LOADING APPLIED TO THE IMPLANT OF TRANSFEMORAL AMPUTEES FITTED WITH A DIRECT SKELETAL FIXATION DURING WALKING IN A STRAIGHT LINE AND AROUND A CIRCLE

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INTRODUCTION

As described by Hagberg and Brånemark (2001) (1), the main sources of pain and discomfort experienced by transfemoral amputees are associated with the interface between the residuum of the limb and the socket keeping the prosthesis attached to the residuum (1,2).

Over the last ten years, a team led by Dr Rickard Brånemark attempted to alleviate these concerns by developing a new method of attachment for transfemoral prosthetic leg using a direct skeletal anchorage (3). In this case, the socket is replaced by a titanium implant fitted into the shaft of the femur. The prosthesis is then attached to the implant via an abutment (fixation system) that protrudes thought the skin.

At this stage, this surgical technique based on osseointegration is essentially intended for transfemoral amputees who cannot be accommodated with current methods of attachment relying on sockets. Around 60 transfemoral amputees living in Europe and two in Australia have experienced the benefits of this surgical technique as developed by Dr Rickard Brånemark. Although this new technique remains experimental, these amputees are experiencing a number of benefits including better walking ability, more stable and simplified attachment and detachment, as well as less pressure sores and pain. The patients declared that their quality of life has been increased overall. However, they were generally discontented with the current prothetic components of their artificial leg including shock absorbers, knees and feet, which were not originally designed for them. Furthermore, one study revealed that a number of patients presented an early loosening of the implant or fractures of the abutment (3).

These two concerns are strongly related to the usage of the prosthetic leg and particularly to the forces and moments applied on the abutment during the daily life activities of the amputees. A number of direct factures of the abutment occured after the amputee experiences a fall. However, it is anticipated that a number of ruptures might also be caused by the fatigue of the titanium abutment due to the load regime acting on the fixation system which is related to the frequency and magnitude of the forces and moments. Large forces can be generated by artificial limbs because of shortcomings in the ability of components, such as knees and feet, to adequately mimic their natural counterparts. For example, despite proper alignment of these components with the body, abnormal moments can be developed during stance, and high transient loads are experienced during heel contact. While traditional sockets can accommodate these abnormal forces and effectively protect the body from them, direct skeletal attachment cannot.

An accurate and comprehensive measurement of the true forces and moments applied to the fixation system during locomotion is essential to address these failures of the fixation system. This measurement is necessary to the design and to assess of these specific components (e.g.: implants, abutments) and other conventional components (e.g.: feet, knees, sockets, shock absorbers, etc).

In principle, this measurement could be achieved by using a typical gait laboratory equipped with fixed force-plates enable ground reaction forces to be measured and arrangements of video or optoelectronic-based cameras enable multiple views of subject to be obtained. Then, the forces and moments along the three axes at the ankle, the knee, the bottom of the abutment and the hip of the amputated side could be derived from inverse dynamic equations (4,5). Such laboratory settings suffer from a number of limitations, including the ability to only determine joint forces and moments from a single stride of walking or running gait. Another limitation is the error associated with quantifying joint forces and moments using inverse dynamics methods. Furthermore, this method is cumbersome, time consuming, requires qualified personal and provides results for a single stride only.

A few groups developed custom-designed transducers that could potentially improve significantly the measurement of these forces and moments (6,7). For example, Nietert et al (1998)(7) developed a pylon equipped with strain gauges to measure directly the loads generated in hip units of amputees with hip disarticulation prostheses. These homemade transducers could be particularly suitable to provide the actual forces and moments applied to the fixation system. The loading on the fixation would be more accurate than the one obtain in a gait laboratory because it would be measured directly without calculations. Unfortunately, custom-designed transducers could pose problems of calibration, reliability and accuracy. In addition, discrete, reliable and accurate commercial transducers are now widely available on the market at affordable price.

However, there is a lack of results of forces and moments using such commercial transducer, already largely used in robotic, despite the fact that it could certainly provide the true load experienced in the prosthetic leg during a wide range of activities. Previous studies had used successfully a transducer to measure directly the forces and moments applied to the socket of transfemoral amputees during daily living activities (8,9). However, no studies applied similar method of measurement of loading applied on the abutment of transfemoral amputees fitted with an osseointegrated implant.

The aims of this present paper were:

1. To detail a method that directly measures the forces and moments applied to the fixation system.
2. To present an example the raw forces and moments obtained with this method during walking in a straight line and around a circle.
3. Examples of derived data that can be obtained with this methods.

METHODS

Participant

One male transfemoral amputee participated in this study (age: 62 years, height: 1.80 m, total mass without prosthesis: 100.45 kg, cause of amputation: trauma, date of insertion of the abutment: 1999). This subject was asked to enter this present study as a patient of the Centre for Orthopaedic Osseointegration of the Sahlgrenska University Hospital located in Gothenburg, Sweden.

The subject was selected on the basis of:

- His functional level, which was determined subjectively by the team of clinicians, allowing him to walk comfortably 200 m without walking aids,
- The length of his residuum of 35 cm (71% of the length of his sound thigh) allowing the transducer to be mounted between the abutment and the prosthetic knee.

The study received the Queensland University of Technology's Human Research ethical approval to conduct this testing. The subject gave his informed consent prior participating in this study.

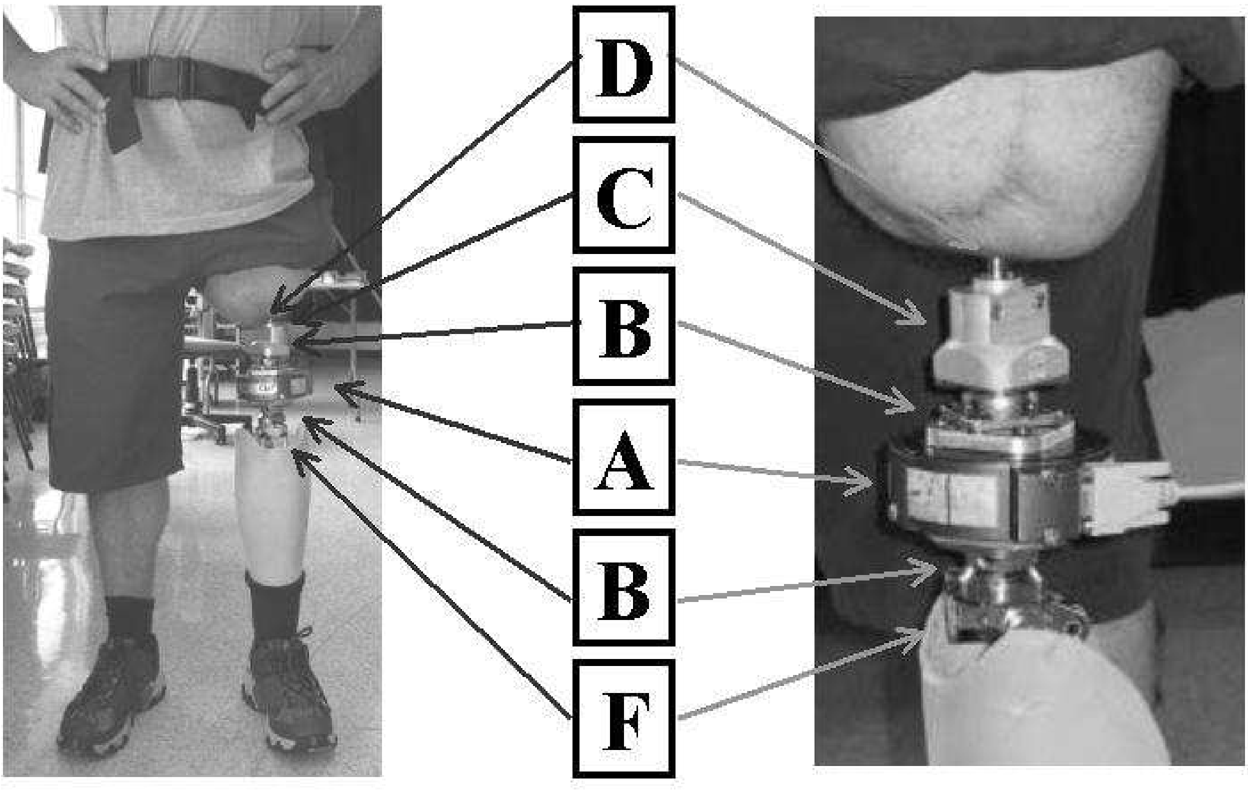
The figure 1 presented an example of a typical prosthetic leg setup for the experiment. For the subject who participated to the testing presented in this paper, the prosthesis used was composed of an adaptor connected to the abutment, the transducer, a Blachford's Adaptive knee and a Endolite Mercury foot. The transducer was attached to the knee and the adaptor using plates that were custom made in house. The mass of this prosthetic leg including the transducer was 4.55 kg. The total mass of the subject with this prosthetic leg was 105 kg. This prosthetic leg was setup and aligned by a qualified prosthetist (MD). The leg was worn for approximately one hour prior to the testing to ensure that the amputee was fully accustomed to it and confident when walking on uneven surfaces.

Instrumentation

The forces and moments were measured directly using a six-channel commercial transducer (JR3 Inc) constructed from a solid billet of aluminum measuring 11.43 cm in diameter, 3.81 cm thick and weighing less than 800 g. Its internal componentry consisted of strain gauges, amplifiers and signal conditioning circuitry. Data was processed using a calibration matrix to eliminate cross-talk. Forces along the three axes were measured with an accuracy better than 1 N. Each channel was recorded at the sampling rate of 200 Hz via a serial cable connected to a laptop.

The transducer was mounted in a way that the long axis of the abutment was aligned with the vertical axis of the coordinate system of the transducer. The two other axes were mutually orthogonal. The antero-posterior (x) and medio-lateral axes (y) of the transducer were aligned with

Figure 1: 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 abutment (D) and the knee mechanism (F). The transducer axes were aligned with anatomical axes of the abutment. Note: these pictures do not present the subject who participated to this present study. No cosmetic foam cover was used in this study.



those of the abutment thanks to a transform matrix applied afterward. Consequently, the coordinate system of the transducer was aligned with the local anatomical axes of the abutment. The antero-posterior and medio-lateral axes were positive on the anterior and lateral directions of the abutment, respectively.

A video camera was used to record both trials in order to provide visual information about the gait pattern demonstrated by the subject.

Procedure

The amputee performed one trial of walking in a 40 m straight line and around a circle of 2 m diameter with his prosthetic leg on the inside. The subject was instructed to perform both activities at his natural pace. In order to avoid a fatigue effect, the subject was asked to take a sufficient resting period between each activity.

Data analysis

The raw force and moment data generated by the transducer was pre-processed and analysed as follows:

- Step 1: Selection of relevant segment of data to analyse. The two first and the last strides recorded for each trial were discarded in order to avoid the initiation and termination of walking. This was done to ensure that the analysis only included the data obtained when the subject walked at a uniform pace.
- Step 2: Determination of gait events. The curve of the vertical force was used to detect manually the heel contact and toe-off with a demonstrated accuracy of ±0.01 second. This accuracy was determined in a preliminary study where the detection of gait events using the method above was compared to force-plate data collected simultaneously.
- Step 3: Averaging and normalisation. For both activities, the forces and moments produced during each support phase of the prosthetic leg were subdivided into 100 equal increments to be time normalised from 0 to 100%. This eliminated time variations among support phases. The force and moment curves could then be plotted with the same time scale as well as the averaging of these curves for both activities. The total number of support phases of the prosthetic leg averaged was 31 for walking in straight line and 4 walking around a circle.

RESULTS

Raw forces and moments

The Figure 2 presented the mean curves and standard deviation of the raw forces and moments directly measured over the support phases during walking in straight line and around a circle. The Table 1 provided the mean and standard deviation of the minimum and maximum of these forces and moments.

The absolute value of the minimum and maximum of force along the antero-posterior axis corresponded to 3.78±0.51% and 4.02±0.39% of the body weight above the transducer during walking in straight line and to 3.05±0.41% and 2.88±0.71% during walking around a circle. The absolute value of the minimum and maximum of force along the medio-lateral axis corresponded to 2.13±0.32% and 25.48±0.70% of the body weight above the transducer during walking in straight line and to 1.91±0.44% and 23.67±1.38% during walking around a circle. The maximum force along the long axis of the abutment occurred during the first peak of the curve and corresponded to 99.61±1.82% of the body weight above the transducer during walking in straight line and to 104.19±2.56% during walking around a circle.

Temporal variables

One of the data set that could be derived from the measurement obtained with the transducer was the temporal parameters of the gait including the cadence, the duration of stride of prosthetic leg as well as the duration of swing and support phases of prosthetic leg expressed in second or in percentage of the gait cycle. Clinicians use regularly these parameters, the cadence in particular, as it represents the level of the functional outcome of a given patient.

The Table 2 presented the mean and standard deviation of the temporal variables of the prosthetic side of the amputee participating to this study during walking in straight line and around a circle. The Table 1 also included the range (minimum and maximum values) of the temporal variables reported in previous studies about the prosthetic side of transfemoral amputees fitted with a conventional socket and constant knee friction [10,13,14,15] as well as able-bodied subjects [10,11,12,13,14] during walking in straight line at free-speed.

The cadence showed by the amputee tested in this study during walking in straight line was clearly slower than able-bodied subjects and fitted in the lower end of the range of the cadence presented by amputees equipped with conventional method of attachment. The cadence showed by the amputee tested in this study during walking around a circle was 2 steps slower than the one presented by amputees equipped with conventional method of attachment. Similar comments could be made for both activities about the other temporal variables.

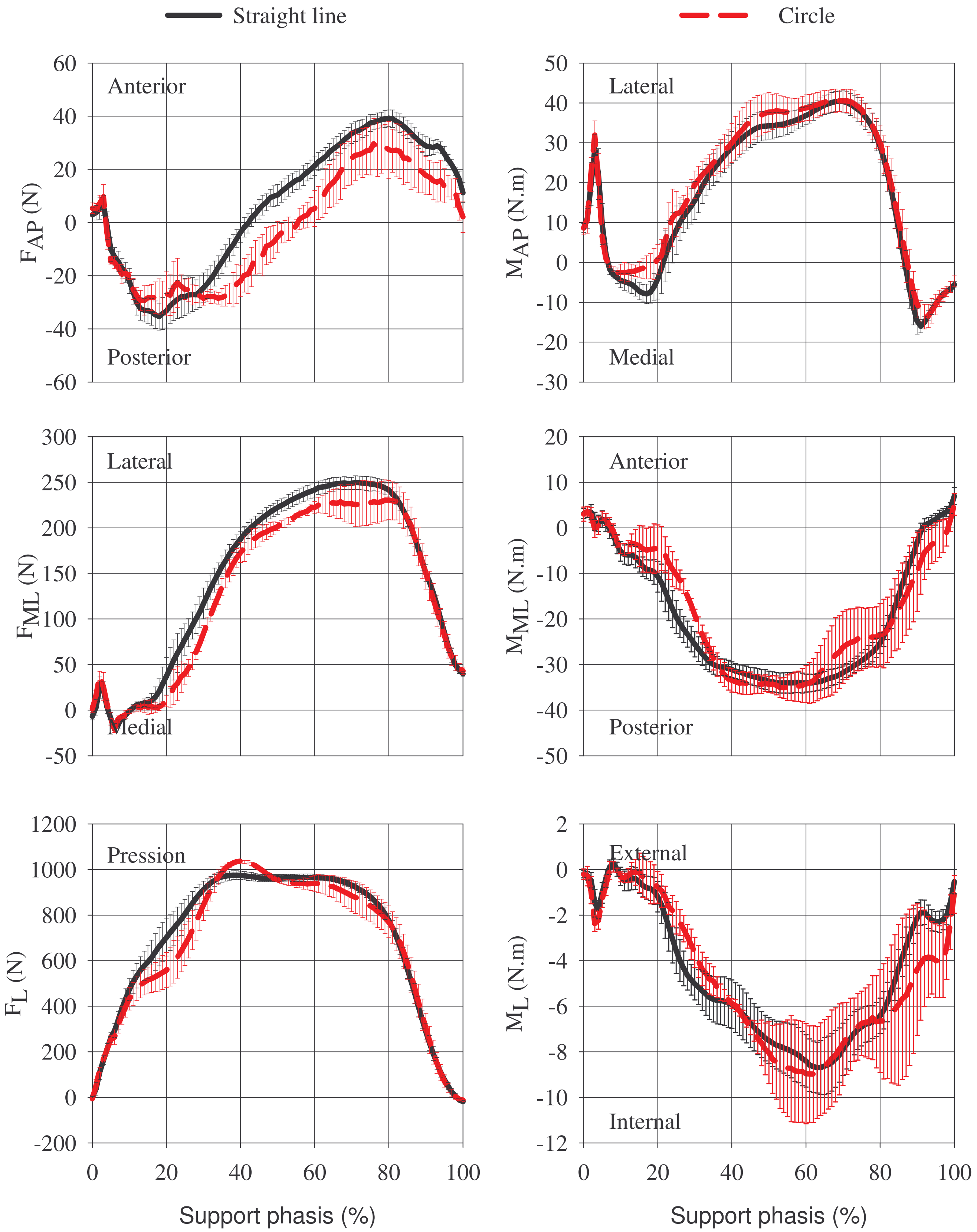
Impulse

Another data set that could be derived from the

Table 1: Mean and standard deviation of the minimum and maximum forces and moments applied on and around the three axes of the abutment during walking in a straight line (31 steps) and around a circle (4 steps).

		Forces (N)				Moments (N.m)			
		Straight line		Circle		Straight line		Circle	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
Antero-Posterior axis	Min	-37.29	5.03	-30.01	4.00	40.58	2.46	41.44	2.40
	Max	39.66	3.88	28.38	7.03	-17.01	1.58	-12.98	5.58
Medio-Lateral axis	Min	-20.99	3.12	-18.82	4.38	2.41	1.93	1.52	3.37
	Max	251.05	6.88	233.25	13.61	-35.12	1.84	-35.45	3.62
Long axis	Min	N/A				0.29	0.22	0.38	0.43
	Max	981.60	17.92	1026.72	25.24	-9.08	1.11	-9.96	1.45

Figure 2: Mean curves and standard deviation of the forces and moments directly measured along the three axes of the abutment over the support phases during walking in straight line (31 steps) and around a circle (4 steps).



measurement obtained with the transducer was the impulse of force. The impulse represented by the force-time integral corresponds to the quantity of forces applied on the abutment [(16)]. This mechanical parameter provides crucial information to engineers concerned with the fatigue of the abutment.

The Table 3 presented the mean and standard deviation of impulse of force applied on the antero-posterior, medio-lateral and the long axis of the abutment during walking in straight line and around a circle.

As expected from the raw results of the forces, the impulse was lower for walking around a circle than in a

Table 2: Minimum and maximum values of the temporal variables reported in previous studies about able-bodied subjects [10,11,12,13,14] and the prosthetic side of transfemoral amputees fitted with a conventional socket [10,13,14,15] walking in straight line. Mean and standard deviation of the temporal variables of the prosthetic side during walking in straight line (31 steps) and around a circle (4 steps) for the amputee fitted with an osseointegrated implant participating to this study. The duration of the support and swing phases were expressed in second and in percentage of the gait cycle of the prosthetic leg.

Variable	Previous studies								Present study			
	Able-bodied subjects				Transfemoral amputees fitted with a conventional socket				Transfemoral amputees fitted with implant			
	Straight line				Straight line				Straight line		Circle	
	Minimum		Maximum		Minimum		Maximum					
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Cadence (strides/min)	56.5	5.00	61.0	-	42.50	-	44.5	1.50	42.77	-	40.34	-
Duration of stride (Sec)	0.98	0.17	1.40	0.11	1.27	0.13	1.43	0.02	1.40	0.05	1.49	0.09
Duration of swing (Sec)	0.59	0.05	0.86	0.08	0.78	0.04	0.80	0.07	0.57	0.02	0.63	0.04
Duration of swing (%)	60.20	2.94	61.42	7.27	61.41	3.01	55.94	3.54	40.36	1.31	42.28	2.15
Duration of support (Sec)	0.38	0.03	0.54	0.04	0.57	0.05	0.61	0.05	0.84	0.04	0.86	0.06
Duration of support (%)	38.77	1.76	38.57	3.63	44.88	3.84	42.65	2.50	59.64	1.31	57.72	2.15

Table 3: Mean and standard deviation of impulse of force applied on the antero-posterior, medio-lateral and the long axis of the abutment during walking in straight line (31 steps) and around a circle (4 steps).

	Straight line (N.sec)		Circle (N.sec)	
	Mean	SD	Mean	SD
Antero-Posterior axis	19.32	1.47	16.25	3.21
Medio-Lateral axis	124.59	8.15	115.53	12.40
Long axis	587.53	30.39	580.91	40.86

straight line on the three axes. Also, the impulse was larger on the medio-lateral axis than antero-posterior axis.

DISCUSSION

The temporal variables indicated that the amputee tested in this study presented a good functional outcome while walking in straight line in comparison with the normal population of transfemoral amputees fitted with conventional methods of attachment. This confirmed the potential benefits of using an osseointegrated implant.

The results of this study seems to indicate that, for this subject, the segmental organization responsible for this functional outcome involves the production of higher force along the medio-lateral axis and moment around the antero-posterior axis than force along the antero-posterior axis and moment around the medio-lateral axis.

This could be due to the fact that the long axis of the transducer wasn't perpendicular to the ground during the support phases as the transducer was aligned with the abutment. Consequently, the vertical pressure in the global coordinate system had a medio-lateral component in the transducer coordinate system. However, the visual inspection of video recording showed that the medio-lateral axis was over-loaded mainly because:

- The subject walked with a wide base of support. This tend to limit the push off phase on the antero-posterior axis at the end of the support and to increase the medio-lateral component.
- The subject presented a lateral flexion of his trunk during the support, which would also contribute to increase the medio-lateral force and antero-posterior moment.

SUMMARY

This paper demonstrates the potential of using a commercial transducer to directly measure the loading acting on the abutment over a large number of steps during daily activities.

The results showed that such transducer could provide valuable information about the strength requirements for the design of specific components for osseointegrated prostheses such as implant, abutment, shock absorber, etc. However, the originality of these results obtained for the subject tested in this study, pointed out that complementary measurements would be necessary to extend further the understanding and the interpretation of the loading regime. Instruments, such as portable accelerometers, could be used to monitor the kinematics of the ankle and the trunk.

It is anticipated that the method presented here will be largely used by the multi-disciplinary teams facing the challenge of safely restoring the locomotion of transfemoral amputees fitted with osseointegrated implant.

REFERENCES

1. Hagberg K and Brånemark R (2001). Consequences of non-vascular trans-femoral amputation: a survey of quality of life, prosthetic use and problems. *Prosth & Ortho Int*. 25, 186-194
2. Mak A, Zhang M, Boone D (2001). State-of-the-art research in lower-limb prosthetic biomechanics-socket interface: A review. *J rehabil Res Dev* ; 38(2):161-174.
3. Brånemark R, Brånemark P-I, Rydevik B, Myers R (2001). Osseointegration in skeletal reconstruction and rehabilitation: A review. *J rehabil Res Dev*; 38(2): 175-81.

4. DiAngelo DJ, Winter DA, Ghista DN, Newcombe WR (1989). Performance assessment of the Terry Fox jogging prosthesis for above-knee amputees. *J. Biomechanics*; 22(6/7): 543-58.
5. Stephenson P, Seedhom BB (2002). Forces at the interface between an artificial limb and an implant directly fixed into the femur in above knee amputees. *Journal of Orthopaedic Science*. 7(3). In press
6. Berme N, Lawes P, Solomonidis S, Paul JP (1976). A shorter pylon transducer for measurement of prosthetic forces and moments during amputee gait. *Engineering in Medicine*; 4(4).
7. Nietert M, Englisch N, Kreil P, Alba-Lopez G. (1998). Loads in hip disarticulation prostheses during normal daily use. *Prosthet. Orthot. Int*; 22:199-15.
8. Frossard L, Beck J, Dillon M, Evans J. (2000). Forces acting on the residuum of above-knee amputees during activities of daily living. *Joint Local Symposium - Physical Sciences and Engineering in Medecine*. 12
9. Frossard L, Beck J, Dillon M, Evans J. (2001). Comparison between the forces and the moments applied to the residuum of above-knee amputees during daily life activities and walking. *Proceedings of 10th World Congress of the International Society for Prosthetics and Orthotics*. MO10.3
10. Skinner H, Efferney D. (1985). Special review "Gait analysis in amputees". *American journal of physical medicine*, vol.64, n°2, p. 82-89.
11. Whittle M. (1991). "Gait analysis: an introduction" Oxford, Butterworth- Heinemann.
12. Murray M, Kory R, Clarkson B, Sepic S. (1966). Comparaison of free and fast speed walking patterns of normal men. *American Journal of Physical Medicine*, p. 8-24, vol. 45, n°1.
13. Murray M, Sepic S, Gardner G, Mollinger L. (1980). Gait patterns of above-knee amputees using constant-friction knee components. *Bulletin of Prosthetics research* BPR 10-34 (vol. 17 n°2), pages 35-45.
14. Murray M, Mollinger L, Sepic S, Gardner G. (1983). Gait patterns of above-knee amputees patients: hydraulic swing control vs constant-friction knee components. *Arch Phys Med Rehabil.* Vol 64, p. 339-345.
15. James U and Oberg K. (1973). Prosthetic gait pattern in unilateral above-knee amputees. *Scand J Rehab Med* 5:35-50.
16. Seliktar R, Yekutiel M, Bar A. (1979). Gait consistency test based on the impulse-momentum theorem. *Prosthet. Orthot. Int*;3:98-8.

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