VISVESVARAYA TECHNOLOGICAL UNIVERSITY

BELGAUM-590014

A SEMINAR REPORT ON

Redistributing the Pressure of Prosthetic Systems

SUBMITTED BY

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APRIL 2019

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CERTIFICATE

Certified that the technical seminar report entitled **"Redistributing the Pressure of Prosthetic Systems"** is a bonafide work carried out by **Mr.ELANGESHWARAN K** bearing **USN – 1DS15ML008** in partial fulfillment of the seminar in 8^{th} semester **Bachelor of Engineering** in **Medical Electronics** of **Visvesvaraya Technological University**, Belgaum during the academic year 2018 – 2019. It is certified that all corrections/suggestions indicated for internal assessment have been incorporated in the report. The seminar report has been approved as it satisfies the academic requirements with respect to technical seminar work prescribed for the mentioned degree.

Name of the Evaluators	**Signature with Date**
1.______________________	______________________
2. ______________________	______________________

Seminar Coordinator **Signature of HOD**

AKNOWLEDGEMENT

I express my deep sense of gratitude and indebt-ness to the institution "**DAYANANDA SAGAR COLLEGE ENGINEERING, Bangalore**", which provided me an opportunity for successful completion of the seminar.

I express my deep sense of gratitude to **Dr. C P S PRAKASH** , Principal, Dayananda Sagar College of Engineering for providing an opportunity to do this technical seminar as a part of curriculum in the partial fulfillment of the degree course.

My sincere gratitude to beloved Head of Department (Medical Electronics Engineering) **Dr. V G SANGAM** for invaluable co-ordination extended by him towards the completion of the seminar.

I am extremely thankful to my guide **Prof. SAHANA M KULKARNI** Dept. of Medical Electronics Engineering, Dayananda Sagar College of Engineering for his skillful guidance, constant supervision, timely suggestion and constructive criticism in successful completion of the seminar.

ABSTRACT:

Amputation of a limb by trauma, medical illness or surgery. It is done to stop the disease process from furthermore affecting the limb, such as malignancy or gangrene and control pain. Limb amputation affects 1.7 million people in the United States. Half among them have experienced a below knee amputation. The prosthetic legs has been of a great use by the amputees which provides them better mobility and increases the chances of returning back to their regular routine, these systems have limitations[3]. Many users experience pain and discomfort while using the current designs of prosthetic limbs, including the pin lock, suspension sleeve systems , and elevated vacuum[1][3]. The goal of this work is to develop a prosthetic system below knee which will reduce the discomfort experienced by the user at the distal end of the residual limb, thus improving quality of life. To examine the source of discomfort on a prosthetic system below knee, a static and dynamic model of the user's impact force during the gait cycle was developed[2]. The two sources of impact force were investigated, which are the impact of the residual limb contacting the bottom of the socket and the impact of heel strike during the gait cycle[2]. The results computed from the static and dynamic model indicate that the impact force due to the residual limb contacting the bottom of the socket is negligible when compared to the impact force generated at heel strike, which were consistent with both the analysis of measured forces obtained using force plates, and later studies that analyzed the impact forces of trans-tibial amputees during their gait cycle using force plates[1]. Aspects of this ongoing effort include evaluating and refining the current testing methods, along with conducting more tests to determine whether the new designs reduce pressure and discomfort in future[1].

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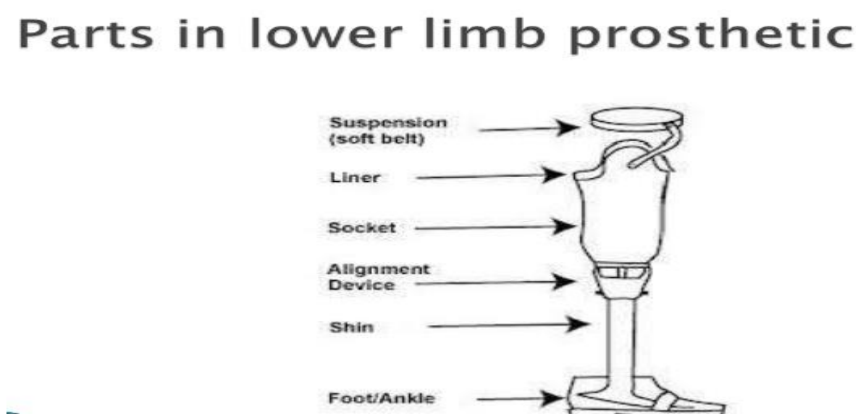
INTRODUCTION

Amputation is the removal of a limb by trauma, medical illness, or surgery. As a surgical measure, it is used to control pain or a disease process in the affected limb, such as malignancy or gangrene. In some cases, it is carried out on individuals as a preventative surgery for such problems. There are many reasons an amputation may be necessary. The most common is poor circulation because of damage or narrowing of the arteries, called peripheral arterial disease. Without adequate blood flow, the body's cells cannot get oxygen and nutrients they need from the bloodstream. As a result, the affected tissue begins to die and infection may set in.

Other causes for amputation may include:

- Severe injury (from a vehicle accident or serious burn, for example)
- Cancerous tumor in the bone or muscle of the limb
- Serious infection that does not get better with antibiotics or other treatment
- Thickening of nerve tissue, called a neuroma
- Frostbite

From research it is considered that 43% of all amputations that occur are below knee amputations. After receiving the amputation, most of these amputees decide to adopt the use of a prosthetic in order to increase their mobility and restore their routine work. A prosthetic is an artificial mechanical device that can either substitute or supplement a missing or defective body part in order to replace the function of the amputed body part up to a certain extent. An example of a below knee prosthetic can be seen in Figure 1, along with the defined components that make up the system.



Though the prosthetic provides a greater level of mobility for the amputee, the system still has its limitations. The primary affecting factor being that users may experience discomfort at the distal end of their residual limb due to the impact forces generated during the gait cycle. This issue has been addressed by making alterations in both the socket and liner, or the respective components individually[4]. However, even with these modified sockets and liners, users still report of experiencing discomfort at the distal end of their residual limb. Therefore, a system analysis of the prosthetic system needed to be performed in order to determine the exact cause of this discomfort[3].

LITERATURE SURVEY

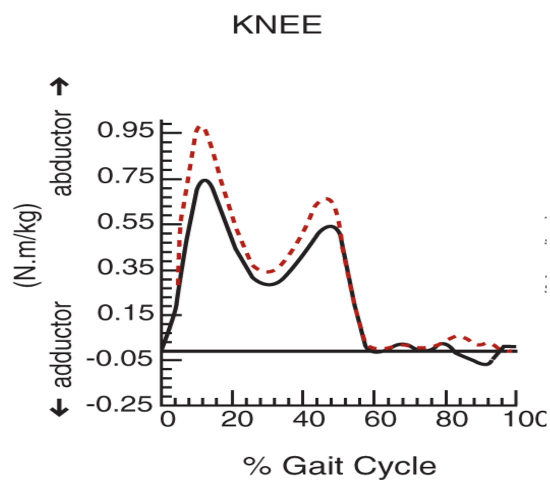
TITLE	AUTHORS	FEATURES	OUTCOMES
Techniques for Interface Stress Measurements within Prosthetic Sockets of Transtibial Amputees: A Review of the Past 50 Years of Research	Ebrahim A. Al-Fakih 1,*, Noor Azuan Abu Osman 1 and Faisal Rafiq Mahmad Adikan 2	The distribution of interface stresses between the residual limb and prosthetic socket using a variety of measurement techniques used for the past 50 years and finding out their advantages & disadvantages, to find a better measurement tool.	A review the operating principles, advantages and disadvantages of conventional and emerging techniques used for interface stress measurements inside transtibial sockets and arriving at a new effective stress measurement tools.
Gait Motion Analysis in the Unrestrained Condition of Trans-Femoral Amputee with a Prosthetic Limb*	Yuichiro Hayashi, Nobutaka Tsujiuchi, Takayuki Koizumi, Ryuji Uno, Yasushi Matsuda, Youtaro Tsuchiya and Yoshio Inoue	The ground reaction forces and kinematic parameters applied on trans-femoral prosthesis are measured by the prosthetic gait motion analysis system using mobile force plate and altitude sensor for the unrestrained gait measurement using force plates and altitude sensors. Proving the	The patterns of antero-posterior axis ground reaction forces and joint moments about the medio-lateral axis are remarkably different among the five activities.

		effectiveness of the developed prosthetic gait training system to consider biomechanics and kinematics in trans femoral prosthesis.	
Dual Mode Pressure Sensing for Lower-Limb Prosthetic Interface †	Maurizio Rossi 1,*, Matteo Nardello 1, Leandro Lorenzelli 2 and Davide Brunelli 1	Electronic sensory system capable of measuring both dynamic and static normal pressure to monitor the pain and stress felt by amputees on contact points between residual limb and prosthetic sockets. Here piezoelectric and piezoresistive materials to detect and to discriminate dynamic and static stimuli, and a digitally controlled amplification circuit that permits the signal acquisition from both kind of transducers with microcontroller.	This design provides valuable information at 1 ksps rate with a global power consumption lower than 25 mW. It can measure both dynamic and static normal pressure.
Redistributing the	Blaize Majdic,	The goal of this work	New designs reduce

Pressure of Prosthetic Systems	Danielle Wilson, Thomas Barrett, Elise Barrella, Heather McLeod	is to develop a below-knee prosthetic system which will reduce the discomfort experienced by the user. Two sources of impact force are investigated. Many design concepts have been developed and tested, which focus on the redistribution of forces experienced due to heel strike.	pressure and discomfort. Refining the current testing methods and materials used to reduce pressure at the point of contact of the residual limb socket.

PROBLEM STATEMENT & ANALYSIS

The target user is a middle-aged adult, below knee amputee with a basic activity level to fulfill their everyday needs such as walking and going upstairs. Here the design is for a user of weight 128kg because this is the weight limit for aluminum pylons. Static and dynamic mathematical models to understand the impact forces applied at the bottom of the socket during the gait cycle are created[2]. The first force being the impact force of the user's heel making contact with the ground, and the other force is a result of the limb making contact with the bottom of the socket, due to pistoning type force experienced within the socket the impact force seen at heel strike being the area of focus that had to be altered during the gait cycle[2][5]. To do this data was collected using force plates[1]. An example data is shown below in Figure2.



This represents the ground reaction forces on prosthetic limb while walking in a straight line. It is identified that the impact forces seen at three key points within the gait cycle. The first peak is the force at heel strike during gait[2]. The valley represents the force seen at mid-stance, where the user's foot is flat on the ground and the second peak is the force seen during toe push off during the gait[2]. The force profile over the prosthetic limb resembled that of an able-bodied person. A model that generalizes this force profile based on the user's weight and walking speed is designed the data was resolved for each trial to account for the force in the X, Y, and Z direction. The data was then normalized to eliminate the weight of the user, so that the model could be applied to all individuals[3][4]. A single gait cycle impact force profile per person was averaged and was then combined into one graph, as shown in Figure3.

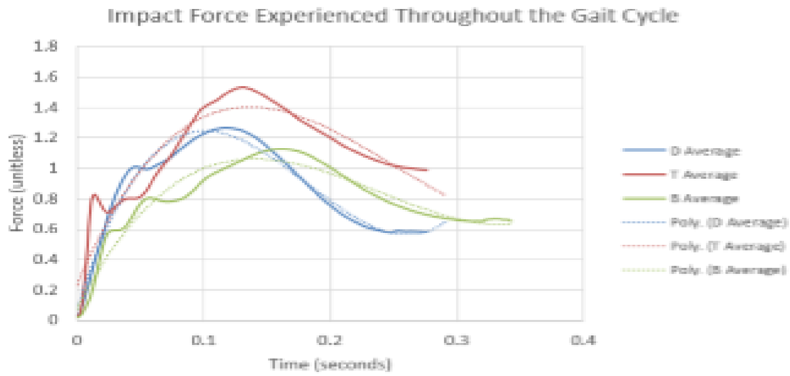


FIGURE 3
AVERAGE IMPACT FORCE FOR EACH TEAM MEMBER USING NORMALIZED DATA

The trendline was graphed using a 3rd degree polynomial. The data set with the best R2 value was selected, which was D average profile. From this graph the impact forces experienced during gait cycle is given by the equation below

$$y = 334.9x3 - 181.81x2 + 26.507x + 0.0772$$

In this equation, y is a unit less metric and x is the time in seconds. This equation will be used to determine the maximum impact force that should be applied to each design during testing, by multiplying the resulting y value by the established user's weight.

METHODOLOGY

Using alternative design

The main goal was to reduce the force of impact that the user experiences at the distal end of their residual limb[4][5]. Therefore redesigning the connection of the pylon with the socket has to be more concentrated so the four concepts were considered which are generated and tested.

Figure 4 shows the four traditional concept designs

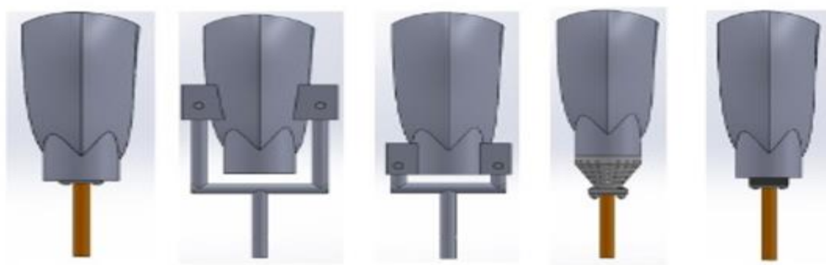


FIGURE 4
CONCEPTS PICTURED FROM LEFT TO RIGHT: DATUM DESIGN OF A TRADITIONAL SYSTEM, OPEN BOTTOMED SOCKET-UPPER CONNECTION (OBS-UC), OPEN BOTTOM SOCKET-LOWER CONNECTION (OBS-LC), HONEYCOMBED PYLON CONNECTOR (HPC), AND SHOCK ABSORBING SORBOTHANE LAYER (SASL).

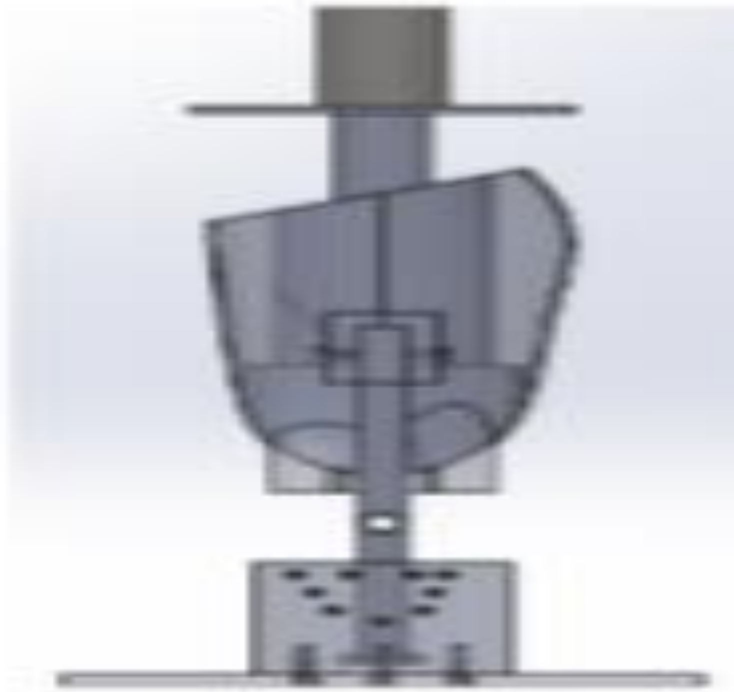
The Open Bottomed Socket-Upper Connection (OBSUC) and Open Bottomed Socket-Lower Connection (OBSLC) concepts were both designed with the idea of relocating the socket-pylon connection point to an alternate location. The Honeycombed Pylon Connector (HPC) concept is meant to provide a connection between the socket and pylon that more evenly distributes the impact force from heel strike along the edges of the socket. Lastly, the Shock Absorbing Sorbothane Layer (SASL) is meant to reduce the impact force that is experienced at the bottom of the socket, its unique properties that allows it to absorb an impact force. Hence, considering on implementing the material into the other designs in some regards. After these concepts were generated in SolidWorks, they were then 3D printed using P430 ABS plastic. These physical designs serve as the basis for our initial testing[5].

Testing Methods

In order to test the whether the design actually reduces pressure at the bottom of the socket while walking. An experiment that was conducted by Curtze, Hof, et al where they analyzed the ground reaction forces that were associated with different types of prosthetic feet throughout the various stages of the gait cycle. In this experiment a fixed mass was placed on a straight metal loading device that resembles a human leg. With the rig connected to a prosthetic foot, it was then rotated manually over a force plate where the ground reaction forces were recorded. The results explained ground reaction forces at heel strike that were similar in magnitude to that of a prosthetic user.

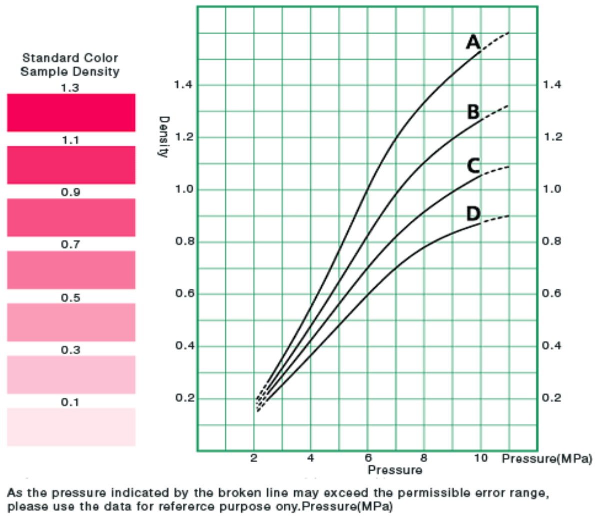
Using this as a reference similar testing rig was developed that would allow the pressure experienced at the distal end of the residual limb to be measured however it was not able to test the various stages of the gait cycle but only during vertical (static) loading[2]. Instead, the concepts were tested in static loading at an angle of 0 to represent the mid-stance of the gait cycle, at loading values of 275lbf, 225lbf, and 175lbf. The resulting pressures were compared to the data to find out whether the pressure in the system is distributed evenly over the residual limb.

A method was later developed to test the pressure impact on the residual limb where Fugi prescale pressure film was used. Similar to litmus paper, when the film is placed between two contact surfaces, where a force is applied, the paper changes color to indicate the amount of pressure experienced. Placing a 1.75” x 1.5” piece of pressure film between the 3D printed limb and the inside of the socket, the pressure experienced at the distal end of the residual limb could be attained. The pressure at the distal end of the limb was measured thrice with various weights[1].



RESULTS

The pressure readings was done through visual inspection. Where the concentrated areas of pressure experienced by the Fujifilm specimens were determined, along with average maximum pressure experienced for each concept under the various loading conditions. The pressure is determined by the color intensity chart that correlates the color intensity of the paper to the experienced pressure value. Figure5 shows the fuji colour intensity chart.



The pressure film's area was divided into 5 key areas

- front right (FR)
- bottom right (BR)
- bottom left (BL)
- front left (FL)
- center (C)

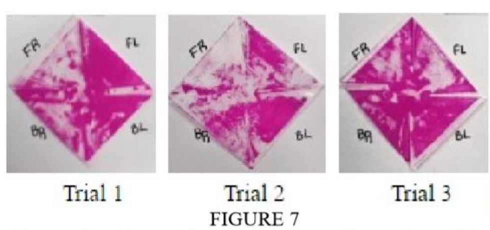


FIGURE 7
PRESSURE FILM RESULTS FOR TRIALS 1-3 OF THE DATUM DESIGN WHEN LOADED AT 275LBF

the result is such that more than 50% of that area was discolored, the predominant color value was logged for that region and recorded . If the area did not experience pressure that resulted in at least 50% of the area being discolored, then that region was logged as white in Figure8

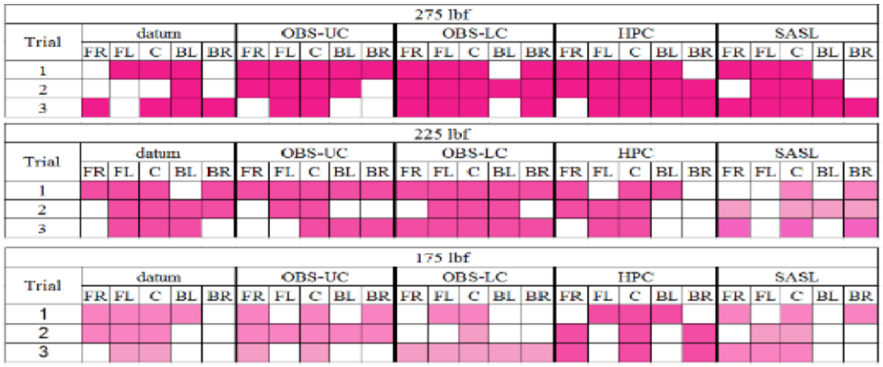
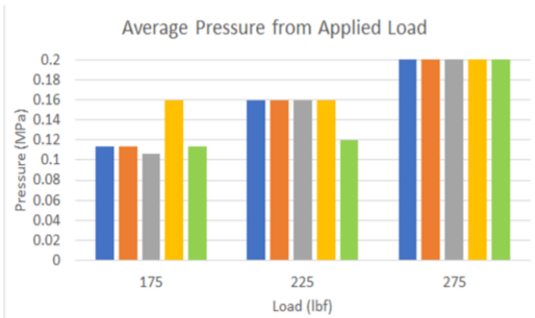


FIGURE 8
PRESSURE CONCENTRATION REGIONS IDENTIFIED FOR EACH CONCEPT WHEN APPLIED DURING DIFFERENT LOADING SCENARIOS

average maximum experienced pressure for each concept at 175lbf, 225lbf, and 275lbf of applied load. These results can be seen below in Figure 9



Discussion

- Analysis of three loading scenarios

  At 275lbf, the SASL design was seen to experience the same amount of pressure as the other designs. This trend was also seen at the applied load of 175lbf. However, at an applied load of 225lbf, the experienced pressure of the SASL design was seen to be significantly as less as 25% than that of the other designs.

  HPC design was seen to experience a higher pressure reading than all the other designs

- Analysis of pressure distribution

  Firstly, with an applied force of 275lbf, the datum appears to perform the best when compared to the other designs. However, with an applied load of 225lbf, the SASL design seems to perform the best.

- Limitations

  Dynamic testing was unable to be performed, due to the lack of appropriate equipment.

CONCLUSION

Based on the promising pressure distribution results of the SASL design, and the idea that there may be an effective loading range, additional testing needs to be performed on this design.

HPC design needs to be slightly revised to fit its intended purpose. Due to the geometry of the design, the experienced forces are unable to travel along the outer walls of the socket.

the top of this component needs to be redesigned so that the flat top is removed, and the honeycomb structure can connect directly to the outer walls of the socket.

REFERENCES

1. “Techniques for Interface Stress Measurements within Prosthetic Sockets of Transtibial Amputees: A Review of the Past 50 Years of Research” Ebrahim A. Al-Fakih 1,*, Noor Azuan Abu Osman 1 and Faisal Rafiq Mahmad Adikan 2 Received: 18 March 2016; Accepted: 2 June 2016; Published: 20 July 2016
2. “Gait Motion Analysis in the Unrestrained Condition of Trans-Femoral Amputee with a Prosthetic Limb*” Yuichiro Hayashi, Nobutaka Tsujiuchi, Takayuki Koizumi, Ryuji Uno, Yasushi Matsuda, Youtaro Tsuchiya and Yoshio Inoue
3. Robert Gailey PhD, P. T. (2008). “Review of secondary physical conditions associated with lower-limb amputation and long-term prosthesis use.” Journal of rehabilitation research and development, 45(1), 15.
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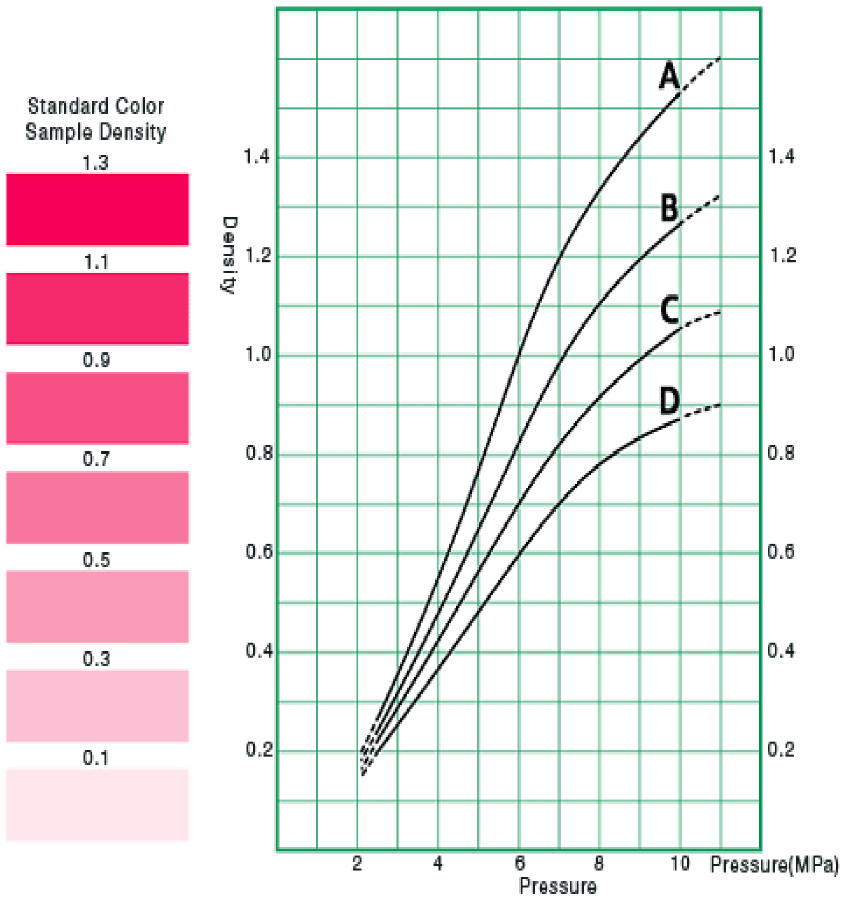
ANNEXURE

Fuji prescale intensity chart

Product	Product Code	Pressure range [MPa] 1MPa≒10.2kgf/cm^2 0.05 0.2 0.5 0.6 2.5 10 50 130 300 7.25 29 73 87 363 1,450 7,250 18,850 43,500 Pressure range [psi] 1psi≒6895pa	Product Size W(mm) x L(mm)	Type
Super High Pressure (HHS)	PRESCALE HHS PS 270X200 5S-E		270 x 200 Five Sheets	Mono-sheet
High Pressure (HS)	PRESCALE HS PS 270X200 5S-E			Mono-sheet
Medium Pressure (MS)	PRESCALE MS PS 270X200 5S-E			Mono-sheet
Low Pressure (LW)	PRESCALE LW PS 270X200 5S-E			Two-sheet
Super Low Pressure (LLW)	PRESCALE LLW PS 270X200 5S-E			Two-sheet
Ultra Super Low Pressure (LLLW)	PRESCALE LLLW PS 270X200 5S-E			Two-sheet



As the pressure indicated by the broken line may exceed the permissible error range, please use the data for refererce purpose ony.Pressure(MPa)

Redistributing the Pressure of Prosthetic Systems

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Abstract – **Limb amputation currently affects 1.7 million people in the United States. Approximately half have experienced a below knee amputation. While current prosthetic leg designs provide amputees with increased mobility, these systems have limitations. Many users experience pain and discomfort while using the current prosthetic designs, including the pin lock, elevated vacuum, and suspension sleeve systems. The goal of this work is to develop a below-knee prosthetic system which will reduce the discomfort experienced by the user at the distal end of the residual limb, thus improving quality of life. To examine the source of discomfort, a static and dynamic model of the user's impact force during the gait cycle was developed. Two sources of impact force were investigated, the impact of the residual limb contacting the bottom of the socket, and the impact of heel strike during the gait cycle. Computational results from the static and dynamic model indicate that the impact force due to the residual limb contacting the bottom of the socket is negligible when compared to the impact force generated at heel strike. These results were consistent with both the analysis of measured forces obtained using force plates, and other studies that analyzed the impact forces of trans-tibial amputees during their gait cycle using force plates. Various design concepts have been developed and tested, which focus on the redistribution of forces experienced due to heel strike. Future aspects of this ongoing effort include evaluating and refining the current testing methods, along with conducting more tests to determine whether the new designs reduce pressure and discomfort.**

Index Terms – Amputee, Gait cycle, Pressure Distribution, Prosthetics

INTRODUCTION

From research, 43% of all amputations that occur are below knee amputations [1]. After receiving the amputation, some of these amputees decide to adopt the use of a prosthetic in order to increase their mobility. A prosthetic is an artificial device that can either substitute or supplement a missing or defective body part. An example of a below knee prosthetic can be seen in Figure 1, along with the defined components that make up the system [2].

While the prosthetic provides a greater level of mobility for the amputee, the system still has its limitations. The primary one being that users may experience discomfort at the distal end of their residual limb due to the impact forces

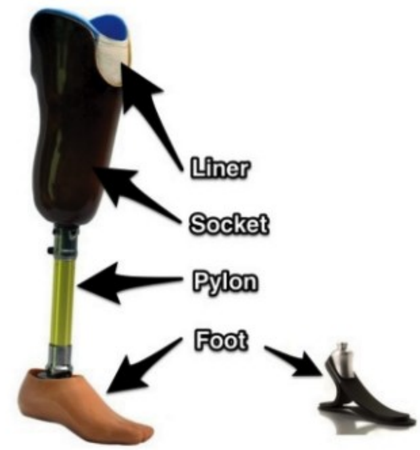

FIGURE 1
LABELED BELOW KNEE PROSTHETIC SYSTEM

that are generated during the gait cycle. Traditionally, this issue has been addressed by making alterations to both the socket and liner, or the respective components individually. However, even with these modified sockets and liners, users still report that they are experiencing discomfort at the distal end of their residual limb [3]. Therefore, a system analysis of the prosthetic system needed to be performed in order to determine the exact cause of this discomfort.

PROBLEM ANALYSIS

Before beginning work on the conceptual design phase of this project, the team needed to identify a target user and gain a better understanding of the forces that are involved with a prosthetic system. The target user is a middle-aged adult, below knee amputee with a basic activity level to fulfill the everyday needs of an amputee such as walking and going upstairs. After talking with a prosthetic physician, the team decided to design for a user weight of 275lbf because this is the weight limit for aluminum pylons.

Once the target user was determined, the team created static and dynamic mathematical models to understand the impact forces applied at the bottom of the socket during the gait cycle. The first force being the impact force of the user's heel making contact with the ground, and the other force is a result of the limb making contact with the bottom of the socket, due to pistoning experienced within the socket. These models determined the force caused by pistoning to be negligible. With the impact force seen at heel strike being the area of focus, the team wanted to understand how that force changes throughout the gait cycle. To do this, the team collected data for each team member, using force plates. An example of this collected data can be seen in Figure 2.

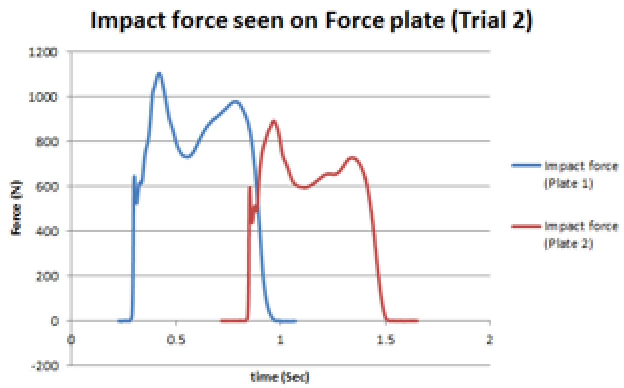

FIGURE 2
IMPACT FORCE OF AN ABLE-BODIED SUBJECT'S GAIT CYCLE

From the figure above, it can be seen that both legs resemble similar impact patterns. Within these patterns, the team identified the impact forces seen at three key points within the gait cycle. The first major peak is the force seen at heel strike. The valley is the force seen at mid-stance, where the user's foot is flat on the ground. The second major peak is the force seen during toe push off. With these profiles being for able-bodied people, the question is how does this profile resemble that of amputees. Several studies plotted the impact forces seen on both sound and above knee prosthetic limbs. The results showed the force profile over the prosthetic limb resembled that of an able-bodied person [4]. With a below-knee amputee's prosthetic limb resembling that of an able-bodied person, it is assumed that the impact force profile is very similar to that of an above-knee amputee. Therefore, with the force profile for able bodied users representing that of below knee amputees, the team created a model that generalizes this force profile based on the user's weight and walking speed.

The team used the data collected by each team member to create a mathematical model to represent the gait cycle. Since the team is assuming all the force from heel strike is transferred to the bottom of the socket, the data was resolved for each trial to account for the force in the X, Y, and Z direction. The data was then normalized to eliminate the weight of the user, so that the model could be applied to all individuals. Due to the fact that the greatest impact force was during heel strike, the team decided to focus on one section of the data, starting from the beginning of the gait cycle and ending at mid-stance. Each individual's data during this time frame was then averaged to obtain a single gait cycle impact force profile per person. The averaged profile per individual was then combined into one graph, shown in Figure 3. The trendline was graphed using a 3rd degree polynomial. The data set with the best R^2 value was selected, which was D average profile.

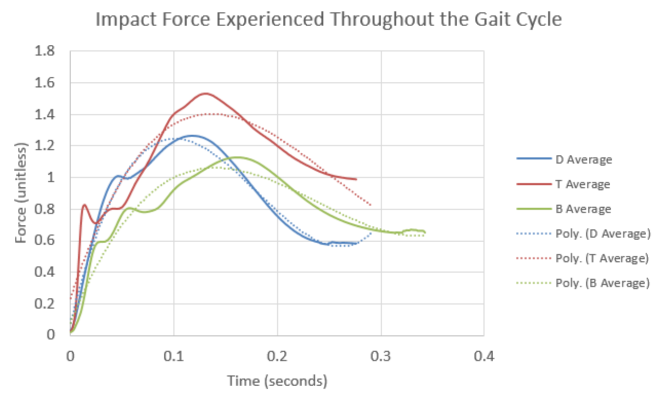

FIGURE 3
AVERAGE IMPACT FORCE FOR EACH TEAM MEMBER USING NORMALIZED DATA

The equation the team arrived at to model the impact forces experienced during the gait cycle can be seen below.

$$y = 334.9x^3 - 181.81x^2 + 26.507x + 0.0772 \qquad (1)$$

In this equation, y is a unit less metric and x is the time in seconds. This equation will be used to determine the maximum impact force that should be applied to each design during testing, by multiplying the resulting y value by the established user's weight.

DESIGN ALTERNATIVES

With the area of discomfort and impact equation established, the next step was to develop concepts that address this issue. When developing these concepts, the main goal was to reduce the force of impact that the user experiences at the distal end of their residual limb. Therefore, the majority of the team's efforts were focused on re-designing how the pylon connects to the socket, so the force could be redistributed to a different area along the socket. With these ideas in mind the, the four concepts seen below in Figure 4 were generated.

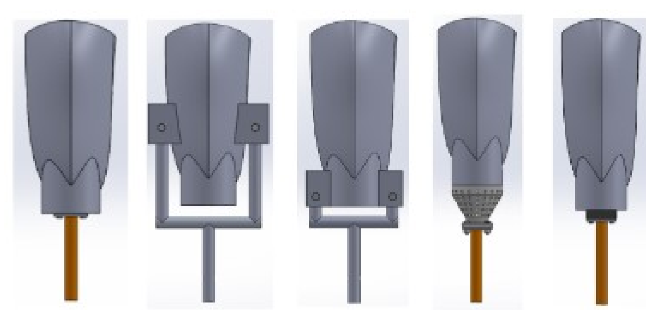

FIGURE 4
CONCEPTS PICTURED FROM LEFT TO RIGHT: DATUM DESIGN OF A TRADITIONAL SYSTEM, OPEN BOTTOMED SOCKET-UPPER CONNECTION (OBS-UC), OPEN BOTTOM SOCKET-LOWER CONNECTION (OBS-LC), HONEYCOMBED PYLON CONNECTOR (HPC), AND SHOCK ABSORBING SORBOTHANE LAYER (SASL).

The Open Bottomed Socket-Upper Connection (OBS-UC) and Open Bottomed Socket-Lower Connection (OBS-LC) concepts were both designed with the idea of relocating the socket-pylon connection point to an alternate location. The Honeycombed Pylon Connector (HPC) concept is meant to provide a connection between the socket and pylon that more evenly distributes the impact force from heel strike along the edges of the socket. Lastly, the Shock Absorbing Sorbothane® Layer (SASL) is meant to reduce the impact force that is experienced at the bottom of the socket. The Sorbothane® material has unique properties that allow it to "absorb" an impact force, so the team is using the SASL concept to test the capabilities of the material. If this concept proves to be effective, it may be worthwhile to consider implementing the material into our other designs in some regards. After these concepts were generated in SolidWorks, they were then 3D printed using P430 ABS plastic. These physical designs will serve as the basis for our initial testing.

METHODS OF TESTING

In order to better understand if the developed prototypes reduce the pressure experienced at the bottom of the prosthetic socket, the team needed to find a way to simulate the impact force profile experienced during walking seen above in Figure 2. To accomplish this task, the team looked at an experiment that was conducted by Curtze, Hof, et al., where they analyzed the ground reaction forces that were associated with different types of prosthetic feet throughout the various stages of the gait cycle [5]. To gather the needed information, a fixed mass was placed on a straight metal loading device that resembles a human leg. With the rig connected to a prosthetic foot, it was then rotated manually over a force plate where the ground reaction forces were recorded. Their results, showed that the developed testing rig produced ground reaction forces at heel strike that were similar in magnitude to that of a prosthetic user.

Using the described study as a reference, a similar testing rig was developed that would allow the pressure experienced at the distal end of the residual limb to be measured. This testing rig can be seen in Figure 5. However, due to the limitations of the available equipment, the developed concepts were not able to be tested at the various stages of the gait cycle but only during vertical (static) loading.

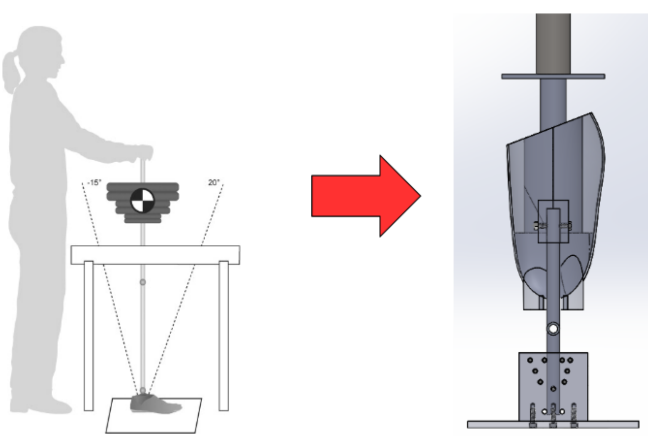

FIGURE 5
PROCESS OF DEVELOPING THE TESTING APPARATUS

Instead, the concepts were tested in static loading at an angle of 0° to represent the mid-stance of the gait cycle, at loading values of 275lbf, 225lbf, and 175lbf. These tests were performed so that the resulting pressure distribution of each concept could be compared to that of the datum. This allows the concepts to be evaluated against the datum, as well as each other, in terms of their ability to redistribute the experienced force to other areas of the residual limb.

After developing a method to apply the desired impact forces, a method was developed to determine the experienced pressure at the bottom of the prosthetic socket. To do this, Fugi prescale pressure film was used. Similar to litmus paper, when the film is placed between two contact surfaces, where a force is applied, the paper changes color to indicate the amount of pressure experienced. Therefore, by placing a 1.75" x 1.5" piece of pressure film between the 3D printed limb and the inside of the socket, the pressure experienced at the distal end of the residual limb could be attained. This dimension was used due to the limited amount of paper, as well as the fact that the primary area of concern is pressure experienced at the distal end of the residual limb. To better understand how this pressure compared among prototypes, each prototype was tested 3 times at each loading value stated above.

RESULTS

Results for the pressure readings was done through visual inspection due to the unavailability of proper analysis tools, as all of them were beyond our budget. Through this method, the concentrated areas of pressure experienced by the Fujifilm specimens were determined, along with average maximum pressure experienced for each concept under the various loading conditions.

In order to analyze the amount pressure experienced by the pressure film, Fuji provides a color intensity chart that correlates the color intensity of the paper to the experienced pressure value. After loading each design, the color intensity produced on the film was visually compared to that of the provided color guide to determine the percent of 0.2MPa pressure experienced during loading. This color intensity chart can be seen below in Figure 6.

Pressure indication chart		
indication color	value indicator	Pressure (MPa)
	1.00	0.20
	0.80	0.16
	0.70	0.14
	0.60	0.12
	0.50	0.10
	0.40	0.08
	0.20	0.04
	0.1	0.02

FIGURE 6
COLOR INTENSITY CHART USED TO VISUALLY DISPLAY THE PRESSURE READINGS EXPERIENCED DURING TESTING

To gain a better understanding of where the majority of pressure was experienced in each design, three trials of loading, for each loading scenario, were performed on each concept. During these trials, the pressure film's area was divided into 5 key areas: front right (FR), bottom right (BR), bottom left (BL), front left (FL) and center (C). An example of the labeled pressure films can be seen below in Figure 7. Upon visual inspection, if an area experienced pressure and more than 50% of that area was discolored, the predominant color value was logged for that region and recorded in Figure 8. If the area did not experience pressure that resulted in at least 50% of the area being discolored, then that region was logged as white in Figure 8.

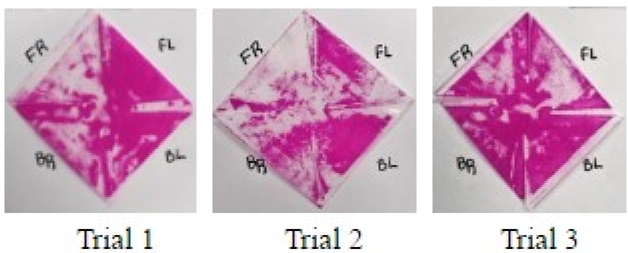

FIGURE 7
PRESSURE FILM RESULTS FOR TRIALS 1-3 OF THE DATUM DESIGN WHEN LOADED AT 275LBF

Using the approach outlined above, the areas of major pressure concentration in Trial 1 of the datum being loaded at 275lbf were identified to be FL, C, and BL. This is due to the fact that more than 50% of these areas showed a color intensity of 1. Thus, the color value for a color intensity of 1 was recorded for those specific areas in Figure 8. For the remaining two areas, being the FR and BR regions, since the experienced pressure did not cause discoloration in at least 50% of these two areas, the recorded color for those areas was white. This process was repeated for each trial of each concept for all three loading scenarios.

With the concentrated areas of pressure identified, the average maximum pressure for each concept was determined to better compare the pressure experienced across the different designs during various loading scenarios. By using the recorded pressure values, the maximum experienced pressure was recorded for each trial and averaged to determine the average maximum experienced pressure for each concept at 175lbf, 225lbf, and 275lbf of applied load. These results can be seen below in Figure 9.

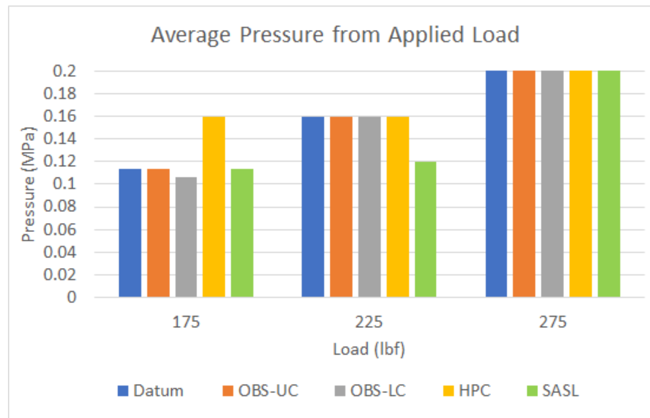

FIGURE 9
AVERAGE PRESSURE EXPERIENCED FOR EACH CONCEPT DURING THE VARIOUS LOAD SCENARIOS

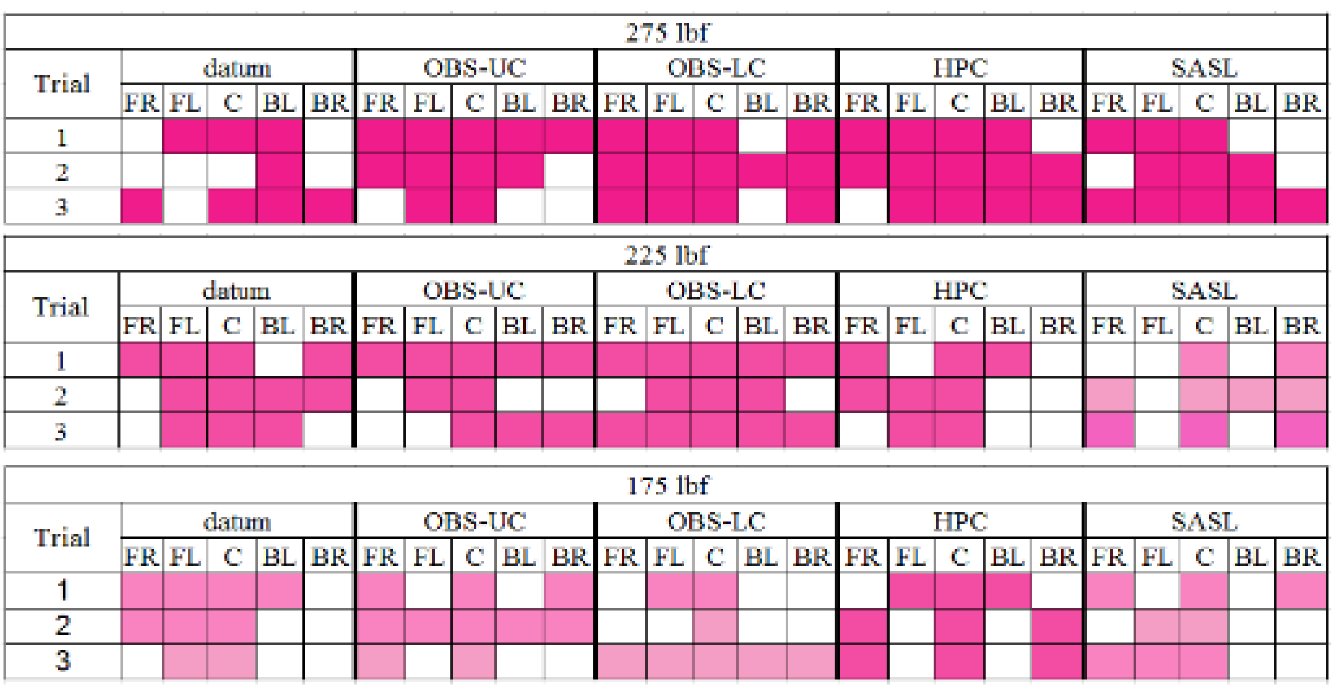

FIGURE 8
PRESSURE CONCENTRATION REGIONS IDENTIFIED FOR EACH CONCEPT WHEN APPLIED DURING DIFFERENT LOADING SCENARIOS

DISCUSSION

I. Analysis of Three Loading Scenarios

After looking at the experienced pressure in each design concept, as seen in Figure 9, as the applied load increased, so did the color intensity of the pressure film, indicating an increase in experienced pressure. One observation worth noting, is that when 275lbf was applied, all designs showed 100% color intensity. This leads the team to believe that the applied load was out of range of the pressure film, as the experienced pressure was greater 0.2MPa.

Another observation that was made during this analysis involved the experienced pressure associated with the SASL design. At 275lbf, the SASL design was seen to experience the same amount of pressure as the other designs. This trend was also seen at the applied load of 175lbf. However, at an applied load of 225lbf, the experienced pressure of the SASL design was seen to be significantly less than that of the other designs, approximately 25% lower. Based on these results, it is believed that there may be an effective loading range for the Sorbothane® material, and that the loads of 275lbf and 175lbf were outside of this range.

The HPC design was seen to experience similar pressure readings to the other designs at applied loads of 275lbf and 225lbf. However, at an applied load of 175lbf, the HPC design was seen to experience a higher pressure reading than all the other designs. This may be due to the geometry of the design, as the top portion of the connector has a flat top that was then attached to the bottom of the socket. This flat top could have negated the intended purpose of the design, which was to redistribute the experienced force along the outer walls of the socket. Instead, the flat top could have redirected the experienced force back to the bottom of the socket, resulting in a greater amount of experienced pressure.

II. Analysis of Pressure Distribution

Based on the areas of pressure distribution, which can be seen in Figure 8, a few key observations can be made. Firstly, with an applied force of 275lbf, the datum appears to perform the best when compared to the other designs. However, with an applied load of 225lbf, the SASL design seems to perform the best. This is due to the fact that it has the fewest areas of affected pressure, in addition to the experienced pressure being the lowest value when compared to the other designs that were tested with this applied force.

III. Limitations

Throughout the course of this research, several limitations were encountered which prevented the team from gathering more conclusive results. The most prevalent limitation is that the project budget consisted of only $1000. This small budget prevented the team from purchasing the necessary equipment that is typically used in the testing of these designs. This budget also impacted the amount of pressure film that was able to be purchased, thus impacting the number of trials that could be done on each concept per loading scenario. Lastly, dynamic testing was unable to be performed, due to the lack of appropriate equipment, which may have provided more conclusive results, as the pressure experienced over time would be able to be quantified and compared across the designs.

CONCLUSION & FUTURE WORK

Based on these findings, there are several conclusions that can be made. Firstly, a different type of pressure film may need to be used for this type of testing. This is due to the fact that 100% color intensity was seen at the load of 275lbf, which was the established weight of an average lower limb prosthetic user. Without being able to gather significant data for this loading scenario, a pressure film with a different range of measurements may be a better option. In addition to using this different pressure film, it would also be beneficial to run more than three trials per concept. This would provide additional data for analysis and allow better interpretation of the results.

Based on the promising pressure distribution results of the SASL design, and the idea that there may be an effective loading range, additional testing needs to be performed on this design. In order to get a better understanding of how effective this design is, Sorbothane® of varying stiffness will be used in future work to determine how the stiffness of the material affects the experienced pressure at the distal end of the residual limb. Additional testing will also be done to determine if there is an effective range of the Sorbothane® material. To achieve this, a separate testing plan must be established for this design, which will allow the experienced pressure to be graphed over the course of smaller loading increments.

Lastly, the HPC design needs to be slightly revised to fit its intended purpose. Due to the geometry of the design, the experienced forces are unable to travel along the outer walls of the socket. Therefore, the top of this component needs to be redesigned so that the flat top is removed, and the honeycomb structure can connect directly to the outer walls of the socket.

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34th Annual International Conference of the IEEE EMBS
San Diego, California USA, 28 August - 1 September, 2012

Gait Motion Analysis in the Unrestrained Condition of Trans-Femoral Amputee with a Prosthetic Limb*

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Abstract— **Trans-femoral amputees must regain moving pattern by refined rehabilitation program using ground reaction forces, joint angles and joint moments applied on a prosthetic limb. On the other hand, understanding those loads and kinematic variables is indispensable for gait analysis based on the biomechanical consideration of trans-femoral amputees. However, conventional prosthetic gait training systems cannot measure long continuous walking motions. In this paper, ground reaction forces and kinematic parameters applied on trans-femoral prosthesis are measured by the prosthetic gait motion analysis system using mobile force plate and attitude sensor for the unrestrained gait measurement. As a result of the experiments, the patterns of antero-posterior axis ground reaction forces and joint moments about the medio-lateral axis are remarkably different among the five activities. Finally, the effectiveness of the developed prosthetic gait training system to consider biomechanics and kinematics in trans-femoral prosthesis is validated.**

I. Introduction

Several studies have investigated trans-femoral prosthetic gait with the artificial knee joint as an alternative function of a knee to control stance phase and swing phase [1, 2]. In this case, it can be important to pay attention to biomechanical characteristics of each joint in trans-femoral prosthesis. On the one hand, it is thought that trans-femoral amputees must regain moving pattern by gait training using kinematic conditions on a prosthetic limb as quantitative evaluation indices to improve their rehabilitation program [3]. For these reasons, our previous studies have suggested a novel six-axis force/moment sensor attached to a prosthetic limb for the unrestrained gait measurement [4, 5]. However, the developed sensor cannot evaluate an asymmetry of trans-femoral prosthetic gait. Besides, it cannot consider ground reaction forces and joint angles. Therefore, we have developed the wearable gait motion analysis system [6] using mobile force plate and attitude sensor as the prosthetic gait training system.

In this paper, ground reaction forces and kinematic parameters such as ankle joint moment applied on the lower limb are measured under a wide range of environmental conditions reflected activities of daily living by the developed system. In particular, activities which include straight-line walking on level, upslope, downslope, upstairs and down stairs are experimented. Load and kinematic mechanisms along each gait cycle as intercomparison of amputated limb with sound limb are analyzed. Finally, the effectiveness of the developed wearable gait motion analysis system to understand biomechanics in trans-femoral prosthetic gait and evaluate an asymmetry of the amputees during gait is validated.

II. Experimental Methodology

A. Subject and Trans-Femoral Prosthesis

In this paper, one male unilateral trans-femoral amputee with a prosthetic limb participates. The characteristics of this subject are as shown in Table 1. He has worn the trans-femoral prosthesis of normal socket-type for at least 29 years. The total mass includes body mass plus the mass of a prosthetic limb. The experiments take place at Doshisha University, Kyoto, Japan. Human research ethical approval is received from Doshisha University and written consent is obtained from this subject.

TABLE I
Subject Characteristics

Gender (Male/Female)	Male
Age (Years)	31
Height [m]	1.70 [m]
Total Mass [kg]	73.0 [kg]
Side of Amputation (Right/Left)	Right
Footwear	Running Shoes
Prosthetic Foot	Vari-Flex
Prosthetic Knee	Total Knee 2100

B. Experimental Facility

The experimental facility for measuring ground reaction forces and joint moments applied on a sound limb and a prosthetic limb of the subject is the developed wearable gait motion analysis system as shown in Fig. 1. This system consists of mobile force plate using the thin-type three-axis

*Manuscript received June 4, 2012.

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force sensor and attitude sensor structured by acceleration, gyro, and geomagnetism sensor. Moreover, the former mobile force plate is fixed beneath a pair of sandals. This system has less cost and fewer constraints. The experimental data measured by mobile force plate and attitude sensor are transferred to PC via data logger by wireless LAN and recorded on the laptop PC. In gait experiments, ground reaction force, center of pressure, joint angle, joint moment and limb postures can be calculated by the outputs of mobile force plate and attitude sensor.

In the definition of coordinate system, forces and moments regarding x, y and z-axes directions are defined as F_x, F_y, F_z and M_x, M_y, M_z when the positive rotation of each axis is clockwise and coordinate systems are right-handed. Specifically, x, y and z-axes correspond to the anatomical medio-lateral (lateral is positive), antero-posterior (anterior is positive) and vertical (upward is positive) directions. It is identified that the original point of the total coordinate system in a one-sided foot with the original point of the coordinate system in the heel-side mobile force plate.

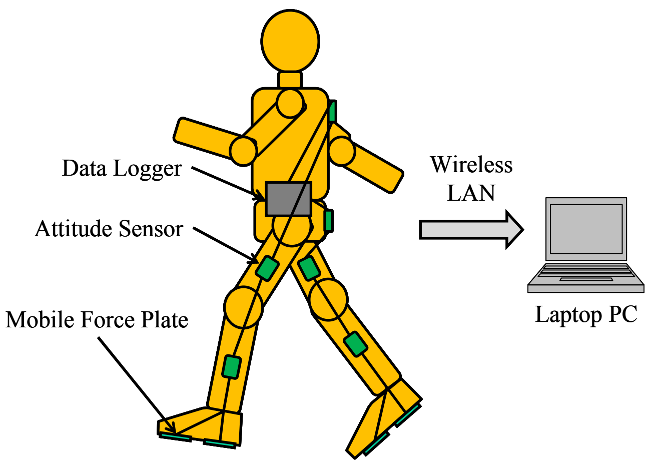


Fig. 1. Constitution of the developed wearable gait motion analysis system.

C. Experiment Description

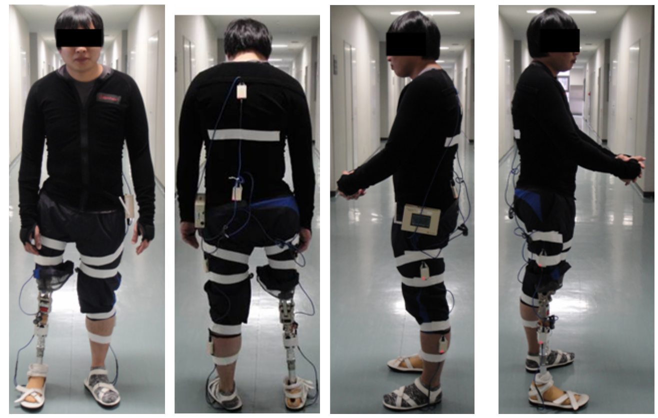
The subject performs each activity of straight-line walking on level, walking upstairs, downstairs, upslope and downslope. Descriptions of each activity and the experimental fields are concretely as shown in Table 2 and Fig. 2. Actually, about 20 [min] of practice is performed before the experiments. Ground reaction forces and kinematic parameters are measured for at least 10 steps of each activity when the subject walks at a self-selected speed because of the unrestrained gait measurement as shown in Fig. 3. Sampling frequency and cut-off frequency of low-pass filter in the experimental facility are 100 [Hz] and 10 [Hz].

TABLE II
DESCRIPTIONS OF EACH ACTIVITY IN THE EXPERIMENTS

Activities	Descriptions
Level Walking	Level walking along a level, straight-line walkway
Downslope	Descending 5 [deg] of a slope
Upslope	Ascending 5 [deg] of a slope
Downstairs	Descending stairs of 0.175 [m] height × 0.3 [m] deep
Upstairs	Ascending stairs of 0.175 [m] height × 0.3 [m] deep

(a) Level (b) Slope (c) Stairs

Fig. 2. Experimental fields.



(a) Front view (b) Back view (c) Left side view (d) Right side view

Fig. 3. Subject with the wearable gait motion analysis system.

D. Data Analysis

Obtained patterns of ground reaction forces and kinematic parameters for each gait cycle of the various activities are analyzed when the first and last steps recorded for each trial are eliminated to avoid the initiation and termination of walking. The stance phase and the swing phase are determined by the curve behavior of F_z. Gait cycle is defined as the period between two consecutive heel contacts.

In a one-sided right foot, all ground reaction forces $\boldsymbol{F} = (F_x \quad F_y \quad F_z)^T$ are as follows when toe-side and heel-side are expressed by suffixes *toe* and *heel*. Hereafter, ground reaction forces and moments of toe-side and heel-side are $\boldsymbol{F}'_{toe}, \boldsymbol{F}'_{heel}, \boldsymbol{M}'_{toe}, \boldsymbol{M}'_{heel}$.

$$\boldsymbol{F} = \begin{pmatrix} F_x \\ F_y \\ F_z \end{pmatrix} = \begin{pmatrix} F'_{x\,toe} + F'_{x\,heel} \\ F'_{y\,toe} + F'_{y\,heel} \\ F'_{z\,toe} + F'_{z\,heel} \end{pmatrix} \tag{1}$$

Then, ankle joint moment about x-axis $M_{x\,ankle}$ is as follows. $g, m_{foot}, l_{y1}, l_{y4}, l_{y7}, l_{z1}, l_{z4}, I_{x1}, \ddot{\theta}_{x1}$ are acceleration of gravity, mass of foot, each moment arm on the lower limb, moment of inertia about x-axis of ankle joint, and angular acceleration about x-axis of ankle joint.

$$\begin{aligned} M_{x\,ankle} &= l_{y1} F'_{z\,toe} - l_{z1} F'_{y\,toe} + l_{y4} F'_{z\,heel} - l_{z4} F'_{y\,heel} \\ &\quad - l_{y7}\, m_{foot}\, g + M'_{x\,toe} + M'_{x\,heel} + I_{x1}\, \ddot{\theta}_{x1} \end{aligned} \tag{2}$$

III. Experimental Results and Consideration

A. Walking Level and Slope

Figure 4-7 show the patterns of ground reaction forces and ankle joint moments of sound limb and prosthetic limb obtained from the experiments in straight-line level walking by way of example in the results.

Larger vertical forces of sound limb are applied by heel contact at the earlier stance phase and the occurrence times of peaks regarding dorsiflexion moments are earlier to strongly shift the weight for maintaining natural standing posture. Moreover, anterior forces of prosthetic limb are applied at the entire stance phase because foot of prosthetic limb has no sense of plantar pressure and applying propulsive forces is difficult.

On the one hand, walking upslope and downslope has similar patterns of ground reaction forces and ankle joint moments to straight-line level walking.

B. Walking Stairs

Figures 8-11 show the patterns of ground reaction forces and ankle joint moments of sound limb and prosthetic limb obtained from the experiments when walking upstairs by way of example in the results. The stance phase times of sound limb are longer than ones of prosthetic limb. In addition, constant dorsiflexion moments of sound limb are applied during the entire stance phase. Besides, smaller anterior forces of prosthetic limb are applied at the entire stance phase. These results may be explained by a sense of insecurity on the stairs. Incidentally, inconsistent moments about antero-posterior and vertical axes are applied throughout the experiments.

Figure 12 and Figure 13 show the patterns of ankle joint moments when walking downstairs by way of example in the results. The patterns of ground reaction forces in walking downstairs are obtained as well as walking upstairs. The data of sound limb have longer stance phase time. In particular, dorsiflexion moments of sound limb are applied during the entire stance phase. As for prosthetic limb, smaller plantar flexion moments are applied during the earlier stance phase and smaller dorsiflexion moments are applied at the later stance phase because of insecurity on the stairs. Therefore, in addition to the patterns of propulsive and braking forces, ones of joint moments among the five activities are effective to evaluate an asymmetry of amputee gait.

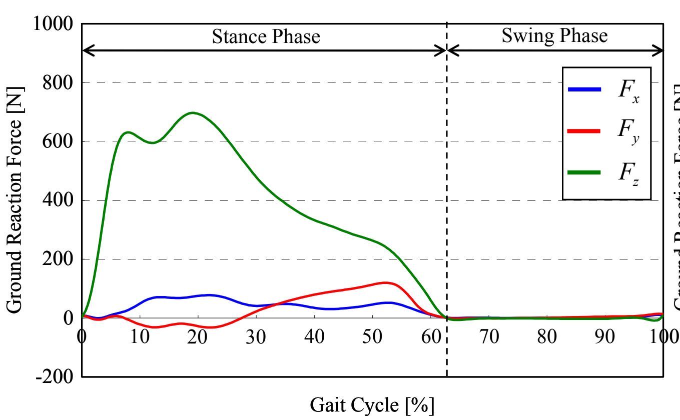


Fig. 4. Ground reaction forces of sound limb in straight-line level walking.

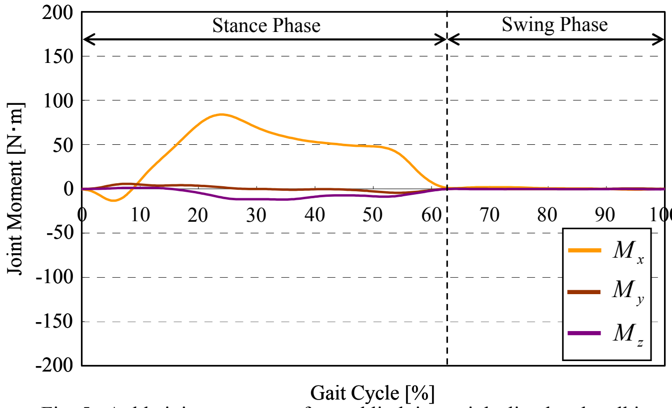


Fig. 5. Ankle joint moments of sound limb in straight-line level walking.

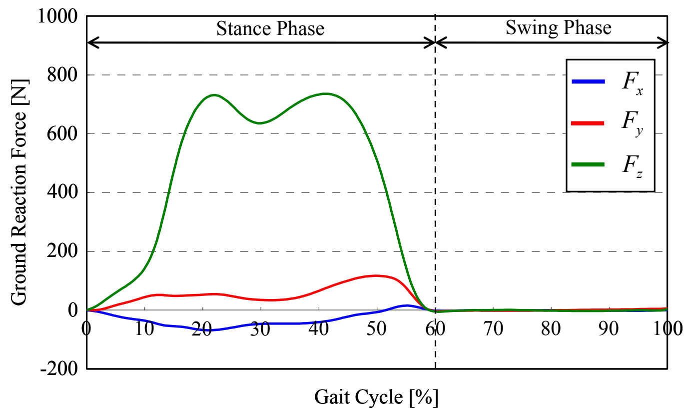


Fig. 6. Ground reaction forces of prosthetic limb in straight-line level walking.

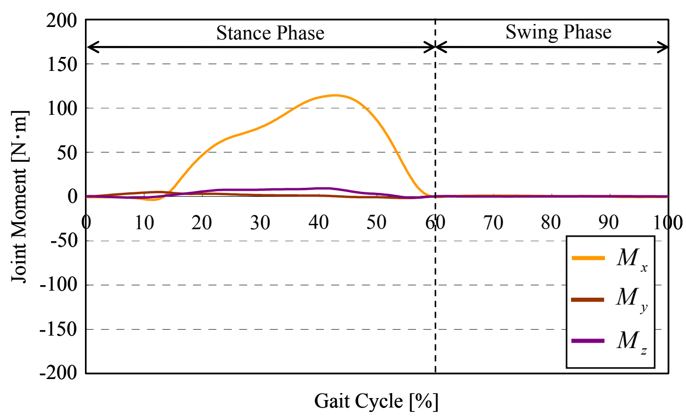


Fig. 7. Ankle joint moments of prosthetic limb in straight-line level walking.

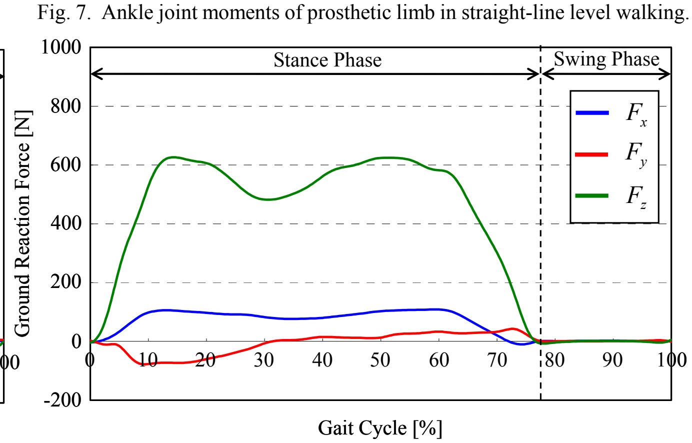


Fig. 8. Ground reaction forces of sound limb in walking upstairs.

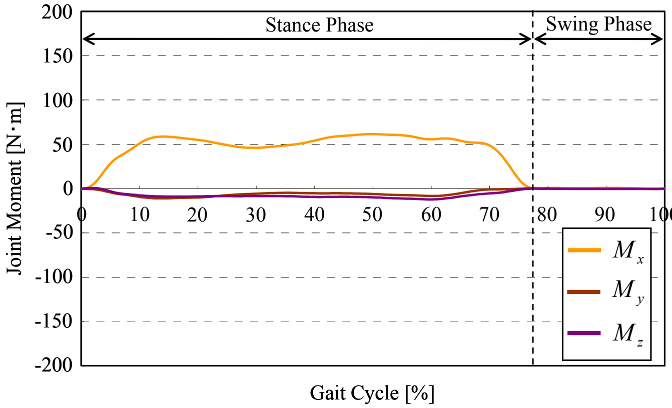


Fig. 9. Ankle joint moments of sound limb in walking upstairs.

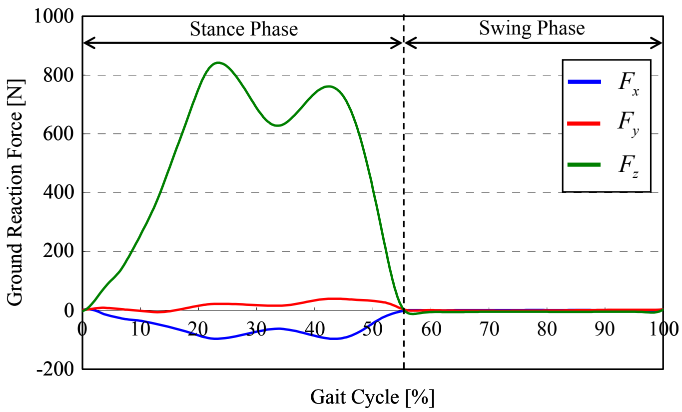


Fig. 10. Ground reaction forces of prosthetic limb in walking upstairs.

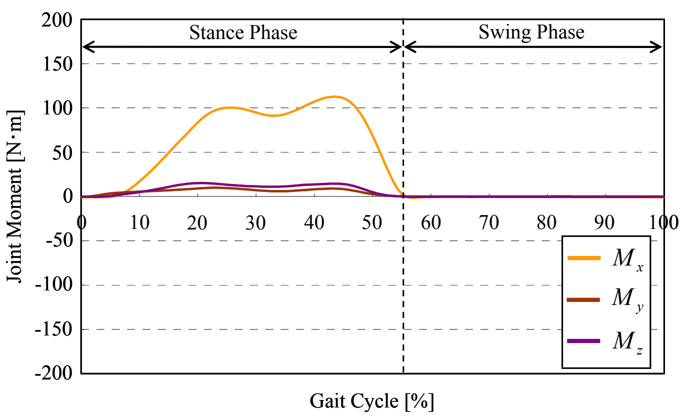


Fig. 11. Ankle joint moments of prosthetic limb in walking upstairs.

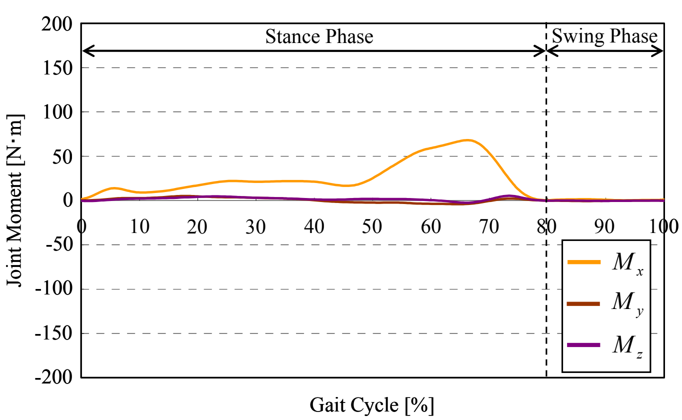


Fig. 12. Ankle joint moments of sound limb in walking downstairs.

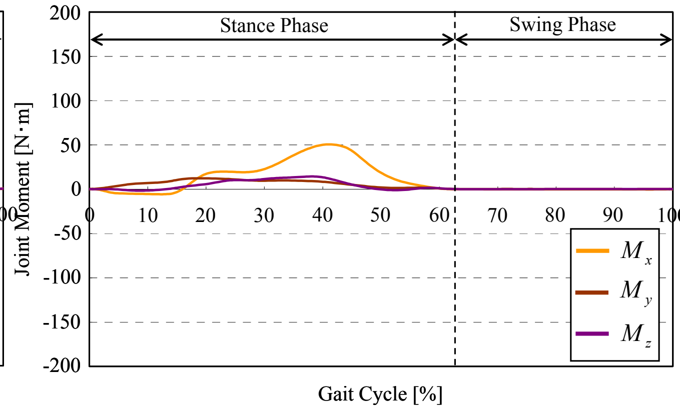


Fig. 13. Ankle joint moments of prosthetic limb in walking downstairs.

IV. Conclusion

In this paper, ground reaction forces and ankle joint moments applied on the lower limb including sound limb and prosthetic limb of a trans-femoral amputee are measured by a novel wearable gait motion analysis system in five terrain conditions. Next, each load component is compared to the others concerning sound limb and amputated limb. As a result of the experiments, in addition to the patterns of propulsive and braking forces, ones of plantar flexion and dorsiflexion joint moments among the five activities are effective to evaluate an asymmetry of amputee gait and control the artificial knee joint for prosthetic gait training. In the end, the effectiveness of the developed wearable gait motion analysis system for the unrestrained gait measurement to analyze and understand biomechanical behaviors in trans-femoral prosthetic gait and quantitatively evaluate them is validated.

Acknowledgment

This study was partially supported by Grant-in-Aid for Scientific Research (A) (23246041), Japan Society for the Promotion of Science.

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Clinical Rehabilitation 2003; **17**: 787–796

Effects of prosthesis alignment on pressure distribution at the stump/socket interface in transtibial amputees during unsupported stance and gait

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Received 7th June 2001; returned for revisions 18th July 2002; revised manuscript accepted 19th September 2002.

Objective: To assess the effects of antero-posterior realignment of the prosthesis on pressure distribution at the stump/socket interface in unilateral transtibial amputees during unsupported stance and gait.
Design: Cross-sectional group study.
Setting: Outpatient rehabilitation clinic.
Subjects: Seventeen unilateral transtibial amputees.
Intervention: Antero-posterior prosthesis realignment using 0.5 cm heel or forefoot wedging.
Measures: Pressure distribution changes at several sites at the stump/socket interface, expressed as peak pressure, peak pressure time, sustained submaximal load (MP_{80+}) and time period of MP_{80+} (TP_{80+}).
Results: During stance, heel wedging led to a 30.4% decrease in mean pressure near the patella tendon and a 40.0% increase near the distal tibia site, whereas forefoot wedging led to a 30.0% decrease in pressure in the tibial end region. Antero-posterior ankle realignment did not lead to significant changes near the fibular head. During gait only heel wedging led to a 11.5% increase in peak pressure in the tibia end region. Mean peak pressure time increased 22.7% using heel wedging and decreased 8.8% using forefoot wedging. MP_{80+} increased 23.8% in the tibia end region during heel wedging and 17.0% in the subpatellar region during forefoot wedging.
Conclusions: Antero-posterior realignment of the ankle joint led to an inverse loading and unloading of the subpatellar region versus tibial end region. However, results indicate that stump/socket interface pressure during stance seems not to be highly predictive as to pressure behaviour during gait. Ankle joint realignment led to significant differences in temporal sequences of tissue (un-)loading in the subpatellar area during gait.

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 10.1191/0269215503cr678oa

Introduction

Patients with a transtibial amputation are fitted with a leg prosthesis providing both stability and (walking) flexibility. A prerequisite for this is an adequate fitting of the prosthesis to the stump, both in terms of alignment as well as total tissue contact. The risk of developing a degenerative tissue ulcer due to either sustained or intermittent (local) peak pressure caused by the prosthetic socket is high. It increases even more in patients with (a) age-related skin/tissue atrophy, (b) sensory loss due to polyneuropathy, (c) vascular disorders or (d) oedema in the stump. Approximately 30% of leg amputees develop complications from their prosthesis, such as pain, pressure ulcers and infections, that prevent them from wearing their prosthesis for a prolonged time, severely disabling them in their daily activities and reducing quality of life.[1,2] Additionally, high costs arise due to repeated adaptations to the prosthesis socket, due to (clinical) management of wounds caused by pressure and tissue shear and due to additional medical care.

In contrast to the high clinical relevance of pressure (ulcer) monitoring in leg amputees, until recently pressure distribution at the interface between stump and prosthetic socket could not be monitored adequately. As a result reliable, quantitative information as to (a) the tolerance for (peak) pressure and (b) the exact magnitude of pressure build-up during normal prosthesis usage is not available. Furthermore, it is unknown what the detrimental (or beneficial) effects of intermittent peak pressure on soft tissue in amputees are. The time factor in loading and unloading of (soft) tissue may play an important role in the prevention of pressure ulcers. Today, preventive actions are mainly based on clinical experience and (visual) skin inspection. In contrast, actually measuring pressure, e.g., during the fitting process, may serve as an 'early warning system' as (excessive) pressure may be detected instantly, i.e., long before any tissue damage occurs. Research concerning pressure distribution until now has mainly focused on case descriptions (e.g., refs 3–8), preliminary reports (e.g., ref. 9) or technical design of instruments (e.g., refs 10–12). Research has been restricted to very short (semi-)static conditions in small numbers of subjects. Pressure monitoring in dynamic conditions, like gait, over a prolonged period at several sites at the stump/socket interface has not been carried out yet. Furthermore, as frequent adaptation (and even redesign) of the prosthesis socket in the alleviation of local tissue (over)loading may be very costly, subtle realignment of the prosthesis at, for example, the ankle level, could be an adequate and clinically cheaper alternative. The effect of the latter on the redistribution of stump/socket interface pressure during dynamic conditions has not been investigated systematically either. The aim of the present research therefore was (a) to assess the reproducibility of pressure signals recorded at the stump/socket interface during gait in unilateral transtibial amputees and (b) to assess the effects of anterior–posterior alignment of the prosthesis on pressure distribution at the stump/socket interface in unilateral transtibial amputees during unsupported stance and gait. The research questions were: (1) To what extent do changes in pressure signals recorded at the stump/socket interface during gait reproduce in unilateral transtibial amputees? (2) To what extent does stump/socket interface pressure change after ankle joint realignment in the sagittal plane during unsupported stance and gait in unilateral transtibial amputees?

Methods

Subjects

Eleven men and six women with a mean age of 45.5 years (SD 10.7) and 47.5 years (SD 12.4) participated in this study. All subjects had a unilateral transtibial amputation. Amputation date was at least 1 year prior to the study. Inclusion criteria were: age >18 years; no neurologic, orthopaedic or rheumatic impairment additional to the amputation; no severe cardiac impairments; no cognitive impairments; no medication that could influence equilibrium or co-ordination; minimum walking distance of 500 metres. All subjects wore a KBM-PTB (Kondylen Bettung Munster–Patellar Tendon Bearing) type socket and a 6-mm-thick silicone liner. Subjects used a 1D10 foot (Otto Bock, Duderstadt, Germany) ($n = 11$), a Flexfoot (Össur hf, Reykjavik,

Table 1 Group composition

	n	Age (years) Mean (SEM)	Weight (kg) Mean (SEM)	Leg length (cm) Mean (SEM)	Stump length (cm) Mean (SEM)	Stump circumference[a] (cm) Mean (SEM)	Amputation cause (n)
Male	11	45.5 (3.2)	90.0 (5.0)	98.4 (1.6)	14.1 (0.8)	35.5 (0.8)	8 trauma 3 vascular
Female	6	47.5 (5.1)	78.8 (9.2)	94.0 (1.8)	13.8 (1.0)	26.7 (1.3)	2 trauma 4 vascular

[a]Stump circumference measured at tibial tuberositas level. SEM, standard error of the mean.

Iceland) ($n = 4$), a Quantum foot (Hosmer Dorrance Corp., Campbell, CA, USA) ($n = 1$) or a Multiflex foot (Blatchford Endolite, Centerville, OH, USA) ($n = 1$). None of the participants had experienced problems with their prosthesis over at least the last six months. At the time of measurement none of the subjects had any pressure ulcers. Group data are presented in Table 1.

Informed consent was obtained from all participants prior to the beginning of this study. All experimental protocols in this study were approved by the medical ethics committee of the Institute for Rehabilitation Research and the Rehabilitation Foundation Limburg.

Task and apparatus

All subjects were asked to walk with their own prosthesis at their own comfortable walking speed. Walking condition was an indoors flat surface. Walkway length was approximately 20 m, which was covered at least twice per measurement.

A portable pressure-monitoring system (IDM, RIS Reha-Technik, Berlin, Germany) that allows dynamic, real-time (50 Hz), telemetric measurement of up to 60 pressure sites within any given prosthetic socket over a prolonged period of time, i.e., minutes, was used. Signals from calibrated force sensing resistor sensor strips measuring normal forces perpendicular to the sensor surface (IEE, FSR-649 linear array sensors, International Electronics & Engineering SARL Luxembourg) were converted to pressure signals. Each sensor strip, measuring approximately 30 × 3 cm, contained 10 round sensors (diameter: 1 cm) spaced 2 cm apart (heart-to-heart). Each sensor provided one signal representing pressure underneath that specific sensor which was digitized and subsequently fed into a computer. Sensor strip thickness was approximately 0.4 mm. Six sensor strips could be used simultaneously. In the present study, however, only three sensor strips were used. Positioning of the sensor strips on the leg stump was performed according to a predefined protocol relative to anatomical bony landmarks. All sensor strips were placed in a position parallel to the longitudinal axis of the leg. The first strip was placed on the anterior aspect of the stump and lower part of the upper leg. Depending on the length of the stump, the strip's sixth or seventh sensor was positioned over the patella tendon directly below the patella, whereas the fifth or sixth sensor was located over the tibial tuberositas. The second strip was positioned over the medial aspect of the stump and the lower part of the upper leg. The strip's first sensor was positioned underneath the tibia end. The eighth or ninth sensor was positioned directly over the medial femoral epicondyle. The third strip was positioned over the lateral aspect of the stump and lower part of the upper leg. The fourth sensor was placed over the fibular head, whereas the fifth or sixth sensor was placed directly over the lateral femoral epicondyle. All sensor positions in each subject were noted. The liner and the prosthesis socket were fitted over the sensor strips. Due to their dimensions sensors did not interfere with either walking comfort or prosthesis fitting. Bilateral foot pressure was monitored simultaneously using 32 pressure sensors in shoe inlays. From the latter signals step parameters like heel-strike and toe-off were calculated.

Three prosthesis conditions were used in which prosthesis alignment in antero-posterior direction at the level of the ankle was experimentally manipulated. In the first condition 0.5-cm bilateral heel wedging was applied. In the second condition 0.5-cm forefoot wedging was used, whereas in the third condition no wedging was used. Condition order was randomized for each subject. In each of the experimental conditions the subjects started by standing straight for 30 s with their prosthetic foot on a forceplate with which ground reaction force, as an indicator of weight bearing, was measured. The nonaffected foot was placed approximately 10 cm lateral to their prosthetic foot. During this period pressure was recorded at the stump/socket interface as well as underneath both feet using shoe inlays using PANDA software (RIS Reha-Technik, Berlin, Germany). Next the total body weight of the participant was recorded. During a 1-minute period stump/socket interface pressure signals were recorded while the subject was walking. All data were stored on computer disk (Compaq Armada E500, Compaq Computer Co., Houston, Texas, USA) and were analysed off-line using Matlab software (The Math Works Inc., Natick, MA, USA).

Data analysis

During the measuring period the participant performed several steps. In the time domain, pressure signals from each sensor were standardized to the gait cycle. In the amplitude domain, signals were normalized for body weight. As an indicator for 'within-subject' signal reproducibility the intraclass correlation coefficient (ICC) was determined for all standardized and normalized signals per subject, per prosthesis condition for all sensors. Average gait cycle pressure signals were calculated for all sensors. For each signal and for each patient peak pressure, time of peak pressure occurrence (T_{peak}), mean pressure level over 80% of peak pressure (MP_{80+}), time (as a percentage of the gait cycle) in which pressure exceeded 80% of peak pressure (TP_{80+}) and the time–pressure integral at TP_{80+} (TPI_{80+}) were calculated. MP_{80+} was used as an indicator for sustained submaximal tissue loading. TP_{80+} was used as an indicator for the time tissues were loaded submaximally. TPI_{80+} was used as a measure of signal power, combining both temporal aspects of tissue loading and extend of tissue loading. An example of the parameter calculation is depicted in Figure 1.

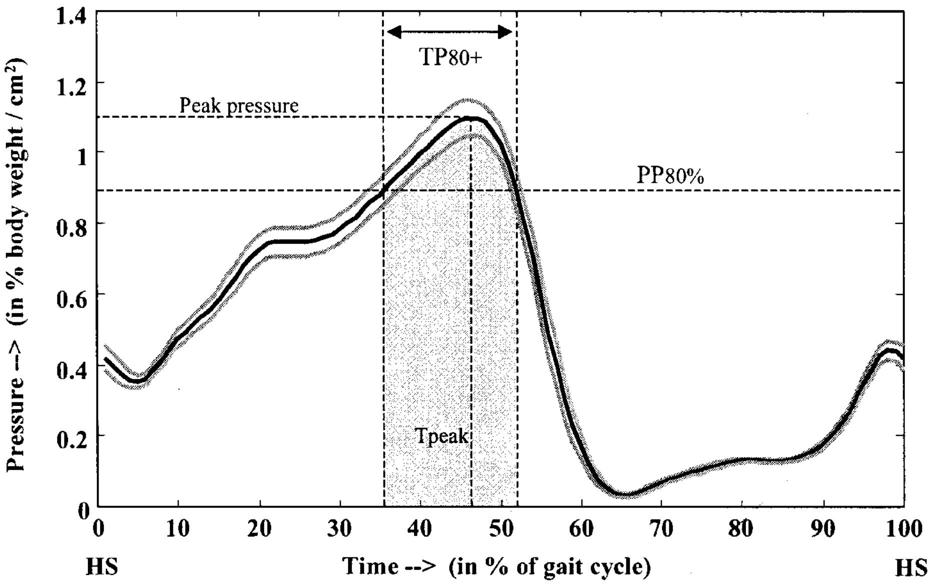

Figure 1 Example of parameter calculation. Dark line shows mean stump/socket interface pressure near fibular head calculated over 46 steps; grey lines show 99% confidence interval of the mean; grey area is TPI_{80+} time–pressure integral during TP_{80+}. HS, heel strike; T_{peak}, time at which peak pressure occurred; $PP_{80\%}$, 80% of peak pressure; TP_{80+}, time during which stump/socket interface pressure is higher than $PP_{80\%}$.

Statistical analysis included permutation tests for matched pairs.[13]

Results

Error analysis

Due to tearing of pressure sensor strips during gait conditions data of three subjects (=nine trials) were malrecorded and were discarded from further analysis. Telemetry interference resulted in loss of four trials of signals recorded during stance. In total 13 trials (12.7%) were lost. No statistical significant differences in this loss of data occurred between the experimental conditions.

Stance

During unsupported quiet stance heel wedging led to a significant reduction of 30.4% in stump/socket interface pressure in the subpatellar (i.e., patella tendon) region ($p < 0.05$), whereas it led to a significant increase of 40.0% in stump/socket interface pressure at the tibia end at amputation level ($p < 0.05$). Forefoot wedging led to a significant decrease of 30.0% near the tibia end ($p < 0.05$). Neither forefoot nor heel wedging led to a significant change in stump/socket interface pressure near the fibular head. Mean stump/socket interface pressure and standard errors of the mean (SEM) for all three conditions, for the subpatellar region, the tibia end region and the fibular head region during unsupported, quiet stance are given in Table 2.

Gait

A typical example of stump/socket interface pressure changes in the patella tendon area, recorded during 46 consecutive steps, in which signals are standardized to the gait cycle and are normalized for body weight, is presented in Figure 2. Mean ICC values (and SEM) for the normalized and standardized stump/socket interface pressure signals recorded in the patella tendon region, the tibia end region and the fibular head region were 0.96 (0.01), 0.97 (0.01) and 0.98 (0.00) respectively.

Mean peak pressure during gait was 11.5% higher at the tibia end when heel wedging was applied, relative to the standard, nonwedged condition ($p < 0.05$). In all other conditions no significant differences in peak pressure during gait were found between wedged and nonwedged conditions. Mean stump/socket interface peak pressure and standard errors of the mean (SEM) for all three wedging conditions, for the subpatellar region, the tibia end region and the fibular head region during gait are presented in Table 3.

MP_{80+} increased by 23.8% ($p < 0.01$) in the tibia end region during heel wedging and by 17.0% ($p < 0.05$) in the subpatellar region when forefoot wedging was used. MP_{80+} values (and SEM) for all three wedging conditions, for the subpatellar, tibia end and fibular head region are also given in Table 3.

Mean T_{peak} (i.e., the time in the gait cycle, starting from heel-strike, at which peak pressure was reached) associated with the pressure recorded in the subpatellar region, increased by 22.7% ($p < 0.05$) when heel wedging was applied, whereas it slightly decreased by 8.8% during forefoot wedg-

Table 2 Mean peak stump/socket interface pressure (in % bodyweight/cm²) (and SEM) during quiet stance for all three conditions, for the subpatellar region, tibia end region and fibular head region

	Subpatellar region			Tibia end region			Fibular head region		
	no-w	he-w	ff-w	no-w	he-w	ff-w	no-w	he-w	ff-w
Mean (SEM)	0.23 (0.05)	0.16 (0.03) *	0.25 (0.05)	0.20 (0.04)	0.28 (0.07) *	0.14 (0.02) *	0.20 (0.03)	0.21 (0.04)	0.16 (0.03)

no-w, nonwedged condition; ff-w, forefoot wedging condition; he-w, heel wedging condition. SEM, standard error of the mean.
*Significant difference at $p < 0.05$ relative to no-w condition.

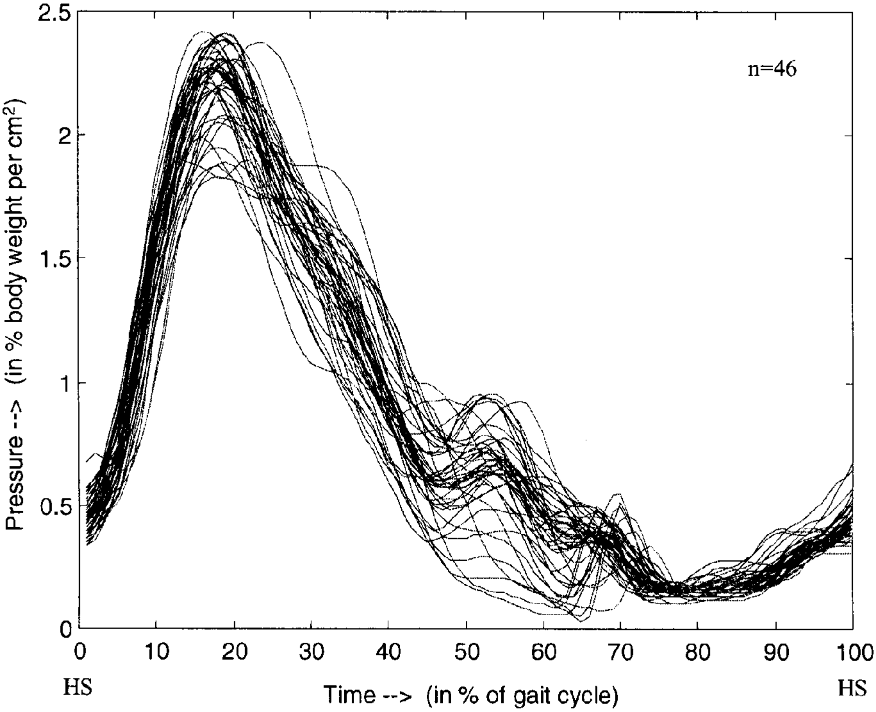

Figure 2 Typical example of stump/socket interface pressure changes near the patella tendon (46 steps). HS, heel strike.

ing ($p < 0.05$). Regarding the tibia end and the fibular head mean T_{peak} did not change significantly. Mean T_{peak} results (and SEM) for all three wedging conditions for the subpatellar, tibia end and fibular head region are given in Table 4.

In the subpatellar region TP_{80+} (i.e., the time span of submaximal tissue loading) decreased by 24.3% when heel wedging was applied ($p < 0.01$). Manipulation of ankle alignment led to significant changes neither in the tibia end region nor in the fibular head region compared with the non-wedged condition. Mean TP_{80+} values (and SEM) for all three wedging conditions for the subpatellar, tibia end and fibular head region are also given in Table 4.

When heel wedging was applied, mean TPI_{80+}, indicating signal power during submaximal tissue loading, decreased by 29.0% in the subpatellar region ($p < 0.01$), whereas it increased by 34.7% in the tibia end region ($p < 0.05$). Conversely, forefoot wedging led to a 47.6% increase of mean TPI_{80+} in the subpatellar region ($p < 0.05$) and a 20.1% decrease in mean TPI_{80+} in the tibia end region ($p < 0.05$). Mean TPI_{80+} values (and SEM) for all three wedging conditions, for the subpatellar, tibia end and fibular head region are presented in Figure 3.

When comparing mean TPI_{80+} recorded in the subpatellar region with the TPI_{80+} results as measured near the fibular head, values proved to be higher in the fibular head region in the no-wedging and heel wedging conditions ($p < 0.01$), whereas differences in mean TPI_{80+} did not differ between the aforementioned stump/socket interface sites when forefoot wedging was applied.

Discussion

The aim of the study was to assess the effects of antero-posterior alignment of the prosthesis on

Table 3 Mean peak stump/socket interface pressure and MP_{80+} values (both in % bodyweight/cm²) (and corresponding SEM) during gait for all three conditions, for the subpatellar region, tibia end region and fibular head region

	Subpatellar region			Tibia end region			Fibular head region		
	no-w	he-w	ff-w	no-w	he-w	ff-w	no-w	he-w	ff-w
PP	0.59	0.55	0.69	0.78	0.87	0.67	0.69	0.74	0.69
(SEM)	(0.10)	(0.09)	(0.12)	(0.17)	(0.21) *	(0.16)	(0.16)	(0.19)	(0.16)
MP_{80+}	0.53	0.49	0.62	0.63	0.78	0.60	0.62	0.67	0.62
(SEM)	(0.09)	(0.08)	(0.11) *	(0.11)	(0.18) **	(0.14)	(0.14)	(0.17)	(0.14)

no-w, nonwedged condition; ff-w, forefoot wedging condition; he-w, heel wedging condition; PP, peak pressure; SEM, standard error of the mean.
*Significant difference at $p < 0.05$ relative to no-w condition; **Significant difference at $p < 0.01$ relative to no-w condition.

Table 4 Mean T_{peak} and TP_{80+} values (both in % of gait cycle) (and corresponding SEM) during gait for all three conditions, for the subpatellar region, tibia end region and fibular head region

	Subpatellar region			Tibia end region			Fibular head region		
	no-w	he-w	ff-w	no-w	he-w	ff-w	no-w	he-w	ff-w
T_{peak}	44.4	54.5	40.5	22.7	26.4	22.5	20.9	26.9	22.7
(SEM)	(4.6)	(7.0) *	(5.1) *	(3.1)	(3.2)	(4.6)	(3.1)	(3.9)	(4.0)
TP_{80+}	20.6	15.6	22.3	24.3	27.0	22.8	31.3	31.7	29.5
(SEM)	(3.9)	(2.2) **	(2.6)	(3.6)	(3.5)	(4.4)	(3.6)	(3.4)	(4.0)

no-w, nonwedged condition; ff-w, forefoot wedging condition; he-w, heel wedging condition; SEM, standard error of the mean.
*Significant difference at $p < 0.05$ relative to no-w condition; **Significant difference at $p < 0.01$ relative to no-w condition.

stump/socket interface pressure distribution during unsupported stance and gait. Three main areas of interest at the stump/socket interface were identified (i.e., the subpatellar region, the tibia end region and the fibular head region). As to the reproducibility of the pressure distribution signals, recorded in dynamic gait conditions, results show a high within-subject reproducibility, reflected in high mean intraclass correlation coefficient values. Clinically, this is of importance. It means that the technique used in the present study is suitable for evaluating the stump/socket interface pressure in individual transtibial amputation patients, offering the clinician and paramedical staff insight in stump/socket interface pressure behaviour in an individual transtibial amputation patient with his or her unique pathology and problems. This evaluation may be done in both static and dynamic conditions, in contrast to clinical procedures used until now, which opens perspectives for early prevention of pressure ulcers and associated pathological phenomena as well as for future research.

In general, results show that antero-posterior realignment of the ankle joint does affect stump/socket interface pressure distribution in transtibial amputees in a systematic, consistent manner. During both unsupported stance and gait this realignment leads to an inverse loading and unloading of the subpatellar region versus tibial end region; that is, when ankle realignment led to an increase in subpatellar stump/socket interface loading (represented by, for example, peak stump/socket interface pressure or TPI_{80+}), tibial end load bearing decreased and vice versa. This may be of interest when trying to relieve the pressure from certain areas of the stump. Our study indicates that this may be done through prosthesis realignment and not necessarily through reshaping of the prosthesis socket, which is more difficult, more expensive and may interfere with fitting comfort and which often merely shifts the locus of the pressure problem to other localized stump/socket interface sites.

Clinically, it is, as yet, unknown whether peak pressure of short duration or submaximal pressure of longer duration is more detrimental in the process of pressure ulcer development. Our results indicate that prosthetic alignment in the antero-posterior direction of the ankle joint may alter the duration of submaximal pressure at the stump/socket interface, which was most prominently observed in the subpatellar region, whereas in the tibial end region this phenomenon was less clear as it failed to attain significance level. On average, the time at which peak pressure occurred shifted towards toe-off time when heel wedging was applied. In the subpatellar region, forefoot wedging led to T_{peak} occurring slightly earlier in the stance phase, relative to the nonwedged gait condition. TP_{80+}, indicating the amount of time in the gait cycle during which

Clinical messages

- Pressure monitoring quickly detects local tissue overloading, in both static and dynamic conditions, well before clinical signs occur.
- Ankle joint realignment may change the pressure redistribution at the stump/socket interface: realignment towards plantar flexion reduces tibia end pressure but increases subpatellar pressure. Realignment towards dorsiflexion causes the opposite effect.

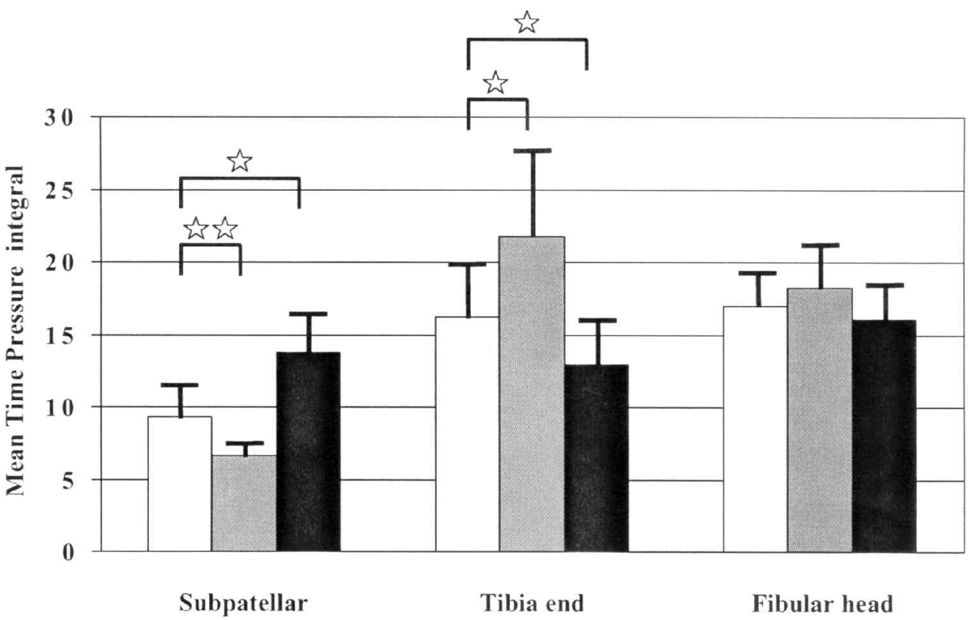

Figure 3 TPI_{80+} (and SEM) values for all three conditions, for the subpatellar region, the tibia end region and the fibular head region during unsupported, quiet stance. White bars show nonwedging condition; grey bars are heel wedging condition; black bars are forefoot wedging condition. *Significant difference at $p < 0.05$ relative to nonwedging condition; **Significant difference at $p < 0.01$ relative to nonwedging condition.

submaximal stump/socket interface pressure was sustained, was lower in the subpatellar region during heel wedging.

Also, the time of peak pressure occurrence could reproducibly be manipulated by changing the prosthetic alignment in the antero-posterior direction. In clinical rehabilitation of transtibial amputees, prosthesis alignment is evaluated mainly during quiet stance. However, our data indicate that the magnitude of stump/socket interface pressure distribution in static conditions seems not to be highly predictive of stump/socket interface peak pressure behaviour in dynamic ambulation conditions. It is therefore advocated to monitor the effects of prosthesis alignment in both static and dynamic conditions. For the latter, new procedures must be developed and (clinically) implemented.

As expected, antero-posterior realignment of the ankle joint did not lead to significant changes in stump/socket interface pressure parameter values near the fibular head, indicating that tissue loading remained near equal. The reason for this is that the fibula head is especially susceptible to lateral forces (i.e., forces perpendicular to the longitudinal axis of the fibula). The ankle joint realignment investigated in the present study resulted mainly in major changes in joint angles in the sagittal plane and only in little (or no) changes in the frontal plane. Our results suggests that, next to changes to the dynamics of the gait cycle, selective manipulation of the ankle joint position may selectively alter (i.e., either reduce or increase) the position of load bearing at the stump/socket interface, relative to the plane in which the manipulation is performed.

Although the technique we used is not novel, it is widely used in foot-pressure monitoring in both research and clinical evaluation, the application in pressure monitoring at the stump/socket interface in transtibial amputees in dynamic conditions indeed is relatively new. However, despite the good consistency of our (first) results some caution is in order. First, sensor strip lay-out as well as sensor spacing allowed for many sites on the stump not to be monitored and pressure to dissipate in between sensors. Secondly, pressure caused by forces perpendicular to the sensor were recorded, whereas shear forces, parallel to the sensor, were not recorded. It is known that shear forces also significantly contribute to tissue stress and degradation. Thirdly, because the sensor strips were very thin (0.4 mm) in order to facilitate placement between prosthetic socket and stump, tearing of the strips occurred, directly leading to loss of data. However, in the present study the amount of data loss did not differ significantly between the experimental conditions. It is therefore unlikely that this technical problem influenced results systematically between conditions. Despite these drawbacks we think that pressure monitoring as described in this paper may give valuable extra information to the clinical assessment of pressure-related complaints of prosthesis-wearing patients as used today. It may for example assist (a) in making clinical decisions about changes to be made both in the socket and the prosthesis alignment, (b) in evaluating the effects of such changes more objectively and (c) in detecting possible tissue overloading at an earlier stage.

Future research is aimed at evaluating the effects of liners on stump/socket interface pressure distribution during stance and gait as well as the effects of other alignment manipulations to the prosthesis on stump/socket interface pressure redistribution. Furthermore, our research will be aimed at evaluating stump/socket interface pressure distribution in other ADL conditions, such as stair climbing and descent.

Acknowledgements

The authors wish to thank J Cluitmans and A Derks at the Hoensbroeck Rehabilitation Centre and F Rings of Livit Orthopedie BV, Hoensbroek, the Netherlands, for their support.

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