Reducing Gait Compensation and Osteoarthritis in Unilateral Amputees Through Prosthesis Design

ENGR 2996-001 Honors Technical Communication

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Source: http://www.bu.edu/today/files/2012/11/t_AK-beach01.jpg

Abstract

The objective of this project proposal is to reduce the secondary physical condition of osteoarthritis in the intact leg in unilateral amputees. Osteoarthritis prevalence is greatly increased in amputees using lower limb prostheses due to compensation while walking. By reducing the compensation in gait and thereby the forces that act on the intact leg, the risk of osteoarthritis is also reduced. Presented solutions to this problem involve the specific design and material properties of the device. A microprocessor-controlled knee joint, controlled energy storage and return foot, and optimization of stiffness in the foot prosthetic are all viable solutions that successfully reduce compensation. By comparison of studies conducted of each solution, the controlled energy storage and return prosthetic foot is determined to be the best option. This design greatly reduces forces on the intact leg and creates higher gait symmetry. Despite the more advanced technology and potentially higher cost, implementation of this solution will promote multiple health benefits in the lives of amputees, in addition to reducing compensation and osteoarthritis.

Keywords: amputee, compensation, gait, osteoarthritis, prosthesis, prosthetic

Document scenario: This document proposes an engineering project to reduce osteoarthritis that arises from compensation due to prosthetic device usage in unilateral amputees. This project would be of specific interest to prosthetic manufacturers, who are interested in developing a prosthesis that would improve the health of amputees. Since a large percentage of amputees are veterans, the Department of Veteran Affairs (VA) and the relating VA hospitals would be interested in the results of this project to aid in the care of amputees. The Executive Summary would be read by officials in the manufacturing company and VA to determine project adoption.

Executive Summary

This engineering project strives to find and implement a lower limb prosthetic device that will reduce compensation during gait and thus reduce osteoarthritis in unilateral amputees. Osteoarthritis is 17 times more prevalent in amputees than non-amputees. This is a painful secondary condition that can further change the lifestyle of amputees. Development and use of a prosthesis that promotes normal gait symmetry and patterns, as well as reducing the forces on the intact leg, will successfully reduce this compensation injury.

Determination of the forces acting on the intact leg, such as ground reaction forces, external adduction moments, and power, gives quantitative data to show how the proposed solutions improve upon current models. Each solution design focuses on a certain part of the prosthetic leg, specifically a knee or foot. Sizing of the device depends on the amputee using the device. Proper fit is important to see the effects of the certain design improvement, and improper fit can contribute to compensation.

The proposed solution of this project is a controlled energy storage and return (CESR) prosthetic foot. In comparison to conventional currently used prosthetic feet, this design produced more power in stride push-off and decreased loading forces on the intact leg. These factors create an overall more symmetrical gait that is closer to unaffected motion. Provided that there is proper fit to the patient, this foot design reduces compensation.

A controlled energy storage and return prosthetic foot is a feasible option for compensation and osteoarthritis reduction in amputees. Although prosthetic devices are expensive, and more complex ones increase in price, if this design could be manufactured and sold for a reasonable cost, benefits in ambulation would be seen in many amputees. Having a prosthesis that makes motion easier will promote activity in amputees. This can go a long way to creating additional benefits in health and overall well-being. Prosthetic devices wear down and patient’s desired functions of their prosthesis change, so this design can be purchased for an upgrade as well as for first time prosthesis users.

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Problem Analysis

The following Problem Analysis section defines the problem that this project attempts to solve. Background information about the problem and the scientific and engineering aspects involved are explained for thorough understanding of the problem and the solutions presented later in the proposal.

Overview of problem and its significance

The goal of this project is to improve the design of lower limb prostheses, in order to reduce the development of osteoarthritis in unilateral amputees. Osteoarthritis is one of the most prevalent secondary physical conditions that arises from the usage of lower limb prosthetic devices. This condition is essentially the degradation of cartilage in a joint because it breaks down faster than it can be recreated. New, stiffer bone also grows around the joint, limiting functions of the joint and preventing proper force distribution. Furthermore, it is painful and decreases overall quality of life (Gailey, Allen, Castles, Kucharik, & Roeder, 2008).

Patients with a unilateral amputation, whether transtibial or transfemoral, will commonly use a prosthetic device. Transfemoral amputees have limb loss across the upper leg femur bone, between the hip and knee, so they will require a prosthesis including the knee joint, ankle, and foot. Transtibial amputees have limb loss across the lower leg bones of the tibia and fibula, between the knee joint and ankle, so they will require a prosthesis including the ankle joint and foot. However, using a prosthetic device causes deviations from the normal gait pattern that results in compensation from the intact limb. Due to the prolonged time spent on the contralateral limb during ambulation and the increased force loads transmitted to the joints on that side, prosthesis use correlates to a higher rate of osteoarthritis in the intact limb. The effects of constant compensation build up in the limb over years of prosthesis use. Many amputations occur relatively early in life, with patients typically under 30 years old during an amputation of traumatic, tumor, or congenital nature. Members of the Armed Forces are heavily affected by amputations. From the Valley Forge Military Hospital, veterans of the Vietnam war that suffered from amputations combined to a mean age of 21.7 (Gailey et al., 2008). With such a young population receiving amputations and successively prostheses, they have many years of prosthesis usage ahead of them. The repetitive compensation is what puts these patients in danger of secondary conditions such as osteoarthritis.

Other secondary conditions exist, such as osteoporosis and back pain. However, this project focuses just on osteoarthritis, although it is very likely that adjusting prostheses to alleviate the effects of osteoarthritis will likely also diminish the effects of the other conditions. The following proposal includes ways of improving the design of lower limb prostheses, that can go a long way to reducing or eliminating painful secondary conditions.

Engineering fundamentals of problem

Understanding normal gait is necessary in order to understand the differences prevalent in prosthesis-affected gait. The typical gait pattern consists of two main stages: stance and swing. The stance phase is 60% of the gait cycle, beginning with the heel strike of one leg and continues through the forward motion of weight shifting with one leg on the ground. The swing phase makes up the remaining 40% of the cycle, when the leg pushes off from the toe, moves through the air and strikes at the heel again to start the next cycle (Harrington, 2005).

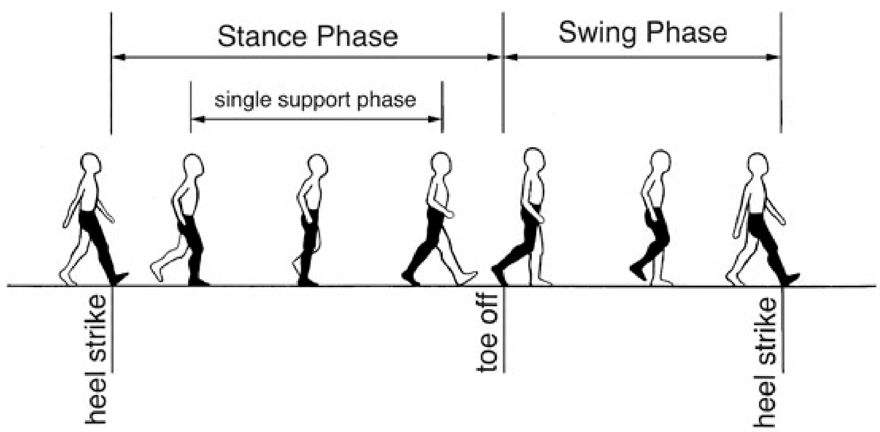

Figure 1: Gait Cycle

Source: Harrington, 2005

During this typical pattern of ambulation, seen in Figure 1, motion is symmetrical in both limbs. The center of gravity exists at the patient's midline, and while walking, it takes on a smooth sine-wave structure. This wave pattern exists in the lower body, up and down and to both sides. Meanwhile, the upper body remains upright with only limited rotation. Conditions such as injury, muscular and/or skeletal disorders, and amputation resulting in prosthesis usage can all cause deviations in this proper gait. Changes in gait due to another condition are referred to as compensatory gait. Often, types of compensatory gait involve a shift of the center of gravity to minimize pain or muscular effort in the impaired limb. This form of limp is called the Trendelenburg lurch, seen in Figure 2 (Harrington, 2005).

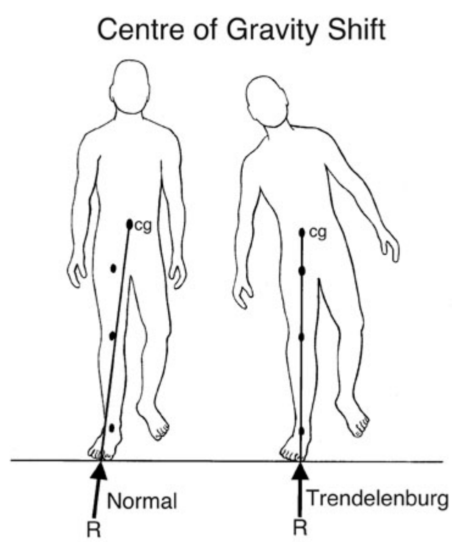

Figure 2: Shift of Center of Gravity in Unaffected and Limping Gait

Source: Harrington, 2005

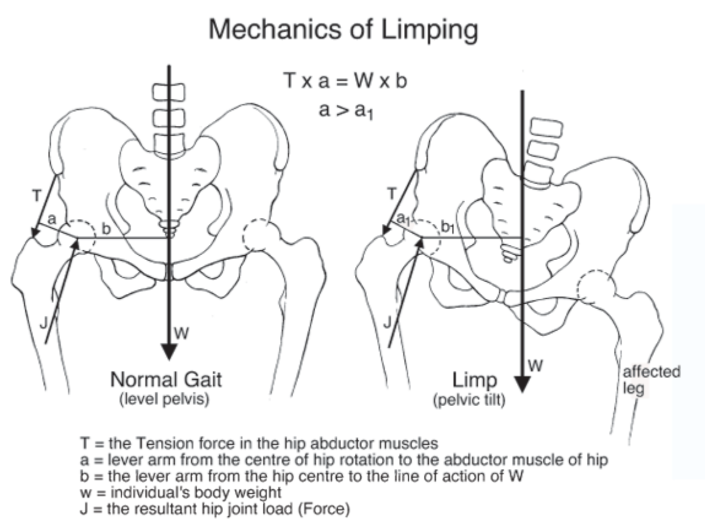

Figure 3: Mechanics in Unaffected and Limping Gait

Source: Harrington, 2005

To further describe the compensatory techniques of unilateral amputees, strides are modified by bringing the intact leg towards the center of the body, meanwhile extending the outward rotation of the prosthetic leg (Gailey et al., 2008). Additionally, the upper body, including the head, neck, trunk, and pelvis, all turn in towards the affected leg while the arm of that side moves outward away from the body. Thus, this compensation shifts the center of gravity, forcing the pelvis to tilt. At the beginning of the stride on the normal leg, i.e. the heel strike when it starts holding the body's weight, the pelvis is rotated away so the hip muscles must increase effort to align the pelvis throughout the gait cycle. As seen in Figure 3 above, a, the distance between the muscle and center line of hip rotation, in the unaffected hip is greater than a_1. The equation $T \times a$, shows that the T, "Tension force in the hip abductor muscles," must increase as the distance a decreases. The extra muscular work compounds with the malalignment in the joint, which lessens the joint-load area, and results in heightened force and pressure within the joint. The pattern of limping is natural as it increases stability while walking and allows less loads and forces to be applied to the residual amputated leg. As a result, however, compensation increases the time spent on the contralateral leg and the load applied to it (Harrington, 2005).

Another compensation mechanism can be slowing down gait speed. This also results in a longer stance phase on the unaffected leg. Longer time on the intact limb has been found to directly link to a greater load applied to that limb while walking than would be applied during normal gait (Gailey et al., 2008). An additional compensation method involves a rapid swing phase to shorten the time of the stance phase on the amputated leg. From kinetics, as the contralateral leg moves forward with greater speed, the heel strike will have more momentum (the product of mass and velocity, $p=mv$), sending greater contact forces (product of mass and acceleration, $F=ma$) into that leg (Harrington, 2005). The forces present when the heel hits the ground are called ground reaction forces. From Newton's third law, every force has an equal and opposite reaction force. Therefore, when the foot strikes the ground with a force that is directed down and back, the ground exerts a force up and forward into the leg. Walking on sensor plates can produce diagrams of the ground reaction forces present in gait, as seen in the example in Figure 4. It has two peaks, corresponding to the heel strike and toe off. Generally, the first peak from the heel strike has the greatest effect and changes based on compensatory gait (Tongen & Wunderlich, 2010).

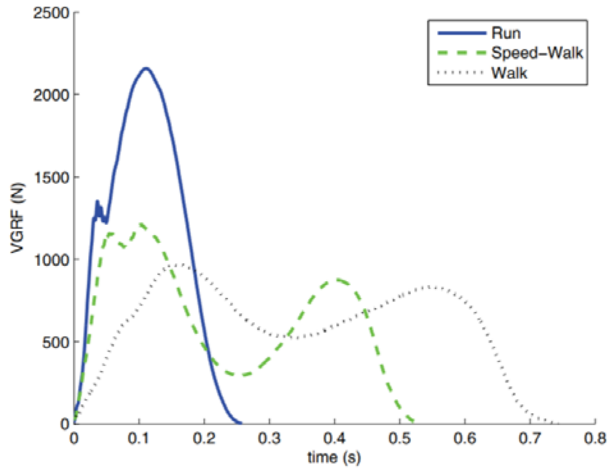

Figure 4: Example ground reaction force diagram

Source: Tongen & Wunderlich, 2010

A study of ground reaction forces in unilateral amputees found that up to a 23% asymmetry in forces could exist between the intact and amputated leg. In comparison, there are less than 10% force discrepancies in people without a prosthesis (Gailey et al., 2008). These heightened ground reaction forces in the intact leg during prosthetic ambulation can expedite development of osteoarthritis in the joints of that leg.

Lessons from prior responses to the problem

A study of World War II veterans with unilateral amputations by Dr. D. S. Hungerford and Mr. J. Cockin was the first published work, in 1975, to claim the relationship between amputation and the development of osteoarthritis. Focusing on patellofemoral osteoarthritis, their study included 63 transtibial and 54 transfemoral amputees that were compared to a control group totaling 117. Results of this study showed that 63% of subjects with above-knee amputations, and 41% of below-knee amputations suffered from osteoarthritis in the knee joint of the contralateral limb. In the control group, only 22% showed the condition, therefore demonstrating that the increased risk does exist. Similar studies were conducted in the following years and also obtained concurring results (Gailey et al., 2008).

Prosthetic devices have been greatly improved over time, with especially large improvements around periods of war because of the surge in the number of amputees. In many common devices, classical prosthetic knees exist as solely mechanical devices. These mechanical knees can be further broken down into specific controlled systems, that are prescribed to patients depending on their age, functionality, activity level, and specific factors of personal importance. For example, single-axis knee joints are the most simplistic, acting as a hinge, while polycentric knees allow for greater rotation and mobility. In advanced mechanical prosthetic devices, pneumatic or hydraulic systems are employed in an attempt to produce a more comparable mechanical knee system to normal knee function (Dupes, 2014).

The simplest and cheapest option of a foot prosthetic device currently on the market is called a solid ankle cushion heel (SACH) foot. However, this design does not properly mimic natural gait. Advancements came about in the form of energy storing foot prosthetics. Using a Delrin Keel (the component that provides foot flexion), which behaves similarly to a spring as weight is shifted on and off of the foot, the device gained the ability to capture and release energy throughout the gait cycle. This function revolutionized the technology of artificial feet and changed the way prostheses can affect an amputee's life. Developments continue to make this energy system more advanced to create ambulation closer to that of non-amputees (Murphy, 2014).

A study by Fey, Klute, and Neptune (2011) researched the correlations between the stiffness of a prosthetic foot to biomechanical factors of gait, such as the forces acting on the legs. A typical prosthetic foot made of carbon fiber was used as the normal stiffness property, and was compared to devices of the same design, but made 50% stiffer and softer. Overall, the stiffer device tended to show lower horizontal ground reaction forces during the heel strike in both legs. However, vertical forces increased in the intact leg heel strike and residual leg toe-off. By these results, it became apparent that a balance between stiffness values would need to be found in order to optimize factors of force, stability, and mobility (Fey et al., 2011).

Project objectives and constraints

The goal of this project is to improve lower limb prosthetic devices to eliminate the need for compensation while walking, and thereby reducing the secondary condition of osteoarthritis. Therefore, the specific engineering objective is to create an ideal prosthesis that mimics natural gait. Compensatory gait is the main concern addressed for the higher rate of osteoarthritis development in unilateral amputees. Deviations to the normal gait pattern can result from the imbalances between one natural leg and one prosthetic leg. These changes result in greater forces applied to the contralateral leg, which increases the likelihood of osteoarthritis on that side in the hip and knee joints. The solutions considered in this project attempt to correct gait imbalances by creating a more ideal prosthesis that better emulates a human leg.

Due to the biomechanical nature of a human prosthetic device, certain constraints inherently exist in its design. First, it must be comfortable to the user. Connection with the body must be properly shaped to prevent discomfort and skin conditions. The socket design is also important for pressure and force distribution (Mak, Zhang, & Boone, 2001). Material of the device is another important consideration. The material will often dictate the strength and weight of the prosthesis, as well as its force absorption and distribution properties. Fiber reinforced polymer composites are used in most prosthetic devices today due to their similar characteristics to bone. The body contains hard and soft tissues, and natural bone has an elastic modulus of about 10-20 GPa. Composites can be crafted to match these stiffness properties. The device must be very strong and durable to withstand daily activities. Finally, cost limits the material and technology involved in the device. There must be a feasible balance between overall design price and complexity (Scholz et al., 2011).

Altering prosthesis design is not the only way to reduce osteoarthritis in unilateral prosthetic users. Other supportive devices like stabilizing footwear or orthotic inserts can help maintain balance and posture without limping. Medicines could help prevent cartilage wearing and prevent pain. Physical therapy techniques like training to use prosthetic limbs properly, balance work, and muscular strengthening may also help patients obtain uncompensated gait (Gailey et al., 2008). However, this project proposal focuses on the engineering methods of improving leg prosthetics for the overall outcome of osteoarthritis decline in amputees.

Candidate Solutions

The following Candidate Solutions section explores three solution possibilities that can help correct amputee gait and reduce osteoarthritis in the intact limb.

Scope of solutions considered

Solutions were considered on the basis of design improvement for lower limb prostheses. Due to the many components involved in a prosthetic leg, a wide variety of possible solutions exist. The three candidates proposed in this document attempt to cover the 3 major categories of potential design improvement areas. Therefore, one solution focuses on the knee design, one on the foot design, and one on the important material property of stiffness in the foot.

The solutions were selected to be the best for the general prosthesis user. However, different levels of amputation affect the prosthetic device options available to each patient. Whether a transfemoral or transtibial amputation, each amputee's residual limb can be of varying length, thus also influencing the type of prostheses available for them. Lifestyle factors also determine the device for each person. Certain prosthetic properties are necessary or more important for patients depending on activity level and age. Finally, it is also important to consider the person's health outside of the amputation and changing health conditions throughout their lifetime may affect the results from the ideal prosthetic.

This project proposal intentionally investigates a broad solution scope in order to present a solution recommendation that will minimize compensation in all general prosthesis users.

Explanation of candidate solutions

The following section will give an in-depth explanation of the three viable candidate solutions: a microprocessor-controlled knee joint, a controlled energy storage and release prosthetic foot, and the optimal pattern of material stiffness within the foot. Each solution will be evaluated based on the results of research studies that test how these designs can reduce compensation gait problems in amputees. Comparison of the benefits and drawbacks of each solution will be conducted in order to propose a recommended solution.

Candidate Solution 1- Microprocessor-Controlled Prosthetic Knee Joint

Microprocessor prosthetic devices for the knee incorporate computer chip sensors that monitor and react according to the specifics of the amputee's current motion (Dupes, 2014). The specialized control through the microprocessors takes place during the gait cycle, maintaining proper flexion and extension of the joint to suit the activity. If an amputee using this device decides to run or walk down stairs, they can confidently do so without needing to manually adjust the device. The knee still contains similar fluid dynamic properties to classical mechanical knees. However, from the information received by the microprocessors, the hydraulic systems open and close either faster or slower, which adjusts how the knee is able to move. One major benefit from this automation is a much higher stability level that enables the patient to recover their balance after stumbling, instead of falling (Murphy, 2014). Most importantly for the basis of this project proposal, informatic regulation of the technology in the joint allows for more natural ambulation (Dupes, 2014).

Figure 5: Microprocessor-controlled knee in the commonly used C-leg

https://media.ottobock.com/_web-site/prosthetics/lower-limb/c-leg/images/33271-cl-jk-ra_11-4c_wb_1_1_teaser_fallback.jpg

Through evaluation of research studies and their results, microprocessor knee joints, like the one in Figure 5, can be credited to normalizing gait. The first study by Kaufman et al. (2007) showed large improvements in ambulation. In this study, 15 subjects participated in tests with both a mechanical prosthetic leg and a prosthesis with a microprocessor-controlled knee. The knee joint in the mechanical prosthesis was a Mauch SNS® (Kaufman et al., 2007) which consists of a “single axis hydraulic knee system with swing and stance control (SNS®)” (Össur Americas, 2018). The specific knee was the only variable of the prosthetic leg changed for the tests. All subjects were accustomed to walking with the mechanical knee, so that was tested first, and then an acclimation period of 4.5 months was given before testing the microprocessor-controlled knee.

The results showed the benefits of the microprocessor-controlled knee over the mechanical joint option. Gait improvements were evident in the flexion and extension of the knee during motion. In walking with the mechanical knee, force with the ground occurs in front of the joint, overextending and locking out the device at the knee, resulting in internal flexion. The patient must work to contract the muscles in their hip for stable knee extension (Kaufman et al., 2007). However, as discussed previously in the section Engineering fundamentals of problem, the muscular tension tilts the pelvis and is a reason of the compensatory gait pattern. When walking with the microprocessor-controlled prosthetic knee, that side could handle more load, so that forces with the ground resulted in internal extension instead of flexion, which is more comparable to natural gait. By monitoring the movement and resistance in the knee, the microprocessor joint creates the ideal smooth wave-like pattern of normal walking (Kaufman et al., 2007). Additionally, since limping helps amputee’s stability (Harrington, 2005), an increase in balance while walking with the microprocessor knee can lower the need for compensation. Subjects using the microprocessor knee were found to have much better balance than when using the mechanical knee (Kaufman et al., 2007).

A further study by Kaufman, Frittoli, and Frigo (2012), continued to support the microprocessor-controlled knee by showing the increased gait symmetry that arises from the use of this joint over a mechanical knee. The data points for each subject throughout the gait cycle were analyzed by calculating the symmetry index to compare the kinetics of the prosthetic leg and intact leg. An index value calculated to be +1 shows perfect symmetry of the legs, -1 shows perfect asymmetry, and 0 shows an unrelated motion. A value was calculated for the hip, knee, and ankle during both the stance phase and swing phase, while using both the mechanical (M) knee and microprocessor-controlled (MPC) knee. These values are displayed in the following Table 1.

Table 1: Symmetry Index (S.I.) Values

Source: Kaufman et al., 2012

Joint	Hip				Knee				Ankle			
Phase	Stance		Swing		Stance		Swing		Stance		Swing	
Leg	M	MPC	M	MPC	M	MPC	M	MPC	M	MPC	M	MPC
S.I.	0.942	0.976	0.846	0.943	0.459	0.640	0.768	0.915	0.835	0.900	0.974	0.987

Symmetry index values close to 1 are desirable because they indicate a better imitation of natural gait, which can be generalized to be perfectly symmetrical. The values calculated in the study show that the microprocessor-controlled knee promotes better ambulation because the index of the MPC is closer to 1 in every category, than the corresponding value for the mechanical knee. The greatest increases in symmetry between the device styles occurred at the knee joint, with a jump from 0.459 to 0.640 in the stance phase and 0.768 to 0.915 in the swing phase. This is because the microprocessor-controlled joint creates internal knee extension and greater symmetry, as in the results of Kaufman et al. (2007). The knee joint is often considered the most important in transtibial gait, making the vast improvement in symmetry with the microprocessor-controlled knee especially significant (Kaufman et al., 2012).

Because asymmetrical compensation gait causes more force to be applied to the non-prosthetic leg, it then increases the development of osteoarthritis. By using the microprocessor-controlled knee to correct gait, osteoarthritis in unilateral amputees can be decreased.

Candidate Solution 2 – Controlled Energy Storage and Return Foot

The foot is an important component to any leg prosthesis. It must bear weight during the amputated leg's stance phase and push off to transition to the intact leg. A controlled energy storage and return (CESR) foot contains a spring that is designed to hold energy transmitted at the heel strike and then release the energy in the toe-off. This style increases the amount of power generated when pushed off the ground to step forward.

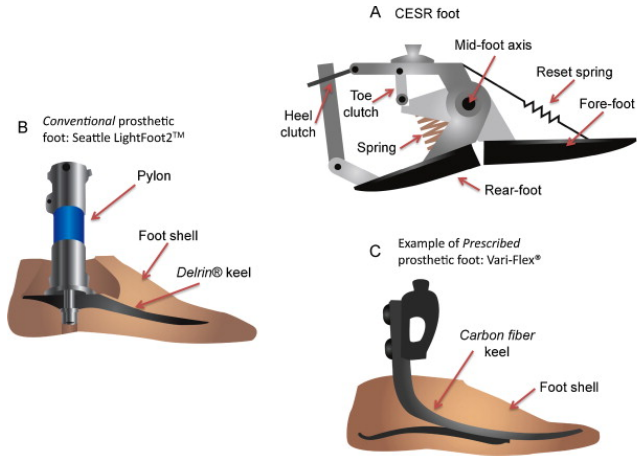

Figure 6: Representation of A) CESR foot, B) Conventional foot, C) Another prescribed possibility

Source: Morgenroth et al., 2011

In the study by Morgenroth et al., (2011) the benefits of the CESR foot on reducing gait deviation were evaluated. For comparison, three prosthetic foot types were used: the foot the patient currently uses (prescribed), the conventional style of prosthesis, and the CESR foot, as seen in Figure 6. After proper acclimation to the device, subjects were studied as they walked on a treadmill at a common speed of 1.14 m/s. The results studied include the power and work of the foot during push off, and the forces acting on the knee of the intact side.

Following the typical sine wave center of mass pattern for normal gait, mass must shift slightly up and forward after the toe-off of the back leg. Energy for this motion is generated by the push of the trailing leg and impulses with the ground of the front leg. However, most prosthetic feet cannot create enough power, so the forces on the front, intact leg must increase to compensate. External adduction moments (EAMs) of the knee directly correspond to the load on the knee (Morgenroth et al., 2011). This force "is the product of the frontal plane ground reaction force and the moment arm" (Zabala, Scanlan, Donahue, & Andriacchi, 2011). By studying the change in push-off and EAMs depending on the prosthesis, it can be seen, in Table 1 and Figure 7, that the CESR foot is effective of reducing compensation and thus the risk of osteoarthritis.

In analysis of power produced and push-off work done by the prosthetic foot, the CESR had results significantly higher than both the conventional and prescribed foot. The average values collected for these factors are displayed in Table 2.

Table 2: Data for power and push-off work

Source: Morgenroth et al., 2011

	CESR	Conventional	Prescribed
Power (W/kg)	3.20	1.35	1.90
Work (J/kg)	0.27	0.11	0.15

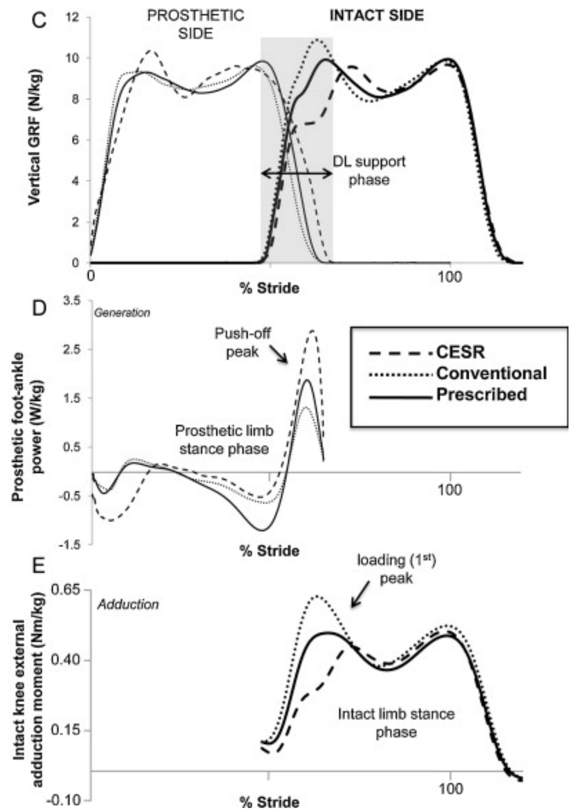

Figure 7: Force comparison graphs

Source: Morgenroth et al., 2011

The CESR foot is successful at producing greater push-off power and work in the prosthetic leg, reaching values very similar to those of subjects with no amputation. Therefore, this should reduce the load and forces in the intact leg. The graphs in Figure 7 corroborate this statement. Low ground reaction forces (GRF) in graph C and EAMs in graph E, along with high power in graph D are the ideal conditions for gait most similar to that of a non-amputated subject. Since the CESR foot achieves all of these conditions, it is a favorable design compared to the conventional model and the patient's prescribed foot.

Since high EAM is generally a large factor in osteoarthritis development in the knee, reduction of the EAM will directly result in reduction of osteoarthritis risk. Trunk lean present in limping can cause a greater moment arm and therefore greater EAM. By reducing the limp, moment arm, and EAM, the load on the knee will also decrease. Furthermore, gait will become more symmetrical by eliminating this lean (Zabala et al., 2011). This study showed a 26% reduction in EAM from the conventional device, and an average 16% reduction from the prescribed foot (Morgenroth et al., 2011).

Candidate Solution 3 – Optimization of Material Stiffness of the Prosthetic Foot

The properties of the materials used in the prosthetic devices are also very important and affect gait. Due to the results of the previous study by Fey, Klute, and Neptune (2011), it was apparent that one constant stiffness in the foot would not be ideal by itself. There were benefits and drawbacks to each of the stiffnesses tested, so integrating different properties for different areas of the foot can allow for the development of a device that harnesses the necessary benefits. Therefore, a year later, the same group of Fey, Klute, and Neptune (2012) conducted this version of the study.

The effects on the loading of the intact knee were observed by altering the stiffness throughout the ankle, mid-foot, and toe regions of the foot. A standard design of an energy storage and return (ESAR) prosthetic foot, the HighlanderTM (Figure 8), was used as the overall design for the foot. Its main outline is shaped by the keel and heel components. Within a prosthetic foot, the keel is a component that causes foot flexion as weight pushes onto the toe. This keel is a contributor, along with the patient's muscles, in forward motion. The model was also broken down into a total of 22 segments, with the keel containing 13 small hinge joints and the heel containing 5, equaling 18 degrees-of-freedom within the model depicted in Figure 9. Each degree-of-freedom gives an opportunity to adjust the stiffness in the material. Selective laser sintering was used to adjust the stiffness of the Rilsan D80 Nylon 11 material in each region. In this technique, a high-power laser heats the material, and the particles fuse together as it cools. Working layer by layer, the heat provided by the laser can precisely adjust how the particles will fuse, and therefore adjust the material stiffness (Palermo, 2013). The ankle region includes 7 joints, the mid-foot 4, and the toe region 2.

Figure 8: HighlanderTM prosthetic foot

Source: http://www.freedom-innovations.com/highlander/

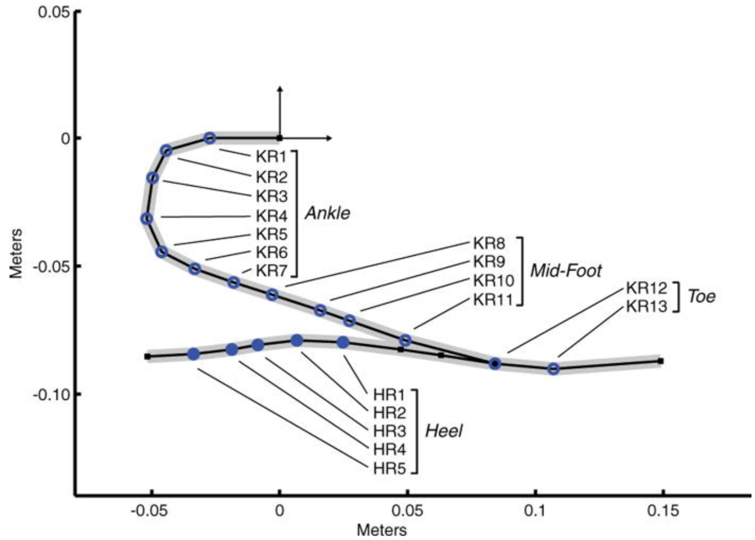

Figure 9: Diagram of the model used to adjust material stiffness

Source: Fey et al., 2012

Data for the study was collected through digital simulations and compared to their 2011 experimental data from amputees walking at a speed of 1.2 m/s with the adjusted device. The previous data is called tracking data and is used to make sure large differences between human function and the simulations do not exist. Results were calculated for the reduction of metabolic cost and for the reduction of forces on the intact knee, as well as for these conditions combined.

When tested to only lower the forces on the intact knee as much as possible, the ideal design was found to be normal ankle stiffness, an increased stiffness in the mid-foot and toe regions, and lowered stiffness in the heel. In this case, normal stiffness relates to the unadjusted stiffness of the Nylon 11 material, which has an elastic modulus value of 1.4 GPa. With this design the functionality of the keel changed to provide a lot of forward push-off, but the amount of stability it provided in the stance phase decreased. The keel also helped to absorb energy and decrease the load on the knee. However, with these changes in the material stiffness, the overall energy expenditure while walking increased, and the forces on other joints than the intact knee also increased. Therefore, despite the lower forces on the knee and potentially lower risk of osteoarthritis in that joint, both hips and residual knee may suffer an increased risk. Even though the force was successfully decreased to around 2500 N, it was still higher than the value of about 2100 N for normal gait.

However, another simulation found that when attempting to reduce metabolic expenditure along with the force on the intact knee, a design most conducive to reducing osteoarthritis was created. This design features lowered ankle and heel stiffness with higher toe and mid-foot stiffness. Utilizing this stiffness power, appropriate forward motion power and stability are achieved while decreasing quadricep reliance and increasing hamstring work. This lowers the forces on the intact side knee, and it has been shown that more reliance on the hamstrings than the quadriceps combats osteoarthritis development (Fey et al., 2012).

Comparative assessment of candidate solutions

Each candidate solution presented comes with benefits and drawbacks. Therefore, a comparative analysis of the three presented possible solutions is used to determine the ideal solution. A summary is listed in Table 3, with further details and explanations below the table.

Table 3. Comparative Analysis

	Microprocessor-Controlled Knee	**CESR Foot**	**Material Stiffness of the Foot**
Method of Data Collection	Personal studies	Personal studies	Digital simulations; patient tracking data
Gait Speed During Study	1) Not specified, normalized through percentages 2) 1.11 m/s	1.14 m/s	1.2 m/s
Forces Studied	Ground Reaction Forces and muscular impacts	Ground Reaction Forces; External Adduction Moments; Power and work from push-off	Ground Reaction Forces and muscular impacts
Results of Forces	Intact leg forces reduced	Intact leg forces reduced	Intact side forces on the knee reduced
Reduction of gait asymmetry	Successful	Successful	Successful
Scope of Application	Transtibial amputees only	All amputees	All amputees

Each of the studies used as evidence for the effects from each solution contain some standardizing factors. The prosthetic devices tested are properly fit to the patients and they are given time to adjust to the different device before data used in the results is collected. This is important so that outlying factors do not influence the results.

The data collected through personal studies involves walking along force plates and video analysis. The digital simulations for the material stiffness studies very closely imitates human locomotion, making the different forms of data collection comparable. The gait speeds in each study are similar and represent an average walking speed for a person. Ground reaction forces are the most common forces to study, as they are used in each of the three candidate solutions. The studies for the microprocessor-controlled knee and foot material stiffness also take into account how the leg muscle functionality changes based on the solution. The CESR foot goes into the most depth by also studying external adduction moments and power and work generated during the push-off with the prosthetic CESR foot. All three solutions have some form of intact side force reduction. However, the material stiffness only shows successful reduction of the knee, while the other two candidates have an overall decrease. As all viable candidates, each solution does reduce gait asymmetry that is responsible for osteoarthritis development. Finally, this project aims to find the best solution for all prosthetic users. Amputees of different types require different types of prosthetics, but the solution of a microprocessor-controlled knee only applies to transfemoral amputees, as transtibial amputees do not require artificial knee joints. All amputees do require the use of a prosthetic foot, so improving foot prosthesis design would have the largest impact, if only one solution can be pursued.

Project Recommendations

The following Project Recommendations section describes the controlled energy storage and return (CESR) foot prosthesis as the recommended solution. Limitations to the design and its impacts are also discussed.

Recommended solution

The ideal solution for normalizing amputee gait and reducing the risk of osteoarthritis, is the use of a controlled energy storage and return (CESR) prosthetic foot design. This candidate solution option is the most successful design at reducing gait compensation in the largest number of unilateral amputees.

Based on its influence to decrease both ground reaction forces and external adduction moments in the intact leg, the CESR foot lowers the total intact leg load by the largest amount. First peak vertical ground reaction forces in the intact leg are reduced by about 4 N/kg and the external adduction moment of the intact knee decreases by approximately 0.30 Nm/kg, as compared to the conventional foot prosthetic model, seen in Figure 7 (Morgenroth et al., 2011). Additionally, the power provided to the patient in push-off from the prosthetic side is greatly increased with this design. All three of the changed force values create a gait model pattern that is more similar to that of a non-amputated subject's gait. Furthermore, the powered push-off enables a sine-wave center of mass motion like the pattern in unaffected gait. The reduction of loading forces and gait asymmetries in compensation are the best ways to solve the problem of osteoarthritis prevalence in unilateral amputees.

Both transtibial and transfemoral amputees require a foot prosthesis, so by implementing this one solution, gait can be corrected in a large number of amputees, which is a goal of this project.

Design and implementation challenges

The design of the CESR foot is a major overhaul from the conventional prosthetic foot model. Technology in the CESR device contains many mechanical parts, seen in Figure 6 A, such as a spring and reset spring, mid-foot axis, heel and toe clutches, along with components of the fore and rear foot. The conventional foot relies mainly on the keel for its source of flexion and energy return. However, this technology already exists and is proving the immense overall benefits it provides.

For the basis of using the CESR foot design in all amputees, further studies would need to be conducted to see the relationship between this foot and the knee joint design in transfemoral amputees. It can be inferred that the improved foot design will still result in gait improvements when used in combination with a standard knee prosthesis.

Cost of the product is always a concern that producers and consumers face. Prostheses are generally covered by insurance, but the extent of coverage depends on the specific plan. A device like the CESR foot would likely cost around $15,000. As cost increases with increasing complexity, any of the advanced solutions presented would have a high price. Additionally, prosthetics do not last a lifetime, so it is reasonable to conclude that a prosthetic would need to be replaced, repaired, or readjusted ("How Much Does a Prosthetic Leg Cost?," 2018). However, medical costs associated to secondary conditions like osteoarthrosis would be reduced or eliminated with the usage of this design.

Conclusion

If a prosthetic device company undertakes this project to create a reliable and affordable controlled energy storage and return foot prosthetic, many amputees would benefit. By enabling gait that imitates the motion in non-amputees, the need for compensation is eliminated. This greatly reduces the risk of osteoarthritis, which affects so many amputees. Physical and mental health benefits, such as weight loss and decreased depression, would also result, since this device would promote increased activity level in amputees.

Prosthetic devices are always evolving. The CESR foot would be a large step forward in reducing compensation and osteoarthritis, but continued advancements and modifications can be made. For example, with more studies, the ideal material stiffness can be combined with the CESR design to create an even more symmetrical gait. However, the initial integration of the CESR foot into leg prostheses would have a large positive impact on amputees.

Glossary

Ambulation – movement by walking freely[1]

Contralateral – the side of the body opposite to a certain condition[2]

Degree-of-freedom – "the number of independent movements [a body/object] has"[3]

External Adduction Moment – "the product of the frontal plane ground reaction force and the moment arm"[4]

Gait Compensation – abnormal patterns of walking due to a condition, such as an amputation, in an attempt to avoid pain or make up for weaknesses or imbalances (Author)

Gait Symmetry – the movements and forces of the body are the same on both sides while walking (Author)

Ground Reaction Forces – walking results in a vector force each time the foot contacts the ground. The force from the foot is directed down and back and the complementary force form the ground is directed up and forward.[5]

Osteoarthritis – a painful joint disorder resulting from the degeneration of cartilage. The cartilage is destroyed faster than it reforms. Additionally, stiff bone grows around the joint. Both factors limit joint functions.[6]

Prosthesis – "an artificial replacement of a part of the body"[2] Plural: Prostheses. The term prosthetic is the adjective form that applies to a prosthesis.

Selective Laser Sintering – a precise form of 3D printing in which a high-power laser is used to heat and fuse together material powder into a solid form, layer by layer. Adjusting the heat, and thereby the melting and particle arrangement in fusion, can change the material stiffness.[7]

Unilateral Amputation – the loss of limb on only one side of the body (Author)

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[1] https://medical-dictionary.thefreedictionary.com/ambulation
[2] https://www.medicinenet.com/medterms-medical-dictionary/article.htm
[3] https://www.cs.cmu.edu/~rapidproto/mechanisms/chpt4.html
[4] Zabala et al., 2011
[5] Tongen & Wunderlich, 2010
[6] Gailey et al., 2008, p.17
[7] Palermo, 2013

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