Title: 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 an appropriately timed push-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. Prosthetic push-off work and 1st peak intact knee EAM varied significantly with foot type. The prosthetic foot condition with the largest push-off work (0.27+/-0.04 J/kg) demonstrated the lowest knee EAM (0.451+/-0.144 Nm/kg), and the prosthetic foot with the lowest push-off work (0.11+-0.03 J/kg) demonstrated the largest knee EAM (0.608+/-0.169 Nm/kg). Overall, trailing prosthetic limb push-off impulse was negatively correlated with leading intact limb loading impulse (slope = -0.34 + -0.14; p=.001), and trailing limb prosthetic push-off work was negatively correlated with leading intact limb 1^{st} peak knee EAM (slope = -0.72 +/- 0.22; p=.011). Prosthetic feet

that perform more prosthetic push-off appear to be associated with a reduction in 1st 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 2050¹. 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 ^{2, 3}. Intact limb knee pain in unilateral lower extremity amputees is reported to be twice as common³, and the prevalence of symptomatic knee OA 17 times higher than in age-matched non-amputees². Imaging studies have also confirmed the increased prevalence of intact limb, knee degenerative changes when compared with control populations^{4, 5}. 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 population³. Since TTAs are known to load their intact limb to a greater extent than their prosthetic limb during gait 6 , 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 minimized by optimizing 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 ⁷⁻¹³. In particular, the first of the two EAM peaks during stance phase has been reported to be associated with increased knee OA severity ¹⁴. 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 ¹⁵. Dynamic walking models and experimental studies of non-amputees suggest that an appropriately timed push-off from the trailing limb can reduce collision forces on the leading limb ¹⁶⁻²⁰. 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 ¹⁶. 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 ¹⁶ (**Figure 2A**). If a prosthetic foot produces a reduced push-off, then the intact limb must perform a greater share of the redirection, with an increased collision with the ground. 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 work and larger associated trailing limb ground reaction forces would lead to reduced ground reaction forces and knee EAM during early stance phase of the intact limb.

Methods

We tested for differences in limb loading during gait in unilateral TTAs. We experimentally varied prosthetic foot push-off with three different prosthetic foot conditions, and tested whether an increase in push-off led to a reduction in intact limb loading and knee EAM. 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 ²¹ (Figure 1A); (2) a conventional prosthetic foot (Conventional) (Figure **1B**); (3) the subject's currently prescribed prosthetic foot (Prescribed) (**Figure 1C**). The CESR foot is an energy recycling foot that is designed to increase prosthetic ankle pushoff 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 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 ²¹. The Conventional foot was a Seattle LightFoot2TM (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 determined to optimize function for each individual subject in the clinical setting.

Figure 1 location

Subjects were given an acclimation period during two different days shortly prior to data collection of approximately 10 to 20 minutes of overground and treadmill walking with the Conventional and Prescribed feet and approximately 45 minutes or until the patient

felt comfortable with the CESR foot prior to data collection. Subjects were given additional acclimation time with the CESR foot due to its novel design and function. Prosthetic alignment was optimized by the same experienced prosthetist for all conditions. All trials were at a controlled walking speed of approximately 1.14 m/s, which is a typical walking speed for transtibial amputees ^{22, 23}.

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 were 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 ± 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 3rd 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. We quantified the magnitude of the 1st and 2nd peaks of the intact knee EAM. Prosthetic foot-ankle power was calculated as the sum of translational and rotational work performed on the distal shank ²⁴⁻²⁶. This method captures the net behavior of the foot and does not assume a rigid-body model of the prosthesis with a fixed joint center of rotation as is necessary with standard inverse dynamics. The latter may not accurately account for energy storage, dissipation and return²⁷ in prosthetic feet which have a deformable foot-ankle segment rather than a fixed axis of rotation. Prosthetic foot-ankle push-off work was calculated as the integral of power generated during the final phase of stance. All quantities were normalized to body mass.

Statistical Analysis:

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. Additionally, associations between trailing prosthetic limb push-off impulse and leading intact limb loading impulse, and between trailing limb push-off work and leading limb knee EAM were assessed using linear mixed effects regression, applied across all of the steps recorded from each subject. Leading limb impulse or leading limb knee EAM was the dependent variable and trailing limb impulse or trailing limb push-off work was the independent fixed effect; subject and subject by independent variable interaction were random effects. Results from these models were summarized as slopes and standard errors. 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 (Age: 52.3 ± 12 yrs; Weight: 80.9 ± 9.9 kg; Height: 1.85 ± 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 tendon-bearing design sockets and used a gel liner interface. All amputees had a dynamic elastic response type of Prescribed prosthetic foot.

Table 1 location

Prosthetic foot-ankle work and peak power varied significantly with foot type (Figure 2D). 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 ^{7, 8, 14}, 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 ⁸. The 1st peak intact knee EAM varied significantly by prosthetic foot condition (**Figure 2E**). Specifically, both CESR and Prescribed showed a significantly reduced mean 1st 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 2nd peak EAM across foot type.

Figure 2 and Table 2 location

Overall, trailing prosthetic limb push-off impulse was negatively correlated with leading intact limb loading impulse (**Figure 2C**) (slope = -0.34 + -0.14; *P*=.001). There was also a statistically significant negative correlation between trailing limb prosthetic foot-ankle push-off work and leading intact limb 1st peak knee EAM (slope = -0.72 + -0.22; *P*=.011).

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 pushoff 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 1st peak EAM. This relationship is likely mediated through the negative correlation found between trailing prosthetic limb push-off impulse and leading intact limb loading impulse from step to step and regardless of prosthetic foot. Examining each prosthetic foot individually, the one with the largest magnitude push-off work, the CESR, was associated with the lowest intact knee 1st peak knee EAM. The foot with the least push-off work, the Conventional, was associated with the largest intact knee 1st peak knee EAM.

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 ²⁸, and the ground reaction force vector falls medial to the knee for the majority of stance phase resulting in an EAM ²⁹ (**Figure 2B**). In our study CESR reduced 1st 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 ³⁰.

Dynamic walking models demonstrate the importance of trailing limb push-off in reducing leading limb loading during the transition between one stance limb to the next ¹⁶⁻²⁰. Consistent with these models, we found that trailing prosthetic limb ground reaction impulse was negatively correlated with leading intact limb loading impulse. A similar

relationship was confirmed as expected between two quantities closely related to the impulses: prosthetic limb push-off work and the intact limb peak knee EAM.

Ankle push-off power constitutes the largest joint contribution to terminal stance push-off ³¹, and since TTAs do not have musculature crossing the ankle joint, push-off power is essentially limited to the energy return characteristics of the prosthetic foot-ankle. 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-off power to nearly normal values in non-amputee subjects walking with a fixed-ankle simulator boot ²¹. In the current investigation, TTA subjects demonstrated a greater than doubling of peak prosthetic foot-ankle push-off power for the CESR compared to Conventional condition, consistent with the prior study. The Prescribed condition also demonstrated a significantly greater peak prosthetic foot-ankle push-off power and 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 LightFoot2TM (Conventional) may have more limited energy return capabilities ³².

The 1st EAM peak is generally the larger peak ^{7, 8, 14} in gait and therefore considered to be more important in association with the pathomechanics of knee OA ¹⁴. If prosthetic footankle push-off power and work affect contralateral knee loading, one would expect that effect to be seen at the 1st (loading) peak rather than at the 2nd peak. Consistent with this hypothesis, we found a significantly larger change in the 1st peak EAM by prosthetic foot condition. However, while the CESR foot provided significantly greater foot-ankle pushoff than the Prescribed foot, the associated reduction in 1st 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.

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 1st 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 ²¹, 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 unfair 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.

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 1st 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.

Disclosures

Drs. Adamczyk and Collins are partners in Intelligent Prosthetic Systems, LLC, which develops technology related to the CESR foot prosthesis.

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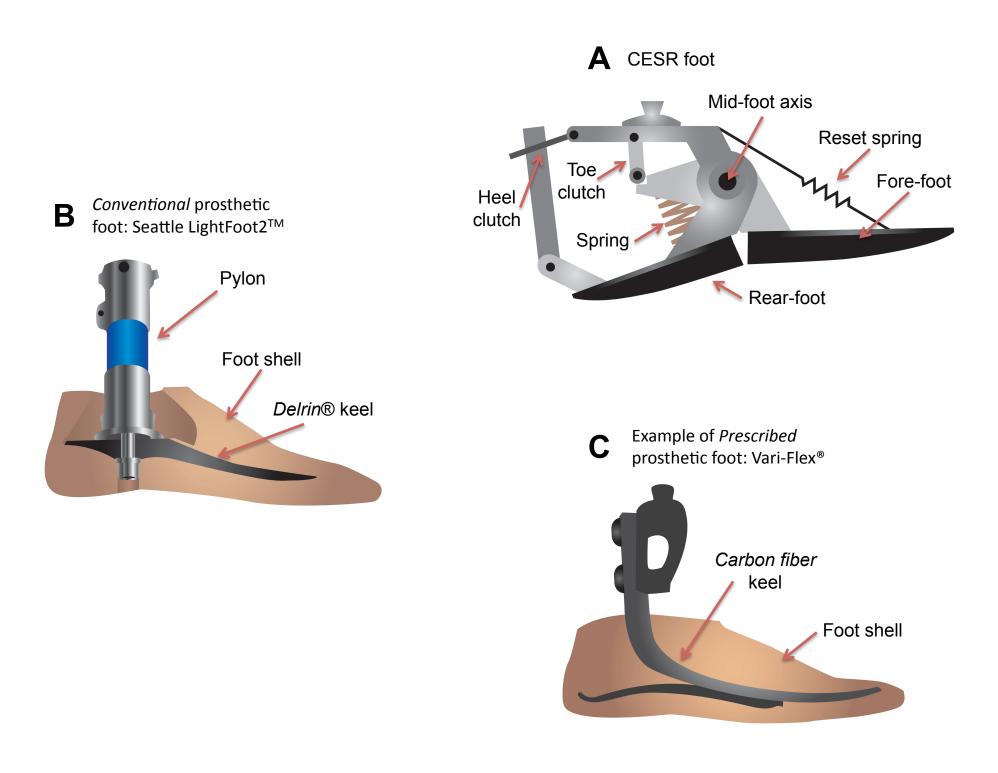
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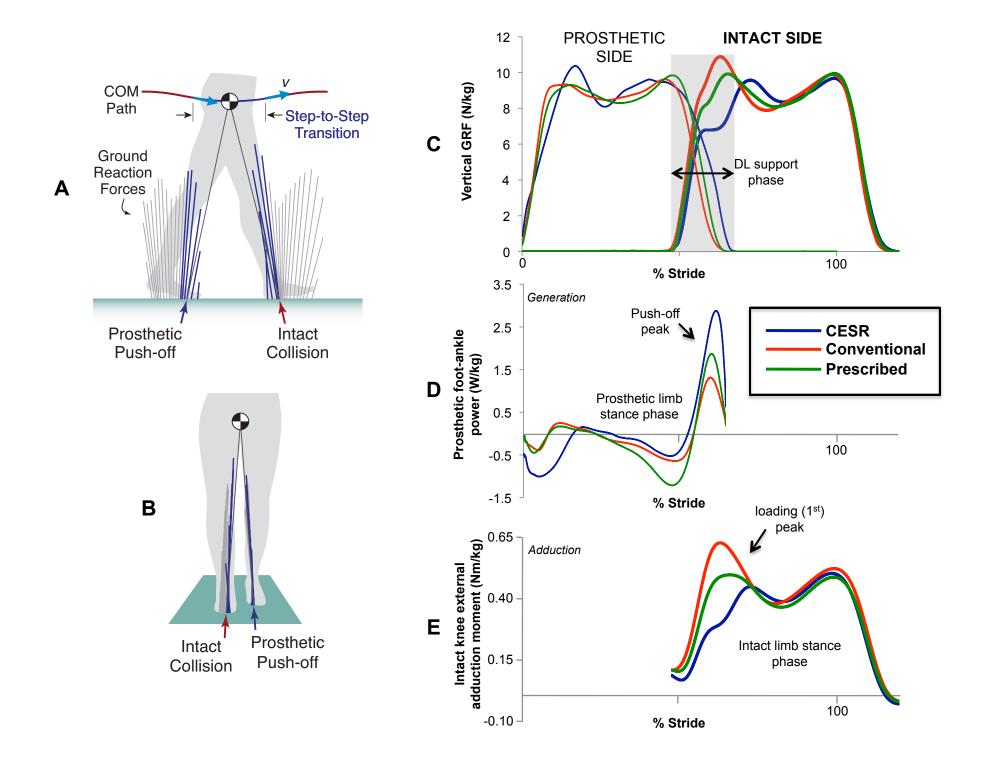
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Figure 1: Schematic diagrams of the three prosthetic foot types used in the study. The Controlled energy storage and return (CESR) foot (A), the Conventional foot (B), and an example of a Prescribed foot (C).

Figure 2: 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 pushoff 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 1st (loading) peak knee external adduction moment (E).





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

Table 1: Prescribed prosthetic foot and suspension mechanism for each subject.

(1) Freedom Innovation Inc; Irvine, California; (2) Ossur, Reykjavik, Iceland; (3) Seattle Systems; Poulsbo, Washington; (4) 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	<i>P</i> -value
Peak prosthetic foot-	3.20 (0.72)	1.35 (0.31)	1.90 (0.53)	.0004 ^{abc}
ankle power (W/kg)				
Prosthetic push-off	0.27 (0.04)	0.11 (0.03)	0.15 (0.04)	<.0001 ^{abc}
work (J/kg)				
1 st Peak intact knee	.451 (.144)	.608 (.169)	.509 (.132)	.015 ^{ab}
EAM (Nmm/kg)				
2 nd Peak intact knee	.483 (.158)	.497 (.143)	.466 (.146)	.054
EAM (Nmm/kg)				

^aSignificant pairwise difference between CESR and Conventional (*P*<.017)

^b Significant pairwise difference between Prescribed and Conventional (P<.017)

^c Significant pairwise difference between CESR and Prescribed (p<.017)