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# Thrust Joint Manipulation to the Cervical Spine in Participants with a Primary Complaint of Temporomandibular Disorder (TMD): A Randomized Clinical Trial

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Thrust Joint Manipulation to the Cervical Spine in Participants with a Primary Complaint of  
Temporomandibular Disorder (TMD): A Randomized Clinical Trial

By:

Breanna Catherine Reynolds

A dissertation submitted in partial fulfillment of the requirements  
for the degree of Doctor of Philosophy

Nova Southeastern University  
College of Health Care Sciences  
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December 2018



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**We hereby certify that this dissertation, submitted by Breanna Reynolds, conforms to acceptable standards and is fully adequate in scope and quality to fulfill the dissertation requirement for the degree of Doctor of Philosophy in Physical Therapy.**

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# Thrust Joint Manipulation to the Cervical Spine in Participants with a Primary Complaint of Temporomandibular Disorder (TMD): A Randomized Clinical Trial

by

Breanna Catherine Reynolds

## Abstract

**Background:** Temporomandibular disorder (TMD) is a common and costly problem often leading to chronic pain. There exists moderate evidence for physical therapy (PT) interventions in the management of TMD. A known relationship between TMD and the cervical spine exists with some evidence to support cervical intervention treatments. Cervical spine thrust joint manipulation (TJM) is an effective PT intervention explored in a limited fashion for this population.

**Objectives:** To determine the immediate and short term (1 and 4 week) effects of cervical TJM on pain, dysfunction, and perception of change in individuals with a primary complaint of TMD.

**Methods:** In this single blind randomized clinical trial, individuals with TMD (n=50) were randomly assigned to receive cervical TJM or sham manipulation in 4 PT visits over 4-weeks. All participants also received behavioral education, a home exercise program, and soft tissue mobilization. Primary outcomes included jaw range of motion (ROM), Numeric Pain Rating Scale (NPRS), TMD Disability Index, Jaw Functional Limitation Scale (JFLS), Tampa Scale of Kinesiophobia (TSK-TMD), and Global Rating of Change (GROC). Self-report and objective measurements (with blinded assessor) were taken at baseline, immediately after baseline treatment, 1-week, and 4-weeks. A 2 x 4 mixed model ANOVA was used with treatment group as the between-subjects factor and time as the within-subjects factor. Separate ANOVAs were performed for dependent variables and the hypothesis of interest was the group by time interaction.

**Results:** Statistically significant 2-way interactions were noted in JFLS ( $p = .026$ ) and TSK-TMD ( $p = .008$ ), favoring the thrust manipulation group. Both groups showed statistically significant main effects in all measures over time. GROC and PASS favored the thrust manipulation group with statistically significant differences in successful outcomes noted immediately after baseline treatment (NNT = 5) and at 4-weeks (NNT = 4).

**Conclusion:** Both groups received identical multi-modal treatments with the addition of the randomized intervention: cervical TJM or sham manipulation. Differences between groups were small, however, improvements favored the TJM on all measures. Cervical TJM may be beneficial in the treatment of TMD.

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## List of Abbreviations

<b>AAOMPT</b> American Academy of Orthopedic Manual Physical Therapy	<b>NDI</b> Neck Disability Index
<b>ANOVA</b> Analysis of variance	<b>NIDCR</b> National Institute of Dental and Craniofacial Research
<b>APTA</b> American Physical Therapy Association	<b>NIH</b> National Institute of Health
<b>AROM</b> Active range of motion	<b>NNT</b> Number needed to treat
<b>BMI</b> Body mass index	<b>NPRS</b> Numeric Pain Rating Scale
<b>BU</b> Bradley University	<b>NSU</b> Nova Southeastern University
<b>CITI</b> Collaborative Institutional Training Initiative	<b>OA</b> Occipitoatlantal (joint)
<b>CN V</b> Cranial nerve five	<b>OPPERA</b> Ororfacial Pain: Prospective Evaluation and Risk Assessment
<b>CONSORT</b> Consolidated Standards of Reporting Trials	<b>OCS</b> Orthopaedic Clinical Specialist
<b>CPR</b> Clinical prediction rule	<b>PA</b> Posterior (to) Anterior
<b>CUSHR</b> Committee on the Use of Human Subjects in Research	<b>PASS</b> Patient Acceptable Symptom State
<b>DC-TMD</b> Diagnostic Criteria-TMD	<b>PEDro</b> Physiotherapy Evidence Database
<b>DI</b> dorsal interosseus	<b>PHQ-2</b> Patient Health Questionnaire-2
<b>DPT</b> Doctorate of Physical Therapy	<b>PI</b> Principal investigator
<b>EMG</b> Electromyography	<b>PPT</b> Pressure pain threshold
<b>FAAOMPT</b> Fellow of the American Academy of Orthopaedic Manual Physical Therapists	<b>PPT-TR</b> Pressure pain threshold temporalis right
<b>FHP</b> Forward head posture	<b>PPT-MR</b> Pressure pain threshold masseter right
<b>GROC</b> Global Rating of Change	<b>PPT-DIR</b> Pressure pain threshold dorsal interosseus right
<b>HA</b> Headache	<b>PPT-TL</b> Pressure pain threshold temporalis left
<b>HEP</b> Home exercise program	<b>PPT-ML</b> Pressure pain threshold masseter left
<b>HVLA</b> High-velocity, low amplitude	<b>PPT-DIL</b> Pressure pain threshold dorsal interosseus left
<b>ICC</b> Intra-class correlation	<b>PT</b> Physical therapy / physical therapist
<b>IFOMPT</b> International Federation of Orthopaedic Manipulative Physical Therapists	<b>R</b> right
<b>IRB</b> Institutional Review Board	<b>RCT</b> Randomized controlled trial
<b>JFLS</b> Jaw Functional Limitation Scale	<b>RDC-TMD</b> Research Diagnostic Criteria for TMD
<b>L</b> left	<b>ROM</b> Range of motion
<b>MC</b> Metacarpal	<b>RVPT</b> Rock Valley Physical Therapy
<b>MCID</b> Minimal clinically important difference	<b>TJM</b> Thrust joint manipulation
<b>MCP</b> Metacarpophalangeal (joint)	<b>TMD</b> Temporomandibular Disorder(s)
<b>MCAR</b> Missing completely at random	<b>TMJ</b> Temporomandibular joint
<b>MDC</b> Minimal detectable change	<b>TSK-TMD</b> Tampa Scale of Kinesiophobia, TMD version
<b>MMO</b> Maximal mouth opening	<b>UE</b> Upper extremity
<b>MSOP</b> Manual of Standard Operating Procedures	<b>UNLV</b> University of Nevada Las Vegas
	<b>VAS</b> Visual analog scale

# Thrust Joint Manipulation to the Cervical Spine in Participants with a Primary Complaint of Temporomandibular Disorder (TMD): A Randomized Clinical Trial

## CHAPTER 1: INTRODUCTION

Chapter 1 will outline pertinent background information and establish a basis of need for the study. Primary aims and hypothesis are explained.

### Background

Orofacial pain refers to heterogeneous conditions contributing to pain in the head, neck or face. Orofacial pain includes headache, temporomandibular disorder (TMD), cancer, autoimmune conditions, burning mouth syndrome, trigeminal neuralgia, and dental pain.<sup>3,4</sup> TMD is the most common diagnosis associated with orofacial pain syndromes,<sup>5</sup> referring to a group of common musculoskeletal conditions<sup>6</sup> present in up to 60% of the population.<sup>7-10</sup> TMD symptoms may include pain in the jaw, head, and neck regions, headaches, periauricular pain, tinnitus, palpable tenderness, joint sounds, limited jaw opening, and loss of function.<sup>7,9</sup>

Only a small percentage of individuals with TMD (5-10%) seek treatment.<sup>6,9</sup> Increased likelihood to seek care is associated with female gender,<sup>11,12</sup> age 20-40,<sup>9,11</sup> and greater intensity of pain.<sup>13</sup> Current conservative treatment for TMD includes the use of dental appliances, medical pharmacological intervention, injection therapy, education, behavioral modification, chiropractic care, and physical therapy (PT).<sup>14,15</sup> Physical therapists who treat TMD acknowledge biomechanical limitations, neurophysiologic input, and the complicated interplay of psychological and social factors in treating pain.<sup>9</sup> Specific PT interventions for TMD have not been well described in the literature, and evidence supporting the effectiveness of these interventions is moderate at best.<sup>16-19</sup> Commonly utilized treatments reported in the literature



include behavioral education, modalities, manual therapy, and exercise for both the masticatory system and the cervical spine.<sup>18</sup>

Manual therapy directed at the jaw, thoracic spine, and cervical spine have been addressed in a limited fashion in the TMD literature. There is a strong correlation ( $r=.82$ ,  $r=.95$ ) between jaw dysfunction and neck disability in persons with chronic TMD.<sup>20,21</sup> While research supporting cervical treatments in the TMD population exists,<sup>16,22,23</sup> further evidence is needed to clarify relationships and expected outcomes. The aim of this randomized clinical trial is to examine the effects of cervical spine thrust joint manipulation (TJM) alongside commonly utilized education, soft tissue mobilization, and exercise in a population with specific pain and dysfunction related to TMD.

### *The Temporomandibular Joint Complex*

The temporomandibular joint is a true synovial joint consisting of 2 bony joint surfaces, a joint capsule, synovial fluid, ligaments, cartilage, and muscles. The joint sits just anterior to the external auditory meatus<sup>24</sup> and is formed between the mandibular condyles and the mandibular fossa of the temporal bone. During movement, the mandibular condyle also comes in contact with the convex articular eminence of the temporal bone. While most synovial joint surfaces are covered in hyaline cartilage, the mandibular condyle is covered primarily in fibrocartilage.<sup>25</sup> An avascular meniscus, or intra-articular disc, made of fibrocartilage fills the space between the two joint surfaces. The temporomandibular disc divides the joint into two functional sections. The upper compartment is a planar joint between the superior disc surface and the mandibular fossa/articular eminence. The inferior compartment is a hinge joint between the inferior surface of the disc and the mandibular condyle.<sup>24</sup> The disc is firmly attached to the mandibular condyle on all sides by ligament (medial and lateral), capsule (anterior), and retrodiscal tissue (posterior).

The posterior retrodiscal tissue is vascularized and highly innervated, potentially creating a nociceptive source for pain in patients with TMD.<sup>26</sup> The primary muscles of mastication are the masseter, temporalis, medial pterygoid, and lateral pterygoid. Secondary muscles include the supra-hyoids, infra-hyoids, and digastrics. These masticatory muscles along with muscles of the cervical spine play a role in both stability and mobility of the temporomandibular joint.<sup>7</sup> The trigeminal nerve (cranial nerve V) supplies sensation to most of the face, and the mandibular branch of the trigeminal nerve innervates the temporomandibular joint and masticatory muscles.

A general understanding of the anatomy of the teeth is necessary in examination of patients with TMD to allow for visual inspection and objective range of motion (ROM) assessment. The incisors are the teeth most centrally located in the mouth with 2 on the top (maxillary incisors) and 2 on the bottom (mandibular incisors). The molars are the most posterior teeth on the right and left sides on both the mandibular and maxillary surfaces. The incisors are used for measurement of ROM of the jaw and the molars for joint mobilization techniques used in treatment of TMD.

Examination of the biomechanics of the temporomandibular joint reveals important considerations in evaluation and treatment of TMD. Opening of the mouth begins with rotation of the lower compartment of the joint followed by anterior translation.<sup>9</sup> Under normal conditions, the disc moves with the mandibular condyle during translation, maintaining a functional relationship in which the center of the disc is in contact with the superior surface of the mandibular condyle.<sup>7</sup> Normal function of the jaw in movement requires simultaneous motion of both the right and left joints. Dysfunction can occur when the disc no longer maintains the functional relationship with the condyle.

## *Temporomandibular Disorders*

TMD refers to conditions, pathologies, or dysfunctions impacting the temporomandibular articular joints, masticatory muscles, and associated musculoskeletal and neurovascular structures.<sup>7</sup> The term TMD, synonymous with craniomandibular disorders and temporomandibular dysfunction, was supported and advocated by the American Dental Association in 1983.<sup>27</sup> Another term, the stomatognathic system, refers to musculoskeletal structures, including innervation and vascularity, relevant to the mouth and jaw.<sup>28</sup> The head, neck, and jaw are referred to as the craniocervicomandibular system. The remainder of this dissertation will focus on pain and dysfunction associated with the stomatognathic system, and therefore, will utilize the term TMD.

Patients with TMD often present with pain in and around the temporomandibular joint or masticatory muscles, impaired ROM, and a change or exacerbation of symptoms with functional activity. Joint noise, earaches, and tinnitus have also been associated with TMD.<sup>9,29</sup> Pain is frequently described as throbbing, tender, or shooting.<sup>30</sup> TMD pain may be related to disc displacement, however, the number of people with true disc displacement is low.<sup>4</sup> Pain may also be related to inflammation, joint or muscle activation, ligament stretch, or other peripheral or central pain mechanisms.<sup>4</sup>

## *Diagnostic Criteria and Classification of Temporomandibular Disorders*

Close to 40% of the general population has at least one sign of TMD.<sup>31</sup> Diagnosis of TMD is generally made via clinical symptom presentation. An initial screening tool has been established by Gonzalez<sup>32</sup> et al, demonstrating high specificity (0.97) and sensitivity (0.99) to identify those with and without TMD See Appendix 7. Internal reliability is excellent with a

coefficient  $\alpha$  of 0.87.<sup>32</sup> The screening tool is recommended for clinical and research use to determine the presence of pain-related TMD and the potential need for treatment.<sup>33</sup> The screen includes inquiry of pain in the last 30 days in the jaw or temple, morning pain or stiffness, and pain that changes with functional movement of the jaw such as chewing hard or tough food.<sup>32</sup> Responses are scored and total scores range from 0-4; a score of 2 or higher yields a positive screen.<sup>32</sup>

TMDs are heterogeneous, and the classification system has changed over time. The Research Diagnostic Criteria for TMD (RDC-TMD) was devised in 1992 to provide order and evidence supporting diagnostic classification; it was later modified and revised. This system utilized a dual axis evaluation system including the pathoanatomical classification (Axis I) and consideration of psychosocial and behavioral factors (Axis II). Revisions to the system ensued, and the most recent classification is the Diagnostic Criteria-TMD (DC-TMD) published in 2010.<sup>34</sup> Both the RDC-TMD and DC-TMD use the 2 axes above and classify TMD patients into the following broad categories: myalgia, arthralgia, disc displacement with reduction, disc displacement without reduction, and subluxation. Distinctions are made to further divide these categories into more specific subcategory diagnoses.<sup>7</sup>

Myalgia refers to pain in muscles impacted by jaw movement and function. Myalgia is the most common category of TMDs, and it is often difficult to distinguish this category from arthralgia. Arthralgia, or joint dysfunction, also refers to pain impacted by jaw movement and function, however, this pain originates in the joint itself. Patients may frequently have both myalgia and arthralgia diagnoses.<sup>35</sup> Disc displacement refers to abnormal biomechanical positioning of the disc. If the disc reduces, a click may be heard or palpated. When the disc no longer reduces, it is referred to as disc displacement without reduction, or closed lock. While

disc displacement can present in different ways, normal disc positioning is not a pre-requisite to reduction in pain or improved function in those with TMD.<sup>36</sup> The DC-TMD added another category called subluxation, referring to hypermobility and potential open lock. In subluxation, the mandibular condyle clicks beyond the convex articular eminence of the temporal bone.<sup>35</sup>

While there is some support for the diagnostic accuracy of special tests in TMD, the ability to distinguish between the categories of myogenic, arthrogenic, and disc displacements is not as strong.<sup>24</sup> The difficulty differentiating various categories of TMD may relate to difficulty classifying all patients in only one category and findings of some patients fitting into no category.<sup>7</sup> Visscher<sup>37</sup> et al found the RDC-TMD to demonstrate high sensitivity and low specificity when examining patients with persistent TMD pain, those with dental pain, and healthy controls. Visscher<sup>37</sup> et al concluded the RDC-TMD was best used to confirm absence of TMD, rather than to rule in the diagnosis. Current study of the validity of the DC-TMD is lacking. Other limitations of the RDC-TMD and DC-TMD include lack of information pertaining to the cervical spine and pain science.<sup>7</sup> The importance of acknowledging the cervical spine is further discussed in this dissertation. Pain neuroscience education refers to a management strategy in chronic pain conditions focused on teaching patients both biology and physiology of pain.<sup>38,39</sup> As acknowledgement of the biopsychosocial model impacts discussions of other pain disorders, and specifically chronic pain syndromes, the importance of broadening diagnostic categories has been recognized.<sup>7</sup>

Imaging is often performed as part of routine evaluation by dental practitioners seeing patients with TMD. Diagnostic imaging is the reference standard for ruling in the joint and disc related pathologies of TMD.<sup>35</sup> As physical therapists have less access to imaging, this limitation adds difficulty integrating the classification system into a PT research or clinical setting.

Understanding normal biomechanical relationships is important, and anatomical changes may be noted in imaging; however, the course of treatment likely remains unchanged.<sup>40</sup> As with other chronic pain conditions, radiographic or image findings demonstrating abnormal positioning of the disc or other anatomical abnormalities are poorly correlated with pain, tenderness, and/or dysfunction.<sup>7</sup> Chantaracherd<sup>41</sup> et al performed a cross-sectional study looking at imaging findings and pain, function, and disability associated with TMD. These authors concluded there was no relationship found between joint status and pain or dysfunction. Stern<sup>42</sup> et al suggest imaging is not actually indicated in all TMD patients.

Both the RDC-TMD and the newer DC-TMD rely heavily on palpatory findings in diagnosis, leaving further debate about the reliability and validity of these diagnostic criteria.<sup>37</sup> The RDC-TMD Consortium is a network of international TMD experts who have worked to make the changes to the original RDC-TMD and continue to meet to discuss the DC-TMD. The Consortium acknowledges the continued lack of specificity with the various diagnostic categories and has made suggestions for continued discussion in a *Next Steps* article published in 2016.<sup>43</sup> At the present time, the lack of reliability and validity of the DC-TMD make it difficult to integrate into research practice.

Some authors have suggested intervention studies utilize a diagnostic classification system to determine the effectiveness of interventions in a subset of individuals with TMD; however, it is possible the interventions may be effective regardless of diagnostic classification. Orhrbach<sup>27</sup> et al acknowledge the DC-TMD focuses on the ‘bio’ of biopsychosocial, and that treatment for chronic TMD may be less dependent on Axis I criteria than previously hypothesized. This study will utilize the cost effective general TMD screen proposed by Gonzalez<sup>32</sup> et al instead of the more specific anatomical diagnoses of the classification systems.

### *Prevalence of Temporomandibular Disorder*

Prevalence of those reporting to a physician for TMD associated symptoms is listed anywhere from 3.9% to 60% of the population.<sup>8,31,44-46</sup> Difficulty classifying or diagnosing this population has led to varying reports of prevalence. In 2013, Okeson<sup>47</sup> et al reported TMD signs and symptoms occurred in 35% or more of the sampled populations. TMD is the third most common chronic pain condition,<sup>40</sup> with an estimated 15% of those with TMD developing chronic pain.<sup>6</sup> Previous reports of cross sectional studies have indicated TMD was more common in women and Caucasians; a negative correlation was found between age and presence of TMD.<sup>48,49</sup> Associative claims made in these cross sectional studies have been challenged with several authors noting a distinction between demographic descriptions of those currently showing signs of TMD and the risk factors of development.<sup>13,50,51</sup>

Beginning in 2006, a large prospective analysis titled *Orofacial Pain: Prospective Evaluation and Risk Assessment*, or OPPERA, began collecting data with National Institute of Health (NIH) funding support. The OPPERA study examined over 3,000 participants without baseline symptoms and approximately 1,000 individuals with chronic symptoms of TMD. Participants were examined at baseline and followed for 2-5 years.<sup>46</sup> Subsequent analysis of this data conducted between 2005 and 2012 is referred to as OPPERA-1 analysis, while data analyzed and reported from 2012-2017 is known as OPPERA-2. There have been over 30 publications reporting results from OPPERA data.

Slade<sup>44</sup> et al reported data from an OPPERA-1 case control analysis, noting 3 times greater risk in women and a positive association with age and chronicity of TMD symptoms. Two years later, in 2013, Slade<sup>50</sup> et al examined data in an OPPERA-2 prospective cohort study, noting approximately equal prevalence of TMD for male and female participants and an average

of 4% of participants with initial onset TMD each year. While previous literature has supported up to 2-4 times greater prevalence in women,<sup>8</sup> this study contradicts those findings. It is possible the previous gender association with TMD was confounded by influences to seek medical care.<sup>51</sup>

Over 33% of the participants without baseline TMD symptoms had 1 or more episodes of facial pain, and this number continued to increase each year of follow-up.<sup>45</sup> An episode of facial pain was defined as 5 or more days per month for 1 month or longer.<sup>45</sup> This number represents a portion of the population with symptoms that did not, or perhaps would not, seek care. Incidence of TMD was highest in individuals in their teens and twenties to early thirties with reduction in incidence in those over the age of 45.<sup>51</sup>

OPPERA results indicate the initial onset of symptoms was twice as likely in African Americans as compared to Caucasians.<sup>45</sup> OPPERA followed the first onset TMD patients noting about half of them still had symptoms 6 months after initial onset.<sup>46</sup> TMD was more likely to persist in women and Caucasians.<sup>46</sup> The results of these studies indicate previous TMD prevalence estimations may have been an indication of those seeking care and those with chronic symptoms rather than actual prevalence of first onset TMD.

#### *Economic Impact of Temporomandibular Disorder*

Pain in the craniofacial region is associated with impaired health status.<sup>52</sup> Chronic TMD, like other chronic pain conditions, can affect quality of life and place an economic burden on society.<sup>40,53</sup> The overall healthcare costs for persons seen at least once for a diagnosis of TMD is 1.6 times higher than that of persons without a TMD diagnosis.<sup>11</sup> Annual healthcare costs associated with TMD are estimated up to \$4 billion.<sup>6,54</sup> Work days lost have been estimated at 17.8 million for every 100 million working adults.<sup>51</sup> In 2016, a review of healthcare costs for



individuals with TMD concluded that consultation was the heaviest financial aspect of care as compared to medication and intervention. The authors hypothesized that individuals with TMD may seek consultation from multiple providers due to persistent symptoms, ineffective treatments, or poor communication and collaboration among dental and medical providers of care.<sup>3</sup> Effective treatment interventions may have an impact on the economic burden of TMD related pain and dysfunction.

### **Statement of the Problem**

Individuals with TMD frequently report first to a dental practitioner,<sup>40</sup> making this profession the most likely referral base to PT. However, dental literature frequently reports lack of quality research supporting the effectiveness of PT in the TMD population.<sup>10,55</sup> PT literature supports manual therapy and exercise (jaw, cervical, and postural) for persons with TMD, but the research is lacking clear description,<sup>56</sup> quality,<sup>18,57</sup> and consistency.<sup>16,17</sup>

The relationship between the cervical spine and TMD has been established, yet treatment interventions directed at the cervical spine have only been examined in a limited fashion. Manual therapy, including cervical non-thrust mobilization, and exercise targeting the cervical spine reduced pain and improved pressure pain thresholds in subjects with TMD.<sup>22,23</sup> Large effect sizes were seen in pain and disability reduction with thoracic spine TJM as part of a multimodal approach in a case series examining participants with myofascial TMD.<sup>58</sup> There is some support for the use of cervical TJM in individuals with TMD; however, previous studies examining cervical TJM utilized a population of children with a history of trauma, subjects with the presence of latent trigger points as opposed to jaw pain or dysfunction, or multimodal intervention plans without randomization of TJM.<sup>16,59</sup> The specific effect of cervical spine TJM on adults with a primary complaint of TMD has yet to be examined.

Further research is needed to support the role of the physical therapist in treatment of individuals with TMD. Understanding the effect of various interventions on pain modulation and functional change can guide informed and evidence-based clinical practice. While cervical spine TJM is only one part of potential intervention packages, a better understanding of the specific effect of this intervention using a randomized design may guide decision making in PT treatments for the TMD population.

### **Specific Aims and Hypothesis**

#### *Specific Aims:*

1. Investigate the effectiveness of cervical spine TJM compared to sham manipulation when combined with behavioral education, soft tissue mobilization, and a home exercise program (HEP) in a well-defined sample of patients with TMD.
2. Investigate immediate response, 1 week, and 4 week outcomes for pain, ROM, fear, and function.

#### *Hypothesis:*

Participants who receive the combined treatment of cervical spine TJM alongside behavioral education, soft tissue mobilization, and a HEP will achieve greater reduction in pain, improved scores on functional outcome measures, greater improvement in ROM, and greater increase in PPT (at all 3 initial data collection points) than those receiving sham manipulation, behavioral education, soft tissue mobilization, and a HEP.

## Relevance and Significance

The NIH and National Institute of Dental and Craniofacial Research (NIDCR) recognize that the TMD population is often left with no clear path to specialists in TMD.<sup>6,54</sup> Physicians may offer pharmacological treatment for pain and frequently refer patients with orofacial pain to dental practitioners with occasional referral to physical therapists. Dentists and physical therapists acknowledge lack of training or knowledge depth specific to this diagnosis in their formal educational programs.<sup>15</sup> Dental practitioners and physical therapists also lack specialists in TMD.<sup>60</sup> In the United States, patients with jaw pain may encounter practitioners without experience or confidence in treating their condition, possibly influencing access to care and outcomes. Barriers to PT treatment may include limited access to clinicians who are comfortable treating individuals with TMD and insufficient evidence of PT effectiveness.

Brown<sup>61</sup> et al reported persons with TMD do not spontaneously recover without treatment intervention. Successful treatment can be defined by return to normal function and reduction in pain.<sup>62</sup> While current evidence is insufficient, manual PT, exercise, and education have demonstrated effectiveness in the successful treatment of TMD.<sup>18,22,23,58,63</sup> A systematic review of manual therapy for TMD reported moderate to high evidence to support manual intervention in reducing pain, increasing pressure pain threshold (PPT), and improving maximal mouth opening (MMO).<sup>64</sup> A subsequent systematic review with meta-analysis reported similar findings for effectiveness of manual therapy approaches.<sup>16</sup> Fair evidence supporting multimodal intervention for TMD was supported in a systematic review by Brantingham<sup>65</sup> et al in 2013.

Cervical spine TJM is a manual therapy intervention utilized by physical therapists since the 1920s, and part of standard PT practice.<sup>66</sup> Cervical TJM has been used in multimodal intervention studies addressing treatment for TMD.<sup>16,59</sup> Biomechanical and neurophysiological

relationships between the cervical spine and temporomandibular joint support the potential benefit of cervical spine TJM on TMD related pain and dysfunction. Evidence supporting cervical spine non-thrust mobilizations demonstrated effectiveness in treatment of TMD.<sup>22,23</sup> Evidence supporting the use of TJM of cervical and thoracic spine is available but limited.<sup>67</sup> Atlanto-occipital TJM produced immediate improvement in mouth opening ROM and PPT in a population of women with neck pain,<sup>68</sup> and a population of individuals with latent myofascial trigger points in muscles of mastication.<sup>69</sup> A 2016 case report noted cervicothoracic TJM combined with exercise and education had positive outcomes in a patient with primary complaint of TMD.<sup>67</sup>

Research and clinical practice guidelines promote use of cervical spine TJM for various conditions including neck and upper extremity pain and dysfunction.<sup>63,70</sup> There is growing support for a neurophysiological effect of spinal TJM with changes seen in pain inhibition, muscle recruitment, and/or function.<sup>22</sup> The effect of spinal TJM on remote locations has demonstrated both local and remote effects.<sup>71,72</sup> Previous research using cervical TJM for the TMD population has been unable to clarify the specific impact of this intervention. Evidence to support TJM of the cervical spine may lead to consideration of this potentially useful intervention in treatment of individuals with TMD. Implementation of effective treatments may have an impact on patient outcomes and/or progression to chronicity for the underserved TMD population. Further research is needed to examine cervical spine TJM on individuals with TMD using a randomized design.

### **Scope of Investigation**

While previous studies provide sufficient evidence to support the hypothesis of interest, there is a need to produce high quality evidence for the effectiveness of TJM of the cervical

spine in individuals with TMD.<sup>17,18</sup> This study included 4 visits over 4 weeks with measurements taken at baseline, immediately after first treatment, 1 week, and 4 week follow-ups. The design randomized cervical TJM and sham manipulation, and utilized a specified population of those with a primary complaint of TMD.

Participants for this study had a primary complaint of TMD and were recruited from the general public, dental offices, and PT clinics. Physical therapists with post professional training in cervical TJM and experience with the TMD population were the treating clinicians. Blinded assessors measured outcomes of interest. Self-report scales were used at all data collection points. All clinicians and blinded assessors were trained by the principal investigator (PI) in standard operating procedures.

Participants completed a standardized evaluation before intervention. Participants were randomly assigned to 1 of 2 groups and blinded to group allocation. Treatments took place at the initial visit, week 1 and week 2. One group received cervical spine TJM while the other group received sham manipulation. All participants received standardized behavioral education, soft tissue mobilization of the suboccipital region, and home exercise instruction. The final 4-week visit included measurement only, and the therapist could continue treatment, discharge, or refer out at their discretion. The randomized design and standardized procedures were necessary to examine the specific effect of cervical spine TJM in the TMD population; the TJM effect was the primary focus of this study.

### **Definition of Terms Used in this Dissertation**

1. Bruxism: Repetitive clenching and grinding of the teeth, could be nocturnal or diurnal<sup>4</sup>

2. Central Sensitization: A prolonged increase in excitability of neurons in central pathways; over-activity of descending pain facilitation, hypersensitivity, and impaired function of descending inhibitory pathways<sup>73</sup>
3. Craniomandibular: The head, cervical spine, temporomandibular joints, and surrounding soft tissues, vasculature, and nerve structures<sup>4</sup>
4. Manual Therapy: Any hands-on treatment provided by the PT including joint non-thrust joint mobilization (NTJM), thrust joint manipulation (TJM), soft tissue treatments, passive muscle stretching or joint movement, or manual resistance activity<sup>74</sup>
5. Masticatory Muscles: Muscles used for mastication, or chewing food<sup>4</sup> including the masseter, temporalis, medial pterygoid, and lateral pterygoid
6. Non-thrust Joint Mobilization (NTJM): Manual therapy technique utilizing skilled passive movement of a joint at varying speeds and amplitudes, excluding thrust joint manipulation, intended to improve motion or reduce pain, or optimize function<sup>74</sup>
7. Occlusal Therapy: Dental intervention designed to normalize occlusion and teeth contact, this may include reversible or irreversible treatments<sup>4</sup>
8. Occlusion: Static relationship between the surfaces of the mandibular and maxillary teeth upon closure<sup>4</sup>
9. Orofacial: Related to the mouth and face<sup>4</sup>
10. Parafunction: Nonfunctional activities of the orofacial region including nail biting, clenching the teeth, bruxism, chewing on the lips, cheeks, or other inanimate objects<sup>4</sup>
11. Regional Interdependence: A concept describing impairments that are directly or indirectly related to other impairments, including musculoskeletal impairments and peripheral or central nervous system impairments<sup>75</sup>

12. Stomatognathic: Related to the mouth (“Stoma”) and jaw (“Gnathic”)<sup>4</sup>
13. Stomatognathic System: A functional unit including the teeth, maxilla, mandible, temporomandibular joints, masticatory muscles,<sup>4</sup> vascular and nerve structures<sup>28</sup>
14. Temporomandibular Disorders (TMD): Broad and heterogeneous diagnosis category of orofacial pain related to temporomandibular joint, masticatory muscles, or both;<sup>4</sup> also known as craniomandibular disorders
15. Thrust Joint Manipulation (TJM): Manual therapy technique utilizing skilled passive high-velocity, short-amplitude movement of the joint intended to improve motion, reduce pain, or optimize function<sup>74</sup>
16. Tinnitus: Subjective complaint of ringing or buzzing in the ear<sup>4</sup>
17. Trigeminal Nerve: Mixed sensory and motor cranial nerve V with 3 branches: ophthalmic, maxillary, and mandibular<sup>4</sup>
18. Trigeminal Nucleus: One of the nuclei of the trigeminal nerve that consists of shared grey matter between the trigeminal nerve and the upper cervical nerve roots. This nucleus contains 3 subnuclei<sup>4</sup>

### Summary

TMD is a common and costly problem often leading to chronic pain and dysfunction. Diagnosis of TMD is generally based on clinical findings. While diagnostic criteria exist, their high sensitivity values demonstrate greatest value in ruling out the condition. A general screening tool is less able to differentiate types of TMD, but better at ruling the diagnosis in from a general perspective.

There is evidence to support a relationship between neck pain or dysfunction and TMD. Further evidence supports cervical spine intervention in this population. Cervical spine TJM has

not been examined specifically in a TMD population using a strong randomized design. Further evidence to support effectiveness of specific PT interventions could describe the potential benefit in minimizing pain and dysfunction in the underserved TMD population. Individuals with TMD may not seek treatment or know what treatment options exist. Evidence to support effective interventions may contribute to earlier access to care, improved interdisciplinary collaboration, and improved outcomes related to pain and function.



## **CHAPTER 2: HISTORICAL OVERVIEW: Theory and Research Literature Specific to the Topic**

### **Introduction**

Chapter 2 describes historical and current literature surrounding intervention specific to temporomandibular disorder (TMD) from a dental and physical therapy (PT) perspective. The relationship between the cervical spine and TMD is discussed. Current evidence of cervical spine intervention for the TMD population as well as the theory to support manual cervical spine thrust joint manipulation (TJM) will be covered. A focus on intervention options, effectiveness, and safety are described and used to support the relevance and significance of the study.

### **TMD Interventions**

Individuals with TMD are primarily treated with medication, dental splint therapy, PT, orthodontic care, and counseling.<sup>19</sup> Surgical intervention is an option, but less frequently utilized. Evaluation and treatment are primarily performed by physical therapists (PTs) and dentists;<sup>7</sup> however, patients frequently present with symptoms of TMD to their dentist first.<sup>35</sup> Among dental professions, there is variation in education, implementation of evaluation and treatment procedures, and consistency of orofacial pain management.<sup>40,76</sup> Similar variation in educational preparation, experience, and confidence treating TMD exists for PTs. Available evidence supporting various PT interventions is sparse. The following sections in this chapter will summarize peer reviewed dental and PT intervention use and effectiveness before moving focus to cervical spine TJM, the specific intervention of interest in this study.

## Dental Intervention

Dentists treat based on an assumed relationship between the contact of teeth, or occlusion, and TMD. Dental intervention for TMD primarily includes use of medications, injections, and splint therapy. These interventions are generally considered to be conservative and reversible therapies and are preferred to irreversible interventions like surgery, occlusal adjustments, or long duration repositioning devices.<sup>77</sup> Occlusal splinting is removable and therefore considered reversible; however, there is controversy related to the effectiveness of occlusal splinting for the TMD population.<sup>78-80</sup> Occlusal adjustments are considered irreversible therapies and have not been shown to prevent or improve symptoms of TMD.<sup>81</sup>

Intra-oral splinting is the most commonly utilized conservative intervention for TMD<sup>82</sup> and has alternative names including intra-oral device, intra-oral appliance, occlusal stabilization, occlusal appliance, and splint therapy. There are several types of splints used in clinical practice, with stabilization, anterior repositioning, and anterior bite appliances utilized most frequently.<sup>79</sup> A stabilization splint focuses on ideal occlusion, or symmetry in occlusion.<sup>40</sup> The theory suggests optimal positioning of occlusion improves jaw position resulting in the least muscular strain,<sup>79</sup> equal distribution of load, proprioceptive improvement,<sup>83</sup> and reduction of pain.<sup>84</sup> It is also possible a placebo effect plays a role in efficacy.<sup>83</sup> These splints can be hard or soft and applied to either the maxillary or mandibular arches. Anterior repositioning appliances are used to move the mandible and mandibular condyle anteriorly to align the condyle and disc closer to anatomical position (centric position) and minimize compression of the highly vascular posterior retrodiscal tissue;<sup>40</sup> however, some patients have reported an increase in pain with the anterior repositioning appliance.<sup>84</sup>

Most splints are custom-made to fit individual patients and are adjusted over time for proper fit. Splints are removable and generally worn at night with occasional suggestion for daytime use. A systematic review by Al-Ani<sup>80</sup> et al in 2005 suggested evidence was insufficient to support stabilization splinting was superior to other active treatments (including non-occluding splints, acupuncture, biofeedback, exercise and relaxation). These authors, however, stated splinting may be more effective than no treatment in reducing pain.<sup>80</sup> In 2009, Thurman<sup>83</sup> et al performed a systematic review of randomized controlled trials reporting the same conclusions as Al-Ani<sup>80</sup> et al; occlusal splints were superior to no treatment but no statistically significant difference was noted between occlusal splinting and other therapies.<sup>83</sup> In 2010, Friction<sup>79</sup> et al reported evidence was mixed, however, a meta-analysis supported the use of splinting over no intervention. List<sup>77</sup> et al published a review of systematic reviews in 2010 concluding there was no evidence to support occlusal adjustments but some evidence to support occlusal appliances, exercise, postural training, and medication use.

While occlusal splinting is generally seen as a conservative and reversible intervention, there is some evidence that this intervention can cause irreversible change in occlusion.<sup>85</sup> The evidence of a causal relationship between occlusal splinting and subsequent occlusal change is debated; however, there is potential need for future dental work or orthodontics in the event of occlusal change. Therefore, other truly conservative and reversible interventions, like PT, should be considered as a first-step intervention. Reid<sup>86</sup> et al reported dentists have an ethical obligation to explore conservative management of TMD in an exhaustive fashion before resorting to more invasive interventions like occlusion adjustments, orthodontics, or mandibular repositioning procedures. Surgical, invasive, and irreversible intervention should be reserved for cases in which conservative management is ineffective.<sup>40,84,87</sup> While many dentists are working together

with physical therapists, the interdisciplinary collaboration or consideration of PT first is inconsistent.<sup>88</sup> Kraus suggests improved outcomes are more likely when the patient receives PT intervention prior to or in conjunction with use of an occlusal splint.<sup>36</sup>

### **Physical Therapy Intervention**

The American Academy of Craniomandibular Disorders and the American Academy of Orofacial Pain support PT evaluation and treatment for the TMD population. From a broad perspective, PT intervention for TMD is similar to that of other joints or chronic pain conditions: manage pain, improve ROM and joint mobility, address deficits in strength, flexibility, and neuromotor control, and ultimately improve function. There is some evidence to suggest PT exercise, relaxation, and biofeedback are more effective than occlusal splints at decreasing pain and increasing mouth opening ROM.<sup>57,89</sup> Friction<sup>79</sup> et al report that most cases of TMD can be treated with self-care, exercise, and PT interventions, even suggesting these be done before an appliance is issued, or in combination with an appliance.

Research has compared PT to occlusal splint therapy, however, many reports in dental journals neglect to define the PT intervention, or describe PT as a modality-only intervention.<sup>90</sup> While some individual studies have suggested PT intervention did not improve outcomes over a control,<sup>91,92</sup> evidence from systematic reviews and meta-analyses do suggest PT intervention also produces better outcomes than no treatment.<sup>18,57</sup> Paco<sup>19</sup> et al performed a systematic review and meta-analysis published in 2016 examining PT intervention effectiveness for the outcomes of pain and jaw ROM. Authors only examined randomized controlled trials and utilized standardized mean difference to compare effectiveness. Methodological quality was assessed with the PEDro scale (physiotherapy evidence database) and revealed scores of 5-10/11. Six of the 7 articles included had strong quality ratings (score higher than 7).<sup>19</sup> Results demonstrated

statistically significant differences for pain reduction at rest with PT versus controls. Although authors found no statistically significant changes in active motion of the jaw, the trend favored PT intervention versus control.

It should be noted that modalities are frequently mentioned as potential treatment options for PT. Six studies looking at electrophysical modalities were examined in a 2006 systematic review. This review concluded there is was no evidence to support use of these modalities to reduce TMD pain; however, there was some support for the use of low level laser and biofeedback training in improving mouth opening ROM.<sup>18</sup> Another systematic review with meta-analysis in 2006 reported some evidence supporting biofeedback and laser, but no evidence to support ultrasound. In 2010 a systematic review of systematic reviews reported no reviews indicate modalities were effective in reducing pain.<sup>77</sup> Frequently, reports of PT utilization in dental studies describe modality-only intervention. It is important for researchers and clinicians to remind medical professionals and the general public that the ‘modality-only’ view of physical therapy is quite limited.<sup>36</sup> The results of these studies may also incorrectly undermine the value of PT intervention.

Multimodal intervention combinations may produce greater and longer lasting improvement in pain, function, and quality of life than isolated interventions.<sup>93</sup> Fair evidence supporting multimodal intervention for TMD was supported in a systematic review by Medlicott in 2006<sup>57</sup> and by Brantingham<sup>65</sup> et al in 2013. The proposed study will utilize manual therapy including soft tissue mobilization of the suboccipital musculature and cervical spine TJM, therapeutic exercise, and education including behavioral modification.

## *Manual Therapy*

Manual therapy involves hands-on, skilled intervention provided by a physical therapist in the treatment of pain and restricted movement. This may include soft tissue intervention, passive movements or movements against resistance of the therapist, and non-thrust joint mobilization or TJM.<sup>36</sup> Manual therapy interventions are used to inhibit pain via facilitation of descending inhibitory pathways and/or improve ROM.<sup>94</sup> Manual therapy reported in the treatment of TMD includes intervention directed at the temporomandibular joint, masticatory muscles, cervical spine, and cervical musculature.<sup>64</sup> The systematic reviews and meta-analyses mentioned here include multiple types of manual therapy; specific examination of cervical manual therapy will be discussed in a subsequent section.

A review of literature by Kalamir<sup>95</sup> et al (2007) found 8 randomized controlled trials (RCTs) worthy of inclusion in examination of the effects of manual therapy on TMD. While authors do not report on the validity of the assessments used to determine inclusion, they do draw conclusions based on these 8 RCTs. Kalamir<sup>95</sup> et al report their review suggests manual therapy is a reasonable treatment option and more cost effective than dental intervention. Another review of 27 articles in 2011 suggested evidence did support improvements in pain, motion, and function related to manual therapy for TMD. These authors acknowledged the use of terms manual therapy, TJM, and mobilization were difficult to differentiate, and suggested future study of individual manual techniques.<sup>96</sup>

A systematic review published by Brantingham<sup>65</sup> et al in 2013 reported level b evidence (defined as limited) suggesting manual therapy was helpful in 3-6 month short-term follow-ups. In 2015, Calixtre<sup>64</sup> et al examined the specific and isolated effects of manual therapy for TMD in a systematic review of RCTs. These authors report moderate to high evidence to support the use

of manual therapy techniques for TMD in reducing pain while increasing pressure pain threshold (PPT) and maximal mouth opening (MMO).<sup>64</sup> Martins<sup>16</sup> et al performed a meta-analysis comparing manual therapy to other active interventions. Authors report overall level b evidence supporting manual therapy (including TJM) for short term treatment of TMD noting statistical support for manual therapy in decreasing pain and increasing active ROM for mouth opening.<sup>16</sup>

Armijo-Olivo<sup>17</sup> et al performed a systematic review with meta-analysis (2016) examining both manual therapy and jaw exercise. Meta-analysis supported manual therapy with jaw exercises for improvement in jaw ROM and pain reduction. The combined treatment was superior to splint use, self-care, and medication with a moderate effect size reported.<sup>17</sup> However, in this same study, pooled results showed exercise alone did not demonstrate the same statistical superiority or effect over splint use, acupuncture, or other active treatments. Authors suggested manual therapy was needed in addition to exercise, and concluded that while results of manual therapy effectiveness were mixed, the data was ‘promising’.<sup>17</sup>

### *Soft Tissue Mobilization*

Manual soft tissue mobilization of masticatory and cervical musculature has been utilized clinically and reported in TMD literature. Several authors support the use of soft tissue mobilization in muscles of mastication over no treatment at all,<sup>97</sup> and suggest results are equivalent to occlusal splints.<sup>98</sup> Heredia-Rizo suggests the use of myofascial techniques are superior to sham or placebo intervention with placement of hands on the temporomandibular joints without pressure. In this study, participants who received the manual intervention had notable improvement in mouth opening and PPT reduction, however, the difference between groups was not statistically significant.<sup>99</sup> Kalamir<sup>100</sup> et al randomized TMD participants into 1 of 2 groups: 1) intra-oral myofascial work or 2) education, self-care, and exercise. Pain reduction

was greater in the intra-oral myofascial group; however, even though the difference was statistically significant, it was not clinically significant (change of  $\leq 2$  on Numeric Pain Rating Scale (NPRS)). There was no difference between groups for mouth opening ROM.<sup>100</sup>

Oliveira-Campelo<sup>69</sup> et al randomized 122 volunteers with the presence of latent trigger points to 1 of 3 groups: 1) suboccipital soft tissue mobilization, 2) atlanto-occipital TJM, or 3) no intervention (control). While immediate results favored the manipulation group, both treatment groups demonstrated statistically significant improvement in mouth opening and PPT of the temporalis, indicating cervical suboccipital soft tissue mobilization may be helpful in reducing TMD related pain.

This study utilized soft tissue intervention only at the cervical spine. While soft tissue mobilization of masticatory musculature is supported in the literature and utilized in clinical practice, the focus of this intervention study is an examination of cervical spine TJM. Kalamir<sup>100</sup> et al suggested education and exercise can provide clinically equivalent results to intra-oral soft tissue mobilization; therefore, there is no reason to believe participants in this study will be undertreated or receive sub-standard care. It is common clinical practice to utilize soft tissue mobilization to the cervical spine before application of TJM, and evidence supports the potential benefit to the TMD population. A case series performed by the principal investigator (PI) prior to this dissertation did not include soft tissue mobilization, leading to the decision to include it in order to provide a more pragmatic approach.

### *Behavioral Modification*

Behavioral modification education is frequently part of pain management interventions. Specific to TMD, behavioral modification has shown comparable results to intra-oral



appliances.<sup>101</sup> Suggestions include improving sleep and diet, avoiding caffeine, minimizing stress, relaxation techniques, and avoiding parafunctional habits. Parafunctional habits are movements of the jaw that are not necessary for normal function;<sup>9</sup> these habits include gum chewing, awake clenching and grinding, biting the tongue or cheeks, holding the jaw forward in protrusion, biting fingernails, and smoking.<sup>9,102,103</sup>

Bruxism, or grinding of the teeth, has been emphasized in TMD evaluation and treatment; however, there is no indication bruxism causes TMD. Bruxism can occur at night or during wake hours. Control of wake time bruxism should be emphasized in educational training. Sleep bruxism may require a dentist to evaluate the wear patterns of the teeth and determine need for an oral appliance to protect the teeth. OPPERA results demonstrated tooth wear or clinician notation of joint noises were not predictors of TMD first onset,<sup>46</sup> and as noted previously, the use of the oral appliance to control bruxism has mixed results regarding symptom relief of TMD.<sup>78-80</sup>

Other behavioral modifications include emphasizing chewing softer foods, avoiding wide open mouth positions such as biting a large sandwich or apple, and avoiding chewing only on one side.<sup>14</sup> Patients with pain at end range of opening or hypermobility in opening should be taught to place the tongue on the roof of their mouth during yawning to control the degree of opening.<sup>14</sup> General education related to behavioral change includes making the patient aware of the habits or behaviors and encouraging reduction in frequency or abolishment. This approach was utilized in the study.

Jaw exercises are the most commonly reported interventions for TMD after patient education and intra-oral appliances.<sup>77</sup> The use of oral and postural exercises for TMD is supported in the literature and considered to be a safe and cost-effective conservative intervention.<sup>56</sup> The Rocabado 6x6 is the most commonly reported exercise intervention,<sup>14,104</sup> but other exercises have been evaluated.<sup>105</sup> Therapeutic exercise including jaw, cervical, and postural exercise is supported for the TMD population,<sup>56,106</sup> however, evidence is lacking support for superiority of any specific exercise. Most research utilizing exercise includes multimodal approaches making it difficult to discern the specific impact of exercise.

A systematic review by McNeely<sup>18</sup> et al in 2006 reports there is evidence to support exercise in reducing TMD-related pain and dysfunction. However, this review was based on 4 studies, and each study was given a weak quality rating by the authors. Medlicott's systematic review in 2006 suggested active exercise of the jaw and postural training were supported in the literature.<sup>57</sup> The previously mentioned systematic review and meta-analysis by Paco<sup>19</sup> et al in 2016 informs readers that the exercise mentioned in some studies could represent any exercise suggested to the patient, even by non- PT providers. The lack of consistency led these authors to only include studies in their analysis if they used physical therapists. Again, results of this study suggested PT intervention was superior to control for pain reduction, but unclear for mouth opening. The 2016 Armijo-Olivo<sup>17</sup> et al meta-analysis supports the use of exercise (jaw, postural, cervical) in the treatment of TMD. These authors showed statistically significant change in mouth opening and subjective reports of less interruption of daily life in TMD patients treated with postural education versus controls.<sup>17</sup>

This project utilized a combination of the Rocabado 6x6, postural exercise, and cervical exercise in a standardized fashion for all participants.

### **Relationship Between Cervical Spine and Temporomandibular Disorder**

Regional interdependence refers to the biomechanical and neurophysiological relationship between various joints and pain responses attempting to explain why impairments at one region may contribute to pain in another region.<sup>75,107,108</sup> Multiple authors have used the concept of regional interdependence as a theoretical basis for evaluation and treatment of the cervical and thoracic spine in TMD patients.<sup>67,75,107,109</sup> The biomechanical and neurophysiological relationship between the cervical spine and TMD is recognized. While the original definition of regional interdependence indicated these relationships existed for ‘seemingly unrelated’<sup>75</sup> locations, a newer perspective suggests the area of primary pain complaint ‘may be directly or indirectly related or influenced by impairments from various body regions and systems regardless of proximity to the primary symptom(s).’<sup>75</sup>

Patients with TMD often have neck pain complaints and some neck pain patients have findings of TMD related impairment. Several authors have reported on the prevalence of cervical spine pain in TMD patients.<sup>22,52,110</sup> Okeson<sup>8</sup> et al examined 357 patients with TMD and found 43.7% of subjects cited coexisting cervical myofascial type pain. In an examination of 511 patients with TMD, 68% reported neck pain.<sup>15</sup> There is also a strong correlation between jaw dysfunction and neck disability in persons with chronic TMD;<sup>20,21</sup> Orofacial Pain: Prospective Evaluation and Risk Assessment (OPPERA) results demonstrate high correlation between muscle pain of the neck and shoulder and both acute and chronic TMD pain.<sup>5</sup> Armijo-Olivo reported a strong positive correlation of  $r = 0.82$  between neck disability and jaw

disability.<sup>111</sup> Bevilacqua-Grossi<sup>112</sup> et al examined 100 women with TMD, noting increases in TMD pain were associated with increases in cervical pain.

Armijo-Olivo found reduced cervical spine flexion and extension muscle endurance (although not statistically significant) in persons with TMD compared to healthy subjects.<sup>111</sup> Grondin et al examined 12 patients with TMD in a 2017 case series and treated each based on individual impairments. In this case series, all patients had a positive cervical flexion rotation test, indicating limited motion of the upper cervical spine in rotation. By the end of the 4-week study, only 50% had a positive test. Neck pain with cervical motion was present in over 58% of patients at the beginning of this study and less than 17% of patients at the conclusion. Authors use this information to provide support to the relationship between neck pain and TMD.<sup>113</sup>

Although less frequent than reports of cervical pain with TMD impairment, presence of TMD pain in individuals with a primary complaint of cervical pain has been reported.<sup>110</sup> Cervical spine disorders can exacerbate or contribute to orofacial pain complaints.<sup>47,114</sup> Ferão<sup>115</sup> et al examined patients seen in PT for neck pain, noting up to 90% of those patients had TMD symptoms. Von Piekartz<sup>116,117</sup> et al added soft tissue mobilization to the orofacial masticatory muscles to cervical spine manual therapy in a population of individuals with neck pain and cervicogenic headache. This group was compared to a group that only received the cervical intervention. Authors found statistically significant changes in headache intensity, neck function, cervical ROM, and manual mobility assessment of the C0-3 in the group that added orofacial muscle treatment.<sup>116,117</sup> The trend of improvement in the combined intervention group was maintained at 6 months. While the emphasis of this dissertation was cervical spine intervention for individuals with TMD, it is interesting to note that the relationship may work the other way as well.

The association of jaw and neck pain and dysfunction is well documented. Regional interdependence concepts utilize biomechanical and neurophysiological (including central sensitization) theories to explain these relationships. From a perspective of regional interdependence, the relationship between areas of pain is important in both diagnosis and treatment. It is possible that treatment of a location outside the primary area of pain can provide clinically meaningful change in the primary location of pain.<sup>75</sup>

### *Biomechanical Relationships*

A biomechanical relationship exists between the cervical spine and TMD. Jaw opening is the primary functional movement at the temporomandibular joint, and this motion occurs with upper cervical extension while closing is coupled with cervical flexion.<sup>118,119</sup> Greater cervical motion occurs during jaw opening than jaw closing.<sup>118</sup> Immobilization of the head and neck will decrease available ROM and muscle activity at the temporomandibular joint.<sup>120</sup> Masticatory and cervical muscles contract together during activities like chewing and talking.<sup>36</sup> Kraus suggests cervical muscle contractions occurring during daily activity or higher load functional activity may lead to increased frequency or intensity of simultaneous masticatory muscle contraction.<sup>36</sup>

Between 50-90 % of individuals with TMD have limited motion of the upper cervical spine (C0-C3), as compared to 16-46% of healthy controls.<sup>121</sup> Grondin<sup>122</sup> et al found significant limitation in the cervical flexion rotation test in individuals with TMD compared to healthy controls; however, no significant difference was noted with flexion/extension ROM.

A correlation between TMD and postural change is supported.<sup>28,123</sup> Forward head posture (FHP) may contribute to neck pain, shortness of the suboccipital musculature, cervical ROM, cervical muscle activation, and headaches.<sup>99,124,125</sup> FHP may contribute to TMD related

symptoms, however causal relationships have not been supported.<sup>126</sup> Both PPT and mouth opening are different in various cervical postures. Greater opening was seen in FHP than neutral posture,<sup>2</sup> possibly related to coupled cervical extension. PPT was highest in the neutral position and lowest in the FHP.<sup>2</sup> From a biomechanical perspective, the FHP elongates the hyoid musculature, which is responsible for depression of the mandible. This tension may draw the mandible inferiorly requiring over-activity of the elevators of the jaw (temporalis, masseter, medial pterygoid). FHP also contributes to alteration in the resting position of the mandible, leading to posterior movement of the mandibular condyle and potential compressive forces on the highly vascularized and innervated retrodiscal tissue.<sup>67,127</sup> The altered mandibular position could also impact occlusion or tooth contact.<sup>15,28,128,129</sup>

OPPERA analysis of first onset TMD showed cervical tenderness to palpation was a risk factor in the development of TMD.<sup>130</sup> Masticatory and cervical spine trigger points (both active and latent) are found in higher frequency and larger areas in individuals with TMD as compared to healthy controls.<sup>131</sup> PPT, an objective measure of tenderness, was reduced in masticatory muscles as well as cervical spine joints and musculature in patients with chronic neck pain who did not have TMD.<sup>132</sup> PPT was also lower in masticatory muscles, C5-C6 facet joints, and tibialis anterior in patients with TMD without associated comorbidities, demonstrating widespread sensitivity.<sup>133</sup> Individuals with widespread pain in the cervical spine or regions outside of the temporomandibular joint itself may be less likely to experience the same degree of improvement as those with localized TMD.<sup>134</sup>

### *Neurophysiological Relationships and the Trigeminal System*

The trigeminal nerve, or cranial nerve five (CN V), innervates the temporomandibular joint and is responsible for sensation to the face and masticatory muscle activation. The

trigeminal nerve has 3 branches innervating most of the head and face. From superior to inferior, the divisions are the ophthalmic, maxillary, and mandibular branches. The trigeminal nerve is mixed, providing both sensory and motor information. The mandibular division of CN V innervates the masticatory muscles, tensor veli palatine, and tensor tympani. A branch off the mandibular division, the auriculotemporal nerve, innervates the temporomandibular joint.<sup>4</sup> The trigeminal sensory nucleus begins in the midbrain and ends in the dorsal horn of the cervical spinal cord. The trigeminal nucleus projects inferiorly converging with grey matter and nerve cell bodies of the upper cervical spine (C1-3) in what is known as the trigeminocervical nucleus.<sup>15,135</sup> Afferent input from the trigeminal nerve branches, cranial nerves VII, IX, and X, and the upper cervical spine (C1 to C3 or C4) converge onto the trigeminal nucleus suggesting the nucleus processes nociception from each of these areas in one shared location.<sup>113,136,137</sup> These upper cervical nerves form the cervical plexus, which innervates the suboccipital region, posterior head and neck, upper cervical facet joints, cervical multifidi and other musculature, superior shoulder, and upper thoracic region.<sup>4,36</sup> The presence of active and latent trigger points in the neck and shoulder in patients with TMD was used to support the concept of afferent fiber convergence from the jaw and neck.<sup>131</sup>

The body processes sensory information in a relay style system. The first order nociceptive neurons send an impulse from the skin or musculoskeletal nociceptors of structures innervated by cranial nerves V (trigeminal), VII (facial), IX (glossopharyngeal), and X (Vagus), or C1-3. This impulse travels to the dorsal horn of the spinal cord, trigeminal nucleus, or brain stem and meets the second order neurons located in the trigeminal nucleus. At this location, the afferent input converges as it is then sent to the third order neuron in the thalamus, terminating in the primary somatosensory cortex. The brain will receive sensory input (pain or temperature)

and subsequently interpret the input to determine response.<sup>4</sup> While examined around the intent to understand cluster and migraine headaches, Bartsch and Goadsby examined second-order neuron responses when noxious stimulation was applied to trigeminal afferents. This study, along with an examination of trigger points and headache, showed changes in cervical and trigeminal systems with increased sensitization of the second-order neurons extending through C3.<sup>137,138</sup> The convergence of afferent inputs of the upper cervical spine and the trigeminal nerve in the shared grey matter of the trigeminocervical nucleus may explain why stimulation of affected tissues could result in pain perceived in a distant location. The increased sensitization shown in the Bartsch and Goadsby work may also describe a process of central sensitization, leading to increased excitability or responsiveness to stimulation.<sup>26,137</sup> This theory implies pain in the neck or jaw region does not necessarily indicate pathology in that specific location. The convergence mechanism is an example of the neurophysiological relationship between the cervical spine and TMD.

There is evidence to suggest neurophysiological change occurs in individuals with TMD. An examination of heat and cold pain thresholds in women with myofascial TMD demonstrated thermal hyperalgesia at the masseter and frontalis as well as an extra-trigeminal region at the wrist. The temperature pain thresholds were statistically different from that of healthy controls in each region.<sup>139</sup> The changes in temperature thresholds were associated with the intensity and duration of pain symptoms, indicating increased excitability or changes in processing of both peripheral and central nervous systems with reduced pain inhibition in patients with TMD.<sup>139</sup> An examination of anatomical size and volume changes in the trigeminal nerve revealed no local changes in this nerve in a TMD population, while there were changes in patients with trigeminal



neuralgia and trigeminal neuropathy. This study led authors to propose that the hyper-excitability existed beyond the trigeminal nerve in the TMD population.<sup>30</sup>

### **Central Sensitization**

The neurophysiologic relationships noted above can be described as segmental mechanisms of pain control. Central mechanisms of control relate to cortical or subcortical structures in the brain, with subsequent changes in descending inhibition.<sup>69</sup> Central sensitization refers to a mal-adaptive process of reduced stimulus threshold with increased facilitation based on potential overload of nociceptive afferent information to second order neurons.<sup>4,73</sup> There is often a simultaneous reduction in inhibitory responses. The increased responsiveness to stimulation presents clinically as pain without tissue provocation, hypersensitivity to stimulus (hyperalgesia), or pain from normally non-painful stimuli (allodynia).<sup>73,133</sup> Where previous theories of pain transmission suggested noxious stimulus was necessary for pain generation, more recent theories acknowledge nociceptive pain can come from low threshold stimulus.<sup>73</sup> Clinical signs of central sensitization include reduction in PPT, sensitivity to thermal stimuli, and temporal summation, or wind-up pain produced after a single or repetitive low threshold stimuli.<sup>140</sup>

Patients with chronic TMD have demonstrated widespread pain, abnormal central nervous system changes in the brain,<sup>141</sup> and signs of central sensitization alongside peripheral sensitization.<sup>140,142</sup> Patients with chronic TMD, like other patients with chronic pain, often have additional comorbidities. There is a positive association between pain intensity and the number of comorbidities in the TMD population.<sup>143</sup> Common comorbidities associated with TMD include headache, depression, chronic fatigue syndrome, interstitial cystitis, restless leg syndrome, fibromyalgia, irritable bowel syndrome, and sleep disruption.<sup>40,143</sup> Individuals with

TMD who also have comorbidities have higher incidence of central sensitization and allodynia.<sup>73,144,145</sup> Chronic TMD is associated with concomitant headache, neck pain and dysfunction, and impaired endogenous pain modulation, which may be related to central sensitization.<sup>146</sup>

Changes in PPT are related to central sensitization.<sup>73</sup> Patients with TMD have notable changes in pain and temperature thresholds.<sup>133,147-149</sup> La Touche<sup>132</sup> et al examined PPT in 23 patients with mechanical neck pain demonstrating reduced PPT in masticatory muscles (masseter and temporalis) as well as the upper trapezius and C5-6 facet joint. They also examined a remote location at the anterior tibialis. While statistically significant changes in PPT were present for the masticatory and cervical regions, the difference between groups (neck pain and healthy controls) at the anterior tibialis was not statistically significant.<sup>132</sup> The results of this study differ from the previously mentioned results of Fernandez-de-las-Penas<sup>150</sup> et al, who did show differences in the anterior tibialis.<sup>133</sup> LaTouche<sup>140</sup> et al published a meta-analysis examining central sensitization in patients with TMD in 2017. The meta-analysis indicated statistically significant reduction in PPT levels was present in both trigeminal and remote areas in patients with TMD, suggesting both peripheral and central nervous system involvement.

### **Cervicothoracic Intervention for Temporomandibular Disorder: Evidence**

Manual therapy directed at the jaw, thoracic spine, and cervical spine has been addressed in a limited fashion in the TMD literature.<sup>16,17,64</sup> A 2013 case series reported on the use of mobilization with movement to the jaw and cervical spine, TJM to the thoracic spine, and trigger point dry needling of the temporalis and masseter muscles in 15 participants. Statistically significant change in mouth opening and pain reduction were reported.<sup>58</sup> Packer<sup>109,151</sup> et al performed a randomized controlled trial evaluating the effect of thoracic spine TJM versus sham

manipulation on a population of individuals with TMD. In this trial, there was no statistical difference between groups at immediate or short-term (2-4 day) follow-up for mouth opening, electromyography (EMG) activity of the masticatory muscles, pain rating, or PPT.<sup>109,151</sup>

Jayaseelan<sup>67</sup> et al added cervicothoracic TJM to manual therapy, education and exercise in a case study reported in 2016. The participant in this case had statistically significant change in neck disability, pain rating, and global rating of change. Cervical TJM has been studied previously as part of a multimodal treatment package demonstrating some indication of support for use with the TMD population.<sup>59,152</sup>

#### *Cervical Spine Non-Thrust Joint Mobilization*

Cervical spine non-thrust joint mobilization has been studied and demonstrated value in the treatment of TMD. La Touche<sup>22</sup> et al (2009) examined the impact of cervical intervention including non-thrust joint mobilization and exercise on 19 individuals with a primary diagnosis of TMD. All participants received 10 treatments solely focused on the cervical spine over 5 weeks; treatment included manual supine upper cervical flexion mobilization and prone C5 central posterior to anterior mobilization, with a supine cranio-cervical flexor stabilization exercise. Results showed a large within group effect size for decreasing pain ( $d > 3.0$ ), increasing active mouth opening ( $d > 0.08$ ), and increasing PPT of both the masseter and temporalis ( $d > 1.0$ ). This effect was noted at a 48-hour assessment and maintained at a 12-week follow-up.<sup>22</sup>

In 2013, La Touche<sup>23</sup> et al published an article reporting the impact of upper cervical spine mobilization over 3 treatment sessions (in 2 weeks) on pain, PPT, and sympathetic system response (heart rate, skin conductance, breathing rate and skin temperature). Clinicians performed prone posterior to anterior (PA) mobilization of C0-C3 segments. While their first

study did not have a control group, the second study utilized a sham technique as a control. The sham mobilization was performed utilizing the same handgrip, but without any delivery of force or mobilization. The 2013 study did show statistically significant changes favoring those with the cervical mobilization intervention over the sham mobilization group,<sup>23</sup> and the reported magnitude between groups demonstrated a very large effect.<sup>64</sup> These between group effect sizes were not reported; see Table 2.1 for hand calculations completed at the 2 week, post treatment visit.

TABLE 2.1	EFFECT SIZE ESTIMATES (BETWEEN GROUPS) AT 2 WEEKS
Variable	d
Pressure pain threshold	
Masseter 1; right	-2.13
Masseter 1; left	-2.05
Temporalis 1; right	-2.53
Temporalis 1; left	-2.44
Visual Analogue Scale	-2.59
<i>Abbreviations: d, Cohen's d effect size calculation.</i>	

In 2016, Calixtre<sup>153</sup> et al reported on a single group pre-test, post-test analysis of 12 women with TMD treated with cervical mobilization and exercise modeled after La Touche<sup>23</sup> et al. These authors investigated improvement at 5 weeks in function of the jaw, subjective pain reports, PPT, and mouth opening. Within group effect sizes were reported using Cohen's d. Mouth opening had the greatest effect,  $d = 0.64$ . The PPT effect was variable for each location with some improvements and some worsening. Both pain scores and PPT were low at baseline leaving little room for change with intervention. The mean baseline pain score was 1.0/10 on the NPRS.

### *Cervical Spine Thrust Joint Manipulation for Temporomandibular Disorder*

Cervical spine TJM is supported for acute and chronic neck pain, as well as cervicogenic headache.<sup>154-157</sup> An update and revision of the cervical spine clinical practice guidelines<sup>158</sup> suggests B level evidence (moderate strength) to support cervical spine TJM in subacute or chronic neck pain with headache, as well as chronic neck pain with radiating pain. C level evidence (weak support) exists for the use of cervical TJM in acute, subacute, and chronic neck pain with mobility deficits. A clinical predication rule (CPR) has been derived for the use of cervical spine TJM in patients with neck pain.<sup>159</sup> This CPR is currently in the process of validation, and may provide further evidence surrounding the use of cervical spine TJM for neck pain.

Specific to TMD, cervical spine TJM has been utilized as part of multimodal treatments. It has also been tested in populations with primary complaints other than TMD. A systematic review and meta-analysis in *Manual Therapy* examined 8 articles using manual treatment in association with TMD. Martins<sup>16</sup> et al concluded that there was evidence to support manual therapy intervention for this population. Of the 8 articles, 3 of them utilized cervical spine TJM. The population tested in these TJM studies included children with a history of trauma,<sup>16,160</sup> and subjects with noted latent trigger points as opposed to jaw pain or dysfunction.<sup>16,69</sup> The third study, Mansilla-Ferragut<sup>161</sup> et al, examined the immediate (5 minutes post-intervention) effects of atlanto-occipital TJM on mouth opening and PPT in a population of women with a primary complaint of neck pain and found statistically significant improvements in both. The magnitude of the effect within groups in this study was large for mouth opening ( $d = 1.5$ ), and moderate for PPT ( $d = -0.05$ ).<sup>64</sup> Between group effect size was not reported; hand calculation reveals a large effect for both mouth opening ( $d = 2.08$ ) and PPT ( $d = 1.28$ ). Other studies that were included in

this systematic review utilized TJM in addition to other manual interventions, making the specific effect of TJM difficult to determine.<sup>16,152</sup>

Oliveira-Campelo<sup>69</sup> et al completed a study (mentioned in the review above) examining 122 volunteers with latent trigger points in the masseter and temporalis. There were 3 arms of this study: 1) atlanto-occipital TJM, 2) suboccipital soft tissue mobilization, and 3) no intervention control group. Examination of 2-minute immediate effects revealed statistically significant changes between both of the intervention groups and the control; however, the between group effect for both mouth opening and PPT was small ( $d = 0.28$ ,  $d = 0.22$ ). This study suggests cervical spine TJM or cervical soft tissue mobilization may have an impact on MMO or PPT. It is important to remember that the population tested did not have a TMD or neck pain diagnosis, however they did have presence of latent trigger points in the muscles of mastication.

Cuccia<sup>152</sup> et al utilized multimodal intervention in 2 groups of patients with TMD. One group received osteopathic cervical spine TJM as well as other manual osteopathic interventions of soft tissue treatment, myofascial release, muscle energy, and craniosacral therapy. The other group received ‘conventional’ care of occlusion splinting, PT stretching and relaxation, hot and cold packs, and electrical stimulation. While there was no difference in pain or mouth opening between groups, the group treated with osteopathic intervention had statistically significant reduction in the use of both anti-inflammatory medications and muscle relaxers.<sup>152</sup>

A systematic literature review by Adelizzi<sup>59</sup> et al in 2016 examined literature surrounding the use of cervical spine TJM for TMD, noting most of the evidence was based on weak study designs, limited availability of research, small samples, and multimodal or combined treatment intervention packages. Only 6 studies were included in the review and 3 articles scored 0/11 on

the PEDRO scale (case reports). One case series utilized an ‘activator’ for spinal treatment. There were only 2 RCTs and both were scored 8/11. Authors neglect to acknowledge the study designs used in their review include various populations of interest, none of which include individuals with a primary complaint of TMD. One RCT utilized a population of women with a primary complaint of neck pain, however, they did have limited mouth opening.<sup>68</sup> Another RCT (the Oliveira-Campelo study mentioned above) utilized a population of individuals with confirmed presence of latent trigger points in masticatory muscles, but no diagnosis of TMD.<sup>69</sup> Despite the limitations noted above, Adelizzi<sup>59</sup> et al reported all 6 studies demonstrated improvements in pain, mouth opening ROM, and PPT; concluding cervical TJM may be beneficial in the TMD population.

### **Cervical Spine Thrust Joint Manipulation for Temporomandibular Disorder: Theory**

The biomechanical and neurophysiological relationships between the jaw and cervical spine have been established<sup>161</sup> and support evaluation and treatment of the cervical spine in the TMD population. The regional interdependence model is used to support thoracic or cervical intervention for shoulder pain,<sup>162-166</sup> and this theory also supports cervical spine intervention for TMD. Cervical spine non-thrust joint mobilization has demonstrated effectiveness, giving reason to believe cervical spine TJM may also impact pain and dysfunction of TMD. The specific impact of cervical spine TJM is yet to be determined in the TMD population and was the focus of this dissertation.

The specific nature of spinal TJM effectiveness is not fully understood. Historically, manual physical therapists have looked at their interventions from a biomechanical perspective. Biomechanical theory surrounding cervical spine TJM in TMD includes relationships with mouth opening or posture. MMO is a functionally relevant measurement in subjects with TMD, and this measurement is dependent on cervical posture.<sup>2</sup> Forward head posture is said to

contribute to neck pain, shortness of the suboccipital musculature, headaches, and potentially TMD.<sup>99</sup> It is possible cervical spine TJM can have an impact on cervical ROM and posture, therefore leading to a change in mouth opening or function for individuals with TMD.

There is also growing support for the neurophysiological effect of TJM to the spine through biochemical, spinal segmental, and central mechanisms. A systematic review and meta-analysis demonstrated biochemical changes in substance-p, neurotensin, oxytocin, interleukin, and cortisol with spinal TJM. These biochemical changes were used to support the theory that spinal TJM can result in pain modulation.<sup>167</sup> The interaction between both central and peripheral nervous systems supports central nervous system change as well as peripheral pain modulation after localized intervention.<sup>168,169</sup> Changes in muscle activation/recruitment, resting muscle tone, pain inhibition, sympathetic nervous system activity, and/or function have been documented with spinal TJM.<sup>19,22,169,170</sup> Increased PPT in local and remote regions after spinal TJM also suggests a possible combined peripheral and central mechanism of control.<sup>171,172</sup> Manual therapy has a role in pain inhibition at the location of pain or treatment and even at remote locations.<sup>169,173</sup> Therefore, it is possible that intervention directed at the cervical spine may have local cervical spine effects as well as distant effects in the face, jaw, or other regions of the body.

Sault<sup>174</sup> et al described a case study of a woman with bilateral TMD and cervical pain. Manual therapy and exercise treatment directed at both the temporomandibular joint and cervical spine resulted in reduction of pain, improved function of the jaw, and increased PPT at the jaw and a remote location at the thenar eminence. Fernandez-de-las-Penas<sup>150,175</sup> et al reported changes in PPT at C5/6 facet joints after cervicothoracic junction TJM<sup>150</sup> as well as changes in PPT at bilateral elbows after C5/6 TJM.<sup>175</sup> The proposed mechanism of pain reduction relates to inhibition of nociceptors, altered sensorimotor integration, and changes in descending pathways



of the spinal cord.<sup>176</sup> The convergence mechanism previously described refers to the shared grey matter in the trigeminocervical nucleus and extends to C3.<sup>15,135</sup> The convergence of the upper cervical nerve roots (C1-3) with the trigeminal nerve suggests a segmental relationship with possible central activation of inhibitory pathways with spinal TJM.

This study utilized cervical spine TJM of bilateral atlanto-occipital (C0/1) joints and an upper/mid-cervical (C2/3) location.

### **Cervical Spine Thrust Joint Manipulation Safety**

Cervical spine TJM is considered standard PT practice, and both thrust and non-thrust mobilizations are routine interventions in orthopaedic PT practice. TJM is considered an entry-level skill and required in first professional Doctor of Physical Therapy Programs. However, the perception of risk associated with cervical spine TJM should be considered. Mild side-effects are an expected potential consequence of TJM, and these include neck pain, headache, and fatigue.<sup>159</sup> The risk for mild side-effects is estimated to be 1-2%, with 74% of these symptoms resolved in 24 hours.<sup>177</sup> Mild side-effects will be distinguished from discussions of potential adverse events.

While causal relationships are not supported, adverse events including death and stroke have been associated with cervical spine TJM. Given the large number of cervical TJMs that occur on an annual basis within the chiropractic and PT community, the numbers show that actual adverse events are relatively low. The relative risk involved with cervical TJM is unknown, but estimated to be 1/50,000 to 1/5.85 million.<sup>178</sup> The definition of an adverse event and tracking have led to difficulty defining the exact prevalence.

PuenteDura<sup>178</sup> et al provided a narrative literature review of adverse events suffered by persons receiving cervical TJM. Events were classified as preventable, unpreventable, or unknown and the use of cervical TJM was classified as appropriate or inappropriate based on known examination findings. Ninety-three case reports examined 134 cases of adverse event. Of these 134 cases, 44.8% were preventable, 10.4% were unpreventable, and the remaining were unknown. The authors concluded ruling out contraindications would have allowed clinicians to prevent at least 44.8% of the reported adverse events with appropriate screening and testing. However, 10.4% of adverse events were unpreventable, yielding acknowledgement of a rare risk association. In this study, physical therapists were the treating clinician in 3.7% of the cases of adverse events, but none of the noted cases of death.

The arterial dissection associated with serious adverse events can occur with trauma or even spontaneously. Trauma can be as significant as a high speed motor vehicle accident or something like a cough, sneeze, performing yoga,<sup>179</sup> or the positioning of the neck during hair washing at the beauty parlor.<sup>180,181</sup> A 2015 report examined risk factors for those with cervical arterial dissection (not only those associated with cervical TJM) and reported cardiovascular risk factors were not “important risk factors”<sup>182</sup> for dissection and “may not be useful indicators or risk”<sup>182</sup>; however, this study will still exclude those with uncontrolled hypertension, hyperlipidemia, and diabetes.

Adelizzi<sup>59</sup> et al report perception of risk may explain their difficulty finding research support for cervical spine TJM in the TMD population. These authors advocate for further research on the topic of TJM. The systematic review and meta-analysis by Armijo-Olivo<sup>17</sup> et al reported there were no reports of adverse events with manual therapy and exercise in the TMD population for the few trials that actually reported adverse events. The revised Clinical Practice

Guidelines for neck pain mention risk with any cervical spine intervention, noting ‘while major adverse events can and do occur on a patient-by-patient basis, reports of serious events in randomized controlled trials are ostensibly absent... For manipulation, rare but serious adverse events such as stroke or serious neurological deficits were not reported in any of the trials.’<sup>158</sup>

In this study, all participants were screened according to the International Federation of Orthopaedic Manipulative Physical Therapists (IFOMPT) safety recommendations. Participants were screened for general red flags and appropriateness of physical therapy as well as contraindications to TJM before enrollment. The PI and all treating therapists were licensed physical therapists with post professional manual therapy training including the specific study of TJM procedures, background, safety, and assessment. A side-effect questionnaire was used to document and report any side-effects.

### **Relevance and Contribution to the Field of Physical Therapy**

Physical therapists often report lack of preparation and lack of confidence in treating the TMD population.<sup>15</sup> In the United States, patients with jaw pain may encounter practitioners without experience or confidence in treating their condition. Understanding the effectiveness of various interventions on pain modulation and changes in function guide informed and evidence-based clinical practice, and may have an impact on outcomes. Effective interventions may minimize the development of chronicity or central sensitization,<sup>5</sup> both of which can be difficult to manage.

Cervical spine TJM is part of standard PT practice.<sup>66</sup> Frequency of cervical spine TJM use by physical therapists in the US is much less than that of lumbar and thoracic TJM.<sup>183,184</sup>

There are a few studies looking at the effectiveness of cervical spine non-thrust mobilization and

TJM treatment for TMD, however, none specifically examine the impact of cervical spine TJM independently in this population. A consideration of cervical spine TJM in the treatment of TMD could be an important adjunct to current standard practice interventions of soft tissue mobilization, behavioral modification, and exercise. Physical therapists treating patients with jaw pain may be unaware of an important treatment option, and evidence supporting effectiveness of TJM may have an impact on utilization in clinical practice. If cervical TJM is an effective intervention, these results could be utilized to guide clinical practice. It is also possible that cervical spine intervention could be preferable to direct treatment to the jaw. As noted by Sault<sup>174</sup> et al, manual intervention directed at the cervical spine had a larger impact on pain and was better tolerated than treatment directed at the jaw. LaTouche<sup>22</sup> et al suggests cervical spine manual intervention be considered as an adjunct to TMD intervention as well as a consideration for those individuals with TMD related allodynia who may not tolerate palpation or intervention directly around the temporomandibular joint.

Adding to the body of literature will support the role of the physical therapist in normalizing function, decreasing pain, and/or improving quality of life in those with TMD. Research examining the effectiveness of cervical spine TJM has the potential to improve the confidence of physical therapists looking for the most effective way to treat the TMD population, support the role of the physical therapist on the interdisciplinary team, and support future study of comparative analysis of interventions as well as cost analysis and impact.

### Summary

Confidence in the effectiveness of PT interventions for those with TMD is moderate at best.<sup>16-18</sup> Dental intervention primarily includes the use of occlusal splinting, and despite inconsistent evidence, this is the most commonly utilized treatment intervention. There is little

evidence to support interdisciplinary care. Calixtre<sup>64</sup> et al acknowledge clinical practice frequently utilizes multimodal interventions, however, these authors advocate for study of the specific impact of each intervention in order to make clinical decisions relevant to the most effective intervention choices. In a 2016 systematic review and meta-analysis of PT intervention for TMD, Paco<sup>19</sup> et al reported more evidence has been published to support PT intervention for this population. However, these authors and Armijo-Olivo<sup>17</sup> et al acknowledged the evidence lacks RCTs, and recommended future RCTs in the TMD population.<sup>17,19</sup>

A strong correlation between TMD related disability and neck disability has been found.<sup>21</sup> Biomechanical and neurophysiological relationships between the cervical spine and TMD are acknowledged. Cervical spine TJM is a commonly utilized, safe, and effective PT intervention. Much of the current evidence surrounding cervical spine TJM for TMD utilized this intervention with other interventions or on different populations, making the specific impact of TJM for individuals with TMD difficult to determine. While this study also utilized other interventions, 2 groups were used and only one group received TJM while the other received a sham manipulation. The goal of this dissertation was to study the impact of cervical spine TJM in the TMD population.

## **Chapter 3: Methodology**

### **Introduction**

This chapter outlines the methodology used for investigating the effects of cervical spine thrust joint manipulation (TJM) on individuals with temporomandibular disorder (TMD). The methodology and reporting follow Consolidated Standards of Reporting Trials (CONSORT) guidelines.<sup>185</sup> CONSORT established guidelines to improve consistency, transparency, and accuracy of reporting randomized controlled trials while supporting efforts to minimize bias and uphold the standards expected of this level of evidence. Additionally, this trial was registered prospectively with the US National Library of Medicine via [clinicaltrials.gov](https://clinicaltrials.gov) (ID: NCT03300297).

This outline describes clinician background requirements, training and procedural methods for clinicians and data collectors, participant recruitment, and facilities. Further information regarding research design including blinding, random assignment, description of subjects, procedures, measurement tools, interventions, and sample size estimations. Data safety, data monitoring, and funding will also be discussed.

### **Research Design and Methods**

This dissertation project was a prospective, longitudinal randomized clinical trial examining the effect of an intervention following the CONSORT guidelines. Two parallel groups were compared over time in a factorial design consisting of 25 participants per group. Eligible participants were randomly assigned to 1 of 2 groups: sham or manipulation. Three locations for data collection included Rock Valley Physical Therapy (RVPT), an outpatient practice with locations in Peoria and Washington, Illinois, Bradley University (BU) Department

of Physical Therapy and Health Sciences, and University of Nevada Las Vegas (UNLV)  
Department of Physical Therapy.

The 3 clinicians trained to assist in data collection were licensed physical therapists, known to the principal investigator (PI). All clinicians had specific post-graduate level spinal TJM training (documentation of coursework or residency/fellowship training) and used cervical spine TJM regularly in practice. A Manual of Standard Operating Procedures (MSOP) was created by the PI. Each clinician received this manual and underwent detailed training before data collection began. The live training was performed by the PI and DPT student research assistants at BU. This 5-hour training included review of human subjects research, standardization of assessments, flow of procedures, common education language/instruction, and standardization of treatments. Clinicians received a copy of the MSOP. See Appendix 10. Video recordings from the training session were taken of each assessment and treatment procedure and an electronic file was shared with clinicians to use as needed for repetition. One of the clinicians trained for data collection never completed the Collaborative Institutional Training Initiative (CITI) training and therefore never collected any data for the study. Another trained clinician, located in Washington, IL, did not have participants interested in that location. Therefore, all data was collected between 2 clinicians (the PI and Dr Emilio Putentedura, PT) at the locations mentioned previously.

Blinded assessors (blinded to treatment group allocation) were used for objective data collection. The blinded data collectors included 6 physical therapists, 1 physical therapist assistant, and 5 doctoral PT students who underwent a separate 4-hour detailed training before data collection began. The training was performed by the PI and included review of human subjects research, standardization of assessments and measurements, common language to be

used, and documentation of findings. Blinded assessors received the MSOP. See Appendix 10. The blinded assessors were trained to measure pressure pain threshold (PPT) as well as active range of motion (AROM) of the neck and jaw. Video recordings from the training session were taken of each assessment procedure and an electronic file was shared with blinded assessors to use as needed for repetition. Interrater reliability was tested at the end of this training using healthy volunteers (college students).

Blinded assessors at University of Nevada Las Vegas (UNLV) were trained by the treating clinician at that location using the MSOP and videos shared by the PI. These blinded assessors were DPT graduate assistants and had prior experience with similar data collection in a neck pain study.

Front office staff at RVPT were trained to assist in scheduling and flow of research. Research assistants in IL and NV organized schedules with a blinded assessor, clinician, and participants. Participant demographic and contact information was collected and kept in a locked file at RVPT, BU, or UNLV in NV. All files were ultimately transferred to a locked file cabinet located at Bradley University in IL. Demographic information collected for descriptive purposes included age, gender, race, body mass index (BMI), occupation, physical activity level, medications, medical history, smoking history, onset/location of symptoms, aggravating/relieving factors, and frequency of episodes. Self-report measures were completed by participants and treating therapists performed all objective assessment/screening procedures excluding those measures that would be used for objective data collection and analysis. See Appendix 7 and Appendix 8 for outcome measures and data collection forms.



### *Recruitment Procedure*

Participants were recruited from Peoria, IL, Washington, IL, Morton, IL, and Las Vegas, NV. Recruitment flyers were posted in several public locations (BU campus, local dental offices, RVPT clinics) to recruit from the general public. See Appendix 2. Electronic advertisement was shared in BU News (weekly announcements sent to BU faculty and staff) and Hilltop Happenings (weekly announcements sent to BU students). At UNLV, persons interested in participating in a neck pain clinical prediction rule validation study who complained of TMD symptoms more than neck pain were asked if they would like to participate in this study.

Consecutive persons sent to RVPT (IL) for evaluation and treatment of TMD were invited to participate in the study if interested. The PT evaluation and treatment performed at RVPT did not require entry into the research study as all procedures were standard of care. RVPT office staff handled scheduling as they did with any new referral. Invitation to participate in the study was provided by office staff or research assistants over the phone or in person as follows: “Rock Valley Physical Therapy is collaborating with Bradley University’s Physical Therapy Department in a study to determine the effectiveness of physical therapy treatments for temporomandibular dysfunction or pain. You are being invited to participate in this study because of complaints of jaw or TMD pain. All of the procedures associated with this study are routinely used by physical therapists. Would you be interested in participating in this study?”

Persons interested in participation in NV were told “UNLV’s physical therapy department is collaborating with Bradley University in IL for a study to determine the effectiveness of physical therapy treatments for temporomandibular dysfunction or pain. You are being invited to participate in this study because of complaints of jaw or TMD pain. All of the procedures associated with this study are routinely used by physical therapists. Would you

be interested in participating in this study?” NV volunteers understood they were participating in research, and if they were not interested or did not qualify, information was provided to suggest other treatment options.

The treating clinician issued and reviewed the informed consent with each participant. Once this information was reviewed, participants were informed they could change their mind at any time and withdraw from the study without consequence. Once a participant was entered into the study they were not removed from analysis or discussion.<sup>64</sup>

#### *Concealed Random Allocation*

A research assistant not involved in subject recruitment or intervention created a computer-generated randomization list with equal numbers of participants in each group for a total of 42 participants. A document stating “sham group assignment” or “manipulation group assignment” was placed in a concealed opaque envelope. After initial screening, evaluation, and baseline assessments were complete, eligible participants were randomly assigned to one of two groups by opening the next envelope. In NV, a random table generator was used for group assignment of the subsequent 8 participants (<https://www.randomizer.org/>). As clinicians were performing treatment, they could not be blinded to group allocation, however patients and assessors used to measure objective data for analysis were blinded to treatment group.

Treatment began immediately after assignment.

#### *Description of Human Subjects*

A total of 50 participants with a primary complaint of TMD related pain and dysfunction who met inclusion and exclusion qualifications participated in the study. All participants consenting to participation were screened for eligibility using a health record form, physical

objective examinations, and self-report measures. See Appendix 7 and Appendix 8. Participants were screened by the evaluating physical therapist according to a general screening tool for a broad inclusion of TMD related pain and dysfunction. This initial screening tool has been established and demonstrated high specificity (0.97) and sensitivity (0.99) to identify those with and without TMD.<sup>32</sup> It is suggested that this tool be used to determine the presence of pain related TMD and the potential need for treatment.<sup>33</sup>

#### *TMD Screen*

1. In the last 30 days, on average, how long did any pain in your jaw or temple area on either side last?<sup>32</sup>
  - a. No pain
  - b. From very brief to more than a week, but it does stop
  - c. Continuous
2. In the last 30 days, have you had pain or stiffness in your jaw on awakening?
  - a. No
  - b. Yes
3. In the last 30 days, did chewing hard or tough food change any pain (that is make it better or make it worse) in your jaw or temple area on either side?
  - a. No
  - b. Yes

Scoring: all “a” responses are scores as 0, “b” response is 1 point, and “c” response is 2 points.

A threshold of a total score of 2 is needed for a positive screen.<sup>32</sup>

#### *Inclusion Criteria:*

1. Numeric Pain Rating Scale (NPRS) score  $\geq 2$  in jaw at baseline

2. Pain-free mouth opening  $\leq 50$  mm
3. Age 18-65
4. Primary complaint of TMD pain
5. TMD pain confirmed by screen listed above
6. Proficiency in the English language
7. Availability to attend 4 appointments in 4 weeks

The following paragraphs explain the choices made for inclusion criteria. A minimum level of disability was established to increase likelihood of capturing change in pain or function. While functional outcome measures are generally used to establish this minimum level of disability, there is not enough evidence utilizing TMD specific outcome tools to determine an appropriate minimum score; therefore, both pain and mouth opening were used to determine a minimum level of disability. There is no established minimum level of disability for the TMD population with NPRS, therefore a score of  $\geq 2$  at baseline was chosen based on previous research<sup>156,186</sup> related to neck pain and the minimum NPRS score noted in a case series performed by the PI before the start of this study. This case series reported the outcomes of 5 individuals with a primary complaint of TMD and treated them with education, exercise, and cervical TJM. The minimum level of pain as measured by the Numeric Pain Rating Scale (NPRS) for these participants was 2. A minimal level of mouth opening was established as  $\leq 50$  mm. While 40 mm of opening is often considered normal or functional opening, it is actually a lower range of normal, which is listed between 40-55 mm.<sup>7,9,187</sup> The use of  $\leq 50$  mm establishes a cut off likely to allow for some improvement over time. The minimum age of 18 was chosen to include those old enough to legally consent to participation. The maximum age of 65 was chosen to exclude those with higher probability of narrowing of the cervical central canal.<sup>188</sup>

Cervical TJM has been studied in a population of persons with neck pain, however, the intent of this study is to look at the impact of cervical spine TJM in a TMD population; therefore, persons included had to have a primary complaint of TMD pain and test positive on the screen. Requiring English language proficiency was necessary for completion of self-report scales and data collection and agreement to participating in 4 visits was included to ensure participants had an intent to complete the study duration.

*Exclusion Criteria:*

1. Traumatic onset of symptoms in the last year
2. History of whiplash in the last 6 weeks; Prior neck surgery
3. Temporomandibular locking in the last month
4. Medical red flags suggestive of non-musculoskeletal origin of pain, systemic or neurological disease
  - a. Two or more signs of cervical nerve root compression (major muscle weakness, diminished upper extremity reflexes, diminished or absent pinprick sensation in a dermatomal pattern); Evidence of central nervous system involvement (hyperreflexia, gait disturbance, nystagmus, impaired facial sensation, change in taste, loss of visual acuity, positive pathological reflexes (Hoffman, Babinski, Inverted supinator, clonus)); unremitting night pain or non-mechanical pain
5. Contraindications to TJM: active cancer, history of prolonged corticosteroid use, acute fracture or tumor in the area to be treated, osteoporosis, joint ankyloses, dislocation, cervical ligament ruptures, acute active inflammatory or infectious disease, rheumatoid arthritis, vertebral artery abnormalities, connective tissue disease (Muscular dysplasia, Marfan syndrome, Down syndrome, Ehlers Danlos syndrome), prolonged anticoagulant

therapy, signs of cranial nerve involvement, drop attacks, dysarthria, dysphagia, nystagmus, new or recent onset of dizziness, new or recent onset of neck pain or headache “unlike any other”, previous cerebrovascular accident or transient ischemic attack, or uncontrolled hypertension, diabetes, or hyperlipidemia

6. Previous cervical spine TJM intervention in the last 3 months; Worker’s compensation or any pending litigation regarding their pain or injury

### Evaluation Procedures

Treating therapists issued the Health History Form and Self-Report Outcome Measures to be completed by the participants before the session began. Table 3.1 describes subsequent assessments, which are described in further detail in the MSOP (See Appendix H).

TABLE 3.1		EXAMINATION AND EVALUATION ASSESSMENT	
Demographic/History	Safety Screening (per IFOMPT Guidelines)	Objective Assessment by Blinded Assessor	
Review health Record Form designed to screen for red flags or contraindications to treatment as well as other inclusion and exclusion criteria	History clarification if needed; Blood pressure, testing/screening of the following: cranial nerves, upper cervical ligaments, vertebral artery, myelopathy signs, reflexes, sensation, UE myotomes, nystagmus, and cervical spine TJM position hold	Cervical ROM, jaw ROM, PPT with digital algometer at 3 locations (1 temporalis, 1 masseter, and 1 remote location at 1 <sup>st</sup> dorsal interossei)	
Abbreviations: UE, upper extremity; TJM, thoracic joint manipulation; ROM, range of motion; PPT, pressure pain threshold.			

A blinded assessor measured baseline and immediate change in cervical and jaw ROM, and PPT on day one. A blinded assessor was also present at the 1-week and 4-week visits to repeat these measurements before treatment. The blinded assessor was not present during treatments to protect the integrity of blinding.

If any participant was excluded, declined to participate, did not meet inclusion criteria, or was lost to follow up, this data was recorded for future reporting. Every effort was made to fully describe these happenings.

### Data Collection

All subjects completed several commonly used instruments to assess pain and function in patients with TMD. There is no consensus in the literature regarding the most appropriate outcome measures to use with this population, and psychometric property analysis of TMD outcome measures is sparse.<sup>189</sup> While there is some evidence to support use of the temporomandibular scale, this outcome measure has 97 items and is not clinically efficient.<sup>189</sup> Therefore, this study used a spectrum of outcome measures that attempt to capture the effect of treatment across multiple constructs including patient's perceived recovery, TMD related disability and functional limitations, neck disability, fear of movement, and pain rating. These instruments are commonly utilized in practice and/or research.

Other measurements for cervical ROM, jaw ROM, and PPT were taken by an assessor blinded to treatment group allocation. The timing of data collection for the self-report and outcome measures is listed below in Table 3.2. See Appendix 7 for copies of all Self-report Measures.

TABLE 3.2	TIMING OF DATA COLLECTION				
Measurement	Baseline	Immediate	1 week	2 weeks	4 weeks
ROM Jaw	Yes	Yes	Yes	No	Yes
NPRS	Yes	Yes	Yes	No	Yes
JFLS	Yes	No	Yes	No	Yes
NDI	Yes	No	Yes	No	Yes
TMD Disability Index	Yes	No	Yes	No	Yes
GROC	No	Yes	Yes	No	Yes

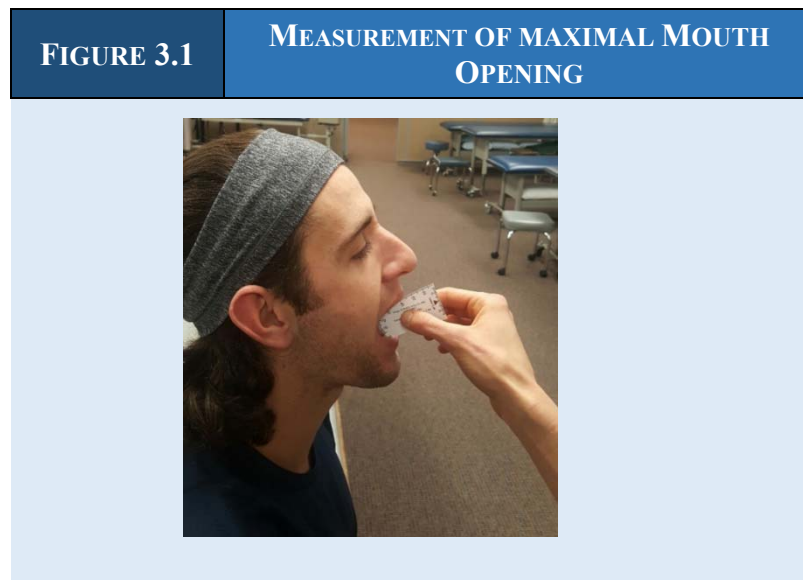
PASS	No	No	No	No	Yes
TSK-TMD	Yes	No	No	No	Yes
ROM Cervical Spine	Yes	Yes	Yes	No	Yes
Pressure Pain Threshold	Yes	Yes	Yes	No	Yes
PHQ-2 Depression Screen	Yes	No	No	No	No
Side Effect Questionnaire	No	No	No	No	Yes
<i>Abbreviations: ROM, range of motion; NPRS, Numeric Pain Rating Scale; JFLS, Jaw Functional Limitation Scale; TMD, temporomandibular disorder; GROC, Global Rating of Change; PASS, Patient Acceptable Symptom State; TSK-TMD, Tampa Scale of Kinesiophobia for Temporomandibular Disorders; PHQ-2, Patient Health Questionnaire-2.</i>					

### *AROM of the Jaw*

A disposable tool (TheraBite ROM scale) was utilized to measure seated MMO and supine lateral deviation. Mouth opening is an essential function of chewing and speech and often a limitation in those with jaw or neck pain.<sup>9,161</sup> Normal mouth opening has been reported in large ranges in the literature, however, 40-55<sup>7,9,187</sup> mm is generally accepted. Without control for cervical head position, 42-68 mm is a normal range for males and 40-57 mm for females.<sup>190,191</sup> Measurement of MMO has shown excellent interrater reliability. Lobbezoo<sup>192</sup> et al report Pearson  $r = .86$  (.82-.90). Kropmans<sup>193</sup> et al report that both interrater and intrarater reliability data in their study show Pearson  $r$  values range from .90-.96; however, these authors do not provide point estimates of findings. Walker<sup>187</sup> et al report intrarater and interrater reliability of TMJ ROM using interclass correlation coefficient (ICC). For mouth opening, intrarater reliability was excellent, ICC (3,1) = 0.94, for both of their raters in those with TMJ disorder. The numbers were lower (adequate to excellent respectively) in those without TMJ with ICC (3,1) reported at 0.77 and 0.89 for each rater. Intrarater reliability ICC (2,k) = 0.99 in those with TMJ disorder and 0.98 in those without TMJ disorder.<sup>187</sup> Minimal detectable change (MDC) ranges from 1.73-6 mm.<sup>190,193,194</sup> Minimal clinically important difference (MCID) has not been



established. While norms have been established, comparison to normal values is not as useful as comparison or change within an individual.<sup>7</sup> Participants in this study were told to sit up tall and open as far as possible without pain.<sup>69,187</sup> Measurement of the distance between maxillary and mandibular central incisor edges was taken using the most vertical incisor (see Figure 1).<sup>113</sup> The tooth used as the most vertical incisor was recorded on the data collection form for consistency at future measurements.



Lateral deviation of the jaw was measured in supine with the TheraBite. A measurement is taken relative to the resting/starting position to measure mm of displacement between the central incisors of the mandible and maxilla. It can be difficult to stabilize the measurement tool during lateral deviation, making consistency with this measurement challenging.<sup>7</sup> Clinical experience led the PI to choose the supine position to improve consistency as much as possible (See Figure 3.2). Normal lateral deviation is approximately 10 mm of motion in each direction for adults.<sup>7</sup>

**FIGURE 3.2****MEASUREMENT OF LATERAL DEVIATION**

### *Numeric Pain Rating Scale (NPRS)*

The NPRS allows patients to quantify their pain on an 11-point scale used to measure pain intensity. Pain is given a number from 0 (representing no pain) to 10 (representing the worst pain imaginable).<sup>195</sup> Psychometric property analysis relevant to the TMD population is limited, however, the scale has been suggested for use in the TMD population.<sup>7,42</sup> One study looking at NPRS in the TMD population reported fair reliability (0.36 Kappa).<sup>196</sup> Sum scores have been suggested to improve reliability,<sup>165</sup> and were utilized for this study. Participants were asked to rate their current pain as well as the best and worst pain scores over the last 24 hours resulting in an average pain score<sup>165,197</sup> that was recorded for jaw pain, neck pain, and headache. A sum score NPRS has demonstrated responsiveness with a MCID of 1.3 in a neck pain population<sup>198</sup> and 2.17 in a shoulder pain (surgical and non-surgical) population.<sup>199</sup> Another study of patients with cervical radiculopathy demonstrated MCID of 2.2 on the NPRS, however, this number was lower than the 4.1 change found for MDC.<sup>200</sup> This study did not utilize the sum score for NPRS. A study of a large heterogeneous chronic pain population revealed an average change of 2 points

reflected clinically meaningful change on the NPRS.<sup>201</sup> Farrar<sup>201</sup> et al examined the NPRS in patients with chronic pain reporting a 1.74-point decrease represented clinically meaningful change. Kalamir<sup>97,100</sup> et al used  $\geq 2$  NPRS to define clinically important change in an intervention study with a population of TMD participants.

The NPRS was used in a case series by Calixtre<sup>153</sup> et al utilizing cervical mobilization and exercise treatment for the TMD population. Authors report 2 of 14 participants actually started with a pain rating of 0 and overall statistically significant changes in NPRS were still observed for the group over a 9 week period.<sup>153</sup>

### *Pain Body Diagram*

A pain body diagram is used to record the location and nature of pain by drawing it on a human figure.<sup>7</sup> There has been an inconsistency in evidence supporting use of a pain diagram in diagnosis, however, there is some clinical utility in localizing areas of primary complaint.<sup>202</sup> Participants were asked to mark their current pain on a pain body diagram.

### *Jaw Functional Limitation Scale (JFLS)*

The JFLS is a 20 item self-report scale assessing three constructs (mastication, vertical jaw movement, emotional/verbal expression) to quantify functional limitation.<sup>203</sup> Each item is scored by the patient from 0 (no limitation) to 10 (severe limitation). The recorded score is the total score of the 20 items; higher scores represent increased level of disability. An 8-item version has also been introduced, but this study will utilize the 20-item version, as this version was suggested for study of intervention effects.<sup>189</sup> Excellent internal reliability (Alpha 0.95)<sup>189</sup> and temporal stability (Alpha 0.87)<sup>204</sup> have been seen in the TMD population with the 20-item JFLS. Content validity was supported using expert clinicians in a qualitative review.<sup>189,203</sup> Construct validity

(discriminate and convergent)<sup>204</sup> has been supported in literature with low correlation (0.02-0.26) seen between JFLS and depression, anxiety, and somatization, and moderate correlation (0.49-0.57) with pain and jaw symptoms.<sup>204</sup> A floor effect, or score of 0 on all responses, was only reported in 7% of subjects and fewer than 3% reported ceiling effects.<sup>204</sup> While no MCID has been established, moderate to large effect sizes have been documented for treatments ( $d = 0.41-0.92$ ).<sup>106,204</sup> The psychometric properties mentioned are based on 2 articles; further support is needed.

#### *Neck Disability Index (NDI)*

The NDI is a 10 question self-report scale assessing levels of neck pain and related disability. NDI is highly responsive<sup>205</sup> and has previously shown test-retest reliability, as well as content and construct validity in a neck pain population.<sup>200</sup> Each item is scored from 0-5 with a maximum score of 50 points. The total score is doubled and interpreted as a percentage of patient perceived disability. Higher scores represent increased level of disability. MDC for NDI in a neck pain population has been reported as 5-10.5;<sup>206,207</sup> a 10%-21% improvement in perceived disability is the minimum change required to demonstrate true change occurred. MCID reports range from 5-19; a 10-38% change in perceived disability is clinically meaningful change.<sup>206</sup> A study of patients with cervical radiculopathy demonstrated MCID of 8.5 (17%) on the NDI, however, this number was lower than the 13.4 (26.8%) change found for MDC.<sup>200</sup> A systematic review published in 2009 reported a score of 5 (10%) for MDC and 7 (14%) for MCID.<sup>206</sup>

### *TMD Disability Index*

The TMD Disability Index is a 10 question self-report scale utilized in research including a study of manual therapy for TMD.<sup>208</sup> Each item is scored 1-5 with a minimum score of 10 and a maximum score of 50. Higher scores are representative of higher levels of disability. While this scale has been used in clinical practice and published studies of intervention effectiveness,<sup>58,208,209</sup> there are no reports of psychometric property analysis in the literature. Previous use of the TMD Disability Index demonstrated improvement of 21.7 points (43.4%) in one study, while another study showed progress in participants with only a 13.9% change in the TMD Disability Index.

### *Global Rating of Change (GROC)*

The GROC scale asks patients to rate their perception of overall change. The scale ranges from -7 (a very great deal worse) to 0 (about the same), then to +7 (a very great deal better).<sup>210,211</sup> Intermittent descriptors of worsening or improving are assigned values from -1 to -7 and +1 to +7 respectively. The global rating was administered at the follow-up examinations only and served as the reference criterion for establishing when a successful outcome occurs. While not specific to the TMD population, face validity (high)<sup>212</sup> and test-retest reliability (ICC .90)<sup>213</sup> have been reported in the literature. GROC scores have been used to identify those with true change in a cervical radiculopathy population noting a change of  $\geq +3$  in those that had improved and a GROC score of -2 to +2 in those who remained unchanged.<sup>200</sup> Intervention studies have used a GROC score  $\geq +4$  or  $\geq +5$  to dichotomize successful outcome.<sup>154,156,214,215</sup> A score of +4 or +5 has been used to define moderate change, while +6 and +7 represent large change.<sup>211</sup> A 3 point change from baseline on GROC has been used to define MCID.<sup>211</sup>

### *Patient Acceptable Symptom State (PASS)*

The PASS is a single question asking patients if their current status is acceptable or unacceptable.<sup>216</sup> Some authors have noted patients who found their current state acceptable often had “unexpectedly high”<sup>217,218</sup> pain ratings. The PASS demonstrated high reliability ( $K=.86$ ) in stable patients with ankylosing spondylitis,<sup>219</sup> but has not been tested in a TMD population. The use of this tool allows for a better understanding of the participant’s perception of their well-being<sup>218</sup> and may suggest they are unlikely to seek further treatment.<sup>220</sup>

Wording was modeled after Mintken<sup>221</sup> et al in 2016; “Taking into account all the activities you have during your daily life, your level of pain, and also your functional impairment, do you consider that your current state is satisfactory?”<sup>221</sup> Individuals responded yes or no; those responding yes were categorized as a success.

### *Tampa Scale for Kinesiophobia for Temporomandibular Disorders (TSK-TMD)*

TSK-TMD is a self-report scale modified from the original Tampa Scale for Kinesiophobia utilized to assess fear of movement commonly associated with chronic pain conditions including neck and back pain.<sup>222</sup> It is a 12-item measure assessing fear of movement/(re)injury. Patients rate each item on a 4-point Likert scale and total scores range from 11-48. Higher scores represent higher levels of fear. The TSK-TMD has demonstrated both internal consistency and good reliability (ICC 0.73 for 12-item version)<sup>223</sup> in the TMD population. It is well accepted that chronic TMD, along with other chronic pain conditions, are multidimensional.<sup>224</sup> Some functional limitations in the TMD population have demonstrated a stronger association with fear than pain,<sup>223</sup> and the association of fear of movement and chronicity of TMD has been supported.<sup>225</sup> Consideration of the construct of kinesiophobia is important to measure in the

TMD population. MDC and MCID have not been established for the TMD population or use of the TMD specific TSK tool. TSK for other chronic conditions, like low back pain, have demonstrated MDC of 5.6<sup>226</sup> An examination of over 900 persons with chronic musculoskeletal pain disorders helped establish cut off points for severe (43-52), moderate (33-42), mild (23-32), and subclinical (13-22) categories of fear using the TSK-13.<sup>227</sup> The TMD version has only 12 questions, therefore care is used with comparisons to these cut points.

### *AROM of the Cervical Spine*

The relationship of the cervical spine to TMD has been previously described. Measurement of cervical motion in this study is necessary as it relates to the clinical picture of TMD<sup>42</sup> and the cervical intervention performed. A bubble inclinometer was used to measure seated flexion/extension, and supine rotation. Use of an inclinometer has demonstrated good intrarater (ICC 0.94) and interrater (ICC 0.84) reliability as well as validity in healthy subjects and those with neck pain.<sup>228</sup> Statistically significant between-group change in cervical ROM has been demonstrated in previous TJM studies, while other studies have revealed no significant between group differences.<sup>229</sup> A change of  $\geq 5^\circ$  in cervical flexion or extension (within one session) has demonstrated predictive value in estimating between session change in motion.<sup>230</sup> Fletcher<sup>231</sup> et al report the standard error of measurement is between  $2.5^\circ$  and  $4.1^\circ$ , and that at least  $5^\circ$  is necessary to demonstrate true change.

### *Pressure Pain Threshold (PPT)*

PPT is defined as the minimum amount of pressure needed to cause a sensation of pain and is a quantifiable palpatory assessment.<sup>232</sup> A digital algometer was used to assess PPT at the masseter, temporalis, and a remote location in the C8 dermatome at the hand. Masticatory

muscle anatomical standards for PPT were modeled after La Touche<sup>23</sup> et al and Heredia-Rizo<sup>99</sup> et al and included 1 point on the masseter and 1 on the anterior temporalis. The first dorsal interossei represents a remote site (ulnar nerve innervation, C8/T1), distant to the dermatomal site of interest (C0-3).<sup>233,234</sup> Reduced thresholds have been seen in distant sites as well as contralateral locations with chronic TMD conditions, leaving speculation of the role of central sensitization.<sup>149,235,236</sup> Previous studies examined facial and cervical musculature and the lateral epicondyle;<sup>149</sup> this study will examine a more distal location innervated by lower cervical nerve roots. Previous studies have indicated the first dorsal interosseous PPT is reliable (ICC, 0.91).<sup>234</sup> Assessment location is described as the midpoint of the muscle belly.<sup>234,237</sup>

A stencil was created to standardize measurement for PPT of the masticatory muscles (Figure 3.3). A mean of 3 trials was used for each site tested with a 10 second pause between testings.<sup>148</sup> One hand applied the load through the algometer while the other hand provided a counterforce on the head to prevent movement. Upon beginning the test, the patient was asked to sit upright with the lips together and teeth apart. The algometer was applied perpendicular to the region of interest, and the patient was asked to tell the examiner when the sensation of pressure turned to pain.<sup>99,233</sup>



**FIGURE 3.3****STENCIL PLACEMENT FOR MASTICATORY MUSCLE PPT****Masseter****Temporalis**

Locations: (MSOP images included in Appendix F)

- a. Masseter 1 (M1): 2.5 cm anterior and 1.5 cm below the tragus<sup>23,99</sup>
- b. Temporalis 1 (T1): 3 cm above an imaginary line drawn between the edge of the lateral eye and the superior external ear and 2 cm posterior to the anterior edge of the temporalis muscle<sup>23,99</sup>
- c. Dorsal interossei (DI): Forearm pronated and resting on solid surface, applied at middle medial aspect of first metacarpal (MC)<sup>1</sup>

Pain thresholds are lower in persons with TMD,<sup>133</sup> however, the OPPERA analysis concluded the lower threshold was not a predictor of onset of symptoms, but instead a repercussion.<sup>46</sup> Increases in PPT are generally seen as pain and function improve, with increase noted in masticatory muscles in intervention studies for those with TMD, myofascial facial pain, and neck pain.<sup>22,23,153,238</sup> Adequate to excellent intrarater reliability (ICC 0.69-0.92) has been reported for PPT of the temple and parietal region in healthy adults.<sup>239</sup> Adequate interrater reliability was demonstrated for PPT in the TMD population with ICC values of .64.<sup>148</sup> Two studies have reported MCID values of  $\geq 1.10$  kg/cm<sup>2</sup>, however, it is important to note these were performed on healthy participants.<sup>237,240</sup> While no specific MCID has been established for PPT in the TMD population, moderate to large effect sizes have been seen in PPT change with cervical mobilization for TMD pain.<sup>22,23,153</sup> Voogt<sup>241</sup> et al performed a systematic review finding 8 of 13 articles included reported PPT changes of  $\geq 15\%$  change in PPT, noting this value had been reported by previous authors as a MCID.

### *PHQ-2 Depression Screen*

Patient health questionnaire-2 (PHQ-2) is a 2-question screen used to identify persons at risk for depression. Previous studies have acknowledged the relationship between anxiety, depression, and chronic TMD symptoms while other authors contradict this finding.<sup>51</sup> It is acknowledged that the potential presence of depression would indicate a need for interdisciplinary examination or treatment. This test is not diagnostic for depression, however is recognized as a brief and effective first step.<sup>242,243</sup> Any participant who scored  $\geq 3$  was referred to their primary care physician for follow-up, but was allowed to continue participation in the study.

### *Side-Effects Questionnaire*

At visit 4 (week 4), patients completed a questionnaire asking about side effects or adverse events associated with their treatment. See Appendix 7.

## **Treatment Interventions**

### *General Procedure*

Participants were randomized to cervical TJM or sham manipulation groups and received this intervention at visit 1, 2, and 3. Both groups received behavioral education, suboccipital soft tissue mobilization, and exercise instruction at the same time intervals. The final visit did not include prescribed treatment, only assessment.

### *Group One*

Treatment included suboccipital release (2 minutes), cervical spine TJM (5 minutes or less), behavioral modification (10 minutes), and exercise (15 minutes). Suboccipital release was used to allow the patient to gain comfort with manual cervical contact. Cervical spine TJM was performed in supine using a rotational up-slope manipulation at C2/3 and a distraction manipulation at C0/1. Cervical TJM was performed on the right and left side and followed common research practice<sup>154</sup> to include delivery of a high-velocity, low amplitude (HVLA) thrust. If cavitation occurred on the first trial, the therapist moved to the next location. If there was no cavitation, the participant was repositioned, and the procedure was performed a second time. A maximum of 2 trials at each level on each side were performed yielding 4-8 HVLA thrusts. See Appendix 9 for handouts that were issued describing behavioral modification and exercise.

## *Group Two*

Treatment included suboccipital release (2 minutes), sham manipulation (5 minutes or less), behavioral modification (10 minutes) standardized as described above, and exercise (15 minutes) standardized as described above. Sham manipulation was performed in a similar supine position as noted above. Clinicians placed the participant in the manipulation position, stopping short of tissue tension, held for 15 seconds,<sup>150</sup> and repositioned to neutral or resting position.<sup>175,244,245</sup> A thrust was not performed and while cavitation could occur, it was rare and there was no expectation of cavitation. The participants in the sham group received 4 manual sham manipulation techniques, 1 at each of 4 locations.

Verbal instruction for cervical intervention was modeled after the cervical spine mobilization versus sham mobilization study by La Touche<sup>23</sup> et al in 2013. Therapists gave all participants the same verbal description, regardless of group assignment. Therapists said “I am going to apply a technique to your neck with my hands placed here. The purpose of this technique is to obtain change in your jaw and/or neck pain.”<sup>23</sup>

### *Specific Interventions: Suboccipital Release*

The patient was positioned supine for comfort. The therapist placed both hands on the posterior aspect of the neck, allowing the fingertips to sink into the space between the occiput and the spinous process of C2. The base of the head was supported with approximately 90° of flexion at the metacarpophalangeal (MCP) joints of fingers 2-4 on both hands (Figure 3.4).<sup>246</sup> The therapist allowed slight traction cranially. This technique was performed for 2 minutes<sup>69</sup> in all participants at each treatment session.

**FIGURE 3.4****SUBOCCIPITAL RELEASE***Specific Interventions: C0/1 Distraction Thrust Joint Manipulation*

The patient was positioned supine without a pillow. For C0/1 distraction TJM on the right side, the therapist would passively side-bend the head and neck to the right and rotate to the left. The first MCP joint of the right hand contacts the right mastoid process. The therapist passively moves the occiput into slight extension while maintaining left rotation. Slight traction is performed, and the right hand will direct the force of the TJM in a cranial direction, perpendicular to the surface of the right atlanto-occipital (C0/1) joint, with a gentle rotatory force (Figure 3.5).<sup>69,247</sup> The patient will be told to inhale and TJM will be performed after exhalation. This procedure will be repeated to the other side.

**FIGURE 3.5****C0/1 DISTRACTION THRUST JOINT  
MANIPULATION***Specific Interventions: C2/3 Upslope Thrust Joint Manipulation*

The patient was positioned supine for comfort. For C2/3 upslope TJM on the right side, the therapist used a cradle hold contacting the posterior right articular pillar of C2 with the lateral border of the proximal or middle phalanx. The left hand was under the head with the fingers spread out to maximize contact. The therapist passively moved the head and neck into right side-bending and left rotation with no significant degree of flexion or extension. The right hand directed the force of the TJM in a direction upward toward the patient's left eye (Figure 3.6).<sup>154,247</sup> This procedure was repeated to the other side.

**FIGURE 3.6****C2/3 UPSLOPE THRUST JOINT MANIPULATION**

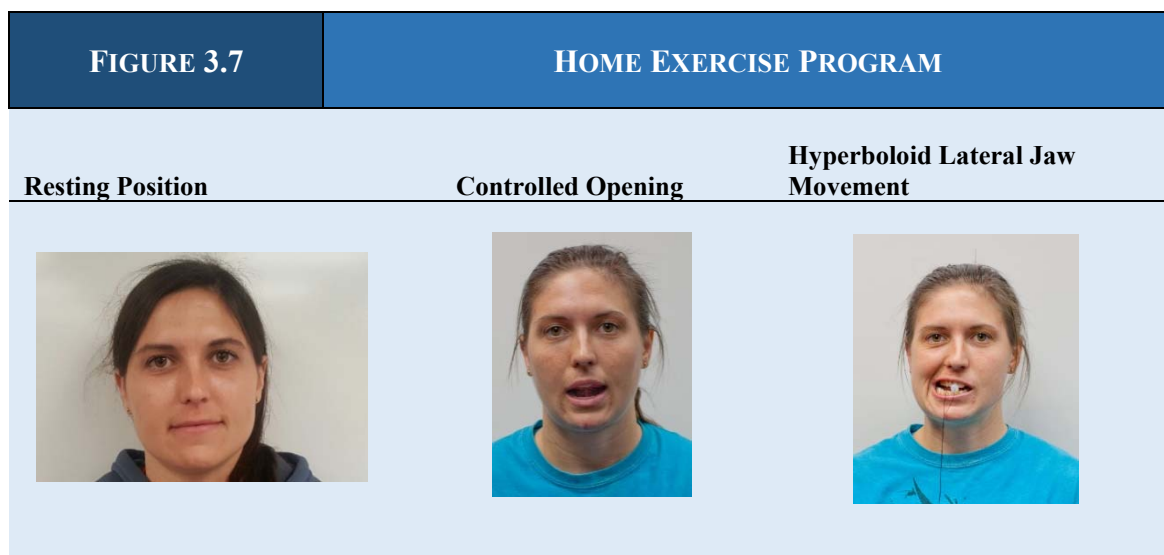
### *Specific Interventions: Behavioral Modification*

Behavioral modification is frequently part of pain management programs; as previously mentioned, this education is frequently utilized in the TMD population. All participants in this study were issued written instructions at their first visit and these instructions were reviewed by the evaluating therapist at each subsequent treatment visit. See Appendix 9. Participants were informed of modifications they could make daily to help control their pain. Participants were instructed to maintain the “lips together, teeth apart” position as often as possible to aide in masticatory muscle relaxation.<sup>84</sup> They were also educated to avoid parafunctional habits and chewing hard and tough foods. Suggestions for eating, minimizing stress, and getting a good night sleep were also included.<sup>9,14,102,103</sup>

### *Specific Interventions: Exercise*

The Rocabado 6x6 includes jaw, cervical and postural exercise. It has been utilized in practice and research;<sup>248</sup> while there is minimal evidence to support use, there are no comparative exercise studies to date. Lateral jaw movement training has been suggested in research and is utilized in clinical practice.<sup>103,249</sup> Lack of coordination with jaw motion has been reported in the TMD population as well.<sup>56</sup>

Participants in this study were instructed to perform 6 standardized exercises as part of their home exercise program (HEP). See Figure 3.7 and Appendix 9. They utilized a hyperboloid (small silicone material used by some clinicians in TMD practice) between the central incisors to perform small ROM lateral jaw movement to address this plane of motion as well as coordinative movement. Participants also performed the following exercises from the Rocabado 6x6: resting position of the jaw, controlled opening with tongue placed on the soft palate, scapular retraction, and C0/1 self-mobilization. The final exercise was the 3-finger exercise for active cervical spine rotation used in previous examination of individuals with neck pain.<sup>154,159</sup>





**C0/1 Self-mobilization****3 Finger Cervical Rotation****Scapular Squeeze**

Treating clinicians fully reviewed this home exercise handout with each participant. Clinicians described and demonstrated each exercise, then asked the participant to perform the exercise in front of them. After all exercises had been instructed, the therapist asked the patient to demonstrate each exercise again with as few verbal cues as necessary.

### **Full Descriptions of Each Visit**

#### *Visit 1: Baseline and First Treatment*

Informed consent was obtained followed by completion of self-report scales and the health record form. Clinicians reviewed this health record and completed objective evaluation excluding measurements taken by the blinded assessor. The initial goal was to screen for inclusion and exclusion criteria to ensure participants were eligible and safe to proceed. The blinded assessor entered the room to measure cervical ROM, jaw ROM, and PPT. The blinded assessor then left the area so that they could not hear or see which treatment group a patient had been randomized to. As noted above, suboccipital release, behavioral education, and exercise were standardized and consistent between groups. The first treatment provided to all participants was the suboccipital release/soft tissue work. *Group One* (cervical spine TJM group) received C0/1 and C2/3 TJMs as described previously. *Group Two* (minimal intervention group) received

sham manipulation (15 second hold before tissue tension) as described previously. After TJM/sham, all participants received education and instruction in the HEP utilizing the handouts for reference. Participants were given a chart to track compliance with the HEP. Blinded assessors then returned to take immediate response measurements. Final measurement of self-report NPRS and GROC were done at the completion of the visit.

#### *Visit 2: 1-Week*

Self-report scales were issued upon arrival. Measurements of cervical and jaw ROM and PPT were taken by the blinded assessor before intervention. Assessment included review of concerning symptoms, blood pressure and heart rate, and a general screen for nystagmus and vertebral artery. Barring no change in medical history or known contraindications, treatment began with 2 minutes of suboccipital release for both groups followed by cervical spine TJM or sham. All participants received review of behavioral education and home exercise instructions.

#### *Visit 3: 2-Week*

No measurement or self-report scale data was collected on this date. Assessment included review of concerning symptoms, blood pressure and heart rate, and a general screen for nystagmus and vertebral artery. Barring no change in medical history or known contraindications, treatment began with 2 minutes of suboccipital release for both groups followed by cervical spine TJM or sham. All participants received review of behavioral education and home exercise instructions.

#### *Visit 4: 4-Week*

No prescribed treatment was performed on this date, only assessment. Self-report scales were issued upon arrival. Measurements of ROM and PPT were taken by the blinded assessor.

Clinicians debriefed participants explaining the intent of the research study, group allocation, and

potential impact of results. Continued treatment frequency, duration, and intervention plan were at the discretion of the treating clinician. Referral to another provider (medical, dental, or other) was done on this date if needed.

### **Sample Size Estimation/Power Analysis**

Sample size estimations were completed before data collection began using G-Power, a free online downloadable program. An F-test family with analysis of variance (ANOVA): Repeated measures, within-between interaction protocol was selected. While it is optimal to power sample size estimations around a functional outcome measure, the limited use of functional measures in this population created an obstacle. One study by Mulla<sup>106</sup> et al utilized JFLS to assess differences between conventional PT (not well described) and the Rocabado exercise program with temporomandibular mobilization. The between group effect size reported for JFLS was  $d = 0.55$ .<sup>106</sup> Another study by Cuccia<sup>152</sup> et al utilizes an index that rates disability, however, this index is time consuming and not clinically applicable. In general, studies utilizing functional outcome tools had small sample sizes and/or large effect sizes, yielding smaller sample size estimations for this research project.

Examination of effect sizes surrounding mouth opening were examined next. Mouth opening is the most frequently reported objective outcome related to TMD and an important consideration in temporomandibular function. Mouth opening effect sizes ranged from  $d = 0.22$  to 2.08. PPT is another commonly reported outcome in TMD related research. An examination of this outcome in a relevant study of upper cervical spine mobilization versus sham mobilization in TMD patients demonstrates effect sizes ranging from  $d = 1.040$  to 2.129.<sup>23</sup>

One study analyzed 50 participants (25 per group) comparing multimodal intervention of cervical spine TJM, myofascial soft tissue work, and muscle energy techniques to oral appliances, PT muscle stretching, relaxation exercises, and modalities.<sup>152</sup> This study found a large effect size ( $d=1.01$ ) for mouth opening at 6 months favoring the cervical TJM group. Another study compared mobilization of the upper cervical spine to sham mobilization following patients for 2 weeks.<sup>23</sup> Large effect sizes were seen for pain (Visual Analogue Scale) and PPT favoring the mobilization group.

Several studies related to TMD intervention (cervical or other) did not report effect sizes but did provide enough information for these to be calculated. Other studies did not report or provide adequate detail to allow for calculation. Table 4 below summarizes outcomes relevant to this study as well as estimates of effect size. A \* indicates the effect size was calculated by the PI of this project due to lack of description provided in the article. The last column represents the suggested sample size for this RCT based on calculations.

TABLE 3.3		REPORTED AND CALCULATED EFFECT SIZE ESTIMATES AND SAMPLE SIZE ESTIMATIONS				
Author	Sample	Comparison Intervention	Time of Data Collection	Outcome	Effect Size	Total Sample Size Estimate
Heredia-Rizo	24 per group, Healthy	RCT: Soft tissue mobilization vs sham mobilization	Immediate response: 5 minutes	PPT, T1	-0.4288*	12
Cuccia	25 per group, TMD dx	RCT: osteopathic multimodal intervention (including HVLA thrust) to neck/jaw vs oral appliance, stretching, relaxation, and modality	6 months	MMO	1.01*	4
			6 months	VAS	1.41*	4
LaTouche, 2013	16 per group, TMD	RCT: upper cervical mobilization vs sham mobilization	2 weeks	PPT, M1	-2.13 Right* -2.05 Left*	4

				VAS	-1.01 to -2.59	4
Mansilla-Ferragut	18 treat, 19 placebo, Primary c/o neck pain but did have limited MMO	RCT: C0/1 manipulation vs sham (contact) manipulation	Immediate response, 5 minutes	MMO	Authors report within group effect 1.5 manip and 0.5 sham  Between group effect: 2.08*	4-10
Oliveira-Campelo	40-42 per group, no pain or dx but + latent trigger points	RCT: 3 groups. C0/1 manipulation, soft tissue mobilization, and no intervention	Immediate response	MMO	0.22	36
				PPT, M	0.28	24
Mulla	15 per group, TMD	Rocabado exercise vs conventional exercise	2 weeks	Jaw ROM	0.360	16
				JFLS	0.55	8
<p><i>Abbreviations: RCT, randomized controlled trial; PPT, pressure pain threshold; TI, temporalis 1; TMD, temporomandibular disorder; dx, diagnosis; HVLA, high velocity low amplitude; MMO, maximal mouth opening; VAS, visual analogue scale; M1, masseter 1; C0/1, atlanto-occipital joints; M, masseter; JFLS, Jaw Functional Limitation Scale.</i></p> <p><i>*Hand calculated and confirmed with online software calculating Cohen d (Program: <a href="http://www.campbellcollaboration.org/escalc/html/EffectSizeCalculator-SMD1.php">http://www.campbellcollaboration.org/escalc/html/EffectSizeCalculator-SMD1.php</a>)</i></p>						

After completing the above sample size estimations, a decision was made to power recruitment around MMO as this most closely relates to function in the TMD population. The PI thought that if a large effect size was seen for MMO, it would be likely that there would be enough subjects to adequately power an analysis of functional outcome measures (TMD Disability index or JFLS) as well. Given the limited evidence to consider, a conservative decision was made to utilize the effect size yielding the largest sample size requirement even though this study examined immediate effects. Oliveira-Campelo<sup>69</sup> et al examined 122 participants with latent trigger points in the orofacial muscles. Participants in this study received 1 of 3 interventions: C0/1 TJM, soft tissue treatment, or no intervention. The reported effect size related to mouth opening was  $d=.22$ . Using the F-test family, a repeated measures within-

between subject interaction statistical test, alpha .05, and desired power of .8, 36 participants will be necessary. PEDro scale quality assessment states outcomes should be attained for more than 85% of the subjects initially allocated to groups.<sup>250</sup> In order to account for 15% attrition,<sup>251,252</sup> and maintain equal participants in each arm of this study, the desired sample size was 42 participants. The initial goal was to enroll 42 participants. Data was collected by 2 clinicians and because of a miscommunication, more participants were enrolled and the final sample size was 50 participants.

### **Patient Remuneration**

Patient recruitment and full participation are essential to the success of clinical trials. Grant funding allowed participant incentives of \$50. If participants were willing to provide information including name, date of birth, and social security number, Bradley University mailed them a \$50 check after the 4-week visit. If a participant was an employee of Bradley University, the controller's office asked that the money be added to the employee's direct deposit as opposed to sending a separate check. If a participant was an employee of BU, they were informed of this process. The personal health information necessary for payment is a requirement of Bradley University Accounting and Sponsored Programs departments. Participants interested in receiving the \$50 stipend received a self-addressed and stamped envelope containing a form to collect necessary information. Participants were instructed to fill out the form and personally seal the envelope without providing this information to anyone on the research team or at the clinic. Both the PI and the Director of Bradley University Sponsored Programs worked together to ensure integrity of funding. Participants at UNLV were entered into this study if they did not meet eligibility for a cervical spine CPR validation study and wished to participate in this study

instead. UNLV did not allow sharing of any of the necessary PHI; therefore, these participants could not receive the incentive.

### **Clinician Remuneration**

Treating therapists were required to participate in training to ensure maximal consistency, efficiency, and reliability. Training was provided by the PI. Treating therapists, who were considered independent contractors for the project, participated in a 5-hour training session to review and standardize evaluation and treatment procedures and will be paid for their time. The treating therapists were paid a stipend of \$250 per therapist for the live training and paid for their time in completing CITI training. The treating therapist at UNLV declined compensation.

Blinded assessors were required for data collection purposes in this study. The blinded assessors were required to participate in a 4-hour training session, provided by the PI, to ensure maximal consistency, efficiency, and reliability of measurements for ROM and PPT. Blinded assessors were paid a stipend of \$175 for this training. Blinded assessors traveled to data collection locations to take measurements at each data collection point. The assessors were paid on a per-session basis (\$40/session for the first visit as it requires 2 measurements and \$30/session for subsequent visits with only 1 measurement) for the data collection to cover time for driving and measurement. Compensation was declined by assessors at UNLV.

### **Risks**

Risks associated with cervical spine TJM are minimal, and the examination and treatment procedures utilized in this study are routinely used by physical therapists. Thrust and non-thrust mobilizations are a routine intervention in orthopaedic clinical PT practice and considered an entry-level skill. Under the Illinois and Nevada Physical Therapy Acts, physical therapists are

licensed and qualified to perform these techniques. Recommendations for evaluation and screening provided by the International Federation of Orthopaedic Manipulative Physical Therapists (IFOMPT)<sup>253</sup> were followed to minimize the potential risk.

It is possible that participants who receive manual therapy to their neck will experience mild muscle soreness, fatigue, or headache after the procedure is performed.<sup>154,254</sup> However, this soreness typically resolves within 1-48 hours after the procedure.<sup>154</sup> Risk was minimized by training for standardization of evaluation/screening procedures, and utilization of standardized cervical spine TJM techniques. In accordance with CONSORT guidelines,<sup>185</sup> side effects and adverse events were recorded and are detailed in Chapter 4. See Appendix 7 for side effect record form.

### **Age, Gender, and Ethnic Considerations**

Recruitment of participants, clinicians, blind assessors, and research assistants for this study will include individuals over the age of 18. While exclusion criteria was closely monitored for safety, no individuals were otherwise excluded based on gender, race, ethnicity, religion, national origin, sexual orientation, disability, or health status.

### **Informed Consent/Institutional Review Board (IRB) Approval**

This research project was approved by Bradley University IRB (CUHSR 59-16) and an Institutional Authorization Agreement was signed by Nova Southeastern University noting Bradley University would be the Designated IRB. Informed consent was attained by all participants prior to participation in the study. See Appendix 4 for IRB documentation and Appendix 5 for the approved Informed Consent.



### **Data Safety Monitoring Plan/ Subject Confidentiality**

The PI was responsible for educating all clinicians, research assistants, and front office staff with RVPT, BU, and UNLV in confidentiality measures and data safety plans. This information was part of the live training and included in the Manuals of Standard Operating Procedures. The PI also periodically checked in (in person or over the phone) with each participating clinician, blinded assessor, and clinic office staff member to review procedures and monitor recruitment and retention.

HIPAA training is required and completed by all RVPT clinicians and staff; therefore, these individuals are already familiar with protecting confidential information. Any documentation of outcomes was stored in a locked file cabinet at the sites of data collection. Only those directly involved in this research project and trained in data safety had access to the cabinet. A case number was assigned to each folder and any electronic sharing of information only included the case number. Personal health information was not shared or transmitted electronically.

### **Assurance of Data Integrity**

Folders were issued to participating locations and included standardized forms for documenting outcomes. Self-report measures were included in this folder and marked by visit date to ensure they were completed on the correct days. Individual forms marked with visit date were used to record measurements taken by the blinded assessor. All forms were completed on the day of the data collection visit and remained in the locked cabinet.

When a participant completed the 4-week visit, the forms in their folder were copied and hard copies mailed to the PI. Once the PI received the hard copies, the clinic would shred copied

pages and any remaining documentation of study materials. All data was entered into a computer database to be used for analysis. Data was entered by a research assistant and verified by another research assistant who would double check score totals and all data entry. Data was backed up frequently to a cloud-based storage system.

### **Funding and Financial Support for the Study**

Bradley University (BU) employs the PI and provided support of time and supplies for research activity. BU also shared existing resources available within the department. Nova Southeastern University gave support in the form of scheduled and unscheduled mentoring of preparatory writing, IRB processes, methods and procedures, data analysis, and oral defense.

Funding was required to support recruitment, training, and adherence to protocol for this research project. The PI received internal grant funding of \$10,000 from BU to support a summer stipend, participant incentives, clinician and blinded assessor training, blinded assessor time for measurements, and supplies (algometers, inclinometers, disposable jaw ROM tools, printing and mailing supplies, and hyperboloids to be used for exercise). The PI also applied for additional external funding through the Orthopaedic Section of the American Physical Therapy Association (APTA) and the American Academy of Orthopaedic Manual Physical Therapists (AAOMPT) Cardon Foundation. Neither grant application was funded. Additional funding was requested, and the PI did receive a second internal grant from Bradley University's Education and Health Sciences College, for \$1,200 as well as \$1,000 from an external grant funded by the Illinois chapter of the APTA. In total, \$12,200 in grant funding was awarded for this project. Both the PI and the Director of Bradley University Sponsored Programs worked together to ensure integrity of fund use throughout this project.

## Summary

This chapter outlined the methodology used in this project. All decisions made in planning were thoroughly researched for evidence-based support and discussed with the dissertation chair and committee members. The chapter outlined detail of those contributing to the project, training involved, and specific design methods while including information about background protection of data and funding.

## CHAPTER 4: RESULTS

### Introduction

This chapter presents results of data analysis for Thrust Joint Manipulation to the Cervical Spine in Participants with a Primary Complaint of Temporomandibular Disorder (TMD): A Randomized Clinical Trial. Descriptions of clinicians, blinded assessors, and participants are included. Results of an interrater reliability analysis during training and baseline group comparisons are reported.

All statistical analyses were performed using SPSS version 23 and a significance level of  $\alpha = 0.05$ . The primary aim of this dissertation study was to assess group differences at 4-time intervals: baseline, immediate response, 1-week, and 4-weeks. Participants were seen for 4 visits (baseline, 1-week, 2-week, and 4-week) and measurements were taken at baseline, immediately post treatment, 1-week, and 4-weeks. The primary outcome of interest was the group\*time interaction. Groups were compared over time for pain, range of motion (ROM), pressure pain threshold (PPT), neck and jaw function, and fear. Participants were dichotomized into success and non-success using the Global Rating of Change (GROC) and Patient Acceptable Symptom State (PASS). Number needed to treat (NNT) was calculated in statistically significant successes. Reported side-effects of treatment are summarized.

One secondary aim of the dissertation study included correlations of the following data: jaw pain and function with neck pain and function, pressure pain threshold at the jaw and a remote site, changes in measured outcomes and functional score changes. Another secondary aim was to examine the functional outcome tools specific to jaw dysfunction: TMD Disability Index (TMD-DI) and Jaw Functional Limitation Scale (JFLS). These outcome tools have been

used in temporomandibular disorder (TMD) research but not studied for psychometric property analysis within physical therapy.

### **Clinicians**

Four clinicians, including the principal investigator (PI), were trained in evaluation and treatment procedures during a 5-hour training session described in Chapter 3. A Manual of Standard Operating Procedures (MSOP) and videos for review were shared with each clinician. One clinician did not finish the Collaborative Institutional Training Initiative (CITI) program after the live training session; therefore, he did not collect data. Another clinician was ready and able to collect data, however, there were no participants interested in coming to her location. Therefore, 2 clinicians participated in data collection. Both of these clinicians held post-professional doctorate degrees in physical therapy and were Fellows of American Academy of Orthopaedic Manual Physical Therapists (FAAOMPT); both utilize thrust joint manipulation (TJM) regularly in both clinical practice and teaching. One treating clinician, the PI, was female, age 39, with 17 years of clinical experience and 4 years teaching experience in a DPT program. The other clinician, a 60 year-old male, had 38 years of clinical experience and 18 years teaching experience in both a DPT program and continuing education programs for physical therapists.

### **Blinded Assessors**

Eleven blinded assessors were trained in data collection methods and participated in a study of interrater reliability during the 5-hour training session described in Chapter 3. The reliability analysis included measurement of PPT at the right masseter, maximal pain-free mouth opening (MMO), cervical flexion, and cervical right rotation in 10 participants. Intraclass correlation coefficients (ICC) were assessed for each measurement using two-way random

effects and consistent agreement (See Table 4.1). Results showed excellent agreement for PPT and good agreement for other measurements.<sup>255</sup>

TABLE 4.1	BLINDED ASSESSOR INTERRATER RELIABILITY: INTRACLAS CORRELATION COEFFICIENT	
Measurement	ICC (2,1)	95% CI
PPT masseter; right	0.936	0.870-0.979
MMO	0.620	0.411-0.842
Cervical flexion	0.675	0.474-0.871
Cervical rotation; right	0.716	0.525-0.890
<i>Abbreviations: ICC, intraclass correlation coefficients; PPT, pressure pain threshold; MMO, maximal mouth opening.</i>		

Blinded assessors were present to measure participants at 3 of the 4 visits (no measurements were scheduled at the 2-week visit). Given 50 total participants, there was a total of 150 data collection or measurement visits. On 3 occasions (3/150, 2% of the measurements), there was no blinded assessor available and the treating clinician (PI in all cases) measured and recorded the data. This situation occurred for 3 different participants (2 in the sham group and 1 in the manipulation group), and only 1 measurement per participant.

## Subjects

### *Participant Characteristics*

Data collection began on 10/18/17 and ended on 10/4/18. A total of 83 participants were screened for eligibility; 50 participants met eligibility requirements and noted interest in participation. Participants were treated in one of four locations: Rock Valley Physical Therapy (RVPT) in Washington, IL (n=1), RVPT in Peoria, IL (n=8), Bradley University in Peoria, IL (n=33), and UNLV in Las Vegas, NV (n=8).

A total of 33 participants were excluded for the following reasons: pain  $<2$  on NPRS (n=13), cervical manipulation in the last 3 months (n=7), primary pain location was not the jaw (n=3), inability to comply with treatment schedule (n=2), concurrent dental (n=3) or PT intervention (n=1), contraindications to manipulation (n=3), and age  $< 18$  (n=1). The contraindications to manipulation included a fear of manipulation noted after reading informed consent, unexplained neurological findings including facial paresthesia and paresthesia in all 4 limbs (seeking neurological evaluation concurrently), and facial paralysis due to meningioma.

All 50 participants were scheduled for 4 visits (200 total visits) and no participants dropped out of the study. Two participants missed a single visit due to illness (2/200, 1% visits missed). One of the missed visits was a 1-week (measurement) and the other was a 2-week (no measurement). Data for the participant who missed a measurement visit were entered using last observation carried forward; this was the 1-week visit, therefore the data from baseline were carried forward to 1-week. This participant was present for the third and final measurement visit. See Flow Diagram, Figure 4.1.

#### *Baseline Group Variables*

Demographic information was collected on the Health History Form and during the baseline examination. Forty-three of the participants enrolled were female (43/50, 86%). All participants had myalgia as confirmed by Diagnostic Criteria for Temporomandibular Disorders (DC/TMD): pain located in a masticatory muscle, pain with palpation of the masseter and/or temporalis, pain with opening, and the patient's symptoms of pain or primary complaint were reproduced with palpation or opening of the mouth.<sup>35</sup> Study participants had a mean age of  $35.5 \pm 13.4$  years and mean duration of symptoms for  $72.3 \pm 84.2$  months (6.03 years). Symptom duration ranged from 1 to 360 months; most participants (43/50, 86%) experienced chronic pain

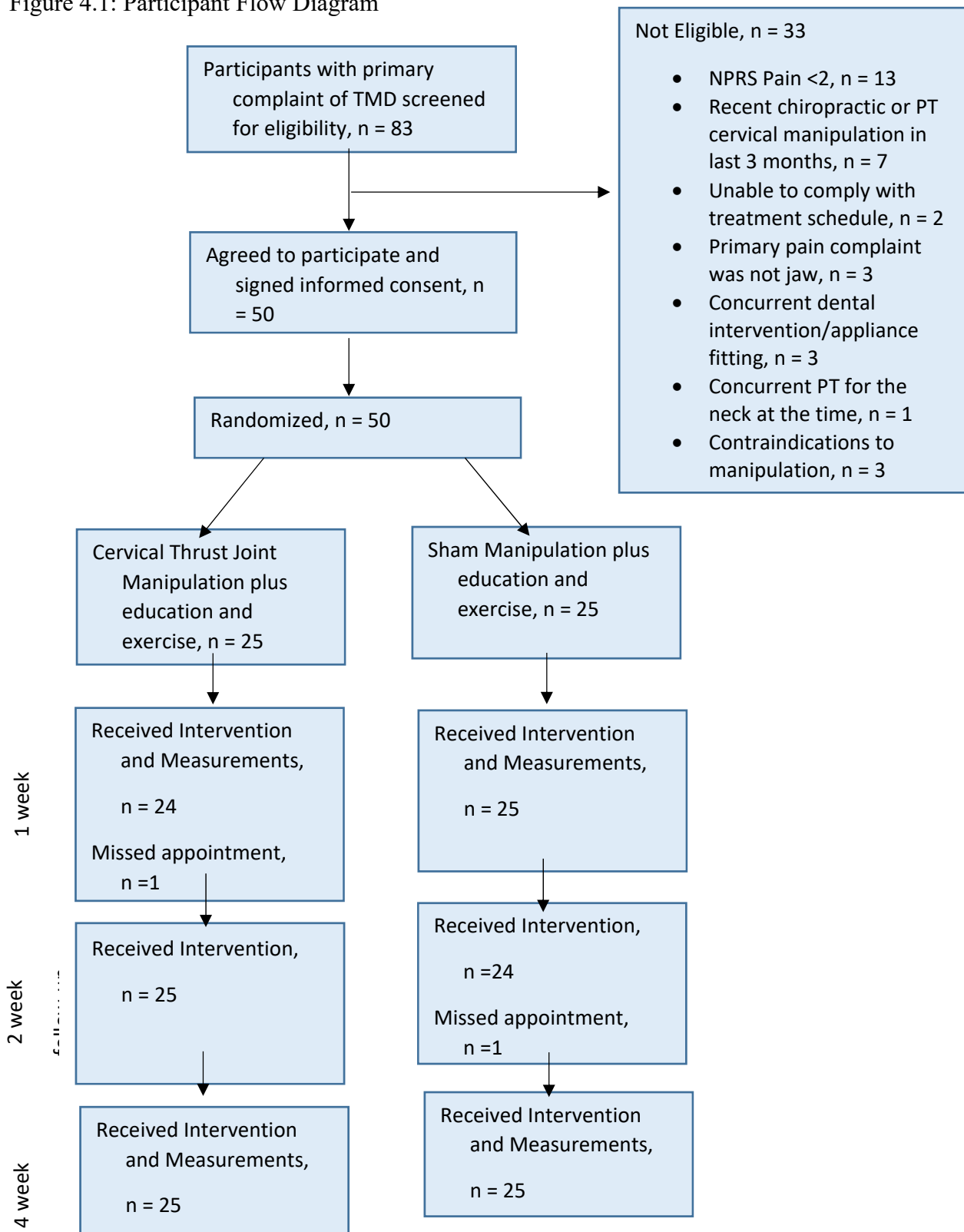
of >3-month duration. In those participants with pain duration  $\leq 3$  months, 4 were in the thrust group and 3 in the sham group.

Most baseline continuous level data met the assumption of normality with a couple violations. A decision was made to run the parametric independent sample *t*-test to assess group differences at baseline, as this test is robust enough to handle violations of normality.<sup>256,257</sup> A non-parametric Mann-Whitney U test was also run to ensure the violation did not impact statistical significance and the results were unchanged. A chi-square test was used to examine group differences for the categorical variable, gender. Groups were similar at baseline in all characteristics excluding left lateral deviation of the jaw ( $p = .023$ ); the thrust manipulation group had more left lateral deviation than the sham group. See Table 4.2 for descriptions of the entire sample and group baseline differences.

It should be noted that the PPT values at baseline for the first dorsal interossei in the 8 participants seen at UNLV were considerably higher than those of other participants. This trend carried forward at subsequent measurement visits. There were 4 participants in each group (sham and thrust joint manipulation) yielding non-significant differences between groups, however, the mean and standard deviation (SD) noted below were impacted by this difference. While not reported below, another analysis excluding these 8 values was performed, yielding mean values around 1.5 to 2.5 kg with much smaller SD (0.78 - 1.5 kg). Another independent samples *t*-test was run to ensure groups were similar with this data excluded, and the result for all PPT values was the same; all *p* values were non-significant indicating similarity at baseline. The data presented in Table 4.2 below includes all data recorded, including these 8 values.



Figure 4.1: Participant Flow Diagram



Abbreviations: TMD, Temporomandibular Disorder; NPRS, Numeric Pain Rating Scale; GI, Gastrointestinal

TABLE 4.2		BASELINE DEMOGRAPHICS, SELF-REPORTED VARIABLES, AND CHARACTERISTICS OF PARTICIPANTS BY GROUP <sup>o</sup>		
Variable	Entire Sample	Thrust Cervical Group	Sham Cervical Group	P Values <sup>§</sup>
Age, y	35.5 ± 13.4	32.2 ± 11.3	38.8 ± 14.8	.082
Gender (female), n (%)	43 (86)	20 (80)	23 (92)	.417 <sup>¶</sup>
Duration, mo	72.3 ± 84.2	81 ± 99.2	63.7 ± 67	.475
TMD Screen Score	3.2 ± 0.6	3.2 ± 0.6	3.2 ± 0.7	.663
Avg NPRS sum scores				
Jaw	3.7 ± 1.5	3.7 ± 1.5	3.7 ± 1.5	.924
Cervical	3 ± 2.4	2.9 ± 2	3.1 ± 2.7	.783
Headache	2.1 ± 1.7	2.2 ± 1.7	2 ± 1.7	.660
JFLS	47.4 ± 35.5	45.3 ± 30.4	50.2 ± 40.5	.635
NDI	21.1 ± 12.6	19.4 ± 9.5	22.8 ± 15	.350
TMDDI	20.7 ± 4.8	20 ± 4.1	21.4 ± 5.4	.298
TSK-TMD	27.7 ± 5.7	27.3 ± 5.6	28.2 ± 5.8	.606
BMI	26.2 ± 5.2	25.7 ± 5	26.7 ± 5.5	.497
Jaw range of motion, mm				
MMO	37.5 ± 5.9	37.8 ± 5.1	37.2 ± 6.7	.707
Lateral deviation; right	7.4 ± 2.7	7.2 ± 2.9	7.5 ± 2.5	.715
Lateral deviation; left	8.8 ± 3.5	9.9 ± 3	7.6 ± 3.7	.023*
Cervical range of motion, deg				
Flexion	59 ± 12.7	61.7 ± 12.6	56.4 ± 12.5	.140
Extension	57.1 ± 13.9	57.7 ± 14.2	56.5 ± 13.8	.764
Rotation; right	74.5 ± 12.9	76 ± 9.1	73 ± 15.9	.409
Rotation; left	76.5 ± 12.9	76.4 ± 9.5	76.6 ± 14.2	.935
Pressure pain threshold, kg				
Masseter; right	1.66 ± 0.85	1.68 ± 0.85	1.65 ± 0.86	.904
Masseter; left	1.59 ± 0.88	1.62 ± 0.94	1.56 ± 0.84	.812
Temporalis; right	1.92 ± 0.89	1.92 ± 0.89	1.92 ± 0.91	.989
Temporalis; left	1.90 ± 0.96	1.94 ± 1.06	1.86 ± 0.86	.779
1 <sup>st</sup> dorsal interossei; right	7.03 ± 10.47	7.24 ± 11.32	6.82 ± 9.77	.889
1 <sup>st</sup> dorsal interossei; left	6.89 ± 10.40	7.17 ± 11.12	6.61 ± 9.85	.852
<p>Abbreviation: y, years; mo, months; avg, average; TMD, temporomandibular disorder; NPRS, Numeric Pain Rating Scale; JFLS, Jaw Functional Limitation Scale; NDI, Neck Disability Index; TMDDI, Temporomandibular Disability Index; TSK-TMD, Tampa Scale for Kinesiophobia for Temporomandibular Disorder; BMI, body mass index; MMO, maximal mouth opening, pain free.</p> <p><sup>o</sup>Values are mean ± SD unless otherwise indicated.</p> <p><sup>§</sup>Values are independent sample t-test unless otherwise indicated.</p> <p><sup>¶</sup>Value is a chi-square test and was a non-significant correlation.</p> <p>*Statistically significant.</p>				

### Primary Aim: Group Differences

A 2 x 4 mixed model analysis of variance (ANOVA) was utilized to compare both within-group and between-group changes over the 4 measurements periods for all continuous level data. Treatment group (sham or thrust joint manipulation) was the between-subjects factor and time was the within-subjects factor. Separate ANOVAs were performed for dependent variables and the hypothesis of interest was the group by time interaction for each ANOVA and subsequent main effects or simple main effects.<sup>257,258</sup> A repeated measures ANOVA is robust enough to handle violations of normality; however, violations of homogeneity of variance/covariance and sphericity are considered more serious.<sup>256,257</sup> Decisions made in the presence of violations of assumptions are explained. The assumption of sphericity was frequently violated, therefore, the Greenhouse-Geisser correction was utilized for interpretation in those cases.<sup>257,258</sup> Mean, standard deviation (SD) and/or 95% confidence interval (CI), change score, and between group change was calculated for each variable and is presented in a chart format below. Partial eta squared (partial  $\eta^2$ ) was provided as a measure of effect size from SPSS and was translated into Cohen d in each table below.<sup>259</sup>

The assumption of normal distribution of data was completed using Shapiro-Wilk's test and outliers were examined visually on box plots as well as through the use of studentized residuals. If outliers were noted, data records were double checked for mistakes in data entry. When outliers remained in the presence of violations of normal distribution, data were transformed if there was significant skewness.<sup>258</sup> Following standard transformation procedure, if data were transformed for one level of a measurement, transformation occurred across that measurement through time and group; all analyses were then run again.<sup>257,260</sup> For most of these transformations, the results regarding violations of assumptions did not change, with the

exception of 2 variables, the Jaw Functional Limitation Scale (JFLS) and Tampa Scale for Kinesiophobia for Temporomandibular Disorders (TSK-TMD). In these cases, interpretation was based on transformed data. If violations remained after transformation, a non-parametric analysis was compared. There is no direct non-parametric alternative to the mixed ANOVA; therefore, any non-parametric testing could only look at the within-group change separate from the between-group change, unable to capture the interaction effect.<sup>258</sup> If no change was noted after transformation with or without use of a non-parametric test, the results of the mixed ANOVA were reported.

Independent *t*-test analysis was used to compare groups in change scores<sup>261</sup> for each variable and those statistically significant values are reported below in each chart. If the between-group change score was statistically significant and the data violated assumptions, a Mann-Whitney U was also run to ensure the violations were not leading to Type I error.<sup>257</sup>

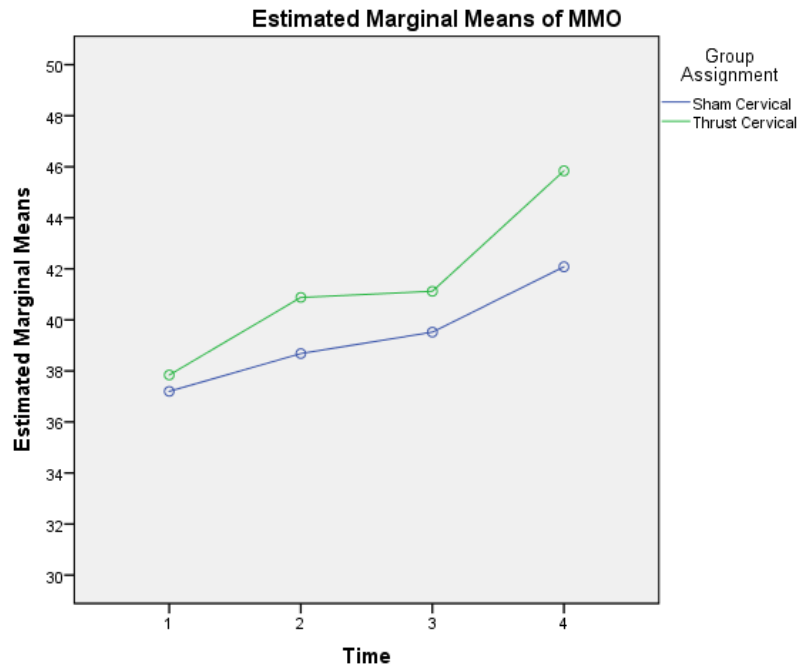
#### *Jaw Range of Motion: Maximal Mouth Opening*

Maximal mouth opening (MMO) was normally distributed across all time intervals and group as assessed by Shapiro-Wilk's test ( $p > .05$ ). There were three outliers noted on the box plots; however, no outliers, as assessed by examination of studentized residuals for values greater than  $\pm 3$ . There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .05$ ), and homogeneity of covariance, as assessed by Box's test of equality of covariance matrices ( $p = .019$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 20.625$ ,  $p = .001$ . Greenhouse-Geisser correction was utilized for interpretation.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of maximal pain-free mouth opening,  $F(2.372, 113.869) = 1.293$ ,  $p = .28$ , partial  $\eta^2 = .026$ . While there were no group\*time interactions, there were statistically significant main effects for time,  $F(2.372, 113.869) = 21.501$ ,  $p < .001$ , partial  $\eta^2 = .309$ . Maximal mouth opening increased from baseline to each subsequent point in time and each change was statistically significant. MMO increased for the sample from  $37.52 \pm 5.936$  mm at baseline to  $43.96 \pm 8.79$  mm at the final visit, a statistically significant difference of 6.44 (95% CI, 3.73 to 9.15) mm,  $p < .001$ . While both groups started at 37 mm of opening, the final measurement was  $42.08 \pm 0.05$  mm for the sham group and  $45.84 \pm 8.28$  mm for the thrust manipulation group.

The main effect of group showed no statistically significant difference in maximal mouth opening between groups  $F(1, 48) = 1.075$ ,  $p = .305$ , partial  $\eta^2 = .022$ . Overall, both groups showed improvement in mouth opening, however, there were no statistically significant group differences to report. See Figure 4.2 and Table 4.3 for further detail.

Figure 4.2: Maximal Mouth Opening, pain-free



#### *Jaw Range of Motion: Jaw Lateral Deviation Right*

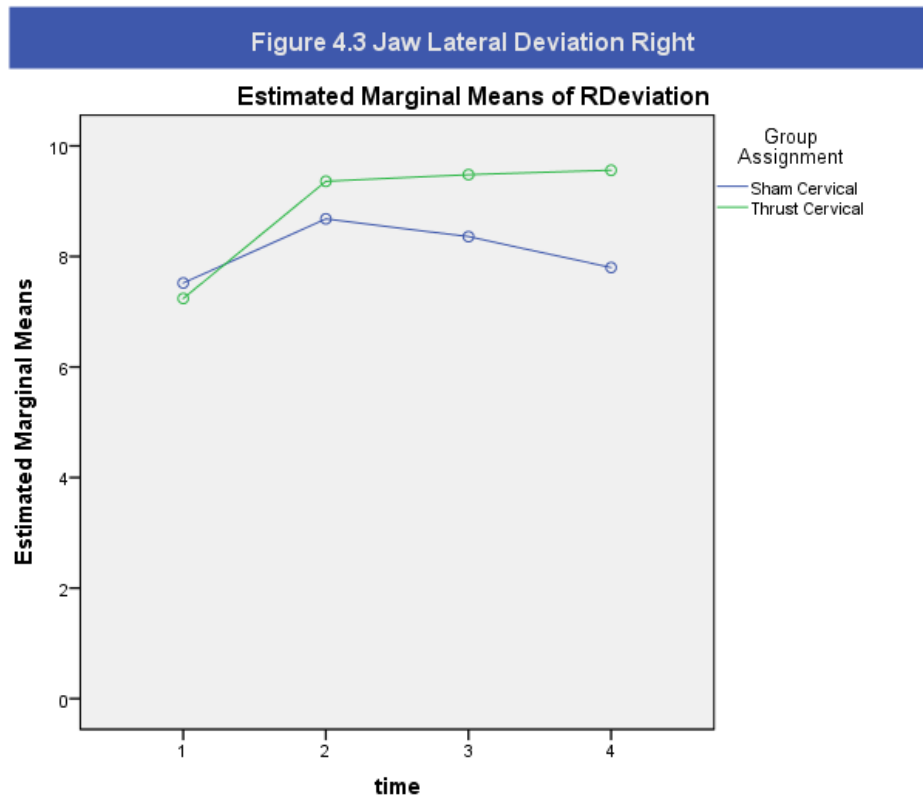
Jaw lateral deviation right was normally distributed across all time intervals and group as assessed by Shapiro-Wilk's test ( $p > .05$ ) with the exception of 4-week right deviation in both groups. There were multiple outliers in the thrust manipulation group and no outliers noted in the sham group on box plots; however, there were no outliers, as assessed by examination of studentized residuals for values greater than  $\pm 3$ . There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .05$ ), and homogeneity of covariance, as assessed by Box's test of equality of covariance matrices ( $p = .731$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 21.707, p = .001$ . Greenhouse-Geisser correction was utilized for interpretation.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of right lateral deviation,  $F(2.266, 108.744) = 2.721, p =$

.063, partial  $\eta^2 = .054$ . While there were no group\*time interactions, there were statistically significant main effects for time,  $F(2.266, 108.744) = 8.565$ ,  $p < .001$ , partial  $\eta^2 = .151$ .

Measurements were  $7.52 \pm 2.485$  mm at baseline, with statistically significant increase to  $9.05 \pm 2.591$  and  $8.92 \pm 2.702$  mm at immediate post-treatment and 1-week, respectively.

The main effect of group showed no statistically significant difference in right lateral deviation between groups  $F(1, 48) = 1.698$ ,  $p = .199$ , partial  $\eta^2 = .034$ . Right lateral deviation improved in both groups over time. Subsequent analysis looked at mean difference or change scores between groups. An independent  $t$ -test showed a statistically significant difference in mean change scores between groups for right lateral jaw deviation from baseline to final measurement,  $t(48) = 2.11$ ,  $p = .04$ , favoring the thrust manipulation group. See Figure 4.3 and Table 4.3 for further detail.



### *Jaw Range of Motion: Jaw Lateral Deviation Left*

Jaw lateral deviation left was normally distributed across all time intervals and group as assessed by Shapiro-Wilk's test ( $p > .05$ ) with the exception of 1-week left deviation in the thrust manipulation group. There were no outliers as assessed by box plots for this variable, and no outliers noted with examination of studentized residuals for values greater than  $\pm 3$ . There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .05$ ), and homogeneity of covariance, as assessed by Box's test of equality of covariance matrices ( $p = .686$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 27.442$ ,  $p < .001$ . Greenhouse-Geisser correction was utilized for interpretation.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of jaw deviation left,  $F(2.280, 109.421) = 0.939$ ,  $p = .404$ , partial  $\eta^2 = .019$ . While there were no group\*time interactions, there were statistically significant main effects for time. Statistically significant improvements were seen in left lateral deviation,  $F(2.280, 109.421) = 3.542$ ,  $p = .027$ , partial  $\eta^2 = .069$ . Left lateral deviation increased from  $8.76 \pm 3.532$  mm at baseline to  $10.06 \pm 3.594$  mm at 4-weeks.

The main effect of group showed a statistically significant difference in left lateral deviation between groups  $F(1, 48) = 5.904$ ,  $p = .019$ , partial  $\eta^2 = .110$ . A mean difference of 1.860 (95% CI .321-3.399) mm was present at 4-weeks and favored the thrust group; however, a similar mean difference was present at baseline (statistically significant difference between groups). Overall left lateral deviation improved in both groups over time and greater change was seen in the sham group; the thrust manipulation group had more left lateral deviation at baseline



and throughout subsequent measurement periods, but there was no statistically significant difference between groups. See Figure 4.4 and Table 4.3 for further detail.

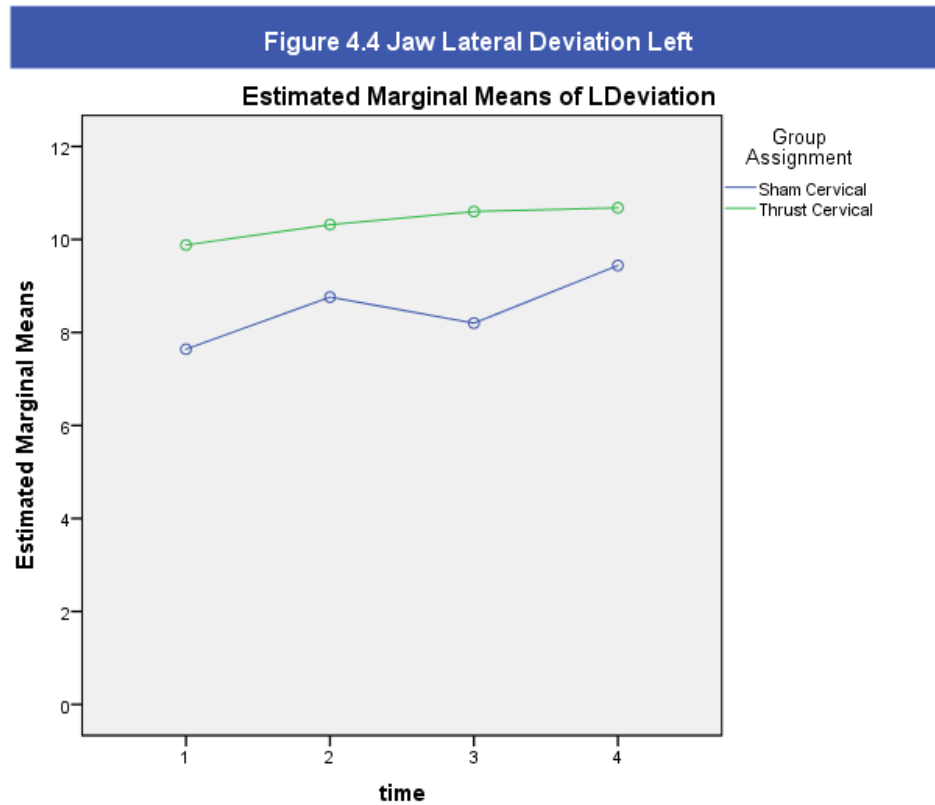


Table 4.3	JAW RANGE OF MOTION: WITHIN-GROUP AND BETWEEN-GROUP CHANGE				
Measurement	Cervical Thrust Group*	Cervical Sham Group *	Between-Group Difference**	P value	Effect Size
MMO (mm)				.28^	0.33
Baseline	37.84 ± 5.1	37.2 ± 6.7			
Immediate	40.88 ± 7.2	38.68 ± 7.8			
Change from baseline to immediate	3.04 ± 5.4	1.48 ± 3.2	1.56 (-0.9-4.1)	.220°	0.35
1 wk	41.12 ± 10.0	39.52 ± 7.4			
Change from baseline to 1 wk	3.28 ± 8.3	2.32 ± 4.6	0.96 (-2.87-4.79)	.615°	0.14
4 wk	45.84 ± 8.3	42.08 ± 9.0			
Change from baseline to 4 wk	8.0 ± 7.2	4.88 ± 6.7	3.12 (-0.84-7.08)	.12°	0.45
Collapsed across time: Baseline to 4 wk				< .001§	1.34
Lateral Deviation				.063^	0.48

Right (mm)						
Baseline	7.24 ± 2.9	7.52 ± 2.5				
Immediate	9.36 ± 2.7	8.68 ± 2.5				
Change from baseline to immediate	2.12 ± 2.5	1.16 ± 1.9	0.96 (-0.28-2.20)	.128°	0.44	
1 wk	9.48 ± 3.1	8.36 ± 2.1				
Change from baseline to 1 wk	2.24 ± 2.7	0.84 ± 2.2	0.70 (0.01-2.79)	.050°	0.57	
4 wk	9.56 ± 3.3	7.80 ± 2.6				
Change from baseline to 4 wk	2.32 ± 3.8	0.28 ± 2.9	2.04 (0.09-4.0)	.040°	0.60	
Collapsed across time: Baseline to 4 wk				< .001§	0.84	
Lateral Deviation Left (mm)						
Baseline	9.88 ± 3.0	7.64 ± 3.7				
Immediate	10.32 ± 3.2	8.76 ± 3.0				
Change from baseline to immediate	0.44 ± 2.4	1.12 ± 2.5	-0.68 (-2.08-0.72)	.334°	-0.28	
1 wk	10.60 ± 3.1	8.20 ± 2.3				
Change from baseline to 1 wk	0.72 ± 3.2	0.56 ± 3.5	0.16 (-1.77-2.09)	.868°	0.05	
4 wk	10.68 ± 4.2	9.44 ± 2.9				
Change from baseline to 4 wk	0.80 ± 3.9	1.80 ± 3.3	-1.00 (-3.04-1.04)	.329°	-0.28	
Collapsed across time: Baseline to 4 wk				.027§	0.54	
Abbreviations: MMO, maximal mouth opening, pain free; wk, week.						
*Values are mean ± SD						
**Values are mean adjusted change scores (95%confidence interval); Change from baseline to 4-week final visit is calculated as thrust group minus sham group.						
^Value is two-way mixed ANOVA, interaction effect						
§Value is two-way mixed ANOVA, group main effect						
°Value is dependent samples t-test used to assess between-group differences in adjusted mean change scores						
P values ≤ .05 are statistically significant						

### Numeric Pain Rating Scale: Jaw

Jaw pain was normally distributed across some intervals as assessed by Shapiro-Wilk's test ( $p > .05$ ), with the exception of baseline jaw pain in the thrust group, immediate post treatment in the jaw (thrust group), 4-week jaw in thrust group. There were outliers noted in both groups via examination of box plots; as assessed by examination of studentized residuals for values greater than  $\pm 3$ , there was 1 outlier at 4-week. There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .05$ ), and homogeneity of covariance, as assessed by Box's test of equality of covariance matrices ( $p = .190$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2$

(2) = 18.177,  $p = .003$ . Greenhouse-Geisser correction was utilized for interpretation. The data were transformed (moderate positive skew) for this variable and while no outliers remained, there were still 2 points in time when data was not normally distributed. The subsequent analysis of mixed ANOVA showed no change in results or trends of change. Reported values and the chart below reflect the non-transformed data.

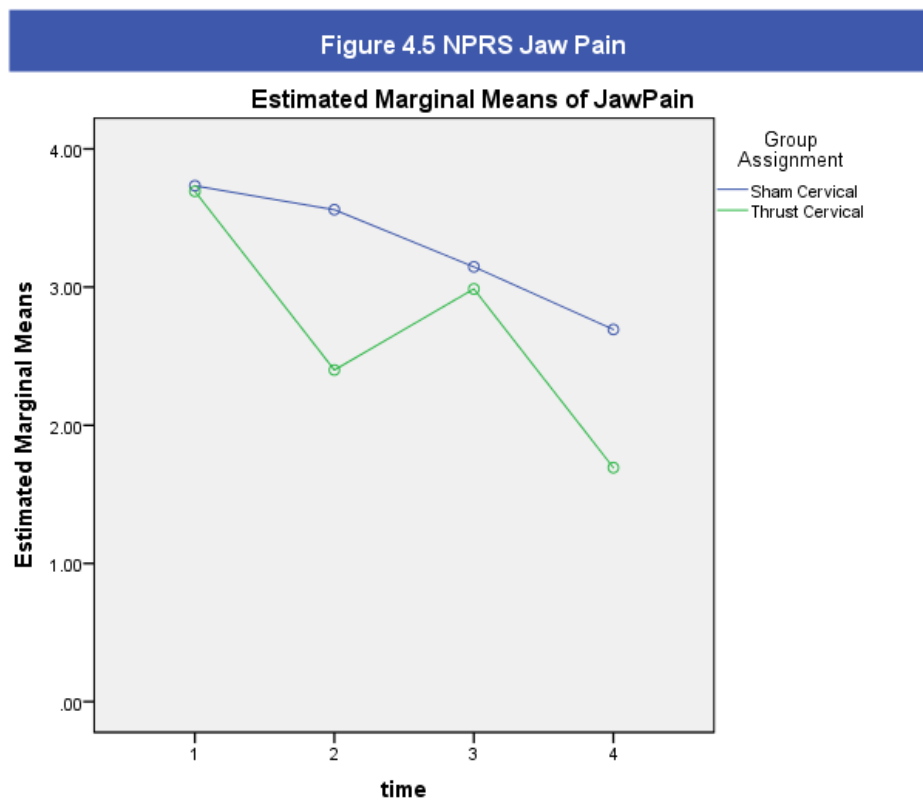
There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of jaw pain on the Numeric Pain Rating Scale (NPRS),  $F(2.364, 113.470) = 2.743$ ,  $p = .059$ , partial  $\eta^2 = .054$ . While there were no group\*time interactions, there were statistically significant main effects for time,  $F(2.364, 113.470) = 13.024$ ,  $p < .000$ , partial  $\eta^2 = .213$ .

Jaw pain decreased from baseline to each subsequent point in time, and each change was statistically significant. There was also a statistically significant change in pain from 1-week to 4-weeks. Both groups started out nearly the same on mean pain scores and the thrust manipulation group's NPRS for jaw decreased more in the immediate post-treatment phase than the sham group; however, this difference between groups was not statistically significant. The mean difference from baseline to immediate post treatment was 0.733 (95% CI .034-1.432),  $p = .035$  and the mean difference from baseline to 4-week was 1.520 (95% CI .894-2.146),  $p < .001$ .

The main effect of group showed no statistically significant difference in jaw pain between groups  $F(1, 48) = 2.069$ ,  $p = .157$ , partial  $\eta^2 = .041$ .

Overall both groups had less jaw pain from baseline to 4-weeks. The trend showed greater reduction in pain at the immediate post treatment visit 1 for the thrust manipulation group. Subsequent analysis looked at mean difference or change scores between groups. An

independent  $t$ -test showed a statistically significant difference in mean change scores between groups for jaw pain from baseline to immediate post treatment,  $t(48) = -2.205$ ,  $p = .032$  and baseline to final visit,  $t(48) = -2.109$ ,  $p = .040$ , favoring the thrust manipulation group. See Figure 4.5 and Table 4.4 for further detail.



#### *Numeric Pain Rating Scale: Cervical*

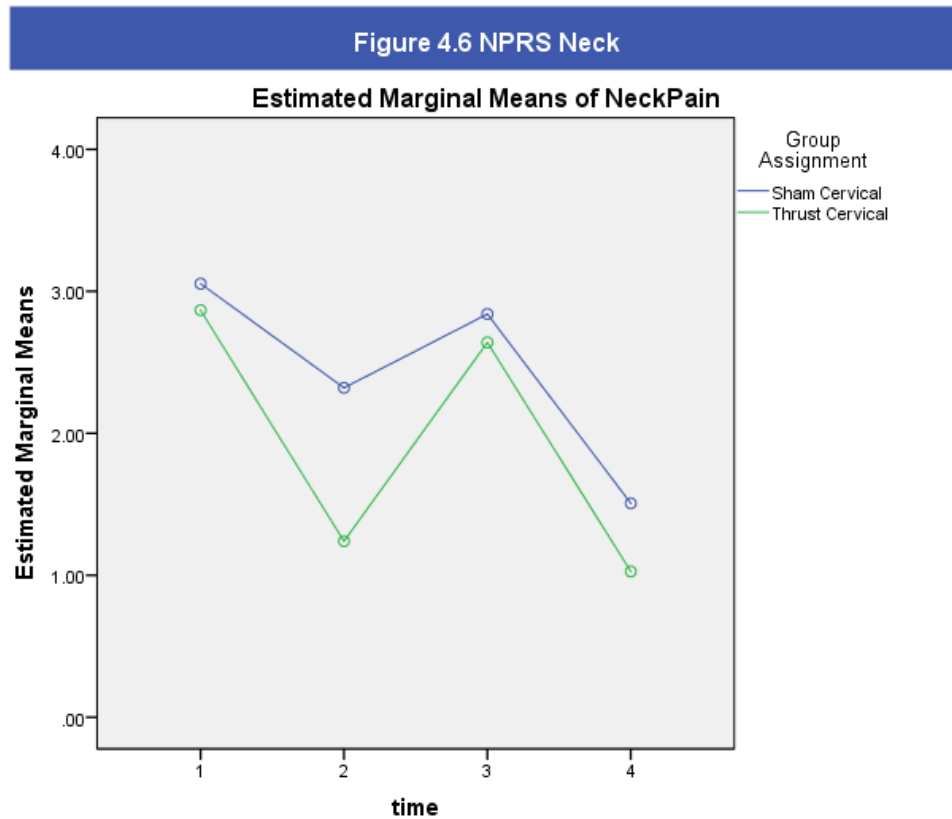
Neck pain was normally distributed across some intervals as assessed by Shapiro-Wilk's test ( $p > .05$ ) with the exception of baseline cervical pain in the sham group, immediate post treatment in the cervical spine (both groups), and 4-week cervical both groups. There were outliers noted in both groups via examination of box plots; however, there were no outliers noted as assessed by examination of studentized residuals for values greater than  $\pm 3$ . There was homogeneity of variance at 3 measurement intervals as assessed by Levene's test of

homogeneity of variance ( $p > .05$ ), however, this assumption was violated at immediate post treatment measurement. The assumption for homogeneity of covariance was met, as assessed by Box's test of equality of covariance matrices ( $p = .206$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was met for the two-way interaction,  $\chi^2(2) = 2.985$ ,  $p = .702$ . Data were transformed (moderate positive skew) for this variable and after transformation, Levene's was no longer violated and the assumption of homogeneity of variance and covariance were both met. Sphericity was then violated and the Greenhouse-Geisser correction was utilized for interpretation; in analyzing these data, there was no change in the outcome or the overall trend of scores for each group over time. Reported values and chart below reflect the non-transformed data.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of neck pain,  $F(3,144) = 1.773$ ,  $p = .155$ , partial  $\eta^2 = .036$ . While there were no group\*time interactions, there were statistically significant main effects for time,  $F(3,144) = 12.585$ ,  $p < .001$ , partial  $\eta^2 = .208$ . Statistically significant improvements were seen in neck pain at all but 2-time intervals (baseline to 1-week, immediate to 4-week). Neck pain decreased from  $2.96 \pm 2.36$  at baseline to  $2.067 \pm 2.06$  at the final visit. The mean difference for the group in neck pain from baseline to immediately post treatment was 1.180 (95% CI .581-1.779),  $p < .001$ ; the mean difference from baseline to visit four was .933 (95% CI .279-1.59),  $p = .002$ . While pain did change over time, a good portion of that change appeared to occur early.

The main effect of group showed no statistically significant difference in neck pain between groups  $F(1,48) = .939$ ,  $p = .337$ , partial  $\eta^2 = .019$ . Subsequent analysis looked at mean difference or change scores between groups. An independent  $t$ -test showed a statistically

significant difference in mean change scores between groups for neck pain from baseline to immediate post treatment,  $t(48) = -2.053$ ,  $p = .046$ , favoring the thrust manipulation group. See Figure 4.6 and Table 4.4 for further detail.



#### *Numeric Pain Rating Scale: Headache*

Pain related to headache (HA) was normally distributed across some intervals as assessed by Shapiro-Wilk's test ( $p > .05$ ) with the exception of immediate post treatment HA (both groups), 1-week HA in both groups, and 4-week HA both groups. There was 1 outlier at week 1, as assessed by examination of studentized residuals for values greater than  $\pm 3$ . There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .05$ ) for all values except pain at 4-weeks. Homogeneity of covariance was met, as assessed by Box's test of equality of covariance matrices ( $p = .366$ ). Mauchly's test of sphericity indicated that the

assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 21.493$ ,  $p = .001$ . Greenhouse-Geisser correction was utilized for interpretation.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of maximal pain-free mouth opening,  $F(2.386, 114.515) = .904$ ,  $p = .423$ , partial  $\eta^2 = .018$ . While there were no group\*time interactions, there were statistically significant main effects for time,  $F(2.386, 114.515) = 6.328$ ,  $p = .001$ , partial  $\eta^2 = .116$ . Statistically significant improvements were seen between baseline and immediately post treatment, baseline and 4-week and between 1-week and 4-weeks. HA pain improved  $2.12 \pm 1.66$  at baseline and  $1.27 \pm 1.24$  at the final 4-week visit. HA pain was low (NPRS of 2) for both groups at baseline. Headache pain decreased by .780 (95% CI .072-1.48),  $p = .023$  from baseline to immediate post treatment. HA pain for the group decreased by .853 (95% CI .249-1.46),  $p = .002$  from baseline to 4-weeks.

The main effect of group showed no statistically significant difference in HA pain between groups  $F(1,48) = .102$ ,  $p = .751$ , partial  $\eta^2 = .002$ . See Figure 4.7 and Table 4.4 for further detail.

Figure 4.7 NPRS Headache

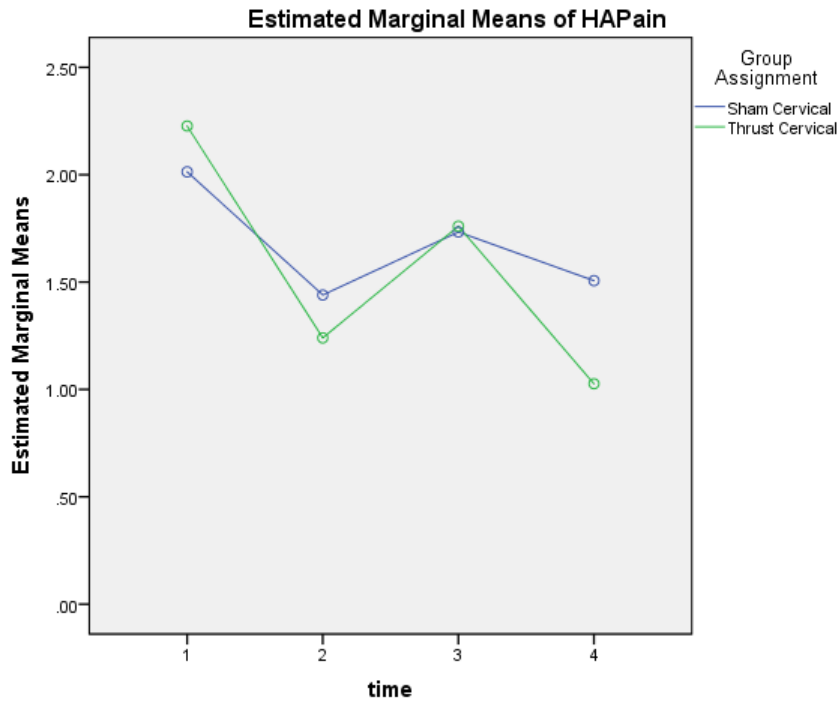


Table 4.4

**PAIN: WITHIN-GROUP AND BETWEEN-GROUP CHANGE**

Measurement	Cervical Thrust Group*	Cervical Sham Group *	Between-Group Difference**	P value	Effect Size
NPRS Jaw				.059 <sup>^</sup>	0.48
Baseline	3.69 ± 1.5	3.73 ± 1.5			
Immediate	2.4 ± 2.2	3.56 ± 2.3			
Change from baseline to immediate	1.29 ± 2.1	0.17 ± 1.5	-1.12 (-2.14- -0.10)	.032 <sup>°</sup>	-0.62
1 wk	2.99 ± 1.5	3.15 ± 1.9			
Change from baseline to 1 wk	0.71 ± 1.4	0.59 ± 1.3	-0.12 (-0.87-0.63)	.749 <sup>°</sup>	-0.09
4 wk	1.69 ± 1.6	2.69 ± 1.9			
Change from baseline to 4 wk	2 ± 1.7	1.04 ± 1.5	-0.96 (-1.87- -0.04)	.040 <sup>°</sup>	-0.60
Collapsed across time: Baseline to 4 wk				< .001 <sup>§</sup>	1.04
NPRS Cervical				.155 <sup>^</sup>	0.39
Baseline	2.87 ± 2.0	3.05 ± 2.7			
Immediate	1.24 ± 1.3	2.32 ± 2.2			
Change from baseline to immediate	1.63 ± 1.7	0.73 ± 1.4	-0.89 (-1.77- -0.02)	.046 <sup>°</sup>	-0.58
1 wk	2.64 ± 2.0	2.84 ± 2.4			
Change from baseline to 1 wk	0.23 ± 1.5	0.21 ± 1.6	-0.01 (-0.9-0.88)	.976 <sup>°</sup>	-0.01
4 wk	1.72 ± 2.0	2.33 ± 2.1			
Change from baseline to 4 wk	1.15 ± 1.5	0.72 ± 1.8	-0.43 (-1.38-0.53)	.374 <sup>°</sup>	-0.25



Collapsed across time: Baseline to 4 wk				< .001 <sup>§</sup>	1.02
NPRS HA				.423 <sup>^</sup>	0.27
Baseline	2.23 ± 1.7	2.01 ± 1.7			
Immediate	1.24 ± 1.7	1.44 ± 1.4			
Change from baseline to immediate	0.99 ± 2.1	0.57 ± 1.5	-0.41 (-0.45-0.62)	.425 <sup>°</sup>	-0.23
1 wk	1.76 ± 1.6	1.73 ± 1.7			
Change from baseline to 1 wk	0.47 ± 1.2	0.28 ± 1.2	-0.19 (-0.89-0.51)	.595 <sup>°</sup>	-0.15
4 wk	1.03 ± 0.9	1.51 ± 1.5			
Change from baseline to 4 wk	1.2 ± 1.6	0.51 ± 1.5	-0.69 (-1.58-0.19)	.121 <sup>°</sup>	-0.45
Collapsed across time: Baseline to 4 wk				.001 <sup>§</sup>	0.72

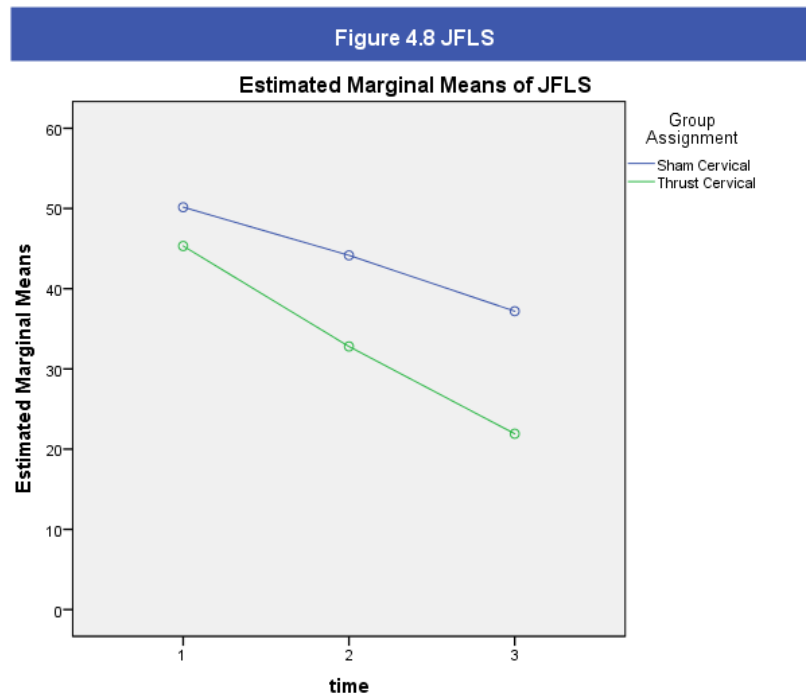
*Abbreviations: NPRS, numeric pain rating scale; HA, headache; wk, week.*  
*\*Values are mean ± SD*  
*\*\*Values are mean adjusted change scores (95%confidence interval); Change from baseline to 4-week final visit is calculated as thrust group minus sham group.*  
*<sup>^</sup>Value is two-way mixed ANOVA, interaction effect*  
*<sup>§</sup>Value is two-way mixed ANOVA, group main effect*  
*<sup>°</sup>Value is dependent samples t-test used to assess between-group differences in adjusted mean change scores*  
*P values ≤ .05 are statistically significant*

### *Jaw Functional Limitation Scale*

Jaw Functional Limitation Scale (JFLS) was not normally distributed across time intervals and group as assessed by Shapiro-Wilk's test ( $p > .05$ ); except for 1-week data for the sham group. Box plots showed outliers in both groups. There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .005$ ) at baseline and 1-week; however, this assumption was violated at 4-weeks. Because of these violations in assumptions, the data were transformed for a moderate positive skew and analyses were run again. In this subsequent analysis, the data did meet the assumption of normal distribution as assessed by Shapiro-Wilk test ( $p > .05$ ) and only one outlier was noted at the 1-week visit in box plots. The assumption of homogeneity of variance was met as interpreted from Levene's test. Homogeneity of covariance was met, as assessed by Box's test of equality of covariance matrices ( $p = .055$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-

way interaction,  $\chi^2(2) = 18.347$ ,  $p < .001$ . Greenhouse-Geisser correction was utilized for interpretation.

There was a statistically significant interaction between group and time on the measurement of JFLS,  $F(1.511, 7572.552) = 4.322$ ,  $p = .026$ , partial  $\eta^2 = .083$ . There was no statistically significant simple main effect of group on JFLS ( $F=3.934$ ,  $p = .053$ ). For the sham group, JFLS showed statistically significant reduction (indicating lower levels of disability) from baseline to 4-week visit ( $M=12.96$ ,  $p = .019$ ). For the thrust group, JFLS change was statistically significant from baseline to 1 week ( $M= 12.5$ ,  $p < .001$ ) and from baseline to 4-weeks ( $M=.23.4$ ,  $p < .001$ ). See Figure 4.8 and Table 4.5 for further detail.



### *Neck Disability Index*

Neck Disability Index (NDI) was normally distributed across time intervals and group as assessed by Shapiro-Wilk's test ( $p > .05$ ) except for 1-week and 4-week data for the sham group.

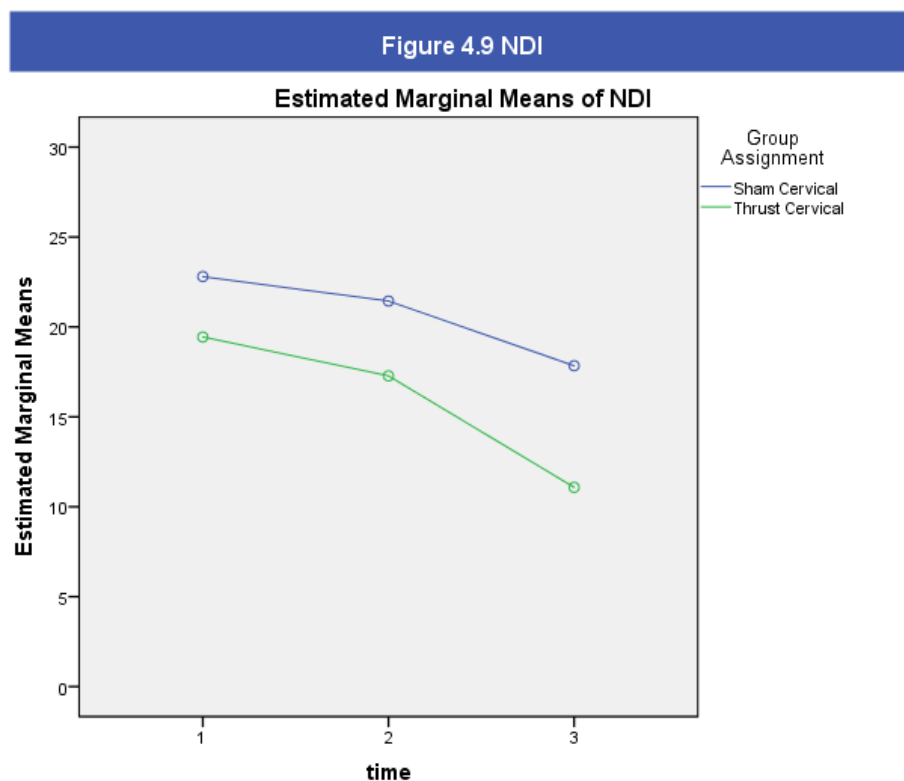
Box plots showed outliers in both groups: 1 outlier at each time interval, as assessed by examination of studentized residuals for values greater than  $\pm 3$ . There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .005$ ) at baseline and 1-week; however, this assumption was violated at 4-weeks. The assumption of homogeneity of covariance was met, as assessed by Box's test of equality of covariance matrices ( $p = .015$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 6.553$ ,  $p = .038$ . Greenhouse-Geisser correction was utilized for interpretation. Data were transformed (moderate positive skew) for this variable. After transformation, normal distribution was found in the sham group, however, the thrust group no longer had a normal distribution at 1-week and 4-weeks. The Box's test of covariance, Levene's homogeneity of variance, and sphericity assumptions were met with the transformed data; however, there was no change in the outcome or the overall trend of scores for each group over time. Reported values and the chart below reflect the non-transformed data.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of NDI,  $F(1.770-84.945) = 1.905$ ,  $p = .160$ , partial  $\eta^2 = .038$ . While there were no group\*time interactions, there were statistically significant main effects for time,  $F(1.770-84.945) = 28.720$ ,  $p < .001$ , partial  $\eta^2 = .374$ .

Statistically significant improvements were seen in NDI between baseline and 4-weeks, and 1-week and 4-weeks. NDI scores are lower as the patient function improves. Scores were recorded as percentage of disability; therefore, lower numbers demonstrate less neck related disability. The mean difference in scores from baseline to 4-weeks was  $-6.660$  (95% CI  $-4.029$  -  $-9.291$ ),  $p < .001$ . Mean difference in scores from 1-week to 4-week was  $-4.900$  (95% CI  $-2.788$  -  $-7.012$ ),  $p < .001$ .

The main effect of group was not statistically significant in NDI between groups  $F(1,48) = 2.174$ ,  $p = .147$ , partial  $\eta^2 = .043$ . For the sample, mean scores were 22.80 % disability  $\pm$  15.033% at baseline and 14.46 % disability  $\pm$  11.5% at 4 weeks.

The baseline disability scores were 22.8% and 19.4% for the sham and thrust manipulation groups, respectively. Overall both groups showed improved function of the neck as measured by NDI over time. See Figure 4.9 and Table 4.5 for further detail.



#### *TMD Disability Index*

TMD Disability Index (TMD-DI) was normally distributed across time intervals and group as assessed by Shapiro-Wilk's test ( $p > .05$ ), except for baseline for the thrust manipulation group. Box plots showed outliers in the thrust manipulation group. 1 outlier was noted at 4-weeks, as assessed by examination of studentized residuals for values greater than  $\pm 3$ .

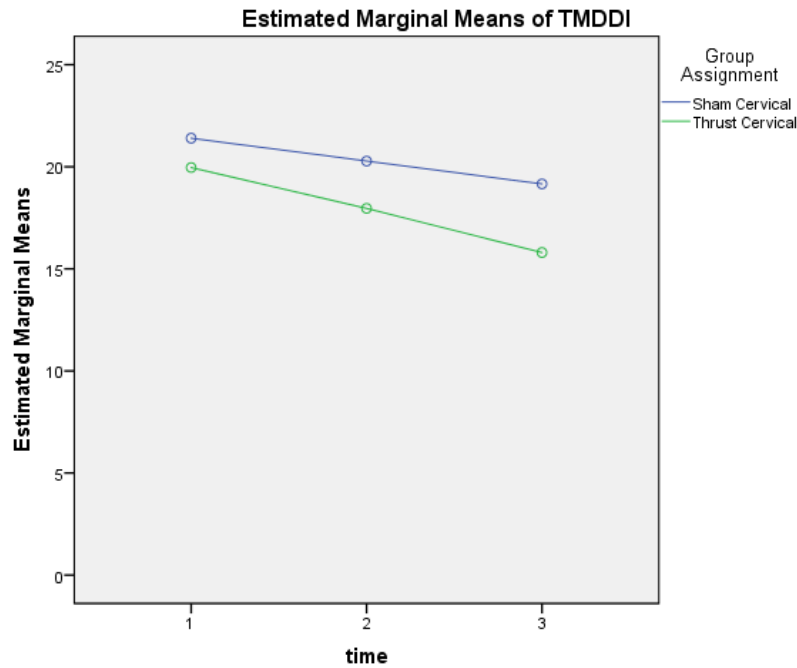
There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .005$ ) at baseline; however, this assumption was violated at 1-week and 4-weeks. The assumption of homogeneity of covariance was met, as assessed by Box's test of equality of covariance matrices ( $p = .029$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 10.869$ ,  $p = .004$ . Greenhouse-Geisser correction was utilized for interpretation. The data were transformed (moderate positive skew) for this variable and there was no change in the outcome or the overall trend of scores for each group over time. After transformation, normal distribution was present in both groups; Levene's showed homogeneity at baseline and 1-week, but not at the 4-week visit; the assumption of covariance was met. Reported values and chart below reflect the non-transformed data.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of TMD-DI,  $F(1.658-79.571) = 2.115$ ,  $p = .136$ , partial  $\eta^2 = .042$ . While there were no group\*time interactions, there were statistically significant main effects for time,  $F(1.658-79.571) = 23.447$ ,  $p < .001$ , partial  $\eta^2 = .328$ .

Statistically significant improvements in TMD-DI were noted at all time intervals. TMD-DI scores lower as the patient function improves. The mean difference in scores from baseline to 4-weeks was  $-3.20$  (95% CI  $-1.802$ -  $-4.598$ ),  $p < .001$ . For the group, mean scores were  $20.68 \pm 5.439$  at baseline and  $17.48 \pm 5.187$  at 4-weeks.

The main effect of group was not statistically significant in TMD-DI between groups  $F(1,48) = 3.849$ ,  $p = .056$ , partial  $\eta^2 = .074$ . Overall both groups showed improved function of the jaw as measured by TMD-DI over time with greater change seen in the thrust manipulation group. See Figure 4.10 and Table 4.5 for further detail.

Figure 4.10 TMD-DI



#### *Tampa Scale for Kinesiophobia for Temporomandibular Disorders*

Tampa Scale for Kinesiophobia for Temporomandibular Disorders (TSK-TMD) was assessed at baseline and 4-weeks. Scores were normally distributed across time intervals and group as assessed by Shapiro-Wilk's test ( $p > .05$ ) except at 4-weeks for the thrust manipulation group. Box plots showed outliers in both groups; however, there were no outliers noted by examination of studentized residuals for values greater than  $\pm 3$ . There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .005$ ) at baseline; however, this assumption was violated at 4-weeks. The assumption of homogeneity of covariances was met, as assessed by Box's test of equality of covariance matrices ( $p = .133$ ). Mauchly's test of sphericity was not indicated for this variable as there were not 3 or more factors for time. The data were transformed (moderate positive skew) for this variable. After transformation, normal distribution was still violated at 4-weeks; however, Levene's

homogeneity of variance was now met and Box's test of equality of covariance was also met ( $p=.241$ ).

There was a statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of fear with the TSK-TMD,  $F(1,48) = 7.69$ ,  $p = .008$ , partial  $\eta^2 = .138$ . Lower TSK-TMD scores represent less fear. There was a statistically significant simple main effect for group showing difference in fear between groups at 4-weeks,  $F(1,48) = 5.770$ ,  $p = .020$ , partial  $\eta^2 = .107$ . There was a statistically significant simple main effect for time showing decreased fear over time in the thrust group only,  $F(1,48) = 16.426$ ,  $p < .001$ , partial  $\eta^2 = .843$ .

Overall, both groups showed reduction in fear as measured by TSK-TMD over time with greater change seen in the thrust manipulation group. Subsequent analysis looked at mean difference or change scores between groups. An independent  $t$ -test showed a statistically significant difference in mean change scores between groups for fear from baseline to 4-week final visit,  $t(48) = -2.813$ ,  $p = .007$ , favoring the thrust manipulation group. See Figure 4.11 and Table 4.5 for further detail.

Figure 4.11 TSK-TMD

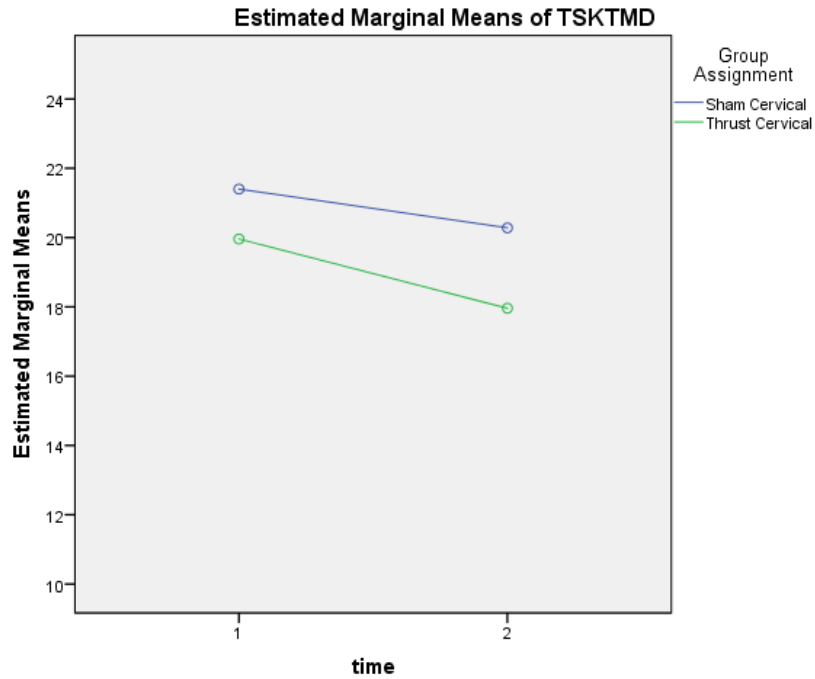


Table 4.5

### SELF-REPORT FUNCTIONAL SCALES: WITHIN-GROUP AND BETWEEN-GROUP CHANGE

Measurement	Cervical Thrust Group*	Cervical Sham Group *	Between-Group Difference**	P value	Effect Size
JFLS				.026^	0.60
Baseline	45.32 ± 30.4	50.16 ± 40.5			
1 wk	32.8 ± 26.8	44.16 ± 34.6			
Change from baseline to 1 wk	12.52 ± 14.7	6 ± 16.1	-6.52 (-15.39-2.25)	.141°	-0.42
4 wk	21.92 ± 22.9	37.2 ± 31.0			
Change from baseline to 4 wk	23.4 ± 23.3	12.96 ± 24.6	-10.44 (-24.06-3.18)	.130°	-0.44
Collapsed across time: Baseline to 4 wk				< .001§	2.24
NDI				.160^	0.40
Baseline	19.44 ± 9.5	22.8 ± 15.0			
1 wk	17.28 ± 8.8	21.44 ± 15.0			
Change from baseline to 1 wk	2.16 ± 6.7	1.36 ± 4.3	-0.8 (-4.03-2.43)	.619°	-0.14
4 wk	11.08 ± 7.3	17.84 ± 13.9			
Change from baseline to 4 wk	8.36 ± 8.2	4.96 ± 6.7	-3.4 (-7.66-0.86)	.115°	-0.45
Collapsed across time: Baseline to 4 wk				< .001§	1.55
TMDDI				.136^	0.42
Baseline	19.96 ± 4.1	21.4 ± 5.4			



1 wk	17.96 ± 3.4	20.28 ± 4.9			
Change from baseline to 1 wk	2 ± 3.3	1.12 ± 2.4	-0.88 (-2.51-0.75)	.282°	-0.31
4 wk	15.8 ± 3.5	19.16 ± 6.1			
Change from baseline to 4 wk	4.16 ± 4.7	2.24 ± 3.1	-1.92 (-4.19-0.35)	.095°	-0.48
Collapsed across time: Baseline to 4 wk				< .001§	1.40
TSK-TMD				.008^	0.80
Baseline	27.32 ± 5.6	28.16 ± 5.8			
4 wk	23.12 ± 6.2	27.48 ± 6.7			
Change from baseline to 4 wk	4.2 ± 5.1	0.68 ± 3.6	-3.52 (-6.04- -1.0)	.007°	-0.80
Collapsed across time: Baseline to 4 wk				< .001§	1.11

Abbreviations: JFLS, Jaw Functional Limitation Scale; wk, week; NDI, Neck Disability Index; TMDDI, Temporomandibular Disorder Disability Index; TSK-TMD, The Tampa Scale for Kinesiophobia for Temporomandibular Disorders.

\*Values are mean ± SD

\*\*Values are mean adjusted change scores (95%confidence interval); Change from baseline to 4-week final visit is calculated as thrust group minus sham group.

^Value is two-way mixed ANOVA, interaction effect

§Value is two-way mixed ANOVA, group main effect

°Value is dependent samples t-test used to assess between-group differences in adjusted mean change scores

P values ≤ .05 are statistically significant

### Cervical Spine ROM: Flexion

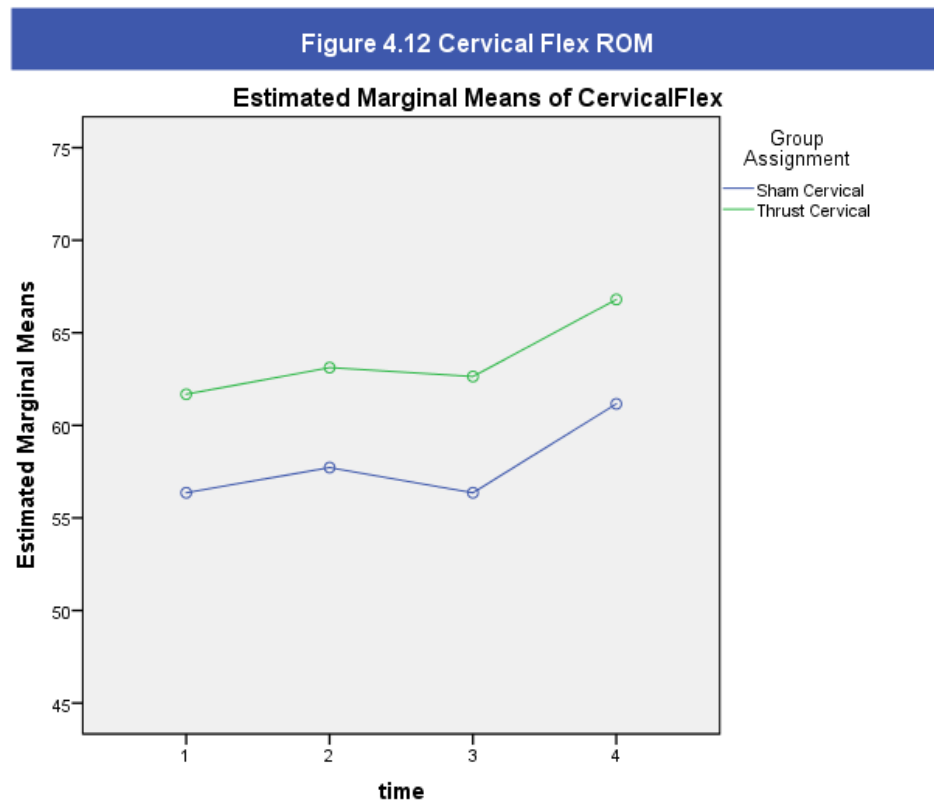
Cervical flexion was normally distributed across all time intervals and group as assessed by Shapiro-Wilk's test ( $p > .05$ ) with the exception of the 4-week visit in the sham group.

Outliers were noted in both groups via box plots; there were no outliers, as assessed by examination of studentized residuals for values greater than  $\pm 3$  with the exception of 1 value at 4-weeks. There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .05$ ) and homogeneity of covariance, as assessed by Box's test of equality of covariance matrices ( $p = .369$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 14.110$ ,  $p = .015$ . Greenhouse-Geisser correction was utilized for interpretation.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of cervical flexion ROM,  $F(2.608, 125.186) = .052$ ,  $p =$

.975, partial  $\eta^2 = .001$ . While there were no group\*time interactions, there were statistically significant main effects for time. Statistically significant improvements were seen in cervical flexion,  $F(2.608, 125.186) = 5.512$ ,  $p = .002$ , partial  $\eta^2 = .103$ . Cervical flexion ROM increased from baseline to 4-week and from 1-week to 4-week. Cervical flexion for the group was  $59.02^\circ \pm 12.493^\circ$  at baseline, increasing to  $63.98^\circ \pm 10.869^\circ$  at the final visit, a statistically significant difference of  $4.960^\circ$  (95% CI, 1.138-3.938),  $p = .005$ .

The main effect of group showed no statistically significant difference in cervical flexion ROM between groups  $F(1, 48) = 3.577$ ,  $p = .065$ , partial  $\eta^2 = .069$ . Overall, both groups improved in cervical flexion in a similar pattern as noted below. See Figure 4.12 and Table 4.6 for further detail.



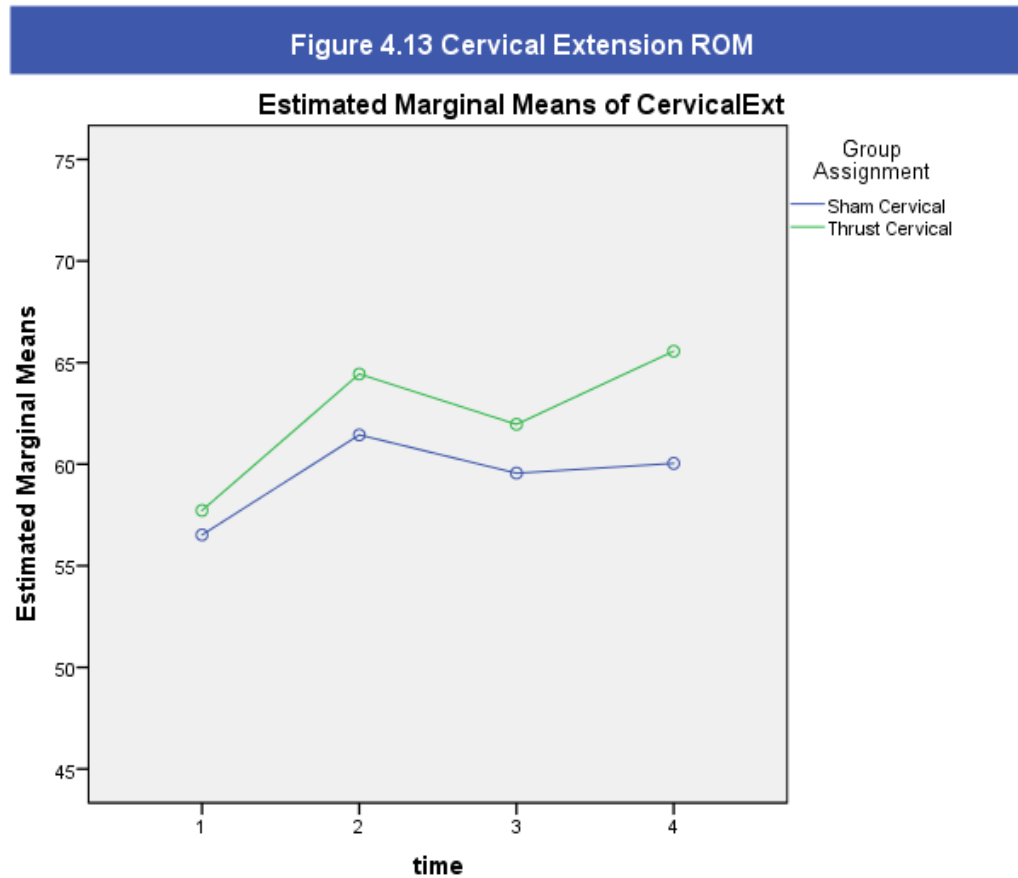
### *Cervical Spine ROM: Extension*

Cervical extension was normally distributed across all time intervals and group as assessed by Shapiro-Wilk's test ( $p > .05$ ) with the exception of 4-week data in both groups. A single outlier was noted in the sham group at 1-week via box plots; there were no outliers, as assessed by examination of studentized residuals for values greater than  $\pm 3$ . There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .05$ ) and homogeneity of covariance, as assessed by Box's test of equality of covariance matrices ( $p = .980$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 11.146$ ,  $p = .049$ . Greenhouse-Geisser correction was utilized for interpretation.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of cervical extension ROM,  $F(2.602, 124.877) = .914$ ,  $p = .425$ , partial  $\eta^2 = .019$ . While there were no group\*time interactions, there were statistically significant main effects for time,  $F(2.602, 124.877) = 8.116$ ,  $p < .001$ , partial  $\eta^2 = .145$ . Cervical extension ROM increased from baseline to immediate post treatment and from baseline to 4-weeks. Cervical extension was  $57.12^\circ \pm 13.9^\circ$  at baseline, increasing to  $62.94^\circ \pm 13.564^\circ$  at the immediate post treatment and  $62.80^\circ \pm 12.204^\circ$  at 4-weeks. As the change was seen immediately and maintained to the end, the mean difference of baseline to immediate post treatment at 1-week is the most relevant data. There was a statistically significant difference of  $5.680^\circ$  (95% CI, 1.758-9.602),  $p = .001$ .

The main effect of group showed no statistically significant difference in cervical extension ROM between groups  $F(1, 48) = .772$ ,  $p = .384$ , partial  $\eta^2 = .016$ . Overall both groups

improved in cervical extension ROM and greater difference in cervical extension was seen in the thrust manipulation group. See Figure 4.13 and Table 4.6 for further detail.



#### *Cervical Spine ROM: Right Rotation*

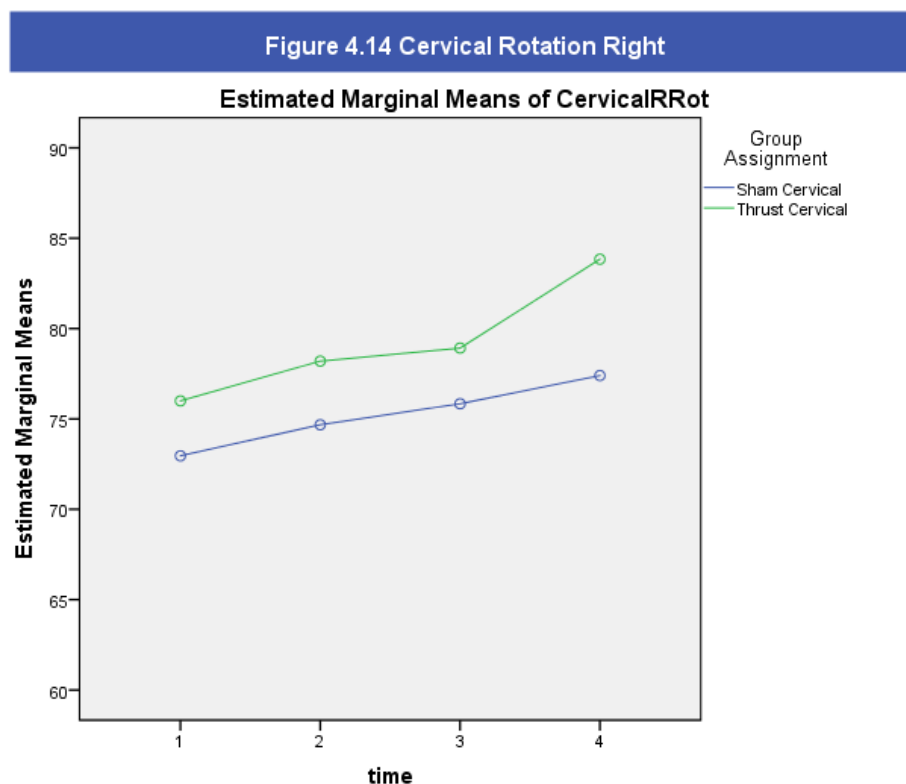
Cervical right rotation ROM was normally distributed in the thrust manipulation group but not the sham manipulation group across all time intervals as assessed by Shapiro-Wilk's test ( $p > .05$ ). Multiple outliers were noted in the sham group via box plots; there was 1 outlier at baseline and 1-week and 2 outliers at immediate post treatment and 4-week as assessed by examination of studentized residuals for values greater than  $\pm 3$ . There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .05$ ) at each time period except for the final 4-week visit. Homogeneity of covariance was met, as assessed by Box's test

of equality of covariance matrices ( $p = .067$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 9.483$ ,  $p = .091$ . Greenhouse-Geisser correction was utilized for interpretation. Data were transformed (moderate negative skew) for this variable, and there was no change in the outcome or the overall trend of scores for each group over time. After transformation, normal distribution was not present in the sham group at baseline or visit 2, but had normalized for the other two points in time. Levene's was still violated at visit 4, but Box's covariance and sphericity were not violated. Reported values above and the chart below reflect the non-transformed data.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of right rotation ROM,  $F((2.617, 125.631) = .1.030$ ,  $p = .375$ , partial  $\eta^2 = .021$ . While there were no group\*time interactions, there were statistically significant main effects for time,  $F(2.617, 125.631) = 10.209$ ,  $p < .001$ , partial  $\eta^2 = .175$ . Right rotation ROM increased from baseline to 4-weeks in both groups, however, the magnitude of difference was greater for the thrust group. Cervical right rotation ROM was  $72.96^\circ \pm 15.839^\circ$  at baseline in the sham group and  $76.00^\circ \pm 9.074^\circ$  in the thrust group. The mean difference overall from baseline to final measurement was  $6.140^\circ$  (95% CI  $.2.723-9.557$ ),  $p < .001$ .

The main effect of group showed no statistically significant difference in right rotation ROM between groups  $F(1, 48) = 1.555$ ,  $p = .218$ , partial  $\eta^2 = .031$ . Subsequent analysis looked at mean difference or change scores between groups. An independent  $t$ -test showed a statistically significant difference in mean change scores between groups for right rotation of the cervical spine from baseline to immediate post treatment,  $t(48) = 2.604$ ,  $p = .012$  and from baseline to 1-week,  $t(48) = 2.495$ ,  $p = .016$ . Overall both groups improved in right rotation ROM and greater

difference in cervical R rotation was seen in the thrust manipulation group. See Figure 4.14 and Table 4.6 for further detail.



#### *Cervical Spine ROM: Left Rotation*

Cervical left rotation ROM was normally distributed across all time intervals and group as assessed by Shapiro-Wilk's test ( $p > .05$ ) with the exception of baseline and 4-week data in the thrust group. Multiple outliers were noted in the thrust group via box plots and 2 outliers in the sham group; there was 1 outlier at each of the following time periods: baseline, 1-week and 4-weeks as assessed by examination of studentized residuals for values greater than  $\pm 3$ . There were violations of homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .05$ ) at each time period except for baseline. Homogeneity of covariance was also violated, as assessed by Box's test of equality of covariance matrices ( $p = .001$ ). Mauchly's test

of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 27.840, p < .001$ . Greenhouse-Geisser correction was utilized for interpretation. Data were transformed (moderate negative skew) for this variable and there was no change in the outcome or the overall trend of scores for each group over time. After transformation, normal distribution was present for both groups at each points in time. Box's M test was  $p=.001$ , still demonstrating violation of the assumption of covariance. Levene's was still violated at 2-weeks and 4-weeks. Reported values above and the chart below reflect the non-transformed data.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of left rotation ROM,  $F(2.275,109.212) = .2562, p = .075$ , partial  $\eta^2 = .051$ . While there were no group\*time interactions, there were statistically significant main effects for time,  $F(2.275,109.212) = 7.826, p < .001$ , partial  $\eta^2 = .140$  with change noted from baseline to immediate post treatment and from baseline to 4-week measurement. Left rotation ROM increased from baseline to visit 4 in both groups, however, the magnitude of difference was greater for the thrust group. Cervical left rotation ROM was  $76.64^\circ \pm 14.23^\circ$  at baseline in the sham group and  $76.36^\circ \pm 9.49^\circ$  in the thrust group. At the final visit, mean left rotation was  $80.08^\circ \pm 14.151^\circ$  in the sham group and  $84.44^\circ \pm 6.862^\circ$  in the thrust group. The mean difference overall from baseline to final measurement was  $5.760^\circ$  (95% CI 1.813-9.707),  $p = .001$ .

The main effect of group showed no statistically significant difference in left rotation ROM between groups  $F(1,48) = 1.666, p = .203$ , partial  $\eta^2 = .034$ . Overall, both groups improved in right rotation ROM and greater difference in cervical right rotation was seen in the thrust manipulation group. See Figure 4.15 and Table 4.6 for further detail.

Figure 4.15 Cervical Rotation Left

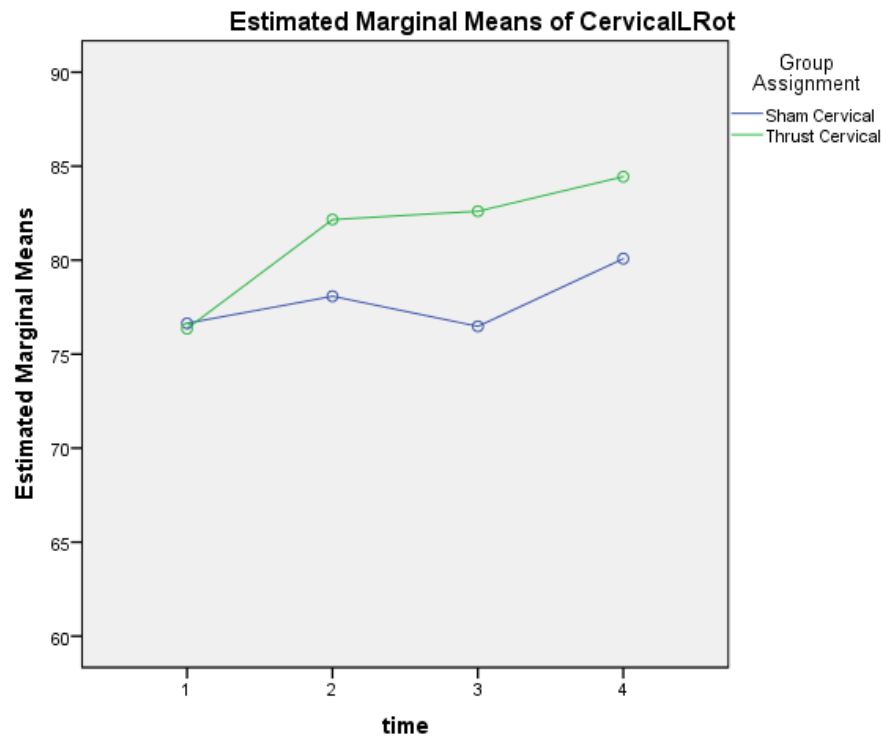


Table 4.6

CERVICAL SPINE ROM: WITHIN-GROUP AND  
BETWEEN-GROUP CHANGE

Measurement	Cervical Thrust Group*	Cervical Sham Group *	Between-Group Difference**	P value	Effect Size
Cervical Flexion				.975 <sup>^</sup>	0.06
Baseline	61.68 ± 12.6	56.36 ± 12.5			
Immediate	63.12 ± 11.6	57.72 ± 13.0			
Change from baseline to immediate	1.44 ± 5.6	1.36 ± 7.3	0.08 (-3.63-3.79)	.966 <sup>°</sup>	0.01
1 wk	62.64 ± 13.3	56.36 ± 12.3			
Change from baseline to 1 week	0.96 ± 11.8	0 ± 6.9	0.96 (-4.57-6.49)	.727 <sup>°</sup>	0.10
4 wk	66.80 ± 11.8	61.16 ± 9.3			
Change from baseline to 4 wk	5.12 ± 10.0	4.8 ± 9.8	0.32 (-5.3-5.94)	.909 <sup>°</sup>	0.03
Collapsed across time: Baseline to 4 wk				.002 <sup>§</sup>	0.68
Cervical Extension				.425 <sup>^</sup>	0.28
Baseline	57.72 ± 14.2	56.52 ± 13.8			
Immediate	64.44 ± 12.8	61.44 ± 14.4			
Change from baseline to immediate	6.72 ± 7.4	4.92 ± 8.4	1.80 (-2.7-6.3)	.425 <sup>°</sup>	0.23
1 wk	61.96 ± 14.1	59.56 ± 14.5			



Change from baseline to 1 wk	4.24 ± 10.7	3.04 ± 10.1	1.2 (-4.7-7.1)	.684°	0.12
4 wk	65.56 ± 12.2	60.04 ± 11.8			
Change from baseline to 4 wk	7.84 ± 10.8	3.52 ± 9.3	4.32 (-1.41-10.05)	.136°	0.43
Collapsed across time: Baseline to 4 wk				< .001§	0.82
Cervical Rotation, right				.375^	0.29
Baseline	76 ± 9.1	72.96 ± 15.8			
Immediate	78.2 ± 9.7	74.68 ± 16.1			
Change from baseline to immediate	2.2 ± 5.9	1.72 ± 7.9	0.45 (-3.48-4.44)	.808°	0.07
1 wk	78.92 ± 8.8	75.84 ± 13.4			
Change from baseline to 1 wk	2.92 ± 8.6	2.88 ± 7.4	0.04 (-4.52-4.6)	.986°	< 0.01
4 wk	83.84 ± 7.5	77.4 ± 15.2			
Change from baseline to 4 wk	7.84 ± 9.1	4.44 ± 8.4	3.4 (-1.59-8.39)	.177°	0.39
Collapsed across time: Baseline to 4 wk				< .001§	0.92
Cervical Rotation, left				.075^	0.46
Baseline	76.36 ± 9.5	76.64 ± 14.2			
Immediate	82.16 ± 8.0	78.08 ± 11.9			
Change from baseline to immediate	5.8 ± 4.7	1.44 ± 6.9	4.36 (0.99-7.73)	.012°	0.74
1 wk	82.6 ± 6.1	76.48 ± 14.1			
Change from baseline to 1 wk	6.24 ± 8.0	0.16 ± 10.0	6.4 (1.23-11.56)	.016°	0.71
4 wk	84.44 ± 6.9	80.08 ± 14.2			
Change from baseline to 4 wk	8.08 ± 10.6	3.44 ± 9.6	4.64 (-1.13-10.41)	.112°	0.46
Collapsed across time: Baseline to 4 wk				< .001§	0.81
Abbreviations: ROM, range of motion; wk, week.					
*Values are mean ± SD					
**Values are mean adjusted change scores (95%confidence interval); Change from baseline to 4-week final visit is calculated as thrust group minus sham group.					
^Value is two-way mixed ANOVA, interaction effect					
§Value is two-way mixed ANOVA, group main effect					
°Value is dependent samples t-test used to assess between-group differences in adjusted mean change scores					
P values ≤ .05 are statistically significant					

### *Pressure Pain Threshold, Temporalis Right (PPT-TR)*

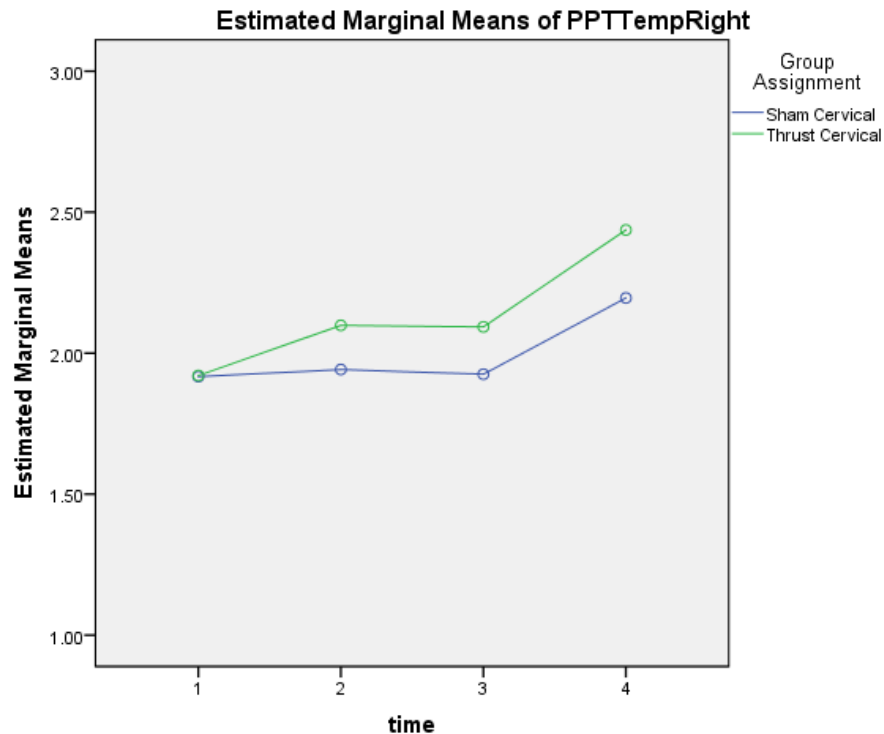
PPT-TR was normally distributed across 3 points and violated normality at 5 points as assessed by Shapiro-Wilk's test ( $p > .05$ ). Outliers were noted in both groups via box plots; 1 outlier was noted at baseline and 1 at the immediate post treatment measurement, as assessed by examination of studentized residuals for values greater than  $\pm 3$ , with the exception of 1 value at the 4-week final visit. There was homogeneity of variances, as assessed by Levene's test of

homogeneity of variance ( $p > .05$ ), and homogeneity of covariances, as assessed by Box's test of equality of covariance matrices ( $p = .299$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 25.375, p < .001$ . Greenhouse-Geisser correction was utilized for interpretation. Data were transformed (moderate positive skew) for this variable and there was no change the outcome or the overall trend of scores for each group over time. Reported values below are on the non-transformed data.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of PPT-TR,  $F(2.150-103.195) = .958, p = .392$ , partial  $\eta^2 = .020$ . While there were no group\*time interactions, there were statistically significant main effects for time,  $F(2.150-103.195) = 11.509, p < .001$ , partial  $\eta^2 = .193$ . A statistically significant increase in PPT was noted from each visit to the 4-week final visit.

The main effect of group showed no statistically significant difference in PPT-TR between groups  $F(1,48) = .283, p = .597$ , partial  $\eta^2 = .006$ . PPT-TR increased in both groups over time with a trend of greater increase for the thrust manipulation group. See Figure 4.16 and Table 4.7 for further detail.

Figure 4.16 PPT Temporalis Right

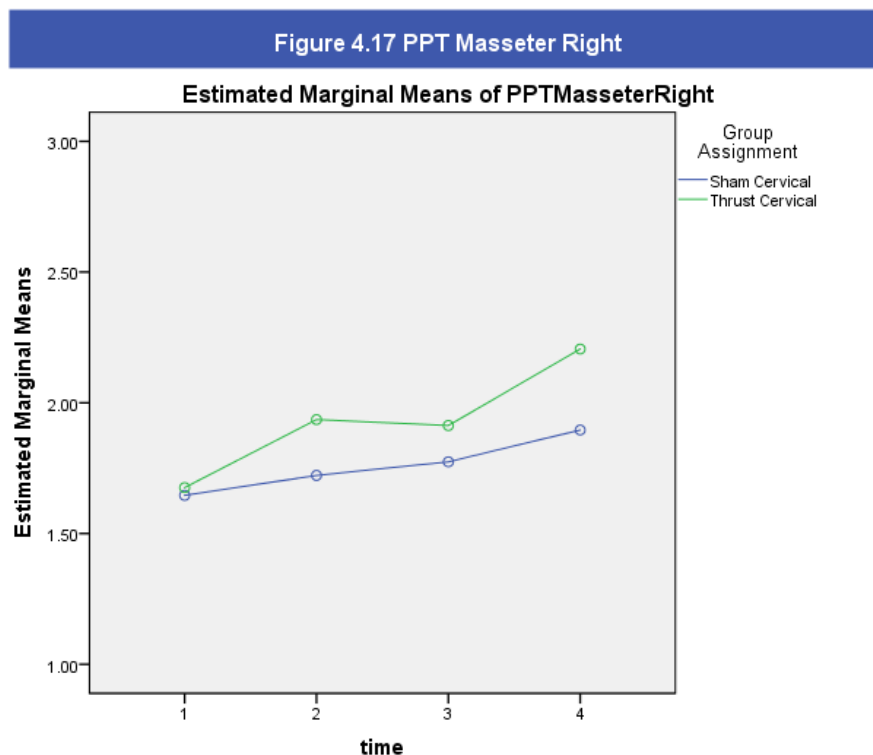


#### *Pressure Pain Threshold, Masseter Right (PPT-MR)*

PPT-MR was not normally distributed across time or group as assessed by Shapiro-Wilk's test ( $p > .05$ ). Outliers were noted in both groups via box plots; no outliers were noted as assessed by examination of studentized residuals for values greater than  $\pm 3$ . There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .05$ ), and homogeneity of covariances, as assessed by Box's test of equality of covariance matrices ( $p = .301$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 28.952$ ,  $p < .001$ . Greenhouse-Geisser correction was utilized for interpretation. I did transform the data (moderate positive skew) for this variable and there was no change in the outcome or the overall trend of scores for each group over time. Reported values below are on the non-transformed data.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of PPT-MR,  $F(2.085-100.092) = .1.655$ ,  $p = .195$ , partial  $\eta^2 = .033$ . While there were no group\*time interactions, there were statistically significant main effects for time,  $F(2.085-100.092) = 12.019$ ,  $p < .001$ , partial  $\eta^2 = .200$ . A statistically significant increase in PPT was noted from baseline to immediate post treatment, from baseline to 4-weeks, from immediate post treatment to 4-week, and from 1-week to 4-week. The largest mean difference was seen from baseline to final measurement and was 0.390 kg (95% CI .161-.619 kg),  $p < .001$ .

The main effect of group showed no statistically significant difference in PPT-MR between groups  $F(1,48) = .438$ ,  $p = .511$ , partial  $\eta^2 = .009$ . Overall, both groups improved in PPT-MR with greater improvement noted in the thrust group. See Figure 4.17 and Table 4.7 for further detail.



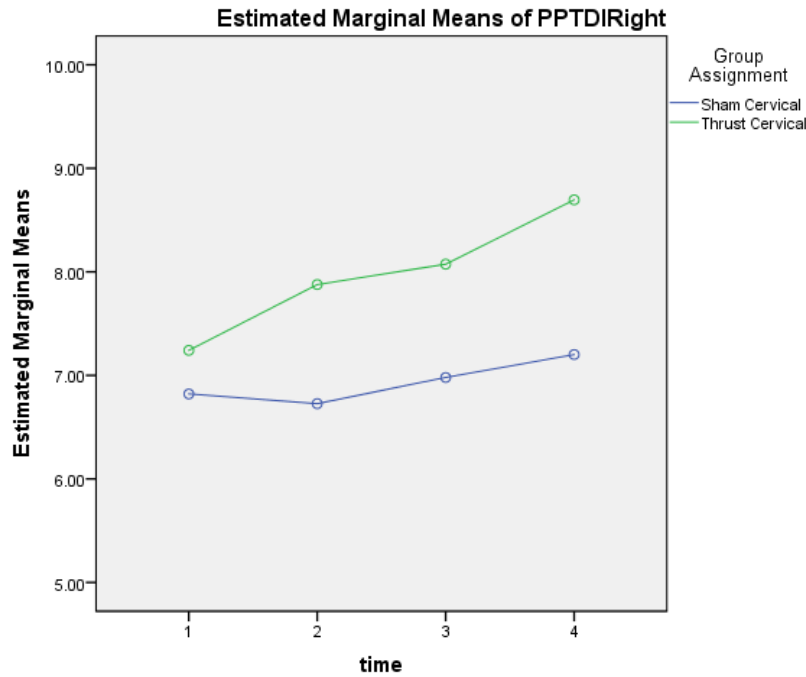
### *Pressure Pain Threshold, 1<sup>st</sup> Dorsal Interossei Right (PPT-DIR)*

PPT- *DIR* was not normally distributed across time or group as assessed by Shapiro-Wilk's test ( $p > .05$ ). Outliers and extreme outliers were noted in both groups via box plots; 1 outlier was noted at each period of time as assessed by examination of studentized residuals for values greater than  $\pm 3$ . There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .05$ ) and homogeneity of covariance, as assessed by Box's test of equality of covariance matrices ( $p = .025$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 47.871$ ,  $p < .001$ . Greenhouse-Geisser correction was utilized for interpretation.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of PPT- *DIR*,  $F(1.795-86.140) = 2.049$ ,  $p = .140$ , partial  $\eta^2 = .041$ . While there were no group\*time interactions, there were statistically significant main effects for time,  $F(1.795-86.140) = 6.118$ ,  $p = .004$ , partial  $\eta^2 = .113$ . A statistically significant increase was noted from baseline to 4-weeks and from immediate post treatment to 4-weeks. The largest mean difference was seen from baseline to 4-weeks and was 0.917 kg (95% CI .040-1.794 kg),  $p = .036$ .

The main effect of group showed no statistically significant difference in PPT- *DIR* between groups  $F(1,48) = .103$ ,  $p = .749$ , partial  $\eta^2 = .002$ . Overall, both groups improved in PPT-DIR with greater improvement noted in the thrust group. See Figure 4.18 and Table 4.7 for further detail.

Figure 4.18 PPT Dorsal Interossei Right



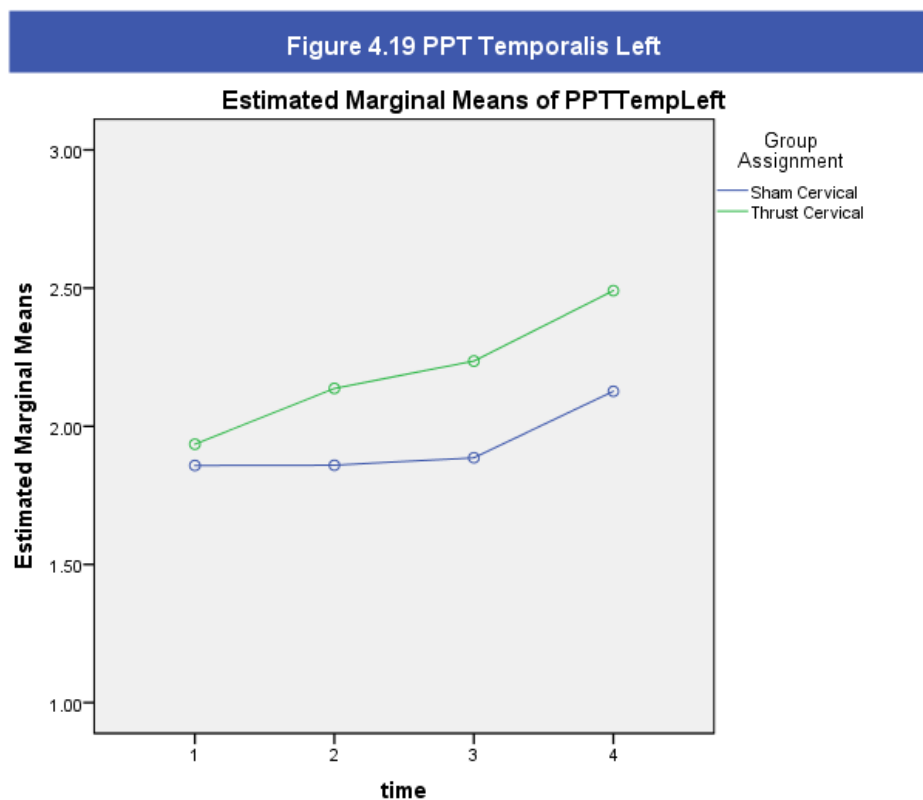
#### *Pressure Pain Threshold, Temporalis Left (PPT-TL)*

PPT-TL was not normally distributed across 4 points and was normally distributed in the other 4 as assessed by Shapiro-Wilk's test ( $p > .05$ ). Box plots showed 1 outlier in the thrust group and studentized residuals for values greater than  $\pm 3$  also showed 1 outlier. There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .05$ ), and homogeneity of covariance, as assessed by Box's test of equality of covariance matrices ( $p = .086$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 15.848$ ,  $p = .007$ . Greenhouse-Geisser correction was utilized for interpretation.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of PPT- TL,  $F(2.442-117.214) = 1.404$ ,  $p = .249$ , partial  $\eta^2 = .028$ . While there were no group\*time interactions, there were statistically significant main

effects for time,  $F(2.442-117.214) = 9.873$ ,  $p < .001$ , partial  $\eta^2 = .171$ . A statistically significant increase in PPT was noted from each baseline to 4-weeks at each interval. The largest mean difference was seen from baseline to 4-weeks and was 0.412 kg (95% CI .150-.674 kg),  $p = < .001$ .

The main effect of group showed no statistically significant difference in PPT- *TL* between groups  $F(1,48) = .964$ ,  $p = .331$ , partial  $\eta^2 = .020$ . Overall, both groups improved in PPT- *TL* with greater improvement noted in the thrust group. See Figure 4.19 and Table 4.7 for further detail.



#### *Pressure Pain Threshold, Masseter Left (PPT-ML)*

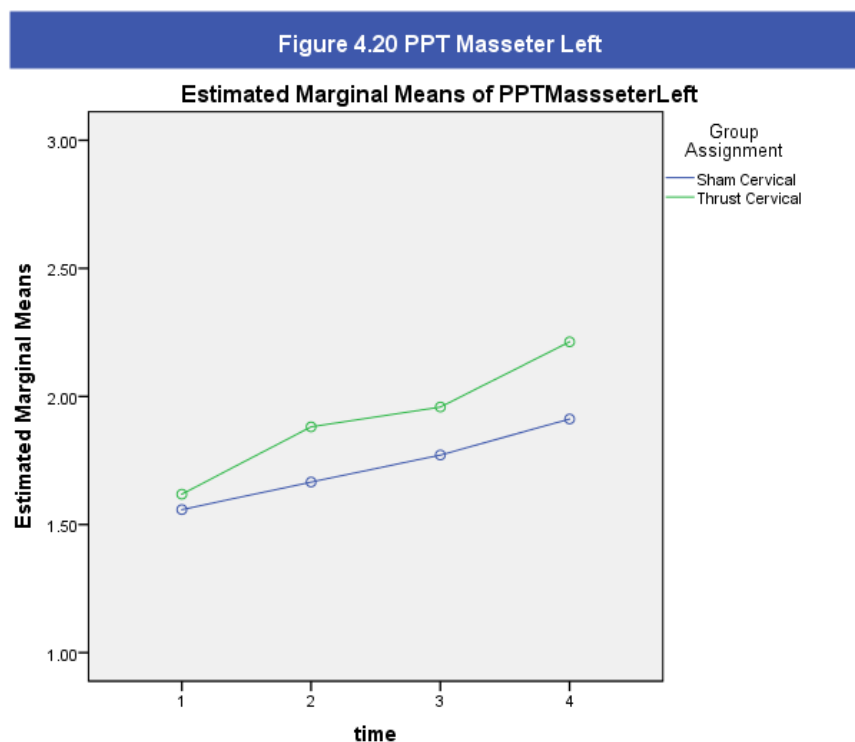
PPT- *ML* was not normally distributed across any time or group variable as assessed by Shapiro-Wilk's test ( $p > .05$ ). Outliers were noted in both groups via box plots, 1 outlier was

noted at baseline and 1-week at immediate post treatment as assessed by examination of studentized residuals for values greater than  $\pm 3$ . There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .05$ ), and homogeneity of covariances, as assessed by Box's test of equality of covariance matrices ( $p = .012$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 26.622, p < .001$ . Greenhouse-Geisser correction was utilized for interpretation.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of PPT- *ML*,  $F(2.150-103.224) = .783, p = .2468$ , partial  $\eta^2 = .016$ . While there were no group\*time interactions, there were statistically significant main effects for time,  $F(2.150-103.224) = 12.240, p < .001$ , partial  $\eta^2 = .203$ . A statistically significant increase was noted across all time points except immediate post treatment to 1-week follow up. The largest mean difference was seen from baseline to 4-weeks and was 0.474 kg (95% CI .223-.725 kg),  $p = < .001$ .

The main effect of group showed no statistically significant difference in PPT- *ML* between groups  $F(1,48) = .474, p = .494$ , partial  $\eta^2 = .010$ . Overall, both groups improved in PPT-*ML* over time. See Figure 4.20 and Table 4.7 for further detail.





#### *Pressure Pain Threshold, 1<sup>st</sup> Dorsal Interossei Left (PPT-DIL)*

PPT-DIL was not normally distributed across any time or group variable as assessed by Shapiro-Wilk's test ( $p > .05$ ). Outliers and extreme outliers were noted in both groups via box plots, 1 outlier was noted at each point in time as assessed by examination of studentized residuals for values greater than  $\pm 3$ . There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance ( $p > .05$ ), however, homogeneity of covariances was violated, as assessed by Box's test of equality of covariance matrices ( $p < .001$ ). Mauchly's test of sphericity indicated that the assumption of sphericity was violated for the two-way interaction,  $\chi^2(2) = 31.832$ ,  $p < .001$ . Greenhouse-Geisser correction was utilized for interpretation.

There was no statistically significant interaction between the sham or thrust manipulation groups and time on the measurement of PPT-DIL,  $F(2.108-101.203) = .1735$ ,  $p = .180$ , partial  $\eta^2 = .035$ . While there were no group\*time interactions, there were statistically significant main

effects for time,  $F(2.108-101.203) = 5.592$ ,  $p = .004$ , partial  $\eta^2 = .104$ . A statistically significant increase was noted between immediate post treatment and 1-week and between immediate post treatment and 4-weeks. The largest statistically significant mean difference was seen from immediate post treatment to 4-weeks and was 0.681 kg (95% CI .050-1.313 kg),  $p = .028$ .

The main effect of group showed no statistically significant difference in PPT-*DIL* between groups  $F(1,48) = .118$ ,  $p = .733$ , partial  $\eta^2 = .002$ . Overall, both groups improved in PPT-*DIL* over time. See Figure 4.21 and Table 4.7 for further detail.

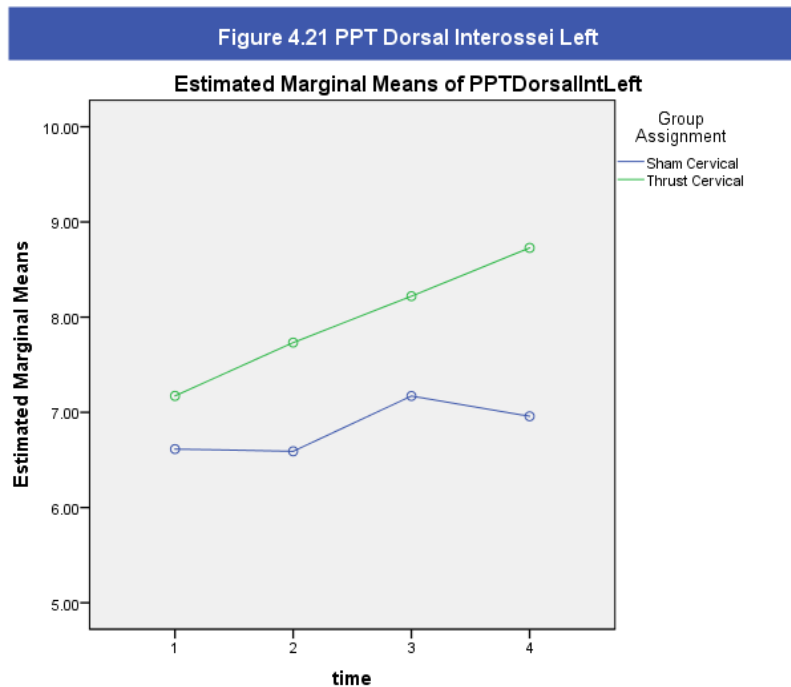


CHART 5		PRESSURE PAIN THRESHOLD: WITHIN-GROUP AND BETWEEN-GROUP CHANGE			
Measurement	Cervical Thrust Group*	Cervical Sham Group *	Between-Group Difference**	P value	Effect Size
Temporalis, right				.392^	0.29
Baseline	1.92 ± 0.9	1.92 ± 0.9			
Immediate	2.1 ± 1.0	1.94 ± 1.1			
Change from baseline to immediate	0.18 ± 0.5	0.03 ± 0.4	0.15 (-0.08-0.39)	.196°	0.37
1 wk	2.09 ± 1.0	1.93 ± 0.9			

Change from baseline to 1 wk	0.17 ± 0.6	0.01 ± 0.5	0.16 (-0.16-0.49)	.316°	0.29
4 wk	2.44 ± 1.1	2.2 ± 1.0			
Change from baseline to 4 wk	0.52 ± 0.8	0.28 ± 0.5	0.24 (-0.12-0.6)	.190°	0.38
Collapsed across time: Baseline to 4 wk				< .001§	0.98
Temporalis, left				.249^	0.34
Baseline	1.94 ± 1.1	1.86 ± 0.9			
Immediate	2.14 ± 1.1	1.86 ± 1.0			
Change from baseline to immediate	0.2 ± 0.5	0 ± 0.4	0.2 (-0.06-0.46)	.123°	0.44
1 wk	2.24 ± 1.2	1.89 ± 0.9			
Change from baseline to 1 wk	0.3 ± 0.7	0.03 ± 0.5	0.27 (-0.07-0.62)	.120°	0.45
4 wk	2.49 ± 1.1	2.13 ± 0.9			
Change from baseline to 4 wk	0.56 ± 0.8	0.27 ± 0.5	0.29 (-0.1-0.67)	.139°	0.43
Collapsed across time: Baseline to 4 wk				< .001§	0.91
Masseter, right				.195^	0.37
Baseline	1.68 ± 0.9	1.65 ± 0.9			
Immediate	1/94 ± 1.0	1.72 ± 0.9			
Change from baseline to immediate	0.26 ± 0.5	0.08 ± 0.3	0.18 (-0.04-10.41)	.099°	0.48
1 wk	1.91 ± 1.1	1.77 ± 0.8			
Change from baseline to 1 wk	0.24 ± 0.6	0.13 ± 0.5	0.11 (-0.18-0.4)	.454°	0.21
4 wk	2.21 ± 1.1	1.9 ± 0.9			
Change from baseline to 4 wk	0.53 ± 0.7	0.25 ± 0.5	0.28 (-0.05-0.62)	.099°	0.48
Collapsed across time: Baseline to 4 wk				< .001§	1.00
Masseter, left				.247^	0.25
Baseline	1.62 ± 0.9	1.56 ± 0.8			
Immediate	1.88 ± 1.1	1.67 ± 1.1			
Change from baseline to immediate	0.26 ± 0.4	0.11 ± 0.4	0.16 (-0.06-0.37)	.155°	0.41
1 wk	1.96 ± 1.2	1.77 ± 0.9			
Change from baseline to 1 wk	0.26 ± 0.4	0.11 ± 0.4	0.16 (-0.06-0.37)	.155°	0.41
4 wk	2.21 ± 1.3	1.91 ± 0.9			
Change from baseline to 4 wk	0.59 ± 0.7	0.35 ± 0.6	0.24 (-0.13-0.61)	.193°	0.37
Collapsed across time: Baseline to 4 wk				< .001§	1.01
1 <sup>st</sup> Dorsal Interossei, right				.140^	0.41
Baseline	7.24 ± 11.3	6.82 ± 9.8			
Immediate	7.88 ± 12.8	6.73 ± 10.1			
Change from baseline to immediate	0.64 ± 1.8	0.09 ± 0.8	0.73 (-0.07-1.53)	.072°	0.53
1 wk	8.07 ± 12.8	6.98 ± 10.3			
Change from baseline to 1 wk	0.83 ± 2.1	0.16 ± 1.4	0.67 (-0.33-1.68)	.184°	0.38
4 wk	8.7 ± 13.6	7.2 ± 10.4			
Change from baseline to 4 wk	1.45 ± 2.7	0.38 ± 1.6	1.07 (-0.21-2.36)	.099°	0.48
Collapsed across time: Baseline to 4 wk				.004§	0.71
1 <sup>st</sup> Dorsal Interossei, left				.180^	0.13

Baseline	7.17 ± 11.1	6.61 ± 9.8			
Immediate	7.73 ± 13.0	6.59 ± 10.0			
Change from baseline to immediate	0.56 ± 2.2	0.02 ± 0.9	0.58 (-0.4-1.57)	.235°	0.34
1 wk	8.22 ± 13.4	7.17 ± 10.8			
Change from baseline to 1 wk	1.05 ± 2.7	0.56 ± 1.4	0.49 (-0.72-1.7)	.421°	0.23
4 wk	8.73 ± 14.0	6.96 ± 10.6			
Change from baseline to 4 wk	1.55 ± 3.2	0.34 ± 1.6	1.21 (-0.26-2.68)	.103°	0.47
Collapsed across time: Baseline to 4 wk				.004§	0.68

Abbreviations: wk, week.

\*Values are mean ± SD

\*\*Values are mean adjusted change scores (95%confidence interval); Change from baseline to 4-week final visit is calculated as thrust group minus sham group.

^Value is two-way mixed ANOVA, interaction effect

§Value is two-way mixed ANOVA, group main effect

°Value is dependent samples t-test used to assess between-group differences in adjusted mean change scores

P values ≤ .05 are statistically significant

## Characteristics of Success

### *Global Rating of Change (GROC) and Patient Acceptable Symptom State (PASS)*

Success in this study was dichotomized based on GROC and PASS. To be considered successful, only scores of GROC  $\geq +5$  were considered. A “yes” response to PASS was considered a success. In order to determine statistical significance, the percentage of successful outcomes at each time interval was examined using chi-square tests of independence. Chi-square allows use of nominal variables and assumes independence of observations. Another assumption of chi-square is that each cell of the frequency comparison has 5 or more; in this analysis, there were cells with less than 5 and cells with a frequency of 0. In those cases, a decision was made to run the Fisher’s exact test acknowledging the assumption was not met. See Figures 4.22 and 4.23.

At the immediate post treatment response, there were no participants reporting success on GROC in the sham group and 6 in the thrust group; therefore, 100% of the successful outcomes at this immediate response were in the thrust manipulation group. A chi-square tests of

independence with Fisher's Exact test showed a statistically significant association,  $p = .022$  between the percentage of successful outcomes in each group.

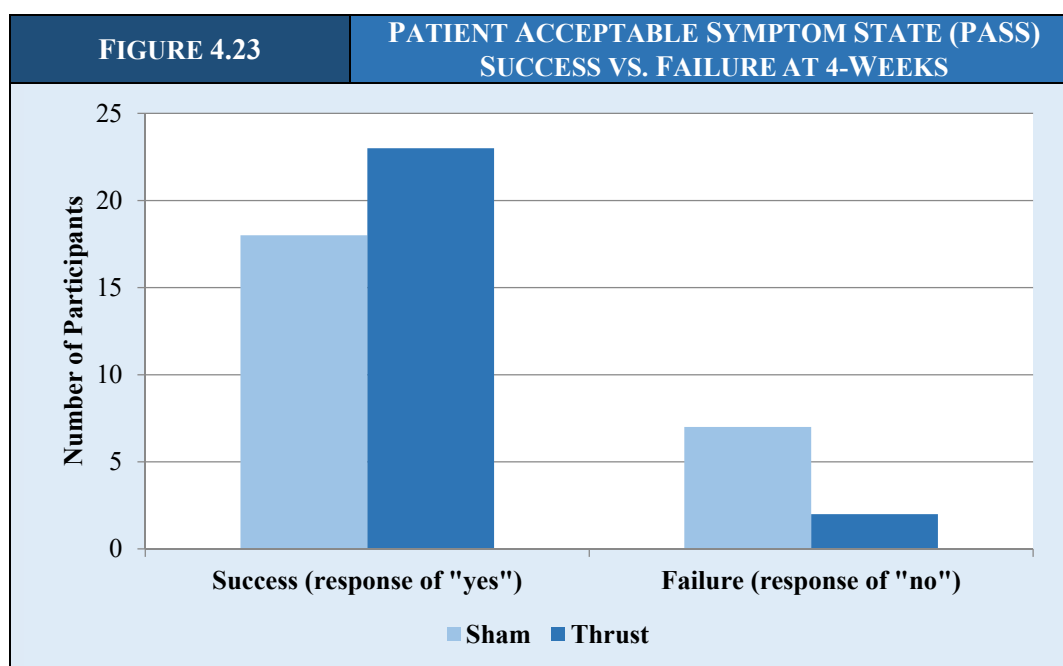
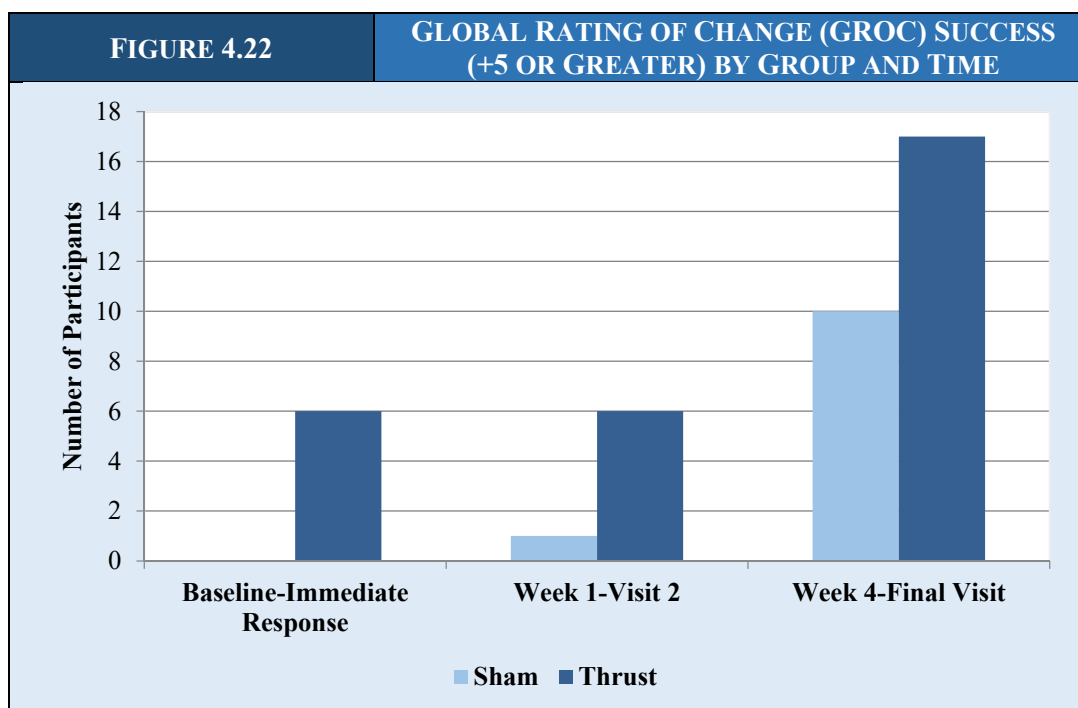
At 1-week, success on GROC was reported in 1 participant in the sham group and 6 in the thrust manipulation group; therefore, 85.7% of the success reported at this visit was in the thrust manipulation group. A chi-square test of independence with Fisher's Exact test shows a non-significant association,  $p = .098$ .

At 4-weeks, there were 10 participants reporting success on GROC in the sham group and 17 in the thrust group; therefore, 63% of the successful outcomes at this final visit were in the thrust manipulation group. All cells had  $>5$  counts. A chi-square test of independence showed a statistically significant association between group and success,  $\chi^2(1)=3.945$ ,  $p = .047$  between the percentage of successful outcomes in each group.

At 4-weeks, there were 18 participants reporting success on PASS in the sham group and 23 in the thrust group; therefore, 56% of the successful outcomes at this final visit were in the thrust manipulation group. All cells had  $>5$  counts. A chi-square test of independence showed a no statistically significant association between group and success,  $\chi^2(1)=3.388$ ,  $p = .066$ .

The percentage of individuals experiencing success on GROC differed statistically at the immediate post treatment response and at 4-weeks. Therefore, success at these 2 points in time was used to determine number needed to treat (NNT). NNT is the number of patients you would need to treat in order for 1 to improve or benefit from the treatment. While NNT does not tell us how much they would improve, it is an indication of effectiveness of treatment. The NNT based on GROC at immediate response was 4.17 (95% CI 2.5,13.8). For every 5 patients receiving treatment, 1 would get better compared to the control /sham group. At 4-weeks the NNT is 3.57

(95% CI 1.8-67.4). At 4-weeks, 4 patients receiving intervention with thrust manipulation would need to be treated for 1 to get better compared to the control/sham group. While the NNT is better at the 4-week interval, caution is used in interpretation due to the large confidence interval.



## Secondary Aim 1: Correlations

### *Function and Fear*

Previous research has supported a correlation in neck disability and jaw disability. NDI, TMD-DI, JFLS, and TSK-TMD were used to assess neck function, jaw function, and fear in this dissertation study. Spearman's rank order correlation was used to measure the strength and direction of relationship between these outcomes in baseline data of all 50 participants. A non-parametric correlation was indicated due to violations of the assumption of a linear relationship, noted outliers, and violation of normal distribution of data in the all measures except the TSK-TMD. Because a larger score on each of these functional scales represents a greater degree of disability, a positive correlation was expected. There was a statistically significant correlation noted among each of the measures. See Figure 4.24.

FIGURE 4.24	CORRELATION: FUNCTIONAL SCORES AND FEAR AT BASELINE		
Tests	Spearman rank, <i>r</i>	P value	Interpretation of association <sup>257</sup>
JFLS and NDI	0.286	.044	Positive and Fair at best
JFLS and TMD-DI	0.639	<.001	Positive and moderate to good
JFLS and TSK-TMD	0.605	<.001	Positive and moderate to good
NDI and TMD-DI	0.592	<.001	Positive and moderate
NDI and TSK-TMD	0.571	<.001	Positive and moderate
TMD-DI and TSK-TMD	0.724	<.001	Positive and good
Abbreviations: JFLS, Jaw Functional Limitation Scale; NDI, Neck Disability Index; TMD-DI, Temporomandibular Disorder Disability Index; TSK-TMD, Tampa Scale of Kinesiophobia.			

### *Pain, ROM, and Function*

Spearman's rank order correlation was used to measure the strength and direction of relationship between NPRS of the jaw and neck, MMO, and functional outcomes for the 50 participants' baseline data. A non-parametric correlation was indicated due to violations of the

assumption of a linear relationship, noted outliers, and violation of normal distribution of data in the all measures except the TSK-TMD. Higher pain and function scores represent higher disability, while lower MMO scores represent higher dysfunction. There was a statistically significant correlation noted among each of the measures with the exception of jaw pain and mouth opening. See Figure 4.25. It should be noted that while neck pain and jaw pain had a moderate correlation at baseline, this correlation was good at 1-week,  $r_s(48) = 0.724$ ,  $p < .001$  and 4-week analysis,  $r_s(48) = 0.708$ ,  $p < .001$ . Correlations between jaw pain and mouth opening also increased over time, but no greater than  $r_s(48) = 0.403$ , or fair relationship.

FIGURE 4.25		CORRELATION: PAIN, MMO, AND FUNCTION AT BASELINE	
Tests	Spearman rank, $r$	P value	Interpretation of association <sup>257</sup>
Jaw Pain and Neck pain	0.547	< .001	Positive and moderate
Jaw Pain and MMO	-0.153	.289	Negative and little to no relationship
Jaw Pain and JFLS	0.573	< .001	Positive and moderate
Jaw Pain and TMD-DI	0.476	< .001	Positive and fair
Jaw Pain and TSK-TMD	0.435	.002	Positive and fair
MMO and JFLS	-0.391	.005	Negative and fair
MMO and TMD-DI	-0.334	.018	Negative and fair
MMO and TSK-TMD	-0.317	.025	Negative and fair
Abbreviations: MMO, maximal mouth opening; JFLS, Jaw Functional Limitation Scale; TMD-DI, Temporomandibular Disorder Disability Index; TSK-TMD, Tampa Scale of Kinesiophobia.			

### Pressure Pain Threshold

Spearman's rank order correlation was used to measure the strength and direction of relationship between PPT in each location and jaw pain for all 50 participants in baseline data. A non-parametric correlation analysis was indicated due to violations of the assumption of a linear relationship, noted outliers, and violation of normal distribution of data in all measures.

Increased thresholds of pain generally represent improvement.<sup>132,140</sup> A statistically significant



correlation was noted among each of the PPT measures including masseter, temporalis, and first dorsal interossei bilaterally. There were no statistically significant associations between jaw pain and PPT at any location. See Figure 4.26

FIGURE 4.26		CORRELATION: PRESSURE PAIN THRESHOLD AT BASELINE	
Test for Correlation with all other PPT measures	Spearman rank, <i>r</i> Range for each measure	P value	Interpretation of association <sup>257</sup>
Temporalis Right	0.712-0.903	< .001 for all	Positive and good to excellent
Masseter Right	0.769-0.903	< .001 for all	Positive and good to excellent
1 <sup>st</sup> Dorsal Interossei Right	0.650-0.891	< .001 for all	Positive and good to excellent
Temporalis Left	0.650-0.916	< .001 for all	Positive and good to excellent
Masseter Left	0.823-0.922	< .001 for all	Positive and excellent
1 <sup>st</sup> Dorsal Interossei Left	0.698-0.891	< .001 for all	Positive and good to excellent

## Secondary Aim 2: Test-Retest Reliability and Construct Validity of JFLS and TMD-DI

As noted in previous chapters, the TMD-DI is a functional outcome measure used in physical therapy research with no evidence to support reliability or validity. The JFLS has been studied in a dental population for reliability and validity, but not within a physical therapy population. Previous research has used GROC to classify patients into groups for the purpose of analyzing psychometric properties in outcome measures.<sup>198,200,262</sup> In this dissertation study analysis, a range of GROC, -2 to +2, was used to define stability or minimal to no change. If a participant is stable, functional outcome scores should be relatively unchanged. If a participant perceives improvement, a change in functional outcome is expected. Before examination of correlations, participants were categorized based on progress at the 1-week and 4-week visit. Those reporting GROC -2 to +2 were considered unchanged or stable, and GROC  $\geq$  +4 was considered improved. A GROC of +3 was unclear and not used in analysis. It should be noted

that a GROC of +4 was included in the success group in this analysis as opposed to the more stringent stipulation of a GROC of +5 to quantify success for the treatment outcomes.

It is important to note change over time for the stable and improved groups. An independent *t*-test was performed to compare only these two groups on change scores for the JFLS and TMD-DI. In order to discuss construct validity, it was hypothesized that the change scores of the improved and stable groups would be statistically different.

Intraclass Correlation Coefficient (ICC) is used to measure reliability of data that has been collected as groups and has been used to assess test-retest reliability in this fashion in previous research.<sup>198,200,262</sup> ICC values represent both correlation and agreement between measures;<sup>255,257</sup> the agreement and correlation between baseline functional scores and follow-up scores were compared. A two-way (model 2,1) repeated measures assessment was used as all participants were fixed and the scores were from a single rating as opposed to a mean. ICC values range from 0-1; the closer to 1, the stronger a relationship. If an ICC is positive, the direction of the relationship is the same: as one score increases, so does the other and vice versa for negative correlations. The degree of agreement will be structured according to Shrout and Fleiss: <0.10 indicates no agreement, 0.11-0.40 indicates slight agreement, 0.41-0.60 is fair agreement, 0.61-0.80 is moderate agreement, and >0.80 is excellent agreement.<sup>263</sup>

#### *Jaw Functional Limitation Scale*

There was homogeneity of variance in each change score variable (stable and improved at 1-week and 4-weeks). There was no statistically significant difference in mean change scores on JFLS between improved (n=11) and stable (n=31) patients at 1-week,  $t(40) = -0.307$ ,  $p=.761$ .

There was also no statistically significant difference in mean change scores on JFLS between improved (n=31) and stable (n=11) patients at 4-weeks,  $t(40) = -1.929$ ,  $p = .061$ .

The ICC calculated for stable patients at 1-week (n=31) and 4-weeks (n=11) for the JFLS were 0.897 (95% CI 0.797-0.949) and 0.949 (95% CI 0.824-0.986) respectively. At both time-periods, the agreement was excellent. These correlations were compared to the correlation of the improved group. The ICC calculated for improved patients at 1-week (n=11) and 4-weeks (n=31) for the JFLS were 0.790 (95% CI .392-.939) and 0.632 (95% CI 0.363-0.804) respectively.

#### *TMD-Disability Index*

There was homogeneity of variance in each change score variable (stable and improved at 1-week and 4-weeks). There was a statistically significant difference in mean change scores on TMD-DI between improved (n=11) and stable (n=31) patients at 1-week,  $t(40) = -2.513$ ,  $p=.016$ . There was also a statistically significant difference in mean change scores on TMD-DI between improved (n=31) and stable (n=11) patients at 4-weeks,  $t(40) = -2.180$ ,  $p = .035$ .

The ICC calculated for stable patients at 1-week and 4-weeks for the TMD-DI were 0.870 (95% CI 0.748-0.935) and 0.912 (95% CI 0.707-0.975) respectively. At both time-periods, the agreement was excellent. These correlations were compared to the correlation of the improved group. The ICC calculated for improved patients at 1-week (n=11) and 4-weeks (n=31) for the TMD-DI were 0.589 (95% CI 0.020-0.870) and 0.408 (95% CI 0.069-0.663) respectively.

## Side-Effects

An adverse event can describe any range of unwarranted or undesirable side-effects from treatment. Adverse events range from mild to severe; severe events can include life threatening or life altering situations. There were no serious adverse events reported in this dissertation study. Mild treatment side-effects are an expected potential consequence of cervical spine manual therapy interventions (thrust joint manipulation, non-thrust joint mobilization, or soft tissue mobilization). Treatment side-effects include neck pain, headache, aggravation of present complaints, and fatigue.<sup>159</sup> Previous research notes up to 50% of participants may have mild side-effects that begin within 24 hours of treatment and resolve within 72 hours.<sup>177,264</sup> Treatment side-effects were tracked in this dissertation study and were considered mild if the intensity of symptoms was rated 1 or 2 (1-4 intensity scale) and symptoms resolved within 48 hours.

### *Thrust Manipulation Group*

In the cervical TJM group, 9 out of the 25 participants (36%) experienced treatment side-effects. Of those 9 participants, 8 (89%) were mild and only 1 participant (11%) reported moderate treatment side-effects. This participant described a headache (HA) after the baseline visit with intensity of 3 on the 1-4 scale; however, it only lasted 2 hours after treatment. The mild treatment side-effects reported in this group included headache, stiffness in neck or jaw, fatigue of jaw with exercises, and aggravation of current symptoms.

### *Sham Manipulation Group*

In the sham group, 12 out of the 25 participants (48%) experienced treatment side-effects. Of those 12 participants, 5 (42%) were mild and 6 (50%) reported moderate treatment side-effects. Moderate effects had intensity of symptoms score of 3 to 4 on the 1-4 scale; however,

almost all symptoms resolved within 48 hours. One participant reported severe (intensity of 4 on 1-4 scale) aggravation of neck pain after the 1-week visit lasting 7 days. The mild treatment side-effects reported in this group included aggravation of present complaints (most frequent), jaw discomfort or pain, soreness, neck pain, and tenderness.

### **Summary of Results**

There were no baseline differences between groups except left lateral deviation of the jaw. The mixed model ANOVA revealed significant group by time interaction for JFLS indicating both groups had statistically significant simple main effects of time from baseline to 4-weeks. The thrust manipulation group also had statistically significant simple main effect of time from baseline to 1-week. A statistically significant interaction was also noted for the TSK-TMD showing simple main effects of time in the thrust group only and a statistically significant simple main effect of group, favoring the thrust manipulation group. Measurement of variables that did not have a statistically significant interaction effect did demonstrate a statistically significant main effect of time.

Change scores examining group differences from baseline to 4-weeks revealed statistically significant differences favoring the thrust manipulation group for right lateral deviation of the jaw, NPRS of the jaw, NPRS of the neck, TSK-TMD, and cervical right rotation. There were no statistically significant change scores favoring the sham group.

GROC and PASS scores favored the thrust manipulation group with a larger percentage of patients reporting success. Functional outcomes for the jaw, neck, and fear scales did show statistically significant correlations of varying strengths. The strongest positive correlation was

between TMD-DI and TSK-TMD. Jaw pain was moderately correlated to neck pain and JFLS. Pressure pain thresholds were all strongly correlated with one another.

Psychometric analysis of the JFLS and TMD-DI showed moderate to excellent agreement of scores in stable participants. However, there was also moderate correlation in the improved group for the JFLS. The TMD-DI showed only fair agreement in the improved group. Statistically significant differences in the change scores between the improved and stable groups were only present for the TMD-DI.

There were no associated adverse events related to this study. Participants in both groups experienced mild treatment side-effects (greater percentage in the sham group) and one participant in the sham manipulation group experienced moderate to severe side-effects lasting 7 days after treatment.

## CHAPTER 5: DISCUSSION

### Introduction

Temporomandibular disorder (TMD) is the third most common chronic pain condition,<sup>40</sup> with an estimated 15% of individuals with TMD developing chronic pain.<sup>6</sup> Chronic TMD, like other chronic pain conditions, can affect quality of life and place an economic burden on society.<sup>40,53</sup> Effective treatment interventions may have an impact on the economic burden of TMD related pain and dysfunction as well as the prevalence of chronicity. The relationship between the cervical spine and TMD has been established, yet treatment of the cervical spine for TMD has only been examined in a limited fashion. There is some support for the use of cervical thrust joint manipulation (TJM) in individuals with TMD through multimodal intervention studies<sup>59,152</sup>; however, the specific effect of TJM could not be determined due to other differences between groups. Other studies have examined TJM through a randomized design; however, the populations studied were children with a history of trauma<sup>160</sup> subjects with neck pain,<sup>68</sup> or subjects with the presence of latent trigger points<sup>69</sup> as opposed to jaw pain or dysfunction. The primary aim of this dissertation's randomized controlled trial (RCT) was to examine 2 groups treated in similar fashion with randomization of either cervical TJM or sham manipulation. To this author's knowledge, this is the first study examining the specific impact of cervical spine TJM on adults with a primary complaint of TMD. Chapter 5 will interpret findings of group differences and group by time interactions for measured variables. Cohen's criteria will be utilized to interpret effect size results as follows: 0.2 small, 0.5 moderate, and 0.8 large effect.<sup>265</sup> Discussion of success rates between groups, secondary findings of meaningful correlations, and the TMD functional outcome tools used in this analysis will also be presented.

Chapter 5 will conclude with acknowledgement of limitations, delimitations, and recommendations for future research.

### **Primary Aim-Group Differences**

#### *Jaw Range of Motion*

Range of motion (ROM) for mouth opening is the most frequently reported objective outcome measure related to TMD; maximal mouth opening (MMO) and lateral deviation ROM are important considerations in temporomandibular function. MMO changes in previous research report effect sizes ranging from  $d = 0.22$  to  $d = 2.08$  (see Table 3.3). Results of this dissertation study showed jaw ROM improved in both groups over time for MMO and lateral deviation. The overall change in MMO for the entire sample in this dissertation study (collapsed over time) showed a large effect ( $d = 1.34$ ). The interaction effect of group and time revealed a small effect ( $d = .33$ ) favoring the TJM group. While the interaction effect size was small, it may have clinical value if participants gain enough ROM to improve function.

Normal MMO has been reported in large ranges in the literature; however, 40-55 mm<sup>7,9,187</sup> is generally accepted. Both the thrust group and the sham group started with a mean of 37 mm MMO. ROM for jaw opening improved in both groups over time with a mean of 45 mm in the thrust group and 42 mm in the sham group at the final 4-week visit. While both groups moved into the normal functional range with MMO over time, there was no statistically significant group by time interaction for MMO or lateral deviation ROM. There was a trend for improvement in all planes (MMO and deviation) over time for both groups, and these main effects were statistically significant. Looking at the entire sample, 36 participants (72%) had final MMO values  $\geq 40$  mm.



Previous research has shown an immediate change in MMO with cervical TJM. Mansilla-Ferragut<sup>68</sup> et al performed atlanto-occipital TJM or sham manipulation on a group of women with neck pain; these authors reported a statistically significant improvement for MMO ( $p < .001$ ) with an increase of 3.5 mm in the thrust group and a 0.3 mm reduction for the sham group. In this dissertation study, immediate post treatment response showed a similar gain of 3 mm MMO for the thrust group; however, the sham group showed a 1.5 mm improvement. Changes from baseline to final measurement were 8 mm in the thrust group and 4.9 mm in the sham group. The minimal detectable change (MDC) is the amount of change needed to improve confidence the change is greater than measurement error. MDC for MMO has been reported to range from 1.73-6 mm.<sup>190,193,194</sup> Change from baseline to final measurement in the thrust group meets the highest reported MDC. Minimal clinically important difference (MCID) is the change in a measurement that is meaningful to the patient.<sup>266</sup> MCID has not been established for MMO.

The sample size estimation in this clinical trial was powered on detecting a significant difference for MMO. As there were no statistically significant interaction effects to report, it is possible previous reports of effect size for MMO overestimated the effect, and this dissertation study did not include a large enough sample size to show a difference if one exists. It is also possible this dissertation study was adequately powered, and there exists no difference between groups. The participants in the sham group from Mansilla-Ferragut<sup>68</sup> et al had a mean reduction in opening, but that was not the case in this dissertation study. Mansilla-Ferragut<sup>68</sup> et al did not provide any additional treatments, while this dissertation utilized a multimodal treatment including education, exercise, soft tissue mobilization (STM) of suboccipitals, and the cervical intervention (thrust versus sham). The addition of these other treatments in the current study may have led to smaller differences between groups.

### *Numeric Pain Rating Scale*

Numeric Pain Rating Scale (NPRS) is an 11-point scale used to measure pain intensity. In this dissertation study, the NPRS was used for jaw, neck, and headache (HA) pain. A mean of best, worst, and current pain for each location in a 24-hour period was reported. The minimal level of disability set for inclusion in this dissertation was jaw pain  $\geq 2$  on NPRS. There was no minimal disability set for neck or headache (HA) pain as the population of interest was individuals with a primary complaint of TMD. Neck pain and HA are common complaints associated with TMD<sup>7,9</sup>; however, average pain for the population studied in this dissertation was lower than expected. Average neck pain at baseline was  $< 2$  for 25 participants, and average HA pain was  $< 2$  for 23 participants. Baseline NPRS for neck pain ranged from 0 (n=6) to 9.7 (mean = 3.0) in this sample, and baseline HA pain ranged from 0 (n=8) to 6.3 (mean = 2.1). It is possible the low level of baseline neck and HA pain created a floor effect on these variables. Between-group effect sizes for neck and HA pain were small; however, a large effect for neck pain ( $d = 1.02$ ) and a moderate effect ( $d = 0.72$ ) for HA pain was noted for the entire sample (collapsed over time).

Patients with TMD often have neck pain complaints, and some neck pain patients have findings of TMD related impairment. Cervical spine disorders can exacerbate or contribute to orofacial pain complaints.<sup>47,114</sup> Bevilaqua-Grossi<sup>112</sup> et al examined 100 women with TMD, noting greater severity of TMD pain was associated with increase prevalence of cervical pain. At baseline, the sample in this dissertation study did show moderate correlation ( $r = 0.547$ ) between jaw pain and neck pain, despite the lower baseline levels of pain.

NPRS of the jaw at baseline was 2 for 13 participants and  $\leq 3$  for 30 participants. While there was no difference between groups at baseline, perhaps the low initial level of baseline pain

had an impact on the potential for change. Mean NPRS for jaw pain at baseline was 3.7 in each group. Final NPRS was 2.7 in the sham group (change = 1.04) and 1.7 in the thrust group (change = 2.0). Psychometric property analysis of NPRS relevant to the TMD population is limited; however, NPRS has demonstrated responsiveness in a neck pain population with a MCID of 1.3.<sup>198</sup> A study conducted of a large heterogeneous chronic pain population suggested an average of 2 points reflected change that was clinically meaningful on the NPRS.<sup>201</sup> Farrar<sup>201</sup> et al examined the NPRS in patients with chronic pain, reporting a 1.74-point decrease represented clinically meaningful change. Kalamir<sup>97,100</sup> et al defined clinically important change in their intervention study with a population of TMD participants as  $\geq 2$  on NPRS. Based on these reports in literature, it is appropriate to say the thrust group may have achieved a clinically meaningful change in jaw pain from baseline to 4-week follow-up. It is worth noting there was little to no association between jaw pain and MMO ( $r = 0.153$ ).

The immediate post treatment response for jaw and neck NPRS represents an interesting topic of discussion. The immediate response of jaw pain showed greater change in the thrust group. NPRS for jaw pain decreased to a mean of 2.40 (change = 1.29) in the thrust group and 3.56 (change = 0.17) in the sham group; the independent *t*-test was statistically significant for between group difference ( $p = .032$ ) in jaw pain change scores from baseline to immediate post treatment, favoring the thrust group. The independent *t*-test for change in neck pain was also statistically significant ( $p = .046$ ) favoring the thrust group in the immediate response. There was a moderate effect size favoring the thrust group for both jaw pain ( $d = 0.62$ ) and neck pain ( $d = 0.58$ ) in change from baseline to immediate post treatment. Previous studies of cervical TJM in a neck pain population report baseline NPRS values of 3.7,<sup>159</sup> 5.6,<sup>173</sup> and 5.3,<sup>267</sup> compared to a lower baseline in this dissertation sample (NPRS =  $3 \pm 2.4$ ). It is possible higher levels of

baseline jaw or neck pain could show larger changes. The trend in this dissertation of greater improvement in neck pain for the thrust group was consistent with these previous studies. In previous studies utilizing cervical TJM with TMD populations, neither Mansilla-Ferragut<sup>68</sup> nor Oliveira-Campelo<sup>69</sup> reported pain as an outcome measure, and Cuccia<sup>152</sup> et al tested pain at baseline but not again until 24 and 36 weeks. The differences in study design make subsequent comparisons difficult. The immediate post treatment reduction in jaw and neck pain may provide a small window of improvement that could be clinically meaningful. It is possible cervical TJM would allow an individual to tolerate exercise or other intervention sooner than without the TJM.

### *Self-Report Functional Outcome Scales*

The Jaw Functional Limitation Scale (JFLS) is a 20 item self-report scale assessing three constructs (mastication, vertical jaw movement, emotional/verbal expression) to quantify functional limitation.<sup>203</sup> Each item is scored by the patient from 0 (no limitation) to 10 (severe limitation); higher scores represent increased level of disability. JFLS did show a statistically significant group by time interaction with a moderate effect size ( $d = 0.60$ ) favoring the thrust group. A large effect size ( $d = 2.24$ ) was noted in the main effect collapsed over time. While no MDC or MCID has been established for JFLS, moderate to large effect sizes have been documented for dental treatments ( $d = .41-.92$ ).<sup>106,204</sup> In the current dissertation study, a mean change of 23.4 was noted in the thrust group and 12.96 in the sham group. A Global Rating of Change (GROC)  $\geq +5$  was used to dichotomize success in this study. Further examination of change scores for JFLS in all individuals who were considered a success at the 4-week visit revealed an average change of 23.8 points. JFLS has been used in dental literature, but has not been reported in physical therapy (PT) literature; however, a cross-sectional study published in

October 2017 suggested use of this tool for future research as a measurement of function.<sup>268</sup> A standardized self-report functional outcome tool is one piece of an assessment of functional performance,<sup>269</sup> allowing for interpretation of functional level from the patient's perspective and change over time.<sup>270</sup> Self-report scales allow readers to discuss effect size of functional change and make comparisons across studies. An applicable functional outcome tool for TMD is needed in research and clinical practice. Examination of JFLS reliability and validity within PT could improve confidence in the use of this tool in the future.

Previous research has supported a strong correlation ( $r = 0.82$ ,  $r = 0.95$ ) between jaw dysfunction and neck disability in persons with chronic TMD.<sup>20,21</sup> Neck Disability Index (NDI) is a self-report functional outcome tool frequently used in clinical practice and research surrounding a neck pain population. This 10-question scale generates a total score interpreted as a percentage of perceived disability, with higher scores representing greater disability. While there are no reports of MDC or MCID for a TMD population, MDC for NDI in a neck pain population has been reported as a 10%-21%;<sup>206,207</sup> MCID reports range from 10-38% change in perceived disability.<sup>206</sup> A systematic review published in 2009 reported a score of 5 (10%) for MDC and 7 (14%) for MCID.<sup>206</sup> Both groups in this study showed reduction in neck disability from baseline to 4-weeks; an 8.36% change in disability was noted in the thrust group and 4.96% in the sham group. The initial baseline disability was 19.44% and 22.80% for the thrust and sham groups, respectively. The low baseline neck disability may have created a floor effect; neither group met the minimum 10% disability change needed for MCID. Further examination of change scores for NDI in all participants considered a success ( $\text{GROC} \geq +5$ ) at the 4-week visit, revealed an average change of 8.53% on NDI.

TMD Disability Index (TMD-DI) is a 10 question self-report scale and has been used in clinical practice and published studies of intervention effectiveness,<sup>58,208,209</sup> yet there are no reports of psychometric property analysis in the literature. Previous use of the TMD-DI demonstrated improvement of 43.4% (21.7 points) in one study, while another study showed only a 13.9% change in TMD-DI for individuals who demonstrated progress. In the current dissertation study, TMD-DI scores improved in both groups; however, the overall change was small. Scores improved by 15.4% (4.2 points) in the thrust group and 10.5% (2.24 points) in the sham group. A large effect size ( $d = 1.40$ ) was noted in the main effect collapsed over time. This tool is difficult to interpret due to the lack support for reliability and validity and the small changes noted in this study.

The Tampa Scale for Kinesiophobia for Temporomandibular Disorders (TSK-TMD) is a 12-item measure assessing fear of movement or (re)injury. TSK-TMD is adapted from the original Tampa Scale for Kinesiophobia (TSK) that has been used to assess fear in individuals with low back pain (LBP), osteoarthritis, and other chronic pain conditions.<sup>223</sup> TSK-TMD did have a statistically significant group by time interaction with a moderate to large effect size ( $d = 0.80$ ) favoring the thrust group. A large effect ( $d = 1.11$ ) was noted in the main effect collapsed over time. Mean change score in the thrust group was 4.2 and 0.68 in the sham group. Some functional limitations in the TMD population have demonstrated a stronger association with fear than pain,<sup>223</sup> and the association between fear of movement and chronicity of TMD has been supported.<sup>225</sup> MDC and MCID have not been established for use of the TMD specific version of this tool, making it difficult to compare cut points to the 13-item tool used for chronic neck and back pain. In chronic back pain, research has reported a MDC of 5.6<sup>226</sup> on the 13-item Tampa Scale for Kinesiophobia (TSK); therefore it is possible the change of 4.2 in the thrust group did

not exceed measurement error. Further examination of change scores for TSK-TMD in all participants considered a success ( $\text{GROC} \geq +5$ ) at the 4-week visit revealed an average change of 5.49 on TSK-TMD.

In this dissertation study, correlations between neck function, jaw function, and other measurements were examined. JFLS and NDI only had a fair correlation ( $r = 0.29$ ); however, the strength of this correlation increased over time ( $r = 0.54$ ). TMD-DI and NDI only had a moderate correlation ( $r = 0.59$ ) at baseline. MMO has been utilized to describe functional limitation in the TMD population; however, there was only a fair association ( $r = 0.32-0.40$ ) between pain-free MMO and any of the functional outcome measures utilized (JFLS, TMD-DI, or TSK-TMD). There was good strength in correlation between TMD-DI and TSK-TMD at baseline ( $r = 0.72$ ) and moderate to good association between JFLS and TSK-TMD ( $r = 0.60$ ) and JFLS and TMD-DI ( $r = 0.64$ ). It is important to keep in mind that functional outcome scale scores, specifically TMD-DI, did not change much over time; therefore, interpretation of correlations may be misleading.

### *Cervical Spine ROM*

ROM of the cervical spine was measured for flexion, extension, rotation right, and rotation left. ROM improved for both groups in all directions, and the change scores from baseline to 4-week visit favored the thrust group for all measurements. The only measurement to show statistically significant differences using the independent  $t$ -test for change scores was cervical right rotation ROM, favoring the thrust group. Fletcher<sup>231</sup> et al report the standard error of measurement for cervical spine ROM is between  $2.5^\circ$  and  $4.1^\circ$ ; these authors also report at least  $5^\circ$  is necessary to demonstrate true change. Mean change for this dissertation from baseline to 4-weeks was  $> 5^\circ$  in the thrust group for all measurements and  $< 5^\circ$  in the sham group for all

measurements. Between-group effect sizes were small; however, a moderate to large effect was noted in all movements for the entire sample (collapsed over time): flexion,  $d = 0.68$ ; extension,  $d = 0.82$ ; rotation right,  $d = 0.92$ ; rotation left,  $d = 0.81$ .

### *Pressure Pain Threshold*

Pressure Pain Threshold (PPT) is a quantifiable palpatory assessment defined as the minimum amount of pressure needed to cause a sensation of pain.<sup>232</sup> Previous research has demonstrated reduced pain thresholds in persons with TMD.<sup>133</sup> Increases in masticatory muscle PPT has been demonstrated in intervention studies for various populations including individuals with TMD, myofascial facial pain, and neck pain.<sup>22,23,153,238</sup>

PPT values found in this study are similar to mean values reported in the literature (See table 5.1). There was an overall improvement in both groups for PPT over time. A notable trend was an increase in PPT immediately post treatment in thrust group more than sham group for all points tested; however, this change, and all change scores noted for PPT of the masseter and temporalis, were  $< 1 \text{ kg/cm}^2$ . It is possible the trajectory of immediate improvement has meaning, as the thrust group had higher PPT values for all tests. However, this difference was not statistically significant. While no specific MCID has been established for PPT in the TMD population, two studies have reported MCID values of  $\geq 1.10 \text{ kg/cm}^2$ ; however, it is important to note these studies were performed on healthy participants.<sup>237,240</sup> The mean difference between groups in this dissertation study ranged from 0.11-0.29 kg. Voogt<sup>241</sup> utilized  $\geq 15\%$  change in PPT to represent MCID. Further examination of dissertation results show the MCID was met from baseline to immediate response in masseter right and left for only the thrust group. At baseline to 1-week, MCID was met for the thrust group only for temporalis left and masseter left.



MCID was met for both groups from baseline to 4-week in temporalis right, masseter right, masseter left, and only the thrust group for temporalis left.

TABLE 5.1		MEAN PPT VALUES ( $kg/cm^2$ ) COMPARED TO REPORTS IN LITERATURE
Author: Population	Location	PPT
Reynolds: TMD	Masseter, Right	1.66 kg $\pm$ 0.85
	Temporalis, Right	1.92 kg $\pm$ 0.89
LaTouche <sup>132</sup> : Neck Pain	Masseter	2 kg $\pm$ 0.4
	Temporalis	2.2 kg $\pm$ 0.5
LaTouche: Healthy	Masseter	3.4 kg $\pm$ 0.5
	Temporalis	3.7 kg $\pm$ 0.6
Fernandez-Camero <sup>238</sup> : TMD	Masseter	1.0-1.11kg
Garrigos-Pedron <sup>271</sup> : TMD and migraine	Masseter	1.78-1.89 kg
	Temporalis	1.81-2.08 kg
<i>Abbreviations: PPT, Pressure Pain Threshold; TMD, Temporomandibular Disorder; kg, kilogram Results are mean <math>\pm</math> SD or range of mean values</i>		

In this dissertation, none of the PPT values were correlated with jaw pain; however, all PPT values were correlated to one another, including the first dorsal interossei. The first dorsal interossei was chosen to represent a remote site (ulnar nerve innervation, C8/T1), distant to the dermatomal site of interest (C0-3).<sup>233,234</sup> There was a good to excellent correlation between PPT of each dorsal interossei location and the masticatory muscles in this study. Reduced thresholds have been seen in distant sites as well as contralateral locations with chronic TMD populations, leaving speculation of the role of central sensitization.<sup>149,235,236</sup> Central sensitization refers to a mal-adaptive process of reduced stimulus threshold with increased facilitation based on potential overload of nociceptive afferent information to second order neurons.<sup>4,73</sup> There is often a simultaneous reduction in inhibitory responses. The increased responsiveness to stimulation presents clinically as pain without tissue provocation, hypersensitivity to stimulus (hyperalgesia),

or pain from normally non-painful stimuli (allodynia).<sup>73,133</sup> Clinical signs of central sensitization include reduction in PPT.<sup>140</sup> Patients with chronic TMD have demonstrated widespread pain, abnormal central nervous system changes in the brain,<sup>141</sup> and signs of central sensitization alongside peripheral sensitization.<sup>140,142</sup> Sault<sup>174</sup> et al described a case study of a woman with bilateral TMD and cervical pain. Manual therapy and exercise treatment directed at both the temporomandibular joint and cervical spine resulted in reduction of pain, improved function of the jaw, and increased PPT at the jaw and a remote location at the thenar eminence. In this dissertation, there was an increase of  $> 1.10 \text{ kg/cm}^2$  for the 1<sup>st</sup> dorsal interossei on both sides in the thrust group from baseline to 4-weeks. The mean difference between groups for 1<sup>st</sup> interossei measurements was 1.07 and 1.21 kg for the right and left side, respectively.

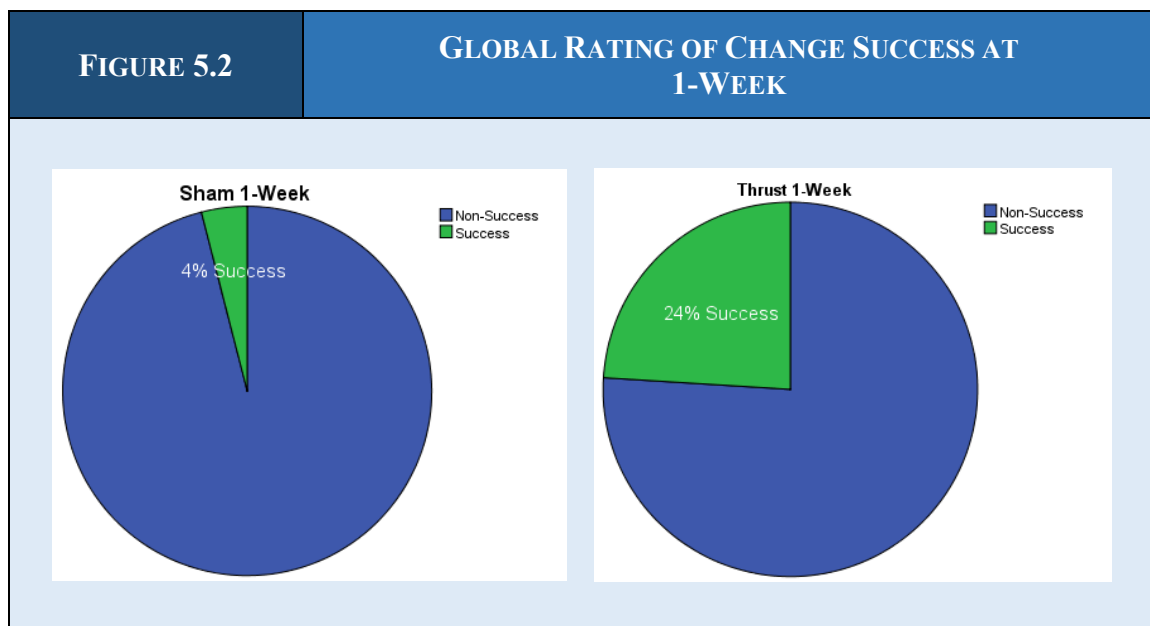
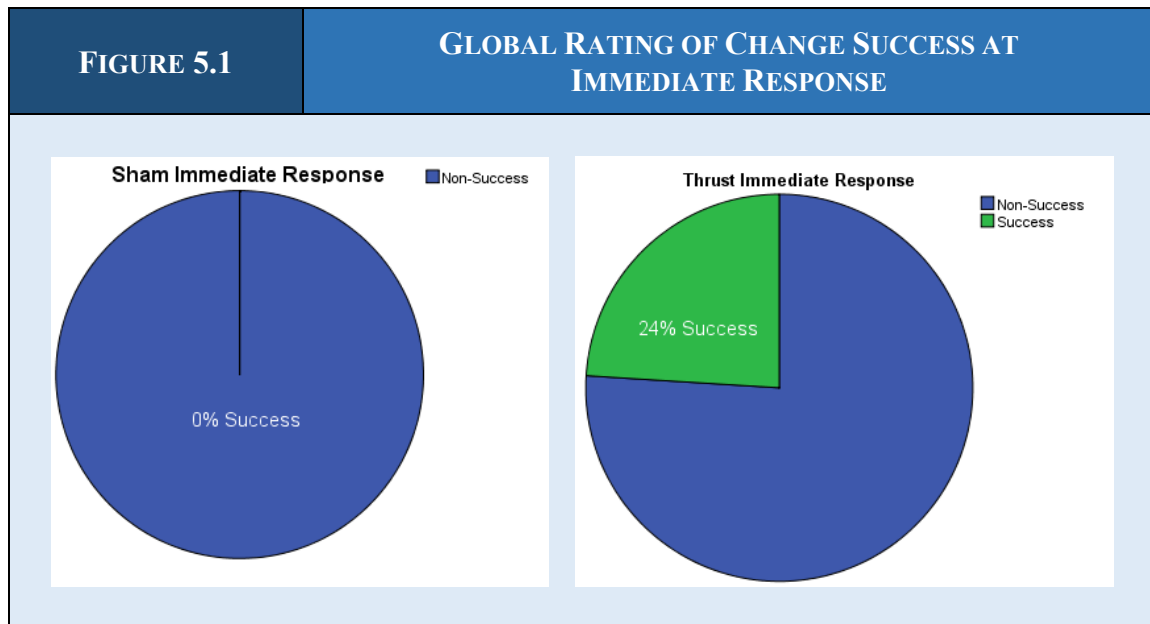
La Touche<sup>132</sup> et al examined PPT in 23 patients with mechanical neck pain demonstrating reduced PPT in masticatory muscles (masseter and temporalis) as well as the upper trapezius and C5-6 facet joint. They also examined a remote location at the anterior tibialis. While statistically significant changes in PPT were present for the masticatory and cervical regions, the difference between groups (neck pain and healthy controls) at the anterior tibialis was not statistically significant.<sup>132</sup> Fernandez-de-las-Penas<sup>133</sup> et al also examined PPT values of anterior tibialis in a TMD population and did show statistically significant differences. LaTouche<sup>140</sup> et al published a meta-analysis examining central sensitization in patients with TMD in 2017. The meta-analysis indicated statistically significant reduction in PPT levels was present in both trigeminal and remote areas in patients with TMD, suggesting both peripheral and central nervous system involvement. Chronic pain conditions like TMD, low back pain (LBP), and neck pain may involve both peripheral and central pain mechanisms. Understanding the differences as well as the relationship between the two can guide treatment.<sup>272,273</sup> The population examined in

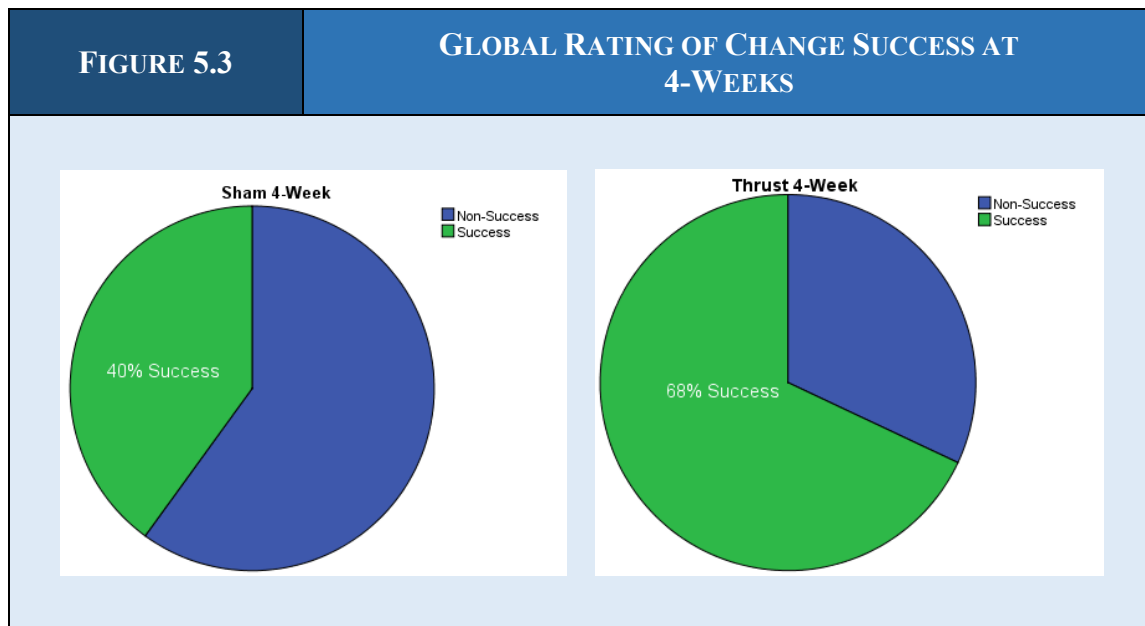
this dissertation study did present with signs of both peripheral and central pain mechanisms. The presence of centrally mediated pain in individuals with TMD may suggest an appropriate indication for spinal TJM,<sup>273</sup> or a combination of manual therapy and pain neuroscience education.<sup>274-276</sup>

### *Characteristics of Success*

This dissertation study was powered around MMO, yet there was no statistically significant interaction effect identified. There was a difference in patient perceived change as measured by GROC. Previous research has used  $\geq +4$ <sup>165,215</sup> or a more stringent  $\geq +5$ <sup>154,159,277</sup> to dichotomize success. A cut-score of +5 or higher on the GROC was used as a measure of success in this dissertation study. Immediately post treatment, 6 individuals in the thrust group and 0 in the sham group reported success. At 1-week, success was noted in 6 participants in the thrust group and 1 in the sham group. At the 4-week visit, 17 participants in the thrust group and 10 in the sham group reported success.

It is interesting to note that if the cut-off for success had been set at  $\geq +4$ , the number of successful outcomes would not change at any time period for the sham group. However, there were participants in the thrust group with +4 on GROC that would have been considered a success. The number of successful outcomes would have increased from 6 to 10 at the immediate response, from 6 to 10 at 1-week, and 17 to 21 at 4-weeks; again, all numbers in the sham group would have remained the same. If  $\text{GROC} \geq +4$  had been set as the criteria of success, the separation between groups would have been larger at each time interval. Figure 5.1, 5.2, and 5.3 detail the percentage of participants with a successful outcome at each data measurement point using the *a-priori* choice of  $\geq +5$  GROC to describe success.





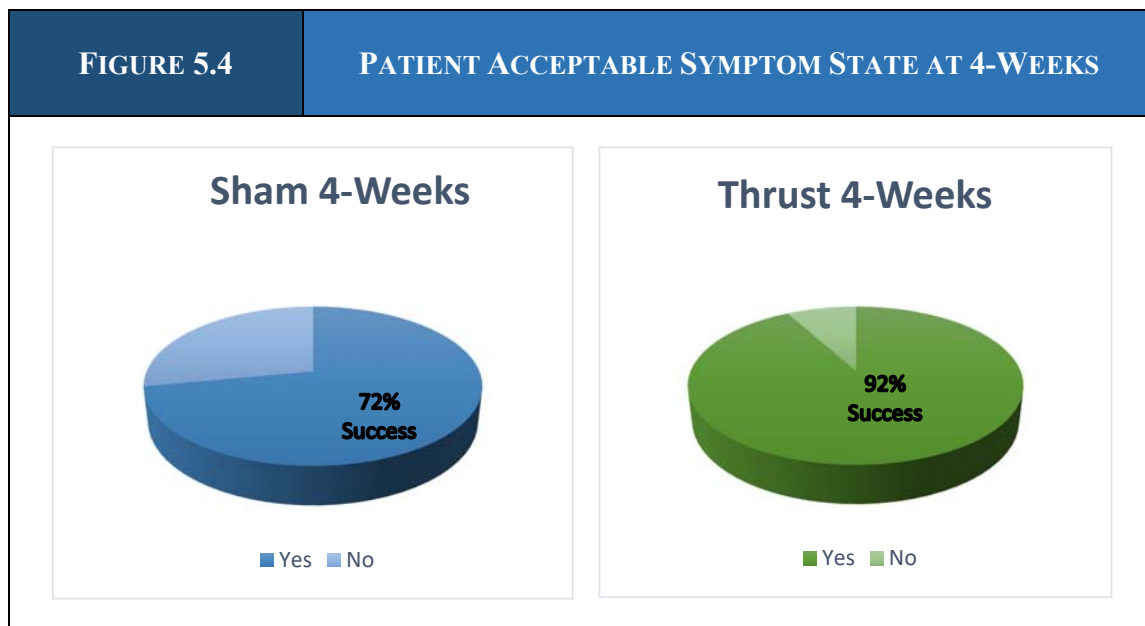
Controversy surrounding the construct validity<sup>278,279</sup> of this measure was taken into account when interpreting results. Previous authors have reported the correlations between GROC and functional outcome measures were weak the further patients got from their initial evaluation. These correlations and predictions of functional outcome scores with GROC were tested in a knee pain population<sup>278</sup> as well as a population with hip, foot, and ankle complaints by Schmitt<sup>280</sup> et al. In both studies, moderate correlations were seen between functional outcomes scores or change scores in 0-30 days, but that relationship weakened over time. Schmitt<sup>278,280</sup> et al and Wang<sup>279</sup> et al suggest GROC should not be a replacement to functional outcome tools, especially beyond the 30-day recall period. As noted previously, functional outcome tools for TMD have not been studied to the same degree as functional outcome measures for other chronic pain populations. Given the duration of data collection in this study was 4 weeks, some confidence in GROC values is warranted. Even if values at the 4-week visit were called into

question, the immediate response differences between groups are less likely to be influenced by recall period.

A 3 point change from baseline on GROC has been used to define MCID.<sup>211</sup> In this dissertation study, the immediate post treatment response showed 17 participants (34%) reported  $\text{GROC} \geq +3$  (sham = 6, thrust = 11). At the 1-week visit, 14 participants (28%) reported  $\geq +3$  on GROC (sham = 4, thrust = 11). At the final 4-week visit, 38 participants (76%) scored  $\geq +3$  on GROC (sham = 15, thrust = 23). Discussing findings with  $\text{GROC} \geq +5$  cut-off for success, there is confidence this change represents a clinically important difference. Results did show a statistically significant difference in the percentage of successful outcomes ( $\text{GROC} \geq +5$ ) for each group at the immediate response ( $p = .022$ ) as well as 4-week measurement ( $p = .047$ ). Number needed to treat (NNT) is the number of patients who would need to be treated in order for 1 to improve or benefit from the treatment. While NNT does not tell us how much they would improve, it is an indication of effectiveness of treatment. The NNT based on GROC at immediate response is 4.17 (95% CI 2.5,13.8). For every 5 patients receiving treatment, 1 would get better compared to the control/sham group. At 4-weeks the NNT is 3.57 (95% CI 1.8-67.4); 4 patients receiving intervention with TJM would need to be treated for 1 to get better compared to the control (sham) group. While the NNT is better at the 4-week interval, caution is used in interpretation due to the large confidence interval. It is possible a larger sample would yield NNT values at 4-weeks with a smaller confidence interval. The value in perceived success, especially at the immediate response, may relate to patient buy-in, tolerance to initiation of an exercise program, expectation of benefit,<sup>281</sup> or therapeutic alliance.<sup>274</sup>

Patient Acceptable Symptom State (PASS) asks participants if their current status is acceptable or unacceptable to them.<sup>216</sup> The use of this tool allows for enhanced understanding of

the participant's perception of their well-being<sup>218</sup> and may suggest they are unlikely to seek further treatment.<sup>220</sup> Examination of PASS success (answering yes, my current state is acceptable) at the final 4-week visit reveals interesting points of discussion. In the sham group, 7 participants (28%) responded "no". Of those 7 participants, the GROC score at this time period ranged from -1 to +2 for all but one participant. There was a single participant in the sham group reporting "no" on PASS but a +6 on GROC; therefore, this participant was considered a success on GROC but not successful regarding PASS. For the thrust group, there were 2 participants (8%) who responded "no" on PASS. One of them had a GROC of -4, and this participant phoned the principal investigator (PI) 2 days later reporting she had a sinus infection that had made her much worse on the final measurement day, which was not diagnosed until the day after the 4-week visit. The other participant who responded "no" on PASS was also considered a success on GROC with a score of +5 at this final visit. Figure 5.4 represents the percentage of successful PASS outcomes in each group at 4-weeks.



A determination of a successful outcome may be represented in various ways; perhaps an optimal analysis would include functional outcome measures, GROC, and PASS when determining success. Wright<sup>282</sup> et al used PASS as an anchor to define success and determine sensitivity and specificity of multiple outcomes. These authors discuss PASS as an alternative to MCID analysis of other measures, even noting it may be the most appropriate tool as it captures “the personal experience of the patient”.<sup>282</sup> Wright<sup>282</sup> et al noted less predictable relationships between a functional outcome scale (Lower Extremity Functional Scale) and PASS, and more predictable relationships between pain based on NPRS and PASS. These authors conclude PASS is related to patient satisfaction and influenced by baseline levels of pain, functional status, depression, or socioeconomic status.<sup>282</sup>

### **Secondary Aim- Test-Retest Reliability and Construct Validity**

The jaw function self-report scales were analyzed further for evidence of reliability and validity. TMD-DI has been reported in literature but has no evidence to support psychometric properties. JFLS has been examined, although not extensively, in a dental population. In this analysis, a GROC range of -2 to +2 was used to define stability or minimal to no change. If a participant is stable, functional outcome scores should be relatively unchanged. If a participant perceives improvement, a change in functional outcome is expected. Correlation statistics were utilized to assess the similarity in scores for those considered stable (GROC = -2 to +2) or improved (GROC =  $\geq +4$ ) in this dissertation study. The expectation was that stable participants would show high correlation of scores while those who were improved would show improvement in scores with lower correlation. Change scores for outcomes were also compared with an independent *t*-test. Readers are reminded that GROC  $\geq +4$  was included in the success



group in this particular analysis as opposed to the more stringent stipulation of  $GROC \geq +5$  to quantify success for treatment outcomes.

Intraclass Correlation Coefficient (ICC) was used to measure agreement and correlation. The degree of agreement was structured according to Shrout and Fleiss:  $<0.10$  indicating no agreement,  $0.11-0.40$  indicating slight agreement,  $0.41-0.60$  was fair agreement,  $0.61-0.80$  is moderate agreement, and  $>0.80$  was excellent agreement.<sup>263</sup> JFLS showed excellent agreement in scores for stable patients at 1-week ( $ICC = 0.897$ ) and 4-weeks ( $ICC=0.949$ ). Moderate agreement was noted in the improved group at 1-week ( $ICC = 0.790$ ) and 4-weeks ( $ICC = 0.632$ ). There was no statistically significant difference in change scores of the stable vs improved participants at 1-week or 4-weeks. While these initial findings may indicate test-retest reliability in stable participants, the moderate correlation in the improved group may be concerning. The lack of difference between groups (stable and improved) in change scores may indicate the JFLS is not valid to capture functional change.

TMD-DI showed excellent agreement in scores for stable participants at 1-week ( $ICC = 0.870$ ) and 4-weeks ( $ICC = 0.912$ ). In this measure, only fair agreement was noted in the improved group at 1-week ( $ICC = 0.589$ ) and 4-weeks ( $ICC = 0.408$ ). An excellent correlation in stable participants accompanied by only a fair correlation in improved participants may indicate good test-retest reliability. There was a statistically significant difference in change scores for the stable vs improved participants at 1-week ( $p = .016$ ) and 4-weeks ( $p = .035$ ). These results could indicate TMD-DI does distinguish improved vs stable participants better than JFLS and may capture functional change in this population.

It is important to note findings in this dissertation study showed a statistically significant group by time interaction for JFLS and not TMD-DI. Effect sizes were larger for JFLS as well.

The total sample size was 50 participants for this RCT. Therefore, the sample of participants who were considered improved or stable was small for each measure at each time-period.

### **Implications**

Fifteen percent of individuals with TMD develop chronic pain.<sup>6</sup> Most participants in this dissertation study (43/50, 86%) experienced chronic pain of >3-month duration. The prevalence of TMD diagnosis is higher in females; however, this is confounded by the increased likelihood of females to seek care.<sup>11,12</sup> Eighty-six percent of participants in this study were female. Likelihood to seek care is also influenced by greater intensity of pain;<sup>13</sup> this sample had an average pain level of 3.7 in the jaw, 3.0 in the neck and 2.1 for headache on NPRS.

TMDs are heterogeneous, and the classification system has changed over time. Several authors report TMD is correlated with stress, anxiety, depression, and pain catastrophization.<sup>283-285</sup> Ohrbach and Slade<sup>27,45</sup> et al acknowledge TMD is more than a local dysfunction, and other factors must be considered. Deyo<sup>286</sup> et al note chronic TMD shares similarities with other chronic musculoskeletal pain conditions, such as LBP, chronic HA, or fibromyalgia. Two participants in this dissertation study tested positive for the depression screen, and many reported concurrent treatment for anxiety and/or depression. Those who tested positive were referred to counseling services or their primary care physician for follow-up. As acknowledgement of the biopsychosocial model impacts discussions of other pain disorders, and specifically chronic pain syndromes, the importance of broadening diagnostic categories as well as treatment options for TMD has been recognized.<sup>7</sup>

Researchers in dentistry and PT acknowledge the current diagnostic criteria for TMD lacks information pertaining to pain science, which may be especially helpful in chronic TMD,

and the cervical spine.<sup>7</sup> There is evidence to support the relationship between the cervical spine and TMD related pain and dysfunction. In the population studied for this dissertation, all participants had a primary complaint of TMD, and 30/50 (60%) had at least 2/10 cervical pain on NPRS. Previous authors have reported concurrent cervical pain in individuals with TMD ranging from 43%<sup>8</sup>-68%.<sup>15</sup> Participants in this dissertation study demonstrated statistically significant main effects for time in all measurements of pain, ROM, PPT, and function. Only 2 variables (JFLS and TSK-TMD) had a statistically significant group by time interaction, both favoring the thrust group. A general trend of greater improvement in all measured variables was noted, favoring the thrust group, and success according to GROC and PASS were higher in the thrust group. While cervical TJM has been supported for chronic neck pain,<sup>158</sup> the impact of cervical TJM on chronic TMD is not clear.

### **Limitations and Delimitations**

Limitations of this dissertation study are acknowledged. Clinical trials attempt to utilize multiple therapists and locations to increase generalizability. While efforts were made to utilize 4 clinicians in 4 locations, only 2 clinicians (1 male and 1 female clinician, both with manual therapy backgrounds including fellowship in AAOMPT) and 2 locations enrolled participants (Las Vegas, NV and Peoria, IL). Results should be generalized with caution beyond these parameters.

Another threat to external validity exists in the methodology of a RCT. Measurement of differences between the group receiving cervical TJM and sham manipulation required all other treatments be consistent. Standardized treatments for all patients does not reflect clinical practice; however, there is a known trade-off of generalizability for increasing internal validity in this design.

An instrumentation threat to validity was present, specifically for the measurement of PPT with a digital algometer. The algometry readings were higher overall for measurements taken in Las Vegas, NV. Specifically, PPT for the first dorsal interossei averaged 2.6-2.7 kg for the Peoria, IL group; whereas the Las Vegas, NV group averaged 29.6-29.9 kg. The average PPT at masseter and temporalis were 2.3-2.6 kg in Las Vegas, NV and 1.4-1.8 kg in Peoria, IL. Algometers were calibrated and all assessors utilized the same Manual of Standard Operating Procedures (MSOP) and video training. There were 8 total participants (4 in each group) in Las Vegas, NV. Data for PPT were run with and without the values from the NV location, and results remained the same. Therefore, a decision was made to include these data in all PPT analyses while acknowledging the potential limitation. Another delimitation relevant to PPT is that the PI did not require a notation of the more painful side with PPT assessment. Previous authors have analyzed data using the most painful side as opposed to only recording right and left sides; future research should consider noting the more painful side.

Additional internal validity threats included history, maturation, repeated testing, and regression toward the mean. The use of 2 groups and random group assignment can decrease the potential impact of these internal validity threats; however, the threat still exists. Both groups were equivalent on all factors except jaw deviation left at baseline, indicating the random assignment may have helped minimize the impact of these threats. Participants in this dissertation study were excluded if they had recent chiropractic, dental, or PT intervention for the neck or jaw and were asked not to add new treatments during the 4-week duration of this study. Participants were also asked not to add new exercise routines and continue what they had been doing on a regular basis. While these efforts were made to minimize the potential impact of confounding variables, there is no guarantee all participants followed instructions.

A true control group would have allowed for examination of each group against the control; however, this was not feasible for this dissertation study and may not be clinically valuable. Previous research has supported treatment is better than no treatment for the chronic TMD population. In this dissertation study, both groups improved over time. Most participants presented with chronic pain; therefore, it is unlikely improvements seen in both groups would have occurred without intervention. However, without a control group, we cannot be certain.

Clinicians were recruited as blinded assessors to collect ROM and PPT data. These clinicians and all participants were blinded to group allocation. However, the wording of the informed consent required by IRB included a brief description of the 2 groups (TJM or sham). The majority of participants did not ask questions about this group assignment and appeared surprised to learn about the difference between the 2 groups at the last visit during debriefing. The potential for participants to realize what group they were allocated to could affect participant blinding to group allocation.

Statistical validity relates to the choice of an appropriate statistical procedure to analyze data. The primary statistical analysis in this dissertation study was a mixed analysis of variance (ANOVA) looking at between-group and within-group differences as well as interaction effects. A nonparametric alternative to a mixed ANOVA including interaction effects does not exist.<sup>257,258,260,287</sup> Separate repeated measures ANOVAs can be run, and in the presence of violations of assumptions, Friedman's F test is used; however, this test does not answer the initial hypothesis of interest in the interaction effect and would pose an increased risk of Type I error with multiple tests performed. Chapter 4 of this dissertation outlines choices made to manage violations of assumptions, including transformation of data when appropriate.

The use of outcome measures without support for reliability and validity could pose a threat to statistical validity as well. The functional outcome tools for self-assessment of jaw function (JFLS and TMD-DI) lack psychometric analysis, therefore challenging the validity of potential findings. This dissertation examined the test-retest reliability and construct validity of these measures; however, the small sample size should be considered in interpretation. A larger sample of study is indicated and may reveal very different findings. Future research into the reliability and validity of these jaw-specific functional outcome measures is warranted.

Finally, low baseline levels of pain and function in multiple tests used in this dissertation led to potential floor effects. Low NPRS values were noted for jaw, neck, and HA; the choice to use NPRS jaw  $\geq 2$  for inclusion may have been too low to capture change. Low baseline scores were noted for NDI as well. There are no criteria to quantify the level of dysfunction of jaw functional outcome scales; therefore, it is also possible the JFLS and TMD-DI had floor effects.

### **Recommendations for Future Research**

Future research should include analysis of jaw specific functional outcome tools for use in PT practice. Reliability, validity, and responsiveness should be measured and could include JFLS, TMD-DI, or other tools commonly used in practice.

Future study of cervical TJM in the TMD population could use functional outcome tools to determine sample size estimations needed for 80% power. This information may lead to a change in the required sample size. Future study of this topic should also include a higher level of disability to avoid the impact of floor effects. Future research could include the use of known predictors of success for cervical TJM in neck pain to determine if those patients have greater success with the intervention for TMD as well.

Little is known about the most effective treatments for TMD through RCTs. Studies examining clinician decision making in the TMD population would be valuable. Examination of treatments as a whole, impairment-based decision-making, or diagnosis-specific intervention could be compared. Multimodal intervention combinations may produce greater and longer lasting improvement in pain, function, and quality of life than isolated interventions.<sup>93</sup> While standardizing treatments for study improves internal validity of research, clinical application and external validity can be discussed if clinicians are allowed to manage patients individually.

We have learned from lumbar and cervical spine chronic pain conditions that the mechanical diagnosis may not have much relevance to the most valuable treatments; however, in clinical practice with TMD, much time is spent in specific mechanical diagnosis. Understanding normal biomechanical relationships is important, and anatomical changes may be noted in imaging; however, the course of treatment likely remains unchanged.<sup>40</sup> As with other chronic pain conditions, radiographic or image findings demonstrating abnormal positioning of the disc or other anatomical abnormalities are poorly correlated with pain, tenderness, and/or dysfunction.<sup>7</sup> Chantaracherd<sup>41</sup> et al performed a cross-sectional study looking at imaging findings as well as pain, function, and disability associated with TMD. These authors concluded there was no relationship found between joint status and pain or dysfunction. Orhrbach<sup>27</sup> et al acknowledge the current diagnostic criteria for TMD (DC-TMD) focuses on the ‘bio’ of biopsychosocial, and treatment for chronic TMD may be less dependent on these criteria than previously hypothesized. As acknowledgement of the biopsychosocial model impacts discussions of other pain disorders, and specifically chronic pain syndromes, the importance of broadening diagnostic categories has been recognized.<sup>7</sup> Further research of treatments based on mechanical diagnosis versus more impairment-based models should be examined.

Pain neuroscience education (PNE) refers to a management strategy in chronic pain conditions focused on teaching patients both neurobiology and neurophysiology of pain.<sup>38,39</sup> Marcos-Martin<sup>288</sup> et al conducted a prospective case series including 9 participants with chronic TMD and neck pain utilizing a biobehavioral intervention focused on helping participants understand and manage their pain. This biobehavioral intervention was added to traditional education, exercise, and manual therapy. Authors report this intervention was effective for pain, function, fear, and ROM, noting previous research had supported the approach with other chronic pain regions (neck, back, knee), and further research should be done studying the impact on chronic TMD.<sup>288</sup> The role of PNE treatment for chronic TMD should also be further explored.

### Summary

TMD refers to conditions, pathologies, or dysfunctions impacting the temporomandibular joints, masticatory muscles, and associated musculoskeletal and neurovascular structures.<sup>7</sup> TMD symptoms may include pain in the jaw, head, and neck regions, headaches, periauricular pain, tinnitus, palpable tenderness, joint sounds, limited jaw opening, and loss of function.<sup>7,9</sup> Only a small percentage of individuals with TMD (5-10%) seek treatment.<sup>6,9</sup> TMD is the third most common chronic musculoskeletal pain condition,<sup>40</sup> and like other chronic pain conditions, TMD can affect quality of life and place an economic burden on society.<sup>40,53</sup> The overall healthcare costs for persons seen at least once for a diagnosis of TMD is 1.6 times higher than that of persons without a TMD diagnosis.<sup>11</sup>

The National Institute of Health (NIH) and National Institute of Dental and Craniofacial Research (NIDCR) recognize the TMD population is often left with no clear path to specialists in TMD.<sup>6,54</sup> Dental professionals may not be aware of PT options in the management of TMD. A survey of Florida dentists asked participants about their TMD treatment methods, including



inquiry of PT management for TMD. Only 59% of the 256 dentists responding the survey reported they were aware physical therapists were “capable of treating patients with TMD.”<sup>289</sup> Dentists who reported making interdisciplinary referrals for TMD management only chose PT 31% of the time; the most frequent referral was to an oral surgeon.<sup>289</sup>

Brown<sup>61</sup> et al reported individuals with TMD do not spontaneously recover without treatment intervention. Given the chronic nature of pain associated with TMD, the fact that all variables measured in this dissertation showed statistically significant change over time is promising. Interdisciplinary management of chronic pain conditions is important, and physical therapists must continue to educate dentists on the role of PT in TMD management. Evidence does exist to support improvement over time with manual physical therapy, education, and exercise.<sup>22,58,59,67,153</sup>

Biomechanical and neurophysiological relationships between the cervical spine and temporomandibular joint support the potential benefit of cervical spine manual therapy on TMD related pain and dysfunction. Evidence from La Touche et al<sup>22,23,132</sup> support cervical spine non-thrust joint mobilization (NTJM) in treatment of TMD. Other authors have supported manual therapy to the cervical and thoracic spine to adjunct TMD treatment, but without randomization.<sup>152</sup> Some authors have suggested both TJM and NTJM are valuable in chronic neck pain.<sup>290,291</sup> A narrative review by Butts<sup>292</sup> et al in 2017 reports spinal TJM and NTJM are “generally supported in the literature”<sup>292</sup> to decrease pain and disability in TMD. It is possible that a combination of TJM and NTJM or patient-specific treatment decisions may be valuable.

Evidence supporting the use of TJM of cervical and thoracic spine for TMD is available but limited.<sup>67,109,151</sup> A systematic literature review by Adelizzi<sup>59</sup> et al (2016) examined the use of cervical spine TJM for TMD, noting most of the evidence was based on weak study designs,

limited availability of research, small samples, and multimodal or combined treatment intervention packages. The use of multimodal interventions where groups were different on variables other than the TJM of the cervical spine make it difficult to interpret the effect of this intervention specifically. There were only 2 quality RCTs to discuss; however, authors neglect to acknowledge the study designs used did not include individuals with a primary complaint of TMD.

Research and clinical practice guidelines promote use of cervical TJM for various conditions including neck and upper extremity pain and dysfunction.<sup>63,70</sup> There is growing support for a neurophysiological effect of spinal TJM with changes seen in pain inhibition, muscle recruitment, and/or function.<sup>22</sup> The effect of spinal TJM on remote locations has demonstrated both local and remote effects.<sup>71,72</sup> The most current clinical practice guidelines for neck pain support the use of TJM in acute, subacute, and chronic neck pain with mobility deficits as well as acute and chronic neck pain with cervicogenic HA.<sup>158</sup> Given the chronic nature of TMD as well as known associated cervical mobility deficits<sup>116,117</sup> and HA,<sup>7,9</sup> it is reasonable to assume cervical TJM would also be potentially helpful in the TMD population.

To the knowledge of the PI, there are no previous studies examining the specific effect of cervical TJM on a population of individuals with TMD. Understanding the impact of various interventions on pain modulation and functional change can guide informed and evidence-based clinical practice. While cervical TJM is only one part of potential intervention packages, a better understanding of the specific effect of this intervention using a randomized design may guide decision making in PT treatments for the TMD population.

The purpose of this dissertation was to determine the immediate and short term (1 and 4-week) effects of cervical TJM on pain, dysfunction, and perception of change in persons with a

primary complaint of TMD. A sample of 50 participants were randomized to a cervical thrust group or cervical sham group. All participants received behavioral education, a home exercise program, and soft tissue mobilization to the suboccipital region. The cervical TJM or sham manipulation was the only difference between groups. Study participants had a mean age of 35 years and mean duration of symptoms for 72 months. Most participants (86%) were female and had chronic nature pain (86%) of > 3 month duration. A 2 x 4 mixed model ANOVA was utilized to compare both within-group and between-group changes over the 4 measurement periods for all continuous level data. Separate ANOVAs were performed for dependent variables; the hypothesis of interest was the group by time interaction for each ANOVA and subsequent main effects or simple main effects. Independent *t*-test analysis was used to compare groups in change scores for each variable.

MMO was used as a measure of function and was the measurement used to power this dissertation study. The sample started with an average of 37.5 mm opening and improved to >40 mm; however, the interaction of group and time for this measure did not show statistically significant differences. Statistically significant interaction effects were noted for function (JFLS) and fear (TSK-TMD). JFLS effect was noted in both groups from baseline to 4-weeks and only the thrust group from baseline to 1-week. TSK-TMD at 4-weeks favored the thrust group. Fear and jaw function had moderate to good correlation at baseline. However, subsequent analysis of the functional outcomes used for jaw function showed the change scores in improved patients compared to stable patients were not statistically different. While there was excellent agreement in scores for stable participants, the lack of statistically significant change in scores for the improved participants must be considered in interpreting results.

Statistically significant main effects for time were noted for all other measured outcomes (MMO, jaw deviation right and left, NPRS for each location, NDI, TMD-DI, cervical ROM all planes, and PPT at all locations tested). A statistically significant independent *t*-test comparing change scores was noted for jaw deviation right, NPRS jaw, NPRS cervical, TSK-TMD, and cervical R rotation ROM. Each statistically significant independent *t*-test favored the thrust group.

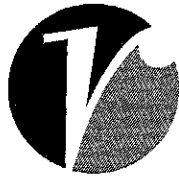
Patient perception of change was measured through GROC and PASS. Results of both tests favored the thrust group at all points. Statistically significant differences in the percentage of success between groups was noted for GROC at immediate response and 4-weeks. NNT was calculated based on the statistically significant GROC findings. NNT was 4 at immediate response and 3 at 4-weeks. PASS favored the thrust group, but the difference was not statistically significant. PASS may reflect patient satisfaction and likelihood to seek further treatment<sup>220</sup>; PASS may be influenced by baseline levels of pain, functional status, depression, or socioeconomic status.<sup>282</sup>

There were no serious adverse events to report and only mild treatment side-effects were noted. Participants in both groups (thrust = 36%, sham = 48%) reported treatment side effects. The majority of side effects were mild in nature and resolved within 48 hours of treatment. One participant in the sham group reported severe aggravation of symptoms lasting 7 days after a treatment visit. This aggravation was related to jaw and neck pain as well as overall soreness.

Both groups were expected to improve over time as evidence does support behavioral modification and exercises can be enough to show meaningful change.<sup>17,19,57,101</sup> This dissertation study included education, behavioral modifications, exercise for the neck and jaw, and manual therapy. Both groups did improve over time for all measured variables, and this improvement

was statistically significant. The addition of cervical TJM to one group did not show statistically significant interaction effects for most variables. Both groups received multimodal interventions; therefore, it is not surprising that the differences between groups was small. However, multiple independent *t*-tests showed statistically significant differences in change scores favoring the thrust group. GROC and PASS favored this group as well, with statistically significant differences at immediate response and 4-weeks. The known relationship between the cervical spine and jaw, concepts of regional interdependence, previous research supporting cervical interventions, and results of this RCT support continued examination of the effect of cervical spine treatments for the TMD population. It is possible treatment of a location outside the primary area of pain can provide clinically meaningful change in the primary location of pain.<sup>75</sup> Evaluation and treatment directed at the cervical spine is warranted in a TMD population. Future studies should include larger samples, study of psychometric property analysis of TMD functional outcome tools, use of these supported functional tools in treatment intervention studies, and the inclusion of PNE intervention in the TMD population.

Appendix 1  
Letters of Support for the Project



*Making Better Lives.*

# **Rock Valley**

## **PHYSICAL THERAPY**

Orthopaedic Section Grant Reviewers,

I am the COO of Rock Valley Physical Therapy. I am writing this letter on behalf of Rock Valley Physical Therapy located of Iowa and Illinois in support of Breanna Reynolds' clinical research study titled "Thrust Joint Manipulation to the Cervical Spine in Patients with a Primary Complaint of Temporomandibular Disorder (TMD): A Randomized Clinical Trial". In support of this project, Rock Valley Physical Therapy will allow Dr Reynolds and the Rock Valley clinicians participating in data collection access to patients referred for TMD. We agree to allow use of our clinic facility space for evaluation, treatment, and data collection. We understand the following:

1. Patient information to be used for this study will be kept in a locked file at our clinic and then moved to Bradley University for safe keeping.
2. All paperwork associated with Rock Valley's intake process and procedures will be stored by Rock Valley according to our standard documentation and storage procedures
3. The general flow of new patient evaluations including verification of insurance benefits will proceed according to standard practice.
4. Blind assessors will be coming into appointments to measure cervical ROM, jaw ROM, and pain pressure threshold. This person does not work for Rock Valley and will not be compensated in any way by Rock Valley. The treating clinician will be present for these measurements.
5. Front office staff will be in contact with a research assistant to coordinate schedules of blind assessors with patient visits.
6. Time spent on manual therapy for both the cervical manipulation group and the sham manipulation group is less than 8 minutes; there will be no charge for either group for the manual therapy portion of treatment.
7. The time spent for evaluation, exercise treatment, and education will be billed according to standard practice

Rock Valley Physical Therapy is in full support of this project and looking forward to supporting the research endeavor. Please feel free to contact me with any questions. Thank you.

*Eric Sacia PT, OCS, COO*

*11/17/16*

Eric Sacia PT, OCS, COO

Rock Valley Physical Therapy

[Eric.sacia@rockvalleypt.com](mailto:Eric.sacia@rockvalleypt.com)

309-743-2070

# BRADLEY

UNIVERSITY

October 17, 2016

Tara Fredrickson, Executive Associate  
Orthopaedic Section, APTA, Inc  
2920 East Avenue South, Suite 200  
La Crosse, WI 54601

Dear Selection Committee,

Please accept this letter on behalf of Dr. Breanna Reynolds, associate professor at Bradley University in Peoria, IL. Professor Reynolds is the PI in the study. Her work is in collaboration with external constituents as well as Bradley University's Doctor of Physical Therapy Program.

This letter is to confirm support of the in-kind contribution of Professor Reynolds 25%, or approximately 2.5 days per month in the following project:

**Project Title:**

Thrust Joint Manipulation of the Cervical Spine in Subjects with a Primary Complaint of Temporomandibular Disorder (TMD): A Randomized Clinical Trial

**Category:**

New Investigator

**Investigators:**

Breanna Reynolds, PT, DPT, FAAOMPT, PhD Candidate, Bradley University

Josh Cleland PT, PhD, Franklin Pierce University

Emilio Puentedura PT, DPT, PhD, University of Nevada, Las Vegas

Morey Kolber PT, PhD, OCS, Nova Southeastern University

Bradley University has also purchased over \$800 of equipment utilized in her pilot work and has agreed to donate the use of this equipment in-kind toward the project above. Thank you for your consideration of this proposal. Her study will add significantly to the literature in this area.

Respectfully,



Steve Tippet PhD, PT

Professor and Chair



Appendix 2  
Recruitment Flyer



Approval stamp

## Do you suffer from JAW pain?

**Bradley University Physical Therapy Department is conducting research to determine if physical therapy and education improve pain or dysfunction for those with Temporomandibular Disorder (TMD).**

**Who can participate:** Individuals age 18-65 with TMD pain

**What will it consist of:** 4 visits of hands on therapy, exercise, and educational information provided by a licensed physical therapist. Doctoral PT Students may also be present.

**When:** Oct 2017 through Dec 2018

**Location:** Rock Valley Physical Therapy

**How:** Ask your dentist for a referral or contact Dr. Bre Reynolds, PT, DPT, [FAAOMPT](#) at (309) 677-3293, research investigator and assistant professor Bradley University Department of Physical Therapy & Health Sciences. [bcreynolds@fsmail.bradley.edu](mailto:bcreynolds@fsmail.bradley.edu)

**Compensation is available for eligible participants**



## Appendix 3

### Facilities

1. Rock Valley Physical Therapy  
1524 W Glen Ave  
Peoria, IL 61614  
Phone: 309-691-1986
2. Rock Valley Physical Therapy  
1003 North Cummings Lane  
Washington, IL 61571  
Phone: 309-444-1030
3. UNLV Department of Physical Therapy School of Allied Health Sciences  
4505 S. Maryland Parkway, Box 453034  
Las Vegas, NV 89754-3034
4. Bradley University Department of Physical Therapy and Health Sciences  
1501 W Bradley Ave  
Peoria, IL 61625  
Phone: 309-677-3293

Appendix 4  
IRB Approvals

# FSMail

Breanna Reynolds <bcreynolds@fsmall.bradley.edu>

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## CUHSR 59-16: Cervical manipulation in patients with a primary diagnosis of Temporomandibular Disorder (TMD): A randomized clinical trial

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Mon, Jan 2, 2017 at 5:17 PM

Ross Fink <rf@fsmall.bradley.edu>  
To: Breanna Reynolds <bcreynolds@fsmall.bradley.edu>  
Cc: "Rast, Sharon" <srast@fsmall.bradley.edu>

Dear Ms. Reynolds:

Your study (CUHSR 59-16) Cervical manipulation in patients with a primary diagnosis of Temporomandibular Disorder (TMD): A randomized clinical trial has been reviewed by the full committee of CUHSR, and approved by this committee on October 28, 2016.

All vita and ethics certificate are on file.

Be aware that future changes to the protocol must first be approved by the Committee on the Use of Human Subjects in Research (CUHSR) prior to implementation and that substantial changes may result in the need for further review.

While no untoward effects are anticipated, should they arise, please report any untoward effects to CUHSR promptly (within 3 days).

As this study was reviewed and approved for one year, the maximum allowed under regulations. Please complete a final status report when the study is completed. If the study is not completed within one year, please submit a Continuing Review form before the one year date (October 28, 2017) with adequate time for CUHSR to review to prevent a lapse in approval. These forms can be found on our website, <http://cushr.bradley.edu/#Forms>.

This email will serve as your written notice that the study is approved unless a more formal letter is needed. Just let me know.

Ross L. Fink  
Chairperson, CUHSR

[Quoted text hidden]

## Institutional Review Board (IRB) Authorization Agreement

Name of Institution Providing IRB Review (Institution A): Bradley U

IRB Registration #: IRB00004423

Federalwide Assurance (FWA) #: FWA00012098

Name of Institution Relying on the Designated IRB (Institution B): Nova Southeastern University

IRB Registration #: IRB00002823

Federalwide Assurance (FWA) #: FWA00004057

The officials signing below agree that Nova Southeastern University may rely on the designated IRB for review and continuing oversight of its human subject research described below: *(check one)*

☐ This agreement applies to all human subject research covered by Institution B's FWA.

☒ This agreement is limited to the following specific protocol(s):

Name of Research Project: **Thrust Joint Manipulation to the Cervical Spine in Patients with a Primary Complaint of Temporomandibular Disorder (TMD): A Randomized Clinical Trial**

NUS IRB Study #: CUHSR 59-16

Name of Principal Investigator: Breanna Reynolds PT, DPT

Sponsor or Funding Agency: Not Applicable

Award Number, if any:

☐ Other *(describe)*: \_\_\_\_\_

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings and IRB determinations will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. IRB at Institution A will serve as the Privacy Board for Institution B. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution A):



Date: 4/26/17

Print Full Name: Sandra Shumaker

Institutional Title: Exec. Dir. Research and Sponsored Programs

NOTE: The IRB of Institution A must be designated on the OHRP-approved FWA for Institution B.

Signature of Signatory Official (Institution B):



Date: 4/26/17

Print Full Name: Donald Rudawsky, Ph.D. Institutional Title: VP of Institutional Effectiveness

Appendix 5  
Informed Consent Document



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## RESEARCH STUDY

### Informed Consent Form

**Study Title:** Thrust Joint Manipulation to the Cervical Spine in Patients with a Primary Complaint of Temporomandibular Disorder (TMD): A Randomized Clinical Trial

**Faculty Advisor:** Breanna Reynolds, PT, DPT, FAAOMPT  
344 Olin Hall, 1501 W. Bradley Ave, Peoria, IL 61625  
309-677-3293

**Principal Investigator:** Breanna Reynolds, PT, DPT, FAAOMPT

**Co-Investigators:** Clara Tostovarsnik SPT, Amanda Baker SPT, Clint Sestak SPT  
Emilio Puentedura PT, DPT, PhD, OCS, FAAOMPT

#### *Introduction:*

The Bradley University Department of Physical Therapy is conducting a randomized controlled clinical trial with Rock Valley Physical Therapy and UNLV. The goal is to determine if physical therapy to the neck and exercise improve pain and dysfunction for persons experiencing jaw pain. You are being invited to participate in this study because you have a primary complaint of jaw pain. Your participation is voluntary. If you are being seen in a physical therapy office, your decision to participate or not to participate will have no effect on the quality of your medical care. All of the procedures associated with this study are commonly used treatments in standard physical therapy practice. Please ask questions if there is anything you do not understand.

Adults between the ages of 18-65 with current jaw pain will be recruited.

#### **What is Involved in the Study?**

This study involves four sessions of physical therapy over one month as well as follow-up surveys in the mail at 3 months and 6 months. If you agree to participate, you will be asked to fill out prescreening forms to tell us about your health status and to check for conditions that may exclude you from the study. In addition, you will be asked to complete a set of questionnaires to help us understand the pain or limitations you are experiencing. Measurements of your range of motion, strength and pain sensitivity will be assessed along with additional screenings.

A licensed physical therapist specializing in manual therapy will perform a standard physical therapy evaluation to include further questions related to history and objective measurements. You will be randomly assigned to 1 of 2 treatment groups, and the physical therapist will initiate treatment. Both groups will receive interventions. One group will receive cervical spine (neck) thrust joint manipulation while the other will receive sham manipulation. You will be positioned

comfortably on your back and a licensed, qualified physical therapist will perform a neck intervention. There will be no manual treatment to the jaw itself.

After this cervical intervention, the clinician will educate you on behavioral modifications and exercises to perform on your own. You will be asked to complete a log tracking progress with your home program and to return for two additional follow-up visits.

One week from the first session (visit 2) you will receive the same intervention and will review your exercises and educational material. Measurements will be taken on this day as well. Two weeks from the first session (visit 3), you will receive treatment without any measurements taken. Four weeks from your first session you will return for a final visit (visit 4) consisting of measurement of progress. At that time the therapist can discuss further treatment options with you. Follow-up surveys will be mailed to your home address at 3 months and 6 months after your first visit.

### **How many people will take part in the study?**

It is anticipated that up to 50 persons will participate in this research study.

### **How long will I be in the study?**

You will be asked to attend 4 sessions of physical therapy over a 4-week period. After the first visit, the second session will be one week later, third 2 weeks later, and a final visit will take place at 4 weeks. The first session is anticipated to last 60-75 minutes while the next three sessions are expected to last 30-45 minutes. Follow up surveys will be sent at 3 months and 6 months, and this will conclude the duration of the study. The estimated time of completion for mailed surveys is 15 minutes total.

### **When does the study end?**

Participation is voluntary and you can stop participating at any time. However, if you decide to stop participating in this study, we strongly encourage you to talk to the researcher first as there may be information the researcher could provide through telephone, email, or other forms of communication. There are no consequences if you choose to suddenly withdraw. If you choose to remain in the study, your participation for physical appointments will end after the 4-week follow up, and completion of the study will occur after the 6-month mailing is received. At 4-weeks, your physical therapist will talk with you about the need for continued physical therapy or other services.

### **What conditions exclude me from being able to participate?**

Certain conditions will prevent you from participating in this study. These include whiplash in the past 6 weeks, prior neck surgery, spinal manipulation of the neck in the last 3 months, osteoporosis, tumor, rheumatoid arthritis, traumatic onset of symptoms, medical red flags suggestive of non-musculoskeletal origin of pain, systemic, or neurologic disease, and contraindications to cervical intervention. Any other exclusion factors applicable would be noted in the first visit examination.

### **What are the risks of participating in the study?**

The risks you will be exposed to in this study are not greater than other risks you experience in receiving regular physical therapy treatment. All of the procedures associated with this study are commonly used treatments in standard physical therapy practice and risk is minimal. Please ask questions if there is anything you do not understand.

It is possible that subjects who receive manual therapy to their neck will experience some very mild muscle soreness, fatigue, or headache after the procedure is performed. However, this soreness typically resolves within 1-48 hours after the procedure. If you feel discomfort you can apply cold to the area to minimize symptoms.

There is a small, albeit rare, risk of a serious adverse event associated with some cervical interventions. This risk is reported to range from 1/50,000 to 1/5.85 million. Similar risk has been noted in activity involving head movements such as leaning the head back at a beauty parlor, coughing, sneezing, or performing yoga. In order to mitigate this risk, researchers will conduct a thorough screening process and exclude individuals who may be at a higher risk for a serious adverse event. Physical therapists are qualified to perform these procedures, and trained in appropriate screening procedures to improve safety. If you have questions about the risks, please contact the researcher.

It is important to call the researcher or your regular physician when you think you are having problems, even if they are not included on the above list.

### **What are the benefits of participating in the study?**

Based on current research supporting the use of cervical intervention, education, and exercise for other conditions, we believe you may experience a positive change in pain, movement, or function related to your jaw pain. However, you may not benefit from being in this study. The information gathered may help people with jaw pain in the future.

You may opt for financial compensation for your participation. Participants attending scheduled visits will be paid \$25 after the second visit, and \$25 after the fourth visit. Participants will be given an IRS Form W-9 to complete and sign if they are interested in the incentive payment for participation. This completed IRS Form W-9 will be immediately placed in a self-addressed envelope and sealed by the participant to protect their privacy. The form will be mailed to Bradley University Controller's Office and payment will be processed accordingly. Participants will receive payment for participation in the form of a check.

### **What other options are there?**

Participation in this study is optional. Instead of being in this study, you have the option to see a medical physician, dentist, physical therapist or other medical provider of your choosing. You also have the option to decline any treatment.

### **What about Confidentiality?**

All efforts will be taken to keep your personal information as confidential as possible, although there is no absolute guarantee that all information will remain confidential. You understand that any information about you or your physical therapy management will be handled in a confidential (private) manner consistent with other hospital medical records in the Physical Therapy office. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of this clinic. All records pertaining to your involvement in this research study will be stored in a locked file cabinet in the Physical Therapy Department. You will not be specifically identified in any publication of research results. However, in unusual cases, your research records may be inspected by appropriate government agencies or be released in response to an order from a court of law.

### **Personal health information about you that will be collected in this study**

Personal health information will be collected and used for research. All efforts will be made to protect the privacy of your personal information.

### **Why your personal health information is being used?**

Your personal contact information is important for the study team to contact you during the study. Your health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care.

The treating therapist may also use the results of these tests and procedures to guide further treatment. If researchers/clinicians feel your medical history, risk factor screen, tests or procedures warrant further consult, you will be informed, and we will call your primary care physician. Your signature below authorizes consent to make this phone call when indicated.

### **The personnel who may use or disclose your personal health information**

A case number will indicate your identity on these records. This information will only be accessible to the investigators listed on the first page of this document and the research study staff.

### **Who, outside of this institution, might receive your personal health information?**

As part of the study, the Principal Investigator, study team and others listed above in item number 3, may disclose your personal health information, including the results of the research study tests and procedures to the following:

- Bradley University Committee on the Use of Human Subjects in Research
- Investigators and data coordinators affiliated with this study

The Principal Investigator or study team will inform you if there are any changes to the list above during your active participation in the trial. Once information is disclosed to others outside this institution, the information may no longer be covered by the federal privacy protection regulations.

### **What are the costs?**

Your insurance will be billed by Rock Valley Physical Therapy as is customary for physical therapy evaluation and treatment. You will be responsible for any co-pay, co-insurance, or deductible specific to your personal insurance plan.

There are no additional costs for participation in this study. In the case of injury or illness, emergency medical services will be enacted if necessary and handled through the individual's own insurance plan. No funds have been set aside to compensate you in the event of injury. Voluntary follow-up to a medical provider based on the recommendation of researchers is outside the scope of this research study and will be handled through the individual's own insurance plan.

The physical therapy procedures you receive while participating in this study will be billed according to standard practice. Because of the short duration of time spent on the randomized portion of treatment, neither group will be charged for the manual therapy intervention. Co-payments will be the same as if you were not part of the research study. These procedures will be charged because they are "standard of care" procedures you would receive regardless of participation in this study. The procedures will be documented in the medical record and are being provided because they are medically indicated and are not being provided simply because of participation in this study.

### **What are my rights?**

Taking part in this study is voluntary; you may leave the study at any time. This study is expected to end after you have completed your physical therapy and all information has been collected.

### **Who should I call with questions or problems?**

Questions about therapy can be directed to your physical therapist. Questions specific to this study may be directed to the researcher in charge of this study, Dr Breanna Reynolds. She can be reached at (309) 677-3293 during normal business hours. If you have general questions about being a research participant, you may contact the Bradley University CUHSR office at (677-3877) during normal business hours. The Chairperson of this committee will discuss the matter with you.

## Documentation of Informed Consent

You are voluntarily making a decision to participate in this study. Your signature means that you have read and understood the information presented and have decided to participate. Your signature also means that the information on this consent form has been fully explained to you and all your questions have been answered to your satisfaction. If you think of any additional questions during the study, you should contact the researcher(s).

I agree to participate in this study.

\_\_\_\_\_  
**Printed Name of Subject**

\_\_\_\_\_  
**Signature of Subject**

\_\_\_\_\_  
**Date**

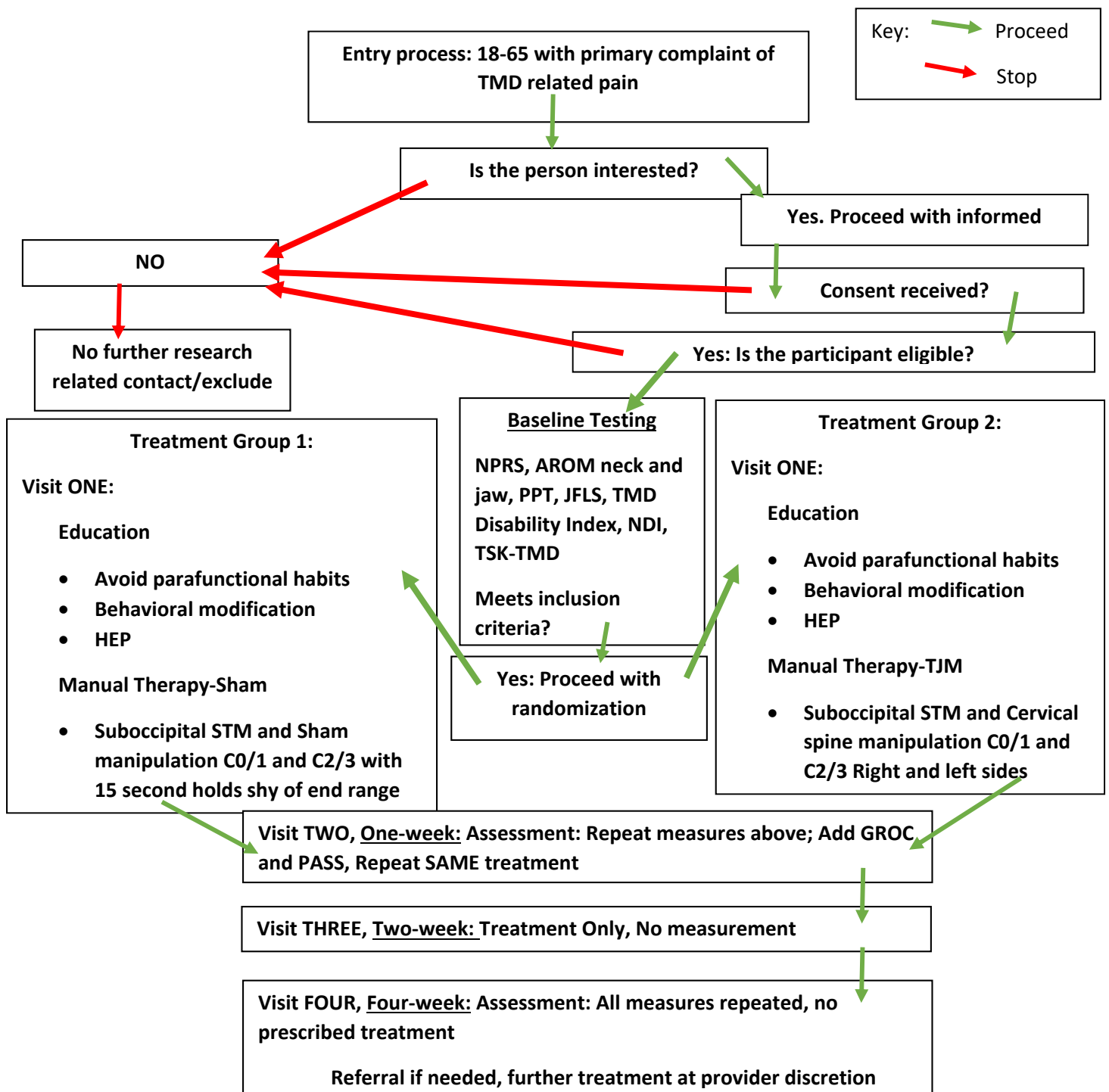
\_\_\_\_\_  
**Printed Name of Person  
Obtaining Consent**

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Date**

CODE: \_\_\_\_\_

Appendix 6  
Plan Diagram





Appendix 7

Self-Report Scales and Outcome Measures

### Initial TMD Screening Tool (Gonzalez et al)

In the last 30 days, on average, how long did any pain in your jaw or temple area on either side last?

- c. No pain (0)
- d. From very brief to more than a week, but it does stop (1)
- e. Continuous (2)

In the last 30 days, have you had pain or stiffness in your jaw on awakening?

- f. No (0)
- g. Yes (1)

In the last 30 days, did chewing hard or tough food change any pain (that is make it better or make it worse) in your jaw or temple area on either side?

- h. No (0)
- i. Yes (1)

NPRS:

Please rate your <b>CURRENT</b> <u>jaw</u> pain	
Please rate your <b>CURRENT</b> <u>neck</u> pain	
Please rate your <b>CURRENT</b> <u>headache</u>	
Please rate your <u>jaw</u> pain at <b>it's BEST</b> over the last 24 hours	
Please rate your <u>neck</u> pain at <b>it's BEST</b> over the last 24 hours	
Please rate your <u>headache</u> at <b>it's BEST</b> over the last 24 hours	
Please rate your <u>jaw</u> pain at <b>it's WORST</b> over the last 24 hours	
Please rate your <u>neck</u> pain at <b>it's WORST</b> over the last 24 hours	
Please rate your <u>headache</u> at <b>it's WORST</b> over the last 24 hours	

## **GROC:**

### Global Rating of Change Scale

Please rate the overall condition of your Jaw/Neck/Headache Pain *FROM THE TIME THAT YOU BEGAN TREATMENT UNTIL NOW* (Check only one):

- |   |   |   |
|---|---|---|
| <input type="checkbox"/> A very great deal worse (-7) | <input type="checkbox"/> About the same (0) | <input type="checkbox"/> A very great deal better (7) |
| <input type="checkbox"/> A great deal worse (-6)      |   | <input type="checkbox"/> A great deal better (6)      |
| <input type="checkbox"/> Quite a bit worse (-5)       |   | <input type="checkbox"/> Quite a bit better (5)       |
| <input type="checkbox"/> Moderately worse (-4)        |   | <input type="checkbox"/> Moderately better (4)        |
| <input type="checkbox"/> Somewhat worse (-3)          |   | <input type="checkbox"/> Somewhat better (3)          |
| <input type="checkbox"/> A little bit worse (-2)      |   | <input type="checkbox"/> A little bit better (2)      |
| <input type="checkbox"/> A tiny bit worse (-1)        |   | <input type="checkbox"/> A tiny bit better (1)        |

From: Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. Control Clin Trials 1989; 407-15.

## **PASS:**

### Patient Acceptable Symptom State

“Taking into account all the activities you have during your daily life, your level of pain, and also your functional impairment, do you consider that your current state is satisfactory?”

Yes

No

### Jaw Functional Limitation Scale – 20

For each of the items below, please indicate the level of limitation **during the last month**. If the activity has been completely avoided because it is too difficult, then circle '10'. If you avoid an activity for reasons other than pain or difficulty, leave the item blank.

	No limitation										Severe limitation
1. Chew tough food	0	1	2	3	4	5	6	7	8	9	10
2. Chew hard bread	0	1	2	3	4	5	6	7	8	9	10
3. Chew chicken (e.g., prepared in oven)	0	1	2	3	4	5	6	7	8	9	10
4. Chew crackers	0	1	2	3	4	5	6	7	8	9	10
5. Chew soft food (e.g., macaroni, canned or soft fruits, cooked vegetables, fish)	0	1	2	3	4	5	6	7	8	9	10
6. Eat soft food requiring no chewing (e.g., mashed potatoes, apple sauce, pudding, pureed food)	0	1	2	3	4	5	6	7	8	9	10
7. Open wide enough to bite from a whole apple	0	1	2	3	4	5	6	7	8	9	10
8. Open wide enough to bite into a sandwich	0	1	2	3	4	5	6	7	8	9	10
9. Open wide enough to talk	0	1	2	3	4	5	6	7	8	9	10
10. Open wide enough to drink from a cup	0	1	2	3	4	5	6	7	8	9	10
11. Swallow	0	1	2	3	4	5	6	7	8	9	10
12. Yawn	0	1	2	3	4	5	6	7	8	9	10
13. Talk	0	1	2	3	4	5	6	7	8	9	10
14. Sing	0	1	2	3	4	5	6	7	8	9	10
15. Putting on a happy face	0	1	2	3	4	5	6	7	8	9	10
16. Putting on an angry face	0	1	2	3	4	5	6	7	8	9	10
17. Frown	0	1	2	3	4	5	6	7	8	9	10
18. Kiss	0	1	2	3	4	5	6	7	8	9	10
19. Smile	0	1	2	3	4	5	6	7	8	9	10
20. Laugh	0	1	2	3	4	5	6	7	8	9	10

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## Neck Disability Index (NDI)

This questionnaire has been designed to give us information as to how your neck pain has affected your ability to manage in everyday life. Please answer every section and **mark in each section only the one box that applies to you.** We realize you may consider that two or more statements in any one section relate to you, but please just mark the box that most closely describes your problem.

<b>Section 1: Pain Intensity</b>  <input type="checkbox"/> I have no pain at the moment <input type="checkbox"/> The pain is very mild at the moment <input type="checkbox"/> The pain is moderate at the moment <input type="checkbox"/> The pain is fairly severe at the moment <input type="checkbox"/> The pain is very severe at the moment <input type="checkbox"/> The pain is the worst imaginable at the moment	<b>Section 6: Concentration</b>  <input type="checkbox"/> I can concentrate fully when I want to with no difficulty <input type="checkbox"/> I can concentrate fully when I want to with slight difficulty <input type="checkbox"/> I have a fair degree of difficulty in concentrating when I want to <input type="checkbox"/> I have a lot of difficulty in concentrating when I want to <input type="checkbox"/> I have a great deal of difficulty in concentrating when I want to <input type="checkbox"/> I cannot concentrate at all
<b>Section 2: Personal Care (Washing, Dressing, etc.)</b>  <input type="checkbox"/> I can look after myself normally without causing extra pain <input type="checkbox"/> I can look after myself normally but it causes extra pain <input type="checkbox"/> It is painful to look after myself and I am slow and careful <input type="checkbox"/> I need some help but can manage most of my personal care <input type="checkbox"/> I need help every day in most aspects of self care <input type="checkbox"/> I do not get dressed, I wash with difficulty and stay in bed	<b>Section 7: Work</b>  <input type="checkbox"/> I can do as much work as I want to <input type="checkbox"/> I can only do my usual work, but no more <input type="checkbox"/> I can do most of my usual work, but no more <input type="checkbox"/> I cannot do my usual work <input type="checkbox"/> I can hardly do any work at all <input type="checkbox"/> I can't do any work at all
<b>Section 3: Lifting</b>  <input type="checkbox"/> I can lift heavy weights without extra pain <input type="checkbox"/> I can lift heavy weights but it gives extra pain <input type="checkbox"/> Pain prevents me lifting heavy weights off the floor, but I can manage if they are conveniently placed, for example on a table	<b>Section 8: Driving</b>  <input type="checkbox"/> I can drive my car without any neck pain <input type="checkbox"/> I can drive my car as long as I want with slight pain in my neck <input type="checkbox"/> I can drive my car as long as I want with moderate pain in my neck <input type="checkbox"/> I can't drive my car as long as I want because of moderate pain in my neck

<input type="checkbox"/> Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned <input type="checkbox"/> I can only lift very light weights <input type="checkbox"/> I cannot lift or carry anything	<input type="checkbox"/> I can hardly drive at all because of severe pain in my neck <input type="checkbox"/> I can't drive my car at all
<b>Section 4: Reading</b>  <input type="checkbox"/> I can read as much as I want to with no pain in my neck <input type="checkbox"/> I can read as much as I want to with slight pain in my neck <input type="checkbox"/> I can read as much as I want with moderate pain in my neck <input type="checkbox"/> I can't read as much as I want because of moderate pain in my neck <input type="checkbox"/> I can hardly read at all because of severe pain in my neck <input type="checkbox"/> I cannot read at all	<b>Section 9: Sleeping</b>  <input type="checkbox"/> I have no trouble sleeping <input type="checkbox"/> My sleep is slightly disturbed (less than 1 hr sleepless) <input type="checkbox"/> My sleep is mildly disturbed (1-2 hrs sleepless) <input type="checkbox"/> My sleep is moderately disturbed (2-3 hrs sleepless) <input type="checkbox"/> My sleep is greatly disturbed (3-5 hrs sleepless) <input type="checkbox"/> My sleep is completely disturbed (5-7 hrs sleepless)
<b>Section 5: Headaches</b>  <input type="checkbox"/> I have no headaches at all <input type="checkbox"/> I have slight headaches, which come infrequently <input type="checkbox"/> I have moderate headaches, which come infrequently <input type="checkbox"/> I have moderate headaches, which come frequently <input type="checkbox"/> I have severe headaches, which come frequently <input type="checkbox"/> I have headaches almost all the time	<b>Section 10: Recreation</b>  <input type="checkbox"/> I am able to engage in all my recreation activities with no neck pain at all <input type="checkbox"/> I am able to engage in all my recreation activities, with some pain in my neck <input type="checkbox"/> I am able to engage in most, but not all of my usual recreation activities because of pain in my neck <input type="checkbox"/> I am able to engage in a few of my usual recreation activities because of pain in my neck <input type="checkbox"/> I can hardly do any recreation activities because of pain in my neck <input type="checkbox"/> I can't do any recreation at all

Score: \_\_\_/50      Transform to percentage score  $\times 100 =$       % points

NDI developed by: Vernon, H. & Mior, S. (1991). The Neck Disability Index: A study of reliability and validity. *Journal of Manipulative and Physiological Therapeutics*. 14, 409-415.

## TMD Disability Index:

### TMD DISABILITY INDEX (STEIGERWALD/MAHER)

NAME \_\_\_\_\_ M/F \_\_\_\_\_ AGE \_\_\_\_\_ DATE \_\_\_\_\_ SCORE \_\_\_\_\_

Please check the one statement that best pertains to you (not necessarily exactly) in each of the following categories.

**1. Communication (talking)**

- ☐ I can talk as much as I want without pain, fatigue or discomfort.
- ☐ I talk as much as I want, but it causes some pain, fatigue and/or discomfort.
- ☐ I can't talk as much as I want because of pain, fatigue and/or discomfort.
- ☐ I can't talk much at all because of pain, fatigue and/or discomfort.
- ☐ Pain prevents me from talking at all.

**2. Normal living activities (brushing teeth/flossing).**

- ☐ I am able to care for my teeth and gums in a normal fashion without restriction, and without pain, fatigue or discomfort.
- ☐ I am able to care for all my teeth and gums, but I must be slow and careful, otherwise pain/discomfort, jaw tiredness results.
- ☐ I do manage to care for my teeth and gums in a normal fashion, but it usually causes some pain/discomfort, jaw tiredness no matter how slow and careful I am.
- ☐ I am unable to properly clean all my teeth and gums because of restricted opening and/or pain.
- ☐ I am unable to care for most of my teeth and gums because of restricted opening and/or pain.

**3. Normal living activities (eating, chewing).**

- ☐ I can eat and chew as much of anything I want without pain/discomfort or jaw tiredness.
- ☐ I can eat and chew most anything I want, but it sometimes causes pain/discomfort and/or jaw tiredness.
- ☐ I can't eat much of anything I want, because it often causes pain/discomfort, jaw tiredness or because of restricted opening.
- ☐ I must eat only soft foods (consistency of scrambled eggs or less) because of pain/discomfort, jaw fatigue and/or restricted opening.
- ☐ I must stay on a liquid diet because of pain and/or restricted opening.

**4. Social/recreational activities (singing, playing musical instruments, cheering, laughing, social activities, playing amateur sports/hobbies, and recreation, etc.).**

- ☐ I am enjoying a normal social life and/or recreational activities without restriction.
- ☐ I participate in normal social life and/or recreational activities but pain/discomfort is increased.
- ☐ The presence of pain and/or fear of likely aggravation only limits the more energetic components of my social life (sports, exercising, dancing, playing musical instruments, singing).
- ☐ I have restrictions socially, as I can't even sing, shout, cheer, play and/or laugh expressively because of increased pain/discomfort.
- ☐ I have practically no social life because of pain.

**5. Non-specialized jaw activities (yawning, mouth opening and opening my mouth wide).**

- ☐ I can yawn in a normal fashion, painlessly.
- ☐ I can yawn and open my mouth fully wide open, but sometimes there is discomfort.
- ☐ I can yawn and open my mouth wide in a normal fashion, but it almost always causes discomfort.
- ☐ Yawning and opening my mouth wide are somewhat restricted by pain.
- ☐ I cannot yawn or open my mouth more than two finger widths (28-32 cm) or, if I can, it always causes greater than moderate pain.



5. **Sexual function (including kissing, hugging and any and all sexual activities to which you are accustomed).**
- ☐ I am able to engage in all my customary sexual activities and expressions without limitation and/or causing headache, face or jaw pain.
  - ☐ I am able to engage in all my customary sexual activities and expression, but it sometimes causes some headache, face, or jaw pain, or jaw fatigue.
  - ☐ I am able to engage in all my customary sexual activities and expression, but it usually causes enough headache, face or jaw pain to markedly interfere with my enjoyment, willingness and satisfaction.
  - ☐ I must limit my customary sexual expression and activities because of headache, face or jaw pain or limited mouth opening.
  - ☐ I abstain from almost all sexual activities and expression because of the head, face or jaw pain it causes.
7. **Sleep (restful, nocturnal sleep pattern).**
- ☐ I sleep well in a normal fashion without any pain medication, relaxants or sleeping pills.
  - ☐ I sleep well with the use of pain pills, anti-inflammatory medication or medicinal sleeping aids.
  - ☐ I fail to realize 6 hours restful sleep even with the use of pills.
  - ☐ I fail to realize 4 hours restful sleep even with the use of pills.
  - ☐ I fail to realize 2 hours restful sleep even with the use of pills.
8. **Effects of any form of treatment, including, but not limited to, medications, in-office therapy, treatments, oral orthotics (e.g., splints, mouthpieces), ice/heat, etc.**
- ☐ I do not need to use treatment of any type in order to control or tolerate headache, face or jaw pain and discomfort.
  - ☐ I can completely control my pain with some form of treatment.
  - ☐ I get partial, but significant, relief through some form of treatment.
  - ☐ I don't get "a lot of" relief from any form of treatment.
  - ☐ There is no form of treatment that helps enough to make me want to continue.
9. **Tinnitus, or ringing in the ear(s).**
- ☐ I do not experience ringing in my ear(s).
  - ☐ I experience ringing in my ear(s) somewhat, but it does not interfere with my sleep and/or my ability to perform my daily activities.
  - ☐ I experience ringing in my ear(s) and it interferes with my sleep and/or daily activities, but I can accomplish set goals and I can get an acceptable amount of sleep.
  - ☐ I experience ringing in my ear(s) and it causes a marked impairment in the performance of my daily activities and/or results in an unacceptable loss of sleep.
  - ☐ I experience ringing in my ear(s) and it is incapacitating and/or forces me to use a masking device to get any sleep.
10. **Dizziness (lightheaded, spinning and/or balance disturbance).**
- ☐ I do not experience dizziness.
  - ☐ I experience dizziness, but it does not interfere with my daily activities.
  - ☐ I experience dizziness which interferes somewhat with my daily activities, but I can accomplish my set goals.
  - ☐ I experience dizziness which causes a marked impairment in the performance of my daily activities.
  - ☐ I experience dizziness which is incapacitating.

NAME \_\_\_\_\_ M/F \_\_\_\_\_ AGE \_\_\_\_\_ DATE \_\_\_\_\_ SCORE \_\_\_\_\_

## Tampa Scale for Kinesiophobia for Temporomandibular Disorders

(TSK-TMD 12-item version from Visscher, Ohrbach et al *Pain* 2010;150(3):492-500)

	Strongly Disagree	Disagree	Agree	Strongly Agree
I'm Afraid that I might injure myself if I move my jaw	1	2	3	4
If I ignored my jaw symptoms, they would get worse	1	2	3	4
My jaw is telling me that something is seriously wrong with it	1	2	3	4
Other people do not take my jaw symptoms seriously enough	1	2	3	4
My jaw symptoms have put my health at risk for the rest of my life	1	2	3	4
My jaw symptoms mean that I have injured my jaw	1	2	3	4
The safest way to prevent my symptoms from getting worse is to be careful and not to move my jaw any more than necessary	1	2	3	4
I would not have this many jaw symptoms if there was not something potentially harmful going on.	1	2	3	4
My jaw symptoms let me know when to stop moving my jaw so that I do not injure myself	1	2	3	4
I cannot do everything other people can do, because it is too easy for me to injure my jaw.	1	2	3	4
No one should have to move the jaw when he/she has a jaw problem.	1	2	3	4
I am afraid to open my mouth wide because then I may not be able to close it again	1	2	3	4

A total score is calculated.

### Side-Effect Questionnaire

1. Did you experience any discomfort after (and related to) any of the physical therapy treatments?  
YES / NO
2. If Yes, Please mark all that apply by checking the box to the left. Describe where symptoms were located or what specific symptoms you experienced. Describe when they started (onset), how long they lasted (duration), and the severity.

<input type="checkbox"/> <input checked="" type="checkbox"/>	Symptom	Description	Onset	Duration	Severity 1= light 2= mild 3= moderate 4= severe
<input type="checkbox"/>	Aggravation of your present complaints		___ Min/Hrs	___ Min/Hrs/Days	
<input type="checkbox"/>	Spasm		___ Min/Hrs	___ Min/Hrs/Days	
<input type="checkbox"/>	Stiffness		___ Min/Hrs	___ Min/Hrs/Days	
<input type="checkbox"/>	Dizziness		___ Min/Hrs	___ Min/Hrs/Days	
<input type="checkbox"/>	Headache		___ Min/Hrs	___ Min/Hrs/Days	
<input type="checkbox"/>	Radiating Discomfort		___ Min/Hrs	___ Min/Hrs/Days	
<input type="checkbox"/>	Fatigue		___ Min/Hrs	___ Min/Hrs/Days	
<input type="checkbox"/>	Nausea		___ Min/Hrs	___ Min/Hrs/Days	
<input type="checkbox"/>	Vomiting		___ Min/Hrs	___ Min/Hrs/Days	
<input type="checkbox"/>	Swallowing Problems		___ Min/Hrs	___ Min/Hrs/Days	
<input type="checkbox"/>	Visible Changes		___ Min/Hrs	___ Min/Hrs/Days	
<input type="checkbox"/>	Breathing Changes		___ Min/Hrs	___ Min/Hrs/Days	
<input type="checkbox"/>	Other		___ Min/Hrs	___ Min/Hrs/Days	

Appendix 8  
Health History and Screening Form

## Health History and Screening Form

### (Initial Visit)

First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_

Date of birth: \_\_\_\_\_ Age: \_\_\_\_\_ Gender (circle one): Male/Female

Can you read/write English (circle one): Yes/No

Phone number: \_\_\_\_\_ Email address: \_\_\_\_\_

Mailing address: \_\_\_\_\_

Preferred contact method (RANK 1-3): Phone \_\_\_\_\_ Email \_\_\_\_\_ Mail \_\_\_\_\_

Occupation: \_\_\_\_\_

PRIMARY CARE PHYSICIAN:

Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_

EMERGENCY CONTACT:

Name: \_\_\_\_\_ Relationship: \_\_\_\_\_

Phone number: \_\_\_\_\_

ASSIGNED CASE NUMBER: \_\_\_\_\_

W 9 Payment Form Mailed In? YES NO

## Medical History

1. Does your jaw LOCK? YES/NO
2. Have you had a whiplash injury in the last 6 weeks? YES/NO
3. Have you ever had neck surgery? YES/NO
4. Have you received spinal manipulation in the last 3 months? YES/NO
5. Do you have Osteoporosis? YES/NO
6. Do you have rheumatoid arthritis or ankylosing spondylitis? YES/NO
7. Has a Doctor ever told you your blood pressure was too high? YES/NO
8. Has a Doctor ever told you your cholesterol was too high? YES/NO
9. Do you have Diabetes? YES/NO
  - a. If YES, is it Insulin Dependent / Non-Insulin Dependent
10. Do you take medication to control your
  - a. Blood Pressure YES/NO
  - b. Cholesterol YES/NO
  - c. Diabetes YES/NO
11. Are you currently pregnant? YES/NO
12. Have you been pregnant or delivered a child in the 6 months? YES/NO
13. Do you take birth control pills? YES/NO
14. Do you smoke? YES/NO
15. Have you been diagnosed with migraines? YES/NO
16. Do you have a new or sudden onset of head/neck pain? YES/NO
17. Do you currently have cancer? YES/NO
18. Do you have a history of cancer in the last 6 months? YES/NO
19. Have you had previous use of steroids? YES/NO
20. Do you have drop attacks? YES/NO
21. Do you have any current fractures? YES/NO
22. Do you have any current infection? YES/NO
23. Do you currently have nausea? YES/NO
24. Do you currently have any of the following: YES/NO
  - a. Dizziness, blurred vision, double vision, ringing in your ears, difficulty swallowing, difficulty speaking (Please CIRCLE all that Apply)
25. Have you had a heart attack, stroke, or mini-stroke (Transient Ischemic Attack) YES/NO

When did the symptoms in your jaw begin? \_\_\_\_\_

Please list any previous treatments you have received for your jaw pain noting if they were helpful, harmful, or indifferent:

---

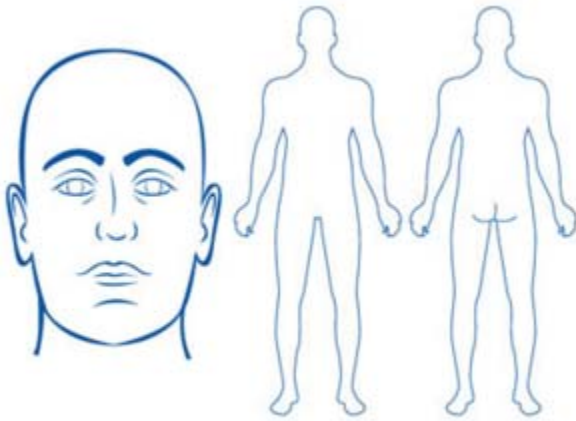
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Have you ever used an oral splint or mouth guard? Yes/No

Over the past 2 weeks, how often have you been bothered by any of the following problems?

	Not At all	Several Days	More Than Half the Days	Nearly Every Day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed or hopeless	0	1	2	3

Please utilize this body diagram to mark an 'X' in the location of any pain.



What makes your pain worse?

---

What makes your pain better?

---

Are you physically active? If so, what do you do for exercise?

---



---

Please list any major surgeries and approximate dates:

---



---



---

List of other medical/health conditions:

---



---

---

List of Medications and dosage:

---

---

---

List any Known Allergies:

---

---

---

General Screen:

4. In the last 30 days, on average, how long did any pain in your jaw or temple area on either side last?<sup>32</sup>
  - a. No pain (0)
  - b. From very brief to more than a week, but it does stop (1)
  - c. Continuous (2)
5. In the last 30 days, have you had pain or stiffness in your jaw on awakening?
  - a. No (0)
  - b. Yes (1)
6. In the last 30 days, did chewing hard or tough food change any pain (that is make it better or make it worse) in your jaw or temple area on either side?
  - a. No (0)
  - b. Yes (1)

Total Score:



**TO BE COMPLETED BY THE CLINICIAN**

☐

VISIT ONE: Please initial this box if medical history form AND informed consent were completed by the subject and fully reviewed by the researcher/clinician.

15 sec HR: \_\_\_\_\_

BP: \_\_\_\_\_

Height: \_\_\_\_\_

Weight: \_\_\_\_\_

If any of the following are Positive, STOP and make a medical referral:

Resting Nystagmus: Positive/Negative

Cranial Nerve Screen: Positive/Negative

Have you noticed change in your ability to smell, read clearly, eat, speak, taste food, or hear?

Pupil constriction to light

Eye movement down and in away from midline by following your finger with eyes

Facial light touch x3 regions

Smile, pucker lips, raise eyebrows, and stick out tongue

Finger rub hearing

Shoulder shrug resisted

Sharp Purser: Positive/Negative

Upper Motor Neuron Assessment: Positive/Negative

Signs of Bilateral or Quadrilateral Paresthesia or Motor Deficits: Positive/Negative

Signs of Cervical Nerve Root Compression: Circle one

2 or more signs present (reflex, sensation, myotome): Positive

1 or none present: Proceed

Vertebral Artery Screen: Positive/Negative

Alar Ligament Screen: Positive/Negative

Transverse Ligament Screen: Positive/Negative

**\*\*Review of Inclusion Criteria**

Is NPRS $\geq 2$ for jaw pain?	Yes: Proceed	No: Exclude
Is <i>pain-free</i> MMO $\leq 50$ mm?	Yes: Proceed	No: Exclude
Is TMD Screen score $\geq 2$	Yes: Proceed	No: Exclude

**STOP HERE AND PASS TO BLINDED ASSESSOR**

**VISIT ONE Pre and Post Treatment Data. To Be Completed by a Blinded Assessor:**

**Forms To Be Completed by a Blinded Assessor:**

**Seated VCs**

**“Sit up tall and ..... Nod head forward as far as possible brining the chin to the chest**

**Extend the head backward as far as possible looking up toward ceiling**

**Open the mouth as wide as possible *without* pain”**

<b>AROM</b>	<b>Baseline</b>
Seated Cervical flexion	
Seated Cervical extension	
Seated MMO <b>PAIN-FREE</b>	
Able to fully close? YES/NO	



Circle Left or Right lower incisor AND mark the same on future tagged pages for blind assessor measurement




**Supine VCs: “turn the head as far as possible to the right/left”**

**“maintain the teeth slightly apart (holding lip if necessary) and move the lower jaw to the right/left”**

<b>AROM</b>	<b>Baseline</b>
Supine Cervical Rotation R	
Supine Cervical Rotation L	
Supine Lateral jaw excursion R	
Supine Lateral jaw excursion L	

**PPT VCs:** “Sit up tall with your lips together and teeth apart during testing. I am going to apply some pressure, let me know when the sensation of pressure turns to pain”

Pain pressure threshold	Baseline
Temporalis R	Trial 1: Trial 2: Trial 3:
Masseter 1 R	Trial 1: Trial 2: Trial 3:
1 <sup>st</sup> Dorsal Interossei R	Trial 1: Trial 2: Trial 3:
Temporalis L	Trial 1: Trial 2: Trial 3:
Masseter 1 L	Trial 1: Trial 2: Trial 3:
1 <sup>st</sup> Dorsal Interossei L	Trial 1: Trial 2: Trial 3:

M1	T1	1 <sup>st</sup> DI	
			Image from McSweeney et al <sup>1</sup>

**Blinded Assessor signature:** \_\_\_\_\_

**STOP HERE AND RETURN TO CLINICIAN** \*\*A similar form will be used for visit 2 (1 week) and visit 4 (4 week).

Appendix G

Home Exercise Program and Behavioral Education

## HEP LOG

The exercise handouts provided to you include instructions on the number of repetitions to be performed. In addition to performing these exercises, you should maintain your usual activities that do not increase your symptoms; avoid activities that aggravate your symptoms. You do not have to discontinue other forms of exercise during participation in this study, however, do not begin new forms of exercise. You should not experience any significant increase in your pain while performing these exercises. Discontinue the exercise if it causes you significant increased pain, and notify your physical therapist. Please record your home exercise sessions in the exercise log provided below. See codes for recording. We ask that you honestly reflect your performance of exercises here. Thank you for your participation in this research and please let your physical therapist know if you have any questions.

**Please use the following Codes in each box to record your exercise sessions**

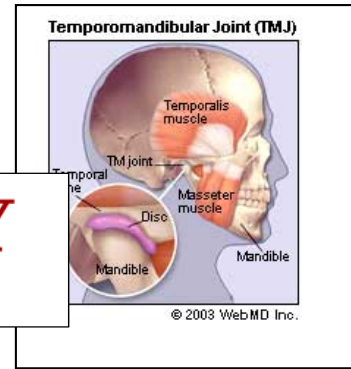
**PT:** If you attended Physical Therapy on this day

**Y:** If you completed your home exercise program

**N:** If you did not complete your home exercise program and please note the reason why (ex: pain, ran out of time, forgot)

**P:** If you completed part of the exercise program, and please note the reason why (ex: pain, ran out of time, forgot)

Date	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Week 1 Date:							
NOTES							
Week 2 Date:							
NOTES							
Week 3 Date:							
NOTES							
Week 4 Date:							
NOTES							
Week 5 Date:							
NOTES							



## Everyday Suggestions for Jaw Pain

The Temporomandibular joint (TMJ) is much like other joints in the body in that it has muscles, ligaments, a capsule, cartilage, and joint fluid. Like other joints, it can be a source of pain and limit daily activities. Physical therapy can help minimize pain and improve range of motion and functional use of the jaw. There are also many things you can do to decrease the pain throughout the day. Please use the following list as a reminder.

- Use the resting position of the jaw as often as you can throughout the day. Lips together, teeth apart, tongue on the roof of the mouth. Think of this as you are driving, working, lying in bed at night and really anytime you can!
- Place the tongue on the roof of the mouth during yawning
- Do your best to decrease the emotional and physical stress on the body that can contribute to clenching, grinding, and pain
- Choose soft foods when you can
- Cut food into smaller bites when possible
- Avoid the following
  - Chewing/biting nails
  - Chewing gum
  - Eating hard candy/food
  - Eating firm or hard breads
  - Wide yawning or singing
  - Chewing only on one side
  - Teeth clenching and grinding
  - Teeth touching- Remember lips together teeth apart!
  - Biting your cheeks, lips or other areas of the mouth
  - Resting your jaw on your hands
  - Jaw strain with playing musical instruments
- Be sure to get a good night's sleep!


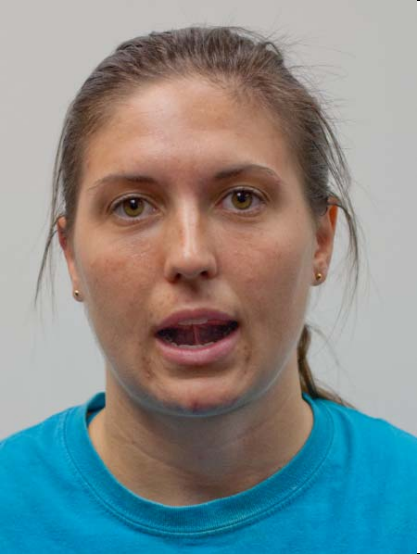
Thank you very much for your participation. Please contact your PT or the primary researcher with any questions or concerns. When the study is complete we are happy to talk with you about further options for treatment!

Bre Reynolds, PT, DPT, FAAOMPT



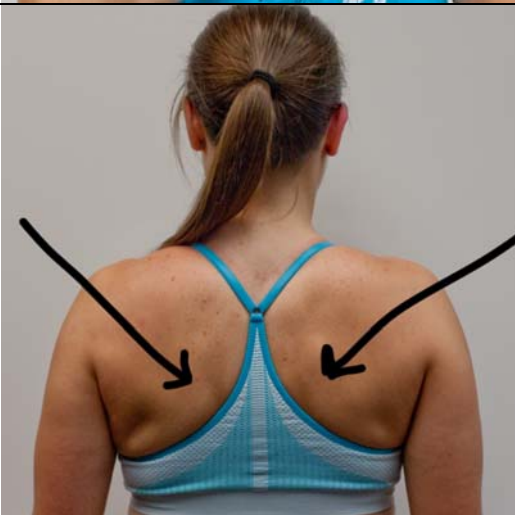
Assistant Professor Bradley University

(309)677-3293, bcreynolds@fsmail.bradley.edu

## Home Exercise Program

Exercise	Instructions	Picture	Sets/Reps
Jaw Resting Position	Place the tip of your tongue on the roof of your mouth with your lips together and teeth apart. Focus on relaxing the muscles of the jaw and face.		Perform throughout the day as often as possible. Specifically times of stress, concentration, driving, working, falling asleep, etc.
Controlled Jaw Opening	Place the tip of your tongue on the roof of your mouth and slowly lower your jaw to open your mouth. Your tongue should stay in contact with the roof of your mouth throughout the movement. Look in a mirror to avoid deflecting to one side.		Perform 6 repetitions, 4-6 x/day
Hyperboloid Lateral Jaw Movement	Place the hyperboloid between the top and bottom front two teeth. Use the string to catch the hyperboloid if it falls. Only provide enough pressure with your teeth to keep the hyperboloid in place and avoid squeezing it. Gently move your lower jaw to the right 10 times and to the left 10 times.		Perform 10 reps in each direction 4-6x/day. When this becomes easy, use one finger resistance on the side of your lower jaw to provide some resistance. This can be progressed to 2 and finally 3 fingers of resistance each direction.



Upper Neck Stretch	<p>Sit up tall with your head facing forward. Lace your fingers together and place them at the base of your head. Move your elbows close together. Slowly bring your chin down toward your chest about 20° and then lift your head up toward the sky with your hands.</p>		<p>Hold the stretch position for 5-10 seconds and repeat 6 times. Perform 4-6x/day.</p>
3 Finger Cervical Rotation	<p>Place three fingers on your chest as shown and rotate to one side as far as possible, then return to neutral. Alternate right and left rotation.</p>		<p>Perform 6 reps each direction 4-6x/day. You may start with 5 fingers and work toward 3 fingers if necessary.</p>
Shoulder Blade Squeeze	<p>Sit or stand with upright posture and draw both shoulder blades down and back. Avoid lifting your shoulder up toward your ears during this exercise.</p>		<p>Hold the position for 6 seconds and repeat 6 times. Perform 4-6x/day.</p>

## Appendix 10

### Manual of Standard Operating Procedures

(Excluding appendices and reference list as they repeat above appendices and references)

# **Thrust Joint Manipulation to the Cervical Spine in Participants with a Primary Complaint of Temporomandibular Disorder (TMD): A Randomized Clinical Trial**

## **Manual of Standard Operating Procedures**

This manual will serve as a reference guiding standardization of screening, evaluation, and treatment of eligible participants as well as data collection and recording.

### **Study Introduction**

Jaw pain is noted in up to 60% of the population<sup>293</sup> and many of these people do not seek treatment or know that treatment is available. Diagnosis is generally made via clinical symptom presentation. Pain can be experienced in the jaw, neck, ear, eye, or other facial regions. Other symptoms can include limited range of motion (ROM) in the jaw or cervical spine, headache, sleep disorders, and vertigo.<sup>293</sup>

An anatomical, biomechanical and neurophysiological relationship between the cervical spine and temporomandibular joint (TMJ) has been established.<sup>161</sup> One potential explanation for the relationship between the cervical spine and jaw is regional interdependence. Regional interdependence refers to the relationship between various joints and pain responses attempting to explain why impairments at one region may contribute to pain in another region.<sup>108,151</sup>

Manual therapy and exercise targeting the cervical spine has been examined in persons with temporomandibular disorder (TMD).<sup>22,23</sup> Cervical mobilization has shown promise with large effect sizes noted for decreasing pain, increasing mouth opening and lowering pressure pain threshold.<sup>22</sup> Cervical thrust joint manipulation has been studied as part of a multimodal intervention plan but the specific impact of cervical thrust manipulation is yet to be determined. Atlanto-occipital thrust joint manipulation has been utilized on populations with neck pain or those with latent trigger points but not specifically on a population with a primary complaint of jaw pain.<sup>69,161</sup>

This study is a prospective longitudinal randomized clinical trial. Subjects will be recruited and will enter the study voluntarily. Intervention will be delivered at the first visit, 1 week, 2 weeks, and 4 weeks. Data related to outcomes will be collected at the first visit, immediately following the first intervention, 1 week and 4 weeks. All subjects will receive suboccipital release, behavioral education, and exercise. The randomized intervention is cervical thrust manipulation vs sham manipulation. The estimated sample size will be 42 patients with 21 per group.

### **Eligibility Criteria**

A total of 42 participants referred from local dentists or recruited from the general population will be needed for completion of this study. All participants consenting to participation will be screened for eligibility using a health record form, physical objective examinations, and self-report measures. Participants will be screened by the evaluating physical therapist. An initial screening tool has been established and demonstrated high specificity (.97)

and sensitivity (.99) to identify those with and without TMD.<sup>32</sup> It is suggested that this tool be used to determine the presence of pain related TMD and the potential need for treatment.<sup>33</sup> The screen listed below is included on the last page of the evaluation/health history form and should be scored to ensure each participant meets inclusion criteria.

7. In the last 30 days, on average, how long did any pain in your jaw or temple area on either side last?<sup>32</sup>
  - a. No pain
  - b. From very brief to more than a week, but it does stop
  - c. Continuous
8. In the last 30 days, have you had pain or stiffness in your jaw on awakening?
  - a. No
  - b. Yes
9. In the last 30 days, did chewing hard or tough food change any pain (that is make it better or make it worse) in your jaw or temple area on either side?
  - a. No
  - b. Yes

Scoring: all “a” responses are scores as 0, “b” response is 1 point, and “c” response is 2 points. A threshold of a total score of 2 is needed for a positive screen.<sup>32</sup>

#### **Inclusion Criteria:**

8. Numeric Pain Rating Scale (NPRS) score  $\geq 2$  in jaw at baseline
9. Pain-free mouth opening  $\leq 50$  mm
10. Age 18-65
11. Primary complaint of TMD pain
12. TMD pain confirmed by screen listed above
13. Proficiency in the English Language
14. Availability to attend 4 appointments in 4 week

A minimum level of disability was established to increase likelihood of capturing change in pain or function. While there is no established minimum level of disability for the TMD population with NPRS, a score of  $\geq 2$  at baseline was chosen based on previous research<sup>156,186</sup> related to neck pain and the minimum NPRS score noted in a case series performed by the PI before the start of this study. Cervical thrust manipulation has been studied in a population of persons with neck pain, however, the intent of this study is to look at the impact of thrust joint manipulation of the cervical spine in a TMD population; therefore, persons included must have a primary complaint of TMD pain.

#### **Exclusion Criteria:**

7. Traumatic onset of symptoms in the last year
8. History of whiplash in the last 6 weeks; Prior neck surgery
9. TMJ locking in the last month
10. Medical red flags suggestive of non-musculoskeletal origin of pain, systemic or neurological disease

- a. Two or more signs of cervical nerve root compression (major muscle weakness, diminished upper extremity reflexes, diminished or absent pinprick sensation in a dermatomal pattern); Evidence of central nervous system involvement (hyperreflexia, gait disturbance, nystagmus, impaired facial sensation, change in taste, loss of visual acuity, positive pathological reflexes (Hoffman, Babinski, Inverted supinator, clonus)); unremitting night pain or non-mechanical pain.
11. Contraindications to thrust joint manipulation: active cancer, history of prolonged steroid use, acute fracture or tumor in the area to be treated, osteoporosis, joint ankyloses, dislocation, cervical ligament ruptures, acute active inflammatory or infectious disease, rheumatoid arthritis, vertebral artery abnormalities, connective tissue disease (Muscular dysplasia, Marfan syndrome, Down syndrome, Ehlers Danlos syndrome), prolonged anticoagulant therapy, signs of cranial nerve involvement, drop attacks, dysarthria, dysphagia, nystagmus, new or recent onset of dizziness, new or recent onset neck pain or headache “unlike any other”, previous cerebrovascular accident or transient ischemic attack, or uncontrolled hypertension, diabetes, or hyperlipidemia.
12. Previous cervical spine thrust joint manipulation intervention in the last 3 months; Worker’s compensation or any pending litigation regarding their pain or injury.

\*\*\*It is important that all evaluating therapists and researchers document any reason for exclusion (including not meeting inclusion/exclusion criteria or patient declination) as well as any attrition at follow-up.

### **Informed Consent**

Have subjects read and sign the Informed Consent document. Any of the participating therapists may consent a patient to participate; however, no other individuals may consent a patient into the study. Ensure the patient initials all pages of each of the two copies of the Informed Consent document (except for the last page where their signature will be present). Both copies should then be signed by one of the participating therapists in the “Investigator’s Signature” block and by another clinic staff member in the “Witness Signature” block (if applicable on your form). Do not have a friend or family member of the subject sign in the “Witness Signature” block. Hand one copy of the Informed Consent document to the subject for them to keep and place the other copy of the Informed Consent document in a folder in the appropriate location. Patients are considered enrolled into the study once they sign this statement.

### **Health History/ Historical Information**

1. Demographic information used for data collection, contact information, and emergency contacts.
2. Medical history check list: Any questions answered ‘yes’ or circled require further examination/explanation from evaluating therapist. If concerns are raised, make a phone call to inform their primary care or referring physician. Any aspect of medical history meeting contraindications for PT or manipulation should be noted and the patient is to be excluded from the study. Keep the documentation of exclusion in his/her file in the locked cabinet.
3. Onset Date: Can be listed as an exact date with note of preceding incident, or a general timeframe of number of days/weeks/months/years ago.

4. Treatment for Prior Episodes of Jaw Pain: If a patient does not have a history of jaw pain, you may proceed to the next question. If the patient does note a prior history, be sure treatments and response to treatment are recorded.
5. PHQ-2 Depression Screen: A patient who scores  $\geq 3$  should be referred to their primary care physician for follow-up, but may continue participation in the study.
6. Pain Diagram: The pain diagram is used to record the location and nature of pain by drawing it on a human figure. The pain diagram has shown to be a reliable tool to localize patient's symptoms.
7. Aggravating/Relieving Factors: If this is left incomplete, ask the patient directly and fill in information.
8. Activity Level: To indicate mode, duration, frequency of exercise.
9. Past Medical History: To note any other surgery, diagnosis, or medications not already covered in the check list.
10. General TMD Screen: A score of 2 is needed for inclusion

### Self-Report Measures and Outcome Data

All subjects will complete several commonly used instruments to assess pain and function in patients with TMD. There is no consensus in the literature regarding the most appropriate outcome measures to use with this population. Therefore, we will use a spectrum of outcome measures that attempt to capture the effect of treatment on the level of the patient's perceived recovery, disability, and functional limitations. Other measurements for cervical range of motion (ROM), jaw ROM, and pressure pain threshold (PPT) will be taken by an assessor blind to treatment group allocation. The timing of data collection for the self-report and outcome measures is listed below in Table 1. Outcomes at 3 and 6 months will be mailed or emailed by the researchers. See Appendix for copies of all Self-Report Measures.

**Table 1: Timing of Data Collection**

Measurement	Baseline	Immediate	1 week	2 week	4 Week	3 Month	6 Month
ROM Jaw	Yes	Yes	Yes	No	Yes	No	No
NPRS	Yes	Yes	Yes	No	Yes	No	No
JFLS	Yes	No	Yes	No	Yes	Yes	Yes
NDI	Yes	No	Yes	No	Yes	Yes	Yes
TMD Disability Index	Yes	No	Yes	No	Yes	Yes	Yes
GROC	No	Yes	Yes	No	Yes	No	No
PASS	No	No	No	No	Yes	Yes	Yes
TSK-TMD	Yes	No	No	No	Yes	Yes	Yes
ROM Cervical Spine	Yes	Yes	Yes	No	Yes	No	No
Pressure Pain Threshold	Yes	Yes	Yes	No	Yes	No	No

Mailed by  
Researchers



PHQ-2 Depression Screen	Yes	No	No	No	No	No	No
Side Effect Questionnaire	No	No	No	No	Yes	No	No

The self-report measures that will be used include the following:

1. **Numeric Pain Rating Scale (NPRS):** The NPRS allows patients to quantify their pain on an 11-point scale used to measure pain intensity. Pain is given a number from 0 (representing no pain) to 10 (representing the worst pain imaginable).<sup>195</sup> Psychometric property analysis relevant to the TMD population is limited. Sum scores have been suggested to improve reliability,<sup>165</sup> and will be utilized for this study. Participants will be asked to rate their current pain as well as the best and worst pain scores over the last 24 hours resulting in an average pain score<sup>165,197</sup> that will be recorded for jaw pain, neck pain, and headache.  
\*\*This is the only scale the clinician must partially score themselves, as a sum score of NPRS for the jaw must be  $\geq 2$ . You will add all 3 pain scores for the jaw (present, best, worst) and divide by 3. This is only necessary on the first visit.
2. **Jaw Functional Limitation Scale (JFLS):** The JFLS is a 20 item self-report scale assessing three constructs (mastication, vertical jaw movement, emotional/verbal expression) to quantify functional limitation.<sup>203</sup> Each item is scored by the patient from 0 (no limitation) to 10 (severe limitation). The recorded score is the total score of the 20 items, ranging from 0-200. Higher scores reflect greater level of dysfunction.
3. **Neck Disability Index (NDI):** The NDI is a 10 question self-report scale assessing levels of neck pain and related disability. Each item is scored from 0-5 with a maximum score of 50 points. The total score is doubled and interpreted as a percentage of the patient perceived disability. Higher scores represent increased level of disability.
4. **TMD Disability Index:** The TMD Disability Index is a 10 question self-report scale utilized in research (including a study of manual therapy for TMD).<sup>208</sup> Each item is scored 1-5 with a minimum score of 10 and a maximum score of 50. Higher scores are representative of higher levels of disability. However, there are no reports of psychometric property analysis in the literature. It is a goal of this study to begin reporting psychometric analysis of this tool.
5. **Global Rating of Change (GROC):** The GROC scale asks patients to rate their perception of overall change. The scale ranges from -7 (a very great deal worse) to zero (about the same) to +7 (a very great deal better).<sup>210,211</sup> Intermittent descriptors of worsening or improving are assigned values from -1 to -6 and +1 to +6 respectively. The global rating will be administered at the follow-up examinations only and will serve as the reference criterion for establishing when a successful outcome occurs. Controversy surrounding the construct validity<sup>278</sup> of this measure will be taken into account when interpreting results.
6. **Patient Acceptable Symptom State (PASS):** The PASS is a single question asking patients if their current status is acceptable or unacceptable.<sup>216</sup> Some authors have noted patients who found their current state acceptable, often had “unexpectedly high”<sup>217,218</sup> pain ratings. The use of this tool allows for a better understanding of the participants’ perception of their well-being<sup>218</sup> and may suggest they are unlikely to seek further treatment.<sup>220</sup> Wording is modeled after Mintken et al 2016; “Taking into account all the activities you have during your daily life, your level of pain, and also your functional impairment, do you consider that your current state is satisfactory?”<sup>221</sup> Individuals are to respond yes or no; those responding yes will be categorized as a success.

7. Tampa Scale for Kinesiophobia for Temporomandibular Disorders (TSK-TMD): TSK-TMD is a self-report scale modified from the original Tampa Scale for Kinesiophobia utilized to assess fear of movement commonly associated with chronic pain conditions including neck pain.<sup>222</sup> It is a 12 item measure assessing fear of movement/(re)injury. Patients rate each item on a 4-point Likert scale and total scores range from 11-48. Higher scores represent higher levels of fear.
8. PHQ-2 Depression Screen: The PHQ-2 is a 2 question screen used to identify persons at risk for depression. This test is not diagnostic for depression, but a recognized brief and effective first step in identification of those at risk.<sup>242,243</sup> A patient who scores  $\geq 3$  should be referred to their primary care physician for follow-up, but may continue participation in the study.
9. Side Effects Questionnaire: At visit 4 (week 4), patients will complete a questionnaire asking about side effects or adverse events associated with their treatment. This information will be summarized and reported.

**\*\*Payment for Participation:** Participants can be paid for participation if they complete the required form and place it into the self-addressed envelope. Participants are to close this envelope themselves to ensure this information remains completely confidential and is only shared with Bradley University for the purpose of processing payment. Please drop these envelopes into the mail.

### Physical Examination

#### To be performed by the treating clinician

1. 15 second heart rate
2. Blood Pressure
3. Height and Weight: Verbal, BMI ok to leave blank
4. Safety screen: Stop and make a medical referral if any of these are positive
  - a. Resting Nystagmus: note if present
  - b. Cranial Nerve Screen
    - i. Ask the patient: Have you noticed a change in your ability to smell, read clearly, eat, speak, taste food, or hear?
    - ii. Assess pupil constriction to light.
    - iii. Assess eye movement down and in as well as away from midline by asking the patient to follow your finger with their eyes.
    - iv. Assess facial sensation in the region of the ophthalmic (above eye brow), maxillary (above upper lip), and mandibular (below lower lip) branches of the trigeminal nerve.
    - v. Ask the patient to smile, pucker the lips, raise the eyebrows (note if impaired), and stick out their tongue (look for deviation to one side).
    - vi. Rub your fingers by each ear asking if the patient hears them both equally.



- c. Sharp-Purser Test: To perform the test, the patient is seated. The examiner places the palm of one hand over the patient's forehead while the opposite hand stabilizes the spinous process of the axis. With the neck in approximately 20-30° of flexion, the examiner applies a posterior shearing force with the hand on the patient's forehead. A positive test is a reduction in signs and symptoms.



- d. Upper Motor Neuron Assessment: Testing of the Hoffman and Babinski reflexes may be necessary if the patient reports symptoms consistent with an UMN lesion. Most therapists are familiar with the Babinski reflex. However, the Hoffmann's reflex is also useful to detect the presence of an UMN lesion. This test is conducted with the patient's hand in the neutral position. The examiner flicks the distal phalanx of the middle finger. Hoffman's reflex is considered positive if there is flexion of the interphalangeal joint of the thumb, with or without flexion of the index finger proximal or distal interphalangeal joints. A positive reflex may denote spinal cord compression or intracranial pathology. A positive test in a patient with other neurologic signs and symptoms warrants referral to a specialist for appropriate management.



- e. Signs of Bilateral or Quadrilateral Paresthesia or Motor Deficits: Note if present.
- f. Vertebral Artery Screen: This test is performed in supine. The patient is moved passively and sequentially into right and left rotation, followed by extension, then extension with rotation in each direction. During each movement the patient holds the position while counting backwards from 15, with the therapist monitoring for the nystagmus or presence of cranial nerve signs and symptoms as previously described. If any one of these signs or symptoms is observed, the therapist should forgo testing of more extreme movements, immediately move the patient's head into a more neutral position, and refer the patient for further consultation.
- g. Alar Ligament Testing: The Alar Ligament Test assesses the integrity of the alar ligaments, which provide stability to the atlanto-occipital complex. With the patient supine, the examiner stabilizes the axis by placing the pad of the left thumb immediately adjacent to the left aspect of the spinous process of the axis. With the right hand, the examiner side bends the patient's head to the right. The examiner should feel the spinous process of the axis immediately move into the left thumb. If the alar ligament is intact, little to no sidebending can occur and the end feel should be capsular. A delay, or lag, in the movement of the spinous process of the axis is suggestive of injury to the alar ligament. The test is then repeated to the opposite side.
- h. Transverse Ligament Screen: The Transverse Ligament Test assesses the integrity of the transverse ligament, which provides stability to the dens at the atlantoaxial

joint. With the patient supine, the examiner stabilizes the axis by placing the left thumb and index finger on the transverse processes of C2. With the right hand, the examiner provides an anterior shearing force to the occiput/C1 and should feel a firm end feel to this motion. Excessive anterior shear without a firm end point, a sensation of a lump in the throat, abnormal pupil response, nystagmus, dizziness, paresthesia in the face or lips indicate a positive test.



- i. 2 or more signs of cervical nerve root compression
  - i. Sensory Exam: Test key UE dermatome sensation (see Table below), After each limb is pricked, ask the patient “Does that feel the same to you on each side?” If a difference is noted, the area should be explored further to map the extent of the sensory deficit. Results are recorded as absent/diminished or normal compared to the other side.
  - ii. Muscle Stretch Reflexes (MSR): The biceps brachii reflex tests the C5 nerve root. The reflex is tested by placing the patient’s arm in about 45° of flexion with the muscle relaxed. The examiner strikes the tendon in the cubital fossa, just proximal to its insertion. The thumb may be placed over the tendon to insure proper technique. The brachioradialis reflex primarily tests the C6 nerve root. The arm is positioned as for the biceps reflex. The examiner strikes the tendon at the distal aspect of the radius with the flat edge of the reflex hammer. The triceps reflex is used to test the C7 nerve root. The examiner supports the patient’s arm and strikes the triceps tendon just proximal to the olecranon. Each reflex is graded as absent/diminished, WNL, or hyperactive.
  - iii. Motor Exam: Key muscles for each cervical nerve root are tested. Each muscle test is graded as WNL or diminished. The examiner should also note if pain was produced during the muscle test. Muscle testing procedures are outlined in the table below.

	Key Muscles for MMT	Dermatomal areas	Key Muscle for MSRs
C5	<u>deltoid</u> (shoulder in 90° abduction, resistance against lateral upper arm into adduction)	Mid-deltoid	biceps brachii (C5, C6)
C6	<u>biceps brachii</u> (elbow at 90° flexion with forearm supinated, resistance against lower forearm into extension)  <u>extensor carpi radialis longus/brevis</u> (wrist extended/ radially deviated with forearm pronated, resistance against dorsum of hand into flexion/ulnar deviation)	radial aspect of 2 <sup>nd</sup> metacarpal/ digit	brachioradialis (C5, C6)
C7	<u>triceps</u> (arm is placed overhead with elbow slightly flexed, resistance against forearm into flexion)  <u>flexor carpi radialis</u> (wrist flexed/radially deviated with forearm supinated, resistance against thenar eminence into extension/ulnar deviation)	dorsum of 3 <sup>rd</sup> finger	triceps (C7)
C8	<u>abductor pollicis brevis</u> (thumb placed in abduction, resistance against proximal phalanx into adduction)	medial aspect of 5 <sup>th</sup> finger	N/A
T1	<u>first dorsal interossei</u> (index and middle finger are separated, resistance against the medial aspect of proximal phalanx of the index finger into adduction)	medial forearm	N/A
*** The nerve root in bold is the primary nerve root assessed by the MSR.			

5. Move to measurement by a blind assessor while treating therapist opens envelope to reveal treatment group allocation. The blind assessor should not know what the envelope reveals and should step out of the treatment area during intervention to avoid visual or auditory clues as to group assignment.
6. **Blinded assessor/data collector** to measure the following:

**AROM of the jaw:** A disposable range of motion scale tool (Therabite™) will be utilized to measure seated maximum mouth opening and supine lateral deviation. Mouth opening is an essential function of chewing and speech and often a limitation in those with jaw or neck pain.<sup>9,161</sup> Care should be used during seated measurements to ensure the patient maintains an upright sitting position throughout the examination and during subsequent follow-up examinations. The following procedures are used to measure the range of motion for the jaw.

- a. **Maximal Mouth Opening (MMO):** The patient is seated with the feet on the floor and told to sit up tall. The patient is asked to “sit up tall and open the mouth as wide as possible without pain.” Measurement is taken as the distance between maxillary and mandibular central incisor edges, with the Therabite notch resting on the most vertical incisor.<sup>113</sup> You will circle on this page which tooth was used AND mark it on subsequent pages (flagged) if you are the first to measure a

patient. The amount of *pain-free* mouth opening is recorded. Inclusion criteria require this initial measurement is  $\leq 50$  mm.



Circle Left or Right lower incisor AND mark the same on future tagged pages for blind assessor measurement



- b. Lateral Deviation: The patient will be supine with the neck in a neutral position. The patient is told to move their lips in order to show the teeth and open the mouth only enough to avoid tooth contact. The Therabite's flat edge is used to record right/left lateral deviation.
  - i. The flat edge of the Therabite is placed so that 0 is aligned with the space between the mandibular central incisors. The patient is asked to "maintain the teeth only slightly apart, and move the lower jaw to the right." The therapist will note the distance from the mandibular central incisors to 0 and record the amount of deviation.
  - ii. This process is repeated for left lateral deviation.



AROM of the cervical spine: Measurements of AROM are performed to determine limitations in motion, and the impact of movement on symptoms. A bubble inclinometer will be used to measure seated flexion/extension and supine rotation. Care should be used during seated measurements to ensure the patient maintains an upright sitting position throughout the examination and during subsequent follow-up examinations. The following procedures are used to measure the range of motion for the cervical spine.

- b. Flexion/Extension: The patient is seated with the feet on the floor and told to sit up tall. The inclinometer is placed on the top of the patient's head with the fulcrum aligned with the external auditory meatus and then zeroed.



- i. The patient is asked to "sit up tall and nod the head forward as far as possible, bringing the chin to the chest." The amount of neck flexion is recorded from the inclinometer.
- ii. The patient is asked to "sit up tall and extend the neck backwards as far as possible looking up toward the ceiling." The amount of neck extension is recorded from the inclinometer.

- c. Rotation: The patient will be supine with the neck in a neutral position. The inclinometer is placed on the anterior base of the forehead with the fulcrum aligned with the center of the forehead and then zeroed.

- i. The patient is asked to "rotate the head as far as possible to the right." The amount of right rotation is recorded from the inclinometer.
- ii. The patient is asked to "rotate the head as far as possible to the left." The amount of left rotation is recorded from the inclinometer.



- d. \*\*Both extension and end range rotation ROM may produce dizziness or nausea in patients with vertebrobasilar insufficiency (VBI).

Pressure threshold (PPT): A digital algometer will be used to assess PPT at the masseter, temporalis, and a remote location in the C8 dermatome at the hand. The PPT is the amount of pressure needed for a subject to report the sensation of pressure changes to pain at a specific location.<sup>233</sup> A mean of 3 trials will be used for each site tested, with a 30 second pause between each trial.<sup>99</sup> The patient will be asked to keep their lips together and teeth apart during testing in order to avoid clenching or muscle contraction during testing.

PPT will be assessed bilaterally at one point on the masseter (M1) and one point on the anterior temporalis (T1) as has been done in previous research.<sup>2,99</sup> The first dorsal interossei (DI) will represent a remote site (C8/T1), distant to the dermatomal site of interest (C0-3).<sup>233</sup>

Assessors will 1<sup>st</sup> use the stencil to mark the skin at M1 and T1 on both sides.

- M1: 2.5 cm anterior and 1.5 cm below the tragus
- T1: 3 cm above an imaginary line drawn between the edge of the lateral eye and the superior external ear and 2 cm posterior to the anterior edge of the temporalis muscle

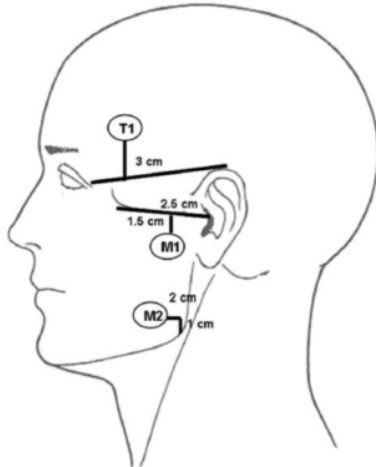


Image from LaTouche et al<sup>2</sup>



The images below show the placement of the stencil and marking location.

**M1**



**T1**



Once marking is complete, you are done with the stencil.

The 3<sup>rd</sup> and final location for PPT is the 1<sup>st</sup> dorsal interossei of the RIGHT hand.

- DI: Forearm pronated and resting on solid surface, applied at middle medial aspect of 1<sup>st</sup> MC<sup>1</sup>



Image from McSweeney et al<sup>1</sup>

The algometer is applied perpendicular to the region of interest. One hand will need to provide a counterforce on the head in order to stabilize the cervical spine when testing the jaw musculature. Assessors will go through one round of each point B, then repeat that cycle so as to allow rest between each of the 3 testing points. With testing all locations, the assessor will tell the patient to “sit up tall with your lips together and teeth apart during testing. I am going to apply some pressure, let me know when the sensation of pressure turns to pain”.<sup>99</sup>

Measurements taken by the blinded assessor will be recorded on standardized documentation records and returned to the locked file cabinet each visit. See Appendix for copies of the Standardized Form.

The person measuring cervical ROM, jaw ROM, and PPT will be blinded to this treatment allocation and must now leave the area during treatment.

#### **Final Clinician Testing Before Treatment:**

1. Test Position Hold: The patient will be placed in the position of TJM and held for 10 seconds. Stop if the patient experiences dizziness, nystagmus, nausea or sign of vascular/neurological compromise in the manipulation hold position.
2. Initial the box noting you have fully reviewed the health record and physical examination confirming it is safe to proceed with treatment.



## Treatment


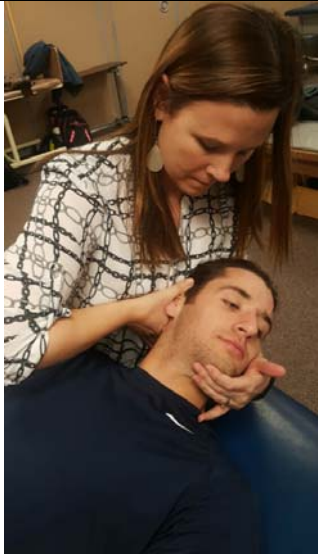

### *Interventions*

Upon completion of health history forms, self-report questionnaires, physical exam, and objective measurements, patients will be randomized to receive either cervical TJM or sham manipulation. Patients in both groups will attend PT at initial evaluation, 1 week, 2 weeks, and 4 weeks for a total of 4 visits in four weeks. Follow up at 3 and 6 months will occur via mail or e-mail.

*Group One:* Suboccipital release (2 minutes), cervical spine TJM (5 minutes or less), behavioral modification (10 minutes), and exercise (15 minutes). Suboccipital release will be used to allow the patient to gain comfort with manual cervical contact. Cervical spine TJM will be performed in supine using a rotational up-slope manipulation at C2/3 and a distraction manipulation at C0/1 (see below for further detail regarding TJM intervention). Cervical TJMs will be performed on the right and left side and will follow common research practice<sup>154</sup> to include delivery of a high-velocity, low amplitude (HVLA) thrust. If cavitation occurs on the first trial, the therapist will move to the next location. If there is no cavitation the participant will be repositioned and the procedure will be performed a second time. A maximum of two trials at each level on each side will be performed yielding 4-8 HVLA thrusts. See Appendix for handouts that will be issued describing behavioral modification and exercise.

*Group Two:* Suboccipital release (2 minutes), sham manipulation (5 minutes or less), behavioral modification (10 minutes), and exercise (15 minutes). Sham manipulation will be performed in a similar supine position as noted above. Clinicians will place the participant in the manipulation position, stop short of tissue tension, hold for 15 seconds,<sup>150</sup> and reposition to neutral or resting position.<sup>175,244,245</sup> A thrust will not be performed and while cavitation may occur, there is no expectation of cavitation. Therefore, these participants will receive 4 manual sham manipulation techniques, one at each of 4 locations. See Appendix for handouts that will be issued describing behavioral modification and exercise.

Verbal instruction for cervical intervention will be modeled after the cervical spine mobilization versus sham mobilization study by La Touche et al in 2013. Therapists will give all participants the same verbal description, regardless of group assignment. Therapists will say “I am going to apply a technique to your neck with my hands placed here. The purpose of this technique is to obtain change in your jaw and/or neck pain”.<sup>23</sup>

Intervention	Description	Image
Suboccipital Release	The patient is positioned supine for comfort. The therapist places both hands on the posterior aspect of the neck, allowing the fingertips to sink into the space between the occiput and the spinous process of C2. The base of the head is supported with 90° of flexion at the MCP joints of fingers 2-4 on both hands. <sup>246</sup> The therapist may allow slight traction cranially. This technique is performed for 2 minutes.	
C0/1 Distraction TJM	The patient is positioned supine without a pillow. The therapist passively sidebends the head and neck to the left and then rotates to the left. The first MCP of the right hand contacts the right mastoid process. The therapist passively moves the occiput into slight extension while maintaining left rotation. The right hand will direct the force of the manipulation in a cranial direction, perpendicular to the surface of the R C0/1 joint, with a gentle rotatory force. <sup>247</sup> The patient will be told to inhale and manipulation performed after exhalation. This procedure will be repeated to the other side.	
C2/3 Upslope TJM	The patient is positioned supine for comfort. The therapist will use a cradle hold contacting the posterior right articular pillar of C2 with the lateral border of the proximal or middle phalanx. The left hand will be under the head with the fingers spread out to maximize contact. The therapist passively moves the head and neck into right sidebending and left rotation with no significant degree of flexion or extension. The right hand directs the force of the manipulation in a direction upward toward the patient's left eye. <sup>154,247</sup> This procedure will be repeated to the other side.	

## Exercise Intervention

The Rocabado 6x6 has been utilized in practice and research<sup>248</sup> with minimal evidence to support use and no comparative exercise studies to date. Lateral jaw movement training has been suggested and is utilized in clinical practice.<sup>249</sup> The Rocabado program includes jaw, cervical spine, and postural exercises. A combination of the Rocabado program, cervical ROM exercise, and lateral jaw training will be used and standardized for a home exercise program (HEP) in this study. See Appendix for the handout of exercise to be provided to all patients.

Treating clinicians will fully review this home exercise handout with each participant. Clinicians will describe and demonstrate each exercise, then ask the participant to perform the exercise in front of them. After all exercises have been instructed, the therapist will ask the patient to demonstrate each exercise again with as few verbal cues as necessary.

### *Visit 1: Baseline and First Treatment*

Informed consent procedures followed by the patient completing self-report scales and the health record form. Clinicians will review this health record and complete objective evaluation excluding measurements to be taken by the blinded assessor. The blinded assessor will enter the room to measure cervical ROM, jaw ROM, and PPT. The blinded assessor will then leave the area so that they cannot hear or see which treatment group a patient has been randomized to. As noted above, suboccipital release, behavioral education and exercise will be standardized and consistent between groups. *Group One* (cervical spine TJM group) will receive C0/1 and C2/3 TJM as described previously. *Group Two* (minimal intervention group) will receive sham manipulation (15 second hold before tissue tension) as described previously.

After cervical TJM/sham, immediate response measurements will be taken by the blinded assessor before the introduction of any education or exercise program. Clinicians will then utilize the behavioral education document to discuss recommendations. The standardized HEP will be instructed and participants will be given a chart to track compliance.

### *Visit 2: Week 1*

Measurements of ROM and PPT will be taken by a blinded assessor before intervention. Treatment will begin with two minutes of suboccipital release for both groups. Barring no change in medical history or known contraindications cervical spine TJM/sham will proceed as done in visit 1 unless a participant notes a complete resolution of complaints (score of 0 on JFLS or +7 GROC). If a complete resolution is noted, no TJM/sham will be performed. All participants will receive education reviewing the behavioral modification instructions and exercise instructions.

### *Visit 3: Week 2*

No measurement or self-report scale data will be collected on this date. Treatment will begin with two minutes of suboccipital release for both groups. Barring no change in medical history or known contraindications cervical spine TJM/sham will proceed as done in visit 1 unless a participant notes a complete resolution of complaints (score of 0 on JFLS or +7 GROC). If a complete resolution is noted, no TJM/sham will be performed. All participants will receive education reviewing the behavioral modification instructions and exercise instructions.

#### *Visit 4: Week 4*

No prescribed treatment on this date, only self-report scales and assessment by the blinded assessor. After measurement is complete, clinicians will debrief participants explaining the intent of the research study, group allocation, and potential impact of results. Clinicians will inform the patient they will receive outcome measures to complete at 3 and 6 months and ask them if they prefer mail or email. Participants will be reminded they will receive an incentive payment for completion of these outcomes as well.

Continued treatment frequency, duration, and interventions are at the discretion of the treating clinician. Referral to another provider (medical, dental, or other) will be done on this date if needed. Please record this information on the last page of the evaluation form.

**\*\*At each treatment visit, be sure to record if cavitation was present with TJM or sham manipulation and verify that suboccipital release, behavioral education, and exercise instruction were completed.**

**Billing:** participants attending Rock Valley Physical Therapy will be billed according to standard clinical practice. Front office staff will check benefits and inform participants of any limitations, co-pay, co-insurance, or remaining deductible. The formal informed consent process and informal discussion with office staff will inform participants that their insurance will be billed and they are responsible for any associated cost. Physical therapists will bill for their time in evaluation and treatment, however, will not bill for the 7 minutes (or less) of manual therapy (cervical spine TJM or sham manipulation). Volunteers at UNLV will be attending a PT research laboratory rather than a clinic and will not be billed.

#### **Handling Data Sets**

Each treating location will use a locked file cabinet to store patient data. The PI will be responsible for educating all clinicians, research assistants, and front office staff with Rock Valley Physical Therapy in confidentiality measures and data safety plans. Front office staff will be responsible for the locked files and scheduling patient appointments. Only those directly involved in this research project and trained in data safety will have access to the cabinet. A case number will be assigned to each folder and any electronic sharing of information will only include the case number. Personal health information will not be shared or transmitted electronically. The front office staff will mark scheduled appointments on a shared calendar using the case number. A research assistant at Bradley University will contact the blinded assessors to get someone to the appointment. If a patient cancels or changes their appointment time, a phone call or email to the PI would be appreciated so that schedules for the blinded assessor can also be modified.

It is suggested that patients are asked to come 15-20 minutes early for the first evaluation, and 10 minutes early for visit 2 and 4 in order to complete paperwork. Patients are to fill out self-report questionnaires before seeing the treating clinician. These forms will be returned to the locked file cabinet when complete. The forms completed by a blinded assessor will be returned to the locked file cabinet each visit. No forms should ever leave the clinic.

The PI will also periodically check in with each participating clinician, blinded assessor, and clinic office staff member to review procedures and monitor recruitment and retention. This check will occur once per month over the phone.

When a participant has completed the 4 week visit, the forms in their folder will be copied and hard copies mailed to the PI at the address below. Once the PI receives the hard copies, the clinic will shred copied pages and any remaining documentation of study materials.

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