

Coronal plane socket stability during gait in persons with transfemoral amputation: Pilot study

Stefania Fatone, PhD, BPO(Hons);^{1*} Michael Dillon, PhD;² Rebecca Stine, MS;^{1,3} Robert Tillges, CP⁴

¹Department of Physical Medicine and Rehabilitation, Feinberg School of Medicine, Northwestern University Prosthetics-Orthotics Center, Chicago, IL; ²National Centre for Prosthetics and Orthotics, La Trobe University, Bundoora, Victoria, Australia; ³Jesse Brown Department of Veterans Affairs Medical Center, Chicago, IL; ⁴Tillges Certified Orthotic Prosthetic Inc, Maplewood, MN

Abstract—Little research describes which transfemoral socket design features are important for coronal plane stability, socket comfort, and gait. Our study objectives were to (1) relate socket comfort during gait to a rank order of changes in ischial containment (IC) and tissue loading and (2) compare socket comfort during gait when tissue loading and IC were systematically manipulated. Six randomly assigned socket conditions (IC and tissue compression) were assessed: (1) IC and high, (2) IC and medium, (3) IC and low, (4) no IC and high, (5) no IC and medium, and (6) no IC and low. For the six subjects in this study, there was a strong negative relationship between comfort and changes in IC and tissue loading ($\rho = -0.89$). With the ischium contained, tissue loading did not influence socket comfort ($p = 0.47$). With no IC, the socket was equally comfortable with high tissue loading ($p = 0.36$) but the medium ($p = 0.04$) and low ($p = 0.02$) tissue loading conditions decreased comfort significantly. Coronal plane hip moments, lateral trunk lean, step width, and walking speed were invariant to changes in IC and/or tissue loading. Our results suggest that in an IC socket, medial tissue loading mattered little in terms of comfort. Sockets without IC required high tissue loading to be as comfortable as those with IC, while suboptimal tissue loading compromised comfort.

Key words: amputation, coronal plane stability, gait, ischial containment, Marlo Anatomical Socket, prosthesis, socket comfort, socket design, tissue loading, transfemoral prosthetic socket.

INTRODUCTION

Transfemoral prostheses are provided to meet the needs of hundreds of thousands of persons living with limb loss. In the United States, it is estimated that there are 1.6 million persons living with lower-limb amputation [1], of which 25 percent have transfemoral amputation [2].

Despite the prevalence of transfemoral amputation, surprisingly little research describes which design features of a transfemoral socket are important during gait. Particularly relevant for persons with transfemoral amputation is the stability between the socket and residual limb in the coronal plane during walking.

Much of what is known about transfemoral sockets and coronal plane stability during gait stems from theoretical work undertaken after World War II [3–4]. Radcliffe's

Abbreviations: ANCOVA = analysis of covariance, BMI = body mass index, CI = confidence interval, IC = ischial containment, MANCOVA = multivariate analysis of covariance, MAS = Marlo Anatomical Socket, SCS = Socket Comfort Score.

*Address all correspondence to Stefania Fatone, PhD, BPO(Hons); Northwestern University Prosthetics-Orthotics Center, 680 N. Lake Shore Dr, Suite 1100, Chicago, IL 60611; 312-503-5717; fax: 312-503-5760.

Email: s-fatone@northwestern.edu

<http://dx.doi.org/10.1682/JRRD.2014.01.0021>

analyses of quadrilateral sockets proposed that compression of the soft tissue along the proximal-medial aspect of the residual limb was important to prevent the socket translating laterally during single-limb support when large internal abduction moments were present, thereby minimizing discomfort and compensatory gait adaptations [3–4].

A number of complications are commonly reported when coronal plane stability of the transfemoral socket is poor. As the socket translates laterally with respect to the residual limb, the proximal-medial brim of the socket impinges on the soft tissue of the groin, causing discomfort [3–4]. Similarly, as the remnant femur becomes abducted inside the socket, the cut bone end contacts the lateral wall of the socket, causing discomfort [3–4]. A range of gait adaptations are commonly employed to minimize this discomfort, such as increased lateral displacement of the trunk (i.e., Trendelenburg gait) and wider step width. In turn, these adaptations are thought to reduce the coronal plane hip joint moment and walking velocity [3–4]. It seems logical to suggest that the degree of discomfort experienced depends on the extent that coronal plane stability has been compromised and how well the user can compensate by adapting his or her gait pattern. The latter depends, to some extent, on physical characteristics such as the inherent stiffness of the residual-limb tissue.

Based on this theoretical understanding, it is possible to appreciate the important role soft tissue loading is thought to play in terms of stabilizing the residual limb and quadrilateral socket in the coronal plane as well as minimizing complications.

Contemporary transfemoral socket designs, such as the ischial containment (IC) socket, also utilize soft tissue compression on the medial aspect of the residuum [5–6]. However, coronal plane stability is thought to be improved in an IC socket because, in addition to soft tissue compression, there is intimate contact between the socket and medial aspect of the ischium. Some have argued that the IC socket can more effectively limit lateral shift of the socket since the bony anatomy of the ischium cannot yield like soft tissue [7].

Since the introduction of the IC socket and more recent variants such as the Marlo Anatomical Socket (MAS) [8], experts have debated the relative contribution to coronal plane stability made by soft tissue loading and containment of the ischium [7,9–11]. It has been argued that in an IC socket, coronal plane stability is derived from containment of the ischium and loading of the

medial soft tissue matters little [7]. By logical extension, the absence of IC—as is the case in a quadrilateral socket or poorly fit IC socket—implies that stiffness of the medial soft tissue of the residual limb will be paramount in maintaining coronal plane stability [7].

Given this understanding, it seems reasonable to contend that changes in coronal plane stability might be related to a rank order of changes in IC and tissue loading conditions and, in turn, socket comfort. For example, a socket with IC and high tissue loading might provide the most coronal plane stability and therefore be the most comfortable. A socket with no IC and very little medial tissue loading might provide the least coronal plane stability and be the least comfortable.

The ability to independently manipulate aspects of socket design, such as the presence or absence of IC, was an important consideration in the design of this experiment. We deemed the MAS to be the most feasible socket design for this purpose because it was possible to design a removable IC component without affecting other elements of the socket design.

The aim of this pilot study was to relate socket comfort during gait to a rank order of changes in IC and tissue loading conditions in persons with unilateral transfemoral amputation. We also aimed to compare socket comfort during gait when soft tissue loading and IC were systematically manipulated in the MAS.

We hypothesized that there would be a significant negative relationship between socket comfort and the rank order of changes in IC and tissue loading, such that sockets with IC and high tissue loading would be the most comfortable and sockets without IC and low tissue loading would be the least comfortable. In terms of the comparison, we hypothesized that sockets with IC would be the most comfortable irrespective of soft tissue loading and that increased tissue loading would only be important in sockets without IC.

To understand gait adaptations resulting from changes in socket comfort, we examined a range of secondary outcome measures. We expected that sockets with IC and high tissue loading would be the most comfortable and therefore require the least adaptation in step width, trunk lean, coronal plane hip moments, and walking velocity. Similarly, we expected that sockets with no IC and very little tissue loading would be the least comfortable and require the most adaptation.

METHODS

Adults with unilateral transfemoral amputation were recruited through a private prosthetic practice by the author (R.T.). Subjects had to be experienced users of the MAS and currently have a well-fitting MAS. Subjects were excluded if they had cognitive deficits that precluded understanding the instructions, breakdown of the skin on the residual limb, or comorbidities affecting gait or function of the contralateral limb.

All prosthetic services were provided by the author (R.T.), who is qualified to provide the MAS having received training from developer Marlo Ortiz through courses provided by the Orthotic and Prosthetic Group of America [8]. The author (R.T.) is recognized as a leading proponent of the MAS in the United States and routinely provides MASs to his patients. The first two study visits allowed the prosthetist (author R.T.) to fabricate and fit a test socket designed specifically for this study. The test socket was a duplicate of the subjects' regular MAS that was fabricated using the circumferential reductions recommended in the MAS orthometry form. The socket included a removable IC component and removable panels that allowed tissue compression on the medial aspect of the residual limb, inferior to the ischial level, to be systematically altered (**Figure 1**). Two IC conditions were tested: with IC and without (no IC). Three soft tissue compression conditions were tested: high, medium, and low, with the high compression condition representing the subject's usual clinical fitting. Except for the removable features, the test socket resembled diagnostic sockets typically used in clinical fittings of prosthetic sockets and were made of clear, high-temperature thermoplastic (polyethylene terephthalate). The subject's prescribed prosthetic components were used with the test socket (**Table 1**). The suspension mechanism (i.e., skin fit suction with a one-way expulsion valve), componentry, and alignment did not change between the different socket configurations tested.

Data were recorded at the third study visit. Subjects' height, weight, and limb lengths were measured. Limb lengths were measured in supine with a tape measure extended from the anterior superior iliac spine to the medial malleolus on the intact limb and the anterior superior iliac spine to the distal end of the residual limb. An eight-camera motion analysis system (Motion Analysis Corporation; Santa Rosa, California) was used to record kinematic data

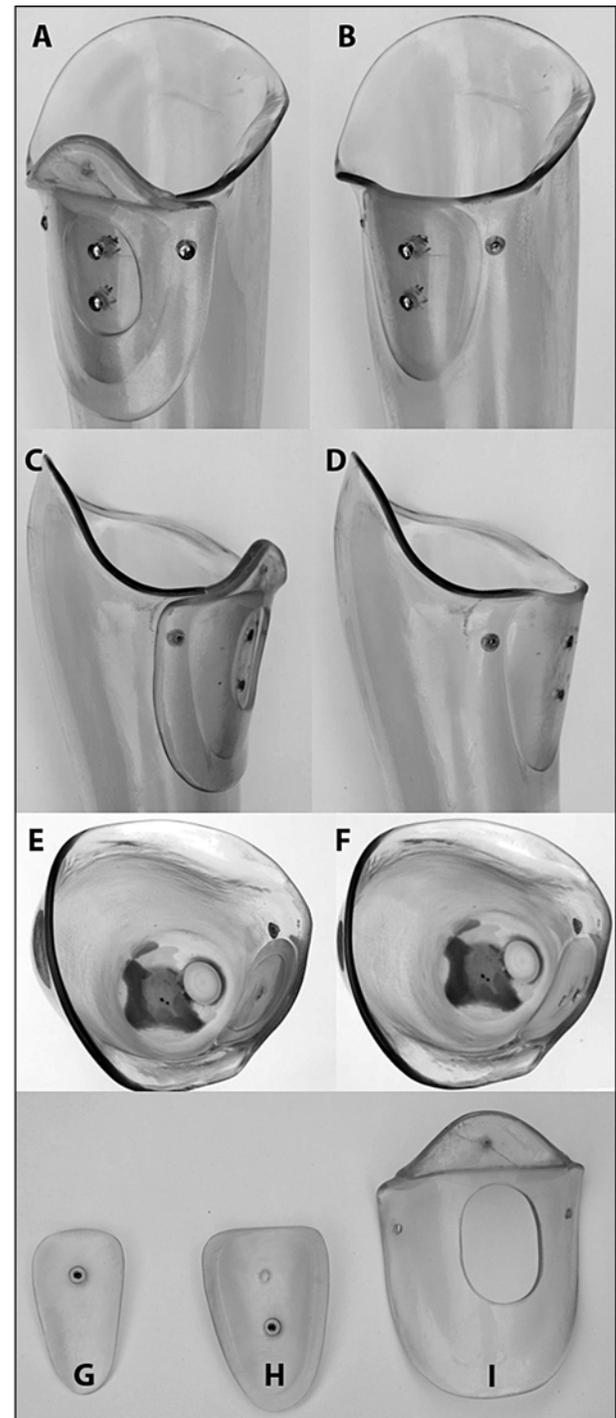


Figure 1. Midsagittal view of Marlo Anatomical Socket (MAS) (a) with and (b) without ischial containment (IC). Coronal plane view of MAS (c) with and (d) without IC. Transverse plane view of MAS with IC removed for clarity, shown (e) with and (f) without medial panels. (g)–(h) Removable medial panels, each 5 mm thick, and (i) IC panel.

Table 1.
Subject characteristics.

Subject	Sex	Age (yr)	Amputation		Time Since Amputation (yr)	Height (cm)	Weight (kg)	BMI	Residual-Limb Length (%) [*]	Prosthetic Components (knee/foot) [†]
			Side	Cause						
1	M	49	L	Trauma	25	182.5	71.6	21.5	—	C-Leg/—
2	M	81	R	Trauma	51	186.0	87.2	25.2	32	C-Leg/Trias
3	F	39	L	Trauma	10	162.0	88.0	33.5	34	Genium/Trias
4	M	67	L	Infection	6	173.0	75.8	25.3	43	C-Leg/Trias
5	M	36	L	Trauma	9	181.0	95.4	29.1	46	Genium/Triton
6	M	35	R	Trauma	8	183.0	77.2	23.1	34	Genium/Triton

^{*}Percentage of intact limb total length.

[†]All components from Ottobock (Duderstadt, Germany).

BMI = body mass index, F = female, L = left, M = male, R = right.

at 120 Hz. Kinetic data were recorded at 960 Hz using six force plates (AMTI; Watertown, Massachusetts) embedded in the middle of a 12 m walkway. Reflective markers were taped to the pelvis and lower limbs according to a modified Helen Hayes model [12]. For dynamic trials, markers were placed on both acromion processes, anterior superior iliac spines, anterior thighs, lateral femoral epicondyles, anterior tibias, lateral malleoli, calcanei and dorsum of the foot (immediately proximal to the 3rd metatarsal head), and on the sacrum. Static trials used to calculate joint centers included additional markers on the medial femoral epicondyles and medial malleoli. These were removed for dynamic trials. OrthoTrak software (Motion Analysis Corporation) was used to calculate kinematic and kinetic variables. Kinematic data were filtered with a bidirectional, fourth-order, low-pass Butterworth filter with a cut-off frequency of 6 Hz. Kinetic data were filtered with a bidirectional, second-order, low-pass Butterworth filter with the same cut-off frequency.

Subjects were asked to walk at a self-selected comfortable walking speed in one of six randomly assigned socket conditions (IC and tissue compression): (1) IC and high, (2) IC and medium, (3) IC and low, (4) no IC and high, (5) no IC and medium, and (6) no IC and low.

The socket was doffed between each condition in order to allow for changes in the socket configuration; hence, a new static trial was recorded for each condition. A minimum of five walking trials were averaged for each condition per subject, representing about 25 to 30 gait cycles per limb, per subject. For each socket condition, we recorded the Socket Comfort Score (SCS) (ordinal scale where 0 = the most uncomfortable socket fit imaginable and 10 = the most comfortable socket fit) [13], walking

speed, step width, maximum lateral trunk lean in prosthetic limb stance, and maximum coronal plane hip moment in prosthetic limb stance. We also recorded trunk kinematics and coronal plane hip moments across the gait cycle given the potential that maximum values may not capture important information about the adaptations employed.

Given our hypothesis that socket comfort was related to the rank order of changes in IC and tissue loading, it was possible to determine the strength of this relationship using a Spearman rho.

For the comparison aim, there were a number of considerations that underpinned our choice of statistical technique. While the primary outcome measure, socket comfort, was measured on an ordinal scale, we chose to adopt a parametric analysis technique using a two-way repeated-measures analysis of covariance (ANCOVA). The parametric approach offered the ability to evaluate the main effects as well as any interaction between independent variables, which was not possible with nonparametric alternatives. We argue that the SCS may be considered a continuous variable, and therefore suitable for parametric analysis, given the large number of ordered categories and the linear nature of changes in socket comfort with different configurations of IC and tissue loading [14]. Given that the number of dependent variables exceeded the number of participants, it was not considered feasible to undertake a multivariate ANCOVA (MANCOVA) or multivariate linear regression.

The two-way repeated-measures ANCOVA was used to identify interaction effects between the two independent variables—IC and tissue compression—and the main effects on the dependent variable—socket comfort—when the inherent stiffness of the residual-limb tissue was

controlled. Given that only scalar variables can be used as covariates in the analysis, we used body mass index (BMI) as a proxy measure of the inherent stiffness of the residual-limb tissue given the strong relationship between the clinician's categorization of tissue stiffness (i.e., firm, average, soft) and BMI ($\rho = 0.86, p = 0.03$).

Assumptions that underpin the ANCOVA were examined as follows: data were initially inspected to identify outliers based on calculation of studentized residuals. Values ± 3.0 standard deviations were left unmanipulated in cases where the data were normally distributed or transformed in cases where data were not normally distributed. Normality of the data were assessed using visual inspection of the normal Q-Q plots and quantified using the Shapiro-Wilks test. Sphericity was tested using Mauchly's test for sphericity, and the Greenhouse-Geisser adjustment was used when the assumption of sphericity was violated. Only when assumptions of the ANCOVA were violated have results from the assumption tests been reported. When interaction between the two independent variables was significant, these observations have been reported and simple main effects determined using one-way repeated-measures ANCOVAs for each of the independent variables. When the interaction between the two independent variables was not significant, the results of the main effects tests were reported directly from the two-way repeated-measures ANCOVA results. In all cases, post hoc tests were undertaken using the Bonferroni adjustment.

To better understand the gait adaptations that resulted from changes in socket comfort, we explored the secondary outcome measures using the same analytical techniques.

RESULTS

Six subjects with unilateral transfemoral amputation participated in this study. Subjects varied in age from 35 to 81 yr and had long-term amputation of nonvascular etiology with relatively long residual limbs (**Table 1**). All subjects wore the MAS as part of their normal prosthesis prior to the study. For this investigation, participants wore the current MAS for an average of 3 mo prior to the study.

Socket Comfort

There was a strong, negative relationship between SCS and the rank order of changes in IC and tissue loading

that described socket stability ($\rho = -0.89$) (**Figure 2**). Decrements in socket stability across the various IC and tissue loading conditions resulted in a less comfortable socket. Changes in socket stability explain 94 percent of the change in the SCS.

The effect of changes in IC and tissue loading on the participants' SCS were examined. Visual inspection of the normal Q-Q plot suggested that the data were normally distributed and Shapiro-Wilk tests confirmed this assessment except for one test condition (no IC and medium tissue loading) where the result was statistically significant ($W = 0.783, df = 6, p = 0.04$). Given that analysis of the studentized residuals did not identify any values outside ± 3.0 standard deviations, it was assumed this violation did not warrant the use of transformations. The assumption of sphericity was not violated for either the interaction or main effect tests ($p > 0.05$).

There was a significant interaction effect between the two independent variables—IC and tissue loading—when the influence of BMI was controlled ($F(2,8) = 5.37, p = 0.03, \text{partial } \eta^2 = 0.573$). Simple main effects for IC showed that the SCS did not change significantly between the IC and no IC conditions during high tissue loading ($F(1,4) = 1.049, p = 0.36, \text{partial } \eta^2 = 0.208$). However, the SCS did change significantly between the IC and no IC conditions in both the medium ($F(1,4) = 9.48, p = 0.04, \text{partial } \eta^2 = 0.703$) and low ($F(1,4) = 14.657, p = 0.02, \text{partial } \eta^2 = 0.786$) tissue loading conditions. Post hoc comparisons showed a difference in the SCS between the IC and no IC conditions of nearly 1 point for medium tissue loading (0.92, 95% confidence interval [CI]: -0.23 to $2.60, p = 0.09$) and nearly 4 points for low tissue loading (3.92, 95% CI: 2.17 – $5.66, p = 0.003$). Simple main effects for tissue loading showed that the SCS did not change in response to the different tissue loading conditions when the ischium was contained ($F(2,8) = 0.831, p = 0.47, \text{partial } \eta^2 = 0.172$). When the ischium was not contained in the socket, changes in tissue loading significantly affected the SCS ($F(2,8) = 7.882, p = 0.02, \text{partial } \eta^2 = 0.663$). Post hoc comparisons showed that when the ischium was not contained, differences in the SCS of nearly 3 points were observed between the low and medium tissue loading conditions (2.7, 95% CI: 0.72 – $4.62, p = 0.02$). There were no significant differences in the SCS between the high and medium tissue loading conditions (0.5, 95% CI: -3.6 to $2.6, p > 0.99$) or the high and low tissue loading conditions (2.2, 95% CI: -0.45 to $4.79, p = 0.09$).

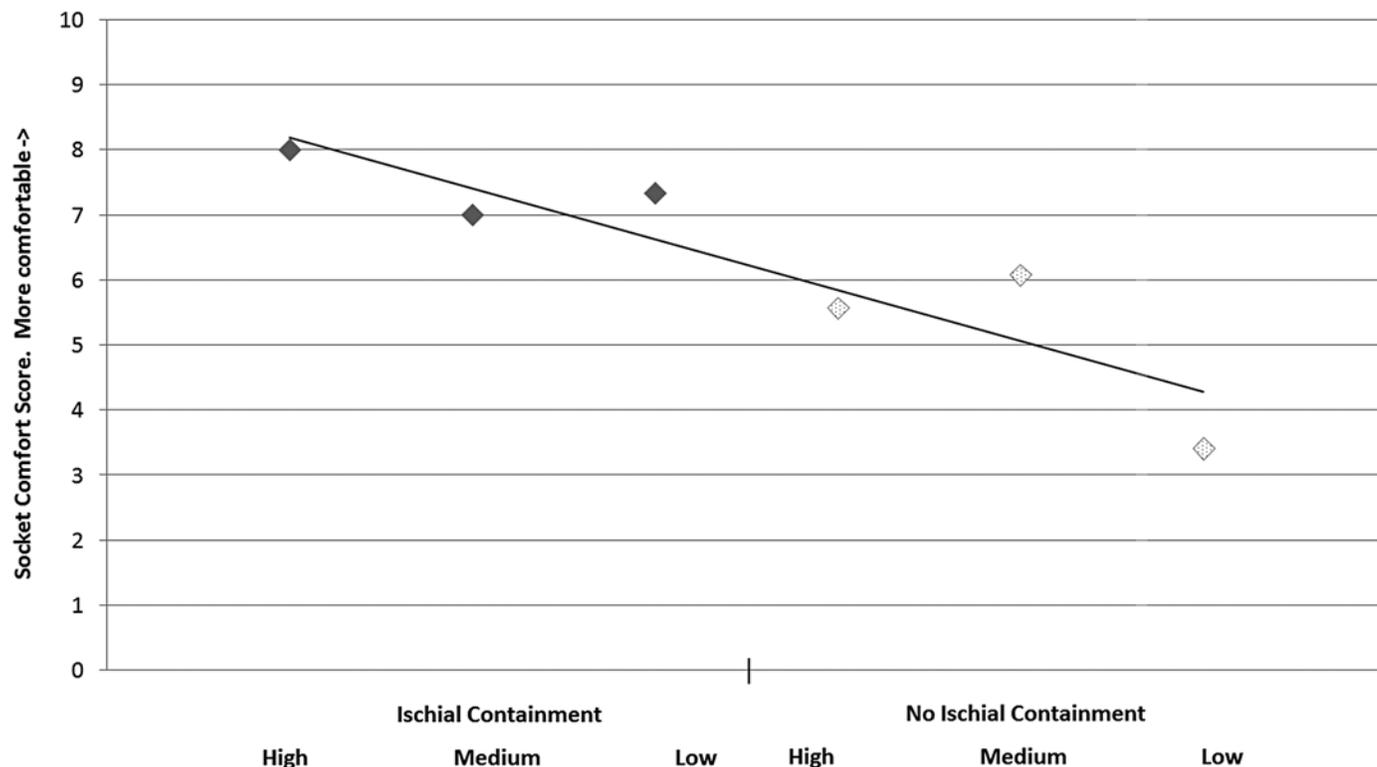


Figure 2.

Relationship between Socket Comfort Score and rank order of changes in ischial containment and tissue loading that describe socket stability. Data represent average for all six participants.

Step Width

The effect of changes in IC and tissue loading on the participants' step width showed a significant main effect for IC ($F(1,4) = 9.228, p = 0.04, \text{partial } \eta^2 = 0.698$). Post hoc comparison showed reduction in step width of nearly 1 cm between the IC and no IC conditions (0.92 cm, 95% CI: 0.639–1.20, $p = 0.001$). The main effect for tissue loading was not significant ($F(2,8) = 0.725, p = 0.51, \text{partial } \eta^2 = 0.153$) (Table 2).

Walking Speed

The effect of changes in IC and tissue loading on walking speed showed that the main effect for IC was not significant ($F(1,4) = 0.031, p = 0.87, \text{partial } \eta^2 = 0.008$). There was a significant main effect for tissue loading ($F(2,8) = 5.64, p = 0.03, \text{partial } \eta^2 = 0.585$). Post hoc comparisons showed no significant differences in walking speed between any of the tissue loading conditions ($p > 0.10$) (Table 2).

Lateral Trunk Lean

The effect of changes in IC and tissue loading on the participants' maximum lateral trunk lean showed that the main effects for IC ($F(1,4) = 0.020, p = 0.89, \text{partial } \eta^2 = 0.005$) and tissue loading ($F(2,8) = 0.616, p = 0.564, \text{partial } \eta^2 = 0.133$) were not significant. We did not observe appreciable differences in trunk kinematics over the gait cycle (Figure 3).

Coronal Plane Hip Moment

Changes in IC and tissue loading on the participants' coronal plane hip moment showed that the main effects for IC ($F(1,4) = 0.053, p = 0.83, \text{partial } \eta^2 = 0.013$) and tissue loading ($F(2,8) = 0.762, p = 0.49, \text{partial } \eta^2 = 0.160$) were not significant. We did not observe appreciable differences in coronal plane hip moment over the gait cycle (Figure 4).

Table 2.

Socket Comfort Score, step width, and walking speed for various combinations of ischial containment (IC) and tissue loading.

Measure	Tissue Loading	IC (mean \pm SD)	No IC (mean \pm SD)
Socket Comfort Score	High	8.00 \pm 1.26	5.58 \pm 2.15
	Medium	7.00 \pm 1.38	6.08 \pm 1.28
	Low	7.33 \pm 1.75	3.41 \pm 2.10
Step Width (cm)	High	16.97 \pm 2.10	15.75 \pm 1.79
	Medium	16.55 \pm 2.17	16.22 \pm 2.52
	Low	16.38 \pm 2.18	15.17 \pm 2.24
Walking Speed (cm/s)	High	122.49 \pm 14.27	120.63 \pm 20.11
	Medium	122.03 \pm 14.51	119.46 \pm 17.58
	Low	119.93 \pm 16.02	118.87 \pm 16.61

SD = standard deviation.

DISCUSSION

What Do Results Tell Us About the Effect of Ischial Containment and Tissue Loading on Socket Comfort and Gait?

The results of this pilot study suggest that changes in socket comfort are strongly related to our hypothesized rank order of changes in IC and tissue loading. It is important to note that the correlation was based on few data points, making it sensitive to the effect of changes in any one. Moreover, the correlation does not explain whether changes in socket comfort are due to changes in IC, tissue loading, or both.

In sockets with IC, differences in tissue loading had no influence on socket comfort. Sockets without IC were equally comfortable when the tissue was highly loaded but significantly less comfortable in the lower tissue loading conditions compared with sockets with IC. This suggests that tissue loading along the medial aspect of the residual limb, inferior to the ischial level, matters little in terms of comfort in an IC socket. Sockets without IC require high (optimal) tissue loading to be as comfortable as those with IC, and suboptimal tissue loading compromises comfort.

Given these significant changes in socket comfort, we were surprised that participants did not adapt their gait consistent with our hypothesis; to a large extent, gait was invariant to changes in IC and/or tissue loading. We did not observe changes in coronal plane hip moments or trunk kinematics as might be expected in response to a deterioration in socket comfort or coronal plane stability of the socket. While we observed statistically significant changes in temporospatial parameters (i.e., walking speed and step width), these were small in magnitude, typical of differences observed in test-retest measurement, and cannot be considered clinically meaningful [15–16].

There may be several explanations for why we did not observe gait adaptations in response to changes in socket comfort. First, the various test conditions were measured back-to-back within one testing session, offering little opportunity for participants to adapt. With a longer acclimation period, problems with socket comfort may become chronic, cause pain, and lead to the sort of gait adaptations we expected. This interpretation is consistent with previous literature that suggests discomfort or low levels of pain do not alter gait, but once the pain becomes more significant (i.e., pain score $>$ 3 on a visual analog scale), reductions in walking speed of about 20 cm/s were observed [17]. Such a reduction in walking speed is about 10 times the change observed between experimental conditions in this investigation. Second, while removing the IC could be considered a dramatic intervention, its effect on gait may be unremarkable in a socket that otherwise fits well. From clinical experience, we suggest that gait adaptations associated with coronal plane instability, such as lateral trunk lean and wide step width, are typically observed in sockets that cause pain and have gross fitting problems that necessitate major adjustments. By comparison, the discrete changes we made to overall well-fitting sockets may have limited our ability to affect gait. Last, people with transfemoral amputation secondary to advanced diabetes and vascular disease may be more susceptible to the effects of manipulating IC and/or tissue loading than our study sample, particularly given comorbidities that affect balance and gait.

What Does It Mean in Terms of Our Understanding of the Way Transfemoral Sockets Work and Implications for Clinical Practice?

Our results support expert opinion that medial tissue loading contributes little to coronal plane stability and comfort in a well-fit IC socket [3]. This may explain why

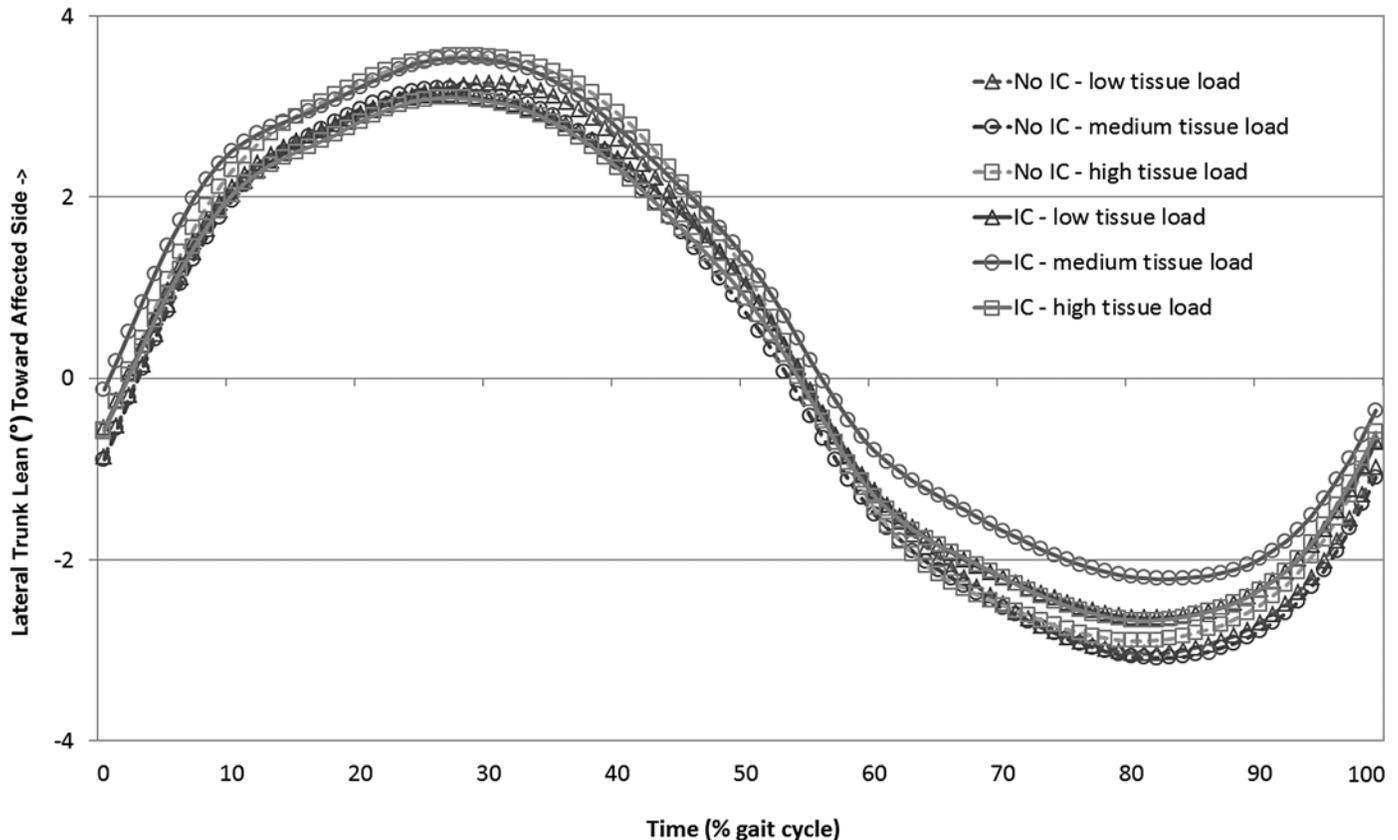


Figure 3.

Mean coronal plane trunk kinematics across gait cycle for different socket conditions: ischial containment (IC) and no IC. Tissue loading conditions: high, medium, and low.

some IC designs place little emphasis on soft tissue loading along the proximal-medial aspect of the residual limb, instead opting for a more rounded, “limb-shaped” profile in the transverse plane [1–2]. For our subjects, soft tissue loading as part of the MAS design had no effect on socket comfort or coronal plane measures of gait.

Our results are consistent with classic theory describing the importance of soft tissue loading along the proximal-medial aspect of the residual limb in sockets without IC [3]. In the quadrilateral design, optimal loading of the proximal-medial aspect of the residual limb precompresses and stiffens the soft tissue, improving its ability to reduce lateral translation of the socket during prosthetic single-limb support [3]. In a quadrilateral socket, this is achieved by flattening the medial wall of the socket, but there are a variety of “generically round” transfemoral socket shapes that will likely achieve the

same tissue precompression and similar outcomes without IC.

The clinical implications of our results suggest that socket comfort may be achieved with a variety of transfemoral socket geometries, but the underlying mechanism for coronal plane stability may differ depending on whether there is IC or the socket relies on soft tissue compression. We believe that these sorts of insights will improve understanding about how transfemoral sockets work and allow prosthetists to more effectively design and problem-solve socket fit and gait-related issues.

Which Outcome Measures Are Sensitive to Changes in Ischial Containment and Tissue Load?

It seems that SCS was more sensitive to changes in IC and tissue loading than any of the gait parameters we measured, particularly when changes to the socket were made in quick succession as is the case in routine clinical

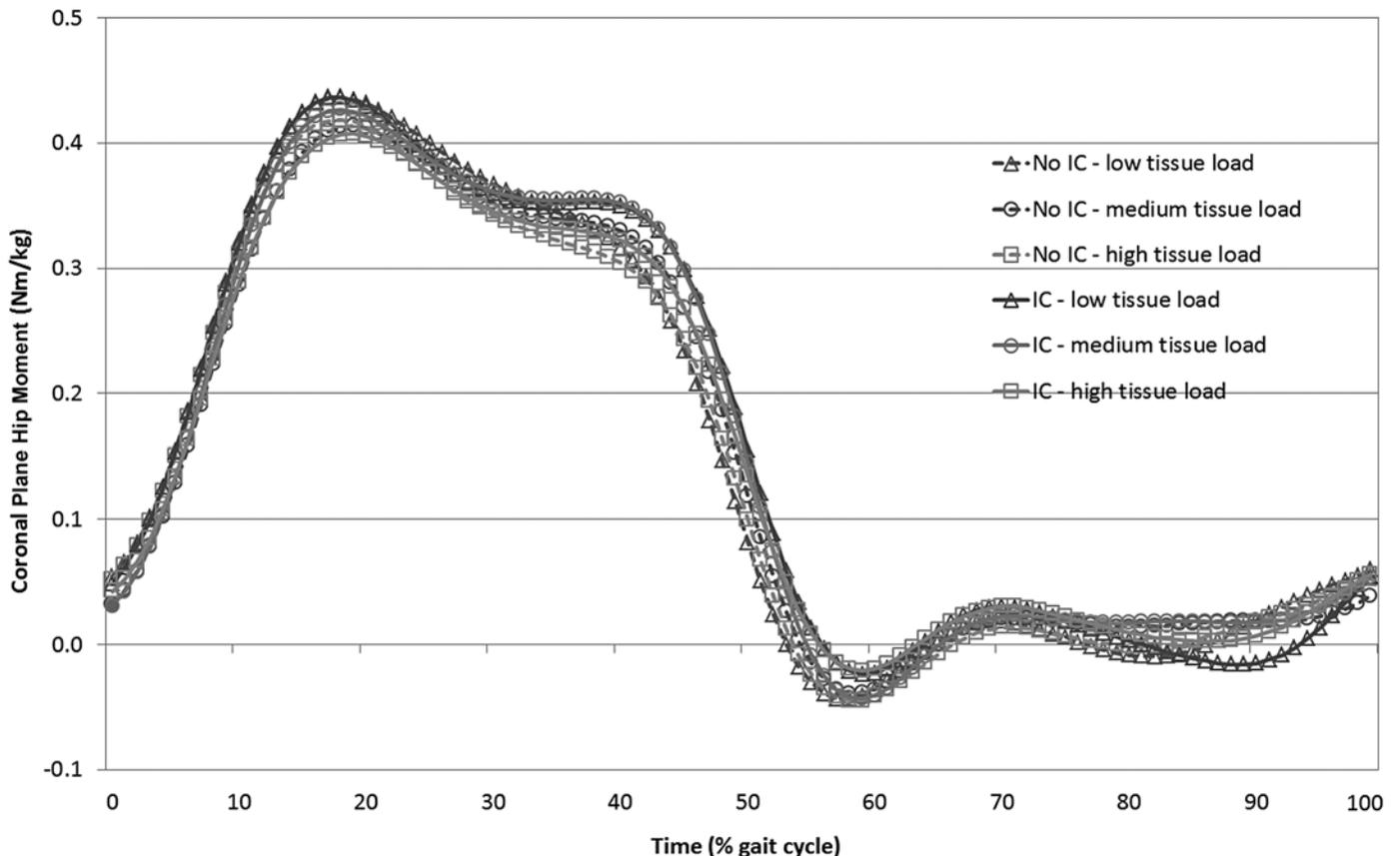


Figure 4.

Mean coronal plane hip moment across gait cycle for different socket conditions: ischial containment (IC) and no IC. Tissue loading conditions: high, medium, and low.

care. This suggests that clinicians could use the SCS to evaluate the immediate effect of socket-related adjustments in preference to clinical measures of gait, such as walking speed.

What Did We Learn That Would Help Further This Work?

While our manipulation of IC and tissue loading was successful in producing meaningful changes in socket comfort, we did not observe the gait adaptations we expected. It is likely that some period of acclimation is required for discomfort to result in pain. Once sockets become painful, we might expect prosthesis users to adapt their gait as hypothesized. Future socket research should consider providing a period of acclimation, with appropriate measures to monitor discomfort and pain, prior to gait data collection. The drawbacks of such a study include (1) the increased risk of dropouts as sub-

jects become disenchanted with wearing painful socket conditions and (2) the unacceptable risk for persons with amputations of vascular etiology in terms of potential for tissue breakdown.

Future investigations should include residual-limb length as a covariate in the ANCOVA, given recent research reporting a significant relationship between residual-limb length and both coronal plane trunk kinematics and walking speed [18]. Unfortunately, we were unable to do so because this information was missing for one participant. There is also the need for future investigations to recruit a larger and more representative sample of persons with transfemoral amputation in terms of cause of amputation.

Given the small number of participants in this pilot study and the comparatively large number of dependent variables, it was not considered feasible to undertake a MANCOVA or multivariate linear regression. Because of

the analytical approach we adopted, significant main effects were occasionally not supported by post hoc comparisons despite our testing of the underlying assumptions (e.g., walking speed) (**Table 2**). It may be that our investigation lacked the power to observe these differences given the need to control for multiple pair-wise comparisons. Future investigators will be able to use this pilot data to determine sample size commensurate with decisions about number of outcome measures and analysis technique.

CONCLUSIONS

Our results suggest that socket comfort may be achieved with a variety of transfemoral socket geometries. In an IC socket, medial tissue loading mattered little in terms of comfort. Sockets without IC required high tissue loading to be as comfortable as those with IC and suboptimal tissue loading compromised comfort. The effect on gait of removing IC may be unremarkable in a socket that otherwise fits well and gait adaptations may not be observed until sockets become painful. Further research is needed to extend these findings to persons with amputation due to vascular etiology and various residual-limb lengths.

ACKNOWLEDGMENTS

Author Contributions:

Study concept and design: S. Fatone.

Acquisition of data: R. Stine, S. Fatone, R. Tillges.

Analysis and interpretation of data: S. Fatone, M. Dillon.

Drafting of manuscript: S. Fatone, M. Dillon.

Critical revision of manuscript for important intellectual content:

R. Stine, R. Tillges.

Obtained funding: S. Fatone.

Financial Disclosures: The authors have declared that no competing interests exist.

Funding/Support: This material was based on work supported by the National Institute on Disability and Rehabilitation Research of the U.S. Department of Education (grant H133E080009, principal investigators: Steven Gard and Stefania Fatone).

Additional Contributions: The authors acknowledge the use of the Jesse Brown Department of Veterans Affairs Medical Center Motion Analysis Research Laboratory for the collection of data. Special thanks to Matthew Major, PhD, for feedback on statistical analysis and Wade Hallstrom for assistance with test socket design and fabrication.

Institutional Review: The Northwestern University Institutional Review Board approved this study and all subjects provided written informed consent prior to participation.

Participant Follow-Up: The authors do not plan to inform participants of the publication of this study.

Disclaimer: The opinions contained in this publication are those of the grantee and do not necessarily reflect those of the U.S. Department of Education.

REFERENCES

- Ziegler-Graham K, MacKenzie EJ, Ephraim PL, Travison TG, Brookmeyer R. Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Arch Phys Med Rehabil.* 2008;89(3):422–29. [PMID:18295618] <http://dx.doi.org/10.1016/j.apmr.2007.11.005>
- Dillingham TR, Pezzin LE, MacKenzie EJ. Limb amputation and limb deficiency: Epidemiology and recent trends in the United States. *South Med J.* 2002;95(8):875–83. [PMID:12190225]
- Radcliffe CW. Functional considerations in the fitting of above-knee prostheses. *Artif Limbs.* 1955;2(1):35–60. [PMID:14351063]
- Radcliffe CW. Alignment of the above-knee artificial leg. In: Klopsteg PE, Wilson PD, editors. *Human limbs and their substitutes: Presenting results of engineering and medical studies of the human extremities and application of the data to the design and fitting of artificial limbs and to the care and training of amputees.* New York (NY): McGraw-Hill; 1954. p. 676–92.
- Hoyt C, Lundt J, Statts TB. *The UCLA CT-CAM above-knee prosthesis.* Los Angeles (CA): UCLA Prosthetics Education and Research Program; 1987.
- Dillon MP. *Ischial containment socket for transfemoral amputees. A manual for assessment, casting, modification and fitting.* Bundoora (Australia): National Centre for Prosthetics and Orthotics; 2006.
- Dillon MP. Ischial containment socket designs: Insights into socket geometry and coronal plane alignment. In: Bach TM, Lemaire E, Hubbard S, Kyberd P, editors. *Proceedings of the 12th World Congress of the International Society for Prosthetics and Orthotics; 2007 Jul 29–Aug 3; Vancouver, Canada.* p. 53.
- Trower TA. Changes in lower extremity prosthetic practice. *Phys Med Rehabil Clin N Am.* 2006;17(1):23–30, v–vi. [PMID:16517343] <http://dx.doi.org/10.1016/j.pmr.2005.10.003>
- Michael JW. Coronal plane stability and alignment of transfemoral prosthetics sockets. In: Bach TM, Lemaire E, Hubbard S, Kyberd P, editors. *Proceedings of the 12th World Congress of the International Society for Prosthetics and Orthotics; 2007 Jul 29–Aug 3; Vancouver, Canada.* p. 54.
- Uellendahl JE. Ischial containment socket designs: Discussion. In: Bach TM, Lemaire E, Hubbard S, Kyberd P, editors.

- Proceedings of the 12th World Congress of the International Society for Prosthetics and Orthotics; 2007 Jul 29–Aug 3; Vancouver, Canada. p. 55.
11. Dillon MP. Ischial containment socket designs: Introduction. In: Bach TM, Lemaire E, Hubbard S, Kyberd P, editors. Proceedings of the 12th World Congress of the International Society for Prosthetics and Orthotics; 2007 Jul 29–Aug 3; Vancouver, Canada. p. 52.
 12. Kadaba MP, Ramakrishnan HK, Wootten ME. Measurement of lower extremity kinematics during level walking. *J Orthop Res.* 1990;8(3):383–92. [PMID:2324857] <http://dx.doi.org/10.1002/jor.1100080310>
 13. Hanspal RS, Fisher K, Nieveen R. Prosthetic socket fit comfort score. *Disabil Rehabil.* 2003;25(22):1278–80. [PMID:14617445] <http://dx.doi.org/10.1080/09638280310001603983>
 14. Unsworth CA, Thomas SA, Greenwood KM. Rehabilitation teams decisions on discharge housing for stroke patients. *Arch Phys Med Rehabil.* 1995;76(4):331–40. [PMID:7717833] [http://dx.doi.org/10.1016/S0003-9993\(95\)80658-X](http://dx.doi.org/10.1016/S0003-9993(95)80658-X)
 15. van Uden CJ, Besser MP. Test-retest reliability of temporal and spatial gait characteristics measured with an instrumented walkway system (GAITRite). *BMC Musculoskelet Disord.* 2004;5:13. [PMID:15147583] <http://dx.doi.org/10.1186/1471-2474-5-13>
 16. Boonstra AM, Fidler V, Eisma WH. Walking speed of normal subjects and amputees: Aspects of validity of gait analysis. *Prosthet Orthot Int.* 1993;17(2):78–82. [PMID:8233772]
 17. Kelly KM, Doyle W, Skinner HB. The relationship between gait parameters and pain in persons with transtibial amputation: A preliminary report. *J Rehabil Res Dev.* 1998;35(2):231–37. [PMID:9651896]
 18. Bell JC, Wolf EJ, Schnall BL, Tis JE, Tis LL, Potter BK. Transfemoral amputations: The effect of residual limb length and orientation on gait analysis outcome measures. *J Bone Joint Surg Am.* 2013;95(5):408–14. [PMID:23467863] <http://dx.doi.org/10.2106/JBJS.K.01446>

Submitted for publication January 27, 2014. Accepted in revised form May 29, 2014.

This article and any supplementary material should be cited as follows:

Fatone S, Dillon M, Stine R, Tillges R. Coronal plane socket stability during gait in persons with transfemoral amputation: Pilot study. *J Rehabil Res Dev.* 2014;51(8):1217–28.

<http://dx.doi.org/10.1682/JRRD.2014.01.0021>

ResearcherID/ORCID: Stefania Fatone, PhD, BPO(Hons): E-8490-2011; Michael Dillon, PhD: M-6311-2014; Rebecca Stine, MS: M-7370-2014



