

## Full length article

# Osseointegrated prostheses improve balance and balance confidence in individuals with unilateral transfemoral limb loss

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## ABSTRACT

**Background:** More than half of patients with lower-limb amputation who use socket prostheses experience at least one fall annually. These falls are primarily attributed to reduced proprioception which negatively affects balance. A promising alternative to socket prostheses are osseointegrated prostheses that involve direct fixation of the prosthetic limb to the residual limb through a bone-anchored implant, yet its effect on balance remains unknown. **Research question:** Do osseointegrated prostheses change static and dynamic balance, as well as patient reported measures of balance confidence, compared to a socket prosthesis?

**Methods:** A sample of 10 patients with unilateral transfemoral amputation scheduled to undergo prosthesis osseointegration were enrolled (6 F/4 M, BMI:  $26.7 \pm 2.9$  kg/m<sup>2</sup>, Age:  $46.1 \pm 6.3$  years). Motion capture data during quiet standing (eyes opened and eyes closed) and overground walking at a self-selected speed, and the Activities-Specific Balance Confidence (ABC) scale, were collected before (with socket prosthesis) and 12-months following osseointegration. Postural sway via the center of pressure (COP), variability of spatiotemporal parameters, and ABC scores were compared using a repeated measures design before and after osseointegration.

**Results:** Following prosthesis osseointegration, COP path length and 95 % confidence ellipse area were reduced during quiet standing ( $d = 0.75$ ,  $P = 0.09$ ;  $d = 0.52$ ,  $P = 0.29$ , respectively) and the variability of step width and length were reduced during overground walking ( $d = 0.50$ ,  $P = 0.06$ ;  $d = 0.72$ ,  $P = 0.06$ , respectively). Furthermore, patients reported significantly improved ABC scores with an osseointegrated prosthesis compared to a socket prosthesis ( $d = -1.36$ ,  $P = 0.01$ ).

**Significance:** Improvements in postural sway, reductions in gait variability, and greater balance confidence indicate that osseointegrated prostheses improve balance for people with unilateral transfemoral amputation.

## 1. Introduction

There are nearly two million adults currently living with a limb amputation in the United States, and this number is expected to more than double by the year 2050 [1]. Within this population, more than half will experience at least one fall annually, nearly half have a fear of falling, and two-thirds have low balance confidence [2]. Collectively, this has a significant negative effect on patient mobility, quality of life, and health care costs [1]. One mechanism for an increased fall risk after

lower-limb amputation is worsened proprioception due to loss of joint(s) and altered load transmission when using a socket prosthesis [3].

Direct anchorage of the prosthetic limb to the residual bone via prosthesis osseointegration is an alternative to a socket prosthesis [4]. Evidence has suggested substantial improvements in quality of life, prosthetic use time, and mobility after prosthesis osseointegration [5–12]. A notable benefit of osseointegrated prostheses is increased osseoperception, which is the ability to identify sensations transduced by various mechanoreceptors and changes in central neural processing

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that originate through the bone-anchored prosthesis [13]. Improved osseoperception is evidenced by increased activation of residual limb mechanoreceptors when using an osseointegrated prostheses compared to a socket prosthesis [14]. Thus, prior evidence has shown that residual limb proprioception is increased when using an osseointegrated prosthesis compared to a socket prosthesis [4,15]. In addition to the visual and vestibular systems, proprioception is one of the three primary somatosensory systems pivotal to balance; thus, we hypothesize that osseointegrated prostheses improve balance, yet this has not yet been explicitly explored.

Postural control, required to maintain balance, is a complex and multifaceted process that involves simultaneous interaction of multiple sensorimotor processes to retain whole-body center of mass position within a base of support [16]. Depending on the task and environment, there are different control mechanisms used to maintain balance, which can be quantified using a variety of measures. Statically, balance is most commonly assessed using the center of pressure (COP) trajectory during quiet standing to quantify postural sway [17,18]. Prior evidence has demonstrated that patients with amputation and socket prostheses have worsened postural sway, as quantified by greater COP displacements, compared to able-bodied individuals [19,20]. Dynamically, increased gait asymmetry and variability are commonly used to assess balance, as increased gait variability has been shown to be associated with increased falls in multiple populations including older adults and post-stroke individuals [21,22]. Similar to postural sway, patients with amputation demonstrate increased levels of gait variability compared to able-bodied individuals [23]. Maintaining balance during both static and dynamic conditions is inherently more difficult for patients with transfemoral amputation with socket prostheses due to the loss of musculature, joint control, and sensory feedback [24]. However, changes in balance following prosthesis osseointegration remain unknown.

In addition to biomechanical measures of postural control, patients' perception of balance and falls are also associated with fall risk [25]. For example, older adults with substantial fear of falling tend to restrict their daily activities, leading to increased muscle weakness and worsened physical health, which subsequently contributes to an increased fall risk [26]. Conversely, increased balance confidence has been shown to mediate fear of falling and has also emerged as a more accurate predictor of falls than fear of falling [27]. Powell and Myers established the Activities-specific Balance Confidence (ABC) scale [28], with lower ABC scores associated with poor balance and increased falls [25,29]. Those with transfemoral amputation and socket prostheses had substantially greater fear of falling and less balance confidence (lower ABC scores) compared to able-bodied individuals [2]. However, it remains unknown if osseointegrated prostheses promote improvements in balance confidence.

Therefore, the primary objective of this investigation was to determine how static and dynamic balance were changed 12-months after prosthesis implantation. Our secondary objective was to determine how patients' self-reported balance confidence was influenced by

osseointegrated prostheses. We hypothesized that static and dynamic balance, as well as balance confidence, would significantly improve when using an osseointegrated prosthesis compared to a socket prosthesis.

## 2. Methods

### 2.1. Participants

A cohort sample of ten patients with unilateral transfemoral amputation who were scheduled to undergo prosthesis osseointegration were included in this study (Table 1). This cohort sample was part of a larger ongoing study that is examining the effect of lower-limb prosthesis osseointegration on clinical outcomes (physical function and patient reported) and biomechanics. Each patient underwent prosthesis osseointegration as a secondary procedure due to complications with their traditional socket prosthesis. Eligibility criteria for prosthesis osseointegration are described previously [30]. Inclusion criteria for the current study included unilateral transfemoral amputation, scheduled to undergo transfemoral prosthesis osseointegration at the University of Colorado, using a socket-suspended prosthesis at baseline, and being able to walk unassisted at each timepoint for at least 4 min. Exclusion criteria included not being able to walk unassisted each timepoint.

All patients received a titanium press-fit implant (OTN Implant BV, The Netherlands) that was implanted by the same orthopedic surgeon (JWS) in two surgical stages. The first surgical stage involved the intramedullary implantation of a femoral prosthesis, followed by 6-weeks of non-weight bearing. The second surgical stage created a stoma through an incision into the skin and soft tissue at the distal end of the residual limb and secured the transcutaneous component into the implant. Each participant then underwent the same 3-week rehabilitation protocol consisting of daily intervention sessions that began two days following the second surgical stage. The rehabilitation protocol involved progression of static and dynamic load bearing exercises designed to ready the limb for activities of daily living [4,31]. Within this protocol, each patient within this current cohort of this investigation achieved independent ambulation at similar timepoints.

Each patient visited the laboratory for two data collections (baseline (~2-days prior) and 12-months after osseointegration) in which whole-body kinematics and ground reaction forces during standing and walking were collected. At the baseline collection, each patient wore their own socket-suspended prosthesis that included an ischial containment socket, microprocessor knee, and a dynamic carbon-fiber response foot. At the 12-month follow-up collection, each patient wore their own prosthesis with the same knee and foot componentry as the baseline collection, with the addition of a torque control adaptor that was then connected to the osseointegrated intramedullary implant via a removable clamp connector. All prosthesis fitting was performed by a single licensed prosthetist. Each participant provided a written, informed consent in accordance with a protocol approved by the Colorado Multiple Institutional Review Board prior to the start of the

**Table 1**  
Patient demographics.

Patient (Pt)	Sex	BMI (kg/m <sup>2</sup> )	Age (years)	Time since Amputation (years)	Amputation Etiology	Residual limb length (cm)
Pt1	L	25.1	55	39	Osteosarcoma	22.0
Pt2	L	30.7	53	9	Chondrosarcoma	25.3
Pt3	R	27.8	37	6	Arterial clot	23.6
Pt4	R	25.8	38	32	Trauma	18.6
Pt5	R	21.3	38	7	Trauma	31.9
Pt6	L	30.2	48	16	Synovial Cell Sarcoma	18.2
Pt7	L	26.9	48	33	Trauma	27.4
Pt8	L	23.5	48	19	Histiosarcoma	22.0
Pt9	R	27.6	48	29	Osteosarcoma	9.1
Pt10	L	27.8	48	6	Trauma	19.5
Mean ± SD	6 F/4 M	26.7 ± 2.9	46.1 ± 6.3	19.6 ± 12.7		21.8 ± 6.1

baseline experimental session.

## 2.2. Data collection and processing

Each patient was instrumented with 38 reflective markers used to obtain whole-body kinematics. Kinematics were recorded from 10 infrared cameras (Vicon, Centennial, CO,  $F_s = 120$  Hz) and ground reaction forces were recorded from 6 embedded force platforms (Bertec, Columbus, OH,  $F_s = 2160$  Hz).

Quiet standing was collected in two 30-second conditions from each participant: eyes opened and eyes closed. The middle 20-seconds of each standing condition was used for analyses. Each patient then walked on a 10-meter walkway at their self-selected speed without the use of any assistive device (e.g., walker or cane) while kinematics and ground reaction forces were simultaneously recorded. Trials were collected until there were three “clean” strikes per limb, in which the stance foot fell completely within the force platform boundary. Therefore, the number of collected trials varied across and within participants, which is common in spatiotemporal parameter calculation on an overground walkway [22,32]. Bilateral spatiotemporal parameters (step width, step length, stance time) were calculated and averaged across all trials for comparison.

The ABC scale was collected at each data collection (baseline and 12-month follow up) and managed using REDCap electronic data capture tools [33]. The ABC scale is a 16-item self-report measure of the patient’s perceived balance confidence while completing various ambulatory activities, such as stepping onto an escalator or walking on a wet surface [28]. Patients estimate how confident they would be to perform each task without losing balance on a scale from 0 % to 100 %, with a higher value indicating better balance confidence. The ABC scale has demonstrated high internal consistency and good test-retest reliability, convergent construct validity, and known-groups construct validity in individuals with lower limb amputation [34].

## 2.3. Data analysis

A fourth-order Butterworth filter was applied to marker trajectories and force platform data with 6-Hz and 20-Hz cutoff frequencies, respectively, determined using a residual analysis [14]. An 8-segment model was then created in Visual 3D using the reflective marker positions (C-Motion, Inc. Germantown, MD).

Postural sway was quantified during each condition of quiet standing through the position of the COP. The excursion in the anteroposterior (AP) and mediolateral (ML) directions, the total path length, and the 95 % confidence area ellipse were calculated and scaled to participant height for comparison. Total path length and ellipse area during quiet standing, which are a basis of COP movement, are representative of overall stability [35]. Dynamic balance was assessed in two variables: 1) the symmetry ratio (amputated/intact) of spatiotemporal parameters [36] and 2) gait variability quantified by the coefficient of variation ( $CV = SD/mean \times 100$ ) of spatiotemporal parameters [37]. ABC scores were analyzed based on the total percent score, which was determined as the cumulative score across all activities.

## 2.4. Statistical analysis

All variables were tested for normality using the Shapiro-Wilks test and homogeneity of variance using Levene’s test ( $\alpha = 0.05$ ). Once normality and homogeneity of variance were confirmed, dependent variables were compared using a one-way repeated measure analysis of variance (ANOVA) with testing timepoint as the factor and a Tukey’s post-hoc test to control for Type I error caused by multiplicity ( $\alpha = 0.05$ ). Additionally, due to our small sample size, effect sizes were determined using Cohen’s  $d$  and categorized as small ( $0.2 \leq d < 0.5$ ), medium ( $0.5 \leq d < 0.8$ ), or large ( $d \geq 0.8$ ) [33]. All statistical analyses were performed in JMP® Pro 16.1.0 (SAS Institute Inc., Cary, NC). Only variables with a

medium or large effect size, which provides insight into the clinical meaningfulness of the differences, will be presented.

## 3. Results

### 3.1. Quiet standing

There was a medium effect of prosthesis osseointegration on COP path length and ellipse area during quiet standing. During the eyes-closed task, patients demonstrated reduced COP path length ( $d = 0.75$ ,  $P = 0.09$ ) and 95 % confidence ellipse area ( $d = 0.52$ ,  $P = 0.29$ ) 12-months after prosthesis osseointegration compared to baseline values in their socket (Fig. 1). Similarly, patients demonstrated reduced COP path length during the eyes-opened condition ( $d = 0.59$ ,  $P = 0.59$ ) 12-months after prosthesis osseointegration compared to baseline values in their socket prosthesis (Fig. 1). No differences were found in the excursion of COP displacement in either direction (AP or ML) or condition (eyes opened or eyes closed) following prosthesis osseointegration (Fig. 1).

### 3.2. Spatiotemporal parameters

There was a large effect of prosthesis osseointegration on spatiotemporal parameters during walking. When using an osseointegrated prosthesis, patients walked at a slower self-selected walking speed ( $d = 0.95$ ,  $P = 0.02$ ) and demonstrated longer stance times on the amputated limb ( $d = -0.93$ ,  $P = 0.004$ ) (Table 2). There was also a moderate effect of prosthesis osseointegration on intact limb step length ( $d = 0.53$ ,  $P = 0.18$ ). No other spatiotemporal differences were found.

### 3.3. Gait variability

There was a moderate effect of prosthesis osseointegration on dynamic gait variability. The coefficient of variation of the step width ( $d = 0.50$ ,  $P = 0.06$ ), amputated limb step length ( $d = 0.51$ ,  $P = 0.28$ ), and intact limb step length ( $d = 0.72$ ,  $P = 0.06$ ) decreased when using an osseointegrated prosthesis compared to baseline values in their socket prosthesis (Fig. 2).

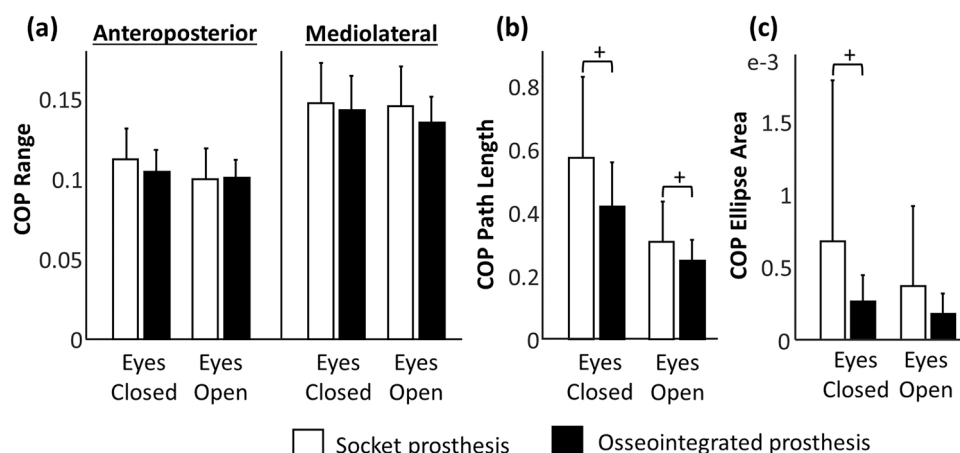
### 3.4. ABC Scale

There was a large effect of prosthesis osseointegration on participants’ balance confidence, with the mean total ABC scores being significantly higher when using an osseointegrated prosthesis compared to a socket prosthesis (Fig. 3) ( $d = -1.36$ ,  $P = 0.01$ ).

Individual patient COP path length, ellipse area, spatiotemporal parameters, gait variability, and ABC scores for each individual participant can be found in the [Supplementary material](#).

## 4. Discussion

The primary objective of this investigation was to determine how osseointegrated prostheses influenced static and dynamic balance, as quantified using measures of postural sway and gait variability. We also sought to determine how osseointegrated prostheses influenced patients self-reported measure of balance confidence. Compared to when using a socket prosthesis, we found medium effects showing reductions in postural sway and gait variability when using an osseointegrated prosthesis. Furthermore, patients also self-reported greater confidence in performing a variety of activities without losing balance when using an osseointegrated prosthesis compared to a socket prosthesis. To our knowledge, these are the first results to demonstrate the positive effect that osseointegrated prostheses have on static and dynamic balance measures. These results indicate that this novel prosthesis may positively affect fall risk, which is significant considering the heightened fall risk of patients with amputation who regularly use a socket prosthesis [38].



**Fig. 1.** Mean  $\pm$  1 S.D. of center of pressure (COP) (a) range in the anteroposterior and mediolateral directions, (b) path length, and (c) ellipse area for both the eyes closed and eyes closed quiet standing conditions with a socket prosthesis (white) and with an osseointegrated prosthesis (black). + denotes medium effect ( $0.5 \leq d < 0.8$ ). All COP variables were normalized by patient height.

**Table 2**

Mean  $\pm$  1 S.D. spatiotemporal parameters during overground walking at baseline (in a socket prosthesis) and in an osseointegrated prosthesis. Shaded values indicate statistically significant differences between socket and osseointegrated prosthesis.

	Baseline (socket)	Osseointegrated Prosthesis	<i>P</i> - value	<i>d</i>
Gait Speed (m/s)	1.09 $\pm$ 0.08	0.97 $\pm$ 0.17	0.02	0.95
Step Width (m)	0.18 $\pm$ 0.05	0.17 $\pm$ 0.05	0.51	0.12
Amputated Limb Stance Time (m/s)	0.67 $\pm$ 0.08	0.76 $\pm$ 0.10	0.004	-0.93
Intact Limb Stance Time (m/s)	0.73 $\pm$ 0.09	0.77 $\pm$ 0.16	0.29	-0.30
Stance Time Symmetry Ratio	0.93 $\pm$ 0.21	1.00 $\pm$ 0.19	0.09	-0.31
Amputated Limb Step Length (m)	0.58 $\pm$ 0.06	0.57 $\pm$ 0.05	0.76	0.14
Intact Limb Step Length (m)	0.65 $\pm$ 0.08	0.61 $\pm$ 0.07	0.18	0.53
Step Length Symmetry Ratio	0.90 $\pm$ 0.15	0.94 $\pm$ 0.09	0.43	-0.31

Postural sway was reduced when using an osseointegrated prosthesis compared to a socket prosthesis, as quantified by a reduction in COP path length and ellipse area. Thus, our results indicate that balance during quiet standing is improved with osseointegrated prostheses. This improvement was more pronounced during the eyes-closed condition compared to the eyes-opened condition. As the visual system was removed, and the vestibular system was unchanged, we attribute this difference to increased proprioception when using an osseointegrated prosthesis. Osseoperception, or the ability to sense external mechanical stimuli [39], likely drives this phenomenon. This sensation occurs as the mechanoreceptors near the implant are stimulated during loading, which increases the patient's ability to identify sensory inputs through the prosthesis [39]. Prior evidence has demonstrated osseoperception is improved with osseointegrated prostheses [13], hypothesized to result in improved balance and less falling, yet more research is needed to support this claim. Because improvements in postural sway have previously been linked to a reduction in falls [40], we hypothesize that this novel prosthesis will reduce the number of annual falls in this at-risk population. Our future work will continue to increase the sample size to assess metrics of postural sway in this population and links to

self-reported fall incidences.

There was a moderate effect of prosthesis osseointegration on reducing the variability of step width and length. Variability of the spatiotemporal components of gait have been well studied in pathologic populations and are consistently associated with falling (i.e., increased variability associated with increased fall risk) [21,37,41]. In the frontal plane, variability in step width negatively impacts postural control. Prior evidence has demonstrated that patients with transfemoral amputation ambulating with a socket prosthesis demonstrate increased step width variability, which was attributed to greater challenges in lateral stability during weight transfer [42]. Interestingly, Lin et al. also demonstrated a strong negative correlation between step width variability and physical activity [42]. The authors attributed this to increased bilateral hip muscle control, which is critical to both physical activity and overall balance. This is supported by our prior work that demonstrated increased hip muscle function following prosthesis osseointegration [30]. Similarly, step length has also been previously linked to fall risk as its variability results from errors in control of foot placement [43]. Our current results demonstrated that step length variability was reduced following prosthesis osseointegration, which

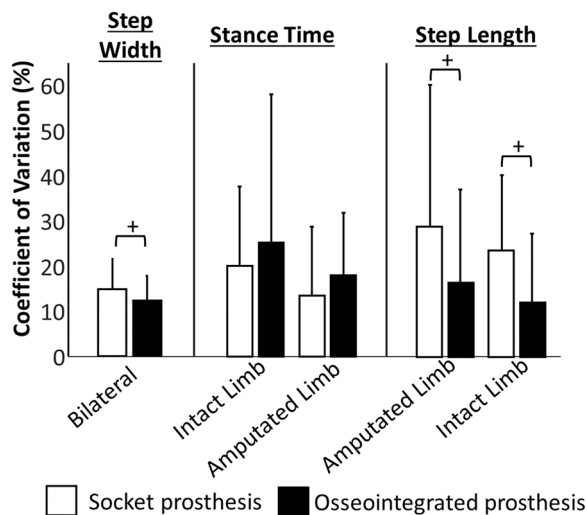


Fig. 2. Mean  $\pm$  1 S.D. coefficient of variation of spatiotemporal parameters during overground walking with a socket prosthesis (white) and with an osseointegrated prosthesis (black). + denotes medium effect ( $0.5 \leq d < 0.8$ ).

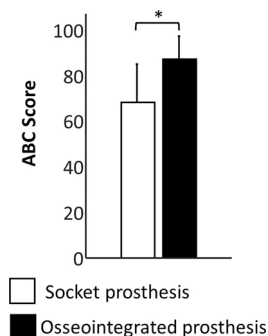


Fig. 3. Mean  $\pm$  1 S.D. ABC score when using a socket prosthesis (white) and an osseointegrated prosthesis (black). Larger ABC scores indicate greater balance confidence. \* indicates statistically significant differences ( $\alpha = 0.05$ ) and a large effect ( $d \geq 0.8$ ).

may be indicative of improved balance control. Although preliminary in nature, our results suggest prosthesis osseointegration may improve dynamic balance through reduced gait variability, which would remain increased with their socket prostheses compared to unimpaired adults.

Contrary to our hypothesis, we found minimal differences in spatiotemporal parameters following prosthesis osseointegration. Surprisingly, self-selected gait speed decreased 12-months following prosthesis osseointegration. Although prior evidence has attributed decreased self-selected gait speed to an increased risk of falling, this evidence is consistently focused on older adults walking below the 1.0 m/s threshold for community-dwelling [37]. Although the average self-selected walking speed following prosthesis osseointegration was slightly below this threshold (0.97 m/s), we do not interpret this to be large enough to be indicative of an increased risk of falling. Contrarily, it is possible the decreased self-selected walking speed is not indicative of worsened balance or function, but rather increased comfort and confidence. This is supported by the increased stance time on the amputated limb, which indicates greater confidence and ability to spend a longer amount of time on the amputated limb with an osseointegrated prosthesis as compared to a socket prosthesis, resulting in improved symmetry of stance times between limbs. Many patients within our cohort qualitatively reported that when using their osseointegrated prosthesis, they did not feel the same urgency to complete the walking trials due to discomfort experienced within their socket prosthesis, which could

explain the slower gait speed and greater stance time on the amputated limb. However, further research and a larger sample size is required to definitively make this conclusion, and determine its effect on dynamic balance, which our future work continues to study.

Our results demonstrated improvements in balance confidence, as indicated by the ABC scale scores. Baseline ABC scale scores were consistent with prior results in individuals with lower limb amputation who ambulate with a socket prosthesis [34]. Based on individual answers, our results indicated that patients' confidence increased more in performing more challenging tasks (e.g., stepping off of an escalator or walking on slippery surfaces) compared to lower demand tasks (e.g., walking around the house) when using an osseointegrated prosthesis. We hypothesize that this population is more confident in their ability to maintain balance as they are more comfortable, have greater prosthesis satisfaction, and increased levels of osseoperception compared to a socket prosthesis. As patients with osseointegrated prosthesis are more confident in their ability to maintain their balance, fall risk and fear of falling is reduced, which likely increases activity and social participation in the community.

There are several limitations in this study. First, the number of trials used for spatiotemporal collection was not controlled for. While variability is likely altered by the number of trials making the greater number of trials more preferable, the total number of trials collected per patient were analyzed due to limited data in light of the paucity of evidence that currently exists surrounding patients with osseointegrated prosthesis. Second, our sample size was small and part of a larger ongoing study that hindered our ability to control for demographic factors (e.g., age, sex, or time since initial amputation), which may influence balance. Our continued work will explore how patient-specific factors are associated with changes in balance following prosthesis osseointegration. Third, we did not standardize the residual limb length within our cohort, which may have an influence on our results as we had a wide range of residual limb lengths ranging from short (9.1 cm) to long (31.9 cm). The residual femur length has shown to substantially influence both balance and spatiotemporal parameters during walking as longer residual limbs provide greater moment arms relative to the hip joint [44]. Thus, it is possible that those with longer residual limbs may have different changes in both static and dynamic balance outcomes after prosthesis osseointegration compared to those with shorter limbs. Fourth, given our small sample size, gait speed was not controlled for which will play a role in the temporal parameters of gait (e.g., stance time). However, because we found differences in stance time on the amputated limb, but not the intact limb, we do not believe changes across the relatively small range of gait speeds substantially influenced the interpretation of our results (Supplemental Table 1). We advise caution in extending these findings across a wider range of gait speeds, which our future work will explore. Finally, after the completion of the acute in-house 3-week rehabilitation program, rehabilitation protocols were not standardized across participants, which may have a confounding effect on our results.

## 5. Conclusion

This investigation was the first to demonstrate the effect of osseointegrated prostheses on static and dynamic balance. When using a transfemoral osseointegrated prosthesis, we found that our cohort of ten patients demonstrated improvements in standing postural sway, reduction in gait variability, and greater balance confidence compared to when using a socket prosthesis. While this is an important first step in establishing the influence of prosthesis osseointegration on balance, our future work, including a larger sample size, will continue to evaluate balance mechanisms following prosthesis osseointegration to determine if this novel prosthesis lowers fall risk.



## CRediT authorship contribution statement

Each author was fully involved in the conception and design of the study, data acquisition and analysis, manuscript preparation, and final approval of the submitted manuscript.

## Conflict of Interest Statement

The authors have no conflicts of interest to disclose.

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## Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.gaitpost.2022.12.011](https://doi.org/10.1016/j.gaitpost.2022.12.011).

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