## **ORIGINAL CONTRIBUTION**

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# The Effects of Patient-specific Sequenced Osteopathic Manipulative Treatment by AGR on Quality of Life

# Abstract

#### Background

Most osteopathic research has been technique, model, or protocol-driven which may not reflect actual clinical practice. Baseline health, mechanisms of injuries, and neuromusculoskeletal compensations are all unique per patient. An osteopathic research design that aligns with individualized patient care may better illustrate the role that OMM can play in health. Patient-specific, sequenced OMT by AGR (psOMT) addresses each patient's unique accrual of and response to somatic dysfunction throughout his or her body over time. To our knowledge, there have been no clinical studies looking at patient-specific, sequenced OMT by AGR and Quality of Life (QoL).

#### Objectives

To assess the effects of patient-specific, sequenced OMT (psOMT) in various Quality of Life areas.

#### Methods

A noncomparative study was conducted on all consenting patients of Pikeville Medical Center's OMT clinic from April 2021 to May 2022. Participants were evaluated and treated with patient-specific, sequenced OMT (psOMT) by Area of Greatest Restriction (AGR). Participants were given 2 modified PROMIS 29 *Quality of Life* surveys to assess nine domains of QoL.

#### Results

Participants who received psOMT showed statistically significant improvements in all 9 metrics of QoL ( $\rho$ <.001).

#### Conclusion

This study presents a paradigm for osteopathic medical research that honors each patient's unique accrual of and response to somatic dysfunction(SD) throughout their lifetime. This study suggests the following: 1) that SD may contribute to impairments in overall QoL, 2) that SD could represent a modifiable risk factor in general medical assessment, and therefore 3) that treatment of SD may contribute to improvements in QoL by relieving impairments to optimal physiologic function.

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# **Keywords**

Quality of Life, Sequencing, Area of Greatest Restriction; Sequencing by Area of Greatest Restriction; Sequencing by AGR; Sequenced OMT by Area of Greatest Restriction; Sequenced OMT by AGR; Patient specific OMT; Sequenced OMT; Osteopathic Manipulative Osteopathic OMM; Medicine; Manipulative Treatment; OMT; Somatic Dysfunction as Modified Risk Factor; Key Lesion; Root Cause; Manual Medicine

# Introduction

Osteopathic Manipulative Medicine (OMM) is the practice of diagnosis, treatment, optimization of health, and prevention of disease that is based on the self-regulatory interrelationships of anatomy and physiology within the mind-body-spirit continuum as emphasized by the founder, Andrew Taylor Still, MD, DO in four osteopathic tenets:<sup>1</sup>

- 1. The human being is a dynamic unit of function
- 2. The body possesses self-regulatory mechanisms that are self-healing in nature
- 3. Structure and function are interrelated at all levels
- 4. Rational treatment is based on these principles

Osteopathic Manipulative Treatment (OMT) is the manual component of OMM that seeks to address dysfunctional areas of somatization which contribute to allostasis and impede general health.<sup>2</sup>

OMM/OMT have been traditionally difficult to quantify within the paradigm of reductionist research which overlook the interplay of complex and dynamic systems. That, along with the limitations of procedural studies,<sup>3</sup> have likely influenced research to be designed with protocolized treatments for specific musculoskeletal complaints (such as a set of techniques for low back pain). However, protocol, technique, or model-driven research assumes all patients arrived at their SD similarly, which may be a fundamental flaw. Baseline health, mechanisms of injuries, and neuromusculoskeletal compensations are all quite different and unique across patients. Although the results of these studies show some overall benefit,<sup>3,4,5</sup> they may not accurately reflect clinical practice nor the role of OMM/OMT in the medical field.

In contrast to protocol or model-driven OMT, is an osteopathic approach to diagnosis and treatment known as Sequencing by Key Area of Greatest Restriction (AGR). This approach was developed in the 1960s by Fred Mitchell, Sr., DO FAAO and expanded and organized by Edward Stiles, DO FAAO Dist.<sup>6,7</sup>

In recent years, Dr. Stiles has described *sequencing OMT by Key AGR* as "patient-specific, sequenced OMT (psOMT)" to better translate his mentor's work into 21st-century medical terms. Sequencing by Key Area of Greatest Restriction is an osteopathic approach in which somatic dysfunction is assessed and treated by initial AGR, then each subsequent AGR upon reassessments,

until the body is moving optimally together. This approach takes into account the complex bio-tensegrity of the human design by honoring each patient's unique SDs and response to treatment throughout the patient's lifetime.<sup>5</sup>

The AGR represents the area of greatest hindrance to the patient's health potential at that moment and can be utilized to sequence osteopathic treatments effectively. The AGR can be identified as the most dysfunctional area with the hardest end feel utilizing blending palpation. Blending Palpation is a dynamic palpatory interface between practitioner and patient through multiple tissue layers in order to gather feedback on the AGR. The key issue is the quality of the tissue, not the quantity of motion restriction because the AGR has the least ability to compensate. The AGR can be verified as such if after effective treatment, not only does it improve, but multiple areas of body-wide compensation also improve, owing to the dynamic design of the human body. It is our supposition that the effects of psOMT can be far greater and improve many aspects of QoL by approaching patients with uniquely sequenced and individualized OMT.

Arguably what matters most to people is their overall QoL-the ability to function in ways that bring satisfaction, purpose, and joy. To date and to our knowledge, there have been no research studies looking at psOMT and QoL. Though not necessarily new to osteopathic clinical practice, patient-specific sequencing of OMT appears new to medical research literature, possibly contributing to the underutilization of OMT in both the osteopathic profession and the healthcare field at large. Yet we clinically found that psOMT can produce efficient, significant, and lasting results both objectively by the physician and subjectively for the patient.

# **Objectives**

The objectives were to assess the effects of psOMT on various QoL metrics including physical function, anxiety, depression, fatigue, sleep disturbance, participation in social roles and activities, pain interference, cognitive function, and average pain intensity scale. We hypothesize that patients receiving psOMT will have improvements in QoL metrics from baseline regardless of what other interventions they may be receiving.



#### Figure 1. Flow diagram of subject inclusion.

## Methods

#### **Study Design**

Due to the uniqueness of psOMT, a noncomparative study was conducted on all consenting new and established patients of Pikeville Medical Center's (PMC) Osteopathic Neuromusculoskeletal & Manipulative Medicine (ONMM) Residency clinic with the intention of hypothesis generation as opposed to testing.<sup>8</sup> This study obtained IRB approval from PMC (IORG0003314, FWA00012796) and spanned the timeframe between April 2021 to May 2022. Participants included pediatric, adult, and OB/GYN patients. Subjects were excluded if they were younger than 16 or if they were not able to complete a paper survey on their own.

Participants were evaluated and treated with psOMT twice by an ONMM resident under the supervision of AOBNMM-certified attending physicians. Participants were given instructions for filling out the surveys after several days but within the first week after each osteopathic evaluation and treatment visit. Surveys were collected either by patient drop off to the clinic or at their next visit.

The survey was a modified PROMIS 29 'Quality of Life' survey that assessed 9 domains or metrics of QoL.<sup>9</sup> The metrics included physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and activities, pain interference, cognitive function, and average pain intensity scale before and after psOMT.

Each domain had one to four subcategories represented by specific questions. The first PROMIS 29 survey served as a baseline and the patient was instructed to complete the form prior to receiving psOMT. The follow-up PROMIS 29 survey was to be filled out after receiving psOMT, ideally within the first week after psOMT intervention.

Osteopathic modalities utilized were dependent on the physician's assessment of patient-specific tissue texture balance and optimal response. These included but were not limited to: Functional: Still/Laughlin (F:S/L), Muscle Energy (ME), Osteopathic Cranial Manipulative Medicine (OCMM) including Sutherland's Sutural Considerations, Balanced Ligamentous Tension (BLT), High Velocity Low Amplitude (HVLA), Articulatory, Facilitated Positional Release (FPR), Myofascial Release (MFR), Visceral, and Strain Counterstrain.

#### **Data Analysis**

Surveys were sent for statistical analysis. All statistical tests were performed using Statistical Package for the Social Sciences (IBM), version 27. Dependent t-tests were used to compare the time differences (pre-psOMT and post-psOMT) in means of the individual survey items and each of the QoL metrics for all of the patients. Effect sizes for all time differences were calculated using Cohen's d; Small (d = 0.2), Medium (0.2<d<0.5), and Large (d>0.8). To reduce the risk of a Type I error, p<0.001 was considered statistically significant. Given an alpha error probability of 0.05 and a power (1-beta error probability) of 0.99, an a priori power analysis estimated a required sample size of 76.

### Results

A total of 78 participants were included in this study, 21 (27%) men and 57 (73%) women. The average age was 48.6 years (SD 16.0), ranging from 16 years old to 80 years old (median 48, bimodal 29 and 48). Participants who received psOMT showed statistically significant improvements in all 9 metrics of quality of life (Table 2). ( $\rho$ <.001): Physical Function, Anxiety, Depression, Fatigue, Sleep Disturbance, Ability to Participate in Social Roles and Activities, Pain Interference, Cognitive Function, and Average Pain Rating. The achieved statistical power of this study is 0.9999996.

Improvements had large effect sizes in the metrics of Physical Function, Fatigue, Sleep Disturbance, Ability to Participate in Social Roles/Activities, Pain Interference, Cognitive Function, and Pain Rating (d=> 0.8) The remaining two metrics, Anxiety and Depression, had medium effect size (0.5 = < d = < 0.8). Within metrics of large effect size, most sub-categories had improvements greater than 1 standard deviation (Cohen's d>1). Additionally, Average Pain improvements were greater than two standard deviations (Cohen's d>2).

QoL metrics are listed in descending order of largest improvements:

1. Average Pain

On a 0-10 pain scale with 0 being no pain and 10 being the worst imaginable, the average pain rated prior to psOMT was 6.54. After ps-OMT this dropped to 4.11, which was both a significant and large improvement, notably greater than 2 SDs.

2. Cognitive Function

Average cognitive function was measured by subcategorical questions assessing how well participants felt regarding the ability to remember to do things like 'take medicine or buy something I need' and the ability to concentrate. Prior to ps-OMT the domain was 3.43. After ps-OMT, it increased to 3.91, with both subcategories resulting in significant and large improvements, greater than 1 SD.

3. Pain Interference

Average pain interference was measured with 4 questions about how often pain affects day-to-day activities, work around the home, household chores, and the ability to participate in social activities. Prior to ps-OMT, it was 3.47. After ps-OMT, it decreased to 2.3, with all 4 subcategories showing significant and large improvements, greater than 1 SD.

4. Sleep Disturbance

Average sleep disturbance was measured by how well or poor participants rated sleep quality, having a problem with their sleep, difficulty falling asleep, and how often it felt refreshing. Prior to ps-OMT, it was 3.34. After ps-OMT, it decreased to 2.56, with all 4 subcategories showing significant and large improvements, greater than 1 SD.

5. Fatigue

Average fatigue was measured by how often participants rated feeling fatigued, having trouble starting things because they felt tired, felt run-down, and how fatigued they felt on average. Prior to ps-OMT, it was 3.46. After ps-OMT, it decreased to 2.59, with all 4 subcategories showing significant and large improvements, greater than 1 SD.

6. Ability to Participate in Social Roles/Activities Mean ability to participate in social roles/activities was measured by how often participants rated having trouble doing all regular leisure activities with others, family activities they want to do, usual work (including work at home), activities with friends they want to do. Prior to ps-OMT, it was 3.12. After ps-OMT, it increased to 3.80, with all 4 subcategories showing significant and large improvements. Notably the improvements in "having trouble doing all of my regular leisure activities with others" was greater than 1 SD.

7. Physical Function

Average physical function was measured by how participants rated their difficulty in their ability to run errands and shop, do chores such as vacuuming or yard work, go up and down stairs at a normal pace, and go for a walk of at least 15 minutes. Prior to ps-OMT, it was 3.42. After ps-OMT, it increased to 4.08 with all 4 subcategories showing significant and large improvements. Notably, the ability to run errands and shop as well as the ability to go up and down stairs, was greater than 1 SD.

8. Anxiety

Mean anxiety was measured by how often participants rated feeling fearful, finding it hard to focus on anything other than their anxiety, feeling uneasy, overwhelmed by their worries. Prior to ps-OMT, it was 2.09. After ps-OMT, it decreased to 1.65. The overall category resulted in significant and medium improvements; the 4 subcategories resulted in significant and large improvements.

9. Depression

Average depression was measured by how often participants rated feeling worthless, helpless, depressed, and hopeless. Prior to ps-OMT, it was 1.81. After ps-OMT, it decreased to 1.47. The overall category resulted in significant and medium improvements. The subcategories of feeling helpless, depressed, or hopeless resulted in significant and large improvements, with feelings of worthlessness showing medium effect size.

Of note, though participants were given instructions for filling out the surveys, many did not adhere to the suggested timeline of "after several days but within the first week after treatment". Therefore some filled it out immediately after psOMT, possibly before they reached 
 Table 1. Demographics.

Demographics

Gender			
	Male	21	26.9%
	Female	57	73.1%
Age			
	16-30	14	18.0%
	31-45	20	25.6%
	46-60	23	29.5%
	61+	21	26.9%
Ethnicity			
	Caucasian	72	92.3%
	African-American	3	3.8%
	Latino or Hispanic	0	0.0%
	Asian	0	0.0%
	Native American	1	1.3%
	Native Hawaiian or Pacific Islander	0	0.0%
	Prefer not to say	2	2.6%
Total Participants		78	100%

Frequency Percentage

their full potential of clinical improvement, while others filled it out long after psOMT at their next follow-up visit, possibly long after their full potential of clinical improvement. The timing of when surveys were filled out may have led to understated results.

# Discussion

Our study found statistically significant improvements in all nine QoL domains after sequenced psOMT across a population that included older teens to geriatrics. Furthermore, the effect size was large for most metrics, and the majority of the large effect sizes were >1. The remaining two metrics, Anxiety and Depression, still showed statistically significant medium-sized effects. These findings are unique for several reasons.

#### Somatic Dysfunction as a Modifiable Risk Factor for Quality of Life?

Firstly, this data suggests that somatic dysfunction (SD) may contribute to impairments in overall quality of life. In line with the fourth osteopathic tenet of rational treatment, SD ought to be considered as a modifiable risk factor for differential diagnoses affecting quality of

life. Somatic dysfunction is defined as impaired or altered function of related components of the somatic system including skeletal, arthrodial, myofascial structures and related vascular, lymphatic, and neural elements.<sup>10</sup> Causes of SD range the spectrum of micro to macro traumas from emotional and mental to physical (mechanical, biological, chemical) stress or strain. Depending on the location, magnitude, and duration, SD may have effects at the cellular, tissue, organ, system, and whole body levels due to the body being a dynamic unit of function (see Figure 2b).<sup>10</sup>

The body's structure-function interrelationship was mechanistically described by Louisa Burns, DO and expanded by J. Stedman Denslow, PhD and Irvin Korr, PhD in their visceral and somatic reflex work (3rd osteopathic tenet). They showed that chronic noxious stimulation to viscera, representing impaired physiologic function, resulted in palpable somatic tissue texture changes of the neuromusculoskeletal system. Reciprocally, dysfunction in somatic tissues also impaired physiologic and visceral function.<sup>11</sup> Therefore, somatic dysfunctions can contribute to inappropriate responses of the autonomic nervous system, with aspects of sympathetic and parasympathetic responses inappropriately stimulated and/or inhibited.

For example, thoracic and ribcage somatic dysfunction tends to correlate clinically with inappropriate sympathetic tone due to facilitation of the sympathetic ganglia located at the thoracic costovertebral junctions.<sup>12</sup> Thoracic and ribcage SD can also have such physiologic effects as impaired ventilation,<sup>13,14</sup> impaired breathing mechanics,<sup>15</sup> impaired metabolic function including increased metabolic demands from accessory muscle use, impaired arterial, venous, and lymphatic circulation at any tissue level affecting any biological system (see Figure 2a,b).<sup>16-22</sup> If early stage or subtle, these may not be obvious until their chronic effects manifest overtly.

Even though somatic dysfunction has implications beyond musculoskeletal pain and decreased physical function, these remain the more common presenting reasons for referral to osteopathic evaluation for and treatment of SD.<sup>23</sup> Evaluation for SD and treatment with OMT remain underutilized for multi-etiological presenting complaints such as fatigue, sleep disturbance, cognitive function and mental health issues such as anxiety and depression.<sup>24</sup> For example, fatigue warrants NOTE: "Improvement" is seen when the average decreases; an asterisk indicates improvement when the average increases (eg. physical function)

Interpreting Cohen's d: Small (d=0.2), Medium (0.2<d<0.5), Large (d>0.8). If Cohen's d is bigger than 1, the difference between means is larger than one standard deviation; larger than 2 indicates the mean difference is larger than two SDs.

Metric	Prior to psOMT mean	After psOMT mean	Cohen's d	ρ value
Physical Function *	3.42	4.08	0.85	0.000
able to do chores such as vacuuming or yard work	3.04	3.44	0.93	0.000
able to go up and down stairs at a normal pace	4.05	3.62	1.07	0.001
able to go for a walk of at least 15 minutes	3.62	4.22	0.91	0.000
able to run errands and shop	3.57	4.25	1.08	0.000
Anxiety	2.09	1.65	0.68	0.000
feel fearful	2.23	1.62	0.96	0.000
find it hard to focus on anything other than my anxiety	1.94	1.56	0.81	0.000
worries overwhelm me	1.99	1.68	0.63	0.000
feel uneasy	2.19	1.75	0.90	0.000
Depression	1.81	1.47	0.61	0.000
feel worthless	1.64	1.41	0.59	0.001
feel helpless	1.97	1.51	0.82	0.000
feel depressed	1.97	1.60	0.73	0.000
feel hopeless	1.66	1.36	0.73	0.001
Fatigue	3.46	2.59	0.98	0.000
feel fatigued	3.55	2.62	1.01	0.000
have trouble starting things because I am tired	3.25	2.36	1.25	0.000
feel run-down on average	3.45	2.64	1.13	0.000
feel fatigued on average	3.49	2.61	0.99	0.000
Sleep Disturbance	3.34	2.56	0.96	0.000
level of sleep quality	3.64	2.81	1.07	0.000
sleep is refreshing	3.64	3.00	1.11	0.000
have a problem with my sleep	3.30	2.43	1.16	0.000
have difficulty falling asleep	2.75	1.97	1.26	0.000
Ability to Participate in Social Roles/Activities *	3.08	3.74	0.85	0.000
have trouble doing all of my regular leisure activities with others	3.04	3.77	1.03	0.000
have trouble doing all of the family activities that I want to do	3.15	3.76	0.84	0.000
have trouble doing all of my usual work (include work at home)	2.96	3.63	0.98	0.000
have trouble doing all of the activities with friends that I want to do	3.14	3.79	0.99	0.000
Pain Interference	3.47	2.30	1.10	0.000
level pain interferes with my day-to-day activities	3.64	2.37	1.17	0.000
level pain interferes with work around the home	3.60	2.35	1.22	0.000
level pain interferes with my ability to participate in social activities	3.19	2.08	1.18	0.000
level pain interferes with my household chores	3.42	2.39	1.21	0.000
Cognitive Function *	3.43	3.91	1.13	0.000
able to concentrate	3.41	3.82	1.17	0.003
able to remember to do things, like take medicine or buy something I need	3.45	4.00	1.25	0.000
How would you rate your pain on average? (o=no pain; 10=worst pain imaginable)	6.54	4.11	2.26	0.000

a large differential, from nutritional deficiencies to malignancies, yet SD is rarely considered a contributing risk factor. Decreased physical function and pain may cause neuromusculoskeletal compensations affecting gait,<sup>25-27</sup> breathing,<sup>28,29</sup> and/or overall body proprioceptive and kinesthetic mechanics,<sup>30</sup> which in turn could impact metabolic processes<sup>31</sup> and contribute to fatigue.

Physiologically, SD can affect the sympathetic nervous system and subsequently vasomotor tone, circulation,<sup>32</sup> and lymphatics in the cranium.<sup>33</sup> This may contribute to impaired cognition where imaging may be unremarkable. SD and pain may also contribute to sleep disturbances and worsen fatigue. Sleep disturbances have been shown to have effects across multiple areas affecting QoL including cognitive and mental health.<sup>34</sup> One mechanism is the augmentation of glymphatic clearance in the third slow wave phase of sleep. Correspondingly, disturbances to this sleep phase reduce optimal glymphatic clearance.<sup>35,36</sup> Advances in our understanding of the brain's glymphatic system suggest it may not only clear metabolic waste products but also facilitate signaling to other body systems.<sup>37</sup>

This, along with interdisciplinary research combining concepts of embryology,<sup>38</sup> quantum biology,<sup>39</sup> biotensegrity,<sup>40-43</sup> and complex systems theory,<sup>6</sup> provide the scientific rationale to suspect how small or distant SD can have whole body effects as a decoupler to a complex system. Furthermore, sleep, cognitive and mental health impairments can worsen pain perception, social roles and participation, which in turn can lead to worsening sleep disturbances and fatigue.<sup>44</sup> This is consistent with increasing evidence of the complex interplay of social, mental, and physical factors in health and disease.<sup>45</sup> We suspect the net effect contributes to a higher allostatic load, which has been correlated with many comorbidities that affect overall quality of life.<sup>46</sup>

Incorporated in a thorough medical workup, this study suggests potential benefits in considering somatic dysfunction as a modifiable risk factor affecting a number of quality of life complaints.

#### Improvements in Quality of Life with Sequenced Osteopathic Treatment of Somatic Dysfunction

Secondly, this study suggests that treatment of SD is rational and may contribute to improvements in overall and various domains and overall of quality of life by relieving impairments of optimal physiologic function. In contrast to symptom management, ps-OMT attempts to reset the stress response to allow inherent physiological processes to optimize towards pre-stress states as illustrated in Figures 2a,b. Notably, for domains with medium effect size such as anxiety and depression, this study also suggests that where SD is present, psOMT could possibly be trialed as a differential diagnostic therapy. It may assist in better stratifying who may benefit from pharmacological interventions, especially in pediatric<sup>47</sup> or geriatric populations<sup>48-50</sup> where side effects and polypharmacy complicates medical management.

# Sequencing OMT by AGR for patient-specific treatment of Somatic Dysfunction

Thirdly, this may well be the first study to address the sequencing of OMT, as opposed to any particular osteopathic or manipulative technique or protocol, which we suspect plays a significant role in diminishing patient-specific somatic dysfunction and improving their quality of life. Sequencing by key AGR honors each patient's unique presentation of allostasis in somatic tissues - how the whole body initially experienced, then dynamically compensated for various types and degrees of trauma (mechanical, chemical, emotional, etc.) from a neuromusculoskeletal perspective. Patient-specific Sequencing of OMT by key Area of Greatest Restriction is the osteopathic process of screening, treating, and rescreening the body as it presents the area of greatest restriction, or the key somatic cause at that moment in time because it has the least ability to compensate anymore. Treating the AGR improves multiple regions of SD at once due to the body's nonlinear, complex, bio tensegrity system of connective tissue.4,51 This explains why a key SD can present in areas far from the patient's chief complaint.

This also explains why treatment of the AGR can improve not only the region of the chief complaint but multiple areas throughout the body. One participant [ID# 031814] presented with chronic bilateral arm pain and swelling. After ps-OMT, she not only had improvement in her edema and algesia, but also whole body improvements including decreases in her chronic tremors and blood pressure. It likely addressed MSK hindrances affecting an optimal SNS response. This is significant because when done correctly, psOMT sequenced by AGR addresses all 4 osteopathic tenets and tends to result in:

1. broad-spectrum clinical improvements as shown in this study,

Figure 2a. Baseline optimal health with minimal allostatic load and somatic dysfunction allowing for normal, self regulatory physiological processes to occur at all levels. This illustrates the first 3 osteopathic tenets.



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**Figure 2b.** Suboptimal health with stress increasing allostatic load, resulting in somatic dysfunction that hinders normal, self regulatory physiological processes at multiple levels. As noted by the dashed lines, arterial and neurological inputs are altered from baseline leading to altered venous, lymphatic, tropic and sensory outputs that feedback as inputs in other systems. This results in impaired physiological function at multiple levels (cellular, tissue, organ, system, body). According to the fourth osteopathic tenet, rational treatment involves addressing somatic dysfunction.



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- 2. long-lasting relief because the key SDs rather than the compensatory SDs are addressed and
- 3. shorter treatment times for both patient and physician.

This last point is important because both referral for, and osteopathic evaluation and treatment of SD remains underutilized. Referrals are less in allopathic medicine due to limited exposure to psOMT/OMM, and also within the osteopathic profession itself due to lack of institutional support and time constraints.<sup>51</sup>

#### Limitations

This study was designed to be a noncomparative study due to the uniqueness of psOMT and the intention of hypothesis generation as opposed to testing.8 As such, this type of study has limitations, including no comparison group, which may limit generalizability. Another limitation was that our data was from a single ONMM residency clinic with primarily one treating resident physician precepted by one primary attending physician, which may also limit generalizability, as well as the potential for participant bias. The study did not differentiate between new and existing participants. Another limitation was time and resources. There were numerous participants who were lost to follow-up, which may have been recouped with more frequent follow-up phone calls or mailed surveys. There were also several patients who desired to participate but could not read and fill out the surveys by themselves due to their education level. These highlight another limitation of sample size though the study sample size was powered for the general population, it was not sufficiently powered to be broken into subcategories such as developmental age range, sex, socioeconomic status, etc.

This study's limitations in resources, time, and number of providers could have been improved with more research support, and variable timeframes to address acute, chronic, and acute on chronic complaints over time, as well as across multiple clinics and providers. More studies are needed in both hypothesis generation and testing of psOMT. Future studies could include randomization into comparison arms of psOMT with no intervention controls or with protocol or technique-driven OMT.

# Conclusion

This study presents a new paradigm for osteopathic medical research that honors each patient's unique accrual of and response to somatic dysfunction throughout the entire body over time, in alignment with the four osteopathic tenets. We assessed the effects of patient-specific sequenced OMT by AGR (psOMT) on Quality of Life metrics via baseline and post-psOMT surveys. Of the 78 mostly adult female participant group, those who received psOMT showed statistically significant improvements in all nine metrics of quality of life ( $\rho$ <.001) including physical function, anxiety, depression, fatigue, sleep disturbance, participation in social roles and activities, pain interference, cognitive function, and average pain intensity scale. Furthermore, all but two domain improvements had large effect sizes. The remaining two, Anxiety and Depression, had medium effect sizes. This study suggests that somatic dysfunction (SD) may contribute to impairments in overall quality of life, and as such SD could be considered as a modifiable risk factor in diagnostic evaluation. Lastly, this study suggests that patient-specific sequenced treatment of SD by AGR may contribute to improvements in quality of life by relieving impairments to optimal physiologic function. This study had limitations in the number of providers, time, and resources and could be improved with more research support, variable timeframes, and being conducted across multiple clinics and providers. More studies are needed in both hypothesis generation and testing of psOMT.

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# References

- Seffinger M. et al. Ch.1 Osteopathic Philosophy. In: Seffinger MA, ed. Foundations of Osteopathic Medicine. 4th ed. Philadelphia: Lippincott Williams & Wilkins; 2018: 3
- Hensel K, Will A, Giusti R, et al. Glossary of Osteopathic Terminology. In: Seffinger MA, ed. *Foundations of Osteopathic Medicine. 4th ed.* Philadelphia: Lippincott Williams & Wilkins; 2018:1575.
- 3. Patterson MM. The use of sham or placebo controls in manual medicine research. The Science and Clinical Application of Manual Therapy. 2011:181-191.
- Licciardone JC, Stoll ST, Fulda KG, et al. Osteopathic manipulative treatment for chronic low back pain: a randomized controlled trial. *Spine* (Phila Pa 1976). 2003 Jul 1;28(13):1355-62. doi:10.1097/01. BRS.0000067110.61471.7D.
- Verhaeghe N, Schepers J, van Dun P, Annemans L. Osteopathic care for spinal complaints: A systematic literature review. *PLoS One.* 2018 Nov 2;13(11):e0206284. doi:10.1371/journal.pone.0206284. Erratum in: PLoS One. 2019 Aug 8;14(8):e0221140.
- Ching LM, Benjamin BA, Stiles EG, Shaw HH. Enabling health potential: exploring nonlinear and complex results of osteopathic manual medicine through complex systems theory. *J Osteopath Med.* 2023 Jan 12;123(4):207-213. doi: 10.1515/jom-2022-0118.
- Hayes, A. Screening Assessment for AGR-H with Somatic Dysfunction [Video]. Youtube. https://www.youtube.com/ watch?v=6FdmQhYF234. Published October 21, 2018. Accessed September 5, 2023.
- Carey TS, Sanders GD, Viswanathan M, Trikalinos TA, Kato E, Chang S. Framework for considering study designs for future research needs [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2012 Mar. Report No.: 12-EHC048-EF.
- Pilkonis PA, Choi SW, Reise SP, Stover AM, Riley WT, Cella D; PROMIS Cooperative Group. Item banks for measuring emotional distress from the Patient-Reported Outcomes Measurement Information System (PROMIS<sup>®</sup>): depression, anxiety, and anger. Assessment. 2011 Sep;18(3):263-83. doi: 10.1177/1073191111411667.
- Hensel K, Will A, Giusti R, et al. Glossary of Osteopathic Terminology. In: Seffinger MA, ed. *Foundations of Osteopathic Medicine. 4th ed.* Philadelphia: Lippincott Williams & Wilkins; 2018:1587-1588.
- Patterson MM, Wurster RD. Chapter 12, In: Seffinger MA, ed. Foundations of Osteopathic Medicine. 4th ed. Philadelphia: Lippincott Williams & Wilkins; 2018: 301-317.
- Yao S, Hassani J, Gagne M, George G, Gilliar W. Osteopathic manipulative treatment as a useful adjunctive tool for pneumonia. *J Vis Exp.* 2014 May 6;(87):50687. doi: 10.3791/50687.
- Jones LM, Regan C, Wolf K, et al. Effect of osteopathic manipulative treatment on pulmonary function testing in children with asthma. *J Osteopath Med.* 2021 May 7;121(6):589-596. doi:10.1515/ jom-2020-0040.
- 14. Guiney PA, Chou R, Vianna A, Lovenheim J. Effects of osteopathic manipulative treatment on pediatric patients with asthma: a

randomized controlled trial. J Am Osteopath Assoc. 2005;105:7-12.

- 15. Bockenhauer SE, Julliard KN, Lo KS, Huang E, Sheth AM. Quantifiable effects of osteopathic manipulative techniques on patients with chronic asthma. *J Am Osteopath Assoc*.2002; 371-375.
- Ramos-González E, Moreno-Lorenzo C, Matarán-Peñarrocha GA, Guisado-Barrilao R, Aguilar-Ferrándiz ME, Castro-Sánchez AM. Comparative study on the effectiveness of myofascial release manual therapy and physical therapy for venous insufficiency in postmenopausal women. *Complement Ther Med.* 2012 Oct;20(5):291-8. doi: 10.1016/j.ctim.2012.03.005.
- Henley CE, Ivins D, Mills M, Wen FK, Benjamin BA. Osteopathic manipulative treatment and its relationship to autonomic nervous system activity as demonstrated by heart rate variability: a repeated measures study. Osteopath Med Prim Care. 2008;2:7. doi:10.1186/1750-4732-2-7.
- Bhilpawar PP, Auroa R. Effects of osteopathic manipulative treatment in patients with chronic obstructive pulmonary disease. *Indian J Physiother Occup Ther.* 2013 7(1):196-201.
- Licciardone JC, Kearns CM, Hodge LM, Minotti DE. Osteopathic manual treatment in patients with diabetes mellitus and comorbid chronic low back pain: subgroup results from the OSTEOPATHIC Trial. J Am Osteopath Assoc.2013;113(6):468-478.
- Saggio G, Docimo S, Pilc J, Norton J, Gilliar W. Impact of osteopathic manipulative treatment on secretory immunoglobulin A levels in a stressed population. *J Am Osteopath Assoc.* 2011;111(3):143-147.
- Nuño V, Siu A, Deo IN, Juster RP. Osteopathic manipulative treatment for allostatic load lowering. *J Am Osteopath Assoc.* 2019;119(10):646-654. doi:10.7556/jaoa.2019.112
- 22. Stiles, E. Primary lesion, Key lesion, Sequencing. *Textbook of Osteopathic Medicine*. 2018; 265-268
- 23. Licciardone JC, Schultz MJ, Amen B. Osteopathic manipulation in the management of chronic pain: current perspectives. *J Pain Res.* 2020 Jul 20;13:1839-1847. doi: 10.2147/JPR.S183170.
- 24. Bohlen L, Shaw R, Cerritelli F, Esteves JE. Osteopathy and mental health: an embodied, predictive, and interoceptive framework. *Front Psychol.* 2021 Oct 27;12:767005. doi:10.3389/fpsyg.2021.767005.
- Sardina AL, Gamaldo AA, Andel R, et al. Cross-Sectional examination of musculoskeletal pain and physical function in a racially and socioeconomically diverse sample of adults. *J Gerontol A Biol Sci Med Sci.* 2021 Jan 18;76(2):368-377. doi: 10.1093/gerona/glaa251.
- Vincent HK, Adams MC, Vincent KR, Hurley RW. Musculoskeletal pain, fear avoidance behaviors, and functional decline in obesity: potential interventions to manage pain and maintain function. *Reg Anesth Pain Med.* 2013 Nov-Dec;38(6):481-91. doi: 10.1097/ AAP.000000000000013.
- Hill CN, Romero M, Rogers M, Queen RM, Brolinson PG. Effect of osteopathic manipulation on gait asymmetry. J Osteopath Med. 2021 Nov 18;122(2):85-94. doi: 10.1515/jom-2021-0046.

- Dimitriadis Z, Kapreli E, Strimpakos N, Oldham J. Respiratory weakness in patients with chronic neck pain. *Man Ther*. 2013;18(3):248-53.
- Wirth B, Amstalden M, Perk M, Boutellier U, Humphreys BK. Respiratory dysfunction in patients with chronic neck pain – influence of thoracic spine and chest mobility. *Man Ther.* 2014;19(5):440–4.
- Peng B, Yang L, Li Y, Liu T, Liu Y. Cervical proprioception impairment in neck pain-pathophysiology,clinical evaluation, and management: A narrative review. *Pain Ther.* 2021 Jun;10(1):143-164. doi:10.1007/ s40122-020-00230-z.
- 31. Bowden Davies KA, Pickles S, Sprung VS, et al. Reduced physical activity in young and older adults: metabolic and musculoskeletal implications. *Ther Adv Endocrinol Metab.* 2019 Nov 19;10:2042018819888824. doi: 10.1177/2042018819888824.
- Roberts B, Makar AE, Canaan R, Pazdernik V, Kondrashova T. Effect of occipitoatlantal decompression on cerebral blood flow dynamics as evaluated by Doppler ultrasonography. *J Osteopath Med.* 2021 Feb 1;121(2):171-179. doi: 10.1515/jom-2020-0100.
- Hitscherich K, Smith K, Cuoco JA, et al. The Glymphatic-Lymphatic continuum: Opportunities for osteopathic manipulative medicine. *J Am Osteopath Assoc.* 2016 Mar;116(3):170-7. doi:10.7556/ jaoa.2016.033.
- Scott AJ, Webb TL, Martyn-St James M, Rowse G, Weich S. Improving sleep quality leads to better mental health: A meta-analysis of randomized controlled trials. *Sleep Med Rev.* 2021 Dec;60:101556. doi: 10.1016/j.smrv.2021.101556.
- Reddy OC, van der Werf YD. The Sleeping Brain: Harnessing the Power of the Glymphatic System through Lifestyle Choices. *Brain Sci.* 2020;10(11):868. Published 2020 Nov 17. doi:10.3390/ brainsci10110868
- Fultz NE, Bonmassar G, Setsompop K, et al. Coupled electrophysiological, hemodynamic, and cerebrospinal fluid oscillations in human sleep. *Science*. 2019;366(6465):628-631. doi:10.1126/science.aax5440
- Hablitz LM, Nedergaard M. The Glymphatic system: A novel component of fundamental neurobiology. *J Neurosci*. 2021 Sep 15;41(37):7698-7711. doi:10.1523/JNEUROSCI.0619-21.2021.
- Wal. Jaap van der. The Embryo in Us: A Phenomenological Search for Soul and Consciousness in the Prenatal Body. Lilipoh – The Spirit of Life, Winter 2014: The Garden; 2014;74(19):35-41.
- Ho M. The Rainbow and the Worm: The Physics of Organisms. 3rd ed. World Scientific; 1998.

- Levin SM. The tensegrity-truss as a model for spine mechanics: Biotensegrity. J Mech Med Biol. 2011;2(No. 03n04), 375-388. Doi:10.1142/S0219519402000472.
- Ingber DE. Tensegrity I. Cell structure and hierarchical systems biology. J Cell Sci. 2003 Apr 1;116(Pt 7):1157-73. doi: 10.1242/ jcs.00359.
- 42. Ingber DE, Wang N, Stamenovic D. Tensegrity, cellular biophysics, and the mechanics of living systems. *Rep Prog Phys.* 2014 Apr;77(4):046603. doi: 10.1088/0034-4885/77/4/046603.
- Guimberteau JC, Delage JP. Les tendons et le système de glissement multifibrillaire [The multifibrillar network of the tendon sliding system]. *Ann Chir Plast Esthet*. 2012 Oct;57(5):467-81. French. doi: 10.1016/j.anplas.2012.07.002.
- Pereira MG, Carvalho C, Costa ECV, Leite Â, Almeida V. Quality of life in chronic pain patients: Illness- and wellness-focused coping as moderators. *Psych J.* 2021 Apr;10(2):283-294. doi:10.1002/pchj.410.
- Bolton D, Gillett G. The Biopsychosocial Model of Health and Disease: New Philosophical and Scientific Developments [Internet]. Cham (CH): Palgrave Pivot; 2019.
- Guidi J, Lucente M, Sonino N, Fava GA. Allostatic load and Its Impact on health: A systematic review. Psychother Psychosom. 2021;90(1):11-27. doi: 10.1159/000510696.
- 47. Golchin N, Johnson H, Bakaki PM, et al. Outcome measures in pediatric polypharmacy research: a scoping review. Drugs Ther Perspect. 2019;35(9):447-458. doi:10.1007/s40267-019-00650-8
- Salwe KJ, Kalyansundaram D, Bahurupi Y. A study on polypharmacy and potential drug-drug interactions among elderly patients admitted in department of medicine of a tertiary care hospital in Puducherry. J Clin Diagn Res. 2016 Feb;10(2):FC06-10. doi:10.7860/ JCDR/2016/16284.7273.
- 49. Nobili A, Garattini S, Mannucci PM. Multiple diseases and polypharmacy in the elderly: challenges for the internist of the third millennium. J Comorb. 2011 Dec 27;1:28-44. doi:10.15256/ joc.2011.1.4.
- 50. Trumic E, Pranjic N, Begic L, Bečić F. Prevalence of polypharmacy and drug interaction among hospitalized patients: opportunities and responsibilities in pharmaceutical care. Mater Sociomed. 2012;24(2):68-72. doi: 10.5455/msm.2012.24.68-72.
- 51. Healy CJ, Brockway MD, Wilde BB. Osteopathic manipulative treatment (OMT) use among osteopathic physicians in the United States. J Osteopath Med. 2021;121(1):57-61. ■