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# MEASURING THE EFFICACY OF REHABILITATION FOR LOW BACK PAIN



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## Introduction

Medical rehabilitation has placed an increasing emphasis on the need to evaluate outcomes, with the goal of reliable and valid measures which treatment efficacy can be assessed. Implementation and analysis of both generic health-related and disease-specific outcomes in clinical practice have the potential to improve quality, help set clinical guidelines, and impact clinical decisions regarding each individual patient [1, 2]. The use of condition specific, standardized outcome measures provides a quantitative assessment of change in an individual's level of function and their adjustment to disability for attributes most relevant to a specific disease or condition. Correlating change in these outcomes with various therapeutic interventions allows clinicians to better understand and optimize their care. This article will illustrate one example of outcome collection in an outpatient Neurosurgical and Orthopedic rehabilitation setting. Low back pain was chosen as it is the most common musculoskeletal condition and comprises a significant percent of the caseload in orthopedic rehabilitation [3].

Low back pain can be caused by injury to many different structures of the spine including muscles, ligaments, facet joints, discs, nerves, and bones. In addition low back pain can be the result of congenital disorders, metabolic and metastatic diseases (for review see [4, 5]). Low back pain is the second leading cause for medical visits in the United States and the fifth most common reason for hospital admissions [3]. It is estimated that 80-90% of people in U.S. will be affected by some form of low back pain during their lifetime with 1-2% requiring surgery, 5-10% suffering from chronic

low back pain, and 1% of that total will be disabled [3]. Psychological issues such as distress, depression, somatization, and fear avoidance may also play a role in low back pain and the ensuing disability that results from low back pain [6, 7].

Recent clinical guidelines published in the Journal of the American Academy of Orthopaedic Surgeons recommend physical therapy as an early option for treatment of low back pain [8]. Strengthening the core muscle groups, which include both the abdominal wall and lumbar musculature, has been suggested to be an important component in the treatment of low back pain [9]. In addition, exercise has been shown to improve physical function and decrease pain in adult patients with chronic low back pain [10-12]. In order to determine the efficacy of physical therapy for low back pain in our outpatient rehabilitation hospital, we implemented a number of standardized outcome measures to be used with all patients admitted for low back pain. In this article we will summarize the outcome measures chosen and provide an initial assessment with a small pilot population.

## Outcome Measures

To effectively assess low back pain, standardized outcome measures were chosen that would attempt to cover the range of functional impairments that may manifest in individuals with low back pain. Patient-reported and clinician-documented measures were chosen to capture both the patient's perceived level of change and the more objective, clinician-

documented functional change. All outcomes measured were collected three times, at the initial evaluation, the mid-point of treatment, and at discharge.

### *Patient-reported outcome measures*

Patient reported outcome measures provide a unique assessment of an individual's perceived level of ability or disability, and the changes they recognize in themselves following a treatment or intervention. The Oswestry Disability Questionnaire (OD) and Fear Avoidance Belief Questionnaire (FABQ) have both been used clinically to evaluate individuals with low back pain (Table 1). The OD is a well-documented diagnosis-specific tool that measures disability in patients with low back pain in relation to activities of daily living [13-16]. The OD has been used extensively in both research and clinical settings due to its good specificity, validity, and test-retest reliability [13, 16]. A lower score on the OD signifies less disability and is correlated with increased functional ability as well as improved quality of life [2, 17-19]. The FABQ was designed to quantify an individual's pain-related fear of movement, specifically, fears and beliefs about the need to change behavior in an attempt to avoid pain [20, 21]. It is divided into two sections, one pertaining to physical activity and the other related to work, which can be completed independent of each other. A high score on the FABQ has been shown to be correlated with an exaggerated perception of pain and a higher level of self-reported disability suggesting that this measure may be used in part to predict an individual's perceived disability [22-24].

While the OD and FABQ are specific for back pain, the SF-12 Quality of Life measure (SF-12) was developed as a generic health status measure [25, 26]. The SF-12 and its longer version the SF-36 are widely used and accepted tools to assess self-reported aspects of health related quality of life [26-28]. The SF-12 is a 12-item subset of the original 36 items in the SF-36 with the same 8 domains being examined including physical function, physical role, bodily pain, general health, social functioning, vitality, emotional roles, and mental health [26, 27]. Two summary scales are reported from the SF-12, the physical and mental component summary scores (PCS and MCS). The SF-12 has been found to be reliable and sensitive in several different paradigms and conditions including longitudinal studies, stroke, pancreatitis, fibromyalgia,

and low back pain [1, 2, 18, 19, 29-32].

### *Physical Functioning Outcomes*

As mentioned previously, low back pain can be the result of injury, congenital disorders, or disease (for review see [4, 5]) with disability resulting from low back pain varying depending on the etiology and the individual. To assess functional change related to low back pain several objective clinician-reported measures were chosen including lumbar range of motion (ROM), neural tension, manual muscle test (MMT) of the lower extremity, gait velocity, the 30 second sit to stand measure, and a number of items looking at core stability (Table 1). Previous studies have observed restricted lumbar ROM in individuals with low back pain [33, 34]. Lumbar ROM can also be indicative of the type of injury resulting in back pain. For example, patients' with disc protrusion or extrusion in the lumbar spine may show limited ROM depending where the lesion is located. Similarly, limited extension ROM or pain with extension ROM may be seen in patients with low back pain as a result of spinal stenosis.

Another potential cause of low back pain, as well as weakness and pain in the lower extremities, is compression or irritation of a nerve in the spine, which may lead to neural tension. Neural tension refers to the nerve's ability to move within the body. When there is tension on the nerve, the ability and freedom for it to move is constrained. In addition to pain, neural tension can lead to a loss of spinal and lower extremity range of motion, which can in turn alter gait pattern. Often with derangements involving a lower lumbar disc, such as a posterior or lateral protrusion or extrusion of the disc, a patient may show a positive neural tension sign secondary to compression of the nerve root [35]. Neural tension can be tested using the straight leg test, which has been shown to be a highly specific test [36]. The straight leg test is performed in the supine position with legs extended. The examiner lifts the leg flexing at the hip while keeping the knee extended [35]. If pain is increased in the lumbar region or the legs after 30 degrees of hip flexion the test is positive for probable herniated disc [37, 38].

Another sign of nerve involvement is weakness in a specific nerve root distribution. Patients with low back pain may show weakness in their lower extremities when there is damage to the nerve

supplying a muscle or group of muscles. Other patients, especially chronic pain patients, may have weakness secondary to being deconditioned. A useful measure in determining the involvement of nerve damage and lower extremity weakness is manual muscle testing (MMT) (for review see [39]). Additional measures that can signify nerve root compression are the inability to heel and toe walk, which affect L4-L5 and L5-S1, respectively.

Trunk Stabilization and strength is understood to play an important role to prevent as well as rehabilitate low back injuries although more research is needed in this area [9]. Muscle groups that are involved in trunk stabilization include the rectus abdominus, external obliques, erector spinae muscles, transversus abdominus, and lumbar multifidi. Measures that monitor trunk stabilization strength and function include the ability to perform abdominal bracing, the ability to perform a partial sit up and hold contraction for 10 seconds, the ability to bridge, the ability to hold neutral spine in quadruped, and the ability to perform the bird dog exercise. Abdominal bracing, defined as the ability to pull the navel to the spine performing an isometric contraction without changing the position of the pelvis or spine, is a basic exercise in core strengthening that mainly recruits the transverse abdominus muscle. The partial sit up, ability to lift one's head and scapula off the mat, recruits mainly the rectus abdominus and external obliques and is often used to determine overall fitness level and can also be an indicator of core strength. One of the main core muscles often affected in patients with low back pain is the multifidus which is the main muscle activated in the bridge exercise (Figure 1A). The bird dog exercise, which is the ability to stabilize in a quadruped position and extend opposite, requires the stabilization, coordination, and recruitment of the core muscles especially external obliques [40]. The ability to perform these core strengthening measures and the correlation between these measures and other clinician-documented and patient-reported measures will provide valuable information helping to further define the role of trunk stabilization in low back pain.

Low back pain can cause both severe back and lower extremity pain that has been shown to cause gait dysfunction [41-43]. Gait velocity, which is the ratio between stride length and step length, is an important indicator of functional status, social

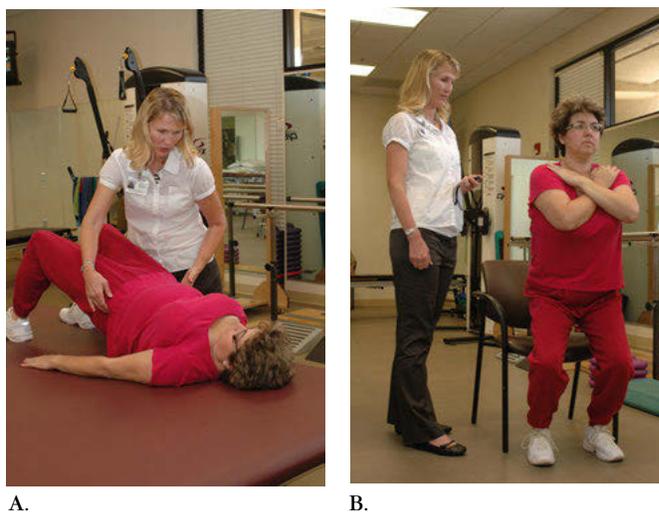


Figure 1. Illustration of a Bridge (A) and Sit to Stand test (B)

participation, and has been shown to predict mobility impairments [44-46]. Research suggests that with low back pain there is a change in the rotation and coordination of the pelvis and thorax during gait leading to slower gait velocity [47]. Exercise programs for patients with chronic low back pain have been shown to improve gait velocity [48]. Measuring gait velocity using the 5M-walk test provides an easy way to administer and retest gait with good reliability and norm values for age. There are also documented values that define pathological gait and the velocity needed for common community gait activities such as crossing a street. Gait velocity has been shown to predict adverse outcomes in well functioning elderly persons [49, 50].

Another assessment tool used to measure functional strength is the 30 second sit-to stand test, which simply measures the number of times a person can perform the transition from sitting to standing in a 30 second time period (Figure 1B). Moving from a sitting to standing position is an activity that is performed daily and if impaired, significant functional limitations can occur [46]. Impaired ability on this task has been found to predict further disability and correlate with greater difficulty in performing activities of daily living [51]. The 30-second sit-to-stand test is easy to administer, has good test retest reliability, normative values for age, and has been shown to be sensitive to change in individuals with low back pain [52].

**Table 1: Outcome measures**

Domain
<b>Patient Reported Outcome measures</b>
Oswestry Disability Questionnaire (OD)
SF-12 Quality of Life (SF-12)
Fear Avoidance Belief Questionnaire (FABQ)
Pain 0-10/10
<b>Physical Functioning outcomes</b>
Range of motion – Lumbar
Straight Leg Raise (SLR) and crossed SLR
Ability to bridge
Ability to maintain neutral pelvis in quadruped
Ability to maintain neutral pelvis in quadruped with opposite arms/legs
Ability to perform abdominal bracing
Ability to lift head and scapula off mat and hold >10
Lower extremity strength
Ability to toe walk
Ability to heel walk
5 meter walk (gait velocity)
# consecutive sit to stand in 30 seconds

## Analysis of Outcome Measures

To illustrate the use of the above outcome measures in an outpatient rehabilitation setting a select pilot population of 12 patients with no surgical history and a diagnosis of low back pain were used. The selected population is comprised of 6 males and 6 females with a mean age of 59.8 years and range from 30 to 84 years (Table 2). This large range in age highlights the extent to which low back pain is a widespread problem effecting old and young. It also demonstrates the ability of these measures to capture a wide variety of individuals with varying degrees of disability and not encounter large issues with floor or ceiling effects. The average number of visits for these patients was 17 but ranged between 8 and 37 visits. Therapy services are referred by a physician and will vary according to patient needs but can include a traditional land-based only physical therapy program and/or aquatic therapy with treatment aimed to decrease pain and improve function. An educational piece is also issued to each patient at

admission discussing proper body mechanics and posture. Participation in these physical therapy services depends on the patient's abilities and is recommended by the physical therapist or referring physician. In this population we had 42% of the patients participating in land-based physical therapy only, 16% in aquatic therapy, and 42% receiving a combination of both (Table 2).

**Table 2: Subject Characteristics (n=12)**

Characteristic	Total (%)
Sex	50% M, 50% F
Age (yrs)	
Mean $\pm$ SD	59.8 $\pm$ 14.8
Range	30 - 84
Number of visits	
Mean $\pm$ SD	17.0 $\pm$ 8.3
Range	8 - 37
Type of therapy	
Land	5 (42%)
Pool	2 (16%)
Both	5 (42%)

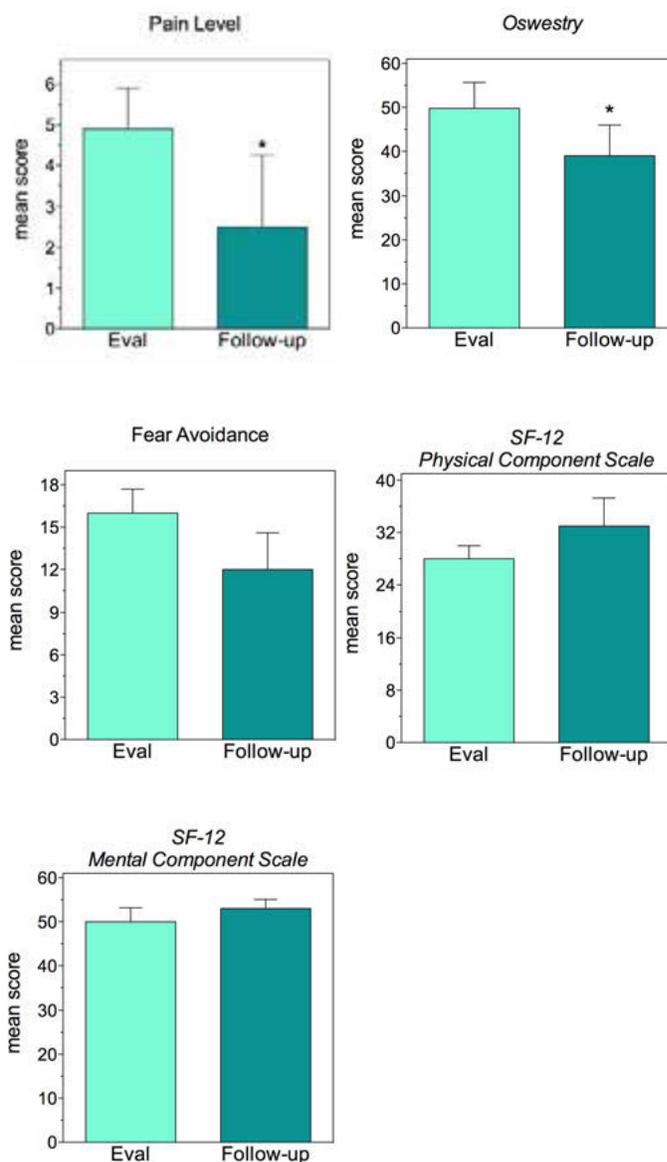
As stated above, patient-reported outcome measures were used to provide an assessment of the patient's perceived level of functional ability and disability. A patient's self-reported pain level is reported at each therapy visit using a scale of 0-10 with 0 = no pain and 10 = highest levels of pain. In this pilot population a significant decrease in pain was reported between the initial evaluation and mid-way through treatment (Figure 2). Correlating with this reduction in pain were significant changes in patient-reported disability using the OD (Figure 1). These changes represent a clinically meaningful reduction in disability. Using the FABQ we observed a trend towards improved understanding about pain and its impact on physical function, suggesting effective patient education. Taken together, the observed changes in overall pain, the OD, and the FABQ support the role of physical therapy in the treatment of low back pain. Interestingly, when patients were grouped according to the type of therapy services they received (land-based only, aquatic-based only, or both) a difference in the mean scores between groups was observed with the aquatic-based patients starting with higher levels of pain and more disability. While the starting mean does appear to be different, the slope of change between admission and follow-up appears to be fairly consistent between the groups, thus identifying different therapy

needs initially but with similar overall outcomes. With a larger data set this trend can be further defined.

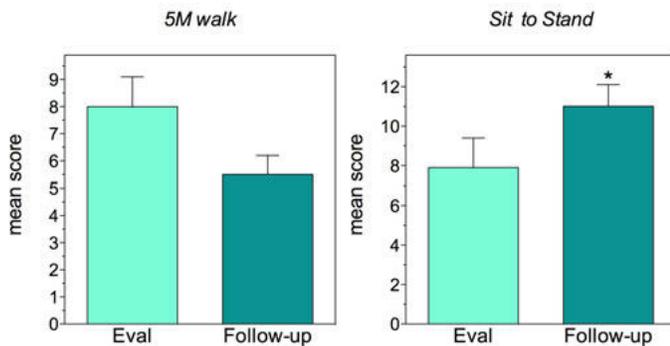
While the SF-36 and SF-12 are known as generic health-related quality of life measures, previous studies have found these outcomes to be effective and sensitive in individuals with low back pain [2, 53]. In this small sample we did not observe significant changes using the SF-12 however, the physical component score of the SF-12 did show a trend towards improved quality of life (Figure 2). Further, a correlation was observed between the OD and the physical component score with a decrease in patient-reported disability predicting an increase in quality of life. Interestingly, we also observed a correlation between admission FABQ scores and a patient's mental component score on the SF-12, signifying a potential relationship between individuals' beliefs about pain and movement and how it affects their quality of life.

The clinician-documented physical function outcome measures that we chose were intended to provide a more objective assessment of a patients' level of functioning. While not all effects were significant or can be defined by numeric change, several improvements in physical function were noted and suggest meaningful changes in a patients functioning as a result of their participation in physical rehabilitation. In two widely used outcome measures the 5-meter walk and the 30-second sit-to-stand test we observe changes in gait, lower extremity strength, and mobility (Figure 3). These functional measures correlate with one another suggesting a previously reported relationship between low back pain, lower extremity strength, and gait speed [41, 44, 47]. Of particular interest was the correlation between patient reported pain levels and the 5M walk, underlying the relationship between pain and gait velocity. With a larger data set these measures can be used to correlate with quality of life, disability, pain, and perhaps even predict overall levels of functioning. In addition, we hope to be able to determine correlations between lumbar ROM, neurotension, lower extremity weakness, functional level, gait velocity, patient-reported pain level and disability and overall outcome. We did observe interesting trends when looking at range of motion in this population, with 80% of patients increasing their lumbar range of motion and 63% increasing in lumbar extension range of motion. When lumbar range of motion was correlated with the OD and FABQ a relationship was observed between restricted range of motion and higher scores on the OD and FABQ, suggesting greater disability. Trunk stabilization, strength

and function, was improved in 100% of the patients who originally experienced difficulties in these areas. While our small sample prevents definitive conclusions regarding trunk stabilization and low back pain, these data suggest a meaningful relationship, which needs to be studied further. Taken together, these functional outcome measures provide a nice basis of a patient's level of functioning and how it correlates to their level of pain, disability, and overall well-being.



**Figure 2: Patient-Reported Outcome Measures.** Significant changes were observed in the level of pain patients were experiencing and in the amount of pain-related disability as measured by the Oswestry Disability Questionnaire. Data show mean scores for each measure at initial evaluation and upon follow-up during physical therapy services (+ SEM). \*p < 0.05 in comparison to the eval scores.



**Figure 3: Physical Functioning Outcome Measures.**  
 A trend towards increased gait velocity was observed using the 5M-walk test. Significant changes were observed in the number of sit-to-stands patients were able to do in 30 second. Data show mean scores for 5M walk and sit-to-stand at initial evaluation and upon follow-up during physical therapy services (+ SEM). \* $p < 0.05$  in comparison to the eval scores.

## Conclusion

Utilization of standardized quantifiable outcome measures for a diagnosis such as low back pain helps to assure effective treatments with positive patient outcomes. To effectively assess low back pain in an outpatient neurosurgical and orthopedic rehabilitation setting, patient-reported and clinician-documented measures were implemented to capture both patient perceived changes and more objective clinician-documented changes, which cover the range from quality of life to functional ability. Findings in this small sample suggest these measures are useful and valid for this population. Our results are supported by the numerous research publications documenting the utility of these outcome measures. We plan to continue this research with a larger data set including a surgical population so the impact of surgery can be evaluated as well as other variables that may underlie a patient's condition and their overall outcomes. We predict that this research will yield important findings supporting the use of these assessment tools for outcome measures in the clinical setting and a role of physical therapy for the treatment of low back pain.

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# GENETIC HYPERCOAGULOBILITY STATE



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## Introduction

Many patients with hypercoagulability state are born with mutations of one or more genes associated with coagulation. Common genetic mutations are Factor V Leiden, Prothrombin G20210A variant, Methylenetetrahydrofolate reductase (MTHFR) mutation, Deficiencies of Protein C, Protein S and Antithrombin III. Less common genetic hypercoagulability conditions involve mutations in Fibrinogen chains, Factor XIII, Platelet Glycoproteins, Plasminogen Activator Inhibitor-1, and Thrombin Activatable Fibrinolysis Inhibitor (1).

Interestingly, people with blood groups other than type O are at a two- to fourfold relative risk. Those with type O have lower levels of the blood protein von Willebrand factor as well as factor VIII, which confers protection from thrombosis (3).

Well known environmental or acquired factors associated with hypercoagulability state include oral contraceptives, hormone replacement therapy, Antiphospholipid syndrome, Lupus anticoagulant, pregnancy, smoking, nephritic syndrome, connective tissue disease such as Systemic Lupus Erythematosus or Rheumatoid Arthritis, Myeloproliferative disorders such as Polycythemia Vera or Essential Thrombocythemia, and solid organ malignancy.

Despite well established hereditary genetic conditions associated with high risk of thromboembolism, current management of the venous thromboembolism especially recommended by American College of Chest Medicine (2) does not take those genetic conditions into consideration, which can result in potential harm or even fatal consequence to patients.

We are presenting 2 patients who developed venous embolism including pulmonary embolism due to their genetic mutations.

## Case 1

PY is a 49 year-old White man who developed Deep Vein Thrombosis (DVT) of the left leg 7 years ago, and he had been treated with Enoxaparin (Lovenox®) followed by Coumadin for 6 months. However, 1 year after he stopped the Coumadin, he had pulmonary embolism. Since then he was taking the Coumadin. However, due to his traveling job situation, he did not take it for the past 1 ½ years. Recently he developed painful swelling of the left leg and the Ultrasound on 3/22/2011 revealed a thrombus in the left greater saphenous vein. Now he is back on the Coumadin therapy.

Family history included his father died of prostate cancer