PAIN CATASTROPHIZING AND PROLONGED OPIOID USE FOLLOWING LUMBAR FUSION

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DEDICATION

This dissertation is dedicated to my parents and siblings for teaching me the value of hard work and my husband and sons for the years of sacrifice that made it possible.

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ABSTRACT

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Healthcare providers commonly prescribe long-term opioid therapy for patients following lumbar fusion despite a lack of evidence that opioids are a safe or effective intervention for chronic pain. The purpose of this prospective, longitudinal study was to examine the prevalence and predictors of prolonged, prescribed opioid use in a cohort of 57 patients undergoing elective lumbar fusion. Prior to surgery, participants completed a demographic and clinical variables questionnaire and the Pain Catastrophizing Scale (PCS). Sixty-one percent (n = 35) of participants reported preoperative opioid use. The mean preoperative pain rating was 7.65 (SD = 1.87), and the mean pain catastrophizing score was 28.85 (SD = 14.72). Three months following lumbar fusion, participants self-reported their prescribed opioid use and their postoperative pain intensity. Forty-four percent (n = 22) of participants reported continued opioid use. The mean postoperative pain intensity rating was 3.12 (SD = 2.15). Pain catastrophizing was neither significantly correlated with time to opioid cessation (r = .03, p = .86), nor with postoperative pain intensity (r = -.04, p = .82). Multiple regression analysis was conducted to identify the best combination of age, sex,

employment status, educational level, preoperative pain intensity, preoperative opioid use, disability status, and pain catastrophizing to predict time to opioid cessation. Bivariate analysis identified a strong correlation between time to opioid cessation and preoperative opioid use (r = .46, p = .000), and a moderate correlation between time to opioid cessation and disability (r = .29, p = .022). Multiple regression analysis indicated that preoperative patient characteristics predicted prolonged, postoperative opioid use, and accounted for 18% of the variance in time to opioid cessation [R^2 = .322, R^2_{adj} = .179, $F(8, 38) = 2.254$, p = .044]. Among preoperative patient characteristics, preoperative opioid use was the sole predictor that significantly contributed to the model (β = .466; p = .005). Thus, screening patients for opioid use prior to lumbar fusion may help to identify patients at increased risk of prolonged opioid use following lumbar fusion.

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CHAPTER I

INTRODUCTION

Lumbar fusion is a common surgical procedure performed to restore stability and eliminate painful motion in a spinal segment by joining, or fusing, two or more vertebrae. Although the surgery has a high rate of producing radiographic fusion, many patients report negative outcomes following the procedure, including persistent pain, functional disability, an inability to return to work, and prolonged postoperative opioid use (PPO). These apparent discrepancies between technical success and patient-centered outcomes have raised questions about the efficacy and medical necessity of lumbar fusion, and have resulted in restrictive payer policies (Cheng et al., 2011; Phillips, Slosar, Youssef, Andersson, & Papatheofanis, 2013). However, associations between specific biopsychosocial factors and negative outcomes suggest that at least some of the variability in outcomes may be due to preoperative patient characteristics.

Among the negative outcomes of lumbar fusion, PPO is of particular concern because it contributes to the epidemic of opioid use and abuse currently plaguing the United States (US). From 1999 to 2010, there was a 300% increase in opioid consumption in the US (Centers for Disease Control and Prevention [CDC], 2014). Concurrently, the number of opioid-related drug poisoning deaths nearly tripled (Rudd, Seth, David, & Scholl, 2016). In 2015, more than 15,000 people died from a prescription opioid overdose (CDC, 2017). Furthermore, although prescribed opioids are indicated for the management of moderate to severe pain, there is increasing evidence that pain is

not the principal driver of PPO. Instead, a variety of biological, psychological, and social factors have been found to predict opioid use following surgery. Younger age, depression, and lower household income have predicted opioid use following non-spinal surgery (Carroll et al., 2012; Clarke, Soneji, Ko, Yun, & Wijeysundera, 2014; Helmerhorst, Vranceanu, Vrahas, Smith, & Ring, 2014). Pain catastrophizing has predicted opioid use immediately following lumbar fusion (Papaioannou et al., 2009). These findings suggest that it may be possible to predict PPO following lumbar fusion by identifying how preoperative patient characteristics relate to time to opioid cessation.

Problem of Study

Patients report high rates of PPO following lumbar fusion. Seventy-six percent of a workers' compensation sample reported PPO three months after surgery (Nguyen, Randolph, Talmage, Succop, & Travis, 2011). Thirty-one percent of a mixed-payer sample reported PPO six months after surgery (Rouben, Casnellie, & Ferguson, 2011). These rates far exceed the 6% of patients using opioids five months following mastectomy, lumpectomy, thoracotomy, total knee arthroplasty, or total hip arthroplasty (Carroll et al., 2012), and the 3.1% of patients using opioids three months following cardiac, intra-thoracic, intra-abdominal, or pelvic elective surgeries (Clarke et al., 2014). High rates of PPO are concerning because lumbar fusion is a frequency performed surgery in the US, and because the use of long-term opioid therapy to manage chronic, non-cancer pain is associated with serious harms.

In 2001, there were 287,600 spinal fusions performed in US operating rooms. A decade later, in 2011, the number of spinal fusions in the US had increased to 488,300

(Weiss & Elixhauser, 2014). This 70% increase in the number of spinal fusions positioned the procedure between hip arthroplasty (40% increase) and knee arthroplasty (93% increase) in terms of increased case volume (Weiss & Elixhauser, 2014). As a result, spinal fusion now ranks as the sixth most frequently performed surgical procedure in US hospitals (Weiss, Elixhauser, & Andrews, 2014). Among all fusion procedures, those performed on the lumbar spine are the most common, closely followed by fusion of the cervical spine (Rajaee, Bae, Kanim, & Delamarter, 2012). In comparison, fusion of the thoracic spine is relatively less common, and comprises fewer than 10% of all fusion procedures (Rajaee et al., 2012).

High rates of PPO following lumbar fusion have been reported despite a lack of evidence to support the use of long-term opioid therapy for chronic, non-cancer pain. Of the 25 recommendations included in clinical guidelines for the use of chronic opioid therapy, 19 are supported by low quality evidence, four are supported by moderate quality evidence, and none is supported by high quality evidence (Chou et al., 2009). Likewise, the evidence upon which the *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016* was based has been characterized as insufficient and limited (Dowell, Haegerich, & Chou, 2016). Nevertheless, opioid prescribing for chronic, non-cancer pain accounted for much of the 300% increase in opioid use between 1999 and 2010 (CDC, 2014; Von Korff, Kolodny, Deyo, & Chou, 2011). Furthermore, the assumption of safety upon which increased opioid prescribing was based has not been supported by experience (Von Korff et al., 2011). Instead, long-term opioid therapy has

been linked to serious harms, including pharmacological adverse effects, opioid use disorders, and drug poisoning deaths.

The pharmacological adverse effects of long-term opioid therapy include constipation, sedation, clouded mentation, pruritus, myoclonus, respiratory depression, falls leading to fracture, hypogonadism, sexual dysfunction, osteoporosis, immunosuppression, and physical dependence (Chou et al., 2009; Deyo, Von Korff, & Duhrkoop, 2015; Freynhagen, Geisslinger, & Schug, 2013; Labianca et al., 2012; Von Korff et al., 2011). Long-term opioid therapy may also decrease the pain-relieving efficacy of opioids through the development of drug tolerance and hyperalgesia. Drug tolerance is manifested by the need to increase opioid dose to maintain pain relief. Hyperalgesia is demonstrated by worsening pain sensitivity in patients chronically exposed to opioids (Freynhagen et al., 2013; Labianca et al., 2012). Long-term opioid therapy is also associated with opioid use disorders and opioid overdose (Paulozzi, Zhang, Jones, & Mack, 2014). Concomitant with increased opioid prescribing in the US, admissions to substance abuse treatment programs increased six-fold (Paulozzi, Jones, Mack, & Rudd, 2011), and opioid-related drug poisoning deaths increased almost three-fold (Rudd et al., 2016). Given the clearly established harms of long-term opioid therapy, multiple clinical guidelines now explicitly discourage the use of opioids for the treatment of chronic pain (Chou et al., 2016; Dowell et al., 2016; Franklin, 2014; Qaseem, Wilt, McLean, & Forciea, 2017; U.S. Department of Veterans Affairs, 2017; Washington State Agency Medical Directors' Group, 2015).

Rationale for the Study

Previous research has identified associations between biological, psychological, and social factors and opioid use following a variety of surgeries. These factors include younger age (Clarke et al., 2014), chronic disease comorbidities (Clarke et al., 2014), preoperative opioid use (Armaghani et al., 2014; Carroll et al., 2012; Rozet et al., 2014), depressive symptoms (Carroll et al., 2012), increased self-perceived risk of addiction (Carroll et al., 2012), and lower household income (Clarke et al., 2014). Pain catastrophizing, and symptoms of anxiety, post-traumatic stress disorder, and depression have also been linked to postoperative opioid use (Helmerhorst et al., 2014). However, it remains unknown which, if any, biopsychosocial factors predict prolonged opioid use following lumbar fusion.

Despite scant research examining opioid use following lumbar fusion, one prior study suggests a possible role for pain catastrophizing. Papaioannou et al. (2009) conducted a prospective, observational study that enrolled a consecutive sample of 61 participants scheduled for lumbar fusion at a hospital in Greece. They identified a positive correlation between level of preoperative pain catastrophizing and postoperative opioid dose (i.e., total amount of intravenous fentanyl administered via patient-controlled analgesia pump) during the first 48 postoperative hours ($r = .53$, $p < .01$). They also found that pain catastrophizing accounted for the largest portion of the variance in opioid dose in a multivariate regression model ($\beta = 0.65$, $p < .05$). Given these findings, an examination of pain catastrophizing as a possible predictor of PPO following lumbar fusion was warranted.

Pain Catastrophizing

Pain catastrophizing is a negative, cognitive-affective response to pain that is characterized by exaggerated negative perceptions during actual or anticipated pain experiences (Sullivan et al., 2001). Pain catastrophizing is conceptualized as a multidimensional construct, composed of elements of rumination, magnification, and helplessness (Sullivan, 2009). Accordingly, the term has been applied to people who are unable to divert their attention away from pain, who magnify the threat value of pain, and who report helplessness and pessimism about their ability to deal with pain (Sullivan et al., 2001).

More than 600 published studies have identified a relationship between pain catastrophizing and pain-related outcomes in patients with a variety of conditions, including low back pain, rheumatoid arthritis, osteoarthritis, fibromyalgia, sickle cell disease, and soft tissue injuries (Sullivan, 2009). Among patients with low back pain, a systematic review found consistent associations between pain catastrophizing and pain and disability regardless of whether pain was acute, sub-acute, or chronic in duration (Wertli et al., 2014). Among patients with chronic pain conditions, pain catastrophizing was positively correlated with pain intensity ($r = .30$, $p < .01$), pain-related disability ($r = .43$, $p < .01$), and psychological distress ($r = .54$, $p < .01$), and negatively correlated with life control ($r = -.48$, $p < .01$; Severeijns, Vlaeyen, VanDenHout, & Weber, 2001). Among patients using opioids for chronic pain, pain catastrophizing was positively correlated with risk for opioid misuse ($r = .45$, $p < .01$; Martel, Wasan, Jamison, & Edwards, 2013). Also among patients using opioids for chronic pain, pain

catastrophizing ($\beta = .33$, $p < .01$) was found to predict opioid craving while controlling for patient age, sex, history of substance use problems, daily opioid dose, pain intensity, and depressive symptoms [$R^2 = .25$, $F(1, 101) = 11.2$, $p < .01$] (Martel, Jamison, Wasan, & Edwards, 2014). Among patients with compensable back injuries, the odds of using opioids one year following injury were more than four times higher in patients with high levels of pain catastrophizing compared to patients with low levels of pain catastrophizing (OR, 4.75; 95% CI, 2.76-8.18; Franklin, Rahman, Turner, Daniell, & Fulton-Kehoe, 2009).

Prior studies have also examined the relationship between pain catastrophizing and surgical outcomes. However, this relationship is less consistent than the relationship between pain catastrophizing and non-surgical outcomes. Preoperative pain catastrophizing was positively correlated with acute postoperative pain following elective Cesarean section ($r = .33$ - $.37$, $p < .05$; Strulov et al., 2007), cardiac surgery ($r = .41$, $p < .001$; Khan et al., 2012), anterior cruciate ligament repair ($r = .48$, $p = .004$; Pavlin, Sullivan, Freund, & Roesen, 2005), lumbar fusion ($r = .72$ - $.89$, $p < .01$; Papaioannou et al., 2009), and abdominal surgery ($r = .81$, $p < .01$; Granot & Ferber, 2005). Preoperative pain catastrophizing was also positively correlated with sub-acute postoperative pain six weeks following total knee arthroplasty ($r = .46$, $p < .005$; Sullivan et al., 2009). However, studies that examined the relationship between pain catastrophizing and chronic, postoperative pain have produced mixed results. Three months following cardiac surgery, patients with high levels of preoperative pain catastrophizing were almost five times as likely to report postoperative pain than patients with low levels of

pain catastrophizing (OR 4.80, 95% CI 1.11-20.80, $p = .036$; Guimaraes-Pereira, Farinha, Azevedo, Abelha, & Castro-Lopes, 2016). Four months following hysterectomy, patients with high levels of preoperative pain catastrophizing were almost twice as likely to report postoperative pain than patients with low levels of pain catastrophizing (OR, 1.753; 95% CI, 1.171-2.624; Pinto, McIntyre, Nogueira-Silva, Almeida, & Araujo-Soares, 2012). Conversely, in a study of patients undergoing total knee arthroplasty, preoperative pain catastrophizing did not significantly correlate with postoperative pain intensity at either eight weeks or one year following surgery (Hovik, Winther, Foss, & Gjeilo, 2016).

In addition to inconsistent findings regarding the relationship between pain catastrophizing and chronic, postoperative pain, prior studies have also produced inconsistent findings regarding the relationship between pain catastrophizing and postoperative opioid use. Although pain catastrophizing was positively correlated with opioid dose during the immediate postoperative recovery period following lumbar fusion ($r = .53$, $p < .01$; Papaioannou et al., 2009), it was not correlated with opioid dose immediately following knee surgery ($r = .05$ - $.19$, $p > .05$; Pavlin et al., 2005). Likewise, pain catastrophizing was not correlated with opioid dose at 48 hours or at seven days following knee surgery ($r = .08$ - $.13$, $p > .05$; Pavlin et al., 2005). Furthermore, in a study of patients undergoing total knee arthroplasty, higher levels of preoperative pain catastrophizing were associated with decreased odds of opioid use at six weeks (OR, .96; 95% CI, .93 – 1.00; Banka, Ruel, Fields, YaDeau, & Westrich, 2015). The latter result indicates that as the level of pain catastrophizing increased, the odds of postoperative opioid use decreased. The researchers noted that this finding was contrary to prior

evidence that increased pain catastrophizing predicts worse postoperative outcomes (Banka et al., 2015).

Previous studies have also yielded varying results regarding how the three domains of pain catastrophizing (i.e., rumination, magnification, and helplessness) relate to pain-related outcomes. Among patients with soft tissue injury, rumination was the only subscale that contributed unique variance to the prediction of pain-related disability ($\beta = .38$, $p < .01$; Sullivan, Stanish, Waite, Sullivan, & Tripp, 1998). Among patients undergoing elective abdominal surgery, large correlations were identified between rumination and postoperative pain ($r = .79$. $p < .001$), and helplessness and postoperative pain ($r = .78$, $p < .001$); however, only a medium correlation was identified between magnification and postoperative pain ($r = .39$, $p = .017$; Granot & Ferber, 2005). Conversely, among patients with chronic musculoskeletal pain, the magnitude of correlation coefficients did not significantly differ across the three subscales, and similar correlation values were reported between opioid craving and rumination ($r = .44$. $p < .001$), magnification ($r = .35$. $p < .01$), and helplessness ($r = .31$. $p < .01$; Martel et al., 2014).

Therefore, although a positive correlation between pain catastrophizing and pain-related outcomes in patients with a range of medical conditions has been well established, how pain catastrophizing relates to pain intensity and opioid use in patients undergoing surgical procedures remains undetermined. Similarly, how the three dimensions of pain catastrophizing independently relate to pain-related outcomes remains unclear. These deficits in understanding how pain catastrophizing relates to pain-related outcomes are

important because a better understanding of pain catastrophizing could lead to improved identification of patients at risk for negative outcomes following lumbar fusion. If preoperative pain catastrophizing were shown to correlate with time to opioid cessation or with postoperative pain intensity, clinicians would have an opportunity to intervene during the perioperative period with strategies aimed at decreasing pain catastrophizing, improving postoperative pain management, and halting the progression to PPO. Such an opportunity would have particular relevance for nurses and nurse practitioners given their roles in perioperative patient care. Nurses are responsible for patient education and the promotion of patient self-management. Thus, they could target patients at risk for PPO and postoperative pain with information about opioid safety, medication adherence, and non-pharmacological pain management strategies, such as progressive physical activity, relaxation therapy, imagery, and distraction (Strayer & Hickey, 2014). Offering pain-related education during the perioperative period would allow nurses to capitalize on the teachable moment of lumbar fusion. Teachable moments are unique opportunities created through clinician-patient interaction that are used to encourage health behavior change (Flocke et al., 2014; Lawson & Flocke, 2009). Nurse practitioners could also use the teachable moment of lumbar fusion to encourage non-opioid pain management strategies. Nurse practitioners rank among the highest volume prescribers of all US healthcare specialties (Centers for Medicare and Medicaid Services [CMS], 2015). Thus, nurse practitioners could influence opioid use rates by incorporating non-opioid pain relievers into patients' medication regimens. Nurse practitioners could also identify patients at risk for opioid use disorder through diligent patient assessment and review of

prescription drug monitoring data (Chou et al., 2009; Deyo et al., 2015). Such interventions could decrease patients' reliance on opioid pain relievers and identify patients for whom psychotherapeutic intervention or opioid use disorder treatment are warranted.

Furthermore, identifying whether one dimension of pain catastrophizing is more strongly correlated to duration of postoperative opioid use would enable clinicians to target that particular domain as a means of minimizing the negative impact of pain catastrophizing on opioid use. For example, if helplessness were shown to be strongly correlated with duration of opioid use, clinicians could promote self-management strategies as a means of increasing self-efficacy. Alternatively, if magnification were shown to be strongly correlated with duration of opioid use, clinicians could assist patients to reevaluate the threat they ascribe to their pain (Sullivan, 2009).

Conceptual Framework

The biopsychosocial model of illness provided the conceptual framework for the study. The model maintains that biological, psychological, and social factors interact to produce illness and disability (Engel, 1977). When introduced in the 1970s, the biopsychosocial model challenged the prevailing biomedical model of disease. The biomedical model is based on a reductionist philosophical view that disease exclusively results from a biochemical defect or deviation, and that its diagnosis and treatment need only consider biological factors. In contrast, the biopsychosocial model is based on a holistic philosophical view that disease is multidimensional. Accordingly, an

understanding of how individuals experience and describe disease must consider the possible influence of biological, psychological, and social factors (Engel, 1977).

Waddell (1987) recommended the use of the biopsychosocial model for the diagnosis and treatment of low back complaints in response to escalating rates of low back disability despite improved biomedical understanding of spinal pathology. In describing how the model should be applied to low back complaints, Waddell (1987) differentiated low back pain from low back disability. He described low back pain as a benign, self-limited disease that results from a physical abnormality, and produces signs and symptoms in proportion to the abnormality. In contrast, he described low back disability as an illness that results from the interplay of biological, psychological, and social factors, and is characterized by distress and illness behaviors that are disproportionate to any identifiable abnormality. Thus, for individuals with low back disability, it is not simply the degree of physical abnormality that determines their prognosis, but also their and society's perceptions, interpretations, and reactions to pain.

In the 25 years since Waddell first recommended that clinicians treating patients with low back pain use the biopsychosocial model as a framework, the model has emerged as the dominant framework for the conceptualization of low back pain and disability (Pincus et al., 2013). Its use has been endorsed by the National Institutes of Health (NIH) Task Force on Research Standards for Chronic Low Back Pain (Deyo et al., 2014). In adopting this model, the researcher conceptualized PPO as a form of low back disability and sought to explore multifactorial contributors to its development (see Figure 1.1).

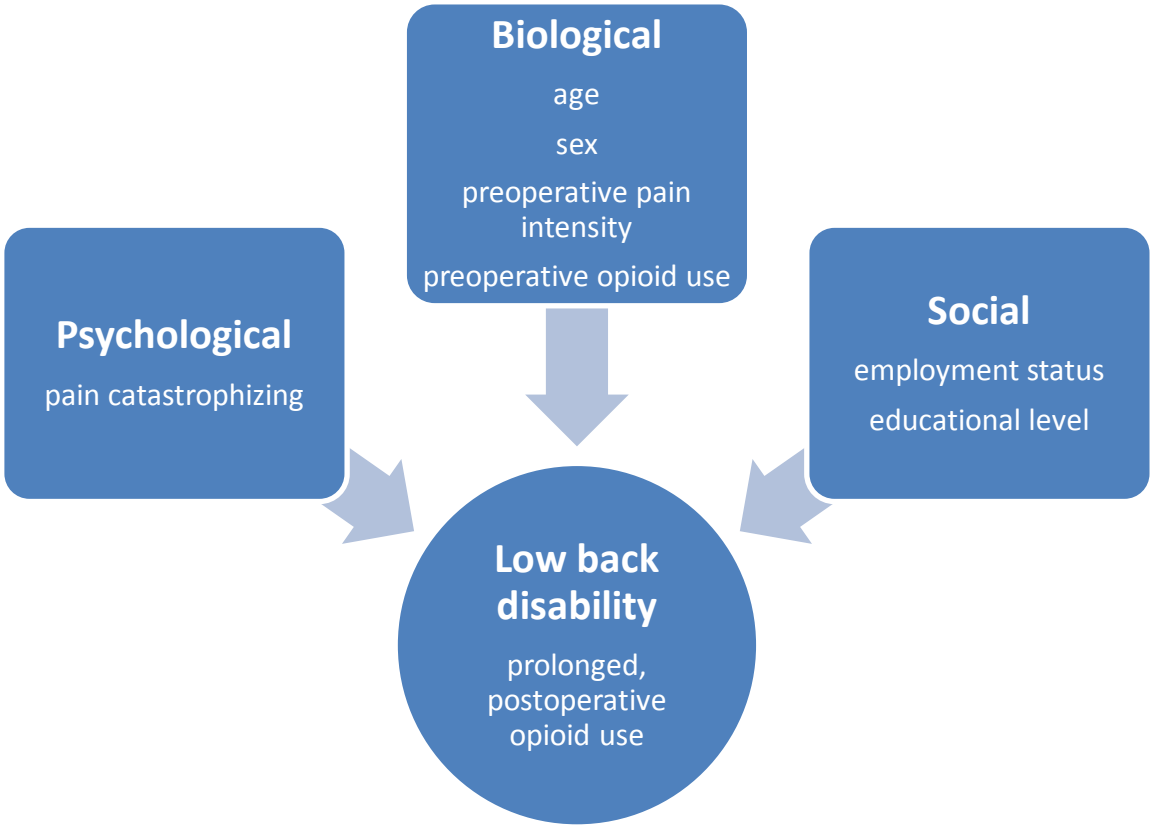

Figure 1.1: Biopsychosocial model of low back pain. Squares represent the three dimensions of the biopsychosocial model: biological, psychological, and social. The circle represents the convergence of these factors to produce low back disability, which is limited in this model to prolonged, postoperative opioid use.

Assumptions

The study was grounded in post-positivist philosophical assumptions. Post-positivism is derived from positivism, a theoretical belief that unambiguous and accurate knowledge of the world exists and that this knowledge, or objective truth, can be discovered through scientific observation and experience (Crotty, 1998). Although post-positivism also maintains the existence of an objective truth, it is distinguished from positivism by conceding that truth may be imperfectly known (Crotty, 1998). Both positivism and post-positivism reflect objectivist epistemology. This epistemology—or theory of knowing—maintains that meaning and meaningful reality exist independent of consciousness (Crotty, 1998).

In adopting post-positivism as the study's theoretical perspective, the researcher considered the study variables to be personal attributes that exist in the world and are discoverable through quantitative methodology. Accordingly, the researcher measured and assigned categorical or numerical values to each variable that represented which attribute, or how much of the attribute, exists in each participant. The researcher statistically analyzed the categorical and numerical values to approximate the association between each independent variable and the two dependent variables. These analyses tested the theorized relationships between biopsychosocial variables and time to opioid cessation and postoperative pain intensity following lumbar fusion. Age, sex, preoperative pain intensity, and preoperative opioid use were conceptualized as biological variables; employment status and educational level were conceptualized as social variables; and pain catastrophizing was conceptualized as a psychological variable.

Unique Role for Pain Catastrophizing

Several studies have identified relationships between psychological variables and lumbar fusion outcomes. Adogwa et al. (2012) found that preoperative depression, as measured using the Zung Self-Rated Depression Scale, predicted functional disability two years after revision lumbar fusion for adjacent segment disease (B = -2.59, p = .01), pseudoarthrosis (B = -3.01, p = .01), and same-level recurrent stenosis (B = -2.01, p = .05). Soriano et al. (2010) reported that better emotional health, as measured using the Mental Component Summary of the Short Form-36 Health Survey, predicted greater functional improvement following instrumented posterolateral lumbar fusion ($\beta = 0.20$, $p < .05$). However, notwithstanding a potential role for depression and emotional health in predicting lumbar fusion outcomes, the researcher only examined pain catastrophizing in the current study because prior research supports a unique role for pain catastrophizing in the prediction of pain-related outcomes.

Among students exposed to a painful stimulus in a laboratory setting, pre-procedure scores on the Pain Catastrophizing Scale (PCS) were positively correlated with scores on the Fear of Pain Questionnaire ($r = .80$, $p < .001$), Beck Depression Inventory ($r = .26$, $p < .05$), State-Trait Anxiety Inventory–Trait Form ($r = .32$, $p < .05$), and the negative affectivity subscale of the Positive Affect–Negative Affect Scale ($r = .32$, $p < .05$). However, multiple regression analysis revealed that only PCS scores ($\beta = .45$, $p < .05$) contributed unique variance to the prediction of pain ratings [$F(1, 56) = 5.4$, $p < .001$] (Sullivan, Bishop, & Pivik, 1995). Similarly, among patients undergoing elective abdominal surgery, positive correlations were identified between preoperative PCS scores

and postoperative pain ratings (r = .81, p < .01) and between preoperative State-Trait Anxiety Inventory-State Form scores and postoperative pain ratings (r = .72, p < .01; Granot & Ferber, 2005). However, scatterplots of the variables revealed different patterns of association. Anxiety and pain were related in a curvilinear pattern; pain catastrophizing and pain were associated in a linear pattern. This distinction was identified by the researchers as evidence that anxiety and pain catastrophizing are unique constructs and operate via separate mechanisms (Granot & Ferber, 2005).

Pain catastrophizing has also been shown to have a unique role in predicting opioid use. Among patients undergoing surgery for musculoskeletal trauma, scores on the PCS and the Center for Epidemiological Studies Depression Scale (CES-D) were positively correlated (r = .70, p < .001), and scores on the PCS, CES-D, Pain Anxiety Symptoms Scale (PASS-20), and Posttraumatic Stress Disorder Checklist-Civilian version (PCL-C) were all significantly higher in patients who used postoperative opioids than in patients who did not use postoperative opioids (Helmerhorst et al., 2014). However, when scores on the PCS, CES-D, PASS-20, and PCL-C were entered into a backward logistic regression model, pain catastrophizing was the single best predictor of opioid use and was the only factor retained (OR, 1.12; 95% CI, 1.07 to 1.18; Helmerhorst et al., 2014). Likewise, among patients undergoing lumbar fusion, scores on the PCS were positively correlated with scores on the Hospital Anxiety and Depression Scale-Anxiety subscale (r = .29, p < .05), and with scores on the Hospital Anxiety and Depression Scale-Depression subscale (r = .43, p < .01; Papaioannou et al., 2009). However, only PCS scores were correlated with total postoperative opioid dose (r = .53,

$p < .01$; Papaioannou et al., 2009). These results suggested a unique role for pain catastrophizing, independent of other psychological variables, in predicting pain-related outcomes. Therefore, an examination of pain catastrophizing as the sole psychological factor in the proposed study was justified.

Pain Catastrophizing as a Trait-Like Variable

Pain catastrophizing was only measured preoperatively because the researcher conceptualized pain catastrophizing as a trait-like variable rather than a state-like variable. Trait-like variables, or trait attributes, are considered to be stable, and to exhibit little variation over time. Thus, measures of trait-like variables are assumed to reflect typical responses over a range of situations and stimuli, and to yield high test-retest reliability coefficients (Waltz, Strickland, & Lenz, 2010). In contrast, state-like variables, or state attributes, are conceptualized as changeable over short periods of time and from one situation to another. Thus, measures of state-like variables are assumed to detect variability, and are not expected to yield high test-retest reliability coefficients unless the original situation in which the phenomenon was measured has been replicated (Waltz et al., 2010).

The conceptualization of pain catastrophizing as a trait-like variable is supported by several studies. During the development of the PCS, two separate studies assessed the instrument's test-retest reliability. In one study, Sullivan et al. (1995) enrolled 40 students and reported a test-retest reliability coefficient of $r = .75$ ($p < .001$) over a six week period; in another study, the same group of researchers enrolled 60 students and reported a test-retest reliability coefficient of $r = .70$ ($p < .001$) over an approximate 10

week period. These results evidence the temporal stability of PCS scores and suggest that pain catastrophizing, in the absence of intervention, exhibits little variation over time. In a third, unrelated study, Strulov et al. (2007) administered the PCS to 47 women undergoing elective Cesarean section and reported that preoperative PCS scores and postoperative PCS scores were strongly correlated ($r = .521$; $p < .001$). This result evidences the stability of pain catastrophizing in the presence of a painful stimulus, and further supports a trait-like conceptualization. Finally, multiple studies have identified correlations between preoperative PCS scores and postoperative pain ratings (Papaioannou et al., 2009; Pavlin et al., 2005; Pinto et al., 2012; Sullivan et al., 1995). These results evidence the predictive validity of the PCS. Therefore, given the temporal stability and predictive validity of PCS scores, pain catastrophizing was conceptualized as a trait-like variable and was only measured as a preoperative patient characteristic.

Prolonged Postoperative Opioid Use as a Manifestation of Low Back Disability

Time to opioid cessation and postoperative pain intensity were the two dependent variables. They were examined as patient-centered outcomes following lumbar fusion. However, opioid use was only considered an illness behavior and a manifestation of low back disability when it extended to three postoperative months, with no more than 5 opioid free days since surgery.

Research Question and Hypotheses

This study examined the prevalence of PPO following lumbar fusion and relationships between preoperative patient characteristics and patient-centered outcomes following lumbar fusion. The research question was: What is the prevalence of PPO

among a cohort of patients three months following elective lumbar fusion? The biopsychosocial model of illness was used to predict the relationships between preoperative patient characteristics and patient-centered outcomes. The three hypotheses were:

1. It is hypothesized that level of pain catastrophizing, as measured with the PCS, will be positively correlated with time to opioid cessation.
2. It is hypothesized that level of pain catastrophizing, as measured with the PCS, will be positively correlated with postoperative pain intensity, as measured with the Numeric Pain Rating Scale (NPRS).
3. It is hypothesized that time to opioid cessation can be predicted by preoperative patient characteristics.

Definition of Terms

Preoperative (Independent) Variables

There were seven preoperative variables: (a) age, (b) sex, (c) employment status, (d) educational level, (e) preoperative pain intensity, (f) preoperative opioid use, and (g) pain catastrophizing. Preoperative variables were examined as independent variables, and possible predictors of time to opioid cessation. They were considered attribute variables because they are preexisting traits of the participants that were not expected to systematically change during the study (Leech, Barrett, & Morgan, 2015).

Age. Age was measured in years, and was examined as a scale-level, biological variable.

Sex. Sex was dichotomized (i.e., male/female) and examined as a biological variable. Sex was included as a preoperative variable because males and females have been shown to differ in regards to several pain-related variables, including risk for chronic pain (Bartley & Fillingim, 2013), receipt of high-potency opioids for cancer-related pain (Donovan, Taliaferro, Brock, & Bazargan, 2008), and report of inadequate cancer pain management (Donovan et al., 2008). Sex has also been shown to influence pain-related treatment decisions made by clinicians (Hirsh et al., 2013).

The examination of sex as an independent variable was distinct from an examination of gender. In contrast to sex, which is determined by genetic material and manifested in reproductive organs and other physiologic characteristics, gender refers to social, cultural, and psychological traits that are expressed in behaviors, roles, and identities (NIH, 2015). Further, although gender is also usually dichotomized (i.e., man/woman), there are diverse understandings and expressions of gender (NIH, 2015). Nevertheless, many studies that have reported gender differences in regards to pain-related variables failed to describe how gender was operationally defined (Campbell et al., 2010; Green, Serrano, Licari, Budman, & Butler, 2009; Kaur, Stechuchak, Coffman, Allen, & Bastian, 2007).

Employment status. Employment status was defined using one of 11 possible employment descriptors. It was examined as a nominal-level, social variable.

Educational level. Educational level was defined using one of nine possible educational descriptors. It was examined as a nominal-level, social variable.

Preoperative pain intensity. Preoperative pain intensity was defined as mean intensity of low back and leg pain during the 7-day period prior to lumbar fusion. Pain intensity included pain in the low back and lower extremities because both findings are included as surgical criteria for lumbar fusion (International Society for the Advancement of Spine Surgery [ISASS], 2011; North American Spine Society [NASS], 2014). Preoperative pain intensity was measured using the NPRS, and was examined as a scale-level, biological variable.

Preoperative opioid use. Preoperative opioid use was defined as the use of prescribed opioid pain relievers for low back pain prior to lumbar fusion. It was examined as a dichotomous, biological variable.

Pain catastrophizing. Pain catastrophizing is a negative, cognitive-affective response to pain, and was conceptually defined as, "an exaggerated negative mental set brought to bear during actual or anticipated pain experience" (Sullivan et al., 2001, p. 53). Pain catastrophizing was operationally defined by PCS scores, and was examined as a scale-level, psychological variable.

Postoperative (Dependent) Variables

The two postoperative variables were time to opioid cessation and postoperative pain intensity. They were measured three months following lumbar fusion to allow sufficient time for surgical wound healing, initial consolidation of the fusion, and liberalization of postoperative activity restrictions (Greenwood, McGregor, Jones, & Hurley, 2015). In addition, opioid use is typically not considered long-term until it has exceeded three months (Chou et al., 2009; Nuckols et al., 2014). Postoperative variables

were examined as dependent variables, and patient-centered outcomes of lumbar fusion that reflected the effect of the independent variables (Leech et al., 2015).

Time to opioid cessation. Time to opioid cessation was defined as the number of weeks from lumbar fusion until the first of 5 consecutive days of zero opioid use. It was examined as a scale-level variable.

Prolonged, postoperative opioid use (PPO). Those participants who reported continued opioid use for back or leg pain at three months, with no more than 5 opioid-free days since surgery, were considered positive for PPO. This criterion was based on a definition of prolonged opioid use that was described by Carroll et al. (2012). Although some participants reported episodic opioid use for back or leg pain at three months, participants were only considered positive for PPO if they did not report at least 5 consecutive days of zero opioid use. PPO was conceptually defined as an illness behavior, and a manifestation of low back disability.

Postoperative pain intensity. Postoperative pain intensity was defined as mean intensity of low back and leg pain during a 7-day period measured three months following lumbar fusion. It was measured using the NPRS, and was examined as a scale-level variable.

Limitations

Several issues were identified prior to data collection that had the potential to weaken the study's internal and external validity. Internal validity refers to the confidence with which it can be inferred that the independent variables, rather than other factors, caused the observed variation in the dependent variables (Polit & Beck, 2012).

External validity refers to the generalizability of results to settings and samples other than those studied (Polit & Beck, 2012).

Internal Validity

In the current study, internal validity referred to inferences that age, sex, employment status, educational level, preoperative pain intensity, preoperative opioid use, and pain catastrophizing predicted time to opioid cessation. There were several threats to internal validity; however, the research design controlled for many of them.

The threat of temporal ambiguity, in which it is unclear if changes in the dependent variables preceded or followed the independent variables, was controlled by the longitudinal design (Polit & Beck, 2012). For example, if a participant had reported continued opioid use for back or leg pain at three months, and the same participant was noted to be on sick leave from work, the longitudinal design would have clarified that the sick leave was antecedent to prolonged, postoperative opioid use.

Threats related to selection were controlled by the use of consecutive sampling. Consecutive sampling increases the likelihood of a representative sample by inviting all participants who meet eligibility criteria to enroll (Polit & Beck, 2012).

Threats related to testing and instrumentation were not anticipated when measuring pain catastrophizing because there was only one administration of the PCS. Thus, there was no possibility that PCS scores were influenced by repeated administrations of the instrument, or that variation in time to opioid cessation or postoperative pain intensity reflected changes in measurement rather than variation in pain catastrophizing (Polit & Beck, 2012). In contrast, the repeated use of the NPRS had

the potential to compromise internal validity because participants' experience of completing the preoperative NPRS may have sensitized them to the instrument, and may have influenced their responses on the postoperative NPRS (Polit & Beck, 2012). That is, participants' responses on the postoperative NPRS may not have exclusively reflected their postoperative pain intensity, but may, instead, have been influenced by recall of their responses on the preoperative NPRS. Nevertheless, despite this potential shortcoming, patients were asked to rate their pain using the NPRS pre- and post-lumbar fusion. The NPRS is the most common measure of pain intensity among patients with chronic low back pain (Chapman et al., 2011). Use of the NPRS has been endorsed by the National Institutes of Health (Deyo et al., 2014). Furthermore, prior research involving patients undergoing lumbar fusion demonstrated that scores on the NPRS can discriminate between patients who experience meaningful improvement following surgery versus patients who experience non-meaningful improvement following surgery (Godil et al., 2014).

The use of self-report to measure preoperative pain intensity, preoperative opioid use, time to opioid cessation, and postoperative pain intensity was also a potential threat to internal validity if participants were to respond in a manner that they perceived to be congruent with prevailing social values or researcher expectations (Polit & Beck, 2012; Waltz et al., 2010). Such responses would create social desirability bias, and could compromise internal validity if participants misrepresented their pain intensity or opioid use to portray themselves in a socially acceptable manner. The possibility of social desirability bias is always a threat when using self-report measures (Waltz et al. 2010),

but it was especially concerning in this study given the widespread coverage of the opioid epidemic in the lay media ("Dangerous pill-popping," 2015; "Painkiller abuses and ignorance," 2015), and the stigma associated with chronic pain and opioid use disorders (Peppin, 2009; Slade, Molloy, & Keating, 2009; Waugh, Byrne, & Nicholas, 2014).

The possibility of social desirability bias has been identified as a limitation in previous studies of opioid use. Dwyer et al. (2015) questioned 51 participants following an opioid-related emergency department visit about their personal overdose history, witnessed overdose history, and 30-day substance use. In discussing their results, the researchers acknowledged that participants might have misrepresented themselves when responding to interview questions (Dwyer et al., 2015). Heimer et al. (2012) also identified the possibility of social desirability bias when discussing the results of their study of opioid misuse. The researchers enrolled 214 participants and reported that scores on the medical domain of the Addiction Severity Index, a measure of addiction severity, were positively correlated with scores on the interference subscale of the Brief Pain Inventory ($r = .46$, $p < .0001$). However, the researchers suggested that participants may have exaggerated their pain as a means of rationalizing their misuse of heroin and prescription opioids (Heimer et al., 2012).

Deshields, Tait, Gfeller, and Chibnall (1995) examined social desirability in a study that enrolled 200 patients with chronic pain. Participants completed the Marlowe-Crowne Social Desirability Scale (MCSDS), a measure of social desirably, as well as self-report measures of pain, disability, quality of life, and psychological distress. The researchers reported that scores on the MCSDS were positively correlated with self-

reported pain levels (r = .20 - .21, p < .01), and were negatively correlated with scores on measures of depression (r = -.34, p < .001) and anxiety (r = -.31, p < .001). Deshields et al. (1995) suggested that participants may have emphasized physical complaints (i.e., pain) and minimized psychological complaints (i.e., depression and anxiety) to avoid a socially unacceptable label of psychosomatic illness.

Ahn et al. (2016) did not discuss social-desirability bias in their study of preoperative opioid use prior to spinal surgery. However, they urged a nonjudgmental approach when assessing preoperative opioid use after they found that 28% of participants denied preoperative opioid use at the initial surgical evaluation, but were subsequently identified as having filled an opioid prescription via review of prescription monitoring program data (Ahn et al., 2016).

Given the threat that social desirability bias posed to the internal validity of the proposed study, the researcher took several actions to reduce the threat. The researcher interviewed participants about time to opioid cessation and postoperative pain intensity via telephone because telephone interviews are less likely to elicit socially desirable responses than are face-to-face interviews (Waltz et al. 2010). Telephone interviews, however, still allowed the researcher to engage with participants and build on the rapport and trust that had been established during enrollment. During interviews, the researcher avoided language that could suggest that certain responses were more positively or negatively valued. The researcher also avoided fixed-response questions (i.e., true/false and yes/no) that could suggest that the participant was choosing between one socially desirable option and one socially undesirable option (Waltz et al., 2010).

Maturation and attrition threats to internal validity were lessened by limiting the time interval between the two data collection points to three months. Maturation refers to participant factors that occur during the study that could affect the dependent variables. Such participant factors were unlikely to arise because the study was limited to adult participants during a three month period. Attrition refers to the loss of participants during a study, and can be expected during any longitudinal study. However, attrition only becomes a threat to internal validity if it is not random, and if the participants who drop out of the study differ from the participants who remain in the study on potentially important independent variables. For example, if a large percentage of people who self-identify as "not working" were to drop out of the study, while participants who self-identify as "working" were to remain in the study, the impact of employment status on the dependent variables could be obscured. Since the threat of attrition was, perhaps, the greatest threat in the proposed study, the researcher assessed the quantity and randomness of missing data.

External Validity

Several factors posed a threat to external validity. A sampling plan that did not enroll a sample that was representative of the target population would limit external validity because the results would only be generalizable to patients who were represented in the sample. For example, if all participants had at least a Bachelor's degree, the results would not be generalizable to patients who have not completed high school. For this reason, the proposed use of a single study site threatened external validity because it increased the possibility of a homogeneous sample (Polit & Beck, 2012). Nevertheless,

despite this threat to external validity, a single site study was conducted because the researcher was required to conduct face-to-face meetings with all potential participants and was not able to enroll participants at multiple locations during the same data collection period.

Summary

High rates of PPO have been reported by patients undergoing lumbar fusion. These rates are concerning because lumbar fusion is a commonly performed surgical procedure, and because the safety and efficacy of long-term opioid use has not been demonstrated. On the contrary, long-term opioid therapy is associated with serious pharmacological adverse effects, opioid use disorders, and drug-poisoning deaths. Since prior research has shown that PPO following non-spinal surgeries can be predicted by preoperative biological, psychological, and social factors, this study was conducted to determine whether PPO following lumbar fusion can be predicted by preoperative patient characteristics. The study also sought to identify the relationship between pain catastrophizing and time to opioid cessation and between pain catastrophizing and postoperative pain intensity.

CHAPTER II

REVIEW OF LITERATURE

The Biopsychosocial Model of Low Back Pain and Patient-Centered Outcomes following Lumbar Fusion

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The Biopsychosocial Model of Low Back Pain and Patient-Centered Outcomes following Lumbar Fusion

Lumbar fusion is a common surgical procedure performed to eliminate painful motion in a spinal segment by joining, or fusing, two or more vertebrae. Although the surgery has a high rate of producing radiographic fusion, many patients report negative outcomes following the procedure, including pain, functional disability, an inability to return to work, and prolonged opioid pain reliever use. These apparent discrepancies between technical success and patient-centered outcomes have raised questions about the efficacy and medical necessity of lumbar fusion, and have resulted in restrictive payer policies (Cheng et al., 2011; Phillips et al., 2013). However, researchers have identified associations between specific biopsychosocial factors and surgical outcomes suggesting that at least some of the variability in outcomes is due to preoperative patient characteristics. Accordingly, it may be possible to identify patients at risk for negative outcomes prior to surgery. Using the biopsychosocial model of low back pain as a framework, this article will present a review of the literature to identify the biological, psychological, and social factors that have been associated with patient-centered outcomes following lumbar fusion.

Biopsychosocial Model of Low Back Pain

The biopsychosocial model of low back pain provides a useful framework to conceptualize how biological, psychological, and social factors can influence patient outcomes following lumbar fusion (see Figure 2.1). The model is based on a holistic philosophical view that illness is multidimensional, and that an appreciation of how

individuals experience and report biomedical defects and deviations must consider the influence of biological, psychological, and social variables (Engel, 1977). When the biopsychosocial model was introduced in the 1970s, it challenged the prevailing biomedical model of disease. The latter model reflects a reductionist philosophical view that disease is the consequence of aberrant biological processes, and that the diagnosis and treatment of disease need only consider these processes (Engel, 1977). Hence, clinicians and researchers espousing the biomedical model would focus an investigation of low back pain on an examination of lumbar spinal anomalies (i.e., biological factor), whereas individuals espousing the biopsychosocial model would explore a range of factors, such as depression (i.e., psychological factor) and educational level (i.e., social factor).

Although the biomedical model provides a sound pathophysiological basis for the study of disease, critics of the model have long decried its inability to explain variations in the human experience of illness (Engel, 1977; Waddell, 1987). For instance, all individuals with diabetes mellitus share similar endocrine dysfunction; however, their management of the illness varies, and reflects differences in dietary habits, exercise capacity, readiness to adopt change, health literacy, etc. Likewise, as noted by renowned Scottish surgeon Gordon Waddell (1987), many individuals share similar findings on lumbar spine imaging studies; however, their clinical presentation may be strikingly different, with some individuals remaining asymptomatic, some reporting only mild pain, and others describing excruciating pain.

In proposing the biopsychosocial model for low back pain, Waddell (1987) also noted that technological advances in the detection and treatment of lumbar spinal disorders during the latter half of the 20th century had not decreased the worldwide prevalence of low back disorders. Paradoxically, improved understanding of spinal disorders had been accompanied by a dramatic increase in the rate of low back disability, particularly in Western countries. These observations convinced Waddell (1987) that the biomedical model was an inadequate model for the study of low back disorders, and that a new, broader model was needed.

In describing how the biopsychosocial model should be applied to low back complaints, Waddell (1987) differentiated low back pain from low back disability. He described low back pain as a benign, self-limited disease that results from a physical abnormality, and produces signs and symptoms proportionate to the abnormality. In contrast, he described low back disability as an illness that results from the interplay of biological, psychological, and social factors, and is characterized by distress and illness behaviors disproportionate to any identifiable abnormality. Accordingly, when studying outcomes following lumbar fusion, low back disability can be conceptualized as negative surgical outcomes, such as pain and functional disability that persist despite successful wound healing and fusion consolidation. Such outcomes are not easily attributed to a single physical abnormality; rather, they reflect the convergence of an individual's perceptions, interpretations, and responses to pain.

In the 25 years since Waddell first advocated the use of the biopsychosocial model, it has become the dominant framework for the study of low back pain and

disability (Pincus et al., 2013). Its use has also been endorsed by the National Institutes of Health (NIH) Task Force on Research Standards for Chronic Low Back Pain (Deyo et al., 2014). In adopting this model, clinicians and researchers commit to exploring multifactorial contributors to low back disability, and to developing treatment strategies that are not solely aimed at correcting a biomedical defect or deviation, but also address an individual's attitudes, beliefs, psychological distress, and illness behaviors (Waddell, 1987).

Spinal Fusion in the United States

Spinal fusion is a frequently performed surgical procedure in US hospitals. During a recent 11 year period, the number of fusion procedures increased every year, from 287,600 procedures in 2001 to 488,300 procedures in 2011 (Weiss & Elixhauser, 2014). This 70% increase in spinal fusion positioned the procedure as the sixth most frequently performed surgical procedure in US hospitals (Weiss, Elixhauser, & Andrews, 2014). Among all fusion procedures, fusion of the lumbar spine is the most commonly performed, and is the exclusive focus of this review. In comparison, fusion of the cervical spine is only slightly less common than lumbar fusion, whereas fusion of the thoracic spine is much less common and comprises fewer than 10% of all fusion procedures (Rajaee et al., 2012).

Lumbar fusion is indicated for patients with spinal instability resulting from disease, surgical intervention, or both (Halpern & Grady, 2014). In the US, most patients undergoing lumbar fusion have a degenerative condition, such as degenerative disc disease, stenosis, or spondylolisthesis (Rajaee et al., 2012). However, lumbar fusion may

also be appropriate for patients with traumatic injuries, flat-back syndrome, pseudoarthrosis, adjacent segment degeneration, recurrent disc herniation, spinal deformity, and infection or tumor involving the spine (ISASS, 2011; North American Spine Society, 2014).

The goal of lumbar fusion is the elimination of painful, abnormal motion. This is frequently accomplished with internal fixation devices (i.e., pedicle and facet screws, rods, and cages) and graft material (i.e., autograph, allograph). The fixation devices stabilize and immobilize the affected spinal segment, and the graph material provides a bridge across the defect. Once these elements are in place, the patient's osteoblasts are meant to form new bone across the defect to lock the involved vertebral components together into a solid mass of new bone. This process, known as arthrodesis, must occur in all fused segments to yield long-term stability (Halpern & Grady, 2014). Thus, from a radiographic perspective, the achievement of arthrodesis is considered a successful fusion, whereas failure to achieve arthrodesis, known as pseudoarthrosis, is considered a failed fusion (Halpern & Grady, 2014).

Lumbar Fusion Outcomes

During the nearly one hundred years since lumbar fusion was first described, a range of outcomes has been reported in the literature. Early reports of the surgery exclusively considered arthrodesis rates (Malkin, 1935; Malkin, 1936). Mid-20th century studies incorporated subjective outcomes, such as symptom relief and work capacity (Spadea & Hamlin, 1952; Tunturi et al., 1979). More recent studies have examined clinician-based outcomes, including complication rates (Bydon et al., 2014; Cheng et al.,

2015; Goz, Weinreb, Schwab, Lafage, & Errico, 2014; Joseph, Smith, La Marca, & Park, 2015; Nguyen et al, 2011; Peng, Yue, Poh, Yeo, & Tan, 2009; Rouben et al., 2011; Talia, Wong, Lau, Kaye, 2015), inpatient hospital length of stay (Goz et al., 2014; Peng et al., 2009; Rouben et al., 2011) and cost (Bydon et al., 2015; Goz et al., 2014). Concurrently, in response to a recommendation from the Institute of Medicine (IOM, 2001) for more patient-centered care, studies have explored patient-centered outcomes, including pain intensity (Abbott, Tyni-Lenne, & Hedlund, 2011; Adogwa et al., 2012; Mendenhall et al., 2014; Peng et al., 2009; Rao, Loganathan, Yeung, & Mobbs, 2015; Rouben et al., 2011; Soriano et al., 2010), functional disability (Abbott et al., 2011; Adogwa et al., 2012; Mendenhall et al., 2014; Nguyen et al., 2011; Peng et al., 2009; Rao et al., 2015; Rouben et al., 2011; Soriano et al., 2010), work status (Mendenhall et al., 2014; Nguyen et al., 2011; Rouben et al., 2011), and postoperative opioid use (Mendenhall et al., 2014; Nguyen et al., 2011; Rouben et al., 2011).

Biopsychosocial Factors and Patient-Centered Outcomes

The spine literature reveals a long-held belief that psychological and social factors could influence patient outcomes. Shaw and Taylor (1956) attributed a participant's failure to achieve symptomatic relief, despite successful arthrodesis, to a suspicion that the patient, "seems to be a hysteric and perhaps should not have been operated on" (p. 493). Tunturi and Pattiala (1980) reported statistically significant associations between social factors (i.e., number of children, population of the place of residence) and return to work. However, because these researchers neither explained the clinical significance of their findings, nor theorized how psychological and social factors influenced their

outcomes, their studies did little to elucidate the role of biopsychosocial factors in predicting lumbar fusion outcomes and, instead, contributed to widespread rebuke of the spine literature.

Farfan and Kirkaldy-Willis (1981) criticized lumbar fusion studies for failing to explain patient selection, surgical indication, and factors contributing to pseudoarthrosis, and remarked, "The literature on spinal fusion is totally inadequate…." (p. 211). Turner et al. (1992) similarly criticized the literature, and disparaged the absence of studies examining psychosocial factors. In response to these critiques, many modern researchers have adopted a more holistic approach to spine research, and have incorporated biopsychosocial variables into their studies. Many researchers have also expanded their studies to include more of the outcomes that are considered by patients to be of greatest importance. For example, Carragee and Cheng (2010) asked patients to specify the absolute worst level of pain intensity, functional disability, work capacity, and medication requirement that they would consider acceptable following lumbar fusion. Such attention to patient-centered outcomes reflects a growing appreciation of the need to align healthcare delivery with patients' preferences and needs. Accordingly, this review will present eight recent studies that examined the influence of biopsychosocial variables on patient-centered outcomes, focusing on pain intensity, functional disability, return to work, and prolonged opioid pain reliever use. A description of the instruments used to measure the four outcomes (see Table 2.1) and recommendations for further research will also be presented.

Pain Intensity

Most lumbar fusions are performed on patients with pain in the low back and lower extremities due to degenerative conditions that is unrelieved with multi-modal, non-operative treatment (i.e., physical therapy, interventional pain management procedures). Thus, pain assessment is an essential component of pre- and postoperative care. Among the most commonly used measures of low back pain is the visual analogue scale (VAS). The VAS is a single-item instrument consisting of a 100 mm horizontal line with the anchors "no pain" and "worst pain imaginable" on which respondents indicate their relative position (Chapman et al, 2011; Scrimshaw & Maher, 2001).

The reliability of the VAS has been adequately supported in studies examining chronic low back pain (Chapman et al., 2011), and other painful musculoskeletal conditions (Crossley, Bennell, Cowan, & Green, 2004). The validity of the VAS has been demonstrated by its strong correlation with the numeric rating scale—another one-dimensional measure of pain intensity (Breivik et al., 2008). In addition, when used with patients undergoing lumbar surgery, postoperative VAS scores have strongly correlated with postoperative patient satisfaction ratings (Zanoli, Stromqvist, & Jonsson, 2001). The VAS has also been shown to be more responsive to clinical change in pain intensity than both the verbal categorical rating scale (i.e., none, mild, moderate, severe; Breivik et al., 2008) and the McGill Pain Questionnaire (Scrimshaw & Maher, 2001). For these reasons, the VAS is considered the gold standard for measuring pain intensity in spine-related studies (Chapman et al., 2011; VanDenKerkhof, Peters, & Bruce, 2013).

Of the eight reviewed studies, seven studies compared preoperative pain intensity to postoperative pain intensity, and all reported significantly improved VAS scores following lumbar fusion (Abbott et al., 2011; Adogwa et al., 2012; Mendenhall et al., 2014; Peng et al., 2009; Rao et al., 2015; Rouben et al., 2011; Soriano et al., 2010). Reviewed studies also identified significant associations between a variety of biopsychosocial factors and postoperative pain intensity. Abbott et al. (2011) conducted a prospective cohort study of patients who underwent lumbar fusion for spinal stenosis, spondylolisthesis, or degenerative disc disease. They found that high levels of preoperative pain catastrophizing predicted higher levels of postoperative back pain intensity. Conversely, they found that high levels of preoperative leg pain—but not preoperative back pain—and a positive straight leg raise (i.e., pain in the sciatic distribution between 30º and 70º passive flexion of the straight leg) predicted lower levels of postoperative back pain intensity. They attributed the latter finding to the likelihood that preoperative leg pain, as compared to back pain, was due to a structural defect that the surgery had corrected. Rao et al. (2015) also conducted a prospective cohort study, and exclusively evaluated outcomes following anterior lumbar interbody fusion. They noted that although all patients experienced significant improvement in pain intensity following surgery, the magnitude of pain relief varied by surgical indication. Patients with degenerative disk disease, spondylolisthesis, and scoliosis reported greater improvement in pain intensity than did patients with failed posterior fusion and adjacent segment disease. Soriano et al. (2010) also found that the magnitude of pain relief varied by surgical indication. In their prospective cohort study, they found that patients with

disc herniation reported greater improvement in pain intensity than did patients with degenerative spinal stenosis or spondylolisthesis. Rao et al. (2015) and Rouben et al. (2011) further reported that magnitude of pain relief varied by payer status. Rao et al. (2015) reported that patients claiming workers' compensation benefits did not report statistical improvement in VAS scores. In contrast, Rouben et al. (2011) reported that all patients reported statistical improvement in VAS scores; nevertheless, the degree of improvement was less in patients receiving workers' compensation benefits compared to patients who did not receive workers' compensation benefits.

For several factors, no significant association with postoperative pain intensity was detected; these included age (Rouben et al., 2011; Soriano et al. 2010), sex (Soriano et al., 2010), body mass index (Rao et al., 2015; Rouben et al., 2011; Soriano et al., 2010), smoking (Rao et al., 2015; Rouben et al., 2011), and surgical technique (Peng et al., 2009).

Functional Disability

The Oswestry Disability Index (ODI) is one of the most widely used measures of functional disability in patients with low back pain (Chapman et al., 2011). The instrument deliberately focuses on physical activities, rather than the psychological sequelae of acute or chronic pain (Fairbank & Pynsent, 2000). It includes 10 items, each with 6 response options, presented in a self-report scaled response format. Options are ordered so that each statement describes a greater degree of difficulty in the task than the preceding statement. Responses are scored from 0 to 5, and then summed (Fairbank & Pynsent, 2000). The summed score is doubled, and expressed as a percentage, with

scores ranging from 0 (no disability) to 100 (complete disability). Prior studies of patients with low back pain have yielded adequate evidence of the reliability, validity, and responsiveness of the ODI in this population (Chapman et al., 2011; Fairbank & Pynsent, 2000).

Of the six studies that compared preoperative level of functional disability to postoperative level of functional disability, all reported significantly improved ODI scores (Adogwa et al., 2012; Mendenhall et al., 2014; Peng et al., 2009; Rao et al., 2015; Rouben et al., 2011; Soriano et al., 2010). Reviewed studies also revealed associations between biopsychosocial factors and functional disability. Soriano et al. (2010) reported that lower postoperative functional disability was associated with higher educational level and with optimistic preoperative expectations. Abbott et al. (2011) reported that lower postoperative functional disability was associated with higher self-perceived effectiveness of coping strategies to control pain. Lower postoperative functional disability was also associated with higher preoperative leg pain (Abbott et al, 2011). This finding paralleled the relationship observed between lower postoperative pain intensity and higher preoperative leg pain, and was similarly attributed to the likelihood that leg pain was due to a structural defect that was corrected during surgery. Conversely, greater postoperative functional disability was associated with higher levels of pain catastrophizing (Abbott et al., 2011).

Several studies examined the degree of change in preoperative and postoperative ODI scores. Less improvement in functional disability was associated with higher levels of depression (Adogwa et al., 2012), and with higher preoperative back pain intensity

(Soriano et al., 2010). Conversely, greater improvement in functional disability was predicted by better emotional health (Soriano et al., 2010).

In two reviewed studies, the magnitude of functional improvement varied by surgical indication. Soriano et al. (2010) reported that patients with disc herniation reported greater improvement in functional disability than did patients with other lumbar spine disorders. Rao et al. (2015) reported that patients with degenerative disc disease and spondylolisthesis reported greater improvement in functional disability than did patients with scoliosis, failed posterior fusion, and adjacent segment disease. Conversely, Rouben et al. (2011) did not detect statistically significant differences in functional improvement among patients with varied surgical indications.

For several factors, no significant association with functional disability was detected; these included age (Rouben et al., 2011; Soriano et al., 2010), sex (Soriano et al., 2010), body mass index (Rao et al., 2015; Rouben et al., 2011; Soriano et al., 2010), smoking (Rao et al., 2015; Rouben et al., 2011), surgical technique (Peng et al., 2009), and payer status (Rouben et al., 2011).

Return to Work

Unlike pain intensity and functional disability, there are no well-established instruments to measure return to work. Therefore, researchers develop their own operational definitions and measurement tools, a situation that results in disparate reporting (Chapman et al., 2011). Such reporting is evidenced by the three reviewed studies that reported return to work outcomes following lumbar fusion. Nguyen et al. (2011) reported a 26% return to work rate and Rouben et al. (2011) reported a 97% return

to work rate. Mendenhall et al. (2014) did not calculate a return to work rate, but instead reported that the median (interquartile range) time of missed work was 6 (4.0 – 10) months. Further examination of these data reveals important differences in sampling and data analysis. While Nguyen et al. (2011) included their entire sample in calculating a return to work rate, Rouben et al. (2011) included only the subset of participants who were working "immediately before surgery" (p. 292). Further, although Mendenhall et al. (2014) included their entire sample in reporting time to return to work, their sample was exclusively comprised of participants who were working prior to surgery. Thus, the outcomes reported by Rouben et al. (2011) and Mendenhall et al. (2014) may reflect the inclusion of only working patients who may have been healthier, possibly less symptomatic, and perhaps quicker to recuperate from surgery than non-working patients. This lack of parity in enrollment and reporting makes it difficult to compare results across studies.

Differing inclusion criteria may also have influenced the results of the reviewed studies. Only 8% of the patients in the Rouben et al. (2011) study had compensable work-related injuries, whereas 100% of the patients in the Nguyen et al. (2011) study had such injuries. Thus, the low return to work rate reported by Nguyen et al. (2011) may reflect, at least in part, the influence of financial incentives related to workers' compensation benefits. This possibility is supported by a closer examination of the Rouben et al. (2011) results. Although 97% of all working patients in the Rouben et al. (2011) study returned to work, only 57% of patients receiving workers' compensation benefits returned to work. Furthermore, patients receiving workers' compensation

benefits had a longer delay in returning to work compared to the entire sample. The mean return to work time for workers' compensation patients was 17 weeks, with a median time of 18 weeks, whereas the mean time for all workers was 11 weeks, with a median time of 8 weeks (Rouben et al., 2011). These results are consistent with other studies that have reported significant associations between workers' compensation programs and poor physical and psychological function (Murgatroyd, Casey, Cameron, & Harris, 2015).

Only Nguyen et al. (2011) explored possible associations between biopsychosocial factors and return to work. They reported that surgical complications, reoperation, total number of days off work before surgery, legal representation, total daily morphine equivalent units (MEQ), and current smoking were negative predictors of return to work; whereas a higher average pre-injury weekly wage was the only positive predictor of return to work. Age, body mass index, sex, education level, marital status, surgical indication, and surgical technique did not significantly predict return to work (Nguyen et al., 2011).

Prolonged, Postoperative Opioid Pain Reliever Use

Similar to return to work, the lack of widely accepted instruments to measure postoperative opioid pain reliever use has resulted in heterogeneous reporting. Nguyen et al. (2011) quantified opioid utilization by converting oral opioid dose to MEQ. They reported both average daily morphine dose and whether a patient was, or was not, using opioid pain relievers 90 days following lumbar fusion. However, the researchers noted that reported morphine dose was an underestimation of total opioid dose because only

oral opioids—and not opioids administered via nasal spray or via transdermal and parental routes—were included in the calculation (Nguyen et al., 2011). In contrast, neither Rouben et al. (2011) nor Mendenhall et al. (2014) calculated opioid dose. Instead, Rouben et al. (2011) dichotomized the variable (i.e., using opioids / not-using opioids) and Mendenhall et al. (2014) reported time to opioid independence. Among the reviewed studies, these were the only studies that reported opioid use rates. Nguyen et al. (2011) reported that 85% of patients undergoing lumbar fusion used opioids throughout the study (pre- and post-lumbar fusion), and 76% continued to use opioids at 90 days post-lumbar fusion. Rouben et al. (2011) reported that 100% of patients used opioids prior to surgery, and 31% continued to use opioids at 6 months post-lumbar fusion. Mendenhall et al. (2014) did not calculate an opioid use rate, but reported that median (interquartile range) duration of postoperative opioid use was 6 (1.4 – 12.2) months.

Despite the routine prescribing of opioids following surgery (Dorian, 2014), none of the reviewed studies examined biopsychosocial factors associated with prolonged, postoperative opioid use.

Discussion

This review demonstrated how the biopsychosocial model can frame an investigation of lumbar fusion outcomes, and identified significant associations between biological, psychological, and social factors and pain intensity, functional disability, and return to work. These findings indicate that at least some of the variability in patient-centered outcomes can be explained by preoperative patient characteristics, and suggest

that patients experiencing negative outcomes following lumbar fusion may benefit from psychological and social interventions.

Unfortunately, the review did not identify biopsychosocial predictors of opioid use. This lack of data regarding prolonged opioid use following lumbar fusion represents an important gap in the spine literature. Ninety percent of patients scheduled for lumbar fusion consider chronic opioid dependency to be an unacceptable surgical outcome (Carragee & Cheng, 2010). Moreover, the use of opioids to treat chronic, non-cancer pain is not supported by high quality evidence and may portend serious harm.

Between 1999 and 2010, opioid use in the US increased 300%, with opioid prescribing for chronic, non-cancer pain fueling much of the increase (CDC, 2014; Von Korff et al., 2011). Although the increase was intentioned to decrease suffering, the assumptions of safety upon which increased opioid prescribing was based have not been supported by experience. Instead, long-term opioid therapy is now linked to serious consequences, including pharmacological adverse effects, opioid use disorders, and drug poisoning deaths.

Pharmacological adverse effects of long-term opioid therapy include constipation, sedation, clouded mentation, pruritus, myoclonus, respiratory depression, falls leading to fracture, hypogonadism, sexual dysfunction, osteoporosis, immunosuppression, and physical dependence (Chou et al., 2009; Deyo et al., 2015; Freynhagen et al., 2013; Labianca et al., 2012; Von Korff et al., 2011). Long-term therapy may also decrease the pain-relieving efficacy of opioid medication through drug tolerance and hyperalgesia—a paradoxical response to opioids that worsens pain sensitivity (Freynhagen et al., 2013;

Labianca et al., 2012). Long-term opioid therapy is also associated with opioid use disorders and opioid overdose (Paulozzi et al., 2014). Consequently, as opioid prescribing for chronic, non-cancer pain increased in recent years, there was a six-fold increase in admissions to substance abuse treatment programs (Paulozzi et al., 2011) and a tripling of opioid-related drug poisoning deaths (Rudd et al., 2016). In fact, one recent study identified opioid-related drug poisoning as the most common cause of death within 3 years of lumbar fusion (Juratli, Mirza, Fulton-Kehoe, Wickizer, & Franklin, 2009). Thus, given the potential sequelae of long-term opioid use, the identification of biopsychosocial predictors of prolonged opioid use following lumbar fusion should be a research priority.

The ability to identify which patients are at risk of prolonged, postoperative opioid use during the preoperative period would enable clinicians to target those patients with strategies designed to curtail opioid use as quickly as possible following surgery. This ability would have particular relevance for nurses and nurse practitioners given their roles in perioperative patient care. Nurses are responsible for patient education and the promotion of patient self-management. Thus, they could educate patients about opioid safety and promote non-pharmacological pain management strategies, such as progressive physical activity, relaxation therapy, imagery, and distraction (Strayer & Hickey, 2014). Nurse practitioners are among the most high-volume prescribers of all US healthcare specialties (CMS, 2015). Thus, they could incorporate non-opioid pain relievers into patients' medication regimens and emphasize functional improvement rather than pain relief when establishing therapy goals. Nurse practitioners could also

identify patients receiving multiple opioid prescriptions by consulting prescription drug monitoring databases and could monitor patients for signs of an opioid use disorder (Chou et al., 2009; Deyo et al., 2015). Such interventions could curtail the use of opioid pain relievers, identify patients for whom psychotherapeutic intervention or opioid use disorder treatment may be warranted, and promote safer surgical recovery.

Conclusion

Biological, psychological, and social factors are associated with pain intensity, functional disability, and return to work following lumbar fusion. These relationships support the biopsychosocial model of low back pain that posits that low back disability is not solely determined by degree of anatomical defect, but rather results from the interaction of biological, psychological, and social factors. However, whether these same factors are associated with prolonged, postoperative opioid use remains unknown. Despite high rates of postoperative opioid use, there are scant data regarding biopsychosocial predictors of this important outcome. For this reason, additional research is warranted. Knowing which patients are at risk for prolonged opioid use following lumbar fusion would enable clinicians to intervene during the perioperative period to promote non-pharmacologic pain relief measures and early discontinuation of opioid pain relievers. In addition, research examining associations between biopsychosocial factors and prolonged opioid use may yield additional support for the biopsychosocial model of low back pain by evidencing the theorized relationship between biological, psychological, and social factors and low back disability.

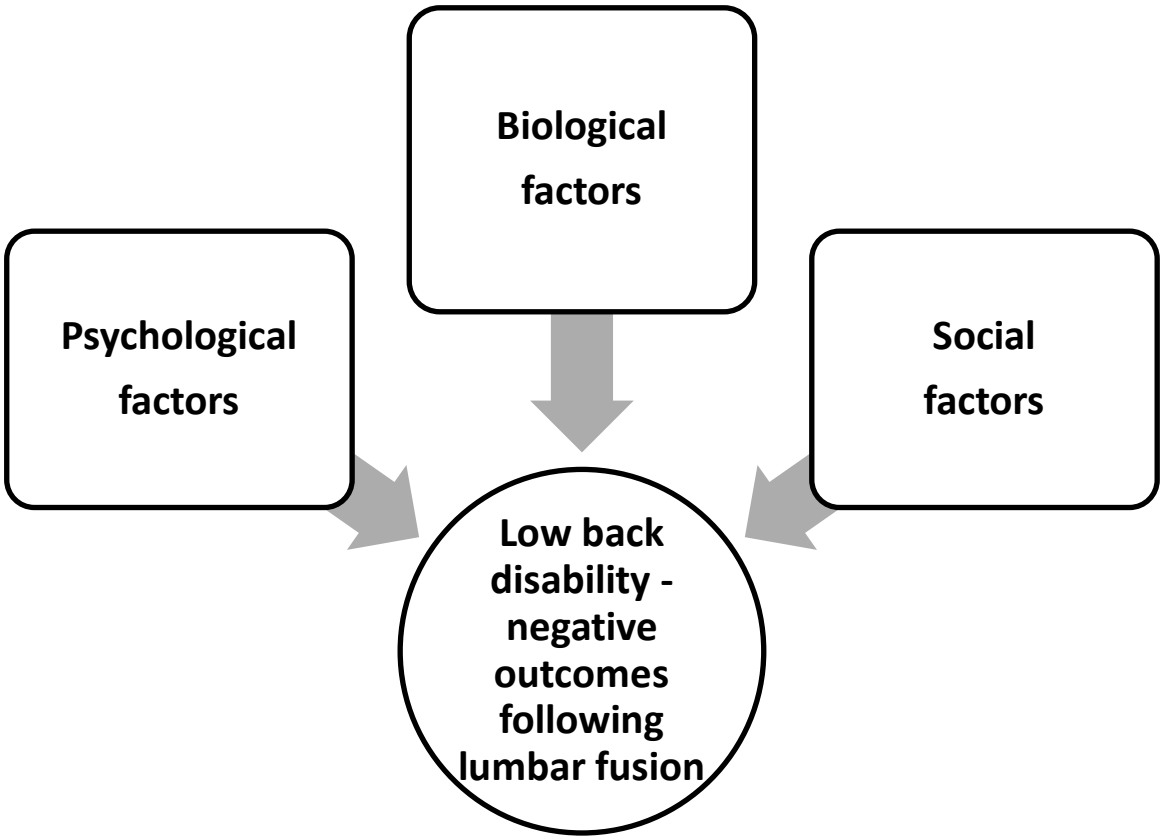

Figure 2.1. Biopsychosocial model of low back pain. Squares represent the three dimensions of the biopsychosocial model: biological, psychological, and social. The circle represents the convergence of these factors to produce low back disability, which, in this model, is conceptualized as negative outcomes following lumbar fusion.

Table 2.1
Summary of Study Designs and Instruments Used To Examine Biopsychosocial Factors and Patient-Centered Outcomes

Authors	Design and follow-up (months)	Pain intensity	Functional disability	Return to work (RTW)	Prolonged, postoperative opioid use
Abbott et al., 2011	Prospective cohort (24-36)	VAS	ODI		
Adogwa et al., 2012	Retrospective cohort (24)	VAS	ODI		
Mendenhall et al., 2014	Prospective cohort (24)	VAS	ODI	Time to RTW	Time to narcotic independence
Nguyen et al., 2011	Historical cohort (24)		Permanent total disability status per workers compensation system (yes/no)	Return to employment 2 years after date of surgery as part-time, full-time worker with same or different employer (yes / no)	Average oral opioid dose converted to daily morphine equivalent units
Peng et al., 2009	Prospective cohort (24)	VAS	ODI		
Rao et al., 2015	Prospective cohort (mean 20)	VAS	ODI		

Authors	Design and follow-up (months)	Pain intensity	Functional disability	Return to work (RTW)	Prolonged, postoperative opioid use
Rouben et al., 2011	Retrospective cohort (minimum 36)	VAS	ODI	RTW (yes/no)	Opioid use for spine-related pain (yes/no)
Soriano et al., 2010	Prospective cohort (12)	VAS	ODI		

Note. VAS = Verbal Analogue Scale; ODI = Oswestry Disability Index

CHAPTER III

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

The researcher conducted a prospective, longitudinal, correlational study with two rounds of data collection. Prospective, correlational studies are also known as cohort studies (Polit & Beck, 2012). As a cohort study, the researcher followed a defined group of participants, over time, to study patient-centered outcomes following lumbar fusion. As a correlational study, the researcher observed how preoperative patient characteristics (i.e., age, sex, employment status, educational level, preoperative pain intensity, preoperative opioid use, and pain catastrophizing) related to time to opioid cessation and postoperative pain intensity. Since the researcher did not manipulate any variables, observed correlations between independent variables and dependent variables would not be interpreted as causal relationships because the possibility of alternate explanations could not be excluded (Polit & Beck, 2012).

Setting

The study was conducted in a 347-bed, acute-care, multi-specialty, community hospital in southeast Texas. The hospital has the highest patient volume among the six hospitals located within its primary service area (L. Stanton, personal communication, June 30, 2017). The county in which the hospital is located is characterized by rapid growth, and racial and ethnic diversity. Between 2010 and 2012, the county was the fifth fastest growing county in the US (Kotkin, 2013). It also ranks among the most ethnically diverse counties in the nation, with approximately equal numbers of Asians, African

Americans, Hispanics, and Anglos (Klineberg, 2017). Approximately 92% of the population within the primary service area are insured; 76% are covered by private insurance, 8% are covered by Medicare, and 8% are covered by Medicaid (L. Stanton, personal communication, June 30, 2017). All surgeons who perform lumbar fusions at the site are either board-certified or board-eligible by the American Board of Neurological Surgery or the American Board of Orthopedic Surgery.

Population and Sample

The population of interest includes all people undergoing elective lumbar fusion in the US. The researcher used consecutive sampling and invited all patients who met eligibility criteria at the study site during a seven month period to enroll in the study. Since consecutive sampling does not enroll randomly selected people from the target population, it is a type of nonprobability sampling. However, consecutive sampling is considered superior to convenience sampling, another form of nonprobability sampling, because all people from an accessible population are invited to enroll, rather than just people who are readily available to the researcher (Polit & Beck, 2012).

Estimation of Effect Size and Calculation of Sample Size

The researcher used the results of a previous study of patients undergoing lumbar fusion to estimate effect size and calculate the required sample size. Papaioannou et al. (2009) reported the correlation between PCS scores and opioid dose to be $r = .53$, and the correlations between PCS scores and postoperative pain ratings to range from $r = .72$ to .89 (Papaioannou et al., 2009). Thus, using the smallest of these correlations, $r = .53$, as a direct estimate of effect size, the researcher anticipated a large effect (Cohen, 1992).

Papaioannou et al. (2009) also conducted multiple regression analysis and found that preoperative variables accounted for a significant portion of the variance in opioid dose ($R^2 = .35$, $p < .001$). This R^2 value (i.e., $R^2 > .30$) confirmed the researcher's use of a large effect in the power analysis (Leech at al., 2015). Thus, a minimum sample size of $n = 41$ would be necessary to determine if time to opioid cessation could be predicted by seven preoperative patient characteristics using multiple regression analysis. This number of participants would enable the researcher to correctly reject the null hypothesis that the multiple correlation coefficient, *R*, equaled zero, indicating that there was no relationship between seven preoperative patient characteristics and time to opioid cessation, with power = .80, alpha (α) = .05, and $R^2 = .30$ (i.e., large effect size), if a relationship existed (Polit & Beck, 2012). This sample size exceeded the sample size of $n = 29$ that a power analysis indicated would be necessary to determine the correlation between pain catastrophizing and time to opioid cessation and between pain catastrophizing and postoperative pain intensity, using correlation statistics with power = .80 and α = .05 (Polit & Beck, 2012). Thus, in consideration of the power analysis, and knowing that prior prospective studies of postoperative opioid use reported enrollment rates of 77% (Papaioannou et al., 2009) and 81% (Carroll et al., 2012), the researcher planned to oversample and recruit 55 participants. This number of participants was expected to yield an adequately powered study, even if some participants were lost to attrition.

Inclusion and Exclusion Criteria

Adult patients (i.e., 18 years old or older) admitted for elective lumbar fusion who were able to read at a minimum of a sixth-grade reading level, and write and speak

English were eligible for the study. Patients who were admitted for emergent lumbar fusion were excluded from the study because the researcher was unable to obtain self-reported preoperative data. Patients were also excluded if they reported a severe underlying systemic or highly specific disease as the indication for lumbar fusion. Disqualifying diseases included cancer, spinal infections, unstable fractures, and inflammatory spondylopathies due to the unknown effect of these conditions on pain catastrophizing, duration of opioid use, and postoperative pain intensity.

Protection of Human Participants

Precautions were taken to safeguard the rights and wellbeing of participants in accordance with the Federal Policy for the Protection of Human Subjects, or the "Common Rule" (US Department of Health and Human Services, n.d.). In addition to informed written consent, procedures to protect the anonymity of participants and the confidentiality of data were established, including the coding of names and identities and maintenance of data in a password-protected and encrypted computer. The researcher informed participants that sensitive information pertaining to opioid use and procurement, such as the possible receipt of opioid pain relievers from more than one healthcare provider, would not be revealed to treating clinicians or to law enforcement authorities.

The researcher remained alert to the possibility that participants could perceive the term "catastrophizing" to have negative social meaning. Such a perception could produce feelings of blame and guilt in participants, and could result in participants adopting prejudicial attitudes toward themselves, a phenomenon known as self-stigma or

internalized stigma (Mak, Poon, Pun, & Cheung, 2007). Internalized stigma, as well as a perceived lack of empathy from healthcare providers, have been reported by patients experiencing chronic pain, and could interfere with care-seeking and rehabilitation (Slade et al., 2009; Waugh et al., 2014). Thus, the researcher took several actions to minimize potential harm from the use of the term catastrophizing. The researcher clearly and concisely defined catastrophizing for participants as a psychological response to pain that produces negative thinking and negative emotions (Sullivan et al., 2001). The researcher explained that PCS scores would remain in the researcher's exclusive possession, scores would not be shared with treating clinicians, and scores would not be used to label participants (i.e., "catastrophizer"). To help participants feel understood, believed, and valued, the researcher used empathetic listening and empathetic action while interacting with participants who reported high pain intensity ratings or who described feelings of blame or guilt (Sternke, Abrahamson, & Bair, 2016). This was done by allowing participants to broaden the conversation to include a discussion of their pain experience, rather than limiting the conversation to their role in the study. The researcher also explained that enrollment in the study could potentially benefit society by expanding knowledge about lumbar fusion outcomes (Waltz et al., 2010).

The researcher was cognizant that patients using long-term opioid therapy often feel marginalized by healthcare providers (Peppin, 2009). The researcher also knew that patients with opioid use disorders have been mischaracterized as having a moral weakness rather than a medical illness (Olsen & Sharfstein, 2014). For these reasons, the researcher adopted non-judgmental language when interviewing participants about time

to opioid cessation and postoperative pain intensity, and validated, rather than devalued, participants' reported outcomes.

Instruments

During the first round of data collection, the researcher administered two instruments: (a) the Demographic and Clinical Variables Questionnaire (Appendix A), and (b) the PCS (Appendix B). During the second round of data collection, the researcher used the Telephone Interview Guide (see Appendix C) to interview patients about their opioid use and pain intensity three months following lumbar fusion.

Demographic and Clinical Variables Questionnaire

The Demographic and Clinical Variables Questionnaire was developed by the researcher, and includes six items from the NIH recommended uniform data set for studies of patients with chronic low back pain (Deyo et al., 2014). The questionnaire can be completed in three minutes, and requires a sixth-grade reading level.

A computerized readability calculator computed a Flesch-Kinkaid Reading Ease score of 74 on a 100-point scale and a Flesch-Kinkaid Grade Level score of sixth grade (Microsoft Word, 2013). These results indicate that the questionnaire is fairly easy to read, and that the words and sentences in the questionnaire are roughly the same length as the words and sentences in sixth grade textbooks (CMS, 2010). However, the researcher removed the list of prescription opioid medications from the sixth item on the Demographic and Clinical Variables Questionnaire before assessing readability because text that is not in full sentences may produce misleading results (CMS, 2010). Further, although manual scoring of reading material is preferred to automated scoring, the

researcher did not manually score the instrument, but instead used the readability calculator included in Microsoft Word (2013) to score the instrument because the short length of the instrument precluded manual scoring (CMS, 2010).

The researcher chose the six items on the Demographic and Clinical Variables Questionnaire because these patient characteristics have been associated with either negative, non-opioid-related lumbar fusion outcomes or with long-term opioid use. Among patients undergoing lumbar fusion, employment status has been associated with postoperative pain intensity (Rao et al., 2015; Rouben et al., 2011) and return to work (Nguyen et al., 2011; Mendenhall et al., 2014; Rouben et al., 2011); educational level and preoperative pain intensity have been associated with functional disability (Soriano et al., 2010); preoperative opioid use has been associated with return to work (Nguyen et al., 2011). Among patients with non-cancer pain, age and sex have been associated with long-term opioid therapy. Older women (i.e., aged 65 years and older) have been found to be more likely to use long-term opioids than younger women and men in any age group (Campbell et al., 2010).

Pain Catastrophizing Scale

The PCS is a 13-item self-report measure of pain-related catastrophic thinking. The PCS can be completed and scored in 5 minutes, and requires a sixth-grade reading level (Sullivan, 2009). When completing the PCS, participants are asked to reflect on past painful experiences, and to indicate the degree to which they have experienced each of the 13 thoughts or feelings on a scale ranging from 0 (“not at all”) to 4 (“all the time”). The PCS yields a total summed score ranging from 0-52, with higher scores indicating

greater pain catastrophizing. PCS scores were treated as a continuous scale variable. The researcher obtained permission from the developer of the PCS to use the instrument in the study (see Appendix D).

Validity. Validity is the degree to which an instrument measures what it purports to measure (Polit & Beck, 2012). Validity of the PCS in patients undergoing lumbar fusion has been supported by exploratory factor analysis in a prior study. Exploratory factor analysis replicated a three-factor solution that accounted for 83.63% of the common variance (Papaioannou et al., 2009). This solution is consistent with the three theorized dimensions of pain catastrophizing (i.e., rumination, magnification, and helplessness).

Reliability. Reliability of self-report instruments is commonly assessed in terms of internal consistency, which is the degree to which items are measuring the same attribute (Polit & Beck, 2012). Internal consistency of the PCS in patients undergoing lumbar fusion has been supported by a Cronbach's coefficient $\alpha = .94$ for the total scale, $\alpha = .91$ for the rumination subscale, $\alpha = .92$ for the magnification subscale, and $\alpha = .94$ for the helplessness subscale (Papaioannou et al., 2009). While the internal consistency reliability statistic for the total scale exceeds the recommended threshold for an existing instrument (i.e., $\alpha > .80$), the very high α value (i.e., $\alpha > .90$) reported by Papaioannou et al. (2009) suggests that the instrument contains redundant items (Polit & Beck, 2012). That is, items on PCS may be repetitive, and the instrument may include more items than are necessary to reliably measure pain catastrophizing (Leech et al., 2015). Nevertheless, similarly high levels of internal consistency reliability were reported when the instrument

was used with independent samples. During a PCS development study that enrolled undergraduate students, Sullivan et al. (1995) reported $\alpha = .87$. During a study that enrolled patients with chronic pain and community members not experiencing pain, Osman et al. (2000) reported $\alpha = .92$ and $\alpha = .95$, respectively. Although these levels of internal consistency reliability may indicate some redundancy in the instrument, it is considered advantageous to have high α values when decisions about individuals will be made on the basis of instrument scores (Polit & Beck, 2012).

Telephone Interview Guide

The Telephone Interview Guide is a 3-item guide. It was developed by the researcher to identify time to opioid cessation and postoperative pain intensity during the follow-up telephone interview. Self-reported opioid use via telephone interview has previously been used with patients following mastectomy, lumpectomy, thoracotomy, total knee replacement, and total hip replacement (Carroll et al., 2012), and following lumbar fusion (Adogwa, Parker, Bydon, Cheng, & McGirt, 2011). Although self-report is susceptible to social desirability bias if participants misrepresent themselves in an attempt to present a favorable image of themselves (Polit & Beck, 2012), prior studies suggest that self-reported opioid use can have adequate reliability and validity. A study involving rural Iranian patients at high risk for esophageal cancer found that self-reported opioid use, measured two months apart and using a questionnaire followed by an interview, showed excellent agreement (kappa = .74 - .96; Abnet et al., 2004). The same self-report questionnaire demonstrated 93% sensitivity and 89% specificity when compared to the results of urine drug testing (Abnet et al., 2004). Another study

involving patients in US ambulatory care settings found moderate agreement between patient reported medication use and medical record data [total agreement = 85%; kappa = .6 (95% CI, .6-.7)] (Tisnado et al., 2006). Although both of these studies support the use of self-report to measure opioid use, another study found a high rate of unreported opioid use among patients in a US emergency department (Monte, Heard, Hoppe, Vasiliou, & Gonzalez, 2015). Twenty-nine percent (n = 16) of patients presenting with a complaint of pain or nausea had prescription drugs detected by urine drug testing that had not been self-reported; nine of which included an unreported opioid (Monte et al., 2015). However, the different settings in which these studies were conducted may, at least partially, explain the discordant results. The study which found a high rate of unreported opioid use enrolled patients who had presented in an emergency department with a complaint of pain or nausea. Thus, it is possible that some patients may have intentionally concealed opioid use if they believed it would increase the likelihood that an opioid would be prescribed during the emergency department encounter. Accordingly, because the researcher neither provided care to participants, nor prescribed opioids for participants, self-report was used to assess opioid use at three months. However, the researcher attempted to minimize the effect of social desirability by exclusively asking participants to identify when they had last used opioids for back or leg pain without intimating a socially acceptable response (Waltz et al., 2010).

The researcher did not use urine drug testing to assess opioid use at three months. Urine drug testing is frequently used to monitor patients using long-term opioid therapy, and to detect non-prescribed opioids and illicit agents. However, results can be affected

by differences in pharmacokinetics, pharmacodynamics, and pharmacogenetics, as well as differences in specimen collection and handling (Christo et al., 2011; Chou et al., 2009). Thus, the use of urine drug testing would have required the researcher to interpret individual results within the context of each participant's unique circumstances and medical history, which would have necessitated a review of each participant's medical record. In addition, urine drug testing would have necessitated a face-to-face meeting between the researcher and each participant instead of a telephone interview. For these reasons, time to opioid cessation was measured exclusively by participant self-report.

The researcher called participants a maximum of three times to collect second round data because repeated attempts are often required to contact research participants (Chen et al., 2011). During the telephone interview, the researcher asked participants to rate their pain using the single-item NPRS. Participants indicated their pain intensity on a scale ranging from 1 ("no pain") to 10 ("worst pain imaginable"). Among studies of chronic low back pain, the NPRS is the most widely used instrument (Chapman et al., 2011), and its use with patients with chronic back pain has been endorsed by the NIH (Deyo et al., 2014). In comparison to the VAS, the NPRS has similar sensitivity in measuring pain intensity as evidenced by strong correlation between instrument scores. However, the NPRS is more practical, easier to understand, does not require clear vision or manual dexterity, and it can be used during a telephone interview (Breivik et al., 2008; Hjermstad et al., 2011). The NPRS is also preferred to the VAS by patients with chronic pain (Hjermstad et al., 2011).

Among patients undergoing lumbar fusion, the validity and responsiveness of the NPRS have been evaluated using area under receiver operating characteristic (AUROC) curves and by calculating standardized response means (SRM). The results suggest that the NPRS is fair at discriminating between participants who have meaningful versus non-meaningful improvement in back pain (AUC = .78) and leg pain (AUC = .72) and that the NPRS is more responsive to changes in back pain (SRM difference = 1.43) than to changes in leg pain (SRM difference = .93; Godil et al., 2014). These results support the use of the NPRS to measure pain intensity in patients undergoing lumbar fusion, but also suggest that the NPRS may be an insufficient measure of patient reported lumbar fusion outcomes if used in isolation (Godil et al. 2014).

Data Collection

The Institutional Review Board (IRB) at the study site approved the study (see Appendix E). The IRB at the study site and the IRB at the researcher's academic institution entered into an institutional authorization agreement (IAA) that designated the IRB at the study site as the reviewing authority (see Appendix F). Subsequent to IRB approval, the researcher identified a typographical error on one of the study's instruments and submitted an amendment to the IRB to correct the error (see Appendix G). When the study extended beyond one year, both IRBs extended their approvals (see Appendices H and I). There were no conflicts of interest or external funding for the study.

Data Collection Procedure

The researcher enrolled 57 participants in the study. Enrollment commenced in May 2016 and continued through November 2016, excluding a two-week period in July

2016 when the researcher was unavailable. Throughout the enrollment period, the researcher reviewed the surgery schedule on a daily basis to identify patients who had been scheduled for lumbar fusion. On the morning of the scheduled surgery, the researcher approached each patient and confirmed that the patient was at least 18 years old, able to read at a minimum of a sixth-grade reading level, and able to write and speak English. The researcher discussed the study with each potential participant using the Recruitment Script (see Appendix J). The researcher explained that each participant would complete two surveys that included questions about the participant's health, educational level, employment status, and thoughts about pain. Three months following surgery, the participant would be interviewed via telephone by the researcher and would be asked about pain medication use and pain intensity. The researcher explained that participation was voluntary and that a patient's decision whether or not to participate in the study would not affect the patient's care during hospitalization.

The researcher administered the Demographic and Clinical Variables Questionnaire (see Appendix A) and the PCS (see Appendix B) to participants while they were on the admission, observation, and discharge (AOD) unit awaiting surgery. All participants completed the Demographic and Clinical Variables Questionnaire; however, two participants (ID# 22 and 29) did not complete the PCS. The surgical team arrived to transport these participants to the operating room before they had completed the PCS. Since these participants were missing preoperative data, the researcher filed an amendment with the IRB to enroll two additional participants. The amendment was approved and the total enrollment number was increased from 55 to 57 participants (see

Appendix K). The researcher added the participants to ensure an adequate cohort size and to minimize missing data. In addition to the two participants who did not complete the PCS, one participant (ID# 38) did not respond to the educational level item on the Demographics and Clinical Variables Scale.

Three months following surgery, the researcher contacted participants via telephone and used the Telephone Interview Guide (see Appendix C) to query patients about their postoperative pain experience. The researcher asked participants when they had last used a prescribed opioid to manage low back and leg pain. If a participant reported opioid cessation greater than 5 days prior to the interview, the researcher recorded time to opioid cessation as the number of weeks from the date of surgery to the first of 5 consecutive days of zero opioid use. The researcher categorized these patients as negative for PPO. If a participant reported opioid use within 5 days of the interview, but reported a period of at least 5 days of zero opioid use since surgery, the researcher recorded time to opioid cessation as the number of weeks from the date of surgery to the first of 5 consecutive days of zero opioid use. The researcher categorized these patients as negative for PPO. If a participant reported opioid use within 5 days of the interview, with no period longer than 5 days of zero opioid use, the researcher recorded time to opioid cessation as 12 weeks. The researcher categorized these patients as positive for PPO. The researcher also asked participants to rate the intensity of their low back and leg pain during the preceding 7 days using the NPRS. The researcher recorded responses on the Telephone Interview Guide (see Appendix C). The three month follow up period allowed sufficient time for wound healing, initial consolidation of the fusion, and

liberalization of postoperative activity restrictions (Greenwood et al., 2015). In addition, opioid use is typically not considered long-term until it has exceeded three months duration (Chou et al., 2009; Nuckols et al., 2014).

Pilot study of proposed sampling plan. The researcher chose to identify potential participants via a daily review of the surgery schedule after a different sampling plan was evaluated in a pilot study conducted in 2014 (Lall, 2014). During 2014, the researcher conducted a pilot study to assess the feasibility of a sampling plan that required the researcher to contact the surgery schedulers in each surgeon's office several times per week to identify patients scheduled for lumbar fusion. The pilot study evaluated the number of lumbar fusions scheduled at the study site during a 5 week period, and the rate at which the researcher was notified when patients were scheduled for lumbar fusion. During the pilot study, being scheduled for lumbar fusion and being at least 18 years of age were the only inclusion criteria. There were no exclusion criteria because an assessment of eligibility would have necessitated access to protected health information. Once the pilot study commenced, the researcher contacted each surgery scheduler via telephone at the close of business on clinic days to inquire if any patients had been scheduled for lumbar fusion. If the scheduler answered in the affirmative, the researcher recorded the patient's first and last initials, surgeon, date of notification, and date of surgery. The researcher recorded data in a Microsoft Excel 2013 workbook file that was maintained in an encrypted and password-protected computer in a locked office at the study site. This information was subsequently shared with practice administrators for confirmation.

Data analysis. All statistical analyses were conducted with Statistical Package for the Social Sciences, version 22. The volume of lumbar fusions was reported as the sum of cases scheduled during the 5-week study. The rate at which the researcher was notified of patients being scheduled for lumbar fusion was computed by dividing the number of cases about which the researcher was notified, by the number of cases that were confirmed by the practice administrators, and multiplying the quotient by 100. Univariate descriptive statistics were used to describe the number of elapsed days between date of notification and date of surgery. Elapsed days was analyzed as a scale variable, and the mean, median, range, and standard deviation were reported.

Findings of pilot study. Fourteen patients were scheduled for lumbar fusion at the study site during the pilot study (n = 14). The notification rate was 100%:

$$\text{Notification rate} = \frac{number\ of\ reported\ lumbar\ fusions}{number\ of\ confirmed\ lumbar\ fusions} = \frac{14}{14} = 100\%$$

The mean number of elapsed days between date of notification and date of surgery was 15.2 (SD = 8.68) and the median was 13.0 (see Table 3.1). Because the distribution of elapsed days was positively skewed, the median value was a better representation of central tendency (see Figure 3.1).

Table 3.1

Summary of Days Elapsed between Date of Notification and Date of Surgery during Pilot Study

Variable	Value	
Elapsed days		
Mean (*SD*)	15.2	8.68
Median (range)	13.0	(3-38)

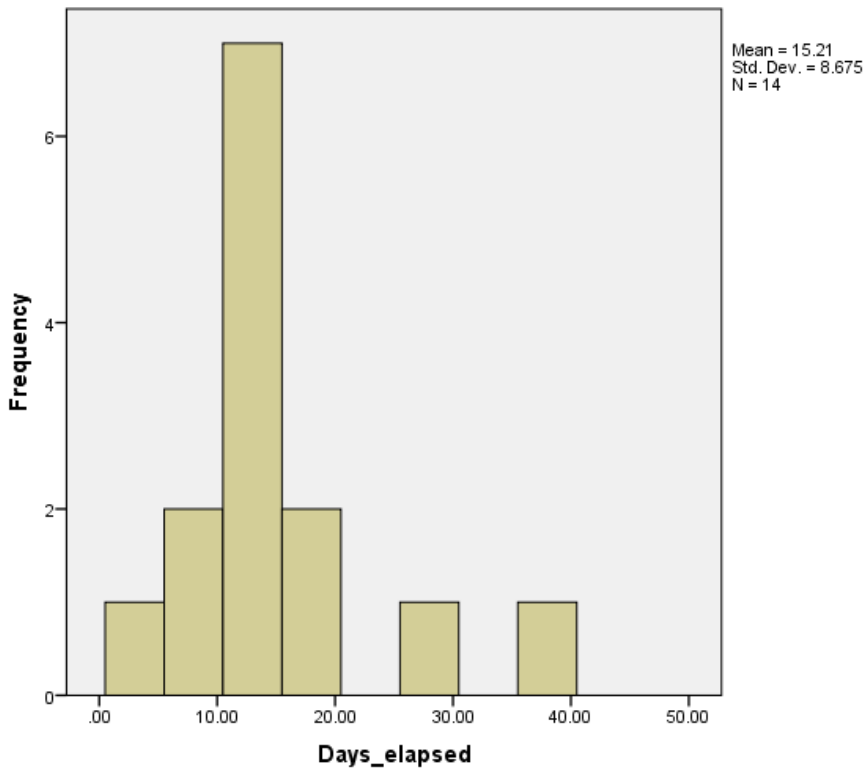

Figure 3.1. Frequency distribution of days elapsed between date of notification and date of surgery during pilot study

Conclusion of pilot study. The pilot study provided answers to the two research questions and demonstrated the feasibility of the proposed sampling plan. There were 14 lumbar fusions scheduled at the study site during the 5-week period. The researcher was informed of 100% of the surgeries at the time that the surgeries were scheduled. By extrapolating the number of lumbar fusions scheduled during the 5-week pilot study to a six month period, the researcher estimated that there would be 72 lumbar fusions performed at the site in a six month period. This number would ensure an adequate sample size. In addition, the range of elapsed days between date of notification and date of surgery suggested that there would be sufficient time for the researcher to contact potential participants, screen them for eligibility, and invite them to participate in the dissertation study. Nevertheless, the researcher subsequently modified the sampling plan evaluated in the pilot study based on several factors.

Although the researcher was notified of all scheduled lumbar fusions during the pilot study, the researcher learned that scheduled lumbar fusions are sometimes rescheduled to another date. Thus, rather than identify patients weeks in advance of a lumbar fusion that could be rescheduled, the researcher decided to identify potential participants on the morning of their surgery upon their arrival on the AOD unit. All enrollment activity and first round data collection would take place on the day of surgery and would eliminate the need for the researcher to schedule an additional meeting with potential participants.

The researcher estimated that enrollment of an adequate sample would take six months based on the case volume of five surgeons performing lumbar fusion during the

pilot study. However, following the pilot study, one surgeon left the institution. This drop in the number of surgeons resulted in a lower case volume and necessitated an extension of the enrollment period to seven months.

Finally, the piloted sampling plan required that the researcher depend on the administrative staff in each surgeon's office to learn about potential participants. By modifying the sampling plan for the dissertation study, the researcher was able to identify potential participants directly from the surgery schedule on the day of surgery.

Treatment of Data

All data analyses for the dissertation study were conducted with Statistical Package for the Social Sciences (SPSS), version 24. Prior to data analysis, the researcher screened data to find survey instruments with incomplete, unclear, or multiple answers.

Description of the Sample

The researcher computed descriptive statistics to present a summary of the cohort and enable an assessment of sample representativeness. Descriptive statistics, skewness statistics, and frequency distributions aided in the identification of outliers and non-normal distributions.

The prevalence of PPO was computed by dividing the number of participants who reported continued opioid use at three months, with no more than 5 opioid-free days since surgery, by the total number of participants:

$$\text{Prevalence of PPO} = \frac{number\ of\ participants\ who\ report\ PPO\ at\ 3\ months}{total\ number\ of\ participants}$$

The researcher reported recruitment and attrition rates to enable an assessment of the study's methodology and aid in the identification of potential strengths and

weaknesses. The researcher reported Cronbach's α to describe the internal consistency reliability of responses on the PCS.

Hypotheses Testing and Conclusions about the Population

The researcher used inferential statistics to test the hypotheses that level of pain catastrophizing is positively correlated with time to opioid cessation, that level of pain catastrophizing is positively correlated with postoperative pain intensity, and that time to opioid cessation can be predicted from preoperative patient characteristics. Inferential statistics enabled conclusions to be drawn about whether the observed results are likely to be found in the study population.

Correlation between pain catastrophizing and time to opioid cessation. The researcher examined the data, including a scatterplot of the variables, to determine if assumptions for correlation were met, to identify outliers, and to identify the most appropriate correlation statistic, (i.e., Pearson's *r* or Spearmen *rho*). Correlation coefficients range from -1.00 (a perfect negative correlation) through .00 (no correlation) to 1.00 (a perfect positive correlation). A high positive correlation would indicate that participants with high levels of pain catastrophizing tended to have longer durations of postoperative opioid use, and that participants with low levels of pain catastrophizing tended to have shorter durations of postoperative opioid use. A scatterplot showing points close to a straight line from the lower left corner of the plot to the upper right corner would be anticipated. In contrast, a high negative correlation would indicate that participants with high levels of pain catastrophizing tended to have shorter durations of postoperative opioid use, and participants with low levels of pain catastrophizing tended

to have longer durations of postoperative opioid use. A scatterplot showing points close to a straight line from the upper left corner of the plot to the lower right corner would be anticipated (Dawson & Trapp, 2004; Morgan, Leech, Gloeckner, & Barrett, 2013).

Correlation between pain catastrophizing and postoperative pain intensity.

The researcher examined the correlation between PCS scores and postoperative NPRS scores using the same process as was used to examine the correlation between PCS scores and weeks to opioid cessation.

Predictors of time to opioid cessation. The researcher used multiple regression analysis to determine if time to opioid cessation could be predicted by a combination of preoperative patient characteristics. Prior to commencing multiple regression, the researcher determined whether conditions and assumptions for its use were met, including the absence of multicollinearity and the presence of linear relationships between each of the independent variables and the dependent variable (Leech et al., 2015). The researcher used the ENTER method of multiple regression. This method, which is also known as the simultaneous method of multiple regression, was used because the dependent variable, time to opioid cessation, is theoretically influenced by each of the independent variables, and the researcher did not have any preexisting ideas as to which independent variable(s) would be the strongest predictor(s) of time to opioid cessation (Leech et al., 2015).

Summary

The researcher enrolled 57 participants in a prospective, longitudinal study in a single study site. The researcher obtained informed consent from all participants and

collected data during two rounds of data collection. Descriptive statistics were expected to provide a description of the cohort that would enable an assessment of the degree to which the cohort represented the population of all people undergoing elective lumbar fusion in the US. Data analysis was expected to identify the prevalence of prolonged opioid use following lumbar fusion and to test three hypotheses about how preoperative patient characteristics related to postoperative outcomes. Inferential statistics would allow the researcher to draw conclusions about whether the results observed in the sample were likely to be found in the target population.

CHAPTER IV

ANALYSIS OF DATA

A prospective, longitudinal study was conducted to identify the prevalence and predictors of PPO in a cohort of patients undergoing lumbar fusion. High rates of PPO have been reported following lumbar fusion despite evidence that long-term opioid use increases the risk of substance use disorder, accidental overdose, and drug poisoning deaths.

This chapter describes data analysis. Exploratory data analysis examines missing data, outlying values, and the distribution of values for scale variables. Descriptive statistics present a summary of the cohort. Inferential statistics test the three hypotheses and allow inferences to be drawn about the associations between preoperative variables: (a) age, (b) sex, (c) employment status, (d) educational level, (e) preoperative pain intensity, (f) preoperative opioid use, (g) pain catastrophizing, and postoperative outcomes: (a) PPO and (b) postoperative pain intensity.

The researcher invited 57 patients to enroll in the study. All invited patients met eligibility criteria, agreed to enroll, and provided written informed consent (see Appendix L). Upon enrollment, the researcher assigned each participant a unique numerical identifier (ID#). The researcher de-identified data by replacing participants' names with the corresponding ID# when entering data into a Microsoft Excel 2013 worksheet. The researcher coded the data by assigning numbers to the values of each variable (see Table

4.1). All data were entered on the worksheet, which was maintained on an encrypted, password-protected computer at the study site.

Table 4.1

Codebook

Value	Code	Label
Sex	0	male
	1	female
Employment	0	Working now
	1	Looking for work, unemployed
	2	Sick leave or maternity leave
	3	Disabled due to back pain, permanently or temporarily
	4	Disabled for reasons other than back pain
	5	Student
	6	Temporarily laid off
	7	Retired
	8	Keeping house
	9	Other
	10	unknown

Value	Code	Label
Education	0	No high school diploma
	1	High school graduate or GED
	2	Some college, no degree
	3	Occupational/technical/vocational program
	4	Associate's degree
	5	Bachelor's degree
	6	Master's degree
	7	Professional school degree (i.e., MD, DDS, JD) or doctoral degree (PhD, EdD)
	8	unknown
Preoperative opioid use	0	no
	1	yes
PPO	0	negative
	1	positive

Exploratory Data Analysis

Nine of the 57 enrolled participants had missing data (see Figure 4.1). Two participants had missing preoperative data, six participants had missing postoperative data, and one participant had missing preoperative and postoperative data (see Figure 4.1). The most common reasons for missing data were a repeat surgery due to a postoperative complication within the follow up period and participant failure to respond to follow-up telephone calls. In total, 3% of data were missing, which is considered a small amount of missing data (i.e., < 5%; Duffy, 2006).

Missing data are common in observational and longitudinal studies for a variety of reasons. Missing data may be the consequence of a participant's decision not to complete one or more procedure(s), or a participant's failure to return survey material (Leech et al., 2015). Since missing data may bias study results, the researcher used Little's Missing Completely at Random (MCAR) Test to test the null hypothesis that data were missing at random. It is generally less problematic to have data that are missing at random than data that are missing in a non-random pattern. Non-random, or systematic, missing data typically indicate that participants chose not to respond to one or more items for reasons that may be unknown to the researcher. Therefore, systematic missing data may misrepresent the population, thereby limiting the generalizability of study findings (Duffy, 2006; Leech et al., 2015; Mertler & Vannatta, 2013).

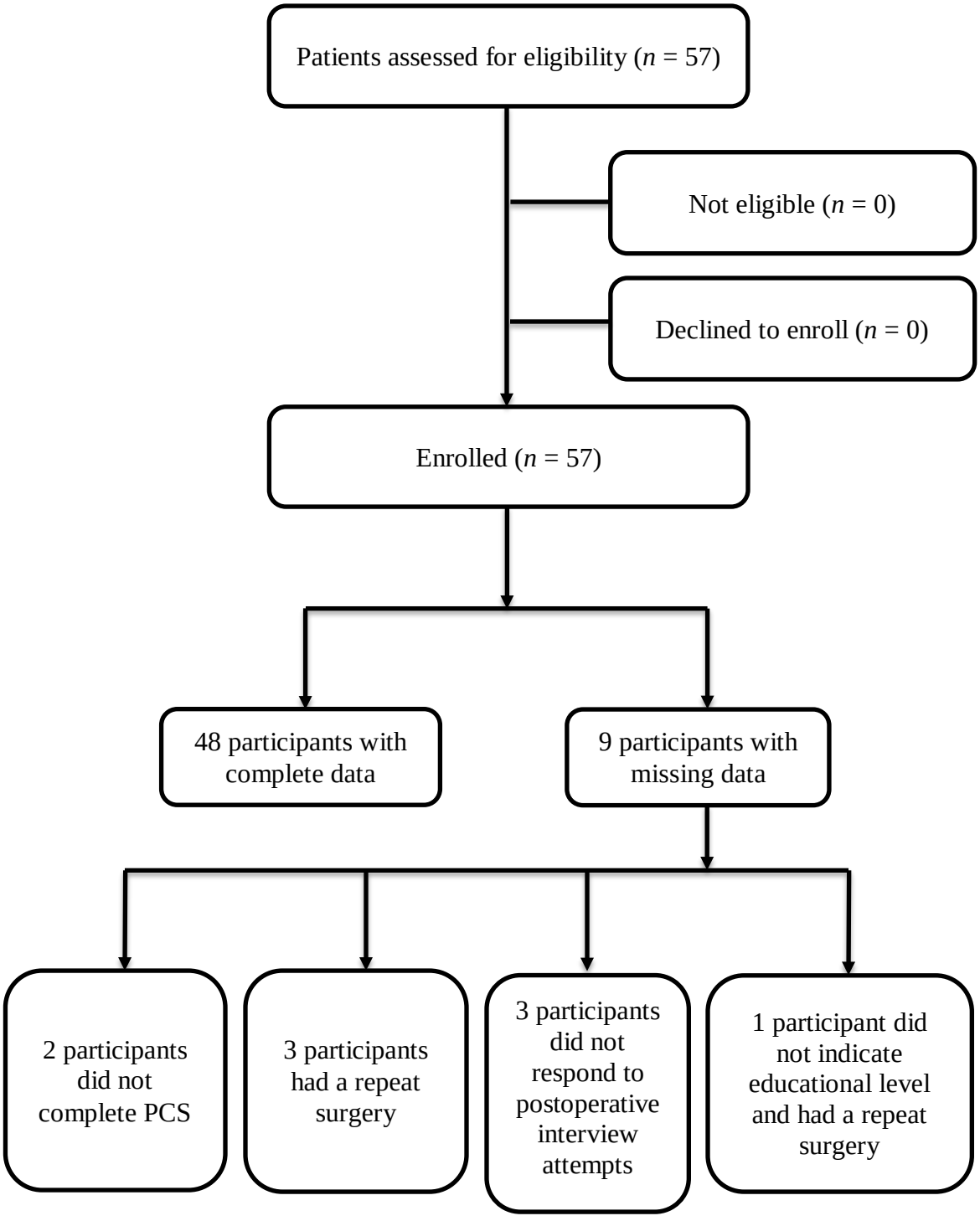

Figure 4.1. Flow diagram of study participants

Since Little's MCAR Test indicated that data were missing at random, the researcher failed to reject the null hypothesis that missing data were missing at random (Duffy, 2006). Thus, in accepting the null hypothesis, the researcher accepted the premise that whether or not a value was missing was not systematically related to the values of that variable or any other variable. Accordingly, the threat that missing data would introduce bias and misrepresent the population was considered minimal (Duffy, 2006; Leech et al., 2015; Mertler & Vannatta, 2013).

The researcher chose pairwise deletion to deal with missing data. Pairwise deletion selectively deletes participants from data analysis (i.e., on a variable by variable basis) when values for a variable are missing (Polit & Beck, 2012). It is an appropriate method for analyzing MCAR data (Duffy, 2006). The researcher chose not to use listwise deletion of missing values because listwise deletion would have eliminated all nine participants with missing data from data analysis. This approach to missing data would have reduced the cohort size by 16%. Such a large reduction in cohort size would have decreased study power and increased the risk of erroneous inference (Leech et al., 2015).

The researcher examined the distribution and skewness statistics of each scale preoperative variable to identify outlying values and to assess the normality of the distributions. The distribution of age was negatively skewed (see Figure 4.2). The absolute value of the skewness statistic (-1.243) was greater than 1 confirming that the distribution of the age variable was non-normal (Morgan et al., 2013). The boxplot for the age variable revealed that one participant (ID# 31) had an age younger than the

expected range of ages, and one participant (ID# 54) was an outlier (see Figure 4.3). The researcher rechecked the raw data and confirmed that the outlying age value (22 years) was correct.

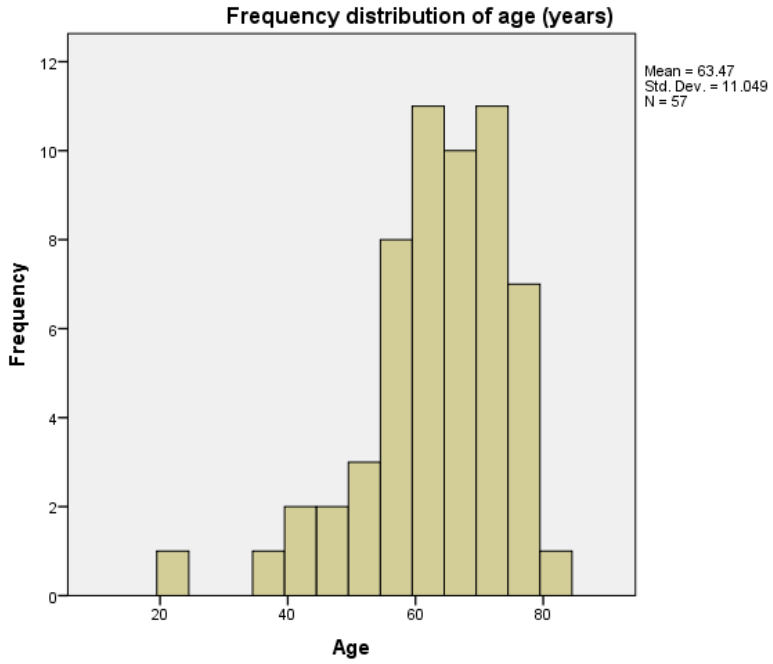

Figure 4.2. Frequency distribution of age (years)

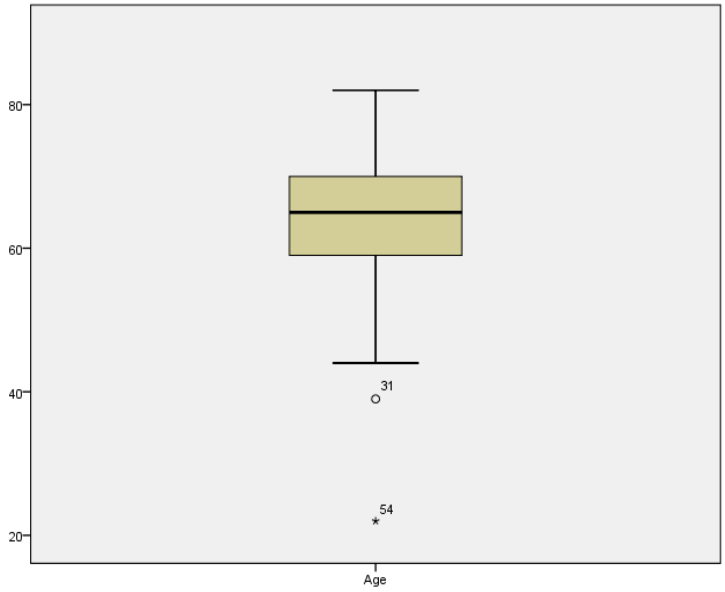

Figure 4.3. Boxplot of age (years)

The distribution of preoperative NPRS appeared negatively skewed (see Figure 4.4) and the absolute value of the skewness statistic (-1.089) was greater than 1 confirming a non-normal distribution (Morgan et al., 2013). An examination of the boxplot for preoperative NPRS revealed that three participants (ID# 23, 36, and 46) had values lower than the expected range; however, there were no outlying values (see Figure 4.5).

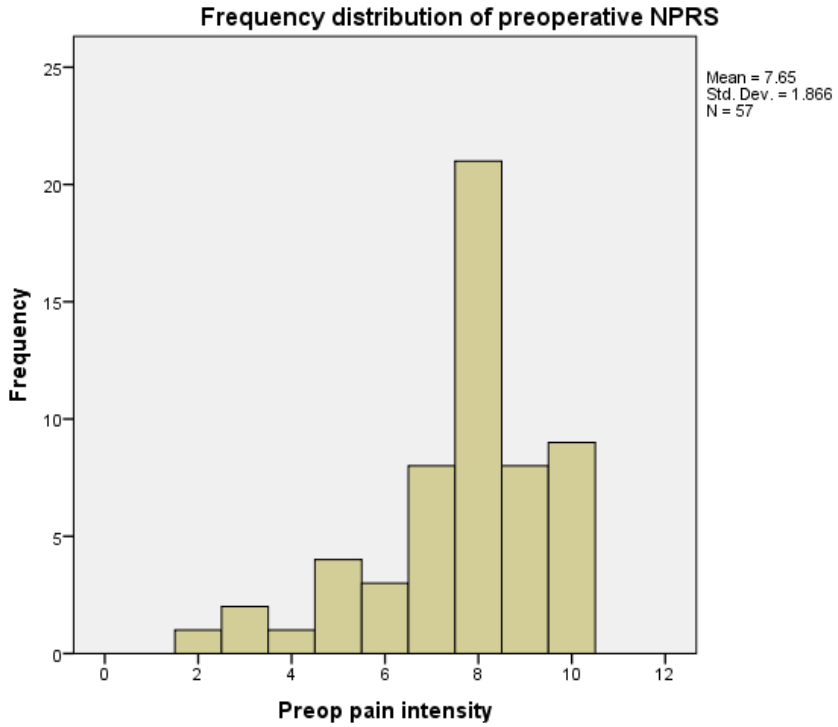

Figure 4.4. Frequency distribution of preoperative NPRS scores

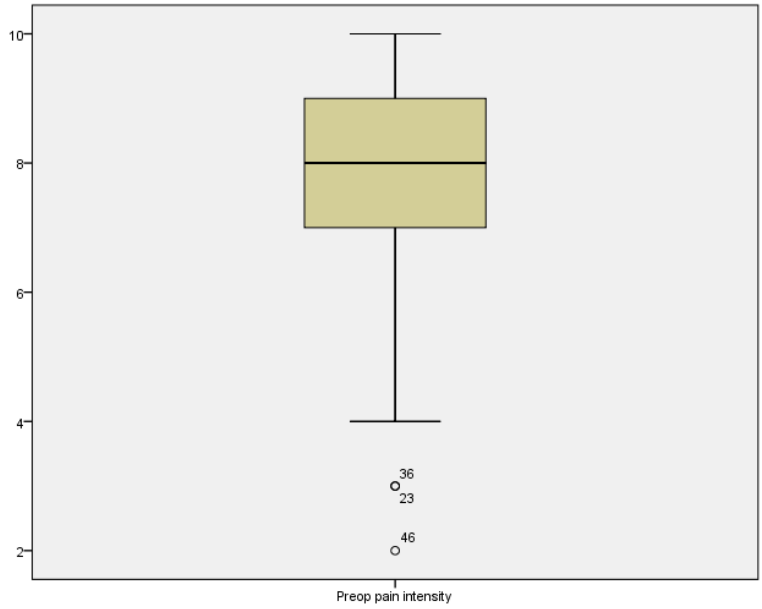

Figure 4.5. Boxplot of preoperative NPRS scores

The frequency distribution of PCS scores appeared approximately normally distributed (see Figure 4.6). The absolute value of the skewness statistic (-.336) was less than 1 which indicated that the distribution was at least approximately normal (Morgan et al., 2013). There were no outlying values on the boxplot of PCS scores (see Figure 4.7). An approximately normal distribution and the absence of outliers are both conditions for the use of parametric statistics (Morgan et al., 2013).

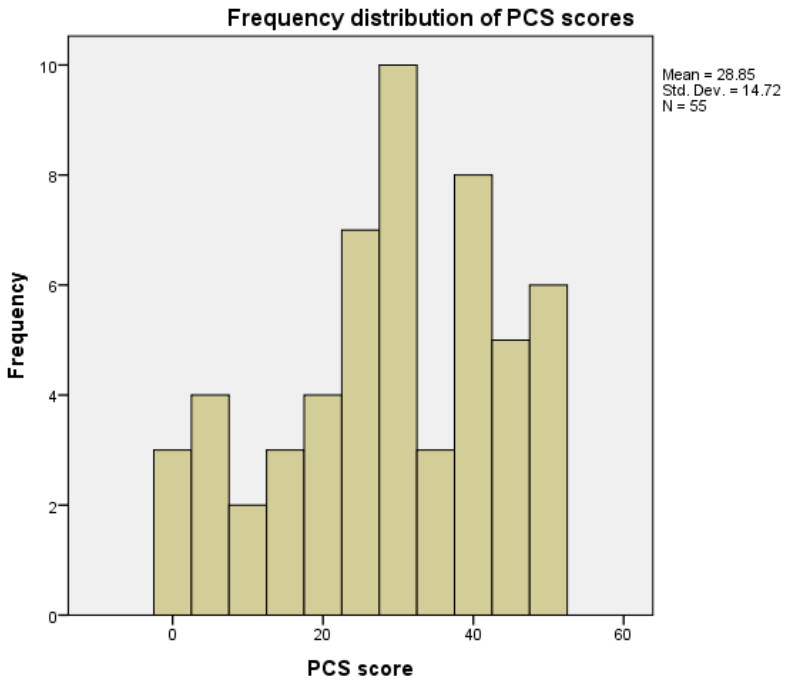

Figure 4.6. Frequency distribution of PCS scores

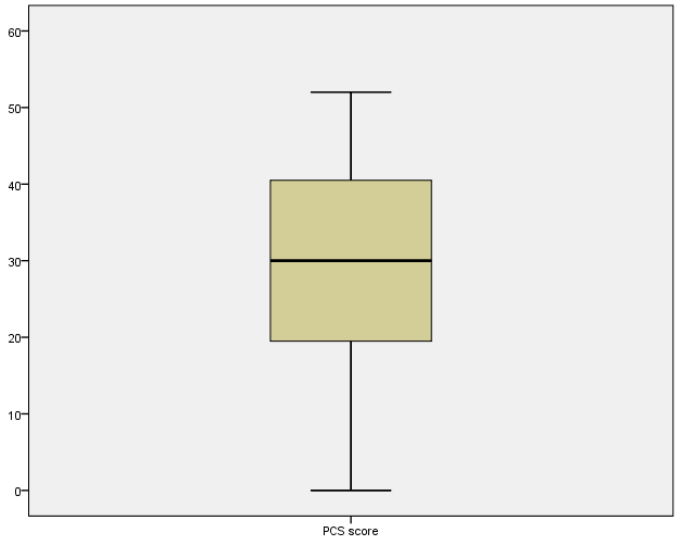

Figure 4.7. Boxplot of PCS scores

Description of the Sample

To present a summary of the cohort and enable an assessment of sample representativeness, the researcher tabulated means, standard deviations, medians, and ranges of scale preoperative variables (see Table 4.2), and frequencies and percentages of categorical variables (see Table 4.3). The mean age of the cohort was 63.47 (*SD* = 11.05), and more than half of participants (54.4%, *n* = 31) were retired. Two-thirds (66.7%, *n* = 38) of participants were female, and 25% (*n* = 14) of participants had a least a bachelor's degree. More than 60% of the participants (61.4%, *n* = 35) were using prescribed opioids prior to lumbar fusion. The mean preoperative pain intensity was 7.65 (*SD* = 1.87) and mean PCS score was 28.85 (*SD* = 14.72). Internal consistency evaluation of the PCS indicated a Cronbach's α = .951. This result suggests that the 13-items on the PCS are all measuring the same the attribute.

Table 4.2

Summary of Age, Preoperative NPRS scores, PCS Scores

Variable	Value	
Age (*N* = 57)		
Mean (*SD*)	63.47	(11.05)
Median (range)	65.00	(22-82)
Preoperative NPRS scores (*N* = 57)		
Mean (*SD*)	7.65	(1.87)
Median (range)	8	(2-10)
PCS scores (*n* = 55)		
Mean (*SD*)	28.85	(14.72)
Median (range)	30.00	(0-52)

Table 4.3

Summary of Sex, Preoperative Opioid Use, Employment Status, and Educational Level

Variable	Value	
	Number	Percent
Sex (*N* = 57)		
Male	19	33.3
Female	38	66.7
Preoperative opioid use (*N* = 57)		
No	22	38.6
Yes	35	61.4
Employment Status (*N* = 57)		
Working now	11	19.3
Sick leave or maternity leave	2	3.5
Disabled due to back pain, permanently or temporarily	10	17.5
Disabled for reasons other than back pain	1	1.8
Retired	31	54.4
Keeping house	2	3.5

Variable	Value	
	Number	Percent
Education level (select highest attained; *n* = 56)		
No high school diploma	2	3.6
High school graduate or GED	12	21.4
Some college, no degree	20	35.7
Occupational/technical/vocational	3	5.4
Associate's degree	5	8.9
Bachelor's degree	12	21.4
Master's degree	1	1.8
Professional school degree (e.g., MD, DDS, JD) or doctoral degree (PhD, EdD)	1	1.8

Findings

The dependent variables, weeks to opioid cessation and postoperative NPRS scores, were summarized using mean (*SD*) and median (range) values. The mean time to opioid cessation was 7.76 weeks (*SD* = 4.47), and the mean postoperative NPRS score was 3.12 (*SD* = 2.15; see Table 4.4).

Prevalence of Prolonged, Postoperative Opioid Use

The researcher calculated the prevalence of PPO by dividing the number of participants who report continued opioid use at 3 months, with no more than 5 opioid-free days since surgery, by the total number of participants:

$$\text{Prevalence of PPO} = \frac{number\ of\ participants\ who\ report\ PPO\ at\ 3\ months}{total\ number\ of\ participants}$$

The prevalence of PPO was 44% (n = 22; see Table 4.5). That is, 44% of participants reported continued use of prescribed opioids for low back or leg pain 3 months following surgery, with no more than 5 opioid-free days since surgery.

Table 4.4

Summary of Postoperative Variables

Variable	Value	
Time to opioid cessation, weeks (n = 50)		
Mean (*SD)*	7.76	(4.47)
Median (range)	9.0	(1-12)
Postoperative NPRS (n = 50)		
Mean (*SD*)	3.12	(2.15)
Median (range)	3.0	(1-9)

Table 4.5

Summary of Prolonged, Postoperative Opioid Use

	Number	Percent
Positive	22	44.0
Negative	28	56.0

The researcher examined frequency distributions and skewness statistics of the scale postoperative variables to assess the normality of their distributions. The frequency distribution of time to opioid cessation appeared negatively skewed with a spike at 12 weeks (see Figure 4.8). However, the absolute value of the skewness statistic (-.408) was less than 1 which indicated that the distribution was at least approximately normally distributed (Morgan et al., 2013). There were no outlying values on the boxplot of time to opioid cessation (see Figure 4.9). The approximate normal distribution and the absence of outliers indicated that the use of parametric statistics may be appropriate (Morgan et al., 2013).

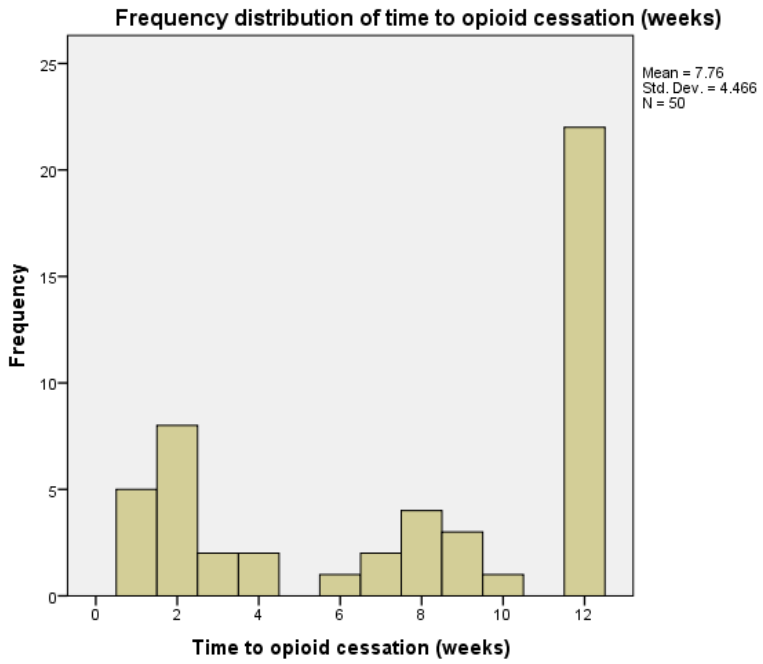

Figure 4.8. Frequency distribution of weeks to opioid cessation

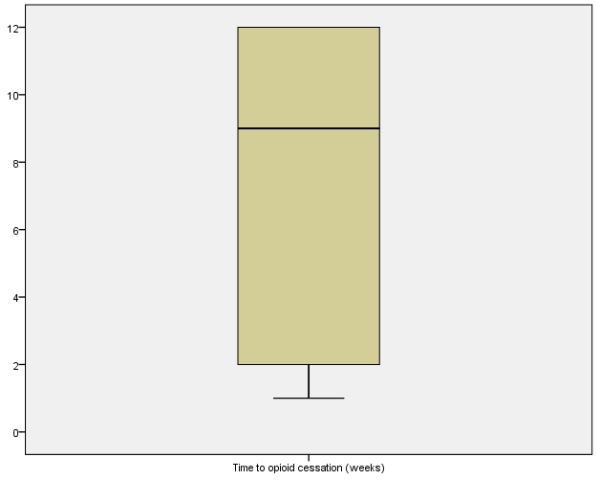

Figure 4.9. Boxplot of weeks to opioid cessation

The frequency distribution of postoperative NPRS scores was positively skewed (see Figure 4.10). The absolute value of the skewness statistic was 1.00. Generally, to be considered at least approximately normal, the absolute value of the skewness statistic should be less than 1 (Morgan et al., 2013). Since the skewness statistic was equal to 1, it did not support an approximately normal distribution. For this reason, the researcher compared the mean, median, and mode values of postoperative NPRS scores. Mean, median, and mode values that are approximately equal support an approximately normal distribution (Morgan et al., 2013). However, postoperative NPRS values were not approximately equal (mean = 3.12; median = 3; mode = 1). Thus, the researcher considered this a non-normal distribution. There were no values out of the expected range and no outliers on the boxplot of postoperative NPRS scores (see Figure 4.11).

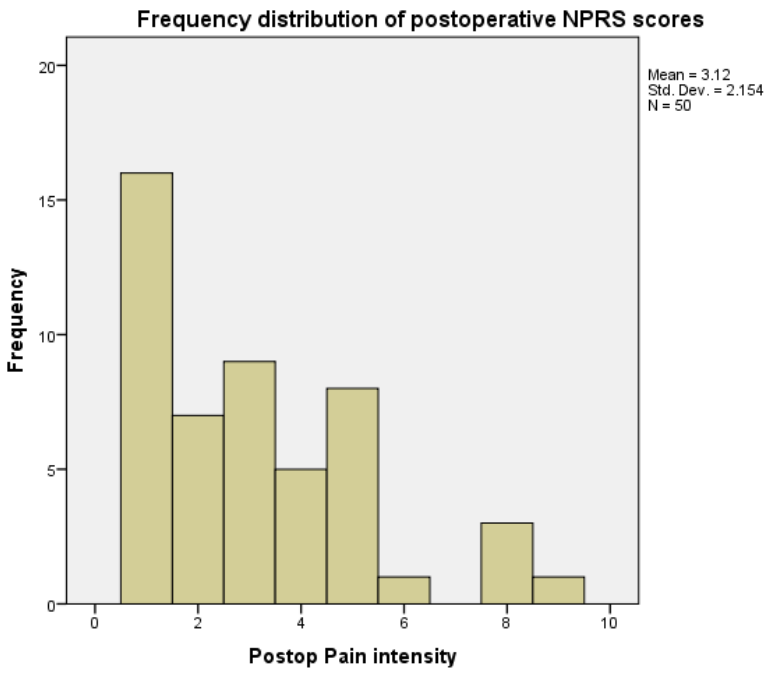

Figure 4.10. Frequency distribution of postoperative NPRS scores

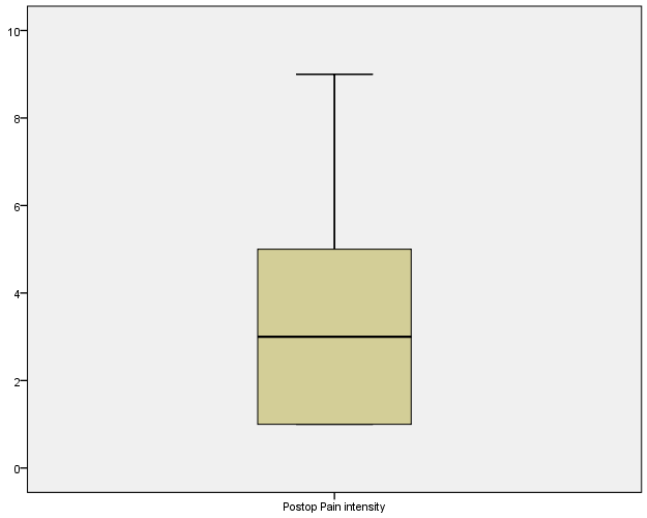

Figure 4.11. Boxplot of postoperative NPRS scores

The researcher used inferential statistics with a p value < .05 considered statically significant to test the three hypotheses that predicted how preoperative patient characteristics related to lumbar fusion outcomes. Significance tests for hypothesis 1 and hypothesis 2 were two-sided. The researcher used two-sided significance tests, which consider both tails of the sampling distribution in determining improbable values, because two-sided significance testing is more conservative than one-sided testing and makes it more difficult to reject null hypotheses (Polit & Beck, 2012). In contrast, the researcher used one-sided significant testing to identify bivariate correlations among the predictor variables because the testing was a component of multiple regression analysis that was testing a directional hypothesis. The hypotheses were as follows:

1. It is hypothesized that level of preoperative pain catastrophizing, as measured with the PCS, will be positively correlated with time to opioid cessation.
2. It is hypothesized that level of preoperative pain catastrophizing, as measured with the PCS, will be positively correlated with postoperative pain intensity, as measured with the NPRS.
3. It is hypothesized that time to opioid cessation can be predicted by preoperative patient characteristics.

Correlation between Pain Catastrophizing and Time to Opioid Cessation

To test the hypothesis that level of preoperative pain catastrophizing is positively correlated with time to opioid cessation, the researcher checked that assumptions and conditions for the use of Pearson's r. The histograms and skewness statistics indicated that the variables were approximately normally distributed. Since both variables were

normally distributed, a bivariate normal distribution could be assumed (Dawson & Trapp, 2004; Polit & Beck, 2012). Boxplots of the variables did not reveal any outliers. However, a linear relationship between the two variables was also a condition for the use of Pearson's *r*, and the scatterplot failed to evidence a linear relationship. The researcher plotted PCS scores on the X-axis and weeks to opioid cessation on the Y-axis, but no relationship between the variables was evident (see Figure 4.12). In addition, the regression line was nearly horizontal and many points were plotted far from the line. Since conditions for the use of Pearson's *r* were not met, the researcher used a Spearman *rho* statistic to assess the association between preoperative pain catastrophizing and time to opioid cessation. Spearman *rho* is a non-parametric statistic and its use is not predicated on the existence of a linear relationship (Morgan et al., 2013). Spearman's *rho* correlation coefficients also range from -1.00 to 1.00, and their interpretation is similar to the interpretation of Pearson's *r* (Polit & Beck, 2012). The Spearman *rho* statistic $r(46) = .03$, $p = .86$ did not support a significant correlation between the variables. The results failed to support the hypothesis that level of preoperative pain catastrophizing is positively correlated with time to opioid cessation.

Since level of preoperative pain catastrophizing was not correlated with time to opioid cessation, the researcher did not compute the PCS sub-scores for the three dimensions of pain catastrophizing (i.e., rumination, magnification, helplessness), nor did the researcher assess the relationships between the PCS sub-scores and time to opioid cessation.

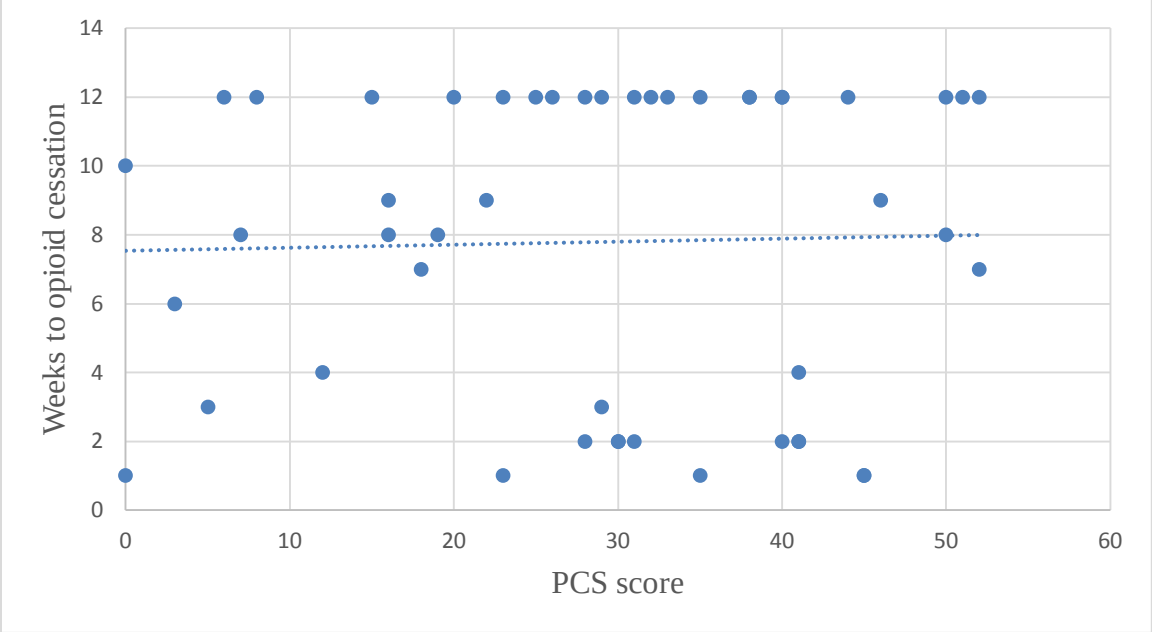

Figure 4.12. Scatterplot of weeks to opioid cessation with PCS scores. The relationship between weeks to opioid cessation and PCS scores appeared nonlinear. The Spearman *rho* statistic, $r(46) = .03$, $p = .86$, did not support a significant correlation between variables.

Correlation between Pain Catastrophizing and Postoperative Pain Intensity

To test the hypothesis that level of preoperative pain catastrophizing is positively correlated with postoperative pain intensity, the researcher checked the assumptions and conditions for the use of Pearson's *r*. The histograms and skewness statistic of preoperative PCS scores indicated that the variable was approximately normally distributed. However, the frequency distribution of postoperative NPRS scores was non-normal. Since one of the two variables had a non-normal distribution, parametric statistics were not appropriate. Furthermore, a scatterplot of the two variables did not support a linear relationship. The researcher plotted PCS scores on the X-axis and postoperative NPRS scores on the Y-axis, but no relationship between the variables was

evident (see Figure 4.13). In addition, the regression line was nearly horizontal and many points were plotted far from the line. Since conditions for the use of Pearson's *r* were not met, the researcher used a nonparametric test, the Spearman *rho*, to assess the association between preoperative pain catastrophizing and postoperative pain intensity. The Spearman *rho* statistic $r(46) = -.04$, $p = .82$ did not support a significant correlation between the variables. The results failed to support the hypothesis that level of preoperative pain catastrophizing is positively correlated with postoperative pain intensity.

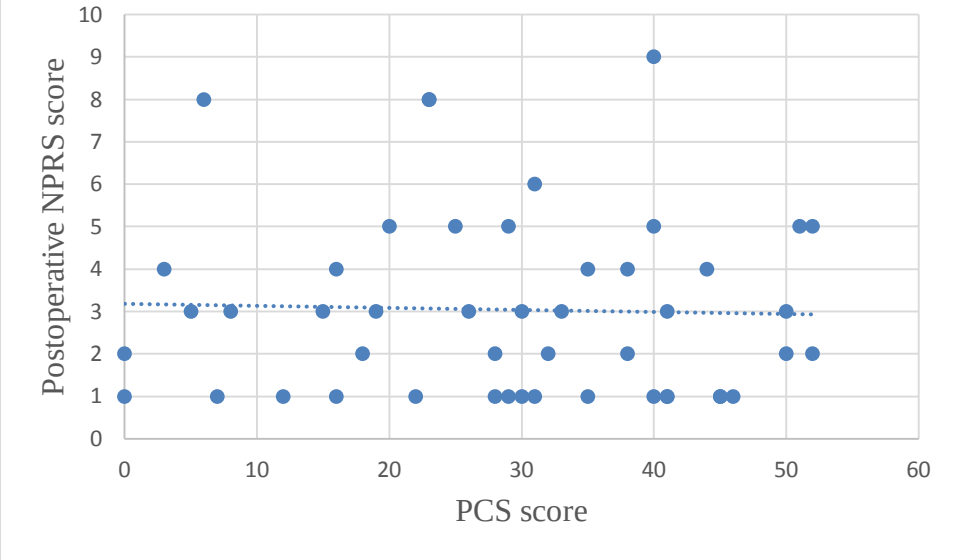

Figure 4.13. Scatterplot of postoperative NPRS score with PCS scores. The relationship between postoperative NPRS scores and PCS scores appeared nonlinear. The Spearman *rho* statistic, $r(46) = -.04$, $p = .82$, did not support a significant correlation between variables.

Predictors of Time to Opioid Cessation

To test the hypothesis that time to opioid cessation can be predicted by preoperative patient characteristics, the researcher conducted multiple regression analysis. This technique identifies the linear combination of independent variables that maximally correlates to the dependent variable (Mertler & Vannatta, 2013). The researcher anticipated that multiple regression analysis would produce an equation that could predict time to opioid cessation from a weighted, linear combination of preoperative variables for all people undergoing elective lumbar fusion in the US.

Conditions for multiple regression. The researcher collapsed and recoded educational level and employment status (see Table 4.6). This was done so that each category of the two variables had a sufficient number of participants to allow statistical analysis (Morgan et al., 2013). Educational level was dichotomized into one variable with two levels. Associate's degree or higher included all participants with an associate's degree, bachelor's degree, master's degree, professional school degree, or doctoral degree. Less than college degree included all participants with less than a high school education, high school diploma, GED, occupational technical/vocational program graduate, and some college, but no degree. Employment status was collapsed into three variables, each with two categories, and coded using dummy coding. The new variables were: (a) working and not working, (b) disabled and not disabled, and (c) retired and not retired. Working included participants who were working now; disabled included participants who were on sick leave or disabled due to back pain or other reasons; retired included participants who were retired or keeping house.

Table 4.6

Transformed Educational Level and Employment Status Variables

Variable	Number	Percent
Educational level (*n* = 56)		
Less than college degree	19	33.9
Associate's degree or higher	37	64.9
Employment status (*N* = 57)		
Working	11	19.3
Disabled	13	22.8
Retired	33	57.9

Multiple regression can be sensitive to outlier variables. The inclusion of outlying values in multiple regression may lead to the misinterpretation of scatterplot patterns and hinder the identification of a predictive model (Mertler & Vannatta, 2013). Thus, the researcher deleted one participant (ID# 54) from multiple regression analysis by using SELECT CASES. The boxplot of the age variable had identified this participant, aged 22 years, as an outlier (Figure 4.2).

Multicollinearity also adversely affects the results of multiple regression. Multicollinearity is evidenced by moderate and high intercorrelations among a pair (or pairs) of independent variables, and suggests that the variables contain the same information, and are, therefore, redundant (Leech et al., 2015; Mertler & Vannatta, 2013). To identify multicollinearity, the researcher examined two collinearity statistics for the independent variables: tolerance and variance inflation factor (VIF). Tolerance measures

collinearity among independent variables and ranges from 0 to 1. Tolerance values close to zero indicate multicollinearity. Thus, the researcher set a value of 0.1 as the cutoff point and would consider multicollinearity a problem if the tolerance value for any independent variable were less than 0.1. VIF indicates whether a strong linear association exists between a given independent variable and the other independent variables. The researcher set a value of 10 as the cutoff point and would consider multicollinearity a problem if any VIF value were greater than 10 (Mertler & Vannatta, 2013). None of the preoperative variables had tolerance or VIF values that suggested multicollinearity (see Table 4.7).

Table 4.7

Collinearity Statistics

	Collinearity statistics	
Variable	Tolerance	VIF
Age	.700	1.428
Sex	.775	1.290
Preoperative NPRS	.624	1.602
Preoperative opioid use	.719	1.391
PCS score	.661	1.513
Educational level	.889	1.125
Working	.565	1.769
Disabled	.734	1.362

Note. VIF = Variance Inflation Factor

Multiple regression analysis. The researcher executed multiple regression analysis using pairwise deletion and the ENTER method. The ENTER method enters all hypothesized predictors into the regression analysis in a single step. This method is recommended when the researcher has no predictions as to which independent variable(s) will create the best prediction model and when the number of predictors is relatively small (Leech et al., 2015). This method was chosen for two reasons: time to opioid cessation is theoretically influenced by each of the independent variables and there were no preexisting ideas as to which independent variable(s) would be the strongest predictor(s) of time to opioid cessation.

Correlation matrix. The correlation matrix showed significant correlations between weeks to opioid cessation and two independent variables (see Table 4.8). Weeks to opioid cessation was highly correlated with preoperative opioid use (r = .458, p = .000), and moderately correlated with sick leave or disabled (r = .290, p = .022). The absolute value of the correlation coefficients were used to estimate effect sizes (Cohen, 1992).

Table 4.8

Correlation Matrix with Pearson Correlations for Eight Independent Variables and One Dependent Variable

		Age	Female[a]	Preop NPRS	Preop opioid use[b]	PCS score	Associate's degree or higher	Working	Disabled
Weeks to opioid cessation	Pearson Correlation	-.288	.068	.009	.458	.034	.234	-.083	.290
	Sig (2-tailed)	.058	.322	.475	.000	.411	.053	.286	.022

Note. [a]Compared to Male. [b]Compared to no preoperative opioid use. [c]Compared to less than college degree.

Scatterplots. The researcher created bivariate scatterplots of weeks to opioid cessation with each of the eight independent variables to check the assumptions of multivariate normality and linearity between the dependent variable and each of the independent variables. The scatterplot of weeks to opioid cessation with PCS score is presented in Figure 4.12, weeks to opioid cessation with age in Figure 4.14, and weeks to opioid cessation with preoperative NPRS score in Figure 4.16. The relationships between weeks to opioid cessation and the three scale independent variables are not clearly linear; however, the patterns of plotted points are closer to straight lines than to curved lines. These straight line patterns evidence that the relations are not curvilinear, which would violate the assumption of linearity. The scatterplot of weeks to opioid cessation with sex is presented in Figure 4.15, weeks to opioid cessation with preoperative opioid use in Figure 4.17, weeks to opioid cessation with educational level in Figure 4.18, weeks to opioid cessation with working in Figure 4.19, and weeks to opioid cessation with disabled in Figure 4.20. The relationships between weeks to opioid cessation and the dichotomous independent variables appear to be linear because the patterns of plotted points on each scatterplot aligned in two parallel columns. A pattern in which the plotted points were bunched at the center of one column and at the ends of the other column, would be suggestive of a non-linear relationship (Leech et al., 2015).

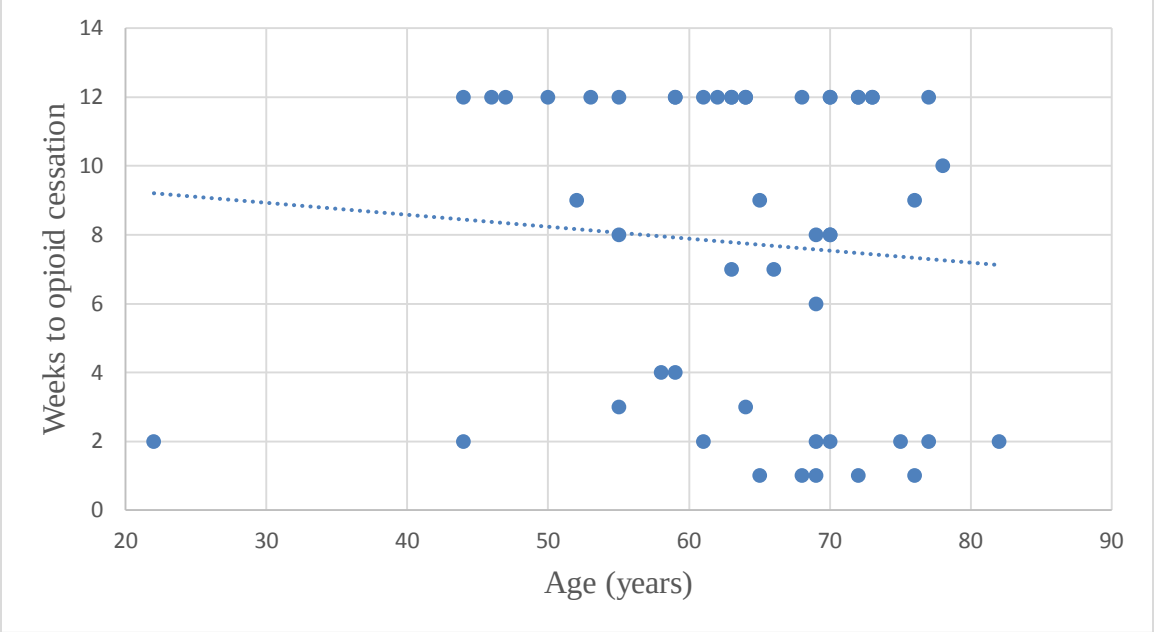

Figure 4.14. Scatterplot of weeks to opioid cessation with age

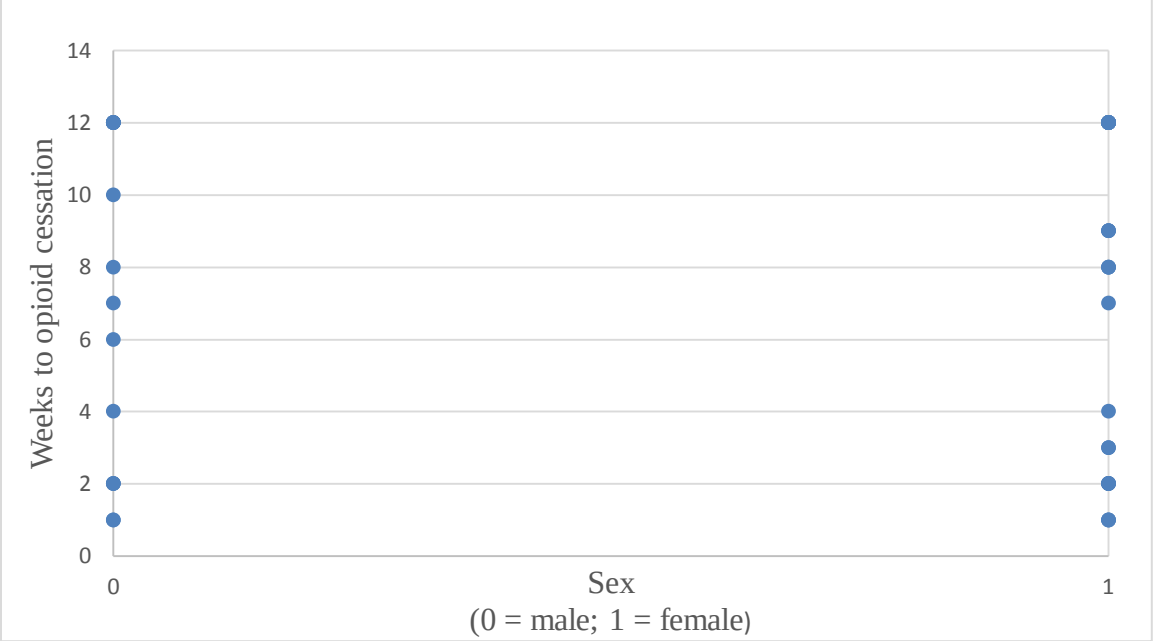

Figure 4.15. Scatterplot of weeks to opioid cessation with sex

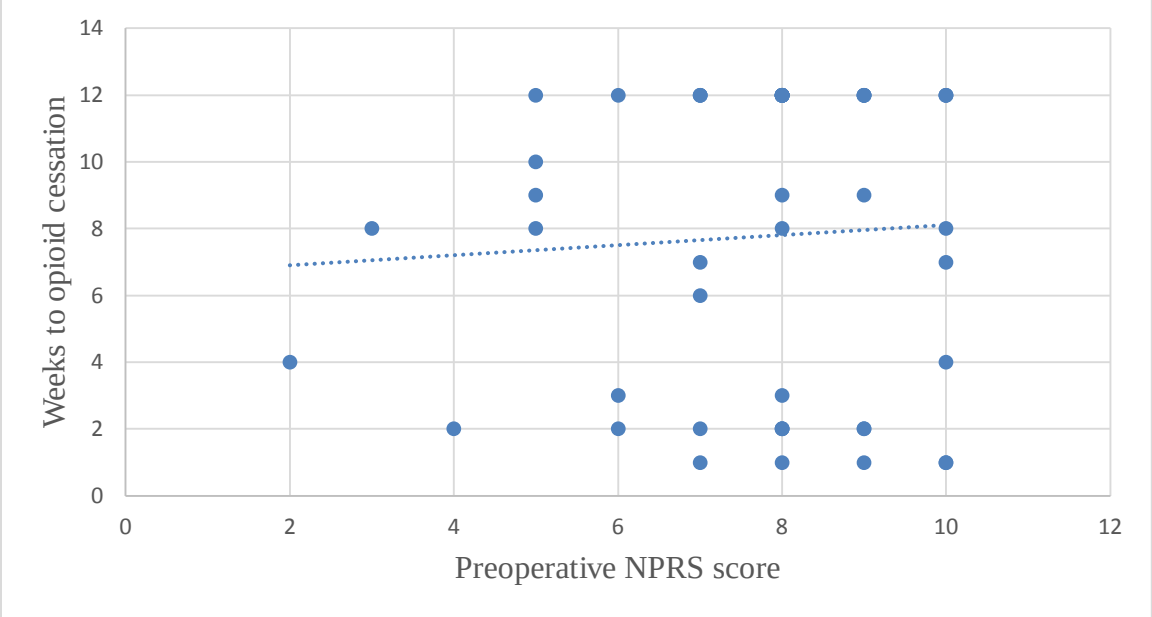

Figure 4.16. Scatterplot of weeks to opioid cessation with preoperative NPRS scores

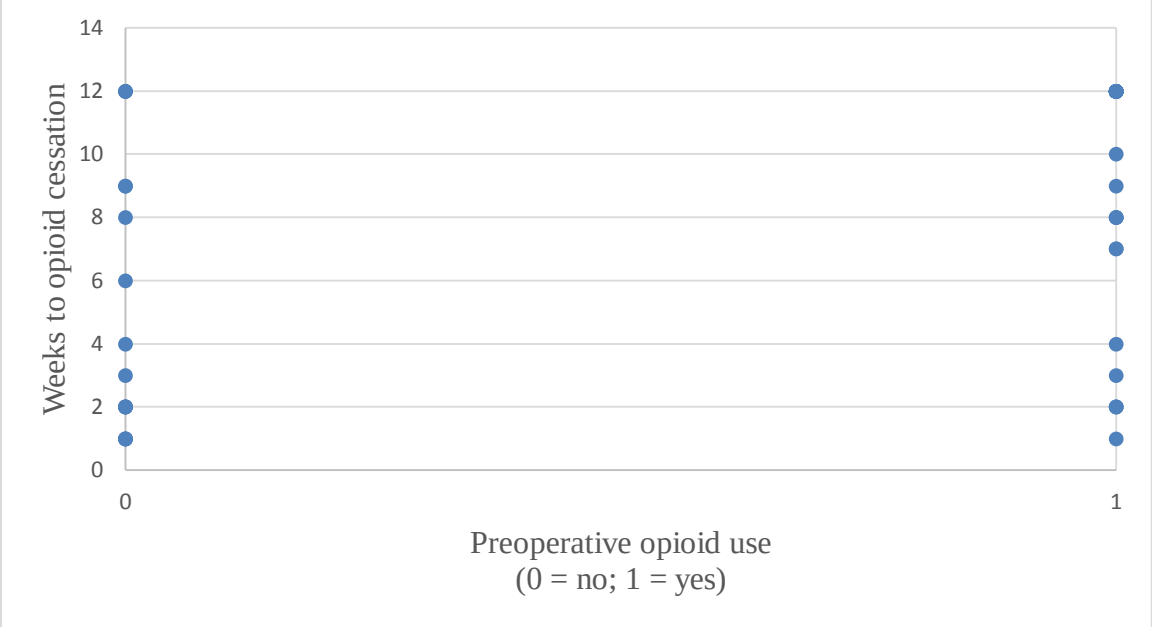

Figure 4.17. Scatterplot of weeks to opioid cessation with preoperative opioid use

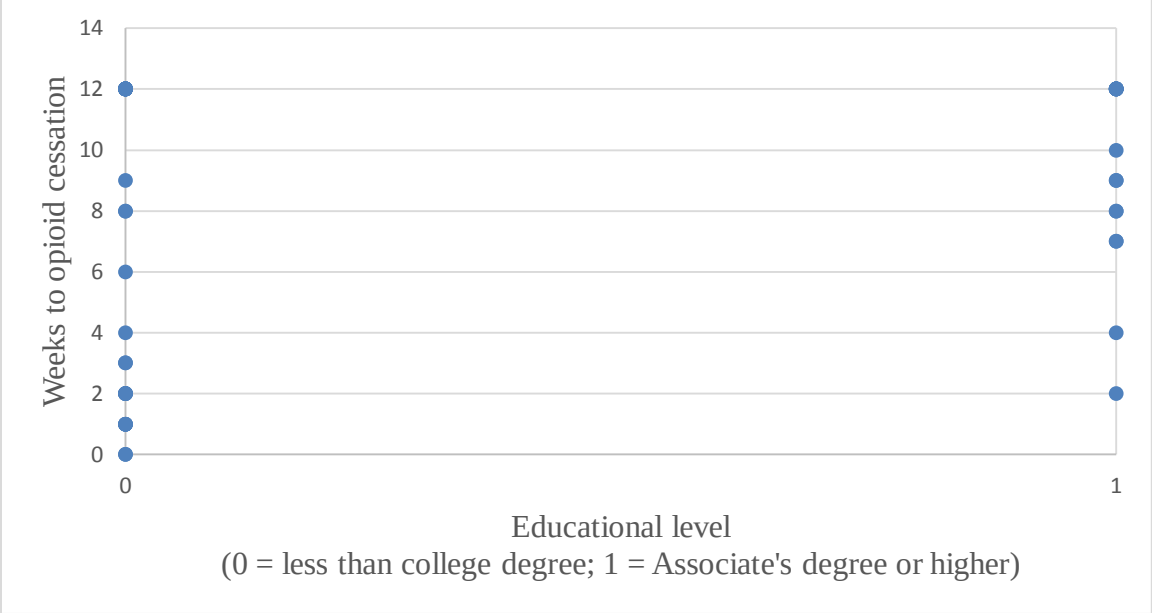

Figure 4.18. Scatterplot of weeks to opioid cessation with educational level

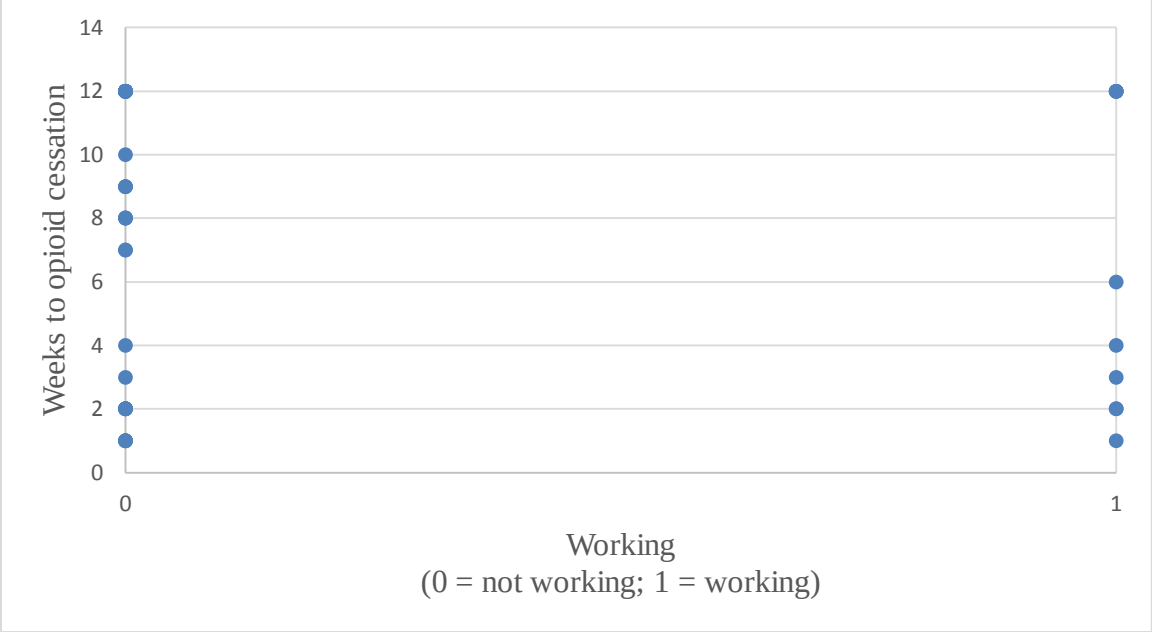

Figure 4.19. Scatterplot of weeks to opioid cessation with working

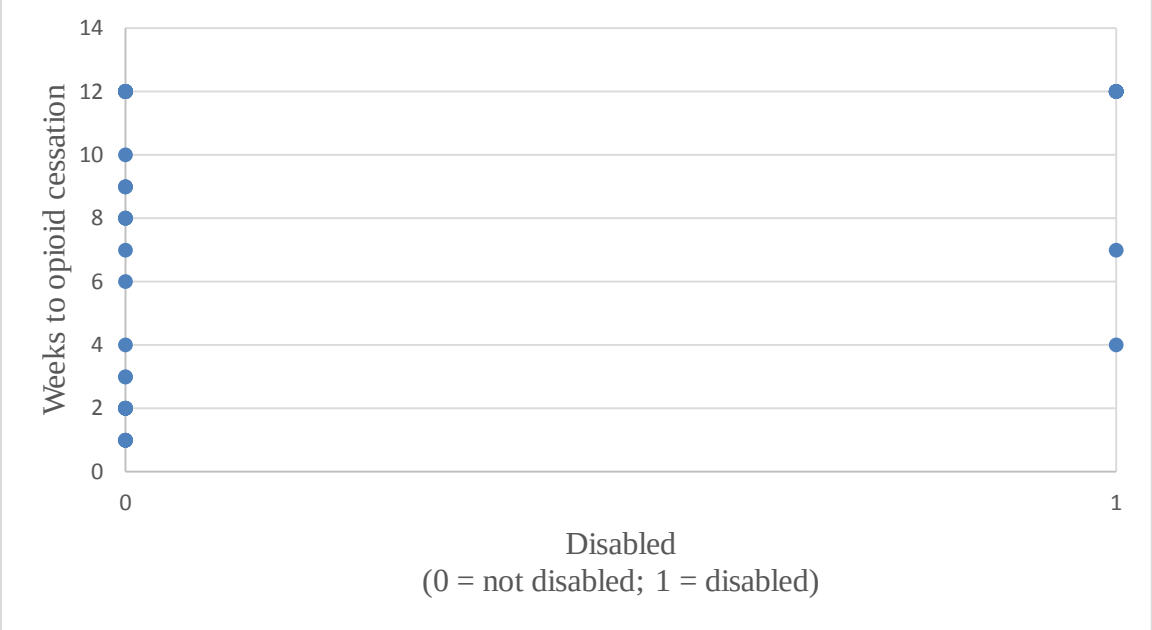

Figure 4.20. Scatterplot of weeks to opioid cessation with disabled

Model summary. The model summary outlines the overall fit of the model (see Table 4.9). It displays three multiple correlation indices that indicate how well the combination of independent variables predicted the actual values on the dependent variable. The multiple correlation (*R*) is a Pearson correlation coefficient between predicted and actual values of time to opioid cessation. The squared multiple correlation (R^2) is the degree of variance in the dependent variable that is accounted for by the independent variables. Since *R* and R^2 typically overestimate the corresponding population values, an adjusted squared multiple correlation (R^2_{adj}) was calculated to account for possible overestimation. R^2_{adj} is modified for the number of independent variables, the magnitude of the effect size, and the sample size and is a more conservative estimate of explained variance (Leech et al., 2015; Mertler & Vannatta, 2013).

The model summary with eight independent variables showed that $R = .567$, $R^2 = .322$, and $R^2_{adj} = .179$. The R^2 value indicated that the independent variables accounted for 32.2% of the variance in weeks to opioid cessation in the model. However, given the small cohort size and multiple independent variables, the researcher used R^2_{adj} to estimate variance in weeks to opioid cessation. Thus, $R^2_{adj} = .179$ indicated that 18% of the variance in weeks to opioid cessation was explained by the combination of independent variables (Mertler & Vannatta, 2013).

Table 4.9

Model Summary with Eight Independent Variables

Model	R	R^2	R^2_{adj}	Std Error of the Estimate
1	.567	.322	.179	4.017

Note. Dependent Variable: Weeks to opioid cessation.

ANOVA. The ANOVA table displays the *F* test, degrees of freedom, and corresponding level of significance for the multiple regression model. The ANOVA table shows that $F(8, 38) = 2.254$ and is significant ($p = .044$; see Table 4.10). This indicated that the relationship between the independent variables and time to opioid cessation was linear. Thus, the researcher rejected the null hypothesis that the population $R = 0$, in favor of the alternative hypothesis that the eight independent variables in the multiple regression equation predicted weeks to opioid cessation (Mertler & Vannatta, 2013).

Table 4.10

ANOVA

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	290.916	8	36.365	2.254	.044
	Residual	613.046	38	16.133		
	Total	903.963	46			

Note. Dependent Variable: Weeks to opioid cessation.

Coefficients table. The coefficients table outlines the degree and significance that each independent variable has on the dependent variable (see Table 4.11). The standardized β coefficients are interpreted similarly to correlation coefficients, and indicate whether an independent variable significantly contributes to the equation predicting the dependent variable. The only variable with a significant β coefficient was preoperative opioid use (β = .466; p = .005). Thus, preoperative opioid use was the sole independent variable among eight predictor variables that significantly contributed to the prediction of weeks to opioid cessation.

The coefficients table also includes the unstandardized regression coefficient (*B*). *B* represents the slope weight for each variable in the model and is used to create the regression equation. *B* weights also indicate how much the value of the dependent variable changes when the independent variable increases by 1 unit and the other independent variables remain the same. A positive *B* indicates a positive change in the dependent variable when the independent variable increases, whereas a negative *B* indicates a negative change in the dependent variable when the independent variable

increases (Mertler & Vannatta, 2013). For preoperative opioid use, $B = 4.230$. Thus, participants who use preoperative opioids increased the time to opioid cessation by 4 weeks compared to participants who do not use preoperative opioids.

Residual scatterplot. Since the bivariate scatterplots between weeks to opioid cessation and the scale independent variables did not clearly evidence linear relationships (see Figures 4.12, 4.14, and 4.16), the researcher created a residual scatterplot to compare standardized residuals to the predicted values of the dependent variable (see Figure 4.21). Since the residuals were randomly scattered on the scatterplot, the assumptions that the errors were normally distributed and the variance of the residuals was constant were met (Leech et al., 2015; Mertler & Vannatta, 2013). Accordingly, the assumptions of linearity, normality, and homoscedasticity were met. A clustering of residuals on the top or the bottom of the scatterplot would have suggested non-normality. A clustering of residuals on the left or the right of the scatterplot would have suggested heteroscedasticity. A curved pattern would have suggested non-linearity (Mertler & Vannatta, 2013).

Table 4.11

Coefficients Table

Predictor	Unstandardized Coefficients		Standardized Coefficients	*t*	*p*
	B	Std. Error	Beta (β)		
Age	-.076	.074	-.165	-1.032	.308
Female[a]	1.350	1.408	.145	.959	.344
Preoperative pain intensity	-.224	.413	-.092	-.544	.590
Preoperative opioid use[b]	4.230	1.430	.466	2.958	.005
PCS score	-.008	.049	-.027	-.167	.868
Associate's degree or higher[c]	1.539	1.309	.167	.342	.734
Working	.698	2.038	.061	.635	.529
Disabled	1.031	1.623	.099	1.176	.247
Constant	10.292	6.238		1.650	.107

Note. [a]Compared to Male. [b]Compared to no preoperative opioid use. [c]Compared to less than college degree.

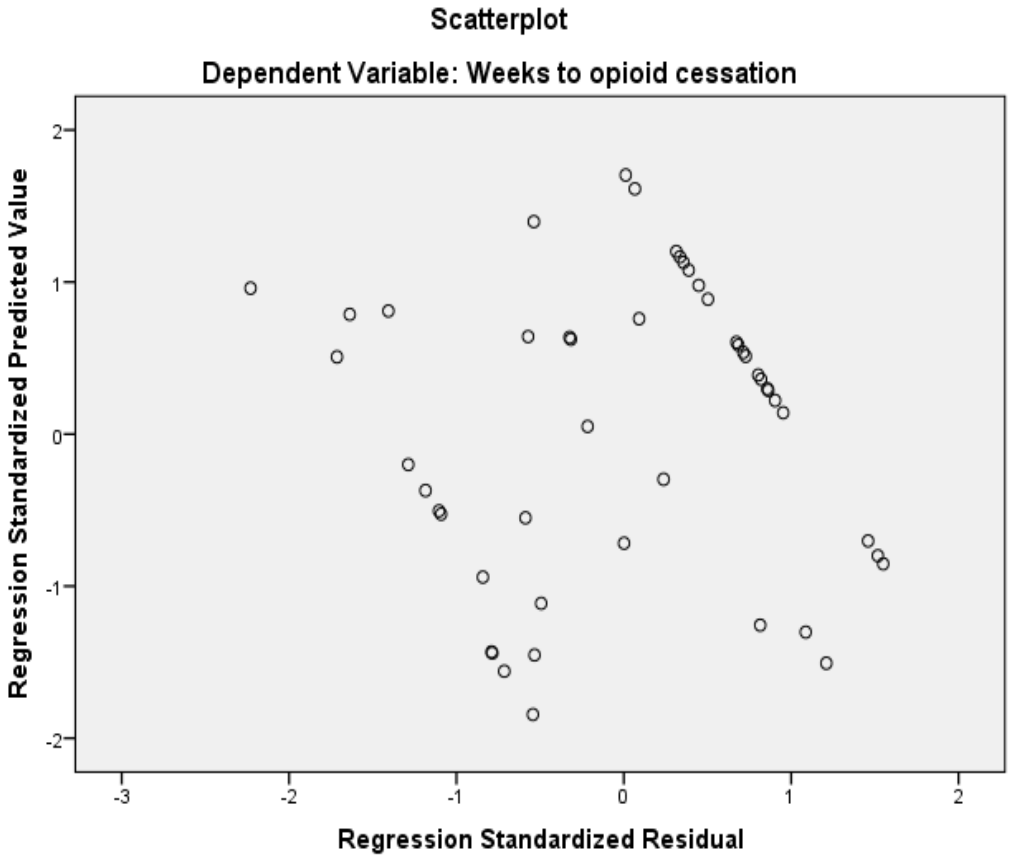

Figure 4.21. Residual scatterplot

Histogram of standardized residuals. The histogram of standardized residuals, with a superimposed normal curve, showed that the residuals were close to being normally distributed. Thus, the assumption that measurement errors in the dependent variable were normally distributed was met (see Figure 4.22).

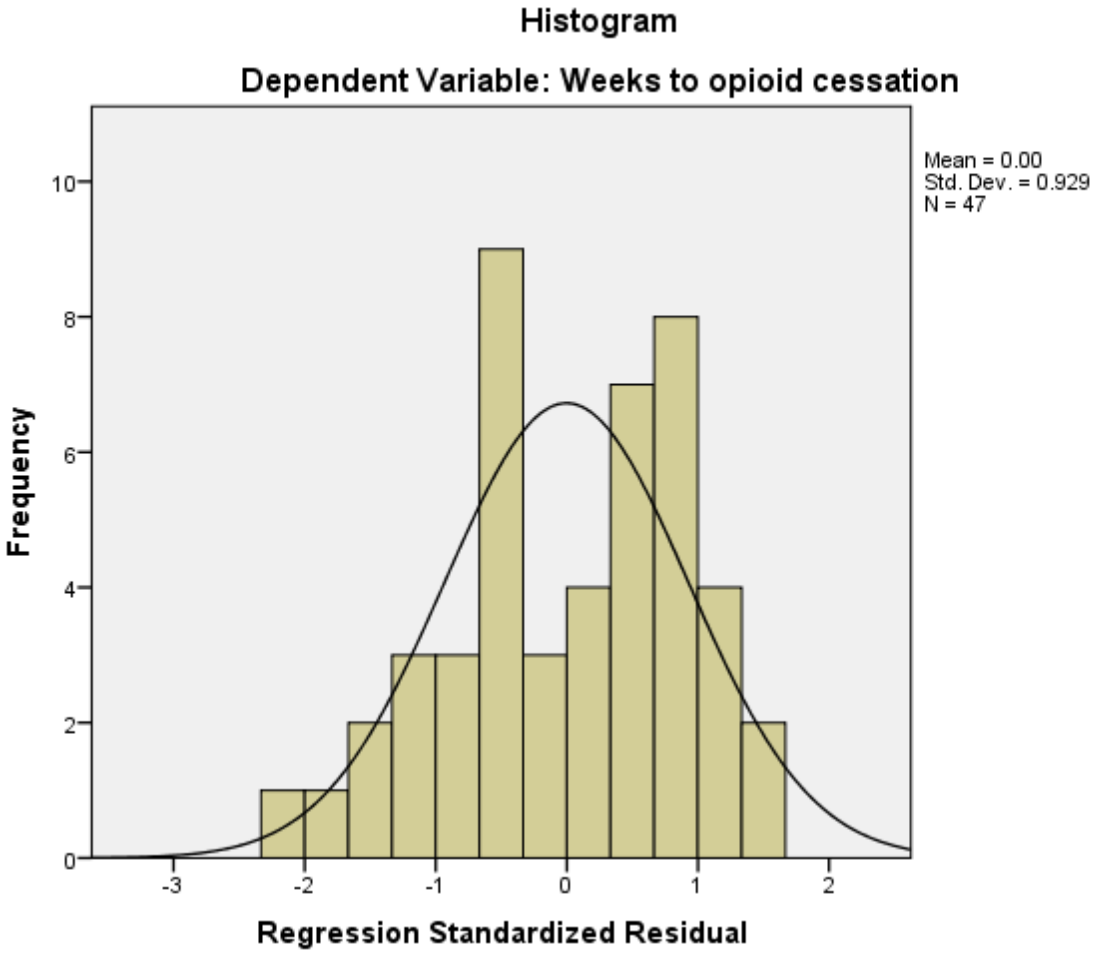

Figure 4.22. Histogram of standardized residuals

Normal probability-probability (P-P) plot. The normal P-P plot is based on the standardized residuals. The observed cumulative probability based on percentiles in the frequency distribution of the residuals is plotted on the X-axis and the expected cumulative probability based on the standardized residual is plotted on the Y-axis. Since the residuals aligned along the diagonal line of the graph, the assumption that the residuals were normally distributed was assumed to have been met (see Figure 4.23).

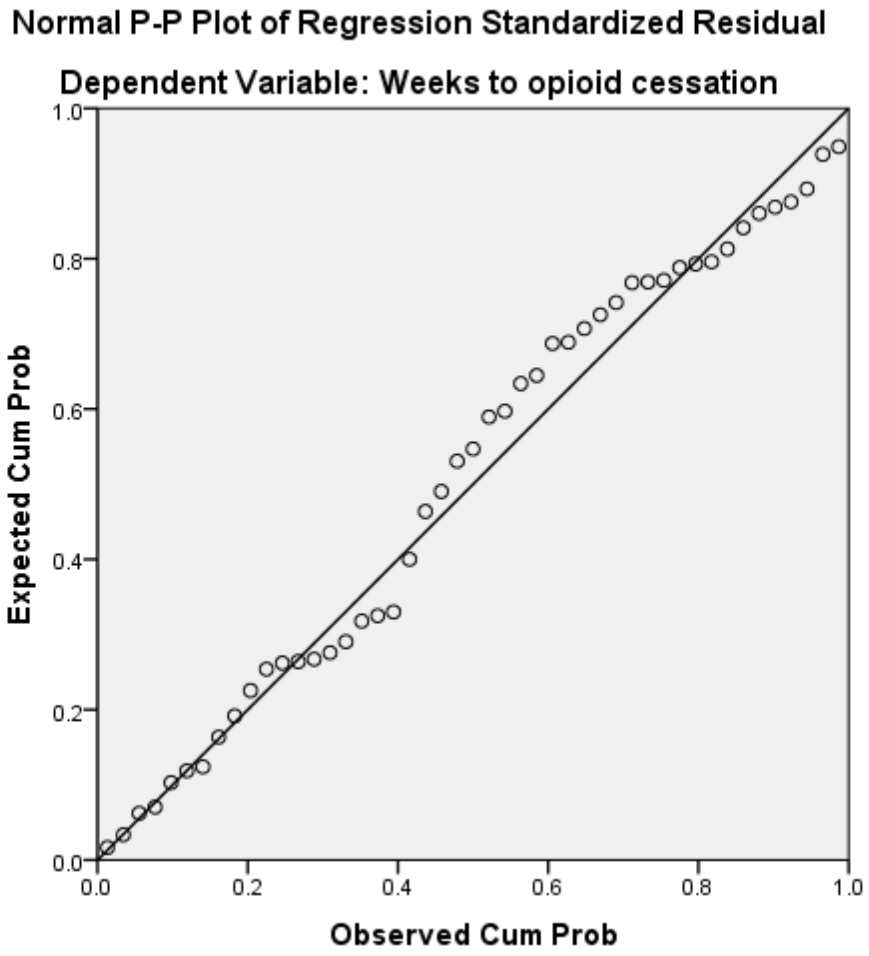

Figure 4.23. Normal probability-probability (P-P) plot

Summary

The mean age of the cohort was 63.47 (*SD* = 11.05), and more than 50% (*n* = 31) were retired. The mean preoperative NPRS was 7.65 (*SD* = 1.87), and the mean PCS score was 28.85 (*SD* = 14.72). The mean time to opioid cessation was 7.76 weeks (*SD* = 4.47), and the mean postoperative NPRS score was 3.12 (*SD* = 2.15). More than 60% (*n* = 35) of participants used opioid pain relievers prior to lumbar fusion, and 44% (*n* = 22) of participants were still using opioids for back or leg pain three months following lumbar fusion.

Data analysis did not support Hypothesis 1 or Hypothesis 2. Pain catastrophizing was neither correlated with time to opioid cessation (r = .03, p = .86), nor with postoperative pain intensity (r = -.04, p = .82).

Data analysis supported Hypothesis 3. Time to opioid cessation can be predicted by preoperative patient factors (i.e., age, sex, employment status, educational level, preoperative pain intensity, preoperative opioid use, disability status, and pain catastrophizing). Bivariate analysis identified positive correlations between weeks to opioid cessation and preoperative opioid use (r = .458, p = .000), and being on sick leave or disabled (r = .290, p = .022). Following the elimination of one case that was identified as an outlier during exploratory data analysis, multiple regression analysis resulted in a model that significantly predicted weeks to opioid cessation [R^2 = .322, R^2_{adj} = .179, $F(8, 38) = 2.254$, p = .044]. Using the more conservative R^2_{adj} value, the model indicated that 18% of the variance in time to opioid cessation was explained by preoperative patient

characteristics. Regression coefficients further revealed that only one patient characteristic—preoperative opioid use—contributed to the model ($\beta = .466$; $p = .005$). For every one unit increase in preoperative opioid use, there was a fourfold increase in weeks to opioid cessation ($B = 4.230$).

CHAPTER V

DISCUSSION OF FINDINGS AND IMPLICATIONS FOR FUTURE RESEARCH

The purpose of the study was to explore relationships between preoperative patient characteristics and postoperative outcomes and to examine the prevalence and predictors of PPO in patients undergoing elective lumbar fusion. The benefits of prescribed opioids in reducing acute postoperative pain are well-established, but there is little evidence to support their use for the management of chronic pain (Dowell et al., 2016).

Biological, psychological, and social factors have been found to predict a variety of pain-related outcomes following lumbar fusion (Abbott et al., 2011; Adogwa et al., 2012; Mendenhall et al., 2014; Nguyen et al., 2011; Rao et al., 2015; Rouben et al., 2011; Soriano et al., 2010). Accordingly, the study sought to identify the prevalence of PPO in a cohort of patients undergoing lumbar fusion and to explore whether biopsychosocial factors predict PPO and postoperative pain intensity. Specifically, the study sought to determine: (1) whether preoperative pain catastrophizing was positively correlated with time to opioid cessation; (2) whether preoperative pain catastrophizing was positively correlated with postoperative pain intensity; and (3) whether time to opioid cessation could be predicted by a combination of preoperative biological, psychological, and social factors. The identification of predictors of PPO would present an opportunity for clinicians to target potentially modifiable risk factors during the perioperative period with

the goal of minimizing the progression to long-term opioid use. This chapter includes a summary of the study, discussion of results, recommendations for further research, and conclusions and implications for clinical practice.

Summary of the Study

A prospective, longitudinal cohort study was conducted. The researcher used consecutive sampling and invited all patients who met eligibility criteria during a seven month period to enroll in the study. On the day of surgery, the researcher administered the Demographic and Clinical Variables Questionnaire and the PCS to participants. Participants self-reported age, sex, educational level, employment status, preoperative pain intensity, preoperative opioid use, and level of pain catastrophizing. Three months following surgery, the researcher conducted a telephone interview with participants to identify time to opioid cessation and postoperative pain intensity.

All eligible patients who were invited to participate in the study agreed to enroll for a 100% enrollment rate (n = 57). Three percent of data were missing and were determined to be missing completely at random. Thus, pairwise deletion was used for data analysis.

The prevalence of PPO was 44% (n = 22). That is, 44% of participants self-reported continued use of prescribed opioids three months following lumbar fusion, with no more than 5 opioid-free days since surgery. Exploratory data analysis did not support the use of parametric statistics to test the correlations between time to opioid cessation and postoperative outcomes. Therefore, the researcher used Spearman *rho*, a non-

parametric test, to evaluate the correlations between the variables. Results revealed that neither weeks to opioid cessation nor postoperative NPRS scores were significantly correlated with PCS scores. Thus, the researcher accepted the null hypothesis for hypothesis 1 that there was no linear relationship between preoperative pain catastrophizing and time to opioid cessation, and the null hypothesis for hypothesis 2 that there was no linear relationship between preoperative pain catastrophizing and postoperative pain intensity.

The researcher used multiple regression analysis to identify if preoperative patient characteristics could predict time to opioid cessation. Bivariate analysis revealed that weeks to opioid cessation was highly correlated with preoperative opioid use ($r = .458$, $p = .000$), and moderately correlated with sick leave or disability ($r = .290$, $p = .022$). Multiple regression analysis indicated that preoperative patient characteristics significantly predicted time to opioid cessation [$F(8, 38) = 2.254$, $p = .044$], and that preoperative opioid use ($\beta = .466$, $p = .005$) was the sole significant predictor of time to opioid cessation.

Discussion of the Findings

This is one of only a few studies that attempted to prospectively evaluate PPO and the relationship between biopsychosocial factors and patient-centered outcomes following lumbar fusion. The results identified high pain catastrophizing levels and a high prevalence of PPO among patients undergoing lumbar fusion. The mean PCS score was 28.85 ($SD = 14.72$), and the median score was 30 (range 0 to 52). Thus, many

participants either met or exceeded the threshold score of 30 that was identified by the developer of the PCS as indicative of a, "clinically relevant level of catastrophizing" (Sullivan, 2009, p. 7). Likewise, the mean PCS score in the current study exceeded mean PCS scores reported in other studies of preoperative pain catastrophizing. These included a mean PCS score of 11.69 (*SD* = 11.1) prior to cardiac surgery (Khan et al., 2012); a mean PCS score of 14.4 (*SD* = 1.2) prior to knee surgery (Pavlin et al., 2005); a mean PCS score of 21.66 (*SD* = 13.15) prior to lumbar fusion (Papaioannou et al., 2009); and a mean PCS score of 25.6 (*SD* = 13.3) prior to abdominal surgery (Granot & Ferber, 2005). The current study's median PCS score of 30.0 also exceeded the median PCS score of 17.0 that was reported in a study of preoperative pain catastrophizing in patients undergoing knee surgery (Hovik et al., 2016).

Sixty-one percent (*n* = 35) of participants reported prescribed opioid use prior to lumbar fusion. Three months following surgery, 44% (*n* = 22) of participants continued to use prescribed opioids on a regular basis for low back or leg pain, with no more than 5 opioid-free days since surgery. This proportion of PPO is consistent with previous findings of prolonged opioid use following lumbar fusion. Opioid use rates of 76% at three months (Nguyen et al., 2011), and 31% at six months (Rouben et al., 2011) have been reported.

Pain catastrophizing was not correlated with time to opioid cessation or with postoperative pain intensity in bivariate analysis. This finding was somewhat unexpected. Previous studies have identified significant relationships between pain

catastrophizing and numerous pain-related outcomes. A systematic review of 16 studies found pain catastrophizing to be associated with pain and disability in patients with acute, sub-acute, and chronic low back pain (Wertli et al., 2014). Other studies have found pain catastrophizing to be associated with pain, disability, psychological distress, opioid craving, and opioid misuse in patients with chronic pain (Martel et al., 2013; Martel et al., 2014; Severeijns et al., 2001). However, these associations were all identified in studies of patients with non-surgical pain. Conversely, the current study exclusively enrolled patients undergoing complex spinal surgery. Moreover, other studies that exclusively enrolled patients undergoing surgical procedures also failed to identify significant relationships between pain catastrophizing and postoperative outcomes. Hovik et al. (2016) failed to identify a significant association between pain catastrophizing and postoperative pain. Pavlin et al. (2005) failed to identify a significant relationship between pain catastrophizing and postoperative opioid dose. Taken together, these findings suggest that the influence of pain catastrophizing on postoperative outcomes is not as well defined as the influence of pain catastrophizing on non-surgical outcomes. Perhaps, there are additional factors that uniquely moderate the effect of pain catastrophizing on postoperative outcomes. Alternatively, perhaps surgical patients with high levels of pain catastrophizing are becoming hypervigilant to the possible harms of prescribed opioids in the context of the national opioid epidemic. This hypervigilance may result in patients opting for non-opioid medications and non-pharmacological interventions to manage postoperative pain.

Preoperative opioid use emerged as the sole predictor of time to opioid cessation. This finding adds to the growing body of evidence that preoperative opioid use predicts postoperative opioid use. An analysis of the health insurance claims of more than 36,000 surgical patients from 2013 to 2014, found that patients who received a prescription for opioid pain relievers in the 30 days prior to surgery had an almost 2-fold higher odds of persistent opioid use after surgery, even after adjustment for covariates (Adjusted Odds Ratio [AOR], 1.93; CI, 1.71-2.19; Brummett et al., 2017). A study that enrolled more than 500 patients undergoing orthopedic surgery found that patients who used preoperative opioids had significantly increased odds of opioid use 6 months following surgery compared to patients who did not use preoperative opioids (OR, 1.07, $p < .001$; Goesling et al., 2016). These findings highlight the importance of preoperative opioid use as a predictor of postoperative opioid use. Furthermore, preoperative opioid use has also been shown to predict other surgical outcomes. Among patients undergoing spine surgery, preoperative opioid has also been associated with depression and anxiety (Armaghani et al., 2013), increased length of stay (Armaghani et al., 2016), decreased patient-reported health status (Lee et al., 2014), and greater pain intensity and disability (Lee et al., 2014; Villavicencio, Nelson, Kantha, & Burneikiene, 2017).

Since preoperative opioid use was considered a biological factor within the framework of the biopsychosocial model, the finding that it was the only predictor of time to opioid cessation would seem to support the biomedical model of disease rather than the biopsychosocial model of illness. However, the characterization of opioid use as

a biological factor may have been overly simplistic. Although prescribed opioids exert physiological effects that support its characterization as a biological factor, opioids have also been associated with mental health issues, most notably opioid use disorders. Opioid use disorder is characterized by the compulsive and prolonged self-administration of opioids in the absence of a legitimate medical purpose (American Psychiatric Association, 2015). Furthermore, although opioids are ostensibly prescribed to treat pain, much pain—especially chronic low back pain—cannot be wholly explained by biological factors. Instead, prescription opioid use and chronic low back pain have been associated with psychological factors. Patients using opioids for chronic pain have high rates of psychiatric conditions and self-reported symptoms of depression and anxiety (Goesling et al., 2015; Merrill et al., 2012; Quinn et al., 2017; Wasan et al., 2015). Patients with low back pain have high rates of depression, anxiety, and somatization (Calvo-Lobo et al., 2017; Christensen et al., 2015; Farajirad, Tohidi, & Farajirad, 2016). These findings underscore the complexity of opioid use and suggest that the characterization of preoperative opioid use solely as a biological factor may have been an error.

The current study notwithstanding, the use of the biopsychosocial model for the study of PPO is supported by other studies that identified biological, psychological, and social predictors of opioid-related outcomes. Among patients undergoing elective spinal surgery, greater preoperative opioid use, greater anxiety, more invasive surgery, and revision surgery were significantly associated with decreased incidence of opioid independence 12 months following surgery (Armaghani et al., 2014). Among patients

undergoing a mix of surgical interventions, preoperative opioid use, self-perceived risk of addiction, and depressive symptoms each independently predicted PPO (Carroll et al., 2012). Among patients presenting for care at a US Veterans Affairs Medical Center, preoperative opioid use was identified as the strongest independent predictor of opioid use three months following knee arthroscopy; however, among the subset of patients who were not taking opioids prior to surgery, post-traumatic stress disorder was also associated with PPO (Rozet et al., 2014). The results of these studies all support the use of the biopsychosocial model for the study of PPO. Furthermore, it is possible that the current study failed to identify psychological and/or social predictors of PPO because it enrolled a small cohort.

Weaknesses of the Study

The study enrolled 57 participants. The researcher enrolled this number of participants based on an expectation of a large effect as was identified in a prior study of lumbar fusion outcomes (Papaioannou et al., 2009). Even after the number of predictors in the multiple regression analysis increased to eight following transformation of the employment status variable to create dichotomous variables, the power analysis table indicated that a cohort size of 44 participants would be adequate to detect a large effect (Polit & Beck, 2012, p. 442). Thus, when 48 of the 57 participants provided complete data, the researcher considered the study to be adequately powered. This assumption was confirmed when the multiple regression analysis yielded a large effect (R^2 = .322; Leech et al., 2015). Nevertheless, recruiting a sample based on the detection of a large effect

left the study too underpowered to detect small and medium effects. If the researcher had used a different sample size recommendation, a larger cohort would have been enrolled which might have led to the identification of additional psychosocial predictors of time to opioid cessation as suggested by the conceptual framework. One multiple regression sample size recommendation suggests a ratio of 15 participants for every predictor (Stevens as cited in Mertler & Vannatta, 2013). Another recommendation suggests $n \geq 50 + 8k$, where k is the number of predictors for testing multiple correlation, and $n \geq 104 + k$ for testing individual predictors (Tabachinick & Fadell as cited in Mertler & Vannatta, 2013). Any of these recommendations would have resulted in the recruitment of a larger cohort than was enrolled in the study. However, even if additional significant predictors of time to opioid cessation had been identified, the clinical importance of a small or medium effect would be subject to additional scrutiny. Whereas, a large effect should undoubtedly influence clinical decision making, small and medium effects might be less important when designing or delivering future interventions.

Another weakness of the current study was the omission of factors from the multiple regression that are known to influence postoperative outcomes. Surgical indication, depression, emotional health, legal representation, smoking, and payer status (i.e., workers' compensation benefits versus no workers' compensation benefits) have been shown to influence pain intensity, functional disability, and return to work following lumbar fusion (Adogwa et al., 2012; Nguyen et al., 2011; Soriano et al., 2010; Rao et al., 2015; Rouben et al., 2011). However, none of these factors was explored in the current

study due to resource constraints. Recruiting participants from a single study site could also be considered a weakness of the study because findings might not be generalizable across different settings and geographic regions. Nevertheless, the relatively advanced age (mean = 63.47, *SD* = 11.05) and female preponderance (66.7%, *n* = 38) of the cohort reflect national trends that show older individuals and females to be the most likely patients to undergo lumbar fusion (Deyo et al., 2010; Pannell, Savin, Scott, Wang, & Daubs, 2015; Rajaee et al., 2012).

The high internal consistency of the PCS could be considered a weakness of the instrument. Internal consistently evaluation of the PCS indicated a Cronbach's $\alpha = .951$. Such a high α value suggests that items on the scale are redundant; however, similar values ($\alpha = .87 - .95$) were obtained with independent samples (Sullivan, 1995; Osman et al., 2000).

Strengths of the Study

The current study had several strengths, including a longitudinal design, consecutive sampling plan, and high rates of enrollment, retention, and follow up. The longitudinal design ensured that the independent variables were measured three months prior to the measurement of the dependent variables. This eliminated the threat of temporal ambiguity that accompanies cross-sectional designs. Consecutive sampling increased the likelihood of a representative sample and decreased the threat of sampling bias by inviting all patients who met eligibility criteria to participate in the study. The 100% enrollment rate also strengthened sample representativeness because no eligible

patients declined to participate. Enrolling less than 100% of eligible patients could have biased the sample if some patients declined to enroll for factors that influenced the study's results. The high rates of retention and follow up resulted in few missing data. Since only 3% of data were missing, and since data were missing at random, it is unlikely that missing data biased the results.

The possibility that history could threaten the study's internal validity was identified prior to enrollment. However, the high-profile death of Prince, a well-known singer who died from an opioid overdose in 2016, occurred several weeks prior to the enrollment of any participants (Eligon & Kovaleski, 2016). Thus, any effect that the celebrity opioid overdose death had on preoperative patient characteristics or postoperative outcomes would have been equally experienced by all participants.

Recommendations for Further Study

The study identified a high prevalence of prolonged opioid use following lumbar fusion and characterized preoperative opioid use as a risk factor for PPO. Additional research is needed to strengthen these findings and possibly identify additional predictors of PPO.

1. Forty-four percent of participants (n = 22) used prescribed opioids at the study's endpoint (i.e., 12 weeks). Studies with a longer follow up period are needed to precisely quantify the duration of PPO following lumbar fusion.
2. Preoperative patient characteristics examined in this study accounted for only 18% of the variance in time to opioid cessation. This suggests that additional

variables, which were not examined in the current study, may predict PPO. Further research is needed to identify these factors, particularly psychosocial factors and potentially modifiable risk factors.

3. The regression equation from the current study was developed from a small cohort. Further research with larger samples is needed to validate the model. The regression equation will only be generalizable to the population of all patients undergoing elective lumbar fusion if the multiple correlation, *R*, retains its value when applied to additional, independent samples of patients. Otherwise, the model will have little predictive power and will not fulfil its intended purpose of identifying patients at risk for PPO.
4. Once risk factors for PPO are confirmed through research examining additional predictors with larger cohorts, screening tools should be developed to assist clinicians in identifying patients at risk for PPO. Such tools would require psychometric evaluation to ensure sufficient evidence of reliability and validity prior to use.

Conclusions and Implications for Clinical Practice

The results of the study add to the growing body of knowledge about prescription opioid use in patients undergoing lumbar fusion. Despite the ongoing opioid epidemic, 61.4% of participants (n = 35) used prescribed opioids prior to surgery, and 44.0% of participants (n = 22) used prescribed opioids for at least three months following surgery. Of the eight biological, psychological, and social variables examined, preoperative opioid

use was the sole significant predictor of time to opioid cessation. This finding suggests that screening patients for preoperative opioid use will help nurses and nurse practitioners identify patients at risk for prolonged opioid use following lumbar fusion. This finding also suggests that it may be possible to reduce the prevalence of prolonged, postoperative opioid use by reducing preoperative opioid use. Such a reduction will require a commitment from all healthcare providers to decrease their reliance on opioid-based interventions in favor of strategies that recognize the biopsychosocial contributors to the pain experience and promote safer and more effective pain management. The study also identified high rates of pain catastrophizing among patients undergoing lumbar fusion. Although pain catastrophizing was not significantly correlated with time to opioid cessation or with postoperative pain intensity, it has previously been associated with negative, pain-related outcomes and warrants continued study.

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APPENDIX A

Demographic and Clinical Variables Questionnaire

Demographic and Clinical Variables Questionnaire

Name: _____ Date: _____

Age: _____ Sex: □ Female □ Male

Employment status:

- □ Working now
- □ Looking for work, unemployed
- □ Sick leave or maternity leave
- □ Disabled due to back pain, permanently or temporarily
- □ Disabled for reasons other than back pain
- □ Student
- □ Temporarily laid off
- □ Retired
- □ Keeping house
- □ Other; specify: _____
- □ Unknown

Education Level (select the highest level attained)

- □ No high school diploma
- □ High school graduate or GED
- □ Some college, no degree
- □ Occupational/technical/vocational program
- □ Associate's degree
- □ Bachelor's degree
- □ Master's degree
- □ Professional school degree (e.g., MD, DDS, JD) or doctoral degree (PhD, EdD)
- □ Unknown

In the past 7 days, how would you rate your low back and leg pain on average?

□	□	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10
No Pain									Worst Imaginable Pain

Are you currently using opioid painkillers for back pain *(these include, but are not limited to, prescription medications such as Vicodin, Lortab, Norco, hydrocodone, codeine, Tylenol #3 or #4, fentanyl, Duragesic, MS Contin, Oxycontin, oxycodone, methadone, tramadol, Ultram, Dilaudid)*?

□ YES □ NO

Note: Adapted from "Report of the NIH Task Force on Research Standard for Chronic Low Back Pain," by Deyo et al., 2014, *Spine, 39*(14), 1128-1143.

APPENDIX B

Pain Catastrophizing Scale

Pain Catastrophizing Scale

Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.
We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

0= not at all	1= to a slight degree	2= to a moderate degree	3= to a great degree	4= all the time

When I'm in pain…

☐ 1. I worry all the time about whether the pain will end.

☐ 2. I feel I can't go on.

☐ 3. It's terrible and I think it's never going to get any better.

☐ 4. It's awful and I feel that it overwhelms me.

☐ 5. I feel I can't stand it anymore.

☐ 6. I become afraid that the pain will get worse.

☐ 7. I keep thinking of other painful events.

☐ 8. I anxiously want the pain to go away.

☐ 9. I can't seem to keep it out of my mind.

☐ 10. I keep thinking about how much it hurts.

☐ 11. I keep thinking about how badly I want the pain to stop.

☐ 12. There's nothing I can do to reduce the intensity of the pain.

☐ 13. I wonder whether something serious may happen.

APPENDIX C

Telephone Interview Guide

Telephone Interview Guide

Name: _____ Date: _____

When was the last time you used opioid painkillers for low back or leg pain *(these include, but are not limited to, prescription medications such as Vicodin, Lortab, Norco, hydrocodone, codeine, Tylenol #3 or #4, fentanyl, Duragesic, MS Contin, Oxycontin, oxycodone, methadone, tramadol, Ultram, Dilaudid)*?

_____

If you have used opioid pain relievers within the past five days, have you ever gone for more than five days without using them since your surgery?

□ YES □ NO If yes, when _____

If participant reports opioid cessation greater than 5 days prior to interview, time to opioid cessation is the number of weeks from date of surgery to the first of 5 consecutive days of zero opioid use. Participant is categorized as negative for PPO.

If participant reports opioid use within 5 days of interview, but reports a period of at least five days of zero opioid use, time to opioid cessation is the number of weeks from date of surgery to the first of 5 consecutive days of zero opioid use. Participant is categorized as negative for PPO.

If participant reports opioid use within 5 days of interview, with no period greater than 5 days of zero opioid use, patient is categorized as positive for PPO.

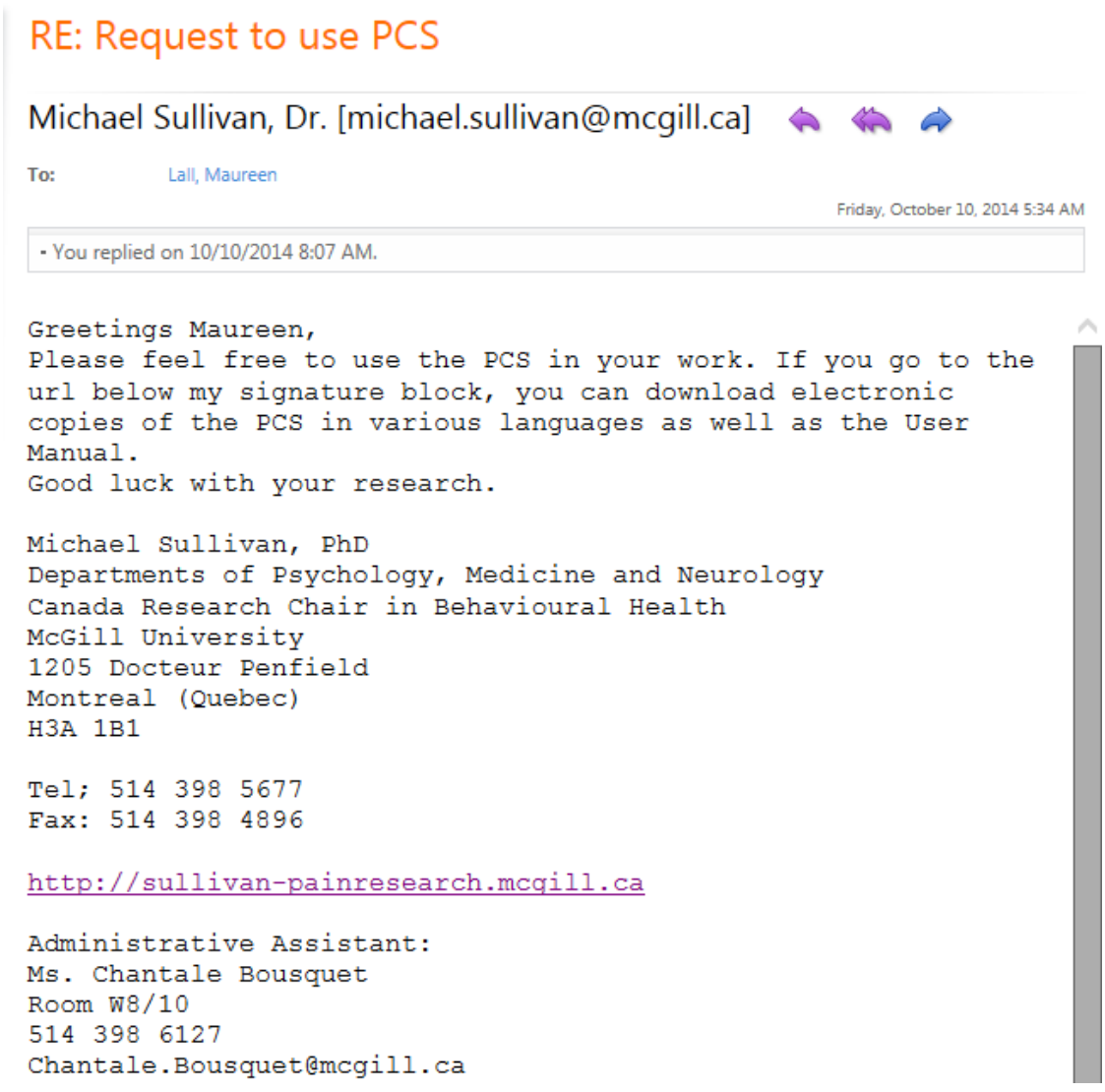
In the past 7 days, how would you rate your low back and leg pain on average?

□	□	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10
No Pain									Worst Imaginable Pain

APPENDIX D

Permission to Use Pain Catastrophizing Scale

Permission to Use Pain Catastrophizing Scale



RE: Request to use PCS

Michael Sullivan, Dr. [michael.sullivan@mcgill.ca]

To: Lall, Maureen

Friday, October 10, 2014 5:34 AM

- You replied on 10/10/2014 8:07 AM.

Greetings Maureen,
Please feel free to use the PCS in your work. If you go to the url below my signature block, you can download electronic copies of the PCS in various languages as well as the User Manual.
Good luck with your research.

Michael Sullivan, PhD
Departments of Psychology, Medicine and Neurology
Canada Research Chair in Behavioural Health
McGill University
1205 Docteur Penfield
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Administrative Assistant:
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APPENDIX E

Houston Methodist Research Institute
IRB Approval Letter

HOUSTON Methodist LEADING MEDICINE

HMRI IRB 1

NOTIFICATION OF INITIAL APPROVAL TO BEGIN RESEARCH (EXPEDITED)

To: Maureen Lall

From: Dr. Susan Miller

Chair, HMRI IRB 1

Date: March 1, 2016

Study ID: Pro00013884

Title: Pain catastrophizing and prolonged opioid use following lumbar fusion

The Institutional Review Board reviewed your Request for Expedited Review and the above named project is determined to qualify for Expedited status according to 45 CFR 46.110. The study is approved from 2/29/2016 through 2/28/2017.

CATEGORY #5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS

regulations for the protection of human subjects. 45 CFR 46.110 (4). This listing refers only to research that is not exempt.)

CATEGORY #7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.110 (2) and (b)(3). This listing refers only to research that is not exempt.)

Informed Consent Document Version 1 Dated 02/29/2016

Pain catastrophizing study protocol(0.01)

Study instruments and telephone interview guide

Demographic and Clinical Variables Questionnaire.docx(0.01)

Pain Catastrophizing Scale.docx(0.01)

Telephone Interview Guide(0.01)

Recruitment script for verbal/personal solicitation

Waiver of Authorization to Use and Disclose Protected Health Information

The IRB has determined all the specified criteria for a waiver or an alteration were met in accordance with 45 CRF 164.512(i).

Under this approval, the following data elements may be used/accessed in connection with this study:

• HIPAA waiver to review charts for Questionnaires or Interviews, Names, Telephone Number and Dates.

Please note that prior to accessing these data elements, you should provide this letter of IRB approval to the applicable medical records personnel. Any changes to this Waiver of Authorization request must be approved by the IRB before the changes can take place.

PROVISIONS: Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered by expedited review, e.g. study documents, etc.

CHANGES: Should you choose to make any changes to the protocol that would involve the inclusion of human subjects or identified data from humans, please submit the change via MORTI to the Committee for the Protection of Human Subjects for review.

Please note that prior to starting any experiments, it is your responsibility to give a copy of this document to all research personnel involved in the project and to discuss the project with each employee. Please ensure that only the most current IRB approved consent may be used during the study. Any changes to the protocol or consent must be approved by the IRB before the changes can take place.

To post information on this clinical trial to the HMRI web site, the study must be listed on ClinicalTrials.gov. Please enter the ClinicalTrials.gov Identifier (i.e., the NCT number) and the Brief Summary from that listing for this trial by clicking on the Submit Web Info activity button in the left navigation list on the study page in the MORTI IRB Module.

If you have any questions or comments, please contact the Office of Research Protection at 713-441-5848 or 713-441- 5837or come to MGJ3-014, 1130 John Freeman Blvd, Houston, TX 77030.

The HMRI IRB is organized, operates, and is registered with the United States Office for Human Research. Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The HMRI IRB operates under the HMRI Federal Wide Assurance No. FWA00000438, as well as those of hospitals and institutions affiliated with the Institute.

APPENDIX F

Texas Woman's University
Institutional Authorization Agreement (IAA)

Institutional Review Board
Office of Research and Sponsored Programs
P.O. Box 425619, Denton, TX 76204-5619
940-898-3378
email: IRB@twu.edu
http://www.twu.edu/irb.html

DATE: April 18, 2016

TO: Ms. Maureen Lall
Nursing

FROM: Ms. Tracy Lindsay, Director of Operations
Office of Research & Sponsored Programs

Re: *Institutional Authorization Agreement (IAA) Processed for Pain Catastrophizing and Prolonged Opioid Use Following Lumbar Fusion (Protocol #: 18973)*

An IAA for the above referenced study between Texas Woman's University and Houston Methodist Research Institute has been processed as an expedited study. The Houston Methodist Research Institute IRB is the designated IRB providing the review for this study. According to our records, this protocol was most recently approved by the Houston Methodist Research Institute IRB on 2/29/2016.

A current protocol file with all correspondence between the researcher and the Houston Methodist Research Institute IRB must be maintained at TWU. Therefore, you are required to place on file any documentation regarding this study including modifications, extensions, notifications of adverse events, etc.

If you have any questions, please contact the TWU IRB.

cc. Dr. Anita Hufft, Nursing
Dr. Elizabeth Restrepo, Nursing
Graduate School

APPENDIX G

Houston Methodist Research Institute
IRB Amendment 1 Approval

HOUSTON Methodist
LEADING MEDICINE

HMRI IRB 1

NOTICE OF EXPEDITED AMENDMENT APPROVAL TO IMPLEMENT REQUESTED CHANGES

Date: April 21, 2016

Study ID: Pro00013884

Title: Pain catastrophizing and prolonged opioid use following lumbar fusion

PI: Maureen Lall

PROVISIONS: Unless otherwise note, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consent, etc.

CHANGE APPROVED: Modification to Protocol Documents: Pain Catastrophizing Scale.docx

APPROVED: by Expedited Review

APPROVAL DATE: 04/21/2016

CHAIRPERSON: Susan M. Miller, MD, MPH

Upon receipt of this letter, and subject to any provisions noted above, you may now implement the changes approved via expedited approval.

Please note that prior to starting any experiments, it is your responsibility to give a copy of this document to all research personnel involved in the project and to discuss the project with each employee.

INFORMED CONSENT: Please ensure that only the most current IRB approved consent is being used during the study. Any changes to the protocol or consent must be approved by the IRB before the changes can take place.

If you have any questions or concerns, please contact the Office of Research Protection at 713-441-5837 or 713-441-9908 or come to MGJ6-014, 1130 John Freeman Blvd, Houston, TX 77030.

The HMRI IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The HMRI IRB operates under the HM Federal Wide Assurance No. FWA00000438, as well as those of hospitals and institutions affiliated with the Institute.

APPENDIX H

Houston Methodist Research Institute
Notification of Continuing Review Approval (Expedited)

HMRI IRB 1

NOTIFICATION OF CONTINUING REVIEW APPROVAL (EXPEDITED)

TO: Dr. Maureen Lall

From: Susan Miller, MD, MPH
Chair, HMRI IRB 1

Date: February 7, 2017

RE: Pro00013884-2017 Review for Pro00013884
Pain catastrophizing and prolonged opioid use following lumbar fusion

Dear Dr. Maureen Lall ,

The Institutional Review Board has reviewed your Continuing Review application and the above numbered protocol has been renewed for the following period:

APPROVED Date: 2/6/2017

EXPIRATION: 2/5/2018

If you have any questions or comments, please contact the Office of Research Protection at 713-441-5848 or 713-441-5837 or come to MGJ6-014, 1130 John Freeman Blvd, Houston, TX 77030.

The HMRI IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The HMRI IRB operates under the HMRI Federal Wide Assurance No. FWA00000438, as well as those of hospitals and institutions affiliated with the Institute.

If you are logging into MORTI from outside the Houston Methodist system, the above link may not work. Please log into MORTI directly at http://morti.tmhs.org and then navigate to the above referenced project.

Houston Methodist Research Institute
6670 Bertner
Houston, TX 77030
713-441-1261

APPENDIX I

Texas Woman's University
Institutional Authorization Agreement (IAA) Extension

Institutional Review Board
Office of Research and Sponsored Programs
P.O. Box 425619, Denton, TX 76204-5619
940-898-3378
email: IRB@twu.edu
http://www.twu.edu/irb.html

DATE: February 7, 2017

TO: Ms. Maureen Lall
Nursing

FROM: Ms. Tracy Lindsay, Director of Operations
Office of Research & Sponsored Programs

Re: Institutional Authorization Agreement (IAA) Updated for Pain Catastrophizing and Prolonged Opioid Use Following Lumbar Fusion (Protocol #: 18973)

An IAA for the above referenced study between Texas Woman's University and Houston Methodist Research Institute was processed as an expedited study. The Houston Methodist Research Institute IRB is the designated IRB providing the review for this study. According to our records, this protocol was originally approved by the Houston Methodist Research Institute IRB on 2/29/2016. The TWU IRB has received an updated approval letter and has revised our records to indicate that the most recent approval date is 2/7/2017.

A current protocol file with all correspondence between the researcher and the Houston Methodist Research Institute IRB must be maintained at TWU. Therefore, you are required to place on file any documentation regarding this study including modifications, extensions, notifications of adverse events, etc.

If you have any questions, please contact the TWU IRB.

cc. Dr. Anita Hufft, Nursing
Dr. Elizabeth Restrepo, Nursing
Graduate School

APPENDIX J

Recruitment Script for Verbal/Personal Solicitation

Pain Catastrophizing – Subject recruitment script – verbal (personal solicitation)

Maureen Lall, MSN, RN, FNP-BC, COHN-S, principal investigator, will invite patients scheduled for lumbar fusion to participate in the study on the morning of their surgery after their arrival at the hospital.

Researcher: Good morning Mr./Ms. _____.

My name is Maureen Lall and I am a nurse practitioner at Houston Methodist Sugar Land Hospital and a doctoral candidate at Texas Woman's University. I am aware that you are scheduled to undergo lumbar fusion today.

I am conducting a study of patient outcomes following lumbar fusion and am inviting you to participate in the study. Your involvement would include the completion of two surveys today. These surveys include questions about your health, education level, employment status, and your thoughts about pain. Three months after your surgery, I would call you via telephone and ask you about your use of pain medication and your pain intensity.

Your participation in the study is completely voluntary and your decision whether or not to participate will in no way affect the care you receive at Houston Methodist Sugar Land Hospital.

APPENDIX K

Houston Methodist Research Institute
IRB Amendment 2 Approval

HMRI IRB 1

NOTICE OF EXPEDITED AMENDMENT APPROVAL TO IMPLEMENT REQUESTED CHANGES

Date: January 11, 2017

Study ID: Pro00013884 - Amendment 2 for IRB Study #Pro00013884

Title: Pain catastrophizing and prolonged opioid use following lumbar fusion

PI: Maureen Lall

PROVISIONS: Unless otherwise note, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consent, etc.

CHANGE APPROVED: Increase in enrollment from 55 to 57 participants

Revised_Pain catastrophizing_Protocol_IRB application (1).docx - (Amendment #2)

APPROVED: by Expedited Review

APPROVAL DATE: 1/06/2017

CHAIRPERSON: Susan M. Miller, MD, MPH

Upon receipt of this letter, and subject to any provisions noted above, you may now implement the changes approved via expedited approval.

Please note that prior to starting any experiments, it is your responsibility to give a copy of this document to all research personnel involved in the project and to discuss the project with each employee.

INFORMED CONSENT: Please ensure that only the most current IRB approved consent is being used during the study. Any changes to the protocol or consent must be approved by the IRB before the changes can take place.

If you have any questions or concerns, please contact the Office of Research Protection at 713-441-5837 or 713-441-9908 or come to MGJ6-014, 1130 John Freeman Blvd, Houston, TX 77030.

The HMRI IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The HMRI IRB operates under the HM Federal Wide Assurance No. FWA00000438, as well as those of hospitals and institutions affiliated with the Institute.

If you are logging into MORTI from outside the Houston Methodist system, the above link may not work. Please log into MORTI directly at http://morti.tmhs.org and then navigate to the above referenced project.

Houston Methodist Research Institute
6670 Bertner
Houston, TX 77030
713-441-1261

APPENDIX L

Informed Consent for Observational/Non-Interventional Research
Houston Methodist Research Institute

HOUSTON Methodist LEADING MEDICINE

Informed Consent for Observational/Non-Interventional Research

Participant's Name: **Subject ID Number:**

Principal Investigator: Maureen P. Lall, MSN, RN, FNP-BC, COHN-S

Study Title: Which patient characteristics predict pain medication use and pain intensity after lumbar fusion?

Principal Investigator: Maureen P. Lall, MSN, RN, FNP-BC, COHN-S

Funding Source (if applicable): Not applicable

Study Purpose/ Summary: This study seeks to identify how patient characteristics are related to opioid ("narcotic") pain reliever use and pain intensity three months following lumbar fusion.

Why me:

You are being asked to take part in this study because you are scheduled to undergo lumbar fusion.

Study Purpose/Executive Summary:

This study will examine the relationships between seven preoperative (i.e., before surgery) factors and opioid ("narcotic") pain reliever use and pain intensity following lumbar fusion. The preoperative factors include thinking about pain, age, sex, pain intensity, opioid ("narcotic") pain reliever use, education level, and employment status.

If you decide to be in this study, the procedures performed will be part of your routine care and will be done whether you participate in the study or not. The research part of the study is the completion of two surveys prior to your surgery and one telephone interview three months after your surgery. The surveys include questions about your health, education, employment, and thinking about pain and should take about 15 minutes to complete. The telephone interview includes questions about pain medication and pain intensity and should take about 10 minutes. The investigators may end the study at any time for administrative reasons, or if data collection is no longer needed.

Your participation in this study is voluntary. You can choose to participate at any time without any penalty or loss of benefits to which you are entitled.

What risk will I face by taking part in the study and how will Researchers protect me from these risks?

- The potential loss of confidentiality is the only known risk of being in this study.

The researchers have taken steps to minimize the risks of this study. Please tell the researchers in the contact section about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

As with any research study, there may be additional risks that are unknown or unexpected. If these become known, the study team will notify you in a timely manner of any changes that may change your willingness to participate. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

Research Related Injury: As with any research study, there may be additional risks that are unknown or unexpected. If you are injured as a direct result of this study, medical care is available. In general, no long-term medical care or financial compensation for research-related injuries will be provided by Houston Methodist. You do not waive (give up) any legal rights by signing this informed consent form.

Please tell the researchers listed in Section 10 about any other problems that you have during this study. You should also tell your regular doctors.

How could I and others benefit if I take part in this study?

You will not benefit directly by taking part in this study. The researcher hopes that other people undergoing lumbar fusion will benefit by the knowledge obtained in this research.

Are there any cost or payments?

The sponsor/study will cover the cost of survey completion and telephone interview.

You and/or your insurance company will be responsible for payment of items and services that you would receive even if you were not participating in the research study. You will be responsible for your normal co-payments and co-insurance/deductibles.

You will not be paid for taking part in the study.

If you have any questions as to what your obligations are for payment for items or services under this study, or would like to see a list of procedures or items for which you are responsible financially, please talk with the study team and/or your insurance company.

If I want to stop participating in the study, what should I do?

If you wish to stop your participation in this research study for any reason you should let the principal investigator/study coordinator know as soon as possible so that you can stop safely. You may be asked why you are leaving the study and your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in "Contact Information".

What happens if I get hurt, my condition worsens, or have other problems as a result of this research?

If you are injured as a direct result of this study, medical care is available. In general, no long-term medical care or financial compensation for research-related injuries will be provided by Houston Methodist. You do not waive (give up) any legal rights by signing this informed consent form.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.
For questions about your rights as a research participant, or if you have complaints, concerns, or questions about the research, please contact Susan M. Miller, M.D., M.P.H., Chair, Houston Methodist Institutional Review Board for the Protection of Human Subjects, at 713-441-2750 or Ethan Natelson, MD, Chair, Houston Methodist Research Institute Institutional Review Board for the Protection of Human Subjects, at 713-441-5154. You may also contact the Director, HMRI Office of Research Protections at HMRI Office of Research Protections, 1130 John Freeman, MGJ6-016, Houston, Texas 77030. Ph: 713-441-7548

The research team will take proper precautions to ensure that any information regarding your identity obtained in connection with this research will remain confidential.

Authorization to use and disclose protected health information

If you decide to participate in this study, information about your health may be used or disclosed (shared outside of the Hospital) for the purposes of conducting this study. This information may include information from your medical record that is relevant to this study, such as your medical history, medications, test results, diagnoses, treatments, operative reports (reports from operations that you have undergone), and discharge summaries. It may also include information relating to: Human Immunodeficiency Virus ("HIV") infection or Acquired Immunodeficiency Syndrome ("AIDS"); treatment for or history of drug or alcohol abuse; or mental or behavioral health or psychiatric care. Information collected by the study doctor and/or research staff specifically for this study, such as test results, blood samples, physical examinations, information about possible side effects, and surveys you might be asked to complete could also be used or disclosed.

Houston Methodist may release your personal health information to other researchers or institutions, or to government agencies for the conduct of this research, for monitoring and safety, or regulatory research. If approved by the Institutional Review Board (IRB), your coded personal information may be released to to other researchers or institutions who may wish to conduct their own research. In most cases, the information released to the above listed individuals or entities will not contain your name, social security number, or any other personal information. However, authorized representatives of your study doctor, IRB, FDA, or other government agencies may review records containing personal information to make sure that the study information is correct. Because of the need to provide information to these parties, absolute confidentiality cannot be guaranteed.

Because this information is being disclosed for research use, there is no expiration date for the use of your information. This authorization is valid until you revoke it. You can revoke this authorization at any time by contacting the investigators and if possible any identifiable information will be destroyed. I understand that the revocation will not apply to information that already has been released or actions that have already been taken in response to this authorization. I have a right to request a copy of any of my health information that is released under this authorization.

Other researchers or institutions that receive your information may not be covered by Federal or Texas privacy laws. As such, your information may not be protected under these laws once it is disclosed and, therefore, may be subject to re-disclosure or use by such individuals or institutions.

Where can I get more information?

If you have any questions regarding your participation in this study, please ask us. If you have any additional questions later, please contact the researchers listed below to:

Principal Investigator: Maureen Lall, MSN, RN, FNP-BC, COHN-S
Mailing Address: [redacted]
Telephone: [redacted]

Study Participant:

I have read this consent form or had it read to me. I have discussed it with the study team and my questions have been answered. I will be given a signed copy of this form. I agree to take part in this study.

Signature of Study Participant or Legally Authorized Representative:

_____ **Date:**_____ **Time:** _____

Name (Print Legal Name): _____

Legal Representative Information (If Applicable)

Phone: _____

Check Relationship to Subject: ☐Parent ☐ Spouse ☐Child ☐Sibling ☐Legal Guardian ☐Other: _____

Reason subject is unable to sign for self:_____

Person Obtaining Consent:

I have given this research subject (or his/her legally authorized representative) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name: _____ **Title:** _____

Signature: _____ **Date of Signature:** _____

Translation Service: I verbally translated the informed consent process and the conversation between the investigator and the study participant.

Name: _____ **Organization:** _____

Signature: _____ Date of Signature: _____

FOR IRB OFFICE USE ONLY
Protocol # Pro00013884 Page 4 of 4
Consent Approval Date: 02/29/2016 ***Expiration Date:*** 02/28/2017
Consent Version: 1
HMRI non-interventional ICF template v. 8/25/14

APPENDIX M

PREDICTORS OF PROLONGED OPIOID USE FOLLOWING LUMBAR FUSION: A PROSPECTIVE COHORT STUDY

A Manuscript Submitted For Publication in

Pain Management Nursing

Maureen P. Lall

Elizabeth Restrepo

Predictors of Prolonged Opioid Use Following Lumbar Fusion:

A Prospective Cohort Study

Abstract

Although the use of opioid analgesics to treat acute, postoperative pain is a well-established practice, the role of opioids in the management of persistent, postoperative pain remains ill-defined. Nevertheless, high rates of prolonged opioid use following lumbar fusion have been reported. The goals of this prospective, longitudinal study were to identify the prevalence and predictors of prolonged opioid use in a cohort of patients undergoing elective lumbar fusion. Prior to surgery, participants self-reported demographic and clinical data and completed a validated measure of pain catastrophizing. Three months following surgery, participants self-reported prescribed opioid use. Forty-four percent (n = 22) of participants reported persistent opioid use three months following lumbar fusion. Bivariate analysis identified a strong correlation between weeks to opioid cessation and preoperative opioid use, r = .46, and a moderate correlation between weeks to opioid cessation and disability, r = .29. The multiple regression model predicting weeks to opioid cessation from age, sex, employment status, educational level, preoperative pain intensity, preoperative opioid use, disability status, and pain catastrophizing was significant, $F(8, 38) = 2.254$, p = .044, and accounted for 18% of the variance. Among preoperative patient characteristics, only preoperative opioid use significantly predicted weeks to opioid cessation, $\beta = .466$; p = .005. Thus, nurses and

nurse practitioners may be able to identify patients at risk for prolonged opioid use following lumbar fusion by screening patients for preoperative opioid use.

Keywords: prescribed opioid use, postoperative opioid, lumbar fusion

Predictors of Prolonged Opioid Use Following Lumbar Fusion:

A Prospective Cohort Study

Healthcare providers have long prescribed opioid analgesics for patients following lumbar fusion. These medications reduce acute pain and facilitate mobilization after complex spinal surgery. Opioids are also frequently used to treat persistent, postoperative pain. However, in the midst of the national opioid epidemic, healthcare providers must reexamine their use of long-term opioid therapy. There is no evidence that long-term opioid therapy for chronic pain is safe or effective, and there is mounting evidence that the risks of long-term opioids typically outweigh the benefits. This study was conducted to identify the prevalence and predictors of prolonged opioid use following lumbar fusion. As a first step to containing the opioid epidemic, healthcare providers must recognize the extent of their opioid prescribing and identify which patients are at risk for prolonged opioid use following lumbar fusion.

Background

Every year, tens of thousands of adults undergo lumbar fusion in the U.S. (Weiss & Elixhauser, 2014). The surgery is performed to protect the spinal cord and eliminate painful, abnormal motion in the low back. The indications for lumbar fusion include degenerative disc disease, spinal stenosis, spondylolisthesis, traumatic injury, spinal deformity, infection, and tumor (International Society for the Advancement of Spine Surgery [ISASS], 2011; North American Spine Society [NASS], 2014). There are several distinct approaches to lumbar fusion, but the common goal of surgery is the

restoration of spinal stability through arthrodesis. Lumbar arthrodesis occurs when two or more vertebral segments are joined—or fused—into a solid mass of new bone.

Although lumbar fusion has a high rate of achieving arthrodesis, patients often use opioid analgesics long beyond the acute recovery period. Among a group of patients receiving workers' compensation benefits, 76% reported opioid use three months after lumbar fusion (Nguyen, Randolph, Talmage, Succop, & Travis, 2011). Among patients in a mixed-payer group, 31% reported opioid use six months after lumbar fusion (Rouben, Casnellie, & Ferguson, 2011). These rates of opioid use are much higher than opioid use rates reported following non-fusion surgeries. Five months after mastectomy, lumpectomy, thoracotomy, total knee arthroplasty, or total hip arthroplasty, 6% of patients reported opioid use (Carroll et al., 2012). Three months following cardiac, intra-thoracic, intra-abdominal, or pelvic surgery, 3.1% of patients reported opioid use (Clarke, Soneji, Ko, Yun, & Wijeysundera, 2014).

Prolonged, postoperative opioid use warrants concern because long-term opioid therapy is associated with significant harms. Long-term opioid therapy causes constipation, sedation, clouded mentation, pruritus, myoclonus, hypogonadism, sexual dysfunction, osteoporosis, and immunosuppression (Chou et al., 2009; Deyo, Von Korff, & Duhrkoop, 2015; Freynhagen, Geisslinger, & Schug, 2013; Labianca et al., 2012; Von Korff, Kolodny, Deyo, & Chou, 2011). Long-term opioids also lead to drug tolerance and hyperalgesia, both of which decrease the pain-relieving efficacy of opioids (Freynhagen et al., 2013; Labianca et al., 2012). Most tragically, long-term opioid use

contributes to the national epidemic of prescription opioid overdose deaths—an epidemic that claimed the lives of more 15,000 people in 2015 (Centers for Disease Control and Prevention [CDC], 2017).

Prolonged, postoperative opioid use also merits concern because it is associated with non-pain related patient characteristics. Chronic disease comorbidities, depression, high self-perceived risk of addiction, low household income, and young age have predicted opioid use following non-spinal surgery (Carroll et al., 2012; Clarke et al., 2014; Helmerhorst, Vranceanu, Vrahas, Smith, & Ring, 2014). Pain catastrophizing, anxiety, post-traumatic stress disorder, and depression have predicted opioid use following surgery for musculoskeletal trauma (Helmerhorst et al., 2014). These findings suggest that postoperative opioid use is not simply a consequence of postoperative pain. Accordingly, this study was conducted to identify the prevalence of prolonged opioid use three months following lumbar fusion and to test the hypothesis that preoperative patient characteristics predict time to opioid cessation.

The biopsychosocial model of low back pain framed the study. The model differentiates low back pain from low back disability. The former is a self-limited symptom arising from a physical abnormality; the latter is a complex illness arising from biological, psychological, and social factors that is manifested by high level of distress and illness behaviors (Waddell, 1987). The researcher examined four biological factors (i.e., age, sex, preoperative pain intensity, and preoperative opioid use), one psychological factor (i.e., pain catastrophizing), and two social factors (i.e., educational

level and employment status) to determine if they predict low back disability, defined as prolonged opioid use following lumbar fusion. Prior research has identified significant relationships between these biopsychosocial factors and either opioid-related outcomes or lumbar fusion outcomes (Bartley & Fillingim, 2013; Campbell et al., 2010; Donovan, Taliaferro, Brock, & Bazargan, 2008; Hirsh et al., 2013; Nguyen et al., 2011; Mendenhall et al., 2014; Rao, Loganathan, Yeung & Mobbs, 2015; Rouben et al., 2011).

Methods

Study Design

The researcher conducted a prospective, longitudinal study and followed a cohort of patients for three months to observe how preoperative patient characteristics related to time to opioid cessation. Institutional Review Board approval was obtained, and all participants provided written informed consent. No external funding was used to conduct the study.

Setting and Participants

The study was conducted at a 347-bed, acute-care, multi-specialty, community hospital in the U.S. Southern region. The researcher used consecutive sampling and invited all patients who met eligibility criteria to enroll. Enrollment and first-round data collection commenced in May 2016 and continued through November 2016, excluding a two-week period in July 2016 when the researcher was unavailable. Second-round data collection commenced in August 2016 and continued through February 2017. Adult patients (i.e., 18 years of age or older) admitted for elective lumbar fusion, who were able

to read at a minimum of a sixth-grade reading level, and write and speak English were eligible to participate. Patients admitted to the study site for emergent lumbar fusion were excluded because the researcher was unable to obtain patient-reported preoperative data. Patients undergoing lumbar fusion for a severe underlying systemic or highly specific disease, including cancer, spinal infection, unstable fracture, and inflammatory spondylopathy, were excluded because of the unknown effect of these conditions on study variables.

Procedure and Instruments

On the morning of surgery, participants completed a demographic and clinical variables questionnaire and the Pain Catastrophizing Scale (PCS). The demographic and clinical variables questionnaire was developed by the researcher, and includes six items from the National Institutes of Health (NIH) recommended uniform data set for studies of patients with chronic back pain (Deyo et al., 2014). The instrument can be completed in three minutes, and requires a sixth-grade reading level. Age was measured in years; sex was dichotomized (i.e., male/female); employment status was categorized using 11 employment descriptors; educational level was categorized using nine educational descriptors. Preoperative pain intensity was defined as the mean intensity of low back and leg pain during the seven days immediately preceding lumbar fusion and was operationalized using the Numeric Pain Rating Scale (NPRS). The NPRS is the most common measure of pain intensity among patients with chronic low back pain (Chapman et al., 2011). This scale was used to rate pain in the low back and lower extremities

because both symptoms are surgical criteria for lumbar fusion (ISASS, 2011; NASS, 2014). Preoperative opioid use was defined as the use of prescribed opioids for low back pain prior to lumbar fusion and was dichotomized (i.e., yes/no). Pain catastrophizing was conceptually defined as, "an exaggerated negative mental set brought to bear during actual or anticipated pain experience" (Sullivan et al., 2001, p. 53). Pain catastrophizing was operationalized using the 13-item PCS. The PCS can be completed and scored in 5 minutes, and requires a sixth-grade reading level (Sullivan, 2009). When completing the PCS, respondents are asked to reflect on past painful experiences and indicate the degree to which they have experienced each of the 13 thoughts or feelings on a scale ranging from 0 ("not at all") to 4 ("all the time"). The PCS yields a summed score ranging from 0-52, with higher scores indicating greater pain catastrophizing. Validity of the PCS in patients undergoing lumbar fusion has been supported by replication of a three-factor solution using exploratory factor analysis that matched the three theorized dimensions of pain catastrophizing (i.e., rumination, magnification, and helplessness; Papaioannou et al., 2009). Reliability of the PCS in patients undergoing lumbar fusion has been supported by internal consistency evaluation that yielded a Cronbach's coefficient $\alpha = .94$ (Papaioannou et al., 2009). This α-value exceeds the recommended internal consistency threshold (i.e., $\alpha > .80$) for existing instruments (Polit & Beck, 2012).

Three months following surgery, participants self-reported prescription opioid use via telephone interview. Opioid use was quantified as the number of weeks from lumbar fusion until the first of five consecutive days of zero opioid use (Carroll et al., 2012).

The duration of the follow-up period allowed sufficient time for surgical wound healing, initial consolidation of the fusion, and liberalization of activity restrictions (Greenwood, McGregor, Jones, & Hurley, 2015). In addition, opioid use is typically not considered long-term until it has exceeded three months (Chou et al., 2009; Nuckols et al., 2014). Participants who reported continued use of prescribed opioids for low back or leg pain at 12 weeks, with no period of at least five consecutive days of zero opioid use, were considered positive for prolonged, postoperative opioid use.

Potential for Study Bias

Several steps were taken prior to data collection to lessen threats to the study's internal validity. The threat of selection bias was controlled by a sampling plan that invited every patient who met eligibility criteria to enroll in the study. The threat of social desirability bias was minimized by data collection methods designed to elicit accurate responses. Social desirability bias arises when participants respond to research questions in a manner they perceive to be aligned with prevailing social values or researcher expectations (Polit & Beck, 2012; Waltz, Strickland, & Lenz, 2010). Given the vast coverage of the opioid epidemic in the lay media, the use of self-report to measure opioid use threatened the study's internal validity because it provided an opportunity for participants to misrepresent their postoperative opioid use. To minimize the risk, the researcher collected postoperative data via telephone because telephone interviews are less likely than face-to-face interviews to elicit socially desirable responses (Waltz et al., 2010). The researcher also avoided fixed-response questions (i.e., true/false

and yes/no) and language that could be interpreted by a participant as a choice between a socially desirable option and a socially undesirable option (Waltz et al., 2010).

The researcher recognized that the use of a single study site posed a threat to the study's external validity. A single study site increased the risk of a homogeneous cohort that would not represent the target population of all people undergoing elective lumbar fusion in the U.S. Nevertheless, the study design required that the researcher be present to conduct face-to-face meetings with potential participants and precluded the use of additional sites.

Sample Size Calculation

Estimation of effect size and calculation of required sample size were based on the results of previous studies of patients undergoing lumbar fusion. Papaioannou et al. (2009) reported the Pearson's (r) correlation between PCS scores and opioid dose was r = .53, and the squared multiple correlation (R^2) that describes how well a combination of independent variables predicted opioid dose was R^2 = .35. These correlation values correspond to large effect sizes (i.e., r > .50; R^2 > .30; Cohen, 1992; Leech, Barrett & Morgan, 2015). Thus, the researcher used a power analysis table and identified a sample size of n = 41 to be the minimum sample size required to detect a large effect using multiple regression and seven independent variables with power = .80 and α = .05 (Polit & Beck, 2012). Prior prospective studies of postoperative opioid use reported enrollment rates of 77% (Papaioannou et al., 2009) and 81% (Carroll et al., 2012). Thus, the researcher planned to oversample and recruit at least 55 participants. This number of

participants was expected to yield an adequately powered study, even if some participants were lost to attrition.

Statistical Analysis

All data analyses were conducted with Statistical Package for the Social Sciences (SPSS), version 24, and statistical significance was set at $p < .05$. Descriptive statistics, recruitment and retention rates, and Cronbach's α present a summary of the cohort and enable an assessment of sample representativeness and the study's methodology. Multiple regression analysis determines whether a combination of preoperative patient characteristics predicts time to opioid cessation. Prior to commencing multiple regression, the researcher determined that the conditions and assumptions for its use, including the absence of multicollinearity and the existence of linear relationships between each of the independent variables and the dependent variable, had been met. The researcher used the ENTER method of multiple regression, which simultaneously enters all independent variables into the analysis, because the conceptual framework theorizes that all independent variables influence the dependent variable.

Results

Participants

The researcher enrolled 57 participants (see Figure M.1). No patients were excluded on the basis of inclusion/exclusion criteria and no patients declined to participate. Only 3% of data were missing. The most common reasons for missing data were a repeat surgery due to a postoperative complication within the follow-up period

and participant failure to respond to follow-up telephone calls. Little's Missing Completely at Random (MCAR) Test indicated that data were missing completely at random. Since the amount of missing data was small (i.e., < 5%; Duffy, 2006) and there was no discernible pattern to the missing data, the researcher used pairwise deletion for statistical analysis. This approach selectively deletes participants with missing data on a variable-by-variable basis rather than eliminates all participants with any missing data from statistical analysis (Polit & Beck, 2012).

Preoperative Data

Preoperative data are presented in Tables M.1 and M.2. The mean age of the cohort was 63.47 (SD = 11.05), and more than half of participants (54.4%, *n* = 31) were retired. Two-thirds (66.7%, *n* = 38) of participants were female, and 25% (*n* = 14) had at least a Bachelor's degree. More than 60% of participants (61.4%, *n* = 35) were using opioid pain relievers prior to lumbar fusion. The mean preoperative pain intensity was 7.65 on a scale of 1 to 10 (SD = 1.87), and the mean PCS score was 28.85 (SD = 14.72). Internal consistency evaluation of the PCS indicated a Cronbach's $\alpha = .951$, which suggests that the 13-items on the PCS are all measuring the same the attribute.

Postoperative Data

Postoperative data are presented in Tables M.3 and M.4. The mean time to opioid cessation was 7.76 weeks (SD = 4.47). The prevalence of prolonged, postoperative opioid use was 44.0% (*n* = 22). That is, 44.0% of participants reported continued opioid

use for low back or leg pain three months following lumbar fusion, with no more than five opioid-free days since surgery.

Multiple Regression Analysis

Exploratory data analysis revealed that the frequency distribution of weeks to opioid cessation appeared negatively skewed with a spike at 12 weeks. However, the absolute value of the skewness statistic (-.408) was less than 1, which indicated that the distribution was at least approximately normal (Morgan, Leech, Gloeckner & Barrett, 2013). There were no outlying values on the boxplot of weeks to opioid cessation.

Multiple regression analysis tested the hypothesis that preoperative patient characteristics predict time to opioid cessation. Prior to executing multiple regression, the researcher collapsed and recoded educational level and employment status. This was done so that each category of the two variables had a sufficient number of participants to allow statistical analysis (Morgan et al., 2013). Educational level was dichotomized into one variable with two categories: less than college degree and Associate's degree or higher. Employment status was collapsed into three variables, each with two categories, and coded using dummy coding. The new variables were: (a) working and not working, (b) disabled and not disabled, and (c) retired and not retired. Working included participants who were working; disabled included participants who were on sick leave or disabled due to back pain or other reasons; and retired included participants who were retired or keeping house.

Multiple regression can be sensitive to outlying values and multicollinearity. Thus, one participant, aged 22 years, was excluded from analysis because the boxplot of the age variable identified the participant as an outlier. No participants were eliminated due to multicollinearity because statistical analysis indicated that all tolerance values were greater than 0.1 and all variance inflation factor (VIF) values were less than 10, which were the cutoff points adopted by the researcher. The correlation matrix showed significant correlations between weeks to opioid cessation and two independent variables. Weeks to opioid cessation was highly correlated with preoperative opioid use (r = .458, p = .000), and moderately correlated with sick leave or disabled (r = .290, p = .022). Table M.5 summarizes the results of multiple regression analysis. The model summary showed R^2_{adj} = .179 and indicated that 18% of the variance in weeks to opioid cessation was explained by the combination of independent variables. The ANOVA indicated that the relationship between the independent variables and weeks to opioid cessation was linear and that the combination of the eight independent variables significantly predicted weeks to opioid cessation, $F(8, 38) = 2.254$, p = .044. The coefficient indices identified preoperative opioid use as the only independent variable that significantly predicted weeks to opioid cessation, β = .466; p = .005. A residual scatterplot, histogram of standardized residuals, and normal probability-probability (P-P) plot confirmed that the assumptions of linearity, normality, and homoscedasticity had been met.

Discussion

The benefits of prescribed opioids in reducing acute, postoperative pain are well-established, but there is little evidence that opioids are safe or effective in treating chronic pain (Dowell, Haegerich, & Chou, 2016). Nevertheless, 44.0% (n = 22) of participants reported continued opioid use three months following lumbar fusion. This rate is consistent with previous reports of prolonged opioid use following lumbar fusion that ranged from 31% at six months (Rouben et al., 2011) to 76% at three months (Nguyen et al., 2011).

This is one of only a few studies that attempted to prospectively evaluate the relationship between preoperative patient characteristics and prolonged opioid use following lumbar fusion. Bivariate analysis revealed that weeks to opioid cessation was highly correlated with preoperative opioid use, and moderately correlated with disability. However, when all patient characteristics were examined in combination using multiple regression analysis, preoperative opioid use emerged as the only significant predictor of weeks to opioid cessation.

The finding that preoperative opioid use predicts time to opioid cessation adds to the growing body of knowledge about how preoperative opioid use influences postoperative opioid use. An analysis of the health insurance claims of more than 36,000 surgical patients found that patients who received an opioid prescription in the 30 days prior to surgery had almost 2-fold higher odds of prolonged opioid use after surgery, even after adjusting for covariates (adjusted Odds Ratio [aOR], 1.93; CI, 1.71-2.19; Brummett et al., 2017). Another study of more than 500 surgical patients found that preoperative

opioid use significantly predicted opioid use six months following orthopedic surgery (OR, 1.07, $p < .001$; Goesling et al., 2016). Preoperative opioid use has also been found to predict non-opioid factors. Among patients undergoing spinal surgery, preoperative opioid use has been associated with depression and anxiety (Armaghani et al., 2013), increased length of stay (Armaghani et al., 2016), decreased patient-reported health status (Lee et al., 2014), and greater pain intensity and disability (Lee et al., 2014; Villavicencio, Nelson, Kantha, & Burneikiene, 2017).

Since preoperative opioid use was considered a biological factor within the framework of the biopsychosocial model, the finding that it was the only variable that predicts time to opioid cessation appears to contradict the study's conceptual model. However, the characterization of opioid use as a biological factor may have been overly simplistic. Preoperative opioid use was characterized as a biological factor because opioids are pharmacological agents that exert physiological effects on the human body. However, the close association of opioids to mental health disorders suggests that their use is not exclusively driven by biological factors. For example, people with opioid use disorders display compulsive and prolonged self-administration of opioids in the absence of biomedical indications (American Psychiatric Association, 2013). Furthermore, both prescription opioid use and chronic low back pain have been associated with psychological factors. People using opioid pain relievers have high rates of psychiatric disorders and self-reported symptoms of depression and anxiety (Goesling et al., 2015; Merrill et al., 2012; Quinn et al., 2017; Wasan et al., 2015). Patients with low back pain

have high rates of depression, anxiety, and somatization (Calvo-Lobo et al., 2017; Christensen et al., 2015; Farajirad, Tohidi, & Farajirad, 2016). These findings underscore the complexity of opioid use and suggest that categorizing preoperative opioid use solely as a biological factor may have been an error.

The current results notwithstanding, the use of the biopsychosocial model for the study of prolonged opioid use is supported by other studies. Among patients undergoing elective spinal surgery, greater preoperative opioid use, greater anxiety, more invasive surgery, and revision surgery were significantly associated with decreased prevalence of opioid independence 12 months following surgery (Armaghani et al., 2014). Among patients undergoing a mix of surgical interventions, preoperative opioid use, self-perceived risk of addiction, and depressive symptoms each independently predicted prolonged opioid use (Carroll et al., 2012). Among patients presenting for care at a U.S. Veterans Affairs Medical Center, preoperative opioid use was identified as the strongest independent predictor of opioid use three months after knee arthroscopy (Rozet et al., 2014). In addition, among the subset of that sample who were not taking opioids prior to surgery, post-traumatic stress disorder was also associated with prolonged opioid use (Rozet et al., 2014). The results of these studies all support the continued use of the biopsychosocial model for the study of prolonged opioid use following surgery. Furthermore, it is possible that the current study failed to identify psychological and/or social predictors of prolonged opioid use due to the small cohort.

Limitations and Strengths

The study enrolled 57 participants based on the expectation of a large effect size. Even after the researcher transformed two independent variables and increased the number of predictors to eight, a power analysis table indicated that a cohort size of $n = 44$ would detect a large effect (Polit & Beck, 2012, p. 442). For this reason, the study was considered adequately powered. In addition, multiple regression detected a large effect ($R^2 = .322$; Leech et al., 2015). Nevertheless, recruiting a sample based on the detection of a large effect left the study too underpowered to detect small and medium effects. It is possible that a larger cohort would have identified additional predictors of weeks to opioid cessation. Another weakness of the study was the omission of factors from multiple regression that are known to influence patient outcomes. Surgical indication, depression, emotional health, legal representation, smoking, and payer status (i.e., workers' compensation benefits versus no workers' compensation benefits) have been shown to influence pain intensity, functional disability, and return to work following lumbar fusion (Adogwa et al., 2012; Nguyen et al., 2011; Soriano et al., 2010; Rao et al., 2015; Rouben et al., 2011). However, none of these factors was explored as possible predictors of prolonged opioid use due to resource constraints. Recruiting participants from a single site is also a weakness because it limits the generalizability of findings. However, the advanced age and female preponderance of the cohort suggest that the demographics of the sample are similar to the demographics of the population of all

patients undergoing elective lumbar fusion in the U.S. (Deyo et al., 2010; Pannell, Savin, Scott, Wang, & Daubs, 2015; Rajaee, Bae, Kanim, & Delamarter, 2012).

The longitudinal design, sampling plan, and high rates of enrollment, retention, and follow up were all strengths of the study. The longitudinal design ensured that the independent variables were measured three months prior to the measurement of the dependent variable. This eliminated the threat of temporal ambiguity that can accompany cross-sectional designs. Consecutive sampling increased the likelihood of a representative sample and decreased the threat of sampling bias. The 100% enrollment rate strengthened sample representativeness because no eligible patients declined to participate. The high rates of retention and follow up resulted in a low percentage of missing data. With only 3% of data missing, the possibility that missing data biased results is low.

Recommendations for Further Study

The current study identified a high prevalence of prolonged opioid use following lumbar fusion and characterized preoperative opioid use as a risk factor for postoperative opioid use. Additional research is needed to strengthen these findings and to develop patient screening tools and opioid-minimizing pain management strategies.

1. Forty-four percent of participants (n = 22) reported prescribed opioid use at the study's endpoint (i.e., three months). Studies with longer follow-up periods will more precisely quantify the duration of prolonged opioid use following lumbar fusion.

2. Preoperative patient characteristics accounted for only 18% of the variance in time to opioid cessation. Studies examining different independent variables may identify additional risk factors for prolonged opioid use, particularly psychosocial factors and potentially modifiable risk factors.
3. Multiple regression analysis identified one significant predictor of weeks to opioid cessation. Studies with larger samples and greater statistical power may identify additional predictors of weeks to opioid cessation.
4. Once risk factors for prolonged, postoperative opioid use are confirmed through research examining additional predictors with larger cohorts, screening tools should be developed to assist clinicians in identifying at-risk patients. Such tools would require psychometric evaluation to ensure sufficient evidence of reliability and validity prior to use.

Conclusions and Implications for Clinical Practice

The results of the study add to the growing body of knowledge about prescription opioid use in patients undergoing lumbar fusion. Despite the ongoing opioid epidemic, 61.4% of participants (n = 35) used prescribed opioids prior to surgery, and 44.0% of participants (n = 22) used prescribed opioids for at least three months following surgery. Of the eight biological, psychological, and social variables examined, preoperative opioid use was the sole significant predictor of time to opioid cessation. This finding suggests that screening patients for preoperative opioid use will help nurses and nurse practitioners identify which patients are at risk for prolonged opioid use following lumbar fusion. The

study's finding also suggests that it may be possible to reduce the prevalence of prolonged, postoperative opioid use by reducing preoperative opioid use. Such a reduction will require a commitment from all healthcare providers to decrease their reliance on opioid-based interventions in favor of strategies that recognize the biopsychosocial contributors to the pain experience and promote safer and more effective pain management.

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Table M.1

Summary of Age, Preoperative NPRS scores, PCS Scores

Variable	Value	
Age (*n* = 57)		
Mean (SD)	63.47	(11.05)
Median (range)	65.00	(22-82)
Preoperative NPRS scores (*n* = 57)		
Mean (SD)	7.65	(1.87)
Median (range)	8	(2-10)
PCS scores (*n* = 55)		
Mean (SD)	28.85	(14.72)
Median (range)	30.00	(0-52)

Table M.2

Summary of Sex, Preoperative Opioid Use, Employment Status, and Educational Level

Variable	Value	
	Number	Percent
Sex (*n* = 57)		
Male	19	33.3
Female	38	66.7
Preoperative opioid use (*n* = 57)		
No	22	38.6
Yes	35	61.4
Employment Status (*n* = 57)		
Working now	11	19.3
Sick leave or maternity leave	2	3.5
Disabled due to back pain, permanently or temporarily	10	17.5
Disabled for reasons other than back pain	1	1.8
Retired	31	54.4
Keeping house	2	3.5

Table M.2 (continued)

Summary of Sex, Preoperative Opioid Use, Employment Status, and Educational Level

Variable	Value	
	Number	Percent
Educational level (select highest attained; n = 56)		
No high school diploma	2	3.6
High school graduate or GED	12	21.4
Some college, no degree	20	35.7
Occupational/technical/vocational	3	5.4
Associate's degree	5	8.9
Bachelor's degree	12	21.4
Master's degree	1	1.8
Professional school degree (e.g., MD, DDS, JD) or doctoral degree (PhD, EdD)	1	1.8

Table M.3

Summary of Weeks to Opioid Cessation

Variable	Value	
Weeks to opioid cessation (n = 50)		
Mean (SD)	7.76	(4.47)
Median (range)	9.0	(1-12)

Table M.4

Summary of Prolonged, Postoperative Opioid Use

Variable	Value	
	Number	Percent
Prolonged, postoperative opioid use (n = 50)		
Positive	22	44.0
Negative	28	56.0

Table M.5

Summary of Multiple Regression Analysis Predicting Weeks to Opioid Cessation

Predictor	Unstandardized Coefficients		Standardized Coefficients		
	B	Std. Error	Beta (β)	*t*	*p*
Age	-.076	.074	-.165	-1.032	.308
Female[a]	1.350	1.408	.145	.959	.344
Preoperative pain intensity	-.224	.413	-.092	-.544	.590
Preoperative opioid use[b]	4.230	1.430	.466	2.958	.005
PCS score	-.008	.049	-.027	-.167	.868
Associate's degree or higher[c]	1.539	1.309	.167	.342	.734
Working	.698	2.038	.061	.635	.529
Disabled	1.031	1.623	.099	1.176	.247
Constant	10.292	6.238		1.650	.107

Note. $F(8, 38) = 2.254$, $p = .044$, $R^2_{adj} = .179$.
[a]Compared to Male. [b]Compared to no preoperative opioid use. [c]Compared to less than college degree.

Figure M.1. Flow Diagram of Study Participants