Comparing the Symmetry of Walking in Transtibial Amputees: Biomechanical Differences of Prosthetic Heel Lifts

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Abstract

Prosthetic devices provide an avenue to accommodate transtibial amputees and mechanically restore some of their walking functionality. The loss of a lower limb results in significant mobility changes for these individuals' prosthetic gait patterns, which are commonly characterized by asymmetry and changes in force distribution, leading to an increased risk of secondary musculoskeletal injuries. Shock absorbing shoe materials seem to provide a potential solution for improving functional outcomes in lower limb amputees to restore symmetrical walking patterns. Based on this evidence, this study examined the effect of two different types of shoe materials on restoring some of the symmetrical characteristics of a normal walking pattern for transtibial amputees. The type of shoe materials included thermoplastic polyurethane (TPU) and a conventional foam heel lift commonly used with prosthetic devices, to observe changes in symmetry of force, energy, and power. The researcher performed static compression tests to observe changes in the properties of the material and identify its energy absorption capabilities. Dynamic impact tests were also performed to examine the effect of heel lift types (TPU heel lift, conventional heel lift, and no heel lift) on measures of force and energy absorption when combined with a passive prosthetic foot and flat-soled shoe during a simulated heel-strike. Finally, the researcher conducted dynamic human participant testing to examine the effect of the shoe material in the symmetry of walking between the amputated and non-amputated limbs of transtibial amputees during the braking and propulsion phases of gait for measures of ground reaction force (GRF), energy, and power. The results of this study revealed that the TPU heel lift, when compared to the conventional heel lift, had a significantly higher capacity for energy absorption during both static compression testing and dynamic impact testing, and generated significantly less force than the conventional heel lift during dynamic testing. This study also

found that the TPU had a significantly increased symmetry ratio for measures of energy during propulsion when compared a no heel condition. No other significant differences were found for the TPU heel lift. The findings of this study may have implications for the design of footwear and insoles that are used with lower limb prosthetic devices and suggest avenues for future research.

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GRF	Ground Reaction Force
TPU	Thermoplastic Polyurethane
SACH	Solid Ankle-Cushion Heel
PSI	Pound Per Square Inch

Chapter 1 - Introduction

There are nearly 8,000 lower limb amputations performed in Canada each year and the majority are transtibial amputations (Imam et al., 2017). Loss of the lower limb results in significant mobility changes and prosthetic devices are often used to replace the missing limb and restore some of its functionalities. Transtibial prosthetics are designed to mimic the mechanisms of the foot, ankle, and shank, which allow the user to bear weight and ambulate independently. Research and development of prosthetic devices have advanced in recent years. Currently, there is a wide range of devices available on the market that closely simulate the natural mechanisms of the lower limbs, which improve patient comfort and outcomes. Although there are several options for the use of advanced prosthetic devices, a significant number of patients do not purchase the new technologies. The reasons for this outcome include the high cost of technologically advanced prosthetics. Furthermore, patients need to replace their prosthetic devices every four to six years, which results in a higher cost over time when using new prosthetic technologies (Pitkin, 2009). Instead, patients continue using older passive prosthetic devices despite the discomfort that results from the prolonged use of these devices (Pitkin, 2009).

Passive prosthetics in lower extremity amputee populations are the most prescribed and widely used prosthetic devices due to their relatively low cost and simple design. Unfortunately, these devices significantly increase the risk of developing degenerative joint conditions in the patients' knees, hips, and lumbar spine due to limitations in heel-strike force absorption capabilities during walking (Gailey et al., 2008). Indeed, impact forces that occur during gait have been identified as the primary agent for degenerative joint conditions at the lower extremity

(Collins & Whittle, 1989). The heel-strike, for example, which occurs at initial contact with the ground, creates the highest magnitude of force during gait in this population (Gailey et al., 2008).

In able-bodied populations, shock absorbing shoe insoles have been found to significantly mitigate impact forces (Gillespie & Dickey, 2003). Commercially available shock absorbing insoles, however, are not currently recommended for transtibial amputees due to the high degree of compression and viscous material leading to feelings of instability during gait (Pitkin, 2009). Additionally, prosthetic feet are designed to fit compactly into one single pair of shoes and are adapted to new shoes through the use of a rigid heel lift. The heel lift is intended to maintain proper alignment of the foot with the prosthetic limb (Yeung et al., 2012) and firm material ensures that the user feels stable while walking (Pitkin, 2009).

Reducing impact forces that occur during heel-strike has been a topic of interest for the lower limb amputee population. Research has focused on the shock absorbing capabilities of the prosthetic device itself. But results in this area are often insignificant or inconclusive (Berge et al., 2005). Major et al. (2018) speculated that the variation in results within this area of research may be due to the inconsistent reporting of the footwear that is worn by amputees during experiments. They highlighted the significant impact that different types of footwear would have on the kinetic and kinematic measures of gait in the amputee population and the importance of controlling for this variable.

To date, several studies have assessed the effects of footwear on measures of gait with amputee participants, although few studies have attempted to simulate the prosthetic foot-ground impact. A study by Klute et al. (2004) examined the energy dissipating capabilities of the heel region in prosthetic feet when combined with footwear. Using a pendulum impactor, the moment of heel-strike was simulated using prosthetic feet combined with different types of shoes. They report that impact force at heel contact was significantly decreased when the prosthetic foot was combined with a shoe and that energy dissipation can vary significantly depending on the material properties of the shoe being used.

To better understand the effects of footwear on measures of ground reaction force (GRF), Klute and Berge (2004) modelled the effects of footwear with prosthetic feet on measures of GRF at heel-ground contact. The aim was to establish a theoretical basis for understanding the effects that prosthetics and footwear can have on measures of GRF during gait. Their research found that changing footwear resulted in large effects on various measures of GRF during a simulated heel-strike.

Currently, only few studies have assessed the effects of conventional prosthetic heel lifts on measures of gait in relation to impact forces during heel-strike. Yeung et al. (2012), for example, examined the effects of heel lifts used by amputees following long distance walking and found significant differences in gait kinematics. It is currently unknown, however, to what degree heel lifts may affect impact forces seen at heel-strike.

Understanding the force absorption and energy dissipation capabilities of prosthetic heel lifts at heel contact will allow clinicians to better understand the effects that these heel lifts have on the symmetry of gait kinetics when comparing the amputated and non-amputated sides of the lower extremity. Additionally, this information can enable the development of heel lifts made from materials that not only provide improved stability for lower extremity amputees during walking but also greater shock absorbing capabilities at heel-strike.

The use of thermoplastic polyurethane (TPU) materials, for example, seems to provide an avenue to develop prosthetic devices with these characteristics. Thermoplastic polyurethane material has gained increasing interest in injury prevention and rehabilitation due to its shock absorbing capabilities and shows potential for a wide variety of applications, including prosthetic heel lifts. The material properties of TPU, along with the use of the three-dimensional printing technology, provides a cost-effective option for more individualized heel lifts designs. This approach has the potential for better prosthetic designs and functional outcomes for lower limb amputees (Aimar et al., 2019).

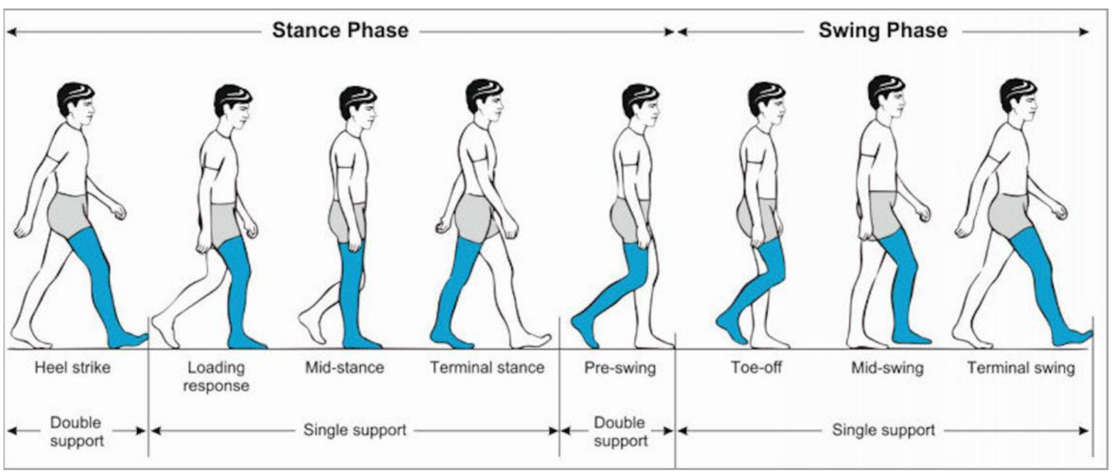
Chapter 2 - Review of Literature

The Gait Cycle

Human gait can be defined as a series of alternating lower limb movements that result in forward progression while also maintaining stance stability of the body (Kharb et al., 2011). During gait, the lower limbs act sequentially with one limb providing support while the other advances forward, switching roles throughout the movement (Kharb et al., 2011). This cycle fundamentally consists of two phases, the swing phase and stance phase, which can then be broken down into several subphases (see Figure 1) that are used to define each part of the gait cycle (Kharb et al., 2011).

Figure 1

Phases of the Gait Cycle



Note: Reprinted from Pirker, W., Pirker, W., Katzenschlager, R., & Katzenschlager, R. (2017). Gait disorders in adults and the elderly: A clinical guide. *Wiener Klinische Wochenschrift*, *129*(3), 81–95.

Stance Phase

The stance phase is described as the percentage of time that one foot is in contact with the ground. The stance phase begins with initial contact, ends with toe-off, and accounts for about 60% of the gait cycle (Rose & Gamble, 2015). The stance phase can be divided into five subphases including the initial contact, loading response, midstance, terminal swing, and pre-swing phases.

The first subphase, initial contact, is when the foot or heel contacts the ground. Initial contact is quickly followed by the loading response due to the body weight transferring onto the stance limb. The goal of these two subphases is to influence the efficiency of walking by minimizing GRFs while maintaining velocity and stability of the gait movement (Rose & Gamble, 2015). During these subphases, the heel behaves as a rocker while the knee remains flexed, with both the heel and knee acting as shock absorbers (Kharb et al., 2011).

The next mid-stance subphase, is the time period in which the stance limb fully supports the weight of the body and begins to propel the body forward (Rose & Gamble, 2015). As the heel of the stance leg elevates from the ground, the terminal swing phase of the opposite leg ends. At this point, the heel of the opposite leg contacts the ground, and the stance leg moves to the pre-swing subphase by shifting the weight to the contralateral leg (Rose & Gamble, 2015). Once the toe of the stance leg elevates from the ground, the stance phase of this leg ends, and the swing phase begins.

Swing Phase

The swing phase is the period following the stance phase in which the foot is elevated from the ground and accounts for 40% of the gait cycle (Kharb et al., 2011). This phase consists of single leg support, and it begins with toe-off and ends with heel or foot contact of the swing leg. This phase can be divided into three subphases including the initial swing, mid-swing, and terminal swing phases.

The initial swing subphase occurs following toe-off when the foot elevates from the ground and begins to propel forward. This phase accounts for one third of the swing phase and ends when the swing foot is parallel with the stance foot (Kharb et al., 2011). The mid-swing subphase begins at this point and aims to advance the limb forward, anterior to the weight line (Kharb et al., 2011). Mid-swing ends when the swinging foot is ahead of the stance foot and the tibia is vertical (Kharb et al., 2011). The terminal swing subphase, begins when the propulsion of the swinging foot has ended, the tibia is vertical, and the leg is preparing for heel contact with the ground (Kharb et al., 2011).

The initial contact of the foot or heel marks the end of terminal swing and the completion of one full gait cycle. When examining the phases of the walking cycle, researchers and clinicians often use kinetic analysis to assess normal and abnormal gait patterns of the lower extremities.

Gait Kinetics

The kinetics of movement describes the forces that are associated with the motion being performed (Hall, 2011). During gait, common measures of kinetics include GRF, energy, and power.

Ground Reaction Forces

Newton's third law of motion states that for every applied force, there is an equal and opposite reaction force (Hall, 2011). In the case of human gait, this law applies when the contact between the foot and ground generates reaction forces known as GRF. The GRF can be influenced by a variety of factors including gait speed, joint angles, stride length, and footwear

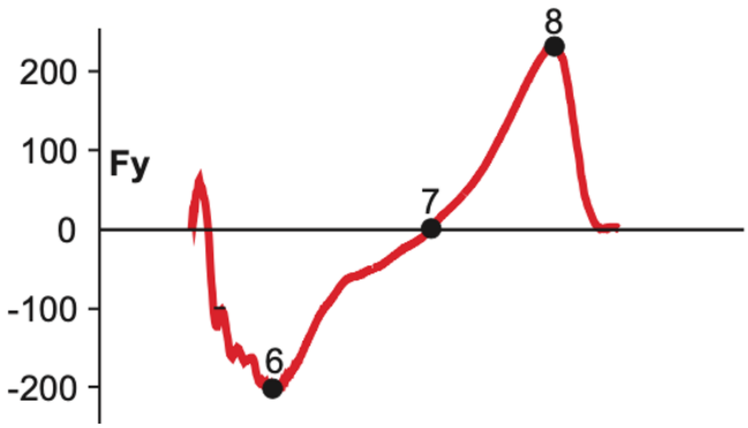
(Hall, 2011). These forces are commonly measured using force plates, which provide data on the three vector components that make up the GRFs. These vectors include a vertical force component and two shear components referred to as anterior-posterior and medial-lateral forces when performing a gait analysis (Marasovic et al., 2009).

Anterior-posterior Ground Reaction Force. The anterior-posterior GRF represents a horizontal component of the GRF and acts in the same direction as walking (forward and backward; Vaverka et al., 2015). This component is much smaller in magnitude when compared to vertical forces as it typically only reaches about 20% of an individual's body weight (Vaverka et al., 2015).

The anterior-posterior GRFs provide important information regarding the propulsion and braking forces that are generated while walking; deficits in these forces can indicate asymmetry and pathological gait. The first impact that is seen in the force curve (Figure 2) is a negative anterior force that is due to the deceleration of the body's center of mass during the braking action that occurs from initial contact to midstance (Vaverka et al., 2015). After midstance, an increase in posterior (positive) force can be seen as single stance begins and the body propels the center of mass forward, with the force curve dropping to zero following toe-off (Vaverka et al., 2015).

Figure 2

Anteroposterior Ground Reaction Forces for Right or Left Foot

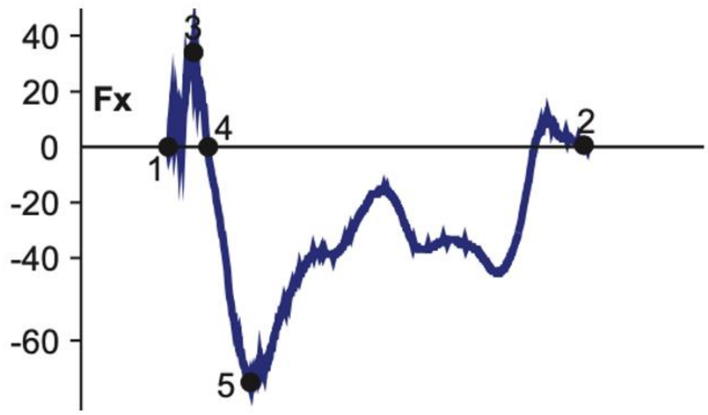


Note: Reprinted from Vaverka, F., Elfmark, M., Svoboda, Z., & Janura, M. (2015). System of gait analysis based on ground reaction force assessment. *Acta Gymnica*, *45*(4), 187–193.

Medial-lateral Ground Reaction Force. The medial-lateral GRF represents the horizontal force that acts medially and laterally. This force is dependent on the position of the center of mass relative to the stance foot (Marasovic et al., 2009). During gait, the center of mass moves laterally with heel-strike and the loading response, which can be seen in Figure 3 as the first rapid increase in force (Marasovic et al., 2009). This loading response is followed by a sharp transfer to medial force that tapers off throughout the rest of the stance phase until hitting zero (Vaverka et al., 2015). Medial-lateral GRFs provide information regarding the acceleration and position of the center of mass and limb placement during walking (John et al., 2012) and may help to indicate pathological gait patterns (Yazji et al., 2015)

Figure 3

Mediolateral Ground Reaction Forces for Right or Left Foot



Note: Reprinted from Vaverka, F., Elfmark, M., Svoboda, Z., & Janura, M. (2015). System of gait analysis based on ground reaction force assessment. *Acta Gymnica*, *45*(4), 187–193.

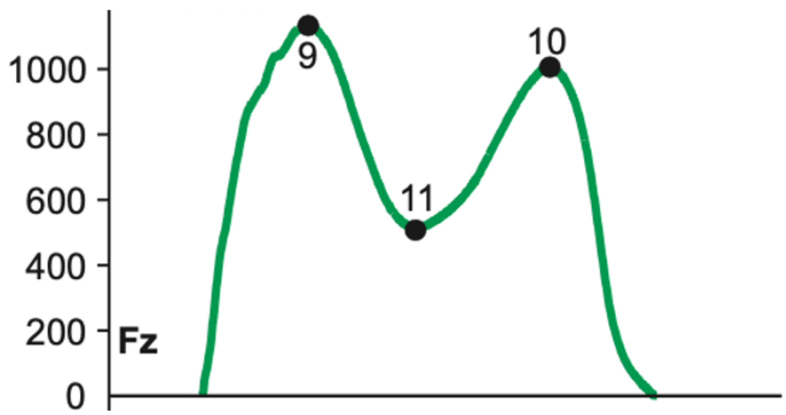
Vertical Ground Reaction Force. The vertical GRF is the largest component and relates to the vertical acceleration of the body's center of mass during gait (Marasovic et al., 2009). Because of its shape, which resembles the letter "M", the force curve is commonly known as the M-curve and can be seen in Figure 4. This curve begins with the heel-strike, which is defined as the time instant at which the heel contacts the ground. At this time instant there is zero force produced between the foot and ground (Marasovic et al., 2009). Following this contact, the force can be seen to rapidly increase as the body weight is shifted onto the foot.

The first peak of the vertical GRF curve is approximately 107% of the individual's body weight, due to both the inertial and gravitational forces acting together (Marasovic et al., 2009). The dip that is seen in the curve occurs during the mid-stance phase and is due to the center of mass accelerating downwards and creating an upwards inertial force that decreases the GRF to about 85% of body weight (Marasovic et al., 2009).

The second force peak occurs during the terminal stance phase when the limbs prepare to move the body forward, which creates a force that is approximately 105% of the body weight (Marasovic et al., 2009). This force then rapidly drops off to zero as pre-swing begins and the body weight is transferred to the new support limb (Marasovic et al., 2009). When examining the gait kinetics of an individual, it is important to examine the GRF at heel-strike.

Figure 4

Vertical Ground Reaction Forces for Right or Left Foot



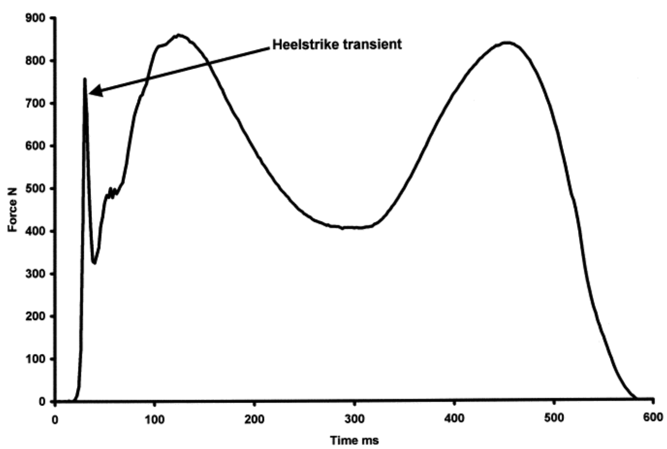
Note: Reprinted from Vaverka, F., Elfmark, M., Svoboda, Z., & Janura, M. (2015). System of gait analysis based on ground reaction force assessment. *Acta Gymnica*, *45*(4), 187–193.

Heel-strike Impact Force. During gait, initial contact of the heel and ground following the swing phase results in a shock wave of force that is commonly known as heel-strike transient force or impact force. It can be measured using force plates and is seen as a rapid increase in the vertical GRF (see Figure 5) immediately following initial foot contact. The magnitude of the impact force is influenced by several factors including the mass and impact velocity of the heel, the properties of the ground surface, and shock absorption capabilities of footwear (Collins & Whittle, 1989).

High measures of impact forces during gait at heel-strike have been correlated with various pathological conditions such as osteoarthritis and low back pain (Collins & Whittle, 1989). These forces are considered particularly harmful for body joints and muscles due to their intensity and their overexerting occurrence at each step of walking (Verdini et al., 2006). In addition to the measures of GRFs, researchers and clinicians also use measures of energy absorption and energy production of the muscles, bones, and tissues during the phases of the gait cycle to assess gait symmetry and detect abnormal walking patterns.

Figure 5

Heel-strike Transient Force



Note: Reprinted from Whittle, M. (1999). Generation and attenuation of transient impulsive forces beneath the foot: A review. *Gait & Posture*, *10*(3), 264–275.

Energy Production and Absorption During Gait

During level-ground steady state walking, the foot and lower extremities undergo phases of energy loading and unloading throughout the stance phase of gait (Winter, 1983). A human foot contains passive tissues, such as the heel pad that act to dissipate energy, as well as passive elastic tissues, such as ligaments, that work to store and return energy (Kelly et al., 2018). The energy loading phase begins at initial impact when the energy that results from foot-ground contact is loaded onto the tissues and either dissipated, stored, or continues to travel through the lower extremities (Riddick & Kuo, 2016).

During the energy loading phase, the heel pad has been identified as a significant source for energy absorption due to the position of the contact limb remaining unchanged and little muscle activity being detected during this period (10-20 milliseconds after heel-strike; Jefferson et al., 1990; Wakeling et al., 2003). Indeed, evidence shows that during the energy loading phase, the heel pad alone accounts for 20-50% of the total energy absorption (Bennett & Ker, 1990; Gefen et al., 2001; Wearing et al., 2014). The energy loading phase lasts until midstance and is then followed by a phase of energy unloading and generation. The energy that was stored within the tissues is unloaded during this phase and additional energy generation is produced through concentric muscle activity throughout late stance and ending with toe-off (Winter, 1983).

Energy generated during walking is a common measure of interest during gait analysis due to the negative effects that the transfer of energy through the limbs can have on musculoskeletal tissues. Energy that is loaded during impact is dissipated in part by the footwear, tissues of the heel pad, and muscular tissues (Rose et al., 2015; Whittle, 1999). Energy dissipation during gait occurs almost entirely during the impact phase (Shorten, 2004) and when these dissipation systems fail or are lost, energy is instead transferred through the lower limbs as a vibration. This loss or failure in energy dissipation is concerning due to the negative effects on the bones, muscles, tendons, and ligaments. For this reason, energy loading and dissipation is a key component of gait analysis and often observed during the testing of shoe materials.

Additionally, evidence suggests the need to reduce impact forces and that high energy loading during gait can lead to compensatory gait patterns (Gard & Konz, 2003). Therefore, high amount of energy during initial impact and loading could be an indication of pathological gait. In addition to energy, researchers often observe measures of power during gait to detect abnormal walking patterns.

Power Production During Gait

Mechanical power during walking is another common measure of interest for gait analysis as it provides significant insight into interlimb symmetry and the metabolic cost of walking (Donelan et al., 2002). There are several methods that can be used to measure power during gait, however, determining mechanical power as a product of walking velocity and the GRFs applied to each limb allows researchers to understand the net power produced by each of the lower limbs and joints, along with the interlimb symmetry (Donelan et al., 2002; Farris & Sawicki, 2012)

Throughout the gait cycle, positive and negative power are produced to maintain a steady walking speed and optimal metabolic consumption (Farris & Sawicki, 2012). Mechanical power can be defined as the time-rate of doing work and is expressed as the work performed per unit of time (Farris & Sawicki, 2012). Positive work can be produced at any point during the gait cycle; however, evidence shows that it is most beneficial for the trailing limb to perform the positive power during toe-off at the same time that the leading limb produces negative power during heel-strike (Farris & Sawicki, 2012).

During the steady state of walking, the path of the body's center of mass is similar to that of an inverted pendulum and mechanical power is required during the transition from single to double support to re-direct the center of mass velocity vector between the arcs of the pendulum (Donelan et al., 2002). The redirection of the center of mass is due to a combination of positive power produced by the trailing limb and negative power produced by the leading limb (Donelan et al., 2002). Donelan et al. (2002) stated the importance of the timing of power production, as a significant amount of energy can be lost if positive power is produced too early and additional power is then needed to redirect the center of mass. The symmetry of power between each limb plays a significant role in metabolic optimization during walking, as interlimb asymmetries have been shown to result in significantly higher metabolic costs and can, therefore, be an indication of pathological gait (Ellis et al., 2013).

Pathological Gait

Normal gait patterns consist of rhythmic, alternating limb movements that follow the patterns described above in the stance and swing phases of gait. Although normal gait may deviate slightly from these patterns, significant deviations result in pathological gait patterns (Vazquez-Gailliano et al., 2014).

Impaired or pathological gait patterns may result from impaired strength, range of motion, proprioception, pain, or balance; or they may be due to underlying health or physical conditions (Vazquez-Gailliano et al., 2014). These impaired pathological gait patterns manifest in lower limb amputees who show a significant deviation from normal walking patterns due to the use of prosthetic devices.

Prosthetics

The loss of limbs or body parts can result from trauma, disease, or birth defects; prosthetic devices can be used to replace the missing segment and restore normal function. In Canada, a majority of limb loss is due to diabetes (Imam et al., 2017) as compared to developing countries in which trauma is the most frequent cause (Bisseriex et al., 2011).

Prosthetics first appeared as early as 1500 BC (Seymour, 2002) and since then, significant advancements and several types of prosthetic devices have been made. Transtibial amputations are the most common form of limb loss (Gailey et al., 2008) and consequently, a large variety of transtibial prosthetic devices have been developed for this population.

Transtibial Prosthetics

Transtibial, or below-knee, amputations involve the removal of the foot, ankle, and sections of the tibia and fibula, along with the surrounding soft tissues. This is replaced with a transtibial prosthetic device composed of different mechanical components to restore some of the naturally occurring mechanisms that aid human gait. The components of a prosthetic limb, although separate, work together to act as a single device (Pitkin, 2009). Each component is interchangeable and selected based on the individual's needs, functional ability, and preference (Pitkin, 2009). The primary components of a transtibial prosthetic device include the socket, pylon, and foot.

Socket. The prosthetic socket is the interface between the amputee and device, as this is where the residual limb is held. In normal gait, the weight of the body is loaded in the skeletal structures; however, this is not the case for amputees, as they must carry the weight on the soft tissues of the residual limb (Fergason et al., 1999). To help relieve the pressure of weight bearing, a socket is designed to not only fit an individual's residual limb, but also to relieve contact points on the limb that are sensitive to increased pressure such as the distal tibia and fibula (Fergason et al., 1999). There are numerous types of sockets available that aim to relieve pressure and pain; however, the outcome of a socket is also greatly dependent on the other components of the prosthetic, more specifically the pylon and foot.

Pylon. The pylon is the portion of the prosthetic that aims to replace the shank of the lower leg. This piece is traditionally formed of a steel or titanium rod and connects the prosthetic socket and foot. There are a broad range of pylons available, with some specific to sports and activity, and others that are focused on function and rehabilitation (Smith et al., 2004). Recently, increased interest in the shock absorbing abilities of various prosthetic components have led to the development of shock absorbing pylons that aim to lessen the impact forces of gait (Smith et al., 2004). Evidence for these pylons is still limited and research currently emphasizes the importance of prosthetic feet and the foot-shoe interface for optimal impact absorption during gait.

Feet. New materials and design advancements have greatly broadened the variety of prosthetic feet that are currently available to amputees. Types of prosthetic feet range from conventional passive feet, semi-passive, to the more technologically advanced active feet (Smith et al., 2004). Prosthetic feet are prescribed based on a variety of factors such as the individual's functional ability and needs, aesthetic preference, and cost. Among the wide range of available prosthetic feet, passive feet are still among the most commonly prescribed and widely used prosthetic due to their simple design and low cost (Smith et al., 2004). Passive feet are designed to mimic the characteristics of a foot and ankle, however, most transtibial amputees continue to show asymmetric kinetic gait patterns.

Transtibial Gait Patterns

Unilateral, transtibial amputee gait is most commonly characterized by reduced self-selected walking speed and bilateral kinetic asymmetry (Hafner et al., 2002; Kulkarni et al., 2005). Gait asymmetry is a primary concern in unilateral amputees, as it often results in excessive loads placed on the sound limb and non-optimal gait mechanics (Nolan & Lees, 2000). Research has found varying results regarding gait patterns for transtibial amputees; however, some deviations from normal gait patterns have commonly been reported in kinetic measures.

Kinetics Measures of Transtibial Gait Symmetry

The kinetics of transtibial gait has received less attention than gait kinematics, partly because of the complexity of the analysis and the need to use more expensive sensory technology to determine kinetic measures across joints while accounting for varying prosthetic components, footwear, and individual gait patterns. Despite the limited amount of definitive research, variation in GRFs between able-bodied and amputated individuals have been consistently reported in the literature (Kovac et al., 2009; Nolan et al., 2002).

Ground Reaction Forces. Significant differences have been found in GRFs between the able-bodied and amputated populations, with the most common findings including decreases in peak vertical GRF, decreased anterior-posterior GRF at the end of the loading response, and decreased maximum medial force on the amputated limb (Kovac et al., 2009). These forces have been found to be much higher on the intact limb side, with unilateral amputees showing up to 23% force asymmetry in GRFs during gait (Nolan et al., 2002).

Prosthetic users have expressed the need to place increased emphasis on the intact limb during gait in order to compensate for shorter stance time on the prosthetic limb due to the pain and discomfort reported that may result with use (Nolan et al., 2002). This emphasis explains the asymmetry in forces between the sound and amputated limb. Although GRFs are often found to be lower overall for the amputated limb, impact shock on the prostheses during initial foot contact is a common complaint for amputees. Indeed, in some instances, forces that occur during initial contact and loading have been found to be significantly higher on the amputated side at heel-strike (Klute & Berge, 2004).

Heel-strike Force in Amputees. The heel-strike transient force that occurs at initial contact during gait has been found to be significantly higher in amputees than in able bodied populations (Gailey et al., 2008). This outcome is likely due to the loss of the natural mechanisms that have been identified to help with shock absorption at initial contact such as the tissues of the heel pad and muscle activation in the ankle joint. This functional limitation over time results in pain in the residual limb (Rose et al., 2015; Whittle, 1999). Edhe et al. (2000), for example, found that 60% of transtibial amputees reported moderate to severe pain in the residual limb due to impact shock from heel-strike when walking.

Additionally, it has been suggested that the need to reduce impact forces at heel-strike can lead to compensatory or asymmetric gait patterns and the reduction of this force may aid in improving symmetry in amputee gait (Edhe et al., 2000). Therefore, a shock absorption mechanism through the prosthetic limb to minimize impact forces and energy loading across body joints of the lower extremity may improve the symmetry of walking. Furthermore, it may provide an avenue to minimize the risk of injuries on transtibial amputees due to overexertion on the tissues such as the muscles, tendons, and ligaments during the gait cycle.

Mechanical Energy in Amputees. The natural mechanisms involving the soft tissues and ligaments, which normally assist with energy absorption during gait, are lost in transtibial amputees; therefore, energy dissipation only relies on the components of the prosthetic device and footwear materials (Collins & Whittle, 1989; Rose et al., 2015; Whittle, 1999). Several passive prosthetic devices have been developed with the goal of replacing the energy loading and unloading mechanisms of human feet, including devices such as the energy storing and return foot, the solid ankle-cushion heel foot, and the dynamic elastic response foot (Hafner et al., 2002).

These prosthetic feet are designed to mimic the two phases of loading and unloading that are seen during normal gait by dissipating high impact forces, storing energy during the loading and midstance phases, and returning the energy during late stance until toe-off (Hafner et al., 2002). Although these devices have allowed for significant improvements in gait mechanics for amputees, they are still limited in their energy dissipation capabilities; and their effects on measures of energy have varied across studies (Hafner et al., 2002). Improving the energy dissipation process, however, would allow the impact energy to be absorbed and used to propel the body forward rather than travelling through the limbs. In addition, it will increase the power production of the amputated limb to improve the symmetry of the gait cycle for the amputee population (Houdijk et al., 2009; Verdini et al., 2006).

Power. Houdijk et al. (2009) described the importance of positive and negative power production during the braking and propulsion phases of gait in amputee populations, under the rationale that insufficient positive power during propulsion is a significant contributor to altered gait mechanics. This outcome is due to the increased demand placed on other muscles and joints of the body to produce positive power later in the gait cycle in order to propel the body forward (Houdijk et al., 2009).

Specifically, reduced power generation during the propulsion phase of gait in transtibial amputees has been associated with significantly greater concentric hip extensor work done in the amputated limb during early stance of the gait cycle, and increased power production throughout the entire stance phase of the non-amputated limb (Houdijk et al., 2009). Research by Nolan and Lees (2000) supported this evidence, as they found that power production was significantly reduced during toe-off in transtibial amputees, resulting in increased power production of hip muscles throughout the single stance of the amputated limb. The researchers also found an increased demand of power for the non-amputated limb as compared to the amputated limb.

Research and design of prosthetic devices have aimed to address this issue with mechanically advanced prosthetic devices. Unfortunately, commonly used passive prosthetic feet do now allow for powered plantarflexion at toe-off and therefore, produces about 20% less power during this phase as compared to non-amputees (Bonnet et al., 2013).

It is important to keep in mind, however, that when the body is forced to produce positive power from other muscles and joints of the body, it significantly increases the cost of energy that is required for ambulation. Consequently, the adaptation of other muscles to generate power throughout the rest of the gait cycle significantly contributes to altered gait mechanics and increased risk of pathological joint conditions in transtibial amputees (Houdijk et al., 2009).

Risk of Pathological Joint Conditions in Amputees

Evidence shows that transtibial prosthetic users are at greater risk of developing degenerative musculoskeletal conditions following their amputation (Gailey et al., 2008). Research has most commonly observed increased rates of osteoarthritis and chronic low back pain in this population.

Osteoarthritis is a degenerative joint condition in which the articular cartilage of the joint breaks down, leading to several symptoms such as functional impairment, inflammation, pain, and stiffness (Goldring & Goldring, 2007). Several studies have reported incidences of osteoarthritis in the knee and hip joints in both the sound and residual limb of transtibial prosthetic users.

Research by Norvell et al. (2005) assessed the prevalence of self-reported osteoarthritis symptoms in the knee joints of both amputee and non-amputee veterans and found that individuals with transtibial prosthetic devices were three times as likely to report osteoarthritic symptoms in their knees. Kulkarni et al. (2005) evaluated the presence of osteoarthritis in the hip joints of lower limb amputees and found osteoarthritis to be present in 55% of hips on the amputated limb and 18% of hips on the sound limb side.

Low back pain is also a common complaint in lower limb amputees. Research has evaluated the various effects that the use of prosthetic devices can have on the lumbar spine, with earlier research showing 43% of prosthetic users to have scoliosis and 76% of users to have varying degrees of degenerative diseases (Burke et al., 1978). More recent research has assessed the time of onset and level of pain in lower limb prosthetic users and found that 52% of lower limb prosthetic users reported persistent back pain, with many claiming that their back pain was the primary and worst pain that they experienced (Ehde et al., 2001). Similar research by Kulkarni et al. (2005) found that 60% of participants reported the onset of back pain within two years of their amputation and over half of those claimed that it greatly interfered with their everyday life.

Since these degenerative musculoskeletal conditions in transtibial amputees have continuously been linked to the impact forces experienced during gait, it may be possible for clinicians to prescribe the use of footwear, insoles, and orthotics to transtibial amputees instead of prescribing a different prosthetic device, which can be costly over time. This approach, although not commonly practiced by clinicians, may provide an avenue to minimize the energy loading and power demand across the lower extremity body joints to propel the body forward and improve the symmetry of the gait pattern for transtibial amputees.

Amputee Orthotic Prescription

Shock absorbing insoles can decrease the magnitude of heel-strike force and the rate of loading by 10-35% in non-amputees (Folman et al., 2004; Gillespie & Dickey, 2003). Furthermore, shock absorbing insoles are found to be effective in reducing the risk of injury and degenerative joint conditions in non-amputees (De Vincenzo et al., 2011; Lullini et al., 2020; Turpin et al., 2012). Based on these findings, it seems that a similar intervention could be utilized for transtibial amputees. The problem, however, is that transtibial amputees are not currently prescribed shock absorbing insoles due to the significant compression and viscous material leading to subjective feelings of instability while weight bearing on the prosthetic limb.

One orthotic often used with a prosthetic device is a rigid heel insert, which aids in proper prosthetic foot alignment when adapting the prosthetic foot from running shoes to flat-soled shoes (Yeung et al., 2012). Clinicians use this approach to elevate the heel of a passive prosthetic foot when using a flat shoe, as prosthetic feet are often designed to fit into running shoes rather that flat-soled shoes.

A commonly prescribed heel lift is often made from a firm foam material that allows for very little compression to ensure that the user feels stable during gait (see Figure 6). Although this heel lift is commonly used and widely prescribed, very little is known about its shock absorbing capabilities or effects on gait kinematics and kinetics.

To date, a few studies have assessed the effects of heel lifting on gait and changes in kinematics have been noted with their use (Yeung et al., 2012). There is currently no known research, however, that has tested the energy absorbing capabilities of prosthetic heel lifts or the effects that it has on the symmetry of walking. Furthermore, there is no known research testing the effects of various materials that could be used as heel lifts to better mitigate impact forces while retaining its rigid structure. One material that has the potential to accomplish both of these goals is TPU.

Figure 6

Transtibial Prosthetic Heel Lift

Note: Commonly prescribed rigid heel lift that is used with transtibial prosthetic devices.

Thermoplastic Polyurethane

The TPU material has recently received increased attention for its potential application in injury prevention and rehabilitation. The TPU material is a blend of polymers that contains both hard segments of urethane groups and soft segments of polyol that allow it to retain both the elasticity of rubber and the strength of plastic (Lin et al., 2016). The plastic properties result in increased rigidity and resistance to tear; however, the elasticity allows the TPU to deform with impact, absorb energy, and quickly return to its original shape (Lin et al., 2016).

Three-dimensional printed TPU has shown promising results in energy absorption due to its strong but flexible structure (Bates et al., 2019). The tailorable nature of three-dimensional printing allows for changes to be made in the rigidity and compressive ability of the material as well. These characteristics make TPU a nearly ideal material to be used in various applications, such as a heel lift and footwear development for transtibial amputees.

Potential Application in Footwear

Kim et al. (1994) showed that the transmission of heel-strike force was greatly affected by the type of material used between the foot and ground, with materials that allow for greater dissipation of energy resulting in decreased force transmission during gait. This research also reported that 80% of participants felt good improvements in knee and hip pain with the use of shock absorbing insoles, and an additional 17% reported satisfactory results.

Peng et al. (2020) tested the effects of footwear made entirely of a polyurethane material in runners and found that the polyurethane shoes resulted in decreased heel-strike peak force, as well as a smaller first peak in vertical GRF. This evidence along with the potential benefits that TPU may provide in energy absorption, increase in power production, and reduction in GRFs suggest that further research with the use of shock absorbing materials, such as TPU, would be beneficial to minimize the risk of injury that impact forces pose on transtibial amputees at heel contact, and to subsequently improve their symmetry of walking.

Research Purpose

This study aimed to examine the material properties of a conventional prosthetic heel lift and a specially designed TPU heel lift as a possible avenue to improve the symmetry of walking on transtibial amputees based on measures of force, energy, and power. The first purpose of this research was to analyze the material properties of a TPU heel lift and conventional heel lift on measures of energy absorption capacity during static testing. The second purpose of this study was to examine the effect of heel lift types on measures of force and energy absorption when combined with a passive prosthetic foot and flat-soled shoe during a dynamic simulated heel-strike. The third purpose was to examine the symmetry of walking in transtibial amputees with the use of a TPU heel lift, a conventional heel lift, and no heel lift for measures of GRFs, energy, and power.

Research Questions

The first purpose was addressed by the following question:

1) Would the TPU heel lift absorb more energy than the conventional heel lift when loaded with compressive and shear force during static testing?

The second purpose was addressed by the following question:

2) Would the TPU heel lift absorb more force and energy than the conventional heel lift during dynamic repetitive impacts when using a prosthetic foot attached to an air driven horizontal impactor?

The third purpose was addressed by the following question:

3) Which heel lift condition would result in better symmetry of walking for the braking and propulsive phases based on the ratio of the amputated and non-amputated limb when measuring power, energy, and GRF, respectively?

Chapter 3 - Methodology

Instrumentation

Chatillon® TCD1100 Force Tester Instrumented with American Mechanical Technology Incorporated (AMTI®) Force Plate

The Chatillon® force tester (see Figure 7) and the AMTI® force plate (see Figure 8) was used to measure the energy absorption properties of the conventional prosthetic heel lift and TPU materials under static testing conditions. Energy absorption refers to the ability of a material to deform under a load and distribute the impact energy over a large area (Di Landro et al., 2002). The energy absorption properties of each material were analyzed by compressing each sample against the TLC series load cell by 25 mm and decompressing it to its original form, for 15 trials or cycles. The force tester collected measures of vertical force and displacement, while the force plate collected force data in the X, Y, and Z directions. The force tester was fitted with angled wooden blocks (see Figure 9) to allow the material to be compressed at a 30° angle, resulting in both compressive and shear forces being applied on test samples. Force plots were created with these data to show the compressive force versus material compression and shear force versus shear displacement. The compression force is the force that is generated when a load compresses a material, while the material compression is the degree to which the material compresses under the given load (Hall, 2011). The shear force is the force that is generated in a direction that is parallel to the surface of the material being tested, while the shear displacement is the degree to which the material is displaced in a direction that is parallel to the material's surface (Hall, 2011). The enclosed area of these plots then provides information about the energy absorption capabilities of each sample.

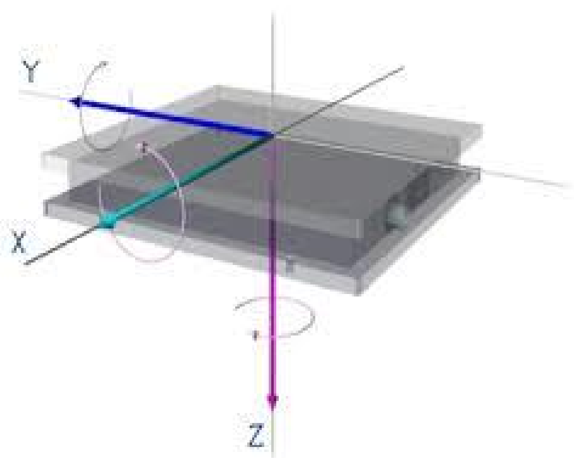
Figure 7

Chatillon® TCD1100 Force Tester

Note: Reprinted from https://www.ametektest.com/service-and-support/obsolete-products/looking-to-replace-your-test-equipment/looking-to-replace-your-tcd225-test-machine

Figure 8

American Mechanical Technology Incorporated Force Plate



Note: Reprinted from https://www.amti.biz/fps-guide.aspx

Figure 9

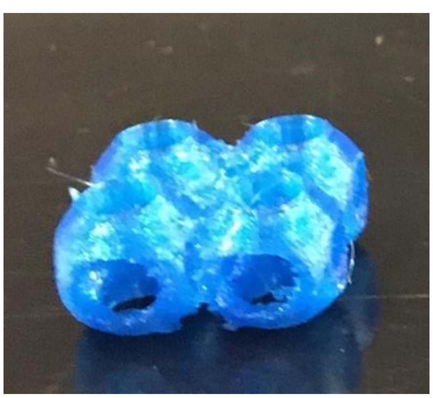
Chatillon® TCD1100 Force Tester with Modified Blocks

Thermoplastic Polyurethane

This study used 3D printed TPU pieces that were arranged to mimic a heel lift (see Figure 10). The TPU is a blend of polymers that contains both hard segments of urethane groups and soft segments of polyol that allow it to retain both the elasticity of rubber and the strength of plastic (Lin et al., 2016). These characteristics make TPU an ideal material to be used in various applications that require increased energy absorption, such as a heel lift for transtibial amputees. The TPU pieces that were used are similar in height when compared to a conventional heel lift.

Figure 10

A Thermoplastic Polyurethane Sample



Conventional Prosthetic Heel Lift

For this study, the researcher used a conventional rigid heel lift (see Figure 11). A rigid heel lift is an orthotic device that is currently recommended for amputees. These inserts aid in proper prosthetic foot alignment when adapting the foot to different types of footwear, particularly for shoes with flat soles as the heel of a prosthetic foot is typically raised above the forefoot. Despite the need for increased shock absorption, these lifts are made from firm materials that allow for little compression to ensure that the user feels stable during gait. Although this heel lift is commonly used and widely prescribed, very little is known about its energy absorbing capabilities or effects on gait kinematics and kinetics. To date, few studies have assessed the effects of heel lifting on gait and current evidence shows changes in kinematics of transtibial amputees when using heel lifts (Yeung et al., 2012).

Figure 11

Conventional Prosthetic Heel Lift

Solid Ankle-Cushion Heel (SACH) Foot

The SACH foot (see Figure 12) is a non-articulated prosthetic foot that is commonly prescribed due to its low cost and simple design. The SACH foot is commonly composed of a soft heel made of rubber, and a rigid keel (or center) that is often made with wood and aims to provide stability throughout midstance. Despite the many advantages of the SACH foot, several studies continue to report gait asymmetry, and non-optimal kinetic and kinematic measures of gait for amputees that use this foot (Macfarlane et al., 1997; Smith et al., 2004). As the SACH foot is a commonly used passive prosthetic foot for transtibial amputees, in the current study this device was used in combination with a flat soled shoe during dynamic testing to mimic the conditions seen during human testing.

Figure 12

Solid Ankle-Cushion Heel (SACH) Prosthetic Foot

Advanced Mechanics Technologies Incorporated Force Plate

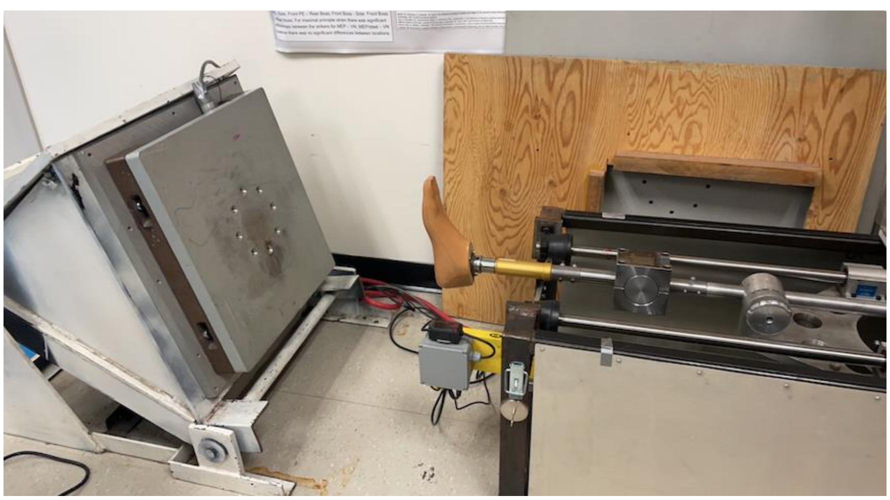
The AMTI® force platforms are mechanical sensing systems that are commonly used to quantify measures of gait in three axes (X, Y, and Z; Lamkin-Kennard & Popovic, 2019). These platforms measure kinetic and temporal information such as GRF, center of pressure, and moment around each of the axes (Lamkin-Kennard & Popovic, 2019). When a force is applied to the platform, the sensors experience deformation and translate the information into measurable signals that are equal to the applied force (Lamkin-Kennard & Popovic, 2019). These platforms are connected to amplifiers and interfaced with a computer through a 12-bit resolution analog-to-digital converter using the PowerLab® hardware and software. This technology allows the information to be displayed on the computer as force versus time plots, in real time, allowing the researcher to view and analyze the data. The AMTI® force platforms have previously been shown to provide strong inter-rater (ICC = .9) and intra-rater (ICC = .95) reliability during various locomotion activities (Moir, 2008).

Air Driven Foot Impactor Instrumented with an AMTI® Force Plate

The foot impactor shown in Figure 13 contains a cylinder with an air driven piston that connects to the foot assembly. The compressed air in the piston was adjusted by a pressure regulator to control the speed of the impactor. The air pressure was calibrated for vertical heel-strike speed ranging from 0.45 m/s to 0.7 m/s. The prosthetic foot attached to the metallic rod of the air piston stroke against an AMTI® force plate to measure the impact forces over time. The foot impactor was also instrumented with a piezoelectric accelerometer and ICP amplifier to collect measures of impact acceleration. For the current study, the measures of force and acceleration were collected simultaneously via a PowerLab® hardware and software unit.

Figure 13

Air Driven Impactor



Piezoelectric Accelerometer and Interfaces

The prosthetic foot impactor rod was instrumented with a piezoelectric accelerometer sensor designed to measure the impact accelerations in the X, Y and ZZ directions (a_x, a_y and a_Z;

Jefferies et al., 2017). A PCB© model 482A04 integrated circuit piezoelectric sensor (ICP) amplifier and AD Instruments® PowerLab26T analog to digital converter captured the signals from the accelerometer during each impact and displayed the results in real time. The acceleration measures would be integrated to obtain the velocity as well as the displacement as will be detailed later (see ***Dynamic Testing*** under **Procedure**).

PowerLab® Software

The PowerLab® data acquisition hardware is used for data recording and signal processing, and when used in combination with the LabChart® software, it can be used to collect up to 32 channels of data in real-time. For the purpose of this study, the PowerLab® analog to digital interface and LabChart® systems were used to collect and synchronize the accelerometer and force plate data at a sampling frequency of 20 kHz. This interface setup allowed the researcher to collect, view, and analyze the data from all of the equipment simultaneously and in real-time.

Brower® Timing Gates

Brower® timing gates were used to determine the walking speed of the participants, which was computed based on the length of time it took for the participant to walk the given distance. The timing gates use an infra-red signal and detector to determine when the light beam is broken, which in turn provides information about the beginning and end of a movement. Brower® timing gates have been found to be highly reliable when used to measure elapsed times of various sprinting speeds, with an ICC between .91 and .99 for each of the sprinting speeds assessed (Shalfawi et al., 2012). Additionally, when compared with a global positioning system (GPS), Brower® timing gates were found to be more reliable and valid for measuring sprinting time (Waldron et al., 2011).

Procedure

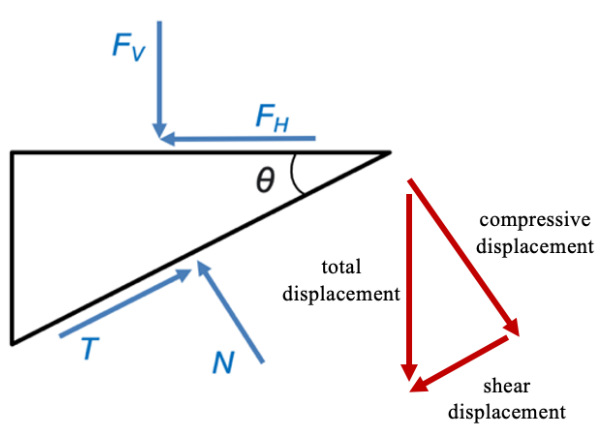
Static Testing

Each type of material underwent static compression testing to analyze the energy absorption capabilities. The samples tested included TPU material arranged to form a heel lift and a conventional prosthetic heel lift. The samples were compressed for 15 trials at a speed of 25 mm/min to ensure that the testing could be considered static. The capacity of the force tester was set to 3000 N to prevent damaging the Chatillon® force tester. The force tester was modified using angled wooden blocks to allow the material to be compressed at a 30° angle, resulting in both compressive and shear forces being applied.

The Chatillon® force tester collected measures of vertical force and displacement while the AMTI® force plate collected the loading and unloading data in the X, Y, and Z directions for each material. The vertical (or total) displacement, shear, and compression displacements, as well as the shear force (T), compressive force (N), horizontal force (F_H) and vertical force (F_V) obtained with the force tester or force plate can be seen in Figure 14, together with displacement components.

Figure 14

Force and Displacement Diagram



The force measures found in the X and Y directions with the AMTI® force plates were then used to find a resultant horizontal force using Equation 1.

$$F_H = \sqrt{Fx^2 + Fy^2} \tag{1}$$

where:

F_X = force in the X direction

F_Y = force in the Y direction

After obtaining the resultant horizontal force, the compressive force (N) and shear force (T) were calculated using Equations 2 and 3, respectively.

$$N = F_V \cos\theta - F_H \sin\theta \tag{2}$$

$$T = F_H \cos\theta + F_v \sin\theta \tag{3}$$

where:

$\theta = 30°$

F_v = force in the Z direction

Using the MATLAB® software, force versus displacement plots were created for each loading and unloading cycle of the vertical, normal and shear forces, and can be seen in Figures 15 through 17 respectively.

Figure 15

Vertical Force Versus Vertical (Total) Displacement

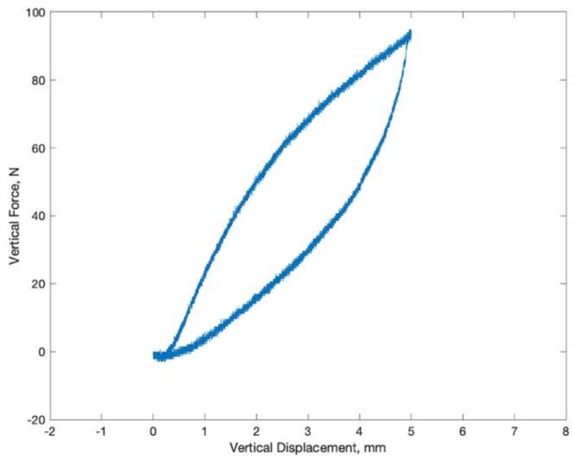


Figure 16

Normal Force Versus Compressive Displacement

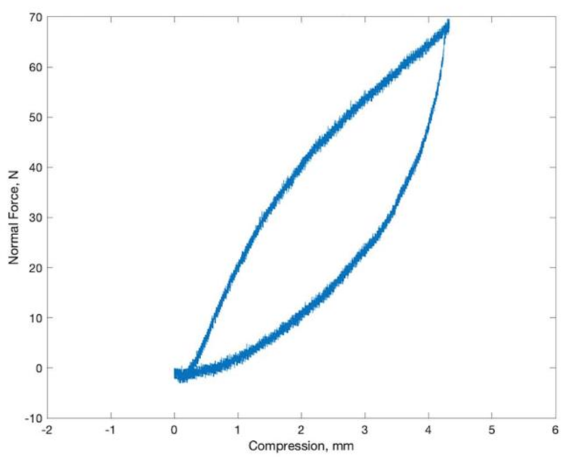
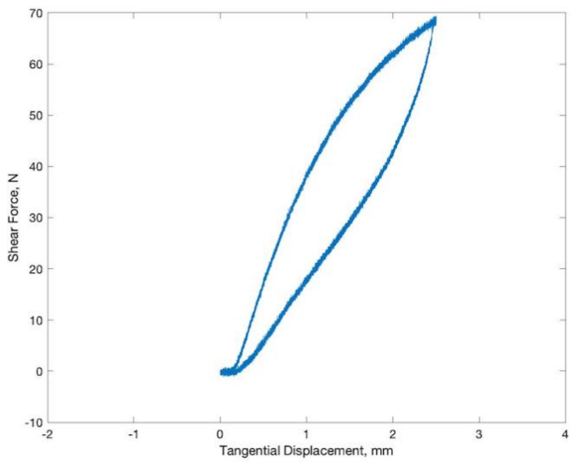


Figure 17

Shear Force Versus Tangential Displacement



Measures of shear, compression, and total energy absorption were found using Equations 4 through 6, respectively. The percentage of energy absorption of the tested material was obtained by taking the average of energy absorptions across 14 cycles.

$$\text{Shear Energy Absorption} = \frac{\text{enclosed area of T versus shear displacement plot}}{\text{area under loading plot of T versus shear displacement}} \tag{4}$$

$$\text{Compression Energy Absorption} = \frac{\text{enclosed area of N versus compression plot}}{\text{area under loading plot of N versus compression}} \tag{5}$$

$$\text{Total Energy Absorption} = \frac{\text{enclosed area of Fz versus total displacement plot}}{\text{area under loading plot of Fz versus total displacement}} \tag{6}$$

Dynamic Testing

Dynamic testing was performed using an air driven piston impactor to assess the properties of each heel lift condition under simulated repetitive, dynamic impacts. Each heel lift condition (TPU heel lift, conventional heel lift, and no heel lift) was combined with a passive prosthetic SACH foot and a flat soled shoe. These combinations aimed to mimic the footwear conditions used during human testing and what would commonly be seen in a real-life application. The prosthetic foot was mounted to the impact rod at an angle of 30° in relation to the force plate to mimic the angle of the shank in relation to the ground during initial heel-ground contact (Klute et al., 2004). Impacts were performed at 26 different velocities ranging from 0.45 m/s to 0.7 m/s to simulate the potential range of vertical heel-strike velocities that are commonly seen in amputee walking (Houdijk et al., 2009; Sions, 2019). A regression equation was used to estimate impact velocity from air pressure (in psi) measures, see Equation 14.

The acceleration, *a*, collected by the piezoelectric accelerometer mounted on the prosthetic foot impactor rod was integrated twice; first to compute velocity based on Equation 7, and again to compute the displacement based on Equation 8.

$$v(t) = v_0 + \int_{t_0}^{t} a(t)dt \tag{7}$$

where:

t = time in seconds;

v = velocity at time t, in m/s;

t_0 = initial time, in seconds;

v_0 = initial velocity or velocity at t_0, in m/s; and

a = acceleration (m/s^2).

$$s(t) = s_0 + \int_{t_0}^{t} v(t)dt \tag{8}$$

where:

s_0 = displacement in m at t_0;

s = displacement in m;

and t_0, t, and v have the same meanings as in Equation 7. It is noted that, after computation by Equations 7 and 8, the computed velocity v(t) and displacement s(t) were converted to the convenient units of cm/s and cm, respectively.

The AMTI® force plate extracted the force data in the Z direction for each heel condition and heel-strike velocity, while the accelerometer mounted on the prosthetic foot impactor rod collected acceleration which, upon integrations twice, yielded displacement to allow for loading and unloading energy to be calculated, based on Equation 9. Energy absorption was then calculated based on Equation 10.

$$E_{loading} = \int_{t_0}^{t_m} F(t)v(t)dt,\ \ E_{unloading} = \int_{t_m}^{t_e} F(t)v(t)dt \qquad (9)$$

where:

t_0 and t_m = time instants representing the beginning and end of the loading period, in seconds;

t_m and t_e = time instants representing the unloading period, in seconds;

F = force in newtons (N); and

v = velocity in m/s

$$\%\ \text{energy absorbed} = \frac{E_{loading} - E_{unloading}}{E_{loading}} \qquad (10)$$

Human Participant Testing

Participants. The researcher aimed to recruit 20 transtibial amputee participants for this study from Northland Prosthetic and Orthotics Inc. Unfortunately, only seven transtibial amputees volunteered to participate in the study to address the third research question, which aimed to examine the kinetic symmetry of walking with each heel lift condition. The kinetic measures included force in newtons (N), power in watts (W), and energy in joules (J). A priori power of analysis, however, supported a sample size of seven participants based on an effect size of η^2=0.25, power of rejection of 80% at $p<.05$ for each of the kinetic measures across the heel lift conditions. The researcher collected additional participant information regarding the amputated limb, type of prosthetic foot, reason for amputation, and time since amputation.

Inclusion Criteria. Participants included males and females from 18 to 80 years of age with a transtibial amputation and a passive prosthetic limb. Participants must have used their prosthesis for at least six months and must have been able to walk without the use of an assistive device, such as a cane. All participants must have been able to understand verbal and written instructions. Participants must have had the capacity to give informed consent. Additionally, all participants were required to wear flat soled shoes during data collection. Finally, all participants were required to provide proof of COVID-19 vaccination and COVID-19 screening through the use of Lakehead University's Mobile Safety Application.

Exclusion Criteria. Participants were not included in the study if they had lesions, defined as skin injuries with visible tissue destruction, or pain in the residual limb that impeded gait. Additionally, participants were not included if they had a history of ankle, knee, or hip trauma within the last year. A history of arthritis, pain in the lower extremities or spine, or a health condition that impeded their gait also resulted in an individual being ineligible to participate. These criteria were selected to minimize variability in gait between subjects due to amputee conditions.

Recruitment. Participants were recruited through word of mouth, social media advertisements, and posters (see Appendix A) placed at Northland Prosthetics and Orthotics Inc., a local prosthetics and orthotics clinic. Participants interested in the study contacted the researcher based on the information provided to the participants on the poster and through word-of-mouth. If the participant met the requirements, inclusion criteria, and COVID-19 regulations established by Lakehead University before coming to campus, the researcher set a date and time that worked best for the participant to meet in the Sanders Building (room SB-1028) for an initial meeting and data collection.

Data Collection. Participants interested in partaking in the study attended an initial meeting and a data collection session in SB-102810281028, School of Kinesiology's research lab located in the Sanders Building at Lakehead University. The initial meeting took approximately 10 minutes and the data collection session 70 minutes to complete. During the initial meeting, the researcher answered any questions or concerns that the interested participants had about taking part in this study and provided them with the information letter (see Appendix B). If a potential participant met the inclusion/exclusion criteria, he/she was then provided with a letter of informed consent (see Appendix C) to read, sign, and return to the researcher. Once participants had signed the informed consent, they were provided with a Get Active Questionnaire (see Appendix D) and a general demographic and health questionnaire (see Appendix E). The Get Active Questionnaire was used to determine if the participants were physically capable of participating in the study. The general demographic questionnaire included data regarding the participants' height, mass, sex, gender, and presence of any condition listed in the exclusion criteria. It also included additional information regarding the type of prosthetic foot, amputated limb, reason for amputation, and time since amputation occurred. If the participants met these requirements, inclusion criteria, and agreed to participate, they were given a chance to become familiar with the equipment and move on to the data collection session. The researcher also gave the participants the opportunity to complete the testing session the same day as the initial meeting or to choose a date and time that worked best for them.

Once a participant completed the preliminary meeting, he/she was given the option to partake in the data collection session. Before data collection began, the researcher fit the participant with a conventional heel lift and an innovated TPU heel lift, respectively, to allow the participant to get familiarized with the equipment and testing protocols before collecting the actual data for the study. Each participant was allowed 10 practice trials for each heel lift type at the normal walking speed across two AMTI® force plates located in the School of Kinesiology research lab (room SB-1028). Once the participant was familiar with the equipment, the researcher randomly selected the heel lift testing condition to limit ordering effects. The conditions included walking without a heel lift, walking with the conventional heel lift, and walking with the TPU heel lift. Randomization was done using the Latin Square method. This method involved the arrangement of conditions in an $n \times n$ matrix, so that each condition was used once in each row and once in each column. In this study, a 3 × 3 design (see Appendix F) was used as there were three different walking conditions. Once the participants were given their condition, they were provided with another chance to practice walking with the given condition to minimize hesitancy and become comfortable with the walking condition.

After the participants were comfortable with the selected condition, they were instructed to walk across the two AMTI® force platforms for a complete gait cycle to collect the GRF which would then be used to compute the power and energy values. Before the power value could be computed, the velocity of a foot had to be evaluated using Equation 11.

$$v = v_0 + \int_{t_0}^{t} \frac{F(t)}{m} dt \tag{11}$$

where m is the mass of the participant, in kg. F represents any one of the GRF components collected by the force plates. It should be pointed out that Equation 11 can be used for the braking as well as the propulsion phases. As a result, t_0 is set to be the time instant signalling the beginning of either the braking phase or the propulsion phase. Accordingly, the upper limit of integration, t, is varied within the braking or the propulsion phase. In other words, for data collected from one participant, Equation 11 was executed 12 times (3 components × 2 phases × 2 force plates).

The power values were subsequently calculated using Equation 12, and the energy values were calculated based on Equation 13. Again, Equations 12 and 13 were executed 12 times, as with Equation 11.

$$P = F(t)v(t) \tag{12}$$

$$E = \int_{t_0}^{t} P(t)dt \tag{13}$$

where t is time in seconds, having the same meaning as in Equation 11. P is power at time t, in watts, and E is energy at time t, in joules

All GRF signals were collected simultaneously from the AMTI® force plates through the PowerLab® hardware and LabChart software. This information could then be viewed and analyzed by the researcher on a computer using the LabChart® software.

For each walking condition, the participant was instructed to perform five walking cycle trials across the two force plates with the non-amputated leg striking one plate and the amputated leg striking the other plate. The type of leg to strike the first platform during the walking trial was randomly selected using a random generator for each condition, respectively. A trial was considered valid if the participant hit each of the force plates with the complete base of the foot for either the amputated or non-amputated leg. Furthermore, if the participant hesitated or broke natural stride, the trial was not considered valid, and the participant was instructed to try it again. Each trial was performed at a self-selected walking speed in order to best replicate normal walking for each participant. The Brower® timing gates measured the length of time it took for the participant to walk the given distance across the force platforms to monitor the average walking speed for each condition. Rest periods of 10 s were given between leg trials and a rest period of 3 minutes was given between conditions to minimize fatigue.

Dependent and Independent Variables

For the static testing, the independent variable was heel lift condition (TPU heel lift and conventional heel lift), and the dependent variable of interest was energy absorption. For the dynamic testing on the air driven impactor, the independent variable was heel lift condition (TPU heel lift, conventional heel lift, and no heel lift), and the dependent variables of interest were force in the Z direction and percentage of energy absorption. For the human participant testing, the independent variables were heel lift condition (TPU heel lift, conventional heel lift, and no heel lift) and leg type (intact and residual limb). The dependent variables of interest were resultant GRF, power, and energy for the braking and propulsive phases of the walking cycle, respectively.

Data Analysis

Descriptive and inferential statistical analysis techniques were used to address each research question separately.

Static Testing

The first research question aimed to assess which material absorbed a higher percentage of energy. This result was determined using the information obtained from the Chatillon® force tester, the AMTI® force plate and MATLAB® software. The compression, shear, and total energy absorptions were found for each material tested. The heel lift materials were compared descriptively using means and standard deviations in terms of energy absorbed as a percentage of the loading energy. The percentage of energy absorbed for each heel lift material was computed by dividing the energy dissipation of the material over the loading energy for measures of compressive, shear, and total energies.

Dynamic Testing

The second research question aimed to assess which heel lift condition generated less impact force and absorbed a higher percentage of energy. This outcome was determined using the information obtained from the force platforms and an accelerometer. The impact force was the force in the Z direction off the AMTI® force plate. The percentage of energy absorption was found using Equation 10 for each material tested.

The no heel measures of force and energy were subtracted from the TPU and conventional heel lifts' measures of force and energy, respectively, to scale the data for further comparison. The scaled measures of force and energy for the TPU and heel lift conditions were averaged across 10 trials for each impact velocity. Repeated measures t-tests were conducted to examine the differences between the TPU heel lift and conventional heel lift across the 26 impact speeds in terms of energy absorption and impact force produced in reference to the no heel lift condition. Means and standard deviations were used to plot the impact force and energy absorption values for the heel lift conditions.

Human Participant Testing

Descriptive statistics including means and standard deviations were found to tabulate the demographic data. Averages across the five trials were computed for the amputated and non-amputated leg, respectively, for each heel lift condition on measures of GRF and walking speed. A MATLAB® script facilitated the computation of maximum force, power, and energy of the amputated and non-amputated legs during both the braking and propulsive phases of gait ®based on Equations 1212 and 1313, as previously stated.

The symmetry of walking was assessed by determining the ratio of force, power, and energy measures for the amputated limb over the non-amputated limb. One-way repeated measures analysis of variance (ANOVA) were conducted to examine the effect of heel lift condition (TPU heel lift, conventional heel lift, and no heel lift) on measures of force, power, and energy during the braking and propulsive stages of the walking cycle, respectively. If significant differences were found among the heel lift conditions for measures of force, power or energy, a Tukey's post hoc analysis was conducted for pair mean comparisons.

Chapter 4 - Results

The results of this study addressed each research question independently when comparing the TPU and the conventional prosthetic heel lifts. The static testing analysis included measures of compressive, shear, and total energy absorption. The dynamic testing analysis included measures of energy absorption and force. The human testing included measures of power, energy absorption, and force.

Static Testing

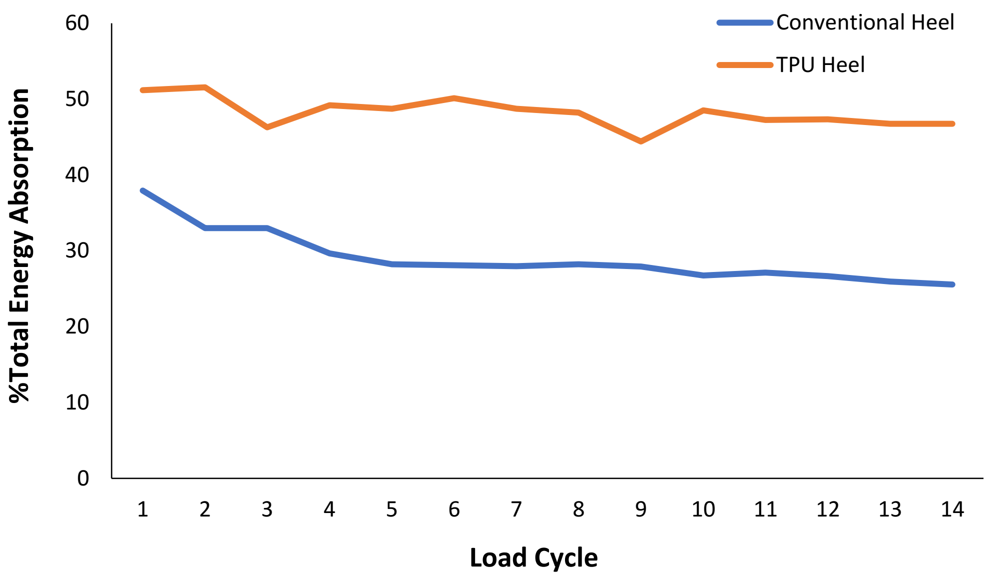
Research Question One

Would the TPU heel lift absorb more energy than the conventional heel lift when loaded with compressive and shear force during static testing?

TPU Heel Versus Conventional Heel Static Testing. Before conducting the statistical analysis, the first cycle for each sample tested was removed and only cycles 2 through 15 were used due to markedly high energy absorption values that were consistently seen in the first cycle across each material tested. When comparing the conventional heel lift with the TPU heel lift, the TPU heel lift absorbed the highest mean percentage of total energy (M = 48.2, SD = 1.9) when compared with the conventional heel lift (M = 29, SD = 3.4). Figure 18 shows the difference between the TPU heel lift and the conventional heel lift for measures of mean percent total energy absorption over 14 loading cycles.

Figure 18

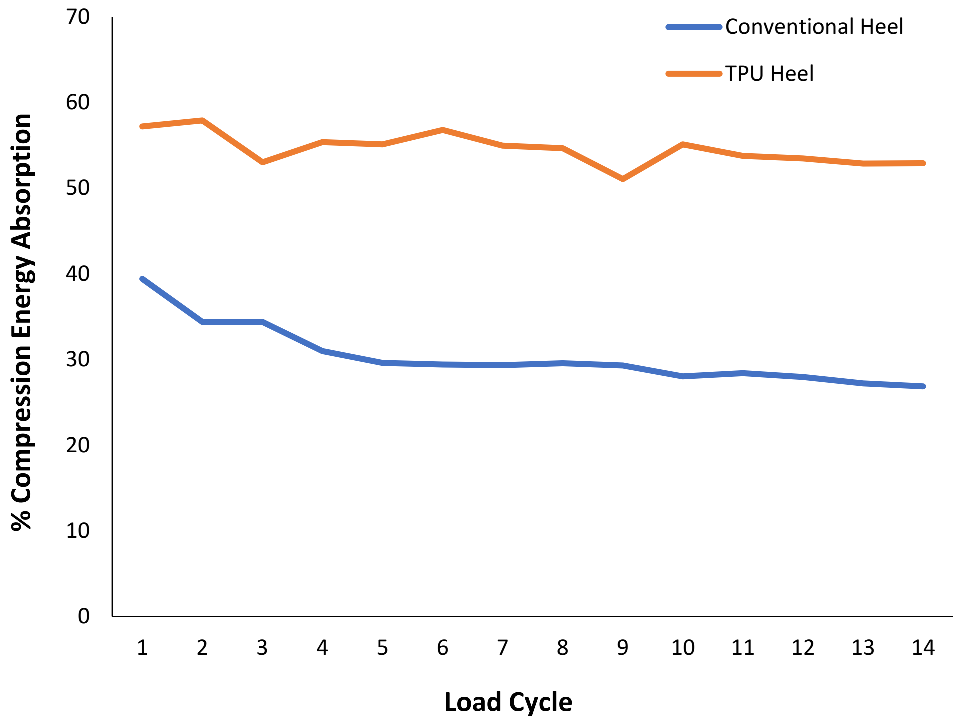
Mean Percent Total Energy Absorption for TPU and Conventional Heel Lift



Energy absorption was analyzed further by determining the amounts of compressive and shear energies absorbed by each material over the 14 load cycles. Similarly, the TPU heel lift absorbed the highest mean percentage of compressive energy ($M = 54.6$, $SD = 1.9$) when compared to the conventional heel lift ($M = 30.3$, $SD = 3.5$). A comparison of the compressive energy absorption means for the TPU heel lift, and the conventional heel lift are shown in Figure 19.

Figure 19

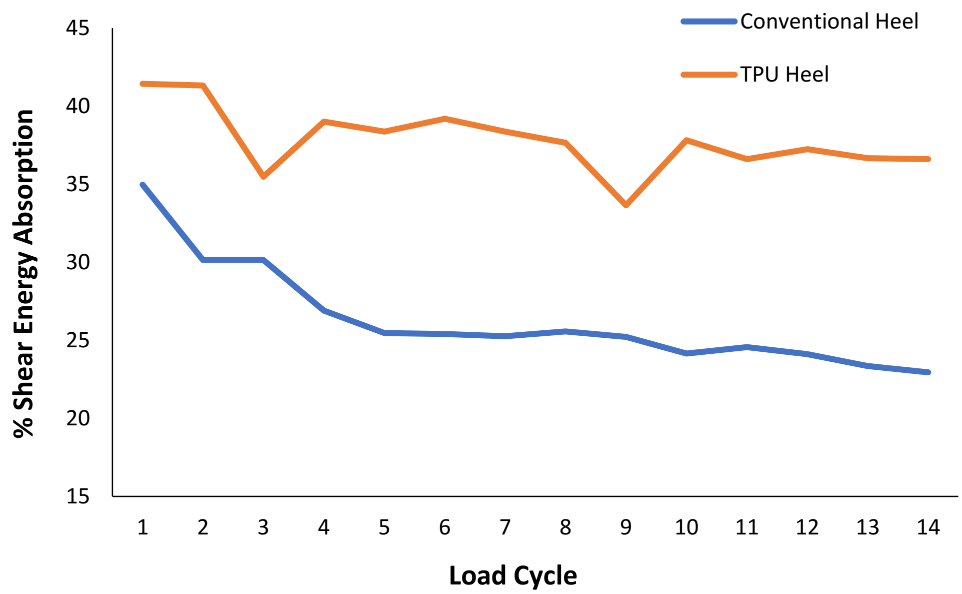
Mean Percent Compressive Energy Absorption for TPU and Conventional Heel Lift



A difference was again seen in the mean percentage of shear energy absorption between each footwear material, with the TPU heel absorbing a higher amount of shear energy (*M* = 37.8, *SD* = 2.1) when compared with the conventional heel lift (*M* = 26.4, *SD* = 3.3). A comparison of the mean percentage of shear energy absorption is shown in Figure 20.

Figure 20

Mean Percent Shear Energy Absorption for TPU and Conventional Heel Lift



Dynamic Testing

Research Question Two

Would the TPU heel lift absorb more force and energy than the conventional heel lift during dynamic repetitive impacts when using a prosthetic foot attached to an air driven horizontal impactor?

Regression Equation to Predict Velocity from PSI Measures. The results shown in Table 1 were obtained for 26 impacts and were used to conduct the regression analysis to predict velocity from measures of pressure per square inch (PSI) as shown in Equation 14 before collecting the dynamic repetitive impact data for the TPU and conventional heel. The model shown in Equation 14 was significant, $F(1, 24) = 11587110.679$, $p < .001$ and it found that air pressure (in psi) significantly predicted velocity ($B = .19$, $p < .001$).

$$y = 0.01911x + 0.04463 \tag{14}$$

where:

x = pressure, in psi; and

y = velocity, in m/s.

Table 1

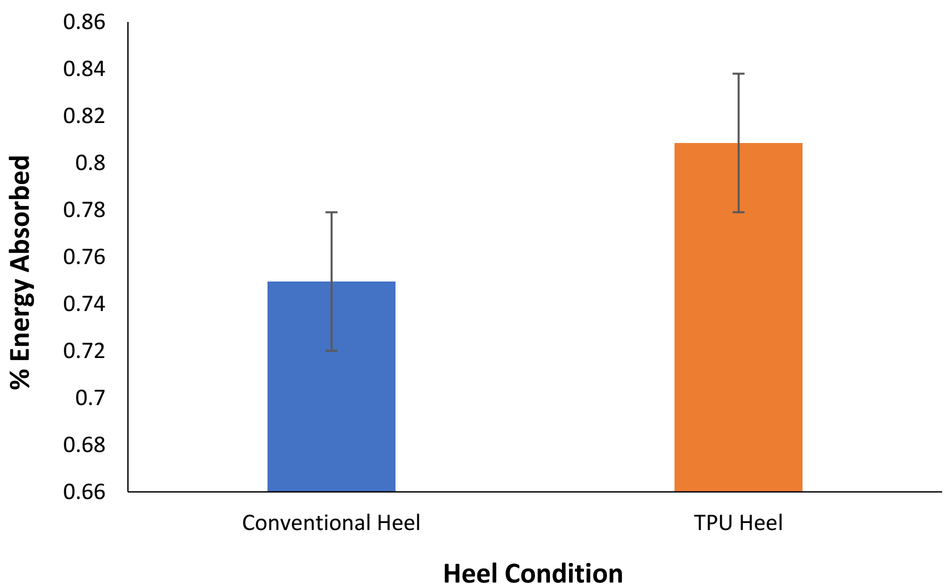
Pressure and Corresponding Velocities

Velocity (m/s^2)	Pressure (psi)
0.45	21.22
0.46	21.75
0.47	22.27
0.48	22.79
0.49	23.32
0.50	23.84
0.51	24.37
0.52	24.89
0.53	25.41
0.54	25.91
0.55	26.46
0.56	26.98
0.57	27.51
0.58	28.03
0.59	28.55
0.60	29.08
0.61	29.60
0.62	30.12
0.63	30.65
0.64	31.17
0.65	31.70
0.66	32.22
0.67	32.74
0.68	33.27
0.69	33.79
0.70	34.31

Conventional Heel Versus TPU Heel Dynamic Testing. The researcher addressed the second research question by conducting repeated measures t-tests to compare the average energy absorption and force produced, for both the TPU heel lift and conventional heel lift across the 26 impact speeds used. The results of the t-tests showed that the mean energy absorption of the conventional heel lift was significantly lower (*M* = .75, *SD* = .29) than the TPU heel lift (*M* = .81, *SD* = .32, *t* (25) = -4.079, *p* < .001, *d* = .06, *CI* [-1.237, -.351]. A comparison of the mean energy absorption of the TPU heel lift and conventional heel lift is shown in Figure 21.

Figure 21

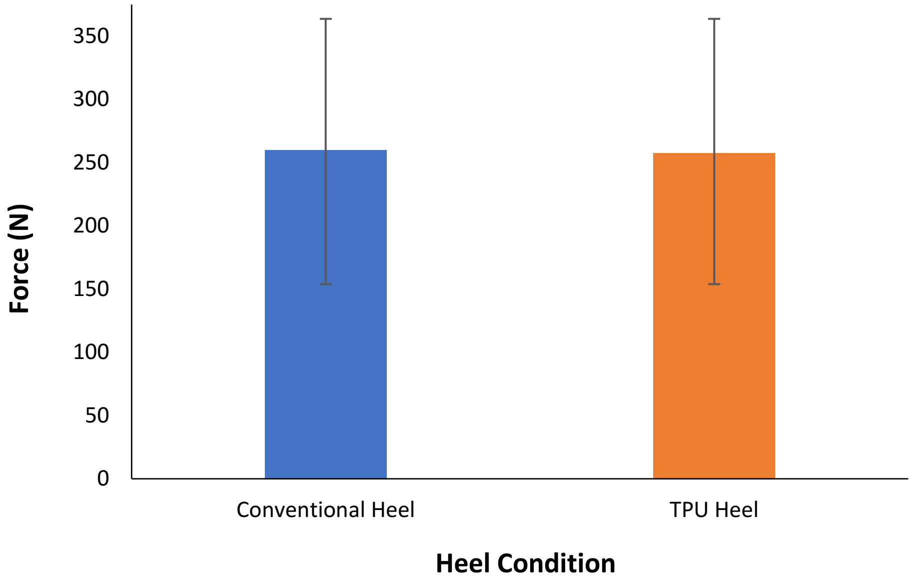
Heel Lift Comparison of Energy Absorbed During a Simulated Heel-strike



The results of the t-tests showed that the mean force production of the conventional heel lift was significantly higher (*M* = 260.08, *SD* = 57.34) than the TPU heel lift (*M* = 257.49, *SD* = 57.82, *t* (25) = 1.945, *p* < .001, *d* = 2.16, *CI* [.684, 1.697]. A comparison of the mean force production of the TPU heel lift and conventional heel lift is shown in Figure 22.

Figure 22

Heel Lift Comparison of Force Produced During a Simulated Heel-strike



Human Participant Testing

Research Question Three

Which heel lift condition would result in better symmetry of walking for the braking and propulsive phases based on the ratio of the amputated and non-amputated limb when measuring power, energy, and GRF, respectively?

Power.

Braking. Descriptive statistics seemed to indicate that the power ratio of the amputated and non-amputated limb during the braking phase of walking was the most similar with the use of the conventional heel (M = .947, SD = .11), which was closely followed by the TPU heel (M = .931, SD = .09), and then the no heel condition (M = .918, SD = .08). A comparison of the mean power ratios for each heel lift condition is shown in Figure 23 and Table 2.

Figure 23

Ratio of Power for Each Heel Condition During Braking

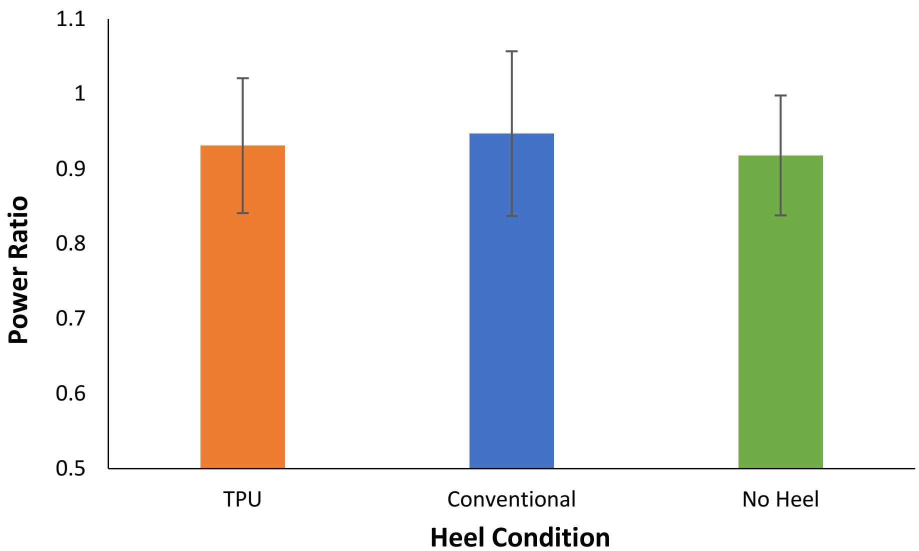


Table 2

Descriptive Statistics of Mean Ratio of Power During Braking

	Mean	Standard Deviation
TPU	.931	.09
Conventional	.947	.11
No Heel	.918	.08

A one-way repeated measures ANOVA determined that the mean ratio of power of the amputated and non-amputated limb during the braking phase of walking did not differ significantly across the three heel conditions ($F(2, 8) = .335$, $p = .725$, $\eta^2 = .08$).

Propulsion. Descriptive statistics seemed to indicate that the power ratio of the amputated and non-amputated limb during the propulsion phase of walking was the most similar with the use of the conventional heel ($M = .929$, $SD = .10$), which was closely followed by the TPU heel ($M = .917$, $SD = .08$), and then the no heel condition ($M = .894$, $SD = .10$). A comparison of the mean power ratio of the amputated and non-amputated limb during propulsion for each heel lift condition is shown in Figure 24 and Table 3.

Figure 24

Ratio of Power for Each Heel Condition During Propulsion

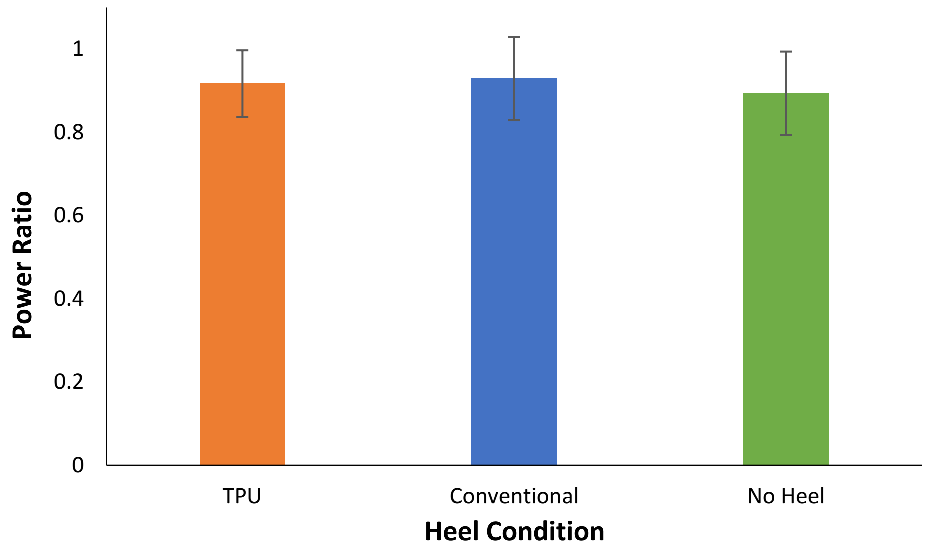


Table 3

Descriptive Statistics of Mean Ratio of Power During Propulsion

	Mean	Standard Deviation
TPU	.917	.08
Conventional	.929	.10
No Heel	.894	.10

A one-way repeated measures ANOVA determined that the mean ratio of power measures of the amputated and non-amputated limb during the propulsion phase of walking did not differ significantly across the three heel conditions ($F(2, 8) = .995$, $p = .411$, $\eta^2 = .20$).

Energy.

Braking. Descriptive statistics seemed to indicate that the energy absorption ratio of the amputated and non-amputated limb during the braking phase of walking was the most similar with the use of the TPU heel (M = .957, SD = .22), which was followed by the conventional heel (M = .873, SD = .21), and then the no heel condition (M = .851, SD = .14). A comparison of the mean energy absorption ratio of the amputated and non-amputated limb during propulsion for each heel lift condition is shown in Figure 25 and Table 4.

Figure 25

Ratio of Energy Absorption for Each Heel Condition During Braking

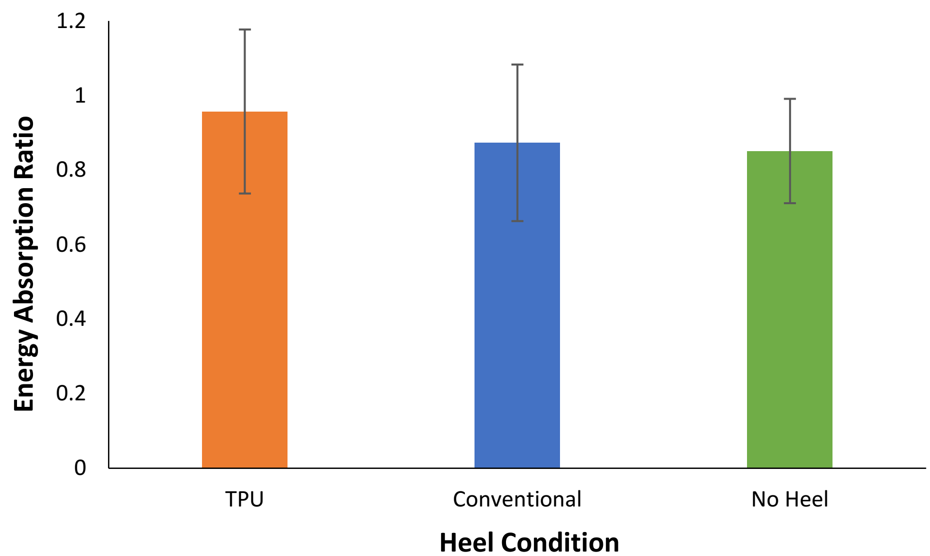


Table 4

Descriptive Statistics of Mean Energy Absorption Ratio During Braking

	Mean	Standard Deviation
TPU	.957	.22
Conventional	.873	.21
No Heel	.851	.14

A one-way repeated measures ANOVA determined that mean energy absorption ratio of the amputated and non-amputated limb during the braking phase of walking did not differ significantly across the three heel conditions ($F(2, 8) = 1.628$, $p = .255$, $\eta^2 = .30$).

Propulsion. Descriptive statistics seemed to indicate that the energy absorption ratio of the amputated and non-amputated limb during the propulsion phase of walking was the most similar with the use of the conventional heel (*M* = .972, *SD* = .16), which was closely followed by the TPU heel (*M* = .863, *SD* = .12), and then the no heel condition (*M* = .804, *SD* = .15). A comparison of the mean energy absorption ratio of the amputated and non-amputated limb during propulsion for each heel lift condition is shown in Figure 26 and Table 5.

Figure 26

Ratio of Energy Absorption for Each Heel Condition During Propulsion

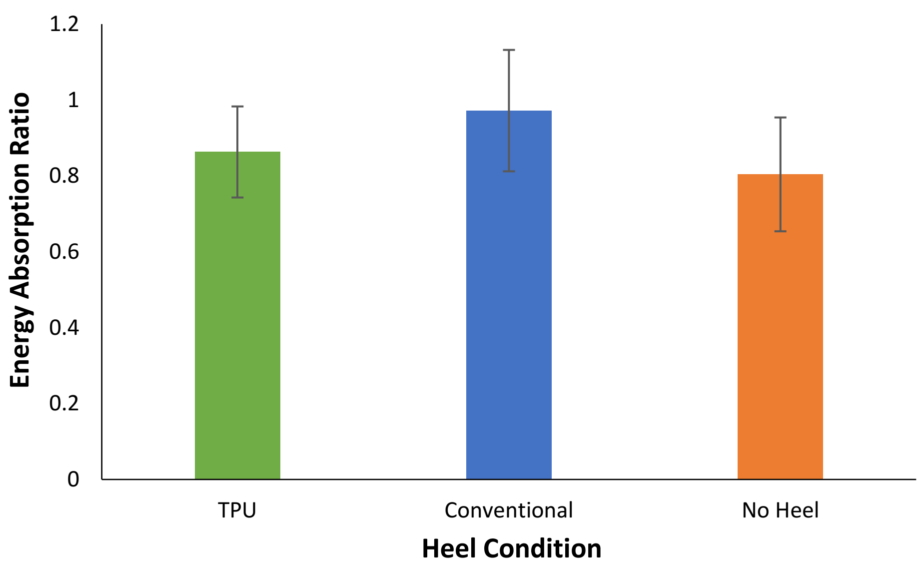


Table 5

Descriptive Statistics of Mean Energy Absorption Ratio During Propulsion

	Mean	Standard Deviation
TPU	.863	.12
Conventional	.972	.16
No Heel	.804	.15

A one-way repeated measures ANOVA determined that the mean ratio of energy absorption of the amputated and non-amputated limb during the propulsion phase of walking differed significantly across the three heel conditions ($F(2, 8) = 12.279$, $p < .05$, $\eta^2 = .75$). A post hoc analysis revealed that the conventional heel had a significantly increased ratio of energy absorption of the amputated and non-amputated limb during propulsion compared to the no heel condition (-.168(95% CI, -.271 to -.065) $p < .05$). Additionally, the TPU heel was found to have a significantly increased energy absorption ratio of the amputated and non-amputated limb during propulsion as compared to the no heel condition (-.059(95% CI, -.154 to .036) $p < .05$). No significant difference was found between the conventional heel and TPU heel conditions, however, for the energy absorption ratio.

Force.

Braking. Descriptive statistics seemed to indicate that the force ratio of the amputated and non-amputated limb during the braking phase of walking was the most similar with the use of the conventional heel ($M = .847$, $SD = .25$), which was very closely followed by the TPU heel ($M = .842$, $SD = .17$), and then the no heel condition ($M = .809$, $SD = .17$). A comparison of the mean force ratio of the amputated and non-amputated limb during braking for each heel lift condition is shown in Figure 27 and Table 6.

Figure 27

Ratio of Force for Each Heel Condition During Braking

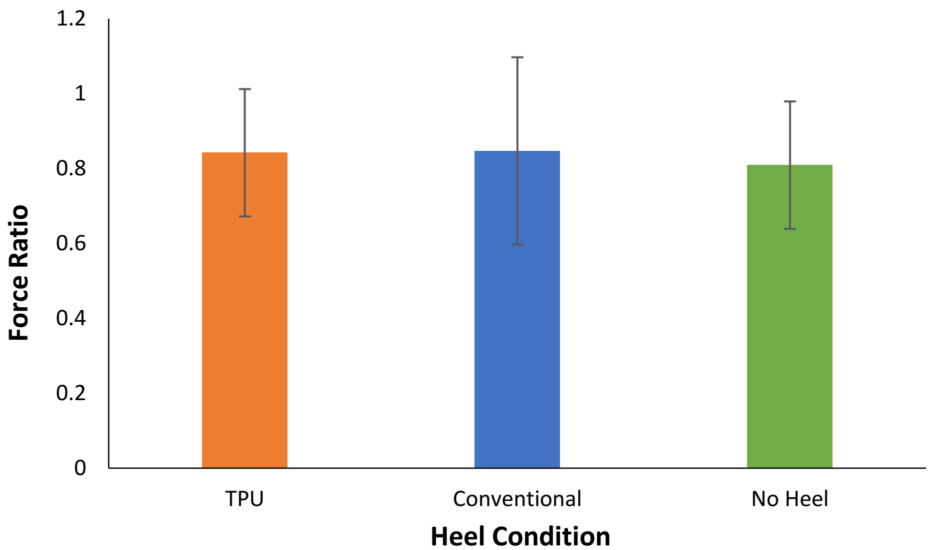


Table 6

Descriptive Statistics of Mean Ratio of Force During Braking

	Mean	Standard Deviation
TPU	.842	.17
Conventional	.847	.25
No Heel	.809	.17

A one-way repeated measures ANOVA determined that mean ratio of force of the amputated and non-amputated limb during the braking phase of walking did not differ significantly across the three heel conditions ($F(2, 8) = .153$, $p = .861$, $\eta^2 = .22$).

Propulsion. Descriptive statistics seemed to indicate that the force ratio of the amputated and non-amputated limb during the propulsion phase of walking was the most similar with the use of the conventional heel ($M = .956$, $SD = .19$), which was followed by the TPU heel ($M = .839$, $SD = .14$), and then the no heel condition ($M = .807$, $SD = .15$). A comparison of the mean force ratio of the amputated and non-amputated limb during propulsion for each heel lift condition is shown in Figure 28 and Table 7.

Figure 28

Ratio of Force for Each Heel Condition During Propulsion

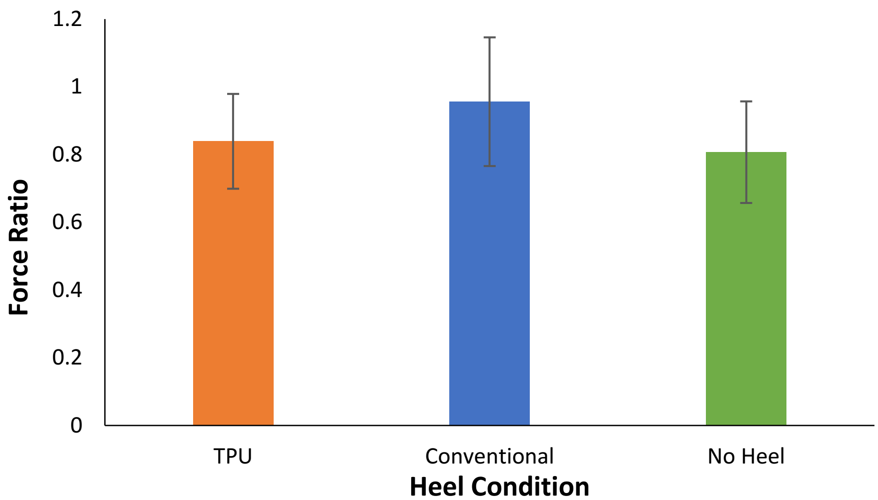


Table 7

Descriptive Statistics of Mean Ratio of Force During Propulsion

	Mean	Standard Deviation
TPU	.839	.14
Conventional	.956	.19
No Heel	.807	.15

A one-way repeated measures ANOVA determined that the mean ratio of force of the amputated and non-amputated limb during the propulsion phase of walking differed significantly across the three heel conditions ($F(2, 8) = 13.803$, $p < .05$, $\eta^2 = .78$). A post hoc analysis revealed that the conventional heel had a significantly increased ratio of force during propulsion compared to the no heel condition (-.150(95% CI, -.228 to -.071) $p < .05$), however, no significant differences were found between the no heel condition and TPU heel or between the conventional heel and TPU heel for the ratio of force.

Chapter 5 - Discussion

Despite significant advancements made in the development of prosthetic devices throughout the years, transtibial amputees continue to encounter gait asymmetry problems and consequently, an increased risk of degenerative joint conditions due to non-optimal gait mechanics (Berge et al., 2005; Collins & Whittle, 1989; Smith et al., 2004). The use of materials that absorb energy during the heel impact of the prosthetic foot can significantly mitigate impact forces during walking and possibly minimize the risk of degenerative joint conditions; however, these materials have not been explored extensively in the transtibial amputee population (Gillespie & Dickey, 2003; Folman et al., 2004; Klute et al., 2004). Yeung et al. (2012), for example, noted significant changes in kinematic gait measures with the use of clinical heel lifts, however, they did not examine kinetic measures, such as GRFs, power, and energy, that are commonly associated with degenerative joint conditions in the transtibial amputee population (Klute & Berge, 2004).

The current study aimed to address some of these problems by creating an innovated prosthetic heel lift using 3D printed TPU material to examine its capability to mitigate the transmission of force through increased energy absorption during foot impact in comparison to a conventionally used prosthetic heel lift. The researcher chose to use the TPU material due to its easily tailorable nature and energy absorbing capabilities (Lin et al., 2016), which allowed for changes to be made in the rigidity and compressive ability of the heel lift. The researcher discussed the results of this study based on the static compression and dynamic impact tests of the heel lift material, as well as the kinetic gait symmetry analysis of transtibial amputees.

Static Testing

The first question in this study was answered by using static compression testing and analysis, which sought to identify the shock absorbing capabilities of an innovated TPU heel lift and compared it to a conventional prosthetic heel lift based on the energy absorption measures. This information is essential for transtibial amputees, as adequate energy absorption is necessary in the materials used between the foot and ground to overcome the loss of the natural mechanisms involved in energy absorption and return, such as the muscles of the shank and the heel pad. Hence, energy absorption relies significantly on the prosthetic device and footwear materials (Collins & Whittle, 1989; Rose et al., 2015).

The results of the static testing seemed to indicate that the TPU was more effective in absorbing shear and compressive forces, and total energy when compared to the conventional heel lift. Across 14 static loading and unloading cycles, the mean energy absorption of the TPU heel lift in terms of total, compression, and shear energies was 48.2%, 54.6%, and 37.8%, respectively. Through observing the mean energy absorption of each material, the TPU heel lift seemed to perform better than the conventional heel lift, which showed total, compressive, and shear mean energy absorption values of 29%, 30.3%, and 26.4%, respectively.

The TPU heel lift absorbed about 10% to 20% more energy than the conventional heel lift. Palhano et al. (2013) used similar testing methods to examine the energy absorption properties and rate of loading of different shoe materials. The researchers found that the materials with increased shock absorption had a decreased rate of loading between 10% and 40%. The outcome of the current study seemed consistent with previous research that showed a decreased rate of loading and decreased peak magnitude of heel-strike force with the use of shock absorbing footwear (Folman et al., 2004; Gillespie & Dickey, 2003). Results from the static testing of the current study provided enough information for the researcher to proceed with the dynamic testing of the TPU heel lift material during foot impact, as a potential avenue to decrease impact force during walking in a transtibial amputee population.

Dynamic Testing

Similar to the research work conducted by Arunachalam and Krishnan (2021), dynamic impact testing provided more information in the current study regarding the material properties of the TPU and conventional heel lift materials when placed under repetitive impact stress (Houdijk et al., 2009; Sions, 2019). The researcher of this study simulated amputees' heel-strike speeds ranging from 0.45 m/s to 0.7 m/s and found differences in force and energy absorption between the TPU and conventional prosthetic heel lifts. These results helped the researcher of this study gained insight into the potential use of TPU material in footwear for transtibial amputees.

Differences in Force for the Dynamic Testing

Gailey et al. (2008) examined the transmission of force during gait in amputees and found that the heel-strike force is significantly higher in amputees than in able bodied populations. Edhe et al. (2000) also found that the need to reduce forces during initial foot impact leads to compensatory or asymmetric gait patterns, however, a shock absorbing mechanism, such as footwear material, might minimize impact forces of the lower extremity and improve the symmetry of walking for amputees.

The results of the current study found that across the 26 velocities tested, the TPU heel generated a significantly lower mean force compared to the conventional heel lift. Chiu and Shiang (2007) used a similar testing method to examine the effect of shock absorbing insoles on force measures during impact to the heel region of the shoe and found that shock absorbing materials significantly reduced peak impact force, at various impact speeds. Research by O'Leary et al.

(2008) also found reductions in for the peak impact force by 6.8% with the use of shock absorbing insoles. Furthermore, the researchers found that the use of shock absorbing insoles did not result in undesirable kinematic changes in the lower extremities.

The results of the current study supported the literature and provided evidence that, in terms of force production, the TPU seemed to be a viable material to replace a conventional heel for the reduction of GRF. These results also supported the hypothesis that the use of TPU as a heel lift seemed to provide an avenue to reduce force during heel-strike. Furthermore, the use of TPU material seemed to have the potential to reduce force shock waves, which transmit through the lower limb joints and cause secondary injury and degenerative joint conditions in the transtibial amputee population (Adderson et al., 2007).

Additionally, this reduction in force under repetitive impacts is vital with the use of a TPU heel lift in a flat shoe, as transtibial amputees mostly use conventional prosthetic heel lifts with flat-soled shoes, which have been shown to result in higher GRFs during heel-strike in the transtibial amputee populations (Klute & Berge, 2004). Along with the measures of force, the researcher found significant differences between the TPU and conventional heel for measures of energy absorption.

Differences in Energy Absorption for the Dynamic Testing

The type of material used between the foot and ground have been shown to affect the transmission of impact force during walking (Kim et al., 1994). The use of materials with a greater capacity for energy absorption, however, have been found to decrease force transmission by up to 35% during heel-strike (Folman et al., 2004; Gillespie & Dickey, 2003). This decrease in force transmission is vital for amputees as reducing the potential for force to transmit through the lower limbs and increasing the energy absorption capacity of the prosthetic material could result in a decreased incidence of secondary injury and degenerative joint conditions in this population (Adderson et al., 2007).

The results of the current study indicated that across the 26 velocities measured, the mean energy absorption of the TPU heel lift was significantly higher than the mean energy absorption of the conventional heel lift as shown in Figure 21. These results were consistent with the energy absorption measures found in the current study during the static testing and provided additional support for the use of TPU as a potential material to increase energy absorption, and possibly reduce harmful impact forces during heel-strike for transtibial amputees. As stated by Chiu and Shiang (2007), it is important to obtain measures from repetitive dynamic impacts across a range of velocities when testing footwear materials during heel impact simulations, as these measures provide a more reliable assessment of how the material will perform in a real-life application.

Furthermore, the use of a material that has the potential to absorb a higher amount of energy and transmit less impact force, could result in a range of positive outcomes in the transtibial amputee population. Some of these outcomes may include decreased pain upon heel-strike with the prosthetic, improved gait symmetry, decreased risk of secondary injury, or degenerative conditions due to gait abnormalities and higher impact force (Collins & Whittle, 1989; Smith et al., 2004). The results of the simulated heel lift repetitive impacts, along with the results of the static testing in the current study, showed promise for the use of TPU as a heel lift in the amputee population.

Human Participant Testing

To assess the real-life application of the TPU and conventional heel lift, the current study used human participant data to compare three heel lift conditions, which included no heel, the TPU heel, and the conventional heel. The researcher used this approach to observe the symmetry of walking when comparing the amputated and non-amputated limb of transtibial amputees on measures of power, energy, and GRFs.

This approach, however, was similar to the work conducted by Yeung et al. (2012) who found significant changes in the symmetry of kinematic gait between the amputated and non-amputated limbs with the use of a prosthetic heel lift when compared to a no heel lift condition. Yeung et al. (2012), however, did not provide insight into the materials used as a heel lift or the effects that it had on kinetic gait measures. As stated by Edhe et al. (2000), the need to reduce impact force on the amputated leg during heel-strike was a significant contributor to asymmetrical gait in this population. The current study aimed to examine this issue with the implementation of a conventional heel lift prosthetic to examine the kinetic symmetry of walking for transtibial amputees.

The researcher of this study also kept in mind that although the measurement of force in footwear material testing and gait analysis has been established as an important biomechanical measure for gait research and assessment, it has been noted that force alone does not provide a complete understanding of an individual's gait (Gordon-Evans et al., 2009). Power and energy absorption are two measures commonly observed in gait analysis in addition to force for amputee populations, as they provide significant information about a prosthetic device or an individual's ability to absorb energy during a foot impact and use the stored energy to generate power throughout the gait cycle (Soares et al., 2009). For this reason, the current study aimed to examine which heel lift condition (TPU heel lift, conventional heel lift, and no heel lift) would result in better symmetry of walking for the braking and propulsive phases based on the ratio of the amputated and non-amputated limb for measures of power, energy absorption, and GRFs, respectively.

Power

Houdijk et al. (2009) described sufficient power storage and production during the braking and propulsion phases of the gait cycle as important elements to generate positive work for push-off to minimize altered gait mechanics. When the body is forced to produce positive power from other muscles and joints of the body, it significantly increases the cost of energy that is required for ambulation, which is one of the reasons that amputees are commonly reported as using more energy than non-amputee individuals while walking (Houdijk et al., 2009).

The results of the current study indicated no significant differences in the power ratio means during the braking phase of the gait cycle. That is, the symmetry ratios of power were statistically similar for the no heel (.918), TPU heel (.931), and conventional heel (.947) conditions. Zmitrewicz et al. (2006) examined the gait power during braking in a transtibial amputee population and found that the type of prosthetic foot or footwear materials used can significantly reduce or increase the symmetry ratio between the amputated and non-amputated limbs. In comparison to the results of the current study, the heel lift conditions produced a symmetry ratio of power that was similar to the ideal materials examined by Zmitrewicz et al. (2006) during the braking phase of the walking cycle.

Yet, it is important to note that although no statistically significant differences were found when comparing the heel lift conditions in the current study, the power ratios of the conventional and TPU heel lifts appeared to be higher than the no heel condition. From a clinical perspective, this trend highlights the need to examine further the use of prosthetic heel lifts with a larger sample size as a possible avenue for power storage at heel-strike to help propel the body forward and consequently minimize the power consumption from other muscles during the gait cycle.

On the other hand, the results of this study showed significant differences among the heel lift conditions for the symmetry ratios of power during the propulsion phase of the gait cycle, with the conventional heel showing an increased symmetry ratio, when compared to the no heel condition. This outcome supported the research work conducted by Houdijk et al. (2009), which highlighted the importance of symmetry between the amputated and non-amputated limbs in terms of power during propulsion. Their research showed that amputees often decreased the production of power on the amputated limb, which results in altered gait mechanics to produce positive power for push-off.

Unfortunately, the results of the current study revealed no significant differences between the TPU heel, and the no heel conditions or between the TPU heel and the conventional heel for the power ratios during the propulsion phase of the gait cycle . Although no statistically significant differences were found , the power symmetry ratio during the propulsion phase of the gait cycle seemed to be higher with the use of the TPU heel. Again, from a clinical perspective, this appeared to show promise for the researcher to further explore the use of a TPU heel lift with a larger sample size, and clearly examine its capacity in generating power during push off on the amputated limb, to decrease altered, asymmetrical gait mechanics (Houdijk et al., 2009; Verdini et al., 2006).

Energy Absorption

The natural mechanisms involving the soft tissues and ligaments, which normally assist with energy absorption and return during gait, are lost in transtibial amputees and, therefore, the energy dissipation only relies on the components of the prosthetic device and footwear materials (Collins & Whittle, 1989; Rose et al., 2015; Whittle, 1999). Energy storing prosthetic devices allow for improvements in gait mechanics; however, they are still limited in their energy dissipation capabilities (Hafner et al., 2002).

In the current study, the symmetry ratios seemed to indicate that the TPU heel produced the most symmetry during the braking phase of the gait cycle with a ratio of .95 as compared to the conventional heel lift, which produced a ratio of .87. The inferential statistical analysis, however, showed no statistically significant differences across heel lift types in terms of energy during the braking phase of the gait cycle.

Given the small sample size and large effect, this outcome seemed to shed light from a clinical perspective on the need to further explore the use of the TPU heel lift as a possible avenue to improve the energy measures on the amputated limb to ameliorate the symmetry of walking. As stated by Hafner et al. (2002), an increase in symmetry of walking for the amputee population decreases energy expenditure due to sufficient energy storage and production in the amputated limb. Furthermore, improving this process would allow the impact energy to be absorbed and used to propel the body forward rather than travel through the limbs, which may result in possible incidents of degenerative joint conditions in transtibial amputees (Collins & Whittle, 1989; Verdini et al., 2006).

On the contrary, the results of this study revealed significant differences across heel lift conditions during the propulsion phase of the gait cycle, with the TPU heel showing an increased symmetry ratio when compared to the no heel condition. Similarly, the conventional heel lift revealed a statistically significant increase in the symmetry ratio of energy during the propulsion phase of the walking cycle when compared to the no heel condition. The results, however, revealed no statistically significant differences between the TPU and conventional heel lifts.

Although the TPU heel did not produce a statistically significant increase in the energy symmetry ratio when compared to the conventional heel during the propulsion phase of the walking cycle, these results suggested that both heel lifts significantly improved the energy return when compared to the no heel condition. As stated by Verdini et al. (2006), insufficient energy return during the propulsion phase of the walking cycle is a significant contributor to asymmetry of energy measures between the amputated and non-amputated limbs in the transtibial amputee population. The results of the current study, however, support the idea that a heel lift designed with TPU material may be a suitable and cost-effective avenue to enhance energy return and improve symmetry between the amputated and non-amputated limbs when compared to a no heel condition during walking.

Force

Tobalina et al. (2013) highlighted the importance of reducing higher GRFs during repetitive foot impact in amputee gait, as these forces have been identified as the main cause of injury production in several populations. The high forces generated during foot impact can lead to increased stress on the musculoskeletal system that ultimately results in a range of degenerative joint conditions, such as those commonly seen in transtibial amputees (Collins & Whittle, 1989; Tobalina et al., 2013).

When examining the symmetry ratios for the force produced during the braking phase of the gait cycle in the current study, the results showed no significant differences across heel lift conditions, however, the effect size was large. Although the results revealed no statistically significant differences between the heels lift conditions to support the research findings of Collins and Whittle (1989) and Tobalina et al. (2013), the symmetry ratio values of force appeared to be higher for the TPU heel lift and conventional heel than the no heel lift condition with a large effect size. From a clinical perspective, this observation highlights the need to examine these heel lift conditions with a larger sample size of transtibial amputees.

It is also essential to point out that similar research by Svoboda et al. (2012) examined the symmetry ratios of force during braking in transtibial amputees without the use of footwear and found a lower symmetry force ratio as compared to the heel lifts results of the current study. The research findings of Svoboda et al. (2012) and the large effect size found when comparing the ratios of force across heel lift conditions, highlight the need to use a larger sample size of transtibial amputees to explore the utility of the TPU and conventional heel lifts as prosthetic devices. This trend also has potential to help improve the design of prosthetic heel lifts as a possible avenue to minimize braking impact forces at heel-strike, while maintaining a symmetrical walking pattern.

In terms of the symmetrical ratio values of force during the propulsion phase of the gait cycle, the results revealed statistically significant differences between the conventional heel lift and no heel lift conditions. The results revealed no statistically significant differences, however, between the no heel and the TPU heel conditions or between the TPU heel and the conventional heel conditions. This outcome seemed to suggest that the conventional heel lift provided better walking symmetry when compared to the force ratio values of the no heel condition. This outcome also seemed to support the research work of Svoboda et al. (2012), which found significant lower force symmetry ratios of the amputated and non-amputated limbs without the use of footwear during the propulsion phase of the gait cycle.

The force symmetry ratios appeared to be higher for the TPU heel lift when compared to the no heel condition during the propulsion phase of the gait cycle, however no statistically significant differences were found. Kovac et al. (2009) explained the effects that using a new prosthetic device or component can have on feelings of instability during gait for amputees, which commonly results in a shorter propulsion phase of the amputated limb as compared to the non-amputated limb, and in turn, creates differences in force measures between the two limbs during this phase. This rationale seemed to suggest that participants' familiarity with a conventional prosthetic heel lift in the current study might have led to increased feeling of stability with this condition, resulting in better symmetry during the propulsion phase of the gait cycle as compared to the TPU heel lift. This rationale also seemed to suggest that the use of a long-term heel lift condition might increase the familiarity of the participant with heel lift type to improve walking symmetry.

Klute and Berge (2004) explained the challenges that researchers face in finding statistical significance when examining the effects of clinical interventions for gait in amputees, and they stated that due to the large variability seen in their gait biomechanics, a large sample size is needed to produce significant results. In the current study, the use of a larger sample size might have helped overcome the possibilities of committing type II error in the analysis to better assess the statistical significance across heel lift types. Based on the results of the static and dynamic repetitive testing, along with the promising evidence provided in previous research, and from the descriptive statistical observations during human testing of the current study, it seems that further research in this area would be beneficial.

Additionally, the similar measures of symmetry ratios that were found between the conventional heel and the TPU heel during human testing seemed to indicate that the TPU could be a viable material to replace the conventional heel lift that is currently prescribed to transtibial amputees without impeding their current gait mechanics. The material properties of TPU along with the use of the three-dimensional printing technology could provide a cost-effective option for more individualized heel lift designs. This approach has the potential for better prosthetic designs and long-term functional outcomes for lower limb transtibial amputees (Aimar et al., 2019).

Chapter 6 - Conclusion

This study aimed to examine the material properties of a specially designed TPU and conventional prosthetic heel lift as a potential avenue to improve the symmetry of walking of transtibial amputees. The results of this study seemed to show promise for the use of a TPU heel lift in a transtibial amputee population as a possible avenue to increase energy absorption within the heel lift and reduce impact force during heel-strike.

The static testing and analysis in the current study seemed to indicate that the TPU heel lift absorbed 10-20%more energy than the conventional heel lift. The dynamic impact testing and analysis found that the TPU heel lift significantly reduced measures of GRFs along with absorbing more energy than the conventional heel lift across a range of heel-strike velocities. The results of the human participant testing and analysis also seemed to suggest that TPU could be a viable material to replace a conventional heel lift without impeding current gait mechanics of transtibial amputees as a more cost-effective option for individualized designs.

The current study built on the work of previous researchers as it sought to provide a more extensive examination of kinetic measures during the gait cycle with the use of energy absorbing shoe materials for transtibial amputee populations (Klute et al., 2004; Yeung et al., 2012). Klute et al. (2004), for example, first examined the energy dissipating capabilities of the heel in prosthetic feet when combined with various footwear and found that impact force differed significantly depending on the material of the shoe being tested. The current study built on their research work by incorporating the use of TPU material with various types of flat-soled shoes and comparing these outcomes with a conventionally prescribed heel lift.

Furthermore, the current study built on the research work conducted by Yeung et al. (2012), which examined kinematic measures during gait in transtibial amputees with the use of a heel lift.

Although they noted significant changes in gait mechanics, they did not examine kinetic measures. The current study, however, examined several kinetic measures including GRFs, energy, and power during walking with the use of a conventional heel lift and a TPU heel lift.

Strengths

The use of several testing methodologies, which examined the properties of each material during static and dynamic impact testing, along with the human participant data was the primary strength of this study. Static and dynamic testing provided strong evidence for the use of the TPU heel lift when compared to the conventional heel lift, primarily owing to high energy absorption capacity during impact. Despite the small sample size, human participant testing also allowed for observation of the real-life application of a TPU heel lift in an amputee population and the results seemed to highlight the potential for the use of TPU in future research with transtibial amputees.

The use of a prosthetic foot and the large range of impact velocities used during the dynamic testing without the influence of human variability was another strength of the current study. The inclusion of a commonly used prosthetic foot attached to the air driven impactor, for example, allowed for the close replication of an amputee heel-strike without the influence of biomechanical variations, which are commonly found in gait analysis for the amputee population. Additionally, the inclusion of multiple heel-strike velocities allowed for a closer replication of the wide range of velocities that are seen during heel-strike with this population.

Limitations

This study also faced a number of limitations that future research could aim to explore or improve upon. The primary limitation of the current study was the small sample size used during the human participant testing. Due to the limited number of available volunteers, a larger sample size was not achieved. Amputee gait analysis often includes high levels of human variability and therefore, a large sample size is needed to help minimize the chance of committing type II error in the analysis and consequently better assess the symmetry of the gait cycle analysis in this population (Klute & Berge, 2004).

Another limitation of this study was the exclusion of kinematic variables such as across the ankle, knee, and hip joints for the amputated and non-amputated limbs to assess the symmetry of gait during walking. Incorporating kinematic measures such as displacements of the ankle, knee, and hip joints along with kinetic analysis could produce a better examination of symmetry of the lower limbs during walking and may provide further insight into the effects of each heel lift condition. Unfortunately, this approach was not possible due to breakdown of equipment.

Future Directions

As there appears to be a correlation between the effects of using a TPU heel lift and a conventional heel lift, future research should examine TPU and other impact absorption materials in comparison to conventionally prescribed heel lifts. As amputees continue to manifest gait asymmetry and higher risks of degenerative conditions, additional shoe materials and prosthetic heel lifts are necessary to mitigate impact forces and to increase energy absorption to acquire a more symmetrical walking pattern. Future research should also explore the use of TPU as a replacement for other shoe components such as insoles or outsoles. Materials used between the foot and ground have shown promise for mitigating impact force during walking. Therefore, research should continue to explore potential uses for impact absorbing materials in footwear for amputee populations.

Kinematic measures of the lower limbs and joints should be examined along with kinetic measures for gait analysis, as this would provide a better overall picture of symmetry between the amputated and non-amputated limbs. Specifically, measures of displacements of the ankle, knee, and hip joints could provide additional information about movement variation in the lower limbs with the use of each heel lift material.

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Appendix A

Recruitment Poster

Lakehead UNIVERSITY

Are you interested in participating in our research study?

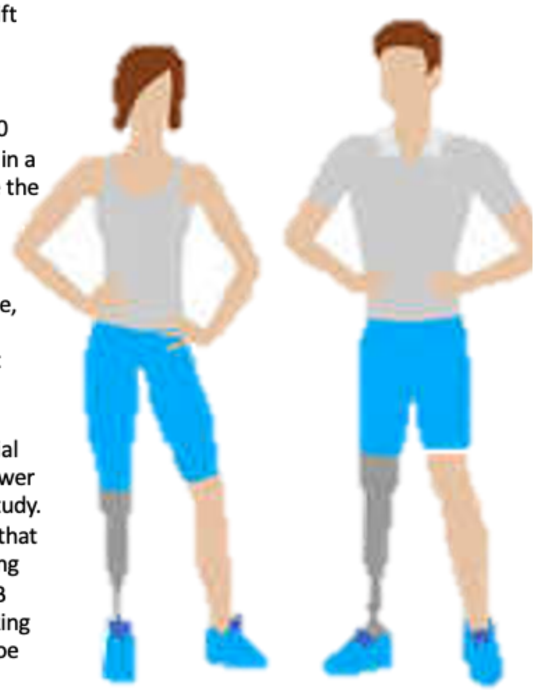
Join our research study assessing the walking symmetry in below knee amputees

Purpose: This study aims to compare a conventional heel lift and an innovated 3D printed heel lift to determine if the innovated heel lift improves walking symmetry in below knee amputees.

Participants:
You are welcome to participate if you are a male/female age 18-80 with a below the knee amputation. You must also be able to walk in a straight line, understand spoken and written instruction, and have the capacity to give informed consent

You are also welcome if you have <u>none</u> of the following:
Use an assistive device when walking, have a history of ankle, knee, hip, or spine injury or pain, or a health condition that impedes walking. Participants must have used their prosthetic device for at least six months.

If you meet the inclusion criteria, the researchers will have an initial meeting with you which will last approximately 10 minutes to answer any questions or concerns you may have about partaking in this study. If you agree to participate, you will be attending a testing session that will take approximately 70 minutes of your time. The initial meeting and testing session will take place at Lakehead University, room SB 1028. Testing will involve 3 conditions: walking in a flat shoe, walking in a flat shoe with a conventional heel lift, and walking in a flat shoe with an innovated 3D printed heel lift.



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Appendix B

Letter of Recruitment

Dear Potential Participant,

We would like to invite you to participate in our research study. The title of our study is: "Comparing the symmetry of walking in transtibial amputees: Biomechanical differences of prosthetic heel lifts". Before you decide to participate in this study, we encourage you to read all the information provided in this letter, consent form, and health assessment questionnaires. This study is being conducted by Celia Berry, a Kinesiology Graduate student at Lakehead University working under the supervision of Dr. Carlos Zerpa from Kinesiology and Dr. Meilan Liu from Mechanical Engineering in conjunction with Dr. Nicholas Ravanelli from Kinesiology at Lakehead University.

Our research aims to compare the symmetry of walking for participants with a lower leg amputation when fitted with two different types of prosthetic heel lifts with the intention to develop an avenue for clinicians to minimize forces transmitted to the lower extremity at heel contact responsible for causing degenerative joint conditions in this population. Before you continue reading, we would like to make sure you meet our inclusion criteria. You are a below knee amputee aged 18-80 years. You have the ability to walk unassisted in a straight line without the use of an assistive device (e.g., cane). You understand spoken and written instructions, and the capacity to give informed consent. You have had your prosthetic device for at least six months. You do not have pain, injury, or arthritis at the foot, knee, or hip, or a neurological condition that impedes walking. You also do not have pain or lesions on the residual limb. If you do not meet these criteria, we thank you for your interest, but you cannot participate in our study at this time.

If you meet the inclusion criteria, the researchers will have an initial meeting with you, which will last approximately 10 minutes to answer any questions or concerns you may have about partaking in this study. If you agree to participate, you will be given a consent letter to read, sign, and return it to the researchers. After returning the consent letter, the researchers will provide you with a Get Active Questionnaire and a demographic questionnaire to get a better understanding of your health status. If you meet these health requirements and agree to participate you will be given a chance to move on to the testing session. You will be given the opportunity to complete the testing session the same day as the initial meeting or book a day and time that works best for you to join us in the lab.

The testing session will take approximately 70 minutes of your time to complete. For this session you will be required to wear flat shoes. Before you begin the testing session, you will be introduced to the researchers, the testing procedures and equipment. You will then be tested under three conditions include walking without a heel lift, walking with the conventional heel lift, and walking with an innovated heel lift. The testing condition will be randomly selected. The heel lift will be placed into the heel of the shoe of your prosthetic foot. You will be given some time to practice walking with the selected heel lift conditions. Once you are comfortable with the equipment and familiar with the testing protocol, you will walk over two force plates to analyze your walking patterns based on measures of force under the three different conditions. A total of 5 walking trials will be performed for each condition. You will be tested individually. You will not be rewarded for taking part in this study. Your participation in this study is voluntary. You may refuse to participate in any parts of the study, decline to answer any questions, and may withdraw from the study at any time. A total of 80 minutes of your time will be needed for the whole data collection process, which includes the initial meeting and testing session.

As with any type of physical activity, there are possible risks. The risks associated with any walking activity include muscle soreness, muscle fatigue, strains, and sprains. These risks are being minimized by giving you a chance to practice using each heel lift, providing proper instruction, and proper fitting of the equipment with the assistance of a Certified Prosthetist.

There will be no direct benefit to you for participating in this study; however, the information gained from this study could be beneficial to the affected populations (e.g., those with transtibial amputations). The results of this study and future research may provide an avenue for health practitioners in making the correct choice when it comes to heel lift prescription type to minimize injuries associated with the lower limb so that users would be more likely to continue using their prosthetic device. The researchers do not have any potential commercial gain through the results of this study.

Upon the completion of this research study, only the researchers Celia Berry, Dr. Carlos Zerpa, Dr. Meilan Liu, and Dr. Nicholas Ravanelli will have access to the data. You will be assigned a code and the data will be kept confidential in a locked cabinet in Dr. Zerpa's office during and after completion of the study. Electronic files will be stored on a password-protected external computer hard drive. These records will be kept for a minimum period of five years. The data will be published in an aggregate form. You will not be identified in published results.

The results of the study will be made available to you via conference presentations, journal publications or upon request. If you have further questions regarding the study, please do not hesitate to contact any of the researchers listed below. If you have any questions related to the ethics of the research and would like to talk to someone other than the researchers, please contact Sue Wright at the Research Ethics Board at (807) 343-8283 or research@lakeheadu.ca.

Due to the COVID-19 pandemic, in-person research carries additional risk. All participants will be provided a mask and access to hand sanitizer prior to and during all experimental protocols. Travel options will be discussed with you to ensure you can maintain appropriate physical distancing. All research personnel will maintain a 2m distance whenever possible. All laboratory equipment will be thoroughly sanitized before and after your arrival to the lab. Lastly, you will be required to conduct the online Ontario Ministry of Health Self-Assessment prior to any experimental trials and confirm that you are free of any COVID-19 signs and symptoms.

Please note that our research team is required to keep logs for the purposes of contact tracing beyond our social circle. We will request your name and telephone number for this purpose. If a research team member or research participant(s) contracts COVID-19, the log would be shared with health authorities if requested. Only your name and telephone number, and not the reason for contact, would be shared with health authorities. Your information will be combined with all other contacts, and you will not be identified as a participant in this research study. Contact logs are kept for 30 days, then all identifying information is destroyed.

This research study is taking place on Lakehead University campus. Lakehead University has a mandatory vaccine requirement for all individuals coming on campus. You will be asked to provide proof of vaccination to the research team. Proof of vaccination can be provided in one of three ways:

- Ministry of Health proof of vaccination document along with government issued photo ID
- Ontario vaccine passport along with government issued photo ID
- Lakehead University MobileSAFETY app

Yours truly,

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Appendix C

Letter of Informed Consent

By signing this form, I agree that I have read and understood the letter of information for this research study "Comparing the symmetry of walking in transtibial amputees: Biomechanical differences of prosthetic heel lifts." I also agree to participate in this research study with the understanding of the following conditions:

1. My participation in this research study is voluntary and I may withdraw at any time. I may also choose not to answer any questions presented to me throughout the study.
2. I understand that this study will require 90 minutes of my time.
3. I understand the potential risks and/or benefits of the study and what they are. The information I provide will be securely stored in Dr. Carlos Zerpa's office for a minimum of five years at Lakehead University. If Dr. Carlos Zerpa should leave Lakehead University, the information will continue to be securely stored with the School of Kinesiology at Lakehead University.
4. I will receive copies of any publications in which the research is discussed if I so wish.
5. I will remain anonymous in any publication of the research findings and will not be identified in published results.

If you wish to receive a copy of your personal results or information about the results of the study as a whole in aggregate form, please provide your contact information below:

____ I would like to receive a copy of my personal results
____ I would like to receive information regarding the study as a whole

Mailing address:

Email Address:

____ The research team has verified, through an approved means, that the research participant is fully vaccinated

All questions have been answered to my satisfaction. I understand and agree to the above statements.

____
Name of Participant (please print)

________________________ ________________________
Signature of Participant Date

____
Name of Researcher (please print)

________________________ ________________________
Signature of Researcher Date

________________________ ________________________
Witness Signature Date

Appendix D

Get Active Questionnaire

Get Active Questionnaire

CSEP | SCPE
THE GOLD STANDARD IN EXERCISE SCIENCE AND PERSONAL TRAINING

CANADIAN SOCIETY FOR EXERCISE PHYSIOLOGY –
PHYSICAL ACTIVITY TRAINING FOR HEALTH (CSEP-PATH®)

Physical activity improves your physical and mental health. Even small amounts of physical activity are good, and more is better.

For almost everyone, the benefits of physical activity far outweigh any risks. For some individuals, specific advice from a Qualified Exercise Professional (QEP – has post-secondary education in exercise sciences and an advanced certification in the area – see csep.ca/certifications) or health care provider is advisable. **This questionnaire is intended for all ages – to help move you along the path to becoming more physically active.**

☐ I am completing this questionnaire for myself.

☐ I am completing this questionnaire for my child/dependent as parent/guardian.

PREPARE TO BECOME MORE ACTIVE

The following questions will help to ensure that you have a safe physical activity experience. Please answer **YES** or **NO** to each question before you become more physically active. If you are unsure about any question, answer **YES**.

YES	NO	
		1 Have you experienced **ANY** of the following (A to F) **within the past six months**?
○	○	**A** A diagnosis of/treatment for heart disease or stroke, or pain/discomfort/pressure in your chest during activities of daily living or during physical activity?
○	○	**B** A diagnosis of/treatment for high blood pressure (BP), or a resting BP of 160/90 mmHg or higher?
○	○	**C** Dizziness or lightheadedness during physical activity?
○	○	**D** Shortness of breath at rest?
○	○	**E** Loss of consciousness/fainting for any reason?
○	○	**F** Concussion?
○	○	**2** Do you currently have pain or swelling in any part of your body (such as from an injury, acute flare-up of arthritis, or back pain) that affects your ability to be physically active?
○	○	**3** Has a health care provider told you that you should avoid or modify certain types of physical activity?
○	○	**4** Do you have any other medical or physical condition (such as diabetes, cancer, osteoporosis, asthma, spinal cord injury) that may affect your ability to be physically active?

NO to all questions: go to Page 2 – ASSESS YOUR CURRENT PHYSICAL ACTIVITY

YES to any question: go to Reference Document – ADVICE ON WHAT TO DO IF YOU HAVE A YES RESPONSE

CSEP | SCPE
THE GOLD STANDARD IN EXERCISE SCIENCE AND PERSONAL TRAINING

Get Active Questionnaire

ASSESS YOUR CURRENT PHYSICAL ACTIVITY

Answer the following questions to assess how active you are now.

1 During a typical week, on how many days do you do moderate- to vigorous-intensity aerobic physical activity (such as brisk walking, cycling or jogging)? ______ DAYS/ WEEK

2 On days that you do at least moderate-intensity aerobic physical activity (e.g., brisk walking), for how many minutes do you do this activity? ______ MINUTES/ DAY

For adults, please multiply your average number of days/week by the average number of minutes/day: ______ MINUTES/ WEEK

Canadian 24-Hour Movement Guidelines recommend that adults accumulate at least 150 minutes of moderate- to vigorous-intensity physical activity per week. For children and youth, at least 60 minutes daily is recommended. Strengthening muscles and bones at least two times per week for adults, and three times per week for children and youth, is also recommended (see csep.ca/guidelines).

GENERAL ADVICE FOR BECOMING MORE ACTIVE

Increase your physical activity gradually so that you have a positive experience. Build physical activities that you enjoy into your day (e.g., take a walk with a friend, ride your bike to school or work) and reduce your sedentary behaviour (e.g., prolonged sitting).

If you want to do **vigorous-intensity physical activity** (i.e., physical activity at an intensity that makes it hard to carry on a conversation), and you do not meet minimum physical activity recommendations noted above, consult a Qualified Exercise Professional (QEP) beforehand. This can help ensure that your physical activity is safe and suitable for your circumstances.

Physical activity is also an important part of a healthy pregnancy.

Delay becoming more active if you are not feeling well because of a temporary illness.

DECLARATION

To the best of my knowledge, all of the information I have supplied on this questionnaire is correct.
If my health changes, I will complete this questionnaire again.

I answered NO to all questions on Page 1

Sign and date the Declaration below

I answered YES to any question on Page 1

Check the box below that applies to you:

- ☐ I have consulted a health care provider or Qualified Exercise Professional (QEP) who has recommended that I become more physically active.
- ☐ I am comfortable with becoming more physically active on my own without consulting a health care provider or QEP.

Name (+ Name of Parent/Guardian if applicable) [Please print]	Signature (or Signature of Parent/Guardian if applicable)	Date of Birth

Date	Email (optional)	Telephone (optional)

With planning and support you can enjoy the benefits of becoming more physically active. A QEP can help.

☐ Check this box if you would like to consult a QEP about becoming more physically active.
(This completed questionnaire will help the QEP get to know you and understand your needs.)

Appendix E

Demographic Questionnaire

Demographic Information Questionnaire - Amputee

Please note that this information is for internal use only and will not be shared to external sources.

1. Name:
2. Age:
3. Sex:
4. Gender:
5. Height:
6. Weight
7. Amputated Limb: Left Right
8. Reason for amputation:
9. Type of prosthetic foot:
10. Time since amputation (years):
11. Do you possess any of the following *(Check all that apply)*

    ____ history of ankle, knee, or hip trauma within the past year that impedes gait

    ____ history of arthritis that impedes gait

    ____ foot/knee/hip/spine pain impeding gait

    ____ neurological condition impeding gait

    ____ use an assistive device (ie. cane) when walking

Appendix F

Latin Square Method of Randomization

No Heel Lift=1
Conventional Heel Lift=2
TPU Heel Lift=3

	Column 1	Column 2	Column 3
Row 1	1	2	3
Row 2	2	3	1
Row 3	3	1	2

The numbers within the table represent the order that each walking condition will be presented to the participant. The number 1 represents the heel lift condition that will be tested first. The number 3 represents the heel lift condition that will be tested last. Approximately an equal number of participants will be randomly assigned to each row to determine the sequence in which they will undergo the experimental conditions.