

EFFECTS OF ABOVE-ANKLE ORTHOSES ON INDIVIDUALS WITH DIABETIC
PARTIAL FOOT AMPUTATION

by

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A THESIS

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Partial foot amputation is becoming more prevalent and costly and if not treated correctly can lead to higher levels of amputation. Despite this, partial foot orthotic research and development has been inadequate. Furthermore, in order to contribute to improved orthotic management, there is a need to understand the biomechanical discrepancies during gait.

Biomechanical goals of orthotic fitting include normalizing the three functional impairments of the transmetatarsal amputee. The first goal is to improve balance, the second is to normalize the toe-off phase of gait, and the third goal involves supporting the plantar surface of the foot to evenly distribute pressure.

In this study, all subjects were evaluated with a below-ankle condition and an above-ankle condition. The below-ankle condition consisted of a total contact foot orthosis fitted into Drew[®] shoes with rocker bottom soles. The below-ankle orthosis was

then fitted with a Blue Rocker[®] ankle foot orthosis and gait was re-evaluated as the above-ankle orthotic gait condition.

Three specific goals were proposed in this study: 1) to determine the differing, if any, effects on balance and vertical ground reaction symmetry during level walking and obstacle crossing between the two orthotic designs, 2) to determine the plantar pressure distribution differences between a below-ankle and an above-ankle design, 3) to learn about patient preferences to provide realistic feedback for quality patient care. We hypothesized that improved balance, symmetry and distribution of pressure would occur with the above-ankle design in individuals with greater disability.

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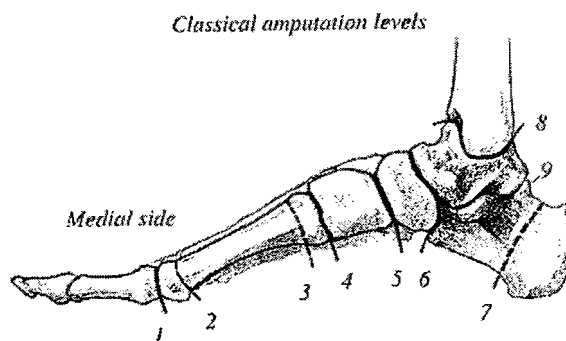
CHAPTER I

INTRODUCTION

Partial foot amputations may result from trauma, peripheral vascular disease (PVD), tumors, or, the number one cause in the United States, diabetes complicated by neuropathic disease (ND). In 2002, for every 1000 people with diabetes 2.6 underwent toe amputations and 0.8 underwent foot amputations (2). The number of amputations continues to grow as diabetes becomes more prevalent. In 2005, 1.5 million new cases of diabetes were diagnosed in people 20 years and older. The prevalence of partial foot amputation is also increasing due to new surgical techniques which encourage a partial foot level of amputation rather than a more proximal transtibial level (3, 4). Partial foot amputation may include any part of the foot, from part of a toe to all of the foot excluding part of the calcaneus. The effects on the biomechanical ability of the individual and the possibility for further complications vary depending on the level of the amputation. Therefore, this study will concentrate on the transmetatarsal level of amputation.

Transmetatarsal amputation (TMA) involves removal of the metatarsal heads resulting in the loss of normal forefoot weight bearing (Figure 1). This leads to a decreased lever arm for push-off and a reduction in the degree of forefoot pronation and supination which helps with ambulation on uneven surfaces. Furthermore, the resection of the first metatarsal head disrupts the medial longitudinal arch. This affects the mediolateral alignment of the plantar surface of the foot because an unsupported first ray will place the foot in a pronated position upon weight bearing (5) (6). Removal of the

Figure 1. Levels of TMA
 2-Distal Transmetatarsal
 3-Proximal Transmetatarsal



forefoot results in the loss of four extrinsic muscles, all the intrinsic muscles and the plantar fascia leading to compensatory biomechanics as the foot contacts the ground (7). Each patient presents unique morphologic characteristics due to the variety of surgical techniques and the patient's pre-operative condition.

There are several advantages associated with this level of amputation. Maintaining a long lever, as compared to the transtibial level of amputation, is always advantageous when dealing with forces, such as pressure distribution and moment arms. Allowing for distal weight bearing is an advantage because it provides some independence from the orthosis (for instance at night). Maintaining ankle motion is thought to be of benefit to the amputee, although this is somewhat controversial. We could speculate that this level of amputation could also lead to less compensatory action of the uninvolved limb because the body weight can be shared more equally between the two feet than would be possible with a higher level of amputation. In order for this level of amputation to succeed interdisciplinary team communication, patient education and compliance, surgical technique, proper orthotic fitting, gait training, and substantial follow-up must be considered as all these factors affect patient outcomes.

Statement of the Problem - How Can We Better Aid Balance and Improve Symmetry?

Important goals of prosthetic and orthotic fitting include decreasing further deformity, distributing pressure and restoring independence (8) to reduce the occurrence of ulceration and the likelihood of further amputation. Biomechanical goals of orthotic fitting include normalizing the three functional impairments of the transmetatarsal amputee. The first goal is to improve balance, the second involves supporting the plantar surface of the foot to maintain normal anatomical alignment, and the third goal is to normalize the toe-off phase of gait (6).

Transmetatarsal orthoses vary in design and materials according to the patient's functional demands, degree of imbalance, alignment, strength, compliance and activity level. For example, some amputees may function well with a below-ankle design (Figure 2) which allows full ankle motion, while others will require an above-ankle design (Figure 3 and 4) for increased balance and greater surface area for pressure distribution. Above-ankle designs look somewhat similar to an ankle foot orthosis (AFO) and may or may not include ankle joints.

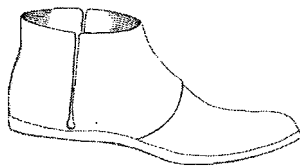


Figure 2.
Below-ankle orthosis

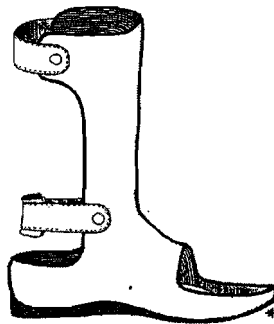


Figure 3.
Above-ankle orthosis

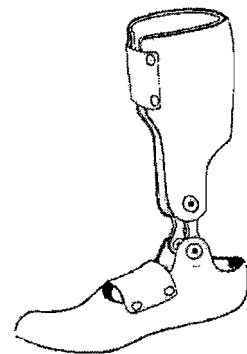


Figure 4.
Above-ankle
articulated orthosis

With the use of the above ankle orthosis both the antero-posterior and medio-lateral ankle motions are expected to be diminished, theoretically providing a more stable base of support. This is more important for the individual with decreased muscle strength. The addition of ankle articulation allows for dorsi/plantarflexion of varying degrees, but limited medio-lateral motion at the ankle (Figure 4). Stopping dorsiflexion but allowing plantarflexion in mid-stance will result in a net extensor moment at the ankle and the knee, therefore corresponding with the requirements for support during stance (Figure 5, this figure does not illustrate well for the knee joint) (9). An ankle dorsiflexion stop during terminal stance should result in the transfer of force from the distal plantar surface of the stump to the anterior tibia, therefore reducing peak plantar pressures and the likelihood of skin breakdown (6). Another orthotic design includes a semi-flexible strut for resistance to plantarflexion, dorsiflexion, inversion and eversion motions (Figure 6). This is a more streamlined and lighter weight design than the ankle joint design but may have decreased durability depending on its fabrication.

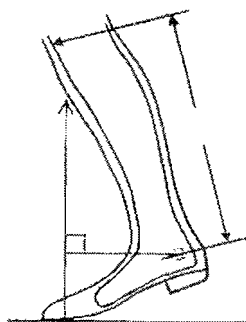


Figure 5.
Moment Alteration
Due to GRF

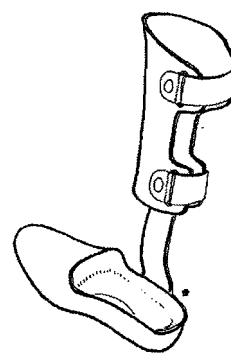


Figure 6.
Semi-flexible Above-
Ankle Orthosis

Specific Aims

Research question 1: How does the orthosis affect balance control during ambulation?

Hypothesis: The partial foot above-ankle orthosis with moderate resistance in sagittal and frontal plane motion will assist ambulation by decreasing the magnitude of the mediolateral sway of the whole body center of mass (COM) during gait.

Research question 2: How do the temporal-spatial parameters change between the above-ankle and the below-ankle conditions?

Hypothesis: The improved rollover with the use of the above-ankle design will allow for more equalized step length and less of a 'limp' as compared to the below-ankle design. The step width might decrease with the use of the above-ankle design.

Research question 3: How does the above-ankle device affect the vertical ground reaction forces between the involved and uninvolved limbs?

Hypothesis: The involved and uninvolved vertical ground reaction force curves will be more symmetrical with the above-ankle as compared to the below-ankle condition.

Research question 4: Does the above-ankle design alter the distribution of the pressures on the plantar surface of the foot as compared to the below-ankle design?

Hypothesis: During terminal stance the pressures on the partial foot amputee occur at the distal-plantar aspect of the foot, i.e. at the location of the cut bones. The magnitude of the plantar pressures with the above-ankle design may not alter as compared to the below-ankle design.

Research question 5: Which device does the subject prefer to wear and why?

Hypothesis: The subject will prefer to wear the lightest weight and least bulky device.

CHAPTER II

REVIEW OF LITERATURE

Function of the Transmetatarsal Amputee (TMA) Patient

Various studies have examined the decreased ambulatory function of the TMA patient. Garbalosa, et. al., 1996, examined kinematic data and plantar pressure of 14 patients with diabetes and TMA (10). When measuring peak plantar pressures and comparing them to a control group, they found there were decreased pressures at the heel and increased pressures at the distal end of the residuum. The researchers felt that this may be due to the decreased dynamic dorsiflexion or increased plantar flexion in stance. Their kinematic data results showed decreased dynamic dorsiflexion motion throughout the gait cycle. It was suggested that the decreased use of available ROM throughout the gait cycle of the TMA group may be due to the decreased lever arm of the foot and a decreased ability of the plantarflexors to resist the forward motion of the tibia over the foot.

While a decrease in dorsiflexion during stance was reported [9], Chrzan et. al., 1993, reported a conflicting increased knee flexion during stance. Increased knee flexion during stance corresponds with increased dorsiflexion due to the closed chain mechanism and need for upright posture. This study discussed joint motion and gait following TMA related to functional disruption of the long toe extensors and flexors, peroneus tertius, intrinsic muscles of the foot, and the plantar fascia (7). Equinovarus positioning is more common after TMA due to the imbalance of muscle strength and subsequent loss of joint

motion control. Gait initial contact occurs in a more inverted and less dorsiflexed position, followed by an irregular rollover. The stance is then finished with little or no push-off. The loss of the intrinsics and plantar fascia affect the integrity of the arches throughout stance and the dynamic stability provided by them during normal push-off. This predisposes the foot to future deformity. The muscular disruption following the TMA results in compensatory gait mechanics including a shorter stride length and a slower pace.

Mueller and Sinacore, 1994, described two important rehabilitation considerations for the TMA patient: skin breakdown and imbalance. Because there is a high incidence of post-operative complications and re-ulcerations in this population, skin vitality is of primary concern. Other factors, such as peripheral neuropathy and the patient's medical history can adversely affect the balance of the TMA patient following the amputation. According to Mueller and Sinacore, this is due to the loss of available power generation of the plantarflexors with the shortened lever arm (11). As a result the researchers express the need for improved orthotic designs and rehabilitation.

The ambulatory function of the TMA patient is decreased. Gait disturbances in the TMA patient are due to the functional loss of the skeletal lever arm and the imbalance of musculature. There is a loss of plantarflexion power generation required for push off and stability during stance. Balance is also adversely affected due to the smaller base of support provided by the shortened foot (6).

Peripheral Neuropathy Effects on Balance

To complicate matters further, balance control of individuals with TMA due to diabetes mellitus and peripheral neuropathy is not only decreased with the smaller base of support, inadequate balance of musculature across joints and inability to generate power at the ankle, but the disparaging influence of peripheral neuropathy on balance is well established (12-23). Both decreased plantar sensation and decreased muscle activation appear to negatively affect balance control.

Ducic et. al., (2004), found a parallel relationship between balance and pedal sensations after evaluating sway in 35 patients with peripheral neuropathy using the MatScan Measurement System (12). As pedal sensations decrease, balance decreases. Uccioli et. al. (1995) evaluated 54 subjects with and without peripheral neuropathy under the age of 35 to remove the age related factor of increased body sway and found that the diabetic subjects with peripheral neuropathy had decreased control of postural balance control (13). In a more recent study, after evaluating 20 healthy subjects' EMG, kinematic and force plate data under 2 different conditions, normal and plantar surface of foot numbed with ice, Eils et al concluded that the reduced plantar sensation resulted in significant gait changes affecting the entire lower limb (21). Meier et al investigated the center of mass (COM) and center of pressure (COP) to determine balance control during gait termination. They found that the elderly diabetic neuropathic subjects adopted a 'slowness strategy', but "despite the slower walking velocity, the Anterior/Posterior and Medial/Lateral COP overshoots of the elderly Type II diabetic subjects are larger than in the elderly healthy subjects" (18).

In conclusion, patients diagnosed with diabetes mellitus with peripheral neuropathy have decreased balance control in weight bearing activities, increased compensatory mechanisms, and decreased ability to control changes to COM during gait transitions. Therefore it seems appropriate to also predict that diabetic patients with peripheral neuropathy and transmetatarsal amputation are predisposed to falls.

Prosthetic/Orthotic Functional Studies

Tang et. al. (2004) found improved temporal spatial parameters, and more normalized sagittal plane ankle angles, moments and powers with the use of a below-ankle TMA orthosis as compared to no orthosis on eight individuals whose TMA was mostly due to trauma (24). The design of the TMA orthosis included a custom molded insole, toe filler and a full length Springlite carbon fiber plate of medium flexibility.

Dillon and Barker (2006) evaluated COP excursion patterns of individuals with various levels of partial foot amputation while wearing their own orthoses. Replacement of the lever arm with an extended shank shoe modification was thought to be a simple remedy to the situation. However, Dillon's biomechanical analysis showed that the center of pressure does not progress beyond the distal end of the residuum when wearing (below-ankle) shoes or inserts fabricated to replace the rigid forefoot lever (25).

Various studies have evaluated effects of ankle foot orthoses (AFO) on balance control for patients following a stroke or with cerebral palsy (26-30). We can compare the function of the AFO to the function of the partial foot orthosis. Mojica et. al. (1988) demonstrated that with the use of an AFO, there was decreased body sway and increased walking speed as compared to no AFO. The degree of balance control needed will

depend on each unique individual's functional needs, biomechanical alignment and muscle function. For instance, an individual with an upper motor neuron disease may likely exhibit extensor tone, which results in some inherent stance phase imbalance; whereas an individual with a lower motor neuron disease may have complete flaccidity, and therefore will require a different amount of support. There remains very little evidence on the stabilizing effects of orthoses and partial foot prostheses on individuals with peripheral neuropathies.

Hirsch et. al. (1996) analyzed the vertical and antero-posterior ground reaction forces (GRF) of a below-ankle and a solid above-ankle design prosthesis on individuals after traumatic (non-diabetic) amputations. Comparisons between the amputated and non-amputated antero-posterior and vertical GRF differences were observed. Symmetry of the ground reaction forces improved with the use of the below-ankle prosthesis, but more so with the above-ankle design. Gait appeared smoother and more symmetrical with the above-ankle design. Two years following the study, participants were contacted and asked which prosthesis they preferred. None of them continued to use the above-ankle design. There is a surprising discrepancy between the functional outcome and the patient's preference of the orthotic design, suggesting that there is a need to better understand and consider the functional demands during gait and the personal comfort of the amputee (31).

Plantar Pressure Studies

Neuropathy leads to biomechanical changes of the foot [43] with increases in peak plantar pressures which lead to increased susceptibility to plantar ulcers. Smith

found that patients with diabetic neuropathy and a history of ulceration had significantly greater plantar pressures (32), while Payne and Armstrong separately found dynamic plantar pressures to be higher in people with diabetes following partial foot amputation (33, 34).

Plantar pressure can be directly altered with the use of insole material [31]. While using PPT under the metatarsal-phalangeal joints, the vertical plantar pressures were significantly reduced as compared to a barefoot condition.

Plantar pressure can also be indirectly altered with the use of shoe modifications; such as various rocker sole modifications, specifically rocker bottom shoes have produced decreased plantar pressures in individuals (35) and forefoot relief shoes have been effective in reducing both mean and peak plantar pressures (36).

Above-ankle devices have also been used in research to quantify differences in plantar pressure. Un-weighting of the plantar aspect of the foot and improved pressure distribution occurred with both the Aircast walking boot and total contact casting as compared to a standardized shoe in healthy individuals (37). The total contact cast healed a higher proportion of diabetic patients in a shorter period of time as compared to the Aircast fracture walker and the Darco half shoe (38), attributed to the direct total contact fit of the device. Lawless (2001) found reduced pressure under the first metatarsal head with the fracture walker and total contact cast as compared to barefoot; moreover, the fracture walker had a reduction in heel pressure as compared to the total contact cast (39). The authors attributed this to the heel rocker on the bottom of the fracture walker.

Above-ankle designs that stop dorsiflexion alter the GRF at terminal stance and allow the center of pressure to extend beyond the end of the residuum [36], but the affect on plantar in-shoe pressures has not been evaluated. Therefore, with ulceration occurring at the sites of peak plantar pressure, we propose to examine if indirect pressure re-distribution occurs with the above-ankle device.

CHAPTER III

RESEARCH DESIGN AND METHODS

Subject Recruitment and Selection

One group of subjects was evaluated to compare the balance characteristics between a below-ankle orthosis and an above-ankle limited motion orthosis both using rocker bottom shoes. Subjects were recruited from the community through contacts with local surgeons, podiatrists and orthotists/prosthetists. The participants included diabetic individuals with a fully healed transmetatarsal amputation and an ability to walk without an assistive device. Any person with a history of head trauma and other neurological impairment besides peripheral neuropathy were excluded from this study. This study has been approved by the University of Oregon IRB.

Each subject filled out a preliminary questionnaire to determine age, height, weight, diabetes duration, date of amputation, eyesight (presence of retinopathy), self perceived activity level, whether or not they smoked, and if there was the presence of peripheral neuropathy, peripheral vascular disease, heart disease, or renal failure (40). They were assessed to determine the length of the residual limb compared to the uninvolved limb, the presence of contracture in sagittal or frontal planes, and strength. A physical examination included range of motion and strength assessment at the lower extremity joints, stance posture, and a timed up and go (TUG) balance score (see Appendix G). The TUG was chosen because it has been shown to be a reliable and valid test to predict functional mobility (41-48) as well as specific validity for physical

mobility of individuals with lower limb amputation (41). An age-matched non-diabetic control population were recruited and evaluated to attain baseline gait measurements for comparison. Finally, the patients were contacted 3-months after the collections to determine the patient's preference between the two devices using the Prosthetic Profile of Amputee Questionnaire.

Design of TMA Orthosis

Each patient was seen by an orthotist/prosthetist (1) for casting, measurement and fitting of orthoses and shoes one month prior to each testing session to allow the subjects to 'break-into' the orthoses. Drew Shoes™ (Drew Shoe Corporation, Lancaster, OH) (Figure 7) were modified on the amputated side with a shank that extended to the toes to prevent the shoe from collapsing at the end of the residuum. The shoes are certified diabetic extra depth shoes. All shoes had rocker sole modifications with the apex of the rocker beginning just proximal to the location of the MTP of the shoe and sound side foot (6) (Figure 8). The sole modifications were identical between the involved and uninvolved limbs.



Figure 7.
Drew Shoe

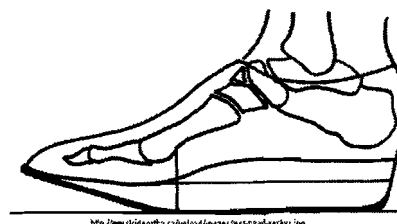


Figure 8.
Rocker Sole Modification

Casting for the below-ankle orthosis was done with plaster holding the foot in subtalar neutral position while the patient sat. The total contact insole was fabricated with Plastizote™ (top layer), poron, a toe filler and a puff base to position the foot in a neutral position (if possible), to position the tibia vertical in both sagittal and frontal planes during quiet stance, and to provide total contact for distribution of plantar pressures (Figure 9). These materials were chosen for their accommodative properties.

The custom below-ankle orthosis was placed on top of the above-ankle orthosis BlueRocker® (Allard USA, Rockaway, NJ) maintaining the same vertical alignment of the lower limb and the sagittal and frontal planes. The BlueRocker orthosis is a carbon fiber off-the-shelf limited motion AFO consisting of a full foot plate and a lateral strut extending to the anterior surface of the tibia (Figure 10). This design was used with all patients to maintain consistent treatment.

All below-ankle orthoses were fabricated from the same materials, the lower legs were aligned to the same angles, and shoes were the same style and manufacturer to maintain continuity as these variables have been shown to affect the biomechanics of gait. Therefore, the only variable to consider was the addition of the AA orthosis.



Figure 9.
Total Contact BA Orthosis



Figure 10.
Blue Rocker
AA Orthosis

Clinical Balance Examination

The Timed-Up-and-Go test was given to compare the clinical measure to the motion analysis measure to determine distinguishing characteristics. This test has been shown to be a good predictor of fallers (43, 44) with a high re-test and inter-rater reliability (41, 46, 48). (See Patient Evaluation Form in the Appendix.)

Gait Analysis

The research took place in the Motion Analysis Laboratory, Department of Human Physiology, University of Oregon. Each subject was evaluated during two randomized visits over a period of one month. Gait evaluation included walking along a 10-meter walkway on level ground during three conditions: without obstructions, and with obstructions at 2.5% and 10% of body height to simulate walking over a doorway threshold and over a curb (49). The obstacle was a 1" diameter PVC pipe positioned in the center of the walkway, between the two forceplates. Data collections of these conditions, again, was be randomized and subjects were allowed to rest between trials to reduce measurement of fatigue affects on gait. Subjects were instructed to walk at a self-selected walking pace.

Three-dimensional kinematic data was collected with an eight camera Motion Analysis System (Motion Analysis, Santa Rosa, Ca, USA) at 60 Hz. Body segments were defined using 29 passive markers arranged using 'Helen Hayes marker placement' as follows. Markers were be placed bilaterally at the tip of the acromion processes, lateral epicondyles of the humerus, centered between the dorsal side of the styloid processes of the radius and ulna, centered on the dorsum of the hands, both ASIS, lateral

femoral epicondyles, lateral malleoli, dorsum of the feet between the 2nd and 3rd metatarsals, posterior calcanei at the level of the foot markers. Thigh and shank wand markers were placed on the vertical line between the trochanter-lateral knee, and lateral knee-lateral malleolus, respectively. One marker was placed between the PSIS. Five markers defined the head and neck segment, one placed anteriorly centered above the brows, one posteriorly at the same level as the anterior marker, one at each temple and one on top of the head centered between the anterior/posterior and the medial/lateral markers. The final marker was placed on the right shoulder blade to define the right side of the body. (Figure 11)

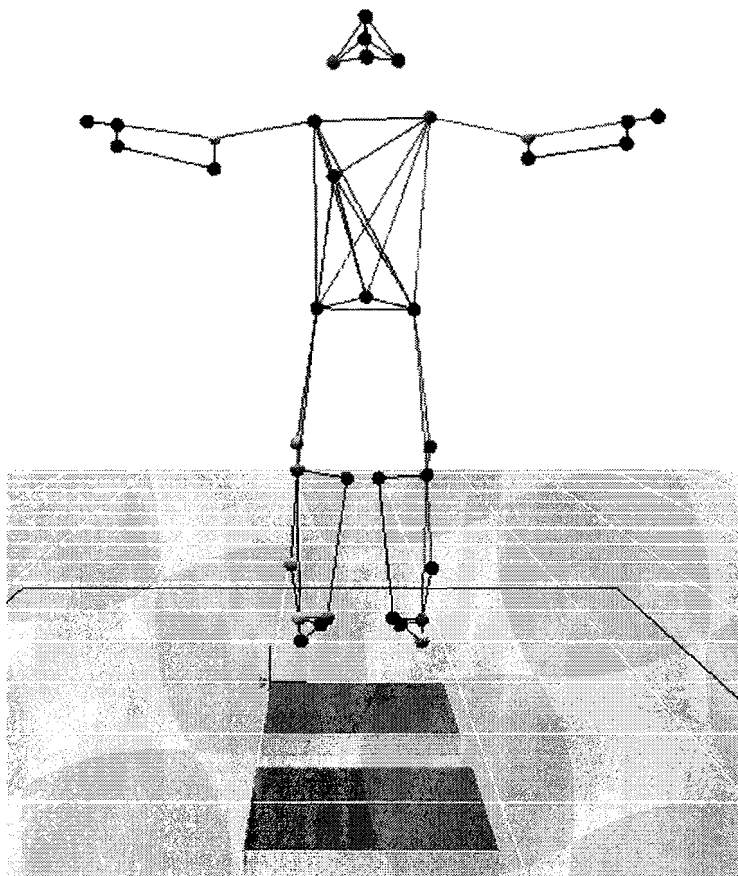


Figure 11.
Marker Set

Kinetic data were collected with two dual AMTI force plates (AMTI, Newton, MA) to calculate instantaneous center of pressure (COP) data at 960 Hz and time-synchronized to the kinematic data.

Pressure Measurement

Plantar pressure was measured separately from gait analysis. Both conditions (rocker soled shoes and above-ankle orthosis with shoes) were measured on the same day to increase reliability. Plantar pressure measurement was collected by a bipedal in-shoe F-Scan sensor system (Tekscan, South Boston, MA) at a sampling rate of 500 Hz with thin (0.15mm), high resolution (4 sensels/cm²) disposable sensors. The sensors were taped on top of flat 1/8" insoles (Puff) so that movement of the sensors didn't change between the conditions. Flat insoling was used because the sensors do not conform well to the total contact custom insoles. The sensor tabs extended laterally up out of the shoes and connected into a cuff unit secured by a Velcro band around the ankles. Pressure information was sent via thin cables up to a remote transmitter that fitted around the waist. The mobile system required no cables to run from the subject to the computer therefore allowing more freedom of movement for the individual.

Patient Satisfaction

Three months after the data collections, all subjects were contacted via telephone to determine their satisfaction of the orthosis with a rocker bottom shoe. We understand that the device can only provide assistance if it is used by the patient. Improvements to

orthotic design need to include the patient's opinions about the level of perceived assistance and acceptance. The Prosthetic Profile of the Amputee Questionnaire has been shown to be valid and reliable (50, 51).

Data Analysis

Marker trajectory kinematic data were identified using EvaRT 4.4 (Motion Analysis, Santa Rosa, Ca, USA) and smoothed using a low-pass Butterworth filter (cutoff frequency = 8Hz).

Figure 12 illustrates the gait events defined in Eva and labeled THS (trailing heel strike), LTO (leading toe off), etc. The red dot located between the two force plates is the obstacle at 10% of the subject's body height. The data between the first and last THS were cut, saved then processed using a custom algorithm written in Matlab. Using Dempster's anthropometric estimates of body segments (52) and a 13-segment model modified from Kadaba et al. and Jian et al. (53, 54), a 3-D COM of each segment was calculated. The partial foot and shoe as well as the shoe and foot on the sound side were assumed as one sum and calculated using the data of the foot.

A weighted sum of these points was then used to define the whole body center of mass. Instantaneous COM-COP inclination angles were quantified as defined by Lee and Chou (55) as the angle formed between a vertical line passing through the COP and the line connecting the COM to the COP. Gait velocity was calculated at the whole body COM linear velocity, step width is the distance between the two ankle joint centers during heel strike and step length is the distance between the heel markers during heel strike to the same side heel marker at the next heel strike.

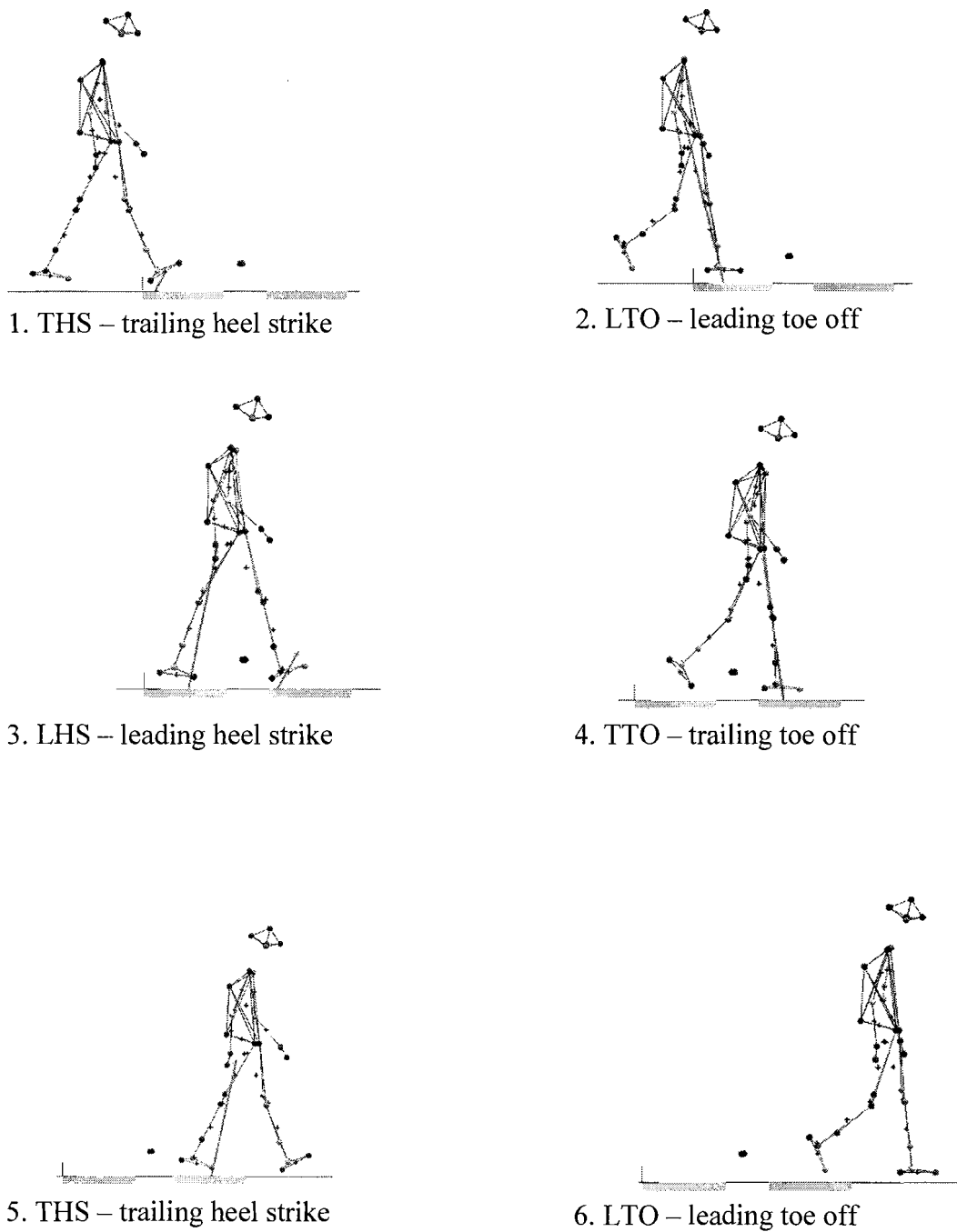


Figure 12. Gait Events

Statistical Analysis

Between group (PF and control) differences in the anthropometric data and temporal-spatial data were assessed using independent t-tests using an alpha level of 0.05.

The between-limb vertical GRF (vGRF) curves were analyzed using a 'goodness of fit' test called the Kuiper Test. Each subject's curves were analyzed separately due to the variability of clinical characteristics and conditions. We analyzed the difference between the involved and the uninvolved legs during the below-ankle and above-ankle conditions. The procedure is explained here: Five level gait conditions were collected with clean foot-strikes on the two separate forceplates. Each, vGRF graph was placed on a 100 point scale and the five trials were averaged resulting with one ensemble involved vGRF curve and one ensemble uninvolved vGRF curve. The 'goodness of fit' between the involved and uninvolved vGRF curves was determined by finding the greatest vertical difference. If the Kuiper p-value under the null hypothesis of no difference between the two limbs was significant (<0.05) the curves were determined to be statistically different.

Kinematic and joint kinetic data were not analyzed as motion was observed between the foot and shoe. The foot and shoe were assumed to be a rigid body in our model. These data, therefore, were not considered valid.

CHAPTER IV

RESULTS

The purpose of this study was to evaluate the gait characteristics, specifically balance control and symmetry, while wearing an above-ankle orthosis compared to a below-ankle orthosis on individuals diagnosed with diabetes and transmetatarsal amputation (TMA). Plantar pressures were also evaluated between the two conditions as reducing peak pressure is one goal of the orthosis. Control subjects were included to obtain baseline values for comparison with our outcome measures.

Subject Characteristics

Six partial foot subjects (36) were evaluated and recruited having TMA (Table 1). These subjects, selected randomly, were male between the ages of 46–77yrs (57.7 ± 10.5 yrs). The diabetes duration (8-43 yrs) and time since amputation (9 mo–18yrs) varied but were not related to the outcome measures.

Table 1. Subject Anthropometrics

	Limb	Age (yrs)	Ht (m)	Mass (kg)
PF1	R	54	1.76	82.5
PF2	R	46	1.94	143
PF3	L	57	1.93	100
PF4	R	59	1.80	117
PF5	Bi	53	1.84	115
PF6	L	77	1.85	108
Average patient		57.7	1.85	110.9
Controls		57.2 ± 9.5	1.8 ± 0.04	$81.7 \pm 10.6^*$
average				

* Between group, $p < 0.05$

The length difference between sound side and affected/amputated side shows the varying levels of TMA. One subject (PF5) had bilateral amputations during the collection. The control subjects (C) were age and gender matched. While their heights did not significantly differ from the PF subjects, their weights (81.7 ± 10.6) were significantly less than the PF patients (110.9 ± 20 kgs), representative of the diabetic population.

In order to bring the results of the study back to the clinical setting with the hope of using this as a pre-prescriptive analysis, each subject was assessed using the timed up and go (TUG) test while barefoot. All PF subjects had longer TUG times compared to C subjects ($p=0.006$) (Table 2). The duration of time that the PF group was diagnosed with diabetes had a significant relationship with TUG ($p=.045$). PF3 had the greatest diabetes duration of 43 years diagnosed with type I when he was 14 years old, and the greatest TUG time (10.36sec). All subjects were being followed by their optometrists regularly and wore corrective lenses if necessary.

Table 2. Subject Clinical Characteristics

	Time since Amputation	Diabetes Duration	Presence of retinopathy?	Diff (cm)	TUG (sec)
PF1	9 mo	25 yrs	No	7	7.54
PF2	3 yrs	8 yrs	No	3.8	6.07
PF3	4 yrs	43 yrs	Yes	9.2	10.36
PF4	3 yrs	8 yrs	Yes	6.9	7.93
PF5	18 yrs	15 yrs	No	1.5	8.38
PF6	13 mo	36 yrs	No	10.9	9.05
Controls					5.55 $\pm 1.12^*$

Diff = sound side minus amputated side length discrepancy

TUG=timed up and go balance test

* Between group, $p<0.05$

Gait Temporal Distance Measures

The gait temporal distance values did not change significantly between use of the below-ankle or above-ankle device, however there was a significant difference in gait velocities between the PF and control groups (Table 3) (Figure 13). Gait velocity of control subjects was greater than partial foot subjects gait velocity during level and both obstacle crossing conditions. When stepping over the obstacle at 10% body height, all PF subjects had slower gait velocity during both orthotic conditions as compared to the controls ($p < 0.002$).

Table 3. Temporal Distance Measures

	Gait Velocity (m/s)		Stride Length /Height (cm)		Step Width /ASIS (cm)	
	Below Ankle	Above Ankle	Below Ankle	Above Ankle	Below Ankle	Above Ankle
	PF Subjects					
Level	1.02	1.08	66.7	69.7	0.49	0.46
2.5% Obstacle	0.96	1.01	70.5	72.5	0.48	0.49
10% Obstacle	0.86	0.89	72.1	73.6	0.47	0.50
Control						
Level	1.47*		89		0.49	
2.5% Obstacle	1.35*		91		0.48	
10% Obstacle	1.23*		94		0.44	

* Between group, $p < 0.05$

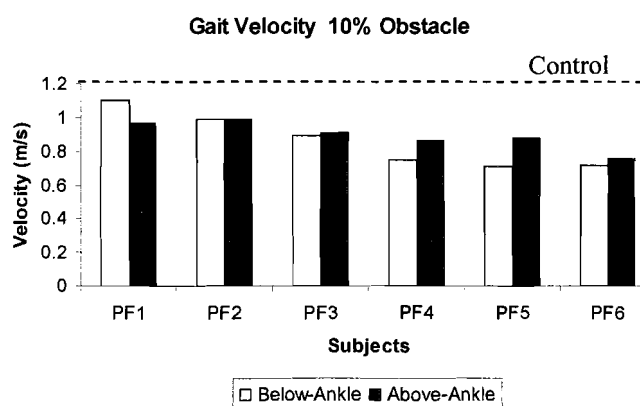


Figure 13. Gait Velocity During 10% Obstacle Crossing

Balance Control During Gait

No significant differences in gait were detected between the above-ankle and below-ankle devices. Only the subject PF3 had considerable improvement with the AFO as compared to the below-ankle condition; the medial COM-COP inclination angle reduced approximately 22% during the 10% obstacle clearance condition. No statistical difference was found in the peak medial COM velocities between orthotic conditions or between PF subjects and controls (Table 4) (Figure 14).

Table 4. Balance Control Measures

	Medial Inclination Angle		M/L Peak Velocity	
	Below Ankle	Above Ankle	Below Ankle	Above Ankle
PF Subjects				
Level walking	5.90±0.95	5.85±0.97	0.17±0.04	0.18±0.04
2.5% Obstacle	5.43±1.29	5.81±0.46	0.19±0.05	0.22±0.02
10% Obstacle	6.11±1.40	6.13±0.96	0.22±0.06	0.22±0.04
Control				
Level walking	5.53±1.39		0.00±0.07	
2.5% Obstacle	5.30±1.44		0.04±0.08	
10% Obstacle	5.25±1.76		0.08±0.05	

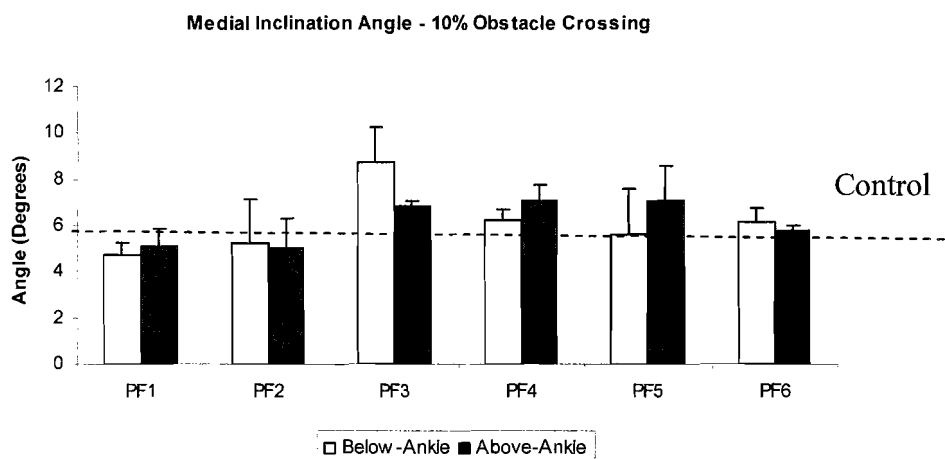


Figure 14. Medial Inclination Angle 10% Obstacle Crossing

Symmetry

The step lengths of the involved and uninvolved sides appeared to become more symmetrical with the use of the above-ankle device as seen in Table 5 and Figure 15.

However, no statistical differences were found.

Table 5. Step Length Symmetry

	Involved Step Length		Uninvolved Step Length		Uninvolved/Involved Step Length	
	Below Ankle	Above Ankle	Below Ankle	Above Ankle	Below-Ankle	Above-Ankle
PF1	75.59	71.144	67.805	67.478	0.90	0.95
PF2	72.967	72.965	64.811	67.356	0.89	0.92
PF3	64.74	63.992	62.914	65.137	0.97	1.02
PF4	62.852	70.023	57.82	66.085	0.92	0.94
PF5	52.372	56.441	56.207	62.539	0.93	0.90
PF6	51.729	57.495	46.324	50.857	0.90	0.88

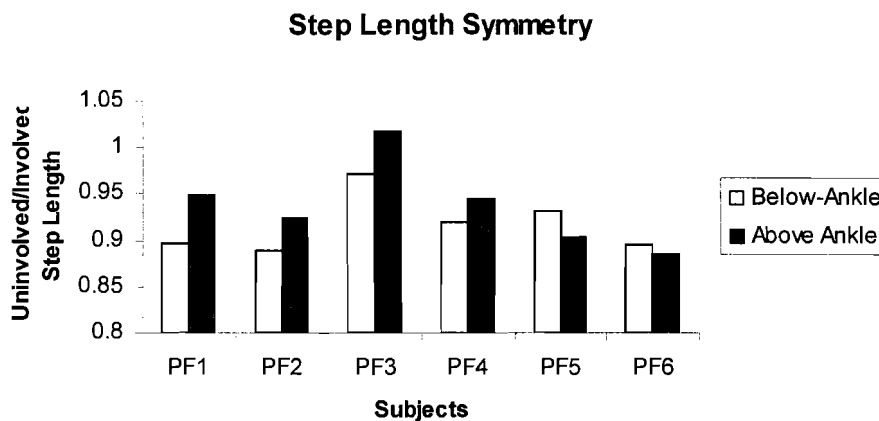


Figure 15. Step Length Symmetry Level Walking

Vertical ground reaction force (vGRF) curves are shown in Figures 16a-l, and the magnitude (x value) and timing (y value) of the two peak magnitudes occurring at early and late stance, respectively, are listed in Table 6 and 7. Differences in the peak force magnitudes and their corresponding times (% stance time) between the involved and uninvolved limbs during the two orthotic conditions were calculated. Statistical differences in the vGRF curves of the involved and uninvolved limbs were determined using the Kuiper EDF Test (Table 8).

PF5 and PF6 appear to have improvements in the 'goodness of fit' with the AA condition during early stance (Table 6). A significant between-limb difference in the vGRF curves was detected with the BA condition for subjects PF5 (Fig 16i, j) and PF6 (Fig 16k, l), (PF5: BE $p=0.0019$; AA $p=0.2346$) (PF6: BE $p=0.0174$; AA $p=0.4984$).

A significant between-limb difference in the vGRF curves was detected with the AA condition for subjects PF1 (BA $p=0.0574$; AA $p<0.0001$) and PF2 (BE $p=0.0606$; AA $p=0.0094$) (Figures 16 a-d). This appears to be due to a greater difference in the peak vGRF magnitude of 45.4N and 35.0, respectively, during the late stance (Table 7).

All but one of the PF subject's peak magnitudes occurred within 10% of each other when comparing the two orthotic conditions. PF6 had improved timing between the involved and uninvolved peak magnitudes during the AA condition, surprisingly during the first peak. Since there was so little similarity between the PF4 trials, the ensemble curves were not considered accurate and not included in this document (Figure 16g and 16i).

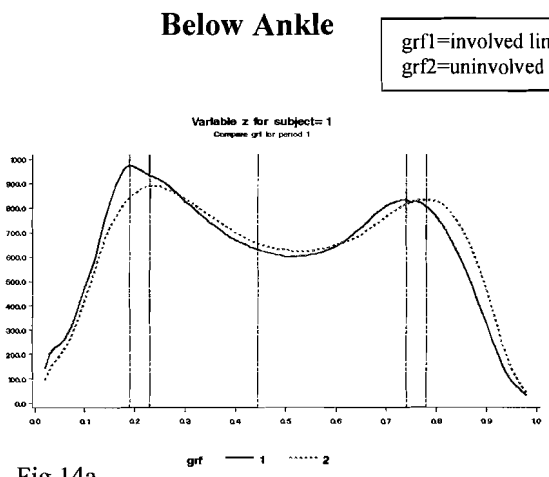


Fig 14a
PF1, BA

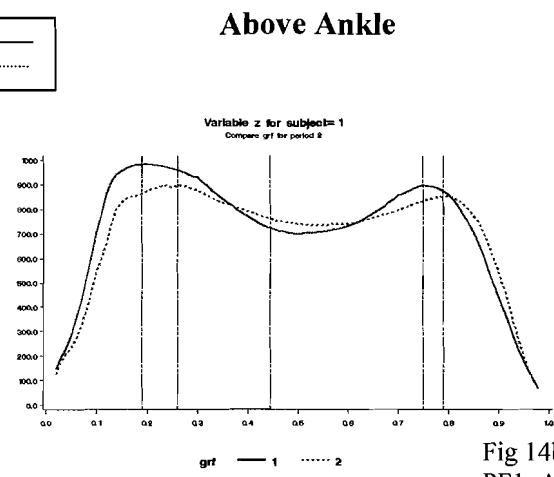


Fig 14b
PF1, AA

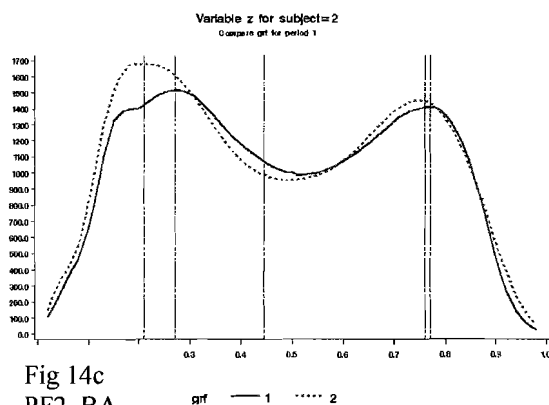


Fig 14c
PF2, BA

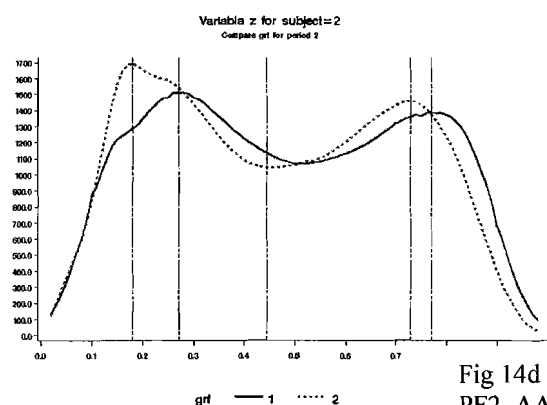


Fig 14d
PF2, AA

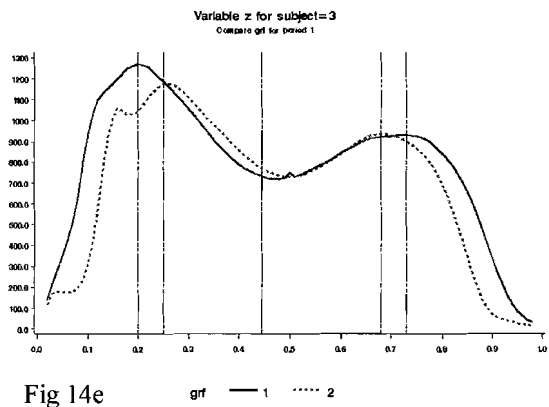


Fig 14e
PF3, BA

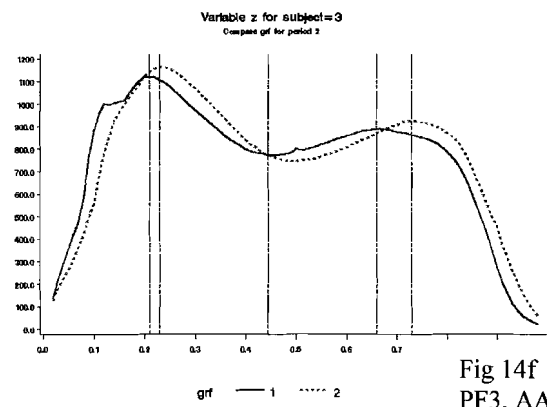


Fig 14f
PF3, AA

Figure 16a-f. Vertical GRF for BA and AA Conditions Level Walking

Below Ankle

Above Ankle

grf1=involved limb —
grf2=uninvolved limb - - -

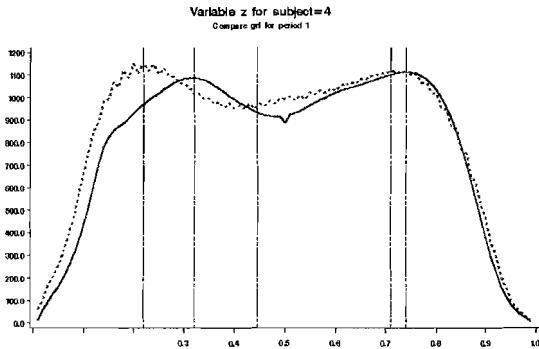


Fig 14g
PF4, BA

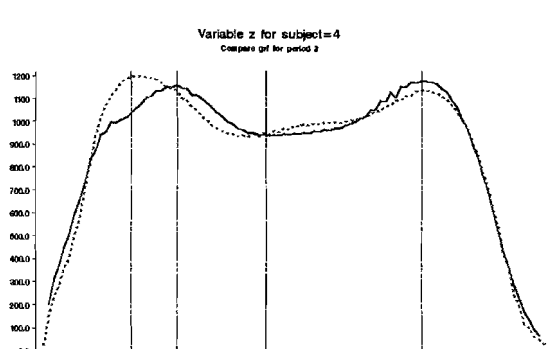


Fig 14h
PF4, AA

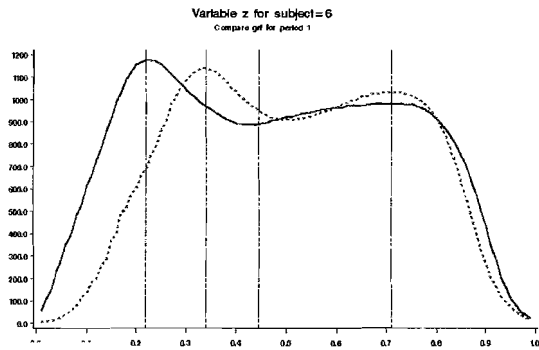


Fig 14i
PF5, BA

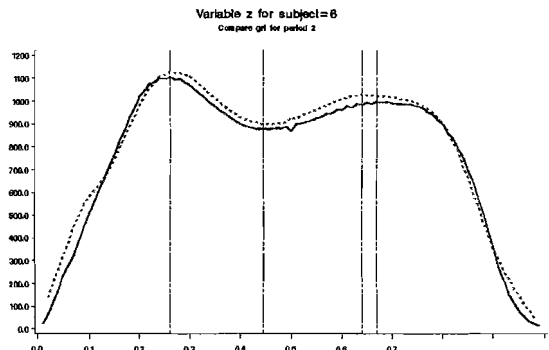


Fig 14j
PF5, AA

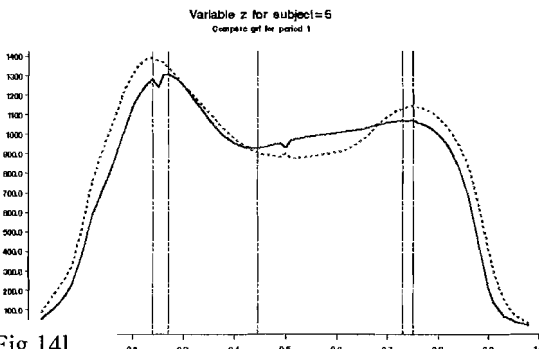


Fig 14l
PF6, AA

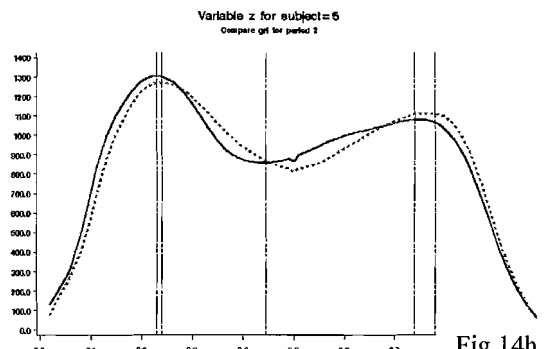


Fig 14k
PF6, AA

Figure 16g-l. Vertical GRF for BA and AA Conditions Level Walking

**Table 6. 1st Peak
vGRF Inter-Limb Peak Force Magnitudes and Times**

	Condition	% of stance time			Peak Magnitude (N)		
		Involved	Uninvolved	Offset	Involved	Uninvolved	Difference in Magnitude
PF1	BA	19	23	4	974.792	892.396	82.3956
	AA	19	26	7	984.881	896.108	88.773
PF2	BA	27	21	6	1517.2	1677.91	-160.713
	AA	27	18	9	1512.07	1694.09	-182.016
PF3	BA	20	25	5	1267.53	1173.03	94.4958
	AA	21	23	2	1121.72	1165.59	-43.8633
PF4	BA	32	22	10	1087.26	1158.39	-71.1277
	AA	27	18	9	1158.11	1197.21	-39.1032
PF5	BA	27	24	3	1306.25	1391.73	-85.4845**
	AA	23	24	1	1307.02	1268.88	38.1418**
PF6	BA	22	34	12	1178.47	1138.94	39.5349*
	AA	26	26	0	1104	1127.68	-23.678*

* p<0.05, ** p<0.01, *** p<0.001

**Table 7. 2nd Peak
vGRF Inter-Limb Peak Force Magnitudes and Times**

	Condition	% of stance time			Peak Magnitude (N)		
		Involved	Uninvolved	Offset	Involved	Uninvolved	Difference in Magnitude
PF1	BA	74	78	4	832.965	833.412	-0.4473***
	AA	75	79	4	898.342	853.313	45.0287***
PF2	BA	77	76	1	1408.76	1449.16	-40.398**
	AA	77	73	4	1388.35	1463.37	-75.023**
PF3	BA	73	68	5	929.37	933.57	-4.2084
	AA	66	73	7	888.02	924.27	-36.2516
PF4	BA	73	71	3	1113.79	1118.58	-4.7885
	AA	75	75	0	1176.55	1136.76	39.7982
PF5	BA	73	75	2	1069.81	1146.03	-76.2221
	AA	74	78	4	1083.04	1113.15	-30.1154
PF6	BA	71	71	0	980.58	1035.6	-55.0105
	AA	67	64	3	997.12	1028.04	-30.922

* p<0.05, ** p<0.01, *** p<0.001

**Table 8. Kuiper Test (Asymptotic)
(Pr > Ka)**

Subject	PF1	PF2	PF3	PF4	PF5	PF6
Below						
Ankle	0.0574	0.0606	0.8945	0.5227	0.0019	0.0174
Above						
Ankle	<.0001	0.0094	0.0848	0.8487	0.2346	0.4984

Plantar Pressure

The indirect effect of the above-ankle device on foot plantar pressures was examined using in-shoe plantar pressure sensors. Only 3 patients were able to participate in this part of the study due to medical conditions. The above-ankle device reduced the ankle motion in the sagittal plane (Table 9). The total ankle range of motion was reduced by approximately 10 degrees (with the use of the above ankle device with about 4.5 fewer degrees of plantarflexion at foot strike and 5.2 fewer degrees of dorsiflexion at terminal stance.)

Table 9. Tibial progression angle

	Maximum involved limb (36)	Minimum involved limb (DF)	Total ROM		Maximum involved limb (36)	Minimum involved limb (DF)	Total ROM
Below Ankle				Above Ankle			
pf2	108.24	74.45	33.78	pf2	103.84	85.3	18.54
pf4	107.36	79.42	27.94	pf4	104.05	82.26	21.79
pf6	111.29	88.48	22.81	pf6	105.48	90.42	15.05
Average	108.96	80.78	28.18	Average	104.46	86	18.46

Table 10 shows the changes in the peak plantar pressure at the distal end of the foot during terminal stance. Peak plantar pressure occurred during terminal stance except for subject PF6 with the use of the above-ankle device.

Table 10. Peak Pressure and Impulse at Distal End of Partial Foot

	Peak Pressure (PSI)		Impulse (kg*sec)	
	Below Ankle	Above Ankle	Below Ankle	Above Ankle
PF2	96.65	84	82.08	81.2
PF4	84.69	85.72	71.52	76.08
PF6	96.68	64.76	65.45	30.23

The COP distance traveled varied between the two conditions. Stance phase displacement for PF6, as seen in Figure 17, illustrates the common pattern of motion during one below- and one above-ankle condition. The distance that the COP traveled decreased during the above-ankle condition as compared to the below-ankle condition by about one-third for PF2, one-quarter for PF4 and one-half for PF6 ($p < 0.001$) (Table 11).

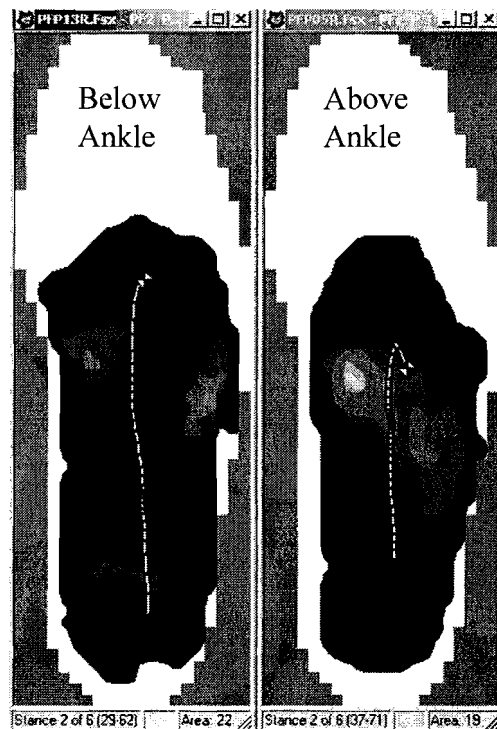


Figure 17. Average COP Motion Level Walking (one trial)

Table 11. COP Distance Traveled (mm)

	PF2	PF4	PF6
Below Ankle	7.86 ± 0.55	7.34 (0.60)	6.28 (0.20)
Above Ankle	5.66 ± 0.27***	5.24 ± 0.54 ***	3.37 ± 0.29***

*** $p < 0.001$

Patient Satisfaction

The patients completed the Follow-up Questionnaire (Adapted from Prosthetic Profile of the Amputee – telephone version) as seen in the appendix. All patients felt at least moderately satisfied with the comfort, appearance, weight and the way they walked with the below-ankle (BA) orthosis. One subject was not satisfied with the appearance nor the gait with the above-ankle (AA) orthosis. Most subjects became quite well adapted to using the BA orthosis, while 3 of the 6 subjects were not at all adapted to the AA orthosis. All subjects stated that they were able to walk about a block and able to walk up and downstairs, but not without the use of a handrail. PF subjects varied in their use of the orthoses. Two of them preferred to walk around the house without the use of any device. Reasons that prevented the subjects from using the orthoses included difficulty in donning, the device being cumbersome, and greater comfort without the use of anything on their foot. All subjects felt more balanced with the use of the BA orthosis as compared to nothing. One subject felt less balanced with the use of the AA orthosis.

CHAPTER V

DISCUSSION

The six PF subjects included in this study varied in age, height and weight characteristics as well as their medical conditions. With either the above-ankle device or the below-ankle device, all patients walked at a significantly slower gait velocity as compared to the control subjects. This agreed with the Timed-Up-and-Go scores, which showed a difference between the PF subjects and controls. When evaluating the PF subjects' between the below- and above-ankle conditions, no differences in velocity or other spatial temporal variables were observed for all three gait conditions – level, 2.5% and 10% obstacle crossing.

Only one subject (PF3) demonstrated a 'noticeable balance improvement' with the AFO. The medial COM-COP inclination angle reduced approximately 22% with the use of the above-ankle orthosis. This subject also had the greatest TUG score.

The TUG score may be proven to be an effective clinical exam. Those patients with greater TUG scores may have decreased functional mobility and a greater need for external support. The control medial inclination angles did not differ from most of the PF subjects, which was surprising. Inclusion of more control subjects could possibly make a difference as two of the control subjects had increased values compared to values measured in previous research. Walking with shoes, as compared to barefoot, may also have altered the values as compared to previous research, but does not explain why the control values were so closely matched to the partial foot subjects. There are a couple of

factors that may have affected this parameter. Trials where the subjects were not able to make two clean foot strikes on the forceplates were withdrawn. This altered the calculations because we only included the 'better' trials. Secondly, the task of stepping over an obstacle may not have been a differentiating enough task.

Symmetry between involved and uninvolved limbs was evaluated using two different variables. Initially, we calculated the step length by dividing the uninvolved length by the involved length. Symmetrical step lengths should approach a ratio equaling one. Four of the six subjects step lengths approached more symmetrical values with the use of the above-ankle orthosis, similar to results shown by Tang et. al. (24).

Our second variable used to evaluate symmetry was vertical ground reaction forces (vGRF) between the involved and uninvolved limbs. Hirsh et. al. (31) found improved symmetry in the vGRF with the use of above-ankle orthoses, although no statistical analysis was performed. We evaluated the two peak magnitudes (y-values) and the timing (x-value) when the peak magnitudes occurred over an average of five trials of level walking. The goodness of fit was calculated using the Kuiper Two-Sample Asymptotic Test. Our results were not consistent. Two PF subjects had statistically improved goodness of fit values comparing the involved and uninvolved limbs with the use of the above-ankle device, two subjects had decreased values, and two were unchanged. We hypothesized that the changes would occur during the second peak of the vGRF, but improvements in symmetry occurred during the first peak of the vGRF. The two subjects whose vGRF curves became less symmetrical had greater differences during the second peak (the push off phase of gait). The magnitude of the vGRF appeared be altered more by the above-ankle device than the percentage of the stance time when the

peak magnitude occurred. This analysis, though, should be interpreted with caution. PF4 whose BA trials were extremely varied had an averaged curve with very little meaning. The AA vGRF curves appear more symmetrical but had no statistical difference between the conditions. This analysis requires further investigation.

Only three PF subjects' plantar pressures were evaluated. One of the subject's data was lost due to equipment problems and two of the subjects had unrelated health issues that precluded them from coming back to the lab. Distal end plantar pressures and COP motion were measured using F-Scan in-shoe sensors. The AA device reduced ankle dorsiflexion, therefore reducing the tibial inclination angle during stance. Changes in peak plantar pressures at the distal end of the amputated foot varied between the subjects. Two of the subject's peak plantar pressures altered only slightly, however one subject had some indirect unloading from the distal end of the foot with the use of an AA device as compared to the BA device. This subject's distal peak plantar pressures decreased by about 30%, with a 50% decrease in the loading rate. The peak plantar pressures remained at the hindfoot while using the AA device throughout stance and unsurprisingly the distance that the COP traveled reduced the greatest amount (by about 50%).

The COP in-shoe motion appears unrelated to the vGRF. All subjects COP motion decreased significantly with the use of the AA device. However, PF2 had an average of about 20N less force whereas PF6 had almost 20N greater force recorded during the second vGRF peak. These decreases in the excursion of the COP differ from Dillon's measures due to the methods used [24]. He used forceplates under the shoes to measure COP excursion and found that the COP actually traveled beyond the distal end of the residuum with the use of the AA devices. Both measures are important to consider

as in-shoe motion describes the direct contact between the foot and the shoe while the forceplate measures may be related to the vGRF curves and the kinetics of the lower extremities.

Patient satisfaction may be one of the most critical parameters to examine to understand patient compliance and improve care. Optimally the prosthetic/orthotic design advantages should outweigh the disadvantages. Disadvantages and patient complaints of the above-ankle orthosis included the following: too cumbersome, too restrictive, difficult to don, and limited choice of shoe wear. Incidentally, most of the patients chose to wear the less bulky, lighter weight orthosis rather than the above-ankle design. Therefore, the subjects did not 'break-into' or get used to the function of the above-ankle design. Even if the above-ankle design may theoretically improve balance and symmetry, patient acceptance needs to be included to determine the appropriate device. Patient education, attitude and training also have an effect on their personal choice. Therefore, it is important that all clinicians involved in the amputee's rehabilitation communicate about the goals and work together as a team for consistent communications to the patient (56).

The number one limitation common in all clinical practice with diabetic subjects was noncompliance - three subjects admitted that they did not wear the orthosis during the break-in time. Although, they "felt more natural while walking" with the use of the above-ankle device, they did not like the inability to move their ankles nor the tighter fit inside the shoe.

Foot motion inside the shoe during the data collection is a second limitation. The foot and shoe were considered a rigid body in our model. The motion between the foot

and the shoe resulted in misleading angular motions and forces generated therefore limiting the variables we were able to examine in this study.

A third limitation included in all studies examining subjects with chronic diseases is transient or brief 'ups and downs' in condition. One example of the fragile nature of prolonged diabetes includes PF1 who was subsequently diagnosed with an intestinal cellulitis and placed on bedrest following the data collections. He underwent TMA on his previously unaffected side unrelated to his prosthetic fitting; he wasn't wearing the prosthesis while on bedrest. Six months later he is now walking and improving. Another example is PF4 who had extreme edema almost doubling the circumference of his legs. These complications alone appear to affect each individual's gait characteristics, regardless of the diagnosis of diabetes or amputation. It is difficult to determine how these conditions may have affected the subjects during the two different data collections.

This study raised more questions: Does limiting the ankle medio-lateral motion eliminate the ankle strategy and increase demand from the hip strategy? This is illustrated by the increased step width and increased medial inclination angle. Dynamic ankle strategy has not been evaluated. Using an above-ankle device to limit ankle motion during gait may provide a useful evaluative tool to measure this. A second question arose: what are the most important clinical parameters to assess when deciding between a below- or above-ankle design? The TUG score may be a reliable measure but needs to be further investigated. Other questions for future study include, 'How joints interact with one another?', 'How does surgical technique affect outcome?', and finally, 'How does the orthosis affect energy expenditure?'

CHAPTER VI

CONCLUSION

Partial foot diabetic patients exhibit gait imbalance and asymmetries. Appropriate orthotic intervention is difficult to determine. Previous studies have demonstrated the functional impairments of TMA patients and expressed a need for improved orthotic designs and performance. This study evaluated the effectiveness of a low-profile AFO design in combination with rocker sole and custom insole to evaluate the effects on plantar pressure distribution, balance, symmetry and patient acceptance.

Our results suggest that changes between the below- and above-ankle devices are individually specific. Only one subject (PF3) demonstrated a 'noticeable balance improvement' with the above-ankle device. This subject also had the greatest clinical Timed-Up-and-Go score. Most subjects had improved step length symmetry with the above-ankle design. Vertical GRF of the involved and uninvolved limbs were affected with the above-ankle device, but the results were not consistent.

The first priority in diabetic care is protection from ulceration. The peak plantar pressures and loading rate, although not proven to be related to ulcer generation, reduced in only one PF subject. Mueller et al found that peak plantar pressure is most reduced with the use of an AFO, custom insert and rocker bottom sole, but reported patient complaints about the inability to move their ankles. Patient satisfaction of the above-ankle device was low with similar complaints of difficulty in donning and discomfort due

to reduction in ankle motion. The benefits of the device must outweigh the disadvantages of wearing an orthosis.

The fragile medical condition of this population warrants interdisciplinary teamwork and individually specific evaluations and treatments. It is difficult to draw conclusions from this study due to the small sample size and lack of patient compliance during the 'break in' schedule. There remains a need to find a comfortable, low-profile design that allows some ankle mobility but still provides strength and durability to support terminal stance.

APPENDIX A
ABBREVIATIONS

Diabetes Mellitus (DM)
Peripheral vascular disease (PVD)
Neuropathic disease (ND)
Transmetatarsal Amputation (TMA)
Range of Motion (57)
Center of Mass (COM)
Center of Pressure (COP)
Anterior/Posterior (AP)
Mediolateral (ML)
Ankle foot orthosis (AFO)

APPENDIX B
ADVERTISEMENTS FOR SUBJECTS

UO Partial Foot Prosthetic Study

Candidates Needed

Effects of Below-Ankle Versus Above-Ankle Partial Foot Prostheses on Gait Imbalance

This study aims to quantify variables to compare the effects of two different partial foot prostheses on individuals with partial foot amputation. We are looking at center of mass relative to center of pressure angles to determine changes in balance, if any. Other parameters include kinematic and kinetic data related to level walking and obstacle crossing as well as plantar pressure changes. The study is a single subject study.

Who is conducting the study:

Data collection: The University of Oregon, Motion Analysis Lab has an eight-camera motion analysis system (Motion Analysis Corp., Santa Rosa, CA) and data will be captured at a sampling rate of 60 Hz. Ground reaction forces will be collected by two force plates (Advanced Mechanical Technology, Inc., Watertown, MA) at a sampling frequency of 960 Hz. Plantar pressures will be measured with an in-shoe sensor system (Tekscan, South Boston, MA).

Patients will be fitted by a certified Orthotist/Prosthetist at a local clinic with a below the ankle custom partial foot prosthesis fabricated with plastizote, poron, and a base of puff posted to neutral including a toe filler. Shoes will be fitted to sound side and partial foot prosthesis will be fitted to the shoe and foot. The shoes will be modified with rocker bottom soles.

The above the ankle prosthesis will include the same below the ankle partial foot prosthesis fitted onto an AFO and fitted into the same shoes with rocker bottom soles.

- ❖ We would appreciate any assistance in finding individuals with partial foot amputation due to diabetes.

Inclusion criteria for patient sample include:

- Ages 30-70
- Diabetes mellitus
- Healed transmetatarsal amputation
- Ankle ROM within normal limits
- Independent ambulation without an assistive device such as a cane or walker

Exclusion criteria

- No history of head trauma
- No history of cerebrovascular accident
- No history of vestibular dysfunction
- No visual impairment uncorrectable by lenses
- No musculoskeletal diagnosis that could account for imbalance.

Thank you for your time and your contribution to our study. Please feel free to contact us with any questions or concerns.

APPENDIX C

HIPPA FORM

AUTHORIZATION FORM FOR RESEARCH DISCLOSURE
OF PERSONAL HEALTH INFORMATION

By my signature below,

I authorize _____ D.P.M./M.D./N.P./ Primary Care
Practitioner to release to Li-Shan Chou, Ph.D. and assistants to have access to the
following medical records:

___ Demographic information, including your name, address, phone number.

We will use the medical records containing your personal health information to study
patients' function with two different partial foot prostheses.

This authorization will expire at the end of the research study.

This authorization can be revoked at any time by delivering a revocation in writing to the
Health Care Provider named above and that the revocation will be effective except to the
extent (1) research has already been conducted in reliance on my previous authorization
or (58) if necessary to protect the integrity of the research (e.g., to account for a person's
withdrawal from the research).

I realize that Li-Shan Chou, Ph D. and assistants may not be bound by the Privacy Rule
and therefore may not be required by that Rule to maintain the confidentiality of my
personal health information.

The researchers can only use or disclose your health information for purposes approved
by the Institutional Review Board at the University of Oregon or as required by law or
regulations and will continue to protect your personally identifiable health information as
described in the attached Informed Consent Form. Data for each subject will be coded.
Only the principal investigator and graduate students directly involved in this project will
have access to information matching particular data sets to individual subjects.

I understand what this document says and authorizes release of my personal health
information as stated above. I understand I will be given a signed copy of this
Authorization for my records.

Signature of research participant

Date

Print Name

APPENDIX D
LETTER TO PATIENT

Dear

You are invited to participate in a research study designed to gain a better understanding of balance and prosthetic designs for individuals with partial foot amputation. The study, conducted by the University of Oregon, Motion Analysis Lab, will provide information for the development of new and better prostheses. The title of the study is, Effects of Below-Ankle Versus Above-Ankle Partial Foot Prostheses on Gait Imbalance.

Participants will be fitted by a certified Orthotist/Prosthetist at a local clinic with a partial-foot prosthesis and shoes. Here is a general timeline for the study:

First appointment	Appointment at orthotic/prosthetic facility for evaluation and measurement of prosthesis.
2 weeks later	Appointment at orthotic/prosthetic facility for fitting of shoes and prosthesis, shoes then need to be modified with rocker sole.
1 week later	Appointment at orthotic/prosthetic facility for follow-up and fitting of shoes.
1 week later	Appointment at University of Oregon Motion Analysis Lab for gait data collection.
2-3 months later	Appointment at the University of Oregon for second gait data collection.
6 months later	Phone call for final follow-up to ask your opinions of the prostheses.

During both visits to the Motion Analysis Lab your body movement will be recorded during several walking trials. During some walking trials, you will be asked to cross an object with a height similar to a door threshold. In addition, strength of your hip, knee, and ankle muscles of both legs will be measured. You will be asked to wear a pair of paper physical therapy shorts and sleeveless shirt (tank top) during testing.

No financial compensation will be provided. However, patients will receive the prosthesis and shoes with modifications at the completion of their participation. All information will be kept confidential. You must not have had any history of significant head trauma, neurological disorders, visual impairment not correctable with contact lenses or glasses, impairments related to bones, muscles and joints, or persistent symptoms of dizziness, lightheadedness, unsteadiness, or falling.

Please feel free to contact us with any questions or concerns. If you wish to participate, please sign the attached form to release your name and contact information to the researcher, and you will be contacted about participating in the study. Thank you for your time and your contribution to our study.

Li-Shan Chou, Ph.D.
University of Oregon
Motion Analysis Lab
541-346-3391

Sue Ewers, CPO, Graduate student
University of Oregon
Motion Analysis Lab
541-912-7614

APPENDIX E
PRELIMINARY QUESTIONNAIRE

Questionnaire

Please complete the following information to the best of your knowledge.
For Yes/No questions, please circle the appropriate response.

Age _____

Height _____

Weight _____

Diabetes duration _____

Date of amputation _____

Left or right foot: _____

Eyesight

Presence of retinopathy Yes/No

Do you wear glasses/contacts? Yes/No

When did you last see your optometrist? _____

Activity level

Are you able to walk around inside your house? Yes/No

Are you able to walk around outside your home? Yes/No

What kind of work? _____

How many hours/day are you on your feet? _____

What kind of hobbies? _____

Do you normally use an assistive device like a cane? Yes/No

Do you feel unsteady when you walk? Yes/No

Have you fallen since your amputation? Yes/No

If so, when? _____

Do you Smoke? Yes/No

Do you have peripheral neuropathy? Yes/No

Do you have peripheral vascular disease? Yes/No

Do you have heart disease? Yes/No

Do you have renal failure? Yes/No

Do you check your feet regularly? Yes/No

APPENDIX F
PATIENT EVALUATION

Patient Evaluation

Involved side: _____

Length of residual limb = _____ = %
 Length of uninvolved limb = _____

ROM:	Right	Left
Dorsiflexion ROM with knee bent		
Dorsiflexion ROM with knee straight		
Calcaneal inversion		
Calcaneal eversion		

Strength:	Right	Left
Hip flexors		
Hip extensors		
Hip adductors		
Hip abductors		
Knee extensors		
Knee flexors		
Dorsiflexors		
Invertors		
Evertors		
Plantarflexors		

Stance posture:

Photos

Balance Test Scores:

Timed up and go _____

Instruction: stand up from a chair, walk 3 m (*as quickly and as safely as possible without running*), cross a line marked on the floor, turn around, walk back, and sit down

APPENDIX G
TIMED UP AND GO BALANCE TEST

Balance Test

Timed “Up & Go” Test (Posiadlo & Richardson, 1991)

Instruction: stand up from a chair, walk 3 m (*as quickly and as safely as possible without running*), cross a line marked on the floor, turn around, walk back, and sit down

Practice: TUG

1. TUG

Time _____

APPENDIX H
INFORMED CONSENT FORMS

PARTIAL FOOT INFORMED CONSENT

Diabetic Partial Foot Prosthesis Study

You are invited to participate in a research study, which will attempt to determine prosthetic fitting parameters for individuals with a partial foot amputation. The principal investigator, Li-Shan Chou, Ph. D., is a faculty member in Department of Human Physiology at the University of Oregon. You were selected as a possible participant in this study because we are specifically looking at partial foot amputees with diabetes who are active and able to walk without a cane or walker.

If you decide to participate, you will be asked to engage in the following two data collections, one with a below-ankle prosthesis and the second with an above-ankle prosthesis. A 3-month follow up phone call will also be made to determine your satisfaction/dissatisfaction and comments regarding the prosthesis. Each data collection will take approximately 1 ½ hours. All of the data collected is coded and therefore maintains all personal confidentiality.

- a. You will be asked to change into shorts and a tank top to allow joint landmarks to be identified. Medio-lateral dimensions of your thigh, leg and foot will be measured. Your weight and height will be recorded. This will take approximately 5 minutes to complete.
- b. A short manual muscle and range of motion exam will be performed along with a balance test. This should take no more than 20 minutes.
- c. Plantar pressure sensors will be placed inside of your shoes, on top of your insoles. These are thin (0.15mm) and are used to record the pressure distribution under your feet. These will provide information about how the pressure under your feet is distributed. We will also be able to, hopefully, see a change in how the pressure is distributed between the two different prostheses.
- d. Next, 35 reflective markers will be taped in place over bony landmarks on your upper and lower joints. These markers will be used to reflect information to 8 cameras for analysis of walking mechanics. You will be asked to perform three different activities. The first activity involves walking along a 20-foot walkway on level ground. The second activity involves walking along the same walkway over an obstacle. Finally the third activity involves walking and coming to an abrupt stop. The obstacle is similar in height to those ordinarily encountered during daily activities such as a door threshold. The obstacles will be two adjustable upright standards with a crossbar. The total time to complete these tests will be approximately 30 minutes.

There are some possible risks involved for the subject. This includes the possibility of mild muscle soreness after testing. However, the following safeguards will be used to eliminate or minimize these risks:

- To minimize the possibility of residual muscle soreness, subjects will be provided ample time to warm-up their muscles and feel comfortable with the apparatus and testing protocol prior to the collection of any data.
- An assistant will remain close to the subject at all times during testing to monitor subject comfort. Data collection will cease if the subject expresses discomfort.
- There is a small risk that you may fall while walking over the obstacle.

All information will be kept confidential. Computer data files, laboratory notes and videotapes will be archived in a locked filing cabinet. All records will be stored with a code number, not your name and will be kept by the principal investigator in the locked and security regulated Motion Analysis Laboratory.

It is hoped that data from this study can assist in selecting appropriate prostheses as well as improvement in designs of prostheses. Upon completion of the test, you will be offered a copy of the test data, which you may share with your healthcare provider, if desired.

Your participation in this study is entirely voluntary and your decision whether or not to participate will have no bearing on the medical treatment you receive or benefits to which you are otherwise entitled. If you decide to participate, you are free to discontinue participation at any time without penalty or loss of medical treatment or benefits to which you are otherwise entitled. There will be no change in the relationship, quality, current or future care with your medical professionals if you decide to withdraw from the study.

If you have any questions about the research at any time, please call Li-Shan Chou, Ph.D., 340 Gerlinger Annex, (541) 346-3391. If you have any questions about your rights as a participant in a research project, or in the event of a research related injury, please call the Human Subjects Compliance Office, University of Oregon (541) 346-2510. You will be offered a copy of this form to keep.

Your signature below indicates that you have read and understand the information provided above, that you willingly agree to participate, that you may withdraw your consent at any time and discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled, that you will receive a copy of this form, and that you are not waiving any legal claims, rights or remedies.

Print Name _____

Signature _____ Date _____

CONTROL INFORMED CONSENT

Diabetic Partial Foot Prosthesis Study

You are invited to participate in a research study, which will attempt to determine prosthetic fitting parameters for individuals with a partial foot amputation. The principal investigator, Li-Shan Chou, Ph.D., is a faculty member in Department of Human Physiology at the University of Oregon. You were selected as a possible control subject participant in this study because you have similar characteristics such as age, height and weight to other subjects in the study who will be fitted with two different types of partial foot prostheses.

In order to be included in this study you must not have any of the following conditions: diabetes, neurological pathology, history of head trauma, history of cerebrovascular accident, history of vestibular dysfunction, visual impairment uncorrectable by lenses, musculoskeletal diagnosis that could account for imbalance.

If you decide to participate, you will be asked to engage in the following activities during two separate data collection periods. Each data collection will take approximately 1 ½ hours. All of the data collected is coded and therefore maintains all personal confidentiality.

- e. You will be asked to change into shorts and a tank top to allow joint landmarks to be identified. Medio-lateral dimensions of your thigh, leg and foot will be measured. Your weight and height will be recorded. This will take approximately 5 minutes to complete.
- f. A short manual muscle and range of motion exam will be performed along with a balance test. This should take no more than 20 minutes.
- g. Plantar pressure sensors will be placed inside of your shoes, on top of your insoles. These are thin (0.15mm) and are used to record the pressure distribution under your feet. These will provide information about how the pressure under your feet is distributed.
- h. Next, 35 reflective markers will be taped in place over bony landmarks on your upper and lower joints. These markers will be used to reflect information to 8 cameras for analysis of walking mechanics. You will be asked to perform three different activities. The first activity involves walking along a 20-foot walkway on level ground. The second activity involves walking along the same walkway over an obstacle. Finally the third activity involves walking and coming to an abrupt stop. The obstacle is similar in height to those ordinarily encountered during daily activities such as a door threshold. The obstacles will be two adjustable upright standards with a crossbar. The total time to complete these tests will be approximately 30 minutes.

There are some possible risks involved for the subject. This includes the possibility of mild muscle soreness after testing. However, the following safeguards will be used to eliminate or minimize these risks:

- To minimize the possibility of residual muscle soreness, subjects will be provided ample time to warm-up their muscles and feel comfortable with the apparatus and testing protocol prior to the collection of any data.
- An assistants will remain close to the subject at all times during testing to monitor subject comfort. Data collection will cease if the subject expresses discomfort.
- There is small risk that you may fall while walking over obstacles.

All information will be kept confidential. Computer data files, laboratory notes and videotapes will be archived in a locked filing cabinet. All records will be stored with a code number, not your name and will be kept by the principal investigator in the locked and security regulated Motion Analysis Laboratory.

It is hoped that data from this study can assist in selecting appropriate prostheses as well as improvement in designs of prostheses. Upon completion of the test, you will be offered a copy of the test data, which you may share with your physician, if desired.

Your participation in this study is entirely voluntary and your decision whether or not to participate will have no bearing on the medical treatment you receive or benefits to which you are otherwise entitled. If you decide to participate, you are free to discontinue participation at any time without penalty or loss of medical treatment or benefits to which you are otherwise entitled.

If you have any questions about the research at any time, please call Dr. Li Shan Chou, 340 Gerlinger Annex, (541) 346-3391. If you have any questions about your rights as a participant in a research project, or in the event of a research related injury, please call the Human Subjects Compliance Office, University of Oregon (541) 346-2510. You will be offered a copy of this form to keep.

Your signature below indicates that you have read and understand the information provided above, that you willingly agree to participate, that you may withdraw your consent at any time and discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled, that you will receive a copy of this form, and that you are not waiving any legal claims, rights or remedies.

Print Name _____

Signature _____ Date _____

APPENDIX I

CONTROL HEALTH HISTORY QUESTIONNAIRE

Control Health History Questionnaire

This brief questionnaire is used to verify some of the information discussed in the phone interview. If you answer yes to any question, and your current daily function is moderately or significantly impaired due to that condition, physician approval will be required for participation in the study.

Print Name: _____ Age: _____ Height: _____ Weight: _____

Have you been under recent medical care for any of the following conditions?

1. Diabetes? _____ Yes _____ No

2. Neurological disorder? _____ Yes _____ No
If yes, is your daily function moderately or significantly impaired?

3. A significant head injury? _____ Yes _____ No
If yes, is your daily function moderately or significantly impaired?

4. Heart disease or blood vessel disorder? _____ Yes _____ No
If yes, is your daily function moderately or significantly impaired?

5. Vision impairment that is uncorrected by glasses? _____ Yes _____ No
If yes, is your daily function moderately or significantly impaired?

6. Muscle, joint or other orthopedic disorder? _____ Yes _____ No
If yes, is your daily function moderately or significantly impaired?

7. Persistent vertigo, lightheadedness, unsteadiness, or falling? _____ Yes _____ No
If yes, is your daily function moderately or significantly impaired?

Signature _____

Date: _____

APPENDIX J
FOLLOW-UP QUESTIONNAIRE

Follow-up Questionnaire

(Adapted from Prosthetic Profile of the Amputee – telephone version)

The questionnaire contains about 10 questions. If needed do not hesitate to ask me to repeat any of the questions or choice answers anytime throughout the questionnaire.

1. I will give you a choice of 5 answers to describe your satisfaction with respect to the comfort, the appearance and the weight of your orthosis, as well as your satisfaction regarding the appearance of your gait with your prosthesis.

- 1=not at all satisfied
- 2=slightly satisfied
- 3=moderately satisfied
- 4=quite well satisfied
- 5=completely satisfied

- a) with respect to the comfort of your prosthesis, would you say you are...?
- b) concerning the appearance (or the look) of your prosthesis, would you say you are ...?
- c) concerning the weight of your prosthesis, would you say that you are ...?
- d) and concerning the way you walk with the prosthesis(or the appearance of gait), would you say you are ...?

2. The question I am going to ask you now has to do with the ADAPTATION (in the sense of “getting used to ...”) to your amputation and to your prosthesis. We know that this ADAPTATION can be more difficult for some people than for others and it is not always easy to evaluate. So, amongst a choice of 5 answers that I will read to you, choose the one which best describes your level of ADAPTATION TODAY.

- 1=not at all adapted
- 2=a little adapted
- 3=moderately adapted
- 4=quite well adapted
- 5=completely adapted

- a) concerning your amputation, would you say that you are ...?
- b) concerning your below-ankle prosthesis, would you say that you are ...?
- c) concerning your above-ankle prosthesis, would you say that you are ...?

3. The next set of questions will be asked twice. There was a choice of four answers:

- 1=no you are not able
- 2=yes if someone helps you
- 3=yes if someone is near you
- 4=yes alone

- a) get up from a chair with your prosthesis
- b) pick up an object from the floor when you are standing with your prosthesis
- c) get up from the floor with your prosthesis (example: if you fell)

- d) walk in the house
- e) walk outdoors on even ground
- f) walk outdoors uneven ground (on grass, gravel, slope...)
- g) walk outdoors in inclement weather (snow, rain, ice)
- h) walk upstairs with handrail
- i) walk downstairs with handrail
- j) step up a sidewalk curb
- k) step down a sidewalk curb
- l) walk upstairs without handrail
- m) walk downstairs without handrail
- n) walk while carrying an object

4. When you move about, approximately what percentage of your moving is done 0%, 25%, 50%, 75% or 100%

- a) in a wheelchair
- b) walking with the prosthesis
- c) walking without the prosthesis

5. What prevents you from using the prosthesis. Answer 'yes or no'.

- a) is it because walking with the prosthesis is not fast enough
- b) because it is too tiring
- c) is it when distances to cover are too long
- d) is it because of problems with your non-amputated leg
- e) because of problems caused by the prosthesis
- f) because of stump problems (wounds)
- g) because you are afraid of falling
- h) is there another reason

6. When walking with your prosthesis, approximately what distance can you cover without stopping?

- a) no limitations
- b) one block
- c) 30 steps
- d) between 10-30 steps
- e) less than 10 steps
- f) you do not walk

7. Do you have to concentrate on every step you take when you walk with your prosthesis?

8. Do you feel more or less balanced while using the below-ankle prosthesis?

9. Do you feel more or less balanced while using the above-ankle prosthesis?

10. Which do you feel improves your comfort while walking?

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