COMPARING DISTRIBUTION-BASED AND ANCHOR-BASED MINIMAL CLINICALLY IMPORTANT DIFFERENCE VALUES FOR TEMPOROMANDIBULAR DISORDER

APPROVED BY SUPERVISORY COMMITTEE

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DEDICATION

I would like to extend my sincerest appreciation to my graduate committee over the past two years. Dr. Robert Gatchel, you have been a constant source of encouragement and wisdom. The foundation of excellence that you set allowed me to grow as a researcher and I am extremely grateful for that opportunity. Mr. Rob Haggard, I want to thank you for your support, patience, and advice day in and day out that allowed me learn and develop. Dr. Chung-Yi Chiu, I greatly appreciate you taking the time to answer every question I had and to helping me develop into a better researcher. To my family, I certainly could not have done this without any of you. Your unwavering support throughout the years is something I will never forget.

COMPARING DISTRIBUTION-BASED AND ANCHOR-BASED MINIMAL CLINICALLY IMPORTANT DIFFERENCE VALUES FOR TEMPOROMANDIBULAR DISORDER

by

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COMPARING DISTRIBUTION-BASED AND ANCHOR-BASED MINIMAL CLINICALLY IMPORTANT DIFFERENCE VALUES FOR TEMPOROMANDIBULAR DISORDER

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The University of Texas Southwestern Medical Center at Dallas, 2011

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The current study is a continuation of studies by Gatchel and colleagues. Data were collected from 101 patients at several community dental clinics. Based on the patients' initial evaluations, they were randomly assigned to one of three treatment groups: Low Risk/Non-intervention Group; High Risk/Biobehavioral Group; or High Risk/Self-Care Group.

This study attempted to better understand and objectively quantify meaningful symptom relief by determining the *minimal clinically important difference* (MCID) for temporomandibular joint disorder (TMD). Despite limitations and controversy with

determining the most appropriate method, this information will play an important role in determining treatment effectiveness for not only TMD, but for other pain conditions as well. The most commonly referenced methods for determining meaningful change are the distribution- and anchor-based approaches. Distribution-based minimal detectable change (MDC) values were calculated using the formula 95% CI=1.96 x $\sqrt{2}$ x SEM, while the anchor-based approach minimal clinically important change (MCID) values were calculated using a Receiver Operating Curve (ROC). Both mean particle size and broadness of distribution served as two separate functional anchors, and normal range and .5 SD as two separate cutoff methods.

Despite some variability, the MCID values were relatively consistent with the MDC values regardless of method, anchor, or cutoff for both the Physical Component Scale (PCS) and Mental Component Scale (MCS) of the SF-36. The Characteristic Pain Inventory and Graded Chronic Pain Scale showed a narrow range of variation within the MCID values; however, the MCID values calculated were significantly higher than the MDC values reported for the same measures.

Findings indicated that the PCS component of the SF-36 provided stronger evidence of clinically meaningful change. The PCS resulted in asymptotic values closer to .1 (at the 90% confidence interval) with areas under the curve that better fit the model compared to the other subjective measures (considered fair at .701 when using the normal range and .740 when using .5SD for the Biobehavioral Group). Additionally, broadness of distribution resulted in more clinically meaningful changes as a result of better metric values when comparing the biobehavioral versus the self-care groups.

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LIST OF ABBREVIATIONS

BDI-II – Beck Depression Inventory 2nd edition

BPS – Biopsychosocial

CBT – Cognitive Behavioral Therapy

CI – Confidence Interval

CPI – Characteristic Pain Inventory

DSM – Diagnostic and Statistical Manual

GCPS – Graded Chronic Pain Scale

HIPAA – Health Insurance Portability and Accountability Act

IRB – Institutional Review Board

MCID – Minimal Clinically Important Difference

MCS – Mental Component Scale of the SF-36

MDC – Minimal Detectable Change

MIC – Minimal Important Change

ODI – Oswestry Disability Index

PCS – Physical Component Scale of the SF-36

PI – Pain Inventory

PILE – Progressive Isoinertial Lifting Evaluation

PSS – Perceived Stress Scale

RDC/TMD – Research Diagnostic Criteria for Temporomandibular Disorder

ROC – Receiver Operating Curve

SEM – Standard Error of Measurement

SF-36 – Short Form of the Medical Outcomes Study

TMD – Temporomandibular Disorder

TMJ – Temporomandibular Joint

CHAPTER ONE
Introduction

Temporomandibular Disorder (TMD) is a widespread disorder that nearly 75% of the U.S. population suffers symptoms from, with pain being the most prevalent symptom. The direct costs of treating and managing TMD can be significant, measuring over a billion dollars a year (American Academy of Orofacial Pain; Gatchel, Stowell, Wildenstein, Riggs, & Ellis, 2006). Although there has been an increase in the research of pain and chronic pain conditions such as TMD, it is difficult to measure the perception and effectiveness of pain treatment objectively. In the past, research in the field of pain has been limited to the perception and description by the patient. Research in the field of neuroscience has assessed the basic neural and biochemical mechanisms involved and, with the development of the biopsychosocial model of pain, new approaches to the management of pain are being made. According to research by Gatchel, Peng, Peters, Fuchs, and Turk (2007):

> "each individual experiences pain uniquely, and a range of psychological and socioeconomic factors can interact with physical pathology to modulate a patient's report of symptoms and subsequent disability." (p.607)

This subjectivity in measures of pain has led researchers to want to find "interpretive guidance from a concrete value that might indicate a clinically significant/important outcome" (Gatchel & Mayer, 2010, p. 322). The next step to better being able to treat pain is to measures a treatment's effectiveness. More scientifically objective measures to describe and measure pain are necessary to better understand how pain is perceived by the patient, and to what degree is that pain relieved by different treatments. These

measures will also play an important role in determining the diagnosis and treatment of pain disorders. Currently, the clinical treatment of pain is often limited to the patient's report of symptom relief. Conducting a *minimal clinically important difference* (MCID) study for TMD will provide a statistically significant and clinically meaningful number in order to quantify the changes in pain, thereby contributing to the evaluation of pain treatment effectiveness.

CHAPTER TWO
Review of the Literature

Pain Theory

The American Academy of Pain Management (2003) estimated that roughly 57% of the adult population in the United States will report experiencing some degree of chronic pain, and nearly 62% of those individuals will report experiencing that pain for more than a year (Gatchel et al., 2007). Pain accounts for approximately 80% of physician visits, with costs greater than $70 billion annually in health care costs and lost productivity (Gatchel et al., 2007). The United States Congress marked 2001-2010 as The Decade of Pain Control and Research, and the Joint Commission on Accreditation of Healthcare Organizations (2000) now requires physicians to consider pain as the fifth vital sign (the other four being pulse, blood pressure, temperature, and respiration); (Gatchel et al., 2007).

Gate Control Theory of Pain

The initial framework for the Gate Control theory of pain was set forth by the Dutch surgeon Nordenbras (1959; Gatchel et al. 2007). Melzack and Wall (1965) subsequently recognized the need for a comprehensive model that took into consideration both the potentially amplifying effects of emotion and the interpretive role of cognitive evaluation, with the specific nerve function and the degree of pattern recognition that is responsible for the underlying peripheral and central processing of noxious information. Melzack and Wall's Gate Control Theory (1996) of pain accounted for a number of facts such as: "(1) the variable relationship between injury and pain; (2) non-noxious stimuli can sometimes

produce pain; (3) the location of pain and tissue damage is sometimes different; (4) pain can persist long after tissue healing; (5) the nature of the pain and sometimes the location can change over time; (6) pain is a multi-dimensional experience, and (7) there is a lack of adequate pain treatments." (p.165)

This theoretical approach suggests that there are six stages that compose the mechanism by which noxious stimuli enter the spinal cord from the periphery, and then proceed to higher-level areas of the brain. The first stage consists of the small peripheral nerve fibers transmission of signals to cells in the spinal cord. Facilitatory interneurons in the spinal cord region explains the fact that cells in the spinal cord can show prolonged after-discharge following the arrival of a signal from the peripheral nerves; this composed the second stage (Wall, 1960). The third stage focused on a group of additional peripheral fiber inputs that could be involved in the processing of pain. This was a change as most research prior to the Gate Theory, focused solely on nociceptive specific neurons that responded to high-threshold stimulation instead of also considering the low-threshold inputs. Inhibitory interneurons that accounted for the occurrence of postsynaptic inhibition in the spinal cord region made up stage four, while the fifth stage consisted of a descending modulatory system to explain the inhibitory influence from the brainstem (Wall, 1967). The last or final stage involves a loop system with the assumption that ascending signals to the brain engage and influence descending modulatory systems.

The Neuromatrix Theory of Pain

The Neuromatrix Theory of Pain also suggests that pain is a multifaceted experience resulting from a "characteristic neurosignature of a widely distributed brain neural network, called the body-self neuromatrix" (Melzack, 2001, 2005; Gatchel et al., pg 584, 2007). Recognition of pain being the consequence of the output of the widely distributed brain neural network (cognitive processes, discriminative sensory processes, and motivation/affect components), rather than a direct sensory input response following injury or inflammation to the tissue, is a critical distinction made by this theory (Melzack, 2001). It proposes that the output patterns "pull on" numerous response systems, including perceptual, behavioral, and homeostatic systems in response to both stress and injury (Gatchel et al., 2007). According to the body-self neuromatrix, no actual sensory input is necessary to produce experiences of the body. This helps the theory explain occurrences of phantom limb pain, such as those in paraplegics who continue to experience sensations and pain below the level of the spinal section (Gatchel et al., 2007).

Etiology of Temporomandibular Disorder

Temporomandibular Disorder (TMD) is defined as a "heterogeneous collection of disorders that are marked by orofacial pain, masticatory dysfunction, or both," where the primary symptoms include periauricular pain, tenderness in the muscles of mastication and the temporomandibular joint, limited mandibular functioning, and joint sounds (i.e. clicking, popping, or grinding) (Edwards, Gatchel, Adams, & Stowell, 2006; Gardea et al., 2001). The Temporomandibular Joint (TMJ) is the hinge joint connecting the mandible, or lower jaw, to the temporal bone of the skull. The range of motion of the

joint allows the jaw to open and close smoothly. The original root or cause of TMD is unknown, but there are several theories, such as grinding teeth, injury to the jaw, osteoarthritis, and even stress. The American Academy of Orafacial Pain estimates that roughly 75% of the U.S. population experiences symptoms related to TMD during their lifetime, and 5-10% of those individuals will require professional treatment (American Academy of Orofacial Pain; Gatchel et al., 2006). Studies using clinical signs as diagnostic criteria report a prevalence rate of 50-60%. However, when studies use objectively measured symptoms, the rates drop to 16-59% (Glaros & Glass, 1993). Researchers have estimated that nearly 5.3 million people in the United States will seek treatment, resulting in direct costs of nearly $2 billion (Gatchel et al., 2006). There appears to be a greater prevalence reported in females (with the female-to-male ratio ranging anywhere from 3:1 to 6:1), as well as higher incidence rates in individuals under the age of 45 (Glaros & Glass, 1993). Thus TMD is not only a widespread disorder, but also a costly one. Al-Jundi and collegues estimated that the need for treatment is substantial, and they reiterate the importance of TMD as a condition through a meta-analysis of 17 studies, where the results indicated an estimated need for TMD treatment to be between 1.5-30% (Al-Jundi, John, Setz, Szentpetery, & Kuss, 2008).

Previous research has focused on the identification of underlying etiologic factors and the differentiation between acute and chronic pain of TMD. Acute pain of TMD is typically associated with a well-defined cause, a characteristic course, and responds well to most treatments within 6 months. Chronic pain of TMD, which can result from the insufficient management of acute pain, is pain lasting longer than 6 months (Gatchel, Garofalo, Ellis,

& Holt, 1996). This led to increased research focused on examining the relationship between pain and various forms of psychopathology due to the number of comorbidities. Rates of psychosocial disorders in patients with both acute and chronic TMD far exceeded the base rates found in epidemiologic studies for the general population (Kinney, Gatchel, Ellis, & Holt, 1992; Gatchel et al., 1996). Acute pain is often associated with anxiety, while chronic pain is often accompanied by depression and increased risk of addictive/appetitive disease such as substance abuse and eating disorders. Gatchel et al. (1996) found that 80% of patients with acute TMD, in fact, had at least one Axis I disorder prior to the onset of their TMD symptoms, while 86% of chronic TMD patients met criteria for at least one Axis I disorder prior to onset according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-III, 1996). Patients with chronic TMD have also displayed higher rates of Axis II disorders than acute TMD patients, with the exception of the following: schizoid, dependent, avoidant, narcissistic and antisocial personality disorders (Gatchel et al., 1996). It should be noted that chronic pain itself might also be interpreted as the expression of a psychosocial disorder that existed before the pain syndrome (Gatchel et al., 1996). Relatively new research has attempted to delineate the physical characteristics of the disorder from that of assessing pain-related disability and the psychosocial status of patients (Dworkin & LeResche, 1992).

Treatment of TMD Related Pain

Pain is the prominent symptom of TMD and the cardinal reason that many patients begin to seek treatment. Pain relief is the major criterion by which patients and clinicians gauge

the success of treatment (Dworkin, Turner, Mancl, Wilson, Massoth, Huggins, LeResche, & Truelove, 2002). In the past, the traditional model embraced a dualistic point of view where the body and mind functioned separately and independently. The most common treatments often include reversible, noninvasive physical medicine methods, such as non-repositioning splints and non-prescription analgesics (Dworkin et al., 2002), physical therapy, and nocturnal alarms (Gardea, Gatchel, & Mishra, 2001). More invasive approaches that are not as easily reversed include TMJ surgery, arthroscopic methods, occlusal equilibration, mandibular repositioning appliances, and craniosacral manipulations (Dworkin et al., 2002). These early models, though inadequate, contributed to the increased recognition that psychosocial factors (such as emotions and stress) impact the reporting of symptoms and response to treatment interventions (Gatchel, Peng, Peters, Fuchs, & Turk, 2007). Many clinical researchers therefore advocate and support an interdisciplinary treatment program for TMD.

The biopsychosocial model has proved to be the most widely accepted and most heuristic approach to both understanding and treating conditions of pain, especially chronic pain, including TMD (Gatchel, Garofalo, et al, 1996; Glaros and Glass, 1993; Parker et al, 1993; Turk, 1997; Gatchel, Peng, et al, 2007). Cognitive Behavioral Therapy (CBT) has grown in popularity, and became one adjunctive treatment modality of choice because of its efficacy and effectiveness. Support for this was examined in both a 51 study meta-analysis by Fernandez and Turk (1989), and in a study by Mishra and colleagues in which long-term efficacy of biofeedback, Cognitive Behavior Skills Training, and a biofeedback and Cognitive Behavior Skills Training combined group were assessed (Mishra, Gatchel,

& Gardea, 2000). During a follow-up study of the same group of participants, participants who underwent the combined treatment showed significant improvement over the course of one-year than the other groups. Planned pairwise contrasts found significant differences between the combined versus no-treatment group (p=0.01), and the Cognitive Behavior Skills Training versus no treatment group (p=0.02) (Gardea, Gatchel, and Mishra, 2001).

Outcome Measures of TMD Pain Treatment

Pain is often measured through clinical studies of responsiveness over time, such as a response to a therapy protocol or a surgical procedure. Beaton, Bombardier, and colleagues (2001) explain that evaluations of responsiveness are designed to assess how a target of interest (such as disability, pain, joint count) as changed over time. Similar to pain in other conditions (e.g., spinal pain disorders), TMD pain has three different types of measures: self-report, overt behavior (maintaining responsibilities at work, social relationships with both family and friends), and physical indices (measures of physical and functional performance); (Gatchel, Mayer, Choi, & Worzer, 2010). Self report measures are typically used in healthcare for a number of reasons. First, the patient may be the only source of information such as in the assessment of physiological responses like pain and nausea. Therefore, the information may only be obtained by directly asking them. Second, clinical measurements may not always match the patient's evaluation.

The concept of minimal clinically important difference (MCID) can be defined as the smallest difference in a specific domain of interest that patients determine to be

significant and beneficial (Jaeschke, Singer, & Guyatt, 1989; Copay, Subach, Glassman, Polly, & Schuler, 2007; Gatchel & Mayer, 2010) . According to Jaeschke et al. (1989), this difference, in the absence of negative or harmful side effects and excessive costs, can lead to changes in how the patient manages his/her pain. In other words, the concept helps distinguish concrete values to determine the importance of an observed effect. There have been a number of recent attempts to determine MCID values in an effort to better distinguish between successful and unsuccessful spinal surgeries (Deviren, Geula, Demir-Deviren, Berven, Metz, & Hu, 2007; Copay, Glassman, Subach, Berven, Schuler, & Carreon, 2008; Gatchel & Mayer, 2010). Copay and others conducted their study using the Oswestry Disability Index (ODI), the physical component summary (PCS) of the Short Form of the Medical Outcomes Study (SF-36), and pain scales to determine the MCID value for a number surgerical treatments performed by the Lumbar Spine Study Group (2008). Jaeschke et al. further explain that clinicians develop "an intuitive sense" of MCID through repeated use. When clinicians become familiar with tests, they have become capable of determining that, for example, "a 10% drop in diastolic pressure in a hypertensive patient is clinically important; that a 10% improvement in spirometry in a patient with chronic airflow limitation is of borderline significance; and a 10% drop in platelet count is clinically trivial (p.408, 1989)."

According to Gatchel and Mayer (2010), though statistical significance can be found in studies with large sample sizes, the outcome changes experienced by individuals may be insignificant or irrelevant to both clinicians and patients. Copay and others (2007) also reference the effects of large sample sizes on determining statistical significance by

stating that most clinical trials use large patient samples such that small treatment effects are considered statistically significant. The clinical significance influences decisions regarding the treatment and management of a patient's condition. It is impossible for one to conclude the clinical significance based solely on statistical significance (Gatchel & Mayer, 2010). Minimal clinically important change and minimal important change (MIC) are other terms often used interchangeably with MCID. MCID was used in the current study. To determine the minimal detectable change (MDC), or minimal detectable change beyond the simple possibility of measurement error, various calculations have been used. The two most referenced methods are distribution-based and anchor-based approaches.

Distribution-based and Anchor-based Approaches of MCID

Distribution-based Approach

Distribution based approaches assess distribution-based characteristics of the sample and then classify the change observed according to a particular variation to find a standardized metric (De Vet et al., 2007). Distribution-based approaches typically use a standard error of measurement. Standard errors of measurement focus on detecting changes that are found to be statistically different from zero, most often at the confidence interval (CI) of 95%. The formula used to calculate the MCID at the 95% CI=1.96 x $\sqrt{2}$ x SEM (Beaten, Bombardier, Katz, Wright, Wells, Boers, Strand, & Shea, 2001; Gatchel & Mayer, 2010; Gatchel et al., 2010). The limitations of calculating distribution-based MCID values reside in the assumption that the degree of change will hold consistent across numerous range of scores (Gatchel et al., 2010)

Anchor-based Approach

The anchor-based approach requires the use of an independent, objective criterion to be used to distinguish a threshold value for the MCID. This is measured by either *mean change* or using a *Receiver Operating Curve* (ROC). The *Mean Change* is the change score of patients who improved and therefore sets its cutoffs as patients who were determined to have a small, moderate, or large change (Turner, Schunemann, Griffith, Beaton, Griffiths, Critch, Guyatt, 2010). The Receiver Operating Curve uses different cutoffs for dichotomization of the cohort into those patients who improved and those who did not (Turner et al., 2010). In order to calculate that threshold, each patient's pre- and post- scores on a chewing performance task were used as the objective, non self-report external criterion. Previous attempts to establish MCID values have been challenged with measuring the same construct, using measures that are independent and use external criterion that are objective (non-self report). Using self-reports as independent measures results in transgressions of basic psychometric assumptions. Using two self-report measures only demonstrates a concurrent validity between the two, which does not define success or failure (Gatchel et al., 2010). Anchor-based approaches have been used to identify cut-off points to distinguish improved and non-improved patients (Gatchel and Mayer, 2010). The goal of the present study was to attempt to calculate distribution-based MCID values and compare them to anchor-based MCID values for TMD pain using chewing performance as the independent, external criteria.

In the past, there have been significant debates regarding what is the most appropriate method, statistically, to measure clinical responsiveness. In a study by Gatchel and others

(2010), distribution-based MCID values were nearly identical to the anchor-based approach. Using self report measures (the SF-36 Physical Component Scale, or PCS, and the Pain Intensity, or PI) that were obtained pre- and post-treatment and then compared to an external physical measure (in their study, the Progressive Isoinertial Lifting Evaluation, or PILE test), the anchor-based MCID value was found to be 13.00, while the distribution-based MCID (MDC) value was 13.77 for the Oswestry Disability Index (ODI), 4.95 and 4.35 for the SF-36, and 1.5 and 1.1 for the Pain Intensity, respectively.

Rationale for Current Study

Previous research on TMD has focused primarily on recognizing and identifying the underlying etiologic factors that distinguish acute and chronic TMD, the occurrence of psychosocial disorders in patients with either acute or chronic TMD, and the effectiveness of numerous treatment procedures to alleviate TMD-related pain. Unfortunately, the clinical treatment and management of pain is often limited to the patient's self-report of symptom relief. The purpose of the current study was to better understand and objectively quantify meaningful symptom relief by determining the *minimal clinically important difference* (MCID) for TMD. This information will play an important role in determining treatment effectiveness for not only TMD, but for other pain conditions as well.

Scope of Current Study

It was anticipated that the scores on the distribution-based and anchor-based approaches for the following analyses would be consistent and not statistically significantly different:

Characteristic Pain Inventory (CPI) and Chewing Performance; Graded Chronic Pain Scale (GCPS) and Chewing Performance; SF-36 and Chewing Performance. Should the results disagree, then the one with the strongest relationship to the measure of Chewing Performance would be the best one to use. Although, distribution-based methods tend to fail to demonstrate clinical importance and anchor-based approaches are only as good as the criteria they are based on, the resulting information will provide significant step forward in better understanding clinically significant changes in acute TMD pain.

CHAPTER THREE
Methodology

Participants

The current study consisted of a consecutive cohort of 101 patients with acute TMD. Participants were referred to UT Southwestern Medical Center in Dallas, Texas through the community dental clinics of Drs. Riggs, Curtis, and Neely, which are located in the Dallas/Ft. Worth area. Dr. Richard Riggs is an active dentist in the city of Richardson, Texas whose scope of practice focuses on the evaluation and management of orofacial pain disorders like TMD, headaches, neuropathic pain, sleep disorders, musculoskeletal, vascular and intra-oral pain disorders of both hard and soft tissues. Dr. Riggs is Board Certified in Orofacial Pain and is a diplomat of the American Board of Orofacial Pain. Dr. David Curtis operates a practice in Colleyville, Texas and specializes in the multidisciplinary treatment and management of TMD. Dr. Curtis has been in practice for over 20 years and is a diplomate of both the American Board of Craniofacial Pain and the American Academy of Pain Management. Dr. Michael Neely holds a Fellowship with the International College of Cranio-Mandibular Orthopedics and currently practices dentistry in the Highland Park area of Texas. He specializes in migraine headaches of a dental origin. In addition to those sites, the Baylor College of Dentistry of the Texas A&M University System Health Science Center and Texas Women's University Dental Hygiene Clinic, supervised by Ms. Trisha Nunn, were also participating sites in the ongoing study of TMD. Advertisements were also placed in local newspapers and flyers. Associate clinical researchers were Master's level and licensed in the fields of Social Work and/or Counseling. The clinicians performing the examinations were trained by

both a clinical psychologist and a licensed counselor experienced with the Research Diagnostic Criteria for TMD (RDC/TMD). They observed each rater reliably conduct a physical exam on a non-subject volunteer prior to the beginning of the study to ensure correct evaluation. The clinicians were given a detailed training video in addition to their supervised training. "Re-calibration" sessions were regularly held to make sure there was continued inter-rater reliability, as well as quality control through the random selection and re-evaluation of selected cases. A licensed psychologist also trained the research clinicians in biobehavioral and self-care treatment protocols. In an effort to ensure quality and protocol adherence, the clinicians were provided weekly supervision by a licensed psychologist through the review of session recordings.

The initial inclusion criteria followed the RDC/TMD (Dworkin, LeResche, & Derouen, 1992). Both men and women were considered eligible if they were over 18 years of age and met the initial criteria of RDC/TMD. These initial criteria involved: 1) participant reports or presents with at least one of the three cardinal signs of TMD: jaw pain, limited range of motion in the jaw, or noise in the temporomandibular joint; 2) feelings of stiffness, tightness, or fatigue in the jaw; and 3) have had these symptoms for less than 6 months at the time of entry into the study. Participants were excluded if they have significant comorbid physical conditions, if they have had cancer, low-back pain, or fibromyalgia that may exacerbate the participant's pain symptoms or have had a history of jaw pain before the most recent episode. Individuals who did not meet the RDC/TMD diagnostic criteria were also excluded. Dentists and research associates/clinicians evaluated each participant to determine eligibility. Those who were considered high-risk

for developing chronic TMD were identified through an algorithm developed in previous studies (Epker, Gatchel, & Ellis, 1999; Wright et al., 2004).

Procedure

Researchers explained the purpose and procedure of the study, and then provided the participant with a packet including the consent form, HIPAA form, patient information form, and payment voucher for $20 dollars. Participants then filled out a general information form and the history form before scheduling a series of pre-intervention biopsychosocial (BPS) evaluations. The pre-intervention biopsychosocial evaluations were completed preferably within one week, and they included physical, psychosocial, and quantitative functional measures. Trained clinicians administered the RDC/TMD, which consisted of the "at risk" algorithm. The algorithm used to assess risk is composed of Question 3 from the RDC History Questionnaire, the Characteristic Pain Intensity (CPI), and the assessment of oral facial pain from muscle palpation on Items 1, 8, and 10 of the Oral Facial exam. The Functional Evaluation of Chewing Performance was administered as a physical measure, while the psychosocial measures of this study included: the Graded Chronic Pain Scale (GCPS); the CPI; the Perceived Stress Scale (PSS); Beck Depression Inventory-II (BDI-II); Health Care Utilization (which gathers information regarding type of treatment received for both jaw and non-jaw related pain); Medication Use Information; SF-36 Health Survey; Symptom Checklist; Headache Questionnaire, Orthodontic History Questionnaire; and Treatment Cost data. Of specific interest to this current study were the CPI, GCPS, SF-36, and Chewing Performance.

Acute participants were assigned to a treatment group based on the results of their initial pre-intervention evaluations and screening. The groups were classified as high risk, biobehavioral treatment; high-risk, self-care treatment; or low-risk, non-intervention. All three groups were continuously matched through randomization for age, gender, race, and time-since-original-onset of TMD. Dentists collaborating on this study were kept blind to the group assignments.

Those participants assigned to the high-risk, biobehavioral group were provided six intervention sessions, which consisted of individual meetings with a trained clinician who adhered to a standardized treatment protocol. Session 1 focused on the clinician providing the participant with an overview and rationale for biobehavioral treatment. At the conclusion of the first session, the participant was educated on diaphragmatic breathing techniques for both the purpose of relaxation and pain management. Session 2 involved more relaxation training, specifically progressive muscle relaxation. In Session 3, the participant was introduced to the idea of using relaxation skills in everyday situations. Biofeedback was also introduced to reinforce the acquisition of skills. During Session 4, biofeedback was integrated and the clinician assisted the participant in learning distraction methods and activity scheduling. The participant received an explanation of the rationale for cognitive interventions in Session 5. Participants were then taught how to identify destructive, automatic thoughts and correct them during the fifth session. In the final session, Session 6, the clinician reviewed with the participant what skills he or she has learned in the past five meetings. Discussion on how to maintain gains and a plan for coping with reoccurrences or pain flares in the future also took place.

Between each session, participants were required to complete assigned homework and handouts. Participants received a comprehensive workbook that included an overview of what was taught in each session and daily logs that provided space for the participant to record their pain, stress level, frequency of stress, pain triggers, amount of sleep, and coping mechanisms. The sessions were conducted within six weeks, preferably.

Those participants that were assigned to the high-risk, self care group were also assigned six intervention sessions, the difference being that these participants did not receive any training on coping techniques like progressive muscle relaxation or cognitive interventions. Rather, participants in this group received readings over the course of their treatment that were geared toward educating the patient on TMD, self-care activities, medications, nutrition, treatment options, and patient-physician communication. Clinicians then reviewed the major points of the readings in each session and requested feedback on the participant's reactions. Participants were required to fill out a daily log recording their pain/discomfort, stress, and tension.

The low-risk, non-intervention group received the standard-of-care that would normally have been offered to them and that they accepted. Any provider with whom the participant consulted with would offer this care. The participant was required to document/log all care pertaining to their jaw pain.

At both post-treatment and the one-year mark, it was requested that all participants participate in a post-intervention BPS evaluation that was identical to the one conducted at the beginning of the study or the pre-intervention BPS evaluation.

The current study was a renewal of an ongoing TMD project with a number of the core co-investigators having been involved with the project for the past 10 years. The study used the same protocol used in Wright et al. (2004) and Stowell, Gatchel, and Wildenstein (2007). The National Institute of Dental and Craniofacial Research through The University of Texas at Arlington and the Baylor College of Dentistry of the Texas A&M University System Health Science Center funded the study. The current study had the approval of each institution's Institutional Review Boards (IRBS) that also oversaw the project, including the required training of all research personnel regarding the ethical treatment of participants.

The external criterion was established by the assessment of chewing performance. The distribution-based MCID values were calculated as the smallest change that are considered above the error of measurement at the 95% CI at CI=1.96 x $\sqrt{2}$ x SEM. The anchor-based MCID value for differentiating improvement or not for the patient was based on a Receiver Operating Curve (ROC) analysis.

Measures

Patient Information Form

The Patient Information Form gathered data such as demographics, education, contact information, employment status, workers compensation, personal injury litigation, history of jaw pain (including onset, date of treatment, type of treatment, etc), and chronic health conditions.

RDC/TMD History Questionnaire and Evaluation

The major outcome measures like pain, disability, and limitations in mandibular function were derived from scores on a History Questionnaire and TMD Examination. The examination form was based on Laskin's criteria of pain and tenderness in the mastication muscles and the TMJ with limited mandibular movement (Laskin, 1969). The Examination Form documented numerous items including: the opening pattern, presence of joint sounds (clicking or popping) at opening or closing, additional measurements of clicks, vertical range of motion, and distance of protrusions (Gardea, Gatchel, & Mishra, 2001).

Both the TMD Examination Form and the History Questionnaire used the RDC/TMD (Dworkin and LeResche, 1992, Schiffman et al., 2010). The RDC/TMD is a multiaxial system. Axis I assesses physiological diagnoses across three groups: 1) Group I assesses the presence or absence of muscle disorders such as myofascial pain, myofascial pain with limited opening, or no diagnosis; 2) Group II assesses displacements of discs within the joint which can include disc displacement with reduction, without reduction limited

opening, without reduction or limited opening, and no diagnosis; 3) Group III assesses miscellaneous joint conditions like arthralgia, osteoarthritis of the TMJ, osteoarthrosis of the TMJ, or no diagnosis. The RDC/TMD also provided a rule out against systematic arthritic disease and acute traumatic injury. Axis II assessed psychosocial status and pain-related disability. The combination of assessing both physical and psychosocial components of TMD is consistent with the biopsychosocial health model (Schiffman et al., 2010). The History Questionnaire assessed psychosocial aspects of TMD which included pain intensity, disability, depression, and non-specific physical symptoms and limitations to mandibular functioning.

The Characteristic Pain Inventory (CPI)

The CPI (Dworkin & LeResche, 1992) is a self-report measure that quantifies aspects of pain over the past three months. The RDC/TMD Examination questions 7, 8, 9 composed the Characteristic Pain Inventory. Pain severity was measured with a range from 0-100 (100 being the most intense pain). The score was then calculated by taking the mean of current pain, worst pain, and average pain and multiplying them by 10.

Graded Chronic Pain Scale (GCPS)

The Graded Chronic Pain Scale is derived from Axis II of the RDC/TMD. Pain Intensity, interferences or changes in activities (work related, family, or leisure), and disability days due to pain were measured on the Graded Chronic Pain Scale (GCPS) which was derived from questions 10, 11, 12, and 13 on the RDC Examination. Scores ranged from 0 (no change) to 100 (extreme change). Scoring rules categorize pain severity in the following

categories: Grade I, low intensity with little pain-related impediment; Grade II, high intensity pain associated with little pain-related impediment; Grade III, high pain intensity and pain related disability; and Grade IV, with severely limiting pain and high disability.

The SF-36

The Short Form-36 health survey (SF-36) was designed by the Medical Outcomes Study and is a multi-purpose health survey that is used to assess quality of life in relation to health status as viewed by the health care recipient (Stewart & Ware, 1992; McHorney, Ware, & Raczek, 1993). The measure was constructed as a representation of both multidimensional health concepts and the full range of health states (McHorney, Ware, & Raczek, 1993). The SF-36 results in an 8-scale profile of functional health and well-being in addition to psychometrically-based physical and mental health summary measures, Mental Component Scale (MCS) and the Physical Component Scale (PCS). The MCS and PCS will be the scales used in this study. Normative data were based on various medical populations making the measure useful for comparative purposes. Lower scores indicate a greater degree of disability. Scoring ranges from 0 to 100, with a mean of 50 and a standard deviation of 10. The SF-36 is considered to have high test-retest reliability coefficients with a Chronbach's alpha exceeding .70, usually above .80 (Ware, Snow, Kosinski, & Gandek, 1993).

Chewing Performance Scale

Chewing performance is the most commonly used measure to assess masticatory performance (Bates, Stafford, & Harrison, 1976; Buschang, 2006). Chewing performance was used as the external measure of physical function and was composed of an evaluation of median particle size, broadness of distribution, and the participant's self-rating of pain. Participants were asked to chew a standardized, tasteless tablet (5mm thick and 20mm in diameter) of new, softer CutterSil® for a total of 20 chews. A total of twenty chews was selected because the majority of studies have estimated masticatory performance using a total of 20 chewing cycles. (Shiere & Manly, 1952; Akeel, Nilner, & Nilner, 1992; Henrikson, Ekberg, & Nilner, 1998; Durante Gayião, Raymundo, & Sobrinho, 2001; English, Buschang, & Throckmorton, 2002; Owens, Buschang, Throckmorton, Palmer, & English, 2002; Buschang, 2006). The new CutterSil is a condensation silicon impression material that is formed using a Plexiglass template. After hardening for an hour, the tablets are cut into quarters. Five portions containing three quarter-tablets each were then packaged for each participant (Buschang, Throckmorton, Travers, & Johnson, 1997). The time for each of the five trials are recorded. Once the chewed samples were obtained from the participants, they were air dried in filter papers over a stainless steel colander. The samples were separated using a series of sieves with mesh sizes of 5.6mm, 4.0mm, 2.8mm, 2.0mm, .85mm, .425mm, and .25mm, which were stacked on a mechanical stacker and vibrated for two minutes. Once separated, the samples were weighed to the nearest 0.01gm and the cumulative weight percentages (defined by the amount of the sample that can pass through each successive sieve) were calculated for each sample. This allows for the determination of median particle size and broadness of particle

distribution using Rosin-Rammler equation (Olthoff, van der Bilt, Bosman, & Kleizen, 1984). Pain was rated on a scale from 1 (no pain) to 10 (pain as bad as it could be). In addition, the patient was asked to state which side of their mouth they chewed on and which felt most comfortable while they were chewing. Then the assessment was performed a second time, the only difference being that the participant chewed on the opposite side of the mouth then they did in the first round. The change scores were calculated as the difference between the initial and the follow-up scores to determine the patient's functional impairment, followed by classifying that data as "unchanged" (with post treatment scores falling outside of the normative range) or "improved" (with post treatment scores falling inside that of the normative range). While participant scores may have improved from the pre-treatment evaluation to post-evaluation, for the premise of this study, only those who improved to within normal limits were classified as "improved" using the Receiver Operating Curve. The normative range for particle size (mm) was 2.2 ± 1.0 for Adult Men, 3.1 ± 0.6 for Adult Women while the normative range used for broadness of distribution was 2.6 ± 2.4 for Adult Men and 4.1 ± 0.7 for Adult Women (Julien, Buschang, Throckmorton, & Dechow, 1996).

A second approach included using .5 SD which corresponded to the MCID across several studies according to Norman et al. (2003) and was equivalent to 1 SEM for a reliability of .75 (Copay et al, 2007). A review conducted by Miller (1965) found the limit of human discrimination to be equivalent to an effect size between 0.36 and 0.63. Previous studies have classified data as unchanged (more than 1 standard deviation below the mean), slightly improved (a change score within 1 standard deviation of the mean), and

substantially improved (more than 1 standard deviation above the mean); however, one criticism of using 1 standard deviation has been the clinical meaning of such criteria.

Statistical Analysis

The change scores were calculated for each self-report measure (the CPI, GCPS, and the SF-36) based on the same criteria as chewing performance as unchanged, slightly improved, and substantially improved. Then, the change scores were classified dichotomously to conduct ROC analyses as "unchanged/slightly improved" or "unchanged/improved."

Distribution Based: Minimum Detectable Change (MDC)

MDC values were defined as values of change that exceed the measurement error. It is calculated as $1.96 \times \sqrt{2} \times SEM$ at the 95% confidence interval ("SEM" represents Standard Error of Measurement). *SEM* is determined by $\times \sqrt{1-r}$, where "*SD" is the* standard deviation of the initial score and "r" represents the test-retest reliability. The reliability coefficient used for the SF-36 was .8 (Ware, et al., 1993), and coefficients for the CPI and the GCPS were considered to be .95 according to Dworkin and LeResche's RDC/TMD (1992).

Receiver-Operating Curve (ROC) Analysis

The ROC curve provides MCID scores on self-report measures. Any differences in a score greater than the minimal change detected were considered as substantially clinically beneficial. ROC curves are limited to a two-class classification; "unchanged" or

"improved." The area under the ROC curve provides the probability of correctly discriminating between improved and non-improved patients, ranging from .5 to 1, with .5 representing the ability to discriminate by chance and 1, the ability to perfectly classify all the patients (Gatchel & Mayer, 2010).

CHAPTER FOUR
Results

Of 318 participants, data for the objective health measure (chewing performance) were available for 101 participants and 98 were available on the self-report measures (PCS, MCS, CPI, and GCPS) at both pre- and post-treatment time points. Due to the small number of participants, the results should therefore be interpreted with some caution.

The changes between pre-treatment and post-treatment were first analyzed using the distribution-based approach for the PCS, MCS, CPI, and GCPS. The anchor-based approach was then applied to all the participants using the normal range anchor and particle size as the functional measure to view changes for the PCS, MCS, CPI, and GCPS. Still using the normal range as the anchor, but using broadness of distribution as the functional measure next, changes were then assessed for the same measures. The anchor-based approach was conducted a third time for all participants using the .5 SD cutoff instead of the normal range to further review meaningful changes on the measures used. Similar to before, with the exception of using the .5 SD cutoff, the data were first analyzed using particle size as the functional measure and then again using the broadness of distribution.

To further understand the meaningful change scores calculated on the PCS, MCS, CPI, and GCPS, the participants were then separated out by intervention group: either High Risk/Biobehavioral Group or High Risk/Self-Care Group. Starting with the Biobehavioral Group, similar to the pattern used to analyze the data from all the participants, the normal

range was used first as the anchor with particle size as the functional measure and then again with broadness of distribution as the functional measure. The Biobehavioral Group was then reviewed using the .5 SD cutoff first with particle size and then with broadness of distribution. The High Risk-Self Care group followed with the same sequence of analyses.

Table 1 shows the descriptive analysis for all four self-report measures for all participants. In an attempt to further review the MCID value calculated for the overall sample, the sample was separated into the assigned treatments groups: High Risk/Biobehavioral Group or High Risk/Self-Care Group. Table 2 displays the statistics for the High Risk/Biobehavioral Group while Table 3 displays the statistics for the 25 members of the High Risk/Self-Care Group.

Distribution-based Analyses (MDC):

All Participants

Table 4 represents the MDC values for all participants calculated at the 95% confidence interval using the formula 1.96 x $\sqrt{2}$ x SEM. The minimal detectable changes were: 1.786 for the PCS; 2.529 for the MCS; 5.705 for the CPI; and 5.656 for the GCPS. The distribution-based approach therefore identified these values as the minimum detectable change for participants with TMD. The MDC values were similar for the PCS and MCS when using an anchor-based analysis, however, the MDC values for the CPI and GCPS were significantly lower than the MCID values calculated by the anchor-based analysis.

Intervention: High Risk/Biobehavioral Group

Table 5 represents the MDC values calculated at the 95% confidence interval using the formula 1.96 x $\sqrt{2}$ x SEM for the High Risk/Biobehavioral Group. The minimal detectable changes were: 3.058 for the PCS; 5.038 for the MCS; 10.107 for the CPI; and 12.008 for the GCPS. As seen when the data were analyzed for all the participants, the MDC values were similar for the PCS and MCS when using an anchor-based analysis, however, the MDC values for the CPI and GCPS were lower than the MCID values calculated by the anchor-based analysis.

Intervention: High Risk/Self-Care Group

Table 6 represents the MDC values calculated at the 95% confidence interval for the High Risk/Self-Care Group. The minimal detectable changes were: 4.609 for the PCS; 3.468 for the MCS; 12.768 for the CPI; and 10.411 for the GCPS. However, the MDC value for the PCS was slightly above the MCID values. The range was larger for the MCS than what was reported previously with overall sample and the High Risk/Biobehavioral Group. The MDC values for the CPI and GCPS were, again, lower than the MCID values calculated by the anchor-based analysis.

Anchor-based Analyses (MCID):

The MCID values were assessed using particle size and broadness of distribution according to two separate cutoff measures: first using the normative range as defined by Julien and colleagues (1996); and using .5 SD according to a review by Copay and colleagues (2007). The asymptotic values address the significance level and should be

less than .05. However, due to the limitations of the current study (such as sample size and recruitment time), asymptotic values corresponding to the 90% confidence interval at .1 were also considered. The area under the curve addresses how well the measure fits the model and are classified: .50-.60 as fail; .60-.70 as poor; .70-.80 as fair; .80-.90 as good, and .90-1.00 as excellent. The values of the "area under the curve" varied and should be interpreted in conjunction with the asymptotic values. The variability in areas could be due to the small sample size, as well as being suggestive of the limited discriminative ability on self-report measures. The MCID values varied slightly depending on measure (particle size vs. broadness of distribution), and the cutoff approach (normal range versus the .5 SD). With the exception of the GCPS, small effect sizes were calculated with a Cohen's d value of .192 for the PCS, -.211 for the MCS, .153 for the CPI, and .575 for the GCPS. The Cohen's d value for particle size was .371 while the Cohen's d value for broadness of distribution was .279.

Using the Normal Ranges

All Participants

Table 7 shows the MCID values for the normal range for particle size and the asymptotic values. The areas under the ROC were as follows: PCS=.507; MCS=.475; CPI=.460; and GCPS=.494. According to ROC analyses sensitivity of .8, which represents the generally accepted and preferred strength of sensitivity. A change of 3.460 (Sensitivity= .821, 1-Specificity=.794) was found for the PCS. A change of 5.665 (Sensitivity=.821, 1-Specificity=.926) was found for the MCS. A change of 33.333 (Sensitivity=.821. 1-Specificity=.868) was found on the CPI. The GCPS resulted in a change score of 28.333

(Sensitivity=.821, 1-Specificity=.838). The PCS and MCS presented much lower change scores then the CPI and GCPS, however significance values varied.

Using the normal range for broadness of distribution, as illustrated in Table 7 with the asymptotic values, the areas under the ROC were as follows: PCS=.569; MCS=.556; CPI=.452; and GCPS=.569. Again, using approximately .8 sensitivity/1-specificity to determine the minimum change because it represents the preferred strength of sensitivity, a change score of 2.745 (Sensitivity=.821, 1-Specificity=.721) was found for the PCS. A change of 2.345 (Sensitivity=.821, 1-Specificity=.838) was found for the MCS. A change of 43.333 (Sensitivity=.821, 1-Specificity=.941) was found for the CPI. And a change of 21.667 (Sensitivity=.821, 1-Specificity=.735) was found for the GCPS. For this group, the PCS appears to be the relatively stronger measure when calculated with broadness of distribution due to its asymptotic value of .293 and corresponding area under the curve at .569.

Intervention: High Risk/Biobehavioral Group

The High Risk/Biobehavioral Treatment Group consisted of 28 members and the MCID values using the normal range are illustrated in Table 8. Using the normative range for particle size, the areas under the ROC were: PCS=.569; MCS=.564; CPI=.300; and GCPS=.413 as demonstrated in Table 8. A change score of 4.2100 (Sensitivity=.846, 1-Specificity.933) was reported for the PCS. A change score of 5.665 (range: 5.665-8.330) (Sensitivity=.846, 1-Specificity=.800) was found for the MCS. A change score of 60.000

(Sensitivity=.846, 1-Specificity=1.000) was reported for the CPI, while a change score of 63.333(Sensitivity=.846, 1-Specificity=1.000) was found on the GCPS.

Using the normative range for particle distribution, also seen in Table 8, the areas under the ROC were: PCS=.701; MCS=.544; CPI=.534; and GCPS=.442. A change score of 0.170 (Sensitivity=.857, 1-Specificity=.524) was calculated for the PCS while a change of 13.410 (Sensitivity=.857, 1-Specificity=1.00) was calculated for the MCS. Change on the CPI was calculated at 60.000 (Sensitivity=.857, 1-Specificity=.952), and a change on the GCPS was calculated at 48.333 (range: 48.333-76.667) (Sensitivity=.857, 1-Specificity=.857). As seen when evaluating all participants, the PCS is the stronger measure with an asymptotic value .118 and corresponding area under the curve of .701 when using broadness of distribution. While the asymptotic value was low for the CPI at .072, the corresponding area was also low.

Intervention: High Risk/Self-Care Group

Using the normal range for particle size for the Self Care Group resulted in areas under the ROC curve at: PCS=.262; MCS=.905; CPI=.607; GCPS=.476. The change score, as shown in Table 9, for the PCS was calculated at 4.180 (Sensitivity=1.000, 1-Specificity=.762). The ROC analyses did not provide a clear change score at the .8 sensitivity level for the MCS, CPI, or GCPS. The change score for the MCS was 10.915 (range: 10.915-10.200) (Sensitivity=.500, 1-Specificity=.095). A change of 21.667 (range: 21.667-23.333) (Sensitivity=.500, 1-Specificity=.667) was calculated for the CPI. A change score of 20.000 (range: 20.000-21.667) (Sensitivity=.500, 1-Specificity=.714)

was found on the GCPS. The Self-Care Group demonstrated greater variability within each measure as scores frequently consisted of ranges with decreased sensitivity.

The normal range for the broadness of distribution within the High Risk/Self Care Group, also shown in Table 9, resulted in areas under the ROC at: PCS=.441; MCS=.706; CPI=.554; and GCPS=.618. A change score of 1.825 (Sensitivity=.833, 1-Specificity=.706) was calculated for the PCS. A change score of 4.540 (range: 4.540– (-) 4.870) (Sensitivity=.833, 1-Specificity=.353) was calculated on the MCS, however, this result is unclear as the range crosses the zero change mark. The CPI resulted in a change score of 23.333 (range: 23.333-61.667) (Sensitivity=.833, 1-Specificity=.706). The GCPS was calculated to have change scores of 21.667 (range: 21.667-36.667) (Sensitivity=.833, 1-Specificity=.706). Again, as seen when using the normal range with particle size, there was greater variability within the results for the Self-Care group and results were more unclear, specifically for the CPI and GCPS. For those participants in the Self-Care Group, the MCS appeared to be the stronger measure with an asymptotic value of .064 and corresponding area under the curve of .905 for particle size and an asymptotic value of .141 and area of .706 when using broadness of distribution.

Using the .5 SD

All Participants

Using a .5 standard deviation from the mean for particle size, the areas under the curve were as follows: PCS=.594; MCS=.460; CPI=.476; and GCPS=.539 as shown in Table 10. Changes scores were found to be: 2.745 (Sensitivity=.800, 1-Specificity=.696) for the

PCS, 1.7500 (Sensitivity=.800, 1-Specificity=.826) for the MCS, 28.333 (Sensitivity=.800, 1-Specificity=.826) for the CPI, and 18.333 (Sensitivity=.800, 1-Specificity=.630) for the GCPS.

Table 10 also showed the results calculated using a .5 standard deviation from the mean for particle distribution. The areas under the curve were as follows: PCS=.641; MCS=.562; CPI=.432; and GCPS=.453. A change of 2.745 (Sensitivity=.805, 1-Specificity=.526) was found on the PCS. A change of 1.460 (Sensitivity=.805, 1-Specificity=.737) was found on the MCS. A change of 30.000 (Sensitivity =.805, 1-Specificity=1.00) was calculated on the CPI, while a change of 23.333 (Sensitivity=.818-.857, 1-Specificity=.684) was calculated on the GCPS. Again, the PCS is the better measure to determine clinically meaningful changes with an asymptotic value of .112 and area of .594 when using particle size and an asymptotic value of .058 and corresponding area of .641 when using broadness of distribution.

Intervention: High Risk/Biobehavioral Group

According to the ROC analysis using the .5 SD cut-off for the High Risk/Biobehavioral Group using particle size, shown in Table 11, the area under the ROC was as follows: PCS=.526; MCS=.438; CPI=.622; and GCPS=.526. A change score of 2.710 (Sensitivity=.833, 1-Specificity=.813) was found for the PCS. A change score of 8.330 (range: 8.330-11.580) (Sensitivity=.833, 1-Specificity=.875) was reported for the MCS. A change of 25.000 (Sensitivity=.833, 1-Specificity=.688) was found for the CPI, while a

change of 25.000 (range=25.000-28.333) (Sensitivity=.833, 1-Specificity=.563) was reported for the GCPS.

Again, using the .5 SD cut-off for particle distribution, the ROC analysis reported areas under that curve as PCS=.740; MCS=.479; CPI=.422; and GCPS=.438. Table 11 presents these results. A change of 2.115 (Sensitivity=.833, 1-Specificity=.500) was calculated on the PCS. A change of 5.665 (Sensitivity=.833, 1-Specificity=.750) was found on the MCS. The change score on the CPI was reported at 40.000 (Sensitivity=.833, 1-Specificity=1.000). The change score on the GCPS was reported at 43.333 (Sensitivity=.833, 1-Specificity=.750). The PCS continues to provide more clinically meaningful change scores with an asymptotic value of .131 and area of .740 when using broadness of distribution.

Intervention: High Risk/Self-Care Group

Using .5 SD for the High Risk/Self Care Group with regards to particle size, the resulting areas under the ROC were as follows: PCS=.854; MCS=.454; CPI=.523; and GCPS=.627. Table 12 reports these results. The ROC analysis resulted in change scores of .030 (Sensitivity=.846, 1-Specificity=.300) for the PCS which was extremely low. A change score of 4.680 (Sensitivity=.846, 1-Specificity=1.000) for the MCS. The CPI was calculated to have a change score of 61.667 (Sensitivity=.846, 1-Specificity=1.000). The GCPS resulted in a change score of 23.333 (Sensitivity=.769, 1-Specificity=.800), however, a change of 26.667 (Sensitivity=.923, 1-Specificity=.800) was also calculated.

The CPI and GCPS continue to report much larger changes necessary to be clinically meaningful.

According to the ROC analysis using .5 SD, as seen in Table 12, for broadness of distribution within the High Risk/Self Care Group, the areas under the curve were: PCS=.656; MCS=.767; CPI=.589; and GCPS=.494. The PCS resulted in a change score of 1.825 (Sensitivity=.833, 1-Specificity=.400) while the MCS resulted in a change score of 1.245 (Sensitivity=.833, 1-Specificity=.600). A change of 41.667 (Sensitivity=.833, 1-Specificity=1.000) was reported on the CPI. A change of 23.333 (Sensitivity=.833, 1-Specificity=.600) was calculated on the GCPS. For this group, the PCS continues to provide a more clinically meaningful result with an asymptotic value of .004 and area of .854 when using particle size and an asymptotic value of .297 and corresponding area of .656 when using broadness of distribution. The MCS also provided a clinically meaningful value for this group when using broadness of distribution with an asymptotic value of .074 and area of .767.

MDC Values Compared to the MCID Values:

All Participants

The MDC values, relative to the MCID values, were consistent with the distributions demonstrated by using either particle size or broadness of distribution, as well as for the cutoff method (either the normal range or a .5 SD cutoff). Table 13 presents this comparison. It appears that either the PCS and MCS may be more sensitive to changes in improvement or participants may have the opportunity to demonstrate greater

discriminability over 36 items as oppose to the CPI and GCPS, which consist of 3 and 4 items respectively. This could be suggested given the lower values that would indicate a clinically meaningful change on the PCS and MCS in addition to the calculated confidence intervals and areas under the ROC. In addition, the PCS and MCS values were more consistent regardless of approach (anchor-based or distribution-based) which could suggest the measure is more useful when seeking an objective value to monitor a patient's appraisal of treatment effectiveness.

Intervention: High Risk/Biobehavioral Group

Table 14 illustrates the comparison of distribution-based and anchor-based change values for the High Risk/Biobehavioral Group. Similar to the pattern seen with the data from all the participants, the distribution-based (MDC) approach was within the range reported from the anchor based MCID approach for the PCS and less than one point from the lower limit of the MCID range for the MCS. The MDC value for the CPI at 10.107 was much lower than the range of 25.000 to 60.000 seen with the anchor-based values.

Intervention: High Risk/Self-Care Group

Table 15 illustrates the comparison of MDC values to the MCID value for the High Risk/Self-Care Group. As seen in the table, the High Risk/Self-Care Group shows a larger variation in anchor-based MCID values. The MDC for the PCS was above the range for the MCID values. However, the MCID values for the PCS also showed more variability, from less than 1 to a change of 4.180. The CPI also showed more variability in the MCID values, ranging from 1.245 (.5 SD using broadness of Distribution) to

10.915 (using the normal range for particle size). The MDC value was within the range though. Similar to previous analyses, the MDC values for both the CPI and GCPS were lower than the MCID values. The CPI, however, similar to the PCS and MCS, showed a much wider range from 21.667 (normal range using particle size) to 61.667 (.5 SD using particle size). This may highlight the variability in effectiveness of self-care treatment protocols.

CHAPTER FIVE
Discussion

Determining clinically important changes continues to be difficult due to the variation in approach and will likely continue to be met with some controversy. Past approaches have been heavily criticized for violating psychometric errors when comparing two self-report measures. Distribution-based approaches frequently fail to demonstrate clinical importance and assume that the degree of change will hold consistent across scores. Anchor-based approaches are limited by how strong the criteria are on which they are based. Because a patient's perception of their health can greatly influence treatment protocols and self-evaluation, there has been increased emphasis on obtaining an objective value that will correspond to a patient's perception of improvement during treatment. The current study used both a distribution-based method and an anchor-based approach with two separate anchors (particle size and broadness of distribution) and two separate cutoff criteria to get a better understanding of the consistency of meaningful changes values for several measures and TMD. By doing so, the findings could also highlight differences resulting between measures, anchors, cutoff, and method.

This study represents the first attempt to evaluate an MCID value for TMD. Due to the low number of participants with available data, the results were preliminary. As stated before, the asymptotic values should be less than .05. However, due to the limitations of the current study, asymptotic values corresponding to the 90% confidence interval at .1 were also considered. The area under the curve addresses how well the measure fits the

model and are classified: .50-.60 as fail; .60-.70 as poor; .70-.80 as fair; .80-.90 as good, and .90-1.00 as excellent.

Clinical Implications

After reviewing the data for anchor-based MCID values of TMD, broadness of distribution appeared to provide stronger evidence of meaningful change as opposed to particle size. Better asymptotic values and corresponding areas under the curve when using broadness of distribution provided change scores that could be interpreted as more clinically meaningful. This conclusion was similar when using the normal range or the .5 SD criterions with both the High Risk/Biobehavioral Group and the High Risk/Self Care groups. This is consistent with previous research stating that particle size distribution of food chewed for a standard number of cycles is one of the most powerful masticatory performance measures used (Bates, Stafford, & Harrison, 1976; Buschang, 2006).

It may be concluded that the PCS component of the SF-36 provided stronger evidence of clinically meaningful change. The PCS resulted in more frequent asymptotic values closer to .1 (at the 90% confidence interval) and corresponding areas under the curve that better fit the model compared to the other subjective measures.

Ranges of Reported Change Scores

As predicted by the hypothesis, the PCS and MCS showed some consistency between the MDC and MCID values. The CPI and GCPS, however, showed significant variation

between MCID values and MDC values. The variation in responses could be due to the sample of participants or the limited discriminability within the measures.

All Participants

PCS

The MCID using particle size for the PCS ranged from 3.46 (normal range) to 2.745 (.5 SD). The PCS reported a consistent change of 2.745 when using particle size and the .5 SD cutoff in addition to both anchor methods with broadness of distribution. Upon review, it appeared the most consistent measure through the analyses. The MDC value was only slightly less at 1.786.

MCS

The MCS values were slightly more varied but the range remained relatively narrow. The .5 SD cutoff method for both particle size and broadness of distribution predicted the smallest meaningful changes at 1.750 and 1.460 respectively. Using the normal range for particle size reported the highest change score of 5.665. The MDC value fell in the middle at 2.529

CPI

The CPI and GCPS reported much larger change scores as necessary to be clinically meaningful. MCID values for the CPI showed a similar variation with regards to the cutoff methods. Using particle size, the range was 33.333 (normal range) to 28.333 (.5 SD). Using particle distribution, the range for the CPI was 43.333 (norm range) to 30.000

(.5 SD). The MDC value for the CPI was significantly lower at 5.705 than the values reported using an anchor-based approach. The CPI reported the largest range in scores.

GCPS

Finally, the GCPS ranged from 28.333 (normal range) to 18.333 (.5 SD) when using particle size but from 21.667 (normal range) to 23.333 (.5 SD) when using broadness of distribution. The GCPS demonstrated a range of scores but the range using an anchor-based approach remained relatively narrow. Similar to the results seen with the CPI, the MDC value was significantly lower at 5.656.

Intervention

Those participants who were assigned to either a Biobehavioral treatment or Self-Care groups demonstrated values with mixed consistency. The Self-Care Group showed the largest discrepancy of values, which could be due to the variability of the treatment effect for this group.

PCS

The MCID values for the PCS, according to treatment group and particle size, varied from 4.210 (normal range) to 2.710 (.5 SD) for the Biobehavioral Group, and from 4.180 (normal range) to .030 (.5 SD) for the Self-Care Group. While using broadness of distribution, the values ranged from .170 (normal range) to 2.115 (.5 SD) for the Biobehavioral Group, and held consistent at 1.825 for both the normal range and .5 SD approaches.

MCS

The MCS using particle size showed a variation of 5.665 (normal range) to 8.330 (.5 SD) for the Biobehavioral Group and a range of 10.915 (normal range) to 4.680 (.5 SD) for the Self Care Group. Broadness of distribution for the MCS resulted in a range from 13.410 (normal range) to 5.665 (.5 SD) for the Biobehavioral Group but a range of 4.540 (normal range) to 1.245 (.5 SD) for the Self Care Group.

CPI

The value for the CPI according to particle size ranged from 60.000 (normal range) to 25.000 (.5 SD) for the Biobehavioral Group and from 21.667 (normal range) to 61.667 (.5 SD) for the Self Care Group. The CPI values using broadness of distribution ranged from 60.000 (normal range) to 40.000 (.5 SD) for the Biobehavioral Group, and from 23.333 (normal range) to 41.667 (.5 SD) for the Self Care Group. The value of 60.000 for the normal range was consistent for both treatment groups.

GCPS

Values for the GCPS also showed some differences. The MCID values determined using particle size for the GCPS varied from 63.333 (normal range) to 25.000 (.5 SD) for the Biobehavioral Group and from 20.000 (normal range) to 23.333 (.5 SD) for the Self Care Group. The variation in broadness of distribution was more narrow; ranging from 48.333 (normal range) to 43.333 (.5 SD) for the Biobehavioral Group and from 21.667 (normal range) to 23.333 (.5 SD) for the Self Care Group.

Limitations and Directions for Future Research

The sample for this study consisted of predominantly Caucasian women. Though consistent with the sample most frequently seen by practitioners in the community, a more diverse sample may have yielded different results. Though a clinically meaningful value was calculated on all four measures, the difference between the distribution-based MDC values and the anchor-based MCID values varied significantly on the CPI and GCPS. This could indicate that participants have a more difficult time providing a cognitive appraisal of their improvement with these two measures. Again, both the PCS and MCS of the SF-36 are calculated based on 36 items. The CPI and GCPS have much fewer items which may significantly limit their utility in determining an objective, clinically meaningful change value.

Future research to determine objective and clinically meaningful changes should continue to emphasize the need for a carefully selected and objective anchor. However, researchers and clinicians should be aware of the limitations of both a MCID and MDC approach. Due to the complexity of pain, both at the nociceptive level and the cognitive level, it may be difficult to objectively define meaningful change. For this reason, developing a consensus through the use of measures of several different domains of pain (psychological, physiological, and functional) is advised in order to reach more meaning conclusions.

TABLES

Table 1. Descriptive Statistics-All Participants

	Pre-Treatment Scores			*Post-Treatment Scores*			*Change Scores*		
	Mean	**SD**	**Range**	**Mean**	**SD**	**Range**	**Mean**	**SD**	**Range**
PCS	49.122	7.933	34.500	49.931	8.173	40.280	.809	6.380	33.670
MCS	46.309	10.179	42.700	49.321	10.776	48.750	3.012	9.033	51.580
CPI	49.524	20.929	90.000	35.374	23.632	73.333	-14.150	20.375	110.000
GCPS	25.544	22.607	86.667	12.619	16.877	73.333	-12.925	20.201	123.333

Table 2. Descriptive Statistics-High Risk/Biobehavioral Group

	Pre-Treatment Scores			*Post-Treatment Scores*			*Change Scores*		
	Mean	**SD**	**Range**	**Mean**	**SD**	**Range**	**Mean**	**SD**	**Range**
PCS	48.363	8.740	34.220	50.940	8.925	40.280	2.577	5.837	22.800
MCS	45.052	11.697	42.270	47.483	12.291	45.110	2.431	9.618	39.640
CPI	64.881	10.980	40.000	45.238	21.876	73.333	-19.643	19.295	86.667
GCPS	37.143	25.055	86.667	15.357	19.842	73.333	-21.786	22.924	93.333

Table 3. Descriptive Statistics-High Risk/Self-Care Group

	Pre-Treatment Scores			*Post-Treatment Scores*			*Change Scores*		
	Mean	**SD**	**Range**	**Mean**	**SD**	**Range**	**Mean**	**SD**	**Range**
PCS	45.253	8.426	30.900	46.488	9.223	31.430	1.236	7.975	33.670
MCS	46.648	9.768	32.670	50.767	9.785	32.240	4.119	6.000	20.200
CPI	62.133	16.857	83.333	45.733	17.573	73.333	-16.400	23.032	110.000
GCPS	28.533	19.078	60.000	18.800	18.656	60.000	-9.733	18.780	83.333

Table 4: *MDC Values for All Participants*

Measure	**Std. Error**	**MDC**
PCS (SF-36)	.645	1.786
MCS (SF-36)	.912	2.529
CPI	2.058	5.705
GCPS	2.041	5.656

Table 5. *MDC VALUES for Biobehavioral Group*

Measure	Std. Error	MDC
PCS	1.103	3.058
MCS	1.818	5.038
CPI	3.646	10.107
GCPS	4.332	12.008

Table 6. *MDC VALUES for High Risk/ Self Care Group*

Measure	Std. Error	MDC
PCS	1.663	4.609
MCS	1.251	3.468
CPI	4.606	12.768
GCPS	3.756	10.411

Table 7: MCID Values using the Normal Range for All Participants

	Particle Size					*Broadness of Distribution*				
Measure	**Area Under Curve**	**Asymptotic Sig.**	**MCID**	**Sensitivity**	**1-Specificity**	**Area Under Curve**	**Asymptotic Sig.**	**MCID**	**Sensitivity**	**1-Specificity**
PCS (SF-36)	0.507	0.920	3.460	0.821	0.794	0.569	0.293	2.745	0.821	0.721
MCS (SF-36)	0.475	0.702	5.665	0.821	0.926	0.556	0.393	2.345	0.821	0.838
CPI	0.460	0.535	33.333	0.821	0.868	0.452	0.458	43.333	0.821	0.941
GCPS	0.494	0.933	28.333	0.821	0.838	0.569	0.293	21.667	0.821	0.735

Table 8: MCID values for the High Risk/Biobehavioral Group using the Normal Range

	Particle Size					*Broadness of Distribution*				
Measure	**Area Under Curve**	**Asymptotic Sig.**	**MCID**	**Sensitivity**	**1-Specificity**	**Area Under Curve**	**Asymptotic Sig.**	**MCID**	**Sensitivity**	**1-Specificity**
PCS (SF-36)	0.569	0.534	4.210	0.846	0.933	0.701	0.118	.170	0.857	0.524
MCS (SF-36)	0.564	0.565	5.665	0.846	0.800	0.544	0.730	13.410	0.857	1.000
CPI	0.300	0.072	60.000	0.846	1.000	0.534	0.791	60.000	0.857	0.952
GCPS	0.413	0.434	63.333	0.846	1.000	0.442	0.652	48.333	0.857	0.857

Table 9: MCID values for the High Risk/Self-Care Group using the Normal Range

	Particle Size					*Broadness of Distribution*				
Measure	**Area Under Curve**	**Asymptotic Sig.**	**MCID**	**Sensitivity**	**1-Specificity**	**Area Under Curve**	**Asymptotic Sig.**	**MCID**	**Sensitivity**	**1-Specificity**
PCS (SF-36)	0.262	0.275	4.180	1.000	0.762	0.441	0.674	1.825	0.833	0.706
MCS (SF-36)	0.905	0.064	10.915	0.500	0.095	0.706	0.141	4.540*	0.833	0.353
CPI	0.607	0.623	21.667	0.500	0.667	0.554	0.700	23.333	0.833	0.706
GCPS	0.476	0.913	20.000	0.500	0.714	0.618	0.401	21.667	0.833	0.706

*Results were unclear as range (4.540 to -4.870) crossed zero

Table 10: MCID values for all participants using the .5 SD cutoff

	Particle Size					*Broadness of Distribution*				
Measure	**Area Under Curve**	**Asymptotic Sig.**	**MCID**	**Sensitivity**	**1-Specificity**	**Area Under Curve**	**Asymptotic Sig.**	**MCID**	**Sensitivity**	**1-Specificity**
PCS (SF-36)	0.594	0.112	2.745	0.800	0.696	0.641	0.058	2.745	0.805	0.526
MCS (SF-36)	0.460	0.498	1.750	0.800	0.826	0.562	0.405	1.460	0.805	0.737
CPI	0.476	0.689	28.333	0.800	0.826	0.432	0.363	30.000	0.805	1.000
GCPS	0.539	0.514	18.333	0.800	0.630	0.453	0.529	23.333	0.818-.857	0.684

Table 11: MCID values for the High Risk/Biobehavioral Group using the .5 SD cutoff

	Particle Size					*Broadness of Distribution*				
Measure	**Area Under Curve**	**Asymptotic Sig.**	**MCID**	**Sensitivity**	**1-Specificity**	**Area Under Curve**	**Asymptotic Sig.**	**MCID**	**Sensitivity**	**1-Specificity**
PCS (SF-36)	0.526	0.816	2.710	0.833	0.813	0.740	0.131	2.115	0.833	0.500
MCS (SF-36)	0.438	0.577	8.330	0.833	0.875	0.479	0.896	5.665	0.833	0.750
CPI	0.622	0.275	25.000	0.833	0.688	0.422	0.622	40.000	0.833	1.000
GCPS	0.526	0.816	25.000	0.833	0.563	0.438	0.694	43.333	0.833	0.750

Table 12: MCID values for the High Risk/Self-Care Group using the .5 SD cutoff

	Particle Size					*Broadness of Distribution*				
Measure	**Area Under Curve**	**Asymptotic Sig.**	**MCID**	**Sensitivity**	**1-Specificity**	**Area Under Curve**	**Asymptotic Sig.**	**MCID**	**Sensitivity**	**1-Specificity**
PCS (SF-36)	0.854	0.004	0.030	0.846	0.300	0.656	0.297	1.825	0.833	0.400
MCS (SF-36)	0.454	0.710	4.680	0.846	1.000	0.767	0.074	1.245	0.833	0.600
CPI	0.523	0.852	61.667	0.846	1.000	0.589	0.551	41.667	0.833	1.000
GCPS	0.627	0.306	23.333	0.769	0.800	0.494	0.970	23.333	0.833	0.600

Table 13: Minimal Clinically Important Differences (MCID) vs Minimum Detectable Change (MDC) For all Participants

	MCID				**MDC**
	Particle Size		*Broadness of Distribution*		
	Normal Range	*.5SD*	*Normal Range*	*.5SD*	
PCS (SF-36)	3.460	2.745	2.745	2.745	1.786
MCS (SF-36)	5.665	1.750	2.345	1.460	2.529
CPI	33.333	28.333	43.333	30.000	5.705
GCPS	28.333	18.333	21.667	23.333	5.656

Table 14. Minimal Clinically Important Differences (MCID) vs Minimum Detectable Change (MDC) for High Risk/Biobehavioral Group

	MCID				**MDC**
	Particle Size		*Broadness of Distribution*		
	Normal Range	*.5SD*	*Normal Range*	*.5SD*	
PCS (SF-36)	4.210	2.710	.170	2.115	3.058
MCS (SF-36)	5.665	8.330	13.410	5.665	5.038
CPI	60.000	25.000	60.000	40.000	10.107
GCPS	63.333	25.000	48.333	43.333	12.008

Table 15. Minimal Clinically Important Differences (MCID) vs Minimum Detectable Change (MDC) For the High Risk/Self Care Group

	MCID				**MDC**
	Particle Size		*Broadness of Distribution*		
	Normal Range	*.5SD*	*Normal Range*	*.5SD*	
PCS (SF-36)	4.180	0.030	1.825	1.825	4.609
MCS (SF-36)	10.915	4.680	4.540*	1.245	3.468
CPI	21.667	61.667	23.333	41.667	12.768
GCPS	20.000	23.333	21.667	23.333	10.411

*Results were unclear as range (4.540 to -4.870) crossed zero

REFERENCES

Akeel, R., Nilner, M., & Nilner, K. (1992). Masticatory efficiency in individuals with natural dentitions. Swedish Dental Journal, *16*, 191-198.

Al-Jundi, M.A., John, M.T., Setz, J.M., Szentpetery, A., & Kuss, O. (2008). Meta-analysis of treatment for temporomandibular disorders in adult nonpatients. *Journal of Orofacial Pain, 22* (2), 97-107.

American Academy of Orofacial Pain. (2004). TMD symptoms. Mount Royal, N.J.: American Academy of Orofacial Pain.

American Academy of Pain Management. (2003). Proceedings of the 2003 annual meeting of the American Chronic Pain Association, Denver, CO.

Beaton, D.E, Bombardier, C., Katz, J.N., Wright, J., Wells, G.A., Boers, M., Strand, V., & Shea, B. (2001). Looking for important change/differences in studies of responsiveness. *Journal of Rheumatology, 28*, 400-405.

Bates, J.F., Stafford, G.D., & Harrison, A. (1976). Masticatory function-a review of the literature. *Journal of Oral Rehabilitation, 3*, 57-67.

Buschang, P.H., Throckmorton, G.S., Travers, K.H., & Johnson, G. (1997). The effects of bolus size and chewing rate on masticatory performance with artificial test foods. *Journal of Oral Rehabilitation, 24*(7), 522-526.

Buschang, P.H. (2006). Masticatory ability and performance: the effects of mutilated and maloccluded dentitions. *Seminars in Orthodontics, 12*(2), 91-101.

Copay, A.G., Glassman, S.D., Subach, B.R., Berven, S., Schuler, T.C., & Carreon, L.Y. (2008). Minimum clinically important difference in lumbar spine surgery patients: a choice of methods using the Oswestry Disability Index, Medical Outcomes Study questionnaire Short Form 36, and Pain Scales. *The Spine Journal, 8*(6), 968-974.

Copay, A.G., Subach, B.R., Glassman, S.D., Polly, D.W., & Schuler, T.C. (2007). Understanding the minimum clinically important difference: a review of concepts and methods. *The Spine Journal,* 7, 541-546.

De Vet, H,C.W, Ostelo, R., Terwee, C., Van der Roer, N., Knol, D., Beckerman, H., Boers, M., & Bouter, L.M. (2007). Minimally important change determined by a visual method integrating an anchor-based and a distribution-based approach. *Quality of Life Research, 16*, 131-142.

Deviren, V., Geula, D., Demir-Deviren, S., Berven,S., Metz, L., & Hu, S. (2007). Contextual and methodological challenges in determining the minimal clinically important difference (MCID). *The Spine Journal,* 7(5), 59S-60S.

Durante Gayião, M.B., Raymundo, V.G., & Sobrinho, L.C. (2001). Masticatory efficiency in children with primary dentition. *Pediatric Dental Journal, 23*, 499-505.

Dworkin. S.F., & LeResche, L. (1992). Research Diagnostic Criteria for temporomandibular disorders: review, criteria, examinations, and specifications, critique. *Journal of Craniomandibular Disorders, 6*, 301-355.

Dworkin, S.F., Turner, J.A., Mancl, L., Wilson, L., Massoth, D. Huggins, K.H., LeResche, L., & Truelove, E. (2002). A Randomized Clinical Trial of a Tailored Comprehensive Care Treatment Program for Temporomandibular Disorders. *Journal of Orofacial Pain, 16* (4), 259-276.

Edwards, D., Gatchel, R., Adams, L., & Stowell, A. W. (2006). Emotional distress and medication use in two acute pain populations: jaw and low back. *Pain Practice, 6* (4), 42-253.

English, J.D., Buschang, P.H., & Throckmorton, G.S. (2002). Does malocclusion affect masticatory performance? *The Angle Orthodontist*, 72, 21-27.

Epker, J., Gatchel, R.J., & Ellis, E. (1999). A model for predicting chronic TMD: practical application in clinical setting. *Journal of the American Dental Association, 130*(10), 1470.

Fernandez, E., & Turk, D.C. (1989). The utility of cognitive coping strategies for altering pain perception: a meta-analysis. *Pain, 38*, 123-135.

First, M.B., Spitzer, R.L., Gibbon, M., & Williams, J.B.W. (1995). Structured Clinical Interview for DSM-IV Axis I Disorders-Nonpatient Version 2.0. New York State Psychiatric Institute, New York.

Gardea, M.A., Gatchel, R.J., & Mishra, K.D. (2001). Long term efficacy of biobehavioral treatment of temporomandibular disorders. *Journal of Behavioral Medicine, 24*, 341-359.

Gatchel, R.J., Garofalo, J.P., Ellis, E., & Holt, C. (1996). Major psychological disorders in acute and chronic TMD: an initial examination. *Journal of the American Dental Association, 127,* 1365-1370.

Gatchel, R.J., & Mayer, T.G. (2010). Testing minimal clinically important difference: consensus or conundrum? *The Spine Journal, 10,* 321-327.

Gatchel, R.J., Mayer, T.G., Choi, Y., & Worzer, W.E. (2010). The MCID challenge: psychometric validity comparing self report to functional measures in a chronic occupational lumbar disorder population.

Gatchel, R.J., Peng, Y., Peters, M.L., Fuchs, P.N., & Turk, D.C. (2007). The biopsychosocial approach to chronic pain: scientific advances and future directions. *Psychological Bulletin, 133,* 581-624.

Gatchel, R.J., Stowell, A.W., Wildenstein, L., Riggs, R. & Ellis, E. (2006). Efficacy of an early intervention for patients with acute temporomandibular disorder-related pain: a one-year outcome study. *Journal of the American Dental Association, 137,* 339-347.

Glaros, A.G., & Glass, E.G. (1993). Temporomandibular disorders. In Gatchel, R.J., and Blanchard, E.B. (Eds.), *Psychophysiological Disorders,* American Psychological Association, Washington.

Henrikson, T., Ekberg, E., & Nilner, M. (1998). Masticatory efficiency and ability in relation to occlusion and mandibular dysfunction in girls. *International Journal of Prosthodontics, 11,* 125-132.

Jaeschke, R., Singer, J., & Guyatt, G. (1989). Measurement of health status: ascertaining the minimal clinically important difference. *Controlled Clinical Trials, 10* (4), 407-415.

Joint Commission on Accreditation of Healthcare Organizations. (2000). *Pain Assessment and Management: An Organizational Approach.* Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations.

Julien, K.C., Buschang, P.H., Throckmorton, G.S., & Dechow, P.C. (1996). Normal masticatory performance in young adults and children. *Archives of Oral Biology, 41*(1), 69-75.

Kinney, R.K., Gatchel, R.J., Ellis, E., & Holt, C. (1992). Major psychological disorders in chronic TMD patients: management implications. *Journal of the American Dental Association, 123,* 49-54.

Laskin, D.M. (1969). Etiology of the pain-dysfunction syndrome. *Journal of American Dentistry, 79*, 147-153.

McHorney, C., Ware Jr., J., & Raczek, AB. (1993). The MOS 36 Item Short-Form Health Survey (SF-36): II. Psychometric and Clinical Tests of Validity in Measuring Physical and Mental Health Constructs. *Medical Care, 31*(3), 247-263.

Melzack, R. (2001). Pain and the neuromatrix in the brain. *Journal of Dental Education, 65,* 1378-1382.

Melzack, R. (2005). Evolution of the neuromatrix theory of pain. *Pain Practice, 5*, 85-94.

Melzack, R. & Wall, P.D. (1965). Pain mechanisms: a new theory. *Science, 150,* 971-979.

Melzack, R. & Wall, P.D. (1996). *The Challenge of Pain*. New York: Penguin.

Miller, G.A. (1956). The magic number seven plus or minus two: some limits on our capacity for processing information. *Psychological Review, 63,* 81–97.

Mishra, K.D., Gatchel, R.J., & Gardea, M.A. (2000). The relative efficacy of three cognitive-behavioral treatment approaches to temporomandibular disorders. *Journal of Behavioral Medicine,* 23, 293-309.

Nordenbras, W. (1959) *Pain*. Amsterdam: Elsevier.

Norman G.R., Sloan J.A., Wyrwich K.W. (2003) Interpretation of changes in health-related quality of life. The remarkable universality of half a standard deviation. *Medical Care*, 41, 582–92.

Olthoff, L.W., van der Bilt, A., Bosman, F., & Kleizen, H.H. (1984). Distribution of particle sizes in food comminuted by human mastication. *Archives of Oral Biology, 29*(11), 899-903.

Owens, S., Buschang, P.H., Throckmorton, G.S., Palmer, L., & English, J. (2002). Masticatory performance and areas of occlusal contact and near contract in subjects with normal occlusion and malocclusion. *American Journal of Orthodontic and Dentofacial Orthopedics, 121*, 602-609.

Parker, M.W., Holmes, E.K., & Terezhalmy, G.T. (1993). Personality characteristics of patients with temporomandibular disorders: diagnostic and therapeutic implications. *Journal of Orofacial Pain, 7*, 337-344.

Schiffmann, E. , Truelove, E., Ohrbach, R., Anderson, G., John, M., List, T., & Look, J. (2010). The research diagnostic criteria for temporomandibular disorders I: overview and methodology for assessment and validity. *Journal of Orofacial Pain, 24,* 7-24.

Shiere, F.R., & Manly, R.S. (1952). The effect of the changing dentition on masticatory function. *Journal of Dental Research, 31*, 526-534.

Stewart AL, & Ware JE. (1992). Measuring functioning and well-being: The Medical Outcomes Study approach. Durham, NC: Duke University Press.

Stowell, A.W., Gatchel, R.J., & Wildenstein, L. (2007). Cost-effectiveness of treatments for temporomandibular Disorders. *Journal of the American Dental Association, 138*(2), 202-208.

Turk, D.C. (1997). Psychosocial and behavioral assessment of patients with temporomandibular disorders: diagnostic and treatment implications. *Journal of Oral Surgery, Oral Medicine, and Oral Pathology, 83*, 65-71.

Turner, D., Schunemann, H.J., Griffith, L.E., Beaton, D.E., Griffiths, A.M., Critch, J.N., & Guyatt, G.H. (2010). The minimal detectable change cannot reliably replace the minimal important difference. *Journal of Clinical Epidemiology, 63*, 28-36.

Wall, P.D. (1960). Cord cells responding to touch, damage, and temperature of skin. *Journal of Neurophysiology, 23*, 197-210.

Wall, P.D. (1967). The laminar organization of dorsal horn and effects of descending impulses. *Journal of Physiology, 188*, 403-423.

Ware JE, Snow KK, Kosinski M, & Gandek B. (1993). SF-36® Health Survey Manual and Interpretation Guide. Boston, MA: New England Medical Center, The Health Institute.

Wright, A.R., Gatchel, R.J., Wildenstein, L., Riggs, R., Buschang, P., & Ellis, E., 3rd. (2004). Biopsychosocial differences between high-risk and low-risk patients with acute TMD-related pain. *Journal of the American Dental Association (1939), 135*(4), 474-483.