Journal of Biomechanics 112 (2020) 110050

Contents lists available at ScienceDirect

Journal of Biomechanics

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

Motion of the residual femur within the socket during gait is associated with patient-reported problems in transfemoral amputees

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ARTICLE INFO

Article history:
Accepted 12 September 2020

Keywords:
Prosthetics
Residual limb
Suspension

ABSTRACT

The purpose of this study was to provide a quantitative description of residual femur motion within the socket during gait and to explore the relationship between residual femur motion and patient-reported comfort and function. It was hypothesized that increased residual bone movement would correlate to worse patient-reported comfort and function. The secondary goals were to assess within-subject step-to-step variability and between-subject variability in residual femur motion within the socket during gait. Dynamic biplane radiography, combined with conventional motion capture, was used to measure residual femur motion within the socket during treadmill walking for 10 unilateral transfemoral amputees. The questionnaire for persons with a transfemoral amputation (Q-TFA) was administered to assess prosthetic use, mobility, health problems, and global health. Increased femur pistoning (proximal-distal translation relative to the socket) correlated with worsening Q-TFA problem and global scores ($\rho = 0.741$, $p = 0.04$ and $\rho = -0.783$, $p = 0.02$, respectively). Average residual femur rotation ROMs were 7.3°±3.7°, 10.8°±4.4°, and 7.7°±4.8° for anterior tilt, internal-external rotation, and varus-valgus, respectively. Average residual femur translation ROMs were 8.6 mm ± 3.0 mm, 28.4 mm ± 13.9 mm, and 20.4 mm ± 7.2 mm for medial–lateral, pistoning, and anterior-posterior directions, respectively. Within-subject rotational and translational variability during gait averaged 2.8° and 2.0 mm or less, whereas the between-subject variability was up to 9.4° and 18.6 mm, which demonstrates residual femur motion relative to the socket is repeatable within subjects, but inconsistent across subjects during gait. The results suggest residual bone motion within the socket is a potential mechanism behind patient-reported problems and suggests a target for intervention aimed at improving transfemoral amputee quality of life.

1. Introduction

The number of people in the United States living with lower limb amputation is projected to rise from 1 million in 2006 to 2.3 million by 2050 (Ziegler-Graham et al., 2008) and with 19 to 27% of lower limb amputations resulting in transfemoral amputations (Belatti and Phisitkul, 2013), an estimated 440,000 to 620,000 people will be living with transfemoral amputations in the United States by 2050. Artificial limbs are generally connected to the residual limb by way of a socket that is designed to facilitate weight bearing, suspension, and force coupling for prosthesis control. All these objectives require substantial surface contact pressure and friction forces between socket wall and residual limb, which makes skin problems a common issue experienced by patients who use lower extremity prostheses. In addition to the skin problems, excessive loading of the soft tissue surrounding the residual bone has been proposed as a cause of deep tissue injuries (Portnoy et al., 2008). Commonly reported problems include ulcers, irritation, cysts, blisters, and erosions (Dudek et al., 2005). These complications are especially worrisome in people with underlying conditions that affect tissue health and regeneration, such as vascular disease, which is a majority of limb-loss patients in the United States (Ziegler-Graham et al., 2008). Because of these health issues, the same people are often ineligible for osteointegration surgery, which facilitates the direct attachment of prosthesis componentry to the residual bone without the need for a socket (Brånemark et al., 2019). In addition to skin and soft tissue problems, amputees are generally found to have reduced mobility and a lower quality of life compared to the general population. They are at a higher risk of both limb and lower back pain,

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https://doi.org/10.1016/j.jbiomech.2020.110050
0021-9290/

osteoarthritis due to altered and excessive tissue loading during gait, and accidental falls. All these problems are exacerbated by poorly fitted prosthetic sockets (Amtmann et al., 2015; Deans et al., 2008; Sinha et al., 2011).

Prosthetists believe that limiting motion between the residual femur and the socket will improve comfort and function. New socket designs, such as the Infinite Socket (LIM Innovations, San Francisco, CA, USA), the Socket-less Socket (Martin Bionics, Oklahoma City, OK, USA), and many others allow for more adjustability compared to traditional designs and are aimed at improving stability between the residual limb and the prosthesis. However, there is a lack of quantitative data describing the relative motion between the residual femur and socket during dynamic motion such as walking, and how that relative motion may be associated with comfort and function.

Static and video fluoroscopy have previously been used to measure movement of the bone in relation to the socket (Darter et al., 2016; Papaioannou et al., 2010; Söderberg et al., 2003). However, most studies only obtained single-plane sagittal radiographs, restricting measurements to the anterior-posterior and superior-inferior directions. Also, there is a lack of knowledge of how the residual bone moves within the socket during gait, the most common lower-body activity of daily living, especially for individuals with transfemoral amputation. One previous study that focused on patients with transtibial amputation reported up to 29 mm of bone movement relative to the socket during a fast stop movement (Papaioannou et al., 2010).

The purpose of this study was to provide a quantitative description of residual femur motion within the socket during gait in individuals with transfemoral amputation and to explore the relationship between residual femur motion and patient-reported comfort and function. It was hypothesized that increased residual bone movement would correlate to worse patient-reported comfort and function. The secondary goals were to assess within-subject step-to-step variability and between-subject variability in residual femur motion within the socket during gait.

2. Methods

2.1. Subjects

Following Institutional Review Board (IRB) approval, participants provided informed consent to participate in this IRB-approved study. Participants were included if they had unilateral transfemoral limb loss, were ambulatory without a walking aid, and were using a socket suspension prosthesis. The recruitment age range was 18 to 80 years old. The target sample size of 10 was comparable with previous studies, and commensurate with the risk/benefit assessment of this study.

2.2. Tool and protocols

Up to five trials of synchronized biplane radiographs of the socket/distal femur area were collected at 100 images/sec for 1.0 sec (maximum 90 kV, 160 mA, 1 ms pulse width) during walking at a self-selected speed (average 0.7 ± 0.2 m/s, 43.3 ± 7.3 steps/min) on an instrumented treadmill that collected ground reaction forces at 1000 Hz (Bertec Corp, Columbus, OH) (Fig. 1a,b). Participants were allowed to use a handrail to maintain balance but were discouraged from using it to support their weight. Images were captured after the participants were fully comfortable walking on the treadmill. The late swing to mid stance portion of the gait cycle was captured due to restrictions in the field of view of the biplane imaging system. Additionally, one neutral standing trial (100 images/sec for 0.1 sec) was captured for baseline measurements. Concurrently, conventional optical motion capture was used to measure socket movement (12- camera Vantage V5, Vicon, Oxford, UK), with the thigh markers placed on the prosthetic socket (full body marker set with 55 total markers, 10 mm diameter) .

Computed tomography (CT) scans of each subject's femur were obtained (average 0.57 × 0.57 mm in-plane resolution, 1.25 mm slice thickness, GE LightSpeed Pro 16). The CT images were resliced to generate cubic voxels. A combination of automated and manual segmentation of bone tissue was performed using commercial software (Mimics, Materialise, Leuven, Belgium) (Fig. 1c). Three-dimensional models of each femur were created from the segmented bone tissue (Treece et al., 1999) (Fig. 1d). The maximum radiation exposure related to this study was estimated to be approximately 0.6 mSv, comprised of 0.5 mSv from the CT scan and 0.1 mSv from biplane radiographic imaging (estimated using PCXMC, STUK - Radiation and Nuclear Safety Authority, Helsinki, Finland).

The Questionnaire for Persons with a Transfemoral Amputation (Q-TFA) was administered at the time of testing to gather information on prosthetic use, prosthetic mobility, prosthetic related problems, and global health. The Q-TFA has been previously shown to have high reliability with a Cronbach's alpha of no less than 0.7 and shown to correlate with Short-Form 36 (SF-36)-Item Health Survey for validity of the measurements (Hagberg et al., 2004).

2.3. Data processing

A previously validated volumetric model-based tracking technique, with *in vivo* accuracy of 0.7 mm or better in translation and 0.9° or better in rotation, was used to match digitally reconstructed radiographs created from the subject-specific CT scans to the biplane radiographs (Fig. 1e) (Anderst et al., 2009).

Coordinate systems for the femur were established using anatomical landmarks (Fig. 2) and the socket coordinate system was established using surface marker data from the static standing trial (Fig. 3).

A separate local coordinate system was established to track the socket during the walking trials using four markers placed on the socket and the medial/lateral knee markers. Up to four variations of these local coordinate systems were created, each using one of the four socket markers and the two knee markers (Fig. 3) to track the socket even if a marker was not visible during a walking trial.

2.4. Data analysis

A custom MATLAB (Mathworks, Natick, MA) program was used to calculate the six degree-of-freedom (DOF) kinematics of the residual femur relative to the socket using Euler angle decomposition. The rotations described were anterior-posterior tilt (sagittal plane rotation), varus-valgus angle (coronal plane rotation), and internal-external rotation. The translations were medial–lateral, anterior posterior, and decompression-compression (i.e. pistoning). The neutral standing trial 6 DOF measurements were used as baseline to normalize the results for the dynamic walking trials by subtracting the static standing values from the dynamic walking values. Range of motion (ROM) for each DOF was calculated from late swing to mid stance. Only portions of the gait cycle common across all subjects were included in the analysis. Within-subject variability was calculated as the average standard deviation across trials, and between-subject variability was calculated as the standard deviations between average subject curves.

Spearman's correlation was conducted using SPSS 26 (IBM) to determine the correlations between the residual femur ROM relative to the socket and patient-reported outcomes measured by Q-TFA. The significance criterion was defined as $\alpha = 0.05$. Subject

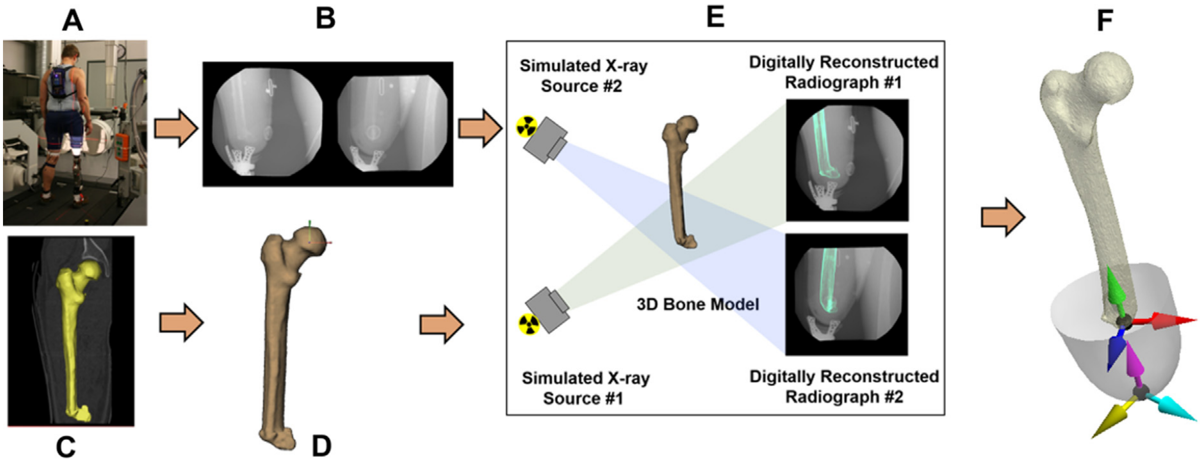

Fig. 1. Data collection and model-based tracking workflow. A) The participant walked on a dual-belt instrumented treadmill within a biplane radiographic imaging system. B) Synchronized biplane radiographs were collected at 100 Hz. C) CT scan was segmented. D) 3D bone models were generated from segmented CT images. E) Volumetric matching process to track 3D bone motion was performed using an automated algorithm to maximize the correlation between the Digitally Reconstructed Radiographs (DRR) and the distortion-corrected biplane radiographs. F) Femur motion was calculated from biplane images and combined with reflective marker data on the socket to calculate femur kinematics relative to socket coordinate system.

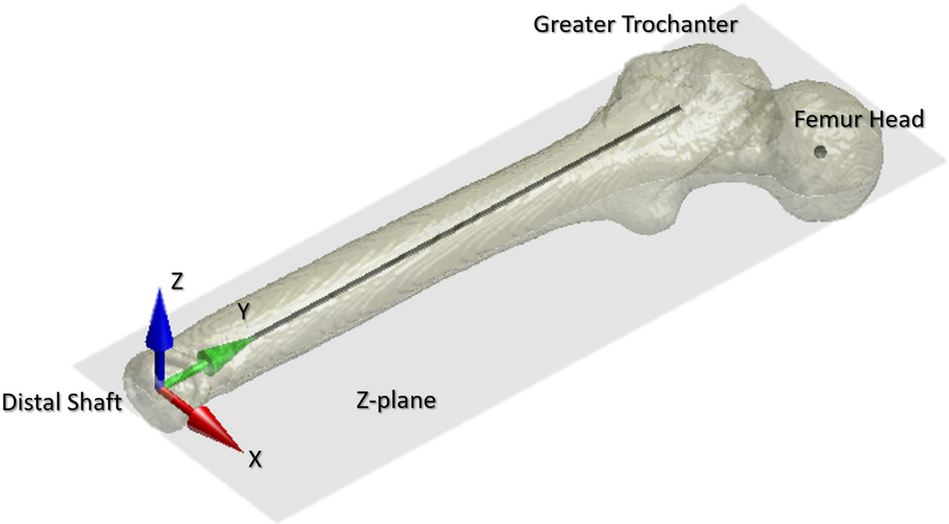

Fig. 2. Anatomical coordinate system assigned to the residual femur bone using landmark locations. Coordinate systems for the residual femur were established from the three-dimensional models generated after segmentation as follows: O_f: Most distal point of the residual femur during CT scan. Y_f: Vector connecting the distal end of the residual femur to the greater trochanter. Z_f: Vector perpendicular to plane formed by Y_f and the center of the femoral head pointing anteriorly for the left side and posteriorly for the right side. X_f: Vector perpendicular to both Y_f and Z_f.

body-mass index (BMI) and residual femur length were used as control variables for the correlation analysis.

3. Results

A total of 10 subjects met the inclusion criteria and participated in the data collection (Table 1).

The 6 DOF kinematics of the residual femur was captured consistently from late swing through mid-stance of the gait cycle (Fig. 4). Average ROMs for rotations were 7.3°±3.7°, 10.8°±4.4°, and 7.7°±4.8° for anterior tilt, internal-external rotation, and varus-valgus, respectively. Average ROMs for translation were 8.6 mm ± 3.0 mm, 28.4 mm ± 13.9 mm, and 20.4 mm ± 7.2 mm for medial–lateral, pistoning, and anterior-posterior directions, respectively.

Greater pistoning ROM was strongly correlated to a higher Q-TFA problem score and lower Q-TFA global score ($\rho = 0.741$, $p = 0.04$ and $\rho = -0.783$, $p = 0.02$, respectively). No other significant correlations between the Q-TFA scores and ROM were found (Table 2).

The 6 DOF continuous waveform describing residual femur motion was highly repeatable from step-to-step within a subject. The average within-subject variability of the 6 DOF continuous waveforms were 1.5°±0.8°, 2.8°±1.0°, and 1.1°±0.4° for anterior tilt, internal-external rotation, and varus-valgus, respectively, and 1.3 mm ± 1.0 mm, 1.5 mm ± 0.6 mm, and 2.0 mm ± 0.6 mm for medial–lateral, pistoning, and anterior-posterior translations, respectively. The average between-subject variability of the 6 DOF continuous waveforms were 8.8°±0.5°, 9.4°±2.0°, and 5.2°±1.6° for anterior tilt, internal-external rotation, and varus-valgus, respectively, and 8.6 mm ± 3.0 mm, 8.0 mm ± 1.5 mm, and 18.6 mm ± 1.1 mm for medial–lateral, pistoning, and anterior-posterior translations, respectively.

All subjects displayed pistoning greater than 20 mm, with maximum compression achieved by 20% of gait cycle (Fig. 4). The maximum compression during the dynamic trial was typically ± 5 mm relative to the static trial, however one outlier subject achieved

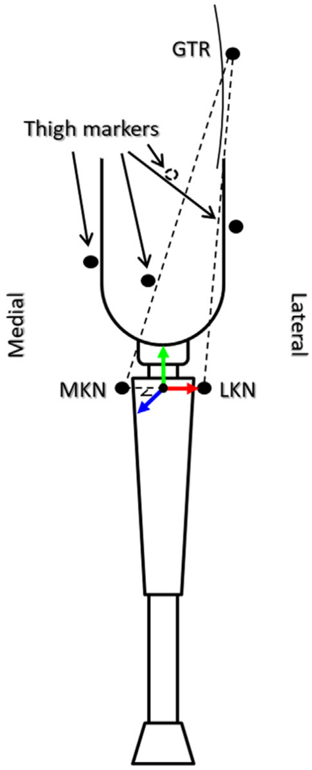

Fig. 3. Illustration of location of reflective markers placed on the prosthetic knee joint and socket, viewed in the posterior to anterior direction. Dotted line denotes the frontal plane used to define the Z axis in the static trial and the dotted thigh marker is located on the anterior side of the socket. The coordinate system for the socket was established using the surface-mounted markers placed on the socket or knee joint (Medial Knee [MKN], and Lateral Knee [LKN]) and the Greater Trochanter (GTR) during the static trial as follows: X_s: The line connecting MK and LK, pointing towards LK. O_s: Midpoint of MK and LK. Z_s: The line perpendicular to plane formed by GTR, MK, and LK, pointing anteriorly for the left side and posteriorly for the right side. Y_s: Vector perpendicular to X_s and Z_s, pointing superiorly.

>20 mm of compression beyond the neutral position and had a total pistoning ROM of 62 mm. All subjects exhibited a lateral translation of the end of the femur as the limb was loaded after foot strike (Fig. 4). Most subjects' residual femur started more medially positioned within the socket at foot strike relative to the static trial, with only one subject starting more laterally positioned. There was also a consistent pattern of the femur going into varus alignment as the limb was loaded after foot strike for all subjects (Fig. 4).

4. Discussion

This novel study measured residual femur motion within the socket of transfemoral amputees during gait. The most clinically significant finding was that the pistoning ROM of the residual femur significantly correlated with a worsening in the patient's problem and global health score. Step-to-step variability in residual femur motion was 3° or less and 2 mm or less, indicating a highly repeatable motion of the residual femur within the socket during gait. Between-subject variation in femur motion was much larger, up to 9° in rotation and 19 mm in translation. However, several consistent movement patterns were observed across subjects in terms of pistoning, lateral translation, and varus rotation from late swing through early support.

The patient's problem score is defined as "the extent of specific problems related to the amputation and the prosthesis and their impact on the quality of life" with higher scores indicating more problems (Hagberg et al., 2004). While only pistoning ROM significantly correlated with an increased problem score, a trend was observed where increased medial–lateral and anterior-posterior translation as well as varus-valgus ROM were associated with increased the Q-TFA Problem score. Although these associations did not reach statistical significance, the relationship may be clinically relevant (Table 2). In addition to the problem score, the global score, defined as "the perception of function and problems with the current prosthesis and the perception of the current overall amputation situation," (Hagberg et al., 2004) was moderately associated with increased ROM in 5 DOF, and strongly correlated with the pistoning ROM. These findings suggest that constraining residual bone motion within the socket may be associated with improved quality of life for the patients. In a clinical setting, the scores may provide guidelines as to how much constraining of the residual bone a patient may need. This can be adjusted by changing socket tightness and/or overall socket design. It is important to note that patient-reported outcome scores have somewhat limited reliability (Hafner et al., 2016) and that short-term and long-term assessments can differ quite substantially. For instance, a fairly loose socket fit may feel preferable initially, but turn out to be intolerable when used under different conditions and over longer periods of time. Therefore, a prosthetist who is trying to optimize socket design should not rely entirely on the subjective feedback from the patient. An objective assessment method as described here could help address this issue.

It was shown in the current study that walking on a treadmill leads to a highly repeatable motion of the residual femur relative to the socket in transfemoral amputees. This coincides with a previous study that reported less variability between steps during treadmill walking compared to over ground walking (Button et al., 2010). Although there have been previous studies that have shown differences between over ground and treadmill walking, the magnitude of the differences in kinematics have been in the order of a few degrees (Button et al., 2010; Parvataneni et al., 2009; Riley et al., 2007), which may be acceptable for assessing socket compatibility. Furthermore, the high repeatability of the femur movement within the socket suggests that there is highly repetitive loading of the soft tissue within the socket. These highly repetitive loading

Table 1
Subject demographics. Residual femur length is calculated as distance from hip joint center to end of distal femur along the shaft.

Subject	Sex (Male/Female)	Age (years)	Height (cm)	Weight (kg)	Body mass index (kg/m^2)	Suspension type	Residual Femur Length (cm)
1	M	42	183	79.4	23.7	Shuttle lock	29.0
2	M	59	183	102.1	41.1	Shuttle lock	32.8
3	F	63	160	108.0	42.3	Vacuum	31.5
4	M	62	177	91.6	29.3	Shuttle lock	23.8
5	M	52	177	80.3	25.7	Vacuum	31.1
6	M	56	175	59.0	19.3	Shuttle lock	18.3
7	M	61	177	92.1	29.5	Vacuum	32.2
8	M	55	180	82.6	25.5	Vacuum	31.8
9	M	24	190	10.2	36.1	Vacuum	35.6
10	F	45	172	83.0	28.1	Lanyard	28.1

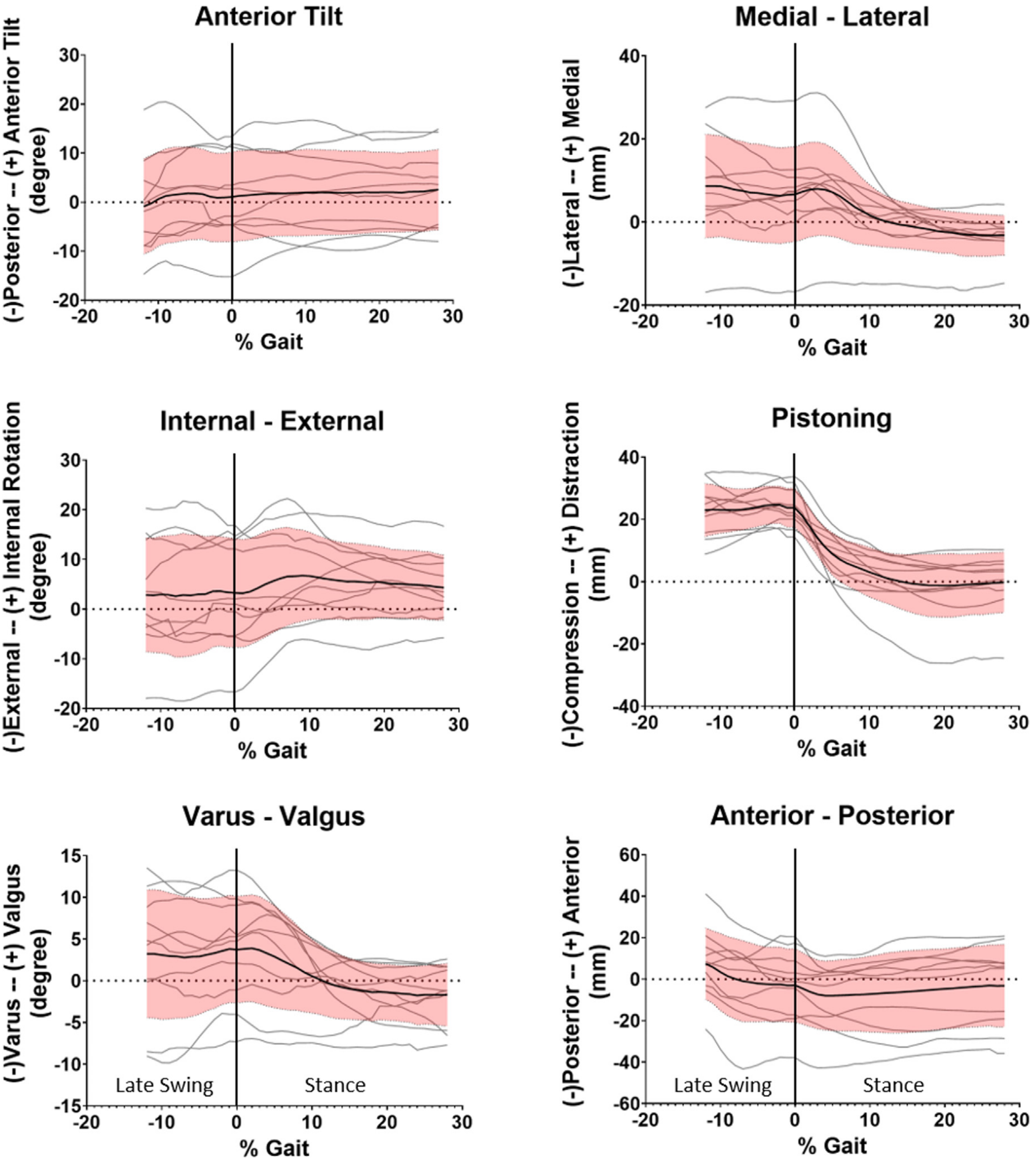

Fig. 4. Six degree-of-freedom kinematics of the femur relative to socket coordinate system. Dark line represents the overall average curve, the grey lines represent individual average curves, and the shaded area represents the 95% confidence interval. 0% of gait cycle represents heel strike.

Table 2
Correlation coefficient (Spearman's Rho) between The Questionnaire for Transfemoral Amputees (Q-TFA) scores and kinematic range of motion (ROM) from late swing to mid stance. Subject residual femur length and body mass index (BMI) were set as control variables. Significant correlations are highlighted in **bold**.

		Q-TFA scores			
		Prosthetic Use Score	Prosthetic Mobility Score	Problem Score	Global Score
Kinematics ROM	Anterior Tilt Rotation	−0.313 (p = 0.45)	−0.546 (p = 0.16)	0.408 (p = 0.31)	−0.670 (p = 0.07)
	Internal-External Rotation	−0.562 (p = 0.15)	0.150 (p = 0.72)	0.240 (p = 0.57)	−0.585 (p = 0.13)
	Valgus-Varus Rotation	−0.143 (p = 0.74)	−0.112 (p = 0.79)	0.658 (p = 0.08)	−0.537 (p = 0.17)
	Medial-Lateral Translation	−0.076 (p = 0.86)	−0.237 (p = 0.57)	0.583 (p = 0.13)	−0.545 (p = 0.16)
	Pistoning Translation	−0.013 (p = 0.98)	0.151 (p = 0.72)	**0.741 (p = 0.04)**	**−0.783 (p = 0.02)**
	Anterior-Posterior Translation	0.102 (p = 0.81)	−0.373 (p = 0.36)	0.682 (p = 0.06)	−0.550 (p = 0.16)

conditions may be a factor in soft tissue breakdown experienced by socket prosthetic users, as previous studies have proposed that there is a threshold in human movement variability where reduced variability may cause repetitive motion injury (Stergiou and Decker, 2011). By assessing patient qualitative feedback and walking kinematics after socket alterations, combined with the correlations that were seen in this study, it may be possible to improve individual socket fit by reducing residual femur motion in patient-specific designs.

Although the femur-socket kinematics were found to be consistent within a subject, there were large variations between subjects. The wide variations in our sample height, weight, residual limb length, and socket design/suspension type, which is representative of the wider subject population, are all possible causes for the variability in residual femur motion seen across subjects. A previous study has reported differences in residual limb motion when comparing elevated vacuum and passive vacuum sockets (Darter et al., 2016), further suggesting that socket design/suspension is a cause of variability in the outcomes. There are further confounding factors such as the design of the knee and ankle joints that may affect gait pattern, therefore affecting the femur-socket motion. The influence of these factors will be investigated in ongoing and future research.

Even with highly variable residual bone kinematics, there were some consistent patterns of residual femur motion observed across subjects. The pattern of residual bone translation in the medial–lateral direction was consistent across subjects after foot strike. The bone translated slightly medially at foot strike, then translated laterally as the limb was loaded during stance. Likewise, all subjects demonstrated similar pistoning and anterior-posterior translation patterns. The fact that the patterns were similar across subjects demonstrates that these motions are common, but differences in the total amount of motion experienced by individuals may affect their overall outcomes.

It is important to note that the kinematic results shown are normalized to each subject's neutral standing. Therefore, kinematics values farther away from 0 indicate a larger difference in femur position within the socket from the standing position. Some subjects exceeded the static standing level of compression during walking, while others failed to reach the standing level of compression. These differences during dynamic movement suggest that static measurements are not sufficient to reliably describe the extent of movement the residuum will undergo during walking.

Limitations of the study include the number of patients tested, which may have prevented us from identifying additional significant relationships between residual femur motion and patient-reported outcome. Although residual femur length and BMI were used as control variables for the correlation analysis, the sample size disallowed sub-analyses to determine if socket suspension type, residual femur length, and/or knee, ankle, and foot prosthetic affects residual femur motion. Given the exploratory nature of this data collection, a correction of the significance criterion for multiple comparisons was not applied. Strengths of the study include dynamic imaging of the residual femur within the socket during gait, synchronized capture of radiographic and conventional motion data, multiple trials collected per subject, and an accurate and validated method used to track residual femur motion within the socket.

The present study established that residual bone motion relative to the socket during gait can be measured using dynamic biplane radiography combined with optical motion capture. The results indicate that static measurements do not accurately characterize the bone motion relative to the socket in everyday activities such as walking. Within subject stride-to-stride variability in residual femur motion is low in comparison to among subject variability. In addition, a strong correlation between femur kinematics relative to the socket and Q-TFA problem and global scores suggests residual bone motion within the socket is a potential mechanism behind patient-reported problems and suggests a target for intervention aimed at improving quality of life for individuals with transfemoral amputation.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

Funded by Univ. of Pittsburgh, Dept. of Orthopaedic Surgery.

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