic vessels and enhance the transport of lymph back to the central circulatory system. The posttreatment survey supports the notion that the pedal pump protocol is well tolerated and is perceived to elicit a perceived physiologic change from baseline. Water volume displacement was found to be an affordable and practical method for studying the effects of the pedal pump protocol in the lower extremities. Further studies are warranted, especially in persons with excess lower-extremity edema, lymphedema, or venous stasis.

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Author contributions: All authors provided substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; all authors drafted the article or revised it critically for important intellectual content; all authors gave final approval of the version of the article to be published; and all authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
Competing interests: None reported.
Informed consent: All participants in this study provided written informed consent prior to participation.
Ethical approval: This study was approved by the Rowan University School of Osteopathic Medicine Institutional Review Board (PRO-2020-72) and was registered with ClinicalTrials.gov (NCT05119517).

References

1. Millard FP, Walmsley AG. Applied anatomy of the lymphatics. Kirksville, MO: The Journal printing company; 1922.

2. Miller CE. Osteopathic treatment of acute infections by means of the lymphatics. J Am Osteopath Assoc 1920;19:494–9.
3. Miller CE. The mechanics of lymphatic circulation: lymph hearts. J Am Osteopath Assoc 1923;22:397–8. 415–416.
4. Miller CE. The specific cure of pneumonia. J Am Osteopath Assoc 1927;27:35–8.
5. Franzini D, Cuny LA, Pierce-Talsma S. Osteopathic lymphatic pump techniques. J Am Osteopath Assoc 2018;118:e43–44.
6. Dery MA, Yonuschot G, Winterson BJ. The effects of manually applied intermittent pulsation pressure to rat ventral thorax on lymph transport. Lymphology 2000;33:58–61.
7. Knott EM, Tune JD, Stoll ST, Downey HF. Increased lymphatic flow in the thoracic duct during manipulative intervention. J Am Osteopath Assoc 2005;105:447–56.
8. Hodge LM, King HH, Williams AG Jr., Reder SJ, Belavadi T, Simecka JW, et al. Abdominal lymphatic pump treatment increases leukocyte count and flux in thoracic duct lymph. Lymphatic Res Biol 2007;5:127–33.
9. Hodge LM, Bearden MK, Schander A, Huff JB, Williams A Jr., King HH, et al. Lymphatic pump treatment mobilizes leukocytes from the gut associated lymphoid tissue into lymph. Lymphatic Res Biol 2010;8:103–10.
10. Schander A, Downey HF, Hodge LM. Lymphatic pump manipulation mobilizes inflammatory mediators into lymphatic circulation. Exp Biol Med (Maywood) 2012;237:58–63.
11. Hodge LM, Creasy C, Carter K, Orlowski A, Schander A, King HH. Lymphatic pump treatment as an adjunct to antibiotics for pneumonia in a rat model. J Am Osteopath Assoc 2015;115:306–16.
12. Creasy C, Schander A, Orlowski A, Hodge LM. Thoracic and abdominal lymphatic pump techniques inhibit the growth of S. pneumoniae bacteria in the lungs of rats. Lymphatic Res Biol 2013;11:183–6.
13. Noll DR, Shores JH, Gamber RG, Herron KM, Swift J Jr. Benefits of osteopathic manipulative treatment for hospitalized elderly patients with pneumonia. J Am Osteopath Assoc 2000;100: 776–82.
14. Noll DR, Degenhardt BF, Morley TF, Blais FX, Hortos KA, Hensel K, et al. Efficacy of osteopathic manipulation as an adjunctive treatment for hospitalized patients with pneumonia: a randomized controlled trial. Osteopath Med Prim Care 2010;4:2.
15. Noll DR, Degenhardt BF, Johnson JC. Multicenter osteopathic pneumonia study in the elderly: subgroup analysis on hospital length of stay, ventilator-dependent respiratory failure rate, and in-hospital mortality rate. J Am Osteopath Assoc 2016;116: 574–87.
16. Kilgore T, Malia M, Di Giacinto B, Minter S, Samies J. Adjuvant lymphatic osteopathic manipulative treatment in patients with lower-extremity ulcers: effects on wound healing and edema. J Am Osteopath Assoc 2018;118:798–805.
17. Zaleska M, Olszewski WL, Durlik M. The effectiveness of intermittent pneumatic compression in long-term therapy of lymphedema of lower limbs. Lymphatic Res Biol 2014;12:103–9.
18. Webb E, Neeman T, Bowden FJ, Gaida J, Mumford V, Bissett B. Compression therapy to prevent recurrent cellulitis of the leg. N Engl J Med 2020;383:630–9.
19. Zasadzka E, Trzmiel T, Kleczewska M, Pawlaczyk M. Comparison of the effectiveness of complex decongestive therapy and compression bandaging as a method of treatment of lymphedema in the elderly. Clin Interv Aging 2018;13:929–34.
20. Ely JW, Osheroff JA, Chambliss ML, Ebell MH. Approach to leg edema of unclear etiology. J Am Board Fam Med 2006;19:148–60.
21. Rabe E, Stucker M, Ottillinger B. Water displacement leg volumetry in clinical studies–a discussion of error sources. BMC Med Res Methodol 2010;10:5.