Prosthetics and Orthotics International, 1999, 23, 225–230

A new alignment jig for quantification and prescription of three-dimensional alignment for the patellar-tendon-bearing trans-tibial prosthesis

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Abstract

Clinically, it is hard to achieve and reproduce prosthesis alignment at will during daily prosthesis fitting. A new alignment jig was designed and developed to facilitate quantification and prescription of prosthesis alignment for patellar-tendon-bearing (PTB) trans-tibial prostheses. The alignment jig provided instantaneous readings of the three-dimensional orientation and position of the socket relative to the prosthetic foot in standardised units. The inter- and intra-tester errors of the alignment jig in measuring prosthesis alignment were evaluated and demonstrated to have good reliability. The alignment jig was recommended to be used clinically after the conventional dynamic alignment procedure to document the prosthesis alignment. Further application of the alignment jig for systematic evaluation of the effects of prosthesis alignment on gait for trans-tibial amputees is suggested.

Introduction

The sequence of providing a lower limb prosthesis includes the events of assessment and measurement, assembly of prosthesis components, alignment procedure, final finishing and fitting. Of these events, the alignment procedure is the most critical and time-consuming process. The alignment of the prosthesis is defined as the three-dimensional orientation and position of the socket relative to the prosthetic foot. For the trans-tibial prosthesis, this refers to 6 alignment parameters, i.e. the anteroposterior (A/P) shift, A/P tilt, mediolateral (M/L) shift and M/L tilt of the socket relative to the foot, length of the prosthesis and the toe-out angle (Berme *et al.*, 1978; Zahedi *et al.*, 1986). Clinically, the alignment at which the amputee feels comfortable and the resulting gait judged by the prosthetist to be functionally acceptable is regarded as an acceptable alignment. This conventional alignment procedure is an experience dependent process and relies on both the prosthetist's subjective judgement and the amputee's feeling of the comfort level. Due to its subjective nature, the alignment achieved may not be optimal for the amputee resulting in the increased possibility of tissue or skin damage due to the resulting stress actions on the stump during functional activities.

Different alignment devices like the Berkeley Adjustable Leg®, the Winnipeg wedge disc alignment units (Foort and Hobson, 1964), the Proteor Alignment Device (distributed by Fillauer Inc.), In-built One-point Alignment (Köhler *et al.*, 1988), the Cup Connector (distributed by the United States Manufacturing Company) are commercially available. There are also commercially available jigs for prosthesis alignment duplication such as the Berkeley Horizontal Duplication Jig, the Vertical Fabrication Jig, the Otto Bock

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Balancing Apparatus, the Otto Bock Alignment Apparatus, the Otto Bock Transfer Alignment Apparatus. These alignment and duplication devices have individual measurement mechanisms for adjusting the alignment. However, they do not provide numerical documentation of the three-dimensional orientation and position of the socket relative to the prosthetic foot. Although the prosthesis alignment can be measured using a conventional plumb line method, the repeatability and accuracy are relatively low. Moreover, it is technically difficult and not reliable to prescribe an alignment using the plumb line method during the alignment procedure.

In 1978, Berme *et al.* developed a socket axis locator for defining and determining the socket axis. By digitising the three-dimensional co-ordinates of several reference points defined on the socket axis and the socket using a scribing block, the 6 alignment parameters were calculated with good repeatability. Evans and Evans (1994) improved the time-consuming digitisation process by using a magnetic tracking device (3SPACE Isotrak, Polhemus, Vermont, USA) and the 6 alignment parameters could be determined automatically. However, the accuracy of the measurement could easily be affected by the interference induced to the magnetic tracking device by nearby metallic components. Moreover, prescription of prosthesis alignment using this method could only be achieved by a trial and error approach. It is therefore, the objective of this study to design and develop a simple alignment jig that can be used for measuring as well as prescribing three-dimensional prosthesis alignment with 6 degrees of freedom (Berme *et al.*, 1978; Zahedi *et al.*, 1986). As the requirements for different types of amputees are different, the current study is mainly for trans-tibial amputees who are the majority of the amputee population.

Particulars of the design

A simple mechanical alignment jig was designed and developed. The alignment jig consisted of 3 major parts, namely an alignment table, an adjustable socket mount and a socket axis locator (Fig. 1). The design of the alignment table and the socket axis locator was originated from Berme *et al.* (1978) for prosthesis alignment measurement. The alignment table was a framework structure with a pair of parallel shafts and a vertical mount. The vertical mount was used for mounting of the shank of the prosthesis to the alignment table. The adjustable socket mount consisted of 4 scaled independent manoeuvrable frames. The 4 frames were used

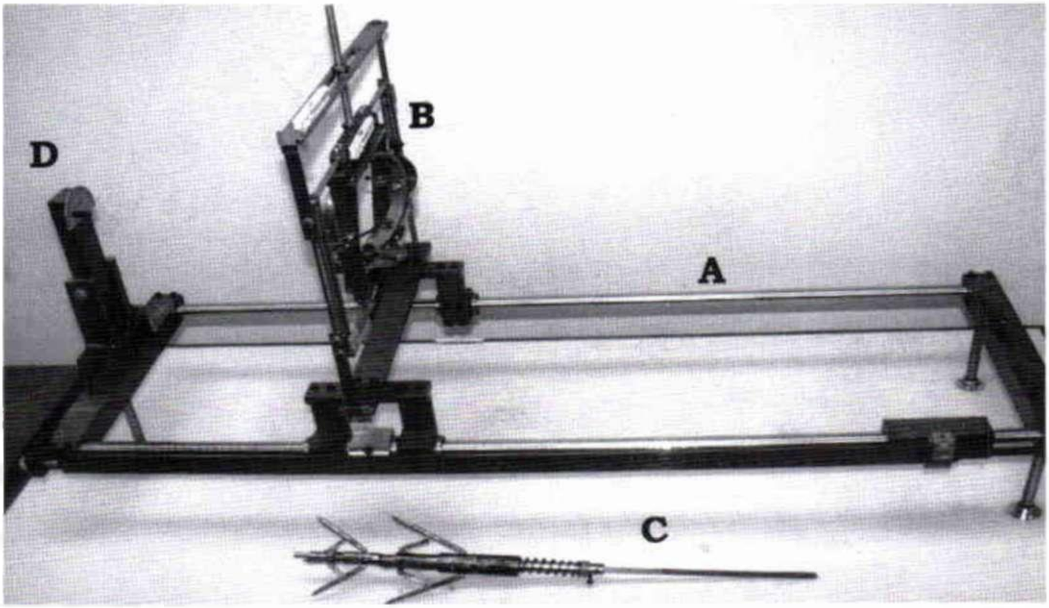

Fig. 1. The alignment jig. A – the alignment table; B – the vertical mount; C – the socket axis locator; D – the adjustable socket mount with 4 scaled independent manoeuvrable frames.

to hold the socket in space and control its position and orientation with 4 degrees of freedom (i.e. the socket tilts and shifts in A/P and M/L planes) (Fig. 2). The 5th frame of the adjustable socket mount was used to hold the 4 frames and could slide along the parallel shafts of the alignment table for controlling the height of the prosthesis. There were scales on the parallel shaft and the vertical mount for measuring the length of the prosthesis and the toe-out angle, respectively (Fig. 2).

The socket axis locator was used to define the axis of the socket (Fig. 1). It was constructed with a square central rod on which there were two sliding sub-assemblies. Both the sliding sub-assemblies consisted of 2 pairs of spring-loaded arms. The two pairs of arms were so designed that they were orthogonal to each other and there was a mechanism to permit the tips of each pair of extendible arms to be kept equidistant to the central rod.

Procedures for determining socket axis

The procedures in determining the axis of a socket using the socket axis locator are as follows. A line was firstly drawn 25mm distal and parallel to the patellar bar on the inner wall of the socket. The socket axis locator was then put inside the socket. The position of the socket axis locator was continuously adjusted until the distal end of the central rod was in contact with the distal socket end and the tips of all the extendible arms touched the inner wall of the socket. For the proximal sliding sub-assembly of the socket axis locator, one pair of the extendible arms was positioned to be parallel to the posterior socket brim and the other pair was so positioned that the tip of its anterior arm touched the marked line. When the socket axis locator was set in such a position, the axis of the socket was defined as the central rod of the locator. Accordingly, there would be 4 points of contact between the tips of the extendible arms of the proximal sliding sub-assembly and the inner wall of the socket. By using an outside calliper, the 4 points of contact were duplicated and marked on the outer wall of the socket. They were labelled as A, P, M and L to denote the anterior, posterior, medial and lateral sides of the socket, respectively. Points P, M and L were used as reference points for determining the prosthesis alignment.

Procedures for measuring and prescribing prosthesis alignment

For a given PTB trans-tibial prosthesis, its

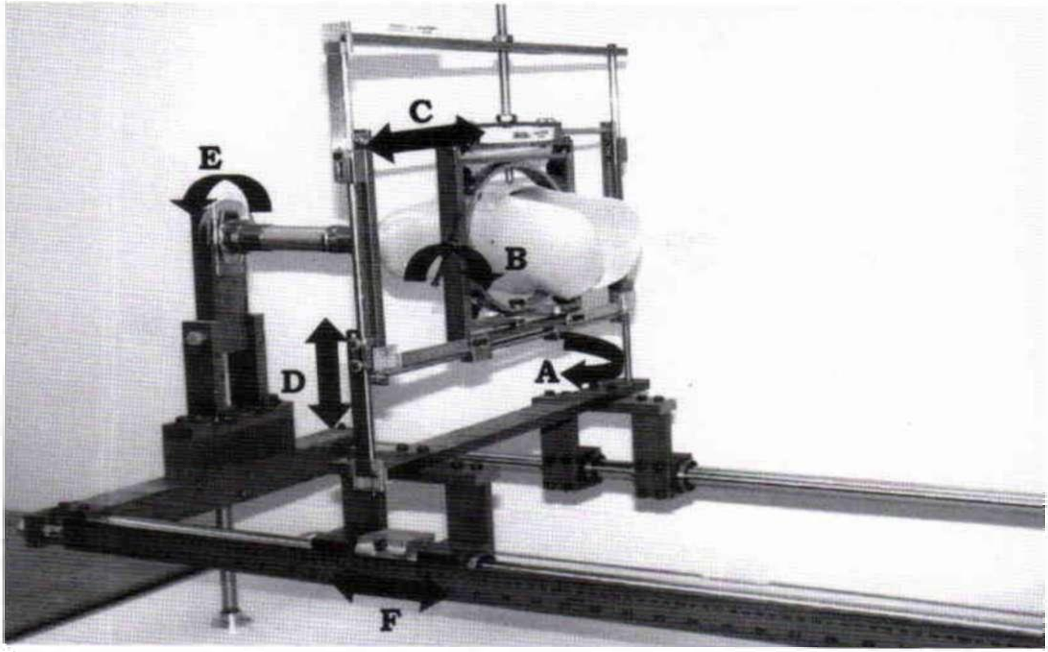

Fig. 2. The mechanisms for inputing the 6 alignment parameters. A – for M/L tilt; B – for A/P tilt; C – for M/L shift; D – for A/P shift; E – for toe-out angle; F – for prosthesis height.

alignment can be measured using the alignment jig as follows. A mark was firstly drawn on the foot adaptor to indicate the orientation of the foot. The foot was then removed. Subsequently, the axis of the socket was determining using the socket was determining using the socket axis locator and the 3 reference points, i.e. points P, M and L, were determined. The prosthesis was then mounted onto the vertical mount at the foot adaptor using an ankle-bolt. The adjustable socket mount was adjusted manually until the tips of 3 positioning screws of the adjustable socket mount touched the 3 reference points. The 6 alignment parameters of the prosthesis were then determined directly from the scales on the vertical mount, the parallel shaft of the alignment table and the 4 manoeuvrable frames of the adjustable socket mount. It was recorded that it took less than 6 minutes for a skilled operator to complete a set of measurement.

For prescribing an alignment, the axis of the socket was firstly determined using the socket axis locator and 3 reference points were marked. The socket was then mounted onto the adjustable socket mount at the 3 reference points using the 3 positioning screws. The shank part of the prosthesis with the prosthetic foot detached was mounted separately onto the vertical mount with the foot adaptor positioned at the required toe-out angle. The required tilts and shifts of the socket in A/P and M/L planes were input using the 4 manoeuvrable frames of the adjustable socket mount. The length of the prosthesis was determined by subtracting the total required length by the foot height and input by using the scale on the parallel shaft of the alignment table. Once all the 6 alignment parameters were confirmed, the socket and the shank were rigidly joined together using a torque wrench. If it was required to modify the alignment, the same reference points would be used and the process above would be repeated. It was also recorded that it took less than 6 minutes to complete a prescription process for a skilled operator.

Reliability study

The resolution of the scales of the alignment jig was 1° for angular and 1mm for linear measurement. The source of errors in using the alignment jig to measure prosthesis alignment may arise from the process in determining the socket axis, duplicating the reference points and measuring prosthesis alignment using the adjustable socket mount. In order to study the intra-tester and inter-tester reliability of the

Table 1. Means (SD) and ranges of the averaged alignments of the 6 prostheses measured by the two prosthetists using the new alignment jig.

Alignment parameter	Prosthetist A	Prosthetist B
Prosthesis height (mm)	352.6 (18.4) 324.7 – 369.5	352.7 (18.4) 324.3 – 369.3
A/P tilt (degrees)[1]	6.3 (1.3) 4.7 – 8.2	6.4 (1.3) 4.7 – 8.3
M/L tilt (degrees)[2]	4.1 (0.4) 3.7 – 4.5	3.9 (0.7) 3.0 – 4.7
A/P shift (mm)[1]	7.8 (1.6) 5.5 – 9.3	7.5 (1.6) 5.7 – 7.5
M/L shift (mm)[2]	5.3 (2.3) 4.0 – 9.7	5.3 (2.4) 3.2 – 9.8
Toe-out angle (degrees)[3]	15.1 (1.2) 13.8 – 17.2	15.1 (1.4) 13.8 – 17.3

[1] Positive for anterior tilt/shift, negative for posterior tilt/shift
[2] Positive for lateral tilt/shift, negative for medial tilt/shift
[3] Positive for toe-out, negative for toe-in

Table 2. Intraclass correlation coefficients, ICC(3,1), for studying the intra-tester reliability of the two prosthetists in measuring the 6 alignment parameters.

Alignment parameter	Prosthetist A		Prosthetist B	
	ICC(3,1)	p-value	ICC(3,1)	p-value
Prosthesis height	1.00	<0.001	1.00	<0.001
A/P tilt	0.86	<0.001	0.80	<0.001
M/L tilt	0.33	<0.001	0.47	<0.001
A/P shift	0.89	<0.001	0.87	<0.001
M/L shift	0.94	<0.001	0.95	<0.001
Toe-out angle	0.79	<0.001	0.85	<0.001

alignment jig, the 6 alignment parameters of 6 randomly selected PTB trans-tibial prostheses were repeatedly measured 6 times by two prosthetists. The 6 trans-tibial prostheses were currently used by the amputees of the out-patient clinic. All the amputees had a stump length longer than 10cm. For each prosthesis, its socket axis was firstly located using the socket axis locator. The 3 reference points were identified and marked using a 0.5mm pencil. The prosthesis alignment was then measured using the alignment jig. The markings of the reference points were removed after the measurement. The reliability of the measurements was assessed using the intraclass correlation coefficient (ICC) (Portney and Watkins, 1993). The ICC of model 3 (i.e. ICC(3,1)) and model 2 (i.e. ICC(2,1)), were used to reflect the intra-tester reliability of the two prosthetists and the inter-tester reliability of the measurements, respectively.

Results

For each prosthesis, the 6 alignment parameters were measured 6 times by each prosthetist. The results of the 6 trials were averaged. The means and standard deviations of the averaged prosthesis alignment for the 6 subjects measured by the two prosthetists were determined (Table 1). It was observed that the M/L tilt of the 6 prostheses used fell within a relatively narrow range.

The intra-tester reliability of the two prosthetists were quantified by the ICC(3,1) values (Table 2). It was found that all the alignment parameters, except the M/L tilt, had good intra-tester reliability with ICC(3,1) ranged from 0.79 to 1.00. The ICC(3,1) values for measuring M/L tilt were 0.33 and 0.47 for the two prosthetists.

In studying the inter-tester reliability of the measurements, only the first set of measurements by each prosthetist was used (Table 3). It was found that all the alignment parameters, except the M/L tilt, had good inter-tester reliability with ICC(2,1) ranged from 0.74 to 1.00. The ICC(2,1) value for measuring M/L tilt was 0.26 ($p=0.301$).

Discussion

In prescribing and measuring the alignment of a trans-tibial prosthesis, the only control required is the three-dimensional position and orientation of the socket relative to the foot. There is no restriction on the relative positions of the other prosthetic components as long as they are rigidly linked together. It is therefore, independent of the types of prosthetic components to be used. In this study, a simple mechanical alignment jig was designed and developed. The alignment jig provided direct read-out of the prosthesis alignment and no numerical calculation was required. The operation of the alignment jig was simple and required only common hand tools. It was recorded that it took less than 6 minutes to prescribe or measure a prosthesis alignment for a skilled operator.

In the current study, 6 prostheses currently used by the amputees were used for the

Table 3. Intraclass correlation coefficients, ICC(2,1), for studying the intra-tester reliability of the two prosthetists in measuring the 6 alignment parameters.

Alignment parameter	ICC(2,1)	p-value
Prosthesis height	1.00	<0.001
A/P tilt	0.84	0.001
M/L tilt	0.26	0.301
A/P shift	0.94	0.001
M/L shift	0.91	0.001
Toe-out angle	0.74	0.038

reliability analysis. The alignments of these prostheses were prescribed by experienced prosthetists using conventional dynamic alignment procedures. The alignments measured using the new alignment jig were compared with the acceptable alignment ranges reported by Zahedi *et al.* (1986). It was found that A/P and M/L tilts of the 6 prostheses fell within the ranges determined by Zahedi *et al.* (1986). However, the A/P and M/L shifts and M/L tilts of the prostheses were much smaller than those reported by Zahedi *et al.* (1986) and the toe-out angles were larger than that reported by them. This might be explained by fact that the results by Zahedi *et al.* (1986) represented the extremes of the maximum acceptable alignment ranges. As there was no absolutely known prosthesis alignment available, only the reliability of the alignment jig could be studied. The intraclass correlation coefficients of the alignment jig in measuring all the alignment parameters were high except that for the M/L tilt. The low intraclass correlation coefficients for measuring M/L tilt were thought to be due to lack of variability among the M/L tilts of the prostheses used (Portney and Watkins, 1993). As the range of the measured M/L tilts was small (Table 1), it is still reasonable to conclude that the alignment jig has good intra- and inter-tester reliability for measuring all the 6 alignment parameters.

With the development of the new alignment jig, an individual's prosthesis alignment could be recorded in clinical notes for future reference and comparison and the recorded alignment could then be reproduced whenever it is necessary.

This may benefit those amputees who need to change their prosthesis frequently. Moreover, the alignment jig will be useful for both training and research purposes. As there are multiple variables related to the prosthesis alignment combinations contributing to the efficacy of prosthesis fitting, the alignment jig could provide a systematic and objective means for the control of individual prosthesis alignment and consequently to facilitate the follow-up evaluation.

It should be noted that the socket axis determined using the socket axis locator might not represent the axis of the tibia or any skeletal structure. Therefore, further investigation is necessary to determine the correlation between the defined socket axis with the anatomical configuration of the stump so that the effects of prosthesis alignment could be systematically evaluated and compared among individual amputees. Finally, the current alignment jig design is suitable only for the PTB trans-tibial prosthesis with prosthetic foot with ankle-bolt attachment. Modification would be necessary for a prosthesis that does not have ankle-bolt attachment.

Conclusion

A simple alignment jig was designed and developed. It can provide direct read-out of the 6 alignment parameters for PTB trans-tibial prostheses without any computation. It could be used to measure and prescribe alignment for trans-tibial prostheses with good reliability.

Acknowledgement

The work described in this paper was substantially supported by the Central Research Grant of the Hong Kong Polytechnic University (Project No. G-V145).

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