Gait & Posture 58 (2017) 23–29

Contents lists available at ScienceDirect

Gait & Posture

journal homepage: www.elsevier.com/locate/gaitpost

Full length article

Dynamic balance changes within three weeks of fitting a new prosthetic foot component

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ARTICLE INFO

Keywords:
Amputee
Rehabilitation
Walking
Biomechanics
Gait

ABSTRACT

Balance during walking is of high importance to prosthesis users and may affect walking during baseline observation and evaluation. The aim of this study was to determine whether changes in walking balance occurred during an adaptation period following the fitting of a new prosthetic component.

Margin of stability in the medial-lateral direction (MOS_{ML}) and an anterior instability margin (AIM) were used to quantify the dynamic balance of 21 unilateral transtibial amputees during overground walking. Participants trialled two prosthetic feet presenting contrasting movement/balance constraints; a Higher Activity foot similar to that of their own prosthesis, and a Lower Activity foot. Participants were assessed before (Visit 1) and after (Visit 2) a 3-week adaptation period on each foot.

With the Higher Activity component, MOS_{ML} decreased on the prosthetic side, and increased on the sound side from Visit 1 to Visit 2, eliminating a significant inter-limb difference apparent at Visit 1 (Visit 1–sound = 0.062 m, prosthetic = 0.075 m, $p = 0.018$; Visit 2–sound = 0.066 m, prosthetic = 0.074 m, $p = 0.084$). No such change was seen with the Lower Activity foot (Visit 1–sound = 0.064 m, prosthetic = 0.077 m, $p = 0.007$; Visit 2–sound = 0.063 m, prosthetic = 0.080 m, $p < 0.001$). Significant changes in AIM were observed at Visit 2 (Visit 1: −0.16 (0.08) m, Visit 2: −0.17 (0.08) m; $F = 23.396$, $p < 0.01$).

These findings suggest that changes in balance during walking can occur following the initial receipt of a device regardless of whether the component is of the same functional category as the one an individual is accustomed to using.

1. Introduction

Technological developments have led to an increase in prosthetic devices available on the market. Components that differ both subtly and markedly in structure and response, degrees of freedom (allowable movements), flexibility and mass theoretically increase the potential to successfully tailor prescription to the unique functional requirements of an individual. In practice, however, the prosthetist is faced with an overwhelming range of options to select from and limited objective measures to inform the decision [1].

While the process of building a custom prosthesis may take many appointments, the final delivery occurs in a single appointment with a prosthetist during which alignment of the device is finalized based on observational analysis of standing and walking and on verbal feedback from the patient. Assessment of the function of a prosthesis at the time of delivery is complicated by the ensuing adaptation to the device. With any functional change to a prosthesis, an individual must reorganize their movement to arrive at an optimal solution that effectively integrates the change into their walking patterns [2]. As this self-organization occurs, it should be expected that many endpoint variables will also change. At delivery, a prosthetist is required to optimize a device and its function based on limited information available prior to acclimation of the individual to the geometry, function and response of the device.

The consideration of balance during walking, or *dynamic balance*, is important in device selection for two reasons. First, the ability to maintain balance and control during walking is in itself of high importance for individuals with limb loss [3], and central to confidence, participation and autonomy in everyday life [4]. Second, a lack of balance may have implications for the quality of the movement produced during the assessment [5]. Compensations, secondary movements and the inability to exploit functional features of a prosthetic foot

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http://dx.doi.org/10.1016/j.gaitpost.2017.07.003
Received 1 July 2016; Received in revised form 8 March 2017; Accepted 3 July 2017
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may simply be a reflection of a lack of experience exploring the new extremity, and a lack of confidence in or appreciation of its boundaries or response. It is therefore important to be mindful of changes that may be expected to take place as the individual adapts to a new component.

One might speculate that an individual would be more readily able to integrate and control components that are functionally similar to one he or she had been accustomed to using. This is of importance as, if true, a prosthetist prescribing a functionally similar component could be reasonably confident that the movement observed on delivery is a reflection of potential function.

The aim of this study was to explore the changes to dynamic balance over an adaptation period following receipt of two new devices; one of which, based on activity level, was more similar to the device the individual was accustomed to, and one markedly different, attempting to induce a greater need to adapt. It was hypothesised that individuals would readily adapt to the former, reflected in a lack of measurable change in dynamic balance over the adaptation period, and conversely, that greater changes to dynamic balance over time would be observed for the less familiar component.

2. Methods

2.1. Participants

Twenty-one unilateral transtibial amputees gave informed consent to participate in a randomized crossover trial, approved by the university institutional review board (Table 1). All were experienced prosthesis users, K3 or K4 level according to Medicare classification, and appropriately wore high activity feet with their personal prostheses.

2.2. Procedures

Participants were tested on two different foot components: one of an activity level similar to their own based on prescribing guidelines (Higher Activity foot) and one rated at a lower activity level (Lower Activity foot), with order of provision randomized. All Higher Activity feet were energy storage and return-type components. For the Lower Activity component, all participants received a Solid Ankle Cushioned Heel (SACH) foot with the exception of one participant who was provided a multi-articulated flexible keel foot which is similarly rated at a lower activity level. Participants maintained their own socket and suspension to reduce confounding elements related to fit. A certified prosthetist performed all fitting and alignment for the study.

The first trial device was fitted during Visit 1 (V1). Individuals donned a tight fitting uniform with retroreflective markers placed on the pelvis and feet. These markers were placed consistently on both sides; superficial to the anterior and posterior superior iliac spines of the pelvis, at the lateral malleoli, and the dorsum of the second metatarsal head. Markers were placed on the prosthetic foot at analogous locations to the sound limb.

Testing was performed following alignment of the new prosthetic setup, after approximately 10 min of walking. Kinematic data were collected at 60 Hz using a 12-camera motion capture system (Eagle, Motion Analysis Systems, Santa Rosa, CA) during 10 traverses of the laboratory at a self-selected walking speed.

Participants wore the foot component for three weeks. After this period, following a repeat assessment (Visit 2: V2), the foot was swapped for the other (Higher/Lower Activity) trial component and the prosthesis setup was re-aligned for the new component. The three week process was then repeated.

Data were tracked in Cortex (Motion Analysis Systems, Santa Rosa, CA) and 10–15 strides from each participant were extracted for analysis. All computations were performed in Visual 3D (C-motion, Germantown, MD).

Table 1
Demographics for 21 participants with unilateral, transtibial amputation. Mean (SD) values reported.

Age (yrs)	Time Since Amputation (yrs)	Height (m)	Mass (kg)	Etiology
53.4 (11.9)	7.7 (6.1)	1.78 (0.08)	100.6 (18.8)	Trauma (n = 13) Vascular (n = 5) Tumor (n = 1) Other (n = 2)

2.3. Margin of stability

Margin of stability is a measure of dynamic balance based on the relative motion of the center of mass of the body with respect to the base of support provided by the feet [6]. Whereas in quiet standing it is accepted that balance can be maintained as long as the vertical projection of the center of mass lies within an individual's base of support, this criterion is insufficient during dynamic activities such as walking. In order to account for this increased challenge to balance, the extrapolated center of mass (XcoM) [6] incorporates an inertial term based on inverted pendulum dynamics:

$$XcoM = x + v\sqrt{l/g}$$

where x and v *are* the instantaneous position and velocity of the center of mass in the horizontal plane respectively, l is leg length and g is acceleration due to gravity. The margin of stability is traditionally defined as the minimum distance between the XcoM and the boundary of the base of support during movement [6].

Margin of stability was calculated in the medial-lateral (MOS_{ML}) direction as defined by Hof et al. [6,7]. In the anterior direction, using a similar approach we calculated the distance between the XcoM and the anterior margin of the base of support of the stance limb at the point of initial contact of the contra-lateral swing limb. In other words, we measured the extent to which the XcoM travelled beyond the base of support of the stance foot before contralateral limb foot contact. Despite the consistency in calculation we refer to this as the Anterior Instability Margin (AIM) due to differences conceptually between its definition of this and the traditional MOS. MOS_{ML} and AIM were both defined such that a positive value implied that the XcoM remained within the boundary of the base of support, i.e. a positive margin of stability implies stability, and a negative value occurs with the movement of the XcoM outside the base of support during a step. A greater magnitude of AIM in the negative direction indicates that the XcoM moves further outside the base of support before the contralateral swing limb is placed.

Lateral base of support was defined by the vertical projection of the lateral ankle markers onto the horizontal [8]. The anterior border was defined using the toe marker. Both markers were selected based on the reliability of their placement across sessions and foot components. The center of mass of the body was approximated by a point half way between midpoints of the markers placed on the anterior superior iliac spines and posterior superior iliac spines. Medial-lateral marker profiles were detrended prior to the calculation of the XcoM and MOS_{ML} to remove the effect of slight deviations in walking direction during the traverse of the laboratory [9]. Prior to calculation of the variable, the coordinates of the ankle markers and center of pressure at each time point were corrected by subtracting from them the vector defined by the center of mass medial-lateral position between the start and end of the trial. Foot contact events were detected via a kinematic algorithm [10] and manually verified. The average speed for each traverse was additionally measured via the displacement of the sacral marker.

Table 2
Self-selected walking speeds of 21 individuals wearing two different prosthetic feet tested before (Visit 1) and after (Visit 2) a three week acclimation period – mean (standard deviation) in meters/second.

Foot	Higher Activity		Lower Activity	
Visit	1	2	1	2
Speed	1.21 (0.24)	1.25 (0.24)	1.20 (0.26)	1.26 (0.25)

2.4. Statistical analysis

MOS_{ML} and AIM were examined using three-way repeated measures ANOVAs (leg x prosthesis x visit) with Fisher's LSD post hoc tests. For speed a two-way repeated measures ANOVA (prosthesis x visit) was performed.

Differences in MOS_{ML} and AIM at the individual level were examined using single subject analysis, performed on ten strides from each session for each measure [11], in order to elucidate any changes on an individual level that may have been masked by grouping results.

3. Results

Participants walked at similar speeds on both component types. A significant and comparable increase in speed was observed with both prostheses in V2 (Table 2, $F = 43.55$, $p < 0.001$).

3.1. Medial-lateral margin of stability

Grouped results showed no significant main effect of visit ($F = 0.65$; $p = 0.430$) or of prosthesis ($F = 0.812$; $p = 0.378$) (Fig. 1a). There was a significant main effect of leg ($F = 10.072$, $p = 0.005$); with marginal means of MOS_{ML} higher on the prosthetic side (Prosthetic: 0.077(0.004) m; sound: 0.064(0.004)m). A significant visit X prosthesis X leg interaction was observed ($F = 4.786$, $p = .041$). Post-hoc tests revealed a lack of a significant difference at V2 for the Higher Activity prosthesis ($F = 3.297$, $p = 0.084$) whereas all other inter-limb comparisons were significant (Higher Activity prosthesis V1: $F = 6.705$, $p = 0.018$; Lower Activity prosthesis V1: $F = 9.059$, $p = 0.007$, V2: $F = 17.301$, $p < 0.001$) (Fig. 1a).

Despite the lack of significant changes across visits at group level, significant changes in MOS_{ML} were observed in individual results. For the Higher Activity prosthesis one third of participants showed a significant change (either negative or positive) on the prosthetic side and over one third on the sound side (Fig. 2a). On the Lower Activity limb sound side proportions were similar but nearly half showed a significant change on the prosthetic side. On average these differences across participants levelled out resulting in no significant group differences.

The inter-limb asymmetry in MOS_{ML} indicated by the grouped

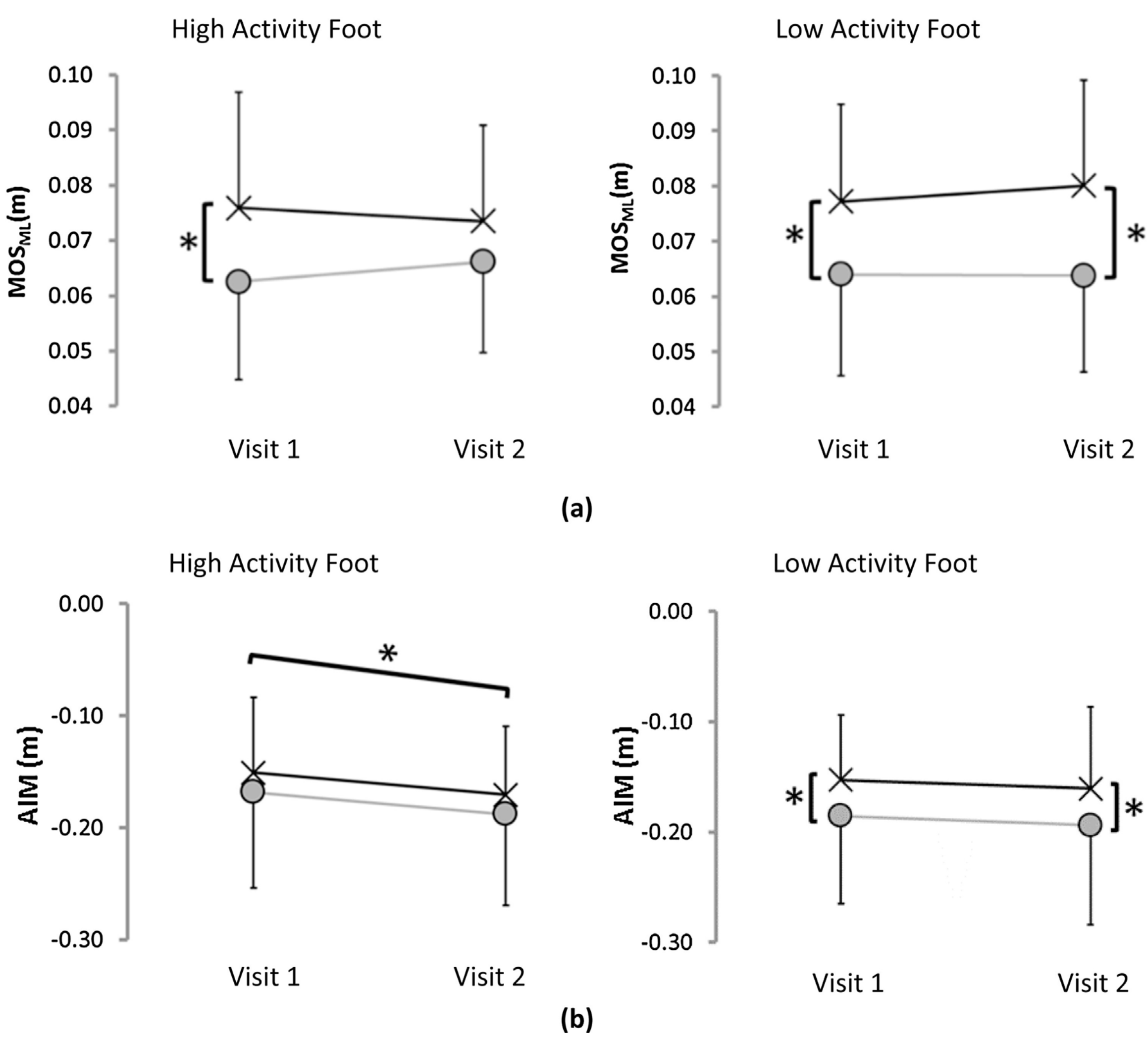

Fig. 1. Ensemble results.
(a) Medial-lateral margin of stability (MOS_{ML}) at Visits 1 and 2 before and after a three week adaptation period on Higher Activity and Lower Activity feet. (b) Anterior Instability Margin (AIM) at Visits 1 and 2 before and after a three week adaptation period on Higher Activity and Lower Activity feet. * differences significant at $p = 0.05$. X – prosthetic side, O – sound side.

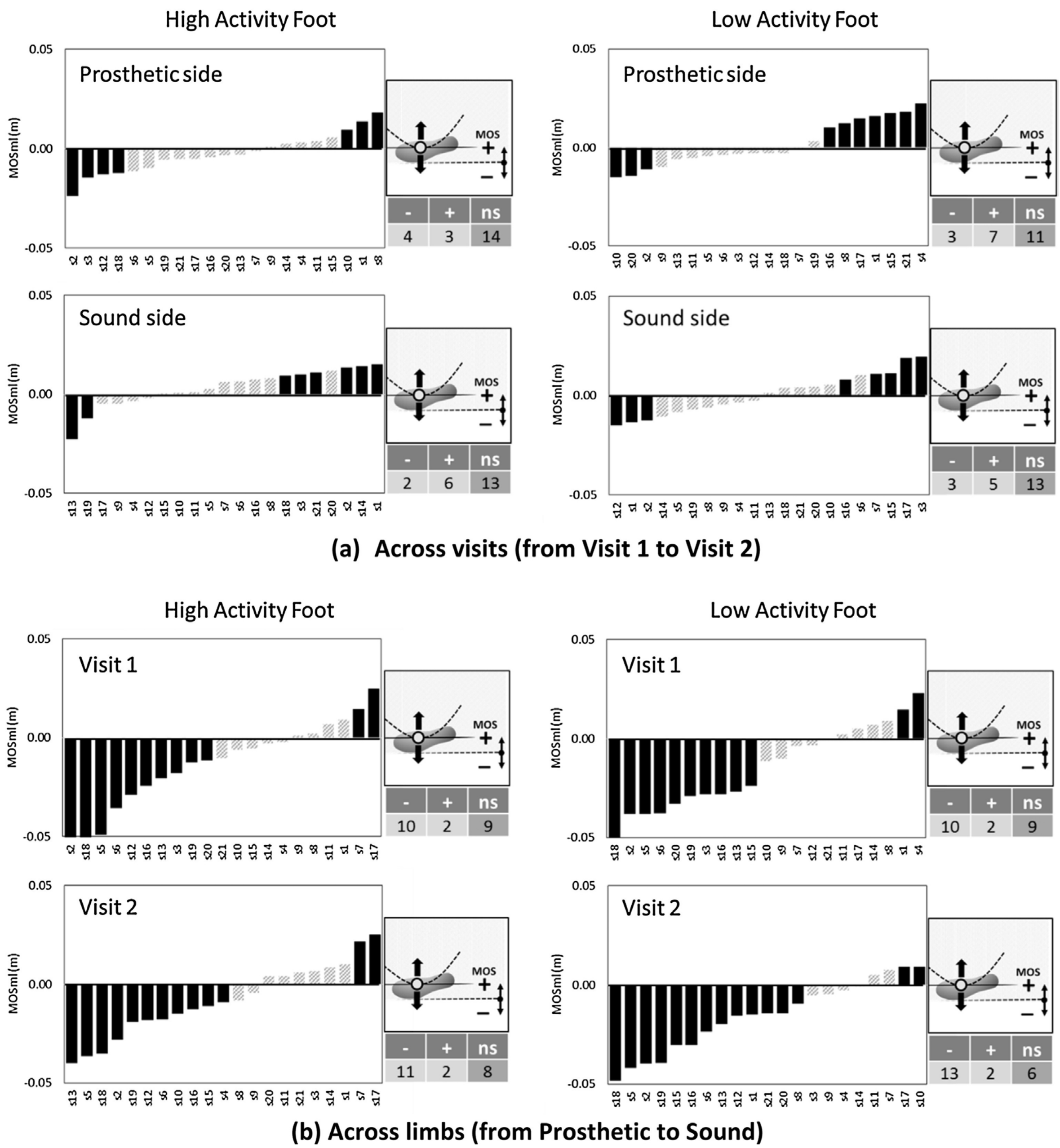

Fig. 2. Medial-lateral margin of stability (MOS_{ML}) for 21 participants with unilateral transtibial amputation on Higher Activity and Lower Activity feet. Solid bars indicate significant differences/changes ($p < 0.05$). Negative values indicate a decrease in margin of stability. Tabulated values indicate the number of individuals who showed significant decreases (−) significant increases (+) and no significant changes (ns).

(a) Individual changes over a three week adaptation period. Positive values indicate an individual increased their margin of stability (XcoM remained further within the lateral boundary of the base of support). (b) Individual differences from prosthetic to sound side. Positive values indicate a greater margin of stability on the sound side (XcoM remained further within the lateral boundary of the base of support). (c) Individual differences from Higher Activity to Lower Activity foot at Visit 1 and Visit 2. Positive values indicate a greater margin of stability on the Lower Activity foot (XcoM remained further within the lateral boundary of the base of support).

results was corroborated by the individual results, which revealed that nearly all individuals had a greater margin of stability on their prosthetic side (Fig. 2b). In V2, a similar number of individuals showed this asymmetry however differences between limbs appear on average smaller.

3.2. Anterior instability margin

Grouped AIM results revealed a significant main effect of Visit (V1: −0.16 (0.08)m, V2: −0.17 (0.08)m; $F = 23.396, p < 0.001$) (Fig. 1b). There was no main effect of prosthesis ($F = 0.596, p = 0.449$). A significant main effect of leg indicated that participants on average had a greater negative AIM on their sound side (Prosthetic: −0.16 (0.07)m, Sound: −0.18 (0.18)m; $F = 10.618, p = 0.004$) (Fig. 1b). A significant prosthesis X leg interaction indicated, however, that differences in AIM between sound and prosthetic sides were significant on the Lower Activity limb only ($F = 18.072, p < 0.001$) (Fig. 1b).

Across visits, significant individual changes in AIM were observed in approximately one third of the values, with proportions comparable for the two prostheses. For the Higher Activity limb all changes were consistent in direction on both sound and prosthetic sides, i.e. negative AIM increased. In contrast, on the Lower Activity limb one participant showed a large and significant increase in AIM on the prosthetic side. On the sound side three of the 21 participants increased their negative AIM at V2, one of which revealed a change of over 100 mm (Fig. 3a).

Significant individual inter-limb differences were observed for the

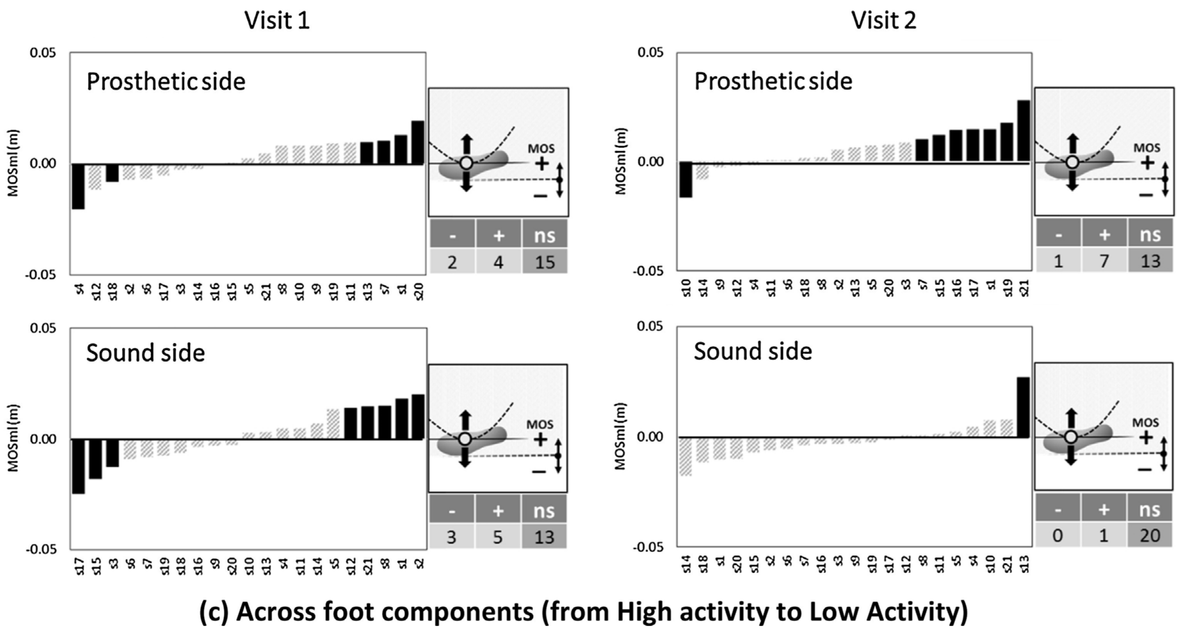

Fig. 2. (*continued*)

Higher Activity limb in over half of the participants in both V1 and V2, despite a lack of group main effects. Proportions of significant results were similar for the Lower Activity limb at V1, and greater at V2 (Fig. 3b).

At V1, there were significant differences across prostheses for the majority of participants. Equal numbers favoured each direction on the prosthetic side. A greater number (8/21) showed a greater negative AIM on the sound side when using the Lower Activity foot (Higher Activity foot: 3/21). Fewer participants showed a significant difference between prostheses at V2 (Fig. 3c).

4. Discussion

Selection of an appropriate prosthetic device for an individual currently relies on the judgement of the prosthetist and the preference of the patient, and difficulty increases with the requirement for rapid evaluation as in the context of a clinical delivery session. As there is typically little time afforded for acclimation is it possible that balance is not optimal during this brief assessment period. In addition to directly affecting the appraisal of the device by both parties as balance in itself is of high importance, this may influence the walking patterns that are observed at this time.

Given the functional relevance of dynamic balance to the individual walking with a prosthesis, margin of stability is an attractive measure for the assessment of device suitability. A low margin of stability by its traditional definition may be interpreted as a decreased safety net that may be either indicative of poorer control and a greater risk of a fall [6] or of greater confidence. The latter interpretation has been adopted for MOS_{ML} in this article based on anecdotal clinical observations of increased confidence in utilizing a device over time. Similarly, an increase in negative AIM has been attributed to increased confidence and awareness of the boundaries and function of the device. Importantly, however, these interpretations may not be mutually exclusive and increased confidence does not necessarily imply reduced fall risk.

All participants in this study were experienced prosthesis users and accustomed to walking with a high activity component. For this reason it was predicted that when provided with a functionally different component, i.e. the Lower Activity foot, greater changes in balance would be observed between assessments at delivery and after a three week period due to a requirement for acclimation. In contrast, it was hypothesised that changes in balance would be negligible when using the Higher Activity foot given that the participants would already be familiar with the mechanisms of a functionally similar component at baseline.

Our hypotheses were partially supported given that the changes that occurred with adaptation differed depending on the device. Against our predictions, however, these changes were not consistently smaller on the Higher Activity device.

There were significant changes in AIM for both devices across visits, however the main finding of a significant increase in negative AIM with the Higher Activity limb specifically refutes our hypothesis. This was highly consistent across participants, and potentially reflects the participants' ability to further rely upon, and exploit the function of, the foot after a few weeks of wear.

The inter-limb asymmetries in MOS_{ML} and AIM observed are consistent with previously published findings (see e.g. [7,8,12,13]), considered to be largely due to functional deficits of the prosthetic limb resulting in overcompensations. For example, a higher MOS_{ML} on the prosthetic side of individuals with amputation has been attributed to a safety mechanism to compensate for the lack of an ankle joint able to correct for small inaccuracies in foot placement [7]. Thus, the smaller inter-limb asymmetries in AIM and MOS_{ML} after a period of acclimation on the Higher Activity foot may indicate a greater confidence in the component. In contrast, on the Lower Activity prosthesis no such reduction in MOS_{ML} asymmetry was observed. In fact, several individuals appeared to settle into a strategy that further favoured their *sound* limb.

The magnitudes of the changes in MOS_{ML} across visits and across prostheses were relatively smaller in comparison to the observed inter-limb asymmetries whereas for AIM they were comparable in magnitude. This indicates a dominance of inter-limb symmetry effects in the ML direction regardless of prosthetic foot and, conversely, a greater impact of adaptation and prosthesis design on stability margins in the anterior direction.

A high heterogeneity across individuals is evident in many of the results reported. The lack of significant changes in the grouped results for MOS_{ML} across visits, for example, would seem to be the result of the competing numbers of individuals that increased versus decreased their margin of stability. Pertinent to any clinical scenario, despite the null group finding it cannot therefore be assumed that balance observed at baseline will be consistent with future ability. In the absence of patient-reported data regarding balance or falls, or further balance-specific functional tests it is difficult to determine what these magnitudes of

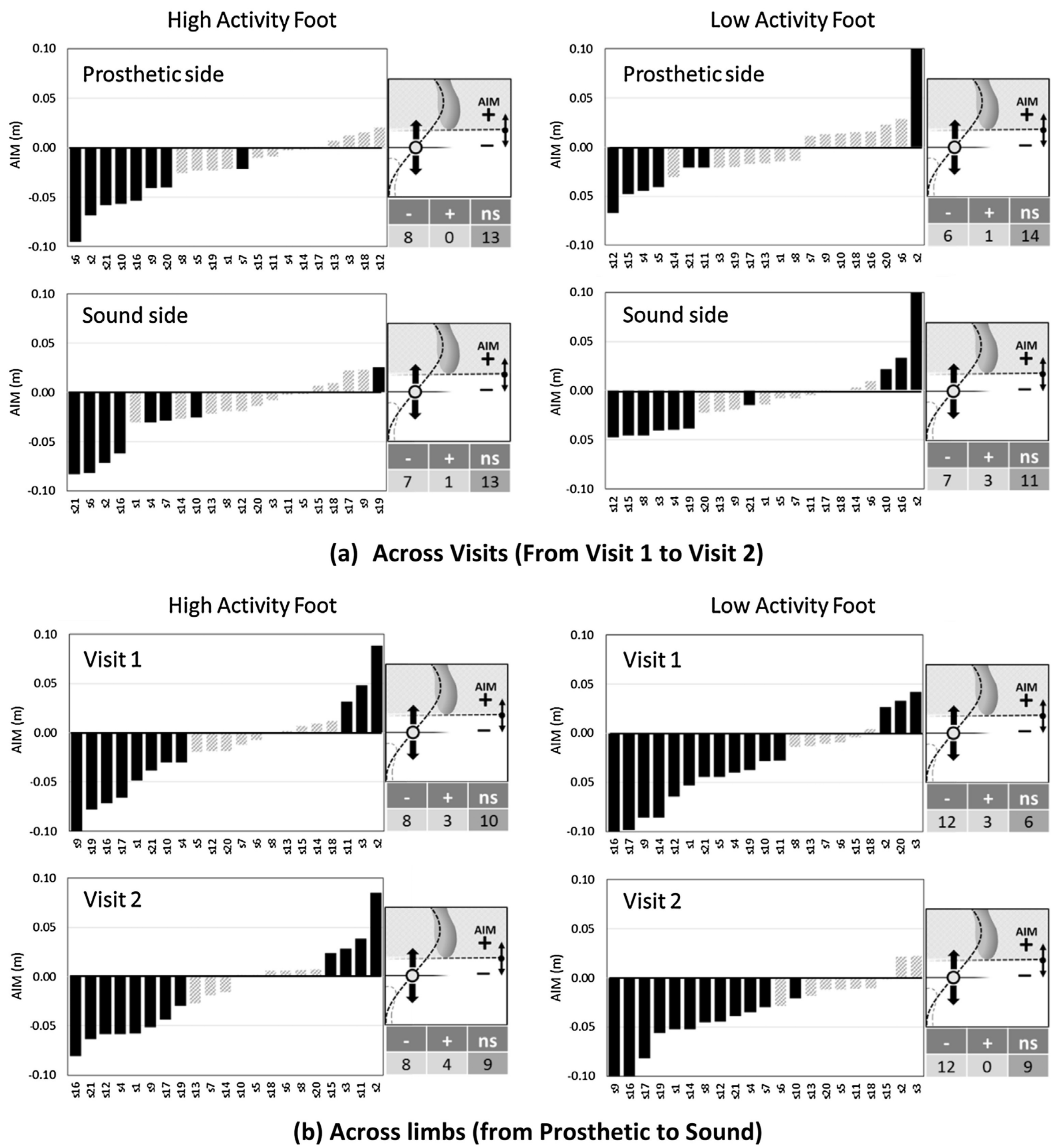

Fig. 3. Anterior Instability Margin (AIM) for 21 participants with unilateral transtibial amputation. Solid bars indicate significant differences/changes ($p < 0.05$). Negative values indicate a decrease in margin of stability. Tabulated values indicate the number of individuals who showed significant decreases (−) significant increases (+) and no significant changes (ns).

(a) Individual changes over a three week adaptation period. Positive values indicate an increase in margin of stability from the initial visit to the end of the adaptation period (XcoM was further within or towards the base of support at contralateral foot contact at Visit 2). (b) Individual differences from prosthetic to sound limb on Higher Activity and Lower Activity feet. Positive values indicate a greater margin of stability on the sound side (XcoM was further within or towards the base of support at contralateral foot contact). (c) Individual differences from Higher Activity to Lower Activity foot limb at Visit 1 and Visit 2. Positive values indicate a greater margin of stability on the Lower Activity foot (XcoM was further within or towards the base of support at contralateral foot contact when using the Lower Activity foot in comparison to the Higher Activity foot).

change may mean at a functional level. The incorporation of such measures in future work would provide a better context for data interpretation.

Margin of stability has been observed in previous studies to be actively maintained in the face of challenges to balance, via the manipulation of speed, step frequency and step width/length [12,14]. Sustaining this invariance has therefore been posited as a potential objective of motor control mechanisms [14]. Our results demonstrate a change in this measure during an early period of familiarization following receipt of a new lower extremity prosthesis. Further of note, and unapparent from grouped data, is the consistent lack of significant differences across foot types on the sound side at Visit 2. All but one (MOS_{ML}) or two (AIM) participants showed no difference in their stability margin on their unaffected leg after an acclimation period, despite wearing two functionally different components, suggesting a convergence to a preferred pattern of walking on this side. This suggests that a plateauing of margin of stability may potentially be used to identify the stage at which an individual has fully acclimated to a device; a challenge that is frequently mentioned but scarcely addressed [2,15,16]. Such findings stress the need for care in applying traditional experimental designs when individual responses that may be of importance potentially oppose each other. Employing both inter- and

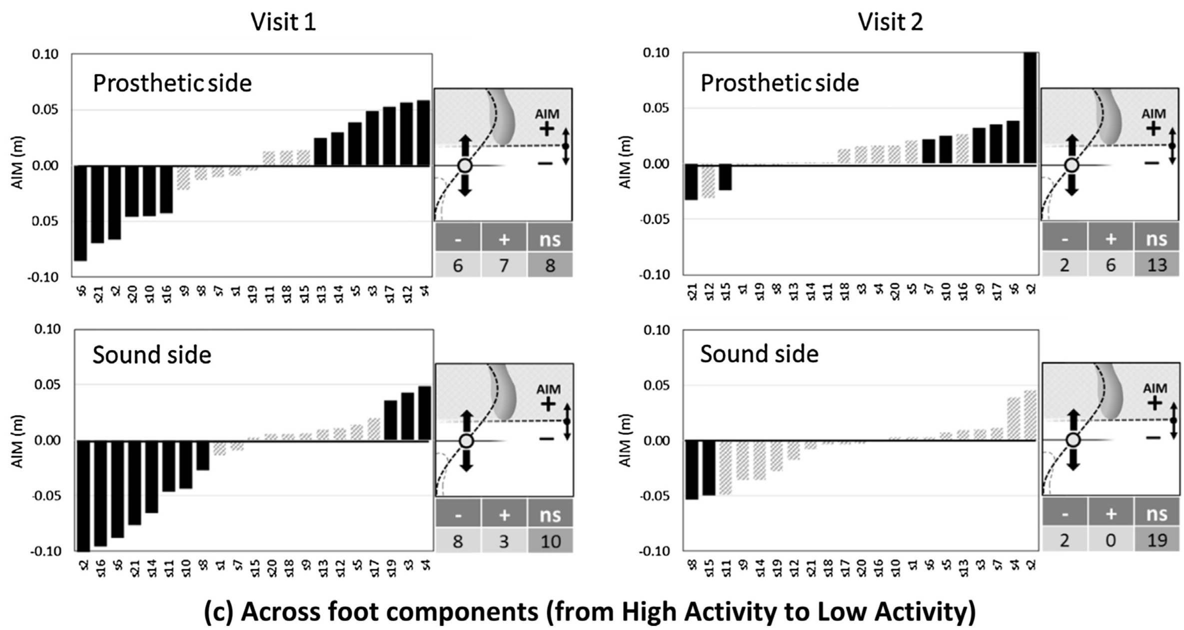

Fig. 3. (*continued*)

intra-subject variability analyses may help to differentiate between significant but inconsistent responses and a true lack of a change or difference.

5. Conclusion

Our results provide quantitative evidence of the changes in dynamic balance that occur over a three week period following receipt and fitting of a new device, regardless of the functional similarity of the component to previous devices used by the individual. While adaptations to balance can be expected, our results suggest that these changes do not occur in a similar manner across individuals.

Conflicts of interest

None.

Role of external funding sources

No involvement in the study design, collection, analysis and interpretation of data, or in the writing of the manuscript or decision to submit for publication.

Acknowledgements

This work was supported by the National Institutes of Health [grant numbers NIH/NIGMS P20 GM109090 and NIH/NICHD R15 HD086828]. The authors would like to thank Jeff Kaipust and Chase Rock for their assistance in data collection and processing respectively.

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