Adjuvant Lymphatic Osteopathic Manipulative Treatment in Patients With Lower-Extremity Ulcers: Effects on Wound Healing and Edema
Teresa Kilgore, DO; Marilyn Malia, DO; Brian Di Giacinto, DO; Stephanie Minter, DO; John Samies, MD

From the Edward Via College of Osteopathic Medicine–Carolinas in Spartanburg, South Carolina (all authors), and the Regional Medical Center in Orangeburg, South Carolina (Dr Samies). Drs Malia, Di Giacinto, and Minter were students at the time of the study but are all now second-year residents.

Financial Disclosures: None reported.
Support: None reported.
Address correspondence to Marilyn Malia, DO, 25 N Johnson St, PO Box 819, Coats, NC 27521-0819.
Email: mmalia@carolinas.vcom.edu

Submitted September 26, 2017; revision received May 1, 2018; accepted June 18, 2018.

Context: In 2012, the US wound registry estimated that the cost of managing chronic wounds in the United States exceeded $50 billion. A large percentage of these wounds are venous stasis ulcers of the lower extremity. Evidence suggests that adjuvant osteopathic manipulative treatment (OMT) may provide a benefit by reducing edema and subsequent healing times in venous stasis ulcers of the lower extremity.

Objective: To determine whether a lymphatic OMT protocol improves wound healing rates among patients with lower-extremity edema.

Methods: This pilot study was a nonrandomized before-after community trial of lymphatic OMT in patients with lower-extremity wounds and edema. Wound surface area measurements for the preliminary phase were obtained retrospectively. During the intervention period, patients received 10 minutes of OMT twice per week. The OMT protocol, which aimed to improve lymphatic flow, included myofascial thoracic outlet release, doming of the diaphragm, pelvic diaphragm release, popliteal release, and pedal pump (2-3 minutes of continuous pump) performed in sequence. Rates of wound healing were compared between the preliminary (standard therapy), intervention (standard therapy plus OMT), and follow-up (standard therapy) phases. Rates of change in edema (measured using leg volume) were evaluated during the intervention phase. A custom-designed questionnaire was used to assess patients’ satisfaction with their treatment and confidence that its effects on their health were good.

Results: Eight patients were included in the study. The wound surface area increased during the preliminary phase by a mean of 10 cm²/wk and decreased during the intervention phase by a mean of 4.9 cm²/wk. Patients’ mean leg volume decreased during the intervention phase. Six patients were “very satisfied” with their treatment.

Conclusion: The adjunctive OMT protocol may have reduced edema and reversed the trend of wound growth in patients with venous stasis ulcers. Edema reduction is a mainstay of current wound therapy, and any modality that decreases edema may subsequently decrease healing times.

J Am Osteopath Assoc. 2018;118(12):798-805

Keywords: edema, lymphatic pump, OMT, osteopathic medicine, venous stasis ulcer
“We strike at the source of life and death when we go to the lymphatics.”

This commonly cited quote from Andrew Taylor Still, MD, DO, is something of a war cry for osteopathic physicians, highlighting the functional importance we place on the lymphatic system. Improved lymphatic flow and subsequent drainage is linked to a reduction in the damaging effects of prolonged exposure to inflammatory mediators. Limiting inflammation is a mainstay of chronic wound management. Ulcers of the lower extremity are notoriously difficult to treat and require protracted periods to heal. These wounds often display evidence of chronic inflammation and impaired lymphatic flow. Frykberg and Banks described chronic wounds of the lower extremities as having a “stalled inflammatory phase,” which causes reactive oxygen species and cytokinetic factors to build up and degrade efforts to reconstruct the extracellular matrix. Impaired lymphatic flow is visually obvious with the presence of edema. This stalled inflammatory phase, coupled with impaired lymph flow, leads to deficient wound healing. Theoretically, wounds would have a greater chance of healing if lymphatic propulsion encouraged clearance of senescent cells and their inflammatory cytokines.

Measuring the static edema surrounding wounds may offer some insight into the propensity of a wound to heal effectively. For some time, studies have linked increased edema with diminished wound healing. It is thought that edema can hinder circulation by limiting arterial elasticity and compressing capillaries. In addition, extremities weighted by edema and the eventual cultivation of necrotic tissue contribute to limited mobility and chronic ulcerations.

Current standards of care in the management of chronic wounds typically begin with an assessment of the patient’s medical status and an evaluation of the wound itself. Factors such as nutrition, glycemic control, renal function, and hydration of the wound are of particular importance and may alter the management of wounds. After the patient’s medical status is determined, surgical interventions, including revascularization procedures or debridement, may be necessary. The wound should then be “off-loaded,” a process that reduces the pressure exposure of an extremity and is accomplished by using foam dressings, shoe inserts, walkers, braces, and casts. Although it is important to reduce external sources of variable pressure that may contribute to the chronicity of a wound, compression therapy aimed at reducing the hydrostatic pressure in subcutaneous tissue is a mainstay of treatment. After initiating these therapeutic interventions, physicians must choose from a diverse array of dressings and topical treatments, ranging from antimicrobials to sterile saline and hydrogel, and they must also take care to address acute infections and osteomyelitis.

The use of adjuvant therapies and novel modalities is based on the response to standard wound care, given for at least 4 weeks but not longer than 12 weeks. Negative pressure wound therapy is a commonly used adjuvant technique that effectively manages drainage and instigates the formation of granulation tissue. Other adjuvant treatments include autografts and ultrasonic mist therapy, a low-frequency noncontact ultrasound technique in which saline mist is delivered via a device that emits ultrasonic waves. Ultrasonic mist therapy has been shown to be effective in wound bed preparation, especially when the wound edge was targeted. Studies have also shown that chronic wounds managed with hyperbaric oxygen have lower rates of amputation; this effect is attributed to the increased oxygen available to the damaged tissue under hyperbaric conditions.

Anglund and Channell called for additional research regarding osteopathic manipulation and its applications to chronic wounds. Specifically, they outlined the utility of lymphatic pump techniques for enhanced lymphatic flow, B-cell response, and overall mobilization of immune cells from lymphoid tissue. They hypothesized that the efficacy of osteopathic manipulative treatment (OMT), specifically lymphatic techniques, is linked to increased lymphatic flow and drainage and a subsequent decrease in edema. Altered...
or impaired lymphatic function leads to stagnation in the normal process of healing; thus, it is plausible to hypothesize that restoration of lymphatic flow may not only mobilize immune cells but may also decrease inflammation.

The tenets of osteopathic medicine from which these lymphatic techniques were derived underscore the philosophy of health emerging when form and function are harmonious. Repeated lymphatic propulsion techniques increase lymphocyte counts as well as thoracic duct lymphatic flow. Results of immunology studies suggest that type 2 macrophages play an integral role in the early stages of wound debridement and extracellular matrix formation critical to wound healing. Lymphatic OMT techniques may accelerate wound healing by delivering these macrophages to the wound site, decreasing the destruction induced by reactive oxygen species and facilitated by neutrophils at the wound site. In animal studies involving mice and dogs, the use of lymphatic pump techniques for 4 minutes dramatically increased the flow of lymph and subsequently increased leukocyte counts in the lymphatic system. Rabbit models showed increased and prolonged B-cell function with lymphatic techniques; in infectious wounds, the infection cleared faster with adjuvant lymphatic techniques. These studies outline the potential mechanisms behind lymphatic OMT and its possible facilitation and acceleration of wound healing.

The aim of the current study was to provide a basis for larger multicenter studies to investigate the inclusion of an adjuvant lymphatic OMT protocol for managing venous stasis ulcers of the lower extremity. In addition, because patient satisfaction has become increasingly important in the landscape of modern health care, we also assessed patient-perceived quality of care after OMT.

Methods

Patient Population
A community-based cohort of 8 participants was selected in sequence from patients seeking care at the wound center within the Regional Medical Center in Orangeburg, South Carolina. Enrollment began in October 2016 and continued for 2 months. Participant age, sex, blood pressure, and wound age were collected. Hemoglobin A1c level was also assessed in patients with diabetes. Inclusion criteria were lower-extremity ulcers and edema in the same extremity and current treatment being the standard of care at least twice per week. Exclusion criteria included active therapy for cancer, deep vein thrombosis, necrotizing fasciitis of the pelvis or lower extremities, or any recent lower-extremity fractures. Patients were also excluded if they were younger than 18 years, if it was less than 6 weeks after surgery, or if they were receiving any other experimental treatments. Patients with diabetes were excluded if their hemoglobin A1c level was above 10% or if they were experiencing active Charcot foot exacerbation. All patients were informed of their rights as study participants and signed an informed consent document approved by the Orangeburg Regional Medical Center Institutional Review Board.

Study Design
This pilot study was a nonrandomized before-after community trial of lymphatic OMT in patients with lower-extremity wounds and edema. Lower-extremity edema was defined as at least 1+ pitting or nonpitting edema on an edema rating scale. Study participants were enrolled on a rolling basis and received the current standard of care with the addition of an OMT protocol aimed at improving lymphatic flow to the lower extremities. Wound surface area measurements for the preliminary phase, during which patients received standard of care, were obtained retrospectively from reviewed data in patients’ medical records.

The intervention and follow-up phases were prospective. The intervention phase lasted for 6 to 8 weeks and was initiated as patients were enrolled. The follow-up phase lasted up to 6 weeks after intervention or complete healing of the ulcer being followed. Patients were removed from the study if any of the
exclusion criteria developed during the intervention phase. The study was approved by the official Regional Medical Center Institutional Review Board. All patients were assigned a study identification number that was used for confidentiality and to blind the statistician to any demographic information.

**Treatment**

All patients continued to receive the current standard of care specific to their ulcer and the defined lymphatic OMT protocol twice per week. The protocol included myofascial thoracic outlet release, doming of the diaphragm, pelvic diaphragm release, popliteal release, and pedal pump, performed in sequence. Myofascial restrictions were diagnosed and documented at the thoracic inlet, abdominal diaphragm, and pelvic diaphragm and used to focus the treatment. Each restriction was rechecked after treatment. Direct techniques were performed initially, and indirect techniques were performed if necessary to achieve therapeutic outcomes. The protocol and documentation were performed over a period of approximately 10 minutes. The protocol was performed by an osteopathic physician or an osteopathic medical student with more than 2 years of experience under the direct supervision of a qualified physician. All study personnel were required to complete Collaborative Institutional Training Initiative ethics certification before treating patients in the study.

**Outcomes**

The primary outcomes of the trial were the mean rates of change in wound size during the preliminary, intervention, and follow-up phases and the mean rates of edema (measured using leg volume) reduction during the intervention phase.

Wound size, or surface area, was defined as the measurements obtained using the longest distance between 2 points of the wound and the width of the widest distance perpendicular to the length, as measured by a standard disposable wound measurement ruler. Wound surface area, calf circumference, and ankle circumference measurements were obtained prospectively for the intervention and follow-up phases of the study.

Leg volume was defined as the frustum of a cone with the apical radius defined by the circumference of the ankle directly superior to the malleoli, the basilar radius defined by the circumference of the leg at the point midway between the tibial tuberosity and malleoli, and the height defined by the distance between the 2 measurements on the anterior aspect of the leg, as measured with a standard medical retractable tape measure.

Secondary outcomes included correlation of ulcer healing with edema reduction and patient self-reports concerning their satisfaction and confidence with the lymphatic OMT protocol, as well as the convenience of the protocol. Patient satisfaction with and confidence in treatment were assessed by means of a custom-designed questionnaire. The Patient Satisfaction Questionnaire (PSQ-III) and the subsequent abbreviated version, the Patient Satisfaction Questionnaire Short Form (PSQ-18), were used as the primary models for the survey created for this study. The PSQ-III has 51 items and uses a scale of 1 to 5, wherein 1 represents “strongly agree” and 5 represents “strongly disagree.” Other tools available from the Agency for Healthcare Research and Quality of the US Department of Health and Human Services were analyzed and incorporated. Data from validation studies involving the treatment satisfaction questionnaire were also considered and incorporated. The final tool used in the present study was a 10-question survey designed to ascertain patients’ level of satisfaction with the treatment protocol and the physicians.

**Statistical Analysis**

The primary outcome of mean rate of change in wound size was assessed using a 2-tailed Wilcoxon rank sum test for nonparametric data, with a significance level set at .15. The Spearman rank correlation coefficient was used to assess the correlation between the rates of wound healing and edema reduction. All other parameters were reported as trends without comparison.
Results

The sample consisted of 8 patients, ranging in age from 31 to 90 years, including 4 men and 4 women, 5 persons who identified as black, and 3 who identified as white. The mean blood pressure was 135/72 mm Hg, the mean hemoglobin A1c level in the 3 patients with diabetes was 6.5%, and the mean wound age was 156 days (range, 2 weeks-19 months).

The mean rates of change in wound size (measured in square centimeters per week) are presented in Table 1 and Figure 1. The wound being tracked for patient 5 healed before the follow-up phase. The preliminary phase showed a mean rate of change in wound size of 10.0 cm²/wk, suggesting wound expansion during that phase. The intervention phase showed a mean rate of −4.9 cm²/wk, suggesting reduction in wound size. Typically, a 30% reduction in wound size carries a good prognosis.41 The preliminary and follow-up rates of change showed trends of wound expansion, whereas the intervention rates showed a mean reduction in wound size.

From the beginning to the end of the intervention phase, there was a mean decrease in leg volume of 120 cm³. Five of the 8 patients had a decrease (range, −115 to −705 cm³) and 3 had an increase (138 to 605 cm³) in leg volume (Table 2). During the intervention phase, 5 patients had a reduction in both wound size and leg volume, 2 had an increase in both, and 1 had an increase in leg volume and a slight decrease in wound size (Figure 2).

A poststudy satisfaction survey, using a 5-point scale, queried patients on both treatment satisfaction (ranging from “very dissatisfied” to “very satisfied”)
and confidence that treatment was good (ranging from “not confident” to “extremely confident”). All patients reported being confident and satisfied with the treatment administered and the physicians. Furthermore, 6 patients were “very satisfied” with their treatment and approximately 5 were “extremely confident” that their treatment positively affected their health.

Discussion

During the current study, wound size was reduced in 6 of the 8 patients, and 5 of these 6 also had a reduction in edema. The data from this study support the literature consensus that edema reduction is correlated with accelerated wound healing. To our knowledge, these are the first quantitative data produced supporting the theoretical notion that patients treated with lymphatic OMT have a measurable reduction in edema.

Preliminary trends suggest that edema reduction facilitated by lymphatic OMT may improve the rate of wound healing. Improved healing may be linked to increased delivery of leukocytes to the wound surface area, neutrophils to clear infections, and type 2 macrophages to stimulate chemical debridement and extracellular matrix formation. If the trends are supported by further studies, more research and multivariate analyses will be required to elucidate a definitive mechanism. Regardless, treatments that improve rates of wound healing may reduce treatment times and cost.42

Our pilot study was limited by its small sample. Confounding issues included the variety of underlying causes and wound types, the varying medical complexity of the patients, and patient adherence to outpatient treatment. As an example of medical complexity, 1 patient had a diagnosis of Castleman disease, the

Table 2. Edema Reduction as Measured by Change in Leg Volume

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Leg Volume, cm³</th>
<th>Initial (Beginning of Intervention)</th>
<th>Final (End of Intervention)</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5561</td>
<td>5446</td>
<td>−115</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>4945</td>
<td>4264</td>
<td>−681</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>2926</td>
<td>3531</td>
<td>605</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>2562</td>
<td>2370</td>
<td>−192</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>4520</td>
<td>4314</td>
<td>−206</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>3540</td>
<td>2835</td>
<td>−705</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>2128</td>
<td>2266</td>
<td>138</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>2333</td>
<td>2523</td>
<td>190</td>
<td></td>
</tr>
</tbody>
</table>

*a Negative values represent decreases in volume and positive values represent increases in volume.

![Figure 2](image-url)
pathophysiologic mechanism of which involves hyperplasia of the lymph nodes. This lymphoproliferative disorder could have affected the patient’s overall responsiveness to treatment. One patient with necrobiosis lipoidica had an increase in wound size during the intervention phase of the study. Another was hospitalized, and that patient’s wound healed completely during the hospital stay. Regarding patient adherence, 2 patients each missed 1 treatment session because of issues with transportation. Furthermore, the patients began the study treatment protocol at different points during their standard treatment and thus had varying lengths of pretreatment time.

Improvements for future studies regarding this adjuvant modality could include a larger sample size, a comparison group, randomization of the participants, and wound and calf measurements recorded at every treatment with a standard measurement tool. The external validity of the present study is based on the diversity of the patients. The sample was representative of the population at risk for lower-extremity ulcers; however, future studies including more participants are required to determine the significance of our results.

The responses to the patient surveys suggest that patients were very satisfied with the care they received and rated their physicians highly in several domains, including satisfaction with treatment and perceived positive effects of the treatment.

Conclusion

The OMT protocol, which was developed to improve lymphatic flow and drainage in this pilot study, reduced edema and accelerated wound healing in most patients with chronic lower-extremity ulcers. Thus, an adjuvant lymphatic OMT protocol may improve wound healing compared with standard therapy alone by improving lymphatic flow and reducing static edema. Edema reduction is a mainstay of contemporary wound therapy, and any modality that decreases edema may subsequently accelerate wound healing. Further studies that replicate these results may support inclusion of OMT techniques in current standards of care. Additional studies with more participants and increased power are warranted.

Acknowledgments

We acknowledge the Wound Center at the Regional Medical Center in Orangeburg, Marie Gehling, MSN, CWON; Laura Fogle, RN, BSN, CWON; and all the staff who devoted their time to this project. We also thank Cheryl Larva, DO, for additional treatment and measurement assistance; Liang Shan, PhD, research biostatistician, for statistical analysis; and Chris Martin, PhD, MHS, for audiovisual support.

Author Contributions

All authors provided substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; Drs Kilgore and Malia 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.

References


37. Ware, JE, Snyder WK, Wright WR. Results Regarding Scales Constructed From the Patient Satisfaction Questionnaire and Measures of Other Health Care Perceptions. NTIS Publication No. PB 298-329. Springfield, VA: National Technical Information Service; 1976. Development and Validation of Scales to Measure Patient Satisfaction With Medical Care Services; vol I, part B.


© 2018 American Osteopathic Association