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Alignment of lower-limb prostheses

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Abstract—Alignment of a prosthesis is defined as the position of the socket relative to the other prosthetic components of the limb. During dynamic alignment the prosthetist, using subjective judgment and feedback from the patient, aims to achieve the most suitable limb geometry for best function and comfort. Until recently it was generally believed that a patient could only be satisfied with a unique "optimum alignment." The purpose of this systematic study of lower-limb alignment parameters was to gain an understanding of the factors that make a limb configuration or optimum alignment, acceptable to the patient, and to obtain a measure of the variation of this alignment that would be acceptable to the amputee. In this paper, the acceptable range of alignments for 10 below- and 10 above-knee amputees are established. Three prosthetists were involved in the majority of the 183 below-knee and 100 above-knee fittings, although several other prosthetists were also involved. The effects of each different prosthetist on the established range of alignment for each patient are reported to be significant. It is now established that an amputee can tolerate several alignments ranging in some parameters by as much as 148 mm in shifts and 17 degrees in tilts. This paper describes the method of defining and measuring the alignment of lower-limb prostheses. It presents quantitatively established values for bench alignment position and the range of adjustment required for incorporation into the design of new alignment units.

INTRODUCTION

Successful rehabilitation of the amputee requires that the prosthesis be acceptable to him or her. Prosthesis acceptability depends on several factors including cosmesis, mass properties of the prosthesis, comfort, and function. Comfort and function are directly dependent on the quality of fit of the socket, the quality of suspension, the type of components used and the relative geometrical position of these components to each other. The position and orientation of these components, the major elements being the socket, joint(s), and terminator (e.g., foot), are defined as *the alignment of the prosthesis*.

If an acceptable alignment of a lower-limb prosthesis cannot be achieved, the limb may be rejected by the wearer. Often the patient complains of discomfort or pain associated with the socket when in fact the alignment of the prosthesis is the root cause. On supply of a new prosthesis, the patient is often aware that, not only is the socket different, but the alignment is also different; this occasionally causes the amputee to consider the new prosthesis as inferior to the old one.

Failure to provide a satisfactory alignment may result in problems for the amputee, such as difficulty in walking, stump pain, or tissue breakdown. This in turn leads to problems for the prosthetist since the patient will inevitably return to the clinic with a complaint. It is therefore important to make every endeavour to provide an acceptable alignment to the patient on every occasion that the need arises and that the alignment arrived at be the "optimum alignment."

During the phase of dynamic alignment, the prosthetist observes the gait of the amputee and listens to the patient's comments. Experience, an understanding of the causes of gait deviations, a knowledge of the loadings applied at the stump/socket interface, and feedback received from the patient assist the prosthetist in making alterations to the geometrical configuration of the prosthesis until an alignment is achieved which is acceptable to both patient and prosthetist.

The positioning of one component relative to another tends to be described by *tilts* and *shifts* without a defined reference system. An original method of measuring alignment based on the definition of unique socket axis system was developed at the Bioengineering Unit, University of Strathclyde (8). This system, which was used during an evaluation of below-knee modular sys-

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tems (17), resulted in the finding that an individual patient could be satisfied with several types of prostheses, each displaying a different alignment. This view was reinforced when above-knee limbs were considered (18). Therefore it was seen that one patient could be satisfied with several alignments. However, it could be construed that the variability of alignment was dependent on the type of prosthesis.

The present study considered the influence that different prosthetists had on the acceptable range of alignment, when the type of limb was held constant.

OBJECTIVES

This study was primarily concerned with the repeatability of achieving optimum alignment in a clinical situation. A second area of interest was the range or *band of alignment* that the patients would tolerate. Many subsidiary factors were considered after collection of sufficient data to form a statistically sound sample. For example, the required range of adjustment of the alignment units could be derived from the range of acceptable alignments, and the results would thus be suitable for inclusion in design criteria. It was also hoped to recommend new or verify existing criteria for the bench alignment of below- and above-knee prostheses.

PATIENTS

Ten below-knee and ten above-knee amputees, all of whom were active and established prosthesis users, were selected from the amputee population attending the local limb-fitting center (Tables 1 and 2).

Activity was classified according to Day (3), the scores attributed to the patients ranged from 19 to 57 (mean 31.86, SD 16.00). Age ranged from 31 to 77 years (mean 51.00, SD 11.85). Two patients were female. The number of years since amputation ranged from 9 to 44 (mean 23.30 SD 11.50). All stumps were considered mature and suitable for fitting pattelar tendon bearing (PTB) sockets to the below-knee subjects and quadrilateral suction sockets to the above-knee subjects.

PROSTHETISTS

Three experienced prosthetists were involved in the major section of this investigation; they were responsible for 150 of the 283 alignments considered. The alignment units preferred by the prosthetists consisted of the Otto Bock system, the Berkeley below-knee jig, and the Hosmer AKAL above-knee jig. Nine other prosthetists were involved at various stages of the study to a variable but lesser extent than the first three.

PROSTHESES

Due to the complexity of the investigation it was desirable to exercise maximum possible control over the variables involved. Consequently, one prosthetist was responsible for stump casting and subsequent cast rectification for all patients. Manufacture of the prostheses was carried out by one prosthetic technician following standard procedures, and the prostheses were bench aligned to the specific prescribed value.

TABLE 1
Below-knee patient data.

Subject, Left/Right	Sex	Activity Score*	Age, yr	Body Mass, kg	Height, m	Own Limb type	Own Limb foot
1 R	M	21	51	105.3	1.85	PTB Supracondylar	uniaxial
2 R	M	22	67	66.1	1.76	PTB MAP supracondylar	SACH
3 L	M	33	47	70.0	1.77	PTB cuff	uniaxial
4 L	M	42	48	68.0	1.74	PTB supracondylar	SACH
5 R	M	43	60	71.0	1.81	No. 8	uniaxial
6 L	M	43	46	67.0	1.71	PTB cuff	uniaxial
7 R	M	57	59	75.5	1.78	PTB cuff	SACH
8 L	M	44	43	76.5	1.75	PTB MAP cuff	Greissinger
9 R	F	37				PTB stocking	uniaxial
10 R	M	33	77	72.0		PTB cuff	SACH

MAP = modular assembly prosthesis
PTB = patellar tendon bearing
No. 8 = conventional below-knee prosthesis with metal shank, leather socket, side steels, and thigh corset.
* Data from Day (ref. 3); activity level: −70 to +50 (above +30 = very active; below −40 = inactive).

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TABLE 2
Above-knee patient data.

Subject, Left/Right	Sex	Activity Score*	Age, yr	Body Mass, kg	Height, m	Own Limb type	Own Limb foot	Knee Mechanism
1 L	M	30	48	81.3	1.79	Quad MAP suction	uniaxial	uniaxial
2 R	M	19	57	86.5	1.81	Quad MAP suction	SACH	uniaxial
3 R	M	42	46	71.5	1.81	H type MAP suction	uniaxial	manual lock uniaxial
4 L	M	49	58	73.2	1.67	Quad metal suction	SACH	uniaxial
5 L	M	42	33	105.0	1.79	Quad metal suction	SACH	uniaxial
6 R	M	4	65	115.85	1.89	H type MAP metal suction	uniaxial	uniaxial
7 R	M	24	55	66.0	1.66	H type MAP metal RPB	uniaxial	uniaxial
8 R	M	20	34	74.0	1.72	H type MAP metal RPB	uniaxial	uniaxial
9 R	F	38	31	57.0	1.68	H type metal suction	uniaxial	uniaxial
10 L	M	43	34	73.0	1.90	Quad wood suction	SACH	uniaxial

MAP = modular assembly prosthesis
RPB = rigid pelvic band, uniaxial hip joint
H type = health socket
* Data from Day (3); activity level: −70 to +50 (above +30 = very active; below −40 = inactive)

The type of limb selected had to fulfill certain criteria. Primarily, the system had to provide the widest range of adjustment at both above- and below-knee levels, thereby imposing little restriction on the prosthetists, freedom to align. Ease of component interchangability and worldwide availability of the system were also considered, thus allowing future comparison of results by other workers. The Otto Bock modular system prosthesis was chosen as the system that met these criteria most closely.

All the below-knee sockets were of the PTB type with supracondylar strap suspension. The above-knee prostheses were fitted with quadrilateral total contact suction sockets and uniaxial knee mechanisms, with extension bias and constant friction swing phase control. SACH feet were fitted to all prostheses. Socket fit was checked by two practicing prosthetists and deemed satisfactory on each occasion.

Initially not all patients were accustomed to wearing the PTB or quadrilateral type sockets and therefore had to undergo a period of familiarization with the new socket. Failure to achieve patient satisfaction with the new socket resulted in withdrawal and replacement of that patient.

MEASUREMENT OF ALIGNMENT

The nonuniform geometrical shape of typical prosthetic sockets has led to difficulties, ambiguities, and misunderstandings in specifying or attempting to measure alignment. A unique axis system for this nonuniform shape was defined to overcome this problem (2, 8). Two parallel planes, perpendicular to the long axis of the socket are defined to lie 25 mm proximal to the distal end of the socket and 25 mm distal to the patellar bar in the PTB socket, or 25 mm distal to the posterior brim (ischial seat/shelf) in the quadrilateral socket. A center point is defined to lie on each plane so that it bisects the diameters of the socket in the anterioposterior plane and the mediolateral plane. The two center points define a line that is a unique axis of the socket (Fig. 1). This unique axis of the socket is shown, as a line within the socket viewed in the ML and AP planes, in the figures throughout this article (e.g., Fig. 3).

With the use of the Cartesian coordinate system shown, the x axis is defined as positive forward along the direction of progression, and this is taken to be perpendicular to the posterior part of the socket (brim); the y axis is defined as positive upwards and perpendicular to the x axis, and the z axis is perpendicular to both x and y axes. Thus the anterioposterior plane of the patient's leg coincides with the xy plane and the mediolateral plane coincides with the zy plane. The origin of this reference system was defined to be the center of the bolt hole of the SACH foot at the surface of the top of the foot.

Several pieces of apparatus were constructed to facili-

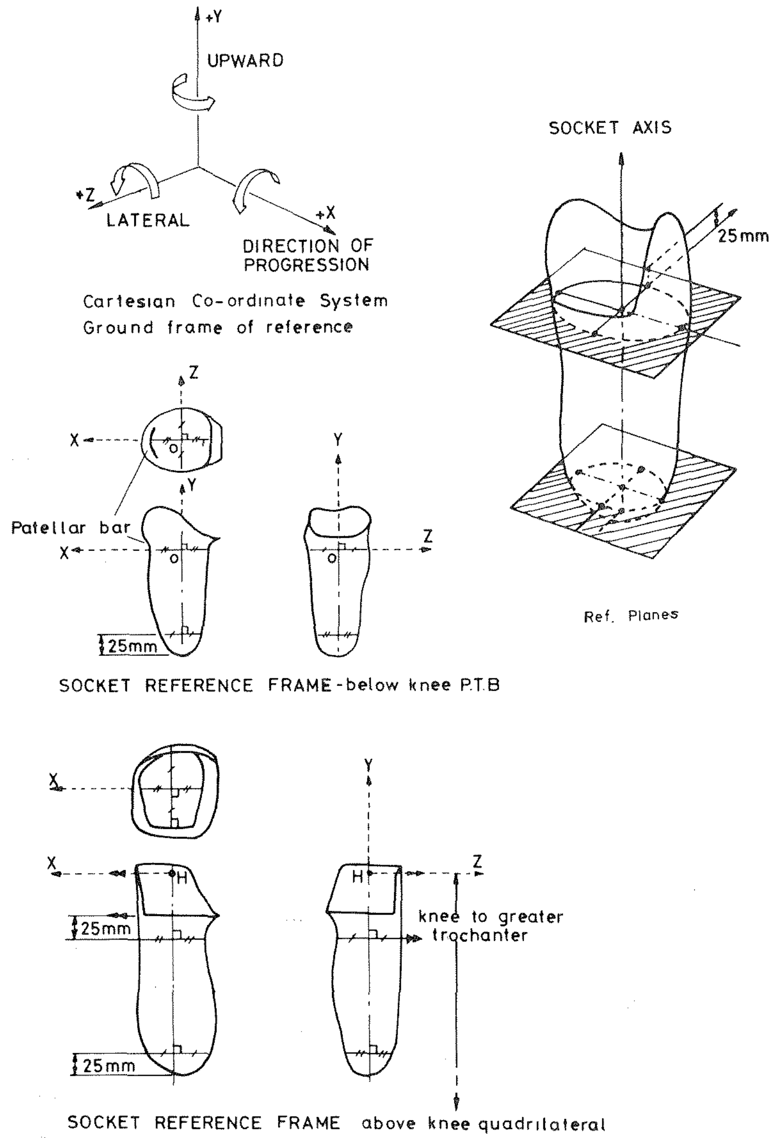

FIGURE 1
Definition of coordinate system and socket axis reference frames.

tate the measurement of limb alignment. A custom-built socket axis locator (12) was further developed by Szulc (19) to locate two reference points on the medial and two on the lateral inside walls of the socket, corresponding to the intersections of the coronal plane with the defined parallel planes, which is necessary for definition of the socket axis. A cast-iron baseplate was fitted with a 120 by 50 cm horizontal perspex plate accurately marked with a grid of 1-cm squares. A bracket was rigidly fixed to the baseplate, which incorporated an accurately machined vertical surface perpendicular to the horizontal surface to provide location and fixation of the prosthesis. As the prosthesis was mounted horizontally it was possible for an above-knee prosthesis to adopt various knee angles in the anterioposterior plane, depending on the load applied. Standardization of this feature was obtained by applying a constant knee hyperextension moment of 50 Nm to each above-knee limb. This was achieved by means of a jacking arrangement incorporating a strain gauged transducer (20). Figure 2 shows these component parts of the measurement system.

Although the system is accurate and relatively quick to use, it is undergoing development to produce an automatic system that alleviates the need for a skilled operator.

Alignment Parameters

After defining the socket axis and the development of the measurement system, parameters needed to be specified which completely defined the socket axis and therefore the socket relative to the knee and foot for

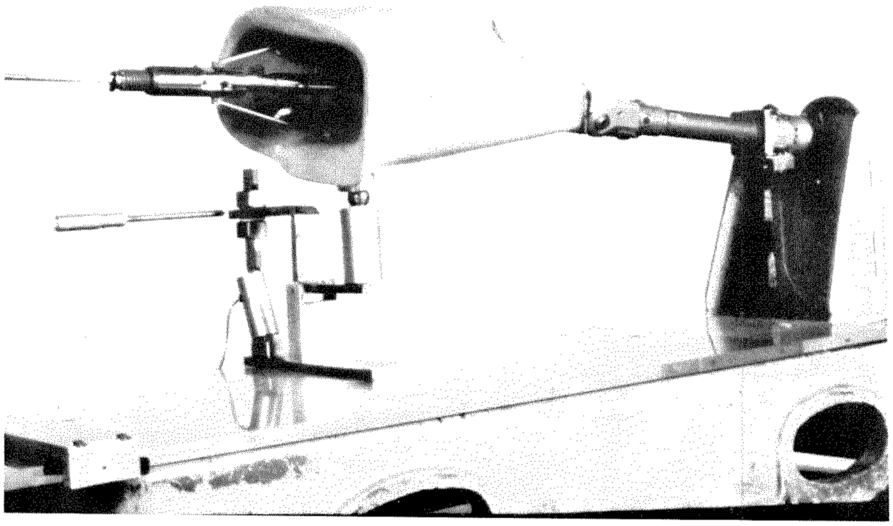

FIGURE 2
Measuring jig and socket axis locator.

above-knee prostheses and to the foot for below-knee prostheses. These parameters are selected to represent the angular tilts and linear shifts that most alignment units embody and are employed by the prosthetist. The proximal reference point of the socket axis (the center of the proximal plane) is used to define linear position, whereas the socket axis is the reference for angulation in both AP and ML planes. Toe out is defined as "the angle formed by the center axis of the foot and the x axis of the socket for below-knee prostheses and the axis of the knee mechanism for above-knee prostheses."

To rationalize the terminology used and to avoid any misunderstanding with respect to previous terminology, the following alignment parameters are proposed:

Below-Knee Prosthesis:	*Above-Knee Prosthesis:*
toe out/in angle	toe out/in angle
socket AP shift	knee AP shift
socket ML shift	knee ML shift
socket AP tilt	knee ML tilt
socket ML tilt	knee height
socket height	socket AP shift
	socket ML shift
	socket AP tilt
	socket ML tilt
	socket rotation
	socket height

The sign convention adopted which incorporates correction for right and left prosthesis is detailed in Figures 3 and 4. When considering any of the values within the tables, one should remember that the sign has been corrected for right/left limbs. Positive translatory values indicate an upward, anterior, or lateral displacement of the socket with respect to the foot. Negative translatory values indicate posterior or medial displacement of the socket. The similar convention applies to angulations except in the case of the above-knee socket AP tilt whereby a positive value, in keeping with more conventional thoughts, indicates flexion of the socket. Figures 3 and 4 show these parameters for below- and above-knee prostheses.

Measurement Procedure

With the aid of the socket axis locator the four reference points inside the socket were determined and permanently marked; these points were used throughout the test period or for the life of the prosthesis, for subsequent measurement of various alignments. The SACH foot and ankle adaptor were removed and replaced by another adaptor. The limb was bolted through the ankle adaptor to the vertical plate of the measuring jig. The knee-extension moment was applied by the jacking device to the above-knee limbs only. At this stage the limb was positioned with the foot axis along the direction of progression. The top socket reference markers in the below-knee socket and the knee reference markers on the above-knee limb were measured for calculation of toe

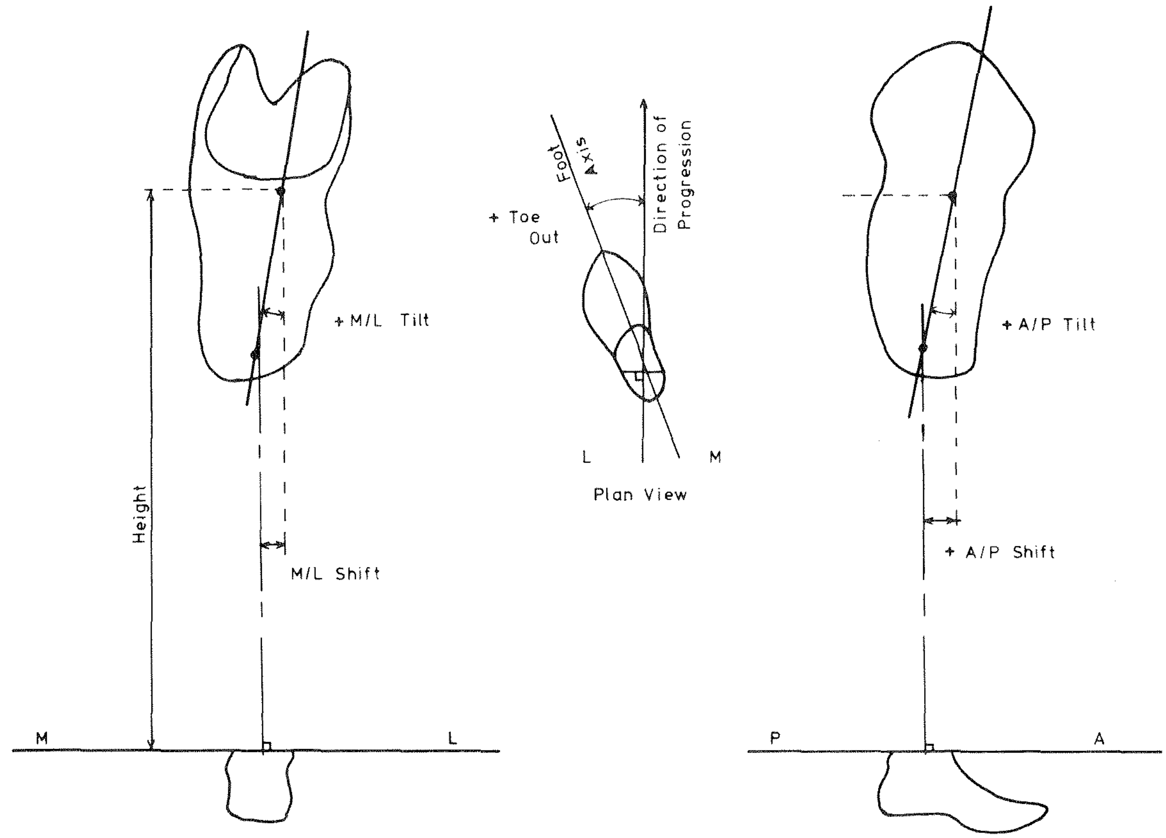

FIGURE 3
Definition of alignment parameters for below-knee prostheses.

out. Accomplishment of this allowed the limb to be rotated until the reference markers for the toe-out measurement were equidistant from the top surface of the table. The limb was now considered to lie along the direction of progression. All the marked reference points were measured with the use of an electromechanical linkage device and rulers. The measured values were input to a PDP 11/34 minicomputer for calculation of the alignment parameters and for further analysis. We plan to substitute the PDP 11/34 by a personal microcomputer in future instrumentation for alignment measurements.

Experimental Procedure

The method of fitting and alignment adopted was similar to typical United Kingdom clinical practice. After dynamic alignment the gait of the patient was observed by other prosthetists who deemed the alignment to be satisfactory or otherwise. Ten below-knee and 10 above-knee patients were considered. The prosthetists dynamically aligned each amputee several times over a two-year period. It must be noted that the bulk of the results were collected on six below-knee and five above-knee patients using three prosthetists in a series of sessions during which each patient's prosthesis was aligned twice.

The initial bench alignment of each limb was measured and the limb was presented to the prosthetist in this state at each stage of the investigation. The time taken to complete the dynamic alignment and the nature of the conversation each prosthetist had with the patient were noted. After dynamic alignment, each amputee was questioned using a structured questionnaire which discussed comfort and alignment of the prosthesis. The prosthetist also answered questions relating to gait deviations displayed by the amputee. The opinions of two other prosthetists regarding the patient's performance with each alignment were also recorded. Appropriate software computed the alignment parameters after measurement and rated the subjective assessment of the individuals involved. The geometrical configurations of the prostheses were plotted graphically and the results listed numerically.

RESULTS

As previously stated, 20 patients and 3 prosthetists were involved in the major part of this investigation.

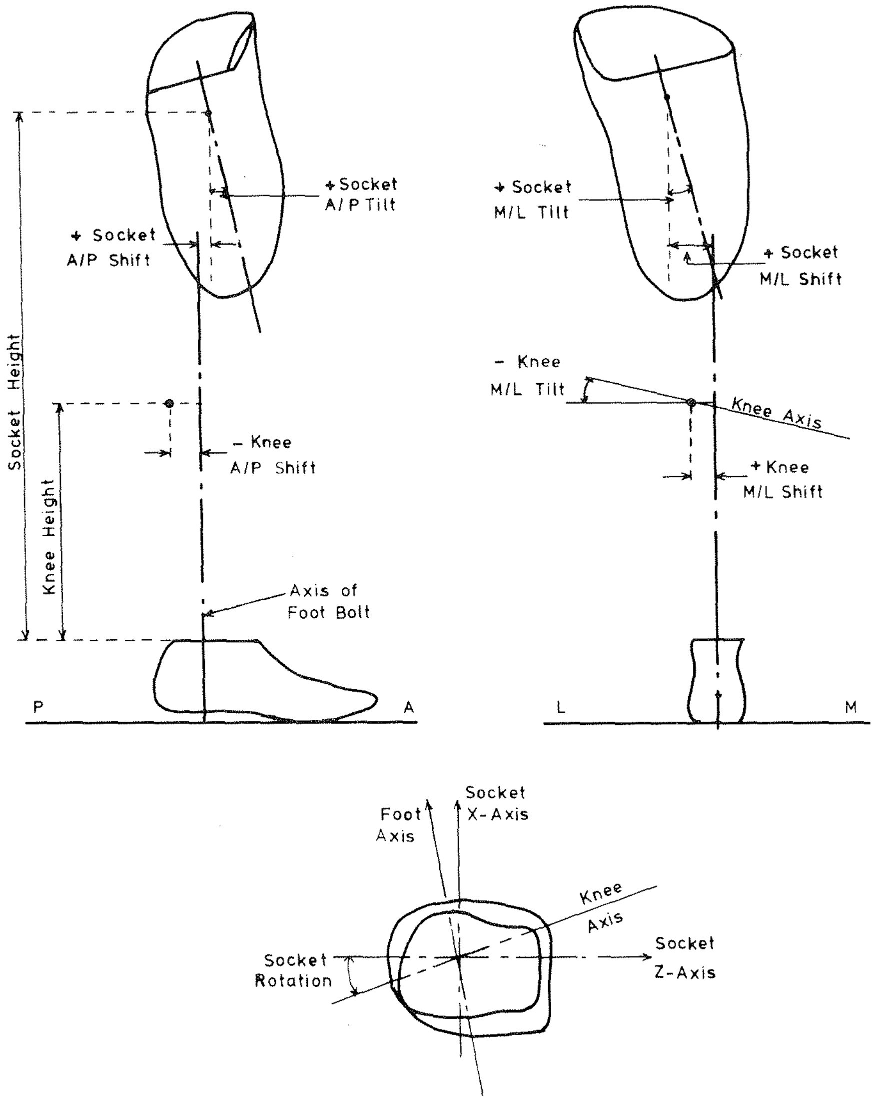

FIGURE 4
Definition of alignment parameters for above-knee prostheses.

Alignment information was collected from 283 fittings. The relevant alignment measurements of all these fittings were recorded. Due to the vast quantity of data collected and the complex interrelation between some of the parameters, it is not possible to discuss and present all aspects of the results so far acquired. However, as much information as is considered conclusive is presented in sample form and, where possible, generalizations are made. The results are presented in several sections for simplicity, although due to interrelations of some sections, an overall view must be considered.

Accuracy and Repeatability of Measuring Systems

As it was anticipated that there would be small changes in the parameters to be studied, it was necessary to evaluate the accuracy and repeatability of every measuring system used in this project and therefore ensure true detection of these small changes. The alignment measuring technique gave rise to several types of errors.

The source of these errors can be classified into two regions: First, errors due to the socket axis locator mechanism and its linearity of movement, operator error, and the error of marking the located point. Second, errors involved in the actual measurement of any one particular reference point due to inaccuracies in the measurement apparatus.

The accuracy of the technique was investigated by measuring (10 times) a known point in space outside the socket, a point inside the socket, and finally marked points inside the socket after spotting with the socket axis locator. The error of the measurement system was found to be ±0.5 mm. However, once each socket was marked, the same points were used throughout the investigation (as the same socket was used). Therefore the only error in the measurement of alignment was of the second type.

To determine this error, one below-knee and one above-knee prosthesis with marked sockets, for location of the socket axis, were each measured 10 times. The alignment parameters were calculated on each occasion and the mean of the largest differences represents the error of measurement and the degree of repeatability. The errors, contained in Table 3, show an overall accuracy of within ±1 degree in tilts and ±1 mm in shifts.

Repeatability of Achieving Optimum Alignment and Establishing the Range

Patient No. 2 BK was dynamically aligned by one prosthetist 19 times over the 2-year time period. Each final alignment was checked for its quality by other prosthetists. It was noted that the prosthetist did not repeat a given alignment every time, and a number of alignments were acceptable to both patient and prosthetist. Figure 5 shows a scaled diagram of the various alignments that were acceptable to the amputee. In the diagram the foot has been fixed and the position of the socket axis corresponding to each alignment has been superimposed. In Figure 5 only one socket has been outlined to illustrate the type of prosthesis and plane of view, however; each axis line contained within that "illustrative socket" represents the axis of the socket in a

TABLE 3
Alignment measurement errors.

Parameter	Below-knee	Above-knee
AP tilt, degree	±0.5	±0.9
ML tilt, degree	±0.4	±0.6
ML shift, mm	±0.6	±0.7
AP shift, mm	±0.6	±0.9
Toe out, degree	±1	±1

TABLE 4
Range, mean, and standard deviation of alignment parameters for below-knee subject No. 2 with prosthetist No. 1.*

	Socket Shifts, mm		Socket Tilts, deg		Toe Out/In, deg
	AP	ML	AP	ML	
Range	12→28	−15→28	8→12	2→7	−2→9.5
Mean	14	0.5	9.1	5.8	7.0
SD	3.1	5.2	1.94	2.3	3.0

*See Figure 5.

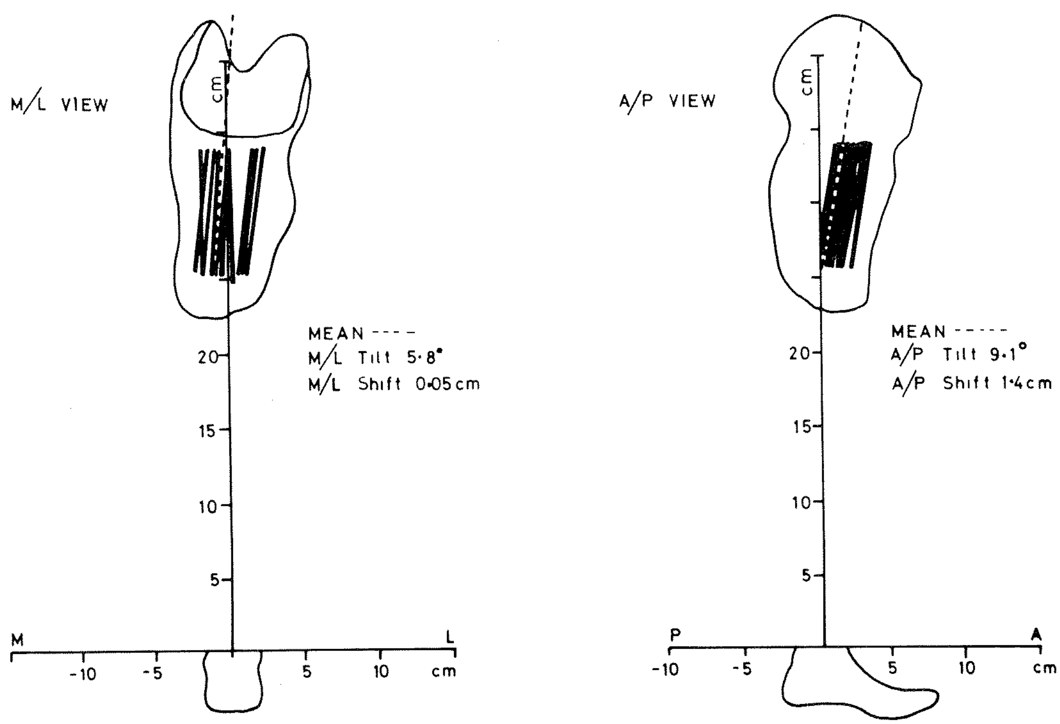

FIGURE 5
Nineteen different acceptable alignments by prosthetist No. 1 for patient No. 2 below knee.

new position. This illustrative technique is also used for the above-knee results displayed in this article. Table 4 shows the range and the mean of all the measured values of alignment parameters. The standard deviation has been calculated assuming a normal distribution of the data on patient No. 2 BK from Table 4; it can be seen that different alignment parameters cover a different range. For example AP shift ranges from 12 to 28 mm, while ML shift ranges from −15 to 28 mm.

It must be emphasized that although each of these alignments was equally acceptable to the patient, not all geometrical configurations within this range were acceptable; this leads to the conclusion that only specific positions of the socket relative to the foot were acceptable. This phenomenon was confirmed by altering the alignment of an acceptably aligned prosthesis by a small amount within the determined range, e.g., by 1 degree in AP tilt. This resulted in an alignment unacceptable to the patient and prosthetist. This procedure of performing small mal-alignments on a prosthesis was used to gain a biomechanical understanding of amputee gait and is described elsewhere (20).

When other prosthetists dynamically aligned the same patient, the effect was to produce individual ranges of alignments specific to the prosthetist (Fig. 6). The range achieved by each prosthetist is shown by the boundary limits illustrated by a pair of matched lines. The ranges for various prosthetists are seen to overlap each other and have the effect of increasing the overall range of acceptable alignments and therefore of increasing the patient's tolerance to alignment configurations. Table 5 shows the range, mean, and standard deviations of individual parameters when all three prosthetists were considered on patient No. 2 BK.

Considering the above-knee case when one patient No. 1 AK, was dynamically aligned on 14 occasions by one prosthetist, again, a range of acceptable alignments was found (Fig. 7). Table 6 shows the range, the calculated mean, and the standard deviation of the alignment parameters for normal distribution of the data. The addition of other prosthetists likewise increased the

TABLE 5
Range, mean, and standard deviation of alignment parameters for below-knee subject No. 2 for all prosthetists.*

	Socket Shifts, mm		Socket Tilts, deg		Toe Out/In, deg
	AP	ML	AP	ML	
Range	12→46	−15→28	8→13	−2→7	−2→12
Mean	15.9	1.4	9.7	5.32	8
SD	3.50	9.8	2.45	1.84	3

*See Figure 6.

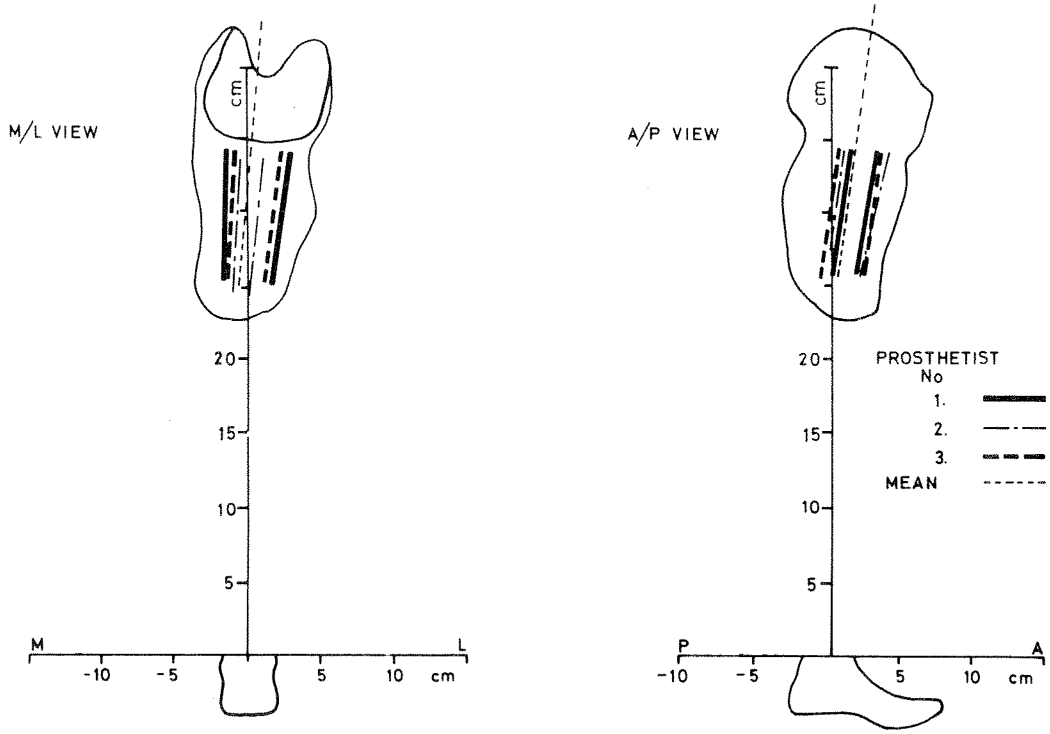

FIGURE 6
Range of alignments acceptable to patient No. 2 below-knee for different prosthetists.

tolerable range; Figure 8 and Table 7 show the results when three prosthetists are considered.

Similar patterns of results were obtained for the other below-knee and above-knee subjects. It was found that one prosthetist exhibiting a wide range of adjustment for one alignment parameter (e.g., socket AP shift) for one patient would not necessarily show the same wide range for another parameter, nor indeed for the same parameter on a different patient. This phenomenon also seemed to vary from the ML plane to the AP plane with no apparent pattern. Thus different prosthetists displayed different ranges of different parameters on different patients. There was, however, no indication that the values of the ranges were prosthetist dependent. Only the mean values of the alignment parameters were noticed to be similar for all the prosthetists. Tables 8 and 9 show the range of the acceptable alignments for the individual subjects.

At this stage of the data presentation it was not planned to compare individual parameters for various patients and prosthetists. This presentation is purely a demonstra-

TABLE 6
Range, mean, and standard deviation of selected alignment parameters for above-knee subject No. 1 with prosthetist No. 1.*

	Socket Shifts, mm		Socket Tilts, deg		Knee Shifts, mm		Knee Tilts, deg	Toe Out/In, deg
	AP	ML	AP	ML	AP	ML	ML	
Range	0 to 100	−50 to 85	−1 to 9	−2 to 8	−5 to 39	−20 to 15	−1.2 to 3.2	3/7.8
Mean	47	11	2.43	3.67	21.2	8.3	2	4.2
SD	35.8	63	3.92	5.42	1.05	22.6	1.8	3.4

* See Figure 7.

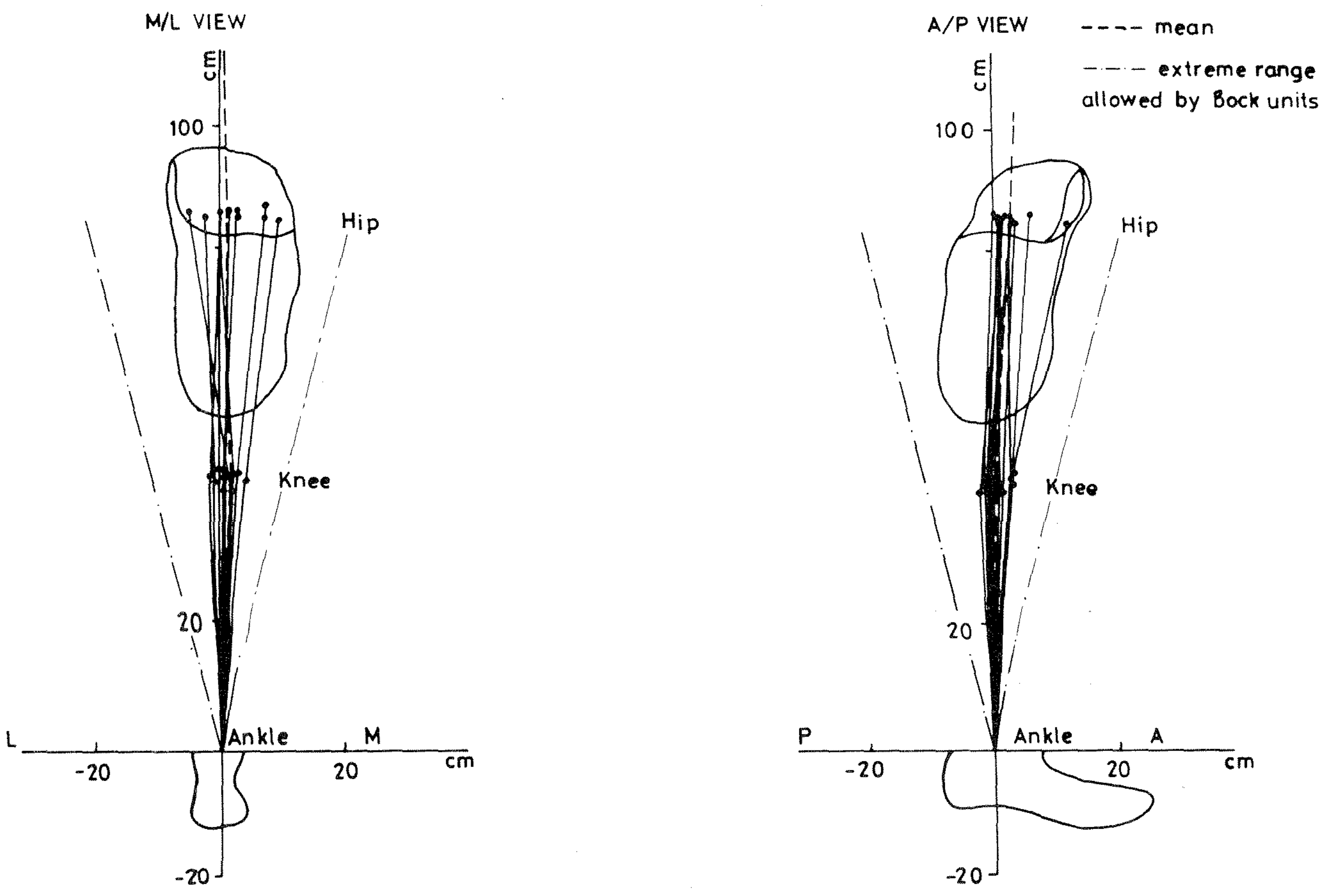

FIGURE 7
Fourteen different acceptable alignments by prosthetist No. 1 on patient No. 1 above-knee. Range of adjustment allowed by Otto Beck system is also shown.

TABLE 7
Range, mean, and standard deviation of selected alignment parameters for above-knee subject No. 1 with all prosthetists.*

	Socket Shifts, mm		Socket Tilts, deg		Knee Shifts, mm		Knee Tilts, deg	Toe Out/In, deg
	AP	ML	AP	ML	AP	ML	ML	
Range	−8.3 to 105	−61.5 to 85	−7.2 to 9.1	−2.7 to 14.2	−18 to 39	−58 to 15	−2.2 to 4.2	0.6 to 7.8
Mean	50	13.7	1.25	7.93	14.5	−28.1	3.16	2
SD	32.8	47.6	4.55	6.24	18.5	36.8	2.75	2.5

* See Figure 8

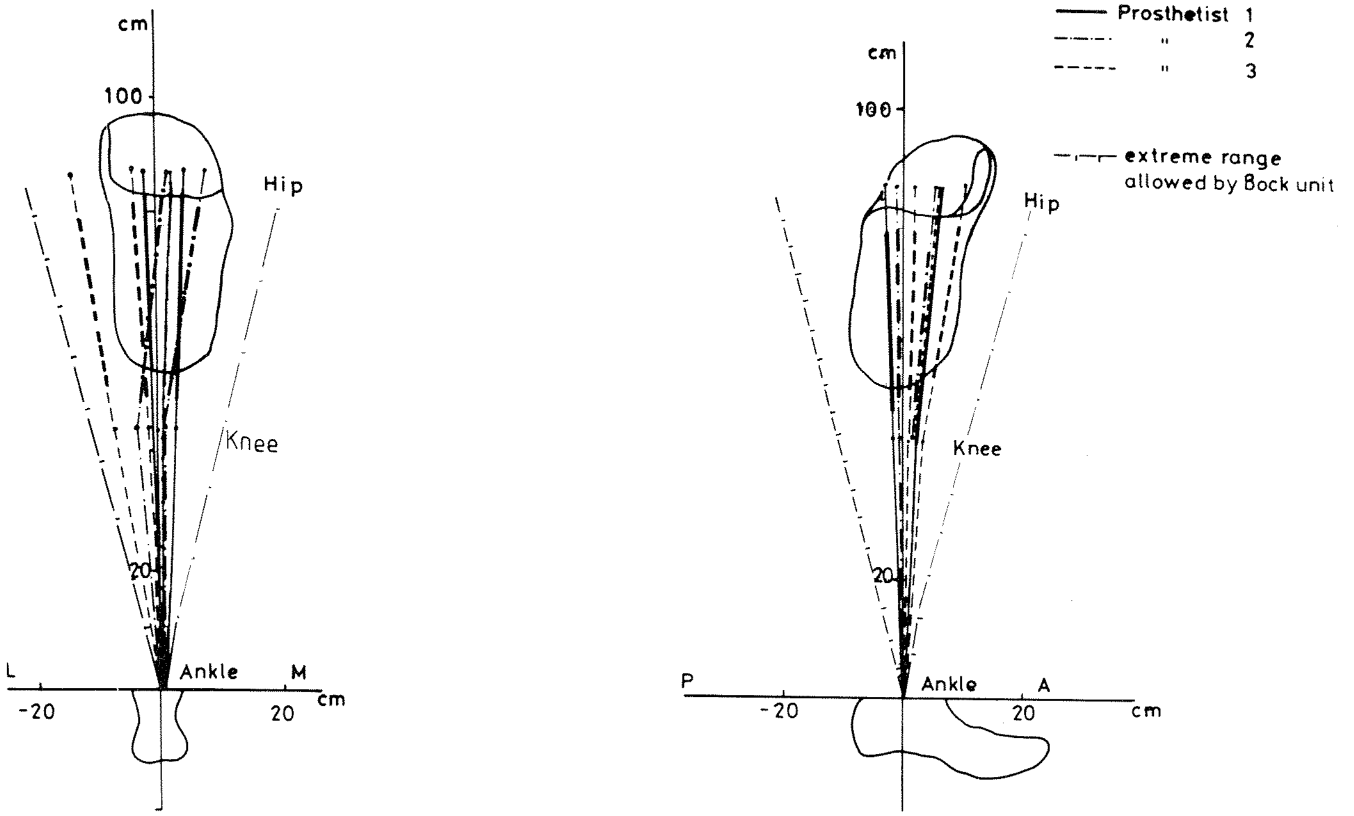

FIGURE 8
Range of alignments acceptable to patient No. 1 above-knee for three prosthetists. Range of adjustment allowed by Otto Bock system is also shown.

tion of the overall individual patient range, the mean, and standard deviation of the alignment configurations. The largest range of the acceptable alignment and the calculated mean of all the fittings for individual alignment parameters are then deduced. This forms the basis for the bench alignment and the required range of the adjustability for alignment units.

Table 10 shows the largest variation of alignment accepted by one patient when all prosthetists were involved. The values in this table indicate that a below-knee patient can be aligned on two occasions to produce alignment configurations which display a 111-mm difference in the AP positions of the socket, and yet that patient and three prosthetists were satisfied with the fit of the socket and the appearance of the patient's gait. Another below-knee patient under the same conditions displayed a 17-degree difference in the ML angulation of the socket. An above-knee patient displayed a 148-mm difference between two positions of the socket in the ML plane; this was still regarded by all concerned as an acceptable alignment. Even a parameter thought to be relatively simple to achieve, such as toe out, displayed a remarkable variation of 12 degrees and was always considered to be correct. The fact that not every position

TABLE 8
Range of alignment parameters for below-knee subjects, for all prosthetists.

Subject Number	No. of Fittings	Socket AP Tilt, degrees			Socket ML Tilt, degrees		
		range	mean	SD	range	mean	SD
1 R	30	−5.5 → 4.6	−0.6	1.94	1 → 10	5.9	2.34
2 R	42	8 → 13	9.7	2.45	−2 → 7	5.32	1.84
3 L	21	−2.5 → 5	0.5	1.67	−2 → 5.8	1.9	2.06
4 L	21	−3 → 4	3.6	0.35	−15 → 2	−6.8	2.36
5 R	21	−1 → 10	5.3	2.96	5 → 10	5.5	1.4
6 L	18	7 → 10.8	9.8	0.68	−10 → −2	−5.9	2.2
7 R	10	−5.2 → 5.9	−0.19	4.65	−6.6 → 1.7	−2.1	3.2
8 L	10	7.25 → 12	9.6	1.94	−8.3 → 2.6	−0.93	4.32
9 R	5	6.4 → 12.8	9.8	2.1	−0.9 → 8.3	3.28	2.68
10 R	5	−2 → 4.5	1.36	2.36	3 → 8	5.67	2.05
Overall:		−5.5 → 13	4.89	4.3	−15 → 10	3.53	3.19

Subject Number	No. of Fittings	Socket AP Shift, cm			Socket ML Shift, cm		
		range	mean	SD	range	mean	SD
1 R	30	−6.5 → 4.6	2.8	1.2	−1 → 1.2	0.645	0.52
2 R	42	1.2 → 4.6	1.59	0.35	−1.5 → 2.8	0.14	0.98
3 L	21	1.8 → 4.2	2.73	0.6	−1 → 2.8	0.47	0.73
4 L	21	1.6 → 5.2	3.3	0.83	−4 → 5	0.9	2.01
5 R	21	1 → 4.6	1.9	0.8	−2 → 1.8	−0.2	1.08
6 L	18	0.06 → 2.2	0.8	0.58	−1.8 → −0.4	−0.7	0.25
7 R	10	−0.8 → 1.8	0.2	0.85	−1.4 → 0.4	−0.6	0.28
8 L	10	2.4 → 6	4.63	1.43	0.1 → 2.75	1.2	0.98
9 R	5	2.9 → 4.55	3.51	0.81	−1.3 → 1.05	−0.04	1.08
10 R	5	−1.5 → 0.5	−0.7	0.68	−6.4 → 0.7	0.07	0.38
Overall:		−6.5 → 6	2.08	1.55	−6.4 → 5	−0.19	0.59

within these ranges leads to an acceptable alignment must be emphasized. The reasons behind this phenomenom are not fully understood. Perhaps by having a more readily applicable method of measurement, a greater understanding could be achieved. The results obtained display a greater-than-expected range, although all alignments were considered to be optimal.

Bench Alignment

The prostheses used for the below-knee amputees were initially bench aligned to the settings recommended by Radcliffe and Foort (14).

Lawes (9) measured the bench and dymanic alignment positions of one below-knee prosthesis. The bench alignment was first set by the prosthetist and then the limb was dynamically aligned. Two prosthetists repeated this procedure several times. The results from those measurements were analyzed in the present study, and it was found that each prosthetist produced an individual range of bench alignment settings and an individual range of dynamic alignment positions. Interestingly, but perhaps not unexpectedly, the range of dynamic settings was greater than the range of bench settings. This held good for both prosthetists although the range of values was different for each prosthetist.

For the above-knee prosthesis there are no simple recommendations for bench alignment settings other than those described by Radcliffe (13, 15) and the general guidelines laid down by the Otto Bock company (10). However, it is appreciated that the bench-alignment prescription is not as straightforward as for the below-knee patient. Many additional factors other than the purely geometrical relationship of the components have to be considered for the above-knee patient: the age and ability of the patient, both physical and mental condition, length and muscle power of the stump and the type of knee mechanism employed. It is because an artificial knee joint has to be employed with the consequent difficulties of control over this mechanism that the selection of a bench-alignment position is more difficult.

It is reasonable therefore to state that, the calculated mean position [Table 11, i.e., AP shift 20.8 mm, ML shift −1.9 mm, AP tilt 4.9 degrees, and ML tilt 3.5 degrees] of all the dynamically aligned below-knee prostheses is a good basis for future bench-alignment

TABLE 9
Range of the alignment parameters

Subject No.	No. of Fittings	Socket AP Tilt, degrees			Socket ML Tilt, degrees			Socket AP Shift, cm		
		range	mean	SD±	range	mean	SD±	range	mean	SD±
1 L	25	−7.17/9.1	1.25	4.55	−2.7/14.15	7.93	6.24	−0.83/10.5	5.00	3.28
2 R	21	−8.6/7.1	1.9	6.62	−7.2/−1.2	−2.84	5.3	2.1/5.8	2.98	1.48
3 R	13	−8.12/9.30	3.6	7.6	−1.88/3.4	0.83	2.52	−4.7/−0.3	−2.25	1.67
4 L	13	5.09/8.91	6.51	1.7	−0.4/3.89	+1.33	1.85	0/9.8	3.14	4.08
5 L	4	−6.2/−2.1	−4.96	1.01	−2.1/1.6	−0.38	1.69	2.5/3.1	2.76	0.27
6 R	4	−4.2/2.4	2.3	1.14	−12.3/−1.8	−8.3	3.95	2.1/7.6	4.68	2.8
7 R	9	−5.18/6.55	2.98	4.8	−6.06/1.57	−2.94	2.99	0.35/7.2	5.26	2.84
8 R	4	−4.2/2	−1.7	2.6	−3.09/1.2	−1.63	2	4.2/6.8	5.33	1.09
9 R	1	−3.2	−3.2		−4.8	−4.8		1.3	−1.3	
10 L	6	−9.2/−2	−6.3	2.73	−1.2/7.2	2.0	3.21	4.2/6.4	4.23	1.76
Overall:		−9.2/9.3	0.24	4.1	−12.3/14.15	2.74	3.25	10.5	3.24	2.2

TABLE 10
Largest range of alignment parameters accepted by individual patients.

Socket Shifts, mm		Socket Tilts, deg		Toe Out/In, deg	Level of Amputation
AP	ML	AP	ML		
111	90	11.1	17	12	below knee
113	148	17.4	16.8	11	above knee

TABLE 11
Calculated mean values of alignment parameters for all below-knee fittings.

	Socket Shifts, mm		Socket Tilts, deg		Toe Out/In, deg
	AP	ML	AP	ML	
Mean	20.8	−1.9	4.89	3.53	5.5
SD	15.5	5.9	4.31	3.19	4.5
Radcliffe/Foort's recommendation*	38.1	12.5	5	5	

* Reference 14.

positions, bearing in mind the prosthetist's ability to effect an increase in socket AP tilt to accommodate flexion contractures or any other such change as is deemed necessary. As stated, the above-knee patient presents an altogether more complex case, therefore the calculated mean (Table 12) is just that, but may form the basis for recommendation of a bench alignment position. It must be borne in mind that the mean was calculated from a fit, active amputee population.

DISCUSSION

Several aspects of the above findings merit individual discussion. However, there are other aspects such as the biomechanical evaluation of the effect of various acceptable alignments on the amputee's gait performed in this investigation that should also be considered. These will form the subject matter of a future publication.

The means and standard deviations that have been presented are calculated by using the statistical equations for the normal distribution of the data. It has been found, however, that the alignment positions are not uniformly distributed about this calculated mean. If the equations for the mean and standard deviation for a nonuniform distribution were used, the table of the mean of all below-knee and above-knee fittings would be slightly different.

In almost all of the above-knee cases the values of socket inclination revealed a greater divergence of attitude in the coronal plane than in the sagittal plane. In other words, when a prosthetist aligned a patient several times the socket AP tilt showed greater conformity to a particular attitude, e.g., 3 degree socket AP tilt compared with the ML plane which displayed a greater spread of results (e.g., −3, −2, 2, 5, 7 degrees). This was true irrespective of the size of the range. This suggests that the above-knee amputee can tolerate more variability in the ML direction than the AP. This is to be expected as the knee joint is locked in the ML plane but free in the AP plane. Should a locked knee be employed the variation in the AP plane parameter would be expected to increase.

This situation was not applicable to the below-knee case when some patients showed larger variability in one plane and some in the other. This variability for the below-knee amputee varied from prosthetist to prosthetist. It appears that a larger variability can be accepted by the below-knee amputee in all planes, which therefore gives more freedom to the prosthetist when positioning the respective components. The above was true for all the for above-knee subjects, for all prosthetists.

Socket ML Shift, cm			Knee ML Tilt, degrees			Knee AP Shift, cm			Knee ML Shift, cm		
range	mean	SD±	range	mean	SD±	range	mean	SD±	range	mean	SD±
−6.15/8.5	+1.37	4.76	−2.2/4.2	3.16	2.75	−1.8/3.9	1.45	1.85	−5.8/1.5	−2.81	3.68
−6.31/0.8	−2.45	2.84	2.16/5.58	3.38	1.4	−0.25/3.35	1.75	1.46	−2.58/0.35	−0.6	1.31
−2/2.8	1.09	2.68	−2.2/4.57	−1.8	1.08	−3/−0.8	−1.88	0.79	−1.90/1.95	−1.8	1.59
−0.6/1.95	−0.47	1.08	−4.57/0.4	−1.57	2.2	−0.4/0.8	0.28	0.48	−1.63/1.38	+0.13	1.18
−3.05/−1.2	−2.05	0.71	1.15/2.3	1.84	0.4	−2.5/0.2	−0.8	1.02	0.15/0.9	0.43	0.31
−2.1/1.2	0.03	1.13	2/8.2	5.25	2.17	1/3.5	2.18	0.89	−4.2/1.2	−0.2	2.4
−3.1/4.2	0.21	2.62	0/2.96	2.17	1.25	−0.8/3.2	1.37	1.47	−3.6/0.8	−1.07	1.49
−2.1/−0.4	−1.06	0.8	1.2/2.3	1.6	0.4	−1.2/1.1	−0.37	1.04	−1.2/0.2	−0.23	0.58
−2.4	−2.4		2.1	2.1	—	0.5	0.5	—	1.25	1.25	—
−2.5/3.7	0.60	2.23	−2.4/−0.6	−1.8	0.8	−2.3/−0.4	−1.10	0.9	−2.1/1.7	−0.8	1.77
−6.31/8.5	−0.4	1.38	−4.5/8.2	1.01	2.5	−3/3.9	0.35	1.27	−5.8/1.95	−0.04	1.11

prosthetists. A crucial difference between the two levels of amputation is, of course the absence or presence of the natural knee joint and its intact controlling mechanism. The above-knee amputee cannot control the prosthetic joint out with certain limits and therefore the possible variability of alignment in the AP plane is, by necessity, reduced.

To date, from the partial analysis of the data, it appears that there is a correlation between some of the alignment parameters. Relationships appear to exist between socket AP shift and socket AP tilt, and between ML shift and tilt for the below-knee amputee. Because there are more parameters for the above-knee case, the analysis becomes more complex. Figure 9 shows that there is an approximately linear relationship between knee set back and socket AP tilt when all fittings are considered. Interestingly, the gradient of the line of best fit appears to be dependent on the prosthetist rather than on any other variable. Radcliffe (14) suggested that when the socket is flexed beyond the suggested datum the knee should be set further back; in other words, a direct proportional relationship between socket flexion and knee set back was implied. Figure 9, however, shows the reverse, i.e., an inverse proportional relationship between socket flexion and knee set back. This situation has also been shown to apply to other types of prostheses, namely Hosmer, USMC, and Blatchford MAP (20).

By comparing the mean of all the values recorded from the below-knee prostheses with the values recommended (14) for bench alignment, it can be seen that the value for socket AP tilt 4.89 degrees is in very close agreement with the figure of 5 degrees from Radcliffe and Foort (14); socket ML tilt is not far removed at 3.5 degrees and 5 degrees respectively for bench alignment. However, the shifts show the largest discrepancy with a 38 mm AP shift attributed to Radcliffe and Foort (14), and a 20.8 mm to this study, and ML shifts of 12.5 and −1.9 mm, respectively (Table 11).

In considering the calculated means of the alignment parameters for individual below-knee patients (Table 8), it is noticed that there is a minimal variation between the values of the means of ML shifts compared with other parameters. Whether this is a significant indicator of the below-knee amputees mediolateral stability or due to a mathematical coincidence is presently unclear.

For the above-knee patient there are no data to compare with the mean figures obtained. The general recommendation by Radcliffe (15) that the socket should be flexed and adducted and that the knee should be set behind the load line has become the accepted standard. Blatchford (1) has recommended that the socket be in 5 degrees flexion and 2.5 degrees adduction and the knee be on the load line. This recommendation was prescribed for the Endolite prosthesis. From the work presented in this article (Table 12) the overall mean of the above-knee fittings shows less than 1 degree flexion and 3 degree abduction of the socket and the knee set forward by 0.75 cm. Interestingly, the mean ML tilt position of the socket is one of abduction. Independent EMG studies carried out by de Vries and Hermans (4) suggest that approximately 5 degrees abduction would provide more stability during ambulation of the above-knee amputee than with an adducted socket. The disparity in magnitude, but not in direction, could be due to differences in measurement of the socket angle or to all the sockets used in this study being initially set in adduction.

The range of angular and translatory movement required of the alignment units is an important feature in that it is necessary to provide enough adjustability for the prosthetist to achieve an acceptable alignment. The

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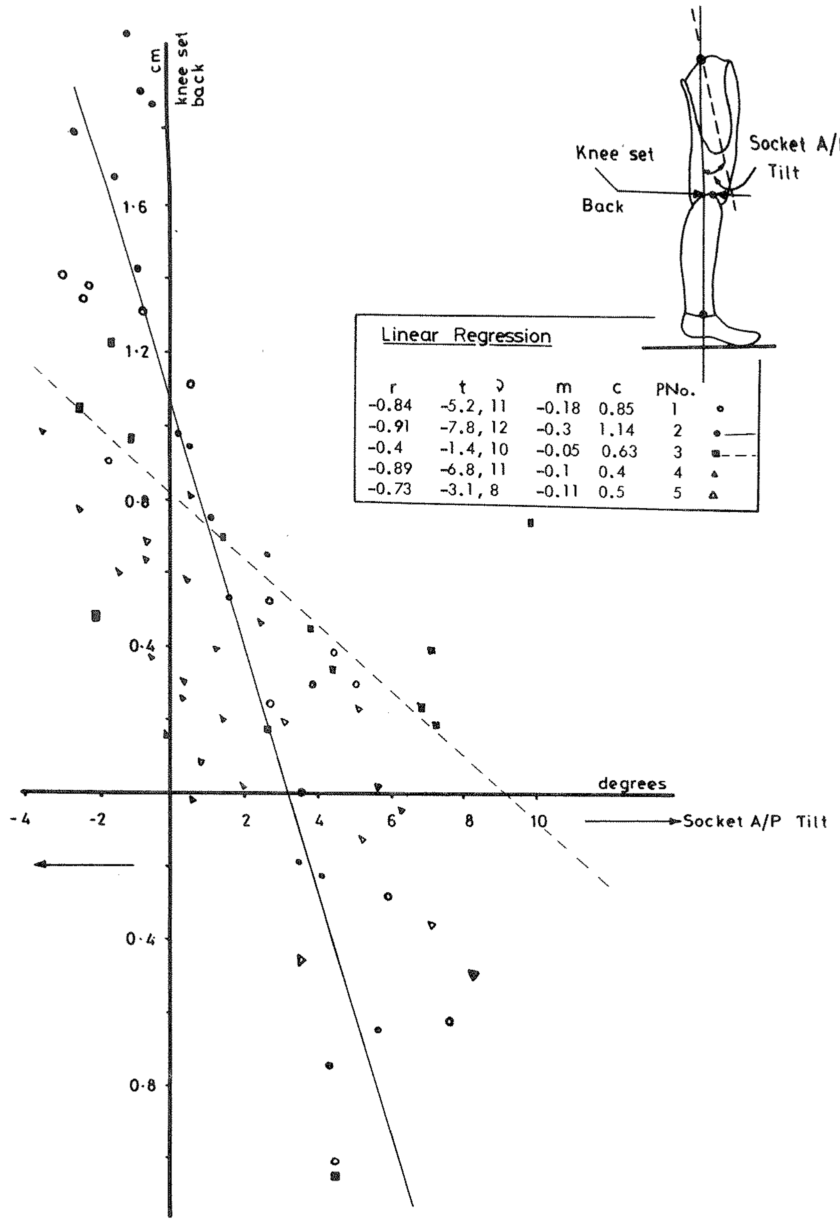

FIGURE 9
Relationship between knee set back and socket anterioposterior tilt for all prosthetists. r = correlation coefficient; t = Students t test; V = degree of freedom; m = gradient; c = intercept.

position of the alignment unit in the prosthesis, the ability to perform independent shifts and tilts, and simplicity of operation are thought to be additional requirements for achieving optimum alignment.

In reference to whether to transfer out the alignment device or to leave the unit in situ as an integral component of the prosthesis, some work done by Jansen (6) and Saleh et al. (16) is of importance. Jansen showed that the alteration in the position of the center of gravity of the prosthesis had an undesirable effect on the kinematic and kinetic parameters of the amputee gait. Saleh et al. (16) showed differences in 50 percent of their recordings between an aligned prosthesis and the same prosthesis at delivery, after transfer out of the alignment device. The large discrepancy between the weights of the limb at the two stages was held responsible for the many gait deviations observed.

Loss of alignment during transfer or manufacture, an ever-present source of frustration and annoyance to prosthetist and patient alike, can often lead to delay or even failure in the successful rehabilitation of the amputee. Until recently, no system was available that could accurately measure the alignment of a prosthesis with the subsequent inability to monitor any undesired alignment alterations. It has been shown that although more than one alignment configuration satisfies the

TABLE 12
Mean values for all above-knee fittings.

	Socket Shifts, mm		Socket Tilts, deg		Knee Shifts, mm		Knee Tilts, deg	Toe Out/In, deg
	AP	ML	AP	ML	AP	ML	ML	
Mean	32.4	−4.0	0.24	2.74	3.5	−0.4	1.01	3.2
SD	22	13.8	3.9	3.25	12.7	11.1	2.5	3.0

patient/prosthetist combination, a small deviation from one of these "acceptable" positions makes the alignment unsatisfactory; therefore, the need arises, not only for a measurement facility, but also for a better understanding of the alignment process.

Kerr et al. (1) described an "alignment protractor" which attached to a below-knee prosthesis and measured angular adjustments on the prosthesis. The quoted accuracy of this device was 1.5 and 3.0 degrees for AP and ML tilts, respectively. It should be noted however that, as shown in the list of errors of measurement of alignment parameters (see Table 3), an angular alteration of less than this magnitude can result in an unacceptable alignment configuration. It is therefore suggested that a clinically acceptable "tool" must be more accurate. Alignment devices should therefore fulfill the following criteria: *1)* They should be as lightweight as possible. *2)* They should not be removed from the aligned prosthesis, i.e., they are an integral part of the limb. *3)* They should fulfill the required range of adjustment. *4)* They should provide independent shift and tilt movements in both planes and have provision for toe-out adjustment. *5)* They should be easily manipulated by the prosthetist with a minimum of tools, yet be capable of adequate locking.

Comparing these criteria with the available units on the market (Table 13), it seems that the majority of the units fall far short of these requirements. In fact the only unit that satisfies most of the requirements is the Proteor Alignment Device (PAD) described by Palfray et al. (11).

When the range of operation of alignment units recommended by Foort (5) is considered, there seems to be a conflict of opinions (Tables 14 and 15). The ranges shown in these two tables are derived from the values presented in Tables 8 and 9 and are in some cases substantially larger than Foort's recommended values. For example, Foort recommended a ±38 mm adjustment facility for both AP and ML shifts. The values reported here indicate that a 120 mm range is necessary to accommodate alignment requirements in these planes. Additionally, the range reported here is not ±60 mm around the zero position, but an offset is required to take account of the fact that the range is biased to one side of the zero position that is −65 to 55 mm. The datum offset position must not be regarded as the bench or starting alignment position. The range of the alignment unit adjustability presented here is based on quantitative measurement of a statistically sound sample of finalized alignment configuration; this conflicts with Foort's values which are based on subjective observation. The topics of bench alignment, the range of adjustment of the alignment devices, and consideration of the calculated mean will be presented in greater detail in a future publication.

It is thought that there is one truly optimum position for each patient; therefore with an appropriate method of detecting and arriving at this position, the range of adjustment required of an alignment device could be reduced. However, any device designed for the measurement of prosthesis alignment must be capable of providing accuracy of measurement to within 0.5 degrees in angulatory terms and 2 mm in translatory terms. It

TABLE 13
Measured range of adjustment embodied by current alignment units.

	No. Units Required	Independent Shift/Tilt	Socket Tilt, deg		Socket Shift, mm	
			AP	ML	AP	ML
Blatchford	1	no	5.25	6	12.5	10
Otto Bock	2(3)	no	8	8		
Hosmer (AKAL)	1	no	25*	15	19	25
Hanger	2	no	7	7		
Staros-Gardner	2	no	6	6	28	16
PAD	1(2)	yes†	10	10	50	50

All values except * are from a datum of 0 ranging + or − around datum, i.e., bidirectional.
* Only a unidirectional movement.
( ) For above-knee.
† As claimed by manufacturer.

TABLE 14
Range required and associated offset position of alignment unit for design purposes.*

	Socket Shifts, mm		Socket Tilts, deg		Toe Out/In, deg
	AP	ML	AP	ML	
Range required (±)	60	60	10	13	12
Datum offset position	−5	−10	3	−2	0
Foort's recommendation (no datum offset) †	38	38	10	10	10

* Calculated from range of alignment for all BK fittings.
† Reference 5.

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TABLE 15
Range required and associated offset position of alignment unit for design purposes.*

	Socket Shifts, mm		Socket Tilts, deg		Socket Rotation, deg	Knee Shifts, mm		Knee Tilts, deg	Toe Out/In, deg
	AP	ML	AP	ML	In/Ex	AP	ML	ML	
Range required (±)	70	70	9	13	11	30	40	5	14
Datum offset position	30	10	0	1	4	10	−20	0.5	0
Foort's (1984) recommendation (no datum offset)	38	38	10	10	10	25			10

* Calculated from the range of all above-knee fittings.

becomes evident that the device described by Kerr et al. (7) is unable to detect small but important differences.

Finally, the system of measurement of alignment used in this investigation provided the static geometrical position of the prosthetic ankle and knee joints and assumed position of the hip joint on the prosthetic side relative to the top of the foot. These static positions were compared with those obtained from the stick/vector diagrams at mid-stance in both the AP and ML views using the Strathclyde TV/forceplate system.

Two sets of acceptable alignments were used for this purpose. Small differences between the measured alignment of a limb and its attitude during walking were apparent. These differences are due to the fact that the measured alignment is relative to the top of the SACH foot while the mid-stance alignment is relative to the ground. The obvious conclusion is that the top of the SACH foot is not parallel to the ground at mid-stance. It is unclear whether this phenomenon is due solely to the prosthetist's inability to observe this particular phase of the gait cycle, to natural compensation by the amputee, to the deformability of the foot, or perhaps a combination of these factors.

CONCLUSIONS

As it is not common practice to repeatedly align one prosthesis on a patient, far less to measure the alignment, its range of variability has not been considered before. The work reported here shows this variability to exist and provides a quantification for it.

The ranges of adjustment of the alignment parameters required to provide acceptable function in an above-knee and a below-knee prosthesis are established. These ranges are applicable to the specific group of patients considered, who were relatively active, but may not necessarily be applicable to the whole amputee population. For example, it is possible that the geriatric amputee population may not require such a large range.

The prosthetist could not repeat a given alignment at will. In fact a number of alignments were acceptable to the patient and prosthetist. Different prosthetists produced different ranges on any one patient, and these ranges varied on AP and ML views with different prosthetists.

A linear relationship has been shown to exist between socket AP tilt and knee AP shift in the above-knee amputee. The gradients of the lines of best fit describing this relationship are attributed directly to the individual prosthetist.

The amputee tolerance of accepting various alignments is undoubtedly related to the degree of control the amputee has over the prosthesis. From the pattern of the alignment configuration within the individual range of alignment for each patient, it is evident that the below-knee patient tolerated a greater degree of variability in alignment than the above-knee subject, suggesting that he has a greater control over his prosthesis. In the above-knee case there is a greater degree of sensitivity in the AP tilt of socket than the ML tilt, which is due to the presence of the uniaxial free prosthetic knee joint and its stability during stance phase. Thus specific restrictions are imposed on the prosthetist resulting in a small variability in the AP tilt of the socket.

The criteria for design of new alignment devices should be based on the ranges deduced for specific alignment parameters, minimum mass of the device, independent motion for each alignment parameter, permanent fixture in the prosthesis and incorporating the recommended basis for bench alignment.

The analysis performed so far on the data has revealed a nonuniform distribution of the alignment data, suggesting the existence of a true optimum alignment configuration which is not readily achieved by the present procedure of dynamic alignment.

From the results of this investigation, which show that prosthetists will accept various alignment configurations as optimum, it is evident that the prosthetists were unable to detect different geometries, different gait patterns and other parameters. There is obviously a need for a system which can assist the prosthetist to visualize the alignment of a prosthesis and guide him to the true optimum alignment. Such a system will incorporate a measuring facility with sufficient accuracy for detection of small alignment changes (as described). This would provide prosthetists with objective information on individual alignment adjustments and overall configuration, in addition to visual subjective observations.

The means for achieving the single optimum alignment for each patient/prosthesis will also require a rapid biomechanical evaluation of the amputee's gait and a comparative optimization procedure for kinetic/kinematic parameters. These topics will be the subject of future publications. ■

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Tracking skill of a deaf person with long-term tactile aid experience: A case study

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Abstract—This paper describes a case study of a single deaf individual who has been using a vibrotactile aid for approximately 13 years. He has acquired the ability to lipread speakers in three languages, using the speech-analyzing device that he and his collaborators have developed. The report describes his communicative abilities with and without the aid in his native language, which is Russian, and in English and Hebrew. When he was tested with the De Filippo-Scott connected-discourse tracking technique, the aid produced a considerable improvement in performance over that for unaided lipreading. The amount of improvement was a function of several factors, in particular his unaided lipreading rates for the different languages.

INTRODUCTION

The tactile senses are used extensively in the training of hearing-impaired persons. Often the student will feel the vibrations of a musical instrument or the pulsations of a balloon when the teacher "speaks" into it. There are also situations in which students place their hands on the teacher-speaker's face or feel the vibrations from their own faces or throats (2). These techniques are used for training in both speech perception and production; they are especially helpful for profoundly deaf persons. One reason for the importance of the sense of touch is that many significant features in speech are not transmitted visually. One system that relies almost exclusively on the sense of touch as the communication channel is called *Tadoma*. The technique, which has been employed by a small number of deaf-blind persons, consists of placing the hand on the face of the talker to sense the vibrations and articulatory movements of speech (see e.g., refs. 10, 12, 13).

The use of mechanical tactile aids to lipread has been confined mostly to brief experimental studies (see e.g., refs. 3, 6, 7, 14), with only a few notable exceptions. This situation has prevailed owing partially to the "bench-top" nature of most of the devices under test, as well as to the limits on the time available from typical laboratory subjects. There are now a few devices, however, that should permit long-term field tests in the natural environment. In this class of "wearable" aids, the Spens MINIVIB3, developed in Sweden, is one of the smallest. It transforms acoustical information into tactual sensations by amplitude-modulating a 220-Hz mechanical vibration so as to match the envelope of the speech signal (15, 17). Nearly 100 of the aids are in use in Sweden, and a smaller number are used elsewhere (16). Another commercially available mechanical aid that is used in the United States is the *Tactaid*, which is also a single-vibrator device, but one that involves a different mode of speech-feature detection. Approximately 200 of these devices are now in use (5).

The experience of any individual with either of the aforementioned aids, or with any of the research devices, has been extremely brief when compared with the number of years the average child spends learning to understand and produce speech. Even the most extended studies, such as those of Brooks and Frost (1) or

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