DO SPINAL FUSIONS NECESSARILY RESULT IN POORER THERAPEUTIC OUTCOMES?

by

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ABSTRACT

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Controversy exists over the relationship between spinal fusion surgery and successful therapeutic outcomes. Common problems include unstandardized outcomes, ignoring the impact of the medico-legal system, and a paucity of investigations going beyond the surgical procedure itself. The present study compared patients who received spinal fusions against patients who did not, within the setting of a tertiary rehabilitation program (i.e. functional restoration) for work-related chronic disabling occupational spinal disorders. Program completers were prospectively evaluated on several objective one-year post-rehabilitation outcomes, including occupational status and level of healthcare utilization. The non-fusion group (N = 2,295) had a statistical advantage over the fusion group (N = 299) on several one-year outcomes. However, these differences were not significant when adjusted for patient demographic factors and psychosocial comorbidity. Significant risk factors for poorer outcomes (e.g. opioid dependence disorder, depressive symptoms) were identified and discussed within the context of prior research on chronic pain and disability.

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CHAPTER 1

INTRODUCTION

Spinal disorders have received considerable attention because they are the most expensive benign condition in medicine. A large epidemiological study estimated a 19% prevalence for chronic spinal pain (back and neck) in the United States for the year 2004, and a 29% lifetime rate (Von Korff et al., 2005). Another study estimated that healthcare costs in the United States associated with back pain alone exceeded $90 billion in 1998 (Luo, Pietrobon, Sun, Liu, & Hey, 2004). Due to the high costs, frequent utilization, and mixed results for treatment effectiveness, spine surgery has been the focus of much controversy (Deyo, Cherkin, Conrad, & Volinn, 1991; Deyo, Gray, Kreuter, Mirza, & Martin, 2005; Gibson, Grant, & Waddell, 1999; Hadler, Tait, & Chibnall, 2007; Taylor, Deyo, Cherkin, & Kreuter, 1994). Among the types of surgical methods for spinal disorders, fusion surgery has generated the most controversy. Recent criticism of spinal fusions cited the “overuse” of this type of surgery, including a tripling of its incidence in the past decade, despite the lack of evidence for treatment efficacy and the unsatisfactory outcomes reported in the literature (Deyo, Nachemson, & Mirza, 2004; Deyo, Gray, Kreuter, Mirza, & Martin, 2005; Weinstein, Lurie, Olson, Bronner, & Fisher, 2006).

Central to the utilization of fusion surgical procedures is the assumption that correcting physiological damage or instability would lead to elimination of pain and its consequent disability. Therefore, a broad review of the theoretical underpinnings of pain will be useful. This will then be followed by a review of spinal fusion procedures and their application for eliminating or reducing pain and disability. Finally, a prelude to the present study will explore the various controversies and weaknesses apparent in the research literature on the outcomes of fusion surgery, as well as highlight some of the more recent findings that provide a more comprehensive description of fusion surgery within the current evidence-based paradigm of pain and disability.

Theories of Pain

Biomedical Reductionism.

This theory is the earliest formulation of pain within the medical field, dating back to the 17th century. The central assumption within this theory was that pain is a consequence of specific physiological damage or impairment (Turk & Monarch, 2002). This damage or impairment to tissue or body part was assumed to be identifiable through objective tests or observations. This assumption proved to be initially successful and resulted in tremendous advancements in medical technology. As a result, specific treatment modalities were developed to correct or alleviate the pathology. However, over time, systematic research revealed that, given the same pathology, patients' self-reports of pain and its consequent disability varied considerably. A similar problem was the diverse responses among patients given the same treatment modality for a given pathology. The paradox that emerged from this discrepancy resulted in the general consensus that the relationship between self-report of pain and pathology is only moderate at best (Flor & Turk, 1988; Turk & Monarch, 2002; Waddell & Main, 1984).

Accompanying the perception of pain is usually a myriad of other factors, such as fear, anxiety, and sleep disturbances. These are usually exacerbated in conditions when pain becomes chronic, and can result in poorer psychosocial functioning and depression. However, all these factors were viewed as a consequence of pathology and were thus considered secondary factors (Turk & Monarch, 2002). The underlying assumption was that, if the pathology was cured or corrected, these consequential factors should also cease to exist. This was known as *somatogenic* pain. In reality, though, many medical conditions arise where severe pain is reported but no specific pathology can be identified. These include conditions like chronic widespread pain and fibromyalgia, temporomandibular disorders, and chronic back pain (Aaron, Burke, & Buchwald, 2000; Epstein et al., 1999; Gatchel, 2002; Gatchel, Stowell, Wildenstein, Riggs, & Ellis, 2006; Gracely, Petzke, Wolf, & Clauw, 2002; Greene, 2001; Gremillion, 2000; Kight, Gatchel, & Wesley, 1999). When no pathology could be reliably identified, the disorder was termed *psychogenic* pain (i.e., the pain has a psychological basis). This dichotomous classification of pain, and its consequent disability, persisted in the field of medicine until relatively recent times.

Gate Control Theory of Pain.

This theory by Melzack and Wall (1965) revolutionized the understanding of pain by implicating the role of psychological factors in the perception of pain. The two major contributions of the gate control theory (GCT) were the modulation of the perception of pain by interacting neurons, and the implication of the central nervous system in processing nociception. At the level of the peripheral nervous system, afferent nociceptive nerves are responsible for sending signals to the central nervous system via ascending pathways. These neurons consist of at least two types of fibers: the $A\delta$ fibers responsible for rapid signaling of intense, acute pain; and the *C* fibers for chronic and throbbing type of pain (Melzack & Wall, 1965). These two afferent nociceptive nerves can be inhibited by non-nociceptive nerves consisting of the $A\beta$ fibers. The GCT identified the dorsal horn area of the spinal cord as one area where pain transmission is modulated by interacting neurons. These areas in the dorsal horn receive input from the nociceptive and the non-nociceptive fibers. The non-nociceptive fibers, when activated, inhibit the firing of the nociceptive fibers in response to some external stimulus, thus "closing the gate" and preventing transmission of pain signals to the brain. In addition, the nociceptive fibers, when activated, can also function as an inhibitor of the non-nociceptive fibers and result in "opening the gate", thereby increasing the likelihood of pain signals being transmitted to the brain. The GCT also identifies a region of the brain responsible for modulating the transmission of pain signals. For example, the periaqueductal grey matter, when stimulated, can inhibit nociceptive neurons that converge in the spinal cord, via a descending pathway, thus reducing the probability of pain signals being transmitted to the brain (Melzack & Casey, 1968).

These physiological mechanisms involved in nociception and subjective perception of pain resulted in several theoretical implications (Turk & Monarch, 2002). Firstly, the central nervous system is implicated as a vital component in understanding pain and its related consequences. Secondly, the dichotomy of somatogenic and psychogenic pain was disproved; the GCT implies that both psychological and physiological factors can modulate the subjective experience of pain. And thirdly, the GCT implies that merely correcting or blocking the physiological pathways implicated in pain perception would be inadequate in totally eliminating perception of pain.

Biopsychosocial Perspective of Pain.

The GCT opened avenues for the formulations of broad and more comprehensive models to explain not only pain, but diseases in general. The biopsychosocial approach to medicine in general was first formulated by Engel (1977). Central to the biopsychosocial perspective is the distinction between *disease* and *illness*. Whereas disease represented specific pathology that could be objectively identified, illness corresponded to the subjective experience of the disease, or its broader manifestation beyond identifiable pathology (Gatchel, 2004; Turk & Monarch, 2002). The pathology serves as a stimulus which is then moderated by the individual's present psychological status, experience, genetic predispositions, and social and cultural factors. The manifestation of illness is thus dependent upon these interacting factors.

Engel's general model of illness identifies distress as the first response to pathology. Distress over the physical problem can be conceptualized as the subjective experience of the pathology. This subjective experience can then lead to emotional responses, characterized by illness behavior. Depending on the type of pathology and the individual itself, these illness behaviors can take on a variety of forms, such as fear, anxiety, or depression. When the pathology becomes chronic, the illness behaviors will eventually lead to the adoption of the "sick role", which is the specific set of behaviors an individual adopts to minimize distress.

In applying this general model in the formulation of a model of pain, Loeser (1982) identified nociception as the basic marker for pathology, which then leads to the subjective experience of *pain*. Pain would then lead to a range of emotional responses, broadly defined as *suffering*. If the nociception persists, and suffering becomes chronic in response to the subjective experience of pain, an individual would then start exhibiting *pain behaviors*. These behaviors, analogous to the sick role, may include such behaviors as avoiding activity due to the fear of triggering pain (Gatchel, 2004). This biopsychosocial model is also consistent with the GCT in that these specific factors identified within the model can interact, and there is not only a one-way progression from pathology to manifestation of illness. This key concept of the biopsychosocial model can be clearly identified in a discussion of the progression of pain from the acute to the chronic stage.

Development of Chronic Pain

The *three-stage model* of progression is, to date, the most comprehensive description of the development of pain from the acute to the chronic stage (Gatchel, 1991;, 1996). *Stage 1* describes the acute phase of pain, and involves basic responses to the perception of pain. These responses include a range of normal emotional reactions such as fear, anxiety, and worry. Such emotional responses serve as a protective function that signals to the individual that some sort of attention may be required to prevent further tissue damage or the development of a complicated medical condition.

The duration of Stage 1 is dependent upon the normal healing period for most painful conditions underlying some sort of pathology, and can range from between two weeks to four months. In general, pain lasting for more than four months begins to develop into chronic pain.

Stage 2 of this model marks the beginning of chronicity and involves the exacerbation of physiological and psychosocial conditions. At the physiological level, physical deconditioning starts to develop (Mayer, Gatchel, Porter, & Theodore, 2006; Mayer & Press, 2005). For example, if the pain is due to injury of a certain body part, an individual's behavior is geared towards avoiding utilization of the injured body part as much as possible for fear of increased pain or re-injury. This results in physical deconditioning. Additionally, the symptoms in this Stage manifest themselves according to the diathesis-stress perspective. At this point in the progression of pain, the stress of coping with pain leads to the exacerbation of underlying psychological characteristics within a given individual. These underlying characteristics include predisposing psychological variables, such as the individual's personality and general psychosocial well-being, as well as external factors such as socioeconomic and environmental factors. Characteristic responses at this Stage include learned helplessness, anger, and distress. These affective consequences of chronic pain can perpetuate and even exacerbate the perception of pain (Fernandez, 1998), which then leads to a pain-stress cycle and increased somatization (Gatchel & Oordt, 2003). Development of comorbid psychopathology also occurs at this Stage, including personality disorders, psychophysiological disorders, major depressive disorders, and substance abuse disorders (Dersh, Gatchel, Mayer, Polatin, & Temple, 2006; Dersh, Gatchel, Polatin, & Mayer, 2002; Dersh, Mayer, Theodore, Polatin, & Gatchel, 2007; Dersh, Polatin, & Gatchel, 2002; Dersh, Gatchel, & Polatin, 2001).

If chronicity is allowed to develop, progression into full-blown chronic pain takes place. *Stage 3* of the model characterizes this stage of pain as a complex interaction among physiological, psychological, and social processes, and the individual becomes preoccupied with the pain. This Stage is analogous to the sick role as discussed in the general biopsychosocial model above (Engel, 1977). In addition to the focus on pain, the individual at this Stage exhibits poor social and occupational functioning, and begins to develop secondary gain issues (Dersh, Polatin, Leeman, & Gatchel, 2004; Fishbain, 1994; Leeman, Polatin, Gatchel, & Kishino, 2000). Such behaviors are characterized by the avoidance of responsibilities, and seeking out financial compensation for the pain. These secondary gain issues then begin to serve as reinforcers that maintain maladaptive behaviors (Gatchel & Oordt, 2003), which then result in complete physical and psychological deconditioning.

The key concept then, in any type of medical setting dealing with pain, is to prevent the development of Stage 3 chronic pain. Pain is best addressed at early stages to prevent the synergistic effect of several interacting and confounding physiological, psychological, and social factors. Consistent with this three-stage model of pain and the advances in the theory of pain, a formal biopsychosocial model for treating pain has been developed. This model involves levels of care that are commensurate with the level of progression of pain. These levels of care within a biopsychosocial paradigm are discussed next.

Biopsychosocial Rehabilitation

Biopsychosocial rehabilitation can be broadly categorized into three levels of care: *primary care*, *secondary care*, and *tertiary care* (Gatchel & Turk, 1996). These levels of care are characterized by a biopsychosocial approach to dealing with pain, and are differentiated primarily by intensity and the comprehensive nature of the treatment modalities. It should be noted, however, that pain patients need not necessarily progress through the levels of care in a sequential manner. A stratified approach is suggested for matching the stage of chronicity with the appropriate level of care required (Von Korff, 1999).

Primary Care.

This level of care is designed to address pain and its related issues at the acute stage. The underlying aim of primary care is to control the pain symptoms. In addition, primary care treatment modalities are geared towards promoting the recovery of the pathophysiology and prevention of physical deconditioning (Mayer, Gatchel, Porter, & Theodore, 2006; Mayer & Press, 2005). Treatment modalities in the primary care setting include medication, thermal application, immobilization of injured joints, bed rest, and traction (Mayer, Gatchel, Porter, & Theodore, 2006; Mayer & Press, 2005). Psychosocial issues are routinely addressed at the primary care level, and these include identification of any barriers to recovery such as fear and anxiety about the pain. Psychosocial interventions at this stage are therefore aimed at reassuring the patient that the pain symptoms are temporary and will soon be alleviated, given adherence to the treatment modality and compliance with any medication regimen.

Secondary Care.

This level of care is targeted towards patients at the post-acute stage of pain who are showing signs of functional limitations due to pain, as well as the development of psychosocial barriers to recovery. The main goals of secondary care are to promote re-activation of the underlying physiology and the prevention of long-term physical and psychological deconditioning. Treatment approaches in secondary care should ideally include an interdisciplinary healthcare team consisting of the primary care physician, clinical psychologists, physical therapists, and nurses or health educators. If one of the goals of rehabilitation include a return to previous occupational status, then an occupational therapist would also be a useful component of the rehabilitation setting (Theodore, Chan, & Gatchel, in press).

Treatment modalities at this level include structured exercise programs, functional training for improving general health and work capacity, and cognitive-behavioral interventions designed to address psychosocial barriers to recovery that play a role in the development of chronicity. Several randomized controlled trials (RCTs) evaluating an interdisciplinary secondary care approach have documented evidence for highly satisfactory outcomes, including increased reduction of pain, improved general health and self-efficacy, increased treatment satisfaction, lower healthcare costs, as well as satisfactory resumption of occupational status and activities of daily living (Hagen, Eriksen, & Ursin, 2000; Indahl, Haldorsen, Holm, Reikers, & Holger, 1998; Karjalainen et al., 2004; Karjalainen et al., 2001; Lindstrom et al., 1992).

Tertiary Care.

The main goal of tertiary care is to prevent permanent disability due to pain. At this stage, the emphasis is on managing pain and its consequent disability. Patients who end up in tertiary care have either not responded well to primary or secondary care, or have been evaluated by the primary care physician as having a complicated medical case that is consistent with the earlier reviewed Stage 3 chronic pain. In addition, this level of care is usually the final step after patients have exhausted all other surgical and conservative approaches for dealing with the pain. Given the complex nature of interactions among several factors within Stage 3 of chronic pain, treatment modalities at this level of care are necessarily more complex and require a multidisciplinary approach. Tertiary care is primarily tailored towards the individual patient, and the healthcare team consists of clinical psychologists or psychiatrists, physical therapists, occupational therapists, disability case managers, and nurses or health educators, in addition to the primary physician.

General treatment modalities are targeted towards reversing physical deconditioning via re-activation of the affected physiology, coping with limited pain and disability, addressing of comorbid psychopathology, and the removal of psychosocial barriers such as secondary gains (Deschner & Polatin, 2000; Mayer et al., 2003; Mayer, Gatchel, Porter, & Theodore, 2006; Mayer & Press, 2005). This level of care can take two broad approaches, differentiated by the ultimate goal of rehabilitation.

Palliative pain management is a lower intensity treatment approach with the goal simply being the management of pain. Pain-relieving narcotics and medication for psychiatric comorbidity are the usual treatment modalities. Additionally, psychological interventions aimed at improving coping techniques and to decrease pain and stress are provided to help patients deal with a lifestyle of reduced function (Mayer & Press, 2005).

The second type of approach to tertiary care includes higher intensity treatment modalities with the goal of preparing chronically disabled patients for resumption of occupational status, in addition to managing pain and disability. These tertiary care rehabilitation approaches include *functional restoration* (Mayer et al., 1985) and general return-to-work programs (Li, Li-Tsang, Lam, Hui, & Chan, 2006). In addition to the general tertiary care treatment modalities discussed above, these intensive rehabilitation approaches also involve narcotic detoxification, structured graded exercises aimed at improving functional capacity, work hardening and skills training aimed at improving work capacity and employability, disability and occupational case management, and individual placement and support for returning to work (Theodore, Chan, & Gatchel, in press).

A large body of evidence has been systematically reported in the literature over the last two decades documenting the treatment efficacy of the functional restoration approach to managing chronic pain, especially for chronic lower back pain (CLBP) and chronic disabling occupational spinal disorders (CDOSD). Objective one-year post-rehabilitation outcomes have been obtained from cohort studies, as well as RCTs, and include: increased resumption of active occupational status and activities of daily living; decreased health care utilization; reduced levels of pain intensity; improved readiness to change; improved psychological well being; and, resolution of outstanding medico-legal issues (Becker, Sjogren, Beck, Olsen, & Eriksen, 2000; Guzman et al., 2001; Hazard et al., 1989; Mayer et al., 1985; Patrick, Altmaier, & Found, 2004). The highly satisfactory results of functional restoration have been shown to be temporally stable (Mayer et al., 1987), can be generalized across different socioeconomic and medico-legal systems (Bendix et al., 1996; Corey, Koepfler, Etlin, & Day, 1996; Hildebrandt, Pfingsten, Saur, & Jansen, 1997; Jousset et al., 2004), and are more cost-effective than standard conservative treatment (Gatchel & Okifuji, 2006; Skouen, Grasdal, Haldorsen, & Ursin, 2002; Turk, 2002; Turk & Okifuji, 1997).

Spinal Fusion Surgery

The preceding sections provided a broad review of the evolution of theories on pain, as well as the general levels of care currently utilized in evidence-driven pain rehabilitation. The principles reviewed above also have direct application in the specific case of pain in the spinal region. Spinal fusion surgery is a specific surgical technique with the underlying goal of reducing neck and back pain, and involves the solid union of two adjacent vertebrae. This is accomplished by means of a bone graft placed between the two vertebrae. During the healing process, the bone graft becomes fused to the vertebrae, preventing motion between each bone (Swann, Gray, & Worth, 1989). The underlying basis for fusion surgery is the theory that excessive motion between two vertebrae can inflame nerves within the spinal cord and cause pain (Hanley & David, 1997). Thus, it should be emphasized that the early development of this surgical procedure was aimed at removing the physiological basis of pain, and is therefore a direct application of the paradigm of biomedical reductionism as discussed above. There are several indications for spinal fusion surgery. In certain disorders, the physiological problem is evident and the need for fusion surgery is clear-cut. These less controversial indications for fusion surgeries include vertebral fractures and dislocations, spinal tumors, scoliosis, and spondylolisthesis (Hanley & David, 1997; Swann, Gray, & Worth, 1989). All these conditions involve some form of vertebral instability; thus, the procedure of fusing the vertebrae is often the only viable option for reducing or eliminating pain and discomfort. However, there has been an increasing, and controversial, use of fusion surgery for chronic spinal pain when no clear indications of instability are present, such as for chronic back pain and degenerative disc disease (Deyo, Nachemson, & Mirza, 2004; Hanley & David, 1997). In most circumstances, this surgical option is undertaken when other conservative, non-invasive treatment modalities have been exhausted and resulted in no improvements. Nevertheless, the research literature, to be discussed in the next section, indicates very poor outcomes overall for the utilization of fusion surgery in such cases.

Fusion surgeries can be classified into two broad categories depending on the incision approach. An *anterior* fusion involves incisions and placing of the bone graft from the front of the body, and is the default approach used for the cervical spine and less frequently, for the lumbar and thoracic spine (Christensen, 2004; Schlegel, Yuan, & Fredricksen, 1997). For the thoracic and lumbar spine, the *posterior* fusion is more commonly used and involves incisions and placing of the bone graft from the back of the body (Christensen, 2004; Zindrick & Lorenz, 1997). The method of fusion surgery in the thoracic and lumbar regions can also be broadly classified into two categories: *posterolateral* and *interbody*. Posterolateral fusions involve the placing of the bone graft between the *transverse process* of two vertebrae (Christensen, 2004; Zindrick & Lorenz, 1997). For interbody fusions, the vertebral disc is completely removed and the bone graft is placed between the vertebrae in the anatomical location of the vertebral disc (Christensen, 2004; Schlegel, Yuan, & Fredricksen, 1997; Simmons, 1997). Anterior lumbar interbody fusion (ALIF) is done with incisions through the abdomen, whereas posterior lumbar interbody fusion (PLIF) is performed through incisions on the back. Sometimes, a combination of an ALIF and PLIF is performed, and this procedure is known as *circumferential* or *360-degree* fusion (Christensen, 2004; Eisenstein, 1997). This procedure is routinely done to improve success in the fusion of vertebrae, and also to remedy a failed posterolateral or PLIF by adding an ALIF procedure (Eisenstein, 1997).

In addition to the bone graft, it is also common for fusion surgeries to utilize some type of instrumentation that aids in the successful union of adjacent vertebrae. These instrumentation devices include metallic screws, rods, cages, or plates with the purpose of providing stability to the vertebrae while the bone graft becomes fused through the normal healing process (Christensen, 2004; Villarraga, 2006). Upon successful fusion, these instrumentation devices are usually removed by a surgical procedure.

Clinical Outcomes of Spinal Fusion

There is a wide range of outcomes reported in the literature on fusion surgery. These can be broadly divided into three categories which include: direct surgical outcomes (e.g,. fusion success); post-surgical clinical outcomes (e.g., pain, disability, patient satisfaction); and occupational outcomes (e.g., resumption of occupational status). In general, most studies focus on one- or two-year post-surgical clinical outcomes as it gives sufficient time for healing at the site of surgery, including the removal of instrumentation. However, during the last two decades, there has been considerable controversy over the efficacy of fusion surgery involving CDOSD patients within the workers' compensation setting (Walsh & Dumitru, 1987). Given that treatment (both surgical and conservative) of patients under the workers' compensation jurisdiction has the resumption of occupational status as one of the primary goals, the use of work status as an objective measure of treatment has gained widespread use (Elfering, 2006). Return-to-work (RTW) is a commonly used outcome of work status, but other measures of work status, such as work retention, disability pension status and sick-leave period, are also frequently reported (Mayer, Gatchel, & Prescott, 2002).

The first meta-analysis evaluating the outcomes of fusion surgery was reported in 1992, and reviewed 47 studies published on the outcomes of fusion surgery between the years of 1966 and 1991. This meta-analysis reported that fusions resulted in 68% "satisfactory" outcomes overall (Turner et al., 1992). However, varying criteria were used to create a composite outcome, with success of the various criteria ranging from 16% - 95%. Within this review, "excellent/good" outcomes for occupational status were reported to stand at 62%, but no criteria were described for how successful outcomes for occupational status were measured or defined, and neither were the workers' compensation status of the studies under review taken into account. The studies reviewed within this meta-analysis were also poor in terms of methodology; there were no randomized controlled trials at all, only 4 were clearly prospective studies, 18 studies were clearly retrospective, and the remaining could not be classified under any methodology whatsoever (Turner et al., 1992).

Since the 1992 meta-analysis, there have been two large scale reviews of the literature specifically on spinal fusions. The first of these was a large-scale review of 20 years worth of published literature on lumbar fusions, including RCTs as well as non-randomized, prospective and retrospective studies investigating the success of fusions (Bono & Lee, 2004). This review of 84 articles in the literature concluded that, despite the increase in use of instrumentation technology over the 20 years, there was no evidence that spinal fusions improved overall clinical outcomes. Additionally, while the increased use of instrumentation resulted in better fusion rates, the difference was only marginal compared to non-instrumented fusions (Bono & Lee, 2004).

A second review summarized the findings of 31 RCTs on fusions for degenerative disc disease, and concluded that there is, overall, no evidence that fusions result in better outcomes than multidisciplinary rehabilitation programs alone and, at best, fusions were only more effective than standard conservative care (Gibson & Waddell, 2005). Included in this review of RCTs was one study from Sweden that showed better outcomes for the fusion group compared to a group of patients who received standard care (Fritzell, Hagg, Wessberg, Nordwall, & Group, 2001). However, the objective measure of outcome in that study (RTW at 2 years) averaged only 36% for the fusion group, compared to the standard care group's rate of approximately 13%. The nature of this anomalous finding was explained by a potential confound in the study that may have resulted in negative patient expectations within the standard care group; these patients received more of the standard care that had already been tried, and failed (Gibson & Waddell, 2005). Two other recent RCT's within this review showed no evidence that spinal fusion surgery resulted in better outcomes compared to exercise and cognitive therapy interventions (Brox et al., 2003; Fairbank et al., 2005). Finally, a recent evidenced-based review of all invasive treatment modalities for back pain, including fusions, also concluded that there is an insufficient body of evidence on the effectiveness of fusion surgery for degenerative disc disease (van Tulder, Koes, Seitsalo, & Malmivaara, 2006).

Weaknesses in the Research Literature on Fusion Surgery

One identifiable weakness in the fusion studies available in the literature, including the studies reviewed above, is that there is no single standardized objective outcome measure used. Among the outcome measures are: patient-rated satisfaction; physician-rated success; improvement in walking distance; re-operation rates; post-treatment sick leave; scores on standardized health inventories that measure disability and general health inventories; and the occasional RTW rates (Bono & Lee, 2004; Gibson & Waddell, 2005; Turner et al., 1992). The diversity of outcomes reported is understandable, given that selection of outcomes is driven by the main goals of the surgery, the research questions being explored, and the patient population under study (Mannion & Elfering, 2006). However, such diverse measures of outcome lead to a major problem for documenting, unequivocally, evidence of treatment efficacy for fusions in a standardized fashion, especially given that some of the utilized outcomes may be compromised by subjective expectations and biases.

Another potential confound that may inflate any composite categorization of various successful outcome criteria is the fact that many of the reviewed studies did not take into account workers' compensation status. Evidence indicates that patients on compensation are more likely to have poorer outcomes relative to non-compensation patients (Flynn & Hoque, 1979; Sander & Meyers, 1986; Waddell et al., 1979). A recent meta-analysis on the association between compensation status and surgery outcomes reported that patients receiving compensation were almost four times more likely to have unsatisfactory outcomes, and this association was consistent across different countries, type of studies, length of follow-up, and types of compensation (Harris, Mulford, Solomon, van Gelder, & Young, 2005). A possible explanation for this finding is that the adversarial medico-legal system within a compensation setting may result in the development of secondary gain issues (Dersh, Polatin, Leeman, & Gatchel, 2004; Fishbain, 1994; Gallagher, 1994; King, 1994; Leeman, Polatin, Gatchel, & Kishino, 2000). Further compounding this problem of poor outcomes is that patients covered by workers' compensation were found to be more likely to receive fusions for their back injuries, and were also more likely to have a re-operation within three years (Taylor, Deyo, Ciol, & Kreuter, 1996). Thus, this subset of fusion patients has a significant effect in driving up healthcare costs, while having little reported success in overcoming overall pain and disability.

Given these two confounding problems, clear distinctions need to be made when reporting the outcome of fusion surgery within systematic reviews. Although the main goal of the surgical intervention, in general, is to prevent instability in the spine and to relieve pain (Resnick et al., 2005), resuming full work status is the main treatment goal of interventions for patients in a workers' compensation setting (Elfering, 2006). Thus, while successful outcomes on measures like fusion rate, reduction of pain, and patient satisfaction are useful evaluations of the surgery, the focus should be on *objective* outcomes of work status when dealing with patients within a workers compensation setting. In addition to work status as an outcome, treatment within a workers' compensation setting is also geared towards resolution of pending compensation claims as well as a decrease in healthcare utilization (e.g., re-operation of the injured area). Therefore, an exhaustive set of objective socioeconomic outcomes are relevant in any assessment of patients within workers' compensation settings, which include healthcare utilization and claims settlement, in addition to work status (Mayer, Gatchel, & Prescott, 2002; Wesley, Polatin, & Gatchel, 2000).

Fusion Surgery in a Workers' Compensation Population

There have been several studies on fusion patients within the workers' compensation setting. The results have thus far been mixed. In contrast to the findings from Turner and colleague's 1992 meta-analysis, a large population-based study in 1994 of a group of injured workers in the Washington State workers' compensation setting found the exact opposite for outcomes of fusion surgery: 2 years following lumbar fusion surgery, 68% poor outcomes were reported (i.e., 32% RTW rate) (Franklin, Haug, Heyer, McKeefrey, & Picciano, 1994). A recent study, in 2006, from the same workers' compensation jurisdiction replicated this dismal finding; 2 years following fusion surgery, 64% of patients were disabled from work (i.e., 36% RTW rate) (Maghout-Juratli, Franklin, Mirza, Wickizer, & Fulton-Kehoe, 2006). Re-operation rates were also very high, averaging 22% compared to approximately 10% (range: 0% - 31%) as reported in the 1992 meta-analysis (Maghout-Juratli, Franklin, Mirza, Wickizer, & Fulton-Kehoe, 2006; Turner et al., 1992). Within the workers' compensation jurisdiction of the State of Utah, the overall outcomes for fusion were slightly better, as reported in a small-sample retrospective study (DeBerard, Masters, Colledge, Schleusener, & Schlegel, 2001). Utilizing the Stauffer-Coventry Index (Stauffer & Coventry, 1972) as a clinical surgical outcome measure, the study reported that, overall, 50% of the patients had poor outcomes at approximately 5 years follow-up. This was a composite that included pain relief, employment status, physical limitations, and medication usage. For the subcategory of employment status, 24% of patients did not return to work. The 76% classified as having returned to work included only 25% returning to previous work status, with the remaining 51% returning to light or modified work (DeBerard, Masters, Colledge, Schleusener, & Schlegel, 2001). In addition, this study reported a 24% re-operation rate, and 25% of the patients were permanently disabled at follow-up.

Fusion Surgery Combined with Biopsychosocial Rehabilitation

The underlying issue with regard to fusion surgeries based on the above reviewed literature is that the outcomes are fairly dismal, with a trend towards being worse within a purely workers' compensation setting. To date, very few studies have gone beyond assessing direct outcomes of the surgical procedure itself to study the outcomes achieved when the surgery is combined with an intensive interdisciplinary rehabilitation program based on the biopsychosocial paradigm. Previous studies that investigated the pairing of fusion surgery with such a rehabilitation program have found satisfactory outcomes. For example, a consecutive, prospective cohort study of fusion patients who were admitted into a functional restoration program averaged 1-year post-rehabilitation RTW rates of 87%, and were not significantly different from a matched comparison group of un-operated patients (90% RTW) within the same program (Mayer et al., 1998). The fusion patients in that study also fared comparably to the un-operated comparison patients on several other objective socioeconomic outcomes, including re-operation rates and percentage of recurrent injuries. Similar results were obtained from a study investigating patients who had anterior cervical fusion followed by rehabilitation, compared to an un-operated cohort of neck pain patients (Mayer, Anagnostis, Gatchel, & Evans, 2002).

The Present Study

The present study is the first large-cohort study within the workers' compensation setting that evaluated several objective socioeconomic outcomes in a prospective manner on a consecutive cohort of fusion surgical patients receiving intensive multidisciplinary rehabilitation. The fusion patients were compared to all the other non-fusion CDOSD patients within the consecutive cohort (i.e., the comparison group was representative of the general patient population within a tertiary rehabilitation setting for work-related injuries). The central hypothesis was that chronically disabled fusion surgical patients receiving a full course of interdisciplinary rehabilitation following surgery would have outcomes comparable to the general population of injured workers within this program who have not had a fusion surgery. Objective one-year post-rehabilitation socioeconomic outcomes included RTW, work retention, healthcare utilization, percentage of re-operations for the same injury, percentage of recurrent injuries to the original site of injury, and workers' compensation case settlement rates. The two groups were also evaluated on several psychosocial measures, including self-reports of depression, disability, and pain intensity, as well as psychiatric diagnoses on substance use disorders. One-year post-rehabilitation outcomes were also evaluated for the impact of several other risk factors in addition to fusion surgery. These risk factors included any patient demographic and psychosocial variables that significantly differed between the two groups prior to rehabilitation.

CHAPTER 2

METHODS

Patients

A consecutive cohort of 3,066 patients were identified as eligible for this prospective cohort design, based on diagnoses for chronic disabling occupational spinal disorders (CDOSD). All patients were admitted to a functional restoration program at the Productive Rehabilitation Institute of Dallas for Ergonomics (PRIDE), between the years of 1992 and 2003. Program participation criteria included: 1) four or more months elapsed since a work-related injury; 2) acute conservative care and/or secondary care failed to improve symptoms sufficient to allow full return to work; 3) surgery had not produced relief, resolution or simply was not an option; 4) severe pain and functional limitations remained; and 5) ability to communicate in English or Spanish. From this cohort, 383 patients were identified as having at least one spinal fusion procedure for degenerative disc disease. These fusion patients did not include spine fractures, dislocations, tumours, infectious etiologies, and neither did they receive a fusion for lumbar spondylolisthesis. This fusion (F) group consisted of 115 cervical fusions and 268 lumbar fusions, and was classified based on the index spinal fusion surgery. The remaining 2,683 patients did not have fusion (NF group), but may have had other types of spinal surgery such as discectomy, decompression, foraminotomy, or nuclear procedures.

Measures

Demographic Data

Demographic data were obtained from patient records, and included the following variables: age; gender; race; number of pre-rehabilitation surgeries; attorney representation; length of disability (in months); injured spinal regions with or without other comorbid body regions; and time (in months) from injury to index surgery, for all patients who had a surgery.

Pre-Rehabilitation Occupational Data

Pre-rehabilitation occupational data were obtained from patient records and case management interviews. These data included the following variables: type of occupation, physical demands of occupation, pre-injury weekly net wages, current weekly compensation from workers' compensation, and workers' compensation jurisdiction. Physical demands of occupation were classified as *Sedentary-Light* (0 – 15 lbs. frequent lifting, 0 – 25 lbs. occasional lifting), *Light-Medium* (16 – 25 lbs. frequent lifting, 26 – 50 lbs. occasional lifting), *Medium-Heavy* (26 – 50 lbs. frequent lifting, 51 – 100 lbs. occasional lifting), and *Heavy-Very Heavy* (greater than 50 lbs. frequent lifting, greater than 100 lbs. occasional lifting).

Psychosocial Measures

Psychosocial measures were collected both at a pre-rehabilitation intake interview and at the completion of the rehabilitation program. Validated self-report questionnaires presented to the patients at pre- and post-rehabilitation included: the Beck Depression Inventory (BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961); the Million Visual Analog Scale (MVAS; Anagnostis, Mayer, Gatchel, & Proctor, 2003) for measuring disability; and a pain drawing with a 10-cm visual analog scale measuring pain intensity (McGeary, Mayer, & Gatchel, 2006). Post-injury substance use disorders were evaluated at pre-rehabilitation using the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (SCID-IV; First, Spitzer, Gibbon, & Williams, 1997). These substance use disorders included alcohol abuse and dependence, non-opioid drug abuse and dependence, and opioid abuse and dependence. The diagnostic criteria for substance abuse and substance dependence are summarized in Table A.1.

One-Year Socioeconomic Outcomes

One-year post-rehabilitation socioeconomic outcomes were collected using a structured telephone interview (Mayer, Prescott, & Gatchel, 2000). These socioeconomic outcomes included: RTW; work retention at one-year; percentage seeking treatment from new healthcare provider; mean visits to a new healthcare provider; new surgeries to original area of injury; new compensable injuries; and, workers' compensation case settlement status. Table A.2 operationally defines each of these one-year socioeconomic outcomes.

Procedure

All patients were enrolled in a functional restoration program at PRIDE, and consented to the collection of data for the purposes of rehabilitation management, workers' compensation documentation, and research. Functional restoration is an intensive, medically supervised interdisciplinary program, combining quantitatively directed exercise progression with a multimodal disability management approach, incorporating psychological and case management techniques (Hazard, 1995; Hazard et al., 1989; Mayer & Gatchel, 1988). Developed in 1983, this rehabilitation program is a variant of chronic pain management based on the biopsychosocial model of pain and disability, and is specifically intended for rehabilitation of compensation injuries (Mayer et al., 1985). The efficacy of functional restoration for CDOSD, as well as the objective outcomes for treatment monitoring, have been extensively reviewed in the literature (Bendix et al., 1996; Hildebrandt, Pfingsten, Saur, & Jansen, 1997; Jousset et al., 2004; Mayer et al., 1998; Mayer et al., 1985; Mayer et al., 1986; Mayer et al., 1987; Wright, Mayer, & Gatchel, 1999).

Initial Evaluation.

All patients within this cohort received an initial multidisciplinary evaluation consisting of medical history, physical examination, quantitative functional evaluation, psychological intake interview, medical case management, and a disability assessment interview. These initial evaluations are required components that help guide the duration and intensity of the rehabilitation regimen by identifying physical and psychosocial limitations of each patient. As such, the rehabilitation process can be tailored towards being maximally efficient for each individual patient. Demographic data and pre-rehabilitation psychosocial measures on all patients were collected during this initial evaluation.

Medical history. These evaluations were conducted via access to patient health records from patients' primary care physician. Information gathered from this evaluation included the nature of injury, date of injury, types of surgery (if any), date of surgery (if any), treatment modalities and levels of care previously administered, and prior and current medication regimen.

Physical and functional capacity evaluations. These evaluations were used to assess a patient's *"weak link"*. For chronic pain patients who are suffering from physical deconditioning, the weak link is the injured area of the body which suffers from limited mobility, strength, and endurance compared to other regions of the body, and is usually the source of the patient's pain. While physical capacity evaluations measured mobility, strength, and endurance at the weak link, functional capacity evaluations assessed patients' ability in performing functional tasks, such as lifting, squatting, climbing, and bending. Reliable measurement apparatus were utilized in these evaluations, including inclinometers for measuring mobility, as well as isometric, isokinetic, and isoinertial devices for measuring strength, endurance, and functional capacity.

Psychosocial assessment. The accurate identification of psychosocial barriers to recovery and risk factors for poorer treatment outcomes, are a central component of functional restoration. All patients completed a battery of screening tests for perceived disability, symptom magnification, and somatization which included the MVAS and a quantified pain drawing with a pain intensity visual analog scale. The BDI was utilized to screen for depression. Several other psychosocial measures, which were beyond the scope of this study, were used for psychosocial screening as part of the functional restoration program. These included the Minnesota Multiphasic Personality Inventory (MMPI) and other types of psychiatric disorders evaluated within the SCID-IV.

Case management and disability assessment interview. All patients received a comprehensive interview with case managers in order to evaluate the nature of the workers' compensation claims, as well as any other compensation the patient may currently be receiving. In addition to the nature of compensation, this stage of the evaluation also determined if patients had any pending litigation associated with their injury, and had attorney representation. Additional information gathered during this interview process was also used to identify potential risk factors for poorer treatment adherence and outcomes, as well as any socioeconomic barriers to recovery. This included, for example, pre-injury occupational demands, level of job satisfaction prior to disability, relationship with employer, and pre-injury wage levels.

Rehabilitation

Phase 1. The rehabilitation stage of a functional restoration program is divided into three phases. The first phase of the program included narcotic detoxification, psychotropic medication management, and light aerobic and mobility training. Patients may be prescribed non-habituating anti-inflammatory medication at this phase if pain is exacerbated by the light exercises. The primary goal of the first phase is to "warm up" the patients for the intensive second phase of the rehabilitation. The light aerobic and mobility exercises also allow patients a gradual increase of activity at their deconditioned site of injury.

Phase 2. Once all the objectives of the first phase were satisfied, the program continued with an intensive second phase involving strength and endurance training under the direction of physical and occupational therapists. This stage of functional restoration has a two- to three-week duration, depending on the initial evaluations and the extent of patients' physical and psychosocial deconditioning. Initial stages of physical therapy involved focused rehabilitation of the weak link within a supervised environment, guided by pre-rehabilitation physical and functional capacity evaluations. Physical exercises were incrementally intensified over the duration of the second phase. Once optimal rehabilitation of strength, mobility, and endurance of the weak link was achieved, patients were then guided through occupational therapy which involved coordinating the weak link with other regions of the body in attempting functional tasks that simulate activities of daily living, as well as common tasks found in the workplace. Counseling and training in coping skills, pain and stress management, and maintaining the goal of returning to work were provided by psychologists and counselors throughout the duration of the second phase. The psychosocial interventions were also targeted towards addressing any fear-avoidance issues that patients may be exhibiting.

Phase 3. Upon completion of the intensive phase of the program, patients were provided with education geared towards maintaining program goals, instruction on home exercise regimens for fitness maintenance, additional counseling, and any necessary non-habituating psychotropic or anti-inflammatory medications. Case managers also provided occupational placement services, helped with any negotiations with patients' employers for temporary light or modified duty upon return to work, as well as in helping with workers' compensation case settlement issues. This final phase of the functional restoration program had a two- to three-week duration, and concluded with a post-program quantitative evaluation. This evaluation consisted of the various physical and a functional capacity evaluations, as well as the psychosocial battery of self-reports administered during the pre-rehabilitation evaluation.

One-year Follow-up Structured Interview

One-year follow-up structured interviews for gathering socioeconomic outcome data were conducted by interviewers independent of the rehabilitation team, and were unknown to the patients (Mayer, Prescott, & Gatchel, 2000). Efforts were made to contact all patients by telephone, unless they appeared for the interview in person. Data were also gathered from additional sources, such as employers, insurance carriers, family members, and attorneys (if patients had representation). Multiple points of data collection ensure reliable outcomes, as well as partial data on outcomes if the patient could not be directly contacted. All one-year socioeconomic outcomes were collected during this structured interview. These outcomes have been consistently reported from this program in the past, and have been shown to be reliable discriminant indicators of patients who complete the program compared to those that refuse treatment or do not complete it (Mayer et al., 1985; Proctor, Mayer, Theodore, & Gatchel, 2005). In addition, direct contact rates ranging from 93% - 98% have been consistently reported from this program (Gatchel, Mayer, & Theodore, 2006; Proctor, Mayer, Gatchel, & McGeary, 2004; Proctor, Mayer, Theodore, & Gatchel, 2005; Wright, Mayer, & Gatchel, 1999). The overall contact rate for one-year outcomes in the present study was

95%. Finally, the reliability of one-year outcomes was also established when compared to outcomes obtained from a two-year follow-up interview reported from this same program (Mayer et al., 1987).

Data Analysis

Univariate tests. Tests of association were conducted based on the Pearson chi-square (χ^2) test statistic for all analyses of differences between the F and NF groups on categorical demographic, psychosocial, and one-year outcome variables. Independent sample *t*-tests were conducted for all analyses of differences between the F and NF groups on continuous demographic, psychosocial, and one-year outcome variables. The significance criterion for all tests were set at $\alpha = .05$. Effect sizes for all significant effects are also reported, consisting of the odds ratio for all dichotomous categorical variables and Cohen's *d* for all continuous variables.

Multivariate tests. Regression analyses were conducted for each of the one-year outcome variables that significantly differed between the F and NF groups. Binary logistic regression analyses were utilized for all categorical outcomes variables, and a multiple regression analysis was utilized for the single continuous outcome variable. In these analyses, the entire cohort of patients were analyzed using the fusion grouping (F vs. NF), as well as any significant demographic and psychosocial covariates of fusion, as predictors in the regression analyses. These regression analyses allowed for the assessment of a comprehensive set of risk factors for poorer outcomes, in addition to fusion surgery. The significance criterion for all tests were set at $\alpha = .05$. Prior to running the regression analyses, all predictor correlation magnitudes were evaluated in a correlation matrix to ensure there was no redundancy among the predictors. The appropriate correlation coefficients were computed based on the nature of the variables: Pearson's *r* for pairs of continuous variables, as well as pairs of continuous and dichotomous variables; *phi* coefficients for categorical pairs of variables; and *eta* coefficients for non-dichotomous categorical and continuous pairs of variables.

CHAPTER 3

RESULTS

Program Completion Status

All data utilized in the analyses in the following sections were from patients who successfully completed the functional restoration program. Out of the total consecutive cohort of 3,066 patients identified with CDOSDs (N = 2683 for the NF group, N = 383 for the F group), there was an 85.5% program completion rate in the NF group (N = 2295) and a 78.1% program completion rate in the F group (N = 299). This difference between groups was significant [$\chi^2(1) = 14.36$, $p < .001$), with the odds of program completion being lower by a factor of 0.61 times (95% CI: 0.46, 0.78) for the F group, relative to the NF group.

Demographic Data

Patients in the F group differed significantly from those in the NF group on several demographic variables. Table A.3 summarizes the demographic differences between the two groups. Compared to the NF group, patients in the F group were older on average (44.20 vs. 42.29 years, $p = .002$), had a greater number of surgeries on average (1.61 vs. 0.29, $p < .001$), and had longer average length of disability since injury (31.57 vs. 13.98 months, $p < .001$). Compared to the NF group, the odds of being male in the F group was 1.30 times (95% CI: 1.01, 1.67) greater, and the odds of attorney representation in the F group was 1.69 times (95% CI: 1.29, 2.23) greater. The overall percentage of patients having had any surgeries (other than fusions) in the NF group was 20.3%, compared to 100% (at least one fusion) in the F group (p < .001). Significant differences were also observed in the breakdown of injured spinal regions, with or without other compensable body parts (p < .001). No significant differences between the two groups were found for race and elapsed time between injury and index spinal surgery (for all patients who had at least one spinal surgery).

Pre-Rehabilitation Occupational Data

The NF group and the F group were homogenous on all pre-rehabilitation occupational characteristics. No significant differences between groups were found on occupational category, physical demand of occupation, pre-injury net wage levels, and workers' compensation payments at the time of admission to the program. The cohort of patients in this study was also homogenous in terms of representation of the Texas workers' compensation jurisdiction. Table A.4 summarizes the pre-rehabilitation occupational data for both groups.

Pre-Rehabilitation Psychosocial Evaluations

Compared to the NF group, patients in the F group had higher pre-rehabilitation levels of depression as measured by the BDI (19.33 vs. 16.29, p < .001). When evaluated according to the percentage of patients suffering from moderate-to-severe depression levels (BDI empirical cut-off point ≥ 20), the F group was more likely to have higher depression levels, with a greater odds of 1.72 (95% CI: 1.34, 2.19) relative to the NF group. The groups also differed in the prevalence of post-injury substance abuse disorders. Relative to the NF group, the odds of having opioid dependence disorder in the F group was 3.21 times (95% CI: 2.40, 4.28) greater, while the odds of having non-opioid drug dependence in the F group was 4.37 times (95% CI: 1.23, 15.59) greater. The groups did not differ significantly on other categories of substance use disorders (alcohol abuse and dependence, drug abuse excluding opioids, and opioid abuse). Additionally, both groups did not differ significantly in terms of self-reports of pre-rehabilitation pain intensity and perceived disability as measured by the MVAS. Table A.5 summarizes the pre-rehabilitation psychosocial evaluation for both groups.

Post-Rehabilitation Psychosocial Evaluations

Upon successful completion of the program, the groups demonstrated no significant differences in terms of self-reported pain intensity ratings and level of disability on the MVAS. In terms of depression, the F group demonstrated a marginally higher BDI score compared to the NF group (10.70 vs. 9.18, $p = .005$). However, these average BDI scores for both groups were not clinically significant when viewed within the context of the empirical cut-off points for the BDI; a score of less than 13 on the BDI signifies minimal depression (if any). Further evaluation on the percentage of patients classified as having moderate-to-severe depression (BDI $\geq$ 20) at post-rehabilitation indicated no significant difference between the two groups. Finally, unlike the pre-rehabilitation psychosocial evaluations, there were no post-rehabilitation evaluations on substance use disorders. This is due to narcotic detoxification being one of the key components of the functional restoration program. Table A.6 summarizes the results of the post-rehabilitation psychosocial evaluations for both groups.

One-Year Socioeconomic Outcomes

The one-year socioeconomic outcomes had a small amount of missing data due to total non-contact with a small number of patients or their representatives at the time of the one-year post-rehabilitation interview. The overall successful contact rate across all outcome measures in this cohort was 95% (N = 2456). No significant differences in overall outcome non-contact rates were evident between the F group and the NF group [6% vs. 5%, $\chi^2(1) = 0.72$, $p = .397$], with similar non-significant differences for each of the one-year outcome variables. Therefore, interpretation of the results on one-year socioeconomic outcomes is valid and free of any bias associated with missing data due to non-contacts.

Initial unadjusted analyses on one-year socioeconomic outcomes indicated significant differences between the two groups on several outcome variables, with the NF group having a statistical advantage over the F group. The odds of returning to work was lower by a factor of 0.56 times (95% CI: 0.40, 0.78) for the F group relative to the NF group (80.7% vs. 88.2%, $p = .001$), while the odds for retaining work at one-year post-rehabilitation was lower by a factor of 0.63 times (95% CI: 0.47, 0.84) for the F group relative to the NF group (73.6% vs. 81.6%, $p = .002$). In addition, the odds of seeking treatment during the one-year post-rehabilitation period was 1.76 times (95% CI: 1.35, 2.30) greater for the F group, relative to the NF group (35.3% vs. 23.6%, $p < .001$). The F group also demonstrated higher number of visits to new healthcare providers during the one-year post-rehabilitation period, compared to the NF group (3.52 vs. 2.17 mean visits, $p < .001$). The groups demonstrated no significant differences on the remaining outcome variables, which included new surgeries to the original region of injury (excluding fusion hardware removal), re-injuries to the original region of injury, and workers' compensation case settlement rates. Table A.7 summarizes the results of the univariate analyses on one-year outcomes unadjusted for demographic or psychosocial covariates.

Evaluation of Risk Factors for Poorer Outcomes

The risk factors for poorer outcomes, in addition to fusion surgery, constitute a subset of the demographic and psychosocial variables. The variables were selected if they significantly differed between the F and NF groups, and include age, gender, number of pre-rehabilitation surgeries, attorney representation, length of disability, injured regions of the body (including comorbid non-spinal injuries), and psychosocial comorbidity (depression, opioid dependence, and non-opioid drug dependence). These variables, along with the fusion grouping, were then analyzed as predictors in regression analyses on the one-year socioeconomic outcomes that significantly differed in the univariate analyses between the F and NF groups.

Correlations among Risk Factors.

Prior to running regression analyses on the outcomes, the correlations among the predictors were evaluated to ensure no two predictors were highly correlated, thus creating redundancy in the set of predictors. Bivariate correlation coefficients were computed for each pair of predictor combinations and are summarized in Table A.8. None of the bivariate correlations indicated a magnitude that warranted concern for redundancy (i.e., magnitudes > .70; as suggested by Tabachnick & Fidell, 2001).

Therefore, all the variables identified as potential risk factors can be used as valid predictors of one-year outcomes in the regression analyses.

Predictors of RTW.

Results from the binary logistic regression on RTW as the outcome variable are summarized in Table A.9. The event modeled for this analysis was successful return to work. After adjusting for all potential risk factors, the significant predictors of poorer RTW rates (as evidenced by odds ratios < 1), in order of magnitude of impact, were opioid dependence disorder, attorney representation, age, and pre-rehabilitation depression as measured by the BDI. The odds of returning to work was lower by a factor of 0.59 times (95% CI: 0.41, 0.84) for patients with opioid dependence disorder, as compared to patients without opioid dependence disorder. Relative to patients without attorney representation, the odds of returning to work was lower by a factor of 0.64 times (95% CI: 0.46, 0.88) for patients with attorney representation. Additionally, for every one-year increase in age, the odds of returning to work were reduced by a factor of 0.95 (95% CI: 0.94, 0.97). Finally, for every one-unit increase in BDI score, the odds of returning to work was reduced by a factor of 0.98 (95% CI: 0.97, 0.99). None of the other predictors in this analysis, including fusion surgery, were significantly associated with RTW.

Predictors of Work Retention.

Results from the binary logistic regression on work retention as the outcome variable are summarized in Table A.10. The event modeled for this analysis was retaining work at one-year post-rehabilitation. After adjusting for all potential risk factors, the significant predictors of poorer work retention rates (as evidenced by odds ratios < 1), in order of magnitude of impact, were opioid dependence disorder, age, and pre-rehabilitation depression as measured by the BDI. The odds of retaining work was lower by a factor of 0.53 times (95% CI: 0.39, 0.72) for patients with opioid dependence disorder, relative to patients without opioid dependence disorder. In addition, every one-year increase in age reduced the odds of returning to work by a factor of 0.96 (95% CI: 0.94, 0.97). Finally, every one-unit increase in BDI score reduced the odds of returning to work by a factor of 0.98 (95% CI: 0.97, 0.99). None of the other predictors in this analysis, including fusion surgery, were significantly associated with work retention.

Predictors of Treatment-seeking from New Healthcare Provider.

Results from the binary logistic regression on treatment-seeking during the one-year post-rehabilitation period as the outcome variable are summarized in Table A.11. Seeking treatment from a new healthcare provider at any time during the one-year post-rehabilitation period was the event modeled for this analysis. After adjusting for all potential risk factors, the significant predictors of greater treatment-seeking rates (as evidenced by odds ratios > 1), in order of magnitude of impact, were female gender, opioid dependence disorder, number of prior surgeries, and age. The odds of seeking treatment was lower by a factor of 0.73 times (95% CI: 0.59, 0.91) for male patients, relative to female patients, thus indicating significantly greater likelihood of treatment-seeking among female patients. Relative to patients without opioid dependence disorder, the odds of seeking treatment was 1.36 times (95% CI: 1.02, 1.82) greater for patients with opioid dependence disorder. For surgeries received prior to rehabilitation, each surgery increased the odds of seeking treatment by a factor of 1.21 (95% CI: 1.06, 1.40). Finally, for each one-year increase in age, the odds of seeking treatment marginally increased by a factor of 1.01 (95% CI: 1.00, 1.02). None of the other predictors in this analysis, including fusion surgery, were significantly associated with treatment-seeking.

Predictors of Mean Visits to New Healthcare Provider.

Results from the multiple regression analysis using mean visits to new healthcare provider as the dependent variable are summarized in Table A.12. After adjusting for all potential risk factors, the significant predictors of mean visits to new healthcare provider, in order of magnitude of impact, were the presence of multiple spinal injuries (β = .10), greater number of prior surgeries (β = .07), and having opioid dependence disorder (β = .05). None of the other predictors in this analysis, including fusion surgery, were significantly associated with mean visits to a new healthcare provider.

Adjusted One-year Socioeconomic Outcomes.

The set of logistic regression analyses revealed that fusion surgery was not a risk factor for poorer one-year socioeconomic outcomes. A summarized version of the results from the analyses of one-year socioeconomic outcomes is reproduced in Table A.13, with the adjusted *p*-values and effect sizes displayed along with the original *p*-values and effect sizes computed from the initial univariate analyses.

CHAPTER 4

DISCUSSION

Given both the direct and indirect high costs associated with CDOSDs and spine surgeries, coupled with the mixed results on treatment efficacy of spine fusion procedures, it is no surprise that there has been much controversy over fusion surgery throughout the last two decades. The major issues that fuel the controversy over mixed results include: the lack of standardized objective criteria in assessing success of surgical outcome; the confounding of the general health population with the workers' compensation population; and the paucity of systematic research that goes beyond evaluating the immediate outcome of the surgical procedure itself, without taking into account the multifaceted nature of pain and disability that is best addressed within the biopsychosocial perspective. To that end, the present study investigated spinal fusion surgeries within a workers' compensation setting using objective socioeconomic outcomes relevant to CDOSDs, complemented by post-rehabilitation self-reports on depression, disability, and pain levels.

The central hypothesis was that chronically disabled spinal fusion patients, receiving a course of interdisciplinary rehabilitation post-surgery, would have outcomes comparable to the general population of injured workers within this program who have not had a fusion surgery. When evaluated without taking into account patient demographic factors, as well as psychosocial comorbidity, the data failed to support this hypothesis. Thus, the NF group evidenced a statistically significant advantage over the F group on several one-year socioeconomic outcomes, including occupational outcomes and healthcare utilization. However, the F group differed markedly from the NF group on several pre-rehabilitation demographic factors. In addition, pre-rehabilitation psychosocial evaluations indicated that fusion patients fared worse on depression levels and had a higher prevalence of substance use disorders, specifically opioid dependence disorder and non-opioid drug dependence disorder. Given the pre-rehabilitation psychosocial comorbidity, and the fairly heterogeneous demographics of the two groups of patients (including more than double the length of disability among fusion patients), it is noteworthy that both groups were comparable on psychosocial functioning upon *completion* of rehabilitation. However, the most promising results emerged when evaluating the one-year post-rehabilitation outcomes adjusted for demographic and psychosocial covariates. This decision to adjust for these demographic and psychosocial factors was also informed by previously reported evidence of these variables being risk factors of poorer outcomes in a workers' compensation setting (DeBerard, Masters, Colledge, Schleusener, & Schlegel, 2001; Franklin, Haug, Heyer, McKeefrey, & Picciano, 1994; Jordan, Mayer, & Gatchel, 1998; Maghout-Juratli, Franklin, Mirza, Wickizer, & Fulton-Kehoe, 2006; Mayer, Gatchel, & Evans, 2001; McGeary, Mayer, Gatchel, Anagnostis, & Proctor, 2003; Wright, Mayer, & Gatchel, 1999). Holding these variables constant between the two groups showed that fusion patients were comparable to those who had no fusions on all one-year outcome variables. The RTW rate of 81%

for fusion patients (79% for lumbar fusions alone) and the re-operation rate of 2.9% for fusion patients (3.2% for lumbar fusions alone) reported in this study stand in stark contrast to the best population-based estimates of two-year post-surgical fusion outcomes from the Washington State Workers' Compensation System (Franklin, Haug, Heyer, McKeefrey, & Picciano, 1994; Maghout-Juratli, Franklin, Mirza, Wickizer, & Fulton-Kehoe, 2006). Figures B.1 and B.2 compare the outcome rates for RTW and re-operations, respectively, of this study's cohort against the population-based outcomes from the Washington State Workers' Compensation System. To facilitate a more accurate comparison, RTW and re-operation rates of lumbar fusions only (79% and 3%, respectively) have been extracted from this study's fusion cohort. Although the one-year outcomes from this study are compared to two-year outcomes from the Washington State Workers' Compensation System, it should be noted that one-year outcomes from this program have been demonstrated to be reliably stable even at two years post-rehabilitation (Mayer et al., 1987).

The multivariate regression analyses allowed evaluation of the outcomes of fusion surgical patients after adjusting for demographic and psychosocial covariates. At the same time, the analyses also allowed for the identification of several risk factors for poorer outcomes. Opioid dependence disorder was the most robust among the risk factors, being associated with both poorer occupational outcomes and increased healthcare utilization. Older age and higher levels of depression were also associated with poorer rates in both RTW and work retention at one-year post-rehabilitation, while attorney representation was associated with lower rates of RTW. In addition to opioid dependence disorder, increased treatment-seeking during the one-year post-rehabilitation period was also associated with female gender and greater number of pre-rehabilitation surgeries. And finally, greater number of pre-rehabilitation surgeries and the presence of multiple comorbid spinal injuries were associated with increased visits to new healthcare providers during the one-year post-rehabilitation period. Overall, the results indicate these variables as *independent* risk factors for poorer one-year socioeconomic outcomes, specifically for occupational and healthcare utilization outcomes.

The risk factors that were identified by these analyses were supported by the literature. A recent study from this same functional restoration program identified opioid dependence as an independent risk factor for poorer one-year socioeconomic outcomes, even after adjusting for demographic and psychosocial factors, including other psychiatric comorbidity (Dersh et al., in press; Mayer et al., In press). This trend remains consistent in the present study, and underscores the need for a greater emphasis on addressing opioid dependence within chronic pain settings, especially given the increasing trend in use of prescription opioids (Luo, Pietrobon, & Hey, 2004). The findings on age and number of prior surgeries replicate the results from similar multivariate regression analyses used in the study on fusion patients in the Utah State Workers' Compensation System to identify demographic predictors of surgical outcome; both variables were robust predictors across almost all of the outcome criteria in that study (DeBerard, Masters, Colledge, Schleusener, & Schlegel, 2001). Older age has also been reported to be associated with a decreasing linear trend in RTW and work retention among CDOSD patients (Mayer, Gatchel, & Evans, 2001). The role of attorney retention in this study also indirectly replicates evidence from previous studies that found unsettled financial disputes and ongoing litigation status as predictors of poorer outcomes within a workers' compensation population, both in a study of direct surgical outcome (DeBerard, Masters, Colledge, Schleusener, & Schlegel, 2001) and also following interdisciplinary rehabilitation (Wright, Mayer, & Gatchel, 1999). Support for the findings in this study on female gender as a risk factor for poorer outcomes has also been demonstrated within this functional restoration program in the past (Gatchel, Mayer, Kidner, & McGeary, 2005; McGeary, Mayer, Gatchel, Anagnostis, & Proctor, 2003), and is also cited as a risk factor for poorer direct outcome of surgery (Mannion & Elfering, 2006). The status of comorbid depression as a predictor of poorer clinical outcomes among chronic pain patients is also widely substantiated in the literature on rehabilitation of chronic pain (Arnow et al., 2006; Currie & Wang, 2004; Keogh, McCracken, & Eccleston, 2006; Weisberg, Gorin, Drozd, & Gallagher, 1996).

Although risk factors have been identified, it is difficult to infer the causal relationship behind their association with poorer outcomes, since such inferences remain in the realm of speculation unless systematically investigated within the patient population in question. For example, while it has been speculated that patients with opioid dependence disorder may be at risk for a relapse on prescription opioids to manage flare-ups of pain during the post-rehabilitation period, it is not possible to definitively conclude this without post-rehabilitation evaluations of opioid consumption during the one-year period (Mayer et al., In press). However, some of these risk factors are consistent with observations made in the literature on chronic pain and treatment outcomes. It is possible that older patients may be close to the age of retirement and thus continue to adopt the sick role during the one-year post-rehabilitation period in order to “ride out” the span of time between rehabilitation and retirement (DeBerard, Masters, Colledge, Schleusener, & Schlegel, 2001). Additionally, older age has been demonstrated to be associated with higher post-rehabilitation perception of disability, which may have a negative impact on motivation to resume occupational activity (Mayer, Gatchel, & Evans, 2001). Higher levels of pre-rehabilitation depression may also reflect underlying, or predisposing, psychosocial structures that may pose a risk for such patients resuming the sick role when faced with challenging situations during the one year post-rehabilitation period (Gatchel, 1991;, 1996). In terms of more complicated physical comorbidity, such as greater number of surgeries and multiple spinal injuries, it has been noted that these patients have increased complications, such as more scar tissues and greater susceptibility to forming psychosocial barriers to recovery (DeBerard, Masters, Colledge, Schleusener, & Schlegel, 2001). Given the increased complexity in such cases, it is no surprise that these factors were associated with greater healthcare utilization in the present study. Additionally, prior investigation within the CDOSD population has shown that patients who have high levels of healthcare utilization following rehabilitation were twice as likely to have had surgery for their injuries (Proctor, Mayer, Gatchel, & McGeary, 2004). Finally, the findings on the association between female gender and increased healthcare utilization is also consistent with prior studies that have elaborated on the greater likelihood of reporting pain and seeking treatment for pain among females (Campbell, Hughes, Girdler, Maixner, & Sherwood, 2004; McGeary, Mayer, Gatchel, Anagnostis, & Proctor, 2003; Unruh, 1996).

The underlying principle demonstrated in this study is that chronic pain and disability due to spinal disorders can be efficiently managed and can result in highly satisfactory outcomes, independent of whether a patient has had a fusion surgery. The key for such positive outcomes is to provide chronically disabled patients with intensive interdisciplinary rehabilitation, if improvement is not initially observed as a result of fusion surgery. It should be noted that patients presenting in a tertiary rehabilitation setting, such as functional restoration, have already exhausted all avenues of treatment, including surgical and non-operative primary and secondary rehabilitation (Mayer, Gatchel, Porter, & Theodore, 2006). Current estimates of workers' compensation patients persisting with work disability 3 to 4 months post-injury across the United States range from 5% - 25% (Mayer & Polatin, 2000). Therefore, the majority of injured patients within the workers' compensation setting, including those who have received spinal fusions, are able to overcome disability and return to work. The remaining patients thus represent the "worst case scenario". Given this patient population, the comparable outcomes reported in the present study between patients who received spinal fusion versus those who did not, clearly demonstrate that spinal fusion surgery does not have to result in poorer outcomes, especially within a workers' compensation setting. However, it should be emphasized that administering interdisciplinary rehabilitation following spinal fusion surgery is not necessarily targeted only for those patients who become chronically disabled post-surgery. Adequate post-surgical rehabilitation utilizing a biopsychosocial approach has been shown to result in satisfactory outcomes for spine surgery patients, including reduced primary healthcare demands in fusion patients, compared to control groups receiving standard care (Donceel, Du Bois, & Lahaye, 1999; Soegaard, Christensen, Lauerberg, & Bunger, 2006). Furthermore, both post-surgical and chronic pain rehabilitation interventions for fusion patients should also focus on addressing the risk factors identified in this study, due to the higher prevalence of these risk factors among fusion patients. The biopsychosocial approach to rehabilitation, that eschews a "one-size-fits-all" interventional approach, provides an optimal foundation for the evaluation and treatment of the complex nature of fusion patients suffering from persistent, disabling chronic pain (Gatchel & Oordt, 2003).

A previous study investigating the outcomes of functional restoration for a smaller-sized consecutive cohort of patients who had received spinal fusion surgery used a matched un-operated comparison group, with patients matched on age, gender, race, length of disability, treatment date, and type of workers' compensation jurisdiction (Mayer et al., 1998). Results of that study demonstrated that fusion patients fared comparably on work outcomes, re-operation rates, and recurrent new injuries, but fared significantly better on health utilization outcomes compared to the un-operated matched comparison group. The decision to not use an un-operated matched comparison group in the present study has good reason. Matching on these variables may lead to criticism that the fusion patients are being compared to a "cherry-picked" sample of the worst un-operated patients, especially given the higher length of disability and older age that have been demonstrated in the fusion group. Using the entire consecutive cohort of non-fusion CDOSD patients as a comparison group provides a more natural comparison, representative of the general population of patients within a tertiary rehabilitation setting. It is also noteworthy that the overall results of the present study have replicated the findings in the earlier un-operated matched comparison study. Although, technically, one could argue that adjusting the *p*-values and odds ratios of the outcomes for the relevant demographic and psychosocial differences is a method of post-hoc controlled comparison, it should be noted that the multivariate analysis of risk factors provided evidence for variables other than fusion surgery that contributed towards the slightly poorer rates of the outcomes in the fusion group.

One potential limitation of this study is that the analyses on outcomes included only program completers. For some, this may open up the question of whether it was really the effect of functional restoration that contributed to better outcomes among the fusion patients compared to the outcome rates in the literature, or if it is perhaps that the population of fusion patients within the Texas workers' compensation jurisdiction simply have a trend towards better outcomes, independent of any tertiary rehabilitation. However, a recent large cohort study of completers vs. non-completers from the same functional restoration program has demonstrated that non-completers (including those who have had spinal fusion surgery) fared dramatically worse on all one-year socioeconomic outcomes. For example, program non-completers had reduced odds for

RTW by a factor of 10, reduced odds for work retention by a factor of 7, and 7 times greater odds for having re-operations (Proctor, Mayer, Theodore, & Gatchel, 2005).

Another potential limitation of this study is that it was not an RCT, thus preventing any inferences of causality. Given ethical considerations and legal requirements with regard to providing the best available care to all patients, it is therefore unrealistic to expect RCT designs for research purposes within this area of investigation. Nevertheless, randomized trials have been utilized in evaluating the functional restoration approach within nations adopting the socialized medical approach, and the results have documented the superiority of the functional restoration approach in rehabilitating CDOSD patients (Bendix et al., 1996; Corey, Koepfler, Etlin, & Day, 1996; Hildebrandt, Pfingsten, Saur, & Jansen, 1997; Jousset et al., 2004). Given the logistical limitations, a prospective cohort design was best suited to explore the research question of interest in this study. Prospective designs define a grouping variable of interest (i.e., fusion surgery) prior to the undertaking of the study. Additionally, data are collected in a prospective manner over time (i.e., one-year outcome variables), eliminating some of the more critical biases associated with non-RCT designs, such as using data from convenience sampling. Therefore, although no inferences of causality can be made from this study, associations and the identification of risk factors are possible given the prospective design.

On a final note, the amount of analyses conducted in this study may raise concerns about the inflation of Type I error levels (i.e., an increased probability of incorrectly rejecting a hypothesis of no difference between the F group and the NF group). There are two points to be made about this issue. Firstly, conventional uses of Type I error control apply to instances where three or more groups are analyzed with multiple comparisons to detect group differences on a given dependent variable (Hays, 1994; Keppel & Wickens, 2004). However, the logic behind Type I error control can also be generalized to instances where multiple tests are done within a given study, as is the case with the present study. This leads to the second point, in terms of applying some type of per-comparison Type I error correction. Applying such per-comparison error corrections would have reduced the level of α dramatically, given the number of tests within the present study. Such large reductions in the probability of committing a Type I error, at a per-comparison level, comes at a considerable cost; namely the increase in the probability of committing a Type II error or falsely concluding that there is no difference between groups when there actually is one (Cohen, 1988). This translates to considerable loss of power. Therefore, consideration needs to be given to the relative costs associated with Type I and Type II errors (Cohen, 1988, p. 5). Moreover, there is still substantial debate in the biostatistical and epidemiologic literature concerning whether such adjustment for multiple tests is warranted (Aickin & Gensler, 1996; Perneger, 1998). Even the less conservative Holm (1979) procedure is viewed by some as too conservative.

Since a major component of this study was to identify risk factors for poorer outcomes, it is therefore more costly to commit a Type II error relative to a Type I error. For example, failing to detect a significant group difference on any of the demographic or psychosocial covariates of fusion surgery simply due to an overly restrictive α level would have resulted in exclusion of that variable in the analyses on risk factors, thus removing a valid assessment of the variability in outcomes associated with that particular variable. This could have then resulted in artificial inflation of the impact of other variables assessed in the analyses of risk factors for poorer outcomes. In practical terms, failure to identify a risk factor solely on the grounds of statistical error control may then result in insufficient attention given to this potentially important factor in future research. If the effect in question was indeed spurious, and a significant difference was concluded as a result of Type I error, it is preferable that such a variable be ruled out as a risk factor through systematic investigation in a follow-up study rather than being ignored altogether. In any case, the potential for being misled by spurious results was negated by the presentation of effect sizes, from which the magnitude of any group differences can be evaluated.

Conclusion

The present study resolves some of the controversy raging over the treatment efficacy of spine fusion surgery. Potential limitations within the literature were identified, including the lack of a standardized, objective measure of outcome following fusion surgery, the confounding of the general health and workers' compensation populations, and the lack of focus on systematic outcomes research pairing fusion surgery with adequate post-surgical rehabilitation. The present study compared a consecutive cohort of fusion patients to a group of patients who had no fusion surgeries, but were representative of the tertiary rehabilitation population with work-related spine injuries. Results indicated that patients who have had fusions fared comparably to patients without fusion surgeries on all of the key outcome variables relevant to a workers' compensation population. There is now substantial evidence that the poorer outcomes associated with fusion patients are driven primarily by patient selection characteristics as well as psychosocial comorbidity. Furthermore, given that pain and disability are multifaceted phenomena, presently best explained by the biopsychosocial perspective (Block, Gatchel, Deardorff, & Guyer, 2003; Gatchel & Okifuji, 2006; Turk & Monarch, 2002), the common focus on direct surgical outcomes do not take into account the psychological, social and environmental aspects of pain and disability. Therefore, the controversy regarding fusions should shift from evaluating direct surgical outcomes towards investigating the treatment efficacy of fusions paired with adequate post-surgical rehabilitation, with a focus on multidisciplinary interventions and a multivariate analytical approach in the spirit of the biopsychosocial paradigm.

APPENDIX A

TABLES

Table A.1. Diagnostic Criteria for Substance Abuse and Dependence Disorders

Substance Abuse Disorder	Substance Dependence Disorder
1. Maladaptive pattern of recurrent substance use, resulting in clinically significant impairment or distress, as manifested by one (or more) of the following, • failure to fulfill major responsibilities • physical endangerment • legal problems • continued use despite recurrent social or interpersonal problems associated with the effects of the substance 2. The above occurring within a 12-month period 3. Does not meet criteria for Substance Dependence	1. Maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, • tolerance to the substance • withdrawal symptoms present • substance taken in larger amounts or over a longer period than was intended • persistent desire or unsuccessful efforts to cut down or control substance use • heavy investment in time spent on activities necessary to obtain the substance, use the substance, or recover from its effects • important social, occupational, or recreational activities are given up or reduced • continued use despite knowledge of having a persistent or recurrent physical or psychological problem associated with the substance 2. The above occurring at any time in the same 12-month period

SOURCE: Adapted from the American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition (DSM-IV).

Table A.2. Definition of One-Year Socioeconomic Outcome Measures

Socioeconomic Outcomes	**Definition**
Return to work	Any reported period of work during the one year post-rehabilitation
Work Retention	Maintaining employment during the time of the one-year interview
Seeking Treatment from a New Healthcare Provider	Percentage of patients seeking additional healthcare from healthcare providers other than the treating or rehabilitation physicians during the post-rehabilitation year
Mean Visits to New Healthcare Provider	Number of visits to providers other than the treating or rehabilitation physicians during the post-rehabilitation year
New spine surgeries to originally injured region	New surgeries to the compensable injured spinal region anytime during the post-rehabilitation year (excluding removal of fusion instrumentation)
New injuries to originally injured region	Recurrent injuries to the original spinal region resulting in lost time from work
Worker's compensation case settlement	Ongoing financial disputes or litigation related to the injury

Table A.3. Demographic Characteristics of Study Patients (N = 2594)

Variables	**NF N = 2295**	**F N = 299**	**χ^2 or *t***	**df**	**p**	**O.R. (95% CI) or Cohen's d**
Age in years (SD)	42.29 (9.90)	44.20 (8.63)	-3.18	2592	.002	0.20
Gender [% Male (n)]	60.6 (1390)	66.6 (199)	4.00	1	.046	1.30 (1.01, 1.67)
Race [% (n)]			1.90	3	.594	N/A
Caucasian	65.2 (1471)	68.5 (202)				
African-American	15.1 (341)	14.2 (42)				
Hispanic	18.7 (421)	15.9 (47)				
Other	1.0 (23)	1.4 (4)				
Mean # of Pre-Rehab Surgeries (SD)	0.29 (0.79)	1.61 (0.92)	-26.64	2592	< .001	1.65
% of Pre-Rehab Surgeries [% (n)]	20.3 (465)	100	809.50	1	< .001	N/A
Attorney Retained [% (n)]	19.3 (405)	28.8 (85)	14.40	1	< .001	1.69 (1.29, 2.23)
Length of Disability in months (SD)	13.98 (20.23)	31.57 (23.06)	-13.86	2592	< .001	0.86
Compensable Regions [% (n)]			30.92	3	< .001	N/A
Cervical only	5.5 (126)	13.0 (39)				
Thoracic and/or Lumbar only	54.3 (1247)	56.9 (170)				
Multiple Spinal	15.9 (365)	12.0 (36)				
Multiple Musculoskeletal (at least one spinal)	24.3 (557)	18.1 (54)				
Time from Injury to Surgery in months (SD)	14.84 (45.28)	16.05 (17.03)	-.41	604	.685	N/A

Table A.4. Pre-Rehabilitation Work-Related Information (N = 2594)

Variables	**NF N = 2295**	**F N = 299**	**χ^2 or *t***	**df**	**p**	**O.R. (95% CI) or Cohen's d**
Occupational Category [% (n)]			5.85	8	.664	N/A
Professional, Technical, Managerial	12.8 (269)	12.7 (37)				
Clerical and Sales	12.5 (262)	11.0 (32)				
Service (food, housekeeping, health aides)	15.5 (326)	15.1 (44)				
Agriculture	0.3 (6)	0.7 (2)				
Chemical and Refining	0.4 (8)	0				
Machine Trade (heavy manufacturing)	6.5 (136)	7.9 (23)				
Light Manufacturing (assembly, repair)	9.1 (192)	8.6 (25)				
Construction Trades	9.6 (202)	12.4 (36)				
Miscellaneous	33.3 (699)	31.6 (92)				
Physical Demand of Occupation [% (n)]			6.31	3	.097	N/A
Sedentary - Light	12.5 (267)	8.1 (24)				
Light - Medium	25.5 (545)	24.0 (71)				
Medium - Heavy	37.9 (811)	39.9 (118)				
Heavy - Very Heavy	24.1 (515)	28.0 (83)				
Pre-Injury Weekly Net Compensation [$ (SD)]	465.19 (262.22)	479.51 (242.41)	-.87	2339	.382	N/A
Current Weekly Compensation [$ (SD)]	261.02 (191.46)	248.20 (182.15)	1.05	2207	.295	N/A
Texas Worker's Compensation System [% (n)]	90.2 (2024)	86.7 (255)	3.40	1	.065	N/A

Table A.5. Pre-Rehabilitation Psychosocial Measures (N = 2594)

Variables	**NF N = 2295**	**F N = 299**	**χ^2 or *t***	**df**	**p**	**O.R. (95% CI) or Cohen's d**
Pre-BDI (SD)	16.29 (10.10)	19.33 (10.69)	-4.81	2527	< .001	0.30
Pre-BDI ≥ 20 [% (n)]	32.4 (723)	45.1 (133)	18.83	1	< .001	1.72 (1.34, 2.19)
Pre-MVAS (SD)	92.91 (23.44)	94.95 (25.74)	-1.05	2527	.293	N/A
Pre-Pain Intensity (SD)	6.63 (1.89)	6.53 (1.95)	.90	2521	.370	N/A
Post-Injury Substance Use Disorder [% (n)]						
Alcohol Abuse	0.9 (16)	0.7 (2)	.08	1	.778	N/A
Alcohol Dependence	1.2 (22)	0.7 (2)	.53	1	.466	N/A
Drug Abuse (excluding opioids)	0	0	N/A	N/A	N/A	N/A
Drug Dependence (excluding opioids)	0.3 (6)	1.4 (4)	6.16	1	.013	4.37 (1.23, 15.59)
Opioid Abuse	0.2 (3)	0	.46	1	.496	N/A
Opioid Dependence	12.7 (228)	31.9 (88)	67.58	1	< .001	3.21 (2.40, 4.28)

Table A.6. Post-Rehabilitation Psychosocial Measures (N = 2594)

Variables	**NF N = 2295**	**F N = 299**	**χ^2 or *t***	**df**	**p**	**O.R. (95% CI) or Cohen's d**
Post-BDI (SD)	9.18 (8.44)	10.70 (9.23)	-2.84	2413	.005	0.18
Post-BDI ≥ 20 [% (n)]	10.6 (226)	14.1 (41)	3.18	1	.074	N/A
Post-MVAS (SD)	64.27 (30.02)	66.10 (29.64)	-.97	2410	.331	N/A
Post-Pain Intensity (SD)	4.71 (2.21)	4.81 (2.20)	-.74	2395	.459	N/A

Table A.7. One-Year Socioeconomic Outcomes of Program Completers (N = 2594)

Variables	**NF N = 2295**	**F N = 299**	χ^2 **or** t	**df**	**p**	**O.R. (95% CI) or Cohen's d**
Return to Work [% (n)]	88.2 (1817)	80.7 (217)	12.04	1	.001	0.56 (0.40, 0.78)
Work Retention [% (n)]	81.6 (1670)	73.6 (198)	9.70	1	.002	0.63 (0.47, 0.84)
Seeking Treatment from New Provider [% (n)]	23.6 (502)	35.3 (97)	17.68	1	< .001	1.76 (1.35, 2.30)
Mean # of Visits to New Provider (SD)	2.17 (5.69)	3.52 (7.35)	-3.55	2389	< .001	0.23
New Surgeries (Orig Area, excl. HW Removal) [% (n)]	2.3 (49)	2.9 (8)	.38	1	.540	N/A
New Injury (Original Area with Lost Time) [% (n)]	2.4 (49)	2.2 (6)	.03	1	.872	N/A
Case Settled [% (n)]	94.5 (2046)	94.3 (263)	.04	1	.846	N/A

Table A.8. Correlations Among Predictors Evaluated as Risk Factors of Poorer One-Year Outcomes (N = 2594)

Variables	Age	Pre BDI	Prior Surgeries	Length of Disability	Gender (%Male)	Attorney Retained	Opioid Dependence	Drug Dependence	Fusion Surgery
Age	1								
Pre BDI	-.01	1							
Prior Surgeries	.12	.10	1						
Length of Disability	.14	.09	.37	1					
Gender (% Male)	-.09	-.12	.03	-.03	1				
Attorney Retained	.03	.07	.06	.07	.00	1			
Opioid Dependence	-.01	.10	.14	.14	.04	.04	1		
Drug Dependence	-.03	.05	.02	.03	-.04	.00	-.03	1	
Fusion Surgery	.06	.10	.46	.26	.04	.08	.18	.06	1
Compensable Regions	.10	.11	.15	.03	.17	.08	.05	.03	.11

Table A.9. Logistic Regression Analysis of RTW (N = 2594)

Variables	B	Std. Error	Wald $\chi 2$	df	p	Exp(B) [95% CI]
Constant	4.81	.51	89.26	1	< .001	123.14
Opioid Dependence	-.53	.18	8.25	1	.004	0.59 (0.41, 0.84)
Attorney Retained	-.45	.17	7.30	1	.007	0.64 (0.46, 0.88)
Age	-.05	.01	36.89	1	< .001	0.95 (0.94, 0.97)
Pre-Rehabilitation BDI Score	-.02	.01	9.24	1	.002	0.98 (0.97, 0.99)
Gender (% Male)	.27	.15	3.23	1	.072	1.31 (0.98, 1.77)
Fusion Surgery	-.19	.22	.76	1	.383	0.83 (0.54, 1.27)
Length of Disability	.00	.00	.94	1	.332	1.00 (0.99, 1.00)
Number of Prior Surgeries	-.13	.09	2.13	1	.145	0.88 (0.74, 1.05)
Drug Dependence (excl. opioids)	-1.09	.74	2.17	1	.140	0.34 (0.08, 1.43)
Compensable Regions						
Cervical Only			1.70	3	.636	1.00
Thoracic and/or Lumbar Only	-.17	.32	.29	1	.591	0.84 (0.45, 1.58)
Multiple Spinal	-.22	.36	.36	1	.551	0.81 (0.40, 1.64)
Multiple Musculoskeletal	.03	.34	.01	1	.919	1.04 (0.53, 2.02)

Table A.10. Logistic Regression Analysis on Work Retention (N = 2594)

Variables	B	Std. Error	Wald $\chi 2$	df	p	Exp(B) [95% CI]
Constant	3.99	.42	88.81	1	< .001	54.3
Opioid Dependence	-.64	.16	16.34	1	< .001	0.53 (0.39, 0.72)
Age	-.04	.01	43.06	1	< .001	0.96 (0.94, 0.97)
Pre-Rehabilitation BDI Score	-.02	.01	9.40	1	.002	0.98 (0.97, 0.99)
Fusion Surgery	-.14	.19	.53	1	.465	0.87 (0.60, 1.26)
Gender (% Male)	.14	.13	1.13	1	.288	1.15 (0.89, 1.47)
Attorney Retained	-.20	.15	1.79	1	.181	0.82 (0.61, 1.10)
Length of Disability	.00	.00	.99	1	.319	1.00 (0.99, 1.00)
Number of Prior Surgeries	-.09	.08	1.30	1	.253	0.91 (0.78, 1.07)
Drug Dependence (excl. opioids)	-.64	.72	.78	1	.378	0.53 (0.13, 2.18)
Compensable Regions						
Cervical Only			.69	3	.875	1.00
Thoracic and/or Lumbar Only	-.13	.27	.24	1	.627	0.88 (0.52, 1.49)
Multiple Spinal	-.14	.30	.22	1	.636	0.87 (0.48, 1.57)
Multiple Musculoskeletal	-.03	.28	.01	1	.926	0.97 (0.56, 1.70)

Table A.11. Logistic Regression Analysis on Seeking Treatment from New Healthcare Provider (N = 2594)

Variables	B	Std. Error	Wald $\chi 2$	df	p	Exp(B) [95% CI]
Constant	-1.85	.36	25.70	1	< .001	0.16
Gender (% Male)	-.31	.11	7.56	1	.006	0.73 (0.59, 0.91)
Opioid Dependence	.31	.15	4.47	1	.034	1.36 (1.02, 1.82)
Number of Prior Surgeries	.19	.07	7.43	1	.006	1.21 (1.06, 1.40)
Age	.01	.01	3.95	1	.047	1.01 (1.00, 1.02)
Fusion Surgery	.32	.17	3.43	1	.064	1.38 (0.98, 1.93)
Pre-Rehabilitation BDI Score	.00	.01	.00	1	.946	1.00 (0.99, 1.01)
Drug Dependence (excl. opioids)	.05	.71	.00	1	.946	1.05 (0.26, 4.21)
Attorney Retained	.04	.13	.08	1	.778	1.04 (0.80, 1.35)
Length of Disability	.00	.00	.15	1	.700	1.00 (0.99, 1.00)
Compensable Regions						
Cervical Only			4.56	3	.207	1.00
Thoracic and/or Lumbar Only	.26	.24	1.10	1	.294	1.29 (0.80, 2.08)
Multiple Spinal	.50	.27	3.35	1	.067	1.64 (0.97, 2.80)
Multiple Musculoskeletal	.18	.26	.50	1	.480	1.20 (0.72, 1.98)

Table A.12. Multiple Regression Analysis of Mean Visits to New Healthcare Provider (N = 2594)

Variables	**B**	**Std. Error**	***t***	**p**	***β***
Constant	.48	.92	.52	.604	
Number of Prior Surgeries	.51	.20	2.54	.011	.07
Opioid Dependence	.84	.40	2.10	.036	.05
Age	.02	.01	1.27	.204	.03
Pre-Rehabilitation BDI Score	.01	.01	1.05	.294	.02
Fusion Surgery	.49	.48	1.01	.315	.03
Gender (% Male)	-.24	.30	-.80	.424	-.02
Attorney Retained	.22	.35	.62	.538	.01
Length of Disability	-.01	.01	-.74	.459	-.02
Drug Dependence (excl opioids)	1.89	1.92	.98	.325	.02
Compensable Regions					
Cervical Only (reference category)					
Thoracic and/or Lumbar Only	.44	.60	.73	.465	.04
Multiple Spinal	1.76	.69	2.56	.011	.10
Multiple Musculoskeletal	.50	.64	.78	.433	.04

Table A.13. One-Year Socioeconomic Outcomes: Before and After Adjustments for Risk Factors (N = 2594)

Variables	**NF N = 2295**	**F N = 299**	**p**	**O.R. (95% CI) or Cohen's d**	**p ***	**O.R. (95% CI) or Cohen's d ***
Return to Work [% (n)]	88.2 (1817)	80.7 (217)	.001	0.56 (0.40, 0.78)	.383	0.83 (0.54, 1.27)
Work Retention [% (n)]	81.6 (1670)	73.6 (198)	.002	0.63 (0.47, 0.84)	.465	0.87 (0.60, 1.26)
Seeking Treatment from New Provider [% (n)]	23.6 (502)	35.3 (97)	< .001	1.76 (1.35, 2.30)	.064	1.38 (0.98, 1.93)
Mean # of Visits to New Provider (SD)	2.17 (5.69)	3.52 (7.35)	< .001	0.23	.315	0.05
New Surgeries (Orig Area, excl. HW Removal) [% (n)]	2.3 (49)	2.9 (8)	.540	N/A	.540	N/A
New Injury (Original Area) [% (n)]	2.4 (49)	2.2 (6)	.872	N/A	.872	N/A
Case Settled [% (n)]	94.5 (2046)	94.3 (263)	.846	N/A	.846	N/A

* p-values and effect sizes adjusted for Age, Gender, Number of Pre-Rehab Surgeries, Length of Disability, Compensable Musculoskeletal Regions, Attorney Representation, and Psychosocial Comorbidity

APPENDIX B

FIGURES

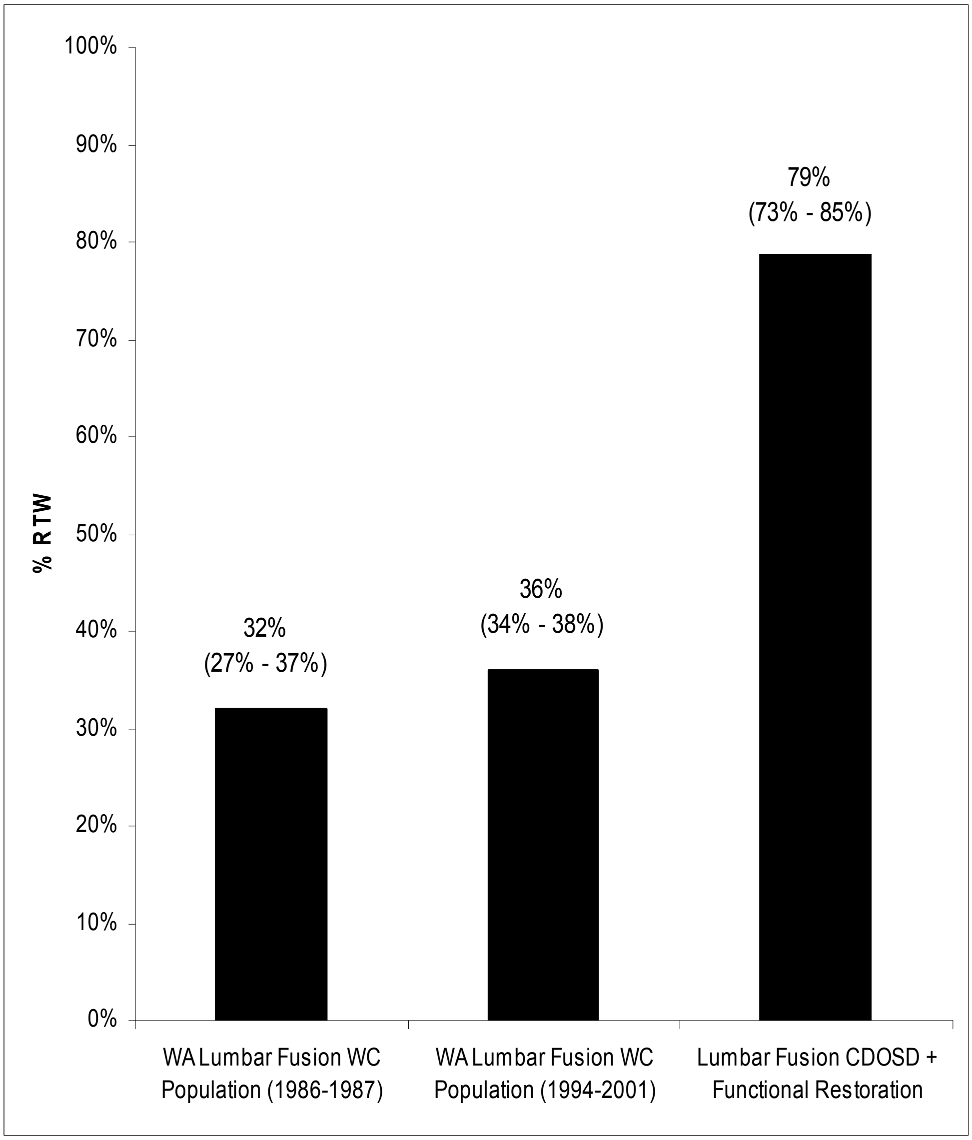

Figure B.1. Return-to-work (RTW) rates of lumbar fusion group compared to population-based estimates of RTW rates from the workers' compensation (WC) system of Washington (WA) State. Overlapping 95% confidence intervals, in parentheses, indicate no significant difference in pairwise comparisons of RTW rates.

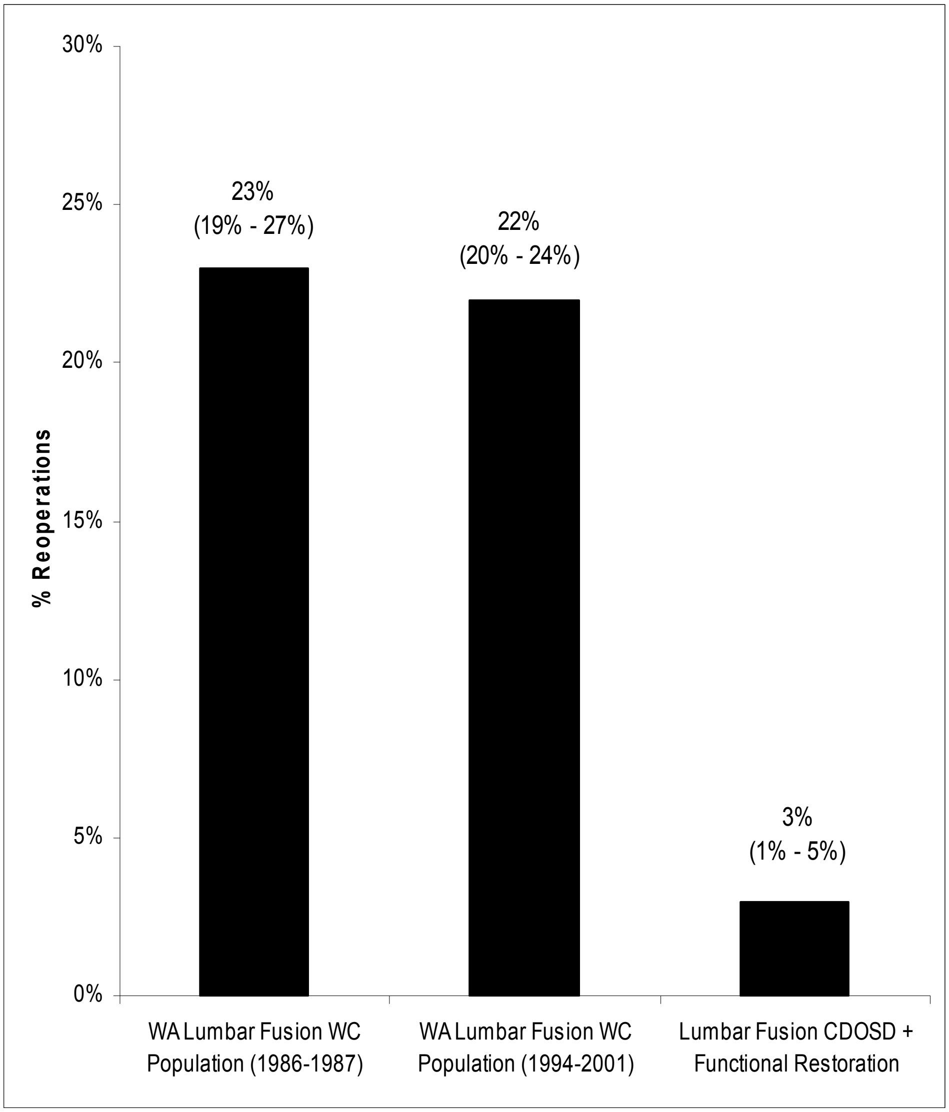

Figure B.2. Re-operation rates of lumbar fusion group compared to population-based estimates of re-operation rates from the workers' compensation (WC) system of Washington (WA) State. Overlapping 95% confidence intervals, in parentheses, indicate no significant difference in pairwise comparisons of re-operation rates.

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