

PRESURGICAL BEHAVIORAL MEDICINE EVALUATION FOR IMPLANTABLE
DEVICES FOR PAIN MANAGEMENT: CLINICAL EFFECTIVENESS
FOR PREDICTING OUTCOMES

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To my husband
Dr. S. Matthew Schocket
With all my love, gratitude, and respect

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DEVICES FOR PAIN MANAGEMENT: CLINICAL EFFECTIVENESS
FOR PREDICTING OUTCOMES

By

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The current study attempts to apply a presurgical psychological screening algorithm to a subset of patients being considered to receive implantable pain management devices, specifically spinal cord stimulators and intrathecal drug delivery systems. The Presurgical Behavioral Medicine Evaluation (PBME) algorithm was designed to evaluate patients prior to spine surgery. The algorithm showed strong outcome predictability in previous studies (Block *et al.*, 2003). A PBME was administered to 60 patients being evaluated for implantable devices at a major pain center that provides interdisciplinary pain management to patients. Patients were classified into

one of five prognostic categories including Green, Yellow-I, Yellow-II, Red-I, and Red-II. This study sought to elucidate the characteristics of patients falling into the separate prognostic categories. Analyses revealed that males were more likely than females to fall in the Green and Yellow-I groups and patients receiving disability were more commonly found in the Red and Yellow-II groups. The biopsychosocial profiles of each category were examined using various physical/functional and psychosocial measures. As hypothesized, the Green group, with the lowest mean scores for each measure, yielded the most positive biopsychosocial profile at initial evaluation. The Green group reported low levels of depression and little impairment in physical functioning. The Red group obtained the highest mean scores, indicating decreased biopsychosocial functioning at initial evaluation. More specifically, the Red group experienced more depressive symptomatology and decreased physical functioning at the time of the initial evaluation. Additionally, the Red group had a greater number of medical risk factors and the presence of adverse clinical features at onset, and was more likely to use catastrophizing as a coping strategy. The patients were also compared at follow-up showing improvements on most physical/functional and psychosocial measures. Lastly, regression analyses were conducted to elucidate those factors most predictive of prognostic assignments. Thus, the algorithm was able to correctly classify those patients who were and were not appropriate candidates for surgery by collecting and analyzing data with regard to the overall biopsychosocial functioning of patients.

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LIST OF ABBREVIATIONS

ADL	Activities of Daily Living
ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
BDI	Beck Depression Inventory
CI	Confidence Interval
CLBP	Chronic Low Back Pain
CPT	Conventional Pain Therapy
CPQ	Confidential Pain Questionnaire
CSQ	Coping Strategies Questionnaire
DCS	Dorsal Column Stimulation
df	Degrees of freedom
DPQ	Dallas Pain Questionnaire
DVS	Database Variable Sheet
F	F Ratio (test statistic)
FBSS	Failed back surgery syndrome
GCTP	Gate Control Theory of Pain
HAM-D	Hamilton Psychiatric Rating Scale for Depression
IDT	Intrathecal Drug Therapy
IT	Intrathecal
JCAHO	Joint Commission for the Accreditation of Health Organizations
MANOVA	Multivariate analysis of variance
<u>M</u>	Mean

MBMD	Millon Behavioral Medicine Diagnostic
MCS	Mental Component Score (SF-36)
MDD	Major Depressive Disorder
MPQ	McGill Pain Questionnaire
MS	Mean Square
MMPI-2	Minnesota Multiphasic Personality Inventory – Second Edition
<u>N</u>	Total Sample Size
<u>n</u>	Subgroup Sample Size
OR	Odds Ratio
OSW	Oswestry
<u>p</u>	Significance level
PBME	Presurgical Behavioral Medicine Evaluation
PCS	Physical Component Score (SF-36)
PMQ	Pain Medication Questionnaire
PPS	Presurgical Psychological Screening
PT	Physical Therapy
RSD	Reflex Sympathetic Dystrophy
SCS	Spinal Cord Stimulator
<u>SD</u>	Standard Deviation
SF-36	Medical Outcomes Survey 36-Item Short Form Health Survey
SS	Sum of Squares
SSDI	Social Security Disability Income
THQ	Treatment Helpfulness Questionnaire

VAS	Visual Analog Scale
WC	Workers' Compensation
χ^2	Pearson's Chi-Square

CHAPTER ONE

INTRODUCTION

Pain is an epidemic in America. In 2003, the American Academy of Pain Management stated that 57% of all Americans experience recurrent or chronic pain. It is estimated that 14 million annual health-care visits are related to pain (Mayer & Gatchel, 1988). In fact, the Joint Commission for the Accreditation of Healthcare Organizations ([JCAHO], 2000) now mandates that pain be recorded as the “fifth-vital sign” in every patient. Mayer, Gatchel, and Polatin (2000) noted that the costs of chronic pain in the United States were over \$70 billion annually.

Once thought of as a purely medical problem, our understanding of pain has been greatly advanced over the past 40 years. The latest theory on pain, the biopsychosocial model, recognizes that pain is the dynamic interaction between psychological, social, and biological processes (D.C. Turk & Monarch, 2002). Concurrently, we have learned that pain cannot be treated as a traditional medical problem, and it has been proven that a multidisciplinary approach to the treatment of chronic pain is far superior to traditional medical treatment alone (Deschner & Polatin, 2000).

Many chronic pain patients are refractory to conservative medical therapy. After failing traditional therapies, such as opioids and other minimally invasive procedures, these patients are often selected for invasive pain management techniques. Spinal cord stimulators and intrathecal opioid delivery systems are two semi-permanent options for these patients. However, they require a large economic input, as well as a rather invasive placement procedure (Kumar *et al.*, 2002b). With success rates greater than 50% (Kupers *et al.*, 1994; R. B. North *et al.*, 1993), these are very powerful tools for the physician;

however, due to the high costs, it would be extremely beneficial to accurately predict those patients who will have good outcomes.

There is a copious amount of literature examining the predictive value of biopsychosocial risk factors in surgical outcomes (Cashion & Lynch, 1979; Epker & Block, 2001; Junge *et al.*, 1995; D. M. Spengler, Ouelette, F.A., Battie, M. and Zeh, J., 1990). Yet, it has only been in the last decade, that studies have begun to look at the relationship between behavioral medicine risk factors and treatment outcomes for implantable modalities (Doleys *et al.*, 1997; Nelson *et al.*, 1996; Prager & Jacobs, 2001). These studies have shown psychosocial factors to have a large impact on treatment outcomes.

The most comprehensive method to date for the examination of psychosocial and medical risk factors was developed by Block and colleagues (Block, 1992; Block *et al.*, 2003; Block *et al.*, 2001). This presurgical psychological screening protocol has been shown to be efficacious in predicting general spine surgery outcomes (Block *et al.*, 2001). The current study will attempt to apply Block's pre-surgical screening method to predict surgical outcomes for a subset of implantable modalities, specifically, spinal cord stimulators and intrathecal opioid systems.

CHAPTER TWO

LITERATURE REVIEW

Scope of the Problem

Pain is one of the most prevalent and costly problems facing society today. Chronic pain, back pain in particular, has generated interest due to associated staggering treatment costs, loss of earnings, reduced productivity, and the individual suffering involved (Kumar et al., 2002b). In 2003, the American Academy of Pain Management estimated that 57% of Americans reported experiencing recurrent or chronic pain during the past year. Of those individuals reporting pain, 62% have been in pain for more than a year, and 40% report they suffer from constant pain. Lifetime prevalence for low back pain is reported as ranging from 60% to 80% (J. Frymoyer & Cats-Baril, 1991; Lances *et al.*, 1995). Mayer & Gatchel (1988) estimated that one out of every 14 people seek medical care for back or neck pain, resulting in 14 million pain related health-care visits annually. Not only is pain a problem in the United States; several surveys in European countries confirm chronic and recurring pain as a significant and extensive problem in their respective populations (D.C. Turk, 2002). In fact, approximately 17% of males and 20% of females responding to a telephone survey in Australia reported experiencing chronic pain (Blyth *et al.*, 2001).

Mayer et al. (1987) cite low back pain as the most expensive benign condition in America, with the total cost of pain estimated at over \$70 billion per year (American Pain Society, 2000). Frymoyer and Durett (1997) report the costs for back pain, the most prevalent pain condition, to exceed \$33.6 billion for health care, \$11 to \$43 billion for

disability compensation, \$4.6 billion for lost productivity, and \$5 billion for legal services. Mayer (1999) suggests that the relatively small number of cases considered chronic account for the majority of costs accrued in relation to back pain, pointing out that the mean cost of low back pain treatment is more than 10 times greater than the median cost.

It has been shown that 70% to 90% of all costs associated with chronic pain relate to the 5% of people who become disabled (either temporarily or permanently) or partially disabled (D. Spengler *et al.*, 1986). Frymoyer and Cats-Baril (1991) claim that during the last 20 years, the number of people with low back pain who enter the permanently disabled group has grown at a rate far exceeding the population growth. Approximately 1% of the population is considered “totally and permanently” disabled by chronic back problems, and many more are partially disabled. The average age for a chronic low back pain patient who receives social security disability income (SSDI) is between 35 and 40; these people will collect benefits for many years resulting in a costly expenditure for our social system (Mayer *et al.*, 1987). Jacobs (1986) reports that 25% of all work injuries in the U.S. are related to low back pain. The National Institute of Neurological Disorders and Stroke (2002) claims that 93 million workdays are lost annually as a result of low back pain. Further, in the United Kingdom, 12.5% of all unemployed people cite back pain as the reason for work-related disability (Elliott *et al.*, 1999).

As a result of the colossal costs of chronic pain and the extremes taken by individuals to alleviate the symptoms associated with pain, various groups within the U.S. have designated pain as a major area of concern today. For example, the Joint Commission on Accreditation of Health-Care Organizations (2000) identified pain as

being the “fifth-vital sign”, alongside temperature, respiration, blood pressure, and pulse. They created a new standard for pain assessment and treatment, viewing pain as a condition that co-exists with many injuries and diseases. Further, the American Pain Society (2000) issued the “Pain Care Bill of Rights” informing patients of these new standards and advising them of their rights to appropriate assessment and treatment for their conditions. In an effort to meet the vast challenges of pain management, the U.S. Congress passed a provision into law declaring this the “Decade of Pain Control and Research” (Research America, 2003).

As evidenced by the literature and societies’ response, chronic pain causes untold suffering and diminished quality of life for millions of Americans, along with enormous economic ramifications. Thus, the importance of finding efficacious modalities for the treatment of chronic pain is unrivaled.

Theories of Pain

Biomedical Model of Pain. The biomedical model of pain, widely accepted as an explanatory model of the pain phenomenon, assumes that an individual’s pain is the result of a specific disease state evidenced by disordered biology (D.C. Turk, 1996; Wright & McGeary, In Press). In this model, treatment interventions are intended to correct the organic dysfunction, and related features of pain, such as depression, sleep disturbance, and psychosocial dysfunction, are seen as reactions to the underlying organic condition. It is believed that once the disease state is “cured,” the secondary reactions will abate. If these symptoms do not remit, then they are suspected to be psychological in nature. Therefore, the biomedical model of pain distinctly separates symptoms into either

somatogenic or psychogenic components (D.C. Turk & Monarch, 2002). Although this model was widely accepted prior to the 1960's, there has been a great movement toward a more integrated model recognizing that the somatic and psychological components of pain are not mutually exclusive.

Gate Control Theory of Pain. The earliest attempt to incorporate both physical and psychological factors in the pain phenomenon was Melzack and Wall's "Gate Control Theory of Pain" (1965). This theory hypothesized that central nervous system mechanisms provided the physiological basis for psychological involvement. Melzack and Casey (1968) differentiated three systems within the neural network—cognitive-evaluative, motivational-affective, and sensory discriminative—that contributed to the pain experience. The Gate Control Theory of Pain (GCTP) challenged the notion that pain is either somatic or psychogenic by attempting to explain the various psychophysiologic aspects that interplay in the process of pain perception (R. J. Gatchel & Gardea, 1999; D.C. Turk, 1996).

The GCTP posited that the dorsal horns of the spinal cord, peripheral nerve fibers, spinal cord transmission cells, and efferent nerves were directly involved in the link between pain and psychological experience. Specifically, the synapses in the dorsal horns of the spinal cord served a gate-like capacity, modulating the transmission and intensity of nerve impulses from peripheral stimuli to the central nervous system. This neural mechanism acts as a pain gate in which nociceptive transmission may be facilitated or inhibited at the spinal level (Humphries *et al.*, 1996).

Melzack and Wall (1982) also hypothesized that there are descending central controls modulating nociceptive transmission at the spinal level. That is, central processes could also open and close the spinal pain gate. Essentially, signals from the cortex can be sent through efferent neurons to the spinal cord to inhibit afferent pain signals. Therefore, incoming pain signals can be modified and controlled by messages coming from the spinal cord, brain, or both.

Melzack and Wall further proposed a critical level of output from spinal cord transmission cells (T cells) was needed to activate the conscious experience of pain and reactions to it (the so called threshold level). Factors that individually might not trip the gate could combine to make pain perceptible (i.e. an additive effect). Such factors might include a sympathetic nervous system over-aroused by stress or a central nervous system altered by depression or anxiety. It is important to note that the process can also work in reverse. Methods such as relaxation or distraction can be employed to reduce the pain signal below threshold needed to trip the gate, and pain would consequently be reduced or blocked (Warga, 1987).

To summarize, the transmission of peripheral nociceptive inputs can be modulated by non-nociceptive (proprioceptive) peripheral inputs or efferent cortical control allowing the person to actively and purposefully control pain input. This is the backbone of psychological methods of decreasing pain, and a central component of the GCTP, making it the first theory to incorporate a physical and psychological model of pain. Although there is criticism of gate control theory, the central tenets of the theory are widely supported in the literature today. While gate control theory was a major breakthrough toward the understanding of pain, later research and physiological advances

criticized the model as being incomplete (Nathan, 1976; Price, 1988; Schmidt, 1972). Nevertheless, it has proven to have tremendous heuristic value in fostering further research relating to scientific processes underlying the pain mechanisms (D.C. Turk, 1996).

The Biopsychosocial Model of Pain. In addition to physiologic and psychological factors, social and cultural variables have also proven to have an important effect in the onset and maintenance of pain. Mechanic (1966) referred to “illness behaviors” as the unique way in which people perceive, evaluate, and respond to physical symptoms. He believed that these patterns of behavior were products of social and cultural conditioning, and an individual’s coping repertoire. Mechanic (1972) went on to describe how perceptions of personal vulnerability and illness, along with social and cultural factors, vocabularies of distress, and effects of emotional distress all interacted to result in a patient’s report of pain symptoms.

Current and past research has consistently shown a strong relationship between chronic pain and psychosocial factors (Flor & Turk, 1984; Fordyce, 1976; Polatin *et al.*, 1993; Romano & Turner, 1985; A. Rush *et al.*, 2000). Responses to pain and pain treatments are by and large variable, reflecting the complex interactions between genetic, developmental, cultural, environmental, and psychological factors (Martelli *et al.*, 2004). Today the interrelationship among biological changes, psychological status, and social and cultural contexts is commonly known as the “biopsychosocial model of pain” (Engel, 1977; D.C. Turk & Rudy, 1987). This model of pain has emerged as the most comprehensive method for assessing, conceptualizing, and treating pain syndromes. In

1996, Gatchel and Turk identified three hallmarks of the biopsychosocial perspective: 1) integrated action; 2) reciprocal determinism; and 3) evolution. They reported that, “No single factor in isolation—pathophysiological, psychological, or social—will adequately explain chronic pain status.” The biopsychosocial model of pain recognizes the importance of taking into account a patient’s physiological, biological, cognitive, affective, genetic, behavioral, developmental, cultural and social factors, all interrelated, in an attempt to understand the reported pain (R. J. Gatchel & Gardea, 1999).

Treatments for Chronic Pain

Consistent with the biopsychosocial model of pain, effective treatment of chronic pain conditions must address the complex array of variables that contribute to the chronic pain experience (Wright & Gatchel, 2002). Various psychological methods have been developed to aid in the treatment of patients with chronic pain (i.e. cognitive behavioral interventions). These interventions must be coupled with appropriate medical treatment in order for patients to receive optimal care. The backbone for medical treatment of pain consists of primarily oral medications; however, when pain becomes chronic and severe, more aggressive measures can be taken. Two of the most common methods for treating refractory, chronic pain are spinal cord stimulation (SCS) and intrathecal opioid delivery systems.

Implantable Modalities

Spinal Cord Stimulators. The concept of treating medical conditions with transcutaneous electric current dates back to 1790, and by the early 20th century, various

types of electrical devices were available for clinical use. Nevertheless, with the increased availability of analgesic drugs and ablative pain relieving procedures such as rhizotomy, cordotomy, and sympathectomy, the electrical devices were of little use and were therefore abandoned. However, with the introduction of the Gate Control Theory of Pain, there was renewed interest in electrical stimulation as a modality for pain relief. Modern SCS introduces low levels of electrical current to the dorsal portion of the spinal cord to augment/modulate the sensation of pain (Raj *et al.*, 2003). The systems are designed to stimulate inhibitory interneurons which effectively “close the gate” to afferent pain signals from the periphery. Essentially, SCS is Melzack and Wall’s theory in action .

In 1967, Shealy and colleagues were the first to devise an implantable device for the spinal cord in an attempt to achieve pain relief. Their technique involved surgically implanting electrodes directly over the dorsal columns of the spinal cord via laminectomy with the aim of activating pain-inhibiting mechanisms. They theorized that stimulation of large myelinated fibers would inhibit the firing of nociceptive C fibers, resulting in the decreased perception of pain. Despite technical problems, Shealy stated, “The initial results were so encouraging that it seems reasonable to think that technical problems can be overcome to make this a potentially practical method for relief of pain” (Shealy et al., 1967, pg.491).

Shortly after this initial report, several groups attempted to use implantable peripheral nerve stimulators (D. M. Long & Erickson, 1975; Sweet, 1976), and Hosobuchi and Adams (1973) reported on the use of an implantable deep brain stimulator. Several thousand stimulators were implanted in the decade following these

first attempts, and although dorsal cord stimulation (DCS) was found to be effective in decreasing pain, side effects such as neural impairment and scarring were observed, along with reports of high complication and failure rates (De La Porte & Siegfried, 1983; D. M. Long *et al.*, 1981; Meglio *et al.*, 1989; Racz *et al.*, 1989; Siegfried & Lazorthes, 1982). Later studies showed that leads placed on the ventral surface of the cord or inserted percutaneously into the epidural space could achieve effective stimulation. Therefore, in an attempt to reduce complications and alleviate side effects while achieving similar efficacy, percutaneous methods for electrode introduction were adapted for use with permanently implanted systems (Erickson, 1975; Hoppenstein, 1975; Hosobuchi *et al.*, 1972; R. B. North *et al.*, 1977; Zumpano & Saunders, 1978).

As SCS became more prevalent, a protocol was developed to determine which patients would receive permanent implants. While pre-surgical psychological assessment was not necessary until more recently, the use of trial stimulation has been prevalent since the 1970's. Essentially, a fully-functional stimulator lead is placed percutaneously into the epidural space and attached to an external power source. The patient then uses the trial stimulator for a period of three to seven days to determine whether they are a responder or non-responder. Those who respond favorably (as defined for each individual practitioner) receive a permanent implant, while non-responders are spared the cost and invasiveness of permanent implantation (Fogel *et al.*, 2003).

Since their introduction into clinical practice in the late 1960's, many studies have shown the effectiveness of spinal cord stimulation. Long, et al. (1981) reviewed 69 patients who underwent DCS implants between 1970 and 1973. They found an overall success rate of 33%, with a minimum follow up of at least 7 years post implantation.

Interestingly, 50% of the original group would not be selected today for implantation due to psychological or drug-related reasons (C. Long, 1981).

North, et al. (1991) studied 53 patients who underwent spinal cord stimulation over a four-year period at John Hopkins University School of Medicine in Baltimore, Maryland. At a mean of 2.2 years postoperatively and 5.0 years postoperatively, 50 and 45 of the original patients, respectively, were available for follow-up and contacted by a disinterested third-party to determine the success of their devices. In this study, “success” was defined as a combination of two criteria that are standard in the literature: 1) at least 50% estimated relief of pain 2 years postoperatively and/or 2) patient satisfaction with treatment determined by whether patient would be willing to undergo the procedure again knowing the post-operative results ahead of time. North, et al. achieved success in 53% of patients at 2.2 years, and in 47% of patients at 5.0 years after implantation.

Simpson (1991) followed 60 patients with spinal cord stimulators implanted for intractable pain of up to 50 years for up to nine years post-implantation. The outcome was assessed at weekly neurostimulator clinics using the following categories: made worse, no effect, modest benefit, and significant benefit. Simpson found that 47% of patients reported significant benefit, 23% achieved modest benefit, 20% indicated they found no effect, and 6.7% claimed the stimulator made their pain worse; overall, 70% of the original 60 patients derived benefit to some degree.

De La Porte & Van de Kelft (1993) reviewed 78 patients who underwent trial stimulation for chronic, intractable pain due to failed back surgery syndrome (FBSS) between 1984 and 1990. Of the original 78 patients, 64 obtained excellent pain relief

(75% or more) during the trial of stimulation and were permanently implanted. These patients were followed by observation every three months for a mean follow up period of four years (range 1-7 years) to assess for continued pain relief. They reported that 35 patients (55%) continued to experience at least 50% of pain relief at the latest follow-up.

In 1993, North et al. reviewed spinal cord stimulation over the past two decades, obtaining current follow-up data by disinterested third-party interviewers on all available patients. Their study population was drawn from 320 patients with chronic, intractable pain who underwent implantation of temporary and/or permanent spinal cord stimulators between 1971 and 1990. After trial screening, 249 patients (78%) proceeded with permanent implants, 205 (64%) of which were available for current follow-up interviews. At mean follow-up of 7 years, 52% reported at least 50% continued pain relief, 60% stated they would repeat the procedure for the same result, and 43% met both these criteria.

In Belgium, Kupers, et al. (1994) described a nation-wide survey on the incidence, indications, and therapeutic efficacy of SCS. One study investigated the subjective evaluation of the SCS by patients; 70 patients, with a mean follow-up of 3.5 years were studied. In 52% of the patients, pain relief as measured by subjective evaluation by patient was judged good to very good.

North, Kidd, and Piantadosi (1995) were the first to design a prospective, randomized comparison study of spinal cord stimulation versus reoperation in patients with persistent radicular pain, with and without low back pain, after lumbosacral spine surgery. The primary outcome measure was the frequency of crossover to the alternate procedure (after six months) if results of the first had been unsatisfactory. Eighty-one

patients were found to be eligible for the study, of which 51 consented to randomization (the remaining 30 patients opted for reoperation). At the time of publication, 27 patients had reached the six-month mark. Of the 15 patients who underwent reoperation, 10 (67%) opted for crossover to SCS at the 6-month mark, whereas, only 2 of 12 (17%) of the SCS patients opted to crossover to reoperation after six months. After statistical analysis, their outcome measure (crossover) showed a statistically significant advantage of SCS over reoperation for FBSS.

Turner, Loeser, and Bell (1995) reviewed the literature to analyze the long-term benefits of SCS for patients with FBSS. They defined success as a patient using a stimulator with at least 50% pain reduction at time of follow-up. At one year, on average 62% of patients were deemed successes (14 studies), at 2 years post-implantation there was a 64% mean success rate (5 studies), at 5 years there was a 53% mean success rate (3 studies), and at 10 years there was a 35% success rate (1 study).

In 1997, Kumar, Nath, and Toth looked at the efficacy of SCS in the management of reflex sympathetic dystrophy (RSD). For fifteen years prior to this publication, they used SCS for the control of pain due to various causes. After review, they found 223 cases of SCS of which 12 were diagnosed with RSD. They used a pain questionnaire and visual analogue scale to quantify pain levels before and after implantation. At average of 41 months follow-up, all 12 RSD patients were continuing to use their stimulators regularly. Patients were interviewed by an outside investigator to record their level of pain control as less than 50% relief (poor), 50 to 70% relief (good), and more than 75% relief (excellent). They found eight patients reported excellent pain relief, and four reported good pain relief. Kumar, et al. concluded that SCS is effective in treating RSD;

in their opinion, the low morbidity of this procedure and its efficacy in patients failing surgical sympathectomy suggest that SCS is superior to ablative sympathectomy in management of RSD.

Kemler, et al. (2000) also looked at the efficacy of SCS in patients with chronic RSD by performing a prospective, randomized, controlled study to determine whether treatment of RSD with SCS and physical therapy (PT) was more effective than treatment with PT alone. Of the 36 patients assigned to receive SCS, 24 were implanted with SCS systems after successful trial stimulations. PT alone was prescribed to 18 patients. Outcomes were assessed at 1-, 3-, and 6-month post treatment initiation. Measures including a self-reported visual analogue pain scale (VAS), response to a 7-point scale measuring global perceived effect (1=worst ever, 2=much worse, 3=worse, 4=not improved and not worse, 5=improved, 6=much improved, and 7=best ever), and functional status as measured by range of motion, grip strength, and foot flexion. They found that at 6-month follow-up the mean score on the Visual Analogue Scale (VAS) for the SCS group was reduced by 2.4 cm, whereas the PT group VAS increased by 0.2 cm ($p<0.001$). Among the 24 patients who were treated with SCS, 14 (58%) had a score of 6 (much improved) for the global perceived effect, as compared to 1 of 18 patients (6%) who received PT alone ($p<0.001$). Although Kemler, et al. did not find functional improvement in either group, they claim that due to the advanced disease state, functional improvement is unlikely. They conclude that SCS is more effective than PT alone in treating RSD associated pain; however, there was no conclusive evidence for overall improvement in functioning with SCS versus PT only.

In 2001, Ohnmeiss & Rashbaum studied a group of 41 patients who underwent trial stimulation for SCS with predominant complaints of chronic, intractable, low back pain. After trial stimulation, 36 patients were permanently implanted. At follow-up, patients completed questionnaires concerning satisfaction levels, potential to recommend SCS to someone with similar problems, likelihood to have proceeded with SCS if they had known the outcome of their procedure ahead of time, and how their current status compared with condition before SCS. Results revealed that 70% of patients were satisfied with their SCS, 78.8% would recommend the procedure, and 75.8% would repeat SCS themselves. It was also determined that 60% of patients indicated their current condition was improved, 33.3% indicated no change, and 6.0% indicated worsening. They concluded that among their chronic, intractable, low back pain population, the majority of patients were satisfied and considered their condition improved post-SCS implantation.

Finally, Cata, et al. (2004) looked at two case studies of SCS and chemotherapy-induced peripheral neuropathy. Both patients had poorly controlled pain using medications alone; however, the trial SCS proved an effective pain management technique. After implantation, pain scores were reduced, gait improved, and leg flexibility increased; additionally, psychophysiological tests demonstrated an improvement for both touch and sharpness detection thresholds.

As is evident by the numerous aforementioned studies, SCS has proven to be an effective method for the treatment of certain chronic, intractable pain syndromes, following the failure of conservative therapies. Pain criteria for success have been difficult to define, but most authors consider SCS successful if there continues to be

>50% relief of index pain at one-year post-implantation (Fogel et al., 2003). Success rates range from 40 to 80%, with an average of 50% pain relief in patients treated with SCS. Common indications for SCS include FBSS, peripheral vascular disease, peripheral neuropathies, multiple sclerosis, and RSD (Cata et al., 2004; De La Porte & Van de Kelft, 1993; Kumar et al., 1997; R. B. North et al., 1995; R. G. North et al., 1991).

Intrathecal Analgesia Therapy. Opioids have been used as analgesics for thousands of years; however, evidence for the direct action of opioids at the spinal level was not proven until 1976. In a landmark study, Yaksh and Rudy (1976) showed that intrathecally injected morphine produced segmental spinal analgesia that was antagonized by naloxone, thus proving the existence of opioid receptors in the spinal cord. This finding created a burst of interest for the use of intrathecal (IT) opioids to manage chronic pain.

The discovery of opioid receptors and endogenous compounds in the spinal cord provided a rationale for early attempts to deliver opioids intrathecally. As a result of this and subsequent animal experiments, Wang, et al. (Wang *et al.*, 1979) attempted to duplicate the results in humans suffering from the intractable pain of inoperable cancer. Eight patients were selected in a double-blind placebo controlled cross-over study following failure of systemically administered narcotic analgesics for pain suppression. They were given injections in random order (morphine or saline) with intervals between the injections, and the visual pain scale (0 to 10) was used to determine amount of pain relief. Results showed 2 of the 8 patients reported complete pain relief after separate injections of morphine and saline solution (25% incidence of placebo effect is consistent

with other studies); however, the other 6 patients distinguished the morphine from the placebo and received significantly more pain relief from the morphine than saline injections. Complete relief of pain allowed patients to have better use of their extremities and greater feelings of well being, yet they did not display signs of sedation, respiratory depression or other behavioral changes; perception to pinprick and touch remained unchanged, along with other neurologic functions. Thus, it appeared that contrary to systemically administered opioid drugs, IT opiates were able to help control pain without influencing motor, sensory, and sympathetic reflexes.

The landmark findings mentioned above led to a worldwide interest in using acute epidural and IT narcotics to achieve analgesia and thus began a new era in the treatment of chronic and acute pain (Bromage *et al.*, 1980; Coombs *et al.*, 1982; Onofrio *et al.*, 1981). Morphine, a long acting and well-studied opioid is one of the most suitable for IT use. Pain resulting from low back pain, ischemic pain associated with peripheral vascular disease, and metastatic cancer pain all appear to be reduced significantly by the spinal action of opiates. Intrathecal drug therapy (IDT) has been considered appropriate for patients who cannot maintain a favorable balance between analgesia and the side effects from systemic opioid administration (e.g. constipation, nausea, and pruritis), and who fail to benefit from less invasive therapies (e.g. TENS unit) (Krames & Olson, 1997). Similar to SCS trials, an IT pump trial takes place prior to permanent placement and is conducted by placing a temporary IT catheter attached to an external drug reservoir. If the trial is successful, a permanent IT catheter is attached to an implanted drug reservoir, which can be refilled percutaneously. Coombs, et al. (1983) placed IT pumps in both cancer-related pain and chronic nonmalignant pain in individuals to determine the efficacy of

continuous intraspinal morphine in controlling the pain. These patients were evaluated every 3 weeks for up to 12 weeks post-implantation, using a battery of measures including the VPAS (sic), narcotic usage, cognitive tests, and depression scales. Results focused on changes from baseline to 12-week follow-up. At baseline, they found the nonmalignant pain group reported significantly higher pain levels on the VAS than the cancer pain group, yet at the 12-week mark, the cancer pain group showed much greater decline in reported pain. This study confirmed the effectiveness of IT morphine infusion for intractable cancer pain, but did not support evidence for efficacy with nonmalignant pain.

In 1985, Auld, Maki-Jokela, & Murdoch reviewed the results of intraspinal narcotic analgesia in 43 patients with chronic nonmalignant pain syndromes 2 years post implantation. FBSS accounted for 81% (35 patients), and the remaining 8 patients had intractable pain resulting from multiple sclerosis. In those patients who were implanted with continuous delivery systems after successful trial phases, 65% received good to excellent pain relief, while 34% were considered failures after permanent implantation.

Follett, et al. (1992) reviewed their experience treating patients with intractable pain by continuous morphine infusion. They evaluated 42 patients between 1984 and 1989 for IDT systems. After trial injections, 37 patients achieved greater than 50% reduction in pain and underwent implantation of infusion pumps. Of the implanted patients, 35 had pain from malignancies and 2 had pain secondary to non-malignant conditions. 77% of patients had good pain relief (intensity <2-3 on 10 point VAS scale) in the majority of follow-up visits post implantation. Thus, Follett et al. concludes that continuous IT infusion of morphine is an effective method of controlling intractable pain,

even stating that they believe IT morphine should be used earlier in the course of diseases, rather than as a last resort.

In 1996, Tutak and Doleys noted good or excellent outcomes in 20 out of 26 patients with IT infusion systems for the treatment of nonmalignant, chronic low back and leg pain. Average pre-implantation pain rating was 8.9 on the VAS for the 26 patients in their study. The average pain rating decreased to 5.5 (39.2%) 6 months post-implantation and to 4.9 (44.9%) at 12 months. Most notable is that 77% of the patients implanted rated their satisfaction as good to excellent at mean of 23 months post-implantation.

Winkelmüller and Winkelmüller (1996) retrospectively examined the long-term effects of continuous IT opioid therapy in 120 patients. Using a VAS (where 0 = no pain and 100 = unbearable pain), they report a baseline pain level of 93.6 prior to pump implantation. Six months post-implantation they found an average pain intensity value of 30.5 reflecting an overall reduction of pain of 67.4%. Their study followed patients for a period of up to six years, citing good results in 74.2% of the patients, with a pain reduction of approximately 60% at long-term follow-up.

As these studies show, the use of IT opioids for the treatment of chronic pain is a safe and highly effective technique. It offers excellent pain relief to the majority of patients while minimizing the typical side effects that are seen with parenteral dosing of these same drugs.

Costs-Effectiveness of SCS and IDT

The costs of medical treatment for chronic pain alone have been estimated to be between \$9,000 and \$19,000 per person per year (Straus, 2003). Although more costly at the outset, SCS and IDT have been proven to be more cost-effective in the long term. Kumar, Malik, and Demeria (2002b) tabulated the actual costs for a series of patients treated with SCS and compared them to costs for a control group treated by conventional pain therapies (CPT). They found that although the mean cost for SCS was greater than that for CPT in the first 2.5 years, the cost of treating patients with SCS became less than conventional therapies after those 2.5 years and remained so during the rest of the follow-up period. Kumar and colleagues reported that the actual mean cost of SCS therapy for a 5-year period was \$29,123 per patient, compared with \$38,029 per patient for CPT. Kemler and Furnee (2002) showed similar results in their study which found that as a result of the initial high costs of SCS therapy, the first year of treatment is \$4,000 more than control therapy; however, in their lifetime analysis, they showed SCS to be \$60,000 cheaper per patient than control therapy. IDT systems have also shown to be more cost-effective in the long term. Researchers show the first 28 months of treatment with IT opioid pumps as more expensive due to the initial high costs of equipment, but after this time the actual cumulative costs for IDT (\$29,410) were much lower than for CPT (\$38,000) (Kumar *et al.*, 2002a).

Need for a More Comprehensive Method of Selection

Patient selection is a critical factor in the determination of successful candidates for many therapies involving significant risk, side effects, and costs. The results for most SCS and IDT studies cite 50-60% success rates in patients implanted. Thus, despite the

large number of people finding relief in these modalities, there are close to as many who succumb to the invasive and costly procedure with unsuccessful outcomes. A need for a more comprehensive method for selecting patients who will undergo these procedures is necessary in order to acquire an increase in successful implantations, and alleviate the practice of putting candidates who will not benefit from implantable modalities through expensive, surgical procedures. As a result of a better cost/benefit ratio, third party payer rates and reimbursements would also improve. Consequently, many third party payers, including Medicare, are now requiring some form of evaluation of potential benefit prior to SCS or pump implantation.

Rationale for Presurgical Psychological Screening

Occasional unsuccessful outcomes are inevitable, even for the most proficient surgeon. The failed procedures result in patients who take up large percentages of the physicians time complaining of pain, requesting refills for medications and/or higher dosages of those already prescribed, and undergoing further invasive interventions, often resulting in declining outcomes over time (Block et al., 2003). The biopsychosocial model of pain dictates that even the most faultless surgical correction of organic pathology may not bring relief of pain, acknowledging that psychosocial factors can have a negative impact on results (Block et al., 2003). In fact, many studies have attempted to identify biopsychosocial factors that correlate with poor surgical outcome.

Spengler, et al. (1979) retrospectively reviewed thirty patients who had failed multiple traditional surgical procedures for low-back pain, sciatica, or both in an attempt to determine the indications for the initial operative procedure and to identify

psychosocial and clinical factors contributing to the poor results. They report that the most common cause of the poor results appeared to be failure of initial selection, even though all patients appeared to meet traditional indications for operative interventions. Upon further investigation, they found drug abuse, alcoholism, marital discord, and personality factors to have impacted outcome. Spengler, et al. (1979) suggests psychological testing will help reduce future unsuccessful procedures.

In 1980, Long, et al. reviewed patients who underwent implantation of dorsal column stimulators between 1970 and 1973. In these years, the only true criterion for implantation was a patient's complaint of pain, as their patients had failed every form of therapy available. They found an insignificant number of patients achieved satisfactory pain relief with SCS. During this same review, Long and colleagues also retrospectively evaluated their patients using updated inclusion criteria. In doing so, they found that 50% of those patients originally selected would have been rejected due to psychological and drug-related reasons, citing psychological factors as the most important reasons for failures.

In 1988, Deyo and Diehl examined the psychosocial predictors of disability in patients with low back pain. They sought to look at a comprehensive set of predictive variables (clinical, demographic, and psychosocial) with regard to the prognosis of uncomplicated low back pain. Deyo and Diehl (1988) concluded that, even among similar patients, there are extensive variations in outcomes. More importantly, they found that psychosocial characteristics often predicted functional disability better than disease factors. They even went so far as to say these variables may ultimately be more important in determining outcome than the prescribed therapy.

Spengler, et al. (1990) used an objective evaluation for assessing patients who had persistent low back pain and sciatica. Their scoring system consisted of four major categories for preoperative assessment: neurological signs, sciatic-tension signs, psychological factors, and imaging studies. In the patients who were followed sufficiently to determine the clinical outcome, psychological factors were the best predictor of the outcome of treatment.

These and other studies show that there are specific biopsychosocial risk factors that can be correlated to poor outcomes in chronic pain patients. The logical next step was to attempt to design a pre-surgical evaluation based on these risk factors to determine those patients who will be poor candidates for surgery/intervention.

Concept of Presurgical Psychological Screening

Presurgical psychological screening (PPS) can be defined as a diagnostic “approach that identifies and quantifies risk factors associated with poor surgical outcome, in order to render a decision concerning surgical prognosis” (Block, 1996, pg. 6). For PPS to be effective, four points must be covered. First, PPS must consist of strong, empirically validated risk factors. Second, these risk factors must be examined in the context of the whole picture represented by the patient, looking at the combination of both risk factors and strengths. Also, it is incredibly important for the psychologist to clearly communicate his/her recommendations for the surgery being considered based on the risk factors identified with the patient to the requesting surgeon. Lastly, the psychological determination of surgical prognosis must be considered only one piece of the comprehensive, diagnostic evaluation of the surgery candidate. It is up to the surgeon

from that point forward to weigh the results from the psychological evaluation against the physical findings to determine whether to commence surgery, find an alternate therapy, or delay surgical intervention until appropriate modifications have been made to the patient's risk factors (i.e. pre-surgical behavioral interventions) (Block et al., 2003).

PPS can be used to identify patients who would benefit from cognitive-behavioral interventions pre- or post-surgery in order to help them with their overall expectation of the surgery, and issues of motivation or compliance. These interventions help boost the effectiveness of the surgery by improving some of the risk factors that may cloud the success of the procedure. Overall, PPS provides a vast amount of information to help the entire inter-disciplinary team treat the “needs, personality, and expectations of individual patients” (Block et al., 2003).

Steps for gathering information. PPS typically consists of drawing information from three main areas: the medical chart, a semistructured interview, and psychological tests. The medical chart provides the psychologist with an array of information about the patient including the general interaction between patient and medical staff, specific risk factors possessed by the patient, the over-utilization of prescription medications, and issues with noncompliance. The medical chart also contains results of the physical exam, including a medical history and may have documentation relating to any inconsistencies in the patient's behavior in relation to the physical diagnosis (Block et al., 2003).

A semistructured interview is administered to the patient after reviewing the medical chart. It is during this interview that psychologists are able to clearly identify risk factors and strengths that the patient possesses. The interview is an opportunity for

the patient to discuss his/her expectations of surgery and any concerns they have regarding the procedure outcome and their own expectations. Psychosocial information such as level of job satisfaction, interpersonal relationships, and history of abuse is assessed to determine if there are any psychosocial risk factors that may impact surgical outcome.

Psychological testing is the final source of information in PPS. Past research has shown that psychological test results are often the best predictors of treatment outcomes (Burchiel *et al.*, 1995; Kupers *et al.*, 1994; D. M. Spengler, Ouelette, F.A., Battie, M. and Zeh, J., 1990). Objective testing results also serve as a statistically sound validity check for impressions developed during the semistructured, clinical interview (Block *et al.*, 2003). Information corresponding to a patient's coping style, presence of psychopathology, such as depression and/or anxiety, and other important personality factors are identified through psychological tests.

Screening Scorecards. Finneson and Cooper (1979) were the first to develop a scorecard with factors they felt made a case for and against a predicted successful surgery outcome. Their scorecard included six negative risk factors, including "poor psychological background" and "history of previous lawsuits for medico-legal problems", and seven positive factors, such as "patient's realistic self-appraisal of future life style". Each of these factors was assigned an *a priori* weight. After the surgeon entered scores for each factor (involving subjective decisions by the surgeons), the scores were combined to predict the patient as having a good, fair, marginal, or poor prognosis. They reassessed their patients at an average 3.8-year follow-up and found that the good

prognostic patients achieved far better results than all other prognostic groups, and the poor prognostic patients improved the very least (statistical results were not reported).

Others followed suit and developed similar scorecards attempting to successfully predict outcomes (Dzioba & Doxey, 1984; D. M. Spengler, Ouelette, F.A., Battie, M. and Zeh, J., 1990). Dzioba and Doxey (1984) launched a prospective investigation into the orthopaedic and psychologic predictors of outcome of lumbar surgery. The purpose of their study was to establish a battery of clinical and psychological tests to be used at pretreatment to indicate a prognosis for surgery outcome. Results from this study demonstrate that the accuracy of both orthopaedic and psychological factors combined produced an 81.7% successful prediction rate. Spengler and colleagues (1990) used four categories in their scoring system: neurological signs, sciatic-tension signs, psychological factors, and imaging studies. Analysis of data showed that psychological factors accounted for 24% of the variance in clinical outcome and were stronger predictors than medical factors. The most powerful predictor of the outcome of treatment was the Minnesota Multiphasic Personality Inventory ([MMPI] Hathaway & McKinley, 1943).

Recommendations. Upon completion of the PPS, the psychologist provides feedback to the physicians about the patient's predicted outcome. Patients who have a low level of risk factors are usually recommended to proceed with the planned surgery. Those patients with multiple levels of risk factors are recommended for non-invasive, conservative procedures. Small numbers of patients are recommended for discharge with no additional treatment. The patients with moderate levels of risk factors are offered psychological treatment, which helps to enhance compliance, motivation, and

expectations for change among other things. Once this has taken place, the patient is once again considered for surgery dependent upon the success of the psychological treatment (Block et al., 2003).

PPS Studies for Spine Surgery in the Literature

There have been recent attempts at psychological pre-screening of patients who are being considered for surgery (Block et al., 2001; Dzioba & Doxey, 1984; Epker & Block, 2001; Junge et al., 1995). Epker and Block (2001) reviewed the methods for predicting positive outcomes for spine surgery in general, pointing out positive and negative psychosocial risk factors impacting recovery from spine surgery. They delineate specific risk factors that have been shown to be predictive of poor surgical outcome, providing a sound basis for evaluating and quantifying these factors before performing spine surgery in order to predict outcome. Three major categories of psychosocial factors are described: 1) personality/emotional, 2) cognitive/behavioral, and 3) environmental/historical. Scale elevations on the Minnesota Multiphasic Personality Inventory-Second Edition ([MMPI-2] Butcher *et al.*, 1989) associated with pain sensitivity (Scale 1 and 3), depression (Scale 2), anger (Scale 4), and anxiety (Scale 7) are among the most noteworthy factors negatively influencing outcomes. Other significant factors include: maladaptive coping strategies, workers compensation, litigation related to pain, and drug and alcohol abuse. Epker and Block also discuss “quasi-medical” risk factors that can predict poor results. They state that the duration of pain and number of previous surgeries for pain are negatively correlated with positive outcomes. Smoking and obesity can also have an effect on recovery from surgery. Lastly, Epker and Block

point to the presence of nonorganic Waddell signs (see G Waddell *et al.*, 1980) that can help identify those candidates who will have poor outcomes.

Other investigators have used forms of PPS to predict surgical outcome. Dzioba and Doxey (1984) examined 116 potential outcome predictors among surgical workers compensation patients over a three-year period in an attempt to create a battery of clinical and psychological tests to be used to arrive at a prognosis for preoperative patients. The five most significant predictor variables were English proficiency, the nonorganic Waddell signs (G Waddell *et al.*, 1980), distribution of pain (back versus leg), Scale 1 elevations on MMPI (hypochondriasis), and the pain drawing (Dennis *et al.*, 1981). Junge *et al.* (1995) created a scorecard based on variables found to be most effective in predicting outcome. They included psychological, physical, and historical factors. Analysis of scorecard totals showed 74% correctly predicted good outcomes and 89% correctly predicted poor outcomes.

The most comprehensive PPS to date has been developed by Block and colleagues (Block, 1996; Block *et al.*, 2003; Block *et al.*, 2001). They developed a PPS “scorecard” to clarify the spine surgery candidate’s psychosocial risk factors, using a multitude of psychosocial risk factors. The scorecard lists and quantifies each of these psychosocial risk factors, along with additional medical risk factors. Based on the extent of research demonstrating predictive ability, each risk factor is assigned an *a priori* weight of high risk (2) or medium risk (1) and the risk factors in each group (medical and psychological risk) are totaled to arrive at a surgical prognosis.

In 2001, Block *et al.* (Block *et al.*, 2001) investigated the effectiveness of their PPS in predicting surgical outcome. Two hundred and four patients referred for

psychological screening were evaluated no more than one month prior to surgery. These patients were followed up at mean of 8.6 months. A semi-structured interview and two psychological questionnaires, the Minnesota Multiphasic Personality Inventory-2 (MMPI-2) and the Coping Strategy Questionnaire ([CSQ] Rosenstiel & Keefe, 1983) were used to evaluate the psychosocial and medical risk factors. Based on the results of the PPS, patients were placed into one of three predictive categories (“good”, “fair”, or “poor”) using a 2 x 2 matrix. The outcome measures used at follow up were the Oswestry Disability Index ([OSW] Fairbank *et al.*, 1980), the Visual Pain Analog Rating Scale (VPAS), and analgesic medication use. Block *et al.* (2001) found that the majority of patients improved postoperatively. Statistically significant improvements were seen in all three measures. Analysis of results showed the PPS achieved an 82% accuracy rate, with 82.3% patients in the “good group” experiencing a good outcome and 83.0% patients in the poor prognostic group resulting in poor outcome. Logistic regression analyses were also conducted to determine which variables were the most significant predictors of outcome. These analyses yielded psychological test data as the most significant cluster of variables to correctly classify patients with a correct classification of 78.4%. The addition of psychological interview data brought the model up to an 83.3% correct classification. Finally, the addition of the medical risk factors contributed slightly, bringing the total model to 84.3% correctly classified. This study was the first empirical study to show a large number of psychological and medical risk factors can be identified, quantified, and used to predict surgery outcomes correctly.

PPS for SCS and IDT

As described earlier, the standard physician selection for SCS implantation involves a therapeutic trial with a temporary percutaneous electrode, which closely emulates long-term therapy. However, between one-third and one-half of patients selected for permanent implantation based on successful results from the trial ultimately fail treatment (R. B. North *et al.*, 1996). Although SCS and IDT delivery systems have shown substantial benefits for some patients, due to the expense of these modalities there is a need for carefully selecting which patients are likely to benefit from these treatments (D.C. Turk, 2002). One of the most important problems associated with SCS is the difficulty in identifying the patients in whom reasonably long-term pain relief can be achieved (De La Porte & Van de Kelft, 1993).

Daniel et al. (1985) predicted outcome for deep brain and SCS implantation using a “functional pain assessment” made up of an interview, a questionnaire for demographic, clinical, and psychosocial characteristics, a health index, and several psychological tests. The researchers used a six-point rating scale to classify patients as poor (0-2) or good (3-5). At follow-up, only 4 of the 17 patients available reported good outcome. The psychologists were able to accurately predict the outcome in 76.5% of the patients.

In a nationwide survey performed by the Belgian health authorities on the incidence, indications, and efficacy of SCS (1994) 100 patients were evaluated for SCS using semi-structured interviews without the addition of psychological tests. Recommendations were divided into three categories: 1) no contraindication for SCS, 2) no firm contraindication, but some reservation due to personality disturbances, and 3)

contraindication for SCS due to one or more major psychological disorders or major compensation/litigation. Six months post surgery, assessment outcome showed that 64% of patients who received positive recommendations were successful whereas only 18% of those with some reservations had a positive outcome (Kupers et al., 1994).

In 1995, Burchiel et al. published a study examining various physical, demographic, and psychosocial variables at pretreatment as predictors of SCS outcome. Their study population consisted of 40 patients with chronic low back and/or leg pain, 85% of those diagnosed with FBSS. The data collected included the MMPI-2, the VAS, the McGill Pain Questionnaire ([MPQ] R. Melzack, 1975), the OSW (Fairbank et al., 1980), the BDI (A. T. Beck *et al.*, 1961), and the Sickness Impact Profile (Bergner *et al.*, 1976). Follow-up data was collected 3 months post-implantation of the permanent systems. After analysis, they found the success or failure of 3 months of SCS was correctly predicted in 88% of the study population; age, MMPI depression scale, and MPQ were found to be useful in the prediction of pain status after 3 months of SCS in their population.

Nelson et al. (1996) published a paper delineating certain psychological-behavioral features that should exclude a patient from consideration for SCS. They include active psychosis, active suicidality, active homicidality, untreated or poorly treated depression or other major mood disturbance, somatization disorder or other somatoform disorder, alcohol or drug dependency, compensation or litigation, lack of appropriate social support, and neurobehavioral complex cognitive deficits. Each of these factors is shown to correlate with poor surgical outcomes (for an in depth analysis of each factor and its significance, see Nelson et al., 1996).

Components of a PPS Algorithm

People are keenly aware that smoking is a medical risk factor. There is much less cognizance of the many more subtle factors that impact health, specifically in regards to recovery from surgery. Many medical and psychosocial variables have been correlated with poor outcomes for surgery. As discussed earlier, the PPS scorecard developed by Block and colleagues (Block, 1996; Block et al., 2003; Block et al., 2001; Block *et al.*, 1996) is the most comprehensive of its kind, including a very broad range of psychosocial and medical risk factors that have been shown to have an effect on surgical outcome.

The original PPS scorecard, which used a 2 x 2 matrix discussed earlier, has since been replaced with a PPS prognostic algorithm, by its original author (Block et al., 2003). This algorithm added several new features, which enhanced its utility. First, the algorithm places psychosocial risk factors above all others since they have proven to have the most predictive power. A category termed adverse clinical features was also included to account for factors such as inconsistency, compliance issues, and medication seeking, often found in the medical chart and observed during the clinical interview. The last major enhancement in the PPS algorithm added a set of general treatment recommendations to the prediction of surgery outcome. The psychologists' recommendations fall into five categories: 1) proceed with surgery, 2) surgery with post-operative psychological sessions, 3) pre-operative psychological sessions prior to surgery, 4) non-invasive therapy recommended, 5) no treatment of any kind (Block et al., 2003).

Medical Risk Factors

Vast amounts of knowledge about a particular patient reside in the medical chart. There are several medical risk factors included in the algorithm including duration of pain, number and type of prior spine surgeries, nonorganic physical signs, and pain drawings. A detailed physical examination will reveal prior medical problems and denote risk factors such as smoking and obesity.

Duration of Pain. Duration of pain, one of the most important medical risk factors, has continuously been shown to be negatively correlated to recovery from spine surgery. Mayer, et al. (Mayer et al., 1987) noted that the chronicity of pain causes physical functioning to decline due to deconditioning syndrome, a phenomenon whereby muscles atrophy after being sedentary for long periods of time. Waddell (G. Waddell, 1987) found that only 50% of the patients in his study returned to work after 6 months of pain, 25% after 12 months, and almost no patients returned to work after 2 years of pain, thus proving the likelihood of pain patients returning to work is inversely related to the duration of pain. Research on spine surgery shows similar results. Junge, Dvorak, and Ahrens (1995) found that discectomy patients with longer duration of pain prior to surgery obtained poorer results. In 2000, Taylor et al. found longer symptom duration to be associated with less favorable outcomes from low back surgery.

Surgery Destructiveness. Many pain patients undergo numerous surgeries in an attempt to alleviate their pain. The level of destructiveness in spine surgeries can affect

treatment outcome, and is an important factor in PPS. In general, the more destructive a surgery, the greater it's associated with poorer outcome, and the possibility of re-operation or complications. Franklin, et al. (1994) found that number of prior low back surgeries and number of levels fused during prior surgeries significantly predicted worse outcomes. Turner (1992) found a trend for more positive outcome in single-level fusions over multiple-level fusions in patients being treated for herniated lumbar discs. Today, surgeons are aware of the destructiveness of spine surgery, which creates many additional problems for patients; therefore, assessing destructiveness is crucial.

Nonorganic Signs. In addition, nonorganic signs (G Waddell et al., 1980) are behavioral responses to examination that appear to have a nonorganic basis. Patients who exhibit significant numbers of nonorganic signs have been shown to have poorer outcome from treatment. In a powerful study of acute back pain patients, Gaines and Hegman (1999) showed that patients with one or more nonorganic signs had a mean return to work time of 58.5 days versus 15.0 days for patients free of nonorganic signs. With respect to surgical results, Dzioba and Doxey (1984) found nonorganic signs to be a major risk factor for poor surgical outcome.

Abnormal Pain Drawing. Pain drawings consist of front and back outlines of human figures. The patient is asked to identify on the drawing the areas where he/she is experiencing pain (Ohnmeiss, 2000; Ransford *et al.*, 1976). Abnormal pain drawings can be indicative of pain that is partially related to psychosocial factors, and can be predictive of treatment outcome. Uden, Astrom, and Bergenudd (1988) found that patients whose

drawings showed poor anatomic localization had poorer outcome after treatment. Many studies have associated abnormal pain drawings with reduced effectiveness of spine surgery (Dzioba & Doxey, 1984; Sorensen, 1992; Takata & Hirotani, 1995).

Number of Previous Surgeries. Lehmann and LaRocca (1981) showed equivocal results from analyses according to a number of previous surgical procedures affecting improvement from subsequent surgeries. However, many studies have shown previous spine surgery to impact treatment outcomes. Pheasant et al. (1979) found that patients with prior spine surgeries had much lower probability of good outcome than compared to others. Turner, et al. (1992) published a review of articles looking at patient outcomes after lumbar spinal fusions. They showed the satisfactory outcome rate was negatively associated with the percentage of patients with prior back surgeries. Taylor et al. (2000) found outcomes among patients with at least one prior back operation to be significantly worse.

Prior Medical Problems. Higher levels of prior medical problems and healthcare utilization may be a risk factor for poor surgical outcomes. Hoffman et al. (1993) examined multiple surgical outcome studies and found that more successful discectomy outcome was generally more likely in patients with lower numbers of hospitalizations. Others have found hypervigilance of physical symptoms, which results in more visits to healthcare providers, to be correlated significantly with poor treatment outcome (Crowell & Barofsky, 1999; Deyo & Diehl, 1988; Lautenbacher & Rollman, 1999).

Obesity and Smoking. The last medical risk factors included in the algorithm are obesity and smoking. There is little in the literature in relation to spine surgery and its correlation with obesity and smoking, although both are factors in maintaining healthy lifestyles. Block, et al. (2001) found obesity to be the only medical risk factor to contribute to predicting the outcome of spine surgery; therefore, it has been included in the PPS algorithm. Despite the fact that Block, et al. (2001) did not find smoking to be a significant predictor of outcome, it is widely accepted that smoking causes serious illness, and thus it remained in the algorithm. Manniche et al. (1994) discovered that smokers were more likely to achieve poorer surgical outcomes. Brown, Orme, and Richardson (1986) showed that smoking affects surgical results. They found that 8% of nonsmokers and 40% of smokers developed pseudoarthrosis, which may be a result of lower levels of oxygen in the blood of smokers as compared to nonsmokers. Both smoking and obesity are considered moderate risk factors for treatment outcome.

Interview Risk Factors

The PPS interview should occur after the psychologist has thoroughly reviewed the patient's medical chart in order to become familiar with the nature of the patient's pain and the proposed treatment. The psychologist can also glean clues regarding issues of motivation and noncompliance from the medical chart. Interviews should begin with an explanation of the rationale for the evaluation. A semi-structured format and a form for recording patients' responses will ensure that none of the information needed to arrive at a recommendation is missed during the interview (Block et al., 2003). Block, Gatchel,

Deardorff, & Guyer recommend starting with history of the injury and previous medical treatments in order to allow the patient ease into the more interpersonal topics, such as the emotional impact of the injury and the pain. Interviews also provide a great backdrop for observing the patient to pick up on clinical features and to decipher if the patient's behavior is consistent with the level of pain reported.

Job Dissatisfaction. Several important vocational factors including job satisfaction, workers compensation status, and presence of litigation are covered in the interview. Job dissatisfaction has been continually correlated to back injuries and pain. Bigos et al. (1991), in a landmark study of 3020 aircraft employees, found that workers who responded positively to a statement, "I hardly ever enjoy job tasks" were 2.5 times more likely to report a back injury than those enjoying their jobs. Boos, et al. (2000) found that physical job characteristics and psychological aspects of work (dissatisfaction) were the best predictors of low back pain. Similarly, Vingard et al. (2000) showed that current job dissatisfaction (among other physical and psychological work factors), tended to increase risk of seeking medical care for low back pain. Although these studies do not look at the relationship of job dissatisfaction to spine surgical outcome, Block, et al. (2003) implicated that patients who are satisfied with their work are more likely to be responsive to all treatments (surgical and non-surgical).

Workers' Compensation. A large proportion of research has focused on the effects of workers' compensation (WC) on recovery, and the literature shows that patients within the WC system have poorer surgical results. Greenough and Fraser

(1989) reviewed 150 patients who recovered from low back pain treatments, comparing those compensable and those noncompensable by WC. They found that the compensation group had a higher incidence of reported pain, disability, psychological disturbance, unemployment and length of time off work. Knox and Chapman (1993) performed a retrospective study on twenty-two patients who underwent lumbar fusion for low back pain. They found patients with workers' compensation had poorer outcomes overall. In a long-term follow-up study (mean 10.8 years) of 984 patients operated on between 1959 and 1991, Davis (1994) showed WC claims to be the most frequent deterrent to good functional outcome. Glassman et al. (1998) also found that WC patients reported significantly less improvement after lumbar fusion than those patients not involved in the WC system. Klekamp, McCarty, and Spengler (1998) compared the outcomes of lumbar discectomy patients involved in WC with those patients not involved in WC. Of the fifty-four patients included in the study, 81% of patients in the noncompensation group achieved good results, whereas only 29% of those patients in the WC group achieved positive outcomes. As evidenced above, compensation is a strong predictor of treatment outcome in pain patients.

Litigation. Some patients in pain resort to litigation, often as a result of pain preventing them from returning to work, and resulting in a loss of income. Attorneys are sometimes retained in order to help patients obtain disability benefits or WC. Alternatively, litigation can be used as a means of retaliation against the person or entity the patient feels is to blame for their injury. Many researchers have shown that litigation has a negative effect on surgical outcomes. Finneson and Cooper (1979) cited patients

with a history of lawsuits and secondary gain issues correlated with poorer results for discectomy. Davis (1994) found pending legal claims to be one of the most common factors associated with disc surgery failure. Similarly, Glassman et al. (1998) found litigation to be a significant factor negatively affecting the outcome of lumbar fusion. At follow-up after laminectomy/discectomy, Klekamp et al. (1998) found that 73% of patients without legal representation achieved good results, compared to 17% of those patients obtaining attorneys.

Spousal Solicitousness and Support. Two important interpersonal factors affecting surgical results are spousal solicitousness and spousal support. Spousal solicitousness is an emotional way of responding to a patient that expresses great care and concern, often seen as a response to pain behaviors in the patient (Block & Boyer, 1984; Block *et al.*, 1980; Lousberg *et al.*, 1992). According to Fordyce's (1976) behavioral assumption, pain behavior can increase if rewarded and decrease if rewards are withheld. Extensive research in this area shows that spousal solicitousness is positively correlated with greater periods of pain (Block & Boyer, 1984; Block *et al.*, 1985; Block et al., 1980). Block, Kremer, and Gaylor (1980) used the notion of operant conditioning introduced by Skinner (1974) to measure the influence of spousal response to pain behaviors. They found that patients with solicitous spouses reported greater levels of pain while being observed by their spouse as opposed to when observed by neutral parties. Spousal solicitousness was included in the original algorithm (Block et al., 2001) and found to significantly contribute to the regression equation. Conversely, spousal support has been shown to have positive effects on recovery and outcome in several

studies. Mutan, Reitzes, Mossey, and Fernandez (1995) examined patients recovering from hip surgery and found that those with low levels of support achieved less improvement in post-surgical ability to walk than those with higher levels of support. Additionally, social support from a spouse was significantly correlated with greater pain relief in patients recovering from lumbar discectomy (Schade, 1999).

History of Abuse or Abandonment. Historical factors such as physical and/or psychological abuse and abandonment, substance abuse, and previous psychological difficulty have also proved to have a major effect on the patient's ability to cope and recover from treatment. Child abuse and/or abandonment can have long-lasting effects on a person, and is common in many pain patients (Haber & Roos, 1985). Haber and Roos (1985) documented the incidence and prevalence of abuse in the pain population and investigated the potential relationship between abuse and the development and maintenance of chronic pain. They found 53% of the 151 women evaluated at a multidisciplinary pain center were physically and/or sexually abused. They also suggest that a large percentage of these women use somatization as their primary coping strategy, citing a significant difference in the number of medical problems in the abused women as compared to the nonabused women. Walker et al. (1988) studied the relationship between childhood sexual abuse and chronic pelvic pain in females. They found that 64% of patients with chronic pelvic pain had been sexually abused before age 14, which is more than double the rate found in the control group. Linton (1997) investigated the relationship between physical and sexual abuse and back pain. He found that women with experiences of sexual and/or physical abuse had significant increases (five-fold and

four-fold, respectively) in the risk of pronounced pain. Bailey, Freeddenfeld, Kiser, and Gatchel (2003) looked at lifetime physical and sexual abuse rates in chronic pain patients, finding that 61% (99 of 162) patients reported a history of physical and/or sexual abuse. Positive histories of abuse and abandonment have also been shown to have an effect on treatment outcomes for pain. Schofferman et al. (1992) interviewed 100 consecutive patients undergoing lumbar spine surgery, questioning them about five types of childhood abuse including physical abuse, sexual abuse, substance abuse by a caregiver, abandonment, and emotional abuse or neglect. They found that patients who reported no instances of abuse or abandonment had a 95% surgical success rate, patients with one or two types of abuse/abandonment had a 73% success rate, and patients with three or more categories of abuse had a 15% success rate. Burton, Polatin, and Gatchel (1997) reviewed 70 patients with upper extremity disorders in a multidisciplinary setting. They found only 33% of those patients with a history of child abuse (physical, sexual, or combined) returned to work after treatment, as compared to 72% of the patients without abuse histories who return to work. Thus, the above evidence strongly points to the fact that individuals with a history of abuse and/or abandonment have an increased risk for developing pain and are less likely to respond positively to treatment.

Substance Abuse. Pain patients have shown a higher prevalence for abuse of substances such as illegal drugs or alcohol. They also have the potential for addiction to pain medications, although this does not occur regularly (Merskey & Moulin, 1999; Portenoy, 1994). Atkinson et al. (1991) compared a group of men with chronic low back pain to a no-pain control group and found 64.9% versus 38.8% to have an alcohol use

disorder. Drug and alcohol abuse is not only prevalent in the pain population, but has shown to affect treatment outcomes. Spengler, Freeman, Westbrook, and Miller (1980) conducted a retrospective review of 30 patients with failed surgical procedures for low-back pain, sciatic pain, or both, and found 25 of the 30 to have a history of medication and/or alcohol abuse. Likewise, Uomoto, Turner, and Herron (1988) found that a history of alcohol abuse significantly correlated with poorer outcome following laminectomy/discectomy. Therefore, it is important to investigate historical and current drug and/or alcohol abuse, as they have shown to affect treatment outcome.

Psychological History. The last factor to consider is a history of prior psychological problems. Many studies have shown a strong association between chronic pain and psychopathology. In 1991, Atkinson et al. assessed the lifetime prevalence of psychiatric disorders in a sample of men with CLBP. They found at least one psychiatric disorder to be present in 81% of patients with CLBP and in 59% of non-pain controls. Kinney et al. (1993) showed 100% of CLBP patients to have at least one Axis I disorder, either past or present. Psychopathology has also been found to significantly reduce surgical outcome (Block et al., 2001; Keel, 1984; Manniche et al., 1994). Keel (1984) reviewed 18 studies on the psychosocial aspects of back pain and found that patients without signs of psychological disturbance tend to have a better outcome after surgery.

Testing Risk Factors

Psychological testing is an important part of PPS for a number of reasons. First, it is an effective way to collect a large amount of information about a patient. It also serves

as a second opinion, so to speak, on the information collected by the psychologist during the clinical interview. Lastly, psychological testing can notably contribute to the selection of treatment for an individual patient by elucidating characteristics of the patient's personality and coping style. The PPS algorithm looks at results from the MMPI-2, BDI, HAM-D, and CSQ, and includes a section containing the following risk factors found in the psychological testing: pain sensitivity, depression (both chronic and reactive), anger, anxiety, depressed pathology, and catastrophizing.

The MMPI and the MMPI-2 (revised version) have been extensively applied and studied in research and is the most widely used objective personality test. It is also the instrument most commonly used for assessing the personality characteristics of chronic pain patients. There are 3 validity scales and 10 clinical scales relating to personality characteristics (see J.R. Graham, 1993).

Pain sensitivity. The Hs (Hypochondriasis) and Hy (Hysteria) scales were created to identify those patients who express emotional distress and psychological problems with physical symptomology (J.R. Graham, 1993). Typically, these patients are thought to show a greater sensitivity to pain, denial of affect, unrecognized needs for affection, general dissatisfaction with life, and "conversion" of psychological difficulties into complaints of physical symptoms (J.R. Graham, 1993).

In 1975, Wiltse and Rocchio claimed that the MMPI scales of Hs and Hy were the best predictors of unsuccessful lumbar surgery. Pheasant, Gilbert, Goldfarb, and Herron (1979) looked at the MMPI as a predictor of outcome in low back surgery. They concluded that the Hy and Hs scale scores appeared to be inversely related to surgical

outcome; the more Hy or Hs exceeded a t-score of 70, the less likely surgery was to succeed. They also found that a conversion-V pattern (Hy and Hs above 70, with depression (D) relatively lower) was associated with poor surgical outcome. Riley, Robinson, Geisser, Wittmer, & Smith (1995) also found the patients with a conversion-V pattern on the MMPI-2 received less favorable results with spinal fusion. The majority of research in the past few decades have been in support of the aforementioned studies and generally found high scores on the Hy scale, and to a lesser extent, high scores on the Hs scale to be accurate predictors of poor surgical outcome (Block et al., 2003; Block et al., 2001; Kuperman *et al.*, 1979; C. Long, 1981; D. M. Spengler, Ouelette, F.A., Battie, M. and Zeh, J., 1990).

Block, et al. (1996) used computed tomography to show patients with elevations on Hs and Hy scales as more likely to over report pain and report discordant positive pain during discographic injections (a procedure in which radiographic contrast is injected into the nucleus of the intervertebral discs). Patients were injected at three disc levels, those suspected of damage and one suspected to be healthy. Block and colleagues found a number of patients with elevations of Hs and Hy ($T > 75$) to report pain when injected into both damaged and non-damaged discs. Block refers to these patients, stating, “because their personality traits may predispose patients toward excessive physical symptoms and a negative attitude toward treatment, good clinical outcomes may be more difficult to obtain”(Block, 1992, pg. 618). Their results suggest that patients with MMPI scale scores greater than 70 on Hs and Hy need to be carefully considered before making recommendations for surgery.

Depression. It is quite common for patients experiencing chronic pain to have many symptoms that are commonly seen in Major Depressive Disorder (MDD). Studies have found depression to be present in up to 85% of patients with chronic pain (Lindsay & Wyckoff, 1981). Difficulty sleeping, excessive worrying, memory and concentration problems and decrease in sexual interest can all occur as a result of the pain one experiences (Block et al., 2003). Chronic pain patients often experience a decrease in their level of functioning, less ability to engage in activities they used to enjoy, and require medication that may have considerable side effects, increasing their propensity for depressive symptoms. Further, the effects of depression worsen the prognosis of chronic pain treatments. Depressed chronic pain patients tend to be more sensitive to pain, reduce their physical activity, and as a result, are more physically inhibited (A. Rush et al., 2000). Kremer, Block, & Atkinson (1983) found that depressed patients have problems recognizing and tend to underreport improvement in functioning. Kjellby-Wendt, Styf, & Carlsson (1999) used the BDI (A. T. Beck et al., 1961) to measure depression prior to lumbar disc surgery and found that patients with depressive symptomatology were more likely to be discontented with surgical outcomes. Furthermore, Block, et al. (2001) showed that elevated scores on scale 2 of the MMPI-2 (Depression) correlated with poorer spine surgery outcomes.

Many studies have shown depressive symptomatology to exist prior to the onset of pain. Polatin et al. (1993) found depression to be the most common current and/or lifetime psychiatric disorder in CLBP patients. Furthermore, 39% of these patients reportedly displayed symptoms of pre-existing depression. Atkinson et al. (1991) looked at depression in males treated at the VA for chronic pain, finding that 42% of the patients

experienced onset of depression before their pain began, whereas 58% experienced depression after their pain started. Although there is no research in the pain literature that examines the impact of pre-existing versus reactive depression on the outcome of surgery, it has been hypothesized that depressive symptoms in those patients with pre-existing depression would be more likely to persist postoperatively, negatively impacting recovery (Block et al., 2003).

Anger. Patients with chronic back pain often experience intense anger (D C Turk & Fernandez, 1995). Fernandez, Clark, and Ruddick-Davis (1999) reported that in a study where chronic pain patients rated the frequency they experienced six emotions—fear, sadness, shame, guilt, envy, and anger—in the last 30 days. Although chronic pain patients often experience all of these emotions commonly, Fernandez, Clark, & Ruddick-Davis found anger was reported most frequently, at an average of about 70% of the time.

Anger may have a negative impact on surgical outcome and recovery (Block et al., 2003). The MMPI scale that best approximates anger is Scale 4 (Psychopathic Deviate [Pd]). Patients with elevations on this scale tend to be hostile, aggressive, rebellious, and antagonistic (J.R. Graham, 1993). Research has shown Scale 4 elevations correlate with poor surgical results (Block et al., 2001; Herron *et al.*, 1992; C. Long, 1981; D. M. Spengler, Ouelette, F.A., Battie, M. and Zeh, J., 1990). Fernandez and Turk (1995) proposed that anger could lead to maladaptive lifestyle changes and health problems (i.e. drug and alcohol abuse). Block, et al. (2003) suggests that angry patients can compromise their recovery by not complying with treatment recommendations. Chronic anger appears to lead to poor surgical outcomes.

Anxiety. The assessment of anxiety and fear is helpful in treating chronic pain patients (McCracken *et al.*, 1996). Anxiety commonly increases prior to undergoing surgery and can become intense just prior to surgery. Characteristics of anxiety are associated with Scale 7 (Psychasthenia, Pt) on the MMPI-2. Elevations on this scale are characterized as “very anxious, tense, and agitated” (J R Graham, 1990, p. 74) and have been associated with poor surgical results. Block, et al. (2001) found that Scale 7 significantly predicted surgical outcome and contributed to a regression equation that determined the significance of variables in the PPS method they used to predict outcomes. Several studies have found the presence of anxiety in psychological test data to be associated with less positive outcomes (Kjellby-Wendt et al., 1999; Schade, 1999; Trief, 2000).

Catastrophizing. Although most patients who undergo spine surgery recover without much difficulty, there are patients with long-standing personality characteristics that appear to be acutely affected by and unable to recover from pain. Researchers have tried to determine why some patients experience extreme distress as a result of their pain, while others are able to cope quite well (Block et al., 2003). Lazarus and Folkman (1984) developed a conceptual model that described the ways in which individuals deal with stress; the concept of coping is derived from this model. Turner and Clancy (1986) defined coping as “the thoughts and behaviors people use to manage their pain or emotional reactions to the pain so as to reduce emotional distress.”

Rosenstiel and Keefe (1983) developed the Coping Strategies Questionnaire (CSQ), which examines six different types of coping strategies as they relate to pain diverting attention, reinterpreting pain sensations, coping self-statements, ignoring pain sensations, praying or hoping, and catastrophizing. Catastrophizing can be broadly defined as “an exaggerated negative mental set brought to bear during actual or anticipated pain experience” (Sullivan *et al.*, 2001). Individuals who tend to catastrophize experience higher levels of psychological distress, poorer physical functioning and increased disability, and greater level of pain intensity (Block *et al.*, 2003).

Several studies have examined the CSQ as it relates to pain and surgical outcomes. Dozois, Dobson, Wong, Hughes, & Long (1996) prospectively compared the individual and composite scores of the CSQ in the prediction of adjustment to low back pain. They found catastrophizing to be positively associated with both perceived disability and psychological distress, and negatively related to the outcome measure functional status. Gross (1986) examined pain intensity, sleep disturbance, and patient-rated surgical outcomes in 50 laminectomy/discectomy patients who were given the CSQ prior to surgery. He found that patients who scored high on the “loss of control” factor (a combination of high scores on the catastrophizing scale and low scores on the pain control scale) reported greater levels of post-operative pain and poorer surgical outcomes than those scoring high on this scale. Block, *et al.* (2001) used the CSQ preoperatively as part of a PPS with 204 patients undergoing spine surgery. The CSQ self-reliance factor was found to be a significant contributor to a hierarchical regression analysis equation

that predicted overall surgical outcomes. Based on the evidence presented, coping strategies appear to have a strong impact on surgical outcomes.

Adverse Clinical Features

Block, et al. (2001) included a group of clinical features not explicitly included on the PPS risk factor scorecard that, in the psychologist's mind, can negatively influence surgical results (Block et al., 2003). They include: inconsistency, medication seeking, staff splitting, compliance issues, threatening, resignation, deception, and personality disorders. These features can be obtained from a patient's medical chart or during the clinical interview, and are somewhat impressionistic in nature. There is little information in the literature about the adverse clinical features as they relate to surgical outcome; however, Block, et al. (2003) chose to include them in the algorithm without assigning them an a priori weight. Block, et al. (2003) presents specific recommendations for patients who present with adverse clinical features.

Scope of the Current Investigation

Implantable devices, specifically SCS and IDT systems, have proven to be effective and safe therapies that improve the quality of life and activities of daily living for many people disabled by chronic, intractable pain. However, a large percentage of patients implanted continue to obtain poor surgical outcomes. In recent years, the importance of psychosocial and medical risk factors in determining patient selection criteria for SCS and IT pump surgery has surfaced, but a thorough, comprehensive method for evaluating these risk factors remains undetermined.

The current study attempted to apply the Block et al. (2003) PPS algorithm to a subset of patients under consideration for a spinal cord stimulator and/or intrathecal opioid system. An effort was made to understand which risk factors in the algorithm are the most predictive of good versus poor treatment results. For the purposes of this study, the evaluation out of which the algorithm derived, is referred to as a Pre-Surgical Behavioral Medicine Evaluation (PBME). This term focuses the attention of both the provider and the patient on behavioral factors that may be predictive of outcome, thus providing the highest level of assistance to the decision making process. This term also serves to avoid misinterpretations that the referral is related to assumptions about the patients' own mental health.

We also refined Block's nomenclature for relaying presurgical prognosis and recommendations to the physician. The results of our PBME algorithm categorizes patients into five recommendation groups—1) Green (no recommendations, proceed with surgery, 2) Yellow-I (surgery with postoperative behavioral medicine treatment recommended, 3) Yellow-II (preoperative behavioral medicine treatment focusing on compliance and motivation measures recommended), 4) Red-I (non-invasive treatment recommended), and 5) Red-II (recommended discharge, no treatment of any kind). For the purposes of this study, the Red-I and Red-II groups have been combined into the Red group, as they are both contra-indications for surgery.

In the context of the above aims, the following hypotheses for this study were proposed:

Hypothesis One: All of the demographic variables collected were analyzed to determine if differences existed among groups at pre-treatment. Analyses of variance

(ANOVAs), chi-squares, and planned contrast analyses were employed to examine the data. It was expected that specific demographic variables, specifically disability payment status, would be statistically significant in determining group recommendation assignments and in predicting outcome status.

Hypothesis Two: The biopsychosocial profiles of patients were explored, using psychological and functional measures, to determine if differences existed among groups at initial evaluation. It was hypothesized that the green group would look better biopsychosocially pre-treatment than all other groups. The initial evaluation measures SF-36, MBMD, MMPI-2, BDI, HAM-D, VAS, CSQ, OSW, and DPQ were examined using ANOVAs and multivariate analysis of variance (MANOVAs) with pairwise comparisons and planned contrasts analyses.

Hypothesis Three: Assuming the algorithm developed by Block and colleagues (2003) is applicable to implantable modalities, the present study attempted to examine the efficacy of using the PBME algorithm to predict surgical outcomes for spinal cord stimulators and intrathecal morphine pumps. It was hypothesized that the Green group would show better biopsychosocial functioning than the other groups at 6-months post-initial evaluation. Psychosocial and functional measures, such as visual analogue pain scale (VAS), Oswestry Disability Questionnaire (OSW), Short-Form Health Survey (SF-36), Beck Depression Inventory (BDI), Physician Medication Assessment, vocational status, and health utilization, were used to determine overall outcome. ANOVAs and repeated measures ANOVAs were used to analyze the data. Additionally, analyses of covariance (ANCOVAs) were employed to examine groups at initial evaluation and 6-months post initial evaluation, using the initial evaluation scores as covariates.

Hypothesis Four: Binary logistic regression analyses were used to determine which individual risk factors in the PPS algorithm were the most significant predictors of prognostic assignments and outcomes. Based on literature, it was hypothesized that psychological test data would have the most predictive power.

Design and Statistical Analyses

The current prospective study design utilized data collected at initial evaluation and 6-months post-evaluation. Due to potential confounding effects of certain group characteristics in the analysis of study hypotheses, analyses were conducted to determine if the four main algorithm groups differed significantly on demographic variables at initial evaluation. ANOVAs and chi-squares were used for pre-treatment comparisons among the four groups with regard to demographic factors.

The major focus of this study is the ability of the PBME algorithm to predict outcome. The data collected at initial evaluation was analyzed using chi-squares and ANOVAs with planned contrast and pairwise comparisons. A series of analyses using paired sample t-tests, repeated measures ANOVAs, chi-squares, and planned contrasts were used to measure changes in the outcome instruments, both psychosocial and functional, collected at 6-month follow-up. ANCOVAs were also employed using initial evaluation scores as covariates, to examine differences among groups at initial evaluation and 6-months post-treatment. Lastly, binary logistic regression analyses were employed to determine which individual risk factors in the PBME algorithm were the most significant predictors of prognostic group assignments.

CHAPTER THREE

METHOD

Subjects

The Presurgical Behavioral Medicine Evaluation (PBME) subject group consisted of 60 patients referred by physicians to the Eugene McDermott Center for Pain Management at the University of Texas Southwestern Medical Center in Dallas, Texas, for a pre-surgical behavioral medicine evaluation prior to making a decision about surgery. These patients were evaluated during the time period from September 2003 to the May 2005 to determine the most effective treatment options for each individual patient. The patients were included in this study if they were being evaluated for an electrical nerve stimulator or an intrathecal pump to help manage their pain.

Procedure

Patients were referred to the Eugene McDermott Center for Pain Management at the University of Texas Southwestern Medical Center at Dallas by their treating physicians for a PBME evaluation. They were given a packet of paperwork by their treating physicians, which they were asked to complete and bring to their PBME appointment with the behavioral medicine psychologist. The packet included an explanation of the PBME, a consent form for psychological assessment and treatment, questionnaires collecting pain levels, medication usage, impact of pain on physical and emotional abilities, and overall impact of pain on lifestyle.

An evaluation by a licensed psychologist was performed, which included a diagnostic interview, a review of available records, and psychological testing. The diagnostic interview and past records were integrated with the psychological testing results to make appropriate recommendations for surgery. These results were faxed to the referring physician, delineating the basic problem areas and the recommendations for surgery. A dictated evaluation was also sent to the referring physician. The psychologists recommendations fell into five categories: 1) proceed with surgery, 2) surgery with post-operative psychological sessions, 3) pre-operative psychological sessions prior to surgery, 4) non-invasive therapy recommended, 5) no treatment of any kind. The referring physician then followed up with the patient to discuss surgery plan. The patient was also given the option of making an additional appointment with the psychologist to discuss the evaluation results directly.

Those patients falling into the recommendation groups where psychological treatment, pre-operative or post-operative, was recommended were given the option of proceeding with that treatment. Pre-operative treatment typically consists of 3-4 behavioral medicine sessions with a psychologist to help prepare the patients to manage the psychosocial factors that can influence recovery after surgery; upon completion of these sessions, these patients were given revised surgery recommendations. Post-operative treatment averaged between 1 and 10 sessions focusing on compliance and motivation to help the patient cope and adjust to issues that arise after implantation.

Patients were followed up at 3- and 6-months post initial evaluation and asked to complete the Oswestry Disability Questionnaire (Fairbank et al., 1980), the Beck Depression Inventory (A. Beck, 1967), and the Medical Outcomes Survey 36-Item Short

Form Health Survey (Ware *et al.*, 1993). Additionally, they were asked to rate their current pain level using visual analogue criteria and to complete a database variables sheet (DVS). The DVS contained questions pertaining to vocational status, healthcare utilization, disability status, and whether or not they had been implanted with an electrical nerve stimulator or an IT morphine pump.

Instruments and Outcome Measures

Confidential Pain Questionnaire (CPQ). The Confidential Pain Questionnaire is a self-report measure that requests patient information including demographic information, date and details of injury/pain condition, previous treatments for pain condition including any surgeries, employment status, education level, disability payment status, workers' compensation or personal injury litigation involvement, health care utilization, additional contact numbers, and other chronic health problems.

Visual Analogue Scale (VAS) or Pain Drawing Analogue ([PDA] Ransford *et al.*, 1976). This instrument is a visual analogue scale designed to rate the patient's degree of pain on a scale from 0 (no pain) to 10 (worst possible pain). The scale consists of a 10-centimeter horizontal line hashed at two-point intervals. The patient is asked to mark an "X" on the line to represent his or her current level of pain. Many studies support the use of the VAS with chronic pain patients. It has also demonstrated good psychometric properties (R.J. Gatchel *et al.*, 1986; Rissanen *et al.*, 1994).

Dallas Pain Questionnaire ([DPQ] Million *et al.*, 1981). The DPQ is an analogue scale comprised of 15-self report questions assessing perceived pain and disability. Subjects indicate their response to each question by marking a point on a 10-centimeter line, representing a range of possible answers from 0 to 10, and the total score is the sum of all responses. Scores of 0 to 39 indicate “mildly disabling” pain; 40 to 84 indicate “moderately disabling pain”; and 85 and above indicate “severely disabling pain.” The Dallas Pain Questionnaire has particular utility when the self-report of pain exceeds that which would be expected given physical findings, suggesting the existence of a psychosocial component in the patient’s disability (Capra *et al.*, 1985).

Oswestry Disability Questionnaire ([OSW] Fairbank *et al.*, 1980). The Oswestry is a self-rating scale that provides an evaluation of the degree of functional impairment. It is comprised of 10 questions assessing limitations of various activities of daily living secondary to pain. The items are scored on a 0-5 point scale, with a potential range of scores from 0 to 50. The Oswestry has demonstrated adequate reliability, with test-retest reliability found to be .99 with 24 hours between administrations; it has also shown adequate validity (Kaplan *et al.*, 1996; Leclaire *et al.*, 1997).

Pain Medication Questionnaire ([PMQ] Adams *et al.*, 2004). Adams (2004) developed the PMQ as a screening instrument to assess the risk of opioid medication misuse among chronic pain patients. It consists of 26 self-report items that were constructed based on behavioral correlates and attitudes suggestive of opioid misuse. The PMQ was found to be psychometrically sound, with a test-retest reliability

coefficient of .85, and examination of internal consistency yielded a Cronbach's alpha of .73. High-risk scores are associated with greater incidence of substance abuse potential and/or history, higher levels of psychological distress, reduced coping, and poorer physical functioning, including higher rates of unemployment (Adams et al., 2004).

Beck Depression Inventory ([BDI] A. T. Beck et al., 1961). The Beck Depression Inventory (BDI) is a 21-item self-report inventory designed to assess the intensity of depressive symptomatology. Each item is scored from zero to three, with a potential range of scores from 0 to 63. A total score of 0-9 is considered normal; 10-15 is mild depression; 16-19 represents mild to moderate depression; 20-29 reflects moderate to severe depression; and 30+ indicates severe depression. Research using the BDI has established good psychometric properties, including internal consistency reliability coefficients exceeding .73 in non-psychiatric samples. The Hamilton Rating Scale for Depression (HAM-D, 1960) and the BDI have correlations of .73, suggesting adequate validity (A. T. Beck *et al.*, 1988).

Millon Behavioral Medicine Diagnostic ([MBMD] Millon *et al.*, 2001). The MBMD is a 165-item, self-report inventory that is designed to assess psychological factors that can influence the treatment course of medical patients. The developers of the MBMD describe it as a substantial upgrading of their previous Millon Behavioral Health Inventory (MBHI). The MBMD yields 29 clinical scales, 3 response pattern scales, 1 validity indicator, and 6 negative health habits indicators. It is appropriate for use with adult clinical and rehabilitation patients (aged 18-85) who are undergoing medical care or

surgical evaluation. The MBMD has demonstrated satisfactory reliability with an internal consistency estimate of .79, and test-retest estimates with a median value of .83 (Millon et al., 2001).

Minnesota Multiphasic Personality Inventory-Second Edition ([MMPI-2] Butcher et al., 1989). The MMPI-2 is a 567-item, self-report measure of personality functioning and psychiatric symptoms. It is the most commonly used personality test for patients with chronic pain. These patients demonstrate a higher prevalence of psychiatric disorders, particularly depression and personality disorders, than the general population (Deardorff, 2001). There are 10 empirically-derived clinical scales and numerous supplementary scales. Several validity scales are provided to assess the test-taking attitudes of the patient.

The MMPI-2 normative sample closely approximated 1980 census data, and demonstrated adequate internal consistency and test-retest reliability (J R Graham, 1990). In the assessment of chronic pain patients, the MMPI-2 is useful in the identification of psychopathology as well as personality and behavioral characteristics, treatment planning, and prediction of treatment outcomes (Deardorff, 2001). A meta-analysis conducted by Parker, Hanson and Hunsley (1988) reported an average stability coefficient of .74 for the MMPI-2 test-retest reliability, and an average internal consistency correlation of .87. In terms of discriminant validity, the MMPI was found to be effective in distinguishing between psychiatric and control groups, neurotic and psychotic groups, and depression and anxiety groups (Zalewski & Gottesman, 1991).

Medical Outcomes Survey 36-Item Short Form Health Survey ([SF-36] Ware et al., 1993). The SF-36 is a 36-item questionnaire that assesses health-related quality of life, both physical and mental, from the point of view of the health care recipient. It is widely used for routine monitoring and assessment of health-care treatment outcomes. It yields eight scales, as well as two standardized summary scales, the Mental Component Scale (MCS) and the Physical Component Scale (PCS), which correspond respectively to patients' overall sense of physical and mental well-being. The availability of population-based normative data from various medical populations makes the SF-36 useful for comparative purposes as well. Numerous studies have reported high test-retest reliability coefficients, and examination of internal consistency has found Cronbach's alphas exceeding .70, and usually above .80 (Ware et al., 1993).

Coping Strategy Questionnaire ([CSQ] Rosenstiel & Keefe, 1983). The Coping Strategy Questionnaire is a 42-item self report inventory that assesses the frequency of use of six cognitive coping strategies and 2 behavioral coping strategies, including diverting attention, reinterpreting pain sensations, ignoring pain, praying and hoping, coping self-statements, increasing behavioral activities, and catastrophizing. It also contains 2 additional items related to subjective ability to control and decrease pain. Patients indicate on a 6-point scale, where 0 = never do that, 3 = sometimes do that, and 6 = always do that, activities they engage in when experiencing pain. The CSQ has demonstrated adequate to excellent internal consistency (Rosenstiel & Keefe, 1983) and test-retest reliability (Main & Waddell, 1991). Factor scores derived from the CSQ have

been shown to be associated with dimensions of pain-related adjustment and functioning (Dozois et al., 1996; Keefe *et al.*, 1987).

Treatment Helpfulness Questionnaire ([THQ] Chapman *et al.*, 1996). The Treatment Helpfulness Questionnaire is an 11-item patient rated inventory of the helpfulness of various aspects of interdisciplinary treatment programs. Patients rate the particular modality on a 16-point scale, in which 0 = very harmful, 4 = harmful, 8 = neutral, 12 = helpful, and 16 = very helpful. The THQ is used first to rate treatments received prior to the patient's entry into the treatment program. After completion of the interdisciplinary treatment program at McDermott, patients then complete another THQ assessing their experiences of the treatment. The scale affords patients to rate the helpfulness of the entire program, medical office visits, medical assessment, medical diagnostic tests, epidural steroid injections, medication management, psychological assessment, group counseling, patient education, and physical therapy assessment and treatment.

Hamilton Psychiatric Rating Scale for Depression ([HAM-D] Hamilton, 1960). The HAM-D evaluates depressive symptomatology using a structured interview format. It consists of 17 items rated on a 3- to 5-point scale, which cover multiple content areas related to depression. The higher scores represent more severe symptomatology. The following cut-off scores are used to assess severity of depression: <12 (none to minimal); 12-20 (mild to moderate); 21-29 (moderate to severe); 30+ (severe). The HAM-D has demonstrated a good inter-rater reliability correlation coefficient of .9 (A. J. Rush *et al.*,

1977). It has also demonstrated acceptable concurrent validity of .73 with the BDI (A. T. Beck et al., 1988).

Physician Medication Assessment. The Medication List-Physician Report is a form with a list of all medications and the possible daily dosages. It is completed by the physician at pre-treatment and post-treatment visits to assess patients' medication utilization

CHAPTER FOUR

RESULTS:

DEMOGRAPHIC VARIABLES

Initial Evaluation Sample: Demographic Variables

Demographic data about the study sample are presented in Appendix B, Table 1. The total sample of 60 patients was analyzed for proportional breakdowns on the categorical variables of gender, race, marital status, disability payment status (receiving disability payments or not), litigation status (involved in pending litigation related to their pain or not), and type of implantable device. The continuous variables of age and pain duration were analyzed for the overall means, standard deviations, minimums, and maximums for each prognostic group. Additionally, all the demographic variables were analyzed to look for differences among the four overall prognostic groups. It was hypothesized that demographic variables would be statistically significant in determining group recommendation assignments and predicting outcomes. The results for these analyses can be found in Table 2.

Demographic Variables: Descriptive Analyses

Sixty patients referred for presurgical behavioral medicine evaluations prior to receiving implantable devices to help manage chronic pain were included in the initial evaluation sample. Of the 60 patients in this sample, 58% were female and 42% were male. The mean age was 55.5 years ($SD = 15.23$), ranging from a minimum of 30 years to a maximum of 90 years. The largest racial group was Caucasian at 90%; African-

Americans, Hispanics, and other races made up the remaining 10%. In terms of marital status, 68.4% of the subjects were married or living with significant others, 13.3% were separated or divorced, 11.7% were widowed, and 6.7% were single. It was found that 36.7% of the sample was receiving disability income, and approximately 8% had pending litigation related to their pain condition at the time of the initial evaluation. The mean length of pain for the sample was found to be 102 months (approximately 8.5 years) with wide variability ($SD = 112.75$). The majority of the sample was evaluated for a type of stimulator (64.4%), while 30.5% were seeking evaluations for IT pumps and 5.1% for other devices.

Comparison of Four Overall Prognostic Groups on Demographic Variables

Pearson Chi-Square analyses were used to compare the groups on the categorical variables of gender, race, marital status, disability payment status, and litigation status, whereas one-way ANOVAs were used to compare the groups on the continuous variables of age and pain duration. No significant differences were found among the four prognostic groups on the variables of age, race, marital status, pending litigation, or pain duration. Significant differences were found for gender, $\chi^2(3) = 8.87$, $p = .03$, and disability payments, $\chi^2(3) = 7.79$, $p = .05$. Pairwise comparisons revealed that, when comparing the Green and Red groups, male patients were 18.7 times more likely (70%) than females (30%) to be classified in the Green group, $\chi^2(1) = 6.74$, $p = .009$, OR = 18.7, 95% C.I.: 1.56-222.93. Males were 5.4 times more likely than females to fall in the Green group when comparing the Green and Yellow 2 groups, $\chi^2(1) = 4.34$, $p = .037$,

OR = 5.44, 95% C.I.: 1.04-28.53. Regarding disability payment status, pairwise comparisons revealed that the Red group (55.6%) contained significantly greater proportions of patients receiving disability than the Green group (0.0%), $\chi^2(1) = 7.54$, $p = .006$. Both the Yellow-I group (38.1%) and the Yellow-II group (45.0%) also contained significantly more patients receiving monies when compared to the Green group (0.0%), $\chi^2(1) = 5.14$, $p = .023$, and $\chi^2(1) = 6.43$, $p = .011$, respectively.

CHAPTER FIVE

RESULTS:

THE BIOPSYCHOSOCIAL PROFILES OF THE FOUR PROGNOSTIC GROUPS AT INITIAL EVALUATION

The current study hypothesized that the patients in the Green group would be functioning better biopsychosocially than all other groups at initial evaluation. The four prognostic groups were compared on a range of physical/functional measures, including the Dallas Pain Questionnaire (DPQ), the Visual Analogue Scale (VAS), the Oswestry (OSW), and the SF-36/Physical Component Score (PCS). A variety of psychosocial measures such as the Beck Depression Inventory (BDI), the Hamilton Psychiatric Rating Scale for Depression (HAM-D), the Coping Strategy Questionnaire (CSQ), the Millon Behavioral Medicine Diagnostic (MBMD), the Minnesota Multiphasic Personality Inventory-Second Edition (MMPI-2), and the SF-36/Mental Component Score (MCS) were also employed to examine differences in psychosocial functioning between the groups at initial evaluation. Lastly, the Physician Medication Assessment was analyzed to determine if differences in medication use existed at initial evaluation among the prognostic groups.

Physical/Functional Measures Relative to Prognostic Group at Initial Evaluation

The physical/functional measures were analyzed using ANOVAs, with post-hoc comparisons to identify specific differences among the groups. No significant differences were found among groups on the measures of perceived pain status (VAS),

perceived pain and disability (DPQ), and physical health-related impairment (SF-36/PCS). The DPQ did show a significant trend ($p = .023$) with scores increasing as prognostic group worsened. Significant differences were found among the four groups on the OSW, a measure of pain-related limitation, $F(3, 48) = 3.63$, $p = .019$ (Table 3). Tukey HSD test/corrections showed that the Red group endorsed significantly more limitations of activities of daily living (ADL) and disability than the Green group, followed by the Yellow-II group also endorsing limited ADLs and disability (illustrated in Appendix A, Figure 1). A significant linear trend was also observed on the OSW ($p = .003$) indicating that the groups progressively endorsed more limitations as prognosis worsened.

Psychosocial Measures Relative to Prognostic group at Initial Evaluation

MMPI-2 clinical scales. The MMPI-2 clinical scales were utilized to examine the relationship between psychological functioning and prognostic determination. A MANOVA was first performed to determine if significant differences existed among the overall mean T-scores of the four prognostic groups on the MMPI-2 clinical scales. The MANOVA revealed significant differences existed among the four groups and MMPI-2 scales, Hotelling's Trace = 1.44, $F(39, 122) = 1.51$, $p = .048$, which justified conducting ANOVAs for each individual MMPI-2 scale. Differences were found among prognostic groups for the F Scale ($p < .001$), K (Correction) Scale ($p = .033$), Scale 1 Hypochondriasis ($p = .004$), Scale 2 Depression ($p = .016$), Scale 3 Hysteria ($p = .030$), Scale 4 Psychopathic Deviate ($p = .006$), Scale 6 Paranoia ($p < .001$), Scale 7 Psychastenia ($p = .008$), Scale 8 Schizophrenia ($p < .001$), and Scale 9 Hypomania ($p = .022$). These

results are presented in Table 4. Planned contrasts revealed that the Green and Yellow-I groups together had significantly lower mean scores on the F scale, Scale 1 Hypochondriasis, Scale 2 Depression, Scale 3 Hysteria, Scale 4 Psychopathic Deviate, Scale 6 Paranoia, Scale 7 Psychastenia, and Scale 8 Schizophrenia than the Yellow-II and Red groups. They also showed that the Green group had a significantly higher mean score than the Red group on the K (Correction) Scale, and a significantly lower mean score than the Red group on Scale 0 Social Introversion (Table 5). Figure 2 illustrates the MMPI-2 profiles for the four prognostic groups.

MBMD clinical scales. The MBMD is designed to assess psychological factors that can affect the course of medical treatment and recovery. A MANOVA was performed to examine the relationship between the 29 MBMD clinical scales and the prognostic groups. A two-tailed analysis of the clinical scales yielded significance, Hotelling's Trace = 6.27, $F(29, 87) = 1.78$, $p < .01$. These findings suggest that univariate analyses of variance may be safely conducted for each individual scale, without undue inflation of Type I error rates. Results of the subsequent one-way analyses of variance revealed significant differences among the prognostic groups on the following scales: Anxiety Tension ($p = .006$), Depression ($p < .001$), Cognitive Dysfunction ($p = .004$), Emotional Lability ($p = .005$), Inhibited ($p < .001$), Dejected ($p < .001$), Cooperative ($p = .003$), Confident ($p = .002$), Nonconforming ($p = .041$), Oppositional ($p < .001$), Denigrated ($p < .001$), Illness Apprehension ($p = .016$), Functional Deficits ($p = .028$), Pain Sensitivity ($p = .010$), Social Isolation ($p = .001$), Interventional Fragility ($p = .006$), Information Discomfort ($p = .007$), Utilization Excess ($p < .001$), Adjustment Difficulties

($p = .002$), and Psych Referral ($p = .001$). The results for these analyses can be found in Table 6. Planned contrast and post-hoc analyses revealed that the differences were largest between the Green and Red prognostic groups for most of the significant scales, with the Green group having a significantly lower mean score when compared to the Red group (Figure 3).

Coping measures. Psychosocial measures were also analyzed using ANOVAs, with post-hoc comparisons to specify the differences among the groups (Table 7). No significant differences were found on the CSQ, a measure of the overall level of coping strategy employed to help manage pain. However, significant differences were found on one of the six cognitive coping strategy scales, the Catastrophizing scale, $F(3, 48) = 7.06$, $p = .001$. Tukey HSD test/corrections revealed that the Red group scored significantly higher on the Catastrophizing scale than the three other groups: Green, Yellow-I, and Yellow-II (Figure 4). A significant linear trend was also observed ($p < .001$) with overall catastrophizing scores increasing as prognostic group worsened. There were also significant differences found on the MCS; post-hoc comparisons showed the differences among the groups, $F(3, 16) = 4.72$, $p = .015$. Particularly, the Red group's score, the lowest score on the MCS among the four groups, was significantly lower than the Yellow-I group's score. A higher score on the MCS indicates that an individual is reporting less mental impairment (Figure 5).

Mood measures. The ANOVA showed significant differences on the HAM-D, $F(3, 56) = 17.14$, $p < .001$. Post-hoc analyses revealed that the Green and Yellow-I groups

scored significantly lower on the HAM-D (scores in the none-minimal range) than the Yellow-II and Red groups. There were also significant differences seen between the Yellow-II and Red groups, with the Red group scoring significantly higher on the HAM-D, reflecting depressive symptomatology falling in the moderate-severe range (Figure 6). A linear trend was observed on the HAM-D ($p < .001$) with prognostic groups endorsing more depressive symptomatology as the prognosis declined. Lastly, significant differences were found on the BDI, a measure of depressive symptomatology, $F(3, 56) = 12.53$, $p < .001$. Once more, Tukey HSD test/corrections revealed that the Red group scored significantly higher on the BDI than all other groups. The Green group scored the lowest on the BDI, endorsing the fewest symptoms of depression, followed by the Yellow-I and Yellow-II groups, respectively (Figure 7). Similar to the HAM-D, a significant linear trend was observed on the BDI ($p < .001$).

Medication Use Relative to Prognostic groups

The Physician Medication Assessment was analyzed using complex chi-squares to determine if differences existed in medication use among the groups. Medication was broken down into three classifications including narcotic use, non-narcotic use, and no medication use. No differences were seen at initial evaluation among the groups. Table 8 presents these data.

CHAPTER SIX

RESULTS:

INITIAL EVALUATION AND SIX-MONTH FOLLOW-UP COMPARISONS FOR PROGNOSTIC GROUPS

The current study hypothesized that the Green group would have a significantly better biopsychosocial profile at six-month follow-up when compared to the other prognostic groups. Overall, the Green group was expected to have significantly lower scores on both physical/functional (with the exception of the PCS, where a higher score indicates more positive physical functioning) and psychosocial measures (with the exception of the MCS, where a higher score indicates more positive mental functioning) at the six-month point. Additionally, it was anticipated that differences would be found between the prognostic groups on similar physical/functional and psychosocial measures. Healthcare utilization, vocational status, and medication use, relative to prognostic group, were also compared. At the time of this project, 34 patients reached the 6-month follow-up point, and of those, 31 completed the follow-up evaluation. Relocation, noncompliance, and intervening medical conditions were the reasons cited for those patients unable to complete the six-month follow-up. Of the 31 completed follow-up evaluations, 20 patients underwent surgery for implantable devices; 25% received SCS and 37.5% received IT morphine pumps, while the rest of the patients had surgery unrelated to their pain (6.3%) or did not have surgery (31.3%) (Table 9).

Physical/Functional and Psychosocial Measures

Paired samples t-tests (for each measure) were conducted for each of the four prognostic groups to compare initial evaluation and six-month scores (Figures 8-11). Although the Green group showed improvement on all five measures, only the OSW proved significant ($p = .011$). These data are summarized in Table 10. The Yellow-I group showed a significant improvement on the VAS ($p = .003$). With the exception of the BDI, the other three measures (OSW, PCS, and MCS) also showed improvement within the Yellow-I group, but the differences were non-significant (Table 11). The Yellow-II group and the Red group showed all five measures to improve; however, none of them proved significant (Table 12 and Table 13). It is important to note that the small sample sizes at six-month follow-up for all four groups likely impacted these analyses, as did the procedure of the study where data was collected six-months post-initial evaluation instead of six-months post surgery. When paired samples t-tests were conducted using only those patients who had undergone surgery, the results were identical to those found above, with the exception of the Yellow-I group which showed significant improvement on the VAS ($p = .018$) and the OSW ($p = .043$).

Because all of the groups showed improvements on most measures, ANCOVAs and repeated measures ANOVAs were used to further examine the improvements and determine whether the four groups differed from one another biopsychosocially. Given the significant differences found at initial evaluation on the BDI, OSW, and MCS, one-way ANCOVAs, with pretreatment scores as covariates, were conducted to determine if there were differences among the four prognostic groups on these physical/functional and

psychosocial measures. Analyses yielded no significant differences in improvement on these measures among the prognostic groups (Table 14).

The four prognostic groups did not differ significantly on two of the physical/functional measures (the PCS or VAS) at initial evaluation. Therefore, repeated measures analyses were used to compare differences on these measures from initial to six-month follow-up. A one-between (Group) and one-within (Time) repeated measures ANOVA was conducted for the PCS and the VAS (Tables 15 and 16). On the PCS, no significant effects were found for prognostic Group [$F(3, 6) = 1.97, p = .220$], Time [$F(1, 6) = .670, p = .444$], or Group x Time [$F(3, 6) = .583, p = .648$]. On the VAS, there proved to be no significant effect for Group ($p = .628$), and no significant effect was found for Group x Time ($p = .711$); however, a significant effect was shown for Time, indicating scores did improve over time on the VAS, $F(1, 24) = 12.29, p = .002$. ANCOVAs and repeated measures ANOVAs using only those patients who underwent surgical procedures yielded similar results.

Healthcare Utilization

The number of healthcare visits and emergency room visits in the past year were analyzed relative to prognostic group (Table 17). One-way ANOVA revealed significant differences among groups with regard to number of healthcare visits in the six months prior to initial evaluation, $F(3, 40) = 4.21, p = .011$, but showed no differences in number of ER visits in the six months prior. Contrary to hypotheses, one-way ANOVAs indicated that no significant differences existed among groups with regard to number of

healthcare visits, $F(3, 24) = 1.10$, $p = .369$ or emergency room visits, $F(3, 27) = .475$, $p = .702$ at the six-month follow-up point (Table 18).

Vocational Status

Pearson Chi-Square analyses were performed to examine vocational status among the four prognostic groups at both initial evaluation and six-month follow-up. The patients were classified into one of the following categories: currently working, not working due to original injury, and not working due to reasons unrelated to original injury. No significant differences were found among prognostic groups with regard to vocational status at initial evaluation (Table 19); however, further examination, using the Mantel-Haenszel statistic, showed a linear trend, $\chi^2(1) = 5.74$, $p = .017$. The Green group had the highest percentage of patients currently working (40%), with the number declining with prognostic level, Yellow-I (19%), Yellow-II (10.5%), Red (0%). In addition, the Red group had the highest percentage of patients not working due to the original injury (66.7%) versus the other groups, Yellow-II (57.9%), yellow 1 (47.6%), Green (20%). Analyses of the groups at six-month follow-up also revealed no significant differences ($p = .45$). These results can be found in Table 20.

Change in Medication Use Relative to Prognostic groups

Change in medication use within each prognostic group was analyzed using the Wilcoxon signed ranks test. Medication use was coded into three groups at both initial evaluation and 6-month follow-up including narcotic use, non-narcotic use, and no medication. Significant differences were found in the Yellow-I ($z = -2.12$, $p = .034$) and

Yellow-II ($z = -2.25$, $p = .024$) groups (Figure 12). Both Yellow groups showed improvements in the overall medication use, as evidenced by reduced narcotic use, change from narcotic to non-narcotic medication, and/or change to no medication. The small sample size in the Green and Red groups likely affected power, and these groups did not show significant differences in medication usage. Table 21 shows medication use by the four groups at initial evaluation and follow-up.

Complex chi-square analyses were also conducted to determine if differences in medication use existed among the groups at six-month follow-up. Differences were not statistically significant; however, a trend was observed among the groups with regard to no medication use. The Green group showed 40% of patients to be taking no medication at six-month follow-up, and this percentage decreased as prognosis worsened (Yellow-I 27.3%, Yellow-II 25%, and Red 0%). These results can be found in Table 22.

CHAPTER SEVEN

RESULTS:

ALGORITHM SCORES FOR FOUR PROGNOSTIC GROUPS

The current study determined which prognostic group patients would fall into based on overall algorithm risk scores. The overall risk score for interview data, psychological test data, and medical factors were evaluated using predetermined *a priori* weights for each factor. One-way ANOVAs and post-hoc comparisons were employed to examine differences among prognostic groups on these overall risk scores. The overall adverse clinical features score was based on the presence or absence of any adverse clinical features, and chi-square analyses and planned contrasts were used to examine differences among groups. The four groups were also analyzed using binary logistic regression analyses to determine which factors were most predictive of group assignments.

Overall Interview Risk Score

During the clinical interview, patients reported on factors such as level of job satisfaction, workers' compensation status, pending litigation related to their pain, history of abuse or abandonment, substance abuse, and psychological history. They also reported on the amount of spousal support and/or solicitousness they received. A one-way ANOVA revealed that there were significant differences among groups at initial evaluation, $F(3, 56) = 6.42, p = .001$ (Table 23). Tukey HSD pairwise comparisons indicated that the Green and Yellow-I groups had significantly lower interview risk

scores when compared to the Red group ($p < .01$). Differences were also found between the Green and Yellow-II group ($p < .05$).

Overall Psychological Risk Score

The psychological measures used at initial evaluation included the BDI, MMPI-2, HAM-D, CSQ, and MBMD. These tests yielded information about the patients' level of pain sensitivity, depression, anxiety, and catastrophizing. A one-way ANOVA showed significant differences among groups on the overall psychological risk score, $F(3, 56) = 6.79$, $p = .001$ (Table 24). Tukey HSD pairwise comparisons revealed significant differences existed between the Green group when compared to both the Yellow-II and Red groups ($p < .01$). Differences were also found between the Green and Yellow-I group ($p < .05$). Thus, the Green group showed a significantly lower overall risk scores on psychological measures than the other three groups.

Overall Medical Risk Score

Similar to the interview and psychological risk scores, one-way ANOVAs showed significant differences existed among groups relative to medical risk factors, $F(3, 56) = 3.12$, $p = .033$ (Table 25). These factors include duration of pain, number and type of prior spine surgeries, nonorganic physical signs, abnormal pain drawings, smoking, and obesity. Tukey HSD test/corrections showed the differences to exist between the Green and Red groups, $p = .031$, with Green groups scoring significantly lower overall medical risk scores when compared to the Red group.

Overall Adverse Clinical Features Score

Adverse clinical features contributing to the algorithm include inconsistency, medication seeking, staff splitting, compliance issues, threatening, resignation, deception, and personality disorders. Pearson Chi-Square analyses showed significant differences existed among groups, relative to the total presence/absence of these adverse clinical features, $\chi^2(1) = 22.76$, $p < .001$ (Table 26). Planned contrasts analyses conducted to further examine these differences showed the Green group to be 31.5 times more likely to have no adverse clinical features when compared to the Red group, $\chi^2(1) = 8.93$, $p = .003$, OR = 31.5, 95% C.I.: 2.35-422.30. The Yellow-I group proved to be 70 times more likely to be absent of adverse clinical features when compared to the Red group, $\chi^2(1) = 17.18$, $p < .001$, OR = 70.00, 95% C.I.: 5.47-896.59. Similarly, the Yellow-II group proved to be 19.8 times more likely to be found without adverse clinical features when compared to the Red group, $\chi^2(1) = 10.83$, $p = .001$, OR = 19.83, 95% C.I.: 2.70-145.67 (Table 27).

In order to more fully evaluate the impact of adverse clinical features, we built upon Block's algorithm and scored each adverse clinical feature with *a priori* weight. Patients were given a score between 0 and 2 for each of the eight adverse clinical features with a total possible score of 16. The cumulative scores were then analyzed using an ANOVA (Table 28). These analyses yielded significant differences among the four prognostic groups ($p < .001$). Further, Tukey HSD test corrections showed the Red group to have a significantly higher mean score than all other groups ($p < .001$).

Logistic Regression Analyses: Factors Predicting Prognostic Groups

Binary logistic regression models were developed for each prognostic group to elucidate the factors that are most predictive of membership. Factors were entered into the regression equation if statistical differences were found in previous analyses. Four factors were found to predict Green group membership, with 90.4% accuracy (95.3% sensitivity and 66.7% specificity). They include the BDI total score, the CSQ Catastrophizing scale, the OSW total score, and the interview risk score (Table 29). The SF-36/MCS and HAM-D total score were the two factors found to predict Yellow-I status in the regression model, with 90.0% accuracy (100% sensitivity and 75.0% specificity) (Table 30). The Yellow-II group also was found to have two predictive factors, the SF-36/MCS and the BDI total score, with 80% accuracy (93.3% specificity and 40.0% sensitivity) (Table 31). The Red group model was found to predict with the most accuracy at 95.0% (96.1% sensitivity and 88.9% specificity). The factors found to be predictive for the Red group include the BDI total score and the presence of adverse clinical features (Table 32).

CHAPTER EIGHT

DISCUSSION

Previous analyses of the Block et al. (2003) presurgical screening algorithm proved to be extremely effective in predicting outcome for patients undergoing spine surgery. The current study sought to apply this algorithm to a subset of patients being evaluated for implantable devices for pain management, namely spinal cord stimulators and IT opioid delivery systems. Analyses were conducted at initial evaluation to determine if significant differences in demographic variables existed among the four prognostic groups. The first hypothesis of the current study predicted that particular demographic variables, namely disability payment status, would be statistically significant among the group assignments and for predicting outcomes. Among the variables of gender, race, marital status, disability payment status, and litigation status, only gender and disability payment status demonstrated significant differences in distribution among the Green, Yellow-I, Yellow-II, and Red groups. Thus, the demographic variables were mostly similar across prognostic groups, and the current findings are likely generalizable to a heterogeneous range of patients evaluated for pain management devices.

Examination of the significant demographic variables showed that males patients were 18.7 times more likely than females to be classified in the Green prognostic group when comparing Green and Red groups, and 5.4 times more likely to fall in the Green group over females when comparing Green and Yellow-II groups. Results from the analysis of disability payment status relative to prognostic group were also significant.

The Red group contained a significantly greater proportion of patients receiving disability monies than all other groups. A significant linear trend was observed showing a correlation between prognostic group and disability payments, where the number of patients receiving disability payments increased as prognosis worsened from Green (0%) to Red (55.6%). This finding supports the idea that patients receiving disability money tend to have poorer surgical results and overall outcomes (Davis, 1994; Greenbough & Fraser, 1991; Knox & Chapman, 1993).

The second hypothesis of the current study predicted that patients in the Green group would show better biopsychosocial functioning than all other prognostic groups at initial evaluation. Physical and functional measures showed the Red and Yellow-II groups endorsed significantly more limitations on ADLs and disability than the Green group, which endorsed the least amount of limitations. Therefore, as expected, perceived physical functioning of patients in the Green group was higher than all other groups. With regard to vocational status, a linear trend analysis showed the Green group with the greatest number of patients currently working, followed by the Yellow-I and Yellow-II groups. The Red group did not contain any patients who were working at initial evaluation. Employment status is a good indication of functionality for patients. Examination of healthcare utilization in the six months prior to the initial evaluation yielded significant results with the Red group citing 6 times more healthcare visits than the Green group.

Psychological and social distress is cited as having significant impacts on surgical results (Block et al., 2001). In the current study, patients in the Green and Yellow-I groups showed significantly lower mean scores on multiple psychological measures when

compared to Yellow-II and Red groups. The Yellow-II and Red groups showed elevations on MMPI-2 scales that have been shown to correlate with diminished surgical results, including the F Scale, Scale 1 Hypochondriasis, Scale 2 Depression, Scale 3 Hysteria, Scale 4 Psychopathic Deviate, Scale 6 Paranoia, Scale 7 Psychastenia, and Scale 8 Schizophrenia. Specifically, Scale 1 and Scale 3 elevations have been correlated with poorer surgical outcomes. In this study, the Red group, followed by the Yellow-II group, showed the highest elevations on these scales. Patients exhibiting symptomatology of depression have consistently been shown to have poor results after surgery. Patients in the Green group showed significantly lower mean scores on Scale 2 of the MMPI-2 than those in the Red group, indicating lower levels of depressive symptomatology. The BDI ($p < .001$) and the HAM-D ($p < .001$) were also consistent, showing the Green group as having significantly lower levels of depressive symptoms (significant linear trends on both BDI and HAM-D). Scale 4 of the MMPI-2 is the best approximate of a patient's anger, which has been shown to have negative effects on surgical outcome and recovery. The Green group showed the lowest scores on Scale 4, exhibiting the least amount of anger among the groups and indicating they would have the greatest likelihood for success of surgery. Anxiety has also been linked to poor surgical outcomes. As expected, the Green group demonstrated the lowest levels of anxiety as measured by the MMPI-2. Research has extensively linked spousal and social support to better overall outcomes and recovery. The Green group also showed a significantly lower mean score on Scale 0 Social Introversion when compared to the Red group. These differences were expected, as the MMPI-2, BDI and HAM-D was used as part of the screening algorithm to determine in which prognostic group patients were placed. Parallel to the psychosocial

measures mentioned above, several of the MBMD clinical scales also showed the Green group to have the lowest mean scores, signifying minimal symptomatology, with the Red group having significantly higher mean scores.

The way in which individuals deal with stress has also been correlated to surgical outcomes. The Red group was shown to have the highest scores on the CSQ Catastrophizing scale, measuring the overall level of the catastrophizing coping strategy employed by an individual to help manage pain. A linear trend was observed indicating that as prognosis worsened catastrophizing increased. Thus, it appears the hypothesis was correct, as the Green group showed the best overall biopsychosocial functioning, and the Red group showed the worst biopsychosocial functioning when compared to the other prognostic groups. Additionally, the Red group indicated having the greatest amount of mental impairment when compared to the other groups, as measured by the SF-36/MCS.

The next hypothesis predicted that the Green group would show the best biopsychosocial profile of the four groups at six-months post initial evaluation. The four prognostic groups were examined individually and compared to each other in order to assess improvements in the physical/functional and psychosocial follow-up measures (VAS, OSW, PCS, MCS, and BDI). Overall, the groups showed biopsychosocial improvements at six-months post initial evaluation. The Green group showed improvements on all five measures; however, only increased ADLs and disability (OSW) was found to be significant. Likewise, the Yellow-II group improved on most measures, but only the decrease in level of pain (VAS) was found significant ($p = .003$). The Yellow-II and Red groups also improved on the measures, but none proved significant.

The small sample sizes of the four groups are important to note, as it will affect the power of the analyses.

After analyzing the groups individually, they were examined together in order to assess whether or not they differed from one another with regard to overall outcomes. No significant differences were found here; however, it is important to note not only the small sample size, but also the fact that many patients had not yet been treated surgically and the changes were not as drastic as would be expected with an increase in the amount of time following initial evaluation. Healthcare utilization and vocational status were also analyzed, but neither showed significant differences among groups at six-month follow-up. Once again, the sample size most likely impacted these results.

The medication use of a patient can be indicative of outcomes, especially with patients who are highly dependent on narcotic medications. Although no significant differences were seen among groups with regard to medication use at initial evaluation, there were significant differences found with regard to improvement in medication use at six-month follow-up point. Patients in the Yellow-I and Yellow-II groups showed significant improvements within groups in medication use by using less narcotic medications, non-narcotic medications or no medication at the follow-up period when compared to medication use at initial evaluation. Significant differences were not seen among groups at six-month follow-up, likely due to small sample size, but a trend showed that the percentage of patients using no medication was correlated to prognostic group. The Green group had the highest percent of patients using no medications at follow-up off all prognostic groups; the percent of patients decreased within each group

as prognosis worsened, and the Red group showed no patients at six-month follow-up as free of medication use.

Analysis of the four overall algorithm risk scores showed the interview risk score, psychological test risk score, and adverse clinical features risk score as significantly different across groups. The differences seen in the medical risk factor score were the least significant. These findings are similar to those of Block and colleagues in their study of the algorithm (2001), where they found medical risk factors to contribute the least to the overall predictive value of the presurgical algorithm. An additional analysis using a revised scoring system for the adverse clinical features, where each feature was scored based on assigned *a priori* weights, yielded significant differences among groups. The Red group showed a significantly greater mean score than all other groups. This scoring system was not used in the original Block algorithm; the original algorithm considered either the presence of adverse clinical features (score of 1) or the absence of adverse clinical features (score of 0). This revised method of scoring adverse clinical features allows for a more comprehensive examination of each group with regard to adverse clinical features, which proved extremely significant for prognostic purposes, especially with poor surgery candidates.

The final hypothesis of this study predicted that psychological test data would have the most predictive value in determining which patients would be good candidates for implantable devices to help manage pain. Regression analyses for each prognostic group revealed that psychological test data was indeed the most predictive. The regression model that most predicted the Green group included the BDI, the CSQ Catastrophizing scale, the OSW, and the overall interview risk score. The Yellow-I

group model indicated that the MCS and the HAM-D scores were most predictive of membership. The MCS and BDI were found to be most predictive in the Yellow-II group model. Lastly, the Red group model, found to have the highest accuracy rate (95%), revealed the BDI and the presence of adverse clinical features to be most predictive of membership in the Red group. As seen by these analyses, the BDI was used in three of the four models, the MCS used in two models, the HAM-D and CSQ Catastrophizing scale were also present in models; thus, psychological test data impacted the results of the group prognosis more than all other factors. The level of depression and overall mental impairment, endorsed by patients, proved to be significantly predictive of overall prognosis. Lower levels of depression were associated with positive outcomes, with higher levels being more indicative of worse outcomes.

Adverse clinical features were surprisingly found to be one of the two factors in the Red group's regression model. These features have not been empirically researched; however, appear to be significant, in that they significantly predicted poor prognosis. The revised scoring methodology used in this study for additional analyses with the adverse clinical features was able to better depict differences among the groups, especially the poor surgery candidates. Adverse clinical features can be described as aspects of each patient's case that can be identified as having potential to negatively affect outcomes (Block et al., 2003). They include things such as inconsistency, medication seeking, staff splitting, and deception. This is an important finding in that these features, added by Block and colleagues in 2003, may be more important to prediction methodology than originally thought. Revising the methodology used to

account for the adverse clinical features is beneficial for more comprehensive identification of the differences among groups.

Limitations and Directions for Further Research

As with most research endeavors, this study is not without its own difficulties. One major limitation of this study is sample sizes throughout, especially for the six-month follow-up analyses. The small number of patients in each group most likely hindered the power of the follow-up analyses, making it very difficult to find statistical differences among the groups. Several of the outcome analyses showed improvements within and between groups; however, the sample size in most cases was not substantial enough to create a statistically significant effect. The distribution of patients among groups was also a limitation, as most patients were clustered in the Yellow-I and Yellow-II groups. This is natural in that most patients fall into the fair (middle) prognostic categories rather than the good and poor.

Additionally, the time period for this study was a limitation, in that the data was collected at initial evaluation and six-month post initial evaluation. Most studies in the literature cite two to five years as the ideal determinant of overall outcomes. It will be important to continue this line of research in the future in an effort to better estimate the overall long-term outcomes with data continually collected at later dates after the initial evaluation. The literature on long-term studies using PPS is sparse, and there are no current studies taking as many variables into account. Thus, continuing to look at these data will allow a better look at the long-term efficacy of the algorithm.

Another possible limitation is that follow-up data were obtained in telephone interviews. These results offer no objective assessment of functional capacity. People with certain psychological characteristics, specifically those commonly seen in chronic pain patients, often tend to underreport improvements in functional abilities; therefore, behavioral observation and face-to-face interviews would have allowed for a more complete estimation of patients' functionality.

Furthermore, the collection of the OSW at six-month follow-up was added after the commencement of the study. The reason for the addition was the lack of a physical outcome measures at the onset of the study. Physical outcomes could not be examined for all patients who reached the six-month follow-up prior to the inclusion of this measure, thus decreasing the reliability of the analyses. The collection of the OSW at the six-month point has been implemented; thus, future research will have more robust estimates of changes in physical functioning over time.

Surprisingly, this study found males to be significantly more likely than females to be categorized in the Green and Yellow-I prognostic groups. Since this study did not attempt to elucidate why males are more likely to fall in the better prognostic groups, future research may attempt to compare males and females to determine the differences in biopsychosocial functioning that differentiates them within the prognostic categories.

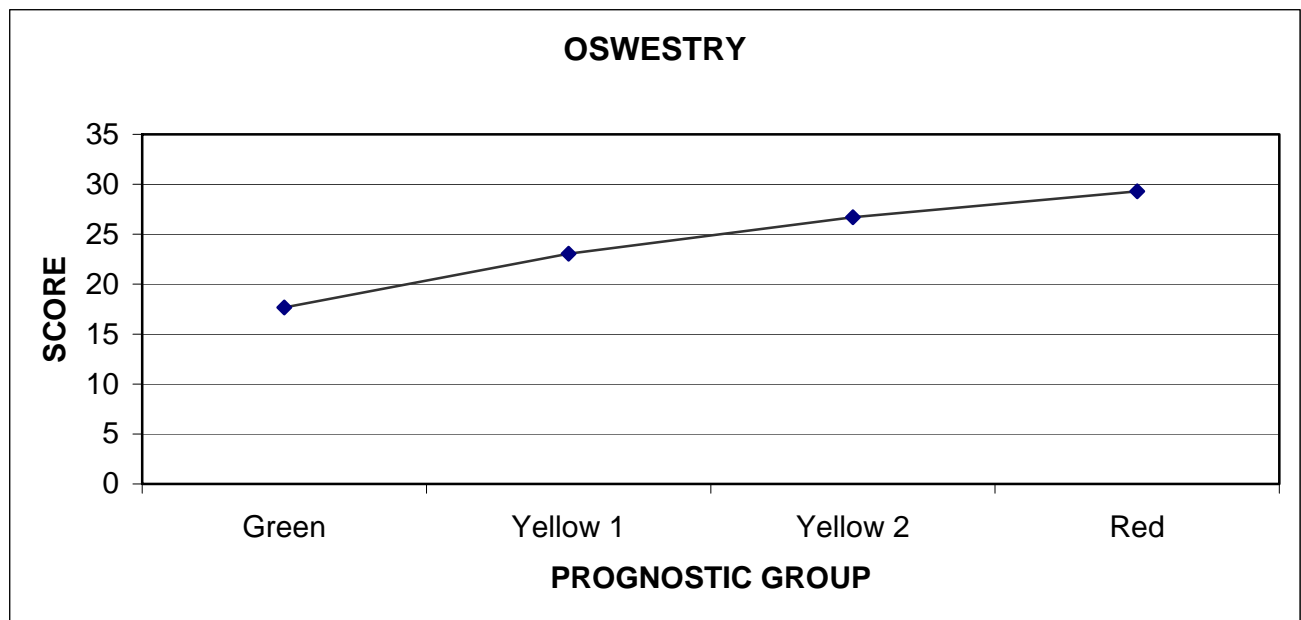
This study also found adverse clinical features to be red flags for poor prognostic patients. Adverse clinical features have not been extensively studied, and further examination and quantification of these factors in future research would be beneficial. By continuing to elicit data, it will be possible to get a better understanding of how these factors, in sum and individually, affect outcomes.

Conclusion

In conclusion, the algorithm originally created by Block and colleagues (2003, 2001) is applicable to patients undergoing examination for implantable devices to help manage chronic pain. By screening patients prior to implanting SCS and IT pumps, physicians are able to better choose the patients who will benefit from the invasive and costly procedures. Patients with lower levels of biopsychosocial stress and dysfunction, specifically low levels of depression and who have effective coping strategies, are the best candidates for such surgeries. They show the highest percentages of success in overall outcomes, by increasing functional abilities and psychological functioning, decreasing pain levels, and decreasing medication intake. Patients exhibiting large amounts of biopsychosocial stress, specifically high levels of depression and the presence of adverse clinical features, are poor candidates for these procedures, as they are often unable to recover successfully and tend to have negative outcomes. Targeting those risk factors that are most predictive of success and failure for implantable devices allows patients to avoid undergoing procedures that are likely to be unsuccessful, physicians to avoid pitfalls with patients who are not appropriate for these devices, and creates an improved system for third party payers to rely on in order to compensate these costly procedures.

APPENDIX A:
FIGURES

Figure 1

Comparison of Prognostic Groups at Initial Evaluation on Oswestry

*Higher scores on OSW indicate > physical impairment.

Figure 2

Comparison of Prognostic Groups at Initial Evaluation on the MMPI-2 Clinical Scale

*Higher scores on MMPI-2 are indicate > levels of pathology.

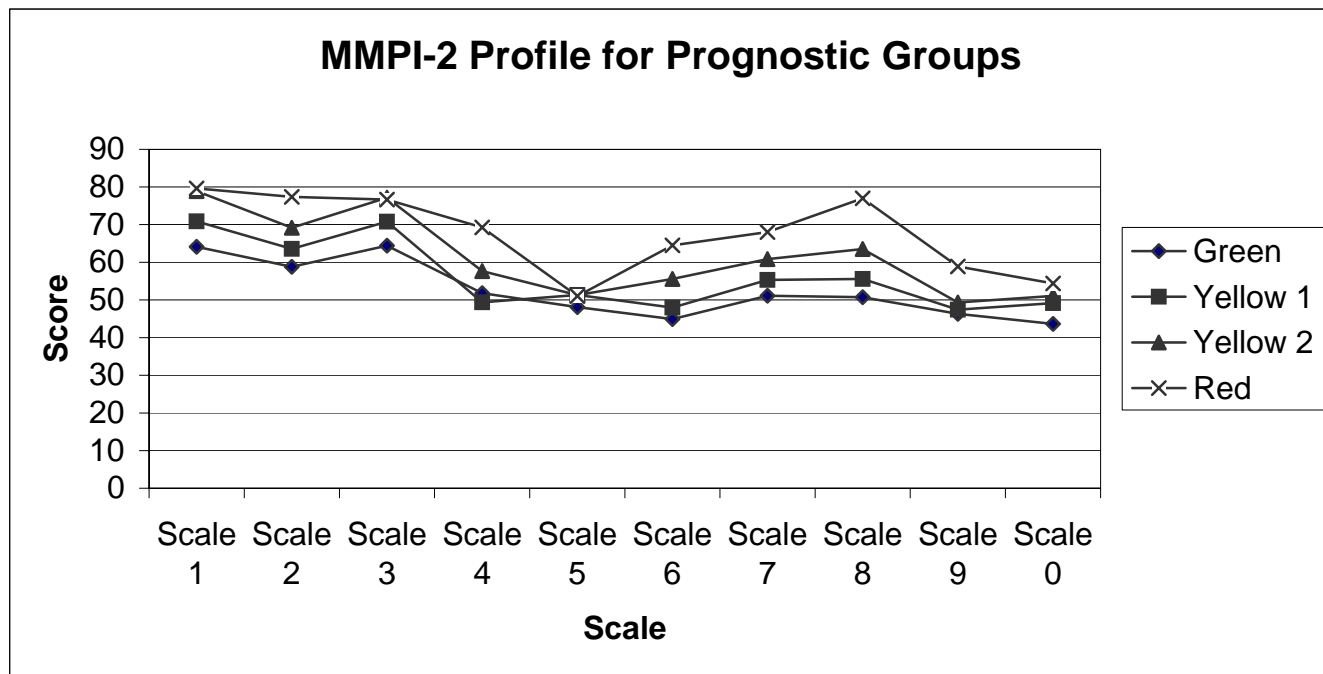
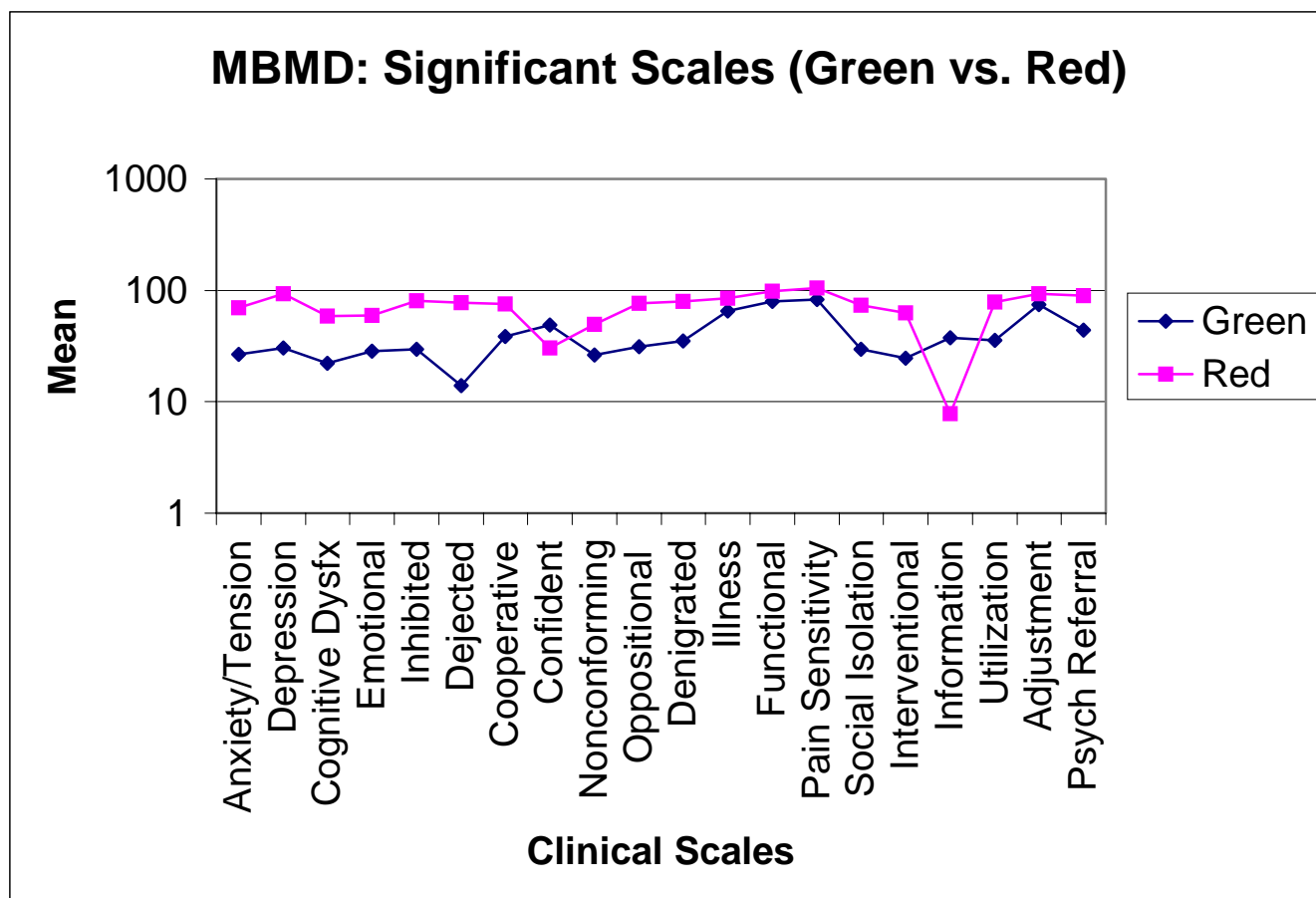


Figure 3

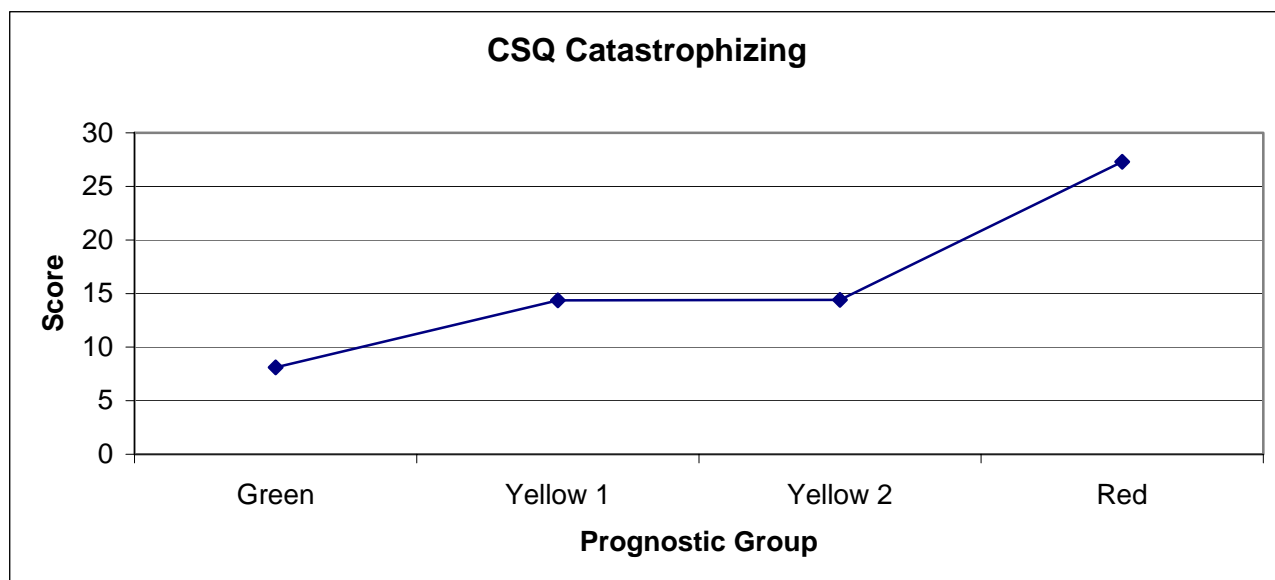
MBMD Clinical Scale Scores (Significant): Comparison of Green & Red Groups



*Higher scores on MBMD indicate > levels of pathology.

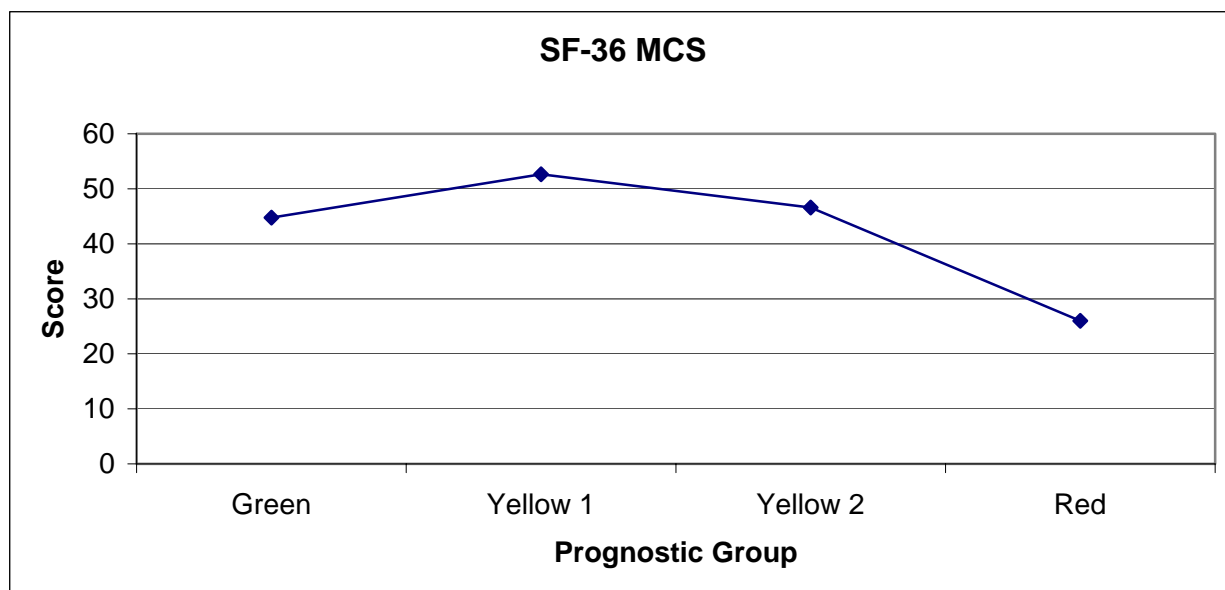
Figure 4

Comparison of Prognostic Groups at Initial Evaluation on the CSQ Catastrophizing Scale



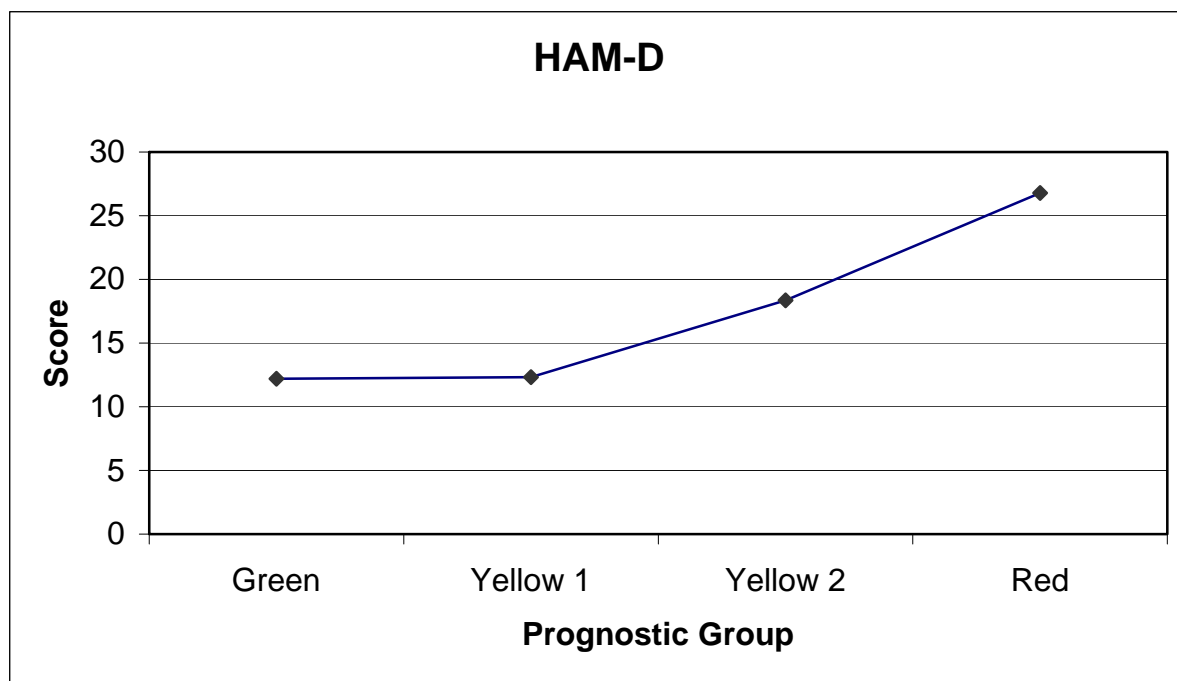
*Higher scores indicate > levels of catastrophizing coping skills employed.

Figure 5

Comparison of the Prognostic Groups at Initial Evaluation on the SF-36 MCS

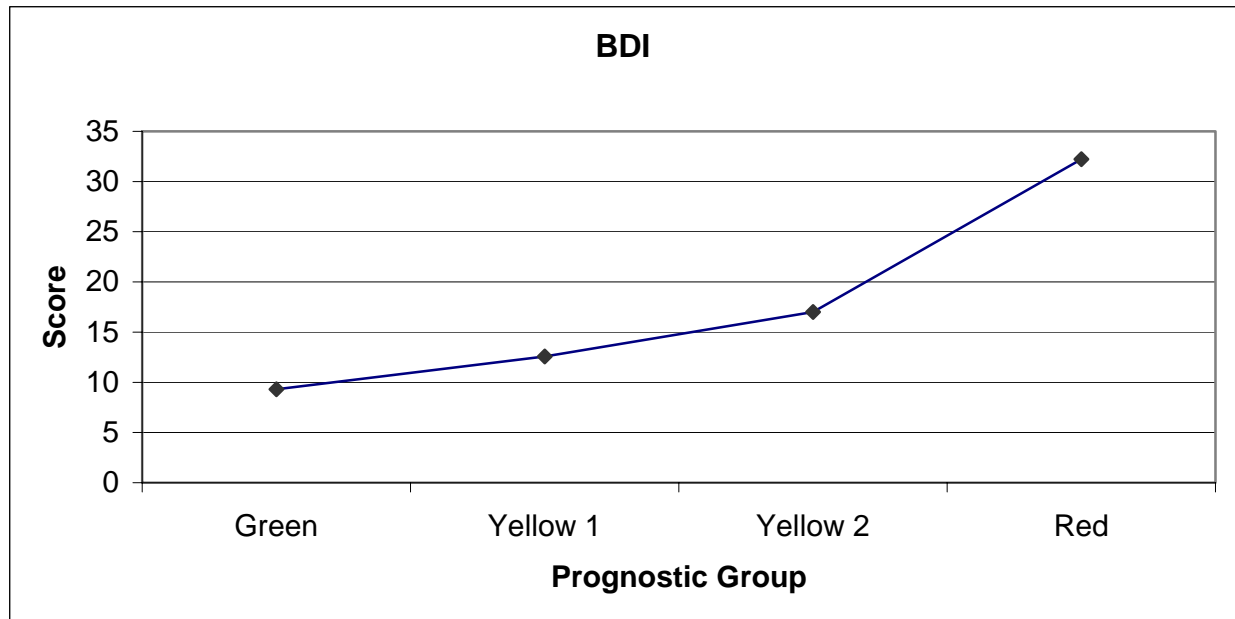
*Higher scores indicate > levels of overall mental functioning.

Figure 6

Comparison of Prognostic Groups at Initial Evaluation on HAM-D

*Higher scores indicate > depressive symptomatology.

Figure 7

Comparison of Prognostic Group at Initial Evaluation on the BDI

*Higher scores indicate > depressive symptomatology.

Figure 8

Green Group: Changes in Outcome Measures from Initial to Six-Month Follow-Up

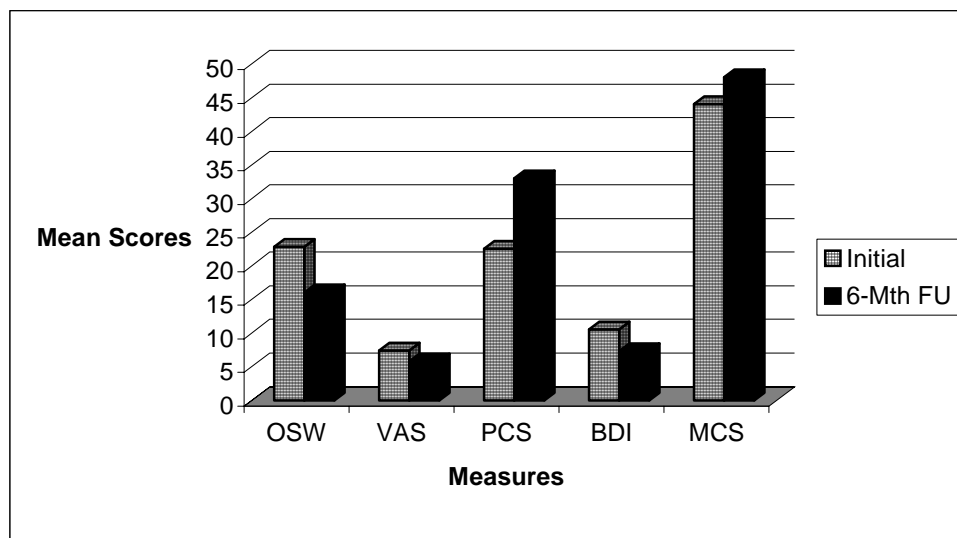


Figure 9

Yellow-I Group: Changes in Outcome Measures from Initial to Six-Month Follow-Up

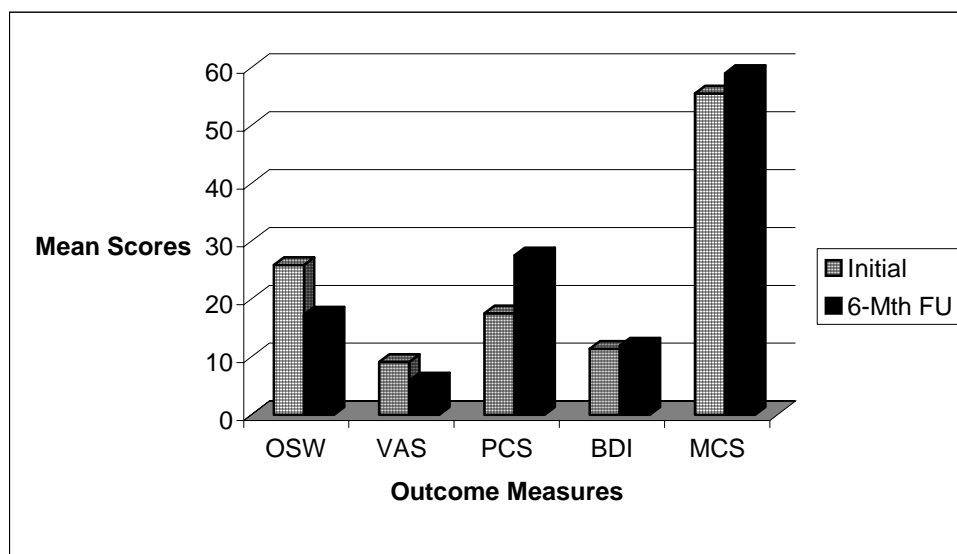


Figure 10

Yellow-II Group: Changes in Outcome Measures from Initial to Six-Month Follow-Up

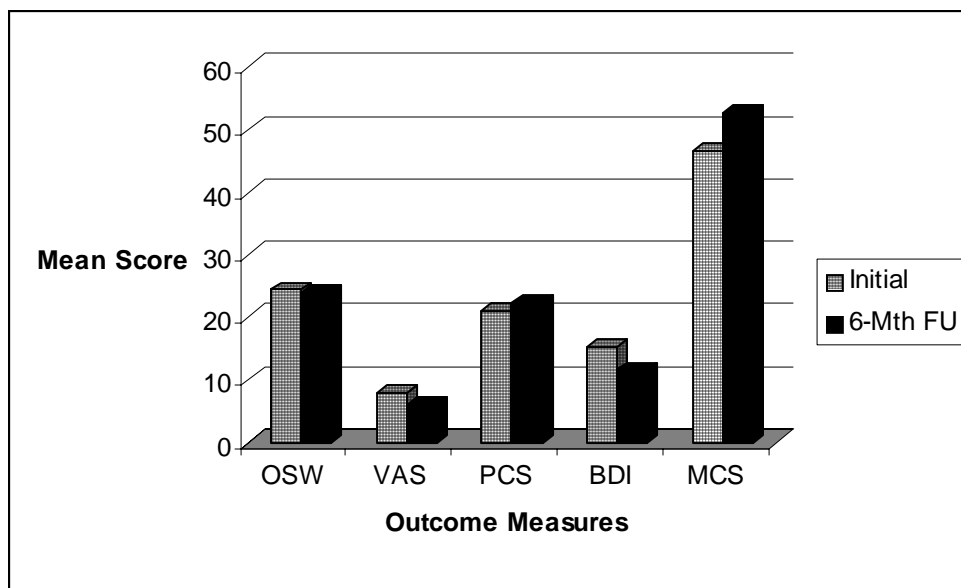


Figure 11

Red Group: Changes in Outcome Measures from Initial to Six-Month Follow-Up

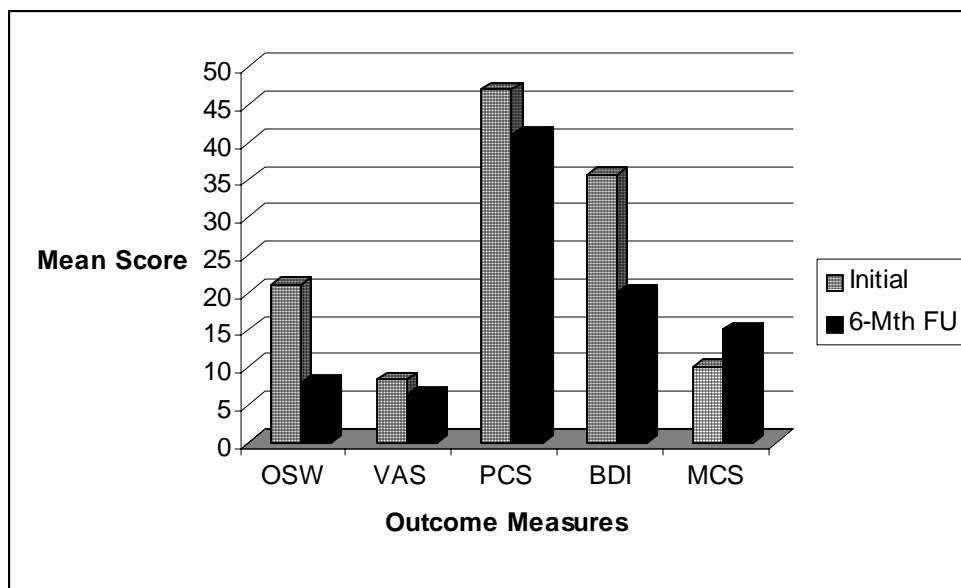
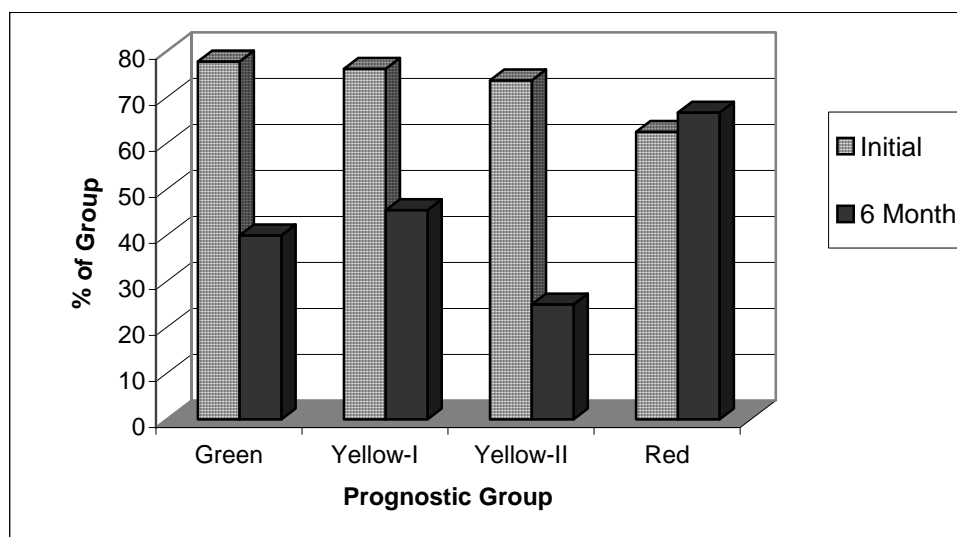


Figure 12

Change in Narcotic Use Relative to Prognostic Groups

APPENDIX B:

TABLES

Table 1

Demographic Variables

Variable	Total Sample (N= 60)	<u>Overall Prognostic Group</u>	
		Green (n= 10)	Yellow1 (n= 21)
Gender (%)			
Female	58.3	30.0	47.6
Male	41.7	70.0	52.4
Age (years)			
Mean (SD)	55.50 (15.26)	60.20 (19.49)	55.52 (16.56)
Minimum	30	31	31
Maximum	90	82	90
Race (%)			
Caucasian	90.0	90.0	95.2
African-American	5.0	10.0	0.0
Hispanic	3.3	0.0	4.8
Other	1.7	0.0	0.0
Marital Status (%)			
Married	66.7	70.0	76.2
Single	6.7	10.0	4.8
Separated/divorced	13.3	10.0	4.8
Widowed	11.7	10.0	14.3
Living w/ sig. other	1.7	0.0	0.0

(cont).

Table 1 (cont.)

Variable	Total Sample (N= 60)	Overall Prognostic Group	
		Yellow 2 (n= 20)	Red (n= 9)
Gender (%)			
Female	58.3	70.0	88.9
Male	41.7	30.0	11.1
Age (years)			
Mean (SD)	55.50 (15.26)	55.00 (10.70)	51.33 (16.90)
Minimum	30	33	30
Maximum	90	78	86
Race (%)			
Caucasian	90.0	85.0	88.9
African-American	5.0	10.0	0.0
Hispanic	3.3	5.0	0.0
Other	1.7	0.0	11.1
Marital Status (%)			
Married	66.7	55.0	66.7
Single	6.7	5.0	11.1
Separated/divorced	13.3	20.0	22.2
Widowed	11.7	15.0	0.0
Living w/ sig. other	1.7	5.0	0.0

(cont.)

Table 1 (cont.)

Variable	Total Sample (N= 60)	Overall Prognostic Group	
		Green (n= 10)	Yellow 1 (n= 21)
Disability Payments (%)			
Yes	36.7	0.0	38.1
No	63.3	100.0	61.9
Pending Litigation (%)			
Yes	8.3	0.0	4.8
No	91.7	100.0	95.2
Duration of Pain (months)			
Mean (SD)	102.27 (112.75)	97.30 (128.41)	98.60 (124.02)
Type of Procedure (%)			
SCS	50.8	50.0	52.4
IT pump	30.5	30.0	28.6
Deep brain stimulator	6.8	0.0	9.5
Occipital nerve stimulator	5.1	0.0	9.5
Jaw stimulator	1.7	10.0	0.0
Other	5.1	10.0	0.0

(cont.)

Table 1 (cont.)

Variable	Total Sample (N= 60)	Overall Prognostic Group	
		Yellow 2 (n= 20)	Red (n= 9)
Disability Payments (%)			
Yes	36.7	45.0	55.6
No	63.3	55.0	44.4
Pending Litigation (%)			
Yes	8.3	15.0	11.1
No	91.7	85.0	88.9
Duration of Pain (months)			
Mean (SD)	102.27 (112.75)	111.55 (117.90)	95.33 (61.12)
Type of Procedure (%)			
SCS	50.8	57.9	33.3
IT pump	30.5	21.1	55.6
Deep brain stimulator	6.8	10.5	0.0
Occipital nerve stimulator	5.1	5.3	0.0
Jaw stimulator	1.7	0.0	0.0
Other	5.1	5.3	11.1

Table 2Statistical Comparison of the Four Overall Prognostic Groups on Demographic Variables

<u>Group</u>	<u>Gender (n)</u>	<u>% w/in Group</u>	<u>χ^2</u>	<u>df</u>	<u>p</u>
Green	Male (7)	70.0	8.87*	3	.03
	Female(3)	30.0			
Yellow 1	Male (11)	52.4			
	Female (10)	47.6			
Yellow 2	Male (6)	30.0			
	Female (14)	70.0			
Red	Male (1)	11.1			
	Female (8)	88.9			
<u>Group (n)</u>	<u>Mean Age (yrs.)</u>	<u>SD</u>	<u>F</u>	<u>df</u>	<u>p</u>
Green (10)	60.20	19.49	.534	3, 56	.66
Yellow 1 (21)	55.52	16.56			
Yellow 2 (20)	55.00	10.70			
Red (9)	51.33	16.90			
<u>Group</u>	<u>Race (n)</u>	<u>% w/in Group</u>	<u>χ^2</u>	<u>df</u>	<u>p</u>
Green	Caucasian (9)	90.0	9.72	9	.37
	African-Am. (1)	10.0			
	Hispanic (0)	0.0			
	Other (0)	0.0			

(cont.)

Table 2 (cont.)

Yellow 1	Caucasian (20)	95.2			
	African-Am. (0)	0.0			
	Hispanic (1)	4.8			
	Other (0)	0.0			
Yellow 2	Caucasian (17)	85.0			
	African-Am. (2)	10.0			
	Hispanic (1)	5.0			
	Other (0)	0.0			
Red	Caucasian (8)	88.9			
	African-Am. (0)	0.0			
	Hispanic (0)	0.0			
	Other (1)	11.1			
<u>Group</u>	<u>Marital Status (n)</u>	<u>% w/in Group</u>	<u>χ^2</u>	<u>df</u>	<u>p</u>
Green	Married (7)	70.0	7.17	12	.85
	Single (1)	10.0			
	Separated/divorced (1)	10.0			
	Widowed (1)	10.0			
	Living w/ sig. other (0)	0.0			
Yellow 1	Married (16)	76.2			
	Single (1)	4.8			

(cont.)

Table 2 (cont.)

Yellow 1	Separated/Divorced (1)	4.8		
	Widowed (3)	14.3		
	Living w/ sig. other (0)	0.0		
Yellow 2	Married (11)	55.0		
	Single (1)	5.0		
	Separated/divorced (4)	20.0		
	Widowed (3)	15.0		
	Living w/ sig. other (1)	5.0		
Red	Married (6)	16.7		
	Single (1)	11.1		
	Separated/divorced (2)	22.2		
	Widowed (0)	0.0		
	Living w/ sig. other (0)	0.0		
<u>Group</u>	<u>Disability</u>	<u>% w/in Group</u>	<u>χ^2</u>	<u>df</u>
<u>p</u>	<u>Payments (n)</u>			
Green .05	Yes (0)	0.0	7.79*	3
	No (8)	100.0		
Yellow 1	Yes (8)	38.1		
	No (13)	61.9		
Yellow 2	Yes (9)	45.0		
	No (11)	55.0		

(cont.)

Table 2 (cont.)

Red	Yes (5)	55.6			
	No (4)	44.4			
<u>Group</u>	<u>Pending Litigation (n)</u>	<u>% w/in Group</u>	<u>χ^2</u>	<u>df</u>	<u>p</u>
Green	Yes (0)	0.0	2.51	3	.47
	No (10)	100.0			
Yellow 1	Yes (1)	4.8			
	No (20)	95.2			
Yellow 2	Yes (3)	15.0			
	No (17)	85.0			
Red	Yes (1)	11.1			
	No (8)	88.9			
<u>Group (n)</u>	<u>Pain Duration (mos.)</u>	<u>SD</u>	<u>F</u>	<u>df</u>	<u>p</u>
Green (10)	97.30	128.41	.07	3, 55	.98
Yellow 1 (21)	98.60	124.02			
Yellow 2 (20)	111.55	117.90			
Red (9)	95.33	61.12			

*p ≤ .05, two-tailed.

Table 3

Comparison of Mean Scores on Physical/Functional Measures for Prognostic Groups

Physical/ Functional Measure	Group (<u>n</u>)	Mean (<u>SD</u>)	<u>F</u>	<u>df</u>	<u>p</u>
DPQ	Green (8)	76.50 (29.28)	2.004	3, 47	.126
	Yellow-I (19)	88.68 (19.51)			
	Yellow-II (17)	96.06 (23.73)			
	Red (7)	102.57 (21.65)			
VAS	Green (9)	7.33 (1.50)	2.607	3, 51	.062
	Yellow-I (20)	8.85 (1.09)			
	Yellow-II (18)	8.22 (1.40)			
	Red (8)	8.75 (2.05)			
OSW	Green (9)	17.67 (7.78)	3.630*	3, 48	.019
	Yellow-I (19)	23.05 (6.54)			
	Yellow-II (17)	26.71 (9.62)			
	Red (7)	29.29 (7.48)			
PCS	Green (4)	27.75 (6.40)	1.023	3, 16	.409
	Yellow-I (8)	21.50 (8.23)			
	Yellow-II (5)	20.40 (6.43)			
	Red (3)	29.00 (15.87)			

* $p \leq .05$, two-tailed.

Table 4

Comparison of Mean Scores on MMPI-2 Clinical Scales for Prognostic Groups

MMPI-2 Scale	Group (n)	Mean (SD)	F	df	p
L	Green (10)	58.40 (9.42)	.353	3, 54	.787
	Yellow-I (20)	60.45 (13.82)			
	Yellow-II (20)	57.65 (14.04)			
	Red (8)	55.38 (7.78)			
F	Green (10)	48.00 (5.89)	7.059**	3, 54	<.001
	Yellow-I (20)	52.75 (8.73)			
	Yellow-II (20)	55.95 (13.76)			
	Red (8)	75.75 (26.09)			
K	Green (10)	58.30 (11.50)	3.128*	3, 54	.033
	Yellow-I (20)	54.75 (11.72)			
	Yellow-II (20)	56.45 (10.06)			
	Red (8)	44.13 (8.54)			
Scale 1					
Hypochondriasis	Green (10)	64.10 (8.02)	4.966**	3, 54	.004
	Yellow-I (20)	70.85 (10.44)			
	Yellow-II (20)	78.90 (9.81)			
	Red (8)	79.63 (18.624)			
Scale 2					
Depression	Green (10)	58.80 (9.05)	3.772*	3, 54	.016
	Yellow-I (20)	63.55 (13.68)			
	Yellow-II (20)	69.15 (13.90)			
	Red (8)	77.38 (11.20)			

(cont.)

Table 4 (cont.)

<hr/>					
Scale 3					
Hysteria	Green (10)	64.40 (9.10)	3.213*	3, 54	.030
	Yellow-I (20)	70.80 (9.50)			
	Yellow-II (20)	77.15 (12.09)			
	Red (8)	76.63 (16.65)			
<hr/>					
Scale 4					
Psychopathic Dev.	Green (10)	51.80 (6.29)	4.603**	3, 54	.006
	Yellow-I (20)	49.35 (14.85)			
	Yellow-II (20)	57.65 (12.01)			
	Red (8)	69.25 (18.82)			
<hr/>					
Scale 5					
Mascul./Femin.	Green (10)	48.10 (7.49)	.294	3, 54	.829
	Yellow-I (20)	51.30 (11.42)			
	Yellow-II (20)	51.25 (9.67)			
	Red (8)	51.00 (5.68)			
<hr/>					
Scale 6					
Paranoia	Green (10)	44.90 (5.67)	10.453**	3, 54	<.001
	Yellow-I (20)	47.95 (6.28)			
	Yellow-II (20)	55.55 (10.41)			
	Red (8)	64.50 (11.41)			
<hr/>					
Scale 7					
Psychastenia	Green (10)	51.10 (5.51)	4.380**	3, 54	.008
	Yellow-I (20)	55.30 (11.32)			
	Yellow-II (20)	60.85 (10.04)			
	Red (8)	68.00 (16.36)			
<hr/>					

(cont.)

Table 4 (cont.)

<hr/>					
Scale 8					
Schizophrenia	Green (10)	50.70 (6.63)	8.041**	3, 54	<.001
	Yellow-I (20)	55.55 (11.03)			
	Yellow-II (20)	63.50 (10.93)			
	Red (8)	77.00 (22.50)			
<hr/>					
Scale 9					
Hypomania	Green (10)	46.30 (7.15)	3.465*	3, 54	.022
	Yellow-I (20)	47.40 (7.35)			
	Yellow-II (20)	49.30 (7.64)			
	Red (8)	58.87 (17.11)			
<hr/>					
Scale 0					
Social Introversion	Green (10)	43.60 (5.40)	2.138	3, 54	.106
	Yellow-I (20)	49.15 (11.14)			
	Yellow-II (20)	51.05 (9.654)			
	Red (8)	54.38 (8.98)			
<hr/>					

*p ≤ .05, two-tailed. **p ≤ .01, two-tailed.

Table 5

Planned Contrasts of Mean Differences for MMPI-2 Scale Scores

<u>L Scale</u>	<u>Pair</u>	<u>Contrast Est.</u>	<u>Std. Error</u>	<u>df</u>	<u>p</u>
	G/R	-3.02	5.99	3, 54	.615
	Y1/R	-5.08	5.28	3, 54	.341
	G&Y1/Y2&R	-5.82	7.19	3, 54	.422
<u>F Scale</u>	<u>Pair</u>	<u>Contrast Est.</u>	<u>Std. Error</u>	<u>df</u>	<u>p</u>
	G/R	27.75	9.41	3, 54	.020
	Y1/R	23.00	9.43	3, 54	.042
	G&Y1/Y2&R	30.95	10.09	3, 54	.012
<u>K Scale</u>	<u>Pair</u>	<u>Contrast Est.</u>	<u>Std. Error</u>	<u>df</u>	<u>p</u>
	G/R	-14.17	5.10	3, 54	.007
	Y1/R	-10.63	4.49	3, 54	.022
	G&Y1/Y2&R	-12.47	6.12	3, 54	.047
<u>Scale 1</u>	<u>Pair</u>	<u>Contrast Est.</u>	<u>Std. Error</u>	<u>df</u>	<u>p</u>
	G/R	15.53	5.37	3, 54	.005
	Y1/R	8.78	4.73	3, 54	.069
	G1&Y1/Y2&R	23.58	6.45	3, 54	.001
<u>Scale 2</u>	<u>Pair</u>	<u>Contrast Est.</u>	<u>Std. Error</u>	<u>df</u>	<u>p</u>
	G/R	18.58	6.07	3, 54	.003

(cont.)

Table 5 (cont.)

<u>Scale 2</u>	<u>Pair</u>	<u>Contrast Est.</u>	<u>Std. Error</u>	<u>df</u>	<u>p</u>
	Y1/R	13.83	5.35	3, 54	.013
	G&Y1/Y2&R	24.18	7.30	3, 54	.002
<u>Scale 3</u>	<u>Pair</u>	<u>Contrast Est.</u>	<u>Std. Error</u>	<u>df</u>	<u>p</u>
	G/R	12.22	5.47	3, 54	.030
	Y1/R	5.83	4.82	3, 54	.232
	G&Y1/Y2&R	18.58	6.57	3, 54	.007
<u>Scale 4</u>	<u>Pair</u>	<u>Contrast Est.</u>	<u>Std. Error</u>	<u>df</u>	<u>p</u>
	G/R	17.45	6.38	3, 54	.008
	Y1/R	19.90	5.63	3, 54	.001
	G&Y1/Y2&R	25.75	7.67	3, 54	.001
<u>Scale 5</u>	<u>Pair</u>	<u>Contrast Est.</u>	<u>Std. Error</u>	<u>df</u>	<u>p</u>
	G/R	2.90	4.56	3, 54	.527
	Y1/R	-0.30	4.02	3, 54	.941
	G&Y1/Y2&R	2.85	5.48	3, 54	.605
<u>Scale 6</u>	<u>Pair</u>	<u>Contrast Est.</u>	<u>Std. Error</u>	<u>df</u>	<u>p</u>
	G/R	19.60	4.09	3, 54	<.001
	Y1/R	16.55	3.60	3, 54	<.001
	G&Y1/Y2&R	27.20	4.91	3, 54	<.001

(cont.)

Table 5 (cont.)

<u>Scale 7</u>	<u>Pair</u>	<u>Contrast Est.</u>	<u>Std. Error</u>	<u>df</u>	<u>p</u>
	G/R	16.90	5.20	3, 54	.002
	Y1/R	12.70	4.59	3, 54	.008
	G&Y1/Y2&R	22.45	6.25	3, 54	.001
<u>Scale 8</u>	<u>Pair</u>	<u>Contrast Est.</u>	<u>Std. Error</u>	<u>df</u>	<u>p</u>
	G/R	26.30	8.23	3, 54	.013
	Y1/R	21.45	5.26	3, 54	.032
	G&Y1/Y2&R	34.25	8.93	3, 54	.003
<u>Scale 9</u>	<u>Pair</u>	<u>Contrast Est.</u>	<u>Std. Error</u>	<u>df</u>	<u>p</u>
	G/R	12.58	6.46	3, 54	.083
	Y1/R	11.48	6.27	3, 54	.104
	G&Y1/Y2&R	14.48	6.88	3, 54	.058
<u>Scale 0</u>	<u>Pair</u>	<u>Contrast Est.</u>	<u>Std. Error</u>	<u>df</u>	<u>p</u>
	G/R	10.77	4.54	3, 54	.021
	Y1/R	5.23	4.01	3, 54	.198
	G&Y1/Y2&R	12.67	5.46	3, 54	.024

G=Green, Y1=Yellow 1, Y2=Yellow 2, R=Red.

Table 6

Comparison of Mean Scores on MBMD Scales for Prognostic Groups

MBMD Scale	Group	Mean (<u>SD</u>)	<u>F</u>	<u>df</u>	<u>p</u>
ANXIETY/ TENSION	Green	26.70 (26.79)	4.63**	3, 54	.006
	Yellow 1	46.00 (26.10)			
	Yellow 2	48.21 (27.39)			
	Red	70.11 (15.82)			
DEPRESSION	Green	30.30 (22.43)	9.55**	3, 54	<.001
	Yellow 1	46.80 (29.53)			
	Yellow 2	60.21 (31.96)			
	Red	93.22 (5.83)			
COGNITIVE DYSFUNCTION	Green	22.20 (14.55)	5.08**	3, 54	.004
	Yellow 1	40.15 (24.55)			
	Yellow 2	45.32 (22.35)			
	Red	58.78 (13.66)			
EMOTIONAL LABILITY	Green	28.50 (19.73)	4.79**	3, 54	.005
	Yellow 1	30.50 (20.77)			
	Yellow 2	34.42 (24.45)			
	Red	59.56 (10.50)			

(cont.)

Table 6 (cont.)

MBMD Scale	Group	Mean (<u>SD</u>)	<u>F</u>	<u>df</u>	<u>p</u>
GUARDEDNESS	Green	33.50 (24.20)	0.96	3, 54	.420
	Yellow 1	38.45 (20.66)			
	Yellow 2	34.84 (19.65)			
	Red	47.67 (19.12)			
INTROVERSIVE	Green	40.00 (23.57)	1.10	3, 55	.356
	Yellow 1	44.95 (31.72)			
	Yellow 2	41.37 (22.83)			
	Red	60.78 (26.79)			
INHIBITED	Green	29.70 (21.60)	9.44**	3, 55	<.001
	Yellow 1	31.00 (22.60)			
	Yellow 2	42.89 (31.10)			
	Red	80.33 (14.76)			
DEJECTED	Green	14.00 (12.65)	17.64**	3, 54	<.001
	Yellow 1	11.75 (13.40)			
	Yellow 2	31.95 (29.94)			
	Red	77.89 (34.47)			
COOPERATIVE	Green	38.50 (21.35)	5.14**	3, 55	.003
	Yellow 1	54.65 (20.95)			
	Yellow 2	58.00 (22.01)			
	Red	75.44 (16.71)			

(cont.)

Table 6 (cont.)

MBMD Scale	Group	Mean (SD)	F	df	p
SOCIABLE	Green	51.70 (17.41)	1.97	3, 55	.130
	Yellow 1	59.65 (16.11)			
	Yellow 2	49.84 (24.31)			
	Red	42.78 (12.78)			
CONFIDENT	Green	49.10 (21.73)	5.46**	3, 55	.002
	Yellow 1	60.15 (15.12)			
	Yellow 2	46.32 (20.09)			
	Red	30.44 (20.49)			
NONCONFORM- ING	Green	26.40 (17.32)	2.95*	3, 54	.041
	Yellow 1	30.95 (18.97)			
	Yellow 2	30.63 (17.74)			
	Red	49.78 (22.54)			
FORCEFUL	Green	29.70 (19.72)	0.28	3, 55	.840
	Yellow 1	32.30 (19.39)			
	Yellow 2	31.05 (19.31)			
	Red	36.78 (25.39)			
RESPECTFUL	Green	55.60 (21.45)	1.12	3, 55	.351
	Yellow 1	54.70 (23.07)			
	Yellow 2	59.47 (21.70)			
	Red	43.11 (32.59)			

(cont.)

Table 6 (cont.)

MBMD Scale	Group	Mean (<u>SD</u>)	<u>F</u>	<u>df</u>	<u>p</u>
OPPOSITIONAL	Green	31.20 (22.14)	7.58**	3, 54	<.001
	Yellow 1	40.80 (18.64)			
	Yellow 2	48.63 (25.63)			
	Red	76.56 (21.54)			
DENIGRATED	Green	35.10 (24.56)	7.75**	3, 54	<.001
	Yellow 1	38.55 (23.25)			
	Yellow 2	55.05 (24.66)			
	Red	79.33 (21.52)			
ILLNESS APPREHENSION	Green	65.11 (17.60)	3.75*	3, 54	.016
	Yellow 1	81.95 (14.54)			
	Yellow 2	80.74 (13.79)			
	Red	84.89 (14.33)			
FUNCTIONAL DEFICITS	Green	80.00 (6.45)	3.29*	3, 54	.028
	Yellow 1	84.15 (14.05)			
	Yellow 2	90.89 (18.92)			
	Red	98.89 (12.63)			
PAIN SENSITIVITY	Green	82.30 (13.32)	4.13**	3, 54	.010
	Yellow 1	88.90 (13.68)			
	Yellow 2	93.05 (17.20)			
	Red	104.44 (8.46)			

(cont.)

Table 6 (cont.)

MBMD Scale	Group	Mean (<u>SD</u>)	<u>F</u>	<u>df</u>	<u>p</u>
SOCIAL ISOLATION	Green	29.50 (24.09)	6.81**	3, 54	.001
	Yellow 1	33.70 (21.19)			
	Yellow 2	45.63 (29.18)			
	Red	73.78 (20.03)			
FUTURE PESSIMISM	Green	72.00 (7.17)	1.37	3, 54	.263
	Yellow 1	71.80 (11.01)			
	Yellow 2	76.00 (18.51)			
	Red	81.89 (9.92)			
SPIRITUAL ABSENCE	Green	21.20 (20.36)	0.40	3, 54	.755
	Yellow 1	33.20 (30.42)			
	Yellow 2	26.21 (36.67)			
	Red	31.44 (28.74)			
INTERVENTIONAL FRAGILITY	Green	24.50 (23.47)	4.64**	3, 54	.006
	Yellow 1	38.90 (22.43)			
	Yellow 2	41.68 (23.02)			
	Red	63.11 (22.18)			
MEDICATION ABUSE	Green	44.10 (29.46)	0.87	3, 54	.463
	Yellow 1	54.60 (16.88)			
	Yellow 2	56.32 (20.21)			
	Red	53.33 (12.26)			

Table 6 (cont.)

MBMD Scale	Group	Mean (SD)	F	df	p
INFORMATION DISCOMFORT	Green	37.70 (35.29)	4.48**	3, 54	.007
	Yellow 1	15.35 (25.04)			
	Yellow 2	5.26 (11.36)			
	Red	7.78 (23.33)			
UTILIZATION EXCESS	Green	35.70 (26.43)	8.18**	3, 54	<.001
	Yellow 1	58.40 (14.33)			
	Yellow 2	64.79 (20.58)			
	Red	78.44 (19.27)			
PROBLEMATIC COMPLIANCE	Green	58.50 (22.76)	0.61	3, 54	.614
	Yellow 1	54.35 (22.85)			
	Yellow 2	48.05 (20.55)			
	Red	47.78 (30.09)			
ADJUSTMENT DIFFICULTIES	Green	74.30 (11.17)	5.65**	3, 54	.002
	Yellow 1	82.50 (9.80)			
	Yellow 2	85.63 (10.83)			
	Red	93.11 (8.78)			
PSYCH REFERRAL	Green	43.90 (18.47)	6.83**	3, 54	.001
	Yellow 1	56.15 (21.91)			
	Yellow 2	60.89 (28.90)			
	Red	89.78 (12.99)			

*p ≤ .05, two tailed. **p ≤ .01, two tailed.

Table 7

Comparison of Mean Scores on Psychosocial Measures at Initial Evaluation for Prognostic Groups

Psychosocial Measure	Group (n)	Mean (SD)	F	df	p
BDI	Green (10)	9.30 (4.64)	12.529**	3, 56	<.001
	Yellow-I (21)	12.57 (5.57)			
	Yellow-II (20)	17.00 (10.03)			
	Red (9)	32.22 (15.21)			
HAM-D	Green (10)	12.20 (5.25)	17.140**	3, 56	<.001
	Yellow-I (21)	12.33 (4.78)			
	Yellow-II (20)	18.35 (5.94)			
	Red (9)	26.78 (6.46)			
CSQ Total	Green (9)	86.33 (50.00)	.307	3, 49	.820
	Yellow-I (20)	99.35 (26.00)			
	Yellow-II (17)	99.00 (42.76)			
	Red (7)	100.86 (34.68)			
CSQ-Cat.	Green (9)	8.11 (4.40)	7.056**	3, 48	.001
	Yellow-I (19)	14.37 (7.07)			
	Yellow-II (17)	14.41 (11.02)			
	Red (7)	27.29 (8.16)			
MCS	Green (4)	44.75 (7.93)	4.724*	3, 16	.015
	Yellow-I (8)	52.63 (6.80)			
	Yellow-II (5)	46.60 (14.64)			
	Red (3)	26.00 (13.89)			

*p ≤ .05, two-tailed. **p ≤ .01, two-tailed.

Table 8

Medication Use at Initial Evaluation Relative to Prognostic Groups

<u>Group</u>	<u>Medication (n)</u>	<u>% w/in Group</u>	<u>χ^2</u>	<u>df</u>	<u>p</u>
Green	Narcotic (8)	88.9	3.017	6	.807
	Non-narcotic (1)	11.1			
	No medication (0)	0.0			
Yellow-I	Narcotic (18)	85.7			
	Non-narcotic (3)	14.3			
	No medication (0)	0.0			
Yellow-II	Narcotic (16)	84.2			
	Non-narcotic (2)	10.5			
	No medication (1)	5.3			
Red	Narcotic (6)	75.0			
	Non-narcotic (2)	25.0			
	No medication (0)	0.0			

Table 9
Breakdown of Patients at Six-Month Follow-Up: Procedures Relative to Groups

Type of Procedure	Total Sample (N=32)	Green (n=6)	<u>Overall Prognostic Group</u>		
			Yellow-I (n=12)	Yellow-II (n=10)	Red (n=4)
SCS	8 (25%)	1 (12.5%)	5 (62.5%)	1 (12.5%)	1 (12.5%)
IT pump	12 (37.5%)	4 (33.3%)	3 (25%)	5 (41.7%)	0 (0%)
Other surgery	2 (6.3%)	0 (0%)	1 (50%)	1 (50%)	0 (0%)
None	10 (31.3%)	1 (10%)	3 (30%)	3 (30%)	3 (30%)

Table 10

Paired Samples t-tests for Green Group: Initial Evaluation to 6 Month Follow-Up

	<u>Time</u>	<u>Mean (SD)</u>	<u>t</u>	<u>df</u>	<u>p</u>
OSW	Initial Eval.	22.80 (5.98)	4.45**	4	.011
	6 Month F/U	16.00 (7.11)			
VAS	Initial Eval.	7.40 (1.67)	1.49	4	.212
	6 Month F/U	5.80 (2.95)			
PCS	Initial Eval.	22.50 (3.54)	-2.33	1	.258
	6 Month F/U	33.00 (2.83)			
BDI	Initial Eval.	10.50 (4.76)	1.45	5	.206
	6 Month F/U	7.33 (3.20)			
MCS	Initial Eval.	44.00 (12.73)	-4.00	1	.156
	6 Month F/U	48.00 (11.31)			

** $p \leq .01$, two-tailed.

Table 11

Paired Samples t-tests for Yellow 1 Group: Initial Evaluation to 6 Month Follow-Up

	<u>Time</u>	<u>Mean (SD)</u>	<u>t</u>	<u>df</u>	<u>p</u>
OSW	Initial Eval.	25.86 (6.79)	2.04	6	.087
	6 Month F/U	17.29 (7.99)			
VAS	Initial Eval.	9.09 (1.04)	3.89**	10	.003
	6 Month F/U	5.91 (2.21)			
PCS	Initial Eval.	17.50 (3.11)	-1.10	3	.350
	6 Month F/U	27.50 (18.48)			
BDI	Initial Eval.	11.36 (6.30)	-0.24	10	.817
	6 Month F/U	11.91(7.62)			
MCS	Initial Eval.	55.50 (5.57)	-0.57	3	.612
	6 Month F/U	59.00 (9.52)			

** $p \leq .01$, two-tailed.

Table 12

Paired Samples t-tests for Yellow 2 Group: Initial Evaluation to 6 Month Follow-Up

	<u>Time</u>	<u>Mean (SD)</u>	<u>t</u>	<u>df</u>	<u>p</u>
OSW	Initial Eval.	24.40 (5.03)	0.29	4	.783
	6 Month F/U	23.80 (4.27)			
VAS	Initial Eval.	7.89 (1.62)	2.35*	8	.046
	6 Month F/U	5.89 (2.09)			
PCS	Initial Eval.	21.00 (7.81)	-0.45	2	.697
	6 Month F/U	22.33 (10.50)			
BDI	Initial Eval.	15.20 (6.61)	1.46	9	.178
	6 Month F/U	11.60 (7.43)			
MCS	Initial Eval.	46.67 (9.29)	-1.73	2	.225
	6 Month F/U	52.67 (14.57)			

* $p \leq .05$, two-tailed.

Table 13

Paired Samples t-tests for Red Group: Initial Evaluation to 6 Month Follow-Up

	<u>Time</u>	<u>Mean (SD)</u>	<u>t</u>	<u>df</u>	<u>p</u>
OSW					
	Initial Eval.	21.00 ^a			
	6 Month F/U	8.00 ^a			
VAS					
	Initial Eval.	8.33 (2.08)	.66	2	.580
	6 Month F/U	6.33 (3.79)			
PCS					
	Initial Eval.	47.00 ^a			
	6 Month F/U	41.00 ^a			
BDI					
	Initial Eval.	35.75 (16.15)	2.40	3	.096
	6 Month F/U	20.00 (9.66)			
MCS					
	Initial Eval.	10.00 ^a			
	6 Month F/U	15.00 ^a			

a. The correlation and t cannot be computed because the sum of caseweights is ≤ 1 .

Table 14

Six-Month Follow-Up Scores Relative to Prognostic Groups (ANCOVA using the 6-month score as dependent variable with the initial evaluation score as the covariate)

Measure	Group (<u>n</u>)	Mean (<u>SD</u>)	Covariate <u>F</u>	<u>df</u>	<u>p</u>	partial <u>η^2</u>
OSW	Green (5)	16.00 (7.11)	1.889	3, 13	.181	.304
	Yellow-I (7)	17.29 (7.99)				
	Yellow-II (5)	23.80 (4.27)				
	Red (1)	8.00				
MCS	Green (2)	48.00 (11.31)	.050	3, 5	.984	.029
	Yellow-I (4)	59.00 (9.52)				
	Yellow-II (3)	52.67 (14.57)				
	Red (1)	15.00				
BDI	Green (6)	7.33 (3.20)	.528	3, 26	.667	.057
	Yellow-I (11)	11.91 (7.62)				
	Yellow-II (10)	11.60 (7.43)				
	Red (4)	20.00 (9.66)				

Table 15

Physical Component Score (PCS): Repeated Measures Analysis of Variance for Initial Evaluation and 6-Month Follow-Up by Group and Time

Prognostic Group (n)	Initial Eval. Mean PCS (<u>SD</u>)	6 Month F/U Mean PCS (<u>SD</u>)
Green (2)	22.50 (3.54)	33.00 (2.83)
Yellow-I (4)	17.50 (3.11)	27.50 (18.48)
Yellow-II (3)	21.00 (7.81)	22.33 (10.50)
Red (1)	47.00	41.00

PCS	<u>SS</u>	<u>MS</u>	<u>F</u>	<u>df</u>	<u>p</u>
Group Effect	864.87	288.29	1.97	3	.220
Error	878.58	146.43		6	
Time Effect	60.17	60.17	.670	1	.444
Error	538.58	89.76		6	
Interaction Effect	156.87	52.29	.58	3	.648

Table 16

Visual Analogue Scale (VAS): Repeated Measures Analysis of Variance for Initial Evaluation and 6-Month Follow-Up by Group and Time

Prognostic Group (n)	Initial Eval. Mean VAS (<u>SD</u>)	6 Month F/U Mean VAS (<u>SD</u>)
Green (5)	7.40 (1.67)	5.80 (2.95)
Yellow-I (11)	9.09 (1.04)	5.91 (2.21)
Yellow-II (9)	7.89 (1.62)	5.89 (2.09)
Red (3)	8.33 (2.08)	6.33 (3.79)

VAS	<u>SS</u>	<u>MS</u>	<u>F</u>	<u>df</u>	<u>p</u>
Group Effect	7.11	2.37	.59	3	.628
Error	96.51	4.02		24	
Time Effect	52.44	52.44	12.29**	1	.002
Error	102.42	4.27		24	
Interaction Effect	5.92	1.97	.46	3	.711

*p < .05, one-tailed. **p < .01, one-tailed.

Table 17

Healthcare Utilization Six Months Prior to Initial Evaluation

Healthcare Visits				
<u>Group</u>	<u>Mean (SD)</u>	<u>F</u>	<u>df</u>	<u>p</u>
Green	4.13 (2.95)	4.21**	3, 40	.011
Yellow-I	6.06 (7.22)			
Yellow-II	9.53 (10.27)			
Red	24.50 (24.04)			
Emergency Room Visits				
<u>Group</u>	<u>Mean (SD)</u>	<u>F</u>	<u>df</u>	<u>p</u>
Green	0.13 (.35)	.589	3, 43	.626
Yellow-I	1.29 (2.37)			
Yellow-II	0.69 (2.50)			
Red	0.67 (1.63)			

**p \leq .01, two-tailed.

Table 18

Healthcare Utilization in Past Year Relative to Prognostic Groups

<hr/>				
Healthcare Visits				
<u>Group</u>	<u>Mean (SD)</u>	<u>F</u>	<u>df</u>	<u>p</u>
Green	14.20 (15.04)	1.099	3, 24	.369
Yellow-I	23.18 (18.66)			
Yellow-II	14.56 (14.40)			
Red	32.00 (23.07)			
<hr/>				
Emergency Room Visits				
<u>Group</u>	<u>Mean (SD)</u>	<u>F</u>	<u>df</u>	<u>p</u>
Green	0.67 (1.03)	.475	3, 27	.702
Yellow-I	1.58 (1.93)			
Yellow-II	1.00 (2.00)			
Red	0.75 (1.50)			
<hr/>				

Table 19

Comparisons of the Four Prognostic Groups on Vocational Status at Initial Evaluation:
Chi-Square Analyses

<u>Group</u>	<u>Vocational Status</u>	<u>Percent</u>	<u>χ^2</u>	<u>df</u>	<u>p</u>
Green	Working	40.0	7.92	6	.244
	Not Working Due To Original Injury	20.0			
	Not Working Due To Other Reasons	40.0			
Yellow-I	Working	19.0			
	Not Working Due To Original Injury	47.6			
	Not Working Due To Other Reasons	33.3			
Yellow-II	Working	10.5			
	Not Working Due To Original Injury	57.9			
	Not Working Due To Other Reasons	31.6			
Red	Working	0.0			
	Not Working Due To Original Injury	66.7			
	Not Working Due To Other Reasons	33.3			

**Mantel-Haenszel trend present: $\chi^2(1) = 5.74, p \leq .01$.

Table 20

Comparisons of the Four Prognostic Groups on Vocational Status at 6-Month Follow-Up:
Chi-Square Analyses

<u>Group</u>	<u>Vocational Status</u>	<u>Percent</u>	<u>X²</u>	<u>df</u>	<u>p</u>
Green	Working	0.0	5.76	6	.451
	Not Working Due To Original Injury	33.3			
	Not Working Due To Other Reasons	66.7			
Yellow-I	Working	0.0			
	Not Working Due To Original Injury	58.3			
	Not Working Due To Other Reasons	41.7			
Yellow-II	Working	20.0			
	Not Working Due To Original Injury	40.0			
	Not Working Due To Other Reasons	40.0			
Red	Working	0.0			
	Not Working Due To Original Injury	50.0			
	Not Working Due To Other Reasons	50.0			

Table 21

Initial and 6-Month Follow-Up Medication Use Relative to Prognostic Group

	Green (n) (%)		Yellow-I (n) (%)	
	<u>Initial</u>	<u>6-Mth</u>	<u>Initial</u>	<u>6-Mth</u>
Narcotic	7 (77.8)	2 (40)	16 (76.2)	5 (45.5)
Non-narc.	1 (11.1)	1 (20)	4 (19)	3 (27.3)
None	1 (11.1)	2 (40)	1 (4.8)	3 (27.3)

	Yellow-II (n) (%)		Red (n) (%)	
	<u>Initial</u>	<u>6-Mth</u>	<u>Initial</u>	<u>6-Mth</u>
Narcotic	14 (73.7)	2 (25)	5 (62.5)	2 (66.7)
Non-narc.	3 (15.8)	4 (50)	3 (37.5)	1 (33.3)
None	2 (10.5)	2 (25)	0 (0)	0 (0)

Table 22

Medication Use at Six-Month Follow-Up Relative to Prognostic Groups

<u>Group</u>	<u>Medication (n)</u>	<u>% w/in Group</u>	χ^2	<u>df</u>	<u>p</u>
Green	Narcotic (2)	40.0	3.267	6	.775
	Non-narcotic (1)	20.0			
	No medication (2)	40.0			
Yellow-I	Narcotic (5)	45.5			
	Non-narcotic (3)	27.3			
	No medication (3)	27.3			
Yellow-II	Narcotic (2)	25.0			
	Non-narcotic (4)	50.0			
	No medication (2)	25.0			
Red	Narcotic (2)	66.7			
	Non-narcotic (1)	33.3			
	No medication (0)	0.0			

Table 23

Comparison of Overall Interview Risk Scores for Prognostic Groups

Risk Score	Group (<u>n</u>)	Mean (<u>SD</u>)	<u>F</u>	<u>df</u>	<u>p</u>
Interview	Green (10)	0.30 (0.48)	6.417**	3, 56	.001
	Yellow-I (21)	0.81 (1.12)			
	Yellow-II (20)	1.90 (1.77)			
	Red (9)	2.78 (2.05)			

**p \leq .01, two-tailed.

Table 24

Comparison of Overall Psychological Testing Risk Scores for Prognostic Groups

Risk Score	Group (<u>n</u>)	Mean (<u>SD</u>)	<u>F</u>	<u>df</u>	<u>p</u>
Psych Testing	Green (10)	2.80 (1.69)	6.786**	3, 56	.001
	Yellow-I (21)	4.24 (1.22)			
	Yellow-II (20)	4.55 (1.50)			
	Red (9)	5.56 (0.88)			

**p \leq .01, two-tailed.

Table 25

Comparison of Overall Medical Risk Scores for Prognostic Groups

Risk Score	Group (<u>n</u>)	Mean (<u>SD</u>)	<u>F</u>	<u>df</u>	<u>p</u>
Medical	Green (10)	4.00 (1.41)	3.122*	3, 56	.033
	Yellow-I (21)	4.48 (1.72)			
	Yellow-II (20)	4.90 (2.17)			
	Red (9)	6.33 (1.22)			

* $p \leq .05$, two-tailed.

Table 26

Statistical Comparison of Presence/Absence of Adverse Clinical Features

<u>Group</u>	<u>Adverse Features (n)</u>	<u>% w/in Group</u>	χ^2	<u>df</u>	<u>p</u>
Green	No (9)		22.76**	3	<.001
	Yes (1)				
Yellow 1	No (20)				
	Yes (1)				
Yellow 2	No (17)				
	Yes (3)				
Red	No (2)				
	Yes (7)				

**p \leq .01, two-tailed.

Table 27

Planned Contrasts of Presence/Absence of Adverse Clinical Features

<u>Pair</u>	χ^2	<u>df</u>	<u>p</u>	Odds Ratio	<u>95% C.I.</u>
Green/Red	8.93	1	.003	31.50	2.35 – 422.30
Yellow1/Red	17.18	1	<.001	70.00	5.47 – 896.59
Yellow 2/Red	10.83	1	.001	19.83	2.7 – 145.67

Table 28

Comparison of Overall Revised Adverse Clinical Features Risk Scores for Prognostic Groups

Risk Score	Group (<u>n</u>)	Mean (<u>SD</u>)	<u>F</u>	<u>df</u>	<u>p</u>
Adverse Clin. Features	Green (10)	0.20 (0.63)	10.50**	3, 56	< .001
	Yellow-I (21)	0.19 (0.51)			
	Yellow-II (20)	0.45 (0.83)			
	Red (9)	2.78 (2.82)			

**p \leq .01, two-tailed.

Table 29

Logistic Regression Analysis of Green Group

Model: BDI total score, CSQ Catastrophizing scale, OSW total score, and Overall Interview Risk Score

		Predicted Green Group		
		<u>No</u>	<u>Yes</u>	<u>% Correct</u>
Observed	<u>No</u>	41	2	95.3 %
Diagnosis	<u>Yes</u>	3	6	66.7%
Overall Correct Classification Rate: 90.4%				
<u>Model X²</u>	<u>df</u>	<u>p</u>		
18.120**	4	< .001		

Summary of Logistic Regression Analysis of Green Group:

Variables	B	SE	Wald Statistic	Odds Ratio (OR)	95%Confidence Interval
BDI total	-.115	.120	.927	.891	.705-1.127
CSQ Cat.	-.111	.096	1.348	.895	.741-1.080
Oswestry	-.114	.066	3.022	.892	.784-1.015
Int. Risk	-.943	.572	2.722	.389	.127-1.194

**p ≤ .01, two tailed

Table 30

Logistic Regression Analysis of Yellow-I Group**Model:** SF-36/MCS and HAM-D

		Predicted Yellow-I Group		
		<u>No</u>	<u>Yes</u>	<u>% Correct</u>
Observed	<u>No</u>	12	0	100.0%
Diagnosis	<u>Yes</u>	2	6	75.0%
Overall Correct Classification Rate: 90.0%				

<u>Model X²</u>	<u>df</u>	<u>p</u>
15.570**	2	< .001

Summary of Logistic Regression Analysis of Yellow-I Group:

<u>Variables</u>	<u>B</u>	<u>SE</u>	<u>Wald Statistic</u>	<u>Odds Ratio (OR)</u>	<u>95%Confidence Interval</u>
SF-36/MCS	-.143	.133	1.161	.866	.667-1.125
HAM-D	-1.321	.725	3.320	.267	.065-1.105

** $p \leq .01$, two-tailed.

Table 31

Logistic Regression Analysis of Yellow-II Group**Model:** SF-36/MCS and BDI total score

		Predicted Yellow-II Group		
		<u>No</u>	<u>Yes</u>	<u>% Correct</u>
Observed	<u>No</u>	14	1	93.3%
Diagnosis	<u>Yes</u>	3	2	40.0%
Overall Correct Classification Rate: 80.0%				

<u>Model X^2</u>	<u>df</u>	<u>p</u>
5.969*	2	.05

Summary of Logistic Regression Analysis of Yellow-II Group:

<u>Variables</u>	<u>B</u>	<u>SE</u>	<u>Wald Statistic</u>	<u>Odds Ratio (OR)</u>	<u>95%Confidence Interval</u>
SF-36/MCS	.234	.140	2.788	1.264	.960-1.664
BDI	.287	.161	3.189	1.333	.972-1.826

* $p \leq .05$, two-tailed.

Table 32

Logistic Regression Analysis of Red Group**Model:** BDI total score and Adverse Clinical Features (present)

		Predicted Red Group		
		<u>No</u>	<u>Yes</u>	<u>% Correct</u>
Observed	<u>No</u>	49	2	96.1%
Diagnosis	<u>Yes</u>	1	8	88.9%
Overall Correct Classification Rate: 95.0%				

<u>Model X²</u>	<u>df</u>	<u>p</u>
32.545**	2	< .001

Summary of Logistic Regression Analysis of Red Group:

Variables	B	SE	Wald Statistic	Odds Ratio (OR)	95%Confidence Interval
BDI	.185	.072	6.645	1.203	1.045-1.385
Adv. Fx	4.779	1.782	7.192	118.936	3.619-3,909.158

** $p \leq .01$, two-tailed.

APPENDIX C:
ALGORITHM

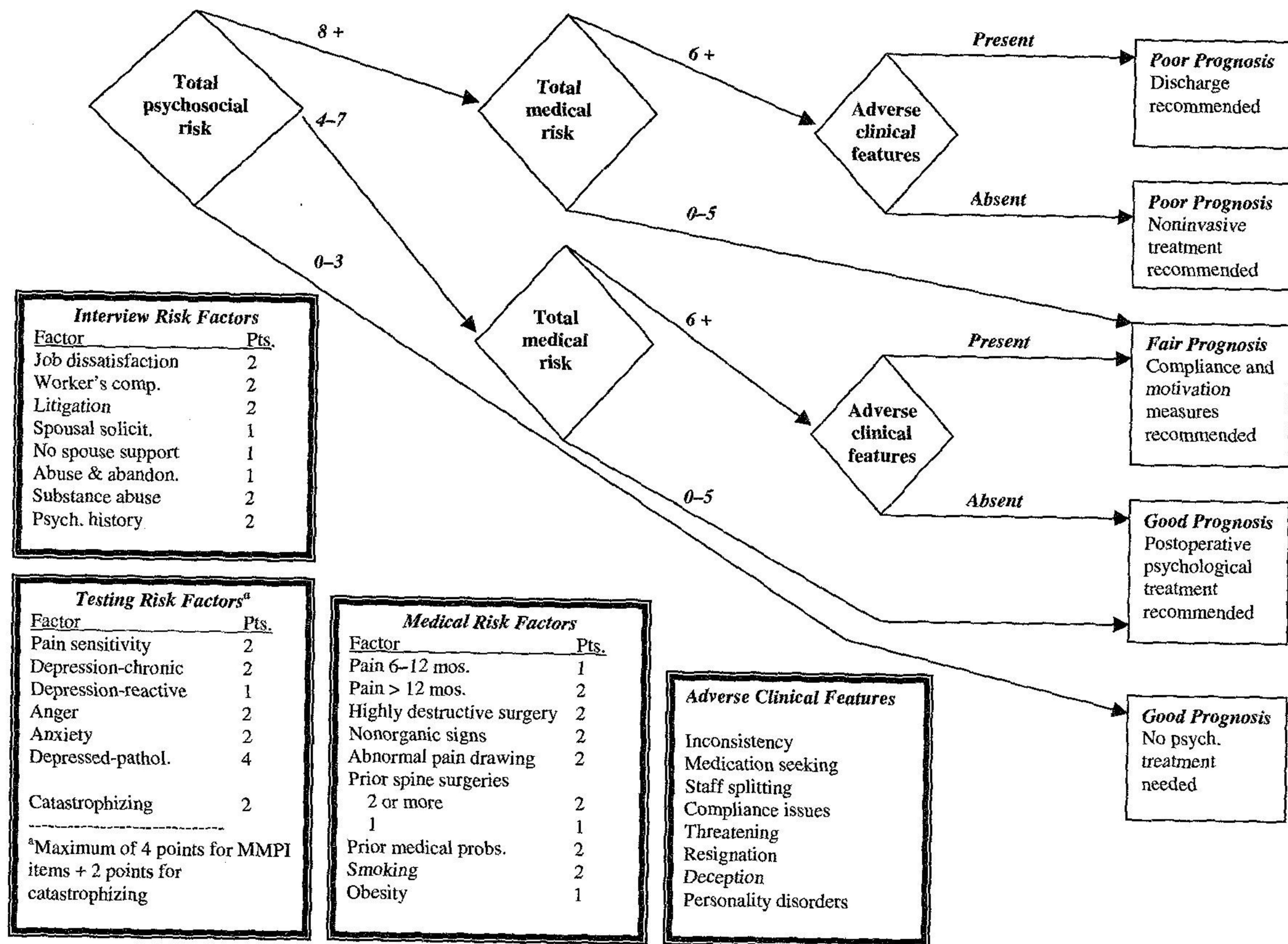


Figure 6.2. Algorithm for determining presurgical psychological screening prognosis. MMPI = Minnesota Multiphasic Personality Inventory.

APPENDIX D:
MATERIAL

SOUTHWESTERN MEDICAL CENTER
AT DALLAS

The Eugene McDermott Center for Pain Management
5323 Harry Hines Blvd. • Dallas, TX 75390-9189 • 214-645-8450 Fax 214-645-8451

Confidential Pain Questionnaire

Please take the time to fill out this medical questionnaire at the request of your treating physician. Having all of the background information will facilitate your visit here, enabling the physicians to focus on your principal concerns.

Name: _____ Today's Date: _____

Address: _____ Telephone # _____

E-Mail: _____ Cell Phone # _____

Additional contact # 1: Tel: _____ Relationship: _____

Additional contact # 2: Tel: _____ Relationship: _____

Additional contact #3: Tel: _____ Relationship: _____

Date of birth: _____ Age: _____ Right- or Left-handed? (Circle one)

Gender: Male Female **Race:** Caucasian African-American Hispanic Asian Other

How did the pain start? (Circle as many as apply):

suddenly	bending
gradually	pulling
lifting	at work
twisting	motor vehicle accident
fall	direct blow to spine
sports injury	other: _____
unknown	

Time Since First Onset of Pain (Approximate Date): _____

Any pending litigation associated with the pain?

Workers Compensation Personal Injury Other None (Circle one)

Are you receiving disability payments? Yes No

Which best describes your pain? (Circle as many as apply):

sharp	dull
burning	splitting
throbbing	crushing
shooting	stabbing
aching	sore
cramping	tingling

What brings on the pain or makes it worse? (Circle as many as apply):

sitting	lifting
standing	pulling
walking	bending forwards
running	bending backwards
twisting	during exercise
no apparent reason	using arms
after exercise	coughing
sneezing	other: _____

What eases or eliminates the pain? (Circle as many as apply):

lying down	exercise
sitting	pain pills
standing	aspirin, Tylenol, Advil
walking	muscle relaxants
arthritis medicine	nothing
physical therapy	other: _____

Is it getting better, worse or staying about the same? (Circle one) **Is it constant or does it vary?** (Circle one)

Does your pain awaken you at night? YES NO (Circle one) **If yes, can you get back to sleep? YES NO** (Circle one)

How many hours do you sleep on an average night? _____ **Do you take medicine to sleep? YES NO** (Circle one)

Do you have trouble controlling your bladder or bowels? _____

PAST MEDICAL TREATMENTS FOR PAIN (Circle as many as apply and list approximate month and year they were administered. if you are uncertain, please have your physician help you complete this):

Bedrest _____	NSAIDS _____	Ilioinguinal Nerve Block _____
Chiropractic _____	Opiates _____	Facet Joint Injection _____
Acupuncture _____	Physical therapy _____	Trigger point injection _____
Muscle stimulator _____	Muscle relaxants _____	Stellate Ganglion Block _____
Braces _____	Antidepressant drug _____	Bier's Block _____
Splints _____	Antianxiety drug _____	Cervical Epidural Steroid Injection _____
Traction _____	Benzodiazepines _____	Somatic Nerve Block _____
TENS _____	Anticonvulsants _____	Lumbar Epidural Steroid Injections _____
Spinal Cord Implant _____	Psychotherapy _____	Other (Specify) _____

Number of healthcare visits during the last six months for your pain condition?: _____

Number of Emergency Room visits during the last six months for your pain condition?: _____

PAST SURGICAL TREATMENT FOR PAIN (Include date):

CURRENT PAIN MEDICATIONS AND DOSE (Bring prescription bottles with you if you are uncertain):

Have you had any tests for your current conditions? (Circle as many as apply):

x-rays	MRI (magnetic resonance imaging)
bone scan	nerve conduction test
CAT scan	EMG (electromyography)
myelogram	

ALLERGIES TO MEDICATIONS?: _____**CURRENT OTHER (NON-PAIN) MEDICATIONS AND DOSE** (Bring prescription bottles with you if you are uncertain):

_____	_____	_____
_____	_____	_____

PAST PAIN DIAGNOSES (Include approximate date):

_____	_____	_____
_____	_____	_____

PAST MEDICAL HISTORY (Circle as many as apply):

high blood pressure	kidney problems
diabetes	arthritis
ulcers	gout
heart problems	stroke
epilepsy	sexual difficulties
thyroid	cancer
bleeding or bruising	other: _____
liver problems (hepatitis)	

PAST SURGICAL PROCEDURES FOR THESE MEDICAL CONDITIONS (Include approximate date):

_____	_____
_____	_____

Are there any diseases that run in your family? _____**Review of current symptoms** (Circle any of the following if they apply to you):

unusual tiredness	unusual bleeding	heavy cough	trouble sleeping
fevers	easy bruising	chest pain	
chills	lumps or bumps	trouble breathing	
unusual sweating	swollen glands	depression	
loss of appetite	change in bowels habits	change in vision	
unexplained weight loss	blood in the urine or stool	seizures	
rashes	impotence	tingling (pins & needles)	

SOCIAL HISTORY

What is your current occupation? _____ **Part-time or Full Time?** (Circle one)

(Please check one): **New employer since onset of pain?** _____ **Same employer since onset of pain?** _____

Have you participated in vocational training/retraining since the onset of your pain? **YES NO** (Circle one)

If you do not work, do you participate in other income producing activities? (i.e., rental properties, crafts, etc.)

YES NO (Circle one) If yes, please describe: _____

If you are not working, is it due to your initial onset of pain/ injury or a new pain/ injury? **YES NO** (Circle one)

Annual Household Income: _____

Marital Status: Single _____ Married _____ Widowed _____

Divorced/Separated _____ Living with Significant Other _____

Number of children: _____

Do you smoke? **YES NO** (Circle one) If yes, how many packs in a day? _____ How long have you smoked? _____ years

If a former smoker, how long ago did you quit? _____

Do you drink alcohol? _____ If yes, how much in an average day, week, or month? _____

Do you have a history of alcohol or drug abuse? **YES NO** (Circle one)

Have you ever felt the need to cut down on your drinking or drug use? **YES NO** (Circle one)

Have people annoyed you by criticizing your drinking or drug use? **YES NO** (Circle one)

Have you ever felt bad or guilty about your drinking or drug use? **YES NO** (Circle one)

Have you ever needed an eye opener the first thing in the morning to steady your nerves? **YES NO** (Circle one)

Do you exercise? **YES NO** (Circle one) How often? _____

Females: Last menstrual period _____

Could you be pregnant? Yes ____ No ____ Birth Control Method _____

Patient Signature Date

Attending Physician Signature Date

Fellow Physician Signature Date

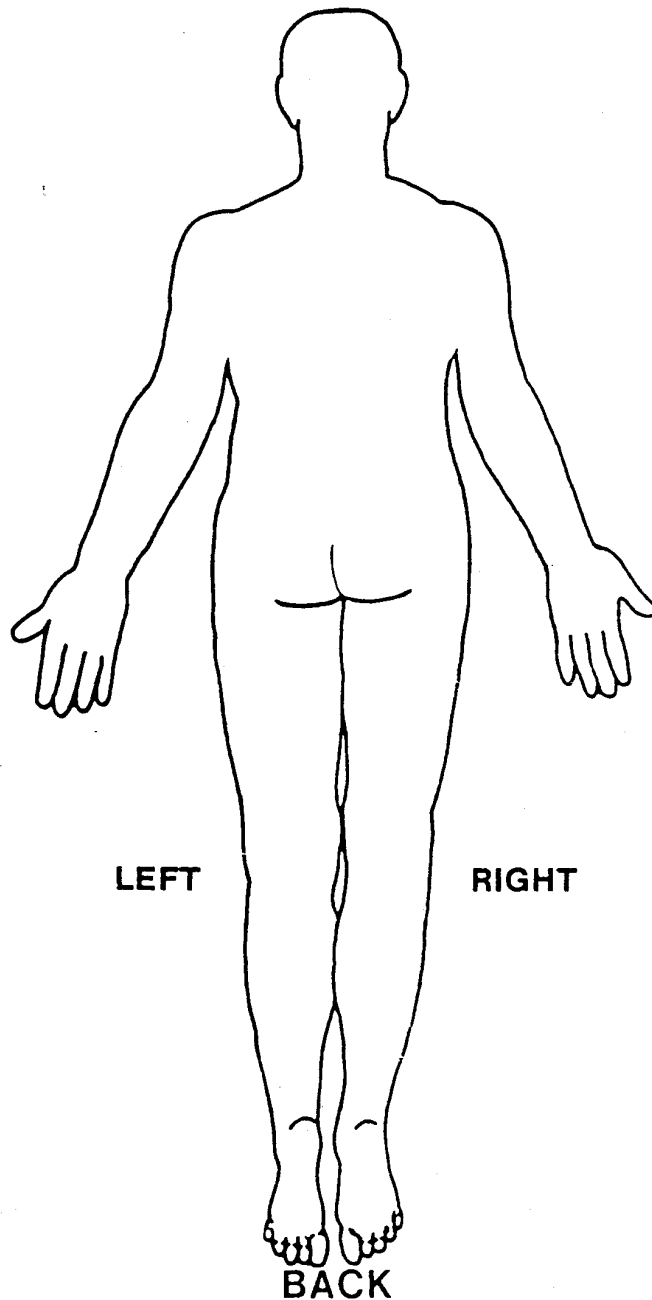
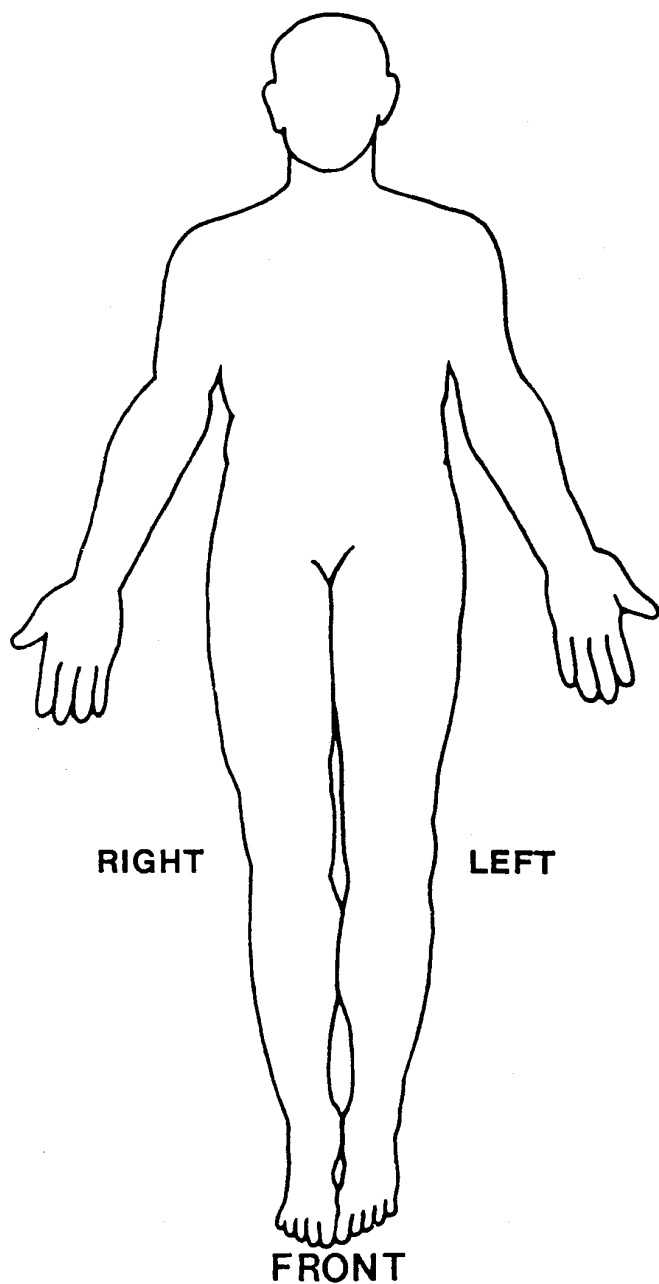
Name: _____

Date: _____ 159

PAIN DRAWING GRID ASSESSMENT

Draw the location of your pain on the body outlines and mark whether it is all back/neck or all arm/leg.

ALL BACK/NECK | | | | | | | ALL ARM/LEG



How bad is your pain?

NO PAIN | | | | | WORST POSSIBLE

DALLAS PAIN QUESTIONNAIRE

NAME: _____ DATE: _____

PLEASE MAKE AN "X" ALONG THE LINE TO SHOW HOW FAR FROM NORMAL TOWARD THE WORST POSSIBLE SITUATION YOUR PAIN PROBLEM HAS TAKEN YOU.

1. How bad is your pain?

no pain				worst possible

2. How bad is the pain at night?

no pain				worst possible

3. Does the pain interfere with your lifestyle?

no problem				total change in lifestyle

4. How good are pain killers for your pain?

complete relief				no relief

5. How stiff is your back?

no stiffness				worst possible stiffness

6. Does your pain interfere with walking?

no problem				cannot walk

7. Do you hurt when walking?

no pain				worst possible pain

8. Does your pain keep you from standing still?

can stand still as long as I want				cannot stand still at all

Name: _____

9. Does your pain keep you from twisting?

--	--	--	--	--

no problem cannot twist

10. Does your pain allow you to sit in an upright position?

--	--	--	--	--

sit as long as I like cannot use a hard chair at all

11. Does your pain allow you to sit in a soft arm chair?

--	--	--	--	--

sit as long as I like cannot use a soft chair at all

12. Do you have back pain when lying in bed?

--	--	--	--	--

no pain no relief at all

13. How much does pain limit your normal lifestyle?

--	--	--	--	--

no limit cannot do anything

14. Does pain interfere with your work?

--	--	--	--	--

no problem totally cannot work

15. How much have you had to change your work because of back pain?

--	--	--	--	--

no change so much that I cannot keep a job

OSWESTRY

NAME: _____ DATE: _____

How long have you had your pain? _____ Years _____ Months _____ Weeks

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

Section 1 - Pain Intensity

- ☐ I can tolerate the pain I have without having to use pain killers.
- ☐ The pain is bad, but I manage without taking pain killers.
- ☐ Pain killers give complete relief from pain.
- ☐ Pain killers give moderate relief from pain.
- ☐ Pain killers give very little relief from pain
- ☐ Pain killers have no effect on the pain and I do not use them.

Section 2 - Personal Care (Washing, Dressing, etc)

- ☐ I can look after myself normally without causing extra pain.
- ☐ I can look after myself normally, but it causes extra pain.
- ☐ It is painful to look after myself and I am slow and careful.
- ☐ I need some help, but manage most of my personal care.
- ☐ I need help every day in most aspects of self care.
- ☐ I do not get dressed, wash with difficulty and stay in bed.

Section 3 - Lifting

- ☐ I can lift heavy weights without extra pain.
- ☐ I can lift heavy weights, but it gives extra pain.
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, e.g., on a table.
- ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
- ☐ I can lift only very light weights.
- ☐ I cannot lift or carry anything at all.

Section 4 - Walking

- ☐ Pain does not prevent me from walking any distance.
- ☐ Pain prevents me walking more than a mile.
- ☐ Pain prevents me walking more than 1/2 mile.
- ☐ Pain prevents me walking more than 1/4 mile
- ☐ I can only walk using a stick or crutches.
- ☐ I am in bed most of the time and have to crawl to the toilet.

Section 5 - Sitting

- ☐ I can sit in any chair as long as I like.
- ☐ I can only sit in my favorite chair as long as I like.
- ☐ Pain prevents me sitting more than 1 hour.
- ☐ Pain prevents me from sitting more than 1/2 hour.
- ☐ Pain prevents me from sitting more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

Section 6 - Standing

- ☐ I can stand as long as I want without extra pain.
- ☐ I can stand as long as I want, but it gives me extra pain.
- ☐ Pain prevents me from standing for more than 1 hour.
- ☐ Pain prevents me from standing for more than 30 minutes.
- ☐ Pain prevents me from standing for more than 10 minutes.
- ☐ Pain prevents me from standing at all.

Section 7 - Sleeping

- ☐ Pain does not prevent me from sleeping well.
- ☐ I can sleep well only by using tablets.
- ☐ Even when I take tablets, I have less than 6 hours sleep.
- ☐ Even when I take tablets, I have less than 4 hours sleep.
- ☐ Even when I take tablets, I have less than 2 hours sleep.
- ☐ Pain prevents me from sleeping at all.

Section 8 - Sex Life

- ☐ My sex life is normal and causes no extra pain.
- ☐ My sex life is normal, but causes some extra pain.
- ☐ My sex life is nearly normal, but is very painful.
- ☐ My sex life is severely restricted by pain.
- ☐ My sex life is nearly absent because of pain.
- ☐ Pain prevents any sex life at all.

Section 9 - Social Life

- ☐ My social life is normal and gives me no extra pain.
- ☐ My social life is normal, but increases the degree of pain.
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests (e.g., dancing).
- ☐ Pain has restricted my social life and I do not go out as often.
- ☐ Pain has restricted my social life to my home.
- ☐ I have no social life because of pain.

Section 10 - Traveling

- ☐ I can travel anywhere without extra pain.
- ☐ I can travel anywhere, but it gives me extra pain.
- ☐ Pain is bad, but I manage journeys over 2 hours.
- ☐ Pain restricts me to journeys of less than 1 hour.
- ☐ Pain restricts me to short necessary journeys under 30 minutes.
- ☐ Pain prevents me from traveling except to the doctor or hospital.

COMMENT: _____

PMQ

PAIN MEDICATION QUESTIONNAIRE

NAME: _____

In order to develop the best treatment plan for you, we want to understand your thoughts, needs and experiences related to pain medication. Please read each statement below and indicate how much it applies to you by marking your response with an "X" anywhere on the line below it.

1) I believe I am receiving enough medication to relieve my pain.

Disagree Somewhat Disagree Neutral Somewhat Agree Agree

2) My doctor spends enough time talking to me about my pain medication during appointments.

Disagree Somewhat Disagree Neutral Somewhat Agree Agree

3) I believe I would feel better with a higher dosage of my pain medication.

Disagree Somewhat Disagree Neutral Somewhat Agree Agree

4) In the past, I have had some difficulty getting the medication I need from my doctor(s).

Disagree Somewhat Disagree Neutral Somewhat Agree Agree

5) I wouldn't mind quitting my current pain medication and trying a new one, if my doctor recommends it.

Disagree Somewhat Disagree Neutral Somewhat Agree Agree

6) I have clear preferences about the type of pain medication I need.

Disagree Somewhat Disagree Neutral Somewhat Agree Agree

7) Family members seem to think that I may be too dependent on my pain medication.

Disagree Somewhat Disagree Neutral Somewhat Agree Agree

8) It is important to me to try ways of managing my pain in addition to the medication (*such as relaxation, biofeedback, physical therapy, TENS unit, etc.*)

Disagree Somewhat Disagree Neutral Somewhat Agree Agree

(Please continue on the next page)

PMQ

PAIN MEDICATION QUESTIONNAIRE

9) At times, I take pain medication when I feel anxious and sad, or when I need help sleeping.

Never Occasionally Sometimes Often Always

10) At times, I drink alcohol to help control my pain.

Never Occasionally Sometimes Often Always

11) My pain medication makes it hard for me to think clearly sometimes.

Never Occasionally Sometimes Often Always

12) I find it necessary to go to the emergency room to get treatment for my pain.

Never Occasionally Sometimes Often Always

13) My pain medication makes me nauseated and constipated sometimes.

Never Occasionally Sometimes Often Always

14) At times, I need to borrow pain medication from friends or family to get relief.

Never Occasionally Sometimes Often Always

15) I get pain medication from more than one doctor in order to have enough medication for my pain.

Never Occasionally Sometimes Often Always

16) At times, I think I may be too dependent on my pain medication.

Never Occasionally Sometimes Often Always

17) To help me out, family members have obtained pain medications for me from their own doctors.

Never Occasionally Sometimes Often Always

(Please continue on the next page)

PMQ

PAIN MEDICATION QUESTIONNAIRE

18) At times, I need to take pain medication more often than it is prescribed in order to relieve my pain.

Never Occasionally Sometimes Often Always

19) I save any unused pain medication I have in case I need it later.

Never Occasionally Sometimes Often Always

20) I find it helpful to call my doctor or clinic to talk about how my pain medication is working.

Never Occasionally Sometimes Often Always

21) At times, I run out of pain medication early and have to call my doctor for refills.

Never Occasionally Sometimes Often Always

22) I find it useful to take additional medications (*such as sedatives*) to help my pain medication work better.

Never Occasionally Sometimes Often Always

23) How many painful conditions (*injured body parts or illnesses*) do you have?

1 painful conditions 2 painful conditions 3 painful conditions 4 painful conditions 5+ painful conditions

24) How many times in the past year have you asked your doctor to increase your prescribed dosage of pain medication in order to get relief?

Never 1 time 2 times 3 times 4+ times

25) How many times in the past year have you run out of pain medication early and had to request an early refill?

Never 1 time 2 times 3 times 4+ times

26) How many times in the past year have you accidentally misplaced your prescription for pain medication and had to ask for another?

Never 1 time 2 times 3 times 4+ times

(Stop)

Coping Strategy Questionnaire

Individuals who experience pain have developed a number of ways to cope, or deal with, their pain. These include saying things to themselves when they experience pain, or engaging in different activities. Below is a list of things that patients have reported doing when they feel pain. For each activity, I want you to indicate, using the scale below, how much you engage in that activity when you feel pain, where a 0 indicates you never do that when you are experiencing pain, a 3 indicates you sometimes do that when you are experiencing pain, and a 6 indicates you always do it when you are experiencing pain. Remember, you can use any point along the scale.

0	1	2	3	4	5	6
Never do that			Sometimes do that			Always do that

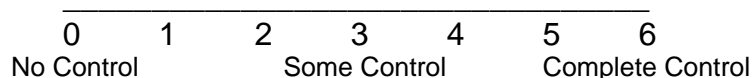
When I feel pain...

- _____ 1. I try to feel distant from the pain, almost as if the pain was in somebody else's body.
- _____ 2. I leave the house and do something, such as going to the movies or shopping.
- _____ 3. I try to think of something pleasant.
- _____ 4. I don't think of it as pain but rather as a dull or warm feeling.
- _____ 5. It is terrible and I feel it is never going to get any better.
- _____ 6. I tell myself to be brave and carry on despite the pain.
- _____ 7. I read.
- _____ 8. I tell myself that I can overcome the pain.
- _____ 9. I count numbers in my head or run a song through my mind.
- _____ 10. I just think of it as some other sensation, such as numbness.
- _____ 11. It is awful and I feel that it overwhelms me.
- _____ 12. I play mental games with myself to keep my mind off the pain.
- _____ 13. I feel my life isn't worth living.
- _____ 14. I know someday someone will be here to help me and it will go away for awhile.
- _____ 15. I pray to God it won't last long.
- _____ 16. I try not to think of it as my body, but rather as something separate from me.
- _____ 17. I don't think about the pain.
- _____ 18. I try to think about years ahead, what everything will be like after I've gotten rid of the pain.
- _____ 19. I tell myself it doesn't hurt
- _____ 20. I tell myself I can't let the pain stand in the way of what I have to do.
- _____ 21. I don't pay any attention to it.
- _____ 22. I have faith in doctors that someday there will be a cure for my pain.
- _____ 23. No matter how bad it gets, I know I can handle it.
- _____ 24. I pretend it is not there.
- _____ 25. I worry all the time about whether it will end.
- _____ 26. I replay in my mind the pleasant experiences in the past.
- _____ 27. I think of people I enjoy doing things with.
- _____ 28. I pray for the pain to stop.
- _____ 29. I imagine that the pain is outside of my body.

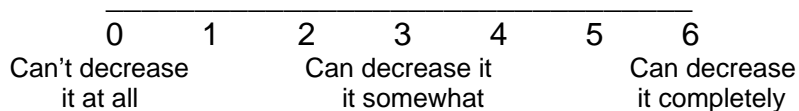
When I feel pain....

- _____ 30. I just go on as if nothing happened.
- _____ 31. I see it as a challenge and don't let it bother me.
- _____ 32. Although it hurts, I just keep on going.
- _____ 33. I feel I can't stand it anymore.
- _____ 34. I try to be around other people.
- _____ 35. I ignore it.
- _____ 36. I rely on my faith in God.
- _____ 37. I feel like I can't go on.
- _____ 38. I think of things that I enjoy doing.
- _____ 39. I do anything to get my mind off the pain.
- _____ 40. I do something I enjoy, such as watching TV or listening to music.
- _____ 41. I pretend it is not a part of me.
- _____ 42. I do something active, like household chores or projects.

Based on all the things you do to cope, or deal with, your pain, on an average day, how much control do you feel you have over it? Please circle the appropriate number. Remember, you can circle any number along the scale.



Based on all of the things you do to cope, or deal with, your pain, on an average day, how much are you able to decrease it? Please circle the appropriate number. Remember, you can circle any number along the scale.



TREATMENT HELPFULNESS QUESTIONNAIRE

_____ Pretreatment

Name: _____

Date: _____

Any treatment a person receives can be rated on a scale ranging from extremely harmful to extremely helpful with neutral (not helpful or harmful) falling in the middle. Below is a list of treatments offered at pain centers. Please rate each treatment you had **before coming to us (regardless of where the treatment was offered - pain center or not)** by making a vertical mark (not a slanted line or check mark) along the line to show how helpful (or harmful) the treatment was for you. Leave blank any treatment you did not receive.

_____ I have never received any of the below treatments

	Extremely Harmful	Harmful	Neutral	Helpful	Extremely Helpful
WHOLE PROGRAM					
MEDICAL ASSESSMENT AND TREATMENT					
PSYCHOLOGY ASSESSMENT AND TREATMENT					
PHYSICAL THERAPY ASSESSMENT & TREATMENT					
Office visits with Physician					
Individual Psychological Therapy					
Medical Diagnostic Tests (Thermography, EMG)					
Medical Work Abilities Testing (i.e. Functional Capacity, Impairment)					
Patient Education Groups					
Group Counseling					
Epidural Steroid Injections					
Medications Alone					

Stage: Pre-Trial / Trial / Post-Trial / Procedure / Post-Procedure (circle)**Duration of Trial (# days)** _____**Method of Trial:** Bolus / Continuous Infusion / Stimulator (circle)**Type of Stimulator** _____**Please Include total daily dose (DD) or infusion rate (IR) [e.g. 30mg Oxycontin tid = 90mg Oxycontin, etc.]**

Opioid Long-Acting <ul style="list-style-type: none"> Duragesic (Fentanyl) _____ Methadone (Dolophine) _____ Morphine Sulphate (Avinza) _____ Short-Acting <ul style="list-style-type: none"> Codeine _____ Tramadol (Ultram) _____ Hydrocodone (Lortab, Vicodin) _____ Meperidine (Demerol) _____ Morphine _____ Oxycodone (Percodan) _____ Oxycontin (Oxycodone HCl) _____ Pentazocine (Talwin) _____ Actiq (Fentanyl) _____ Other _____ NSAID <ul style="list-style-type: none"> Diclofenac (Voltaren) _____ Etodolac (Lodine) _____ Fenoprofen (Nalfon) _____ Flurbiprofen (Ansaid) _____ Ibuprofen (Motrin, Advil) _____ Indomethacin (Indocin) _____ Ketoprofen (Orudis, Oruvail) _____ Ketorolac (Toradol) _____ Meclofenamate (Meclomen) _____ Mefenamic acid (Ponstel) _____ Naproxen sodium (Anaprox) _____ Naproxyn (Naprosyn) _____ Piroxicam (Feldene) _____ Tolmetin (Tolectin) _____ Other _____ Anticonvulsant <ul style="list-style-type: none"> Clonazepam (Klonopin) _____ Keppra (Levetiracetam) _____ Neurontin (Gabapentin) _____ Topamax (Topiramate) _____ Zonegran (Zonisamide) _____ Other _____ Muscle Relaxants <ul style="list-style-type: none"> Baclofen (Lioresal) _____ Carisoprodol (Soma) _____ Chlorzoxazone (Parafon Forte) _____ Cyclobenzapine (Flexeril) _____ Methocarbamol (Robaxin) _____ Orphenadrine (Norflex) _____ Zanaflex (Tizanadine) _____ Metaxelone (Skelaxin) _____ Other _____ Antianxiety <ul style="list-style-type: none"> Benzodiazepine <ul style="list-style-type: none"> Alprazolam (Xanax) _____ Clordiazepoxide (Librium) _____ Diazepam (Valium) _____ Lorazepam (Ativan) _____ Oxazepam (Serax) _____ 	<ul style="list-style-type: none"> Other (Antianxiety) <ul style="list-style-type: none"> Antihistamines _____ Buspirone (BuSpar) _____ Other _____ Sedative / hypnotic <ul style="list-style-type: none"> Benzodiazepines <ul style="list-style-type: none"> Flurazepam (Dalmane) _____ Temazepam (Restoril) _____ Triazolam (Halcion) _____ Barbiturates _____ Chloral derivatives _____ Zolpidem (Ambien) _____ Sonata (Zaleplon) _____ Other _____ Neuroleptic <ul style="list-style-type: none"> Chlorpromazine (Thorazine) _____ Clozapine (Clozaril) _____ Fluphenazine (Prolixin) _____ Haloperidol (Haldol) _____ Loxapine (Loxitane) _____ Molindone (Moban) _____ Perphenazine (Trilafon) _____ Risperidone (Risperdal) _____ Thioridazine (Mellaril) _____ Thiothixene (Navane) _____ Trifluoperazine (Stelazine) _____ Olanzapine (Zyprexa) _____ Other _____ Lithium _____
	Antidepressant <ul style="list-style-type: none"> SSRI <ul style="list-style-type: none"> Citalopram (Celexa) _____ Clomipramine (Anafranil) _____ Escitalopram (Lexapro) _____ Fluvoxamine (Luvox) _____ Fluoxetine (Prozac) _____ Paroxetine (Paxil) _____ Sertraline (Zoloft) _____ Tricyclic <ul style="list-style-type: none"> Amitriptyline (Elavil) _____ Amoxapine (Asendin) _____ Desipramine (Norpramin) _____ Doxipin (Sinequan) _____ Imipramine (Tofranil) _____ Nortriptyline (Pamelor) _____ MAOI <ul style="list-style-type: none"> Isocarboxazid (Marplan) _____ Phenelzine (Nardil) _____ Tranlycypromine (Parnate) _____ Other <ul style="list-style-type: none"> Trazadone (Desyrel) _____ Nefazodone (Serzone) _____ Venlafaxine (Effexor) _____ Bupropion (Wellbutrin) _____ Maprotiline (Ludiomil) _____

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VITAE

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