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Direct Measurement of 3D Force and Moment on Lower-Limb Osseointegrated Fixation

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Abstract— **Occasional mechanical failures is a concern for transfemoral amputees using osseointegrated fixation. Understanding the true load applied on osseointegrated fixation is one important step in solving this problem. Conventionally, the load magnitude can be calculated based on the motion of the prosthesis and the ground reaction forces measured by a force plate using inverse dynamics. However, this approach allowed only one or two walking steps to be measured and errors are compounded when involving more than one joint above the ankle. In this study, the load applied on the lower-limb osseointegrated fixation was directly measured with a load transducer. Twelve transfemoral amputees fitted with a fixation and their usual prosthesis (knee and foot) were assessed during approximately 51±12 normal walking steps in straight line. Three-dimensional force and moment local extremas and patterns at the fixation along a gait cycle were displayed. Step-to-step variability of each subject was low. This tends to validate gait laboratory-based studies focusing on one or two steps. High subject-to-subject variability was demonstrated. This could be due to the wide variety of components, alignments and anthropometric characteristics within the tested population.**

Keywords:* *Gait, Transducer, Variability, Transfemoral amputation, Osseointegration, Prosthetics.

I. INTRODUCTION

Conventional socket-type lower limb prosthesis sometimes induces problems of residual limb pain and soft tissue breakdown [1]. A new surgical approach developed by Dr Rickard Brånemark for a direct anchorage into living bone using a titanium implant (osseointegration) may help to alleviate these problems [2]. External prosthesis is attached to an osseointegrated implant. This technique is considered for transfemoral amputees presenting complications while using a socket-type prosthesis [2,3]. So far, there are over 80 amputees were fitted with lower-limb osseointegrated fixation world-wide.

The quality of life of the recipients of the fixation was significantly increased through improved comfort, walking and sensory feedback [2,3]. However, some occasional mechanical failures of fixation have been reported. This problem occurred essentially due to a bending of the fixation following a fall of the amputee [3]. This problem must be addressed as it represents a potential hazard for the amputees. Furthermore, there is a need for further improvement of the mechanical design of different prosthetic components for amputees of osseointegrated fixation, such as hydraulic knees, torque protective devices shock absorbers, etc.

Knowing the true load applied on the residuum is one important step to the design improvement of the fixation. Conventionally, the load magnitude can be calculated based on the motion of the prosthesis and the ground reaction forces measured by a force plate using inverse dynamics, [4]. The drawbacks, however, are that only one or two steps of walking can be measured, alerted gait can be produced due to force-plate targeting [5], accurate determination of material inertia of limb segments are needed, and errors are compounded when involving more than one joints above the ankle. Recent studies have described the direct measurement of the forces and moments applied on the residuum of transfemoral amputees fitted with conventional socket [6] or osseointegrated fixation [7,8] using a load transducer and recording device (telemoden or data logger). Unfortunately, these studies focused on small size sample.

The aim of this study was to measure directly the true load applied on the osseointegrated fixation for twelve transfemoral amputees during normal walking in straight line in the view of analyzing (A) the step-to-step (intra) variability within subjects and (B) the subject-to-subject (inter) variability. Amputees were fitted with their usual prosthesis and alignment in order to assess the true inter variability among different subjects and prostheses set-up.

II. METHOD

Participants

A total of twelve transfemoral amputee subjects fitted with osseointegrated fixations, representing approximately 15% global population in 2003, participated in this study. All

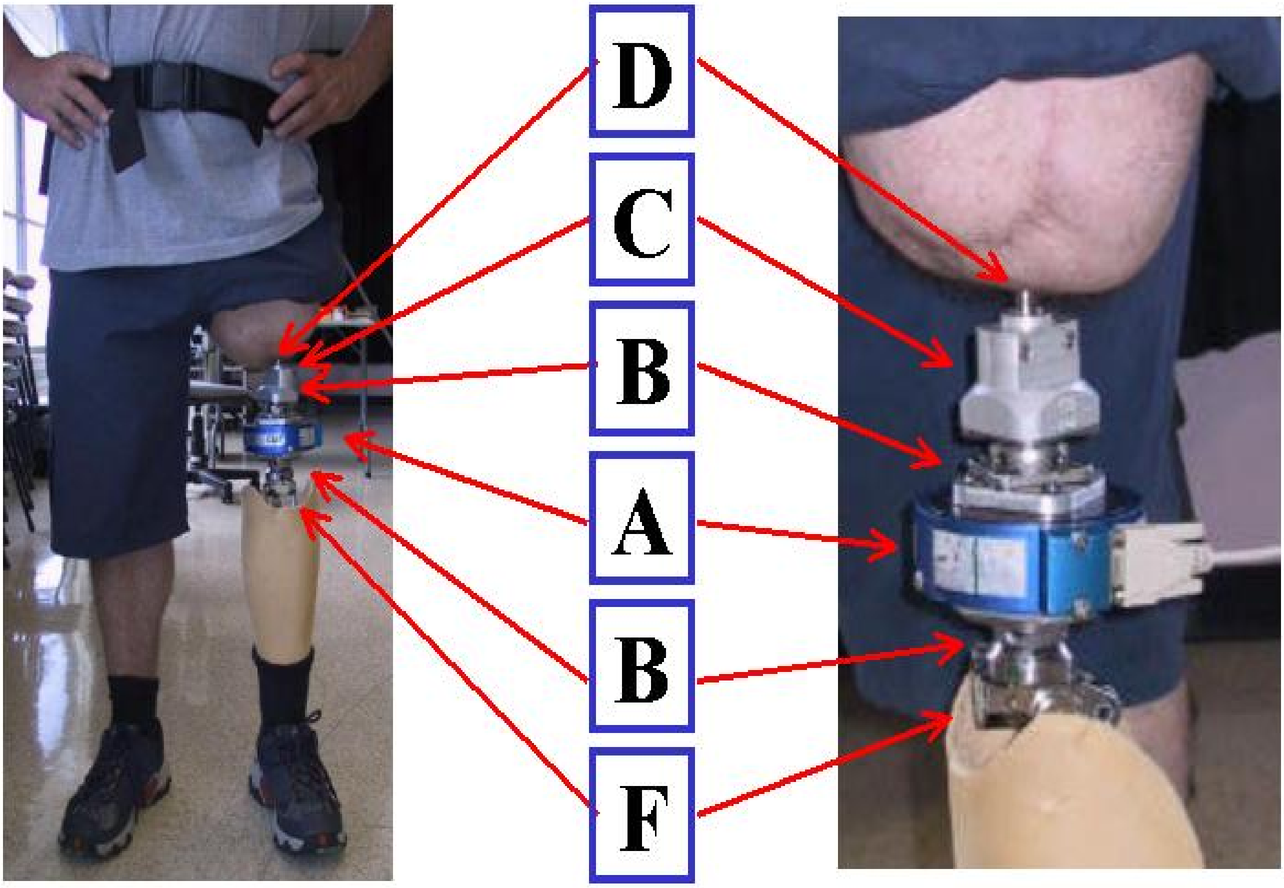

Figure1. Example of a typical prosthetic leg setup used to directly measurement the forces and moments applied on the fixation system of transfemoral amputee (left: front view, right: side view). A commercial transducer (A) was mounted to specially designed plates (B) that were positioned between the adaptor (C) connected to the fixation (D) and the knee mechanism (F)

participants (age: 54±12 years, mass: 84.3±16.3 kg, height: 1.78±0.10 m) have used osseointegrated prostheses for over one year. Their body mass had to be below 110 kg to avoid saturation of the load cell. Participants had to be able to walk 200 m without walking aids. Load measurement was taken place in clinical environment in Caulfield General Medical Centre, Melbourne, Australia (N=2), and Sahlgrenska University Hospital, Gothenburg, Sweden (N=10) where the subjects were recruited. The subjects used their current prostheses with the objective to measure the true load during walking for each individual amputee.

Apparatus

3D force and moment applied to the fixation were measured with a six-channel transducer (Model 45E15A; JR3 Inc., Woodland, CA), weighing less than 800g. The transducer can measure up to 1140N with accuracy of 1% of the full scale. A wireless transmitter was used to transmit data from the transducer to a nearly laptop computer. Sampling frequency was set at 200Hz. The transducer was mounted to two customized aluminum plates, which were anchored to the fixation and the prosthetic knee joints. The transducer was aligned in a way that its long axis (L) was coincident with the long axis of the residuum. The other axes referred to the antero-posterior (AP) and medio-lateral (ML) directions were aligned with the anatomical axes of the prosthetic knee. Figure 1 provides an example of the apparatus mounted within the prosthesis.

Protocol

Load measurement was first taken in unloaded condition when there was no external force exerted to the transducer for calibration purpose. Subjects were given 15 minutes to get accustomed to the instrumented prostheses before load measurement. They were then required to walk along a level walkway at self-selected comfortable walking speed. The number of walking steps along the walkway depended on the stride length of each subject ranged from 24 to 64 steps (51±12 steps). The cadence ranged from 42.3 to 53.4 strides/min (47.1±3.66 strides/min).

Data reduction

The raw data was processed by Matlab software program (Math Works, Inc.). Any offset in the data during the initial unloaded condition was removed. The first and the last strides recorded for each trial were discarded. Force data was normalized by body weight of each subject. Local extrema of each component of forces (F_{AP}, F_{ML}, F_L) and moments (M_{AP}, M_{ML}, M_L) were identified for each step on prosthetic limb. Force and moment were averaged for each complete gait cycle across various walking steps of each subject, and were plotted against the percentage of a gait cycle. For each parameter, mean, standard deviation (S.D.) and coefficient of variance (C.V), defined as the standard deviation divided by the mean modulus were produced in two ways: within subject on repeated steps (intra-subject) and across subjects (inter-subjects).

III. RESULTS

Forces

The forces on the antero-posterior, medio-lateral and long axes for a complete gait cycle of each subject were plotted in Figure 2. Although there were noticeable differences in the magnitude of forces among different subjects, similar force patterns were shown. Step-to-step variability was low as demonstrated by the small coefficient of variance for each subject. However, high subject-to-subject variability was shown. The mean magnitude and coefficient of variance of the local extremas forces within and across subjects is provided in Table 1.

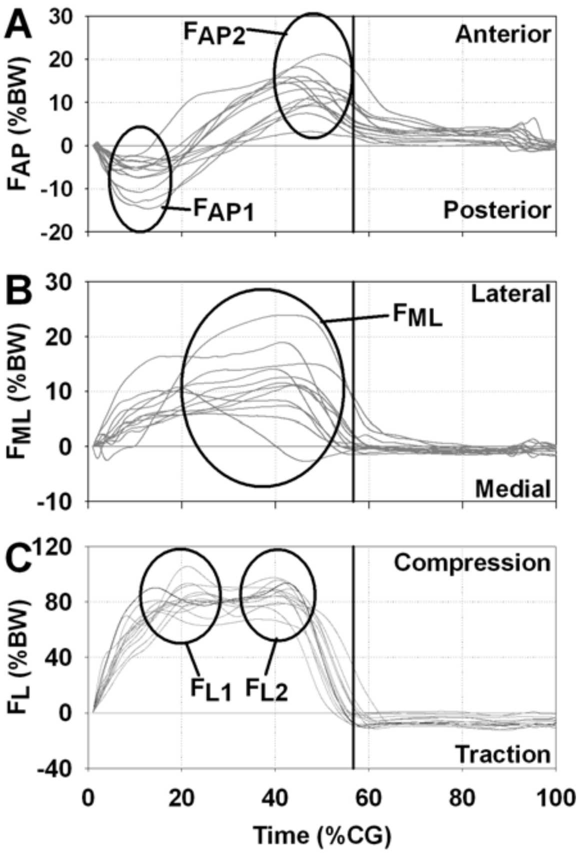

Figure 2. Normalized (a) F_{AP}, (b) F_{ML} and (c) and F_L of 12 amputees along a gait cycle.

TABLE I. LOCAL EXTREMA OF FORCE EXPRESSED IN PERCENTAGE OF BODY WEIGHT (%BW)

	F_{AP1} (%BW)		F_{AP2} (%BW)		F_{ML} (%BW)		F_{L1} (%BW)		F_{L2} (%BW)	
	Mean	C.V.	Mean	C.V.	Mean	C.V.	Mean	C.V.	Mean	C.V.
Step-to-step variability (intra-variability)										
Subject 1	-5.07	0.108	10.80	0.096	10.82	0.070	105.40	0.018	97.17	0.023
Subject 2	-9.82	0.128	14.52	0.043	14.08	0.056	91.81	0.040	87.88	0.025
Subject 3	-13.20	0.016	21.73	0.018	7.36	0.071	80.74	0.034	83.39	0.017
Subject 4	-5.78	0.107	14.61	0.048	8.42	0.046	86.96	0.038	94.41	0.016
Subject 5	-15.40	0.132	10.19	0.074	11.57	0.049	88.50	0.038	101.94	0.022
Subject 6	-4.22	0.141	3.22	0.100	23.58	0.112	96.52	0.032	93.73	0.024
Subject 7	-11.10	0.068	15.86	0.038	19.24	0.045	97.34	0.036	99.59	0.018
Subject 8	-5.07	0.170	13.24	0.040	11.08	0.036	83.17	0.027	86.86	0.025
Subject 9	-7.46	0.085	11.46	0.061	11.37	0.092	79.06	0.046	72.16	0.036
Subject 10	-7.41	0.101	15.15	0.030	12.42	0.117	85.16	0.033	84.32	0.024
Subject 11	-5.46	0.119	21.51	0.020	15.32	0.068	89.61	0.029	81.43	0.048
Subject 12	-4.90	0.306	16.20	0.048	5.63	0.101	87.88	0.027	82.35	0.041
Subject-to-subject variability (inter-variability)										
Mean	-7.91	0.123	14.04	0.051	12.57	0.072	89.35	0.033	88.77	0.027
S.D.	3.66	0.069	4.99	0.027	5.01	0.028	7.53	0.007	8.75	0.010
C.V.	-0.46	0.563	0.36	0.523	0.40	0.384	0.08	0.221	0.10	0.374
Max	-4.22	0.306	21.73	0.100	23.58	0.117	105.40	0.046	101.94	0.048
Min	-15.40	0.016	3.22	0.018	5.63	0.036	79.06	0.018	72.16	0.016

Moment

Lateral rotational moment (M_{AP}) was consistently experienced during stance phase of the gait as presented in Figure 3. Axial rotational moment (M_L) was the lowest in magnitude comparing to M_{AP} and M_{ML} because of the

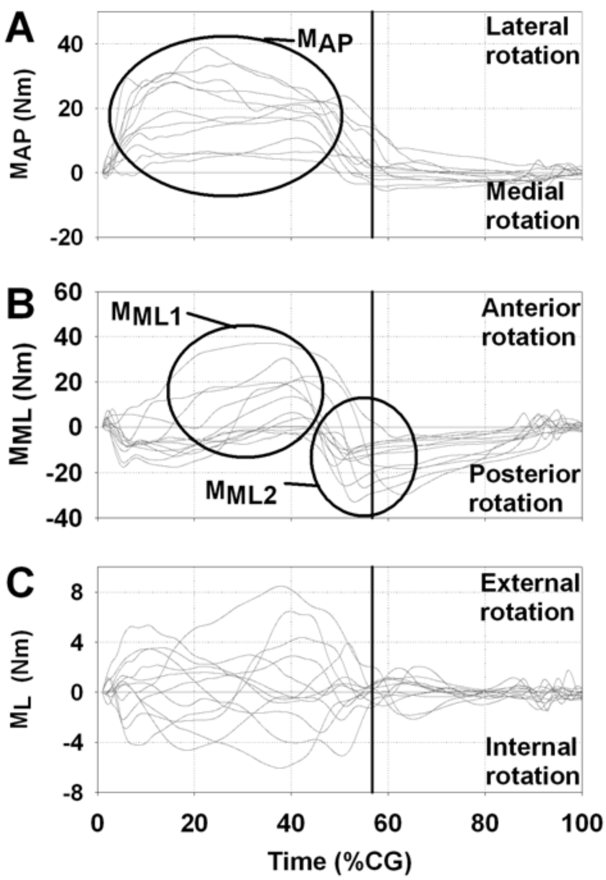

Figure 3. Moment about (a) AP axis, (b) ML axis, and (c) L axis of 12 amputees along a gait cycle

shorter moment arm. Inconsistent M_L patterns were shown among different subjects. The mean, step-to-step and subject-to-subject variability of moment data were provided in Table 2. Similar to the force data, subject-to-subject variability was noticeably higher than step-to-step variability.

TABLE II. LOCAL EXTREMA OF MOMENT

	M_{AP} (Nm)		M_{ML1} (Nm)		M_{ML2} (Nm)	
	Mean	**C.V.**	**Mean**	**C.V.**	**Mean**	**C.V.**
Step-to-step variability (intra-variability)						
Subject 1	10.90	0.225	4.31	0.430	-11.30	0.115
Subject 2	39.10	0.049	6.10	0.510	-30.50	0.110
Subject 3	6.32	0.142	0.75	1.690	-12.00	0.042
Subject 4	17.90	0.053	13.60	0.080	-15.20	0.059
Subject 5	29.00	0.065	6.73	0.300	-33.20	0.037
Subject 6	28.10	0.100	38.10	0.070	-6.07	0.466
Subject 7	19.20	0.059	-1.18	0.930	-10.70	0.058
Subject 8	9.06	0.179	-1.96	1.220	-16.80	0.121
Subject 9	28.20	0.059	-2.17	0.930	-26.70	0.049
Subject 10	31.50	0.051	20.50	0.270	-27.60	0.253
Subject 11	33.70	0.059	22.50	0.100	-28.40	0.039
Subject 12	17.70	0.085	20.40	0.110	-14.90	0.100
Subject-to-subject variability (inter-variability)						
Mean	22.56	0.094	10.64	0.553	-19.45	0.121
S.D.	10.53	0.058	12.55	0.526	9.21	0.124
C.V.	0.47	0.617	1.18	0.950	-0.47	1.030
Max	39.10	0.225	38.10	1.690	-6.07	0.466
Min	6.32	0.049	-2.17	0.070	-33.20	0.037

IV. DISCUSSIONS AND CONCLUSIONS

This study is the first attempt of measuring the variability of the load applied on osseointegrated fixation twelve trans-femoral amputees during normal walking.
Results showed a:

- Low step-to-step variability among the twelve subjects. This suggests measuring force in one to two steps of walking may adequately reflect the loading pattern of a subject. This tends to validate gait laboratory-based studies focusing on a limited number of steps.
- High subject-to-subject variability. This could be due to the wide variety of alignments (e.g. walking basis), prosthetic components (e.g. knee, foot, protective device, etc) and anthropometric characteristics (e.g. angle of femur with residuum) within the tested population. This outcome tends to highlight the need for individual-based rather than population-based biomechanical analyses of transfemoral amputees.

It is anticipated that this study will provide essential information to Biomechanists facing the challenge of analyzing the locomotion of lower-limb amputees within experimental conditions.

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