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Task dependent changes in mechanical and biomechanical measures result from manipulating stiffness settings in a prosthetic foot

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ABSTRACT

Background: Adaptation of lower limb function to different gait tasks is inherently not as effective among individuals with lower limb amputation as compared to able-bodied individuals. Varying stiffness of a prosthetic foot may be a way of facilitating gait tasks that require larger ankle joint range of motion.

Methods: Three stiffness settings of a novel prosthetic foot design were tested for level walking at three speeds as well as for 7,5° incline and decline walking. Outcome measures, describing ankle range of motion and ankle dynamic joint stiffness were contrasted across the three stiffness settings. Standardized mechanical tests were done for the hindfoot and forefoot.

Findings: Dorsiflexion angle was incrementally increased with a softer foot and a faster walking speed / higher degree of slope. The concurrent dynamic joint stiffness exhibited a less systematic change, especially during INCLINE and DECLINE walking. The small difference seen between the stiffness settings for hindfoot loading limits analysis for the effects of stiffness during weight acceptance, however, a stiffer foot significantly restricted plantarflexion during DECLINE.

Interpretations: Varying stiffness settings within a prosthetic foot does have an effect on prosthetic foot dynamics, and differences are task dependent, specifically in parameters involving kinetic attributes. When considering the need for increased ankle range of motion while performing more demanding gait tasks, a foot that allows the users themselves to adjust stiffness according to the task at hand may be of benefit for active individuals, possibly enhancing the user's satisfaction and comfort during various daily activities.

1. Introduction

The intact human locomotor system modifies several gait parameters by adaptive mechanisms in response to changes in slopes and gait speed (de David et al., 2015; Fukuchi et al., 2019; Lelas et al., 2003; McIntosh et al., 2006; Stoquart et al., 2008; Wu et al., 2019) providing enhanced stability and security during gait in different and sometimes unstable terrains (Gates et al., 2012b). Individuals with lower limb amputations, however, do not have the same capabilities at the ankle joint level to respond to more demanding terrains, and must rely on compensatory movement and loading adaptations at more proximal joint levels, as well as spatial-temporal modifications (Gates et al., 2012a; Langlois et al., 2014; Varrecchia et al., 2019). Limited ankle dorsiflexion during incline or stair walking may for example result in knee hyperextension and increased forward trunk lean as the transtibial amputee attempts to maintain their center of mass over the stance foot (Langlois et al., 2014). Such resulting asymmetries in the gait of transtibial amputees may adversely affect the intact side or the residual joints in the long term (Hurwitz et al., 2001; Nolan et al., 2003; Struyf et al., 2009).

Due to its important contribution to all upright human movement, the ankle has been extensively researched and analyzed, and more recently in the context of advancing design features for prosthetic feet or assistive devices (Argunsah Bayram and Bayram, 2018; Safaeepour et al., 2014; Zelik and Honert, 2018). Stiffness characteristics are among mechanical properties of interest when pursuing the design of prosthetic devices. The high practical importance of achieving an understanding of this property is evident in that the typical Energy-Storing and Return (ESAR) prosthetic foot has a fixed stiffness category, a value that is set by

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the prosthetic foot manufacturer. As expected, the function of a particular prescribed prosthetic device may not always be optimal for all aspects of a person's life or during different activities. Various prosthetic designs can, via hydraulic systems and microprocessor control, change features such as stiffness/damping to allow for a more effective transition between a variety of terrains or walking conditions. Similarly, a few passive prosthetic feet make it possible for a certified prosthetist and orthotist (CPO) to align and alter the setup to adjust stiffness. However, such alignments are not adjustable by the user and can therefore affect user satisfaction as a set stiffness category might not be suitable for different gait tasks, such as walking on a hilly or uneven terrain, power-walking for exercise or carrying loads.

Dynamics joint stiffness (DJS) is the relationship between a concurrent joint angle and joint moment and has been a subject of interest in gait analyses of able-bodied individuals (Argunsah Bayram and Bayram, 2018; Hansen et al., 2004; Safaeepour et al., 2014). This relationship can provide a comprehensive insight as to the behavior and dynamics of a prosthetic foot during walking (Davot et al., 2021; Pillet et al., 2014), by taking into account the motion of the ankle as well as the forces that govern the moments of the ankle, which inherently reflects what is happening more proximally in the movement chain.

Several research groups have shown with varied methodology and prosthetic devices that a more compliant foot not only exhibits the expected increased ankle range of motion (RoM) (Adamczyk et al., 2017; Fey et al., 2011; Klodd et al., 2010; Major et al., 2014; Shell et al., 2017; Shepherd and Rouse, 2017; Ventura et al., 2011), but also greater power generation (Glanzer and Adamczyk, 2018), energy return (Adamczyk et al., 2017; Fey et al., 2011; Glanzer and Adamczyk, 2018; Koehler-McNicholas et al., 2018; Zelik et al., 2011), and increased symmetry in spatial parameters (Major et al., 2016). In the current study the immediate effects of altering exclusively the stiffness of a prosthetic foot during different gait tasks were examined. A novel foot, the VSA prosthetic foot (Lecomte et al., 2021) was used, allowing for a manual systematic change of stiffness during a series of walking tasks. The design concept for this novel foot is based on the availability of a stiffness modification on an already commercially available prosthetic foot as perceived comfort for each prosthetic user differs. Therefore, the main objective was to gain a greater understanding of when and how the ability to change stiffness might be of value for the user. In light of the increased demand of ankle RoM to facilitate faster walking as well as incline and declined walking, which presumably could be met with a softer prosthetic foot, a specific aim of this study was to examine how different stiffness settings of the VSA foot influenced ankle kinematics, and the applicability of the DJS to characterize a prosthetic foot stiffness during each of those tasks. Data from standardized mechanical tests for each setting were collected for the hindfoot and forefoot as representative stiffness data.

2. Methods

2.1. Prosthetic foot device

The design of the prosthetic foot used in this study has been previously described (Lecomte et al., 2021). The VSA prosthetic foot is comprised of a Variable Stiffness Ankle (VSA) unit, using a leaf spring (Soleus Leaf Spring), with a movable Leaf Spring Support, that is mounted on a standard commercially available ESAR prosthetic foot (Proflex LP, Össur, Reykjavík, Iceland) (Fig. 1). Translation of the Leaf Spring Support on the pylon alters the beam length of the leaf spring, making stiffness adjustments possible. This translation is made possible with a linear servo motor (MightyZap, IRrobot, California USA), which can either be controlled manually or with a smartphone (Arduino, Turin, Italy). This design was intended to allow for a user-control to be managed by the user, but for the purposes of this study three fixed positions along the pylon were analyzed. The design aim to reach at least +/− 10% of stiffness change as recommended by Shepherd (Shepherd

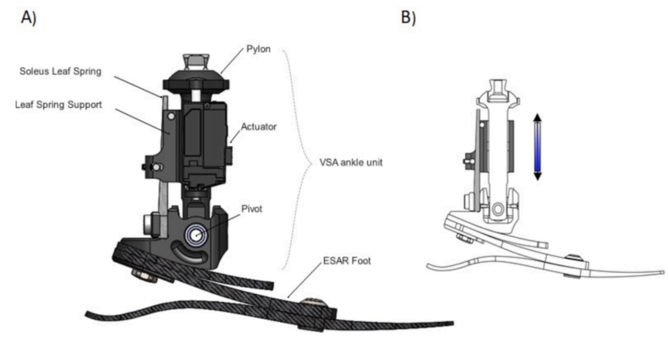

Fig. 1. A) VSA ankle unit mounted on an ESAR prosthetic foot. B) View of the movable Leaf Spring Support (grey part) on the pylon. For the stiffest setting it is positioned at the bottom, and for the softest at the top.

et al., 2018) was reached with these three fixed stiffness setting (Lecomte et al., 2021). Preliminary test subjects did report a perceived difference between settings, which confirmed the determination of chosen stiffness settings analyzed in this study. The position of the Leaf Spring Support was thereby changed by the same amount; from the "neutral" or at the middle of the on the pylon (referred to as the ALIGN setting in the study), to the bottom of the pylon (STIFF setting), or to the top of the pylon (SOFT setting) (Fig. 1).

To characterize the prosthetic foot stiffness, for the three stiffness settings being analyzed, hindfoot and forefoot (category 5, size 27) were tested with a single axis load compression test bench (Zwick, Switzerland) following AOPA guidelines (American Orthotic and Prosthetic Association, 2013). A 1200 N load was applied with a constant speed of 200 N/s.

2.2. Participants

Five individuals took part in this study. The experimental design of the biomechanical data collection was rather strenuous due to many gait tasks measured. To minimize the effect of fatigue, only active individuals (Medicare Functional Classification Level (MFCL) K3-K4) were included in the study. Other inclusion criteria were: Unilateral transtibial amputation; Prosthetic users for more than 1 year, walking confidently without assistive devices; A score above 8 (out of 10) with the Socket fit comfort score; Over the age of 18 years. Ethical approval was granted by the Icelandic National Bioethics Committee and all participants signed an informed consent form prior to participation.

2.3. Experimental design

During the first of two laboratory visits, each participant received the VSA prosthetic foot, which was subject specific in size and left/right side. The VSA unit mounted on the ESAR prosthetic foot was initially set midway on the pylon (ALIGN stiffness setting) and the foot aligned in a way that would be considered optimal for a prescribed foot, as evaluated by an experienced CPO and accepted by the user. The same CPO aligned all participants. When the stiffness setting of the foot was changed, the alignment of the foot was not changed. Changing the alignment would have compromised the aim to examine the effects of stiffness specifically, due to the possible mechanical differences induced by alignment changes, and therefore the effects of alignment and effects of stiffness could have been hard to distinguish between (Halsne et al., 2020; Hansen, 2008). Participants used their current sockets and other components of their prosthetic device were not manipulated. The same type of shoes (Viking, Norway) was worn by all participants during both alignment and data collection. During the same session, the comfortable self-selected gait speed (SSS) to be used in the study was determined on a treadmill, on which they all had prior experience with.

Although the VSA prosthetic foot had been tested without failure for

100.000 cycles according to the ISO 10328:2016 standard, the VSA unit had not been approved for use outside the laboratory, which limited the participant's opportunity to get accustomed to the foot. Therefore, ample time was given during both the first visit and prior to data collection between stiffness settings, for the participants to adjust to the new foot device. Data collection was done in the second visit, where a total of five gait tasks were tested on an instrumented treadmill with (Bertec, Ohio, USA), on each of the three stiffness settings: LEVEL ground at three speeds, and a 7.5° incline/decline RAMP walking at SSS. Apart from the self-selected comfortable walking speed tested (SSS) the effects of increasing gait speed were of interest, so 0.4 m/s were added (FAST speed) on one hand, and on the other hand detracted (SLOW speed) to see the broad range of speed effects. The order of the stiffness settings during data collection was randomly chosen and both the user and the investigator were blinded as to the settings throughout. Each trial was approximately 30 s long, or enough to reach 15–20 good force plate hits per foot.

2.4. Data collection and analysis

Kinematic data were captured with an eight camera 3D motion capture system (Qualisys Corporation, Gothenburg, Sweden), collected at 400 Hz. A split-belt instrumented treadmill (Bertec, Ohio, USA) was used to collect ground reaction forces (GRF) at 400 Hz. Initial processing was performed within the Qualisys Track Manager software, and then exported for further data processing and analysis which was done in Visual 3D (C-motion, Germantown, USA). A six degrees of freedom (6DOF) model, consisting of eight segments was constructed with the following marker setup: First, second and fifth metatarsals, lateral and medial malleoli, heel, medial and lateral femoral epicondyles, greater trochanter, crista iliaca, anterior and posterior superior iliaca spines, sacrum, acromion processes, T10, C7, manubrium and xiphoid process in addition to a cluster of 4 markers that tracked the shank and thigh segments. Marker placement on the prosthetic foot was approximated to that of the sound limb. Marker placement was performed by the same experienced investigator for all participants. A Butterworth filter was applied to the kinematic and kinetic data with a cut-off at 6 Hz and 10 Hz, respectively. All kinetic data were normalized by body weight. For all analyzed variables, data from 12 consecutive (excluding bad force plate hits) steps were included for analysis, for each of the stiffness settings during all five gait tasks.

2.5. Outcome measures

Plantarflexion range of motion (PF RoM) was defined from heel strike to peak plantarflexion. Dorsiflexion range of motion (DF RoM) was defined from the neutral position of the prosthetic foot to peak dorsiflexion towards the end of stance phase. The relationship between the ankle angle and the ankle moment during gait, representing the DJS was divided into two subphases, from heel strike to peak PF referred to as Controlled Plantarflexion subphase (CP), and from peak PF to peak DF referred to as Controlled Dorsiflexion subphase (CD). The slope values of the best linear fit of the curves of each of the two subphases (CP and CD) were calculated, where a higher value reflects a higher DJS.

2.6. Statistics

Mixed model analysis was used, where a model was constructed to allow for the within-subject comparison between prostheses stiffness conditions, using 12 steps per task a) across the three speeds of LEVEL ground walking and b) across incline and decline for RAMP walking. Data were analyzed for *Stiffness*Speed* (LEVEL) and *Stiffness*SlopeDirection* (RAMP) interactions as well as main effects of *Stiffness*. Alpha was set at 0.05 to determine the statistical significance. Additional analysis was done regarding the possible benefits of a softer foot during FAST, INCLINE and DECLINE walking. Tukey's Post hoc tests were therefore performed to contrast data from all stiffness settings and analyzed specifically for a) FAST walking, b) DECLINE and c) INCLINE, according to the proposed secondary analysis. Statistical analysis was not performed on mechanical data.

3. Results

Five males, all fitting the inclusion criteria, participated in this study. Their mean (SD) age was 57 (11) years, mean (SD) weight was 97.5 (8.7) kg, and mean (SD) height was 1.81 (0.038) m. All participants were classified as MFCL K3 users by a CPO and trauma was the cause of amputation for all of them. Time since amputation ranged from 4 to 43 years. For all participants an ESAR foot was the prescribed foot prior to the study. Participantś SSS ranged from 0.8–1.0 m/s. Results on mechanical data and prosthetic foot biomechanics will be presented separately.

3.1. Mechanical testing

The expected incremental increase in displacement across settings was seen for the forefoot displacement. The hindfoot, however, demonstrated a negligible difference seen between the ALIGN and SOFT settings for hindfoot displacement. The maximum overall displacement at maximum loading was larger for the forefoot across settings (Fig. 2).

3.2. Biomechanical testing

Main effects of *Stiffness* were evaluated, as well as the interaction of *Stiffness* and the gait tasks (*Stiffness*Speed* for LEVEL / *Stiffness*SlopeDirection* for RAMP). Post – hoc results are displayed in Table 1 and results relevant to the additional analysis presented.

3.2.1. Prosthetic foot kinematics

3.2.1.1. Plantarflexion RoM. PF RoM was significantly affected by *Stiffness* ($p < 0.001$) during LEVEL walking, with less RoM associated with the STIFF setting. A *Stiffness*Speed* interaction was also seen ($p = 0.007$), as incremental differences were seen at SSS but negligible differences between the SOFT and ALIGN settings during FAST and SLOW, (Fig. 3). Post-hoc tests contrasting stiffness settings during FAST reflected no difference in PF RoM between ALIGN and SOFT, but a significantly smaller PF RoM for STIFF ($p < 0.001$) (Table 1).

During RAMP walking PF RoM a significant interaction was seen for *Stiffness*SlopeDirection* ($p = 0.03$, Fig. 3), as the expected incremental increase in PF RoM with softer settings is seen after heel strike during DECLINE, whereas SOFT demonstrates the least PF RoM during

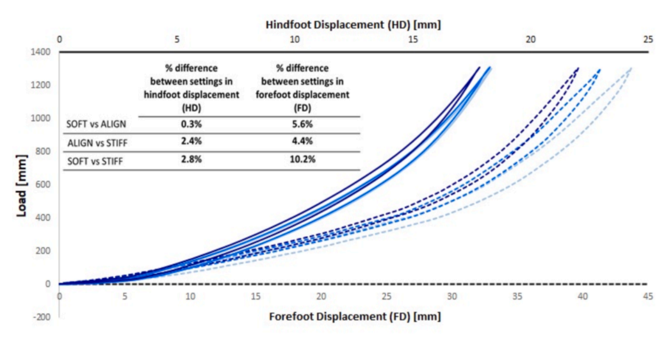

Fig. 2. Hindfoot (solid line, upper horizontal axis) and forefoot (dashed line, lower horizontal axis) displacement tested mechanically with a 1200 N load applied at a constant rate of 200 N/s. The inset table presents the % difference in displacement at maximum loading between all the three stiffness settings. FD: Forefoot displacement. HD: Hindfoot displacement.

Table 1
Mean (SD) for all outcome measures.

	LEVEL									RAMP					
	FAST			SLOW			SSS			DECLINE			INCLINE		
	STIFF	ALIGN	SOFT	STIFF	ALIGN	SOFT	STIFF	ALIGN	SOFT	STIFF	ALIGN	SOFT	STIFF	ALIGN	SOFT
PF RoM[°]	−8.69 (1.2) ●○	−9.71 (0.97)	−9.59 (1.14)	−5.3 (1.31) ●○	−5.84 (1.07)	−5.84 (1.05)	−7.51 (1.38) ●○	−7.86 (0.96)	−8.07 (1.3)	−9.56 (1.76) ●	−9.68 (1.63)	−9.97 (1.6)	−2.86 (0.86)	−2.98 (1.06)	−2.68 (1.45)
DF RoM[°]	15.3 (1.58) ●	16.1 (1.66)	16.6 (1.78)	12.1 (1.36) ●○	12.7 (1.36)	13.3 (1.62)	13.9 (1.35) ●○	14.6 (1.41)	15.1 (1.57)	13.3 (1.73) ●○	14.2 (1.95)	14.7 (1.94)	15.2 (1.29) ●○	16.4 (1.46)	17 (1.48)
DJS CP [N/kg/°]	0.046 (0.007) ●	0.045 (0.006)	0.043 (0.007)	0.034 (0.006) ●	0.033 (0.005)	0.030 (0.004)	0.044 (0.007) ●○	0.038 (0.004)	0.034 (0.005	0.0429 (0.004)	0.0394 (0.007)	0.039 (0.006)	0.0424 (0.016) ●	0.0417 (0.015)	0.0487 (0.029)
DJS CD [N/kg/°]	0.065 (0.004) ●○	0.062 (0.004)	0.059 (0.005)	0.068 (0.006) ●○	0.064 (0.006)	0.061 (0.01)	0.070 (0.005) ●○	0.064 (0.005)	0.060 (0.005)	0.0602 (0.007) ●	0.0597 (0.005)	0.0564(0.006)	0.0709 (0.007)	0.0694 (0.008)	0.0723 (0.009)

Statistical significance between stiffness settings during each gait task indicated with symbols; ●: STIFF vs. SOFT, ○: ALIGN vs. STIFF, ALIGN vs. SOFT. Abbreviations: PF RoM: Plantarflexion Range of Motion; DF RoM: Dorsiflexion Range of Motion; DJS CP: Dynamic Joint Stiffness during Controlled Plantarflexion; DJS CD: Dynamic Joint Stiffness during Controlled Dorsiflexion.

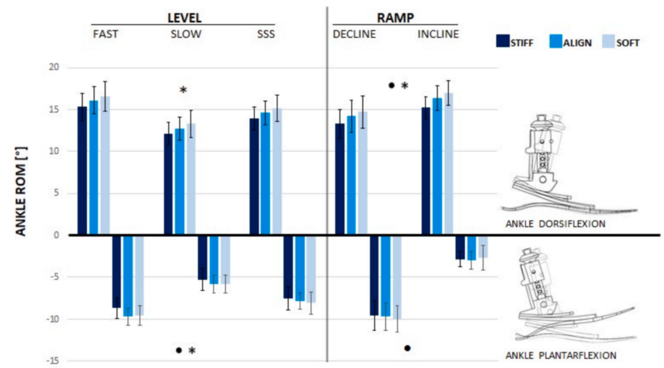

Fig. 3. Ankle RoM mean value and SD durIng all gait tasks. Ankle dorsiflexion is above the black horizontal line, plantarflexion below. Statistical significance within terrain (LEVEL and RAMP) indicated with symbols; *: Significant main effect of Stiffness, ●: Significant Stiffness*Speed/SlopeDirection interaction.

INCLINE.

3.2.1.2. Dorsiflexion RoM. For DF RoM a stiffer setting yielded a smaller RoM during LEVEL walking at all speeds (main effect of *Stiffness*, $p < 0.001$; Fig. 3), with no significant *Stiffness*Speed* interaction. Post-hoc tests contrasting the DF RoM between stiffness settings during FAST walking confirmed a significantly greater RoM (0.5°) for SOFT compared to ALIGN setting ($p < 0.001$) (Table 1).

For DF RoM a main effect of *Stiffness* was also seen for RAMP walking ($p < 0.001$), and a significant *Stiffness*SlopeDirection* interaction ($p = 0.04$) as the ALIGN and SOFT settings showed a greater response to *SlopeDirection* than STIFF. Post-hoc testing confirmed that during INCLINE walking, the SOFT setting provided significantly greater DF RoM (0.6°) than with the ALIGN setting ($p < 0.001$) (Table 1).

3.2.2. Dynamic joint stiffness

3.2.2.1. DJS during CP subphase. For the DJS-CP there was a significant main effect of *Stiffness* seen for LEVEL walking ($p = 0.006$). The *Stiffness*Speed* interaction was significant as well ($p < 0.001$) due to relatively larger incremental differences between stiffness settings during SSS walking compared to other walking speeds. Post-hoc tests demonstrated significant differences between all stiffness settings during SSS, but only between SOFT and STIFF during FAST (Table 1).

For RAMP walking no main effect of *Stiffness* was seen. The DJS-CP of the SOFT setting differed vastly between INCLINE and DECLINE, indicated by the significant interaction of *Stiffness*SlopeDirection* ($p = 0.01$)

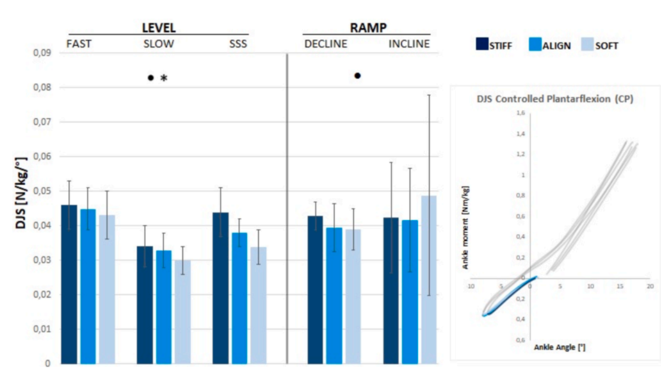

Fig. 4. Dynamic joint stiffness (DJS) for the Controlled Plantarflexion (PF) subphase of the gait cycle. Statistical significance within each terrain (LEVEL and RAMP) indicated with symbols; *: Significant main effect of Stiffness, ●: Significant Stiffness*Speed/SlopeDirection interaction. Example data for one trial shown for the DJS in the inset graph.

(Fig. 4).

3.2.2.2. DJS during CD subphase. DJS-CD was significantly affected by *Stiffness* during LEVEL walking ($p < 0.001$). A significant *Stiffness*Speed* interaction was seen for LEVEL walking ($p < 0.001$) as for the DJS-CP, where larger differences between stiffnesses were seen during SSS compared to the other speeds. Post-hoc tests showed that all differences between stiffnesses at all speeds were statistically significant, with the highest DJS-CD for STIFF and lowest for the SOFT setting (Table 1, $p < 0.001$).

For RAMP walking *Stiffness* also significantly affected the DJS-CD (main effect $p < 0.001$), and the *Stiffness*SlopeDirection* interaction was significant ($p < 0.001$), due to the different pattern seen during INCLINE, where the SOFT setting behaves differently than the other two settings (Fig. 5). This was also reflected in the post-hoc tests for INCLINE ($p = 0.02$) (Table 1).

4. Discussion

In this study, the mechanical and biomechanical properties of the VSA foot, were analyzed. A specific subject of interest were the effects of a stiffness change during the more demanding gait tasks such as increased gait speed and sloped gait conditions, on the examined outcome measures. Among several necessary biomechanical requirements for such tasks are increased ankle RoM. Therefore, the value of having a prosthetic foot that the user can adjust to vary stiffness, and hence RoM, according to the gait task performed, was examined.

4.1. LEVEL walking

4.1.1. Effects of speed

Differences between stiffness settings in both PF and DF RoM as well as DJS-CP and CD were generally incremental, but most notably during SSS, as opposed to the other speeds (Fig. 3–5, Table 1). Importantly, this indicates that properties demonstrated during standardized mechanical testing, which usually collects data for one speed, do not necessarily equate to how the prosthesis behaves during functional use, where users' technique and ability come into play (Langlois et al., 2014). The speed dependent differences of the DJS-CP might be related to the kinetic component of the DJS being influenced by proximal compensatory mechanisms, which could be altered with a change of speed, such as a shift in the weight of the upper body.

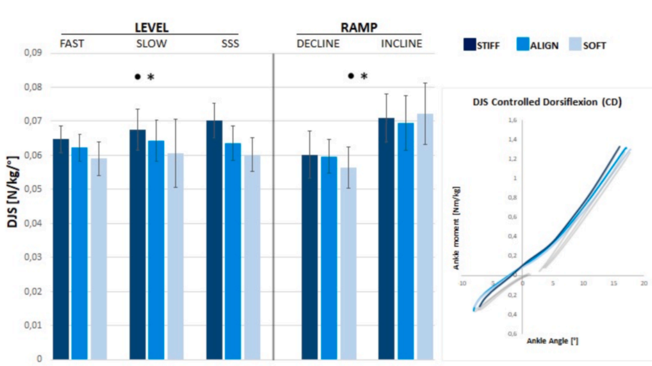

Fig. 5. Dynamic joint stiffness (DJS) for the Controlled Dorsiflexion (CD) subphase of the gait cycle. Statistical significance within each terrain (LEVEL and RAMP) indicated with symbols;*: Significant main effect of Stiffness, ●: Significant Stiffness*Speed/SlopeDirection interaction. Example data for one trial shown for the DJS in the inset graph.

4.2. RAMP walking

4.2.1. Decline

For RAMP walking, the expected incremental increase from STIFF to SOFT for PF RoM was seen during DECLINE, where it is inevitable that stance is initiated by a heel strike followed by plantarflexion motion towards foot-flat. Differences seen across stiffnesses during DECLINE were mostly related to DF RoM and concurrent DJS-CD (Table 1). As seen in Fig. 3 the DF RoM during DECLINE was only slightly lower than during LEVEL walking at SSS. Therefore, there does not seem to be increased need for higher DF RoM for DECLINE. Increased PF RoM with a softer foot was seen during DECLINE although not significantly larger than the ALIGN setting (Table 1). Increased PF RoM is inherently an important factor during the weight acceptance of decline walking as it influences the timing of foot flat and kinematic events up the chain. However, the small difference seen between the SOFT and ALIGN settings for hindfoot displacement in the mechanical and biomechanical data may have limited further analysis or conclusion on possible benefits for a softer hindfoot.

4.2.2. Incline

Patterns seen during INCLINE walking were markedly different than those found for DECLINE, especially for the weight acceptance period, where the ALIGN setting showed the largest PF RoM and the SOFT setting the smallest (Fig. 3), contrary to what was to be expected. A few factors may have influenced this finding. The INCLINE angle of the treadmill in this study was set at 7.5°. This is a challenge that may have caused a different foot placement of the prosthetic foot at initial contact (Fradet et al., 2010; Vrieling et al., 2008). This could be a compensatory strategy to avoid hyperextension and achieve the necessary knee flexion required in an incline terrain to progress up the slope. Additionally the trunk will increase its forward lean (Leroux et al., 2002), inherently moving the position of COM over the prosthetic foot in a different manner than seen in other gait tasks, effectively influencing the footś dynamic response. Post-hoc tests showed no differences between stiffness settings of PF RoM during INCLINE, indicating that the effect of *Stiffness* at heel strike is low. As the DJS-CD curve is defined from peak PF to peak DF, smaller PF RoM due to the altered foot placement has an effect on the slope of the DJS curve, which likely explains the unexpected findings of greater DJS with a softer setting. The high variability seen in the data for DJS-CP indicates inconsistent gait patterns, as has been reported previously in the literature (Rodrigues et al., 2019), limiting interpretation of this parameter. However, the foot significantly increased the DF RoM during the stance phase of this task, which is an inherent requirement needed for incline walking. With regards to the reported increased DF RoM a SOFT setting in a prosthetic foot during INCLINE walking could possibly benefit the user, although gait training to optimize weight acceptance may be of value as well.

4.2.3. Limitations and future work

The low number of participants is a limitation to this study. However, each individual provided multiple steps for all five conditions, and the results still demonstrate how this novel foot performs during gait. The individuals recruited for the study were all fairly active individuals which also limits generalizability of the results of the study to prosthetic users of a broader activity level.

Due to the material properties of ESAR prosthetic feet, deformation occurs when a load is applied to it. As such the basic assumptions for rigid body segments for intersegmental moment calculations via the inverse dynamic approach with a 6DoF model, may not apply. Despite this, these observation of DJS were included in this study, on account of using the same method and model across all trials for the stiffness settings comparison.

While the differences seen in the reported results are statistically significant, they are small and so the clinical relevance is unclear and needs to be investigated further. To address this, long-terms studies with a variable stiffness feature are needed, including subjective evaluations and motion analysis with users that have acclimated to various stiffness changes. Changes at the ankle level may have concurrent effects on joints or segments higher in the movement chain, which are clinically relevant e.g. in terms of compensatory mechanisms. Although the prosthetic foot analyzed in this study was designed to allow the user to adjust the stiffness setting, the scope of this study was not to test the applicability of the user-adjustable feature as such. The main rationale for the design was to provide the adjustability based on preference, while maintaining the available range to a limited set number of stiffness categories and hence small changes were seen in ankle RoM. Having a prosthetic foot that can be easily adjusted in terms of stiffness may be of value when undertaking tasks such as walking faster for a cardiovascular benefit or during closed kinetic changes such as lower limb exercises, which are extremely important for the amputee. A positive impact on motivation and participation may, in turn, affect the quality of life in the long term. Further studies are needed to define the optimal, personalized stiffness settings for a given task and where the threshold for an advantage vs disadvantage for a softer or a stiffer foot lies.

The foot was tested both mechanically and biomechanically to fully understand its dynamics during different terrains and gait tasks and the users' biomechanical data during LEVEL walking generally reflected mechanical results well. There are however limitations in how mechanical data reflect more complex tasks, in particular during weight acceptance. For further iterations of the VSA foot, increased capacity to decrease or increase compliance in the hindfoot would be of interest. As previously reported in the literature (Webber and Kaufman, 2017) a single axis load compression test does not have the ability to provide a thorough understanding of the mechanical properties during different activities. The behavior of the prosthetic foot is, as shown by the results of this study, dependent on the gait tasks performed. Therefore, a more precise task-oriented mechanical setup for testing feet would be of value in today's rapid development, as the initial stages of the design process do not always allow for user gait trials.

5. Conclusions

Biomechanical results of this study indicate that a softer foot may be of value when increased joint RoM requirements are presented during more demanding gait tasks such as during faster and/or sloped walking. Dynamic response and behavior of prosthetic feet are highly task-dependent, as reflected in DJS outcome parameter for the INCLINE data specifically, highlighting kinetic attributes that are otherwise unexplained in plain RoM values. Methods for analyzing stiffness characteristics of prosthetic feet must be chosen with specific tasks in mind and so must interpretation of results. Enhanced understanding of the dynamic response of various features of prosthetic devices, and how movement strategies differ in gait during different activities of daily life, is of value, both for prosthetic foot development and rehabilitation outcomes.

Declaration of interest

One of the authors of this manuscript is currently an employee of Össur (CL).

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