

Ultrasonographic Evaluation of the Effect of Osteopathic Manipulative Treatment on Sacral Base Asymmetry

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A. Specific Aims

The long term objective of this study is to establish objective measurements of musculoskeletal changes that occur in response to osteopathic manipulative treatment (OMT). Many patients who suffer from low back pain (LBP) receive OMT to the lumbar, pelvic, sacral, and lower extremity body regions that helps resolve or manage their pain. The indication for OMT in a patient suffering from LBP is the presence of somatic dysfunction found during the physical examination. Somatic dysfunction is diagnosed when one or more of the following physical findings are present: tenderness, asymmetry, restricted range of motion, and tissue texture abnormalities. OMT is performed to specifically target these physical findings, after which the patient is reassessed for a reduction or resolution of the findings. In the clinical setting the assessment and reassessment of somatic dysfunction is performed using palpatory examination. Because palpatory findings commonly demonstrate poor interexaminer reliability, the proposed study will use ultrasound to establish pre- and postOMT musculoskeletal measurements of the relative asymmetry between the participants' pelvic and sacral bony landmarks. The investigators will use a control group to compare the changes in the pre and post OMT measurements to participants who have not received OMT. If ultrasonography is able to detect a significant change in the relative asymmetry between the pelvis and sacrum, then ultrasound may be useful for assessing and quantifying outcomes for OMT in a variety of body regions such as spine, shoulders, and knees. To determine if ultrasound is a reliable objective measure to assess OMT outcomes in LBP patients the following specific aims are proposed:

- Determine if ultrasound measurements of sacral landmarks are stable over 30 minutes in untreated participants.
- Determine the extent to which OMT affects the relative asymmetry between the pelvic and sacral landmarks as measured by ultrasonography.
- Determine if ultrasound measurements of sacral base asymmetry agree with palpatory assessment.

B. Background and Significance

Numerous studies have demonstrated the clinical efficacy of manual medicine techniques such as OMT in the care of patients with LBP.¹⁻⁴ The clinical efficacy is indicated by the reduction of the patient's pain. But the mechanisms of how these techniques work remains unclear. Clinically, patients are reassessed after OMT for changes in pain level, tenderness, tissue texture abnormalities, restricted range of motion and asymmetry. While palpatory assessment of somatic dysfunction before and after OMT is useful clinically, it is not reliable for use as pre- and post-treatment outcome measures because of generally poor interexaminer reliability. Individual examiners are often not accurate in their identification of bony landmarks⁵⁻⁷ and therefore any measurements derived from those findings would not be valid. Therefore the use of objective measurements to assess pre- and post-treatment outcomes is desirable.

Most studies objectively assessing somatic dysfunction before and after manual medicine techniques have evaluated changes in tenderness using algometers to measure pressure pain thresholds (PPT). These studies have overwhelmingly found that manual medicine increases PPT, meaning that after manipulation the tissues tolerate more pressure before inducing pain.⁸⁻¹⁰ However, this finding may be an indirect effect of the technique rather than primary mechanism of action. Other studies have demonstrated that manual medicine techniques induce changes in serum biomarker levels^{8, 11-15} and muscle activation^{16, 17} which also may be an indirect effect. A potential mechanism for OMT inducing these physiologic responses is the change in bony symmetry around a dysfunctional articulation. The change in symmetry would affect joint range of motion and muscular and ligamentous balance which in turn can affect the neurological proprioceptive responses and thus, a wide variety of processes.¹⁸ Childs et al¹⁹ found that improvements in lumbopelvic symmetry following spinal manipulation were associated with pain reduction, however lumbopelvic symmetry was assessed using

palpation. For a more in depth understanding of these mechanisms, an objective measurement of symmetry is needed.

The choices for objective measurements of bony landmarks include plain film radiography, computed tomography (CT), magnetic resonance imaging (MRI), and ultrasonography (US). While all of these studies are useful for obtaining images of bony landmarks, radiography and CT expose study participants to potentially harmful ionizing radiation and MRI is very expensive. Therefore, US, which is inexpensive and radiation-free, is a good choice for obtaining objective outcome measures. Several studies have used ultrasound measurements as outcome measures in manual medicine studies. Brenner et al¹⁶ measured the lumbar multifidus muscle thickness (LMMT) pre and post contraction in a single person before and after spinal manipulation and found that spinal manipulation greatly increased the change in LMMT between pre and post contraction, suggesting that the intervention marked improved ability of the muscle to contract. Shaw et al²⁰ used ultrasonography to assess lumbar vertebral transverse process asymmetry before and after OMT and found that the OMT significantly improved the symmetry. Therefore, the proposed study will investigate the use of ultrasonography to assess changes in lumbopelvic bony symmetry that occur in response to OMT.

A Reliability and Reproducibility of Ultrasound Measurements in the Lumbosacral Region

Real-time ultrasound imaging is well established as a safe and feasible method to evaluate musculoskeletal structures. As with any imaging modality, reliability of ultrasound measurements is an important characteristic that reflects the degree to which repeated measurements provide similar results. Demonstrating acceptable reliability is essential for any kind of measurement and for making valid assumptions based on the data. Multiple studies have found that ultrasound assessment of lumbosacral bony landmarks is as reliable as CT or MRI. Liu et al²¹ compared US to CT measurements of facet joint height and width and found no significant difference. Chleboun et al²² compared US to MRI measurements of distance between lumbar spinous processes in neutral, flexion and extension, and found no significant difference in the measurements obtained by the two types of studies. In a recent study we evaluated the depth of the sacral sulcus by measuring the depth of posterior superior iliac spine (PSIS) and depth of the sacral base using ultrasonography through real-time and direct visualization and evaluation of above-mentioned structures.²³ This study yielded consistent results establishing sacral base position using US.

Sacral Base Asymmetry

Several studies have demonstrated that patients with LBP have a significantly greater incidence and severity of somatic dysfunction in the lumbar, pelvic, and sacral body regions than people without LBP.²⁴⁻²⁶ Sacral somatic dysfunction is diagnosed, in part, by the presence of asymmetry of the sacral bases. The sacral bases are the superior portions of the sacrum located medial to the sacroiliac joints (Figure 1A). Palpatory assessment of sacral base asymmetry is performed by comparing the relative anterior or posterior position of each sacral base and by determining the relative depth of each sacral sulcus (deep or shallow) (Figure 1B).²⁷ These findings, along with information regarding the symmetry of other sacral landmarks, tenderness, tissue texture abnormalities, and restricted range of motion, are used to determine what types of OMT techniques will be used to treat the sacral somatic dysfunction. The sacral bases are ideal for objective measurement of landmarks because their close proximity to the PSIS of the iliac bones allows for a comparison of two bony landmarks on either side of the sacroiliac joint. Sacral base asymmetry can also be measured objectively with US, which allows for objective measurements that can be used to assess the effect of OMT on sacral base asymmetry.

C. Purpose Statement and Hypotheses

The objective of the proposed study is to quantify the change in sacral base asymmetry as measured by ultrasonography before and after OMT. The proposed study will utilize a control group to determine the stability of the sacral measurements and compare those findings to a treatment group that will receive OMT to

specifically address sacral somatic dysfunction as identified clinically. The proposed study will also compare the clinical palpatory assessment of sacral base asymmetry to the ultrasound measurements. Since the primary aim of this study is to assess the effect of OMT on sacral base asymmetry, the investigators will recruit participants with a recent history of LBP to ensure a high likelihood that the participants will have sacral

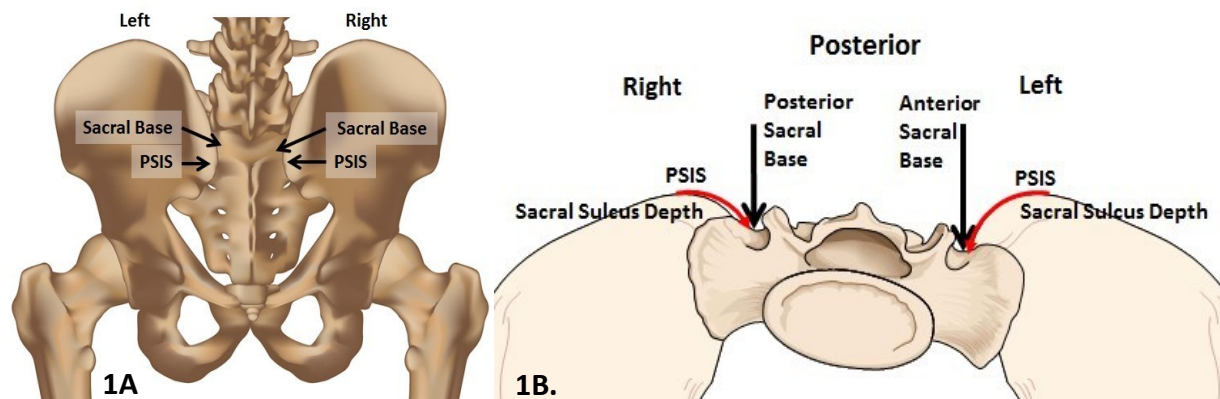


Figure 1. (A) Posterior view of the pelvis. The sacral base is the posterior superior surface of the sacrum divided into the right sacral base and the left sacral base. Posterior superior iliac spines (PSIS) are tubercles that project posteriorly from the posteromedial portion of the iliac bones on either side. (B) Superior view of the posterior pelvis. Sacral bases are traditionally palpated to assess for asymmetry by determining the relative anterior or posterior positioning of each sacral base and the relative depth of each sacral sulcus (deep or shallow).

somatic dysfunction which would include sacral base asymmetry. This assumption is based on several studies that have found that people with LBP have a significantly greater incidence and severity of somatic dysfunction in the lumbar, pelvic and sacral regions than people without LBP.²⁴⁻²⁶

D. Research Design and Methods

This prospective, randomized, controlled trial is proposed to investigate the effect of OMT on sacral base asymmetry as assessed by US. The study will be conducted over the course of two months. Forty men and women ages 20 to 55 years with at least one or more episodes of LBP in the past two weeks will be randomly assigned into one of two groups – control or OMT groups. Twenty participants will be assigned to each group. The study will begin recruitment in July 2016 pending institutional review board approval. Participants will be recruited from the surrounding Kirksville area. Individuals with prior spinal surgery, fractures, or known congenital anomalies of the lumbar vertebra and sacrum will be excluded. Individuals who cannot lie prone for 30 minutes, or who cannot tolerate OMT will be excluded. Subjects will be randomly assigned into two groups, control or OMT using a random number generator. Males and females will be randomized separately to ensure equal distribution into the two study groups. Demographics including sex, age, and body mass index (BMI) will be collected on all participants.

All participants will receive an initial palpatory assessment of the sacral base asymmetry and then an initial ultrasound evaluation of sacral base asymmetry. After the ultrasound assessment, the control group will wait in another room for approximately 30 minutes. Participants in the OMT group will receive OMT to address sacral base asymmetry after the initial ultrasound assessment. Following the treatment period for the OMT group, all subjects will receive a second ultrasound assessment of sacral base asymmetry. The ultrasonographer will be blinded on whether the subject received an OMT or not.

Palpatory Assessment

Prior to the initial ultrasound evaluation all participants will receive a palpatory assessment of the relative position of the sacral bases (anterior or posterior) and the relative depth of the sacral sulci (deep or shallow) as illustrated in Figure 1B. For this assessment, the participant will be in the prone position. The sacral bases will be palpated at a point just slightly superior and medial to the PSIS midpoint. The sacral base that is further forward toward the front of the participant will be designated as anterior. The sacral base that is positioned more toward the back of the participant will be designated as posterior. Sacral bases that are equal in the coronal plane, with neither side more anterior or posterior will be considered level. The sacral sulcus depth will be palpated as the relative distance from a point just slightly superior and medial to the PSIS midpoint down to the sacral base. The sacral sulcus that has the greater depth from the PSIS to the sacral base will be designated as deep. The sacral sulcus that has the lesser depth from the PSIS to the sacral base will be designated as shallow. After both the palpatory assessment of sacral base asymmetry and the initial ultrasound assessment have been performed, the findings will be compared.

Ultrasound Assessment

All participants will receive two ultrasound assessments evaluating sacral base asymmetry: an initial ultrasound assessment after the palpatory assessment, then a second ultrasound assessment after the treatment period. Ultrasound assessment will include the ultrasound imaging of the participants in the prone position during which an experienced ultrasonographer, who is blinded to the participant group assignment, will measure the depth from the skin to the PSIS (SPSIS) and the depth from the skin to the sacral sulcus base (SSB) on the right and left sides before and after the treatment period as illustrated in Figure 2. For each measurement, the ultrasound transducer will be placed directly over the landmark and consistent contact pressure will be used. The skin surface over the measurement locations will be marked with waterproof ink to ensure consistency in measurement locations between the first and second ultrasound assessments. The sacral sulcus depth (SSD) will be calculated from the two ultrasound measurements as $(SSD) = (SSB) - (SPSIS)$. The measurements will be compared before and after the intervention period. For comparison of the palpatory assessment of sacral base asymmetry to the ultrasound measurements, the larger SSB measurement will be considered the anterior sacral base, the smaller SSB will be considered the posterior sacral base, the greater SSD will be considered the deep sacral sulcus, and the lesser SSD will be considered the shallow sacral sulcus.

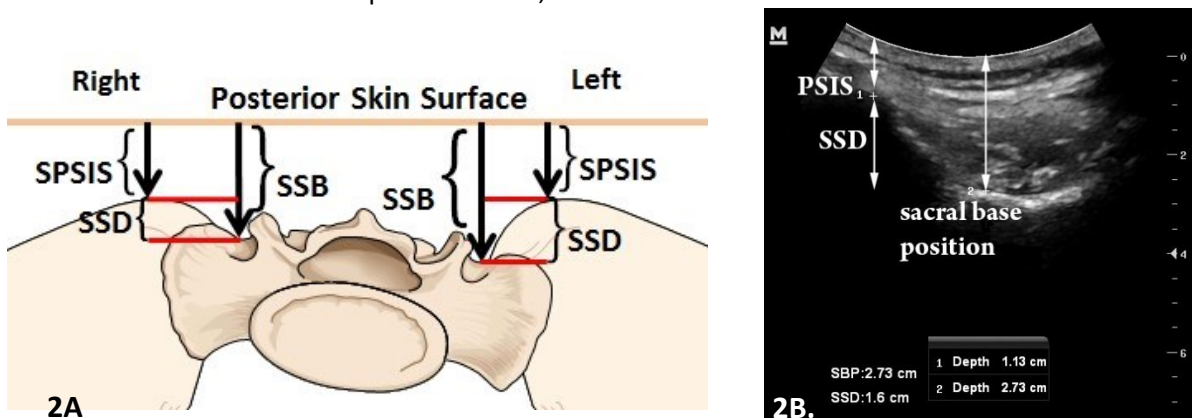


Figure 2. (A) Sacral base depth (SBD) will be measured as the distance between the skin and the sacral base position. Posterior superior iliac spine (PSIS) depth will be measured as the distance between the skin and the PSIS (SPSIS). Sacral sulcus depth (SSD) is calculated as $(SSB) - (SPSIS) = (SSD)$. (B) Ultrasound image illustrating the measured distance between the skin and the sacral base position, the distance between the skin, and the PSIS and the SSD.

OMT Treatment

The OMT treatment will begin with a brief physical examination to identify somatic dysfunction in the lumbar, pelvic, sacral, and lower extremity body regions that the treating physician judges to be relevant to the individual participant's sacral asymmetry. OMT will be performed with the specific goal of improving sacral asymmetry by treating the sacrum and the surrounding regions (lumbar, pelvis, and lower extremities). The types of OMT techniques used will include muscle energy, articular, or high velocity-low amplitude (HVLA) as indicated by the physical findings and will be at the discretion of the treating physician. Additional techniques such as Still, counterstrain, facilitated positional release, balanced ligamentous tension, and cranial techniques may also be used at the discretion of the treating physician with the total treatment time not to exceed 20 minutes. To encourage participation in the proposed study, participants who are assigned to the control group will have an opportunity to receive OMT after the second ultrasound assessment.

Preliminary Data

As part of a study investigating the feasibility of integrating ultrasound into an OMM curriculum, 247 students assessed the sacral base asymmetry of another student using US.²⁸ They measured SPSIS and SSB on the right and left sides, then calculated the SSD as $(SSB) - (SPSIS) = (SSD)$. The results are shown in Table 1. The calculated SSD demonstrated a wide range of depths (0 to 4.03 cm). The sacral sulcus depth difference (SSDD) between the right and left sides also demonstrated a wide range (-2.01 to 2.52 cm). Negative SSDD values indicated that the right sacral sulcus depth was shallower than the left and positive values indicate that the right sacral sulcus was deeper than the left, although these differences were not statistically significant.

Table 1: Student measurements of sacral base landmarks (N=247).

	Left SPSIS (cm)	Left SSB (cm)	Right SPSIS (cm)	Right SSB (cm)	Left SSD (cm)	Right SSD (cm)	SSDD (cm)
Maximum	6.33	8.24	4.94	8.29	3.65	4.03	2.52
Minimum	0.49	1.48	0.37	1.67	0.00	0.33	-2.01
Average	1.72	3.61	1.64	3.62	1.88	1.98	0.10
STDev	0.81	0.96	0.77	0.97	0.59	0.63	0.57

Abbreviations: SPSIS, distance from skin to posterior superior iliac spine (PSIS); SSB, distance from skin to sacral base (SSB); SSD, sacral sulci depth calculated as $(SSB) - (SPSIS) = (SSD)$; SSDD, sacral sulcus depth difference between right and left SSD.

Data analysis

Power calculations performed on preliminary SSDD data suggested that recruiting 38 participants would allow us to detect mean difference of ± 0.5 cm in the two treatment groups at pre-post treatment analysis at 0.05 significance level with 80% power. We plan to recruit 40 participants total (20 in each group). While the students, who collected the preliminary data, were not expert ultrasonographers, the quantity of data allows for an estimation of the likely range of measurements that will be seen in the proposed study. Descriptive statistics such as means, ranges, and standard deviations (SD) for continuous variables and frequency and percent will be used to summarize the categorical data. Two sample *t*-tests will be used to compare mean age and BMI across groups.

Correlations between BMI and US measurements will be calculated for each landmark (SPSIS, SBP, SSD). Absolute asymmetry between left and right landmark measurements will be calculated as follows:

$$\text{absolute asymmetry} = |\text{landmark}_{\text{left}} - \text{landmark}_{\text{right}}|$$

To determine if absolute asymmetry increased, decreased, or stayed the same after intervention, direction of change in asymmetry will be calculated as follows:

$$\begin{aligned} \text{direction of change in asymmetry} &= |2^{\text{nd}} \text{ US landmark}_{\text{left}} - 2^{\text{nd}} \text{ US landmark}_{\text{right}}| >, <, \text{ or} \\ &= |1^{\text{st}} \text{ US landmark}_{\text{left}} - 1^{\text{st}} \text{ US landmark}_{\text{right}}| \end{aligned}$$

To account for total change in measurements at both left and right landmarks between the first and second US measurements, total change in asymmetry between first and second US assessments will be calculated as follows:

$$\text{total change in asymmetry} = |(1^{\text{st}} \text{ US landmark}_{\text{left}} - 1^{\text{st}} \text{ US landmark}_{\text{right}}) - (2^{\text{nd}} \text{ US landmark}_{\text{left}} - 2^{\text{nd}} \text{ US landmark}_{\text{right}})|$$

The Fisher exact test is to be used to test associations between group and direction of change in asymmetry at each landmark. Multiple linear regression models will be built to compare mean absolute asymmetry for each landmark measured during the first US assessment between groups while controlling for demographic characteristics, date of last pain, and frequency of pain. Similar multiple linear regression models will be built to compare mean total change in asymmetry from first to second US assessment between groups for each landmark between groups.

Mean absolute asymmetry at the first and second US assessments and mean total change in asymmetry for seated control and OMT groups will be compared using a 2-sample t test. To compare qualitative palpatory assessment of SBP and SSD with quantitative US measurements, US measurement of landmark position will be first converted to a qualitative assessment as follows:

- right anterior SBP or deep SSD = right US measurement > left US measurement
- right posterior SBP or shallow SSD = right US measurement < left landmark measurement
- equal SBP or SSD = right US measurement = left US measurement

To compare agreement between qualitative palpatory and US assessments of SBP and SSD, κ and associated 95% CIs will be calculated. Values less than or equal to 0 indicated no agreement; 0.01 to 0.20, none to slight; 0.21 to 0.40, fair; 0.41 to 0.60, moderate; 0.61 to 0.80, substantial; and 0.81 to 1.00, almost perfect agreement.

To determine if US localization of landmarks at the sacral base was reliable, intraclass correlation coefficients (ICC) and associated 95% CIs will be calculated for US measurements from the first to second US assessment for each landmark. For ICC, 0.7 to 0.8 was considered good; 0.8 to 0.9, very good; and 0.9 to 1.0, excellent. $P \leq .05$ was considered significant. Data analysis will be performed using SAS statistical software version 9.4 (SAS Institute, Inc.).

Potential Limitations

The primary limitation to the ultrasound measurements is maintaining consistency in location of the initial and second ultrasound measurements. This limitation will be addressed by using a single, highly experienced ultrasound examiner. To ensure that the ultrasound measurements are made at the exact same locations during the initial and second ultrasound assessments on an individual participant, the

ultrasound examiner will mark the skin overlying the measurement locations using waterproof ink. The use of multiple types of OMT techniques in this study may introduce some potential treatment bias; however multiple techniques are typically used in on a single patient in a clinical setting. Future studies could assess the efficacy of individual techniques to improve asymmetry. The control group will be used to evaluate whether the ultrasound sacral measurements are stable over a period of time. To determine if participant sex, age, or BMI affect the reliability of the ultrasound or palpatory assessments, additional analyses may be run to assess if participant sex, age, or BMI confound the percent agreement between the two assessments.

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