A Measurement Device to Assist Amputee Prosthetic Fitting

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A measurement device to assist in amputee prosthetic fitting is described. The device consists of a modular shank pylon instrumented with strain gages and a portable, microprocessor-based unit with a liquid crystal display configured together to measure and present biomechanical force versus time data. The root-mean square error from nonlinearity, crosstalk, noise, and drift was less than 5% of full-scale output for each of the six force and moment measurement directions. Preliminary data collected on below-knee amputee subjects indicated distinct features for different alignment settings, suggesting that algorithms could be developed to recommend alignment modifications based on the measured force data.

Index Under: Prosthetic Fitting; Measurement, Shank Loads During Ambulation; Shank Load Measurement; Amputee Prosthetic Device Fitting.

INTRODUCTION

Gait analysis laboratories have become useful clinical tools in several disciplines of medicine. For example, in presurgical assessment of children with muscular disorders, they provide quantitative information on joint forces and segment energies. These data can then be compared with that of normals to identify abnormalities that need correction (DeLuca, 1991). The gait data help to indicate which muscle groups need surgical modification (such as tendon transfers) to improve gait biomechanics. After surgery, gait labs provide quantitative outcome assessment and, therefore, a means for evaluating the effectiveness of the treatment.

In lower-limb prosthetics, gait analysis laboratories have served principally as research tools, but findings suggest they could be useful clinical tools for prosthetic fitting, as well. Characteristic features of the force versus time curves potentially serve as indicators of gait stability and prosthetic fit, particularly force and moment magnitudes, because they have a strong impact on the level of stress applied to the residual limb and to the energy demands on the amputee's muscles. For example, in a study comparing amputee gait for different prosthetic feet, knee extension moment maxima during early stance were negligible with a SACH (solid ankle cushion heel) prosthetic foot, although they were high (close to that of normals) for a Gressinger foot (Winter, 1988). Thus, the results suggest that the Gressinger foot allows the residual limb muscles of the knee and hip to act more normally than the SACH foot. In a study investigating amputee running, the knee extensor moment immediately after heel contact was essentially normal for a Flex foot but was significantly larger for Seattle and SACH feet (Czerniecki, 1991), suggesting

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that the Flex foot created a more normal gait. Temporal features of gait have also been suggested as indicators of fit. Timing of heel-contact to foot-flat was essentially normal for a uniaxial foot, although it was double of normal for a SACH foot (Goh, 1984). Stance/swing ratios were greater for a SACH foot than a uniaxial foot (Culham, 1984). An explanation is that, because the SACH foot had a rigid ankle, pivoting about the ankle axis was prevented; but with the uniaxial foot, a rear bumper allowed foot plantarflexion about the hinge joint. The gait lab findings suggest that, for an "inactive" amputee, a uniaxial foot might be better because the early foot-flat provides greater stability. In another study, stance phase durations were shown to increase significantly when the prosthesis was misaligned (Pinzur, 1992), suggesting that misalignment increased potential tissue breakdown and that stance phase duration may be an indicator of misalignment.

Although features indicative of fit quality have been suggested, gait labs are not typically used in prosthetic treatment. Part of the reason is the significant cost of a gait lab. Ground reaction force plates, a large computer (typically, a workstation), and a video tracking system are all expensive equipment. In addition, there are limitations in terms of clinical practicality:

- A large space is required for the force plates, data processing equipment, and video motion analysis system.
- Unless more than two force plates are used, no more than one stride of data can be collected in a trial. Thus, if statistical significance is to be achieved, many trials must be performed, which is not only time-consuming, but also can cause subject fatigue, affecting the data.
- Some subjects have difficulty hitting the force plates.
- From a computational standpoint, much off-line signal processing time is required to translate raw data into segment force data, limiting a clinician's capability to associate his or her visual assessment in the clinic with the postprocessed gait data.

Instrumented pylons overcome some of the above limitations. An instrumented pylon is a hollow shaft with strain-gages bonded to the outside surface, providing measurements proportional to forces in the shaft. The instrumented pylon replaces the section of the prosthesis between the foot/ankle and the socket alignment device. Because the measurement system is within the prosthesis, data from multiple steps can be collected, and extensive lab space for force plates and a video motion analysis system is not required. The instrumented shank is portable and relatively inexpensive. Instrumented pylons, however, provide only kinetic data in the prosthetic limb and thus reveal only a subset of information provided by a gait lab. But, as described above, force and timing data alone are useful to prosthetic fitting.

Several instrumented pylons have been developed. Many were designed exclusively to measure axial force, for use as feedback tools during the postoperative period by indicating a sound to the patient when a threshold weight-bearing level was exceeded (Moore, 1976; Miyazaki, 1986; Symington, 1979; Flowers, 1986; Cullen, 1990). For fitting of a definitive prosthesis, however, measurements in more than a single direction are desired. In three investigations, the prosthetic shank was instrumented with strain gages in an arrangement that allowed all six forces and moments to be measured simultaneously (Berme, 1976; Winarski, 1987; Morimoto, 1992). Data from the transducers were collected through a cable attached to a minicomputer. The transducers performed acceptably well in terms of sensitivity, but suffered from two principal limitations:

(1) Because of the physical size of the data acquisition system, subject mobility was limited. The long and bulky instrumentation cables potentially interfered with normal amputee gait.

(2) Processing was conducted off-line, limiting the capability to associate visual assessment of the subject with the gait data.

The purpose of this paper is to extend from previous instrumented shank research to make a mobile, self-contained system for shank force and moment display. The data are processed and presented in graphical form to the user almost instantaneously after they are collected. It is important to emphasize that this device is not intended to be an improvement on gait laboratories but, instead, an extension of them. The device is a tool to facilitate transmission and expansion of the knowledge gained to more widespread clinical practice. Also, selection of appropriate gait features indicative of fit quality is an in-progress research effort; thus, the system described below is a first step to achieving a practical prosthetic force measurement tool for fitting.

INSTRUMENTATION

The measurement device consists of an instrumented shank pylon and a *portable visual display unit* (PVDU) (see Figure 1). The instrumented shank is put in place of the usual pylon that integrates with the Berkeley alignment jig, and the cable is attached to the PVDU. The clinician carries the PVDU while walking behind the patient, or the cable can be extended and the PVDU placed in a stationary location.

The instrumented shank pylon is a 15.2-cm long, 4.13-cm outer diameter aluminum tube. Twenty metal foil strain gages (**Micro-Measurement Group** — Raleigh, NC) are mounted to the external surface (see Figure 2) to measure axial force (gage model CEA-13-125WT-350), torsion (EA-13-125TK-350), shear forces (CEA-13-125UN-350), and bending moments (CEA-13-125UN-350) in an orthogonal reference frame. A low-viscosity, slow-drying (1 hour at 175°C) bonding cement (M-Bond 610) is used in combination with a custom-designed spring-loaded clamping jig to ensure proper gage bonding. Completion resistors for two-arm Wheatstone bridges (see Figure 3) are

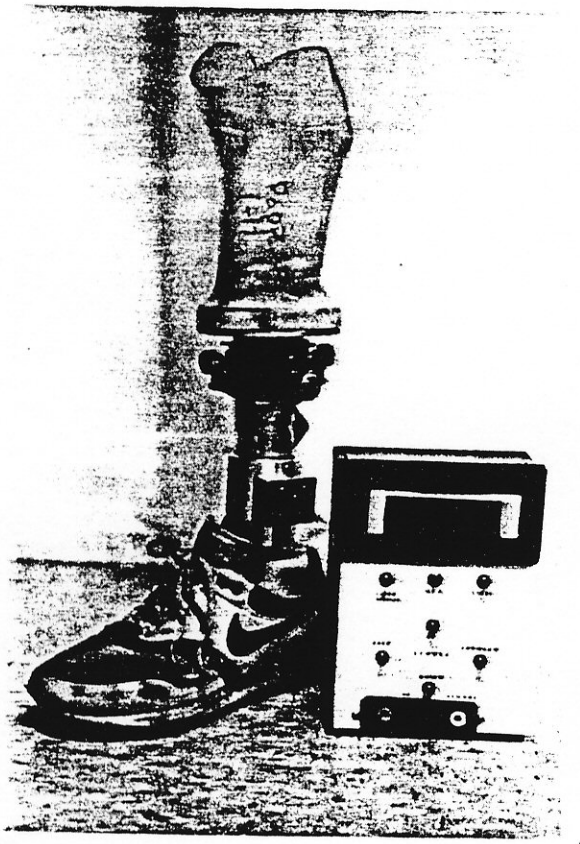

Figure 1
Prosthesis with the instrumented pylon (left) and the PVDU (right).

mounted in the cable connector attached to an aluminum shield concentric with the pylon. The shield is held in place with a set screw at a distance 4cm from the top of the pylon.

The instrumented shank is attached to a Berkeley alignment jig at the top and to a **Seattle™ LiteFoot (Model and Instrument Development Inc.** — Seattle, WA) at the bottom with snug-fit, insert-type connectors and single-slit collars. The connectors can be easily fabricated using lathe machining operations, and the collars are commercially available (**Boston Gear** — Quincy, MA). The inserts and collars, which replace some of the usual Berkeley jig components, are necessary to achieve uniform hoop stress in the pylon at the connections.

From the cable connector on the shield, a shielded cable with 14 conductors extends to a 20 cm × 18 cm × 5 cm and 250 gram PVDU that contains instrumentation for bridge balancing, radio frequency filtering, and amplification of each channel, as well as visual display of the data. The filter cut-off frequencies are 60Hz and do not affect the phase shift in the bandwidth of interest during walking. Amplifier gains to 10,000 are possible, but 4,000 are typically used in clinical studies. The bridge voltage is regulated to 5V.

For visual display of the data, the PVDU system contains a microprocessor-driven device capable of displaying a digitized representation of one of the six analog channels on a *liquid crystal display* (LCD). The main components in the system are an ADC0803 8-bit *analog-to-digital converter* (ADC), an **Intel** (Santa Clara, CA) 80C31BH microcontroller, an AND1101 graphic LCD (160 × 32 dot matrix) with internal *random access memory* (RAM) and controller, a 6264 static RAM, and a 2764 *erasable programmable read-only memory* (EPROM). Also present are a 74138 demultiplexer used in memory mapping and a 74373 latch for latching the eight lower address lines that were shared with the data bus. The system is powered using 9V batteries.

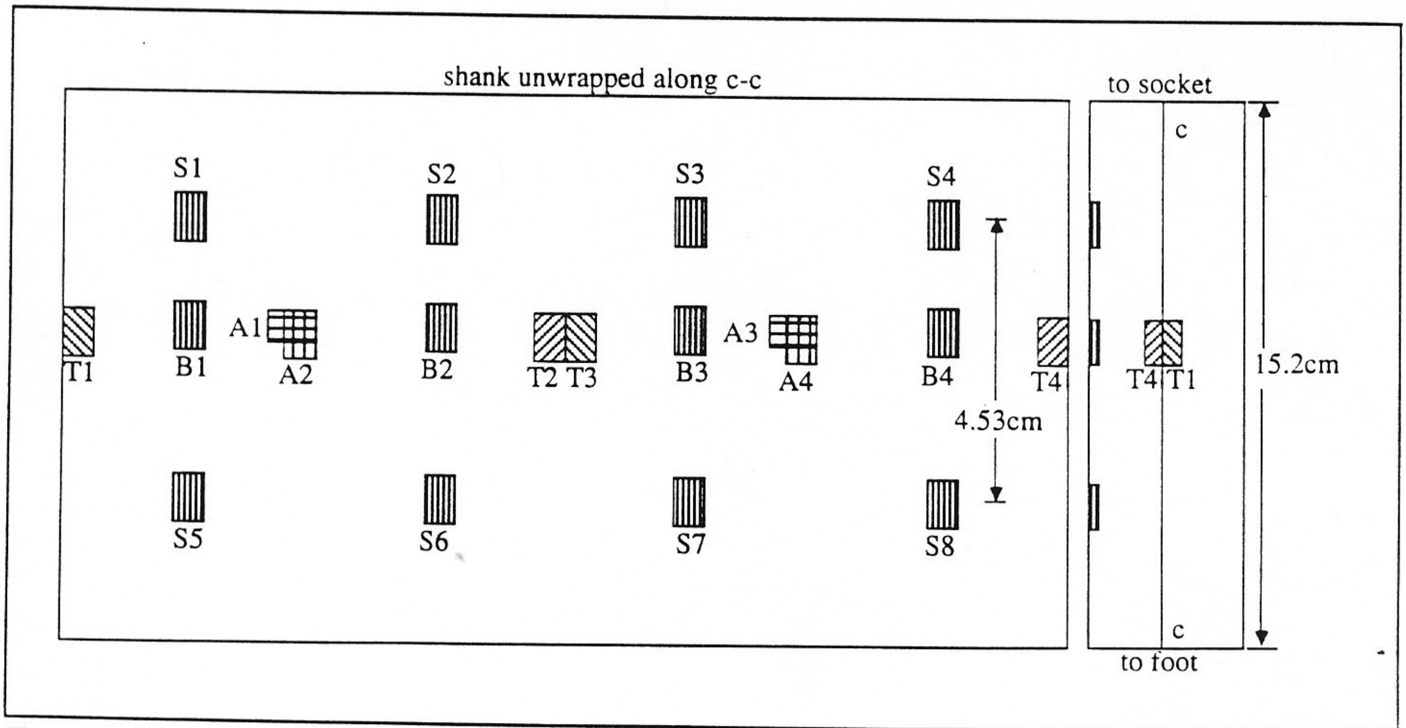

Figure 2
Strain-gage layout.

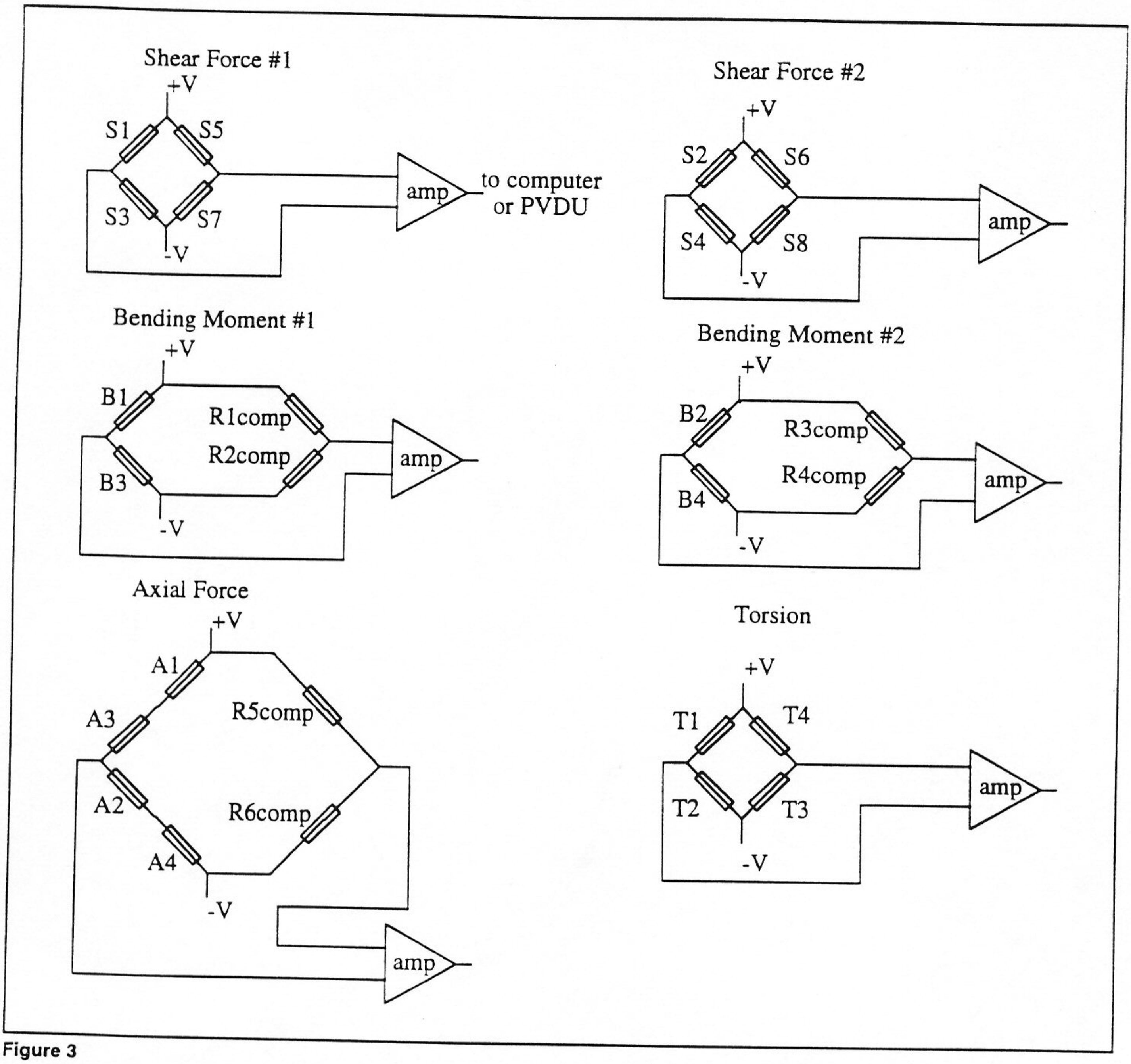

Figure 3

Bridge configuration for the instrumented pylon. S=shear force; B=bending moment; A=axial force; T=torsional moment; amp=amplifier; Rcomp=bridge completion resistor.

When the system is activated by depressing a reset button, the program stored in EPROM memory causes the ADC to sample the signal for ten seconds at approximately 130Hz. The converted samples are then stored in the system's RAM. When acquisition is completed, the stored samples are formatted and displayed on the LCD module. The data are presented in units of force or moment.

The use of scrolling and a graticule enhance viewing of the data on the LCD. For the horizontal direction, the time axis, interrupts to the main program allow a user to view a one-second-long display window that can be scrolled over the ten seconds of stored data, increasing the display resolution by ten times. The increased resolution allows the user to more easily identify unusual features in the data, possible indicators of an unhealthy gait. A graticule (a digital scale) on the left side of the display gives a numerical representation of both the time, measured relative to initiation of data collection, and the force level of the waveform where it intersects the graticule. The graticule gives the user quantified data that can be used to compare force magnitudes and timings from different steps and different trials.

PERFORMANCE

Calibration tests were conducted for each of the six force and moment directions in the instrumented shank. Axial force calibration was conducted using a uniaxial testing machine (**Instron Model #1122** — Canton, MA) at a loading rate of 0.05cm/min and a sampling rate of 1Hz. An A/D board (**Data Translation DT2801A**) and personal computer (**International Business Machines XT™** — Armonk, NY) were connected to the instrumented pylon in place of the digital portion of the PVDU. Tube inserts and single-slit collars were in place during testing.

For calibration in the remaining five directions, a different apparatus was used. One end of the shank pylon was held fixed in a dividing head on a milling machine, while the other end was loaded with weights through a custom-designed "T"-shaped jig that attaches to the end of the pylon. The "T"-shaped jig allowed calibration loads to be applied in each of the remaining five orthogonal force and moment directions. Static calibration in at least eight steps to *full-scale output* (FSO) was conducted for each of the five directions.

Calibration results showed good sensitivity with little crosstalk (see Table I). Nonlinearity was less than 2% for all channels.

Additional evaluation tests were conducted. Dynamic response evaluation showed the resonant frequency to be 250Hz. Noise, defined as the peak-to-peak voltage when the prosthesis was unloaded, was less than 1% FSO. Drift, assessed by measurement of changes in swing phase forces during eight-second trials on amputee subjects, was less than 1% FSO for all channels. Total RMS errors from nonlinearity, crosstalk, electronic noise, and drift were less than 5% FSO for all directions.

The PVDU was evaluated by storing data simultaneously to the PVDU and a stationary computer data acquisition facility, and then comparing the results. Evaluation showed that the PVDU performed within the resolution limit of the LCD's 160 × 32 matrix dimensions.

PRELIMINARY STUDIES

The device was used to study the effects of prosthetic alignment modifications on below-knee amputee gait. The time to set up the system was approximately 15 minutes. Data were collected at three alignment settings: zero (optimal alignment as deemed by a team of prosthetists), dorsiflexion, and plantarflexion. No translational adjustments were made to accommodate the angular modifications. The alignment angle adjustments were measured relative to the center of rotation of the Berkeley jig using a custom-designed device (Sanders, 1990). Subjects walked to the cadence of a metronome set at 95 steps/minute. Interface stress measurements were collected simultaneously using instrumentation described elsewhere (Sanders, 1993); however, those measurements are not included in the analysis presented here.

Data were collected on three unilateral below-knee amputee subjects. All were amputees because of a traumatic injury, and none had diseases or abnormalities other than their amputated limb. They ranged in age from 23 to 46 years and had been amputees for 4 to 8 years. Approximately 60 steps of data were collected at each alignment setting in each of nine data collection sessions.

There were differences in the force-time data for different alignment settings. For example, the sagittal plane bending moment in early stance phase changed from negative to positive at a later time for plantarflexion than for dorsiflexion alignment for all subjects. Figure 4 shows the sagittal bending moment for three steps from one subject, one at each alignment setting. The difference for different alignments can be explained. For the plantarflexion setting, the foot was quickly forced to foot flat at heel contact, causing the body to be propelled forward over the pylon

TABLE I
Error for the Instrumented Pylon

	Bending Moment	Shear Force	Axial Force	Torsional Moment
Nonlinearity	1.12%	1.4%	0.37%	1.37%
Crosstalk*	1.7%	4.0%	1.4%	2.3%
Noise	0.27%	0.27%	0.16%	0.10%
Drift**	0.01%	0.01%	0.38%	0.02%
Total RMS error	2.0%	4.2%	1.5%	2.7%

*with all other directions loaded to FSO.

**average from three 30-minute sessions.

All results are presented as a percentage of full-scale output. The average for the two orthogonal directions are shown for data for the bending moment and shear force channels.

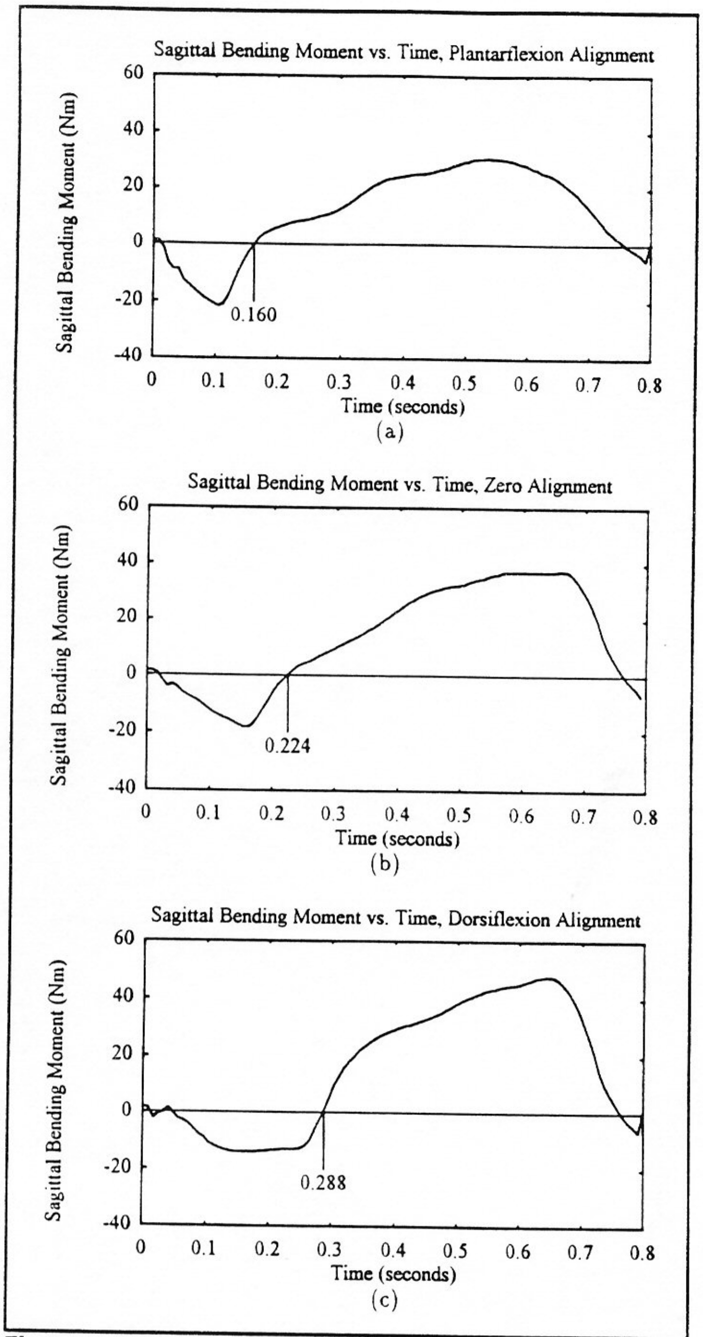

Figure 4

Sagittal plane bending moment from three steps for a single amputee subject (Subject #3). Alignment settings: (a) plantarflexion (-9°); (b) zero; and (c) dorsiflexion (5°).

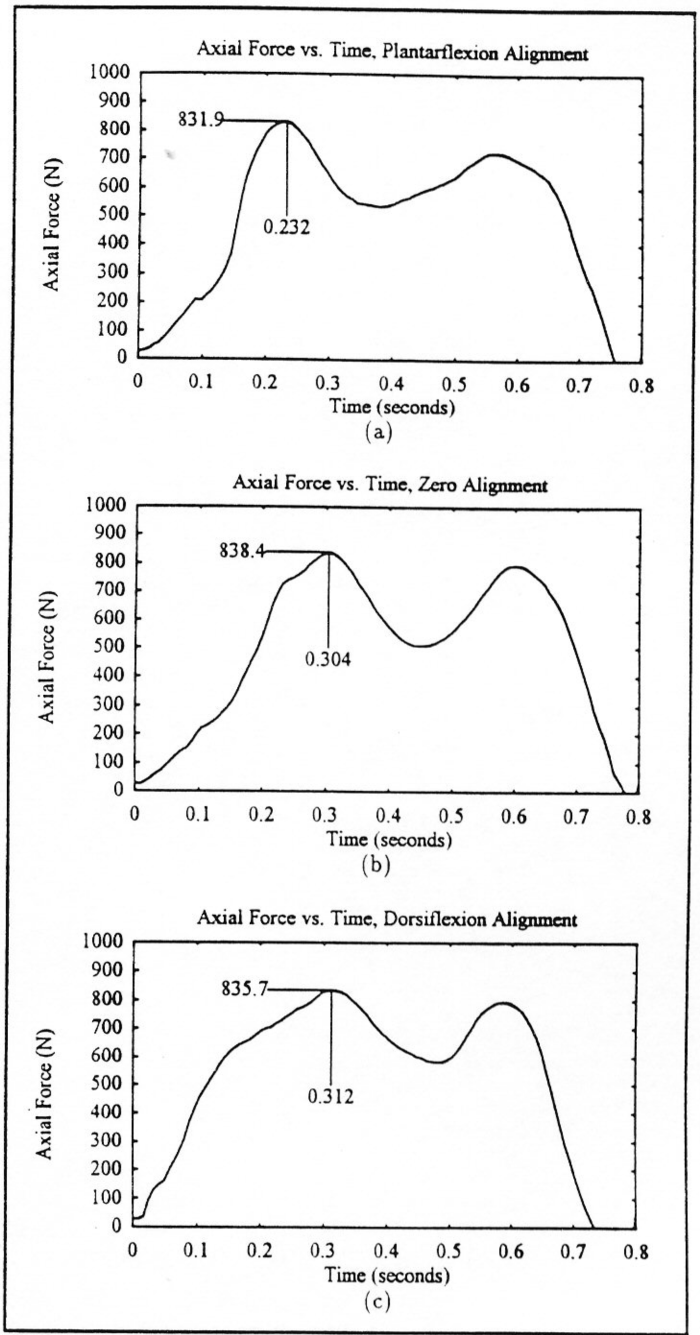

Figure 5

Axial force from three steps for a single amputee subject (Subject #2). Alignment settings: (a) plantarflexion (-5°); (b) zero; and (c) dorsiflexion (8°).

axis quickly. At the dorsiflexion setting, the opposite occurred. Other gait features, however, showed minimal change. For example, the difference in peak axial force during stance phase for different alignments was minimal for all subjects (see Figure 5). It is likely the amputees compensated their gait to achieve consistent interface stress levels on their residual limbs, accomplished by maintaining consistent prosthetic shank maximal axial forces.

Off-line processing was conducted to investigate the consistency of correlations between prosthetic alignment and gait features among all three subjects. If consistent changes could be found, then potentially, feature values could be used to identify misalignment and indicate appropriate alignment modifications during a fitting session. To conduct the correlation analysis, a Pearson matrix was generated, and absolute values of the coefficients for the following features determined: timings of the change in polarity of sagittal plane bending moment normalized to stance phase duration; and force maxima normalized relative to weight. The results are presented in Table II.

The results indicate a finding that is opposite of that determined from visual assessment of the force-time curves for the single subjects described above. Alignment correlations were poor for the sagittal bending zero-crossing, while they were relatively high for the axial force

TABLE II
Pearson Correlation Coefficients between Gait Force Data Variables And Prosthetic Alignment Angle

Variable	Absolute Value Of Correlation Coefficient
Timing of the negative to positive transition in the sagittal bending moment normalized relative to stance phase duration	0.199
Maximal stance phase axial force normalized relative to weight	0.453
Ratio between the first and second peaks in axial force	0.653

Approximately 130 steps for each subject were used in the analysis.

magnitudes (see Table II). As stated above, and as shown in Figures 4 and 5, data for single subjects showed the opposite trends. Further, correlation coefficients could be improved by considering the ratio of the first maxima to the second maxima in the axial force curve. The absolute value of the correlation coefficient with alignment for the ratio was greater than that for the maximal axial force normalized relative to weight.

DISCUSSION

To date, prosthetic fitting procedures are typically based on nonquantitative methods of assessment. A prosthetist will use his or her visual inspection of gait and prosthetic fitting experience to design and fit a prosthesis to an amputee patient. Minimal quantification is involved. Although the methods have proven effective, they are limited because much time is required to carry out the fitting procedure, and effective fitting requires a clinician with extensive prosthetic fitting experience. Because studies indicate that there will be a shortage of qualified prosthetists in the next decade (Hughes, 1992), tools to facilitate the speed and standardization of alignment fitting are needed.

In prosthetics research, gait analysis laboratories have provided useful information on amputee gait. Features of the force-time curves suggest that there exist correlations with prosthesis fitting parameters. Possibly, quantification could enhance fitting by providing information to the clinician that would allow him or her to more quickly and effectively fit the prosthetic limb to the amputee patient.

The tremendous expense of gait labs and clinical practicality issues, however, has limited their widespread clinical use in prosthetics. The described system is a simple, inexpensive device that reduces these difficulties.

The described device has both strengths and limitations. It performs well in terms of instrumentation linearity, crosstalk, noise, and drift error and is relatively easy to use. The device integrates with a Berkeley jig, a popular alignment unit for over 20 years, but one that is slowly being replaced with more lightweight systems. The device needs to be modified to integrate with those new assemblies. An ideal design would be a thin, six-axis load cell inserted between the socket adaptor and socket that could integrate with many of the newer systems.

The existing device, in our preliminary studies, was shown to provide data indicative of fit. For each of three subjects, the force-time curves demonstrated differences for different alignment settings. In particular, the timing of the change in direction of the sagittal plane bending moment differed for different alignments. It is interesting to note, however, that the correlation between alignment and timing of the sagittal bending polarity change across subjects was relatively poor, suggesting that, for a single alignment value, the timings were not consistent for all subjects.

For axial force maxima, however, normalization of subject weight was effective. That normalized feature showed good correlation with alignment. The ratio of the first to the second peak in the axial force curve correlated even more strongly with the prosthetic alignment. Thus, if a generalized algorithm were to be developed to suggest alignment modifications based on gait data, the ratio of axial force first peak/second peak would be a more appropriate feature compared to axial force normalized by weight or timing of the negative to positive change in the sagittal plane bending moment.

Further research on more subjects is needed to verify the above findings and to identify further important features relevant to fit so as to be able to make clinically relevant generalizations about the force data. Also, larger datasets than those used here are needed to reduce error in the correlation analysis. In addition, the process of relating the quantitative data to prosthesis modifications is an ongoing research effort in which feature selection is based on a sound correlation with clinical interpretation.

Once a reliable set of features is identified, it potentially can be incorporated into the PVDU microcontroller program and the results displayed shortly after data collection is completed. The information would be useful for fitting. The device would not necessarily improve time efficiency of fitting, however, unless used by clinicians familiar with the features and their meaning. New users of the device might find it takes longer than using traditional methods.

To substantially reduce prosthetic fitting time, the device needs to be extended by incorporation of an *artificial intelligence* (AI) system. The AI system should interpret the gait feature data, determine the appropriate alignment adjustment, and present it to the user.

Layered perceptron *artificial neural networks* (ANNs) would be ideal AI systems for this application because they learn by example. After being presented data for known degrees of misalignment, the ANNs can then predict alignment adjustments for new data. The ANN software program could be incorporated into the microcontroller and the result presented to the user on the LCD.

CONCLUSIONS

A system to measure forces and moments within the shank portion of a below-knee amputee prosthetic limb was developed and shown to be accurate to within 5% of FSO. A portable visual display unit collected and displayed ten seconds of data on an LCD and allowed further inspection of the data via scrolling and a graticule.

Preliminary data collected on three amputee subjects showed distinct features in the force-time data for different prosthetic alignment settings. The magnitudes of the features were not the same for all subjects, however, indicated by low correlation coefficients. Correlations were improved by normalization.

The results suggest that further work is necessary to make the instrumentation lightweight and more compact, and to further investigate correlations between shank forces and fit parameters. The goal is to develop a useful prosthetic fitting tool to improve the quality and time efficiency of the prosthetic fitting process.

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Joan E. Sanders received her B.S. degree in Mechanical Engineering from Stanford University in 1983, M.S. degree in Mechanical Engineering from Northwestern University in 1985, and Ph.D. degree in Bioengineering from the University of Washington in 1991. From 1991 to 1993, she directed Bioengineering Research at the Prosthetics Research Study in Seattle, and now holds a faculty position in the School of Engineering at the University of Washington. She is a member of the Institute for Electronic and Electrical Engineers (IEEE), RESNA, International Society for Prosthetics and Orthotics, American Society of Mechanical Engineers (ASME) and Biomedical Engineering Society. Her research interests are in application of innovative engineering methods to enhance prosthetic treatment, and development of techniques to assess skin response to mechanical stress and improve skin mechanical quality.

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