Understanding the Effect of Epidural Steroid Injection in Lower Back Pain Using Inertial Measurement Unit Wearable Device

by

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ABSTRACT

Low back pain (LBP) is the most common symptom leading to hospitalization and medical assistance. In the US, LBP is the fifth most prevalent case for visiting hospitals. Approximately 2.06 million LBP incidents were reported during the timeline between 2004 and 2008. Globally, LBP occurrence increased by almost 200 million from 1990 to 2017. This problem is further implicated by physical and financial constraints that impact the individual's quality of life. The medical cost exceeded $87.6 billion, and the lifetime prevalence was 84%. This indicates that the majority of people in the US will experience this symptom. Also, LBP limits Activities of Daily Living (ADL) and possibly affects the gait and postural stability. Prior studies indicated that LBP patients have slower gait speed and postural instability. To alleviate this symptom, the epidural injection is prescribed to treat pain and improve mobility function. To evaluate the effectiveness of LBP epidural injection intervention, gait and posture stability was investigated before and after the injection. While these factors are the fundamental indicator of LBP improvement, ADL is an element that needs to be significantly considered. The physical activity level depicts a person's dynamic movement during the day, it is essential to gather activity level that supports monitoring chronic conditions, such as LBP, osteoporosis, and falls. The objective of this study was to assess the effects of Epidural Steroid Injection (ESI) on LBP and related gait and postural stability in the pre and post-intervention status. As such, the second objective was to assess the influence of ESI on LBP, and how it influences the participant's ADL physical activity level.

The results indicated that post-ESI intervention has significantly improved LBP patient’s gait and posture stability, however, there was insufficient evidence to determine the significant disparity in the physical activity levels.

In conclusion, ESI depicts significant positive effects on LBP patients’ gait and postural parameters, however, more verification is required to indicate a significant effect on ADL physical activity levels.

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TABLE OF CONTENTS

APPENDIX Page

LIST OF TABLES

LIST OF FIGURES

Figure Page

Figure Page

Figure Page

CHAPTER 1:

INTRODUCTION

1.1 MOTIVATION

Fall accidents are a significant societal problem, especially for older adults. (O'sullivan et al., 2009; Sekaran et al., 2013; Tinetti et al., 1988; WHO, 2021). The consequence of falls to older adults has immense negative effects, such as resulting increase in fracture, morbidity, mortality, and healthcare cost (Bergen et al., 2016; Florence et al., 2018). Mortality caused by fall accidents has been progressively rising since 2000 (Hartholt et al., 2019). Fall injuries create a substantial restriction on patients' physical capabilities and demand vast financial and physical burdens on their families. In the United States, the economic burden due to fatal falls is substantially increasing, where the medical cost due to this problem was $754 million, while non-fatal fall related injuries healthcare expenditure was $50 billion (Florence et al., 2018). The impact of falling has multifaceted negative effects on the individual, such as exacerbating the physical activity level and increasing postural instability. Furthermore, the composition of these impacts can lead to psychological issues, such as fear of falling (Chen et al., 2019; Doshi et al., 2023; Jefferis et al., 2014; Legters, 2002; Toebes et al., 2015). For the patients diagnosed with a certain illness, such as Low Back Pain (LBP), a single unintentional fall accident could cause critical injury due to their physical condition and the consequence could be devastating due to various physical factors. As such, this study investigates the relationship between LBP and various fall risk factors – such as gait and postural stability and ADLs.

LBP is the leading cause of physical disability and another predominant common health issue that is widespread in the United States. More than 80% of the population is expected to suffer from this problem (Dieleman et al., 2016; Katz, 2006; Walker B, 2000). This illness is frequently generated by repeated lifting tasks using lower back muscles to generate counter reactive torque and, create a compressive force to the spinal column which can be injured (Partanen et al., 2010). Furthermore, LBP can influence gait and postural stability (i.e., decreased gait speed and postural instability compared to health groups (Fayez et al., 2010; Lamoth et al., 2006)). Additionally, LBP causes decreased daily activity performance and results in mobility decrement. Accordingly, the physical activity limitation is due to pain generated during the execution of various movements and maintaining certain postures and performing activities, such as walking, sitting, standing, and laying down (Fairbank & Pynsent, 2000; Gordon & Bloxham, 2016; Meier et al., 2019; Jonathan A. Smith & Osborn, 2007). Combination of these aspects, LBP is closely linked with fall risk, and it could be assumed that numerous types of LBP could increase the propensity of falling.

1.2 SPECIFIC AIMS

The aim of this project was to determine the effects of ESI on LBP patients in terms of gait and postural instability and ADLs before and after the injection to determine fall risks associated with ESI.

Aim: Compare the efficacy of pre and post-epidural steroid injection intervention on LBP patient gait, postural, and Activities of Daily Living

Hypothesis 1: We hypothesize that gait/postural and dynamic stability will be significantly improved after the epidural steroid injection.

Past studies have indicated that LBP patients have slower gait speeds compared to their healthy counterparts (Khodadadeh & Eisenstein, 1993). Additionally, postural instability was observed due to the protective strategy. As such, LBP patients may prevent excessive low back movements to reduce pain and influence dynamic gait stability.

Hypothesis 2: We hypothesize ESI will alleviate the LBP significantly and increase the physical activity level of the patient's ADL, which will be assessed within the subject's dwelling home setting to veer away from the white coat syndrome effect (Weiss et al., 2014).

Various studies have depicted that LBP reduces the physical activity level due to difficulties they have encountered performing normal daily routines. As stated, LBP plays an essential role in decreasing the performance on daily physical activity level, which is closely related to fall risk (Stamm et al., 2016). Particularly, in this study, patient physical activity level differences before and after the epidural injection were further quantified to determine the influence of EPI on LBP ADLs'.

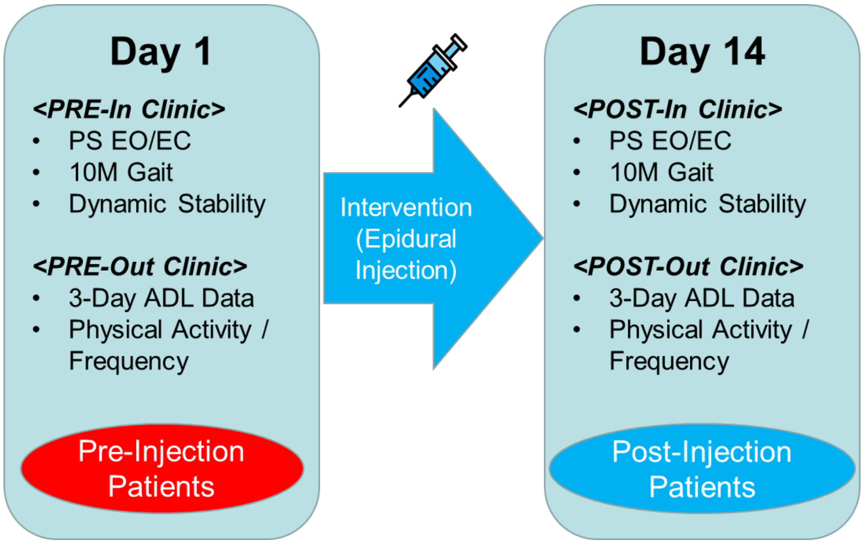


Figure 1-1. Epidural Steroid Injection Study design layout

1.3 ORGANIZATION

This dissertation has a total of 6 chapters. Chapter 1, Introduction - depicts the purpose of the dissertation and justifies the execution of why indicating the efficacy of the epidural injection research is necessary. Chapter 2, The Background section reviews the fundamental definition of LBP illness and indicates how it negatively influences the patient's life. This chapter also provides further detail on the problematic cause of LBP, and how it may influence gait, postural stability, and ADLs. Additionally, the methodology of gait/postural stability and physical activity level assessment was further elaborated. Chapter 3 investigates in-clinical research of the ESI efficacy on the alleviation of pain, as well as examining the effectiveness of the injection on the LBP gait and postural stability. Chapter 4 depicts the result of the ESI effect on the 3-day physical activity level analysis.

CHAPTER 2:

BACKGROUND

2.1 Low Back Pain (LBP)

LBP is a prevalent issue that increases the fall risk and exacerbates the consequence when it occurs. Low back pain (LBP) is the predominant issue that is the leading cause of numerous complications and injuries that occur associated with the older adult group, who are 65 years and older. This illness condition is the highest cause of physical disabilities in the world (Hoy et al., 2014) and the research has indicated that LBP was the most widespread irritation that 25% of United States adults have experienced (Deyo et al., 2006). In 1990, 377.5 million cases of LBP symptom was reported around the world and it has continuously increased ever since, and the number has significantly elevated till 2017, where the identified cases were 577 million (Wu et al., 2020). In the United States, the National Electronic Injury Surveillance System reported that nearly 2.06 million LBP symptoms occurred from 2004 to 2008, and this was roughly more than 3% of total emergency visits (Waterman et al., 2012). The development of LBP involves complex and multiple intricate reasons, but the most common cause of generating this problem is a damaged muscle or ligament strain issue. This commonly progresses after the lifting excessive overweight or repetitive motion that continuously generates a force on the lower spine level, such as lumbar vertebrae and sacrum, which eventually develops into LBP (Partanen et al., 2010).

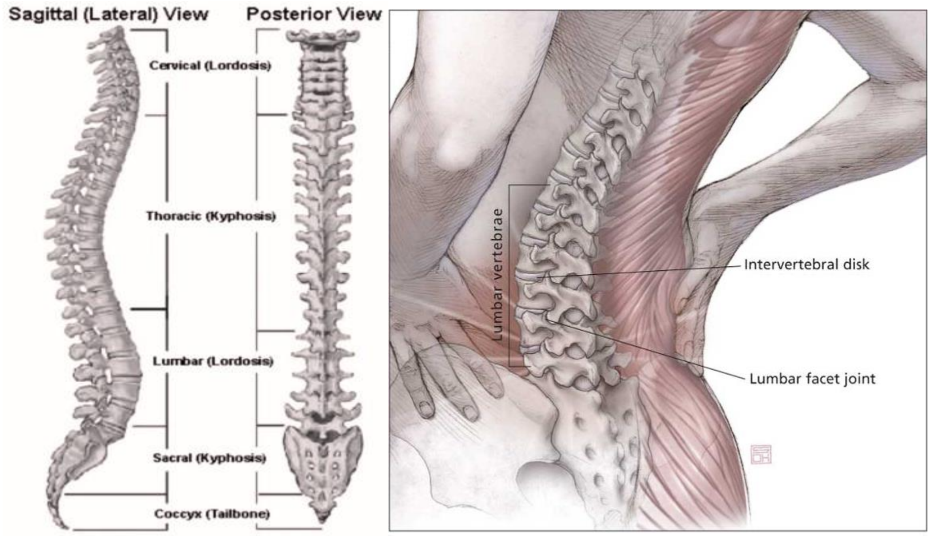


Figure 2-1. Spine structure layout (*Low Back Pain Management: Making the Diagnosis*, 2010; Rodts, 2008).

The presence of LBP symptoms can also be caused by complications with the lumbar intervertebral disc which is the source of 26-42% of LBP issues (Peng, 2013). Furthermore, intervertebral disc pain can be initiated from the herniated, bulged, or rupture disc that puts pressure on the nerve root and possibly causes inflammation (Comer & Conaghan, 2009; Dydyk et al., 2022). In addition, several diseases cause LBP such as osteoarthritis and osteoporosis (Bogduk, 2008). Due to osteoarthritis in the spine, which generates the reduction of the spinal cord area that puts stress on the nerve, this symptom is called spinal stenosis (Goode et al., 2014). Broadly, the determination of the LBP is scored with the Oswestry LBP disability index (Fairbank & Pynsent, 2000). This survey consists of ten questions, pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, traveling, and changing the degree of pain.

The total point was 50 points, and each question was worth 5 points. The point was converted into percentages and separated into five categories of disability, minimal, moderate, severe, crippled, and disabled (Table 2-1).

Table 2-1. Oswestry Low Back Pain Disability Index Score Interpretation.

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

This illness has an immense impact on the physical condition and also leads to an economic burden on those suffering from it. According to Dieleman et al. (Dieleman et al., 2016), in 2013, low back and neck pain-related medical expenses were 87.6 billion dollars and other studies indicated that estimated medical cost associated with LBP surpasses 100 billion dollars per year and the lifetime prevalence of this disorder was 84% (Katz, 2006; Walker B, 2000).

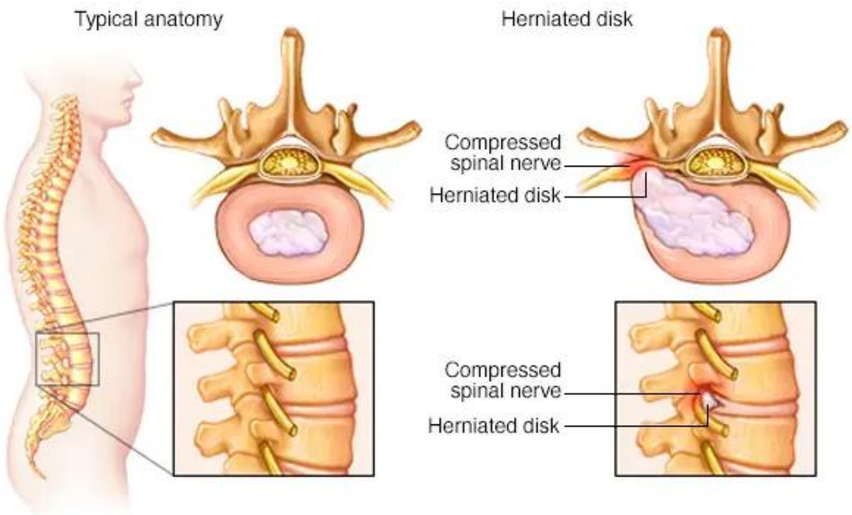


Figure 2-2. Illustration between normal and herniated disk (*Herniated Disk*, 2023).

In addition, 75 years and older adults have reported that low back pain was 3rd most prevalent case in the musculoskeletal system (H. K. Koch & Smith, 1985). This explicitly shows the significant issue of the LBP that should be alleviated immediately. Furthermore, this problematic symptom restricts the individual from voluntary physical activities and accelerates the degradation of physical function, which is significantly linked to the risk of falling (Deyo et al., 2006; Di Iorio et al., 2007; Makris et al., 2011; Marshall et al., 2016; Muraki et al., 2013; Patel et al., 2013; Rudy et al., 2007; Weiner et al., 2003). Fall risks are also a growing healthcare concern that significantly burdens older individuals and it continuously escalates the threat of critical human suffering and economic losses in medical expenses (Tinetti, 2003). The US population is rapidly aging and by the year 2060, older adults who are older than 65 years are expected to reach 98 million (Mather et al., 2015). The likelihood of experiencing a fall incident is closely related to aging, more than 50% of older adults who have experienced falls were 80 years or older (O'loughlin et al., 1993). The consequences of falls have various outcomes, such as minor bruises, fractured bones, traumatic brain injuries, and in the worst-case fatality (Sterling et al., 2001). Also, the estimated total medical expense for fall accidents alone took a portion of approximately 0.85 to 1.5% of all healthcare expenditures (Heinrich et al., 2010). In 2010, the expenditure spent by the emergency department related to injuries with unintentional falls nearly cost a 111billion dollars (S. K. Verma et al., 2016).

Overall, fall accidents linked with LBP not only have an adverse influence on physical well-being but also create detrimental influences on the cognitive function of patients. One common cognitive concern is the Fear of Falling (FOF). This problem could be caused by a range of factors, including accelerated physical function deterioration, perturbation in walking habits, and standing postures issue (Arfken et al., 1994; Bryant et al., 2015; S. Verma & Pal, 2015). However, the LBP has the most significant impact on restricting the ADL of elderlies who have experienced falling (Lavedán et al., 2018; Tinetti et al., 1988; S. Verma & Pal, 2015). To resolve this LBP-related issue, an ESI is generally used to relieve the LBP. The efficacy of this method was promising, where previous studies depicted that 70 to 90% of patients have reported successfully alleviating the LBP (Pandey, 2016). The procedure of this ESI, Initially, live x-ray guided fluoroscopy is executed to determine the accurate location for the steroid injection. To perform this procedure, the liquid contrast dye is infused into the epidural space to locate the exact needle placement. After this procedure, anesthetic and steroid medication is injected to relieve the pain (Figure 2-3). The application of steroids into the epidural area has an anti-inflammatory effect that decreases the pain caused by spinal nerve irritation and possibly functional recovery of the lower extremity (Manchikanti et al., 2015).

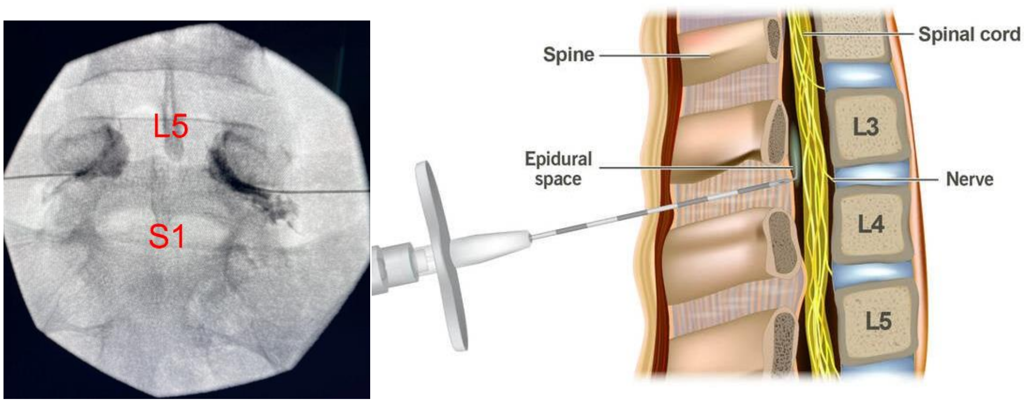


Figure 2-3. X-ray Image of Epidural Steroid Injection process on Low Back Pain (*Epidural: What It Is, Procedure, Risks & Side Effects*, 2021).

To assess the effect of epidural injection on postural stability sway area, and dynamic stability, a general fall risk assessment approach is implemented (Fan et al., 2016; Hong et al., 2013; Lockhart & Liu, 2008; Lusardi et al., 2017; I. Melzer et al., 2004). These parameters are essential because LBP patients are likely to modify their balance and gait characteristics as participants are inclined to choose a protective strategy to reduce the pain and the force required on the lower back. Previous studies found that participants tend to limit the range of motion in the thoracic and lumbar areas (Hodges & Tucker, 2011; C. Koch & Hänsel, 2019; Lee et al., 2007). Therefore LBP patients are likely to have higher

COP sway velocity and area (Ruhe et al., 2011; Sohn et al., 2013). These fundamental aspects are also essential for differentiating faller and non-faller, where most of the previous studies have proceeded within the controlled laboratory environment. This setting has the advantage of eliminating unnecessary variables which have the potential of improving the data accuracy. However, there is a contradicting perspective with the data collected from this arrangement such as “white coat syndrome.” This symptom occurs when the participant is under surveillance or observed by physicians or researchers, where they tend to optimize their movement nature. This restricts participants from performing their normal behavior which could lead to misrepresentation of their normal activity. Eventually, the collected data could be skewed and the authenticity of participant data could be compromised (Weiss et al., 2014). To veer away from “white coat syndrome”, activity parameters must be measured from a participant’s daily household without any surveillance or restrictions. Measuring multiple days of ADL could discover the participant’s periodic day-to-day pattern and quantify their physical activity level (Scheers et al., 2012). Various studies have been conducted to investigate LBP patients, whether it tends to decrease the physical activity level or has a problem with executing normal activities, such as gait movement, lifting, and shopping (Aromaa et al., 2003; Kothe et al., 2007; Leveille et al., 1999; Stamm et al., 2016), and the result indicated that LBP reduces the ADL physical activity. Additionally, people with higher physical activity level has lower fall risk compared to sedentary behavior person (Thibaud et al., 2012). As depicted in these studies, LBP correlates with performance on physical activity level and generally these studies were conducted with subjective self-monitored questionnaires (Abolfotouh et al., 2015; Andersen et al., 2007; Björck-van Dijken et al., 2008; Failde et al., 2000; George et al., 2012; Heneweer et al., 2009). In comparison, utilization of the IMU wearable system would be a unique approach of measuring physical activity levels. Since LBP has the potential of limiting the patient's capability to maintain a stable gait /postural stability and physical activities of ADL, these factors share a similar characteristic that increases the fall risk (Johansson et al., 2017). Therefore, these circumstances require immediate intervention solutions to decrease the injuries and mortality that are caused by this LBP illness.

2.2 Postural Stability Analysis

Fall risk is closely related to the individual's ability to maintain their balance. Postural stability analysis has been utilized to indicate fall prone individuals for decades (Johansson et al., 2017; Lockhart et al., 2014, 2019; I. Melzer et al., 2004; Itshak Melzer et al., 2010). Various studies have presented that the fallers have lower postural stability capability, where one study has indicated that fallers had higher mediolateral sway (I. Melzer et al., 2004), and another study has indicated that the postural sway during quiet stance has shown that center of pressure (COP) sway length was significantly great compared to non-fallers. (Johansson et al., 2017). A retrospective analysis study has found that mediolateral sway and sway area was significantly larger for the people who have fallen within 6 months (Itshak Melzer et al., 2010). As presented in previous studies, postural stability is one of the fundamental parameters that need to be assessed to determine fall risk. The Inertial Measurement Unit (IMU) system is a contemporary method of measuring postural stability. This system is evolutionary that it does not require a complete laboratory setting to execute the balance assessment, it could be carried out in any field and assess the postural stability, such as a hospital clinic (Doshi et al., 2023; Soangra et al., 2014). IMU could be manufactured as small as 3.0 × 3.0 ×0.6mm, which is implemented within the smartphone, and this device could be utilized as measuring the postural stability of the patients (Lahrach, 2018)

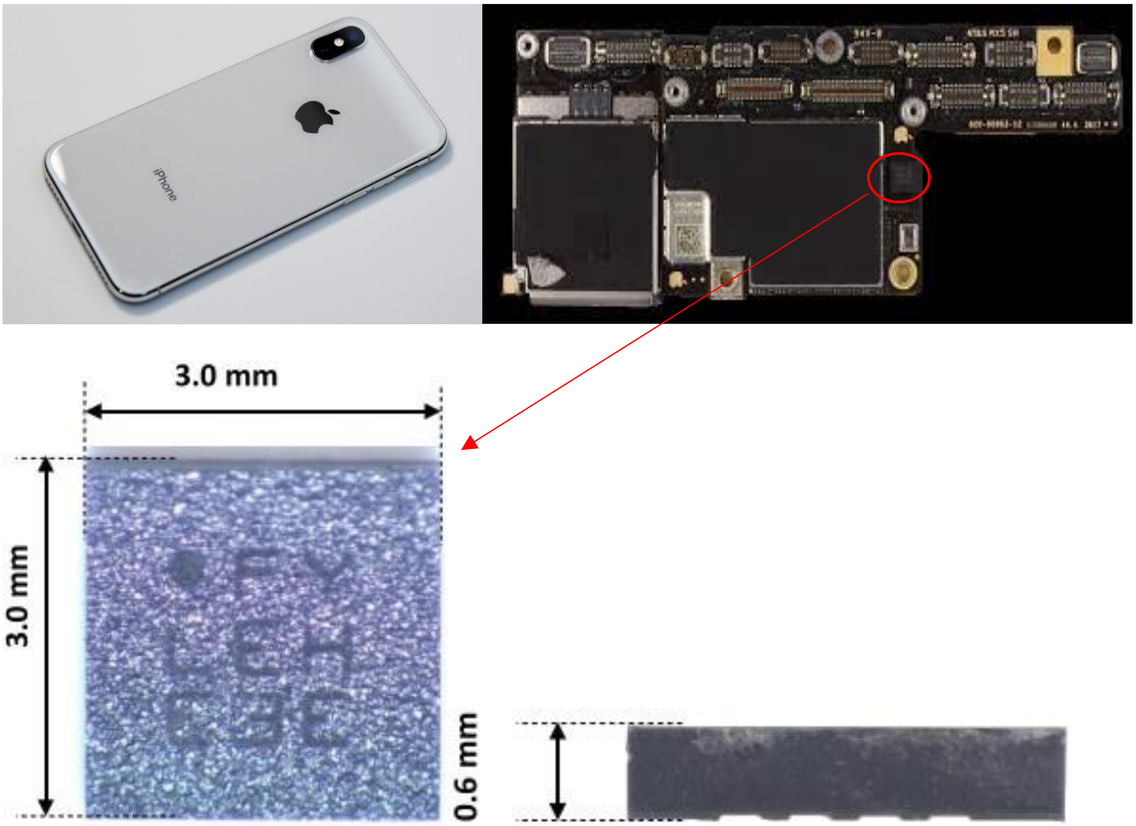


Figure 2-4. Bosch IMU implemented within the iPhone (Lahrach, 2018).

To calculate the postural stability, the current system uses acceleration data from the IMU accelerometer. The vertical sensor position (h) is required to calculate the postural stability. To indicate the direction of the IMU sensor pathway, the acceleration data from all three axes was applied to compute a combined vector and then projected onto the floor. The three-axis acceleration data was an a_x, a_y, and a_z, and the resultant of these three accelerations is A. This distance can be determined with trigonometric ratios, where D is the hypothenuse distance from the vertical Z axis.

$$A\ (\text{mm/s}^2) = \sqrt{(a_x)^2 + (a_y)^2 + (a_z)^2} \quad (1)$$

$$D = \left(\frac{-d_z}{\cos \gamma}\right) \quad (2)$$

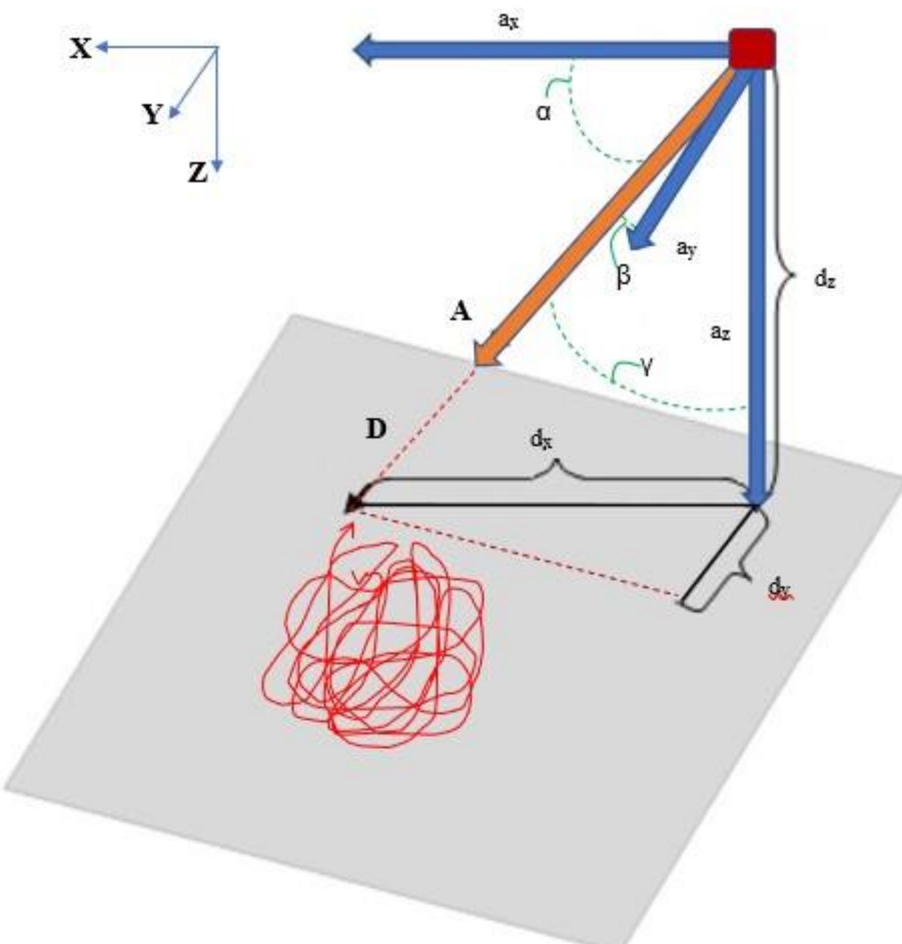


Figure 2-5. Postural stability projection from the IMU system.

As the directional cosines, cos α, cos β, and cos γ, are identical for the spatial system, d_z indicates the height of the IMU sensor located at the subject, where usually it is at the sacrum area of the person.

$$\cos\alpha = \left(\frac{a_x}{\sqrt{(a_x)^2 + \left(a_y\right)^2 + (a_z)^2}}\right) \tag{3}$$

$$\cos\beta = \left(\frac{a_y}{\sqrt{(a_x)^2 + \left(a_y\right)^2 + (a_z)^2}}\right) \tag{4}$$

$$\cos\gamma = \left(\frac{a_Z}{\sqrt{(a_x)^2 + \left(a_y\right)^2 + (a_z)^2}}\right) \tag{5}$$

To determine the magnitude of vector D, which is parallel to the resultant acceleration A, this parameter can be calculated using cos γ and the height of the IMU sensor which is d_z. Furthermore, d_x and d_y are utilized to plot the projected coordinate D onto the floor.

$$D = \left(\frac{-dz}{\cos\gamma}\right) \quad (5)$$

$$d_x = D \times \left(\frac{a_x}{\sqrt{(a_x)^2 + \left(a_y\right)^2 + (a_z)^2}}\right) \quad (6)$$

$$d_y = D \times \left(\frac{a_y}{\sqrt{(a_x)^2 + \left(a_y\right)^2 + (a_z)^2}}\right) \quad (7)$$

Consequently, by utilizing this methodology, it is possible to compute postural stability parameters including sway area, path, and velocity. These elements are critical factors to determine the fall risk of elderly individuals.

2.3 Gait Stability Analysis

Gait analysis has been applied to identify the fall risk of older people for a considerable period. Previous studies have indicated that older adults in the acute care setting have slower gait speed compared to regular hospital environments (Peel et al., 2013). Additionally, older adults tend to reduce gait speed, stride length, and single-leg support time compared to younger adults (Bohannon et al., 1996; Feltner et al., 1994; Prince et al., 1997). Similarly, another study has indicated that age and body mass index is significantly correlated with decreased gait speed (Kasović et al., 2021). Generally, gait speed measurement is completed by designating 10 meters and utilizing a stopwatch to assess the total time duration for the subject to transverse the pathway with a customary walking pace. The measurement is initiated when the subject's limb passes the start point and stopped when the limb crosses the stop point (Fritz & Lusardi, 2009). This is a common method for measuring gait speed, however, this method is questionable since the indication limb passing the start and stop point is vulnerable to human error. Through the development of the IMU system, gait speed evaluation can be executed immediately and accurately through the resultant acceleration analysis.

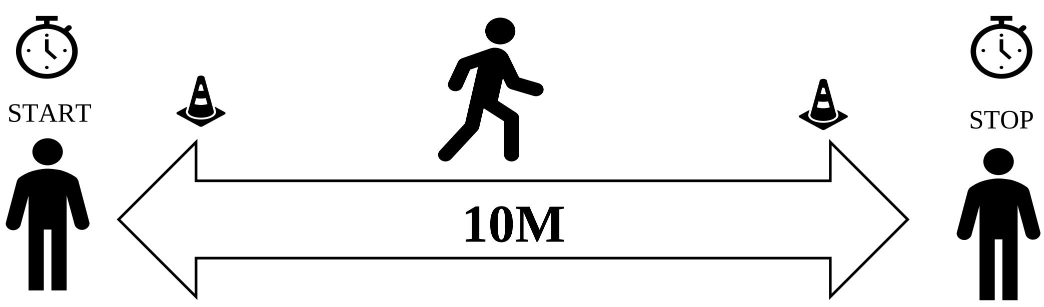


Figure 2-6. A conventional method for assessing 10m walk gait speed.

Dynamic stability is another gait characteristic that was utilized to identify the individuals who are susceptible to fall risk. The Lyapunov exponent is a metric that is applied to quantify the dynamic stability parameter. This parameter analyzes the average value of the distance between the orbiting two neighbors, which diverges or converges exponentially. Lyapunov exponent (λ) value is positive, this indicates that trajectories will exponentially diverge, and if λ is less than zero, trajectories tend to converge exponentially. To compute the Lyapunov exponent, the time-delayed coordinate methodology is applied to reconstruct a multi-dimensional state space. Takens' theorem has presented that the intrinsic dynamic structure can be adequately depicted by single-dimensional time series data (Takens, 2013). Therefore, minimum embedding dimension and time delay are required to calculate the time delayed method. Lyapunov exponent parameter is utilized to quantify the dynamic stability from the reconstructed state space. This can be determined by identifying the nearest neighbors from the separate trajectories that are in closest proximity to each other for all the data points within that state pace. This distance dictates whether the system will diverge or converge, and with the higher Lyapunov exponent, the divergence rate will be rapid which signifies the lower stability, depicting that system has inadequate resistance to the local perturbation (Lockhart & Liu, 2008). In contrast, a lower Lyapunov exponent demonstrates that the system is exhibiting securely stable behavior. For the computational protocol of the Lyapunov exponent, the slope of a least squared fitted line on the curve from the natural logarithm of the separation of the two trajectories versus the time graph indicates the Lyapunov exponent (Stergiou, 2016). Utilizing of Lyapunov exponent allows the quantification of the local dynamic stability with assessing the sensitivity of the dynamic system to the infinitesimally small perturbations (Dingwell & Cusumano, 2000). The application of local dynamic stability has provided countless insights for human locomotion research. Implementation of the Lyapunov exponent analyzes the intrinsic dynamics of each body segment, such as trunk movement (Granata & England, 2006) and knee joint (Stergiou et al., 2004). Furthermore, diabetic neuropathic patients tend to have higher kinematic variability compared to healthy subjects, where these subjects adopt a more locally stable gait pattern with slower gait speed (Dingwell & Cusumano, 2000).

Overall, historically, gait analysis has been used to investigate fall prone individuals and integration of various gait parameters and dynamic stability has the ability to distinguish between fall and non-fall groups. In addition, it concludes the potential of foreseeing fall risk personnel.

2.4 Activities of Daily Living (ADL) Analysis

ADL consists of various useful data that relate to fall risk. Aging results in a significant effect on the deterioration in human mobility, this is directly associated with physical activity level in ADL. Adequate volume of physical activities during daily life depicts improvement in musculoskeletal health, and bone mineral density, promoting positive mental health, reduction of fall risk, and eventually increment in the total life expectancy (Bushman, 2019). Previous research has depicted that evaluating multiple days of ADL data projects an individual's daily pattern and physical activity level, which is closely correlated with fall risk and it could be utilized to distinguish fall prone individuals (Scheers et al., 2012). Physical inactivity leads to muscle weakness and an increment of frailty (Campbell & Buchner, 1997). This issue causes ineffective lower limb control and balance issue, that is closely related to fall risk (Deandrea et al., 2010).

Traditionally, measuring scope for the Activity of Daily Living (ADL) was subjective, such as using the Physical Activity Scale for the Elderly (PASE) (Washburn et al., 1993). The PASE measurement was a simplified way of assessing older adults' level of physical activity. This methodology was structured to measure the duration, frequency, exertion level, and physical activity level for seven consecutive days from the subjects (Washburn et al., 1993).

Table 2-2. Structure of the Physical Activity Scale for the Elderly (PASE) (Washburn et al., 1993).

PASE SCORING FORM

PASE Item	Type of Activity	Activity Weight	Activity Frequency	Weight times Frequency
2.	Walk outside home	20	a.	
3.	Light sport / recreational activities	21	a.	
4.	Moderate sport / recreational activities	23	a.	
5.	Strenuous sport / recreational activities	23	a.	
6.	Muscle strength / endurance exercises	30	a.	
7.	Light housework	25	b.	
8.	Heavy housework or chores	25	b.	
9a.	Home repairs	30	b.	
9b.	Lawn work or yard care	36	b.	
9c.	Outdoor gardening	20	b.	
9d.	Caring for another person	35	b.	
10.	Work for pay or as volunteer	21	c.	
			PASE SCORE:	

Activity Frequency Values:

a. Use hours per day conversion table below
b. 1 = activity reported in past week, 0 = activity not reported
c. Divide work hours reported in Item 10.1 by seven; if no work hours or if job involves mainly sitting with slight arm movements (Item 10.2 = 1), then activity frequency = 0.

ACTIVITY TIME TO HOURS PER DAY CONVERSION TABLE

Days of Activity	Hours Per Day of Activity	Hours Per Day
0. Never		0
1. Seldom	1. Less than 1 hour	.11
	2. 1-2 hours	.32
	3. 2-4 hours	.64
	4. More than 4 hours	1.07
2. Sometimes	1. Less than 1 hour	.25
	2. 1-2 hours	.75
	3. 2-4 hours	1.50
	4. More than 4 hours	2.50
3. Often	1. Less than 1 hour	.43
	2. 1-2 hours	1.29
	3. 2-4 hours	2.57
	4. More than 4 hours	4.29

Although subjective measurement is beneficial in assessing the physical activity levels of older adults, there is a risk of authenticity issues, bias of self-evaluation, and cognitive impairment that may affect the result of these questionnaires (Carlsson et al., 2012). Therefore, improving the reliability issue needs immediate intervention, which is required to determine accurate physical activity levels.

Advancement of wearable devices such as IMU, figure 2-7 has enabled self-monitoring of personal health, identifying step number, walking speed, and even sleep duration. This tool could be applied to assess the longitudinal recording of a subject's physical activity level, which contains that person's unique signature frequency movement and several transitions etc.

Figure 2-7. Utilizing Inertial Measurement Unit to assess the Activities of Daily Living of Subjects (Weiss et al., 2013)

Therefore, measuring the acceleration value from physical activity is a crucial factor in evaluating the likelihood of future falls, making it one of the most significant aspects to consider.

As aforementioned, physical activity is the utmost critical feature that could evaluate the likelihood of future fall risk, which is quantified with a resultant acceleration value. Additionally, increasing the quantity of physical activity tends to reduce fall risk (Cameron et al., 2010; Gillespie et al., 2012; Graafmans et al., 2003; Peeters et al., 2010). However, engaging in additional physical activity could lead to a side effect of exposure to extrinsic falls (Skelton, 2001). Consequently, to identify these environmental hazard exposures, evaluation of ADL data is mandatory for establishing intrinsic and extrinsic factors of fall risk during physical activity. From the ADL IMU data, frequency-based acceleration measurements can differentiate healthy individuals and old frailty people. A previous study has indicated that the dynamic and stationary activities can be determined with resultant acceleration filtered by high and low-pass Butterworth filters, and then the cut-off frequency of 1Hz was applied to detect dynamic and stationary activities (Moon, 2021).

Numerous subjective measurements are established and applied to measure fall risk, however, there are inevitable weaknesses in subjective measurements, such as bias issues and low reliability. Therefore, wearable sensor IMU performs a beneficial role in capturing and analyzing quantitative metrics for LBP ADL.

CHAPTER 3:

EFFICACY OF EPIDURAL STEROID INJECTION ON LOW BACK PAIN PATIENT'S GAIT AND POSTURE

3.1 Introduction

LBP is one of the most common and debilitating disorders that millions of people are suffering in our society. Approximately 60 to 80% of the population is predicted to encounter LBP, furthermore, 7-10% have been diagnosed with chronic LBP, where this symptom negatively influences the quality of life and work efficiency (Deyo et al., 1992). The underlying cause of LBP is many and occasionally ambiguous. Previous research has indicated that poor sitting posture requiring prolonged sitting causes discomfort in the scrum area. This results in higher intradiscal forces that are pressing the lower spines which leads to LBP (Jung et al., 2021; Lis et al., 2007; Pynt et al., 2002). In addition, Muscle strains and sprains are another significant cause that generates LBP. These issues tend to occur when the torso is excessively twisted or bent when the movement exceeds a person's range of motion (ROM) capability. Lower back muscle strain is followed when the muscle fibers are exceptionally elongated or damaged, and similar sprain symptom appears when the ligaments are ruptured (Busse et al., 2020; Koes et al., 2006). These problematic indicators of LBP influence the patient's gait and posture stability, which are closely related to fall risk. Various studies indicated that LBP patients' gait had a less gait speed and longer step time (Lamoth et al., 2006; Lee et al., 2007; Najafi et al., 2019; Jo

Armour Smith et al., 2022). This is an indicator of LBP patients compensating their movement to reduce the pain by limiting hip and lumber spine motion to minimize the force that is applied to the lower back (Lee et al., 2007). Cheng et al, indicated that LBP patients tend to have lower gait speed since they attempt to lessen the vertical reaction force impacting their lower back (Cheng et al., 1998).

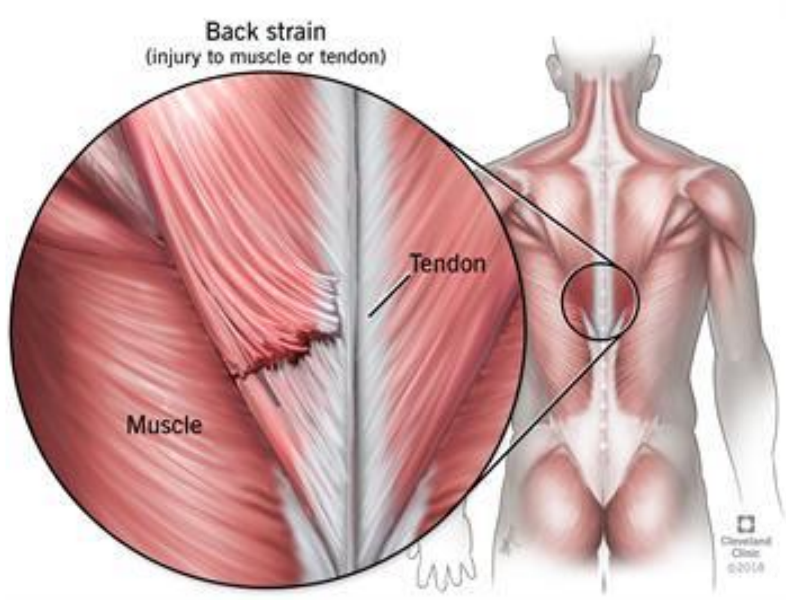


Figure 3-1. Demonstration of muscle strain causing lower back pain (*Back Strains and Sprains*, 2018).

Furthermore, LBP not only affects the gait characteristic but also influences how the patients control their postural stability. A previous study has indicated that LBP causes the redistribution of position, which leads to modification of mechanical postural behavior to ease the pain experience. However, regardless of the direct alleviation, this instantaneous solution is not recommended, since the prospected result of this approach turns out to be negative for the body structure over time (Hodges & Tucker, 2011; Van Daele et al., 2009). In addition, during the postural stability testing to alleviate pain, LBP patients tend to utilize the protective strategy to maintain their stability. To reduce the pain and the force required on the lower back, participants tend to restrict the range of motion in the thoracic and lumbar areas (Ringheim et al., 2015).

In reducing pain exertion in lower back patients, ESI is the most effective way to alleviate pain, it has been utilized for more than 50 years. Past studies have indicated that ESI significantly reduces pain for patients and has the effect of delaying possible surgery (Kreiner et al., 2014). In addition, ESI is significantly effective in patients diagnosed with disc herniation (Shamov et al., 2020). Also, various studies have demonstrated the effectiveness of ESI in alleviating LBP (Choi et al., 2013; McLain et al., 2005; Pandey, 2016; Yang et al., 2020). A previous study indicated that for osteoarthropathy patients, the paravertebral spinal injection has depicted improvements in gait speed by 14% and hip sway balance by 63% (Toosizadeh et al., 2016). Therefore, it is essential to investigate the gait and posture of the LBP patient, as they share similar conditions as fall prone individuals.

The purpose of this study is to perform an in-depth analysis of the effectiveness of ESI before and after the intervention on LBP gait/postural and dynamic stability. We hypothesized that gait/postural stability will be improved after the epidural injection, which was measured with gait speed, dynamic stability, and postural sway length and area.

3.2 Method and Materials

For this study, we recruited a total of 15 LBP patients (table 3-1) who underwent ESI procedures to alleviate their LBP. This sample size was determined by utilizing a priori power analysis using G*Power statistical software and a target Type I error of 0.05 and Type II error of 0.2. Prior to initiating the data assessment, we dismiss all the participants that were in the exclusion criteria, such as minors who were under the age of 18, pregnant women, a participant who cannot walk 10 meters without assistance, a participant who had shortness of breath, dizziness, frequent headache, a participant with a severe mental, cardiac, respiratory, neurodegenerative disorder, and who had major surgery less than 6 weeks before enrollment in the study. Since this study required basic activity, such as walking and balancing, these minimum exclusion standards were required for avoiding possible participant injuries. The severity of LBP was diagnosed by orthopedic surgeons who decided to provide the ESI, where the patients authorized the ESI procedure, because of the agonizing pain.

Table 3-1. Faller and Non-faller LBP patient's anthropometry.

Characteristics	Total (n=15)
	Mean (SD)
Age (years)	70.73 (10.89)
Gender	5M /10F
Height (cm)	168.95 (9.47)
Weight (kg)	89.73 (23.71)
BMI (kg/m^2)	31.34 (7.35)

Once the participant meets all the inclusion criteria, they were asked to fill out medical history questionnaire which was designed specifically for this study, Activities-specific Balance Confidence Scale (ABC), and Oswestry Low Back Pain Disability Questionnaire. The purpose of the ABC Scale was to assess a participant’s self-confidence level for executing certain activities or movements without losing balance (Powell & Myers, 1995). The Oswestry LBP disability questionnaire evaluated the magnitude of the LBP intensity and continuous functional limitation caused by LBP (Fairbank & Pynsent, 2000). These inquiry forms were provided to measure a subjective aspect of the participant’s current activity, balance, and LBP level. Once the survey was completed, qualified participants were equipped with the IMU system on their L5/S1 sacrum area as shown in 3-2a.

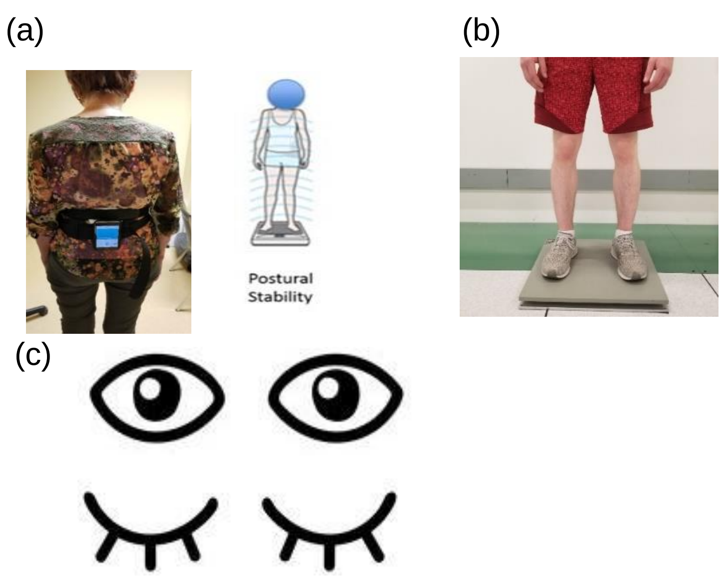


Figure 3-2. (a) Location of IMU system attached on the participant’s sacrum area for the gait and postural stability assessments, (b) All participants performed

postural stability testing for 60 seconds, (c) Two different eyes open and close conditions were tested during the postural stability assessment.

Postural sway parameters were applied to determine the elderly's frailty (Moraes et al., 2019). Moreover, to distinguish between fallers and non-fallers, the generally observed parameters include the extent of postural sway area, sway velocity, and sway path length (Johansson et al., 2017; Itshak Melzer et al., 2010; Watt et al., 2018).

For the experiment method, first, a postural stability test was executed. As depicted in Figure 3-2b, participants were requested to maintain their normal postural stability for 60 seconds with eyes open and closed condition (Figure 3-2c). To analyze the postural stability parameters, the Center of Pressure (COP) sway path length was computed with the distance traveled by COP divided by a set time interval by summation of Euclidean distance between the data points (n).

$$\text{COP Path Length (cm)} = \sum_{n-1}^{n} \sqrt{(x_n - x_{n-1})^2 + (y_n - y_{n-1})^2} \qquad (1)$$

As presented in Figure 3-3, The ellipsoid presents a 95% confidence ellipse around the area covered by COP. This parameter is calculated by utilizing the variance/covariance matrix eigenvalues. The COP sway velocity was calculated with the movement from the total sway of the COP in the anterior-posterior (AP) and medial-lateral (ML) direction over the total temporal data measurement period.

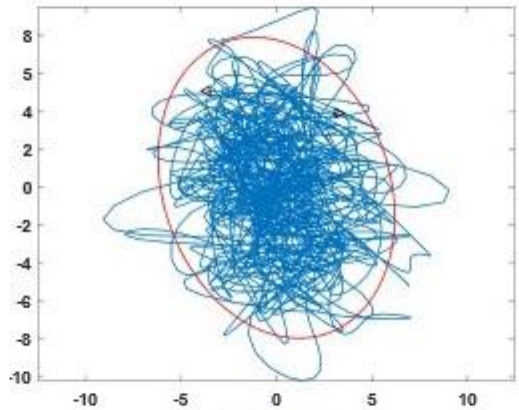


Figure 3-3. Ellipse sway area from the postural stability assessment.

For the gait stability assessment, the 10-meter walking protocol was utilized by identifying a 10-meter distance with a tape measure for participants to walk with their normal gait speed (Figure 3-4). The application indicated the start of the data collection with a beeping sound signal. In this process, the first monotone alert represented the calibration signal, in this phase, the IMU calibrated the steady state of the body movement from the sacrum area. The second monotone alert requested the participant to initiate the 10-meter walk. Finally, when the participant comes to a complete stop after walking 10 meters, the final monotone sound announced the end of the trial. To indicate the dual-task effect on walking with LBP participants, we asked participants to start counting backward from 100 with serial subtraction of 7 (Soangra & Lockhart, 2017). This methodology has normalized the cognitive task by performing this technique.

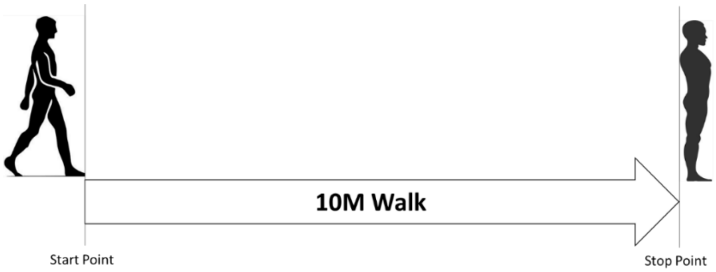


Figure 3-4.10-meter walk procedure executed during the gait parameter measurement.

The detection method for the starting and stopping of this 10-meter walk, the threshold algorithm was used as indicated in Figure 3-5. First, the variance of the 1-second window segment from the resultant acceleration data was computed to convert the initial resultant acceleration into acceleration variance. Second, the threshold boundary was indicated with the mean value-added with two standard deviations of the variance in the primary standing calibration phase. Lastly, starting and stopping moment was determined when the resultant acceleration variance surpassed the threshold limit and when it decreased under the threshold limit.

From the 10m walk testing, Gait Cycle Time (GCT) was determined which indicates the total cycle of time for single foot heel contact to heel contact. This parameter is important, as the previous study has indicated that fallers had significantly higher GCT compared to non-fallers (Chiba et al., 2005; Sadeghi et al., 2021). In addition, the Double Support Time (DST) parameter is observed, this depicts the temporal duration of the right and left foot contacted with the ground during the total gait cycle. Kwon et al, presented that double support time was higher in the faller group (Kwon et al., 2018; Sadeghi et al., 2021). Moreover, the Step Time (ST) demonstrates the time duration between the heel contact of the right foot and the instant moment of the left foot's heel contact on the ground. The past study indicated that the faller has substantially extended ST compared to non-fallers (Toulotte et al., 2006). Also, Gait Speed (GS) has been utilized to determine faller and non-faller, where faller had significantly slower GS (Kwon et al., 2018; Sadeghi et al., 2021; Toulotte et al., 2006)

To compute the gait speed from this acceleration data, the total distance (d) was 10 meters, and it was divided by the period of the time (t) that took the participant to complete the entire walking distance.

$$\text{Gait speed (m/s)} = \frac{d}{t} \quad (2)$$

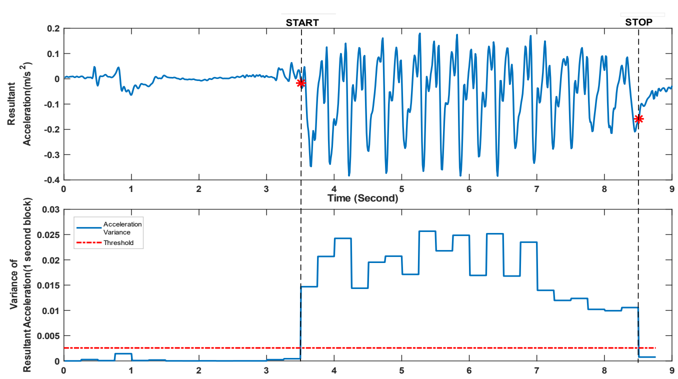


Figure 3-5. Gait detection algorithm by using the threshold method with acceleration variance.

Lastly, to measure the Maximum Lyapunov Exponent (LyE) that depicts the dynamic stability (Lockhart & Liu, 2008), for a minimum of 120 seconds continuous walking was performed on a clear path where the participant was not interrupted.

$$X(t) = [x(t), x(t+T), x(t+2T), \ldots, x(t+(dE-1)T)] \quad (3)$$

To calculate the maximum LyE, the Time-delayed coordinate method was applied. This implies that any adequate size of fundamental dynamic information that was performed in single dimension temporal time series can be reconstructed into multi-dimensional state space (Takens, 1981). Initially, we assessed 3 minutes of the continuous gait cycle as demonstrated in figure 3-6, which contained necessary dynamic information, and then proceeded with state-space X(t) calculation, as presented in figure 3-7, where minimum embedding dimension (d_E) and time delay (T) components were required to be determined from the single dimension time series data.

$$\lambda = \frac{\{In[Dj(i)]\}}{\Delta t} \quad (4)$$

After determining the state space, all the nearest neighbors were collected which has the closest distance from the stride trajectories in the reconstructed state space. To calculate the Maximum LyE, all the distance (D) was assessed by selecting the total nearest neighbor's data points from the distinct strides. This process was measured regarding time (t), where it depicts the logarithmic divergence in the function of time, and Figure 3-8 depicts the finalized divergence curve. Dj(i) represents the Euclidean distance of *i* discrete time steps and a *j* th pair of nearest neighbors. Also, Δt denotes the time series data sampling duration.

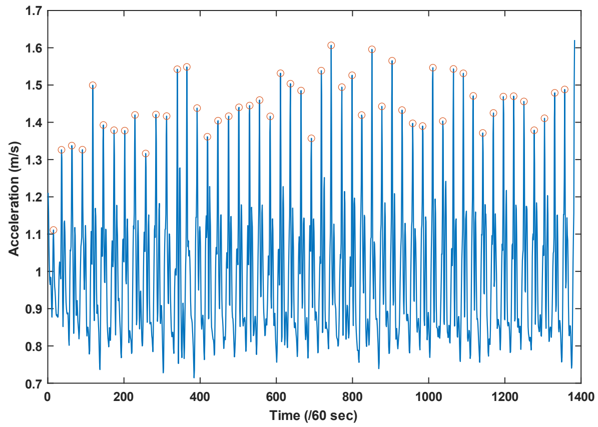


Figure 3-6. Continuous gait cycle from single dimension time series that contains fundamental dynamic data.

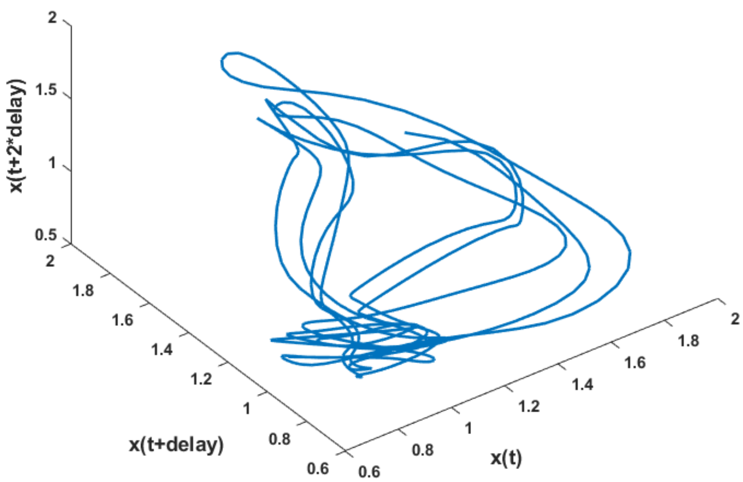


Figure 3-7. Reconstructed multidimensional state space by using minimum embedding dimension and time delay coordinate method.

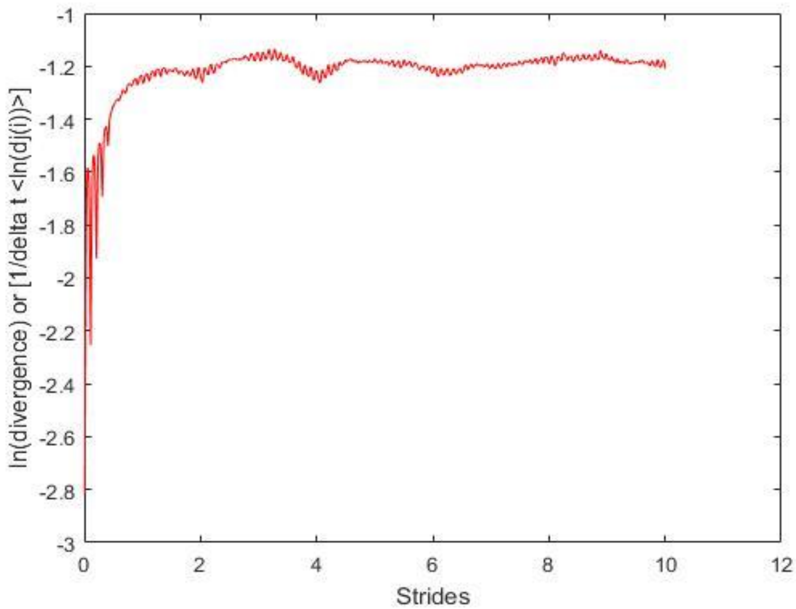


Figure 3-8. Graph of completed divergence curve from average divergences of nearest neighbor trajectories.

These postural and gait parameters are frequently utilized to determine the fall risk patients (Hausdorff et al., 2001; Lockhart & Liu, 2008; Pua et al., 2017; Studenski et al., 2011), and these factors can furthermore indicate the instability of the LBP patient before and after the injection.

For this study protocol, 1st pre-injection data collection was executed one to two weeks before the spinal injection, 2nd the post-injection data collection could be initiated anytime between immediately after the ESI was executed to a maximum limit of up to two weeks after the injection, depending upon the patient's availability. In this study, the average return date for the post-data assessment was 8 days after the injection. Additionally, when subjects revisited the clinic for the post-injection data collection, they were asked to fill out the questionnaires, which included fall history, Oswestry Low Back Disability, and ABC scale questionnaire.

John's Macintosh Project (JMP) statistical analysis software program (JMP Pro 16, SAS Institute Inc., Cary, NC, USA, 2021) was used to execute statistical evaluation. To investigate the efficacy of the ESI on the subject's gait and posture parameters, Multiple Analysis of Variance (MANOVA) was applied to examine the independent variable's effect on the multiple response variables.

3.3 Results

QUESTIONNAIRES

Oswestry Low Back Pain disability index score*:* Oswestry pain disability scale quantifies the LBP patient's pain level and functional disability (Halfaker et al., 2011).

The result indicated that the Oswestry pain scale depicted a significant difference ($p < 0.001$*) between pre (56 ± 14.74) and post (23.43 ± 15.95) ESI conditions.

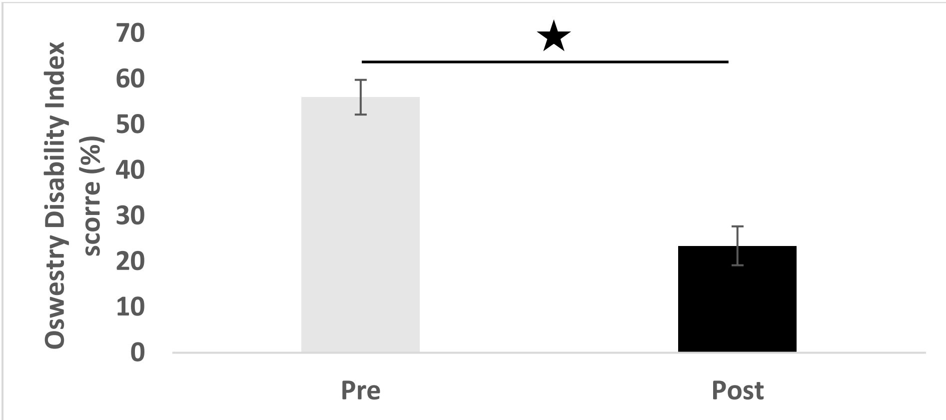


Figure 3-9. The Oswestry scale difference between pre and post-ESI intervention. (Standard Error is used as the error bar)

Activities-Specific Balance Confidence Scale (ABC) Score: The ABC score indicates the confidence level of subject performing certain activities without losing balance, and if they have never executed specific activities, subjects simulated how self-confident they would be able to execute that movement (Powell & Myers, 1995). The pre (72.6 ± 19.89) and post (79.21 ± 13.28) ESI conditions showed no significant difference ($p = 0.2033$).

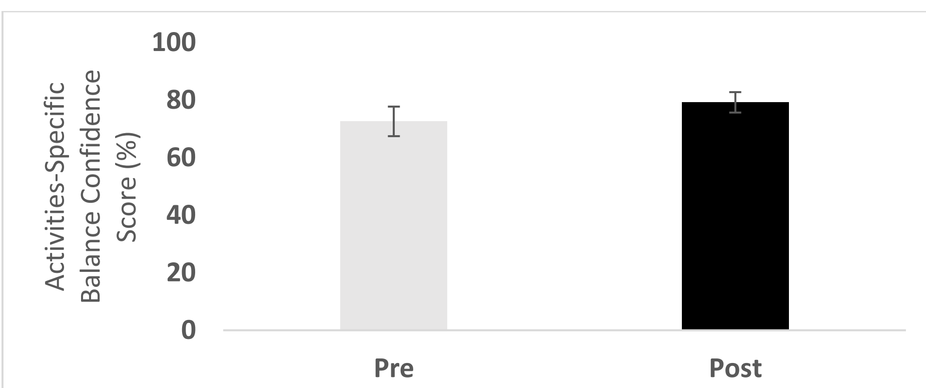


Figure 3-10. ABC score difference between pre and post ESI intervention.

POSTURAL STABILITY

Sway Anterior-Posterior (AP): Sway AP indicates the front and back sway movement of the subject while performing postural stability testing. There were no significant differences between pre (9.54± 5.58) and post (8.84 ± 5.46) ESI conditions for the sway AP for postural stability testing (p = 0.244).

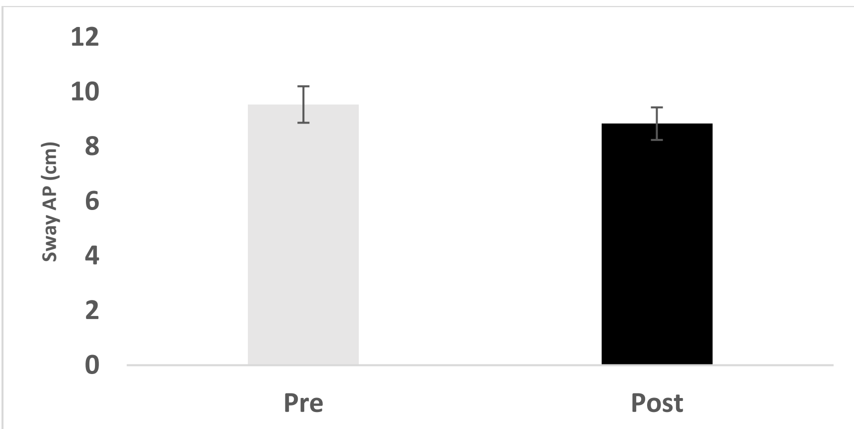


Figure 3-11. Sway AP difference between pre and post in ESI intervention.

Sway Medial and Lateral (ML): Sway ML indicates the left and right sway movement of the subject while performing postural stability testing. There were no significant differences between pre (6.08 ± 5.14) and post (5.14± 4.93) ESI conditions for the sway ML for postural stability testing (p = 0.107).

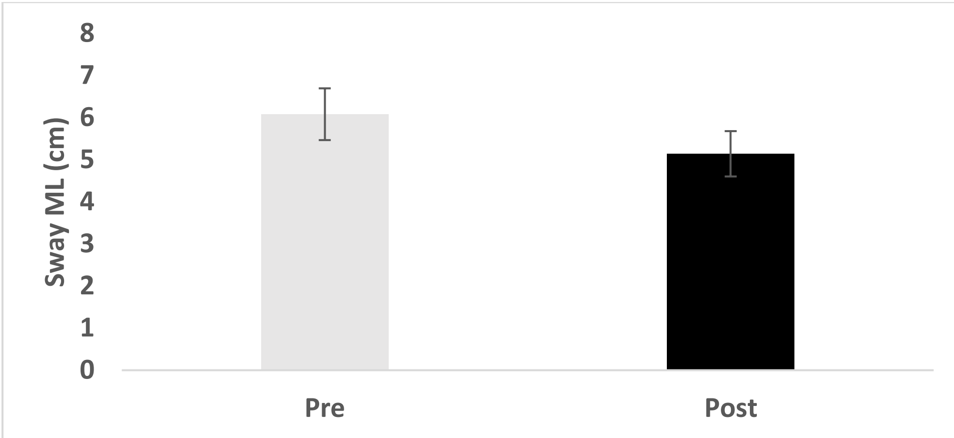


Figure 3-12. Sway ML difference between pre and post in ESI intervention.

Sway Path: Sway path is the distance traversed by the IMU sensor on the standing subject, performing postural stability testing. There were significant differences between pre (44.53 ± 31.12) and post (36.11 ± 18.23) ESI conditions for the sway path for postural stability testing ($p = 0.03$*).

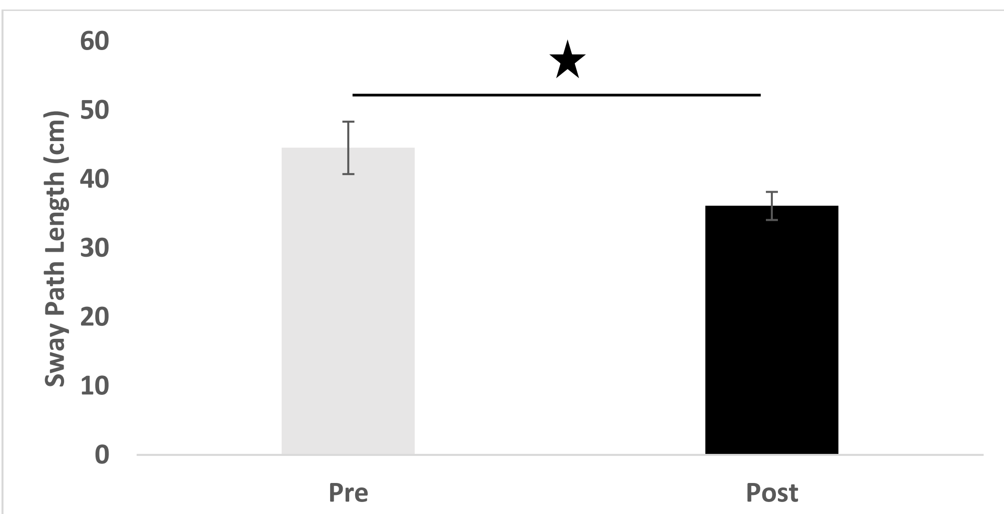


Figure 3-13. Sway path difference between pre and post in ESI intervention.

Sway Velocity: Postural sway velocity is the mean horizontal range covered by the range of the center of mass per second, in AP and ML directions. A significant difference was determined in sway velocity in pre (8.0 ± 5.35) post (6.28 ± 3.15) ESI condition (p = 0.009*).

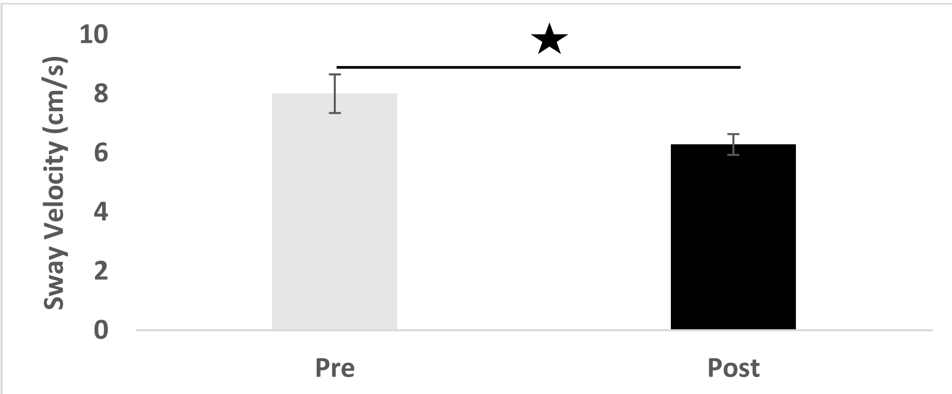


Figure 3-14. Sway velocity difference between pre and post in ESI intervention.

Sway Area: the sway area is the scope of the area where the subject performs the quiet standing sway movement. The result indicated that no significant difference was found between pre (22.92± 27.13) and post (16.41 ± 19.18) ESI conditions (p = 0.123).

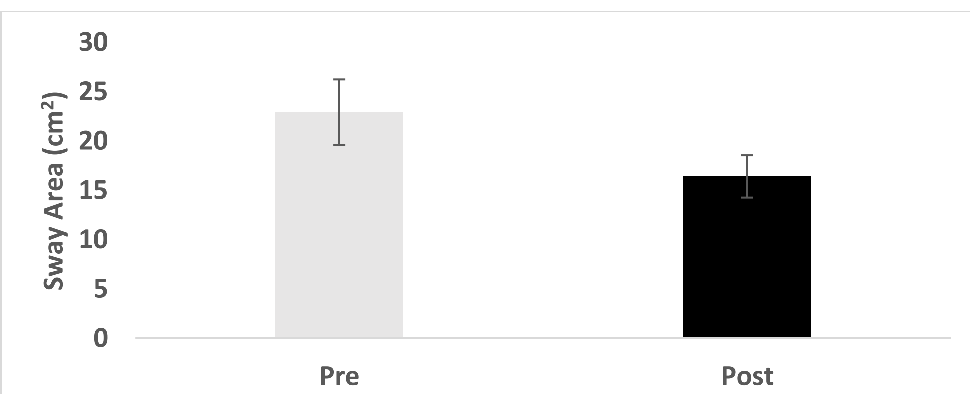


Figure 3-15. Sway area difference between pre and post in ESI intervention.

GAIT STABILITY

Gait Cycle Time (GCT): Gait cycle time refers to the time duration between two consecutive heel contacts of the same foot. The total GCT indicated a significant difference pre (1.16 ± 0.11) and post (1.11± 0.09), (p = 0.0298*)

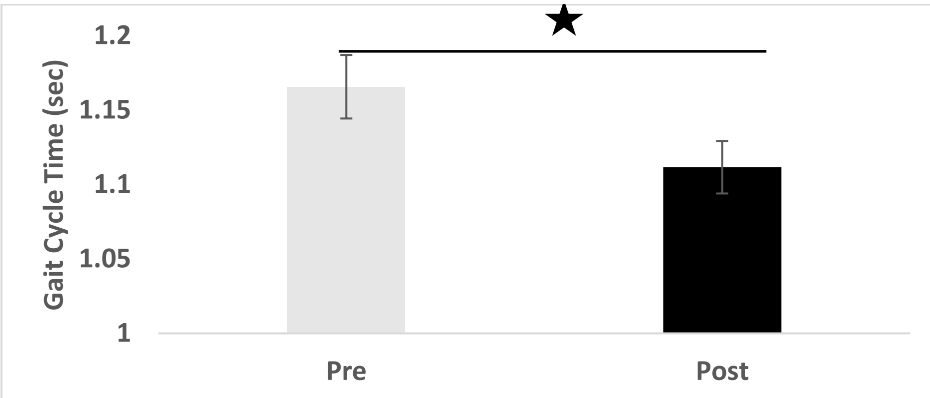


Figure 3-16. GCT difference between pre and post-in ESI intervention.

Double Support Time (DST): Double support time refers to the time duration of both feet attached to the ground during walking. The total DST did not indicate a significant difference (p = 0.296) among the pre (0.26 ± 0.08) and post (0.24± 0.07) ESI conditions.

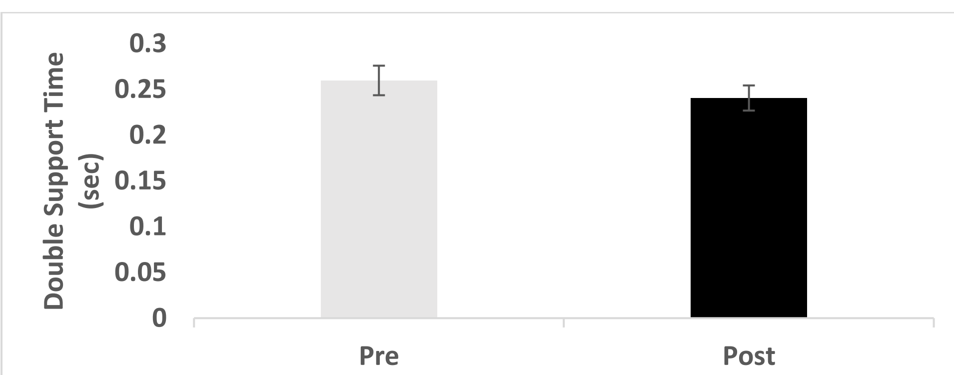


Figure 3-17. DST difference between pre and post in ESI intervention.

Step Time (ST): The step time is the time interval between the initial contact of the right foot to initial contact of the left foot. The total ST indicated no significant difference pre (0.58 ± 0.05) and post (0.56 ± 0.05) ESI condition, (p = 0.09).

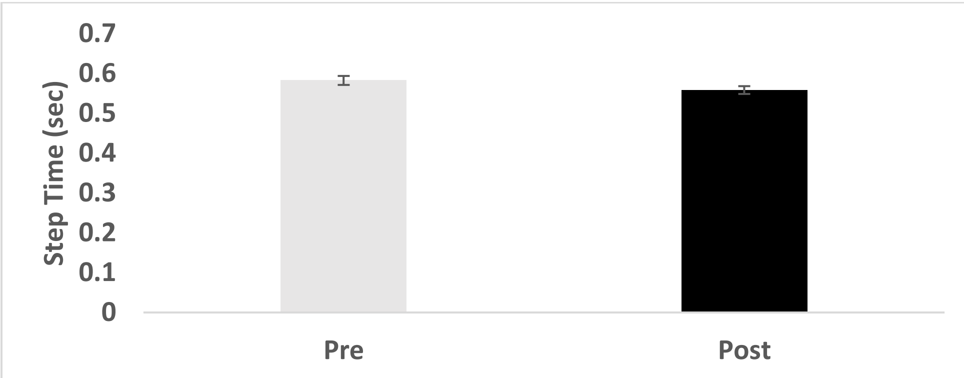


Figure 3-18. ST difference between pre and post in ESI intervention.

Gait Speed (GS): Gait speed is calculated with total distance divided by total time duration. The GS presented a significant difference in pre (0.83 ± 0.26) and post (0.91 ± 0.25) ESI (p = 0.045*).

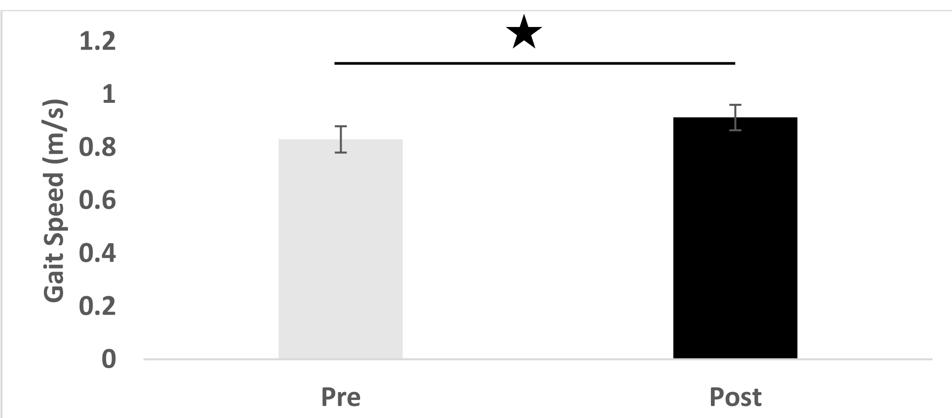


Figure 3-19. GS difference between pre and post in ESI intervention.

Dynamic Stability (DS): For the DS there is no significant difference between pre (1.80 ± 0.15) and post (1.73 ± 0.15), (p = 0.233).

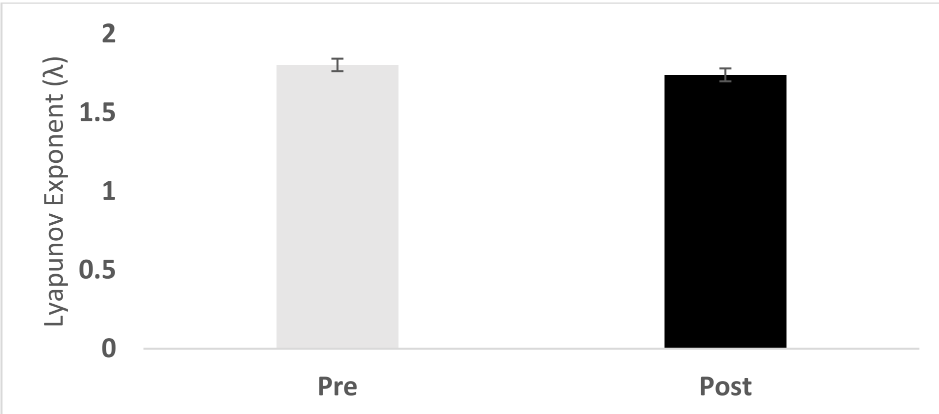


Figure 3-20. DS difference between pre and post in ESI intervention.

Table 3-2. Effect of ESI on LBP patient's gait & postural characteristics

Characteristics	Pre	Post	P-value
	Mean (SD)	Mean (SD)	
Oswestry(%)	56 (14.74)	23.43 (15.95)	< .001*
Sway Path(cm)	44.52 (31.12)	36.12 (18.23)	.031*
Sway Velocity(cm/s)	8.00 (5.35)	6.28 (3.15)	.009*
Gait Cycle Time(sec)	1.16 (0.11)	1.11 (0.09)	.0298*
Gait Speed(m/s)	0.83 (0.26)	0.91 (0.25)	.045*

3.4 Discussion

The purpose of this study was to determine the efficacy of the ESI on pre and post-intervention conditions, in various questionnaires, gait, and postural stability testing conditions. For the questionnaire assessment, the Oswestry pain scale indicated a significant decrease after the post-injection state, which as hypothesized the ESI alleviates the pain scale immensely for LBP patients (Carassiti et al., 2022). Erçalık et al, this study observed pain relief after the ESI with several questionnaire outcomes such as Oswestry Disability Index(ODI), The Numeric Rating Scale (NRS), and Istanbul Low Back Pain Disability Index (ILBPDI). All of these parameters depicted a significant decrease (ODI : $P<0.0001^*$, NRS : $P<0.0001^*$, ILBPDI : $P<0.0001^*$) in pain score at three weeks from the baseline pain score data (Erçalık et al., 2019). The ABC score did not indicate a significant difference after the ESI, where which depicts that the confidence level of the balance does not modify along with the LBP level. These observations are analytically important, yet questionnaires are considered to have low reliability due to their susceptibility to variation and subjectivity, which can lead to inconsistency. Therefore, we assessed and quantified parameters such as postural and gait stability.

In this clinical study, for the postural stability aspects, the sway parameter anterior-posterior and medial-lateral direction did not depict significant differences before and after the ESI intervention, but the total sway pathway was significantly decreased after the injection. A previous study has indicated that less sway pathways represent higher stability in postural balance (Blaszczyk et al., 1994; Rhea et al., 2014). This demonstrates that after ESI intervention stabilizes the postural total path length of LBP patients. Comparatively, the sway velocity parameter of the post-ESI conditions depicted a significantly reduced rate in contrast to the pre-injection state. Past research has indicated that higher sway velocity was observed with an increase in sensory impairment, which demonstrates less stability (Seimetz et al., 2012). In addition, older adults who exhibit lower postural stability due to the degradation of vestibular, somatosensory, and visual sensors depicted higher sway velocity (Roman-Liu, 2018). Similarly, one study has illustrated the paravertebral spinal injection for osteoarthropathy patients, and their hip sway balance has notably improved ($P<0.03^*$) after the injection medication (Toosizadeh et al., 2016). As a result, ESI improves postural sway velocity between the pre and post ESI. The sway area parameter did not indicate a significant improvement after the ESI intervention. Various studies indicated that low back pain can impact negatively for patients and restrict mobility outcomes (Eggermont et al., 2014; Karttunen et al., 2012; Leveille et al., 2009), where this can affect the postural stability of LBP patients. Therefore, the outcome represents an ESI that has a beneficial effect on postural sway velocity and pathway. This implies that ESI has the valuable impact of improving postural stability and fall risk.

The gait parameters such as the GCT showed a significantly decreased after the ESI intervention, where GCT is a sensitive gait parameter that could distinguish faller and non-faller in geriatric groups (Hamacher et al., 2011). Furthermore, GS indicated a significant increase after the ESI, and previous studies have indicated that aging and fallers were closely associated with declined walking speed (Mortaza et al., 2014; Pirker & Katzenschlager, 2017). Similarly, prior research has presented that after the paravertebral spinal injection for Degenerative Facet osteoarthropathy (DFO) patients, they have significantly improved Gait Speed(GS) and Gait Cycle Time(GCT) after the injection (GS : P<0.01*, GCT : P<0.05*) (Toosizadeh et al., 2016). Therefore, the substantial improvement before and after the injection determines the positive influence of the ESI. For the DST ESI intervention did not indicate a significant difference. Similarly, ST did not significantly reduce after the ESI condition and DS was also not substantially impacted by the ESI. Past study has indicated that the more fragile individuals have a tendency of increasing GCT, DST, and ST (Mortaza et al., 2014). This result could lead to the rational conjecture that the ESI effect accelerates the recuperation of LBP and positively influences the gait parameters. This indicates that ESI intervention was effective and beneficial for the major gait parameters, such as GCT and GS. Despite the immense effort to optimize the research protocol, there were several limitations that need to be addressed. The lack of a control group is a limitation of this study, where it was not feasible to incorporate the plausible control group since it was voluntary clinical research study. Also, subjects were asked to wear athletic running shoes to ensure their optimal performance for the gait and balance testing. However, it was unfeasible to have them wear identical footwear. Additionally, performing the data collection at the same time of the day was problematic since subjects had different schedule, where it could be effect by the different cortisol level difference throughout the day (Timmermans et al., 2019). To normalize this procedure, the data collection was done between 9AM to 3PM of the day. The subject's nature pain characteristic could be highly subjective where the pain determination could be influenced by psychological aspect. Moreover, there are various injection technique for ESI where these alternatives can impact the results and create challenges to compare the outcomes.

Overall, evidence led to determine that the ESI intervention effectively enhances postural and gait stability despite the intricate circumstance. As a result, ESI has a considerable effect on improving the gait and posture stability in pre and post-injection conditions.

3.6. Conclusion

The main objective of this study was to determine the pre and post-ESI efficacy on gait and postural stability associated with ESI on LBP. Various outcomes verified that there was an improvement in LBP patients' gait and postural stability. For postural stability parameters, the result depicted that the sway path, velocity, and area were significantly decreased after ESI injection, where the ESI influences the rapid movement of postural sway and improves stability. Correspondingly, the post-injection condition for GCT depicted a significant reduction. This indicates that the total time duration of the gait cycle and walking speed were positively affected (better stability) by the ESI.

CHAPTER 4:

EFFICACY OF EPIDURAL STEROID INJECTION ON LOW BACK PAIN PATIENT'S ACTIVITIES OF DAILY LIVING

4.1 Introduction

In the age of rapid growth of the older population, LBP is one of the most prevalent issues that current society is facing. LBP problems tend to occur more during the senescence phase, where this issue reaches its peak at the age of 80 to 89 years older (Wu et al., 2020). In addition, The World Health Organization (WHO) has indicated that LBP was the number one contributor to musculoskeletal condition disorders. For instance, 570 million prevalent cases were indicated as LBP which influences the most on the musculoskeletal disorder. Other musculoskeletal disorder condition was as follows, 528 million cases of osteoarthritis, 222 million neck pain, 180 million of amputation, 54million of gout condition, and lastly, 18 million cases of rheumatoid arthritis (*Musculoskeletal Health*, 2022; Wu et al., 2020). Moreover, this issue causes the patient physical discomfort and also puts a vast economic burden on society and the family. In the United States, a past study has discovered that low back and neck pain reported the third highest medical care expenditure at $87.6 billion (Dieleman et al., 2016).

The source of this critical issue is primarily maintaining a poor posture that puts force on the lower back that gradually impacts the deterioration causing the LBP (Brumagne et al., 2008). Previous studies indicated that the combination of numerous deteriorated complications causes LBP patients to be vulnerable to fall risk (Marshall et al., 2017; Sohn et al., 2013). Eventually, LBP significantly affects the Activities of Daily Living (ADL) which leads to a decrease in physical activity levels. This develops a sedentary lifestyle, where the majority of daily activities are sitting or lying down, resulting in substantially less active movement that leads to various adverse health conditions (Booth et al., 2012). Mahdavi et al, this study has depicted the correlation between LBP and sedentary behavior, the LBP occurrence proportionally increased as a sedentary lifestyle was more prevalent among the subjects (Mahdavi et al., 2021). In addition, it is reported that patients who are diagnosed with LBP reported difficulty in performing typical ADL movements compared to other musculoskeletal diseases, such as osteoarthritis, gout, and rheumatoid arthritis, or healthy individuals (Stamm et al., 2016).

To reduce this deteriorating effect for LBP patients, ADL is one of the most important aspects that need to be analyzed. Past studies have presented that the evaluation of multiple days of Activities of Daily Living (ADL) data provides the subject’s daily pattern and physical activity level, which is significantly correlated with fall risk and capable of evaluating fall prone individuals (Scheers et al., 2012). As a result, it is crucial to assess this genuine fundamental ADL data to determine the practical physical activity level and fall risk individuals. A sufficient amount of physical activities throughout the casual lifecycle could improve muscle and bone strength, increase cognitive health, reduce fall risk, and eventually increase total life expectancy (Olson et al., 2018).

Table 4-1. General acitivity assessment model of the Health Assessment Questionnaire (HAQ) (Bruce & Fries, 2003a).

The STANFORD HEALTH ASSESSMENT QUESTIONNAIRE©
Stanford University School of Medicine, Division of Immunology & Rheumatology

HAQ Disability Index:
In this section we are interested in learning how your illness affects your ability to function in daily life. Please feel free to add any comments on the back of this page.

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY difficulty 0	With SOME difficulty 1	With MUCH difficulty 2	UNABLE to do 3
DRESSING & GROOMING				
Are you able to:				
-Dress yourself, including tying shoelaces and doing buttons?	☐	☐	☐	☐
-Shampoo your hair?	☐	☐	☐	☐
ARISING				
Are you able to:				
-Stand up from a straight chair?	☐	☐	☐	☐
-Get in and out of bed?	☐	☐	☐	☐
EATING				
Are you able to:				
-Cut your meat?	☐	☐	☐	☐
-Lift a full cup or glass to your mouth?	☐	☐	☐	☐
-Open a new milk carton?	☐	☐	☐	☐
WALKING				
Are you able to:				
-Walk outdoors on flat ground?	☐	☐	☐	☐
-Climb up five steps?	☐	☐	☐	☐

Please check any AIDS OR DEVICES that you usually use for any of these activities:

☐ Cane
☐ Walker
☐ Crutches
☐ Wheelchair

☐ Devices used for dressing (button hook, zipper pul long-handled shoe horn, etc.)
☐ Built up or special utensils
☐ Special or built up chair
☐ Other (Specify:____________)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

☐ Dressing and Grooming
☐ Arising

☐ Eating
☐ Walking

Generally, the assessment method for the ADL is a primarily subjective method, such as questionnaires. For instance, the Stanford Health Assessment Questionnaire (HAQ) and the Katz Index of Independence in Activities of Daily Living were utilized to assess the physical activity level (Bruce & Fries, 2003b; Shelkey & Wallace, 1999). HAQ (Table 1) is a fundamental scoring measurement model for identifying the longitudinal effect of various chronic illnesses. This questionnaire was considered to focus more on generic structure measuring.

Table 4-2. Katz Index of Independence in Activities of Daily Living Questionnaire (Shelkey & Wallace, 1999).

Katz Index of Independence in Activities of Daily Living		
Activities Points (1 or 0)	**Independence** (1 Point) **NO** supervision, direction or personal assistance.	**Dependence** (0 Points) **WITH** supervision, direction, personal assistance or total care.
BATHING Points: ___________	**(1 POINT)** Bathes self completely or needs help in bathing only a single part of the body such as the back, genital area or disabled extremity.	**(0 POINTS)** Need help with bathing more than one part of the body, getting in or out of the tub or shower. Requires total bathing
DRESSING Points: ___________	**(1 POINT)** Get clothes from closets and drawers and puts on clothes and outer garments complete with fasteners. May have help tying shoes.	**(0 POINTS)** Needs help with dressing self or needs to be completely dressed.
TOILETING Points: ___________	**(1 POINT)** Goes to toilet, gets on and off, arranges clothes, cleans genital area without help.	**(0 POINTS)** Needs help transferring to the toilet, cleaning self or uses bedpan or commode.
TRANSFERRING Points: ___________	**(1 POINT)** Moves in and out of bed or chair unassisted. Mechanical transfer aids are acceptable	**(0 POINTS)** Needs help in moving from bed to chair or requires a complete transfer.
CONTINENCE Points: ___________	**(1 POINT)** Exercises complete self control over urination and defecation.	**(0 POINTS)** Is partially or totally incontinent of bowel or bladder
FEEDING Points: ___________	**(1 POINT)** Gets food from plate into mouth without help. Preparation of food may be done by another person.	**(0 POINTS)** Needs partial or total help with feeding or requires parenteral feeding.
TOTAL POINTS: ________	**SCORING:** 6 = High (*patient independent*) 0 = Low (*patient very dependent*	

The Katz Index of Independence in Activities of Daily Living measurement is a prompt and less complex method of assessing older adults' health functionality level and the subject's capability to execute activities of daily living independently. As demonstrated in Table 4-2, the Katz questionnaire measures the performance ability throughout six functions of bathing, dressing, toileting, transferring, continence, and feeding, then provides an index ranking result. Subjects are questioned whether they are dependent or independent of each of the six selected activities and this is scored 0 or 1. The scoring system of the Katz index is separated into three sections. First, 5 to 6 points indicate that the subject's functionality is fully operational, and 3 to 4 points imply a moderate level of impairment. Lastly, 2 or less points present a critical functional impairment level of the subject (Shelkey & Wallace, 1999). These questionnaires support clinicians and researchers to extract valuable data sets from physical activity information with a low-cost approach. Yet these subjective measurements provide useful data to evaluate the physical activity status of the patients. However, there is a possibility of data incorporating biased aspects (Carlsson et al., 2012). This contains an elevated risk of data being unreliable because the data evaluation has the chance of being governed by the participant's emotional perception, which could exhibit immense volatility. Consequently, replacement of this methodology is necessary due to appearing issues. The exceptional development of wearable technology such as the Inertial Measurement Unit (IMU) has immensely improved its measuring capability. This has allowed researchers to assess the quantitative ADL physical activity level, and energy expenditure and provided objective measurement of ambulatory parameters (Jakicic et al., 1999; Nam et al., 2019; Nguyen et al., 2018). Moreover, a particular study has conducted a physical performance assessment of ADL after the injection with a count of steps per day (Tomkins-Lane et al., 2012). Therefore, utilizing the IMU wearable system and implementing our algorithm to assess ADL physical activity level is necessary for LBP patients.

The objective of this study was to assess 3 days of LBP patients' ADL with IMU wearable technology and analyze the quantitative longitudinal data to distinguish the physical activity level difference before and after the ESI on LBP patients.

4.2 Method and Materials

4.2.1 Protocol

This study had a total of fifteen subjects who were 50 years or older, who were diagnosed with severe LBP disorder, where the patient indicated severity where they can no longer bear the pain. Once a precise LBP diagnosis was executed by the orthopedic surgeons, both patient and the doctor reached a mutual agreement to administer the ESI injection. The inclusion criteria for the subjects were the patient who was older than 18, and able to perform more than 10 meters walk without assistance, patients without shortness of breath, dizziness, headache, severe mental issue, cardiac, respiratory, or neurodegenerative disorder, and who did not have had any major surgical operation done within 6weeks before the data collection. The LBP patients who were considered qualified for these standards were recruited for this study. The anthropometry specification of the subject's data is stated in Table 4-1.

Table 4-3. The anthropometry information of Low Back Pain subjects.

Characteristics	**Total (n=15)**
	Mean (SD)
Age (years)	70.73 (10.89)
Gender	5M /10F
Height (cm)	168.95 (9.47)
Weight (kg)	89.73 (23.71)
BMI (kg/m^2)	31.34 (7.35)

For the ADL physical activity level measurements, the physician and research affiliate elaborates on the procedure of the ADL assessment and proposed patients enroll in the study. After getting verbal agreement from the participant approving to take part in the study, investigators thoroughly consulted with subjects and addressed all the related questions and concerns they might have about the research before proceeding to the next phase, this advisory procedure was executed within The CORE institute, Pain management department office (3591 S. Mercy Rd. Suite 204. Gilbert, AZ 85297). This was the location where the subjects were recruited and initiated the ADL data collection. Prior to progressing to data collection, informed consent was signed by subjects, which was approved by Mayo and Arizona State University Institutional Review Board. Once the consent form is signed, Dynaport MM+ (Motion Monitor+, McRoberts BV, The Hague, Netherlands) IMU device was provided for the subject. The device is equipped with state-of-the-art technology that contains a sampling frequency of 100Hz, the feature of a triaxial gyroscope, dimensions of 106.6×58×11.5mm, weight of 55 grams, and a measuring capability of more than 3 consecutive days.

For the 3 days of ADL data collection, this device was given to the subject for longitudinal data collection with instructions on how it should be retained. Before leaving the clinic, subjects were required to set the launching date and time for starting 3 days of ADL data collection for Dynaport. By establishing the initiation time, 72 hours of continuous data were assessed from this device. They are instructed to have the Dynaport placed on the sacrum area as shown in Figure 4-1, at all times unless for changing clothes, hygiene purposes, or any other activity that is associated with submerging in water.

Figure 4-1. Dynaport is affixed on the subject's lumbar region to perform ADL for 3days.

4.2.2 Data Analysis

From the ADL data that was collected from the Dynaport IMU sensor, we were able to proceed with various analyses of the longitudinal data. The main various analysis processed with this information were threshold physical activity level and wavelet frequency analysis.

4.2.3 Threshold Physical Activity Level Analysis

This analysis was evaluated with Detrended Resultant Acceleration (DRA), which was calculated from raw accelerometer data assessed from ADL. The resultant acceleration was calculated from the raw X, Y, and Z accelerometer data. From the resultant acceleration, we were able to compute the DRA by subtracting the gravity (g) from the resultant acceleration

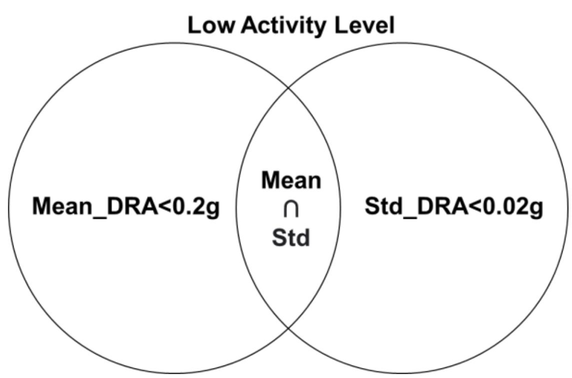
$$\text{Resultant}_{x,y,z} = \sqrt{([AccelerationX]^2 + [AccelerationY]^2 + [AccelerationZ]^2)} \quad (1)$$

Detrended Resultant Acceleration (DRA) =

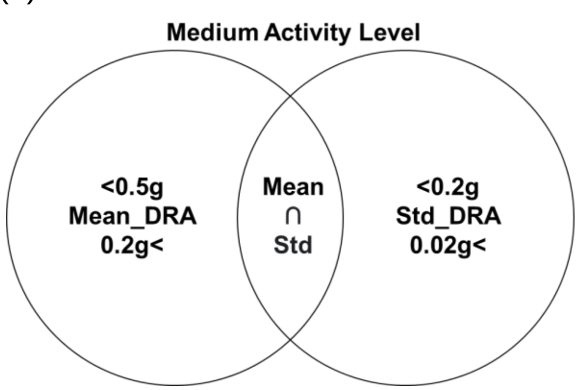
$$\left| \sqrt{[AccelerationX]^2 + [AccelerationY]^2 + [AccelerationZ]^2} - g \right| \quad (2)$$

To determine the magnitude of physical activity level, the one-second segment of sliding window size was implemented in this time series accelerometer data (Lockhart et al., 2013). Assessed 24hours of the data was marked and separated into four-time sections, Time section 1 (12 pm to 6 pm), Time section 2 (6 pm to 12 am), Time section 3 (12 am to 6 am), Time section 4 (6 am to 12 pm). Within these four time zones, the subject's daily activity levels were categorized into three separate degrees, low, medium, and high. Low activity levels, such as respiratory motion, the gesture of the head, and minor stretching movement were determined with below mean DRA of 0.2 g and standard deviation DRA of 0.02 g. For the medium activity level, this intensity of movement was similar to the normal gait motion. This particular status was defined with mean DRA greater than 0.2 g and less than 0.5 g, and standard deviation DRA greater than 0.02 g and less than 0.2 g. Lastly, high activity level was specified with movements such as jogging and fast walking, which mean DRA was higher than 0.5 g and the standard deviation DRA was higher than 0.2 g. With this threshold classification, we were able to explore and validate the various activity level in different time sections. In addition, the computation of activity magnitude was accomplished with the integration of DRA over temporal intervals.

(a)



(b)



(c)

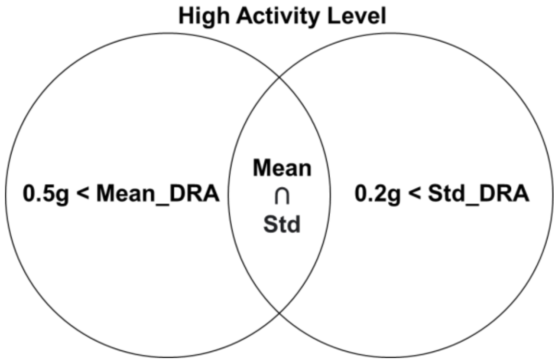


Figure 4-2. (a) Low activity level determination Venn diagram (b) Medium activity level determination Venn diagram (c) High activity level determination Venn diagram.

4.2.4 Wavelet signal frequency analysis in Time and Frequency Domain

Before initiating the frequency analysis, it is important to comprehensively understand the definition of the Fourier transform (FT). The FT is generally applied in signal processing, where it can decompose the original signal into sine and cosine components. However, the FT has a critical limitation where it is only able to depict the frequency characteristic and does not provide the temporal localization of the data, this occurs because FT was processed by computing the dot product between a fixed size sine wave that has constant amplitude for the total signal length. Consequently, the constant sine wave was equally weighted in the time series data, and it does not provide the temporal dynamic of the signal. Therefore, wavelet transformation was ideal for time-frequency decomposition which is an accurate and faster analysis.

Morlet Wavelet: Generally, a Morlet wavelet was applied for the time-frequency decomposition, which could be contemplated as a temporal localization of the Fourier transform. The Morlet wavelet is typically identified as a continuous sinusoidal wave that was tapered with Gaussian, which was composed by multiplying these two components.

$$Gaussian = a * e^{\left(\frac{-(t)^2}{2*\left(\frac{n}{2*\pi*f}\right)^2}\right)} \quad (3)$$

For the equation, a is the amplitude of the Gaussian curve, t is time, n is the wavelet cycle number, and f is frequency.

Complex Morlet Wavelet (CMW) is utilized in wavelet signal processing, and for this to function precisely, the IMU sample data quantity per second must be equivalent to the sampling frequency rate of the wavelet, where our data collection was 100Hz.

There were two convolution ways to compute this raw time series data. Firstly, Time Domain convolution is the dot product of raw time series data and temporally localized complex Morlet wavelet. Second, Frequency domain convolution, where we take FFT of raw signal and Morlet wavelet which demonstrates the frequency depiction of these wave signals. Subsequently, the pointwise multiplied two individual frequency spectra generate multiplied spectra, which is the computed wavelet signal represented in the frequency spectrum. This algorithm secures the lower frequencies of the raw signal and attenuates the higher signal component of the frequency. Lastly, the Inverse fast Fourier transform (IFFT) process was implemented to convert the frequency domain phase into the time domain convolution, where its result indicates the identical value as the dot product of the raw signal and Morlet wavelet. The power signal at a certain frequency is determined by dividing the squared amplitude in half.

The longitudinal data was separated into low, medium, and high-frequency bands, which were presumed to maintain the subject’s ADL physical activity movements. The range of the first band was 0.1, 0.2, 0.3, 0.4, 0.5 Hz, and the second band was 0.8, 1.1, 1.4, 1.7, 2 Hz and the third band was 4, 6, 7, 10, 12 Hz. These bands characterize what form of activities were performed in specific frequencies.

John's Macintosh Project (JMP) statistical analysis software program (JMP Pro 15, SAS Institute Inc., Cary, NC, USA, 2019) was utilized to operate statistical evaluation on these different frequency bands. Multiple Analysis of Variance (MANOVA) was applied, and this investigated the multiple independent variable's effects on the response variable. Each independent variable was applied with cross-validation which created interaction or polynomial effects.

4.3 Results

Katz Index: The Katz Index of Independence in Activities of Daily Living measurement is an efficient and quick structure evaluating older adults' capacity of performing certain activities of daily living by themselves (Shelkey & Wallace, 1999). The result of pre (5.8 ± 0.41) and post (5.86 ± 0.36) ESI depicted that there was no significant difference ($p = 0.417$) between before and after the ESI.

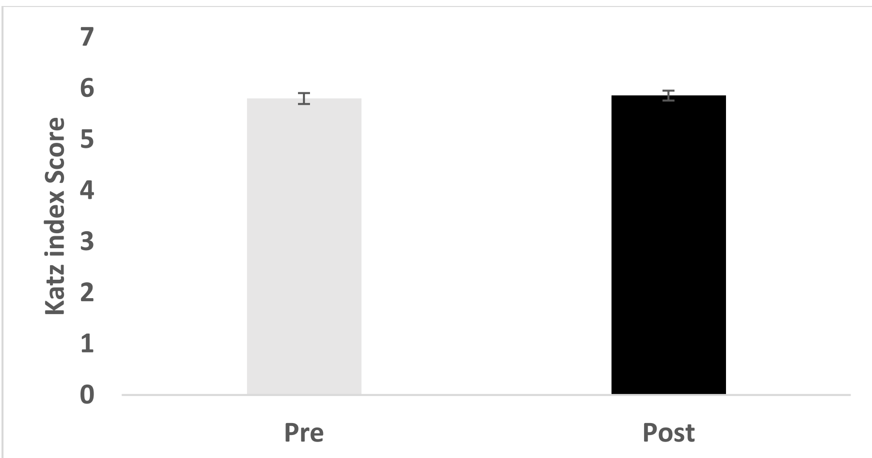


Figure 4-3. Pre and Post-ESI condition on Katz Index difference.

Threshold Physical Total Activity Level: As a result, threshold physical activity level amplitude has indicated that there was no significant difference between pre (16365.19 ± 20916.34) and post (16651.23 ± 20001.47) ESI, where the total activity amplitude p-value was 0.542.

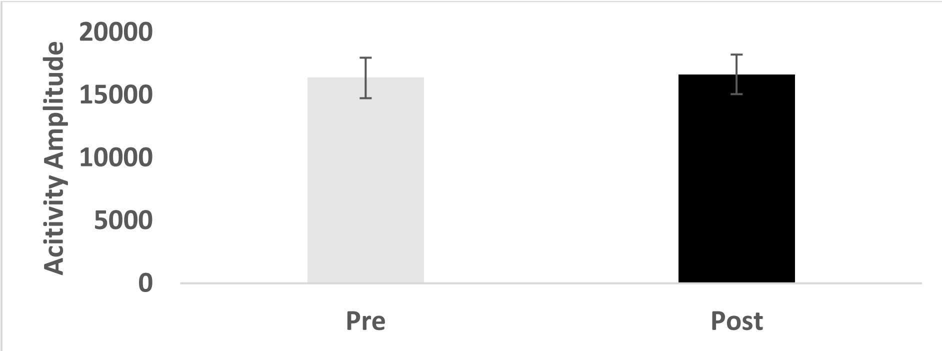


Figure 4-4. The difference in Pre and Post-ESI Physical activity total amplitude level.

Also, the result depicted that there was no significant difference between low-level activity amplitude pre (37110.29 ± 20536.99) and post (33472.46 ± 20748.29) injection, (p = 0.161), medium-level activity amplitude pre (7947.61 ± 10505.35) and post (12326.03 ± 14133.91) injection, (p = 0.076), high-level activity amplitude pre (955.81 ± 2038.59) and post (2370.05 ± 7156.73) injection, (p = 0.515).

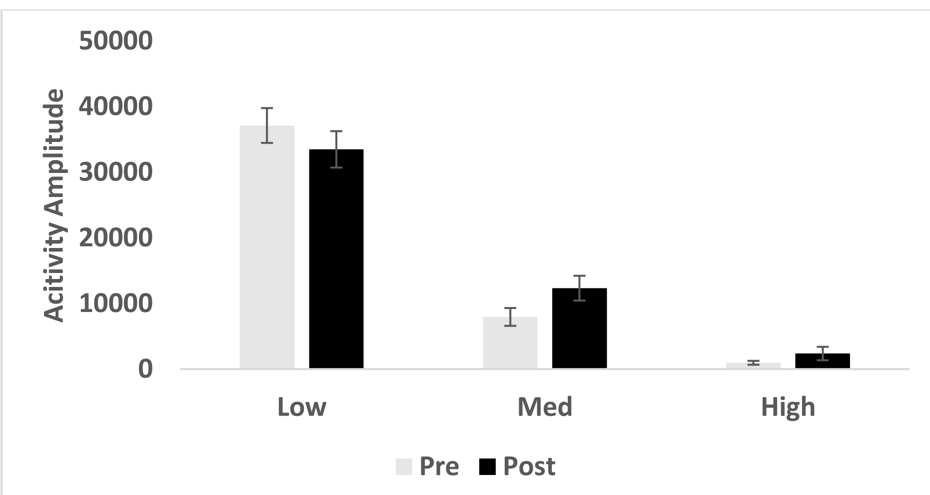


Figure 4-5. Pre and Post ESI Low, Medium, High level Physical activity total amplitude differences.

Lastly, different time section 1 (12 pm to 6 pm) pre (19946.39 ± 23606.25) and post (21613.70 ± 22255.90), (p = 0.543), section 2 (6 pm to 12 am) pre (15799.99± 22152.89) and post (17963.51± 21265.25), (p = 0.441), section 3 (12 am to 6 am) pre (9931.96 ± 13632.91) and post (8285.08± 12253.91), (p = 0.948) and section 4 (6 am to 12 pm) pre (18581.73 ± 21068.27) and post (17578.71± 20179.89), (p = 0.959). In different time sections before and after ESI condition depicted no significant differences in physical activity level amplitude.

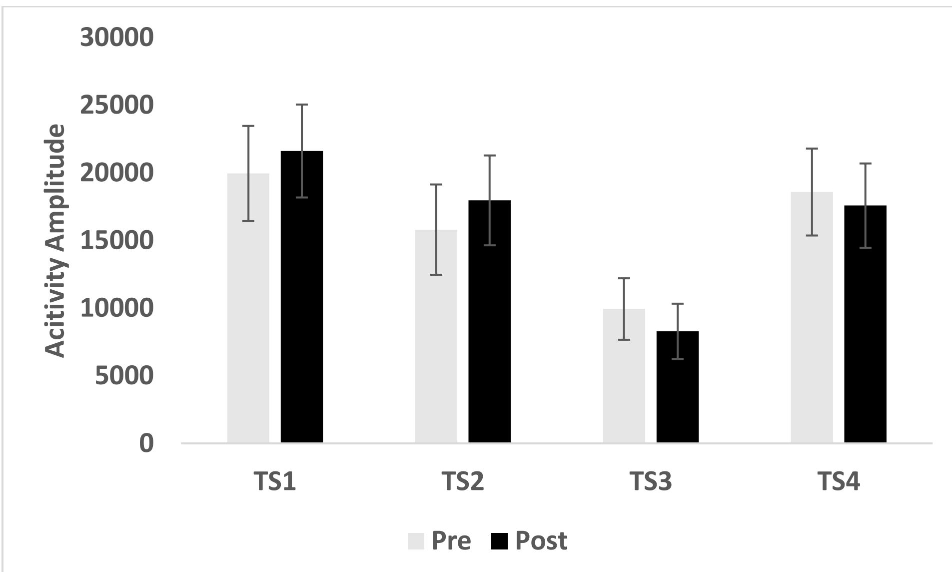


Figure 4-6. Pre and Post ESI Time Sections 1,2,3, and 4 Physical activity total amplitude differences.

Wavelet Signal Analysis in Frequency Domain: Wavelet signal frequency analysis exhibited there was no significant ADL amplitude power difference in pre (140.93 ± 448.61) and post (165.36 ± 529.07) injection (p = 0.086).

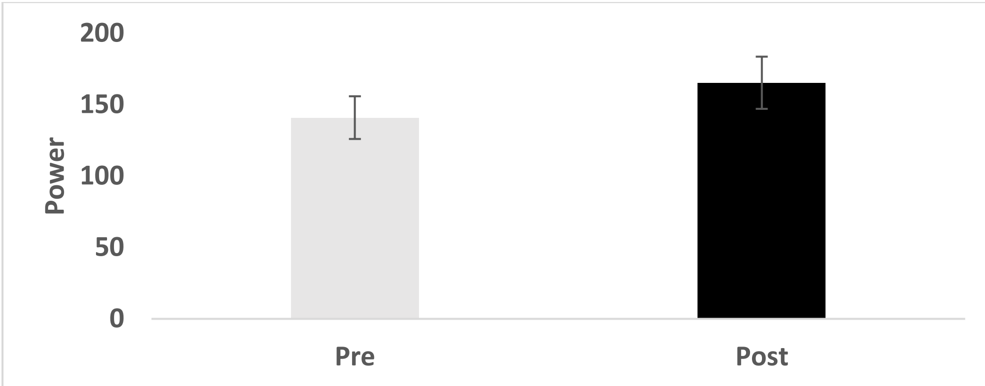


Figure 4-7. Pre and Post ESI frequency level difference.

Also, frequency amplitude in different band levels was analyzed, Band 1 (0.1, 0.2, 0.3, 0.4, 0.5 Hz), pre (362.73 ± 726.69), and post (406.17 ± 849.83), ($p = 0.259$), Band 2 (0.8, 1.1, 1.4, 1.7, 2 Hz), pre (25.40 ± 32.30) and post (33.44 ± 51.59), ($p = 0.834$), Band 3 (4, 6, 7, 10, 12 Hz), pre (35.41 ± 57.50) and post (58.19 ± 182.43), ($p = 0.553$). Results indicated no significant difference found between pre and post ESI conditions on different frequency band levels.

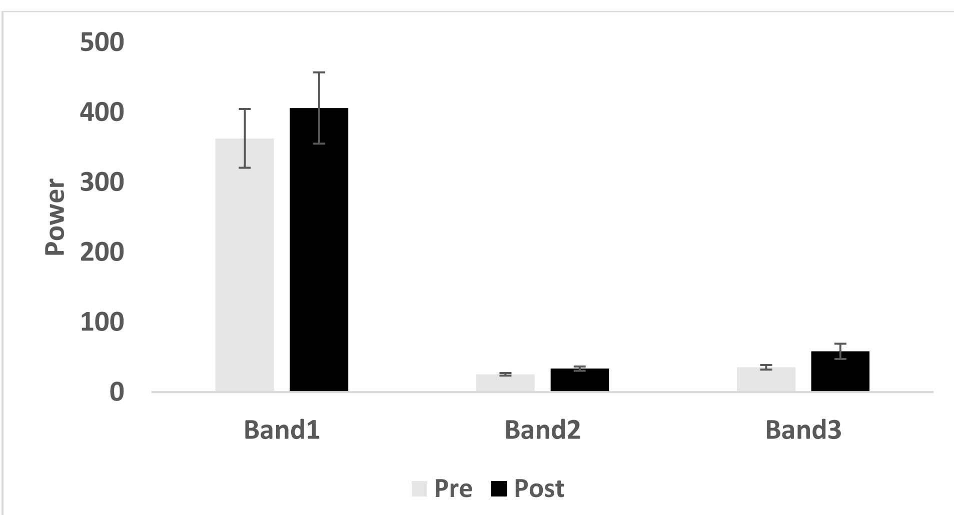


Figure 4-8. Pre and Post ESI in different frequency Band 1,2,3 Levels.

In addition, frequency amplitude difference in various time section 1 (12 pm to 6 pm) pre (223.36 ± 625.58) and post (261.18 ± 749.88), (p = 0.224), section 2 (6 pm to 12 am) pre (128.66 ± 406.97) and post (121.41± 350.94), (p = 0.884), section 3 (12 am to 6 am) pre (26.65 ± 99.51) and post (38.16± 122.79), (p = 0.542) and section 4 (6 am to 12 pm) pre (185.26 ± 467.79) and post (240.43 ± 624.02), (p = 0.080). This indicates that there is no significant difference in frequency amplitude level in time sections 1 through 4.

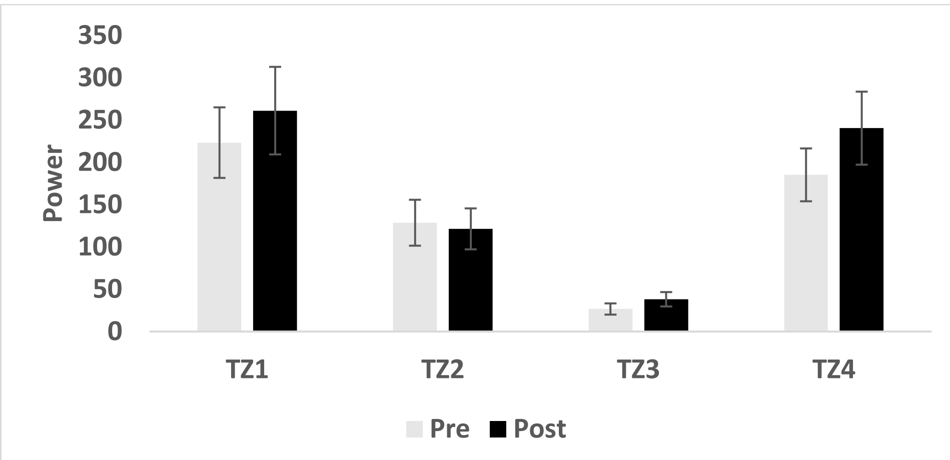


Figure 4-9. Pre and Post-ESI Time Sections 1,2,3, and 4 frequency amplitude level difference.

Table 4-4. Effect of ESI on LBP patient's ADL characteristics

Characteristics	Pre	Post	P-value
	Mean (SD)	Mean (SD)	
Katz(%)	5.8 (0.41)	5.86 (0.36)	.417
Total Activity Amplitude(%)	16365.19 (20916.34)	16651.23 (20001.47)	.542
Frequency(power)	140.93 (448.61)	165.36 (529.07)	.086

4.4 Discussion

The objective of this study was to investigate the efficacy of ESI on LBP patients' ADL physical activity levels between pre and post-injection status. LBP is one of the most widespread disorders in the world that threatens the physical condition of people who are suffering from LBP, and ADL physical activity level is significantly affected negatively, increasing sedentary life behavior (Booth et al., 2012; Jonsdottir et al., 2019; Mahdavi et al., 2021). This leads to the worsening of quality of life, where patients veer away from social life and lessen their physical activity engagement (Jonsdottir et al., 2019).

Katz Index of Independence in Activities of Daily Living Questionnaire: Katz index determines the ability to perform an independent lifestyle of elderly individuals in certain activities such as bathing, dressing, toileting, transferring, continence, and feeding (Shelkey & Wallace, 1999). The results did not demonstrate a significant difference between the pre and post-ESI status for the LBP patients. This depicts that the ESI does not have significant efficacy in performing independent activities for LBP patients before and after the injection.

Threshold Physical Total Activity Level: Threshold methodology computes the DRA from the 3 days of raw accelerometer data measured from the LBP patients. Threshold analysis has indicated that there was no significant difference before and after the ESI condition for total physical activity level amplitude on LBP patients' ADLs. In addition, low, medium, and high-level activity amplitude did not depict significant differences between pre and post ESI conditions. Yet, the medium activity amplitude demonstrates movement such as general gait motion, which has presented a minor inclination in activity amplitude at the post-injection condition. This could be a prospect as the initiation of LBP patients' recovery and increment of physical movement. Lastly, physical activity amplitude was computed by various time sections of the day, time section 1 (12 pm to 6 pm), time section 2 (6 pm to 12 am), time section 3 (12 am to 6 am), time section 4 (6 am to 12 pm). No significant differences were observed from these time sections for pre and post-ESI conditions, yet one intriguing piece of information was that in the time section 3, activity amplitude revealed less movement. This could be the representation of less movement during sleeping since the time section 3 is 12 am to 6 am, where the majority of people tend to sleep during this stage of time. In the prior study that assessed total activity performance after the injection, where 58.8% of subjects indicated an increase in total activity, 59% has increased step per day, and 53% depicted improvement in maximum continuous activity. Still, no significant improvement was depicted in the post the injection condition for ADL (Tomkins-Lane et al., 2012). This past study aligns with our result, where the activity level of ADL is not substantially affected by the pre and post-ESI intervention. Nonetheless, minor improvement trends were observed, however, the available data was not adequate to determine its significance.

Overall, threshold activity level analysis of the ADL did not indicate a significant difference between the before and after ESI intervention, among different performance levels and time sections.

Wavelet Signal Analysis in Frequency Domain: Wavelet frequency analysis is executed to sort out the physical activity level of ADL into low, medium, and high-frequency levels. Still, the frequency amplitude has a minor increase, this evaluation indicated that there was not enough data to demonstrate the substantial difference between the pre and post ESI LBP conditions. Additionally, the post-injection status did not indicate a significant difference in the frequency amplitude compared to the pre-injection condition on time sections 1 (12 pm-6 pm), 2 (6 pm-12 am), 3 (12 am-6 am) and 4 (6 am-12 pm). This demonstrates that the majority of LBP patients are expected to perform similarly before and after ESI. During the particular time period during the ADL, time sections 1 and 4 performed inconsequential increases in the frequency amplitude, where morning and afternoon time span subjects tend to execute more activities. Overall, this result depicts that generally there was no statistically significant difference between pre and post-ESI intervention on wavelet frequency analysis. However, the tendency of slight enhancement was observed after the ESI in the morning and afternoon time section, which shows the propensity for improvement.

Minor limitations could be implied in this ADL study, is the assessment of ADL. The IMU sensors are effective at measuring the signal of gross motor movement, such as walking and standing. However, it has difficulties for them to distinguish more complex activities such as dual tasking and dexterity, where understanding the contextual information of ADLs is critical for interpreting the data accurately. Therefore, to provide more comprehensive observation on ADL, additional assessment of camera or radar visualization of subjects can offer more elaboration of their activities.

4.5 Conclusion

The main objective of this study was to evaluate the efficacy of ESI in improving ADL physical activity levels pre and post-intervention with multiple analytical approaches. Initially, the subjective questionnaire the Katz Index of Independence in Activities of Daily Living Questionnaire was used to indicate the independent performance of LBP patients' ADL, and after accessing 3 days' worth of IMU data, quantitative threshold physical activity level and wavelet frequency analysis were executed. The result depicted ESI showed no significant difference in pre and post-state for ADL physical activity levels in Katz index, threshold, and wavelet frequency evaluations. Still, a few specific portions indicated the propensity of improvement, such as medium intensity threshold level and wavelet frequency amplitude improvement at time sections 1 and 4.

In conclusion, pre and post-ESI do not demonstrate a significant improvement in physical activity level ADL, but a propensity of increased in activities levels was observed.

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APPENDIX A

RELATED PEER REVIEWED PUBLICATION

Assessment of Gait and Posture Characteristics Using a Smartphone Wearable System for Persons with Osteoporosis with and without Falls

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Abstract

We used smartphone technology to differentiate the gait characteristics of older adults with osteoporosis with falls from those without falls. We assessed gait mannerism and obtained activities of daily living (ADLs) with wearable sensor systems (smartphones and inertial measurement units [IMUs]) to identify fall-risk characteristics. We recruited 49 persons with osteoporosis: 14 who had a fall within a year before recruitment and 35 without falls. IMU sensor signals were sampled at 50 Hz using a customized smartphone app (Lockhart Monitor) attached at the pelvic region. Longitudinal data was collected using MoveMonitor+ (DynaPort) IMU over three consecutive days. Given the close association between serum calcium, albumin, PTH, Vitamin D, and musculoskeletal health, we compared these markers in individuals with history of falls as compared to nonfallers. For the biochemical parameters fall group had significantly lower calcium (P=.01*) and albumin (P=.05*) and higher parathyroid hormone levels (P=.002**) than nonfall group. In addition, persons with falls had higher sway area (P=.031*), lower dynamic stability (P<.001***), gait velocity (P=.012*), and were less able to perform ADLs (P=.002**). Thus, persons with osteoporosis with a history of falls can be differentiated by using dynamic real-time measurements that can be easily captured by a smartphone app, thus avoiding traditional postural sway and gait measures that require individuals to be tested in a laboratory setting.

Keywords: Dynamic stability; Fall; Fall risk; Inertial measurement unit; Osteoporosis; Smartphone mobile app

INTRODUCTION

Injuries associated with falls continue to pose a substantial burden for older adults both in human suffering and economic losses. Falls among older adults are also a growing public health concern and are responsible for over 684,000 deaths and nearly 37.3 million annual visits for medical intervention worldwide [1]. In the Unites States of America, costs for fatal and nonfatal fall-related injuries in 2015 were approximately $50 billion, and medical expenditures for fatal falls were estimated at $754 million[2]. Of 2.4 million emergency department visits in 2018 among adults aged 65 years and older, unintentional falls were responsible for approximately 90% of injury-related visits [3]. Falls are also the most common reason for older persons being forced to transition from independent living to assisted care [4,5]. With this transition often comes a decrease in quality of life [6] and a tremendous increase in health care costs [7–9], which will not be sustainable with the higher numbers of elderly persons forecasted in the coming decades [10].

Osteoporosis is a multifactorial skeletal disease characterized by reduced bone mass and deterioration of the microarchitectural structure of bone tissue, with a resulting increase in bone fragility and fracture risk, and is a widely prevalent condition, in adults 50 years and older, and affecting twice as many women as men [11–13]. Fractures, which are widely prevalent complication of osteoporosis take a large economical toll on the individual, family, health care and society at large. This worrisome trend is predicted to continue. In the United States of America, the total annual direct and indirect expenditures for Medicare beneficiaries was approximately $57 billion in 2018 and is projected to increase to a staggering $95 billion by 2040 [14]. In Europe, the total medical care costs for osteoporosis, including hospitalization and rehabilitation are also excessive: €37 billion in 2010 [15], with the corresponding projected costs for 2050 at €76.8 billion[16]. Besides personal and economic deficits, osteoporosis related fractures are a common cause for loss of personal independence and can pivot an individual with hip fracture from independence to dependent living [17,18]. It is vastly underappreciated that individuals with osteoporosis related fractures have a lower life expectancy [14,19,20], plausibly due to fracture event, comorbidities or confounding musculoskeletal frailty that coexists with elderly individuals [21]. Indeed, 15% of Medicare beneficiaries experienced a second osteoporotic fracture, and 32% of beneficiaries died within two to three years of their first fracture. In addition, mortality rate instantly increases in the months of the initial fracture [22].

Given these enormous estimates in terms of cost, quality of life and mortality, effective strategies to prevent and reduce the incidence of osteoporotic fractures must be swiftly implemented.

Fracture reduction strategies are complex, multi-dimensional and require recognition of 'double whammy' effect that drives the increased incidence of fragility fractures in the elderly, in whom the combination of two usually adverse circumstances- i.e., falls and underlying osteoporosis – frequently coexist together. This double association of increase fall frequency in presence of underlying osteoporosis is correlated with increased fracture incidence.

The current mainstay strategy to prevent fractures is to screen for osteoporosis by bone density test and then to treat individuals at high risk of fracture with anti-fracture pharmacotherapy. However, the strongest risk factor for fracture in a person with underlying osteoporosis is falls [23,24]. Despite this fact, assessment of fall risk is often overlooked as an important strategy to prevent fractures.

Postural balance is a primary independent risk factor for falls [25]. A previous study depicted that static and dynamic balancing ability in older women with osteoporosis significantly decreases as compared to an age-matched cohort, which increases fall risk in this group [26]. Wearable Inertial Measurement Unit (IMU) could be utilized to assess the physically frailty in fall prone individuals in variety of ways. Prior studies have determined that the dynamic test, such as gait speed has improved the possibility of forecasting fall prone individuals [27]. Many studies have discovered that slower walking speed was closely related with increased fall risk, and the IMU system is currently the most reliable system that can provide an accurate assessment of gait speed accurately [28–33]. The main cause of this phenomenon is the conscious compensatory gait mechanism, where fall prone people tend to intentionally adjust their gait speed to secure their steps. Reduced muscle mass, and strength as well as fear of falling were identified as mechanistic causes [34,35]. Moreover, static testing, such as postural sway is one of the most practiced assessment for fall risk [36–38]. Frames et al. [36] reported that the obese faller has significant larger sway area and velocity compared to obese non-faller. Matinolli et al. [39] has indicated that the Parkinson's patients with falling experience has larger sway area compared to the non-fallers. Lastly, reduced physical activity level may indicate higher risk of fall [40]. Therefore, versatile application of the wearable system for accurately assessing these parameters would immensely support researchers and clinicians to prevent fall accidents, especially in individuals with osteoporosis who are more vulnerable to fractures [11,12].

We hypothesized that gait characteristics that increase fall risk could be assessed in persons with osteoporosis with and without prior falls by using gait and postural stability parameters measured from a smartphone-wearable system. Additionally, we hypothesized that activity level (measured by inertial measurement unit [IMU]) would be different for persons who had falls than nonfallers. Given the close association between serum calcium, PTH, Vitamin D, albumin, and musculoskeletal health, we compared these markers in individuals with history of falls as compared to nonfallers.

RESULTS

Patient characteristics are reported in Table 1. Both groups were well-matched for age and body mass index. The mean (SD) age of the fall group was 75.6 (8.3) years and of the nonfall group 71.1 (9.7) years, 86% of participants were women (43/49). The mean (SD) body mass index was 24.9 (6.0) for the fall group and 23.5 (4.3) for the nonfall group.

We found no significant differences in sway path and velocity between the fall and nonfall groups but did find a significant difference in sway area (P=.031*). We also found significant differences in gait velocity (P=.012*) and dynamic stability (P<.001***) between the fall and nonfall groups. In general, participants in the nonfall group walked faster (0.96 m/s) than those who had fallen (0.79 m/s), and had better dynamic stability, as measured by the Lyapunov exponent (1.66). Furthermore, the nonfall group was much more active than the fall group at the 17.56% dynamic physical activity level as compared to 8.36% respectively (P=.002**).

Significant biochemical differences were noted in both groups. Participants in the fall group had a lower mean [SD] total serum calcium concentration (9.37 [0.4] mg/dL) than those in the nonfall group (9.67 [0.3] mg/dL) (P=.01*), higher parathyroid hormone (PTH) levels (79.14 [48.7] pg/mL) than the nonfall group (40.23 [19.0]) (P=.002**), and lower albumin levels (4.27 [0.33] g/dL) than the nonfall group (4.46 [0.28] g/dL) (P=.05*). Both groups had comparable serum vitamin-D and creatinine levels. Participants in the fall group took significantly more medications than those in the nonfall group. Furthermore, five deaths occurred over 3 years of the data collection effort (4 in the fall group [28.6%] and one in the nonfall group [2.9%]). (Table 1)

Characteristics	Mean (SD)		
	Fall group (n=14)	**Nonfall group (n=35)**	**P value**
Age, y	75.6 (8.3)	71.1 (9.7)	.13
Women, No. %	11 (78.6)	31 (88.6)	
Men, No. %	3 (21.4)	4 (11.4)	
Height, cm	162.8 (8.0)	162.5 (9.8)	.90
Weight, kg	65.2 (14.5)	62.36 (15.1)	.55
BMI, kg/m^2	24.9 (6.0)	23.5 (4.3)	.35
Medications, No.	5.57 (3.30)	3.50 (3.28)	.05*
Total serum calcium, mg/dL (Reference range: 8.6-10.3 mg/dL)	9.37 (0.4)	9.67 (0.3)	.01*
PTH, pg/mL (Reference range: 11-51 pg/mL)	79.14 (48.7)	40.23 (19.0)	.002**
Albumin, g/dL (Reference range: 3.4-5.4 g/dL)	4.27 (0.33)	4.46 (0.28)	.05*
Creatinine, mg/dL (Reference range: 0.6-1.3 mg/dL)	1.54 (2.2)	0.84 (0.21)	.08
Vitamin D, ng/mL (Reference range: 25-80 ng/mL)	42.42 (15.34)	44.47 (13.60)	.67
Dynamic physical activity level, %	8.36 (5.16)	17.56 (9.25)	.002**
Sway Area (cm^2)	13.89 (14.90)	9.63 (11.04)	.031*
Sway Path Length (cm)	36.17 (13.51)	30.69 (19.26)	.053

Sway Velocity (cm/s)	6.24 (2.33)	5.29 (3.32)	.053
Dynamic stability, Lyapunov exponent (λ)	1.96 (0.21)	1.66 (0.08)	<.001***
Gait velocity (m/s)	0.79 (0.16)	0.96 (0.22)	.012*

Abbreviations: BMI, Body Mass Index; PTH, Parathyroid Hormone

Table 1. Characteristics of Participants in the Fall and Nonfall Groups (*$*p < 0.05$, $**p<0.01$, $***p<0.001$*)

DISCUSSION

For older adults, walking, standing up from a chair, turning, and other activities are necessary for independent mobility. Gait speed, physical activities, and dynamic stability are independent predictors of the ability to perform ADLs as well as of the risk of falls and life expectancy [41]. In this study, we showed that persons with osteoporosis who had fallen within a year of entry into the study were less stable than those who had not fallen and exhibited unstable gait by dynamic gait pattern analysis (i.e., dynamic stability as measured by Lyapunov exponents). We also showed that individuals with osteoporosis at greater fall risk (due to occurrence of fall in prior year) could be differentiated using dynamic real-time measurements which can be easily captured by a smartphone app rather than by traditional postural sway and gait measures, which must be done in a laboratory setting.

A person's inability to walk in a repetitive and stable manner predicts an evolving gait disorder that can lead to falls [42]. For those at the greatest risk for falling, the amount of variability during a linear gait analysis helps to quantify gait impairment. Furthermore, intracycle gait variability, despite no obvious gait impairment, may predict the potential for the gradual deterioration of stability mechanics. Thus, gait variability identified by nonlinear analysis could be a robust measure of a person's neuromuscular function. Our finding calls for increased awareness of IMU device using a smartphone app as a simple and useful tool for evaluating and quantifying gait deficits of fall-prone individuals by providing important insights into the dynamic stability of walking.

Several other clinical and biochemical risk factors have been linked to a higher risk of falls in older adults with osteoporosis. Vitamin D and calcium are two nutrients essential for bone health. In our study, the fall group had lower serum calcium and higher PTH levels than the nonfall group. Vitamin D levels and kidney function did not differ between the two groups. Low serum calcium reflects a low dietary calcium intake or reduced intestinal calcium absorption and is one of several important causes of osteoporosis [43]. It also predicts significant muscle loss in adults [44], thus calcium deficiency increases the risk of osteoporosis, sarcopenia and falls, serving as a catalyst for fractures. Similarly, Vitamin D deficiency causes lowering of bone density while lowering bone strength, thereby increasing instability, tendency to falls and fractures [45]. Vitamin D deficiency is corrected easily with over-the-counter supplements and is associated with better lower extremity function in older ambulatory adults, regardless of their physical activity or sedentariness [46]. Both low serum calcium and low Vitamin D results in secondary hyperparathyroidism, which when untreated contributes to bone loss, bone mineralization defects and ultimately increases incidence of hip and other fractures [47]. Elevated PTH [47] and Vitamin D deficiency [48] are also associated with muscle weakness. Elevated PTH levels are associated with significantly lower bone mineral density [49]and have also been linked to falls independent of vitamin D level, especially in frail elderly persons. Studies conducted in nursing and assisted living facilities examined the association between serum PTH [50–53] and falls and showed more falls among men and women with higher PTH levels (approximately 30% higher in one study) [50]. High PTH levels also significantly predicted time to first fall in another study of nursing and assisted living residents [51].

Serum albumin is a biomarker of protein calorie malnutrition [54,55], and low serum albumin is shown to be associated with frailty, leaving elderly individuals vulnerable to falls [56]. Our fall group had a significantly lower mean serum albumin level than the nonfall group. A low albumin level is closely related to future deterioration of appendicular skeletal muscle mass in older adults, which can lead to sarcopenia [57]. A lower serum albumin level has been cross-sectionally related to the decline of muscle force; after three years, the muscle intensity of persons in a longitudinal study decreased significantly [58].

Polypharmacy exposure increases the risks of numerous negative health consequences for elderly persons, including falls [59–61]. Our study supports this association; those in our fall group used significantly more medications than those in the nonfall group.

Data from US National Vital Statistics System mortality files show an increase in mortality from falls particularly with advancing age [62]. Our data is concordant with these results. In our study, the all-cause mortality was 28.6% (4/14) for those with falls vs 2.9% (1/35) for those without.

Strengths and Limitations Strength of our study is as follows; our study data were obtained from a community-based clinic in an ambulatory setting reflecting real world situation. Standard methods were used for all assessments and data collection. Furthermore, 3-day assessments of ADLs were done with the participants wearing a portable IMU system and recording activities manually in a journal, which allowed researchers to make exact correlations. Our study has following limitations, the study was done in open-label fashion; thus, participants were aware that gait was being measured. From the gait assessment, we only focused on the gait speed, which is most fundamental data for fall risk and depicts the overall frailty status. Osteoporosis is more prevalent in women, thus as anticipated significantly more women (86% of participants) participated in the study, results of our study may not be applicable to men. It should be noted that hypothesis of this study was not focused on gender differences on fall mechanisms but focused on fall and nonfall groups regardless of their gender did not evaluate dietary calcium intake or calcium supplementation. Our study had a small number of participants. Finally, we did not adjudicate the cause of death in the groups.

METHODS

Participants. To be included in the fall group, participants had to have fallen once in the year before they entered the study. To be included in the nonfall group, participants could have no falls within the year previous to study entry. We included adult men and women over the age of 50 years with a diagnosis of osteoporosis (with and without prior fragility fracture) who were living and ambulating independently. We excluded patients with a history of fractures not due to osteoporosis (such as pathologic fractures due to cancer metastases) and major comorbid conditions (such as dementia or visual problems). A research affiliate (S.M) following the participant recruitment protocol, asked eligible patients whether they were interested in being part of the study. If the patient agreed to participate, a physician (K.B.D., M.D.W.) discussed the study with the patient, answered all relevant questions. Participants were enrolled after written informed consent. The research was approved by the Mayo Clinic IRB (and Arizona State University IRB). All research was performed in accordance with relevant guidelines and regulations.

Instrumentation. A smartphone (with inbuilt IMU) with a holster and clip was used for monitoring. The IMU sensor signals were sampled at 50 Hz by using the customized smartphone app Lockhart Monitor [63] (Locomotion Research Laboratory, Arizona State University, available through the iOS App Store), and longitudinal data were collected by using the DynaPort MoveMonitor+ IMU device (Motion Monitor+, McRoberts BV, The Hague, Netherlands) at 100-Hz frequency.

The Lockhart Monitor has the capability of assessing linear and nonlinear parameters of a person's gait and postural stability. Further data processing was accomplished using custom-made MATLAB routines (MATLAB version 9.3, 2017, The MathWorks Inc). The mobile app consists of a start and stop button and recorded voice instruction, with ample rest duration built in between each performed activity. The signals were truncated using the temporal information of voice commands through the app.

In-Clinic Data Collection and Analyses. Participants' blood samples were collected by a licensed phlebotomist at the study site or at a CLIA-certified laboratory (2 x 10mL whole blood). Various standardized biochemicals were extracted and reported. For the testing procedure (Figure 1), participants were asked to maintain their natural standing posture for 60 seconds in 2 different situations: eyes open and eyes closed for 2 times each. For the gait speed assessment using the 10-meter walking protocol, the smartphone data collection was begun at the initial footfall after the start line and automatically stopped with the first footfall after the 10-meter line. This automated assessment was determined by the threshold algorithm, which is a sum of mean and two standard deviation of the variance from the 5 seconds of fixed standing calibration session [64]. This process was repeated twice with adequate time for the participants to recuperate between trials. The walking speed and other linear gait parameters were securely saved within the IMU system embedded in the smartphone for later processing.

In the clinical environment, we measured participants' postural stability (or postural sway) and their walking velocity (ie, gait velocity or walking speed) [37,65,66]. To analyze the sway area from the postural stability, mean sway radius was calculated with anterior/posterior and medial/lateral movement of center of mass divided by the sample of data points (*n*) and multiplied by pi (π). Sway path length was computed with the summation of Euclidean distance among the points during the total sway period. Sway velocity was calculated with sway path length divided by the total sway period.

$$\text{Sway Area (cm}^2\text{)} = \left(\frac{\sqrt{x^2+y^2}}{n}\right)^2 * \pi \quad (1)$$

$$\text{Sway Path Length (cm)} = \sum_{n-1}^{n} \sqrt{(x_n - x_{n-1})^2 + (y_n - y_{n-1})^2} \quad (2)$$

Figure 2 illustrates the 10-meter walking speed protocol and the assessment and analysis of the ambulatory signal from the IMU. To compute the gait velocity from this acceleration data, the total distance (*d*) was 10 meters, and it was divided by the period of the time (*t*) that participant took to complete the entire walking distance.

$$\text{Gait velocity (m/s)} = \frac{d}{t} \quad (3)$$

For the dynamic stability assessment (ie, the nonlinear dynamic measure of the short term Lyapunov Exponent (LyE) [42,67]), a 3-minute continuous walking exercise was performed on a clear uncluttered pathway at Mayo Clinic. For this assessment, participants were asked to walk continuously for 3 minutes at their normal walking speed while wearing a smartphone at their sacral area. To calculate the LyE, time-delayed coordinate method was applied. This method indicates that any adequate size of fundamental dynamic information that is performed in single dimension temporal time series can be reconstructed into multi-dimensional state spaces. After determining the state space, all the nearest neighbors were collected which has the closest distance from the trajectories [68].

A)

B)

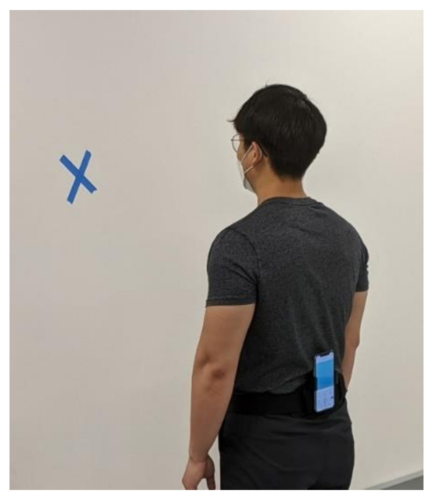

Figure 1. A) A smartphone was affixed in the participant's lumbar region for the in-clinic walking speed and postural stability assessments. B) All participants were required to perform postural stability testing for 60 seconds with eyes open and closed. The cross on the wall provided a visual cue for the participants

A)

B)

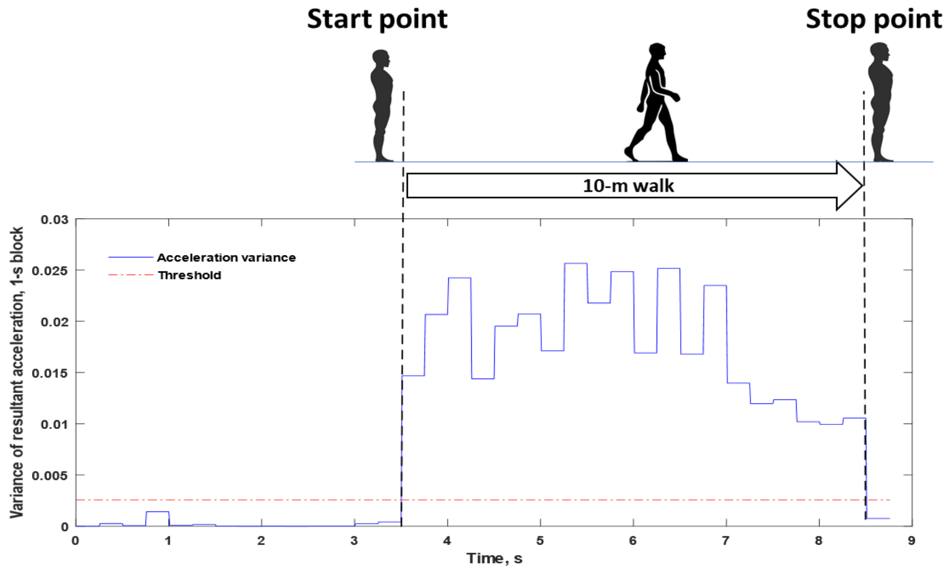

Figure 2. Ten-Meter Walking Speed Protocol and Gait Analysis. A) Gait speed assessment is initiated automatically as the participant takes a step from standing still. After the participant steps completely over the 10-meter marker and stands still again, the assessment is completed. B) Acceleration signals the moving window (0.5 sec) variance of low-pass-filtered resultant acceleration, which was used to calculate the gait speed.

Longitudinal Data Collection and Analyses. Longitudinal data collection was conducted at the participants' dwellings. Participants were asked to maintain an activity journal reflecting their activities of daily living (ADLs). Activities during the day were categorized with four main movements such as sitting, standing, walking, and lying down. Participants were instructed to log in these motions on a minute scale, to ensure that activities were recorded accurately (Table 2). They also reported the location where activity was performed, described the activity as well as the type of movement required. In the non-clinic environment, participants' activity levels were measured as the percent average each day.

ADLs data was also collected for 72 hours via the DynaPort MM + IMU device located at the sacral part of the spine (Figure3). Activity journal was independently reviewed (by S.M.) to ensure concordance with the DynaPort data. Participants were allowed to disconnect the sensor only when bathing or swimming. Longitudinal data were analyzed with MATLAB. The X, Y, and Z coordinate acceleration data were refined with high- and low-pass Butterworth filters to remove noise from the raw data. Subsequently, the 1-Hz cut-off frequency was modified to determine the dynamic physical activity level of the participants [69–71]. This algorithm allowed us to compare ADL activity levels between participants with and without falls. Figure 4 summarizes the procedure for in-clinic and 3-day longitudinal data collection.

Figure 3. DynaPort MM+ IMU device is affixed on the participant's sacrum region to perform 3 days of Activities of Daily Living data collection

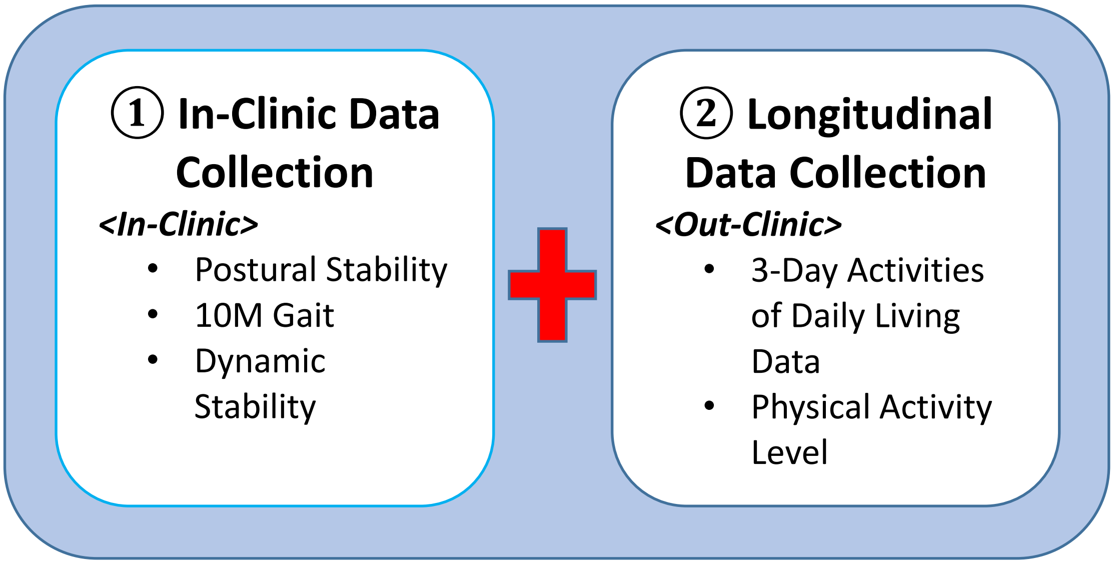

Figure 4. Study Design Layout for the 1. In-clinic Data collection, 2. Longitudinal Data Collection

Time (h:min:sec)	Activity	Duration, min	Location	Comment
12:30:00	Walking	5	Clinic	Floor
12:35:00	Sitting	7	Clinic	Chair
12:42:00	Walking	1	Clinic	Floor
12:43:00	Sitting	9	Car	Chair
13:56:00	Laydown	4	Home	Bed
14:00:00	Laydown	136	Home	Bed
16:16:00	Walking	24	Home	Floor
16:40:00	Standing	4	Kitchen	Floor
16:44:00	Sitting	3	Home	Chair
16:47:00	Walking	3	Home	Floor

Table 2. Example of Activities of Daily Living Journal from a Participant

Statistical Analyses.

Dependent variables were analyzed using multivariate analysis of variance (MANOVA). Wilk Λ test was used to determine which factors of MANOVA were most relevant to participants in the fall vs nonfall groups. Then, univariate analyses (1-way analysis of variance) were performed on each of the dependent variables with each participant treated as a random variable, using falling vs nonfalling as significant factor (α=.05) (Table 1)

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KD and TL conceived and designed the study. SM, KD, MW collected data. SM, TL, KD analyzed and interpreted the study results. KD, SM, and TL prepared the manuscript draft. SM and TL prepared the tables and figures. KD and SM contributed equally to this work. All authors reviewed the results and approved the final version of the manuscript.

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COMPETING INTEREST:

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Effects of Rucksack Military Accessory on Gait Dynamic Stability

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ABSTRACT

Various factors are responsible for injuries that occur in the U.S. Army soldiers. In particular, rucksack load carriage equipment influences the stability of the lower extremities and possibly affects gait balance. The objective of this investigation was to assess the gait and local dynamic stability of the lower extremity of five subjects as they performed a simulated rucksack march on a treadmill. The Motek Gait Real-time Interactive Laboratory (GRAIL) was utilized to replicate the environment of the rucksack march. The first walking trial was without a rucksack and the second set was executed with the All-Purpose Lightweight Individual Carrying Equipment (ALICE), an older version of the rucksack, and the third set was executed with the newer rucksack version, Modular Lightweight Load Carrying Equipment (MOLLE). In this experiment, the Inertial Measurement Unit (IMU) system, Dynaport was used to measure the ambulatory data of the subject. This experiment required subjects to walk continuously for 200 seconds with a 20kg rucksack, which simulates the real rucksack march training. To determine the dynamic stability of different load carriage and normal walking condition, Local Dynamic Stability (LDS) was calculated to quantify its stability. The results presented that comparing Maximum Lyapunov Exponent (LyE) of normal walking was significantly lower compared to ALICE ($P=0.000007$) and MOLLE ($P=0.00003$), however, between ALICE and MOLLE rucksack walking showed no significant difference ($P=0.441$). The five subjects showed significantly improved dynamic stability when walking without a rucksack in comparison with wearing the equipment. In conclusion, we discovered wearing a rucksack result in a significant ($P < 0.0001$) reduction in dynamic stability.

1. INTRODUCTION

Load carrying equipment is used in various daily contexts, ranging from school backpacks carrying textbooks/supplies and recreational hiking backpacks to military applications.

Accordingly, the purpose of the load carriage equipment in a military context is to enhance and maximize a soldier’s performance. However, inadequate design can reduce performance and even result in injuries given the increase in mass, fatigue, and duration. Therefore, it is necessary to evaluate the effect of these supportive devices and whether they hinder the potential stability of a soldier. One of the most important pieces of equipment that is utilized in the U.S military is the rucksack, a simple form of load carriage. In the military recruitment qualification process, a rucksack march evaluates the basic physical strength and stamina of a soldier and whether they qualify for the military. Also, it is essential to indicate gait instability with various load carrying equipment to determine their effects on injuries during training (Knapik et al., 1992).

The U.S military has reported that the recommended standard rucksack weight should be less than 33kg for a soldier to perform at their optimal physical condition (Meehan, 1990). Additional equipment, such as a rifle, bulletproof vest, and Kevlar, will increase the weight demand that soldiers need to carry. Previous investigations report that during military training, 82% of the majority of accidents are the direct result of slips, trips, and falls (Okeeffe et al., 2014). Thus, the heavier the rucksack, the greater increase in gait instability. To lower the rate of musculoskeletal injuries and reinforce the rucksack, the U.S. army has replaced ALICE, an older version of rucksack built with a metal frame which was manufactured by the United States Army Support Center, with a more efficient rucksack made of a plastic frame called MOLLE, manufactured by Specialty Defense System.

To assess different load carriage conditions on gait stability, LDS was quantified with the Maximum LyE. Maximum LyE(λ) delineates the average logarithmic rate of divergence, in which a higher value means the system is unstable with a larger divergence between the nearest neighbor, and a lower value indicates that the structure of the system is more stable. The previous study indicated that fall prone subjects have higher Maximum LyE compare to healthy old and young subjects, which present that fall prone individuals have significantly lower LDS compared to healthy counterparts (Bizovska et al., 2018; Lockhart & Liu, 2008; Toebes et al., 2012).

The objective of this study was to compare normal walking condition with two different types of load carriage equipment and determine the variations of the LDS.

2. METHODS

2.1 Experimental Protocol

Five healthy male subjects were recruited from Arizona State University. The subjects' anthropometric data were the followings: 24 ± 2.5 years of age; 178.5 ± 2.4 cm of height; 77.3 ± 19.8 kg of weight; 24.2 ± 6.0 kg/m^2 of Body Mass Index (BMI). To reproduce the rucksack march in the laboratory environment, Motek Gait Real-time Analysis Interactive Laboratory (Motek, GRAIL, Amsterdam, Noord-Holland, the Netherlands) system was used to simulate the rucksack march. For the data assessment, a single IMU accelerometer (DynaPort MM+, Den Haag, the Netherlands) with a sampling frequency of 100 Hz was utilized to assess the gait data from the subject. The device was located at the sacrum area with elastic waistbands. All participants who participated in this study provided written consent before the beginning of data collection, which this study was approved by the Institutional Review Board (IRB: STUDY 00003645) of Arizona State University.

ID	Subject Anthropometry				
	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m²)	Gender
S001	24	180.8	79.2	24.23	Male
S002	22	177	48.65	15.53	Male
S003	22	179.5	104.25	32.36	Male
S004	28	175	75	24.49	Male
S005	24	180	79.4	24.51	Male

Table1. Each subject's anthropometric data

Prior to the data collection, subjects were asked to walk at least five minutes on the treadmill to acclimatize themselves to the treadmill, rucksack, and environment. Participant's preferred walking velocity was determined with and without the load carriage (Yang & King, 2016). All participants walked at their preferred walking speed. Subsequently, participants carried out all walking trials for 200 seconds: First, normal walking was performed without any load carriage; second, subjects carried an established type of steel frame rucksack, ALICE with 20 kilograms of weight to simulate the real-life rucksack march; third, subjects wore the MOLLE rucksack with a carrying load of 20kg. Participants were asked to wear the U.S. army Kevlar helmet, vest, and rucksack to simulate the actual rucksack march that enlisted soldiers would perform. Appropriate rest was provided between each trial to avoid fatigue influencing the stability of walking.

Figure 1. Subject Load Carriage Simulation on GRAIL system

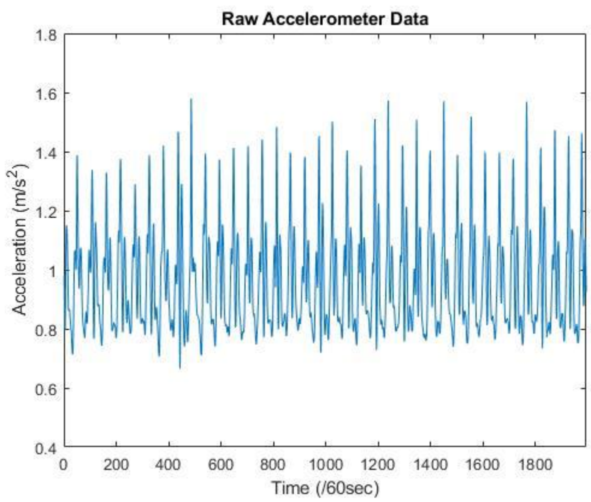

Figure 2. Raw Acceleration Data measured from Inertial Measurement Unit

2.2 DATA ANALYSIS

The following procedure was processed to calculate the dynamic stability of each subject's normal and load carriage data. Before proceeding into the calculation of dynamic stability, raw gait data from the IMU accelerometer was low pass filtered using zero-lag fourth order Butterworth filter to remove high frequency noise from sensor data (Yu et al., 1999). Once the data is filtered consistent gait cycles were extracted. After a consistent, steady-state speed was achieved, a threshold-based peak detection algorithm was used to identify 50 gait cycles and truncate the dataset for analysis. Then, the dataset was normalized so that each gait cycle was resampled to 100 data points each. Normalizing the gait cycle to 100 data points is a standard technique in gait analysis. To calculate the dynamic stability, the most important process is finding maximum LyE. Maximum LyE indicates the average logarithmic rate of divergence, hence, the higher value designates instability of the larger divergence between the nearest neighbors, in contrast, a lower value determines more stableness (Dingwell & Cusumano, 2000). In this computation, the Rosenstein method was utilized to calculate the maximum LyE (Rosenstein et al., 1993). To establish the proper time delay coordinate, it was determined by using average mutual information. From the plotted graph of average mutual information, the first minimum was set as the time delay. Lastly, the maximum LyE value was determined with reported time delays coordinate (10^{th}) and embedding dimension (5^{th}) (Packard et al., 1979; Takens, 1981). The result was utilized to determine the difference between the normal and various load carriage walking conditions which reported varied maximum LyE values.

2.3 Statistical analysis

To determine the most stable status from three different situations, the mean of maximum LyE was calculated for each carriage condition. To calculate the significant difference between various conditions, data were compared for all mean pairs by using post-hoc Tukey-Kramer HSD (Honestly Significant Difference) analysis. Tukey-Kramer HSD test was applied to perform an exact alpha level test of the same sample size (Kramer, 1956; Tukey & Braun, 1994). The dependent value was the maximum LyE value, and the independent value was the three load conditions, which were no load, ALICE and MOLLE. The outcome showed how the maximum LyE value differed given each condition.

3. Results

We found that ALICE had the highest mean LyE value of 1.31, MOLLE had the value of 1.25, and the normal walking showed a mean LyE value of 0.89, which was the lowest divergence rate among all others. This demonstrates that the load carriage and rucksack usage component has a considerable effect on dynamic stability.

	Maximum LyE (λ) bits/s		
ID	**Normal Walk**	**ALICE**	**MOLLE**
S001	0.82	1.40	1.29
S002	1.01	1.31	1.24
S003	0.79	1.14	1.22
S004	0.93	1.34	1.24
S005	0.91	1.39	1.26

Table 2. Maximum Lyapunov Exponent for Each Subject with Different Load Carriage Condition

In addition, as presented in figure 3, the results indicated that ALICE and MOLLE do not show significant differences in maximum LyE between these walking conditions (P-value=0.441). However, when comparing the result of ALICE with Normal walk, the p-value was 0.000007; MOLLE and Normal walk's p-value was 0.00003. Therefore, we were able to determine significant differences between the normal walking and both of the bag types, however, no significant differences were revealed amongst ALICE and MOLLE.

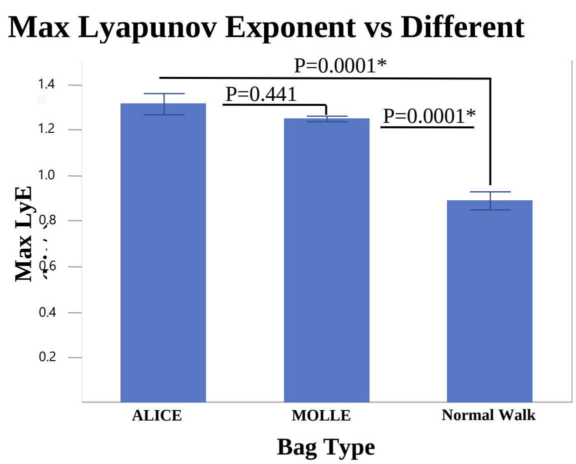

Figure 3. Bar graph analysis of three different walking condition effect on dynamic stability

4. Discussion

The purpose of this study was to determine how the weight and material of the load carriage affect the dynamic stability of the subject's gait. Previous studies reported that load carriage modifies the push-off force and generates massive fatigue affecting gait instability (Birrell & Haslam, 2010; Qu & Yeo, 2011). Considering these factors, as hypothesized, normal walking without any bag had the most stable dynamic stability, while MOLLE had the second highest dynamic stability, and ALICE was the least stable condition among the three circumstances. Compared to ALICE and MOLLE bag type walking, normal walking was found to have the lowest values of maximum LyE values. This indicates that certain physical forces applied during walking may develop significant gait instability. In addition, the maximum LyE rate comparison between material difference among the ALICE (Metal) and MOLLE (Plastic) indicated no significant difference. Therefore, whether the load carriage material is metal or plastic frames, it does not influence the dynamic stability significantly.

Despite the significant findings, there are several limitations in this study. This research was conducted with five young male people, which could be considered a low sample size. A larger and more diverse sample population would provide a more accurate and reliable translation to the larger population. Furthermore, increasing the sample size, such as 95^{th} to 5^{th} percentile male should be tested in order to acquire the normally distributed sample for dynamic stability. Moreover, different age groups and gender should be considered for the potential subject. This will increase the reliability of the data and understand how dynamic stability performance differs in another experimental group.

Understanding the limitations of the current research, future studies should consider assessing overground load carriage. This is important since practically military use of rucksacks is in varied terrain environments instead of constrained treadmill walking conditions. However, this data collected in a virtual reality environment simulated natural walking to some extent. Accordingly, investigating the overground load carriage with various circumstances, such as providing a different kind of land terrain and incline/decline sloped surfaces would provide more understanding of how dynamic stability is effect by various load carriage situations.

5. CONCLUSION

This study investigated the effect of load carriage and material difference on young healthy adult's dynamic stability. The result revealed that normal walking without any load carriage had the most stable dynamic stability, and the other two bag types reported higher LyE values compared to normal walking. In addition, these two-load carriage conditions showed that there was no significant difference in dynamic stability. This implies that certain load conditions have a significant effect on dynamic stability, however, given equal weight, different material component of load carriage does not alter the subject's dynamic stability.

NOMENCLATURE

ALICE	All-Purpose Lightweight Individual Carrying Equipment
MOLLE	Modular Lightweight Load Carrying Equipment
LDS	Local Dynamic Stability
LyE	Lyapunov Exponent

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THREE DAYS MONITORING OF ACTIVITIES OF DAILY LIVING AMONG YOUNG HEALTHY ADULTS AND PARKINSON'S DISEASE PATIENTS

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ABSTRACT

Parkinson's Disease (PD) is a neurodegenerative disorder affecting the substantia nigra, which leads to more than half of PD patients are considered to be at high risk of falling. Recently, Inertial Measurement Unit (IMU) sensors have shown great promise in the classification of activities of daily living (ADL) such as walking, standing, sitting, and laying down, considered to be normal movement in daily life. Measuring physical activity level from longitudinal ADL monitoring among PD patients could provide insights into their fall mechanisms. In this study, six PD patients (mean age=74.3±6.5 years) and six young healthy subjects (mean age=19.7±2.7 years) were recruited. All the subjects were asked to wear the single accelerometer, DynaPort MM+ (Motion Monitor+, McRoberts BV, The Hague, Netherlands), with a sampling frequency of 100 Hz located at the L5-S1 spinal area for 3 days. Subjects maintained a log of activities they performed and only removed the sensor while showering or performing other aquatic activities. The resultant

acceleration was filtered using high and low pass Butterworth filters to determine dynamic and stationary activities. As a result, it was found that healthy young subjects performed significantly more dynamic activities (13.2%) when compared to PD subjects (7%), in contrast, PD subjects (92.9%) had significantly more stationary activities than young healthy subjects (86.8%).

Keywords: Parkinson's Disease (PD), Activity of Daily Living (ADL), Inertial Measurement Unit (IMU), Physical Activity Level, Dynamic activity, Stationary activity

INTRODUCTION

Parkinson's disease (PD) is a neurodegenerative disorder affecting the substantia nigra. The substantia nigra plays a role in controlling the movement of the body, and, in PD, can be related to symptoms such as tremor, rigidity, bradykinesia, and postural instability [1]. These symptoms increase the possibility of falling among PD patients and significantly reduce physical activity in their daily activities [2]. Approximately 2.8 million elderly adults, aged 65 years and older, fall and receive treatment in emergency departments. Hospitalizations due to fall accidents totaled more than 800,000 patients in 2016, of which 95% of patients had hip fractures. The total medical costs of fall related visits exceed $50 billion annually [3]. In the PD population, 50% to 70% of patients have a fall accident a year, which increases the population's total annual medical cost to almost 27 billion dollars [4]. In addition to economic costs, falls can negatively impact activity level, fear of falling, and quality of life [5]. Past studies indicated that most falls occur within the subject's home environment; therefore, assessment of fall risk should be executed in the subject's normal home environment. Home monitoring also lowers the risk of "white coat syndrome" and the normal authentic Activities of Daily Living (ADL) could be recorded and evaluated [6]. Previously ADL measurement was assessed with a questionnaire or survey, which is considered to be subjective. With this approach, there is a possibility of results being skewed and the outcome could be unreliable [7]–[9]. Therefore, utilizing the Inertial Measurement Unit (IMU) could resolve this issue and output more dependable objective data [10]. In this research, the three consecutive days of ADL data was assessed with IMU from the PD patients and Young healthy adult. From the result, we compared the two group's physical activity levels from collected ADL data and evaluate how often dynamic activities were performed. The main principal objective of this study was to examine the physical activity difference among these two groups and to determine whether their dynamic and stationary level shows a significant difference from the ADL measurement.

MATERIALS & METHODS

For this study, there were a total of twelve subjects, six PD patients and six young healthy subjects, where the detailed anthropometric data is presented in Table 1.

Table 1: Young Healthy and Parkinson's Diseases Subject's anthropometric data

	PD Subject	Young Subject
Age (years)	74.3 ± 6.5	19.7 ± 2.7
Height (cm)	173.8 ± 7.3	166.7 ± 11.1
Weight (kg)	77.3 ± 16.5	71.8 ± 13.6
BMI (kg/m²)	25.4 ± 3.5	25.9 ± 4.2

Subjects with any recent surgery, musculoskeletal, cardiovascular, and respiratory diseases were excluded. This research was approved by the Institutional Review Board (IRB) of Arizona State University and Barrow's Neurological Institute (IRB#6518). All the participants signed the written consent as per Arizona State University and Barrow's Neurological Institute before initiating the study. The IMU device that was used to assess the ADL in this study was Dynaport MM+ (Motion Monitor+, McRoberts BV, The Hague, Netherlands). The dimensions of this sensor are 85 ×58×11.5 mm, with a weight of 55 grams, and had a sampling frequency of 100 Hz. As indicated in Figure 1, this device was located at the posterior lumbar region of the spine area. The data was continuously collected for 3-days and removing the device was only allowed when taking a bath or otherwise the device was in a situation of immersing into water. In addition, subjects recorded a log of activities they performed during the ADL. Data analysis was completed with MATLAB (MathWorks, Natick, MA, USA). As shown in Figure

2, the resultant acceleration of the X, Y, and Z-axis was filtered by using high and low pass Butterworth filters. Then the cut-off frequency of 1 Hz was applied to identify dynamic and stationary activities (Figure 3). Using this method, the quantity and duration of dynamic and stationary activities will be compared between healthy and PD groups. As indicated in Table 2, first, the subjects were asked to write a daily log of their activity history into four main categories, such as sit, stand, walk, and laying down (Figure 4). Second, participants were requested to record their actions on a scale of minutes, for the investigators to monitor the activities more precisely. Third, the location was reported to indicate where the activity was held. Lastly, an additional comment was made to elaborate on the specific activities that were executed in that period. These activities were compared with the IMU data to support researchers to match the activities that were performed by subjects at a certain time so that investigators could analyze whether the accelerometer signal matches the action. We utilized One-Way ANOVA (Analysis of Variance) for statistical analysis to compare the significant difference of the mean between the PD group and the healthy adult group. The dependent variables were dynamic and stationary activity levels.

Figure 1: Location for Dynaport on the subject during the longitudinal data collection

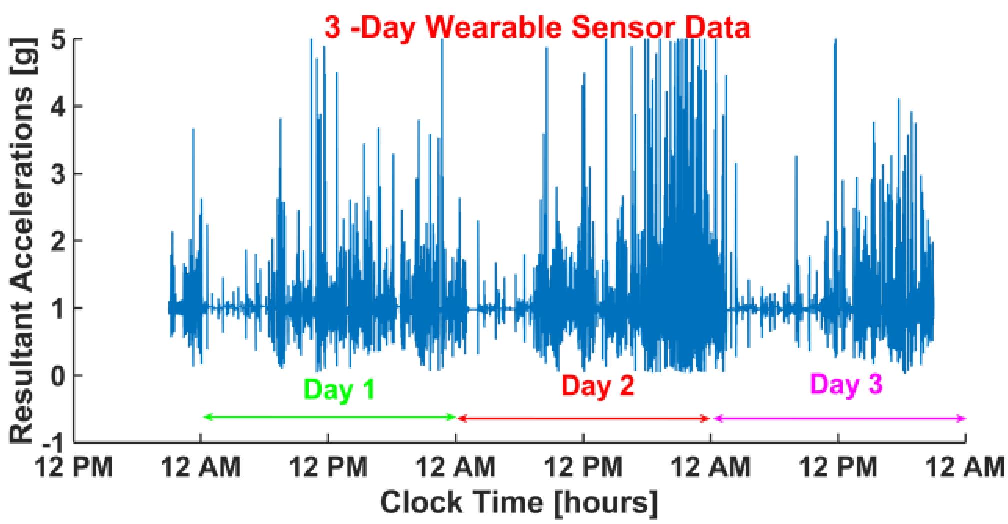

Figure 2: The resultant acceleration for 3days ADL data from the subjects

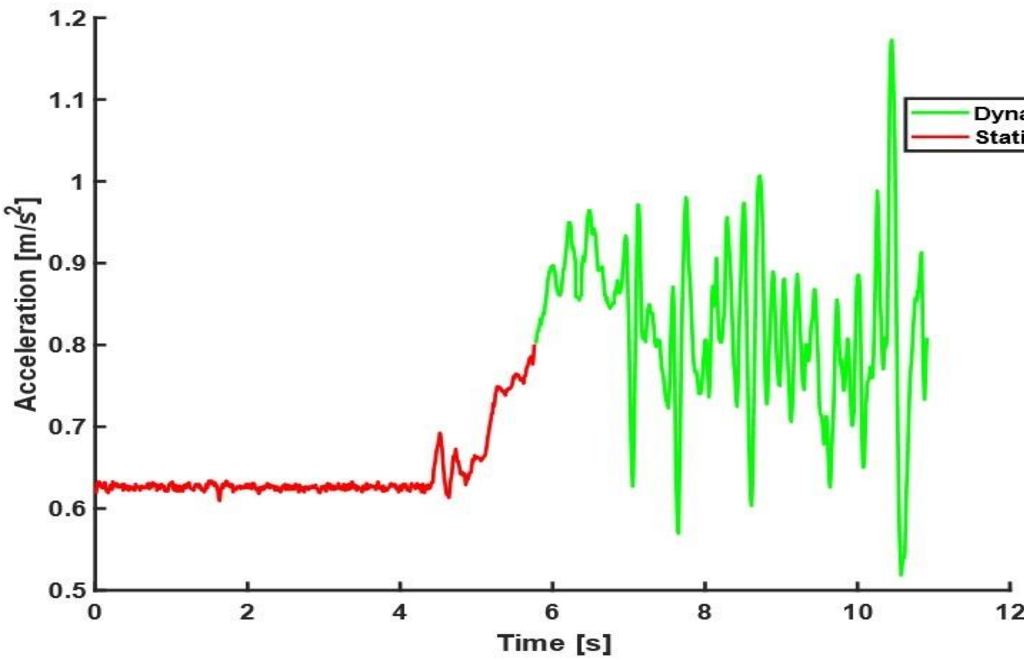

Figure 3: The expanded version of acceleration data presenting the Dynamic (Green) and Stationary (Red) signals

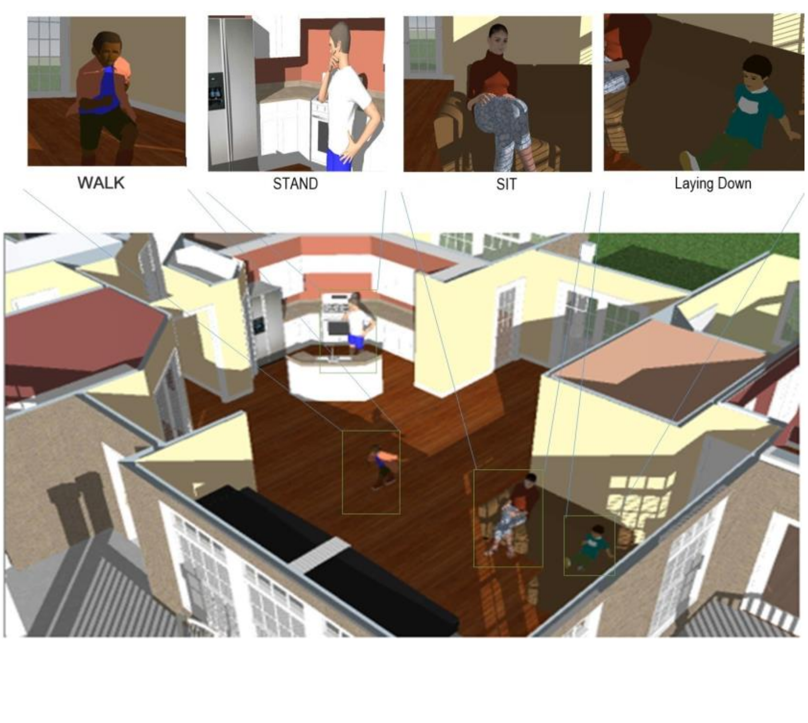

Figure 4: Virtual reality 3D human character performing stand, sit, walking, and laying down activities

Table 2: Format of Sample ADL activity journal from subject

Time (day-month hr:min:sec)	**Activity**	**Duration (min)**	**Location**	**Comment**
19-Apr 22:00:00	Sitting	20	bedroom(3)	chair
19-Apr 22:40:00	Laydown	20	bedroom(3)	bed
19-Apr 00:15:00	Walking	2	bathroom	
19-Apr 05:25:00	Walking	5	to car	walking to car
19-Apr 05:30:00	Sitting	20	driving	in the car
19-Apr 06:00:00	None	60	studio	workout class
19-Apr 07:00:00	Sitting	20	driving	to campus
19-Apr 07:20:00	Walking	20	to dorm	
19-Apr 07:40:00	Standing	40	in dorm	
19-Apr 08:20:00	Walking	5	to class	
19-Apr 08:25:00	Sitting	125	class	human event
19-Apr 10:30:00	Laydown	120	dorm	lap

RESULTS

The result found that the dynamic activity level for the young healthy subject was 13.2%, and the PD subject was 7.0%. This indicates that there was a significant decrease in dynamic activity level for the PD subjects (p=0.0063) (Figure 5). Additionally, the stationary level for young healthy subjects was 86.8% and PD subjects were 92.9%. This also indicates that the stationary level for the young healthy subject was significantly lower than PD subjects. As hypothesized, the young healthy group had approximately twice more dynamic activity levels compared to the PD group.

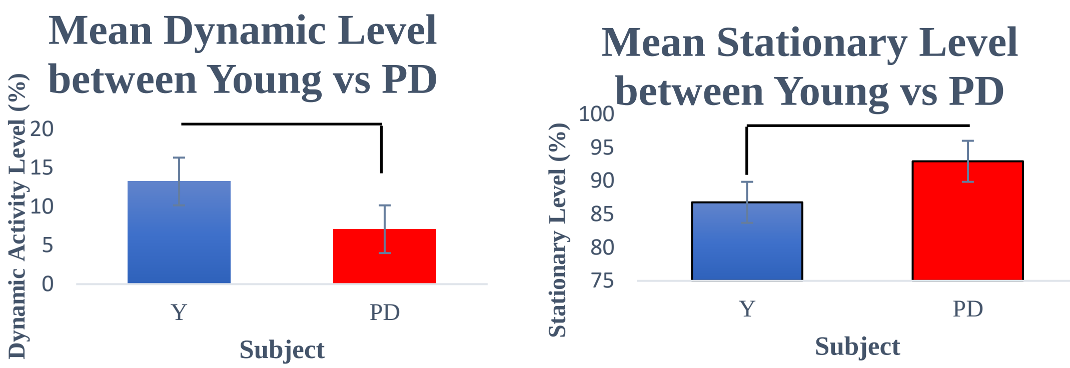

Figure 5: This graph represents the average percentage difference between dynamic and stationary performance among the young healthy and PD subjects.

DISCUSSION

The objective of this study was to evaluate the physical activity level from three consecutive days of regular ADL of PD patients and young healthy subjects and compare the difference between dynamic and stationary measurements. In previous research, physical activity level from ADL was measured subjectively with survey or questionnaires. One study indicated that PD patients are 29% less active than normal healthy elderly subjects, which was measured based on Longitudinal Aging Study Amsterdam Physical Activity Questionnaire (LAPAQ) [2]. This interview-based questionnaire had various limitations that depend on the individual's perception of activity level that could lead to deceiving the authentic quantity of ADL. To collect physical activity levels precisely, usage of the IMU sensor is inevitable. This device has allowed researchers to collect the data objectively with accurate acceleration data. Applying the proper analysis method, cut off frequency of lower than 1 Hz to detect the stationary activities [11], [12], this algorithm has determined dynamic and stationary measurements accurately. As hypothesized, young healthy subjects had significantly more dynamic activities compared to PD patients. There were several limitations to this study. First, consisting of a total of twelve subjects, six in each group, the sample size was limited. Second, the age difference between the two groups was considered a confound. The average age of PD patients was 74.3 but the young healthy subject's average age was 19.7. This age variability could affect the result of the physical activity level. However, this was the first comparative study to analyze high ADL performance (healthy) and expected low ADL performance (PD) utilizing a single wearable sensor in their home environment. Also, our prior study has reported healthy young and older adults have similar activity profiles with young performing high-frequency activities and old performing more low-frequency activities [13]. Therefore, physical activity comparison will provide a fundamental understanding of the necessity for dynamic activity during ADL.

In future work, more sample sizes will be added, and the inclusion of age-matched healthy older subjects will decrease the age variation and resolve the constraint. As result, the outcome of the study will publish more concrete reliable outcomes.

CONCLUSIONS

This study has determined the physical activity level difference from Young healthy subjects to PD subjects. The result provided the urgency of requiring a more dynamic physical activity level for the PD patients since this group had a significantly lower activity level compared to the young healthy group. Besides, data assessment with the IMU system has allowed a quantitative measure of ADL, which establishes the reliability of the result. The utilization of quantitative measures will enhance ADL measurement in the future and inform the subject with deficient activity levels.

DISCLOSURES

"All authors have nothing to declare."

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ASU IRB ID: 6518

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APPENDIX B

INSTITUTE REVIEW BOARD (IRB) APPROVAL FROM ARIZONA STATE UNIVERSITY (IRB ID: STUDY00015978)

APPROVAL: EXPEDITED REVIEW

Thurmon Lockhart
IAFSE-BHSE: Bioengineering, Harrington Department of
-
Thurmon.Lockhart@asu.edu

Dear Thurmon Lockhart:

On 9/2/2022 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Observational study of effects of acute low back pain spinal injection on activities of daily living and gait and balance
Investigator:	Thurmon Lockhart
IRB ID:	STUDY00015978
Category of review:	
Funding:	None
Grant Title:	None
Grant ID:	None
Documents Reviewed:	• Application, Category: IRB Protocol; • Consent Form, Category: Consent Form; • IRB Certification for Marc Jacofsky, Category: Other; • Letter of Collaboration, Category: Off-site authorizations (school permission, other IRB approvals, Tribal permission etc); • Medical History Form, Category: Screening forms; • Questionaire, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Questionnaire, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Questionnaire, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Recruitment ad, Category: Recruitment Materials; • The Core letter, Category: Other;

The IRB approved the protocol from 9/2/2022 to 9/1/2023 inclusive. Three weeks before 9/1/2023 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 9/1/2023 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the “Documents” tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

REMINDER - - Effective January 12, 2022, in-person interactions with human subjects require adherence to all current policies for ASU faculty, staff, students and visitors. Up-to-date information regarding ASU's COVID-19 Management Strategy can be found here. IRB approval is related to the research activity involving human subjects, all other protocols related to COVID-19 management including face coverings, health checks, facility access, etc. are governed by current ASU policy.

Sincerely,

IRB Administrator

cc:
Seong Hyun Moon

APPENDIX C

INFORMED CONSENT FORM DOCUMENT FOR IRB (IRB ID: STUDY00015978)

Consent Form: Bioscience

Title of research study: Observational Study of Effects of low back pain spinal injection on gait and balance and Activities of Daily Living (ADL)

Investigator: Thurmon E. Lockhart, Ph.D., Professor, School of Biological and Health Systems Engineering. Marc Jacofsky, Ph.D., The CORE Institute, AZ, USA. Seong Hyun Moon, Graduate Student, School of Biological and Health Systems Engineering.

Please read this information carefully. This document informs you the important matters about this research study. A member of our research team will talk to you about participating in this research study. If you have questions at any time, please ask us.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision will not cause any penalties or loss of benefits to which you are otherwise entitled.

If you decide to take part in this research study, you will sign this consent form to show that you want to participate. We will give you a copy of this form to keep.

Why am I being invited to take part in a research study?

We invite you to take part in this research study because you may be eligible for a study identifying the effects of spinal injection on balance, stability, fall risk and Activities of Daily Living (ADL).

Why is this research being done?

The purpose of the research is to perform gait and balance stability assessments, using an Inertial Measurement Unit (IMU) device before and after back pain intervention to ascertain effect of injection, and possibly identify high fall risk individuals.

How long will the research last?

We expect that individuals will spend at least 30 minutes for each study session participating in the proposed activities. There are 4 sessions.

1) At the time of procedure scheduling (1-3 weeks before LBP intervention procedure).
2) After the LBP intervention, first post-injection analysis (approximately within 2 weeks after the intervention).
3) After the LBP intervention, second post-injection analysis (approximately within 4 weeks after the intervention)
4) After the LBP intervention, third post-injection analysis (approximately 12 weeks after the intervention / Post-injection survey link).

How many people will be studied?

We expect about 100 people to participate in this research study.

What happens if I say yes, I want to be in this research?

The proposed activities in this research include postural stability eyes open and eyes closed, 10m walk, Timed-up-and-Go (TUG), and 3-minute walking in The CORE Institute's clinical area. Prior to any assessment, you will first sign this document and then fill out a medical history form to determine your eligibility for the study. In addition, The Katz Index of Independence in Activities of Daily Living questionnaire, Oswestry Low Back Disability Questionnaire (ODQ), and Activities-specific Balance Confidence Scale (ABC) will also be collected at all clinic visit time points. The survey will take approximately 10-15 minutes for completion. If you are not eligible to participate in the study, we will thank you for your time and you will be free to go. If you are eligible, then we will measure your height and weight and proceed with testing. This study includes a total of 4 sessions and each session will be conducted at The CORE Institute/Self Home environment. For the in-clinic data collection, you will be equipped with one or more IMU sensors which will be used to collect data. You will then perform standing balance (postural stability), 10M walk, TUG and minimum of 2-minute continuous walking trials. Each session will take about half an hour in duration. For the out of clinic (home) data collection, you will be provided with a special IMU system that will be placed on your sacrum area and held in place with a belt, which you will wear for three consecutive days. Also, you will be asked to keep an Activity of Daily Living diary and report any fall or unusual events. The researcher will provide you with a more detailed procedure and timeline at the time of signing this consent form. In addition, if patients fail to follow up in the study, they will be given up to three phone calls and a certified letter in an attempt to contact them for follow up before they are withdrawn from the study by the investigators. Post-injection survey link will be provided, which includes fall history, Oswestry Low Back Disability, Katz index, and ABC scale questionnaire.

This will partially depict efficacy of the spinal injection on LBP and ADL level and support the researchers.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you stop being in the research study, any data already collected may not be removed from the study database.

Is there any way being in this study could be bad for me?

There is no expected benefit to participating in this study. There are no foreseeable risks in performing any of the protocols in this study. We are using non-invasive, minimum risk devices and asking participants to perform common daily living activities, such as walking and standing. The ASU IRB has review this proposed study and determined that it is in compliance with federal laws and ASU policies governing the protection of human subjects in research.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. De-identified data may be shared with the company who makes the mobile application to troubleshoot or improve the software. No medical records will be accessed by this research team during the study.

What else do I need to know?

Your participation in this study is voluntary. You must be at least 18 years old, and we ask that you wear athletic, non-reflective clothing and athletic sneakers for this experiment. If you are not wearing the appropriate clothing, we will provide a change of clothes for you to wear for the duration of the experiment. If you agree to participate in the study, then consent does not waive any of your legal rights. However, no funds have been set aside to compensate you in the event of injury.

This study is an observational study and will not affect the medical care you receive in any way. You may be asked to sign additional consent forms related to the treatment you will undergo. These forms and your treatment are not part of this study.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Arizona State University – Dr. Thurmon E. Lockhart, thurmon.lockhart@asu.edu, or 480-965-1499.

This research has been reviewed and approved by the Bioscience IRB (“IRB”). You may talk to them at (480) 965-6788 or research.integrity@asu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
  - You cannot reach the research team.
  - You want to talk to someone besides the research team.
  - You have questions about your rights as a research participant.
  - You want to get information or provide input about this research.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of participant	Date

Printed name of participant

Signature of person obtaining consent	Date

Printed name of person obtaining consent

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

Signature of witness to consent process	Date

Printed name of person witnessing consent process

APPENDIX D

LETTER OF COLLABORATION – THE CORE INSTITUTE (IRB ID: STUDY00015978)

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THE CORE INSTITUTE®

Marc Jacofsky, Ph.D.
Chief Scientific Officer
marc.jacofsky@thecoreinstitute.com

August 12, 2022

Institutional Review Board
Arizona State University
ASU Centerpoint, STE 312
660 South Mill Ave
Tempe, AZ 85281-611

To Whom It May Concern:

This letter confirms our desire to collaborate with Dr. Thurmon Lockhart and his student Seong Hyun Moon on the study entitled "Effects of low back pain spinal injection on gait and balance and Activities of Daily Living (ADL)." The CORE Institute will defer human subjects' regulatory oversight of this study to the ASU IRB and will permit ASU researchers and graduate students to collect data from patients in our clinic locations. This study is an observational study design because all clinical care and procedures will be performed as standard of care for The CORE Institute and treating physician.

Specific locations from which recruitment may take place include:

The CORE Institute Gilbert Clinic
3591 S Mercy Rd, STE 204
Gilbert, AZ 85297

The CORE Institute Spine Center
3591 S. Mercy Rd., STE 101
Gilbert, AZ 85297

We request that the IRB approval also cover access to The CORE Institute's electronic health records for the limited research purposes described in the protocol and for activities preparatory to research to facilitate patient screening by ASU researchers.

Should any further information be required please do not hesitate to contact me.

Sincerely,

Marc Jacofsky, PhD

Chief Scientific Officer:
The CORE Institute
Executive Director:
MORE Foundation
Adjunct Faculty of Bioengineering:
Arizona State University

APPENDIX E

OSWESTRY LOW BACK PAIN SCALE QUESTIONNAIRE (IRB ID: STUDY00015978)

Oswestry Low Back Pain Scale

Please rate the severity of your pain by circling a number below:

No pain	0	1	2	3	4	5	6	7	8	9	10	*Unbearable pain*

Name ______________________________ **Date** ______________

Instructions: Please circle the ONE NUMBER in each section which most closely describes your problem.

Section 1 – Pain Intensity
0. The pain comes and goes and is very mild.
1. The pain is mild and does not vary much.
2. The pain comes and goes and is moderate.
3. The pain is moderate and does not vary much.
4. The pain comes and goes and is severe.
5. The pain is severe and does not vary much.

Section 2 – Personal Care (Washing, Dressing, etc.)
0. I would not have to change my way of washing or dressing in order to avoid pain.
1. I do not normally change my way of washing or dressing even though it causes some pain.
2. Washing and dressing increase the pain but I manage not to change my way of doing it.
3. Washing and dressing increase the pain and I find it necessary to change my way of doing it.
4. Because of the pain I am unable to do some washing and dressing without help.
5. Because of the pain I am unable to do any washing and dressing without help.

Section 3 – Lifting
0. I can lift heavy weights without extra pain.
1. I can lift heavy weights but it gives extra pain.
2. Pain prevents me lifting heavy weights off the floor.
3. Pain prevents me lifting heavy weights off the floor, but I can manage if they are conveniently positioned, e.g., on a table.
4. Pain prevents me lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
5. I can only lift very light weights at most.

Section 4 – Walking
0. I have no pain on walking.
1. I have some pain on walking but it does not increase with distance.
2. I cannot walk more than 1 mile without increasing pain.
3. I cannot walk more than ½ mile without increasing pain.
4. I cannot walk more than ¼ mile without increasing pain.
5. I cannot walk at all without increasing pain.

Section 5 – Sitting
0. I can sit in any chair as long as I like.
1. I can sit only in my favorite chair as long as I like.
2. Pain prevents me from sitting more than 1 hour.
3. Pain prevents me from sitting more than ½ hour.
4. Pain prevents me from sitting more than 10 minutes.
5. I avoid sitting because it increases pain immediately.

Section 6 – Standing
0. I can stand as long as I want without pain.
1. I have some pain on standing but it does not increase with time.
2. I cannot stand for longer than 1 hour without increasing pain.
3. I cannot stand for longer than ½ hour without increasing pain.
4. I cannot stand for longer than 10 minutes without increasing pain.
5. I avoid standing because it increases the pain immediately.

Section 7 – Sleeping
0. I get no pain in bed.
1. I get pain in bed but it does not prevent me from sleeping well.
2. Because of pain my normal nights sleep is reduced by less than one-quarter.
3. Because of pain my normal nights sleep is reduced by less than one-half.
4. Because of pain my normal nights sleep is reduced by less than three-quarters.
5. Pain prevents me from sleeping at all.

Section 8 – Social Life
0. My social life is normal and gives me no pain.
1. My social life is normal but it increases the degree of pain.
2. Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g., dancing, etc.
3. Pain has restricted my social life and I do not go out very often.
4. Pain has restricted my social life to my home.
5. I have hardly any social life because of the pain.

Section 9 – Traveling
0. I get no pain when traveling.
1. I get some pain when traveling but none of my usual forms of travel make it any worse.
2. I get extra pain while traveling but it does not compel me to seek alternate forms of travel.
3. I get extra pain while traveling which compels to seek alternative forms of travel.
4. Pain restricts me to short necessary journeys under ½ hour.
5. Pain restricts all forms of travel.

Section 10 – Changing Degree of Pain
0. My pain is rapidly getting better.
1. My pain fluctuates but is definitely getting better.
2. My pain seems to be getting better but improvement is slow.
3. My pain is neither getting better or worse.
4. My pain is gradually worsening.
5. My pain is rapidly worsening.

TOTAL ____________

APPENDIX F

ACTIVITIES-SPECIFIC BALANCE(ABC) CONFIDENCE SCALE QUESTIONNAIRE (IRB ID: STUDY00015978)

Patient Name: ______________________________________ Date: ____________________

The Activities-specific Balance Confidence (ABC) Scale*

Instructions to Participants: For each of the following activities, please indicate your level of confidence in doing the activity without losing your balance or becoming unsteady from choosing one of the percentage points on the scale from 0% to 100% If you do not currently do the activity in question, try and imagine how confident you would be if you had to do the activity. If you normally use a walking aid to do the activity or hold onto someone, rate your confidence as if you were using these supports.

0%	10	20	30	40	50	60	70	80	90	100%
No Confidence										Completely Confident

How confident are you that you will not lose your balance or become unsteady when you...

1. ...walk around the house? _____%
2. ...walk up or down stairs? _____%
3. ...bend over and pick up a slipper from the front of a closet floor? _____%
4. ...reach for a small can off a shelf at eye level? _____%
5. ...stand on your tip toes and reach for something above your head? _____%
6. ...stand on a chair and reach for something? _____%
7. ...sweep the floor? _____%
8. ...walk outside the house to a car parked in the driveway? _____%
9. ...get into or out of a car? _____%
10. ...walk across a parking lot to the mall? _____%
11. ...walk up or down a ramp? _____%
12. ...walk in a crowded mall where people rapidly walk past you? _____%
13. ...are bumped into by people as you walk through the mall? _____%
14. ...step onto or off of an escalator while you are holding onto a railing? _____%
15. ...step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing? _____%
16. ...walk outside on icy sidewalks? _____%

*Powell LE & Myers AM. The Activities-specific Balance Confidence (ABC) Scale. Journal of Gerontology Med Sci 1995; 50(1):M28-34.

Total ABC Score: __________

Scoring: ____________ **/ 16 =** | __________% of self confidence |
Total ABC Score

MEDICARE PATIENTS ONLY
100% - _____% Function = _____% Impairment

Patient Signature: ______________________________________ Date: ____________________

Therapist Signature: ______________________________________ Date: ____________________

APPENDIX G

KATZ INDEX OF INDEPENDENCE IN ACTIVITIES OF DAILY LIVING QUESTIONNAIRE (IRB ID: STUDY00015978)

Patient Name:____________________ **Date:**____________

Patient ID #______________________

Katz Index of Independence in Activities of Daily Living

Activities Points (1 or 0)	**Independence** (1 Point) NO supervision, direction or personal assistance.	**Dependence** (0 Points) WITH supervision, direction, personal assistance or total care.
BATHING Points: ________	**(1 POINT)** Bathes self completely or needs help in bathing only a single part of the body such as the back, genital area or disabled extremity.	**(0 POINTS)** Need help with bathing more than one part of the body, getting in or out of the tub or shower. Requires total bathing
DRESSING Points: ________	**(1 POINT)** Get clothes from closets and drawers and puts on clothes and outer garments complete with fasteners. May have help tying shoes.	**(0 POINTS)** Needs help with dressing self or needs to be completely dressed.
TOILETING Points: ________	**(1 POINT)** Goes to toilet, gets on and off, arranges clothes, cleans genital area without help.	**(0 POINTS)** Needs help transferring to the toilet, cleaning self or uses bedpan or commode.
TRANSFERRING Points: ________	**(1 POINT)** Moves in and out of bed or chair unassisted. Mechanical transfer aids are acceptable	**(0 POINTS)** Needs help in moving from bed to chair or requires a complete transfer.
CONTINENCE Points: ________	**(1 POINT)** Exercises complete self control over urination and defecation.	**(0 POINTS)** Is partially or totally incontinent of bowel or bladder
FEEDING Points: ________	**(1 POINT)** Gets food from plate into mouth without help. Preparation of food may be done by another person.	**(0 POINTS)** Needs partial or total help with feeding or requires parenteral feeding.

TOTAL POINTS: _______ **SCORING:** 6 = High (*patient independent*) 0 = Low (*patient very dependent*

APPENDIX H

MEDICAL HISTORY AND EMERGENCY CONTACT FORM (IRB ID: STUDY00015978)

MEDICAL HISTORY AND EMERGENCY CONTACT FORM

Study Title: EFFECT OF LOW BACK PAIN ON FALL RISK and ACTIVITY OF DAILY LIVING

Date: ________________ Participant Code Number (ID): ________________

Gender: ☐ Male ☐ Female Age: _____

Height (ft/in): ________ Weight (lb): ______

Other Study Specific Measurement(s): ____

In Case of an Emergency, Contact:
Name: _____________________ Phone: ____________

GENERAL INFORMATION		
Do you experience: Shortness of breath Dizziness Headache Easily fatigued Pain in arm, shoulder or chest	 ☐ NO ☐ NO ☐ NO ☐ NO ☐ NO	 ☐ YES ☐ YES ☐ YES ☐ YES ☐ YES
Are you able to walk 25 feet?	☐ NO	☐ YES
Do you require an assistive device when walking (i.e. cane, walker)	☐ NO	☐ YES
Are you able to ascend and descend a flight of stairs without assistance, aside from the railings?	☐ NO	☐ YES
Have you had surgery in the past 3 months? If yes, when?	☐ NO	☐ YES
Do you have an active form of cancer (excluding melanoma)?	☐ NO	☐ YES
Do you play any sports? If so, which ones and how many hours a week do you spend playing?		
How many hours per week do you exercise and/or perform physical activities?		

Are you currently taking prescription or other medication? If so, please list:

FALL HISTORY (Note: falls during normal walking or during daily activities)		
Have you experienced any falls over the past 6 months? More than 2? Were you injured? If so, what were your injuries?	☐ NO ☐ NO ☐ NO	☐ YES ☐ YES ☐ YES
Have you experienced any falls over the past year? More than 2? Were you injured? If so, what were your injuries?	☐ NO ☐ NO ☐ NO	☐ YES ☐ YES ☐ YES
Have you experienced any falls over the past 2 years? More than 2? Were you injured? If so, what were your injuries?	☐ NO ☐ NO ☐ NO	☐ YES ☐ YES ☐ YES
BONE AND JOINTS		
Have you been diagnosed with osteoporosis (thinning of the bones)?	☐ NO	☐ YES
Have you experienced fractures of one or more bones in the past 3 years?	☐ NO	☐ YES
Have you had hip or knee replacement surgery, or ankle surgery? If so, which of these surgeries have you had and when did you get them?	☐ NO	☐ YES

Are you missing, or have you had an amputation of a limb?	☐ NO	☐ YES
Do you have arthritis in your hands, knees, ankles, etc.?	☐ NO	☐ YES
Do you use one or more orthotic devices? If so, what kind?	☐ NO	☐ YES
VISION	CHAPT	CHAPTE
Do you wear glasses, contact lenses, or other prescription eyewear?	☐ NO	☐ YES
BRAIN AND NERVOUS SYSTEM		
Have you ever had a stroke?	☐ NO	☐ YES
If you have had a stroke, has it left you with weakness in an arm or leg?	☐ NO	☐ YES
Do you have Parkinson's disease?	☐ NO	☐ YES
If you have Parkinson's disease, does it affect your balance or walking?	☐ NO	☐ YES
Do you have any inner ear problems causing dizziness or affecting your balance?	☐ NO	☐ YES
Have you ever been diagnosed with a seizure disorder?	☐ NO	☐ YES
Have you ever been diagnosed with a severe mental disability? (e.g., schizophrenia, post-traumatic stress disorder (PTSD) , Down Syndrome, etc.)	☐ NO	☐ YES
MUSCLES		
Do you frequently experience muscle weakness?	☐ NO	☐ YES
Have you been diagnosed with any muscle wasting disease?	☐ NO	☐ YES
Do you require a cane or a walker to facilitate your walking?	☐ NO	☐ YES
HEART AND CIRCULATORY SYSTEM		
Have you had a heart attack?	☐ NO	☐ YES
Do you have an enlarged heart or congestive heart failure?	☐ NO	☐ YES
Do you have diabetes?	☐ NO	☐ YES
If you have diabetes, have you been told that you have diabetic neuropathy in your feet (affecting sensation or circulation in your feet)?	☐ NO	☐ YES
Do you have hemophilia (inability of your blood to clot)?	☐ NO	☐ YES
SKIN		
Are you allergic to tape, adhesives, or gels used to attach reflective markers?	☐ NO	☐ YES

Additional Inclusion and Exclusion Criteria (determined by yes, no answers)

1. Inclusion criteria:

1. Subject has voluntarily signed and dated an informed consent form (ICF), approved by an Independent Ethics Committee (IEC)/Institutional Review Board (IRB) prior to any participation in the study.
2. Subject should be in good physical condition in terms of general movements.
3. Subject is male or female and is ≥ 18 years of age.
4. Subject is ambulatory and able to walk ≥ 25 feet without the use of an assistive device.
5. Subject is able to follow the protocol.

2. Exclusion criteria:

1. Subject is unable to walk without human assistance
2. Subject has a severe mental disability
3. Subject reports having undergone major surgery, less than 6 weeks prior to enrollment in the study.

APPENDIX I

CO-AUTHOR PERMISSIONS

All authors of the publications presented in this document have granted their permission.