# Safety of Osteopathic Cranial Manipulative Medicine as an Adjunct to Conventional Postconcussion Symptom Management: A Pilot Study

Komal G. Patel, DO; Rosanna C. Sabini, DO

From the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell in Hempstead, New York (Drs Patel and Sabini) and Southside Hospital in Bay Shore, New York (Dr Sabini). Dr Patel is a fourth-year resident.

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Address correspondence to Komal G. Patel, DO, 1554 Northern Blvd, Manhasset, NY 11030-3006.

Email: kpatel21@northwell.edu

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**Context:** Osteopathic cranial manipulative medicine is not a well-established adjunct to conventional treatment for patients with postconcussion symptoms.

**Objective:** To determine whether adjunctive osteopathic cranial manipulative medicine is safe for patients with concussion when accompanied by conventional treatments.

**Design:** Prospective observational pilot study.

**Setting:** Outpatient concussion clinic.

**Participants:** Patients who sustained a concussion were prospectively recruited from an outpatient concussion clinic by a neuropsychologist specialized in concussion. All participants were identified to have a cranial dysfunction.

**Intervention:** Each eligible participant received 1 session of the osteopathic cranial manipulative medicine vault hold technique.

**Main Outcome Measures:** Self-reported adverse events during or after 1 session of the osteopathic cranial manipulative medicine procedure and improvement in concussion symptoms at return to follow-up.

**Results:** None of the 9 participants reported adverse events during or immediately after receiving osteopathic cranial manipulative medicine. Five of the 7 participants who returned for follow-up demonstrated improvement in their overall concussion symptoms based on the Post-Concussion Symptom Scale scores.

**Conclusions:** Osteopathic cranial manipulative medicine was considered a safe adjunctive treatment option to improve concussion-related symptoms and recovery.

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According to the American Academy of Neurology, a concussion is defined as a clinical syndrome caused by a biomechanically induced alteration of brain function.[1,2] Symptoms of a concussion can vary and may include headaches, vertigo, fatigue, irritability, difficulty with concentration and memory, sleep impairment, and reduced stress tolerance.[3,4] The most commonly reported symptom is a headache.[4-7] Management of headaches and other postconcussion symptoms focuses on symptomatic relief, identification of underlying comorbid psychosocial stressors, lifestyle modification

(eg, sleep hygiene, minimizing stress, avoiding triggers), and over-the-counter analgesics.[4,8,9] Although concussion symptoms typically resolve within a few weeks,[2,10,11] some people may continue to experience persistent symptoms—greater than 10 to 14 days in adults and greater than 4 weeks in children.[2] In some circumstances, patients may seek nonpharmaceutical therapies, such as osteopathic cranial manipulative medicine (OCMM), when concussion symptoms do not respond to current conventional postconcussion treatment options.[4,12] Currently, OCMM is not considered part of the conventional treatment for patients with postconcussive symptoms.[4,8,9]

William G. Sutherland, DO, developed OCMM in the early 1930s to assess and alleviate cranial bony and myofascial dysfunctions[13,14] that may arise from various injuries. Assessment of cranial dysfunctions requires a working knowledge of the cranial bony anatomy and how the cranium is connected via the falx cerebri, falx cerebelli, and tentorium cerebelli to the base of the spine at S1 to S2, the terminus of the dura. It is at the sphenobasilar symphysis (SBS)—the junction of the basisphenoid and basiocciput—where direct and indirect forces may result in major cranial strain patterns.[15]

In a review of the literature, 2 studies demonstrated cranial dysfunctions after a traumatic brain injury. In one study, 95% of patients with traumatic brain injury showed some form of craniofacial disruption, with lateral strain and torsional dysfunctions being the most frequent.[16] In another study, reduced craniosacral impulse with SBS compression was noted after traumatic brain injury, as well as increased SBS lateral and vertical strain, torsion, and anterior-posterior compression within the craniofacial bones, all of which improved with direct decompression.[15]

To date, there has been limited research regarding the use and safety of OCMM after concussion. A small-sample study[17] showed improvement in posttraumatic headaches after OCMM in combination with other manipulative techniques and pharmacotherapy. Furthermore, adjunctive osteopathic manipulative treatment has been shown to reduce posttraumatic headache, as well as the number of days per week with headache, compared with conventional treatment alone.[18,19] Given the paucity of data on OCMM in the management of concussion, this study sought to determine whether OCMM was a safe option in postconcussion symptom management when accompanied by conventional treatments.

## Methods

The study protocol was performed with the approval of the local institutional review board, and informed consent was obtained from participants in accordance with the Declaration of Helsinki. Participants were prospectively recruited from an outpatient concussion program, in which they were either self-referred or referred by other practitioners for the evaluation and management of concussion. The initial encounter consisted of obtaining a medical history, which included the Post-Concussion Symptom Scale (PCSS), and performing a physical examination by a neuropsychologist. The PCSS contains a list of 22 symptoms of concussion, each rated by the patient using a Likert scale from 0 (absent) to 6 (severe).

After the diagnosis of concussion was confirmed by the physician (R.C.S.), potential participants were referred for possible study enrollment during the same visit. The inclusion criteria for participation included having been injured within 8 weeks of the time of the initial visit, an age of 14 years or older, and a PCSS score of 10 or greater. The exclusion criteria included the following: cervical or thoracic surgery within the past 3 months; receipt of worker's compensation within the past 3 months; currently or potentially becoming involved in litigation related to the injury; receipt of OCMM within the past 3 months; history of hydrocephalus, infection or active tumor; or active or marked depression, anxiety, or psychosis.

If a participant was excluded from the study, he or she was educated to continue receiving concussion care. If a participant met the study criteria, he or she was asked to sign a consent form. Participants received

1 session of OCMM by a single board-certified osteopathic physician (R.C.S.) with a fellowship in osteopathic manipulative medicine.

### OCMM Procedure

The treatment was performed with the participant lying comfortably in a supine position. The examiner's hand was initially placed at the occipitoatlantal junction of the top of the cervical spine to evaluate for fascial restrictions. Any palpated restrictions were released using myofascial release, with no passive or active range of motion performed to the cervical region. Once the occipitoatlantal junction was determined to be free of restrictions, fingers were placed on the head using the vault hold (**Figure**). This technique was used in the standard manner, with bilateral finger placement: thumbs off the head, index fingers on the sphenoid bones, middle fingers on the temporal bones, fourth fingers on the mastoid, and fifth fingers on the occipital bone. Once assessment of cranial restrictions was made, OCMM was applied until the cranial restrictions were normalized. Each procedure lasted less than 30 minutes.

Changes in symptoms or development of adverse effects were monitored by direct questioning of the participant about any symptoms during the procedure. Additional subjective outcome measures regarding overall symptoms were further delineated on the PCSS at the follow-up evaluation.

Participants were educated to continue their concussion care as directed by their physician and recommended to follow up with the physician after this treatment session. The treating physician in this study was blinded to which participant received the OCMM.

**Figure.**
In participants with postconcussion symptoms, osteopathic cranial vault hold was applied until the cranial restrictions were normalized. Bilateral finger placement: thumbs off the head, index fingers on the sphenoid bones, middle fingers on the temporal bones, fourth fingers on the mastoid, and fifth fingers on the occipital bone.

## Results

During the 4-week study, 26 potential participants were screened for inclusion and exclusion criteria. Seventeen patients were excluded (for receipt of workers compensation, concussion >8 weeks prior, or a history of active psychiatric disorder). Nine participants met the inclusion criteria and enrolled in the study. Seven participants completed the study, and 2 were lost to follow-up.

The study sample comprised participants aged 14 to 58 years (mean [SD] age, 27.5 [16.4] years) (**Table 1**). Five of the participants were female and 4 were male. The mechanism of injury by which the participants sustained their concussion was as follows: 4 resulted from a motor vehicle accident, 4 were sports-related, and 1 was related to a fall. Two participants had a history of psychiatric disorder (depression and bipolar disorder) that was considered stable according to the

**Table 1.**
**Osteopathic Cranial Manipulative Medicine as an Adjunct to Conventional Postconcussion Symptom Management: Participant Characteristics**

| Participant No. | Age, y | Sex | Mechanism of Injury | History of Headaches or Migraines | History of Psychiatric Disorder | Days to Initial Visit Since Concussion | Days to Follow-up |
|---|---|---|---|---|---|---|---|
| 1 | 56 | Male | Motor vehicle accident | N | N | 40 | 21 |
| 2 | 16 | Female | Sport-related injury | N | N | 8 | 20 |
| 3 | 17 | Female | Fall | Y | N | 18 | 21 |
| 4 | 14 | Female | Sport-related injury | Y | N | 34 | 15 |
| 5 | 23 | Male | Motor vehicle accident | N | Y | 26 | 56 |
| 6 | 18 | Male | Sport-related injury | N | N | 53 | 27 |
| 7 | 16 | Female | Motor vehicle accident | Y | N | 29 | 139 |
| 8[a] | 58 | Female | Motor vehicle accident | N | Y | 20 | … |
| 9[a] | 30 | Male | Sport-related injury | Y | N | 37 | … |

[a] Lost to follow-up.

participants. Four participants had a history of migraines or headaches, but none were currently receiving treatment.

The number of days from the date of concussion to the initial study visit ranged from 8 to 53 days (mean [SD], 29.4 [12.6] days). The number of days before participants followed up with their personal physician ranged from 15 to 139 days (mean [SD], 42.7 [41.3] days).

Of the 9 participants who received a single session of OCMM, no participant had adverse effects during or immediately after the procedure as indicated by participant reporting. We considered adverse effects to include worsened headache, nausea, dizziness, increased pain or soreness, lightheadedness, and fatigue. At the follow-up evaluation, no participant reported the development of such adverse effects for the remainder of the day after receiving the OCMM.

Palpation of the occipitoatlantal joint and the cranium revealed cranial dysfunctions in all of the participants (Table 2). Two-thirds of the participants exhibited an extension dysfunction of the occipitoatlantal joint and one-third exhibited a flexion dysfunction. Six participants demonstrated a left sidebending and rotation cranial dysfunction; 1 participant, a right sidebending and rotation cranial dysfunction; 1 participant, a right sidebending and rotation with translation cranial dysfunction; and 1 participant, a left torsion cranial dysfunction.

Of the 7 participants who returned for follow-up, 5 demonstrated an improvement in their PCSS scores (Table 2). Two of the 7 participants reported an increased PCSS score at the follow-up visit.

**Table 2.**
**Cranial Dysfunctions and PCSS Scores in Participants With Postconcussion Symptoms Who Received Osteopathic Cranial Manipulative Medicine as an Adjunct to Conventional Treatment**

| Participant No. | Occipitoatlantal Somatic Dysfunction | Cranial Dysfunction | Initial PCSS Score | Follow-up PCSS Score | PCSS Score Change |
|---|---|---|---|---|---|
| 1 | $ES_RR_L$ | $S_LR_L$ | 50 | 29 | –21 |
| 2 | $FS_RR_L$ | $S_RR_R$, translation | 20 | 0 | –20 |
| 3 | $ES_LR_R$ | $S_RR_R$ | 50 | 17 | –33 |
| 4 | $ES_RR_L$ | $S_LR_L$ | 22 | 40 | 18[a] |
| 5 | $ES_LR_R$ | $S_LR_L$ | 80 | 18 | –62 |
| 6 | $FS_RR_L$ | $S_LR_L$ | 27 | 11 | –16 |
| 7 | $FS_RR_L$ | $S_LR_L$ | 31 | 50 | 19[a] |
| 8[b] | $ES_RR_L$ | $S_LR_L$ | 83 | … | … |
| 9[b] | $ES_LR_R$ | Left torsion | 39 | … | … |

[a] Patients did not have improvement in Post-Concussion Symptom Scale (PCSS) at follow-up after osteopathic cranial manipulative medicine.
[b] Lost to follow-up.

**Abbreviations:** E, extended; F, flexed; $R_L$, rotated left; $R_R$, rotated right; $S_L$, sidebent left; $S_R$, sidebent right.

## Discussion

The natural time course for concussion symptom resolution is typically less than a month.[2,10,11] The conventional treatment for patients with concussion includes activity modification and analgesics. Use of adjunctive treatment is limited, and safety profiles of some treatments have not been extensively studied. Our pilot study sought to determine the safety of OCMM as an adjunctive treatment for postconcussive symptom management.

One study[16] reported that 5% of participants' iatrogenic adverse events (eg, increased headaches and anxiety) developed after OCMM. The current study did not replicate those results. Participants who received OCMM were monitored for increased or worsened headaches, nausea, dizziness, pain, lightheadedness, or fatigue. However, none of the participants reported adverse events at the time of the procedure or at the follow-up visit. In general, adverse effects are typically difficult to capture in patients who receive any osteopathic manipulative treatment; therefore, a limitation of this pilot study is the small sample size and the subjective nature of symptom reporting. A larger treatment group may produce reported adverse effects of OCMM. Therefore, the need for a larger study protocol with inclusion of a control or sham group to evaluate the use and efficacy of OCMM as an adjunctive treatment option for concussion symptom management is warranted.

The PCSS indicates the presence and severity of self-perceived concussion symptoms. It is important to note that the PCSS is a nonspecific subjective measurement of 22 symptoms that could also be shared by the general population and persons who have other medical comorbidities, such as mood disorders or sleep difficulty. Despite the potential bias, the PCSS can assist in measuring the current state of symptoms and monitor progression through recovery. Five of the 7 participants who completed the study had improved PCSS scores. It is possible that the improvement in the

PCSS score at the follow-up visit was a reflection of the natural progression and recovery of concussion symptoms. Therefore, although OCMM may have influenced improvement in the PCSS score, no control group was included to determine whether OCMM improved the PCSS score to a greater extent than the conventional care alone. Future studies, such as a randomized controlled trial, would be required to help determine the degree of symptom relief directly related to the OCMM.

The PCSS of 2 participants, 4 and 7, did not improve at the follow-up visit but rather worsened by a total of 18 and 19 points, respectively (**Table 2**). As discussed, most people who sustain a concussion have resolution of their symptoms within a few weeks (<2 weeks for adults, <4 weeks for children), but 20% have persistent symptoms.[20] According to the most recent consensus statement on concussion in sport,[2] persistent symptoms are considered to be a failure of normal clinical recovery and a constellation of nonspecific posttraumatic symptoms possibly linked to premorbid and current psychosocial stressors. Increased risk of persistent symptoms developing include having a history of a learning disability, migraines, or psychiatric disorders, such as anxiety or depression; having associated amnesia or loss of consciousness associated with the injury; and being younger than 18 years.[21] It is possible that participants 4 and 7 had persistent symptoms. They both reported a history of headaches or migraines and were younger in age (14 and 16 years, respectively). However, participants 3 and 5 had a similar history as 4 and 7 but demonstrated improved symptoms at the follow-up visit. Thus, participants 4 and 7 could have had other premorbid factors or psychosocial stressors that contributed to their worsened PCSS scores but were not identified by our screening criteria. One study[22] reported that other factors, such as mental and physical activity, stress, and sleep, can also cause daily spikes and fluctuation in concussion symptoms. Therefore, a higher PCSS score at the follow-up visit may have reflected a temporary symptom spike and not necessarily indicated worsened recovery. If additional follow-up visits were included in the study, the status of participants 4 and 7 could have been better ascertained. A future study would need to consider ongoing follow-up visits of at least 3 or more months to assist in determining recovery in patients who may have prolonged symptoms.

All of the participants who received a diagnosis of concussion were also found to have a craniosacral dysfunction. However, correlation or causation of the craniosacral dysfunctions with a history of concussion could not be concluded. Craniosacral dysfunctions have been described as being physiologic in origin, caused by daily strains on the body, or traumatic in origin.[23] In addition, it has also been suggested that at least 1 cranial strain pattern will develop in all humans as a result of birthing mechanics.[24] A retrospective review[25] on cranial strain prevalence in healthy individuals demonstrated that all participants were identified to have cranial strain patterns, with torsions and rotations being the most common. Therefore, our results cannot conclude whether the craniosacral dysfunctions diagnosed were a direct result of the concussion or physiologic.

## Conclusion

This pilot study demonstrated safe implementation of OCMM for the adjunctive management of postconcussion symptoms in a small sample size. Although limited by the small sample size, which may have affected the study's ability to expose adverse events related to OCMM, this study elucidated the challenges of implementing OCMM and the need to design a larger-scale study with a control or sham group. If replicated, OCMM may be considered as an adjunctive or alternative treatment option to improve concussion-related symptoms and recovery.

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## Author Contributions

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