2009

A Comparative Analysis of Two Gait Training Approaches for Individuals with Transtibial Amputation

Nannette Wright Hyland

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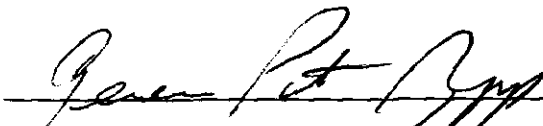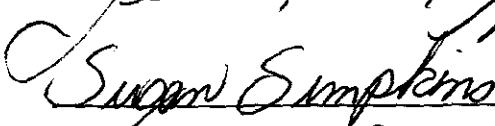Transtibial Amputation

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_____ Date: 6 23-09

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Submitted in partial fulfillment of the
requirements for the degree of Doctor of Philosophy in Health Sciences
Seton Hall University
2009

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Chair: Dr. Genevieve Pinto-Zipp

Statement of the Problem: There is a lack of research on early prosthetic gait training and its influence on function. The current healthcare trend is to limit the amount of prosthetic rehabilitation an individual receives. The purpose of this study, therefore, was to compare the effectiveness of two strategies: impairment (IO) versus task-oriented (TO) for initial gait training of individuals with transtibial amputation (TTA). Methods: The study utilized an experimental, prospective, randomized, single factor, pretest/post-test design. Twenty-two individuals were randomly assigned to the impairment (n=11) or task (n=11) oriented group. All subjects completed a ten-day gait training protocol (impairment versus task-oriented) as part of their inpatient rehabilitation. Outcome data consisting of the Amputee Mobility Predictor (AMP), Berg Balance Scale (Berg), mean normalized velocity (MNV), and spatial/temporal gait parameters obtained from the GAITRite® were taken at baseline (third day of training) and day ten. Results: Significant improvements were noted within groups for the AMP, Berg, and velocity measures. The IO group improved from 14.4 ± 7.1 to 25.3 ± 8.1; $p=0.000$ (AMP), 15.5 ± 8.6 to 27.1 ± 9.2; $p=0.000$ (Berg) and 0.13 ± 0.07 to 0.22 ± 0.10; $p=0.002$ (MNV). The TO group improved from 19.7 ± 9.5 to 29.6 ± 9.5; $p=0.000$ (AMP), 22.4 ± 11.7 to 32.9 ± 13; $p=0.000$ (Berg), and 0.34 ± 0.1 to 0.49 ± 0.2; $p=0.028$ (MNV). There were no significant differences between the groups for these measures. The IO group showed a significant change in the following spatial/temporal measures: cadence (31.5 ± 8.2 to 42.7 ± 7.3; $p=0.001$), % stance (83.8 ± 8.9 to 79.1 ± 8.2; $p=0.04$), swing time (16.6 ± 8.9 to 20.8 ± 8.2; $p=0.04$) and double limb support time (70.7 ± 11.8 to 62.6 ± 13.4; $p=0.023$). The TO group did not have any significant changes for those measures. No significant differences were found between or within the two groups for symmetry of single limb support time or step length. Conclusions: Both training strategies resulted in equivalent improvement in unilateral TTA functional mobility. Although significant improvements were demonstrated in function during the ten-day protocol, the subjects continued to have a high fall risk and low level of functioning as shown by the Berg, AMP and velocity measures. Future studies should examine the impact of timing and amount of prosthetic rehabilitation.

ACKNOWLEDGMENTS

With great appreciation to:

Genevieve Pinto-Zipp, Ed.D, P.T., for your support and mentorship throughout this entire process. Your guidance has been holdfast. It is always a pleasure to learn from you, as you are nurturing yet straightforward. Thank you for all of your guidance throughout the years;

Susan Simpkins, Ed.D., P.T., for your willingness to continue on with this project even after you moved. I have thoroughly enjoyed working with you and learning from you. You have helped me develop my writing skills to a new level, and I will always appreciate all the support you have given me;

Lee Cabell, Ph.D., for your willingness to give so much of your time on this project and your different perspective on many issues. It has been a pleasure working with you;

My co-workers at Mercy College, for your invaluable support and assistance with this project. Thank you for all the times you assisted me in helping to answer a question and challenged me to continue on;

My former physical therapy students at Mercy College who assisted with the data collection by calling facilities, carrying equipment, and logging in data.

DEDICATION

To my parents, who not only gave me life but also taught me how to live it. Their encouragement and unconditional love led to the completion of this project.

To my husband and best friend, Matthew Hyland. You have been very patient and understanding during this long process. You have the ability to take my jumbled thoughts and put them into understandable sentences. I thank you for all of your assistance and support and look forward to a life after dissertation with you.

To James and Kelly. May this work be an encouragement to you to accomplish all that you set out to do. During this process I have watched you grow into the wonderful young adults that you are. Thank you for understanding and for all the sacrifices you have made for me during this journey.

To my whole family. Now that this project is completed, I look forward to spending more time with you.

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Chapter I

INTRODUCTION

<u>Background of the problem</u>

Over 1.7 million Americans have a major limb amputation, and this number is on the rise (D. D. Fletcher et al., 2001; D.D. Fletcher et al., 2002; Ziegler-Graham, MacKenzie, Ephraim, Travison, & Brookmeyer, 2008). Primary causes of amputation include: dysvascular (including peripheral vascular disease and diabetes), trauma, cancer and congenital limb anomalies. The incidence of amputations due to dysvascular causes has risen over the past 20 years, accounting for 82% of all amputations. Ninety-seven percent of dysvascular amputations occur at the lower extremity with 28% occurring most distally at the transtibial level (TTA). Amputations resulting from trauma or cancer have decreased over the last ten years while congenital limb deficiency has remained stable over the last thirty years (Staff, 2008). Interestingly, the majority of current rehabilitation research is focused on the traumatic amputee population even though the greatest percentage of amputations is due to dysvascular causes.

Interestingly, while the overall rate of amputations due to vascular disease has decreased, the overall incidence of amputations is on the rise (D.D. Fletcher et al., 2002) . This trend may be a result of the aging

population of America. The majority of amputations due to vascular disease occur in the elderly (D.D. Fletcher et al., 2002). Given the projected increase in the number of amputations, it is important to determine factors that create successful outcomes in prosthetic rehabilitation.

Rehabilitation after an amputation can be divided into nine phases: preoperative, surgical, acute post-surgical, pre-prosthetic, prosthetic prescription/fabrication, prosthetic training, community integration, vocational rehabilitation and follow-up (Esquenazi & DiGiacomo, 2001). Each phase has a unique set of rehabilitation goals. Pre-prosthetic (acute postsurgical through prosthetic fabrication) goals emphasize function and compensatory strategies due to the limb loss and the need to prepare the residual limb for the prosthesis. The individual phases of amputee rehabilitation are critically important in order for the individual to advance from one phase to the next. The ultimate goal is reintegration into society and prevention of future complications secondary to the limb loss. Physical therapy intervention is important during all post-surgical phases. The role of the therapist is to assist individuals through each stage and help them achieve established goals.

Factors that predict successful outcomes in prosthetic rehabilitation include: age, gender, level of amputation, co-morbidity, psychological factors, delay in prosthetic fitting and duration of prosthetic rehabilitation (M. C. Chen et al., 2008; Davies & Datta, 2003; Geertzen, Martina, & Rietman, 2001; Hermodsson, Ekdahl, & Persson, 1998; Kent & Fyfe, 1999; Leung, Rush, & Devlin, 1996; Munin, 2001; Singh, Hunter, Philip, & Tyson, 2008; Taylor et al.,

2008). Generally, older and less healthy individuals have poorer outcomes.

Higher level amputations such as transfemoral (TFA) and poor sound limb

quality also result in lower overall functional outcomes (Arwert et al., 2007).

Iatrogenic factors have been identified in three outcomes studies correlating

overall outcome to the amount of pre-training waiting time or delay in

receiving training and the length of prosthetic training (M. C. Chen et al.,

2008; Gauthier-Gagnon, Grise, & Potvin, 1999; Munin, 2001; M. G. Stineman

et al., 2008; Margaret G. Stineman et al., 2006). Current research

demonstrates that individuals who receive their prosthesis quickly and have a

longer prosthetic rehabilitation have better functional outcomes (Munin, 2001;

M. G. Stineman et al., 2008); however, with the trend for hospital stays for

prosthetic training decreasing (or even providing prosthetic training

decreasing), care is inadequate and individuals are going home unsafe

(Adams, 1999; Dillingham, Pezzin, & MacKenzie, 1998, 2003; Margaret G.

Stineman et al., 2006).

In 2006 Stineman et al. looked at the national rehabilitation care

patterns using a sample of veterans who underwent amputation. The results

found 25% of the patients had no record of rehabilitation services and only

17% had been admitted for prosthetic rehabilitation (Margaret G. Stineman et

al., 2006). In Maryland inpatient rehabilitation was provided to only 10% of all

dysvascular amputee patients with discharge to home being the most

common outcome (Dillingham et al., 2003). Currently the maximum number

of days reimbursed by Medicare for vascular-related surgical amputation is

only 13.3 (Marzen-Groller et al., 2008). With the trend of even shorter inpatient stays and increasing frequency of discharge to home it becomes imperative to utilize rehabilitation time most effectively.

When individuals lose a major part of their lower extremity they experience significant physical and psychological changes (Esquenazi & DiGiacomo, 2001). The physical loss leads to a decrease in the individual's function, including self-care activities and ambulation. Physical therapists provide rehabilitative services to patients with the primary functional goals of independence in self-care and maximizing functional mobility. Functional mobility includes: bed mobility (ability to move around in bed), transfer mobility (ability to go from the bed to a chair, for example) and upright mobility (walking or gait). Mobility has been highly correlated with overall quality of life in individuals who have lost part of their lower extremity (Pell, Donnan, Fowkes, & Ruckley, 1993). The main goal for the prosthesis is to compensate for the loss of a limb and allow the individuals mobility so that they may reintegrate into their environment. It also enables them to execute activities of daily living and social activities to enhance their overall quality of life. Learning to walk with a prosthesis requires individuals to use their available muscles, as well as incorporate new sensory feedback while bearing weight on the distal portion of the residual limb. These tasks require repetitive practice. Individuals who receive prosthetic rehabilitation training are noted to have better mobility outcomes, which impacts their overall quality of life (Kent & Fyfe, 1999; Munin, 2001; M. G. Stineman et al., 2008).

Research regarding the early prosthetic training phase is mostly empirical, with only one randomized control study noted (Rau, Bonvin, & de Bie, 2007). Baker and Hewison (1990) examined the gait recovery pattern during early rehabilitation in individuals' status post amputation. They noted velocity increased 55% within the first fifteen days, demonstrating the importance of early consistent training (Baker & Hewison, 1990). Rau, Bonvin & de Bie performed a randomized study of early prosthetic intervention. Their research training protocol examined a three-day, 30-minute intensive physiotherapy program consisting of strengthening exercises, weight bearing exercises, corrected walking, obstacle management and functional training with individuals with lower limb amputation. When compared to an untrained group the physiotherapy group demonstrated significant improvement on the two-minute walk test, walking speed and Timed Up and Go test (TUG) (Rau et al., 2007).

Research documents that individuals who perform functional prosthetic ambulation independently exhibit asymmetries between their prosthetic and sound limb (Czerniecki, 1996; Donker & Beck, 2002; Hermodsson, Ekdahl, Persson, & Roxendal, 1994a; E. Isakov, Keren, & Benjuya, 2000; M. E. Jones, Bashford, & Mann, 1997; D.J. Sanderson & Martin, 1997). Commonly, individuals bear less weight through the prosthesis, which decreases stance time and creates unequal step length (M. E. Jones, Bashford, & Bliokas, 2001; M. E. Jones, Bashford et al., 1997; M. E. Jones, Steel, Bashford, & Davidson, 1997). This asymmetry leads to a number of secondary

impairments including increased incidence of low back pain (Friel, Domholdt, & Smith, 2005; Kulkarni, Gaine, Buckley, Rankine, & Adams, 2005; Smith, Comiskey, & Ryall, 2008; Stam, Dommisse, & Bussmann, 2004) and arthritis in the sound limb (Lemaire & Fisher, 1994; Melzer, Yekutiel, & Sukenik, 2001; Nolan & Lees, 2000; Nolan et al., 2003; Royer & Koenig, 2005). An asymmetrical walking pattern also creates a larger displacement of one's center of mass, increasing the energy required to walk (D.A. Winter, 1991; D. A. Winter & Sienko, 1988). Training an individual to have a more symmetrical gait may decrease not only the secondary impairments but also the overall energy expenditure needed to walk (Czerniecki, 1996; Detrembleur, Vanmarsenille, De Cuyper, & Dierick, 2005; Donker & Beck, 2002).

Existing research supports the need for rehabilitation after amputation; however, an evidence-based standard of care does not exist for individuals who undergo transtibial amputations. Presently, once the individual receives his or her prosthesis a variety of techniques may be utilized for initial gait training. Unfortunately, there are no randomized control studies examining the differences during the initial prosthetic training period for these various techniques. Most entry-level physical therapy texts, such as May (2003) and O'Sullivan and Schmidt (2000), mention pre-gait activities prior to walking. These activities include static standing balance activities as well as single stepping to promote dynamic balance and weight acceptance. Other activities include strengthening exercises and a variety of functional tasks such as transfer training (R. S. G. Gailey, A.M., 1989). May (2003) also notes

that symmetrical weight bearing should be achieved prior to walking. One might categorize this approach as a bottom-up approach in which the task is broken down in order to work at the impairment level focusing on neuromuscular control. Practicing the smaller task continues until control is achieved and then integrated into the larger overall functional task.

Alternatively, the more functional task-oriented approach to gait training involves walking practiced as a whole task and not broken down into the different gait components (Shumway-Cook, 2001). More top-down, this approach utilizes task-specific training to improve task performance. Here the task in practiced in a complete manner. If an individual is not able to perform the functional task as a whole, however, then the individual is evaluated at the impairment level to try to identify the neuromuscular component that is inhibiting the successful completion of the task. Once the functional task of walking on level surfaces is successful, both approaches add variety to the training sessions by including elevations, uneven surfaces and distractions.

It is not known whether one rehabilitative approach is more commonly utilized than the other for prosthetic training in the United States. Treatment interventions range from breaking the gait cycle down and practicing parts of it to pure, continuous walking. According to survey research completed in the tri-state area there are no set parameters for the amount of time or technique each therapist utilizes (Hyland, 2003). The present study is designed to examine outcomes of two prosthetic gait training strategies in the acute prosthetic rehabilitation phase on individuals with a unilateral TTA.

Need for the Study

The number of individuals with a lower limb loss due to dysvascular reasons is expected to double by the year 2050 (Ziegler-Graham). Concomitantly, the length of stay and number of rehabilitation visits for these individuals is on the decline (Dillingham et al., 1998, 2003). With functional mobility being critical to an individual's quality of life and a finite number of treatment sessions available, therapists need to implement the most effective and efficient method of prosthetic training. Given the paucity of existing research on early prosthetic gait training and the importance of functional mobility for one's quality of life, a need for this study exists. Increased knowledge regarding the effects of physical therapy intervention will help to assure the best quality of care to individuals who undergo a life-changing event such as transtibial amputation.

Purpose

The purpose of this study is to compare the effectiveness of two different gait-training strategies with regard to functional outcomes, balance and temporal/spatial gait parameters in individuals with unilateral transtibial amputations.

Experimental Questions:

1. Which gait training strategy has a greater effect on functional outcome as measured by the Amputee Mobility Predictor [©]?

2. Which gait training strategy has a greater effect on velocity?

3. Which gait training strategy has a greater effect on balance as measured by the Berg Balance Scale?

4. Which gait training strategy has a greater effect on temporal measure of gait such as double limb support time, stance time or swing time?

5. Which gait training strategy has a greater effect on gait symmetry as measured by step length and single limb support time?

Hypothesis

The hypothesis is there will be no difference between the two gait training strategies, impairment-oriented versus task-oriented, with regard to balance, functional outcome, velocity or spatial-temporal gait parameters.

Chapter II

RELATED LITERATURE

The topics addressed in the following review of related literature are: (a) rehabilitation outcomes; (b) balance in elderly adults and individuals with lower extremity amputation (LEA); (c) gait patterns in adults and for individual with LEA; (d) factors that influence gait of individuals with LEA; (e) training based on motor learning principles; and (f) prosthetic rehabilitation.

Rehabilitation Outcomes

Rehabilitation of an individual with a lower-extremity amputation can be divided into nine phases: preoperative, surgical, acute postsurgical, preprosthetic, prosthetic prescription/fabrication, prosthetic training, community integration, vocational rehabilitation and follow-up (Esquenazi & DiGiacomo, 2001). Often the preoperative and operative phases are performed as a lifesaving effort in the geriatric population, where a high mortality rate is noted (Bo Ebskov, 2006; Collin & Collin, 1995; Hermodsson et al., 1998). A mortality rate of up to 6% within the first thirty days of the postsurgical/preprosthetic phase has been documented (Feinglass, 2001). For those who survive to the prosthetic phase, rehabilitation training is important to investigate in relation to successful outcome achievement

(Asano, Rushton, Miller, & Deathe, 2008; Bo Ebskov, 2006; Callaghan & Condie, 2003; M. C. Chen et al., 2008; Collin & Collin, 1995; Cutson & Bongiorni, 1996; Davies & Datta, 2003; Harness & Pinzur, 2001; Hermodsson et al., 1998; Kent & Fyfe, 1999; Leung et al., 1996; Pandian & Kowalske, 1999; Taylor et al., 2008; Wan Hazmy, Chia, Fong, & Ganendra, 2006; Ziegler-Graham et al., 2008); however, it is important to determine a consistent definition of "successful outcomes" in order to measure and interpret the results accurately (Taylor et al., 2008).

A number of factors have been examined to identify predictors of successful outcomes in prosthetic rehabilitation such as: age, gender, level of amputation, co-morbidity, delay in prosthetic fitting and duration of prosthetic rehabilitation (M. C. Chen et al., 2008; Davies & Datta, 2003; Geertzen et al., 2001; Hermodsson et al., 1998; Kent & Fyfe, 1999; Leung et al., 1996; Munin, 2001; Singh et al., 2008; Taylor et al., 2008). Age was correlated with poor prosthetic outcomes in several studies (Davies & Datta, 2003; Kent & Fyfe, 1999; Munin, 2001); however, other studies have shown that age does not adversely affect outcome (M. C. Chen et al., 2008; Hermodsson et al., 1998; Leung et al., 1996). The lack of a consistent definition of successful outcomes may have led to the contrasting conclusions. Another factor that has been identified as a predictor of prosthetic outcomes is gender, with females demonstrating a poorer outcome than males for prosthetic wearing times (Heikkinen, Saarinen, Suominen, Virkkunen, & Salenius, 2007; Hermodsson et al., 1998; Singh et al., 2008; Virkkunen, Heikkinen, Lepantalo,

Metsanoja, & Salenius, 2004). Level of amputation is another factor that may negatively impact the overall success of prosthetic ability, with higher levels of amputation associated with poorer outcomes (Davies & Datta, 2003; Gauthier-Gagnon et al., 1999; Leung et al., 1996). Conversely, other outcome studies have not found a correlation between level of amputation and functional outcome (M. C. Chen et al., 2008; Munin, 2001). One consistent negative impact identified in the literature is the number of co-morbidities. The fewer co-morbidities an individual has, the better the outcomes (M. C. Chen et al., 2008; Davies & Datta, 2003; Gauthier-Gagnon et al., 1999; Hermodsson et al., 1998; Leung et al., 1996; Taylor et al., 2008; Virkkunen et al., 2004). Taylor et al. found three independent predictors of outcome for individuals with transtibial or transfemoral amputation. These included two co-morbidities: presence of coronary artery disease or cerebrovascular disease, and impaired mobility prior to the lower extremity amputation. Prior mobility level can also be linked to the overall healthiness of an individual (Taylor et al., 2008).

Cognitive and psychological factors such as fear or depression have also been noted to impact overall functional outcomes (Cutson & Bongiorni, 1996; W. C. Miller, Speechley, & Deathe, 2001). Cutson and Bonfiorni (1996) stated the importance for the geriatric population to receive timely prosthetic rehabilitation even though the mortality rate is high. Early mobility avoids secondary complications that immobility can cause, such as decreased muscle functioning, decreased cardiorespiratory functioning and depression.

Depression has been linked to an overall decrease in motivation that can negatively impact final prosthetic outcomes (M. C. Chen et al., 2008; Iwasa et al., 2009; Larner, van Ross, & Hale, 2003; McKnight & Kashdan, 2009; Sinikallio et al., 2009). Fear also can lead to decreased mobility. When individuals are afraid of falling, they are less likely to move. Miller et al. assessed 435 community-dwelling elderly individuals with lower extremity amputation (LEA) and noted that balance confidence and the fear of falling were correlated to three quality of life measures: mobility capability, mobility performance and social activity level. While balance confidence and the fear of falling decreases quality of life measures, actual falls within the last 12 months did not (W. C. Miller, Deathe, Speechley, & Koval, 2001; W. C. Miller, Speechley et al., 2001). When an individual loses the motivation or is too afraid to walk, function decreases to a point where the prosthesis is often left unused. This sequence of events can deteriorate the individual's physical health contributing to the high mortality rate noted in elderly individuals with vascular disease. Early mobility training in the acute post-operative phase improved functional mobility outcomes and decreases the percentage of associated medical complications (Marzen-Groller et al., 2008)

Balance in the Elderly

Falling is a national concern. Healthy elderly individuals (over the age

of 65) have a higher percentage of falls than younger individuals (Center for

Disease Control 2008). As one ages, increased sway is noted during static

balance (Demura 2008). This increased sway is coupled with a decrease in

one's overall limits of stability (Shumway-Cook & Woolcott 2005, Demura

2008). When an individual's center of gravity falls outside his or her stability

limits, a balance strategy is activated to maintain upright balance. There are

three main balance strategies: ankle, hip and stepping. A healthy younger

individual utilizes the ankle strategy to maintain the center of gravity inside

their stability limit. This strategy requires the anterior tibialis and

gastrocnemius muscles to control the sway of the body over the feet. The hip

strategy is employed if the ankle strategy does not achieve the goal of

balance. This strategy utilizes the hip extensor and hip flexor muscles to flex

or extend the hip to maintain the center of gravity within the balance of

support. The stepping strategy is the last strategy employed when the center

of gravity cannot be maintained within the limits of stability, resulting in the

need for one to take a step to keep from falling. Literature has noted that as

we age we shift from the ankle strategy to the hip strategy as our first line of

defense to maintain balance (Horak et al 1989, Manchester et al 1989). A

few theories about why the shift occurs include: decreased ankle range of

motion, decreased lower extremity muscle strength, and decreased neuronal

activity (Horak et al 1989), all leading to a slower initial response time. This

allows the center of gravity to reach the limits of support, thereby limiting the strategies available to maintain balance. This decreased balance ability is noted in both static and dynamic balance activities and contributes to the increase in the number of falls in the elderly (Horak, Shupert, & Mirka, 1989; Lajoie & Gallagher, 2004). Elderly individuals who have LEA present with a more compromised balance ability increase their risk for falls when compared to age-matched healthy individuals.

Balance in the Amputee

Elderly individuals with a LEA have changes in their musculoskeletal system due to the natural aging process and experience a significant change in their neuromuscular system due to the loss of their limb. Initially after limb loss the transected peripheral nerve does not emit signals; however, within 24 to 48 hours it becomes responsive to stimuli near the deafferented area (Moore, 1999). Sensory feedback is critical to the motor control loop used to maintain equilibrium and posture during upright activity (Shumway-Cook, 2001; J.-M. M. Viton, L.; Mille, M.; Cincera, M.; Delarque, A.; Pedotti, A.; Bardot, A.; Massion, J., 2000). The sensory-motor loop is altered, however, in individuals with LEA secondary to the loss of significant proprioceptive feedback and strength from key postural muscles such as the gastrocnemius and anterior tibialis. This neuromuscular loss contributes to the decreased overall static and dynamic balance noted in individuals with a lower extremity loss (E. Isakov, Mizrahi, Ring, Susak, & Hakim, 1992; M. E. Jones, Steel et

al., 1997; J.-M. M. Viton, L.; Mille, M.; Cincera, M.; Delarque, A.; Pedotti, A.; Bardot, A.; Massion, J., 2000). Additionally, individuals with LEA do not have the ankle strategy available, not only due to loss of their lower limb but also from the limitation of the prosthetic ankle component. This further compromises their balance. Frequently, the ankle component of a prosthesis is often fixed or rigid, restricting movement and the flexion and extension needed at the ankle to execute the ankle strategy.

Individuals with LEA exhibit a decrease in their limits of stability and a anteroposterior and mediolateral sway during static double limb stance (Aruin, 1997; Buckley, 2002; Hermodsson, Ekdahl, Persson, & Roxendal, 1994b; E. Isakov et al., 1992; L. M. Mouchnino, M.L.; Cincera, M; Bardot, A.; Delarque, A.; Pedotti, A., 1998; J.-M. M. Viton, L.; Mille, M.; Cincera, M.; Delarque, A.; Pedotti, A.; Bardot, A.; Massion, J., 2000). This increased sway may be due to the loss of afferent feedback in the transected limb from critical postural muscles: the gastrocnemius and the tibialis anterior (Rossi, 1995; J.-M. M. Viton, L.; Mille, M.; Cincera, M.; Delarque, A.; Pedotti, A.; Bardot, A.; Massion, J., 2000). Both the increased sway and loss of sensory feedback are contributing factors to the increased fear of falling in individuals with LEA (W. C. Miller, Deathe et al., 2001; W. C. S. Miller, M.; Deathe, A.B., 2002).

Hermodsson, et al. (1994) also noted differences within individuals with LEA. Those who had an amputation due to vascular reasons exhibited a greater lateral sway then either healthy age-matched individuals or individuals whose amputations were due to trauma. The authors proposed that those

patients who undergo amputation due to vascular insufficiency often have

often been battling a chronic disease process that weakened their physical

status prior to the amputation.

Balance is linked to function through mobility. The ability to prepare the

body for single limb support is a requirement for walking. Coordination of

postural muscles during a leg lift while maintaining equilibrium is a complex

process. Feed forward mechanisms have been noted in healthy individuals,

activating the appropriate postural muscles prior to the actual leg lift (L.

Mouchnino, Aurenty, R., Massion, J., Pedotti, A., 1992). Aruin, Nicolas and

Latash (1997), Mouchnino et al (1998) and Viton et al (2000) studied the

postural reorganization during leg lifting in individuals with unilateral transtibial

amputations. These studies noted a change in the electromyographic (EMG)

activity as compared to healthy individuals. Trunk musculature was noted to

fire symmetrically during a leg lift, however the bicep femoris and rectus

femoris fired asymmetrically on the sound limb. In healthy individuals the

bicep femoris and rectus femoris typically fire symmetrically (Aruin, 1997; L.

M. Mouchnino, M.L.; Cincera, M; Bardot, A.; Delarque, A.; Pedotti, A., 1998).

Another noted difference is that healthy individuals fire the contralateral

gastrocnemius prior to the leg lift, whereas the amputee patient does not.

Instead they fire the tensor fascia latae earlier (L. M. Mouchnino, M.L.;

Cincera, M; Bardot, A.; Delarque, A.; Pedotti, A., 1998). These changes

indicate a reorganization of postural muscles in amputee patients when

compared to healthy individuals. Despite this reorganization of postural

control, transitioning from double limb stance to single limb stance remains a difficult task for individuals with LEA. This is demonstrated by decreased single limb stance times on either the sound or residual limb and higher transition failure rates (Aruin, 1997; Buckley, 2002; Hermodsson et al., 1994b; E. Isakov et al., 1992; L. M. Mouchnino, M.L.; Cincera, M; Bardot, A.; Delarque, A.; Pedotti, A., 1998; J. M. Viton et al., 2000). The initiation of gait reflects the transitioning from static double limb support to dynamic single limb support. Individuals with LEA demonstrate different movement strategies noted in temporal patterns, center of mass trajectories and ground reaction forces as compared to age-matched healthy individuals (S. F. Jones, Twigg, Scally, & Buckley, 2005; Michel & Chong, 2004; Rossi, 1995; Tokuno, Sanderson, Inglis, & Chua, 2003; Vrieling et al., 2008). The decreased ability to maintain equilibrium and the difficulty transitioning from double to single limb support contributes to the requirement of developing new movement strategies and to the overall gait deviations noted in individuals with unilateral transtibial amputation.

Normal Gait

Normal gait in the healthy adult is characterized by smooth movements, reciprocal arm swing and minimal oscillations of the center of gravity (D.A. Winter, 1991). A gait cycle (GC) is the single sequence of one limb during walking, which includes a stance and swing phase. This is measured by the time of initial heel contact of one limb to the sequential heel

contact of the same limb (Craik & Oatis, 1995; Whittle, 2002). The stance phase accounts for 60% of the gait cycle and begins when one foot contacts the ground and ends when the same foot leaves the ground. Stance phase can further be divided into double and single limb support. Double limb support is the period of time when both feet are in contact with the ground, and single limb support is the period when only one foot is in contact with the ground (Craik & Oatis, 1995; Whittle, 2002). The swing phase accounts for the rest of the GC (40%) and is the period of time when the limb is not in contact with the ground. During the gait cycle the body progresses forward creating mobility.

Gait can be measured by temporal and spatial variables. Temporal measures include time-related events such as speed, cadence, step time, stance time, and double limb support time. Speed is defined as the distance (stride length) per second; therefore, speed is influenced by leg length. To normalize speed for comparison between subjects, one can divide the stride length by the leg length to get a mean normalized velocity. Cadence is defined as the number of steps per minute. Step time is the time from initial contact of one limb with the ground to initial contact of the opposite limb. Stance time is the time from initial contact of one foot with the ground until the same foot leaves the ground. Double limb support time (DLS) is amount of time both feet are in contact with the ground during one gait cycle. Single limb support time (SLS) is the amount of time only one foot is in contact with the ground during one gait cycle. Spatial measures include distance-related

measures such as step length and stride length. Step length (SL) is the distance measured from initial contact with the ground of one limb to initial contact of the opposite limb (E. Isakov, Burger, Krajnik, Gregoric, & Marincek, 1997). The symmetry noted during normal gait is achieved when the temporal/spatial measures are equal between the right and left gait cycle (Craik & Oatis, 1995; Whittle, 2002; D.A. Winter, 1991). Speed is noted to influence cadence and symmetry. One can increase speed while maintaining the same cadence by increasing their stride length. Cadence in normal healthy adults remains fairly consistent with walking speed by adjusting cadence and stride length accordingly (Whittle, 2002). Speed also influences the stance/swing phase ratio. The faster the speed, the shorter the stance phase; the slower the speed, the longer the stance phase with increasing double limb support time. Age also has an affect on gait parameters. As we age our overall walking speed decreases, with norms reported at 0.9 – 1.6m/sec (Craik & Oatis 1995, Gibbs et al 1996, Whittle 2002). The decreased speed is a result of a decreased stride length with a stable cadence. With age, an increased stance phase is also noted. This may be related to the slower self-selected walking speed or secondary to decreased balance (Craik & Oatis, 1995; Gibbs, Hughes, Dunlop, Singer, & Chang, 1996; Whittle, 2002).

Gait in the Amputee

The gait pattern of an individual with a prosthesis resulting from a LEA is significantly different than that of a healthy, age-matched individual (E. Isakov et al., 1997; E. Isakov et al., 2000; D. A. Winter & Sienko, 1988). Differences are noted in the self-selected walking speed, step length, stance and swing time, single and double limb support, and symmetry between limbs (Hermodsson et al., 1994a; E. Isakov et al., 2000; Robinson, 1977; D. A. Winter & Sienko, 1988). The differences may be due to the loss of the neuromuscular system in the lower extremity.

Hermodsson et al. 1994 examined 24 individuals with unilateral TTA and noted a decreased self-selected walking speed (SSWS) (0.85 m/sec) when compared to healthy age-matched controls (1.42 m/sec) (Hermodsson et al., 1994a). Slower self-selected walking speeds ranging from 0.5m/sec to 1.24 m/sec have also been noted in numerous other studies when compared to normal standards (Bateni, 2002; Czerniecki, 1996; E. Isakov et al., 1997; E. Isakov et al., 2000; Robinson, 1977). Individuals who experienced a TTA secondary to vascular disease also exhibited a significantly slower SSWS when compared to individuals with TTA secondary to trauma or healthy individuals (0.85 (+/-0.2) m/sec, 0.99(+/- 0.2) m/sec and 1.42 (+/- 0.2) m/sec respectively) (Hermodsson et al., 1994a, 1994b). The noted difference was attributed to a lack of push off forces in the vascular group that was present in both the traumatic and healthy groups. This finding led the researchers to include only participants with TTA due to vascular reasons in the study.

In relation to temporal and spatial gait parameters, individuals with TTA exhibit an asymmetrical gait pattern in relation to step length, stance time and double limb support times (Bateni, 2002; Hermodsson et al., 1994a; E. Isakov et al., 1997; E. Isakov et al., 2000; E. B. Isakov, H.; Krajnik, J.; Gregoric, M.; Marincek, C., 1996; Lewallen, 1986; Robinson, 1977; D.J. Sanderson & Martin, 1997; D. A. Winter & Sienko, 1988; M. S. Zahedi, W.D.; Solomonidis, S.E.; Paul, J.P., 1987). The most commonly documented asymmetrical gait pattern is a longer prosthetic step length and shorter prosthetic stance time versus the sound limb (Bateni, 2002; E. Isakov et al., 1997; E. Isakov et al., 2000; Robinson, 1977; D. A. Winter & Sienko, 1988; M. S. Zahedi, Spence, Solomonidis, & Paul, 1987). The percentage of the gait cycle spent in stance phase overall is increased (60 – 73%) compared to age matched healthy individuals (50 – 60%), with longer double limb support time (29 % of stance) also noted (Hermodsson et al., 1994a; E. Isakov et al., 1997). The prosthetic side has a longer DLS than the sound side; which could be related to the decreased ability to go from double to single limb support (E. Isakov et al., 1997). Sanderson et al. (1996), however, documented near-normal spatial/temporal gait parameters between age-matched subjects and six individuals with TTA (D. J. Sanderson & Martin, 1996). In Sanderson et al's study individuals were running between 2.7m/sec and 3.5m/sec, whereas in the previously mentioned studies in which asymmetry was noted speed averaged between 0.62m/sec to 1.24m/sec.

Factors that Influence Gait of Individuals with Transtibial Amputation

Several factors including pain, type of prosthetic ankle/foot component, the use of assistive devices and velocity have been demonstrated to have an influence on gait pattern of individuals with LEA (Hsu, Nielsen, Lin-Chan, & Shurr, 2006; M. E. Jones et al., 2001; Kelly, Doyle, & Skinner, 1998; Marinakis, 2004; Rietman, Postema, & Geertzen, 2002; Tsai, Kirby, MacLeod, & Graham, 2003; Zmitrewicz, Neptune, Walden, Rogers, & Bosker, 2006). These factors can limit overall mobility or impact the temporal and spatial gait parameters, leading to decreased velocity and symmetry.

Pain is considered a vital sign that is defined by intensity, characteristics, location and quality. After the surgical removal of a limb an individual experiences significant pain. One post-surgical goal is to manage the individual's pain. Pain is also often experienced during the prosthetic rehabilitation phase when the individual first bears weight through his or her residual limb onto the prosthesis. Prosthetic socket fit is critical for a successful functional outcome. Initial prosthetic training is influenced by the ability of the individual to accept the body weight into the prosthesis. Jones et al. 2001 documented the static weight bearing (SWB) of the prosthetic limb in 29 individuals with unilateral TTA with a mean age of 65 during their first four weeks of prosthetic training. Results indicated that pain was inversely correlated to SWB. Pain limits the ability to bear full weight through the prosthesis. It creates an uneven weight distribution through the lower extremities, decreasing upright static and dynamic balance (M. E. Jones et

al., 2001). SWB was positively correlated with increased speed, which may explain why individuals with TTA who experience pain while wearing the prosthesis demonstrated a slower self-selected walking speed (M. E. Jones et al., 2001; Kelly et al., 1998). Unequal weight distribution between limbs also leads to gait deviations such as unequal step length and stance times. Individuals with LEA who bear equal weight through both limbs present with higher walking velocities (M. E. Jones, Bashford et al., 1997).

There are numerous prosthetic components available for a transtibial prosthesis. The ankle/foot component influences the kinematic and kinetic abilities of a prosthesis. Prosthetic components can mimic some inertial properties of a human limb; however, the decreased mobility of the ankle unit and loss of ability to generate power create kinematic and kinetic differences between the natural and prosthetic limbs. Researchers have investigated the differences among various prosthetic foot and ankle components. Prosthetic components are noted to influence gait parameters, with the more advanced components allowing for a more normalized gait pattern (Czerniecki, 1996; Geil, 2000; Hsu et al., 2006; Marinakis, 2004; Powers, 1994; Rietman et al., 2002; Selles, Janssens, Jongenengel, & Bussmann, 2005; van der Linden, 1999; D. A. Winter & Sienko, 1988; Zmitrewicz et al., 2006).

An assistive device is defined as any device utilized by an individual to achieve a goal. Walking devices are often used to achieve the goal of upright mobility. The use of assistive devices during prosthetic ambulation is a common outcome (Kirby et al 2002). Assistive devices give individuals the

ability to distribute their body weight through their arms, therefore decreasing the weight through the prosthesis. Assistive devices influence gait patterns by limiting the amount of arm, trunk and hip rotation as well as decreased overall walking speed and symmetry (McDonough & Razza-Doherty, 1988; Tsai et al., 2003). Tsai et al. 2003 examined the gait patterns of twenty individuals with LEA while walking with a 4-footed and a 2-wheeled walker. When walking with the 2-wheeled walker, individuals walked at a faster speed and demonstrated stance and swing ratios closer to a normalized walking pattern (Tsai et al., 2003). Common training progression for prosthetic training is documented as starting in the parallel bars, transitioning to a walker (2-wheeled or four footed), then to two crutches or two canes and finally to a single cane (Kirby, Tsai, & Graham, 2002; May, 2002). The most prominent assistive device utilized during prosthetic training and at discharge is the 2-wheeled walker (Kirby et al., 2002). The combination of utilizing an assistive device and LEA sets an individual up for a slower walking speed and decreased symmetry.

Walking speed influences gait parameters such as step and stride length as well as the overall percentage of time spent during stance or swing phase. This has been documented in normal healthy adults (D.A. Winter, 1991). As noted earlier, individuals with LEA demonstrate a slower self-selected walking speed as well as decreased symmetry between the prosthetic and sound limbs (Hermodsson et al., 1994a; E. Isakov et al., 1997; E. Isakov et al., 2000); however, Sanderson et al. (1996) demonstrated that

individuals with TTA can achieve normal values at higher speeds (2.7 m/sec-
3.5 m/sec) (D. J. Sanderson & Martin, 1996). Nolan et al. (2002), Zucker-
Levin et al. (2003) and Isakov et al. (1996) performed a gait analysis on 4, 15,
and 14 individuals respectively with TTA. Analysis was performed at the
individual's SSWS and then at faster walking speeds (up to 130% of their
SSWS). External pacing was utilized to achieve the higher walking speeds.
At higher walking speeds the percentage of the gait cycle spent in stance or
double limb support time decreased, and symmetry between limbs improved
(E. Isakov, Burger, Krajnik, Gregoric, & Marincek, 1996; Nolan et al., 2003;
Zucker-Levin, 2003). Donker and Beek (2002) examined the interlimb
coordination of seven individuals using an above-knee prosthesis
(transfemoral level) at different walking speeds. They also found that
interlimb coordination improved at higher speeds, leading to greater overall
stability (Donker & Beck, 2002): thus, training an individual at higher walking
velocities may enhance the individual's symmetry.

Training Based on Motor Learning Principles

There are a number of existing theories on how to rehabilitate an
individual after an injury. Two theories revolve around the control of
movement. One involves a more top-down approach in which motor control
starts with the central nervous system and ends with the actual movement of
a distal extremity. This requires the coordination of many muscles, nerves
and joints. This coordination occurs in the brain. If the system has a

deficiency in any area, movement becomes more difficult and the original control patterns in the brain will have to shift. An individual who loses a limb experiences movement difficulty, and the original map in their brain becomes incorrect since they have lost a part of their body. Through training and use it has been noted that a reorganization can occur in the brain after the loss of an extremity (R. C. Chen, B.; Yaseen, Z.; Hallett, M.; Cohen, L., 1998; Irlbacher, 2002; Wu, 1999). The motor learning top-down approach focuses on the reorganization through the training of a task in which movement revolves around a behavioral goal. If a task is completed as a continuous movement the thought is that the reorganization will occur in a functional manner and become automatic, allowing the individual to perform more than one task at once (Shumway-Cook, 2001). Geurts et al. (1991) further suggests that motor output is not a separate entity but tied to motor behavior. In their study eight individuals with LEA were pre/post tested after prosthetic rehabilitation on postural balance during single and dual tasks (Geurts, 1991). Individuals initially had greater postural control during the single task trial; however, the difference between the two trials (single and dual) at the end of rehabilitation decreased significantly, demonstrating that less cognitive attention was required to maintain postural control and thereby signaling a central reorganization process (Geurts, 1991). In the current study this theory is referred to as a task-oriented approach.

The second theory, which focuses more on impairments, can be referred to as a bottom-up or impairment-oriented approach. For an

individual with LEA the focus is on the use of the prosthesis and how an individual controls it. Proper weight bearing through the prosthesis and strength of the proximal muscles is integral. An example of exercises utilized in prosthetic rehabilitation would be the progressive weight-bearing exercises. Jones (1997) compared prosthetic weight bearing in a static standing position to dynamic vertical ground reaction forces (VGRF) in ten elderly individuals with dysvascular unilateral TTA. The static weight bearing (SWB) measure correlated with the dynamic weight bearing measure (VGRF) (M. E. Jones, Steel et al., 1997). They recommended that rehabilitation goals for new amputees include prosthetic weight bearing and that specific training procedures to improve prosthetic weight bearing be carried out (M. E. Jones, Bashford et al., 1997). Overall, proper utilization of the prosthesis leads to increased functional ability and improves overall functional outcomes. Jones' et al. (1997) research in which walking velocity was impacted by SWB of the prosthesis supports this notion (M. E. Jones, Bashford et al., 1997). Three other studies examined the impact of muscle strength on prosthetic control (Centomo, Amarantini, Martin, & Prince, 2008; Klingenstierna, Renstrom, Grimby, & Morelli, 1990; Nadollek, Brauer, & Isles, 2002). All three demonstrated a link between increased walking speed and/or balance with increased muscle strength on the prosthetic side. If a functional task is not achieved independently, the task is broken down into smaller parts. These parts are then practiced individually or progressively until the individual can

successfully achieve the functional task. For this study this theory will be referred to as the impairment-oriented approach.

The two training theories, task or impairment-oriented, strive for the same goal: independent functioning. The majority of the literature comparing the two approaches examines a neurologic population (Dean, 1997; Nugent, 1994; Winstein, 1989). No studies comparing the two approaches exist in the LEA population. Very limited research exists regarding any type of initial prosthetic training.

Prosthetic Rehabilitation

Standard rehabilitation procedures prior to receiving the prosthesis include limb shaping in preparation for the prosthesis, patient education geared toward positioning and proper skin care, functional training such as transfer training, bed mobility and mobility (either wheelchair or upright), range of motion activities and strengthening of the upper and lower extremity in preparation for prosthetic gait. There are no documented standard protocols for early mobilization during post-surgical rehabilitation. A paucity of research or information exists during the prosthetic phase of rehabilitation, as well.

Baker & Hewison (1990) were the first to document the effects of early prosthetic rehabilitation. In their work, initial prosthetic walking was observed in a group of 20 individuals with LEA (15 with TTA, 5 with TFA) for one year (Baker & Hewison, 1990). It was noted that walking speed increased 55%

within the first fifteen days and 150% within 30 days. Symmetry improved during the first 30 days of training, but even after one year individuals continued to exhibit an asymmetrical gait. Baker and Hewison (1990) did not document the kind or amount of therapy the individuals received, only that they received it. Confounding these findings is that some individuals continued to receive therapy on an outpatient basis while others went home, leading to an incomplete data set after the 30 days. Although these findings provided badly needed information, they did not give any insight into early prosthetic training protocols because there was no treatment protocol documented and randomization was not utilized.

Rau, Bonvin and de Bie (2007) performed a randomized controlled trial that examined the effectiveness of a three-day intensive physiotherapy program to that of usual care (walking only). Fifty-eight individuals with LEA secondary to trauma from a mine (43 with TTA and 15 with TFA) participated. For the 58 participants it was the first prosthesis and rehabilitation for only 12 of them. The other participants had their prosthesis for one or more years of use. The experimental group performed seven exercises consisting of strengthening, weight bearing, coordination tasks, corrected walking, obstacle management and functional training lasting approximately one hour. Individuals in the usual care group walked with supervision. Training time remained constant for both groups. The group that participated in the intensive physiotherapy had significant improvement noted in the two-minute walk test, walking speed, Locomotor Capabilities Index (LCI) and Timed Up

and Go test (TUG) (Rau et al., 2007). The protocol utilized in this study combined both the impairment and task-oriented approach during the one hour of training. The strengthening, weight bearing and coordination exercises fit into the impairment model, whereas the functional training and corrected walking that were described were performed utilizing a continuous task-oriented approach. Overall, the finding supports the need for physical therapy during prosthetic rehabilitation.

Standard physical therapy texts also promote a combined training approach for initial prosthetic rehabilitation (May, 2001, 2002). Initially the training emphasis is on the impairment level to promote equal weight bearing through progressive weight bearing exercises and then focus changes to the task-oriented level for functional training (May, 2001, 2002). Based upon a survey of therapists in the tri-state area it was noted that therapists utilize a variety of approaches, with a common thread of using a combination of approaches for each individual (Hyland, 2003). No one reported a pure approach to initial prosthetic training (Hyland, 2003).

With little published research on initial prosthetic training, one turns to the research that does exist. Two studies revolve around balance training (Geurts, 1991; Lee, Lin, & Soon, 2007; Matjacic & Burger, 2003). In the first study fourteen independent prosthetic ambulators with unilateral TTA participated in five twenty-minute balance training sessions (Matjacic & Burger, 2003). The balance training sessions took place on a Balance ReTrainer, a computerized balance training device. Pre/Post measurements

consisted of the Timed Up and Go (TUG), single limb stance on the prosthesis and a ten-minute walk. After the five sessions a significant statistical change was noted in the ten-minute walk. The TUG and single limb stance both improved, however not statistically (Matjačić & Burger 2003). Walking reflects both static and dynamic balance; therefore, since no other training occurred during the five sessions it appears the improved balance noted after training transferred to improved walking.

The study conducted by Lee, Lin and Soon 2007 had seven subjects with unilateral TTA participate in a single training session with and without feedback. The feedback given was a low-level electrical stimulation to the quadriceps. They performed six trials of single limb stance (three with/three without electric stimulation). They also performed two thirty-minute trials of treadmill ambulation with and without visual-auditory biofeedback for heel contact and toe-off. The application of sensory feedback (visual-auditory and sub-sensory electrical stimulation) improved static and dynamic balance as noted, with improved holding time, decreased sway index, improved stance/swing ratio and single/double limb support period. Giving the individual more sensory feedback, possibly to substitute for the loss of feedback they experience from the LEA, improved their functional ability. Both of the balance studies focused more on the impairment-oriented approach by practicing balance activities versus performing a functional task such as walking. Neither study addressed early prosthetic training however.

The use of sensory feedback to improve prosthetic ambulation has also been tested (Chow & Cheng, 2000; Dingwell, Davis, & Frazier, 1996). Chow and Cheng (2000) utilized audio feedback to promote weight bearing with 6 individuals with unilateral TTA. Each subject performed a 5-day protocol of progressive weight bearing utilizing a load-monitoring device to measure prosthetic weight bearing. After the 5 days the individuals were able to control the amount of weight born through the prosthesis more consistently with the feedback versus without it (Chow & Cheng, 2000; Dingwell et al., 1996). Dingwell et al (1996) researched the impact of visual feedback on symmetry during prosthetic ambulation. Six individuals with unilateral TTA participated in a one-time gait trial with and with visual feedback. All individuals were able to ambulate for twenty minutes on a treadmill and had mean wearing time with a prosthesis of 6 years. The visual feedback was real-time feedback given while walking on the treadmill and consisted of foot centers of pressure, percent stance times, and relative push off forces for both the right and left limbs. Significant improvement in symmetry between the limbs was noted for all measures (foot center of pressure, percent stance time and push off force) five minutes after the feedback was stopped (Dingwell et al., 1996). No follow-up was performed in either study nor did they examine any other functional task to identify if learning or transfer occurred overall.

Randomized control prosthetic gait training studies do not exist in the literature for the TTA population. However, there are two studies that do

examine gait training strategies for individuals at the transfemoral level

(Sjodahl & Persson 2001 and Yigiter et al. 2002). Sjodahl & Persson (2001)

examined a ten-month training protocol on nine subjects with unilateral TFA.

All were independent community walkers prior to the study. The treatment

consisted of exercises to improve body awareness and center of gravity.

They added a "conscious therapeutic approach" in which the therapist

mirrored what the patient was saying to allow for emotional response to the

training. Outcome measure was a gait analysis utilizing the VICON

movement analysis system. When individuals received the added

"conscious therapeutic approach" their self-selected walking speed increased.

Patients also reported improved body awareness and overall increased self-

esteem/confidence (Sjodahl, Jarnlo, & Persson, 2001). Yigiter et al. (2002)

randomized 50 subjects (all unilateral TFA) into two training groups:

traditional versus proprioceptive neuromuscular facilitation (PNF) training.

Training was performed in 30 minutes/day, with 10 sessions for both groups.

The traditional training group performed weight-shifting activities, stool

stepping, dynamic balancing activities, braiding, gait exercises and stair

training. The PNF group performed the same activities; however,

approximation was utilized during the balance activities, stool stepping, and

stair training. In addition, a static balance exercise with resistance given in

the antagonistic direction was added along with rhythmical initiation for trunk

and pelvic motions. Both groups improved in weight-bearing and gait

parameters (velocity, stride length, step width and cadence), with greater

improvements noted in the PNF group (Yigiter et al., 2002). The use of neurofacilitation (PNF) and conscious awareness taps into central processes for learning, more consistent with a top down approach. However, the exercise protocols combined both approaches: impairment-oriented (breaking a task down through weight-shifting and stool-stepping) and task-oriented (whole practice of a task using walking and stair training). It is difficult to support one approach over the other.

Research regarding prosthetic rehabilitation is limited for randomized control trials and early prosthetic training. The current research supports that trained, guided rehabilitation can impact functional outcomes even for individuals who have been walking with their prostheses for many years. The use of feedback, conscious awareness and PNF all support a top-down approach; however, the progressive weight bearing exercises and balance training included in the approach all support the bottom-up or impairment-oriented approach. The purpose of this study is to try to fill in some gaps noted in the literature. It focuses on early prosthetic rehabilitation randomizing participants into two groups: one participating in a task-oriented approach and the other in a combination of impairment and task-oriented approaches.

Chapter III

METHODS

Subjects

Incidental sampling was used to recruit participants with unilateral transtibial amputation from multiple inpatient facilities between January 2005 and May 2008. During that time period 27 individuals were identified for the study. Two qualified individuals did not consent, and three were discharged early (two for medical reasons and one for insurance reasons), leaving a total of 22 participants completing the study. The facilities included two rehabilitation hospitals and two hospitals with subacute units. The project was approved by Seton Hall and all the hospitals' Institution Review Boards. All subjects signed the appropriate informed consent prior to participation.

Participants were screened for entry by their primary physical therapist based upon the inclusion and exclusion criteria listed in Table 1. The primary investigator met with the qualified participants to explain the study, determine if they met the inclusion and exclusion criteria, obtain their informed consent, and complete the initial data intake form.

Table 1

Inclusion and Exclusion Criteria for Participation

Inclusion Criteria	Exclusion Criteria
Unilateral transtibial amputation secondary to dysvascular causes	Neurologic co-diagnosis
Adult (> 30 years)	10 degree or greater loss of knee extension
Able to follow verbal directions	Absent sensation in the intact limb
First time prosthetic user	Lower extremity musculoskeletal surgery within the last 6 months
Suture line closure	
Inpatient rehabilitation	
Medically stable	
Able to tolerate wearing the prosthesis for 15 minutes	

Instrumentation

Copies of all outcome instrumentation are located in the Appendix.

Amputee Mobility Predictor© (AMP)

The AMP is a twenty-item functional scale utilizing a 3 point rating scale of 0 – 2. The maximum attainable score on the AMP is 47. The following tasks are included: sitting balance, sit to stand, standing balance, transfers, single limb balance, standing reach, picking objects off the floor, gait characteristics during walking with the prosthesis, stepping over an object and ability to walk at variable speeds (R. S. Gailey et al., 2002; R. S. R. Gailey, K.E.; Applegate, E.B.; Cho, B.; Cunniffee, B.; Licht, S.; Maguire, M.; Nash, M., 2001). The AMP is designed to be administered with a prosthesis (AMPPRO) or without a prosthesis (AMPPRE). Subjects in this study utilized their prosthesis for the test. The AMPPRO takes approximately 15 minutes to administer. AMP Scores have been correlated with the functional Medicare classification levels of 0 – 4 (refer to Table 2). Mean AMP scores for each level are: Level 0-1 (25), level 2 (34.6), level 3 (40.5), level 4 (44.7). The AMPPRO is reliable and valid for individuals with transtibial amputations with excellent intrarater and interrater reliability and with intra class coefficient (ICC) scores ranging from 0.96 to 0.99 (R. S. Gailey et al., 2002). In a prior study the primary investigator had an intra class correlation (ICC) of 0.985 on the AMPPRO.

Table 2
Medicare Classification Levels

Level	Description	Mean AMP scores
0	Unable to ambulate	
1	Household ambulation	25
2	Limited community ambulation	34.6
3	Community ambulation	40.5
4	Community ambulation	44.7

(R. S. Gailey et al., 2002)

Berg Balance Scale (BBS)

The Berg Balance Scale (BBS) is a reliable and valid method for evaluating the risk of falls in the elderly population (K. Berg & Norman, 1996; K. Berg, Wood-Dauphinee, & Williams, 1995; K. O. Berg, Maki, Williams, Holliday, & Wood-Dauphinee, 1992; K. O. Berg, Wood-Dauphinee, Williams, & Maki, 1992; Stevenson, 1996). It has fourteen items, which are scored on a four-point scale with a maximum score of 56. Nine of the fourteen items are included in the Amputee Mobility Predictor© scale. The other five items include a 360-degree turn, looking over each shoulder, tandem standing and repetitive alternating placing of feet on a stool. It is scored on a scale of 0 – 4 with 0 as the inability to perform the item and 4 as the ability to complete the task independently with a total maximum score of 56 points. A score below 46 corresponds to a high probability of falling (Bogle Thorbahn & Newton, 1996; Lajoie & Gallagher, 2004; Muir, Berg, Chesworth, & Speechley, 2008) . The BBS has high interrater (ICC=0.98) and intrarater (ICC=0.99) reliability (K. Berg & Norman, 1996; K. Berg et al., 1995; K. O. Berg, Wood-Dauphinee et al., 1992). In a prior study the primary investigator had an ICC of 0.922 with the amputee population for the BBS.

GAITRite®

The GAITRite® is a computerized gait analysis system consisting of a 3 by 15 foot long, pressure-sensitive mat walkway connected to a computer. As participants walk across the GAITRite® mat, pressure sensors running the

length of the mat are activated under the foot, therefore allowing the computer to calculate the location and timing for each footstep. An interface cable connected via a serial port transfers the information from the walkway to a personal computer. The GAITRite® software processes the raw data and calculates spatial and temporal parameters. The GAITRite® was connected to a Dell Inspiron 600m laptop from which spatial and temporal gait parameters were calculated with GAITRite® software, version 3.4sh. The baud rate was set at 57.6 hertz. This system is reliable and valid for measuring spatial and temporal gait parameters in the adult, elderly and neurologic populations with interclass correlation coefficients ranging from 0.95 to 0.99 (Bilney, Morris, & Webster, 2003; McDonough, Batavia, Chen, Kwon, & Ziai, 2001; Menz, Latt, Tiedemann, Mun San Kwan, & Lord, 2004).

Locomotor Capabilities Index (LCI)

The Prosthetic Profile of the Amputee (PPA) questionnaire is a measurement tool utilized to collect information regarding the use of a prosthesis. One portion of the PPA is the Locomotor Capabilities Index (LCI). The LCI is a tool that is widely used as a separate instrument (Franchignoni, Orlandini, Ferriero, & Moscato, 2004). It contains fourteen items broken into seven basic locomotor activities (e.g., walking in the house and on even ground, getting up from a chair and going up/down stairs with a handrail) and seven advanced locomotor activities (e.g., getting up from the floor, walking on uneven surfaces or outside in inclement weather, walking while carrying

an object, and going up/down the stairs without handrails). The LCI is a self-assessment in which the individual answers each item as follows: unable to perform, able to perform if someone helps me, able to perform if someone is near me or able to perform alone. Each item is scored from 0 (not able to) to 3 (able to accomplish the activity alone), with a maximum score of 42. The LCI can be administered in a written or verbal format. The LCI is valid and reliable in individuals with lower-limb amputation undergoing prosthetic training with a Cronbach's alpha coefficient of 0.95 (Franchignoni et al., 2004; Gauthier-Gagnon, Grise, & Lepage, 1998).

Numeric Rating Scale (NRS) for pain

The Numeric Rating Scale is a pain scale that can be administered as a self-assessment or by a health care professional. Patients are asked to rate the intensity of their pain on a scale of 0 to 10, with 0 as no pain and 10 equal to the worst pain possible. The validity of the scale itself has been established ($r= 0.963$) (Ferraz et al., 1990; Jensen, 1992), as well for method of administration to adults ($r=0.847-0.901$) (Ferraz et al., 1990; Paice & Cohen, 1997).

Procedures

Participants were recruited after they received their initial prostheses and the primary fittings were complete. Once each participant was ready to start gait training with his or her initial prosthesis, the primary researcher

completed a data intake form. The data intake form consisted of screening for lower extremity hip, knee and ankle range of motion, hip and knee muscle strength, lower extremity sensation and a pain while wearing the prosthesis. The NRS was utilized to rate pain. Participants were then randomly assigned to either to the task-oriented or impairment-oriented group by the supervising therapist on the unit. The training therapist then began the ten-day protocol based upon group assignment. Physical therapists from the inpatient units were the training therapists for the study. All training therapists were instructed in the two gait training protocols by the primary investigator. Nine therapists in total were trained in the protocol and carried out the treatment over the data collection period. A ten-day protocol was chosen based upon a pilot study and the average length of stay for prosthetic training. In the Hudson Valley area of New York the average length of stay for prosthetic training is 17 days (Hyland, 2003). This included days not spent in therapy. Two participants in the pilot study were discharged within two days of completing the protocol. The ten-day protocol helped to eliminate participant attrition resulting from early discharge.

Baseline data consisting of: the Amputee Mobility Predictor© (AMPPRO), Berg Balance Scale (BBS), Locomotor Capabilities Index (LCI), and spatial and temporal gait parameters using the GAITRite® electronic walkway were taken after the third day of training. All testing took place at the patient's rehabilitative facility in a quiet area near the therapy room. The third day was chosen based on pilot study data in which it was noted that changing

assistive devices between day one and three of initial prosthetic gait training impacted gait characteristics. Performing all data collection on day three eliminated the need to control for different assistive devices. All subjects participated in ten days of therapy with their prosthesis; however, the actual pre/post measurements only reflect seven days of training.

Data were collected in the following order: spatial and temporal gait parameters using the GAITRite®, BBS, LCI and the AMPPRO. The participants completed all data collection while wearing their prostheses. The participants were instructed to walk on the GAITRite® three times at a self-selected walking speed using a rolling walker. To prevent the impact of acceleration and deceleration on gait parameters, participants started to walk approximately five feet prior to the mat and continued to walk for five feet after the mat. Subjects were guarded with close supervision for safety during the test. Rest periods of two to three minutes were given to each participant between the three trials to minimize fatigue. All participants utilized a rolling walker during ambulation testing, since the majority of individuals with amputations utilize a rolling walker at discharge (Kirby et al., 2002). After completion of the walking trials the BBS was administered. Subjects were allowed to rest as needed between BBS tasks. The primary investigator then verbally administered the LCI while the subject was seated. Following this, the remaining AMPPRO tasks were completed. Nine AMPPRO items are part of the BBS, three items were observed during the BBS and four items were analyzed during the walking trials on the GAITRite®. The remaining five

items (sitting reach, nudge test, variable cadence test, the ability to step over an obstacle, and go up and down two steps) were then completed. At the end of the testing, the participant's prosthesis was removed, a skin inspection was performed and the patient was returned to his or her room.

All participants continued their assigned training protocol during the remaining seven days. Both groups received the same amount of training time from a training therapist. Daily log sheets were completed by the training therapist, including a description of the therapy completed, time in therapy, pain scale, and distance walked. The ten-day protocol did not include non-rehab days on which the participant did not receive therapy.

The primary researcher, a physical therapist blinded to group assignment, performed all testing. All testing, walking on the GAITRite®, BBS, LCI and AMPPRO, was completed again at the end of the ten-day training protocol in the same method as noted above. The same rolling walker was utilized for pre and post-test data to prevent different influences of assistive devices.

Gait Training Protocol

Two gait training protocols were utilized. One focused more at an impairment level, and the other at a task level. The training protocol for the impairment-oriented group or bottom-up approach consisted of breaking down the functional activities into parts. Pre-gait training activities were practiced in standing and included balance training,

weight shifting in all planes, dynamic reaching, stepping up and down from a low step, and single stepping. Participants practiced these activities for no less than 50% of their overall upright physical therapy time. Continuous corrective walking made up the remainder of the treatment time with a therapist. For corrective walking, therapists gave verbal and manual cues to the participants while they were walking to promote a symmetrical gait pattern. The participants used the appropriate assistive device as determined by the training therapists during walking. This was noted on the daily training logs.

The task-oriented or top-down group performed functional tasks as a whole. Continuous corrective walking was utilized for at least 90% of their overall treatment time with the physical therapist. For corrective walking, therapists gave verbal and manual cues to the participants while they were walking to promote a symmetrical gait pattern. The participants utilized the appropriate assistive device during walking. This was also noted on the daily training logs. Therapists were allowed to utilize pre-gait activities or break down a task as noted earlier for 10% of the individual therapy time. (See Table 3)

The physical therapy program for both protocols consisted of individual time with the physical therapist and possibly a group session, consisting of one of the following: leg exercises, transfer training or ambulation. These group sessions were factored into the

participants' overall therapy time. If any upright pre-gait activities or walking occurred during the group session, it was documented so the therapist could adjust the treatment session on that day to meet the training protocol. Participants in both groups engaged in other programs typically offered to patients on the inpatient unit (e.g., occupational and recreational therapy).

Table 3

Gait Training Protocol: % Time Spent on Activities for the Impairment-Oriented and Task-Oriented Protocols

Tasks	Impairment-Oriented (% of therapy time)	Task-Oriented (% of therapy time)
Static and Dynamic Balance activities in single & double limb support		
Pre-gait activities: Single stepping, Weight-shifting in all directions, Step-ups	50	10
Corrective Walking, Stair climbing Transfers (complete tasks)	50	90

Data Analysis:

The study utilized an experimental, prospective, randomized, single-factor,

pretest/posttest design. The GAITRite® system recorded spatial and temporal

measurements on a Dell Inspiron 600m laptop during data collection. The

pressure markings from the assistive device (rolling walker) were deleted

prior to calculating temporal and spatial parameters. The GAITRite® software

version 3.4sh averaged the three trials for each session for the statistical

analysis. Dependent variables measured for the study were: mean

normalized velocity, cadence, step length, single limb and double limb

support time and percentage of time in stance and swing phase. Descriptive

statistics were utilized to describe demographics including age, gender, pain

level, number of co-diagnoses and length of time between surgery and

prosthetic training. Between-group analyses utilized median scores for BBS,

LCI and AMPPRO and the means scores of all spatial and temporal

measures. Change scores were calculated for between-group comparisons

when significant differences were noted in baseline measures between

groups. The symmetry index (SI) was calculated for both single limb support

time and step length. The SI is calculated as follows: $SI = X_p - X_i / 0.5(X_p + X_i)$

x 100 (Crenshaw & Richards, 2006). X_p is the gait variable for the prosthetic

limb, and X_i is the corresponding variable for the intact limb. The magnitude

of the SI indicates the degree of asymmetry, and the sign of SI indicates

which limb has a longer step length or stance time. Perfect symmetry would

be indicated by a value of zero. SI has been utilized to report symmetry in the amputee population (Crenshaw & Richards, 2006).

Statistical Analysis

All analyses were performed using SPSS version 16.0. The alpha level was set at 0.05 to determine significance. All analysis was based upon a two-tailed distribution. All subject identifiers were coded to ensure subject privacy.

To test the hypothesis that no difference exists between two gait training strategies, an independent t-test was utilized to determine differences between groups for the gait parameters (velocity, double limb support time, stance time, swing time, cadence and symmetry scores). A Mann Whitney U test was utilized to determine between group differences for AMPPRO, BBS and LCI values.

Paired t-tests were utilized to determine change within a group for all gait parameters, and a Wilcoxon Signed Rank test was utilized for the AMPPRO, BBS, and LCI values.

A Power Analysis for the t-test was performed on all outcome measures utilizing methodology outlined in Appendix C in *Foundations of Clinical Research* (Portney & Watkins, 1993). The effect size index is calculated by dividing the difference between the group means with the common standard deviation. Power was then determined utilizing table C.2

based upon the value of the effect size index and the sample size in each group (Portney & Watkins, 1993).

Data were tested for normality using the Shapiro-Wilk test. All data were determined to have normality except double limb support time. Parametric testing was performed as noted above on all data except for double limb support time, in which non-parametric testing was performed.

Chapter IV

RESULTS

Subject Characteristics

Subjects were equally divided into the impairment-oriented (IO=11) and task-oriented (TO=11) groups. There were no significant differences between the two groups with regard to age (p=0.781), number of co-existing diagnoses (p=0.243), prosthetic pain level (p=0.766) or time since amputation (p=0.230) (Table 4). All participants had prostheses with a weight-bearing specific socket fit. Twenty-one participants had a solid-ankle-cushioned heel (SACH) foot, and one had a C-foot. Eighteen subjects had a pin-lock suction suspension, and the remaining four utilized a supracondylar cuff for their suspension.

Functional Outcomes and Balance

No significant differences were noted between the groups for the LCI, AMPPRO or BBS. Significant improvement was noted within each group from baseline to post treatment. Table 5 reports the mean and standard deviation for functional outcome and balance measures.

Locomotor Capabilities Index

For the LCI no significant differences were noted between groups at baseline (p=0.130), post treatment (p= 0.540) or change scores (p= 0.380). Significant differences were noted within groups for both the impairment-oriented (IO) (p= 0.000) and task-oriented (TO) (p= 0.000) groups.

AMPPRO Score

For the AMPPRO no significant differences were noted between groups for baseline (p=0.114), post treatment (p=0.211) or change scores (p = 0.495). Significant differences were noted within groups for both the IO (p = 0.000) and TO (p= 0.000) groups. (See Figure 1)

Berg Balance Score

For the BBS no significant differences were noted between groups at baseline (p=0.130), post treatment (p= 0.308) or change scores (p= 0.339). Significant differences were noted within groups for both the impairment-oriented (IO) (p= 0.000) and task-oriented (TO) (p= 0.000) groups. (See Figure 2)

Spatial and Temporal Gait Parameters

Overall, no significant differences were noted between the two groups for change scores. Significant differences were noted within the IO group from baseline to post treatment for velocity, cadence, double limb support time and percentage of the gait cycle in stance and swing for both lower

extremities. The TO group only had a significant difference from baseline to post treatment in velocity. Table 6 reports the means and standard deviations for spatial and temporal gait parameters.

Mean Normalized Velocity

For MNV significant differences were noted between groups at baseline (p=0.000) and post treatment (p = 0.002); however, no significant difference was noted between the groups for the change score (p = 0.362). Significant differences were noted within groups for both the IO (p= 0.002) and TO (p= 0.028) group. (See Figure 3).

Cadence

For cadence significant differences were noted between groups at baseline (p=0.014) and post treatment (p = 0.001); however, no significant difference was noted between the groups for the change score (p = 0.302). Significant differences were noted within the IO group (p= 0.001) but not the TO group (p= 0.352). (See Figure 4).

Double Limb Support Time (Prosthetic Limb)

For DLS significant differences were noted between groups at baseline (p=0.001) and post treatment (p = 0.020); however, no significant difference was noted between the groups for the change score (p = 0.607). Significant differences were noted within the IO group (p= 0.023), but not the TO group (p= 0.312). (See Figure 5).

Stance/Swing Percentage of Gait Cycle

Table 6 reports means and standard deviations.

Prosthetic Side

Significant differences were noted between groups at baseline stance (p= 0.015) and swing (p= 0.016) on the prosthetic side.   No significant differences were noted at post treatment between groups for stance (p= 0.094) and swing (p= 0.089) or change scores of stance (p= 0.493) and swing (p= 0.479). Significant differences were noted within the IO group for both stance (p= 0.036) and swing (p= 0.036). No significant differences were noted within the TO group for stance (p= 0.976) or swing (p= 0.986) on the prosthetic side.

Intact Side

Significant differences were noted between groups at baseline stance (p= 0.015) and swing (p= 0.016), and post treatment for stance (p= 0.017) and swing (p= 0.017). No significant difference was noted between groups for change scores of stance (p= 0.446) and swing (p= 0.280). Significant differences were noted within the IO group for both stance (p= 0.001) and swing (p= 0.004). No significant differences were noted within the TO group for stance (p= 0.950) or swing (p= 0.745) on the intact side.

Symmetry Index (SI) for Single Limb Support

No significant differences were noted between the groups at baseline

(p= 0.099), post treatment (p= 0.238) or change score (p= 0.438) on the SI.

No significant differences were noted within either the IO (p= 0.184) or TO (p=

0442) groups. The negative SI represents a longer time in single limb support

on the intact side compared to the prosthetic side. One trend noted was the

mean SI remained negative for the IO group and positive for the TO group.

Symmetry Index (SI) for Step Length

Significant differences were noted between the groups at baseline

(p=0.021), post treatment (p= 0.012) or change score (p=0.110) for the SI.

No significant differences were noted within either the IO (p= 0.870) or TO

(p=0.276) groups. The negative SI represents a longer step length on the

intact side compared to the prosthetic side. The mean SI remained negative

for the TO group and positive for the IO group.

Power Calculation

An estimated sample size was calculated based upon a medium effect

size and 80% power utilizing pilot data with ST Plan version 3.0 from the

University of Texas. Results indicated that an estimated sample size of 54

(27 per group) was needed to achieve 80% power for all outcome variables.

Due to changes in healthcare and the limited number of individuals who met

the inclusion criteria of the study from the four inpatient settings, data

collection was stopped after 22 subjects in a period of 3 ½ years. Due to this factor, power was recalculated for this data and is as follows: MNV and cadence 94%, symmetry of step length 76%, DLS 61%, stance and swing time 43%, AMPPRO and BBS 20%, and symmetry of single limb support 14%. Power scores were based upon two-tailed distribution.

Post Hoc Analysis: Not A Priori Hypothesis

Secondary to the lack of standardized functional outcome tools for the amputee population a post hoc analysis was performed to determine if a relationship between balance and functional outcome, balance and walking speed, and functional outcome and walking speed existed. A Spearman rho correlation was utilized between the BBS and AMPPRO, between the AMPPRO and velocity, and BBS and velocity. Spearman correlations for post-training values were as follows: Berg Balance Score and AMPPRO (0.902, p=0.000), Berg Balance Score and Velocity (0.604, p=0.003) and AMPPRO and Velocity (0.0694, p=0.000). See Table 8.

Table 4

Subject Characteristics for Groups (Impairment-Oriented IO: Task-Oriented TO) Mean (+/- Standard Deviation)

Characteristics	IO	TO	Significance
Age (years)	65.2 (±12.6)	63.6 (±14.6)	0.78
Gender			
Male	6	9	
Female	5	2	
Co-Diagnosis	2.6 (±0.7)	3.3 (±1.6)	0.24
Pain (VAS)	0.9 (±1.1)	1.1 (±1.6)	0.77
Side of amputation			
Left	8	6	
Right	3	5	
Length of time since amputation (months)	4.2 (±3.3)	2.7 (±1.4)	0.23

Table 5

Mean Values and Standard Deviations of Functional Outcome Measures at Baseline and Post Treatment (Tx). Change Score with Mean Difference and Confidence Interval (CI). Mean (+/- Standard Deviation)

	Impairment-Oriented Group	Task-Oriented Group	Mean Difference	95% CI Mean Difference
LCI (Score)				
Baseline	21.11 (±8.6)	21.50 (±7.4)		
Post Tx	24.78 (±9.4)*	28.00 (±11.8)*		
Change	3.67 (±1.94)	6.88 (±6.38)	-3.32	-8.80 – 2.19
Berg Balance Scale (score)				
Baseline	15.45 (±8.6)	22.45 (±11.7)		
Post Tx	27.09 (±9.2)**	32.91 (±12.96)**		
Change	11.64 (±5.8)	10.46 (±5.1)	1.18	-3.7 – 6.06
AMPPRO (Score)				
Baseline	14.36 (±7.1)	19.73 (±9.5)		
Post Tx	25.27 (±8.1)* *	29.64 (±9.50)**		
Change	10.91 (±3.86)	9.82 (±3.49)	1.09	-2.18 – 4.36

Note. * p<0.05 ** p<0.000

Table 6
Mean Values and Standard Deviations of Spatial and Temporal Gait
Parameter at Baseline and Post Treatment (Tx). Change Score with Mean
Difference and Confidence Interval. Mean (+/- Standard Deviation)

	Impairment-Oriented Group	Task-Oriented Group	Mean Difference	95% CI Mean Difference
MNV (LL/sec)				
Baseline **	0.13 (±0.07)	0.34 (±0.10)		
Post Tx*	0.22 (±0.10)	0.49 (±0.20)		
Change	0.09 (±0.07)	0.14 (±0.16)	-0.52	-0.17 – 0.07
Cadence (steps/minute)				
Baseline *	31.57 (±8.2)	59.30 (±13.8)		
Post Tx*	42.74 (±7.3) *	65.84 (±16.9)		
Change	11.17 (±7.23)	16.32 (±12.59)	-5.15	-15.5 – 5.22
DLS (% gait cycle)				
Baseline *	70.74 (±11.80)	52.34 (±9.8)		
Post Tx *	62.62 (±13.5) *	48.89 (±12.9)		
Change	8.68 (±8.86)	6.70 (±7.42)	1.98	-5.98 – 9.94
Symmetry SLS (SI index)				
Baseline	-25.47 (±37.2)	11.07 (±59.4)		
Post Tx	-14.03 (±33.8)	2.44 (±29.6)		
Change	18.55 (±16.29)	25.68 (±25.11)	-7.13	-25.96 – 11.69
Symmetry Index Step Length				
Baseline *	63.89 (±76.5)	-13.95 (±69.6)		
Post Tx*	67.17 (±65.4)	-.0.32 (±48.0)		
Change	44.20 (±35.48)	22.25 (±25.16)	21.96	-5.40 – 49.31

Note. * p<0.05 **p<0.001 differences between groups

Figure 1. Mean AMPPRO Scores (±1 SD) for Impairment-Oriented and Task-Oriented (n = 11 per group) Baseline, Post Treatment and Change Score. Significant differences were noted within groups but not between. * p<0.001

Figure 2. Mean Berg Balance Scores (±1 SD) for Impairment-Oriented and Task-Oriented (n = 11 per group) Baseline, Post Treatment and Change score. Significant differences were noted within groups but not between. * p<0.001

Figure 3. Mean Normalized Velocity (LL/sec) scores (±1 SD) for Impairment-Oriented (IO) and Task-Oriented (TO) (n = 11 per group) Baseline, Post Treatment and Change score. Significant differences were noted between groups at Baseline and Post Treatment (**p<0.05); however, no significant difference was noted between groups for the change score. Significant differences were noted within groups. * p<0.05
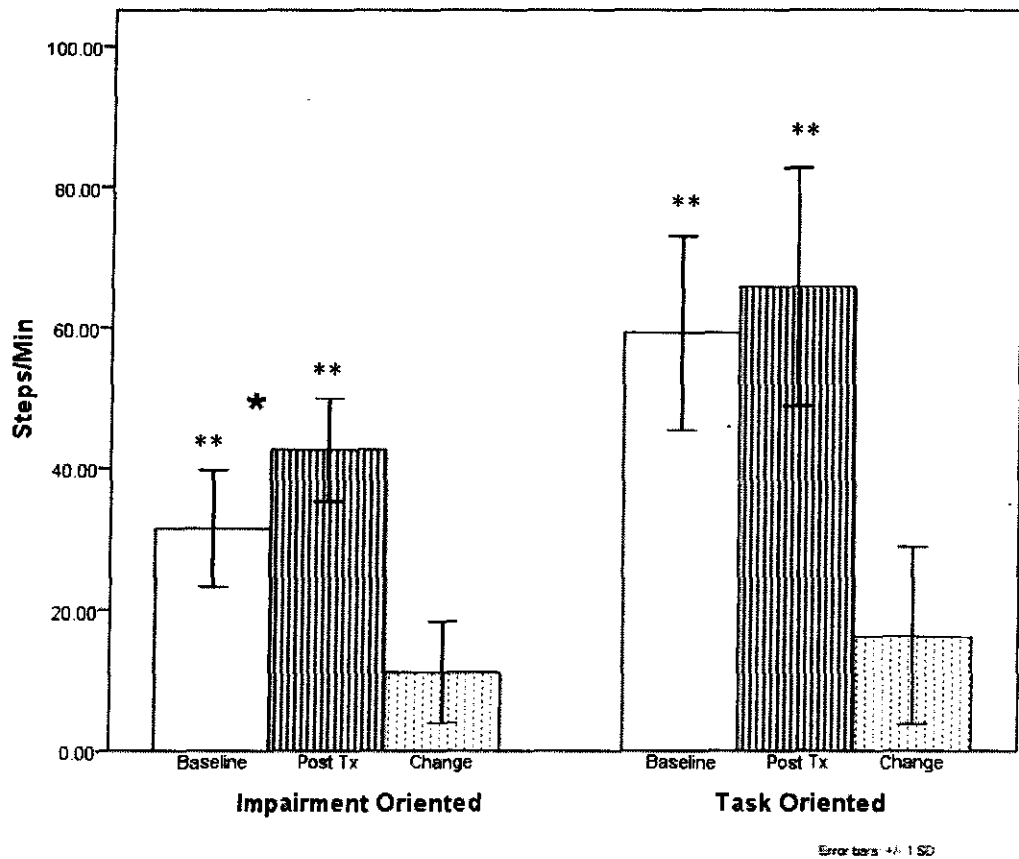
Figure 4. Mean Cadence Values (steps/min) (± 1 SD) for Impairment-Oriented and Task-Oriented (n = 11 per group) Baseline, Post Treatment and Change score. Significant differences were noted between groups at both Baseline and Post Treatment (**p<0.05); however, no difference was noted between the change score. Significant differences were noted within group for the impairment-oriented group only. *p<0.001.
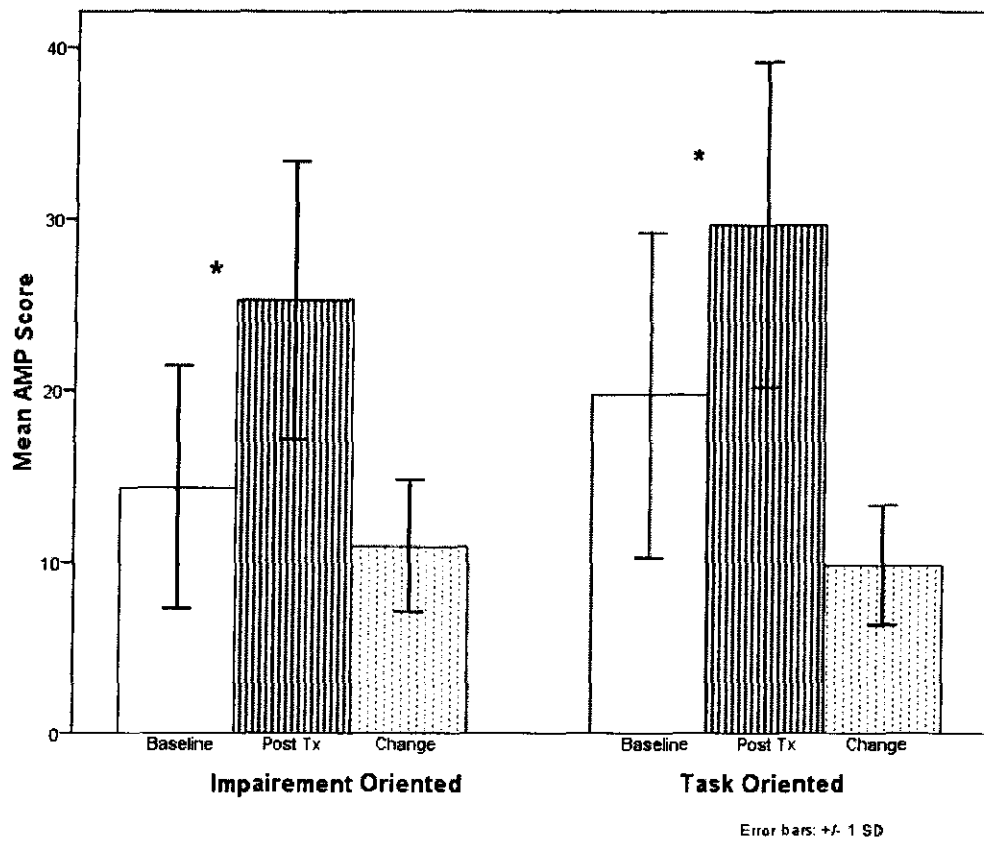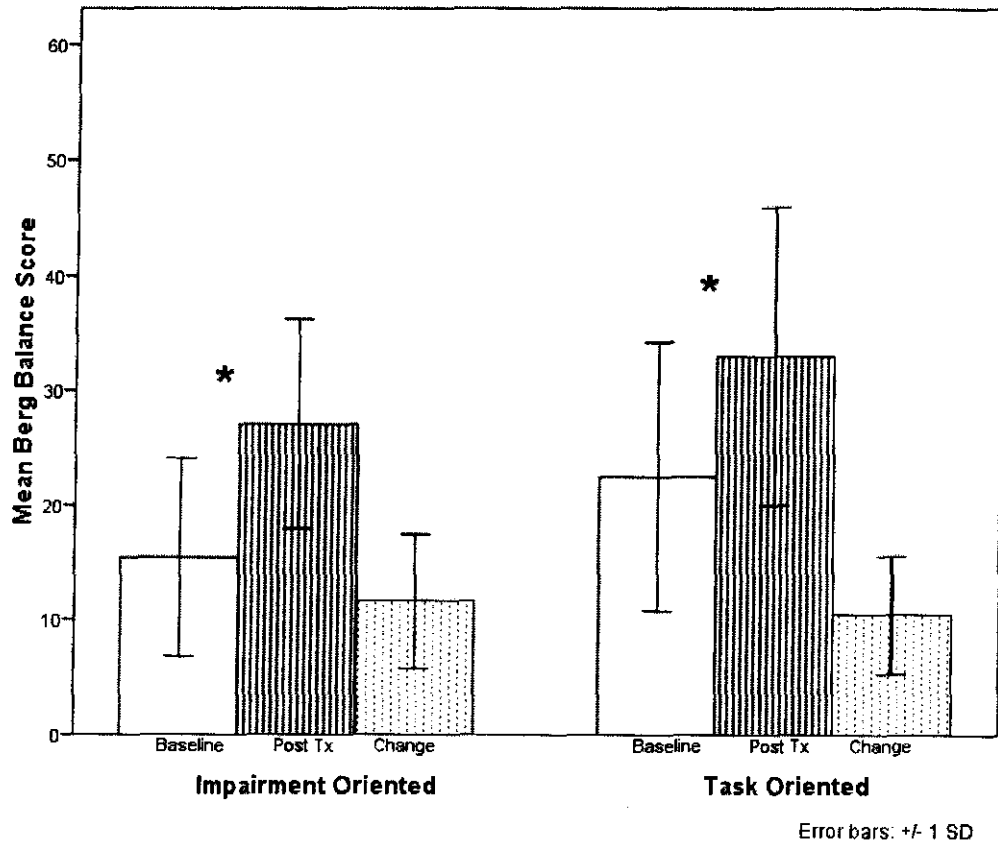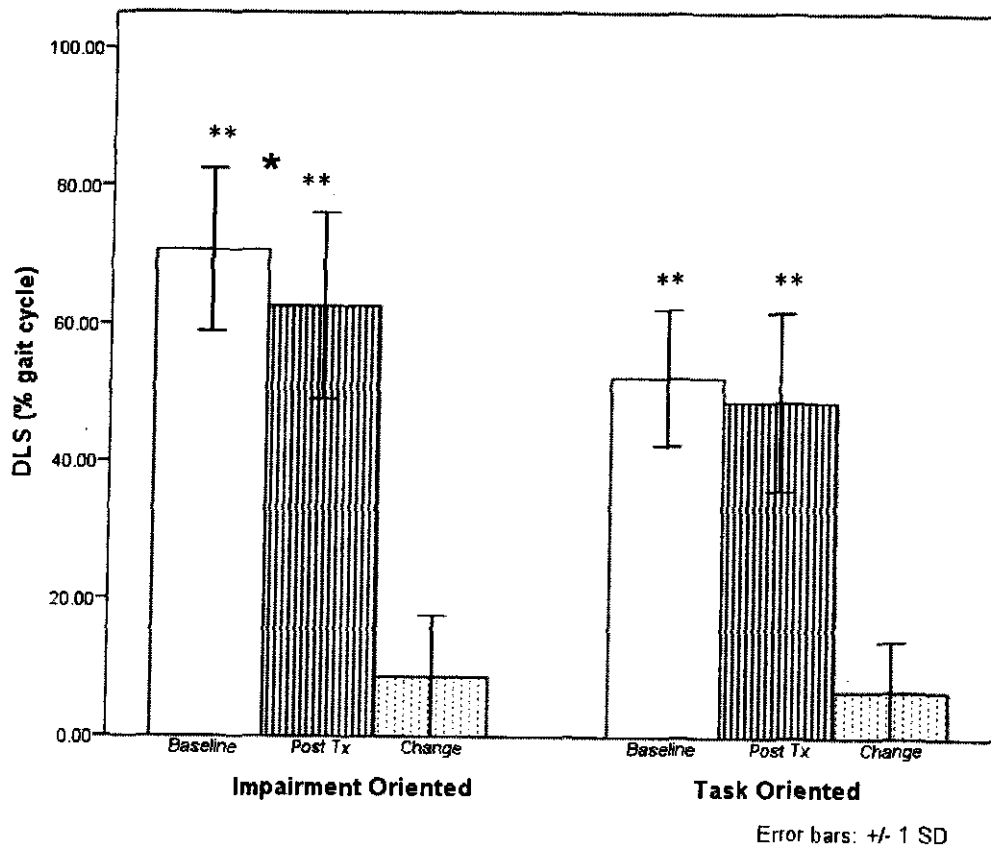
Figure 5. Mean Double Limb support time (% gait cycle) (± 1 SD) for Impairment-Oriented and Task-Oriented (n = 11 per group) Baseline, Post Treatment and Change score. Significant 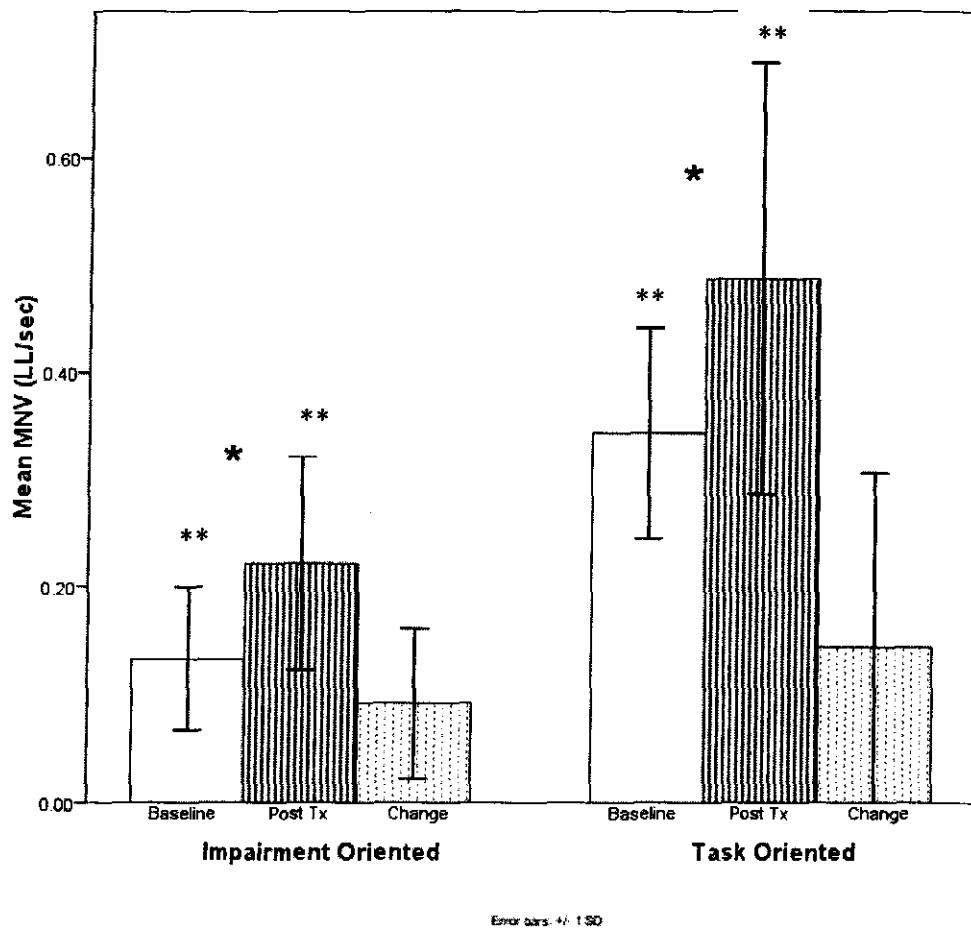differences were noted between groups at both Baseline and Post Treatment (**p<0.05); however, no difference was noted between the change score. Significant differences were noted within group for the impairment-oriented group only. * p<0.05.

Table 7
Mean Values and Standard Deviations of Percentage of Gait Cycle in Stance and Swing Phase broken down by group and limb at Baseline, Post Treatment and Change score. No significant differences were noted between groups for the change Scores. Significant differences were noted between groups for baseline measures (p<0.05). Significant differences were noted within the Impairment Group from baseline to post treatment on both phases for both limbs (p<0.05).

	Normal	Impairment-Oriented Group		Task-Oriented Group	
		Intact Limb	Prosthetic Limb	Intact Limb	Prosthetic Limb
Baseline Stance Phase*	60	88.61 (±5.0)	83.38 (±8.9)	76.91 (±9.7)	72.50 (±8.7)
Swing Phase*	40	11.84 (±6.2)	16.61 (±8.9)	24.92 (±14.8)	27.48 (±8.7)
Post Tx Stance Phase	60	83.45 (±5.7)*	79.16 (±8.2)*	76.71 (±5.4)	72.56 (±8.0)
Swing Phase	40	16.54 (±5.7)*	20.84 (±8.2)*	23.30 (±5.4)	27.51 (±7.9)
Change Score Stance		5.16 (±3.5)	5.12 (±4.5)	6.98 (±6.4)	3.79 (±3.7)
Swing		4.70 (±3.8)	5.12 (±4.5)	8.87 (±11.1)	3.74 (±3.7)

* p<0.05

Table 8
Correlations between functional scores at Day 10

	Berg Balance Score	AMPPRO	Velocity
Berg Balance Score	1	.902**	.604*
AMPPRO		1	.694**
Velocity			1

* Correlation is significant at 0.01 level (2-tailed)
** Correlation is significant at 0.001 level (2-tailed)

Chapter V

DISCUSSION

Two gait training approaches for early prosthetic training of individuals with unilateral transtibial amputation were studied. Results indicated all subjects, regardless of group assignment, significantly improved in functional outcomes including: balance (BBS), velocity, and AMPPRO during the training protocol. This supports the hypothesis that no difference between the two training strategies exists. The impairment-oriented group, however, exhibited significant improvement in several spatial/temporal measures including: cadence, double limb support time, and percentage of gait cycle in stance and swing phase as compared to the task-oriented group. The two groups were significantly different in the baseline measures of cadence, double limb support time and percentage of gait cycle in stance/swing phase, and therefore change scores were examined for differences between groups post treatment. Interestingly, no significant differences were noted between the groups for change scores on these measures. Neither group demonstrated significant improvement in symmetry of step length or single

limb stance time.   Overall, both training approaches led to improved function and ambulation noted within the seven days.

The sample recruited for this study is representative of this patient population both demographically and functionally as noted in previous literature. Demographically forty-two percent of the amputee population is older than 65 years of age and thirty-eight percent fall between 45 and 64 years. The mean age of the current study was 64.3 years, which is consistent with the population and what is reported in literature (Adams, 1999; Czerniecki, 1996; Dillingham et al., 2003; Munin, 2001; Ziegler-Graham et al., 2008). Males represent the highest percentage of dysvascular amputee patient population, consistent with this study in which 81% were male (Staff, 2008). Literature identifies that two-thirds of individuals with dysvascular amputation have a co-diagnosis. In the present study 81% had at least one other diagnosis with a mean of 3 ±1 (Ziegler-Graham et al., 2008).

Functionally, the gait patterns exhibited in the study participants are also consistent with published literature. Specifically, the slower self-selected walking speed (SSWS) and spatial/temporal patterns of longer double limb support time, longer step length on the prosthetic side, shorter stance times on the prosthetic side and unequal step lengths noted in this study are consistent with literature and therefore support prior findings (Czerniecki, 1996; Hermodsson et al., 1994a; E. Isakov et al., 1997; E. Isakov et al., 2000; E. B. Isakov, H.; Krajnik, J.; Gregoric, M.; Marincek, C., 1996; S. F. Jones et al., 2005; D.J. Sanderson & Martin, 1997). Overall, this sample represents

the population identified in the literature in all aspects except for the length of time since amputation. Time since amputation for subjects in this study was 3.4 months (±2.5), whereas the average time since amputation in the literature is greater than 8 years.

Functional Outcomes

Presently there is a dearth of existing literature on early prosthetic training or functional outcomes after transtibial amputation. Discharge trends after a dysvascular lower-limb amputation have changed over the years. Today the most common setting for post-acute discharge is home, seconded by admission to a nursing home (Dillingham et al., 2003). Less than 10% are discharged to a rehabilitation center (Dillingham et al., 2003).

Discharge is determined by many factors, two of them being insurance and functional success. Functional success, however, can be defined in many ways, including: (1) the ability to walk with a prosthesis at least 45 m with the use of an assistive device (Munin, 2001) and (2) the ability to complete independence in activities of daily living (Weiss, Gorton, Read, & Neal, 1990). The ability to perform functional skills also coincides with one's quality of life. Indeed, independent mobility is reported to have the greatest impact on quality of life in persons with lower limb amputation (Pell et al., 1993). Consequently, independent mobility is the primary goal of rehabilitation for individuals with lower-limb amputations.

Successful functional outcomes for study participants were defined as significant improvements from day 3 to day 10 on functional measures including the AMPPRO, BBS and velocity. Results indicated significant improvement in both groups (IO and TO) for all three measures. Change scores were utilized to determine whether training strategy had a significant impact on improvement between baseline (Day 3) and post intervention (Day 10). No differences were noted between the groups for the change scores on the AMPPRO, BBS or velocity: training approach did not make a significant difference in functional outcomes.

Despite functional improvements in all subjects at day 10 as measured by the AMPPRO, BBS and velocity, subjects continued to function well below published scores in the literature. Participants' mean AMPPRO scores (25.3 and 29.6 for IO and TO respectively) fall into the Medicare Level 1 category of household ambulation (mean score of 25) (R. S. Gailey et al., 2002). Berg Balance scores were 27.1 and 32.9 for the IO and TO groups respectively, indicating that all subjects post treatment had a high potential to fall. The score of 46 on the BBS is utilized as the cut-off point for identifying individuals at a high risk for falling (Bogle Thorbahn & Newton, 1996; Lajoie & Gallagher, 2004). Velocity improved 67% and 42% respectively for the IO and TO groups within 7 days (between day 3 and day 10). Baker and Hewison noted a 55% improvement within the first 15 days of gait training with this same population (Baker & Hewison, 1990). Although subjects improved their walking speeds in this study, the mean values are still below the published

walking speeds for the transtibial amputee (0.5-0.9 m/sec compared to our 0.3-0.5 m/sec). Lower speed and balance values may be due to the limited training and prosthetic use of only ten days in the current study as compared to samples in previous studies in which individuals had been walking with a prosthesis for greater than one year on average. Discharging subjects at a low functional level (Medicare level 1) who have a high probability of falls can lead to decreased use of the prosthesis and further disablement. Individuals need more time to utilize their prosthesis with sufficient training to achieve higher functional outcomes and decrease the future risk of falls.

Gait Pattern

Differences between the two groups were noted for the following spatial/temporal gait parameters: double limb support time, stance/swing percentage of the gait cycle and cadence. It was noted that the impairment-oriented group started at a lower functioning level on these measures as compared to the task-oriented group. Change scores did not reveal any differences between the two groups post treatment; however, within groups only the impairment-oriented group demonstrated significantly improved in all three measures. Both groups continued to demonstrate poor spatial/temporal values post treatment as compared to norms.

Double limb support time can also serve as an index for dynamic balance. In a normal gait cycle the percentage of time in double limb support equals 20% of the gait cycle (Whittle, 2002; D.A. Winter, 1991). It is noted

that individuals with lower-extremity loss spend a greater percentage of time in double limb support (Hermodsson et al., 1994a; E. Isakov et al., 1997; D. A. Winter & Sienko, 1988). The impairment-oriented group significantly decreased their double limb support time from day 3 to day 10 as compared to the task-oriented group, yet differences between the groups in the balance measure (BBS) were not noted. This may be because the Berg Balance Score (BBS) is not designed to detect small changes in dynamic balance. The BBS provides an overall measure of balance as related to fall risk (K. Berg & Norman, 1996). Double limb support time (DLS) is a more specific measurement of dynamic balance during gait and therefore may have been a more sensitive measure of balance improvement. A more advanced measuring tool such as a force plate can also pick up dynamic balance. For purposes of this study, however, DLS is the only dynamic balance available. Since the impairment-oriented group practiced balance in both static and dynamic activities, whereas the task-oriented group practiced only dynamic balance while walking, one would expect both groups to show a significant increase in a dynamic balance measure secondary to the specificity of the measure. Only the impairment-oriented group had significant changes within the group. The increased amount of static balance training performed by the IO group may have transferred over to increased weight bearing through the prosthesis, leading to improved dynamic balance. Jones et al. identified a correlation between weight bearing and dynamic balance (M. E. Jones, Steel et al., 1997).

The stance/swing ratio in healthy adults is 60/40. Both groups exhibited longer stance times overall and asymmetrical stance times between limbs with the longest stance on the sound limb (Table 7). Significant changes in the stance/swing ratio from day 3 to day 10 were noted in the impairment-oriented group moving toward the 60/40 norms. No change was observed in the task-oriented group. In fact, the task-oriented group moved further away from 60/40 ratio on the intact side between days 3 and 10. The IO approach included more specialized practice in the stance and swing phase. Breaking the gait cycle down and practicing a single step or stride allows individuals to increase their attention on each phase. Corrective walking draws attention to equal step lengths versus gait phases, and while walking the individual must increase focus on maintaining balance and moving forward, devoting all attention toward overall function versus a gait cycle. The specificity of gait cycle training is transferred over as shown in the improvement of the stance/swing ratio demonstrated by the IO group.

Differences in cadence were also noted between the two groups. Since cadence is a measure of steps per minute, there are several ways one can increase cadence: by increasing stride length while maintaining the same speed, by increasing speed while maintaining stride length, and by increasing both stride and speed. Both groups increased their cadence from day 3 to day 10; however, improvement was only significant in the IO group. Further analysis revealed that the IO group increased cadence by increasing their step length and walking speed. The task-oriented (TO) group increased

speed, but their step length did not significantly increase. The pattern noted in the IO group may be linked to increased weight bearing through the prosthesis. Increased weight bearing can lead to increased stance time on the prosthesis, allowing the opposite leg a longer opportunity to move forward. The TO group exhibited a longer mean stance time as compared to the impairment-oriented group. This did not change during the study (See Table 7). The stance time change noted in the IO group could be linked to the increased stride length. Stride length and velocity both influenced cadence in the IO group, leading to the changes noted within the group.

Symmetry between the limbs during gait promotes a smooth and efficient gait pattern. As noted earlier, individuals with lower-limb amputation demonstrate decreased symmetry between the prosthetic and sound limbs. Both groups in this study also demonstrated decreased symmetry in step length and single limb support time, with no significant improvements noted in either group. Large variances as evidenced in high standard deviations were noted for both symmetry of step length and symmetry of single limb support limiting. Variability in performance is expected in early learning (Shumway-Cook, 2001). When mastery of a task is achieved, variances between trials decrease. Subjects in this study continued to demonstrate large variability between trials, signifying that ten days of prosthetic training is not enough time for one to master a new motor task of prosthetic gait.

Symmetry is also influenced by velocity (Donker & Beck, 2002; Nolan et al., 2003; Zucker-Levin, 2003). Greater inter-limb symmetry is noted at

higher externally paced velocities (Nolan et al., 2003; Zucker-Levin, 2003). Participants in this study all ended with low walking velocities (self-selected), limiting the ability to achieve inter-limb symmetry. The lower velocities may be attributed to the use of an assistive device or overall decreased functional ability at the end of ten days of training with a prosthesis.

Asymmetry in gait following an amputation is also hypothesized to be caused by: loss of muscle groups and sensation; pain, fear or habit; decreased weight bearing through the prosthesis; and the rigid ankle/foot complex of the prosthesis (Donker & Beck, 2002; Hermodsson et al., 1994a; E. Isakov et al., 1996, 1997; E. Isakov et al., 2000; E. B. Isakov, H.; Krajnik, J.; Gregoric, M.; Marincek, C., 1996; M. E. Jones et al., 2001; M. E. Jones, Bashford et al., 1997; D. A. Winter & Sienko, 1988; M. S. Zahedi et al., 1987). In the present study all of these factors except pain may have limited the subjects' ability to improve symmetry since all subjects had a pain rating between 0 – 1 out of 10 when walking with the prosthesis. In relation to fear, all subjects self-assessed their abilities (LCI score) at a higher level at day ten compared to baseline, corresponding with increased self-confidence. An actual fear of falling measure was not taken; however, it is reasonable to conclude that individuals with increased self-confidence may be less fearful. In terms of habit, all subjects trained with their prostheses for the first time. It should be noted that participants' gait patterns prior to the amputation were not assessed. If an individual had pain or weakness in the affected lower extremity, an asymmetrical gait pattern may have been developed prior to

prosthetic training. Low velocities and the factors noted above may have limited the participants' ability to improve symmetry, and the large variances and low power due to the small sample size further limit the ability to find statistical changes in symmetry.

Testing Correlations

Three measures utilized in this study were: a functional outcome scale, the Amputee Mobility Predictor (AMP©); a balance test, the Berg Balance Scale (BBS); and gait velocity. A post hoc analysis examined whether the three measures would be correlated secondary to the functional nature of the tests. Results indicated that the three measures were correlated. The AMP© and BBS demonstrated a high correlation, whereas the AMP© and velocity or the BBS and velocity demonstrated a moderate correlation. All were significant at the 0.01 level for a two-tailed analysis. The correlation between the AMP© the BBS is not surprising, since these tests have nine items in common. Velocity is often considered an overall measure of function. This is demonstrated here by the moderate correlation between the functional measure and balance scale, even though neither directly measures velocity. Therapists must choose their tests carefully in order to best represent what they are seeking. If they want to determine risk of falls, the BBS would be the most appropriate choice. If they are looking more for functional mobility as needed for re-integration into the community, velocity may be the best overall measure. With the moderate to strong correlation noted among the three

measures, therapists would not need to measure all three. They could individualize their examinations by selecting the most appropriate measure for each patient.

Limitations

Limitations of the present study include threats to external and internal validity. The small sample size is an acknowledged limitation (n=22). Based upon the pilot study and power analysis, it was determined that each group should have 27 subjects for 80% power at the 0.05 level for all measures. After three years of data collection, health care trends limited the available subjects in inpatient rehabilitation for prosthetic training. The study was concluded due to the lack of new potential subjects. A current power analysis demonstrated 94% power for cadence, 94% power for velocity, 76% power for symmetry of step length, 61% power for double limb support time, 43% power for stance/swing ratio, 20% power for BBS and AMP and 14% power for symmetry of single limb support time. Results are, therefore, reported with caution. The sample is representative of the dysvascular amputee patient population. Changes in the length of stay for individuals with transtibial amputation limit the external validity of the treatment protocols. The study took place in an inpatient setting, and therefore it is difficult to project whether the results of the two protocols will have the same impact in an outpatient or home care setting.

Methodological limitations create threats in internal validity.

Multicenter studies present a potential methodology problem, such as

compensatory equalization of treatments. Compensatory equalization occurs

when one gives extra attention to a certain experimental protocol. Three

centers were utilized in this study with nine therapists. To help control for

consistent protocol delivery, therapists were trained by the primary

investigator in both techniques. Therapists were not assigned to administer

only one protocol. If a therapist had a bias for one protocol over another,

compensatory equalization may have occurred. To help control for this a

daily log sheet was maintained, and the primary investigator reviewed the

daily log sheets to ensure that the protocol was carried out properly. Another

potential threat to internal validity was the varying amount of overall physical

therapy time in different settings. Eleven subjects participated while in a

subacute setting, and eleven were in an inpatient rehabilitation setting. The

subacute setting only delivered 30 - 60 minutes (mean of 45 minutes) of

therapy and the rehabilitation setting 60 - 90 minutes (mean of 70 minutes) of

therapy. The ratio of walking time to pre-gait/balance training was maintained

throughout. Statistical analysis did not reveal any significant differences

between the two settings for Day 10 and change score values.

There were a number of confounding factors that could have

influenced the results of the study. These include the use of an assistive

device, healthiness of an individual, cause of amputation, influence of

depression and level of function prior to the amputation. Factors for which

there were controls were the use of an assistive device, healthiness of an

individual and cause of amputation. The use of assistive devices was

controlled for by having all subjects utilize a rolling walker during all testing.

The randomization of subjects controlled for the overall healthiness, and no

significant difference was noted between the groups for the number of co-

diagnoses. Limiting the sample only to dysvascular transtibial amputations

controlled for the differences noted in function related to the level of

amputation and to the higher outcomes noted in individuals with traumatic

amputation (Hermodsson et al., 1994a; Leung et al., 1996; Weiss et al.,

1990). Two confounding factors for which there were no controls were the

influence of depression and level of function prior to the amputation.

Depressed individuals are noted to participate less during therapy and have

decreased motivation to improve (Cutson & Bongiorni, 1996; W. C. Miller,

Speechley et al., 2001). This study did not assess depression; however,

individuals did complete the locomotor capability index (LCI), which is a self-

assessment tool. All subjects rated an improvement in their functional

abilities in their self-assessment. The second factor, prior level of

functioning, is unknown. Literature documents a correlation between prior

level of functioning and the length of time between amputation and prosthetic

training with functional prosthetic outcomes (Munin, 2001). Although this

study did not gather prior level of functioning, the time between amputation

and prosthetic training was gathered. No difference was found between the

two groups on the length of time from amputation to prosthetic training. The

final limitation is the lack of follow-up. Measurements were taken directly

after the final treatment, with no follow-up. Without such follow-up, retention

of learning cannot be assessed.

Chapter VI

CONCLUSION

The purpose of the study was to compare two gait training approaches

for early prosthetic training in individuals with transtibial amputation. All

subjects improved in the following outcome measures: velocity, the Amputee

Mobility Predictor and the Berg Balance Scale during the training period. No

between-group differences were found for any of these measures. Although

improvement was noted across the ten days of training, all subjects continued

to function at a low level. The subjects would be classified as household

ambulatory according to Medicare based upon the Amputee Mobility Predictor

and a high fall risk based upon their Berg Balance Scale scores. Differences

were noted between the groups for double limb support time, stance/swing

ratio and cadence. The impairment-oriented treatment group demonstrated

significant improvement on all three measures, whereas the task-oriented

treatment group did not. By completion of the treatment protocol these gait

parameters moved toward more normal values for the impairment-oriented

group. Measuring gait parameters such as the stance/swing ratio requires a

task analysis that divides walking into parts or gait cycles. Measurement at

this level correlates with the type of training performed during the impairment-

oriented protocol. This raises the question whether a therapist should be concerned with overall function or with a deeper assessment of the gait pattern. Overall function is highly linked to quality of life, and therefore utilization of a functional outcome measures and walking speed should be examined. Improving gait quality and symmetry, however, may limit the secondary complications due to a poor gait pattern often noted in this population. Symmetry was not achieved with either gait training protocol. Several factors such as significantly decreased walking speeds and the utilization of a solid ankle foot component limit the ability to achieve symmetry (Donker & Beck, 2002; E. Isakov et al., 1996). The impairment-oriented group demonstrated increases in overall function, changes in double limb support time and more normal stance/swing ratios. Gait patterns changed in the impairment-oriented group, clearly reflecting the type of practice (breaking down the gait cycle). By measuring specific parts of a gait cycle such as double limb support time and stance/swing ratios, changes can be linked to the specificity of training.

This study brought to light the possible impact of healthcare changes on rehabilitation. The number of individuals receiving inpatient prosthetic rehabilitation continues to decrease. Although significant improvements in function were noted with the training protocol, all subjects in the study continued to have a high fall risk and decreased function at the end of ten days. Many patients who receive their prostheses do not even have this amount of prosthetic training. Length of prosthetic training has been linked to

better success rates of prosthetic utilization (Munin, 2001). More research needs to be completed in order to examine the timing and length of prosthetic rehabilitation.

The projected doubling of the amputee population by 2030 will put an increased strain on an already taxed healthcare economy. The present trend in addressing the needs of this population is to limit or deny appropriate prosthetic training. Such limitations on necessary rehabilitation create an amputee population that is more likely to be sedentary and can potentially lead to harmful and expensive secondary complications such as cardiopulmonary dysfunction, increased obesity leading to diabetes mellitus and increased likelihood of falling. A sedentary lifestyle also leads to decreased mobility, thereby compounding the risk of secondary complications as well as the need for assistance with activities of daily living. Limiting prosthetic rehabilitation may actually create higher healthcare costs secondary to decreased activity and mobility. This study supports the need for physical therapy during initial prosthetic rehabilitation and sheds light on the potential impact of decreased prosthetic training.

Future Areas of Study

While the present study supports physical therapy for prosthetic training, the limitations of this study make it difficult to determine definitively whether one protocol is better than another. Further generalization of findings is also limited to an inpatient setting and to individuals with a unilateral transtibial amputation. This study focused on early function and spatial/

temporal gait parameters in the amputee population. Further analysis and research in kinematic and kinetic parameters during early prosthetic gait may clarify which motor learning strategies will be most successful as treatment interventions for this population. Future areas of research should also evaluate the impact of length and delivery of physical therapy in the outpatient and home care settings as well as expanding to other levels of lower extremity amputation. Long-term retention should be examined through the use of follow-up studies. Time-limited protocols are needed to determine the minimum dosage for successful prosthetic outcomes and long-term prosthetic use.

In view of a projected doubling of the amputee population and the skyrocketing cost of healthcare, it is essential that successful, researched and cost effective treatment techniques be implemented into professional practice. Physical therapy is one of the most cost effective and high impact interventions available in healthcare today. Understanding how and when to utilize this intervention during prosthetic training will be critical in decreasing overall healthcare costs and optimizing patient outcomes. Further extensive research needs to be done in all domains of physical therapy to identify the successes the profession can create in this changing marketplace.

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LIST OF APPENDIXES

A. IRB approval

B. Informed Consent(s)

C. Amputee Mobility Predictor© (AMP)

D. Berg Balance Scale

E. Locomotor Capabilities Index (LCI)

F. Initial Data Collection Form

G. Daily Log Sheet

Appendix A

SETON HALL 🏛️ **UNIVERSITY.**

April 5, 2006

Nannette Hyland
39 Overlook Drive
Valhalla, NY 10595

Dear Ms Hyland,

The Seton Hall University Institutional Review Board has reviewed your Continuing Review application for your research proposal entitled "The Comparison of Gail Training Strategies for Individuals with Transtibial Amputations".

You are hereby granted another 12-month approval from the date of this notice. In addition, the enclosed Consent Form from Burke Rehabilitation Hospital is stamped.

Thank you for your cooperation.

Sincerely,

Mary F. Ruzicka, Ph.D.

Mary F. Ruzicka, Ph.D.
Professor
Director, Institutional Review Board

cc   Dr Genevieve Pinto-Zipp

ENRICHING THE MIND, THE HEART AND THE SPIRIT

Appendix B

APPROVED

APR 25 2005

IRB
SETON HALL UNIVERSITY

Burke Institutional Review Board
Approval Date
3/23/05
Termination Date
3/31/06

**Burke Rehabilitation Hospital
CONSENT FORM**

Study Title: Comparison of gait training strategies for individuals with transtibial amputations

Research Project #_____

Principal Investigators: Nannette Hyland PT, MS and Laura Toohig PT, MS

You are being asked to participate in a study that will compare two different physical therapy approaches to teaching one how to walk with a prosthesis (artificial leg).

II. **Purpose of Study:** Due to the decreasing length of hospital stays, we want to examine two different treatment approaches in teaching patients with a below the knee amputation to walk. The study will take place over ten therapy days and both of the therapy strategies to be used are acceptable physical therapy treatments. This study will help physical therapists better understand the use of physical therapy in training someone how to walk with a prosthesis.

III. **Qualifications to Participate:** Criteria to enter the study include: amputation below only one knee, able to follow commands, able to wear a prosthesis, and between the ages of 30 – 85. You have met the above criteria and are being asked to volunteer for this research. If at any time you want to discontinue participation from this study you may do so without any penalty or decrease in the physical therapy services provided to you.

IV. **Study Procedures :** If you choose to participate you will be assigned by chance (like the flip of a coin) to receive one of the following training strategies during the study: whole walking or part/whole walking. In the whole walking group, therapy time with the physical therapist will mainly consist of time spent on walking. In the part/whole walking group, your therapy time with your physical therapist will consist of walking and a number of standing activities to work on your balance. Both groups will receive the same amount of therapy with a physical therapist and you may also attend a mat and/or walking class. The study will take place over 10 therapy days. This study will not change the amount of therapy from other therapists that you would normally receive as an inpatient at Burke Rehabilitation Hospital.

You will be asked to walk on a pressure sensitive mat with a rolling walker and complete some function activities which look at balance near the beginning of the study and at the end of the study to measure how you walk. You will be closely supervised to prevent falling during all testing sessions by a physical therapist. You will also be asked fill out a questionnaire on how you feel you are walking at the beginning, end and 2 months after the training part of the study. The testing sessions will not interfere with your regularly scheduled therapy sessions.

V. **Possible Risks:** While learning to walk with a prosthesis you may experience pain or skin redness. This is normal and the training strategies are not expected to cause any increased pain or skin redness. During the therapy with the physical therapist your skin will be checked throughout each session and the therapy will not continue if your skin can not tolerate it.

VI. **Possible Benefits (or none):** Your participation in the study will have no direct benefit to you other than the potential benefit of the treatment to learn how to walk with a prosthesis. The major potential benefit is to find out if one treatment strategy is more effective than another.

VII. **Confidentiality:** All medical information and any factors that could possible identify you will be kept confidential. A code will be assigned to you for all of your data and the code key as well as any document with identifying factors will be kept in a locked cabinet in which only the primary investigator, Nannette Hyland, has a key to. If this study is published your identity will not be included in the publication.

VIII. **Compensation:** You will receive no compensation for participating in the study.

IX. Your decision whether or not to participate will not prejudice your future relations with The Burke Rehabilitation

Version 2, 4/2/04

Hospital. If you decide to participate you are free to discontinue participation at any time.

X. In accordance with Federal regulation, we are obligated to inform you about our policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, emergency medical care and treatment will be provided on our premises to the extent possible. We will assist you in obtaining additional medical care, as needed, but you will be responsible for the costs of such further medical treatment, either directly or through your medical insurance and/or other forms of medical coverage.

Signed Consent:

I understand that my participation is voluntary, and that refusal to participate will involve no penalty or loss of benefits to which I may otherwise be entitled, and that I may discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled.

I understand that medical records that reveal my identity will remain confidential, except they will be provided if required by law. The protected health information to be used or disclosed is limited to the following information: age, height, diagnosis, functional status and contact information for follow-up upon discharge. Only the principal investigators listed on this consent form will have access to this information. I agree that the medical information listed can be shared between the research team listed for the duration of the study which is expected to be until April 2006.

I understand that even if I sign this agreement, I can take back at any time my permission to have my medical information shared by the research team, although some of this information may have been shared already. I understand that in order to take back my permission to share information, I have to give a written notice to a member of the research team.

I recognize that the protected health information used or discloses pursuant to this authorization may be subject to re-disclosure by the recipient and no longer be protected.

I understand that the study is ongoing, and will be informed of any new developments that might have an impact on my participation in the project.

Nannette Hyland has answered to the best of her ability all questions that I have asked and will answer to the best of her ability any questions I may have in the future. Nannette Hyland can be reached at 914-674-7825.

I understand that I will receive a signed copy of this consent form. I understand that I waive no legal rights by signing this consent form.

I have read the material above and have had my questions answered to my satisfaction. I agree to participate in this study and will be given a copy of this informed consent for my reference.

_____   _____   _____
Subject's Signature   Name of Subject   Date

_____   _____   _____
Signature of Witness   Name of Witness (Print)   Date

_____   _____   _____
Signature of Investigator   Name of Investigator (Print)   Date

The Burke Rehabilitation Hospital Institutional Review Board has approved the solicitation of subjects for this study, and Donna Rundel M.S. (914)597-2192 or Ken Kupetsky (914)597-2202 will be happy to answer any questions that you may have about the research subject's rights.

Version 2, 4/2/04

APPROVED

APR 25 2005

IRB
SETON HALL UNIVERSITY
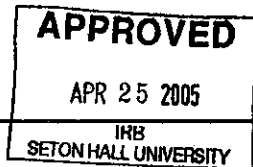
Helen Hayes Hospital
CONSENT FORM

Study Title: Comparison of gait training strategies for individuals with transtibial amputations

Principal Investigators: Arun Bhattacharyya, M.D.
Co-Investigators: Nannette Hyland, M.S., P.T., Barb Hanley, M.S., P.T.

You are being asked to participate in a study that will compare two different physical therapy approaches to teaching one how to walk with a prosthesis (artificial leg).

II. **Purpose of Study:** Due to the decreasing length of hospital stays, we want to examine two different treatment approaches in teaching patients with a below the knee amputation to walk. The study will take place over ten therapy days and both of the therapy strategies to be used are acceptable physical therapy treatments. This study will help physical therapists better understand the use of physical therapy in training someone how to walk with a prosthesis.

III. **Qualifications to Participate:** Criteria to enter the study include: amputation below only one knee, able to follow commands, able to wear a prosthesis, and between the ages of 30-85. You have met the above criteria and are being asked to volunteer for this research. If at any time you want to discontinue participation from this study you may do so without any penalty or decrease in the physical therapy services provided to you.

IV. **Study Procedures :** If you choose to participate you will be assigned by chance (like the flip of a coin) to receive one of the following training strategies during the study: whole walking or part walking. In the whole walking group, therapy time with the physical therapist will mainly consist of time spent on walking. In the part walking group, your therapy time with your physical therapist will consist of walking and a number of standing activities to work on your balance. Both groups will receive the same amount of therapy with a physical therapist and you may also attend a mat and/or walking class. The study will take place over 10 therapy days. Each session will last approximately ½ hour two times per day. This study will not change the amount of therapy from other therapists that you would normally receive as an inpatient at Helen Hayes Hospital.

You will be asked to walk on a pressure sensitive mat at the beginning of the study and at the end of the study to measure how you walk. You will be closely supervised to prevent falling during all testing sessions by a physical therapist. The testing sessions will take place towards the end of the afternoon after all of your regularly scheduled therapy sessions are completed. Other measurements, such as leg length, knee range of motion,

and standing ability will also be taken by a physical therapist in the beginning and end of the study.

V. Possible Risks: While learning to walk with a prosthesis you may experience pain or skin redness. This is normal and the training strategies are not expected to cause any increased pain or skin redness. During the therapy with the physical therapist your skin will be checked throughout each session and the therapy will not continue if your skin can not tolerate it. If needed the therapist may try using a gel dressing called "Vigilon" to reduce the amount of friction put on your skin while wearing a prosthesis. This gel dressing is commonly used with individuals learning to walk with a prosthesis and is not part of the treatment strategy.

VI. Possible Benefits (or none): Your participation in the study will have no direct benefit to you other that the potential benefit of the treatment to learn how to walk with a prosthesis. The major potential benefit is to find out if one treatment strategy is more effective than another.
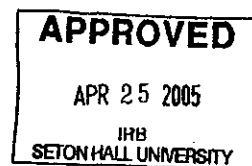
VII. Confidentiality: All medical information and any factors that could possible identify you will be kept confidential. A code will be assigned to you for all of your data and the code key as well as any document with identifying factors will be kept in a locked cabinet in which only the primary investigator as a key to. If this study is published your identity will not be included in the publication.

Authorization Statement:
"I understand that under current laws I have control over who has access to my medical records. I agree that any medical information about me that comes up as a result of this research study can be shared and discussed with all the members of the research team for the duration of this study. The research team may include, in addition to Helen Hayes Hospital staff, researchers from other hospitals, universities, drug companies, or government agencies. I understand that all members of the research team will be following government regulations or Helen Hayes Hospital Institutional Review Board rules to safeguard my privacy."

I understand that although I have control over my medical information, medical research studies often require that research subjects not know whether, for example, they are taking real or "dummy" treatments. I understand and agree that medical information about me that becomes available as a result of this study may not be made available to me. I understand, however, that I will be made aware of all available information that may make this study dangerous to me, or that may make me want to reconsider my participating in this study.

I understand that Helen Hayes Hospital needs me to sign this consent form in order for me to participate in the research study. If I choose not to sign this agreement, I will not

get the treatments that are part of this study, but I will in no way lose any of the benefits or privileges of any Helen Hayes Hospital patient.

I understand that even if I sign this agreement, I can take back at any time my permission to have my medical information shared by the research team, although some of this information may have been shared already. I understand that in order to take back my permission to share information, I have to give a written notice to a member of the research team."

VIII. **Illness or Injury Statement**: In the event of illness or injury while participating in this research project, Dr. Bhattacharrya will arrange for your appropriate medical care at Helen Hayes Hospital, or if medically necessary, you will be referred or transferred to another hospital. You will be responsible for the cost of care at a non-Department of Health hospital, either personally or through your own medical insurance. If you experience illness or injury as a result of this research project, the Commissioner of Health may waive or reduce the cost of care provided at Helen Hayes Hospital, but only with the prior approval of the State Comptroller and the Attorney General.

IX. **Compensation**: You will receive no compensation for participating in the study.

Signed Consent:
I understand that my participation is voluntary, and that refusal to participate will involve no penalty or loss of benefits to which I may otherwise be entitled, and that I may discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled.

I understand that medical records that reveal my identity will remain confidential, except they will be provided if required by law.

Arun Bhattacharyya or Nannette Hyland has answered to the best of their ability all questions that I have asked and will answer to the best of her ability any questions I may have in the future.

I understand that the study is ongoing, and will be informed of any new developments that might have an impact on my participation in the project.

I understand that if I experience illness or injury while participating in this research project, Dr. Bhattacharrya will arrange for appropriate medical care at Helen Hayes Hospital, or if medically necessary, I will be referred or transferred to another hospital. I understand that I will be responsible for the cost of care at a non-Department of Health hospital, either personally or through my medical insurance. I understand that if I experience illness or injury as a result of this research project, the Commissioner of Health may waive or reduce the cost of care provided at Helen Hayes Hospital, but only with the prior approval of the State Comptroller and the Attorney General.

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IX. **Compensation**: You will receive no compensation for participating in the study.
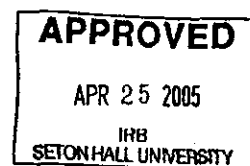
Signed Consent:

I understand that my participation is voluntary, and that refusal to participate will involve no penalty or loss of benefits to which I may otherwise be entitled, and that I may discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled.

I understand that medical records that reveal my identity will remain confidential, except they will be provided if required by law.

Arun Bhattacharyya or Nannette Hyland has answered to the best of their ability all questions that I have asked and will answer to the best of her ability any questions I may have in the future.

I understand that the study is ongoing, and will be informed of any new developments that might have an impact on my participation in the project.

I understand that if I experience illness or injury while participating in this research project, Dr. Bhattacharrya will arrange for appropriate medical care at Helen Hayes Hospital, or if medically necessary, I will be referred or transferred to another hospital. I understand that I will be responsible for the cost of care at a non-Department of Health hospital, either personally or through my medical insurance. I understand that if I experience illness or injury as a result of this research project, the Commissioner of Health may waive or reduce the cost of care provided at Helen Hayes Hospital, but only with the prior approval of the State Comptroller and the Attorney General.

I understand that I may contact Dr. Arun Bhattacharyya at 786-4101 if I have pertinent questions about the research or in the event of a research-related injury. I understand that I will receive a signed copy of this consent form. I understand that I waive no legal rights by signing this consent form.

I understand that I will receive a signed copy of this consent form.

I have received a copy of the Helen Hayes Hospital Notice of Privacy Practices.

I understand that I waive no legal rights by signing this consent form.

Signed: _____   _____
                 Research Subject   Date

_____   _____
Signature of Witness   Name of Witness (Print)

_____   _____
Signature of Investigator   Name of Investigator (Print)

The Helen Hayes Hospital Institutional Review Board has approved the solicitation of subjects for this study, and the Institutional Review Board (845-786-4494) should be contacted to answer any questions about the research subject's rights.

Appendix C

AMPUTEE MOBILITY PREDICTOR SCORING FORM

Instructions: Testee is seated in a hard chair with arms. The following maneuvers are tested with or without the use of the prosthesis. Advise the person of each task or group of tasks prior to performance. Please avoid unnecessary chatter throughout the test. Safety first. No task should be performed if either the tester or testee is uncertain of a safe outcome.

Right Limb is: TT__ TF__ Intact____   Left Limb is: TT__ TF__ Intact__

1.	Sitting balance: sit forward in a chair with arms folded across chest for 60s.	Cannot sit upright independently for 60s	=0
		Can sit upright independently for 60s	=1
2.	Sitting reach: reach forward and grasp the ruler. (Tester holds ruler 12in beyond extended arms midline to the sternum.)	Does not attempt	=0
		Cannot grasp or requires arm support	=1
		Reaches forward and successfully grasps item	=2
3.	Chair to chair transfer: 2 chairs at 90. Pt. may choose direction and use their upper extremities.	Cannot do or requires physical assistance	=0
		Performs independently, but appears unsteady	=1
		Perfoms independently, appears to be steady and safe	=2
4.	Arises from a chair: ask pt to fold arms across chest and stand. If unable, use arms or assistive device.	Unable without help (physical assistance)	=0
		Able, uses arms/assist device to help	=1
		Able, without using arms	=2
5.	Attempts to arise from a chair (stopwatch ready): if attempt in no.4 was witout arms then ignore and allow another attempt without penalty.	Unable without help (physical assistance)	=0
		Able requires>1 attempt	=1
		Able to rise 1 attempt	=2
6.	Immediate standing balance (first 5s): begin timing immediately.	Unsteady (staggers, moves foot, sways)	=0
		Steady using walking aid or other support	=1
		Steady without walker or other support	=2
7.	Standing balance (30s) (stopwatch ready): For items nos. 7&8, first attempt is without assistive device. If support is required, allow after first attempt.	Unsteady	=0
		Steady but uses walking aid or other support	=1
		Standing without support	=2
8.	Single-limb standing balance (stopwatch ready): time the duration of single limb standing on both the sound and prosthetic limb up to 30s. Grade the quality, not the time.	**Nonprosthetic side**	=0
		Unsteady	=1
		Steady but uses waking aid or other support for 30s	=2
	Sound side ___ seconds	**Prosthetic side**	
		Unsteady	=0
		Steady but uses walking aid or other support for 30s	=1
	Prosthetic side ___ seconds	Single-limb standing without support for 30s	=2
9.	Standing reach: reach forward and grasp the ruler. (Tester holds ruler 12in beyond extended arm(s) midline to the sternum.)	Does not attempt	=0
		Cannot grasp or requires arm support on assistive device	=1
		Reaches forward and successfully grasps item no support	=2
10.	Nudge test (subject at maximum position #7): with feet as close together as possible, examiner pushes firmly on subject's sternum with palm of hand 3 times (toes should rise).	Begins to fall	=0
		Staggers, grabs, catches self, or uses assistive device	=1
		Steady	=2
11.	Eyes closed (at maximum position #7): if support is required grade as unsteady.	Unsteady or grips assistive device	=0
		Steady wityout any use of assistive device	=1
12.	Picking up objects off the floor (pick up a pencil off the floor placed midline 12in in front of foot).	Unable to pick up object and return to standing	=0
		Performs with some help (table, chair, walking aid,etc)	=1
		Performs independently (without help from object or person).	=2
13.	Sitting down: ask pt to fold arms across chest and sit. If unable, use arm or assistive device.	Unsafe (misjudged distance, falls into chair)	=0
		Uses arms, assistive device, or not a smooth motion	=1
		Safe, smooth motion	=2

14. Initiation of gait (immediately after told to "go").	Any hesitancy or multiple attempts to start	=0		
	No hesitancy	=1		

15. Step length and height: walk a measured distance of 12ft twice (up and back). Four scores are required or 2 scores (a&b) for each leg. "Marked deviation" is defined as extreme substitute movements to permit clearing the floor.

a. Swing foot

Does not advance a minimum of 12 in	=0	
Advances a minimum of 12in	=1	

Prosthesis   Sound

b. Foot clearance

Foot does not completely clear floor without deviation	=0	
Foot completely clears floor without marked deviation	=1	

Prosthesis   Sound

16. Step continuity.

Stopping or discontinuity between steps (stop & go gait)	=0	
Steps appear continuous	=1	

17. Turning: 180° turn when returning to chair.

Unable to turn, requires intervention to prevent falling	=0	
Greater than 3 steps but completes task without asssistive aid	=1	
No more than 3 continuous steps with or without assistive aid	=2	

18. Variable cadence: walk a distance of 12ft fast as safely as possible 4 times. (Speeds may vary from slow to fast and fast to slow, varying cadence.)

Unable to vary cadence in a controlled manner	=0	
Asymmetrical increase in cadence in controlled manner	=1	
Symmetrical increase in speed in a controlled manner	=2	

19. Stepping over obstacle: Place a movable box of 4in in height in the walking path.

Cannot step over the box	=0	
Catches foot, interrupts stride	=1	
Steps over without interrupting stride	=2	

20. Stairs (must have at least 2 steps): try to go up and down these stairs without holding on to the railing. Don't hesitate to permit pt to hold on to rail. Safety first, if examiner feels that any risk is involved, omit and score as 0.

Ascending

Unsteady, cannot do	=0	
One step at a time, or must hold on to railing or device	=1	
Steps over step, does not hold onto the railing or device	=2	

Descending

Unsteady, cannot do	=0	
One step at a time, or must hold on to railing or device	=1	
Steps over step, does not hold onto the railing or device	=2	

21. Assistve device selection: add points for the use of an assistive device if used for 2 or more items. If testing without prosthesis, use of appropriate assisitive device is mandatory.

Bed bound	=0	
Wheelchair	=1	
Walker	=2	
Crutches (axillary or forearm)	=3	
Cane (straight or quad)	=4	
None	=5	

Total Score_____ /47

Trial___ no prosthesis___ with prosthesis   Observer_____   Date_____

Abbreviation: PF=partial foot; TT=transtibial; KD=knee disarticulation;
TF=transfemoral; HD=hip disarticulation; Pt=patient

Appendix D

BALANCE SCALE

Name: _____   Date: _____

Location: _____   Rater: _____

ITEM DESCRIPTION   SCORE (0-4)

1. Sitting to standing   _____
2. Standing unsupported   _____
3. Sitting unsupported   _____
4. Standing to sitting   _____
5. Transfers   _____
6. Standing with eye closed   _____
7. Standing with feet together   _____
8. Reaching forward with outstretched arm   _____
9. Retrieving object form floor   _____
10. Turning to look behind   _____
11. Turning to 360 degrees   _____
12. Placing alternate foot on stool   _____
13. Standing with one foot in front   _____
14. Standing on one foot   _____

                            TOTAL   _____

GENERAL INSTRUCTIONS

Please demonstrate each task and/or give instruction as written. When scoring, please record the lowest response category that applies for each item.

In most items, the subject is asked to maintain a given position for specific time. Progressively more points are deducted if the time or distance requirements are not met, if the subject's performance warrants supervision, or if the subject touches an external support or receives assistance from the examiner. Subjects should understand that they must maintain their balance while attempting the tasks. The choices of which leg to stand on or how far to reach are left to the subject. Poor judgment will adversely influence the performance and the scoring.

Equipment required for testing are a stopwatch or watch with a second hand, and a ruler or other indicator of 2,5 and 10 inches. Chairs used during testing should be of reasonable height. Either a step or a stool (of average step height) may be used for item #12.

II-E-8

Appendix E

Locomotor Capabilities Index (LCI)

5. **Whether or not you wear your prosthesis, at the present time, would you say that you are «able» to do the following activities «WITH YOUR PROSTHESIS ON»?**

«Check [√] for each statement»

	NO	YES, IF SOMEONE HELPS ME	YES, IF SOMEONE IS NEAR ME	YES ALONE
a) Get up from a chair	O	O	O	O
b) Pick up an object from the floor when you are standing up with your prosthesis	O	O	O	O
c) Get up from the floor (eg. : if you fell)	O	O	O	O
d) Walk in the house	O	O	O	O
e) Walk outside on even ground	O	O	O	O
f) Walk outside on uneven ground (eg. : grass, gravel, slope)	O	O	O	O
g) Walk outside in inclement weather (eg. : snow, rain, ice)	O	O	O	O
h) Go up the stairs <u>with</u> a handrail	O	O	O	O
i) Go down the stairs <u>with</u> a handrail)	O	O	O	O
j) Step up a sidewalk curb	O	O	O	O
k) Step down a sidewalk curb	O	O	O	O
l) Go up a few steps (stairs <u>without</u> a handrail	O	O	O	O
m) Go down a few steps (stairs) <u>without</u> a handrail	O	O	O	O
n) Walk while carrying an object	O	O	O	O

Appendix F

INITIAL SUBJECT INFORMATION SHEET

Subject Name: _____ Subject Code:_____ Today's Date _____

Age:_____ Gender:_____ Date of Amputation: _____

Diagnosis(es): _____

Residual Limb Length: _____ Knee ROM: _____
(from tibial tubercle)

Pain Scale (0-10): Without _____ With _____ Years of Experience PT_____
Prosthesis prosthesis Years with population _____

Sensation: {INT=Intact / IMP=Impaired}

	Residual Limb (circle choice)		Intact Limb (circle choice)	
Superficial Pain	INT	IMP	INT	IMP
Light Touch	INT	IMP	INT	IMP
Knee Proprioception	INT	IMP	INT	IMP
Ankle Proprioception			INT	IMP

Type of Prosthesis: _____

Comments: (MMT – general in UE and LE) and any other comments

_____

_____

_____

_____

_____

DATA COLLECTION SHEET

Patient Code: _____
Starting Date: _____

P.T.#:	Day 1	Day 2	Day 3 (Testing)	Day 4	Day 5	Day 6 (Testing)	Day 7	Day 8	Day 9	Day 10 (Testing)
Prosthetic Wearing Time (minutes)										
Time with P.T. (minutes)										
Walking (minutes/distance)										
Pre-Gait Activities (minutes)										
➤ Standing Balance										
➤ Lateral Weight Shift										
➤ A-P Weight Shift										
➤ Diagonal Weight Shift										
➤ Single-limb Stepping										
➤ Step-ups										
Use of Feedback for Weight Shift										
Daily Pain (0-10/10 scale)										
Assistive Device										

Comments:

Appendix G