Comparing the Effect of Osteopathic Manipulative Medicine versus Concussion Education in the Treatment of Concussion
A Pilot Study

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HYPOTHESIS

We hypothesize that osteopathic manipulative medicine (OMM) will lead to improvement in symptoms as measured through the 3rd edition of the Sport Concussion Assessment Tool (SCAT-3) and Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT) assessment tools in post-concussion subjects as compared to a control group, who will receive concussion education.

INTRODUCTION

Concussions are a form of mild traumatic brain injury, which are caused by trauma to the head or body (*Figure 1*). Concussions are diagnosed by history and physical examination reported by the patient and/or witnesses. The current treatment is immediate removal from play or work, and rest.[1] However, previous studies have shown that bed rest following a concussion does not improve recovery time and may negatively impact recovery.[2] Therefore more treatment options are needed to address concussion symptoms and expedite the healing process.

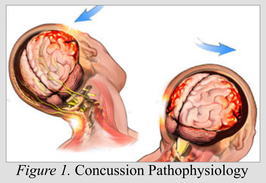


Figure 1. Concussion Pathophysiology

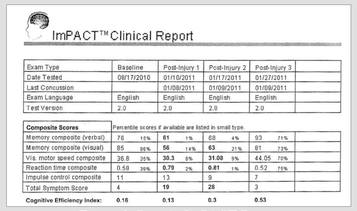
SCAT-3 and ImPACT are a few tools that monitor concussion severity. SCAT-3 is a subjective questionnaire, assessing twenty-two different symptoms on a numerical scale from zero to six, in a self-reported manner (*Figure 2*).[4] ImPACT is a computer-based neurocognitive test battery that evaluates a patient's cognitive function after concussion and compares it to their baseline score (*Figure 3*).[3]

How do you feel?

"You should score yourself on the following symptoms, based on how you feel now".

	none	mild	moderate	severe	
Headache	0	1	2	3	4 5 6
"Pressure in head"	0	1	2	3	4 5 6
Neck Pain	0	1	2	3	4 5 6
Nausea or vomiting	0	1	2	3	4 5 6
Dizziness	0	1	2	3	4 5 6
Blurred vision	0	1	2	3	4 5 6
Balance problems	0	1	2	3	4 5 6
Sensitivity to light	0	1	2	3	4 5 6
Sensitivity to noise	0	1	2	3	4 5 6
Feeling slowed down	0	1	2	3	4 5 6
Feeling like "in a fog"	0	1	2	3	4 5 6
"Don't feel right"	0	1	2	3	4 5 6
Difficulty concentrating	0	1	2	3	4 5 6
Difficulty remembering	0	1	2	3	4 5 6
Fatigue or low energy	0	1	2	3	4 5 6
Confusion	0	1	2	3	4 5 6
Drowsiness	0	1	2	3	4 5 6
Trouble falling asleep	0	1	2	3	4 5 6
More emotional	0	1	2	3	4 5 6
Irritability	0	1	2	3	4 5 6
Sadness	0	1	2	3	4 5 6
Nervous or Anxious	0	1	2	3	4 5 6

Figure 2. Sample SCAT-3 Symptom Evaluation



ImPACT™ Clinical Report

Exam Type	Baseline	Post-Injury 1	Post-Injury 2	Post-Injury 3
Date Tested	08/17/2010	01/10/2011	01/17/2011	01/27/2011
Last Concussion		01/08/2011	01/09/2011	01/09/2011
Exam Language	English	English	English	English
Test Version	2.0	2.0	2.0	2.0

Composite Scores	Percentile scores if available are listed in small type.							
Memory composite (verbal)	76	15%	**61**	1%	68	4%	93	71%
Memory composite (visual)	85	86%	**56**	14%	**63**	21%	81	73%
Vis. motor speed composite	36.8	25%	**30.3**	8%	**31.08**	5%	44.05	78%
Reaction time composite	0.58	39%	**0.70**	2%	**0.61**	1%	0.52	75%
Impulse control composite	11		13		9		7	
Total Symptom Score	4		**19**		**28**		3	
Cognitive Efficiency Index:	**0.16**		**0.13**		**0.3**		**0.53**	

Figure 3. Sample ImPACT Report

OMM can potentially address musculoskeletal restrictions that may occur due to trauma and treat somatic dysfunctions, which can improve symptoms from concussion. Prior studies have found that OMM has a positive effect on concussion-like symptoms, such as vertigo and imbalance,[5] but there is limited evidence documenting the effects of OMM on post-concussion patients. One retrospective chart review showed improvement of symptoms utilizing Sport Concussion Assessment Tool (SCAT-2) surveys post-OMM on sports-related concussion patients.[6] To date, there have been no randomized control trials published examining the effects of OMM on post-concussion patients.

MATERIALS AND METHODS

DESIGN

- This is a randomized treatment control experimental trial comparing OMM to concussion education
- *IRB:* Approved on November 10, 2015 by the NYIT-IRB: #BHS-1139 and is registered at clinicaltrials.gov (NCT02750566). The authors of this study have no conflict of interest to disclose. No outside funding was used for this research project.

SETTING

- This study was conducted at the NYIT Academic Health Care Center (AHCC)
- *Subject Population*: Concussion patients
- *Inclusion Criteria*:
  - ICD9/10 diagnosis of concussion
  - Subject age between 18 and 50 years
  - Cleared by neurologist/clinician for any life threatening conditions
- *Exclusion Criteria*:
  - History of underlying neurodegenerative condition or spinal cord injury that may confound test results
  - Lost consciousness for greater than 2 minutes in the field as reported by self/witnesses or had seizures, intractable vomiting or paralysis during the trauma

Visit #	Specific Time Points	Intervention/Assessment Tools
Visit 1	Pre-Intervention	ImPACT SCAT-3 Symptom Evaluation
	Intervention (30 minutes)	Group 1: OMM Group 2: Concussion Education
	Post-Intervention	SCAT-3 Symptom Evaluation
Visit 2 (48-72 hours after Visit 1)	Pre-Intervention	ImPACT SCAT-3 Symptom Evaluation
	Intervention (30 minutes)	Group 1: OMM Group 2: Concussion Education
	Post-Intervention	SCAT-3
Visit 3 (1 week after Visit 1)	Follow-up	ImPACT SCAT-3 Symptom Evaluation

Table 1. Study Schedule of Assessments

INTERVENTIONS/OBSERVATIONS

- The enrolled subjects (n=8) were randomized into two groups: OMM as the intervention (n=4), and the controls, receiving concussion education (n=4). All investigators delivering the 30-minute interventions were certified in either Neuromusculoskeletal Medicine/OMM (NMM/OMM) or Family Practice/OMT (FP/OMT).

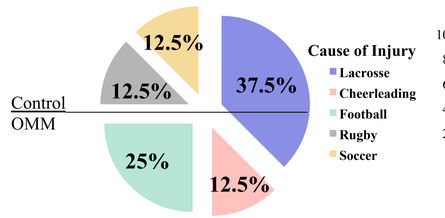


Figure 4a. Demographics: Cause of Injury

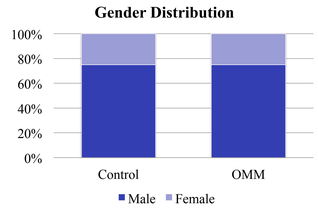


Figure 4b. Demographics: Gender

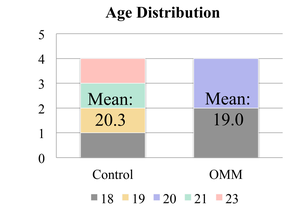


Figure 4c. Demographics: Age

- *Statistical Analysis:* Repeated measures ANOVA and Mann-Whitney U tests on IBM® SPSS® Version 23.0 were used to compare the scores for long term and acute change. For the long term change, the pre-intervention scores for all 3 visits were compared for both of the assessment tool scores. For the acute change, the change between Visit 1 and 2 pre- and post-intervention scores were compared for the SCAT-3 symptom evaluation scores.

Interventions	
Group 1: OMM	• Individualized osteopathic structural examination and treatment (Bolded techniques were applied during all OMM treatment sessions) • Cranial – **occipitoatlantal (OA) decompression, V-Spread, venous sinus drainage, balanced membranous tension (BMT) for strain patterns, cranial lifts, CV4** (*Figure 5*) • Cervical, thoracic, and lumbar spine dysfunctions – treated with techniques including balanced ligamentous tension (BLT), muscle energy techniques (MET), facilitated positional release (FPR), articulatory techniques (ART) (*Figure 6*), high-velocity low-amplitude (HVLA), and counterstrain (CS) • Rib Cage – **thoracic outlet release (TOR)** (*Figure 7*), **diaphragm doming**, rib raising, ART • Sacrum/Pelvis – treated with techniques including BLT (*Figure 8*), MET, FPR, ART, HVLA, and CS
Group 2: Concussion Education	• CDC "What to Expect After a Concussion" (*Figure 9*) • CDC "Facts About Concussion and Brain Injury – Where to Get Help" • American Academy of Family Physicians (AAFP) "Concussion"

Table 2. Study Arms and Interventions

Figure 5. CV4

Figure 6. Thoracic ART

Figure 7. TOR

Figure 8. BLT Pelvis

Figure 9. CDC Article

RESULTS

	Change Between Visit 1 Pre and Post			Change Between Visit 2 Pre and Post			Between-Subject Effects
	Mean (SD)			Mean (SD)			
SCAT-3	**OMM**	**Control**	**P-value**	**OMM**	**Control**	**P-value**	**P-value**
Symptom #	-5.5(4.1)	-0.5(0.6)	0.029*	-3.0(2.2)	-1.0(2.2)	0.340	0.022*
Severity	-12.0(4.5)	-1.0(1.4)	0.029*	-4.3(2.9)	-3.5(5.1)	0.686	0.010*

Table 3. SCAT-3 ("Acute Change" Analysis)

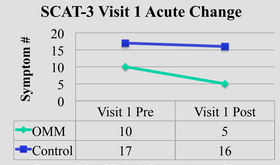


Figure 10a. Visit 1 Symptom # Change

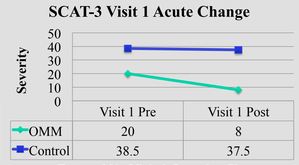


Figure 10b. Visit 1 Severity Change

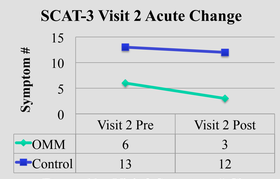


Figure 11a. Visit 2 Symptom # Change

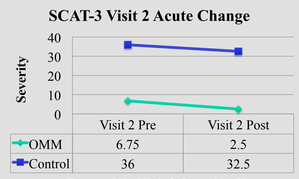


Figure 11b. Visit 2 Severity Change

Statistical significance was set at $\alpha = 0.05$. Long term evaluation using the pre-intervention scores for SCAT-3 and ImPACT did not reach statistical significance. For the acute change, the OMM group showed statistically significant improvements in symptom number and severity in Visit 1 when analyzed with the Mann-Whitney U test (p=0.029, p=0.029), as compared to the control group. The between-subject effects for change in symptom number (p=0.022) and change in symptom severity (p=0.010) were also statistically significant.

CONCLUSION

While the assessment tool scores did not exhibit a statistically significant difference for the long-term analysis, it did show significance when analyzed for acute change. The data obtained from this pilot study demonstrates that there is an improvement after OMM treatment acutely as compared to concussion education.

A limitation to the current project includes the small sample size with only four subjects in each group. The subjects were randomized, but the control group exhibited more severe manifestations of post-concussion symptoms as shown through the mean pre-intervention SCAT-3 and ImPACT scores on Visit 1. As this is a pilot study, further studies should be considered to investigate the application of OMM in improving symptoms in post-concussion subjects.

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