What Is the Scientific Evidence for Osteopathic Manipulation?

A. T. Still, MD, DO and his students demonstrated the efficacy of Osteopathic Principles and Practices primarily through the use of OMT, alleviating their patients’ illnesses caused by trauma, overuse injuries, or inflammatory and infectious diseases. Cellular, animal and human research investigating the effect of OMT on organic functions and immunity followed in the first 25 years of the 20th century. Osteopathic research in the first 75 years of the 20th century also focused on neurologic pathophysiology that characterizes the “osteopathic lesion”, now called somatic dysfunction, which can be reversed by OMT (e.g., see the career works of Burns, Denslow, Korr and Johnston that spanned over 40 years each, a combined total of over 150 years of research studies, available from the American Academy of Osteopathy – http://www.academyofosteopathy.org; also see Northup 1987). Osteopathic research in the last 25 years of the 20th century and the first decade of the new millennium have focused on clinical outcomes of pain relief and increased function, as well as laboratory animal models and cell cultures assessing the metabolic or cellular pathophysiological processes related to artificially induced strains, sprains or somatic dysfunction and disease, which can be improved and possibly reversed by OMT.

It is helpful to group osteopathic research into the functional categories for which the techniques are designed, e.g., “metabolic studies” that assess the effects of OMT on inflammatory, infectious or endocrine system related conditions, “neurological studies” that assess the effects of OMT on pain or other neurological conditions, “respiratory and circulatory studies” that assess the effects of OMT on breathing and circulation, and “behavioral studies” that assess the effects of OMT on, e.g., sleep or depression.

Metabolic perspectives entail the pathophysiological processes of inflammation and infection. The five articles listed below are a sample of clinical trials designed to assess the morbidity of inflammatory or infectious conditions (e.g., pancreatitis, ankle sprain, pneumonia, otitis media) that have standard of care guidelines recommended by physician expert panels upheld by both DOs and MDs. The intervention being tested is the addition of OMT to the standard practice of medicine to see if it decreases the course and degree of illness. Osteopathic care per se is not on trial here; it is the OMT performed by DOs as an adjunct to standard medical care that is on trial.

**Inflammation**

1. **Patients hospitalized with pancreatitis** (Radjieski et al 1998)
   Hospitalized adult patients with uncomplicated pancreatitis (n= 14) were randomly assigned to two groups: six received standard care plus OMT; the rest received standard care only. OMT was provided by an osteopathic family medicine resident physician and entailed a general joint mobilization of the hips, pelvis, shoulders, sacrum, spine and ribs using standard myofascial release, articular and muscle energy procedures; tenderpoints found on the torso, spine and extremities were treated with standard strain/counterstrain techniques. Physicians making medical decisions in regards to treatment and discharge were blinded as to patient group allocation. Results: Patients in the OMT group spent significantly fewer days in the hospital before discharge (mean reduction of 3.5 days, p< .039).
Emergency patients with ankle sprain (Eisenhart et al 2003)

Adults who presented to an emergency department with a unilateral first- or second-degree acute ankle sprain (n=55) were randomized into two groups: one group received standard care plus OMT and the other group received standard care for acute ankle injuries. An osteopathic physician resident in emergency medicine provided the OMT which entailed myofascial release and strain/counterstrain techniques. Results: The OMT group had decrease in edema (P<.001) and pain (P<.001) immediately after OMT and 1 week later, and increased range of motion (P < .01) at 1 week follow up.

Infection

1. Hospitalized elderly patients with pneumonia (Noll et al 2000)

Patients over 60 years of age hospitalized with pneumonia (n= 58) were randomized to one of two groups: standard care plus OMT or standard care plus light touch sham OMT. OMT and light touch were provided by osteopathic physicians in residency programs in an osteopathic post-graduate training hospital and an osteopathic physician specializing in OMT. Results: There was significantly decreased IV antibiotics use (P<.005), length of stay (P<.014) and total antibiotics used in the OMT group as compared to the light touch group.

2. Hospitalized elderly patients with pneumonia (Noll et al 2010)

A multi-site (n=7) randomized, controlled, double-blind, clinical trial evaluated the effect of OMT on patients over 50 years of age hospitalized with pneumonia (n=406). Participants were randomized to one of three groups: standard medical care plus OMT, standard medical care plus light touch (LT) sham or standard care only control group. OMT and light touch were provided by osteopathic physicians in a neuromusculoskeletal medicine/osteopathic manipulative medicine residency, and an expert physician board certified in neuromusculoskeletal medicine/osteo manipulative medicine. Physicians managing the patients were blinded to the patients’ group allocation. All subjects received conventional treatment for pneumonia. OMT and LT groups received group-specific protocols for 15 minutes, twice daily until discharge, cessation of antibiotics, respiratory failure, death, or withdrawal from the study. The primary outcomes were hospital length of stay (LOS), time to clinical stability, and a symptomatic and functional recovery score. Results: Intention-to-treat (ITT) analysis (n = 387) found no significant differences between groups. Per-protocol (PP) analysis (n = 318) found a significant difference between groups (P = 0.01) in LOS. Multiple comparisons indicated a reduction in median LOS (95% confidence interval) for the OMT group (3.5 [3.2-4.0] days) versus the CCO group (4.5 [3.9-4.9] days), but not versus the LT group (3.9 [3.5-4.8] days). Secondary outcomes of duration of intravenous antibiotics and treatment endpoint were also significantly different between groups (P = 0.05 and 0.006, respectively). Duration of intravenous antibiotics and death or respiratory failure were lower for the OMT group versus the CCO group, but not versus the LT group.

3. Otitis Media (Mills et al 2003)

Children 6 months – 6 yrs. of age with recurrent acute otitis media (AOM) (n= 57) were randomized to one of two groups: standard care plus OMT (n=25) or standard care only (n=32). OMT was provided by osteopathic physicians specializing in NMM/OMM; primary care
physician managing the patients was blinded to group allocation. Results: patients in the OMT group had fewer episodes of AOM (p<.04) and surgical procedures (p<.03); had more mean surgery-free months (p<.01) and increased frequency of normal tympanograms (p<.02).

Another aspect of metabolic processes are those involving the endocrine system, and although pregnancy is not considered pathological, and is self-limiting and episodic, there are clinical studies regarding the efficacy of OMT in pregnancy.

**Pregnancy (King et al 2003)**

OMT has historically been used during pregnancy, but no prospective, randomized clinical trials have been done on applications and outcomes. Studies in the early twentieth century showed decreased labor times, decreased forceps deliveries, and decreased maternal death. A retrospective study of pregnant patients compared 160 women who received OMT throughout pregnancy to 161 women who did not. The study demonstrated decreased frequency of meconium-stained amniotic fluid (P<.001) and decreased occurrence of preterm delivery (P<.01). A marginally significant decrease in the use of forceps (P < .07) was also shown.

**Neurological conditions**

The following clinical trials assess the effect of OMT on a painful condition in a cohort of patients.

**Low Back Pain**

1. **Ambulatory adults with low back pain** (Andersson et al 1999)
   This randomized, controlled, clinical trial evaluated outcomes (pain, disability, activities) from MD (n=72) vs. DO (n=83) care of patients (n=155, ages ranged 20-59) with subacute low back pain (greater than 6 weeks but less than 3 months). Both MDs and DOs could prescribe medicine and order physical therapy, but the MDs and PTs were restricted in that they could not perform manipulation, whereas the DOs could. Only patients with lumbar, sacral or pelvic somatic dysfunction diagnosis were included in the study before randomization. OMT was performed by DOs who specialized in OMT. Outcomes were similar, but the DOs prescribed fewer medications (NSAIDS utilized by DOs was 24% vs. 54% for the MDs; muscle relaxants were used in 6% by DOs vs. 25% by MDs) and referred less to physical therapy (0.2% for DOs vs. 2.6% for MDs). Patients were equally satisfied with either treatment methods. This is the only randomized clinical trial in America that compared DO with MD patient care. It was run by MDs in collaboration with DOs, reported by the MD lead researcher in the New England Journal of Medicine (November 4, 1999); it was the first and only OMT research article published in that journal.

2. **OMT for back pain during 3rd trimester pregnancy** (Licciardone et al 2009),
   A randomized, placebo-controlled trial was conducted to compare usual obstetric care and osteopathic manipulative treatment, usual obstetric care and sham ultrasound treatment, and usual obstetric care only. Outcomes included average pain levels and the Roland-Morris Disability Questionnaire to assess back-specific functioning. OMT was performed by osteopathic physicians specializing in NMM/OMM. Results: Intention-to-treat analyses included
144 subjects. The Roland-Morris Disability Questionnaire scores worsened during pregnancy; however, back-specific functioning deteriorated significantly less in the usual obstetric care plus OMT group (effect size, 0.72; 95% confidence interval, 0.31–1.14; P = .001 vs usual obstetric care only; and effect size, 0.35; 95% confidence interval, -0.06 to 0.76; P = .09 vs usual obstetric care and sham ultrasound treatment). During pregnancy, back pain decreased in the usual obstetric care plus OMT group, remained unchanged in the usual obstetric care plus sham ultrasound treatment group, and increased in the usual obstetric care only group, although no between-group difference achieved statistical significance. Osteopathic manipulative treatment slows or halts the deterioration of back-specific functioning during the third trimester of pregnancy.

3. **Post operative pain** (Goldstein et al 2005)
A randomized, double-blind, controlled clinical trial was performed to assess the effect of OMT on pain control in post operative patients after hysterectomy. Thirty-eight hospitalized patients status post total abdominal hysterectomy participated and were assigned to one of four treatment groups in addition to standard medical and surgical care:

1. Preoperative saline and postoperative sham manipulative treatment;
2. Preoperative saline and postoperative OMT;
3. Preoperative morphine and postoperative sham manipulative treatment; or
4. Preoperative morphine and postoperative OMT.

Saline (control) or morphine, 10 mg, was delivered intravenously (IV) 10 minutes before surgical incision. All patients received a postoperative patient-controlled IV analgesia pump containing morphine. At specified intervals following preoperative IV injections, blood was drawn and analyzed for morphine concentrations. Subjects were also asked to rate their postoperative levels of pain, nausea, and vomiting. Subjects also received sham OMT or OMT (thoracic & lumbar myofascial soft tissue and sacral myofascial release techniques) three times following surgery. Results: there were no differences in either pain, or nausea and vomiting scores among the four study groups. Patients in Group 4 used less morphine than those in the Group 3 for the first 24 hours (P=.02) and from 25–48 hours (P=.01) after elective TAH. Morphine blood concentrations were lower after 24 hours in Group 4 compared with Group 2 (P=.04). Administration of postoperative OMT enhanced pre- and postoperative morphine analgesia in the immediate 48-hour period following elective TAH, demonstrating that OMT can be a therapeutic adjunct in pain management following this procedure.

4. **Low back pain meta-analysis and systematic review** (Licciardone et al 2005)
A meta-analysis of randomized controlled studies evaluated the literature for OMT used for acute low back pain. Six randomized controlled studies (3 from the United States and 3 from the United Kingdom), from 1973 to 2001, were reviewed, and they included a total of 525 patients with low back pain treated by osteopathic physicians. OMT significantly reduces low back pain in the acute setting (P<.01) with short term (P < .01), intermediate-term (P<.001), and long-term (P < .03) follow-ups. OMT relieves pain better than both no treatment and placebo controls (effect size, -0.30; 95% confidence interval, -0.47 to -0.13; P = .001). Pain relief persists for at least 3 months.

Further evaluation of low back pain manipulation studies shows that OMT decreases use of medications (analgesics, antiinflammatory agents, and muscle relaxants) and physical therapy,
improves physical and psychological outcomes with little additional cost and is more effective for acute than chronic low back pain.

**Neck pain (McReynolds and Sheridan 2005)**

An effectiveness study (comparing OMT to another commonly used therapy) randomized 58 emergency department patients with less than 3 weeks of neck pain into 2 groups. One group was treated with standard medical care plus OMT (n=29) and the other was treated with standard medical care plus ketorolac 30 mg intramuscularly (n=29). Both groups showed a significant reduction in pain intensity ($P<.001$), but the OMT group showed a significantly greater decrease in pain intensity ($P < .02$).

**Fibromyalgia (Gamber et al 2002)**

A randomized, controlled clinical trial of 24 female patients with fibromyalgia assessed the effect of standard care plus OMT. Participants were randomly assigned into 4 groups: (1) standard care plus OMT, (2) standard care plus OMT and teaching (patients were taught home tender point treatment), (3) standard care plus moist heat, and (4) standard care only. Patients were allowed to continue their chronic medications. The OMT group showed significant improvement in pain threshold, perceived pain, attitude toward treatment, activities of daily living, and chronic pain.

**Headaches**

1. **Tension-type headaches (Hanten et al 1999)**

A randomized controlled clinical trial evaluated the effect of standard care plus OMT on patients with chronic tension-type headaches. Twenty-two patients were randomly assigned into 3 groups: (1) standard care plus OMT, (2) standard care plus palpatory diagnosis (placebo), or (3) standard care plus 10 minutes of relaxation (control). The group of patients treated with OMT showed significant decrease in rated headache pain ($P<.0003$).

2. **Chronic tension-type headaches (2006).**

OMT for chronic tension-type headaches was studied in a randomized, controlled, clinical trial. Twenty-nine patients were randomized into either a standard care plus OMT group or a standard care only control group. Both groups did regular home relaxation exercises and continued chronic medications. One group received 3 osteopathic treatments (once weekly). Significant improvement was shown for the OMT group in the number of headache-free days ($P < .016$).

**Neurological Studies other than Pain Conditions**

Besides pain, there have been randomized, controlled clinical trials that looked at the effect of OMT on a cohort of patients with a neurological condition, such as Parkinson’s disease or infantile colic.

**Parkinson disease**
Gait analysis was performed in 20 patients with Parkinson’s disease before and after receiving OMT for spinal somatic dysfunction by an osteopathic physician who specialized in OMT. Patients were randomly assigned to either a standard care plus OMT or standard care plus sham manipulation group. Patients receiving sham manipulation of limb range of motion evaluation and structural measurements showed no significant change compared with their baseline. Significant changes including stride length, cadence, and maximum velocities of various joints, however, were shown in the OMT treatment group, who each received a standard 14 osteopathic techniques.

Colic

Infantile colic is another condition thought to involve the nervous system as patients are agitated and irritable. OMT is commonly used in conditions that do not have effective medical or surgical treatments, including infantile colic. One study randomized 28 infants with colic into 2 groups to receive either osteopathic cranial manipulation or no treatment. The study showed a highly significant improvement in time spent crying (P<.001) and time spent sleeping (P<.002).

Respiratory and Circulatory Conditions

The following clinical trials assess OMT effects on pulmonary or cardiovascular functions.

Asthma (Guiney et al 2005)

A randomized, controlled trial evaluated the effect of OMT on peak flow measurements in children with asthma. One hundred forty patients (ages ranged from 5-17) with asthma were randomly assigned to two groups: standard medical care plus OMT (n=90) or standard medical care with light touch placebo (n=50). OMT was performed by various osteopathic physicians and the placebo was provided by an MD physician. The OMT group showed a statistically significant improvement of 7 L per minute to 9 L per minute for peak expiratory flow rates (95% confidence level).

Post Coronary Artery Bypass Graft surgery (O-Yurvati et al 2005)

To determine the effects of OMT on cardiac hemodynamics post-CABG surgery, researchers performed a prospective clinical study on 10 patients post CABG who received OMT within two hours of the surgery while unconscious and still under the influence of anesthesia; results were compared to 19 matched controls not treated with OMT. The primary assessment compared pre-OMT versus post-OMT thoracic impedance, mixed venous oxygen saturation (SvO2), and cardiac index. Records of control subjects who underwent CABG surgery, but who did not receive OMT, were assessed for SvO2 and cardiac index at 1 hour and 2 hours postsurgery. Osteopathic physicians specializing in OMT performed primarily myofascial release OMT procedures to alleviate anatomic dysfunction of the rib cage caused by median sternotomy and to improve respiratory function. Results: A post-OMT increase in thoracic impedance (P<.02) in OMT subjects demonstrated that central blood volume was reduced after OMT, suggesting an improved peripheral circulation. Mixed venous oxygen saturation also increased (P<.005) after OMT. These increases were accompanied by an improvement in cardiac index (P<.01). Comparisons of postoperative measurements in OMT subjects versus those in control subjects revealed statistically significant differences for SvO2 (P<005) and cardiac index (P<.02) between the two groups.
Behavioral Conditions

Sleep (Cutler et al 2005)

To determine if osteopathic cranial manipulation (osteopathy in the cranial field) is associated with altered sleep latency and muscle sympathetic nerve activity (MSNA) as a potential mechanism for altered sleep latency, researchers recruited twenty (20) healthy volunteers (12 male, 8 female; age range, 22–35 years) and randomized them to one of three groups: compression of the fourth ventricle (CV4), CV4 sham (simple touch), and control (no treatment). Sleep latency was assessed during each of the interventions in 11 subjects, using the standard Multiple Sleep Latency Test protocol. Concurrently, directly recorded efferent MSNA was measured during each of the interventions in the remaining 9 subjects, using standard microneurographic technique. Results: Sleep latency during the CV4 trial was decreased when compared to both the CV4 sham or control trials ($P < .05$). MSNA during the CV4-induced temporary halt of the cranial rhythmic impulse (stillpoint) was decreased when compared to prestillpoint MSNA ($P < .01$). During the CV4 sham and control trials MSNA was not different between CV4 time-matched measurements ($P > .05$). Moreover, the change in MSNA prestillpoint to stillpoint during the CV4 trial was different compared to the CV4 sham and control trials ($P < .05$). However, this change in MSNA was similar between the CV4 sham and control trials ($P > .80$).

Depression (Plotkin et al 2001)

In a randomized controlled clinical trial 17 patients with depression were randomly assigned to a standard care plus OMT (n=8) or standard care plus placebo group (n=9). Standard care consisted of paroxetine anti-depressant medication and psychotherapy. The placebo consisted of a standard structural evaluation but no actual OMT. Osteopathic student physicians administered the structural exams and OMT under the direction of an OMT specialist faculty. All subjects in the OMT group reverted to normal Zung Depression Scale scores compared to only 33% of those in the placebo group by week 8.