Journal of Biomechanics 96 (2019) 109330

Contents lists available at ScienceDirect

Journal of Biomechanics

journal homepage: www.elsevier.com/locate/jbiomech
www.JBiomech.com

# Ideal operating conditions for a variable stiffness transverse plane adapter for individuals with lower-limb amputation

Corey Pew [a,*], Ava D. Segal [b], Richard R. Neptune [c], Glenn K. Klute [d,e]

[a] Department of Mechanical and Industrial Engineering, Montana State University, Bozeman, MT 59715, United States
[b] Department of Mechanical Engineering, Colorado School of Mines, Golden, CO 80401, United States
[c] Walker Department of Mechanical Engineering, The University of Texas at Austin, Austin, TX 78712, United States
[d] Department of Mechanical Engineering, University of Washington, Seattle, WA 98195, United States
[e] Department of Veterans Affairs Center for Limb Loss and Mobility, Seattle, WA 98108, United States

ARTICLE INFO

*Article history:*
Accepted 30 August 2019

*Keywords:*
Turning
Below-knee amputee
Prosthesis
Torsion adapter
Gait
Biomechanics

ABSTRACT

Transverse plane shear stress between the prosthetic socket and residual limb often results in soft tissue breakdown and discomfort for individuals with lower-limb amputation. To better understand the effects of reduced transverse plane stiffness in the shank of a prosthesis, a second-generation variable stiffness torsion adapter (VSTA II) was tested with individuals with a transtibial amputation (n = 10). Peak transverse plane moments, VSTA II deflection, range of whole body angular momentum (WBAM), ground reaction impulse, joint work, and personal stiffness preference were evaluated at three fixed stiffness levels (*compliant*: 0.25 Nm/°, *intermediate*: 0.75 Nm/°, *stiff*: 1.25 Nm/°) at three walking speeds (self-selected, fast and slow: +/− 20% of self-selected, respectively) while straight-line walking and performing left and right turns. Residual limb loading decreased and VSTA II displacement increased for reductions in stiffness and both metrics increased with increasing walking speed, while ground reaction impulse and joint work were unaffected. The range of WBAM increased with decreased stiffness, which suggests an increased risk of falling when using the VSTA II at lower stiffness settings. Preference testing showed no significant result, but trends for lower stiffness settings when turning and walking at self-selected speeds were noted, as were stiffer settings when walking straight and at faster speeds. These results show that a device with rotational compliance like the VSTA II could reduce loading on the residual limb during straight walking and turning activities and that factors such as walking speed, activity type and user preference can affect the conditions for optimal use.



## 1. Introduction

Lower-limb loss is a life-altering event, but with recent advances in prosthetic technologies, amputees are capable of leading active lives. Currently, there are approximately 2 million individuals living with amputation in the United States, and that number is estimated to increase by 25% by the year 2050 (Ziegler-Graham et al., 2008). While new prosthetic technologies are constantly under development, they often focus primarily on straight-line walking and movement in the sagittal plane. However, turning comprises a significant portion of daily steps (Glaister et al., 2007a) and requires varied transverse plane motion and loading in the lower-limbs (van der Linden et al., 2002).

Modern lower-limb prostheses couple the prosthesis to the body through an exoskeleton socket system. This requires the residual limb soft tissues to transmit loads from the prosthesis to the skeletal system. Increased soft tissue stress can lead to chronic dermal issues including abrasions, cysts and ulcers (Levy, 1995). A transverse rotation adapter (TRA) may reduce soft tissue loading and alleviate shear stresses between the socket and residual limb (Lamoureux and Radcliffe, 1977; van der Linden et al., 2002; Segal et al., 2009). Inclusion of a TRA in a lower-limb prosthesis can also reduce step width and metabolic cost during straight-line walking (Buckley et al., 2002; Su et al., 2010), improve negotiation of turns and rough terrain (Su et al., 2010) and marginally increase activity level (Segal et al., 2014). While current TRA devices have the potential to improve the comfort and mobility of lower-limb amputees, they are limited to a single, fixed stiffness and can only be adjusted by a prosthetist (Flick et al., 2005). This means that they are incapable of adapting to changing needs

* Corresponding author at: Montana State University, Roberts Hall 220, Bozeman, MT 59715, United States.
*E-mail address:* Corey.Pew@montana.edu (C. Pew).

https://doi.org/10.1016/j.jbiomech.2019.109330
0021-9290/

during activities of daily living. Meanwhile, the intact ankle has the ability to vary stiffness in response to changing task demands (Glaister et al., 2007b; Hansen et al., 2004). Thus, a TRA with variable stiffness would likely benefit lower-limb amputees.

To this end, we designed and tested a variable stiffness torsion adapter (VSTA) (Pew and Klute, 2015, 2017a). We found that a reduced transverse plane stiffness in a lower-limb prosthesis significantly reduced peak transverse moments exerted on the limb by the prosthesis during various activities. This reduced peak loading could lead to reduced peak displacements of the soft tissues that result in damaging stress, improving user comfort when ambulating with a lower-limb prosthesis. While initial results using the VSTA were promising, the ideal transverse plane stiffness levels and how the device should be adjusted for individual user preference and in response to varying walking conditions remains unknown.

We subsequently revised the VSTA to create the VSTA II, which allows for advanced testing of variable transverse plane stiffness (Pew and Klute, 2017b) (Fig. 1). The VSTA II design features five torsion springs in parallel that can be individually engaged or disengaged by solenoids to provide five discrete stiffness settings ranging from 0.25 to 1.25 Nm/° in 0.25 Nm/° increments, plus a fully locked setting. Our initial testing showed that a control algorithm that automatically adjusts the stiffness in real-time would be of benefit to the user (Pew and Klute, 2017c). However, the information needed to develop such an algorithm is lacking. The present study uses the VSTA II to investigate the biomechanical effects of varied transverse plane stiffness and walking speeds during different activities to better determine how such a device might be controlled to provide the greatest user benefit. Specifically, we investigated how the peak transverse plane loading of the socket, deflection of the VSTA II, range of whole-body angular momentum (WBAM), ground reaction impulses (GRI), joint work and user preferences varied during different stiffness settings, walking speeds and activities.

We hypothesize that: (1) reduced transverse plane stiffness will produce the greatest difference in the reduction of peak transverse plane loading when turning vs. straight-line walking, (2) peak loading will increase with increased walking speed, (3) balance control will not decrease with reduced stiffness as indicated by the range of WBAM (Nott et al., 2014; Silverman and Neptune, 2011; Vistamehr et al., 2016), (4) variations in stiffness will not elicit undesirable compensations in an individual's turning biomechanics as indicated by their ground reaction impulse or the joint work at the hip, knee and ankle (Segal et al., 2011; Ventura et al., 2011), and (5) user preference for stiffness will vary proportionally based on walking speed and activity.


**Fig. 1.** VSTA II instrumentation. System included a standalone controller with on-board battery, an iPecs 6-axis load cell to measure limb loading at the socket interface and the VSTA II device attached to the shank of the lower-limb prosthesis.

## 2. Methods

Ten unilateral transtibial amputees (one female, nine males, age: 51 ± 17 years, mass: 84 ± 13 kg, height: 1.78 ± 0.08 m, Table 1) provided informed consent to participate in this Institutional Review Board-approved protocol. All participants were free from concurrent musculoskeletal injuries or other health conditions that would prevent them from completing the full protocol by self-report. Gait kinematics and kinetics were collected using a 12-camera Vicon system (Vicon, Centennial, CO, USA), 8 force plates (AMTI, Watertown, MA, USA), and an iPecs 6-axis load cell (College Park, Warren, MI, USA) installed on the proximal end of the VSTA II to directly measure transverse plane loading (Fiedler et al., 2014; Koehler et al., 2014) of the prosthetic socket. To this end, the peak transverse plane moments (normalized by participant mass) were measured directly with the iPecs. Kinetic data (force plates and iPecs) were recorded at 1200 Hz while kinematic data were recorded at 120 Hz. Raw data were processed using a lowpass Butterworth filter at 25 Hz and 6 Hz for the kinetic and kinematic data, respectively.

All participants were instrumented with 71 motion tracking markers according to a modified Plug-in-Gait full body model (Pew and Klute, 2017a). Modification to the model included the addition of marker clusters on the thighs and upper arms and individual markers on the 1st and 5th metatarsal heads, tibial tuberosity, fibula head and the medial aspects of the ankle, knee and elbow joints. In addition, three markers were placed on both the iPecs and VSTA II to measure the rotation of each device. The model was further modified by separating the shank of the prosthetic limb into upper and lower segments. The two independent shank segments represented the new VSTA II joint and accounted for the specific mass of the VSTA II and iPecs. A certified and licensed prosthetist aligned the iPecs and VSTA II with the participant's existing, definitive, carbon fiber socket and liner and a Vari-Flex Low Profile foot (Össur, Reykjavík, ISL).

Gait data were analyzed in Visual 3D (C-Motion, Germantown, MD, USA) to determine the range of WBAM (normalized by participant height (m), mass (kg) and walking speed (m/s)) (Silverman and Neptune, 2011). The range of WBAM was determined as the peak positive minus the peak negative value in the sagittal, coronal and transverse planes over the course of a single stride (heel strike to heel strike of the prosthetic limb) as variations in WBAM have been documented for all planes of motion when turning (Nolasco et al., 2019). In the sagittal plane WBAM has a double peak, one each during the stance and swing phases of a stride; therefore, the range of WBAM was given as separate values during the stance and swing phases in the sagittal plane. Using force plate measurements, joint powers (normalized by participant mass (kg)) were calculated as the product of the three-dimensional joint moments and corresponding angular velocities. Positive (negative) joint work were calculated as the time integral of the positive (negative) joint power over the gait cycle. Positive (negative) ground reaction impulse (normalized by participant weight (N)) were calculated as the time integral of the positive (negative) ground reaction forces over the gait cycle.

Participants performed testing using three fixed stiffness settings (*compliant*: 0.25 Nm/°, *intermediate*: 0.75 Nm/°, *stiff*: 1.25 Nm/°) at three walking speeds (self-selected, fast and slow: +/- 20% of self-selected, respectively) during three activities (straight-line walking (ST), prosthesis outside turning (PO), and prosthesis inside turning (PI)). Straight-line walking was performed over-ground along a 7-meter walkway and turning gait was performed by walking around a 1-meter radius circle (Segal et al., 2009, 2011). Participants identified their preferred stiffness setting during blinded testing for each speed-activity combination. For a given activity and speed, the user performed three trials each with the *compliant* and *stiff* settings to give the highest contrast. Participants were then required to choose their preference. That preferred setting was then compared to the middle (*intermediate*) setting for three trials each. A final stiffness preference was then chosen between the *intermediate* and the first preference settings. After any change in stiffness, speed or activity, participants were given time to acclimate to the new settings/conditions until they indicated they were comfortable. Nine preference testing series were completed for each participant (3 speeds for 3 activities) over the course of two days. The order of stiffness settings within each round, speed and activity were block randomized for each series and participant. All participants were able to complete the entire testing series in the allotted time except for one who did not complete the PO turns at the *fast* and *self-selected* speeds.

A linear mixed effects statistical model was used to investigate relationships between varying stiffness settings and speeds on the peak prosthetic socket transverse plane moment (normalized by participant mass), the angular displacement of the VSTA II (maximum minus minimum deflection), range of WBAM, ground reaction impulse for each limb and joint work for the hip, knee and ankle of each limb. The model utilized fixed effects for the stiffness setting and walking speed and random intercept by participant and slope by speed. An analysis of variance (ANOVA) was then used to look at overall effects of varying stiffness and speed for the given metrics of the linear mixed effects models. If an overall significance ($p < 0.05$) was found, a pairwise comparison was performed using the estimated marginal means and Tukey method for comparing families of three estimates to determine specific differences between conditions averaged over the different stiffness levels or speeds for each activity individually. A Wilcoxon signed rank test was also used to compare how stiffness varied the reduction of loading between activities. Additionally, an initial analysis indicated that no significant interactions existed between the stiffness and speed variations for any of the tested outcome metrics, so those observations were treated as independent variables in the models. An exact multinomial test was used to analyze differences between categorical participant preferences for varying stiffness and speed combinations. All statistical testing was performed in RStudio (v1.2.1335, Boston, MA, USA).

## 3. Results

Significant variations in peak transverse plane moments occurred for both varying stiffness ($p < 0.01$) and speed ($p < 0.02$) when walking with the VSTA II (Table 2). Reductions in stiffness produced a consistent pattern of reduced peak transverse plane moments for all activities. Significant reductions in peak transverse plane moment were found between the *stiff* and *compliant* settings ($p < 0.001$) for all activities and between the *intermediate* and *compliant* settings ($p < 0.01$) for PI turns and ST walking. Reductions between the *stiff* and *intermediate* ($p = 0.006$) settings were found only for PO turns. Increased walking speed resulted in increased peak transverse plane moments when turning ($p < 0.02$) but not during straight-line walking.

The range of VSTA II angular deflection consistently decreased with increasing transverse plane stiffness between all stiffness settings during all activities ($p < 0.001$) (Table 3). Additionally, the range of deflection significantly increased for increased walking speed for all activities but only between the fastest and slowest walking speeds ($p < 0.02$).

Decreased VSTA II stiffness corresponded to increased range of WBAM in the coronal plane for PI turns and ST walking ($p < 0.01$), in the transverse plane for PO turns and ST walking ($p < 0.05$) and in the sagittal plane during stance for PI turns ($p = 0.03$) (Table 4). The range of WBAM significantly decreased with increasing speed for all planes and activities ($p \leq 0.03$), except in the transverse plane during turning. The increase in the range of WBAM in the transverse plane with increasing walking speed was significant for PI turns ($p < 0.01$), but not significant for PO turns ($p = 0.60$).

The ANOVA found no significant results for the metrics of ground reaction impulse (Fig. A1) or joint work (Fig. A2) except in the transverse plane of the prosthetic ankle during a PI turn. Lastly, preference results showed no statistically significant trend for preference for varied stiffness setting or walking speed. (Table 5).

**Table 1**
Demographic data for participants.

| Participant | Amputation Etiology | Time Since Amputation (Years) | Liner | Age | Height (m) | Mass (kg) |
|---|---|---|---|---|---|---|
| 1 | Trauma | 23 | WillowWood Alpha Classic | 49 | 1.79 | 85.5 |
| 2 | Trauma | 6 | Össur Iceross Synergy | 26 | 1.76 | 87.5 |
| 3 | Trauma | 43 | WillowWood Alpha Classic | 70 | 1.83 | 87.8 |
| 4 | Trauma | 8 | WillowWood Alpha Silicone | 48 | 1.87 | 98.9 |
| 5 | Trauma | 49 | Össur Iceross Sport | 67 | 1.84 | 92.1 |
| 6 | Trauma | 11 | Össur Iceross Comfort | 41 | 1.81 | 72.6 |
| 7 | Tibial Hemimelia | 21 | Össur Iceross Sleeve | 25 | 1.58 | 48.9 |
| 8 | Cancer | 1 | WillowWood Alpha Hybrid | 68 | 1.74 | 80.9 |
| 9 | Diabetic Vascular | 3 | WillowWood Alpha Silicone | 70 | 1.75 | 90.7 |
| 10 | Trauma | 2 | Össur Iceross Dermo | 42 | 1.80 | 92.5 |

**Table 2**
Peak transverse plane moments (mean ± SE) at the distal end of the prosthetic socket for varying stiffness and walking speed. Activities defined as straight-line walking (ST), prosthesis inside turn (PI) and prosthesis outside turn (PO). Stiffness settings were compliant 0.25 Nm/°, intermediate: 0.75 Nm/° and stiff: 1.25 Nm/°. Walking speeds were self-selected (SSW), slow and fast. Internal rotation was positive. Significant differences ($p < 0.05$) shown in bold.

| Peak Transverse Plane Moment (PTPM) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Comparison of Stiffness Settings, Independent of Walking Speed | | | | | | | |
| Activity | Direction | Peak Transverse Plane Moment (Nmm/kg) | | | Pairwise Comparisons (p-Value) | | |
| | | Compliant | Intermediate | Stiff | Compliant vs Intermediate | Compliant vs Stiff | Intermediate vs Stiff |
| PI | Internal | 129.2 ± 13.2 | 133.5 ± 13.2 | 134.4 ± 13.2 | **0.007** | **<0.001** | 0.798 |
| | External | −6.9 ± 2.2 | −9.1 ± 2.2 | −9.5 ± 2.2 | **0.006** | **<0.001** | 0.821 |
| PO | Internal | 52.0 ± 4.8 | 53.4 ± 4.8 | 53.6 ± 0.6 | 0.182 | 0.067 | 0.958 |
| | External | −25.8 ± 7.5 | −27.4 ± 7.5 | −29.8 ± 7.5 | 0.126 | **<0.001** | **0.006** |
| ST | Internal | 84.7 ± 7.7 | 89.1 ± 7.7 | 90.1 ± 7.7 | **0.003** | **<0.001** | 0.697 |
| | External | −13.6 ± 5.8 | −14.7 ± 5.8 | −15.9 ± 5.8 | 0.662 | 0.119 | 0.604 |
| Activity | Direction | Peak Transverse Plane Moment (Nmm/kg) | | | Pairwise Comparisons (p-Value) | | |
| | | Slow | SSW | Fast | Slow vs SSW | Slow vs Fast | SSW vs Fast |
| PI | Internal | 125.5 ± 13.4 | 133.8 ± 13.4 | 137.8 ± 13.4 | 0.126 | **0.019** | 0.598 |
| | External | −7.5 ± 2.4 | −8.5 ± 2.4 | −9.6 ± 2.3 | 0.830 | 0.428 | 0.762 |
| PO | Internal | 46.9 ± 5.3 | 50.6 ± 5.2 | 61.5 ± 5.2 | 0.569 | **0.003** | **0.018** |
| | External | −26.9 ± 7.6 | −28.4 ± 7.5 | −27.7 ± 7.6 | 0.746 | 0.911 | 0.942 |
| ST | Internal | 88.8 ± 8.0 | 86.4 ± 8.0 | 88.9 ± 8.1 | 0.864 | 1.000 | 0.842 |
| | External | −10.8 ± 6.1 | −13.6 ± 6.2 | −19.7 ± 6.0 | 0.739 | 0.065 | 0.260 |

**Table 3**
VSTA II angular deflection (mean ± SE) for varying stiffness and speed. Activities were straight-line walking (ST), prosthesis inside turn (PI) and prosthesis outside turn (PO). Stiffness levels were compliant: 0.25 Nm/°, intermediate: 0.75 Nm/° and stiff: 1.25 Nm/°. Walking speeds were self-selected (SSW), slow and fast. Internal rotation was positive. Significant differences ($p < 0.05$) shown in bold.

| Range of VSTA II Deflection During Stance | | | | | | |
|---|---|---|---|---|---|---|
| **Comparison of Stiffness Settings, Independent of Walking Speed** | | | | | | |
| Activity | Range of VSTA II Deflection (Degrees) | | | Pairwise Comparisons (p-Value) | | |
| | Compliant | Intermediate | Stiff | Compliant vs Intermediate | Compliant vs Stiff | Intermediate vs Stiff |
| PI | 7.2 ± 0.9 | 4.4 ± 0.9 | 3.5 ± 0.9 | **<0.001** | **<0.001** | **<0.001** |
| PO | 4.7 ± 0.3 | 3.5 ± 0.3 | 2.8 ± 0.3 | **<0.001** | **<0.001** | **<0.001** |
| ST | 4.2 ± 0.5 | 3.2 ± 0.5 | 2.5 ± 0.5 | **<0.001** | **<0.001** | **<0.001** |
| **Comparison of Walking Speeds, Independent of Stiffness Setting** | | | | | | |
| Activity | Range of VSTA II Deflection (Degrees) | | | Pairwise Comparisons (p-Value) | | |
| | Slow | SSW | Fast | Slow vs SSW | Slow vs Fast | SSW vs Fast |
| PI | 4.8 ± 0.9 | 5.0 ± 0.9 | 5.4 ± 0.9 | 0.389 | **0.014** | 0.182 |
| PO | 3.4 ± 0.3 | 3.7 ± 0.3 | 3.9 ± 0.3 | 0.181 | **0.015** | 0.380 |
| ST | 2.8 ± 0.6 | 3.2 ± 0.6 | 3.8 ± 0.6 | 0.299 | **0.006** | 0.124 |

## 4. Discussion

This study investigated the effects of varying transverse plane stiffness and walking speed on the lower-limb biomechanics of transtibial amputees when turning around a 1-meter radius circle and straight-line walking. While we previously discovered that reduced transverse plane stiffness could reduce loading at the residual limb (Pew and Klute, 2017a), a more in-depth analysis was required to optimize stiffness depending on walking speed and activity in a larger sample of amputee participants. Additionally, this study further examined the effects of varying stiffness on lower-limb biomechanics to determine if additional compensations result from altered transverse plane stiffness.

Our first hypothesis that *reduced transverse plane stiffness will produce the greatest difference in the reduction of peak transverse plane loading when turning versus straight-line walking*, was not supported. Significant reductions in peak transverse plane moments (Table 2, upper half) were found between the *stiff* and *compliant* settings for all three activities individually ($p < 0.001$). Peak loading was reduced by 5.2 ± 1.3 Nmm/kg, 4.0 ± 0.7 Nmm/kg and 5.3 ± 1.2 Nmm/kg between the *stiff* and *compliant* settings for the PI turns, PO turns and ST walking, respectively. Contrary to our hypothesis, the reduction in loading between the stiff and compliant settings showed no significant differences across the three activities ($p > 0.375$). However, it is important to note that PI turns produce a greater peak load as compared to the PO and ST activities (134.4 ± 13.2 compared to 53.6 ± 0.6 and 90.1 ± 7.7 Nmm/kg, respectively, at the stiff setting). It has been shown that increased loading of the soft tissues is the greatest contributor to cell death for compression induced deep tissue injury (Gawlitta et al., 2007; Gefen, 2007; Linder-Ganz and Gefen, 2007) and therefore reductions in loading during PI turning may be more beneficial to reducing tissue damage than reductions during PO and ST activities.

In contrast, our previous VSTA testing showed a reduction of 40 Nmm/kg and 14 Nmm/kg for 90° prosthesis inside and outside turns between *stiff* and *compliant* settings with no difference for ST walking. This suggests that continuous turning around a 1-meter radius circle is more gradual, and therefore has a decreased

**Table 4**
Range of whole body angular momentum (mean ± SE) for varying stiffness and walking speed. Activities were straight-line walking (ST), prosthesis inside turn (PI) and prosthesis outside turn (PO). Stiffness levels were compliant: 0.25 Nm/°, intermediate: 0.75 Nm/° and stiff: 1.25 Nm/°. Walking speeds were self-selected (SSW), slow and fast. Significant differences (p < 0.05) shown in bold.

| Peak to Peak Whole Body Angular Momentum | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Comparison of Stiffness Settings, Independent of Walking Speed** | | | | | | | |
| Activity | Plane of Motion | Range WBAM Normalized by Mass, Height and Speed | | | Pairwise Comparisons (p-Value) | | |
| | | Compliant | Intermediate | Stiff | Compliant vs Intermediate | Compliant vs Stiff | Intermediate vs Stiff |
| PI | Sagittal Stance | 0.0615 ± 0.0030 | 0.0612 ± 0.0030 | 0.0604 ± 0.0030 | 0.750 | **0.028** | 0.218 |
| | Sagittal Swing | 0.0583 ± 0.0061 | 0.0583 ± 0.0061 | 0.0581 ± 0.0061 | 0.999 | 0.972 | 0.963 |
| | Coronal | 0.0736 ± 0.0043 | 0.0717 ± 0.0043 | 0.0712 ± 0.0043 | **0.001** | **<0.001** | 0.524 |
| | Transverse | 0.0181 ± 0.0014 | 0.0181 ± 0.0014 | 0.0180 ± 0.0014 | 0.969 | 0.738 | 0.894 |
| PO | Sagittal Stance | 0.0424 ± 0.0032 | 0.0431 ± 0.0032 | 0.0431 ± 0.0032 | 0.174 | 0.133 | 1.000 |
| | Sagittal Swing | 0.0772 ± 0.0076 | 0.0774 ± 0.0076 | 0.0760 ± 0.0076 | 0.986 | 0.152 | 0.167 |
| | Coronal | 0.0673 ± 0.0039 | 0.0667 ± 0.0040 | 0.0667 ± 0.0040 | 0.401 | 0.331 | 1.000 |
| | Transverse | 0.0224 ± 0.0015 | 0.0219 ± 0.0015 | 0.0220 ± 0.0015 | **0.048** | 0.054 | 0.970 |
| ST | Sagittal Stance | 0.0433 ± 0.0021 | 0.0430 ± 0.0021 | 0.0427 ± 0.0021 | 0.851 | 0.585 | 0.933 |
| | Sagittal Swing | 0.0528 ± 0.0026 | 0.0540 ± 0.0027 | 0.0533 ± 0.0026 | 0.249 | 0.780 | 0.540 |
| | Coronal | 0.0400 ± 0.0012 | 0.0392 ± 0.0012 | 0.0391 ± 0.0012 | **0.029** | **0.001** | 0.828 |
| | Transverse | 0.0121 ± 0.0007 | 0.0117 ± 0.0007 | 0.0116 ± 0.0007 | **0.024** | **<0.001** | 0.637 |
| **Comparison of Walking Speeds, Independent of Stiffness Settings** | | | | | | | |
| Activity | Plane of Motion | Range WBAM Normalized by Mass and Height (m/s) | | | Pairwise Comparisons (p-Value) | | |
| | | Slow | SSW | Fast | Slow vs SSW | Slow vs Fast | SSW vs Fast |
| PI | Sagittal Stance | 0.0662 ± 0.0031 | 0.0622 ± 0.0031 | 0.0548 ± 0.0031 | **0.017** | **<0.001** | **<0.001** |
| | Sagittal Swing | 0.0635 ± 0.0061 | 0.0596 ± 0.0061 | 0.0515 ± 0.006 | **0.026** | **<0.001** | **<0.001** |
| | Coronal | 0.0782 ± 0.0045 | 0.0721 ± 0.0045 | 0.0662 ± 0.0045 | 0.066 | **<0.001** | 0.075 |
| | Transverse | 0.0167 ± 0.0015 | 0.0181 ± 0.0015 | 0.0195 ± 0.0015 | 0.168 | **<0.001** | 0.153 |
| PO | Sagittal Stance | 0.0474 ± 0.0032 | 0.0433 ± 0.0032 | 0.0378 ± 0.0032 | **0.003** | **<0.001** | **<0.001** |
| | Sagittal Swing | 0.0830 ± 0.0078 | 0.0782 ± 0.0077 | 0.0693 ± 0.0077 | 0.257 | **<0.001** | **0.008** |
| | Coronal | 0.0707 ± 0.0041 | 0.0676 ± 0.0041 | 0.0622 ± 0.0041 | 0.232 | **<0.001** | **0.023** |
| | Transverse | 0.0216 ± 0.0017 | 0.0219 ± 0.0017 | 0.0228 ± 0.0017 | 0.966 | 0.603 | 0.744 |
| ST | Sagittal Stance | 0.0468 ± 0.0027 | 0.0429 ± 0.0027 | 0.0392 ± 0.0027 | 0.352 | **0.022** | 0.409 |
| | Sagittal Swing | 0.0584 ± 0.0029 | 0.0534 ± 0.0029 | 0.0483 ± 0.0029 | 0.060 | **<0.001** | 0.057 |
| | Coronal | 0.0451 ± 0.0011 | 0.0384 ± 0.0011 | 0.0348 ± 0.0011 | **<0.001** | **<0.001** | **0.003** |
| | Transverse | 0.0132 ± 0.0008 | 0.0116 ± 0.0008 | 0.0106 ± 0.0008 | **0.010** | **<0.001** | 0.221 |

**Table 5**
Grouped preference results for varying stiffness and walking speed. Values in the table represent the count of individuals who selected a particular setting for the given conditions. The left half of the table combines all walking speed results to show difference by activity: straight-line walking (ST), prosthesis inside turn (PI) and prosthesis outside turn (PO). The right half of the table combines all activity results to show differences by walking speed. Walking speeds defined as: self-selected (SSW), slow and fast. Stiffness levels defined as: compliant: 0.25 Nm/°, intermediate: 0.75 Nm/° and stiff: 1.25 Nm/°.

| Overall Stiffness Preferences | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| All Speeds Combined | | | | | All Activities Combined | | | | |
| Activity | Compliant | Intermediate | Stiff | p-value | Speed | Compliant | Intermediate | Stiff | p-value |
| PI | 10 | 13 | 7 | 0.429 | Slow | 7 | 14 | 8 | 0.257 |
| PO | 9 | 14 | 5 | 0.127 | SSW | 10 | 13 | 6 | 0.304 |
| ST | 5 | 13 | 12 | 0.133 | Fast | 7 | 13 | 10 | 0.429 |

benefit from reduced transverse plane stiffness compared to 90° turns from the VSTA testing (Pew and Klute, 2017a). Another notable difference is the VSTA II features a wider stiffness range (0.25–1.25 Nm/°) compared to the VSTA (0.30–0.91 Nm/°), providing greater differences between peak loading values leading to significant differences in ST walking that were not found previously. These results suggest that sharper turns may benefit more from reduced stiffness settings and that the radius and length of the turn may be factors that could influence the future control of VSTA-like devices.

The second hypothesis, *peak loading will increase with increased walking speed*, was supported during turning but not during straight-line walking (Table 2, lower half). While turning, the peak internal transverse plane moment was reduced by 12.8 ± 4.0 Nmm/kg ($p = 0.018$) and 16.7 ± 4.3 Nmm/kg ($p = 0.005$) between the *fast* and *slow* speeds for PI and PO turns, respectively. This suggests that walking speed is only a factor when turning and that control of the VSTA II should consider walking speed as an important control variable when turning but not during straight-line walking.

Because the iPecs load cell and VSTA II act in series, we assumed that the angular deflection (Table 3) would be proportional to the applied moment and that deflection would also be indicative of angular motion displaced from the residual limb to the VSTA II, thus reducing soft tissue shear stress. Contrary to that assumption, we observed a consistent, significant increase in deflection with decreasing stiffness between all stiffness settings and activities ($p < 0.001$). Additionally, while PI and ST activities saw similar reductions in loading (5.2 and 5.3 Nmm/kg, respectively) they produced differing corresponding increases in deflection ($3.7 \pm 0.1°$ and $1.7 \pm 0.1°$, respectively) between the *stiff* and *compliant* conditions. These results suggest there are more factors than just the passive VSTA II stiffness setting that influence the residual limb loading that should be investigated in future work using the collected data as a part of an in-depth musculoskeletal simulation analysis to better understand how the varying conditions affect limb loading.

Our third hypothesis, *balance control will not decrease with reduced stiffness as indicated by the range of WBAM*, was not fully supported. An increased range of WBAM in the coronal plane has been shown to relate to clinical measures of balance, indicative of an individual's risk of falling (Nott et al., 2014; Vistamehr et al., 2016). There were significant increases in the coronal plane range of WBAM with decreasing stiffness during PI turns ($0.0025 \pm 0.0005$ increase, 3% change, $p < 0.001$) and ST walking ($0.0010 \pm 0.0003$ increase, 3% change, $p = 0.001$) between the *stiff* and *compliant* conditions. The increase in coronal plane range of WBAM with decreased stiffness suggests the VSTA II may introduce a higher risk of falling for the user. Significant increases in the range of WBAM also occurred in the sagittal plane for reduced stiffness during stance for PI turns, which has been previously related to reduced braking impulse in the residual limb when turning (Ventura et al., 2011). This suggests that more compensation is required during PI turns at low stiffness settings; however, no significant difference in braking impulses were observed. Lastly, the range of WBAM in the transverse plane during PO turns and ST walking increased for lowered stiffness; however, these changes were small and may not be clinically relevant. Variations in walking speed resulted in a decreased range of WBAM with increasing walking speed during all activities except in the transverse plane when turning. A decrease in the range of WBAM when walking faster is consistent with previous analyses of straight-line walking (Bennett et al., 2010; D'Andrea et al., 2014; Silverman and Neptune, 2011). However, during both turning activities the range of transverse WBAM increased with increasing speed. The range of WBAM during amputee turning at varying speeds has not been thoroughly investigated, thus the implication for the observed transverse plane trend is unknown and remains an area for future work.

Our fourth hypothesis, *variations in stiffness will not elicit undesirable compensations in an individual's turning biomechanics as indicated by their ground reaction impulse or the joint work at the hip, knee and ankle*, was supported. No significant differences were observed in these metrics when turning or straight-line walking between the three stiffness settings except ankle work by the prosthetic limb during PI turns. However, because the prosthetic foot is rigidly attached to the VSTA II device, the joint work of the prosthetic ankle can be attributed to the work done by the VSTA II device and is not considered a compensation by the individual. Overall, lowered transverse plane stiffness does not result in compensatory strategies from the joints of the lower-limbs.

Lastly, our fifth hypothesis, *user preference for stiffness will vary based on walking speed and activity*, investigated individual preference for different stiffness settings during the varying activities and speeds. While contrary to this hypothesis, no significant differences were found in the preference trends, some grouping can be inferred from the results (Table 5). The data show preference outcomes for activities independent of walking speed (Table 5, left half). During the turning activities, in general participants tended to choose the lower (*compliant* and *intermediate*) settings compared to straight-line walking where they tended to choose the higher (*intermediate* or *stiff*) settings. This suggests that users may prefer a lower stiffness setting when turning and stiffer setting when straight-line walking. The data also show a preference for speed independent of activity (Table 5, right half). Preferences during self-selected speed walking tend to be grouped in the lower end (*compliant* and *intermediate*) while preferences during fast walking tend to be biased toward the upper end (*intermediate* or *stiff*), with no specific trend observed for slow walking. This suggests that individuals like a more compliant setting when walking normally but prefer a stiffer, more responsive setting when walking quickly. At slower walking speeds the range of WBAM in the coronal plane tends to increase suggesting that individuals may be at higher risk for falling when walking slowly. This may explain the mix of preferences at the slow speed since some individuals may feel less stable when walking slowly and prefer a stiff setting while others may not be affected as dramatically and prefer a *compliant* setting. Overall, an individual's preference for stiffness may vary widely depending on the different speed and activity conditions. Subjectively, the participants indicated that they like the VSTA II and its ability to adapt to varying activities. These results suggest that a device like the VSTA II might require different levels of stiffness for each individual depending on their specific needs and abilities.

This testing was conducted to better understand how the VSTA II might be used during varying activities of daily living; however, some limitations should be noted. This data is from a relatively small sample size, mostly male, traumatic, transtibial amputees. While statistical significance was found for some outcome metrics, more participants would be needed to apply these results to the general amputee population including amputees of diabetic/dysvascular etiology as well as transfemoral amputees. All participants were relatively able walkers who could easily adapt to the changes in stiffness, walking speed and activity. Testing with less capable walkers may reveal that some amputees are not able to tolerate decreased transverse plane stiffness while maintaining mobility. Another potential limitation is that participants performed testing on the same three stiffness settings, regardless of body mass or ability. Additional testing may reveal how stiffness settings should be modulated to accommodate varying users. Finally, the testing protocol only allowed participants a short period of time to acclimate. Acclimation to a new device varies, and may take weeks (English et al., 1995; Segal et al., 2009) or months (Orendurff et al., 2006; Segal et al., 2006), which can affect an individual's ability to use the new device effectively. Future testing should utilize a device that can be taken home for extended acclimation and testing.

## 5. Conclusions

This study found that all activities saw the benefit of reduced limb loading in response to reductions in transverse plane stiffness. Walking speed was also found to be a significant factor contributing to peak transverse plane loading of the residual limb, however, only when turning and not when straight-line walking. These findings suggest that future control algorithms should focus on the identification of upcoming activities and walking speed to determine how to adjust the stiffness setting during varying activities of daily living. Ideally, limb loading would be reduced to increase comfort when walking with a prosthesis. However, large reductions in transverse plane stiffness also increased the coronal range of WBAM, which may increase risk of falling. The range of WBAM that will significantly increase fall risk when walking is likely associated with an individual's walking ability. Therefore, the preferred stiffness level was likely related to a combination of the participant's dynamic balance and desired prosthesis responsiveness. This suggests that stiffness levels for a device like the VSTA II should be personalized for a given user to balance decreases in limb loading with personal safety, mobility and preference. Future work will include development of a device capable of long-term testing, outside of the laboratory such that more in-depth information about how a user interacts with the device during daily activities and how preferences for stiffness may change as users acclimate.

## Declaration of Competing Interest

The authors have no conflicts of interest to disclose.


## Acknowledgement

This work was supported by awards I21 RX001933, IK6 RX002974, and I50 RX002357 from the United States (U.S.) Department of Veterans Affairs Rehabilitation Research and Development Service. The contents do not represent the views of the U.S. Department of Veterans Affairs or the United States Government.

The study sponsors were not involved in the study design, data collection, analysis and interpretation, writing or submission of this work.


## Appendix

See Figs. A1 and A2.

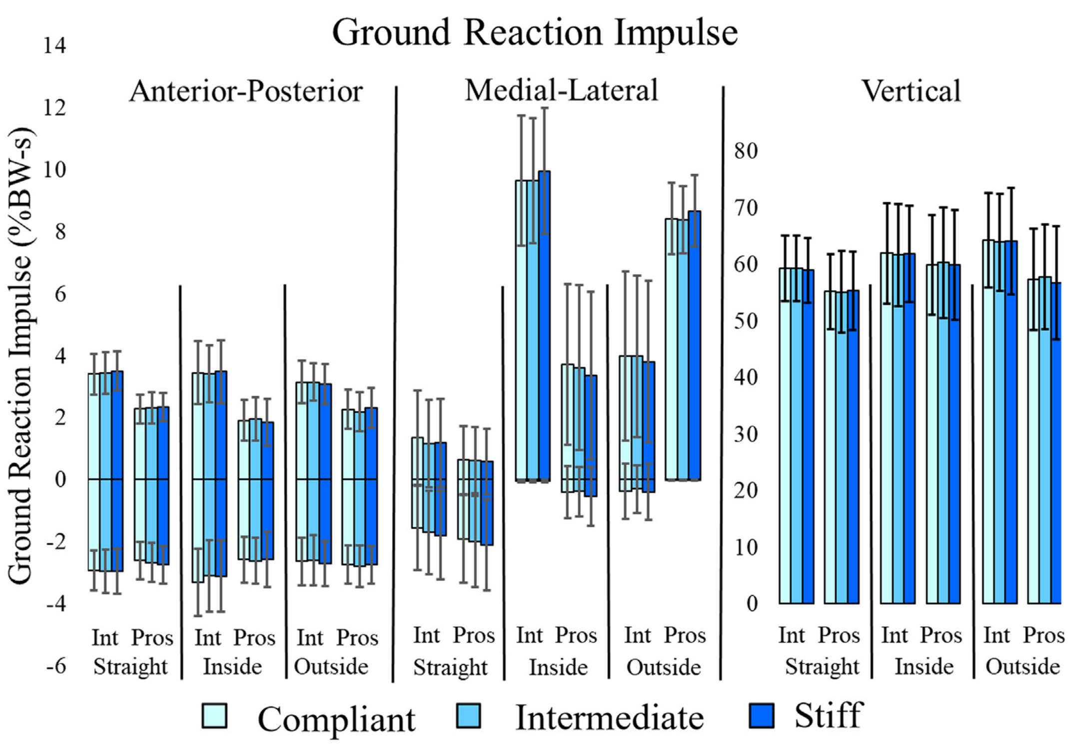


**Fig. A1.** Ground reaction impulse mean (±1 standard deviation) for each stiffness setting across walking speeds during the stance phase for the Intact (Int) and Prosthetic (Pros) limbs. Activities defined as straight-line walking (Straight), limb on the inside of the turn (Inside) and limb on the outside of the turn (Outside). Stiffness levels defined as: compliant 0.25 Nm/°, intermediate: 0.75 Nm/° and stiff: 1.25 Nm/°. Means were normalized by participant mass.

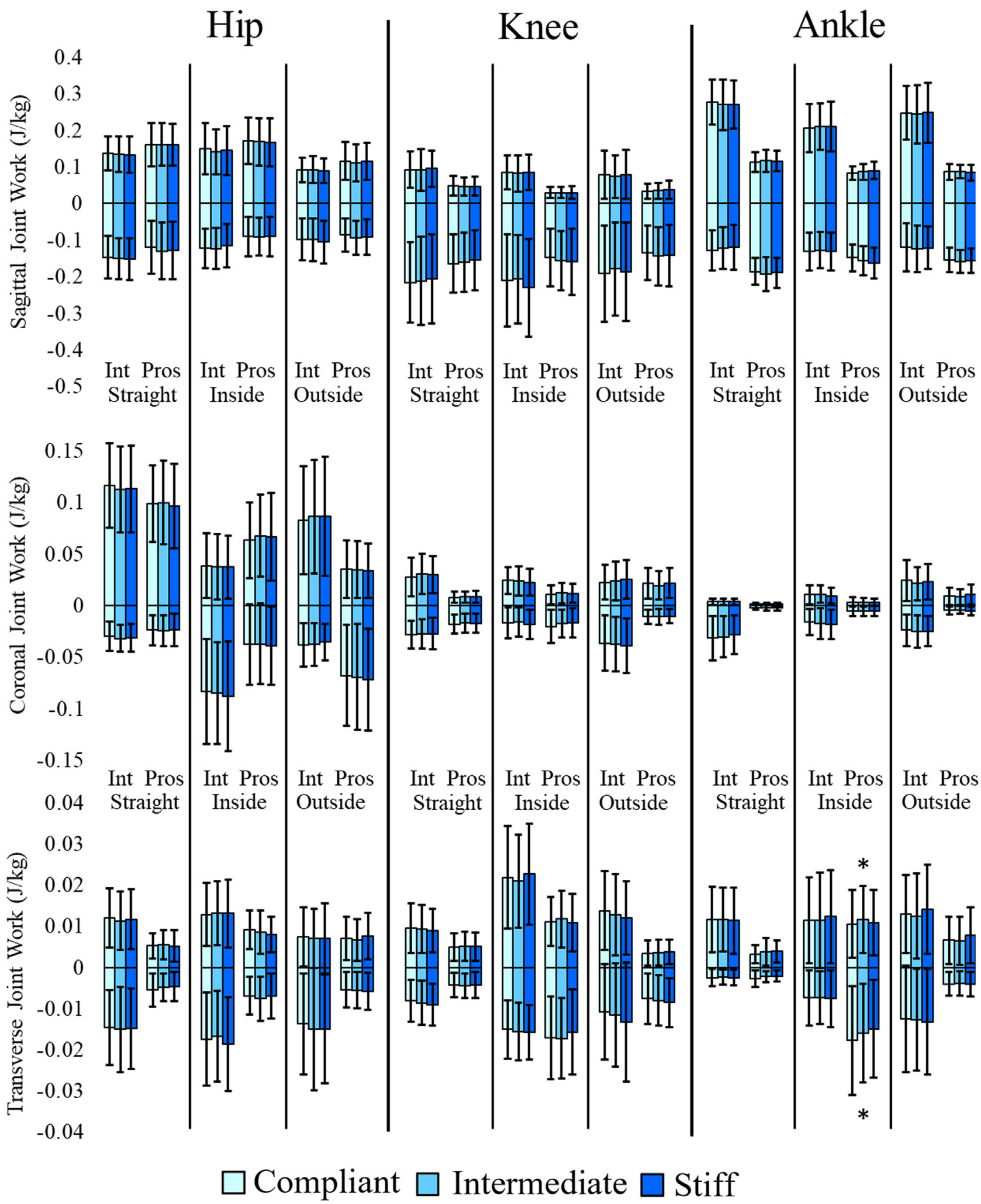


**Fig. A2.** Joint work mean (±1 standard deviation) for each stiffness setting across walking speeds during the stance phase for the Intact (Int) and Prosthetic (Pros) limbs. Activities defined as straight-line walking (Straight), limb on the inside of the turn (Inside) and limb on the outside of the turn (Outside). Stiffness levels defined as: compliant 0.25 Nm/°, intermediate: 0.75 Nm/° and stiff: 1.25 Nm/°. Means were normalized by participant mass. Significant difference ($p < 0.05$) indicated with *.

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