HOW DOES STIFFNESS OF A SHOCKABSORBING PROSTHETIC FOOT INFLUENCE THE BIOMECHANICS OF GAIT?

by

PETUR SIGURDSSON

(Under the direction of Kathy J. Simpson)

ABSTRACT

To improve shock absorption during gait for individuals with trans-tibial amputation (Ind-TTA), shock-absorbing pylons (SAP) have been designed to replace the rigid pylon of prosthesis. However, it is not known if a viscoelastic rod-air pressure SAP (Ceterus®) improves gait mechanics and/or vertical ground reaction forces (VGRF) during initial contact are attenuated within an optimal range of air pressure settings. Therefore, the purposes of these gait studies were to determine, for Ind-TTA, whether: a) Study 1--- increased air pressure affects kinematic and VGRF and, b) Study 2--- interlimb kinematic symmetry and mechanics are similar to those displayed by controls (CON) without an amputation.

Seven Ind-TTA men, (age 20-65 yr) participated in both studies, and seven matched Ind-CON) engaged in Study #2. For both studies, each participant walked across an eight meter walkway while motion and ground reaction force (GRF) signals were collected. For Study #1, seven stiffness settings (0 - 60 psi) were used. Friedman's 2-way ANOVAs were used to investigate the effect of air pressure (Study #1) and TTA group and limb (Study #2) on GRF and kinematic variables. For Study #1, single-subject analyses also were used. All tests: $\alpha = .05$.

Study #1: No significant group or single-subject differences were found among air-pressure settings for the prosthetic limb (ProsL). Therefore, no consistent mechanical effects or compensatory kinematic strategies were detected. Qualitatively, for first peak VGRF, a U-shaped response to increased air pressure exhibited by three Ind-TTA suggests that an optimal range of air pressures (~10 to 30 psi) existed in which the impact force was attenuated for these participants.

Study #2: Compared to Ind CON, Ind-TTA displayed increased interlimb asymmetry for knee flexion displacement occurring during the first double limb stance phase. Furthermore, knee joint displacement, duration of the single limb stance phase and maximum VGRF slope were decreased significantly for the Ind-TTA ProsL compared to the matched CON limb. This allows the user of SAP to increase stability, through decreased knee joint flexion, without losing significant shock absorption on ProsL.

INDEX WORDS: Prosthetics, below-knee amputation, gait symmetry, ground reaction force, Shock-absorbing pylon.

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CHAPTER 1

INTRODUCTION

Background

Many individuals who have had a transtibial amputation (Ind-TTA) participate in demanding physical activities, such as running, basketball, mountain climbing, triathlons, etc. This has created an increased demand for prostheses that allow the user to participate more successfully in these activities (DiAngelo, Winter, Ghista, & Newcombe, 1989; Hafner, Sanders, Czerniecki, & Fergason, 2002; Marinakis, 2004)). In addition, for any Ind-TTA, regardless of the level of physical activity, the quality of life is, in many ways, dependent on the lower limb prosthesis worn.

There are several areas of concern regarding an optimal prosthesis, such as injury prevention, falling, functionality, and social aspects.

Among these concerns, rated among the most important to the person who uses a lower-extremity prosthesis is preventing injury (Legro et al., 1999). Tissue damage can occur not only to the prosthetic limb (ProsL), but also to the nonprosthetic (nonProsL) limb and other body regions. a Ind-TTA compared to those without a TTA experience a higher rate of lower back pain; and hip joint osteoarthritis, and cartilage degeneration in both limbs (Gailey, Allen, Castles, Kucharik, & Roeder, 2008; Norvell et al., 2005). These ailments have been associated with increased stress placed on particular regions of the body (Collins & Whittle, 1989b; Hurley, McKenney, Robinson, Zadravec, & Pierrynowski, 1990; Kulkarni, Gaine, Buckley, Rankine, & Adams, 2005; Lemaire & Fisher, 1994; Nack & Phillips, 1990; Voloshin & Wosk, 1982a).

Falling is a concern as prosthetic users do not want to incur a serious fall-related injury. Kulkarni et al. (1996) and Miller, Speechley, and Deathe . (2001) reported that 58% and 52%, respectively, of lower limb amputees in their studies hand fallen at least once during the previous year. Furthermore, prosthetic users are concerned about feeling of balance and are afraid of falling (Legro et al., 1999; W. C. Miller, Speechley, & Deathe, 2001). Therefore, for gait, maintaining balance is an important goal (Legro et al., 1999). The ankle joint of an intact limb allows the foot to adapt to an uneven surface without disturbing the equilibrium of the rest of the body. However, at present, few prostheses can mimic this function very well.

The concern of users wanting to walk without visible abnormalities allows the user to feel more socially accepted (Legro et al., 1999). Hence, a prosthesis should enable the user to walk with a natural, symmetric gait.

Therefore, the ideal prosthesis, when worn by a user for daily life or physical activity, must be able to ameliorate these concerns. To do so for gait, elements of the prosthesis must compensate for the mechanical functions of the missing tissues of the amputated leg, such as energy absorption when impact forces are applied to the foot; muscle force generation to prevent gravity from causing the prosthetic leg from buckling during weight bearing; muscle force generation to propel the body forward; joint motion control and stability.

Therefore, for these studies in which gait is the movement of interest, the mechanical goals of highest interest were energy absorption and joint motion control. For the goal of impact force attenuation during the support phase of gait, a prosthesis should not transmit excessive force from the ground to the affected limb. Ind-TTA who sense pain and discomfort during gait may also attempt to reduce ProsL loading to ameliorate the discomfort (Lloyd, Stanhope, Davis, & Royer, 2010; Silverman et al., 2008; D. A. Winter & Sienko, 1988).

Due to the lack of intact tissues of the ProsL that reduce the ability to absorb impact forces via movement techniques and muscle energy absorption, (D. A. Winter & Sienko, 1988), the Ind-TTA experiences increased impact on the ProsL compared to individuals without amputation. During the weight-acceptance phase of gait, when impact forces are applied to the foot, for energy absorption related to the foot-ankle complex, mechanical energy absorption by the plantar flexor muscles and passive tissues, e.g., fat pads in the plantar side of the foot is crucial. For TTA gait, however, depending on the prosthetic foot system used, when the prosthetic foot hits the ground there is reduced energy absorption.

The ability for Ind-TTA to absorb impact forces is also diminished due to decreased knee joint flexion during the weight acceptance on the ProsL (Nolan et al., 2003; D. A. Winter & Sienko, 1988; D. A. Winter, 1991). In typical gait the primary mechanical energy absorption during weight acceptance is done by the knee joint extension muscles through knee joint flexion (Lafortune, Hennig, & Lake, 1996; Lafortune, Lake, & Hennig, 1996; D. A. Winter & Sienko, 1988). As Ind-TTA exhibit decreased flexion at the ProsL knee joint during the weight-acceptance phase, there is an further increase in ProsL stresses due to greater vertical ground reaction forces (VGRF) acting on the body (D. A. Winter & Sienko, 1988).

The reduced shock absorption in Ind-TTA compared to non-TTA gait can have functional consequences, the user will adjust gait to minimize the discomfort (Gard & Konz, 2003; Lloyd et al., 2010; Perry, 1992; Sanderson & Martin, 1997; Silverman et al., 2008; Tokuno, Sanderson, Inglis, & Chua, 2003)). One example of how TTA adjust their gait is done by slowing down the walking speed. By decreasing the walking speed the peak VGRF magnitude will decrease during the initial contact phase, hence less force will be perceived to be acting on the residual limb and the discomfort is minimized (Gard & Konz, 2003; Powers, Rao, & Perry, 1998).

Moreover, TTA spend less time on the ProsL and more on the intact limb during stance phase in order to minimize the forces acting on the residual limb (Gard & Konz, 2003). Hence, by increasing the shock absorption capabilities of the prosthesis, I predict that the Ind-TTA should be able to walk faster with improved overall gait symmetry.

It is evident, therefore, that improved shock absorption continues to be an important need. In order to improve shock absorption, prosthetic companies have produced SAP that are supposed to increase the prostheses' abilities to absorb the VGRF and to produce more 'natural' gait. Various methods for incorporating shock-absorption into an SAP system include using coil spring (CS), carbon fiber spring (CFS), or a viscoelastic rod (VER) alone or in combination with an air compartment, for dampening the impact force. Users of SAP systems (using CS and CFS system) have reported improved comfort during walking, 'smoother' walking, less stiffness of the prosthesis and less effort during walking up or down steps (Buckley, Spence, & Solomonidis, 1997; Gard & Konz, 2003(Berge, Czerniecki, & Klute, 2005; L. A. Miller & Childress, 1997)).

Among the types of SAP systems on the market today, some (e.g. VER system) are designed mainly to absorb some of the mechanical energy during the initial contact phase of gait, with limited energy return. Other SAP systems (e.g., CS and CFS) can store mechanical energy, some of which can be regained during the push-off phase.

The type of SAP system used in this study (Figure 1.1), the Ceterus® SAP (Ossur hf), is energy-absorption with limited energy return. However, as is typically done, this SAP was combined with an 'energy-storing' foot (Flex-Foot®, Ossur hf.).

As shown in Figure 1, there are two mechanical elements that directly influence the 'stiffness' and damping coefficients, an VER, placed inside the user's pylon and the amount of air pressure pumped into a piston-type chamber. Theoretically, the combination of the VER and

Figure 1.1 Ceterus ® SAP attached to the Re-Flex ® foot (top left); Ceterus components (top right), and the air pump (bottom). One of four viscoelastic rods (top right) are placed into the black tube of the SAP (left of rods). The pump is used to adjust the air pressure in the blue bulb of the SAP.

air pressure, therefore, modulates the amount of mechanical energy absorbed during gait. The VER has the greatest influence on the stiffness and damping coefficients. As each of the four available rods exhibits a different damping and stiffness coefficient, the choice of a VER for a user is based on the user's weight and physical activity level.

Air pressure is the subsequent and more precise level of adjustment. The recommended procedure to determine the desired air pressure is to set the air pressure no greater than 20 psi for everyday use and have the prosthetist and the user adjust the pressure until satisfied. Hence, once the user leaves the prosthetist's office, the amount of air pressure is dependent on the user. The client can choose a different air pressure whenever desired or may not even monitor the air pressure (Larry Rice, CPO, personal communication, 2005).

Although most users self-reported that their gait improved while wearing an SAP system compared to a conventional, rigid pylon, it has not been shown conclusively that using a SAP significantly increases shock absorption compared to a nonSAP system ((Adderson, Parker, Macleod, Kirby, & McPhail, 2007; Berge et al., 2005; Gard & Konz, 2003; L. A. Miller & Childress, 1997)).

Probable reasons for equivocal findings among prior research studies include variance among studies for: a) SAP technology; b) stiffness settings; c) and walking velocity, which also varied considerably among participants within a given study ((Berge et al., 2005; Gard & Konz, 2003)). It is likely that the SAP technology affects gait, although no direct comparisons among different SAP types (e.g., springs versus VER) have been performed. Moreover it is not known how the air pressure setting affects gait biomechanics of the user.

For walking speed, several investigators have suggested that at walking speeds lower than 1.3 m/s, the SAP user does not benefit from using SAP system (Gard & Konz, 2003; L. A.

Miller & Childress, 1997). Gard et al. (2003), for example, detected reduced forces applied to the residual limb during the weight acceptance phase during SAP compared to nonSAP gait, but only at speeds greater than 1.3 m/s. Thus, Gard et al. (2003) suggested that the SAP system can benefit the user during ambulation, but only if the user has a fast enough gait. This observation was confirmed by Hsu, Nielsen, Yack, and Shurr (1999) who found that energy expenditure decreased significantly when using a SAP compared to a rigid pylon during walking and running at speeds above those of the Ind-TTA's self-selected speeds.

However, I believe that other reasons that the SAP did not display reduced impact forces at the lower velocities of these prior studies were the interactions among the SAP stiffness and participant-related factors; such as participant age, length of time that the participants had been given to adapt to the SAP, and the individuals' perceptions of the SAP relative to their original prosthesis. For example, among the adults in Gard's et al.(2003) study, the oldest adults (69-79 yr) were the least comfortable wearing the SAP, as it was very novel to them at the time of testing. Thus, they may also have walked much more slowly when wearing the SAP rather than their own prosthesis, thereby potentially attenuating biomechanical differences that were displayed by the other participants. Maybe, too, the limited number of stiffness settings (three settings), of the SAP used in Gard´s study could have affected the individuals' ability to utilize the SAP more effectively and make better use of the SAP mechanical characteristics.

Despite great improvements in lower limb prostheses, however, there still are biomechanical differences between individuals with and without a TTA that affect the stresses placed on the body. Individuals with a TTA compared to non-TTA experience a higher rate of lower back pain, osteoarthritis in hip joints, and cartilage degeneration, not only in the ProsL but also the nonProsL (Collins & Whittle, 1989b; Voloshin & Wosk, 1982a). These ailments have been associated with increased stress placed on particular regions of the body (Collins & Whittle, 1989; Hurley, McKenney, Robinson, Zadravec, & Pierrynowski, 1990; Kulkarni, Gaine, Buckley, Rankine, & Adams, 2005; Lemaire & Fisher, 1994; Nack & Phillips, 1990; Voloshin & Wosk, 1982).

The increased stresses on specific tissues that a Ind-TTA experiences can be attributed to the increased asymmetry in Ind-TTA gait compared to nonTTA gait (Gard & Konz, 2003). The flexion occurring during the weight acceptance phase of gait of the knee and ankle joints (and the hip joint to a lesser extent) help reduce the impact forces (Kirtley, 2006; Perry, 1992; Rose & Gamble, 1994). However, for Ind-TTA, not only is there asymmetry in temporal variables of TTA gait, such as increased stance time on the non-ProsL, but also there is interlimb asymmetry of the kinematic variables of the stance phase. Exhibited by the ProsL compared to the nonProsL is less ankle plantarflexion, increased hip flexion, and decreased knee flexion during weight acceptance (Bateni, H., Olney,S.J., 2002; Marinakis, 2004; Sanderson & Martin, 1997; D. A. Winter & Sienko, 1988).

Hence, it is important to understand how the stiffness affects gait so that the prosthesis user can utilize the benefits of a SAP to walk naturally and safely. Based on the existing SAP biomechanical literature, no investigators have determined the effect of varying the ‘stiffness’ of the SAP on gait biomechanics. Moreover, for this SAP system, I believe that there should be an optimal air pressure setting for a given user to benefit from using the SAP during natural-speed gait.

Furthermore, none of the previous SAP studies compared Ind-TTA gait to typical gait. As it has been reported that Ind-TTA prefer SAP over non-SAP systems (Berge et al., 2005;

Gard & Konz, 2003; L. A. Miller & Childress, 1997), it is interesting to see how SAP system affects Ind-TTA gait biomechanics compared to typical gait.

Purpose of the Study

The purpose of the first research study was to determine how different air pressure settings (0 psi = 'most compliant' to 60 psi = 'stiffest') of the Ceterus® SAP affect the kinematics and GRF of Ind-TTA during gait. The purpose of the second study was to determine if using an SAP at the recommended stiffness setting for walking (10 – 20 psi) affects inter-limb gait symmetry of Ind-TTA compared to matched, controls (Ind-CON) who do not have a limb disorder or amputation.

For the first study, I anticipated that, during the prosthetic-limb support phase of gait, the biomechanical responses to increased air pressure could be either similar across individuals, and/or individual-participant dependent. For responses similar among participants, the group statistical tests were expected to be significant. If a biomechanical response to air pressure was individual-participant dependent, however, then a group test likely would not be significant, but individuals' responses would be detectable from significant single-subject comparisons.

Regardless whether a set of biomechanical outcomes was individual-dependent or not, compared to moderate air pressure settings (i.e., 10-30 psi), at the higher air pressure settings (40-60 psi), one of two major sets of outcomes were expected to be displayed by an individual. The first set of outcomes was predicted for a participant if the individual's behavioral adaptation to increased air pressure was low and a more mechanical response to increased prosthesis stiffness occurred. Therefore, for this viscoelastic prosthetic foot-SAP system, a nonlinear pattern of increased greater peak impact VGRF magnitude and rate of application would be observed as air pressure increased.

For the second study, I expected that the biomechanical outcomes displayed during weight-bearing phases of the ProsL would be influenced by the competing mechanical goals of axial force attenuation and increased stability. By attenuating vertical impact forces and the rate that they are applied, axial forces applied to the distal residual limb should also be reduced. Adaptive strategies would increase the stability of a limb whose neuromuscular control of the foot-lower limb complex is compromised. Knee flexion displacement of the ProsL that occurs during the first double limb stance phase is one of the most important impact force attenuation strategies (Button, Moyle, & Davids, 2010; D. A. Winter & Sienko, 1988), but for Ind-TTA, maintaining a more extended knee joint reflects a useful compensatory strategy to improve stability during weight bearing (Berge et al., 2005; Button et al., 2010).

Therefore, I anticipated one of two sets of outcomes. For the first set of outcomes, if the SAP does attenuate impact forces, then similar magnitudes of first VGRF peak, time to first VGRF peak, and maximum rate of impact VGRF would be exhibited for the prosthetic (ProsL) and the matched Ind-CON group limb (CON-ProsL). Simultaneously, to ensure stability for Ind-TTA, less knee flexion displacement could be used as a shock-attenuation strategy by the Ind-TTA compared to the CON group.

For the second set of possible biomechanical outcomes, if the SAP does not attenuate impact forces, then compared to the CON-ProsL, the ProsL would demonstrate greater peak impact VGRF magnitude and rate of impact VGRF application. Furthermore, to reduce the time during which the ProsL was loaded axially, less time would be spent on the ProsL when bearing weight during the stance phase. Consequently, the kinematic asymmetry of the Ind-TTA group would be greater than the Ind-CON gait.

Therefore, the following hypotheses were used to test the purposes of the studies:

Hypotheses

For the first study, with increased air pressure:

For the ground reaction forces (GRF):

1. The magnitude of the 1st VGRF peak will increase linearly with increased air pressure.
2. The relative time to 1st VGRF peak will decrease linearly with increased air pressure.

For the kinematics:

3. Knee flexion displacement of the ProsL occurring during the 1st DBLS will increase with increased air pressure.
4. ProsL hip flexion displacement of the ProsL 1st DBLS will decrease with increased air pressure.
5. The duration of the 1st DBLS will increase with increased air pressure.
6. The duration of the single limb stance phase will decrease with increased air pressure.
7. The stride length of the ProsL will increase with increased air pressure.

Study #2:

For the kinematic variables, compared to the NonProsL and Ind-CON limbs, the ProL of the Ind-TTA will exhibit:

1. Decreased knee and hip joint displacement during 1st DBLS
2. Decreased stance phase time for ProsL
3. Increased 1st DBLS time for ProsL.
4. Decreased single limb stance duration for ProsL.

For GRF-related variables, the ProsL of Ind-TTA compared to matched limb of Ind-CON will display decreased:

1. first VGRF peak ;
2. maximum rate of VGRF;

Significance of the study

Trauma to the residual limb, low back pain, osteoarthritis in lower limb joints, are examples of medical problems linked to the lack of shock absorption during gait for individuals who use a lower-extremity prosthesis (Collins & Whittle, 1989b; Hurley et al., 1990; Kulkarni et al., 2005; Legro et al., 1999; Nack & Phillips, 1990; Voloshin & Wosk, 1982a). The lack of shock absorption has been attributed to the diminished capabilities for shock absorption by the affected limb (D. A. Winter & Sienko, 1988). Therefore, the main goals for an Ind-TTA when wearing a prosthesis are achieving a natural looking gait that is comfortable; limiting the risk of trauma to the stump; limiting falling; preventing acute and chronic mechanical-stress related injuries; optimizing physiological economy; and maximizing effectiveness during participation in everyday and physical activities. The SAP systems were designed to help Ind-TTA achieve these goals.

Previous researchers (Berge et al., 2005; Gard & Konz, 2003; Hsu, Nielsen, Yack, & Shurr, 1999; L. A. Miller & Childress, 1997) have shown that the use of an SAP compared to a rigid, non-SAP during gait may have some benefits to some, but not all users. I surmise that greater biomechanical improvements of Ind-TTA gait would be displayed with increased knowledge regarding SAP stiffness settings.

However, no study to date has compared how different stiffness settings affect TTA gait. Moreover, the range of stiffness settings that will improve shock absorption without degrading the gait kinematics or perceived stability and comfort is not known for this particular SAP system. Once this range is known, Ceterus® users and their prosthetists will be able to set the SAP with less trial and error and more rapidly decrease the potential risks of injury.

Furthermore, the Ceterus® system allows the user to adjust instantaneously the stiffness of the SAP according to the activity the user currently is doing. Therefore, armed with the knowledge of the optimal SAP settings anticipated for that activity, users could modulate their impact forces more effectively.

Therefore, these findings may provide guidance for prosthetic improvements and/or evidence-based recommendations for the range of optimal air pressure setting so that fewer Ind-TTA will be likely to develop back pain, osteoarthritis, and other degenerative conditions. More people, consequently, may stay physically active at a higher-effort level for a longer length of time in their lives. Furthermore, this knowledge would not only benefit TTA users of Ceterus® but it might also suggest future research directions focused on determining appropriate stiffness of other SAP systems.

It is essential to understand how biomechanical characteristics in TTA gait are affected by the impact forces and how different stiffness settings affect those characteristics. Not only is this knowledge important for users of SAP, but this will also help in the search for the best prosthetic technology that will allow prosthetic users to live their dreams. Whether it is to be able to do daily activities, such as going to the kitchen to get a snack, or to climb to the top of Mt. Everest and have one's picture taken on top of the world, the prosthesis should be an integral part of an individual's success in performing the physical activities of their choice.

CHAPTER 2

REVIEW OF LITERATURE

The purpose of this study of the Ceterus® shock absorbing prosthetic system (SAP) is to find out what stiffness/damping settings produce the greatest improvements in gait kinematics and GRFs for individuals with a transtibial amputation (Ind-TTA) and how SAP affects gait kinematics and GRFs for Ind-TTA compared to non-amputees (Ind-CON). Hence, we start this review with basic information on gait biomechanics, then compare and contrast gait kinematics and kinetics of Ind-TTA to the gait characteristics of Ind-CON. Last, we address the SAP literature, including what is currently known about the effects of SAP on Ind-TTA gait characteristics compared to Ind-CON gait and non-SAP TTA gait.

Biomechanics of gait

In order to analyze the biomechanics of a cyclic motion like gait, it is important to define the starting point and the end point of one cycle and then break the cycle into parts (phases). Several slightly different gait phase descriptions have been developed (Perry, 1992; Rose & Gamble, 1994; D. A. Winter, 1991). The following breakdown and description of the gait cycle is drawn and compiled from these sources.

Gait cycle

As shown in Figure 2.1, the gait cycle (i.e., the stride for the foot of interest) starts when the foot of interest (ipsilateral) foot hits the ground and ends at the instant that the ipsilateral foot hits the ground again. The gait cycle can be broken down into two phases, the stance phase and

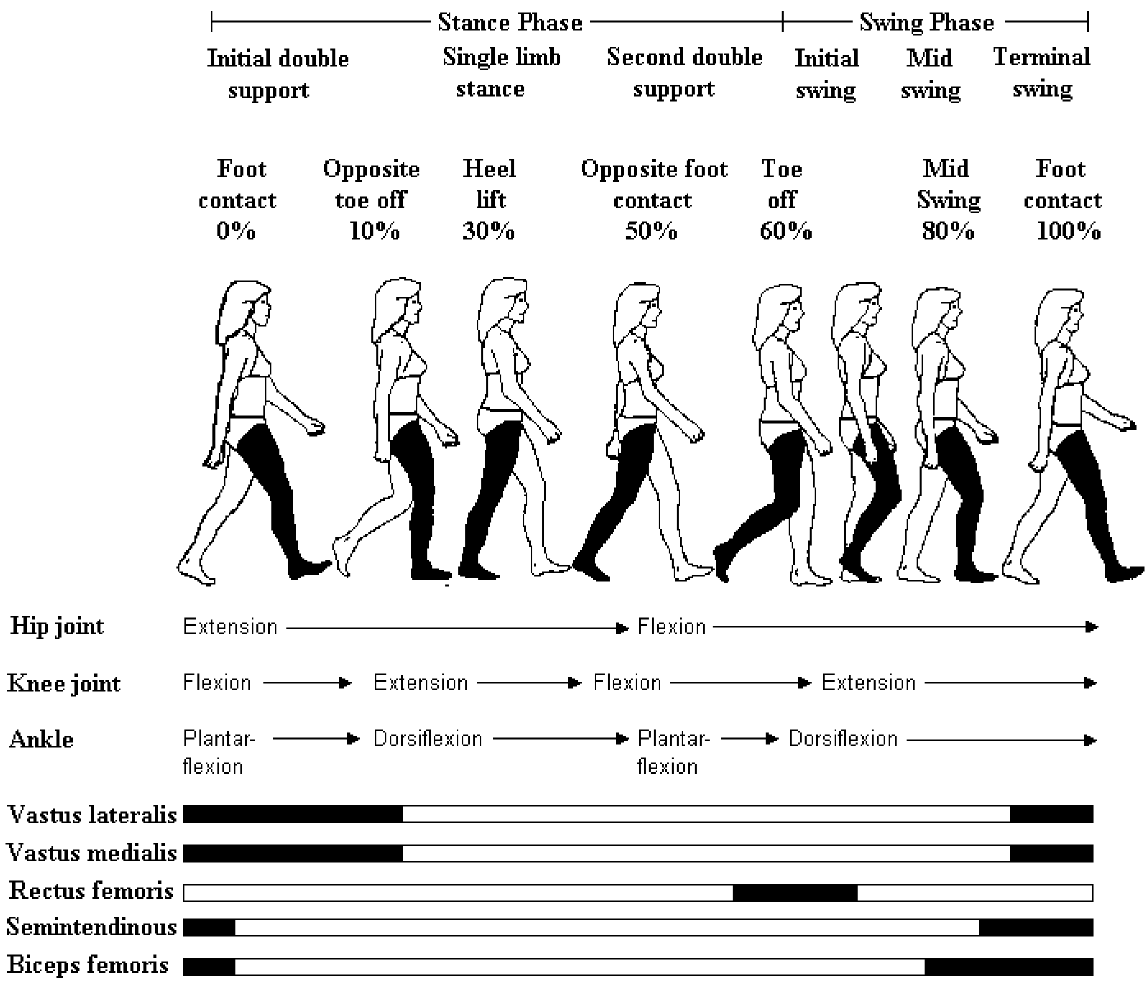

Figure 2.1 Representation of the breakdown of a gait cycle.

the swing phase. During the stance phase ipsilateral foot is in contact with the ground and during the swing phase the ipsilateral foot is not in contact with the ground. The stance phase can be further split up into sub-phases: Loading Response (also called first double limb stance), Mid Stance (also called single limb stance, is sometimes broken up into two phases, mid stance and terminal stance), and Pre Swing (also called second double limb stance). During the swing phase the contralateral limb is in contact with the ground while the ipsilateral limb is off the ground and swinging forwards. The swing phase can also be split up into sub-phases: Initial Swing, Mid Swing, and Terminal Swing.

Phase descriptions:

Stance phase

- Loading Response (1st DBLS) starts as the ipsilateral foot contacts the ground and ends as the contralateral foot comes of the ground, lasts from the start of the gait cycle and ends about 10% into the cycle. During this phase the body weight is being transferred from the contralateral foot to the ipsilateral foot. Furthermore, the shock from the ground is being absorbed by the foot and knee. When the ipsilateral foot hits the ground the ankle starts to plantarflex until the foot is flat on the ground. An eccentric contraction of the tibialis anterior facilitates a controlled plantarflexion of the foot, as well as pulling the tibia forwards. At foot contact the knee is almost fully extended then it starts to flex, the quadriceps eccentrically contract for a controlled flexion of the knee. The hip is extending through a concentric contraction of the hip extensors.
- Mid Stance starts as the contralateral foot comes off the ground and ends when the contralateral foot hits the ground again, it lasts from about 10% to 50% into the gait cycle. During this phase the ipsilateral limb supports the full body weight, while the

trunk moves forwards over the foot. The ankle joint moves from plantar flexion to dorsiflexion as the tibia rotates forwards about the ankle joint. The gastrocnemius and the soleus are contracting eccentrically for a controlled dorsiflexion. At the start of the mid stance phase the knee is at its greatest flexion and then starts to go back into extension. The ankle reaches its maximum dorsiflexion soon after heel rise as the tibia rotates forwards. Towards the end of mid stance phase the ankle starts to plantar flex again. At the start of the contralateral heel strike the knee reaches its max extension during the stance phase then it starts to flex again. The hip is still extending and reaches its peak extension at the end of the terminal stance phase.

- Pre Swing (2nd DBLS) starts as the contralateral foot contacts the ground and ends as the ipsilateral foot comes off the ground, it lasts from about 50% to about 60% into the gait cycle. During this phase the body weight is being transferred to the contralateral limb. The ankle is continuing to plantar flex due to concentric contraction of the gastrocnemius and the soleus throughout the pre swing phase. The knee is still flexing, but now the rectus femoris is eccentrically contracting to prevent flexion from occurring to rapidly. At the start of this phase the hip reaches its peak extension and starts to flex.

Swing phase

- The initial swing starts as the toe comes off the ground and ends when the feet are adjacent to each other; it lasts from about 60% to about 75% into the gait cycle. The ankle reaches its maximum plantarflexion just after the toe comes off the ground and then it starts to dorsiflex to a neutral position through a concentric contraction of the tibialis anterior. The ankle stays in a neutral position throughout the swing phase. At toe off the knee is about halfway to its maximum knee flexion that it will reach during the swing phase just before the start of the mid swing phase. The knee flexion during the swing phase is mainly caused by hip flexion and inertial affects of the lower leg. The hip continues to flex throughout this phase.

- Mid swing starts as the feet are adjacent to each other and ends as the tibia is in a vertical position; it last from about 75% to about 85% into the gait cycle. At the start of the mid swing the ankle is just reaching its neutral position as the toes clear the ground. The knee has just started to extend as this phase starts, this is mainly due to the pendulum like action of the lower leg as it swings forwards. The hip is still flexing throughout this phase and is reaching its max flexion towards the end of the phase.
- Terminal swing starts as the tibia is in a vertical position and ends as the foot contacts the ground again (which is the end of the gait cycle); it last from about 85% to 100% into the gait cycle. The ankle can be slightly dorsiflexed to being slightly plantarflexed during this phase, since the toe has cleared the ground. The tibialis anterior is in an eccentrical contraction to hold the ankle in position and prepare it for the loading at the start of a new gait cycle. The knee moves into an almost full extension prior to the initial contact of the new gait cycle. The hamstrings prevent hyperextension of the knee through an eccentric contraction. The hip is in a fixed flexion during this phase in preparation for the next gait cycle.

Critical events: There are several critical events occurring during the gait cycle:

1. Foot contact (0%) – When the foot contacts the ground, initiation of the stance phase, start of the loading response phase.

2. Contralateral toe off (10%) – When to contralateral foot leaves the ground and starts the contralateral swing phase, the end of the loading response, hence, also the start of the midstance.
3. Heel lift (30%) – The heel of the ipsilateral foot comes of the ground.
4. Opposite foot contact (50%) – The contralateral foot contacts the ground, the body weight starts to be transferred to the contralateral limb and the ipsilateral limb starts to push-off. This is the end of the terminal stance and the start of the pre swing.
5. Toe off (60%) – The ipsilateral foot comes off the ground. This is the end of the stance phase and the start of the swing phase, thus the start of the initial swing.
6. Feet adjacent (75%) – The ipsilateral foot is adjacent to the contralateral foot. This is the end of the initial swing and the start of the mid swing.
7. Tibia vertical (85%) – The tibia of the ipsilateral leg is vertical. This is the end of the mid swing and the start of the terminal swing. This is the last critical event of the gait cycle.

Ind-TTA v. nonTTA gait kinematics

There are a considerable number of studies on how lower limb prostheses affect gait variables. It has been reported, particularly within earlier research, that greater interlimb asymmetry is displayed during Ind-TTA compared to nonTTA gait for a variety of biomechanical factors: temporal, spatial, GRF, and EMG ((Arya, Lees, Nirula, & Klenerman, 1995; Bateni, H., Olney,S.J., 2002; Beyaert, Grumillier, Martinet, Paysant, & André, 2008; Breakey, 1976; E. Isakov, Keren, & Benjuya, 2000; Lloyd et al., 2010; Nolan et al., 2003; Powers et al., 1998; Robinson, Smidt, & Arora, 1977; Sanderson & Martin, 1997; Zmitrewicz, Neptune, Walden, Rogers, & Bosker, 2006)

. Some of the interlimb asymmetries reported for Ind-TTA gait are shorter stance phase time and single leg support time on the ProsL compared to the nonProsL side, (Breakey, 1976; E. Isakov et al., 2000; Powers et al., 1998).

Furthermore, considerable differences in the joint kinematics of TTA compared to Ind-CON gait have been observed (Bateni, H., Olney,S.J., 2002; E. Isakov, Burger, Krajnik, Gregoric, & Marincek, 2001; Marinakis, 2004; Powers et al., 1998; Sanderson & Martin, 1997). For the Ind-TTA, due to the lack of a foot-ankle complex (and potentially some of the lower leg), there is a loss of important mechanical properties that impacts on the production of gait. At initial foot contact during nonTTA gait, the foot plantarflexes rapidly until the foot is flat. The dorsiflexor muscle work done to the foot during this plantarflexion motion is important to control the foot motion so that the foot lands smoothly to stabilize the body as the body moves downwards and forwards to strike the ground. In addition, this action also serves to attenuate the magnitudes of vertical ground reaction forces (VGRF), so that high forces are not transmitted from the foot upwards to the skull.

Thus, the TTA individual may not be able to control plantarflexion during early stance phase, especially if the prosthesis has no artificial ankle articulation or heel designed for this purpose. Perhaps due to the constraints of the rigid shape of the prosthesis, the Ind-TTA individual also does not display knee flexion as occurs when using a second potential method to absorb VGRF when impacting with the ground. For nonTTA gait, at initial contact the knee is nearly extended, and progressively flexes 15-20° degrees until the end of the first double support phase (Perry, 1992). This knee flexion and knee extensor muscle work during weight acceptance not only acts to ‘absorb shock’ (i.e., reduce magnitudes of VGRF), but also prevents excessive vertical translation of the body’s center of mass (Powers et al., 1998; Rose & Gamble, 1994;

Whittle, 1996)(. In comparison, during Ind-TTA gait, the knee joint flexes significantly less during loading phase and the first part of the mid stance (Bateni, H., Olney,S.J., 2002; Marinakis, 2004; Powers et al., 1998; Sanderson & Martin, 1997) and achieves this peak flexion later in the stance phase (Powers et al., 1998)

Asymmetry is not only found in temporal and spatial variables of Ind-TTA gait, but it has also been found in some of the GRF variables. The peak VGRF and the loading rate during weight acceptance have been found to be significantly greater on the non-ProsL compared to the ProsL and for non-TTA (Arya et al., 1995; Beyaert et al., 2008; Lloyd et al., 2010; Nolan et al., 2003; Pinzur et al., 1995). The possible reason for this could be due to the fact that Ind-TTA adopt a gait strategy that reduces the loading on the ProsL (Sanderson & Martin, 1997).

Due to a greater vertical alignment of the ProsL during stance phase the AP-GRF peaks are significantly smaller compared to both the non-ProsL and non-TTA (Hermodsson, Ekdahl, Persson, & Roxendal, 1994; Sanderson & Martin, 1997; Zmitrewicz et al., 2006). Furthermore, AP braking and propulsive impulses are also significantly smaller for the ProsL. Due to the lost mechanical ankle functions on the ProsL the ProsL cannot generate the equivalent amount propulsion compared to the non-ProsL and CON-ProsL (Arya et al., 1995; Silverman et al., 2008; Zmitrewicz et al., 2006). The ProsL-to-non-ProsL braking and propulsive ratio has improved as the prosthetic design has gotten better, but it is still significantly less compared to Ind-CON (Zmitrewicz et al., 2006).

SAP literature

Only few studies have looked at how SAP affect gait for Ind-TTA. DiAngelo (1989) did a single subject study using a Terry Fox jogging prosthesis. This prosthesis was a rudimentary design of SAP system designed for jogging. Its main purpose was to store energy in early stance and release it during late stance. DiAngelo (1989) found that it did not improve the gait characteristics or the forward thrust during jogging as had been expected. Thus, further development of the prosthesis was stopped.

Childress (1997) looked at how the Re-Flex SAP system affected gait in five conditions: freely selected walking pace, fast walking pace, jogging in place, and stepping down a curb for both the intact limb and the prosthetic limb. Childress (1997) found that by walking at freely selected speed the stance time increased for the intact limb, increased the swing time of the prosthetic limb, and increased the vertical motion of the trunk during intact limb stance. For the fast walking pace Childress found that one subject walked faster using the SAP. As a result of walking faster the vertical GRF and the peak-to-peak trunk motion was greater. Also, there was an increased stance time for the intact limb, a shorter swing time for the intact limb than the prosthetic limb, and the prosthetic limb stance phase became shorter when using the SAP. Both subjects preferred using the SAP system over the non-SAP. Childress did not find strong biomechanical differences between SAP and non-SAP.

Gard *et.al* (2003) studied how Endolite Telescopic Torsion Pylon affected gait characteristics and GRF in trans-tibial amputees. They did not find many statistical differences in AP gait when using SAP compared a non-SAP. Still, they found that the forces acting on the stump were smaller during prosthetic loading response phase when using the SAP. Their results were inconsistent among the subjects. Some subjects improved their gait characteristics when using SAP while others did worse. Gard *et al.* reported the gait differences at two speed levels, freely selected speed and fastest speed, even though they collected data for five different speeds. Although there were no statistical differences found between SAP and non-SAP gaits (except for one variable) there were some trends observed, especially at the fastest walking speed. The time to max GRF peak tended to increase when using SAP, several subjects also increased the speed when using SAP. The only statistical difference found was in the magnitude of the forces acting on the stump. The forces acting on the stump were smaller when using the SAP, especially at the faster speed. A questionnaire the subjects did after the testing showed that all but two amputees preferred using the SAP over their older prosthesis. The two subjects preferring their older prosthesis were considerably older than the rest of the group and they were not able to walk at speeds higher than 1.3m/s. Hence, it was suggested that the SAP mainly benefits those amputees that are able walk at greater speeds than 1.3m/s.

Ross *et al.* (2003) found that using Endolite Telescopic Torsion Pylon SAP did not lower the peak GRF significantly compared to a non-SAP. But they found that there was an average 37% delay in the timing of the peak force when using SAP, which indicates that the forces acting on the stump are exerted more gradually and would therefore cause less discomfort. Furthermore, during the mid stance there is a less dip in the GRF when using the SAP this makes the rollover easier for the AP. Ross *et al.* observed a higher second peak during the late stance phase, which indicates that there was some energy return from the SAP. Furthermore, Ross et al. noted that the GRF vector passed closer to the hip joint while using SAP. This allowed for earlier onset of knee flexion in late stance, which allows for easier roll over.

Although these studies do not show a significant improvement in TTA gait when using SAP the participants reported that they preferred to use the SAP over the non-SAP. This is supported by the findings from the works of Hsu et al. (1999) and Buckley et al (2002). They looked at how the SAP affected energy expenditure, gait efficiency, and relative exercise intensity. Buckley et al. also had the participants rate the comfort of use. They found that SAP positively affects energy cost, oxygen consumption, and relative exercise intensity. This was especially true at higher speeds I both studies. Four out of six participants in Buckley's study reported that they preferred the SAP over the non-SAP.

In summary, there does not seem to be very significant improvements in the kinematics of TTA gait when using SAP compared to non-SAP. So, it might be surprising to find that most participants in these studies preferred using the SAP. But, these studies had a fairly low number of participants, Gard and Ross had 10 each while Childress only had 2 participants. This might limit the statistical power of the studies. On the other hand, the subjective reports from the participants and the improvements in physiological variables indicate that SAP benefits TTA during ambulation, especially for more active TTA.

CHAPTER 3

HOW DO DIFFERENT STIFFNESS SETTINGS OF A SHOCK-ABSORBING PROSTHESIS AFFECT TRANS-TIBIAL AMPUTEE GAIT MECHANICS?[1]

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Abstract

Shock absorption pylons (SAP) have been designed to improve shock absorption in the gait of individuals with transtibial amputation (Ind-TTA). The effects of different stiffness settings of a shock absorbing pylon (SAP) in a lower limb prosthesis on the mechanics of gait in individuals with transtibial amputation (Ind-TTA) was examined. Ground reaction force (GRF), spatiotemporal, and kinematic data was collected from seven Ind-TTA walking at self-selected speed on a level surface using seven different stiffness settings on SAP. The results showed no significant differences in any of the variables examined. Potential reasons for this are: a) the air pressures didn't affect gait at these self-selected walking velocities, b) low sample size, c) and differing participant responses to the air pressures. Thus it seems that different air pressure settings do not have behavioral effects on Ind-TTA gait.

Keywords: Shock Absorbing Pylon, Prosthesis, Trans-tibial amputees, Ground reaction force, Gait

Introduction

For an individual who uses a lower-extremity prosthesis due to amputation or limb dysfunction to ambulate, one mechanical function that is diminished in the affected limb is vertical impact force attenuation (Kirtley, 2006; Perry, 1992; Rose & Gamble, 1994). Consequently, during gait, individuals with transtibial amputation (Ind-TTA) compared to those without a transtibial amputation (Ind-CON) can develop problems associated with increased mechanical stresses, such as knee and hip osteoarthritis (in either leg) and back pain (Collins & Whittle, 1989b; Gard & Konz, 2003; Kulkarni et al., 2005; Voloshin & Wosk, 1982a)).

Furthermore, impact force attenuation during gait is affected by perceived stability. During the ProsL support phase, Ind-TTA tend to limit knee flexion to increase ProsL stability (Bateni, H., Olney,S.J., 2002; Berge et al., 2005; Powers et al., 1998; Sanderson & Martin, 1997). However, reduced knee flexion impairs impact force attenuation (Greene & McMahon, 1979; Lafortune et al., 1996; Lafortune, Lake et al., 1996).

To minimize discomfort due, in part, to abnormal pressure to the residual limb (ProsL), Ind-TTA, may make adjustments to gait (D. A. Winter & Sienko, 1988)(Sanderson & Martin, 1997; D. A. Winter & Sienko, 1988)). Gard and Konz (2003) surmised that this explained why the ProsL support phase time and walking velocity of Ind-TTA were less compared to Ind-non-TTA. Such adjustments led to decreased vertical ground reaction forces (VGRF) on the ProsL compared to the non-prosthetic limb (non-ProsL), but led to increased stress on the contralateral side of the body (Beyaert et al., 2008; Nolan et al., 2003).

One method purported to improve impact force attenuation capabilities of the prosthesis for Ind-TTA (if they need a pylon to bridge the distance between their socket and prosthetic foot), is a ‘shock-absorption’ pylon (SAP) system, a term coined by prosthetic companies (Berge et al., 2005; Gard & Konz, 2003; L. A. Miller & Childress, 1997). This is done by replacing the rigid pylon with a pylon-like unit containing a spring-dampener element, such as a coil spring (CS), carbon fiber spring (CFS); or a viscoelastic rod (VER) alone or in combination with an air compartment as shown in Figure 1.1. Typically, the prosthetist selects the 'stiffness' of the element from several that the manufacturer offers. The stiffness selected is typically based on the user's mass and activity level.

Biomechanical outcomes of previous gait research, however, have been mixed. Gard and Konz (2003) found that the forces applied to the ProsL can be decreased when using a coil-system SAP. An SAP with a leaf-spring system was found to significantly reduce energy cost (Hsu et al., 1999)(Hsu et.al., 1999) for those participants whose walking velocities were greater than 1.3 m·s-^{1}. Furthermore, users of SAP (CS, CFS) system have reported improved comfort and 'smoothness' during walking, less prosthesis 'stiffness', and less effort during stair use (Berge et al., 2005; Buckley, Spence, & Solomonidis, 1997; Gard & Konz, 2003; L. A. Miller & Childress, 1997)

It is unclear if using an SAP improves gait kinematics compared to a conventional, rigid pylon (Berge et al., 2005; Gard & Konz, 2003; L. A. Miller & Childress, 1997; Ross, J., Luff, R., Ledger,M., 2003). Gard (2003) found that, for some participants, their gait asymmetry increased rather than improve as predicted. Neither Berg (2005) nor Miller (1997), though, reported increased gait asymmetry.

These mixed outcomes may be influenced by the methods used to attenuate impact forces and/or the particular stiffness of the SAP used in the prior research. To our knowledge, no research exists to understand the biomechanics gait when a viscoelastic rod/air pressure SAP system is used. Moreover, for such a system, no investigators have determined how different stiffness settings of such an SAP affect gait biomechanics. Of the two components that influence the pylon's static stiffness and dampening coefficients of the SAP system used in this study (Figure 1.1), the VER inside the pylon and air pressure in the pylon chamber, we manipulated the air pressure. Therefore, the purpose of our study was to investigate how different air pressure of the Ceterus® SAP (Össur hf.) viscoelastic rod/air pressure SAP system affects gait kinematics and GRFs for Ind-TTA.

We anticipated that, during the prosthetic-limb support phase of gait, the responses to increased air pressure would be individual-participant dependent. Compared to moderate air pressure settings (i.e., 10-30 psi), at the greater air pressure settings (40-60 psi), the participant's biomechanical outcomes could fall closer to one of the two ends of the response continuum: a) primarily mechanical, and b) primarily participant-response. One end of the continuum of responses was predicted for a participant if a behaviorally-driven adaptation to increased air pressure was low, and a more mechanical response to increased prosthesis stiffness occurred. Thus, as dampening of the prosthesis is most likely nonlinear , a nonlinear pattern of greater peak impact VGRF magnitude, an increased rate of application, and decreased relative time to VGRF peak would be observed for greater air pressure settings.

Predicted outcomes closer to the other end of the continuum were expected to occur if the participant adopted some type of adaptive strategy to attenuate the potentially greater GRF impact forces. At greater (40 – 60 psi) compared to lower air pressures (0 psi - 30 psi), we therefore expected greater knee joint flexion displacement during the 1st DBLS in order to improve shock absorption. The increase in knee joint flexion will lead to decreased hip flexion displacement, Furthermore, at the higher air pressures, we also expected that the 1st DBLS would decrease, but the single stance phase durations of the ProsL would decrease, as a strategy to minimize vertical GRF impact loading on the ProsL

Methods

Participants

Seven male[2] Ind-TTA participants volunteered via recruitment by local prosthetists, (see table 3.1 for characteristics). The participants signed an informed subject consent form approved by our institutional review board. A proprietary health status questionnaire (see appendix A) was used and medical clearance obtained to determine if a potential participant was healthy, free from other conditions or impairments that could affect performance or health/safety; and had used a lower-limb prosthesis for more than one year. Any eligible participant not already wearing a Ceterus® system was fitted with one by his prosthetist and had at least a two week acclimation period. The prosthetist placed an appropriate viscoelastica rod in the SAP for each participant, according to manufacturer's recommendation. The researcher were blinded to the rod stiffness in the SAP.

Data Collection

To prepare for data collection, anthropometric values were obtained for each participant, including the dimensions of the residual limb. Then reflective markers were placed on the trunk, pelvis, and lower extremities of the participant. A modified Helen Hayes marker system (Lu & O´Connor, 1998; 1999) was used for the lower extremities, while a modified VICON© Plug-In-Gait© (Vicon, Inc., Englewood, CA) marker system was used for the upper extremities (see appendix B for marker placements). Marker placements for the prosthesis were located to correspond to marker placements of the non-ProsL. Then the participant performed 5 min. of

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[2] No females volunteered although recruitment of all potentially eligible participants occurred.

Table 3.1 Participant characteristics

	Mean ± SD	Min.	Max.
Age (yr)	48 ± 15	23	70
Height (cm)	179.4 ± 5.5	170	187
Mass (kg)	92.1 ± 17.4	70	116

walking at his self-selected speed. During this time, to determine the participant's step rate, the researcher first adjusted a silent metronome to match the frequency with that of the participant's step frequency. Then, using the metronome's aural signals, further refinements of the metronome frequency were made as necessary until the performer confirmed that the metronome frequency matched his pace. Next, the participant performed several practice trials to demonstrate the ability to maintain natural gait at the metronome cadence throughout the entire walk distance. In order to keep the gait consistent among trials the participant performed the trials walking to the cadence of the metronome.

The participant performed 3 successful walking trials at each of the seven different air pressure conditions (0 psi, 10 psi, 20 psi, 30 psi, 40 psi, 50 psi, 60 psi). The order that the experimental air pressure settings performed were quasi-counterbalanced among the participants. The performer was blinded as much as possible to the current air pressure setting. After trials of a given pressure condition were completed, during a two-minute minimum rest period, the prosthesis air pressure was set to the next air pressure condition by a researcher. The participant then performed several practice trials to adapt to the new air pressure before testing resumed. For each trial, the participant walked approximately 4 m before and after stepping onto the force platform with the ProsL. Based on visual inspection of the GRF curves, visual observation of the participant, and the participant's self-report of an atypical trial, if the performer had an atypical step onto/off the force platform, the trial was repeated.

During the gait trials the spatial locations of the markers were captured by seven MX-40® digital video cameras using a Vicon® motion measurement system (120 fps; software: Workstation™, v.5.2.4; Vicon, Inc., Los Angeles, CA)(see figure 3.1 for experimental setup). An AMTI® force platform and conditioner-amplifier (Model OR6-6-1 and SGA6-4, respectively;

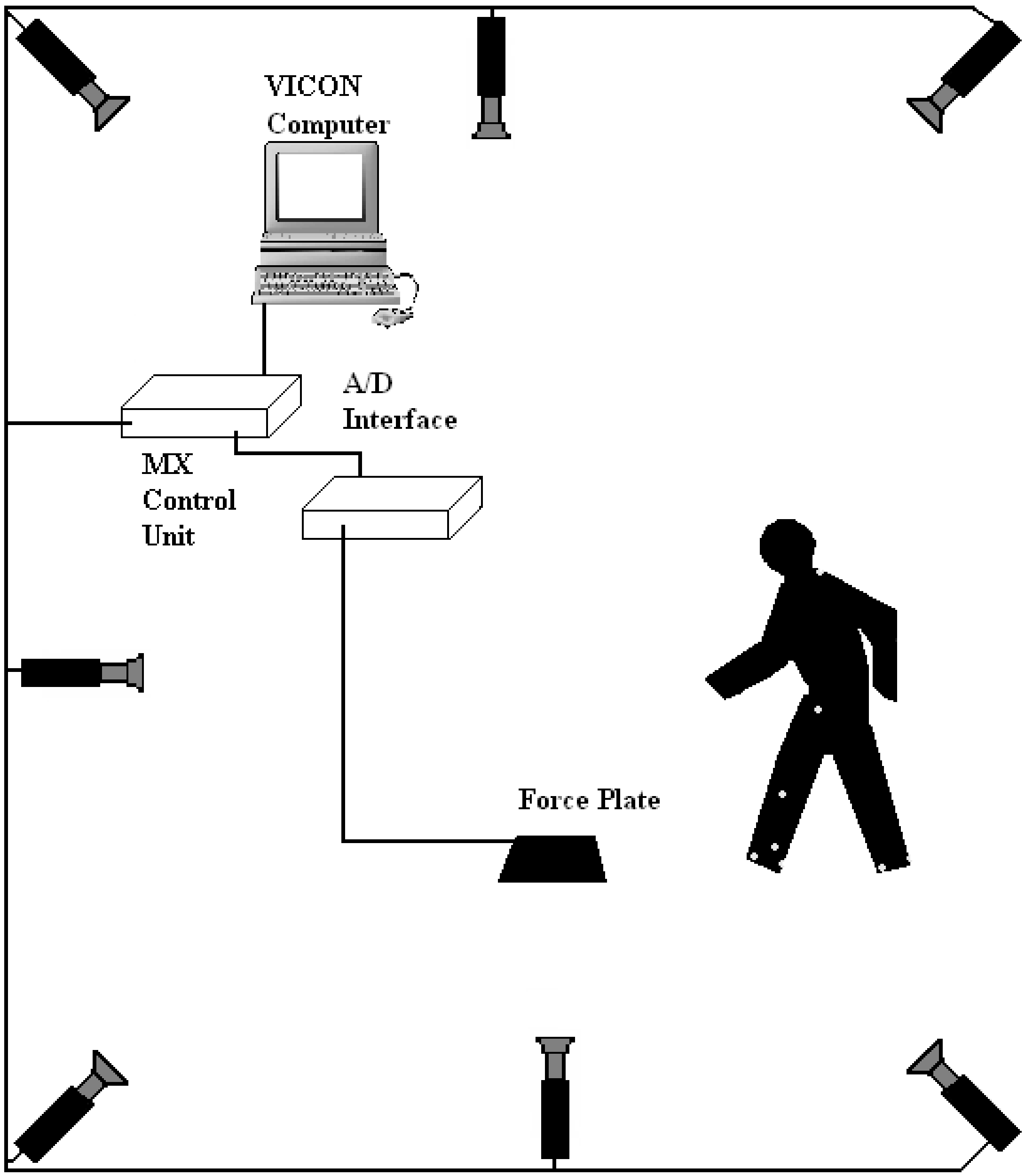

Figure 3.1Experimental setup.

Advanced Mechanical Technology, Inc., Newton, MA) were used to collect GRF data (1200 Hz; low-pass filter = 1050 Hz).

At the end of the testing session all the participants were informally asked how they liked the Ceterus® and how it compared their previous prosthesis.

Data reduction

GRF curves were analyzed using in-house software (MatLab® v.7.0). For the GRF variables in the vertical (VGRF) and antero-posterior (AP-GRF) directions, maximum magnitudes and times to maximum magnitudes were generated. GRF and temporal variables were scaled to body mass and duration of the stance phase (%ST). In addition, the AP-GRF braking, propulsive, and total impulses were calculated.

Marker locations were reconstructed using a VICON© proprietary algorithm and the data filtered (generalized cross-validated spline algorithm)(Woltring, 1986). A modified Plug-in-gait model was used to reconstruct the spatial locations of the upper extremities. The segmental coordinate systems were defined using the International Society of Biomechanics recommendations (ISB)(Wu & Cavanagh, 1995) . For the Cardan joint angles of the lower extremities (Wu & Cavanagh, 1995), the angles were expressed relative to the angles demonstrated during natural standing. The kinematic data of interest for the stance phase were the flexion/extension knee and hip joint displacements and overall gait kinematics for the stride of each leg.

Statistical Analysis

Due to a small sample size, Friedman's two-way repeated measures of variance (RM ANOVA) were used to test for limb and air pressure effects on the aforementioned variables. Furthermore, we did single-subject analyses for the variables of major interest if outcomes of the

Friedman´s ANOVA testing were insignificant. Model Statistics were used (Bates, 1996) for the single subject analysis. In this method, for a given participant and variable, to compute the critical difference between any two air pressure means, the root mean square of the standard deviations of the air pressure conditions is generated, then multiplied by a table value based on trial size for the desired alpha level (Bates, 1996). The difference between any two air pressure means of interest must have exceeded the critical difference to be considered significant. An alpha level of .05 was used for all significant tests.

Results

The self-selected walking speed mean for the group across all air pressure conditions was 1.18 ± 0.15 $^{m \cdot s\text{-}1}$. There was no significant difference in the walking velocity between conditions ($\chi^2(6) = 4.926$, $p = .533$), with the greatest absolute difference between air pressure conditions being 0.06 $^{m \cdot s\text{-}1}$.

Values for kinematic and temporal variables are represented in table 3.2. There were no significant differences for step or stride length ($\chi^2(6) = 4.347$, $p = .630$; $\chi^2(6) = 3.980$, $p = .679$) or duration of stance phase of either limb (figure 3.2) ($\chi^2(6) = 6.306$, $p = .390$) between air pressure conditions. The stance phase lasted from about 63.7% to 64.9% of the stance (figure 3.3). For the group means, the minimum and maximum values for the duration of the stance phase occurred at 60 and 30 psi, respectively.

For the knee and hip joint kinematic outcomes shown in figure 3.4, there were no significant differences detected between air pressure conditions for the ProsL and nonProsL. Moreover, group means of air pressure conditions for the knee joint displacement displayed during the 1st DBLS varied only by 1° and 3° for the ProsL and nonProsL, respectively. For individual participants, the range of differences among air pressure conditions was 2° to 4° for

Table 3.2. Kinematic and temporal variable: group means + SD, range of mean values among air pressure conditions, and the range of within-participant values among the minimum and maximum air pressure values. KFD= knee joint displacement; HFD=hip joint displacement; SL=step length; SP=stance phase; SLSP=single limb stance; GC, gait cycle.

		Range for group means		Range for participant values	
Variable	Mean ± SD	Max	Min	Max	Min
KFD 1st DBLS (°)					
ProsL	10 ± 5.57	10	10	19	0
nonProsL	19 ± 4.47	20	19	26	10
HFD 1st DBLS (°)					
ProsL	11 ± 4.20	13	11	23	6
nonProsL	5 ± 2.86	6	4	14	1
SL (% leg length)					
ProsL	7.77 ± 1.33	7.9	7.7	9.09	5.89
nonProsL	7.80 ± 0.95	7.9	7.7	9.35	6.76
SP duration (% of GC)					
ProsL	64.33 ± 3.76	64.9	63.7	68.87	57.55
nonProsL	66.45 ± 1.89	66.7	66.1	70.14	64.44
1st DBLS SP duration (% of GC)					
ProsL	16.53 ± 0.24	16.9	16.13	22.4	11.44
nonProsL	13.59 ± 1.58	14.00	13.26	15.80	11.62
SLSP duration (% of GC)					
ProsL	33.50 ± 1.68	34.01	32.74	34.70	29.86
nonProsL	36.33 ± 3.00	36.80	35.99	41.03	32.11

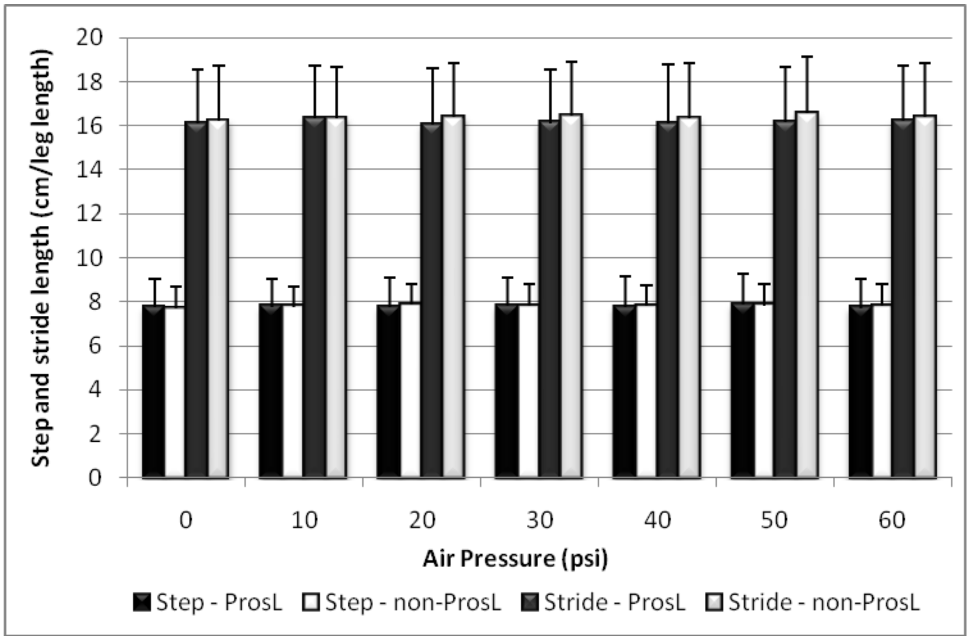

Figure 3.2. Means (error bars:1 SD) for step and stride lengths for both limbs scaled to leg length. No significant limb x pressure interactions or main effects were detected ($p > 0.50$)

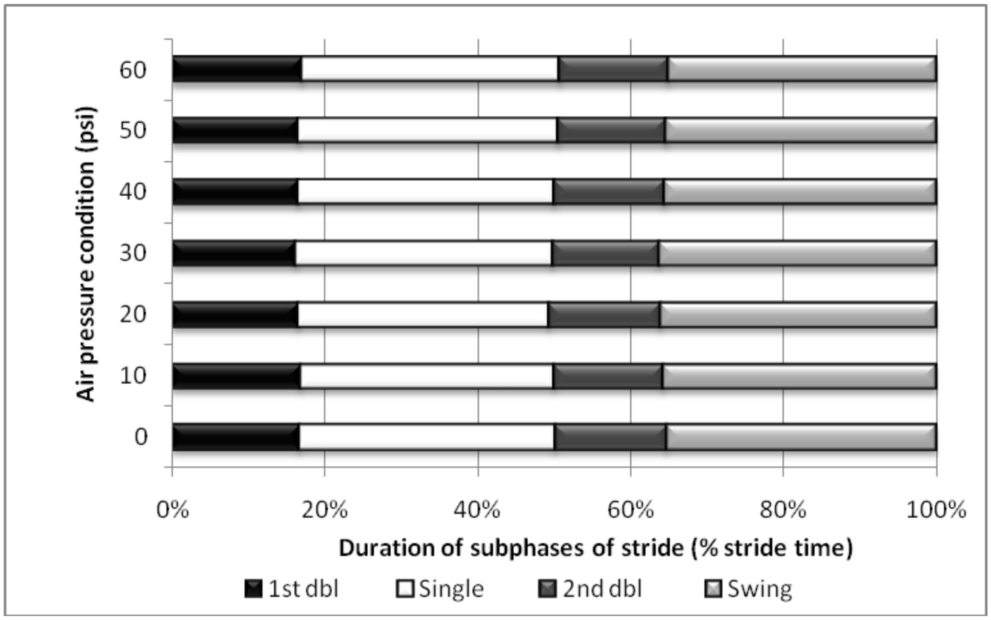

Figure 3.3. Mean durations of stride subphases for the prosthetic (ProsL) and nonprosthetic (nonProsL) limb. No significant limb x pressure interactions or main effects were detected ($p > 0.50$)

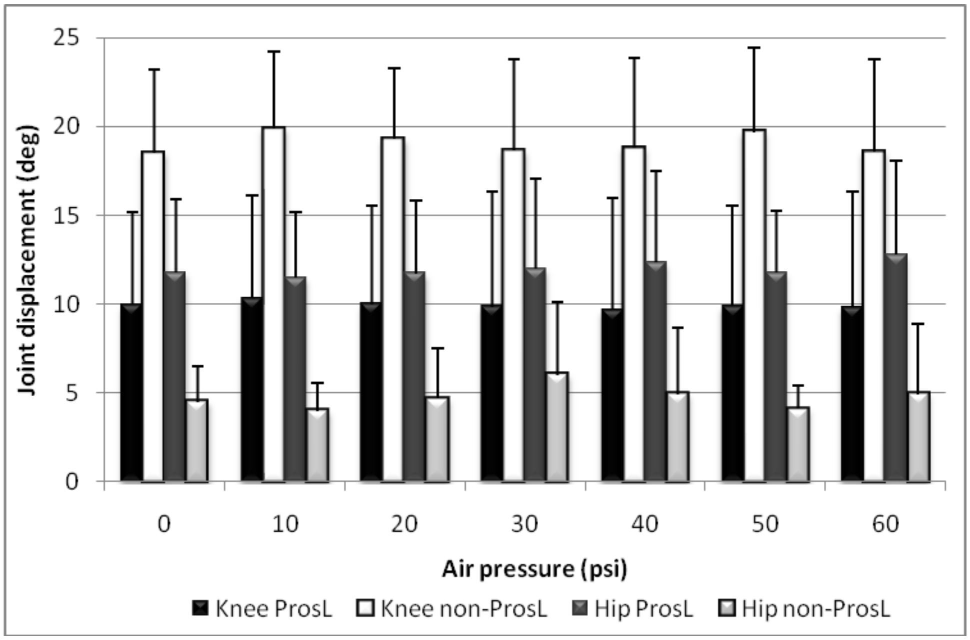

Figure 3.4 Knee and hip joint displacements during 1st DBLS support phase the for ProsL and nonProsL (p = .944 to .396). No significant limb x pressure interactions or main effects were detected (p > 0.50)

the ProsL and 2° to 9° for non-ProsL. Air pressure group means for the hip joint displacement displayed during stance varied by 2° and 1° for the ProsL and nonProsL, respectively. Range of differences for individual participants among air pressures for the ProsL were from 2° to 9°and from 1° to 5° for the nonProsL.

The GRF variables are represented in figures 3.5 – 3.6 and table 3.3. No significant differences were found for any of GRF variables for the Friedman's ANOVAs (p = .107 to .570). The percentage differences in group means between air pressure conditions for the GRF variables if interest ranged from 1% to 16%.

No significant differences that indicated affects of air pressure settings were found among conditions for single subject analysis. Qualitatively, the difference among condition for individual participants is low (see table 3.4) and does not follow any observable patterns. However, with increased air pressure, the 1st peak VGRF magnitude displayed one discernible pattern among seven participants (figure 3.7). The pattern (was a U-curve for the 0 – 40 psi conditions (3 participants). For the other five participants, no discernible patterns were exhibited.

When asked informally, all participants had positive comments on using the Ceterus®. Furthermore, all but one participant preferred the Ceterus® over the prosthesis they had previously used.

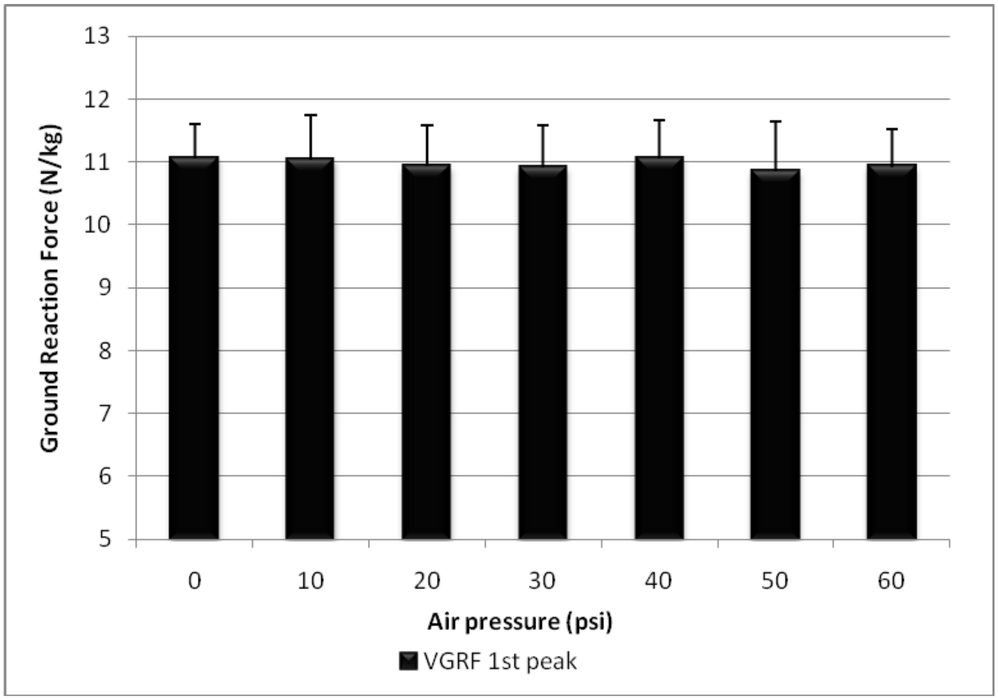

Figure 3.5. Group means (error bars:1 SD) for the first peak VGRF (p = 0.57).

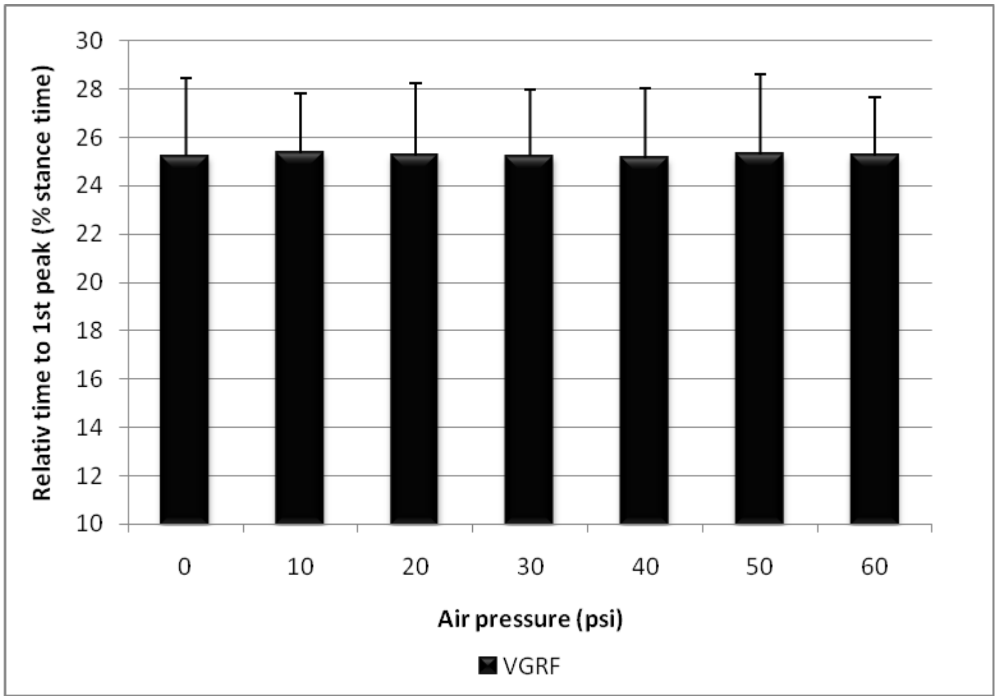

Figure 3.6. Group mean (error bars:1 SD) for the relative time to first VGRF peak (p = .522).

Table 3.3. VGRF variables for the prosthetic limb: group means + SD, range of mean values among air pressure conditions and the range of within-participant values among the minimum and maximum air pressure values. Rel. t,= relative time; ST=stance.

		Range for group means		Range for participant values	
Variable	Mean	Max	Min	Max	Min
1st peak (N/kg)	10.96 ± 0.62	11.06	10.85	12.43	10.03
Rel. t to 1st peak (% ST)	25.42 ± 2.71	25.35	25.12	29.44	19.38

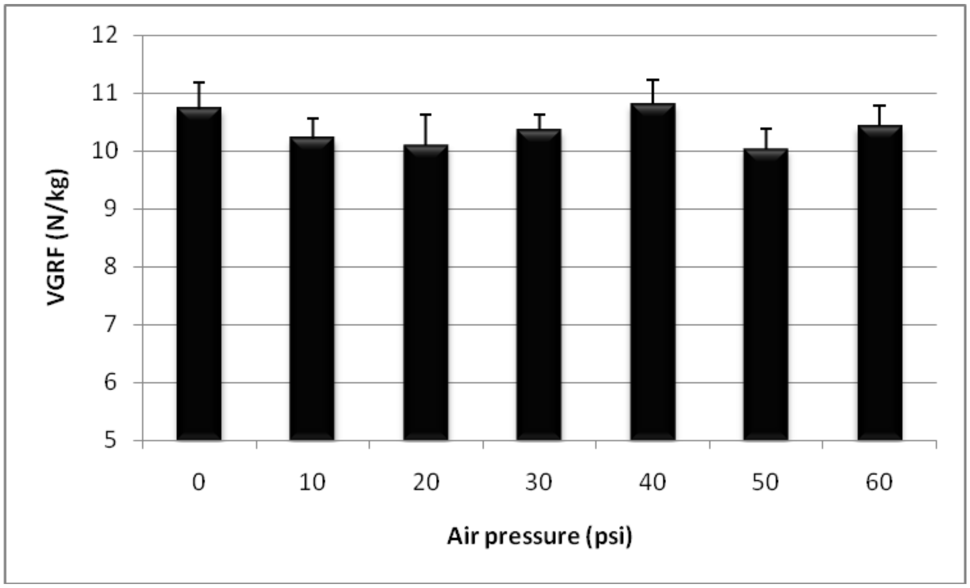

Figure 3.7. Representative first VGRF peak (error bars:1 SD) graph for qualitative u-pattern displayed by 3 participants.

Table 3.4. Range of within-participant differences among air pressure conditions. KFD=knee joint displacement; HFD=hip joint displacement; SP=stance phase; GC, gait cycle.

	Intraparticipant differences between conditions	
Variable	Max	Min
KFD 1st DBLS (°)		
ProsL	3	2
nonProsL	10	2
HFD 1st DBLS (°)		
ProsL	5	1
nonProsL	8	1
SP duration (% of GC)		
ProsL	7	1
nonProsL	3	1
1st DBLS duration (% of GC)		
ProsL	5	1
nonProsL	3	1

Discussion

We had hypothesized that, for the Ceterus® SAP, tendencies toward one of two responses to greater air pressure would be more prevalent among participants: a) the 1st VGRF peak value would increase, while the relative times to the 1st VGRF peak would decrease; or b) there would be increased knee and hip joint displacements during the 1st DBLS. However, no significant group differences were detected for any of the variables of interest, nor did we detect significant differences from the single subject analyses.

There are several potential explanations why there was a paucity of significant differences between the air pressure settings. As the air pressure setting on the Ceterus® is a secondary method to fine-tune the stiffness of the pylon, it is possible that air pressure does not significantly affect shock absorption during natural walking. Furthermore, we had much inter-participant variability and a small sample size, thus, low statistical power. The relatively low average walking velocity might have diminished the effects of air pressure on VGRF.

GRF variables also could have been affected little by air pressure changes as this is the secondary method for changing the stiffness of this SAP system. Most of the shock absorption occurs in the VER, thus, even though the air pressure setting set at zero the Ceterus® still provides significant shock absorption (Freygardur Thorsteinsson, personal communication, 2008). Furthermore, in all but one prior research study in which a rigid pylon was compared to an SAP, only one study reported decreased first maximum VGRF (i.e., impact force) during gait (Ross, J., Luff, R., Ledger,M., 2003), whereas others reported no difference (Adderson et al., 2007; Berge et al., 2005; Gard & Konz, 2003; L. A. Miller & Childress, 1997). Even though we observed one pattern for 1st peak VGRF with greater air pressure for three of the participants, the pattern was not pronounced enough to demonstrate statistical significance of the single-subject comparisons. Thus, it is difficult at present to draw any conclusions about the air pressure affects on VGRF variables.

The somewhat lower average walking velocity in this study, 1.2 ± .2 $m \cdot s^{-1}$, compared to approximately 1.3 $m \cdot s^{-1}$ for non-TTA-Ind (Perry, 1992), might explain the lack of significant findings. Nolan et al. (2003) found that with increased walking velocity (above 1.5 $m \cdot s^{-1}$), Ind-Amp demonstrated a significant increase in maximum 1st VGRF, while at velocities between 0.5 – 1.2 $m \cdot s^{-1}$, there was no increase. Furthermore, neither Gard and Konz (2003) nor Berge et al. (2005) found a significant difference for 1st peak VGRF when comparing SAP and a conventional pylon when their participants walked at self-selected velocity (ranging from 1.11 $m \cdot s^{-1}$ to 1.25 $m \cdot s^{-1}$).

Thus, it is possible that air pressure differences for the impact forces (if they exist) may become more evident at faster walking velocities (Nolan et al., 2003). However it is unclear if this would occur, as one of our participants who walked at velocity around 1.44 $m \cdot s^{-1}$ displayed no consistent or significant responses to increased air pressure.

The participants did not exhibit changes in knee joint displacement during the 1st DBLS among air pressure conditions, suggesting that these Ind-TTA likely did not use a knee flexion strategy to compensate for increased air pressure. By increasing the knee flexion during the 1st DBLS, during typical gait, limbs' shock absorption capabilities increase (Lafortune et al., 1996; Lafortune, Lake et al., 1996), and the body is less affected by the increased loading. It also has been observed in previous studies that Ind-TTA increase knee joint flexion during the 1st DBLS stance phase for both limbs as limb loading increases, compared to the contralateral limb and Ind-CON limb (Snyder, Powers, Fontaine, & Perry, 1995). However, as loading on the ProsL increases a greater knee joint flexion is demonstrated at the non-ProsL (Bateni, H., Olney,S.J., 2002; Kendell, Lemaire, Dudek, & Kofman, 2010; Powers et al., 1998; Sanderson & Martin, 1997). It has been suggested these adjustments decrease discomfort on the stump caused by the increased loading (Berge et al., 2005; Sanderson & Martin, 1997; Silverman et al., 2008)(Tokuno et al., 2003).

In contrast to typical gait, Ind-Amp show greater knee extension displacement by the ProsL during the stance phase in order to increase knee stability (Berge et al., 2005; Button et al., 2010; Kendell et al., 2010). Berge et al. (2005) found that when Ind-TTA used an SAP (Mercury Telescopic Torsion Pylon®, CS system) they exhibited even greater ProsL knee extension compared to wearing regular pylons, which he attributed (although not measured) to participants feeling less stable (Berge et al., 2005). Our lack of finding a significant difference for knee joint displacement, if not due to low sample size, further supports the notion that the difference between air pressure conditions may not be sufficient enough to produce discomfort; consequently, the user does not make significant adaptations to the gait.

The last potential, but perhaps primary, explanation for the lack of kinematic and kinetic group differences among is individual participant responses to increased air pressure. Hence, it is likely that air pressure does not have the same effect on the majority of these individuals. It has been well documented that people will uniquely either consciously or subconsciously adapt their mechanics to minimize impact forces (Berge et al., 2005; Robbins & Gouw, 1991). Berge et al. (2005) believed that this was the most likely explanation for the lack of any biomechanical differences displayed between the rigid pylon and the SAP of their gait study. The U-pattern observed for the VGRF, even though not significant, can give some credibility to the notion of individual adaptation.

However, from single-subject analysis and through qualitative observation (see table 3.4) individual participant adjustments were not found among the conditions. Thus, even though people will make unique adjustments to their gait (Berge et al., 2005; Robbins & Gouw, 1991), it seems that individual participant responses to increased air pressure did not affect their gait. This might further support the idea that increased air pressure does not have behavioral affects on Ind-gait, or at lease only minor affects.

Some participants had definite and unique opinions about how the prosthesis felt at different air pressures. Participant perceptions of the prosthesis at different air pressure settings could have been affected by familiarity with whatever air pressure setting they had used long term. Furthermore, all but one long-term Ceterus® users reported not ever adjusting the air pressure and did not know their air pressure when they arrived. However, from the single subject analyses, we were not able to find any statistically significant unique patterns for any of the variables we looked at.

Even though none of the SAP studies have reported improved gait mechanics for Ind-TTA using SAP, most of their participants reported preference for using SAP over rigid pylons (Berge et al., 2005; Gard & Konz, 2003; L. A. Miller & Childress, 1997) All but one participant in this study reported informally that they preferred the Ceterus over their previous prosthesis. Thus, it seems like the users of SAP perceive improvements in their gait and feel more comfortable during gait. It is possible that these improvements the user perceives are so small that they are hard to quantify by using traditional gait analysis.

Summary and Conclusion

No group differences were detected for GRF and kinematic variables among the air pressure settings of the Ceterus® as predicted. Potential reasons for this are: a) the air pressures didn't affect gait at these self-selected walking velocities, b) low sample size, c) and differing participant responses to the air pressures. Even though we were not able to detect an optimal air pressure range for the participants as a group or individually, most of the participants preferred the Ceterus® over their previous prosthesis. Further studies are needed to explore how greater difference in stiffness settings affects Ind-TTA gait as well as comparing Ind-TTA wearing Ceterus and Ind-CON.

CHAPTER 4.

HOW DOES A SHOCK ABSORPTION PYLON OF A TRANSTIBIAL PROSTHESIS AFFECT KINEMATIC INTERLIMB SYMMETRY AND GROUND REACTION FORCES DURING GAIT?[3]

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Abstract

The purpose of this study was to evaluate the effects of the Ceterus® on the gait of Ind-TTA and compare Ind-TTA gait to Ind-CON gait. Gait analysis on lower extremity kinematic and ground reaction force (GRF) data was carried out for seven Ind-TTA walking with the Ceterus® SAP prosthesis and seven matched Ind-CON. Results show significantly greater gait asymmetry for Ind-TTA compared Ind-CON. The symmetry index (SI) for first double limb stance (1st DBLS), single limb stance (SLS), and knee and hip joint displacement during 1st DBLS were less for Ind-TTA. Ind-TTA exhibited less knee joint flexion displacement during 1st DBLS and greater single limb stance period compared to Ind-CON. Significantly lower maximum rate of VGRF application was registered during the 1st DBLS for Ind-TTA. The significant difference in maximum rate of VGRF application indicates that the SAP used in this study is effective in reducing the rate at which impact forces from the ground are applied to the prosthetic-side limb, which allows for increased stability.

Keywords: Shock Absorbing Pylon, Prosthesis, Trans-tibial amputees, Ground reaction force, Gait, Gait symmetry

Introduction

For individuals who use a transtibial prosthesis due to amputation or limb dysfunction (Ind-TTA), important mechanical functions to be accomplished during locomotor activities may not be achieved optimally and/or the person may use compensatory adaptations (Button et al., 2010; Kendell et al., 2010; Nolan et al., 2003; Perry, 1992; D. A. Winter & Sienko, 1988; Zmitrewicz et al., 2006). For gait, one diminished mechanical function is the attenuation of impact forces in situations that can potentially cause excessive stresses placed on the residual limb (Collins & Whittle, 1989b; Kulkarni et al., 2005; Voloshin & Wosk, 1982a).

Consequently, if the result is pain or discomfort, gait functionality is negatively affected (Gard & Konz, 2003). Therefore, to prevent increased prosthetic limb (ProsL) stresses, and to compensate for missing tissues, Ind-TTA exhibit the following gait adjustments compared to control individuals (i.e., individuals without an amputation (Ind-CON): decreased gait speed; less stance time on the prosthetic limb (ProsL) and increased stance time on the nonprosthetic limb (nonProsL); and greater knee joint displacement of the nonProsL and less knee joint displacement on the ProsL during the stance phase , (Bateni, H., Olney,S.J., 2002; Beyaert et al., 2008; Gard & Konz, 2003; Sanderson & Martin, 1997). Therefore, due to these gait adjustments, Ind-TTA gait is less symmetrical compared to Ind-CON.

These gait adjustments affect the ground reaction forces (GRF) acting on the lower extremities of Ind-TTA. There is significantly lower vertical GRF (VGRF) acting on the ProsL compared to the non-ProsL and CON-ProsL (Lloyd et al., 2010; Nolan et al., 2003; Sanderson & Martin, 1997; Silverman et al., 2008; Zmitrewicz et al., 2006). Not only has it been reported that there is greater VGRF acting on the non-ProsL compared to ProsL, but also compared to Ind-CON (Lloyd et al., 2010; Nolan et al., 2003; Sanderson & Martin, 1997; Silverman et al., 2008;

Zmitrewicz et al., 2006). Thus, the non-ProsL is experiencing even greater loading stress compared both ProsL and Ind-CON.

These gait adjustments, however, may lead to mechanical stress-related problems in other body tissues, especially those of the non-ProsL (Collins & Whittle, 1989; Hurley, McKenney, Robinson, Zadravec, & Pierrynowski, 1990; Kulkarni, Gaine, Buckley, Rankine, & Adams, 2005; Lemaire & Fisher, 1994; Nack & Phillips, 1990; Voloshin & Wosk, 1982). Ind-TTA compared to Ind-CON experience a higher rate of lower back pain, osteoarthritis in proximal weight-bearing joints, and cartilage degeneration of either/both legs (Collins & Whittle, 1989b; Norvell et al., 2005; Voloshin & Wosk, 1982a). When these ailments cause pain and discomfort, quality of life can be greatly affected and may limit occupational options (Deans, McFadyen, & Rowe, 2008).

It is evident, therefore, that reduced shock-absorption capacity of a prosthesis potentially affects not only the tissue integrity of the ProsL but also that of the nonProsL. Hence, by increasing the shock absorption capabilities of the prosthesis, Ind-TTA should display greater interlimb symmetry and other gait kinematics and kinetics more similar to those displayed by Ind-CON.

Therefore, several prosthetic companies have produced ‘shock- absorption’ pylons (SAP) to replace the rigid pylon of the prosthesis that bridges the prosthetic foot and socket. Metal-coil springs (CS), carbon-fiber leaf springs (CFS) or viscoelastic rods (VER) have been used as dampeners in SAP. For this gait study, the SAP (Ceterus, Össur h/f) is comprised of a VER and an air pressure shock tube to produce GRF attenuation (see Figure 1.1).

The evidence supporting the effectiveness of SAP systems for improving the gait mechanics of Ind-TTA, however, is mixed. Prosthetic users rated SAP systems (CS and CFS systems) compared to nonSAP systems as providing improved comfort, 'smoother' walking, and less 'stiffness' of the prosthesis during gait' and also perceived less 'effort' was required when walking up or down steps (Buckley, Spence, & Solomonidis, 1997; Gard & Konz, 2003, Berge et al. 2005). Gard and Konz (2003) found that the forces applied to the ProsL can be decreased when using SAP with CS (Gard & Konz, 2003). Other benefits shown for particular SAP's (e.g., the Re-Flex VSP® (CFS) and Endolite TTA® (CS), compared to rigid pylons are significantly reduced energy cost (Hsu et al., 1999), and improved gait for Ind-TTA walking at velocities greater than 1.3^{m*s-1} (Gard & Konz, 2003; Hsu et al., 1999).

Conversely, investigators of three gait studies did not find that the use of a SAP (Re-Flex VSP® and Endolite TTA®) compared to a nonSAP significantly affected the maximum impact magnitude or rate of application of VGRF on the ProsL (Adderson et al., 2007; Berge et al., 2005; L. A. Miller & Childress, 1997). Although Ross et al. (2003) reported a slight decrease in the VGRF impact peak, as it was not statistically significant they did not believe that, overall, it affected gait. Additionally, improved gait symmetry was not reported for any of the studies that compared SAP to nonSAP prosthetic systems (Berge et al., 2005; Gard & Konz, 2003; L. A. Miller & Childress, 1997; Ross, J., Luff, R., Ledger,M., 2003). Moreover, Gard and Konz (2003) actually observed decreased symmetry for the SAP condition in their study.

To our knowledge, none of the previous SAP studies determined how an SAP system with a VER and air chamber affects Ind-TTA gait mechanics compared to Ind-CON. Thus, the purpose of this study was to understand how SAP (Ceterus®, Ossur, h.f.) affects Ind-TTA gait kinematics and GRFs compared to Ind-CON. We expected to see less knee joint flexion displacement, increased hip joint flexion, less stance phase duration, and greater first double limb stance phase (1st DBLS) duration for the ProsL compared to non-ProsL. Consequently, the asymmetry of the Ind-TTA gait would be greater compared to Ind-CON gait. We also expected to see decrease in the VGRF peak impact magnitude and maximum rate of VGRF application and increase in relative time to VGRF peak impact.

Methods

Participants

All potential participants signed an informed subject consent form approved by the University of Georgia's Institutional Review Board. Eligibility to participate also was assessed using a proprietary health-status questionnaire. Participants included seven male Ind-TTA individuals and seven Ind-CON males, matched a given Ind-TTA based on age (± 5 years) height (± 3 cm), and mass (± 5 kg) (see Table 4.1). The Ind-TTA had used a lower limb prosthesis daily for at least one year and had worn the Ceterus SAP for a minimum of two weeks just prior to testing (five participants had been using the Ceterus as their primary prosthesis for daily use). All participants met the following inclusionary criteria not experiencing pain or any physical or cognitive impairment that could affect walking performance; taking any form of medication known to impair balance or physical ability to walk; and free from any known cardio-vascular impairment not controlled by medication.

Protocol

Test session procedures

Anthropometric characteristics were obtained from each participant (including residual shank length). Next, reflective markers were placed on the participant's trunk, pelvis and lower extremities using a modified Helen Hayes marker system (Lu & O´Connor, 1998; 1999) for the lower extremities, while a modified VICON© Plug-In-Gait© (Vicon, Inc., Englewood, CA) marker system was used for the upper extremities (see appendix B for marker placements).

Table 4.1 Participant characteristics

Group		Characteristics		
		Age (yr)	Height (cm)	Mass (kg)
Ind-TTA	Mean ± SD	48 ± 15	179 ± 6	92. ± 17
	Minimum	23	170	70
	Maximum	67	187	116
Ind-CON	Mean ± SD	47 ± 14	181 ± 7	90 ± 16
	Minimum	21	173	70
	Maximum	66	187	111

Markers placed on the prosthesis were similarly located to those of the corresponding marker placements of the nonProsL.

Before performing gait trials, the participant performed several practice trials at a self-selected, natural pace to warm up the body, acclimate to the experimental setup, and determine the performer's natural pace to be used during testing. While the person walked, the frequency of a metronome was adjusted silently, and then the auditory mode was used so that the participant could have the researcher adjust the speed of the metronome if necessary. This was done to keep the gait consistent among trials.

For each gait trial, the person walked approximately 8 m to the beat of the metronome while the spatial locations of the reflective markers were captured by seven MX-40™ visible-red digital video cameras using a Vicon® motion measurement system (120 fps; software: Workstation™, v.5.2.4; Vicon, Inc., Los Angeles, CA). The Ind-TTA and Ind-CON stepped with the ProsL and the matched limb, respectively, onto a force platform (sampling rate = 1200 Hz; low-pass filter = 1050 Hz; AMTI Model OR6-6-0™) embedded in the floor midway along the walkway.

Six acceptable trials were collected; for Ind-TTA, three trials each at 10 psi and 20 psi were obtained (researchers were blinded to viscoelastic rod stiffness). These two pressures were selected as they are in the range of the recommended settings for daily use. Furthermore, for this same prosthesis, no significant pressure differences were exhibited for gait in a previous study (Sigurdsson, et al 2010).

<u>Data reduction</u>

Laboratory software programs (MatLab® v. 7.0) were used to calculate variables for one stride of each leg. The GRF variables included the peak magnitudes of the 1^{st} VGRF, and time to the corresponding peak magnitudes; and maximum rate of VGRF application between foot contact and first peak VGRF. All GRF and temporal variables were scaled to body mass and duration of the stance phase time (% ST), respectively.

For the kinematic data, 3D locations of the reflective markers were reconstructed via a proprietary method (Workstation™ software, Vicon) Kinematic data were then smoothed using Woltring´s generalized cross-validated spline (GCVSPL) algorithm (Woltring, 1986) . A MatLab® software (v. 7.0) was used to calculate kinematic and biomechanical quantities. Cardan rotation order was used to calculate the lower extremity joint angles (Wu & Cavanagh, 1995). The kinematic variables of interest were stance phase characteristics, and for the knee and hip joints , flexion displacements occurring during the 1st DBLS . Temporal variables were scaled to the duration of the gait cycle for comparison.

Group differences for the interlimb symmetry of kinematic gait variables were of interest. The symmetry index for each variable of interest was calculated as follows (Marinakis, 2004) :

$$\mathrm{S.I.} = 100 \times \min(V_{PL}, V_{NPL}) \div \max(V_{PL}, V_{NPL}),$$

where S.I. stands for symmetry index, V_{PL} stands for value of variables measured for ProsL and V_{NPL} stands for the nonProsL. The limb with the smaller variable value was divided by the value for the opposite limb (Marinakis, 2004).

Statistical Analysis

Due to the small sample size and unique morphology of Ind-TTA participants, 2-way Friedman's ANOVA was used to test for group differences for the variables previously identified. An alpha level of 0.050 was considered significant and *p* values of 0.051 to 0.060 were considered as potential tendencies toward statistical significance for all comparisons. Coefficients of variation (CV) were calculated to show participant variability.

Results

The descriptive data and statistical outcomes for the kinematic variables are presented in table 4.2 and representative joint angle-time curves are presented in appendix C. Walking velocity was not significantly different between the two groups ($\chi^2(1) = 1.286$, $p = .257$). The Ind-CON walked at approximately 1.3 m/s while the Ind-TTA walked at approximately 1.2 m/s Furthermore, no significant differences were found for step and stride length.

The durations of stance sub-phases are presented in figure 4.1. The single limb stance duration was the only statistically significant variable ($\chi^2(1) = 7.00$, $p = .008$) (CV = 5.4, Ind-TTA; 2.5, Ind-CON). The single limb stance phase lasted about 2.5% longer for Ind-CON compared to Ind-TTA on the ProsL.

The knee and hip joint displacements exhibited within the 1st DBLS are displayed in figure 4.2. The knee flexion displacement during 1st DBLS was 11° less for the Ind-TTA compared to Ind-CON ($\chi^2(1) = 7.00$, p = .008) (CV: Ind-TTA = 55.6; Ind-CON = 10.6,). There was a tendency for greater hip flexion displacement for Ind-TTA compared to the Ind-CON, but it was not statistically different ($\chi^2(1) = 3.571$, p = .059)(CV = 33.3, Ind-TTA; 10.6, Ind-CON). No other significant differences were detected for knee and hip joint kinematics.

Values and statistical outcomes for GRF variables are presented in table 4.2. Only one VGRF variable of interest was found to be significantly different. The maximum rate of VGRF application (see figure 4.3) was 311 N/kg/s greater for Ind-CON compared to Ind-TTA ($\chi^2(1) =$ 7.00, p = .008CV: Ind-TTA = 18.6; Ind-CON = 25.3).

Shown in table 4.3 are the SI values and the statistical outcomes for the knee and hip joint variables. There was significant difference found in symmetry for both the knee and hip joint

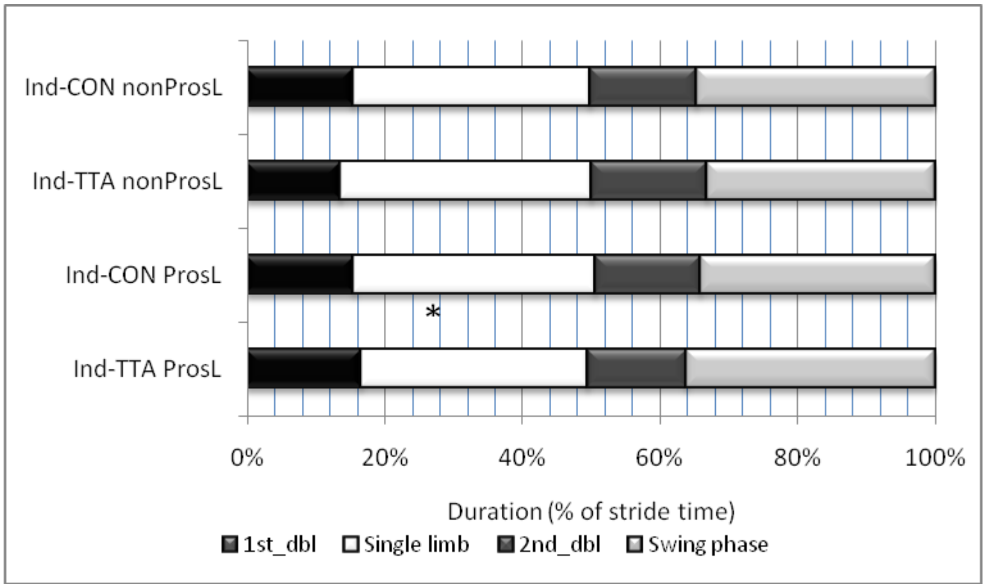


Figure 4.1. Durations of subphases of stride for Ind-TTA and Ind-CON for the ProsL and nonProsL. * indicates significant difference at $p < .05$ for single limb stance on ProsL between Ind-TTA and Ind-CON.

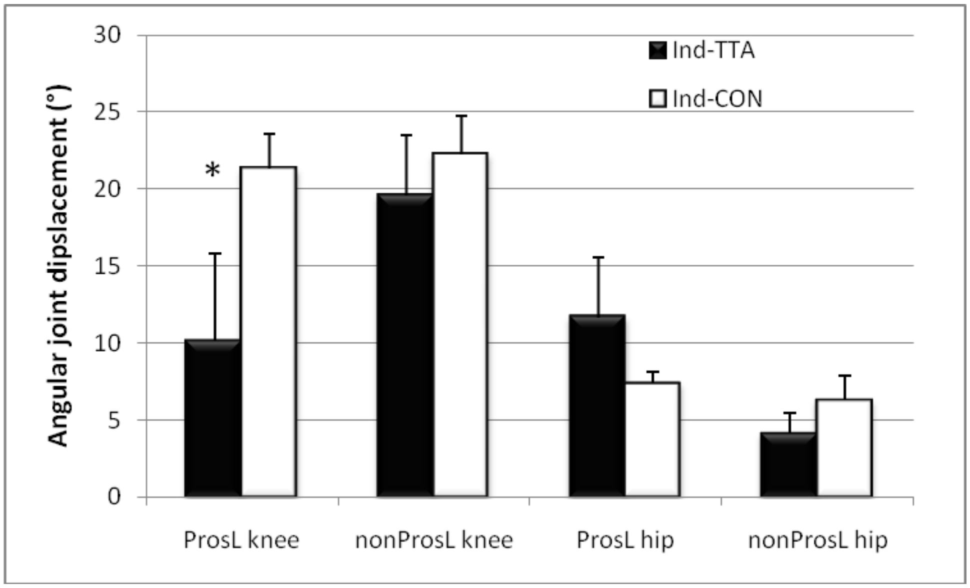


Figure 4.2. Knee and hip joint flexion displacements (error bars:1 SD) demonstrated within 1st DBLS for Ind-TTA and Ind-CON for the ProsL and nonProsL. * indicates significant difference at $p < .05$.

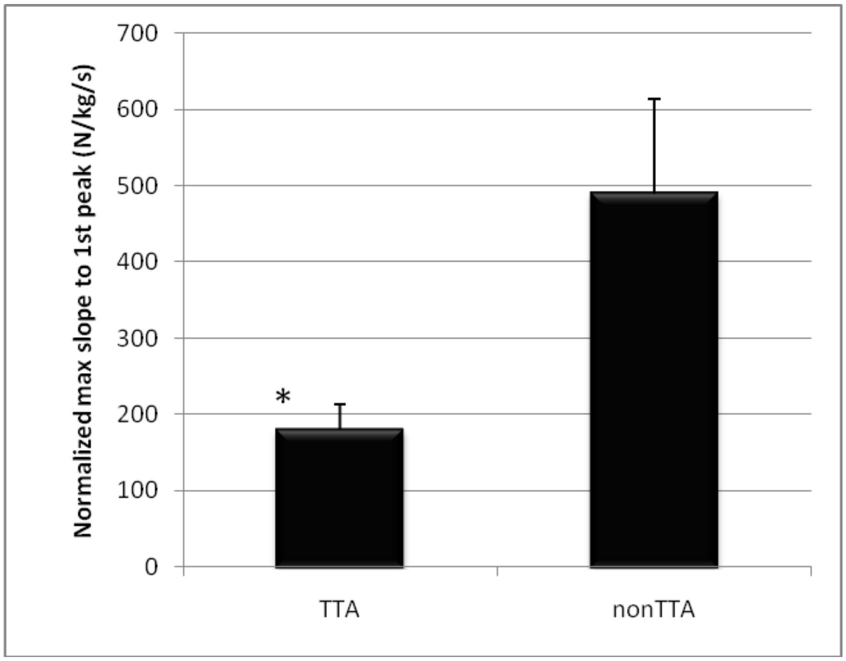


Figure 4.3. Maximum rate of VGRF application that occurs during the impact phase (error bars:1 SD). * indicates significant difference at $p < .05$.

Table 4.2. Means ± 1 SD, p-values and statistical power for kinematic and GRF variables of individuals with transtibial amputation (Ind-TTA) and control participants (Ind-CON). Stance subphase durations and temporal GRF variables are expressed as a % of the stride time (% ST).

	Participant Group			
Variables	Ind-TTA	Ind-CON	p value	Power
Walking velocity	1.2 ± 0.2	1.3 ± 0.1	0.257	0.22
Vertical GRF				
1st peak (N/kg)	11.0 ± 0.7	11.29 ± 0.7	0.705	0.08
Rel. time to 1st peak (%ST)	25.3 ± 3	24.6 ± 1.7	0.705	0.07
Max slope to 1st peak ()	179 ± 33	490 ± 124	0.008*	0.80

* indicates significant difference between groups, $p < .05$.

Table 4.3. Means ± 1 SD for symmetry index (S.I.) values for Overall Gait Characteristics and Joint Displacement Variables. p values and statistical power are shown for Friedman's non-parametric repeated measures.

	Participant Group			
S.I. variables	Ind-TTA	Ind-CON	p-value	power
Step length	92.5 ± 5.4	97.9 ± 1.9	0.257	0.35
Stride length	96.6 ± 2	98.6 ± 1.8	0.059	0.36
Stance subphase duration				
1^{st} DBLS	82.6 ± 11.8	96.7 ± 2.3	0.008*	0.66
Single limb	90.3 ± 6.1	98.1 ± 1.1	0.008*	0.69
2^{nd} DBLS	86.9 ± 9.2	96.5 ± 2	0.059	0.55
Full stance	94.3 ± 4.6	99.1 ± .6	0.059	0.45
Joint angle displacement				
Knee 1^{st} DBLS	52 ± 26	94 ± 6	0.008*	0.72
Hip 1^{st} DBLS	36 ± 11	84 ± 14	0.008*	0.80

* indicates significant difference between groups, $p < .05$.

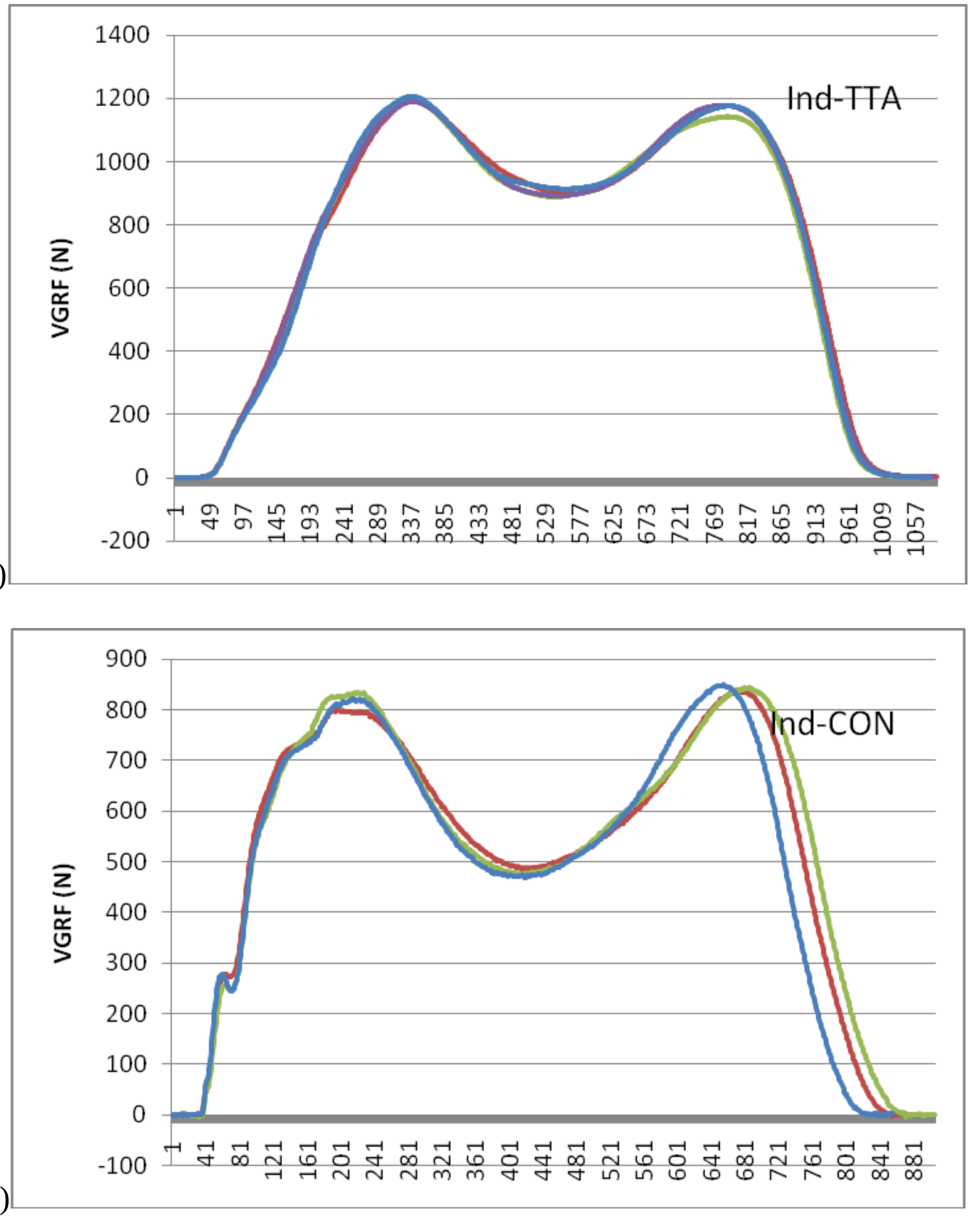
displacement during 1st DBLS ($\chi^2(1) = 7.00$, $p = .008$; for both variables) (CV: Ind-TTA = 50.5 and Ind-CON = 4.31 for knee; Ind-TTA = 14.1 and Ind-CON = 3.6 for hip).

As shown in table 4.3 for the SI outcomes of the temporal, overall gait characteristics, Ind-TTA showed significantly greater asymmetry for the duration of the 1st DBLS, the difference in S.I. value was 14.1 ($\chi^2(1) = 7.00$, $p = .008$) (CV: Ind-TTA = 14.3; Ind-CON = 2.3), with the ProsL 1st DBLS lasting longer. The non-ProsL was on the ground for a greater time during single limb stance for the Ind-TTA compared to the Ind-CON, as the difference in S.I. values was 7.8 SI, ($\chi^2(1) = 7.00$, $p = .008$) (CV: Ind-TTA = 6.7; Ind-CON = 1.1).
No significant differences were found for the S.I. values of the duration of the stance and the 2nd DBLS , nor step and stride lengths (presented in table 4.3).

From qualitative assessments of the VGRF graphs (see figure 4.4 for representative graphs) all Ind-CON exhibited a heel-strike transient early in the 1st DBLS, while none of the Ind-TTA.

Discussion

During gait, the primary purpose of an SAP is to minimize the VGRF transmitted to the ProsL during the early part of the stance phase, by improving the shock absorption (Berge et al., 2005; Gard & Konz, 2003; L. A. Miller & Childress, 1997). We had anticipated that, compared to Ind-CON, the Ind-TTA would exhibit lower magnitudes for the 1st VGRF peak, the maximum rate of VGRF application and increased time to GRFs peaks of interest. We also expected seeing greater asymmetry for spatiotemporal and kinematic variables of interest exhibited in the Ind-TTA gait compared to Ind-CON. Differences were found for some of the variables that supported some of our predictions.



a)
b)

Figure 4.4 Representative graphs for VGRF curve. In figure a (Ind-TTA) there is no observable heel strike transient, while in figure b (Ind-CON) there is an observable heel strike transient.

For the VGRF-related variables, our hypotheses were partially supported. Although there were no significant group differences for the 1st VGRF peak magnitude nor the time to this peak, there was a decreased maximum rate of VGRF application displayed by Ind-TTA (179 N/kg/s SD 33) compared to Ind-CON (490 N/kg/s SD 124). There are several potential explanations for the non-significant group differences for the 1st VGRF peak magnitude.

Our findings suggest that the SAP may not have been instrumental in attenuating impact forces. This is in agreement with previous findings from SAP studies which did not detect differences of peak vertical impact forces between an SAP and a rigid pylon condition, concluding that coil and spring leaf SAP systems may have limited force attenuation capabilities (Adderson et al., 2007; Berge et al., 2005; Gard & Konz, 2003; L. A. Miller & Childress, 1997). It is also possible that the low statistical power caused by inter-participant variability and small sample size explains why we did not find significant difference for the 1st VGRF peak.

However, it might also be possible that there is not a significant difference between Ind-TTA and Ind-CON and that the mechanics of the Ceterus® effectively reduces the impact and discomfort experienced on the ProsL by Ind-TTA. When comparing the values for the VGRF peak there is only a 0.34 N/kg difference (3% difference) between the groups. Our lack of significant finding is in contrast to previous findings, where Ind-TTA were reported exhibiting less 1st VGRF peak compared to Ind-CON (Lloyd et al., 2010; Nolan et al., 2003; Sanderson & Martin, 1997; Silverman et al., 2008; Zmitrewicz et al., 2006).

For the maximum rate of VGRF application, the significantly lower value of the Ind-TTA compared to the Ind-CON and the lack of heel strike transient displayed by Ind-TTA may indicate that the SAP-prosthesis unit is effective at decreasing the rate at which the GRF are being applied to the ProsL (percent difference 174). Heel strike transient has been correlated to degenerative This maximum rate occurs during the 1st DBLS phase when the body's weight is being shifted onto the ProsL and VGRF impact forces are being applied to the prosthesis. As mentioned above, increased rate of VGRF application has been linked to increased discomfort and degenerative diseases on the ProsL. As the heel strike transient has also been linked to degenerative joint diseases ((Collins & Whittle, 1989a; Voloshin & Wosk, 1982b; Voloshin & Wosk, 1982c; Wosk & Voloshin, 1981), the SAP possibly diminishes the negative affects of the heel strike transient.

Moreover, the lack of heel-strike transient may be a feature of this but not all types of SAP systems. To the best of our knowledge, Gard and Konz (2003) found that, for a coil system SAP, a heel strike transient was demonstrated by all participants Moreover, compared to the rigid pylon condition, the magnitude of the transient decreased only for the four participants who walked at speeds at or above 1.3 m/s.

Adderson et al. (2007) found that all participants, when wearing their own prosthetic foot and a pressurized-air SAP or a rigid pylon, displayed at least one trial without a transient. However, the presence/absence of the heel strike transient was only dependent on the individual participant and not the SAP. Furthermore, Adderson et al. found no difference for the magnitude of the heel strike transient between SAP conditions.

Knee flexion displacement during the 1st DBLS, one of the most important shock absorption strategies (Lafortune et al., 1996; Lafortune, Lake et al., 1996), typically is minimized during the Ind-TTA´s compared to typical gait in order to increase stability. Moreover, according to investigators of prior SAP gait studies, the use of an SAP does not improve the knee flexion displacement value towards the ranges of typical values for individuals without amputation compared to a non-SAP (Berge et al., 2005; Buckley et al., 1997; Gard & Konz, 2003). In agreement with these previous studies , in our study the Ind-TTA did exhibit less knee joint displacement compared to Ind-CON.

It has been suggested that decreased knee joint displacement is part of an adaptive strategy Ind-TTA use to feel more stable during the 1st DBLS when the body's weight is being transferred to the ProsL (Berge et al., 2005; Button et al., 2010; Kendell et al., 2010; D. A. Winter & Sienko, 1988). Because the prosthetic foot cannot generate active plantarflexor muscle moments required to stabilize the foot-ankle complex (D. A. Winter & Sienko, 1988), the Ind-TTA feels unstable, as has been reported (Kendell et al., 2010; Legro et al., 1999; W. C. Miller et al., 2001). Conversely, to increase stability, when the ProsL remains in a more extended knee joint position at heel strike and through the 1st DBLS, the antero-posterior location of the center of gravity will be within the foot earlier in the stance phase compared to nonProsL and Ind-CON.

A consequence of decreased knee joint displacement is diminished shock absorption during 1st DBLS (Lafortune et al., 1996; Lafortune, Lake et al., 1996). The decreased maximum rate of VGRF application we found in this study compensates to some level for this diminished shock absorption on the ProsL. This allows the Ind-TTA to increase stability by decreasing knee joint displacement, without increasing the negative effects of increased impact forces during 1st DBLS, as mentioned above. Thus, possibly reducing fear of falling, a major concern for Ind-TTA (Kulkarni et al., 2005; Legro et al., 1999; W. C. Miller et al., 2001). This would give the user improved gait experience.

Increased asymmetry for Ind-TTA gait, caused by adaptations to lack of shock absorption, such as decreased knee joint displacement and stance time on ProsL, has been linked to degenerative joint diseases (Collins & Whittle, 1989b; Hurley et al., 1990; Kulkarni et al., 2005; Voloshin & Wosk, 1982a). Thus, it has been suggested that it is important to improve gait symmetry for Ind-TTA minimize the risk of degenerative joint disease. However, it has also been suggested that the most effective gait pattern for Ind-TTA might not be a symmetrical gait pattern, as the Ind-TTA is missing major mechanical properties of a nonProsL (D. A. Winter & Sienko, 1988).

As we predicted the asymmetry for 1st DBLS phase and single limb stance duration was greater for Ind-TTA. The 1st DBLS phase lasted for longer time on ProsL, while the single limb stance phase lasted for shorter time on the ProsL. Although not significant, there was a tendency for the full stance phase duration asymmetry to be greater for the Ind-TTA, with it lasting longer for non-ProsL. This is in line with previous findings (Bateni, H., Olney,S.J., 2002; Beyaert et al., 2008; Sanderson & Martin, 1997).

There are at least two suggested reason for why Ind-TTA show increased asymmetry for the stance phase duration. One reason could be due to the fact that Ind-TTA tend to feel less stable on the ProsL compared to nonProsL (Bateni, H., Olney,S.J., 2002; Breakey, 1976; Powers et al., 1998). Thus, by spending greater time on the ProsL during 1st dbl stance phase and less time on the ProsL during the single limb stance, they might be increasing their stability. Another possible explanation might be that by spending less time on the ProsL the Ind-TTA is minimizing the time the GRFs are acting on the stump, thus making the step less uncomfortable (Berge et al., 2005; Gard & Konz, 2003; Lloyd et al., 2010; Perry, 1992; Sanderson & Martin, 1997).

One goal in designing prosthesis is to minimize the excessive asymmetry in Ind-TTA gait, with the hope to reduce the increased stress on the body. We only found significant difference in four of ten symmetry variables we looked at; Ind-TTA showing greater asymmetry for all four. Furthermore, we found tendencies for five more symmetry variables to be more asymmetrical for Ind-TTA. Thus, using SAP does not seem to improve Ind-TTA gait symmetry to be on par with Ind-CON. These findings are similar to what has previously been reported in the SAP literature with no detected improvement in symmetry when comparing SAP with non-SAP (Berge et al., 2005; Gard & Konz, 2003; L. A. Miller & Childress, 1997). Gard and Konz (2003) even found some evidence for increased asymmetry when using SAP. Force attenuation is only one of many factors that affect asymmetry in Ind-TTA gait. So, it cannot be expected that by improving prosthetic force attenuation the asymmetry will improve drastically. It is important that the asymmetry in Ind-TTA gait is not great, as it has been shown that it can put increased stress on the body. However, there are just too many variables that affect Ind-TTA gait for it to be viable to get close to perfect symmetry (Winter and Sienko 1988). .

Similarly to previous findings (Berge et al., 2005; Gard & Konz, 2003; L. A. Miller & Childress, 1997), all but one participant when asked informally reported that they were satisfied with the SAP. This suggests that the force attenuation provided by the SAP is effective in making Ind-TTA feel more comfortable when walking. Thus, the lowering of the rate of VGRF application seems to play a role in improving Ind-TTA gait experience.

There are some limitations to this study. First of all, the statistical power was low for the non-significant variables. Also, the participants walked at their self-selected velocity which might affect the outcome. However, the average velocity difference between the groups was only 0.1 m/s and was not significantly different. Furthermore, the effect of SAP prosthesis may have affected the GRF of the nonProsL, but this was not investigated. GRF data were only collected for the ProsL and the matched limb of the Ind-CON. It has been reported that there is a significant difference in the GRF variables between the ProsL and the nonProsL for gait (Arya et al., 1995; Beyaert et al., 2008; Hermodsson et al., 1994; Lloyd et al., 2010; Nolan et al., 2003; Pinzur et al., 1995; Silverman et al., 2008; Zmitrewicz et al., 2006). In order to gain a better understanding of the possible benefits of this SAP system, the interlimb symmetry for joint moments and power and the actual amount of force applied to the residual limb should be investigated. Finally, the uniqueness of how each Ind-TTA adjusts his/her gait makes it hard to find consistent trends in their gait, compared to the matched Ind-CON. This would also exacerbate the statistical power problem.

In summary, there are some indications that the SAP-prosthesis system of this study reduces the rate of impact force application on the ProsL for Ind-TTA. This might allow the user to increase the stability on the ProsL through decreased knee joint displacement without sacrificing shock absorption on the ProsL. Thus, this might support the view that increased asymmetry is not necessarily the most effective way to improve gait for Ind-TTA Even though the users of this system demonstrate somewhat greater kinematic interlimb asymmetry compared to Ind-CON, , almost all the participants preferred the SAP over the type of prosthesis they had used previously, as did participants wearing SAP in previous studies (Berge et al., 2005; Gard & Konz, 2003; L. A. Miller & Childress, 1997).

CHAPTER 5

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

Summary

The purpose of these studies was to examine the affects of a shock-absorbing pylon (SAP) on gait mechanics of individuals who use a transtibial prosthesis due to unilateral, transtibial amputation (Ind-TTA) or another reason. This SAP (Ceterus®, Össur hf.) uses a viscoelastic rod and air pressure as the primary and secondary methods, respectively, to adjust the stiffness and dampening parameters of the pylon that bridges the socket and prosthetic foot. For Study #1, we asked if there was a particular range of air pressure settings of the SAP that would attenuate impact forces without otherwise negatively affecting gait kinematics. For Study #2, we wanted to determine if the vertical ground reaction forces and gait kinematics of the Ind-TTA when the SAP contained the manufacturer-recommended amount of air pressure were atypical compared to control individuals (Ind-CON).

Seven Ind-TTA males (age 20-65 yr) participated in both studies, while the seven matched Ind-CON participated only in Study #2. For the first study, seven air pressure conditions (0 – 60 psi) were administered in a partially-counterbalanced order. Participants for both studies walked across an eight meter walkway while spatial locations of reflective markers placed on both lower extremities were captured via high-speed, digital video (120 frames/s) and vertical ground reaction force (VGRF) signals were collected (1200 samples/s). VGRF, and knee joint motion and overall gait kinematic variables were analyzed. For Study #2, interlimb symmetry index also was calculated for the kinematic variables. 2-way Friedman´s ANOVA were used for group statistical analyses. Single-subject analyses also were used for Study #1 to determine if individual participants responded differently to the varied air pressures.

For the first study, no significant group differences for any variables were detected among air pressure conditions. The single-subject analyses displayed some differences for some variables. Qualitatively, the participants reported that liked the comfort of the Ceterus as much or more than their previous, nonSAP system. However, there were was only one minor trend of air pressure effects among the variables or individual participants of which three participants displayed a U-shaped trend for the first peak VGRF. Thus, this could indicate the SAP was having some effect on the impact forces for these individuals.

There are several possible explanations for why we did not find significant group and few individual-participant differences between air pressure conditions. The statistical power was low due to the small sample size and the interparticipant variability. Furthermore, air pressure is the method used to ‘fine-tune’ the stiffness and dampening of the pylon, and therefore, it is possible that the differences in air pressure do not significantly affect the gait mechanics.

For the second study, we found significant differences for two of the kinematic variables and significant greater asymmetry for four of the SI variables. For Ind-TTA compared to Ind-CON, the single limb stance lasted for longer, there was less knee joint displacement that occurred during the 1st double-limb support phase, and the maximum rate of VGRF application was decreased. These findings suggest that Ind-TTA can make adaptations that increase stability, through decreased knee joint flexion, during stance without sacrificing shock absorption.

CONCLUSIONS

Although the Ind-TTA were comfortable using the Ceterus, were not able to detect changes between stiffness settings, it appears that the different air pressure settings may not affect Ind-TTA gait mechanics greatly. However, the Ceterus® seems to have some positive effects on shock absorption on the ProsL during gait when compared to typical gait.

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APPENDICES

Appendix A

Participant #: ______
Date: _____________
Invest. initials: _____

Health Status Questionnaire

Instructions:

- Please respond as completely as possible. Your responses to this questionnaire will be kept confidential and will only be reviewed by the two main investigators.

- IF you wear ***prostheses on both limbs***, for questions regarding your legs and/or protheses, please be sure to answer the questions ***for both legs*** and indicate **R** (for right leg) and **L** (for left leg).

Enter answers:

____ Male ____ Female Age _______

Amputated side (circle) - Left Right Both

How many years have you worn a prosthesis on your leg(s)?
____

What manufacturer and model of prosthesis (and components if relevant) are you currently using for daily life (if known)? (If you wear more than one prosthesis, list all, starting with the one you use the most during daily life)

____
____

If you wear only one prosthesis or wear prothesis on one limb only, how long have you worn your current prosthesis/prostheses: years: ______

OR:

If you wear more than one prosthesis or wear prostheses on both limbs, answer for each prosthesis/limb: limb or prosthesis: ______________________ years: _____

other limb or other prosthesis: ____________________ years: _____

Are you currently having any problems with any part of your prosthesis, including the socket?

Circle: Yes No If yes, explain the problem briefly:

____

____

____

<u>Health Conditions</u>

1) Please identify how you would evaluate your health overall (circle best choice below)

Excellent Good Fair Somewhat poor Very poor

2) Do you have any current medical problems? Circle: yes no

If yes, complete the following table. Use one row of table for each medical problem. Use space below table if more space is needed.

Describe the problem	***Has it been diagnosed by a physician? (yes/no)***	***Treated by a physician or other medical professional? (yes/no)***	***Does the problem affect your balance, strength, vision, movements; produce nausea or dizziness? (yes/no)***	***Are you currently taking medication for problem? (yes/no). If yes, list the medication.***
a.				
b.				
c.				

3) Have you previously had or presently have any of the following medical conditions? (If yes, please indicate the *date of first symptoms or diagnosis* by month/year; for example "5/2003").

Date	Previously	Presently	
_______	__________	_________	Pain in heart or chest
_______	__________	_________	Heart attack
_______	__________	_________	Heart murmur
_______	__________	_________	Extra or skipped heart beats
_______	__________	_________	Abnormal EKG
_______	__________	_________	Any other heart or cardiovascular problem:

specify:

____

_______	__________	_________	Phlebitis
_______	__________	_________	Dizziness or fainting spells
_______	__________	_________	Stroke
_______	__________	_________	Hypertension
_______	__________	_________	Gout
_______	__________	_________	Diabetes
_______	__________	_________	Epilepsy
_______	__________	_________	Asthma
_______	__________	_________	Other lung diseases: specify

____

_______	__________	_________	Nervous or emotional problems
_______	__________	_________	Injuries to back, arms, legs or joints
_______	__________	_________	Back pain
_______	__________	_________	Swollen, stiff or painful joints
_______	__________	_________	Arthritis of arms or legs
_______	__________	_________	Allergies to adhesive tape or to gel used for

EKG or

ultrasound

Explanation or

comments:____

4) Have you experienced any of the following conditions within the last week, or experiencing any of the following today? (Circle Yes or No)
   a) Balance problems? Yes / No
   b) Nausea, especially during physical activity? Yes / No
   c) Dizziness? Yes / No
   d) Vision problems? Yes / No
   e) Uncoordinated, e.g., clumsy, wobbly or shaky? Yes / No
   f) Impaired ability to think or follow directions? Yes / No
   g) Pain/discomfort/injury? Yes / No   If YES, explain:

5) Noticeable side effects from medications (prescription or nonprescription)? Yes / No.
   If YES, list the medication and the side effects experienced:

6) Date of last complete medical exam: _______ Were there any abnormalities or conditions diagnosed that we need to be aware of? Yes No   If YES, explain

____

____

____

7) Have you ever experienced the following? Place a checkmark under "yes" or "no." If yes, then check off the appropriate spaces.

Yes No Broken bone? If so, to: ____ right leg ____ left leg ____ spine ____ intact foot

Yes No Surgery? If so, to: ____ right leg ____ left leg ____ spine ____ intact foot

Yes No Sprain to: ____ right or left hip ____ right or left knee ____ intact ankle

8) Yes No Are you currently recovering from an illness or an injury? If yes, or not sure, describe:

____

____

9) Yes No Is there any other information related to your health that we should know and/or might affect your ability to complete the task for this research? If yes, explain.

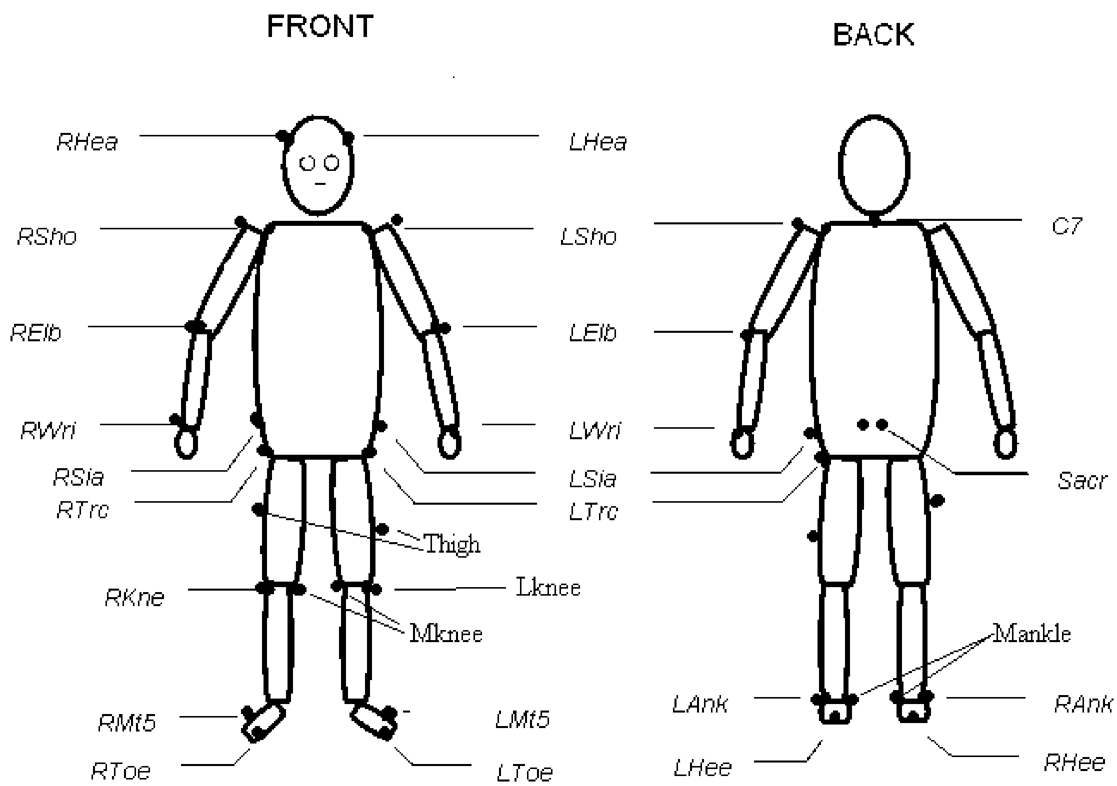
____

____

Other comments:

Appendix B

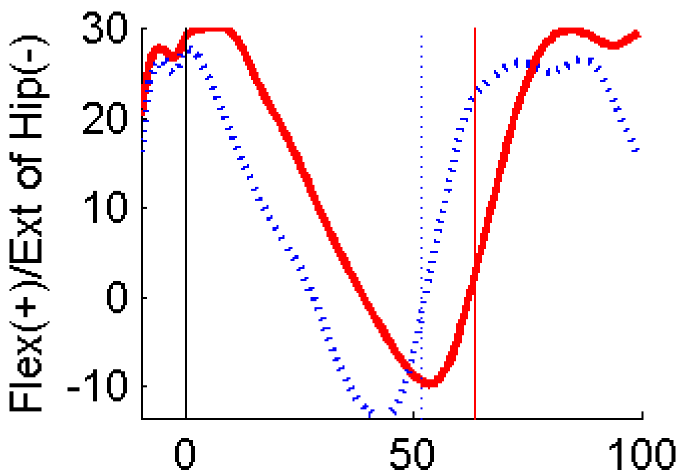
Marker placement



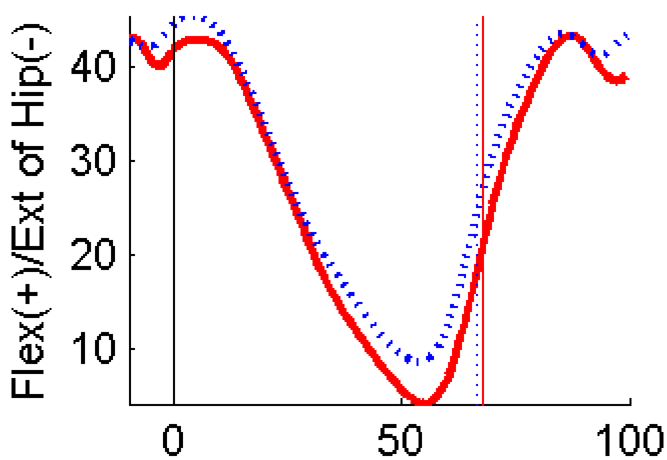
Appendix C

Representative Joint Angle Curves

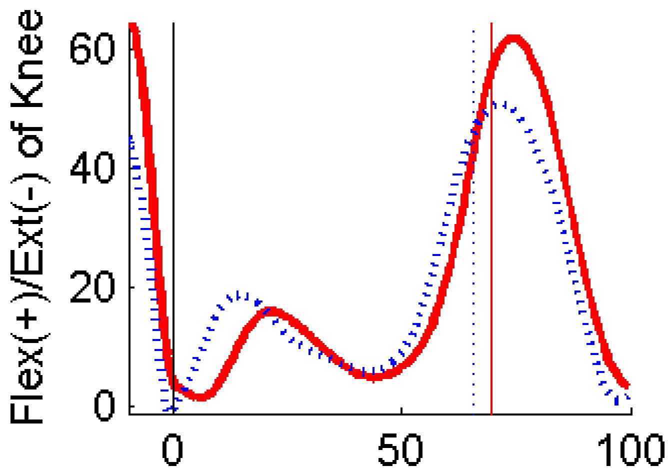
(I am just putting this in here for to see the graphs, this needs a lot of work)



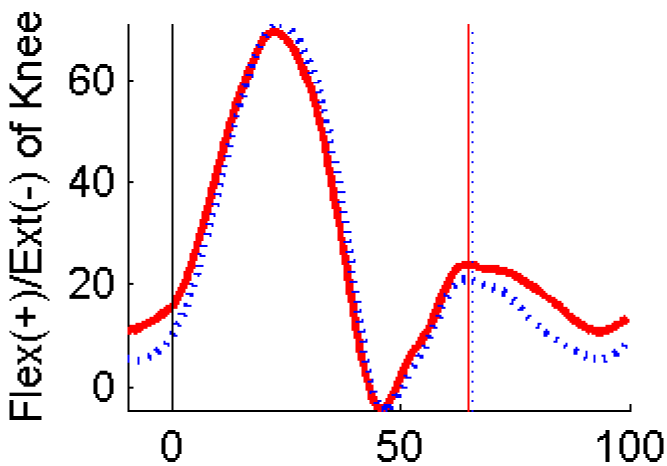
Representative Ind-TTA hip displacement (dotted line ProsL)



Representative Ind-CON hip displacement



Representative Ind-TTA knee displacement



Representative Ind-CON knee displacement