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Significance of non-level walking on transtibial prosthesis fitting with particular reference to the effects of anterior-posterior alignment

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Abstract—Despite the fact that non-level walking is known to be important for prosthesis fitting, its clinical significance has not been investigated. In this study, the acceptable prosthesis alignment ranges of six subjects with transtibial amputation on level and non-level walking were determined and compared. With the aid of a recently developed alignment jig, prosthesis fitting was performed for each subject with varied anterior-posterior (AP) alignments. Conventional assessments and the subjects' comment were used to determine whether the alignment was acceptable or not. The results showed that the acceptable alignment range for non-level walking consistently fell within and was significantly smaller than that for level walking with $p<0.05$. It was evident that non-level walking is important for better approximation of optimum alignment and should be included in routine prosthesis fitting.

Key words: *non-level walking, prosthesis alignment, prosthesis fitting, transtibial amputation.*

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INTRODUCTION

Socket design and fit is the most important parameter when determining the success of a lower-limb prosthesis fitting (1). However, correct prosthesis alignment has a significant impact on the walking ability of people with amputation. Improper prosthesis alignment will result in undue stress on the residual limb. Clinically, alignment is obtained by a dynamic alignment procedure using subjective assessments including the subject's feedback on the comfort of the prosthesis and the gait pattern observed by the prosthetist. It was demonstrated that the definitive alignment achieved for a person with transtibial amputation using these subjective assessments was never unique, and fell in a large range (2). Thus, the definitive alignment achieved might be functionally acceptable, but presents the possible risk of inducing undue stress on the residual limb. It is expected that this risk will be reduced if the optimum alignment is better approximated.

In an attempt to better approach the optimum alignment, non-level walking may be considered in the dynamic alignment procedure. Non-level walking is a common and more demanding daily activity in comparison with level walking. We believed that although a person with transtibial amputation can walk smoothly with an acceptable alignment determined during level walking, such alignment might not be adequate for them to cope with non-level walking such as stairs and ramp. In spite of the fact that non-level walking is known to be important for prosthesis fitting, its clinical significance has not been systematically investigated.

In current clinical practice, it is difficult to reproduce prosthesis alignment at will during daily prosthesis fitting. Recently, a simple mechanical jig was designed and developed by the authors (3) to facilitate quantification and prescription of prosthesis alignment for patellar-tendon-bearing (PTB) transtibial prostheses. The alignment jig provided instantaneous readings of the three-dimensional orientation and position of the socket relative to the prosthetic foot in standardized units. The inter- and intratester errors of the alignment jig in measuring prosthesis alignment were evaluated and demonstrated to have good reliability (3). With the aid of the alignment jig, the effects of non-level walking on alignment during prosthesis fitting were systematically evaluated in this study. The acceptable alignment ranges for people with transtibial amputation during level and non-level walking were determined and compared. The null hypothesis of this study was that non-level walking was statistically equivalent to level walking as a discrimination of adequacy of alignment.

METHODOLOGY

Subjects

Six subjects (five males and one female) with unilateral transtibial amputation were recruited by convenience sampling. The cause of their amputation was trauma. Their residual limb lengths were longer than 10 cm. Their age ranged from 26 to 52 years (mean 42.0, SD 10.3) and their experience on prosthesis usage ranged from 2.5 to 34 years (mean 12.1, SD 14.8). The activity level of the subjects in using their current prostheses was classified according to Day (4), with scores ranging from high to very high (mean 31.3, SD 8.5). All residual limbs were deemed to be mature and suitable for fitting PTB sockets. They were able to walk with the prosthesis independently without any walking aid.

Methods

Prior to the experiment, the subjects' general information and anthropometric measurements were recorded (**Table 1**). For each subject, an experimental prosthesis was fabricated, because the prostheses currently used by the subjects did not allow any alignment adjustment. The effect of socket fit was not investigated in this study. In order to minimize possible variation, only one prosthetist was responsible for residual limb casting and subsequent cast rectification for all subjects. A PTB socket design with supracondylar suspension was used. Due to the need for a wide range of adjustment, Otto Bock modular transtibial prosthetic components, including two sliding adapters, and a Solid Ankle Cushion Heel (SACH) prosthetic foot were used.

The alignment procedures followed conventional clinical practice. After the conventional bench alignment procedure, the subject was asked to try the prosthesis with his/her own customary footwear of appropriate heel height. Subsequently, the subject underwent a static

Table 1.
Subjects' data

Subject	Side	Sex	Activity Score (Day 1981)	Age (Year)	Body Mass (kg)	Height (m)	Prosthetic History (year)	Own Prosthesis Suspension	Own Prosthesis Foot
1	Right	M	26(High)	34	74.9	1.50	3	PTB Cuff	SACH
2	Right	F	48 (Very High)	26	74.9	1.58	2.5	PTB SC	SACH
3	Left	M	28 (High)	52	63.8	1.62	2.5	PTB SC	SACH
4	Left	M	26 (High)	47	51.2	1.64	2.5	PTB SC	SACH
5	Left	M	32 (Very High)	51	62.8	1.67	28	PTB Cuff	SACH
6	Left	M	28 (High)	42	71.3	1.67	34	PTB SC	SACH
	Mean		31.3	42.0	66.5	1.61	12.1		
	Standard Deviation		8.5	10.3	9.2	0.10	14.8		

SC=Supracondylar (socket suspension), Cuff=Cuff Suspension, PTB=Patellar Tendon Bearing alignment procedure to assure standing balance and the comfort of the prosthesis. The subject was asked to report his/her comfort of the prosthesis to the prosthetist. When there was no complaint of discomfort and the subject's skin condition was acceptable to the prosthetist, the fitted prosthesis was used in the forthcoming determination of acceptable alignment range.

The convention for measuring alignment was adopted from Zahedi et al. (2). The alignment was defined with respect to the center of the bolt hole at the proximal surface of the SACH foot. In this study, only the effects of sagittal plane alignment, in terms of anterior-posterior (AP) displacement and AP rotation of the socket relative to the prosthetic foot, were investigated. Throughout the experiment, the displacement and rotation of the socket relative to the foot in the medial-lateral (ML) plane were kept at the "zero" position defined by Berme et al. (5) and Zahedi et al. (2) and the prosthetic foot was aligned with the toe-out angle of the unaffected side. Eight possible combinations of alignments were investigated: anterior displacement, posterior displacement, anterior rotation, posterior rotation, combined anterior displacement and anterior rotation, combined posterior displacement and posterior rotation, combined anterior displacement and posterior rotation, and combined posterior displacement and anterior rotation.

A simple mechanical alignment jig (3) was used to prescribe prosthesis alignment in this study. The alignment jig consisted of a vertical mount, a maneuverable frame, and a sliding mechanism (**Figure 1**). For each prosthesis, the axis of the socket was determined using a socket axis locator (5), and three reference points with fixed relationship to the socket axis were marked on the outer socket wall (2). In prescribing an alignment, the socket was mounted onto the alignment jig at the three reference points. The shank part of the prosthesis with the prosthetic foot detached was mounted separately onto the vertical mount of the alignment jig with the foot adapter positioned at the required toe-out angle. The socket was then positioned to the required rotations and displacements in AP and ML planes using the maneuverable frame of the alignment jig. The length of the prosthesis was controlled by the sliding mechanism. Once all the six alignment parameters were confirmed, the socket and the shank were rigidly joined together using a torque wrench. The inter- and intratester errors of the alignment jig in measuring prosthesis alignment were evaluated and demonstrated to have good reliability (2). With the aid of the alignment jig, the prosthesis alignment could be adjusted with 1° increment for AP rotation and 5-mm increment for AP displacement.

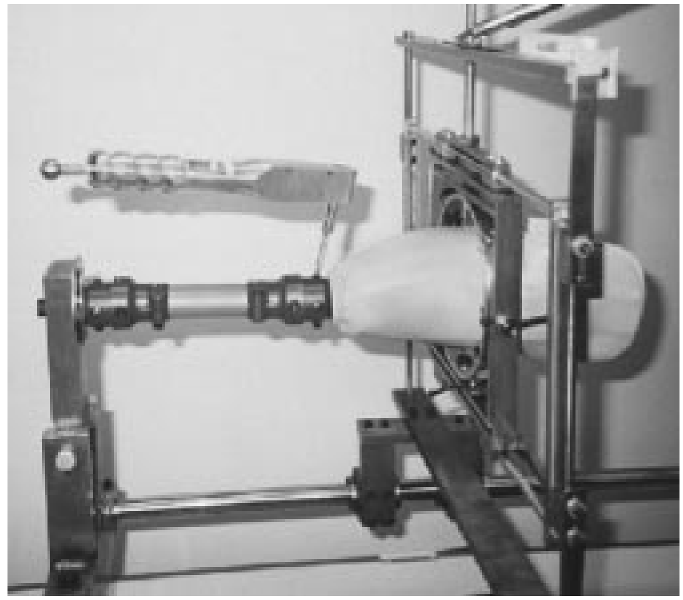

Figure 1.
The mechanical jig used for prescribing prosthesis alignment. Prosthesis alignment was confirmed, and the prosthetic components were joined together using a torque wrench.

A series of alignments was prescribed for each subject, and its sequence was randomized to minimize the subject's anticipation. Conventional assessments were employed to determine whether a prescribed alignment was acceptable or not. For each prescribed alignment, the subject's gait was observed by two experienced prosthetists who deemed the alignment to be satisfactory or otherwise. The residual limb condition was also examined after every walking trial to ensure there was no observable or potential impingement. A 10-minute rest was allowed between successive trials. The maximum limits of alignments acceptable to the subject on level and non-level walking were recorded, and the corresponding acceptable alignment ranges were determined. For level walking, the subject was asked to walk to and from a 10-m-long level walkway three times. For non-level walking, the subject was asked to walk three times to and fro a flight of 15-step stairs of 135-mm riser and 245-mm depth, a 25-m-long pavement, and a 4-m- long ramp with slope of 1 in 10. The determination of the acceptable alignment was a time-consuming process. It was estimated that about 20 minutes were required to complete a test of each prescribed alignment. To ensure repetitive walk-

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ing trials were within the subject's tolerance, each experimental session was limited to 3 hours, and the whole experiment was completed within 5 consecutive days to minimize possible day-to-day variation.

RESULTS

The maximum acceptable sagittal plane alignments of the six subjects with transtibial amputation on level and non-level walking were determined and plotted (**Figure 2**). The boundaries of the acceptable alignment ranges for level and non-level walking were found to be different and varied among the subjects. The acceptable alignment range for non-level walking was consistently smaller than and fell within that for level walking. The areas of the plots of the acceptable alignment ranges for level and non-level walking were determined (**Table 2**) and compared using one-tailed paired-samples t-test. The area of the acceptable alignment range for non-level walking was statistically smaller than that for level walking with p=0.007.

Table 2.
Areas of the acceptable alignment ranges determined for level and non-level walking in degree mm

Subject	Level	Non-level
1	315	57.5
2	315	25
3	210	47.5
4	50	10
5	125	90
6	325	87.5
Mean	223.3	52.9
Standard Deviation	115.8	32.4

The maximum acceptable alignment range for level walking was −15 mm to 35 mm for AP displacement and −5° to 13° for AP rotation (**Figure 2**). For non-level walking, it was −10 mm to 20 mm in AP displacement and −4° to 5° in AP rotation (**Figure 2**), which was about half of that for level walking. Positive and negative signs were respectively used to denote anterior and posterior displacement/rotation. The averages of the acceptable

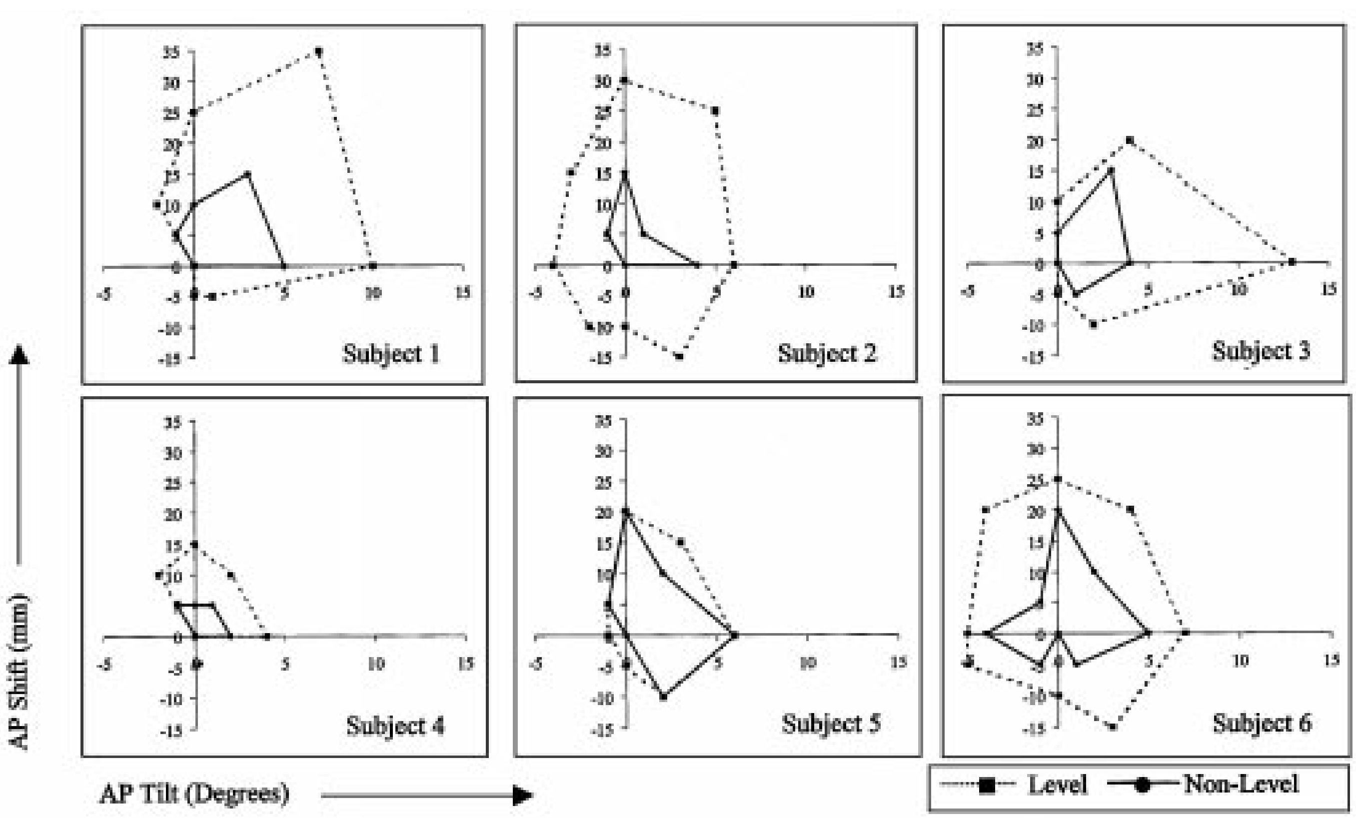

Figure 2.
Acceptable alignment ranges of the six subjects on level and non-level walking.

alignment ranges were also determined, and a critical alignment zone was identified (**Figure 3**). Alignments within this zone were acceptable to all the subjects on both level and non-level walking.

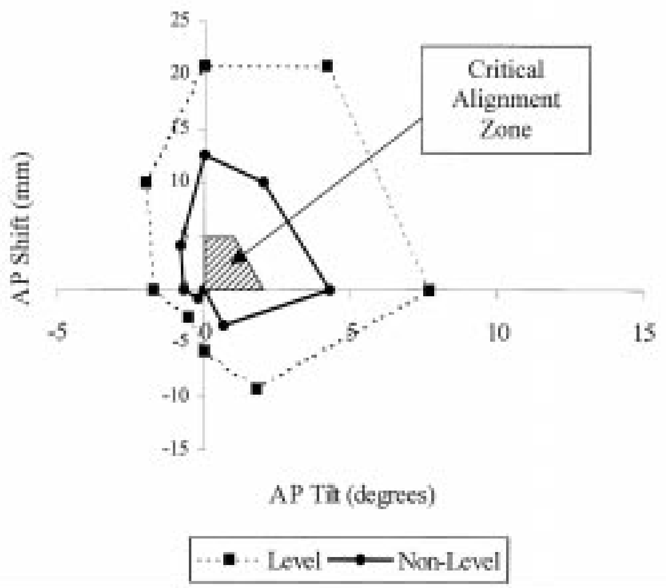

Figure 3.
Averaged acceptable alignment ranges for level and non-level walking and the identified critical alignment zone.

For non-level walking, the subjects were asked to walk up and down a flight of stairs and a ramp. According to the subjects' feedback, walking down the ramp was more sensitive to the change in the alignment than walking up the ramp, which in turn was more sensitive than walking up/down the stairs.

DISCUSSION

In order to approximate actual clinical practice, the subjects in this study were given only limited time to become accustomed to the experimental prosthesis. Thus, the acceptable alignment ranges determined might not reflect any long-term acceptance by the subjects. However, this shortcoming is unavoidable and, in fact, only a short period of trial is affordable and used clinically in deciding whether the alignment is acceptable or not. It should also be noted that the subjects were recruited by convenience sampling, and only one female subject was investigated. This sampling bias might affect the ability to generalize the finding.

Zahedi et al. (2) recorded the acceptable alignment ranges for 10 people with transtibial amputation from 183 random prosthesis fittings for level walking. The maximum acceptable alignment range was found to be −65 mm to 60 mm for AP displacement, −5.5° to 13° for AP rotation. Their results, based on a bulk of acceptable alignments of arbitrary combinations, were comparable to the range of AP rotation obtained in this study for level walking. However, the range of AP displacement determined in this study for level walking was smaller than that reported by Zahedi et al. (2). No comparison could be made for the alignment range determined for non-level walking.

In this study, only the effects of prosthesis alignment in the AP plane (i.e., 2 degree-of-freedom) were evaluated, and the alignments in the ML plane were kept at the zero position defined by Berme et al. (5) and Zahedi et al. (2). It was interesting to note that the zero position was consistently at the boundary of the acceptable alignment range for non-level walking, and the alignments within the critical alignment zone were acceptable to all the subjects. This finding suggests that prostheses might be set within this zone as the initial alignment for prosthesis fitting.

For determining whether a prosthesis alignment was acceptable or not, subjective assessments were employed. The boundary of the acceptable alignment range could only be determined with limited accuracy. Further biomechanical investigation should be conducted to evaluate the gait of people with amputation within the determined acceptable alignment ranges, in an attempt to establish objective criteria for optimum alignment.

Clinically, the tolerance of people with amputation in accepting various alignments is related to the degree of the subject's control over the prosthesis. If people with amputation walk on a more demanding terrain, the tolerance will decrease expectedly. As non-level walking is more demanding than level walking, the acceptable alignment determined for level walking might therefore not work well for daily non-level walking. This phenomenon was evident from the results of the current study. It is logical to expect that the alignments within the acceptable alignment range for non-level walking are closer to the optimum alignment. It is therefore recommended that non-level walking should be included in routine prosthesis fitting to better approximate the optimum alignment.

During the experiment, the subjects reported walking down the ramp to be more sensitive to the change in the alignment than walking up the ramp, which in turn was more sensitive than walking up/down the stairs. It seems that walking down a ramp is a more demanding activity compared with other non-level walking. It is possible that such walking condition would be enough for determining the acceptable alignment for non-level walking. However, further study is required to confirm this observation.

CONCLUSION

The acceptable alignment ranges of subjects with transtibial amputation on level and non-level walking were determined and compared with the aid of an alignment jig. It was found that the acceptable alignment range for non-level walking fell within and was significantly smaller than that for level walking. It is concluded that non-level walking, especially walking down a ramp, is clinically important for better approximation of the optimum alignment and should be included in routine prosthesis fitting.

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