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Dynamic Lower-Limb Alignment Focusing on Gait Stability

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Abstract

Introduction: Prosthetic limbs must be developed with proper alignment to facilitate safe and efficient gait patterns. This study aimed to identify factors impacting clinically proper gait patterns by objectively evaluating them in persons with lower-limb amputations who use prosthetic limbs. **Materials and Methods:** This non-experimental descriptive study assessed 58 persons with amputation who used prosthetic limbs. The mechanical axis angle (MAA) of the lower limb during the heel contact, midstance, and toe-off phases and the angle between the tube and floor during the midstance phase were measured using coronal plane gait images. We also investigated whether the MAA and tube angle during the midstance phase have a multimodal distribution. In case of multimodal distributions, we tested for significant between-group differences in patient characteristics. **Results**: The MAA and tube angle in the coronal plane during the midstance phase had a bimodal distribution (mean 0˚). There was a significant difference in the duration of prosthetic limb use between the MAA < 0˚ and ≥0˚ groups during the midstance phase. Deviations in the lower limb MAA between the heel contact and midstance phases were 3.3˚ ± 2.2˚ and 3.1˚ ± 2.3˚ for persons with lower limb amputations in the MAA < 0˚ and ≥0˚ groups, respectively. **Conclusions**: In this study, prosthetic alignment during the midstance phase had a bimodal distribution. In both groups, deviations in the lower limb MAA were aligned to be approximately 3˚.

Keywords

Prosthetic Limbs, Alignment, Gait, Below-the-Knee Amputation

1. Introduction

Prosthetic limbs are important devices that help patients with below-the-knee amputation retain walking ability. Below-the-knee amputations are often performed secondary to injury (e.g., those sustained in traffic accidents), peripheral circulatory failure due to diseases such as diabetes, renal failure, and infection [1] [2]. According to one estimate, 250 - 500 individuals per million undergo amputation each year in western countries [3]. With a recent increase in the prevalence of diabetes, the number of persons with amputation using prosthetic limbs has increased significantly.

Persons with amputation who use prosthetic limbs have various gait patterns. Therefore, safe and efficient gait requires the development of well-aligned (nominally aligned) prosthetic limbs. Nemoto *et al.* reported that factors affecting normal gait included foot placement during the heel contact phase (HC) and tube perpendicular to the floor with no tilt of the trunk and socket during the midstance phase (MS) [4]. Some studies evaluated the effects of prosthetic alignment tuned to a nominally aligned condition (e.g., adduction, abduction, plantar flexion, and dorsiflexion) on walking speed, step length [5] [6] [7], and joint angle of lower limbs [5] [6] [8], in an attempt to define prosthetic limbs in the nominally aligned condition. In addition, it has been reported that alignment affects moments in the sagittal and coronal planes during gait [9] [10] [11] [12]. However, it remains unclear what the ideal alignment of a prosthetic limb should be in a clinically relevant setting.

It is important to note that an ideal coronal plane alignment has previously been established. However, no study has evaluated a clinically relevant and nominally aligned condition and gait. In a study by Zahedi *et al.*, alignment adjustment and evaluation of the acceptable range of static alignment in ten persons with amputation were performed by three prosthetists. Their findings showed differences in the adjustment of the alignment set by multiple prosthetists (*i.e.*, the adjustment range of the socket in the anteroposterior direction [16 mm per amputee] and the mediolateral direction [43 mm per amputee] among the prosthetists) [13]. However, these studies evaluated static alignment. To the best of our knowledge, no study has evaluated nominally aligned condition in dynamic alignment.

This suggests that the conventional determination of prosthetic limbs in the nominally aligned condition has been made based on the experience of prosthetists, the experience and subjective judgment of health care professionals (orthopedic surgeons, rehabilitation physicians, physical therapists), and subjective feelings of patients. The main reasons that the development of prosthetic limbs has been based on subjective information are the fact that most prosthetists have encountered many persons with amputation and because healthcare professionals, including prosthetists, are unable to collect actionable data due to low number of patients in any given hospital. The fact that the sample size of the largest study to be performed on this issue is 17, illustrates our point. Such a small sample size is insufficient for optimal clinical evaluation and may lack sufficient power to be conclusive.

Our facility produces most braces (prosthetic limbs and braces) used in Kyoto and is involved in the development and adjustment of prosthetic limbs for approximately 40 persons with amputation per year. We attempt to achieve ideal alignment of the prosthetic limbs using the method described by Nemoto *et al.* [4]. However, many persons with amputation reported that prosthetic limbs with a familiar prosthesis alignment are easier to use than those that were adjusted to ensure an ideal alignment. In fact, according to the experience of multiple prosthetists specializing in the development of prosthetic limbs, the number of patients with an "ideal" alignment is low.

We hypothesized the presence of multiple patterns of dynamic alignments in the coronal plane during gait in persons with amputation with prosthetic limbs. Given that most prosthetics are designed based on subjective evaluation of the prosthetists, the objective of this study was to identify factors affecting clinically proper gait patterns through objective evaluation of gait patterns in persons with amputation using prosthetic limbs.

2. Materials and Methods

Persons with amputation who were able to walk, for whom prosthetic limbs were developed in our hospital between April 2019 and January 2022, were included in this study. The main inclusion criterion was the presence of prosthetic limbs that met and were aligned to the subjective needs of persons with amputation. Proper alignment was defined as that without a whipping motion.[2] Another inclusion criteria was no adduction or abduction of the foot during HC and no trunk tilt during MS as deemed by physicians, therapists, and prosthetists. Persons with amputation with previous prosthetic limbs or walking aids, such as a cane, were excluded from this study.

Prior to this study, a power analysis for moderate effect size ($|d| > 0.15$) was performed to obtain a power of 80% and α of 0.05. The target sample size for univariate analysis was set at 55 persons with amputation. It was expected that approximately 10% of the subjects would have measurement errors due to significant external rotation of the hip joint during gait (e.g., due to a severely limited range of motion in the hip, knee, and ankle joints) and that these subjects should be excluded from the study. Therefore, the target sample size for this study was set as 60 persons with amputation. The study was approved by Ethics Committee of our hospital (approval number: RBMR 201903). The subjects were provided with a sufficient explanation of the study and written informed consent was obtained prior to performing the study procedures.

Patient information, such as age, sex, the age of amputation, the cause of amputation, prosthetic limb types, and the duration of use of prosthetic limbs was obtained.

We used the mechanical axis angle (MAA) of the lower limb as an indicator of dynamic lower limb alignment [14]. We marked the upper end of the prosthetic limbs and the lower end of the tube. MAA was defined as the angle between the line connecting the center of the maximum lateral diameter of the femur distal and the center of the tube and a line perpendicular to the floor (**Figure 1**).[14] A video camera (frame rate: 30 fps) was fixed at a height of 30 cm from the floor to record the gait of persons with amputation. Video analysis software (Dartfish) was used to measure MAA during HC, MS, and the toe-off phase (TO). In addition, the difference between MAA during HC and MAA during MS was calculated. A negative value (−) represented a lateral tilt, whereas a positive value (+) represented a medial tilt.

In addition, we measured the angle between the floor and the tube (the tube angle) during MS which is an ideal predictor of alignment. Persons with amputation with incorrect measurements due to a short shell structure or a tube were excluded from the study. The Timed Up and Go test (TUG) and grip strength were used as predictors of balance ability and muscle strength.

MAA and patient information are presented in mean ± standard deviation. First, MAA during MS was tested for significant correlation with the tube angle. Next, kernel density estimation was performed after bandwidth selection using MAA during MS and the Sturges' rule to evaluate the presence or absence of multiple gait patterns [15]. In the case of a multimodal distribution, Student's t-test was used to evaluate the characteristics of each group. A simple linear regression analysis was used to evaluate the relationship between MAA during HC and MAA during MS for each group. Furthermore, each group was tested for significant correlation between several other factors. Based on previous studies, the following criteria were used in the simple linear regression analysis: $0 \leq R2 < 0.16$ (non-significant correlation), $0.16 \leq R2 < 0.49$ (a weak to moderate correlation), and $0.49 \leq R2$ (a strong correlation). Fisher's exact test was used to examine sex differences and the presence or absence of diabetes. Student t-test was used to identify other factors. $p < 0.05$ was considered statistically significant.

The mechanical axis angle (MAA) of the lower limb was defined as the angle between the line between the proximal-medial part and the medial part of the prosthetic limb and the line perpendicular to the floor.

3. Results

Of the 60 persons with amputation, 58 (43 men and 15 women) with a mean age of 65.7 years (range, 28 to 91 years) were included in the current analyses. Two persons were excluded from the analysis due to severe external hip joint rotation resulting in measurement errors. Prosthetic limbs were of skeletal (n = 47) and shell (n = 11) structure types. Overall, there were 30 persons with amputation using patellar tendon-bearing (PTB) socket and 28 with amputation using liners. The prosthetic foot types were short axis (n = 14), multi-axial (n = 3), and solid ankle cushion heel (SACH) (n = 39). The causes of amputation were diabetes (n = 18), accidents (n = 24), arteriosclerosis obliterans (n = 9), and other (n = 7).

Figure 1. Mechanical axis angle of the lower limb.

1) MAA and the tube angle during MS

There was a very strong correlation between MAA during MS and the tube angle in 26 persons with amputation who underwent measurement of tube angle (R2 = 0.68; y = 0.798x + 0.497) (**Figure 2**).

2) MAA during MS

MAA during MS had a bimodal distribution with a mean of almost 0˚ (**Figure 3**).

A bimodal distribution can be seen.

3) Characteristics of the two patterns of MAA during MS

The subjects in this study were divided into the following two groups to evaluate patient characteristics and MAA for each phase: group with MAA < 0˚ during MS and group with MAA ≥ 0˚ during MS. The overall deviation in MAA during HC and MS was 3.3˚ ± 1.7˚ (group with MAA < 0˚, 3.3˚ ± 2.2˚; group with MAA ≥ 0˚, 3.1˚ ± 2.3˚).

The duration of use of prosthetic limbs was longer in the group with MAA < 0˚ compared to MAA ≥ 0˚ (25.0 years vs. 10.4 years). We also observed significant differences in MAA during HC and MAA during TO. Furthermore, there was a significant difference in MAA (tube) during MS between the two groups (MAA (tube) < 0˚, −3.0; MAA (tube) ≥ 0˚, 2.1˚) (**Table 1**). We did not observe any significant correlations between other factors.

A simple linear regression analysis of MAA during HC and MS showed a strong correlation between MAA during HC and that during MS in the group with MAA < 0˚ during MS (R2 = 0.6294; y = 0.762x − 3.397). There was a weak to moderate correlation between MAA during HC and that during MS in the group with MAA (tube) ≥ 0˚ during MS (R2 = 0.243; y = 0.269x + 0.855) (**Figure 4**). We did not observe any significant correlations between other factors.

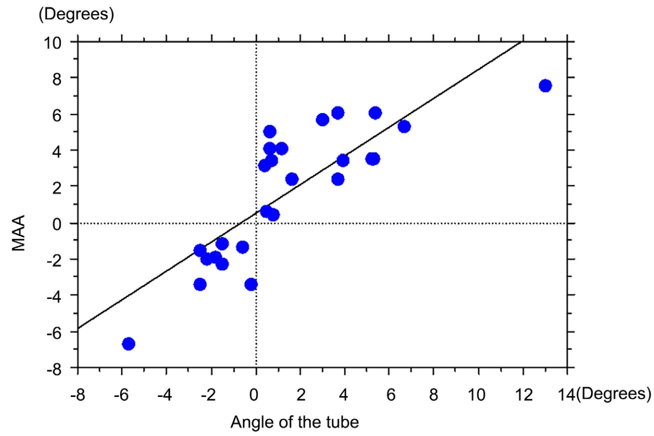

Figure 2. Relationship between the tube angle and mechanical axis angle during midstance phase.

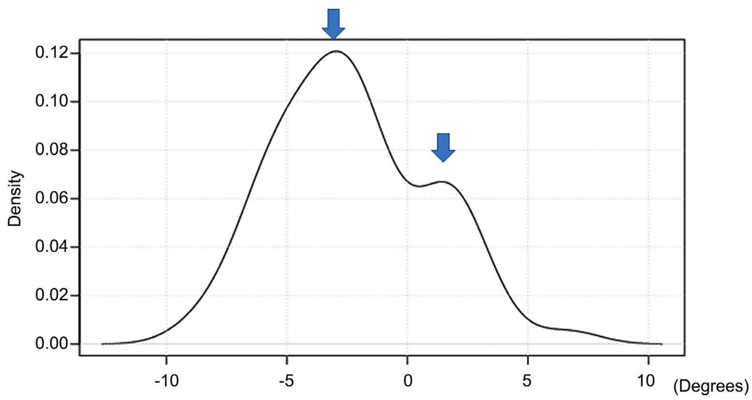

Figure 3. Mechanical axis angle during midstance phase.

Table 1. Comparisons of the groups with mechanical axis angle (MAA) of <0˚ and ≥0˚ during midstance (MS) phase.

	Total	MMA MS < 0	MMA MS ≧ 0	*p* value
Age (years)	65.7 ± 14.9	66.4 ± 15.6	63.5 ± 12.5	0.5351
Sex (male/female)	43/15	31/13	12/2	0.2206
Duration of use of prosthetic limbs (years)	21.5 ± 20.3	25.0 ± 20.4	10.4 ± 15.6	0.0170
Age of amputation (years)	44.2 ± 23.2	41.3 ± 23.3	53.1 ± 21.3	0.0973
Diabetes (presence or absence)	18/40	14/30	4/10	0.5496
Time of one-leg standing on the unaffected side (s)	15.4 ± 12.4	15.0 ± 12.4	16.8 ± 13.0	0.6755
Time of one-leg standing on the unaffected side (s)	2.0 ± 1.5	1.9 ± 1.0	2.2 ± 2.5	0.6068
TUG (s)	12.0 ± 3.4	11.7 ± 3.5	12.9 ± 3.3	0.3298
Grip strength (kg)	33.6 ± 10.6	33.3 ± 10.8	34.7 ± 10.4	0.7199
MAA				
HC (degrees)	1.0 ± 3.3	−0.4 ± 2.0	5.4 ± 2.7	<0.0001
MS (degrees)	−2.3 ± 3.2	−3.7 ± 2.1	2.3 ± 1.5	<0.0001
TO (degrees)	−1.2 ± 3.3	−2.5 ± 2.5	2.8 ± 2.2	<0.0001
Deviations (degrees)	3.3 ± 1.7	3.3 ± 2.2	3.1 ± 2.3	0.7354
Angle of the tube				
MS (degrees)	−1.3 ± 3.8	−3.0 ± 3.4	2.1 ± 1.6	0.0003

HC: heel contact phase, TO: toe-off phase, TUG: timed up and go test.

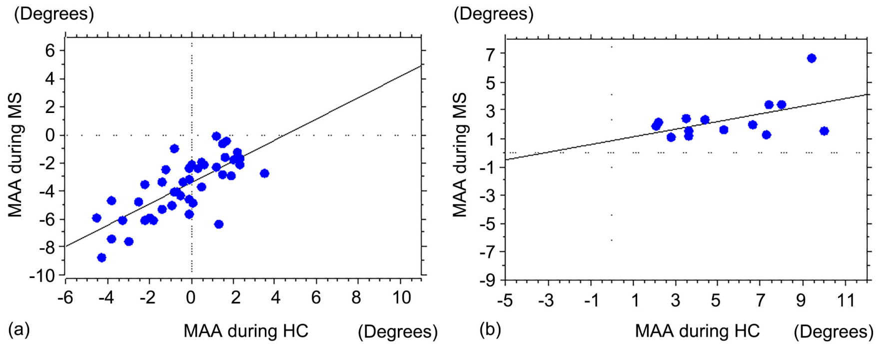

Figure 4. Relationship between mechanical axis angle (MAA) during heel contact and that during midstance (MS) phases. (a) Group with MAA of <0˚ during MS; (b) Group with MAA of ≥0˚ during MS.

4. Discussion

In this study, we used MAA as a predictor of dynamic alignment. Higher amounts of change in MAA have been shown to affect lateral sway. To compensate for such high amounts of change in MAA, studies have shown that patients employ reduced walking speed, reduced step length and increased trunk tilt. Therefore, MAA can be used as a predictor of gait stability [16] [17]. In a study by Tokuda *et al.*, changes in MAA between HC and MS were 2.7˚ and 3.9˚ in healthy individuals and patients with Kellgren-Lawrence grade 1 and 2, respectively [14]. In addition, regarding the ideal dynamic lower-limb prosthetic alignment, it has been reported that the lateral movement of the knee during MS is desirable if it is approximately 1 cm (approximately 1.4˚ in MAA deviations). However, if it is ≥2 cm (approximately 2.8˚ in MAA deviations), loosening of the socket should be considered [18]. In this study, deviations in lower limb MAA between HC and MS was 3.3˚ for persons with amputation with MAA during MS < 0, and 3.1˚ in persons with amputation with MAA during MS ≥ 0˚. In both groups, coronal plane instability in persons with amputation with prosthetic limbs was higher than that in healthy individuals and lower than that in mild patients with knee osteoarthritis. This may be caused by the compensatory increase in MAA due to significantly reduced varus and valgus angulation of the ankle joint because the gravity line needs to be shifted to the base of support during MS. In persons with amputation without problems with the fit of prosthetic limbs (e.g., those with no loosening of the socket), lateral knee deviations during the stance phase may be acceptable even in the case of large changes in MAA (up to 3.3˚).

The shank axis being perpendicular to the floor during the heel contact phase has been reported to be ideal for prosthetic gait in the coronal plane. In addition, an ideal gait is considered to be one with less trunk tilt, with no tilt of the socket, and with the tube being perpendicular to the floor. In addition, ideal prosthetic gait during TO has been reported to include vertical lifting of the foot without a whipping motion [4]. However, previous studies did not present objective measurement data. Cases with a short tube of the prosthetic limbs or a short shell structure are likely to lead to measurement errors. Therefore, future studies should further examine gait patterns using MAA as a criterion. In other words, ideal MAA during MS should have a unimodal distribution with a mean of 0˚. However, in this study, MAA during MS had a bimodal distribution with a mean of 0˚. In addition, there was a significant correlation between MAA during HC and that during MS in both groups. Furthermore, in both groups, MAA (tube) during MS did not have a bimodal distribution with a mean of 0˚. In the group with MAA < 0˚ during MS, a lateral tilt was present, whereas in the group with MAA ≥ 0˚, a medial tilt was present.

In persons with amputation with MAA ≥ 0˚ during MS, a medial tilt is observed because they try to increase the base of support to maintain stable heel contact during HC. The presence of a medial tilt can be attributed to difficulty in shifting the gravity line to the base of support during MS. In a simple linear regression analysis of MAA during HC and MS, the x intercept was small (0.269). In 13 of 14 persons with amputation, MAA was within the range of 0˚ - 3.5˚. Therefore, even in the presence of medial tilt, the alignment should be adjusted to fit within the range.

However, persons with amputation with MAA < 0˚ during MS showed multiple patterns of changes in MAA between HC and MS (*i.e.*, medial to lateral tilt, lateral to lateral tilt). This may be due to the difference in muscle strength and balance ability between the two groups. In addition, the center of gravity is transferred to the back of the foot during MS, possibly leading to a lateral tilt. These patterns are also seen in the tube angle. In other words, they suggest that tube is not always perpendicular to the floor, and that medial or lateral tilt remains depending on the gait pattern.

A longer duration of use of prosthetic limbs was found in the group with MAA of <0˚ than in the group with MAA ≥ 0˚ during MS. This indicates that persons with amputation with long-term prosthesis use have more stable gait because the center of gravity is transferred to the back of the foot during MS. The age of amputation was lower in the group with MAA < 0˚ than in the group with MAA ≥ 0˚ during MS; however, the difference was not statistically significant (41.3 years vs. 53.3 years, $p = 0.097$). In persons with amputation with higher age at amputation and shorter duration of use of prosthetic limbs, a medial tilt persists during MS. Therefore, lower limb alignment may need to be focused on gait stability even without a sufficient shift in the gravity line.

This study has some limitations. First, semi-static (two-dimensional) images were used in the study. Gait can be recorded using a three-dimensional motion capture. Therefore, gait can be fully evaluated in three dimensions. Prosthetic limbs can be controlled without resulting in a whipping motion during alignment adjustment, preventing errors due to skin movement during the operation in which problems with motion capturing can arise. Therefore, a method using semi-static (two-dimensional) images may be useful for prosthetic measurements. However, future studies should include an analysis using a three-dimensional motion capture system to evaluate the present findings.

Second, the patients in this study were those in the chronic phase with more than one year use of prosthetic limbs. Prosthetic alignment may change in persons with amputation in the recovery period within one year after amputation. Therefore, future studies warrant longer term examination of the effects of rehabilitation intervention on the dynamics of prosthetic alignment.

5. Conclusion

This study objectively evaluated the dynamic alignment of prosthetic limbs to identify factors affecting alignment during gait, using MAA instead of conventional clinically appropriate subjective measures. MAA during MS had a bimodal distribution with a mean of 0˚. There was a significant difference in the duration of use of prosthetic limbs between the group with MAA < 0˚ and the group with MAA ≥ 0˚ during MS. In both groups, there was a significant correlation between MAA during HC and that during MS.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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