Development and preliminary evaluation of a new anatomically based prosthetic alignment method for below-knee prosthesis

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Abstract

The objectives of current study were to a) assess similarities and relationships between anatomical landmark-based angles and distances of lower limbs in unilateral transtibial amputees and b) develop and evaluate a new anatomically based static prosthetic alignment method. First sub-study assessed the anthropometrical differences and relationships between the lower limbs in the photographs taken from amputees. Data were analysed via paired t-test and regression analysis. Results show no significant differences in frontal and transverse planes. In the sagittal plane, the anthropometric parameters of the amputated limb were significantly correlated to the corresponding variables of the sound limb. The results served as bases for the development of a new prosthetic alignment method. The method was evaluated on a single subject study. Prosthetic alignment carried out by an experienced prosthetist was compared with such alignment adjusted by an inexperienced prosthetist but with the use of the developed method. In sagittal and frontal planes, the socket angle was tuned with respect to the shin angle, and the position of the prosthetic foot was tuned in relation to the pelvic landmarks. Further study is needed to assess the proposed method on a larger sample of amputees and prosthetists.

Keywords: anatomical landmarks, anthropometry, prosthetic alignment, transtibial prosthesis, laser instrument

Introduction

Prosthetic alignment, which is concerned with the spatial relationship between prosthetic components and an amputee's skeleton, is an important issue for lower limb amputees (Klute et al., 2009). Proper alignment is necessary for ground reaction force symmetry between sound and amputated limbs, improved residual limb loading, and reduced energy expenditure (Chow, Holmes, Lee, & Sin, 2006; Schmalz, Blumentritt, & Jarasch, 2002; Seelen, Anemaat, Janssen, & Deckers, 2003). In common clinical practice, prosthetists adjust eight variables to achieve clinically acceptable alignment, namely, prosthetic height, socket anteroposterior tilt, socket mediolateral tilt, foot anteroposterior shift, foot anteroposterior tilt, foot mediolateral tilt, foot mediolateral shift, and toe in/out angle. The acceptable alignment is usually accessed in three steps, namely, bench alignment, static alignment, and dynamic alignment. Bench alignment involves adjustments to the spatial position of prosthetic components and is conducted without having an amputee wear a prosthesis (Fleer & Wilson, 1962). In static alignment, amputee wears the prosthesis while assuming a static standing position and prosthetic alignment is further adjusted in relation to the skeleton. In dynamic alignment, prosthetist fine-tunes alignment on the basis of the visual analysis of amputee's gait symmetry and the amputee's feedback and comfort. This step is usually repeated until both the amputee and the prosthetist are satisfied with the quality of prosthetic alignment. The subjectively agreement is the only criteria that uphold final clinically acceptable alignment. Given that this process is time-consuming and dependent on user and prosthetist experiences, it lacks inter- and intra-rater reliability (Zahedi, Spence, Solomonidis, & Paul, 1986). The improvement of prosthetic alignment measurement systems is a key prerequisite to achieve repeatable clinically acceptable alignment (Klute et al., 2009).

Two commercial systems have been developed in an attempt to objectively assess prosthetic alignment. The Laser Assisted Static Alignment Reference (LASAR) posture system employs ground reaction force to define the location of a projected laser line in relation to limb in a static standing position (Blumentritt, 1997). The authors stated acceptable alignment based on the laser line location in the sagittal and the frontal planes (Blumentritt, 1997, 1998). Another system is Computerized Prosthetic Alignment System (COMPAS), which detects forces and moments at the base of the socket and sends the information to a PC via Bluetooth (D.A Boone, 2005). The installed software then analyzes the input and suggests essential corrections that are based on predefined requirements for optimum alignment (D.A Boone, 2005). Chen et al. (2015) compared the prosthetic alignment defined by COMPAS with that determined through a conventional method and revealed that the external varus moment of the knee during walking was significantly greater under the COMPAS system (Chen et al., 2015). Regardless of alignment accuracy and repeatability, the aforementioned systems, to some extent, provide insight into objective prosthetic alignment. However, they do not provide options for adjusting all the necessary variables that influence clinically acceptable alignment.

Studies indicated that in otherwise normal populations, the right and left limbs share many anthropometrical similarities in relation to overall alignment (Dargel, Feiser, Gotter, Pennig, & Koebke, 2009; Nguyen & Shultz, 2009). The sound limb has been employed as a useful reference in developing or implementing therapeutic interventions for unilateral lower limb injuries; these interventions include the reconstruction of the anterior cruciate ligament and total knee arthroplasty (Anderson, Snyder, Federspiel, & Lipscomb, 1992; Moon, Kim, Ahn, & Lee, 2016). There may be similarities and relationships anthropometrical measures in sound and amputated limbs of unilateral transtibial amputees. Incorporating this information into prosthetic alignment systems can facilitate easy, accurate, and rapid prosthetic alignment. A challenge to achieving this goal is the lack of evidence on alignment relationships and similarities between the sound and amputated lower limbs of unilateral transtibial amputees.

The analysis of lower limb axes on the basis of long-leg radiographs is considered a gold standard in assessing lower limb alignment (Brouwer, Jakma, Bierma-Zeinstra, Ginai, & Verhaar, 2003). Such analysis features an accuracy of <1 mm in measurements of mechanical axis deviations of the leg (Mooney et al., 2013). Despite the advantages of this method, this may be impractical and unwarranted for prosthetic alignment. Digital photography is a safe, ethical, reliable and inexpensive alternative for assessing joint angles and postural alignment (Simonsen, Thomsen, Skou, & Andersen, 2013). It has also been shown that palpation of anatomical landmarks by a single trained rater is a reliable method in measuring lower limb joint angles when using digital photographs (Moriguchi et al., 2009).

Correspondingly, the objectives of current research were a) to assess similarities and relationships between anatomical landmark-based angles and distances of lower limbs in unilateral transtibial amputees who were users of clinically acceptable and comfortable prosthesis and then, based on the results to 2) develop a new anatomically based static prosthetic alignment method and evaluation of this method in a single subject study.

Materials and Methods

The study defines a new static prosthetic alignment method which utilizes a laser instrument to guide objective static prosthetic alignment assessment. Two sub-studies were conducted corresponding to each objectives of the study. The study was approved by the ethics committee of University of Social Welfare and Rehabilitation Sciences (reference number: USWR.REC.1393.226). All the participants signed the informed consent form before taking part in the research.

Sub-study I: Assessing Anthropometrical Features of Lower Limbs

The first sub-study assessed the similarities and relationship between anatomical landmark-based anthropometrical parameters of sound and prosthetic limbs in a sample of amputees wearing clinically acceptable aligned and comfortable prosthesis.

Subjects

The inclusion criteria were as follows: unilateral below-knee amputation with no obvious gait deviation, with at least 4 years of prosthetic use; at least 6 months of regular use of current prosthesis; Scores ≥7 out of 10 on the amputees' perceived comfort with prosthetic alignment (assessed using the visual analogue scale (Fu & Duan, 2008)), and socket fit (assessed using the socket comfort score (Hanspal, Fisher, & Nieveen, 2003)); residual limb length >12 cm; use of the patellar tendon-bearing (PTB) socket with silicon liner suspension and dynamic prosthetic foot (1 D 10, Otto Bock®), and a body mass index (BMI) of 18.5 to 30 ("Body mass index - BMI. ," 2017). The exclusion criterion was a history of musculoskeletal complications in the amputated and/or sound lower limbs (e.g., fracture and osteoarthritis). Sample recruitment and data collection were conducted at the Kowthar Orthotics and Prosthetics Center in Tehran, Iran from March 2015 to November 2016. The number of cases available at the center during the study period determined the sample size of study.

Two experienced prosthetists evaluated and confirmed absence of gait deviations in amputees. For this, a "yes/no" checklist was designed on the basis of the transtibial gait deviations indicated by the American Academy of Orthopedic Surgeons (Kapp, 2004). We translated the checklist into Persian, after which an expert panel of prosthetists validated the contents and constructs.

Data Collection

All the patients wore identically designed shoes that comfortably fit their feet. The lower limb anatomical landmarks were palpated and marked (Reichert, 2010) twice with a black 8 mm non-reflective adhesive tape, after which the marks were verified using ultraviolet light. These included the inferior pole of the anterior superior iliac spine (ASIS), the lateral border of the greater trochanter, the center line of the knee joints, and the medial and lateral malleolus of the sound side. The center points of the knees and ankle joints in each plane were also determined and marked using a caliper.

Whole body photographs were then taken while amputees stood in a comfortable position with equal weight placed on both amputated and sound sides; the balance in weight was confirmed by a pair of digital body scales. The location of the digital camera (Canon A560 PowerShot) was kept consistent for all the subjects, and photos were taken in frontal and sagittal views of both limbs (figure. 1). A vertical plump line and a scaling object were also used for each photograph. The foot angle in the horizontal plane was measured by tracing shoe perimeter on both sides. The photography and tracing were repeated after 12 minutes. The entire data collection process was carried out by a well-trained prosthetist.

Data Analysis

The photographs were imported into Photoshop 8 and rescaled to actual size (Moreira, 2008). Two sets of variables—angular and dimensional variables—were measured for each amputee (figure. 2, table 1). To differentiate various directions, changes in the angular and dimensional directions toward the midline were ascribed a negative sign in the frontal and transverse planes; in the sagittal plane, the anterior direction was assumed positive. The intra-class correlation coefficient (ICC) was used to examine the reliability of two data collections variable measurements for entire data set collected at two time points, for both sub studies.

Given that all values showed acceptable reliability (ICC>0.7) (Campbell, Machin, & Walters, 2007), the average of two measurements was calculated and used for further analysis. The Shapiro–Wilk test showed that all the variables followed a normal distribution pattern. A paired sample t-test was conducted to compare the mean values of the sound and amputated limbs. When a p-value less than 0.05 was derived, linear regression analysis was carried out to assess the possible relationship between the variables of the sound limb as independent variable and the corresponding variable of the amputated limb as dependent. The linear regression analysis was also performed between the independent variable of stump length and dependent variables [i.e., sagittal socket angle and shin angle, frontal socket angle and shin angle] of the amputated limb. One sample t-test was carried out to examine the difference between pelvic tilt and zero.

Sub-study II: Anatomical-based Prosthetic Alignment Method

The results of the first sub-study was used to develop and examine an anatomical based alignment method. A laser instrument was developed to facilitate measuring the anthropometrical features of the lower limb for aligning prosthesis components in a clinical environment as subjects assume standing position. The objective anatomical based prosthetic alignment, was evaluated in single subject design study.

Laser instrument

The laser instrument consists of 13 laser line projection units with similar electronic structures. Twelve laser line units are mounted on the base plate, comprising of front, right and left components; located in frontal and sagittal planes (figure. 3 a). Each component is equipped with three rails, each containing a laser line unit. Two of the rails contain vertical laser line units with one ruler at the side, with an index attached above each rail (figure. 3, b and c). The indexes of two parallel rails have similar locations. The difference in location of rulers with respect to the indexes indicates the horizontal distance of two parallel vertical laser lines. The third rail contains an angular laser line unit with two extra parts, namely, a scaled plate and a pointer connected to a laser beam. A prosthetist can change the angle of line projection using the pointer which shows angular difference from 90° with respect to the scaled plate. The vertical and angular laser line units are precise up to 1 mm and 1°, respectively. The thirteenth laser line unit is set to the horizontal direction and mounted on a tripod which provided height adjustment for the horizontal laser line unit. Each laser line projection was calibrated using a DeWalt® instrument.

The instrument also included two digital body scales with a frequency of 50 Hz and a precision of 50 g for real time monitoring of weight bearing on each limb. The electronic output of each scale was connected to an hx711 module and an Arduino module; a USB port connected to a computer. The program run on MATLAB displayed the weight on each digital body scale. Two coordinate pages were symmetrically glued onto the digital body scales which enabled the prosthetist to compare the shoe coordinates of lower limbs when an amputee stood on the digital body scales.

The New Prosthetic Alignment Process

The proposed alignment method involved two stages, namely, bench alignment and static alignment. The bench alignment was based on the principles put forward by Fleer and Wilson (Fleer & Wilson, 1962). Following the bench alignment, amputee wore the prosthesis and pose an upright posture, on the scales to ensure equal weight bearing on both legs. The prosthetist then measured the target variables using the laser instrument and asked the amputee to sit to be able to implemented possible adjustments to prosthetic alignment. This procedure was repeated for each individual variables of interest important for acceptable prosthetic alignment. Two vertical laser line projection units were implemented to measure horizontal distances of selected anatomical landmarks at each side. A vertical laser line projection unit besides of an angular laser line projection unit were implemented to measure each angular variable.

First, prosthetic height was checked and adjusted using the horizontal level of ASIS processes perceived by the horizontal laser line. Then, the prosthesis was aligned in the frontal plane. The socket mediolateral tilt was adjusted by equalizing the frontal socket angle with the frontal shin angle of the sound limb (figure 2). The foot mediolateral tilt and shift were then tunned; obtained by equalizing the frontal shin angle of the amputated and sound limbs and the horizontal distance from ASIS to the center of the prosthetic foot bolt with corresponding variable of sound limb in the frontal plane. These steps were repeated for the sagittal prosthetic alignment. Socket anteroposterior tilt was calculated using the magnitude of the sagittal shin angle of the sound limb multiplied by 0.57 (derived from sub study I). The foot anteroposterior tilt and shift were obtained by equalizing the sagittal shin angle of the lower limbs and adjusting the horizontal distance from ASIS to the foot bolt; the horizontal distance from ASIS to the foot bolt in the sagittal plane should be equal to the cross product of the sagittal ASIS to the lateral malleolus horizontal distance, and 0.57. Finally, toe in/out angle of prosthetic foot was adjusted using the prosthetist's trace of the shoe perimeter on coordinate pages.

Study design

The second substudy was of an A-B-B-A single-subject study design. One 54 years old male veteran, spent 29 years as a traumatic unilateral transtibial amputee participated in the second substudy. He was 167 cm high, with 74 kg of body weight, and the length of 15 cm. In the first round of data collection (A1), the amputee used his own prosthesis which was aligned by an experienced prosthetist six months prior to the study data collection time using conventional subjective method. The prosthesis was then disassembled and an inexperienced prosthetist reassembled and aligned it using the new prosthetic alignment method described before. After 15 minutes of prosthesis use, data were again collected (B11). The amputee was asked to use the prosthesis for two weeks and come back to the laboratory. After data collection (B12), the prosthesis was disassembled, after which the B1 phase was repeated. The B21 and B22 phases are the same as the B11 and B12 phases, respectively. After B22, the prosthesis was disassembled and reassembled by the experienced prosthetist. After 15 minutes of prosthesis use, data were collected (A2).

Data collection

In addition to the variables measured in the whole body photography, the 3- meter Timed Up and Go (TUG) test was also measured for this sub-study (Schoppen et al., 1999). The TUG test was carried out twice to verify reliability.

Results

To determine eligibility at first substudy, we assessed 50 veteran amputees, of which 31 did not satisfy the inclusion criteria. These individuals were excluded for the following reasons: orthopedic problems in the sound or amputated limb (e.g., knee osteoarthritis or knee laxity) (n=14), residual limb shorter than 12 cm or longer than 2/3 of contralateral shin length (n=12), surgical removal of ASIS (n=1); soft tissue problems in the residual limb (n=3), and improper socket fit (n=1). Data from the 19 male veterans who underwent traumatic unilateral transtibial amputation were used for the analysis. The patients' demographic information is summarized in table 2.

(A) Assessing Anthropometrical Features of Lower Limbs

The descriptive data and statistical results are presented in table 3. In the frontal and transverse plane, no significant difference in the angular and dimensional variables was found between the two limbs ($p>0.05$). The pelvis showed a significant tilt of 0.89±1.55 degree toward the amputated limb ($p=0.017$). In sagittal plane, the two limbs exhibited statistically significant differences in sagittal thigh and knee angles, sagittal ASIS to ankle horizontal distance, and knee-to-floor vertical distance. These variables, showed a significant regression relationship ($p<0.05$). The mean difference of socket angle and shin angle of sound limb was not significant in frontal plane; the difference was statistically significant in the sagittal plane. The sagittal socket angle was significantly associated to sagittal shin angle of sound limb ($p<0.05$, figure 4a). The association between the shin angle of the amputated limb and the stump length were significant in both of the frontal and sagittal planes ($p<0.05$, figure. 5b and 5c).

(B) Feasibility of Anatomical-based Prosthetic Alignment Method

The patient's manner of walking was observed and recorded using the checklist designed for the purposes of the study. No gait deviations were reported at any of the phases of the second substudy. The amputee's satisfaction with prosthetic alignment and socket comfort were both 7 initially, increasing after prosthetic alignment using the new method (table 4). The TUG duration fluctuated at various phases of the second substudy, with durations being shorter at the B12, B21, and B22 phases (figure. 4a).

Prosthetic alignment was assessed on the basis of eight objective variables, which all fluctuated at various phases of the second substudy (figure. 4). The highest pelvic tilt value was related to the A1 phase (2.5°), and the least was associated with the B21 phase (–0.15°) (figure. 4 b). It was assumed that in the frontal plane, socket angle should be similar to the shin angle of the sound limb; In the second substudy, the differences of the two variables were less than 7.5°. The frontal ASIS-to-ankle horizontal distance of lower limbs assumed to be similar; the differences in frontal-ASIS-to-ankle horizontal distance of the sound and amputated limbs were less than 3 cm (table 4). The sagittal socket angle and the sagittal ASIS to the center point of foot bolt in the horizontal distance were adjusted to follow the assessed regression relationship between the same variables in the first substudy. The differences in the sagittal socket angle and sagittal shin angle of sound limb were less than 5° after prosthetic alignment via the newly developed method. The differences in the sagittal ASIS to the lateral malleolus and correspondent variable of amputated limb were less than 5 cm at various phases of the second substudy.

The shin angle of lower limbs in frontal and sagittal planes assumed to be similar after prosthetic alignment via the proposed method. The differences in shin angle of the sound and amputated limbs in both sagittal and frontal planes were less than 4° in the second substudy; the B11 phase was an exception for sagittal shin angle.

Discussion

In this study the new prosthetic alignment method was developed on the basis of the anatomically landmark based similarities and relationships between the angular and dimensional parameters of sound and amputated limbs and then, the feasibility of new method was assessed. The new prosthetic alignment method utilizes the novel laser instrument to guide prosthetists to acquire the angular and dimensional measurements of both limbs in all cardinal planes. We propose that this method can provide an objective clinical criterion for the assessment and adjustment of prosthetic alignment.

(A) Assessing Anthropometrical Features of Lower Limbs

To the best of our knowledge, no study has examined the symmetry of lower limb alignment in transtibial amputees on the basis of the anatomical landmarks identified in the sagittal and frontal planes. The assessed repeatability of results suggested the postural pose of the individual may be repeatable. Previous research on healthy subjects measured lower limb alignment by using tools such as goniometers, photographs, and long-leg radiographs revealed significant symmetrical alignment in the left and right limbs (Ferreira, Duarte, Maldonado, Bersanetti, & Marques, 2011; Jabalameli, Moghimi, Yeganeh, & Nojomi, 2015; Nguyen & Shultz, 2009). The findings of the current study showed no statistically significant difference between sound and amputated limbs in terms of the angular and dimensional parameters measured in the frontal plane except for pelvic tilt. The ASIS location was slightly lower on the amputated limb—a result that contrasts with those on healthy subjects (Ferreira et al., 2011). The ASIS-floor vertical distances were not statistically significant between the two limbs. This result led us to conclude that the horizontal levels of the ASIS would be useful in predicting or adjusting prosthesis height and that the other angular and dimensional parameters of the sound limb in the frontal plane would be beneficial in predicting prosthetic alignment variables.

The knee-to-floor vertical distance was significantly greater at the amputated limb. The difference can be ascribed to either the difficulty in locating the knee center over the prosthetic socket wall or the increased knee flexion in the amputated limb. The differences of sagittal angular measurements indicating a more flexed posture in the amputated limb; this aligns with findings of Blumentritt et al. (Blumentritt, 1997). The participants in the current study and those of Blumentritt et al. used the PTB socket design, in which sockets are aligned with a few degrees of the initial anterior tilt (Fleer & Wilson, 1962). Anterior socket tilt is employed for more comfortable loading over the patellar tendon and anterior tibial plateau (i.e., decreased resultant shear force during weight bearing). Prosthetists increase the socket flexion angle, especially in residual limb with shorter length, to improve load bearing. This was further confirmed by the significant negative association of sagittal shin angle in the amputated limb with stump length in the current study. The increased flexion in the amputated limb could be explained by the increase socket flexion in closed-chain body kinematics during standing. However, the regression analysis showed a significant dependence of the values of the amputated limb on the corresponding sound limb values for all mentioned variables. Therefore, sagittal shin angle of sound limb would be beneficial in predicting the prosthetic alignment variable namely socket anteroposterior tilt.

The knee flexion could have also resulted in a more posteriorly located prosthetic foot in relation to the sound foot; this was confirmed by the significant difference in sagittal ASIS to ankle horizontal distance of amputated limb which showed a significant association with the same measurement for the sound limb. This finding and the non-significant difference in sagittal shin angle of two limbs suggests that the sound limb can be used as reference in predicting the shift and tilt of prosthetic foot in the anteroposterior direction. The mean value of transverse foot angle was slightly smaller on the amputated limb than on the sound limb, but the difference was not statistically significant—a finding that aligns with those reported by Beyaert et al. (Beyaert, Grumillier, Martinet, Paysant, & Andre, 2008). Therefore, transverse foot angle could be predicted using the sound limb.

(B) Feasibility of Anatomical-based Prosthetic Alignment Method

The second substudy was aimed at assessing the feasibility of the proposed prosthetic alignment method for one participant. Statistical analysis was inapplicable, highlighting the need to interpret the results with caution. The subjective verification of an experienced prosthetist regarding lack of gait deviation, along with subjective feedback of an active and experienced prosthetic user is the clinical gold standard for acceptable alignment assessment (D. A. Boone et al., 2012; Fiedler & Johnson, 2017). The results of proposed method revealed no report of gait deviation and the quality of prosthetic alignment was evaluated highly favorably by the patient. The TUG duration was slightly shorter when the amputee used a prosthesis aligned using the new method which reveals a patient's function and balance improvement (Berg, Maki, Williams, Holliday, & Wood-Dauphinee, 1992). Therefore, the amputee's functioning was the same as his previous condition or even better.

The pelvic tilt was assumed to be about 1° or less. The observed value of pelvic tilt was 2.5° toward the amputated limb at A1 phase, the value decreased after the use of the prosthesis aligned using the new method. Although the transverse foot angle was assumed to be equal in the sound and amputated limbs, some differences toward external foot rotation was observed. Transtibial amputees are more sensitive to internal rotation and can accept a wide range of external rotation of prosthetic feet (Beyaert et al., 2008; Fridman, Ona, & Isakov, 2003). Therefore, that variations in transverse foot angle seems to be acceptable.

The socket angle assumed to be equal to shin angle of sound limb in the frontal plane and be associated with same parameter in the sagittal plane; same assumptions were also used for ASIS-to-ankle horizontal distances. Although, some differences were observed between the two values, the range of differences when prosthesis aligned via the newly proposed method and the values of these variables under prosthetic alignment via the subjective method were similar. The value of the sagittal socket angle somewhat increased in the second substudy. The maximum difference in the variable was 6.8° which seems to be acceptable for transtibial amputees x. The differences of ASIS-to-ankle horizontal distance falling within the confidence interval obtained in the first substudy for both of sagittal and frontal planes. The shin angle was assumed to be equal in both of frontal and sagittal planes and the differences of sound and amputated limbs were less than 4° at both planes. Therefore, the sound limb seems to be an acceptable predictor for prosthetic alignment assessment.

Although the results of this study indicate the possibility of using the contralateral limb to predict the prosthetic limb alignment parameters, future sufficiently powered studies are needed to develop and examine the validity and reliability of the new alignment method. There could have been some issues with regard to palpation repeatability and tissue movement compensations. The assessor checked the palpation protocol in a pilot study of three healthy participants. The repeatability was acceptable (ICC > 0.7). One assessor did the data collection of all participants to improve reliability All the participants used the PTB socket design; future research should replicate the method proposed in the current work on participants who use other transtibial prosthetic socket designs. For example, sockets based on hydrostatic weight bearing principle do not rely on patellar tendon weight bearing and may not require establishing increased initial socket flexion. These configurations would not cause increased hip and knee flexion, thereby improving bilateral symmetry in alignment.

Conclusions

We conclude that the new prosthetic alignment on the basis of anthropometrical features of lower limbs of unilateral transtibial amputees is a feasible method. Our findings could lay a foundation for development of future prosthetic alignment systems. More investigations on validity and repeatability of the new method and amputees who use transtibial socket designs other than PTB are suggested.

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Table 1. Definitions for study variables.

	Variable Name	Variable Description
Frontal Plane	Frontal ASIS to -ankle horizontal distance	Horizontal distance from ASIS to the centre of ankle in frontal plane
	Frontal Knee Angle	ASIS-knee- ankle angle in frontal plane
	Frontal Shin Angle	Angle between the line connecting the centre of knee to, to the centre of ankle and vertical plumb line
	Frontal Socket Angle	Angle between the line connecting the centre of patellar shelf to the centre of distal connection of socket to pylon at same plane in frontal plane and vertical plumb line
	Frontal Thigh Angle	Angle between the line connecting ASIS to the centre of knee and plumb line
	Pelvic tilt	The angle between the line connecting right and left ASIS and horizontal line measured in frontal plane
Transverse plane	Transverse Foot Angle	The angle between longitudinal bisecting line of shoe tracing and progression line
Sagittal Plane	ASIS to Floor vertical distance	Vertical distance between the ASIS landmark and the floor in sagittal plane
	Sagittal knee Angle	Greater trochanter- knee centre-lateral malleolus angle in sagittal plane
	Knee to Floor Vertical Distance	The vertical distance from the knee centre to the floor
	Sagittal ASIS to ankle horizontal Distance	Horizontal distance from ASIS to the centre of ankle /lateral malleolus in sagittal plane
	Sagittal Shin Angle	Angle between the line connecting the centre of knee to lateral malleolus and vertical plumb line
	Sagittal Socket Angle	Angle between the line drawing at the centre of socket, connecting the centre of the socket at patellar shelf level to the centre of distal connection of socket to pylon and vertical plumb line in sagittal plane

Note: The centre of ankle at amputated side was assumed as the connection centre point of pylon and prosthetic foot connection point

Table 2. Demographic information of participants.

Variable	Minimum	Mean (SD)	Maximum
Age (years)	22	49.58 (8.28)	59
Height (cm)	160	170.5 (7.14)	189
Mass (kg)	60	76.50 (11.04)	93
Stump Length (cm)	13	18.58 (4.29)	27.91
Scores for perceived comfort with prosthetic alignment	7	8.34 (2.05)	10
Scores for socket comfort	7	8.26 (1.37)	10

Table 3. Results of paired t-test and regression analysis for sound and amputated limbs.

	Mean (SD)		Paired t-test		Regression				
	Sound Side	**Amputated Side**	**CI for differences[1]**	**p-value**	**R**	**p-value**	**Constant**	**p-value**	**R^2**
Frontal ASIS to ankle horizontal distance	3.05 (3.29)	2.06 (4.09)	-1.74 to 2.58	0.287					
Frontal knee angle	179.42 (4.19)	177.62 (3.31)	-0.30 to 3.91	0.088					
Frontal shin angle	-1.30 (2.34)	0.16 (2.95)	-2.98 to 0.07	0.084					
Frontal thigh angle	1.99 (3.75)	2.22 (3.58)	-1.73 to 1.26	0.743					
ASIS to floor vertical distance	95.06 (4.92)	94.47 (5.25)	-0.41 to 1.59	0.230					
knee to floor vertical distance	48.87 (2.91)	50.52 (3.48)	-2.40 to -0.90	**<0.001**	1.07	**<0.001**	-1.93	0.763	0.90
Sagittal knee angle	170.45 (5.72)	166.87 (5.81)	0.78 to 6.36	**0.015**	0.51	**0.030**	80.67	**0.041**	0.50
Sagittal thigh angle	1.63 (4.44)	6.50 (3.43)	4.80 to 11.69	**<0.001**	0.44	**0.009**	5.78	**<0.001**	0.58
Sagittal shin angle	7.90 (2.56)	6.46 (3.36)	-2.74 to 0.49	0.189					
Sagittal ASIS to ankle horizontal distance	-15.82 (3.06)	-11.44 (3.23)	-5.52 to -2.39	**<0.001**	0.57	**0.049**	2.77	0.517	0.22
Transverse foot angle	8.65 (4.91)	6.84 (4.29)	0.03 to 4.92	0.092					

1- The values of amputated limb are subtracted from the values of sound limb

Table 4. Values of prosthetic alignment related parameters at second sub study

	A1		B11		B12		B21		B22		A2	
	Sound Side	Amputated Side	Sound Side	Amputated Side	Sound Side	Amputated Side	Sound Side	Amputated Side	Sound Side	Amputated Side	Sound Side	Amputated Side
Frontal shin angle	-2.70	-4.35	0	-1.85	-4.25	-5.40	-4.95	-4.40	-6.55	-6.15	-5.45	-7.15
Frontal socket angle		-9.45		-7.25		-9.32		-8.30		-10.7		-10.50
Frontal ASIS to ankle horizontal distance	-1.81	-2.37	-0.91	-3.12	-1.90	-4.68	-2.52	-3.54	-3.71	-4.06	-2.89	-4.70
Sagittal shin angle	-10.80	-7.45	-10.75	-4.70	-11.40	-11.10	-11.30	-11.25	-11.85	-10.60	-11.25	-10.10
Sagittal socket angle		-6.35		-6.80		-12.10		-10.75		-13.15		-10.04
Sagittal ASIS to ankle horizontal distance	14.52	9.69	13.30	8.57	8.31	11.77	10.20	11.61	10.46	12.41	13.59	13.30
Transverse foot angle	13.5	9.5	26.5	18.5	24	21.25	16	19	22	13	23.5	9.5

* The unit of angular parameters was in degree and the unit of distance parameters was in centimetre.

Table 4. Values of subjective outcomes in the second substudy

	A1	B11	B12	B21	B22	A2
Scores for perceived comfort with prosthetic alignment	7	8	10	10	10	10
Scores for socket comfort	7	10	10	10	10	10

Figure 1. Location of anatomical landmarks in frontal view and two sagittal views

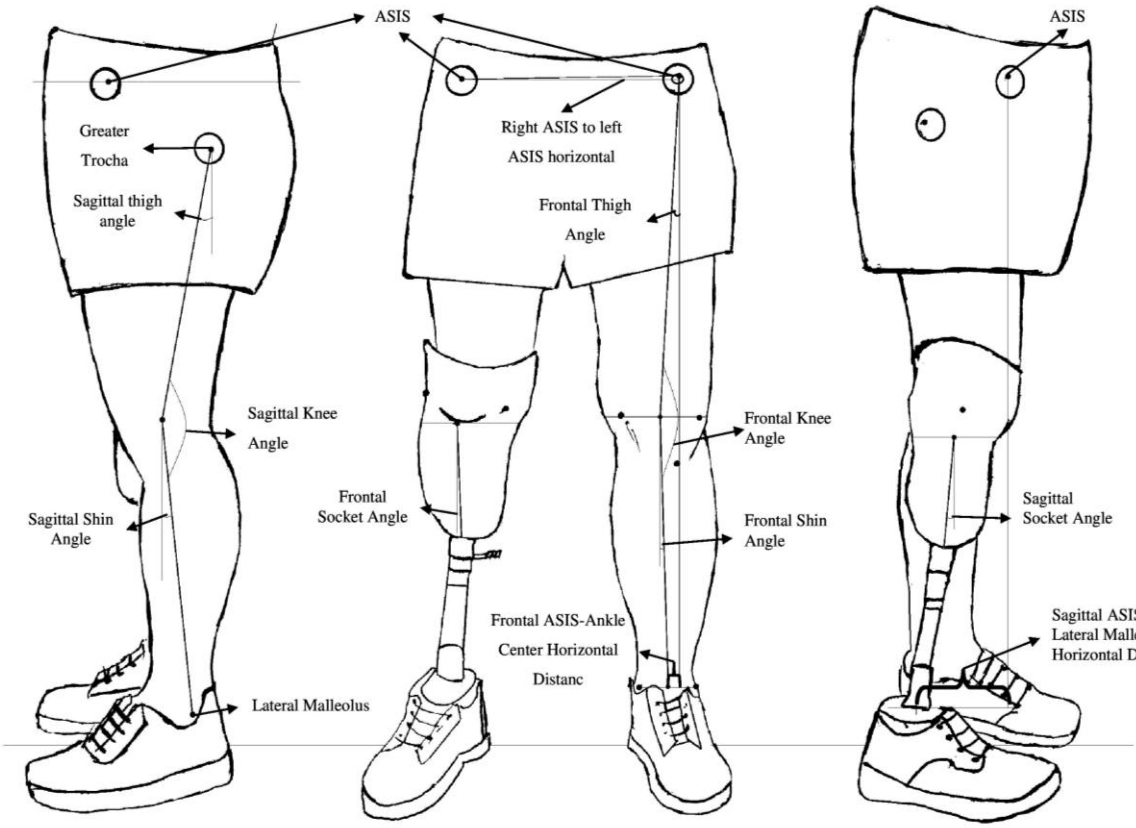

Figure 2. Schematic view of anatomical landmarks and resultant angular and dimensional variables.

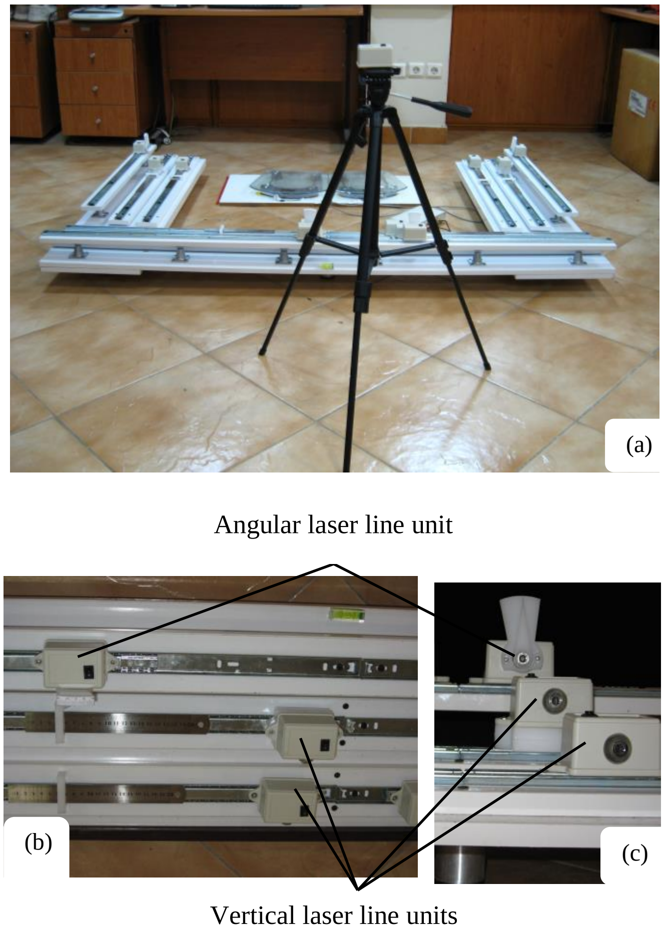

Figure 3. a) laser instrument, b and c) the above and front views of three rails at each part of base plate

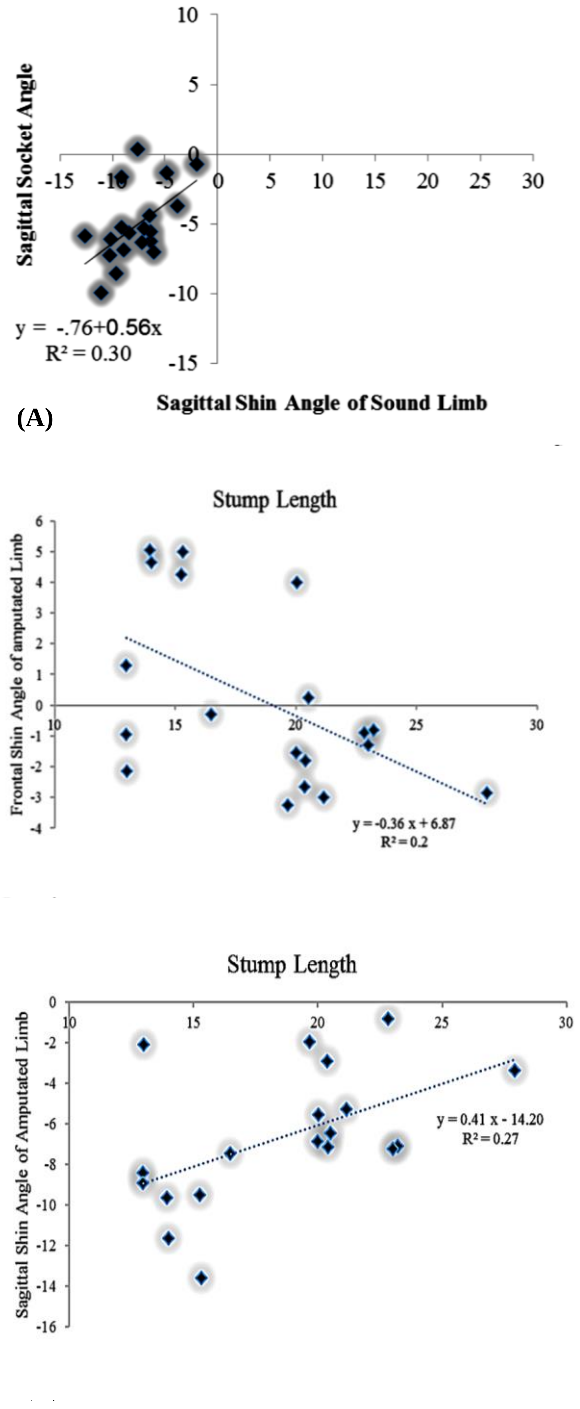

Figure 4. (A) Regression diagram of sagittal shin angle of sound limb (independent variable) and Sagittal socket angle (dependent variable). (B and C) Regression diagrams of stump length (independent variable) and frontal shin angle (B) and sagittal shin angle (C) (dependent variables) of amputated limb.

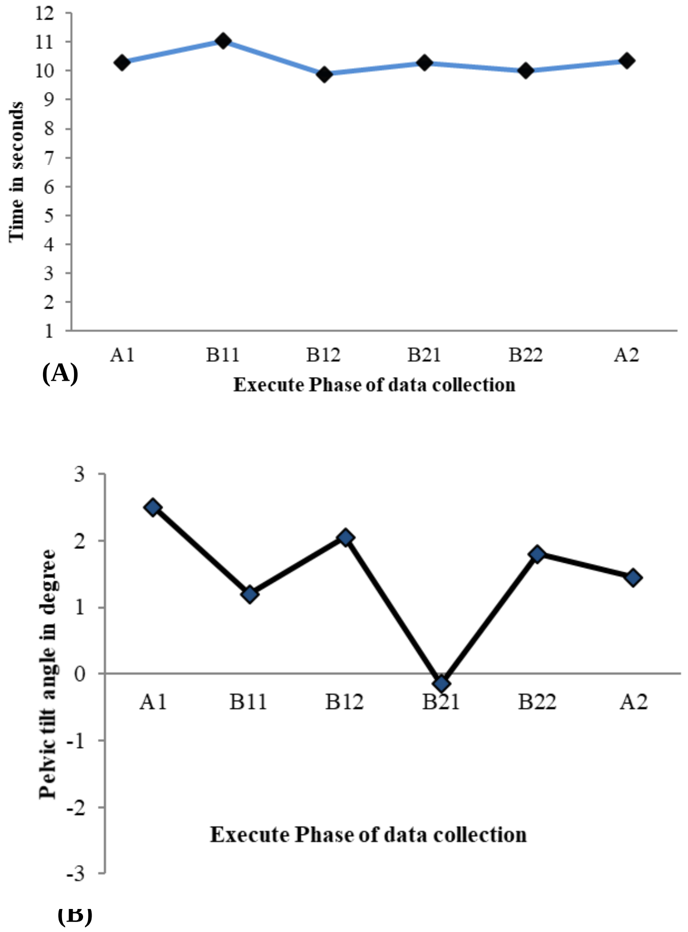

Figure 5. (a) TUG duration and (b) Pelvic tilt at each phase of the second sub study