# TERTIARY OUTCOME PREDICTION OF THE MMPI-2 IN SPINAL CORD STIMULATOR TRIALS

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To my grandmother Lorraine & to my parents Ron and Ruth
for their constant love, support, and encouragement.

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## ABSTRACT

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Spinal cord stimulation (SCS) is a promising treatment for chronic intractable pain. For a certain subset of the chronic pain population, it is highly efficacious at reducing pain and increasing quality of life. Presurgical psychological screening (PPS) and selection criteria have been used in the past to exclude patients who are likely to fail SCS treatment; however, PPS and selection criteria for predicting outcome are widely debated. The present study examined MMPI-2 data from 59 patients who underwent SCS trials in an attempt to identify predictive factors for SCS success leading to SCS

implant. Scale 4 (Pd) of the MMPI-2 provided the best predictive model, correctly classifying trial outcome for 81.4% of all cases. The present study is first in the literature to indicate the central importance of scale 4 in the prediction of SCS trial outcome. Future research is needed to confirm the present study's findings and to continue to identify predictive factors of SCS outcome to improve PPS selection criteria and to aid in the development of appropriate interventions that will lead to better SCS outcomes.

# CHAPTER I

## INTRODUCTION

Chronic or recurrent pain, defined as pain lasting 6 months or more, has been referred to as an epidemic affecting an estimated 76.2 million Americans over the age of twenty (American Pain Foundation, 2009). Pain is a trademark of many chronic conditions and the American Pain Foundation contends that pain affects more Americans than diabetes, heart disease, and cancer combined. Despite its prevalence, pain management has only recently been mandated into patient care. In 2000, the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) began requiring that pain be recorded as a "fifth-vital sign" in addition to respiration, blood pressure, heart rate, and temperature (JCAHO, 2000). In spite of JCAHO's attempts to provide better pain management to patients, pain remains a pervasive problem that tends to be largely ignored because it is often considered a symptom of another condition rather than a condition unto itself (National Center for Health Statistics, 2006). Unfortunately, ignoring pain as a condition has created a costly problem.

In a health report released by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC), it was reported that the average cost of treating just one person with chronic pain, in 2004 was $6,280 (NCHS, 2006).

Taken together, the all-encompassing cost of chronic pain in the United States was estimated, over a decade ago, to be between $100 billion and $150 billion dollars annually (National Institutes of Health, 1998; U.S. Bureau of the Census, 1996). Unfortunately, no current estimates of overall cost have been published, however it can be confidently assumed pain remains a costly problem. The cost of chronic pain may seem exorbitant, but many factors contribute to overall costs including disability compensation, legal fees, lost tax revenue, medical treatments for pain, and treatment of side effects (Turk & Burwinkle, 2005). In addition, Stewart and colleagues (2003) estimate a loss of $61.2 billion dollars annually due to pain-related loss of work productivity (as cited in Turk & Burwinkle, 2005).

To date, there is no single treatment that can guarantee a complete remission in chronic pain symptoms. Chronic pain patients can have a spontaneous remittance in symptoms but often times they suffer resurgence in pain symptoms over time. Research consistently indicates chronic pain can only be managed, not cured by any one approach or treatment. Appropriate treatment selection is vital to reducing medical costs, since treatment non-responders often incur the most cost due to multiple treatment failures, which drives the search for an adequate treatment to control the patient's pain. The focus of the present study is on spinal cord stimulation (SCS)— a type of treatment often reserved for those chronic pain patients incurring the most cost due to previously failed treatments and poorly managed pain; but first, we will examine past theories of pain that have shaped our understanding of pain and how it can be managed.

*Theoretical Perspectives of Pain*

*Early Pain Theories.* The earliest pain theories were sensory-based theories that characterized pain as a solely physiological phenomenon occurring in peripheral structures. Pain sensations were thought to directly correlate with painful stimulation and degree of physiological injury. *Specificity theory*, established in the 19th century, was grounded in scientific experiments and formulated on the theoretical concepts postulated by the ancient Greeks and 17th century philosopher Descartes. The specificity theory proposes that pain is a unique sensation utilizing specialized neurons to carry the pain signal from the periphery to the spinal cord and then to the brain (Gatchel et al., 2007; Robinson & Riley, 1999). At the start of the 20th century, sensory-based pain theories became increasingly complex with the addition of the *pattern response theory* (Robinson & Riley, 1999). This theory proposed that pain was due to a pattern of responses of the afferent systems and not solely due to the activation of specific receptors and pathways as proposed by the specificity theory (Gatchel et al., 2007). In proposing pain perception as variable despite consistent painful stimulation, the pattern response theory addressed the major weaknesses of the specificity theory, which could not explain these varied perceptions of intensity (Gatchel et al., 2007).

Alongside sensory-based theories of pain, subjectively-driven theories of pain began to surface. Credence for these theories stemmed from the philosophical writings of Aristotle, in which pain was interpreted as an emotional quality of the soul (Gatchel et al., 2007). Unfortunately, the medical community largely ignored these theories due to a lack of scientific evidence. Fortunately, the *central summation theory* was able to incorporate subjective experiences without compromising the value of research. Central

summation theory was the first theory to establish the importance of emotional states in the perception of pain by implicating higher brain centers alongside peripheral sensory systems. This theory survived criticism because it developed out of advances in research regarding the central nervous system, which is the main route for sensory information to the brain for processing and perception (Robinson, & Riley, 1999). Overall, the central summation theory along with specificity and pattern response theories provided a strong foundation for a major shift in the conceptualization of pain as both a sensory and subjective experience (Gatchel et al., 2007; Robinson & Riley, 1999). Furthermore, these theories led to the development of a more comprehensive theory of pain called the gate control theory (Gatchel et al., 2007; Robinson & Riley, 1999).

*Gate Control Theory of Pain.* The gate control theory (GCT) was developed by Melzack and Wall in 1965, and has become one of the most influential and widely accepted theories of pain (Robinson & Riley, 1999). The GCT has not only acted as a catalyst for spinal cord stimulation (SCS) therapy but has also paved the way for multidisciplinary care by advancing our knowledge of how psychological factors influence pain, thereby making the GCT an integral part of the proposed study. The GCT hypothesized that pain is the result of an interaction of sensory pain signals with psychological factors by means of ascending and descending pathways to and from the brain. From the periphery, pain signals travel by way of ascending nerve fibers to the dorsal horn of the spinal cord where the proposed "gate" is located. The purpose of the gate is to modulate the pain signal before it is relayed to the brain. On this ascending route, stimulation from large diameter fibers relaying non-noxious stimuli (touch) will have an inhibitory effect—closing the gate, whereas stimulation of small diameter fibers

(A-delta and C-fibers) carrying painful signals will stimulate transmission (T) cells at the gate in the dorsal horn—opening the gate and allowing pain signals to be relayed to various regions of the brain (Robinson & Riley, 1999). On the descending route, the GCT postulates that inputs from the brain relaying cognitive and emotional information work to either inhibit pain signals by closing the gate, or enhance pain signals by opening the gate (Melzack, 1993; as cited in Zautra, 2003). As a result, the present study contends that psychological factors could be crucial indicators of SCS success or failure, since these descending systems can work either for or against SCS therapy.

In 1968, Melzack and Casey further defined the different components of the descending neural network as cognitive-evaluative, sensory-discriminative, and motivational-affective components (Gatchel et al., 2007). Each of these components, referred simply as cognitive, sensory, and affective components relay information through a network of neurons called the neuromatrix (Melzack, 2001). Melzack (2001) contends that neurons in the brain send signals in a loop from the thalamus to the cortex and also from the cortex to the limbic system integrating information from various areas in the brain to be sent via descending pathways to the proposed gate, which may then modulate ascending signals. The communication on these loops is an interaction of signals relayed from sensory, affective, and cognitive areas of the brain creating an individual's overall perception of pain (Melzack, 2001). Psychological processes believed to influence pain perception result primarily from the affective and cognitive components of the neuromatrix (Zautra, 2003). Melzack (2001) explains that the cognitive component integrates inputs from the brain involving attention, expectation, anxiety, and depression, and the output relayed via descending pathways depends on the

individual's past experiences, cultural learning, and personality factors. The affective component, Melzack (2001) explains, is influenced not only by the emotional center (limbic system) in the brain but is also influenced greatly by stress hormones from the hypothalamic-pituitary-adrenal system (HPA-axis) seeking to restore homeostasis disrupted by chronic pain. How the body restores homeostasis via the HPA-axis seems to be largely influenced by genetic factors, thereby making the affective component an unlikely target for change in integrative pain management centers.

Fortunately, psychological treatment designed to modulate affect is more easily achieved through the modulation of the cognitive component, which is known to interact with the affective component. The modulation of cognitive components can be learned, whereas the modulation of the affective component lies just beyond the voluntary control of the individual. For example, a person suffering from fear and distress may not be able to control the activity of the HPA-axis or the limbic system, but by utilizing relaxation and distraction techniques that the person has learned, he or she could influence the signals from the cognitive component thereby altering the affective component and ultimately changing the message sent along the descending pathway to close the gate, inhibiting upcoming ascending pain signals and reducing the overall perception of pain. Without specifically learned coping strategies to alter the cognitive and affective components of the neuromatrix, personality factors will naturally influence pain perception. For instance, a person with a resilient personality (positive cognitive component) will be likely to cope with stress and anxiety (negative affective components) much better than a person with a personality prone to anxiety and depression (negative cognitive components). The cognitive component is the likely target for psychological

treatment and intervention not only because of its ability to influence affective components, but also because the patient can manage pain by willfully changing the cognitive component of the neuromatrix.

In summary, the GCT, with the addition of the neuromatrix theory, proposes that sensory, affective, and cognitive components interact in response to pain signals arriving along ascending pain pathways. The present study seeks to explore personality factors defined within the cognitive component of Melzack's (2001) neuromatrix model, as measured by the MMPI-2, because personality may account for the variability in SCS outcomes. In doing so, future research may be able to target personality factors for intervention and treatment, thereby increasing SCS success rates. Overall, the brain is believed to act as a highly complex neural network sending signals via descending pathways regarding emotions, cognition, and sensation to modulate ascending signals regarding pain. Moreover, pain modulation becomes even more complex because modulation occurs beyond the gate in other areas of the brain, such as the brainstem, thalamus, and cerebral cortex (Block, 1996). Currently, it is unclear exactly how to close the gate completely via descending pathways, but the importance of higher brain systems is becoming more evident because of the GCT.

Turk and Monarch (2002) applaud the GCT for highlighting the central nervous system and state its most noteworthy achievement was providing a physiological basis for psychological involvement, but in general, the GCT can be credited with the birth of two major advancements since its inception. From its work regarding ascending neural systems, SCS therapy was created for the clinical treatment of pain. Additionally, from its work regarding descending neural systems, the GCT provided a strong foundation for

the creation of the biopsychosocial model, which is responsible for integrative care. Next, we will examine SCS therapy followed by a look at the different treatment orientations (biomedical vs. biopsychosocial models) and how type of treatment orientation may influence patient care and outcomes.

*Treating Chronic Pain*

*Spinal Cord Stimulation (SCS).* After the publication of the GCT, Shealy and colleagues (1967) performed the first implantation of electrodes within the dorsal columns of the spinal cord at the substantia gelatinosa level, where the proposed "gate" was believed to be located (North & Wetzel, 2002; Sundaraj et al., 2005). This was the first clinical application of the GCT for the treatment of chronic pain and it was believed to work by stimulating large diameter touch fibers, on the ascending route, thereby closing the gate and blocking the passage of pain signals to the brain. Unfortunately, early studies of SCS efficacy were not impressive, with success rates often falling below 40 percent (Sundaraj et al., 2005). Deer and Mason (2008) suggests faltering success rates with early SCS procedures were likely due to the fact that electrode placement within the dorsal columns was highly invasive and these early procedures were done with rudimentary devices and with relatively poor patient selection criteria. Despite such high failure rates, Shealy and colleagues (1967) reported some success in controlling chronic intractable lower extremity pain, thereby spurring the search for better techniques, equipment, and selection of patients to be medically indicated for the procedure (as cited in North & Wetzel, 2002).

SCS has evolved in many ways over the years and is currently indicated as an efficacious treatment for vascular ischemic pain, complex regional pain syndrome

(CRPS) type I and II (a.k.a. RSD), failed back surgery syndrome (FBSS), and for chronic low back pain (Oakley, 2003). Oakley (2003) indicates SCS is also, but less frequently, used for disease-specific pain related syndromes or utilized as an experimental treatment especially when all other therapies have failed. The key features of these SCS systems are the lead wires, which contain the electrodes at the end of the tip, and the power source, which conducts the electrical impulse down the lead wire to stimulate the affected area. The goal is to provide paresthesia, often experienced as a tingling or massaging sensation, over the entire painful area without stimulating other areas. Since its inception, SCS systems have evolved from single pulse generators with unipolar electrode leads to battery-powered, programmable, dual channel pulse generators with multicontact epidural electrode leads (Holsheimer, 2002). With these advancements, North and Guarino (1999) believe better overlap of paresthesia has become possible, making SCS an efficacious treatment for various pain conditions.

Despite being an efficacious treatment, SCS therapy is typically not offered as a first line of treatment even if the patient's pain condition has been known to respond favorably to SCS (Oakley, 2003). As Oakley (2003) reports, SCS is often offered as a last resort after the patient has failed many traditional treatment options and typically after the patient has been labeled as drug resistant or a surgical failure. In fact, one of the most commonly cited conditions for indicating treatment via SCS in the United States is failed back surgery syndrome (FBSS; North & Guarino, 1999; Oakley, 2003). FBSS is a term used to describe persistent or recurrent pain after anatomically successful spine surgery (Leveque et al., 2001). North and Guarino (1999) report that annually over 200,000 patients undergo spine surgery and of those, 20-40% develop FBSS, currently

making FBSS one of the most commonly cited conditions indicated for SCS in the United States.

It has become quite obvious that SCS tends to be a last chance treatment for many pain conditions, mainly FBSS (Leveque et al., 2001; North & Guarino, 1999; Oakley, 2003). Due to the high rate of SCS candidates having failed multiple treatments in the past, it was imperative that non-invasive, easily retractable trial techniques be developed to select out likely treatment non-responders, and to give an indication of the probable long-term success with the fully implanted SCS, thereby reducing failure rates (North & Guarino, 1999). As a result, percutaneous (needle puncture) methods for trials were developed in the 1970s and because of their success these methods were later adapted for use in implant procedures because these methods were far less invasive (did not require the exposure of the spine via incision) and generally had better results (North et al., 1993). During SCS trials, the power source remains external, allowing the patient to try out the device for a set amount of time before deciding whether or not to have the power source implanted into either the abdomen or buttocks depending on body type and power source (Oakley, 2003).

Percutaneous methods for SCS trials are done one of two ways (temporary or anchored lead) with each method having advantages and disadvantages. In both percutaneous methods, the lead wire is inserted through a needle tract into the epidural space and is placed in the appropriate spot, guided by fluoroscopic imaging (video X-ray), and then programmed with the patient awake to communicate effectiveness and location of the stimulation. After the electrode is appropriately placed and the stimulation is effectively programmed, the procedure varies for temporary versus

anchored lead methods. In the temporary lead method, the needle tract is then removed from the back and the protruding lead wire is taped securely to the skin. The lead wire is definitely temporary in this technique because it is not anchored down in any way, therefore the lead wire must be removed at the end of the trial period. Removal is very simple and is usually removed by the doctor pulling out the lead wire at the patient's office visit. In the anchored lead method, an incision is made and the lead is anchored to fibrous tissue. Temporary percutaneous extension wires are connected to an implanted connector, and then through a technique called *tunneling*, the wires are connected to the external electrical stimulation source system. This method is a little more invasive and requires the use of an operating room, but it ensures that the lead will not pull out or move during trial. North and Wetzel (2002) also state that the lead anchored approach is also beneficial because the cost of another electrode is not wasted and the placement of the electrode will not change, therefore reducing the possibility of the patient reporting less effective results which might happen if the lead is removed and has to be reinserted precisely by comparing X-ray images. However, it could be argued that the temporary lead approach is probably best since not everyone goes on to implant. A failed trial period after having a lead anchored trial would cost the patient yet another trip to an operating room, more anesthesia, and unfortunately more pain. In this case, the temporary lead technique is advantageous because it eliminates the cost of scheduling an operating room and avoids the added pain of incision, anchoring, and tunneling (North & Wetzel, 2002). Additionally, the less invasive nature of this technique allows for it to be done under local anesthetic and light sedation and can be done as an outpatient procedure at a hospital, pain clinic, or day surgery center. Regardless of the exact methodology

chosen, trial procedures were developed because it was believed trials would be a good indicator of future success with the permanent implant, therefore sparing those who failed trial the extra time, money, and invasiveness of removing a fully implanted device.

To examine long-term SCS efficacy after trial screening, Van Buyten and colleagues (2001) reviewed SCS treatment at one pain center over the course of 10 years. All patients indicated for SCS therapy were chronic pain patients with neuropathic pain, of which 78.4% were classified as having FBSS. In all, 254 patients underwent an extended trial screening of at least 1 month from which 217 patients (85%) succeeded and continued to have the SCS permanently implanted. In 1998, Van Buyten and colleagues (2001) were able to contact 123 patients for a follow-up interview. Follow-ups from date of implant ranged from 3 months to 10 years with a median follow-up of 3.4 years. Van Buyten and colleagues (2001) found SCS, preceded by a trial, was highly efficacious, with 68% of patients describing their pain relief as excellent to good at long-term follow-up.

In a similar study, Kay et al. (2001) conducted a long-term retrospective study of 70 patients with chronic pain, the majority of which underwent SCS after all conventional treatments and surgical procedures had been exhausted (>50% indicated FBSS). The study included SCS procedures over a 13-year time frame then follow-ups were conducted on 58 patients with length of follow-up ranging from 1-13 years (median 5.2 years). Kay et al. (2001) noted 60% of patients reported substantial (>50%) relief of pain at follow-up. Kay and colleagues (2001) found that the majority of patients who succeeded in trial also reported success with implant, however they also warn that successful trial does not assure success with the implant. Moreover, Kay and colleagues

(2001) note trial procedures have not been universally established and vary greatly in standards amongst the literature in trial length and percent of pain relief required.

North et al. (1993) found great variability within the literature regarding percentage of pain relief required to proceed with implant. North et al. (1993) noted some studies required as much as a 70% reduction in the patients' reported pain before deciding to implant even though the standard pain reduction required for long-term success is typically 50% reported pain relief. Additionally, Turner and colleagues (1995) spotted inconsistencies in their review of 34 SCS studies noting that only 8 studies specified percentage of pain reduction criteria, and the requirement in these studies ranged from 30-75% reported pain reduction required. When reviewing trial length in these studies, Turner and colleagues (1995) found trial length varied from 1 day to 2 weeks amongst the 18 studies reporting trial length. In addition, North et al. (1993) reported finding a trial period lasting as long as 2 months, and even though trial time varies, the typical length of time for a trial is 3-7 days. To date, these trial procedures remain a fast and effective means of narrowing the field of potential responders, but there is little consistency in terms of exact standards and criteria to indicate when it is appropriate to fully implant the SCS device.

To further complicate matters, some pain clinics, typically multidisciplinary pain centers, have added various forms of presurgical psychological screening (PPS) prior to trial procedures. The foundation of PPS typically consists of a clinical interview followed by some form of standardized psychological testing, commonly including the Minnesota Multiphasic Personality Inventory (MMPI). Unfortunately these PPS systems appear to be just as inconsistent with little consensus about the inclusion and exclusion

criteria. Despite these inconsistencies, promising results are ensuing with the use of psychological screening prior to SCS trial procedures. Sundaraj and colleagues (2005) investigated the long-term efficacy of SCS of 138 patients who underwent behavioral health treatment as part of their comprehensive medical management program prior to SCS trial. Over the span of seven years Sundaraj and colleagues (2005) noted that of the 138 patients, who underwent behavioral health treatment followed by a SCS trial, 103 (75%) proceeded to implant and of those, 84.4% patients reported long-term success with the permanent implant at one-year follow-up. This success rate far exceeds the success rates reported in the Van Buyten et al. (2001) study and the Kay et al. (2001) study, both of which did not include any type of PPS prior to SCS trial. Length of follow-up may have contributed to the difference in efficacy rates, as success rates may have dropped if the patients were followed past one year. However, it may be that by adding psychological screening and a comprehensive medical management program addressing behavioral health issues, this study was able to increase their long-term success rates. However, Sundaraj and colleagues (2005) contend the predictive value of presurgical psychological screening is still widely debated. The debate continues mainly due to differences in the theoretical orientation of researchers and medical providers regarding approaches to treatment. A description of the two major approaches to treatment are considered next.

*Biomedical vs. Biopsychosocial Models.* Chronic pain has been treated in various ways throughout history and the type of treatment utilized always depends upon the accepted treatment orientation of the treating physician. Traditionally, medical doctors have operated under the principles of the biomedical model. The biomedical model is a

disease driven model that dates back to the ancient Greeks, but was not incorporated into Western medicine until the 17th century by Descartes (Turk & Monarch, 2002). As a disease driven model, the biomedical model assumes that symptoms are the result of a specific disease and therefore represent some form of disordered biology. In this model, practitioners seek to find the cause of damage or impairment through objective diagnostic tests to confirm hypothesized diagnoses based on a set of symptoms. Medical interventions are directed at correcting or curing the biological source of dysfunction.

Treatments based on the philosophies of the biomedical model remain fairly adequate at treating acute pain conditions with known organic causes; however the treatment of chronic pain remains elusive (Gatchel et al., 2007; Turk & Burwinkle, 2005). Chronic pain conditions are most perplexing because the degree of physical pathology does not always match with the reported level of severity or with observed disability impairments. Instead of integrating psychosocial factors with biological factors, the biomedical model holds steadfast to a dualistic approach labeling the patient's symptoms as either somatogenic or psychogenic (Turk & Monarch, 2002). For instance, if a patient reports chronic pain for which no organic cause can be found, the biomedical model would postulate that the patient's pain condition is psychogenic in nature and should be treated solely by mental health providers. In addition, Turk and Monarch (2002) note that the biomedical model has been criticized for ignoring psychosocial factors in the course of an organic chronic pain condition. Researchers and medical providers utilizing this treatment approach will likely undervalue the impact of psychosocial factors, such as personality, and the potential ability of PPS to add greatly to the screening procedures for outcome prediction of SCS.

Fortunately, some of the downfalls of the biomedical model in the treatment of chronic pain are remedied with the philosophies of the biopsychosocial model. The biopsychosocial model has been praised as the most appropriate way of viewing chronic conditions mainly because it integrates biological with psychological and social factors, making a precise distinction between understanding and treating *disease* versus *illness* (Gatchel et al., 2007). Turk and Monarch (2002) explain disease as a purely objective biological event in which there have been anatomical, pathological, or physiological disruptions to the organism's body. Disease is treated under the biomedical model; however, patients suffering from chronic conditions such as chronic pain do not typically have diagnoses that meet the stringent disease criteria. Illness on the other hand, incorporates all psychological and social factors associated with the disease; in other words, illness signifies the subjective experience of a disease (Turk & Monarch, 2002). Engel (1977) proposed four dimensions of illness: the physical problem, distress, illness behavior, and the sick role (as cited in Gatchel et al., 2007). Loeser (1982), later incorporated this theory's ideas and applied the four dimensions of illness to chronic pain, proposing that pain is experienced in increasing increments; first, through nociception, followed by an experience of pain, then suffering, and finally outwardly expressed through pain behaviors (as cited in Gatchel et al., 2007).

Gatchel et al. (2007) explains that the earliest conception of the biopsychosocial model addressed the limitations of the dualistic biomedical model and offered a more comprehensive approach. To date, pain is best understood under this model because pain is experienced with the interaction of both physical and mental perceptions as explained by the GCT. However, the application of the biopsychosocial model to chronic pain may

not have been possible without foundation of the GCT. Block (1996) credits Melzack and Wall's (1965) GCT as the first integrative theory of pain, ultimately leading to the birth of the biopsychosocial model. In addition, Block (1996) contends that the biopsychosocial model is the most appropriate treatment model thus far for understanding and treating chronic pain because it incorporates the importance of psychological processes in conjunction with sensory perception. Overall, the biopsychosocial model allows for a complete assessment of the person, and how the illness pathology affects the person psychologically and socially, as well as biologically. Turk and Monarch (2002) state it is impossible to remove the person from the pain; therefore, assessment of the person rather than the pain should be stressed. Gatchel and colleagues (2007) agree that solely focusing on one dimension such as biological pathology versus biological, psychological, and social components will lead to an incomplete understanding of the patient's perception and response to pain and illness. Medical providers and researchers oriented to this treatment approach are often apart of multidisciplinary pain management programs. Under this treatment approach, the development of presurgical psychological screening (PPS) came to fruition as a way to assess the patient to indicate appropriateness of treatment intervention and to predict likely treatment outcomes.

*Presurgical Psychological Screening (PPS)*

*Origins of Presurgical Screening.* Presurgical screening first surfaced in the literature in the early 1990s as "surveillance systems" developed to provide quality care to pain patients considering surgery (Garvey & Wiesel, 1991; Mooney, 1991; as cited in Gatchel, 2001). These early systems used algorithms to aid in decision-making by providing an organized set of well-defined rules that would guide the physician to

making the best decision for his or her patients. Gatchel (2001) asserts the early use of algorithms to spot good surgical candidates was not fully embraced by the medical community until the initiation of the biopsychosocial model into clinical practice. According to Gatchel (2001), prediction algorithms based on the biomedical model did exist before the first biopsychosocial-based algorithm; however these early algorithms lacked predictive power due to the exclusion of psychosocial variables, which turned out to be very important predictive information. With the application of the biopsychosocial approach to chronic pain, presurgical psychological screening (PPS) methods gained support as confirmatory evidence began to surface. The first PPS protocol utilizing psychometric testing with the MMPI was applied selectively to lumbar discectomy surgical candidates (Carragee, 2001; as cited in Gatchel, 2001). The predictive success of PPS reported in lumbar discectomy surgery led to a more extensive investigation by Epker and Block (2001) to investigate the use of PPS for a broader range of spinal surgery (as cited in Gatchel, 2001).

In 2003, Block and colleagues wrote *The Psychology of Spine Surgery*, in which the detailed use of PPS is outlined. Block et al. (2003) assert PPS can provide a means to screen out patients who are likely to have poor surgical outcomes while providing an empirically validated justification for avoiding procedures likely to be ineffective. Block et al. (2003) assert that PPS utilization is especially important for spine surgery candidates in order to decrease the rate of failed back surgery syndrome (FBSS). FBSS as discussed earlier, affects 20-40% of spine surgery patients (North & Guarino, 1999), therefore a means of reducing failure rates would increase patient care and reduce additional costs incurred by failed surgery. Utilizing PPS to avoid FBSS is the main

target proposed by Block et al. (2003). Block and colleagues (2003) explain that as the patient experiences the distress of a failed surgery the surgeon is often the first to be blamed and is under great pressure from the patient as well as the patient's family and caretakers to remedy the situation. Therefore, a means to predict surgical failures is of great value to medical providers, third party payers, patients and caretakers.

*Application to SCS.* As PPS became a popular way to predict surgery success, applications of PPS were expanded to include other surgical avenues in which success rates were less than satisfactory. PPS for implantable devices, such as SCS, seemed inevitable since many early SCS studies with low success rates emphasized the need for better selection criteria. From the very beginning, Shealy (1975), who pioneered work in SCS but often had low success rates, discussed the importance of psychological factors, specifically naming disturbed personalities a key component in outcome failure (as cited in Nelson et al., 1996). However, enthusiasm for psychological prediction began to fade as studies began reporting contradictory evidence. Nelson and colleagues (1996) reviewed studies throughout the 70s and 80s, which examined psychological outcome predictors. Nelson and colleagues (1996) found outcomes varied widely from study to study with some studies reporting greater than 75% accuracy in predicting outcome when using the MMPI, while other studies showed mixed or conflicting evidence using the MMPI or clinical interviews. The lack of strong and consistent supportive evidence for psychosocial predictors of outcome led some to rely solely on biomedical selection criteria, even though psychosocial factors have never been completely disregarded as potential predictive factors (Beltrutti et al., 2004; Ruchinskas & O'Grady, 2000; Sundaraj et al., 2005; Williams et al., 2003). The debate continues with various scattered opinions

throughout the literature regarding the prognostic value of psychosocial variables in predicting SCS outcomes.

Beltrutti and colleagues (2004) argue that there is a great need for the psychological assessment and screening of SCS candidates because SCS fails despite strong clinical indications for the procedure and flawless techniques. They argue that if there are no technical or procedural flaws and the patient is clinically indicated for the procedure then efficacy rates should be higher. Additionally, Beltrutti and colleagues (2004) contend that if psychosocial factors did not account for any variability in efficacy, then efficacy rates should be near perfect, especially if technical and procedural flaws are taken out of the equation and if the patient has been medically indicated for the procedure. North et al. (1993) agreed that psychological factors should be investigated to see if these factors account for the variability in SCS outcomes especially when no technological or biological complications exist and the patient has been clinically indicated for SCS. However, North and colleagues (1996) found no evidence of psychosocial predictive factors when investigating patient outcomes with SCS and go on to suggest psychological factors may not be as important to SCS outcome prediction. Nevertheless, these results must be interpreted cautiously because the participants in the study had already been preselected by a rigorous biological and psychological screening process, introducing selection bias.

Overall, the literature lacks consensus regarding the importance of psychosocial predictors of SCS success and many researchers and clinicians have called for uniform standards in clinical practice and in the collection of data. Kay et al. (2001) asserts that the establishment of standards for patient selection and assessment is lacking, due to the

deficiency of strong evidence defining best practice. Kay and colleagues (2001) acknowledge technology and hardware have advanced but they admit problems with failure rates still persist. Even though the technology has progressed, our understanding of psychosocial assessment and criteria for SCS outcome prediction is still in its infancy. To date, selection criteria for SCS implants emphasizes biomedical philosophy while disregarding psychosocial factors. The importance of psychosocial factors in the prediction of SCS outcome is uncertain at this point in the literature. Nonetheless, attempts have been made by clinicians to adopt a standard PPS system that can distinguish good candidates from poor candidates based on a set of risk factors thought to predict poor outcomes (Heckler et al., 2007; Nelson et al., 1996; Prager & Jacobs, 2001; Schocket et al., 2008).

Unfortunately, the attempts to create a standard protocol have only confused the literature, and with no real empirical support to define best practice, the actual use of PPS for SCS varies greatly. In general, PPS for SCS candidates, sometimes referred to as a presurgical behavioral medicine evaluation (PBME), is completed by mental health or behavioral health providers and typically involves a review of the patient's records and a semi-structured clinical interview followed by one or more psychological tests. Often, PPS for SCS is used as a way to identify psychosocial risk factors. Nelson and colleagues (1996) proposed several psychosocial risk factors for SCS candidates including: active psychosis, suicidality, or homicidality, untreated or poorly managed major depression or other mood disorders, somatization disorders, alcohol or drug dependency, current compensation or litigation, lack of social support, and neurobehavioral cognitive deficits impacting the patient's sound judgment and decision

making skills. These risk factors are generally used as exclusionary criteria for SCS candidates and are not based on empirical support but rather the result of clinical judgment; therefore, Nelson and colleagues (1996) advise flexibility in the decision to pass or fail a potential candidate for SCS, recommending the consideration of other factors such as abnormal pain ratings, personality disturbances, Waddell signs (group of physical signs that may indicate non-organic pain), and psychological testing results to aid the practitioner's decision about the severity and degree of risk of treatment failure. Unfortunately, none of these "risk" factors have been empirically validated for SCS.

More recently, Schocket et al. (2008) and Heckler et al. (2007) have attempted to apply Block's algorithm for spine surgery to SCS candidates labeling prognostic groups into one of four categories: Green (good prognosis, cleared for surgery), Yellow I (good prognosis, post-operative treatment needed), Yellow II (fair prognosis, pre-operative treatment needed), and Red (poor prognosis, do not proceed with surgery). Unfortunately, nothing is known about the algorithm's predictive potential for SCS outcome because Red flagged patients were not allowed to proceed to SCS surgery. Additionally, the researchers decided to solely measure the effectiveness of the algorithm in correctly identifying patients into diagnostic category at long-term follow-up, completely ignoring SCS implant success or failure at follow-up. In other words, if one patient was categorized in the Green group, all that was determined is that at follow-up the patient was likely to still be classified in the Green group regardless of SCS outcome.

Doleys (2002) warns against these types of PPS for SCS because the risk factors used to categorize people into prognostic groups are *theoretical* risk factors for SCS taken from the experience of other types of therapies, such as spine surgery, rather than

from controlled studies involving SCS. Van Dorsten (2006) agrees, noting PPS for spine surgery is being applied to SCS procedures making it nearly impossible to know for certain which factors predict SCS outcomes. Although some similarities do exist between spine surgery candidates and SCS surgery candidates, it is important to recognize the inherent differences in these treatments. For example, spine surgery procedures are often much more invasive than SCS procedures. Furthermore, PPS protocols such as Block's et al. (2003) algorithm were developed to screen out patients who may potentially develop FBSS after surgery, yet the majority of SCS candidates have had multiple failed surgeries and are already diagnosed with FBSS at the time of their consideration for SCS. In other words, it may be inappropriate to use a PPS protocol that was meant to screen out patients likely to develop FBSS especially if the main population for SCS consists of FBSS patients.

For this reason, Prager and Jacobs (2001) shy away from strictly using spine surgery PPS risk factors and instead recommend a set of guidelines tailored to SCS. Although Prager and Jacobs (2001) recommend a similar categorical approach to PPS for SCS as Schocket et al. (2008), and Heckler et al. (2007), they do not use the algorithm method developed for spine surgery. Prager and Jacobs' (2001) recommendations depend not on weighted risk factors but on sound clinical judgment after a records review, clinical interview, and battery of psychosocial testing to be determined by the psychologist. In addition, Prager and Jacobs (2001) have tailored the clinical interview to include questions directly related to SCS including the procedure, the device, and the patient's expectations of pain relief. Although Prager and Jacobs (2001) attempt to tailor PPS for SCS, their screening method does not allow itself for use universally because it

lacks uniformity in the selection process. For example, one clinician may deny a patient yet another clinician may accept the same patient for SCS because of the emphasis on the clinician's judgment rather than scientific evidence of identified psychosocial risk factors for SCS outcomes.

Currently there are no established PPS systems for SCS that have been empirically validated. Researchers and clinicians have not agreed on the best way to handle PPS for SCS, nor have the PPS systems proposed been empirically validated over one another for predictive power of proposed risk factors and exclusion criteria. Many of the exclusion criteria in these PPS models have been based on risk factors for other therapies and decisions have been based on clinical judgment rather than strong empirical evidence. Unfortunately, it may be unethical to empirically validate some risk factors that have been serving as exclusion factors, because once excluded, patients are not allowed to proceed with SCS procedures. As a result, it may be important to take a step back and examine the psychometric testing used in PPS. Psychometric testing is a common protocol for PPS and is used to aid the clinician in making sound decisions; however, it has only been moderately investigated for its predictive capabilities and with mixed results.

*Psychometric Testing.* The Minnesota Multiphasic Personality Inventory (MMPI & MMPI-2, 1942, 1989; as cited in Friedman et al., 2001) has been the most commonly administered psychometric test for predicting surgical outcome in pain patients (Vendrig, 2000). Analysis of the MMPI and the MMPI-2 typically involve examining the 10 main clinical scales and the 3 validity scales for scale elevations (T scores >65). T scores ranging from 50 to 65 are considered to be within the normal range but T scores can

range from 30 to 120 on each of the scales (Friedman et al., 2001). Friedman et al. (2001) explain that elevations above 65 are not the absolute standard for marking psychopathology, but rather a T score of 65 is a guideline for determining degree of psychopathology as clinically significant. In analyzing the clinical scales, it is important to examine any elevations on the validity scales before proceeding with an interpretation of clinical scale elevations. Validity scales (L, F, and K) were originally designed to measure the test-taker's attitude toward the test (Friedman et al., 2001). Specifically, the L (lie) scale detects social desirability, the F (infrequency) scale detects irregular patterns of responding that typically stem from comprehension problems or careless responding, and the K (correction) scale detects symptom suppression or defensive responding (Friedman et al., 2001).

After looking at the various validity scales, the clinician next looks at the 10 clinical scales, which include: Scale 1—Hypochondriasis (Hs), Scale 2—Depression (D), Scale 3—Hysteria (Hy), Scale 4—Psychopathic Deviate (Pd), Scale 5—Masculinity-Femininity (Mf), Scale 6—Paranoia (Pa), Scale 7—Psychasthenia (Pt), Scale 8—Schizophrenia (Sc), Scale 9—Hypomania (Ma), and Scale 0—Social Introversion (Si) (see Table 1).

**Table 1** MMPI-2 Clinical Scales with Harris-Lingoes Subscales

| |
|---|
| **Scale 1**: Hypochondriasis (Hs) |
| **Scale 2**: Depression (D) |

| | |
|---|---|
| **D1**:Subjective Depression | **D4**:Mental Dullness |
| **D2**:Psychomotor Retardation | **D5**: Brooding |
| **D3**:Physical Malfunctioning | |

**Table 1 continued.**

**Scale 3**: Hysteria (Hy)

| | |
|---|---|
| **Hy1**: Denial of Social Anxiety | **Hy4:** Somatic Complaints |
| **Hy2:** Need for Affection | **Hy5:** Inhibition of Aggression |
| **Hy3:** Lassitue-Malaise | |

**Scale 4**:Psychopathic Deviate (Pd)

| | |
|---|---|
| **Pd1:** Familial Discord, | **Pd4:**Social Alienation |
| **Pd2:** Authority Problems | **Pd5:** Self-Alienation |
| **Pd3:** Social Imperturbability | |

**Scale 5**: Masculinity-Femininity (Mf)

**Scale 6**: Paranoia (Pa)

| | |
|---|---|
| **Pa1:** Persecutory Ideas | **Pa3:** Naivete |
| **Pa2:** Poignancy | |

**Scale 7**: Psychasthenia (Pt)

**Scale 8**: Schizophrenia (Sc)

| | |
|---|---|
| **Sc1:** Social Alienation | **Sc4:** Lack of Ego Mastery, Conative |
| **Sc2:** Emotional Alienation | **Sc5:** Lack of Ego Mastery, Defective Inhibition |
| **Sc3:** Lack of Ego Mastery, Cognative | **Sc6:** Bizarre Sensory Experiences |

**Scale 9**: Hypomania (Ma)

| | |
|---|---|
| **Ma1:** Amorality | **Ma3:** Imperturbability |
| **Ma2:** Psychomotor Acceleration | **Ma 4:** Ego Inflation |

**Scale 0:** Social Introversion (Si)

| | |
|---|---|
| **Si1:** Shyness/Self-Consciousness | **Si3:** Alienation-Self and Others |
| **Si2:** Social Avoidance | |

Elevations on the different clinical scales indicate a set of psychological traits characterizing the patient (Doleys & Olson, 1997). For example, elevations on Scale 1 (Hs) may indicate excessive worry about one's health, and for chronic pain patients, Doleys and Olson (1997) suggest that a patient with an elevated Scale 1 will have a tendency to complain about the pain more so than a patient without an elevated Scale 1. Scale elevations on Scale 2 (D) may signify the patient is struggling with clinically significant depression, whereas elevations on Scale 3 (Hy) may indicate the patient is denying problems and developing somatic complaints in response to those problems (Doleys & Olson, 1997). High Scale 4 (Pd) scores may indicate the patient has a low frustration tolerance or has trouble adjusting to different circumstances, whereas a high or low score on Scale 5 (Mf) can indicate the patient does not typically observe traditional gender roles (Doleys & Olson, 1997). Patients with high Scale 6 (Pa) scores are thought to be paranoid or hypersensitive, whereas patients with high Scale 7 (Pt) scores often suffer from anxiety (Doleys & Olson, 1997). Elevations on Scale 8 (Sc) often identify a patient who feels socially alienated or has bizarre thoughts, whereas elevations on Scale 9 (Ma) characterize someone with high levels of energy or activity. The tenth scale, referred to as Scale 0 (Si), will identify introversion with high scores and extroversion with low scores (Friedman et al., 2001).

In addition to examining the main clinical scale elevations, clinicians often examine different content scales, typically the Harris-Lingoes, derived from the clinical scales to further clarify the meaning of scale elevations (Friedman et al., 2001). The Harris-Lingoes subscales are content scales that were developed for the MMPI-2 to aid in

the interpretation of clinical scale elevations by breaking down the heterogeneity of the clinical scale (a.k.a. *parent* scale) into more homogeneous subscales. The Harris-Lingoes subscales break apart 6 of the 10 clinical scales (Scales 2, 3, 4, 6, 8, and 9) into their component parts dissolving the heterogeneity of the parent scales (Friedman et al., 2001). For an overview of the MMPI-2 clinical scales and the associated Harris-lingoes subscales see Table 1.

Throughout the literature, the MMPI and its predecessor the MMPI-2 have been extensively studied in the chronic pain population for prognostic capabilities (Vendrig, 2000). Vendrig (2000) contends outcome prediction of the MMPI has been analyzed in the literature on three levels: primary, secondary, and tertiary outcome prediction from which PPS stems. In primary outcome prediction, researchers seek to evaluate the predictive capabilities of the MMPI to correctly identify within the normal population those who are at risk of developing a pain condition. Secondary outcome prediction with the MMPI attempts to predict which individuals from an acute pain population are most likely to develop chronic pain conditions based on individual scaled scores or profiles. In contrast, tertiary outcome prediction involves predicting treatment responders from non-responders within a chronic pain population based on pretreatment MMPI scaled scores or profiles. Vendrig (2000) asserts tertiary outcome prediction with the MMPI is the most widely studied for predicting surgical outcomes, making this a probable explanation for the common use of the MMPI in many PPS testing batteries.

According to Vendrig (2000), tertiary outcome prediction of the MMPI in surgical candidates was first studied in 1973 by Wilfling and colleagues. Patients in Wilfling's (1973) study were categorized into three groups: poor, fair, and good outcome, from

which those with poor to fair outcomes had elevated pretreatment MMPI scores on Scales 1 (Hs), 2 (D), and 3 (Hy) compared to those with good outcomes (as cited in Vendrig, 2000). In reviewing later studies, Vendrig (2000) reports Scale 1 (Hs) remained a frequent predictor and Scale 3 (Hy) to a lesser extent, while Scale 2 (D) oscillated in predictive power. As a result, Vendrig (2000) questions the suitability of the MMPI as a tool to prescreen surgical patients. In contrast, Block (1996), who developed the first PPS algorithm, asserts the MMPI is a useful psychometric tool that has been proven throughout the literature to contain several scale elevations that predict poor surgical outcome including elevations on Scales 1 (Hs), 2 (D), 3 (Hy), 4 (Pd), and 7 (Pt); however he cautions that outcomes were assessed differently from one study to the next. Despite these variations in methodology, Block (1996) contends elevations on Scales 1 (Hs) and 3 (Hy) consistently predicted poor surgical outcome.

In predicting SCS outcome success, only a few studies have systematically investigated the predictive capabilities of the MMPI even though it is commonly administered during PPS for SCS. Burchiel and colleagues (1995) examined the prediction literature for SCS and found only 3 studies, from the mid 70s to the early 90s, had examined the MMPI. Of these studies, two studies indicated Scales 1 (Hs) and 3 (Hy), while the other study indicated Scales 2 (D) and 9 (Ma) as prognostic factors for SCS success at follow-up greater than or equal to 6 months (Burchiel et al., 1995). With the publication of the MMPI-2 (Butcher et al., 1989), Burchiel et al. (1995) was first to examine the MMPI-2 for prognostic factors associated with SCS early outcomes. In their analysis of 40 patients implanted with SCS, Burchiel and researchers (1995) found that younger patients with less depression as measured by the MMPI-2 scale 2 (D) were more

likely to experience greater pain relief from SCS. In addition, patients who viewed their pain as more intense were found to report greater relief with SCS. From these significant correlations, Burchiel and colleagues (1995) were able to develop a prediction equation utilizing the MMPI-2 clinical Scale 2 (D), age, and the McGill Pain Questionnaire (evaluative component) to predict percent of change in reported pain as measured by the visual analogue scale (VAS). Burchiel and researchers (1995) were able to predict with 88% accuracy the patients' SCS outcome success at 3 month follow-up, as defined by >50% reduction in pain. The results of Burchiel's et al. (1995) study suggest the MMPI-2 may be a good tool for PPS, but more research is needed to confirm its ability to stand alone as a prognostic factor.

In an attempt to catch SCS treatment non-responders even earlier, Olson and colleagues (1998) examined the MMPI-2 for group differences and also for its predictive qualities in SCS trial outcomes. The motivation for identifying prognostic factors earlier in the screening process comes from the idea that knowing the likely prognosis earlier is more beneficial to the patient and all those involved in the patient's care. Olson et al. (1998) examined, retrospectively, 40 patients who had already been cleared medically and psychologically for a SCS trial procedure. Of these 40 patients, 23 patients (58%) were considered trial successes, and 17 patients (42%) were considered trial failures. Patients in the trial success group reported at least a 50% reduction in pain, whereas patients in the failure group reported less than 50% pain relief. Olson et al. (1998) analyzed the group means through multiple t tests for each clinical and validity scale of the MMPI-2 and found that patients in the trial success group had lower scale 2 (D) and

higher scale 9 (Ma) scores. Unfortunately, the likelihood of a Type I error increases when multiple t tests are used, therefore these results should be interpreted cautiously.

In a secondary analysis, Olson and colleagues (1998) included scale 2 (D), scale 9 (Ma), and scale 0 (Si) in a stepwise logistic regression and found that patients with less depression and more energy are more likely to have better outcomes after SCS trials. Although Olson and colleagues (1998) reported the MMPI-2 scale 2 (D) and scale 9 (Ma) to be prognostic factors for trial outcome, however it is unclear whether other scales of the MMPI-2 may be better predictor variables than scales 2 (D) and 9 (Ma). Seven out of the 10 clinical scales were not allowed into Olson's el al. (1998) regression model making it hard to know whether the other 7 scales of the MMPI-2 may predict better than scales 2 and 9. In addition, little is known about the accuracy of the prediction model in Olson's et al. (1998) study since no statistics were reported regarding the classification rate or model fit. Olson and colleagues (1998) only reported that scales 2 and 9 accounted for 25% of the variance in outcome and they proposed that many other factors could be contributing greatly to trial outcome.

*Study Rationale*

Overall, the research into tertiary outcome prediction (the prediction of treatment responders from nonresponders) of the MMPI-2 for SCS is very limited. Further research is needed to identify prognostic factors that can accurately classify those who will succeed and those who are likely to fail SCS trials. Currently, not enough is known about what psychosocial factors predict SCS trial and implant success or failure. In order to enhance appropriate selection of candidates and boost success rates, there must be strong evidence that psychosocial testing used for selection leads to promising prediction of SCS

trial and implant outcomes. The present study is an exploratory study seeking to further expand on the limited research of the prognostic value of the MMPI-2 in the early trial outcomes of SCS. Specifically, the present study will first attempt to replicate (using alternative statistical methods) Olson's et al. (1998) findings that scales 2 (D) and 9 (Ma) are predictive of SCS trial outcome. Next, the present study will explore content subscales of the MMPI-2 to further investigate tertiary outcome prediction of the MMPI-2 in SCS trials. Overall, the present study seeks to elucidate which, if any, components of the MMPI-2 provide predictive ability in determining SCS trial outcome.

The present study will use archival data from a multidisciplinary pain clinic in central Texas to replicate Olson and colleagues (1998) findings. The present study will analyze the MMPI-2 data from patients who underwent PPS protocol for SCS prior to receiving a SCS trial. PPS protocol at the pain clinic involved the administration of several psychometric tests following a clinical interview with a behavioral health provider prior to the scheduling of a SCS trial. The present study will only examine patients' data from the MMPI-2, as this was the only psychometric testing found to significantly contribute to SCS outcome prediction in Olson's et al. (1998) study. Once testing was complete as part of PPS protocol at the clinic, the behavioral health provider wrote up his or her impressions of the patient's strengths and weaknesses for a likely positive outcome, and in some cases, patients were asked to complete individual therapy before or after SCS procedures. The pain clinic did not have rigid standards regarding which patients were refereed for behavioral health services. If cleared for SCS procedures by behavioral health, the medical provider was given clearance to proceed with a SCS trial. Trials at this pain clinic were conducted using percutaneous methods

and trials typically lasted for 5-7 days, at which time trial success or failure was recorded in the patient's electronic medical file as either a percentage of pain relief or as a dichotomous variable (yes or no) based on the conversation between the patient and doctor. Once trial success was determined, the patient was allowed to schedule the SCS implant procedure, and at this point the decision to have the SCS implanted was completely up to the patient. Chart notes following the patient's decisions regarding SCS implantation were saved in the patient's electronic medical chart. The PPS protocol, trial lengths, and trial success criteria of the present study may vary from Olson's et al. (1998) study, but in general these differences should not be detrimental to replication especially if providers at both clinics followed standard administration of the MMPI-2.

*Research Questions*

In summary, the present study seeks to answer three main questions. First, can SCS trial outcome be correctly predicted from the MMPI-2 alone? Second, if SCS trial outcome can be predicted correctly, then which MMPI-2 scales or subscales are central in the prediction of trial outcome? Lastly, how good is the model at classifying patients into the correct trial outcome status? With regard to the first two questions, the present study expects to find that the MMPI-2 can be used as a predictive tool for SCS trials and that clinical scales 2 (D) and 9 (Ma) may be of central importance in predicting outcome, based on the results reported by Olson and colleagues (1998). Unfortunately, nothing about model fit or classification rates was reported in Olson's et al. (1998) study therefore it is not known whether these two scales provide the best model for SCS outcome prediction. Therefore, the present study will take an alternative statistical approach than Olson et al. (1998) in order to determine if clinical scales 2 (D) and 9 (Ma)

are the best predictors of SCS trial outcome or whether other MMPI-2 scales can provide a better fitting predictive model. The present study seeks to expand the number of MMPI-2 main clinical scales that have previously only been explored at one time so that the scales are allowed to compete against each other for the best predictive model in order to identify the best MMPI-2 predictors of SCS trial success.

After exploring the main clinical scales of the MMPI-2 through logistic regression, the present study will additionally explore a subset of Harris-Lingoes subscales to determine if better classification of SCS trial outcome can be achieved by breaking down the heterogeneity of the main clinical scales. The rationale for this approach is that content scales, such as the Harris-Lingoes, are intrinsically more homogeneous than the clinical scales as a whole, and therefore may provide a better predictive model by flushing out non-predictive content. In examining the Harris-Lingoes subscales, the hope is that better predictor variables are discovered bringing to light important aspects of the MMPI-2 that contribute to SCS trial outcome. This part of the analysis was completely exploratory. To date, there have been no studies analyzing the prognostic value of the Harris-Lingoes subscales, so it is largely unknown which, if any Harris-Lingoes subscales will significantly contribute to the regression model. In particular, the Harris-Lingoes subscales for clinical scales 2, and 9 are of special interest, since these scales have been implicated for their prognostic value for SCS trial outcome (Olson et al., 1998). Analysis of these subscales is expected to increase prediction by allowing non-predictive content (subscales) to be taken out and highly predictive content (subscales) to be left in the regression model. In doing so, the hope is to determine which combination of MMPI-2 subscales can correctly predict classification of SCS trial

outcome, leading to a better understanding of the types of candidates that tend to succeed versus fail SCS treatment.

# CHAPTER II

## METHOD

### *Participants*

The present study collected archival de-identified data, over the course of a 2-year period of time from all of 2007 and 2008, pulled from the electronic medical files of 59 chronic pain patients (33 women, 26 men) who underwent a PPS procedure, which included a review of the patient's medical and behavioral health charts by a behavioral health clinician, followed by a semi-structured interview, then the administration of psychological testing with the MMPI-2 prior to a SCS trial. All patients were being treated by Austin Pain Associates (APA), which is a multidisciplinary pain clinic in Austin, TX. All patients in the present study were referred, by the treating physician, to behavioral health clinicians at RestoreFx or other APA offices sites when required by third party payers or when the physician believed psychosocial factors could potentially cause difficulties for the SCS procedure and/or recovery.

Patients (N = 59) in the present study ranged in age from 26 to 87 years old (M = 53.92, S.D. = 14.16). The majority of these patients (47.5%) were diagnosed with FBSS, 23.7% were diagnosed with RSD, 1.7% was dually diagnosed with FBSS and RSD, and 27.1% were being treated for chronic pain conditions other than FBSS and RSD. Location of the pain being treated did not vary greatly, with 93.2% of the patients being

treated for low back and/or leg pain (37.3% low back pain, 35.6% low back and leg pain, and 20.3% lower extremity pain). Of these 59 patients, 71.2% (N = 42) were reported as trial successes and 28.8% (N = 17) were reported as failed trials in the patient's medical chart.

During the analysis, 16 participants (27.12%) were excluded from further analyses because these participants were believed to have invalid or questionable MMPI-2 profiles. These participants (N = 16) with invalid or questionable MMPI-2 profiles had validity scale elevations beyond what is considered normal validity elevations for chronic pain patients. The behavioral health examiner, with the aid of a clinical psychologist, made this judgment at the time of the psychometric testing report. Of these 16 participants (11 women, 5 men), 10 had successful trials and 6 had failed trials. The resulting screened sample consisted of 43 total participants (22 women, 21 men) reporting 32 successful trials and 11 failed trials. See Table 2 for details regarding the final sample, broken down by outcome group (success vs. failure).

**Table 2** Demographic Information per Trial Outcome Group

| **Trial Success**<br>**N = 32** | **Trial Failure**<br>**N = 11** |
|---|---|
| 15 Men (46.9%), 17 Women (53.1%) | 6 Men (54.5%), 5 Women (45.5%) |
| Ages:<br>26-87 (*Mdn* = 55.5) | Ages:<br>29-79 (*Mdn* = 55.0) |
| Condition:<br>17 FBSS (53.1%)<br>6 RSD (18.8%)<br>1 FBSS & RSD (3.1%)<br>8 Other (25.0%) | Condition:<br>3 FBSS (27.3%)<br>4 RSD (36.4%)<br>4 Other (36.4%) |
| Pain Location:<br>12 Low Back (37.5%)<br>14 Low Back & Leg (43.8%)<br>5 Lower Extremity (15.6%)<br>1 Upper Extremity (3.1%) | Pain Location:<br>4 Low Back (36.4%)<br>1 Low Back & Leg (9.1%)<br>4 Lower Extremity (36.4%)<br>2 Other (18.2) |

No other exclusion factors were imposed on the present study's sample in an attempt to increase generalizability to the actual chronic pain population seeking SCS treatment. By not limiting the present study's data through extensive exclusion criteria, the present study should give a fairly accurate viewing of the actual population of chronic pain patients seeking relief through spinal cord stimulation.

*Measures*

*Minnesota Multiphasic Personality Inventory-2 (MMPI-2).* The MMPI-2 (Butcher et al., 1989) consists of 567 true/false statements that measure participant's response patterns. Participant's response patterns were compared to a normal reference group as well as compared to different diagnostic groups of psychiatric patients to determine T scores. To score the MMPI-2, Q local software was used for all MMPI-2 evaluations to obtain T scores for the main clinical scales, validity scales, and content scales. Interpretation of the MMPI-2 clinical scales is based on scale elevations resulting from the participant's pattern of responding, not from individual item responses. The present study recorded T scores for the main clinical and validity scales as well as the Harris-Lingoes content subscales of the MMPI-2.

*Procedure*

The present study involved the collection of archival data in the form of both medical records and behavioral health records pertaining to pre-surgical evaluations for Spinal Cord Stimulators (SCS). IRB exemption approval was obtained from Texas State University-San Marcos prior to the collection and analysis of the archival data for the present study. Non-identifying data were abstracted from these electronic files and used in the present research database. The present study did not obtain any identifiable private

information or coding system that could potentially breach the privacy rights of the patients. All HIPAA regulations for de-identifying protected health information (PHI) for use in research were followed while collecting information from these electronic medical and behavioral health records. Additionally, all patients included in the present study signed an informed consent form prior to being provided with any medical and behavioral health services at APA and RestoreFx, respectively, stating that the patient's de-identified medical information may be used for research purposes in the future.

Participants for the present study (N = 59) were selected using the medical providers billing information for all of 2007 and 2008 for SCS trials and implants. From this list of 146 patients, each patient's medical and behavioral health records were searched to determine if the patients completed a presurgical psychological evaluations with psychological testing using the MMPI-2 prior to SCS trial. Originally, 71 patients (48.6%) were found to have completed PPS with psychological testing prior to SCS trial, although missing chart data excluded 12 patients from the present study because the original MMPI-2 scanned document could not be found for these patients. MMPI-2 profile validity was assessed by reading through the behavioral health clinician's psychological testing report in which the clinician reported the patient's MMPI-2 profile as valid, invalid, or of questionable validity. Additionally, data collected from the patient's original MMPI-2 results printout were recorded into the present study's database including the *cannot say* score (number of skipped items on the MMPI-2, ranging from 0-567, ≥ 11 indicates questionable profile and ≥30 indicates an invalid profile) and the MMPI-2 T scores (ranging from 30-120) for the main clinical and validity scales as well as for the Harris-Lingoes subscales. These data were collected

from each patient's medical chart as a scanned file of the Q local hardcopy printout of the MMPI-2 results.

Other data collected for the present study included patient demographic variables (non-PHI variables: age, sex, pain condition, and location of treated area), trial outcome status (success or failure), and profile validity (valid, questionable, or invalid MMPI-2 profile) taken from chart notes and clinical reports in the patient's medical and behavioral health charts. Trial success or failure was recorded in these medical charts one of two ways, either as a dichotomous variable based on the subjective reports of the patient (success or failure) or as percentage of pain relief (success = >50% relief), however to remain consistent, the present study recorded trial success or trial failure as a dichotomous value (success or failure) into the database.

*Analytic Strategy*

All data in the present study were statistically analyzed using SPSS v17.0 software. The analytic strategy for the present study was twofold. In the first part of the analysis, the data were screened for outliers, and the main clinical scales of the MMPI-2 were explored using a stepwise logistic regression (Forward: Likelihood Ratio method) to assess the ability of the clinical scales to classify patients correctly into trial outcome groups (success vs. failure). The default cut value for SPSS was changed from .50 to .30 for all logistic regressions to aid in the classification of trial outcome status since the proportion of trial success to trial failure in the study's population was approximately 70% trial success and 30% trial failure. Therefore, a cut value of .30 was appropriate to the actual percent of trial failures. For the first set of analyses, the present study attempted to replicate Olson's et al. (1998) findings that scales 2 (D) and 9 (Ma) of the

MMPI-2 are prognostic factors for SCS trial outcome. The present study chose alternative statistical methods than those utilized in Olson's et al. (1998) study in an effort to reduce the likelihood of a Type I error: instead of performing multiple t tests to determine the independent variables in the regression, the present study used a correlation matrix to identify problems of multicollinearity between the independent variables and to aid the decision as to which independent variables could be safely dropped from the regression model without affecting the classification rate of trial outcome status.

Due to the exploratory nature of the present study, the number of MMPI-2 clinical scales (IVs) entered into the regression model was greater than that of Olson's et al. (1998) study which only explored 3 clinical scales (2 (D), 9 (Ma), & 0 (Si)). The present study explored 8 independent variables including clinical scales 1 (Hs), 2 (D), 3 (Hy), 4 (Pd), 6 (Pa), 7 (Pt), 9 (Ma), and 0 (Si), while still maintaining at least a 5:1 ratio of cases (patients) to variables, necessary to maintain predictive power (Mertler & Vannatta, 2005). Due to the restrictions of a small sample size, clinical scales 5 (Mf) and 8 (Sc) were excluded from the regression model to increase predictive power. Scale 5 (Mf) was excluded because it is a measure of traditional gender roles, which did not seem to have much relevance in predicting trial outcome and it also did not significantly correlate with trial outcome ($p > .05$). Additionally, scale 8 (Sc) was excluded from the regression model because it was highly correlated with scale 7 (Pt) ($r = .910, p = .000$). Although both scales significantly correlated with trial outcome ($p < .05$), scale 7 was kept in the model over scale 8 because scale 7 was more strongly correlated with trial outcome ($r = .383, p = .011$; versus $r = .352, p = .021$).

In part two of the analysis, the Harris-Lingoes subscales of the MMPI-2 were explored using the same stepwise logistic regression (Forward: LR method) as in the first set of analyses. This analysis of the Harris-Lingoes subscales is an attempt to find greater tertiary outcome prediction of the MMPI-2 than is possible with just an analysis of the very heterogeneous clinical scales by themselves. The hope is that the present study will see an improvement in the predictive capabilities of the MMPI-2 by using the Harris-Lingoes subscales. In order to test this theory, the Harris-Lingoes subscales of interest (based on the results of the first set of analyses; D1-D5, Ma1-Ma4, & Pd1-Pd5) were examined a group at a time and their classification rates and model fit were compared with the classification rates and model fit produced by the corresponding parent scale alone. For an overall summary of the predictive models analyzed in part one and two of the present study see Table 3.

**Table 3** Summary of the Predictive Models Generated by Logistic Regression for Part I & Part II of the Statistical Analyses

| Analysis | Model | N = | IVs Explored | Predictor variable(s) | Compared w/ |
|---|---|---|---|---|---|
| Part I | 1 | 59 | Clinical scales: 1,2,3,4,6,7,9,0 | Scale 4 | Model 2 |
| Part I | 2 | 43 | Clinical scales: 1,2,3,4,6,7,9,0 | Scale 4 | Models 1 & 3 |
| Part I | 3 | 43 | Clinical scales: 2,9,0 | Scale 9 | Model 2 |
| Part II | 4 | 43 | Harris-Lingoes: D1, D2, D3, D4, D5 | D2 & D5 | Model 5 |
| Part II | 5 | 43 | Clinical scale: 2 (Enter method) | Scale 2* | Model 4 |
| Part II | 6 | 43 | Harris-Lingoes: Ma1, Ma2, Ma3, Ma4 | Ma2 | Model 3 |
| Part II | 7 | 43 | Harris-Lingoes: Pd1, Pd2, Pd3, Pd4, Pd5 | Pd4 | Model 2 |

*Denotes non-significant predictor variable, $p = .418$

# CHAPTER III

## RESULTS

*Primary analyses*

A stepwise logistic regression (Forward: LR method) was conducted to determine which, if any MMPI-2 main clinical scales were predictors of SCS trial outcome. Data screening led to the elimination of some but not all outliers. When explored case by case, several outliers were found to have invalid or questionable MMPI-2 profiles based on two factors: reported validity in the examiner's report and a *cannot say* raw score ≥ 11. Therefore, in part one of the analysis, the first logistic regression (exploring IV scales: 1, 2, 3, 4, 6, 7, 9, & 0) was conducted with all participants left in (N = 59) and with the questionable and invalid MMPI-2 profiles taken out (N = 43). Filtering out cases with questionable and invalid MMPI-2 profiles allowed for a better fitting regression model (see Figure 1 at end of chapter). As a result, all further analyses were done with the filter on (N = 43), excluding 16 participants.

Regression results of the overall model (N = 43, exploring IV scales: 1, 2, 3, 4, 6, 7, 9, & 0) indicate clinical scale 4 (Pd) of the MMPI-2 was statistically reliable in distinguishing between trial success and trial failure outcomes (-2 Log Likelihood = 35.610; Model fit: $\chi^2$ (1) = 13.292, $p$ = .000; $R^2$ = .266-.391 (Cox & Snell $R^2$ &

Nagelkerke $R^2$, respectively); Hosmer-Lemeshow Test: $\chi^2$ (7) = 5.182, $p$ = .638). Clinical scale 4 (Pd) was able to correctly classify 81.4% of all cases, 84.4% into the trial success group and 72.7% into the failed trial group (cut value = .30).

Another regression model solely exploring scales 2 (D), 9 (Ma), and 0 (Si) was conducted in an attempt to replicate Olson's et al. (1998) stepwise logistic regression results indicating that scales 2 and 9 were predictors of trial outcome accounting for 25% of the variance. Regression results did not support Olson's et al. (1998) findings. Only scale 9 (Ma) appeared to distinguishing between trial outcome status (-2 Log Likelihood = 44.584; Model fit: $\chi^2$ (1) = 4.318, $p$ = .038; $R^2$ = .096-.141). Moreover, the overall classification was poor (65.1%) with 75% of cases being correctly classified as trial success and only 36.4% of cases being correctly classified as trial failures (cut value = .30). With the trial failure classification rate being so low (36.4%) and the Hosmer-Lemeshow Test approaching significance ($\chi^2$ (8) = 14.719, $p$ = .065), the model fit for the predictor (Scale 9) was questionable.

*Secondary Analyses*

In part two of the analyses, several stepwise logistic regressions (Forward: LR method) were conducted to analyze the Harris-Lingoes subscales ability to predict trial outcome in comparison with the corresponding parent scale alone. In the first regression model Harris-Lingoes subscales (D1-D5) of the parent scale 2 (D) were explored. Regression results indicate Harris-Lingoes subscales D2 and D5 were statistically reliable in distinguishing between trial outcome status (perhaps due to an enhancer/suppressor effect present in the data; -2 Log Likelihood = 33.379; Model fit: $\chi^2$ (2) = 15.524, $p$ = .000; $R^2$ = .303-.446; Hosmer-Lemeshow Test: $\chi^2$ (8) = 4.105, $p$ = .848). Harris-Lingoes

subscale D5 (Exp*(B)* = 1.121 (Step 1), 1.208 (Step 2); as enhanced by D2, Exp*(B)* = .878) was able to correctly classify 79.1% of all cases, 81.3% correctly classified as trial successes and 72.7 % correctly classified as trial failures (cut value = .30).

When the parent scale (clinical scale 2) was analyzed alone by logistic regression (Enter method), scale 2 (D) was not found to be a statistically reliable predictor of trial outcome (-2 Log Likelihood = 48.245; Model fit: $\chi^2$ (1) = 0.657, $p$ = .418; $R^2$ = .015-.022; Hosmer-Lemeshow Test: $\chi^2$ (8) = 6.877, $p$ = .550). Although scale 2 (D) was able to correctly classify 81.3% of the trial success group, the model was only able to correctly classify 18.2% of the failed trial group, dropping overall classification to 65.1% (cut value = .30). Overall, scale 2 (D) did not generate a good predictive model for trial outcome, but when analyzing the Harris-Lingoes subscales of the parent scale (clinical scale 2), D2 and D5 were able to generate a good predictive model for trial outcome.

The second set of Harris-Lingoes subscales (Ma1-Ma4), corresponding to parent scale 9 (Ma) were explored by stepwise logistic regression (Forward: LR method). Regression results indicate Harris-Lingoes subscale Ma2 was statistically reliable in distinguishing between trial outcome status (-2 Log Likelihood = 40.150; Model fit: $\chi^2$ (1) = 8.752, $p$ = .003; $R^2$ = .184-.271; Hosmer-Lemeshow Test: $\chi^2$ (7) = 7.522, $p$ = .377). Harris-Lingoes subscale Ma2 was able to correctly classify 72.1% of all cases, 75% into the trial success group and 63.6% into the trial failure group (cut value = .30). When comparing this model to an earlier model (in part one of the analysis where the predictor was scale 9) Ma2 provided a much better predictive model than the predictive model for the parent scale (clinical scale 9) where the overall classification rate was 65.1%.

Lastly, the Harris-Lingoes subscales (Pd1-Pd5) of the parent scale (clinical scale 4) were analyzed using a stepwise logistic regression (Forward: LR method). Regression results indicate Harris-Lingoes subscale Pd4 was statistically reliable in distinguishing between trial success and trial failure (-2 Log Likelihood = 36.874; Model fit: $\chi^2$ (1) = 12.028, $p$ = .001; $R^2$ = .244-.359; Hosmer-Lemeshow Test: $\chi^2$ (7) = 1.867, $p$ = .967). Harris-Lingoes subscale Pd4 correctly classified 78.1% of the trial success group, 72.7% of the trial failure group, and 76.7% of cases overall (cut value = .30). Although the predictive model for Pd4 had a good classification rate and overall fit, the predictive model for the parent scale (clinical scale 4; generated in part one of the analysis) had a marginally better overall classification rate of 81.4% and a slightly better fitting predictive model (Model fit: $\chi^2$ (1) = 13.292, $p$ = .000). For a comparison of all the predictive models' classification rates for trial outcome see Figure 1.

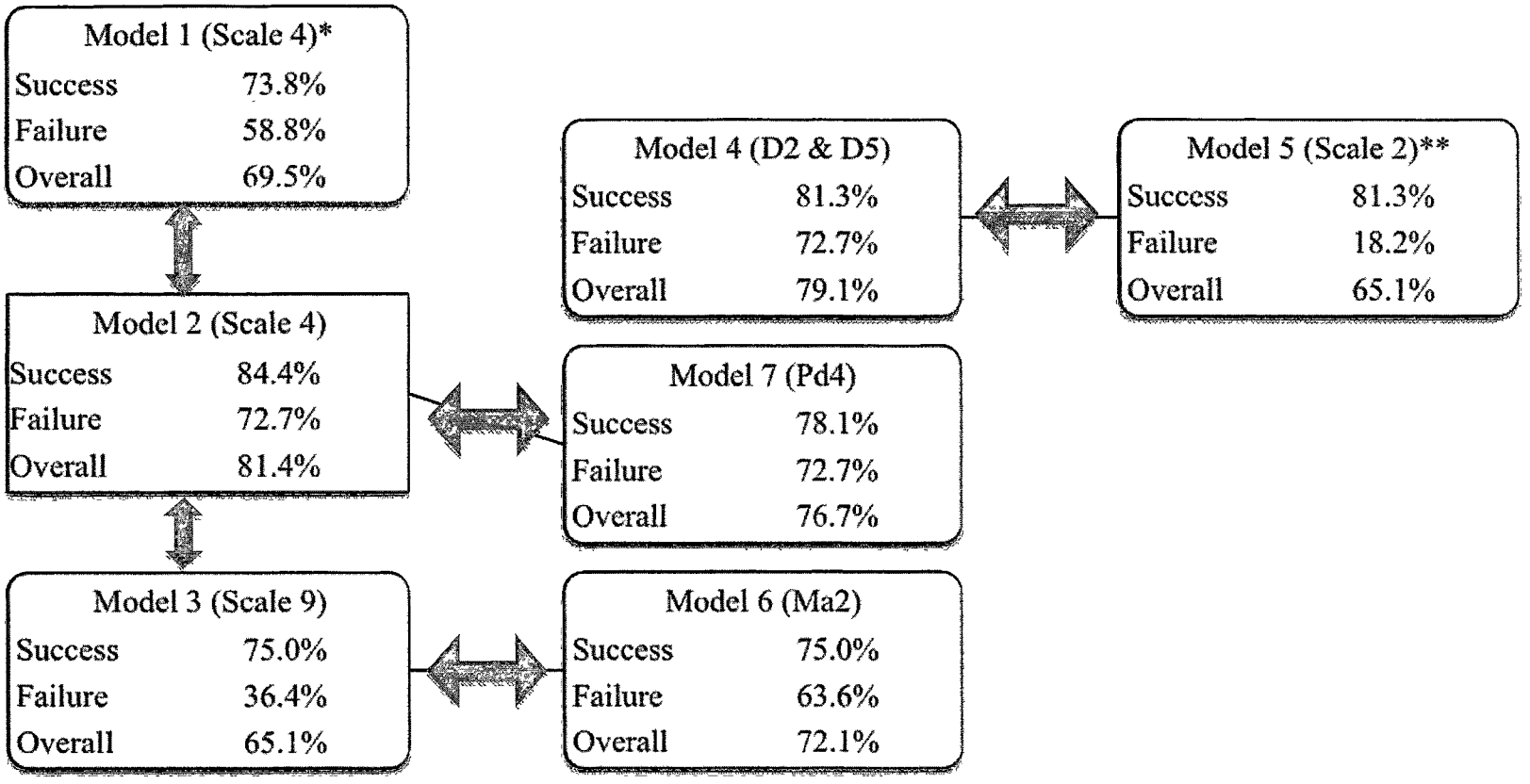


**Figure 1** Trial Outcome Classification Rates per Predictive Model.

Note: Arrows indicate direct model comparisons
* Denotes sample size N = 59, all cases included in this model. N = 43 for predictive models 2-7.
**Denotes non-significant predictor variable, $p = .418$

# CHAPTER IV

## DISCUSSION

Tertiary outcome prediction for SCS trials is still in its infancy and much more research is needed to identify predictive factors that can be used to improve PPS protocols and selection criteria. The purpose of the present study was to investigate whether the MMPI-2 commonly used as a part of PPS testing protocols can predict with accuracy the likelihood of SCS trial success or trial failure. Currently, the MMPI-2 is used and interpreted as having the capability to spot likely treatment non-responders. These judgments have commonly been a result of clinical opinion rather than empirical support; therefore the present study sought to scientifically validate the use of the MMPI-2 in SCS PPS protocol. In all, 43 patients were retrospectively analyzed using a forward logistic regression to explore whether the MMPI-2 could accurately predict SCS trial outcome. As predicted, the MMPI-2 generated a predictive model utilizing the clinical scales (as seen in the primary analyses) and the Harris-Lingoes subscales (as seen in the secondary analyses).

In part one of the statistical analysis, clinical scale 4 (Pd) of the MMPI-2 was the independent variable of central importance to outcome prediction. The results indicate that the MMPI-2 clinical scale 4 (Pd) correctly identified trial outcome status with an overall classification rate of 81.4%. Clinical scale 4 (Pd: Psychopathic Deviate) was first

developed to capture psychopathic personality disorders but due to the diversity of the content that forms the scale, there are many reasons a patient may elevate on this scale (Friedman et al., 2001). Generally, a high scale 4 implies social maladjustment leading to feelings of alienation (Friedman et al., 2001). Traumatogenic experiences early in life may account for an elevation on scale 4 and as a result of these experiences these patients may have poor frustration tolerance and antisocial attitudes (Friedman et al., 2001). Scale 4 elevations also overlap with depressive symptomology to some degree (7 items on scale 4 overlap with scale 2; Friedman et al., 2001). Feelings of emptiness and alienation often characterize patients with an elevated scale 4, which may or may not be a sign of situational stress (Friedman et al., 2001).

In the present study, patients with higher scale 4 scores were more likely to fail trial. Scale 4 proved to be of central importance in predicting SCS outcome and did a much better job of classification than scales 2 & 9 as postulated by Olson et al. (1998). Support for Olson's et al. (1998) results were not found in the present study, with scale 2 not contributing any predictive power to the predictive model and with scale 9 only producing a moderate overall classification rate (65.1%) of trial outcome. It is not surprising that Olson's et al. (1998) results could not be supported with the present study because it is very likely that Olson's et al. (1998) results were the product of Type I error. In addition, Olson's et al. (1998) study did not report enough statistical information regarding their predictive model to determine whether or not goodness-of-fit was established for the predictive model, and if so what the classification rates were for predicting SCS trial outcomes. This lack of information coupled with the possibility of a

Type I error when choosing their predictor variables could explain why the present study was unable to replicate Olson's et al. (1998) results.

In part two of the present study's analysis, the Harris-Lingoes subscales were analyzed for predictive power in relation to the clinical scales analyzed in part one of the analysis. Harris-Lingoes subscales were analyzed separately in the present study because sample size (N = 43) was too small to place all Harris-Lingoes subscales into the regression model at one time. In generating multiple predictive models rather than one predictive model including all Harris-Lingoes subscales, the results of the present study are speculative and therefore should be interpreted with caution. The results of the present study are not able to determine how sets (coinciding with the respective parent scales) of Harris-Lingoes subscales from different parent scales may work together to produce a predictive model. By running separate regression models for each set of Harris-Lingoes subscales the present study was only able to test how the Harris-Lingoes subscales would compare against the clinical (parent) scale alone as a predictor variable. The results indicated that the Harris-Lingoes subscales generated better predictive models but only when the parent scale by itself did not generate a very strong predictive model. These results are discussed in more detail below.

Even though the present study was unable to replicate Olson's et al. (1998) findings, which indicated scales 2 and 9 were predictor variables for trial outcome, some Harris-Lingoes subscales coinciding with clinical (parent) scales 2 and 9 were found to have predictive power. By allowing the non-predictive subscales to drop out of the predictive model, subscales D2 and D5 of the parent scale 2 (D) were able to create a predictive model where scale 2 by itself could not, and this model is comparable with the

clinical scale 4 predictive model (classifying 81.4% overall). Specifically, Harris-Lingoes subscales D2 and D5 for parent scale 2 (D) generated a good predictive model capable of classifying 79.1% of all cases into the appropriate trial outcome status. In this predictive model, D5 is the predictor variable of central importance to trial outcome, whereas D2 has no correlation with trial outcome. It appears that D2 is suppressing the error in D5, thereby enhancing the ability of D5 to predict trial outcome. Harris-Lingoes subscale D5 (Brooding) is comprised of 10 items from the 57-item parent scale which measure general distress and maladjustment to one's social environment and/or situational circumstances. The enhancer/suppressor variable, D2 (Psychomotor Retardation), is comprised of 14 items, in which elevations signify a lack of energy or initiative. In this predictive model, patients with higher D5 scores appear more likely to fail SCS trial (due to the enhancer/suppressor effect present in data). Overall, this predictive model suggests that maladjusted patients were more likely to fail SCS trials than well-adjusted patients who were more likely to succeed at SCS trials.

When Harris-Lingoes subscales for parent scale 9 were analyzed, a better predictive model was generated with Ma2 as the predictor variable for trial outcome, although this model did not have as great of a classification rate (72.1%) as the D2 and D5 predictive model (79.1%). In this predictive model, Ma2 (Psychomotor Acceleration), often associated with increased energy, was more likely to be elevated in patients who failed trial than in patients who had a successful trial. Interestingly, the results of the present study, with regard to parent scale 9, are contradictory to Olson's et al. (1998) study, which found that patients with increased energy were more likely to succeed at trial. The reason for this contradiction is unknown and may be due to an

artifact of the small sample sizes in both studies, or it may be the result of comparing two models lacking in strong predictive power. Unfortunately, Olson's et al. (1998) study did not report any statistics on their predictive model's goodness-of-fit, classification rates, or odds ratios, therefore direct comparison of predictive models is not possible. Overall, it appears that breaking up the content of parent scales 2 and 9 into their respective Harris-Lingoes subscales allows for the removal of non-predictive subscales, thereby allowing better predictive models to be obtained.

Interestingly, when analyzing the Harris-Lingoes subscales for parent scale 4, the subscale (Pd4) model did not produce a greater overall classification rate (76.7%) than the parent scale (4) alone (81.4%). Although, one could argue that a classification rate of 76.7% is still a sign of a very good predictive model especially when considering the fact that the predictor, subscale Pd4, is comprised on 13 items versus the 50 items that make up the parent scale. Pd4 (Social Alienation) describes people who feel socially alienated from others and are characteristically vulnerable, lonely, and unhappy due to a lack of belonging (Friedman et al., 2001). Patients with elevated Pd4 scores often externalize blame and as a result often feel they have been unfairly treated (Friedman et al., 2001). In the present study, patients with higher Pd4 scores were more likely to fail trial than those with lower Pd4 scores. This finding may suggest that social support and a sense of belonging is an important factor for trial success. Additionally, if a patient lacks trust in his or her medical providers, then he or she may be expecting treatment with SCS to fail from the very start and the lack of social support surrounding the patient may make recovery from SCS procedures very difficult. To date, no research exists testing these assumptions therefore these assumptions remain speculative. Furthermore, the present

study is the first study to indicate clinical scale 4 and Harris-Lingoes subscale Pd4 as tertiary outcome predictors for SCS trials, therefore caution must be taken in applying these results clinically without first replicating these findings. The results of the present study may not hold true when tested among other samples.

In conclusion, the results of the present study have shown that the MMPI-2 can stand alone as a predictive measure but only certain scales and subscales appear to be useful in predicting SCS trial outcomes. Primary analyses indicated clinical scale 4 (Pd) provided the best predictive model for SCS trial outcome. Secondary analyses indicated Harris-Lingoes subscales D2 and D5 provided the best predictive model for SCS trial outcome and this model was comparable to the predictive model generated in the primary analyses. Future research is needed to replicate these results, especially with larger sample sizes in order to enter more independent variables into the regression model without violating the 5:1 ratio of cases to variables to maintain predictive power. Future studies should further explore the predictive capabilities of content scales such as the Harris-Lingoes subscales since it appears that these subscales allow for better predictive model when the parent scales are not generating models with good fit or classification rates.

Overall, more research needs to be conducted in order to determine if the MMPI-2 is the right measure for tertiary outcome prediction for SCS trials, and which subscales might have the greatest utility in PPS. Although preliminary, the results of the current study suggest that Harris-Lingoes subscales could be useful in predicting SCS trial outcome even when the coinciding clinical scales as a whole do not prove to be predictive. At the moment, PPS protocols for SCS contain many exclusionary criteria

lacking in strong empirical validation. The intent of the present study has been to take a step back and examine psychological testing for its ability to predict outcomes in SCS trials, therefore any changes to SCS PPS protocol is beyond the scope of the present study.

*Limitations*

There are several limitations of the present study. First, the present study assumed that the MMPI-2 was a good predictor of SCS trial success or failure based on its current use in PPS testing protocols for SCS, even though this assumption is strongly based on clinical opinion rather than strong empirical support. All studies to date on tertiary outcome prediction of the MMPI-2 for SCS, including the present study, have been retrospective in nature with small sample sizes. These previous studies and the present study potentially suffer from selection bias due to current selection protocols which screen out SCS candidates based on a set of unconfirmed risk factors. Furthermore, these retrospective studies and the present study have not included information about SCS outcomes of patients who were screened out after PPS evaluations. These patients not allowed to proceed with SCS procedures have been held back because of clinical judgment indicating likely risk of failure rather than because of empirically validated evidence of these factors predicting SCS failure. Unfortunately, it is a limitation of all retrospective studies that have screened out patients utilizing the current PPS protocols for SCS. Regrettably, the present study was not able to identify the subset of patients that underwent a PPS evaluation for SCS but were not cleared for SCS trial, therefore the present study cannot say how these patients differed from patients cleared for trial.

Other limitations of the present study include the overall narrowed focus and small sample size. The present study only examined a small set of demographic variables and the MMPI-2. Previous studies of SCS tertiary outcome prediction have found age and the McGill Pain Questionnaire (MPQ) to have predictive capabilities (Burchiel et al., 1995). It is very likely a multitude of factors contribute to SCS trial success or trial failure and this study only examined one psychometric test for its predictive capabilities while ignoring other commonly used psychometric tests in PPS protocols for SCS. Although this narrowed approach greatly limits the possibility of discovering predictive factors for SCS outcomes, it is beneficial to know whether or not the MMPI-2 can stand alone and still account for a majority of the variance in SCS outcome prediction. The present study did find that the MMPI-2 could stand alone from other psychometric tests and still generate a predictive model although the present study may have been limited by a small sample size (N = 43). To maintain predictive power, no more than 8 variables were entered into a regression model at a time. With a restriction on the number of variables entered at a time the possibilities of finding better predictive models was limited. For example, the Harris-Lingoes subscales were analyzed a set at a time due to restrictions on the number of variables entered, but if the study had a larger sample size it may have been possible to enter in all sets of the Harris-Lingoes subscales, which may have produced a much better predictive model. Also with a larger sample size, the present study may have been able to introduce other diagnostic measures into the predictive model, such as the MPQ, which was found to be predictive in Burchiel's et al. (1995) study.

*Future Directions*

Despite the limitations of the present study, several possibilities for future research and clinical application of the results exist. The present study has demonstrated that tertiary outcome prediction with the MMPI-2 is possible, but these results may only hold true for the current sample and may not generalize to other samples. Future studies replicating these findings would deeply impact the state of the literature. Studies that can validate psychometric testing as tertiary outcome predictors would aid the clinical selection of SCS candidates for the procedure. Empirically validated prognostic factors are needed due to the fact that all studies into SCS tertiary outcome prediction have been done with very small samples that likely suffer from selection bias.

In the future, empirically validated prognostic variables could be used clinically to help intervene with the patient before a SCS trial procedure is done in order to improve the patient's chances of a positive outcome with SCS therapy. We must remember that there is often a lot at stake for the patient regarding the SCS outcome, since SCS therapy has been often used as a last resort—after countless treatment failures (see Kay et al., 2001; Sundaraj et al., 2005; and Van Buyten et al., 2001). Gatchel and colleagues (2007) explain chronic pain patients often feel rejected and blamed when they do not respond to treatment creating emotional distress and further perpetuating their desire to find a treatment that works. With each failed treatment, these patients' options begin to diminish and the stakes of finding relief are raised with each successive failed treatment, therefore subsequent treatment failures are especially devastating.

Additionally, special interest in PPS prediction has become increasingly important in recent years by 3$^{rd}$ party payers since SCS therapy requires a large economic input

initially, but becomes more cost-effective over time if the patient has success. Bell and colleagues (1997) investigated the cost-effectiveness of SCS therapy in comparison with non-SCS treatments for FBSS patients. Bell and colleagues (1997) reported that patients who responded favorably to SCS therapy reduced their need for medical care so much that SCS paid for itself within 2.1 years. Furthermore, regardless of SCS clinical effectiveness, medical cost savings were seen within 5.5 years on average for patients who underwent SCS therapy (Bell et al., 1997). Consequently, any research identifying prognostic screening tools that may increase SCS success rates should be of interest to 3rd party payers, because patients with favorable outcomes will lead to greater medical cost savings.

Future research indicating the predictive qualities of diagnostic tools such as the MMPI-2 for SCS outcomes may lead to many advances in PPS protocols and screening criteria. However, the incorporation of PPS protocols into standard screening for SCS may be difficult to achieve. Despite the general acceptance and acclaim of the biopsychosocial model from which PPS protocols have been developed, treatment of chronic pain today is still largely governed by biomedical principles, therefore clinicians and medical providers still debate the importance of psychosocial factors in predicting SCS outcome success. Future research conducted by medical providers incorporating the principles of the biopsychosocial model is greatly needed in order to determine which, if any psychosocial factors are important in the outcome of SCS therapy. Finally, the recommendations of the proposed study are that future research studies take a step back and work to first empirically validate psychosocial variables they believe to be risk

factors for SCS therapy before creating screening protocols that could be denying a small subset of pain patient-responders from receiving a chance at pain relief.

## REFERENCES


American Pain Foundation. (2009). *Pain facts & figures.* Retrieved May 11, 2009 from http://www.painfoundation.org/newsroom/reporter-resources/pain-facts-figures.html

Bell, G. K., Kidd, D., & North, R. B. (1997). Cost-effectiveness analysis of spinal cord stimulation in treatment of failed back surgery syndrome. *Journal of Pain and Symptom Management, 13(5),* 286-295.

Beltrutti, D., Lamberto, A., Barolat, G., Bruehl, S., Doleys, D., Krames, E., et al. (2004). The psychological assessment of candidates for spinal cord stimulation for chronic pain management. *Pain Practice, 4(3),* 204-221.

Block, A. R. (1996). *Presurgical psychological screening in chronic pain syndromes: A guide for the behavioral health practitioner.* Mahwah, NJ: Lawrence Erlbaum Associates.

Block, A. R., Gatchel, R. J., Deardorff, W. W., & Guyer, R. D. (2003). *The psychology of spine surgery.* Washington, DC: American Psychological Association.

Burchiel, K. J., Anderson, V. C., Wilson, B. J., Denison, D. B., Olson, K. A., & Shatin, D. (1995). Prognostic factors of spinal cord stimulation for chronic back and leg pain. *Neurosurgery, 36(6),* 1101-1111.

Butcher, J. N., Dahlstrom, W. G., Graham, J. R., Tellegen, A., & Kaemmer, B. (1989). *Minnesota Multiphasic Personality Inventory-2 (MMPI-2): Manual for administration and scoring.* Minneapolis: University of Minnesota Press.

Deer, T., & Masone, R. J. (2008). Selection of spinal cord stimulation candidates for the treatment of chronic pain. *Pain Medicine, 9(S1),* S82-S92.

Doleys, D. M. (2002) Preparing patients for implantable technologies. In D. C. Turk & R. J. Gatchel (Eds.), *Psychological approaches to pain management: A practitioner's handbook* (2nd ed., pp. 334-348). New York: The Guilford Press.

Doleys, D., & Olson, K. (1997). *Psychological assessment and intervention in implantable pain therapies.* [Brochure]. Minneapolis, MN: Medtronic.

Friedman, A. F., Lewak, R., Nichols, D. S., & Webb, J. T. (2001). *Psychological assessment with the MMPI-2.* Mahwah, NJ: Lawrence Erlbaum Associates.

Gatchel, R. J. (2001). A biopsychosocial overview of pretreatment screening of patients with pain. *The Clinical Journal of Pain, 17,* 192-199.

Gatchel, R., Peng, Y., Peters, M., Fuchs, P., & Turk, D. (2007). The biopsychosocial approach to chronic pain: Scientific advances and future directions. *Psychological Bulletin, 133(4),* 581-624.

Heckler, D. R., Gatchel, R. J., Lou, L., Witworth, T., Bernstein, D., & Stowell, A. (2007). Presurgical behavioral medicine evaluation (PBME) for implantable devices for pain management: A 1-year prospective study. *Pain Practice, 7(2),* 110-122.

Holsheimer, J. (2002). Technological innovation in spinal cord stimulation. In K. J. Burchiel, *Surgical Management of Pain* (pp.933-947). New York: Thieme.

Joint Commission on Accreditation of Healthcare Organizations. (2000). *Pain assessment and management: An organizational approach.* Oakbrook, IL: Author.

Kay, A. D., Mcintyre, M. D., Macrae, W. A., & Varma, T. R. K. (2001). Spinal cord stimulation—A long-term evaluation in patients with chronic pain. *British Jounal of Neurosurgery, 15(4),* 335-341.

Leveque, J., Villavicencio, A., Bulsara, K., Rubin, L, & Gorecki, J. (2001). Spinal cord stimulation for failed back surgery syndrome. *Neuromodulation, 4(1),* 1-9.

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

Mertler, C. A., & Vannatta, R. A. (2005). *Advanced and multivariate statistical methods (3rd ed.).* Glendale, CA: Pyrczak Publishing.

National Institutes of Health. (1998). *The NIH guide: New directions in pain research I.* Washington, DC: U.S. Government Printing Office.

National Center for Health Statistics. (2006, November 15). *New report finds pain affects millions of Americans.* Retrieved May 11, 2009, from http://www.cdc.gov/nchs/pressroom/06facts/hus06.htm

Nelson, D., Kinnington, M., Novy, D. M., & Squitieri, P. (1996). Psychological selection criteria for implantable spinal cord stimulators. *Pain Forum, 5(2),* 93-103.

North, R., & Guarino, A. (1999). Spinal cord stimulation for failed back surgery syndrome: Technical advances, patient selection and outcome. *Neuromodulation, 2(3),* 171-178.

North, R. B., Kidd, D. H., Wimberly, R. L., & Edwin, D. (1996). Prognostic value of psychological testing in patients undergoing spinal cord stimulation: A prospective study. *Neurosurgery, 39(2),* 301-311.

North, R. B., Kidd, D. H. Zahurak, M., James, C. S., & Long, D. M. (1993). Spinal cord stimulation for chronic, intractable pain: Experience over two decades. *Neurosurgery, 32(3),* 384-395.

North, R., & Wetzel, F. (2002). Spinal cord stimulation for chronic pain of spinal origin. *Spine, 27(22),* 2584-2591.

Oakley, J. C. (2003). Spinal cord stimulation: Patient selection, technique, and outcomes. *Neurosurgery Clinics of North America, 14(3),* 365-380.

Olson, K., Bedder, M., Anderson, V., Burchiel, K., & Villanueva, M. (1998). Psychological variables associated with outcome of spinal cord stimulation trials. *Neuromodulation, 1(1),* 6-13.

Prager, J., & Jacobs, M. (2001). Evaluation of patients for implantable pain modalities: Medical and behavioral assessment. *The Clinical Journal of Pain, 17,* 206-214.

Robinson, M. E., & Riley, J. L., III. (1999). Models of Pain. In A. R. Block, E. F. Kremer, & E. Fernandez (Eds.), *Handbook of pain syndromes* (pp. 23-40). Mahwah, NJ: Lawrence Erlbaum Associates.

Ruchinskas, R., O'Grady, T. (2000). Psychological variables predict decisions regarding implantation of a spinal cord stimulator. *Neuromodulation, 3(4),* 183-189.

Schocket, K., Gatchel, R. J., Stowell, A., Deschner, M., Robinson, R., Lou, L., et al. (2008). A demonstration of a presurgical behavioral medicine evaluation for categorizing patients for implantable therapies: A preliminary study. *Neuromodulation, 11(4),* 237-248.

Sundaraj, S. R., Johnstone, C., Noore, F., Wynn, P, & Castro, M. (2005). Spinal cord stimulation: A seven-year audit. *Journal of Clinical Neuroscience, 12(3),* 264-270.

Turk, D. C., & Burwinkle, T. (2005). Clinical outcomes, cost-effectiveness, and the role of psychology in treatments for chronic pain sufferers. *Professional Psychology: Research and Practice, 36(6),* 602-610.

Turk, D. C. & Monarch, E. S. (2002). Biopsychosocial perspective on chronic pain. In D. C. Turk & R. J. Gatchel (Eds.), *Psychological approaches to pain management: A practitioner's handbook* (2nd ed., pp. 3-29). New York: The Guilford Press.

Turner, J. A., Loeser, J. D., & Bell, K. G. (1995). Spinal cord stimulation for chronic low back pain: A systematic literature synthesis. *Neurosurgery, 37(6),* 1088-1096.

U.S. Bureau of the Census. (1996). *Statistical abstract of the United States: 1996* (116th ed.). Washington, DC: U.S. Government Printing Office.

Van Buyten, J., Van Zundert, J., Vueghs, P., & Vanduffel, L. (2001). Efficacy of spinal cord stimulation: 10 years of experience in a pain centre in Belgium. *European Journal of Pain, 5,* 299-307.

Van Dorsten, B. (2006). Psychological considerations in preparing patients for implantation procedures. *Pain Medicine, 7(S1),* S47-S57.

Vendrig, A. A. (2000). The Minnesota Multiphasic Personality Inventory and chronic pain: A conceptual analysis of a long-standing but complicated relationship. *Clinical Psychology Review, 20(5),* 533-559.

Zautra, A. (2003). *Emotions, stress, and health.* New York: Oxford University Press.

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