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Effectiveness of a Manual Therapy Approach in Treatment of Patients with Lumbar Spinal Stenosis

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Effectiveness of a Manual Therapy Approach in Treatment of Patients with Lumbar Spinal Stenosis

by

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We hereby certify that this dissertation, submitted by Haitham Ramadan, PT, MS, conforms to acceptable standards and is fully adequate in scope and quality to fulfill the dissertation requirement for the degree of Doctor of Philosophy in Physical Therapy.

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Abstract

Background: The use of manual therapy for the management of lumbar spinal stenosis (LSS) has not been adequately systematically reviewed in an attempt to determine its effectiveness on patients with LSS. The lack of evidence in support of commonly used conservative interventions continues to result in a lack of clarity regarding what interventions should be used to manage patients with LSS. **Objective:** To use a randomized comparative trial to compare the functional clinical outcomes achieved by patients with LSS receiving two different physical therapy interventions. **Methods:** In this randomized controlled trial, a total of 40 participants diagnosed with LSS were randomized into two groups. Both groups received 6 weeks of treatment. Participants assigned to group 1 (EX Group) received impairment-based exercises. Participants assigned to group 2 (EXMT Group) received impairment-based exercises as well as manual physical therapy techniques. The evaluation parameters included (1) McGill Pain Questionnaire, (2) the original version of the Oswestry Low Back Pain Disability Questionnaire (ODQ), (3) double inclinometer measurement for measuring thoracolumbar flexion and extension, (4) self-pace walking test, (5) hip abductor and extensor strength, and (6) hip external rotation and extension range of motion. All participants were evaluated before starting treatment, once at the end of 6 weeks of treatment, and again at 6 weeks following the completion of treatment. **Results:** In terms of overall treatment efficacy, there were notable improvements observed over time regardless of treatment group. Results indicated significant improvement in perceived disability using ODQ in the EXMT treatment group in comparison to the EX group at follow-up. For the EXMT group, there were notable improvements in comparison to the

EX group in multiple objective functional improvement measures. **Conclusion:** Results of this study suggest that a multimodal approach using manual therapy and therapeutic exercises is an effective treatment option for providing clinically significant short-term reduction in back pain and disability, as well as improvements in back mobility in patients with LSS. Physical therapists should strongly consider the impairment-based approach of manual therapy and specific exercises program for lumbar spine and hips as a treatment option for patients with lumbar spinal stenosis.

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TABLE OF CONTENTS

List of Tables

List of Figures

CHAPTER ONE: INTRODUCTION

Overview

Lumbar spinal stenosis (LSS) is defined as a narrowing of the spinal canal resulting in compression of spinal nerves, which leads to low back and leg pain.[1] The symptoms of LSS can be divided into two main categories: neurogenic intermittent claudication and radiculopathy.[2] LSS is a slowly progressing disease affecting 5 out of every 1,000 adults older than 50 years in the United States.[3] It has also been reported that approximately 1.2 million people in the United States suffer from back and leg pain due to LSS.[1] In addition, 5% of all patients seeking care from a physician, and 13-14% of patients seeking a specialist,[3-5] suffer from LSS. It is also the leading cause of surgery in adults older than 65 years.[3-6]

Management of spinal stenosis is focused on symptomatic relief and prevention of neurologic symptoms. Conservative measures such as pharmacologic therapy and physical therapy provide only temporary relief; however, they remain an important adjunct in the overall treatment options preceding surgical decompression. Nonsurgical measures focused on symptomatic relief—analgesics, anti-inflammatory agents (including judicious use of steroids), and antispasmodics—can provide relief during acute exacerbations.[1] A comprehensive rehabilitation program of manual therapy, stretching, and strengthening exercises for the lumbar spine and hip region have been advocated for those with LSS.[3,4] The importance of endurance exercises to delay the adverse consequences of inactivity and deconditioning is also emphasized.

Statement of the Problem

Manual therapy, including both thrust and non-thrust manipulations, is an intervention often used by physical therapists.[5] Despite the fact that manual therapy has been used by skilled physical therapists for a long time, its use for the management of LSS has only recently begun to gain attention in the literature.[5,7-12]

There are an insufficient number of high quality studies and clinical research articles to clearly determine the role of manual therapy for patients with LSS. While some research reviews demonstrated the potential for manual therapy and exercise intervention in patients with LSS, the effectiveness of manual therapy and whether specific types of manual therapy or multimodal approaches are more beneficial is not clearly established; therefore, further research is needed in this area.

The lack of evidence in support of commonly used conservative interventions continues to result in a lack of clarity regarding what interventions should be used to manage patients with LSS. Therefore, there is a need for:

- an appropriately–powered randomized controlled trial (RCT) using standardized techniques and validated outcome measures to compare different physical therapy treatment protocols used on patients with LSS;
- a controlled trial to investigate the effectiveness of manual therapy technique as a conservative approach in treating patients with LSS using standardized techniques and validated outcome measures.

Purpose of the Study

This purpose of this study was to compare the functional clinical outcomes achieved by patients with LSS receiving two different physical therapy interventions. The

first intervention included impairment-based exercises for (1) core strengthening, (2) stabilization, (3) hip flexibility, and (4) hip strengthening exercises. Exercises for lumbar spine and hip were tailored to assessment findings and progressed within each participant's ability to maintain a stable and minimally painful spine. The second intervention included the impairment-based exercises listed in the first intervention and manual physical therapy techniques including passive soft tissue, and joint mobilization—possibly to lumbar, dorsal spine, sacroiliac joint and specifically the hip joint—tailored to assessment findings.

Relevance and Significance

This study used an RCT design to compare the functional clinical outcomes achieved by patients with LSS receiving two different physical therapy program interventions to investigate the effectiveness of an impairment-based manual physical therapy approach as a conservative measure in the management of patients with LSS. This process allowed the researcher to capture detailed clinical outcomes of manual therapy applied to patients with LSS using objective tools for measurement after 6-week of intervention.

Comprehensive rehabilitation programs of manual therapy, stretching, and strengthening exercises for the lumbar spine and hip region have been advocated for those with LSS.[4-6] Most patients with symptomatic LSS are treated with a variety of conservative interventions in spite of little evidence to guide their care. Much of the evidence for these treatments is extrapolated from studies of patients with non-specific low-back pain or patients with radiculopathy as a result of a disc herniation. The need for better evidence from studies involving patients with LSS is recognized.[4,5] This research

helps to fill a gap of sufficient randomized control trials that validate the nonsurgical approach in management of patients with LSS.

Explanation of Worthiness

LSS, a focal narrowing of the spinal canal, nerve root canals, or inter vertebral foramina, is a common and disabling condition in older adults.[13,14] High depression scores have been associated with more severe LSS symptoms such as pain, poor walking capacity and less conservative treatment satisfaction, as well as poor postoperative treatment satisfaction.[15,16] These physical and mental impairments may continue to increase in prevalence with the aging process, which may further increase the financial and societal burden. A surgical approach is one of the treatment options for patients with LSS. The effectiveness of surgical treatment as compared to nonsurgical treatment for patients with LSS found no clear benefits of one approach versus the other; additionally, the quality of the published evidence was graded low due to the high risk of bias, study design, and imprecision because of incomplete outcome data.[17-18,19]

It is noted that the rate of side effects ranged from 10% to 24% in surgical cases, and no side effects were reported for any conservative treatment.[19,20] In addition to the high cost of surgical intervention for patients with LSS, adverse events associated with spinal surgery must also be considered. Adverse events included (1) myocardial infarction, (2) wound infections, (3) renal failure, (4) congestive heart failure, (5) cerebrovascular accident, and (6) dural tears.[21] Controversy still exists as to the best practice strategies for patients with LSS. As a result, a trial of conservative management has been recommended for patients with LSS prior to surgical intervention.[22,23] To date,

there is a limited number of published randomized control trials that investigated the effectiveness of manual therapy in patients with LSS.

Research Hypotheses

H_0: There is no difference in functional mobility in subjects who receive a formal 6-week physical therapy program that includes impairment-based exercises in the form of core strengthening, stabilization, hip flexibility, and strengthening, as well as manual physical therapy techniques compared to subjects who receive only the impairment-based exercises (EX group).

H_1: Subjects who receive a formal 6-week physical therapy program that includes impairment-based exercises in the form of core strengthening, stabilization, hip flexibility, and strengthening, as well as manual physical therapy techniques will show a greater improvement in functional mobility than subjects who receive only the impairment-based exercises (EX group).

Operational Definitions

Spinal stenosis: Abnormal narrowing of the spinal canal due to degenerative changes and aging process/wear and tear that leads to pressure on spinal cord and nerves.

Manual therapy techniques: *Mobilization:* The passive movement of a joint to restore motion or relieve pain. Small oscillatory movements (grades I and II) used for reducing pain and inflammation. Larger oscillatory movements (grades III and IV) are used to increase joint play.[24] *Stretching*: technique that involves (actively or passively) pulling involved extremity or body region from existing anatomical position to end of available range of motion, to improve the involved structure's length or motion.[24]

Therapeutic exercise: Impairment-based exercises based on evaluation results that are performed to achieve a specific physical benefit, including increasing and maintaining range of motion, strengthening weak muscles, increasing joint flexibility, or improving cardiovascular and respiratory function.[24]

Permissions and Baseline Forms

This study was approved by the Nova Southeastern University IRB on February 11, 2015 (Appendix A). Baseline intake forms, including the Patient Intake From (Appendix B) and the Medical Screening Form (Appendix C) follow the IRB approval form in this manuscript.

Chapter Summary

Most patients with symptomatic LSS are treated with a variety of conservative interventions in spite of little evidence to guide their care. This study used an RCT design to compare the functional clinical outcomes achieved by patients with LSS receiving two different physical therapy program interventions to investigate the effectiveness of an impairment-based manual physical therapy approach as a conservative measure in the management of patients with LSS. In the next chapter, a review of the literature relevant to this study will be reported.

CHAPTER TWO: REVIEW OF THE LITERATURE

Introduction

Lumbar spinal stenosis (LSS) is defined as a narrowing of the spinal canal resulting in compression of spinal nerves which leads to low back and leg pain.[1] It was first described by Verbiest in 1954.[25] Defining LSS has evolved from an anatomical concept to a clinical syndrome.[26] LSS is currently recognized by the North American Spine Society as "a clinical syndrome of buttock or lower extremity pain, which may occur with or without back pain, associated with diminished space available for the neural and vascular elements in the lumbar spine."[27] The symptoms of LSS can be divided into two main categories: neurogenic intermittent claudication and radiculopathy.[2] LSS is a slowly progressing disease affecting 9% in the general population, and up to 47% in people over age 60.[28] LSS is the most common reason for spine surgery in patients over 65 years of age,[29] with an estimated 2-year cost of $4 billion in the US.[30,31] Given the aging population, both the prevalence and economic burden of LSS are expected to increase dramatically.[27,29-32]

Etiology of Lumbar Spinal Stenosis

LSS can be classified into two main groups: inherited/developmental and acquired. In addition, central or lateral stenosis is also identified by some as a main group of LSS.

Inherited/Developmental Lumbar Spinal Stenosis

Inherited causes are relatively rare compared to those that are acquired, presenting usually between the ages of 30 to 40 years. They include congenital lumbar stenosis,

scoliosis, and achondroplasia, a condition that results in short, thick pedicles and a narrower spinal canal.

Acquired Lumbar Spinal Stenosis

The acquired conditions include (1) degenerative; (2) combined congenital and degenerative spondylolytic/spondylolisthetic; (3) post-traumatic, metabolic; and (4) iatrogenic causes. They usually present from 1 to 2 decades later in life.[1-6]

Acquired spinal stenosis is the most common condition leading to spine surgery in the geriatric population. Degenerative changes lead to central stenosis from ligamentum flavum hypertrophy, disc bulging, and osteophytes. Lateral recess or foraminal compression can result from facet hypertrophy and settling. Several studies on non-operative treatment of patients with between 1 and 5 years of follow-up suggest that 15 to 43% of patients will have continuous improvement after non-operative treatment.[33]

Central or Lateral Lumbar Spinal Stenosis

Another classification of LSS is grouped as central or lateral stenosis.[6,33,34] Central spinal stenosis refers to the narrowing of the central spinal canal, which compresses the cauda equina and is mainly caused by disc bulging and hypertrophy of ligaments. Lateral spinal stenosis results from compression of the nerve root at the lateral foramen, caused mainly by formation of an osteophyte or bone spur because of degeneration of the spine.[3] During this disease process, it has been postulated that either microvascular compromise of the cauda equina or an inflammatory response is required for the symptoms of lumbar spinal stenosis. Both venous congestion and arterial insufficiency are thought to lead to nerve root injury and play an important role in the development of intermittent claudication.[1,2]

Pathophysiology of Lumbar Spinal Stenosis

The average anterior-posterior diameter of the lumbar canal in adults is 15-23 mm.[1] Narrowing of the lumbar canal from the average diameter to 10-12 mm is indicative of relative stenosis, and narrowing to less than 10 mm in diameter is indicative of absolute stenosis.[35] Both relative and absolute narrowing of the canal are associated with various symptoms, which include low back and leg pain as well as numbness and fatigue in the legs. The leg pain is usually bilateral, sometimes involving the buttocks, and is described as burning, cramping, and tingling in the thigh and legs.[1-3] This is a characteristic pattern of symptoms associated with LSS and is termed "neurogenic claudication"; the symptoms are posture-dependent,[6,10] and pain is often aggravated by walking, prolonged standing, or lying prone, with relief by sitting and lying supine.[1,3,6,12,35,36]

Patients with LSS frequently experience low-back pain, stooped standing posture, stiffness of the lumbar spine, decreased range of motion at the lumbar spine and hip joint, and tightness of iliopsoas and rectus femoris.[1,3,35] Symptoms of sensory deficits, motor weakness, and pathological reflexes appear with walking. Elderly patients with severe degenerative stenosis of the lumbar spine have restricted walking capacity and exercise intolerance leading to decreased function and quality of life.[2,6,35,37,38]

Myeloscopic studies were performed on participants with and without stenosis. Significant changes in the diameter of blood vessels in the cauda equina were found only in the stenosis group.[39] One study showed a 26% decrease in arterial blood flow to porcine cauda equina that were mechanically compressed to simulate stenosis.[40]

Compression was performed at more than one level, which also has been shown to be an important factor.[40] Another study performed computed tomography (CT) and myelography on participants with symptoms of neurogenic claudication. It was found that either multi-level central stenosis or central stenosis with root canal stenosis was necessary for these symptoms to occur.[41] In addition, one study noted that extension significantly decreases the canal area, whereas flexion has the opposite effect. These biomechanical factors contribute to the vascular changes observed in this condition.[42]

Along with mechanical compression, it is postulated that an inflammatory response plays a role in symptomatic patients. An inflammatory cascade results in response to neural or other tissue injury. In the case of radicular pain, the presence of multiple biochemical mediators are hypothesized to lead to nerve root symptoms by way of (1) excitation of the nociceptors, (2) direct neural injury, (3) nerve inflammation, and (4) increased sensitization to pain producing substances. The inflammatory response supports the clinical use of non-steroids anti-inflammatory drugs (NSAIDS) and steroids, especially in the acute stage.

Clinical Symptoms and Physical Findings

The condition most commonly associated with LSS is neurogenic claudication, also referred to as pseudo-claudication. Neurogenic claudication refers to leg symptoms encompassing the buttock, groin, and anterior thigh, as well as radiation down the posterior part of the leg to the feet. In addition to pain, leg symptoms can include fatigue, heaviness, weakness, or paresthesia. Patients with LSS also report nocturnal leg cramps[43] and neurogenic bladder symptoms.[44] Symptoms can be unilateral, or more commonly,

bilateral and symmetrical. Patients may also report accompanying back pain; however, leg pain and discomfort is usually more bothersome.

Diagnosis of Lumbar Spinal Stenosis

There is no standard criterion for the clinical diagnosis of LSS.[26] In the absence of valid objective criteria, it has been suggested that expert opinion be considered the gold standard in LSS diagnosis because it provides a reasonable method of establishing a clinical diagnosis. Diagnosis of the clinical syndrome of LSS is generally accomplished using a combination of clinical signs and examination of history, physical examination, and imaging studies.

Clinical History and Physical Findings

Clinicians generally conduct a history and a physical examination of potential LSS patients aimed at detecting findings characteristic of LSS. There are a number of historical and physical findings consistent with LSS which may lead to a diagnosis. Historical findings shown to be most strongly associated with LSS are (1) ages greater than 50 years, (2) severe lower extremity pain, (3) absence of pain when seated, (4) improvement of pain with sitting/flexion, and (5) worsened symptoms with walking.[4] Physical findings shown to be most highly associated with LSS include (1) wide-based gait, (2) abnormal Romberg test (balance), (3) neuromuscular signs in the lower extremity including decreased strength (weakness), (4) sensory deficits (numbness), and (5) absent or decreased Achilles and patellar reflexes.[4,45] Neurogenic claudication is likely the cause of the most specific symptoms of LSS, but can be observed during certain activity such as when a patient is actually walking and with sustained static activity such as lumbar extension.[12] Thigh pain that occurs within 30 seconds of sustained

lumbar extension from standing as a result of neurogenic claudication has also been shown to be strongly associated with LSS.

Imaging

Definitive diagnostic information relating to LSS is most readily obtained from lumbar spine imaging.[46] The most appropriate, non-invasive test for imaging LSS is magnetic resonance imaging (MRI).[4] MRI allows examination of the size, shape, and anatomic relationships of spinal and neural elements.[46] Computerized tomography (CT) is also commonly used in diagnosis of patients with LSS when MRI is contraindicated or unavailable. Myelography has also been used extensively with LSS populations; however, it is used less frequently given the technological advances of MRI and CT.[47] Although imaging reports showing compression are a necessary component of LSS diagnosis, alone they are not sufficient. Spinal stenosis is a clinical condition, not a radiological finding or a diagnosis. Therefore, it is necessary to use imaging studies in combination with an examination of history and clinical presentation, as a clear relationship has not yet been established between the severity of clinical symptoms and the degree of anatomical stenosis determined by imaging studies.[3]

Interventions for Lumbar Spinal Stenosis

Lumbar spinal stenosis can be treated with surgical or conservative methods. Studies have compared the effect of surgical versus nonsurgical management in LSS.[12,37,48,49] Data indicates decompressive surgery is effective 80% of the time in patients with severe symptoms, while conservative treatments are found to be effective 70% of the time in patients with mild to moderate symptoms.[4] Although surgical treatments offer early symptomatic relief, nonsurgical interventions are found to be

effective, and may be viable alternatives to the risks associated with surgery in the elderly.[3,5] Additionally, nonsurgical treatments are cost-effective in mild and moderate conditions. In 1987, the total annual inpatient cost for surgery for LSS was estimated to be around one billion dollars.[6,9] Although non-operative/conservative treatment is the mainstay of treatment for LSS in the initial stages,[3,5,12,36] surgical interventions have proven to be beneficial in severe cases.[4,50] Patients with LSS are encouraged to undergo conservative therapy before considering surgery.[5,12,36,51] Non-operative treatment is a preferred alternative to surgery for mild to moderate symptoms of LSS.[6,51-54]

Non-operative treatment includes a combination of medications, bed rest, epidural steroid injections, physical therapy in the form of modalities such as aerobic conditioning, strengthening, stretching, lumbar stabilization exercises, spinal manipulation and mobilization, posture and balance training, physical modalities, braces, traction, and transcutaneous electrical nerve stimulation (TENS). Although nonsurgical treatment cannot change the underlying pathology of the condition, it has been reported that it reduces the progression of the symptoms.[54]

Physical therapy is described as an active phase of nonsurgical treatment. Therapeutic exercise is one of the many types of conservative treatments available to manage symptoms of LSS and is known to play an important role for patients with mild to moderate symptoms.[4,52,53] The therapeutic exercises for LSS are based on the patho-anatomic changes and should be modified to each patient based on his or her symptoms and physical examination findings.[6] Therapeutic exercises include aerobic, strengthening/stabilization and flexibility exercises, posture education, and endurance

training. Manual therapy includes soft tissues mobilization and joint mobilization or manipulation.

Exercises focus on modifying the position of the lumbar spine; thus, reducing the narrowing of the canal. Extension of the spine causes a 20% reduction in the intervertebral foraminal cross sectional area in normal and degenerative spine.[6,9] It has been reported that the degree of the stenosis does not remain the same during movement, rather stenosis worsens by 11% in lumbar spine extension and improves by 11% with lumbar flexion.[55] Therefore, the flexion-based lumbar stabilization exercises[52] such as William's flexion exercise along with abdominal strengthening is encouraged, as these activities increase the diameter of the spinal cord and hence decrease pain.[53]

Treadmill walking with body weight support, cycling, and swimming as forms of aerobic exercise are often prescribed in patients with back disorders.[6,33,53,56] Body weight-supported treadmill walking has been part of a physical therapy plan of care in several studies for patients with LSS.[5,7,13] The suspension force from the body weight-supported system decreases the compressive forces on the spine in the upright position, preventing the narrowing of the neuroforamen and central spinal canal. Compressive forces, or axial loading, has been demonstrated to decrease the cross-sectional area (CSA) of the neuroforamen and central spinal canal, and non–weight-bearing positions have been demonstrated to increase CSAs.[57-59] Because a body weight supported ambulation system decreases the downward excursion of the center of gravity and decreases the ground reaction forces associated with gait, symptoms are ameliorated.[60,61]

Because water provides buoyance that supports the body's weight and places minimal stress on the spine, swimming is also a consideration for the treatment of

LSS.[6,36] However, as with all forms of exercise, one needs to be careful as many strokes such as the butterfly, breast stroke, and freestyle, as these strokes tend to require extension of the lumbar spine. The backstroke is a better choice of swimming exercise for patients with LSS.[52,53] Another major aerobic exercise frequently prescribed is the stationary bicycle as the lumbar spine is usually flexed while in the sitting position, likely increasing the intervertebral cross sectional area and is better tolerated than walking.[53]

Manual therapy includes manipulation and mobilization of the tight structures and stabilization of the spine to restore normal function.[52] Normal mobility of the spine can be attained by stretching the tight structures such as hip flexors, adductors, and myofascial tissues.[36,52,62] Postural education is necessary to encourage flexion of the lumbar spine and flattening of the lordotic curve.[12,36,53] Although patients improve with surgical or nonsurgical treatments, a study of the natural history of LSS using 32 untreated patients reported improvement of symptoms in 15% of the participants, 70% remained the same, and 15% worsened as a natural course of LSS.[52] Another study involving 49 patients with LSS concluded that epidural steroid injections prior to initiating physical therapy is warranted in patients with moderate to severe symptoms.[3,33]

Surgical vs. Non-Surgical Interventions

Several studies evaluated the long-term outcomes of patients with LSS to determine the influence of surgical and nonsurgical interventions. The Maine Lumbar Spine Study[49,63] assessed the 4- and 8-year outcome to the 10-year outcome of surgical and nonsurgical treatments for patients with LSS. It was demonstrated that patients treated non-surgically reported decreased back and leg pain. Although nonsurgical treatment was proven to be relatively effective in these studies, there is no indication of

the type of therapeutic exercise used in the physical therapy intervention. Also, as the non-conservative group included interventions other than therapeutic exercise, the effect of therapeutic exercise alone on the improvement of symptoms cannot be determined.

Another study investigated chronic low back pain from the economic aspect.[64] It compared the effectiveness and cost-effectiveness of three kinds of physiotherapy commonly used to reduce disability in chronic low back pain. A total of 212 chronic patients with low back pain were randomized to individual physiotherapy, spinal stabilization, or physiotherapist-led pain management. Disability, pain, time off work, and quality of life all improved at 18 months and intermediate points. Interventions were equally effective. Pain management was associated with the least health service consumption and costs, and was the most cost-effective. Although the cause of chronic low back pain was a result of LSS or other reason, the study highlighted the cost effectiveness of a physical therapy approach in addition to the treatment effect.

A few other studies have compared the efficacy of surgical and non-surgical treatment for LSS; however, the exclusive effect of therapeutic exercise or manual therapy has not been addressed.[4,5,18,62-68] An evidence-based clinical guideline published in 2008 reported that there is insufficient evidence to draw conclusions on the effects of physical therapy or exercise in management of LSS.[4] In the review, a wide variety of therapeutic exercise programs were assessed in the 11 studies included in the review article.[4] Most of the 11 studies demonstrated the effects of mixed interventions such as aerobic exercise in combination with flexibility exercise and manipulation. Three of the 11 studies assessed only aerobic exercise, and two used either manual therapy or strengthening exercises. All of the11 studies included in the review selected pain as their

primary or secondary outcome measure. Pain was measured primarily by a visual analogue scale (VAS), also by the Numerical Pain Rating Scale (NPRS), the Brief Pain Inventory, and the Roland Morris Pain Rating Scale. Disability was a common measure used in most of the studies. Five of the 11 studies used the Modified Oswestry Low Back Pain Disability Questionnaire (MODQ). Four of the studies used the RMDQ, and two of the studies used both RMDQ and ODQ as their outcome measure. Walking capacity/tolerance was used as another outcome measure in five of the studies. This was measured either by the distance walked in meters or by a treadmill test. The Satisfaction Subscale of Spinal Stenosis was used in two of the studies as an outcome measure. The Symptom Severity Scale was used in two of the studies to detect pain and function. Anxiety, depression or mood states were assessed in two of the studies as a secondary outcome measure. The overall functional status of the patient was used as a primary outcome measure in two of the studies as measured by the Global Rating Change Scale (GRC), and the Short Form-36 (SF-36) Physical Function Subscale.

Physical Therapy Interventions for Lumbar Spinal Stenosis

Published literature about physical therapy interventions for patients with LSS vary widely. Such interventions include aerobic exercise only, mixed interventions, individual interventions, and manual therapy techniques.

Aerobic Exercise Only

Three studies identified the exclusive effect of aerobic exercise on patients with LSS.[11,18,65] One of the three studies was a randomized controlled trial that investigated the difference between treadmill walking with body weight support and cycling in people with lumbar spinal stenosis.[65] Patients were divided into two groups. In first and second

weeks of the trial, patients walked/cycled at their own comfortable pace. During weeks 3 through 6, they increased the intensity to moderate level. Both interventions were performed 2 times per week for 6-week. Their level of disability was measured using the ODQ and the RMDQ, and pain was measured on the VAS. At week 3 and 6, the authors did not report any significant difference in improvement in disability between the two groups on the ODQ ($p = 0.44$) or the RMDQ ($p = 0.31$). When the two groups were combined, the result revealed a significant improvement of ODQ and the RMDQ results ($p < 0.001$) after intervention for both groups. The authors concluded that cycling was just as effective as unweighted treadmill walking in reducing disability over time.[65]

Another study that used aerobic exercise as the intervention was a prospective cohort study.[18] The investigators studied the efficacy of endurance bicycle training in an elderly population with chronic low-back pain (CLBP). Although the title of the study referred to patients with CLBP, the focus of study was on developing an intervention to reduce disability in elderly with CLBP resulting from degenerative lumbar changes and LSS. They included 29 patients in their study; the inclusion criteria of the study included (1) male or female patients, aged 55 years and older; (2) low back, buttock, and/or leg pain exacerbated by passive lumbar extension in standing; and (3) duration of symptoms of at least 6 months. The patients were prescribed bicycle exercise for 30 minutes, 3-4 times a week which included a 5-minute warm up session, 20 minutes of exercise, and 5 minutes of cool down. Patients exercised 3-4 times a week for 12-weeks. The intensity of exercise was based on their exercise endurance test at baseline. The intensity of the exercises was increased at week 7, following a second endurance test. Patients improved by 8% on the pain scale and 11% on the function scale, and no side effects were reported.

The authors concluded from their study that bicycle training is an effective and safe method of exercise program for the management of CLBP in elderly.[11]

Lin and Lin evaluated 34 patients with low-back pain, (mean age = 47.68 years).[11] The cause of low-back pain was either herniated nucleus pulposus, degenerative changes of the disc, lumbosacral strain, or spinal canal stenosis. Participants were divided into 2 groups: aerobic exercise (n = 17) and control (n = 18). Participants were followed for 2.5 years. Participants in the exercise group were prescribed a home-based aerobic exercise program, which consisted of walking or cycling. This was performed 4 times per week for a period of 10 weeks, and the intensity of the exercise was maintained at 60% of the patient's maximal heart rate.

In the first week, participants exercised for 20 minutes.[11] In the second week, they exercised for 30 minutes, followed by 45 minutes from week 3 onwards.[11] Participants in the control group were instructed not to participate in any exercise program. The outcome measures used were (1) a questionnaire, (2) the Profile of Mood States (POMS) to evaluate mood changes, and (3) the Brief Pain Inventory[69] (BPI) to evaluate pain on a 0-10 scale. At the 5-week follow-up, the authors reported a significant decrease in depression ($p = 0.012$), anger ($p = 0.002$), and tension ($p = 0.020$) on the POMS in the exercise group and no change in the control group. At 10 weeks, depression was significantly decreased ($p = 0.019$), as was anger ($p = 0.013$), and total mood disturbances ($p = 0.009$) in the exercise group compared to the control group. The authors reported no significant changes in pain between the two groups. The authors concluded that aerobic exercise at a low to moderate level over a long period improves the overall

mood and function; hence, aerobic exercises should be recommended in patients with CLBP.[11]

Mixed Interventions

Six studies have been investigated under this category; one of them was a randomized clinical trial,[5] two were cohort studies,[67,68] and three were case series/reports.[7,13,14] In the randomized clinical trial,[5] the patients were divided into 2 groups. The first group received lumbar flexion exercises, a progressive treadmill ambulation program, and sub-therapeutic pulsed ultrasound. The second group received impairment based manual physical therapy (spine, pelvis, and lower extremities), impairment based exercises (designed to improve mobility, strength and coordination), and a body weight-supported treadmill ambulation program. In addition, all subjects received a home exercise program that included taking a daily walk. The perceived recovery was measured with the Global Rating Scale (the patient self-reported pain, disability, satisfaction, and function). There were no significant baseline differences identified between groups in demographics, baseline physical impairment, or outcomes. There was also no statistical difference in self-reported home exercise compliance between groups during the 6-week treatment period or in the time period between the 6-week and 1-year follow-up session. All of the secondary outcomes favored the manual therapy group over flexion exercise group at 6-week and 1 year except improvements in NPRS for lower extremity symptoms from baseline to 1 year; however, these differences were not statistically significant. The author concluded that physical therapy can be beneficial for patients with spinal stenosis. A program including manual physical therapy, exercise, and body-weight supported treadmill training may yield additional

improvements in clinically important outcomes beyond those achieved with a program including lumbar flexion exercises and level treadmill training.[5]

A prospective study by Onel, Sari, and Dˆnmez[67] evaluated the effect of salmon calcitonin (s-CT) and physical therapy on 145 patients with lumbar stenosis. All participants were hospitalized for one month and received medical treatment defined by the author as 100 IU synthetic s-CT that was administered subcutaneously every day for five days and every other day for the consecutive 3-week period. In addition, calcium salts were administered daily; the authors did not specify the dosage of calcium salts or how it was administered. All participants also received physical therapy in the form of infrared radiation for 30 minutes, ultrasonic diathermy of 1.5 w/cm^2 for ten minutes, and active William's flexion and McKenzie's extension exercises daily. The authors reported a significant improvement in pain relief using (1) the visual analogue scale, (2) extension and flexion ranges on lumbar spinal functional capacity for spinal mobility, (3) walking capacity on pain free walking distance in meters for neurological claudication, muscle strength on manual muscle test, and (4) increased sensory function ($p < 0.001$).[67] They did not report a significant improvement in the restoration of normal reflexes ($p > 0.05$). The authors concluded that physical therapy alone, or medical treatment alone, is not effective and suggested combined treatments including medical and physical therapy as the preferred mode of treatment before seeking surgery.[67]

The National Spine Network database was used in an observational study[68] to evaluate the effectiveness of physical therapy in the management of chronic spine disorders. According to the author, differences in observed covariates between the intervention and control groups can lead to biased estimates of treatment effects because

the groups are not comparable at baseline. To avoid this bias, the author used the propensity score approach.[70] The propensity score approach, introduced by Rosenbaum and Rubin,[71] is an approach that can be used to reduce this bias. Participants were classified into two groups. One group received physical therapy as the intervention group, and the other group served as the control group. Outcomes included the ODQ and the SF-36. The type, intensity and the duration of physical therapy, used were not mentioned in the study. A total of 2,724 participants with chronic spine disorders were included in this study, which were divided equally with 1,362 participants in the control group and 1,362 in the intervention group. In the intervention group, 124 patients were diagnosed with LSS, while in the control group, 114 patients had LSS. The authors did not report the results for patients with LSS separately. The results of the study showed that both groups improved between the initial and the follow-up visits for all variables except the SF-36 general health score. The amount of improvement was statistically significant for the intervention group ODQ ($p < 0.001$), SF-36 role physical and bodily pain scores ($p < 0.001$) but not in in SF-36 general health score ($p = 0.871$). Although these improvements were statistically significant, they were small and not clinically meaningful.
The authors concluded that the physical therapy was effective in the management of chronic spine disorders in participants with the greatest propensity score for receiving physical therapy.[68]

Whitman et al[7] described 3 patients with lumbar stenosis who were managed with manual physical therapy. The three patients received 5 sessions of impairment specific intervention focusing on each patient's prioritized impairments. The intervention included both rotational and posterior to anterior mobilization or manipulation to the spine, which

was given for 9-10 sessions. The therapist addressed hip stiffness by manually stretching the rectus femoris and iliopsoas muscles, followed by strengthening of gluteal muscles and lower abdominal muscles. This procedure was performed for 5-6 sessions. The patients were also instructed to do specific home exercises to reinforce physical therapy outcomes along with a walking regimen. Patients 2 and 3 received treadmill walking with body weight support. In addition, patient 3 was prescribed orthotics. All 3 patients reported substantial improvements in their condition on the ODQ and modified Subscale of Spinal Stenosis, the Symptom Severity Scale, and the overall Global Rating Scale from the baseline to discharge, and at the 10-week follow-up.[7]

A case report evaluated the effect of flexion exercise on pain and disability in knee-to-chest exercises for patient 1 and quadruped spinal flexion for patient 2, who were two elderly patients diagnosed with degenerative LSS.[13] Patients performed 10 repetitions of flexion exercises 3 to 4 times a day. Both patients performed treadmill walking as part of their interventions; however, patient 2 had a higher tolerance for ambulation and engaged more in treadmill exercises than patient 1 as measured by time and speed. After six weeks of physical therapy, patients 1 and 2 increased their walking speeds from 0.7 to 0.8 mph and from 1.5 to 2.5 mph, respectively. At the end of the therapy, the maximum walking time for patients 1 and 2 increased from 7 1/6 to 15 min, and from 5 1/6 to 15 min, respectively. Both patients reported no pain in the low back or leg at 6-week. The authors noted an improvement in pain and disability of 90% and 84% for patients 1 and 2 respectively, and concluded that both patients improved significantly in their ambulation and range of motion and strength in the lower extremity.[7]

Pe[14] determined the effect of strengthening and flexibility exercises on the walking capacity and pain in 15 patients with spinal stenosis. An intensive physical therapy program was provided in 4 stages: Stage 1 included proprioceptive balance training, followed by muscle stretching to address symmetry in stage 2, retraining of weak and inhibited muscles in stage 3, and aerobic conditioning in stage 4. The author did not report any statistical data, yet stated that all patients improved in walking tolerance and pain at discharge and were symptom free at follow-up.[8]

Individual Interventions

Only one study[72] demonstrated the effect of strengthening exercise alone on patients with LSS. In a study assessing the efficacy of aquatic spinal stabilization exercises on pain reduction and disability for persons with LSS, six patients with LSS and neurogenic claudication were enrolled. The RMDQ and the Pain Rating Scale were used to measure pain and disability pre- and post-intervention. A treadmill test was conducted to measure walking capacity. The aquatic stabilization exercise program included a warm-up session, followed by 30 minutes of aquatic stabilization exercises, three-times per week for a period of six weeks. At the end of the intervention, patients reported a 1.8-point decrease in pain score ($p < 0.05$) and a 5-point decrease in disability. Furthermore, five of the six patients demonstrated first neurogenic claudication symptoms after 15 minutes as compared with 6.3 minutes pre-treatment. Overall, pain improved by 72%, disability improved by 50%, and function improved by 66% in all patients. No severe symptoms were reported post-treatment versus 10.8 minutes pre-treatment. Thus, the authors recommended the use of aquatic spinal stabilization in the management of patients presenting with LSS.[72]

Murphy et al[11] reported the effect of manipulation alone on patients with LSS. This prospective case series determined the effect of distraction manipulation (DM) and neural mobilization (NM) in 55 patients with LSS. All patients were seen 2-3 times per week for 3 weeks. The outcome measures used to determine improvement in disability was the RMDQ and 3-level numerical rating scale to determine pain intensity. The study also included a self-rating scale for patients to report their perceived improvement. Pain intensity improved by 30% post-treatment. The authors reported statistically significant and clinically meaningful changes in disability of 5.1 and 5.2 points (40%) on the RMDQ scale from the baseline to the end of treatment ($p < 0.0001$), and from the baseline to the long-term follow-up (16.5 months; $p < 0.0001$), respectively. The mean patient-rated improvement from the baseline to the after-treatment was 65.1% immediately following intervention ($p < 0.001$), and at the long-term follow-up was 75.6% ($p < 0.002$). Although firm conclusions cannot be drawn from this study because of the small sample size, the authors concluded that the combination of DM and NM is a safe and effective approach as a nonsurgical option for patients with LSS.[11] The results of this case series are compromised by the inclusion of additional physical therapy treatments. In addition, there was considerable variation in the age (32-80 years old), number of treatments (2 to 50), and follow-up of subjects (3 to 48 months). Also, the authors reported a 23% dropout rate in this study.[11]

A prospective randomized controlled trial[73] assessed the effectiveness of therapeutic exercises alone and in combination with ultrasound in the treatment of lumbar spinal stenosis. Of the 45 consecutive patients included in the study, 15 were randomized to each group—exercise with ultrasound, exercise and sham ultrasound, and control (no

exercise or treatment). At the 3-week follow-up, leg pain decreased in groups 1 and 2 compared to the control group, and disability scores decreased in groups 1 and 2 compared to the control group. There were no statistically significance differences between groups 1 and 2 ($p > 0.05$). The authors concluded that therapeutic exercises—stretching, strengthening and low-intensity cycling exercises—improved the level of pain and disability in patients with lumbar spinal stenosis. In addition, adding ultrasound to the treatment group was found to reduce the amount of analgesic consumption substantially compared to the control group ($p < 0.05$).[73] The results of this study have limited clinical applicability because of the small sample size and short follow-up period.

Koc et al[74] conducted a prospective randomized controlled trial of the effects of epidural steroid injections and a conservative inpatient physical therapy program on pain and function in patients with LSS. A total of 33 patients who were diagnosed with LSS by medical history, physical and neurologic examination, as well as MRI findings. The patients were randomized into 3 groups. Group 1 received a conservative inpatient physical therapy program 5 day per week for 2 weeks: ultrasound 1.5 W/cm2 for 10 minutes, a hot pack for 20 minutes, and TENS for 20 minutes to the lumbar region. Group 2 received lumbar epidural steroid injections under fluoroscopic imaging. Group 3 served as the control group, and all three groups received diclofenac and a home-based exercise program. Patients were measured for the following clinical parameters at baseline, 2 weeks, 1 month, 3 months, and 6 months after treatment. The outcome measures used were pain severity by VAS, finger floor Distance (FFD) (cm), treadmill walk test, sit-to-stand Test (seconds), weight-carrying (WC) test (seconds), and Roland-

Morris Disability Index (RMDI). The Nottingham Health Profile (NHP) was also administered in order to assess the functional level and the quality of life of the patient.[74]

The results[74] showed the following: In group 1, significant improvements were observed in pain (VAS), WC test, and RMDI at all follow-up visits, in TFS at six months, and in sit-to-stand test at one month and three months. In group 2, significant improvements were observed in pain (VAS), TFS, and RMDI at all follow-up visits, in FFD at two weeks and three months, in TAT at three months, and in WC test at two weeks. In group 3, significant improvements were observed in TFS and RMDI at all follow-up visits, in pain (VAS) at one month, and in TAT at one, three, and six months. Comparison of percent changes in the parameters set among the 3 groups revealed no statistical significant difference except in pain intensity (VAS). Significantly more improvement in pain intensity (VAS) was obtained in group 2 compared with group 3 at two weeks (Mann-Whitney *U* test, p =0.008). RMDI scores were significantly improved in all 3 groups, at all follow-up visits, and among group analysis, which showed that the improvement in group 2 was significantly higher compared with group 3 at two weeks (Mann-Whitney *U* test, p = 0.007). The authors concluded that epidural steroid injections and physical therapy were both effective in LSS treatment up to 6 months follow-up, whereas epidural steroid injections provide better improvement in the short-term. The results of this study have limited clinical applicability due to the small sample size.

A systematic review by Kent et al[75] attempted to determine the efficacy of targeted manual therapy and/or exercise on pain and activity limitation in adults with non-specific low back pain (NSLBP).[75] The authors used an electronic search of MEDLINE, EMBASE, Current Contents, AMED and the Cochrane Central Register of

Controlled Trials. The inclusion criteria of studies were as follows: Randomized controlled trials (RCT) that were hypothesis-testing studies (hypothesis-setting studies) published in English, Danish, or Norwegian, and the RCTs were required to be either a "two-group plus subgroup covariate RCT" or a "multi-arm subgroup system RCT." (p. 3) The exclusion criteria included studies that were observational studies, uncontrolled studies, studies comparing non-targeted interventions, studies comparing 2 targeted interventions, and studies containing participants with specific low back pain (e.g., fracture, infection, cancer, or inflammatory arthritis).[75] Participants needed to be experiencing NSLBP, but they could not be pregnant. For inclusion criteria, "more than 85% of participants needed to be aged 18 years or over. Trials containing people with both low back pain and leg pain were included if at least 85% of the participants had no symptoms or signs of neurocompression (numbness, pins and needles, or lower limb muscle weakness) or sciatica. Studies containing participants with specific low back pain (for example, fracture, infection, cancer or inflammatory arthritis) were excluded."(p. 3) The authors were unclear in regards to the remaining 15% of participants for the inclusion criteria. Types of interventions used were mobilization, manipulation, and traction, which were classified as "manual therapy," and therapeutic exercises were classified as "exercise." Outcome measures included were self-reported pain and activity limitation. Results were as follows: short term: up to 3 months after randomization, intermediate: three months up to one year after randomization, and long term: greater than one year. The study concluded that statistically significant effects for short-term activity and pain limitation were rare and when present, were only for short-term outcomes. The clinical implications of these results were that there was no evidence that

spinal manual therapy is superior to other standard treatments for patients with NSLBP, and the authors stated that these results have yet to be adequately researched. The research implications were that high quality RCTs using designs capable of providing objective and valid information on treatment effect modification are infrequent, and further studies using this research method should be a priority for the clinical and research communities.[75]

Van Middelkoop et al[76] conducted a systematic review to determine the effectiveness of physical and rehabilitation interventions (i.e., exercise therapy, back school, transcutaneous electrical nerve stimulation (TENS), low level laser therapy, education, massage, behavioral treatment, traction, multidisciplinary treatment, lumbar supports, and heat/cold therapy) for chronic low back pain (CLBP).[76] The selection criteria in this review included RCTs only that examined adults 18 years or older with non-specific CLBP that persisted for 12 weeks or more. The exclusion criteria included (1) studies on post-partum LBP or pelvic pain due to pregnancy, as well as post-operative studies and prevention studies; (2) studies with a follow-up less than 1 day; and (3) RCTs including participants with specific LBP caused by pathological entities such as vertebral spinal stenosis, ankylosing spondylitis, scoliosis, and coccydynia. RCTs studying physical and rehabilitation interventions included exercise therapy, back schools, transcutaneous electrical nerve stimulation (TENS), superficial heat or cold, low-level laser therapy (LLLT), individual patient education, massage, behavioral treatment, lumbar supports, traction, and multidisciplinary rehabilitation. The outcome measures that were assessed in this review were pain intensity (e.g., visual analogue scale (VAS), McGill pain questionnaire), back-specific disability (e.g., Roland-Morris, Oswestry Low

Back Pain Disability Questionnaire [ODQ]), perceived recovery (e.g., overall improvement), return to work (e.g., return to work status, sick leave days), and side effects.[76]

Five studies were identified that compared exercise treatment with spinal manipulation or manual therapy.[76] Two of them were low quality studies level 3b. Quality of evidence was evaluated through the GRADE (Grades of Recommendation, Assessment, Development, and Evaluation) approach and based on four principles: limitations, consistency of results, generalizability of findings, sufficient data, and other factors (i.e., bias). Quality was considered high when all these factors were met and would be downgraded by one level for each factor that was not met.[76] Post-treatment data were available for three studies. One study reported that manual therapy was statistically significant better than exercise. Difference post treatment was measured by global perceived effect. The other 4 studies reported that there was no statistically significant difference in effect (pain intensity and disability) for exercise therapy compared to manual therapy/manipulation at short and long-term follow-up.[76]

The overall evidence from the randomized controlled trials demonstrates low quality evidence for the effectiveness of exercise therapy compared to usual care, low evidence for the effectiveness of behavioral therapy compared to no treatment, and moderate evidence for the effectiveness of a multidisciplinary treatment compared to no treatment and other active treatments for decreasing pain (short-term) in the treatment of chronic low back pain. Based on the variations of the populations, interventions, and comparison groups, the authors concluded there is insufficient evidence to draw a strong conclusion on the clinical effect of back schools, low-level laser therapy, patient

education, massage, traction, superficial heat/cold, and lumbar supports for chronic LBP.[76]

Aure et al[77] compared the effect of manual therapy, consisting of specific exercises and segmental techniques, to general exercise therapy in chronic low back pain patients. Forty-nine patients were randomized into manual therapy (MT, n=27) or exercise therapy (ET, n=22) groups. The treatments were performed at several facilities. A blocking design was used to randomize patients into age and gender strata.[77] The article did not state whether randomization was concealed from the participants. The randomization was successful and both groups were similar at baseline.[77] Inclusion criteria were as follows: male and female patients, age range 20-60 years, who had been sick-listed with CLBP or radicular pain for at least eight weeks but no more than six months. Exclusion criteria were as follows: Being unemployed or forced to retire early because of CLBP history, surgery for herniated disk, pregnancy, spondylolisthesis, spondylolysis, fractures, suspicion of malignancy, osteoporosis, previous back surgery, known rheumatic, neurologic, or mental disease, and lack of pain with musculoskeletal testing.[77]

One outcome measure was the modified Schober test to measure spine range of motion (ROM). Pain intensity due to LBP was recorded on a 100-mm visual analogue scale (VAS), 0 indicating no pain and 100 the worst pain ever. Pain at the moment, worst pain the last 14-days, and mean pain during the last 14-days were scored.[77] The final outcome measure used in the statistical analyses was the mean of these three recordings. Functional disability using the ODQ and General Health: Dartmouth COOP function charts, and Return to Work: patient reports. All outcomes of interest were measured 5

times during the study: before treatment, immediately after treatment, and again at 4 weeks, 6 months, and 12 months after treatment ceased.[77]

Three participants dropped out of the study, 2 from the MT group and 1 from the ET group.[77] Participants who dropped out for reasons other than those related to the treatments were given baseline registration scores for missing data points. Participants who dropped out because of treatment were given the worst score registered for any patient in their assigned group. All participants were analyzed in their respective groups. There were significant improvements for the MT and ET groups on the VAS and OSW after the last treatment session, although greater improvement was observed in the MT group ($p < .01$). The mean decrease on the VAS was 33mm for MT and 17mm for ET. The mean decrease for MT on the VAS was greater than 31mm at the first follow-up period (after eight weeks of treatment) and at the 12-month follow-up there were no clinically significant changes between MT and ET based on the mean change scores for the VAS. The MT group experienced a mean decrease of 21% on the OSW, and the ET group experienced a mean decrease of 9% on the OSW. At the 12-month follow-up, the mean decrease for the MT group on the OSW was greater than 11% and at the 1-year follow-up there were no clinically significant changes between the MT and ET groups based on the mean change scores. For the ET group clinical changes were statistically significant only at the 12-month follow-up based on the mean scores. Also of note, at the 1-year assessment there were no clinically significant changes between the MT and ET groups in disability. The study concluded that MT appears to significantly improve functioning and decrease pain in patients with CLBP. However, stabilization exercises still play an important role in the long-term treatment of CLBP. It is important for

therapists to be knowledgeable in both types of treatments and be able to individualize their treatments to adapt to different patients and the underlying causes of their CLBP.[62]

Goldby et al[78] compared the effectiveness of a spinal stabilization rehabilitation program and manual therapy in patients with CLBP. Three hundred forty-six patients with a diagnosis of CLBP were recruited for this study. Patients had been referred to the St George's Hospital (London, UK) physical therapy department. After the initial evaluation, 44 were excluded. In addition, some participants withdrew or failed to attend any treatment sessions (n = 89). Participants were randomized into one of 3 treatment groups and stratified by age, gender, and referral location. A research assistant was blinded to group allocation. Participants in each group were similar at baseline. Inclusion criteria included (1) diagnosis of CLBP at least 12-weeks in duration, (2) ages 18-65 years, and (3) ability to comprehend and communicate in English. Exclusion criteria included (1) diagnosis of non-mechanical low back pain, (2) pregnancy, (3) anxiety neurosis, (4) mechanical back pain that could be treated with alternative treatments, (5) history of metastatic disease, or (6) lower limb pathology. For the spine-stabilization (SS) group, it was a 10-wk (1-time/week) ET program with an emphasis on training the transversus abdominis, pelvic floor muscles multifidi, and the muscles of the diaphragm.[78]

Two physical therapists (PTs) conducted each 1-hour class. Patients also watched a spine-related educational video before and after each training session. Participants in the MT group were treated by PTs for up to 10 sessions. Any form of MT was allowed, and specific examples were not provided. The aforementioned SS exercises were not allowed to be performed; however, the PTs were allowed to prescribe any other form of

exercise.[78] Again, there is a lack of information regarding what exercises may have been prescribed. At the end of the ten sessions, the participants were discharged to the Back School.[78] The patients in the education group were educated from the booklet *Back in Action*. In addition, they were enrolled in the Back School, in which each group participated in a one 3-hour class addressing spine anatomy, ergonomics, treatment, and exercise. Outcome measures were as follows: (1) Pain, measured with a 0-100 numerical rating scale; (2) functional disability, measured with the Modified Oswestry Low Back Pain Disability Questionnaire (MODQ) and the low-back outcome score; and (3) general health, measured with the Nottingham Health Profile. Outcome measures were recorded at baseline and 3, 6, 12, and 24 months after treatment.[78]

A total of 213 participants (ST = 84, MT = 89, education = 40) completed the treatment sessions.[78] One hundred twenty-two failed to complete all follow-up tests (ST = 35 participants, 49 dropouts, 55.7% dropouts; MT=37 participants, 52 dropouts, 58.4% dropouts; education = 19 participants, 21 dropouts, 52.5% dropouts). Both the SS and MT groups experienced significant reductions in pain between baseline and each testing point ($p < 0.001$). There were fewer patients in the SS group experiencing symptoms ($p < 0.009$) than in the MT group at six months. The SS experienced significant reduction (from baseline to 12 months) on the MODQ ($p = 0.0098$) compared with the MT and education groups. The SS demonstrated greater improvements in quality of life on the Nottingham Health Profile than the MT and education groups; however, the between-groups differences were not significant. The SS group did demonstrate significant improvements on the Nottingham subsection of sleep ($p = 0.025$).[78] The study concluded that the stabilization group had the lowest scores of pain and better quality of life

measures (Nottingham Health Profile score) compared to the manual therapy group. The authors stated, “spinal stabilization…is significantly more effective than manual therapy at reducing pain, disability, dysfunction, medication intake, and improving the quality of life in patients with chronic low back disorder.”[78 (p. 1902)]

Manual Therapy Interventions

As a result of the recurrent nature of low back pain in patients with LSS, many people seek alternate forms of treatment such as acupuncture, spinal injections, medications, physical therapy, and even surgery.[79] Although LSS patients are typically treated by physical therapists, there is no clear agreement on utilization strategies.[80-82] Wainner et al[83] reported that a more comprehensive management strategy for people with these musculoskeletal symptoms stems from a rising paradigm referred to as regional interdependence in which "seemingly unrelated impairments in a remote anatomical region that may contribute to, or be associated with, the patient's primary complaint."[(p.658)] This treatment approach has been used in the management of co-morbidities involving not only the lumbar spine, but the lower extremities as well. There is an abundance of literature regarding the anatomical relationship between the lumbar spine and hips;[79-82,84-99] therefore, a regional interdependence approach should be taken into account for patients with LSS. Several studies have shown a correlation between low back pain and hip impairments that include restrictions in hip internal rotation, total hip rotation, flexion, abduction, and external rotation ROM.[86] One study revealed that pain in chronic low back pain (CLBP) patients was provoked with maximal hip internal rotation and/or the FABER (flexion, abduction, external rotation) test which implicates involvement of hip in low back pain (LBP). Another correlation has been found between

LBP and neuromuscular control between the hip and lumbopelvic region, as patients with LBP demonstrated less active hip motion with early compensatory lumbopelvic motion, which suggests distorted lumbopelvic control and coordination.[85,87] Another study suggests that the hip joint may be a causal pain initiator in about 12.5% of LBP patients.[89] Radiographic evidence supports this finding as hip osteoarthritis (OA) has been shown to be a contributing factor for progression of lumbar disc degeneration[88] while older adults with hip or knee OA complain of simultaneous LBP.[89,90] In one study, investigators performed THA procedures on 25 patients suffering from concurrent hip and lumbar spine and found that these patients reported a significant decrease in lumbar disability scores and pain at three months follow-up and two years post-THA.[94] Brown et al[95] found hip impairments in 81% of patients with LBP, even though there is scarce literature on physical therapy interventions aimed at the hips for LBP patients. Two other case studies found that addressing impairments in hip motion and hip-lumbopelvic control and coordination lead to successful management of patients with LBP.[97,99] Furthermore, Di Lorenzo et al[98] investigated patients with first time back pain after an open reduction internal fixation procedure secondary to hip fractures, and found that interventions directed at the hip resulted in a statistically and clinically significant decrease in LBP, while interventions directed at the hip and lumbar spine lead to an even greater reduction in LBP.[83] When patients with chronic LBP present with concurrent hip impairments, clinical decision-making can be difficult; therefore, impairment-based manual therapy and exercise for the hips can result in significant improvements in pain and disability.[99] The response to interventions directed at the hips in patients with CLBP is not adequately investigated.

Only one case study[96] investigated the short-term outcomes in patients with CLBP managed with impairment-based manual therapy and exercise to the hip joints.[96] Eight patients with CLBP were treated with manual physical therapy and exercise to bilateral hip impairments for a total of three sessions over one week. Inclusion criteria included patients with primary report of LBP for more than six months without radiating pain below the knee, age between 18 and 65 years, score of MLBPDQ more than 30%, and at least two of the following ROM impairments in one or both hips: prone internal rotation less than 30°; prone external rotation less than 30°; supine flexion less than 110°, and prone extension less than 10°.[96]

Exclusion criteria included any medical red flags that would contraindicate manual therapy to the hips, previous surgical or non-surgical management within the last six months, signs of nerve root compression, evidence of central nervous system involvement, pending litigation, insufficient English language skills, recently missed menstrual cycle in women, onset of symptoms from a motor vehicle accident, and inability to comply with treatment protocol.[96] Outcome measures used were the numeric rating pain scale (NPRS), ODQ, fear-avoidance beliefs questionnaire (FABQ), and patient-specific functional scale (PSFS). Baseline outcome measures and screening for inclusion criteria were performed by the primary physical therapist. Each patient received manual therapy and exercise directed at one or both hip joints. The manual techniques included supine long axis distraction thrust manipulation, supine caudal non-thrust manipulation, supine anterior-to-posterior non-thrust manipulation progression, prone posterior-to-anterior non-thrust manipulation in neutral and flexion/abduction/external rotation positions, and mobility exercises targeting the lumbopelvic-hip region. All non-

thrust manipulations were performed as grade III or IV oscillations for three sets of 30-seconds. All patients were also instructed to perform mobility and stretching exercises twice a day as a home exercise program.[96]

The therapist selected two out of four potential exercises based on patient-specific physical assessment findings.[96] Four exercises were provided and included a kneeling iliopsoas stretch, kneeling hip internal rotation stretch, supine piriformis stretch, and a prone hip "FABER" stretch. The two exercises were chosen by the therapist based on the primary ROM impairments and/or patient response. Only two exercises were selected to maximize patient compliance.[96] Each patient was instructed to perform two sets of 30-second holds for each exercise, twice a day. The patients returned to the treatment two more times within seven days of initial enrollment and the global rating of change (GROC) was done at visits 2 and 3. The results of the study showed five out of eight patients reported feeling "moderately better" at the 3rd session, indicating a moderate improvement in self-reported symptoms. These five individuals also experienced a 24.4% reduction in ODQ scores.[96] This study suggests that an impairment-based approach directed at the hip joints may lead to improvements in pain, function, and disability in patients with CLBP.

Overall, these research articles concluded that controversy still exists about surgical management of LSS. Conservative management has been recommended for patients with LSS prior to surgical intervention. Limitations in published research include insufficient evidence due to several factors including: 1) lack of specifics of interventions used and which were effective or not, 2) inclusion of other treatment techniques, 3) wide range of population age and number of subjects, 4) number of treatments, 5) short follow

up periods, and 7) ambiguous diagnoses in which cause of low back pain is unknown (no specificity for LSS). Manual therapy and stabilization exercises to the lumbar spine have documented efficacy, as improvements were found with both interventions. However, there is a paucity of high quality studies that clearly determine the role (if any) of manual therapy for patients with LSS. The effectiveness of manual therapy and whether specific types of manual therapy or multimodal approaches are more beneficial is not clearly established, and further research is needed in this area. Furthermore, the studies investigating the role of the hip joint on back pain were more generalized, as LSS was included under the broad term LBP, and these studies were not specific to LSS. Based on this review, there is no significant evidence that supports the use of manual therapy over stabilization exercises, and there is insufficient evidence that supports the importance of hip mobilization in management of patients with LSS. Future studies need to be conducted to determine whether one treatment approach is superior to the other.

Outcome Measures

McGill Pain Questionnaire

The McGill Pain Questionnaire is the most widely used assessment tool for clinical pain, as it provides information for 3 primary measurements of pain which include sensory-discriminative, motivational-affective, and cognitive-evaluative.[100] This scale consists of 3 sections which include: (1) What Does Your Pain Feel Like? (2) How Does Your Pain Change with Time? and (3) How Strong is Your Pain? Interpretation of scores is as follows: minimum pain score: 0 (would not be seen in a person with true pain), maximum pain score: 78 (the higher the pain score the greater the pain). This scale has been widely used and is well-known for its established reliability and validity, and is

among the measures most commonly used to evaluate pain in both clinical and research settings.[100] In a prospective observational cohort study of 57 patients with osteoarthritis, the MPQ was administered twice at five days apart to evaluate test-retest reliability.[101] For the MPQ total, sensory, affective, and average pain score, ICC-values of 0.96, 0.95, 0.88, and 0.89, respectively, were reported.[102] This scale is not only known for being valid and reliable, but it also assesses the quality and quantity of pain through use of exclusive pain descriptors.[103] The MPQ may be useful in clinical trials of patients who suffer from multiple morbidities leading to pain that occurs from multiple causes. Despite the superior qualities of this scale, limitations include difficulty of comprehension because of the complex vocabulary used, as well as the possibility of gender and ethnic differences affecting the selections of pain descriptors. Nonetheless, the clinician can remediate this limitation by providing clear definitions of words during administration of the test.[104]

Oswestry Low Back Pain Disability Questionnaire

The Oswestry Low Back Pain Disability Questionnaire (ODQ) is one of the primary condition-specific outcome measures used in the management of spinal conditions.[69] This questionnaire consists of ten sections, and for each section, the total possible score is 5, the first statement in the section = 0 and the last statement = 5. If all ten sections are completed the score is calculated as follows: 50 (total possible score) x 100 = patient's score. If one section is missed or not applicable the score is calculated without that section: 45 (total possible score) x 100 = patient's score. A study of 32 patients with LSS[69] reported an ICC-value of 0.89 for the test-retest reliability of the ODQ. Several studies have reported the minimal detectable change (MDC) for this

measure. One study[105] reported an 17 points as the MDC in the original version of the ODQ. In a prospective multi-site study[102] of 106 patients with LBP, five different disability questionnaires were administered and evaluated for both reliability and responsiveness. Repeated measures at a 6-week interval were taken for the Modified Low Back Pain Disability Questionnaire (MLBPDQ). The MDC was determined in two subgroups of patients. The MDC value was 15 points in a group of 47 patients with LBP who reported that their overall disability status was unchanged. The MDC value was 10.5 for patients with LBP who self-rated as *about the same*. The minimally clinically important difference (MCID) can be defined as patient-derived scores that reflect changes in a clinical intervention that are meaningful to the patient. Fritz, Erhard, and Vignovic[13] reported that the MCID value was approximately 6 points for the MLBPDQ in a group of 67 patients with acute work-related LBP. For this study, the original version of the ODQ was used.

Self-Paced Walking Test (SPWT)

The definition for self-paced walking capacity is the distance a person with LSS is able to walk without support on a level surface at a self-selected speed before being forced to stop because of symptoms of LSS. This definition encompasses the aspects of walking which are most relevant to and representative of LSS patients' actual walking capacities in real life situations including functional distance, self-selected speed, and a symptom-limited end point. The self-paced walking test requires patients to walk on a level surface without support at their own pace until forced to stop because of symptoms of LSS or a time limit of 30 minutes. The SPWT is meant to mimic authentic walking conditions using a standardized setting and protocol. This test has content validity

evidence supporting its use, given that it is a direct measure of the construct of interest.[106] The SPWT is a feasible and reproducible criterion or gold standard measure of walking capacity in patients with LSS (ICC = 0.98).[106]

Lumbar Spine Range of Motion

Diminished lumbar mobility has been observed in patients with LBP.[107] As such, baseline spinal mobility measurements have aided physical therapists in patient diagnosis and in guiding the prescription of a suitable exercise program.[108] The measurement of spinal mobility has also been used to monitor the response of LBP patients to physical therapy interventions. Examination of the lower back in patients with LSS will often reveal non-specific reduced mobility. For example, a physical therapist may find his/her patient is more limited in low back extension than flexion.[50]

Lumbar spine flexion and extension range of motion is often measured using the double inclinometer technique.[109] The advantage of the inclinometer technique is that both lumbar and pelvic movements during flexion and extension are taken into consideration. The angle of the tangent at a particular point with regard to the vertical was recorded from the inclinometer. The subtraction of the measurement at L5–S1 (reflecting the pelvic movement) from the measurement at T12–L1 (reflecting both lumbar and pelvic movement) gives the regional lumbar motion. A number of previous studies have examined the validity and intra-tester reliability of the inclinometer used to measure flexion and extension range of motion of the lumbar spine. Various levels of reliability were found in these studies ranging from moderate reliability to good reliability.[101,110-115]

Hip Range of Motion and Muscle Strength

A few studies[89,116] reported the association of limited hip flexion, extension, and internal rotation range of motion and low back pain, particularly in males. Other published research found significantly high levels of limitation in hip extension and internal rotation ROM and hip abductors and extensors strength as related to low back pain.[117-119] Nadler et al[118] examined hip abductor and extensor strength in college athletes. Logistic-regression analysis indicated a difference in side-to-side hip-extension strength as a potential predictive variable of future treatment for LBP among female athletes only.

Kankaanpää et al[120] investigate the difference in lumbar paraspinal and gluteus maximus muscle fatigability between the CLBP patients and healthy controls during a back extension endurance test to exhaustion using objective surface EMG spectral analysis. The authors reported that paraspinal fatigability was similar between groups, whereas the gluteus maximus fatigued more rapidly in the chronic LBP group than the control group. Given the role that hip extensor strength and endurance,[120,121] along with the role the hip abductor and adductor muscles play in providing lateral stability of the pelvis,[117] it is important for clinicians to carefully examine the strength of these muscle groups. Research in this area still evolving to help guide decision making. Identification of hip impairments would allow an impairment-based approach to treatment. Hip extension, internal rotation, and external rotation ROM were selected to be measured using a universal goniometer, and hip abductor and extensor muscle strength were measured by manual muscle testing.

Summary of What is Known and Unknown about Lumbar Spinal Stenosis

LSS can be treated with surgical or non-surgical methods. Symptoms of LSS include low back pain, poor posture, stiffness, decreased ROM, and decreased muscle flexibility of the lumbar spine, pelvis, and hip joints, along with sensory, motor, and pathological reflex deficits. These impairments have led to restricted walking capacity, intolerance to activity, and overall diminished quality of life. Based on the literature review, treatment of LSS includes conservative physical therapy methods such as flexion-based lumbar stabilization exercises, abdominal strengthening, stretching, postural education, aquatic therapy, aerobic exercise (cycling and treadmill), manipulation/mobilization techniques, combination of epidural steroid injections with physical therapy interventions as stated above, and even the cognitive-behavioral approach. Although conservative treatment is the main approach for mild to moderate symptoms of LSS, surgical interventions have been known to be effective for severe cases. Authors demonstrate varying results for effects of physical therapy alone versus medical treatment alone for treatment of LSS; however, a combination of these treatments may be the best treatment choice prior to seeking surgery.

Limitations in the studies include insufficient evidence as a result of several factors, including (1) lack of specifics of interventions used and which were effective or not, (2) inclusion of other treatment techniques, (3) wide range of population age and subject size, (4) number of treatments, (5) short follow up periods, (6) study dropout rates, and (7) ambiguous diagnoses in which cause of low back pain is unknown (no specificity for LSS). Despite a wealth of research articles and studies conducted on LSS, further studies need to be done to determine the best treatment approaches to address

symptoms, impairments, and quality of life for patients suffering with this condition. Because the majority of the current evidence on this topic is of low quality and limited clinical applicability, there is an urgent need for high-quality research to better guide clinical practice.

Practical Application of the Findings

The analysis of changes in clinical outcomes achieved from the use of two different treatment protocols (EX and EXMT) in patients with LSS should allow for the development and validation of a comprehensive rehabilitation program for patients with LSS that addresses both impairments and functional deficits and improves the quality of life for patients with LSS. This RCT offers further insight on manual treatment techniques, outcomes, and an impairment-based approach specifically for treating patients with LSS. The findings of this study provide pertinent information regarding the considerable role of hip mobility and strength in low back pain for patients with LSS, an issue for which research studies are scarce in the literature. This study offers more detailed information on specific manual interventions used in conjunction with other therapeutic exercises and aerobic training versus the traditional treatment approach of passive modalities and general stretching exercises. It is important to focus not only on the low back alone, but also on other areas that may contribute to symptoms of LSS. Expanding the focus of treatment could lead to better management and outcomes, and as a result, contribute to a greater quality of life for this patient population. The research implications are that high quality RCTs using objective and valid methods on treatment effect are sporadic and further studies shoulder be conducted for the LSS patient population. The literature for patients with LSS is lacking, and there is a need for high

quality, long-term RCTs investigating the most superior interventions (manual and exercise) for these patients.

Barriers and Issues

Based on existing literature reviewed, preliminary evidence indicates a lack of well-designed controlled trials, and the evidence suggests that manual therapy combined with exercise demonstrates potential benefit in the treatment of LSS; however, further evidence of effectiveness is needed. The development of an RCT requires the use of a control group for appropriate research design. Using an untreated control group in the study may be an ethical concern. A home exercise program was therefore issued to both treatment groups in this study.

Chapter Summary

Some studies suggest manual therapy is ineffective while several other studies reveal improvement in pain and function in this group. Despite one review concluding that spinal manipulative therapy is not beneficial for any group of patients with general back pain, it may be effective for only a small subgroup of back pain patients,[122] other studies found that additional gains were made with the combination of manual therapy and therapeutic exercise.[5] This study revealed the addition of manual therapy to exercise and treadmill walking was more effective than lumbar flexion exercises and walking. Another study describes more detailed manual techniques involving hip mobilizations, manipulations, and manual stretches that were impairment-specific interventions along with therapeutic exercises and a walking regimen.[7] Patients in this study reported significant improvement in their condition as evidenced by established assessment scales.

An additional study looked at the effects of manipulation alone on LSS patients with specific focus on distraction manipulation and neural mobilization and found that this combination proved to be an effective approach as a non-surgical option for this patient group.[122] Several studies in the literature review revealed that manual therapy, especially when combined with other interventions such as therapeutic exercise, is in fact beneficial and highly effective for patients suffering from LSS. In an effort to further investigate the effects of manual therapy and exercise on LSS, this study aims to use a randomized comparative trial to compare the functional clinical outcomes achieved by patients with LSS receiving two different physical therapy programs that include impairment-based exercises and specific manual physical therapy techniques.

CHAPTER THREE: METHODOLOGY

Research Design

This is a prospective, randomized controlled clinical trial on patients diagnosed with lumbar spinal stenosis (LSS). Using a random number table, the subjects were randomized into two groups. Subjects in the study received PT twice a week for 6-week, for a total of 12 sessions. All measurements were taken before the first treatment session at the initial visit, the last visit (discharge), and 6-week after discharge. The study was conducted at three locations: Chicago, Orland Park, and Palos Heights. Each location had a physical therapist that served as a treating therapist. The measuring therapist travelled between the centers to evaluate each patient before treatment, at the time of discharge, and 6-week follow up after discharge.

Subjects

The sample of this study is a sample of convenience. Patients with lumbar spinal stenosis referred by their primary care physician to Chicago Rehabilitation Services Inc., were recruited to participate in this study. The receptionist handed out a flyer (Appendix A) to the subjects. After the subject expressed interest, the receptionist notified one of the research therapists to explain the details of the research to the subject. The therapist described the purpose of the research and answered any questions that the subject had prior to obtaining consent. When a subject agreed to participate, he/she signed a consent form approved by the Nova Southeastern University Institutional Review Board and received a copy of the signed consent form for their records. After signing the informed consent, all subjects completed a series of self-report questionnaires and received a standardized history and physical examination to determine eligibility.

Inclusion Criteria

The following inclusion criteria were used to determine eligibility for this study. Each subject should have:

1. Positive history for LSS.
2. Positive radiographic findings indicating LSS.
3. Ability to read and speak English.
4. Provocation of symptoms upon lumbar backward bending.
5. Ability to attend 2 intervention session per week for 6-week.
6. No physical therapy for his/her current back pain during the previous three months.

Exclusion Criteria

The following exclusion criteria were used to determine ineligibility for this study:

1. Change of medical treatment protocol 6-week before the start of the study or during the study including new medication, interventional pain management, or surgical intervention.
2. Participants with decreased cardiovascular capacity (coronary artery or peripheral artery disease).
3. Participants with lumbar spinal fusion surgery.
4. Participants with recent vertebral fracture.
5. Participants with progressive neurologic deficit or cauda equina syndrome.
6. Participants with vascular claudication or vestibular problems.
7. Other medical conditions, such as vertigo, diabetic neuropathy or CVA.

8. Pending legal action regarding their back pain.
9. Insufficient English language skills to complete all questionnaires.
10. Inability to comply with treatment and follow-up schedule.

Study Protocol

After obtaining informed consent, all eligible subjects received a detailed standardized history and physical examination, which were administrated by the testing therapist. Then they completed the series of self-reporting questionnaires, which are part of the outcome measures.

History and Physical Examination

The baseline examination included the following four elements: 1) collection of demographic information and a medical history, 2) a neurologic screening examination, 3) thoracolumbar flexion and extension, 4) measurement of hip extension, external rotation, and internal rotation, 5) measurement of hip abductor and extensor muscle strength, 6) Self-Paced Walking Test, 7) soft tissue evaluation of lumbar paraspinal muscles, 8) core strength evaluation, 9) lumbar segmental mobility evaluation, and 10) neurodynamic testing.

Demographic information and medical history. The evaluating therapist reviewed and confirmed this information from the intake form during history taking along with review of list medications.

Neurologic screening and examination. All subjects were screened for evidence of nerve root compression. Screening includes assessment of the Hoffman's and Babinski pathological reflexes, manual muscle testing of major muscles groups for myotomes from

L1-S1, pinprick sensation testing of dermatomes from L1- S1, and testing the patellar and Achilles tendon reflexes.

Thoracolumbar flexion and extension. First, the participants of this study were asked to stand in his or her usual, relaxed posture. Using a double inclinometer, the baseline inclinometer values were recorded at T12–L1 and L5–S1. Second, the participants were asked to bend forward and then backward to the end of their active range with maximal effort. The readings at T12–L1 and L5–S1 were measured in the maximum flexed and maximum extended positions.[109] Third, the measurement at L5-S1 was subtracted from the thoracic measurement to determine the amount of lumbar motion that occurred.

Hip extension, external rotation, and internal rotation ROM. Measurement of hip extension was taken using universal goniometer. Subjects were positioned in prone with hips and knees in neutral and feet extending off the end of the table. The pelvis was stabilized through straps or manual fixation. The goniometer axis was placed on the greater trochanter with the proximal arm parallel to midaxillary line of the trunk and the distal arm parallel to longitudinal axis of femur in line with lateral femoral condyle. Patients were asked to extend their hips with knee extended while keeping the ASIS on the plinth.

Measurement of hip internal and external rotation was taken using an universal goniometer. Patients sat with the hip and knee in 90° flexion. The untested extremity rested on a foot stool with hip slightly abducted. The goniometer axis was placed at mid-patella with the proximal arm perpendicular to the floor and the distal arm parallel to the long axis of the tibia. Patient was asked to move his/her foot toward the opposite limb

followed by moving foot away from the opposite limb. ROM for hip joint extension, internal rotation, and external rotation was measured on both legs to determine the limited side and focus treatment based on the impairment findings.

Hip abduction and extension muscle strength. Hip abductors and extensors muscle strength were tested using manual muscle testing. Manual muscle testing is a procedure for evaluating strength and function of an individual muscle or a muscle group in which the patient voluntarily contracts the muscle against gravity load or manual resistance. The key to muscle grading by Kendall and published by National Institute of Health (Appendix D) was used to recode the data from 1 to 10. A sample of the lower extremity muscle exercises used in this study can be found in Appendix E.

Hip extension muscle strength was measured with the patient in the prone position with the knee in extension. One hand of the tester stabilized the low back area and the other hand applied pressure to the posterior lower leg.

Hip abductor muscle strength was tested with the patient positioned in side lying with the underneath leg flexed at the hip and knee. The leg to be tested was placed in a neutral position of the hip while the knee was extended. One hand of the tester stabilized the iliac crest while the other hand applied pressure to the lateral leg just above the ankle.

During the initial evaluation, both hips were evaluated to identify the weak and limited side. For each muscle, the weak side was identified. No intervention was applied to the strong side.

Self-Paced Walk Test (SPWT). Each participant was instructed to walk continuously at their own pace around an indoor environment until they needed to stop because of symptoms of LSS (or other reasons), or until the time limit of 30 minutes had

been reached. Participants were asked to indicate when they first experienced a change in symptoms. The evaluator followed 1 meter behind the patient, without conversing, with a distance instrument to measure distance and used a stopwatch for timing.

Soft tissue evaluation of lumbar paraspinal muscles. To determine the need for soft tissue mobilization, lumbar paraspinal muscles were palpated for tenderness, spasm, and trigger points.

Core strength evaluation. All patients were assessed for their capacity to effectively recruit the "core stabilizers" using the lower abdominal strength test as described by Sahrmann, which is commonly used in the clinical evaluation of patients with low back pain.[123] This evaluation model is based in part on the notion that the abdominal muscles provide important support for the spine during functional activities and low level muscle activation is needed for many tasks. The Sahrmann protocol aims to assess this level of abdominal muscle activation and contains 5 testing levels, each designed to make it increasingly difficult to maintain a neutral spinal position using the involved core stabilizers. Previous studies have found this a valid and reliable clinical measure of the capacity to isometrically recruit lower abdominal muscles involved in core stabilization.[124]

Lumbar segmental mobility evaluation. Evaluation of spinal segmental mobility included manual application of a posterior to anterior (PA) force on the vertebral spinous process.[125] The amount of motion, or resistance to force, was assessed using categories of hypo-mobile, normal, or hypermobile. Presence, absence, or change in pain resulting from the test was also noted. Studies have generally failed to support the reproducibility of mobility judgments between different examiners[125,126] leading some to suggest that PA

mobility testing has little value as an examination procedure.[125] However, more recent studies have suggested that PA mobility testing may improve decision making when combined with other examination information.[126,127]

Flynn et al[8] reported that a finding of hypo-mobility in the lumbar spine with PA mobility testing, combined with several other historical and physical examination findings, formed a clinical prediction rule that was predictive of a successful reduction in disability with a mobilization or manipulation intervention. A randomized trial by Childs et al[128] validated this prediction rule and its usefulness in predicting which patients with LBP are most likely to improve with mobilization or manipulation. Hicks et al[127] found that a judgment of hypermobility was a factor in a multivariate clinical prediction rule that was predictive of a reduction in disability with a stabilization exercise program. Fritz et al[129] studied the diagnostic accuracy of various findings from the history and physical examination for predicting radiographic lumbar segmental instability and reported that a judgment of hypermobility was predictive of radiographic instability, and that the predictive accuracy of PA mobility judgments were enhanced when combined with other examination findings.

Neurodynamic testing. Neurodynamic testing is designed to examine the neurological structures for adaptive shortening and inflammation of the neural structures. Neurodynamic mobility examination consist of a series of tension tests. The tension tests are designed to apply controlled mechanical and compressive stresses to the dura and other neurological tissues, both centrally and peripherally. It employs a sequential and progressive stretch to the dura until the patient's symptoms are reproduced.[130] Two main

tests were included in this study to evaluate neural tension: the slump test, and the prone knee bending (PKB) test.

The slump test, popularized by Maitland, is a combination of other neuromeningeal tests including the seated SLR, neck flexion, and lumbar slumping. Maitland asserted that the slump test enables the tester to detect adverse nerve root tension caused by spinal stenosis, extra foraminal lateral disc herniation, disc sequestration, nerve root adhesions, and vertebral impingement.[130] The prone knee bending (PKB) test stretches the femoral nerve using hip extension and knee flexion to stretch the nerve termination in the quadriceps muscle, and has been used to indicate the presence of upper lumbar disc herniation and adverse nerve root tension caused by spinal stenosis particularly when hip extension is added.[130]

Measurement points. Measurement of lumbar spine range of motion flexion and extension, hip extension, external and internal rotation ROM, measurement of hip abductor and extensor muscle strength, and self-pace walking test were taken at the beginning of the initial treatment (first visit), after the final treatment visit (twelfth), and 6-week follow up after discharge.

Self-Reporting Measures

McGill Pain Questionnaire. The McGill Pain Questionnaire was administered at the beginning of the initial treatment (first visit), after the final treatment visit (twelfth), and 6-week follow up after discharge. To see actual assessment tool and interpretation of scales, please refer to Appendix F.

Oswestry Disability Questionnaire. Each Subject also completed the ODQ at the beginning of the initial treatment (first visit), after the final treatment visit (twelfth), and

6-week follow up after discharge. To see actual assessment tool and interpretation of scales, please refer to Appendix G.

Interventions

Group 1: Impairment-based exercise group. Patients in Group 1 (EX) received instructions on muscle stretching and strengthening directed at improving overall core and hip strength and flexibility. Tight muscles that promote lumbar extension and hip flexor flexibility were progressively stretched, and weak muscles that promote core stabilization and hip control were strengthened. Exercises for the lumbar spine and the hip were tailored to the assessment findings and progressed within each participant's ability to maintain a stable and minimally painful spine. Therapeutic exercises for core strengthening started with supine posterior pelvic tilt exercise and Sahrman protocol (Appendix H) and progressed based on the protocol and the subjects' limits of pain.

Strengthening exercises for hip abductors and extensors started and progressed based on the grade attained from manual muscle testing. All exercises were performed in each treatment session, twice a week for 6-week. The treating physical therapist provided supervision to maintain good posture and ensure proper technique within the subjects' limits of pain during the exercises. Exercises were progressed from assisted exercise to assist-free to resisted exercises based on progress, strength gained, and pain associated with therapeutic activities. Exercise instruction was provided and reviewed at each session and was part of a progressive, structured home exercise program. All subjects performed the strengthening exercises for 2 sets of 10 repetitions each and hold each position for 5 seconds. All subjects performed the stretching exercise for 5 repetitions each and hold each position for 20 seconds (see Sample in Appendix

L). Subjects were instructed to perform the same exercises once per day during 6-week active treatment and also during 6-week after discharge. Gradual walking and/or stationary cycling program to improve lower extremity conditioning and overall fitness was part of the home exercise program.

Group 2: Manual physical therapy and exercise. Participants in group 2 (EXMT) received an impairment-based exercise program described previously with manual therapy to improve the flexibility of the lumbar spine and to facilitate lumbar inter-segmental mobility. A manual therapy protocol was designed individually for each patient by the treating therapist based on the impairment findings during the initial evaluation. At each session, manual therapy was directed to the lumbar spine. Specific techniques included grade I to III central and lateral posterior-anterior mobilization within limits of pain for the limited segment. Soft tissue mobilization, including lumbar flexion-distraction, manual muscle stretching, and hands-on techniques, were used to break down adhesions, tightness, muscle spasm, and trigger points of paraspinal muscles.

Neurodynamic flossing and stretching for sciatic and/or femoral nerve was done based on neurodynamic evaluation findings. The specific combination of manual therapy techniques used to improve intervertebral motion and to improve hip mobility were at the discretion of the treating therapist based on identified underlying impairments. Treating therapists were instructed to start with soft tissue and joint mobilization and progress to neurodynamic mobility to decrease pain and improve spinal mobility. The dosages of manual therapy were between 15-30 minutes of manual therapy techniques based on the evaluation findings.

All participants in the two groups were evaluated again at time of discharge

following completion of the initial 6-week of treatment by the evaluating therapist. All participants were instructed to continue with their home exercise program throughout the length of the study until the final evaluation at the 6-week post discharge follow up. All participants were allowed to continue with the previously prescribed medications or over-the-counter medications for their symptoms associated with LSS; however, they were advised not to change the dosage of these medications during the study period. All participants were instructed to document their medication usage and any changes throughout the study. No interventional pain management procedures were received by any participant from 6-week before the baseline testing session through the end of the treatment period.

Data Analysis

Descriptive statistics were used to describe participants' demographics and outcome measures including participants' age, gender, and ethnicity. A two-way mixed analysis of variance (ANOVA) was used to assess the impact of the 2 interventions (i.e., EX and EXMT) on each of the previously described measures across three time periods (pretreatment, post treatment, and six-week follow-up). For significant interaction effects, given the presence of only 2 groups, the between-subjects parameter estimates were used. However, for the strong hip side and unrestricted hip side analyses, only the effect of time was evaluated given there was no expectation for a significant interaction, as there was no intervention provided to the strong side. To determine statistical significance, an alpha level of 0.05 was used. Data were analyzed by using the SPSS Version 22 statistical software package (SPSS Inc., Chicago, IL).

For the mixed ANOVA, the data was evaluated for normality (i.e., normally distributed scores), homogeneity of variance, and sphericity of the covariance matrix, given the underlying assumptions of this analytic approach. To assess for data normality, scores of kurtosis and skewness were evaluated using -2 to +2 as acceptable values. Additionally, to assess for violation of assumptions of sphericity and homogeneity of error variances, Mauchly's Test of Sphericity and Levene's Test of Equality of Error Variances were evaluated. When the assumption of sphericity is violated, and observed $\hat{\varepsilon}$ is less than .75, the Greenhouse-Geisser degrees of freedom correction should be used as opposed to the Huynh-Feldt correction, which is more appropriate for observed sphericity values greater than .75. However, there are minimal differences between the Greehouse-Geisser and Huynh-Feldt corrections when observed sphericity values are greater than .75.[139] In the case of violations of the assumption of homogeneity of variance, the effect on the *F* test is significantly decreased when sample sizes are equal, which in the present case was expected to be minimal given the equal groups (n = 20). Pairwise comparisons were conducted using a one-way ANOVA for each treatment group (i.e., EX and EXMT) with post-hoc comparisons testing for differences in observed scores as a function of time within each group.

Chapter Summary

In this chapter, the research design, study protocols, and data analysis were presented. In the next chapter, the results of the study will be presented.

CHAPTER FOUR: RESULTS

Introduction

This chapter presents the results of the research study. It provides a description of the study participants and variables considered throughout the study. A comprehensive description and analysis of the study outcome variables and the effect of the two different treatment protocols for patient with LSS will be presented. Each outcome variable was measured at three different points: baseline, discharge, and 6-weeks follow up.

All consecutive patients reporting to Chicago Rehabilitation Services with diagnosis of lumbar spinal stenosis were recruited and screened for eligibility after they agreed to participate in this study. A total of 70 patients were screened and 53 patients satisfied the inclusion criteria. Of those 53 patients, 8 did not consent to participate in the study and 5 dropped out after consenting to participate. A flow diagram showing subject recruitment and drop outs can be seen in Figure 1. Forty subjects who completed the study protocol through the 6-weeks treatment and 6-weeks of follow up were included in the statistical analysis. Data were collected on 20 subjects for group one (EX group) and 20 subjects for group two (EXMT group).

Descriptive Statistics

Forty individuals were assigned to one of two groups: EX and EXMT. Participants' demographic information is presented in Table 1.

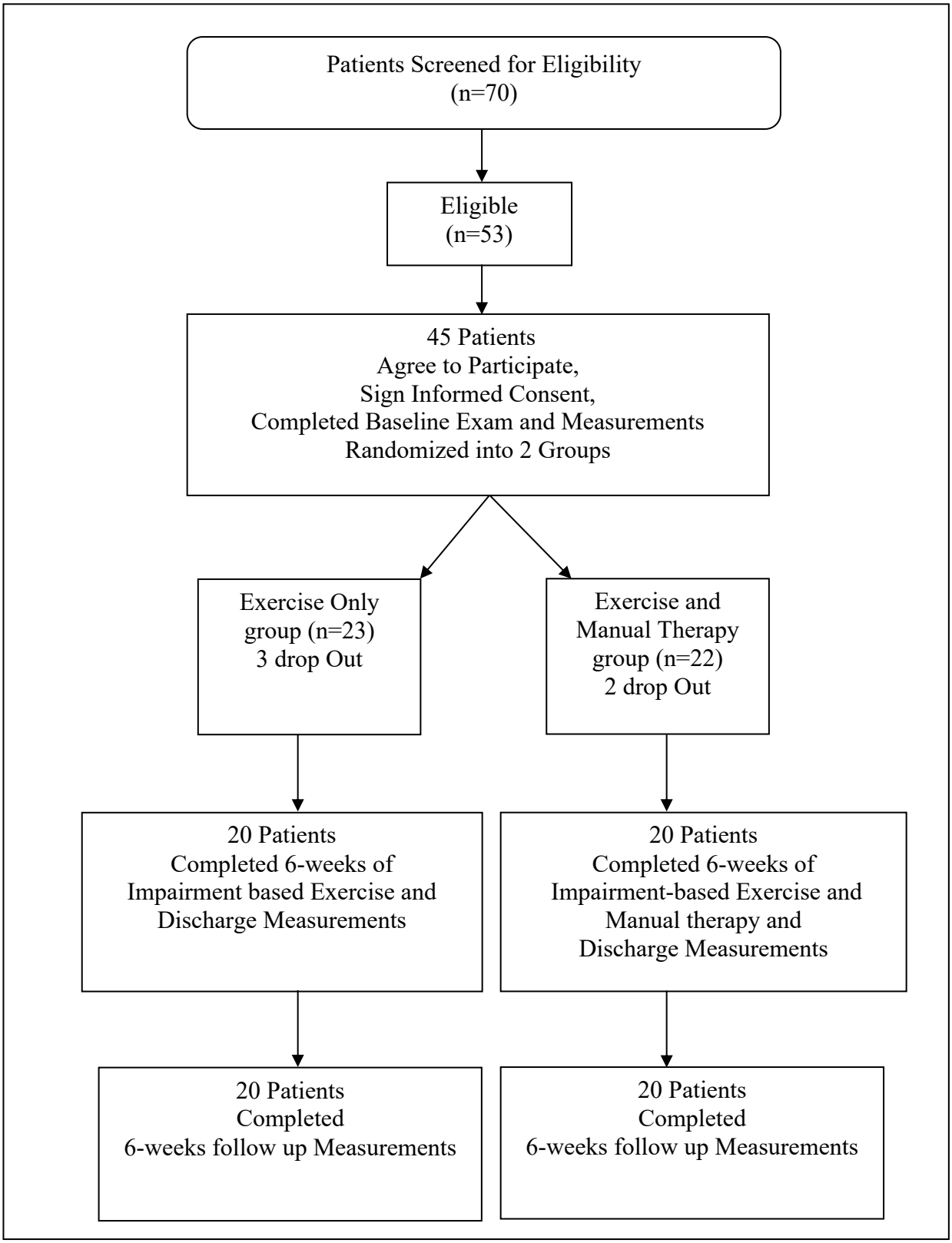

Figure 1. Flow Diagram of Patient Recruitment and Retention

Table 1. Participant Demographic Information

Variable	f (%)
Ethnicity	
Caucasian	31 (77.5%)
African-American	6 (15.0%)
Hispanic	3 (7.5%)
Sex	
Female	23 (57.5%)
Male	17 (42.5%)
	***M* (SD, range)**
Age, mean (SD, range), years	61.53 (5.45, 51-73)
Clinic	
Orland Park	13 (32.5%)
Palos Heights	10 (25%)
Chicago	17 (42.5%)

Study Variables

For the present study, participant outcomes were assessed using 5 variables: (1) self-reported pain using McGill pain questionnaire, (2) self-reported functional disability using Oswestry low back pain disability, (3) lumbar spine flexion and extension range of motion (4) hip extension, internal rotation, and external rotation range of motion, and (5) hip extension and hip abduction muscle strength. Pooled and group means and standard deviations by each time point are presented in Appendix I. In addition, inferential statistics by study dependent variable are found in Appendix J, tests of sphericity for each

variable are found in Appendix K, pairwise comparisons between treatment groups are found in Appendix L, and probed effects of changes over time are found in Appendix M.

McGill Pain Questionnaire

For the MPQ analyses, experimental groups were included as the between-subjects factor, and the MPQ scores were the within-subjects factors. Mauchly's test indicated that the assumption of sphericity was violated, $\chi^2(2) = 71.10$, $p < .001$. For the present case, observed $\hat{\varepsilon} = .54$. Additionally, all Levene's Tests of Equality of Error Variances were nonsignificant $p > .05$.

A group main effect was not observed, $F(1,38) = 3.51$, $p = .069$, $\eta_p^2 = .45$, which does not indicate a significant statistical difference between the two groups regardless of time. The detailed ANOVA output is listed in Table 2. There was a statistically significant main effect of time, $F(1.08, 41.00) = 552.29$, $p < .001$, $\eta_p^2 = .94$, which indicated a significant change in MPQ scores across the three assessment points. Pairwise comparisons indicated significant statistical differences between baseline ($M = 26.40$, $SD = 8.10$) and discharge ($M = 7.85$, $SD = 4.75$), $F(1,38) = 633.89$, $p < .001$, $\eta_p^2 = .94$. However, no difference was noted between discharge ($M = 7.85$, $SD = 4.75$) and 6-week follow-up ($M = 7.68$, $SD = 4.65$) in perceived pain, $F(1,38) = 0.77$, $p = .385$, $\eta_p^2 = .02$. This suggests that there was a significant decrease in perceived pain from baseline to discharge for both groups and the change was sustained until the 6-week follow-up.

Pairwise comparisons at each time showed no difference at baseline between the EXMT ($M = 25.70$, $SD = 7.96$) and EX ($M = 27.10$, $SD = 8.38$) groups, $B = 1.40$, $SE = 2.59$, $t = 0.54$, $p = .591$, $\eta_p^2 = .01$. However, there was a significant difference between

EXMT (M = 6.00, SD = 4.52) and EX (M = 9.70, SD = 4.32) groups at discharge, B = 3.70, SE = 1.40, $t(38) = 2.65$, p = .012, η_p^2 = .16, with patients in the EXMT reporting less pain in comparison to the EX group. This pattern of results was also observed at 6-weeks follow-up, B = 4.45, SE = 1.31, $t(38) = 3.41$, p = .002, η_p^2 = .23, with EXMT (M = 5.45, SD = 3.87) demonstrating less pain in comparison to the EX group (M = 9.90, SD = 4.36). This support the hypothesis that EXMT would demonstrate more improvements in subjective reports of pain in comparison to the EX group.

Table 2. McGill Pain Questionnaire Inferential Statistics

	Source	SS	df	MS	F	p value	η_p^2
Between	Group	101.34	1	101.34	3.51	.069	0.09
	Error	1097.86	38	29.89			
Within	Time	9263.45	1.08[a]	8585.48	552.29	<.001	0.94
	Time x Group	50.17	1.08[a]	46.82	3.01	.087	0.07
	Error	637.37	41[a]	15.46			

[a] Greenhouse-Geisser degrees of freedom correction

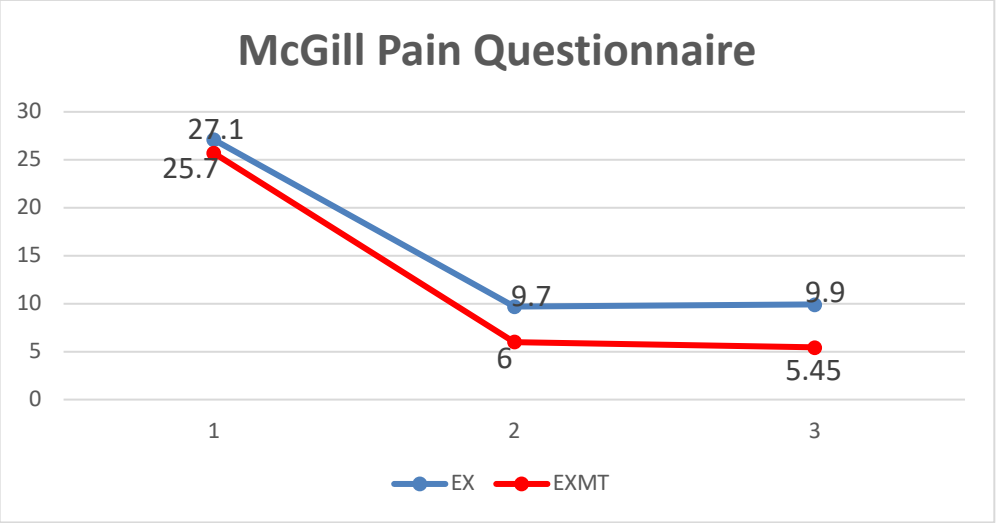

Figure 2. Means of McGill Pain Questionnaire at each assessment point for both treatment groups.

Oswestry Low Back Pain Disability Questionnaire

For the Oswestry Low Back Pain Disability Questionnaire (ODQ) analyses, similar to the previous analysis, these variables violated the sphericity assumption, $\chi^2(2) = 37.71$, $p < .001$ (see Table 3). The observed $\hat{\varepsilon} = .61$, which indicates the Greenhouse-Geisser correction is appropriate. Additionally, all Levene's Tests of Equality of Error Variances were nonsignificant $p > .05$.

A group main effect was not observed, $F(1,38) = 2.34$, $p = .134$, $\eta_p^2 = .06$, which does not indicate a significant statistical difference between the two groups regardless of time. The detailed ANOVA output is listed in Table 3. There was a statistically significant main effect of time, $F(1.22, 46.37) = 1440.20$, $p < .001$, $\eta_p^2 = .97$, which indicates a significant change in ODQ scores across the three assessment points.

Within each treatment group, there were notable changes observed over time. More specifically, for the EXMT group, there was significant statistical difference in perceived disability from baseline ($M = 44.90$, $SD = 10.13$) to discharge ($M = 14.50$, $SD = 8.23$), $F(1, 19) = 1108.53$, $p < .001$, $\eta_p^2 = .98$, which suggests decreased disability from baseline to discharge. A significant statistical difference in perceived disability was also observed from discharge ($M = 14.50$, $SD = 8.23$) to 6-weeks follow-up ($M = 13.50$, $SD = 7.32$), $F(1, 19) = 6.33$, $p = .021$, $\eta_p^2 = .25$. Similarly, for the EX group, there was a statistical significant decrease in perceived disability from baseline ($M = 44.80$, $SD = 10.93$) to discharge ($M = 20.80$, $SD = 8.69$), $F(1, 19) = 594.78$, $p < .001$, $\eta_p^2 = .97$. However, there was not a statistically significant difference in ODQ between discharge

(M = 20.80, SD = 8.69) and 6-weeks follow-up (M = 20.10, SD = 8.75), $F(1, 19) = 3.44$, $p = .079$, $\eta_p^2 = .15$.

Further pairwise comparisons at each time showed that, there was no difference at baseline between the EXMT (M = 44.90, SD = 10.13) and EX (M = 44.80, SD = 10.93) groups, B = -.10, SE = 3.33, t = -0.03, p = .976. However, there was a significant difference between EXMT (M = 14.50, SD = 8.23) and EX (M = 20.80, SD = 8.69) groups at discharge, B = 6.30, SE = 2.68, $t(38) = 2.35$, p = .024, η_p^2 = .127, with patients in the EXMT reporting less disability in comparison to patients in the EX group. This pattern of results was also observed at 6-weeks follow-up, B = 6.60, SE = 2.55, $t(38) = 2.59$, p = .014, η_p^2 = .150, with EXMT (M = 13.50, SD = 7.32) demonstrating less perceived disability in comparison to the EX group (M = 20.10, SD = 8.63).

Table 3. Oswestry Low Back Pain Disability Questionnaire Inferential Statistics

	Source	SS	df	MS	F	p value	η_p^2
Between	Group	182.04	1	182.04	2.34	.134	0.06
	Error	2958.22	38	77.85			
Within	Time	20364.87	1.22[a]	16689.84	1440.20	<.001	0.97
	Time x Group	286.47	1.22[a]	234.77	20.26	<.001	0.35
	Error	537.33	46.37[a]	11.59			

[a] Greenhouse-Geisser degrees of freedom correction

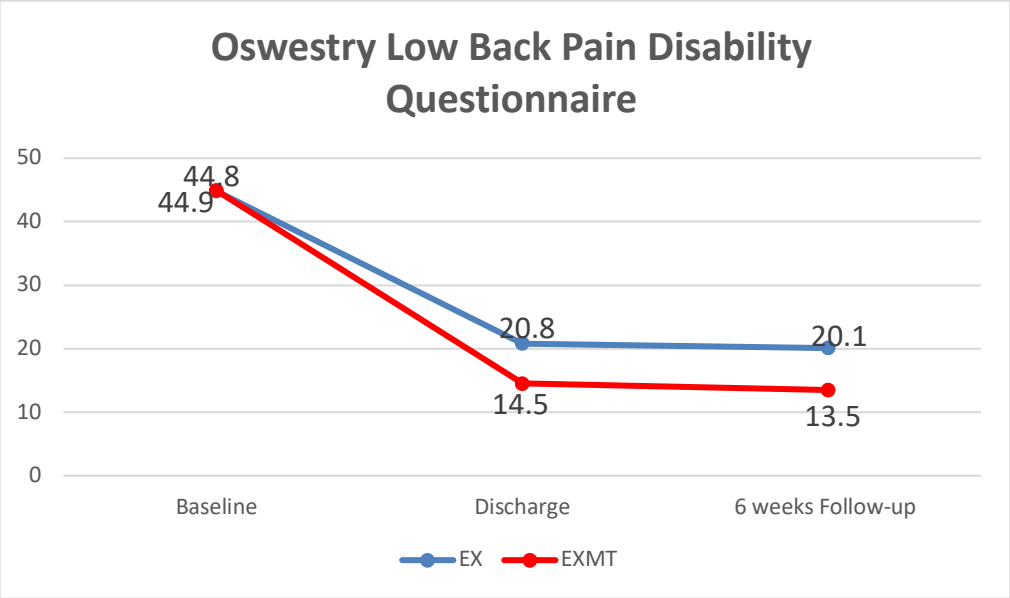

Figure 3. Means of Oswestry Low Back Pain Disability Questionnaire at each assessment point for both treatment groups.

Distance Walked (SPWT)

Similar to the previous analysis, the variables for the distance walking analyses violated the sphericity assumption, $\chi^2(2) = 90.96$, $p < .001$. The observed $\hat{\varepsilon} = .52$, which indicates the Greenhouse-Geisser correction is appropriate. Additionally, all Levene's Tests of Equality of Error Variances were nonsignificant $p > .05$.

A group main effect was observed, $F(1,38) = 20.13$, $p < .001$, $\eta_p^2 = .35$, which indicates a significant statistical difference between the two groups regardless of time. The detailed ANOVA output is listed in Table 4. This result supports the hypothesis that the EXMT would demonstrate greater improvements in walking distance in comparison to the EX group. Pairwise comparisons at each time showed that, there was no difference at baseline between the EXMT ($M = 799.95$, $SD = 529.40$) and EX ($M = 561.00$, $SD = 527.48$) groups, $B = -238.95$, $SE = 167.11$, $t(38) = -1.43$, $p = .161$, $\eta_p^2 = .05$. However,

there was a significant difference between EXMT (M = 2615.65, SD = 1313.68) and EX (M = 1008.05, SD = 539.23) groups at discharge, B = -1,607.60, SE = 317.53, $t(38)$ = -5.06, $p < .001$, $\eta_p^2 = .40$, with the EXMT walking distance greater in comparison to the EX group. This pattern of results was observed at 6-weeks follow-up, B = -1708.85 SE = 347.01, $t(38)$ = -4.93, $p < .001$, $\eta_p^2 = .39$, as there was a statistically significant difference in walking distance between the EXMT (M = 2836.40, SD = 1428.57) and the EX group (M = 1127.55, SD = 606.16). A significant main effect of time was also observed, $F(1.11, 42.19) = 100.57$, $p < .001$, $\eta_p^2 = .73$, which indicates a significant increase in distance walked. For the EX group, there was a significant difference between baseline (M = 561.00, SD = 527.48) and discharge (M = 1008.05, SD = 539.23), $F(1, 19) = 86.87$, $p < .001$, $\eta_p^2 = .82$, on distance walked during the SPWT protocol, which indicates notable improvement in distance walked from baseline to discharge. Additionally, there was a significant difference between discharge (M = 1008.05, SD = 539.23) and 6-weeks follow up (M = 1127.55, SD = 606.16), $F(1, 19) = 46.72$, $p < .001$, $\eta_p^2 = .71$. For the EXMT group, there was a significant difference between baseline (M = 799.95, SD = 529.4) and discharge (M = 2615.65, SD = 1313.68), $F(1, 19) = 64.71$, $p < .001$, $\eta_p^2 = .77$, on distance walked during the SPWT protocol, which indicates notable improvement in distance walked from baseline to discharge. In addition, there was a statistically significant difference in walking distance between discharge (M = 2615.65, SD = 1313.68) and 6-weeks follow-up (M = 2836.40, SD = 1428.57), $F(1, 19) = 25.13$, $p < .001$, $\eta_p^2 = .57$.

Table 4. Distance Walked (SPWT) Inferential Statistics

	Source	SS	df	MS	F	p value	η_p^2
Between	Group	14045410.16	1	14045410.18	20.13	<.001	0.35
	Error	26518132.31	38	697845.59			
Within	Time	40038055.43	1.05[a]	38324946.21	100.57	<.001	0.73
	Time x Group	13480201.31	1.05[a]	12903423.63	33.86	<.001	0.47
	Error	15127987.2	42.19[a]	381071.20			

[a] Greenhouse-Geisser degrees of freedom correction

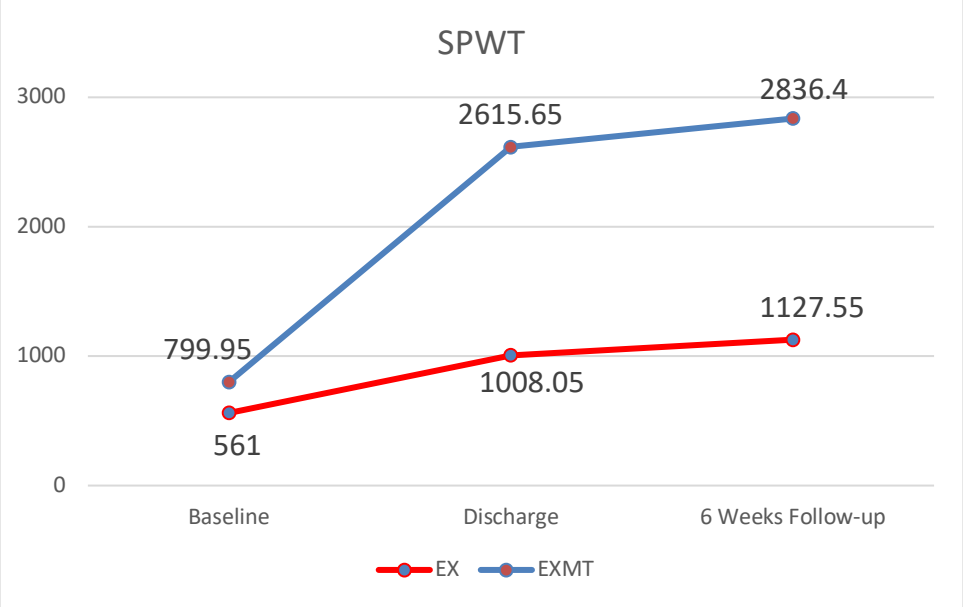

Figure 4. Means of Distance Walked (SPWT) at each assessment point for both treatment groups.

Lumbar Spine Flexion Range of Motion

For the lumbar spine flexion range of motion (ROM, flexion) analyses, these variables violated the sphericity assumption, $\chi^2(2) = 32.59$, $p < .001$. The observed $\hat{\varepsilon} =$

.63, which indicates the Greenhouse-Geisser correction is appropriate. Additionally, all Levene's Tests of Equality of Error Variances were nonsignificant $p > .05$.

A group main effect was not observed, $F(1,38) = 3.67$, $p = .063$, $\eta_p^2 = .09$, which does not indicate a significant statistical difference between the two groups regardless of time. The detail ANOVA output is listed in Table 5. There was a statistically significant main effect of time, $F(1.70, 64.56) = 170.60$, $p < .001$, $\eta_p^2 = .82$, which indicates a significant change in lumbar spine flexion ROM scores across the three assessment points regardless of treatment administered. For the EX group, there was a significant difference between baseline ($M = 28.05$, $SD = 9.90$) and discharge ($M = 36.70$, $SD = 9.69$), $F(1, 19) = 57.03$, $p < .001$, $\eta_p^2 = .75$, which indicates notable improvement in lumbar spine ROM (flexion) from baseline to discharge. However, there was not a significant difference in ROM between discharge ($M = 36.70$, $SD = 9.69$) and 6-weeks follow-up ($M = 37.80$, $SD = 8.87$), $F(1, 19) = 1.41$, $p = .249$, $\eta_p^2 = .07$.

For the EXMT group, there was a significant difference between baseline ($M = 31.55$, $SD = 8.41$) and discharge ($M = 43.55$, $SD = 8.43$), $F(1, 19) = 198.81$, $p < .001$, $\eta_p^2 = .91$, which indicates notable improvement in lumbar spine ROM (flexion) from baseline to discharge. However, there was not a significant difference between discharge ($M = 43.55$, $SD = 8.43$) and 6-weeks follow-up ($M = 43.45$, $SD = 9.17$), $F(1, 19) = .02$, $p = .902$, $\eta_p^2 = .00$, suggesting that there was not a significant increase in lumbar spine ROM (flexion) between discharge and 6-week follow-up.

Table 5. Lumbar Spine Flexion ROM Inferential Statistics

	Source	SS	df	MS	F	p value	η_p^2
Between	Group	282.7	1	282.7	3.67	.063	0.09
	Error	2923.77	38	76.94			
Within	Time	2980.62	1.70[a]	1490.31	170.60	<.001	0.82
	Time x Group	56.12	1.70[a]	33.03	3.21	.055	0.08
	Error	663.93	64.56[a]	20.38			

[a] Greenhouse-Geisser degrees of freedom correction

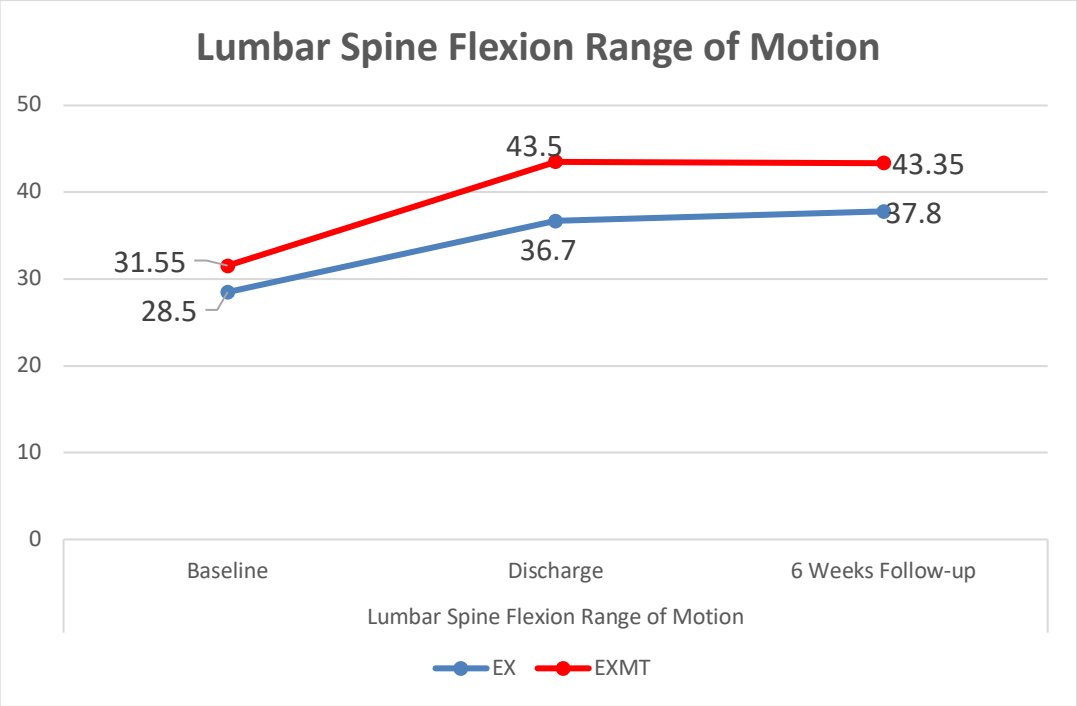

Figure 5. Means of Lumbar Spine Flexion Range of Motion at each assessment point for both treatment groups.

Lumbar Spine Extension Range of Motion

For the lumbar spine extension range of motion analyses, these variables violated the sphericity assumption, $\chi^2(2) = 28.06$, $p < .001$. The observed $\hat{\varepsilon} = .65$, which

indicates the Greenhouse-Geisser correction is appropriate. Additionally, all Levene's Tests of Equality of Error Variances were non-significant $p > .05$.

A group main effect was observed, $F(1,38) = 19$, $p < .001$, $\eta_p^2 = .33$, which indicates a significant statistical difference between the two groups regardless of time. The detail ANOVA output is listed in Table 6. This supports the hypothesis that the EXMT would demonstrate greater improvements in walking distance in comparison to the EX group. Regarding differences between groups over time, there was a significant difference at baseline between the EXMT ($M = 9.40$, $SD = 2.80$) and EX ($M = 7.70$, $SD = 2.43$) groups, $B = -1.70$, $SE = 0.83$, $t(38) = -2.05$, $p = .047$, $\eta_p^2 = .10$. Additionally, there was a significant difference between EXMT ($M = 16.95$, $SD = 3.27$), and EX ($M = 12.40$, $SD = 2.50$) groups at discharge, $B = -4.55$, $SE = 0.92$, $t(38) = -4.95$, $p < .001$, $\eta_p^2 = .39$. This pattern of results was observed at 6-weeks follow up, $B = -4.35$, $SE = 0.87$, $t\ (38) = -4.99$, $p < .001$, $\eta_p^2 = .40$, with EXMT group scored higher ($M = 16.65$, $SD = 3.15$) in comparison to the EX group ($M = 12.30$, $SD = 2.30$).

Additionally, there was a statistically significant main effect of time, $F(1.3, 49.62) = 300.37$, $p < .001$, $\eta_p^2 = .89$, which indicates a significant change in lumbar spine extension ROM scores for both groups across the three assessment points.

The EXMT group demonstrated significant improvement in lumbar spine extension ROM from baseline ($M = 9.40$, $SD = 2.80$) to discharge ($M = 16.95$, $SD = 3.27$), $F(1, 19) = 274.36$, $p < .001$, $\eta_p^2 = .94$. However, the difference between discharge ($M = 16.95$, $SD = 3.27$) to 6-weeks follow up ($M = 16.65$, $SD = 3.15$) was not statistically significant, $F(1, 19) = 1.41$, $p = .249$, $\eta_p^2 = .07$. Similarly, for the EX group there was a

significant change from baseline (M = 7.70, SD = 2.43) to discharge (M = 12.40, SD = 2.50), $F(1, 19) = 85.48$, $p < .001$, $\eta_p^2 = .82$. However, there was no difference in lumbar spine ROM (extension) between discharge (M = 12.40, SD = 2.50) and 6-weeks follow up (M = 12.30, SD = 2.30), $F(1, 19) = 0.39$, $p = .541$, $\eta_p^2 = .02$.

Table 6. Lumbar Spine Extension ROM Inferential Statistics

	Source	SS	df	MS	F	p value	η_p^2
Between	Group	124.84	1	124.84	19.00	<.001	0.33
	Error	249.64	38	6.57			
Within	Time	968.82	1.31[a]	741.9	300.37	<.001	0.89
	Time x Group	50.62	1.31[a]	38.76	15.69	<.001	0.29
	Error	122.57	49.62[a]	2.47			

[a] Greenhouse-Geisser degrees of freedom correction

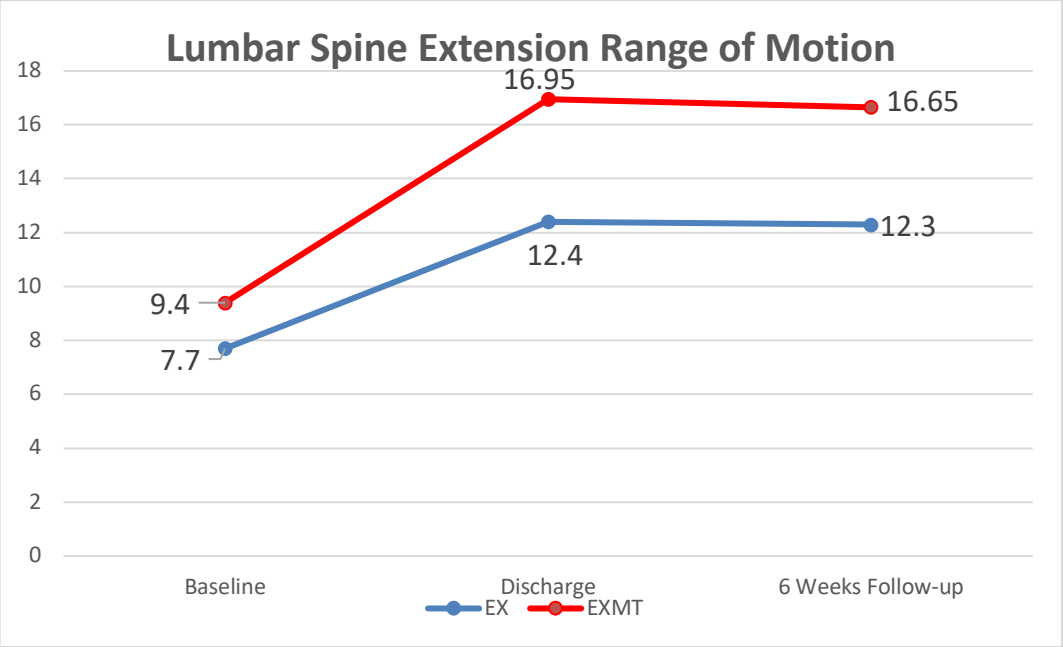

Figure 6. Means of Lumbar Spine Extension Range of Motion at each assessment point for both treatment groups.

Hip Extensor Muscle Strength

For the hip extensor muscle strength analyses, these variables did not violate the sphericity assumption, $\chi^2(2) = 1.11$, $p = .573$, which does not indicate that a sphericity adjustment is required. Additionally, all Levene's Tests of Equality of Error Variances were nonsignificant $p > .05$.

A group main effect was observed, $F(1,38) = 8.75$, $p = .005$, $\eta_p^2 = .19$, which indicates a significant statistical difference between the two groups regardless of time. The detail ANOVA output is listed in Table 7. Pairwise comparisons at each time showed that, there was a statistically significant difference at baseline between the EXMT (M = 5.50, SD = 1.05) and EX (M = 4.85, SD = 0.88) groups, B = -0.65, SE = .31, t (38) = -2.13 p = .040, η_p^2 = .05. There was also a significant difference between EXMT (M = 8.40, SD = 0.82) and EX (M = 7.40, SD = 1.14) groups at discharge, B = -1.00, SE = 0.32, t(38) = -3.18, p = .003, η_p^2 = .21, with the EXMT demonstrating greater hip extensor muscle strength in comparison to the EX group. This pattern of results was also observed at 6-weeks follow-up, B = -0.45 SE = 0.19, t(38) = -2.44, p = .020, η_p^2 = .14, as there was a statistically significant difference in hip extensor muscle strength between the EXMT (M = 9.25, SD = 0.64) and the EX group (M = 8.80, SD = 0.52).

A main effect of time, $F(2, 76) = 535.04$, $p < .001$, $\eta_p^2 = .93$, was observed, suggesting that there were statistical significant difference within the groups over time regardless of treatment administered. For the EX group, there was a significant difference between baseline (M = 4.85, SD = 0.88) and discharge (M = 7.40, SD = 1.14), $F(1, 19)$ = 276.08, $p < .001$, η_p^2 = .94, which indicates notable improvement in hip extensor muscle

strength between baseline and discharge. There was a significant difference in hip extensor strength between discharge (M = 7.40, SD = 1.14) and 6-weeks follow up (M = 8.8, SD = 0.52), $F(1, 19) = 50.32$, $p < .001$, $\eta_p^2 = .73$.

For the EXMT group, there was a significant difference between baseline (M = 5.50, SD = 1.05) and discharge (M = 8.40, SD = 0.82), $F(1, 19) = 326.10$, $p < .001$, $\eta_p^2 = .95$, which indicates notable improvement in hip extensor muscle strength between baseline and discharge measurements. There was a significant difference between discharge (M = 8.40, SD = 0.82) and 6-weeks follow up (M = 9.30, SD = 0.66), $F(1, 19) = 26.02$, $p < .001$, $\eta_p^2 = .58$, suggesting that there was a significant increase in hip extensor muscle strength between discharge and 6-week follow-up.

Table 7. Hip Extensor Muscle Strength Inferential Statistics

	Source	SS	df	MS	F	p value	η_p^2
Between	Group	4.90	1	4.90	8.75	.005	0.19
	Error	21.28	38	0.56			
Within	Time	315.52	2	156.76	535.04	<.001	0.93
	Time x Group	1.55	2	0.78	2.65	.078	0.07
	Error	22.27	76	0.29			

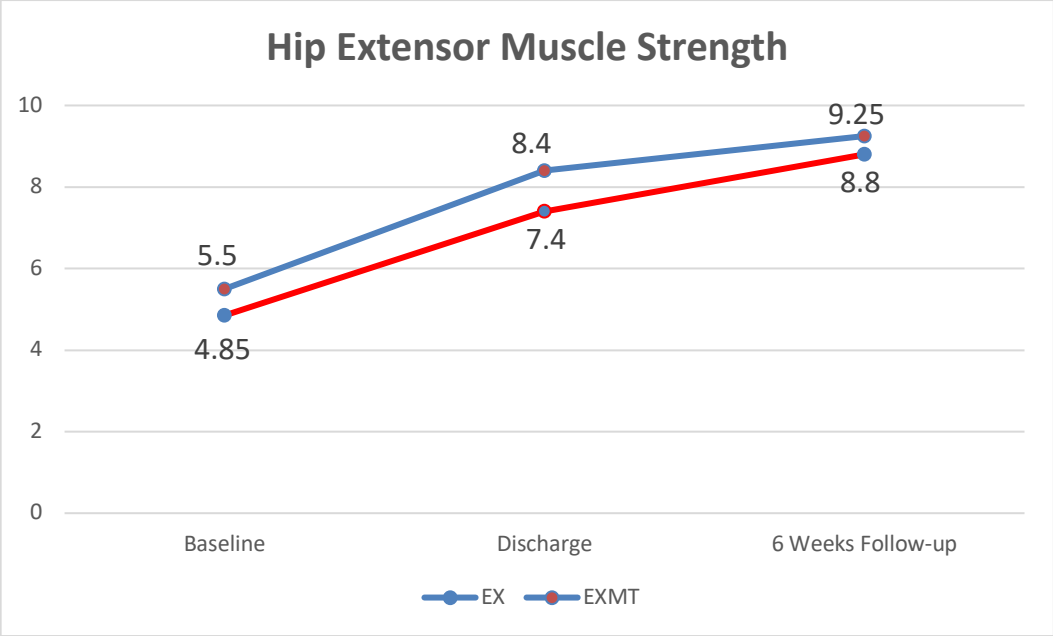

Figure 7. Means of Hip Muscle Strength (Extension) at each assessment point for both treatment groups

Hip Abductor Muscle Strength

For hip abductor muscle strength analyses, these variables violated the sphericity assumption, $\chi^2(2) = 7.46$, $p = .024$. The observed $\hat{\varepsilon} = .85$, which indicates the Greenhouse-Geisser correction is appropriate. Additionally, all Levene's Tests of Equality of Error Variances were nonsignificant $p > .05$.

A group main effect was observed, $F(1,38) = 8.16$, $p = .007$, $\eta_p^2 = .18$, which indicates a significant statistical difference between the two groups regardless of time. The detail ANOVA output is listed in Table 8. There was no significant difference at baseline between the EXMT ($M = 5.50$, $SD = 0.94$) and EX ($M = 5.00$, $SD = 1.17$) groups, $B = -0.55$, $SE = 0.34$, $t(38) = -1.64$, $p = .110$, $\eta_p^2 = .07$. There was a significant difference between EXMT ($M = 8.45$, $SD = 0.60$), and EX ($M = 7.95$, $SD = 0.83$) groups

at discharge, B = -0.50, SE = 0.23, $t(38)$ = -2.19, p = .035, η_p^2 = .11. This pattern of results was observed at 6-weeks follow up, B = -0.60, SE = 0.20, t (38) = -3.08, p = .004, η_p^2 = .20, with EXMT group scored higher (M = 9.30, SD = 0.66) in comparison to the EX group (M = 8.70, SD = 0.57).

Additionally, a main effect of time was observed, suggesting that there were significant improvements in the overall sample over time regardless of treatment group, $F(1.69, 64.26)$ = 333.98, p < .001, η_p^2 = .90. For the EX group, there was a significant difference between baseline (M = 5.00, SD = 1.17) and discharge (M = 7.95, SD = 0.83), $F(1, 19)$ = 114.23, p < .001, η_p^2 = .86, which indicates notable improvement in hip abductor muscle strength from baseline to discharge. There was a significant difference between discharge (M = 7.95, SD = 0.83) and 6-weeks follow up (M = 8.70, SD = 0.57), $F(1, 19)$ = 15.55, p = .001, η_p^2 = .45. For the EXMT group, there was a significant difference between baseline (M = 5.50, SD = 0.94) and discharge (M = 8.45, SD = 0.60), $F(1, 19)$ = 202.27, p < .001, η_p^2 = .91. There was also a significant difference between discharge (M = 8.45, SD = 0.60) and 6-weeks follow up (M = 9.30, SD = 0.66), $F(1, 19)$ = 41.92, p < .001, η_p^2 = .69.

Table 8. Hip Abductor Muscle Strength Inferential Statistics

	Source	SS	df	MS	F	p value	η_p^2
Between	Group	3.03	1	3.03	8.16	.007	0.18
	Error	14.08	38	0.37			
Within	Time	307.62	1.69[a]	181.9	333.98	<.001	0.90
	Time x Group	0.05	1.69[a]	0.05	0.03	.924	0.00
	Error	35	64.26[a]	0.55			

[a] Greenhouse-Geisser degrees of freedom correction

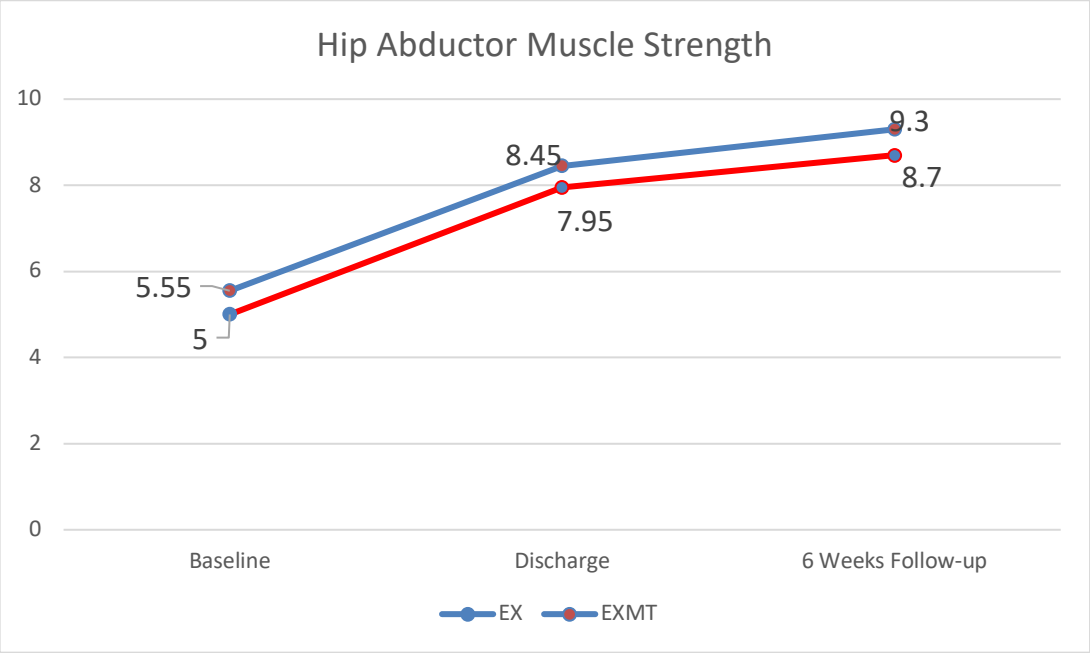

Figure 8. Means of Side Hip Abduction Muscle Strength at each assessment point for both treatment groups.

Hip External Rotation Range of Motion

For hip external rotation ROM analyses, these variables violated the sphericity assumption, $\chi^2(2) = 8.90$, $p = .012$. The observed $\hat{\varepsilon} = .82$, which indicates the Greenhouse-Geisser correction is appropriate. Additionally, all Levene's Tests of Equality of Error Variances were nonsignificant $p > .05$.

A group main effect was observed, $F(1,38) = 124.00$, $p < .001$, $\eta_p^2 = .76$, which indicates a significant statistical difference between the two groups regardless of time. The detail ANOVA output is listed in Table 9. Further analysis showed there was a significant difference at baseline with the EXMT ($M = 24.90$, $SD = 2.38$) group demonstrating greater ROM in comparison to the EX ($M = 20.55$, $SE = 2.14$) group, B = -

4.35, SE = 0.72, t(38) = -6.08, p < .001, η_p^2 = .49. Additionally, there was a significant difference between EXMT (M = 36.95, SD = 1.96), and EX (M = 30.95, SD = 1.97) groups at discharge, B = -6.00, SE = 0.62, t(38) = -9.62, p < .001, η_p^2 = .71, with the EXMT demonstrating greater ROM in comparison to the EX group. This difference was observed at 6-weeks follow up, B = -5.95, SE = 0.55, t(38) = -10.92, p < .001, η_p^2 = .76, between the EXMT (M = 37.65, SD = 1.39) and the EX groups (M = 31.70, SD = 2.00) with the EXMT demonstrating greater ROM in comparison to the EX group.

There was a statistically significant main effect of time, F(1.65, 82.62) = 741.63, p < .001, η_p^2 = .95, which indicates a significant change in hip external rotation ROM scores across the three assessment points. Within each treatment group, there were notable changes observed over time. For the EXMT group, a significant statistical difference between baseline (M = 24.90, SD = 2.38) and discharge (M = 36.95, SD = 1.96), F(1, 19) = 535.96, p < .001, η_p^2 = .97, was observed suggesting significant improvement of hip external ROM from baseline to discharge. However, the difference between discharge (M = 36.95, SD = 1.96) to 6-weeks follow up (M = 37.65, SD = 1.39) was not statistically significant, F(1, 19) = 2.32, p = .144, η_p^2 = .11. For the EX group, there was a significant statistical between baseline (M = 20.55, SD = 2.14) and discharge (M = 30.95, SD = 1.97), F(1, 19) = 452.65, p < .001, η_p^2 = .96. A significant difference was also observed between discharge (M = 30.95, SD = 1.97) and 6-weeks follow up (M = 31.70, SD = 2.00), F(1, 19) = 8.30, p = .010, η_p^2 = .30. Taken together, these results suggest that there were significant improvements of hip external rotation ROM for both

the EXMT and EX groups, with ongoing improvements between discharge and 6-weeks follow up only observed for the EX group.

This suggests that overall, there was a significant statistical difference between both groups and that the EXMT group demonstrated more overall improvements hip external rotation ROM at discharge and 6-weeks follow up.

Table 9. Hip External Rotation ROM Inferential Statistics

	Source	SS	df	MS	F	*p* value	η_p^2
Between	Group	295.21	1	295.21	124.00	<.001	0.76
	Error	90.47	38	2.38			
Within	Time	3591.05	1.65[a]	2179.2	741.63	<.001	0.95
	Time x Group	17.62	1.65[a]	10.69	3.64	.040	0.09
	Error	184	62.62[a]	2.94			

[a] Greenhouse-Geisser degrees of freedom correction

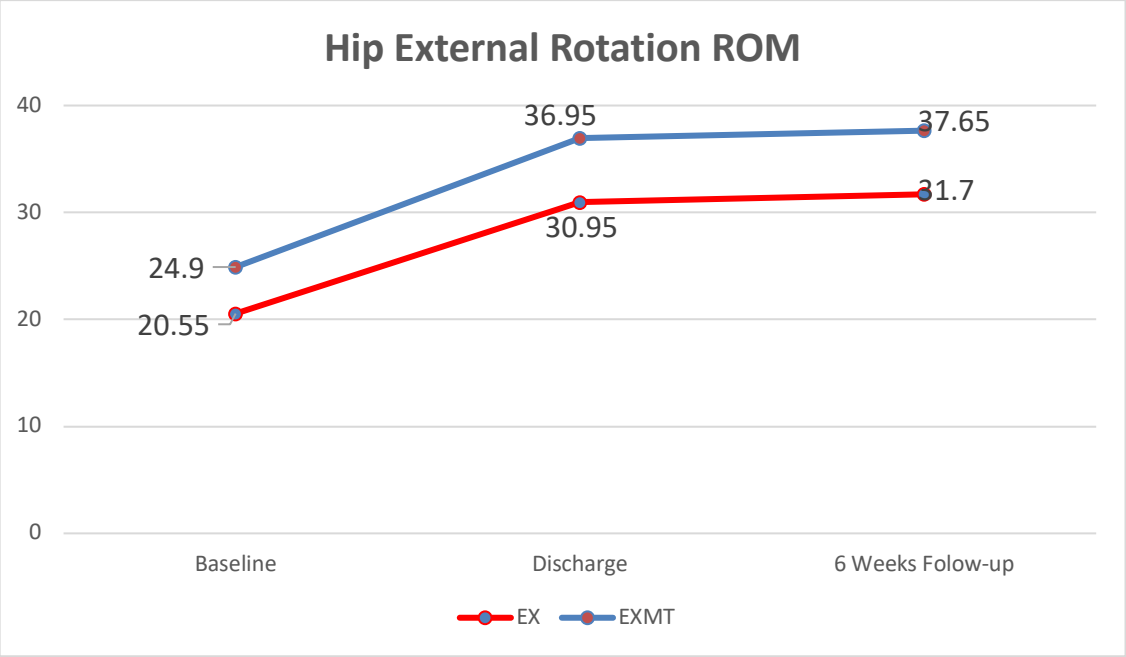

Figure 9. Means of Hip External Rotation ROM at each assessment point for both treatment groups.

Hip Internal Rotation Range of Motion

For hip internal rotation ROM analyses, this variable did not violate the sphericity assumption, $\chi^2(2) = 5.03$, $p = .081$, which does not indicate the Greenhouse-Geisser correction is recommended. Additionally, all Levene's Tests of Equality of Error Variances were nonsignificant $p > .05$.

A group main effect was observed, $F(1,38) = 79.71$, $p < .001$, $\eta_p^2 = .68$, which indicates a significant statistical difference between the two groups regardless of time. The detail ANOVA output is listed in Table 10. Regarding differences between groups there was a significant difference at baseline with the EXMT ($M = 23.70$, $SD = 2.81$) group demonstrating greater ROM in comparison to the EX ($M = 19.70$, $SD = 2.68$) group, $B = -4.00$, $SE = 0.89$, $t(38) = -4.61$, $p < .001$, $\eta_p^2 = .36$. Additionally, there was a significant difference between EXMT ($M = 36.60$, $SD = 2.44$), and EX ($M = 31.30$, $SD = 1.66$) groups at discharge, $B = -5.30$, $SE = 0.66$, $t(38) = -8.04$, $p < .001$, $\eta_p^2 = .63$, with the EXMT demonstrating greater improvement of hip internal rotation ROM in comparison to the EX group. This difference persisted at 6-weeks follow up, $B = -6.15$, $SE = 0.64$, $t(38) = -9.69$, $p < .001$, $\eta_p^2 = .71$, between the EXMT ($M = 37.45$, $SD = 1.90$) and the EX groups ($M = 31.30$, $SD = 2.11$). This suggests that the EXMT group showed greater improvement at discharge and 6-week follow-up regarding hip internal rotation ROM in comparison to the EX group.

There was a statistically significant main effect of time, $F(2, 76) = 699.37$, $p < .001$, $\eta_p^2 = .95$, which indicates a significant change in hip external rotation ROM scores

across the three assessment points. Within each treatment group, there were notable changes observed over time. For the EXMT group, a significant difference between baseline (M = 23.70, SD = 2.81) and discharge (M = 36.60, SD = 2.44), $F(1, 19)$ = 674.16, $p < .001$, $\eta_p^2 = .97$, was observed suggesting significant improvement between baseline and discharge. Additionally, the difference between discharge (M = 36.60, SD = 2.44) to 6-weeks follow up (M = 37.45, SD = 1.90) was statistically significant, $F(1, 19)$ = 6.16, $p = .023$, $\eta_p^2 = .25$. For the EX group, there was a significant difference between baseline (M = 19.70, SD = 2.68) and discharge (M = 31.30, SD = 1.66), $F(1, 19)$ = 276.69, $p < .001$, $\eta_p^2 = .94$. There was not a statistically significant difference between discharge (M = 31.30, SD = 1.66) and 6-weeks follow up (M = 31.30, SD = 2.11), $F(1, 19)$ = 0.00, $p = 1.000$, $\eta_p^2 = .00$. Taken together, these results suggest that there were significant improvements in hip internal rotation ROM for both the EXMT and EX groups from baseline to discharge, with statistically significant change observed between discharge and 6-weeks follow up for only the EXMT group.

Table 10. Hip Internal Rotation ROM Inferential Statistics

	Source	SS	df	MS	F	p value	η_p^2
Between	Group	265.23	1	265.23	79.71	<.001	0.68
	Error	126.44	38	3.33			
Within	Time	4145.32	2	2072.66	699.37	<.001	0.95
	Time x Group	23.45	2	11.73	3.96	.023	0.09
	Error	225.23	76	2.96			

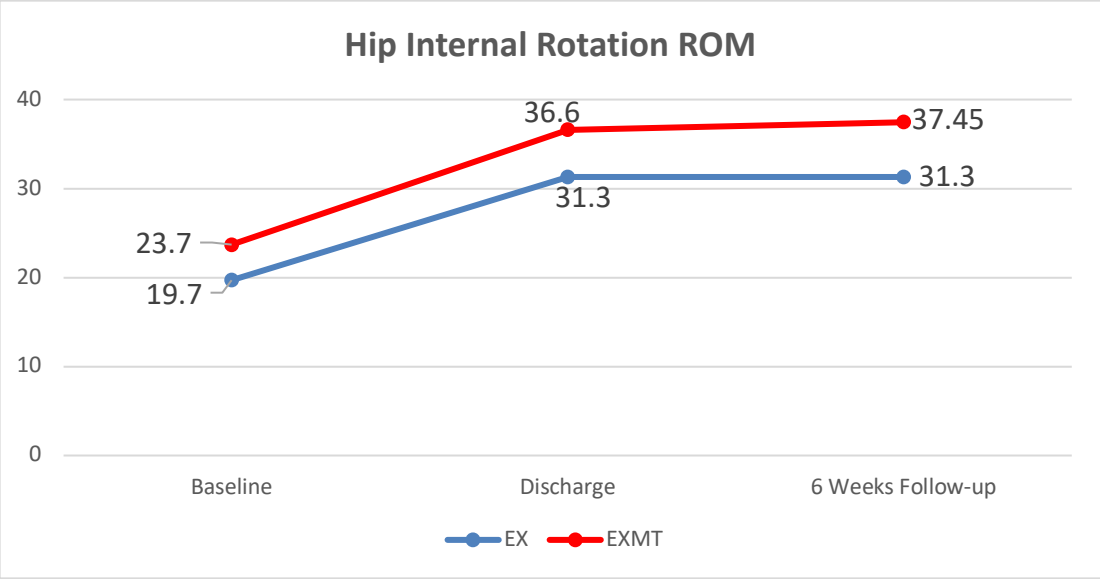

Figure 10. Means of Hip Internal Rotation ROM at each assessment point for both treatment groups.

Hip Extension Range of Motion

For hip extension ROM analyses, these variables violated the sphericity assumption, $\chi^2(2) = 6.45$, $p = .040$. The observed $\hat{\varepsilon} = .86$, which indicates the Greenhouse-Geisser correction is appropriate. Additionally, all Levene's Tests of Equality of Error Variances were nonsignificant $p > .05$.

A group main effect was observed, $F(1,38) = 38.7$, $p < .001$, $\eta_p^2 = .51$, which indicates a significant statistical difference between the two groups regardless of time. The detail ANOVA output is listed in Table 11. In regard to differences over time, there was a significant difference at baseline between the EXMT ($M = 9.50$, $SD = 1.96$) group and the EX ($M = 7.70$, $SD = 1.49$) group, $B = -1.80$, $SE = 0.55$, $t(38) = -3.27$, $p = .002$, $\eta_p^2 = .22$. Additionally, there was a significant difference between EXMT ($M = 15.20$, $SD = 1.61$), and EX ($M = 11.65$, $SD = 1.66$) groups at discharge, $B = -3.55$, $SE = 0.52$, $t(38) = -6.86$, $p < .001$, $\eta_p^2 = .55$, with the EXMT demonstrating greater functional hip extension

ROM in comparison to the EX group. This difference persisted at 6-weeks follow up, B = -2.20, SE = 0.45, $t(38)$ = -4.92, $p < .001$, $\eta_p^2 = .39$, between the EXMT (M = 14.90, SD = 1.33) and the EX groups (M = 12.70, SD = 1.49)..

There was a statistically significant main effect of time, $F(1.72, 65.53) = 240.37$, $p < .001$, $\eta_p^2 = .86$, which indicates a significant change in hip extension ROM scores across the three assessment points. Within each treatment group, there were notable changes of hip extension ROM observed over time. In regards to the EXMT group, a significant change from baseline (M = 9.50, SD = 1.96) to discharge (M = 15.20, SD = 1.61), $F(1, 19) = 150.20$, $p < .001$, $\eta_p^2 = .89$, was observed suggesting significant improvement from baseline to discharge. However, the difference between discharge (M = 15.20, SD = 1.61) to 6-weeks follow up (M = 14.90, SD = 1.33) was not statistically significant, $F(1, 19) = 0.81$, $p = .379$, $\eta_p^2 = .04$. For the EX group, there was a significant change from baseline (M = 7.70, SD = 1.49) to discharge (M = 11.65, SD = 1.66), $F(1, 19) = 237.63$, $p < .001$, $\eta_p^2 = .93$, and between discharge (M = 11.65, SD = 1.66) and 6-weeks follow up (M = 12.70, SD = 1.49), $F(1, 19) = 15.55$, $p = .001$, $\eta_p^2 = .45$. These results suggest that there were significant improvements in hip extension ROM for both the EXMT and EX groups from baseline to discharge, with significant improvements, though very small, from discharge to 6-weeks follow up observed only for the EX group.

Table 11. Hip Extension ROM Inferential Statistics

	Source	SS	df	MS	F	p value	η_p^2
Between	Group	63.34	1	63.34	38.70	<.001	0.51
	Error	62.19	38	1.64			
Within	Time	672.82	1.72[a]	390.19	240.37	<.001	0.86

Time x Group	16.82	1.72[a]	9.75	6.01	0.006	0.14
Error	106.37	65.53[a]	1.62			

[a] Greenhouse-Geisser degrees of freedom correction

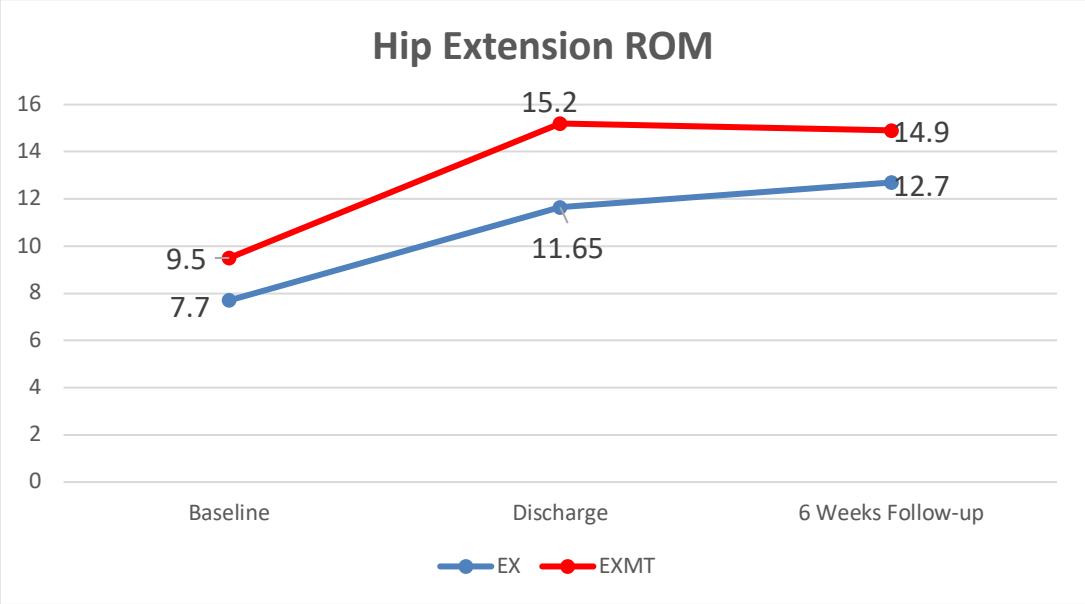

Figure 11. Means of Hip Extension ROM at each assessment point for both treatment groups.

Chapter Summary

This study provides some evidence of improved treatment response to the EXMT treatment in comparison to the EX treatment. There was significant statistical difference between the two treatment groups for the following variables: self-paced walking test, hip abductor and extensor muscle strength, lumbar extension ROM, and hip external, internal rotation and extension ROM. Further analysis revealed that there was no significant baseline difference between both treatment groups for SWPT and hip abductors muscle strength. These results are in agreement with the study hypotheses. However, there were significant baseline differences between both groups for lumbar spine flexion ROM,

lumbar spine extension ROM, hip extensors muscle strength, hip extension, and hip external and internal rotation ROM.

Contrary to study hypotheses, there was no statistically significant difference between EXMT and EX groups in reported pain measured by McGill pain questionnaire, perceived disability measured by ODQ and lumber spine flexion ROM. which suggested no differential effect of treatment between both treatment groups.

Overall there was statistically significant improvements observed over time in both treatment groups for all variables. In the next chapter, the meaning of these results and a comparison of these results to other similar studies will be discussed.

CHAPTER FIVE: DISCUSSION

Introduction

The results of this study indicated that in patients with lumbar spinal stenosis (LSS), 6-week of clinical impairment-based approach of therapeutic exercises targeted to normalize common physical impairments was effective in reducing pain, improving lumbar and hip mobility, and improving function. The addition of an impairment-based manual therapy approach to the lumbar spine and hip joints added additional benefits to therapeutic exercises for improving some of the short-term clinical and functional outcomes in patients with LSS. Although there was a statistically significant difference between the two treatment groups for the variables of lumbar spine extension ROM, hip extension ROM, the self-paced walking test, and strength of the hip abductors, extensors, external rotators, and internal rotators, further analysis revealed that there was significant baseline difference between both groups in lumbar spine flexion ROM, lumbar spine extension ROM, hip extensors muscle strength, hip extension, external and internal rotation ROM which might contribute partially to the statistical differences between both groups. Thus, the research hypothesis that an intervention for patients with lumbar spinal stenosis that combines an impairment-based manual therapy approach and therapeutic exercises to the lumbar spine and hips would be more effective in improving lumbar spine and hip ROM, increase hip abductors and extensors strength, and reduce pain and disability, was not fully supported.

The group differences observed could be the impact of mobilization/manipulation in itself or a positive influence of specific impairment based manual therapy approach

used. The manual therapy protocol that was used was an effective approach for joints that lack adequate mobility and range of motion. These limitations can cause discomfort, pain, and an alteration in function, posture, and movement. The manual physical therapy approach used helped to restore mobility to these stiff joints, reduce muscle tension, and return the patient to more natural movement without pain. Enhancing the effectiveness of specific exercise protocol by adding impairment based manual therapy approach as a part of the intervention also contributed to the outcomes. Thus, performing specific exercises following impairment-based manual therapy, may have helped in obtaining better outcomes and improving function.

Findings

Pain

Both groups demonstrated substantial clinically and statistically significant reductions in pain. However, the reduction in pain in the EXMT group was more than in the EX group. The EXMT group showed a decrease in pain score by 19.5 points between baseline measurement and discharge measurement versus 17.4 points for the EX group. The EXMT group showed a further decrease of the pain score by .05 at the 6-week follow up versus an increase by 0.2 for the EX group.

The mean initial MPQ pain score for both groups was 26.40/78, which was associated with moderate pain; the mean score after 6-week of treatment was 7.85/78 which was associated with mild pain; and the mean final score taken 6-week later was 7.68/78. This is a decline of almost 19 points (24%). Findings of this study are consistent with those from previous studies on patients with low back pain (LBP).[76,131]

In the current study, there were no statistical differences in perceived pain between the two groups over time; however, there was a significant decrease in perceived pain in both groups from baseline to initial follow-up. In addition, there was no observed difference between discharge and the 6-week follow up in perceived pain between both groups, which suggests that patients in both groups sustained improvement of perceived pain over a 6-week period after the end of the treatment. Although, there was no statistical difference between both groups at baseline testing, there was a statistically significant difference between both groups at discharge, with patients in the EXMT reporting less pain in comparison to the EX group. This pattern of results was also observed at the 6-week follow-up, with EXMT demonstrating less pain in comparison to the EX group. This supports the hypothesis that EXMT would demonstrate greater improvement in subjective reports of pain in comparison to the EX group.

The effect of exercises on pain and disability was reported by Fritz et al.[13] These authors conducted a case report of two elderly patients diagnosed with degenerative LSS to evaluate the effect of flexion exercise on pain and disability. The authors noted an improvement in pain and disability of 90 and 84% for patients 1 and 2, respectively, and concluded that both patients improved significantly in their ambulation and lower extremity range-of-motion and strength.[13]

This finding of the current study is supported by Goren et al,[73] who evaluated the effect of therapeutic exercises alone and in combination with a single physical agent (ultrasound) in patients with LSS. They used therapeutic exercises (stretching and strengthening exercises for lumbar, abdominal, and leg muscles and low-intensity cycling exercises), and the results revealed that leg pain scores (measured by a visual analogue

scale) were significantly lower in both treatment groups; however, they did not find any statistically significant difference between groups ($p > 0.05$).

Our findings relative to pain are also in accordance with results reported by Whitman et al[5] who compared two physical therapy programs for patients with LSS. They found that the program consisting of manipulation of the spine and lower extremity joints, manual stretching, muscle strengthening exercises, and progressive body-weight supported treadmill walking program showed greater rates of improvement than the same program without manipulation. All of the outcomes favored the manual therapy at 6 weeks and 1 year except NPRS for lower extremity symptoms from baseline to 1 year; however, these differences were not statistically significant.[5] In the same context, Whitman et al[7] described outcomes of three patients with LSS managed with manual physical therapy, strengthening, and stretching exercises. All patients reported substantial improvements in pain from baseline to discharge after 10 visits and at the18-month follow-up.

Another study that corroborates the findings of the current study was done by Murphy et al[11] who conducted a prospective cohort study to determine the effects of distraction manipulation and neural mobilization on pain in 55 patients with LSS. The authors used the Three Level Numerical Rating Scale to measure changes in pain, the Roland-Morris Disability Questionnaire (RMDQ) to measure changes in function and disability, and a self-reported improvement survey. All patients were seen 2-3 times a week for 3 weeks, and the mean duration of follow-up was 16.5 months. Pain intensity improved by 30% post-treatment in comparison to 24% pain improvement in the current study. The authors concluded that the combination of distraction manipulation and neural

mobilization was a safe and effective approach to manage symptoms for patients with LSS.[10]

The findings of the current study are also supported by Pua et al.[65] The authors compared the effects of two different exercise interventions for patients with LSS using a randomized controlled design. Both groups also performed exercise therapy (lumbar traction and flexion exercises), in addition to treadmill walking with body-weight support or cycling. Modified Oswestry Low Back Pain Disability Questionnaire (MODQ) and RMDQ were used to assess disability, and VAS was used for pain severity. Pain severity was 2mm (95% CI –5 to 10) on a 100-visual analogue scale. The authors found that both groups improved; however, there were no statistical differences between the two groups.[43]

Functional Disability

Consistent with the reduction in self-reported levels of back pain, participants in this study also reported a significant reduction in self-reported levels of disability as measured by the ODQ scores. The mean initial ODQ score for participants in this study was 44.9. The score represents a moderate level of disability.[132] Following 6 weeks of treatment, the mean ODQ score for the participants in this study was 17.7, which represents a minimal level of disability.[132] The change of 27.2 points is substantially greater than the minimal clinically important difference (MCID) for the ODQ in patients with chronic back pain.[105,133-137]

The results of the current study indicated that there is a significant difference between the two groups over time. For the EXMT group, there was a significant decrease in perceived disability from baseline to discharge, and from discharge to the 6-week

follow up. Similarly, for the EX group, there was a significant decrease in perceived disability from baseline to discharge, but not a significant change from discharge to the 6-week follow up. In regards to pairwise comparisons at each time, there was no difference between both groups at baseline. However, there was a significant difference between EXMT and EX groups at discharge, with the EXMT demonstrating a greater decrease in perceived disability in comparison to the EX group. This pattern of results continued at the 6-week follow up with EXMT demonstrating a greater decrease in perceived disability in comparison to EX group. This suggests that the EXMT group showed greater improvement and possibly improved treatment efficacy regarding perceived disability in comparison to the EX group at both follow up assessments.

These findings are supported in the study by Goren et al.[73] The authors reported a decrease in ODQ scores and increased ambulation scores in patients with lumbar spinal stenosis, which reflects the effectiveness of therapeutic exercises in treating pain and disability.[73] In addition, Whitman et al[5] reported reductions in disability measured by the MODQ (mean difference 5.03 for flexion group, 7.14 for manual group, and mean difference between groups was 2.10). Another study by Whitman et al[7] reported a case series of three patients with LSS who received 10 treatment sessions. The interventions included supine iliopsoas stretch, prone hip posterior to anterior mobilization, prone rectus femoris stretch, lumbar rotation mobilization/manipulation in neutral, caudal glide to hip joint in flexion, and unilateral posterior to anterior lumbar spine mobilization. In agreement with the current study, all 3 patients demonstrated substantial positive changes that were sustained up to 18 months. OSW score improvement ranged from 66% to 95% of subject baseline scores by discharge and 33% to 82% at 18 months.

In another study by Franca et al,[138] the effects of two exercise programs (segmental stabilization exercises [SSEs] and stretching of trunk and hamstrings muscles) were compared on functional disability, pain, and activation of the transversus abdominis muscle (TrA) for patients with chronic LBP. Severity of pain (using a visual analog scale and the McGill Pain Questionnaire), functional disability (as measured by the Oswestry Low Back Pain Disability Questionnaire), and TrA muscle activation capacity (using the Pressure Biofeedback Unit, or PBU) were compared as a function of the intervention. Authors reported that both treatments were effective in relieving pain and improving disability ($p < .001$). Those in the SSE group had significantly higher gains for all variables. Similar to the purpose of our study, the Franca et al study highlighted the importance of exercises as an intervention for management of chronic low pain resulting from LSS.

Distance Walked (SPWT)

Patients with LSS often experience significant functional limitations in walking as well as other associated disabilities.[139] Both the distance and intensity of walking ability are significantly lower in patients with LSS when compared to patients with hip and knee osteoarthritis.[140] Additionally, individuals with LSS have a risk of falling that is comparable to patients with severe knee osteoarthritis.[141,142] Ambulation is a key component of overall health, independent living, and fall prevention. The ability to walk is essential for most activities of daily living and has been identified as one of the most important outcomes in LSS.[143]

The distance walking analyses in this study demonstrated a significant statistical difference between the two groups regardless of time. Additionally, pairwise comparisons

at each time showed that there was no difference at baseline between the EXMT and EX groups. However, there was a significant difference between EXMT and EX groups at discharge, with the EXMT subjects walking distances greater than the EX group subjects. This pattern of results was also observed at the 6-week follow-up, as there was a statistically significant difference in walking distance between the EXMT and the EX group. This result supports the hypothesis that the EXMT would demonstrate greater improvements in walking distance in comparison to the EX group.

A significant main effect of time was also observed, which indicates a significant increase in distance walked within each group. For both the EX and EXMT groups, there was a statistically significant difference between baseline, discharge, and at the 6-week follow up on distance walked during the SPWT protocol, which indicates notable improvement in distance walked from baseline to discharge to follow up. Additionally, there was a significant difference between discharge and the 6-week follow up.

A limitation in walking resulting from neurogenic claudication is considered to be one of the main criteria of disability in patients with LSS.[144] The results of the current study are in agreement with some of the published evidence about the effectiveness of non-surgical interventions to improve walking ability among individuals with LSS. Other studies are inconsistent in their conclusions about the effectiveness of interventions for walking limitations. In some studies, improved walking ability with a supervised exercise program was found to be no better than no treatment or other combined treatments. Three physical therapy clinical trials[145-147] used validated measures of walking ability to determine if exercise had an effect on walking abilities. In the end, these studies showed no improvement in walking capacity.[6,148,149]

Some studies have shown that subjective measures of pain and disability do not correlate with walking performance,[150,151] while in a study examining predictors of walking in neurogenic claudication, one of the strongest predictors of both performance and capacity was pain,[151-153] which is in full agreement with the results of the current study.

Lumbar Spine Mobility

The current study showed significant improvement in lumbar extension ROM from baseline to discharge; however, there was a non-significant change from discharge to the 6-week follow up for both groups. For the EX group, there was a significant change from baseline to follow-up; however, there was no difference in lumbar spine extension ROM between discharge and the 6-week follow up. Maintaining sustained improvement in comparison to the EX group, the EXMT group showed greater improvement and possibly improved treatment efficacy for the lumbar spine extension ROM in comparison to the EX group at both follow-up assessments.

There was notable improvement in lumbar flexion ROM over time regardless of treatment group. A significant difference was found between baseline and follow-up; however, the difference between discharge and the 6-week follow up was not significant. The results suggest that there was an overall improvement in the sample from baseline to discharge, but no change in lumbar ROM between discharge and the 6-week follow-up, regardless of intervention type, which means that both groups sustained the improvement they had gained in lumbar flexion ROM.

The significant change in lumbar mobility reported in this current study is supported by several other studies, one of which is by Aure et al.[77] Aure et al compared

the effects of manual therapy to exercise therapy in sick-listed patients with chronic low back pain. A total of 49 patients were randomized to either manual therapy (spinal manipulation, specific mobilization, and stretching techniques) or to exercise therapy (strengthening, stretching, mobilization, coordination, and stabilization exercises for the abdominal, back, pelvic, and lower limb muscles). Pain intensity, functional disability (ODQ), general health (Dartmouth COOP function charts), and spinal range of motion (Schober test) were measured before and immediately after the treatment period. Spinal range of motion was measured only at the pre-and post-treatment sessions. Significant improvements were found both within ($p < 0.01$) and between groups, with the MT group showing significantly larger improvement. The mean improvement in the MT group was 31 mm (95% CI: 26–36) and in the ET group 9 mm (95% CI: 6–12; $p < 0.01$).[62] Also, Shum et al[154] measured the immediate effects of postero-anterior mobilization on back pain and the associated biomechanical changes in the lumbar spine. Grade III postero-anterior mobilizations (three cycles of 60 seconds) were applied at the L4 level on participants with low back pain (n = 19) and on healthy participants (n = 20). The researchers found there were significant increases in the active flexion and extension range of motion after mobilization in participants with LBP ($p < .05$).[123]

Konstantinou et al[155] provided results that do not agree with the results of the current study, although the author did not specify the cause of back pain. They evaluated the effect of flexion mobilizations with movement techniques (MWMs) on spinal range of motion and pain in patients with low back pain, using a double inclinometer to measure lumbar ROM. Using a crossover, double-blinded, placebo-controlled study design, 26 individuals with low back pain on lumbar flexion, who were thought to be

appropriate for treatment with MWMs, were included. Participants received an MWM intervention and a placebo intervention in a randomized order. The MWMs produced statistically significant, but small immediate spinal mobility increases when compared with the placebo group. The mean spinal range of motion increased significantly with the MWM intervention as compared with the placebo (true flexion: MWMs 49.2 degrees [SD 16.4], placebo 45.3 degrees [SD 14.1], P = .005; total flexion: MWMs 76.7 degrees [SD 22.4], placebo 69.7 degrees [SD 21.5], P = .005). This improvement may have been attributed to the immediate reassessment after intervention, along with targeting the specific restricted plane of movement.[124] These results are in agreement with the results of the current study, as there was significant change in lumbar spine flexion ROM scores across the three assessment points regardless of treatment administered. For the EX group, there was a significant increase from between baseline (M = 28.05, SD = 9.90) to discharge (M = 36.70, SD = 9.69), and for the EXMT group, there was a significant increase from baseline (M = 31.55, SD = 8.41) to discharge (M = 43.55, SD = 8.43). The increase of lumbar flexion ROM was sustained at the 6-week follow up for both groups.

Although research controversy exists about the effectiveness of interventions that focus on impairments, the results of our study suggest that addressing specific impairments such as muscle tightness, muscles weakness, poor endurance, and decreased mobility through a comprehensive treatment program may be beneficial for individuals who suffer from LSS. Recent clinical practice guidelines[156] and systematic reviews[157,158] for the management of patients with LSS have reported that a combination of manipulation/mobilization and exercise is more effective for reducing back pain and disability than manipulation and mobilization alone. The studies referenced in these

guidelines and reviews were trials primarily involving patients with acute back pain. Similarly, in the current study involving patients with LSS, the group receiving exercise and manipulation (EXMT) performed better on posttest measures of mobility, pain level, and disability than the exercise-only group (EX).

Hip Mobility

In this study, there were significant improvements of hip extension, external rotation, and internal rotation ROM of the limited side for both the EXMT and EX groups, with sustained improvements between discharge and the 6-week follow up assessment. In addition to that, the EXMT group showed greater improvement and possibly improved treatment efficacy at post-treatment and at the 6-week follow-up in hip ROM as compared to the EX group.

The relation between limited hip mobility and low back pain dysfunction and impairments has been identified in current research.[84,94,159,160] The existing research evidence suggests that altered hip and spine mobility may contribute to the development of low back pain, as it may alter the mechanics of lumbar spine movement.[117,161] Several studies supported a positive response to interventions targeting the hip in patients with low back pain and restricted hip mobility.[143,144,162-164] Some other studies demonstrated successful incorporation of interventions targeting the hip into a more comprehensive treatment program for patients with LSS.[165] The research in this area is still developing.

The results of the current study support the positive effect of interventions targeting identified hip impairments in patients with LSS. The current study suggests that mobilization procedures can be used to improve hip mobility and reduce pain and disability in patients with LSS.

Hip Muscle Strength

This study revealed that for strength of the hip extensors and abductors on the weak side, there was a main effect of group, suggesting overall mean differences between the two groups regardless of time, with the EXMT group demonstrating greater improvement of weak hip abductor muscle strength in comparison to the EX group. These results are in agreement with a study conducted by Kendall et al[166] that compared the efficacy of two exercise programs in reducing pain and disability for individuals with non-specific low back pain, and that examined the underlying mechanical factors related to pain and disability for individuals with non-specific low back pain. Eighty participants were recruited from 11 community-based general medical practices and randomized into 2 groups completing either a lumbo-pelvic motor control or a combined lumbo-pelvic motor control and progressive hip strengthening exercise therapy program.[136] Hip strength (force dynamometer) and two-dimensional frontal plane biomechanics were measured during the static Trendelenburg test and while walking. All outcomes were measured at baseline and at a 6-week follow-up. The between-group comparisons revealed significant differences in both right ($z = -2.57$, $p = 0.001$) and left ($t = -1.83$, $p = 0.003$) hip internal rotation strength measures with a greater increase in strength occurring within the group of hip strength in right ($t = 4.17$, $p = 0.002$) and left ($t = 3.27$, $p = 0.003$) hip extension, right hip external rotation ($t = 4.65$, $p = 0.0001$), and right hip internal rotation ($t = 4.52$, $p = 0.0001$).[136]

In a cross-sectional study by Arab et al,[167] 300 participants with and without LBP were categorized in three groups: LBP with ITB tightness (n = 100); LBP without ITB tightness (n = 100); and no LBP (n = 100). Hip abductor muscle strength was measured

in all participants. There was a significant difference in hip abductor strength between the 3 groups ($p < 0.001$). Post-hoc analysis showed no significant difference in hip abductor muscle strength between the LBP participants with and without iliotibial band (ITB) tightness ($p = 0.59$). However, participants with no LBP had significantly stronger hip abductor muscle strength compared to participants with LBP with ITB tightness ($p < 0.001$) and those with LBP without ITB tightness ($p < 0.001$).[137]

Our study showed that the increase of hip ROM and muscle strength could have an effect on decreasing pain and ODI scores in patients with LLS. However, the effect of hip-musculature strengthening on LLS is an area that requires further research to determine whether increased hip strength and ROM leads to decreases in pain and improvements in function.

Statistical Power Analysis

The null hypothesis was not rejected for between-group differences in the McGill Pain Questionnaire, Oswestry Low Back Pain Disability Questionnaire, and lumbar spine flexion ROM variables. A series of statistical power analyses were conducted to assess whether we committed a Type II error. This analysis indicated that the observed statistical power in the study was large for specific effects and lower for other effects (see Table 12). Pain measured with the McGill Pain Questionnaire, the Oswestry Low Back Pain Disability Questionnaire, and lumbar spine flexion ROM had committed Type II errors.

Table 12. Power Analysis by Dependent Variable (N = 40)

Dependent Variable	Observed Power (1-β)
McGill Pain Questionnaire	0.45
Oswestry Low Back Pain Disability Questionnaire	0.32
Lumbar spine flexion ROM	.46

Effects of an Impairment-Based Approach

Applying combined treatment techniques based on impairments/dysfunction can be referred to as *multimodal care*. There is evidence to suggest that manual therapy, in addition to exercise therapy, produces greater results compared to using exercise only. Niemisto et al[168] conducted a study that supported the multimodal care approach. They concluded that combination treatment including manual therapy with stabilizing training and patient orientation was more effective in reducing pain and disability than a consultation group. Similarly, Aure et al[77] reported that manual therapy combined with general and specific exercises (5 general exercises for the spine, abdomen, and lower limbs; and 6 specific and localized exercises for spinal segments and the pelvic girdle) showed significantly greater improvement than exercise alone, and this improvement in both groups was reflected in short-term measures and maintained in follow-up after 1 year.

Another interpretation that can be made is that interventions addressing hip mobility and strength deficits used in the current study were exceptionally helpful interventions in decreasing pain, improving mobility, and decreasing disability. This impairment-based approach is supported by Reiman et al[84] who recommended that

clinicians consider a regional interdependence model for the examination and treatment of LBP. For example, the researchers studied the link between impairments at the hip and LBP. They claimed that decreased hip ROM and strength might contribute to pain in the lumbar area. Based on this relationship, attention should be paid to the hip joint and its surrounding soft tissue, and interventions should be applied based on the impairments identified. In addition, a relation was noticed between limited hip internal rotation on one side versus external rotation on the other side; patients with limited hip internal rotation on one side showed limited hip external rotation on the other side. Another point of interest was that weakness was noted in hip extensors and abductor muscle groups of the symptomatic lower extremity in patients with LSS, which is in agreement with Fairbank and Pynsent.[69] These findings are in agreement with limited evidence that support treating the hip when LBP is present.[84,169] Cibulka[169] described the case of a 35-year-old male with unilateral LBP diagnosed as sacroiliac dysfunction. The subject was found to have hip-ER asymmetry that was treated with an impairment-based stretching and strengthening program aimed at the hip, as well as the low back. Results indicated a 38% reduction in disability as measured by the Oswestry Disability Index, which was maintained at 1-year follow-up. Whitman et al[7] examined the effect of manual therapy and exercise applied to the lumbar spine, hip, and lower extremity in patients with lumbar spinal stenosis in a case series, as well as a in a randomized controlled trial.[5] In both studies, impairment-based manual therapy treatments of the hips and lumbar spine were applied with accompanying home exercises. Outcomes indicated positive functional improvements at both the short- and long-term follow-ups.

Overall, the results of this current study provide evidence that impairment-based therapeutic exercise instructed to and implemented by participants to the lower back and hip, in additional to a manual therapy approach, was beneficial for patients with LSS.

Clinical Implications of the Study

This study provides evidence that adding manual therapy to an impairment-based approach is effective in improving some of the symptoms and function among patients with LSS. Published systematic reviews have demonstrated marginal treatment effect across the diverse group of patients with low back pain.[141,142] Published research has demonstrated that spinal manual therapy is effective for subgroups of patients, and as a component of a comprehensive treatment plan, rather than in isolation. Whitman et al[5,7] demonstrated that for patients with clinical and imaging findings consistent with central lumbar spinal stenosis, a comprehensive treatment plan including thrust and non-thrust mobilization/manipulation directed at the lumbopelvic region is effective at decreasing pain and disability. Murphy et al[11] published a prospective cohort study of 57 consecutive patients with central, lateral, or combined central and lateral lumbar spinal stenosis. Patients were treated with lumbar thrust manipulation, nerve mobilization procedures, and exercise. The mean improvement in disability, as measured by the Roland-Morris Disability Questionnaire, was 5.1 points from baseline to discharge, and 5.2 points from baseline to long term follow-up, satisfying the criteria for a minimally clinical important difference. Pain at worst was also reduced by a mean of 3.1 points. In a recent systematic review based on the Whitman trial and several lower quality studies, Reiman et al[84] recommends manual therapy techniques, including thrust and non-thrust mobilization/manipulation to the lumbopelvic region, for patients with lumbar spinal

stenosis. The findings of this study and previously published research provide the rationale to conduct future studies to test the manual therapy impairment-based approach for lumbar stenosis. Developing and testing novel nonsurgical approaches to improve outcomes in lumbar stenosis is important given its increasing prevalence and high morbidity.

The findings from this study also provide evidence that the exercise strategies recommended in the *Back Pain Clinical Practice Guideline*[24] are beneficial to patients with chronic back pain in reducing pain and disability and improving back mobility, muscle endurance, and movement coordination. The findings are consistent with the emerging data that active therapeutic approaches such as exercises, consistently have superior outcomes when compared to passive therapeutic approaches such as application of physical modalities or manipulation in the management of spinal pain. The positive outcomes associated with interventions using an active approach and incorporating exercises is also consistent with the recommended management of patients with chronic low back pain who have related generalized pain. These guidelines are subject to ongoing reviews and updates to address advances in the peer-reviewed scientific literature. Dissemination and publication of this study, along with similar research or systematic reviews on the management of patients with LSS, may result in the development of a distinct category that contains the clinical findings, measures, and intervention strategies for patients with LSS, following the precedent established by the low back pain clinical practice guidelines.

Limitations of the Study

In this study, steps were taken to account for non-normality of results; however, there were notable statistical violations of normality within the data that may have led to biased results. Thus, results should be interpreted with caution. Additionally, there were statistically significant effects that were relatively small in value when considering the proportion of variance explained, such as in the case of the strong hip extension muscle strength results. While multiple comparisons were made in this study, which inflated the experimenter-wise error, a Bonferroni correction was not applied in this study. The relatively small sample size (n=40) suggested that the ability to detect a significant effect was already relatively low (Table 12). However, the results do provide reasonable evidence for further study into the treatment effects of EXMT for patients with spinal stenosis.

Despite the positive changes in the variables from the pretest to the posttest measures, further limitations in the study design also prevented definitive conclusions. One of those limitations was a small sample size. A larger sample size should be used in future studies as it would minimize the possibility of a Type II error -- the error of failing to reject a null hypothesis when it is in fact not true. In other words, this is the error of failing to observe a difference, when in truth, there is a difference. Future studies should include a larger sample size in order to improve generalizability, or to include a subgroup analysis to determine those who more likely to benefit from impairment based manual therapy approach to lumbar spine and hips.

A further limitation applicable to this study was that the manual techniques used might not have been specific to the targeted vertebral segments, and length of the

treatment session was more for the EXMT group than the EX group. Another limitation is the variability in exercise prescribed by the treating therapist and patient's baseline variation in term of mobility and strength. In the current study, the treating therapists had the flexibility of designing the impairment-based approach of therapeutic exercise and manual therapy based on identified impairments of each patient. Although this approach might be one of the limitations of the study, is also opens the door for generalization of results. The scope of the study was not to investigate specific exercises or manual therapy techniques; the main purpose was to investigate the effect of manual therapy in addition to an impairment-based approach in patients with LSS. These impairments varied from patient to patient, and specific treatments (including manual therapy) varied from patient to patient based on recognized impairments.

Recommendations for Future Research

No long-term follow-up was conducted in this study; therefore, the improvements in outcomes may diminish over time. Future long-term studies of the effectiveness of an impairment-based approach using manual therapy for lumbar stenosis is needed using more rigorous study designs.

An area for future study is to subgroup patients with LSS who also have hip mobility deficits to determine if those patients respond better to manual therapy and exercise or exercise alone focused on the affected hip. There is currently very limited published literature available about the effectiveness of addressing hip mobility and strength and its relationship to back pain and disability.

Conclusion

LSS is multifactorial disease with impairments involving different areas of the body in addition to the lumbar spine. Use of a multi-impairment evaluation approach is essential to identify impairments and apply interventions for every impairment. This study suggests that manual therapy and therapeutic exercise are effective for providing clinically significant short-term reduction in back pain and disability as well as improvements in back mobility in patients with LSS. Significant changes were noted for some of the measurements over the 12-week time period of this study. The addition of interventions to address deficits in hip mobility and strength in the impairment-based approach was beneficial in decreasing pain and improving function. The results of this study suggest that a multimodal approach including manual therapy and exercise to the lumbar spine and hips, based on identified impairments, was an effective treatment approach for patients with LSS. Furthermore, this study suggests that physical therapists should strongly consider impairment-based approaches of manual therapy and specific exercises program for lumbar spine and hips, as this could be an effective treatment option for patients with LSS.

Appendix A: IRB Approval and Consent Form for Participation

NOVA SOUTHEASTERN UNIVERSITY
Institutional Review Board

MEMORANDUM

To: Haitham Ramadan, PT, M.S.
HPD – College of Health Care Sciences

From: Matthew Seamon, Pharm.D., JD
Chair, Institutional Review Board

Date: February 12, 2015

Re: *Effectiveness of Manual Therapy Approach in Treatment of Patients with Lumbar Spinal Stenosis* – NSU IRB No. 02031502Exp.

I have reviewed the revisions to the above-referenced research protocol by an expedited procedure. On behalf of the Institutional Review Board of Nova Southeastern University, *Effectiveness of Manual Therapy Approach in Treatment of Patients with Lumbar Spinal Stenosis* is approved in keeping with expedited review category #4. Your study is approved on **February 11, 2015** and is approved until **February 10, 2016**. You are required to submit for continuing review by **January 10, 2016.** As principal investigator, you must adhere to the following requirements:

1) CONSENT: You must use the stamped (dated consent forms) attached when consenting subjects. The consent forms must indicate the approval and its date. The forms must be administered in such a manner that they are clearly understood by the subjects. The subjects must be given a copy of the signed consent document, and a copy must be placed with the subjects' confidential chart/file.

2) ADVERSE EVENTS/UNANTICIPATED PROBLEMS: The principal investigator is required to notify the IRB chair of any adverse reactions that may develop as a result of this study. Approval may be withdrawn if the problem is serious.

3) AMENDMENTS: Any changes in the study (e.g., procedures, consent forms, investigators, etc.) must be approved by the IRB prior to implementation.

4) CONTINUING REVIEWS: A continuing review (progress report) must be submitted by the continuing review date noted above. Please see the IRB web site for continuing review information.

5) FINAL REPORT: You are required to notify the IRB Office within 30 days of the conclusion of the research that the study has ended via the IRB Closing Report form.

The NSU IRB is in compliance with the requirements for the protection of human subjects prescribed in Part 46 of Title 45 of the Code of Federal Regulations (45 CFR 46) revised June 18, 1991.

Cc: Dr. Madeleine Hellman
Dr. M. Samuel Cheng
Mr. William Smith

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(954) 262-5369 • Fax: (954) 262-3977 • Email: irb@nova.edu • Web site: www.nova.edu/irb

NOVA SOUTHEASTERN UNIVERSITY
Health Professions Division
College of Health Care Sciences
Physical Therapy Department

Consent Form for Participation in the Research Study Entitled: Effectiveness of Manual Therapy Approach in Treatment of Patients with Lumbar Spinal Stenosis

Funding Source: None.

IRB Protocol No:

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For questions/concerns about your research rights, contact:
Human Research Oversight Board (Institutional Review Board or IRB)
Nova Southeastern University
(954) 262-5369/Toll Free: 866-499-0790
IRB@nsu.nova.edu

Sites Information
Chicago Rehabilitation Services

- 10 Orland Square Dr. Orland Park, IL 60462. Ph: 708-966-4304
- 6314 S. Pulaski Chicago, IL 60629. Ph: 773-284-9888
- 7600 W. College Dr. 2nd Fl Palos Heights, IL 60463. Ph: 708-671-0888

Initial _____ Date _____

What is this study about?

You are invited to participate in a research study. The goal of this study is to compare the functional clinical outcomes achieved by patients with lumbar spinal stenosis receiving 2 different physical therapy programs: Group 1) Subjects who will receive specific exercises based evaluation findings including core strengthening, stabilization, hip flexibility, and strengthening exercises. Group 2) Subjects who will receive exercises similar to subjects in group 1, along with manual stretching, soft tissue, and joint mobilization to the lumbar, the thoracic spine, the sacroiliac joint, and the lower extremity joints, tailored to assessment findings.

Why are you asking me?

We are inviting you to participate because a physician is currently treating you for your back pain, and you have been referred to physical therapy for additional treatment for back pain. There will be around 40 participants in this research study.

What will I be doing if I agree to be in the study?

- After you have consented to participant by signing this consent form, you will complete a series of self-report questionnaires, medical screening forms, and receive a standardized history and physical examination to determine your eligibility to participate in the study.
- If during the interview the researchers learn that you have any medical conditions that make you ineligible for the study, the interview will be terminated and you will no longer be part of this study.
- If you meet the inclusion and exclusion criteria you will be randomly assigned into one of the two treatment groups
    - Group 1 receive specific exercises based evaluation findings including core strengthening, stabilization, hip flexibility, and strengthening exercises
    - Group 2 will receive exercises similar to subjects in group 1. In addition, they will receive manual stretching, soft tissue, and joint mobilization to the lumbar, the thoracic spine, the sacroiliac joint, and the lower extremity joints, tailored to assessment findings.
- The physical therapy program for you back treatment will be provided twice a week, for 6 weeks (total of 12 sessions). The completion of the questionnaires and the physical examination will take about 90 min, each treatment session will last for about 60 min and overall length of the study is about 12 weeks.
- You will be interviewed and evaluated by the therapist before the first treatment session, after the 12th treatment visit, and at the follow up 6 weeks after discharge..

Is there any audio or video recording?

This research study will not include audio or video recording.

What are the dangers to me?

- The risks you will be exposed to in this study are not greater than other risks you experience in receiving regular physical therapy treatment. After the physical therapy session, you may experience minimum muscle and or joint soreness for short periods of time. It could last up to 48 hours after treatment however it should subside afterward. If you feel discomfort, you can apply some cold or heat in the area to alleviate the symptoms or you can use your pain medication as prescribed by your physician.
- Your confidentiality cannot be guaranteed, as other people may know that you are participating in this research project. Taking the following measures will minimize this risk:
    - All information collected in this study will be placed in a secured, electronic medical record database. Only the participating clinicians will have access to this database. The research record will be part of the medical record except the signed consent form. The signed consent form will be collected by the PI and stored in a locked cabinet in the PI's office.

If you have any questions about the research, your research rights, or if you experience an injury because of the research, please contact Haitham Ramadan at 773-284-0888 or Dr. Hellman at 954-262-1282. You may also contact the IRB at the numbers indicated above with questions regarding your research rights.

Are there any benefits to me for taking part in this research study?

The treatment protocol conducted in this study could potentially benefit you by reducing your back pain, improving your lower back and hip range of motion, strengthening your trunk, lower back, and upper leg muscles, and decreasing your back-related disability. There are no added benefits from participating in this research study as you would in any typical therapy program. However, this research will be allow us to conclude what is a better approach to patients with similar conditions based on the aggregated data.

Will I get paid for being in the study?

No. There is no payment made for participating in this study.

Will it cost me anything?

There is no extra cost for participation in this study. The treatment you will receive in this study will be billed to your health insurance carrier as part of the standard treatment of your back problem.

How will you keep my information private?

- All information obtained in this study is strictly confidential unless law requires disclosure. We will save all electronic medical records on the computer with password protection and all paper records in a locked cabinet in the PI's office. These data are not accessible to others however the IRB and the regulatory agencies may review research records.

Initial _____ Date _____

- After the physical therapist records your measures, he/she will make a photocopy and remove your name, and put the number ID assigned to you during the randomized process, which will be used as a research record.

What if I do not want to participate or want to leave the study?

You have the right to leave this study at any time or refuse to participate. If you decide to leave or not to participate, you will not experience any penalty or loss of services that you have a right to receive. If you choose to withdraw, any information collected about you **before** the date you leave the study will be kept in the research records for 36 months from the conclusion of the study and may be used as a part of the research.

Other considerations:

If significant new information relating to the study becomes available, which may relate to your willingness to continue to participate, this information will be provided to you by the investigators.

Voluntary consent by participant

By signing below, you indicate that this study has been explained to you

- this study has been explained to you
- you have read this document or it has been read to you
- your questions about this research study have been answered
- you have been told that you may ask the researchers any study related questions in the future or contact them in the event of a research-related injury
- you have been told that you may ask Institutional Review Board (IRB) personnel questions about your study rights
- you are entitled to a copy of this form after you have read and signed it
- you voluntarily agree to participate in the study entitled, "Effectiveness of Manual Therapy Approach in Treatment of Patients with Lumbar Spinal Stenosis"

Participant's Signature: _____ **Date:** _____

Participant's Name: _____ **Date:** _____

Signature of person obtaining consent: _____ **Date:** _____

NOVA
Institutional Review Board
Approval Date: FEB 11 2015
Continuing Review Date: FEB 10 2016

Initial _____ Date _____

CALL FOR RESEARCH SUBJECTS

Do you have chronic Back Pain?

If so you may be eligible to participate in a research study titled

"Effectiveness of Manual Therapy Approach in Treatment of Patients with Lumbar Spinal Stenosis"

Haitham Ramadan, Physical Therapist and founder of Chicago Rehabilitation Services, Inc. is conducting a clinical study on subjects with chronic back pain. This study is part of the requirement for Haitham Ramadan's Ph.D. dissertation at Nova Southeastern University. A total of 60 men and women between the ages of 18 and 65 will participate in this study. If you have Chronic Low Back Pain and are interested in participating in the study, please notify the front office staff and they will schedule you with a therapist involved in collecting data for the study.

The study is to investigate the Effectiveness of Manual Therapy Approach in Treatment of Patients with Lumbar Spinal Stenosis. All of the procedures associated with this study are routinely used by physical therapists in the management of low back pain. In other words, we are not testing a true "experimental" form of treatment that has not previously been used in subjects with low back pain

For More Information Please Contact:

Haitham Ramadan

(708) 269-9116

NOVA
Institutional Review Board
Approval Date: FEB 11 2015
Continuing Review Date: FEB 10 2016

Appendix B: Patient Intake Form

Chicago Rehabilitation Services, Inc.
Patient Intake Form

LAST NAME	FIRST NAME	MI	DOB	

STREET ADDRESS: (Not P.O. Box)	CITY, STATE	ZIP CODE

HOME TELEPHONE	WORK TELEPHONE	CELL	OTHER

E-MAIL ADDRESS	NEXT OF KIN AND CONTACT NUMBER

SEX	MARITAL STATUS	EMERGENCY CONTACT: NAME/TELEPHONE #
□ M □ F	□ MARRIED □ PARTNERED □ DIVORCED □ WIDOWED □ SINGLE	

PRIMARY CARE PHYSICIAN (Required)	TELPHONE	

EMPLOYER INFORMATION □ Retired □ Unemployed □ Disabled □ Other: _____

EMPLOYER NAME	EMPLOYER PHONE NUMBER

STREET ADDRESS (Not P.O. Box)	CITY, STATE	ZIP CODE

Appendix C: Medical Screening Form

Medical Screening Form

To ensure you receive a complete and thorough evaluation, please provide the following important background information below. If you do not understand a question leave it blank and your physical therapist will assist you. Thank you.

Name: _____ **Occupation:** _____

Hobbies: _____ **Allergies:** _____

Have you or anyone in your immediate family been diagnosed with any of the following conditions?

	Self		Family			Self		Family	
Cancer	Yes	No	Yes	No	Asthma	Yes	No	Yes	No
Diabetes	Yes	No	Yes	No	Bronchitis	Yes	No	Yes	No
High Blood Pressure	Yes	No	Yes	No	Headaches	Yes	No	Yes	No
Heart Disease	Yes	No	Yes	No	Thyroid Issues	Yes	No	Yes	No
Stroke	Yes	No	Yes	No	Ulcers	Yes	No	Yes	No
Osteoporosis	Yes	No	Yes	No	GI Disease	Yes	No	Yes	No
Osteoarthritis	Yes	No	Yes	No	Seizures	Yes	No	Yes	No
Rheumatoid Arthritis	Yes	No	Yes	No	M.S.	Yes	No	Yes	No
Rheumatic Fever	Yes	No	Yes	No	Kidney Disease	Yes	No	Yes	No

Past Surgical History:

Total joint replacements	Yes	No
Spinal Surgeries	Yes	No
Metal Implants (rods, pins, screws)	Yes	No
Pacemaker	Yes	No
Other _____		

In the past 3 months have you had or did/do you experience:

A change in your health?	Yes	No	Difficulty Swallowing?	Yes	No
Nausea/Vomiting?	Yes	No	Changes in bowel or bladder function?	Yes	No
Fever/Chills/Sweats?	Yes	No	Shortness of breath?	Yes	No
Unexplained weight change?	Yes	No	Dizziness?	Yes	No
Numbness or tingling?	Yes	No	Upper respiratory infection?	Yes	No
Changes in appetite?	Yes	No	Urinary tract infection?	Yes	No

Have you fallen in the last year? Yes No
If yes, how many times in the last 12 months? _____
Did you experience any injuries due to the fall? Yes No
If yes, please explain:

_____

_

Are you currently:

Pregnant? Yes No **Depressed?** Yes No **Under Stress?** Yes No

How are you able to sleep at night? (Circle one)

Fine Moderate difficulty Only with medication

Do you have problems with: (Circle **ALL** that apply)

Hearing Vision Speech Communication

Do you or have you in the past smoked tobacco? Yes No

If yes, how many cigarettes a week? _____ Packs per year? _____

Do you drink alcoholic beverages? No
Yes

If yes, how many drinks do you have per week? _____

Do you drink caffeinated coffee or beverages? No
Yes

If yes, how often?: Monthly Weekly Daily

What brings you in for treatment?

_____

Onset of Pain (circle one); Was there an:

Accident Injury Trauma (Violence) Specific Activity

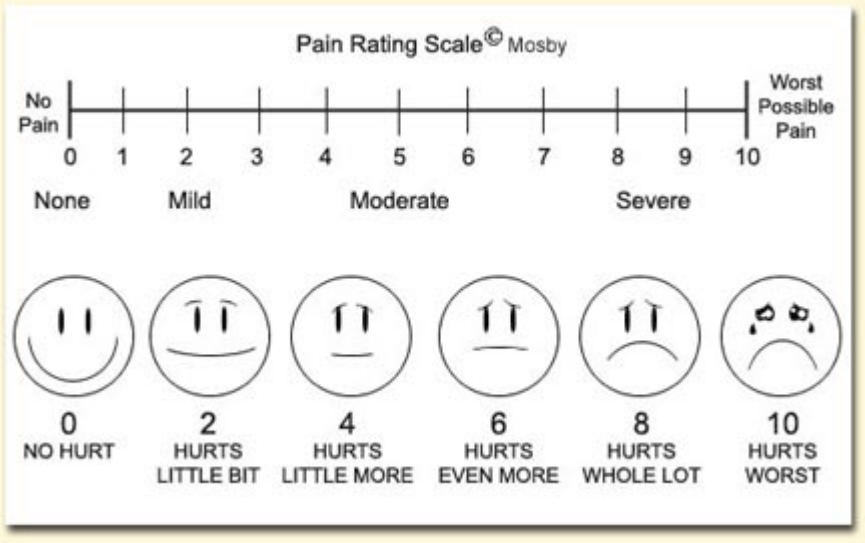
If yes, describe: _____

Have you received any treatment for this problem in the past?

_____

History of pain in this area? Yes No

If yes, for how long? _____



Using the scale above, what is the pain at:

Best _____
Worst _____
Today _____

What other symptoms have you had with this problem? (Circle ALL that apply):

Burning	Difficulty breathing	Hoarseness
Skin rash	Heart palpitations	Bleeding of any kind
Dizziness	Constipation	Tingling
Numbness	Vision changes	Cough
Joint Pain	Weight Change	Night Pain
Sweats	Weakness	Swallowing problems

Are there any other pain and/or symptoms of any kind anywhere else in your body that we have not talked about yet? Yes No

If yes, describe: _____

Date of last Physical Examination: _____

_____ _____

Therapist Signature Date

Appendix D. Manual Muscle Testing Procedures: Key to Muscle Grading

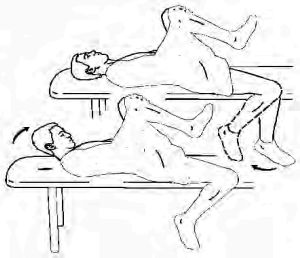
	Function of the Muscle	**Grade**		
No Movement	No contractions felt in the muscle	0	0	Zero
	Tendon becomes prominent or feeble contraction felt in the muscle, but no visible movement of the part	T	1	Trace
Test Movement	**MOVEMENT IN HORIZONTAL PLANE**			
	Moves through partial range of motion	1	2-	Poor-
	Moves through complete range of motion	2	2	Poor
	ANTIGRAVITY POSITION	3	2+	
	Moves through partial range of motion			
Test Position	*Gradual* release from test position	4	3-	Fair-
	Holds test position (no added pressure)	5	3	Fair
	Holds test position against slight pressure	6	3+	Fair+
	Holds test position against slight to moderate pressure	7	4-	Good-
	Holds test position against moderate pressure	8	4	Good
	Holds test position against moderate to strong pressure	9	4+	Good+
	Holds test position against strong pressure	10	5	Normal

Modified from 1993 Florence P. Kendall. Author grants permission to reproduce this chart

Appendix E. Sample of Lower Extremity Muscle Exercises

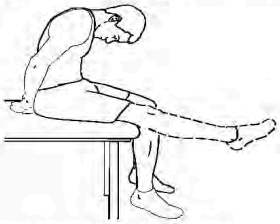
LOWER EXTREMITY - 6
SUPINE KNEE BEND: Mobilization VI

Lie on back, left knee pulled toward chest, other leg, including thigh, hanging over edge, knee bent a bit further. Tuck chin to chest.



Do _____ sets of _____ repetitions per session.
Do _____ sessions per day.

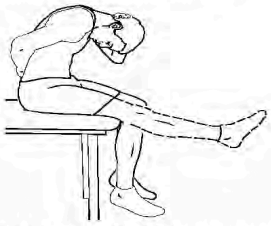
SPINE - 2 SLUMP: Mobilization II



Slouched, hands behind back, chin tucked. Straighten right knee.

Do _____ sets of _____ repetitions per session.
Do _____ sessions per day.

SPINE - 7 SLUMP: Mobilization VII

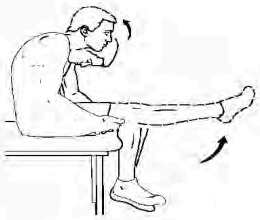


Slouched, chin tucked, one hand behind back, other hand on back of head applying gentle pressure. Straighten right knee.

Do _____ sets of _____ repetitions per session.
Do _____ sessions per day.

SPINE - 10 SLUMP: Flossing II

Sloched, chin tucked, right thigh lifted. Simultaneously straighten knee and look up.



Do _____ sets of _____ repetitions per session.
Do _____ sessions per day.

LOWER BACK - 1 Extensors / Gluteal

Bring knee to chest and hold. For more stretch, bring head to knee and hold. Hold _____ seconds. Repeat with other knee.

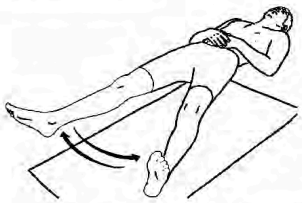
Repeat _____ times. Do _____ sessions per day.

HIP OBLIQUE - 4 External Rotators

Keeping head, neck and back flat, bring right leg over left. Use right leg to pull left leg to floor until stretch is felt. Hold _____ seconds. Repeat with left leg over right.

Repeat _____ times.
Do _____ sessions per day.

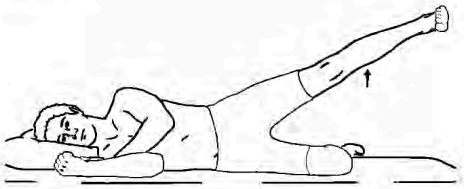
HIP / KNEE - 50 Hip Abduction / Adduction: with Extended Knee (Supine)



Bring left leg out to side and return. Keep knee straight.

Repeat 10 times per set. Do 2 sets per session.
Do 1 sessions per day.

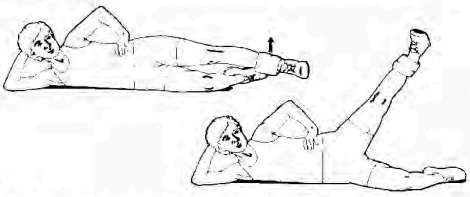
HIP / KNEE - 21 Strengthening: Hip Abduction (Side-Lying)



Tighten muscles on front of right thigh, then lift leg _____ inches from surface, keeping knee locked.

Repeat 10 times per set. Do 2 sets per session.
Do 1 sessions per day.

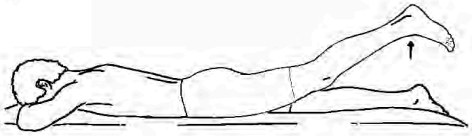
LEGS: GLUTES / THIGHS - 34 Leg Abduction: Single Leg (Ankle Weight)



Top leg weighted and straight, sweep leg upward as far as possible. Complete all repetitions to one side. Repeat on other side.

Do _____ sets. Complete _____ repetitions.

HIP / KNEE - 20 Strengthening: Hip Extension (Prone)

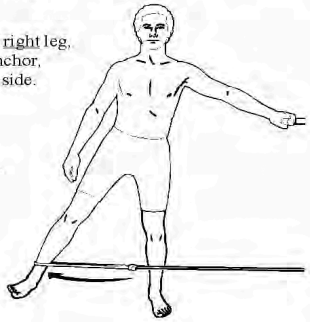


Tighten muscles on front of left thigh, then lift leg _____ inches from surface, keeping knee locked.

Repeat 10 times per set. Do 2 sets per session.
Do 1 sessions per day.

HIP / KNEE - 27 Strengthening: Hip Abduction – Resisted

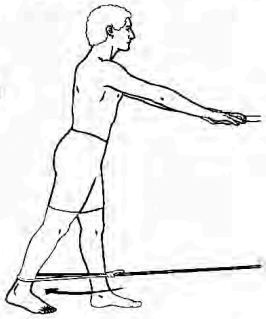
With tubing around right leg, other side toward anchor, extend leg out from side.



Repeat _____ times per set.
Do _____ sets per session.
Do _____ sessions per day.

HIP / KNEE - 28 Strengthening: Hip Extension – Resisted

With tubing around right ankle, face anchor and pull leg straight back.



Repeat _____ times per set.
Do _____ sets per session.
Do _____ sessions per day.

HIP OBLIQUE - 8 Internal Rotators

Gently pull foot and knee toward shoulder, rotating at hip.
Hold _____ seconds. Repeat with other leg.
Repeat _____ times. Do _____ sessions per day.

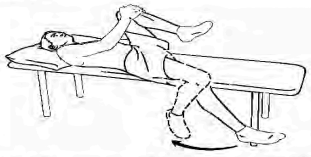
LOWER TRUNK - 1 Isometric Stabilization

Tighten abdominal muscles as if tightening a belt.
Hold _____seconds.
Do _____ times, _____ times per day.

LOWER EXTREMITY - 1 PRONE KNEE BEND: Mobilization I

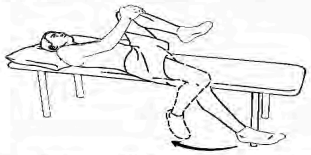
Lie on stomach. Bend left knee.
Do _____ sets of _____ repetitions per session.
Do _____ sessions per day.

LOWER EXTREMITY - 5 SUPINE KNEE BEND: Mobilization V



Lie on table, left knee pulled toward chest, other leg, including thigh, hanging over edge. Bend hanging knee.
Do _____ sets of _____ repetitions per session.
Do _____ sessions per day.

LOWER EXTREMITY - 5 SUPINE KNEE BEND: Mobilization V



Lie on table, left knee pulled toward chest, other leg, including thigh, hanging over edge. Bend hanging knee.
Do _____ sets of _____ repetitions per session.
Do _____ sessions per day.

Appendix F: McGill Pain Questionnaire

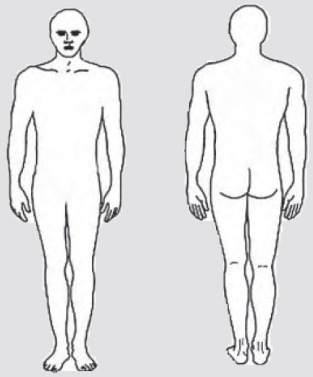
McGill Pain Questionnaire

PATIENT'S NAME _____ DATE _____ TIME _____ AM/PM _____

PRI: S _____ A _____ E _____ M _____ PRI(T) _____ PPI _____
(1-10) (11-15) (16) (17-20) (1-20)

1 FLICKERING ___ QUIVERING ___ PULSING ___ THROBBING ___ BEATING ___ POUNDING ___	11 TIRING ___ EXHAUSTING ___	
2 JUMPING ___ FLASHING ___ SHOOTING ___	12 SICKENING ___ SUFFOCATING ___	
3 PRICKING ___ BORING ___ DRILLING ___ STABBING ___ LANCINATING ___	13 FEARFUL ___ FRIGHTFUL ___ TERRIFYING ___	
4 SHARP ___ CUTTING ___ LACERATING ___	14 PUNISHING ___ GRUELLING ___ CRUEL ___ VICIOUS ___ KILLING ___	
5 PINCHING ___ PRESSING ___ GNAWING ___ CRAMPING ___ CRUSHING ___	15 WRETCHED ___ BLINDING ___	
6 TUGGING ___ PULLING ___ WRENCHING ___	16 ANNOYING ___ TROUBLESOME ___ MISERABLE ___ INTENSE ___ UNBEARABLE ___	
7 HOT ___ BURNING ___ SCALDING ___ SEARING ___	17 SPREADING ___ RADIATING ___ PENETRATING ___ PIERCING ___	
8 TINGLING ___ ITCHY ___ SMARTING ___ STINGING ___	18 TIGHT ___ NUMB ___ DRAWING ___ SQUEEZING ___ TEARING ___	
9 DULL ___ SORE ___ HURTING ___ ACHING ___ HEAVY ___	19 COOL ___ COLD ___ FREEZING ___	
10 TENDER ___ TAUT ___ RASPING ___ SPLITTING ___	20 NAGGING ___ NAUSEATING ___ AGONIZING ___ DREADFUL ___ TORTURING ___	
	PPI 0 NO PAIN ___ 1 MILD ___ 2 DISCOMFORTING ___ 3 DISTRESSING ___ 4 HORRIBLE ___ 5 EXCRUCIATING ___	

BRIEF ___ MOMENTARY ___ TRANSIENT ___	RHYTHMIC ___ PERIODIC ___ INTERMITTENT ___	CONTINUOUS ___ STEADY ___ CONSTANT ___



E = EXTERNAL
I = INTERNAL

COMMENTS:

The descriptors fall into four major groups: sensory, 1 to 10; affective, 11 to 15; evaluative, 16; and miscellaneous, 17 to 20. The rank value for each descriptor is based on its position in the word set. The sum of the rank values is the pain rating index (PRI). The present pain intensity (PPI) is based on a scale of 0 to 5. Copyright © 1970 Ronald Melzack.

Appendix G: Oswestry Low Back Pain Disability Questionnaire

Oswestry Low Back Pain Disability Questionnaire

Sources: Fairbank JCT & Pynsent, PB (2000) The Oswestry Disability Index. *Spine*, 25(22):2940-2953.

Davidson M & Keating J (2001) A comparison of five low back disability questionnaires: reliability and responsiveness. *Physical Therapy* 2002;82:8-24.

The Oswestry Disability Index (also known as the Oswestry Low Back Pain Disability Questionnaire) is an extremely important tool that researchers and disability evaluators use to measure a patient's permanent functional disability. The test is considered the 'gold standard' of low back functional outcome tools [1].

Scoring instructions

For each section the total possible score is 5: if the first statement is marked the section score = 0; if the last statement is marked, it = 5. If all 10 sections are completed the score is calculated as follows:

Example: 16 (total scored)

50 (total possible score) x 100 = 32%

If one section is missed or not applicable the score is calculated:

16 (total scored)

45 (total possible score) x 100 = 35.5%

Minimum detectable change (90% confidence): 10% points (change of less than this may be attributable to error in the measurement)

Interpretation of scores

0% to 20%: minimal disability:	The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting sitting and exercise.
21%-40%: moderate disability:	The patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity and sleeping are not grossly affected and the patient can usually be managed by conservative means.
41%-60%: severe disability:	Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation.
61%-80%: crippled:	Back pain impinges on all aspects of the patient's life. Positive intervention is required.
81%-100%:	These patients are either bed-bound or exaggerating their symptoms.

Oswestry Low Back Pain Disability Questionnaire

Instructions

This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking ONE box in each section for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement which most clearly describes your problem.

Section 1 – Pain intensity

- ☐ I have no pain at the moment
- ☐ The pain is very mild at the moment
- ☐ The pain is moderate at the moment
- ☐ The pain is fairly severe at the moment
- ☐ The pain is very severe at the moment
- ☐ The pain is the worst imaginable at the moment

Section 2 – Personal care (washing, dressing etc)

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

Section 3 – Lifting

- ☐ I can lift heavy weights without extra pain
- ☐ I can lift heavy weights but it gives extra pain
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed eg. on a table
- ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- ☐ I can lift very light weights
- ☐ I cannot lift or carry anything at all

Section 4 – Walking*

- ☐ Pain does not prevent me walking any distance
- ☐ Pain prevents me from walking more than 1 mile
- ☐ Pain prevents me from walking more than 1/2 mile
- ☐ Pain prevents me from walking more than 100 yards
- ☐ I can only walk using a stick or crutches
- ☐ I am in bed most of the time

Section 5 – Sitting

- ☐ I can sit in any chair as long as I like
- ☐ I can only sit in my favourite chair as long as I like
- ☐ Pain prevents me sitting more than one hour
- ☐ Pain prevents me from sitting more than 30 minutes
- ☐ Pain prevents me from sitting more than 10 minutes
- ☐ Pain prevents me from sitting at all

Section 6 – Standing

- ☐ I can stand as long as I want without extra pain
- ☐ I can stand as long as I want but it gives me extra pain
- ☐ Pain prevents me from standing for more than 1 hour
- ☐ Pain prevents me from standing for more than 30 minutes
- ☐ Pain prevents me from standing for more than 10 minutes
- ☐ Pain prevents me from standing at all

Section 7 – Sleeping

- ☐ My sleep is never disturbed by pain
- ☐ My sleep is occasionally disturbed by pain
- ☐ Because of pain I have less than 6 hours sleep
- ☐ Because of pain I have less than 4 hours sleep
- ☐ Because of pain I have less than 2 hours sleep
- ☐ Pain prevents me from sleeping at all

Section 8 – Sex life (if applicable)

- ☐ My sex life is normal and causes no extra pain
- ☐ My sex life is normal but causes some extra pain
- ☐ My sex life is nearly normal but is very painful
- ☐ My sex life is severely restricted by pain
- ☐ My sex life is nearly absent because of pain
- ☐ Pain prevents any sex life at all

Section 9 – Social life

- ☐ My social life is normal and gives me no extra pain
- ☐ My social life is normal but increases the degree of pain
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests eg, sport
- ☐ Pain has restricted my social life and I do not go out as often
- ☐ Pain has restricted my social life to my home
- ☐ I have no social life because of pain

Section 10 – Travelling

- ☐ I can travel anywhere without pain
- ☐ I can travel anywhere but it gives me extra pain
- ☐ Pain is bad but I manage journeys over two hours
- ☐ Pain restricts me to journeys of less than one hour
- ☐ Pain restricts me to short necessary journeys under 30 minutes
- ☐ Pain prevents me from travelling except to receive treatment

Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine 2000 Nov 15;25(22):2940-52; discussion 52.

Appendix H. Sahrmann's Testing Progression/Scoring Criteria for Lower Abdominal Strength/Core Activation.

Manual Muscle Test Grade	Criteria
1/5	The subject lifts one leg at a time to 90° of flexion with the knees positioned in flexion. From this position the subject lowers one leg at a time to the client position. Back remains flat.
2/5	The subject successfully performs Level 1, but upon lowering one leg to the table, s/he slides the leg into extension. The heel of the active leg may slide on or touch the surface of the treatment table during execution. The opposite leg must maintain a position of hip flexion of 90°, but no more, and its heel cannot touch the treatment table. Once the active leg has completed the slide into extension, the subject will rest the leg on a table, lift it back off the table, and return to the position of 90° of hip flexion before repeating with the other leg.
3/5	For Level 3, the subject performs Level 2, but instead of sliding the leg, s/he extends the leg while maintaining it off the treatment table through the entire range of motion. Once the subject completes extension, she rests the leg on the table, lifts the leg from the table, and returns it to the 90° hip flexed position before repeating the motion within the other leg.
4/5	The subject repeats level 1, but instead of lifting one leg at a time off the table, both legs and lifted simultaneously to the 90° hip flexed position, returned to the hook lying position, and fully extended. The return movement is completed by simultaneously sliding both legs back to the hook lying position followed by a bilateral leg lift into 90° of hip flexion.
5/5	For Level 5, the subject repeats the task for Level 4, but rather than sliding both legs along the surface of the treatment table, s/he extends both legs simultaneously, rests the legs of the completion of extension, lifts both legs from the table, and finally returns lands to the 90° hip flexed position.

Appendix I. Means and SD for each Study Variable by Assessment and by Group

Means and SD for each Study Variable by Assessment and by Group					
Variable	**Time**	**Group**	***M***	***SD***	**N**
McGill Pain Questionnaire	Baseline	EX	27.10	8.38	20
		EXMT	25.70	7.97	20
		Both	26.40	8.10	40
	Discharge	EX	9.70	4.32	20
		EXMT	6.00	4.52	20
		Both	7.85	4.75	40
	6-week follow up	EX	9.90	4.36	20
		EXMT	5.45	3.87	20
		Both	7.68	4.65	40
Oswestry Low Back Pain Disability Questionnaire	Baseline	EX	44.80	10.93	20
		EXMT	44.90	10.13	20
		Both	44.85	10.40	40
	Discharge	EX	20.80	8.69	20
		EXMT	14.50	8.23	20
		Both	17.65	8.94	40
	6-week follow up	EX	20.10	8.75	20
		EXMT	13.50	7.32	20
		Both	16.80	8.63	40
Distance Walked (SPWT) (ft)	Baseline	EX	561.00	527.48	20
		EXMT	799.95	529.40	20
		Both	680.48	535.47	40
	Discharge	EX	1008.05	539.23	20
		EXMT	2615.65	1313.68	20
		Both	1811.85	1282.60	40
	6-week follow up	EX	1127.55	606.16	20
		EXMT	2836.40	1428.57	20
		Both	1984.98	1386.37	40
		EX	28.05	9.90	20

Lumbar Spine ROM (Flexion)	Baseline	EXMT	31.55	8.41	20
		Both	29.80	9.24	40
	Discharge	EX	36.70	9.69	20
		EXMT	43.50	8.43	20
		Both	40.10	9.60	40
	6-week follow up	EX	37.80	8.87	20
		EXMT	43.45	9.17	20
		Both	40.63	9.35	40
Lumbar Spine ROM (Extension) (°)	Baseline	EX	7.70	2.43	20
		EXMT	9.40	2.80	20
		Both	8.55	2.73	40
	Discharge	EX	12.40	2.50	20
		EXMT	16.95	3.27	20
		Both	14.68	3.68	40
	6-week follow up	EX	12.30	2.30	20
		EXMT	16.65	3.15	20
		Both	14.48	3.50	40
Strong Hip Muscle Strength (Extensor) (in what unit?)	Baseline	EX	9.20	0.52	20
		EXMT	9.40	0.50	20
		Both	9.30	0.52	40
	Discharge	EX	9.70	0.47	20
		EXMT	9.45	0.51	20
		Both	9.58	0.50	40
	6-week follow up	EX	9.40	0.50	20
		EXMT	9.65	0.49	20
		Both	9.53	0.51	40
Weak Hip Muscle Strength (Extensor)	Baseline	EX	4.85	0.88	20
		EXMT	5.50	1.05	20
		Both	5.18	1.01	40
	Discharge	EX	7.40	1.14	20
		EXMT	8.40	0.82	20
		Both	7.90	1.10	40

		EX	8.80	0.52	20
	6-week follow up	EXMT	9.25	0.64	20
		Both	9.03	0.62	40
		EX	9.23	0.44	20
	Baseline	EXMT	9.10	0.31	20
		Both	9.18	0.38	40
Strong Hip Muscle Strength (Abductor)		EX	9.30	0.57	20
	Discharge	EXMT	9.90	0.31	20
		Both	9.60	0.55	40
		EX	9.40	0.60	20
	6-week follow up	EXMT	9.75	0.44	20
		Both	9.58	0.55	40
		EX	5.00	1.17	20
	Baseline	EXMT	5.55	0.94	20
		Both	5.28	1.09	40
Weak Hip Muscle Strength (Abductor)		EX	7.95	0.83	20
	Discharge	EXMT	8.45	0.60	20
		Both	8.20	0.76	40
		EX	8.70	0.57	20
	6-week follow up	EXMT	9.30	0.66	20
		Both	9.00	0.68	40
		EX	34.45	1.57	20
	Baseline	EXMT	37.65	1.39	20
		Both	36.05	2.14	40
Strong Hip ROM External Rotation		EX	36.20	1.64	20
	Discharge	EXMT	38.25	1.45	20
		Both	37.23	1.85	40
		EX	35.35	1.76	20
	6-week follow up	EXMT	37.60	0.82	20
		Both	36.48	1.77	40

		EX	20.55	2.14	20
	Baseline	EXMT	24.90	2.38	20
		Both	22.73	3.14	40
Weak Hip ROM External Rotation					
		EX	30.95	1.97	20
	Discharge	EXMT	36.95	1.96	20
		Both	33.95	3.61	40
		EX	31.70	2.00	20
	6-week follow up	EXMT	37.65	1.39	20
		Both	34.68	3.46	40
		EX	34.70	2.54	20
	Baseline	EXMT	38.40	1.10	20
		Both	36.55	2.69	40
Strong Hip ROM Internal Rotation					
		EX	36.60	2.35	20
	Discharge	EXMT	39.25	0.91	20
		Both	37.93	2.21	40
		EX	36.25	2.10	20
	6-week follow up	EXMT	39.15	0.75	20
		Both	37.70	2.14	40
		EX	19.70	2.68	20
	Baseline	EXMT	23.70	2.81	20
		Both	21.70	3.38	40
Weak Hip ROM Internal Rotation					
		EX	31.30	1.66	20
	Discharge	EXMT	36.60	2.44	20
		Both	33.95	3.38	40
		EX	31.30	2.11	20
	6-week follow up	EXMT	37.45	1.90	20
		Both	34.38	3.69	40
		EX	16.90	2.61	20
	Baseline	EXMT	17.15	1.31	20
		Both	17.03	2.04	40
Strong Hip ROM Extension					
		EX	16.80	1.24	20
	Discharge	EXMT	18.40	1.10	20

		Both	17.60	2.04	40
		EX	16.60	1.31	20
	6-week follow up	EXMT	18.05	1.19	20
		Both	17.33	1.44	40
		EX	7.70	1.49	20
	Baseline	EXMT	9.50	1.96	20
		Both	8.60	1.95	40
Weak Hip ROM Extension		EX	11.65	1.66	20
	Discharge	EXMT	15.20	1.61	20
		Both	13.43	2.42	40
		EX	12.70	1.49	20
	6-week follow up	EXMT	14.90	1.33	20
		Both	13.80	1.79	40

Appendix J. Inferential Statistics by Study Dependent Variable (N = 40)

Variable	Main and Interaction Effects	Inferential Tests				
		F	*df*	*p* value	η_P^2	1-β
McGill Pain Questionnaire	Time	552.29	1.08, 41.00[a]	<.001	.94	1.00
	Group	3.51	1, 38	.069	.09	.45
	Time × Group	46.82	1.08, 41.00[a]	.087	.07	.41
Oswestry Low Back Pain Disability Questionnaire	Time	1440.20	1.22, 46.37[a]	<.001	.97	1.00
	Group	2.34	1, 38	.134	.06	.32
	Time × Group	20.26	1.22, 46.37[a]	<.001	.35	.99
Distance Walked (SPWT)	Time	100.57	1.05, 39.70[a]	<.001	.73	1.00
	Group	127.50	1, 38	<.001	.77	1.00
	Time × Group	33.86	1.05, 39.70[a]	<.001	.47	1.00
Lumbar Spine ROM (Flexion)	Time	170.60	1.70, 64.56[a]	<.001	.82	1.00
	Group	3.67	1, 38	.063	.09	.46
	Time × Group	3.21	1.70, 64.56[a]	.055	.08	.55

Lumbar Spine	Time	300.37	1.31, 49.62[a]	<.001	.89	1.00
ROM	Group	19.00	1, 38	<.001	.33	.99
(Extension)	Time × Group	15.69	1.31, 49.62[a]	<.001	.29	.99
Strong Hip Muscle Strength (Extension)	Time	2.87	2, 76	.063	.07	.55
Weak Hip	Time	535.04	2, 76	<.001	.93	1.00
Muscle Strength	Group	8.75	1, 38	.005	.19	.82
(Extension)	Time × Group	2.65	2, 76	.078	.07	.51
Strong Hip Muscle Strength (Abductor)	Time	11.90	2, 76	<.001	.24	.99
Weak Hip	Time	333.98	1.69, 64.26	<.001	.24	.99
Muscle Strength	Group	8.16	1,38	.007	.18	.80
(Abductor)	Time × Group	0.05	1.69, 64.26	.947	.00	.06
Hip External	Time	14.39	2, 76	<.001	.28	1.00

Rotation ROM (Non-Limited Side)						
Hip External Rotation ROM (Limited Side)	Time	741.63	1.65, 62.62	<.001	.95	1.00
	Group	124.00	1, 38	<.001	.76	1.00
	Time × Group	3.64	1.65, 62.62	.031	.09	.66
Hip Internal Rotation ROM (Non-Limited Side)	Time	31.92	2, 76	<.001	.48	1.00
Hip Internal Rotation ROM (Limited Side)	Time	699.37	2, 76	<.001	.95	1.00
	Group	79.71	1, 38	<.001	.68	1.00
	Time × Group	3.96	2, 76	.023	.09	.69
Hip Extension ROM (Non-Limited Side)	Time	2.31	1.33, 50.62	.107	.06	.45
Hip Extension ROM	Time	240.37	1.72, 65.53	<.001	.86	1.00
	Group	38.70	1, 38	<.001	.51	1.00

(Limited Side)	Time × Group	6.01	1.72, 65.53	.006	.14	.87

[a]Greenhouse-Geisser adjustment for violations of sphericity

Appendix K. Tests of Sphericity For Each Variable Across the Three Assessment Points

	Mauchly's W	χ^2	*df*	*p* value	Greenhouse-Geisser ($\hat{\varepsilon}$)
McGill Pain Questionnaire	.15	71.10	2	<.001	.54
Oswestry Low Back Pain Disability Questionnaire	.36	37.71	2	<.001	.61
Distance Walked (SPWT)	.09	90.96	2	<.001	.52
Lumbar Spine ROM (Flexion)	.82	7.22	2	.027	.85
Lumbar Spine ROM (Extension)	.47	28.06	2	<.001	.65
Strong Hip Muscle Strength (Extension)	.97	1.10	2	.595	.97
Weak Hip Muscle Strength (Extension)	.97	1.11	2	.573	.97
Strong Hip Muscle Strength (Abductor)	.85	5.90	2	.052	.87
Weak Hip Muscle Strength (Abductor)	.82	7.46	2	.024	.85
Strong Hip ROM External Rotation	.98	0.88	2	.646	.98
Weak Hip ROM External Rotation	.79	8.90	2	.012	.82
Strong Hip ROM Internal Rotation	.97	1.21	2	.545	.97
Weak Hip ROM Internal Rotation	.87	5.03	2	.081	.89

Strong Hip ROM Extension	.50	25.75	2	<.001	.67
Weak Hip ROM Extension	.84	6.45	2	.040	.86

Appendix L. Pairwise Comparisons Between Treatment Groups at Each Time Point.

			β	*SE*	*t*	*p value*	η_P^2	1-β
Oswestry Low Back Pain Disability Questionnaire	T1	Intercept	44.90	2.36	19.06	<.001	.91	1.00
		Ex vs. EXMT	-0.10	3.33	-0.30	.976	.00	.05
	T2	Intercept	14.50	1.89	7.66	<.001	.61	1.00
		Ex vs. EXMT	6.30	2.68	2.35	.024	.13	.63
	T3	Intercept	13.50	1.80	7.49	<.001	.60	1.00
		Ex vs. EXMT	6.60	2.55	2.59	.014	.15	.71
Distance Walked (SPWT)	T1	Intercept	799.95	118.16	6.77	<.001	.55	1.00
		Ex vs. EXMT	-238.95	167.11	-1.43	.161	.05	.29
	T2	Intercept	2615.65	224.53	11.65	<.001	.78	1.00
		Ex vs. EXMT	-1607.60	317.53	-5.06	<.001	.40	.99
	T3	Intercept	2836.40	247.37	11.56	<.001	.78	1.00
Lumbar Spine	T1	Intercept	9.40	0.59	16.04	<.001	.87	1.00

ROM (Extension)		Ex vs. EXMT	-1.70	0.83	-2.05	.047	.10	.52
	T2	Intercept	16.95	0.65	26.05	<.001	.95	1.00
		Ex vs. EXMT	-4.55	0.92	-4.95	<.001	.39	1.00
	T3	Intercept	16.65	0.62	27.01	<.001	.95	1.00
		Ex vs. EXMT	-4.35	0.87	-4.99	<.001	.40	1.00
Weak Hip Muscle Strength (Abductor)	T1	Intercept	5.50	0.24	23.35	<.001	.94	1.00
		Ex vs. EXMT	-0.55	0.34	-1.64	.110	.07	.36
	T2	Intercept	8.45	0.16	52.22	<.001	.99	1.00
		Ex vs. EXMT	-0.50	0.23	-2.19	.035	.11	.57
	T3	Intercept	9.30	0.14	67.56	<.001	.99	1.00
		Ex vs. EXMT	-0.60	0.20	-3.08	.004	.20	.85
Limited Hip ROM External Rotation	T1	Intercept	24.90	0.51	49.19	<.001	.99	1.00
		Ex vs. EXMT	-4.35	0.72	-6.08	<.001	.49	1.00

	T2	Intercept	36.95	0.44	83.76	<.001	.99	1.00
		Ex vs. EXMT	-6.00	0.62	-9.62	<.001	.71	1.00
	T3	Intercept	37.65	0.39	97.75	<.001	.99	1.00
		Ex vs. EXMT	-5.95	0.55	-10.92	<.001	.76	1.00
Limited Hip ROM Internal Rotation	T1	Intercept	23.70	0.61	38.61	<.001	.98	1.00
		Ex vs. EXMT	-4.00	0.89	-4.61	<.001	.36	.99
	T2	Intercept	36.60	0.47	78.55	<.001	.99	1.00
		Ex vs. EXMT	-5.30	0.66	-8.04	<.001	.63	1.00
	T3	Intercept	37.45	0.45	83.43	<.001	.99	1.00
		Ex vs. EXMT	-6.15	0.64	-9.69	<.001	.71	1.00
Limited Hip ROM Extension	T1	Intercept	9.50	0.39	24.40	<.001	.94	1.00
		Ex vs. EXMT	-1.80	0.55	-3.27	.002	.22	.89
	T2	Intercept	15.20	0.37	41.54	<.001	.98	1.00

		Ex vs. EXMT	-3.55	0.52	-6.86	<.001	.55	1.00
	T3	Intercept	14.90	0.32	47.12	<.001	.98	1.00
		Ex vs. EXMT	-2.20	0.45	-4.92	<.001	.39	.99

Appendix M. Probed Effects of Changes Over Time by Treatment Group

			df	F	*p value*	η_P^2	1-β
ODQ	EX	Level 1 vs. Level 2	1	594.78	<.001	.97	1.00
		Level 2 vs. Level 3	1	3.44	.079	.15	.42
	EXMT	Level 1 vs. Level 2	1	1108.53	<.001	.98	1.00
		Level 2 vs. Level 3	1	6.33	.021	.25	.67
Distance Walked (SPWT)	EX	Level 1 vs. Level 2	1	86.87	<.001	.82	1.00
		Level 2 vs. Level 3	1	46.72	<.001	.71	1.00
	EXMT	Level 1 vs. Level 2	1	64.71	<.001	.77	1.00
		Level 2 vs. Level 3	1	25.13	<.001	.57	.99
Lumbar Spine Range of Motion Extension	EX	Level 1 vs. Level 2	1	85.48	<.001	.82	1.00
		Level 2 vs. Level 3	1	0.39	.541	.02	.09

	EXMT	Level 1 vs. Level 2	1	274.36	<.001	.94	1.00
		Level 2 vs. Level 3	1	1.41	.249	.07	.20
Limited Hip Range of Motion External Rotation	EX	Level 1 vs. Level 2	1	452.65	<.001	.96	1.00
		Level 2 vs. Level 3	1	8.30	.010	.30	0.78
	EXMT	Level 1 vs. Level 2	1	535.96	<.001	.97	1.00
		Level 2 vs. Level 3	1	2.32	.144	.11	0.30
Limited Hip Range of Motion Internal Rotation	EX	Level 1 vs. Level 2	1	276.69	<.001	0.94	1.00
		Level 2 vs. Level 3	1	0.00	1.000	0.00	0.05
	EXMT	Level 1 vs. Level 2	1	674.16	<.001	0.97	1.00
		Level 2 vs. Level 3	1	6.16	.023	0.25	0.65
Limited Hip Range of Motion Extension	EX	Level 1 vs. Level 2	1	237.63	<.001	.93	1.00
		Level 2 vs. Level 3	1	15.55	.001	.45	.96

	EXMT	Level 1 vs. Level 2	1	150.20	<.001	.89	1.00
		Level 2 vs. Level 3	1	0.81	.379	.04	.14

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