PSYCHOLOGICAL DISTRESS IN PATIENTS WITH ORTHOPAEDIC TRAUMA INJURIES

By

ROBERT TARKINGTON BARNES

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To Leslie, Mr. Deuce, and above all, Miss Juan. She would certainly not stand, or sit, for anything less. Lovingly, each of you sprang into my life.

I knelt down and put my arms around them. I knew that if it hadn't been for their loyalty and unselfish courage I would have probably been killed by the slashing claws of the devil cat. 'I don't know how I'll ever pay you back for what you've done,' I said, 'but I'll never forget it.'

-Wilson Rawls, *Where the Red Fern Grows*
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The aim of this investigation was to examine the prevalence, magnitude and contributors of psychological distress in patients suffering from orthopaedic trauma injuries. The absence of research on the topic is unexpected considering the multiple experts today’s Level-I trauma facilities have at their disposal, and the millions of trauma injuries occurring annually. As such, 50 consecutive participants who met inclusion criteria and had incurred orthopaedic trauma injuries were administered the state-version of the State-Trait Anxiety Inventory (STAI) and the Beck Depression Inventory Second Edition (BDI-II) following their hospital discharge at a scheduled in-clinic trauma appointment. Patients with severe orthopaedic trauma injuries were asked to participate. “Severe” was defined as patients who sustained multiple fractures, received more than one surgical procedure, and stayed multiple days in the hospital while rehabilitating their orthopaedic trauma injuries.

Results indicated that the prevalence and magnitude of psychological distress in the study cohort far exceeded norms established in the general population. Of note, each participant experienced elevated levels of anxiety (STAI = 63.2 ± 7.1), while 92% of the study cohort suffered from moderate or severe depression (BDI-II = 29.8 ± 8.6).
In all, 94% of patients self-reported that they believed psychological distress was “caused” or “exacerbated” by their orthopaedic trauma injury. Due to the prevalence and magnitude of psychological distress in the study cohort, no significant differences in anxiety or depression scores were found for those with a prior history of psychological distress compared to participants without a history. Furthermore, no correlation was evidenced between Injury Severity Scores (ISS) and anxiety or depression. Unexpectedly, participants receiving treatment for their psychological distress did not differ from participants who did not. Finally, significant negative correlations were evidenced between social support and anxiety and social support and depression. Participants with less social support as measured by the Multidimensional Scale of Perceived Social Support (MSPSS) experienced greater anxiety and depression scores. Considering the prevalence and magnitude of psychological distress in the study cohort, traumatologists should consider adopting an interdisciplinary team to help restore optimal physical recovery, to assist in ameliorating psychological distress, and to provide empathetic and complete care.
CHAPTER 1
INTRODUCTION

From the moment of injury, the wheels of trauma care are set in motion with two overarching goals acting as guidance: 1) increasing the likelihood of the patient’s survival, and 2) minimizing the lasting physical effects of injury. In orthopaedic trauma care, the initial medical response is focused on the physical injuries that warranted hospital admission. Advancements in technology, improvements in medical training and innovative treatment procedures have markedly improved patients’ physical recovery. Indeed, the coordination and continuity that now exists among those providing physical care for orthopaedic trauma patients is impressive. First responders, traumatologists, hospital staff and rehabilitation scientists work in concert to attain optimal recovery.

The process of rehabilitating an orthopaedic trauma patient to his or her pre-injury level of functionality is complex. Variables that extend beyond one’s physical needs, such as psychological wellness, are now acknowledged as integral components of the rehabilitation process by movement scientists.¹ Addressing psychological needs, as discussed in the Institute of Medicine model (IOM), helps transition the orthopaedic trauma patient from a state of disability to ability. In part, this is achieved by ameliorating the psychological impact of the traumatic incident. Equally important, addressing psychological distress during rehabilitation may diminish the likelihood of the onset of comorbidities triggered by affective disorders (e.g., heart attacks).² ³

Anxiety and Depression in the General Public

The National Institute of Mental Health (NIMH) estimates that over 40 million individuals suffer from depression, anxiety and related disorders in the United States, while the Centers for Disease Control and Prevention (CDC) approximate that roughly
twenty-percent of Americans are affected.\textsuperscript{4,5} The global picture is equally as bleak, with the World Health Organization predicting that by the year 2020, the number of individuals suffering from psychological distress will be outnumbered solely by those suffering from heart disease.\textsuperscript{6,7}

The financial toll of psychological distress in the general public is also significant. Previous work estimates that anxiety and depression exact a substantial toll on the U.S. economy by costing $42.3 billion and $83.1 billion, respectively.\textsuperscript{8} Specifically, $26.1 billion of the costs attributed to depression were spent on direct medical treatment, while suicide-related mortality costs resulted in $5.4 billion annually. With the increasing prevalence of psychological distress in the U.S., this cost estimate will likely increase dramatically within the next decade.

**Statement of the Problem**

It is likely that few incidents are as likely to serve as a catalyst for creating psychological distress, or exacerbate already present psychological symptomology, as sustaining an orthopaedic trauma injury. In the U.S., over 2.8 million trauma patients are hospitalized annually.\textsuperscript{9} Accordingly, to keep pace with a shifting patient demographic, orthopaedic trauma teams need to be aware of potential effects of psychological distress on orthopaedic surgery outcomes and functional recovery.

While the physical effects and medical treatment for orthopaedic trauma patients are well documented, the psychosocial mechanisms that underpin patients' reaction to orthopaedic trauma injuries remain unclear. Scant research exists documenting the post-injury experiences of orthopaedic trauma patients and their psychological well-being. Existing evidence suggests that the psychological disposition following an orthopaedic trauma injury may accurately predict the recovery response, and/or the
likelihood of persistent physical disability.\textsuperscript{10,11} It is possible that the surgical status of the patient may affect the psychological state as well, as multiple surgeries may be more stressful than singular encounters, but this is not yet known.

Estimates range as high as 45\% of orthopaedic trauma patients experiencing psychological distress that is clinically significant as well as psychological wellness being compromised out to two years post-hospital discharge.\textsuperscript{12,13} Complexity of injury may also exacerbate psychological distress, as patients with open fractures and severe lower-limb injuries exhibit higher depression scores than those with other injuries.\textsuperscript{10,11,14}

It is unimaginable that a patient’s physical injuries would remain untreated for 24 months following injury. But, this is frequently the case with patients plagued with psychological distress, as orthopaedic trauma patients often remain undiagnosed, untreated or ignored for multiple years following their return to society.\textsuperscript{10} Finally, the updated IOM model was published in 1997 and advocated the inclusion of psychological variables for progress tracking during rehabilitation and for research outcomes.\textsuperscript{1} Yet currently, the prevalence, magnitude, and additional contributors to psychological distress after orthopaedic trauma are not clear. Understanding the relationships between psychological distress, injury severity, multiple surgeries and the trajectory of recovery would help optimize rehabilitation planning and long-term functional outcomes after an orthopaedic trauma injury.

**Specific Aims**

To assess the degree to which orthopaedic trauma patients experienced depression, anxiety and negative affect multiple specific aims and hypotheses were developed. The specifics aims planned were threefold:
1. To determine the prevalence of psychological distress in patients who experienced an orthopaedic trauma injury.

2. To investigate the magnitude of psychological distress in patients who experienced an orthopaedic trauma injury.

3. To investigate the contributors (e.g. social support, prior psychiatric history) that ameliorate or exacerbate psychological distress levels in patients who experienced an orthopaedic trauma injury.

**Hypotheses**

The below hypotheses contribute to a greater understanding of the prevalence, magnitude and contributing factors associated with psychological distress in orthopaedic trauma patients.

With respect to Specific Aim 1 - Prevalence, research hypotheses include:

1. Anxiety and depression will be considerably greater in an orthopaedic trauma cohort compared to that of the general public.

2. Patients with no pre-injury history of anxiety and depression will self-report that their orthopaedic trauma injury “caused” their current psychological distress.

With respect to Specific Aim 2 - Magnitude, research hypotheses include:

3. Orthopaedic trauma injuries will cause significantly greater anxiety and depression in patients with a history of affective disorders compared to patients without.

4. Severity of orthopaedic trauma injury will be significantly associated with anxiety and depression.

With respect to Specific Aim 3 - Contributors, research hypotheses include:

5. Anxiety and depression would be significantly decreased in patients who have been treated for their symptomology, with “treatment” being defined as talk therapy and/or psychopharmacological medications. This will hold true, irrespective of the time elapsed between orthopaedic trauma patients’ injury and their data collection.

6. A significant correlation between social support and anxiety, and social support and depression will be evidenced. Orthopaedic trauma patients with greater social support will exhibit less psychological distress as measured by the MSPSS.
Significance

The dearth of research regarding psychological wellness on orthopaedic trauma outcomes is unfortunate. The absence of research regarding psychological wellness in orthopaedic trauma patients may have significant ramifications for orthopaedic trauma facilities basing their practices and procedures on evidence-based research. Insight into the psychological disposition of orthopaedic trauma patients may help shift the paradigm of how traumatologists are trained and how they interact with and treat their patients. A greater understanding may bring compassion to the examination room, reframing the accepted boundaries of current orthopaedic trauma practices by re-establishing the link between a healthy mind and a healed body.

Historically, metrics such as psychological wellness have not been focused on in orthopaedic trauma care. Now, there is a growing need for traumatologists and care teams to provide optimal, efficient, empathetic and complete care. With an extreme shortage of orthopaedic trauma surgeons and decreased time for high quality supplemental training (e.g., psychological and communication) a deficit in patient care has developed. A growing population coupled with a dramatic increase in patient volume supports the need for optimal orthopaedic trauma care. As such, a premium should be placed on adjuvant training that traumatologists receive regarding factors that have been traditionally ignored yet may impact outcomes. Finally, quality research examining the psychological characteristics and distress levels of orthopaedic trauma patients will help identify areas for clinical care improvement.

Definition of Terms

Below follows operational definitions of the terms used in the study. Psychological terms were defined using the Diagnostic and Statistical Manual of Mental
Disorders Fourth Edition Text Revision (DSM-IV-TR) and the psychological questionnaires used in the experiment.\textsuperscript{15–20} Trauma was defined by Robinson’s text on orthopaedic rehabilitation.\textsuperscript{21}

**AFFECT.** A pattern of observable behaviors that is the expression of a subjectively experienced feeling state (emotion). Common examples of affect are sadness, elation, and anger. In contrast to mood, which refers to a more pervasive and sustained emotional “climate,” affect refers to more fluctuating changes in emotional “weather.”

**ANHEDONIA.** The inability to find pleasure from activities one previously found enjoyable.

**ANXIETY.** The apprehensive anticipation of future danger or misfortune accompanied by a feeling of dysphoria (dissatisfaction) or somatic symptoms of tension. The focus of anticipated danger may be internal or external.

**DEPRESSION.** A feeling associated with significant despondency and dejection, accompanied by feelings of hopelessness and inadequacy.

**NEGATIVE AFFECT.** The degree to which an individual feels distressed, upset, guilty, scared, hostile, irritable, ashamed, nervous, jittery, and afraid.

**POSITIVE AFFECT.** The degree to which an individual feels interested, excited, strong, enthusiastic, proud, alert, inspired, determined, attentive, and active.

**SOCIAL SUPPORT.** The physical and emotional comfort provided family, friends, and/or a significant other.

**STATE-ANXIETY.** The current state of one’s anxiety that may fluctuate from time-to-time.

**Trait-Anxiety.** The relatively enduring characteristics of anxiety that a person possesses, or in other words, one’s “general” or enduring level of anxiety.

**TRAUMA.** Injury to the body caused by a sudden exposure to environmental energy that is beyond the body’s resilience.
CHAPTER 2
REVIEW OF LITERATURE

Orthopaedic Trauma Defined

Robinson\textsuperscript{21} provides an operational definition of the term \textit{trauma}. He defines it as, “damage to the body caused by a sudden exposure to environmental energy that is beyond the body’s resilience.” The origin of the word \textit{trauma} provides a simpler explanation, as it stems from the Greek word for \textit{physical injury}. The process of caring for patients with orthopaedic trauma injuries also has a long history and has been practiced for thousands of years. Evidence documents ancient Egyptians and Greeks performing medical procedures that are now commonplace in today’s finest Level-I trauma centers, such as amputations and fracture care.\textsuperscript{21}

As stated by Cole and colleagues,\textsuperscript{22} the inherent longing for a greater understanding of the rehabilitation process, as well as the intrinsic need for humankind to advance from disability to ability has resulted in marked improvements in interdisciplinary rehabilitation. Ironically, it has been history’s darkest and most disturbing moments (such as World War I and World War II) that have catalyzed the development of rehabilitation science. Indeed, the same appears to hold true regarding orthopaedic trauma injuries and psychological distress, as by definition, research conducted on this topic, is advanced via tragic circumstances.

Traumatic accidents prompt a chain of events that may be perceived as novel (e.g. transportation by ambulance) and stressful (e.g. invasive medical procedures).\textsuperscript{23} Said events may result in elevated levels of distress in healthier patients not suffering from the deleterious effects of serious traumatic injuries. Thus it can be argued, that a novel experience, coupled with pain, fear, and the uncertainty associated with injury
might be the perfect storm for a patient’s subsequent psychological distress. Before examining the scant peer-reviewed articles germane to orthopaedic trauma injuries and psychological distress, it is necessary to provide a framework for understanding how rehabilitation scientists might view the interaction of orthopaedic trauma injuries, psychological distress and disability. To this end, the review of rehabilitation science models is useful.

**Examination through the Lens of Rehabilitation Science**

Advancements in the field of rehabilitation science over the last 50 years are impressive. Rehabilitation scientists have exponentially expanded the breadth of knowledge specific to their scientific domain, created and increased the efficaciousness of treatment modalities and have assisted greatly in altering society’s perception and treatment of the disabled and injured. Despite these advances, scientists and clinicians have historically overlooked the restoration of mental health as part of the rehabilitative process. Multiple newer rehabilitation models now make amends for this oversight and provide a solid structure for conducting psychological research and clinical interventions. As such, a review of rehabilitation science models follows.

**The Evolution of Rehabilitation Science Models**

When looking objectively at the creation and subsequent evolution of models in rehabilitation science, Nagi\(^{24,25}\) is considered the founding father, as his quintessential works predate his peers. His efforts resulted in the creation of an influential model consisting of four domains. These domains are: *active pathology*, *impairment*, *functional limitation* and *disability*. In order to better understand the model, examples of each domain are provided.
Active pathology refers to basic science research such as clinicians conducting research on problems specific to the molecular or cellular level. The next domain in Nagi’s model is referred to as impairment. Expanding in scope, impairment pertains to an organ or organ systems. It may also include an individual’s loss of mental, physiological, or biomechanical functions. Functional limitation is the third construct within Nagi’s model and may best be summed up as an individual’s “hampered ability” to perform a given task. The final domain in the Nagi model is referred to as disability, and differs from impairment, in that it applies to social rather than organismic functioning. In essence, disability is the composite of multiple factors impacting the individual within an ecologically valid context. It is within this domain that the study of psychological distress and patients suffering from orthopaedic trauma injuries would fall.

Nagi’s work was revolutionary in that it provided a springboard for rehabilitation scientists to advance their work. As expected, and largely due to being one of the earliest attempts at creating a model, Nagi’s work has been criticized. Nagi’s critics argue that his model fails to create a, “framework of four distinct but interrelated concepts” as he claims. This is frequently debated, as the model’s ability to delineate where one domain begins and another ends is not obvious to several scholars. Moreover, it has been suggested that Nagi fails to recognize the multidirectional nature of the rehabilitation process. This becomes increasingly evident when more recent and comprehensive models are directly compared to Nagi’s work.

The International Classification of Impairments, Disabilities, and Handicaps (ICIDH) was spawned by work that was being conducted in Europe by the World Health Organization. This model is similar to Nagi’s in that it differentiates between three
distinct yet related dimensions - *impairments, disabilities, and handicaps*. As discussed by Jette\textsuperscript{26}, this was intended to produce an etiological framework for classifying disabilities. Critics highlight the inability of the model to account for environmental factors as a shortcoming. Thus, the International Classification of Functioning, Disability and Health (ICF) was created. The ICF model presents a *biopsychosocial* view by recognizing contextual factors necessary to the rehabilitative process.\textsuperscript{26} Likewise, the term *health condition* was implemented to define the cause of the problem (such as orthopaedic trauma injury or disease). To date, the biopsychosocial view remains an often-used model for framing rehabilitation science research.

**The IOM Model’s Relevance to the Current Study**

As previously discussed, the IOM model is logically constructed and accounts for multiple shortcomings overlooked by Nagi and others.\textsuperscript{1} In particular, the creation of interwoven *transitional factors* allow for a more complete and useful model. The flexibility of movement between the domains within the IOM model aids it in being implemented as a framework for conducting science or rehabilitating patients. In sum, this subtle yet elegant revision takes into consideration that rehabilitation is a dynamic and fluid process.

Its utility is also evidenced in the *transitional factors* being presented in a simple and straightforward schematic. Equally important, the IOM contains a “*no disabling condition*”. This is appealing to the rehabilitation scientist, as increasing a patient’s “*quality of life*” is the guiding principle for those charged with bettering the outcomes of patients suffering from orthopaedic trauma injuries. Additionally, the bidirectional arrows within the IOM model, helps explain how research implications predict a trend away from *disability*, and toward *ability*, making it a useful model for investigating
psychological distress in orthopaedic trauma patients. In summary, the utility of a model is best judged by its ability to frame and predict aspects related to one’s given area of scientific inquiry. For these reasons, the IOM was adopted for the current research study. Next follows a review of the limited research studies specific to psychological distress in patients suffering from an orthopaedic trauma injury.

The Cornerstone Articles

Mattisson\(^{27}\) established the correlation between injury and psychological distress over three decades ago, yet little has been done to follow-up his originating work. Some exceptions do exist, but these studies are now either dated or answer tangential questions less germane to today’s traumatologist (e.g. “travel anxiety in patients who experience motor vehicle collisions”\(^{28,29}\)). While there are multiple challenges when conducting psychological research on patients with orthopaedic trauma injuries, peer-reviewed articles on the topic do exist. Thus, the cardinal papers relevant to orthopaedic trauma injuries and psychological distress are discussed next.

Complexity of Injury and Prevalence of Psychological Distress

Crichlow and colleagues\(^{12}\) examined 161 patients who incurred a traumatic orthopaedic injury, investigating how degree of injury and levels of depression are associated. Using the AO Fracture Classification, the Injury Severity Score (ISS) the Abbreviated Injury Scale (AIS) and Gustilo and Anderson score for open fractures, injury severity was correlated with depression scores obtained via the BDI. Patients’ levels of depression experienced were significant, especially when compared to those of the general public who experience depression at a level from 3.2% to 19.8%.

Fifty-five percent of trauma patients reported minimal depression, while 28% and 13%, were classified as suffering from depression ranging from moderate to severe,
respectively.\textsuperscript{12} Moreover, 45\% of individuals experienced psychological distress that was clinically significant. Additional findings indicated that open fractures were associated with higher depression scores, suggesting that complexity of injury may intensify psychological distress. The study was significant for multiple reasons. First, it attempted to differentiate psychological symptomology experienced. In this case, depression was examined as opposed to more global constructs such as “quality of life”. Second, it established prevalence rates for depression according to magnitude of symptomology, ranking depression along a continuum from low-to-severe.

McCarthy’s\textsuperscript{10} findings echoed that complexity of injury should be considered when understanding the relationship between poor mental health and orthopaedic trauma injuries, as severe lower-limb injuries were correlated with higher psychological distress. Not surprisingly, additional findings suggest that depression is not the lone affective disorder experienced by trauma patients. Evidence of anxiety and Posttraumatic Stress Disorder (PTSD) have been documented in patients treated by orthopaedic units.\textsuperscript{11} Of note, both disorders have been identified as strong predictors of poor physical recovery and ongoing disability.

**Time-Course of Psychological Distress in Orthopaedic Trauma Patients**

Level I evidence collected across multiple time periods regarding the psychological well-being of orthopaedic trauma patients require great resources and are limited. One exception is the ongoing work of Sodberg\textsuperscript{13} who analyzed data obtained from questionnaires such as the Short Form-36 (SF-36) and World Health Organization Disability Assessment Schedule II (WHODAS II). In a study of 105 patients admitted to a Level-I trauma center, data suggested that physical, social and emotional functioning were significantly compromised in patients long after their injury had occurred (6-weeks
post discharge and at one-year and two-year post-injury assessments). As such, it is evident that psychological distress can be both persistent and/or episodic in orthopaedic trauma patients.

An additional study providing Level I evidence echoed the findings of Sodberg. Five hundred sixty-nine trauma patients enrolled from eight Level-I trauma centers were administered the Brief Symptom Inventory (BSI), which quantifies levels of distress. Results indicated only a six-percent decrease in the number of individuals experiencing psychological distress two-years following their traumatic injury (from 48% to 42%). Furthermore, they found that two-years post injury only 22% of patients reported receiving psychological services of any kind to help ameliorate their psychological distress. Finally, Gustafsson, Windahl, and Blomberg examined psychological distress in patients with an acute hand injury. Patients completed questionnaires via mail at specific time increments following their injury with results suggesting that patients exhibiting psychological distress for longer than three months should be referred to appropriate psychiatric services.

**An Emerging Area of Inquiry in Other Countries**

Countries outside the U.S. are taking the lead in understanding the link between orthopaedic trauma injuries and psychological distress. While much of this research has methodological issues and reaches a lower level of evidence, worthwhile findings are being documented. In addition to previously mentioned articles such as Sodberg’s work in Norway and Gustafsson’s research in Sweden, multiple researchers in Japan, Korea and the UK appear to be interested in how lessening psychological distress can assist patients within their healthcare systems.
Japanese researchers have attempted to identify whether personality differences between orthopaedic and non-orthopaedic patients exist.\textsuperscript{31} Using the Maudsley Personality Inventory, orthopaedic and non-orthopaedic patients were found to have similar personalities, but orthopaedic trauma patients exhibited a higher percentage of “eccentric” behaviors such as neuroticism. Confounding the study was the fact that all personality inventories were collected after the injury, with no attempts made to capture the personality of their patients prior to the time of injury (through health records or other archival evidence).

A study in Korea compared patients with distal radius fractures who had undergone volar plating or cast immobilization.\textsuperscript{32} No difference was found in patient depression levels based on type of fracture care received. However, a secondary finding was clinically relevant as pain was identified as an accurate predictor of depression. Therefore, early screening for psychological distress in patients with high pain levels should be considered.

Similar results were found in a 2012 UK study conducted by Wood, Maclean and Palliester.\textsuperscript{33} The researchers found that anxiety and depression were correlated with patients’ pain ratings. A possible limitation of the study was the authors’ suggestion regarding the direction of the relationship between pain, anxiety and depression. As delineated in the BDI-II and DSM-IV, multiple somatic symptoms are intricately tangled within the construct that is depression. Thus, teasing out whether depression precedes pain, or vice versa is impossible via correlation analyses. Nonetheless, the observation that anxiety and depression might lead to a hypervigilant response to somatic symptomatology and subsequent lifestyle changes, is of importance to clinicians.
Gender Differences and Coping Skills

Gender differences have also been noted in how trauma patients experience psychological distress. In a large-scale prospective epidemiologic study examining multiple outcomes, Holbrook and Hoyt\textsuperscript{34} found that women have a significantly poorer quality of life compared to that of men, following an orthopaedic traumatic injury. This finding held true at multiple time intervals following the traumatic injury (six-, twelve- and eighteen- months post) and after multiple factors including severity of injury, location of injury, whether the injury was blunt or penetrating and whether the injury was intentional or unintentional were controlled for.

Examining how individuals cope following a traumatic injury is pertinent to those charged with rehabilitating patients. A meta-analysis by Littleton, Horsley and Nelson\textsuperscript{35} investigated coping strategies adopted by individuals who experienced a traumatic incident. While few of the thirty-nine articles included in the final analyses were specific to orthopaedic trauma injuries, a clear correlation between avoidance coping strategies and psychological distress was witnessed. Avoidance strategies can be defined as ignoring the stressor (e.g. orthopaedic trauma injury) or feelings that are resultant from the stressor (e.g. anxiety). Specific actions that would be classified as avoidant behaviors include withdrawing from others, ignoring the thoughts associated with the incident and denying that the stressor exists.\textsuperscript{36} A UK study echoed these findings as maladaptive coping strategies predicted poorer quality of life in 47 patients with external fixation devices, while adaptive coping strategies predicted a greater quality of life.\textsuperscript{37}

In general, distinct differences have been witnessed in the types of individuals who seek and are granted mental health help, but trends have also been evidenced in injured populations. Minorities, those with less education, lower incomes and addictive
behaviors are less likely to seek psychological assistance, or are more likely to be lost to follow-up (Narrow, 2000). Of note, to the best of our knowledge quality research conducted on the interplay among social support, psychological distress and orthopaedic trauma injuries have not been collected.

**Limitation in the Literature**

The volume of research conducted on patients experiencing orthopaedic trauma injuries is the most glaring limitation when reviewing the literature. The quality of experimental design and depth of inquiry in the aforementioned research were also disparate. Some studies appeared to be executed with a more watchful eye and rigorous design. Yet others were ambiguous regarding crucial details such as inclusion/exclusion criteria and rationale for the psychological inventories implemented. The current study aims to add to the knowledge base regarding the psychological distress experienced by patients sustaining an orthopaedic trauma injury while considering the previously mentioned shortcomings.
CHAPTER 3
METHODS AND MATERIALS

Participants

In all, 50 patients participated in this prospective cohort study. A sample of convenience of injured orthopaedic trauma patients that met inclusion criteria was adopted. English-speaking patients between the ages of 18 to 80 who were receiving follow-up care for an orthopaedic trauma injury were eligible for inclusion in the study. Patients with severe orthopaedic trauma injuries were included. Specifically, this was defined as patients who received multiple surgical procedures for their orthopaedic injuries. These patients were selected due to sustaining multiple fractures, staying multiple days in the hospital and/or recuperating for an extended time period at a rehabilitation facility or at home. To avoid selection bias, 50 consecutive patients who met these criteria were accepted into the study. ISS scores were only accessible following patients granting their consent, thus, this metric was not used to select participants a priori.

Sample size was determined by an a priori analysis using the G*Power general power analysis program. The alpha level was set at .05 with a corresponding power of 0.80 to detect a medium effect size on anxiety. A medium effect size was selected according to the convention established by Cohen for estimating effect size in the absence of existing data. Hence, a sample size of 50 was shown to be appropriate to address the primary research question. Participants were selected from the total sample of patients seeking treatment over the course of one year at the University of Florida Department of Orthopaedics and Rehabilitation Trauma Clinic (UFTC) at the Orthopaedics and Sports Medicine Institute (OSMI). The UFTC cares for patients
discharged from the Level-I Trauma Center at Shands Hospital in the University of Florida Healthcare System. This hospital serves a population base that geographically reaches patients in all 67 Florida counties, multiple states and over 12 countries annually.

Patients were excluded from the study if they sustained a traumatic brain injury that resulted in lasting cognitive impairments. Additional exclusion criteria included patients that lacked the ability to communicate effectively (e.g., at a level where self-report measures could be answered completely). Finally, patients that were psychotic or suicidal were also denied inclusion into the study and were immediately seen by a healthcare professional and referred for additional psychological care. In all, 92% of patients contacted consented to participate in the study, while two patients’ data were discarded due to unintentional variations in the study protocol.

**Instrumentation**

Self-report measures were employed as the primary method for quantifying patients’ psychological distress following an acute orthopaedic trauma injury. As opposed to implementing inventories based on convenience, the questionnaires implemented in the current study are considered the “gold standard” in the field of psychology and have a long history of implementation in multiple research settings. Accordingly, the MSPSS, the state version of the STAI, the Patient Health Questionnaire-2 (PHQ-2), the Positive and Negative Affect Schedule (PANAS), and the BDI-II were implemented.

**Multidimensional Scale of Perceived Social Support (MSPSS)**

The MSPSS measures participants perceived level of social support. The inventory is comprised of 12 items quantifying three subscales of perceived support:
family (e.g., father, mother, brother or sister), friends and significant others (e.g., wife or husband). Subjects completed each question by circling the appropriate response that best answered each question. Answers were formatted on a 7-point Likert scale ranging from “very strongly disagree” to “very strongly agree”. Participants overall score were comprised by totaling their response to all questions, while subscales can be scored by totaling participants’ responses and dividing by the number of questions within a given subscale. The reliability score for the inventories total score is .91, while the reliability scores for each of the subscales range from .90 to .95.20

State-Trait Anxiety Inventory (STAI)

The state version of the STAI assesses transient levels of anxiety. The inventory is a unidimensional tool for assessing anxiety, with an individual’s state-anxiety score calculated by totaling scores on differing questions assessing several components of anxiety including: apprehension, tension, nervousness, and worry. The inventory was comprised of 20 questions scored on a 4-point Likert scale. Due to the ephemeral nature of state-anxiety, low reliability scores (0.16 to 0.62) confirm its utility in tracking the transient nature of state-anxiety.18

Patient Health Questionnaire-2 (PHQ-2)

The PHQ-2 is a two-item inventory implemented as an initial step for assessing depression and anhedonia. The inventory consists of the first two questions of the Patient Health Questionnaire-9 and explicitly asks patients to consider “the last two weeks” when completing answers. The questionnaire has been shown to be useful in clinical settings where short-form questionnaires assist with mitigating time-demands placed on clinicians.17 The inventory correlates strongly with the BDI-II. Possible
answers are presented on a 4-point Likert scale ranging from “not at all” to “nearly every day.” The inventory is scored by totaling the responses to both questions.\textsuperscript{17}

**Positive and Negative Affect Schedule (PANAS)**

The PANAS is a 20-question self-report measure quantifying positive and negative affect on a 5-point Likert scale. The 10 positive affects are: interested, excited, strong, enthusiastic, proud, alert, inspired, determined, attentive, and active. The 10 negative affects are: distressed, upset, guilty, scared, hostile, irritable, ashamed, nervous, jittery, and afraid. Both the positive and negative affect subscales are scored by calculating the aggregate of the 10 positive and 10 negative answers. The test-retest reliability of the positive affect and negative affect scales are 0.89 and 0.85, respectively.\textsuperscript{19} The PANAS question rating “strong” was the only question of interest as it allowed participants to self-rate their physical recovery at the point of intake.

**Beck Depression Inventory-Second Edition (BDI-II)**

Given the comorbidity between anxiety and depression, the BDI-II\textsuperscript{16} was administered to delineate the two conditions. The BDI-II measures characteristic attitudes and symptoms associated with depression. The inventory consists of 21 items each rated on a 4-point scale with 0 being the lowest score and 3 being the highest score for each item presented. Total scores above 30 are indicative of severe depression. The measure is routinely implemented and found to be reliable 0.93.\textsuperscript{16} The BDI-II was created using the characteristics and symptomology associated with depressed individuals as defined by the DSM-IV.
Procedure

The University of Florida’s Institutional Review Board approved all procedures and participants provided written informed consent (Appendix A) prior to participating in the study. Psychological data were collected during patients’ scheduled clinic visit to the UFTC. Prior to checking-in for their scheduled visit, patients were naïve to the study and that they may be asked to participate. As is standard procedure, upon arrival to the UFTC participants were greeted by medical staff and asked to complete requisite forms updating their medications and symptomology. In all cases, x-rays to assess patients’ rehabilitation were completed next. Patients were then escorted to a quiet patient examination room by a Trauma Clinic nurse where they waited to be examined by the Trauma Physician Assistant or Orthopaedic Trauma Resident and finally by the Chief of the Orthopaedic Trauma Service.

Once patients were seated comfortably in their examination room they were introduced to the researcher. The researcher was a member of the Orthopaedics and Rehabilitation Trauma Team trained in psychology and in the collection of quantitative and qualitative data. Formal introductions were made to each potential participant in an identical manner.

To assuage patients’ concerns associated with being in a medical setting and being asked deeply personal questions, and to help ensure that honest answers were given, special attention was paid to reiterate the following points while consenting a prospective participant: 1) responses would remain completely confidential and de-identified to everyone but the researcher (unless, suicidal ideations or the intent to harm others was explicitly stated), 2) participants would not incur any financial costs for participating in the study, and 3) participants responses to psychological questions
would no way impact the type, or quality of healthcare they received during their
scheduled (or future) visit. Patients were also informed that they would receive no direct
compensation for participating, but rather that indirect benefits may include: 1) helping
researchers and future patients understand the psychology associated with traumatic
orthopaedic injuries, and 2) while occasionally it has been reported that recounting
traumatic events can be emotionally disturbing, patients frequently state that they feel
“better” or “relieved” after discussing the circumstances surrounding their traumatic
incident with a trained professional. Once patients’ questions and concerns had been
addressed and the experimenter obtained written informed consent data collection
commenced.

Participants were next asked to complete a Demographic, Health Behavior and
Medical Information Form. Upon completion of the form, the MSPSS, STAI, PHQ-2,
PANAS and BDI-II were administered. All forms were given to each patient with the
experimenter reading the directions and questions aloud. The experimenter also
recorded patients’ verbal responses to questions. Pilot testing indicated that some
patients needed assistance from the experimenter due to the type (e.g. upper extremity
fractures) or severity of their injuries. Thus to remain consistent, this procedure was
repeated with each participant regardless of injury. This method varies from most large-
scale epidemiological studies that do not allocate the requisite resources and time (up
to 45 minutes) to use staff members to read the directions and questions for each
questionnaire. Precedence has been established for this more thorough approach, as
the PHQ-2 has been administered via verbal directions.¹⁷ The qualitative training of the
researcher also ensured that data collection was completed in a consistent manner.
Following the completion of the psychological inventories patients were prompted via an open-ended question to briefly discuss the circumstances leading up to, and following, their orthopaedic trauma injury. They were informed that answering this question was optional and would not preclude them from being involved in the study. Complete and rich qualitative responses, such as the mechanism of injury (e.g. gunshot wound), the decision making process that precipitated their orthopaedic injury (e.g. drunk driving), mitigating or exacerbating circumstances (e.g. drug use), whether additional individuals were injured or killed in the accident, and the recovery process were discussed in specific detail. Each patient was given the open-ended question and was allowed to elaborate on their answer until they felt the question had been sufficiently answered. Each patient enrolled in the study agreed to answer this question. Finally, patients’ questions and comments were addressed and participants were thanked for their involvement.

Answers to questions were stored in patient folders. Folders included an experimenter checklist to ensure that 1) data were collected in the proper order, 2) patient responses to qualitative questions were present, 3) medical records describing the operative procedure(s) performed were present, and 4) the Demographic, Health Behavior and Medical Information sheet, current medications prescribed and answers to the psychological inventories were present. Patient folders were stored in a locked file cabinet within the Department of Orthopaedics and Rehabilitation. Data from completed patient folders were then entered into REDCap for secure storage and for latter analyses.
Figure 3-1: Study design and flowchart.

Data Analysis

SPSS version 21.0 (Chicago, IL) was implemented for all statistical analyses. Statistical significance was set \textit{a priori} at $p<.05$. Hypotheses and how they were analyzed follow below.

\textbf{Hypothesis 1}

\begin{quote}
Anxiety and depression scores would be considerably greater in an orthopaedic trauma cohort compared to that of the general public. Descriptive statistics including frequency and percentages were used to compare prevalence of psychological distress
\end{quote}
in orthopaedic trauma patients to generalized norms established by epidemiological reviews.

**Hypothesis 2**

*Patients with no pre-injury history of anxiety and depression would self-report that their orthopaedic trauma injury “caused” their current psychological distress.*

Descriptive statistics including frequency and percentages and self-report data were used to quantify the number of patients who reported that their orthopaedic trauma injury acted as a catalyst for their psychological distress.

**Hypothesis 3**

*Orthopaedic trauma injuries would cause significantly greater anxiety and depression in patients with a history of affective disorders compared to patients without.*

Two separate independent-samples t-tests were performed to compare the effect of patients’ psychiatric history on psychological distress. The t-tests conducted were psychiatric history x anxiety and psychiatric history x depression.

**Hypothesis 4**

*A significant correlation between injury severity and anxiety and injury severity and depression would be evidenced. Orthopaedic trauma patients with more severe injuries would exhibit increased psychological distress as measured by the STAI and BDI-II.* Separate Pearson Product Moment correlation analyses were calculated to assess the relationship between injury severity and anxiety and injury severity and depression.

**Hypothesis 5**

*Anxiety and depression would be significantly decreased in patients who had been treated for their symptomology, with “treatment” being defined as talk therapy.*
and/or psychopharmacological medications. This would hold true, irrespective of the time elapsed between orthopaedic trauma patients’ injury and their data collection. Two separate independent-samples t-tests were conducted to compare the effect of patients’ psychiatric treatment (treatment, no treatment) on psychological distress. The t-tests performed were psychiatric treatment x anxiety and psychiatric treatment x depression.

**Hypothesis 6**

A significant correlation between social support and anxiety and social support and depression would be evidenced. Orthopaedic trauma patients with greater social support would exhibit less psychological distress as measured by the Multidimensional Scale of Perceived Social Support. Separate Pearson Product Moment correlation analyses were calculated to assess the relationship between social support and anxiety and social support and depression.
CHAPTER 4
RESULTS

Demographic data for participants are discussed first in this chapter. This is followed by the prevalence of psychological distress in the study cohort. These scores are presented alongside established norms for the general public. Descriptive and observational data are presented to examine whether patients suffering from orthopaedic trauma injuries felt as if their orthopaedic injury “caused” their depression and/or anxiety. Next, depression and anxiety scores are compared between patients with a history of psychological distress to those without. Severity of orthopaedic trauma injury is then analyzed to determine if it correlated with anxiety and depression scores. Finally, therapeutic methods and social support were analyzed independently to see if they ameliorated depression and anxiety.

Demographics

Fifty participants (30 females, 20 males; mean age 43.2 years, ± 13.2) completed the study. Participants’ mean education was grade 11.3 ± 1.9. The ethnicities of participants were 46 Caucasians, two Hispanics and two African Americans. Marital status of participants included 22 married, 16 single, seven divorced and five cohabitating. Due to the severity of injuries, only one participant reported that she had returned to work at the time of intake. Maladaptive coping mechanisms were calculated with nicotine consumption (packs per day) and alcohol consumption (drinks per week) equaling .41 ± .51 and 3.4 ± 12.3, respectively.

All participants underwent multiple surgical procedures and were hospitalized for an average of 12.85 ± 11.26 days. The aforementioned hospitalization time does not include the often-lengthy stays that participants had in rehabilitation facilities. The mean
elapsed time between participants’ hospital discharge date and collection of data was 159.3 ± 238.8 days. The average ISS score was 15.9 ± 12.1. Two hundred and nine injuries sustained were fractures with the majority occurring to the lower extremities (Table 4-1). In total, 287 injuries were diagnosed with each patient averaging 5.7 injuries incurred. The most common mechanisms of injury were related to motor vehicle and motorcycle accidents, together they accounted for 64% of all participant injuries (Figure 4-1).

Variables and Data Reduction

The primary dependent variables measured were state-anxiety (STAI) and depression (BDI-II) scores. The primary independent variables selected were participants’ history of psychological distress (history, or no history), severity of orthopaedic trauma injuries (ISS), whether participants received treatment for their psychological distress following their orthopaedic trauma injury, and participants’ level of social support (MSPSS).

H1-Cohort Anxiety and Depression Levels Compared to the General Public

Prevalence of anxiety and depression in the general population compared to the study cohort following their injury are presented in Table 4-2, while population norms and study cohort means for the STAI, BDI-II, PHQ-2 and MSPSS are described in Table 4-3. Based on mean scores, participants were classified as having high anxiety (STAI = 63.2 ± 7.1), severe depression (BDI-II = 29.8 ± 8.6), and low social support (MSPSS = 3.9 ± 1.6). These scores were significantly worse than established norms for the general population (Table 4-3). The percentage of the study cohort suffering from anxiety (100%) and some degree of depression (98%) also greatly exceeded that of the U.S. population 18.1% and 9.5%, respectively (Table 4-2).
Prior to their accident, the percentage of the study cohort that was clinically diagnosed with anxiety (26%), depression (22%) or a combination of anxiety and depression (18%) mirrored established percentages in the general population (anxiety 9.5% and depression 18.1%). One participant had been hospitalized prior to their orthopaedic trauma injury for psychological issues. This number coincides with the national population that indicates 995 per 100,000 U.S. citizens are hospitalized annually for psychological issues.42

**H2-Self-Reported Psychological Distress Following Orthopaedic Trauma**

Thirty-five participants (70% of total sample) self-reported no history of psychological distress prior to their orthopaedic trauma injury. Thirty-three of these participants (94%) self-reported that they believed psychological distress was “caused” by their orthopaedic trauma injury. All 15 participants (30% of total sample) with a history of psychological distress believed that their orthopaedic injury resulted in a relapse of psychological distress (if it had previously been resolved) or that the injury “exacerbated” their current symptoms. In all, 30 participants where clinically diagnosed with psychological distress following their orthopaedic injury (anxiety 38%, depression 42% or combination of anxiety and depression 26%). These percentages were confirmed by participants’ medical records data.

**H3-Psychological Distress Scores in Patients with and without a History of Psychological Distress Following Orthopaedic Trauma**

An independent-samples t-test was conducted to compare anxiety in participants with a history of psychological distress to participants without a history of psychological diagnoses. No significant difference in anxiety scores as measured by the STAI for those with a prior history of psychological distress (M=64.1 ± 5.8) and participants
without a history of psychological distress (M=62.9 ± 7.6); t(48) = -.55, p = .58 was evidenced. The same trend held true for depression as measured by the BDI-II, as no significant difference was found between those with a prior history of psychological distress (M=30.4 ± 6.6) and those without (M=29.6 ± 9.4); t(48) = -.30, p = .77.

**H4-Anxiety and Depression Correlations with Injury Severity**

A Pearson product-moment correlation coefficient was conducted to analyze the relationship between anxiety and injury severity as measured by the Injury Severity Score. No significant correlation between the variables was found r = -0.08, n = 40, p = .593. With respect to depression and injury severity, the same trend held true r = -0.08, n = 40, p = 608. In sum, no correlation was found between anxiety and depression scores and injury severity.

**H5-Impact of Treatment on Psychological Distress Following Orthopaedic Trauma**

Two independent-samples t-tests were conducted to compare if treatment of psychological distress following an orthopaedic trauma injury ameliorated anxiety and depression. There was no significant difference in anxiety scores for those who received treatment (M=64.1 ± 7.3) and participants who did not receive treatment (M=62.3 ± 6.7); [t(48) = -.91, p = .36]. Analysis of depression scores were similar, as no significant difference was found between those who received treatment (M=30.5 ± 8.0) and those without (M=29.2 ± 9.2); [t(48) = -.51, p = .61]. As such, it is apparent that the treatment obtained by participants in the study cohort did not adequately ameliorate either anxiety or depression.

**H6-Anxiety and Depression Correlations with Social Support**

A Pearson product-moment correlation coefficient was conducted to analyze the relationship between social support and anxiety. A significant correlation between the
two variables was evidenced \( r = -0.28, n = 50, p = .048 \). A correlation between social support and anxiety was witnessed as participants with higher anxiety scores had decreased social support. A correlation between depression and social support was also evidenced, \( r = -0.47, n = 50, p < .001 \). In sum, a negative correlation between social support and depression was evident as those with elevated depression scores tended to have less social support than those with lower scores.

Table 4-1. Location, type and frequency of patients’ injuries.

<table>
<thead>
<tr>
<th>Location &amp; Injury Frequency</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total: 287</td>
<td></td>
</tr>
<tr>
<td>Skull/Spine</td>
<td>32</td>
</tr>
<tr>
<td>Thorax</td>
<td>62</td>
</tr>
<tr>
<td>Arm</td>
<td>23</td>
</tr>
<tr>
<td>Pelvis</td>
<td>18</td>
</tr>
<tr>
<td>Femur</td>
<td>19</td>
</tr>
<tr>
<td>Lower Leg</td>
<td>42</td>
</tr>
<tr>
<td>Foot</td>
<td>13</td>
</tr>
<tr>
<td>Fractures</td>
<td>209</td>
</tr>
<tr>
<td>AKA</td>
<td>3</td>
</tr>
<tr>
<td>BKA</td>
<td>3</td>
</tr>
<tr>
<td>UE</td>
<td>1</td>
</tr>
<tr>
<td>Toe</td>
<td>1</td>
</tr>
<tr>
<td>Amputations</td>
<td>8</td>
</tr>
<tr>
<td>Organ</td>
<td>15</td>
</tr>
<tr>
<td>Joint</td>
<td>14</td>
</tr>
<tr>
<td>Infection</td>
<td>12</td>
</tr>
<tr>
<td>Laceration/Wound</td>
<td>24</td>
</tr>
<tr>
<td>Vascular</td>
<td>4</td>
</tr>
<tr>
<td>Blinded</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>70</td>
</tr>
</tbody>
</table>

Table 4-2. Prevalence of anxiety and depression in the normal population compared to the study cohort following their injury.

<table>
<thead>
<tr>
<th></th>
<th>U.S. Population (^{6,43,44}) N=296,410,404</th>
<th>Study Cohort N=50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxious: (STAI&gt;40)(^6)</td>
<td>18.1%</td>
<td>100%</td>
</tr>
<tr>
<td>Depressed: (BDI-II)(^44)</td>
<td>9.5%</td>
<td></td>
</tr>
<tr>
<td>0-13: None-Minimal</td>
<td></td>
<td>2%</td>
</tr>
<tr>
<td>14-19: Mild</td>
<td></td>
<td>6%</td>
</tr>
<tr>
<td>20-28: Moderate</td>
<td></td>
<td>44%</td>
</tr>
<tr>
<td>29-63: Severe</td>
<td></td>
<td>48%</td>
</tr>
</tbody>
</table>
Table 4-3. General population norms and study cohort means for the STAI, BDI-II, PHQ-2 and MSPSS.

<table>
<thead>
<tr>
<th>Inventory</th>
<th>General Norms</th>
<th>Cohort Mean (±sd)</th>
<th>Classification based on Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAI</td>
<td>Males: 35.7 (±10.4)\textsuperscript{18}</td>
<td>63.2 (±7.1)</td>
<td>High Anxiety (≥ 40)\textsuperscript{45}</td>
</tr>
<tr>
<td></td>
<td>Females: 35.2 (±10.6)\textsuperscript{18}</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>BDI-II</td>
<td>9.11\textsuperscript{46}</td>
<td>29.8 (±8.6)</td>
<td>Severe Depression (≥29)\textsuperscript{16}</td>
</tr>
<tr>
<td>PHQ-2 \textsuperscript{a}</td>
<td>4.4 (±1.8)</td>
<td>Positive Depression (≥3)\textsuperscript{17}</td>
<td></td>
</tr>
<tr>
<td>MSPSS</td>
<td>5.58\textsuperscript{20}</td>
<td>3.9 (±1.6)</td>
<td>Lower scores reflect less social support</td>
</tr>
</tbody>
</table>

\textsuperscript{a}No established general population norms in the literature as clinical cutoffs are used.

Figure 4-1. Participants’ mechanism of injury by percentage.
CHAPTER 5
DISCUSSION, LIMITATIONS AND FUTURE DIRECTIONS

In summary, the STAI and BDI-II questionnaires were administered to patients who had suffered severe orthopaedic trauma injuries that resulted in multiple surgeries and/or multiple fractures. Participants’ data was collected by a member of the orthopaedic trauma team during the patients’ in-clinic visit to the UFTC. Consistent and elevated anxiety and depression scores made comparisons between participants with a history of psychological distress and without a history of psychological distress problematic. This was also true for the relationship between injury severity scores and anxiety and depression, and analyses regarding “treatment”. A discussion of the results, limitations and future directions follows.

An Anxious and Depressed Study Cohort

Without question, the crucial findings of the study were the alarming prevalence and magnitude of anxiety and depression experienced within the study cohort. Indeed, it was this persistent finding across patients, irrespective of differentiating variables that confounded additional comparisons. The percentage of the study cohort suffering from anxiety (100%) and depression (98%) greatly exceeds that of the U.S. population 18.1% and 9.5%, respectively (Table 4-2). The magnitude of psychological distress is also impressive as participants were classified as having high anxiety (STAI = 63.2 ± 7.1) and severe depression (BDI-II = 29.8 ± 8.6). On average, the STAI scores were 23 points greater than the cutoff point frequently used to classify an individual as highly anxious.\textsuperscript{18,45} The PHQ-2 was implemented as a method of checks and balances for the BDI-II data and to ensure the integrity of the data. The mean PHQ-2 score (4.4 ± 1.8) echoes data obtained from the BDI-II, as the clinical cutoff for positive depression is a
score greater than three. All questionnaire scores obtained were markedly worse than the established norms for the general population (Table 4-3) illustrating that the study cohort under investigation was under significant psychological distress.

The psychological distress reported is also far greater than that described in prior research on the topic. Crinchlow reported that 45% of trauma patients reported psychological distress that was clinically significant. Factors accounting for the discrepancy between the aforementioned study and the current investigation may include the level of injury severity, the number of fractures sustained, the multiple surgical procedures experienced, and the decreased social support among this study’s participants.

Often overlooked by other researchers and not discussed in any prior literature that could be found, was the propensity for larger studies to obtain data via methods that are less conducive to building rapport and trust between the patient and researcher. Thus, it is possible that the severity and prevalence of psychological distress were underreported in prior studies. The researcher in the current investigation was an embedded member of the orthopaedic trauma team who was familiar with the patients and had interacted with them prior to their hospital discharge. Thus, it can be safely assumed that in most cases an atmosphere of trust was established prior to intake, decreasing the likelihood of psychological distress being underreported.

The current study does coincide with the work of McCarthy, who found that patients with lower-extremity injuries experienced significantly greater psychological distress. The Chief of Orthopaedic Trauma supervising the UFTC primarily treats lower-extremity injuries. Thus, the majority of patients seeking care in the current study were
being seen for lower-extremity fractures. Additional support for lower-extremity patients experiencing elevated levels of psychological distress comes from participants’ responses to the PANAS gauging how physically “strong” they felt. On average, participants reported a score of 2.6 (rated on a 5-point Likert scale). Translated into words, this score would classify their average strength rating as falling between “a little” to “moderate”. Responses from the open-ended question that followed the completion of participants’ questionnaires shed light on these responses, as several participants cited their lack of ambulation as the root cause for their poor strength rating and comorbid psychological distress.

**Contributing Factors**

Twenty-four patients self-reported that they received psychological services after their orthopaedic trauma injury. Of these, none received extensive talk therapy, or talk therapy without psychopharmacological medications also being prescribed. Seventeen percent of patients receiving treatment for their psychological distress did so with “talk therapy and medications,” meaning the remaining 83% were treated exclusively with medication. With the vast majority of patients lacking a primary care physician, being out of work and uninsured, the task of obtaining long-term medications and/or talk therapy was unlikely. When this is coupled with the fact that resources such as “hospitalizations” for those under psychological distress have decreased steadily due to a lack of hospital beds and more stringent insurance criteria, the prognosis for these patients’ long-term psychological well-being is not good.

It would be presumptuous to assume that medications do not ameliorate anxiety and depression. Pharmacological solutions may not be the panacea, but they have been shown to be effective in at least temporarily ameliorating the burden of anxiety and
depression. Under the current study’s structure, it was impossible to know how long patients adhered to taking psychiatric medications that may have been prescribed at the time of their hospital discharge and the true reason their doctor prescribed the medication. Despite a limited sample, data strongly indicates that medications alone might not be strong enough to treat the root causes of psychological distress, suggesting that “throwing” medication at the problem cannot solve complex issues like anxiety and depression. Future randomized controlled studies need to incorporate extensive talk therapy interventions to assess their efficacy with patients suffering from orthopaedic trauma injuries.

A Novel Approach

The current study went to great lengths to investigate participants’ psychological history prior to their orthopaedic trauma accident. This differs from previous research, which appears to agree that quantifying patients’ mental health prior to their orthopaedic injury is an inherent limitation when investigating this line of research. For this reason, the current study provides a novel contribution. It is also in contrast to the studies presented in the review of literature, which did not allocate the adequate resources and time to research their participants’ past incidences of anxiety and depression. Sifting through medical records and conducting detailed intake interviews with patients are requisite if accurate data on the subject is to be obtained. Accordingly, aforementioned oversights by prior researchers have significantly delayed a better understanding of the probable interaction between orthopaedic trauma injuries and psychological distress.

Inquiring about previous psychological history provides a snapshot of how this study’s cohort compares to the general public. As previously noted, prior to their accident the percentage of the study cohort that was clinically diagnosed with anxiety,
depression or a combination of anxiety and depression was 26%, 22% and 18%, respectively. This data fell in line with established percentages in the general population (anxiety 9.5% and depression 18.1%). Following participants’ injuries, a noticeable shift occurred as 30 participants were clinically diagnosed with psychological distress (anxiety 38%, depression 42% or combination of anxiety and depression 26%). While 96% of all participants’ reported that that their injury had “caused” distress, 100% of participants with a history of psychological issues self-reported that their orthopaedic injuries resulted in a relapse of psychological distress (if it had previously been resolved), or that the injury worsened their symptoms. Thus, researching patients’ medical records and implementing more detailed patient history provides valuable data and should be considered.

If the current study had adopted a research design similar to previous work, the inability to determine the direction of the relationship between orthopaedic trauma injuries and psychological distress would still be ambiguous. While causal determinations cannot be elucidated by the current study’s design, the aforementioned data does provide support for orthopaedic trauma injuries acting as a catalyst for causing psychological distress in patients with orthopaedic trauma injuries. Thus, this study provided innovative methods for addressing problems that have hindered progress in this area of inquiry.

A Closer Look at Demographics

A more detailed understanding of the current study’s patient demographics is integral to applying the aforementioned results. Worthy of note, the mean age of the participants in this study was 43.2 years ± 13.2. This is significant because, according to the National Institute of Mental Health, the average age when the onset of major
depression occurs in the general population is 32 years. While this number falls within the standard deviation of the study cohort, it would be expected that most psychological issues that would confound the current study’s data would have manifested much earlier in the study cohort’s lives. Again, this provides additional evidence that it is likely that orthopaedic trauma injuries cause psychological distress. Equally important, it provides a counterpoint to the critic claiming that orthopaedic trauma injuries tend to “find” those with psychological issues. This data indicates that those subscribing to this opinion might be ill-informed. It also helps dispel negative stereotypes often attached to those suffering from anxiety and/or depression following an orthopaedic trauma injury.

Examining participants’ level of education is also pertinent in trying to predict whether they will experience psychological distress and how (or if) they might go about seeking treatment. Several of the study’s participants failed to graduate from high school (mean education grade 11.3 ± 1.9), and the number of college graduates within the study cohort (four) was surprisingly low. Thus, the likelihood of this study cohort seeking psychological services is significantly lower, as it has been documented that low income individuals and those with lower educational levels are less likely to seek treatment and are often lost during follow-up. As opposed to seeking mental health care that is often not available to them, it has been shown that these individuals often resort to maladaptive coping strategies to treat their psychological distress. Surprisingly, the frequency of alcohol and nicotine use were low in this study’s cohort. This might be attributed to changes made by the patients while they were in the hospital, concerns they might have regarding possible interactions with prescribed medications, or worries that poor lifestyle habits may impede the healing process.
Limitations

Inherent limitations exist in studying the psychological state of patients who have suffered an orthopaedic trauma injury. A significant limitation of the current study was the implementation of ISS to analyze the relationship between anxiety and injury severity, as well as depression and injury severity. It has been argued that alternative options such as the Abbreviated Injury Scale more accurately depict patients’ level of injury and should be considered in future research designs. Additional limitations include the lack of a true randomized design or a comparison group. This criticism is not easily resolved, as the resources necessary to implement a true randomized study in this line of research would need to be substantial. With that being stated, collecting participants’ data at multiple time points might bolster future studies, providing a rich and detailed account of the orthopaedic trauma patient’s psychological experience.

Moving Forward

Currently there are few programs that embed rehabilitation scientists within orthopaedic trauma teams. Indeed, it was the recognized lack of resources by the UF Department of Orthopaedics and Rehabilitation that helped prompt the current research study. Thus, employing individuals who are trained in collecting psychological data while helping patients transition from disability to ability should be considered a priority. Additional obstacles preventing a more in-depth understanding of psychological distress in orthopaedic trauma patients might also be overcome if increasing resources are allocated. The preponderance of trauma injuries (e.g. car accidents) occur at night and on weekends, times when access to psychological services for both patients and their families are limited. Clearly this creates a delay in the ability to assess psychological distress and provide mental health services for patients. It is also problematic for time-
sensitive studies that are interested in the assessment of individuals’ psychological symptomology immediately following injury. Moreover, trauma patients are often injured and/or treated far from their residence, making follow-up visits that may provide assessment and care difficult. Advancements in technology provide a potential solution to this problem as systems such as Telehealth, the delivery of healthcare services through telecommunications, become increasingly feasible.

**Clinical Connection**

The current study provides supporting evidence for traumatologists and orthopaedic trauma clinics to adopt a more humanistic approach toward patient care. Humanism is defined as focusing on the needs, well-being and interests of a person, particularly their dignity and worth. When applied to medicine, humanism aims to treat the whole patient, healing their physical injuries while nurturing and restoring their sense of self. In order to do this effectively, it requires a multidisciplinary team, each operating under the aims of providing integrated, empowering and complete patient care. The current model of fractured healthcare runs juxtaposed to these ideas. In order to continue to work toward achieving this end, it is recommended that the following steps be considered by those charged with overseeing orthopaedic trauma care:

1. Implementing multidisciplinary orthopaedic trauma teams that foster integrated care, whereby the whole patient is the focus of treatment.

2. Guidance for orthopaedic trauma teams in the compassionate application of the practice of medicine through continual training and education.

3. Continued identification of variables that are often overlooked in orthopaedic trauma that frequently confound the healing process, while also detracting from patients’ self-worth (e.g. psychological distress).

By working to achieve these goals, the traumatologists and healthcare staff will be better equipped to treat their patients. While this is an essential area of inquiry, simply
identifying psychological distress in trauma patients without implementing a mechanism for change would be insufficient. Thus, additional training is required for tomorrow’s orthopaedic trauma teams. With a concerted effort focused on empathetic care, healthcare providers trained in understanding the psychological distress of their patients are more likely to respond appropriately to patient cues and will likely have improved outcomes. Equally important, it will help shift the standard of how Level-I trauma centers provide care and educate their staff. Furthermore, a focus on improved empathetic care will lead to a greater number of educated and empowered patients.

**Future Directions**

Simultaneous and related lines of research regarding patients suffering from orthopaedic trauma injuries and their subsequent psychological distress were concurrently collected while this study was completed. These studies included the efficacy of psychological and prosthetic education for patients preparing to undergo a lower-extremity amputation and a comparison of psychological distress in orthopaedic trauma patients with severe injuries to patients with less severe injuries (e.g., closed and/or non-surgical fractures).

There are multiple future directions relevant to this line of research which are worthy of investigation and further exploration. Of specific interest is whether the relationship between orthopaedic trauma injuries and psychological distress is multidirectional. Put differently, do individuals suffering from anxiety, depression and other psychological issues suffer an increased number of orthopaedic trauma injuries when compared to the general population? The clinical application of these findings would be worthy of note, as those in the fields of psychology and psychiatry concur that the motor system and mood are linked.\(^{15}\) Constructs such as “motor tension” are established
diagnostic criteria for assessing affective disorders including general anxiety disorder. Indeed, understanding motor deficits brought on by varying levels of psychological distress might be of paramount importance, as deficiencies altering movement quality may lead to subsequent movement errors, which may cause additional orthopaedic trauma injuries.

Additional work delineating the factors that ameliorate psychological distress should also be examined. It stands to reason that variables analogous to social support, such as “belief systems,” may ameliorate psychological distress, as well as playing a key role in the functional recovery of patients suffering orthopaedic trauma injuries. Until additional studies are conducted determining if “faith” and/or “belief” are mediating variable, anecdotal evidence must be considered compelling, as patients in the current study frequently self-reported that their “faith” or “belief” served as a support system and coping mechanism. In addition, finding cost effective solutions that alleviate psychological distress for orthopaedic trauma patients such as meditation and stage appropriate exercise appear promising. An added benefit being that it helps lessen the financial burden for patients that are lacking resources. Finally, quantifying the psychological distress of trauma care providers may result in tangible benefits to their patients, as providers are frequently subjected to repeated bouts of stress and strain. Without question, empathetic and optimal care is not possible without a healthy and functional orthopaedic trauma team.
APPENDIX A
INFORMED CONSENT FORM

INTRODUCTION

Name of person seeking your consent:__________________________________________

Place of employment & position: ____________________________

Please read this form which describes the study in some detail. A member of the
research team will describe this study to you and answer all of your questions. Your
participation is entirely voluntary. If you choose to participate you can change your mind
at any time and withdraw from the study. You will not be penalized in any way or lose any
benefits to which you would otherwise be entitled if you choose not to participate in this
study or to withdraw. If you have questions about your rights as a research subject,
please call the University of Florida Institutional Review Board (IRB) office at (352) 273-
9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

________________________________________________________________________

2. What is the Title of this research study?
   Psychological Sequelae and Psychosocial Adjustment Following Orthopaedic Trauma
3. Who do you call if you have questions about this research study?
   Principal Investigator: Kalai Sadasivan, M.D. at (352) 273-7384
   Other research staff: MaryBeth Horodyski, EdD at (352) 273-7074

4. Who is paying for this research study?
   The sponsor of this study is University of Florida.

5. Why is this research study being done?
   The purpose of this research study is to examine the psychological symptoms experienced by patients following their traumatic orthopaedic injuries.
   You are being asked to be in this research study because you have experienced a traumatic orthopaedic injury.

**WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?**

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?
   During your hospitalization and follow-up visits to our trauma outpatient clinic, information will be obtained as part of the standard of care for your injury. This information is used to see how well you are recovering from surgery and/or treatment for your injury and to make decisions about your treatment.
   The questionnaires you will be asked to complete for this study are also part of your normal standard of care.

7. What will be done only because you are in this research study?
   Depending on the time point you received treatment for your injury, you will be categorized under one of two populations. The population group you fall into will determine how you will be asked to take part in the study and how your data will be collected. Please read all population scenarios below to understand which population you fall into.

   **Group 1:**
   You will be offered the opportunity to participate in this study during hospitalization for your injury. If you give consent, you will be asked to take a number of questionnaires. If you give consent, we will also use some of your standard of care information that have been or will be recorded in your medical record chart. Some of the standard of care data we will collect from your medical record chart and use for research include your self reported mental health status, your past medical history (to determine
eligibility and for study purposes), your demographic information, your use of any medications or assistive devices, and your responses on clinical diaries or clinical questionnaires. For a full list of all data to be collected from your medical record chart, please refer to Item 17 of this Informed Consent Form. After hospitalization for your injury and one follow-up visit to our outpatient trauma clinic, you will be asked to take the questionnaires again.

**Group 2:**

You would have received surgery or treatment for your injury and would have already consented in another study to take the questionnaires. Your data are currently being stored for research purposes because you had signed a consent form allowing us to store your answers in a secure and encrypted orthopaedic research database. We are now asking for additional consent to review and analyze your data that we collected and stored in the database and for your consent to continue taking the questionnaires in this study. If you give consent, you will be asked to take the questionnaires one additional time during a follow-up visit to our trauma outpatient clinic. If you give consent, we will also use some of your standard of care information that have been or will be recorded in your medical record chart. Some of the standard of care data we will collect from your medical record chart and use for research purposes include your self reported mental health status, your past medical history (to determine eligibility and for study purposes), your demographic information, your use of any medications or assistive devices, and your responses to clinical diaries or clinical questionnaires. For a full list of all data to be collected from your medical record chart, please refer to Item 17 of this Informed Consent Form.

**Telephone Contact:**

In the event that you are unable to make follow-up visits to our trauma outpatient clinic during the selected time points for this study, we will send to you a letter informing you that we will contact you by telephone to administer the questionnaires.

**If You Have Had or are Scheduled to Have an Amputation:**

If you have had or are scheduled to have an amputation procedure, we are also requesting your consent to contact you in the future to request your participation in a telephone survey about your amputation and psychological status. If you give consent, we will send to you a letter reminding you about this aspect of the study prior to contacting you by telephone to request your verbal consent to administer the questionnaire. This questionnaire should take approximately 15 minutes to complete.

**If You Have Thoughts about Hurting Yourself or Others:**

During the research, if we learn you are having thoughts about suicide or hurting yourself or others, the research staff will ask you more questions about your thoughts. Based on your response, the staff may provide you with help to get treatment. This may include:

- contacting a Clinical Psychologist or licensed therapist to discuss your thoughts,
• working with you on a plan that may include getting you to a hospital for safety,

• providing you with national suicide or depression prevention hotline telephone numbers to discuss your thoughts with a professional.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

 Regardless of which study population you are assigned to, participation in this study will last approximately one year. Each session that you take the questionnaires for this study will last approximately 15 minutes.

9. How many people are expected to take part in this research study?

 Approximately 500 participants.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

 Some of the questions may ask you to recall difficult times in your life. A few questions are very direct and may require immediate intervention by the researcher. For example, if you indicate that you have thoughts of harming yourself or others.

 Although a minimal risk, completing the questionnaires may cause stress to some participants who may believe that they are not providing correct answers to the research team. To reduce this stress, the investigators would like to reassure you that all survey answers are based on what you are feeling, and there are no "correct" answers.

 Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

 This study may include risks that are unknown at this time.

 Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the
research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

11a. What are the potential benefits to you for taking part in this research study?

Experts in mental health generally agree that taking the time to identify how you feel about your trauma injury is a helpful and worthwhile process. Completion of the questionnaires may assist you with a quicker and a more complete mental recovery.

11b. How could others possibly benefit from this study?

The present study may improve upon our understanding of the psychological issues faced by trauma patients, which may ultimately lead to more effective treatment of psychological symptoms. Potential benefit to others may result from the knowledge gained from current orthopaedic trauma patients’ participation in this research. In this event, new methods of measurement and treatment may become available in the future to benefit orthopaedic trauma patients.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

The option to taking part in this study is doing nothing. If you do not want to take part in this study, tell the Principal Investigator and do not sign this Informed Consent Form.

Although the questionnaires in this study may be presented to you as standard of care, you have a right to choose whether or not you would like to give consent for us to use your responses to the questionnaires and other standard of care information for research purposes.

Participation in this study is entirely voluntary. You are free to refuse to be in the study, and your refusal will not influence current or future health care you receive at this institution.

University of Florida Student Participants:
You have been invited to participate in this research project because you have sustained an orthopaedic injury. The investigators associated with this project may or may not teach in your college or be associated with courses for which you are enrolled or might be expected to register in the future. Your participation in this study is voluntary and any decision to take part or not to participate will in no way affect your grade or class standing.

If you believe that your participation in this study or your decision to withdraw from or to not participate in this study has improperly affected your grade(s), you should discuss this with the dean of your college or you may contact the IRB office.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

All information obtained prior to your withdrawal can be used or analyzed for study purposes. However, new information obtained about you following your withdrawal from this study will not be used or collected.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- You do not qualify to be in this study because you do not meet the study requirements. Ask the Principal Investigator if you would like more information about this.
- The Principal Investigator feels that participation in this study is not in your best interest.

**WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?**

14. If you choose to take part in this research study, will it cost you anything?

The Sponsor will provide at no cost to you the following study-required services:
1) Psychological questionnaires.

If you receive a bill for these services, please contact Kalia Sadasivan, M.D. at (352) 273-7384 or the study coordinator at (352) 273-7361.

Any other medical services you receive would have been provided to you even if you were not in this study. These services will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, co-payments, for those services, and for any non-covered or out-of-network services.

Some insurance companies may not cover costs associated with studies. Please contact your insurance company for additional information.

15. Will you be paid for taking part in this study?

No.

16. What if you are injured because of the study?

Since this is a data collection study, there is a very low risk of study-related injury. However, if you are injured as a direct result of your participation in this study, the Sponsor will pay for all reasonable and necessary medical expenses required to treat your injury, as long as:

1) the injury occurs during your participation in the study;

2) the injury results directly from the Study Product or Study-related procedures that you would not have received as part of your routine medical care.

The Sponsor and the Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.
Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Complete past medical history to determine eligibility criteria.
- Demographic information.
- Records of physical exams.
- Radiology images and reports.
- Laboratory, x-ray, MRI, and other test results.
- Surgery reports.
- Clinical diaries and clinical questionnaires.
- Clinic visit notes.
- Records about medications.
- Records about assistive devices (e.g. prostheses, wheelchairs).
- Your self reported mental health status or condition.
- Complete past medical history (there are some studies that use the first statement but the medical history is kept as a part of the study and not for the sole purpose of determining eligibility criteria).

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.
18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

To review and examine the psychological symptoms experienced by patients following their traumatic orthopaedic injuries.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- the study sponsor (listed in Question 4 of this form).
- United States and foreign governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.
21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.
SIGNATURES

As an investigator or the investigator’s representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant’s protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization

Date

You have been informed about this study’s purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing

Date
LIST OF REFERENCES


BIOGRAPHICAL SKETCH

Born in 1975, Robert Tarkington Barnes grew up in Long Beach, California. As the son of David and Sherry Barnes, and brother to Alison and Zak, the importance of faith, academics, sports, loyalty and loving English Springer Spaniels were deeply instilled by his parents. After graduating from Los Alamitos High School, he attended Long Beach City College where he played basketball for Hall of Fame coach, Gary Anderson. He left Southern California to earn a Bachelor of Arts degree in psychology from California State University, Chico (CSUC). Following the completion of his undergraduate degree, he completed his Master of Arts degree with Distinction in Sport Psychology at CSUC under the mentorship of Dr. Linda Kline. Robert was accepted into the doctoral program at the University of Florida in rehabilitation science under the guidance of Dr. MaryBeth Horodyski. His work with Dr. Horodyski and the Chief of Orthopaedic Trauma Surgery, Dr. Kalia Sadasivan, led to an expertise in understanding the interaction of psychological distress in patients suffering from orthopaedic trauma injuries. While at UF, he married his graduate school sweetheart, Leslie. They have two loyal English Springer Spaniels – Miss Juan and Mr. Deuce. Robert was awarded his Ph.D. in August 2013.