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An Outcome Study of Spinal Cord Stimulation Implants in a Retrospective Cohort of Failed Back Surgery Syndrome Patients

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AN OUTCOME STUDY OF SPINAL CORD STIMULATION IMPLANTS IN A RETROSPECTIVE COHORT OF FAILED BACK SURGERY SYNDROME PATIENTS

by

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ABSTRACT

An Outcome Study of Spinal Cord Stimulation Implants in a Retrospective Cohort of Failed Back Surgery Syndrome Patients

by

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The current study was designed to test the effectiveness of spinal cord stimulation (SCS) in a retrospective group of 43 failed back surgery syndrome (FBSS) patients. A medical record review was conducted on study participants to capture relevant presurgical biopsychosocial variables deemed to be of potential prognostic value. In addition, a multidimensional approach to outcome assessment was undertaken along three general domains: general health status, disease specific outcomes, and surgical outcomes. Descriptive statistics of presurgical variables and outcome measurements are provided as well as a model of outcome prediction based on these prognostic variables. Results suggest that the use of neurostimulation may help to reduce low back and/or leg pain in some patients with FBSS; however, a large number of patients reported continuing pain, physical disability, and inability to work despite treatment. The

current study calls into question the efficacy of SCS for FBSS.

Recommendations for future studies are presented.

(141 pages)

DEDICATION

I would like to dedicate this work to my parents, James H. and Wilma A. Browning, and to my wife, Jennifer S. Browning, without whom this work would never have come to fruition.

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Anthony Davis Browning

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CHAPTER I

INTRODUCTION

Low back pain (LBP) has been dubbed the "nemesis of medicine" and the "albatross of industry" (Pope, Andersson, Frymoyer, & Chaffin, 1991; Raskind & Sedgwick, 1967). Indeed, it has been estimated that approximately 70 - 80% of individuals in the United States will experience LBP at some point in their lives (Block & Callewart, 1999; Deyo, Cherkin, Conrad, & Volinn, 1990; Fordyce, Brockway, & Spengler,1986; Frymoyer, 1988; Hult, 1954). Fortunately, most LBP episodes are mild and approximately 90% of cases will resolve within 6 weeks (Dillane, Fry, & Kalton, 1966; Indahl, Velund, & Reikeraas, 1995; Wilson, 1967).

Individuals with LBP typically begin to treat their symptoms by self-administration of over-the-counter pain relievers and anti-inflammatory drugs to reduce inflammation. In addition, the usage of cold and/or hot compresses are often employed and have been shown to help reduce pain and inflammation and allow greater mobility for some patients (Patel & Ogle, 2000). Bed rest is typically recommended for only 1-2 days at most and individuals are encouraged to resume activities as soon as possible (Deyo, Diehl, & Rosenthan, 1986). This is because exercise is thought to be an effective way of speeding recovery from LBP by strengthening back and abdominal muscles. For this reason, techniques such as Pilates (an exercise system that focuses on improving flexibility and strength in the spine as well as throughout the entire body) are often encouraged by those plagued with LBP.

Another alternative for such patients is chiropractic treatments. One such treatment that is commonly employed is called the "Flexion-distraction" technique. This involves the use of a specialized table that gently distracts or stretches the spine allowing the chiropractor to isolate the area of disc involvement while slightly flexing the spine in a pumping rhythm (Yuan, Booth, & Albert, 2005). This gentle pumping of the involved area allows the central area of the disc, the nucleus pulposus, to assume its central position in the disc. As a result, these actions are thought to move the disc away from the nerve, reducing inflammation of the nerve root, and eventually the associated pain and inflammation in the back and/or legs.

For LBP patients that do not get adequate symptom relief from consecutive nonoperative treatments, surgery is often the next option. Surgery for LBP is, in fact, quite common and it has been estimated that over 280,000 surgeries for LBP are performed each year in the United States alone (Block & Callewart, 1999; & Graves, 1990, 1991, 1992) making lumbar surgery one of the most frequently performed inpatient surgical procedures in the country. Such procedures are quite expensive, however, with total expenditures of both LBP treatment and disability ranging from around $14 to $18 billion annually with some estimates reaching as much as $100 billion (Pope et al., 1991).

Existing data indicate surgical outcomes for patients with LBP are inconsistent (Deyo, Cherkin, Loeser, Bigos, & Ciol, 1992; Turner et al., 1992). While some patients appear to benefit from lumbar surgery and realize an

improved quality of life, many do not. For example, Spengler and Freeman (1979) have reported successful surgical outcome rates between 46 – 90%. A review of 47 published studies by Turner et al. on the effectiveness of spinal fusion for LBP found that successful outcome ranged from 16 – 95% with an average of 68%. In addition, a large-scale study conducted by Franklin, Haug, Heyer, McKeefrey, and Picciano (1994) on successful fusion outcomes found that patients reported a worsening of LBP following surgery (67.7%) and no significant change in quality of life (58.8%). Moreover, this study found that 68% of patients undergoing spinal fusion remained disabled, with 23% requiring subsequent surgical intervention within two years after surgery.

It seems evident from the literature that large numbers of patients undergoing lumbar surgery for low back and/or leg pain do not improve, have been dissatisfied with the results, and/or continue to experience persistent LBP with sciatica (pain radiating into one or both buttocks and often descending down the back of the leg/s). In fact, a number of patients have reported a worsening of symptoms following their initial surgery. Eager for greater pain relief, many patients go on to have additional surgeries/procedures only to appreciate very little (if any) added relief, notwithstanding the many recent advances and reported improvements in lumbar surgical techniques (Casper, Campbell, & Barbier, 1990; Davis, 1994). Reportedly, between 20 and 40% of all patients undergoing lumbar surgery will continue to experience persistent or recurring intractable pain with varying degrees of physical dysfunction in spite of surgical

intervention. Such poor surgical outcomes following lumbar surgery have, in fact, become so widespread that a unique diagnosis has been established in order for clinicians to identify and characterize such patients. The clinical term used to describe patients meeting criteria for this condition is failed back surgery syndrome (FBSS; North, Kidd, Lee, & Piantodosi, 1994; Turner, Loeser, & Bell, 1995).

Although the exact etiology and precise mechanisms underlying FBSS remain unclear at this time, it has been generally agreed upon by most practitioners to be multifactorial in nature (Anderson & Israel, 2000). Currently, the most universally held view as to the causes of FBSS are believed to be (a) the formation of scar tissue or adhesions along the outside of the dura mater ("epidural fibrosis"), and/or (b) chronic inflammation occurring within the arachnoid layer of the meninges (known as "arachnoiditis"; Burton, 1978; Kawauchi, Sakou, & Yone, 1996). Following the initial injury to a bundle of nerve fibers (e.g., as the result of a disc herniation), local surgical repair and tissue regeneration can sometimes result in abnormal signal transmissions. This abnormal regeneration combined with the formation of such adhesions following lumbar surgery has been posited as a major culprit in complicating effective pain management in the FBSS patient (Laitt, Isherwood, & Jackson, 1996). This could potentially explain why repeated surgery for this condition is frequently so ineffective in relieving pain for these patients. Based on this hypothesis, the reason for the failure of numerous surgical interventions in the FBSS patient is

because of previous scar formation and abnormal tissue regeneration resulting from the initial surgery (Epstein et al., 1978). Subsequent resection of scar tissue typically engenders even more scar tissue and increased abnormal tissue regeneration (Haig, 1991; MacNab, 1978). It is for this very reason that clinicians and researchers alike have sought alternative treatment modalities that may provide more effective methods of pain relief for the FBSS patient.

One relatively new therapy that offers potential relief of intractable low back and leg pain is a form of neuromodulation known as spinal cord stimulation (SCS; Bell, Kidd, & North, 1997). SCS is a reversible, nonablative technique that has been in use for over 30 years for the management of a variety of chronic pain syndromes (Shealy, Mortimer, & Reswick, 1967). It involves the surgical implantation of electrically stimulating electrode(s) within the dorsal horn of the spine superior to damaged vertebrae(s) engendering painful stimuli. The leads are attached to a receiver or a pulse generator that delivers a low voltage electrical current to the spinal column near the spinal nerves corresponding to the patient's area(s) of pain. The exact neurophysiological mechanisms of action by which neuromodulation relieves pain is unclear, however, a number of hypotheses have been proposed. According to the "gate control" theory of pain, SCS is thought to activate the body's central inhibitory pain mechanisms influencing sympathetic efferent neurons (Krames, 1996). This theory suggests that it is possible to stop the pain signals or "close the gate" by activating certain nonnoxious nerve fibers in the dorsal horn of the spinal cord (A-beta fibers) that,

in turn, inhibits the transmission of pain signals via small nerve fibers (A-delta fibers and C-fibers; Burchiel et al., 1996; North, Ewend, Lawton, Kidd, & Piantadosi, 1991). SCS is thought to provide pain relief without interfering with normal sensation, normal muscular ability, or other bodily functions. Consequently, over the past two decades, many neurosurgeons have begun using SCS for a variety of chronic pain conditions including FBSS. In fact, FBSS is the single largest indication for SCS implantation in the United Sates today (Barolat & Sharan, 2000).

Individuals who receive SCS for pain management typically undergo a trial period of stimulation previous to receiving a full-system implantation. This is done to determine how well a patient responds to the stimulation and at what level(s) of the spinal column the stimulation provides maximal pain relief for the patient. The trial period typically lasts from 1-10 days to ensure that the patient achieves adequate pain relief throughout different times of the day and with different types of activities. If, at the end of the trial period, the stimulator is not providing sufficient pain relief, the system may be reprogrammed and the trial period extended to assess for satisfactory pain control. If the patient decides that the SCS unit is providing sufficient pain relief at the end of the trial period (usually considered to be at least 50% pain relief) and there are no complications, a full-system implantation can then be performed.

As stated above, SCS has become a fairly common end-stage treatment approach for the FBSS patient. Unfortunately, relatively few large scale studies

have been conducted to assess the efficacy of SCS in this population. Most of the studies that have been conducted have involved small sample sizes, short follow-up periods, and less-than-optimum outcome assessment measures. Of the outcome studies that do exist, the majority have reported success rates between 55 - 60%. Other studies have demonstrated highly variable and unpredictable success rates (De La Porte, & Siegfried, 1993; Fiume, Sherkat, Callovini, Parziale, & Gazzeri, 1995; Meglio, Cioni, & Rossi, 1989; North, Kidd, Zahurak, James, & Long, 1993; Urban & Nashold, Jr.,1978; Winkelmuller, 1981). Successful outcomes have generally been defined as at least a 50% reduction in pain (North, Campbell, et al., 1991; Tomlinson, McCabe, & Collett, 1997; Turner et al., 1995) with very little focus on other important outcome measurements such as quality of life, work status, and other important domains. A multidisciplinary approach to the assessment of treatment outcomes in SCS is essential in order to generate a comprehensive and accurate picture of a patient's status.

As is the case with many other surgical treatment modalities for LBP (e.g., discectomy, laminectomy, spinal fusion, etc.) there are a number of presurgical biopsychosocial variables (e.g., past medical history, compensation issues, psychological status, social support, etc.) that appear to be correlated with outcomes. Such variables may have predictive value when it comes to surgical outcomes of patients receiving SCS (Burchiel et al., 1995; DeBerard, Masters, Colledge, Schleusener, & Schlegal, 2001; Franklin et al., 1994; Frymoyer, 1992;

Frymoyer & Cats-Baril, 1987, 1991; Frymoyer et al., 1983; Uomoto, Turner, & Herron, 1988). Given the variable outcomes of SCS in FBSS patients, and due to the exorbitant medical costs associated with the treatment of chronic LBP and FBSS in general, further investigations are needed to identify patient variables that may maximize the therapeutic potential of SCS.

To date, previous studies have failed to adequately assess and document treatment outcomes in FBSS patients receiving SCS for the management of low back and/or leg pain as well as the presurgical, biopsychosocial variables that may potentially influence SCS outcome. In addition, multidimensional outcome measurements have not been optimally utilized in order to get a clear indication of exactly how "successful" this treatment mode is within the FBSS population. Pain relief, in and of itself, is not the only outcome measurement that must be considered when considering the appropriateness of implementing SCS in the control of chronic LBP.

The primary purpose of the current study is to collect surgical outcome measurements in a retrospective cohort of FBSS patients having undergone SCS for the management of low back and/or leg pain in order to ascertain the effectiveness of SCS within this group of patients. The secondary purpose of the study is to conduct an objective assessment of existing presurgical, biopsychosocial variables and evaluate the potential for such prognostic variables to successfully predict SCS outcome. Identification of such predictive

variables may allow for optimization of surgical outcomes through the systematic use of appropriate screening protocols and presurgical intervention strategies.

CHAPTER II

LITERATURE REVIEW

The purpose of this literature review was to critically examine the methodological approaches used in previous studies on SCS in patients with FBSS and analyze the correlations that have been found between presurgical, biopsychosocial variables, and surgical outcome measurements. Primary and secondary sources were identified by utilizing the Medline and PsychLit databases. The following key words and key word combinations were used to perform the literature search: (a) failed back surgery syndrome AND low back pain, (b) spinal cord stimulation AND low back pain, (c) spinal column stimulation AND low back pain, (d) percutaneous electrical nerve stimulation AND low back pain, (e) low back pain, (f) leg pain, (g) electrostimulation AND low back pain, (h) neuromodulation AND low back pain, (i) epidural fibrosis and spinal cord stimulation, (j) and spinal cord stimulaion, and (k) failed back surgery syndrome. Criteria for inclusion into the review were limited to FBSS patients having undergone SCS for low back and/or leg pain.

The primary objectives for this review were:

1. To describe the current state of knowledge in the area of SCS as applied to patients with FBSS along with average success rates that have been demonstrated;

2. To analyze the strengths and weaknesses of the research methodologies used in previous research studies;

3. To identify the potential factors generating the variable conclusions found within the literature review; and

4. To provide recommendations for improved methodological strategies in determining the effectiveness of SCS in patients with FBSS.

Several articles were identified that provided valuable information on outcome data for patients with FBSS having received SCS implantation. Other studies were also identified that, along with their own results, provided background information on the use of SCS in FBSS patients. Such information was very useful in determining the average effectiveness of this treatment within this population of patients. A number of these articles also provided details on predictive factors that have been observed over the years. A brief description of selected articles describing this data is provided below along with their reported findings. These articles were chosen because of their scientific rigor in establishing SCS outcome measurements and because their results exemplify the prevalent findings in this area. Articles involving SCS implantation in surgical populations other than FBSS were screened out.

The only major review identified to summarize the long-term risks and benefits of SCS for FBSS patients as well as information on the overall effectiveness of this treatment was conducted by Turner and colleagues in 1995. All of the studies in this review were case series and no randomized clinical trials were included. Across studies, the range of successful outcomes (defined as a patient using SCS stimulation with $\geq$ 50% pain reduction in back and /or legs at

follow-up) was 15 - 100%, with a mean of 59%. On average across nine studies, 23% of patients were taking opioid pain medications at the time of follow-up (range, 0 - 57%). On average across the few studies that reported work status, 29% of patients were working at follow-up (full-time, 22%; part-time, 7%). Across five studies, 17 - 100% (mean, 58%) of patients reported that they had experienced an improvement in their ability to perform activities. Successful outcomes were reported by 62% of patients on average at 1 year (14 studies), 64% of patients at 2 years (5 studies), 53% of patients at 5 years (3 studies), and 35% at 10 years (1 study). Because so few studies evaluated patients at systematic, yearly intervals, it could not be determined whether or not the effectiveness of the neurostimulators did in reality decrease over time. The articles contained in this review also failed to report to a significant degree patient demographic and clinical descriptive data.

Unfortunately, the majority of studies in this review also failed to separately report outcomes on critical aspects of pain perception and functioning (e.g., back and leg pain, ability to work, ability to engage in activities of daily living, and medication usage). Such data would be important to determine the practical validity and overall effectiveness of implementing SCS therapy in these patients. Moreover, 82% of the studies did not appear to have a planned study protocol and the source of follow-up data was unclear in 64% of studies. Also, no information on presurgical, biopsychosocial predictor variables was reported. In summary, serious methodological problems were present in the majority of

studies reviewed, potentially yielding biased results and, therefore, erroneous conclusions. Although some patients did experience an improvement in their condition, no definite conclusions could be determined regarding the efficacy of SCS in patients with FBSS relative to other treatment interventions, placebo treatments, or to no treatment.

North, Ewend, and colleagues (1991) published the results of a retrospective review of 50 consecutive patients with FBSS who underwent SCS implantation, with follow-up evaluations being performed by a disinterested third party interviewer at 2.2 years and 5.0 years postoperatively. In this study, "success" was defined by the combination of the following two criteria: at least 50% pain reduction and patient satisfaction with the treatment results. Mean estimated pain relief was 61% at 6 weeks, 59% at 6 months, 52% at 2 years, and 47% at 5 years after SCS implantation. Fifty-four percent of patients reported that SCS was more effective than previous operations and 28% described it as less effective. A total of 48% reported an overall decrease in pain resulting from stimulation and 12% reported an increase in pain. Ten out of 40 patients who reported being disabled preoperatively were able to return to work after stimulation implantation and were working at the time of follow-up (6 full-time and 4 part-time). Improvements in activities of daily living were recorded in most patients for most activities and loss of physical functioning was rare. In addition, most patients were able to reduce the amount of narcotic analgesic intake. Statistical analysis of patient characteristics as prognostic factors showed

significant advantages for female patients and for those with programmable multicontact implanted devices. However, no significant correlations were found between any of the outcome measures and the following independent variables: duration of follow-up, time elapsed since first operation, number of previous operations, outcomes of previous operations, and pain location (axial vs. radicular). The authors concluded that there remains a need for a closer inspection of selection criteria, a more critical analysis of treatment outcomes, and a need for prospective studies of SCS.

In 1995, Burchiel and colleagues conducted a prospective study consisting of 40 patients with pain chronic low back and/or leg pain of whom 85% were diagnosed with FBSS. In this study, 55% of patients reported at least a 50% reduction of pain after 3 months of stimulation. Overall, patient satisfaction with SCS was quite good with 78% of patients reporting that they considered the treatment beneficial or partially beneficial. Outcome assessment measures were based on a comparison of pretreatment and posttreatment pain appraisals obtained from patient responses on the Visual Analog Scale (VAS) and the patient's categorical description of pain at its most and least. Women tended to report greater pain relief as compared to men (mean for women, 56% vs. mean for men 35%). In addition, regression analysis of the data found several pretreatment variables (responses to a variety of psychological, pain, and functional measures) to be notable predictors of posttreatment pain status. Specifically, the Oswestry Disability Questionnaire (an assessment of function in

nine common areas of daily life), and the Beck Depression Inventory (a measure of depression) showed significant improvements after 3 months of SCS treatment. Significant improvements in global quality of life measurements were also demonstrated as measured by the Sickness Impact Profile (a measure of the effects of illness on 12 categories of daily living).

More recently, Allegri et al. (2004) conducted a prospective study involving 170 patients with (a) neuropathic pain syndrome, (b) vascular disease, or (c) FBSS who had received SCS implantation. A total of 89 men and 81 women were enrolled in this study (with an average age of 61.1 years and a range of 15 – 89 years). Out of these 170 patients, 17% (n = 29) had received a diagnosis of FBSS. These researchers assessed the success rates of SCS in their study population by measuring pain control, functional status, medication use, patient satisfaction ratings, and improvements in quality of life measurements. Overall, this study showed a success rate of just over 50% ("success" being defined as the percentage of patients that successfully completed the trial period and went on to receive a definitive implant) and an efficacy rate of approximately 70% (with "efficacy" being the percentage of patients that received a definitive implant and improved in at least more than half of the outcome parameters considered by the researchers and that still had the implant after one year).

The initial success rate for FBSS patients in this study was 70.4%, however, after one year the success rate fell to 55.5%. In addition, the pain and functional VAS scores were found to be significantly reduced in all three

subgroups. Moreover, the consumption of narcotic pain medications was also found to be significantly reduced. Overall patient satisfaction was found to be statistically significantly lower in all three subgroups; however, those with FBSS reported less satisfaction (50%) than the other two subgroups (75% in the neuropathic pain subgroup and 79% in the vascular pain subgroup). An improvement in quality of life was reported by 71% of those with neuropathic pain and 79% of those with vascular pain as compared to 57% of FBSS patients (Allegri et al., 2004).

Only one randomized controlled trial was identified. This study found a significant benefit ($P = 0.047$) in the proportion of patients with FBSS reporting 50% or more pain reduction with SCS (37.5%) as compared to patients undergoing lumbar reoperation (11.5%; North, Kidd, Farrokhi, & Piantadosi, 2005). The authors reported that SCS eliminated the need for subsequent spine surgery in those patients identified as reoperation candidates. In addition, they also observed that patients randomized to SCS achieved greater success than those who crossed over to SCS after an additional low back operation. While this appears to be very promising for FBSS patients, it is worth pointing out that this study was funded by Medtronic Incorporated, a major producer of spinal cord stimulation units around the world, and may not be completely free from bias. Nevertheless, additional studies such as this should be encouraged as they provide a more direct comparison of SCS and other treatments for FBSS.

The shortage of randomized controlled trials makes it difficult to determine the overall effectiveness of SCS for FBSS patients relative to other treatment alternatives. In addition, many studies failed to consistently report outcome measurements on dimensions of patient functioning that are crucial in determining the effectiveness of the treatment (e.g., ability to return to work, ability to perform activities of daily living, etc.). This review of the data has shown that average success rates of SCS in FBSS patients appear to fall between 40 - 60% (Barolat & Sharan, 2000), with "success" generally being defined as $\geq$ 50% reduction in pain.

As described above, only one major review of SCS within this population was identified in the current literature review. While some investigators report excellent patient outcomes with minimal complications, these results do not appear to reflect the majority of cases. This illustrates the highly unstable nature of the effectiveness of this procedure at the present time. Since its inception, SCS has been shown to likely be an effectual mode of therapy for a number of patients with certain types of pain syndromes. However, determining which patients will most likely receive the most benefit and the least complications from the procedure is not so clear. There are likely many reasons for this difficulty. For one, the way in which "successful outcome" is defined tends to be problematic. In order to evaluate the effectiveness of this procedure, more objective outcome criteria for success needs to be defined in the literature and utilized by practitioners. The current review of literature identified an assortment of outcome

criteria whereby success could be measured. Given that chronic pain affects individuals on a number of domains, such a multidimensional approach to outcome assessment is appropriate. What appears to be lacking, however, is an outcome assessment paradigm that is consistent across studies. Such a standard would facilitate cross-study comparisons of outcomes and assist researchers in making adjustments to study protocols and designs that would, hopefully, expedite improvements to the procedure and engender enhanced patient selection criteria.

The first step in accomplishing this would seem to be the utilization of standard outcome assessment instruments. By utilizing the same assessment instruments across studies, comparisons could be made despite differences found within the study populations. This study will employ an outcome assessment instrument consistent with this multidimensional approach to outcome assessment in order to more fully elucidate those factors that constitute a favorable outcome. A more detailed description of this instrument will be provided later.

Prognostic Variables Previously Identified

A description of the various prognostic factors that have been shown to have an impact on treatment outcomes will now be provided. As previously stated, a number of presurgical, biopsychosocial predictors of SCS treatment outcome in patients with FBSS have been identified. These variables are not all

equivalent in their predictive ability, however, and factors judged to be prognostic in one study have typically not maintained their significance across studies. Although conclusive evidence is generally lacking in the literature, some rather significant correlations have been reported that are deserving of a critical review. Appendix A provides a summary of these findings and a more thorough discussion of some of the more significant prognostic variables is offered below.

Gender

Gender has been demonstrated in some cases to be a moderately reliable predictor of successful outcome. In general, females tend to show greater improvements (i.e., greater reductions in pain) after SCS than do their male counterparts (Fiume et al., 1995; North, Campbell, et al., 1991; North, Ewend et al., 1991; North et al., 1993). Some have reported that certain factors such as psychological distress, employment, job satisfaction, higher physical activity, short duration of symptoms prior to implantation, and symptoms confined to the low back area with sudden onset are significant predictors for male patients (Arner, 1998; White, LeFort, & Amsel, 1997; Williams, Pruitt, & Doctor, 1998). Interestingly, these authors were unable to establish these same factors as being relevant predictors of outcome in female patients.

Age

Age also appears to be related to SCS treatment outcome; however, findings are not uniform in this respect. On average, older age has been found to

have a positive relationship with unsuccessful outcomes. That is, the older one is, the more likely that he/she will have a poor outcome after SCS implantation. As indicated in the above finding, North, Campbell, et al. (1991) determined by statistical analysis (through the use of univariate and multivariate logistic regression) that young, female patients had particularly good results from SCS as compared to males (North, Campbell, et al.). Burchiel et al. (1995) generated a prediction equation by a combination of three variables (via stepwise linear regression) that was found to successfully predict outcomes in 30 out of 34 cases (88%); age being one of the three variables (Burchiel et al.). Others have not found age to be a significant predictor of treatment outcome.

Previous Surgeries

Interestingly, some have reported that the number of previous surgeries is also predictive of SCS treatment outcomes in patients with FBSS. The term itself (FBSS) was constructed in order to accommodate the possibility that the surgery itself complicates the patient's condition pathologically, psychologically or both. Back surgery is just one treatment on the therapy continuum although as an invasive treatment it can create new pathology, which may be implicated in morbidity. An example of this potential for the number of previous surgeries to be predictive of outcome was demonstrated by North and colleagues in a 1993 article where they reported a significant correlation between the amount of pain relief produced by SCS and the number of prior surgeries. Specifically, greater pain relief was associated with fewer previous operations (North et al.). However,

2 years earlier, this same author was involved in an additional clinical trial and reported no significant associations between any of the outcome measures assessed and the number of previous operations or the outcome of these procedures (North, Ewend, et al., 1991).

Pain Topography

It has frequently been reported that SCS is more effective with certain types of pain topography. Indeed, one of the major purposes of the trial period is to ensure that the evoked parasthesias topographically map the patient's distribution of pain. Some authors have reported that the procedure is typically more useful for patients with neuropathic pain, especially unilateral extremity pain with a radicular pattern (nerve root pain or sciatica) in one leg as opposed to axial LBP (pain limited to the distribution of the lower spine) (Anderson & Israel, 2000; Fiume et al., 1995; Hassenbusch, Stanton-Hicks, & Covington, 1995; North, 1990). However, this finding has not been consistently reported. North et al. (1993) reported minimal associations between the presence of axial LBP and treatment outcome. In a review of 320 consecutive patients (153 with FBSS) treated with SCS at Johns Hopkins Hospital between 1972 and 1990, unilateral, radicular pain was not shown to be treated more effectively than axial pain by SCS (North et al.).

Type of Stimulator

One of the most challenging problems to overcome in SCS treatment is the proper placement of the electrode in the spinal column. In order to provide adequate paresthesia coverage, it is necessary to correctly place the electrode in a location where this coverage can be achieved without simultaneously stimulating the dorsal roots; the arousal of which can engender extreme discomfort and/or motor sensations in the patient (Anderson & Israel, 2000; North et al., 1993). It has been reported that certain types of electrodes are better able to provide this coverage than others, therefore creating more favorable outcomes for some patients. The advent of multielectrodes has reduced the incidence of repositioning and has improved long-term outcomes. Devices capable of providing dual stimulation have allowed more wide-spread parasthesias mapping to difficult bilateral cases and over a more complete area of the low back. North, Campbell, and colleagues found that patients with programmable, multicontact electrode implants fared much better than those with simple, single-channel bipolar electrodes (North, Campbell, et al., 1991). Moreover, it has been reported that these single-channel leads are more prone to migration errors (spontaneous malpositioning of the electrode after implantation), technical failures, and fatigue fracture of the conductors and/or insulation failure. They have also been shown to be less reliable when compared to the programmable, multichannel devices (North, 1990; North et al., 1993). In fact, in all but one of the studies reviewed reporting correlational data between treatment outcome and the type of

instrumentation used, the conclusion was made that these programmable multichannel are superior to the single-channel devices.

Secondary Gain and Substance Abuse

When SCS was first introduced for LBP in the late 1960's it quickly became a highly prevalent procedure (Shealy et al., 1967). At that time, the importance of patient selection criteria and the potential to predict SCS outcome by analyzing certain presurgical variables was not well understood. Since that time, however, the requirement that the patient be free of significant substance abuse problems and free of major secondary gain issues have been increasingly adopted as general selection criteria (North, 1990). The social, occupational, or interpersonal advantages a patient derives from his/her back pain symptoms constitute what is known as secondary gain. A patient's being relieved of his or her share of household chores by other family members would be an example of secondary gain. The importance of considering these issues when screening patients for SCS implantation has been stressed by many authors (Burton, 1991; Hoppenstein, 1975; Long, Erickson, Campbell, & North, 1981; Meglio et al., 1989; Spiegelmann & Friedman, 1991). Historically, patients with these types of problems have routinely been excluded from treatment as they have a strong tendency to interfere with long-term benefits that can be realized from the procedure. Some have been reconsidered for implantation after these issues have been resolved (North et al., 1993).

Patients with chronic LBP undergo many losses (e.g., financial, vocational, recreational, impaired relationships, etc.). However, they also frequently incur benefits that may be financial or involve emotional support from family, friends, and coworkers. Pain may also serve as a way to avoid unpleasant family or job situations. According to Fishbain, Rosomoff, & Cutler (1995), if the secondary gains outweigh the secondary losses, then there may be motivational factors impeding the recovery. These factors are frequently unconscious and are not usually the "cause" of the pain. Moreover, malingering may occur in those rare situations where the patient is consciously lying about their condition(s) for reasons of gain. Also, the situation may arise where the patient is consciously lying about symptoms, but without conscious benefit or gain; this represents a factitious disorder and is, again, thought to be quite rare.

Though it is often difficult to determine the existence of secondary gain issues in the LBP patient, one way to assess for their presence is to ascertain if there have been previous litigation issues related to any other injuries and to determine whether or not the patient has had previous involvement in the worker's compensation system.

Substance abuse problems are quite common in the FBSS patient and exist conjointly with other psychological and social problems (Aronoff, 1999). Patients may be dependent on narcotic analgesics and/or sedative hypnotics and the medications themselves become part of the pathological problem. There may be dependence, drug-seeking behavior, worsening of depression, and episodes

of withdrawal that are manifested as increased pain, anxiety, or sleep disturbance. There is frequently impairment of familial, social, or occupational roles directly related to misuse of narcotic analgesics or sedatives. This issue can severely affect the overall success rate of the FBSS patient receiving SCS and should be carefully evaluated. If present, this issue should ideally be resolved prior to implantation in order to achieve the best possible surgical outcome.

Duration of Symptoms

Certain physical manifestations such as long duration of pain symptoms prior to SCS implementation have been regarded as indicators of poor treatment outcome (Law, 1983, 1987). It has been pointed out that individuals with longer duration of pain typically do not appreciate a significant amount of relief and tend to have poor long-term follow-up outcome rates. Evidence supporting this suggestion is, however, lacking in the literature. In the study by North and colleagues (1993), it was reported that among those patients studied, no association between long duration of symptoms and SCS treatment outcomes was identified. In addition, North and colleagues reported an association between physical weakness on preoperative neurological examination and functional outcome measures upon follow-up; a finding that has not been frequently described in the literature (North et al.).

Employment

Work status has commonly been viewed both as a prognostic indicator as well as a measure of outcome in a number of studies (Anderson & Israel, 2000; Burchiel et al., 1995; De La Porte & Siegfried, 1983; Fiume et al., 1995; Law, 1992; LeDoux & Langford, 1993; North, Ewend, et al., 1991; North et al., 1993; Rainov, Heidecke, & Burkert, 1996; Turner et al., 1995). In a retrospective review by North, Ewend, et al. (1991), for example, the experience with repeated operations in 102 patients with persistent or recurrent pain after spinal surgery was undertaken to identify factors associated with a favorable outcome. These patients underwent repeated operations for lumbosacral decompression and/or stabilization (average 2.4 operations per patient). Among the significant results of this study was the finding that employment before surgery was associated with successful surgical outcome.

Education

Education level is another variable that has been professed by some to be predictive of SCS outcome in FBSS patients (Beals & Hickman, 1972; Long, Brown, & Engelberg, 1980; Long et al., 1981). It has been infrequently reported that individuals with higher education report greater pain relief and have better long-term outcome rates than those without such education. For example, Long et al. and Beals and Hickman have both reported education status to be significant modifiers of SCS outcome. No other relevant information on education

and SCS outcome was identified in this review of the literature, however, clearly indicating the need for additional research on this particular variable.

Patient Description of Pain

Patients undergoing SCS are frequently asked to describe their pain at the initial screening. To facilitate the verbalizations of this subjective experience, an abbreviated checklist of potential adjectives (including sensory, affective, and evaluative adjectives) describing the pain experience is often employed (e.g., McGill Pain Questionnaire). The total number of adjectives chosen from such a list and/or the individual items have frequently been employed in order to make predictions concerning treatment outcome. One study found the choice of the adjectives "pressing" and "terrifying" to be statistically significant predictors of outcome (North, Ewend, et al., 1991). Also, the total number of descriptors chosen has also been found to be predictive of SCS outcome. The more adjectives an individuals chooses, the more likely that he or she will have poor initial and long-term results following SCS implantation. Other such reports of patient pain relief that have proven to be predictive of SCS outcome are those designed to measure pain intensity (the Visual Analog Scale) and the effects of the patient's back condition on 12 categories of daily living (the Sickness Impact Profile). However, this has not been proven to be consistently effective in terms of outcome projection.

Personality Factors

A number of personality factors have also been regarded as reliable predictors of SCS treatment outcome. For example, it has been noted that patients with high "Hy" (hysteria) scores on the *Minnesota Multiphasic Personality Inventory, 2nd Edition* (MMPI-2; Butcher, Dahlstrom, Graham, Tellegen, & Kaemmer, 1989) have a tendency to be more suggestible and conforming. These patients may report improvements on self-report measures of pain relief and functional improvement but show contrasting scores on the more objective outcome assessment measures. These patients have frequently been shown to successfully pass the trial stimulation phase and go on to receive permanent implantation, only to report less-than-optimum outcomes on follow-up visits. Not surprisingly, this makes long term prediction difficult (McCreary, Turner, & Dawson, 1979; North, Kidd, Wimberly, & Edwin, 1996). According to some, the presence of a "Conversion V" profile on the MMPI-2 indicates a strong potential for psychological and personality factors to be playing a major role in the development and maintenance of an individual's pain condition, including those with a diagnosis of FBSS (Gentry, Shows, & Thomas, 1974). Positive findings on such psychological tests as the MMPI-2 may, on the other hand, be more reflective of the severity and chronicity of a particular organic disease processes (such as rheumatoid arthritis) rather than the amount of cognitive and/or psychological involvement at work (North et al.).

Depression

Also measured by the MMPI-2 as well as numerous other assessment questionnaires/instruments, depression has also been implicated as a negative prognostic factor. Elevated measures of depression, for example, may indicate increased cognitive and/or psychological involvement in their physical symptoms and, as a result, show a decreased response to spinal stimulation (Brandwin & Kewman, 1982). Interestingly, the difference between the "D" (depression) and "Ma" (mania) scores on the MMPI-2 have been shown to be predictive of long-term success rates of SCS patients with permanent implants (Burchiel et al., 1995; Olson, Bedder, Anderson, Burchiel, & Villanueva, 1995). Others have found similar results (Burchiel et al., 1995).

Summary of Literature Review Findings

As presented above, SCS appears to be an effective solution for those suffering from chronic low back and/or leg pain when implemented in the appropriate patients. While there seems to be a number of published studies of FBSS patients being successfully treated with SCS in the literature, the one systematic review on the subject (Turner et al., 1995) presented data that does not demonstrate efficacy for this procedure. There appears to be a general consensus among researchers that a number of presurgical, biopsychosocial variables exist that can have a major influence on FBSS outcomes. However, there remains a general lack of evidence firmly establishing the majority of these

variables as reliable indicators of SCS outcome in this population. As a result, the formation of definite conclusions based on this literature review is not possible at this time. There have been no studies published that have examined the relationships between such presurgical variables and multidimensional SCS outcome measures. With few exceptions, significant associations and/or correlations observed in one study have not consistently maintained their significance across investigations. It has been suggested that one explanation for the lack of such stable, time-independent predictors of SCS may be due to the fact that many patients do not display stable results over time. Alternatively, however, it may also be possible that the lack of enduring, positive results may be due to our present inadequacies in properly selecting the appropriate patients for SCS implantation.

As a technology, SCS has made many advances over the years and has become an accepted part of the overall pain management regimen for patients with intractable pain in whom other surgical interventions are not appropriate or have failed to provide acceptable relief. As yet, however, no predictors have been able to consistently identify patients most likely to benefit most from the procedure. Moreover, outcome data has not proven that SCS is a more effective treatment strategy than other chronic pain interventions. In conclusion, previous outcome data has not shown SCS to be a dependable treatment intervention for FBSS patients. This may be due, in large part, to the fact that clinicians are currently unable to reliably predict which patients will realize adequate degrees of

pain relief from the procedure. Research is needed to examine these presurgical variables more closely in order to identify those patients best suited for SCS. These answers will hopefully allow clinicians to more effectively treat this debilitating condition.

Purpose of Study

The current study consisted of a retrospective cohort sample of FBSS patients that had previously undergone SCS implantation for the management of low back and leg pain. This methodology has been successfully utilized in a recent study published by DeBerard and colleagues (2001) in assessing long-term outcomes and presurgical prognostic factors in a group of Utah workers undergoing posterolateral lumbar fusion. The purpose of the study was to collect surgical outcome measurements from these patients and conduct an objective assessment of presurgical, biopsychosocial variables in order to ascertain: (a) the therapeutic effectiveness of SCS in patients with FBSS, and (b) the potential of such prognostic variables to successfully predict surgical outcome in this group of patients. Outcome measurements were collected via telephone interviews and medical records were reviewed in order to code existing presurgical variables. Statistical analyses were used to establish patient outcome data and to identify prognostic variables.

The following is a summary of the specific aims for this study:

1. Creation of a presurgical coding instrument to facilitate the collection of relevant variables identified in the medical record review.

2. Completion of presurgical data collection and coding of patient variables through an objective and standardized medical record review.

3. Creation of a telephone outcome data collection instrument to facilitate the gathering of patient outcome measurements.

4. Creation a computer program (via Questionnaire Programming Language, or QPL) to facilitate the administration of the telephone outcome data collection instrument.

5. Completion of a telephone outcome survey.

6. Computation of multivariate statistical analyses of presurgical patient variables, patient outcomes, and prognostic factors.

Specific research objectives and questions for each of the above aims, along with the statistical procedures used in answering these questions, are provided below.

Study Objectives

This study will address the following research objectives and questions:

Objective #1: Based on the medical record review, describe the sample in terms of presurgical variables.

Objective #2: Based on the telephone outcome survey, describe the sample in terms of outcome measurements following SCS implantation.

Objective #3: Based on the statistical analyses of the data collected in the medical record review and the telephone outcome survey, describe any significant relationships (including predictive relationships) between presurgical patient variables and patient outcome measurements.

The following questions will be answered to evaluate Objective #1:

Question #1: What is the nature of the sample in terms of presurgical, biopsychosocial variables of interest? Descriptive statistics (i.e., frequency distributions, percentage breakdowns, etc.) will be performed in order to answer this question.

Question #2: What are the intercorrelations among presurgical predictor variables of interest?

The following questions will be answered to evaluate Objective #2:

Question #3: What is the percentage breakdown for patient satisfaction variables?

Question #4: What is the percentage breakdown of good, fair, and poor outcomes (i.e., based upon reduction of pain, ability to perform activities of daily living, return to work, and medication usage) for the sample?

Question #5: What are the intercorrelations among the outcome variables?

The following questions will be answered to evaluate Objective #3:

Question #6: What relationships exist between the presurgical variables of interest and patient outcome measurements?

Question #7: What presurgical variable(s), or combinations thereof, most strongly predict surgical outcome in this sample?

As mentioned earlier, because chronic pain affects individuals on a number of domains, a multidimensional approach to outcome assessment was needed. In an effort to critically examine patient outcomes in this study, an instrument designed to objectively analyze patient outcomes along with a script for the telephone interviewer was created. This instrument incorporates a number of standardized questionnaires that have been widely accepted as reliable and valid measures and, in fact, has been used in previous studies investigating lumbar surgery outcomes (DeBerard et al., 2001; Franklin et al., 1994). A list of the predictive variables to be assessed in this study and the instruments that will be used in evaluating patient outcomes is presented in Figure 1.

Due to the size of the study sample, it was necessary to limit the number of predictive variables used in the regression analyses to those determined likely to be the most robust predictors of outcome. Therefore, as can be seen in Figure 1, educational level, smoking status at time of surgery, perceived degree of pain severity, and depression were chosen as the primary prognostic variables to be included in the statistical analyses.

Chart Review Variables	Patient Outcome Variables
Demographic Variables	**Stauffer-Coventry Index**
Age at injury	Pain reduction
Socioeconomic status	Ability to work
Gender	Physical limitations
*Educational level	Medication usage
Ethnicity	
Marital status	**Roland & Morris Pain Disability Questionnaire**
Income	Measure of disability
	Dysfunction related to back pain
Medical/HealthVariables	
Diagnosis	
Physical exam data	**Short-Form Health Survey-36 (SF-36)**
Pain topography	Physical Functioning
Number of previous surgeries	Role/Physical
Number of levels stimulated	Bodily Pain
Type of electrode implanted	General Health
Surgical history	Vitality/Energy
Complications	Social Functioning
Duration of pain before surgery	Role/Emotional
	Mental Health Emotional Well-Being
Psychosocial Variables	
*Smoking status at time of surgery	
Substance abuse/Alcohol use	**McGill Present Pain Intensity (PPI)**
*Perceived degree of pain severity	Current pain intensity
Use of pain meds before surgery	
Disability status	
Secondary gain issues	
Legal involvement	
Employed at time of injury	
Personality factors	
*Depression/Anxiety	

* = Predictive variables to be included in regression analyses

Figure 1. Predictor and outcome variables.

Methods

Population and Sample

Potential participants were identified through one of the primary collaborator's electronic neurosurgery database of SCS patients (Dr. Kim Burchiel's Neurosurgery Clinic at Oregon Health Sciences University; OHSU). All adults identified in this database between the ages of 18 and 65 with complete electronic demographic data and the following characteristics were considered potential candidates for inclusion into the study:

1. Have a primary or secondary diagnosis of FBSS, radiculopathy, chronic low back/extremity pain, epidural fibrosis, or arachnoiditis.

2. Have received SCS implantation by Dr. Kim Burchiel between October of 1988 and June of 1999.

3. Be at least 2 years out from their SCS implantation at the time of follow-up.

Study Design

A retrospective cohort design was used for this study. This cohort included patients having previously received SCS implantation between 1988 and 1998 by Dr. Kim Burchiel at the Neurosurgery Clinic, OHSU. A retrospective chart review was conducted and relevant presurgical variables coded on an instrument designed for this purpose. The telephone follow-up survey was administered to the patients in order to assess and document important outcome measures. Descriptive statistical analyses were performed to characterize the

presurgical status and postsurgical outcomes of the study cohort and will be presented below. Finally, multiple correlational and linear regression analyses were conducted on the previously selected presurgical variables of interest and patient outcomes.

Data and Instrumentation

A medical record review was conducted on all study participants to ensure each met inclusion criteria for the study. This was felt to be necessary in order to capture any and all relevant presurgical, biopsychosocial variables deemed to be of potential prognostic value. This medical record review included both those patients agreeing to be contacted by telephone for follow-up outcome assessment as well as any and all who declined to participate. Moreover, this assisted in the capture and comparison of presurgical characteristics of both groups and helped rule out any significant sample response biases.

The study coordinator (this author) conducted the medical chart review that took place on the Utah State University (USU) campus. All collected information was kept strictly confidential and the data was stored in a locked cabinet in a room specifically designated for this purpose. Only the study coordinator and Dr. DeBerard had access to this room and to the data. A copy of the instrument utilized in collecting the patients' presurgical data from the medical chart review may be reviewed in Appendix B.

The medical chart review included the following:

1. An assessment of patient demographic data (e.g., age, gender,

SCS implantation date, address, phone number, etc.).

2. Medical history (e.g., date of pain onset, pain duration before SCS implantation, diagnoses, general health problems other than LBP, surgical history, etc.).

3. Compensation and legal status (e.g., currently receiving Worker's Compensation, applying for compensation, legal assistance involvement, etc.).

4. Psychological and socioeconomic information (e.g., ethnicity, smoking status, educational level, alcohol and/or illegal drug use, psychological evaluation data, etc.).

Assessment of Prognostic Variables

Although a number of prognostic variables were identified in the literature review, certain factors emerged as more consistent prognosticators of SCS outcome than others. While we collected data on numerous prognostic variables as a function of the medical chart review, it was imperative to limit the number of variables to include in our final set of statistical computations so that a well-developed prediction analysis could be performed. This is in keeping with the current conventional standard of approximately one predictor variable per 8 – 10 study participants (Kleinbaum, Kupper, & Muller, 1988). As the total number of subjects completing the outcome survey was 43, only four predictors could reliably be included in the regression model. The variables chosen for this model were: depression, pain severity, smoking status, and education level.

Outcome Assessment Measures

Individuals with chronic pain are affected in many different ways. Not only does the pain itself cause profound suffering, but individuals with LBP are often unable to participate in their normal daily activities. As a result, many patients cannot work and may experience financial difficulties as well. They may not be able to participate in social events and/or other recreational activities. Often times, this will cause the individual experiencing LBP to become depressed and dissatisfied with life. After repeated unsuccessful attempts at pain relief, the patient quickly become hopeless. Moreover, these feelings of depression and hopelessness can lead to a heightened experience of physical pain. Therefore, in order to adequately assess the effectiveness of SCS in these patients, it was necessary to adopt a multidimensional approach to outcome assessment. The following three general domains were be considered in assessing patient outcomes in this study:

1. General health status (e.g., general health status of the individual after receiving SCS implantation - both mental and physical, patient satisfaction with his or her back condition at the time of follow-up, etc.).

2. Disease specific outcomes (i.e., percentage of pain reduction experienced by the patient following SCS implantation, ability to perform activities of daily living without undue back and/or extremity pain, etc).

3. Surgical outcomes (i.e., appropriate lead placement providing adequate paresthesia coverage of the low back area, absence of major

complications, etc.).

By assessing all these domains it is hoped that a comprehensive evaluation of the treatment effectiveness can be established for the study population.

Outcome Survey Procedures

A letter explaining the study procedures/purposes and requesting their participation was sent to each potential study candidate by the primary collaborators (Valerie Anderson, Ph.D., and Kim Burchiel, M.D.). A copy of this letter may be found in Appendix C. This letter detailed the necessary and standard issues regarding informed consent. Interested individuals were asked to sign and return the included self-addressed, stamped postcard (Appendix D) indicating their desire to participate in the study. After the study coordinator received the postcard, a telephone call was made to the individual in order to administer the follow-up survey. A copy of the survey including the standardized script that was utilized is located in Appendix E. Before initiating the survey, the participant was reminded of his/her patient confidentiality and the right to withdraw their participation at any time during the interview was reiterated. The 20 – 30-minute survey was then conducted.

In an effort to maximize the study's participation rate (always considering and honoring their right to decline to participate), individuals not responding to the initial contact letter were sent one additional letter inviting them to participate in the study. Those study candidates not responding to this letter were then

given one reminder phone call to ascertain whether or not they had received the invitation letters. Finally, a verbal invitation to participate in the study was extended during this final follow-up phone call. The study coordinator conducted all of the follow-up surveys.

Outcome Survey Instrument

The outcome survey instrument used in this study was made up of four standardized questionnaires. The first questionnaire used was the Stauffer-Coventry Index. This instrument was selected because of its extensive use in assessing low back surgical outcomes (DeBerard et al., 2001; Franklin et al., 1994; Turner et al., 1992). This measure is designed for postsurgical outcome assessment and consists of four self-report questions regarding pain reduction, ability to work, physical limitations, and medication usage. Based on their responses to these multiple response items, patients are assigned to one of the following three clinical outcome groups: (a) Good: 76 - 100% relief of back and/or leg pain, return to normal work, minimal to no limitations in physical activities, occasional mild analgesic to no analgesics needed to control pain; (b) Fair: 26 - 75% relief of back and/or leg pain, return to lighter workload, moderate limitations in physical activities, regular use of nonnarcotic analgesics; and (c) Poor: 0 - 25% relief of back and/or leg pain, no return to work after surgery, severe limitations in physical activities, occasional to regular use of narcotic analgesics. This measure was used to describe patient outcomes (pain and functional measures) and also served as a dependent measure in statistical analyses.

Also, chosen was the Roland and Morris Pain Disability Questionnaire. This instrument is a 24-item self-report measure designed to assess dysfunction related to back pain and disability status at the time of follow-up. Participants were asked if they had ever received disability benefits for their back condition and, if not, if they intend on seeking disability benefits for their condition in the future. Reliability of this instrument (test-retest on the same day) was reported to be rather high (r = .91; Roland & Morris, 1983). Construct validity has also been shown to be quite sensitive to changes in acute LBP over time.

The Short-Form Health Survey-36 (SF-36) Version 2 was also included as a major assessment instrument. The SF-36 is a self-administered questionnaire that has been well validated in the social science and medical literature, and is being used extensively as a tool for assessing clinically relevant patient outcomes. The 36 questions in the SF-36 survey elicit information on eight different aspects of health that is combined into two summary scales called the Physical Component Summary (PCS) and the Mental Component Summary (MCS). The four subscales that comprise the PCS are: (a) physical functioning (PF): assesses limitations on normal physical activities, designed to estimate the severity of limitation; (b) role/physical (RP): assesses limitations on the individual's work function that are caused by physical health problems; (c) bodily pain (BP): assesses both the severity of pain and the extent to which it interferes with normal activities; and (d) general health (GH): assesses physical health status and has been documented to be a good predictor of health care

expenditures. The four subscales that comprise the MCS are: (a) vitality/energy (VT): assesses a subjective feeling of well-being including energy and fatigue; (b) social functioning (SF): assesses the quantity and quality of interactions with others, extending measurement beyond exclusively physical and mental health concepts; (c) role/emotional (RE): assesses limitations on the individual's work functions, but restricts the cause of the distinct from those caused by physical problems; and (d) mental health/emotional well-being (MH): assesses the four major mental health dimensions of anxiety, depression, loss of behavioral or emotional control, and psychological well-being.

Extensive psychometric testing has been conducted on the SF-36 Version 2 in the United States (Garratt, Ruta, Abdalla, Buckingham, & Russell, 1993; Jenkinson, Coulter, & Wright, 1993; McHorney & Ware, 1995), and in numerous other countries (Rampal, Martin, Marquis, Ware, & Bonfils, 1995; Sullivan, Karlsson, & Ware, 1995). The reliability and validity of the SF-36 have been well documented by the developers of the instrument. A comparison of a series of generic health status measures indicated that the SF-36 is not only psychometrically sound but is also more responsive to clinical improvement than the other instruments tested (Beaton, Bombardier, & Hogg-Johnson, 1994).

The McGill Present Pain Intensity (PPI) rating scale was also incorporated into the follow-up survey instrument as a measure of current pain intensity. The PPI is a well validated and reliable means whereby one may assess changes

with regard to perceived pain and has been used extensively throughout the chronic pain population (North et al., 1993).

CHAPTER III

RESULTS

The results of this study, along with their associated research questions (as delineated in Chapter III) are summarized below according to the following outline: (a) descriptive statistics (based on the medical record review) presenting the nature of the sample in terms of presurgical characteristics, (b) descriptive statistics and intercorrelations among presurgical predictor variables, (c) descriptive statistics of patient satisfaction rates and outcome assessment measurements based on the telephone outcome survey (to provide an appraisal of the sample as a function of status (i.e., physical mobility, return to work, medication usage, ability to perform ADLs, etc.), (d) intercorrelations among surgical outcome measurements, (e) correlations between presurgical variables and outcome measurements, and (f) prediction of outcomes via regression analysis.

Descriptive statistics were generated for the presurgical variables of interest and for the outcome measures. Multivariate analysis of variance (MANOVA) comparing follow-up survey respondents versus nonparticipants on these presurgical variables were also conducted in order to determine if the two groups (respondents vs. nonrespondents) differed in systematic ways. This was done to identify potential sampling biases that could undermine the internal and external validity of the study. A series of simultaneous-entry regressions were

also conducted in order to analyze the prognostic value of the presurgical variables of interest and are presented below.

Respondents Versus Nonrespondents Bias Check

Of the 61 patients identified as potential study candidates, 18 (29.5%) opted not to respond to the invitation to participate or decided not to be involved in the follow-up phone interview. Although a 70.5% response rate was obtained in this study, a MANOVA was performed in order to determine whether or not systematic differences were present in the responders (n = 43) and nonresponders (n = 18) in terms of presurgical characteristics.

The following presurgical variables were obtained from the medical chart review and were available for all patients and used in the ANOVA calculations: age at implant, gender, pain duration, number of prior back operations, pain severity before surgery, education level, and smoking status. Upon analyzing these statistics and assessing the differences between the two groups on these variables as well as considering the individual effect sizes, no significant differences were found between respondents and nonrespondents. Therefore, based on these data, the two groups appeared statistically equivalent. Please see Table 1 for more details.

Table 1

ANOVA of Presurgical Characteristics for Responders Versus Nonresponders Including Effect Sizes

Presurgical variables	Sum of squares		*df*	*F*	Sig.	Effect size
Age	Between groups	1225.929	2	4.034	.023	.004
	Within groups	8660.655	57			
	Total	9886.655	59			
Gender	Between groups	.200	2	.388	.680	.156
	Within groups	14.948	58			
	Total	15.148	60			
Pain duration	Between groups	243.147	1	.022	.882	.248
	Within groups	492266.800	45			
	Total	492509.900	46			
Number of prior Back operations	Between groups	.825	2	.390	.679	.080
	Within groups	56.032	53			
	Total	56.857	55			
Education level	Between groups	4.656	1	2.115	.153	.028
	Within groups	99.047	45			
	Total	103.702	46			
Pain severity prior to surgery	Between groups	.049	1	.504	.481	.120
	Within groups	4.419	45			
	Total	4.468	46			
Smoking status	Between groups	.003	1	.015	.904	.298
	Within groups	9.401	45			
	Total	9.404	46			

Descriptive Statistics of Presurgical Sample Characteristics

Our preliminary review of the electronic neurosurgery database detected 70 consecutive patients as potential study candidates. After a thorough review of each medical record, 63 of these 70 patients were found to meet all three inclusion criteria. According to the study protocol, an initial letter was sent to each of these individuals. Although we had a large number of first time responders to provide informed consent by way of returning the postcard included in the initial letter, it remained necessary to send out an additional letter to approximately 15 individuals. In addition, a reminder phone call was made to the remaining number of nonresponders. Ultimately, we received informed consents and were able to administer the follow-up telephone survey to a total of 43 willing participants.

After completing the telephone surveys, it came to our attention that two of our 43 participants had received cervical rather than lumbar SCS implantation and were, therefore, being treated for cervical rather than lumbar pain. These two participants were excluded from our data analyses. This changed the total number of eligible study participants from $n = 63$ to $n = 61$. As the number of patients to complete the follow-up telephone questionnaire was $n = 43$, we obtained our desired follow-up rate of 70% (43/61 = 70.49%). Thus, we based our follow-up rate on a total of 61 (instead of 63) participants; 43 of whom we

were able to administer and collect telephone survey data, in addition to data gleaned from a review of their medical charts.

Descriptive Statistics for Selected Presurgical Variables

The first research objective of this project was to characterize the sample in terms of presurgical demographic, compensation, litigation, health, surgical, and psychosocial variables. Two research questions were posed in order to satisfactorily meet this objective (#1: What is the nature of the sample in terms of presurgical, biopsychosocial variables of interest? #2: What are the intercorrelations among presurgical predictor variables of interest?).

The first question ("What is the nature of the sample in terms of presurgical, biopsychosocial variables of interest?") was answered through a calculation of descriptive statistics for each of the presurgical variables of interest. As shown in Table 2, the mean age at time of SCS surgery was 53.88 years. Seventy-two percent of the sample reported three or more prior low back operations with the vast majority (88.4%) describing their pain as "severe." Interestingly, 58.1% of the sample reported having undergone psychological evaluation prior to SCS implantation. Nearly 70% of patients reported regular narcotic usage for pain control prior to surgery. The average time interval between when the patient first began experiencing pain and surgery was 8.8 years (range = 1 - 40 years). The most common type of implantable pulse

Table 2

Descriptive Statistics for Selected Presurgical Variables (N = 43)

Variable	Percent	Mean	*SD*	Min	Max	Mode	Median
Age		53.88	11.95	30.00	87.00	49.00	51.00
Gender							
1 = Male	53.5						
2 = Female	46.5						
Marital Status							
1 = Married	67.4						
2 = Divorced	7.0						
3 = Single	25.3						
Workers Compensation Status							
1 = Yes	34.9						
2 = No	65.1						
Educational Level							
1 = Diploma/GED	37.2						
2 = Some College	30.2						
3 = Trade School/AA	4.7						
4 = College Degree	14.0						
5 = Advanced Degree	14.0						
Litigation Status							
1 = Yes	39.5						
2 = No	60.5						
Months Experiencing Pain Prior to Surgery(Does not include an outlier (*N*=1) of 480 months)		96.74	88.26	12	360	60	102
Weight in Pounds		172.79	37.84	90	245	160	178
Height in Inches		67.67	4.16	60	76	70	69

(table continues)

Variable	Percent	Mean	*SD*	Min	Max	Mode	Median
Clinical Depression at Time of Original SCS Implant							
1 = Yes	34.9						
2 = No	65.1						
Pain Level Prior to Surgery							
1 = Moderate	11.6						
2 = Severe	88.4						
Medication Usage Prior to Surgery							
1 = Occasional Non-Narcotics	7.0						
2 = Regular Non-Narcotics	18.6						
3 = Occasional Narcotics	4.7						
4 = Regular Narcotics	69.8						
Smoking Status at Time of Surgery							
1 = Smoker	27.9						
2 = Non-smoker	72.1						
Location of Most Recent Pain							
1 = Low Back and Single Leg	41.9						
2 = Low Back and Bilateral Leg	34.9						
3 = Single Leg Only	18.6						
4 = Bilateral Leg Only	4.7						
Trial Date		09/27/96		02/14/94	12/16/98		
Implant Date		10/02/96		02/16/94	12/23/94		
Time Interval Between Trial and Implant Date		8.8	9.9	2.0	79.0	7.0	7.0
Presurgical Diagnosis							
1 = Failed Back Surgery Syndrome	91.0						
2 = Chronic Pain Syndrome	100.0						

(table continues)

Variable	Percent	Mean	*SD*	Min	Max	Mode	Median
Prior Low Back Operations							
1=None	9.3						
2=One	7.5						
3=Two	10.0						
4=Three or more	72.5						
Complication Rate							
1=Positive	4.7						
2=Negative	95.3						
IPG Type							
1=Itrel 2	13.9						
2=Itrel 3	77.7						
3=Matrix Rec/Trans	9.3						
Total Number of Electronic Leads Implanted (100% Quad)							
1=One	79.1						
2=Two	18.6						
3=Three	2.3						
Psychological Evaluation Conducted Prior to Implantation							
1=No	41.9						
2=Yes	58.1						

generator (IPG) device implanted was the Itrel 3 (77.7%). Many of the patients in the sample reported at least some education with 67.4% admitting to receiving their diploma/GED or having attended at least some college.

Intercorrelations Among Presurgical Variables

The second research question used was, "What are the intercorrelations among presurgical predictor variables of interest?" In order to answer this question, a correlational matrix of the presurgical variables of interest was calculated. Only one statistically significant positive correlation stands out. This was between worker's compensation status and lawyer involvement as procured by the patient ($R = .706$, $p < .01$). This result would seem to make sense when considering that most individuals receiving worker's compensation would likely tend to seek out an attorney in order to assist them in this rather complicated legal process. The results of this correlational matrix are presented in Table 3.

Major Spinal Cord Stimulation

Outcome Measurements

The second study objective was to describe the sample in terms of outcome measurements following SCS implantation. This research objective was met by answering the three research questions regarding the outcome measurements that were obtained via the telephone survey. In order to assess the outcome measurements of the sample, the following two research questions

Table 3

Intercorrelations Between Presurgical Variables

Presurgical variables	Age	Worker's Compensation status	Depression	Pain severity	Smoking status	Education level
Worker's Compensation status	-.316					
	.030					
	42					
Depression	-.232	.079				
	.139	.616				
	42	43				
Pain severity	-.041	.113	-.191			
	.796	.470	.219			
	42	43	43			
Smoking status	-.185	-.020	.197	.226		
	.240	.898	.205	.146		
	42	43	43	43		
Education level	-.057	-.222	-.087	-.107	-.196	
	.722	.153	.579	.494	.208	
	42	43	43	43	43	
Lawyer involvement	-.258	.706[a]	.007	.145	-.185	.055
	.099	.000	.965	.354	.235	.726
	42	43	43	43	43	43

[a]Correlation is significant at the 0.01 level (2-tailed).

were asked: (a) "What is the percentage breakdown for patient satisfaction variables?" and (b) "What is the percentage breakdown of good, fair, and poor outcomes?" Descriptive statistics were generated in order to adequately analyze these data. The results of this analysis along with the survey results of the Stauffer-Coventry Index, which gives an overall indication of patient pain relief, are presented below.

As can be seen in Table 4, only 8 patients (18.6%; $n = 43$) admitted to achieving "good" results (76 – 100% improvement in pain relief) with SCS utilization. The remaining 35 participants were divided between "fair" and "poor" results (48.8%; $n = 43$; and 32.6%; $n = 14$, respectively) after SCS implementation. Because "successful" SCS treatment is generally defined as at least a 50% reduction in pain (North, Campbell, et al., 1991; Tomlinson et al., 1997; Turner et al., 1995), it is difficult to determine exactly what percentage of patients achieved satisfactory results based on these data as nearly 68% of patients fell in the "good" or "fair" categories. What is clear, however, is that a third of these patients reported a "poor" treatment outcome.

Another good indication of treatment outcome after SCS implantation that has been identified is the ability to return to work after surgery. Table 5 provides a breakdown of the sample in terms of postsurgical employment status. Because the average age of the study group was shown to be just over 53 years, it is not overly surprising to see 34.9% of the sample ($n = 43$) retired before surgery. The fact that these patients remained retired after surgery would not appear to be a

Table 4

Stauffer-Coventry Index: Since your SCS Surgery, How Much Pain Relief Have You Experienced in Your Back and Lower Extremities?

Outcome category	Frequency	Percentage
Good (76 - 100% improvement)	8	18.6
Fair (26 - 75% improvement)	21	48.8
Poor (0 – 25% improvement)	14	32.6

Table 5

Stauffer-Coventry Index: With Regard to Your Employment Status, Which of the Following Best Describes Your Status After SCS Surgery?

Outcome category[a]	Frequency	Percentage
Return to previous work status following surgery	10	35.7
Return to lighter work following surgery	4	14.3
No return to work following surgery	14	50.0

[a]Individuals (n = 15) who were retired before surgery not included.

relevant indication of the effects of their condition on employment status. However, it is relevant that nearly 10% of participants who were working before surgery necessitated returning to a lighter work status after implantation of their SCS device. It is also pertinent to see that nearly a third (32.6%) of working patients did not return to work at all following SCS surgery. Based on this data, its would appear that SCS implantation allowed 23.3% of the sample to return to their previous work status whereas 41.9% of the sample either could not return to work at all or had to take on a lighter work detail after their SCS surgery.

Somewhat related to the postsurgical employment status is overall patient mobility. Restriction of physical activity after SCS implantation has been found to be a major factor with regard to the patient's ability to return to work. Postsurgical employment status has been shown to be an important aspect of SCS treatment outcome assessment.

As Table 6 demonstrates, the sample was fairly evenly split between the three levels (minimum, moderate, severe) of physical restriction. This is an interesting finding as it seems to show an interesting relationship with the previous findings regarding "return to work" status.

In Table 7, we see that 67.4% of patients receiving SCS implantation reported using narcotic analgesics either occasionally or regularly. One would hope to see a decrease in the use of narcotic analgesics with the utilization of SCS for the treatment of pain. Based on our findings, it would appear that supplementary pain control was required for the majority of the sample.

Table 6

Stauffer-Coventry Index: With Regard to Your Physical Activities After Surgery, Which of the Following Best Describes Your Status After SCS Surgery?

Outcome category	Frequency	Percentage
Minimal or no restriction of physical activities	14	32.6
Moderate restrictions of physical activities	15	34.9
Severe restrictions of physical activities	14	32.6

Table 7

Stauffer-Coventry Index: With Regard to Your Use of Analgesic Medications After SCS Surgery, Which of the Following Best Describes Your Usage?

Outcome category	Frequency	Percentage
Occasional nonnarcotic analgesics or no analgesics	10	23.3
Regular use of nonnarcotic analgesics	4	9.3
Occasional or regular narcotic analgesics	29	67.4

Multidimensional measurement in determining treatment outcomes is essential in determining whether or not such a surgical procedure is considered a success. For this reason, several outcome measurements designed to assess

multiple patient domains regarding pain, functionality, work status, perception, and so forth were used. It is important to note, however, that it is expected for individuals to experience a certain amount of postsurgical pain. The data below would seem to suggest, however, that a large percentage of patients required supplemental pain relief in the form of narcotic analgesics.

Spinal Cord Stimulation Patient Satisfaction

Because pain is by and large a subjective experience (i.e., there are no truly objective measures of pain), measurements of treatment outcome also are subjective in nature. The next six tables will speak specifically to subjective patient satisfaction ratings.

As can be seen in Table 8, 44.2% of patients in the sample (n = 43) reported that their back or leg pain was worse than expected, while 46.5% reported their back and/or leg pain to be no worse than expected surgery. This measure was less than satisfactory as no option for "Back or leg pain is better than expected" was provided. However, it is somewhat enlightening to see that close to one half of patients failed to realize their expectations for treatment effectiveness. This is particularly interesting when considering there is often a significant positive correlation with treatment expectation and actual treatment outcome.

Overall quality of life measurements have also been shown to be a good indication of SCS treatment effectiveness. If the patient is experiencing a

Table 8

Patient Satisfaction Outcomes: Perception of Back or Leg Pain Improvement Following SCS Surgery

Outcome category	Frequency	Percentage
Back or leg pain is worse than expected	19	44.2
Back or leg pain is no worse than expected	20	46.5
Back or leg pain is no better than expected	4	9.3

reduction in pain, an increase in physical mobility, and is able to be involved in providing for him/herself, scores along this domain generally are expected to be rather elevated. The results obtained with regards to subjective quality of life ratings are provided below in Table 9.

As shown, 58% of study participants rated their quality of life as improved, while 23.3% reported no change in quality of life. Somewhat disturbing in light of the dictum, "Primum non nocere" (or "First, do no harm") is to see that nearly a fifth (18.7%) of the patients reported that their quality of life had worsened as the result of SCS surgery. While there is always some risk to any type of surgery, it appears that individuals with FBSS may be at a greater risk of realizing a poor treatment outcome, at least with SCS.

Table 9

Patient Satisfaction Outcomes: Quality of Life Improvement Resulting from SCS Surgery

Outcome category	Frequency	Percentage
A great improvement	12	27.7
A moderate improvement	7	16.3
A little improvement	6	14.0
No Change	10	23.3
A little worse	2	4.7
Moderately worse	3	7.0
Much worse	3	7.0

In terms of sheer patient satisfaction rates, Table 10 provides a good illustration of the statistical breakdown of satisfaction measurements as a result of SCS implantation. As demonstrated below, 51.2% of patients reported feeling "dissatisfied" with their current back condition, while only 37.2% reported that they were "satisfied." Five patients (11.6%) fell into the "neutral" category indicating they were neither satisfied nor dissatisfied with their current back condition. Table 10 provides a more detailed breakdown of the degrees satisfaction.

Table 10

Patient Satisfaction Outcomes: Satisfaction with Back Condition As It Is Right Now

Outcome category	Frequency	Percentage
Extremely dissatisfied	15	34.9
Very dissatisfied	5	11.6
Somewhat dissatisfied	2	4.7
Neutral	5	11.6
Somewhat satisfied	8	18.6
Very satisfied	3	7.0
Extremely satisfied	5	11.6

As previously discussed, an important aspect that needs to be taken into consideration is patient expectations. When trying to determine the effectiveness of a treatment such as SCS, the actual reported outcomes as compared to reported patient expectations can be enlightening. Additional expectation ratings for treatment outcome are presented in Table 11. Eleven patients (37.2%) reported their experience with SCS treatment to be "much better" or "somewhat better" than was expected, while 20 patients (46.5%) described their experience to be "somewhat worse" or "much worse" than expected. Five patients (11.6%)

Table 11

Overall, Is Your Back or Leg Pain Problem Better Than or Worse Than You Expected It To Be At This Point. That Is, Is It:

Outcome category	Frequency	Percentage
Much Better	11	25.6
Somewhat Better	5	11.6
What I Expected	2	4.7
Somewhat Worse	3	7.0
Much Worse	17	39.5
No Expectations	5	11.6

reported having no prior expectations and only 2 patients (4.7%) indicated that the treatment went as expected.

Another interesting finding was uncovered when patients were asked if, in retrospect, they would choose to have the SCS procedure again. Here, patients appeared to be fairly evenly split on the issue. As indicated in Table 12, 21 patients (48.8%) reported to the affirmative, while 18 (41.9%) reported they would not choose to have the procedure again. Only 4 patients (9.3%) reported being undecided on this issue. This is particularly interesting when viewed in light of the other findings with regard to patient satisfaction ratings.

Table 12

Patient Satisfaction Outcomes: In Retrospect, Would You Have SCS Surgery Again?

Outcome category	Frequency	Percentage
Yes	21	48.8
No	18	41.9
Undecided	4	9.3

Table 13 illustrates the current degree of pain reported by patients at the time of the telephone interview. As shown, only 1 patient (2.3%) reported "no pain" at the time of follow-up. Eight patients (18.6%) described their current pain intensity as "mild" and 3 patients (7.0%) reported "discomforting" pain levels. The remainder of the group (72.2%) rated their pain intensity as "distressing" (n = 19, 44.2%), "horrible" (n = 10, 23.3%), and "excruciating" (n = 2, 4.7%). This would seem to indicate that only about one fifth of the sample was achieving satisfactory pain relief at the time of follow-up.

Table 14 provides a breakdown of the various methods of pain control the study participants were currently using at the time of follow-up. Of the 43 patients having received SCS implantation for pain control, only 9 patients (20.9%) were continuing to exclusively utilize SCS for the treatment of their low back and leg pain. A total of 13 patients (30.2%) reported that their pain was being treated

Table 13

Present Pain Intensity Rating at Time of Follow-Up

Outcome category	Frequency	Percentage
No Pain	1	2.3
Mild	8	18.6
Discomforting	3	7.0
Distressing	19	44.2
Horrible	10	23.3
Excruciating	2	4.7

Table 14

Describe Your Current Primary Method of Pain Control

Outcome category	Frequency	Percentage
SCS	13	30.2
Morphine pump	14	32.6
Narcotic pain medicine	14	32.6
Nonnarcotic pain medicine	1	2.3
No current therapy	1	2.3

entirely by an intrathecal morphine pump (a device that delivers concentrated amounts of morphine into the intrathecal space at a set rate via a small catheter).

The same number of patients (n = 13, 30.2%) reported that they were treating their pain with oral narcotic analgesics and 1 patient (2.3%) reported using only nonnarcotic oral pain medications. Two patients stated that they were not currently undergoing any form of treatment for their LBP. The remainder of study participants (n = 5, 11.7%) indicated that they were using a combination of SCS and morphine pump (n = 2, 4.7%), SCS and oral narcotic analgesics (n = 2, 4.7%), or a combination of SCS, morphine pump, and oral narcotic analgesics (n = 1, 2.3%).

As some patients were using a combination of SCS and other therapies, it was thought to be important that we ask the study participants what they considered to be their primary method of pain control. The results are illustrated in Table 15. A total of 13 patients (30.2%) identified SCS as their primary method of pain control while 14 patients (32.6%) stated their primary method of pain control was morphine pump. The remaining participants indicated that they were primarily taking either oral narcotic analgesics (n = 14, 32.6%) or nonnarcotic analgesics (n = 1, 2.3%) for the relief of their low back and/or leg pain. Again, one patient reported not currently receiving any form of treatment whatsoever for pain control. Therefore, it would appear that a little less than a third of patients in this sample receiving SCS for their low back and/or leg pain were continuing to use the device as their primary method of pain control. In order to get a better

Table 15

Describe Your Current Methods of Pain Control at Follow-Up

Outcome category	Frequency	Percentage
SCS only	9	20.9
Morphine pump only	13	30.2
Oral narcotic pain medicines only	13	30.2
Oral nonnarcotic pain medicines only	1	2.3
Both SCS and morphine pump	2	4.7
Both SCS and oral narcotic pain medicines	2	4.7
SCS, morphine pump, oral narcotic pain medicines	1	2.3
No current treatment	2	4.7

understanding of the reasons why those individuals who decided to stop using their stimulator chose to do so, the open-ended question, "If you stopped using your SCS unit, what was/were the reason(s)?" was asked. Appendix F shows the various responses to this question.

Out of the 13 patients reporting the utilization of SCS as their primary method of pain control at the time of follow-up, Table 16 shows how often these patients reported using their stimulator on a daily basis in an attempt to relieve themselves of pain. As shown below, 8 patients (61.5%) indicated that, on a daily basis, they used their SCS "constantly" in order to relieve their pain. Three patients (23.1%) reported using their stimulator "frequently" and 2 patients

Table 16

On a Daily Basis, How Often Do You Use Your Spinal Stimulation Unit for Pain Control?

Outcome category	Frequency	Percentage
Constantly	8	61.5
Frequently	3	23.1
Occasionally	2	15.4

(15.4%) reported only "occasionally" utilizing their SCS on a daily basis. It is not uncommon for individuals undergoing SCS implantation to have their leads subsequently explanted due to inefficiency at relieving pain, certain side effects for which SCS was thought to be responsible, and so forth.

Table 17 illustrates that in our sample of 43 study participants, 11 patients (25.6%) reported having had their unit explanted (e.g., have their SCS unit and leads surgically removed). Based on these data, it appears that although only 32.6% of patients (see Table 13) reported using SCS as a primary or secondary method of pain control, a full 74% did not opt to have the stimulator leads explanted.

The percentage of study participants receiving SCS is contrasted against a comparable group of patients having undergone lumbar fusion for relief of back pain and a group of patients experiencing nonsurgical back pain in Table 18.

Table 17

Was Your SCS Unit (Including Leads) Explanted?

Outcome category	Frequency	Percentage
Yes	11	25.6
No	32	74.0

Table 18

Percent of SCS Patients and Comparative Samples Achieving a Roland-Morris Back Pain Disability Questionnaire Score Consistent with a Poor Outcome (Score of 14 or Greater)

Percent of SCS patients with postsurgical scores of 14 or greater	Percent of Roland-Morris Original Normative Group (nonsurgical back pain) with score of 14 or greater [a]	Percent of compensated lumbar fusion patients from Utah with postsurgical scores of 14 or greater[b]
79	15	43

[a]Norms based on Roland-Morris' original back pain standardization sample.
[b]Based upon DeBerard et al. (2001).

These groups are compared on their scores on the Roland-Morris Back Pain Disability Questionnaire. A score of 14 or greater on this measure has been shown to be consistent with a poor outcome. Seventy-nine percent of our study group received a score of 14 or greater, indicating that the vast majority of the

sample did not have a good outcome (as measured by the Roland-Morris Questionnaire). The percentage of patients having received lumbar fusion surgery to receive a score consistent with a poor outcome was 43%. These scores are compared to the percentage of the original normative group for this measurement who received a score of 14 or greater (15%).

As previously demonstrated, a good indication of surgical outcome is working status. Table 19 provides a percentage breakdown of study participants currently working at the time of follow-up. Twenty-nine patients (67.4%) reported they were not working at the time of the phone interview, while 14 patients (32.5%) described themselves as working. Working patients were then further broken down into categories of "full time" and "part time" working status (n = 9, 20.9% and n = 5, 11.6%, respectively).

Those individuals not currently working were asked to provide the reason for their nonworking status. In Table 20, data is presented to demonstrate that 18 out of the 29 patients (62.1%) not working at the time of follow-up indicated the reason for this nonworking status to be due to continuing disability as the result of their back injury/pain.

The remaining 11 participants (37.9%) reported that they were retired before surgery and remained so thereafter. This would appear to be a fairly high percentage of continuing disability after SCS surgery. In terms of successful outcome measurements, one would hope to provide for more individuals who are receiving SCS the opportunity to return to work should they so desire.

The number of study participants who reported having previously retained

Table 19

Proportion of SCS Patients Currently Working

Outcome category	Frequency	Percentage
No	29	67.4
Yes, full time	9	20.9
Yes, part time	5	11.6

Table 20

Reasons for Not Working

Outcome category	Frequency	Percentage
I am still disabled due to my back injury/pain	18	62.1
I am retired	11	37.9

legal counsel as a direct result of his/her back condition is provided in Table 21. Here, the group is represented bimodally with 20 patients (46.5%) reporting not to have previously retained an attorney for their back condition, and 23 patients (53.5%) having previously done so. As shown in Table 2, there is a significant positive correlation between lawyer involvement and worker's compensation status ($R = .706$, $p < .01$). It is possible that many patients opted to seek legal

Table 21

Have You Ever Retained an Attorney Because of Your Back Condition?

Outcome category	Frequency	Percentage
No	20	46.5
Yes	23	53.5

guidance to navigate through the complexities of worker's compensation law in order to secure the maximum amount of benefits to which he/she was entitled.

Table 22 provides a breakdown of smokers versus non-smokers at the time of follow-up. Thirty-four study participants (79.1%) classified themselves as "non-smokers" and 9 patients (20.9%) as "smokers." Unfortunately, due to lack of sufficient data a comparison of smoking status at time of surgery with smoking status at time of follow-up cannot be provided. Since our study sample consisted of patients with FBSS, there was a chance that a certain number would subsequently require further operation(s) for their back/leg pain after receiving SCS implantation.

Table 23 illustrates that the majority of patients (n = 27, 62.8%) did, in fact, receive subsequent surgical procedure(s) in an effort to control their pain. As shown in Table 23, 37.2% of patients reported receiving a morphine pump in order to assist with their pain control efforts. This would appear to indicate that the remaining 25.6% of those patients receiving additional back operations were

Table 22

Smoking Status at Follow-Up

Outcome category	Frequency	Percentage
Nonsmoker	34	79.1
Smoker	9	20.9

Table 23

Percent of Patients with Back Operation Since SCS Implant Surgery?

Outcome category	Frequency	Percentage
Yes	27	62.8
No	16	37.2

undergoing other procedure(s) other than to receive an implantable morphine delivery device.

In addition to the specific outcome measurements presented above, a more general indication of the overall physical and mental health status of these patients was also desired. In order to adequately assess these general domains of health and functioning, the SF-36 was utilized. Mean values for the eight subscales as well as the two summary scales were examined and compared with

existing norms provided by Ware and colleagues (Ware, Snow, & Kosinski, 2000; Ware & Sherbourne, 1992).

Table 24 provides a detailed breakdown of descriptive statistics for the SF-36 survey subscales for this sample as compared to the normative sample of patients with comorbid back pain/sciatica with hypertension. This normative sample was chosen due to its similarities with the current study sample as compared to the general sample normative data. As can be seen, the mean scores of all 8 subscales are considerably lower than the comparative sample. It is broken down into the mean scores with standard deviations received on each subscale along with a comparison to the SF-36 normative group mean for the co-morbid back pain/sciatica with hypertension. Effect sizes are also included.

Intercorrelations Among Surgical Outcome Measurements

In order to complete the second research objective, a third and final research question was asked: "What are in the intercorrelations among the outcome variables?" Our findings indicate that, as expected, the individual subscales of the SF-36 were highly correlated with each other on practically every instance. However, when the different subscales are calculated into two main composite scores (PCS and MCS), no correlation is achieved. This enables the SF-36 to discriminate between the overall physical and mental health status of the individual.

Table 24

Descriptive Statistics for SF-36 Version 2 Health Survey Subscales

SF-36 Version 2 subscale[a]	SCS patient mean (*SD*)	Normative comparison mean (*SD*)[b] for patients with back pain/sciatica with hypertension	SCS patient effect size
Physical functioning (10-items)	28.35 (12.23)	66.32 (28.60)	-1.33
Role physical (4-items)	28.83 (11.36)	46.71 (40.51)	-.44
Bodily pain (2-items)	33.65 (7.89)	59.34 (24.63)	-1.04
General health (5-items)	40.47 (12.79)	58.45 (21.63)	-0.83
Vitality (4-items)	36.99 (12.05)	52.29 (22.74)	-.67
Social functioning (2-items)	36.55 (16.33)	81.48 (24.38)	-1.84
Role emotional (3-items)	37.89 (14.74)	70.90 (38.97)	-.85
Mental health index (5-items)	41.95 (15.20)	74.93 (18.62)	-1.77

[a] Possible range of all scores was 0-100. Higher scores indicate better reported health. A subscale score of 50 represents the average score of a 1998 general US population survey (N = 5,038).
[b] Normative comparison sample consists of males and females, mean age 60.4 years, with comorbid back pain/sciatica with hypertension who participated in the 1988 US population survey (N = 481).

The only major finding with regards to statistically significant intercorrelations between the various outcome variables was shown to be between pain relief and every subscale on the SF-36. In addition, pain relief was significantly correlated with both the PCS and MCS, r (47) = -.501, p < .01; and r (47) = -.321, p < .05, respectively, composite scores of the SF-36. These

negative correlations would seem to support the notion that pain is highly influenced and motivated by both physical and mental health factors.

Correlations Between Presurgical Variables and Outcome Measurements

The final research objective in this study was to describe any significant relationships between presurgical variables and outcome measurements. In order to determine this two research questions were asked, The first question was, "What relationship exists between the presurgical variables of interest and patient outcome measurements?" To answer this question, Pearson correlation measurements were obtained for selected presurgical variables and outcome measurements. These results are presented in Table 25. Two presurgical variables were found to be correlated with the first outcome variable. Both pain severity and smoking status demonstrated statistical significance ($r = .518$, $r = .320$, respectively) with pain relief. In addition, prior number of low back operations approached but did not reach statistical significance with pain relief. Four presurgical variables were found to have significant correlations with physical limitations at the time of follow-up. These were worker's compensation status, smoking status, education level, and number of previous back operations. Of particular interest was the negative correlation found between education level and degree of physical limitation ($r = -.518$, $p < .05$) as measured by the Stauffer-Coventry Index. Both depression and pain severity prior to SCS implant were

Table 25

Pearson Correlations Among Selected Presurgical Variables with Selected Outcome Variables

	Outcome variables													
Pre-surgical variables	Pain relief	Physical limitation	PPI	DQTOT	SF36 PF	SF36 RP	SF36 BP	SF36 GH	SF36 VT	SF36 SF	SF36 RE	SF36 MH	SF36 PCS	SF36 MCS
Age	-.147	-.159	-.181	-.086	-.326*	.015	.147	-.037	.221	.125	.128	.123	-.210	.222
Compen-sation	-.076	.423*	.074	.073	.224	-.047	-.043	.206	-.044	-.020	.005	-.010	.154	-.050
Depression	.133	.000	.033	.316*	-.209	-.323*	-.099	-.213	-.325*	-.316*	-.437*	-.367*	-.091	-.407*
Pain severity	.518*	.058	.207	.311*	-.175	-.395*	-.170	-.227	-.241	-.196	-.057	-.142	-.306*	-.106
Smoking status	.320*	.386*	.141	.118	-.067	-.347*	-.069	-.001	-.176	-.076	.049	.013	-.215	.019
Education level	.040	-.518*	-.068	.103	-.067	.179	.019	-.058	-.091	-.182	-.051	-.094	.068	-.131
Attorney	-.014	.173	.286*	.175	.117	.042	-.223	.269*	.003	-.007	.080	.190	.021	.100
Prior LB operations	.239	.278*	.039	.015	-.200	-.102	-.075	-.059	-.175	-.099	-.082	-.113	-.122	-.092

*$p < .05$.

shown to have fairly strong positive correlations with the Roland-Morris composite disability score (DQTOT). Moreover, depression demonstrated a significant negative correlation with the MCS of the SF-36 (r = -.407, p < .05). Lastly, pain severity prior to SCS implantation was shown to be negatively correlated with the physical composite score of the SF-36 (r = -.306, p < .05).

Prediction of Outcomes

The second and final research question asked in order to meet the third study objective was, "What presurgical variable(s), or combinations thereof, most strongly predict surgical outcome in this sample?" In order to determine whether or not a significant prediction model could be formulated, regression analyses were conducted. As shown above in Table 25, several of the linear correlations were found to be significant; however, these were unable to maintain significance when combined with other variables in multiple regression analyses.

One model that appeared to have predictive potential with regards to SCS outcome measurements was a combination of three presurgical variables (worker's compensation status, smoking status, and education level) with degree of physical limitation ("With regard to your physical activities, since your SCS surgery what degree of physical limitation have you experienced?) at follow-up. This model found that this combination of presurgical variables could account for a good deal of the variance in physical limitation at the time of the follow-up phone interview (R = .682, p < .001). In this model, patients who smoked, had less education, and were involved in worker's compensation for their back

condition at the time of surgery were more likely to have a higher degree of physical limitation at follow-up. See Table 26 for more details.

Another multiple regression model that shows promise relates to the working status of patients at the time of follow-up. In this model, four of the presurgical variables accounted for a great deal of the variance in this outcome measure: worker's compensation status, smoking status, depression, and education level at the time of surgery. As can be seen in Table 27, this model also achieved statistical significance ($R = .475$, $p = .041$). It should be noted, however, that unlike the multiple regression model for physical limitation, the dependent variable in this model ("Are you currently working?") is also partly influenced by age at the time of surgery ($r = .333$, $p = .031$).

It is important to note here that none of the presurgical variables chosen for these calculations were intercorrelated. Therefore, they each added their own individual predictive power to the regression models.

Table 26

Multiple Regression Analysis: Worker's Compensation Status, Smoking Status, and Education Level with Physical Limitation at Follow-up

Model summary								
			ANOVA					
R	*R*-square	Adjusted *R*-square	Model	Sum of squares	*df*	Mean square	*F*	Sig.
.682	.465	.424	Regression	13.024	3	4.341	11.306	.000
			Residual	14.976	39	.384		
			Total	28.000	42			

Coefficients					
	Unstandardized coefficients		Standardized coefficients		
Variable	β	*SE*	β	*t*	Sig.
Smoking status	.573	.215	.318	2.660	.011
Educational level	-.211	.068	-.379	-3.086	.004
Worker's compensation	.585	.204	.346	2.872	.007

Table 27

Multiple Regression Analysis: Worker's Compensation Status, Smoking Status, Depression, and Education Level with Work Status at Follow-up

Model summary

R	*R*-square	Adjusted *R*-square
.475	.225	.144

ANOVA

Model	Sum of squares	*df*	Mean square	*F*	Sig.
Regression	4.639	4	1.160	2.761	.041
Residual	15.965	38	.420		
Total	20.605	42			

Coefficients

	Unstandardized coefficients		Standardized coefficients		
Variable	β	*SE*	β	*t*	Sig.
Depression	-.435	.212	-.299	-2.046	.048
Smoking status	.390	.229	.253	1.701	.097
Educational level	.150	.072	.313	2.090	.043
Worker's compensation	.385	.214	.265	1.802	.079

CHAPTER V

DISCUSSION

The primary purpose of the current study was to collect surgical outcome measurements in a retrospective cohort of FBSS patients receiving SCS surgery for the management of low back and/or leg pain in order to ascertain the effectiveness of SCS within this population. A secondary purpose was to conduct an objective assessment of existing presurgical, biopsychosocial variables in order to evaluate the potential for certain prognostic variables to successfully predict SCS outcome. It is possible that through the identification of such prognostic variables improved SCS outcomes may be realized through optimization of patient selection. It is thought that such improvements would be possible through the systematic use of appropriate screening protocols and presurgical intervention strategies based on the results of this and previous studies on SCS outcome. Results of the current study have helped to identify certain presurgical factors that are related to SCS surgery outcome measurements.

Summary of Findings

Presurgical Characteristics

Based on the medical record review and at the time of SCS implantation, this sample of FBSS patients were well represented by both genders and had been experiencing LBP for an average of nearly 9 years (median and mode both = 5 years). The average age of the study participants at the time of SCS surgery

was 54 years (*SD* = 12) and most of the study participants were married (67.4%). Twenty-eight percent of study participants had previously received some type of worker's compensation benefits at the time of surgery and nearly 40% of subjects had sought ought legal assistance for their back condition. The sample appeared to be fairly well educated with 63% reporting at least some college experience. In terms of smoking status, 28% of participants considered themselves to be smokers. Thirty-five percent of patients reported depressive symptomology at the time of SCS implantation; however, only 58% admitted to a psychological evaluation prior to surgery.

The majority of patients (88.4%) reported severe LBP prior to SCS surgery and most (70%) were being prescribed narcotic medications and reported using these on a regular basis for pain control. In addition, a large number of participants (72.5%) reported having undergone at least three previous back operations for their pain condition. Seventy-eight percent of these patients received the Itrel 3 SCS system by Medtronic Inc. (with the remaining patients receiving either the Itrel 2 system, 13.9%, or the Matrix system, 9.3%, and there were very few complications reported during surgical implantation (4.7%). Most patients required only one electronic lead (79.1%) for appropriate paresthesias; however, some did require two leads to be implanted (18.6%) in order to achieve appropriate pain coverage. Only 2.3% of study participants required three electronic leads.

Outcome Measurements

One of the most important aspects to consider is the patient's subjective experience of treatment success and perception of back and/or leg pain following SCS implantation. Sixty-seven percent of study participants reported achieving fair results (26 – 100% improvement as per the Stauffer-Coventry Index) with the remainder reporting poor improvement (0 – 25% improvement) of pain relief utilizing SCS. Although useful information, these data fail to allow for a direct comparison between a "successful outcome" of at least 50% improvement. However, only 44% of patients reported either a "great" or "moderate" improvement in their overall quality of life. Moreover, 58% of participants stated their pain was worse than they had expected it would be at the time of follow-up. Seventy-two percent of participants described their pain intensity as either "distressing" (n = 19), "horrible" (n = 10), or "excruciating" (n = 2). Overall, 37% of patients reported various degrees of satisfaction with their back/leg condition. It is interesting to note, however, that 42% of patients reported that, in retrospect, they would not choose to have the procedure again.

A total of 58% (n = 25) reported occasional or regular use of narcotic pain medications prior to surgery. In addition, 29 patients (67.4%) reported occasional or regular usage, which is nearly a 10% increase in the overall consumption of narcotic pain relievers compared to presurgical status. Only 20.9% of patients reported the use of SCS as their exclusive method of pain control with 30.2% reporting utilization of SCS as their primary method of pain control when used in

conjunction with other treatments (i.e., narcotic pain medication and/or implantable morphine pump).

Many of these patients reported being retired before undergoing their surgery (n = 15, 34.9%); however, 14 patients (32.6%) reported that they were unable to return to their previous work status after surgery. Another 9.3% reported that it was requisite that they return to a lighter work status when compared to that in which they were engaged prior to surgery. Therefore, of those patients who were working before undergoing SCS implantation, 50% (n = 14) were unable to return to work at all despite the utilization of SCS in the treatment of their pain and an additional 14% (n = 4) could not return to their presurgical work status. Only 32.5% of study participants reported that they were currently working (20.9% reporting full-time work and 11.6% reporting part-time status). Of those individuals reporting to be unemployed (n = 29, 67.4%), a total of 62.1% (n = 18) reported the reasons for their unemployment to be continued disability as a direct result of their painful back/leg condition.

It has been pointed out by Long et al. (1981) that a middle-aged worker who has undergone multiple lumbar surgeries, suffer from arachnoiditis, and who has been unemployed for over two years as a direct result of physical disability is unlikely to return to any job for which he is qualified even with good pain relief. Therefore, these data need to be viewed in this light when trying to make a determination as to the effect of SCS treatment on work status.

Overall physical mobility (or lack thereof) is another critical SCS outcome measurement. In this sample, it appears that patients were fairly evenly divided between "minimum" restriction of physical activity (n = 14, 32.6%), "moderate" restriction (n = 15, 34.9%) and "severe" restriction (n = 14, 32.6%). Moreover, the Roland-Morris Back Pain Questionnaire portion of the phone interview showed that 79% of study participants' scores were consistent with that of a poor surgical outcome. This is of particular interest when viewed in light of the percentage of poor outcome (43%) in a similar group of back/leg pain patients who received lumbar fusion surgery (see Table 17).

Of the original 43 patients receiving SCS, only 14 (32.6%) were continuing to utilize their SCS unit for pain relief. Moreover, only 9 of these patients reported using their SCS unit exclusively, while the other 5 reported they were supplementing their SCS with other methods of pain relief. A total of 13 patients, however, reported that SCS was their primary method of pain control although this only constituted 30.2% of study participants. Overall, it would seem the effectiveness of SCS in reducing back/leg pain in this sample was not sufficient for the majority of patients. In fact, 62.8% (n = 27) of study participants reported the need for subsequent surgical procedure(s) in an attempt to realize adequate pain relief.

A final point to consider with regards to successful SCS outcome is percentage of unit/lead(s) explanted. A wide range of statistics has been found when reviewing the reported percentage of SCS units and/or leads that have been explanted in FBSS patients. Explant rates from 1% (Winer, 2000) to 47%

(Alo, Redko, & Charnov, 2002) and even higher have been reported. The current study found an explant rate of 25.6% (n = 11), a percentage that falls within the range of explant rates as reported in the literature. Although this would seem to indicate that nearly three fourths of patients retained their IPG device and/or leads, it is important to recall that only 32.6% (n = 14) of study participants admitted to using their stimulator at the time of follow-up and that, instead, 60.4% were using either oral narcotic analgesics and/or morphine pump for their pain control.

External Validity

As indicated in Table 1, an analysis of group statistics and assessment of mean differences between responders and nonresponders on selected presurgical variables showed no significant differences between these two groups (Wilks' Lambda = .949, p = .963). An attempt has been made in designing this study to ensure a homogenous group of patients (FBSS patients) who have received the same treatment (SCS) for the treatment of back/leg pain. In the sense that this study was devised to investigated a group of patients in "the real world" setting (i.e., not in a laboratory setting) it can be said to have achieved a high degree of external validity by its very design. In order to further determine its external validity, it is necessary to analyze to what extent these results typify those of other such studies as reported in the literature.

In order to determine the degree of external validity, the articles identified in the literature review section were revisited in order to compare their findings

with those of the current study. Unfortunately, the articles reported surprisingly few patient demographic and clinical descriptive data. Therefore, a number of the variables for which data were collected in the current study were not consistently reported in previous literature. As a result, a direct comparison of presurgical characteristics is difficult. However, an attempt has been made to provide such a comparison below.

Comparison of Study Sample to Previous Studies

Presurgical Status

In order to determine whether or not the current study group was similar in age to those in the literature review, the mean age across these studies was averaged and was shown to be 49.5 years of age (range, 20 – 84 years). In comparison, the mean age of our sample was found to be 53.88 (range, 30 – 87 years); thus, it would appear that the sample of FBSS patients in this study was fairly representative of other studies as reported in the literature. In addition, close to 54% of participants in the current study were male as compared to an average of approximately 58% in previous studies.

Unfortunately, compensation status was not a variable for which the majority of previous researchers chose to provide data. In fact, none of the 19 studies reviewed designated compensation status and only one of the studies in the literature synthesis by Turner et al. (1995) reported data related to this variable. In the review by Turner et al., 86% of study patients were receiving worker's compensation at the time of SCS implantation. In the current study,

34.9% of participants were receiving worker's compensation. This is one aspect that the current study suggests may be important with regards to SCS outcome measurements, especially with that of degree of physical limitation because this study found a positive correlation between these two variables.

Presurgical psychological screening is frequently mentioned in the literature as well as the need for follow-up psychological assessment. In fact, in 33% of the studies identified in the review by Turner et al. (1995) psychological assessment was stated to be a systematic component of patient selection. However, in reviewing the data reported in the literature, specific data regarding percentage of patients with clinical depression prior to surgery are not widely available. For example, in the article by North et al. (1996), patients receiving permanent implants after a successful trial period had elevated scores on the Depression scale ("D" scale) of the MMPI. Unfortunately, basic results in terms of percentage of depressed patients were not provided. Based on the data provided, it is clear that a significant number of study participants received high "D" scale scores. What is unclear is the extent to which depression influenced SCS outcome in this group of patients based on the data provided.

In this sample of FBSS patients, it was found that 35% reported being clinically depressed at the time of implantation. While depression may very well be a common response to chronic pain, it would be helpful to illuminate the impact that such depression can have on surgical outcome in this group of patients. It would also be helpful to determine to what extent presurgical treatment of depression can improve upon SCS outcome measurements.

In addition, by utilizing the McGill Pain Questionnaire, the study by North et al. (1993) found approximately 24% of patients reporting "distressing" presurgical pain, 27% reporting "horrible" pain, and 26% reporting excruciating pain prior to surgery. By comparison, the following results were obtained in the current study with regards to the McGill Pain Questionnaire: "distressing" = 44.2%, "horrible" = 23.3%, and "excruciating" = 4.7%. While differently distributed, one can see that over 70% of all patients in both studies reported the top three adjectives from the McGill Pain Questionnaire with regards to presurgical pain intensity.

When patients in the current study were asked to rate their pain severity before receiving the neuromodulation device, 88.4% of patients reported their pain to be "severe" and 11.6% to be "moderate." Unfortunately, a direct comparison of VAS scores was not possible. However, one can see that 100% of the current study participants fell in the upper two thirds (mild, moderate, severe) of the pain severity category.

Only one article of those reviewed provided data with regards to education level (Burchiel et al., 1995). It was shown that 90% of study participants had > 12 years of education compared to 63% of those in the current study who had the same amount of reported education. This is an important finding because education level was another factor in the regression model herein provided. Thirty-seven percent of participants in the current study reported having received either a diploma or GED but went no further with their education. It may be that

higher education has an affect on perception of pain intensity, ability to better cope with low back and/or leg pain or some other as yet undetected influence.

A review of the 19 studies on FBSS and SCS and the literature synthesis provided by Turner et al. (1995) demonstrate the current study group to be similar with regards to the number of prior operations. As reported in these articles, patients underwent an average of 3.5 surgeries (1 – 8) previous to receiving SCS treatment. In the current study, it was found that 72.5% of participants in the current study had previously underwent three or more surgical procedures prior to SCS implantation and, on average, reported having undergone 2.4 previous operations. Therefore, this sample had a better chance for a good outcome than those presented in the literature as, typically, the more surgeries one has the poorer chances for a successful outcome.

In terms of pain duration prior to SCS implantation, the current study found that, on average, patients reported experiencing pain for 105.7 months (range: 12 – 480 months). By comparison, previous studies demonstrate that on average, patients experienced pain for approximately 76.7 months (range: 1 – 480 months).

Patient Outcomes

A major problem encountered while attempting to compare patient outcomes in this study sample with those of previous studies is that most studies did not report outcomes for a number of important dimensions of pain and functional mobility (e.g., work status, degree of physical limitation, medication

usage). The current study found such dimensions to be quite important in terms of making decisions regarding SCS.

For example, return to work status is an important outcome measurement according to some authors (Sweet & Wepsic, 1975; Young, 1978). Currently there is no standard definition of what constitutes "success" with regard to this particular outcome. On average across previous studies, 29% of participants were working (full-time, 22%; part-time, 7%) as compared to 32.5% (n = 14) of patients reporting to be working in the current sample (full-time, 20.9%, n = 9; part-time, 11.6%, n = 5).

Continued use of potent narcotic medications after SCS implantation makes it difficult to tease out the effects of medication on pain relief from the effects neuromodulation on pain relief. In terms of medication usage, approximately 23% of patients in prior studies reported to be taking narcotic analgesics at follow-up. By comparison, 67.4% (n = 29) of the current study participants reported utilizing narcotic analgesics for pain control at follow-up. In fact, 32.6% (n = 14) of patients reported narcotic analgesics as their primary method of pain control at follow-up. Clearly, this sample of patients appeared to need supplemental pain relief in addition to that provided by neuromodulation. In fact, only one study was found that reported the number of patients who said at follow-up that if they could choose again, they would still choose to undergo SCS implantation (53%). In the current study, 48.8% (n = 21) of participants reported they would choose such a course.

In the few studies reporting degree of physical limitation, an average of 58% of patients reported to have experienced an improvement of their ability to perform activities. In the current study, 32.6% (n = 14) of participants reported to have minimal or no restriction of physical activity after their SCS implantation. The remainder of patients reported either a moderate restriction on their activity level (34.9%, n = 15) or severe restrictions (32.6%, n = 14).

Across the studies reporting the number of patients receiving ≥ 50% pain relief as derived from SCS, an average of approximately 59% appeared to have achieved this. Although a direct comparison of this is not feasible, the current study found that only 8 patients (18.6%, n = 43) admitted to achieving "good" results (76 – 100% improvement in pain relief). The remaining 35 participants were divided between "fair" and "poor" results (48.8%, n = 43; and 32.6%, n = 14; respectively) after SCS implementation.

Correlation of Presurgical Variables and Outcomes

Several important points stand out in terms of the significant correlations found in other studies with regard to successful SCS outcome. First, it appears that in some studies, outcomes were not found to be correlated with age, gender, number of previous operations, or duration of pain (Fiume et al., 1995; Kumar, Nath, & Wyatt, 1991; North, Campbell, et al., 1991). In the current study, the number of previous operations was positively correlated with the degree of physical limitation as reported by patients. Similarly, North et al. (1993) reported

that individuals with fewer prior back operations were more likely to achieve a successful outcome with SCS implantation. While age was not found to be a significant predictor of outcome in this sample of patients, one author reported mixed findings in this regard (Devulder, Laat, Bastelaere, & Rolly, 1997).

In addition, one author reported age and depression to contribute negatively to reported pain levels at the time of follow-up (Burchiel et al., 1995). Specifically, younger and less depressed patients reported to have better experiences with pain relief with SCS treatment than older more depressed patients.

While gender was not found to be significantly correlated with patient outcomes in the current study, some authors have found females to have greater successes with SCS as compared to their male counterparts (Burchiel et al., 1995; Fiume et al., 1995; North, Ewend, et al., 1991). One author, however, reported to have found the opposite to be the case (Simpson, 1991).

Higher presurgical pain ratings in the current sample were found to be positively correlated with greater reports of pain relief at follow-up. This finding has been reported elsewhere in the literature as well (Burchiel et al., 1995). One explanation for this could be that those with greater pain have more room for improvement. Another explanation might be that SCS seems to be more effective for those with more intense pain ratings. Due to the high positive correlation found in this study between higher presurgical pain ratings with greater reports of pain relief at follow-up it seems clear that additional research on these variables should be conducted.

Lastly, one author reported to have found no correlation between any independent variables with follow-up work status (North et al., 1993). This included both age and presurgical work status as well. The current study found that age was negatively correlated with work status at the time of follow-up. Specifically, the older the patient the more likely he/she was not working at the time of follow-up.

The main correlational findings in the current study suggest that individuals who smoked, had less education, and was involved in worker's compensation for their back condition at the time of surgery were more likely to have a higher degree of physical limitation at follow-up ($R = .682$, $p < .001$). In addition, worker's compensation status, smoking status, depression, and education level at the time of surgery appeared to account for some of the variance ($R = .475$, $p = .041$) in work status at the time of follow-up.

Implications

Taken together, these data would seem to indicate that there is currently insufficient evidence that SCS improves functional disability, work status, or medication usage in this sample of FBSS patients. There is some evidence to suggest that the use of neurostimulation may help to reduce low back and/or leg pain in some patients, however, when considering the number of patients being supplemented with narcotic pain relievers and/or receiving intrathecal morphine delivery it becomes difficult to ascertain the source of the majority of pain relief. Also, a large number of patients reported continuing disability status and inability

to work despite SCS treatment. This suggests that there remains more to be desired with regards to SCS outcome measurements other than patient reports of pain reduction. Multidimensional outcome measurements such as those included in the current study seem to be more suited to determining the degree of "success" an individual has with neurostimulation.

Over the years, SCS has become a fairly common end-stage treatment approach for the patient with FBSS. Efforts have been made to make better presurgical decisions regarding which patients are best suited for SCS and which will achieve desired outcomes. One thing that seems to be clear from the current research is that overall percentage of pain reduction does not necessarily constitute treatment success. Measurements across a range of domains (i.e., physical limitation, work status, satisfaction rates, and continued utilization of SCS unit) seemingly provide a more accurate depiction of how successful this treatment is in this population.

Relevant to determining SCS outcome in this population is concomitant pain relieving efforts such as medication management and/or utilization of an implantable morphine administration unit. As discussed earlier, only 20.9% (n = 9) were continuing to solely use SCS for pain management whereas 60.4% (n = 26) of study participants were utilizing narcotic pain medications or morphine pump. The remaining patients (n = 8) were either using a combination of SCS and medications and/or morphine pump or receiving no treatment. Typically, patients receiving SCS have exhausted other avenues for pain management. This is unfortunate because these data show only 37.2% of study participants

reporting satisfaction with SCS for the treatment of their low back and/or leg pain. Overall, therefore, the data obtained from this retrospective study call into question long-term efficacy of SCS for these patients with FBSS.

A major finding in the current study was the large percentage of patients using narcotic pain medications both before and, perhaps more importantly, after receiving SCS. The question arises as to why so many patients were utilizing such potent medications and why SCS did so little to reduce the frequency of narcotic analgesic usage in this sample. It is possible that narcotic analgesics are the best treatment for the type of severe pain experienced by these patients. Another possible explanation could be that these patients had become addicted to these pain relieving medications. Unfortunately, these data do not supply ample information to make a determination as to the answer to this question; however, it does seem to show a preference, for whatever reason, for opioid pain medications among this sample of FBSS patients. Is there a qualitative difference between the type of pain FBSS patients experience and that experienced by chronic pain patients with different diagnoses? Are these patients more prone to narcotic addiction for some reason? The findings of the current study would seem to indicate that additional research on the usage of narcotic pain medications in this population is warranted.

The chief concern for studies seeking for causes and effects is that an observed effect may be due to a factor or factors other than the one of primary interest. Several study designs incorporate comparison groups to reduce the chance of drawing false conclusions because of this type of problem. The study

design capable of providing the most rigorous defense against this is the randomized control trial (RCT), in which subjects are allocated at random to a group to be exposed to the factor being studied (cases) or to a control group. Unfortunately, very few RCTs were identified in the literature.

A prospective assessment of pertinent biopsychsocial variables in two or more randomized treatment groups would be ideal for more accurately determining the effectiveness of SCS in FBSS patients. Ideally, it would be interesting to see the effectiveness of SCS in this population when compared to intrathecal morphine administration, oral narcotic medications, and other approaches to pain control. By so doing, it would be possible to determine whether or not SCS is a better alternative than these other approaches.

Intrathecal morphine delivery is typically considered a second line treatment approach for LBP in this population, while SCS is considered the first line treatment. Because a large percentage of the FBSS patients in this study went on to receive intrathecal morphine delivery after undergoing SCS surgery, it would seem to be of particular clinical relevance to make a direct comparison of the effectiveness of these two approaches within this population of pain patients. It may be that intrathecal morphine delivery has certain advantages over SCS for certain types of FBSS patients and should be considered a first line treatment approach for such patients.

The current study findings also indicate that it may be possible to improve patient outcomes by providing presurgical interventions for certain patients. For example, patients who smoked at the time of surgery showed a tendency toward

greater physical disability ($r = .386$, $p < .05$) at the time of follow-up. By providing a smoking cessation intervention to such patients in the presurgical environment one might expect to see a decrease in the degree of physical limitation at follow-up. Again, RCTs could provide researchers with the ability to conduct such an intervention and evaluate any subsequent effects it may have on the overall disability status of the FBSS patient.

In addition, depression was identified as being positively correlated with the total disability score (DQTOT; $r = .316$, $p < .05$) at follow-up. Depression was also negatively correlated with five of the eight SF-36 subscales (see Table 25). By screening patients in the presurgical setting for depressive symptomology and providing appropriate clinical intervention it may be possible to improve patient outcomes on this measure. RCTs would provide optimum methodology whereby to evaluate the effectives of such an intervention.

Other potential subjects of investigation might include the effects of regular activity and/or strength training (suitable for patients with FBSS) on reported measurements of pain control, disability status, and other outcome measurements at the time of follow-up. Moreover, data obtained regarding improvements in quality of life measurements and patient expectations of treatment effectiveness indicate that it may be possible to enhance patient outcomes by providing appropriate patient education regarding realistic SCS outcomes.

Limitations

Several presurgical variables were identified in this sample of FBSS patients that correlate with SCS outcome. In addition, a regression model was presented that seems to suggest a potential for outcome prediction based on worker's compensation status, smoking status, and education level with degree of physical limitation. It was also pointed out that, in addition to pain relief, functional status (especially in relation to work status) also seems to characterize overall successful outcome rates in this group of patients. Nevertheless, a major limitation of the current study is its retrospective cohort design and correlational nature. A prospective design would allow for several advantages over the retrospective design including inclusion of a control group and would allow for multiple follow-ups for data collection. This would be useful to determine the effectiveness of SCS at different points in time and would assist in determining the rate of tolerance to the stimulator. In addition, the current study could be improved upon by the inclusion of a greater number of study participants in order to generate a regression model that could take into consideration more than four predictor variables.

Another limitation of the current study is the fact that all of these patients lived in the Northwest (in or around the Portland, Oregon area) and were all operated on by one neurosurgeon at the Oregon Health Sciences University. Although this university represents the most comprehensive health care services in Oregon and is considered a leader in the health care industry, it would be nice

to see how patient outcomes might vary based on different locations and different surgeons.

Directions for Further Research

The current study results suggest that additional investigations into the nature of existing presurgical, biopsychosocial variables and their relation to SCS outcome is warranted. In addition, more research is needed to evaluate the potential for certain presurgical variables to successfully predict SCS outcome along these biopsychosocial domains. It is recommended that researchers and practitioners begin to measure treatment success by assessing such domains as: patient satisfaction rates, work status, degree of physical limitation, and concomitant utilization of other therapies (i.e., narcotic pain relievers, morphine pump). By utilizing these assessment parameters in addition to percentage of pain relief it may be possible to identify those presurgical variables that are related to SCS outcome.

In addition, because so many SCS patients with FBSS in this study appear to utilize concomitant therapies to control their pain, it may be possible to identify in the presurgical arena which patients are more likely to move on to other treatments in their search for pain relief. By so doing, it might be possible to identify those patients who are likely to discontinue SCS utilization and bypass this as a treatment option. This would save both time and effort on the clinician's part and money and heartache on the part of the FBSS patient.

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APPENDICES

Appendix A

Table 28

Outcomes and Prognostic Factors for Patients Undergoing SCS

Author & year	Study design	# of patients	% FBSS	F/U period	Results (% success)	Conclusion(s)	Predictor of success	Predictors of failure	Confidence
Burchiel et al., 1995	Prospective study	40	85	3 mos.	Mean = 45.6; (*SD* = 31.9)	Equation predicted success or failure in 88% of patients; Success was defined as % change in pre, post VAS scores of average pain; 54% of the variance in VAS change was accounted for by this combination of variables.	Young age; ↓ depression; Equation (patient age (p = 0.0002), "depression" score of MMPI-2 (p = 0.007), and evaluative subscale of MPQ (0.002) predicted successful outcome in most patients.	Not reported (NR)	Low – 3 months is insufficient time to produce significant changes in some outcome measures.
DeVulder et al., 1992	Retro-spective study	69	100	13 yrs. max	Rated success based on combination of "category of pain" score and pain ratings	Psychological impairment can be an important prognostic factor for success of SCS.	↑ use of stimulator (p=0.0002); Male (p=0.055)	↑ age	Medium
Dumoulin et al., 1996	Prospective study	40	100	6 mos.	Incorporated a 24-item questionnaire to compared an "indication factor" (I.F.) with an "evaluation factor" (E.F.) in order to define the relationship between the presurgical prognosis (I.F.) and the success rates (E.F.) after implantation.	The correlation between I.F. and E.F. had a coefficient value of 0.8083 (p = 000), indicating a very close correlation between them. Clinical psychologists could potentially use such an instrument to predict success rates of FBSS patients receiving SCS. Psychological and organic diagnosis is mandatory before considering invasive treatment.	Scores between 54 and 58 on the questionnaire indicated a favorable evaluation and predicted successful outcomes.	Scores < 50 indicated a poor surgical outcome.	High

(table continues)

Author & year	Study design	# of patients	% FBSS	F/U period	Results (% success)	Conclusion(s)	Predictor of success	Predictors of failure	Confidence
Fiume et al., 1991	Retro-spective study	55	100	Mean = 55 mos.	Mean = 56	If FBSS can be established preoperatively, SCS offers better chance at pain reduction than repeated surgery.	Female, radicular pain (as opposed to axial pain).	NR	Low – Medium
Hassen-busch et al., 1995	Retro-spective study	26	42	Mean = 2.6 yrs.	Mean = 62	Spinal morphine infusion shown to be better for bilateral or axial pain not responding to SCS. SCS more effective for neuropathic pain, especially unilateral pain with radicular pattern in one leg.	NR	NR	Low – Medium
Kumar et al., 1991	Prospective study	116	56	Mean = 40 mos.; Range = 6 mos. - 10 yrs.	Mean = 51	Pain secondary to arachnoiditis after previous operation(s) responded favorably to SCS. Patient selection criteria remain the most important determinant of success.	NR	NR	High
LaPorte & Siegfried, 1983	Retro-spective study	94	40	Mean = 35.8 mos. (*SD* = 25.4)	Mean = 47.5	Good results overall with a low complication rate. SCS is recommended before undergoing repeated surgical procedure(s).	NR	NR	Low – Medium

(table continues)

Author & year	Study design	# of patients	% FBSS	F/U period	Results (% success)	Conclusion(s)	Predictor of success	Predictors of failure	Confidence
Law, 1992	Retro-spective study	196	60	30 mos.	Mean = 27	Poor results slightly less frequent for FBSS patients with LBP (26%) than with FBSS patients with leg pain (32%).	Projection of paresthesia (p = 0.005).	NR	Low
LeDoux & Langford, 1993	Prospective study	32	100	1 mon., 6 mos., 1 yr., 2 yrs., 5 yrs.	1 mo.: 87 (n = 23); 6 mos.: 82 (n = 22); 1 yr.: 76 (n = 21); 2 yrs.: 74 (n = 19); 5 yrs.: 37.5 (n = 8)	Psychological testing helped to rule out psychopathology. More refined surgical technology is needed. Low complication rate. Better patient selection criteria	NR	NR	Medium
Meglio et al., 1994	Retro-spective study	33	85	45.5 mos.	Mean = 43	SCS is very useful in treating LBP and leg pain in patients with FBSS.	NR	NR	Low
North et al., 1991	Retro-spective study	50	100	2.2 yrs. - 5.0 yrs.	53 – 60 @ 2.2 yrs.; 47 –54 @ 5.0 yrs.; Also reports % success on review of 32 studies (with F/U of 6 months to 8 yrs): Mean = 53; Range = 12– 88	Need for better assessment of selection criteria and a more critical analysis of treatment outcome. There is a need for prospective studies.	Programmable multi-channel implants (p = 0.047); Female (p = 0.009)	Male (p = 0.003); Total # adjectives chosen (p = 0.052); Choice of adjective "terrifying" (p = 0.09)	High

(table continues)

Author & year	Study design	# of patients	% FBSS	F/U period	Results (% success)	Conclusion(s)	Predictor of success	Predictors of failure	Confidence
North et al., 1993	Prospective study: Initial results of the first randomized comparison between SCS and reoperation for LBP.	27	100	6 mos.	SCS showed a significant advantage over reoperation ($p = 0.018$). Of 15 patients undergoing reoperation, 10 (67) opted to crossover to SCS. Of 12 patients undergoing SCS, 2 (17) opted for reoperation.	Selection criteria shown to be very important in predicting SCS success.	NR	NR	High. Randomizd controlled studies have much higher statistical power.
North et al., 1993	Retro-spective study	320	48	Mean = 7.1 yrs. ± 4.5 yrs.; Range = 1.5 yrs. - 20.4 yrs.	Mean = 52	No significant predictors of SCS outcome were identified.	Short-term outcome (6 months): Overlap of pain by paresthesia, female, ↓ prior operations; choice of adjective "sharp" ($p < 0.05$) Long-term outcome (7 yrs.): ↓ previous operations, ↓ report of % LBP, not choosing adjective "wretched" ($p = 0.05 - 0.10$)	Short-term outcome (6 months): Choice of adjective "pounding", "sickening". Total # of affective or descriptor adjectives chosen.	Medium - High
North et al., 1996	Prospective study	58	70	Mean = 3.5 yrs.; Range = 2 yrs. - 13.5 yrs.	% success for FBSS not separately reported.	↓ evidence for selecting patients for SCS on the basis of psychological testing. Psychological tests fail to explain most of the variance in success or failure of treatment with SCS.	Young age; ↑ in "Hy" (Hysteria) score (MMPI-2) ($p = 0.02$); ↓ "anxiety" score on Derogatis Affects Balance Scale (DABS) & ↑ "organic symptoms" score on Wiggins (MMPI-2) predicts "successful" trial phase ($p \leq 0.01$); No significant predictors of long-term outcome identified.	↑ age. Straight leg raising, & bilateral pain (when adjusted for psychological testing).	Low – Medium; Criticized for not testing for interaction effects that might have identified predictive factors.

(tables continues)

Author & year	Study design	# of patients	% FBSS	F/U period	Results (% success)	Conclusion(s)	Predictor of success	Predictors of failure	Confidence
Rainov & Burkert, 1996	Prospective study	29	100	2 yrs. - 3.5 yrs.	Mean = 78	Selection criteria is very important and psychological testing is absolutely necessary.	Very early response to SCS in trial phase (24 hrs. – 78 hrs. after placement), predicted late outcome in most cases.	Very early response to SCS in trial phase (24 hrs. – 78 hrs. after placement), predicted late outcome in most cases.	Medium
Segal et al., 1998	Prospective study	27	48	Mean = 21 mos.	50 = "Very good"; 33.3 = "good"	Psychological evaluation prior to SCS is very important.	NR	NR	Low
Simpson, 1991	Retro-spective study	62	12	Range = 2 weeks - 9 yrs.; Median = 29 mos.	Mean = 57 (for FBSS patients only)	Case selection is very important. Patients with history of previous operations have ↑ benefit from SCS. Tolerance to SCS can be prevented by avoiding continuous use.	NR	NR	Low – Medium
Spiegel-man & Friedman, 1991	Retro-spective study	43	42	Mean = 13 mos.; Range = 2 mos. - 33 mos.	Mean = 50	SCS shown to be successful for FBSS patients. More prospective studies are needed to assess alternatives treatments.	NR	Trial phase failure. Truncal pain ($p < 0.03$)	Low

(table continues)

Author & year	Study design	# of patients	% FBSS	F/U period	Results (% success)	Conclusion(s)	Predictor of success	Predictors of failure	Confidence
Turner et al., 1995	Meta-analysis; Systematic review of 39 case series, no randomized trials included.	39 studies reviewed	100	1 yr.	29 studies reported sufficient info to calculate % of success: Mean = 59; Range = 15-100%	None able to be drawn as to SCS effectiveness for FBSS relative to other treatment, placebo, or no treatment. ↑ need for randomized trials.	NR	NR	High

Appendix B:

Medical Chart Review Instrument

1. Patient Name:	2. Address:	3. Phone Number (home):
4. Medical Record #:	5. Study ID #:	6. Date of Birth:
7. Marital Status at Time of Surgery: 0=Not Reported 1=Married 2=Divorced 3=Separated 4=In a significant relationship (i.e., boyfriend or girlfriend) 5=Single	8. Date of Index Spinal Stimulation Surgery: Date of Trial: Date of Implantation:	9. Workers' Compensation Case: 0=Not Reported 1=No 2=Yes
10. Date of Original Pain Onset: Location of Original Pain: Type of Original Pain: Sensory Descriptor for Pain:	11. Date of Most Recent Pain Onset: Location of Current Pain: Type of Current Pain: Sensory Descriptor for Pain:	12. Pain Duration: Number of Months: Categorical Rating: 0=Not Reported 1=6-12 Months 2=1-3 Years 3=3-5 Years 4=>5 Years
13. Diagnosis (Primary) Note 1: 1-8=Degenerative Conditions 10-12=Trauma Diagnosis 13=Pain 14-19=Spondylolisthesis 0=Not Reported 1=Painful degenerative disc 2=Herniated nucleus pulosus 3=Spinal stenosis 4=Instability, w/o deformity 5=Instability w/o angular motion or 5mm translocation 6=Instability with angular motion or 5mm translocation 7=Spondylosis w/o stenosis 8=Facet arthropathy 10=Fracture 11=Dislocation/ligament instability 12=Sprain-strain 13=Chronic pain syndrome 14=Congenital 15=Spondylolysis 16=Degenerative 17=Internal disc disruption 18=Failed back syndrome 19=Arachnoidits 20=Other:	14. Diagnosis (Secondary) Note 1: 1-8=Degenerative Conditions 10-12=Trauma Diagnosis 13=Pain 14-19=Spondylolisthesis 0=Not Reported 1=Painful degenerative disc 2=Herniated nucleus pulosus 3=Spinal stenosis 4=Instability, w/o deformity 5=Instability w/o angular motion or 5mm translocation 6=Instability with angular motion or 5mm translocation 7=Spondylosis w/o stenosis 8=Facet arthropathy 10=Fracture 11=Dislocation/ligament instability 12=Sprain-strain 13=Chronic pain syndrome 14=Congenital 15=Spondylolysis 16=Degenerative 17=Internal disc disruption 18=Failed back syndrome 19=Arachnoiditis 20=Other:	Notes:

15. Physical Exam Data:	16. General Health Problems (List up to 5 conditions): 0=None reported 1=Diabetes 2=Heart disease	17. Number of Prior Low Back Operations: 0=None 1=One 2=Two 3=Three or more
a. Height_____ b. Weight_____ c. Straight Leg Raising Supine 0=Not reported 1=Positive 2=Negative d. Patellar Reflexes 0=Not reported 1=Positive 2=Negative e. Ankle Reflexes 0=Not reported 1=Positive 2=Negative f. Back Pain without Radiation 0=Not reported 1=Positive 2=Negative g. Pain with Radiation Below the Knee 0=Not reported 1=Positive 2=Negative h. Focal Weakness 0=Not reported 1=Positive 2=Negative i. If yes, does focal weakness correspond to nerve root placement? 0=Not reported 1=Positive 2=Negative 9=Not Applicable j. Response to Pin Prick 0=Not reported 1=Positive 2=Negative k. Is there a Temporal Aspect of Pain Experience? 0=Not reported 1=Positive 2=Negative Specifics:_____ _____ _____ _____ _____ l. Any Activities that Modulate Pain Experience? _____ _____	3=Stroke 4=Arthritis 5=Asthma 6=Depression 7=Hypertension 8=Colitis 9=Psoriasis 10=Cancer history 11=Trauma history 12=Infectious history 13=Auto-immune history 14=Steroid usage 15=Other:	18. Back Surgery History (Include Present): Dr: Procedure: Date: Dr: Procedure: Date: Dr: Procedure: Date:
	19. Imaging Studies Conducted prior to Surgery: 0=None 1=X-Ray 2=CT 3=MRI 4=CT Myelogram 5=Discography 6=Other_____	20. Surgical & Device Complications: 0=Not reported 1=No revision of hardware or wound infection reported 2=Subcutaneous wound infection 3=Migration of electrodes 4=Fatigue fracture of electrodes 5=Surgical revision of electrode placement 6=Surgical replacement of receiver 7=Surgical replacement of electrodes
	21. Number of Levels Stimulated: 0=Not reported 1=One level 2=Two levels 3=Three or plus three levels	IPG Type: 1=Itrel 1 2=Itrel 2 3=Itrel 3 4=Matrix Receiver/Transmitter System Other:_____
	22. Electrode Combinations: 0=Not reported 1=Bipolar 2=Multichannel Other:_____ _____	Total Number of Leads Implanted: Location:_____ Type: 1=Pisces Quad 2=Octad Lead 3=Four Plate Other:_____
	23. Were Leads Explanted: 1=No 2=Yes Date of explant:_____ Reason for explantation:_____ _____ _____ _____	24. Was Patient Discontinued (leads/receiver in place but patient and/or Dr. chose to stop treatment)? 1=No 2=Yes Date of Discontinuance:_____ Date of Explanation:_____

25. Has Receiver Battery been Replaced? 0=Not reported 1=No 2=Yes	54. Ethnicity 0=Not reported 1=Caucasian 2=African American 3=Hispanic 4=Asian or Pacific Islander 5=Native American 6=Other (Specify):_____	58. Use of Pain Medications Prior to Surgery 0=Not reported 1=No 2=Occasional mild analgesics or no analgesics 3=Regular use of nonnarcotic analgesics 4=Occasional or regular narcotic analgesics Listing of Medications for Low Back Pain / Lower Extremity Pain: _____ _____ _____ _____ _____
55. Amount of Pain Before Surgery? 0=No pain or minimal pain 1=Mild 2=Moderate 3=Severe	57. Educational Level: 0=Not reported 1=Less than 12 years 2=12 years (HS Degree) 3=Some college 4=Trade School/AA 5=College Degree 6=Advanced Degree	56. Smoking at Time of Surgery? 0=Not reported 1=No 2=Yes
59. Alcohol Use at the Time of Surgery? 0=Not reported 1=No 2=Yes		
Illicit Drug Use? 0=Not reported 1=No 2=Yes	Was a Psychological Evaluation Completed Prior to Surgery? 0=Not reported 1=No 2=Yes Date of Evaluation:_____	Litigation Relative to Back Condition? 0=Not reported 1=No 2=Yes

Appendix C:

Subject Letter

Study Participant
Address
City, State (zip code)

Date Field

Dear Participant:

During the months of September through October we will be conducting a study of patients who have received surgically implanted spinal column stimulators (SCS). This survey is being conducted by the Department of Neurological Surgery at Oregon Health & Science University and Utah State University. The Institutional Reviews Boards for protection of human research participants at OHSU and USU have approved this research. We are very interested in hearing about the results of your SCS surgery and have sent this letter to inform you in advance about our request for an interview.

We obtained your name and address from our records and want to emphasize that this research is being conducted independently from insurance companies and your participation will in no way affect your compensation status or treatment. The risks of participating in this study are considered minimal and your input will help us learn which patients benefit most from SCS and how to better predict and improve SCS outcomes.

The interview will be conducted over the telephone and will take only 20-30 minutes. All of your responses will be strictly confidential and your information will be kept in a locked file cabinet in a locked room and only the investigators and a research assistant will have access to the data. The data will be kept for 7 years and then destroyed. For your participation, we will send you a check for $20.00. You may refuse to participate or withdraw anytime from the study without consequence, however, the compensation will be void.

In order for us to contact you, you need to complete the attached consent form card and return it to us as soon as possible. To help us in contacting you, please fill in your name, address, and phone number within the appropriate sections on the enclosed postcard and drop it in a mailbox. Your participation will be greatly appreciated since this is a very important study. If you have any questions, or need further explanation, please do not hesitate to call me at (503) 494-4846.

Sincerely,

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Appendix D:

Subject Return Postcard

OHSU SCS OUTCOME STUDY

(PATIENT CONSENT & ADDRESS/TELEPHONE UPDATE CARD)

I agree to participate in the SCS Outcome Study and will receive $20 for completing the Outcome Survey

Yes _____ **No** _____

NAME: _____

SIGNATURE: _____

ADDRESS: _____

_____

_____

TELEPHONE NUMBER: (____) _____

The best time to contact me is:

Appendix E:

SCS Telephone Survey Cover Sheet

SUBJECT NUMBER ____

NAME:_____

SURG DATE:_____
TELEPHONE NUMBERS:

Telephone # 1: ( ) ___-____
Telephone # 2: ( ) ___-____
Telephone # 3: ( ) ___-____

Checklist:	
Verify Subject Phone and Address?	yes
Circle Address for subject payment?	yes
Check through chart review instrument for incomplete items?	yes
Check through outcome instrument for completeness?	yes

ADDRESSES (Circle address that subject payment should be sent to):

Address # 1: _____
_____
_____
_____

Address # 2: _____
_____
_____
_____

Address #3: _____
_____
_____
_____

Address # 4: _____
_____
_____
_____

CONTACT HISTORY:
Did Patient Receive A Reminder Phone Call: Yes:_____(Date:____) No:_____(Reason)

Date	Time	Outcome of Call
1.		
2.		
3.		
4		
5.		
6.		

FINAL STATUS OF SUBJECT PARTICIPATION:
1=Contacted but declined to participate
2=Contacted and completed only part of survey
3=Contacted and completed entire survey
4=Could not be reached
5=Participated and wants a study summary sent to them
6=Other_____
Notes:_____

SCS OUTCOME STUDY
TELEPHONE INTERVIEW SCRIPT

Hello. Is this the _____residence? (If wrong number, then terminate).

This is _____ calling from Oregon Health Sciences University. We received your consent to participate in a study to learn more about people who have had Spinal Cord Stimulation for chronic low back and leg pain.

The survey will take about 15 minutes to complete. Is this a good time"?

Yes: Proceed with Survey

No: When would be a time to call you back?

Date:_____
Day: _____
Time:_____

You were chosen for this study because you had Spinal Cord Stimulation for your chronic low back and/or leg pain. Your opinion of how you have progressed since the surgery is critical to this study and results of the survey will be used to help others who are considering having Spinal Cord Stimulation. Your participation is voluntary and your treatment or compensation status will in no way be affected by your participation. For your participation in the survey we will be sending you a check for $20. All of your answers will be kept confidential as provided by law and you may skip any questions you prefer not to answer. Okay?

Please feel free to ask questions at any time during the survey and if at any point you feel that you want to stop the survey, please let me know.

Stauffer-Coventry, Patient Satisfaction, and Demographic Outcome Questions

SURVEY QUESTIONS-PAGE 1

SCS Outcome Study Telephone Survey - General Questions This part of the survey will involve some general questions about how your have done since your surgery. Please respond to each question according to how you feel today. Okay?		
1. Since your surgery, how much pain relief have you experienced in your back and lower extremities? Please provide a percent rating from 0 to 100. _____ **Category Rating:** 1=Good (76-100% improvement) 2= Fair (26-75% improvement) 3= Poor (0-25% improvement)	**2. With regard to your employment after SCS, which of the following best describes your status after surgery?** 1=Return to previous work status following surgery 2=Return to lighter work following surgery 3=No return to work following surgery	**3. With regard to your physical activities after SCS surgery, which of the following best describes your status after surgery?:** 1=Minimal or no restrictions of physical activities. 2=Moderate restrictions of physical activities 3=Severe restrictions of physical activities
4. With regard to your use of analgesic medications after SCS surgery, which of the following best describes your usage: 1=Occasional mild analgesics or no analgesics 2=regular use of nonnarcotic analgesics 3=occasional or regular narcotic analgesics	**5. With regard to your back/leg pain following SCS surgery, which of the following is true:** 1=Back or leg pain is worse than expected 2=Back or leg pain is no worse or better than expected 3=Back or leg pain is better than expected	**6. Is the quality of life better or worse as a result of lumbar fusion surgery? That is, is it:** 1=A great improvement 2=A moderate improvement 3=A little improvement 4=No change 5=A little worse 6=Moderately worse 7=Much worse
7. Given what you know: If you could go back in time, would you choose to have the spinal fusion surgery? 0=Undecided 1=No 2=Yes	**8. What was your principal occupation/job title at the time of your injury?:**	**9. Are you currently working?** 1. No 2. Yes, Full Time 3. Yes, Part Time 4. No answer
10. If not working, which of the following best describes why you are not employed?: 1. I am still disabled 2.I am not disabled & I want to work but cannot find a job. 3. I was laid off. 4. I am a student. 5. I am a homemaker. 6. I am retired 7. Other_____ 8. No answer	**11. How many days have you worked in the past 4 weeks?**	**12. How many hours a week do you usually work at your job?**
	13. Did you change jobs because of your back problem? 1=no 2=yes 3=not applicable 0=No answer	**14. Do you currently retain an attorney because of you back problems?** 1=no 2=yes 0=No answer
	15. Do smoke now? 1=no 2=yes 0=No answer	**16. Have you had any back operations since your fusion surgery?** 1=No 2=No, but I'm scheduled to 3=Yes 4=_____
17. Overall, is your back or leg pain problem better than or worse than you expected it to be at this point? That is, is it? 1. Much better 2. Somewhat better 3.What I expected 4. Somewhat worse 5. Much worse 6. No expectations	**18. What is the highest year in school you completed?** 1. Less than High School 2. Some High School 3. High School Graduate/GED 4. Attended or graduated from technical school 5. Attended college but did not graduate 6. College graduate 7. Graduate Studies	**19. If you had to spend the rest of your life with your back condition as it is right now, how would you feel about it?** 1. Extremely dissatisfied 2. Very dissatisfied 3. Somewhat dissatisfied 4. Neutral 5. Somewhat satisfied 6. Very satisfied 7. Extremely satisfied

Roland-Morris Back Pain Disability Questionnaire

SURVEY QUESTIONS-PAGE 2

Disability Questionnaire

Now we are going to ask you more specific questions about your back.....

"When your back hurts, you may find it difficult to do some of the things you normally do. The list I'm going to read you now contains some sentences people have used to describe themselves when they have back pain. As I read the list, think of yourself today. When I read a sentence that describes you today, please indicate so by telling me yes. If the sentence does not describe how you feel today, please indicate so by telling me no. Do you have any questions?"

Yes	No	Items
1	2	1. I stay at home most of the time because of my back.
1	2	2. I change positions frequently to try and get my back comfortable.
1	2	3. I walk more slowly than usual because of my back.
1	2	4. Because of my back I am not doing any of the jobs I usually do around the house.
1	2	5. Because of my back, I use a handrail to get upstairs.
1	2	6. Because of my back, I lie down to rest more often.
1	2	7. Because of my back, I have to hold on something to get out of an easy chair.
1	2	8. Because of my back, I try to get other people to do things for me.
1	2	9. I get dressed more slowly than usual because of my back.
1	2	10. I only stand up for short periods of time because of my back.
1	2	11. Because of my back, I try to not bend or kneel down.
1	2	12. I find it difficult to get out of a chair because of my back.
1	2	13. My back is painful almost all of the time.
1	2	14. I find it difficult to turn over in bed because of my back.
1	2	15. My appetite is not very good because of my back pain.
1	2	16. I have trouble putting on my socks (or stockings) because of pain in my back.
1	2	17. I only walk short distances because of my back pain.
1	2	18. I sleep less well because of my back.
1	2	19. Because of my back pain, I get dressed with help from someone else.
1	2	20. I sit down for most of the day because of my back.
1	2	21. I avoid heavy jobs around the house because of my back.
1	2	22. Because of my back pain, I am more irritable and bad tempered with people than usual.
1	2	23. Because of my back, I go upstairs more slowly than usual.
1	2	24. I stay in bed most of the time because of my back.

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SURVEY QUESTIONS-PAGE 3-5

Instructions:
This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

	Excellent	Very good	Good	Fair	Poor
	1	2	3	4	5

2. Compared to one year ago, how would you rate your health in general now?

	Much better now than one year ago	Some-what better now than one year ago	About the same as one year ago	Some-what worse now than one year ago	Much worse now than one year ago
	1	2	3	4	5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a.) **Vigorous activities,** such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b.) **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c.) Lifting or carrying groceries	1	2	3
d.) Climbing **several** flights of stairs	1	2	3
e.) Climbing **one** flight of stairs	1	2	3
f.) Bending, kneeling, or stooping	1	2	3
g.) Walking **more than a mile**	1	2	3
h.) Walking **several blocks**	1	2	3
i.) Walking **one block**	1	2	3
j.) Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
a.) Cut down on the **amount of time** you spent on work or other activities	1	2
b.) **Accomplished less** than you would like	1	2
c.) Were limited in the **kind** of work or other activities	1	2
d.) Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
a.) Cut down on the **amount of time** you spent on work or other activities	1	2
b.) **Accomplished less** than you would like	1	2
c.) Didn't do work or other activities as **carefully** as usual	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

	Not at all	Slightly	Moderately	Quite a bit	Extremely
	1	2	3	4	5

7. How much bodily pain have you had during the past 4 weeks?

	None	Very mild	Mild	Moderate	Severe	Very severe
	1	2	3	4	5	6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

	Not at all	A little bit	Moderately	Quite a bit	Extremely
	1	2	3	4	5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	A Good Bit of the Time	Some of the time	A little of the time	None of the time
a.) did you feel full of pep?	1	2	3	4	5	6

b.) have you been a very nervous person?	1	2	3	4	5	6
c.) have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d.) have you felt calm and peaceful?	1	2	3	4	5	6
e.) did you have a lot of energy?	1	2	3	4	5	6
f.) have you felt downhearted and blue?	1	2	3	4	5	6
g.) did you feel worn out?	1	2	3	4	5	6
h.) have you been a happy person?	1	2	3	4	5	6
i.) did you feel tired?	1	2	3	4	5	6

10. During the <u>past 4 weeks</u>, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
	1	2	3	4	5

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a) I seem to get sick a little easier than other people	1	2	3	4	5
b) I am as healthy as anybody I know	1	2	3	4	5
c) I expect my health to get worse	1	2	3	4	5
d) My health is excellent	1	2	3	4	5

Appendix F:

Open-Ended Question:
"If You Stopped Using Your SCS Unit, What was/were the reason(s)?"

Patient	Patient Comment
1	The battery is dead, I'm thinking about getting it replaced.
2	Because it's unable to relieve the pain, there's not enough intensity to it.
3	Because the 2nd one never worked and the discectomy relieved the pain
4	It didn't work. I couldn't get any relief.
5	It didn't work well.
6	I was having problems with my stomach and think the SCS was responsible.
7	I could never get used to the paresthesias.
8	It didn't help.
9	It didn't work because of vibration. It never stayed where it was supposed to.
10	It died and I was angry about the treatment so I didn't go back.
11	It made the pain worse.
12	It quit working. It worked well for a year and then stopped.
13	It shocked me whenever I moved around. It was very uncomfortable.
14	It stopped giving me relief.
15	It stopped providing pain relief.
16	It stopped relieving my pain after 1 – 2 years.
17	It stopped working.
18	It wasn't doing any good.
19	It wasn't helping.
20	It wasn't helping. I was disappointed.
21	Because of lack of effectiveness and discomfort of connector and device.
22	My body rejected the metal, but I liked how the SCS was controlling my pain.
23	The pain returned and wasn't getting better. It wasn't helping for 6 months.
24	I started having breakthrough pain and it wasn't helping much with that.
25	It stopped working after 6 months.
26	It stopped working after about 1 ½ months.
27	The battery went dead and I made the decision to go on to the morphine pump because the SCS wasn't helping.
28	The pain was increasing.
29	The stimulator made me hurt more.