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Outcomes and Presurgical Correlates of Lumbar Interbody Cage Fusion

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OUTCOMES AND PRESURGICAL CORRELATES OF LUMBAR INTERBODY CAGE FUSION

by

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ABSTRACT

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Rates of lumbar fusion surgery have been increasing with an estimated 192,000 procedures performed annually. However, satisfactory outcomes of lumbar fusion vary considerably and often emphasize technical success, such as arthrodesis, rather than functional and quality of life outcomes. Interbody cage fusion was recently developed and touted as a superior alternative to existing lumbar fusion procedures. There is, however, a paucity of research to support these claims, particularly with regards to functional and quality of life outcomes. Moreover, predictive correlates of outcomes for interbody cage fusion have not been given adequate attention in the literature. The aims of this study were to characterize patients undergoing this new procedure, examine functional and multidimensional outcomes, and investigate the predictive efficacy of presurgical variables. A retrospective cohort research design was employed and entailed medical record reviews for presurgical data and telephone outcome surveys at least 18 months following surgery.

Seventy-three patients who had undergone lumbar interbody cage fusion were identified from the private practice of an orthopedic surgeon and the Workers' Compensation Fund of Utah. Presurgical variables coded for analysis included age at the time of surgery, severity rating of presurgical spinal pathology, smoking tobacco,

depression, and pursuing litigation at the time of surgery. Of the total sample, 56 patients (76.7%) completed outcome surveys that assessed patient satisfaction, back-specific functioning, disability status, and physical and mental health functioning.

While arthrodesis was achieved for most patients (84%), almost half were dissatisfied with their current back condition. Outcomes regarding disability and functioning were mixed. Arthrodesis was only moderately associated with better outcome and for a quite limited set of measures. Three of the five presurgical variables (tobacco use, depression, and litigation) were consistently predictive of patient outcomes.

Findings are discussed and compared to existing data on lumbar fusion procedures, and clinical implications for improved patient selection and possible interventions are highlighted. Consideration is given to the limitations of this study, such as retrospective design, no matched controls, and sample size. Directions for future research are suggested.

(161 pages)

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LIST OF DEFINITIONS

Arthrodesis: Process by which solid bony material is eventually formed between spinal vertebrae resulting in a fusion.

Degenerative disc disease: A chronic and progressive condition, which leads to spinal instability and higher intradiscal pressure/biochemical abnormality. This condition results in leg and low back pain.

Disc herniation: Disc material between the vertebrae that has ruptured, resulting in compression of adjacent nerve roots. Disc herniation is often painful and may result in neurologic deficits and bowel/bladder dysfunction.

Diskectomy: Surgical procedure developed to remove herniated disc material that has seeped into adjacent spinal areas.

Hollingshead Index of Social Position: A widely used index of Socioeconomic Status that uses both education and occupation. This index has seven levels with higher scores representing lower status.

Lumbar fusion: Surgical procedure used to foster the development of solid bony material between lumbar spinal vertebrae. The procedure often uses instrumentation devices, such as titanium interbody cages and or screws and rods, to facilitate successful stability and fusion.

Pseudarthrosis: Failure to achieve solid fusion between spinal vertebrae.

Radiographs: Imaging studies, such as x-rays, computed tomography scan, or magnetic resonance imaging, used to document spinal alignment or abnormalities, as well as arthrodesis/pseudarthrosis.

Segmental instability: Refers to an abnormality of the spinal anatomy, whereby the vertebrae become easily misarranged and may impinged upon nerve roots.

Spondylolisthesis: A condition of the spine in which one vertebra slips forward upon another. This may result from trauma to the spine or degenerative processes over time, and may be present with back and leg pain. However, rarely are bowel or bladder symptoms also present.

Spondylolysis: A condition of the spine that is characterized by the presence of a bony defect at the pars interaticulars (posterior to the vertebrae) which can result in spondylolisthesis. Appears related to repetitive hyperextension of the spine.

Spinal stenosis: A condition of the spine in which the nerve root canal becomes narrower, through degenerative processes and misalignment, and entraps nerves.

CHAPTER I

INTRODUCTION

Statement of the Problem

The prevalence and deleterious effects of low back pain (LBP) have been well documented throughout the literature, and are, arguably, approaching epidemic proportions in industrialized countries (Frymoyer & Cats-Baril, 1991; Papageorgiou, Croft, Ferry, Jayson, & Silman, 1995; Waddell & Turk, 2001). It is believed more than 31 million Americans are affected by LBP annually and, at any given time, 2-5% of the U.S. population has a disabling low back condition (Andersson, 1991; Frymoyer & Cats-Baril 1987). More recently, Garofalo and Polatin (1999) reported up to 80% of the population in western industrialized societies is affected by LBP at some point in their lives, while 30 - 70% of those will experience a recurrence (i.e., three or more episodes of pain).

Consequently, the economic costs resulting from LBP and disability are astounding. It is estimated that medical treatment of chronic LBP costs $9,000 to $19,000 per person annually, while the total impact as a nation is nearly $171 billion (Straus, 2002). Not surprisingly, workplace injuries and compensation claims are an important part of the fiscal equation with more than $11 billion paid annually for workers' compensation benefits for work-related LBP and disability (Webster & Snook, 1994). Additional estimates suggest that LBP is the leading cause of disability and accounts for approximately 16% of all workplace compensation claims and about 33% of total claims costs (Hadler, Carey, & Garrett, 1995; Nachemson, 1992).

In response to the escalating costs, there is a growing body of literature devoted to the prevention and treatment of LBP. In fact, the U.S. Department of Health and Human Services (1994) published Clinical Practice Guidelines in an effort to provide physicians

with information about the efficacious assessment and treatment of LBP. Barring potentially dangerous underlying physical maladies, the guidelines emphasize conservative treatment consisting of anti-inflammatory medications, physical therapy, patient education, and light exercise. Although a great deal of attention has been given to nonoperative treatment of LBP (Atlas, Keller, Chang, Deyo, & Singer, 2001; Gatchel & Turk, 1999; McCracken & Turk, 2002; Wheeler & Hanley, 1995), some individuals do not show improvement from such strategies. Rather, these individuals may experience chronic and disabling LBP and turn to surgical treatment as a potential remedy.

In fact, chronic disabling LBP is one of the most common conditions resulting in surgery, with upwards of 300,000 surgeries performed annually (Taylor, Deyo, Cherkin, & Kreuter, 1994; Taylor et al., 1995). One particular surgical intervention, lumbar fusion, has seen a dramatic increase in rates of utilization since the 1980s (Katz, 1995). Although not meant as a first line of surgical treatment, lumbar fusions account for 17% of the low back operations with approximately 192,000 performed annually (National Center for Health Statistics, 1998; Taylor et al., 1994). It is widely thought in the surgical community that unremitting LBP may originate from degenerated intervertebral lumbar disc or disc injury resulting in spinal instability (Weiner & Fraser, 1998). Lumbar fusion is largely believed to reduce pain and disability by correcting this instability. An inspection of the literature reveals that lumbar fusion treatment is, by no means, a single technique that surgeons uniformly perform. Several options exist regarding approach (anterior, posterior, or combined) and method of fixation (spinal plate, pedicle screw, or interbody device). Although the approach and method of fixation may vary, the objective of lumbar fusion remains consistent across surgical techniques.

Despite the increased utilization of lumbar fusion, the efficacy of this surgery in treating LBP remains controversial. Turner and colleagues (1992), for example, reviewed spinal fusion studies from 1966 to 1991, and found modest satisfactory clinical outcomes

ranging from 15 - 95% (with an average of 68%). Some researchers more readily contend that lumbar fusion has not been shown to be effective in treating LBP resulting from degenerative discs (Franklin, Haug, Heyer, McKeefrey, & Picciano, 1994; Nachemson, 1992; Nachemson, Zdeblick, & O'Brien, 1996). A myriad of possible explanations for mixed lumbar fusion outcomes have been suggested, including instrumentation failure, poor surgical technique, pseudarthrosis, poor patient selection, and psychosocial variables such as litigation, socioeconomic status, secondary gain, and psychological distress (Block & Callewart, 1999; DeBerard, Masters, Colledge, Schleusener, & Schlegel, 2001; Epker & Block, 2001; Franklin et al., 1994; Hadler et al., 1995; Herkowitz & Sidhu, 1995; Robinson & Riley, 2001).

More recently, a surgical technique known as lumbar interbody cage fusion has been advanced in an effort to improve outcomes. The interbody cage method, unlike the techniques using posterolateral pedicle screws/rods, was developed to accomplish fusion without such additional spinal fixation devices. It is thought that interbody cage fusion reduces LBP by providing improved stabilization, disc space decompression, and extraction of painful intervertebral disc material (Burke, 2001; Matge & Leclercq, 2000; Onesti & Ashkenazi, 1998; Weiner & Fraser, 1998). The interbody cage method of lumbar fusion has been initially touted as a more cost-effective alternative with a shorter operative period, fewer complications, and increased rates of arthrodesis relative to other lumbar fusion procedures (Hacker, 1997; Kuslich, Ulstrom, Griffith, Ahern, & dowdles, 1998; Kuslich et al., 2000; Ray, 1997b).

Although a small number of studies have presented preliminary support for the interbody cage method, few studies have been conducted independent of the developers of the different cages. In one such study, Agazzi, Reverdin, and May (1999) concluded that the interbody cages did not show the superior results, in terms of fusion rates and clinical success, that were initially reported by the developers of the apparatus. Moreover, the

emphasis within the extant literature has been on biomechanical and medical outcomes with little attention given to quality of life and functional ability. Thus, it appears that evidence as to the long-term effectiveness and clear benefit for the use of interbody cage fusion is equivocal, at best. Additionally, patient characteristics for those at risk of having a poor response to surgery or for whom this method may be contraindicated have yet to be clearly identified in the literature. Given the importance of patient selection for spinal surgery (Block & Callewart, 1999; Robinson & Riley, 2001), appropriate candidate identification for lumbar interbody cage fusion is also needed and has, to date, not been adequately addressed. It seems that psychosocial and demographic presurgical antecedents that have been shown to be predictive of patient functioning and disability status following other lumbar fusion procedures (DeBerard et al., 2001; Franklin et al., 1994) could be important in determining successful outcomes and patient well-being with interbody cage fusion, as well. Thus, when considering the economic costs involved, increasing utilization of lumbar fusions, and few studies examining this relatively new fusion method, it is critical that outcomes be identified and steps taken to minimize the number of patients experiencing poor outcomes.

Purpose and Research Questions

The purpose of this study was to describe patients, examine multidimensional outcomes, and investigate predictive correlates for lumbar interbody cage fusion in a sample of Utah patients. Patients having undergone interbody cage fusion were characterized with regard to presurgical and outcome variables (e.g., length of hospital stay, arthrodesis rates, patient satisfaction, disability and back-specific functioning, and overall health), with particular attention directed toward examination of the predictive strength of the presurgical variables. To accomplish this aim, both a retrospective medical record review and telephone outcome survey (at least 18 months postsurgery) were

conducted. The following research questions were addressed in this study:

1. What is the average length of hospital stay for the patient sample?
2. What is the nature of the patient sample with regard to the presurgical variables?
3. What are the intercorrelations of the presurgical variables?
4. What are the rates of surgical complications for the sample?
5. What is the rate of arthrodesis in the sample?
6. What are the rates of satisfaction for the sample?
7. What are the rates of good, fair, and poor outcomes for the sample, based upon pain reduction, returning to work, physical functioning, and medication usage?
8. What is the rate of continued work disability for the sample following surgery?
9. What is the level of postsurgical back-specific functioning for the sample?
10. What are the levels of postsurgical functioning across a multidimensional health-index for the sample, and how does it compare with existing norms?
11. What are the interrelationships among the outcome variables for the sample?
12. To what degree is arthrodesis a predictor of outcomes for the sample?
13. To what degree is a multivariable biopsychosocial presurgical model predictive of the outcome variables for the sample?

CHAPTER II

REVIEW OF THE LITERATURE

The effects of low back pain (LBP) are wide reaching in terms of both the number of people involved and the economic cost in the United States. It is estimated that 80% of people will experience LBP at some point in their lives, resulting in an estimated overall economic toll of nearly $171 billion (Garofalo & Polatin, 1999; Straus, 2002). Interestingly, while a minority of individuals experience chronic LBP, they account for the majority of the economic impact (Robinson & Riley, 2001). Moreover, LBP and injury constitute 10 - 19% of all workers' compensation claims but account for about 33 - 41% of total claims costs (Hadler et al., 1995; Nachemson, 1992).

Traditionally, LBP less than 6 months in duration is classified as acute, whereas pain persisting beyond this period is considered to be more chronic in nature. The distinction between acute and chronic pain, however, is now considered less clear than previously thought (de Vet et al., 2002; Turk & Okifuji, 2001; Waddell & Turk, 2001), which affects choice of treatment and may complicate its amelioration. In spite of these recent distinctions, conservative nonoperative treatment has generally been considered the typical first line of treatment for LBP (Atlas et al., 2001; Garofalo & Polatin, 1999; Gatchel & Turk, 1999; McCracken & Turk, 2002; Nachemson, 1992; Wheeler & Hanley, 1995). However, in some cases where nonoperative regimens for treating pain fail to show improvements, surgical interventions are considered the next line of attack (Herkowitz & Sidhu, 1995; Holm, 2002; Mooney, Saal, & Saal, 1996). Lumbar fusion ranks as the second most common low back operation with nearly 192,000 performed annually (Davis, 1994; National Center for Health Statistics, 1998), and by most accounts does not appear to be on the decline. In fact, various indices suggest that rates of lumbar fusion procedures are steadily increasing (Katz, 1995; Straus, 2002).

Indications for Lumbar Fusion

Although controversial, lumbar fusion has been advocated for many conditions resulting in LBP (Elam, Taylor, Ciol, Franklin, & Deyo, 1997; Nachemson et al., 1996). For instance, surgical fusion has been broadly used as a treatment for spinal deformity and segmental instability, secondary to degenerative, congenital, infectious, neoplastic, traumatic, and iatrogenic conditions (Burke, 2001; Fraser, 1995; Hanley, Phillips, & Kostuik, 1991; Sonntag & Marciano, 1995; Tay & Berven, 2002). More typically, however, the indication for lumbar fusion procedures has been disabling chronic pain that is secondary to degenerative disc disease or injury. In fact, Davis (1994) reported that between 1979 and 1990 the diagnoses (and their rates) most associated with lumbar fusion include intervertebral disc disorders (51%), spondylolisthesis (24%), spinal stenosis (10%), spondylolysis (10%), and vertebral fracture (7%). It is noteworthy that these spinal conditions/diagnoses may, and often do, overlap each other, which may help explain why researchers (e.g., Turner et al., 1992) often find no significant differences in outcomes with regard to diagnosis.

Lumbar conditions and instability are often assessed by physical examination and imaging techniques, such as magnetic resonance imaging (MRI) and computed tomography (CT) scan (Mooney et al., 1996). Unfortunately, findings from these methods have been shown to have substantial variability, inherent subjectivity, and disagreement on what constitutes relevant pathology (Waddell & Turk, 2001). For instance, studies evaluating MRI scans in asymptomatic subjects (with no history of back problems) have found significant rates of bulging disc (50% - 79%), disc herniation (21% - 36%), and degenerative disc (34% - 93%; Boden, Davis, Dina, Patronas, & Wiesel, 1990; Jensen et al., 1994). Additionally, Fraser (1995) has pointed out that the terms of spinal instability and motion do not indicate the exact pain source, which may exist in the disc, facet joints, ligaments, or other surrounding soft tissue. Consequently, Hambley (1998) asserted that

only 15% of the individuals presenting with LBP are accurately diagnosed. More recently, Saal (2002) concluded that an integral part of the problem of diagnosis of lumbar spine disorders is the lack of an adequate Agold standard@ (particularly where the presence or absence of pain is the end point). Many authors (e.g., Loeser, Deyo, Cherkin, Conrad, & Wiesman, 1993; Taylor et al., 1994) have also suggested that the problems associated with inadequate assessment of lumbar instability, and indications for surgery, are reflected in the substantial variations in regional rates of spinal fusion. For instance, Katz (1995) argued that the 40% higher fusion rate in the South (relative to the West) is reflective of a wide range of beliefs about the indications for surgical intervention. Thus, evidence from many sources reveals the difficulty in accurately and appropriately selecting individuals suitable for spinal fusion.

Lumbar Interbody Cage Fusion Apparatus and Procedure

In spite of these obstacles, a variety of techniques and procedures for lumbar spine fusion have developed over the years. In fact, a number of options exist regarding graft material used, surgical approach, and method of fixation/instrumentation (Agazzi et al., 1999; Fraser, 1995; Herkowitz & Sidhu, 1995; Weiner & Fraser, 1998). Relatively recent technological advances in the field of spinal surgery, based upon animal spine models, have resulted in the design of interbody fusion cages, which are purported to represent a significant step forward in the treatment of LBP (Hacker, 1997; Hambley, 1998). The most widely used interbody cage apparatus in the United States utilizes a perforated horizontal threaded cylinder made of titanium alloy that is screwed into the disc space and filled with bone graft material. It is thought that such a design allows for bony growth during the postoperative healing phase, and eventual arthrodesis (i.e., solid bone fusion)

usually by the 12th month (Brodke, Dick, Kunz, McCabe, & Zdebdlick, 1997; Hacker, 1997; McAfee et al., 2001; Tay & Berven, 2002). The Bagby and Kuslich (BAK; Kuslich et al., 1998) apparatus and Ray threaded fusion cage (RTFC; Ray, 1997a, 1997b) are two of the few interbody fusion devices currently approved by the U.S. Food and Drug Administration (FDA) and, consequently, the most extensively used and studied. Although the respective cage manufacturers have made unique adaptations (e.g., varying perforation pattern), the BAK and RTFC share a fairly uniform design and surgical technique (Onesti & Ashkenazi, 1998).

In performing spinal fusion, the surgeon removes intervertebral disc material, restores disc height, drills and taps the disc space between the vertebrae for proper fit, and inserts the interbody cage into the anteroposterior plane. Routinely, a pair of interbody cages are inserted bilaterally; though, arthrodesis has been recently attempted with a single threaded cage (Zhao, Wang, Hou, & He, 2002). Interbody cage fusion can be performed from either a posterior or anterior approach on multiple lumbar levels with the most frequent occurring in the L4 - L5 and L5 - S1 vertebral spaces. Although interbody cages have been designed to accomplish arthrodesis as a stand-alone procedure without additional means of fixation, adjunctive methods (e.g., pedicle screws) have also been used in some cases to increase stabilization (McAfee et al., 1999). The risk of possible complications, as seen with other spinal fusion methods, is thought to be reduced with interbody cage fusion by necessitating less dissection of muscle and soft tissue and requiring briefer operative exposure and duration (Hambley, 1998). The advances with spinal fusion resulting from the use of interbody threaded cages have also recently generated interest in their application via the more technically demanding laparoscopic procedure (McAfee, Regan, Geis, & Fedder, 1998; Mulholland, 2000; Regan, Hansen, & McAfee, 1999).

Lumbar Interbody Cage Fusion Outcome Studies

Interbody cage fusion has been touted as having distinct mechanical and surgical advantages. Animal studies and initial reports indicated that interbody cage devices produce remarkable lumbar stability/stiffness, increased arthrodesis rates, disc space preservation, and fewer complications relative to other methods of spinal fusion (Agazzi et al., 1999; Bagby, 1988; Brodke et al., 1997; Leclercq, 1995; Rapoff, Ghanayem, & Zdeblick, 1997; Ray 1997a). Given that the BAK and RTCF interbody cages were developed to limit complications of graft extrusion, disc space collapse, and pseudarthrosis, it follows that initial studies emphasized detailing their biomechanical properties and advantages. Findings from recent clinical studies are also supportive of the interbody cage being a safe and effective means for achieving spinal arthrodesis. Unfortunately, randomized controlled clinical trials are nonexistent for this procedure, and few studies have sufficiently examined long-term functional outcomes of patients.

In a nonrandomized comparison between lumbar anteroposterior fusion (360° fusion) and the BAK device, Hacker (1997) found favorable results for the use of the interbody cages. That is, lumbar interbody cage fusion yielded shorter operative periods, reduced blood loss, and was a more cost-effective alternative. Similarly, the BAK fusion patients experienced briefer hospitalizations (3.50 vs. 5.33 days) following lumbar surgery. Patients undergoing the BAK interbody cage fusion were found to return to work sooner and have less need for additional reparative surgery than their non-BAK counterparts. However, Hacker also found that the two fusion techniques yielded similar levels of patient satisfaction and that potential predictors (e.g., age, gender, number of levels fused) were not associated with surgical outcome. In a similar study, Ray (1997b) nonrandomly assigned 50 patients to either the RTCF or 360° fusion technique. Although all patients were reported to have achieved arthrodesis at 1-year postsurgery, significantly greater costs were evidenced with the 360° fusion technique across all expensed categories (e.g.,

hospitalization charges, surgeon' fees, reoperation expenses). In fact, the RTCF and 360° fusion procedures were $25,171 and $41,813, respectively, for a single-level fusion, which reflects a 40% difference in cost.

In one of the few prospective multicenter clinical trials, Ray (1997a) investigated outcomes from the RTCF at several points after surgery up to 2 years. The mean length of hospitalization following surgery for either a one- or two-level lumbar fusion was 5 days. Although the sample size was considerable in this study, the patients appeared to be closely screened and met strict selection criteria. The arthrodesis rate was an impressive 96% at the 2-year follow up. Interestingly, successful clinical outcomes (based on a good/excellent rating of pain and functional status) occurred for 47% of the patients at 6 months and only 65% at 2-years postsurgery. The author did not, however, report any additional functional outcomes for the patients in this study or in the comparison with the 360° fusion procedures.

Kuslich and colleagues (1998), in perhaps the most frequently cited prospective multicenter clinical trial, examined outcomes for the BAK device in 143 patients up to 3 years after lumbar fusion. The mean length of hospitalization was 4.4 days postfusion with the longest stays seen with the two-level posterior approach. The authors reported excellent arthrodesis rates of nearly 91% and 98% at 2- and 3-years postsurgery, respectively. Further, they found that more than 85% of the patients reported pain relief/reduction at 2-year followup. Ninety-one percent of the patients experienced improved functioning at followup, whereas 78% returned to work by 2 years postsurgery. The rates of surgical complications appeared low (i.e., major complication rate of 2%) in this study, and the authors concluded that the BAK method is preferable to pedicle screw fusions when weighing reoperation rates, length of hospital stay, operative blood loss, and work resumption rates (Kuslich et al., 1998). Although these findings are impressive, it is

notable that the authors did not include a randomized control group for comparison in this study.

In a study of a highly select subset of the original cohort, Kuslich and colleagues (2000) examined 4-year follow-up data for the BAK interbody cage. Unfortunately, the authors also had an overall low response rate (21%) at followup. Across the assessments between 2 and 4 years, arthrodesis rates ranged from 68 - 100%, with the overall solid-fusion rate being 95%. The authors found that pain relief and functional improvement were evident as early as 3 months postsurgery and were maintained at the 4-year followup period. Seventy-four percent of the patients had returned to work by 2 years after surgery, whereas 2 years later approximately 71% of the sample were working. Given only 21% of the patients from the original BAK cohort were included in the 4-year follow-up, it is impossible to know the true incidence of successful outcome. Several authors (e.g., Lonstein, 2001; Winter, 2001; Zdeblick, 2000) have also suggested that the study may have been influenced by the potential financial affiliation of the surgeons with the cage product. Thus, one should interpret this highly select subset of data cautiously.

In a nonrandomized study, Vamvanij, Fredrickson, Thorpe, and Stodnick (1998) compared BAK cage fusion with three other spinal fusion techniques in 56 patients diagnosed with disc desiccation (without herniation). This study also investigated arthrodesis rates, clinical outcome, functioning, and reports of pain levels and interference. With regard to arthrodesis, the patients undergoing the BAK technique showed the highest rate of consolidation (i.e., 88% vs. 50%, 60%, and 69%). Similarly, the BAK cage yielded a clinical outcome success rate of 63% as compared to the rates ranging from 36 - 46% for the other spinal methods. The BAK surgical condition also generated lower reports of pain interference with daily activities. However, functional outcome (e.g., rates of work resumption) did not vary significantly among the different fusion techniques. All the procedures also appeared similar in terms of hospitalization periods and complication

rates. Although generally supportive of the improved efficacy of the BAK method, this study's conclusions are limited by the low numbers of patients in all of the spinal fusion conditions and the usual concerns associated with nonrandomization.

More recently, Matge and Leclercq (2000) conducted a retrospective analysis of 222 patients who underwent either the RTCF or BAK interbody cage lumbar fusion. Similar to the findings of Kuslich et al., (1998; 2000), and Ray (1997a), arthrodesis rates at 1- and 2-year follow-up intervals were 91 and 96%, respectively. Clinical follow-up, however, was reported to vary between 1 and 7 years postfusion with specific assessment periods and rates left unreported. Additionally, nearly 91% of the interbody fusion procedures in the study involved only a single lumbar level. Successful clinical outcomes were noted for 80% of the patients, whereas 15% were described as improved but still disabled from their original employment. The remaining 5% of the patients were characterized as demonstrating minimal to no improvement, having total disability preventing any employment, and needing prescribed analgesics. Few complications were observed in the study, and the authors concluded that lumbar interbody cage fusion (i.e., RTCF and BAK) appears to be safe and efficacious.

Elias, Simmons, Kaptain, Chadduck, and Whitehill (2000), also using a retrospective design, examined the complications associated with the RTCF for 67 patients operated on by a single surgeon. The mean hospitalization period was 4.25 days following surgery. Although patient followup extended to 2 years in some cases, the mean was approximately 10 months with only 67% of the patients being followed for more than 6 months after spinal surgery. Unlike the findings of Matge and Leclercq (2000) and Ray (1997a), the authors found that 34% of the patients experienced loosening of the interbody cage, while 21% underwent a second surgery to treat pseudarthrosis. The authors concluded that 25% of the patients required additional surgery to correct a problem directly related to the RTCF. Additionally, Elias et al. noted that 42% of the

patients had LBP 3 months after surgery, and at least 15% had pain that persisted for a year or longer. In spite of the limitations of the study's design and restricted follow-up, these findings are in striking contrast to those of previous studies.

In a rare examination of multidimensional functional outcomes, DeBerard. Colledge, Masters, Schleusner, and Schlegel (2002a) compared BAK interbody cages with posterolateral lumbar fusion in samples of workers' compensation patients at least 2 years after their surgery. Arthrodesis was significantly higher in the BAK sample (94%) than the comparison group (74%), whereas rates of total disability status (25% vs. 18%) did not significantly vary at followup. However, self-reported indices for quality of life and patient satisfaction consistently reflected better outcome for the BAK cage. For instance, 87% of the BAK sample indicated that their quality of life improved as a result of the lumbar surgery compared to 59% of the posterolateral fusion sample. Similarly, nearly 72% of the BAK patients reported satisfaction with their outcome at 2 years postsurgery, while 39% of the noncage sample were satisfied with the results from surgery. Examination of both general health and specific LBP dysfunction surveys also revealed favorable outcomes for the BAK cage fusion over posterolateral fusion. That is, patients undergoing interbody cage fusion reported less back-pain-related disability, and perceived better health with regard to role functioning and mental health. Although these findings are suggestive of an advantage for interbody cage fusion (with workers' compensation patients), interpretations should be tempered by the fact that the follow-up rate was low and patients for the two procedures were extracted from intact samples from different geographical regions.

The findings from these studies provide tentative support for use of the interbody cage spinal fusion method. However, significant limitations (e.g., nonrandomized comparisons, low numbers of subjects, highly selected patients) exist, which prevent unequivocal conclusions regarding the benefits and efficacy of interbody cage fusion as

well as restricted generalizability of the findings. Additionally, few independent studies of interbody cage fusion have been performed. It is noteworthy that a review of the current studies indicates some areas of inconsistency. For instance, the reported benefits of the interbody cage device with regard to rates of disability/work resumption, length of hospital stay, and surgical complications were not consistently confirmed by the different researchers. Finally, assessment of multidimensional functional outcomes has been overlooked in the interbody cage fusion literature, with the exception of the work of DeBerard and colleagues (2002a). Consequently, much work is yet to be done in examining outcomes of lumbar interbody cage fusion.

Variables Predictive of Lumbar Fusion Outcomes

Poor outcomes from surgical procedures may have a considerable impact on the limited resources of health care systems, as well as incalculable burden and pain on patients and their families. Given these dangers, patient selection and the prediction of outcomes are of considerable interest. In fact, a large body of research exists that has attempted to identify predictors of LBP, disability, and response to various treatments (e.g., Block & Callewart, 1999; McCracken & Turk, 2002; Robinson & Riley, 2001). Interestingly, psychosocial variables have been found, in several studies (Gatchel & Gardea, 1999), to be as important as physical indicators. It should be noted, however, that relatively few studies evaluating spinal fusion have attempted to identify variables predictive of outcomes, with even fewer studies examining predictors of interbody cage fusion outcomes. However, this review of variables predictive of outcomes will include those factors most robust in predictive efficacy (regardless of type of intervention/ surgery), and place particular emphasis upon those indicated in the lumbar interbody fusion literature.

Demographic Variables

Several variables have been identified and are subsumed under this particular factor. More specifically, this review will consider age, gender, ethnicity, marital status, household income, and SES as demographic variables relevant to lumbar fusion outcomes.

It is widely believed that older patients are more refractory to intervention and are less likely to return to work. For instance, Mayer, Gatchel, and Evans (2001) conducting a large-scale examination of the association between age and outcomes of tertiary rehabilitation for LBP, found that 100% of the individuals under age 25 returned to work whereas only 69% of the individuals over 55 years of age returned to work. Moreover, employment retention rates for these individuals were similarly maintained at followup 1 year later. Several other nonfusion studies (e.g., McIntosh, Frank, Hogg-Johnson, Bombardier, & Hall, 2000; Stevenson, Weber, Smith, Dumas, & Albert, 2001) have also found that older age is predictive of more LBP and dysfunction. Although a few lumbar fusion studies have not found age to be predictive of outcome (Andersen et al., 2001; Greenough, Taylor, & Fraser, 1994; Greenough, Peterson, Hadlow, & Fraser, 1998; Vaccaro, Ring, Scuderi, Cohen, & Garfin, 1997), many more have indicated that younger patients are more likely to experience satisfactory results than their older counterparts. For instance, age at the time of injury has been found to be associated with less satisfactory arthrodesis with spinal fusion patients beyond 60 years of age (Chen, Baba, Kamitani, Furusawa, & Imura, 1994). Additionally, Franklin and colleagues (1994) reported that for each 10-year increase in age the risk of a poor spinal fusion outcome increased by 37%. More strikingly, DeBerard et al. (2001) found that for each 5-year increase in age, beyond 25 years of age, there was a 119% increase in postfusion disability. Thus, the evidence suggests age may be an important variable to consider in patient selection.

Lumbar surgical outcomes have also been associated with patient occupational and educational levels. For example, workers in blue-collar occupations have been found to

experience more disabling LBP and less beneficial results than do their white-collar counterparts (Frymoyer, 1992; Taylor, 1989). More recently, Junge, Dvorak, and Aherns (1995) found job and education levels of spinal diskectomy patients were inversely related to poor surgery outcomes at 12 months followup. However, the literature specific to lumbar spinal fusion has not consistently demonstrated the impact of these variables on outcomes (Greenough et al., 1998). For instance, an examination of posterolateral fusion by Snider et al. (1999) found education less than 12 years was predictive of poor outcome, whereas several occupational variables failed to predict outcome. Interestingly, a similar variable, household income, has received some initial support as a predictor of surgical outcome. In a study of lumbar surgery (inclusive of diskectomy as well as fusion) for degenerative spinal stenosis, Katz et al. (1999) noted that income below $15,000 was associated with lower walking capacity and more symptom severity 2 years after the operation. DeBerard (1998) found, with regard to SES (i.e., aggregation of educational level and occupational status using the Hollingshead Index) and household income at the time of injury, that only the latter substantially contributed to the prediction of postfusion disability level. More specifically, the author found that each $100 increase in weekly wages was related to a 32% decrease in disability following posterolateral spinal fusion.

Much of the support for the potential predictiveness of the variables of gender, ethnicity, and marital status has come from the literature examining chronic pain and negative response to other nonspinal fusion treatments (Block, 1999; Epker & Block, 2001; Gatchel & Gardea, 1999; Truchon & Fillion, 2000). For instance, MacFarlane et al. (1999) found that among patients with LBP seeking care in a general practice setting, improvement for men was associated with low emotional distress, higher physical activity, being employed, satisfaction with work status, and sudden onset of symptoms. For women, only shorter delay before seeking treatment and body weight were linked to outcome. Using data from industrial insurance claims, Vollin, Van Koevering, and Loeser

(1991) found that family status doubled the risk for LBP chronicity. That is, patients who were widowed/divorced and had no children were twice as likely to develop chronic pain compared to single individuals without children. In contrast to the findings on the predictive strength of these factors for chronic pain, the findings from surgical outcomes have been less apparent. A recent study found an inverse association between perceived spousal social support and spinal diskectomy outcome as measured by reduced pain (Schade, Semmer, Main, Hora, & Boos, 1999). However, these variables have received quite limited attention in the literature directed toward evaluation and prediction of spinal fusion outcome. In fact, marital status and gender have been examined previously in only a few lumbar fusion studies (e.g., Boos, Marchesi, & Aebi, 1992; Greenough et al., 1998; Snider et al., 1999; Vaccaro et al. 1997) with the results indicating these variables were not predictive of spinal fusion outcomes.

In summary, several sources of LBP research are suggestive of the predictiveness of the demographic variables reviewed here. That is, the variables of age, SES, marital status/support, gender, and ethnicity have some differential predictive efficacy across the LBP literature. In the spinal fusion outcome literature, however, the greatest attention and support to date has been with the presurgical variable of age, as opposed to SES, marital status/support, gender, or ethnicity. Although all these variables were collected on patients in the current study, only age will be included in the predictive model. The discussion will now turn to reviewing the predictive utility of compensation and litigation variables.

Compensation and Litigation Variables

Examination of compensation and litigation as predictors of pain and disability has a robust and well-documented history in the LBP literature. In fact, the relationship between compensation/litigation and disability has been characterized by the term "compensation neurosis" (Block & Callewart, 1999). In one frequently cited nonsurgical

study on the link between compensation and recovery from LBP, Greenough and Fraser (1989) found compensation status was related to poorer outcomes as measured by increased pain, disability, and delay in returning to work. Individuals with a history of compensation-related litigation and disability pension claims have also been shown to have poorer surgical outcomes (Bernard, 1993; Junge et al., 1995; Kaptain et al., 1999). Haddad (1987) found that 77% of workers' compensation patients who had an attorney had poor lumbar surgery results compared to only 9% of those without legal representation. Research indicates that compensation and litigation may serve as powerful disincentives and barriers to recovery from LBP because of secondary gain issues (Frymoyer, 1992; Frymoyer & Cats-Baril, 1987; Gatchel & Gardea, 1999). That is not to say, however, that patients involved in litigation are malingering or fabricating their symptoms. Rather, the belief is that patients receiving financial incentives experience an increased sensitivity/vigilance to pain and become less likely to respond to treatment designed to alleviate pain (Block & Callewart, 1999; Epker & Block, 2001).

Increasing attention has recently been paid to the association between compensation/litigation and surgical outcomes in the spinal fusion research. For example, Greenough and colleagues (1994, 1998) compared workers' compensation with noncompensation patients receiving lumbar fusion, and found less satisfactory outcomes (i.e., increased pain, lower rates of returning to work, greater psychological disturbance) for those individuals receiving compensation. Interestingly, no association was found between technical success (i.e., arthrodesis) and clinical success (based upon pain relief, analgesic use, frequency of physician consultation, and level of functioning). In conducting a retrospective case series to identify factors influencing fusion outcome, Vaccarro et al. (1997) found that the single most powerful predictor of poor outcome following surgery was active management regarding workers' compensation/disability claims and the related litigation. More recently, DeBerard et al. (2001) discovered that the involvement of legal

representation in the compensation claim increased the probability of remaining disabled 2 years following lumbar fusion by an astonishing 376%. The same authors also observed that litigation was predictive of poorer clinical outcomes and back-specific functional status at followup.

Some studies of lumbar fusion patients have, however, been more mixed with regard to the influence of compensation/litigation. In a prospective study of predictors of lumbar surgery (of which 68% were spinal fusions), Trief, Grant, and Fredrickson (2000) found pending litigation was predictive of reductions in leg, but not back pain or other outcome measures at 1 year following surgery. Similarly, Kuslich et al. (1998) found that patients receiving compensation had less pain relief at 1 year following lumbar interbody cage fusion, but this relief was no longer evident at 2 years postfusion. Interestingly, Tandon, Campbell, and Ross (1999) examined posterior interbody fusion in patients free of ongoing litigation or compensation claims, and concluded that exclusion of these individuals did not improve the clinical outcomes. Similarly, Vamvanij, Fredrickson, Thorpe, & Stadnick, (1998) reported that compensation status did not significantly differ between those achieving a clinically successful versus unsuccessful outcome across four types of lumbar fusion procedures.

In LBP literature, a longer time interval between injury and intervention/surgery has been predictive of poorer outcomes. In a lumbar fusion outcome study, Franklin et al. (1994) found that longer time from injury to index fusion predicted poorer work disability status at 2-years postsurgery. It is believed that such delays may be linked to poorer results from conservative interventions as well as protracted LBP and disability. However, data on this variable with lumbar spinal fusion procedures have been mixed. For instance, DeBerard et al. (2001) failed to find time delay from injury to surgery predictive of any outcomes that they assessed at followup.

Overall, the predictive importance of compensation/litigation and time delay from injury to intervention is well established within the LBP literature. However, studies examining these variables have been less consistent for lumbar spinal fusion procedures, with litigation appearing to show the strongest predictive efficacy. Thus, the present study will include litigation status in the predictive model.

General Health Variables

Obesity, substance abuse, and smoking have been widely recognized as public health problems, and are associated with numerous medical complications. Initially, obesity was found to be predictive of poor lumbar surgery outcome (Hurme & Alaranta, 1987). Many surgeons consider obesity, defined as greater than 50% above ideal body weight, to be a risk factor for poor outcome, and recommend/require some degree of weight loss prior to surgery. However, it seems that the support for obesity as a risk factor for poor spinal surgery outcome appears to be largely accounted for by the indirect influence of lower physical mobility/activity rather than the direct effects of being obese (Frymoyer, 1992; Frymoyer & Cats-Baril, 1987; Junge et al., 1995). In spite of this dearth of empirical evidence, obesity is still considered a moderate risk factor for poor back surgery outcomes (e.g., Block & Callewart, 1999; Epker & Block, 2001).

Individuals with LBP appear to be at increased risk of relying on analgesic substances for pain relief (Bernard, 1993; Deyo, Rainville, & Kent, 1992; Frymoyer, 1992; Stevenson et al., 2001). In the few studies examining either narcotic pain medication or alcohol abuse in spinal surgery patients, overuse of substances was associated with poor surgical outcome, with nearly 75% of the patients with unsuccessful results involved in abusing substances (Spengler, Freeman, Westbrook, & Miller, 1980; Uomoto, Turner, & Herron, 1988). There is, however, little other evidence that alcohol or medication abuse influences surgical outcomes, particularly in the case of lumbar spinal fusion (Block & Callewart, 1999; Turner et al., 1992; Vamvanij et al., 1998; Young, 1996).

Unlike obesity and substance abuse, habitual cigarette smoking has considerably more support as a risk factor for developing LBP as well as predicting poor health status and surgical outcomes (e.g., Garofalo & Polatin, 1999; Goldberg, Scott, & Mayo, 2000; Vogt, Hanscom, Lauerman, & Kang, 2002). For instance, nicotine use and cigarette smoking have been shown to decrease revascularization of bone graft, slow rates of healing and bone metabolism, and increase the risk of unsuccessful spinal fusion (Boos et al., 1992; Gill & Blumenthal, 1993; Hadley & Reddy, 1997; Silcox et al., 1995). In fact, the rate of pseudarthrosis in smokers following lumbar spinal fusion has been reported to be three to five times higher than in nonsmokers (Brown, Orme, & Richardson, 1986).

More recently, Andersen and colleagues (2001) conducted a prospective study to examine the smoking habits of 396 patients who had undergone noncage lumbar fusion procedures. The authors found that approximately 55% of the patients were smoking in the 3 months prior to surgery, while a mere 12% of these individuals discontinued tobacco use at the time of surgery. Moreover, 48% of those who had stopped smoking in connection with their lumbar fusion had resumed by 2 years postsurgery. In terms of surgical outcomes, preoperative smoking significantly predicted pseudarthrosis and patient dissatisfaction. However, functional outcomes appeared unaffected by either pre- or postoperative smoking. Glassman et al. (2000) found mixed support for the relationship between smoking and pseudarthrosis for patients undergoing spinal fusion with pedicle screw and rod instrumentation. That is, pseudarthrosis was not associated with presurgical smoking quantity or cessation duration, whereas postsurgical cessation was linked to increased rates of arthrodesis. Overall, nonsmokers had lower rates of pseudarthrosis than smokers (i.e., 14% vs. 21%). Also of interest, Glassman et al. found that improved return-to-work rate was associated with smoking cessation, regardless of the potential benefits of increased arthrodesis. This latter finding seems to suggest, as some researchers have contended (e.g., Deyo & Bass, 1989), that cigarette smoking may also be a marker for

other factors related to LBP and poor functioning, such as social, psychological, economic, occupational, or behavioral factors.

A few studies have reported cigarette smoking is not associated with arthrodesis or functional outcomes. For instance, neither Ray (1997a) nor Kuslich et al. (1998) found a significant difference in arthrodesis for smokers and nonsmokers. Similarly, Vamvanij et al. (1998) reported that smoking did not significantly affect achieving arthrodesis or markedly differ between successful and unsuccessful outcomes (49% vs. 39%). More recently, DeBerard et al. (2001) failed to find cigarette smoking, at the time of lumbar fusion, predictive of functional outcomes, perceived health indices, or disability status at 2 years postsurgery. However, the authors believed this null finding was likely a product of measurement error rather than a true representation of the predictive strength of smoking.

Despite the findings of these few studies and potential underlying mechanisms, habitual cigarette smoking has the greatest amount of support of the three variables discussed (i.e., obesity, analgesic/substance abuse, cigarette smoking) in this section for predicting lumbar spinal fusion outcomes. Therefore, smoking will be included in the predictive model utilized in the current study. However, unlike nearly all of the previous lumbar fusion and LBP studies (Goldberg et al., 2000), duration and quantity of cigarette smoking will be assessed so that the importance of a dose-response effect may be considered.

Psychological Disturbance and Distress Variables

It is not surprising, given the subjective experience of pain, that psychological variables, such as depression, are thought to play an important role in determining the onset of pain, response to treatment, and chronic disability (Croft et al., 1996; McCracken & Turk, 2002; Rush, Polatin, & Gatchel, 2000; Sullivan, 2001). Within the area of lumbar spine surgery several psychological variables have been suggested as predictors of outcome and determined to be more strongly associated with outcomes than radiographic

findings and biomedical variables (DeBerard et al., 2001; Garofalo & Polatin, 1999; Young, 1996). In fact, several authors (e.g., Block, 1999; Block & Callewart, 1999; DeBerard, Masters, Colledge, Schleusener, & Schlegel, 2002b; Robinson & Riley, 2001) have begun to consider the utility of presurgical psychological screenings for patients about to undergo lumbar surgery.

Psychological instruments, such as the Minnesota Multiphasic Personality Inventory (MMPI, MMPI-2), have a lengthy history of being used to identify patients whose personality characteristics place them at risk for poor surgical outcome. The MMPI and MMPI-2 clinical scales of hypochondriasis (HS), hysteria (HY), and depression (D) have been found to be most consistently predictive of negative outcomes in lumbar surgeries (Block, 1999; Masters, Shearer, & Ogles, 2000). These findings have also been confirmed in a rare study with lumbar spinal fusion patients (Riley, Robinson, Geisser, Wittmer, & Smith, 1995). In this study, the poorest lumbar fusion outcome, at an average of 20 months postsurgery, was predicted in those individuals with either a "conversion V" profile (high HS and HY scales) or elevations on the D scale.

Although the vast majority of early analyses relied on the MMPI in prediction of spine surgery outcomes, more recent studies have tended to use other measures of depression/psychological distress that have greater clinical utility and satisfactory completion rates by patients. For example, using brief instruments such as the Beck Depression Inventory, several authors have confirmed that depression is a negative predictor of lumbar diskectomy outcome (Hasenbring, Marienfeld, Kuhlendahl, & Soyka, 1994; Junge et al., 1995; Katz et al., 1999). Trief and colleagues (2000) prospectively examined anxiety, depression, and hostility in lumbar surgery patients, of whom the majority (68%) underwent spinal fusion. At 1 year postsurgery, an index combining depression and somatic anxiety found that higher levels of distress predicted poorer functional status, smaller reductions in back and leg pain, and lower rates of returning to

work. Somewhat surprisingly, hostility, as measured by a MMPI subscale, did not predict surgical outcome. In an examination of noncage interbody spinal fusion, Greenough et al. (1994) demonstrated that "psychological disturbance" (as measured by pain drawings and Waddell's signs) predicted poorer outcomes of LBP and disability, but not patient satisfaction at a 2-year follow up. More recently, DeBerard et al. (2001) found that the presence of a diagnosis of depression (in a retrospective review of workers' compensation medical records) predicted poorer posterolateral fusion outcomes at 2 years postsurgery. That is, depression was associated with mental health and pain scales of the Short Form-20 Multidimensional Health Survey at followup.

In sum, the literature demonstrates that psychological disturbance and distress is predictive of several treatment and surgical outcomes. It appears that depression and anxiety indices are most consistently predictive of outcomes, while hostility has not demonstrated the same results. In the current study, a presurgical diagnosis of depression (as documented in medical records) will be included in the overall predictive model.

Surgical and Spinal Pathology Variables

Spinal pathology and fusion procedures may necessitate multiple levels of vertebrae being fused to promote lumbar stability. Not surprisingly, a great deal of attention has been directed toward examining various aspects of the surgery procedure and spinal pathology in an effort to predict lumbar fusion outcomes. It is widely thought that the more levels that are attempted to be fused the poorer the surgical outcomes. For instance, Chen et al. (1994) found that multiple-level fusions were associated with lower levels of arthrodesis than were single-level fusions. More recently, Kuslich et al. (2000) found higher arthrodesis rates for single- versus two-level BAK cage fusions (98% vs. 85%, respectively) at 2 years postsurgery; however, this appeared to also be associated with the surgical approach with a posterior procedure yielding a 23% lower rate of solid fusion. Interestingly, these differences in attempted levels fused and surgical approach

were not evident at the other follow-up periods (i.e., 1, 4, and 5 years). Snider and colleagues (1999) found that the number of levels fused did not predict pseudarthrosis with posterolateral procedures, even when adjusting for the use of adjunctive instrumentation.

Multiple-level fusion has been shown to be predictive of disability 2 years following spinal fusion (Franklin et al., 1994). Similarly, Turner et al. (1992) demonstrated a negative association between satisfactory patient outcomes and the number of vertebrae levels fused. However, Vamvanij et al. (1998) reported that the number of vertebral levels attempted fused did not appear to influence achieving arthrodesis or successful clinical outcome. Nonetheless, the authors did find that single-level fusions were associated with higher rates of returning to work (i.e., 42% vs. 28%). Kuslich et al. (1998) found with the BAK procedure that the number of levels fused and surgical approach did not correlate with the degree of functional improvement or pain relief. A previous surgery at the same vertebral level was, however, associated with less pain relief at 2 years postfusion.

Other studies have also shown that successful spine fusion is less likely if a previous low back surgery was performed (DeBerard et al., 2001; Franklin et al., 1994; Turner et al., 1992). In one such study, DeBerard (1998) found that each low back operation prior to a posterolateral pedicle screw spinal fusion increased the probability of disability following surgery by 105%. Conversely, Bernard (1993) re-evaluated patients with residual symptoms after spine surgery who underwent repeated lumbar operation. At 2 years followup, the number of previous surgeries was not predictive of clinical outcomes. Rather, scarring and fibrosis were predictive of poor outcome.

As discussed earlier, spinal pathology (e.g., lumbar instability and motion) is often assessed and documented by imaging techniques, such as MRI and CT scan. These imaging techniques are thought to be useful in clarifying the diagnosis of patients with chronic lumbar pain when found to be unresponsive to conservative interventions

(Mooney et al., 1996). Interestingly, studies evaluating imaging techniques have found significant rates of bulging disc, disc herniation, and degenerative disc in individuals without LBP or disability (Boden et al., 1990; Jensen et al., 1994). Despite these findings, several physiological variables (e.g., sciatica, diagnosis, pain-free straight leg test) have demonstrated some predictive utility for patient outcomes with lumbar surgery (Boos et al., 1992; Frymoyer, 1992; Frymoyer & Cats-Baril, 1987; Hurme & Alaranta, 1987; Junge et al., 1995; Young, 1996). Combining diagnostic criteria and imaging techniques has yielded further improved prediction of surgical outcomes (Hasenbring et al., 1994; Saal, 2002).

These findings have been, however, generally limited to LBP surgical intervention studies, rather than spinal fusion studies. For instance, preoperative diagnosis did not predict the occurrence of arthrodesis and outcomes in lumbar fusion patients following surgery (Greenough et al., 1994; Snider et al., 1999; Turner et al., 1992). Similarly, DeBerard et al. (2001) failed to find presurgical diagnostic severity ratings predictive of postsurgical disability and functioning in posterolateral lumbar fusion patients. Boos and colleagues (1991) have, however, reported prediction of outcome in lumbar spinal fusion surgery based on four graded preoperative categories of severity with spondylolisthesis. Bernard (1993) also found that presurgical imaging techniques could be predictive of surgical outcome, with greater spinal pathology associated with poorer outcome.

In conclusion, prior low back surgery, attempted levels fused, and surgical approach have been linked to fusion outcomes, with the former showing the most consistent predictive efficacy. With regard to spinal pathology and fusion, the findings are equivocal. However, based on LBP intervention studies, one might expect that presurgical severity indices hold some potential in also predicting fusion outcomes and, consequently, require further investigation. Thus, this study will collect data on these variables, but will include a single presurgical spinal pathology severity index in the predictive model.

Arthrodesis as an Intermediate Variable

Solid fusion between vertebrae is the fundamental objective in spine fusion techniques because it is thought to abate spinal instability and motion, and reduce/ eliminate the accompanying pain. However, determination of successful arthrodesis has been controversial and the subject of discussion by several researchers (e.g., Goldstein, Macenski, Griffith, & McAfee, 2001; Jones, 2001; McAfee et al., 2001). As evident in this literature review, technical success (e.g., segmental realignment, solid fusion) does not necessarily guarantee achieving clinical success (e.g., reduction in pain). Arguably, a successful surgery and/or arthrodesis is somewhat variable depending upon the viewpoint of the observer (patient-versus-surgeon-versus-radiologist). Several discussants, in a published symposium, concluded that absolute determination of arthrodesis is not currently possible due to the nature of the interbody cage devices and the inexact science of imaging studies/radiographs (McAfee et al., 2001).

In spite of the limitations of visualizing fusion development in and around spinal fusion devices, several important clinical outcomes have been associated with arthrodesis. For instance, work status, improved functioning, and decreased reports of pain have been predicted by arthrodesis of previously unstable vertebrae in the lumbar region of the spine (Chen et al., 1994; DeBerard, 1998; Turner et al., 1992; Young, 1996). Alternately, spinal pseudarthrosis has been indicated in poorer clinical outcomes (e.g., Sonntag & Marciano, 1995). Given that arthrodesis is the primary objective and expected result of spinal fusion surgery in 6 to 12 months, other extended surgical outcomes should be a corollary of solid fusion. Arthrodesis would be expected to provide predictive value for long-term patient outcomes (e.g., disability status) in the present study of lumbar interbody cage fusion. Thus, arthrodesis is conceptualized as both a predictor and outcome variable and, therefore, will be analyzed separately from the five-variable predictive model.

Conclusions from the Literature Review

Several demographic, work, compensation, disability, health, psychological, physical, and surgical variables have been found in the literature to be predictive of lumbar fusion outcomes. Unfortunately, many studies have not concurrently examined multiple categories of the predictive variables, but rather have tended to identify and analyze variables from a single class (e.g., demographic). The work by DeBerard and colleagues (2001) appears to be one of the first large-scale studies to have developed a multivariate predictive model and simultaneously examined multiple predictive variables for lumbar fusion. Additionally, these researchers analyzed multiple dimensions of clinical fusion outcomes (e.g., back-specific and global health, functional status associated with LBP) which also appears to be a rarity in the lumbar fusion literature.

While DeBerard and colleagues (2001) have attempted to address several limitations found in the research literature with traditional spinal fusion, this has not yet been the case for the recently FDA-approved interbody cage fusion procedures (i.e., BAK and RTFC). Some initial research on the BAK and RTFC devices (compared to more traditional fusion techniques) has reported better surgical outcomes (e.g., higher rates of arthrodesis, fewer surgical complications); however, these findings, as well as other meaningful outcome variables, need to be examined more thoroughly. Thus, this study was designed to replicate the methods of DeBerard and colleagues (1998, 2001) in examining interbody cage fusion outcomes from a multidimensional approach. This study also identified a multivariate predictive model of surgical outcomes based on a number of presurgical variables from the classes of variables reviewed. The variables in this model then, include the following: age at the time of surgery, litigation at the time of surgery, presurgical depression, smoking history, and diagnostic severity rating based upon presurgical radiographs.

CHAPTER III

METHODS

Participants

This study examined adults who underwent lumbar interbody cage spinal fusion that was nonfracture-related and completed at least 18 months prior to the time of followup. Participants were solicited through the Workers' Compensation Fund of Utah (WCFU). It was initially anticipated that a sample size of approximately 100 participants would be available through WCFU. However, after access to WCFU records was granted and chart review commenced, it became apparent that a sample of this size was not available, and so other sources of participants were sought. The author was eventually granted access to patients in the private practice of an orthopedic surgeon in central Utah. Incidentally, the orthopedic surgeon who granted access to his patient pool had also provided interbody cage fusions to 2 participants in the WCFU sample.

The total accessible WCFU population included 43 patients who had a verified work-related low back injury and medical records documenting the lumbar interbody cage fusion. Thus, medical chart reviews were completed on the entire accessible population. Of these patients, 34 were male (79.1%) and 9 female, and 100% were Caucasian with one individual being a Czechoslovakian immigrant. The WCFU patients ranged in age, at the time of their index surgery, from 28 to 64 years (M = 43.90 years, SD = 8.92). The total accessible population meeting the study's inclusion criteria from the orthopedic surgeon's practice included 30 patients. There were 14 males (46.7 %) and 16 females (53.3%) and, in terms of ethnicity, 100% were Caucasian. Their ages ranged from 18 to 72 years (M = 43.76, SD = 12.99). Thus, the overall population meeting the study's inclusion criteria and available for medical chart review were 48 men (65.8%) and 25

women (34.2%), all Caucasian, and ranging in ages from 18 to 72 years ($M = 43.84$, $SD = 10.69$).

Study Design

This study is considered a retrospective cohort design involving data collection at two distinct phases. Presurgical information about patients was gathered from the medical files and composed Time 1 variables. Following review of the patient medical records, all potential participants were mailed letters about participating in the study and completing a brief telephone survey. The telephone survey consisted of the Time 2 variables (i.e., outcome variables). Thus, the first phase of this study consisted of collecting information from the medical files, while the second phase involved garnering outcome data via telephone surveys.

Procedures

Phase 1

Presurgical medical record data were collected on-site, by this author, from the WCFU's computer databases and the orthopedic surgeon's medical charts using a slightly modified coding format developed by DeBerard (1998). This coding instrument is presented in Appendix A, and took approximately 1 to 2 hours to complete per individual medical file. Presurgical radiology reports were also obtained from the databases to calculate a diagnostic severity score for each patient's lumbar spine. The presurgical diagnostic severity instrument, presented in Appendix B, was completed by a physician with expertise in spine surgery (Alan Colledge, MD).

When questions arose regarding the correct coding of medical files the author sought consultation and clarification from Drs. Colledge and DeBerard. However, to assess consistency of the diagnostic severity index ratings, a second physician (William

Bacon, MD) who was experienced in spinal surgery independently reviewed 26.03% (19) of the same presurgical radiology reports. The concordance between the ratings of the two physicians was assessed by dividing the total number of congruent observations by the total number of observations and multiplying by 100. Percent agreement was calculated for the summary index score as well as for seven specific indices of spinal pathology (e.g., disc degeneration, facet changes, stenosis) used to compose the summary score. Eighty-percent agreement was the established criteria of acceptable interrater concordance.

Phase 2

All lumbar interbody cage fusion patients identified through both the WCFU and orthopedic surgeon's practice were initially approached for the telephone survey by means of a contact letter sent to their most recent address identified in the medical file. The patient contact letters are presented in Appendices C and D. These letters introduced the study, its purpose and procedures, confidentiality of information, and request for their voluntary participation. Additionally, patients were informed of two incentive drawings of $500 and the availability of a report of the research findings for those participating in the study. Included with the letter to patients was a self-addressed stamped postcard to obtain an update of any telephone or address changes for the patient (see Appendix E). If patients did not return the postcard, a telephone contact was attempted by the author to review the contents of the letter and solicit participation in the outcome survey.

Patient consent for completion of the outcome surveys was obtained verbally at the time of telephone contact. The telephone survey was introduced using the written script, provided in Appendix F, utilized by DeBerard (1998). The survey with the participants generally required approximately 30 to 45 min to complete (during a single contact). On the rare occasion when potential study participants declined completing the survey during the initial telephone contact, a second contact and request was attempted at a later date by the author. At the beginning of the telephone survey, the participation incentive drawing

and confidentiality of information, as explained in the contact letter, was reiterated and emphasized to the participant.

In the event that contact letters were returned as undeliverable, the author attempted to contact patients via their listed telephone number to introduce the study as outlined in the aforementioned materials. In some cases neither the patient's address nor telephone was correct, and more involved search methods were used. For instance, patient medical records were reviewed again for alternate addresses, directory assistance was contacted for listings, and internet searches were conducted. Although these methods did not yield all the patients from the selected populations, 9 participants were contacted (and agreed to participate) through such means.

Materials and Instruments

Medical Record Review Forms

The Medical Chart Review Instrument and the Imaging Diagnostic Severity Index were briefly discussed earlier and are identified in Appendices A and B, respectively. These instruments have been used for gathering information from workers' compensation files in previous research (i.e., DeBerard, 1998) for examination of an alternate form of lumbar spinal fusion. The medical record review form consists of several items that have been identified as variables of interest in studies of low back pain discussed in the literature review. This form has, however, been slightly altered for the purposes of this study, but is believed to continue to be reliable and valid. Modifications were made in hopes of improving the depth of data collection and to accommodate examination of the interbody cage spinal fusion. For instance, smoking history was reconfigured to also gather duration and amount of tobacco use rather than simply continued usage versus abstinence. Also added to the form in Appendix A was the variable of length of hospital stay following the index fusion. As for the surgery, approach and type of interbody cage fusion were included.

It should be noted that the Imaging Diagnostic Severity Index was initially developed by Alan Colledge, MD and Rand Schleusener, MD based on their medical expertise and experience interpreting presurgical imaging information such as CT scans and MRIs. For the current study, this form was slightly modified from its original format, at the recommendation and direction of Dr. Colledge, to include a more precise rating of degenerative disc and facet changes for all the lumbar levels analyzed. Because patients' actual presurgical imaging studies were unavailable for examination, this instrument was used with the radiology reports found in medical files. As discussed earlier, one physician reviewed and rated all patients, while a second conducted an independent coding of approximately 25% of the same individuals. This strategy allowed for assessment of the interrater reliability between the physicians and increased confidence in the instrument's format and the primary rater's consistency.

Telephone Survey Instruments

The script and instruments used for the telephone survey are identified in Appendices F through J. Following the initially scripted survey introduction, study participants were asked about their level of satisfaction with their spinal fusion and how their workers' compensation claim was dealt with (as applicable), surgical outcome, level of dysfunction, disability status, and demographics. In a few cases, patients were asked during the survey to supply information that was absent from their medical record. Most notable of these cases was the patient's status with arthrodesis following the index spinal fusion surgery. Review of the postsurgical medical records most often revealed documentation, from the operating surgeon, whether the fusion had formed a solid mass or resulted in pseudarthrosis. Often arthrodesis status was able to be deduced from the follow-up care (e.g., re-operation); nonetheless, patients were asked to confirm the actual status of the fusion.

Patient satisfaction. Patient satisfaction is an important outcome of treatment; however, few published measures, aside from satisfaction with care in general, exist for assessing patients with lumbar problems (Hudak & Wright, 2000). Consequently, a few specific items relevant to lumbar spinal surgery, rather than an outcome measure per se, were used to gauge satisfaction. The patient satisfaction (with the index surgical intervention) questions are included in Appendix H (items 5, 6, 7, 17, and 19) and have been used elsewhere in evaluating spinal surgery outcomes (DeBerard, 1998; DeBerard et al., 2001; Franklin et al., 1994). The questions are all close-ended and vary from a 3- to 7-point response format with a balance of positively and negatively worded items. The five questions inquire about the patient's satisfaction and behavioral intention with regard to the index fusion procedure, whether they would consider having the procedure again, and their perceived back/leg pain improvement following surgery.

Disability status. Several researchers have advocated the importance of assessing disability status because of its meaningful impact on the individual, as well as the associated business and societal costs (Amick, Lerner, Rogers, Rooney, & Katz, 2000; Deyo et al., 1998). Although a complex phenomenon that involves several factors (Waddell & Turk, 2001), disability status was conceived as a dichotomous variable that grouped the patient as either disabled or not at the time of followup. It was determined that disability status would be designated in this manner primarily because other scales were also used to characterize role and physical functioning. Disability status of the patient, in the current study, was determined by two methods. The primary method was at the time of followup and involved asking the participants if they currently receive total disability benefits for the condition of their low back (see Appendix H, item 10). The second method, used as a verification of the participant's report, involved a review of the medical records.

Stauffer-Coventry Index. The Stauffer-Coventry Index (SCI; Stauffer & Coventry, 1972) is a widely used instrument that is thought to be a practical and quick index for identifying a good, fair, or poor outcome following surgery. The SCI contains four questions asking the patient about pain relief, work status, restriction of physical activities, and analgesic medication usage (see Appendix H, items 1 - 4). The surgical outcome category is designated based upon the patient's lowest rated response of the four items. Thus, the three outcomes appear as follows: (a) Good: 76-100% relief in leg and back pain, return to previous work status, minimal or no restrictions of work activities, occasional mild or no analgesics; (b) Fair: 26-75% relief of leg and back pain, return to lighter work, moderate restrictions of physical activities, regular use of nonnarcotic analgesics; (c) Poor: 0-25% relief of leg and back pain, no return to work following surgery, severe restrictions of physical activities, occasional or regular use of narcotic analgesics. In spite of several researchers (e.g., Boos et al., 1992; DeBerard et al., 2001; Schade et al., 1999; Turner et al., 1992) having utilized the SCI as a clinical low back surgical outcome measure, its reliability and validity have not been documented in the literature. However, the SCI appears to assess relevant and face valid outcomes to spinal fusion patients, and its use in this study will allow for comparisons with previous studies on lumbar fusions.

Roland-Morris Disability Questionnaire. The Roland-Morris Disability Questionnaire (RDQ; Roland & Morris, 1983a, 1983b) was devised to assess physical disability due to low back pain, and was used in this study to appraise participants' functional status. The RDQ is a widely used instrument that is well suited to administration by telephone and has been recommended by an international group of researchers as a standard measure for outcomes research in patients with back pain (Deyo et al., 1998). A short and simple instrument, the RDQ is composed of 24 dichotomous items that are prefaced with the phrase "because of my back pain" (see Appendix I).

Content of the RDQ includes: physical activities, housework, mobility, dressing, getting help, appetite, irritability, and pain severity. Scores are calculated by adding up the number of items endorsed by the patient with them ranging from 0 to 24 (no disability to maximum disability). This measure has been found to be sensitive to functional improvement in low back pain (Beaton, 2000; Roland & Morris), yet scores seem to have little or no relation to the age, sex, or social class of respondents (Roland & Fairbanks, 2000). Additionally, the RDQ correlates well with pain ratings and other measures of physical functioning, while not so well with measures of psychological distress (Beurskens, deVet, & Koke, 1996; Jensen, Strom, Turner, & Romano, 1992; Kopec, 2000). Given that the RDQ does not attempt to measure psychological distress, this further supports the construct validity of this instrument as an index of physical functioning and disability.

Short Form Health Survey-36. A ubiquitous general health survey, the Short Form Health Survey-36 (SF-36; Ware, Snow, Kosinski & Gandek, 2000) is a brief and comprehensive measure also suitable for telephone administration. The SF-36 has been used to study several chronic health conditions, including low back pain (Atlas et al., 2001; Deyo et al., 1998). The specific items that make up this instrument can be found in Appendix I. All of the 36 items but one (item 2; health transition) were used to score the eight scales. The SF-36 assesses the following eight dimensions of functioning: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. Scores are often reported as scaled-scores with higher scores reflecting better functioning, but more recently are being transformed into T-scores ($M = 50$, $SD = 10$). The finding that 80-85% of the reliable variance was accounted for in the eight scales led to the development of physical and mental health summary scores (Ware, 2000). That is, the eight scales may be aggregated into physical health (PCS) and mental health component (MCS) summary scores that allow for statistical analyses on two high-order constructs rather than on each of the scales (without a substantial loss of

information). The physical functioning, role-physical, and bodily pain scales contribute most to the scoring of the PCS, while social functioning, role-emotional, and mental health scales contribute to the MCS. However, vitality, general health, and social functioning have notable correlations to both of the component summary scales (Ware, 2000).

Extensive psychometric assessment has been completed on the SF-36 scales and reliability estimates (internal consistency, test-retest) have consistently exceeded the minimum standard of 0.70, while most have exceeded 0.80 (Ware et al., 2000). As for the PCS and MCS scales, reliability statistics usually exceed 0.90. Ware and colleagues (Ware, 2000; Ware et al., 2000) have concluded, across a variety of applications and numerous studies, that there is sufficient evidence for content, concurrent, criterion, construct, and predictive validity for the SF-36. In a comparison of several widely used general measures of health status, the SF-36 was recommended over the others when studying patients with back pain (Lurie, 2000).

Statistical Analyses

Data gathered from the patients were analyzed using the Statistical Packages for Social Sciences (SPSS) graduate student version 10.0 for Windows. Descriptive statistics such as percentages, means, and standard deviations were used to characterize patients undergoing interbody cage spinal fusion. Patients were characterized with regard to preoperative diagnosis, as well as demographic, disability, health, surgical, and physiological variables. Intercorrelations among the presurgical variables (patient weekly income, legal representation/involvement, diagnosis of depression, smoking history, and Diagnostic Severity Index) were also assessed. Interrater reliability between the physicians examining the radiology reports was estimated by calculating their percent of agreement. Patient response rates were estimated along with a multivariate analysis of variance (MANOVA) on the presurgical variables to check for any biases in response rate or

discrepancies between the WCFU patients versus the non-WCFU patients. Outcome variables (rates of solid arthrodesis, patient satisfaction, surgical outcome, length of hospital stay, functional improvement, and mental and general health functioning) were characterized using descriptive statistics and examined for intercorrelations. A series of logistic and multiple regression analyses were completed to assess the predictive strength of the multiple variable model of patient outcomes assessed at followup. Discriminant function analysis was used to evaluate the model's ability to assign patients into good, fair, and poor outcome classifications.

CHAPTER IV

RESULTS

The results of this study are presented according to the following sections: (a) concordance rates for severity index ratings; (b) preoperative diagnoses, type of fusion, and hospitalization; (c) descriptive statistics and intercorrelations of presurgical variables; (d) surgical complications and arthrodesis rates; (e) response rates and bias checks; (f) patient outcomes; (g) intercorrelations of outcomes; and (h) prediction of outcomes. Each of the pertinent research questions are also highlighted and presented throughout the analyses.

Concordance Rates for Severity Index Ratings

As a means of examining the reliability of the diagnostic imaging-based severity scores, 25% of the radiographs were rated independently by a second physician (with expertise in spine surgery) for comparison. Concordance rates, as previously discussed, were calculated for a summary index score as well as seven specific markers of spinal pathology. Interrater agreement for the seven indices ranged from 89.47 - 100% with a mean agreement of 93.23%. As seen in Table 1, the summary score agreement between the two physician raters was 89.47%. Thus, the two physician raters had good agreement and exceeded the required cut-off of 80%, allowing for reasonable confidence that the scores produced by the primary physician rater reflected a reliable and valid quantification of the presurgical radiology studies for the patients in this study.

Preoperative Diagnoses, Type of Fusion, and Hospitalization

Categorization for preoperative diagnoses was based upon the work of Turner et al. (1992), and was composed of seven distinct groupings. Patients may, however, have

Table 1

Concordance Rates for Imaging-Based Severity Index Ratings

Rating	Inerrater agreement % ($N = 19$)
Summary score	89.47
Disc degeneration	94.74
Facet changes	94.74
Disc bulges	94.74
Listhesis	89.47
Lysis	100.00
Stenosis: formina/lateral	89.47
Stenosis: central/spinal	89.47

more than a single diagnosis, which is reflected in the reported percentages. For the 73 patients identified and included in the current study, the possible diagnoses and percentages are as follows: degenerative disc disease (63%), disc herniation (57.5%), spinal stenosis (21.9%), spondylolisthesis (20.5%), segmental instability (13.7%), and pseudarthrosis (9.6). In approximately 85% of the patients, the indexed interbody cage procedure was their first lumbar fusion, while it was the second for 8.2% and third for 6.8% of the cases. Of those with a previous lumbar surgery, patients had one, two, or four levels attempted fused in 36.4%, 45.4%, and 18.2% of the previous lumbar surgeries, respectively.

As can be seen in Table 2, the approach and type of interbody cage fusion performed for the index analyses were posterior (47.9%), anterior (41.1%), and combined (11.0%), with Ray and BAK cages clearly specified in 53.4% and 31.5% of these fusions, respectively. Patients had one lumbar level fused during the procedure in 58.9% of the cases, while the remaining 41.1% had two levels fused. The vast majority of surgeries

Table 2

Descriptive Statistics for Interbody Cage Fusion and Hospitalization Ratings

Variable	Frequency ($N = 73$)	Percentage
Approach for fusion		
Anterior	30	41.10
Posterior	35	47.95
Combined	8	10.96
Type of cage		
Ray	39	53.42
BAK	23	31.51
Not specified	11	15.07
Number of levels fused		
One	43	58.40
Two	30	41.10
Three	0	0.00
Level Fused[a]		
L_2 - L_3	2	2.74
L_3 - L_4	7	9.59
L_4 - L_5	42	57.53
L_5 - S_1	52	71.23
Hospitalization (days)[bc]		
Three	9	12.50
Four	30	41.67
Five	22	30.56
Six	6	8.33
Seven	1	1.39
Eight	3	4.17
Nine	1	1.39

Note. Ray = Ray Threaded Fusion Cages, BAK = Bagby and Kuslick Interbody Cages
[a] Mean and standard deviation for number of levels fused = 1.41 (0.50).
[b]Mean and standard deviation for duration of hospitalization = 4.63 (1.24).
[c]Based on 72 patients due to in hospital mortality of one patient.

involved either the L5-S1 or L4-L5 levels, with the former site being targeted in 71.2% of the fusions.

One research question of interest in the current study was: What is the length of hospitalization for patients undergoing the lumbar interbody cage fusion procedure? This question was addressed by calculating descriptive statistics. Duration of hospitalization for the fusion procedure ranged from three to nine days in this sample with a mean of 4.63 days (SD = 1.24), which is slightly higher than lengths reported elsewhere (Elias et al., 2000; Hacker, 1997; Kuslich et al., 1998) for this procedure. Approximately 85% of the surgeries required five or fewer days of hospitalization, while a stay of 4 days was the modal duration (41.7%).

Descriptives and Intercorrelations of Presurgical Variables

An objective of this study was to characterize patients who had undergone interbody cage fusion. Research question 2 inquired into the nature of the patient sample with regard to several presurgical variables. To that end, descriptive statistics were performed for the entire sample of patients on the following variables: age at time of fusion, index of social position, diagnostic severity rating, number of low back surgeries, time delay between injury and index fusion, lawyer involvement, depression, and smoking history. Patient's tobacco use was determined by both reviewing the medical file and surveying the patient during followup. Figures reflect the overall sample as well as those only participating in the telephone survey.

The average age of patients undergoing an interbody cage fusion, as can be seen in Table 3, was 43.84 years (SD = 10.69). Patients' education and occupation, gleaned from the review of medical files, were converted to a composite index score using a simple formula based upon the widely used (e.g., DeBerard, 1998; Lynch & Kaplan, 2000) Hollingshead Index of Social Position. The composite index score revealed that the

Table 3

Descriptive Statistics of Presurgical Characteristics

Presurgical characteristic	Frequency ($N = 73$)	Percentage	*M*	*SD*	Min - Max
Age at time of fusion			43.84	10.69	18.00 - 71.97
Index of social position			51.29	11.83	25.00 - 69.00
I (scores = 11-17)	0	0.00			
II (scores = 18-27)	4	5.40			
III (scores = 28 - 43)	14	19.18			
IV (scores = 44 - 60	35	47.95			
V (scores = 61 - 77)	20	27.40			
Diagnostic severity rating			9.10	4.61	2.00 - 29.00
Number of back surgeries			0.92	0.98	0.00 - 3.00
None	32	43.84			
One	21	28.77			
Two	14	19.18			
Three or more	6	8.22			
Time delay between injury and index fusion (months)			32.80	24.89	0.77 - 87.03
Lawyer involvement					
Yes	24	32.88			
No	49	67.12			
Depression					
Yes	12	16.44			
No	61	83.56			
Smoking at time of fusion (per medical record)					
Yes	31	42.47			
No	42	57.53			
Smoking at time of fusion (per telephone survey)[a]					
Yes	24	42.86			
Smokes currently	17	70.83			
Abstinence < 1 year	1	4.17			
Abstinence > 1 year	6	25.00			
Lifetime consumption (packs)			5951.40	4035.81	913 - 13,688
No	32	57.14			

[a]Based on followup $N = 56$.

patients were at the lower end of the SES. That is, the mean composite index score was 51.29 (SD = 11.83), which falls in Level IV, while nearly 77% of the patients were in the two lowest levels (Level IV and V) of the scale. These lower levels are consistent with semiskilled/unskilled occupations and high school level education. Approximately 44% of the patients had not had any low back surgeries prior to their spinal fusion, while nearly 29% and 19% had one and two prior low back operations, respectively. Overall, patients had a mean presurgical diagnostic severity rating of 9.10 (SD = 4.61) and a delay of 32.80 months (SD = 24.89) between the time of injury and the interbody cage fusion surgery. Lawyer involvement, at the time the interbody cage fusion, was documented in 32.88% of the cases. Attorney involvement was specifically related to the patient's LBP and involved either mediation for a workers' compensation claim or attempts to obtain disability benefits. Presurgical depression was reported in 16.44% of the cases. Roughly 42% of the patient sample was smoking at the time of the interbody cage fusion with a mean lifetime tobacco habit consisting of 5,951.40 packs. Smoking habit was explored and verified at followup for 56 patients, which revealed that nearly 30% reported discontinued use of tobacco since the spinal fusion, with 25% of the sample having been abstinent for more than a year.

In order to address research question 3, intercorrelations were calculated on the original set of predictor variables and are presented in a correlation matrix (see Table 4). The intercorrelations ranged from -.17 to .45, and, of the 36 possible combinations, three were statistically significant at an alpha of .05. Patient's age at the time of fusion was positively related to the diagnostic severity rating (.45, $p < .01$, $N = 73$) as well as the number of prior low back operations (.36, $p < .01$, $N = 73$). That is, older patients had higher severity ratings (indicating more spinal pathology) and more low back surgeries than their younger counterparts. Number of low back operations was also positively correlated to the delay between the patient's injury/onset of symptoms and the interbody

Table 4

Pearson Correlations Between Presurgical Variables Ratings

	Variable								
Variable	1	2	3	4	5	6	7	8	9
1. Age at time of fusion	---								
2. Index of social position rating	-.1	---							
3. Diagnostic severity rating	.45*	-.03	---						
4. Number of prior back operations	.36*	-.09	.16	---					
5. Levels fused	-.06	-.10	.19	.04	---				
6. Time delay (months)	.10	-.06	.06	.38*	.18	---			
7. Lawyer involvement	.04	.08	.04	.06	-.17	-.06	---		
8. Presurgical depression	.10	.15	.14	.11	.01	-.03	.08	---	
9. Smoking at time of surgery	-.08	.04	.13	.02	.13	-.15	-.01	-.16	---

*$p = .05$, $N = 73$.

cage fusion (.38, $p < .01$, $N = 73$). Thus, as the time interval between the initial injury increased so did the number of low back surgeries (before the interbody cage fusion).

Surgical Complications and Arthrodesis Rates

Research questions 4 and 5 relate to the rates of surgical complications and arthrodesis for lumbar interbody cage fusion, respectively. Approximately 92% of all the fusions were reported to have no surgical complications. However, for six of the 73 patients the following complications were documented in their medical files: instrumentation failure (2.7%), deep infection (1.4%), superficial infection (1.4%), deep venous thrombosis (1.4%), pulmonary embolism (1.4%), and in-hospital mortality (1.4%). In none of the cases were there reports of neural injury, graft extrusion, or donor site complications. For the overall sample of patients, arthrodesis was eventually established in 82.2% with one individual not included due to in-hospital mortality. Of those participating in the outcome survey, documentation was present (and confirmed by the patient) in all cases and yielded rates of 83.9% and 16.1% for arthrodesis and pseudarthrosis, respectively.

Response Rates and Bias Checks

Overall, 73 patients were identified as having had a lumbar interbody cage fusion and were included in the medical file review (Phase 1). Of these, 56 agreed to complete all or part of the telephone outcome survey (Phase 2), yielding a response rate of 76.7%. Three (4.1%) of these individuals agreed to only complete the initial questions of the outcome survey, while an additional three (4.1%) patients were contacted but declined to participate altogether. The remaining 14 nonresponders could not be located (17.8%) or had died (1.4%). Response rates between the WCFU and non-WCFU patients were quite similar with 34 (79.1%) and 22 (73.3%) of the individuals completing all or part of the

surveys, respectively. As for the WCFU patients, 2 (4.7%) completed part of the outcome survey, 2 (4.7%) were contacted but refused participation, 6 (14.0%) could not be located, and 1 (2.3%) was deceased. Similarly, in the non-WCFU sample 1 (3.3%) patient completed part of the survey, 1 (3.3%) was contacted but declined participation altogether, and 7 (23.3%) could not be located. Overall, the average time to outcome followup was 2.62 (SD = 0.77) years, while it was 2.50 (SD = 0.82) for the WCFU and 2.80 (SD = 0.65) years for the non-WCFU participants.

Although the response rates were high in this study, a MANOVA was performed to check for potential bias between the respondents (n = 56) and nonrespondents (n = 17). The following presurgical variables were available on all patients and used in the comparison: age at time of index fusion, depression, smoking at time of fusion, lawyer involvement, index of social position, diagnostic severity rating, number of prior low back surgeries, time delay (in days) from injury to fusion, and number of levels fused. The comparison was not statistically significant (Wilks' Lambda = 0.931; F = 0.521, p = .854) indicating the multivariate null hypothesis that the means for the two groups did not differ was accepted. That is, the two groups were statistically equivalent and no additional univariate tests were warranted for the individual variables. See Table 5 for the descriptive statistics on the medical and presurgical sociodemographic characteristics of the respondents and nonrespondents.

A second MANOVA, using the same presurgical variables, was performed to compare the WCFU with the non-WCFU patients. As in the previous analysis, the multivariate null hypothesis was that the means for the two groups would not differ on the identified variables. The Wilks' Lambda (0.880) was not statistically significant (F = 0.955, p = .486) indicating that the null hypothesis could, once again, not be rejected. Thus, the WCFU and non-WCFU patients were indistinguishable on the combined analysis of the nine presurgical variables. This is of importance because it allows for the two

Table 5

Descriptive Statistics of Presurgical Characteristics for Responders Versus Nonresponders and WCFU versus Non-WCFU Patients

Presurgical Characteristics	Responders[a] (N = 56)		Nonresponders (N = 17)		WCFU[b] (N = 43)		Non-WCFU (N = 30)	
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Age at time of fusion	44.39	11.07	42.05	9.42	43.90	8.92	43.76	12.99
Index of social position	50.00	12.21	55.53	9.61	50.52	11.65	52.40	12.18
Diagnostic severity rating	9.09	5.02	9.12	3.00	9.67	4.69	8.27	4.45
Number of low back surgeries	0.95	1.00	0.82	0.95	1.09	0.95	0.67	0.99
Number of levels fused	1.38	0.49	1.53	0.51	1.44	0.50	1.37	0.49
Time delay (months)	32.51	25.08	33.75	24.98	36.58	23.63	27.39	26.03
Lawyer involvement	1.34	0.48	1.29	0.47	1.37	0.49	1.27	0.45
Depression	1.16	0.37	1.18	0.39	1.19	0.39	1.13	0.35
Smoking	1.43	0.50	1.41	0.51	1.47	0.50	1.37	0.49

	R	NR	WCFU	NWCFU
1 = No	66.1%	70.6%	62.8%	73.3%
2 = Yes	33.9%	29.4%	37.2%	26.7%

	R	NR	WCFU	NWCFU
1 = No	83.9%	82.4%	81.4%	86.7%
2 = Yes	16.1%	17.6%	18.6%	13.3%

	R	NR	WCFU	NWCFU
1 = No	57.1%	58.8%	53.5%	63.3%
2 = Yes	42.9%	41.2%	46.5%	36.7%

Note. R = Responders, NR = Nonresponders, WCFU = Workers Compensation Fund of Utah, NWCFU = Non-Workers Compensation Fund of Utah.
[a]MANOVA: $F = .521$, $p = .854$.
[b]MANOVA: $F = .955$, $p = .486$.

groups to be combined for subsequent analyses with reduced concern of a systematic bias in patient selection based on the two separate sites of data collection. The medical and presurgical sociodemographic descriptive statistics of the WCFU and non-WCFU patients are available for review in Table 5.

Patient Outcomes

Descriptive outcomes from the index lumbar fusion are grouped and presented in the following sequence: (a) patient satisfaction, (b) categorization of outcome, (c) disability status and low back functional condition, and (d) general physical and mental health functioning. These analyses answer research questions 6 through 10, with the particular question highlighted in the respective section.

Patient Satisfaction with Outcome

Research question 6 inquired about the rate of patient satisfaction with the outcome of the interbody cage spinal fusion. This section presents descriptive analyses to address this question via four patient satisfaction variables (expected pain reduction, improved quality of life, satisfaction with current condition, and whether they would repeat surgery), which are presented in Table 6. It should be noted, that at followup, patients were asked on two separate occasions about their back/leg pain and whether it corresponded to their expectations. For the first question, patients were simply asked if their pain was worse than expected, no worse or better than expected, or better than expected, which yielded the rates of 41.8%, 12.7%, and 45.5%, respectively. The second inquiry into patient expectation of back/leg pain relief entailed a 6-item response format that can be seen in Table 6, along with the percentages for each selection. Patients reported a slightly higher level of back/leg pain on the second question than they had on the briefer question. That is, almost 50% of the patients felt their pain improvement was

Table 6

Patient Satisfaction with Outcomes of Interbody Cage Fusion

Outcome category	Frequency ($N = 55$)	Percentage
Back leg pain		
Much better	12	21.8
Somewhat better	11	20.0
What expected	3	5.5
Somewhat worse	10	18.2
Much worse	17	30.9
No expectation	2	3.6
Quality of life		
Great improvement	14	25.5
Moderate improvement	11	20.0
A little improvement	6	10.9
No change	3	5.5
A little worse	4	7.3
Moderately worse	10	18.2
Much worse	7	12.7
Satisfaction with back condition		
Extremely satisfied	11	20.0
Very satisfied	8	14.5
Somewhat satisfied	9	16.4
Neutral	3	5.5
Somewhat dissatisfied	15	27.3
Very dissatisfied	4	7.3
Extremely dissatisfied	5	9.1
Retrospectively, would repeat surgery		
Yes	35	63.6
No	14	25.5
Undecided	6	10.9

either somewhat worse or much worse than what they had expected it to be at this point following the fusion. Conversely, approximately 42% of the patients considered their back or leg pain was either somewhat better or much better than expected, while nearly 6% indicated their pain improvement was at the level they expected at this point.

Patients' perception of improvement in overall quality of life resulting from the lumbar fusion surgery was examined using a seven-item response format, as also displayed in Table 6. For this question, almost 57% of the patients indicated their quality of life had improved either a little, moderately, or greatly as a result of the cage interbody fusion. Alternately, quality of life resulting from the surgery had become either a little, moderately, or much worse for about 38% of the patients. Approximately 6% of the patients, weighing the change in their quality of life, believed that the spinal surgery had not altered it in either direction. Similar trends were found with patient's satisfaction with their current back condition and behavioral intention to repeat the fusion. As seen in Table 6, roughly 51% of the patients indicated that if they had to spend the rest of their life with their back condition as it is currently, they would be either somewhat, very, or extremely satisfied, while approximately 44% felt similar levels of dissatisfaction. Finally, 63.6% of the patients would, in retrospect, choose to repeat the interbody cage fusion in the same position and given what they now know, whereas 25.5% would not.

Stauffer-Coventry Index Outcome Categories
Good, Fair, and Poor

This section addresses the research question posed regarding characterizing the rates of good, fair, and poor outcomes for the interbody cage fusion. The SCI was used to address this question and provides an overall outcome rating as well as four subscale ratings of functioning (pain relief, return to work, physical activities, and analgesic utilization). Rates are presented in Table 7 for both the subscales and overall classification

Table 7

The Stauffer-Coventry Index Outcomes

	Overall index rating[a]		Pain relief			Employment status[b]			Physical limitations			Medication usage		
Category	Freq.	%	Rating	Freq.	%	Rating	Freq.	%	Rating	Freq.	%	Rating	Freq.	%
Good	3	5.4	76-100% Improvement	15	26.8	Return to Previous work status	17	30.4	Minimal or no restrictions	8	14.3	Occasional or no use of mild analgesics	16	28.6
Fair	18	32.1	26-75% Improvement	25	44.6	Return to Lighter work	20	35.7	Moderate restrictions	28	50.0	Regular use on non-narcotic analgesics	12	21.4
Poor	35	62.5	0-25% Improvement	16	28.6	No return to work	15	26.8	Severe restrictions	20	35.7	Occasional or regular use of narcotic analgesics	28	50.0

Note. Percentages based upon follow-up *n* of 56 patients.

[a]Final classification based upon lowest rated single category.

[b]Four patients (5.5%) were retired and/or not working prior to surgery and were not factored into employment status.

of outcome. The SCI overall rating yielded the following patient outcomes: good 5.4%, fair 32.1%, and poor 62.5%. Recall from the earlier discussion of this index that overall classification is based upon the lowest rating across the four subscales. That is, a patient may report good functioning in three of the four areas with fair functioning in the fourth and, consequently, receive an overall classification of fair. However, if the modal rating were used as the criteria the overall rating of outcome becomes: good 26.8%, fair 41.1%, and poor 32.1%.

Approximately 71% of patients obtained fair to good pain relief following their interbody cage fusion, whereas the remainder (28.6%) reported 25% or less relief of their presurgical pain. The basis of this classification was participants' rating of pain relief from 0 to 100, which when calculated yielded a mean of 53.22 ($SD = 31.23$). Approximately 66% of the patients reported returning to work, at either previous work status or lighter duty, upon followup, while 26% indicated they had not returned to work or had retired prior to surgery. Of the patients participating in the outcome survey, only 14.3% felt that they had minimal to no restrictions of physical activities. Alternately, almost 36% of the patients believed they had severe restriction of activities since their spinal fusion. When surveyed, 28.6% of patients ascribed to occasional/no use of mild analgesics and 21.4% indicated regular usage of non-narcotic analgesic medications. Fifty percent of the participants, however, reported current occasional/regular use of narcotic analgesics for pain relief.

Disability Status and Functional Impairment

Rates of patient work-disability and back-specific functional impairment following interbody cage fusion, as pertaining to research questions 8 and 9, were investigated and are presented in Table 8. Nearly 38% of the patients at the time of followup were considered totally disabled as a consequence of their back condition. According to responses on the Roland-Morris Disability Questionnaire (RDQ), which measures the

Table 8

Disability Status and RDQ Outcomes

Outcome	*N*	Frequency	Percentage
Total disability	56		
Yes		21	37.5
No		35	62.5
RDQ--Poor Outcome[ab]	53		
Yes		25	47.2
No		28	52.8

[a] Poor outcome is defined as a score of 14 or greater.
[b] Overall *M* (*SD*) for patients = 12.47 (7.44).

extent of functional impairment due to back pain, 47.2% of the patients scored at or above the recommended (Roland & Morris, 1883a, 1983b) cut-off of 14 points. That is, nearly half of the patients reported considerable LBP impairment and limitations. The mean RDQ score for the patient sample was 12.47 (*SD* = 7.44), while the modal and median scores were both 12, which are the equivalent of "quite bad pain." Visual inspection of the RDQ data (see Figure 1) reveals that scores ranged from 0 to 24 reflecting a broad distribution.

General Physical and Mental Health Functioning

More general physical and mental health functioning were examined, to address research question 10, via the SF-36 (Ware et al., 2000). Mean values for the eight subscales [physical functioning (PF), role-physical functioning (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional functioning (RE), and mental health (MH)] as well as two summary scales (PCS and MCS) were examined and compared with existing norms provided by Ware and colleagues (Ware, 2000; Ware et al., 2000). Normative samples include the often cited general U.S. adult population (*N* = 2,474) as well as the norms for adult patients reporting the co-morbid conditions of back pain/sciatica (within the last 6 months) and hypertension (*N* = 481).

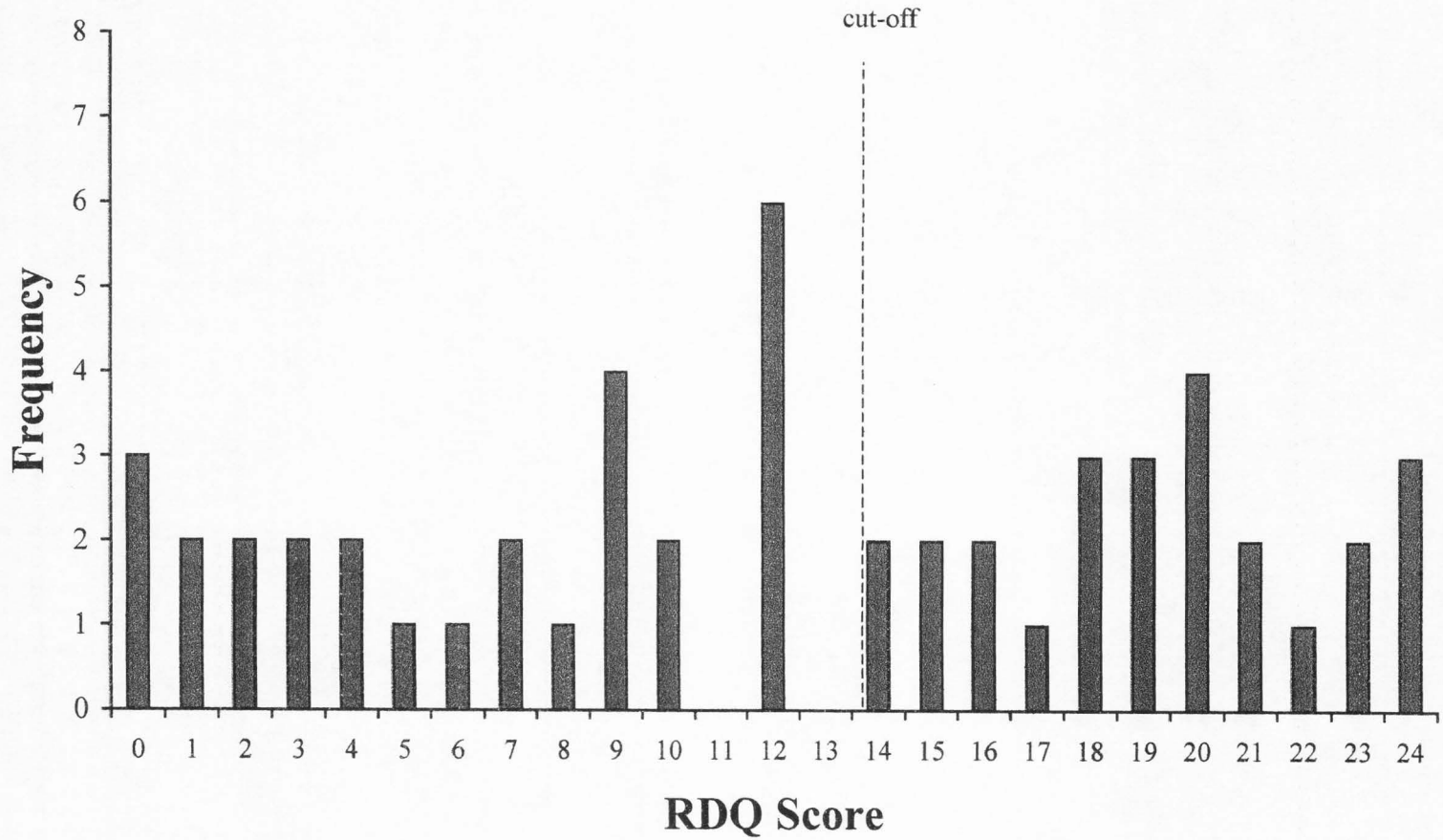

Figure 1. Frequency distribution of Roland-Morris Disability Questionnaire scores.

As can be seen in Table 9, the mean scores of all eight subscales are considerably lower than the general population values. In fact, the standardized mean difference effect sizes range from -0.76 to -1.52, with seven of the eight subscales considered large in magnitude (Stevens, 1990). Thus, the patients having undergone interbody cage fusion were reporting substantially poorer health than the general population across nearly all SF-36 subscales. The subscale scores for the back pain/sciatica sample were also consistently higher than the patients undergoing lumbar interbody cage fusion, although, as expected, to a lesser extent than the general normative sample. The standardized mean difference effect sizes between the back pain/sciatica sample and interbody cage fusion patients ranged from -0.26 to -0.98, with seven of the eight considered medium in magnitude. Thus, patients having undergone interbody cage fusion reported moderately poorer health than those experiencing co-morbid health concerns (back pain/sciatica and hypertension) across SF-36 subscales. A visual representation of the scaled scores for all eight subscales for the interbody cage fusion patients, general normative sample, and normative co-morbid patient sample can be seen in Figure 2.

Based on the eight subscales, as discussed previously, the SF-36 also yields the PCS and MCS summary scores. These scores, however, are configured as T-scores with $M = 50$ and $SD = 10$. More recently, norm-based scoring algorithms using T-score transformations for all eight scales have been developed to make interpretations and comparisons with the summary scores easier (Ware, 2000). In fact, scoring utility software has been made available by the instrument developers on the Internet (www.sf-36. com/ nbs) to facilitate re-estimation of the subscales, and was used for the T-score transformations presented in Table 9. Examination of the PCS and MCS values (34.6 and 44.1, respectively) for the lumbar interbody cage fusion sample revealed scores considerably below the general adult population. Although not as pronounced, a similar trend was found comparing the fusion sample to the back pain /sciatica normative group.

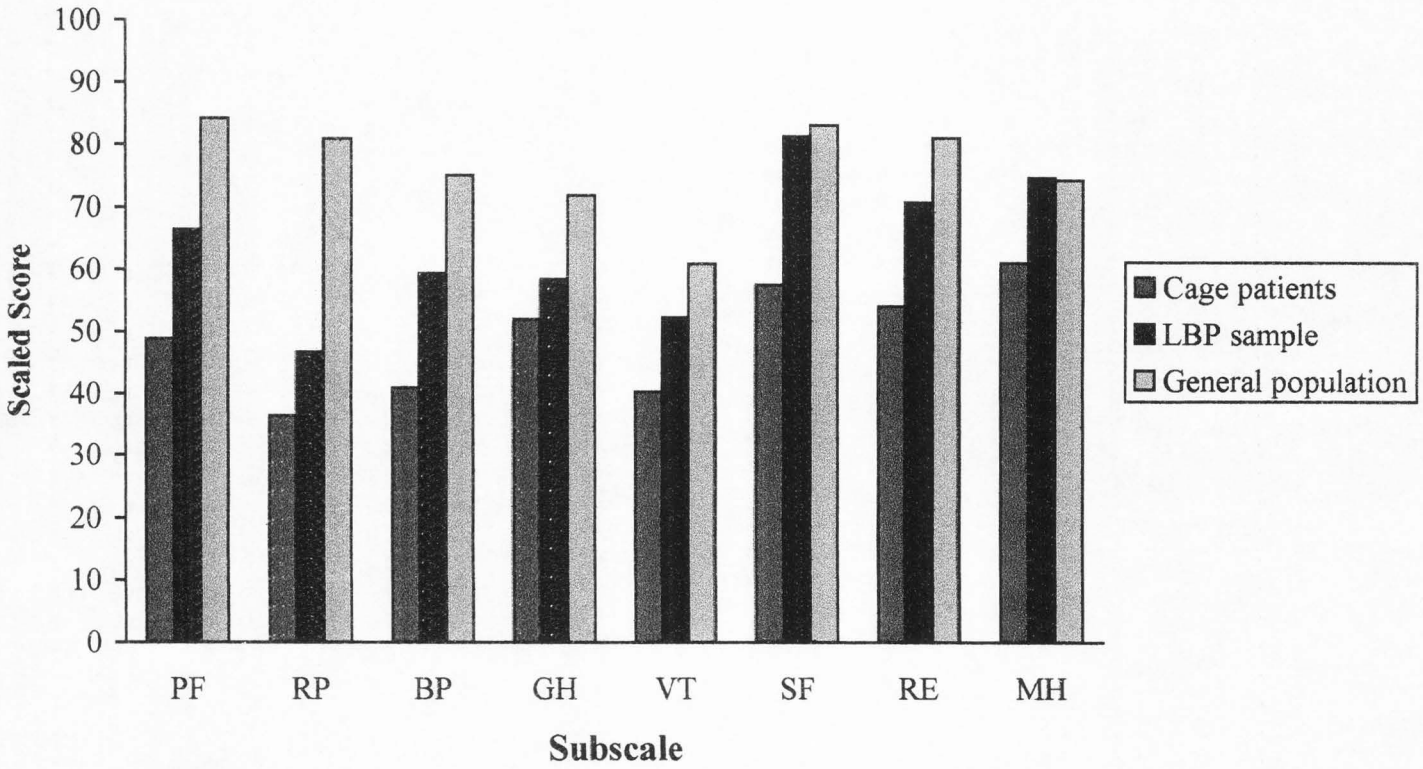

Figure 2. Short Form-36 subscale scores for cage patients, back pain/sciatica sample, and general population.

Table 9

SF-36 Multidimensional Health Outcomes and Comparisons

Scale	Cage sample[a]			General population sample[ab]			Back pain/sciatica sample[c]			
	M	*SD*	*T*[d]	*M*	*SD*	*T*	*M*	*SD*	*T*[d]	
Physical functioning (PF)	48.87	30.57	34.4	84.15	23.28	50	66.32	28.60	42.0	-1.52
Role-physical (RP)	36.32	38.16	36.7	80.96	34.00	50	46.71	40.51	39.8	-1.31
Bodily pain (BP)	40.92	22.31	35.3	75.15	23.69	50	59.34	24.63	43.1	-1.44
General health (GH)	51.94	23.39	39.9	71.95	20.34	50	58.45	21.63	43.2	-0.98
Vitality (VT)	40.28	24.46	40.0	60.86	20.96	50	52.29	22.74	45.8	-0.98
Social functioning (SF)	57.56	30.65	38.4	83.28	22.69	50	81.48	24.38	49.1	-1.13
Role-emotional (RE)	54.09	40.42	41.8	81.26	33.04	50	70.90	38.97	46.9	-0.80
Mental health (MH)	61.06	25.31	42.3	74.46	18.05	50	74.93	18.62	50.0	-0.76
Physical component summary (PCS)			34.6			50			39.6	
Mental component summary (MCS)			44.1			50			51.3	

[a] Observed range of all scores is 0 - 100. A high score indicates better health status.

[b]General U.S. adult population; $N = 2,474$ (Ware et al., 2000).

[c]Norms for comorbid condition: back pain/sciatica (in last 6 months) with hypertension; $N = 481$ (Ware et al., 2000).

[d]Patient sample scale scores were transformed to T-scores ($M = 50$, $SD = 10$) to facilitate comparisons with PCS and MCS scores. Used scoring utility software available on the Internet (www.sf-36.com/nbs).

[e] Standardized mean difference effect size between current cage sample and general population norms.

That is, the PCS scores differed from the two reference groups by 1.56 and 0.5 standard deviations, respectively, while the MCS differed by 0.59 and 0.72 standard deviations, respectively (see Figure 3). Thus, the patients undergoing spinal fusion perceived more limitations in self-care, physical, social, and role activities as well as more severe bodily pain than the normative groups. Additionally, the patients undergoing fusion reported more frequent psychological distress and social and role disability due to emotional problems. PPF and RP and BP were the areas of greatest perceived impairment for patients who underwent fusion.

In addition to subscale and summary scores, the SF-36 allows for examination of four dichotomous indicators to identify patients with: (a) physical limitations, (b) emotional limitations, (c) role disability, and (d) an unfavorable personal evaluation of their health in general (Ware et al., 2000). Individuals are identified as having a physical limitation if they acknowledge any activity restrictions on the 10-item PF scale, while emotional limitation is operationalized as a scaled score of 52 or lower on the MH subscale. As for role disability, an endorsement of any of the 4 items on the RP or 3 items on the RE subscales identifies the patient as having functional role limitations. The final indicator, unfavorable personal evaluation of health, is based solely on the individual's endorsement of the "fair" or "poor" description of his/her health on the first item of the GH subscale. As can be seen in Table 10, nearly all of the follow-up fusion patients (98.1%) were identified as having a physical limitation, whereas only 61.2% of the normative adult sample qualified as physically limited. Similar comparative trends were found with the remaining indicators, although the rates of limitation were not nearly as striking. Interestingly, approximately 40% of the fusion sample evaluated their health unfavorably compared to about 15% of the individuals included in the national norms. In summary, the dichotomous identification of limitations yielded similar findings to the other

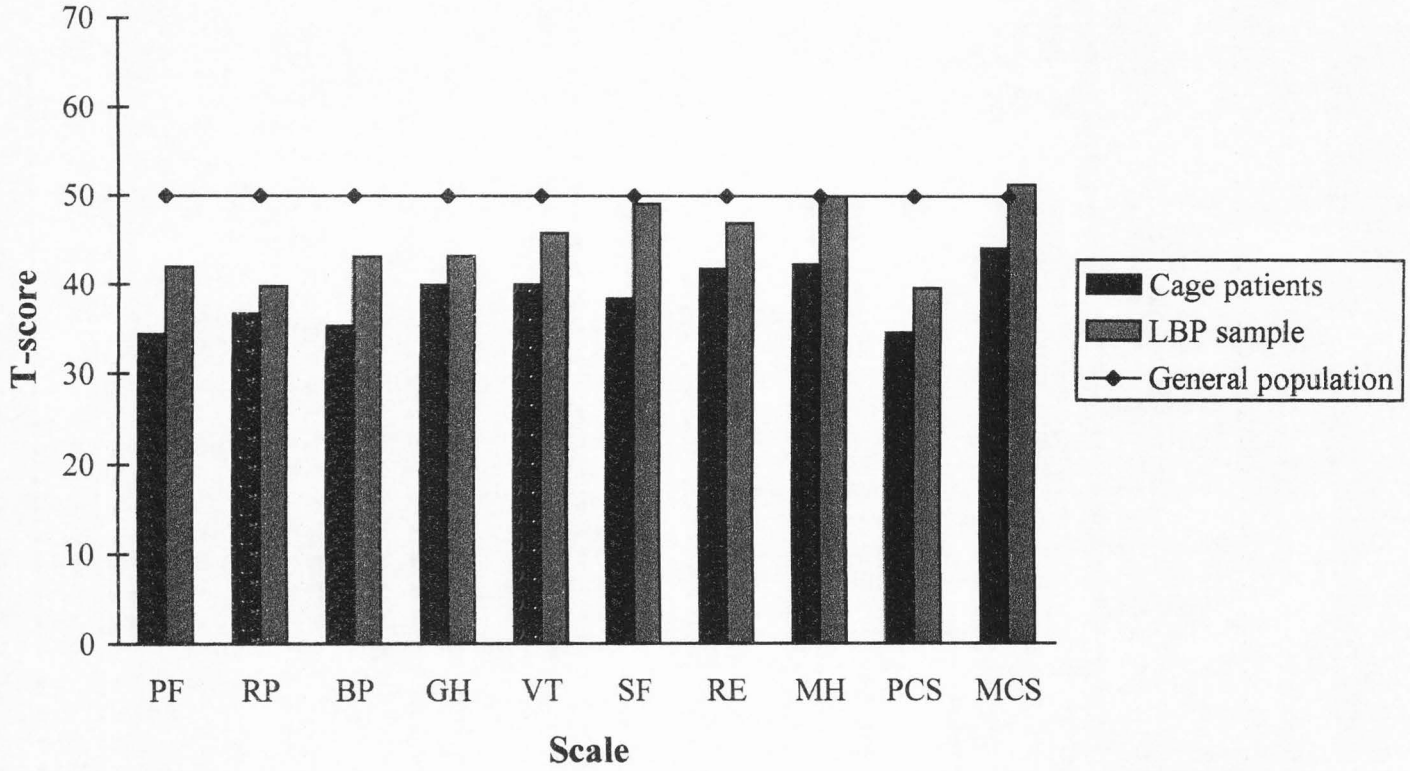

Figure 3. Short Form-36 norm-based component and subscale T-scores for cage patients and back pain/sciatica sample.

Table 10

SF-36 Dichotomous Limitation Indicator Outcomes

	Cage sample ($N = 53$)		National norms[a] ($N = 2,474$)	
Indicator	Frequency	Percentage	Frequency	Percentage
Any physical limitation				
Yes	52	98.1	1502	61.2
No	1	1.9	97	38.8
Any role disability limitation				
Yes	45	84.9	1049	42.8
No	8	15.1	1425	57.2
Emotional limitation				
Yes	22	41.5	329	13.4
No	31	58.5	2145	86.6
Fair/poor personal evaluation				
Yes	21	39.6	359	14.6
No	32	60.4	2115	85.4

[a] General U.S. adult population (Ware et al., 2000)

SF-36 indices and indicated that patients having undergoing lumbar interbody cage fusion endorse having more limitations than do general normative samples.

Intercorrelations of Outcomes

Interrelationships among the outcome variables, as indicated by research question 11, were examined by calculating Pearson product-moment correlations on 23 different indices. As seen in Table 11, the outcome variables included: duration of hospitalization (in days), arthrodesis (yes/no), quality of life and satisfaction with outcome (four questions), Stauffer-Coventry Index (four items and overall rating), total disability status (yes/no), Roland-Morris Disability Questionnaire total score, and the Short Form-36 Health Survey (subscales and summary scores). Nine of the outcome indices were reverse coded for these calculations, for ease of interpretation of the intercorrelations, so that

Table 11

Pearson Correlations Between Outcome Variables

	Variable																					
Variable	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
1	---																						
2	.02	---																					
3	.30*	.27*	---																				
4	.37*	.13	.67*	---																			
5	.15	.27*	.76*	.50*	---																		
6	.37*	.14	.85*	.66*	.78*	---																	
7	.20	.33*	.72*	.48*	.73*	.69*	---																
8	.19	.11	.61*	.18	.46*	.48*	.57*	---															
9	.02	.15	.66*	.29*	.61*	.60*	.56*	.60*	---														
10	.26	.34*	.50*	.47*	.52*	.45*	.65*	.44*	.32*	---													
11	.22	.23	.52*	.31*	.56*	.56*	.63*	.55*	.68*	.71*	---												
12	.06	.26*	.53*	.39*	.47*	.42*	.54*	.64*	.41*	.41*	.44*	---											
13	.28*	.05	.77*	.43*	.78*	.80*	.73*	.72*	.70*	.50*	.67*	.56*	---										
14	.19	.04	.70*	.45*	.69*	.67*	.57*	.66*	.66*	.42*	.59*	.58*	.85*	---									
15	-.14	.20	.47*	.16	.59*	.42*	.39*	.45*	.49*	.31*	.40*	.39*	.60*	.64*	---								
16	.03	.13	.53*	.31*	.70*	.60*	.71*	.53*	.53*	.57*	.64*	.51*	.75*	.70*	.64*	---							
17	-.03	.01	.46*	.21	.47*	.44*	.41*	.52*	.33*	.27	.34*	.48*	.51*	.66*	.54*	.63*	---						
18	-.05	-.02	.44*	.21	.61*	.50*	.41*	.47*	.33*	.41*	.43*	.36*	.64*	.65*	.69*	.65*	.61*	---					
19	.11	.00	.49*	.24	.60*	.50*	.42*	.55*	.42*	.39*	.43*	.47*	.65*	.63*	.61*	.63*	.57*	.69*	---				
20	.19	-.09	.47*	.34*	.52*	.45*	.41*	.49*	.39*	.30*	.30*	.44*	.56*	.62*	.46*	.47*	.48*	.50*	.58*	---			
21	-.21	-.07	.59*	.53*	.57*	.63*	.56*	.49*	.43*	.48*	.55*	.39*	63*	.59*	.40*	.56*	.46*	.54*	.61*	.62*	---		
22	-.05	.17	.54*	.21	.63*	.52*	.50*	.56*	.56*	.37*	.51*	.51*	.72*	.84*	.82*	.80*	.76*	.69*	.59*	.36*	.32*	---	
23	-.19	-.12	.50*	.41*	.56*	.54*	.46*	.49*	.33*	.42*	.41*	.39*	.59*	.55*	.43*	.52*	.49*	.66*	.76*	.82*	.89*	.30*	---

Note. 1 = hospitalization (days)[a]; 2 = arthrodesis (yes/no); 3 = quality of life change[a]; 4 = retrospectively, would repeat surgery; 5 = satisfaction with current back condition; 6 = back/leg pain change[a]; 7 = SCI: Pain Relief (%); 8 = SCI: Employment Status[a]; 9 = SCI: Physical Limitations[a]; 10 = SCI: Medication Usage[a]; 11 = SCI: Overall Rating[a]; 12 = disability status[a] (yes/no); 13 = RDQ total score[a]; 14 = SF-36: Physical Functioning; 15 = SF-36: Role Physical Functioning; 16 = SF-36: Bodily Pain; 17 = SF-36: General Health; 18 = SF-36: Vitality; 19 = SF-36: Social Functioning; 20 = SF-36: Role Emotional; 21 = SF-36: Mental Health; 22 = SF-36: Physical Component Summary; 23 = SF-36: Mental Component Summary.

[a]Reverse coded so higher scores reflect better functioning/outcome.

*$p \leq .05$; $N = 53$.

higher correlations reflected better functioning/outcome. Overall, intercorrelations ranged from -0.19 to 0.89 with 212/253 correlations being statistically significant. Interrelationships among the outcomes were consistently significant for all but the hospitalization and arthrodesis (which are discussed in more detail below). Hospitalization was only statistically correlated ($p < .05$; 0.28 to 0.37) with four outcome variables, three of which were patient satisfaction items. The patient satisfaction items, however, had several significant intercorrelations with other variables and ranged from 0.13 to 0.78 ($p < .05$). As expected, the correlations among the four satisfaction items were higher than the intercorrelations with other variables and ranged from 0.50 ($p < .05$) to 0.85 ($p < .05$). The SCI correlations among the five scales ranged from 0.32 ($p < .05$) to 0.71 ($p < .05$), whereas the correlations with the other outcome variables ranged from 0.02 to 0.73 ($p < .05$). Similarly, the SF-36 had correlations among the eight subscales and two component summary scores ranging from 0.30 ($p < .05$) to 0.89 ($p < .05$) with the lowest correlation occurring, as expected, between the PCS and MCS scores. Interrelationships between the SF-36 scales and other variables ranged from -0.19 to 0.71 ($p < .05$). Overall, the interrelationships among and between the outcome variables are consistent with what would be expected. That is, it appears there is generally overlap and differentiation with the outcome variables where conceptually anticipated.

Prediction of Outcomes

The final objective of the current study was to examine predictions of patient outcomes following the lumbar interbody cage fusion. This will be presented in two parts, the first of which is addressing research question 12 and involves determining the efficacy of arthrodesis in predicting outcomes. The second, and more extensive section, addresses research question 13, and involves examining the predictability of patient outcomes based on a model of presurgical variables. Thus, for the second part, separate regression analyses

were conducted for disability status, RDQ total score, SCI overall rating, and the SF-36 component summary scores and subscales. However, different forms of regression analyses were performed for these outcomes and will be discussed, in more detail, in accordance with the respective section.

Arthrodesis and Patient Outcomes

Given that arthrodesis was expected to and did occur, for most patients, prior to the 18-month cut-off for collection of the follow-up surveys, it was not considered a presurgical variable or long-term patient outcome, per se. Rather, arthrodesis was conceptualized as constituting an intermediate variable, and as such, it was examined separately from the other proposed predictors of long-term outcomes. Therefore, the Pearson product-moment correlations, presented in Table 11, were used for this investigation. As seen in column two, arthrodesis had statistically significant ($p < .05$) intercorrelations with 5/21 of the longer-term patient outcomes at followup, ranging from 0.26 to 0.34. Two of these correlations occurred with the patient satisfaction variables of *quality of life* and *satisfaction with current back condition*, indicating that a solid lumbar fusion was related to higher levels of satisfaction. Similarly, arthrodesis was significantly ($p < .05$) related to better patient outcomes on two of the SCI subscales, *percentage of pain relief* (0.33) and *medication usage* (0.34, reversed coded). Thus, solid fusion predicted less pain and less use of narcotic medications at 18-months postsurgery. Finally, arthrodesis was also related to disability status ($p < .05$, 0.26, reverse coded) at followup, indicating that solid fusion was associated with less total disability. Arthrodesis was not, however, significantly correlated with the RDQ or any of the SF-36 subscales. Overall, arthrodesis appeared to be related to better patient outcomes, although only for approximately 25% of the outcome variables and correlations were only moderate.

Presurgical Variables and Patient Outcomes

Several regression analyses were completed to address research question 13; however, due to fewer subjects than initially anticipated in this study the presurgical predictive model was limited to five variables. That is, given the conventional standard of approximately one predictor per 10 subjects (Kleinbaum, Kupper, & Muller, 1988; Stevens, 1996) and that the total number of subjects completing the outcome survey ranged from 53 to 56, only five predictors could be reliably included in the model. These variables were previously discussed in the literature review and include: age at the time of lumbar interbody cage fusion, diagnostic severity rating, smoking history at the time of surgery, presurgical depression, and lawyer involvement. Patient outcomes that were predicted from the five-variable model included: SCI aggregate outcome category, disability status, RDQ total score, and SF-36 component summary and subscale scores.

The first analysis examining the predictive efficacy of the regression model relied on discriminant function analysis. Because the SCI overall score grouped patients into one of three nominal groups (i.e., good, fair, or poor), it was determined that discriminant function analysis would be more appropriate than linear regression. That is, discriminant function analysis entails using a nominal dependent variable, whereas classical regression analysis involves a continuous dependent variable (Kleinbaum et al.,1988). Additionally, discriminant function analysis would, by its presentation, allow for more readily interpretable explanation of classification results. Neither the first discriminant function (Wilks' Lambda = .759, p = .169) or second discriminant function (Wilks' Lambda = .939, p = .520) were statistically significant in the analysis. Consequently, no further interpretations or classifications were undertaken with the SCI overall outcomes.

The second regression analysis involved predicting postsurgical disability status at the time of followup. Given that disability status was dichotomous (yes/no), logistic regression analysis was better suited than classical linear regression. That is, the outcome

variable has a binomial distribution of scores, as opposed to a normal distribution assumed with linear regression, which lends itself to clinically meaningful interpretations. Logistic regression analysis has become the standard model to describe the probability (or risk) of developing some disease over a specified period of time as a function of certain risk factors (Hosmer & Lemeshow, 2000). For the current analysis, three of the presurgical predictors were recoded from their original continuous values to an equal-interval continuous format. Thus, age was recoded to five-year intervals, while the diagnostic severity rating was reformatted to intervals of five units. Additionally, smoking history was recoded from the number of packs smoked per day to equal-intervals of 1,825 packs, which is the equivalent of smoking one pack per day for five years. Such variable formatting allows for greater ease and clarity in interpreting the logistic regression coefficients without sacrificing information, and is a widely accepted practice (e.g., Hosmer & Lemeshow).

The overall logistic model was statistically significant (chi-square = 24.27, $p <$ .001), indicating that the five-variable model resulted in a better prediction of disability status than expected with observed base-rates alone. As depicted in Table 12, the logistic regression model had an overall hit rate of nearly 79%, while the rate for correctly predicting nondisabled and disabled patients at followup was 91.4% and 57.1%, respectively. Compared to the base-rate of 62.5% (35/56) for nondisabled patients, the regression model improved the hit rate nearly 29%. Similarly for disabled patients, the model improved the hit rate nearly 20% from the base-rate of 37.3% (21/56). Adjusting the cut-value from 50% to a more conservative rate of 75%, which is not included in the table, resulted in the same overall rate of correct predictions. However, the hit rate for predicting nondisabled patients increased to 97.1%, whereas the correct prediction of disabled patients decreased to 47.6%.

Table 12

Logistic Regression Model: Disability Classification[a]

	Predicted		
Observed	Not disabled	Disabled	% Correct
Not disabled	32	3	91.4
Disabled	0	12	57.1
Overall correctly predicted			78.6

[a]The cut-value for group membership is .50.

Given that the overall logistic regression model was significant, attention moves to the individual variables to examine their respective contribution. As shown in Table 13, the Wald values were statistically significant ($p \leq .05$) for lawyer involvement and diagnostic severity rating, while depression approached significance ($p = .06$). The presurgical variables of age and smoking, however, did not predict a statistically significant amount of the variance for disability status. For interpretation of the presurgical variables, emphasis shifts to examination of the logistic coefficients, which indicate the log odds of an event occurring (i.e., disability status). Thus, the logistic coefficient is a measure of association that approximates how much more likely (or unlikely) it is for the outcome to be present per one unit of change in the independent variable. Note that each independent variable has both a logistic coefficient (â) and estimated logistic coefficient (Exp â). The logistic coefficient allows for the interpretation of log odds, while the estimated logistic coefficient is a translation of the log odd to odds and is somewhat easier to interpret (Hosmer & Lemeshow, 2000). For the estimated logistic coefficient, values greater than 1 indicate the odds of occurrence are increased, where values less than 1 mean the odds are decreased. Thus, a value of 1 would indicate the odds are unchanged or that the independent variable (i.e., presurgical variable) essentially had no relationship with

Table 13

Logistic Regression Equation Predicting Disability Status with Five Presurgical Varables as Predictors

Variable	β	Wald	*P*	Exp (B)	95% CI
Age	0.235	1.334	.25	1.265	0.85 - 1.89
Diagnostic sev rating	0.947	3.780	.05	2.578	0.99 - 6.69
Smoking	0.275	1.966	.16	1.317	0.90 - 1.93
Depression	2.041	3.532	.06	7.701	0.92 - 64.73
Lawyer involvement	2.214	6.770	.01	9.148	1.73 - 48.48
Constant	-3.658	4.796		0.26	

the dependent variable (i.e., disability status). As shown in Table 13, the largest values were for lawyer involvement (9.148), presurgical depression (7.701), and diagnostic severity rating (2.578). This can be interpreted for lawyer involvement, for instance, as the odds for being disabled increasing by 815% with the presence of an attorney, assuming all the other variables in the model remain constant. Similarly, the presence of presurgical depression increased the odds of being disabled at followup by 670%. Additionally, for each five-unit increment increase on the diagnostic severity rating scale there was a 158% increased risk of being disabled. In summary, three of the variables (lawyer involvement, presurgical depression, diagnostic severity rating) contributed substantial predictive efficacy to the logistic regression model, while the remaining two variables (age and smoking) were of less importance. Additionally, the overall model was accurate in predicting disability status compared to observed base-rates, with the greatest predictive efficacy occurring for prediction of nondisabled cases.

The third regression analysis involved predicting postsurgical back-specific functioning (using the five-variable model). For this analysis, the RDQ total score was used, which unlike disability status, was a continuous variable and better suited for

classical linear regression. Using simultaneous-entry multiple regression analysis, the five-variable model was statistically significant ($F = 6.60$, $p < .001$) with an R^2 of .412. That is, 41% of the total variance of the RDQ total score was accounted for by the set of predictors. As seen in Table 14, three of the predictor variables (smoking, presurgical depression, and lawyer involvement) were statistically significant at an alpha level of .05, while the fourth variable (age) approached significance. In multiple linear regression, beta weights are interpreted as indicating the expected change in the dependent variable (e.g., RDQ total score) associated with a unit change in the predictor variable, while partialing out the other predictor variables (Stevens, 1996). However, because of the lack of comparability of the beta weights, it is helpful to examine the standardized beta weights to address the relative importance of the respective predictor variables. Given this, smoking at the time of surgery ($\beta = .342$) and presurgical depression ($\beta = .320$) were comparable in terms of predictive importance, while lawyer involvement ($\beta = .273$) and age ($\beta = .229$) proved to be slightly less influential in accounting for variance. Thus, more tobacco consumption at the time of surgery, having presurgical depression, retaining an attorney, and being older at the time of surgery predicted higher RDQ total scores (i.e., poorer back-specific functioning) approximately two years following spinal fusion.

The remaining regression analyses examine of the SF-36 component summary and subscale scores and, because these are continuous variables, follow a similar format as that just presented. Thus, using simultaneous-entry multiple regression analysis to predict the SF-36 PCS score, the five-variable model was statistically significant ($F = 7.46$, $p < .001$). The model resulted in an R^2 of .442, indicating that 44% of the total variance of the PCS was accounted for by the set of predictors. As noted in Table 15, presurgical depression ($\beta = -.399$), smoking ($\beta = -.359$), and lawyer involvement ($\beta = -.342$) were statistically significant ($p < .01$) predictors of the variance. Thus, having presurgical depression,

Table 14

Linear Multiple Regression Model Predicting the RDQ Total Score[a]

	Coefficients			
	Unstandardized coefficients		Standardized coefficients	
Variable	β	*SE*	β	*P*
Age	0.150	p.085	0.229	.08
Diagnostic severity rating	-0.005	0.205	-0.004	.98
Smoking	0.000	0.000	0.342	.01
Depression	6.281	2.317	0.320	.01
Lawyer Involvement	4.243	1.791	0.275	.02
Constant	-8.771	4.400		

[a]Model summary: $p < .01$, $R = .642$, $R^2 = .412$, adjusted $R^2 = .350$.

Table 15

Linear Multiple Regression model Predicting the SF-36 Physical Component Summary Score[a]

	Coefficients			
	Unstandardized coefficients		Standardized coefficients	
Variable	β	*SE*	β	*P*
Age	-0.717	0.120	0.179	.16
Diagnostic severity rating	0.423	0.292	0.198	.15
Smoking	0.001	0.000	-0.359	.01
Depression	-11.447	3.300	-0.399	.01
Lawyer Involvement	-7.788	2.551	-0.342	.01
Constant	64.672	6.267		

[a]Model summary: $p < .01$, $R = .665$, $R^2 = .442$, adjusted $R^2 = .383$.

consuming larger amounts of tobacco, and having an attorney involved in the case predicted lower PCS scores (i.e., poorer physical functioning) postsurgery.

The simultaneous-entry multiple regression analysis predicting the SF-36 mental component summary (MCS) score was also statistically significant ($F = 2.54$, $p = .041$). The five-variable model yielded an R^2 of .213, indicating that the set of predictors accounted for 21% of the total variance of the MCS score. As denoted in Table 16, smoking at the time of surgery ($\beta = -.340$) was the only statistically significant predictor of the group, while a trend toward significance ($p = .10$) was seen with presurgical depression ($\beta = -.230$). In sum, greater quantities of tobacco use as of the time of surgery, and to a lesser extent, presurgical depression predicted lower MCS scores at followup.

Given that both PCS and MCS regression equations were statistically significant, it was decided to also examine the eight SF-36 subscales comprising the summary scores as a means of providing a more detailed examination of patient functioning. Thus, Tables 17 through 24 depict the simultaneous-entry multiple regression analyses for the eight subscales, respectively. The first subscale, physical functioning (PF), includes a variety of items, such as intensity of activities, climbing stairs, walking, bathing/dressing, that assess the extent to which health impedes physical functioning. The results for the regression analysis of PF was statistically significant ($F = 10.36$, $p < .001$) with an R^2 of .524, indicating the five-variable model accounted for 52% of the total variance of the score. Presurgical depression ($\beta = -.379$), lawyer involvement ($\beta = -.368$), age ($\beta = -.320$), and smoking ($\beta = -.299$) were statistically significant predictors at an alpha level of .05 (see Table 17). Thus, having presurgical depression, retaining an attorney, older age at the time of surgery, and consuming larger amounts of tobacco as of the time of surgery all predicted poorer physical functioning at followup.

The results of multiple regression equation using the five-variable for the RP subscale of the SF-36 are presented in Table 18. The RP subscale pertains to work

Table 16

Linear Multiple Regression Model Predicting the SF-36 Mental Component Summary Score[a]

	Coefficients			
	Unstandardized coefficients		Standardized coefficients	
Variable	β	*SE*	β	*P*
Age	-0.717	0.161	-0.159	.29
Diagnostic severity rating	0.006	0.390	0.003	.99
Smoking	-0.001	0.000	-0.340	.02
Depression	-7.407	4.408	-0.230	.10
Lawyer Involvement	-1.704	3.407	-0.067	.62
Constant	65.175	8.370		

[a]Model summary: $p < .04$, $R = .461$, $R^2 = .213$, adjusted $R^2 = .129$.

Table 17

Linear Multiple Regression Model Predicting the SF-36 Physical Component Summary Score[a]

	Coefficients			
	Unstandardized coefficients		Standardized coefficients	
Variable	β	*SE*	β	*P*
Age	-0.860	0.312	-0.320	.01
Diagnostic severity rating	0.591	0.758	0.097	.45
Smoking	-0.002	0.001	-0.299	.01
Depression	-30.592	8.569	-0.379	.01
Lawyer Involvement	-23.524	6.623	-0.368	.01
Constant	154.832	16.271		

[a]Model summary: $p < .00$, $R = .724$, $R^2 = .524$, adjusted $R^2 = .474$.

Table 18

Linear Multiple Regression Model Predicting the SF-36 Physical Subscale[a]

	Coefficients			
	Unstandardized coefficients		Standardized coefficients	
Variable	β	*SE*	β	*P*
Age	-0.587	0.494	-0.175	.24
Diagnostic severity rating	1.589	1.200	0.212	.19
Smoking	-0.003	0.001	-0.273	.05
Depression	-24.877	13.560	-0.247	.07
Lawyer Involvement	-21.181	10.481	-0.265	.05
Constant	112.001	25.747		

[a]Model summary: $p < .02$ $R = .485$, $R^2 = .236$, adjusted $R^2 = .154$.

Table 19

Linear Multiple Regression Model Predicting the SF-36 Bodily Pain Subscale[a]

	Coefficients			
	Unstandardized coefficients		Standardized coefficients	
Variable	β	*SE*	β	*P*
Age	-0.207	0.264	-0.105	.44
Diagnostic severity rating	0.273	0.642	0.062	.67
Smoking	-0.002	0.001	-0.394	.01
Depression	-19.153	7.248	-0.325	.01
Lawyer Involvement	-12.176	5.602	-0.261	.04
Constant	912.906	13.762		

[a]Model summary: $p < .001$, $R = .601$, $R^2 = .361$, adjusted $R^2 = .293$.

Table 20

Linear Multiple Regression Model Predicting the SF-36 Physical Component Summary Score[a]

	Coefficients			
	Unstandardized coefficients		Standardized coefficients	
Variable	β	*SE*	β	*P*
Age	-0.185	0.252	-0.090	.47
Diagnostic severity rating	0.854	0.612	0.186	.17
Smoking	-0.003	0.001	-0.470	.01
Depression	-26.381	6.916	-0.427	.01
Lawyer Involvement	-13.626	5.346	-0.278	.01
Constant	108.480	13.132		

[a]Model summary: $p < .001$, $R = .686$, $R^2 = .471$, adjusted $R^2 = .415$.

Table 21

Linear Multiple Regression Model Predicting the SF-36 Vitality Subscale[a]

	Coefficients			
	Unstandardized coefficients		Standardized coefficients	
Variable	β	*SE*	β	*P*
Age	-0.142	0.308	-0.066	.65
Diagnostic severity rating	0.638	0.748	1.33	.40
Smoking	-0.003	0.001	-0.470	.01
Depression	-18.404	8.458	-0.285	.04
Lawyer Involvement	-4.725	6.537	-0.092	.47
Constant	75.916	16.059		

[a]Model summary: $p < .008$, $R = .526$, $R^2 = .276$, adjusted $R^2 = .199$.

Table 22

Linear Multiple Regression Model Predicting the SF-36 Social FunctoningSubscale[a]

	Coefficients			
	Unstandardized coefficients		Standardized coefficients	
Variable	β	*SE*	β	*P*
Age	-0.426	0.390	-0.158	.28
Diagnostic severity rating	0.590	0.947	0.098	.54
Smoking	-0.003	0.001	-0.309	.03
Depression	-33.451	10.699	-0.414	.01
Lawyer Involvement	-1.867	8.269	-0.290	.82
Constant	118.718	20.314		

[a]Model summary: $p < .01$, $R = .512$, $R^2 = .263$, adjusted $R^2 = .184$.

Table 23

Linear Multiple Regression Model Predicting the SF-36 Role Emotional Subscale[a]

	Coefficients			
	Unstandardized coefficients		Standardized coefficients	
Variable	β	*SE*	β	*P*
Age	-1.104	0.497	-0.311	.03
Diagnostic severity rating	-0.675	1.207	-0.085	.58
Smoking	-0.002	0.001	-0.156	.24
Depression	-19.612	13.637	-0.184	.16
Lawyer Involvement	-20.736	10.540	-0.245	.06
Constant	163.946	25.893		

[a]Model summary: $p < .003$, $R = .558$, $R^2 = .311$, adjusted $R^2 = .238$.

Table 24

Linear Multiple Regression Model Predicting the SF-36 Mental Health Subscale[a]

	Coefficients			
	Unstandardized coefficients		Standardized coefficients	
Variable	β	*SE*	β	*P*
Age	-0.301	0.330	-0.135	.37
Diagnostic severity rating	0.289	0.801	0.158	.72
Smoking	-0.003	0.001	-0.379	.01
Depression	-12.978	9.057	-0.194	.16
Lawyer Involvement	-7.840	7.001	-0.148	.27
Constant	103.530	17.198		

[a]Model summary: $p < .03$, $R = .474$, $R^2 = .225$, adjusted $R^2 = .142$.

functioning (or other daily activity), such as limitations in type or amount, secondary to physical health problems. Results for the simultaneous-entry multiple regression analysis of the RP subscale were statistically significant ($F = 2.90$, $p = .023$) with an R^2 of .236. Lawyer involvement (β = -.265) was the only statistically significant predictor of the variance, although smoking (β = -.273) and presurgical depression (β = -.247) were both approaching significance, and had similar beta weights. Thus, retaining an attorney, consuming larger amounts of tobacco up to the time of surgery, and having presurgical depression predicted poorer role performance as related to physical functioning.

The next SF-36 subscale, BP, includes two items assessing the intensity of pain and extent of its interference with work. The simultaneous-entry multiple regression analysis predicting the BP subscale was also statistically significant ($F = 5.32$, $p = .001$). The five-variable model resulted in an R^2 value of .361, indicating that the set of predictors accounted for 36% of the total variance of the BP score. As seen in Table 19, smoking at the time of surgery (β = -.394), presurgical depression (β = -.325), and lawyer

involvement (β = -.265) were all statistically significant predictors. In sum, consuming larger amounts of tobacco up to the time of surgery, having presurgical depression, and to a lesser extent, retaining an attorney predicted greater bodily pain (and its interference) at followup.

Table 20 presents the results of the simultaneous-entry multiple regression analysis predicting the SF-36 GH subscale. This subscale pertains to the evaluation of personal health and the expectation that it will decline (or improve). The five-variable model was statistically significant ($F = 8.37$, $p = .000$) with an R^2 value of .471, denoting the set of predictors accounted for 47% of the total variance of the GH subscale score. The following three predictors were statistically significant: smoking (β = -.470), presurgical depression (β = -.427), and having an attorney (β = -.278). Thus, higher rates of tobacco consumption as of the time of surgery, having presurgical depression, and, to a lesser degree, retaining an attorney predicted poorer evaluations of GH postspinal fusion.

The simultaneous-entry multiple regression analysis predicting the SF-36 VT subscale is presented in Table 21. The VT subscale contains four items assessing the extent to which the individual acknowledges feeling worn out versus full of energy. The regression model was statistically significant ($F = 3.59$, $p = .008$), with an R^2 of .276. Smoking (β = -.470) and presurgical depression (β = -.285) were the only statistically significant predictors of the set, indicating that higher consumption of tobacco as of the time of surgery, and to a lesser extent, having presurgical depression predicted lower levels of VT at followup.

The next simultaneous-entry multiple regression analysis, presented in Table 22, examined the five-variable model in relation to the SF-36 SF subscale. This subscale assesses the extent to which physical or emotional difficulties interfere with normal social activities. As with the previous subscales, SF was also statistically significant ($F = 3.45$, $p = .011$). The model yielded an R^2 value of .263, indicating that the set of predictors

accounted for 26% of the total variance for SF. The only statistically significant predictors from the model were presurgical depression (β = -.414) and smoking (β = -.309). In summary, having presurgical depression and higher tobacco consumption, to a lesser extent, predicted poorer SF following spinal surgery.

The prediction of the SF-36 RE subscale, using simultaneous-entry multiple regression model, is presented in Table 23. The RE subscale is an index of difficulty with work (or other daily activities) as a consequence of emotional factors. The five-variable model was statistically significant ($F = 4.24$, $p = .003$) and predicted 31% of the total variance (R^2 of .311) of the RE subscale score. Age at the time of surgery (β = -.311) was the only statistically significant predictor of the group, while a trend toward significance ($p = .055$) was seen with lawyer involvement (β = -.245). Thus, older age at the time of surgery, and to a lesser extent, having an attorney predicted more difficulty with functioning as a result of emotional problems.

Table 24 summarizes the simultaneous-entry multiple regression analysis for the final SF-36 subscale, MH. This subscale contains five items to assess the extent of feeling anxious and depressed. The five-variable model was statistically significant ($F = 2.73$, $p = .030$) and resulted in an R^2 value of .225. Smoking (β = -.379) was the only statistically significant predictor of the set, indicating that higher rates of tobacco use as of the time of surgery predicted higher levels of depression/anxiety at followup.*Summary of*

Prediction of the Outcome Variables

Overall, arthrodesis appeared to be moderately related to better patient outcomes, such as higher satisfaction, greater percentage of pain relief, less medication usage, and less disability. However, solid fusion was not associated with RDQ total score or any of the SF-36 subscales. The five-variable multiple regression model was statistically significant with all the outcome variables, except for the SCI overall rating. Thus, disability status, RDQ total score, and SF-36 summary component scores and subscales

had significant levels of variance accounted for by the overall regression model. Three of the five predictors in the model (smoking, presurgical depression, lawyer involvement) appeared to be consistently accounting for the variance across the regression equations. The predictors and their occurrence of statistical significance are as follows: smoking at the time of surgery (9/12), presurgical depression (7/12), lawyer involvement (7/12), age at the time of surgery (2/12), and diagnostic severity rating (1/12).

CHAPTERV

DISCUSSION

This retrospective cohort study addressed several research questions related to the newly developed and FDA-approved lumbar interbody cage fusion apparatus. These questions can be encompassed by the overarching aims of: (a) identifying primary characteristics of individuals who underwent the spinal fusion procedure in Utah, (b) examining multidimensional outcomes following a sufficient period of recovery, and (c) investigating the predictive efficacy of a biopsychosocial presurgical multivariable model with regard to outcomes. This chapter includes a summary and interpretation of the findings, as well as a discussion of the implications. Additionally, the limitations of this study are discussed, as are suggestions for future research.

Characteristics of the Patient Sample and Fusion

An aim of this study was to describe primary characteristics of individuals who underwent lumbar interbody cage fusion in Utah. Examination of these data revealed that the entire sample was Caucasian, 66% of which were males, and the mean age at the time of spinal fusion surgery was nearly 44 years. These characteristics are consistent with samples from other lumbar interbody cage fusion studies (e.g., Elias et al., 2000; Hacker, 1997; Kuslich et al., 1998, 2000; Matge & Leclercq, 2000; Ray, 1997a, 1997b) summarized earlier. Interestingly, none of these previous studies reported the ethnicity of their samples. However, DeBerard et al. (2001, 2002b) also found restrictions in ethnicity (i.e., 96% Caucasian) within their Utah sample of posterolateral fusion patients. Examination of Utah and U.S. census data (U.S. Census Bureau, 2000) revealed an almost equal split between males and females, and greater racial diversity (i.e., 89% and 75% Caucasian in Utah and U.S., respectively) than the present sample of interbody cage fusion

patients. Notably, the current sample's disproportionate Caucasian representation somewhat limits the generalizability of the findings and conclusions that may be drawn from the study.

In terms of compensation status, the current study consisted of 59% WCFU patients and 41% private practice patients of an orthopedic surgeon in central Utah. However, some overlap existed in these samples, as evidenced by the private practice surgeon providing spinal fusions to WCFU patients, as well as several of the private practice patients being involved in litigation (27%) and seeking compensation outside of the WCFU system (e.g., self-insured employers). It is estimated that the WCFU provides insurance to nearly 55% of the workers in Utah (DeBerard et al., 2001), which appears concordant with the proportion of the current sample. Moreover, comparison of the two sets of patient samples, in this study, revealed no significant differences across several presurgical variables. Thus, the results of this study tentatively generalize to workers' compensation and noncompensation patients undergoing the lumbar interbody cage fusion in Utah (given the limitations noted above). Although it is plausible that WCFU compensation status may be associated with poorer outcomes, it was beyond the scope of this study, and thus not examined further. It is worthy of mention that compensation status has been found to be predictive of outcomes within the LBP literature; however, its predictive efficacy has been less consistent for lumbar spinal arthrodesis procedures, particularly interbody cage fusion (Kuslich et al., 1998; Tandon et al., 1999; Vamvanij et al., 1998).

Nearly all of the lumbar interbody cage fusion studies, to date, have failed to include data on SES, litigation, and presurgical depression. Given this dearth of literature, the ability to make direct comparisons between these samples is limited in this study. Examination of SES, based upon an index of education and occupation, revealed that over three fourths of the current sample had attained levels commensurate with high school

education and unskilled/semiskilled employment. Using the same SES index, DeBerard (1998) found that 83% of the patients who underwent posterolateral fusion and were involved with WCFU occupied this same status. In a study of the BAK cage apparatus with a Minnesota workers' compensation sample, DeBerard et al. (2002a) reported education levels that were nearly identical to those found in the present Utah sample. In the current study, 33% of the patients was involved in litigation and 16% had a history/diagnosis of depression prior to surgery. In the WCFU posterolateral and Minnesota samples, rates of litigation were somewhat higher (39 - 44%) and presurgical depression slightly lower (9 - 10%) than that found in this study.

Given that the incidence of clinical depression in patients with chronic LBP has been reported to range from 30 - 57% (Epker & Block, 2001; Rush et al., 2000; Simmonds, Kumar, & Lechelt, 1996), the findings on the rates of depression across these three sample deserve further comment. These data suggest that the method used for identifying presurgical depression, in this sample of lumbar fusion patients, was more conservative than that used elsewhere in the literature. That is, establishing a clinical diagnosis of depression from a patient's medical record is prone to underestimate the presence of psychological disturbance/depression experienced by someone with chronic LBP and about to undergo lumbar spinal fusion. This likely underestimation may be a product of lacking a sufficiently sensitive measure used prospectively and/or reflective of spinal surgeons' reluctance to acknowledge the relevance of psychological status (Sullivan, 2001). Alternatively, even if physicians may be sensitive to the clinical and predictive importance of a diagnosis of depression, they may be hesitant to document its presence in the medical record for fear of potential prejudice to patients by insurance companies, workers' compensation organizations, or legal proceedings.

Patients undergoing spinal fusion operations are commonly refused surgery or advised to begin a smoking cessation program prior to and at least 6 months following

arthrodesis procedures. Given this, it was somewhat surprising that nearly half of the participants (42%) in this study admitted to being smokers at the time of their spinal fusion surgery. Further, they appeared to report substantial tobacco consumption, with a mean lifetime habit of approximately 5,950 pack years (i.e., equivalent of 1 pack per day for 16 years). Notably, about 25% of the adult population in the United States smoke cigarettes, whereas the rate in Utah is estimated to be nearly 17% (Utah Department of Health, 1993; Vogt et al., 2002). In the few interbody cage fusion studies that have inquired about smoking, the rates have ranged from 17 - 35% (DeBerard et al., 2002a; Elias et al., 2000; Kuslich et al., 1998; Ray, 1997a). Interestingly, the rate of smoking (44 - 55%) in noncage fusion samples has often been reported to be higher (Andersen et al., 2001; DeBerard et al., 2002a; Glassman et al., 2000). Although, these somewhat disparate rates of smoking are not entirely understood, it appears to be the case in some of the studies (e.g., Hacker, 1997; Kuslich et al., 1998; Ray, 1997a) that inclusion criteria for interbody cage fusion candidates were considerably more selective. Results of the present study are likely a better estimate of actual smoking rates among lumbar fusion patients.

With regard to presurgical lumbar pathology, spinal diagnoses, surgical characteristics, and length of hospitalization, the current sample appeared unremarkable relative to those reported elsewhere. For instance, the mean presurgical diagnostic severity rating, based upon imaging radiographs (see Appendix B), was 9.1 with a range of 2 to 29, which, given the slight modifications made in this study, is consistent with that reported by DeBerard and colleagues (2001). Similarly, spinal diagnoses (and rates) were consistent with several studies (e.g., DeBerard et al., 2001, 2002a), yet less so with those of the developers of the interbody cage devices (e.g., Kuslich et al., 2000). Examination of surgical characteristics (i.e., approach, levels operated upon, complication rates) also revealed compatible findings with most interbody cage studies, except in those cases

where surgery was restricted to a posterior approach and/or single level of fusion (Elias et al., 2000; Hacker, 1997; Matge & Leclercq, 2000; Ray, 1997b).

Much has been made in the literature about the shorter length of hospitalization for interbody cage fusion devices, with individuals requiring as little as 2 days of inpatient care following surgery (e.g., Kuslich, see McAfee et al., 2001). However, the present study found a mean hospital stay of 4.63 days, which was slightly higher than many other studies (e.g., 4.25 days, Elias et al., 2000; 3.5 days, Hacker, 1997; 4.4 days, Kuslich et al., 1998). Interestingly, only a few studies have reported higher periods of hospitalization (e.g., 6.8 days, Vamvanij et al., 1998) for interbody cage fusion, which were similar to intrastudy comparisons with other spinal fusion procedures. Without randomized controlled trials, the data appear inconclusive, at best, and the assertion that interbody cage fusion offers a significantly shorter length of hospitalization is premature. Although speculative, a closer examination of patient characteristics suggests that cigarette smoking may offer an explanation into these seemingly disparate rates of hospitalization. For instance, the study by Vamvanij and colleagues (1998) included samples with considerably higher rates of smoking (up to 60%) compared to the sample used by Hacker (1997), that initially excluded smokers and then only included those who smoked less than one pack per day. Thus, smoking may have contributed to a more physically deconditioned surgery patient and necessitated longer postoperative recovery and hospitalization. It is also plausible that these differences may reflect poorer health habits, in general, (and overall worse health status) which tend to co-vary with smoking patients and samples (DeBon & Klesges, 1995).

Multidimensional Outcomes of Interbody Cage Fusion

Seventy-three individuals were identified as having lumbar interbody cage fusion in this study, and of these, 77% participated in part or all of the follow-up telephone

outcome survey at a mean of 2.6 years postsurgery. The overwhelming reason participants did not complete the outcome measures was that they were unable to be located following a change of address (despite several attempts at searching public databases). Those who responded to the outcome survey were found to be statistically indistinguishable from the nonresponders across several demographic and presurgical variables. Moreover, the rate and average time to outcome followup are congruent with rates published elsewhere in the literature (e.g., DeBerard et al., 2001). Thus, the followup for the outcome surveys is considered to be reasonably inclusive and exhaustive, as well as allowing for sufficient time to pass before assessment of rehabilitation. Incidentally, this agrees with the findings of short-term outcomes (e.g., 6 months) being strongly predictive of long-term followup beyond 3 years (Greenough et al., 1998; Rompe, Eysel, & Hopf, 1995).

The following summary and discussion of patient outcomes will proceed in line with the general format presented in the previous chapter. This includes findings related to rates of arthrodesis, patient satisfaction, categorization of outcome, disability status and low back functional condition, and general physical and mental health functioning.

Arthrodesis Rates

Given that LBP is thought, within the surgical community, to be largely a consequence of vertebral instability and motion, it follows that arthrodesis is the fundamental objective in spinal fusion procedures. As discussed in previous chapters, however, arthrodesis is expected to generally occur between 6 and 12 months, which gives rise to it being conceptualized as an intermediate variable. That is, arthrodesis is both an outcome variable and predictor of longer-term objectives and outcomes. Nonetheless, what follows will be limited to arthrodesis as an outcome, with attention to the prediction of other variables addressed in later sections.

Arthrodesis occurred for 84% of the patient sample, while, conversely, pseudarthrosis took place in the remaining 16% of the patients. When compared to

noncage fusion procedures, these rates are generally commensurate or perhaps moderately more favorable than those reported in the literature. For instance, in a frequently cited meta-analysis of 37 studies (of mostly nonworkers' compensation patients), Turner et al. (1992) found a mean arthrodesis rate of 86%, with a broad range spanning from 56 - 100%. Similarly, Franklin and colleagues (1994) noted a solid fusion rate of 85% in a workers' compensation sample, whereas DeBerard et al. (2001), Greenough et al. (1994), and Snider et al. (1999) observed arthrodesis rates ranging from 68 - 74%.

The current study's arthrodesis rate did not, however, match the impressive percentages reported by the developers of the interbody cage devices. For instance, Ray (1997a) declared that arthrodesis, at 2 years postsurgery, was present in 96% of the patients having the RTCF apparatus. Kuslich et al. (2000,1998) have also reported exceptional arthrodesis rates of 91, 98, 98, and 100% for 2, 3, 4, and 5 years postsurgery, respectively. It is noteworthy that two independent studies (Elias et al., 2000; Vamvanij et al., 1998) examining the RTCF and BAK interbody cages with sufficient follow-up periods did not replicate these arthrodesis rates. In fact, Elias et al. found a pseudarthrosis rate of 34% for the RTCF, while Vamvanij et al. observed a solid fusion rate of 88% for the BAK device. Thus, it appears that the developers of interbody cage fusion devices have reported quite impressive rates of solid fusion, while the few independent studies (including the current study) completed so far have found rates more commensurate with, to moderately better than, noncage fusion techniques.

These differences in rates of arthrodesis are likely attributable, as Kuslich et al. (1998) has suggested, to "carefully" selected patients. That is, the studies with solid fusion rates approaching 100% (e.g., Hacker, 1997; Kuslich et al., 2000, 1998; Ray, 1997a) have either excluded or minimally included patients with psychiatric history, litigation, secondary gain issues, or smoking cigarettes at the time of intervention. Moreover, Ray (1997a) reported that 80% were working just prior to surgery, which suggests LBP

impairment (or delay before surgery) may have been less problematic than for the patients in present study. Similarly, Kuslich et al. (2000) only included patients with no previous attempted lumbar fusions. In summary, it appears that lumbar interbody cage fusion procedures yield arthrodesis rates at least as good as other procedures, but often slightly to moderately better. However, in studies such as the current report, where samples were not highly screened and selected (and may represent the more typical LBP patient), the impressive rates of solid fusion failed to be replicated.

In the current study, arthrodesis between the designated spinal vertebrae was determined by documentation in the medical record by either a radiologist and/or physician. It is uniformly practiced by physicians and radiologists to rely on imagining radiographs to detect bridging bone in the interbody space, an absence of radiolucencies, and limited motion of the spine during lateral flexion-extension positions. Within the surgical community, however, considerable controversy surrounds the measurement of and criterion for arthrodesis (cf. McAfee et al., 2001). In fact, the only clear consensus on this issue is that the current imaging radiographs do not allow an absolute determination of solid fusion with interbody cage devices (Jones, 2001; McAfee et al., 2001). Thus, to some extent, the discrepancy in arthrodesis rates observed in the current study as well as the literature on spinal fusion, may be attributed to the variability in assessing arthrodesis. The limitations of documenting arthrodesis, then, provides further support for evaluating multidimensional outcomes, toward which this discussion will now direct its attention.

Patient Satisfaction Outcomes

Although patient satisfaction is arguably an important outcome of treatment (Hudak & Wright, 2000), few lumbar fusion studies have included it in their evaluation of surgical outcome. The patient satisfaction questions included in this study were replicated from previous studies evaluating spinal surgery outcomes (DeBerard et al., 2001, 2002a; Franklin et al., 1994). Overall, there were substantial rates of patient dissatisfaction with

the interbody cage fusion procedure, though the proportions tended to be evenly divided between satisfaction and dissatisfaction. For instance, patients endorsed similar levels of satisfaction/dissatisfaction (51% vs. 44%) with regards to their current back condition. Similarly, across two questions concerning pain relief, patients' acknowledged somewhat to much better relief than expected in 42 - 46% of the cases, whereas 42 - 50% of the sample claimed somewhat to much worse pain relief at followup. Responses about quality of life resulting from the spinal fusion yielded somewhat less balanced divisions, with 57% indicating an improvement and 38% judging that a decline had occurred for them. In spite the fairly bimodal distribution for satisfaction with expected pain relief, nearly two thirds of the patients stated they would, in retrospect, choose the spinal fusion again, while only a quarter of the sample would not.

Thus, it appears that some patients may have gone into the interbody cage fusion procedure with somewhat inflated expectations about the potential for pain relief and improvement in functioning. Despite disconfirmation of these beliefs for some individuals, it appears as though they may have been experiencing such dissatisfying presurgical levels of pain/impairment that, by comparison, their surgical outcome was better than the alternative. It may also be that these patients experienced some degree of cognitive dissonance following the spinal fusion. That is, patients undergoing this procedure endured considerable financial, social, and personal stakes and may experience intrapsychic distress and conflict at the notion that undergoing interbody cage fusion was a poor choice for them. Consequently, patients in these circumstances may assert that they would indeed retrospectively repeat the spinal surgery.

Interestingly, Franklin and colleagues (1994) found even higher levels of dissatisfaction regarding back pain (68%) and quality of life (56%), while retrospective decisions to repeat posterolateral lumbar fusion (62%) were similar to the findings of this study. More recently, DeBerard et al. (2001) observed similar proportions as the current

study, though slightly lower levels of dissatisfaction (i.e., 3 - 6% differences across categories). In a data set including BAK devices, DeBerard et al. (2002a) found striking differences favoring interbody fusion over the original posterolateral fusion technique. In fact, these data consistently had substantially higher rates (i.e., mean of 23% greater) of patient satisfaction than those found in the current study. Similarly, DeBerard et al. (2002a) noted that 88% of the BAK fusion sample would choose to have the surgery again, which was nearly 25% greater than the RTFC and BAK samples reported earlier. The explanation for such striking differences between the BAK data of DeBerard and colleagues (2002a) and those found in the present study are not entirely apparent. However, these were intact groups from different geographical regions with the DeBerard et al. (2002a) cohort demonstrating a somewhat low rate for follow-up responses (56%), fewer cigarettes smokers (17%), and a higher rate of arthrodesis (93%). Because smoking and pseudarthrosis are risk factors for poorer fusion outcomes, these may explain the more favorable findings.

Categorization of Outcome

Using the SCI aggregate rating, patients were categorized into good (5%), fair (32%), and poor (63%) functioning. Examination of its four subscales, however, revealed better functioning than indicated by the aggregate rating. Recall that the SCI aggregate score is based upon the lowest rating in any of the subscales, which may result in an underestimate of overall functioning. This becomes apparent if the modal subscale rating is used rather than the lowest rating. That is, the aggregate SCI ratings shift upward to the following: good (27%), fair (41%), and poor (32%).

A brief comparison of these data with those of DeBerard et al. (2001, 2002a) reveal that patient functioning was slighter better for the posterolateral fusion, though this appeared to be accounted for largely by the considerable rates of poor outcome with medication usage. More noticeably, the BAK-only sample demonstrated better functioning

for the aggregate rating (good, 14%; fair, 44%; and poor, 42%) as well as across all four subscales. In general, the SCI aggregate ratings demonstrated a considerable rate of poor outcomes across surgical procedures/samples and studies. Because the SCI aggregate rating is a conservative characterization and likely to underestimate functioning, one is advised to approach interpretation of this index with some caution.

Low Back Functional Impairment and Disability Status

Poor functioning due to LBP, as gauged by the RDQ recommended cut-off of 14, occurred in 47% of the interbody cage fusion patients at followup. The mean rating was 12.5 (*SD* = 7.4), which is considered *quite bad pain*. Not surprisingly, this rate of poor outcome was substantially higher than that found by Roland and Morris (1883a, 1983b) with the LBP standardization group (15%). The current study, however, found only slightly higher rates of poor outcome and mean scores relative to posterolateral spinal fusion patients (DeBerard et al., 2001) in which poor outcome was found in 43% of the sample with a mean score of 11.4 (*SD* = 7.0). Conversely, a BAK sample of patients having completed the RDQ following surgery had a mean score of 8.8 (*SD* = 7.4), which is consistent with *moderate pain*. Thus, the Utah interbody cage fusion sample reported more back-specific functional limitations (which appear to roughly correspond with the rates of dissatisfaction reported earlier in the current study).

Total disability subsequent to interbody cage fusion occurred for 38% of the patients at the time of followup, in the current study. Reported rates of disability and returning-to-work following surgery have also been variable within the spinal fusion literature. By way of illustration, Franklin et al. (1994) reported a 62% postfusion disability rate, whereas DeBerard et al. (2001) found a rate as low as 25%. Similarly, interbody cage fusion studies have reported total disability rates (or failure to return-to-work) ranging from 18 - 62% (DeBerard et al., 2002a; Kuslich et al., 1998, 2000;

Vamvanij et al., 1998). A definitive explanation for these differences is unclear, nonetheless, some possibilities come to mind. For instance, a few studies report disparate rates of prior low back surgeries (e.g., 45%, DeBerard et al., 2001; 61%, Franklin et al., 1994), which have been predictive of outcomes. As suggested earlier, some of these studies (e.g., Kuslich et al., 2000) have included highly selective samples of patients in terms of limiting presurgical psychological disturbance, tobacco use, and compensation/litigation, which have also been predictive of worse outcomes with LBP patients. Moreover, disability evaluations are often confounded by decision-making biases and, in fact, lack sufficient evidence for reliability and predictive validity (Robinson, 2001). Additionally, although total disability status and returning-to-work may be used synonymously, the two are not necessarily equivalent. A patient may fail to return-to-work, for instance, yet not have been deemed medically disabled due to a low back condition (Mayer et al., 2001).

General Physical and Mental Health Functioning

Examination of the SF-36 revealed that interbody cage fusion patients reported substantially poorer functioning than the general population, as well as moderately more impairment than the back pain/sciatica sample. Patients who underwent spinal fusion perceived more limitations in physical (e.g., self-care) and general health, social and role activities (e.g., work), vitality, greater psychological distress, and more severe bodily pain than the normative groups. Moreover, physical/role functioning and bodily pain were the areas of greatest perceived impairment for interbody cage fusion patients at followup. Forty percent of the fusion sample appraised their health unfavorably compared to 15% of those in the national norms. Similar rates were found for self-endorsements of emotional limitations following lumbar surgery.

There are no other studies available within the spinal fusion literature to make a direct comparison of the SF-36 findings. However, DeBerard et al. (2002a) administered a shorter, 20-item version of the same measure to spinal fusion patients, which allows for some comparisons. Similar to the current study, they found the greatest impairment occurred in physical/role functioning and pain severity across the spinal fusion procedures, with better outcomes for BAK fusion (compared to posterolateral). However, effect sizes were consistently larger in the present study, indicating poorer functioning relative to the normative samples.

The examination of outcomes throughout this study has provided a rare and unique investigation of lumbar interbody cage fusion, and provided further argument for inclusion of functional and multidimensional patient outcomes. The intrastudy findings have generally been congruent and suggestive of considerable patient dissatisfaction, disability, and functional limitations in spite of fairly typical arthrodesis rate of 84% (Turner et al., 1992). Moreover, the findings do not support the claims of the superiority of the interbody cage fusion procedure, as advocated in the initial studies by developers of the cage devices. That is not to say, however, that interbody cage fusion is not and/or cannot be an efficacious and safe method of performing lumbar spinal fusion. For instance, McAfee et al. (1999), studied unsuccessful interbody cage fusion devices in 20 patients, and concluded that all the fusions failed because of surgical techniques rather than an intrinsic defect in the cage technology. Nevertheless, as many have asserted (e.g., Elias et al., 2000), interbody cage fusion is a demanding procedure that requires extensive technical training and has a lengthy learning curve. Suggestions for future research to assist in clarification of the efficacy and effectiveness of interbody cage fusion will be discussed in later sections. Attention will now be directed toward the prediction of interbody cage fusion outcomes.

Prediction of Interbody Cage Fusion Outcomes

Many have suggested the mixed findings for lumbar fusion may be due to such factors as instrumentation failure, poor surgical technique, pseudarthrosis, or psychosocial variables (DeBerard et al., 2001; Franklin et al., 1994; Hadler et al., 1995). In recent years, there has been a developing interest in recognizing those patients at risk for having poor surgical outcomes aimed at relieving pain and improving functioning. The present study, in hopes of identifying patients at risk of having a poor response to lumbar interbody cage fusion, examined the associations and predictive relationships between arthrodesis and several outcomes. A five-variable model, thought to include a biopsychosocial and empirically based sampling of presurgical factors, was utilized for its potential predictive efficacy of functional and multidimensional outcomes.

Arthrodesis as a Predictor of Outcomes

Arthrodesis was only moderately associated, in the expected direction, with a few patient outcomes, such as satisfaction with current back condition and quality of life, percentage of pain relief, medication usage, and disability status. Overall, a relationship between solid fusion and long-term outcome was not found for most (i.e., 75%) of the multidimensional measures. Given the reports (e.g., Bernard, 1993; DeBerard, 1998; Turner et al., 1992) on the positive relationship between arthrodesis and satisfactory outcomes (as well as the emphasis placed upon it within the medical community), it was somewhat surprising that arthrodesis did not evidence more significant associations with functional outcomes such as the RDQ and SF-36 subscales. However, the arthrodesis findings of the current study did appear in line with previous reports (e.g., Boden et al., 1990; Jensen et al., 1994) of significant spinal abnormalities in pain-free and asymptomatic individuals. In fact, Ray (see McAfee et al., 2001) admits that nearly 15% of the patients achieving arthrodesis fail to improve clinically, while a similar percentage experience

clinical resolution of symptoms despite pseudarthrosis. Thus, these findings suggest, as argued earlier, that technical success does not guarantee clinical/functional success or reductions in LBP impairment. This finding is likely to be disheartening to patients desperately seeking a reprieve from LBP and return to previous levels of functioning. Moreover, the disappointingly low association between technical success (i.e., arthrodesis) and functional outcomes may prompt from critics of spinal fusion the question, "Why should spinal fusion, more specifically interbody cage lumbar fusion, be performed if it does not produce better functioning?" The difficult task of justifying the continued emphasis upon and benefits of arthrodesis falls to those who continue to advocate and perform procedures whose chief goal is solid fusion with the belief that this will "cure" the problem. However, because the rate of spinal fusion procedures performed each year does not appear to be on the decline, it behooves us to clarify the utility of presurgical variables in assisting with identification of patients likely to have a poor response to such procedures. Thus, the importance and implications of identifying patients is addressed and discussed in more detail later in this document.

Given the limited relationship between technical success and functional outcomes, how might one conceptualize the arthrodesis findings of the current study? Traditional medical models, not surprisingly, emphasize physiological processes and have tended to view chronic LBP and dysfunction as being either "organic" or "psychogenic" in origin. Such a conceptualization does not appear to offer much elucidation of the current arthrodesis data (or reports of discrepancies with imaging studies and asymptomatic individuals, for that matter). Rather, the arthrodesis findings suggest that chronic disability and LBP dysfunction reflect more than just the presence of a physical symptom or abnormality. The notion of integrating "nonphysiological" processes into understanding LBP and functioning is, by no means, a novel conceptualization within the pain literature.

Perhaps the earliest attempt, to take into account psychological aspects, was the *gate control theory of pain* by Melzack and Wall (1965). Briefly, this model asserted that central nervous system mechanisms (e.g., dorsal horns) provided the physiological basis for psychological involvement in pain perception, and that their interplay determined if and to what extent a particular stimulus led to pain. More recently, the biopsychosocial model has synthesized various aspects of chronic pain to include cognitive, affective, social, behavioral, and physiological processes. In contrast to mechanical or strictly physiological models of pain, the biopsychosocial perspective integrates these variables to explain the expression of any illness, including its duration, severity, and effects for the individual (Turk & Flor, 1999). That is, the interrelationship among the biological changes, psychological processes, and social-contextual factors are thought to cause/perpetuate pain and shape the person's response to it. Thus, in terms of arthrodesis and lumbar fusion outcomes, achieving a solid bony fusion should not be the entire measure of improved functioning and successful clinical outcomes. Rather, psychosocial aspects and variables warrant considerably more attention if we are to sufficiently understand patient outcomes, design effective interventions, and identify appropriate candidates for such interventions. The discussion will now turn toward considering a biopsychosocial model used to predict lumbar fusion outcomes.

Five-Variable Model as a Predictor of Outcomes

Examination of the five-variable multiple regression model revealed predictive efficacy with regard to disability status, back-specific functional impairment, and SF-36 scales (both subscale and physical/mental health component scores). The regression model had an overall hit rate of nearly 80% for prediction of disability status, and improved identification of disabled and nondisabled patients over base-rates by 20% and 29%, respectively. Similarly, the model consistently accounted for significant amounts of

variance (22 - 52%) across multidimensional patient outcomes, such as the RDQ and SF-36. The categorization of outcome with the SCI aggregate, however, failed to be significantly predicted by the model. Notably, the most consistent predictors of poor patient outcomes were tobacco use (75%), depression (58%), and litigation (58%). Age at the time of lumbar fusion surgery (17%) and diagnostic severity rating (8%) were also predictive of outcomes, albeit considerably less often. These five presurgical variables will now be discussed in greater depth.

Tobacco consumption as a predictor. In contrast to the findings of DeBerard (1998), in which tobacco use failed to demonstrate predictive efficacy, smoking habit was a robust predictor of multidimensional outcomes in the present study. An important distinction between the two studies was the assessment of tobacco use with regard to a dose-response relationship between consumption and outcomes. It is believed that such an approach allowed for greater sensitivity in assessment of effects relative to a dichotomous *yes/no* method. The findings from this study are consistent with recent attempts at assessing a dose-response relationship. For example, Andersen et al. (2001) found that smoking more than 10 cigarettes per day was related to poorer outcome. Interestingly, Andersen and colleagues found that increased quantities of tobacco consumption were associated with pseudarthrosis for noncage fusion procedures. To consider this possibility further in the current study, an additional analysis was performed to examine the association between smoking and arthrodesis for lumbar interbody cage fusion. The Pearson correlation coefficient was not statistically significant ($r = .03$, $p = 0.83$), indicating that there was no apparent relationship between tobacco use and arthrodesis.

How then might the consistent association between tobacco consumption and rather poor multidimensional outcomes with interbody cage fusion patients be explained? Although several studies have suggested that tobacco use is an independent risk factor for developing LBP, recent reviews have suggested that smoking may not be a cause of LBP

(Goldberg et al., 2000; Leboeuf-Yde, 1999). Moreover, the few studies of interbody cage fusion to report on smoking habits of patients have found no association between arthrodesis rates and use of tobacco (Vamvanij et al., 1998). Thus, the previously proposed biological mechanisms of cigarette smoking appear insufficient, with regard to explaining multidimensional outcomes found in the present study. An alternative explanation may be that patients who were more likely to smoke (and for longer durations and/or amounts) were also at a greater risk of engaging in poorer lifestyle habits. Perhaps the cigarette smokers undergoing interbody cage lumbar fusion were less likely to exercise, engage in proper self-care and rehabilitation, and were more poorly physically conditioned. Consequently, smoking may have been a marker of poor lifestyle habits that are associated with increased LBP and poor functioning. Although such lifestyle habits were not assessed in the current study, other researchers (e.g., Droomers, Schrijvers, & Makenback, 2002; Vogt et al., 2002) have provided evidence that individuals engaging in smoking are disposed toward poorer self-care habits (e.g., failure to exercise, insufficient nutrition, excessive alcohol consumption), fewer social supports, lower levels of education, and employment in more physically strenuous jobs. Thus, it follows that tobacco use may also be a proxy for a cluster of lifestyle, social, economic, and occupational factors related to poorer functional outcomes for the interbody cage fusion sample, rather than an independent risk factor for LBP and pseudarthrosis.

Depression as a predictor. Depression was a strong and significant predictor of several interbody cage fusion outcomes. In fact, the presence of presurgical depression increased the likelihood of being considered totally disabled at followup by 670%. Similarly, depression predicted higher levels of back-specific impairment, as well as poorer functioning on several SF-36 subscales such as BP, GH, VT, and SF and PF. Given the insensitive measure of depression utilized in the current study, the strength of this association is surprising. That is, using a diagnosis of depression (in the medical record) is

a relatively imprecise method to measure depression and likely introduced greater measurement error. Thus, the strength of the association between presurgical depression and outcomes may conceivably be higher than that found in the current study. In summary, these findings support recent studies of patients undergoing other spinal fusion procedures (e.g., DeBerard et al., 2001; Trief et al., 2000), and provide further testimony for the importance of assessing depression prior to spinal fusion.

It is noteworthy to mention, however, that the high comorbidity of depression (ranges from 30% - 57%) and chronic LBP has led to frequent discussions regarding the chronology of these conditions (Epker & Block, 2001; Rush et al., 2000; Simmonds et al., 1996). That is, "the chicken versus the egg" quandary has been debated by several authors attempting to advocate either cause or consequence for pain/impairment and psychological distress. Most frequently, it is argued that protracted pain leads to psychological distress such as depression, rather than the converse (Fishbane, Cutler, Rosomoff, & Rosomoff, 1997). However, there is some evidence that the relationship between chronic pain and psychological distress/depression is bidirectional. For instance, Polatin, Kinney, Gatchel, Lillo, and Mayor (1993) found that in a study of 200 patients with chronic LBP and depression, 55% of the sample had depression develop prior to the onset of chronic pain, whereas 45% became depressed subsequent to the onset of pain. In a prospective population-based study, Croft et al. (1996) similarly found that psychological distress was predictive of subsequent onset of new episodes of LBP. Thus, in the current study with interbody cage fusion patients, it is plausible that the presurgical diagnosis of depression preceded LBP, although impossible to assert convincingly given the retrospective design using medical records of varying comprehensiveness. What can be stated about a presurgical diagnosis of depression, nonetheless, is that it demonstrated robust predictive efficacy of several outcomes. Moreover, it consistently provided a better prediction of patient outcomes than did an index of spinal pathophysiology based upon radiographs.

Litigation as a predictor. Litigation was found to be an efficacious predictor across functional and multidimensional patient outcomes. For instance, retaining an attorney increased the odds of being disabled at followup by a striking 815% in lumbar interbody cage fusion patients. Additionally, lawyer involvement predicted greater levels of back-specific impairment, poorer physical and role functioning, general health, and bodily pain. These findings are in agreement with those in the LBP literature that have found poorer outcomes, such as delays in returning-to-work, increased rates of disability, and greater levels of pain (Bernard, 1993; DeBerard et al., 2001; Haddad, 1987; Junge et al., 1995; Kaptain et al., 1999; Vaccarro et al., 1997).

It is tempting to conclude that patients involved in litigation with workers' compensation/independent insurers are malingering or exaggerating symptoms and impairments to increase financial settlements, extend paid leaves from work, or exact requital from an inequitable employer. In fact, there is evidence in the literature that attorneys may advise their clients how to respond on psychological tests as well as what to emphasize or omit with examining psychologists (Lees-Haley, 1997; Wetter & Corrigan, 1995; Youngjohn, 1995). However, it is important to note that the presence of secondary gain issues does not necessarily mean that lumbar fusion patients are fabricating their symptoms or impairments. Regardless of potential incentives, before performing spinal fusion procedures surgeons require some confirmation of a pathophysiological basis for pain via routine radiographs (Burke, 2001; Mooney et al., 1996). The findings with lumbar interbody cage fusion patients may imply, as suggested elsewhere (e.g., Block & Callewart, 1999; Epker & Block, 2001), that litigious patients may experience an increased somatic sensitivity to pain as a consequence of financial incentives and social-contextual variables. Moreover, hypersensitivity to pain, according to the biopsychosocial model, may increase the likelihood of restricting activities and bringing about physical deconditioning, which produces a cascading detrimental effect on functioning,

exacerbation of pain, and poorer response to treatment intended to allay pain (McCracken & Turk, 2002; Turk & Flor, 1999; Turk & Okifuji, 2002).

Age and diagnostic severity rating as predictors. Although less influential than the preceding presurgical variables, age and diagnostic severity rating of spinal pathophysiology were predictive of select patient outcomes. Age was found to significantly predict physical and role-emotional functioning, whereas diagnostic severity rating was predictive of disability status at followup. Indeed, for every five-unit increase in presurgical spinal pathology, based upon the quantification of radiograph images, the risk for total disability increased by 158% nearly 2.5-years postoperatively. These findings are supportive, though less than anticipated, of the LBP and spinal surgery research that has found older patients and those with more severe spinal pathophysiology have poorer outcomes (Bernard, 1993; Boos et al., 1992; Mayer et al., 2001; McIntosh et al., 2000; Stevenson et al., 2001).

Interestingly, of the presurgical variables included in the model, only age at the time of fusion and diagnostic severity rating were correlated with each other. This finding is not entirely surprising given that an often cited explanation for older patients' inferior response to treatment is the supposition that it is biologically more difficult for these patients to recover than their younger counterparts. More specifically, natural degenerative physical changes in the nucleus pulposus and discs, bony materials, and diminished blood supply may lower normal baseline levels of strength, flexibility, endurance, and rates of healing (Boos et al., 2002; Mooney et al., 1996). In line with this thinking is the finding by Chen et al. (1994) that patients beyond 60 years of age had less satisfactory spinal fusion arthrodesis rates. To evaluate this prospect further with interbody cage fusion patients, an additional Pearson correlation analysis was completed. The correlation coefficient was statistically significant ($r = -.26$, $p = 0.02$), affirming that older age was moderately associated with lower occurrence of solid fusion. This is not to

say that psychosocial factors have no influence on the effects found with older age. For instance, "cumulative lifetime work fatigue" and financial incentives (e.g., easier acquisition of disability income) may also contribute to the propensity to retire after a late onset of LBP or injury (Mayer et al., 2001, p. 1383).

Implications

The findings from this study have several notable implications for lumbar interbody cage fusion. To begin, many lumbar fusion studies have emphasized biomedical outcomes and technical success such as arthrodesis, rather than clinical outcomes that may be more salient to the patient. Indeed, successful spinal surgery and fusion is partially contingent upon the observer's perspective. For example, Kuslich (see McAfee et al., 2001) makes the point that a patient considers spinal fusion successful if functioning is improved, pain is relieved, and no complications or reoperations occur. In contrast, a radiologist considers spinal fusion successful when bony structures have formed, no motion occurs when flexing the vertebrae, and there is no evidence of radiolucency at the fusion site when viewing the radiographs. The surgeon, however, often defines successful spinal fusion as the patient being satisfied, no occurrence of complications, an efficient surgical procedure, and postsurgical imaging studies of a stable spinal segment that requires no further operations.

Thus, the case for multidimensional outcomes of spinal fusion may appear intuitive and obvious to the reader. However, as evident in the literature review, such a perspective has generally been either overlooked entirely or given limited attention. Consequently, comparisons across spinal fusion studies remain difficult (Turner et al., 1992) even after several years of investigation. The current study is a step toward this end, as it heeded the recommendations for more standardized outcome measurement (Deyo et al., 1998) and utilized several patient outcomes from a broad domain of functioning.

Consequently, comparisons were more easily made with more recent studies (e.g., DeBerard et al., 2001, 2002a) that also used such methodology.

Another implication of the current study involves providing additional support for the biopsychosocial model, which has been gaining attention within the chronic pain literature (Truchon, 2001). Briefly, this model emphasizes the influence and interaction between biological, psychological, and social factors that are involved in the initiation, exacerbation, and maintenance of chronic pain. It is thought that biological factors are more influential in the initiation of physical symptoms, while psychological factors are involved in pain perception/experience and maintenance, and social factors affect the demonstration of pain behavior (Garofalo & Polatin, 1999; Keefe, Beckham, & Fillingim, 1991; Schultz et al., 2002; Truchon 2001). For instance, stress may instigate hormonal and inflammatory changes, which can contribute to emotional/psychological distress and chronic illness. Moreover, these may propel the cascade of decreased physical capacity and further distress/helplessness, and the eventual receipt of support and release from duties. This, in turn, may further amplify physical and psychological factors.

Although this study was not developed solely to test the biopsychosocial model of chronic pain, the predictive efficacy of the presurgical variables does appear to provide support for it. For instance, the variables that emphasized psychological (e.g., depression), behavioral (e.g., smoking), and social factors (e.g., litigation) were robust in predicting long-term functional patient outcomes, whereas the biological variables (e.g., age, diagnostic severity rating) accounted for less variance. This finding is not surprising, given that biological factors appear to be more instrumental in the initiation of pain, while psychological/social factors play a greater role in the exacerbation and maintenance of chronic pain.

A related implication of this study is the potential utility of presurgical variables in assisting with identification of patients likely to have a poor response to spinal fusion

procedures. In particular, recognition of patients experiencing presurgical depression and/or using tobacco could allow for utilizing interventions designed at reducing (or more effectively managing) these risk factors. For instance, behavioral and cognitive-behavioral treatments focusing on depression, beliefs about pain, coping strategies, behavioral disengagement, and social influences have been effective for improving functioning levels in chronic pain patients (Keefe et al., 1991; McCracken & Turk, 2002). Recommendations for such interventions ought to be made and utilized more often pre- and postsurgery than what appears to be the current trend in clinical practice (DeBerard et al., 2002b). Similarly, smoking cessation interventions tailored toward patients (with considerable smoking histories) awaiting spinal fusion may be more beneficial than the current standard practice of physician advice. For instance, such a program may involve a combined pharmacological and behavioral therapy approach with sufficient relapse prevention training and followup (DeBon & Klesges, 1995). Moreover, patients may also benefit from specific attention toward negative affect (e.g., depression), pain, and risk for smoking relapse.

A significant problem with most invasive and surgical interventions is the emphasis on a disease model (rather than biopsychosocial) in which there is an inherent curative message of "being fixed." Such an emphasis for chronic LBP patients may contribute to misguided expectations about likely outcomes as well as a passive role that is detrimental to remedying functional limitations (McCracken & Turk, 2002). In the present study, many patients' expectations appeared to match this profile, perhaps, reflecting an emphasis on pain relief and a continued desire to be Acured@ of existing impairments. Thus, educating patients and families in more clear and realistic terms as to what the multidimensional and functional outcomes are likely to be, given their profile of risk factors, appears warranted. In fact, a presurgical screening heuristic has recently been developed by Block and Callewart (1999) and could provide some guidance and assistance

in this direction. Albeit less well received, an alternative possibility for individuals with significant risk factors for poor outcomes may be that spinal fusion is cancelled altogether, and other less invasive interventions with a greater emphasis on social contingencies and functioning (rather than pain relief) are sought.

Limitations and Future Research

This study has several limitations that are worthy of mention. First and foremost, a retrospective cohort design without matched controls was used to study patient outcomes. Consequently, this design lacked direct comparison/control groups, used existing groups of patients, and relied upon extant medical records. Thus, potential bias and error may have influenced the data and findings. For instance, patient outcomes could be influenced by regression to the mean, natural history, and/or placebo effects (Turner, Deyo, Loeser, VonKorff, & Fordyce, 1994). It is notable that these biases would, however, likely produce effects appearing as more favorable patient outcomes such as reduced pain and increased functioning. The findings with the Utah interbody cage fusion patients do not suggest this is to be the case, particularly in contrast to the better patient outcomes reported by other studies (e.g., DeBerard et al., 2002a; Kuslich et al., 1998, 2000; Ray, 1997a).

Reliance on medical records for gathering presurgical information has several inherent problems that were unavoidable in the current examination of spinal fusion. Although thorough and standardized reviews were conducted, data were sometimes missing, and thus could not be collected on all variables across all patients. Further, presurgical depression was based upon a diagnosis documented within the medical record. It appears likely that rates of depression were underestimated, given that the current study recorded depression in 16% of the patients whereas epidemiological studies have found considerably higher rates in chronic LBP patients. Interestingly, in spite of this lack of

measurement sensitivity, a diagnosis of depression was shown to be a robust predictor of poorer patient outcomes. Perhaps a prospective and more sensitive method of determining depression would have yielded improved predictive efficacy.

Another limitation of this study is the smaller sample size than initially anticipated. That is, approximately 100 patients were thought to have undergone interbody cage fusion through the WCFU and be available for inclusion in this study. However, the entire WCFU sample consisted of 43 patients, which necessitated seeking interbody cage fusion patients elsewhere. The overall sample size eventually rose to 73 patients with 56 (77%) of those responding to the outcome survey. The primary consequence of this reduced sample size, however, was that the multiple regression models would become less stable statistically and fewer presurgical variables (i.e., 5 vs. 7) could be included. Thus, the presurgical model was reduced in scope and fewer variables were examined than initially proposed.

Based on the limitations noted above, several considerations and recommendations can be made for future research. To date, no prospective randomized-controlled trials have been performed for lumbar interbody cage fusion procedures. In fact, prospective studies for this procedure have been virtually nonexistent outside of those few conducted by the developers of the BAK and RTFC devices. Toward this end, a randomized controlled trial including an interbody cage fusion group, a noncage fusion group, a conservative treatment group, and a "sham surgery" group (i.e., placebo group) with sufficient long-term follow-up is necessary to establish both the technical and clinical success of interbody cage fusion across outcomes. This study would likely necessitate a multisite collaborative effort and considerable expense; however, such research is clearly needed to determine the effectiveness of interbody cage fusion. In a similar vein, standardized multidimensional outcomes (Deyo et al., 1998) need to be utilized in these

studies to facilitate a keener understanding of patient functioning, as well as to facilitate comparisons across studies.

The current investigation is the only known study having used a multivariable model to predict lumbar interbody cage fusion outcomes. This study is, therefore, in need of replication with larger sample sizes and with different populations (e.g., non-Caucasians, outside of Utah). Moreover, further elucidation of the relationship between tobacco consumption and arthrodesis is required, as is clarification of the underlying mechanisms for predictors such as litigation and depression. Perhaps these efforts would be beneficial in the development of tailored presurgical interventions (e.g., smoking cessation) for spinal fusion patients. Similarly, the long-term condition of patients undergoing spinal fusion might be improved by specific postoperative interventions aimed at improved psychosocial adjustment and coping, and reductions of fatigue and pain during daily activities/functioning. Based upon the biopsychosocial model, additional presurgical variables should be considered in future research as potential patient outcome predictors, such as anxiety, coping strategies, SES, gender, spousal support and reinforcement, substance abuse, and obesity. Finally, more comprehensive predictive/heuristic models should be developed and validated for spinal fusion procedures and more widely distributed to practicing psychologists and spinal surgeons.

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APPENDICES

Appendix A:

Medical Record Review Instrument

DEMOGRAPHIC VARIABLES		
1. Patient Name:	2. Address:	3. Phone Number (home):
4. WCFU Number:	5. Gender 0 = Not reported 1 = Male 2 = Female	6. SSN:
7. Study Number:	8: Date of Birth:	9. Date of Injury
10. Marital Status at Time of Injury: 0 = Not reported 1 = Married 2 = Divorced 3 = Separated 4 = In a significant non-marital relationship 5 = Single 6 = Widowed	11. Date of Index Lumbar Fusion Surgery:	12. Time Interval Between Injury and Fusion Surgery (Days):
13. Occupation at Time of Injury:	14. Household Income Prior to Injury: Average Weekly Wage: 0 = not reported	15. Child Care Responsibility 0 = Not reported 1 = No 2 = Yes
16. Date WCFU File Created:	17. Number of Months worked for employer prior to injury:	18. Lawyer involvement in compensation case? 0 = Not reported 1 = No 2 = Yes
WORK/COMPENSATION VARIABLES		
19. Date Last Worked:	24. Total Paid ALAE:	32. Grand Total Paid Out:
20. History of Prior Industrial Claim (Generic)? 0 = Not reported 1 = No 2 = Yes	25. Total Paid Comp Type PPD	33. Percent Physical Impairment Paid Out:
	26. Total Paid Comp Type PTD:	34. Total permanent Benefits Paid Out:
21. History of Prior Industrial Claim? (Low Back Pain) 0 = Not reported 1 = No 2 = Yes	27. Total Paid Comp Type TPD:	35. Reserves:
22. Rehabilitation following Surgery? 0 = Not reported 1 = No 2 = Yes	28. Total Paid Comp Type TTD	36. Medical Stability Date:
	29. Total COMP:	
23. Light Duty Available? 0 = Not Reported 1 = No 2 = Yes	30. Total MEDICAL:	37. Time to Medical Stability From Date of Fusion (days):
	31. Total REHAB:	

(From Chart) BIOLOGICAL VARIABLES		
38. Diagnosis (Primary) Note 1: 1-8 = Degenerative Conditions 10-12 = Trauma Diagnoses 13 = Pain 14-19 = Spondylolisthesis 0 = Not Reported 1 = Painful degenerative disc 2 = Herniated nucleus pulposus 3 = Spinal stenosis 4 = Instability, w/o deformity 5 = Instability, w/o angular motion or 5 mm translocation 6 = Instability with angular motion or 5mm translocation 7 = Spondylosis w/o stenosis 8 = Facet arthropathy 10 = Fracture 11 = Dislocation/ligament instability 12 = Sprain-strain 13 = Chronic pain syndrome 14 = Congenital 15 = Spondylolysis 16 = Degenerative 17 = Internal disc disruption 18 = Failed back syndrome 19 = Other Options: (Washington Study, 1994) 1 = Definite/probable radiculopathy 2 = Disc herniation 3 = Stenosis 4 = Spondylolisthesis 5 = Instability 6 = Pseudarthrosis Turner et al., 1992 (Meta-analysis) 1 = Disc herniation 2 = Degenerative disc disease (internal disc derangement) 3 = Degenerative scoliosis 4 = Segmental Instability 5 = Pseudarthrosis 6 = Spondylolisthesis 7 = Spinal Stenosis	39. Diagnosis (Secondary): Note 1: 1-8 = Degenerative Conditions 10-12 = Trauma Diagnoses 13 = Pain 14-19 = Spondylolisthesis 0 = Not Reported 1 = Painful degenerative disc 2 = Herniated nucleus pulposus 3 = Spinal stenosis 4 = Instability, w/o deformity 5 = Instability, w/o angular motion or 5 mm translocation 6 = Instability with angular motion or 5mm translocation 7 = Spondylosis w/o stenosis 8 = Facet arthropathy 10 = Fracture 11 = Dislocation/ligament instability 12 = Sprain-strain 13 = Chronic pain syndrome 14 = Congenital 15 = Spondylolysis 16 = Degenerative 17 = Internal disc disruption 18 = Failed back syndrome 19 = Other Options: (Washington Study, 1994) 1 = Definite/probable radiculopathy 2 = Disc herniation 3 = Stenosis 4 = Spondylolisthesis 5 = Instability 6 = Pseudarthrosis Turner et al., 1992 (Meta-analysis) 1 = Disc herniation 2 = Degenerative disc disease (internal disc derangement) 3 = Degenerative scoliosis 4 = Segmental Instability 5 = Pseudarthrosis 6 = Spondylolisthesis 7 = Spinal Stenosis	Notes

PHYSICAL/HEALTH/SURGICAL VARIABLES (from medical record)

41. Physical Exam Data
a. Height
b. Weight
c. Straight leg raising supine
0 = Not reported
1 = Positive
2 = Negative
d. Patellar reflexes
0 = Not reported
1 = Positive
2 = Negative
e. Ankle reflexes
0 = Not reported
1 = Positive
2 = Negative
f. Back pain without radiation
0 = Not reported
1 = Positive
2 = Negative
g. Pain with radiation below the knee
0 = Not reported
1 = Positive
2 = Negative
h. Focal weakness
0 = Not reported
1 = Positive
2 = Negative
i. If yes, does focal weakness correspond to nerve root placement?
0 = Not reported
1 = Positive
2 = Negative
9 = Not applicable

42. General Health Problems
(List up to 5 conditions)

0 = None reported
1 = Diabetes
2 = Heart Disease
3 = Stroke
4 = Arthritis
5 = Asthma
6 = Depression
7 = Hypertension
8 = Colitis
9 = Psoriasis
10 = Cancer history
11 = Trauma history
12 = Infectious history
13 = Auto-immune history
14 = Steroid usage
15 = Other

43. Imaging Studies Conducted Prior to Surgery?
0 = None reported
1 = X-ray
2 = CT
3 = MRI
4 = CT Myelogram
5 = Discography
6 = Other

44. Number of Levels Fused & site:
0 = Not reported
1 = One level
2 = Two levels
3 = Three or three plus levels
L2-3___ L3-4___ L4-5___ L5-S1___

45. Type of Fusion
0 = Not reported
1 = Endoscopic cage
2 = 360 degree cage
3 = Anterior interbody cage
4 = Posterior interbody cage
Type of cage: _____

46. Use of Additional Instrumentation?
1 = No
2 = Yes

47. If Yes, was Instrumentation Removed?
0 = Not Reported
1 = No
2 = Yes

48. Number of Prior Low Back Operations?
0 = None
1 = One
2 = Two
3 = Three or more
# Prev. fusions ____
#Prev. levels fused ____
#Redo fusions ____
#Post index fusions ____

49. Back Surgical History (Include present)
Dr:
Procedure:
Date:
Dr:
Procedure:
Date:
Dr:
Procedure:
Date:

50. Surgical Complications
0 = Not reported
1 = In hospital mortality
2 = Deep infection
3 = Superficial infection
4 = Deep vein thrombosis thrombophlebitis
5 = Pulmonary embolus
6 = Neural injury
7 = Any donor site complication
8 = Donor site infection
9 = Donor site, chronic pain
10 = Donor site pelvic instability
11 = Graft extrusion
12 = Instrumentation failure
13 = Failed back syndrome
14 = Other

50b. Length of Hospital Stay
# of days:

51. Was Solid Arthrodesis Achieved?
0 = Not reported
1 = No
2 = Yes

PHYSICAL/HEALTH/SURGICAL VARIABLES (Cont.)		
52. Previous Chiropractic Treatment? 0 = Not Reported 1 = No 2 = Yes	55. Amount of Pain Before Surgery? 0 = No Pain or Minimal Pain 1 = Mild 2 = Moderate 3 = Severe	58. Use of Pain Meds Prior to Surgery 0 = Not reported 1 = No 2 = Yes Notes on amount & duration of use, &/or length of abstinence (if available):
53. Significant testing after surgery? 0 = None reported 1 = X-ray 2 = CT 3 = MRI 4 = CT Myelogram 5 = Discography 6 = Other	56. Smoking at Time of Surgery? 0 = Not reported 1 = No 2 = Yes If information available calculate: Pack/Day X Years of Smoking -	59. Alcohol Use at Time of Surgery? 0 = Not reported 1 = No 2 = Yes Notes on amount & duration of drinking, &/or length of abstinences (if available):
54. Ethnicity 0 = Not reported 1 = White 2 = Black or African American 3 = Hispanic 4 = Asian or Pacific Islander 5 = Native American Indian 6 = Other (Specify _____)	57. Educational Level 0 = Not reported 1 = Less than 12 years 2 = 12 years (HS degree) 3 = Some college 4 = Trade school/AA 5 = College Degree 6 = Advanced Degree	60. Lifting Restrictions in Pounds Following Surgery?

Appendix B:

Diagnostic Severity Rating Form

Diagnostic Severity Rating Form

Patient's Name _____ Patient's I.D. Number

Latest Preoperative Films Plain Films CT Scan MRI Date of Film _____

L2-3 LEVEL				
Disc Degeneration	None	Mild Desiccation	Moderate Desiccation	SevereVacuum Modic Changes
Facet Changes	None	Mild	Moderate	Severe Facet Overgrowth
Disc Bulges	None	I Bulging - No Abutment	II (Abutting-Crowding of Nerves)	III (Displacing Nerve Tissue)
Listhesis Anterior or Posterior	None or 2mm or less		< 5mm	5mm or more
Lysis	None	Present		
Stenosis (Formina or Far Lateral)	None	Mild	Moderate	Severe
Stenosis (Central or Spinal) *size noted in mm	None	Mild	Moderate	Severe
Discography	None	Discordant (Atypical Pain or Typical Pain with Normal Anatomy)	Concordant (Typical Pain with Abnormal Anatomy)	

L3-4 LEVEL				
Disc Degeneration	None	Mild Desiccation	Moderate Desiccation	SevereVacuum Modic Changes
Facet Changes	None	Mild	Moderate	Severe Facet Overgrowth
Disc Bulges	None	I Bulging - No Abutment	II (Abutting-Crowding of Nerves)	III (Displacing Nerve Tissue)
Listhesis Anterior or Posterior	None or 2mm or less		< 5mm	5mm or more
Lysis	None	Present		
Stenosis (Formina or Far Lateral)	None	Mild	Moderate	Severe
Stenosis (Central or Spinal) *size noted in mm	None	Mild	Moderate	Severe
Discography	None	Discordant (Atypical Pain or Typical Pain with Normal Anatomy)	Concordant (Typical Pain with Abnormal Anatomy)	

L4-5 LEVEL				
Disc Degeneration	None	Mild Desiccation	Moderate Desiccation	SevereVacuum Modic Changes
Facet Changes	None	Mild	Moderate	Severe Facet Overgrowth
Disc Bulges	None	I Bulging - No Abutment	II (Abutting-Crowding of Nerves)	III (Displacing Nerve Tissue)
Listhesis Anterior or Posterior	None or 2mm or less		< 5mm	5mm or more
Lysis	None	Present		
Stenosis (Formina or Far Lateral)	None	Mild	Moderate	Severe
Stenosis (Central or Spinal) *size noted in mm	None	Mild	Moderate	Severe
Discography	None	Discordant (Atypical Pain or Typical Pain with Normal Anatomy)	Concordant (Typical Pain with Abnormal Anatomy)	

L5-S1 LEVEL				
Disc Degeneration	None	Mild Desiccation	Moderate Desiccation	SevereVacuum Modic Changes
Facet Changes	None	Mild	Moderate	Severe Facet Overgrowth
Disc Bulges	None	I Bulging - No Abutment	II (Abutting-Crowding of Nerves)	III (Displacing Nerve Tissue)
Listhesis Anterior or Posterior	None or 2mm or less		< 5mm	5mm or more
Lysis	None	Present		
Stenosis (Formina or Far Lateral)	None	Mild	Moderate	Severe
Stenosis (Central or Spinal) *size noted in mm	None	Mild	Moderate	Severe
Discography	None	Discordant (Atypical Pain or Typical Pain with Normal Anatomy)	Concordant (Typical Pain with Abnormal Anatomy)	

Appendix C:

WCFU Subject Contact Letter

Study Participant
Address
City, State (zip code)

Dear Participant:

During the month of _____ one of our interviewers will be calling you regarding a low-back surgery outcome survey. This survey is being conducted by a team of researchers from the Psychology Department at Utah State University. We are very interested in hearing about the results from your past back surgery and have sent this letter to inform you in advance about our request for an interview.

We obtained your name and address from the Workers Compensation Fund of Utah (WCFU). We want to emphasize that this research is being conducted independently from WCFU and that your participation will in no way affect your compensation status or treatment. We are interested in learning how to better predict low-back surgery outcome and the information you provide will help future back surgery candidates. People who have had back surgery often report both positive and negative results. Your unique experience, whether positive or negative, is very important to us.

The interview will be conducted over the telephone, at your convenience, and will take only 15 minutes. All of your responses will be strictly confidential and your participation is completely voluntary. Two participants will be selected at random to each receive $500.00 for their assistance in this project. If you would like, we can also send you a summary of our study results.

To help us in contacting you, please fill in your name, address, and phone number on the enclosed postcard and drop it in a mailbox. Your participation will be greatly appreciated since this is a very important study. If you have any questions, please do not hesitate to call me at (435) 797-3871.

Sincerely,

Kevin Masters, Ph.D.
Research Director
Utah Lumbar Fusion Outcome Study

Appendix D:

Non-WCFU Subject Contact Letter

Study Participant
Address
City, State (zip code)

Dear Participant:

During the month of _____ one of our interviewers will be calling you regarding a low-back surgery outcome survey. This survey is being conducted by a team of researchers from the Psychology Department at Utah State University in conjunction with Drs. William Bacon and Alan Colledge. We are very interested in hearing about the results from your past back surgery and have sent this letter to inform you in advance about our request for an interview.

We are interested in learning how to better predict low-back surgery outcome and the information you provide will help future back surgery candidates. People who have had back surgery often report both positive and negative results. Your unique experience, whether positive or negative, is very important to us.

The interview will be conducted over the telephone, at your convenience, and will take only 20 minutes. All of your responses will be strictly confidential and your participation is completely voluntary. Two participants will be selected at random to each receive $500.00 for their assistance in this project. If you would like, we can also send you a summary of our study results

We want to point out that although this research is being conducted with Drs. Bacon and Colledge the results are being analyzed independent from their practice and that your participation will in no way affect your treatment (or workers? compensation status - should that even apply to you). That is, your physician will not be made aware of your individual responses but rather only the overall study results will be known to them.

To help us in contacting you, please fill in your name, address, and phone number on the enclosed postcard and drop it in a mailbox. Your participation will be greatly appreciated since this is a very important study. If you have any questions, please do not hesitate to call me at (435) 797-3871.

Sincerely,

Kevin Masters, Ph.D.
Research Director
Utah Lumbar Fusion Outcome Study

Appendix E:

Subject Return Postcard

UTAH LUMBAR FUSION OUTCOME STUDY

(ADDRESS/TELEPHONE UPDATE CARD)

NAME:_____

ADDRESS:_____

_____

_____

TELEPHONE NUMBER: (_____)_____

Appendix F:

Telephone Survey Script

UTAH LUMBAR FUSION OUTCOME STUDY
TELEPHONE INTERVIEW SCRIPT

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

This is _____ calling from Utah State University. We are conducting a study to learn more about people who have lumbar fusion surgery.

Earlier this month a letter describing the study was sent to you. Did you receive it?

If yes: Proceed with the rest of the introduction.

If no: I am sorry it did not reach you. The letter was to inform you of this call and the nature of the study. Proceed to introduction.

INTRODUCTION

As the letter (or The letter indicated) indicated you were chosen for this study because you had lumbar fusion surgery. Your opinion of how you have progressed since the surgery is critical to this study and result of the survey will be used to help others who are considering having lumbar fusion surgery. Your participation is voluntary and your treatment or compensation status will in no way be affected by your participation. For you participation in the survey we will be enrolling you in a drawing for $500.00 and we could also send you a brief report of the study findings. All of your answers will be kept confidential as provided by law and you may skip any questions you prefer not to answer. Okay?

Please feel free to ask questions at any time during the survey. The survey will take about 30 minutes to complete. Is this a good time?

Yes: Proceed with survey
No: When would be a time to call you back?
Date: _____
Day: _____
Time:_____

Appendix G:

Workers' Compensation-Employer Satisfaction Questions

SURVEY QUESTIONS - PAGE 1

Let's begin with a few questions about how you feel your claim was handled by the Workers Compensation Fund and you employer. Okay?

WORKERS COMPENSATION QUESTIONS

1. Overall, were you satisfied with how the workers Compensation Fund of Utah handled your back surgery claim?
1 = Yes
2 = No
3 = Undecided
4 = Other

_____
_____
_____
_____
_____

2. Overall, did you feel that the Workers Compensation Fund of Utah responded fairly to your health concerns?
1 = Yes
2 = No
3 = Undecided
4 = Other

_____
_____
_____
_____
_____

3. Overall, did you feel that your employer responded fairly to your health concerns?
1 = Yes
2 = No
3 = Undecided
4 = Other

_____
_____
_____
_____
_____

Appendix H:

Stauffer-Coventry Index, Patient Satisfaction, and Demographic Questions

Utah Lumbar Fusion Outcome Study Telephone Survey – General Questions

The next part of the survey will involve some general questions about how you have done since your surgery. Please respond to each question according to how you feel today. Okay?

1. Since your surgery, how much pain relief have you experienced in your back and lower extremities? Please provide a percent rating from 0 to 100. **Category Rating:** 1 = Good (76-100%) 2 = Fair (26-75%) 3 = Poor (0-25%)	**2. With regard to your employment after fusion surgery, which of the following best describes your status after surgery?** 1 = Return to previous work status following surgery 2 = Return to lighter work following surgery 3 = No return to work following surgery	**3. With regard to your physical activities after fusion surgery, which of the following best describes your status after surgery?** 1 = Minimal or no restrictions of physical activities. 2 = Moderate restrictions of physical activities 3 = Severe restrictions of physical activities
4. With regard to your use of analgesic medications after fusion surgery, which of the following best describes you usage: 1 = Occasional mild analgesics or no analgesics 2 = Regular use of non-narcotic analgesics 3 = Occasional or regular narcotic analgesics	**5. With regard to your back/leg pain following surgery, which of the following is true:** 1 = Back or leg pain is worse than expected 2 = Back or leg pain is no worse or better than expected 3 = Back or leg pain is better than expected	**6. Is the quality of life better or worse as a result of lumbar fusion surgery? That is, is it:** 1 = A great improvement 2 = A moderate improvement 3 = A little improvement 4 = No change 5 = A little worse 6 = Moderately worse 7 = Much worse
7. Given what you know: If you could go back in time, would you choose to have the spinal fusion surgery? 0 = Undecided 1 = No 2 = Yes	**8. What was your principal occupation/job title at the time of your injury?**	**9. Are you currently working?** 1 = No 2 = Yes, full time 3 = Yes, part time 0 = no answer
10. If not working, which of the following best describes why you are not employed? 1 = I am still disabled 2 = I am not disabled and I want to work but cannot find a job 3 = I was laid off 4 = I am a student 5 = I am a homemaker 6 = I am retired 7 = Other 0 = No answer	**13. Did you change jobs because of your back problem?** 1 = No 2 = Yes 3 = Not applicable 0 = No answer	**14. Do you currently retain an attorney because of your back problems?** 1 = No 2 = Yes 0 = No answer
11. How many days have you worked in the past 4 weeks?	**15. Smoking history:** 1 = abstinence > last year 2 = abstinence ≤ last year 3 = abstinence ≤ last 7 days 4 = no history of smoking 5 = smokes currently/at time of surgery **15b. Amount smoked in above period** 1 = .5 pack or less per day 2 = .6 – 1 pack per day 3 = Other **Pack/Day X Years of Smoking:**	**16. Have you had any back operations since your fusion surgery?** 1 = No 2 = No, but I□am scheduled to 3 = Yes
12. How many hours a week do you usually work at your job?		
17. Overall, is your back or leg pain problem better than or worse than you expected it to be at this point? That is, is it: 1 = Much better 2 = Somewhat better 3 = What I expected 4 = Somewhat worse 5 = Much worse 6 = No expectations	**18. What is the highest year in school you completed?** 1 = Less than high school 2 = Some high school 3 = High school graduate/GED 4 = Attended or graduated from technical school 5 = Attended college but did not graduate 6 = College graduate 7 = Graduate Studies	**19. If you had to spend the rest of your life with your back condition as it is right now, how would you feel about it?** 1 = Extremely dissatisfied 2 = Very dissatisfied 3 = Somewhat dissatisfied 4 = Neutral 5 = Somewhat satisfied 6 = Very satisfied 7 = Extremely satisfied

Appendix I:

Roland-Morris Disability Questionnaire

Disability Questionnaire

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

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

Appendix J:

Short Form-36 Multidimensional Health Survey

Short Form-36 Multidimensional Health Survey

Okay, Were just about finished. To complete the survey, I would like to ask you some questions about your overall health in general. Your answers should reflect your perceptions of how you view your overall health, including both your back problems and other health problems as well. Okay?

1. In general, would you say your health is:	**2. Compared to one year ago, how would you rate your health in general now?**
1 = Excellent 2 = Very good 3 = Good 4 = Fair 5 = Poor	1 = Much better now than one year ago 2 = Somewhat better now than one year ago 3 = About the same as one year ago 4 = Somewhat worse now than one year ago 5 = Much worse now than on year ago

3. The following questions are about activities you might do during a typical day. I would like you to indicate how much (if at all) has your health limited you in each of the following activities? You can provide one of three responses for each question.	Yes, limited a lot	Yes, limited a little	No, not limited at all
a.) Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b.) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c.) Lifting or carrying groceries	1	2	3
d.) Climbing several flights of stairs	1	2	3
e.) Climbing one flight of stairs	1	2	3
f.) Bending, kneeling, or stooping	1	2	3
g.) Walking more than a mile	1	2	3
h.) Walking several blocks	1	2	3
i.) Walking one block	1	2	3
j.) Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?	Yes	No
a.) Cut down on the amount of time you spent on work or other activities	1	2
b.) Accomplished less than you would like	1	2
c.) Were limited in the kind of work or other activities	1	2
d.) Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?	Yes	No
a.) Cut down on the amount of time you spent on work or other activities	1	2
b.) Accomplished less than you would like	1	2
c.) Did not do work or other activities as carefully as usual	1	2

Short Form-36 Multidimensional Health Survey (continued)

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all	Slightly	Moderately	Quite a bit	Extremely	
	1	2	3	4	5	
7. How much bodily pain have you had during the past 4 weeks?	None	Very mild	Mild	Moderately	Severe	Very severe
	1	2	3	4	5	6
8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all	A little bit	Moderately	Quite a bit	Extremely	
	1	2	3	4	5	
9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a.) did you feel full of pep?	1	2	3	4	5	6
b.) have you been a very nervous person?	1	2	3	4	5	6
c.) have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d.) have you felt calm and peaceful?	1	2	3	4	5	6
e.) did you have a lot of energy?	1	2	3	4	5	6
f.) have you felt downhearted and blue?	1	2	3	4	5	6
g.) did you feel worn out?	1	2	3	4	5	6
h.) have you been a happy person?	1	2	3	4	5	6
i.) did you feel tired?	1	2	3	4	5	6
10. During the past 4 weeks how much of the time has your physical health or emotional problems interfered with you social activities (like visiting friends, relatives, etc.)?	Not at all	A little bit	Moderately	Quite a bit	Extremely	
	1	2	3	4	5	
11. How true or false is each of the following statements for you?	Definitely true	Mostly True	Don't know	Mostly false	Definitely false	
a.) I seem to get sick easier than other people	1	2	3	4	5	
b.) I am as healthy as anybody I know	1	2	3	4	5	
c.) I expect my health to get worse	1	2	3	4	5	
d.) My health is excellent	1	2	3	4	5	

CURRICULUM VITAE

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Education

Doctor of Philosophy — Utah State University, Logan, UT; 2003
Combined Clinical/Counseling/School Psychology
APA Accredited

Dissertation: *Outcomes and Presurgical Correlates of Patients with Lumbar Interbody Cage Fusions*

Thesis Equivalent: *The Effects of Cognitive Strategy and Exercise Setting on Running*

Master of Arts — Ball State University, Muncie, IN; 1993
Clinical Psychology

Bachelor of Science — University of Wisconsin-Whitewater, WI; 1988
Psychology, *cum laude*

Clinical Experience and Employment

Pre-Doctoral Clinical Internship

7/02 - 6/03 ***Clinical Health Psychology Internship***, APA Accredited
University of Wisconsin Hospital and Clinics, Madison, WI

Major Rotations:
Inpatient Rehabilitation. Provided brief neuropsychological assessment and short- and long-term psychotherapies on both an inpatient and outpatient basis. Patient populations included traumatic injuries andprogressive disabling conditions. Participated in rounds as a member of the multidisciplinary treatment team.
MeDical/Surgical Consultation. Consulted with medical staff and provided evaluations and interventions to patients on multiple services (transplantation, cardiology, orthopedics, neurology, geriatrics, oncology, burn, pulmonary, and trauma life center). Also consulted throughout the hospital to provide evaluations for decisional capacity and competency. Conducted transplantation evaluations and co-facilitated a group for transplant recipients. Participated in rounds for palliative care.
Minor Rotations:
Outpatient Clinical Psychology. Provided assessment and individual psychotherapy as well as co-facilitated an interpersonal process group at an outpatient clinic. Provided consultation to graduate practicum students.
Pediatric Health Psychology. Provided evaluations and interventions with pediatric patients and their families on multiple medical issues. Co-facilitated a group for pediatric oncology patients.

Elective Rotations:
Pain Management. Provided assessment and intervention for chronic pain patients in an outpatient interdisciplinary setting. Was trained in and provided thermal and EMG biofeedback techniques.
Preventive and Rehabilitative Cardiology. Provided assessments and interventions to patients who were at risk of or had experienced a cardiac event. Co-facilitated a psychoeducational group to facilitate lifestyle changes and behavioral modification.
Research. Examined the effects of a 16-week exercise intervention for breast cancer patients. Provided statistical analyses, assisted in preparing the poster presentation, and manuscript.

Clinical Practica

1/01 - 8/01 ***Health Psychology Practicum***
Cardiac Rehabilitation, Brigham City Community Hospital, UT.
Provided psychological interventions to patients participating in a cardiac rehabilitation program. Conducted stress management groups for cardiac and diabetic patients, as well as worked with individual patients to improve exercise and program adherence.

8/99 - 5/00 ***School Psychology Practicum***
Center for Persons with Disabilities, Utah State University, Logan, UT.
Conducted educational, developmental, and psychological assessments of children and adolescents with behavioral disorders, learning disabilities, and intellectual deficits. Provided inservice training and case coordination, and participated in IEPs.

8/98 - 5/99 ***Clinical Psychology Practicum***
Psychology Community Clinic, Utah State University, Logan, UT.
Provided individual and couples psychotherapy to clients with a variety of psychiatric diagnoses. Conducted assessments and evaluations.

8/91 - 5/92 ***Counseling Psychology Practicum***
Counseling and Psychological Services, Ball State University, Muncie, IN.
Provided individual psychotherapy to university students with a variety of psychological concerns. Conducted outreach and consultation workshops for stress management, test anxiety, and rape prevention. Co-lead a group for clients with self-esteem concerns.

Clinical and Supervisory Positions

1/00 - 5/02 ***Diagnostician***, Weber School District, Ogden, UT.
Conducted educational, developmental, and psychological assessments of students with behavioral disorders, learning disabilities, and intellectual deficits.

8/98 - 8/99 ***Clinic Assistant***, Community Clinic, Utah State University, Logan, UT.
Assisted with requests for psychotherapy, crisis intervention, and orienting students to clinic procedures. Maintained assessment instruments and client database.

10/94 - 7/98 ***Residential Coordinator***, Center for Mental Health, Anderson, IN.
Responsible for staff hiring, training, supervision, evaluation, and program development. Evaluated several quality indicators of service/utilization for residential services. Developed and organized the residential on-call crisis system, trained the response team, and monitored its effectiveness.

Conducted assessments of dually-diagnosed/severely mentally ill clients for local agencies and hospitals, and functioned as liaison with the state hospitals to evaluate and facilitate countywide admissions and discharges.

7/97 - 12/97 ***Group Facilitator***, Women's Alternative, Inc., Anderson, IN.
Facilitated a group for male domestic abuse perpetrators with an emphasis on anger management, effective communication, and healthy relationship skills.

4/93 - 10/94 ***Addictions Clinician***, Center for Mental Health, Anderson, IN.
Conducted substance abuse evaluations and provided individual, family, and group therapies. Co-facilitated the following groups: intensive outpatient program, men's issues, relapse prevention, and aftercare. Provided educational outreach to local agencies.

5/92 - 10/94 ***Case Manager***, Quantum Health Resources, Indianapolis, IN.
Provided case management services to children and adults with hemophilia and von Willebrand's. Provided additional support to family members when the client was diagnosed with HIV/AIDS.

2/89 - 7/90 ***Facility Manager***, Productive Living Systems, Inc., Whitewater, WI.
Managed daily operations of a community-based residential facility, which included training and supervising staff, and developing and implementing policies. Functioned as treatment coordinator for chronic mentally ill clients, and provided on-call crisis intervention services. Led group activities to assist clients in developing life skills for continued community adjustment.

3/88 - 2/89 ***Assistant Facility Manager***, Brotoloc Health Care, Whitewater, WI.
Fulfilled routine assistant duties and assisted in training and supervising staff. Developed and implemented treatment plans for mentally ill clients. Led group activities to assist clients in developing life skills for continued community adjustment. Provided on-call support for crisis intervention.

11/89 - 8/90 ***Psychiatric Technician***, Rock County Health Care Center, Janesville, WI.
Conducted admissions to acute psychiatric/detoxification units, provided crisis intervention, and conducted awareness groups.

Teaching Experience

1/01 - 5/01 ***Instructor***, Abnormal Psychology, Utah State University.
Prepared and delivered lectures to a class of approximately 65 students.

8/00 - 12/00 ***Instructor***, Introductory Psychology, Weber State University.
Prepared and delivered lectures to a class of approximately 40 students.

8/99 - 12/00 ***Instructor***, Introductory Psychology, Utah State University.
Prepared and delivered all lectures toapproximately 430 students over the span of three semesters of teaching the course.

1/00 - 12/00 ***Teaching Assistant***, Introductory Psychology, Utah State University.
Prepared and delivered lectures, developed laboratory curriculum, and supervised laboratory instructors. Responsible for exams and grading.

8/98 - 12/98 ***Teaching Assistant***, Intellectual Assessment, Utah State University. Provided assistance and evaluation to graduate students learning to administer, score, and interpret the Wechsler Scales.

8/97 - 5/98 ***Adjunct Faculty***, Introductory Psychology, Ivy Tech College. Prepared and delivered all lectures to approximately 50 students over the span of two semesters of teaching the course.

Research Experience

6/00 - 7/03 ***Dissertation Research***, Utah State University.
Using a retrospective cohort design to examine the predictive efficacy of psychosocial presurgical variables as well as multidimensional health outcomes of lumbar spinal fusion two years postsurgery.

8/01 - 5/01 ***Graduate Research Assistantship***, Utah State University.
Oversaw project with Workers' Compensation Fund to examine surgical outcomes and the predictive efficacy of presurgical variables for lumbar diskectomy.

1/01 - 12/01 ***Research Assistant***, Utah State University.
Assisted with conducting a meta-analysis to examine characteristics of individuals with binge eating disorder, obese nonbinge eaters, and bulimia nervosa. The study also examined efficacy of various interventions for binge eating disorder.

6/99 - 10/01 ***Thesis Equivalent Research***, Utah State University, Logan, UT.
Designed and conducted an experiment to examine the effects of different cognitive strategies and exercise settings on performance, perceived exertion, satisfaction, and affect for runners.

1/92 - 5/92 ***Independent Research***, Ball State University, Muncie, IN.
Reviewed literature on test anxiety interventions and peer support. Conducted a pilot study assessing student concerns with test anxiety and preferences for method and setting for assistance.

8/91 - 5/92 ***Graduate Research Assistantship***, Ball State University, Muncie, IN.
Collaborated on a study examining sibling interactions from intact and single parent homes as well as mothers' perceptions of the interactions.

8/90 - 5/91 ***Graduate Research Assistantship***, Ball State University, Muncie, IN.
Collaborated on a study examining the use of window substitutes by secretaries in office settings. Assisted with instrument development and data collection.

Publications

LaCaille, R.A., Masters, K.S., Heath, E.M. (in press). Effects of cognitive strategy and exercise setting on running performance, perceived exertion, affect, and satisfaction. Psychology of Sport and Exercise.

Masters, K.S., LaCaille, R.A., & Shearer, D.S. (2003). The acute affective response of Type A behaviour pattern individuals to competitive and noncompetitive exercise. Canadian Journal of Behavioural Science, 35, 25-34.

Kolden, G., Woods, T., Ward, A., LaCaille, R., Mullen, B., Kuta, J., Sanborn, L., & Burt, C. (in preparation). Follow-up on physical, psychological, and functional benefits of group exercise training for women with primary breast cancer.

Presentations

Kolden, G., Woods, T., Ward, A., Mullen, B., LaCaille, R., Kuta, J., Sanborn, L., & Burt, C. (April, 2003). Follow-up on psychological and functional benefits of group exercise training for women with primary breast cancer. Poster presented at the meeting of the Canadian Association of Psychosocial Oncology, Banff, Canada.

LaCaille, L., LaCaille, R., & Stein, D. (March, 2003). Obese individuals who do not binge eat differ from those who do: A meta-analysis. Poster presented at 24th Annual Meeting of the Society of Behavioral Medicine, Salt Lake City, UT.

LaCaille, L., Stein, D., & LaCaille, R. (March, 2003). Effects of perceived sugar on chocolate intake on cravings, mood, and food intake: A double-blind, placebo-controlled study. Poster presented at the 24th Annual Meeting of the Society of Behavioral Medicine, Salt Lake City, UT.

Tschanz, J., Norton, M., Welsh-Bohmer, K., Corcoran, C., LaCaille, R., & Breitner, J. (July, 2002). Cognitive screening and self-perception of memory problems predict mild cognitive impairment and dementia. Poster presented at the 8th Annual Meeting of the International Conference on Alzheimer Disease and Related Disorders, Stockholm, Sweden.

LaCaille, R., DeBerard, M., Masters, K., & Colledge, A. (April, 2002). A retrospective cohort study of interbody cage lumbar fusion in injured workers: Biopsychosocial predictors and functional outcomes. Paper presented at the 23rd Annual Meeting of the Society of Behavioral Medicine, Washington, D.C.

LaCaille, L., Stein, D., LaCaille, R. (April, 2002). Treatment outcomes for binge eating disorder: A meta-analysis. Poster presented at the 23rd Annual Meeting of the Society of Behavioral Medicine, Washington, D.C.

LaCaille, R., Masters, K., Heath, E., & Schultz-LaCaille, L. (May, 2001). Cognitive strategy affects performance for runners on the track. Poster presented at the meeting of the 81st Annual Western Psychological Association Convention, Maui.

LaCaille, R., Masters, K., Heath, E., & Schultz-LaCaille, L. (May, 2001). Setting and cognitive strategy affect runners' emotions and RPE. Poster presented at the meeting of the 81st Annual Western Psychological Association Convention, Maui.

LaCaille, R., Masters, K., Heath, E., Bailey, B., Burton, E., & Daly, E. (April, 2001). Cognitive focus and music predict performance for runners on the treadmill. Poster presented at the 71st Annual Rocky Mountain Psychological Association Convention, Reno, Nevada.

Larsen, B., LaCaille, R., & Heath, E. (March, 2001). A comparison of aerobic capacity protocols in male runners: A pilot study. Poster presented at the 4th Annual Intermountain Paper and Poster Symposium, Logan, Utah.

LaCaille, R., DeBerard, M., Masters, K., & Colledge, A. (March, 2001). Psychosocial factors predict lumbar interbody titanium cage fusion outcomes in injured workers. Poster presented at the 22nd Annual Meeting of the Society of Behavioral Medicine, Seattle, Washington.

LaCaille, R., Summers, M., Ascione, F., & Summers, C. (March, 1992). Mother perception of sibling interactions in single-parent and intact families. Poster presented at the Southwestern Society for Research in Human Development, Tempe, Arizona.

Burns, R., Hoffman, M., Scott, P., Park, J., Hissong, A., LaCaille, R., Pelc, M., Lovegrove, T., Butler, D., Biner, P. (1990). Substitutes for a window. Paper presented at the Annual Undergraduate Research Conference, Indianapolis, Indiana.

Hoffman, M., Burns, R., Scott, P., Park, J., Hissong, A., LaCaille, R., Pelc, M., Lovegrove, T., Butler, D., Biner, P. (1990). Do people compensate for not having windows in their offices? Paper presented at the Annual Undergraduate Research Conference, Indianapolis, Indiana.

Honors and Awards

2001 - 2002	Walter R. Borg Scholarship; Utah State University
2001	Workers Compensation Fund of Utah Research Grant ($2,500)
1999 - 2000	Elected Graduate Student Rep.; Utah State University
1998 - 2001	Graduate Student Honor Roll; Utah State University
1987 - 1988	National Dean's List
1986 - 1988	Psi Chi, National Honor Society in Psychology
1986 - 1988	Alpha Kappa Delta, International Honor Society in Sociology
1987	Outstanding College Students of America
1985 - 1988	Dean's Honor Roll; University of Wisconsin-Whitewater

Professional Affiliations

2001 - present	Student Affiliate, Society of Behavioral Medicine
1999 - present	Student Affiliate, American Psychological Association
1999 - present	Student Affiliate, Health Psychology, Division 38 of APA
1996 - 1998	Member, North American Association of Masters in Psychology
1996 - 1998	Member, Indiana Association of Masters in Psychology
1990 - 1992	Student Affiliate, American Psychological Society