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## The Effect of Prosthetic Foot Push-off on Mechanical Loading Associated with Knee Osteoarthritis in Lower Extremity Amputees

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## Abstract

Lower extremity amputation not only limits mobility, but also increases the risk of knee osteoarthritis of the intact limb. Dynamic walking models of non-amputees suggest that pushing-off from the trailing limb can reduce collision forces on the leading limb. These collision forces may determine the peak knee external adduction moment (EAM), which has been linked to the development of knee OA in the general population. We therefore hypothesized that greater prosthetic push-off would lead to reduced loading and knee EAM of the intact limb in unilateral transtibial amputees.

Seven unilateral transtibial amputees were studied during gait under three prosthetic foot conditions that were intended to vary push-off. Prosthetic foot-ankle push-off work, intact limb knee EAM and ground reaction impulses for both limbs during step-to-step transition were measured.

Overall, trailing limb prosthetic push-off work was negatively correlated with leading intact limb  $1^{st}$  peak knee EAM (slope = -0.72 + -0.22; p=0.011). Prosthetic push-off work and  $1^{st}$  peak intact knee EAM varied significantly with foot type. The prosthetic foot condition with the least push-off demonstrated the largest knee EAM, which was reduced by 26% with the prosthetic foot producing the most push-off. Trailing prosthetic limb push-off impulse was negatively correlated with leading intact limb loading impulse (slope = -0.34 + -0.14; p=.001), which may help explain how prosthetic limb push-off can affect intact limb loading.

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Prosthetic feet that perform more prosthetic push-off appear to be associated with a reduction in 1<sup>st</sup> peak intact knee EAM, and their use could potentially reduce the risk and burden of knee osteoarthritis in this population.

## Introduction

Approximately one million people in the United States are living with lower extremity amputation and this number is projected to more than double by the year 2050<sup>1</sup>. Lower extremity amputation not only limits mobility, but also predisposes individuals to painful secondary impairments that can result in additive disability. Knee osteoarthritis (OA) of the intact limb is one such secondary impairment <sup>2, 3</sup>. Intact limb knee pain in unilateral lower extremity amputees is reported to be twice as common  $^3$ , and the prevalence of symptomatic knee OA 17 times higher than in age-matched non-amputees<sup>2</sup>. Imaging studies have also confirmed the increased prevalence of intact limb, knee degenerative changes when compared with control populations <sup>4, 5</sup>. While transtibial amputees (TTAs) are more likely to develop knee pain in their intact limb, they are five times less likely to develop knee pain in their amputated limb than a control population<sup>3</sup>. Since TTAs are known to load their intact limb to a greater extent than their prosthetic limb during gait <sup>6</sup>, the marked asymmetry in knee pain and degeneration suggests that mechanical loading factors are likely an important contributor to the increased incidence in this population. It is possible that this loading asymmetry might be associated with specific mechanical characteristics of the prosthetic limb and therefore might be reduced by improving these characteristics.

Although mechanical loading factors have not been extensively studied in the amputee population, there is a foundation of literature that has demonstrated the importance of the peak knee external adduction moment (EAM) during walking on the development of knee joint degenerative changes in the general population <sup>7–13</sup>. In particular, the first of the two EAM peaks during stance phase has been reported to be associated with increased knee OA severity <sup>14</sup>. The factors that modify knee EAM in the intact limb of amputees have not been studied to date.

One potential explanation for increased mechanical loading in the intact limb is reduced prosthetic limb push-off power and ground reaction forces seen with conventional prosthetic feet <sup>15</sup>. Dynamic walking models and experimental studies of non-amputees suggest that pushing off from the trailing limb can reduce the collision of the leading limb with the ground <sup>16–20</sup>. During the transition from one stance leg to the next, the velocity of the body center of mass must change from a forward-and-down direction to a forward-and-up direction <sup>16</sup>. This redirection is due to the ground reaction impulse (the integral of ground reaction forces) across the step-to-step transition period, roughly corresponding to double support <sup>16</sup> (Figure 1A). If the trailing prosthetic limb produces a reduced push-off, the leading intact limb must perform a greater share of the center of mass velocity redirection, thus increasing the ground reaction loading impulse on the leading limb. This is expected to result in greater loading of the intact limb, and hence greater knee EAM. Prosthetic feet that improve push-off could therefore potentially reduce intact limb loading, and specifically peak knee EAM during early stance.

The goal of this study was to determine whether the amount of push-off from a prosthetic foot affects intact knee EAM during gait in unilateral TTAs. We studied three prosthetic foot conditions that we expected to be associated with varying amounts of prosthetic push-off. We hypothesized that greater prosthetic push-off would lead to reduced loading, and hence reduced knee EAM, during early stance phase of the intact limb.

## Methods

We tested for differences in limb loading during gait in unilateral TTAs. We examined variations in prosthetic foot-ankle push-off work including those that occurred systematically due to the type of foot (by applying three different prosthetic foot conditions), as well as those that occurred spontaneously as a result of gait variability. We then tested whether increases in push-off work, whether systematic or spontaneous, was associated with reductions in intact limb loading and knee EAM.

In order to explore the potential mechanistic connection between these two clinically relevant variables, we also subdivided the relationship between prosthetic foot-ankle pushoff work and intact knee EAM into the following three paired relationships: First, push-off impulse from the prosthetic limb should increase with prosthetic push-off work, because pushing off causes a change in COM velocity, which entails a change in both momentum and kinetic energy, and therefore involve both impulse and work <sup>16, 21</sup>. Second, the intact limb loading impulse should decrease linearly with push-off impulse, because the two must sum to redirect the COM velocity by a relatively fixed amount dictated by the particular gait <sup>21</sup>, which we assume to be relatively fixed within each trial. Third, the intact limb peak EAM is expected to increase in proportion to the loading impulse. This is because the ground reaction loading impulse is the integral sum of ground reaction forces during double support, and the ground reaction force is the primary determinant of the EAM (assuming a relatively fixed moment arm of the ground reaction force relative to the knee joint center). To assess this flow of logic, we tested for correlation for each of the expected relationships. The measurements consisted of kinematics and kinetics of overground walking, according to the procedures detailed below.

### **Subjects**

Seven unilateral TTA subjects participated in the study. They were recruited through bulletin board advertisements and a local amputee clinic, and all signed informed consent prior to participation as approved by the Institutional Review Board. Inclusion criteria consisted of the following: being between the ages of 18 and 80; having used a prosthesis for at least two years and wearing the prosthesis at least eight hours per day; self-report of being at least a moderately active community ambulator; being able to walk without the use of upper extremity aids; not having a history of falls within the previous 6 months; being free from neurological deficits and underlying musculoskeletal disorders that might affect gait characteristics.

#### Experimental protocol and instrumentation

Subjects were tested under three prosthetic foot conditions in a randomized order in this within-subjects design: (1) the prototype Controlled Energy Storage and Return (CESR) prosthetic foot <sup>22</sup> (Figure 2A); (2) a conventional prosthetic foot (Conventional) (Figure 2B); (3) the subject's currently prescribed prosthetic foot (Prescribed) (Figure 2C). The CESR foot is an energy recycling foot that is designed to increase prosthetic ankle push-off as compared to conventional prosthetic feet. It is intended to store and capture energy in a spring at foot strike. This energy is stored until later in stance phase, when a latch opens, transferring the spring energy into plantarflexion push-off. The CESR foot has been shown to increase push-off impulse and to almost double peak positive prosthetic foot-ankle push-off power compared to a conventional prosthetic foot in non-amputees wearing a fixed-ankle simulator boot <sup>22</sup>. The Conventional foot was a Seattle LightFoot2<sup>TM</sup> (Seattle Systems; Poulsbo, Washington) that has a Delrin keel with some elastic qualities. We included a Prescribed prosthetic foot condition in order to represent the prosthetic foot that was

previously selected by a clinician with the goal of optimizing function for each individual subject.

Subjects were given an acclimation period on two different days, and returned on a third day for data collection. They practiced walking overground and on a treadmill using the conventional and prescribed feet for approximately 10 to 20 minutes and for approximately 45 minutes or until the patient felt comfortable with the CESR foot. Subjects were given additional acclimation time with the CESR foot due to its novel design and function. Data collection occurred on a separate day from the acclimation sessions to avoid the effects of fatigue. Prosthetic alignment was adjusted by the same experienced prosthetist for all conditions. All trials were at a walking speed of approximately 1.14 m/s, which is a typical walking speed for transtibial amputees <sup>23, 24</sup>.

#### Data collection and processing

Kinematic and ground reaction force data were measured while subjects walked overground across force plates embedded along a 10-meter walkway. Gait kinematics were collected with a 12-camera motion capture system (Vicon, Centennial, CO) sampled at 120 Hz. Thirty-five 14 mm reflective markers were placed on each subject at locations consistent with a modified Vicon Plug-in-Gait full-body model. All prosthetic foot conditions included a prosthetic heel marker, a toe marker, and a marker at the distal end of the rigid shank, mirroring placement on the intact limb. Anthropometric measurements were taken for each individual according to the Vicon Plug-in-Gait requirements for static and dynamic modeling. Ground reaction forces were collected with 2 Bertec force plates (Columbus, OH) and 2 AMTI force plates (Watertown, MA) sampled at 1200 Hz.

A minimum of six successful overground trials was collected for each condition. Trials were defined as successful if they met the following two criteria: (1) walking speed was within the range of  $1.14 \pm 0.11$  m/s as measured by a timing light system and (2) at least two sequential foot strikes occurred on separate force plates. All gait data were filtered with Vicon's Woltring quintic spline algorithm with a mean-square-error value of 20, prior to computing 3D inverse dynamics using the Vicon Plug-In-Gait dynamic model, and subsequently using a low pass 25 Hz 3<sup>rd</sup> order Butterworth filter after the calculation of joint moments and powers.

Prosthetic limb push-off impulse and intact limb loading impulse were calculated by integrating the ground reaction force under the trailing prosthetic limb and the leading intact limb respectively, over the double support phase. Coronal knee moments (adduction and abduction moments) were calculated using a standard inverse dynamics approach, and the magnitude of the 1<sup>st</sup> and 2<sup>nd</sup> peaks of the intact knee EAM were quantified. Prosthetic footankle power was calculated as the sum of translational and rotational power performed on the distal shank <sup>25–27</sup>, where the former was defined as the dot product of the ground reaction force and translational velocity at the lateral malleolus ankle marker, and the latter as the dot product of the joint moment about the lateral malleolus and the angular velocity of the shank. This method captures the net behavior of the foot and does not assume a rigidbody model of the prosthesis with a fixed joint center of rotation as is necessary with standard inverse dynamics. Inverse dynamics may not accurately account for energy storage, dissipation and return<sup>28</sup> in prosthetic feet which have a deformable foot-ankle segment rather than a fixed axis of rotation. Prosthetic foot-ankle push-off work was defined as the integral of positive power generated during the final phase of stance (approximately 50–60% of the gait cycle). All quantities were normalized to body mass.

#### **Statistical Analysis**

Paired associations were tested using linear mixed effects regression, applied across all of the steps recorded from each subject. The primary test was between trailing limb push-off work and leading limb knee EAM. Secondary tests were performed between prosthetic foot-ankle push-off work and push-off (trailing prosthetic limb) impulse, between push-off impulse and loading (intact leading limb) impulse, and between loading (intact leading limb) impulse and the same limb's knee EAM. The first variable of each pair acted as the independent fixed effect, and the second as the dependent variable, with subject and subject by independent variable interactions as random effects. Results from these tests were summarized as slopes +/- standard errors.

The relationship between intact knee peak EAM and prosthetic foot condition was assessed using linear mixed effects regression. Peak intact knee EAM was the dependent variable, foot condition was the independent variable and subject and subject by foot condition were modeled as random effects. Overall significance (P<.05) across all foot conditions was assessed first, and if significant, pair-wise comparisons among the three foot conditions were then tested for significance using linear contrasts (P<.017, applying Bonferroni's correction). The same procedure was used to determine the association between prosthetic peak foot-ankle power or push-off work and foot condition. All analyses were carried out using R 2.9.0 software (R Foundation for Statistical Computing, Vienna, Austria).

## Results

Seven male unilateral transtibial amputee subjects (mean +/– SD age:  $52.3 \pm 12$  yrs; Weight:  $80.9 \pm 9.9$  kg; Height:  $1.85 \pm 0.05$  m) were studied while walking overground. All subjects had a traumatic etiology of amputation. Table 1 describes the Prescribed prosthetic feet as well as the socket suspension type for each subject. All subjects wore patellar tendonbearing design sockets and used a gel liner interface. All amputees had a dynamic elastic response type of Prescribed prosthetic foot.

Overall, there was a statistically significant negative correlation between trailing limb prosthetic foot-ankle push-off work and leading intact limb 1<sup>st</sup> peak knee EAM (slope = -0.72 + -0.22; *P*=.011). For the proposed subdivided relationships, there was a significant correlation between prosthetic foot-ankle push-off work and trailing prosthetic limb push-off impulse (slope = 0.88 + -0.18; *P*=.002); trailing limb push-off impulse was negatively correlated with leading intact limb loading impulse (Figure 1C) (slope = -0.34 + -0.14; *P*=.001); and there was a trend toward a correlation between leading limb impulse and 1<sup>st</sup> peak intact knee EAM (slope = 0.25 + -0.17; *P*=.14).

Prosthetic foot-ankle work and peak power varied significantly with foot type (Figure 1D). On average, the CESR foot performed 68% more push-off work than the Prescribed foot, and 137% more than the Conventional foot (Table 2).

Consistent with prior studies <sup>7, 8, 14</sup>, the knee EAM throughout the stance phase has a typical two-peak shape similar to that seen in graphs of the vertical ground reaction force during walking <sup>8</sup>. The 1<sup>st</sup> peak intact knee EAM varied significantly by prosthetic foot condition (Figure 1E). Specifically, both CESR and Prescribed showed a significantly reduced mean 1<sup>st</sup> peak knee EAM compared with Conventional (Table 2). First peak knee EAM in the CESR condition appeared less than that of the Prescribed condition on average, however this difference did not achieve statistical significance (P=.077). There were no significant differences in mean 2<sup>nd</sup> peak EAM across foot type.

## Discussion

In this study we investigated the effects of three different prosthetic foot conditions on the intact knee EAM in unilateral transtibial amputees, a population with a high prevalence of knee OA. Our aim was to explore the effects of prosthetic foot-ankle push-off on the mechanical loading of the intact knee. In support of our hypothesis, we found that increased prosthetic foot-ankle push-off work was associated with a reduction in intact knee 1<sup>st</sup> peak EAM. Examining each prosthetic foot individually, the one with the largest magnitude push-off work, the CESR, was associated with the lowest intact knee 1<sup>st</sup> peak knee EAM. The foot with the least push-off work, the Conventional, was associated with the largest intact knee 1<sup>st</sup> peak knee EAM.

We propose the following potential chain of mechanisms to explain the association found between prosthetic foot-ankle push-off work and 1<sup>st</sup> peak intact knee EAM: Ankle push-off work constitutes the largest joint contribution to terminal stance push-off <sup>29</sup>, and dynamic walking models demonstrate that the push-off impulse causes a change in COM velocity and hence kinetic energy, with the change in energy determining the amount of push-off work <sup>21</sup>. We observed a positive correlation between push-off work and impulse. Similarly, models show that trailing limb push-off impulse can reduce leading limb loading impulse during the transition between one stance limb to the next <sup>16–20</sup>; consistent with these models we found that trailing prosthetic limb push-off impulse was negatively correlated with leading intact limb loading impulse. Lastly we found a trend toward a relationship between leading limb loading impulse and leading limb 1<sup>st</sup> peak knee EAM. This is likely because the loading impulse is the integral of ground reaction forces that make up an important component of the knee EAM. Of course, correlation does not prove causation, and these proposed mechanisms deserve further study.

Peak knee EAM is an indicator of the knee joint loading that has been associated with knee OA  $^{7-13}$ . Knee OA affects the medial tibiofemoral compartment 10 times more commonly than the lateral compartment  $^{30}$ , and the ground reaction force vector falls medial to the knee for the majority of stance phase resulting in an EAM  $^{31}$  (Figure 1B). In our study CESR reduced 1<sup>st</sup> peak intact knee EAM by 26% and Prescribed reduced the value by 16%, when compared to Conventional. Changes on the order of even 5–7% of peak knee EAM have been argued to be clinically significant in prior study assessing the effect of lateral wedge insoles on a population with knee OA  $^{32}$ .

The first peak in EAM is considered to be more important in association with the pathomechanics of knee OA<sup>14</sup> due to being usually larger in magnitude<sup>7, 8, 14</sup> and having a steeper rate of rise <sup>33</sup>. If prosthetic foot-ankle push-off work affects contralateral knee loading, one would expect that effect to be seen at the 1<sup>st</sup> (loading) peak rather than at the 2<sup>nd</sup> peak. Consistent with this hypothesis, we found a significantly larger change in the 1<sup>st</sup> peak EAM by prosthetic foot condition. However, while the CESR foot provided significantly greater foot-ankle push-off than the Prescribed foot, the associated reduction in 1<sup>st</sup> peak intact knee EAM did not reach statistical significance. The lack of significance may be due to the less controlled nature of the Prescribed foot condition (which differed with each subject), or to the much greater accommodation time that subjects had with that foot. It may also suggest that other prosthetic design factors, for example foot length or timing of energy release, may be important as well. Future study is therefore warranted to explore these other prosthetic factors that may influence the mechanical loading conditions of the intact knee.

While commercially available dynamic elastic response prosthetic feet are unable to match intact ankle peak push-off power, the prototype CESR foot has been shown to restore push-

Gait Posture. Author manuscript; available in PMC 2012 October 1.

off power to nearly normal values in non-amputee subjects walking with a fixed-ankle simulator boot <sup>22</sup>. In the current investigation, TTA subjects demonstrated a greater than doubling of peak prosthetic foot-ankle push-off work for the CESR compared to Conventional condition, as well as greater push-off impulse. The Prescribed condition also demonstrated a significantly greater prosthetic foot-ankle push-off work relative to the Conventional, albeit a smaller increase than the CESR. This finding was expected given that all of the prosthetic feet in the Prescribed condition are commercially categorized as dynamic elastic response feet while the Seattle LightFoot2<sup>TM</sup> (Conventional) may have more limited energy return capabilities <sup>34</sup>.

There are several potential limitations to this study, including a relatively small number of subjects. This could have led to type two error in not finding a statistically significant difference in 1<sup>st</sup> peak intact knee EAM between CESR and Prescribed foot conditions. However, the within-subjects design minimizes other potentially confounding variables to which a between-subjects design may be more prone. But it does not address the limited accommodation time of the CESR and Conventional prosthetic foot conditions.

While similar accommodation times have been used in prior study <sup>22</sup>, there is no definitive literature to our knowledge examining the effect of various accommodation times when comparing different prosthetic feet. The Prescribed condition may therefore have had an advantage since these were the feet used by subjects prior to participation in the study. Although these limitations may affect the ability to detect the hypothesized effects, they appear not to reduce the overall relationship observed between prosthetic push-off work and intact knee EAM. Similarly, differences in other variables such as walking speed, double support duration, and COM displacement between foot conditions would be unlikely to affect the overall relationship we observed.

In conclusion, prosthetic foot characteristics have a significant effect on the intact knee EAM during gait in unilateral TTAs. Specifically, feet that perform more prosthetic footankle push-off appear to be associated with a reduction in intact knee 1<sup>st</sup> peak EAM, and their use may therefore reduce the risk and burden of knee osteoarthritis in this population. Future study is warranted to explore other prosthetic foot factors that may also be contributing to this difference in intact knee loading conditions. Studying the effects of prosthetic foot design on the loading conditions associated with knee OA offers a clinically relevant prevention strategy to this common secondary disability in lower extremity amputees.

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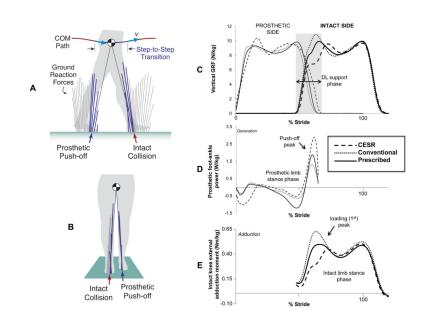
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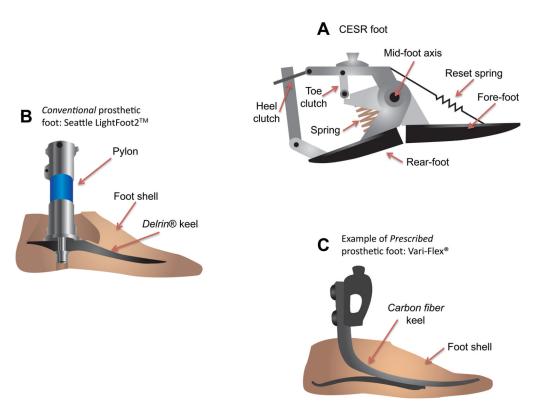
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Morgenroth et al.



#### Figure 1.

Conceptual diagrams demonstrating the prosthetic and intact side ground reaction forces associated with the step-to-step transition (A, B) and graphic display of subject average vertical ground reaction force (C), prosthetic foot-ankle power (D), and intact knee external adduction moment (E), across the gait cycle for each prosthetic foot condition. (A) Sagittal view: the body center of mass (COM) is redirected during the step-to-step transition, as a result of forces applied by both legs against the ground (indicated by lines originating at center of pressure points throughout the gait cycle from a representative trial). (B) Coronal view: the ground reaction force is directed medial to the knee joint center of rotation essentially throughout stance phase leading to an external adduction moment. (C) Push-off and loading impulses were defined as the area under the vertical ground reaction force curves during double limb support. Prosthetic limb push-off impulse was negatively correlated with intact limb loading impulse. There was also a negative correlation between prosthetic foot-ankle push-off work (D) and intact limb 1<sup>st</sup> (loading) peak knee external adduction moment (E).



#### Figure 2.

Schematic diagrams of the three prosthetic foot types used in the study. The Controlled energy storage and return (CESR) foot (A), the Conventional foot (B), and an example of a Prescribed foot (C).

## Table 1

## Prescribed prosthetic foot and suspension mechanism for each subject.

	Prescribed prosthetic foot	Suspension mechanism	
Subject 1	FS1000 <sup>(1)</sup>	pin lock	
Subject 2	Renegade $^{(1)}$ with rotator $^{(4)}$	pin lock	
Subject 3	Ceterus <sup>(2)</sup>	suction	
Subject 4	Seattle Carbon LightFoot 2 $(3)$	pin lock	
Subject 5	Flex Foot <sup>(2)</sup>	pin lock	
Subject 6	Luxon Max <sup>(4)</sup>	pin lock	
Subject 7	Vari-flex <sup>(2)</sup>	pin lock	

<sup>(1)</sup>Freedom Innovation Inc; Irvine, California;

<sup>(2)</sup>Ossur, Reykjavik, Iceland;

<sup>(3)</sup>Seattle Systems; Poulsbo, Washington;

<sup>(4)</sup>Otto Bock, Duderstadt, Germany

## Table 2

Mean (SD) of peak prosthetic ankle power, prosthetic push-off work, and peak intact knee external adduction moment (EAM) by prosthetic foot condition.

	CESR	Conventional	Prescribed	P-value
Peak prosthetic foot- ankle power (W/kg)	3.20 (0.72)	1.35 (0.31)	1.90 (0.53)	.0004 <i>abc</i>
Prosthetic push-off work (J/kg)	0.27 (0.04)	0.11 (0.03)	0.15 (0.04)	<.0001 <i>abc</i>
1 <sup>st</sup> Peak intact knee EAM (Nm/kg)	.451 (.144)	.608 (.169)	.509 (.132)	.015 <sup>ab</sup>
2nd Peak intact knee EAM (Nm/kg)	.483 (.158)	.497 (.143)	.466 (.146)	.054

<sup>a</sup>Significant pairwise difference between CESR and Conventional (P<.017)

 $^b {\rm Significant}$  pairwise difference between Prescribed and Conventional (P<.017)

<sup>c</sup>Significant pairwise difference between CESR and Prescribed (p<.017)