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An Outcome Comparison on the Use of Mckenzie Technique with and without Mulligan Mobilizations on the Treatment of Low Back Derangement

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AN OUTCOME COMPARISON ON THE USE OF MCKENZIE TECHNIQUE WITH AND WITHOUT MULLIGAN MOBILIZATIONS ON THE TREATMENT OF LOW BACK DERANGEMENT

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This Independent Study, submitted by Jason J Vila in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

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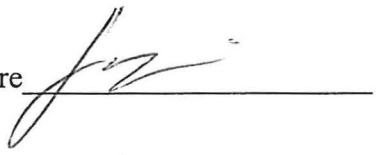
Signature 

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ABSTRACT

Effective research and outcome studies are currently lacking evidence to support the use and reimbursement of manual therapy interventions such as McKenzie techniques and Mulligan mobilizations. The purpose of this study was to compare the cost-effectiveness, efficiency, and outcomes of McKenzie techniques and McKenzie techniques with Mulligan mobilization on the treatment of patients with low back derangement through performing a chart review. Twenty-two subjects with a diagnosis of low back derangement were included in this study with sixteen subjects in the McKenzie group and six subjects in the McKenzie with Mulligan mobilizations group. An independent sample T-test showed no significant difference for age, total treatment costs, average cost per PT treatment, duration of PT services, number of PT treatments, initial and final pain level ratings, number of modalities used, initial and final ADL abilities, and for initial and final functional abilities. Subjective rating of percent improvement was the only category indicating a significant difference between the intervention groups ($p < .05$). Although there was only one indicator found to be significantly different, two major trends were observed: 1) the McKenzie group appeared to be more cost effective and efficient compared to the McKenzie with Mulligan mobilization group. 2) The McKenzie with Mulligan mobilization group averaged slightly lower pain ratings at discharge, significantly higher subjective percent improvement, and slightly higher ADL and functional ability scores at discharge.

CHAPTER I

INTRODUCTION

Low back pain is one of the most prevalent and costly medical problems in today's industrial society.[1] It is estimated that 60-80% of our population will experience episodes of acute back pain at some stage in their lives.[2] It is also estimated that direct medical costs for treatment of low back pain and indirect costs such as lost earnings can range from more that $50 billion per year to an extreme of $100 billion per year.[3] Furthermore, direct medical costs related to low back pain have been increasing steadily over the past 20 to 30 years.[4] Back related work intolerance and an increase in disability awards have contributed to these increases, putting further financial stress on an already stressed health care system.[3]

In this day and age of sky rocketing health care costs, the question remained to be answered is: "How do we control these costs?"

Controlling escalating health care costs is essential, now more than ever, as resources available for health care services have exceeded the payer's ability to continue to pay for unlimited services.[5] One strategy utilized by public and private payers has been to shift further responsibility to the health care provider. Public and private reimbursement payers have done so through examining utilization patterns and outcomes of health care services.[6] The goal of the payers is to encourage health care practitioners to provide the most cost effective and efficient treatments to lower ballooning health care costs.

Because of the increasing costs related to the treatment of low back pain, the focus of this study will be placed on physical therapy procedures, as physical therapy techniques are one of the most common treatments for the rehabilitation of the low back.[7,8] Furthermore, physical therapy in relation to treatment of the low back will be studied because of the high proportion of low back patients treated by physical therapists. It has been estimated that almost half of outpatient physical therapy visits and greater than 25% of physician referrals are for the treatment of patients with low back pain.[3] Understanding the high volume of patients with low back dysfunction treated by physical therapists and understanding the related increases in costs, demands the development of the most cost-effective and cost-efficient physical therapy treatments.

Despite the prevalence of the number of patients and referrals to physical therapy for treatment of low back pain, there has been an absence of adequate clinical trials to evaluate the effectiveness of most available treatments.[9] This lack of clinically based evidence fosters the necessity for research in physical therapy to assist providers in managing costs and to formulate effective clinical management strategies.[6] One effective research option is through performing outcome research.

Outcome research is a system of analyzing specific indicators and patterns to assist in determining the most effective and cost efficient treatments.[10] It involves gathering and interpreting results of medical process and procedures and then utilizes the data to better manage certain diagnoses and treatments.[5] With outcome research, common indicators are tracked for patients with a similar diagnosis and then analyzed to determine the outcome.[10] For example, indicators such as costs, number of total treatments, and patient satisfaction can be analyzed to determine the more effective and

efficient treatment. Finding the most useful and efficient treatments is particularly important now in today's health care system for reimbursement purposes given the limitations in health care dollars.[11]

In this current outcome research study, the utilization of manual therapy for treatment of the low back in physical therapy practice will be examined. Pursuance of further research is necessary as the efficacy of manual therapy techniques remains controversial.[12] Manual therapy has been long advocated as a treatment of patients experiencing low back dysfunction,[13-16] but its effectiveness has been poorly documented. Despite this lack of evidence, the common use of manual therapy techniques suggests some degree of success in its application.[17] Because of the common use of manual therapy for treatment of the low back as well as the rising costs for management of these patients; outcome research would be beneficial to determine the most effective and efficient manual techniques for the low back.

The McKenzie method is said to be the most popular approach for managing patients with back pain.[11] A survey questionnaire conducted by Battie et al. surveyed 186 licensed physical therapists and reported that greater than 50% of therapists incorporated the McKenzie method during evaluations, 85% of therapists perceived the McKenzie approach as moderate to very effective, and 48% of therapists rated the method as the "most useful" approach.[11] Given the popularity of the use of the McKenzie method in physical therapy practice and the Battie et al. survey reporting 44% of therapists incorporating a variety of methods as the "most useful" approach, it is beneficial to further study and document the efficacy of the use of the McKenzie method in conjunction with other physical therapy techniques.

One technique that has gained popularity and is increasingly being utilized with the McKenzie method is the manual technique adapted by Brian Mulligan. Mulligan utilizes spinal mobilizations accompanied by active and passive movements to decrease pain and to improve joint mobility.[18] Currently, many therapists are combining the techniques adapted by Mulligan and McKenzie for treatment of patients with disc related pathology.

Given the increased use of combining Mulligan and McKenzie techniques, the **purpose of this study** is to perform a chart review to compare the outcomes of treatments on patients with low back derangement utilizing McKenzie techniques alone in comparison with McKenzie techniques with Mulligan mobilization. **The significance of this study**: to determine which of the two techniques will allow the patient to recover and improve function in the most effective and efficient manner. This is significant in today's health care system as this information will provide physical therapy clinicians with more knowledge regarding which manual technique to employ to achieve optimal results as well as provide support for the use of these techniques for reimbursement by third party payers.

The following **research questions** will be addressed with this study: What are the outcomes of patients treated with McKenzie method alone compared to patients treated with McKenzie method and Mulligan mobilizations? Indicators to be assessed include: number of total visits, percent improvement, intake versus discharge functional level, gross cost per treatment, and total gross cost for all treatments.

The **null hypothesis**: there is no significant difference in the number of total visits, percent improvement, intake versus discharge functional level, gross cost per

treatment, and total gross cost for all treatments between the McKenzie group and the McKenzie with Mulligan mobilization group.

The **alternate hypothesis**: there is a significant difference in the number of total visits, percent improvement, pre and post-intervention functional level, gross cost per treatment, and total gross cost for all treatments between the McKenzie group and the McKenzie with Mulligan mobilization group.

CHAPTER II

LITERATURE REVIEW

The McKenzie Method

The McKenzie approach for treatment of mechanical low back pain was developed and named after the prominent New Zealand spinal therapist, Robin McKenzie. McKenzie is known throughout the physical therapy world for developing a system for spinal diagnosis and treatment of low back pain through exercise.

McKenzie's system of diagnosis of mechanical low back pain is based upon three syndromes: postural syndrome, dysfunction syndrome, and derangement syndrome. McKenzie believes that all spinal pain of mechanical origin can be classified in one of these three categories.[19]

The first McKenzie syndrome is the postural syndrome.[19] The postural syndrome is thought to be caused by mechanical deformation of soft tissue due to postural stresses. Maintained postures in abnormal or stressful positions yields such deformation, which eventually manifests itself as patient symptoms of low back pain. Postural syndrome symptoms are characterized by intermittent pain aggravated by particular postures or positions at end range sustained for a long period of time. The pain associated with the posture syndrome ceases with either a change of position or through posture correction.

The second McKenzie syndrome is the dysfunction syndrome.[19] The dysfunction syndrome is caused by mechanical deformation of soft tissue through poor postural

habits, spondylosis, and derangement, which results in adaptive shortening. Adaptive shortening of tissues leads to a decrease in range of motion (ROM) as well as pain production before achieving full range of motion. The pain produced with the dysfunction syndrome is caused by stressing the shortened tissue at end range and thus the goal of treatment for this syndrome is to lengthen the shortened tissue and thereby achieve full ROM.

The third, potentially the most disabling, and the diagnosis which will be focused on in this study, is the derangement syndrome.[19] The derangement syndrome is caused by mechanical deformation of soft tissue due to internal derangement. Internal derangement, as defined by McKenzie, is "the situation in which the normal resting position of the articular surfaces of two adjacent vertebrae is disturbed as a result of a change in the position of the fluid nucleus between the surfaces." [19(p110)] Through this altered position of the nucleus pulposis and possibly the surrounding annulus fibrosis, the ability of the joint surfaces to produce their normal movements is also changed causing a reduction or complete loss of ROM. Furthermore, depending on the size and the direction of the internal derangement or nuclear position the signs and symptoms may vary.

To classify the extent of the internal derangement, McKenzie developed seven classifications to characterize the size and direction of the altered disc shape.[19] Depending on the progression of the disc protrusion, the patient may experience either central or asymmetrical pain and/or non-radiating or radiating pain into the buttock, thigh, or calve. The seven classifications are included in figure 1.

Lumbar Derangement Classification

Derangement One:
- Central or symmetrical pain across L4/L5.
- Rarely buttock or thigh pain.
- No deformity.

Derangement Two:
- Central or symmetrical pain across L4/L5.
- With or without buttock and/or thigh pain.
- With deformity of lumbar kyphosis.

Derangement Three:
- Unilateral or asymmetrical pain across L4/L5.
- With or without buttock and/or thigh pain.
- No deformity.

Derangement Four:
- Unilateral or asymmetrical pain across L4/L5.
- With or without buttock or thigh pain.
- With deformity of lumbar scoliosis.

Derangement Five:
- Unilateral asymmetrical pain across L4/L5.
- With or without buttock and/or thigh pain.
- With leg pain extending below the knee.
- No deformity.

Derangement Six:
- Unilateral or asymmetrical pain across L4/L5.
- With or without buttock and/or thigh pain.
- With leg pain extending below the knee.
- With deformity of sciatic scoliosis.

Derangement Seven:
- Symmetrical or asymmetrical pain across L4/L5.
- With or without buttock and/or thigh pain.
- With deformity of accentuated lumbar lordosis.

Figure 1- Lumbar derangement classification.[24]

Derangement 1 through six are either postero-central or postero-lateral derangements.[19] Derangement 1 is known as the embryonic stage and presents with central pain and each successive derangement will present with peripheralization of symptoms. Peripheralization is defined as pain which starts proximal in the lumbar spine and moves to an area more distal or lateral such as the buttocks, thigh, or calve. The primary goal of treatment of the derangement is to centralize the pain and reduce all derangements to derangement one. Centralization is opposite of peripheralization and is defined as moving the pain from an area distal or lateral to a location more central or near midline position in the lumber spine.[19,20]

Derangement 7 is the least common derangement and is characterized by an anterior or antero-lateral disc protrusion.[19] Symptoms and presentation of derangement seven are different, but the goal is still to centralize pain and to reduce the disc deformity.

The centralization phenomenon is one of the main goals of the McKenzie treatment for derangement, but studies have also shown that centralization of symptoms also has prognostic value in patients with low back pain. Donelson et al. performed a study on 87 patients with low back pain and associated radicular symptoms and found that when patient's symptoms centralized during lumbar movement testing the patient achieved good to excellent results with treatment.[21] Research performed by Long studied 243 patients with diagnosis of low back pain participating in a work hardening program found that centralization of symptoms during the initial evaluation was associated with greater reduction of pain and higher percentages of return to work following the program.[22] Karas et al. studied 126 patients and concluded that the inability

to centralize radiating symptoms during the initial evaluation decreased the likelihood of the patient to return to work within six months.[23] Studies such as these support the importance of centralization of the patient's pain, both for treatment and for prognostic purposes.

Furthermore, the McKenzie technique has also been shown to have diagnostic value. Another study performed by Donelson et el., concluded that the McKenzie assessment is able to reliably differentiate discogenic and nondiscogenic pain as well as competent from incompetent annulus in a symptomatic disc when compared to provocation discography.[25] The reliability of the McKenzie evaluation, provides an inexpensive clinical assessment and provides relevant information regarding the intervertebral disc comparable to noninvasive diagnostic imaging.

The McKenzie Evaluation

Through understanding each syndrome and recognizing the typical presentations listed in figure 2, an evaluation can be performed in order to identify the syndrome in which the patient presents.

As with any initial evaluation, the McKenzie evaluation begins with taking a patient history.[19] McKenzie believes that taking an accurate history is the most important aspect of the initial consultation and feels that certain questions are essential to ask patients with mechanical low back pain. The patient interview should include questions which aid the practitioner to thoroughly understand the patient's presentation as well as assist in determining the associated syndrome (see figure 3).

Following the patient interview is McKenzie's physical examination.[19] During the examination the practitioner begins with recording the patient's posture in both sitting

Typical Presentation for the Postural Syndrome

- Female
- Less than 30 years of age
- No pathology, symptoms progress over time
- Abnormal stress on normal tissue
- Negative provocation exam

Typical Presentation for the Dysfunction Syndrome

- Male
- Greater than 30 years of age
- Constant or intermittent pain
- Pathology present (adaptively shortened tissue)
- Normal stress on abnormal tissue
- End Range Pain (ERP)

Typical Presentation for the Derangement Syndrome

- Male
- 20-55 years of age
- Pathology present
- Intermittent or constant pain
- May have deformity (lateral shift or kyphosis)
- Loss of ROM
- Pain During Movement (PDR) and/or ERP

Figure 2- Typical presentations for postural, dysfunction, and derangement syndromes.[24]

Questions To Ask During McKenzie Evaluation

1) Where is the present pain being felt?
2) How long has the pain been present?
3) How did the pain commence?
4) Is the pain constant or intermittent?
5) What makes the pain better or worse?
6) Is pain experienced with coughing or sneezing?
7) Does the pain disturb your sleep?
8) Is there pain upon arising in the morning?
9) Are you currently taking any medication?
10) Are you or have you been on steroids?
11) How is your general health? Have you experienced any recent weight loss?
12) Have you had any major surgeries or accidents, recently or previously?
13) Do you experience saddle anesthesia or have bladder control problems?

Figure 3- Questions to ask during patient interview of a McKenzie evaluation.[19]

and standing positions looking for any reduced or accentuated posture, lateral shifts, or leg length discrepancies. Next, the patient's movements are evaluated. The patient's range of movement and the movement pathway are observed first, followed by assessment of the patient's movement in relation to pain. After these tests are performed, McKenzie believes it is appropriate to assess hip and sacroiliac joint if they are thought to be involved in the patient's pathology.

Through incorporating the information from the patient's history, the physical examination, and through understanding typical patient presentation of each syndrome, it can be determined if the patient is suffering from a postural, dysfunction, or derangement syndrome.[19] Once the patient is classified into one of the syndromes, the appropriate and specific treatment can be applied.

The Intervertebral Disc

In order to truly understand the McKenzie treatment for derangement, the anatomy and function of the intervertebral disc must first be discussed. The intervertebral disc consists of two main structures: the annulus fibrosis, which is the outer fibrous material and the nucleus pulposis or the gelatinous central mass.[19,26]

The annulus fibrosis consists of concentric layers of fibrocartilage rings, which forms the circumference of the intervertebral disc.[19,26] Each layer contains obliquely directed fibers in various directions and connects the vertebra above and below the disc.

The intervertebral disc creates a strong bond between the vertebra, with the exception of the posterior disc where the peripheral attachment is weakened and fibers are less numerous. The posterior longitudinal ligament is also attached to the disc posteriorly, but is narrower and weaker than the anterior longitudinal ligament in the

lumbar spine. These factors cumulatively make the posterior, in particular the postero-lateral disc more susceptible to disc pathology.

The nucleus pulposis is the central core of the disc.[26] It is more cartilaginous than fibrous, normally elastic, high in water content, and behaves as a viscous fluid.[19,26] It contains as much as 90% water at birth, 75% in the third decade, and 70% in old age. Due to its fluid like properties, the nucleus pulposis acts as a shock absorber during all vertebral movements and becomes broader when it is compressed. One may think that the nucleus is positioned centrally within the disc, but because the fibers of the annulus fibrosis are thinner and fewer posteriorly the nucleus is actually positioned postero-central.[19]

During movements of the spine, the nucleus undergoes positional changes. When the vertebral column moves from full flexion to full extension, there is a slight, but significant anterior movement of the nucleus between the involved segments.[27-29] The opposite is true when there is movement from full extension to full flexion.[27-29] It is the movement of the nucleus pulposis that permits spinal movement.[19]

During spinal flexion and extension , the annulus fibrosis also alters its positions.[19] The annulus will undergo tangential stress and produce bulges in the disc depending on the direction of the vertebral movement. Flexion, for example, compresses the disc anteriorly creating a tangential stress at the posterior annulus and a bulge at the anterior annulus. Again, the opposite is true during extension. In this case, there is compression of the disc posteriorly creating a tangential stress anteriorly and a disc bulge posteriorly.

McKenzie has concluded that with an intact annular wall, a bulge in the posterior annulus is normal during extension.[19] However, if the annular wall is damaged posteriorly, upon flexion a more prominent posterior bulge will result and the nucleus will migrate further posterior creating a subsequent disc protrusion and stressing the surrounding structures.

McKenzie believes that such damage to the posterior annular wall is created by sustained lumbar flexion.[19] Sustained and repeated flexion stresses the already weaker posterior annulus, thus fatiguing and over stretching the annulus. As a result of this weak posterior annulus, the nucleus is able to move into the damaged outer annulus during lumbar flexion creating an abnormal disc bulge and potentially stressing the posterior longitudinal ligament and nearby nerve roots.

Furthermore, should the weakening and tearing of the annulus be postero-centrally located the patient will exhibit a kyphotic deformity and if the weakening is postero-laterally situated the patient will exhibit a scoliotic deformity or a lateral shift.[19]

With the weakening of the annulus and the extrusion of the nuclear material, the disc loses its ability to function normally and thus limits normal lumbar extension.[19] The ability of lumbar extension is impaired due to the approximation of the involved vertebra posteriorly, resulting in increased pressure on the disc protrusion. This explains why patients with disc protrusions present with flattened lumbar spines, as any attempt to extend or maintain lumbar lordosis compresses the disc bulge resulting in low back pain and/or radicular symptoms.

When the intervertebral disc is damaged through derangement, the bodies natural healing process is initiated through laying down of scar tissue in the inner annulus and

nucleus.[19] Scar tissue deposits result in formation of inelastic structures within the normally elastic intervertebral disc. The inelastic properties of the scar tissue will eventually lead to lumbar dysfunction syndrome. Understanding the potential development of this dysfunction provides insight in the prevention of further complication following a derangement. It is essential for practitioners to include early lumbar movement (when appropriate) in treatment to encourage formation of extensible scar tissue.

The Intervertebral Disc and Pain Production

Pain in the low back may originate from the vertebrae, ligaments, fascia, facet joints, or the intervertebral disc.[19,30] It is believed that intervertebral disc pathology, in particular, plays a significant role in nonspecific low back pain syndrome[31] and in chronic low back pain.[32] The contributing factors to low back pain related to the intervertebral disc are the annulus fibrosus, specifically the outer annulus, containing pain sensitive nerve endings in the fibers[33,34] and the inflammatory properties of the nucleus pulposis tissue.[35,36]

Neural compromise may also cause sciatic pain.[30] Disc herniations may cause mechanical compression or distention of the lumbar nerve root, dorsal root ganglion, or smaller nerves surrounding the intervertebral disc.[30,34] Further studies have also suggested that chemical irritation also contributes to sciatic pain. Sciatic symptoms include pain, parasthesia, and numbness along the distribution of the sciatic nerve explaining patient symptoms into the buttock, thigh, or calf.[19]

McKenzie Treatment for Low Back Derangement

Now that there is an understanding of the intervertebral disc anatomy and pathology, the McKenzie treatment can be discussed in relation to reducing the derangement and the associated symptoms.

In the early and acute stages of the derangement syndrome, the initial emphasis should be placed on maintaining lumbar lordosis.[19] McKenzie believes that failure to do so inhibits the possibility of fully reducing the derangement. In addition, the patient should be educated regarding the mechanism of the mechanical derangement and how their normal activities, movements, and flexed postures contribute to aggravation of their signs and symptoms. It should be emphasized to the patient that bending and stooping postures should be avoided, as these positions apply pressure on the intervertebral disc bulge and may reproduce their low back pain. Providing this knowledge to the patient is essential, as it will give them the necessary information upon how to reverse and prevent future episodes.

In general, the McKenzie treatment for derangement follows these four stages: reduction of the derangement, maintenance of the reduction, recovery of function, prevention of reoccurrence.[19]

Reduction of the Derangement

As was mentioned previously, the primary goal of treatment is to centralize the pain and to reduce the disc deformity.[19] For derangements 1 through 6, this is achieved through first correcting any lateral shift that may be present and through performing extension exercises (flexion for derangement 7). These treatments allow the displaced

nucleus to reverse its flow back within the disc. This is achieved through performing extension exercises, either in sustained positions or through repeated movements.

Maintenance of the Reduction

To maintain the patient's reduction of symptoms, the patient must retain lumbar lordosis as well as perform lateral shift (if necessary) and extension exercises every waking hour for the first 24 hours after the initial evaluation.[19] Performing the exercises hourly prevents significant accumulation of the nucleus within the posterior compartment of the disc and thus minimizing peripheralization of symptoms. While performing the exercises, 1 set of 10 repetitions are suggested.

The second physical therapy treatment should be scheduled 24 hours after the initial evaluation.[19] This is necessary in order to re-evaluate the patient and to determine if the correct diagnosis has been made and to determine if the correct treatment has been applied. If the patient returns with improvements indicated by centralized symptoms and/or reduction of frequency of pain, then positive change has resulted from the treatment and the exercises should be continued. As a basic rule of treatment, the "technique presently resulting in improvement should not be added to, modified, or replaced in any way until all improvement ceases."[19(p124)] When improvement does cease, exercises may be progressed to the next level of force. As further improvement progresses, frequency of exercises may be reduced to 2-3 times per day preferably during the morning, noon, and evening. Full reduction of symptoms is assumed when lumbar extension is painless, as posterior derangement cannot exist with full and pain free extension.

When prescribing exercises, the patient should be informed that while performing the exercises, pain that increases or peripheralizes is contraindicated and the exercises should be stopped.[19] At this point, the patient should seek further advice from the physical therapist. The patient should also be informed regarding normal pain in the upper back, between the shoulder blades, and in the arms due to the body adjusting to new positions and movements.

Recovery of Full Function

In order to maintain full recovery of function, full range of motion is required. After the patient performs extension exercises and derangement symptoms have subsided, flexion exercises may be introduced.[19]

Lumbar flexion must be introduced to stretch the scar tissue laid down for healing of the disc lesion.[19] When initiating these exercises, the exercises should be performed in the supine position to eliminate gravitational stresses and to unload the lumbar spine. To ensure that lumbar flexion is appropriate, assessment of the patient's initial response is necessary. If flexion becomes more painful upon repetition, this indicates that flexion exercises are premature and if continued, derangement may reoccur. If flexion becomes less painful with repetition, adaptively shortened tissues are being stretched without fear of returning derangement. This indicates that flexion activities are appropriate to introduce.

Whenever flexion exercises are performed, extension exercises must always follow.[19] This is done to ensure that the nucleus pulposis is maintained in its optimal position within the disc. Full recovery of flexion is complete when full lumbar range of motion in standing and lying are achieved in pain free movement.

Prevention of Reoccurrence

When the patient has achieved full recovery, it is suggested that the patient continue with the prescribed exercises for a minimum of six weeks.[19] Extension in lying should be performed 2 times per day once in the early morning and again in the late evening, flexion in lying should be performed once per day, and extension in standing should be performed as the patient feels it necessary. The patient should also be instructed to perform slouch over-correct exercises for maintenance of proper posture.

Research on the McKenzie Technique

The McKenzie protocol for treatment of the low back has shown significant improvement in patient condition when compared to other forms of intervention. Studies have shown that the McKenzie technique is significantly more effective in treatment of low back pain than the William's flexion protocol and a 45-minute patient education session. [37, 38]

In a study by Ponte et al., it was concluded that subjects receiving the McKenzie protocol improved in a significantly greater extent than subjects receiving the Williams protocol.[37] Results from this study indicated that the McKenzie protocol was significantly better than that of the Williams protocol in decreasing pain, improving comfortable sitting time, increasing pain-free forward flexion range, and increasing pain-free straight leg raise range. The study also reported that the McKenzie group required significantly less number of total treatments than the Williams group.

A study by Stankovic and Johnell, also reported the advantages of utilizing the McKenzie protocol, in this case compared to a 45-minute mini back school.[38] Results from this study reported significantly less time required to return to work, decreased

number of reoccurrence during the year observed, decreased pain, and significant improvements in spinal flexion, extension, and side gliding. In a 5-year follow up study, also performed by Stankovic and Johnell, results showed significantly less recurrence of pain and fewer sick leave days.

Mulligan Mobilizations

Mulligan mobilizations are techniques developed by Australian/New Zealand therapist Brian Mulligan. Mulligan's main principle of mobilization is known as mobilization with movement, or MWM. "SNAGS" or sustained natural apophyseal glides are the main MWM used in the lumbar spine.[18] Although SNAGS have yet to be scientifically vindicated, Mulligan states that these mobilizations are useful, safe, and painless. In order for SNAGS to be performed correctly, the following are essential criteria for application.[18]

1) SNAGS are performed in the weight bearing position. Mulligan feels that mobilization in this position is an advantage over conventional spinal mobilization in that the improvements via SNAGS are more likely to be retained.[18]
2) SNAGS are mobilizations performed in combination with active or passive movements along with overpressures applied at end range. These techniques are believed to enhance the patient's response to therapy.[18]
3) SNAGS are applied in the same treatment plane rule as extremity joints. Mulligan states that failure to mobilize spinal joints within the plane of the facet joints is incorrect and pain will result with movement.[18]

4) SNAGS, as the name implies, are sustained glides rather than traditional Maitland glides which are oscillatory. SNAGS are sustained throughout the available range and maintained until the joint returns to its starting position.[18]
5) All SNAGS are painless. Any production of pain is contraindicated and suggests that either the treatment plane is not being followed or the wrong segment is being mobilized.[18]
6) SNAGS are mobilizations applied at end range unlike conventional mobilizations, which are applied in the joint's resting position.[18] Mulligan believes that if normal end range is limited that the application of SNAGS will restore or dramatically improve end range without associated pain. If SNAGS are indicated and performed correctly, improvements will be observed upon first application.
7) Within two applications, the practitioner can determine if the use of SNAGS will be a useful intervention.[18]
8) For each movement limitation, a specific SNAG procedure can be applied to restore movement and decrease pain.[18]
9) Mulligan mobilizations are contraindicated for lumbar lesions involving sciatic scoliosis or lateral shift.[18]

SNAGs and Lumbar Spine Disc Lesions

Through Mulligan's experiences as a therapist, he has found that his techniques, which act directly on the facet joints, are beneficial in the treatment of disc lesions.[18] He also feels that his SNAG technique compliments McKenzie's approach for treatment of lumbar derangement.[18]

As was mentioned previously, during normal lumbar flexion, the involved vertebral bodies approximate anteriorly and separate posteriorly. In addition, the nucleus pulposis will migrate posteriorly and remain under the umbrella of the vertebral bodies during normal conditions.[18] In order for these motions to occur functionally, Mulligan states that the facet joints must first be mobile.[18]

Problems and symptoms of the low back occur when the facet joints are hypomobile.[18] In this case, during lumbar flexion, the vertebral bodies will be able to approximate anteriorly, but unable to separate posteriorly secondary to the hypomobility of the joints. It is hypothesized that the disc will no longer remain within the vertebral bodies and the disc will bulge posteriorly resulting in low back symptoms. To add further complication, if there is weakening of the posterior disc wall, hypomobility of the facets will produce more serious symptoms, as the disc bulge will increase in size.

Mulligan implies that many low back problems are caused by disc pathology and related facet joint hypomobility.[18] To support this hypothesis of facet joint hypomobility and its relation to disc lesions, he suggests applying the SNAG technique to a patient who presents radicular pain into the lateral leg upon lumbar flexion, if pain disappears with the SNAG he states that the practitioner will support his theory.[18]

Application of the SNAG to Increase Lumbar Flexion and/or Decrease the Pain Associated with the Movement

First, the technique to be applied must be thoroughly explained to the patient.[18] Mulligan states that this is essential as lack of patient understanding of the technique can exacerbate their symptoms. In addition, the patient should be informed of the procedure, as patient cooperation is essential for correct application of the SNAG.

It should be explained to the patient that the practitioner will apply a force through the hand while the patient actively moves through a pain free range of motion.[18] Also, the patient should understand that they should not experience any form of pain during the mobilization.

To apply the SNAG technique to increase lumbar flexion and/or to decrease the pain associated with the movement, the patient is positioned standing or sitting.[18] In sitting, the patient is seated over the edge of the treatment plinth and the therapist is positioned standing behind the patient. A belt is positioned below the patient's anterior superior iliac spines and below or at the level of the therapist's sacrum. The ulnar border of the right hand or both thumbs are positioned under the spinous process of the suspected vertebral segment. The patient is then asked to flex forward until pain is felt and then instructed to back off from this position. The therapist now applies a sustained gliding force along the treatment plane as the patient flexes forward again. If the correct force is applied and the correct segment is being mobilized, the patient should flex without pain to full or almost full range of motion. At full flexion range, sustain the glide and the position for a few seconds and then maintain the same force until the patient is fully erect. If the patient is able to flex painlessly with increased range of motion, repeat only three times, as more than three repetitions may aggravate the patient's symptoms.

In standing position, many of the same techniques apply with a few variations. Prior to having the patient flex forward, have the patient flex their knees slightly to minimize hamstring and sciatic nerve tension.[18] Also, position the patient close to the treatment plinth on which the patient can place a hand for further stability.[18] Other than these variations, the technique is the same for the seated position.

When a patient with an acute lumbar lesion positively responds to flexion SNAGS, Mulligan suggests taping the spine into hyperextension to prevent aggravation of symptoms.[18] He recommends using two strips of 2.5-centimeter adhesive tape placed diagonally across the lumbar spine. Mulligan also encourages McKenzie extension exercises for further treatment of the disc lesion.

Review of Manual Therapy Research

Manual therapy has been long advocated for its use as treatment for low back pain and dysfunction.[13-16] Despite its prevalence in use, the clinical efficacy of manipulations and mobilizations has yet to be established under reliably controlled conditions. Methodological flaws such as poorly randomized procedures, insufficient size of study populations, failure to blind subjects, ineffective measurements, and inadequate analysis and presentation of data have all led to inconclusive results regarding the efficacy and effectiveness of the application of manual techniques.[39]

Although the majority of clinical trials to validate the use of manual techniques have been inconclusive, there have been some studies supporting the benefits of the application of spinal mobilizations. Studies by Jayson et al. and Sims-Williams et al. applied Maitland mobilization techniques and found improvements in pain reduction and in spinal motion.[40,41] Jayson et al. further concluded that although manipulations and mobilizations hasten improvements in pain and range of motion, the application of these techniques have no effect on long-term prognosis.[40] Glover et al. also supports this claim, concluding positive results of these advantages, but also concluding no long-term effects.[42]

In summary of manual therapy research, when properly controlled clinical trials for spinal manipulations and mobilizations are performed, a conclusive, but small, short-term effect is evident.[17] Longer-term effects of manipulation and mobilization, however, remain equivocal, complicated by procedural flaws. Further controlled studies are essential to fully understand and determine the efficacy and effectiveness of these therapy techniques, including Mulligan's techniques, which also lacks such clinical evidence. These studies will provide physical therapists with necessary information to utilize effective manual therapy intervention, as well as, be critical of the continuing development of other manual techniques.

McKenzie and Spinal Manipulative Therapy

In McKenzie's "A Perspective on Manipulative Therapy", the question "is spinal manipulative therapy really necessary"[43(p443)] was asked. In response to the question, McKenzie answers, "undoubtedly yes". [43(p443)] As McKenzie agrees that it is necessary at times to use manipulation, he also suggests a concern of caution when applying spinal manipulation techniques. McKenzie's main concern with spinal manipulation is that it creates patient dependency on the therapist. He believes that by avoiding the use of therapist applied techniques in the initial stages of treatment and utilizing patient generated techniques, such as the McKenzie exercises, the patient themselves will recognize that their recovery is a result of their own efforts.

McKenzie states that patient generated forces and techniques are more beneficial and practical than therapist applied technique for three main reasons.[43] First, he feels that patient generated mobilizations through McKenzie exercises can bring about the same results as therapist generated mobilizations. Secondly, McKenzie exercises in place of

spinal mobilizations is a form of self-treatment, as exercises can be performed independently throughout the day. Lastly, McKenzie believes patient generated techniques are more beneficial then mobilizations in that his exercises provide long term benefits. Through providing the patient with the ability to mobilize themselves, the therapist encourages independence of the patient. Through providing independence, the patient becomes responsible for their own care, which essentially provides the patient with the knowledge and ability to treat themselves during current and future low back pain episodes. This, McKenzie believes, is an undeniable long-term effect.

The Eclectic Approach for the Treatment of the Low Back

A study performed by Battie et al., surveyed 186 physical therapists regarding treatment preferences for management of low back pain.[11] Of the 186 therapists, 48% rated the McKenzie technique as the "most useful" technique and 44% of therapists cited a variety of other methods as useful techniques. These techniques included an eclectic approach utilizing patient education, postural advice, Maitland principles, pelvic stabilization, and various strengthening, stretching, and conditioning exercises.

A case study, written by Beattie, also emphasized the benefits of utilizing an eclectic approach for treatment of the low back.[44] In this case study, Beattie reiterated the controversy of the insufficient evidence to establish the efficacy of manual techniques and describes an eclectic treatment approach for an individual with low back pain. Beattie's intervention included Maitland P-A glides, McKenzie prone press-ups, therapeutic exercise, and posture correction. Through utilizing this eclectic treatment plan, the patient experienced decreased pain and improved lumbar range of motion after two therapy treatments.

Understanding that many therapists utilize eclectic treatment interventions and finding positive results from its use, along with the current health care reform taking a more critical view of the effectiveness of physical therapy techniques, emphasizes the necessity to determine the most effective and efficient treatment interventions.[11] The current study, will attempt to determine the most useful technique and answer if it is more appropriate to use McKenzie exclusively or is it more appropriate to use a more eclectic approach utilizing McKenzie in conjunction with Mulligan mobilizations.

CHAPTER III

METHODOLOGY

Subjects

A retrospective chart review of twenty-two adult subjects, eighteen years of age or older, with a diagnosis of low back strain (793.3) or low back derangement (847.3) treated at a North Dakota physical therapy clinic by a specific physical therapist were included in this study. To be eligible, the subject must 1) be treated with either McKenzie techniques alone or McKenzie techniques with Mulligan mobilization, 2) have a specific diagnosis for low back derangement, and 3) must have completed the entire PT program.

Procedure

Prior to collection of data, written consent from the University of North Dakota IRB board, the physical therapy facility, and the treating physical therapist were obtained (see appendix).

Using the clinic's outcome services, a cross-reference between the physical therapists name and the ICD-9 codes 739.9 and 847.3 were utilized to obtain a list of possible patient charts to be reviewed. Along with possible subjects, the list also provided the patient's admit date, discharge date, total number of visits, length of stay, percent improvement, functional level at admit and discharge, and percent capability to return to work.

Charts of all possible subjects were then pulled and reviewed to determine if the subject fit the eligibility criteria. Subjects who fit the criteria were considered eligible and were included in the study.

The information received through the cross-reference query were recorded on a data collection form. To determine if the therapist used McKenzie treatment alone or McKenzie treatment with Mulligan mobilizations, as well as, to determine the patient's age, sex, and the use of other physical therapy techniques, review of the patients' charts were performed and the data recorded on the data collection form. Financial information, including cost per treatment and total cost of physical therapy services, were also recorded through review of the clinic's financial database. Total cost of physical therapy services included charges for evaluation, therapeutic exercises, joint mobilization, and any other physical therapy technique or modality used. Cost per treatment was calculated by dividing the total cost of physical therapy services by total number of visits.

Data Analysis

Data was analyzed using descriptive and analytical statistics to compare subjects treated with McKenzie techniques alone versus McKenzie techniques with Mulligan mobilization.

The Statistical Power for the Social Sciences (SPSS 8.0 ^{TM}) program was utilized for statistical analysis. The data was analyzed using a one-tail design with a level of significance of $p < .05$.

An independent sample T-test was chosen to compare the differences between the McKenzie group and the McKenzie with Mulligan mobilization group. This test was used to indicate differences between the groups for: age, total cost of physical therapy

services, average cost per treatment, total number of treatments, initial and final pain levels, total number of modalities used, percent improvement, work status, initial and final ADL status, and initial and final functional status.

CHAPTER IV

RESULTS

A total of twenty-two patients were considered eligible for this study based on the criteria established in the methods section. Sixteen subjects were treated with McKenzie techniques and six subjects were treated with McKenzie techniques and Mulligan mobilization. Of the twenty-two subjects, twelve were diagnosed under the ICD-9 code 739.3 and ten subjects were coded under 847.2. In regards to subjects' gender, thirteen subjects were male and nine were female. The mean age of the McKenzie group was 42.8 (SD=11.63) and the mean age for the McKenzie with Mulligan mobilization group was 38.83 (SD=8.84). Independent sample T-test showed that the groups were not significantly different in age (p= .313). Tables 1-3 present the descriptive and T-test statistics for the McKenzie group and McKenzie with Mulligan mobilization group.

One of the main purposes of outcomes studies is to track costs of physical therapy services and cost per physical therapy treatment. The average total cost of physical therapy service, for the McKenzie treated group was $450 (SD=289) and for the McKenzie with Mulligan mobilization group the averaged cost was $612 (SD=342). Statistical comparison showed that this was not a significant difference (p=.991). The mean cost per physical therapy treatment also revealed that the groups were not significantly different (p=.098) with the McKenzie group averaging $73 (SD=18.40) per treatment and the McKenzie with Mulligan mobilization group averaging $90

Table 1. Descriptive Statistics for Patient's Undergoing McKenzie PT Intervention

Variables	n	X	SD	Maximum	Minimum
Age	18	41.89	11.47	60	20
Total PT Cost	16	450.13	289.58	1088	163
Average Cost of PT Visit	16	73.67	18.41	96	47.6
Total Number of Treatments	16	6.25	3.70	15	2
Duration of PT Services	16	21.63	17.81	64	4
Initial Pain Rating	14	6.43	2.06	9	2
Final Pain Rating	13	1.46	1.13	4	0
Number of Different Modalities Used	15	2.33	1.05	4	1
Percent Improvement	14	88.79	12.46	100	60
Initial ADL Rating	15	3.24	0.60	4	2.33
Final ADL Rating	13	4.69	0.33	5	4.33
Initial Function Rating	15	2.99	0.60	4.09	2.09
Final Function Rating	13	4.64	0.50	5	3.45

Table 2. Descriptive Statistics for Patient's Undergoing McKenzie with Mulligan Mobilization PT Intervention

Variables	n	x	SD	Maximum	Minimum
Age	7	40	8.64	61	48
Total PT Cost	6	612.04	342.09	1282	337
Average Cost of PT Visit	6	90.35	10.99	108.25	78.6
Total Number of Treatments	6	6.67	3.27	13	4
Duration of PT Services	6	25.50	20.34	58	10
Initial Pain Rating	5	7.00	2.00	10	5
Final Pain Rating	4	0.50	0.58	1	0
Number of Different Modalities Used	6	2.83	1.33	5	2
Percent Improvement	5	97.8	4.38	100	90
Initial ADL Rating	4	3.69	0.69	4.5	3
Final ADL Rating	3	4.83	0.29	5	4.5
Initial Function Rating	5	3.08	0.65	4.18	2.64
Final Function Rating	3	5.00	0.00	5	5

Table 3. Independent Sample T-Test Analysis for Comparison of McKenzie Intervention to McKenzie with Mulligan Mobilization Intervention.

Variables	n	x	SD	t	p
Age					
McKenzie	18	41.89	11.47	.446	.335
McKenzie & Mulligan	7	40	8.64		
Total PT Cost					
McKenzie	16	450.13	289.58	-1.03	.991
McKenzie & Mulligan	6	612.04	342.09		
Average Cost of PT Visit					
McKenzie	16	73.67	18.41	-2.60	.098
McKenzie & Mulligan	6	90.35	10.99		
Total Number of Treatments					
McKenzie	16	6.25	3.7	-.257	.657
McKenzie & Mulligan	6	6.67	3.27		
Duration of PT Services					
McKenzie	16	21.63	17.81	-.411	.481
McKenzie & Mulligan	6	25.50	20.34		
Initial Pain Rating					
McKenzie	14	6.43	2.06	-.544	.989
McKenzie & Mulligan	5	7.00	2.00		
Final Pain Rating					
McKenzie	13	1.46	1.13	2.26	.285
McKenzie & Mulligan	4	0.50	0.58		
# of Different Modalities Used					
McKenzie	15	2.33	1.05	-.825	.341
McKenzie & Mulligan	6	2.83	1.33		
% Improvement					
McKenzie	14	88.79	12.46	-2.33	.016*
McKenzie & Mulligan	5	97.8	4.38		
Initial ADL Rating					
McKenzie	15	3.24	0.60	-1.19	.737
McKenzie & Mulligan	4	3.69	0.69		
Final ADL Rating					
McKenzie	13	4.69	0.33	-1.08	.505
McKenzie & Mulligan	3	4.83	0.29		
Initial Function Rating					
McKenzie	15	2.99	0.60	-.261	.951
McKenzie & Mulligan	5	3.08	0.65		
Final Function Rating					
McKenzie	13	4.64	0.50	-.260	.062
McKenzie & Mulligan	3	5.00	0.00		

* Significant at $p < .05$

(SD=10.99) per treatment. Figures 4 and 5 provides a graphical comparison of the intervention groups for total cost of treatment and for average cost per PT treatment.

Along with costs, duration of physical therapy services and number of treatments are also important factors to be compared in outcome studies. The average duration of physical therapy services for the McKenzie group was 22 days (SD=17.8) and for the McKenzie with Mulligan mobilization group the average was 26 days (SD=20.3) from initial evaluation to discharge. These results revealed that the groups were not significantly different (p=.481). The total number of physical therapy treatments also showed no significant difference between groups (p=.567). The McKenzie group averaged 6.25 (SD=3.69) treatments and the McKenzie with Mulligan mobilization group averaged 6.67 (SD=3.26) treatments. Figures 6 and 7 demonstrate these comparisons for the duration of PT services and for total number of PT treatments.

Upon initial evaluation and discharge of physical therapy services, a pain level was tracked and statistically compared. Each patient subjectively rated their pain level on a 0 to 10 scale, with 0 being "no pain" and 10 being "excruciating pain". The initial pain level for the McKenzie group was 6.4 (SD=2.06) and the pain level for the McKenzie with Mulligan mobilization group was 7.0 (SD=2.00). This was not significantly different (p=.989). Upon completion of the physical therapy program, the subjective pain rating was repeated. The McKenzie group mean score was 1.5 (SD=1.12) and the McKenzie with Mulligan mobilization mean was 0.5 (SD=.577). Statistical analysis revealed that this was not a significant difference between the groups (p=.285). Comparisons of pain levels at initial evaluation and discharge for each treatment group are

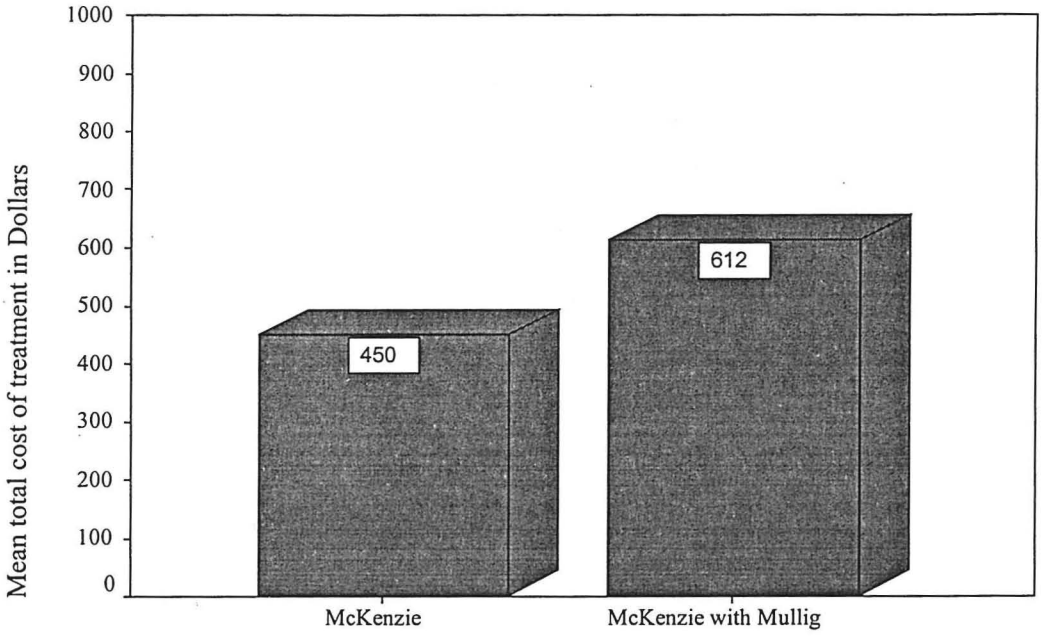

Figure 4. Comparison of McKenzie group versus McKenzie with Mulligan mobilization group for mean total cost of treatment in dollars.

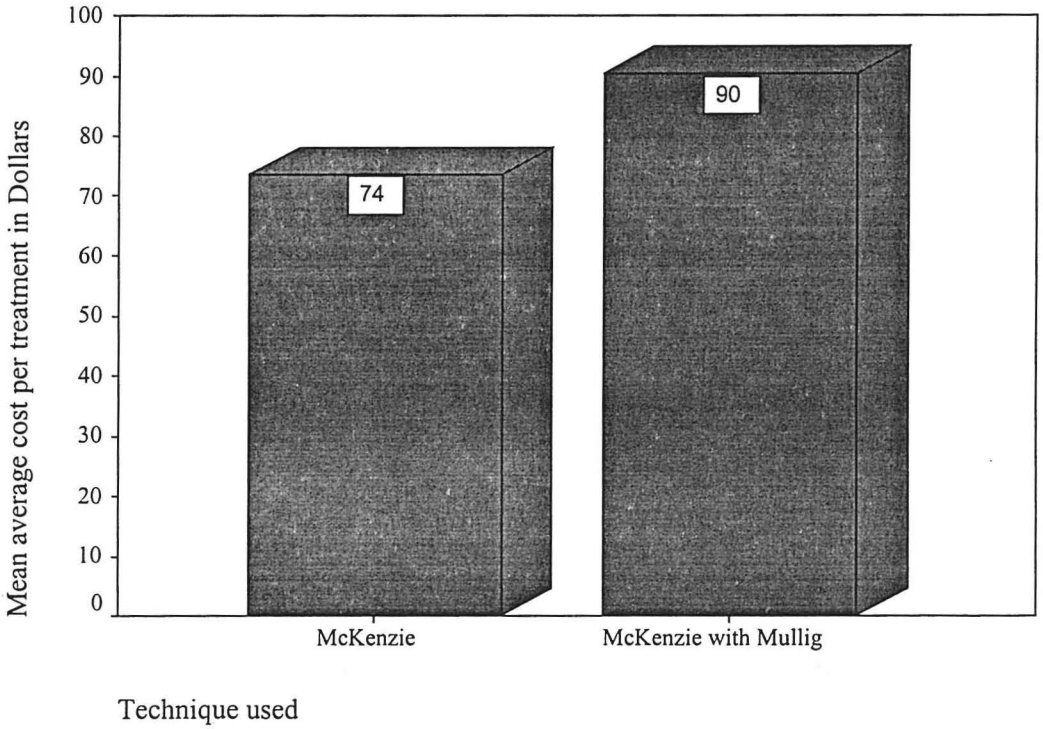

Figure 5. Comparison of McKenzie group versus McKenzie with Mulligan mobilization group for mean average cost per treatment.

represented in figure 8.

Modality use was also tracked and compared for total number of the different modalities used throughout the physical therapy program. The McKenzie group received an average of 2.33 (SD=1.05) different modalities throughout the physical intervention while the McKenzie with Mulligan mobilization group received 2.83 (SD=1.33) modalities. This was not a significant difference for modality use (p=.341).

At the completion of physical therapy the patient subjectively rated their improvement during therapy based on a percentage, with 0% indicating "no improvement" and 100% indicating "full recovery". For the McKenzie group the mean percent improvement was 88% (SD=12.46) and for the McKenzie with Mulligan mobilization group the mean was 97% (SD=4.38). This was significantly different between the two groups (p=.016). This information is presented in figure 9.

Activities of daily living (ADL's), including reading, headaches, sleep, and recreation, were tracked and subjectively rated on a score from 1 to 6 (a score of 6 was considered not applicable), with a score of 1 in each category indicating "unable" and 5 indicating "unrestricted and fully capable". On initial evaluation, the McKenzie group averaged a score of 3.23 (SD=.3.24) and the McKenzie with Mulligan mobilization group averaged 3.69 (SD=.69). This was not significantly different (p=.737). The same information was also rated at the end of physical therapy with the mean score of the McKenzie group being 4.63 (SD=.33) and the mean for the McKenzie with Mulligan mobilization group was 4.83 (SD=.29). This was not significant between the treatment groups (p=.062). Figure 10 presents this comparison between the groups for ADL function.

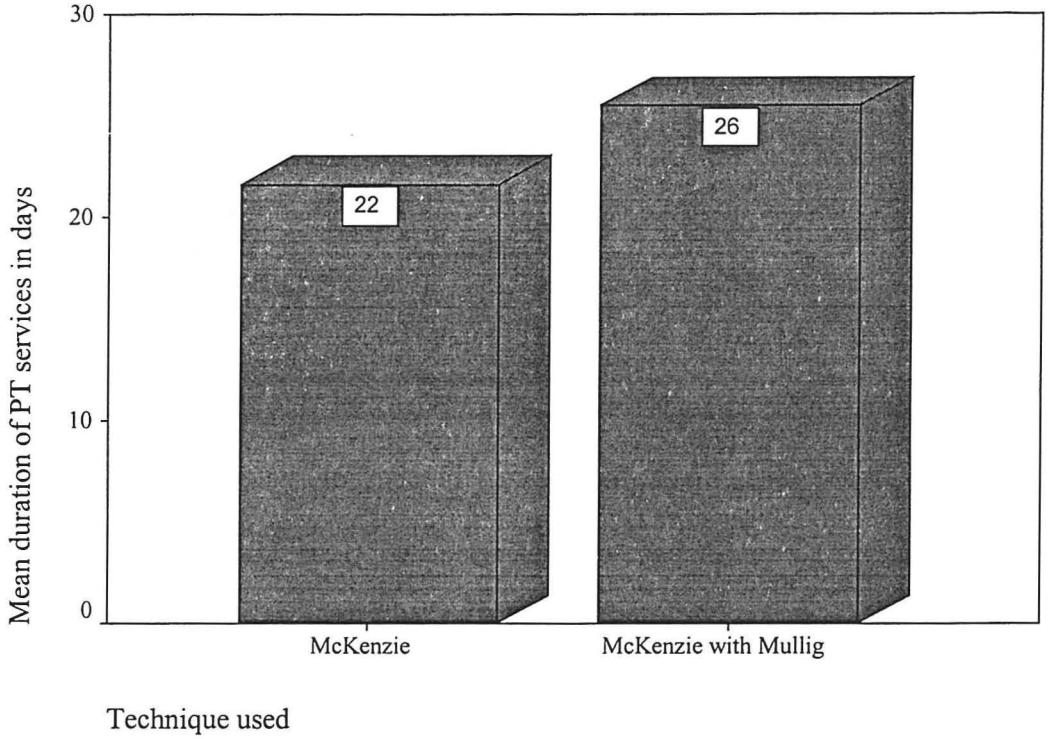

Figure 6. Comparison of McKenzie group versus McKenzie with Mulligan mobilization group for mean duration of PT services.

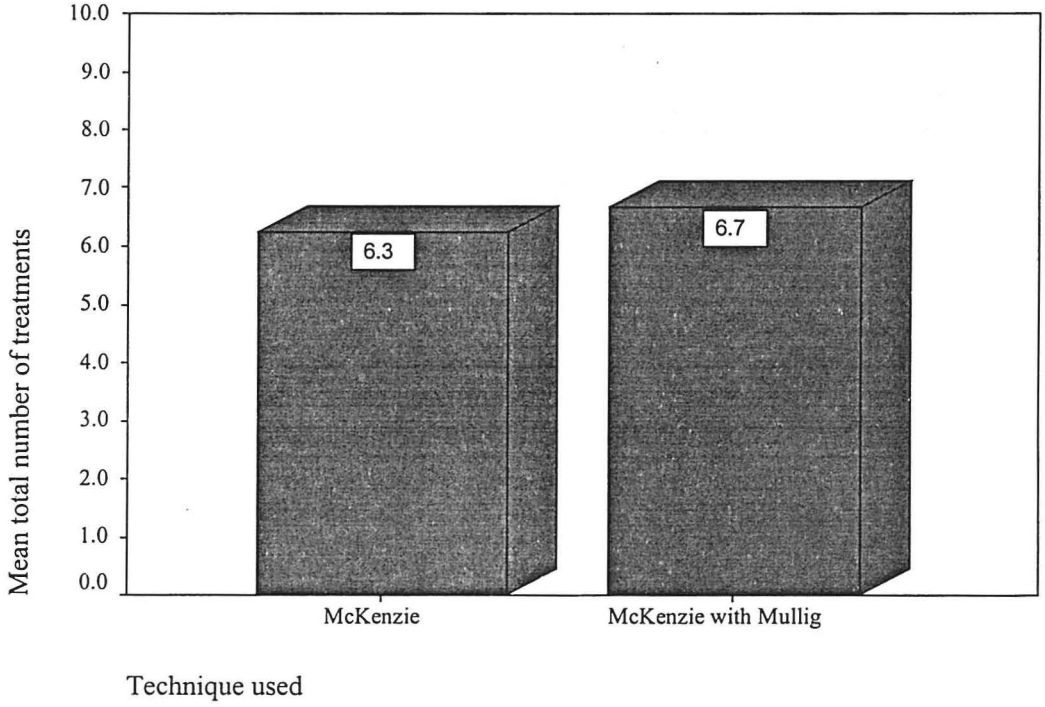

Figure 7. Comparison of McKenzie group versus McKenzie with Mulligan mobilization group for mean total number of treatments.

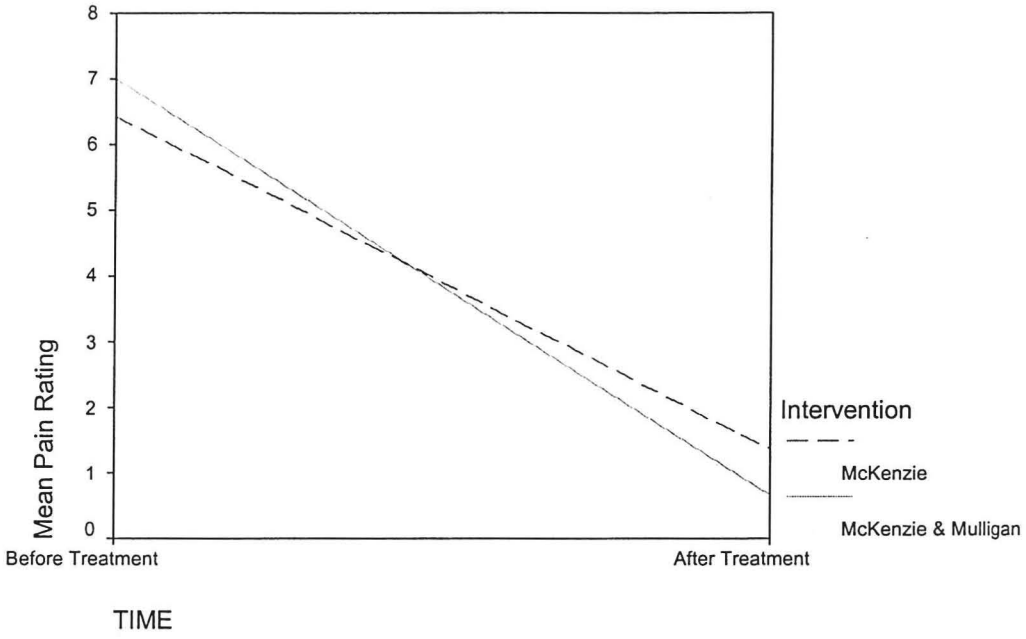

Figure 8. Comparison of McKenzie group versus McKenzie with Mulligan mobilization group for subjective pain level at initial evaluation and at discharge.

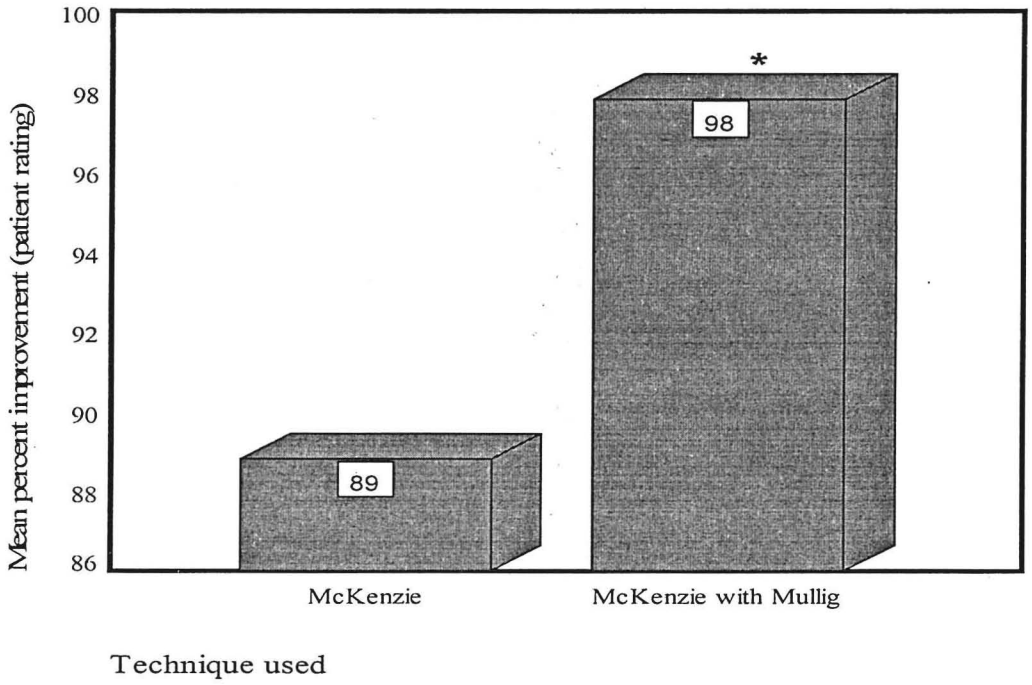

Figure 9. Comparison of McKenzie group versus McKenzie with Mulligan mobilization group for subjective rating of percent improvement. (*= $p<.05$)

Lastly, functional capabilities were compared. Functional capabilities included: driving, arms overhead, sitting, lifting weights, lifting from floor, work ability, squatting body weight, walking, standing, bending, and unilateral stance. These activities were rated by the physical therapist and given a score from 1 to 6 (6= not applicable), with 1 being "unable" and 5 being "unrestricted and fully capable". At initial evaluation, the McKenzie treated group received a mean score of 2.99 (SD=.60) and the McKenzie with Mulligan mobilization treated group received a mean score of 3.08 (SD=.65). This was not a significant difference. At the completion of therapy, the McKenzie group received a mean score of 4.64 (SD=.50) and the McKenzie with Mulligan mobilization group received a mean score of 5.00 (SD=0). This was not significantly different between the groups. Figure 11 represents the comparisons of the McKenzie group versus McKenzie with Mulligan mobilization group for functional ability.

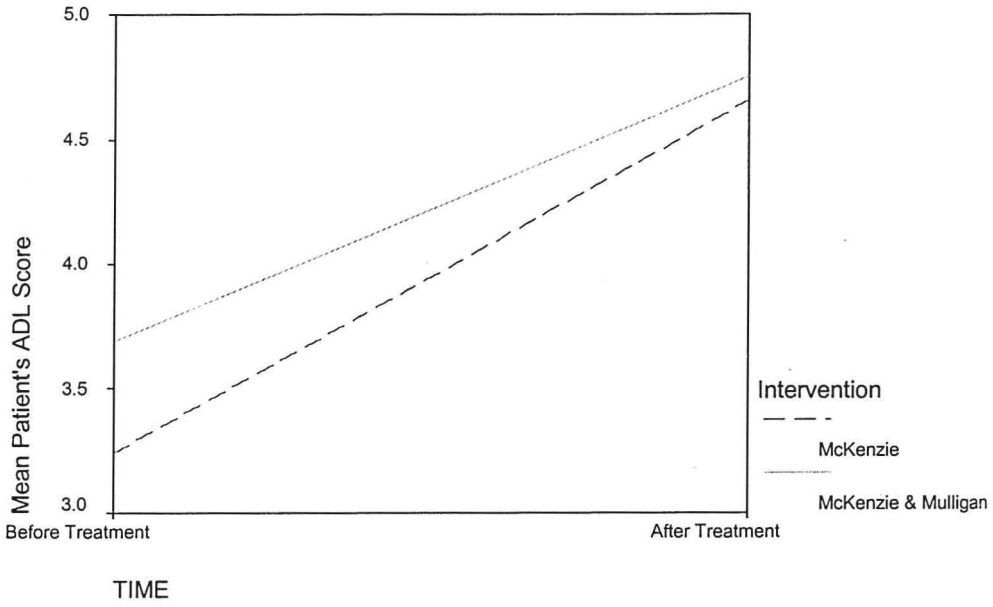

Figure 10. Comparison of McKenzie group versus McKenzie with Mulligan mobilization group for ADL ability at initial evaluation and at discharge.

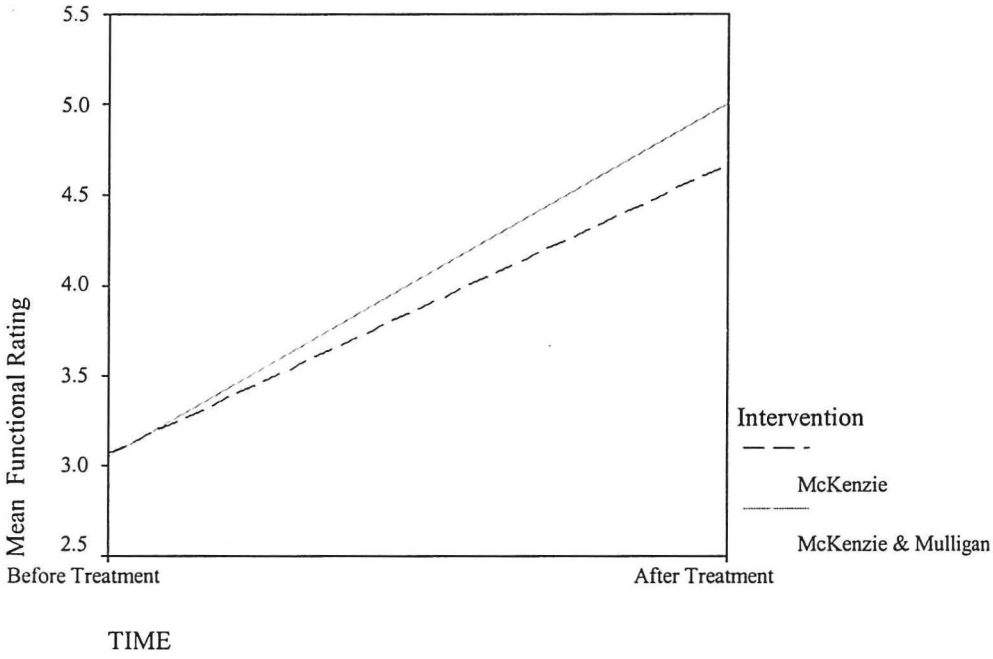

Figure 11. Comparison of McKenzie group versus McKenzie with Mulligan mobilization group for functional ability at initial evaluation and at discharge.

CHAPTER V

DISCUSSION

The purpose of this study was to perform a chart review to compare the outcomes of treatments on patients with low back derangement utilizing McKenzie techniques alone in comparison to McKenzie techniques with Mulligan mobilizations. Through independent sample T-test, statistical analysis indicated that there were no significant differences for age, total treatment costs, average cost per PT treatment, duration of PT services, number of PT treatments, initial and final pain level ratings, number of modalities used, initial and final ADL abilities, and for initial and final functional abilities. One indicator, subjective rating of percent improvement, did reveal a significant difference between the intervention groups. Despite many of the indicators showing no significant difference, several trends can be extrapolated based on this particular set of data.

As healthcare progresses to increased restrictions on coverage of PT services, research such as this study must be performed to determine the most cost-effective and efficient PT intervention. Although the current study showed no significant difference in total treatment cost, average cost per PT treatment, duration of PT services, and for number of PT treatments, specific trends and differences were evident. In each of these categories, the McKenzie group was on average $162 less expensive for total cost of treatment, $17 more economical per PT visit, required 3.9 days less from initial

evaluation to discharge, as well as 0.42 treatments less than the McKenzie with Mulligan mobilization group. From the data collected in this study, the results indicate the clinical application of a McKenzie protocol alone may be a more cost-effective and efficient intervention than the McKenzie with Mulligan mobilization treatment.

Along with determining which intervention is more cost-effective and efficient, determining the patient's subjective rating of their improvement is also an important factor to consider, as for many patients, improvement is based on decreasing their pain level. In this study, there was no significant difference between initial and final pain rating, but a specific trend was observed between the two intervention groups. The trend showed that the McKenzie with Mulligan mobilization group began therapy at a more painful level indicated by 0.57 points higher than the McKenzie group, but completed PT at a lower pain level at an average of 1 point. This difference in pain, along with subject rating of percent improvement showing to have a significant difference between the treatment groups, may indicate that the McKenzie with Mulligan mobilization group may have a larger impact on the patient's subjective response to therapy. Clinically, this may indicate that the McKenzie with Mulligan mobilization intervention may be more effective in reduction of the patient's pain, which may increase the patient's subjective view of their improvement in PT.

Modality use throughout the PT services was also tracked and found to have no significant difference between the groups. On average, the McKenzie with Mulligan mobilization group received .5 more modalities. This is a minimal difference and may have no major implications on clinical intervention.

One of the main goals of PT is to return the patient to the highest level of activity and ability. For this reason, this study tracked ADL and functional capability to determine which group has a larger impact on these abilities. Statistical analysis, again, showed no significant difference between the two interventions, but the McKenzie with Mulligan mobilization group appeared to have a slightly larger effect on improving ADL and functional abilities. The comparison of ADL ability showed that McKenzie with Mulligan mobilization group starting at a slightly higher level by an average of .45 points and also finished at a higher level by .2 points. Functional ability ratings revealed no significant difference for the initial evaluation, but the McKenzie with Mulligan mobilization group completed PT at an average of 5 out of 5, which was .36 points higher than the McKenzie group. This data indicates that clinically, the McKenzie with Mulligan mobilization intervention may have a very slight advantage in improving the patient's ADL and functional abilities.

It is important to note that these trends and clinical assumptions are valid for only this sample group and cannot be extrapolated or concluded to the entire population. The Central Limit Theorem of statistics states that when a sample size is less than thirty, the results of comparing groups cannot be generalized to the population due to the increased variability created by utilizing a small sample size.[45]

This limitation of this study is based on having less than thirty subjects in each treatment group. The McKenzie group had sixteen subjects in the group and the McKenzie with Mulligan mobilization group had only six subjects.

Furthermore, with the McKenzie with Mulligan mobilization group having only six subjects, the means that were reported may not be an appropriate representation of the

population. Fewer subjects result in fewer numbers that contribute to the mean, which may skew the reported averages for the McKenzie with Mulligan mobilization group.

A third limitation of this study was some subjects' charts reported incomplete data. As a result of less data, fewer numbers were utilized for statistical analysis, which again may skew the mean and thus report inaccurate and possibly deceiving results.

A fourth limitation of this study was some subjects being more involved than others. In both groups, there were patients who reported symptoms that radiated further down the lower extremity and who were more chronic than others. This resulted in longer duration of PT and therefore higher costs. This particularly affects the smaller McKenzie with Mulligan mobilization group because higher numbers will produce a mean that may be higher than if there were more subjects to counter these few aberrant subjects.

A final limitation was the physical therapist's proficiency of utilizing the Mulligan mobilization techniques. The physical therapist whose charts were reviewed is McKenzie certified and has incorporated McKenzie techniques into their treatments for several years. In contrast, the therapist has only incorporated Mulligan mobilizations into their treatment intervention for one-year. The therapist's lack of experience using Mulligan mobilizations may be a contributing factor to the McKenzie with Mulligan mobilization group yielding higher means for costs and duration of PT services.

It is recommended that for future studies the researcher(s) utilize the following: 1) a prospective study to randomly select appropriate patient's to one of the two groups prior to actual intervention, 2) greater than thirty subjects in each group, 3) compare patients with equivalent diagnoses (for example- comparing McKenzie intervention for derangement 3 with McKenzie with Mulligan mobilizations for derangement 3), and 4)

performing the study when the therapist has more experience in utilizing Mulligan mobilizations.

CHAPTER VI

CONCLUSION

In conclusion, there was no significant difference between the McKenzie intervention when compared to McKenzie with Mulligan mobilization intervention for age, total treatment costs, average cost per PT treatment, duration of PT services, number of PT treatments, initial and final pain level ratings, number of modalities used, initial and final ADL abilities, and for initial and final functional abilities. The only indicator that was found to be significantly different was the patient's subjective rating of percent improvement. Although, there was only one indicator found to be significantly different between groups, two main trends were observed based on this particular sample of patient subjects.

The first trend observed was the McKenzie group appearing to be more cost effective and more efficient compared to the McKenzie with Mulligan mobilization group. The second trend observed showed the McKenzie with Mulligan mobilization group displaying slightly greater improvements in comparison to the McKenzie group for pain, ADL ability, functional ability, and a significant difference for subjective percent improvement.

Despite the study finding no significant difference for most of the categories, the trends observed may indicate some clinical applications based on the findings of this particular research study. Based on today's healthcare system, a system that encourages practitioners to provide the most cost-effective and efficient treatments to lower rising

healthcare costs, these trends observed in this study may provide preliminary insight on the use of McKenzie techniques with Mulligan mobilizations. Strictly based on the results of this research, the McKenzie intervention is the more cost-effective and efficient treatment in comparison to McKenzie with Mulligan mobilizations. Although the McKenzie with Mulligan mobilization group displayed some slight advantages in pain, percent improvement, ADL ability , and functional ability, these improvements are minimal and may be outweighed by the economic savings and the efficiency of the McKenzie intervention.

APPENDIX

___ EXPEDITED REVIEW REQUESTED UNDER ITEM ____ (NUMBER[S]) OF HHS REGULATIONS
_x_ EXEMPT REVIEW REQUESTED UNDER ITEM _4?_ (NUMBER[S]) OF HHS REGULATIONS

UNIVERSITY OF NORTH DAKOTA HUMAN SUBJECTS REVIEW FORM FOR NEW PROJECTS OR PROCEDURAL REVISIONS TO APPROVED PROJECTS INVOLVING HUMAN SUBJECTS

Please include ALL information and check ALL blanks that apply.

PRINCIPAL INVESTIGATOR: David Relling, Jason J Vila **TELEPHONE:** 777-2831 **DATE:** 3/30/2000

ADDRESS TO WHICH NOTICE OF APPROVAL SHOULD BE SENT: PT Department, PO Box 9037, Grand Forks, ND 58202-9037

SCHOOL/COLLEGE: Medicine **DEPARTMENT:** Physical Therapy **PROPOSED PROJECT DATES:** 4/1/2000-4/1/2001
(E.g., A&S, Medicine, EHD, etc.) (Month/Day/Year)

PROJECT TITLE: An Outcome Comparison on the Use of McKenzie Techniques with and without Mulligan Mobilizations on the Treatment of Low Back Derangement

FUNDING AGENCIES (Include copy of proposal): _____

TYPE OF PROJECT (Check ALL that apply):

_x_ NEW PROJECT ___ CONTINUATION ___ RENEWAL ___ DISSERTATION OR THESIS RESEARCH _x_ STUDENT RESEARCH PROJECT

___ CHANGE IN PROCEDURE FOR A PREVIOUSLY APPROVED PROJECT

DISSERTATION/THESIS ADVISER, OR STUDENT ADVISER: David Relling PT, MS

PROPOSED PROJECT: ___ INVOLVES NEW DRUGS (IND) ___ INVOLVES NON-APPROVED USE OF DRUG _x_ INVOLVES A COOPERATING INSTITUTION

IF ANY OF YOUR SUBJECTS FALL IN ANY OF THE FOLLOWING CLASSIFICATION, PLEASE INDICATE THE CLASSIFICATION(S):

☐ MINORS (<18 YEARS) ☐ PREGNANT WOMEN ☐ MENTALLY DISABLED ☐ FETUSES ☐ PERSONS WITH
☐ PRISONERS ☐ ABORTUSES ☒ UND STUDENTS (>18 YEARS)

IF YOUR PROJECT INVOLVES ANY HUMAN TISSUE, BODY FLUIDS, PATHOLOGICAL SPECIMENS, DONATED ORGANS, FETAL MATERIAL, OR PLACENTAL MATERIALS, CHECK HERE ____

IF YOUR PROJECT HAS BEEN\WILL BE SUBMITTED TO ANOTHER INSTITUTIONAL REVIEW BOARD(S), PLEASE LIST NAME OF BOARD(S): _____

Status: ____ Submitted; Date _____ ____ Approved; Date _____ ____ Pending

1. **ABSTRACT:** (LIMIT TO 200 WORDS OR LESS AND INCLUDE JUSTIFICATION OR NECESSITY FOR USING HUMAN SUBJECTS.)

Effective research and outcome studies are currently lacking evidence to support the use of various physical therapy techniques. These studies are essential to the profession in order to justify the efficiency and validity of physical therapy services as they relate to patient care and third party reimbursement. One of the skill that physical therapists utilize which lacks such evidence is the use of manual therapy techniques. This research study will perform an outcome assessment on the use of McKenzie techniques with and without Mulligan mobilizations on treatment of low back disc bulges and the associated pressure on the nerve roots, otherwise known as derangement. McKenzie techniques are repeated movements and postural positioning commonly used for treatment and evaluation of spinal problems. Mulligan mobilizations are repositioning and movements of spinal joints frequently used by physical therapists for back realignment. The study will review charts of a selected physical therapist who has used these techniques and evaluate each in regards to the effectiveness on pain, range of motion, duration of treatment, total number of treatments, and total costs of therapy services. The techniques will be evaluated through

statistical comparison to determine the more effective and efficient therapy technique for low back derangement.

PLEASE NOTE: Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal (if seeking outside funding).

2. PROTOCOL: (Describe procedures to which humans will be subjected. Use additional pages if necessary. Attach any surveys, tests, questionnaires, interview questions, examples of interview questions (if qualitative research), etc., the subjects will be asked to complete.)

This study is a retrospective study of completed patient charts documenting techniques generally used in the physical therapy setting. Written consent from the physical therapy facility and the physical therapist whose patient charts will be reviewed will first be obtained. Sixty charts written by this selected therapist will be reviewed. The charts will be selected based upon fitting the criteria of a low back strain (739.3 ICD-9 code) or derangement diagnosis (847.3 ICD-9 code). ICD-9 billing codes are established and commonly used for billing of physical therapy services.

Each chart will then be reviewed following the attached data collection form. Data collected will include: the type of manual therapy technique used, patient's age, patient's sex, diagnosis, ICD-9 billing code, if diagnosis is chronic or acute, total cost of treatments, duration of therapy services, average cost per treatment, pain level, low back range of motion, functional limitations, and the use of other physical therapy techniques.

Following collection of this data, data analysis will then be performed comparing the McKenzie technique group and the McKenzie technique with Mulligan mobilization group in regards to the effectiveness on pain level and range of motion as they relate to total number of treatments, total cost of treatments, average cost per treatment, and duration of physical therapy services. Data analysis will then be performed to determine the significance of the use of McKenzie techniques compared to McKenzie techniques with Mulligan mobilizations on treatment of low back derangement.

3. **BENEFITS:** (Describe the benefits to the individual or society.)

The main benefit of this study are the benefits that the physical therapy patient will receive. With outcome studies such as this proposed study, physical therapy techniques can be studied further to determine which techniques will allow the patient to recover and improve function in the most effective manner. Secondly, with the results of this study, physical therapy clinicians can become more knowledgeable regarding which manual therapy techniques are the most effective and efficient, from a treatment and economic stand point. Thirdly, evidence may be used to support the effectiveness of these treatments on pain, range of motion, costs, duration of treatments, and number of treatments and be used to provide support for reimbursement by third party payers for the use of these techniques.

4. **RISKS:** (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psychological, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to insure the confidentiality of data obtained, debriefing procedures, storage of data for the required three years, final disposition of data, etc.

With a review of a patient chart, patient confidentiality is a concern. To protect the identity of the patient's charts to be reviewed, identification numbers will be issued. Any information that is obtained regarding this study that can identify the patient will be kept confidential. All names, identification numbers, and data will be kept in a locked cabinet in room 1531 at the University of North Dakota physical therapy department for a duration of three years following completion of this study. Only those associated with conducting this study will have access to this information. All data will be destroyed at the end of the three-year period.

5. **CONSENT FORM:** Attach a copy of the **CONSENT FORM** to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no **CONSENT FORM** is to be used, document the procedures to be used to assure that infringement upon the subject's rights will not occur.

   Describe where signed consent forms will be kept for the required 3 years, including plans for final disposition or destruction.

No consent forms will be used as this is a chart review and patient identity will remain anonymous through assignment of identification numbers for the purpose of this study.

A letter of permission and support from the managing physical therapist at the facility where the charts will reviewed is attached.

6. For **FULL IRB REVIEW** forward a signed original and fifteen (15) copies of this completed form, including fifteen (15) copies of the proposed consent form, questionnaires, examples of interview questions, etc. and any supporting documentation to the address below. An original and 19 copies are required for clinical medical projects. In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency should be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 7 copies if the proposal is clinical medical.

   Office of Research & Program Development
   University of North Dakota
   Grand Forks, North Dakota 58202-7134

   On campus, mail to: Office of Research & Program Development, Box 7134, or drop it off at Room 105 Twamley Hall.

   For **EXEMPT** or **EXPEDITED REVIEW** forward a signed original, including a copy of the consent form, questionnaires, examples of interview questions, etc. and any supporting documentation to one of the addresses above. In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency should be attached to the completed Human Subjects Review Form.

The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedures governing the use of human subjects.

SIGNATURES:

Principal Investigator	Date
Project Director or Student Adviser	Date
Training or Center Grant Director	Date

(Revised 4/1998)

REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW

University of North Dakota Institutional Review Board

Date: April 10, 2000 **Project Number:** IRB-200004-202

Name: David Relling, Jason J. Vila **Department/College:** Physical Therapy

Project Title: An Outcome Comparison on the Use of McKenzie Techniques With and Without Mulligan Mobilizations on the Treatment of Low Back Derangement

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on April 24, 2000 and the following action was taken:

☐ Project approved. **EXPEDITED REVIEW** Category No. _____
Next scheduled review is on: _____

☑ Project approved. **EXEMPT REVIEW** Category No. 4
No periodic review scheduled unless so stated in the Remarks Section.

☐ Project approved **PENDING** receipt of corrections/additions. These corrections/additions should be submitted to ORPD for review and approval. **This study may NOT be started UNTIL final IRB approval has been received.** (See Remarks Section for further information.)

☐ Project approval **deferred. This study may not be started until final IRB approval has been received.** (See Remarks Section for further information.)

☐ Project **denied.** (See Remarks Section for further information.)

REMARKS: Any changes in protocol or adverse occurrences in the course of the research project must be reported immediately to the IRB Chairperson or ORPD.

PLEASE NOTE: Requested revisions for student proposals MUST include adviser's signature.

Kurt 4-24-00

Signature of Designated IRB Member
UND's Institutional Review Board

Date

cc: David Relling, Adviser
Dean, School of Medicine

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 310 Form may be required. Contact ORPD to obtain the required documents.

1(1/98)

Data Collection Form

Chart Identification Number:_____

Technique used (circle one):

McKenzie Alone or McKenzie with Mulligan Mobilization

Diagnosis/ICD-9 Code (circle one):

Lumbar Strain/739.3 or Lumbar Derangement/847.3

Patient Age: _____
Sex: _____

How Long Since Initial Problem (weeks):

1 2 3 4 5 6 7 8 Chronic

Total cost of Treatment: $_____
Total Number of Treatments: _____
Average cost per Treatment: $_____
Date of Initial Evaluation: _____
Date of Discharge:_____
Duration of PT Services: _____

Pain Level (out of 10):

Initial: _____/10__ **Discharge:** _____/10__

Pain Location:

Initial: _____ **Discharge:** _____

Derangement #:

Initial: _____ **Discharge:** _____

Modalities Used (circle):

US	Electrical Stimulation
Heat	Cold
Traction	Pool
Soft Tissue Mobilization	Massage
Joint Mobs	Ther-ex

Data Collection Form

Chart Identification Number:_____

Is the Patient Currently Working:

Initial: Yes or No **Discharge: Yes or No**

Which best describes the Patient's Working Status:

Initial:

(a) Working without restrictions
(b) Working without restrictions (modified duty)
(c) Unable to work due to injury
(d) Homemaker
(e) Student
(f) Retired
(g) Other _____

Discharge:

(a) Working without restrictions
(b) Working without restrictions (modified duty)
(c) Unable to work due to injury
(d) Homemaker
(e) Student
(f) Retired
(g) Other _____

Percent Return to Work _____

Mark the following which best describes the patient's ability to perform or how it affects the patient's daily living (circle initial, mark an "x" for discharge):

	Unable	Significantly Limited	Limited	Mildly Limited	Unrestricted/ Fully Capable	Not Applicable
Reading	1	2	3	4	5	6
Headaches	1	2	3	4	5	6
Sleeping	1	2	3	4	5	6
Recreation	1	2	3	4	5	6

FUNCTIONAL LEVEL: Intake _____ **D/C**_____

Data Collection Form

Chart Identification Number:_____

Number of Repeated Repetitions in Flexion:

Initial: _____ **Discharge:** _____

Mark the following (circle initial, mark an "x" for discharge):

	Unable	Significantly Limited	Limited	Mildly Limited	Unrestricted/ Fully Capable	Not Applicable
Arms Overhead	1	2	3	4	5	6
Sitting	1	2	3	4	5	6
Lifting (weights)	1	2	3	4	5	6
Lifting (Lift from floor)	1	2	3	4	5	6
Work (ability)	1	2	3	4	5	6
Squatting (body weight)	1	2	3	4	5	6
Walking	1	2	3	4	5	6
Standing	1	2	3	4	5	6
Bending (ability)	1	2	3	4	5	6
Unilateral Stance	1	2	3	4	5	6

Stretches: _____

Therapeutic Exercises: _____

_____

Patient's Functional Limitations: _____

_____

Additional Information: _____

_____

HEALTHSOUTH
Sports Medicine & Rehabilitation Center

To Whom It May Concern:

Re: Research Project for Jason Vila and Dave Relling

As the administrator for Healthsouth in Grand Forks ND, I agree to provide the necessary information and access to the information required to complete this research project. I look forward to being a part of this research project. If the IRB has any questions of myself please feel free to call me at any time. Thank you

Sincerely

C Lafreniere PT

Clifford Lafreniere PT cert MDT

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