A COMPARISON OF CLINICAL OUTCOMES BETWEEN EARLY PHYSICAL THERAPY INTERVENTION AND USUAL CARE IN INDIVIDUALS FOLLOWING ANTERIOR CERVICAL FUSION

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DEDICATION

To my dear husband Tom, who has been beside me all of the way through this very long journey. To my parents, Betty and Ken McVicar, who always supported and encouraged the dream.

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ABSTRACT

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A COMPARISON OF CLINICAL OUTCOMES BETWEEN EARLY PHYSICAL THERAPY INTERVENTION AND USUAL CARE IN INDIVIDUALS FOLLOWING ANTERIOR CERVICAL FUSION

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Early physical therapy (PT) intervention with emphasis on spinal stabilization has been shown to benefit individuals undergoing lumbar spinal surgery. Further, training cervical spine stabilizers (deep cervical flexors and cervical multifidus) has been shown to be effective in reducing neck pain, restoring cervical spinal function and mobility in many types of cervical spine dysfunction. However, the training of stabilizers has not been studied in individuals undergoing cervical spinal surgery, even though these individuals often have problems with residual pain and weakness after the surgery. The purpose of this study was to compare clinical outcomes between an early physical therapy intervention including training of stabilizers and usual care in patients who have undergone Anterior Cervical Fusion (ACF) surgery. The clinical outcomes included: 1) pain level using the numeric pain rating scale (NPRS), 2) patient's perceived disability associated with neck pain as determined by Neck Disability Index (NDI), 3) Deep cervical flexor (DCF) strength, and 4) DCF endurance. This study was a double-blinded randomized clinical trial with a two-factor (2x2) research design. The four clinical

outcomes measurements were collected before surgery for baseline, then at 6-week post-operative visits with the surgeon. In addition, at 6 weeks after surgery, the Global Rate of Change (GROC) was a fifth outcome measure to determine the patient's perception of overall improvement as a result of surgery. The study also examined the relationships among the patient's perceived disability due to pain, DCF strength, and DCF endurance. Additionally, test-retest reliability of the craniocervical flexion (CCF) test of DCFs in surgical patients was determined in the post operative condition. A 2x2 MANOVA was performed to identify interactions between group and time frame. Thirty participants were randomly assigned to early PT intervention or usual care groups, and 29 of these completed 6 week post-operative testing. There were no significant interactions with group by time frame. Results showed significant improvements of all outcome measures by time frame only. Concordance correlation coefficient (ρ_C) calculations on eight participants who completed between day testing showed excellent reliability for CCF-S (0.82) and good reliability for CCF-E (0.70). Pearson correlations showed significant relationships between DCF strength and DCF endurance in all cases, and between NDI and DCF strength and endurance before surgery and with overall data. This study showed that over a 6 week period there is no difference between an early PT intervention and usual care in improving pain and function after ACF surgery. However both groups showed significant improvement from before ACF surgery to 6 weeks post.

TABLE OF CONTENTS

LIST OF TABLES

Table Page

LIST OF FIGURES

CHAPTER I

INTRODUCTION

Background

Neck pain is a very common complaint in several medical practice settings including physical therapy clinics and is thought to affect most adults during some point in their lives.[1] Because of the large number of causes of neck pain, clinicians frequently disagree about diagnosis and management. In order to address this problem, the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders was developed to rate and review current best evidence and report consensus of findings of qualified published studies to date.[2] The Task Force identified many areas without adequate information or conflicting reports of effectiveness of treatment.[2] In general, rehabilitation did not have sufficient evidence to identify effective methods for any cervical disorder. The Task Force described four grades of neck pain, with grades III and IV involving pathology that would be appropriately treated surgically.[3] These two surgical groups included individuals with neurologic loss (Grade III) or with significant degeneration of structures (Grade IV).[1] However, rehabilitation for cervical pathology requiring surgery was not mentioned in the Task Force reports.[3]

Evidence is limited regarding the benefit or need for rehabilitation after spine surgery. To date, more studies have been conducted to investigate the effectiveness of

rehabilitation for lumbar spine surgeries than for cervical spine surgeries.[4-6] Pain and dysfunction symptoms that have been reported with chronic neck pain or whiplash appear similar to those seen in patients after cervical spine surgery.[7,8] Studies have shown successful management of pain and dysfunction with specific conditioning of cervical spine stabilizers in patients without surgery.[9-14] Therefore, it is reasonable to conjecture that this same specific training could help reduce pain and dysfunction after cervical spine surgery.

Since the Task Force reports, many more studies on cervical spine rehabilitation have been published. Studies have associated neck pain, muscular strength deficits, range of motion loss and abnormal posture with cervical spine pathology.[9,15-17] Specifically, muscle strength deficits in the cervical spine segmental stabilizers (i.e. deep cervical flexors (DCFs) and cervical multifidus muscles) have been identified in patients with neck pain, abnormal postures, and cervical spine dysfunction.[16,18-22] Therefore, proper function of these muscles is believed to be essential for stability and protection of the cervical spine as well as for its complex biomechanics.[18] Muscular deficits in the cervical segmental stabilizers in individuals with neck dysfunction have been identified in studies using in magnetic resonance imaging (MRI),[23-25] electromyography (EMG),[14,20] and rehabilitative ultrasound imaging (RUSI).[26-28] MRI studies have shown decreased cross sectional area and fatty infiltrate in suboccipital muscles including cervical multifidus in individuals with whiplash associated disorders and chronic tension type headache.[23-25] While MRI was used to study cross sectional area of muscle in a static

condition, EMG and RUSI have been used to study muscle activity of cervical stabilizers in dynamic conditions. In an ultrasonographic study, an increase in muscle thickness of the DCFs was demonstrated with increased demand during DCF muscle tests in healthy individuals.[26] This study identified craniocervical flexion (CCF) testing as a valid muscle test that targeted the DCFs primarily without having the superficial muscle groups being the dominant movers.[26] Additionally, EMG studies have shown decreased muscle activity and delayed activation of the DCFs in individuals with chronic neck pain.[14,18,20] Similar findings were reported for cervical extensors, specifically for the cervical multifidus muscle.[29-30] Cervical extensor fatigue has been identified using EMG in work-related neck pain.[29] RUSI studies of the cervical multifidus have found smaller changes in cross sectional area and in thickness during contraction in individuals with neck pain when compared to those without neck pain.[28,30]

The most frequently researched and cited field test used to assess segmental stabilization capability in the cervical spine muscles, is the craniocervical flexion (CCF) test.[14-16,19] The CCF test was designed to assess muscle performance of both the DCFs and the cervical multifidus in a clinical setting and has been validated using EMG.[14,17,26] The CCF is flexion of the upper cervical spine that can be accomplished with a small head nodding, chin-tuck movement.[16,31] When this movement is performed correctly, there is a slight flattening of the cervical lordosis.[16,31] For measuring the contraction, a pressure sensing device is placed behind the neck to measure the increased pressure that occurs with the flattening.[16,25,31] This pressure has been found to be reduced in patients

with chronic neck pain and pathology when compared to testing of asymptomatic controls.[15,16,22,32]

Given evidence that indicates muscle deficits in the DCFs and cervical multifidus in patients with neck pain, it is essential to restore the muscle performance of these two stabilizers. Studies have shown that the specific CCF exercise is effective in reducing neck pain.[11,18,20] The CCF exercise involves the same chin tuck type of movement that is required during the CCF test. During the CCF exercise, the patient lies fully supported in supine and is instructed to nod the head as if saying "yes" with the head remaining in contact with supporting surface.[11,18] Clinicians believe that having the head supported in the supine position is the best position for patients to learn the small amount of chin tuck with the CCF exercise. Then the CCF exercise can be more effectively performed in combination with other posture exercises. O'Leary et al[11] demonstrated an immediate hypoalgesia with successful recruitment of the DCFs with the CCF exercise.[11] One hypothesis for the hypoalgesia effect is reciprocal relaxation that occurs in the suboccipital muscles.[11] Several additional studies have shown that the CCF exercise was effective in reduction of pain when practiced over a period of six weeks.[13,19,20] The CCF exercise has been shown to target the DCFs optimally, and therefore contribute to the stability of the cervical spine.[17,18] Because of the amount of evidence supporting the use of the CCF exercises for management of non-surgical neck pain, we speculate that the CCF exercises could benefit patients following cervical spine surgery. Since the DCFs

contribute to the stability of the cervical spine, they have the potential to augment surgical stabilization of cervical fusion.[33,34]

Beneficial effects of stabilization exercise have been demonstrated in the lumbar spine after surgery.[6,35-37] However, DCF and cervical multifidus have not been studied in individuals undergoing cervical spine surgery. So we do not know if weakness is present before the surgery, as it is in individuals with neck pain, or if weakness occurs after surgery. We also do not know if training these muscles after surgery will result in less postoperative pain and earlier return to function, as seen in the patients with nonsurgical cervical spine therapy.

One of the most common cervical surgeries performed for the pathology of the Task Force grade III and IV levels is anterior cervical fusion (ACF).[33,34] In this surgery, the symptomatic disc or discs are removed and the intervertebral space is replaced and often increased with a spacer, either bone implant or metal cage.[34,38,39] The spacer allows improved intervertebral distance which also helps open the foraminal area, allowing more room for exiting nerves and resolving nerve impingement.[34,38] If the disc itself is degenerated and a cause of pain, ACF will stabilize the segment as well as replacing pain generating tissue.[34,39] Studies on ACF have shown fairly good and sometimes immediate short term pain relief and improvement in neurologic symptoms.[34,39,40] Although ACF successfully reduces pain or paresthesia symptoms, several post-surgical complications and residual impairments have been reported, including persistent pain,[7,41] dysphagia,[42,43] postural/spine alignment changes,[44,45] instability/degeneration of the adjacent

segments,[40,46,47] and poor results on functional testing.[48,49] Studies have also identified impairments in cervical range of motion,[50-52] cervical muscle strength or endurance,[8,53,54] and spinal canal space reduction.[55] To date, relatively little has been published regarding rehabilitation after cervical spine surgery.[33] However, many studies have shown the effectiveness of physical therapy interventions on the impairments as described earlier in patients with neck dysfunction but without surgical interventions.[9,12,13,20] A Cochrane systematic review (2005) of exercises for mechanical neck pain in 31 studies showed that 20-35% of the studies demonstrated conclusive evidence of exercise as a beneficial treatment for patients with neck pain.[12] Since this Cochrane review, many studies have investigated the effectiveness of cervical exercises such as CCF exercise and have demonstrated success with pain control.[10,11,13,20]

With deficits in DCFs, a resultant decreased anterior support of the cervical spine can occur, which may result in a change in cervical lordosis.[17] Cervical and thoracic postures have been shown to change with cervical pathologies and following cervical spine surgery.[29,45,55] Both neck pain and pathology have been considered a cause of poor postural control, which in turn has been related to loss of balance, inefficient use of postural muscles, and even abnormal respiratory patterns.[18,56,57] Forward head carriage and increased thoracic kyphosis are commonly found in patients with neck pain.[29,56,57]

It has been hypothesized that the abnormal posture in the cervical spine is a result of degenerative segments.[58] Further, osteophytes would be likely to develop on the posterior vertebral bodies, and the canal space could be narrowed, resulting in bony

prominences impinging the canal area.[55] One of the goals for the cervical spine surgery is to preserve normal cervical lordosis. By restoring normal cervical lordosis, the spinal canal space would be adequate to allow optimal intervertebral mechanics without affecting the spinal cord.[44,55] Researchers also proposed that once the optimal alignment is obtained, the cervical segmental stabilizers could activate more efficiently, thus supporting the spine.[14,18,57]

Rehabilitation following ACF is not considered standard care. There are a limited number of studies on musculoskeletal impairments or recovery interventions following ACF.[8,53,54] Muscle weakness in the cervical spine has been identified as a post surgical problem following ACF in a few studies, but tests were limited to general endurance activities.[8,54] Muscle training specifically for segmental stabilizers such as the CCF exercise is an effective intervention for patients who have cervical disorders but do not have surgery.[10,19,20] However, we do not know if this specific muscle training would benefit patients following cervical spine surgery because research on this subject is scarce.

Lastly, most orthopedic surgeries are addressed immediately with post surgical rehabilitation starting in the hospital.[5] Goals of the early approach include enhancing circulation to help healing and pain control, avoiding muscle atrophy from disuse, placing beneficial forces on healing structures for remodeling, and reinforcing safety and surgical protection to the patient.[5,59] Although all of these factors would also appear to benefit patients undergoing spine surgeries, rehabilitation is often delayed 6-12 weeks, and often

omitted altogether following spine surgery.[5,33,35] A randomized controlled trial on early rehabilitation following lumbar spine fusion resulted in improved outcomes and better pain management at follow up from three months to three years.[36] Other early intervention studies have been conducted for lumbar spine surgery, and produced similar findings.[35,37,60,61] Because of the success seen with early intervention after lumbar spine surgery, investigation of the effectiveness of rehabilitation following cervical spine surgery appears warranted.

Statement of the Problem

As discussed in the previous paragraphs, rehabilitation is not routine care for patients with cervical spine surgery. However, deficits in muscle strength, posture and function remain after surgery, even though neck pain is often significantly reduced. To date, no study has been conducted to examine the effectiveness of rehabilitation interventions in this patient population. Although the evidence has shown that early physical therapy intervention is effective in patients following lumbar surgery, we do not know if this approach would have the same effect on patients after ACF. Furthermore, the specific CCF exercise is effective for treating non-surgical neck pain, but we do not know if this CCF exercise would have the same effect on patients following ACF surgery.

Purposes of the Study

The primary purpose of this study was to compare effectiveness of clinical outcomes between an early physical therapy intervention and usual care in patients who

have undergone ACF surgery. The clinical outcomes included: 1) pain level using the numeric pain rating scale (NPRS), 2) patient's perceived disability associated with neck pain as determined by Neck Disability Index (NDI), 3) DCF strength, and 4) DCF endurance. These four clinical outcomes measurements were collected pre-operatively for baseline, then at the six-week post-operative visit with the surgeon. In addition, at six weeks, the Global Rate of Change (GROC) scale was used to obtain patient's perception of overall improvement as a result of surgery.[62] A secondary purpose of this study was to compare these clinical outcome measurements in patients undergoing the ACF before surgery and at six weeks after surgery. The study also examined the relationships among the level of patient's perceived disability, DCF strength, and DCF endurance. Additionally, test-retest reliability of the CCF test in patients six weeks post-ACF was assessed.

Variables

There were two independent variables in the study: 1) group with two levels: the usual care group and early intervention group, and 2) time in relation to the surgery with two levels: before surgery and 6 weeks after surgery. The patients were randomly assigned in one of the two levels of care following ACF surgery: "usual care" and "early physical therapy intervention" groups. The dependent variables included: pain level (NPRS score), patient's rated perception of disability (NDI score), the CCF test score for DCF strength (CCF-S), the CCF test score for DCF endurance (CCF-E), and the patient's perception of postoperative change (GROC) scale. All outcome measurements (i.e.

dependent variables), except for the GROC scale, were collected from each participant two times: before surgery and six weeks after surgery. The GROC score was collected only at six weeks after surgery.

Research Questions

1. Does early PT intervention result in different outcomes in pain level, patient's rated perception of disability, DCF strength, and DCF endurance than usual care over six weeks?
2. Does early PT intervention increase patient's perception of change on the GROC scale than usual care at six weeks after surgery?
3. Is there a strong correlation ($r \geq 0.7$, $\alpha = 0.05$) among patient's rated perception of disability, DCF strength, and DCF endurance in individuals undergoing ACF surgery?
4. Does the CCF test have acceptable within-day and between-day reliability, with interclass correlation coefficient of ≥ 0.70 ($\alpha = 0.05$) in individuals undergoing ACF?

Research Hypotheses

This study tested four hyphotheses.

1. Early PT intervention results in different outcomes in the pain level, patient's rated perception of disability, DCF strength, and DCF endurance than usual care over six weeks.

2. Early PT intervention increases the patient's perception of change on the GROC scale than usual care at six weeks after surgery.
3. There is a strong correlation ($r \geq 0.7$, $\alpha = 0.05$) among patient's rated perception of disability, DCF strength, and DCF endurance in individuals undergoing ACF surgery.
4. The CCF tests have acceptable within-day and between-day reliability, with interclass correlation coefficient of ≥ 0.70 ($\alpha = 0.05$) in individuals undergoing ACF.

Operational Definitions

The following operation definitions were used for the purposes of this study:

1. ACF was defined as anterior cervical spine fusion performed on one or more adjacent cervical intervertebral levels.
2. Acceptable reliability was defined as interclass correlation coefficient larger than 0.7 ($\alpha = 0.05$) in between-day reliability.
3. GROC improvement was defined as a change score of +2 or greater. Each participant was dichotomized into the group of the "improved" or "not improved" categories, based on this criterion.
4. Postoperative precautions will be defined as those covered on the "patient information sheet" given to all patients prior to discharge from the hospital.

Assumptions

For the purposes of this study, the following assumptions were made:

1. The participants of this study were representative of the larger population of individuals undergoing ACF surgery.
2. All participants were classified correctly to one of the Task Force categories for grade of neck pathology by the surgeons.
3. Participants truthfully reported their pain intensity and perceived disability on the NPRS scale and NDI questioning.
4. Participants truthfully reported their perceived level of change on the GROC scale following surgery.
5. Participants in both groups followed all instructions as given in the hospital. The early intervention group performed all of the training as prescribed and accurately recorded their training.
6. Participants made a maximal effort possible in performing the CCF test.
7. All of the hospital physical therapists gave standard instructions as detailed in the Methods section to the participants.

Limitations

1. Surgeries for this study only included one-level and two-level ACF surgeries, which may limit generalizability of the study.
2. Performance of the CCF test may have been limited by pain symptoms.

3. Pain may have also limited compliance with early rehabilitation or complete adherence to post operative instruction.
4. This study consisted of a six week follow-up that was relatively short-term. The results of the study may not be generalized to a long-term effect of more than six weeks.

Significance of the Study

Little study had been conducted with regard to muscular deficits, especially in the cervical spine stabilizers, in individuals undergoing cervical spine surgery. There was also little information on relationships among pain level, muscle performance, posture, and functional impairments in these individuals. Cervical spine surgery outcomes studies have been typically based on the pain relief, incidence of complications, risk factors and radiological assessment.[7,34,39] In addition, studies have described post operative problems, but have not addressed possible therapeutic measures that could be included in peri-operative care for individuals undergoing cervical spine surgery.[34,40,41] Decreased overall neck strength and range of motion have been identified in individuals undergoing ACF.[8,50,54] Specific stabilization capability using the CCF test had not been studied in the post surgical cervical spine population. Further, early rehabilitation intervention had not been examined in post operative cervical spine as it has been in lumbar spine surgeries. Given that the evidence strongly supported the use of cervical spine stabilization training in patients with cervical dysfunction who had not had surgery, a randomized control trial was needed to investigate the effectiveness of an early physical therapy intervention

primarily designed to strengthen the cervical spine stabilizers on the patients undergoing a cervical spine surgery. If the results favored the early physical therapy intervention approach, physical therapists could offer the interventions to patients undergoing cervical spine surgery to augment recovery. Furthermore, if the CCF test showed good test-retest reliability, this test could be used to monitor the progress of the muscle performance of the cervical spinal stabilizers in patients undergoing ACF.

CHAPTER II

REVIEW OF LITERATURE

Pain and dysfunction are common following cervical spine surgeries, as seen in patients with chronic neck pain.[7,40,41] Muscular deficits are widely studied in non-surgical cervical dysfunction, and have been shown to be a key factor associated with neck pain.[14,18] In addition, several studies have shown specific training to correct muscular deficits help decrease neck pain and dysfunction.[9-11] However, there has been little study of specific musculoskeletal impairments in patients who undergo cervical spine surgery other than generalized weakness and pain.[7,8] Furthermore, patients frequently do not receive rehabilitation after cervical spine surgery. Early physical therapy (PT) interventions are considered standard care after most orthopedic surgeries to help healing, pain control, and place beneficial forces on healing structures.[5,59] We do not know if PT interventions addressing musculoskeletal impairments beginning immediately after cervical spine surgery would improve outcomes and decrease complications. Anterior Cervical Fusion (ACF) is one of the most common cervical spine surgeries, often with reported favorable outcomes of reduction of pain and dysfunction, and resolution of neurologic deficits.[34,63,64] However, many individuals have difficulty with remaining pain and weakness after ACF.[7,63]

The primary purpose of this study was to compare effectiveness of clinical outcomes between an early PT intervention and usual care in patients who have undergone ACF surgery. The clinical outcomes included: 1) pain level using the numeric pain rating scale (NPRS), 2) patient's perceived disability due to neck pain as determined by Neck Disability Index (NDI), 3) a test for deep cervical flexor (DCF) strength, 4) a test for DCF endurance, and 5) patient's perceived improvement as a result of surgery. The first four clinical outcomes measurements were collected before surgery for baseline, then at the six week postoperative visits with the surgeon. In addition, at six weeks, the Global Rate of Change (GROC) scale was an outcome measure to obtain the patient's perception of overall improvement as a result of surgery. A secondary purpose of this study was to compare these clinical outcome measurements in patients undergoing the ACF surgery before surgery and at six weeks postoperatively. The study also examined relationships among the patient's perception of disability, DCF strength, and DCF endurance. Additionally, test-retest reliability of the cranio-cervical flexion (CCF) test for DCF strength and endurance in surgical patients will be determined in the post operative condition.

This literature review covers background work leading to the need for this study and includes: 1) prevalence of neck pain and cervical spine pathology, 2) purpose of ACF surgery and reported outcomes, 3) muscle dysfunction related to neck pain, 4) evidence of muscular segmental spine stabilization, 5) testing muscles for cervical spine stabilization, 6) evidence supporting training of cervical spine stabilizers, 7) outcome

instruments for neck pain interventions, and 8) studies of therapy intervention for spine surgeries.

Prevalence of Neck Pain and Cervical Spine Pathology

Neck pain has been reported by numerous authors to be prevalent among the general population, becoming an increasing burden on the healthcare system.[1,2] It has been reported that most everyone will experience an episode of neck pain at some point in their lifetime, especially because it can occur with almost any musculoskeletal or neurologic disorder involving the upper quarter.[2] This multiple causes of neck pain lead to a lack of understanding of accurate diagnoses, which have resulted in inconsistent medical management.[2] During the Bone and Joint Decade 2000-2010, a Task Force on Neck Pain was developed to review research to date and develop an evidence-based model for identifying reasons for onset, course of episodes of neck pain over a lifetime, and options for care.[1] Several studies were reviewed in the Task force reports that identified causes of neck pain and proposed interventions.[1,3] Many mechanical and neurological causes of neck pain and chronic neck dysfunction have been studied, resulting in many possible interventions, without consensus.[1-3] There was much disagreement and controversy around whether surgical or non-surgical approaches were more effective for certain pathologies.[3] As part of a new conceptual model for neck pain, the Task Force proposed an evidence based classification system that could also help determine appropriate interventions.[1]

There are four classifications of neck pathology according to the Task Force, the first two of which are appropriate for non-surgical interventions.[1] Grade I is neck pain without signs of major structural pathology and also with little to no interference with daily living activities. The Task Force described major structural pathology as fracture, dislocation, spinal cord injury, infection, tumor, systemic disease processes in the cervical spine area.[1] Grade II also has no signs of major structural pathologies, but neck pain interferes with daily living.[1] The next two classifications are ones that are considered appropriate for surgical intervention.[3] Grade III has no signs of major structural pathologies, but neurological deficits are present, which could be sensory, motor, or reflex changes.[1] Grade IV has signs and symptoms of major structural pathologies with or without neurologic deficits. In the case of Grade IV pathology, neurologic deficit may also include myelopathy from structural deficits restricting the spinal canal. Other factors must be considered in the decision for surgical intervention such as duration and pattern of the neck pain, as well as the extent of the neurological deficits.[1]

Purpose of ACF Surgery and Reported Outcomes

ACF surgery is performed to manage painful cervical spine pathology in the Grade III and IV levels as defined by the Task Force.[1] Although, the most common indication for ACF surgery is cervical radiculopathy producing radiating pain or neurological deficit, ACF may also be done for neck pain in the presence of degenerative disc disease.[3,63,64] In a Cochrane review of the studies on ACF, there was less conclusive

evidence supporting surgery for degenerative disc disease with neck pain only when compared to cases with cervical radiculopathy.[34] However, Grob reports that ACF can resolve central neck pain effectively in a study discussing surgical interventions for degenerative disease of the cervical spine.[39] Oktenoglu et al compared anterior cervical discectomy with and without fusion and found both procedures reduced radicular arm pain, but only procedures with fusion reduced neck pain.[38] In a study of predictive factors for long-term outcome of ACF, Peolsson et al (2008) reported that lower preoperative pain and perceived disability were two factors that showed good prognosis with surgery.[63] Matz reviewed outcome studies of ACF compared to conservative care for radiculopathy including therapy or immobilization.[64] Their study found that ACF was reported to give more rapid relief of radicular symptoms in 3-4 months than conservative care.[64] Many of the above studies also describe or compare various surgical techniques or devices for ACF and cite its success rate in overall pain relief.[34,38,39,63]

In ACF surgery, the symptomatic disc or discs are removed, the intervertebral space is replaced and often increased with a spacer, either bone implant or metal cage.[34,38,44] The spacer allows increased intervertebral distance which also helps open the foraminal area, allowing more room for exiting nerves and resolving nerve impingement.[34,39] If the disc itself was degenerated and a cause of pain, ACF would stabilize the segment as well as replacing the degenerative tissue.[34,38] The stabilizing effect of the surgery on a previously degenerative unstable spinal segment is considered an advantage of the ACF.[33] In one text book with a PT protocol for ACF, treatment

logically focuses on protecting this spine stability.[33] However, there are no studies yet giving supporting evidence for this approach for rehabilitation of ACF.

Although studies on ACF have shown fairly good, sometimes immediate short term pain relief and improvement in neurologic symptoms, several post-surgical complications and residual impairments have been reported, including persistent pain,[7,40,41] dysphagia,[42,43] and poor results on functional testing.[49,63] Peolsson et al performed a multivariate analysis to determine predictive factors for neck pain and disability after ACF surgery.[7] The study concluded that non-smokers, male gender, those with lower pain frequency before the surgery, and those with lower scores on pre-operative psychological screens were most likely to have pain relief and better surgical outcome.[7] In one of Peolsson's more recent predictive studies on ACF, Peolsson reports that the Neck Disability Index (NDI) is an important functional outcome measure for ACF and that poor scores describe poorer outcome.[63] Zoega et al tested several outcome measures and determined that the Oswestry scale and Millon Index, both measures of patient's perception of disability due to pain, also predicted surgical outcome.[49] Persistent pain is a problem frequently cited by review articles on ACF, and represents an adverse outcome, according to Daniels in a summary study of adverse outcomes.[41] Dysphagia is another complication of ACF, because of the anterior incision and the proximity to the esophagus.[41,43] However, Smith Hammond et al conducted swallowing studies on patients undergoing anterior and posterior cervical spine surgeries, and found incidence

of dysphagia in both groups, although anterior approach incidence was much higher (near 50%) than posterior approach (20%).[42] The study suggested that the dysphagia may also be related to neck pain as well as the soft tissue disturbance in the anterior structures.[42] Since most reports of dysphagia have been retrospective studies, Riley et al conducted a large prospective observational study on 454 patients undergoing ACF.[43] This study found that much of the dysphagia was short term, 3-6 months, but longer term dysphagia was more likely to occur in those individuals having more spinal levels fused, or those having more persistent pain.[43] All of the above difficulties may be possible to reduce with appropriate PT interventions, but have not been reported in the literature.

Studies have also identified ACF postoperative impairments in cervical range of motion,[50,51,66] instability or degeneration of the adjacent segments,[40,65,67] and decreased cervical muscle strength or endurance.[8,54] Hillibrand et al measured cervical range of motion before, 3 months, and 1 year after ACF surgery and compared this range to healthy, unoperated control subjects.[50] Twenty-five subjects had from 1 to 4 levels fused and all had the most reduction in range before surgery, had increased range of motion after surgery, but still less than the range measured in the control subjects.[50] The study concluded that although range of motion significantly increases after ACF surgery, it does not reach the range of asymptomatic individuals.[50] Schwab et al. measured motion changes in levels adjacent to one level cervical fusion in a cadaver study.[51] Schwab found sagittal motion increases mostly above the fusion with single fusions at C3-4 or C4-5.[51] At C5-6 or C6-7 increases were found above and below the fusion, but greater

C4-5.[51] At C5-6 or C6-7 increases were found above and below the fusion, but greater compensation occurred below.[51] Galbusera et al modeled 4 different types of ACF using various types of fixation and studied the stability and remaining movement in each model.[66] They concluded there was significant difference in motion distribution among spinal levels depending on fixation device and type of spacer used.[66] Elsawaf et al studied motion and spine alignment for 1-2 years following ACF in a cohort of 20 patients and found that adjacent segments showed an increase in range of motion, which in some cases lead to degeneration of those segments.[65] Seo & Choi challenged the contention that movable artificial disc replacements in the cervical spine would avoid the degeneration at adjacent levels that have been thought to be related to fusions.[40] They found that degeneration at adjacent levels occurred with either type of surgery.[40] Both biomechanical studies and follow up studies looking at repeat surgeries have described the concern of load on adjacent discs as a problem with fusion surgeries, such as ACF.[66,67] Cheng et al developed a mathematical model of the cervical spine to calculate forces at each spinal level on flexion/extension radiographs.[67] They concluded that additional load and directional forces occur at adjacent levels which may then lead to excessive motion and eventual instability and degeneration of the adjacent levels.[67] An important follow up question for these biomechanical studies would be whether or not stabilizing muscular activity could reduce these adjacent disc motion changes.

There is not much information available on the recovery of muscle performance following ACF surgeries. Although several muscles may go through changes with ACF,

these changes have not been well described. Peolsson and Kjellman (2007) have compared neck muscle endurance in patients with nonspecific neck pain and patients following anterior cervical fusion.[54] They found neck muscle endurance deficits, in both timed static flexion and extension held against gravity from recumbent positions, in patients with neck pain and following surgery, compared with controls.[54] The group with neck pain trained with general neck exercise rehab and the surgical group with "conventional physiotherapy" after 6 weeks of immobilization in a hard collar. This training study showed that neck muscle endurance and pain levels improved in both surgical and non surgical groups of patients.[54] However, deficits were still present at the end of the training period, so investigators concluded longer duration or more specific training was needed.[54] Studies describing changes in the cervical stabilizing muscles in most cases of cervical dysfunction should be considered following cervical spine surgery. Ylinen et al studied patients after anterior cervical discectomy, many with fusion, testing neck range of motion and isometric strength, compared to healthy control subjects.[8] The investigators found significant loss in strength and range of motion in the post surgical group, ranging from 16-25%. The authors concluded that the deficits occurred even in the presence of pain relief in most cases, and pointed out that effects of early testing and rehab needed to be studied.[8] In spite of this, almost nothing exists in the literature indicating the importance of muscle function after cervical spine surgery.

Many of the problems following ACF and spine surgery in general seem to be problems that could be helped with PT interventions. Many of these PT interventions are

considered necessary for most other orthopedic surgeries.[5,59] Again to date, very little has been published regarding rehabilitation after cervical spine surgery other than a few text book recommendations for postoperative therapy protocols.[33] But again, postural training, stabilization exercises and general retraining of neck muscle strength and endurance all appear to be potentially beneficial interventions that remain to be studied.

Muscle Dysfunction Related to Neck Pain

Training of neck muscles may be neglected in physical conditioning programs, but more recently has had considerable study indicating its importance. In a review report on neck muscle training in individuals with chronic neck pain, Ylinen (2007) describes functions of the neck muscles that make training an important consideration, including: 1) providing isometric force against the force of gravity to keep the head upright; 2) control of head movements, especially acceleration and deceleration; 3) positioning the head for the best sensory functions of hearing, sight, olfaction, and 4) input to the vestibular system.[68] So there are many areas of muscle performance needed from the neck muscles that protect the cervical spine that often show deficits in the presence of chronic pain. The review was of randomized controlled studies of several types of neck muscle training addressing one or more of the above functions and concluded that only the intensive or specific training programs made long term changes in chronic neck pain.[68] Exercise studies also suggest that prevention of neck pain may be helped by exercise, although Ylinen points out that there is not any consensus on amount and type of exercise.[68] Studies that support importance of neck muscle training include

those that have found relationships between neck pain with more sedentary lifestyles, general disuse, and work settings involving extending sitting again resulting in disuse.[9,69] Bernaards et al reported an incidence of 25% or greater incidence of neck pain and disability in computer workers in several European countries, and studied workplace intervention.[69] The interventions included ergonomic education only, education and physical activity, compared to a control group. Although both intervention groups improved symptoms and increased physical activity, the education only group showed the most improvement.[69] The study reported that it could not conclude that increasing physical activity would resolve work related neck pain and disability, but again did not study intensity or specificity of training.[69] Nikander et al studied 180 female office workers with chronic neck pain, citing previous studies that had shown decreased pain with either strength or endurance physical training.[9] The authors stated that the amount and type of exercise had not been previously quantified, and that studies showing intensive training showed more consistent improvement in neck pain.[9] The Nikander study randomized the workers into 3 groups: strength training, endurance training and control, with specific dosage was set for both exercise groups by metabolic equivalents (METs) per week to provide a consistent level of intensity.[9] The control group had a gentle stretching and mild aerobic exercise program. Both types of intensive dosage specific exercise showed improvements over the control group, with the study conclusion that exercise of the study intensity was safely effective for women with chronic neck pain.[9] Although these studies focus on different possible sources of weakness, they all

appear to indicate that specific therapeutic exercise produces the best resolution for the weakness as well as the pain.

Posture is also a problem related to many forms of neck pain and some question remains regarding its link to muscle weakness. Patients with neck pain have been shown to demonstrate characteristics of 1) forward head posture,[56,70,71] 2) changes in cervical lordosis,[72,73] and 3) fatigue in key postural muscles increasing postural sway and decreasing stability.[21,74] Watson and Trott measured posture and upper cervical flexor strength in 60 subjects with and without cervicogenic headache.[71] They found increased forward head posture and decreased upper cervical flexor strength and endurance in the group with headache.[71] In addition, they found forward head posture statistically related to the decreased muscle performance of the upper cervical flexors.[71] Silva et al also found forward increased forward head posture in 40 subjects with neck pain when compared to age matched asymptomatic patients.[70] Kapreli et al also found increased forward head posture in individuals with neck pain, and found that these individuals also had decreased respiratory function.[56] McAviney et al measured cervical spine lordosis using Cobb angle from C2 to C7 on 277 lateral view radiographs divided into "cervical complaint" and "non-cervical complaint" groups.[72] They found a significant relation between neck pain and cervical lordosis of less than 20 degrees, and defined a "clinically normal lordosis range of 31 to 40 degrees.[72] The study, which concluded that decreased cervical lordosis was related to neck pain was refuted by Grob et al in their study of lordosis measures in symptomatic vs. non symptomatic individuals.[73] Grob et al found

no differences in curvatures between groups and also identified postural abnormalities in both groups.[73] Postural deviations frequently involve weakness of more global stabilizing muscles and also need to be considered when treating a patient with neck pain.[9]

Falla and Farina reviewed several studies showing neuromuscular deficits occurring with neck pain which affect motor control, muscle fatigue and postural control.[21] They concluded that knowledge of these deficits could help identify the most effective therapeutic intervention for neck pain.[21] Stapley et al studied patients with whiplash associated disorder (WAD), identifying neck muscle fatigue and increased postural sway characteristics in these individuals.[74] The study also tested a PT intervention directed at neck muscle training that relieved symptoms.[74] Therefore, faulty postural alignment has been shown to be related, though not proportionately, to muscular deficits, degenerative disease and instability of the cervical spine. Both posture and instability have been shown to be helped by specific cervical stabilization training, which is discussed in the next section.

Evidence of Muscular Segmental Spine Stabilization

In recent years, there has been an increasing interest in studying specific muscles that stabilize the spine segmentally, as instability is considered a cause of degenerative segments and pain.[18,19] Initial focus was on stabilization training of the lumbar spine, and some pioneering research showed training segmental stabilizers of the lumbar vertebrae was a key factor in recovering pain free function.[75] Textbooks covering this research made a conclusive argument in favor of attention to these muscles for low back

dysfunction, in particular, lumbar multifidus and transverse abdominis.[59,75] These segmental stabilizers are starting to be recognized by surgeons, as seen in the study by Ward (2009) in Journal of Bone and Joint surgery on multifidus and its role in lumbar stability.[6] In Ward's study, the role of the multifidus with its anatomical orientation was reviewed, pointing out the potential segmental support to improve spinal mechanics.[6] With this information, more recent attention has been placed on muscles providing cervical spine segmental stabilization. Initially, MRI studies of patients with cervical spine injuries, noted and studied atrophy in specific paraspinal muscles.[23-25,76] Andary et al described suboccipital atrophy in a case study of an individual with chronic neck pain and headache.[76] The investigators described the atrophy accompanied by fatty infiltration of the rectus capitus muscles bilaterally and identified denervation with subsequent EMG testing.[76] Elliott found a difference in cross section area of the cervical extensors on MRI of women with chronic whiplash associated disorders (WAD) when compared with healthy controls.[23] In Elliott's study, they found larger cross sectional areas of the cervical multifidus in the group with WAD, but also widespread fatty infiltration in all of the cervical muscle extensors which had been identified in previous studies as well.[23,24] The increased cross sectional area was found at all spinal levels from C3-7 of individuals with WAD only in the cervical multifidus, and varied at different levels other cervical extensors.[23] Fernandez de las Penas et al demonstrated decreased cross sectional area of both rectus capitus posterior major and minor in individuals with chronic tension headache.[25] Moreover this decrease was inversely proportionate to the frequency,

intensity and duration of the headache.[25] Studies showing this atrophy have been important to suggest the relationship between stabilizing muscle deficits and neck pain, something that has not been widely accepted in the past.

More recent work on identifying key muscles for cervical spine stabilization has identified cervical multifidus and deep cervical flexors (DCFs) longus colli and longus capitus as the primary muscles for segmental stabilization.[14,18] Biopsy, cadaver, and biomechanical studies have examined the tissue of the stabilizing muscles to investigate their morphology In a study of dorsal and ventral muscle tissue, Uhlig et al (1995) performed biopsies during anterior or posterior cervical spine fusion and identified transitional muscle fiber type IIC indicating fiber type changes occurring in all muscles tested.[77] These muscles included anterior groups: sternocleidomastoid, omohyoid, longus colli, and posterior groups: rectus capitus posterior major, splenius capitus, and trapezius. The investigators concluded that the muscular changes occurring in spinal disorders were due to fiber type changes that occur as a result of neck pain.[77] Anderson et al describe the cervical multifidus in a cadaver study with biomechanical modeling.[78] The study describes the deep location and segmental attachments of the cervical multifidus, with alignment providing mostly stabilizing more than movement function. In addition, multifidus attachments on facet capsules from C4 through C7 were identified as possible sources of pain with injuries.[78] In a study of cervical spine injuries with motor cycle accidents, Hayashi et al identified abnormal signal intensity in cervical paraspinals on contrast MRI associated with nerve root avulsion.[79] Their study identified

increased enhancement of cervical multifidus as the strongest indicator of nerve root avulsion.[79] Mayoux-Benhamou et al studied cross-sectional area and orientation of longus colli in a radiological study indicating its role in anterior support of the cervical lordosis and described its function with paraspinals providing a stabilizing "sleeve" around the cervical spine.[80]

Falla has conducted numerous studies over several years on neck pain and importance of muscle control of DCFs and cervical multifidus for cervical spine segmental stabilization as a key factor in normal function.[14] She summarizes the findings from several studies leading up to testing and training programs for the segmental stabilizers in her very elegant report "unraveling the complexity of neck pain" in 2004.[14] Later, in 2007, Falla and Farina describe both neural and muscular components of deficits that occur with cervical dysfunction and pain.[21] Falla has several studies have used EMG testing of cervical multifidus and the DCF. The studies have identified reduced EMG in DCF in individuals with neck pain, indicating both fatigue and weakness during muscle testing.[17,20] In addition, they have shown that training the DCF can reduce both the fatigue and neck pain.[20] In a review of several studies associating pain and altered muscle control in the neck, Falla has described DCF and paraspinal inhibition, substitution with larger muscles, and decreased stabilization control and reactions during limb movement.[21]

Rehabilitative Ultrasound Imaging (RUSI) is a relatively new technique that allows visualization of soft tissue structures and their movements in real time.[27] Recent

studies have investigated contraction patterns and cross sectional areas of the cervical spine stabilizers and found these measurements could be made with good reliability.[27,28] Cervical multifidus atrophy has been identified in individuals with chronic neck pain and headache, supporting the findings from earlier MRI studies.[28,3] Longus colli has also been studied with RUSI in a study by Jesus et al (2008) that validated a muscle test recruiting the DCFs.[26] Information from RUSI and EMG studies has helped improve specificity of exercise for improved spine stabilization and symptom management.

Testing Muscles for Cervical Spine Stabilization

Falla et al (2004) showed EMG changes in DCF during a specific test targeting these muscles in individuals with chronic neck pain.[17] This specific clinical test, the craniocervical flexion (CCF) test, has been designed to determine deep cervical flexor activation, and has been shown to be reliable and valid.[15-19] Reliability has been tested in normal subjects and in those with neck pain.[16,32] Fernandez-de-la-Penas et al showed ICC values of 0.84-0.90 with CCF testing of patients with chronic tension headache.[32] Chiu et al found 80% agreement on test-retest reliability.[16] Validity has been established using both concurrent EMG testing and functional MRI. Falla et al established validity of the CCF test for individuals with neck pain by showing a strong linear association between CCF test scores and EMG amplitudes in the deep neck flexors which were done concurrently.[17] Cagnie et al (2008) showed construct validity of the CCF testing in healthy individuals using functional MRI of the DCF during the tests. They concluded

the CCF movement was most specific to test DCF alone without contribution from larger neck muscles.[81]

The CCF test involves maintaining a posterior pressure of the cervical spine on a pressure sensing device such as a Stabilizer ™, or air bladder such as blood pressure cuff, for given increments of time. Jull's protocol describes using a resting pressure in the Stabilizer of 20 mm., and having the participant increase the pressure in 2mm. increments for 10 sec. each.[31] The maximum pressure the individual is able to hold for 10 sec. is called the "activation score", using the number of mm above 20 that represents the maximal hold, and thus ranges from 0-10.[31] Performance index is an endurance score multiplying the activation score by number of repetitions 0-10 that can be done at the activation score level, ranging from 0-100.[31] The activation score and performance index scores cited in many studies. Normal activation scores found in Jull's studies were 7.6 +/- 2.1.[31] Chiu reported mean score of individuals with neck pain was 24mm or and activation score of "4", with asymptomatic individuals scoring 28 mm or "8", agreeing with Jull's normative values.[16] In individuals with headache, activation scores between 4 and 6 have been reported compared to asymptomatic score of 8, with performance indexes of 30 vs. 60 respectively.[32] Using the pressure sensing device allows testing in other positions such as sitting or standing, or can test stabilization during movements of other areas of the body.[19]

Another form of CCF test involves flexion of the upper cervical spine, usually against gravity with a forward head lift from a supine position, maintaining this position

for 30-60 seconds.[82] This test has also been used as a measure of neck muscle endurance when the lift is held as long as possible, with norms reported as 2.5 min for men and 0.5 for women.[83] The cut off time indicating cervical flexors deficit in this study was 56 sec for men and 23 sec for women.[83] Harris described a technique for determining if the subject was holding a flexed position by drawing a line across the anterior neck skin folds during the contraction, stopping the time when the line broke.[82] Harris reported values of 20-25 seconds in individuals with neck pain vs. 35-45 seconds in those with no neck pain, and found ICC 0.80-.90 intrarater reliability, and 0.6-0.7 interrater reliability for this test.[82] This test has lower reliability in the presence of pain, and involves more involvement of larger muscles than Jull's test.

O'Leary et al (2007) tested the specificity of CCF testing with a dynamometer placed under the mandible to test isometric strength of the DCF.[84] They compared this CCF test with a standard resisted cervical flexion test using isometric force against a dynamometer placed at the forehead. EMG was used to compare levels of muscle activation between the superficial neck flexors (sternocleidomastoid, anterior scalenes, and sternohyoid) and the DCFs for each testing method. The cervical flexion test with resistance at the forehead had highest level of activation in superficial muscles, particularly the sternocleidomastoid, on EMG. The CCF test with resistance under the mandible showed the highest level of EMG activation of the DCFs primarily, and less superficial muscle.[84] Since deficits in CCF test muscle performance have been shown to

be valid and reliable, as well as related to neck pain symptoms, this test could be a clinically important test to assess function following cervical spine surgery.

Evidence Supporting the Training of Cervical Spine Stabilizers

Retraining of deep neck flexors either with supine head lift or with application of posterior cervical pressure into the air bladder sensing devices have both been shown to reduce neck pain, both long term and immediately upon muscle contraction.[10-12] The deep cervical flexors are an important specific muscle group to target for treatment of many cervical disorders because of their direct support of the cervical lordosis, which in turn can help stabilize the cervical vertebrae and lessen the tendency for excessive stresses on the posterior structures including cervical facets.[14,18,80] The cervical facet joints are primary posterior structures which are often identified as pain generators for mechanical neck pain disorders, but decreased foraminal opening can also occur as a result of excessive stress on posterior structures.[14,80] Although ligamentous support accounts for a component of the stability in the cervical spine, muscular support accounts for an estimated 80% of the stabilization force.[14] Furthermore, the ligamentous support is present at the end range, while the muscular function becomes more important for stability and function during mid range activities.[14,80]

Jull et al compared the results of a neck flexor strengthening exercise program to a specific low load CCF exercise program and found that only the low load CCF program improved DCF recruitment as assessed with EMG.[10] In one study by O'Leary, "immediate hypoalgesia" was noted on performance of craniocervical flexion exercise in

patients with chronic neck pain.[11] Specifically, the deep cervical flexors, longus colli, longus capitus, and rectus capitus anterior have been shown to be important segmental stabilizers of the cervical spine that fire as synergists with posterior muscle groups cervical multifidus, rectus capitus major and minor.[19] These muscle groups have been the subject of several studies in the past decade, because of their apparent function in normal neck stability and therefore pain control.[14,18,80]

Outcome Instruments for Neck Pain Interventions

Because of the increasing awareness of the frequency of cervical pathologies and pain complaints in the general population, many instruments have been designed for assessing patients' perceptions of their limitations due to pain. For this study, the outcome measures of patient perceptions that will be used are the numerical pain rating scale (NPRS), The Neck Disability Index (NDI), and Global Rate of Change Score. CCF test of strength and endurance described by Jull will be the clinician's measures of cervical functional outcome, which is described in detail in the previous sections.

Numerical pain rating scales are used frequently for a single rating of pain that can be easily identified by individuals experiencing pain of any type. The zero to ten numerical pain scale is very commonly used in medical practices and hospital settings. It has had validity and reliability established for lumbar spine pain, but reportedly not established for cervical spine pain.[62] Cleland et al reported reliability of NPRS in patients with mechanical neck pain with ICC of 0.78, with MDC of 1.3.[85] Because of the

frequency of use of the NPRS in hospital records and surgeon's reports for patients undergoing spine surgery, it was chosen as a dependent variable for this study.

The NDI is one that is frequently used in cervical spine outcome studies, and has been identified in one multifactorial surgical outcome study as an important test for patients undergoing ACF.[63] It is a 10 item scale with points ranging from zero to five for each of 10 potential functional limitations from neck pain, such as reading, driving, performing daily self-care, sleeping, and concentrating. Each item is scored from not being limited at all or "0" to being extremely limited or completely unable or "5".[62] The total number of points is multiplied by 2, so is expressed as a percentage, and has been shown to have a minimal clinically important difference of 10.2.[62] In a review of the NDI by Vernon (2008), the NDI was reported to be the "most strongly validated for assessing self-rated disability" due to neck pain at the time, and had been used in more than 300 studies as of 2007.[86] In another review by MacDermaid (2009), variable rates of reliability between studies was shown with ICC's ranging from 0.5 to 0.98, with the majority of studies showing "acceptable reliability".[87] MacDermaid also reports that NDI is strongly correlated ($r>0.70$) with many other similar indices measuring both physical and psychological effects of neck pain on daily activities.[87] Minimal detectable change on NDI is reported to be 5/50 for neck pain without radiculopathy, and 10/50 for neck pain with radiculopathy.[87]

The Global rate of change (GROC) is used as a measure of patient's perception of change resulting from a surgical or nonsurgical intervention, originally described by

Jaeschke et al.[88] Patients are first asked to assess whether they are better, worse or the same since the intervention.[62,88] They are then asked to rated the amount of change if better or worse, on a 1-7 point scale with 1 representing very little change and 7 representing a very great deal of change.[88] GROC scores are helpful as they represent the patient's perception of the success of an intervention as opposed to the degree of symptoms or disability.[88]

Studies of Therapy Inteventions after Spine Surgery

Spine surgeries have been reported to be increasing in number at least partly due to the aging population.[35,89] Unfortunately, there has also been a large variability in outcome and patient satisfaction reported, part of which is due to lack of information provided to patients.[89] In a qualitative study by Davis et al, patients were interviewed in detail about the surgical care experience following two types of lumbar surgeries.[89] The study reported that patients identified several areas of need for a satisfactory procedure including: more clarity on the need for the procedure, more complete information and preparation, less waiting time, and more continuity and frequency with follow up.[89] Along those lines, recent studies have tested more complete education and closer follow up with rehabilitation following lumbar surgeries. A randomized controlled trial of a 12 week immediate post-operative rehabilitation following lumbar spine fusion by Abbott et al resulted in improved outcomes and better pain management with the early therapy at follow up from 3 months to 3 years.[36] Abbott et al pointed out the lack of active retraining for motor control of the segmental spine stabilizers in most typical post

operative lumbar fusion rehab programs. The experimental group in Abbott's study worked on segmental stabilization for lumbar spine motor control retraining on a daily basis, and had three outpatient sessions with counseling and educational support. The control group performed a 12 week daily home program of global spine stabilization and kept an exercise diary. Although both groups showed improvements, the experimental group showed more improvement in functional disability levels, and outcome scores, with less fear avoidance.[36] Other early intervention studies have been conducted for lumbar spine surgery, and produced similar findings.[35,37] Hebert et al reported a single case report of early therapy intervention after lumbar microdiscectomy with weekly instruction on segmental stabilization of the lumbar spine and a daily home exercise program.[37] Hebert's study supported the concept of the importance of motor control retraining in producing early improvements in muscle performance. The study used RUSI and MRI assessment of multifidus muscle performance and identified improvements in the early postoperative weeks as the specific exercise was carried out.[37] Neilsen et al created a pre-operative trunk strengthening exercise program called "prehab", and repeated some of the exercise immediately after lumbar fusion surgery.[35] In their European clinical trial, patients normally spent 8 days in the hospital in order to reach benchmarks of safe transfers, bed mobility, and gait for discharge home. Neilsen's study showed patients who had the prehab and early rehab were able to be discharged after 5 days and reached markers for recovery sooner. However, there was no difference in postoperative pain level or incidence of complications.[35] McGregor et al proposed a

multicenter study of postoperative rehabilitation following lumbar fusion comparing evidence based education with a rehabilitation protocol, with four groups, one for each intervention alone, one for both interventions, and one "usual care" group.[61] However, the final analysis did not show a difference in long term self reported pain and disability scales between groups.[61] The success with early intervention after lumbar spine surgery gives strong support to the concept of early PT intervention after cervical spine surgery.

However, the rehabilitation literature has very little information on patients who have undergone ACF. Since ACF is one of the most common cervical spine surgeries for neck pain with or without radiculopathy, rehabilitation sources would be expected. Yet, therapy interventions for these patients after surgery has only recently been recommended in a very few texts.[5] Little literature exists describing ways to recover strength, mobility, function, or manage symptoms after cervical spine surgeries.

While there is limited research on PT interventions following cervical spine surgery, PT following lumbar surgeries has been studied more frequently.[81] In a case report of successful PT intervention after spine surgery, Puentadura describes the exercise and manual therapy successfully used in a patient following a minimally invasive lumbar partial disc replacement.[90] Flanagan et al (2007) identified back extensor strength deficit in the months following lumbar microdiscectomy surgery and showed its relationship fear-avoidance behavior patterns found in control subjects. These fear avoidance behavior patterns are felt to be barriers to participating in activity.[91] The study pointed out the importance of assessing lumbar spine muscle performance to help determine

lumbar surgery outcome. In a more recent training study, Kulig et al found that intensive training of lumbar stabilizers following lumbar microdiscectomy resulted in decreased disability scores and improved walking distance.[92] Hodges et al have shown rapid atrophy of the lumbar multifidus occurring in a study of experimental lumbar nerve injury in animals. Again the association of lumbar multifidus atrophy with lumbar disc disease indicates an area requiring attention during the rehabilitation of these patients.[93] Hides et al have shown that multifidus atrophy also associated with pain symptoms is not automatically recovered when pain symptoms are relieved.[94] In the lumbar spine, it is clear that multifidus training is critical to returning protective stabilization and mechanical function of the entire area.[6] More studies of this type are needed to definitely show the need for attention to specific strengthening following spine surgery in general, and are especially lacking for cervical spine surgeries.

Summary

With increasing numbers of studies showing frequency of cervical spine pathology, with relationships between muscular deficits, posture, and pain, it is apparent that intervention should address the musculoskeletal deficits. Given that specific focus on cervical muscle length and strength successfully helps resolve many nonsurgical cervical spine cases, research efforts are needed for the more neglected patient population of post-surgical patients. We do not know if muscle performance of deep cervical flexors and cervical multifidus is as important to the post surgical patient as the other groups with various types of neck pain. Also we do not know if early intervention with specific

recruitment of deep cervical flexors and cervical multifidus could help circumvent typical common post surgical problems. This study was designed to answer these questions.

CHAPTER III

METHODS

The primary purpose of this study was to compare effectiveness of clinical outcomes between an early physical therapy (PT) intervention and usual care in patients who underwent ACF surgery. The clinical outcomes included: 1) pain level using the numeric pain rating scale (NPRS), 2) patient's perceived disability associated with neck pain as determined by Neck Disability Index (NDI), 3) deep cervical flexor (DCF) strength, and 4) DCF endurance. These four clinical outcomes measurements were collected before surgery for baseline, then at six week post-operative visit with the surgeon. In addition, at six weeks after surgery, the Global Rate of Change (GROC) was a fifth outcome measure to determine the patient's perception of overall improvement as a result of surgery. A secondary purpose of this study was to compare these clinical outcome measurements in patients undergoing anterior cervical fusion (ACF) surgery before surgery and at six weeks post-operatively. The study also examined the relationships among the patient's perceived disability due to pain, DCF strength, and DCF endurance. Additionally, test-retest reliability of the CCF tests in patients with ACF surgery was determined at six weeks after surgery.

Research Design

The research design of this randomized clinical trial was a prospective double-blinded mixed design comparing outcome measures following ACF surgery. There were two independent variables: 1) type of post-operative management with two levels, early PT intervention and usual care, and 2) time frames with two levels, before surgery and six weeks after surgery. There were five dependent variables or outcome measurements: pain level (NPRS), patient's perception of disability due to neck pathology (NDI score), DCF strength (craniocervical strength (CCF-S) test score), DCF endurance (craniocervical endurance (CCF-E) test score), and patient's perception of change after surgery (GROC score). The relationship among the three dependent variables of the NDI score, CCF-S, and CCF-E, were studied at each of the two time frames. NPRS and GROC were used to explore the patient's perceptions of surgical outcomes. The primary investigator (PI), who collected the outcome measurements, did not perform the PT interventions for participants and was blinded to group assignment.

Participants

Participants were 30 individuals who had ACF surgery performed by spine surgeons at Texas Spine and Joint Hospital (TSJH) in Tyler, Texas. Participant recruitment took place in conjunction with pre-operative office visits with the surgeons or pre-operative clearance testing at TSJH. The physician's office staff informed potential participants about the study. Once the potential participants gave permission to release their contact information, the PI contacted the participants and provided further

information about the study. After an individual agreed to participate in the study, he or she received the study details and requirements for each of the two testing sessions. All of the tests were taken once before surgery and again at six weeks post-operatively, in conjunction with their physician office visits.

Inclusion criteria for the participants were: 1) men and women between the age of 30 to 75 years, 2) individuals who were scheduled for ACF surgery which was performed by one of the three participating spine surgeons at TSJH, and 3) surgical candidates classified as Task Force Grade III, with neurologic deficit without major structural pathology, or Grade IV, with or without neurologic deficit with major structural pathology.[1] The age range of 30-75 was chosen for this study to minimize variability that may be seen in musculoskeletal outcome measures with very young or very old participants. Exclusion criteria will be: 1) musculoskeletal or systemic disorders with functional impairments that limited tolerance of testing, 2) pain greater than 8/10 on the NPRS if it limited testing tolerance, 3) prior cervical spine surgeries, and 4) more than two-level cervical spine surgery.

Approval for this study was obtained through the Institution Review Board (IRB) at Texas Woman's University prior to the commencement of this study, and all requirements were observed during participant selection and participation in the study. For the IRB approval from the university, a written agreement (Appendix A) with TSJH was required, and was obtained, agreed and signed by investigator and TSJH administration prior to commencement of the study. Please see Appendix B for the IRB

approval from TWU. Also, the study was registered with ClinicalTrials.gov Protocol Registration system, as required for clinical research studies.

Instrumentation

Several instruments were used in this study in both testing and intervention, including the Stabilizer™ Pressure Biofeedback, NPRS, NDI, and GROC scales. These were used to assess cervical spine muscle strength and endurance, pain level, patient's perception of disability, and patient's perception of change, either better or worse, after surgery.

The Stabilizer™ Pressure Biofeedback

The Stabilizer™ Pressure Biofeedback (Chattanooga Group Inc., Chattanooga TN) was used to measure DCF (i.e.,longus colli and capitus) muscle strength and endurance in a testing protocol previously described by Jull et al in 2008.[31] The Stabilizer is an air bladder pressure with a gauge similar to a blood pressure cuff that gives feedback on load changes to the device (Appendix C). CCF testing with the Stabilizer has identified deficits in the DCF of individuals with chronic neck pain, headache, and whiplash disorders.[15,16,32] Tests of CCF-S and CCF-E have been identified as reliable and valid for quantifying DCF muscle performance in several studies on patients with various symptom level.[16,17,31] However, most of these studies have not established a minimal clinically important difference (MCID) for CCF-S and CCF-E tests.[14,16,31]

Numerical Pain Rating Scale

The NPRS of 0-10 was used to assess pain level at the time of each data collection. Participants were asked to rate their average pain level at the time of the visit on a scale of 0 to 10 with 0 being no pain, and 10 being the worst pain imaginable. The MCID for the NPRS was reported to be 1.3 in a study of psychometric properties of functional scales for the cervical spine.[63] The NPRS has been widely used in clinics as well as in research because of its easy administration and good reliability. The NPRS has been shown to be reliable with ICC reportedly being 0.83 on average and ranging from 0.74-0.92.[63,64]

Neck Disability Index

The NDI used in this study is a self-reported questionnaire to determine a patient's perceived disability associated with neck pain.[61-64] Vernon reported that the NDI is considered the most widely used and "strongly validated" instrument.[61] Vernon reviewed several convergent validity studies where investigators compared the NDI to 11 other validated scales.[62] Vernon reports that reliability was established from the earlier studies to be 0.89.[61] The NDI consists of 10 impairments common to patients with cervical symptoms (e.i. reading, driving, sleeping) Each impairment question is quantified on a scale of 0-5 by the patient, with a total possible score of 50 for maximum disability.[61] The score is often multiplied by 2 and expressed as a percentage. In a systematic review of the NDI, MacDermid et al (2009) reported that the minimal detectable change on NDI is 5/50 or 10% for uncomplicated neck pain, and 10/50 or 20%

for cervical radiculopathy.[62] The clinically important difference of the NDI reportedly ranged from 5/50 (10%) to 19/50 (38%).[62] The NDI form is included in Appendix D.

Global Rate of Change Scale

The global rate of change (GROC) was used to determine the patient's perception of the outcome of spine surgery. The GROC was initially designed to rate improvement in patients with respiratory disorders.[65] It has now been extended to evaluate changes with many musculoskeletal treatments, including those for cervical spine pathology.[66,67] This scale is the patient's rating of the amount of improvement that he or she perceives at a given time frame after the intervention. The original rating scale started with three initial ratings: better, no change, or worse. No change would be 0, negative values -1 to -7 would rate the level of change from " very slightly worse",-1, to "a very great deal worse",-7. Positive values indicate improvement from +1, very slightly better, to +7 representing the most improvement "a very great deal better".[65,66] It has been proposed that changes between 1 and 3 are considered to be minimal change, 4 and 5 are moderate change, and 6 and 7 are major change.[65]

Participant Enrollment

All eligible participants who were recruited for the study were informed of the purpose of the study, the procedures, potential risks, and benefits. Participants read and signed an informed consent form approved by the IRB at TWU. According to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, an identification number was assigned to each participant and was the only identification used on all

testing forms. Each participant completed a brief medical intake form, including age, sex, height, weight, medical history, symptom duration, and symptom intensity. At the time of the enrollment, participants had been randomly assigned to either the early PT intervention or the usual care group by one independent research assistant (not the PI). Each group had its own consent form so that the participants were informed about study details regarding their own group (see Appendix E for both the consent forms). The research assistant had placed consent forms for the assigned group in opaque numbered envelopes, and gave these to the PI in numerical order for each initial patient visit. The PI gave each participant the assignment in the envelope at the time of enrollment, which the patient read, signed and returned to the envelope, so the PI remained blinded to assignment. The research assistant, who could not be present at the initial visit provided a copy of the informed consent to the participant at a later time.

Procedures

After the participants signed the informed consent, the cervical pathology and the presence or absence of radiculopathy identified by the surgeon were collected for each participant. In addition, the PI performed a neurological examination on the upper quadrant of each participant to confirm the presence or absence of cervical radiculopathy. The neurological examination included dermatomal sensory testing of C5-T1, deep tendon reflex testing of C5-C7, and myotomal testing of C4-T1, slump test and the upper limb tension testing (ULTT). All of the tests were performed following the procedures described by Cook and Hegedus.[95] These neurological tests have shown good reliability

and diagnostic accuracy for cervical radiculopathy.[62,95,96] In addition, the ULTT has been shown to be a sensitive and a specific test for cervical radiculopathy.[96] These neurological tests are described in Appendix F. The neurological tests were performed and recorded before surgery and at six weeks post-operatively.

Administration of the NPRS, NDI, and GROC

After the neurological examination was completed, the PI began to collect all outcome measurements. First the PI administered NPRS and NDI. For the NPRS, patients were asked to rate their pain level from 0 (no pain) to 10 (worst pain imaginable). For the NDI questionnaire, patients were asked to rate their level of function and pain for each of the 10 questions on a scale of 0-5. The NPRS and the NDI questionnaires were collected before surgery and at 6 week post-operative testing. During the six week post-operative testing, the GROC was also assessed. Each participant was asked to rate the amount of change since surgery on a 15 point numerical scale from -7 to +7 with descriptions provided with each number for the participant.

Cranio Cervical Flexor Strength (CCF-S) Testing

Once these outcome measurements were collected, the PI performed the CCF tests to collect both outcome measures for the muscle strength and endurance of the DCFs. Testing of DCF muscle strength was performed using the Jull et al's method. Jull et al developed the craniocervical flexion (CCF) test approximately 15 years ago, and has established reliability and validity of the test in individuals with and without neck pain symptoms.[31] The CCF test was developed specifically for the DCFs using the

Stabilizer™ Pressure Biofeedback (Chattanooga Group, Inc, Chattanooga, TN).[31] The investigator asked participants to lie in a supine hooklying position with the Stabilizer placed under the neck so that it supported the cervical spine from just below the occiput to the cervicothoracic junction. Positioning for the test is shown in Appendix I. The cuff was inflated to 20 mm Hg., which has been described to support the cervical spine without adding anterior forces to the vertebrae.[31] The PI instructed the participant to do a slight nodding movement, a chin-tuck, that produced enough additional pressure on the cuff to increase the pressure to 22 mmHg. The participant was asked to hold the pressure at this level for 10 seconds. If the participant was able to perform at the pressure of 22 mmHg and hold for 10 seconds successfully, the participant was then asked to try to increase the pressure to 24 mm Hg for 10 seconds, and if successful, increased to 26 mm. Testing proceeded in 2 mm Hg increments up to a maximum of 30 mmHg. The highest pressure that the participant was able to hold for 10 seconds was defined as the "activation score", and was used to determine DCF muscle strength. The activation score is expressed in studies as the pressure held minus the 20 mm initial pressure of the cuff, so the CCF-S test activation score would range between 0 and 10.[31] The participants performed the CCF-S test twice and the better of two trials was used as the activation score.

Cranio Cervical Flexor Endurance (CCF-E) Testing

The CCF-E test for muscle endurance of the DCFs was performed by asking the participant to hold the pressure at activation score level for 10 seconds, rest 20 seconds,

then repeat the ten second hold up to a maximum of 10 repetitions. The "performance index" reports the CCF-E as activation score x number of successful repetitions holding at the activation level for 10 seconds.[31], Therefore, the CCF-E test has a possible maximum value of 100. This test was stopped when a participant failed to hold the target pressure on the Stabilizer and only successful repetitions were counted. At times failure occurred due to pain, or substitute motions were observed, so that testing was stopped.[31,32] The performance index was determined with a single trial and was used to define CCF-E in this study.

Although the reliabilities of both the CCF-S and CCF-E tests have been established for individuals with and without neck pain, the reliabilities of these two tests have not been established for individuals who have undergone cervical spine surgery. The CCF-S test was performed twice on the same day, as stated above, but all testing was done by the PI. Test-retest reliability on the same day was not practical for just one investigator. Between-day reliability was planned for ten participants who lived in close proximity to the hospital and were willing to participate second test for CCF-S and CCF-E on a different day.

Intervention

Training of Physical Therapists

Two physical therapists (PT), assisted by 2 physical therapist assistants (PTA) at TSJH were responsible for administering interventions to the participants during their hospital stay following ACF surgery. The two PTs had at least one or more years of

experience at TSJH. To minimize variation during the interventions, PTs and PTA's were trained by the PI in both the usual care and early PT intervention protocols. The training lasted approximately four hours, with the PI available to answer questions as needed throughout the study. All four therapists completed training and received NIH certificates of completion for "Protecting Human Research Subjects" required by the TWU IRB prior to the beginning of the study. When an enrolled participant was admitted to the hospital for surgery, the treating PT received a packet with the materials needed for the assigned group from the research assistant. The packet consisted of items (Appendix H): the group assignment of the participants, the ACF specific patient instructions and instructions provided at the hospital for all spine surgeries, the First Six Weeks DVD, a check list for the therapist to follow. For participants in the early PT intervention group, the packet also included the early PT intervention program.

Usual Care Protocol for Group 1

For participants in the usual care group, the intervention closely followed what is currently done at TSJH in the first six weeks post-operatively for patients after ACF. These individuals were seen in the hospital by one of the trained PTs before discharge. The PT evaluated the patient for proper positioning of head and neck, use and fit of cervical collar if applicable, proper body mechanics, and safety with transfers and gait. The participants were instructed in and given the hospital's patient information sheet on ACF (Appendix K). This information includes strategies for symptom control such as head and shoulder posture correction, position and support of the entire spine such as

lumbar support, ice application, deep breathing and relaxation techniques. A recommended activity program was included for Group 1 participants, encouraging patients to walk daily to help the fusion along with instructions for safe extremity movements given to all patients after spine surgery. They also viewed and were given a copy of the hospital DVD of the "First Six Weeks", a summary of the general post spine surgery precautions (script of DVD in Appendix J). The PT also addressed any questions about the video. The PT completed the packet checklist and documented the visit on the hospital electronic medical record. The research assistant collected checklists and recorded the completion of the visit.

Early Physical Therapy Intervention for Group 2

Participants in this group received the components listed for the usual care group: PT evaluation for proper positioning of head and neck, body mechanics, and safety with transfers and gait, hospital patient information sheet for ACF, and the "First Six Weeks" DVD. In addition, they were instructed in a series of surgery-specific protective exercises referred to as "Exercise Program, 0-6 weeks Post ACF". This program included explanation of the purpose of the exercises and how specific CCF exercise has also been shown to help with pain control. All exercises emphasized attention to head and shoulder positioning and posture, as well as recruiting cervical segmental stabilizers with CCF. The exercises were also designed to recruit specific overall postural muscles, for example, a slight chin-tuck combined with scapular retraction and abdominal bracing. The participants were informed of the pain control function that may occur with all of the

exercises described above via improved circulation, oxygen delivery and relaxation response. Participants were instructed to perform the CCF exercise, beginning in a neutral pain-free head over shoulders position with slight chin tuck, cued as "crown up", in sitting or standing to promote overall postural strength. During the CCF exercise, the participants also learned abdominal bracing, and scapular retraction, also done with the "crown up" cue. The exercise program will be advanced by asking the participants to perform gentle upper extremity movements while the head is held in the neutral pain-free position. Sit-to-stands and heel raises were also combied with the CCF exercise while the participants were asked to maintain "crown up" CCF, abdominal bracing and scapular retraction posture. The participants were asked to perform the exercises two to three times daily starting with repetitions and frequency indicated on the exercise log as instructed by the treating PT. They were instructed to increase one repetition every other day until they can perform 30 repetitions without aggravating symptoms. Illustrated written instructions with an exercise log (Appendix K) were given to the participants to record their exercise repetitions and frequency. The exercise log also includes a grid to record daily walking distance or time, unlike the usual care in which walking was encouraged but not monitored.

The early rehabilitation intervention developed for this study incorporated the concepts in previous studies of early postoperative rehabilitation interventions in lumbar spine and other peripheral joints.[11-14] This intervention emphasizes patient education, precautions for post surgery, safe gait, transfers with proper body mechanics, attention to

body positioning and early protective muscle recruitment. All exercises were designed to be performed in a hard collar that is usually prescribed for the first six weeks. If the collar was not ordered or ordered as needed, the participants were instructed to maintain a neutral spine position while performing all of the exercises.

Follow up for Both Groups

Follow-up calls to each participant in both groups were conducted by a research assistant at 2 and 4 weeks post surgery to verify compliance with the program and address any questions. The research assistant made all follow up calls, and used a script prepared by the PI (Appendix L). A list of frequently asked questions was included with the script to assist the research assistant in answering participants' questions. The research assistant made notes on the script for each call and relayed information to the PI. Questions that required help from the therapist were relayed to the PI without identifying the treatment group. All participants in both groups were also encouraged to call the assistant with any questions throughout the study.

Data Analysis

The PASW 18 statistical package (IBM Corporation, Somers, NY) was used to analyze the collected data. Descriptive statistics were used for the characteristics of the participants including age, gender, body mass index (kg/m^2), preoperative diagnosis, duration of symptoms, employment status, smoking habit, history of depression, and type of surgery with regard to levels operated. The BMI was calculated using participant's height and weight information with the formula above, dividing weight by height

squared. The results of neurologic tests of the upper quadrant before surgery and at 6 weeks were presented in a descriptive format, including: motor, sensory, reflex, and neural tension tests. A chi square analysis was done to assess group differences on categorical results, and independent t-tests were done on age and BMI for group differences. An alpha level of 0.05 was set for all statistical tests conducted.

A 2x2 MANOVA with repeated measures was used to assess differences in the data collected for the four outcome measurements (NPRS, NDI, CCF-S and CCF-E scores) between the two groups with the repeated measures of before surgery and six weeks post ACF surgery. A Mann-Whitney U test was used to compare the differences in the GROC data between the intervention and the usual care groups at six weeks post ACF surgery, with alpha set at 0.05. Pearson correlations were used to test relationships between NDI scores and CCF testing results. Concordance correlation coefficients (ρ_C). were calculated for between-day test retest reliability testing of CCF-S and CCF-E. These coefficients will be interpreted using scales proposed by Pinto et al[97]: "poor" ($\rho_C <$ 0.40), "fair" (ρ_C = 0.40 - 0.59), "good" (ρ_C=0.60- 0.74), and excellent (ρ_C 0.75-1.00).

CHAPTER IV

RESULTS

Participants

Forty-seven participants were referred for the study from February 2012 to August 2012 and 30 participants were enrolled and tested for the study. Seventeen were excluded from the study due to either declining to participate in the study or not meeting inclusion criteria (17 total excluded). The consort diagram in Figure 1 summarizes the enrollment, screening and randomization of participants.

The characteristics of the participants are summarized in Table 1, including gender, age, body mass index (BMI), smoking, spine diagnostic category, number of spinal levels fused, duration and onset of symptoms, employment status, other medical conditions, and diagnosis of depression. All participants were classified as being in Grade III or IV of the Task Force Diagnostic Classification system for neck disorders. Therefore all participants had conditions that warranted cervical spine surgery. Chi square analysis performed on the above mentioned characteristics except for age and BMI variables showed no differences between the two groups (usual care and early physical therapy (PT) intervention). The chi-square analysis results (p values) are listed in Table 1. In addition, the independent t-test revealed no difference in age and BMI between the groups. The results of the independent t- test are listed in Table 1 as well.

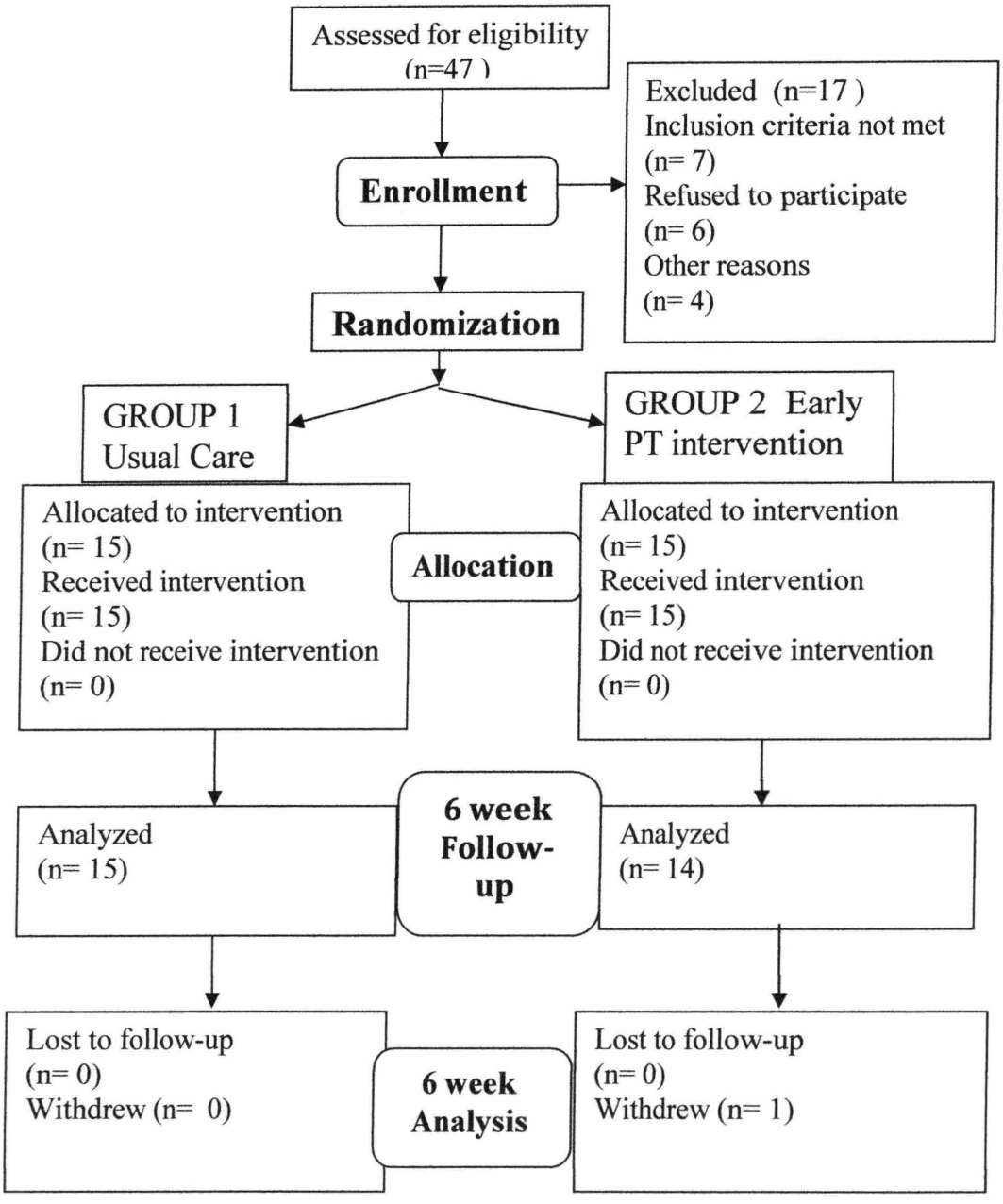

Figure 1

The Consort Diagram

Table 1

Characteristics of the Participants

	Usual Care	Early PT Intervention	Between Group p value *
N	15	15	30
Gender, # female	6	9	0.27
Age, mean (SD)	56.0 (9.77)	54.7 (10.52)	0.68
Age, range	37-67	38-71	
BMI	30.7 (6.35)	28.4 (5.37)	0.313
Smoker, # yes	5	3	0.71
Task Force Grade 3	11	8	0.26
Task Force Grade 4	4	7	
One level fused	6	6	1.0
Two levels fused	9	9	
Duration of symptoms			
6-12 months	2	0	0.117
1-5 years	7	4	
> 5 years	6	11	
Onset of symptoms			
Gradual	7	9	0.765
Sudden increase	8	6	
Working? #yes	8	6	0.765
Medical conditions			
Diabetes, cancer or cardiovascular	8	8	1.0
Neurologic	5	9	0.343
Other orthopedic	5	6	0.931
Depression #yes	5	7	0.705

*t-test for age and BMI, chi-square analysis for all others

There were equal number of men and women for the entire study, but there were more men in Group 1 (usual care) while there were more women in Group 2 (early PT intervention).

Posture Observation and Neurologic Examination

The findings of the posture and neurological tests are summarized in Table 2. The frequencies were based on numbers of positive findings in the categories of the type of tests including: postural tests, radicular symptoms, dermatomal sensory deficit, abnormal reflexes, myotomal motor loss, abnormal neural tension testing with the slump test and the upper limb tension test (ULTT). Radicular symptoms were obtained from patient history and report. Postural deviations were evaluated subjectively and were considered present if forward head and shoulders, excessive thoracic kyphosis, or scoliosis was identified. Reflex, motor, sensory, and cord compression tests were all done by the techniques described in Chapter 3 using Cook's text[95] with details on technique and psychometrics found in Appendix F. Chi-square significance levels are listed and once again showed no significant differences in all of the clinical test results between groups before surgery. Therefore groups were considered equivalent in terms of demographics and physical exam characteristics.

Table 2

Posture Observation and Neurologic Examination

	Usual Care	Early PT Intervention	Between Group p value *
Positive Radicular Symptoms (total)	10	12	
Unilateral arm	8	7	0.604
Bilateral arm	2	5	
Type			
Numbness	5	7	0.656
Weakness	3	2	
Pain	1	1	
Combination	1	2	
***Posture Deviations number identified**	9	10	0.705
Positive Upper limb tension test	13	11	0.439
Positive Slump test	6	4	0.439
****Reflex changes in biceps, triceps, brachioradialis**			
Diminished or absent	5	1	0.456
Dermatomal sensory deficit upper extremity	7	7	1.0
Myotomal deficit upper extremity motor	10	8	0.456

*Posture deviations include: Forward head and shoulders, excessive thoracic kyphosis, or scoliosis

**Reflex diminished or absent in biceps, triceps, or brachioradialis

Between Day Reliability of CCF-S and CCF-E Tests

The between-day test-retest reliability of the cranio cervical flexor strength (CCF-S) and the cranio cervical flexor endurance (CCF-E) tests was determined from measurements taken on two separated visits at the six week follow-up. A within-day test was not applicable for this study with a single investigator and limited time to test participants. Only eight participants were willing to undergo repeat testing of the CCF tests on a different day. Concordance correlation coefficients (ρ_C) for test-retest reliability showed excellent reliability for the CCF-S test (0.82) and good reliability for the CCF-E tests (0.70).[97]

Outcome Measurements

The descriptive data for the Numerical Pain Rating Scale (NPRS), Neck Disability Index (NDI), CCF-S, CCF-E and Global Rate of Change (GROC) scale, are summarized in Table 3. Each outcome measure met the normality testing. Therefore, the collected data was normally distributed. The t-tests of initial values of the first four measurements taken before surgery showed no significant difference between groups. Results of the 2 x2 MANOVA with repeated measures showed no significant interactions for group by time ($F= 0.465(DF=24)$, $p = 0.761$), but a significant time effect for all outcome measures (NPRS, NDI, CCF-S, and CCF-E) ($p<.001$). There was no significant effect of group on any of the outcome measures ($F = 0.857$, $df = 24$, $p = 0.503$). In addition, the Mann-Whitney U tests show no significant differences between groups for GROC changes ($p = 0.162$) from pre-operation to the six week follow-up.

Table 3

Mean (SD) for Outcome Measures by Group Across Time

	Usual Care M (SD)	Early PT Intervention M (SD)	p-value between groups
Numerical Pain Rating Scale (NPRS)			
Before surgery	4.57 (2.56)	5.83 (2.56)	0.134
6 weeks post ACF	2.2 (1.57)	2.7 (2.26)	0.202
Neck Disability Index (NDI)			
Before surgery	44.6 (19.27)	46.4 (17.89)	0.793
6 weeks post ACF	29.13 (12.41)	28.93 (18.36)	0.972
Cranio Cervical Flexor-Strength (CCF-S)			
Before surgery	6.4 (2.16)	6.13 (2.20)	0.740
6 weeks post ACF	7.73 (3.1)	8.0 (2.6)	0.933
Cranio Cervical Flexor Endurance (CCF-E)			
Before surgery	30.53 (20.12)	29.53 (15.31)	0.879
6 weeks post ACF	58.8 (28.09)	64.43 (25.45)	0.831
Global Rate of Change Scale			
6 weeks post ACF	4.3 (1.4)	4.9 (1.9)	0.162

Note: p-values for data before surgery is from t-tests; p-values for 6 week data taken from between group comparisons in MANOVA; p-values for GROC are from Mann-Whitney U test.

Correlations between Outcome Measures

Pearson Product correlations were calculated to determine relationships between NDI, CCF-S, and CCF-E. These were performed for all three outcome measures for all participants at both time frames, before surgery and at six weeks after surgery, and with data both before and after surgery data combined. The results of the correlations tests are summarized in Tables 4 through 6. Pearson correlation using total data show significant negative correlations between the NDI and the CCF-S scores and between the NDI and the CCF-E scores both before surgery and with the overall data. The results also revealed that the CCF-S scores have a significant positive correlation with the CCF-E score regardless of which of the above comparisons was used. However, at the six week follow-up, there was a weaker correlation between the NDI and both the CCF tests as well as the CCF-S as seen in Table 6.

Table 4

Correlation Table for Combined Data from Before Surgery and 6 Weeks Post

	Neck Disability Index (NDI)	**Cranio Cervical Flexor Strength (CCF-S)**	**Cranio Cervical Flexor Endurance (CCF-E)**
Neck Disability Index			
Pearson Correlation	**0**	**-0.645**	**-0.548**
p-value		**<0.01**	**<0.01**
CCF-S			
Pearson Correlation		**0**	**0.855**
p-value			**<0.01**
CCF-E			
Pearson Correlation			**0**
p-value			

Table 5

Correlation Table for Data Collected Before Surgery

	NDI Before Surgery	CCF-S Before Surgery	CCF-E Before Surgery
NDI Before Surgery			
Pearson Correlation	**0**	**-0.605**	**-0.548**
p-value		**<0.01**	**<0.01**
CCF-S Before Surgery			
Pearson Correlation		**0**	**0.855**
p-value			**<0.01**
CCF-E Before Surgery			
Pearson Correlation			**0**
p-value			

Table 6

Correlation Table for Data Collected at 6 Weeks Post Surgery

	NDI 6 weeks post ACF	CCF-S 6 weeks post ACF	CCF-E 6 weeks post ACF
NDI 6 weeks post ACF			
Pearson Correlation	**0**	**-0.354**	**-0.255**
p-value		**0.06**	**0.18**
CCF-S 6 wks post ACF			
Pearson Correlation		**0**	**0.895**
p-value			**<0.01**
CCF-E 6 wks post ACF			
Pearson Correlation			**0**
p-value			

CHAPTER V

DISCUSSION

Results of Hypothesis Testing

Hypothesis 1

Early PT intervention results in different outcomes in the pain level, the patient's rated perception of disability, the DCF strength, and the DCF endurance than usual care over time.

The primary purpose of this study was to compare clinical outcomes between an early PT intervention and usual care in patients who underwent ACF surgery. The clinical outcomes included: 1) pain level using the numeric pain rating scale (NPRS), 2) patient's perceived disability associated with neck pain as determined by Neck Disability Index (NDI), 3) deep cervical flexor (DCF) strength, and 4) DCF endurance. The outcomes were measured before and six weeks after ACF surgery. Results showed that there was no significant difference between groups on any outcome score. Therefore, the alternative hypothesis above is rejected and the null hypothesis remains true. However, both groups showed statistically significant improvements in each outcome measure from before surgery to six weeks after surgery. The results indicate that both the early PT intervention and usual care groups made the same amount of improvements in their pain reduction, perception of disability level, CCF strength and endurance at six weeks post-

ACF surgery. Adding the CCF exercises to the usual care did not appear to have benefits to this patient population in the first six weeks of recovery after ACF surgery. However, recovery from surgery such as ACF usually takes up to a year or more.[34] Since the data was collected in a relatively short period of time (six weeks) after surgery, it is unclear whether or not differences between groups would be seen at a later point of time.

When examining the data for each of the outcome measures, the early PT intervention showed a slightly greater change in the NPRS scores, an improvement of 3.1 points compared to the usual intervention score of improvement of 2.4 points. The improvements in the NDI, CCF-S, and CCF-E scores were also greater in the early PT intervention group, although to a lesser degree. For the NDI , the minimal clinically important difference (MCID) has been reported by Cleland et al as 10 points or 10 percent.[62] Both groups made improvements in the NDI scores more than the MCID with the early PT intervention making a 17.5 point improvement in NDI, and the usual care making 15.5 points of improvement in NDI. This finding is clinically significant and may indicate that when patients have signs and symptoms appropriate for ACF surgery, they likely will have good outcomes in their perceived disability level at six weeks post-operation. The differences in CCF testing scores are similar to those found with NDI: the CCF-S scores improved by 1.9 mmHg in the early PT intervention group, and by 1.3 mmHg in the usual care group, and the CCF-E scores improved by 35 points (out of 100) in the early PT intervention group and by 28 points in usual care group.

Our findings are different from those reported by Abbott et al,[36] who investigated the effects of early intervention on lumbar fusion. The authors reported improvements in both groups, but more with the early segmental stabilization. In Abbott et al's study, the early intervention group had a 12-week training period of the segmental stabilization (motor control retraining) and three out-patient sessions where the participants received additional education.[36] Our study only had one educational session, and two follow-up phone calls. Perhaps a longer time frame or additional education would show differences between groups. Further study with longer follow-ups may be warranted.

In both Abbott et al's and McGregor et al's studies, the authors emphasized the importance of the educational component of the therapy program.[36,61] In addition, patient satisfaction reportedly increased in surgical cases when more education was provided.[89] In our study, both groups of patients received more education than usual for ACF surgery during the enrollment process, the PI initial testing, and the follow-up phone calls from the research assistant. The PI was blinded to group assignment, but answered all patient questions possible at all testing sessions. Usually these questions were about the expected course after surgery and not related to their group assignment. Also, being participants in the study, and not knowing which group assignment they were given, it is possible that they were more attentive to the therapist hospital visit. The hospital visit may have also been given more attention by the therapist for the same reason. There were many possible factors influencing the improvements in both groups.

Hypothesis 2

Early PT intervention results in greater patient's perception of change since surgery on the GROC scale than usual care over time.

At the six-week post-operative test, the Global Rate of Change (GROC) scale was administered to participants to obtain their perception of change since this surgery. A Mann Whitney U test was performed to assess the difference in the GROC scores between the two groups. Although there was an observable difference with the early PT intervention group having a great improvement of the GROC score, the difference was not statistically significant. Therefore, the alternative hypothesis given above was rejected and the null hypothesis was retained. Once again, although the GROC scores were not significantly different between groups, both groups showed a significant improvement in GROC scores, 4.9 for early PT intervention, and 4.3 for usual care. Although six-weeks is relatively a short time for assessing surgical success of a spinal fusion, both groups perceived significant improvement at six weeks post ACF surgery. Most surgical studies had longer follow-up periods of one or more years to assess outcomes. Sasso et al[48] reported their outcomes at one and two years after ACF surgery.. Sasso et al[48] used the NDI and NPRS to determine differences in outcome between ACF and artificial disc replacement. However, more improvement was found in the disc replacement group in this study.

Hypothesis 3

There is a strong correlation ($r \geq 0.7$, $\alpha = 0.05$) among patients' rated perception of disability, DCF strength, and DCF endurance in individuals undergoing ACF surgery.

Results of Pearson correlations of combined data from before and after surgery showed one strong correlation ($r = 0.86$, $\alpha < 0.01$) which occurred between CCF-S and CCF-E. The results also showed a significant negative correlation between the NDI and CCF-S ($r = -0.57$, $\alpha < 0.01$) as well as the NDI and CCF-E ($r = -0.67$, $\alpha < 0.01$), representing the better (lower) NDI scores associated with better (higher) CCF scores. We found similar correlations between the outcome measures of the participants before surgery: $r = 0.855$ between the CCF-S and CCF-E scores ($\alpha < 0.01$), $r = -0.605$ between the NDI and CCF-S scores ($\alpha < 0.01$), and $r = -0.548$ between the NDI and CCF-E scores (, $\alpha < 0.01$). NDI and CCF testing scores were not significantly correlated at six weeks, but had fair correlations: $r = 0.895$ between the CCF-S and CCF-E scores ($\alpha < 0.01$), $r = -0.354$ between the NDI and CCF-S scores ($\alpha = 0.06$), and $r = -0.255$ between the NDI and CCF-E scores ($\alpha = 0.18$). Therefore, the alternative hypothesis was retained because of the strong correlations found.

Since the outcome measures have such strong relationships, these measures may be important clinical measures to track progress following ACF. Several previous studies[14,21] have shown the inverse relationship between DCF muscle performance (i.e. CCF-S and CCF-E tests) and neck pain symptoms. The CCF tests of DCF muscle performance reported in the literature have been lower in individuals with chronic neck

pain, and neck pain symptoms including headache.[16,32] Our study shows a similar relationship between DCF muscle performance and neck symptoms after surgery. Our findings were similar to other studies that have shown relationship between different measures used to assess outcome of ACF. In addition to the Sasso study mentioned earlier, Zoega et al[49] assessed relationships between functional level, pain level, and surgical outcome rating scales for ACF at two years post, finding good correlations between instruments.[49]

Hypothesis 4

The CCF tests have acceptable within-day and between-day reliability, with interclass correlation coefficients (ICCs) of ≥ 0.70, ($\alpha = 0.05$) *in individuals undergoing ACF.*

A within-day test was not applicable for this study with a single investigator and with limited time to test participants at the post-operative office visits. The time between the two sessions on the same day may not have been long enough for the PI to objectively collect the data twice. Additionally, it was not practical to ask the participants to stay longer for a repeated test. However, eight participants were willing to return for between-day test-retest reliability of their CCF tests. After examining our reliability data (Table 7), we found that all eight participants (5 in the usual care group 3 in the early PT intervention group, and 6 men, 2 women) who were in the reliability portion of the study made significant improvements in the outcome. Five reached the maximal score of 10 during the CCF-S test. With a small sample size and low variability, a concordance correlation coefficient was selected to assess the test-retest reliability. The results

showed an excellent between-day reliability for the CCF-S test ($\rho_C = 0.82$) and a good reliability for the CCF-E test ($\rho_C = 0.70$) using Pinto et al's criteria.[97]

Table 7.

Reliability Data for Eight Participants

CCF –S test 1	CCF-S test 2	CCF-E test 1	CCF-E test 2
8	10	64	100
10	10	80	100
10	10	80	80
10	10	90	100
8	8	64	80
10	10	80	100
8	10	80	90
10	10	80	100

The reliability data could have improved by increasing the sample size. The number of participants in the reliability testing all had CCF scores at the high end of the range of all participants. We planned to recruit a random sample of 10 participants to return for the second CCF tests to assess the between-day reliability at the time of their six-week follow-up. The testing at six weeks was done in conjunction with the return office visit with the surgeon. Most of our participants traveled anywhere from 30 minutes to two hours for this visit, and also were scheduled for radiology prior to seeing the surgeon. The study testing took place in between radiology and the appointment with the surgeon. Because of the time and travel often involved with the office visit and the fact that many were released back to work at that visit, it was difficult to randomly select the participants to come back on a different day. Only eight of the patients agreed to

come back for the second test and these participants who were willing to return for the repeat testing seemed to be the ones who performed the test easily. In the previous studies,[15-17] the most variability that occurred with either of the CCF tests was due to pain with testing. In contrast, pain was at a minimum level (NPRS between 1 and 2 for all 8 participants) in these participants which may have affected reliability.

Participant Recruitment

As shown in the consort diagram (Figure 1) of the previous chapter, 17 out of 47 eligible patients were excluded from the study. We encountered several difficulties in participant recruitment for the study. Six refused to participate in the study, seven either had extensive co-morbidities or was scheduled for surgery on more than two cervical levels. Four could not be reached prior to the surgery to offer study participation. In addition, the participants who declined to participate in the study were concerned about extra trips to the hospital for testing or training. Lastly, the targeted patients were individuals who had activity-limiting neck pain and were scheduled to have a high-risk surgery, making them hesitant to make a commitment for what they might imagine would be an intolerable activity after surgery. Some had pain exacerbations in the past when attempting to exercise and had fear avoidance associated with activity. Some had been told by other medical professionals in the past to avoid all activity and movement. However, the PI made every effort to provide the potential participants with details about specific expectations for their group.

Characteristics of the Participants

The participants who completed our study were a diverse group of individuals, both by history and by clinical tests. Based on chi-square analysis, the groups were considered equal before surgery. Overall, participants in both groups tended to be mildly overweight, had many co-morbidities, did no exercise prior to the study, and were still working. Since smoking is strongly associated with poor surgical outcome for spinal fusions, the number of the participants who smoked may have affected the results of the study.[7,63] Only eight out of 29 the participants were smokers, five in the usual care group and three in the early PT intervention group. In addition, the participants, regardless of group, perceived a significant improvement in their symptoms (GROC scores ranged from +4 to +5) as a result of surgery. Therefore, the smoking factor may not have had a significant impact on the results of our study. Because of the number of individuals with risk factors including inactivity, comorbidities, being overweight, and lacking previous exposure to exercise, activity-based rehabilitation combined with wellness education could play a more important role in management of cervical pathologies. The variability between participants in many physical characteristics may have presented some confounding factors in the data analysis.

Outcome Measures

The CCF tests are low-intensity tests which measure muscle control of the DCFs. Because the CCF tests use a movement that can also help with pain control, they appear to be a good choice for patients to use with cervical spine surgery rehabilitation.

However, at times in this study, especially before surgery, testing was frequently limited due to pain. Some participants had difficulty tolerating the testing position, which made it difficult for them to learn the test movement properly. Most participants had not been previously instructed in CCF which may also have biased the study results, as CCF scores are influenced by practice.[16,32] Because most of the participants in the study had instability in the cervical spine prior to the surgery, it also appeared that the CCF tests may be useful in determining improvements in spine stability.

The NPRS is used throughout the peri-operative care for ACF. Not only was it used for an outcome measure for the study, it was used by the surgeons' office staffs to record pain levels during all office visits and phone communications, and it was used as a means to report pain levels on the two follow-up phone calls made by the study research assistant. We found that participants were very familiar with this test, and most could respond to this easily. On the contrary, the Neck Disability Index (NDI) was not a familiar instrument for many of the participants, and did not always change proportionately to the NPRS. This might indicate that these two instruments measure different perspectives of the patient's recovery from surgery. This might be interpreted as disability not due to pain, or that a part of the disability may be due to fear avoidance of certain activities. The NDI was identified by Peolsson as an important outcome score specifically for ACF because poor NDI scores were found in patients with poor outcomes after ACF.[63] The average score of our participants on the NDI after surgery was 29, suggesting low disability. In addition, our participants demonstrated good outcomes

following surgery as demonstrated by the GROC scores and improved postural and neurologic tests. Therefore, our study appears to support the findings of Peolsson's study.

Changes in Postural Observations and Neurologic Testing

Although these clinical tests also showed improvements in both groups at six weeks, they were not dependent variables and therefore not analyzed statistically. However to illustrate the changes, Table 8 below summarizes changes seen in these characteristics before surgery and at six weeks post. This information is of value for describing changes that may be expected as a result of ACF surgery in the early phases and could be very encouraging for patients undergoing this procedure.

Table 8

Frequency of Positive Postural Observations and Neurologic Testing Before Surgery and at 6 Weeks Post ACF (Number of Participants)

Deficits identified	Usual care before surgery	Usual care 6-week post surgery	Early PT before surgery	Early PT 6-week post surgery
Postural deviations	9	8	10	10
Positive upper limb tension test	13	5	11	6
% with radicular symptoms (#)	10	5	9	2
Positive slump test	6	1	4	1
UE deep tendon reflex changes	5	3	1	3
UE sensory deficit	7	3	7	2
UE motor deficit	10	4	8	2

There were limited changes in postural deviations, which included forward head and shoulders, increased thoracic kyphosis, or scoliosis. These would be likely not to

change in a six-week period unless they were a postural response to pain. The neural tension signs of positive upper limb tension, radicular pain, and positive slump test all showed improvement at six weeks. Although abnormal reflex did not show much change, both motor and sensory deficits improved at six weeks in both groups. These are likely improvements to be expected with surgery regardless of intervention, but again were encouraging to many of our participants.

Limitations of the Study

There were several limitations in the study that may have contributed to the lack of significant difference between groups. This study only included 30 of the 40 participants that were calculated to be needed for significant findings by power analysis. Forty participants were determined to be needed, with 20 in each group, for a power of 80% ($\alpha = 0.05$). Because of the large variability in characteristics of individuals who were candidates for ACF, more than 40 participants may be needed to produce significant findings. The first 30 participants enrolled in this study were selected in order to examine and report outcomes six weeks after surgery. Six weeks is an expected time frame to see some improvements following spine surgery, as was seen in both groups with this study. However, many more improvements may be expected as all components of the spinal system have time to fully heal and retrain, as reported in the lumbar surgery rehabilitation studies.[35-37]

The variability of the participant characteristics may have also presented some confounding factors. There were three different surgeons involved in the study, with an

unequal distribution of the surgeons' patients between groups. In addition, although the surgeons practiced in the same office group, variability between their techniques and approach to patient care may have also resulted in difference in their outcomes. In addition, there were differences in pathology before surgery, grades III or IV that were not evenly distributed between groups. The grade IV participants have more of long-term, degenerative condition that creates a different clinical picture than those with grade III pathology which represents more sudden neurologic change often with more rapid symptom increase. Increasing group homogeneity could improve the capability to generalize the findings to other patients.

Another limitation was the lack of a true control group. As mentioned above, the usual care group was provided with education and monitoring that was in addition to the instruction and care usually given after ACF. The additional education and monitoring occurred during the study may have affected the results. The testing before the surgery was likely to have prepared the patient to be attentive to the information that followed. When patients asked questions before or after surgery, the PI was unaware of group, and always provided the requested information.

One limitation for the early intervention group was the fact that the participants in this group were instructed with a motor control retraining exercise program in a relatively limited time by the treating therapist. Time and practice are important for motor learning in spine stabilization.[19] Abbott et al emphasized this importance of motor learning which requires repetition and attention to patient education.[36] In this study, every attempt was

made to produce very clear instructions, and give complete verbal explanation in the hospital. However, the participants in the early intervention group may not be given sufficient time to fully acquire skills to perform the CCF exercises correctly. Further study with a few more face-to-face sessions with the therapist may help to ensure adequate motor learning.

Conclusion

Early PT intervention following ACF results in improvements in pain, perceived disability due to neck pain, and DCF muscle performance; however there was no difference in the amount of improvement from patients receiving usual care. The outcome measures used in this study appeared to be good tools for assessing progress and improvement after ACF surgery. Because there was no difference between groups at six weeks after surgery, usual care may be recommended from cost containment perspective. However, long-term follow-ups to examine the carry-over effects may reveal a different conclusion.

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APPENDIX A

Agreement with the Texas Spine and Joint Hospital

STANDARD RESEARCH AGREEMENT

This Standard Research Agreement ("Agreement"") is entered into between Texas Spine and Joint Hospital, Ltd. ("HOSPITAL") and Carol McFarland, PT ("INVESTIGATOR"), a post-professional graduate student at Texas Woman's University in Dallas.

RECITALS:

1. HOSPITAL supports research services in accordance with the scope outlined within this Agreement, herein after referred to as (the "Research"); and

2. The performance of the research is consistent, compatible and beneficial to the role and mission of the HOSPITAL; and

3. INVESTIGATOR has the capability to provide for the conduct of the research;

NOW, THEREFORE, the parties agree as follows:

SECTION I
SCOPE OF WORK

INVESTIGATOR will undertake the research program described in the research proposal attached hereto as **Exhibit 1**, approved by the Institutional Review Board of Texas Woman's University.

SECTION II
CONTRACT PERIOD

This Agreement shall become effective on December 15, 2011 and shall be completed on December 15, 2012, unless subsequent time extension, supplement, addition, continuation or renewal is mutually agreed upon in writing between the parties.

SECTION III
TERMINATION

Performance under this Agreement may be terminated by HOSPITAL upon sixty (60) days written notice; performance may be terminated by INVESTIGATOR if circumstances beyond her control preclude continuation of the Research.

In the event that either party hereto shall commit any breach of or default in any of the terms or conditions of this Agreement, and also shall fail to remedy such default or breach within thirty (30) days after receipt of written notice thereof from the other party hereto, the party giving notice may, at its option and in addition to any other remedies which it may have at law or in equity, terminate this Agreement by sending notice of termination in writing to the other party to such effect, and such termination shall be effective as of the date of the receipt of such notice.

SECTION IV
ASSIGNMENT

Neither party shall assign this Agreement to another without the prior written consent of the other party; however, the HOSPITAL may assign this Agreement to a successor in ownership of all or substantially all its business assets, provided that such successor shall expressly assume in writing the obligation to perform in accordance with the terms and conditions of this Agreement. Any other purported assignment shall be void.

SECTION V
INDEPENDENT CONTRACTOR

In the performances of all services under this Agreement, each party and its personnel shall be deemed to be and shall be an independent contractor and, as such, shall not be entitled to any benefits applicable to employees of the other party;

Neither party is authorized or empowered to act as agent for the other for any purpose and shall not on behalf of the other enter into any contract, warranty, or representation as to any matter. Neither party shall be bound by the acts or conduct of the other.

SECTION VI
REPORTING REQUIREMENTS

INVESTIGATOR will provide reports on the progress of the research described in **Exhibit 1** as follows: Quarterly updates submitted to Office of Administration of the HOSPITAL via Chief Nursing Officer on March 15, 2012, June 15, 2012, September 15, 2012, and at completion of the research.

SECTION VII
ACCESS TO RECORDS

All records pertaining to this Agreement must be retained by the HOSPITAL for a period of three (3) years from the completion date. If any litigation, claim or audit pertaining to this agreement is started before the expiration of the three (3) year period, the records must be retained until the litigation, claim or audit findings have been resolved.

SECTION VIII
PUBLICATION AND CONFIDENTIALITY

A. INVESTIGATOR, working under direction of a State institution of higher education, engages only in research that is compatible, consistent and beneficial to its academic role and mission. Therefore significant results of research activities must be reasonably available for publication. Before publishing, INVESTIGATOR agrees to give HOSPITAL a copy of any proposed publication and HOSPITAL shall have 45 days to review the publication. INVESTIGATOR shall consider HOSPITAL'S suggested modifications; however, the decision

of the dissertation committee of Texas Women's University as to what the publication shall contain is final.

B. INVESTIGATOR agrees to take reasonable steps to keep confidential any HOSPITAL proprietary information supplied to her by HOSPITAL during the course of research performed by INVESTIGATOR and designated in writing as "confidential", and such information will not be included in any published material without the prior written approval of HOSPITAL. Publication by either party shall give proper credit to the other party.

SECTION IX
NO WARRANTIES

INVESTIGATOR makes NO WARRANTY whatsoever regarding any research outcome obtained hereunder. Any decision regarding safety, applicability, marketability, effectiveness for any purpose or other use or disposition of any research outcome shall be the sole responsibility of HOSPITAL and/or its assigns and licensees.

SECTION X
SIMILAR RESEARCH

Nothing in this Agreement shall be construed to limit the freedom of INVESTIGATOR from engaging in similar research made under other grants, contracts or agreements with parties other than HOSPITAL.

SECTION XI
OWNERSHIP OF WORK

The INVESTIGATOR will retain right, title and interest, including the right of copyright, in all work reduced to writing or fixed in any media; including reports, articles, photographs, recordings, data, computer programs and related documentation, produced by the INVESTIGATOR under this Agreement.

SECTION XII
MODIFICATION

This Agreement contains the entire agreement between the parties, and no statements, promises or inducements made by either party, or agents of either party, that are not contained in this agreement are valid or binding. This Agreement may not be enlarged, modified or altered except by written amendment by the parties.

The parties hereto have executed this agreement on the date set forth below by their duly authorized representatives.

Each party hereby assumes any and all risks of personal injury and property damage attributable to the negligent acts or omissions of that party and the officers, employees, and agents thereof.

SECTION XIII
INSURANCE

HOSPITAL and INVESTIGATOR shall each maintain a professional liability insurance policy (covering the conduct of the research), worker's compensation (INVESTIGATOR may be covered by employer), and a general liability insurance policy providing sufficient coverage for its indemnification obligations hereunder (including coverage for any employees or third parties who provide services related to the research), and consisting of coverage that is primary to any insurance coverage that the indemnified party may maintain. INVESTIGATOR and HOSPITAL shall provide to each other copies of the certificates of insurance for the insurance policies obtained pursuant to this provision, as may be requested from time to time. Further, throughout the period(s) covered by this provision, INVESTIGATOR and HOSPITAL shall provide written notice to each other of any changes to the insurance policies obtained pursuant to this provision.

SECTION XIV
NOTICES

Notices and communications hereunder shall be deemed made if given by registered or certified envelope, postage prepaid, and addressed to the party to receive such notice, invoice, or communication at the address given below, or such other addresses as may hereafter be designated by notice in writing. Notices may also be delivered in person to Administration at the address noted below.

If to the HOSPITAL or

Texas Spine and Joint Hospital, Ltd.
1814 Roseland Blvd.
Tyler, Texas 75701
Attn: Tony Wahl, CEO

INVESTIGATOR:

Carol McFarland, PT

_____

_____

_____

SECTION XV
GOVERNING LAW

This Agreement shall be governed by the laws of the State of Texas. Venue of any dispute related to this Agreement shall be exclusively in Tyler, Smith County, Texas.

SECTION XVI
ENTIRE AGREEMENT

Unless otherwise specifically provided, this Agreement embodies the entire understanding between the Investigator and the HOSPITAL for this project, and any prior or

contemporaneous representations, either oral or written, are superseded. No amendments or changes to this Agreement, including without limitation, changes in the statement of work, total estimated cost, and period of performance, shall be effective unless made in writing and signed by authorized representatives of the parties.

INVESTIGATOR:	**HOSPITAL:**
CAROL McFARLAND, PT	**TEXAS SPINE AND JOINT HOSPITAL, LTD.**
BY: Carol McFarland	**BY:** Tony Wahl
TITLE: PT, Investigator	**TITLE:** CEO
DATE: 1-11-12	**DATE:** 1-11-12

APPENIDIX B

Approval Letter from Institutional Review Board

Texas Woman's University

TWU
TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON

Institutional Review Board
Office of Research and Sponsored Programs
P.O. Box 425619, Denton, TX 76204-5619
940-898-3378 FAX 940-898-4416
e-mail: IRB@twu.edu

November 22, 2011

Ms. Carol M. McFarland
740 Bunker Drive
Tyler, TX 75703

Dear Ms. McFarland:

Re: A Comparison of Clinical Outcomes between Early Physical Therapy Intervention and Usual Care in Individuals Following Anterior Cervical Fusion (Protocol #: 16841)

Your application to the IRB was reviewed and approved on 11/22/2011. This approval is valid for one (1) year. The study may not continue after the approval period without additional IRB review and approval for continuation. It is your responsibility to assure that this study is not conducted beyond the expiration date.

Any modifications to this study must be submitted for review to the IRB using the Modification Request Form. Additionally, the IRB must be notified immediately of any unanticipated incidents. If you have any questions, please contact the TWU IRB.

A final report must be submitted to the IRB at the conclusion of the study. If using a consent form, copies of the signed informed consent are to be submitted with the final report before the study file can be closed.

The Institutional Review Board is pleased to acknowledge your sense of responsibility for ethical research. If you have any questions concerning this review, please contact me at (214) 706-2461 or email SLin@twu.edu.

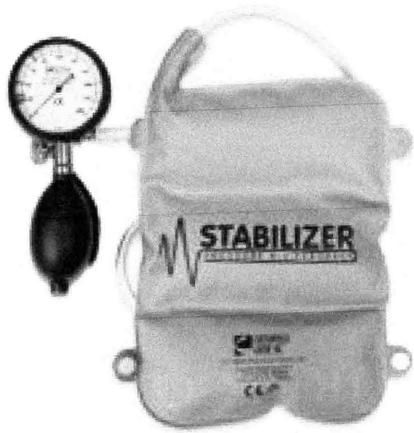
Sincerely,

Dr. Suh-Jen Lin, Chair
Institutional Review Board - Dallas

cc. Dr. Venita Lovelace-Chandler, School of Physical Therapy - Dallas
Dr. Sharon Wang, School of Physical Therapy - Dallas
Graduate School

APPENDIX C

The Stabilizer™ Pressure Biofeedback Sensor


STABILIZER

APPENDIX D

The Neck Disability Index Questionnaire

Neck Disability Index

Please Read: This questionnaire is designed to enable us to understand how much your neck pain has affected your ability to manage everyday activities. Please answer each Section by circling the **ONE CHOICE** that most applies to you. We realize that you may feel that more than one statement may relate to you, but Please **just circle the one choice which closely describes your problem *right now*.**

SECTION 1--Pain Intensity

0) I have no pain at the moment
1) The pain is mild at the moment.
2) The pain comes and goes and is moderate.
3) The pain is moderate and does not very much.
4) The pain is severe but comes and goes.
5) The pain is severe and does not very much.

SECTION 2--Personal Care (Washing, Dressing etc.)

0) I can look after myself without causing extra pain.
1) I can look after myself normally but it causes extra pain.
2) It is painful to look after myself and I am slow and careful.
3) I need some help, but manage most of my personal care.
4) I need help every day in most aspects of self-care.
5) I do not get dressed, I wash with difficulty and stay in bed.

SECTION 3--Lifting

0) I can lift heavy weights without extra pain.
1) I can lift heavy weights, but it causes extra pain.
2) Pain prevents me from lifting heavy weights off the floor but I can if they are conveniently positioned, for example on a table.
3) Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
4) I can lift very light weights.
5) I cannot lift or carry anything at all.

SECTION 4 --Reading

0) I can read as much as I want to with no pain in my neck.
1) I can read as much as I want with slight pain in my neck.
2) I can read as much as I want with moderate pain in my neck.
3) I cannot read as much as I want because of moderate pain in my neck.
4) I cannot read as much as I want because of severe pain in my neck.
5) I cannot read at all.

SECTION 5--Headache

0) I have no headaches at all.
1) I have slight headaches which come infrequently.
2) I have moderate headaches which come in-frequently.
3) I have moderate headaches which come frequently.
4) I have severe headaches which come frequently.
5) I have headaches almost all the time.

SECTION 6 -- Concentration
0) I can concentrate fully when I want to with no difficulty.
1) I can concentrate fully when I want to with slight difficulty.
2) I have a fair degree of difficulty in concentrating when I want to.
3) I have a lot of difficulty in concentrating when I want to.
4) I have a great deal of difficulty in concentrating when I want to.
5) I cannot concentrate at all.

SECTION 7--Work
0) I can do as much work as I want to.
1) I can only do my usual work, but no more.
2) I can do most of my usual work, but no more.
3) I cannot do my usual work.
4) I can hardly do any work at all.
5) I cannot do any work at all.

SECTION 8--Driving
0) I can drive my car without neck pain.
1) I can drive my car as long as I want with slight pain in my neck.
2) I can drive my car as long as I want with moderate pain in my neck.
3) I cannot drive my car as long as I want because of moderate pain in my neck.
4) I can hardly drive my car at all because of severe pain in my neck.
5) I cannot drive my car at all.

SECTION 9--Sleeping
0) I have no trouble sleeping
1) My sleep is slightly disturbed (less than 1 hour sleepless).
2) My sleep is mildly disturbed (1-2 hours sleepless).
3) My sleep is moderately disturbed (2-3 hours sleepless).
4) My sleep is greatly disturbed (3-5 hours sleepless).
5) My sleep is completely disturbed (5-7 hours sleepless).

SECTION 10--Recreation
0) I am able engage in all recreational activities with no pain in my neck at all.
1) I am able engage in all recreational activities with some pain in my neck.
2) I am able engage in most, but not all recreational activities because of pain in my neck.
3) I am able engage in a few of my usual recreational activities because of pain in my neck.
4) I can hardly do any recreational activities because of pain in my neck.
5) I cannot do any recreational activities at all.

DISABILITY INDEX SCORE: (___/50 * 100)%

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APPENDIX E

Informed Consent

TEXAS WOMAN'S UNIVERSITY
CONSENT TO PARTICIPATE IN RESEARCH

Title: A Comparison of Clinical Outcomes between Early Physical Therapy Intervention and Usual Care in Individuals following Anterior Cervical Fusion
Investigator: Carol McFarland, PT, MS..... (214)706-2300

Explanation and Purpose of the Research
You are being asked to participate in a research study. The purpose of this study is to find out which one of two physical therapy treatments is better after your neck surgery. You have been assigned to the **treatment 1** group.

Research procedures
We ask you to participate in this study because you are scheduled to have surgery on your neck. If you agree to be in the study, we will perform tests on you three times. We will test you at the surgeon's office on the same day of your doctor's appointments, once before the surgery and at 6 and 12 weeks after the surgery. It will take about 30 to 40 minutes for each testing session.

During each testing session, we will first ask you to complete a medical history form, and a form about any neck pain. It will take about 10 minutes to complete these forms. Next, we will test your reflexes, sensation, arm movements and strength. After that, we will test your neck muscles while you are lying on your back. You will simply push the back of your neck into a pressure sensor and watch a gauge that tells you how much pressure you are applying. You will try to hold the pressure at different levels that I will show you for 10 seconds if you can. You will repeat this step a few times, but the entire test will take less than 10 minutes. If you live in the Tyler area, you may be asked to return for a repeat neck muscle test the day after your doctor's office visit. This repeat test will take about 10-15 minutes.

A physical therapist will see you right after the surgery in the hospital. The physical therapist will give you specific instructions about what to do during the first 6 weeks after your surgery. You will receive instructions in best positions and care for your neck after this neck surgery. This will include information on activity restrictions and precautions to take during this first 6 weeks. You will also be instructed to walk daily and receive information on why walking is an important part of your recovery. A research assistant will call you during the second and fourth week after your surgery. She will answer any questions and verify that you are following your instructions. You can contact this research assistant any time you have questions about your treatment. If she cannot answer your question, she will ask me. You cannot talk directly with me about your treatment, because I should not know which treatment group you are in.

Potential risks

One possible risk is loss of modesty or embarrassment during testing, since I will be examining your neck and upper back as we do in physical therapy. We will do everything to protect your modesty by testing you in a private room. We will ask you to change to a hospital gown before testing. We will only uncover your neck and upper back. The gown will cover you in the front.

Another possible risk is the release of your private information. Confidentiality will be protected to the extent that is allowed by law. We will use a code number, rather than your name on your forms. Only the investigator will have access to your private information. We will keep all the forms in a locked filing cabinet in the investigator's office. We will also shred the forms and erase the electronic files within 5 years. The results of this study will be published in the investigator's dissertation, and in other research publications. However, no names will be included in any publication.

Participation and Benefits

You will be given a $30 gift card for participation in the study. However, you will be given a $40 gift card instead, if you return for a repeat neck muscle test at week 6. Participation in this study is completely voluntary and you may withdraw at any time without penalty. There is no additional cost to participate in this study. A potential direct benefit of this study is to know which method is better for helping people after this neck surgery. Another possible benefit is that at the end of the study, a summary of the results will be mailed to you if you wish.*

Questions Regarding this Study
If you have questions about this study, you can call the number at the top of this form. If you have questions about your rights as a participant in this study, or the way this study is conducted, you may contact the Texas Woman's University Office of Research and Sponsored Programs at 940-898-3378 or via email at IRB@twu.edu . You will be given a signed copy of this signed and dated consent form to keep.

Your signature below indicates that you agree to participate in the study and that you give permission to release needed information to the investigator for the study.

Signature of participant Date

*If you would like to receive a summary of the results of this study, please provide a mailing or email (preferred) address to which the summary should be sent:

_____

_____

_____

TEXAS WOMAN'S UNIVERSITY
CONSENT TO PARTICIPATE IN RESEARCH

Title: A Comparison of Clinical Outcomes between Early Physical Therapy Intervention and Usual Care in Individuals following Anterior Cervical Fusion
Investigator: Carol McFarland, PT, MS..... (214)706-2300

Explanation and Purpose of the Research
You are being asked to participate in a research study. The purpose of this study is to find out which one of two physical therapy treatments is better after your neck surgery. You have been assigned to the **treatment 2** group.

Research procedures
We ask you to participate in this study because you are scheduled to have surgery on your neck. If you agree to be in the study, we will perform tests on you three times. We will test you at the surgeon's office on the same day of your doctor's appointments, once before the surgery and at 6 and 12 weeks after the surgery. It will take about 30 to 40 minutes for each testing session.

During each testing session, we will first ask you to complete a medical history form, and a form about any neck pain. It will take about 10 minutes to complete these forms. Next, we will test your reflexes, sensation, arm movements and strength. After that, we will test your neck muscles while you are lying on your back. You will simply push the back of your neck into a pressure sensor and watch a gauge that tells you how much pressure you are applying. You will try to hold the pressure at different levels that I will show you for 10 seconds if you can. You will repeat this step a few times, but the entire test will take less than 10 minutes. If you live in the Tyler area, you may be asked to return for a repeat neck muscle test the day after your doctor's office visit. This repeat test will take about 10-15 minutes.

A physical therapist will see you right after the surgery in the hospital. The physical therapist will give you specific instructions and an exercise program. This exercise program will consist of walking and neck muscle exercises. You should do these exercises every day, after the surgery. It will take about 10 to 15 minutes twice a day to do the neck exercises. We will give you a log so that you can record your exercise and walking time for us. A research assistant will call you during the second and fourth week after your surgery. She will answer any questions and verify that you are following your instructions. You can contact this research assistant any time you have questions about your treatment. If she cannot answer your question, she will ask me. You cannot talk directly with me about your treatment, because I should not know which treatment group you are in.

Potential risks

One possible risk is loss of modesty or embarrassment during testing, since I will be examining your neck and upper back as we do in physical therapy. We will do everything to protect your modesty by testing you in a private room. We will ask you to change to a hospital gown before testing. We will only uncover your neck and upper back. The gown will cover you in the front.

Another possible risk is the release of your private information. Confidentiality will be protected to the extent that is allowed by law. We will use a code number, rather than your name on your forms. Only the investigator will have access to your private information. We will keep all the forms in a locked filing cabinet in the investigator's office. We will also shred the forms and erase the electronic files within 5 years. The results of this study will be published in the investigator's dissertation, and in other research publications. However, no names will be included in any publication.

Participation and Benefits

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Questions Regarding this Study

If you have questions about this study, you can call the number at the top of this form. If you have questions about your rights as a participant in this study, or the way this study is conducted, you may contact the Texas Woman's University Office of Research and Sponsored Programs at 940-898-3378 or via email at IRB@twu.edu. You will be given a signed copy of this signed and dated consent form to keep.

Your signature below indicates that you agree to participate in the study and that you give permission to release needed information to the investigator for the study.

Signature of participant Date

*If you would like to receive a summary of the results of this study, please provide a mailing or email (preferred) address to which the summary should be sent:

APPENDIX F

Neurological Screening Tests

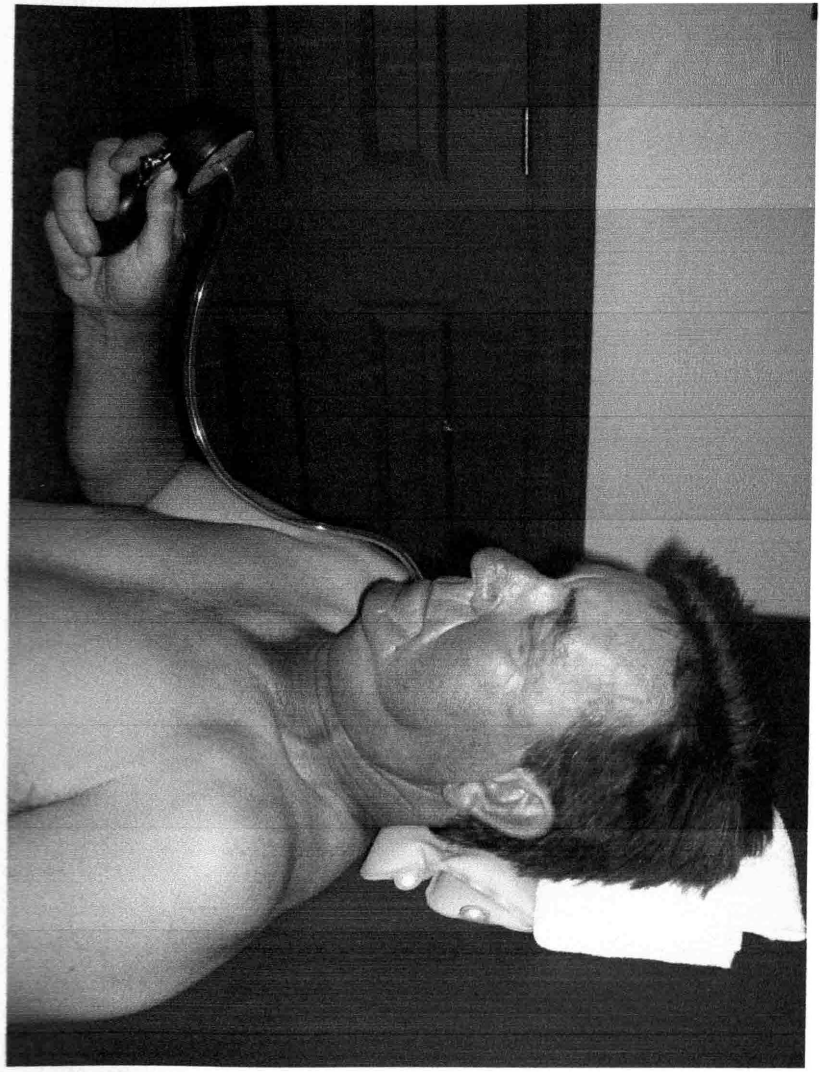
Neurological Screening Tests

As described by Cook and Hegedus *Orthopedic Physical Exam Tests*. 2008.[95]

Dermatomal testing C4 C5 C6 C7 C8 T1	 Trapezius region Lateral upper arm Lateral forearm Palmar surface Middle finger Medial forearm Medial upper arm	Light touch using cotton balls was used for dermatomal testing
Deep tendon reflexes: C5 C6 C7	 Deltoids Biceps brachii and brachioradilis Tricpes brachii	The participant was seated during the deep tendon reflex testing. The deep tendon reflex was performed using a reflex hammer. Grading: 0+: no reflex 1+: diminished 2+: normal and reactive 3+: exaggerated
Myotomal testing C5 C6 C7 C8 T1	 Resisted shoulder shrug Resisted elbow flexion Resisted wrist flexion Resisted thumb extension Resisted finger abduction	The participant was seated during the manual muscle testing for each muscle group
Slump test	Seated dural stretch produced by bilateral hip flexion and knee extension. The participant slowly flexes head forward	A positive sign is radicular pain, numbness, or tingling into any distal extremities.
Upper limb tension test	The scapula stabilized, the glenohumeral joint is passively abducted to 110 degrees with slight extension. If this is not symptomatic, the forearm is supinated , wrist extended and fingers extended. If this is not symptomatic, the elbow is fully extended.	A positive test is symptom occurrence and a difference in symptoms between right and left arm.

APPENDIX G

Position for Craniocervical flexion testing



The craniocervical flexion test using the Stabilizer

APPENDIX H

Packet contents for hospital treatment by PT

Protocol packet contact by group

Usual Care

- First Six Week DVD, general post op spine precaution for patients at TSJH
- Patient Information sheet for ACF from TSJH
- Evaluation, bed mobility (log roll), transfer, and safe gait instruction by hospital PT

Early Rehabilitation Intervention

- First Six Week DVD, general post op spine precaution for patients at TSJH
- Patient Information sheet for ACF from TSJH
- Evaluation, bed mobility (log roll), transfer, and safe gait instruction by hospital PT
- Postural and neck protection training printout
  - Instruct in CCF exercise seated and standing
  - Incorporated CCF with head posture cuing "crown up" during
  - Shrugs, rows from above, below, and shoulder level
  - External rotation with elbows flexed and arm at side
  - Abdominal bracing activity sitting and standing
  - Deep breathing rib cage expansion with and without arm motions
  - Functional leg strength, slow sit downs and heel raises
  - Walking program, recording time walked per day.

APPENDIX H

Hospital Patient Information Sheet for Anterior Cervical Fusion

Patient Instructions for ANTERIOR CERVICAL FUSION:

1. Watch "The First Six Weeks" tape and follow all advice. Wear your collar at all times, except when bathing, unless the surgeon tells you otherwise.

2. Be ultra-aware of your posture. Your head will tend to move forward on your shoulders. Fight this tendency! Keep your head directly over your shoulders with your chin tucked *in*. You want to do everything you can to let all structures in your neck heal in a good position.

3. Support the low back with a firm cushion that will keep an arch in your back when you sit. This will also help keep your head and shoulders straight. If you are in a seat with a high back or head rest, press the back of your head into the seat at times for some extra muscle support work. Be sure to *keep your chin tucked.*

4. Practice the basic stabilization exercises, a few repetitions at a time, several times a day. Remember, you are reprogramming the muscles to work with the new mechanics of the fusion. Learning to hold good neutral spine positions.

5. Do not lift more than ten pounds for at least six weeks. There are some special tests the physical therapist can do to determine when it is safe for you to resume lifting.

6. The muscles in the front of the neck are usually weak after this surgery and can help support and protect the neck if you recondition them. Pressing your chin into the hard collar is one exercise (press for 10 seconds, 10 times, 10 times a day). Once you are out of the collar, you can press your chin into your fist. Be very careful to keep your head in a GOOD NEUTRAL POSTURE throughout this exercise. Ask your therapist about other exercises that can help protect you by stabilizing your neck.

7. Practice swallowing several times in a row to help the muscles in the front of your neck regain their flexibility and smooth movement. Cold thick liquids may help reduce discomfort.

8. Deep breathing, with effort to expand and contract the ribcage as much as possible is helpful for many systems in the body, but also can work the vertebra in the mid back and reduce the tension on the neck.

9. Use an ice pack at the base of your skull for headaches.

10. Walk, walk, walk-- as much as you can without causing neck or arm pain. The walking will help you deliver more blood to the healing area and will load the bone to help it heal. If you turn the palms of your hands forward and thumbs out when you walk, this will help your posture.

Be sure to contact your therapist at _____ with any questions. Many patients are referred to physical therapy at the first postop office visit with the doctor. Ask your doctor for a therapy referral if you feel you have not regained all of your strength or capabilities.

APPENDIX I

Hospital DVD script for patient education after spine surgery

This tape will answer some of the questions you have about spine surgery. It is very important to ask all the questions that you have and not rely on guess work. There are many activities you do without thinking during the day, but will now require your attention until your back has had time to heal. If you pay attention to caring for your back during this period, you can be sure it will have the best possible chance for healing well and staying healthy into the future. When we refer to the spine, we are talking about both low back and neck problems alike. This tape is designed to cover the general rules of safety, bearing in mind precautions for both areas. It is a good idea to know about your entire spine, even though the problem may be just in your low back or just in your neck. Your recent operation has the best chance of success if you observe a set of rules during the first six weeks after your surgery. We believe if you practice these rules, that you can make them life style changes, protecting your back in the long term.

There are eight rules, but they basically boil down to one overriding concept. Any strain or trauma to your spine could severely lessen the chance of successful recovery. Specifically, the rules are: avoid twisting, avoid any forward bending without some support, push instead of pull, follow the lifting rules, which will be covered a little later. Do your exercise, do your exercise, do your exercise. Do your stretching. Use lumbar support even if you are a neck patient. Plan and think ahead. Now it's all very relative to say all of this, but you are probably wondering, "How do they apply to me?" Well, let's take a closer look at each of these rules and the practical application.

Avoid twisting. Twisting, especially with any speed, can be harmful to the disc, it can also damage discs, other than the ones repaired or replaced with surgery. Often with the type of twisting which damages the disc, you might not feel any pain. Twisting can also compress the joints or facets in the back of the spine and this can be painful. So, these are good reasons not to twist. A lot of twisting is required getting in and out of a car and this is one of the reasons we restrict driving in the first six weeks. Getting in and out of bed incorrectly can involve twisting also. It is important to practice the correct way to get in and out of bed using the "log roll" technique. Several other activities that seem to be like can be damaging to the spine and could put you at risk for further injury. Examples of light activity that involve twisting include: transferring wash from the washer to the dryer, mopping or sweeping, or even washing up. Try to think about all of the activities you do and work on eliminating twisting for every situation that you can think of.

Avoid forward bending. Use your arms and legs to help you get up from a sitting position and maintain a straight back. Use either the crouch method or to the deep squat or go down on one knee to pick up a light object. Be careful not to exceed the five pound weight limit. All post operative patients are given a five pound lifting limit until at least six weeks after surgery and usually this limit will be extended by your physical therapist. Remember, if you bend forward without support, it's putting load on your spine too. This can be a heavy load, even if you are not a big person, if you stay unsupported for a long period of time. Examples of this occur when you do your daily health and beauty regimen, such as shaving, brushing your teeth or applying your makeup and brushing your hair. You need to be constantly aware of the position you're in and using the correct techniques. If you are an avid reader, you need to be especially careful to watch your head position. Be sure and hold the reading material or support it at eye level. Think carefully about your positioning when you put on hose, socks or shoes. If you are seated, you

will be more protected when bending forward because many times the upper body can be supported with an arm on your lap. If you can bring your foot up and across the opposite leg, this is a very helpful and safe position to put on shoes and socks. You can also prop your foot on a foot stool or you may bend down to put on your shoes, you can use upper body support. If you don't have the flexibility or it is too painful to put on your shoes and socks in the beginning, be sure and talk to a therapist about corrective stretching exercises and some back saving ideas, such as wearing slip-on shoes. Avoid bending forward unsupported in the first six weeks after surgery. Now this applies to both neck and back surgeries.

Push instead of pull: one example is the tendency to use the trapeze or the helping hands of your spouse to pull yourself up out of bed. The problem here is that your arms are much stronger than your recently operated on spine and it would be very easy to do some damage if too much pressure is placed on the spine. The correct way to get out of bed is to bend your knees upward and then "log roll" onto your side being careful not to twist or pull up. Once on your side, lower your feet to the floor. Remember your legs can increase your leverage at the same time push up with your arms and roll forward slightly so you can now push yourself to the standing position using both arms. Follow the lifting rules: light, light, Light. During the first six weeks, you should lift nothing heavier than five pounds. Remember, babies and grandchildren all weigh more than five pounds. A very light baby may be handed to you while you're seated if necessary. If you have doubts, don't lift it. For safety sake, it is probably best to avoid lifting anything at all. If you have to, remember these simple guidelines: get close, feet apart, knees bent, stay low. For the first few times you squat to pick up anything, it is recommended that you have something solid close by to support you. When in doubt, leave it alone.

Do your exercise. Aerobic exercise is your best friend and is the way to a speedy and successful recovery. Be sure to start your walking program as soon as possible. Gradually increase your walking time until you can walk continuously for at least twenty minutes. Check your heart rate often until you reach the target your therapist helps you set. Heart rate is a way to measure the intensity of your exercise. If you are able to exercise for at least twenty minutes with enough intensity, the exercise becomes aerobic. Aerobic exercise has great benefits. It delivers oxygen more quickly to the tissues to help the healing process. It improves your metabolism to help with weight control as well as to help speed the healing process. It can also help with pain control and mood elevation with the release of endorphins which are your body's natural pain killers. It helps the heart and lungs too.

Do your stretching. Remember, a long muscle is a strong muscle. During the time you were injured and right after surgery, the muscles of the body tend to shorten, irritated nerves do the same thing. The more stretching you do early on, the easier it will be later. This needs to be done gradually. You need to take the stretch to the point where you feel a moderate pull, but no pain. Hold the stretch for about thirty seconds. Be sure you understand where you should feel the stretch. Ask your therapist if you're not sure. Go into all stretches and release them with slow motions. Use your lumbar support. Correct posture is the best way to prevent re-injury. Use lumbar support behind the low back when sitting. It should apply enough pressure to the low back to support the arch and encourage the shoulders and upper back to pull back for better posture. This is necessary for both back and neck patients. If it is uncomfortable, ask your

therapist to check the fit or positioning. You may need another size or firmness of support or just to move it into a better position. A rocking chair is very helpful as it aids circulation.

Plan and think ahead: the planning stages of your recovery actually start well before you leave the hospital. Some of the things you need to consider and discuss with your family include: the physical restrictions your injury is going to place on you and what adjustments both you and your family are going to have to make. Bear in mind, some of these changes may have to be permanent. But, certainly for the next six weeks, the physical activity will be strictly limited. Arrangements will have to be made for grocery shopping, laundry, child care, house cleaning and pick-up and delivery. Now this may include taking kids to sporting, church or social activities. Remember you will not be allowed to drive for the first six weeks and any travel must be kept to a minimum. Think about transportation home from the hospital. What vehicle will be used? Discuss with your physical therapist the best way to get in and out of the car. Are there any stairs or steps in your home? What are the strategies for climbing the steps easily for you? Do you have railings? What about the condition of your bed, sofa or that favorite chair? Too soft and no support could have disastrous results. Another question which seems to be upper most in peoples' minds is when is it safe to resume sexual relations? It is not recommended that you have any sexual relations in the first two weeks after surgery. For fusion surgeries we recommend waiting for the first six weeks. However, after the first two weeks, the decision rests with you, depending on how you feel. But remember, you must follow the general rule: no twisting, no unsupported forward bending, push rather than pull and no lifting or supporting another person's body weight. If nothing else, it will become an interesting exercise in determination. Usually, two weeks after your discharge from the hospital, you will go in and have your stitches or staples removed. It is during this two week time period that the most severe restrictions on your movement will be imposed. Enjoy your time as much as possible. Get plenty of rest, drink lots of fluids and eat nutritious meals. Do the exercises as prescribed and walk as much as you comfortably can. If you have stopped smoking during your hospitalization, it is important that you not resume. At the same time as having your stitches or staples removed, you will be given an appointment to see the physical therapist. You can use this time to discuss with your physician any problems or questions you may have about activities or the recovery process. There are some important points to be aware of concerning the use of medication and care of your wound.

It's important that in a recovery period that you take your medication as prescribed. This medication that we give you when you leave the hospital is usually a narcotic analgesic in the hydro-codone family. For example: vicadin or loratab or something like that. This medication does not need to be mixed with any other type of medication that you may take without first contacting the doctor's office. This even includes over the counter medications, like cough syrup and anti-histamins and things of that nature. Now, you need to remember also whatever you do, don't drink alcohol while you're taking your pain medication because this can cause you some serious problems. There are some side effects to this medication to include dizziness, blurred vision, the dryness of mouth and drowsiness. In reference to wound care: the tape and the gauze that were given to you, you will need to use to change your dressing daily, as you were instructed to in the hospital. Now, when you change your dressing, you need to be aware of certain things: for example, the wound site itself. You need to make sure that you don't have an excessive amount of drainage coming from the incision site. Now, a moderate or a small to moderate amount of clear drainage is usually normal for the first few days after your surgery. But if you

have a significant amount of clear drainage, you do need to let the doctor know about that because it could mean that you have a spinal fluid leak or something of this nature. The other significant drainage that you do need to make us aware of is perulin or pus-like drainage that comes out. This drainage would be green in color to maybe off-white in color and usually accompanied with a foul odor. Another thing you need to check when you're looking at the wound is the temperature, you need to use your hand and check the temperature of the skin around the incision site. Usually, if there's an infection, the temperature will increase around the wound site. If you have some drainage coming out of your wound, it's okay to change the dressing two or three times a day because we want you to be sure that you keep your wound clean and dry. Now, when you leave the hospital, you may be given a brace. This brace is usually there to remind you to not do anything that you're not supposed to do. It also keeps some stress off from the incision site itself. You may be told that you need to wear your brace at all times. Except maybe when you bathe, then you can take it off. There are other instances that you may be told to wear your brace only when you're up and mobile. Now, if you have any questions of when or where or how to wear your brace, you need to call the doctor's office or your physical therapist's office and they will be happy to tell you when and where and how to wear your brace. Now, on your two week check up, the physical therapist may feel that you would benefit from wearing a brace and you're not wearing a brace at that time, then we will fit you for a brace at that time and check with our office to make sure it's okay with us first. Now, in summary, we need to remember some key points here: (1) Take your medication as prescribed. Don't mix it with any other type of medication, especially anything with alcohol or drinking alcohol while you're taking your medication. (2) You need to keep your wound clean and dry. Whatever you do, check the wound for infection. That's the third point: Make sure that you check the wound closely for infection. (4) Wear your brace as instructed.

This tape has been produced to remind you of some of the important things that you need to do to make sure that your surgery has the best chance of success and to promote healing with the least amount of discomfort. The best piece of advice that you can take to heart during this time is to be observant. If you are unsure about something or don't understand the instructions, please don't hesitate to ask. Remember, you are not in this alone. We are here to support and guide you and the more you know and understand, the faster and smoother will be your recovery. Remember, be patient. Corrective changes will not happen overnight no matter how much we want them to. If you push too hard and try to do more than you really know you are capable of, you lessen your chances of a successful recovery. Allow your body to get well at its own rate. Listen to it. Talk to your doctor, nurse or therapist about how you feel. The more information you can give them will determine the best course of treatment to take. You have already learned how to be an expert in reading your own pain, at this stage you are going to be an expert in your recovery. Your input is vital, after all as much as we would like to, we can't read minds. You are the only one who knows how you feel. At this stage, all that remains is to wish you a speedy and successful recovery.

APPENDIX J

Exercise instruction handout for early PT intervention group

Exercise program, 0-6 weeks after ACF

Recent research has shown certain neck muscles can be trained to help the stability of vertebrae in the neck. Training these muscles has been shown to greatly help people with whiplash, neck pain, headache, and many disc problems. For this reason, we believe this muscle training can help people who have surgery, especially if training is started right away, to stabilize the newly operated spine.

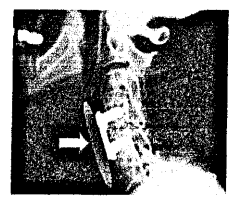
These exercises involve very small movements which activate the deep supporting muscles of the neck and will protect the surgical area. The movements involve working postural strength of the rest of the spine too.

**** If you are using a hard collar brace for your neck surgery, wear it during all exercises.***

11/20/2011

"Chin tuck" exercise seated and standing

Starting in a good sitting or standing posture, tuck your chin slightly, as shown, and try to push your head up toward the ceiling, or up away from the collar. You should feel as if you are making you as tall as possible. Think "crown up". Be sure to breathe normally throughout this exercise. Do this 10 times every few hours.



The "Chin Tuck" contracts deep muscles in front of the neck:

This can help support and protect the vertebrae, including those repaired with your ACF surgery.

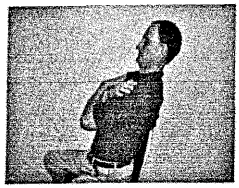
"Crown up": Remember to push your head toward ceiling with chin tucked during standing exercises. Be as tall as possible! Try to do crown up movement every time you stand and off and on while you walk.

Chin tuck, with "crown up"1 set of 10 every few hours: tally # sets

	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6
MON						
TUES						
WED						
THURS						
FRI						
SAT						
SUNDAY						

1

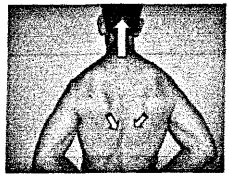
Chin tuck exercise while pushing shoulders back into the back of a chair to work upper back and shoulders. This helps your posture muscles. Do this 5 times at least 4 times a day.



Deep Breathing with and without arm motion

- Practice taking deep breathes with your arms up to help you expand your rib cage. (hands do not have to be behind your head)
- Be sure to tuck your chin at the same time.
- Breathe out as you let your arms down
- Do this as a good slow stretch in sets of 5

Also each time you tuck your chin: Bring your shoulder blades in and down toward lower back, while doing "crown up" movement making straightening your spine.



Posture practice: straighten back against back of chair, deep breath, shoulders back: any of these 3 exercises in sets of 5. Tally sets done per day below (try at least 4 sets).

	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6
MON						
TUES						
WED						
THURS						
FRI						
SAT						
SUNDAY						

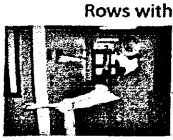
Work on abdominal muscles when standing and sitting. This protects your back!

- When standing, practicing drawing abdomen in, as if you were zipping up pants. Do this at least 10 while walking.
- Practice drawing your abdomen in when you brush your teeth.
- Practice in seated position draw abdomen in, tuck your chin down and hold for 5-10 seconds! Do this seated 10 times. Work up to 3 x10 per day
- Stretching one leg out at a time while doing this strengthens abs more!

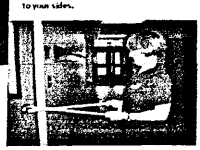
Tally each set of 10 abdominal draw-ins sitting or standing

	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6
MON						
TUES						
WED						
THURS						
FRI						
SAT						
SUNDAY						

Rows with "Crown Up"



First, draw in your abs, do a chin tuck with "crown up". Then bend your elbows and pull the hand back keeping arms close to your sides.



Start with 1 set of 10 a day and gradually work up to 3 sets of 10 a day.

Tally number of sets of 10 rows with "crown up", start with one set per day

	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6
MON						
TUES						
WED						
THURS						
FRI						
SAT						
SUNDAY						

Slow sit downs

- This exercise is exactly what it says: you stand up then sit at slowly as possible.
- At first, you may want to use a chair with arms and use your arms to help.
- As your legs get stronger and control the movement, try to do without arms
- Start with 10 repetitions a day and work up to 2 sets of 10.

These will strengthen your legs and help your balance

Wall slides (WS)

- With your back supported against the wall, practice slowly sliding up and down the wall.
- Until you feel steady with this exercise, *do not go as low as shown.*
- Keep a foot stool below you for safety.
- Start with 5 very slow repetitions taking 15 seconds per repetition. Work up to 2 sets of 10.

Heel Raises

- These will help your leg strength and your balance.
- Hold on to a counter or be near something solid to keep your balance.
- Raise up on your toes then slowly lower your heels back to the floor.
- Take 1 second to go up and 2 seconds to lower
- Start with 10 reps. Work up to 3 sets of 20.

Leg work: Try for at least one set 10 of slow sit downs (SSD), Wall Slides (WS) and heel raises (HRA) each day. When this gets easy, increase sets!

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
MON						
TUES						
WED						
THURS						
FRI						
SAT						
SUNDAY						

Reach and Pull

#1- Reach forward, slowly and gently, with arms just below shoulder level. When you feel a mild stretch behind your shoulders, hold for 5 seconds.

#2 - Pull your arms back as shown with forearms as close to vertical as possible. Keep your chin tucked down throughout this movement. Hold your arms back as far as you can in this position for 5 seconds. Then return to position # 1 above.

Move slowly, this should not hurt! Repeat this exercise 5 times and work up to 10.

Posture pulls:

*With your elastic theraband, grasp the band with palms up.

*Keeping your elbows against your sides, pull your hands apart.

*The band should give enough resistance that you only move out a few inches with each hand.

* At the same time, draw in your abs with "crown up"!

* Start with 10 reps, work up to 3 sets of 10 per day.

This exercise works shoulder rotator cuff, which helps the neck too.

Posture Pulls, from start to finish

Starting Position

Finishing position and back to start makes 1 repetition

Record number of sets of 10 Posture pulls (PP) and of Reach/Pull (RP)

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
MON						
TUES						
WED						
THURS						
FRI						
SAT						
SUNDAY						

Walking program will help the fusion and will help you get your stamina back!

- Walk every day, at least once.
- Record time of walk(s) and distance in your exercise log.
- Increase distance gradually.
- On days that you feel tired or sore, just walk less, but still record distance.
- At times, turn your thumbs outward during your arm swing, which will make you pull your shoulders back.
- Draw in abdomen and crown up!

Rocking in a rocking chair is another oscillatory motion that can help with pain control

- Rocking motion helps blood flow
- Lumbar support (small pillow behind low back) will position neck and shoulders best

Use of ice, ice, ice

- Helps inhibit muscle spasm
- Works as an anti-inflammatory aid
- Helps with headaches
- Can also help at times with dizziness and nausea!

RECORD YOUR WALKING DISTANCE(S) OR TIME OF CONTINUOUS WALKING (in minutes) HERE

	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6
MON						
TUES						
WED						
THURS						
FRI						
SAT						
SUNDAY						

1

Early PT Intervention Stabilizer Training Instruction

APPENDIX K

Script for telephone follow-up at 2 and 4 weeks after surgery

Script for follow up phone calls:

Hello, is this _____? Hi, _____, this is _____, and I am doing follow up phone calls to check on our study participants. We want to be sure that you are following the instructions you were given by the therapist in the hospital and that you are not having any problems with this. I will be relaying information to Carol, but I cannot let her know which group you are in. If you have a question about a particular part of your program, I will ask her without identifying you as the person who asked. She will give me a response which I will relay back to you. Remember that medical and surgical questions should go to the surgeon's office.

It has been 2weeks/4 weeks since your surgery, so first of all

1. How are you doing in general?
    a. How much pain are you having (scale 0-10)
        i. Neck pain
        ii. Arm pain
    b. Do you feel that you are improving or not at this point?
2. Are you following the instructions the therapist gave you in the hospital?
    a. If YES, that's great. Do you have any questions about your instructions.
    b. IF NO, why not?
        i. Get reason and relay it to me.
        ii. Can you start following them now?
        iii. Do you have any questions about these instructions?
3. Are you having any difficulties with any of your post operative instructions?