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Postural Stability in Unilateral Transtibial Amputees Using Two Suspension Systems: SmartpuckTM vs Lock and Pin

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POSTURAL STABILITY IN UNILATERAL TRANSTIBIAL
AMPUTEES USING TWO SUSPENSION SYSTEMS:
SMARTPUCK™ VS LOCK AND PIN

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ABSTRACT

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The number of individuals with lower limb amputation is growing. Individuals with transtibial amputation (TTA) face an increased risk of falling. Center of pressure (COP) is measured during quiet stance to assess postural stability and fall risk. The purpose of the present study was to examine postural stability of individuals with TTA using two suspension systems: SmartPuck™ (PUCK) and lock and pin (PIN). Four participants with TTA (71.34 ± 41.52 kg, 1.39 ± 0.08 m; 49.2 ± 27.79 years, K3 - K4) performed 30 seconds of quiet standing for four different conditions with each suspension system: (a) rigid surface eyes open (RSEO), (b) rigid surface eyes closed (RSEC), (c) compliant surface eyes open (CSEO), and (d) compliant surface eyes closed (CSEC). Center of pressure and vertical ground reaction forces (GRF) (1000 Hz) were collected using two force plates (AMTI, Watertown, MA).

Throughout the four conditions, significant interlimb differences were observed in mean resultant velocity, mean AP velocity, 95% CE area, sway area, and %BWT, demonstrating greater reliance of the intact limb. As conditions increased in difficulty, more interlimb differences in measures of postural stability were present, demonstrating increased reliance of the intact limb when stability is challenged. No significant differences were found in either limb between PUCK and PIN suspensions. However, trends demonstrating increased control of postural stability were observed with PUCK suspension in the RSEO, RSEC, and CSEO

conditions. Conversely, trends in measures of postural stability in the CSEC condition suggest increased stability with PIN suspension.

As vision was removed and the standing surface was manipulated, participants demonstrated loss of control of postural stability, or instability. Confidence in the significance of the results is low due to the small number of individuals who participated in the study. Considering the direct relationship between instability and increased fall risk, it is important to identify whether different prosthesis designs can aid in postural steadiness. Further research with more participants is needed to understand the differences in postural stability caused by suspension systems.

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CHAPTER I

GENERAL INTRODUCTION

Introduction of the Study

In the United States, an estimated 185,000 people undergo a major amputation each year (Zeighler-Graham et al., 2008). Worldwide, major amputations are highly correlated to complications with diabetes, infection, and peripheral vascular disease in both men and women (Unwin, 2000). Due to the aging population and the prevalence of diabetes and obesity, the number of people living with an amputation is expected to double by 2050 (Zeighler-Graham et al., 2008).

Many major amputations are of the lower limb (Zeighler-Graham et al., 2008) and are commonly accompanied by inactivity, weight gain, metabolic disease (Kurdibaylo, 1996), and secondary musculoskeletal injury (Farrokhi et al., 2018). About 25% of all lower limb amputations are transtibial (TTA), or below the knee (Zeighler-Graham et al., 2008). Instability and increased fall risk are also secondary to TTA (Bigelow & Berme, 2011; Buckley et al., 2002; Hlavackova et al., 2011; Quai et al., 2005) resulting from reduced proprioception of the affected limb and increased reliance of the sound limb (Isakov et al., 1992; Kanade et al., 2008; Lord & Smith, 1984; Mayer et al., 2011; Nadollek et al., 2002; Quai et al., 2005).

The standard treatment for TTA involves healing of the residual limb, rehabilitation (less common), and fitting of a prosthetic limb. The three main components of a below-the-knee prosthesis are: (a) socket, (b) pylon, and (c) ankle/foot. Most issues such as pain and poor fit experienced with a prosthesis are related to the limb/prosthesis interface, meaning the suspension

system and socket (Board et al., 2001; Ferraro, 2011; Gerschutz et al., 2010; Goswami et al., 2003).

Two of the most prescribed suspension systems are lock and pin (PIN) and vacuum assisted suspension systems (VASS). Lock and pin suspension is achieved with a tightly fitted liner worn on the residual limb. The liner has a pin protruding from the distal end that is inserted into a mechanical lock within the socket, securing the prosthesis (Beil & Street, 2004). Vacuum assisted suspension systems involve a gel liner worn on the residual limb beneath the socket and a neoprene sleeve that extends over the proximal end of the socket creating a seal. A pump, either electric or manual, works to create a negative pressure in the space between the liner and the socket (Ferraro, 2011; Street, 2006).

Due to the simple design, PIN suspension allows for easy and convenient donning and doffing of the prosthesis. Donning is as simple as inserting the residual limb with the liner into the socket and doffing is achieved by pressing a release button (Beil & Street, 2004). Vacuum assisted suspension systems have demonstrated the ability to help maintain residual limb volume (Ferraro, 2011; Gerschutz et al., 2010; Goswami et al., 2003) and improve residual limb skin profusion (Rink et al., 2016). Improved wound healing has also been observed as a result of VASS use (Gerschutz et al., 2010). Maintenance of limb volume and improved profusion contribute to a reduced occurrence of pain, discomfort, blisters, and redness (Ferraro, 2011; Goswami et al., 2003).

While these two suspension systems offer unique benefits, neither are perfect, and prosthesis users often experience issues as a result. Pistoning and change in volume of the residual limb are common issues experienced by prosthesis users (Board et al., 2001; Eshraghi et al., 2014; Ferraro, 2011; Gholizadeh et al., 2014; Goswami et al., 2003; Klute et al., 2011;

Samitier et al., 2016). These issues are often a result of a poor fit at the limb/prosthesis interface. Flaws of prosthetic suspension such as being too heavy, loss of pressure, and not being secure enough can contribute to the above-mentioned issues.

The SmartPuck™ (PUCK) is a newly developed elevated VASS. The PUCK is unlike traditional vacuum systems in that it is housed within the distal end of the socket, and vacuum levels are controlled with a smartphone. Housing the PUCK internally to the socket helps to address one flaw in current vacuums: loss of pressure. Superior control of pressure may contribute to enhanced proprioception of the residual limb and lead to improvements in postural stability. To date, no research has been performed evaluating PUCK and the effects PUCK has on postural stability.

Purpose

The purpose of the present study was to examine postural stability of individuals with TTA using two suspension systems: PUCK and PIN. We hypothesized that:

H0 There would be no differences in COP displacements, velocities, frequencies, or time to boundary between PUCK and PIN under multiple surface and vision conditions.

H1 Stability would decrease as surfaces changed from rigid to compliant and visual input was removed.

CHAPTER II

REVIEW OF LITERATURE

Introduction

In the United States, an estimated 185,000 people undergo a major amputation each year (Zeighler-Graham et al., 2008). Worldwide, major amputations are highly correlated to complications with diabetes, infection, and peripheral vascular disease in both men and women (Unwin, 2000). Due to the aging population and the prevalence of diabetes and obesity, the number of people living with an amputation is expected to double by 2050 (Zeighler-Graham et al., 2008).

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Treatment

Treatment for TTA involves healing of the residual limb, rehabilitation (less common), and fitting of a prosthetic limb. There are three main components of a below-the-knee prosthesis: (a) socket, (b) pylon, and (c) ankle/foot. The socket is attached to the residual limb with a suspension system. Most issues such as pain and poor fit experienced with a prosthesis are related to the limb/prosthesis interface, meaning the suspension system and socket (Board et al., 2001; Ferraro, 2011; Gerschutz et al., 2010; Goswami et al., 2003). One of the most challenging

aspects of a prosthesis fitting is attaching the prosthesis to the limb securely and comfortably. Two of the most prescribed suspension systems are PIN and VASS.

Lock and Pin

Lock and pin suspension is achieved with a tightly fitted liner worn on the residual limb. The liner has a pin protruding from the distal end that is inserted into a mechanical lock within the socket, securing the prosthesis (Beil & Street, 2004). Due to the simple design, PIN suspension allows for easy and convenient donning and doffing of the prosthesis. Donning is as simple as inserting the residual limb with the liner into the socket, and doffing is achieved by pressing a button to release the pin from the lock (Beil & Street, 2004).

Vacuum Assisted Suspension System

The VASS involves a gel liner worn on the residual limb beneath the socket and a neoprene sleeve that extends over the proximal end of the socket creating a seal. A pump, either electric or manual, works to create a negative pressure in the space between the liner and the socket (Ferraro, 2011; Street, 2006). To don and doff, VASS requires more effort and is considered frustrating and difficult by some users (Klute et al., 2011).

Functional Outcomes

Research has evaluated functional outcomes between PIN and VASS systems and found differences between the two suspension systems in use, mobility (including transfers and turns), and balance (Buckley et al., 2002; Eshraghi et al., 2014; Ferraro, 2011; Gholizadeh et al., 2014; Samitier et al., 2016).

Use

The Houghton scale is a self-reported measure of prosthetic use which quantifies when, where, how, and for how long the prosthesis is used daily (Devlin et al., 2004). Houghton scale

scores, although not significantly different, are higher with VASS in comparison with PIN, indicating more daily use (Samitier et al., 2016). In a study from 2011, the majority of a less active sample of patients with TTA reported increased walking time with VASS compared to PIN use (Ferraro, 2011). Klute et al. (2011) reported conflicting results. Using a pedometer, participants took significantly fewer steps in a two-week period with VASS than with PIN (38000 ± 9000 steps per 2wk and 73000 ± 18000 steps per 2wk, respectively; $P = .0056$). All three experiments used a different number of participants who were different ages, had different activity levels, and different prosthetists. Considering this and how the same measurement techniques were not used, it is difficult to make any definitive conclusions from these results. However, any improvement in use or increased physical activity is a meaningful finding. Inactivity associated with amputation can result in loss of strength, flexibility, and bone density (McGraw et al., 2000), and an increase in activity can slow decrements in physical fitness.

Mobility

Medicare functional classification levels (MFCLs) describe overall mobility levels of patients with TTA. The MFCL-2 describes individuals with limited community ambulation abilities, and the MFCL-3 describes those who are capable of unlimited community ambulation. Walking ability of MFCL-2 and MFCL-3 TTAs was measured with and without VASS (Samitier et al., 2016). A non-significant (> 0.05) increased 6 Minute Walk Test (6MWT) distance was observed in the MFCL-2 group with VASS use (without VASS 263.6 ± 30.01 m and with VASS 274 ± 90.88 m). The MFCL-3 group walked significantly further with VASS, suggesting improvements in mobility (without VASS 301 ± 67.84 m and with VASS 349.8 ± 43.05 m, $P = 0.013$).

Samitier et al. (2016) also administered the Locomotor Capabilities Index (LCI) which evaluates overall locomotor ability and patient independence (Franchignoni et al., 2004). The LCI scores were significantly improved with VASS use compared to without VASS use in the MFCL-3 group (49.4 ± 7.51 and 41.6 ± 11.08, respectively; $P = 0.04$). No significant differences in LCI score were observed in the MFCL-2 participants. Vacuum assisted suspension systems may improve mobility in patients with higher MCFLs more than it does in patients with lower MCFLs.

Balance and Fall Risk

There are three sensory inputs that contribute to balance: visual, vestibular, and proprioceptive. When one of these input channels is compromised, balance consequently is compromised. Proprioception, or spatial awareness of one's body, is achieved through sensory organs in the muscles, joints, and skin. Proprioception of the leg is absent on the amputated side of individuals with TTA, resulting in a compromised balance strategy. Compensatory strategies, such as increased sound limb loading are adopted (Isakov et al., 1992; Kanade et al., 2008; Mayer et al., 2011; Nadollek et al., 2002; Quai et al., 2005). Despite compensations, reduced proprioceptive input in individuals with lower limb amputation contributes to a greater fall risk than individuals without amputation (Bigelow & Berme, 2011; Buckley et al., 2002; Hlavackova et al., 2011; Quai et al., 2005). Therefore, understanding the balance of amputees is imperative to developing therapy or exercises that address increased fall risk.

Dynamic Balance. Dynamic balance assessment is often used in stability assessment. Limits of stability (LOS) is a commonly used dynamic balance assessment and involves leaning in anteroposterior (AP) and mediolateral (ML) directions to the point just before loss of balance. Although accurate with some populations, it appears that LOS is population specific and is not

able to distinguish fallers from non-fallers with TTA (Barnett et al., 2018; Melzer et al., 2004). Similarly, the Motor Control Test (MCT) and Sensory Organization Test (SOT) were not able to identify fallers with TTA from non-fallers with TTA (Vanicek et al., 2009).

The use of other dynamic balance assessments as fall risk prediction tools have been determined valid across a wider range of populations (Dite et al., 2007; Major et al., 2013). The Berg Balance Scale (BBS), Timed Up and Go (TUG) test, 180° turn test, and the Four Square Step Test (FSST) have demonstrated high interrater reliability and the ability to predict falls in individuals with TTA (Cardoso et al., 2019; Dite et al., 2007; Major et al., 2013). Specific scores achieved on TUG, 180° turn test, FSST, and LCI may even be able to predict the likelihood of falls (Dite et al., 2007). However, these results were obtained on new prosthesis users that were within six months of discharge from inpatient rehabilitation and may not be representative of individuals who do not receive rehabilitation or who are more experienced prosthesis users.

The FSST is a timed test requiring the patient to step through four squares on the ground in a clockwise direction, then step backwards in a counterclockwise direction. Lower FSST times indicate reduced fall risk (Dite et al., 2007). The time it takes to complete the FSST is significantly reduced in MFCL-2 patients using VASS over other suspension systems (17.41 ± 4.22 s and 20.58 ± 5.02 s, respectively; $P = 0.046$), suggesting reduced fall risk resulting from VASS use (Samitier et al., 2016).

Improvements in the TUG test are also observed in patients using VASS (Samitier et al., 2016). The TUG test measures the ability to ambulate, transfer, and turn. The test requires the patient to stand from a seated position, walk 3 m, turn around, walk back to the chair, and return to a seated position (Dite et al., 2007). The MFCL-3 participants completed TUG with an average of 13.73 s without VASS and 10.68 s with VASS ($P = 0.011$) (Samitier et al., 2016). A

small, non-significant improvement was also observed in MFCL-2 TUG time with the use of VASS.

The BBS evaluates balance with 14 separate scale items. Scores vary between 0 and 56, with lower scores reflecting a reduced ability to balance (Berg et al., 1992). The BBS scores are significantly greater with VASS than without VASS in MFCL-3 patients (50.1 ± 3.9 and 50.1 ± 3.9, respectively; $P = 0.028$) (Samitier et al., 2016), indicating a greater ability to balance with VASS use.

Perception of Balance. Regardless of activity level, VASS has demonstrated the ability to improve balance confidence (Ferraro, 2011). The Activity Balance Confidence (ABC) scale measures stability during everyday activities and the probability of future falls. The ABC scale scores for individuals with TTA are significantly better when using VASS over PIN, and fewer falls have also been reported as a result of VASS use (Ferraro, 2011). The ABC scale scores and number of falls have a negative linear relationship, whereas when ABC scores increase, the number of falls decreases. This suggests that fear of falling may contribute to a greater fall risk. Reduced number of falls with VASS may be related to a better socket fit and reduced pistoning. The above results from dynamic balance assessment suggest improved balance and reduced fall risk in MCFL-2 and MCFL-3 patients using VASS. Considering the reliability, validity, and ease of administering certain dynamic balance tests, they may be useful clinical tools in assessing fall risk, especially in addition to static stability tests performed on force plates.

Center of Pressure and Center of Pressure Derivatives

In order to assess balance and how balance relates to fall risk, postural stability of quiet double leg stance is also assessed. Postural stability, commonly referred to as balance, is the ability to maintain one's center of mass (COM) over its base of support (Shumway-Cook et al.,

1988). A sign of instability is when COM movement, or sway, extends beyond the base of support. Instability is directly related to fall risk, especially in at-risk populations such as lower limb amputees, the elderly, and patients suffering from musculoskeletal disorders (Bigelow & Berme, 2011; Melzer et al., 2004; Muir et al., 2013; Prieto et al., 1996). Instability is often assessed by measuring COP behavior during quiet standing (Bigelow & Berme, 2011; Buckley et al., 2002; Hermodsson et al., 1994; Isakov et al., 1992; Jayakaren et al., 2015; Kanade et al., 2008; Koceja et al., 1999; Mayer et al., 2011; McGraw et al., 2000; Melzer et al., 2004; Nadollek et al., 2002; Prieto et al., 1996; Quai et al., 2005).

Center of pressure and derivatives of COP are the most frequently used dependent variables in postural stability research. Center of pressure is defined as the center of distribution of the total force applied to a force plate (Palmieri et al., 2002). While there is no universally adopted standard methodology, COP measures have been accepted as a valid tool for predicting fall risk in aging populations (Bigelow & Berme, 2011; Maki et al., 1994; Melzer et al., 2004; Muir et al., 2013; Prieto et al., 1996). Common dependent variables include mean distance, velocity of sway, frequency of sway, 95% confidence ellipse (CE), amplitude, excursion, and root mean squared (RMS) distance. Mean distance and velocity are time domain distance measures. Mean distance represents the average distance from the mean COP. Mean velocity is a measure of the average COP velocity. Mean frequency is the rotational frequency (Hz) of the COP if it had traveled the total excursions around a circle with a radius of the mean distance. Ninety-five percent CE area is expected to enclose approximately 95% of the points on the COP path (Prieto et al., 1996). Maximum amplitude is the maximum absolute displacement of the COP from its mean (Palmieri et al., 2002). Mean amplitude, considered to be a more representative measure of postural control, is the average value over all data points collected in a

trial (Palmieri et al., 2002). Total excursion is the length of the COP path and is often broken down into the AP and ML directions (Prieto et al., 1996). Previous research has established good test-retest reliability and an absence of systematic errors of COP based measures for postural stability (Moghadam et al., 2011; Qiu & Xiong, 2015; Swanenburg et al., 2008). Standard deviation (SD) of amplitude and velocity, mean velocity, and 95% CE area have been proven to have moderate to very high test-retest reliability (Moghadam et al., 2011).

Older Populations

Based on differences in COP behavior, research has been able to distinguish elderly fallers from non-fallers (Bigelow & Berme, 2011; Maki et al., 1994; Melzer et al., 2004; Muir et al., 2013; Prieto et al., 1996). Bigelow & Berme, (2011) were able to distinguish between recurrent fallers and non-recurrent fallers by evaluating COP. Due to high associations between postural instability measured by COP and fall history, COP assessment may have the ability to predict future falls in elderly populations.

Clear patterns of COP behavior in elderly individuals with an increased fall risk have been identified (Koceja et al., 1999; Melzer et al., 2004; Merlo et al., 2012; Muir et al., 2013; Prieto et al., 1996). Increased AP and ML COP displacements and greater sway velocity generally characterize postural stability of elderly fallers (Koceja et al., 1999; Melzer et al., 2004; Muir et al., 2013). However, the methodology used to measure postural stability is inconsistent and varies between individual experiments. In order to better understand postural stability patterns of elderly individuals, the following findings are organized according to major methodological differences.

Stance. Elderly COP behavior varies significantly when stance is controlled and when stance is self-selected (Bigelow & Berme, 2011; Koceja et al., 1999; Maki et al., 1994; Melzer et

al., 2004; Muir et al., 2013). When a self-selected stance is used, fallers experience a greater amplitude in COP displacement in both AP and ML directions, as well as increased ML sway velocity in contrast with non-fallers (Bigelow & Berme, 2011; Maki et al., 1994). When stance is constrained to hip width, elderly fallers demonstrate greater COP displacement, maximum RMS, and COP velocity than elderly non-fallers (Koceja et al., 1999; Muir et al., 2013). Melzer and colleagues (2004) observed no differences in postural sway between fallers and non-fallers when using a wide stance, suggesting differences in measures of postural stability are not detectable in wide stances between groups. Existing postural sway deviations of elderly fallers are amplified, and additional deviations are present when stance is controlled at hip width than when stance is self-selected.

Eyes Closed. Fall risk evaluation often includes examining postural stability with removed visual stimulus (Bigelow & Berme, 2011; Hermodsson et al., 1994; Jayakaren et al., 2015; Koceja et al., 1999; Maki et al., 1994; Melzer et al., 2004; Merlo et al., 2012; Nadollek et al., 2002; Prieto et al., 1996). Removing visual stimulus alters postural stability in young healthy adults, elderly fallers, and elderly non-fallers (Bigelow & Berme, 2011; Koceja et al., 1999; Maki et al., 1994; Melzer et al., 2004; Prieto et al., 1996). In contrast with non-fallers, fallers experience greater COP total excursion, AP and ML excursion, COP velocity (especially in the ML direction), elliptical area, and mean frequency with their eyes closed (Bigelow & Berme, 2011; Melzer et al., 2004). When vision is removed, increased sway in fallers is largely a result of increased AP sway. Fallers also experience greater COP excursion with eyes open; however, it is a result of increased ML sway (Koceja et al., 1999). The differences observed between fallers and non-fallers when visual stimulus is removed suggests visual manipulation is a useful fall risk evaluation tool.

Compliant Surface. The use of compliant surfaces is often used as a postural stability assessment tool (Melzer et al., 2004; Merlo et al., 2012; Son, 2016). Compliant surfaces increase the level of task difficulty by creating an unstable standing surface. Through use of a compliant surface, Melzer et al. (2004) was able to distinguish between elderly fallers and non-fallers. Fallers experienced a greater elliptical area and ML sway than non-fallers. Fallers also had a significantly greater 95% CE area, AP and ML RMS, and mean ML velocity than non-fallers when standing on a compliant surface (Merlo et al., 2012). The use of compliant surfaces mimics real-life unstable standing surfaces. If used in conjunction with the removal of vision, compliant surfaces may be better able to distinguish fallers from non-fallers and, thus, predict fall risk based on postural stability. Additionally, considering it is possible to identify specific COP patterns that predict falls in elderly populations, we may be able to identify future fallers in other at-risk populations who experience similar patterns of instability.

Other at-Risk Populations

Obesity. Fallers of advanced age do not exclusively exhibit unstable COP behavior. Children and young adults who are obese experience some similar patterns of instability (McGraw et al., 2000; Son, 2016). McGraw et al. (2000) observed reduced stability in prepubertal boys indicated by increased ML excursions. When visual stimulus was removed, significantly greater maximum COP displacement and RMS were observed in the same group of obese boys. Non-obese boys in the same experiment did not show reduced instability when visual stimulus was removed, suggesting stability of obese children is more influenced by challenges to the visual system. Son (2016) observed similar results in obese young adults. Sway distance on both the firm and compliant surfaces was greater with eyes closed in the obese group in comparison with non-obese individuals. Considering the similarities in COP characteristics in

elderly and obese youth, postural stability assessment may be a useful tool in assessing fall risk of obese populations.

Transtibial Amputation. Like elderly fallers and obese populations, persons with TTA experience increased ML COP excursion (Buckley et al., 2002; Mayer et al., 2011). Interestingly, this is observed in young, highly active adults more than it is in older, less active TTAs (Buckley et al., 2002). The fewer years of prosthesis experience may contribute to the unique COP behavior of young amputees (Mayer et al., 2011). Mayer et al. (2011) observed an increased ML excursion in first-time prosthesis users compared to able bodied controls that was not observed in skilled prosthetic users with more years of experience. Unfortunately, research examining postural stability in young, active adults with TTA is extremely limited.

Excess AP excursion is more commonly observed in individuals with TTA (Jayakaren et al., 2015; Kanade et al., 2008; Nadollek et al., 2002; Quai et al., 2005). When examining interlimb differences, the sound limb appears to be primarily responsible for the increase in AP COP excursion (Jayakaren et al., 2015; Nadollek et al., 2002; Quai et al., 2005). This may be related to the increased load distribution and perhaps a compensatory method for reduced proprioception on the amputated side. Considering increased AP excursion is also experienced by elderly fallers with their eyes closed, the same trend in TTAs may be related to compromised proprioception. Research investigating interlimb differences in postural stability of TTAs is sparse.

Center of pressure velocity is closely related to instability and fall risk in individuals with lower limb amputation (Hlavackova et al., 2011; Jayakaren et al., 2015). Jayakaren et al. (2015) has found an increased AP mean velocity in individuals with TTA in comparison with able bodied individuals. The interlimb velocity differences are consistent with AP excursion in that

they are both greater in the sound limb than the prosthetic limb. Individuals with transfemoral amputation (TFA) also experience a greater COP velocity on the sound side than the amputated side; unfortunately, the direction of velocity was not reported (Hlavackova et al., 2011).

Time to Boundary

While the aforementioned COP measures are commonly used to analyze postural stability, they do not provide a complete understanding of postural stability (Hertel & Olmsted-Kramer, 2007; Hertel et al., 2006; Linens et al., 2014; Pope et al., 2011; Slobounov et al., 1998; van Wegen et al., 2001, 2002). Time to boundary (TTB) provides insight into the spatiotemporal characteristics of postural stability while using the velocity and the placement on the foot where excursions occur (Hertel et al., 2006). Time to boundary can detect differences in postural stability of single and double leg stance that traditional COP measures cannot (Hertel & Olmsted-Kramer, 2007: Hertel et al., 2006; van Wegen et al., 2001, 2002). Additionally, TTB has been able to detect increased instability in aging populations, as well as populations with postural deficiencies such as Parkinson's Disease and chronic ankle instability (Linens et al., 2014; Pope et al., 2011; Slobounov et al., 1998; van Wegen et al., 2001, 2002). Time to boundary may be an especially important tool in detecting instability in the ML directions (Hertel & Olmsted-Kramer, 2007; Linens et al., 2014, van Wegen et al., 2001, 2002). This is especially important in identifying those with an increased risk of falling (Maki et al., 1994). Currently, no research has been performed analyzing TTB of TTA postural stability.

Interlimb Differences

A commonly observed interlimb difference in individuals with TTA is increased loading of the sound limb (Isakov et al., 1992; Kanade et al., 2008; Lord & Smith, 1984; Mayer et al., 2011; Nadollek et al., 2002; Quai et al., 2005). This is most likely a strategy adopted to increase

stability through proprioception and provide a sense of confidence in balancing. Previous research has demonstrated greater sound limb loading as a result of pain, number of medications used, and poor hip abductor strength on the amputated side (Nadollek et al., 2002). These results indicate a need for reforming physical/occupational therapy and considering comorbidities beyond those which affect balance when performing postural stability analyses. Fortunately, limb loading asymmetry can decrease over time. Mayer et al. (2011) found more symmetrical interlimb loading in TTAs with more years of experience wearing a prosthesis in comparison with first-time prosthesis users. However, interlimb weight bearing differences still exist and may contribute to reduced balance and confidence using the prosthesis.

Issues with Current Suspension Technology

Pistoning

Compromised balance and mobility are not the only issues individuals with TTA face. Pistoning, or distraction of the prosthesis from the residual limb during activity, is a commonly reported problem associated with TTA prostheses (Eshraghi et al., 2014; Ferraro, 2011; Gholizadeh et al., 2014; Klute et al., 2011; Samitier et al., 2016). Complications associated with pistoning include blisters, redness, sounds with ambulation, and pain (Ferraro, 2011; Gholizadeh et al., 2014). Pistoning occurs when either the socket is too large or the suspension system is not properly functioning. Compared to VASS, PIN results in a greater occurrence of pistoning (Ferraro, 2011; Klute et al., 2011; Samitier et al., 2016).

Volume Change

Pistoning is also associated with daily residual limb volume loss (Ferraro, 2011) which contributes to poor socket fit (Board et al., 2001; Gerschutz et al., 2010; Goswami et al., 2003). To combat volume loss, PIN users add ply to the residual limb (Beil et al., 2002; Board et al.,

2001; Gerschutz et al., 2010). Adding ply requires doffing of the prosthesis and can be inconvenient, especially if needed multiple times per day (Gerschutz et al., 2010). Volume loss occurs more commonly with PIN than VASS suspension (Ferraro, 2011). The VASS has demonstrated unique interface pressure patterns that may be responsible for reducing volume loss (Beil et al., 2002). During stance, VASS produces lower pressure impulses and average peak pressure. During swing phase, VASS average and peak negative pressures are higher (Beil et al., 2002). Reduced pressure during stance may minimize the amount of interstitial fluid being pushed out of the soft tissue, and greater negative pressure during swing may increase the amount of fluid being drawn back in. This pressure pattern may be responsible for limiting volume loss throughout the day.

Vacuum Assisted Suspension System

Benefits

In addition to maintenance of residual limb volume (Ferraro, 2011; Gerschutz et al., 2010; Goswami et al., 2003), VASS has demonstrated the ability to improve residual limb skin profusion in treadmill walking compared to PIN suspension (Rink et al., 2016). Improved wound healing has also been observed as a result of VASS use (Gerschutz et al., 2010). Maintenance of limb volume and improved profusion contribute to a reduced occurrence of pain, discomfort, blisters, and redness (Ferraro, 2011; Goswami et al., 2003). The VASS produces an overall healthier residual limb than PIN suspension.

Issues

Although VASS mitigates complications due to pistoning and volume changes, there are flaws associated with the VASS system. Patients often prefer PIN suspension over other suspension methods because donning and doffing can be performed without the removal of long

pants (Gholizadeh et al., 2014). Vacuum assisted suspension systems also present issues such as added weight from the electrical or mechanical vacuum pump, leaks in the system which could lead to limb volume fluctuations and ultimately, poor socket fit (Komolafe et al., 2013). Complications with donning and doffing, pistoning, residual limb volume fluctuation, and design can negatively influence the number of hours of daily prosthetic use and physical activity (Ferraro, 2011; Samitier et al., 2016).

Transtibial Amputation
Comorbidities

Individuals with TTA spend less time being physically active than other people (Pepin et al., 2018). Those who do maintain active lifestyles are faced with an elevated risk of musculoskeletal overuse injuries of the lumbar spine, upper limb, and lower limb (Farrokhi et al., 2018). Risks of physical inactivity include loss of strength, flexibility, and bone density (McGraw et al., 2000) as well as weight gain and metabolic disease (Kurdibaylo, 1996). To improve the quality of life of amputees, attempts to innovate prosthetic technology are being made.

SmartPuck™

The SmartPuck™ is a newly developed elevated vacuum suspension system. The PUCK is unlike traditional vacuum systems in that it is housed within the distal end of the socket, and vacuum levels are controlled with a smartphone. Housing the PUCK internally to the socket helps to address one flaw in current vacuums: loss of pressure. Superior control of pressure may contribute to enhanced proprioception of the residual limb and lead to improvements in postural stability.

To date, no research has been performed evaluating PUCK and the effects PUCK has on postural stability. Therefore, the purpose of the present study was to examine postural stability of individuals with TTA using two suspension systems: PUCK and PIN. We hypothesized that:

H0 There would be no differences in COP displacements, velocities, frequencies, or time to boundary between PUCK and PIN under multiple surface and vision conditions.

H1 Stability would decrease as surfaces changed from rigid to compliant and visual input was removed.

CHAPTER III

METHODOLOGY

Purpose

The purpose of the present study was to examine the postural stability of individuals with unilateral TTA using two suspension systems: PUCK and PIN.

Participants

Institutional review board approval was obtained prior to any participant interaction (Appendix C). Seven individuals with TTA (97 ± 18.59 kg, 1.78 ± 0.09 m; 52.86 ± 11.48 years, K3 - K4) participated in this study. Participants were recruited through prosthetists in the northern Colorado area. Inclusion criteria included: (a) 18 to 65 years of age; (b) amputation resulting from trauma, bone cancer, or birth defect; (c) currently wearing a PIN or PUCK suspension system; (d) at least 6 months of experience in their current prosthesis; (e) healthy residual limb; (f) no neurological, cardiac, or vascular problems that limit function; (g) no diagnosis of health conditions that affect muscle function; (h) body mass index under 35 $kg \cdot (m^2)$; and (i) able to walk continuously for 10 minutes without assistance. Additionally, participants needed to be classified as K3 or K4 ambulators. K classification, developed by the American and Orthotic and Prosthetic Organization, describes functional levels of prosthetic users (Health Care Financing Administration [HCFA], 2001). Amputees classified as K3 are able to ambulate with their prosthesis at variable speeds and traverse most environmental barriers. K3 ambulators are capable of prosthetic use beyond simple locomotion. K4 ambulators are capable of prosthetic

ambulation that exceeds basic skills. K4 ambulators are typically children, active adults, or athletes (HCFA, 2001).

Data Collection

Two visits occurred in a random order with participants wearing PUCK or PIN suspension systems. Participants were randomly assigned to either their original suspension system or to the alternative suspension system and were fitted by certified prosthetists. Before each visit, participants had at least one-week accommodation time for each suspension system. Data collections were performed in the Biomechanics Laboratory of the University of Northern Colorado. The present study obtained approval by the Institutional Review Board at the University of Northern Colorado. Upon arrival to the Biomechanics Laboratory and prior to data collection, participants provided their written and verbal consent.

Thirty-seven 14mm retroreflective markers were placed over anatomical landmarks on the body, along with 6 lower extremity marker clusters and 4 upper extremity clusters using Coban™ and hypoallergenic tape. Posterior, anterior, and lateral views of marker placement can be found in Appendix A. Marker clusters were placed bilaterally on the laces of the shoes, and laterally on the: shank, thigh, forearm, and arm. Sixteen markers were removed upon completion of calibration as these markers were only used to identify joint axis orientation. A 10-camera motion capture system (VICON, Oxford, UK) was used to collect motion data at 100 Hz.

Participants stood shod with a self-selected stance, with each foot positioned on a separate force plate (AMTI, Watertown, MA). Force plates were embedded in the ground and a part of a tandem belt treadmill. Foot location was measured to ensure similar placement between trials/visits. A tape measure was used to find the distance from the most lateral, medial, anterior,

and posterior aspects of the participant's foot to the four edges of each force plate. For each trial, COP and vertical GRF (1000 Hz) were collected.

Prior to testing, participants were instructed to maintain their gaze at a fixed point on the wall in front of them at approximately eye level. Participants were instructed to begin with arms abducted in a "T" position, upon verbal cue lower their arms to their sides, stand as still as possible, and raise their arms back to the "T" position. Participants maintained a quiet standing position for 30 s for four separate conditions: (a) RSEO; (b) RSEC; (c) CSEO; and (d) CSEC. The compliant surface consisted of two viscoelastic mats placed on each force plate. Once the compliant surface was placed, both force plates were zeroed. Each foot was then placed back on to the force plates according to the previously recorded location. One trial was recorded for each condition.

Data Analysis

The middle 20 s of each trial were analyzed to avoid artifact resulting from arm movement. Kinetic data were filtered using a fourth order, zero lag, low pass filter (F_c= 5Hz). Basic dependent variables were calculated according to methods described by Prieto et al. (1996). Dependent variables included mean vertical GRF (normalized to body weight), mean velocity, mean velocities in the AP (X) and ML (Y) directions, 95% CE area, sway area, mean frequency of total COP excursion, mean frequency of AP, mean frequency of ML, and fractal dimensions for CE. Vertical GRF was expressed as a percentage of body weight (% BWT) supported by each limb.

Time to boundary was calculated according to methods by Hertel et al. (2006). Time to boundary is an estimate of the time it would take for COP to reach the edge of the foot if it were to continue in the same direction and at the same velocity (Hertel et al., 2006). Each foot was

modeled as a rectangle using the measurements taken for consistent foot placement. The instantaneous ML and AP COP positions (ML_i, AP_i) and velocity for each COP data point were calculated. (Eq. 1) shows how TTB was calculated in the ML direction.

$$V_{COPML1} = d_{COPML1}/Time$$

$$TTB_{ML1} = d_{MLbound1}/V_{COPM1} \quad (1)$$

The distance between COP ML_i and the medial border of the foot was calculated. This distance was then divided by the corresponding velocity of COP ML_i to calculate TTB (Hertel et al., 2006). Prior to calculations, COP data were filtered using a fourth order, lowpass Butterworth digital filter ($F_c = 5Hz$), and COP velocities were calculated using Visual3D (C-motion, Germantown, MD). Outcome measures were calculated for each limb under each condition.

Statistical Analysis

Repeated measures MANOVA was used to identify significant differences in postural stability between PUCK and PIN suspension systems. The alpha level was set at 0.05 and was used to determine any significant effects of suspension system on the dependent variables that represent balance. Effect sizes (Cohen's d) were used to determine the magnitude of experimental effect. Effect sizes are considered large when they are greater than or equal to 0.8, moderate when they equal to 0.5, and small when they are equal to or less than 0.2.

CHAPTER IV

RESULTS

Participants

Seven individuals participated in the present study (Table 1). Five of the participants were able to complete data collection using both suspension systems. Two participants were not able to come in for both data collections due to scheduling difficulties and difficulties with the PUCK system. For this reason, there was a different number of participants for PIN and PUCK suspensions (n = 5 and n = 7, respectively). One participant completed data collection sessions for both suspensions but was unable to execute the CSEC condition with either suspension system (n = 4 PIN, n = 6 PUCK). A repeated measures MANOVA with an alpha level of 0.05 was used to determine statistical significance in postural stability between suspension systems. Due to the small sample size, effect sizes (Cohen's d) were used to determine the magnitude of the experimental effect.

Table 1

Participant Information

N	Age (y)	Height (m)	Mass (kg)	Time Since Amp (y)	Cause of Amputation
1	55.00	1.70	73.1	28.00	traumatic
2	65.00	1.84	101.9	44.00	traumatic
3	62.00	1.64	83.5	50.00	traumatic
4	64.00	1.78	98.2	6.00	traumatic
5*	46.00	1.82	89.5	6.00	bacterial infection
6*	39.00	1.81	100.8	12.00	traumatic
7[†]	39.00	1.94	132	21.00	traumatic
Mean	52.86	1.79	97	23.86	

* Participant did not complete the PIN trial.
[†] Participant did not complete the CSEC condition.

Table 2

Time to Boundary

Surface	Suspension System	Mean (s)	Absolute Minimum (s)
Rigid surface eyes open	PIN Amp	0.596 ± 0.121	0.276 ± 0.037
	PIN Int	0.536 ± 0.180	0.245 ± 0.046
	PUCK Amp	0.792 ± 0.414	0.337 ± 0.204
	PUCK Int	0.654 ± 0.340	0.318 ± 0.127
Rigid surface eyes closed	PIN Amp	0.581 ± 0.108	0.264 ± 0.050
	PIN Int	0.479 ± 0.131	0.244 ± 0.057
	PUCK Amp	0.769 ± 0.347	0.330 ± 0.155
	PUCK Int	0.602 ± 0.225	0.293 ± 0.096
Compliant surface eyes open	PIN Amp	0.461 ± 0.186	0.207 ± 0.081
	PIN Int	0.415 ± 0.078	0.243 ± 0.029
	PUCK Amp	0.839 ± 0.446	0.418 ± 0.253
	PUCK Int	0.664 ± 0.333	0.297 ± 0.097
Compliant surface eyes closed	PIN Amp	0.424 ± 0.180	0.194 ± 0.072
	PIN Int	0.396 ± 0.073	0.240 ± 0.043
	PUCK Amp	0.689 ± 0.410	0.218 ± 0.159
	PUCK Int	0.492 ± 0.232	0.199 ± 0.129

Note. Time to Boundary measures the time required for the COP to reach the boundary of the base of support if it were to continue at its instantaneous direction and velocity. Time to boundary examines COP excursions in any direction and is not limited to either the AP or ML planes. Mean ± SD, no significant differences were found. Int = intact limb; Amp = amputated limb.

Table 3

Mean Center of Pressure Velocities and Percent Body Weight

Surface	Suspension System	Mean Resultant Velocity (mm/s)	Mean AP Velocity (mm/s)	Mean ML Velocity (mm/s)	%BWT (%)
Rigid surface	PIN Amp	$12.57 \pm 5.02^{\dagger\dagger}$	$8.15 \pm 5.18^{\dagger\dagger}$	7.64 ± 1.94	52.39 ± 3.78
eyes open	PIN Int	$30.28 \pm 7.97^{*}$	$25.38 \pm 9.76^{*}$	11.49 ± 3.18	48.12 ± 3.75
	PUCK Amp	$11.28 \pm 6.26^{**}$	$6.23 \pm 2.62^{**}$	7.87 ± 5.64	50.94 ± 4.13
	PUCK Int	$32.28 \pm 13.48^{\dagger}$	$28.80 \pm 14.34^{\dagger}$	9.35 ± 5.15	48.94 ± 3.81
Rigid surface	PIN Amp	$15.17 \pm 6.53^{\dagger\dagger}$	$10.75 \pm 7.43^{\dagger\dagger}$	7.88 ± 2.09	51.84 ± 3.01
eyes	PIN Int	$45.78 \pm 14.82^{*}$	$41.87 \pm 16.56^{*}$	12.75 ± 4.81	48.67 ± 2.87
closed	PUCK Amp	$13.43 \pm 6.69^{**}$	$9.33 \pm 5.48^{**}$	7.24 ± 4.98	50.52 ± 4.57
	PUCK Int	$50.91 \pm 32.46^{\dagger}$	$48.55 \pm 32.67^{\dagger}$	10.12 ± 5.81	49.38 ± 4.36
Compliant	PIN Amp	$22.72 \pm 14.94^{**}$	$13.28 \pm 6.26^{\dagger\dagger}$	15.23 ± 12.32	$47.95 \pm 3.02^{\dagger\dagger}$
surface	PIN Int	$36.24 \pm 9.03^{*}$	$30.79 \pm 8.4^{*}$	13.50 ± 5.05	$52.53 \pm 2.76^{*}$
eyes open	PUCK Amp	$14.27 \pm 7.54^{**}$	$9.66 \pm 4.89^{**}$	7.89 ± 6.93	49.54 ± 1.36
	PUCK Int	42.45 ± 23.04	$39.50 \pm 23.12^{\dagger}$	10.11 ± 5.09	$50.74 \pm 1.31^{\dagger}$
Compliant	PIN Amp	27.04 ± 17.44	$15.51 \pm 6.18^{**}$	18.47 ± 15.54	$47.30 \pm 2.96^{\dagger\dagger}$
surface	PIN Int	49.76 ± 15.01	44.00 ± 15.50	15.80 ± 6.52	$53.21 \pm 2.54^{*}$
eyes	PUCK Amp	34.30 ± 22.20	$27.81 \pm 22.36^{**}$	14.17 ± 10.48	$45.81 \pm 3.37^{**}$
closed	PUCK Int	92.70 ± 67.44	88.68 ± 67.56	17.53 ± 8.51	$52.10 \pm 4.27^{\dagger}$

Note. Mean Resultant Velocity is the sum velocities in all directions. Mean AP and ML Velocities are the average velocities of COP movement in the AP and ML directions (respectively) throughout the trial. %BWT is the percent body weight applied to each limb. Mean ± SD.

*Indicates statistically significant difference from PUCK Amp; ** from PUCK Int; † from PIN Amp; †† from PIN Int ($p < 0.05$). Int = intact limb; Amp = amputated limb; ML = Mediolateral; AP = Anteroposterior; %BWT = percent of body weight.

Table 4

Mean 95% Confidence Ellipse Area, Sway Area, Frequencies, and Fractal Dimensions for CE 95%

Surface	Suspension System	95% CE Area (mm^2)	Sway Area (mm^2/s)	Mean Resultant Freq (Hz)	Mean AP Freq (Hz)	Mean ML Freq (Hz)	FD for CE
RSEO	PIN Amp	153.43 ± 288.60	15.62 ± 20.51	0.79 ± 0.38	0.55 ± 0.30	2.62 ± 1.29	1.66 ± 0.20
	PIN Int	300.32 ± 333.47	36.73 ± 18.97	0.80 ± 0.33	0.76 ± 0.36	2.03 ± 1.09	1.73 ± 0.19
	PUCK Amp	41.65 ± 37.15	9.51 ± 8.91	0.84 ± 0.55	0.60 ± 0.32	2.25 ± 1.12	1.64 ± 0.16
	PUCK Int	233.75 ± 149.25	34.03 ± 30.60	0.77 ± 0.30	0.76 ± 0.26	1.65 ± 1.09	1.75 ± 0.22
RSEC	PIN Amp	125.12 ± 136.76	16.13 ± 11.12††	0.73 ± 0.35	0.82 ± 0.67	2.75 ± 1.42	1.61 ± 0.14
	PIN Int	537.93 ± 624.04	62.37 ± 27.49*	0.71 ± 0.17	1.35 ± 0.77	2.24 ± 1.22	1.75 ± 0.11
	PUCK Amp	50.66 ± 36.32	9.89 ± 7.03**	0.82 ± 0.30	0.92 ± 0.72	2.11 ± 0.89	1.66 ± 0.12
	PUCK Int	471.79 ± 427.67	47.44 ± 39.07†	0.76 ± 0.20	1.27 ± 0.65	1.69 ± 0.65	1.78 ± 0.16
CSEO	PIN Amp	157.65 ± 160.05††	42.27 ± 50.74	0.71 ± .023	0.51 ± 0.14	2.48 ± 0.70	1.65 ± 0.10
	PIN Int	522.28 ± 166.70*	64.81 ± 28.54	0.55 ± 0.09	0.52 ± 0.07	1.31 ± 0.47	1.59 ± 0.06
	PUCK Amp	75.64 ± 74.65**	13.99 ± 12.02	0.71 ± 0.47	0.53 ± 0.19	1.98 ± 1.07	1.63 ± 0.16
	PUCK Int	451.80 ± 292.37†	49.78 ± 31.49	0.67 ± 0.24	0.69 ± 0.25	1.48 ± 0.73	1.72 ± 0.17
CSEC	PIN Amp	228.92 ± 165.62	53.20 ± 48.79	0.78 ± 0.34	0.56 ± 0.20	2.37 ± 0.69	1.65 ± 0.12
	PIN Int	945.34 ± 509.55	112.03 ± 84.02	0.59 ± 0.18	0.60 ± 0.24	1.27 ± 0.19	1.62 ± 0.13
	PUCK Amp	18694.95 ± 45445.49^	67.98 ± 96.97	0.81 ± 0.40	0.73 ± 0.40	1.54 ± 0.84	1.65 ± 0.34
	PUCK Int	14805.38 ± 34644.03^	244.89 ± 331.81	0.87 ± 0.49	0.95 ± 0.54	1.53 ± 0.88	1.81 ± 0.38

Note. Confidence Ellipse Area is expected to enclose 95% of the points on the COP path. Sway Area estimates the area enclosed by the COP per unit time. Frequency (Freq) is the rotational frequency (Hz) of the COP if it had traveled the total excursions around a circle with a radius of the mean distance. Mean AP and ML Frequency are the frequencies of a sinusoidal oscillation with an average value of the mean AP or ML distance and the total AP or ML COP path length. Fractal Dimensions for Confidence Ellipse (FD for CE) is based on the 95% CE Area and measures the degree to which a curve fills the metric space which it encompasses and the degree of irregularity of planar curves composed of connected line segments (Prieto et al., 1996). Mean ± SD.

*Indicates statistically significant difference from PUCK Amp;** from PUCK Int; † from PIN Amp; †† from PIN Int ($p < 0.05$). Int = intact limb; Amp = amputated limb; RSEO = rigid surface eyes open; RSEC = rigid surface eyes closed; CSEO = compliant surface eyes open; CSEC = compliant surface eyes closed. ^ indicates a skewed mean by one participant who experienced extreme values.

Rigid Surface Eyes Open

No statistically significant differences in mean VGRF, mean ML velocity, 95% CE area, sway area, mean resultant frequency, mean AP frequency, mean ML frequency, fractal dimensions for CE, %BWT, mean TTB, or absolute minimum of TTB between suspension systems were detected in the RSEO condition. Additionally, no significant differences were found in the amputated limb between PUCK and PIN suspensions. Although not significantly different, the effect size shows suspension had a moderate effect (effect size 0.54) on amputated limb 95% CE area and mean TTB (effect size 0.64); PIN suspension resulting in a greater 95% CE area and reduced mean TTB. Similarly, the suspension system had a moderate effect (effect size 0.50) on ML velocity and absolute minimum TTB of the intact limb. These effect sizes suggest significant differences may be observed between suspension systems with an increased sample size.

As expected, differences between the amputated and intact limbs were observed. Statistically significant differences were observed between amputated and intact limbs in mean resultant velocity and mean AP velocity. Mean resultant and AP velocities were significantly higher in the intact limb for both the PUCK and PIN suspensions (Table 3).

Rigid Surface Eyes Closed

No statistically significant differences in the RSEC condition were detected between suspension systems in mean VGRF, mean ML velocity, 95% CE area, mean resultant frequency, mean AP frequency, mean ML frequency, fractal dimensions for CE, %BWT, mean TTB, or absolute minimum of TTB. Further, no significant differences were observed in the amputated limb between suspension systems. While not significantly different, 95% CE area, sway area, and mean ML frequency of the amputated limb were increased with PIN and produced moderate

effect sizes (0.74, 0.67, and 0.54, respectively). Mean TTB and absolute minimum TTB were also moderately influenced by suspension system and increased with PUCK (Appendix B). Intact limb mean ML frequency was also moderately affected by suspension. Statistically significant differences were observed between amputated and intact limbs in mean resultant velocity, mean AP velocity, and sway area. Mean resultant velocity (Table 3), mean AP velocity (Table 3), and sway area (Table 4) were significantly higher in the intact limb for both suspension systems.

Compliant Surface Eyes Open

No statistically significant differences in the CSEO condition were observed between suspension systems in mean VGRF, mean ML velocity, sway area, mean resultant frequency, mean AP frequency, mean ML frequency, fractal dimensions for CE, mean TTB, or absolute minimum of TTB. Similar to the RSEO and RSEC conditions, no differences in any postural stability measure were observed in the amputated limb between suspensions. However, the effect sizes (Appendix B) suggest that suspension system has a moderate to large influence on the amputated limb mean resultant, AP, ML velocities, 95% CE area, sway area, mean ML frequency, %BWT, mean TTB, and absolute minimum TTB. Mean resultant, AP, ML velocities, 95% CE area, sway area, and mean ML frequency were all increased with PIN, while %BWT, mean TTB, and absolute minimum TTB were greater with PUCK suspension.

More interlimb differences were found in this condition than any other vision/surface condition. Statistically significant differences were observed between amputated and intact limbs in mean resultant velocity, mean AP velocity, 95% CE area, and %BWT in the CSEO condition. Mean AP velocity (Table 3) and 95% CE area (Table 4) were significantly higher in the intact limb with both PUCK and PIN suspensions. Using the PUCK suspension, mean resultant velocity was significantly higher in the intact limb (42.45 ± 23.04 mm/s) compared to the

amputated limb (14.27 ± 7.54 mm/s). However, there was no significant difference in mean resultant velocity between limbs with PIN suspension. Two very high mean resultant velocity values were present in the PUCK data that may explain the significant interlimb difference.

The %BWT was significantly different between limbs with PIN suspension and not with PUCK. The intact limb (52.53 ± 2.76% BWT) bore significantly more %BWT than the amputated limb (47.95 ± 3.02% BWT) with PIN suspension. With the small sample size, results can be easily swayed one way or another by just one participant. There were two participants using PIN suspension that had a %BWT greater than 1 SD away from the mean favoring the intact leg, and this could explain the significant difference with PIN suspension that was not observed with PUCK. Also, even though there was no significant difference, the effect size for %BWT between limbs with PUCK suspension was large (0.90) and shows a meaningful difference.

Compliant Surface Eyes Closed

Similar to the previous conditions, no statistically significant differences in mean VGRF, mean velocity, mean ML velocity, 95% CE area, sway area, mean resultant frequency, mean AP frequency, mean ML frequency, fractal dimensions for CE, mean TTB, or absolute minimum of TTB were detected. Mean AP velocity and mean TTB were elevated in the amputated limb with PUCK and although the differences were not significant, the effect sizes show that they were largely influenced by suspension system (Appendix B). Similarly, 95% CE area and mean AP frequency were increased with PUCK and moderately influenced by suspension (Appendix B). The moderate effect size found in 95% CE area may be a result of the very extreme values observed in the data of one participant whose balance was disrupted during the trial (Table 4).

Statistically significant differences were observed between amputated and intact limbs in mean AP velocity with PUCK suspension and %BWT for both suspensions. Using both suspensions, the intact limb bore a larger %BWT than the amputated limb (PUCK Int. = 52.10 ± 4.27%; PUCK Amp. = 45.81 ± 3.37%; PIN Int. = 53.21 ± 2.54; PIN Amp. = 47.30 ± 2.96). In the PUCK system, mean AP velocity was significantly higher in the intact limb (88.68 ± 67.56 mm/s) than the amputated limb (27.81 ± 22.36 mm/s). There were no statistically significant differences in mean AP velocity between amputated and intact limbs with PIN suspension.

The difference in mean AP velocity between PUCK intact and amputated limbs may be attributed to two very high values observed in the CSEC condition. The mean AP velocity was 88.68 ± 67.56 mm/s, but there was one participant who had a mean AP velocity that was over 1 SD away from the mean (214.11 mm/s). The observed extreme value could have skewed the results and may not accurately represent the sample as a whole. Considering the small sample size of the present study, we must be careful in how we interpret these significant differences.

Between Conditions

As conditions became more difficult, more interlimb differences were present with both suspensions, except in the CSEC condition. Two statistically significant interlimb differences were observed in the RSEO condition (mean resultant and AP velocities), three statistically significant interlimb differences were observed in the RSEC conditions (mean resultant and AP velocities and sway area), and four statistically significant interlimb differences were observed in the CSEO condition (mean resultant and AP velocities, 95% CE area, and %BWT). Interestingly, only two interlimb differences were present in the CSEC condition (mean AP velocity and %BWT). Similar to instances of interlimb differences, as conditions became increasingly difficult, more moderate and large effect sizes were observed when comparing PUCK and PIN.

The manipulation of vision and the addition of a compliant surface had significant effects on measures of stability. Mean resultant velocity and mean sway area were significantly higher in the CSEC condition than in all other conditions. Mean AP velocity was significantly higher in the CSEC condition than the two normal vision conditions, RSEO and CSEO. Mean ML velocity was greater in the CSEC condition than in the two rigid surface conditions, RSEO and RSEC. Mean AP frequency was greater in the RSEC condition than in all other conditions.

CHAPTER V

DISCUSSION AND CONCLUSIONS

Discussion

The purpose of the present study was to examine the postural stability of individuals with unilateral TTA using two suspension systems: PUCK and PIN. We established the null hypothesis that there would be no differences in COP displacements, velocities, frequencies, body weight distribution, or time to boundary between PUCK and PIN conditions under multiple surface and vision conditions. We hypothesized that stability would decrease as surfaces changed from rigid to compliant and visual input was removed. We do not reject the null hypothesis in some measures. There were no differences in COP displacements, velocities, or frequencies between PUCK and PIN under multiple surface and vision conditions.

However, there were three instances where significant differences were observed between amputated and intact limbs within conditions. During the CSEO condition, there were significant differences in mean resultant velocity, and during the CSEC condition, there were significant differences in mean AP velocity between amputated and intact limbs with PUCK that were not observed with PIN suspension. In contrast, the intact limb bore significantly more %BWT than the amputated limb during the CSEO condition with PIN suspension and not with PUCK suspension. Our hypothesis was partially supported: stability decreased as surfaces changed from rigid to compliant and visual input was removed.

In the present study, mean resultant velocity was significantly higher in the intact limb in the rigid surface conditions with both suspensions. In addition, increased mean resultant velocity

was observed in the intact limb with PUCK suspension in the CSEO condition. No previous research supporting or contradicting these findings was found. The only study examining interlimb differences in resultant velocity in lower limb amputees used participants with TFA (Hlavackova et al., 2011). Hlavackova et al. (2011) also observed greater resultant velocity in the intact leg than the amputated leg. The conditions of the study were different than those of the present study with a 10cm apart parallel foot placement, use of only eyes-closed conditions, and no compliant surface conditions. Despite the methodological differences, reported values were similar to values reported in the present study (Hlavackova et al., 2011). Further research needs to be done to better understand the interlimb differences in mean resultant velocity of individuals with TTA.

Similar to mean resultant velocity, mean AP velocity was significantly greater in the intact limb with both suspension systems in RSEO and RSEC conditions. Increased AP velocity was also observed in the CSEC condition with PIN suspension. Although limited, previous research has found similar results with amputees having increased AP velocity during quiet standing in the sound limb than in healthy controls (Geurts et al., 1992; Jayakaren et al., 2015). Individuals with both traumatic and dysvascular TTA experienced a greater AP velocity in the sound limb with normal vision, standing on a rigid surface than in healthy controls (Jayakaren et al., 2015). The methodology used by Jayakaren et al. (2015) was similar to that of the present study where participants used a self-selected stance and had their arms relaxed by their sides. Geurts et al. (1992) did not allow for self-selected stance, had participants fold their hands behind their backs, and did not use compliant surfaces; however, AP velocities similar to the those in all conditions of the present study were produced.

Examination of interlimb differences of individuals with TTA in standing balance is limited in previous research (Geurts et al., 1992; Hlavackova et al., 2011; Isakov et al., 1992; Jayakaren et al., 2015; Nadollek et al., 2002; Quai et al., 2005; Vrieling et al., 2008). There is little evidence as to why interlimb differences in resultant and AP velocities exist between intact and amputated limbs. Some research suggests that the stiff ankle of the prosthesis limits movement and velocities on the amputated side in static and dynamic balance tasks. This limited movement is most evident in the AP direction (Geurts et al., 1992; Geurts et al.,1991; Jayakaren et al., 2015; Vrieling et al., 2008). During quiet standing, Geurts et al. (1992) found significantly reduced AP COP velocity under the prosthetic foot compared to the intact foot in normal and removed vision conditions and reduced ML COP velocity under the prosthetic foot in removed vision conditions. Jayakaren et al. (2015) also observed reduced AP velocities on the prosthetic side, in addition to reduced AP root mean squared distance (RMSD). During balance perturbation, Vrieling et al. (2008) observed reduced AP COP displacement of the prosthetic side with normal vision and during dual task conditions and stated the reason for this was the prosthetic foot lacks necessary flexibility for normal mobility. Geurts et al. (1991) link limited prosthesis ankle mobility to the loss of ankle strategy which they described as important in maintaining balance by controlling AP sway.

Explanation of the more symmetrical resultant and AP velocities observed in the CSEO and CSEC conditions, respectively, with PIN suspension is unknown. As this was a randomized design, some of the participants used PIN as their daily suspension system. There may be a relationship between how comfortable prosthesis users are with PIN suspension and the more symmetrical velocities; however, the present study attempted to control for this by randomizing which suspension systems the users wore (PIN or PUCK) which may have also changed their

current system. Further, the sample size needs to be considered when attempting to explain differences or lack thereof. It is possible that significant differences were not detected here due to the small sample size allowing for means to be easily skewed by one individual.

It is well established that increases in COP velocity indicate instability leading to increased fall risk in older adults (Bigelow & Berme, 2011; Koceja et al., 1999; Maki et al., 1994; Melzer et al., 2004; Merlo et al., 2012; Muir et al., 2013). Specific to individuals with TTA, increased COP velocity is also associated with instability and increased fall risk (Hlavackova et al., 2011; Jayakaren et al., 2015). Past research also indicates individuals with TTA experience greater instability than older adults without lower limb amputation (Maki et al., 1994; Merlo et al., 2012; Prieto et al., 1996). There is a link between increased AP velocities in older adults and increased fall risk, but there is no link between increased AP velocities in individuals with TTA and increased fall risk (Maki et al., 1994; Merlo et al., 2012). Maki et al. (1994) and Merlo et al. (2012) both reported greater AP velocities in older adults categorized as fallers than those who are not fallers in normal vision, vision deprived, and compliant surface tests. Anterior-posterior velocities reported for fallers in all conditions were similar to those reported in the present study (Maki et al., 1994; Merlo et al., 2012). Future research should be conducted to determine whether a relationship between increased AP velocity of the sound limb is related to instability and increased fall risk in individuals with TTA.

In the present study the intact limb bore a greater %BWT than the amputated limb with PIN suspension in the CSEO condition, but not with PUCK suspension. Additionally, increased %BWT was observed in the intact leg with both suspensions in the CSEC condition. Increased weight bearing asymmetry is correlated with increased COP excursion, especially in the AP plane, in older adults (Blaszczyk et al., 2000). Increased COP excursion is an indicator of

instability, therefore, increased weight bearing asymmetry is likely associated with instability (Bigelow & Berme, 2011; Blaszczyk et al., 2000; Melzer et al., 2004; Muir et al., 2013; Prieto et al., 1996). Our results may indicate greater stability in the rigid surface conditions with both suspensions than in the compliant surface conditions, conveyed by the lack of limb loading asymmetry in the RSEO and RSEC conditions. Similarly, PUCK suspension may improve stability on compliant surfaces considering there were no observed interlimb differences in %BWT in the CSEO condition (Blaszczyk et al., 2000). However, considering the small sample size, we need to be careful with how we interpret these significant differences. Any improvements toward symmetry are important and suggest higher amputated limb loading tolerance demonstrated by Jones et al. (2001).

Previous research reveals lack of confidence and balance, discomfort, poor hip abductor strength, pain, and number of medications used as reasons why individuals with TTA favor their sound limb (Nadollek et al., 2002; Summers et al., 1987). Another possible explanation for increased weight bearing imbalance is the strategy to increase proprioception by favoring the intact limb (Jayakaren et al., 2015; Quai et al., 2005). Reduced somatosensory response caused by amputation is associated with increased instability and weight bearing imbalance (Quai et al., 2005). Quai et al. (2005) used vibration sense, light touch sensation, and circulatory health to assess somatosensation of both limbs in individuals with TTA. Increased COP excursion and weight bearing imbalance were observed as a result of poor somatosensation in the residual limb (Quai et al., 2005). It is likely that the interlimb loading differences observed in the present study are related to reduced somatosensory input and proprioception in the amputated limb leading to increased reliance of the intact limb where somatosensory input was not compromised when the conditions were most difficult--compliant surfaces (Jayakaren et al., 2015; Quai et al., 2005).

A relationship exists between weight bearing imbalance during quiet standing and in dynamic tasks (Jones et al., 1997, 2001). Jones et al. (1997) observed a relationship between weight bearing tolerance on the prosthetic side and walking velocity where lower weight bearing tolerance was associated with reduced walking velocity. They examined static weight bearing (SWB) of the prosthetic limb and how it related to gait kinetics and kinematics by comparing SWB to VGRF at impact, midstance and push-off of gait, limb velocities, and stance time and found that lower SWB was associated with an increased stance duration on the prosthetic limb. Greater SWB also corresponded to greater velocity of the sound limb throughout the gait cycle (Jones et al., 1997). Static weight bearing was measured by having the participants balance on their prosthetic limb on a bathroom scale while using a stable fixture adjacent to the scale to lean on. To calculate SWB, the weight on the scale was divided by total body weight. Lower SWB was associated with weight bearing intolerance and can provide an assessment of the weight bearing tolerance on the prosthetic limb of individuals with TTA (Isakov et al., 1992; Jones et al., 1997). Other research has concluded that weight bearing on the prosthetic side is a predictor of walking velocity (Jones et al., 2001). The results discussed above suggest that weight bearing imbalance during quiet standing influences the kinetics and kinematics of gait.

Weight bearing imbalances in individuals can pose several health risks to individuals with lower limb amputation including osteoarthritis in the intact limb knee and hip (Burke et al., 1978; Kulkarni et al., 1998), osteoporosis and osteopenia in the amputated limb (Burke et al., 1978; Kulkarni et al., 1998; Rush et al., 1994), lower back pain (Ehde et al., 2001), and secondary musculoskeletal injury (Farrokhi et al., 2018). Additionally, injuries caused by interlimb asymmetry can lead to reduced physical fitness that is associated with weight gain and

metabolic disease (Kurdibaylo, 1996). It is critical to address asymmetrical limb loading as a result of TTA in order to prevent comorbidities associated with TTA.

Contrary to previous research, significant weight bearing differences were not observed in the two rigid surface conditions. Favoring the intact side during rigid surface conditions and a more pronounced asymmetry as conditions increase in difficulty is the commonly observed pattern (Hlavackova et al., 2011; Isakov et al., 1992; Kanade et al., 2008; Mayer et al., 2011; Nadollek et al., 2002; Quai et al., 2005; Rougier & Bergeau, 2009). Confidence using prosthetic limbs can increase as years of experience using a prosthesis increase, resulting in improved symmetry (Mayer et al., 2011). The two groups of participants were categorized as skilled prosthesis users (SPU) and first fitted amputees (FFA) with mean time since amputation of 4.15 years and 5.6 months, respectively (Mayer et al., 2011). The participants in the present study had a mean time of 28 years since amputation. It is possible that we did not observe interlimb weight bearing differences in the rigid surface conditions because our participants were experienced and confident prosthesis users (Mayer et al., 2011). Considering how common limb load asymmetry is (Duclos et al., 2008; Hlavackova et al., 2011; Isakov et al., 1992; Kanade et al., 2008; Mayer et al., 2011; Nadollek et al., 2002; Quai et al., 2005; Rougier & Bergeau, 2009; Summers et al., 1987), future research should examine the causes of limb loading asymmetry in individuals with TTA.

Our results show greater sway areas in the intact limb in the RSEC condition with both suspension systems. Sway area is a hybrid measure that is an estimate of the COP area per unit time; greater sway area indicates reduced postural control (Prieto et al., 1996). Our data are in accordance with Prieto et al. (1996) who also saw an increase in sway area with removal of vision in both young and older adults. Additionally, Prieto et al. (1996) observed a significant

difference between the two groups. Older adults had a greater sway area than the young adults. The sway areas reported for older adults with eyes closed are lower than the sway measures we report for RSEO. This suggests that healthy older adults have greater postural stability control with their eyes closed than individuals with TTA do with their eyes open. Surprisingly, interlimb differences in sway area were not present in either compliant surface condition. Very high values were observed in the intact limbs during CSEC with both suspensions and may indicate that this task was too difficult. The lack of interlimb sway area difference may be a result of the small sample size and extreme values. The medium, large effect sizes (PIN 0.86, PUCK 0.72) suggest that there may be a meaningful difference in sway area between limbs in the CSEC condition if the sample size was larger.

Our results indicate greater 95% CE area in the CSEO condition in the intact limb than all other conditions with both suspensions. The 95% CE area is a time domain, area measure, which is expected to enclose approximately 95% of the points of the COP, and smaller values indicate more control over postural stability (Prieto et al., 1996). Merlo et al. (2012) reported similar results in the older adult population looking at non-fallers, fallers, and recurrent fallers. Our data from the intact limbs have similar and greater 95% CE areas to those of older adults, fallers, recurrent fallers, and older individuals who have a high risk for falling in every condition (Merlo et al., 2012; Norris et al., 2005; Prieto et al., 1996). Merlo et al. (2012) administered the same conditions that were used in the present study: RSEO, RSEC, CSEO, and CSEC. All groups experienced an increased 95% CE area as the conditions became more difficult (Merlo et al., 2012).

Though no measures of postural stability were statistically different between suspension systems, moderate to large effect sizes were noted between PIN and PUCK. Although not

significant, the finding of large effect sizes may suggest that with a larger sample size, these differences may become significant. With the exception of two dependent variables (intact mean and AP frequencies) in the CSEO condition, when comparing the two systems, all measures of postural stability that had a moderate to high effect size in the first three trials (RSEO, RSEC, and CSEO) indicated smaller values with PUCK suspension than with PIN (Tables 5 and 6). This trend includes values recorded from both amputated and intact limbs. Specifically, the amputated limb during RSEO produced an increased 95% CE area (Table 4) with PIN, while mean TTB (Table 2) was lower with PIN. Increased 95% CE area and reduced mean TTB both indicate instability (Hertel et al., 2006; Merlo et al., 2012; Norris et al., 2005; Prieto et al., 1996). Similar trends were observed on the intact side using PIN with increased mean ML velocity and decreased absolute minimum TTB. Again, increased ML velocity and reduced absolute minimum TTB are indicators of instability (Hertel et al., 2006; Prieto et al., 1996). Interpretation of this observed trend should consider the small sample size of the experiment.

As conditions became more difficult, more trends between suspension systems became visible through moderate and large effect sizes, all supporting lower values of postural stability measures with PUCK suspension. Most notably, in both the RSEC and CSEC conditions, instability was demonstrated by increased amputated limb 95% CE area, sway area, ML frequency (Table 4), and decreased mean TTB and absolute minimum TTB (Table 2) using PIN. Moreover, the CSEO condition also saw increased amputated limb mean resultant, AP, and ML velocities were higher with PIN and %BWT closer to 50% with PUCK suspension (Table 3). More symmetrical %BWT is likely associated with stability (Bigelow & Berme, 2011; Blaszczyk et al., 2000; Melzer et al., 2004; Muir et al., 2013; Prieto et al., 1996) and can reduce the risk of musculoskeletal injuries associated with asymmetrical limb loading observed in

individuals with lower limb amputation (Burke et al., 1978; Kulkarni et al., 1998). Using PIN suspension, participants became more reliant on the intact limb. Increased weight bearing on the intact side could be a strategy to gain motor control of stability (Jayakaren et al., 2015; Quai et al., 2005). Effect sizes indicate suspension had a moderate to large experimental effect on these variables.

Interestingly, the opposite was true in the CSEC trial, differences between suspension systems indicated by medium and large effect sizes demonstrate smaller values of postural stability measures with PIN in this condition (Tables 5 and 6). Anteroposterior velocity and frequency, and 95% CE area of the amputated limb were increased with PUCK suspension, while intact limb resultant and AP velocity, 95% CE area, sway area, mean frequency, AP frequency, and FD for CE were also increased with PUCK in comparison with PIN (Tables 3 and 4). With both suspension systems, increased reliance of the intact limb was demonstrated by increased %BWT. Oddly, mean TTB of both limbs remained increased with PUCK. Higher mean TTB is associated with stability and contradicts the other trends observed in the CSEC condition. Considering these results oppose the trends observed in the other three conditions, we are inclined to think they were skewed by outliers. One participant in particular experienced a disruption of balance causing their 95% CE area and sway area to be substantially higher in both limbs than the other participants, therefore, skewing the mean.

When considering effect sizes, certain dependent variables were more sensitive than others in detecting differences in postural stability caused by suspension system. Medium to large effect sizes were observed with amputated limb 95% CE area in every condition (Table 6). Sway area, mean TTB, and absolute minimum TTB were nearly as sensitive to differences in suspension systems in both the intact and amputated limbs (Tables 5 and 6). The TTB offers

unique insight into ankle instability and the spatiotemporal characteristics of postural stability by detecting differences that traditional COP measures cannot (Hertel & Olmsted-Kramer, 2007; Hertel et al., 2006; Linens et al., 2014; van Wegen et al., 2001, 2002). Mean and absolute minimum TTB of both limbs were largely affected by suspension system in every condition (Table 5).

It is evident that vision and surface manipulation influenced measures of postural stability in the present study when looking at differences in measures of postural stability between the four conditions. Considering the compromised somatosensation caused by amputation, the importance of visual and vestibular input in control of postural stability becomes more pronounced in individuals with TTA (Dornan et al., 1978; Jayakaren et al., 2015; Quai et al., 2005). Dornan et al. (1978) stated that due to lost proprioception resulting from amputation, individuals with TTA experience increased visual control of posture. Additionally, with the removal of vision, individuals with dysvascular amputation experienced greater instability compared to healthy individuals, while individuals with traumatic TTA did not show increased instability compared to healthy controls (Jayakaren et al., 2015). Dysvascular amputation caused by diabetes is often accompanied by neuropathy, which reduces sensation in the extremities (Vileikyte et al., 2017). Somatosensation in an amputated limb is compromised, even more so if the cause of amputation is dysvascular (Dornan et al., 1978; Jayakaren et al., 2015; Quai et al., 2005; Vileikyte et al., 2017). Therefore, we can assume that vision plays an especially critical role in maintaining postural control in individuals with TTA. Possible participants in the present study were excluded if the cause of their amputation was dysvascular to avoid additional interference with residual limb somatosensation. Proprioception and somatosensation may be improved by VASS, which draw the residual limb and socket together creating more contact

between the two than with PIN suspension. Superior somatosensation with VASS is supported by the %BWT results in the CSEO condition; where while using PUCK, participants did not become significantly more reliant on their intact limb as they did with PIN. Additionally, improved somatosensation with VASS was underlined by trends of lower values of postural stability measures with PUCK, made visible by effect sizes. Lower values reflect better postural stability where somatosensation has an important role.

The importance of vision in the control of balance in individuals with TTA is supported by research examining postural stability and visual manipulation (Arifin et al., 2014; Dornan et al., 1978; Duclos et al., 2008; Geurts et al., 1992; Isakov et al., 1992; Nadollek et al., 2002; Quai et al., 2005). Removal of visual stimuli is associated with increased AP and COP excursions, increased resultant velocity, and general instability (Arifin et al., 2014; Duclos et al., 2008; Geurts et al., 1992; Isakov et al., 1992; Nadollek et al., 2002; Quai et al., 2005). However, it appears that the relationship between vision and postural stability becomes more complicated with the addition of compliant surfaces. Additionally, interpreting the results of the present study presents a unique challenge due to the absence of previous research analyzing postural stability in individuals with TTA with the simultaneous manipulation of both vision and surface.

The results of the present study confirm the importance of vision as well as somatosensory input in postural stability (Arifin et al., 2014; Dornan et al., 1978; Duclos et al., 2008; Geurts et al., 1992; Isakov et al., 1992; Jayakaren et al., 2015; Lenka & Tiberwala, 2010; Nadollek et al., 2002; Quai et al., 2005). In the case of mean resultant velocity and sway area, the CSEC values were significantly higher than all other conditions and support our hypothesis that instability would decrease as conditions became more difficult. Although our sample size was low, there is some confidence in the resultant velocity results because they agree with previous

research (Duclos et al., 2008; Lenka & Tiberwala, 2010). Increased resultant COP velocity with the removal of vision was observed when postural stability in individuals with TTA was examined (Duclos et al., 2008; Lenka & Tiberwala, 2010). No research evaluating postural stability in individuals with TTA has reported calculations of sway area similar to those used in the present study (Prieto et al., 1996).

Patterns of increased mean AP velocity also confirm the role of vision in postural stability. Mean AP velocity was significantly increased in the CSEC condition compared to the two normal vision conditions, RSEO and CSEO. This appears to highlight the importance of vision and may suggest participants were more stable with normal vision on rigid and on compliant surfaces. However, compliant surfaces may have also contributed to the higher AP velocities observed in the CSEC condition. The pronounced effect of vision on postural stability was conveyed by significantly higher AP velocities in the CSEC condition than the CSEO condition, where the only difference between these two conditions was vision. Caution needs to be exercised when interpreting the significance of these results due to the small number of individuals who participated in the present study. The AP velocity results reported by Jayakaren et al. (2015) and Lenka and Tiberwala (2010) are similar to those in the present study in that they increased with the removal of vision.

Mean ML velocity was higher in the CSEC conditions than in the two rigid surface conditions (RSEO and RSEC), suggesting the combination of surface and vision manipulation challenges stability in the ML direction more than vision alone. Surface manipulating helps highlight the importance of somatosensation in postural stability (Jayakaren et al., 2015; Quai et al., 2005). Jayakaren et al. (2015) suggested that individuals with traumatic TTA use available somatosensory information when visual stimuli are absent or inappropriate. Results reported by

previous research demonstrate that ML velocity increases with the removal of vision in participants with TTA; however, our results suggest that removed vision does not affect ML velocity as much as the combination of vision and surface manipulation does (Jayakaren et al., 2015; Lenka & Tiberwala, 2010). The results of the present study may not be generalizable due to the small sample size.

Between condition results for mean AP frequency were even more complicated. Mean frequency is a time-domain hybrid measure, and greater values indicate instability (Prieto et al., 1996). In the present study, mean AP frequency was lower in the RSEO, CSEO, and CSEC conditions than in the RSEC condition. These results do not support our hypothesis and do not seem to indicate any clear pattern. Revisiting the importance of vision in balance control, it is probable that the RSEC values were higher than the RSEO due to the absence of visual input (Lenka & Tiberwala, 2010). Previous research has observed higher AP frequency resulting from the removal of vision (Lenka & Tiberwala, 2010). However, if this were the case, we would also expect significantly higher AP frequency in the CSEC condition than in the CSEO condition. Patterns in our data may be obscured by the small participant sample size. Additionally, the CSEC condition may have been too difficult for some participants to complete and may have skewed the statistical analysis.

Limitations

Due to the small sample size, our results may not be generalizable to all individuals with TTA. The variability in results in addition to the small sample size may have obscured patterns otherwise observed with a larger sample.

Although foot position was the same for individual participants across all conditions and suspensions, a standardized foot position across all participants was not adopted. A non-

standardized foot position used in the present study may have acted as a confounding variable and created intersubject variability (Geurts et al., 1992). However, using a standardized foot position in conjunction with removed vision can be too difficult for individual participants and can contribute to increased COP excursion (Bigelow & Berme, 2011). Using a comfortable stance during stability testing is suggested to be the best way to evaluate fall risk in older adults (Bigelow & Berme, 2011).

We felt one week would be sufficient, though ideally, participants would have had more time to become familiar with the new socket. The current study had an accommodation period of at least one week, and the time period was not the same for all participants. There is insufficient research examining ideal accommodation periods with new prostheses for lower amputees (Wanamaker et al., 2017).

Conclusion

The participants in the present study demonstrated greater reliance on the intact leg in all four conditions demonstrated by interlimb differences with both PUCK and PIN suspension. As the conditions became more difficult, more interlimb differences became apparent, except in the CSEC condition which was hypothesized to be too difficult to produce accurate representation of postural stability. Interlimb differences did not appear in all measures of postural stability, mean resultant velocity, mean AP velocity, 95% CE area, sway area, and %BWT were affected. Interlimb differences may be a result of limited mobility of the prosthetic ankle, reduced proprioception in the amputated leg, and compensatory postural adjustments.

Five measures of postural stability were affected by vision and surface manipulation, highlighting the roles that vision and somatosensation play in maintenance of postural control. The combination of removed vision and a compliant surface caused significantly greater

instability demonstrated by increased mean resultant velocity, mean AP velocity, mean ML velocity, and sway area. Reduced stability with the removal of vision was illustrated by an increased AP frequency in the RSEC condition. Increased instability indicates increased fall risk and should be addressed by rehabilitation and other aspects of treatment for lower limb amputation.

No significant differences between suspensions were detected. However, there were two instances where interlimb differences were observed with PUCK suspension that were not present with PIN. Further, there was one case where an interlimb difference was observed with PIN suspension and not with PUCK. Medium and large effect sizes suggest that the suspension system has an effect on measures of postural stability and may suggest that with a larger sample size, these results may become significant in areas where they have not reached statistical significance. In order to investigate the nuanced differences between suspension systems, future research should investigate postural stability using PUCK and PIN suspensions with a larger number of participants.

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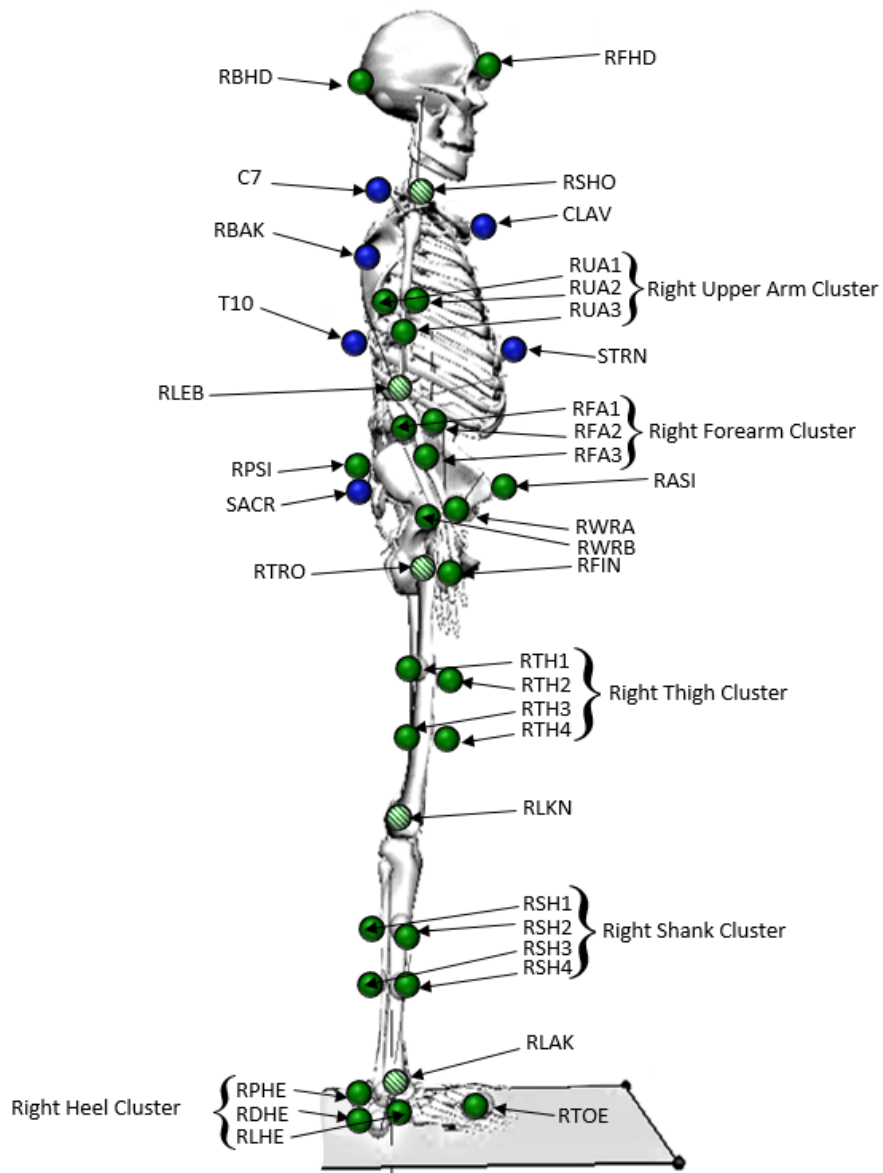   *Archives of Physical Medicine and Rehabilitation, 89*(3), 422-429.

    https://doi:10.1016/j.apmr.2007.11.005

APPENDIX A

MARKER PLACEMENT

Marker Placement
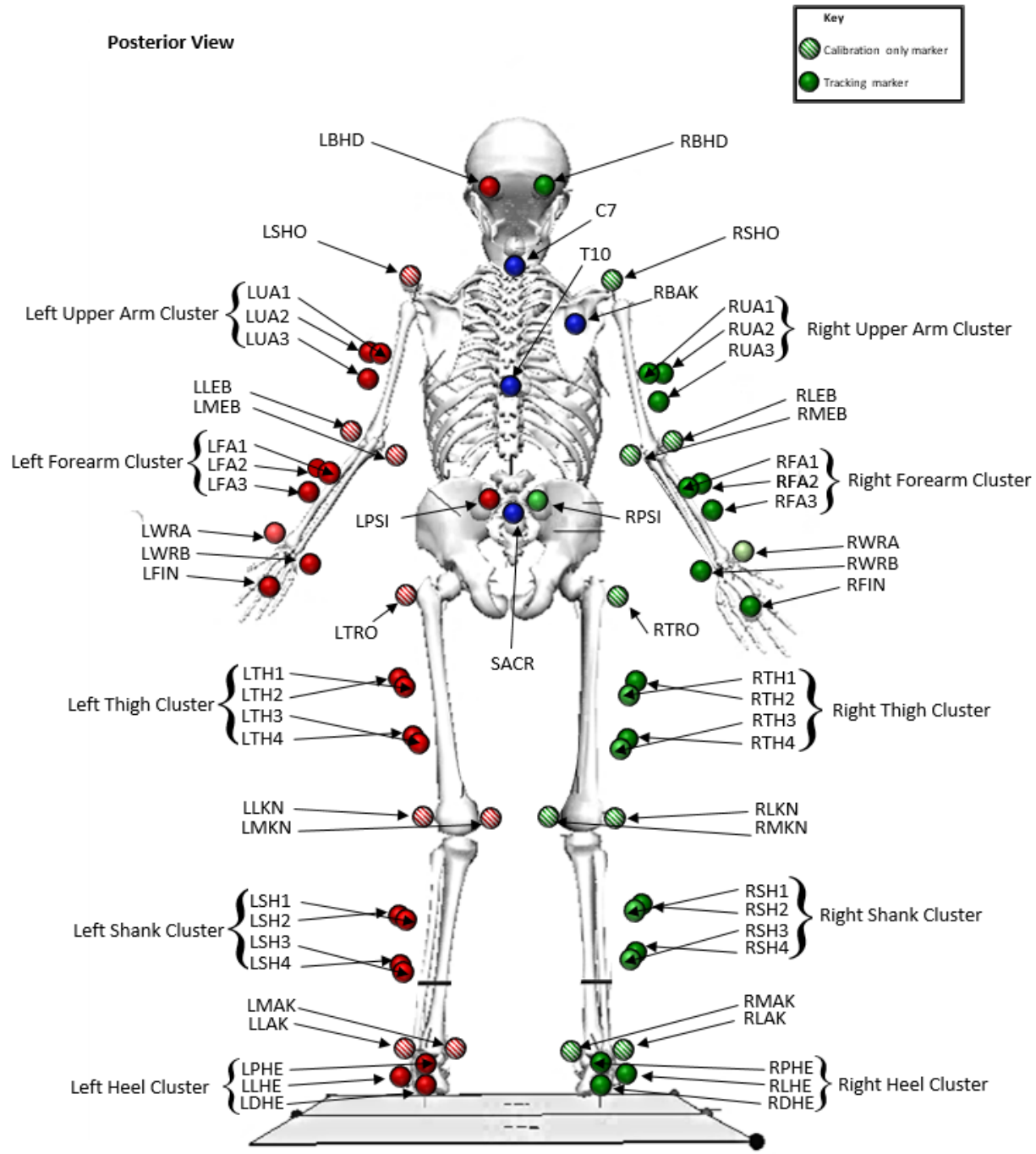
Posterior View

Anterior View
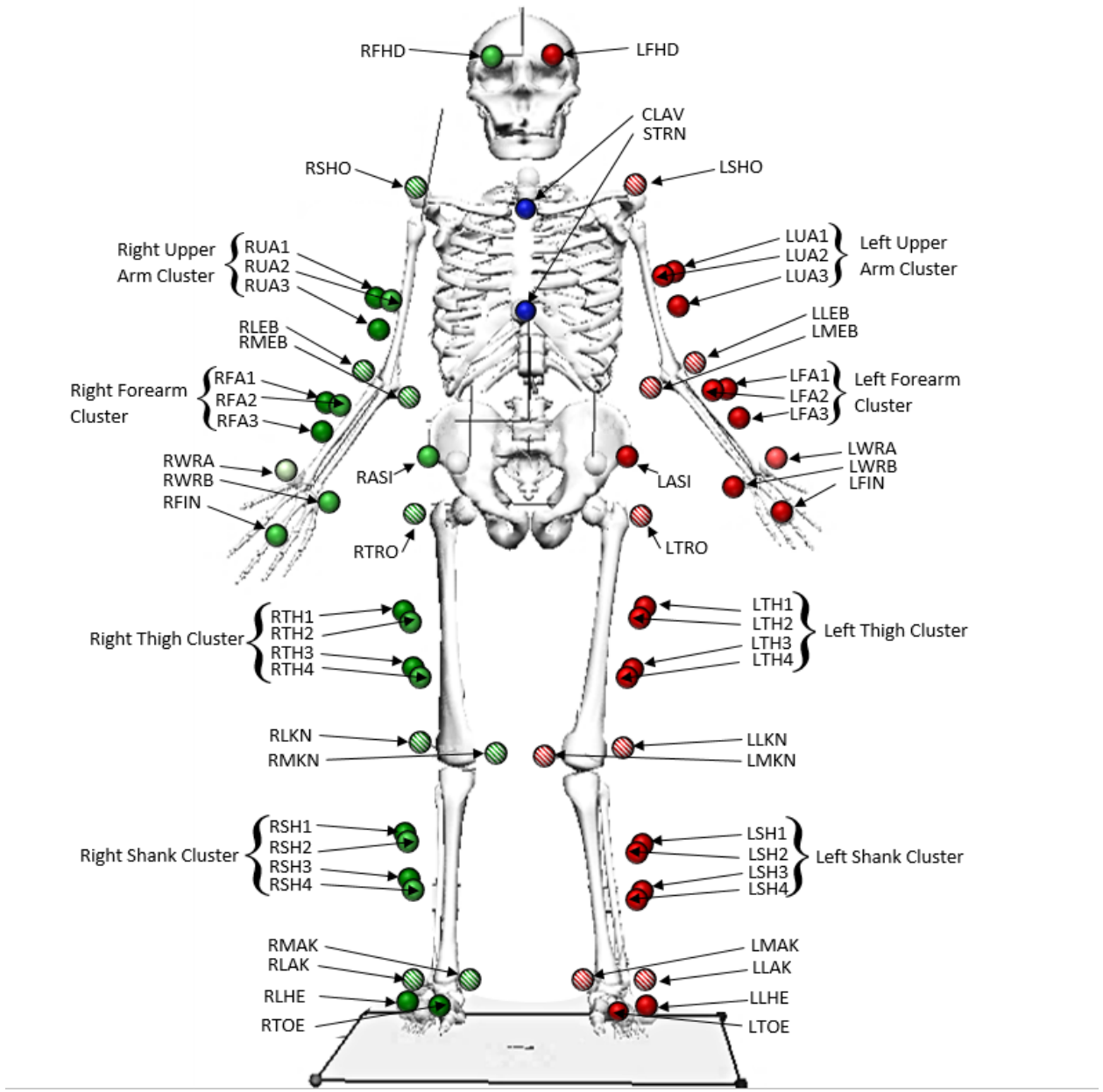
Lateral view

APPENDIX B

EFFECT SIZES

Table 5

Effect Sizes: Velocities, %BWT, Mean TTB, Absolute Minimum TTB

		Mean Resultant Velocity	Mean AP Velocity	Mean ML Velocity	%BWT	Mean TTB	Abs min TTB
RSEO	PUCK Amp vs PIN Amp	0.22	0.47	0.05	0.37	0.64	0.42
	PUCK Amp vs PUCK Int	2	2.19	0.27	0.5	0.36	0.11
	PIN Amp vs PIN Int	2.66	2.21	1.46	1.13	0.39	0.74
RSEC	PUCK Amp vs PIN Amp	0.13	0.22	0.17	0.34	0.73	0.57
	PUCK Amp vs PUCK Int	1.6	1.67	0.53	0.26	0.57	0.29
	PIN Amp vs PIN Int	2.67	2.42	1.32	1.08	0.85	0.37
CSEO	PUCK Amp vs PIN Amp	0.71	0.64	0.73	0.68	1.11	1.12
	PUCK Amp vs PUCK Int	1.64	1.79	0.36	0.9	0.45	0.63
	PIN Amp vs PIN Int	1.11	2.36	0.18	1.58	0.32	0.59
CSEC	PUCK Amp vs PIN Amp	0.36	0.75	0.32	0.47	0.84	0.19
	PUCK Amp vs PUCK Int	1.16	1.21	0.35	1.64	0.59	0.13
	PIN Amp vs PIN Int	1.4	2.41	0.22	0.14	0.2	0.78

Note: Effect sizes ≥ 0.8 were considered large, effect sizes or 0.5 were considered moderate, effect sizes ≤ 0.2 were considered small.

Table 6

Effect Sizes: 95% CE Area, Sway Area, Frequencies, FD for CE

		95% CE Area	Sway Area	Mean Freq. COP	Mean AP Freq	Mean ML Freq	FD for CE
RSEO	PUCK Amp vs PIN Amp	0.54	0.39	0.11	0.16	0.31	0.11
	PUCK Amp vs PUCK Int	0.85	1.09	0.16	0.55	0.54	0.57
	PIN Amp vs PIN Int	0.47	1.07	0.03	0.63	0.49	0.36
RSEC	PUCK Amp vs PIN Amp	0.74	0.67	0.28	0.14	0.54	0.38
	PUCK Amp vs PUCK Int	1.39	1.37	0.24	0.51	0.53	0.85
	PIN Amp vs PIN Int	0.91	2.21	0.07	0.73	0.38	1.11
CSEO	PUCK Amp vs PIN Amp	0.66	0.77	0	0.12	0.55	0.14
	PUCK Amp vs PUCK Int	2.19	1.5	0.11	0.72	0.55	0.55
	PIN Amp vs PIN Int	2.23	0.55	0.92	0.09	1.96	0.73
CSEC	PUCK Amp vs PIN Amp	0.57	0.19	0.11	0.54	1.09	0
	PUCK Amp vs PUCK Int	0.1	0.72	0.13	0.46	0.01	0.44
	PIN Amp vs PIN Int	1.89	0.86	0.7	0.18	2.17	0.24

Note: Effect sizes ≥ 0.8 were considered large, effect sizes or 0.5 were considered moderate, effect sizes ≤ 0.2 were considered small.

APPENDIX C

INSTITUTIONAL REVIEW BOARD DOCUMENTS

Institutional Review Board

DATE: February 18, 2019

TO: Abbie Ferris, PhD
FROM: University of Northern Colorado (UNCO) IRB

PROJECT TITLE: [1014426-3] Comparison of Prosthetic Suspension Systems on Function and Satisfaction

SUBMISSION TYPE: Continuing Review/Progress Report

ACTION: APPROVED
APPROVAL DATE: February 18, 2019
EXPIRATION DATE: February 8, 2020
REVIEW TYPE: Expedited Review

Thank you for your submission of Continuing Review/Progress Report materials for this project. The University of Northern Colorado (UNCO) IRB has APPROVED your submission. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on applicable federal regulations.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require that each participant receives a copy of the consent document.

Please note that any revision to previously approved materials must be approved by this committee prior to initiation. Please use the appropriate revision forms for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others and SERIOUS and UNEXPECTED adverse events must be reported promptly to this office.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this office.

Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of February 8, 2020.
Please note that all research records must be retained for a minimum of three years after the completion of the project.

If you have any questions, please contact Nicole Morse at 970-351-1910 or nicole.morse@unco.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Northern Colorado (UNCO) IRB's records.