Load applied on a bone-anchored transfemoral prosthesis: characterisation of a prosthesis – A pilot study

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ABSTRACT

The objectives of this study were (A) to record the inner prosthesis loading during activities of daily living (ADL), (B) to present a set of variables comparing loading data, and (C) to provide an example of characterisation of two prostheses. The load was measured at 200 Hz using a multi-axial transducer mounted between the residuum and the knee of an individual with unilateral transfemoral amputation fitted with a bone-anchored prosthesis. The load was measured while using two different prostheses including a mechanically (PRO1) and a microprocessor controlled (PRO2) knee during six ADL. The characterisation of prosthesis was achieved using a set of variables split into four categories, including temporal characteristics, maximum loading, loading slopes and impulse. Approximately 360 gait cycles were analysed for each prosthesis. PRO1 showed a cadence improved by 19% and 7%, a maximum force on the long axis reduced by 11% and 19%, as well as an impulse reduced by 32% and 15% during descent of incline and stairs compared to PRO2, respectively. This work confirmed that the proposed apparatus and characterisation can reveal how changes of prosthetic components are translated into inner loading.

KEYWORDS

Activities of daily living; Artificial limb; Bone-anchorage; Gait; Impulse; Loading; Osseointegration; Prosthetic knee unit; Temporal characteristics; Transfemoral amputation

JRRD AT GLANCE

This study explores the potential of portable kinetic recording system to determine the effect of prosthesis on the load applied of the residuum. In this case, this load was measured during several activities of daily living performed by an individual with unilateral transfemoral amputation fitted with a bone-anchored prosthesis. This work confirmed that the proposed apparatus can reveal how changes of prosthetic components (e.g., mechanically vs microprocessor controlled knee) are translated into inner loading. This indicates that such apparatus might have the ability to support evidence-based fitting and, therefore, to address issues related to under- or over-prescription of components.

1. INTRODUCTION

Individuals with transfemoral amputation (TFA) are normally supplied with socket-suspended prostheses. Some of the issues associated with the interface between the residuum and the socket can be resolved by a bone-anchored prosthesis [1]. In this case, the prosthesis is attached to the residuum using an implant inserted into the bone [2-4]. To date, approximately 300 individuals with lower limb amputation worldwide have been treated with this kind of attachment using either the ITAP (Stanmore Implant, UK) [5], EFFT (Eska, Germany) newly sold as Integral Leg Prosthesis (Orthodynamics GmbH, Germany) [6] or OPRA (Integrum AB, Sweden) [7] system. This technique can contribute to a significant improvement in quality of life [8] despite of the length of treatment [9], sporadic fractures of implant parts following a fall [10-12] and the occasional infections [8, 12, 13]. Some of these problems are believed to be somehow associated with the prosthetic components fitted during restricted and unrestricted loading.

1.1. Selection of components for bone-anchored transfemoral prosthesis

Currently, the selection of knee and ankle units is based on the clinical experience and depends mainly of manufacturer's instructions, strength of the bone anchorage, lifestyle and costs.

Although there are variations, the choice of the knee is often determined around the following options. A polycentric knee could be suited during the initial restricted prosthetic loading, because the application of partial body weight loading is enough to secure stance-phase stability of the knee mechanism. A microprocessor controlled knee could be used in a more definitive prosthesis, during unrestricted loading, as it requires the application of the full body weight. Also, it can accommodate active lifestyle, while potentially reducing risks of falls [14].

Clearly, these choices are critical in the development of rehabilitation programs as well as design and management of fixation parts (e.g., load limits, strength of implant parts, threshold of protective device) [1, 7, 12, 15]. However, to date, there is little information on the effect of prostheses on the load applied on the fixation backing up these fitting options.

Some of this information can be gained through a characterisation of the prosthesis, defined as a process of assessing the inner loading profile of an ensemble of components during the actual usage of the prosthesis, including not only typical clinical observations (e.g., fitting, alignment) but, more importantly, activities of daily living (ADL).

1.2. Conventional characterisation of a prosthesis

Typically, such characterisation relies on kinetic data for ankle, knee and hip of sound and prosthetic limbs [16-25] "*to evaluate how loads are transmitted through the prosthesis*" [26] p206. This load can be calculated using inverse dynamics equations requiring kinematic data captured by a motion analysis system and ground reaction forces measured by force-plates [27, 28].

Some of the most important shortcomings of this method are inherent to the experimental setting of these instruments [28]. In particular, instrumentation of stairs and inclines with floor-mounted force-plates is possible, but tedious, and often leads to assessments that could only be somewhat ecological. Marginal calculation errors due to location of centre of pressure and joint centre thought external markers could be increasingly propagated upward between the ankle, the knee and the hip [29-31]. Finally, data processing is often time-consuming and labour intensive.

Consequently, this method can only partially accommodate the clinical expectations for an ecological assessment of the inner prosthetic loading.

1.3. Characterisation based on direct kinetics measurements

Alternatively, prosthesis could be characterised using load sensors embedded between components. Recently, portable kinetic systems based on multi-axial transducer connected to recording device were used to measure the load applied on the residuum of individuals with lower limb amputation [32, 33]. To date, studies of the load applied on the osseointegrated fixation of TFAs focused only on the effects of load bearing exercises [9], walking aids [34], walking [35], standardized ADL [36], ADL in open-environment [37, 38] and falls [10, 11].

All combined, more ecological information were provided, demonstrating that this alternative approach is relevant and practical to clinicians. Furthermore, these studies, particularly the ones examining locomotion [34-36], give some preliminary information demonstrating the potential benefits of this approach to characterise bone-anchored prosthesis.

These studies provided key practical cues about the transducer included in the portable kinetic systems (e.g., mounting, orientation, calibration). More importantly, they demonstrated that these systems are capable to measure directly the three components of force and moment without calculations and for a large number of gait cycles, in contrast with inverse dynamics. Furthermore, these studies described a set of standardized ADLs including, but not limited to, the ones usually considered to assess prosthetic components (e.g., straight level walking, ascending and descending stairs and incline) [14, 35, 36, 39-41]. Finally, these studies laid out some basic ways to extract gait temporal variables, peaks and local extremas, and impulse from inner loading data.

1.4. Need for more evidence

Nonetheless, more evidences are required to evaluate to what extent the apparatus, protocols and the analyses previously presented are actually suitable to characterise bone-anchored prostheses. Indeed, a need exists for a pilot study replicating a typical data collection and, eventually, exploring further possible analyses, in the view of differentiating loading between prostheses.

1.5. Aim, purpose and objectives

The ultimate aim of this study was to contribute to an evidence-based prescription of prosthetic components for individuals with TFA fitted with bone-anchorage prosthesis. The purpose of this pilot study was to propose a characterisation of prostheses from collection to the analysis of inner loading data. The specific objectives were:

A. To directly record forces and moments applied on the three axes of the fixation during six standardized ADL, including short level walking and descending stairs and incline commonly considered when assessing prosthetic components, as well as long level walking and ascending stairs and incline,
B. To analyse and to interpret the load applied on the fixation using a set of variables split into four categories, including temporal characteristics, maximum loading and impulse routinely used in previous studies, as well as loading slopes newly presented here,
C. To provide an example of characterisation and comparison of two bone-anchored prostheses of an individual with unilateral TFA fitted with an OPRA fixation, including a mechanically and a microprocessor controlled knee unit, namely Total Knee (Ossur, Reykjavik, Iceland) and C-Leg (Otto Bock, Vienna, Austria), respectively.

2. METHODS

2.1. Participant

One male with unilateral TFA due to trauma (41 yrs, 1.77 m, 96.55 kg) participated in this study. The initial amputation and the completion of osseointegration treatment took place 14 years and eight years before this study, respectively. The participant was fully rehabilitated and active with an overall functional level corresponding to K4, indicating a fairly high ambulatory capacity. The participant provided informed written consent. The research institution's human ethics committee approved this study.

2.2. Apparatus

The load applied on the fixation was measured while using two different prostheses, labelled as PRO1 and PRO2 (Figure 1). Both prostheses included a connector, 4-hole standard adapter and designed plate, and a transducer. The connector was used to attach the prosthesis to the fixation.

*** Insert Figure 1 here ***

As detailed in Table 1A, PRO1 included a C-Leg, a tube adapter, a C-Walk (Model 1C40) and a hard running shoe. PRO2 included a Total Knee, a Total Shock, a tube adapter, a Trustep and same footwear. Providers are detailed in Figure 1. PRO1 and PRO2 were purposely assembled with unique knee and ankle joints combinations, in order to assess the loading effect of the whole prosthesis as it is usually wear by the participant. This is in contrast with typical studies assessing a particular component (e.g., microprocessor controlled knee) that tend to fit the rest of the prosthesis with the same components (e.g., sockets, ankles, feet, footwear) to reduce confounding effects.

A prosthetist (CPO) with over 15 yr of experience, including several 1 years working with bone-anchored prostheses, handled all aspects of prosthesis fitting. The prosthetist replicated the alignment of each prosthesis as closely as possible to the participant's original alignment. The connector and the transducer replaced the device usually fitted including a fail-safe mechanism [7]. Both knees were dropped by approximately 2.5 cm compared to the usual alignment to provide sufficient space to mount the transducer. Positions and orientations of each component in relation to three axes of the hip coordinate system are presented in Table 1B. The difference in position for each component was less than 2.11 and 2.75 cm on the medio-lateral and long axes, respectively. The difference on the anterio-posterior axis was nil for the transducer as well as 1.72 cm and 6.16 cm for knee and ankle joints, respectively. These differences were due to a smaller knee flexion angle of the C-leg in the upright standing position.

*** Insert Table 1 here ***

The load was measured and recorded at 200 Hz using a multi-axial transducer and a laptop [9-11, 29, 34-37, 42, 43]. The three components of forces and moments were measured with accuracy better than 1 N and 1 Nm, respectively. The transducer was mounted between the fixation and the prosthetic knee and aligned so that its vertical axis was co-axial with the long (LG) axis of the fixation. The other axes corresponded to the anatomical anterio-posterior (AP) and medio-lateral (ML) direction of the fixation.

2.3. Recording

The load was recorded during two sessions, starting with PRO1 in the morning and followed by PRO2 in the afternoon after a long rest. Each session occurred according to the protocol previously published [35, 36, 42], including the following key steps.

First, the prosthesis including the transducer was set up and aligned. Acclimation time was limited because the participant was familiar with both prostheses. PRO2 was his first prosthesis after amputation and following osseointegration treatment. The participant wore it for several years. PRO1 has been his daily prosthesis for several months. Approximately 15 minutes of practice was allowed before recording to ensure participant confidence, safety and comfort.

Then, the participant was asked to perform six standardized ADL regularly performed during ADL [44, 45] that are likely to generate some of the highest loads. Walking on a 5-metre long walkway (WA-S), descending stairs made of 11 steps that were 30 cm high and 34 cm deep (ST-D), and descending a 6.5-degree incline that was 30-metre long (IN-D) are activities commonly considered when assessing prosthetic components [39]. However, walking on a 20-metre long walkway (WA-L), ascending stairs (ST-A) and incline (IN-A) were also recorded to provide more comprehensive characterisation and, eventually, to establish ground for future considerations. At first glance, the two walking activities might appear redundant. Short walking is usually assessed in gait laboratory settings. A longer walking was included to measure a larger number of steps. Ecological assessments were insured by instructing the participant to complete each activity at a self-selected comfortable pace, to use the stairs handrail if needed and to take sufficient rest between trials to avoid fatigue. The number of trials recorded for each activity is provided in Table 1C.

Finally, the prosthesis was removed to allow bench top measurement of the inertial characteristics for the calibration (i.e., zero-offset).

2.4. Processing

The raw data for each trial were imported into a customized Matlab software program (Math Works Inc, Natick, USA) implementing the following data processing steps [35, 36, 42]:

- Application of a calibration matrix to eliminate cross-talk and to correct the offset of electrical zero,
- Selection of relevant segment of data to eliminate gait cycles (GC) corresponding to gait initiation and termination,
- Identification of heel contact and toe-off for each selected cycle using the curve of the force on LG axis of the fixation (F_{LG}),
- Detection of maximal loading as well as the beginning and the end points of the regression line for each slope,
- Normalisation from zero to 100 of the curves of forces and moments of each cycle to facilitate averaging of trials and reporting of events in percentage of gait cycle (%GC).

2.5. Characterisation

The characterisation of each prosthesis relied on 32 loading variables split into the four categories, corresponding to temporal characteristics, maximum loading and impulse as described previously as well as the loading slopes:

- ***Temporal characteristics*** of the prosthetic leg including the cadence in strides/min for a given trial as well as the duration of each cycle in second, and the duration of support and swing in %GC [46]. The characteristics are surrogate measurements of the functional outcomes[37, 47].
- ***Maximum loading*** described by the onset in %CG and magnitude of the maximal force in percentage of the body weight (%BW) and moment in %BWm along the three axes of the fixation [35, 36]. This information is necessary to determine the loading limits of components.
- ***Loading slopes*** of the forces and moments along the three axes during initial and terminal loading phases. A slope was represented by the angle in degree between the time and the regression line that passed by a flat segment of a loading curve selected manually. The algebraic congruence between the time in second and the forces in N and the moments in Nm was obtained through rescaling by a factor 1,000 and 10, respectively [10]. Small and large magnitudes corresponded to flat and steep slopes, while positive and negative values indicated upward and downward inclinations, respectively. Emphasis was placed on the slopes occurring during the first and last sections of the support because both phases are mainly concerned with safety (e.g., buckling of knee mechanism) and propulsion (e.g., forward push). The slopes reflect the loading pattern using a single value combining none-normalised time and load magnitude.
- ***Impulse*** of the norm and the three components of forces in Ns were determined using the trapeze method. The overall impulse was used as a clinical indicator reflecting the loading regimen [9, 34-36] that is useful to determine prosthesis usage and to estimate components fatigue.

2.6. Comparative analysis

All gait cycle data were collated to determine the average and one standard deviation, as detailed in Table 1C. The difference between prostheses was determined by PRO2 minus PRO1. Therefore, a positive and negative difference between variable indicated that PRO2 is algebraically larger and smaller than PRO1, respectively. A simple two-sided t-test with p-values considering differences significant at $p<.05$ was deemed acceptable for this pilot study relying on single-case.

Comparison of both prostheses relied on the count of the maximum absolute difference and its corresponding activity, the number of positive and negative differences that were not statistically significant as well as significantly different.

3. RESULTS

A total of 727 gait cycles were analysed including 363 for PRO1 and 364 for PRO2 (Table 1C). An overview of the forces and moments applied on the three axes of the residuum during walking, stairs and incline activities is provided in

Figure 3 and Figure 4, respectively.

The participant used the handrail with the opposite hand. Moreover, the participant climbed one stair per step for the three first trials and two stairs per steps for three last trials. Stair descent was done “step over step” with PRO1 and “one at a time” with PRO2.

*** Insert Figure 2,

Figure 3, Figure 4 here ***

3.1. Temporal characteristics

As presented in Table 2, the difference was negative and positive for all activities for the cadence and duration of GC, respectively. The difference was negative and positive for two and four activities for the duration of support, respectively. The difference was significantly different for 21 (88%) of the 24 possible comparisons of temporal characteristics.

*** Insert Table 2 here ***

3.2. Maximum loading

As presented in Table 3, the maximum absolute differences were 30.19 %BW for F_{AP}, 0.35 %BWm for M_{AP} and 0.72 %BWm for M_{LG} during IN-D, as well as 15.28 %BW for F_{LG} during ST-D, 4.69 %BWm for M_{ML} during IN-A, and 2.39 %BW for F_{ML} during WA-S. The difference was positive for all activities for F_{AP}, F_{ML}, F_{LG} and M_{ML}. The number of activities presenting positive and negative differences was 5 and 1 for M_{AP}, and 4 and 2 for M_{LG}, respectively. The difference was significantly different for 30 (83%) and 34 (94%) of the 36 possible comparisons of onset and magnitude of the maximal load, respectively.

*** Insert Table 3 here ***

3.3. Loading slope

All the slopes occurred within the first 57%, 41%, 34%, 24%, 55% and 48% of GC during initial loading and between 12% and 72%, 31% and 70%, 24% and 71%, 15% and 80%, 14% and 82%, 33% and 93% of GC during terminal loading for F_{AP}, F_{ML}, F_{LG}, M_{AP}, M_{ML} and M_{LG}, respectively.

As presented in Table 4, during initial loading, the difference was positive for all activities for F_{AP}, M_{ML} and M_{LG}. The number of activities presenting positive and negative differences was 3 for F_{ML} and F_{LG}, as well as 4 and 2 for M_{AP}, respectively. During terminal loading, the difference was negative for all activities for F_{AP} and M_{ML}. The number of positive and negative differences was 3 for F_{ML}, 2 and 4 for F_{LG} and M_{AP}, 5 and 1 for M_{LG}, respectively. The difference was significantly different for 27 (75%) and 33 (92%) of the 36 possible comparisons of slope occurring during initial and terminal loading, respectively.

*** Insert Table 4 here ***

3.4. Impulse

As presented in Table 5, the difference of impulse was positive for all activities on ML and LG axes. It was positive and negative for 4 and 2 activities on AP axis, respectively. The difference of overall impulse was positive for all activities. All the 24 possible comparisons of impulse were statistically significant.

*** Insert Table 5 here ***

4. DISCUSSION

4.1. Characterisation of prosthesis

The primary contribution of this work was to demonstrate that the proposed characterisation (e.g., apparatus, protocol, analysis) can described how changes in prostheses are translated into loading on the fixation.

In addition, this study highlights a limit of the maximum-to-maximum comparison, mainly due to the lack of systematic onset concordance of algebraic maximum loading between patterns. Therefore, complementary analysis of the loading slopes and, eventually, a peak-to-peak comparison are needed. For example, the comparison of maximum of M_{ML} during IN-D corresponding to -6.05±0.24 %BWm for PRO1 and -1.95±0.50 %BWm for PRO2 (Table 3) can be misleading since the terminal slope occurring between 46 %GC and 59 %GC was 88.42±0.19 deg with PRO1 and -87.97±1.36 deg with PRO2 (Table 4).

Furthermore, this study reports mixed evidences supporting a systematic inclusion of ascent activities in prostheses characterisation. Differences between both prostheses during stairs and incline ascents were negligible for F_{LG} but more significant for I_N, as detailed below. This suggests that prosthesis characteristics might have little effects on these activities and support previous studies discarding them [39]. Nonetheless, loading patterns and maximum magnitudes must be known for all activities to provide benchmark data for predictive models of prosthesis usage during ADL (e.g., activities pattern recognition, fatigue prediction, finite elements models [48, 49]).

Also, the succinct comparison of short and long walks reveals significant differences in most loading variables. This provides ground to hypothesise that assessments in experimental and real world conditions might differ. Further investigations will be required to substantiate these findings.

Finally, this pilot study demonstrated the capacity of the proposed characterisation to address the issues of under or over prescription of prosthetic components, corresponding to the disagreement between the functional capacity of the individual and the performance of the components [50, 51]. For instance, this characterisation can contribute to match the walking abilities of individuals with TFA fitted with a fixation or a conventional socket with relevant prosthetic knee unit, particularly those classified as limited community ambulators (e.g., medicare functional classification level 2)[44, 52].

4.2. Prostheses comparison

The secondary contributions of this study are associated with the actual results of the comparison between two prostheses for this participant. The results showed that cadence, duration of GC and support-to-swing ratio for all activities with both prostheses were amongst the best when compared to similar populations using socket-suspended prostheses [37, 46]. Prosthetic benefits of the osseointegration fixation were translated into high functional outcomes for this participant [7, 8, 13, 46].

Furthermore, the performances in some key variables appear favourable to PRO1 compared to PRO2. Despite of being approximately 0.28 kg heavier, PRO1 showed:

- A cadence significantly improved by 19 %, 8 %, 7 % and 4 % during IN-D, IN-A, ST-D and WA-S, respectively.
- A maximum F_{LG} consistently reduced by 19 %, 11 %, 6 %, 5 %, 1 % and 1 % during ST-D, IN-D, WA-L, WA-S, IN-A and ST-A, respectively.

- The overall impulse (I_N) consistently reduced by 32 %, 15 %, 10%, 9 %, 7 % and 6 % during IN-D, ST-D, IN-A, WA-L, ST-A and WA-S, respectively.

Some of these differences appear small when observed over one cycle. However, they can become increasingly important when cumulated over a large number of cycles [37, 38].

By definition, the load measured by the transducer reflects the interaction between the body segments (e.g., trunk bending, hip range of movement, walking base) and all components of the prosthesis (i.e., fixation, knee, tube, ankle, foot, footwear). However, several studies demonstrated that this interaction tends to be predominantly driven by the prosthetic knee unit [53]. Therefore, differences presented here can be expected to be mostly due to differences between the Total Knee and the C-Leg.

Consequently, the results illustrate well the dilemma around the choice of initial and definitive knee unit after osseointegration treatment, as described earlier. The Total Knee is lighter and requires only partial weight-bearing to insure locking of the knee mechanism. However, it creates larger loading in a number of ADL and presents potential higher risks of falls. In comparison, the C-Leg generates smaller load in several ADL and presents lower risks of falls [14]. However, it requires the application of nearly the full body weight to control the knee mechanism. In addition, this choice could be complicated by the prescription of walking aids, making the ability to apply full body-weight a selection criterion less critical. A previous study demonstrated that the loading is reduced by approximately 2% to 10% depending on walking aid [34].

Furthermore, this study gives an example of a potential paradox with the fitting of the microprocessor controlled knee in a bone-anchored prosthesis. On one side, these knees tend to minimize fatigue of fixation parts both directly by reducing the actual load regime and indirectly by decreasing the risks of falls [14]. On the other side, these knees maximise the functional outcome that can possibly lead to an increase in overall number of cycles taken in real world. This might prevent bone loss around the fixation [54] while accelerating fatigue of fixation parts [37, 38]. However, all combined, a microprocessor controlled knee might provide the best compromise between gain in functional outcomes, promoting bone health and risks of fracture.

4.3. Limits for generalisation

The generalization of the results limited mainly because of the typical intrinsic shortcoming of a single-case study, as well as the short acclimation time with PRO2 and the small alignment variations. Furthermore, the interpretation of the results is limited by the lack of assessment of confounders associated with spatial variables (e.g., walking base, step and stride length), as well as dynamics (e.g., ground and handrail reaction forces), kinematics (e.g., trunk bending, hip range of movement) and kinetics (e.g., ankle, knee and hip joints moments and work [29-31]).

4.4. Future studies

The proposed characterisation will facilitate future longitudinal studies comparing prostheses constructions (e.g., socket design, components, alignment) for a larger cohort of individuals with TFA fitted with a osseointegrated fixation or socket. This will provide benchmark information and, eventually, a better understanding of intra and inter-variability between attachments, components, participants and activities.

The possibilities for cross-sectional studies are endless, particularly for the ones associating the proposed characterisation with complementary biomechanical (e.g., dynamics, kinematics and kinetics characteristics) and physiological (e.g., EMG of the hip and residuum muscles [55], metabolic energy consumption) data.

5. CONCLUSIONS

This was the first attempt to establish to what extent prostheses can be characterised through inner loading applied on the residuum of an individual with TFA during ADL. This study is a stepping stone in components characterisation. It can hopefully provide key information to clinicians facing the challenge to restore safe functions of individuals with a lower limb amputation, supporting an evidence-based fitting of prosthesis, rehabilitation programs and design of prosthetic components.

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8. ABBREVIATIONS

ADL: Activities of daily living
AP: Antero-posterior axis
BW: Body weight
GC: Gait cycle
HC: Heel contact
IN-A: Ascending incline
IN-D: Descending incline
LG: Long axis
ML: Medio-lateral axis
PRO: Prosthesis
ST-A: Ascending stairs
ST-D: Descending stairs
TFA: Transfemoral amputation
TO: Toe-off
WA-L: Walking on long walkway
WA-S: Walking on short walkway

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10. LIST OF TABLES AND FIGURES

Table 1: Overview of components (A), alignment (B) and data collection (C) for the two prostheses, PRO1 and PRO2, used during the load measurement of activities of daily living.

	PRO1		PRO2	
A-Prosthetic components				
Type				
Transducer	JR3		JR3	
Knee joint	C-Leg		Total Knee	
Protective device below knee	None		Total shock	
Ankle joint and foot	C-Walk		Trustep	
Mass				
	(kg)		**(kg)**	
Mass of prosthesis	3.98		3.70	
Mass below transducer	2.45		2.30	
B-Alignment in relation to the hip coordinate system				
	Position (cm)	**Orientation**	**Position (cm)**	**Orientation**
Centre of transducer				
Antero-posterior axis	-0.02	Anterior	-0.02	Anterior
Medio-lateral axis	-8.45	Medial	-9.16	Medial
Long axis	-31.91	Inferior	-34.17	Inferior
Centre of prosthetic knee joint				
Antero-posterior axis	-0.18	Anterior	1.54	Posterior
Medio-lateral axis	-8.36	Medial	-9.72	Medial
Long axis	-38.63	Inferior	-41.3	Inferior
Centre of prosthetic ankle joint				
Antero-posterior axis	3.47	Posterior	9.64	Posterior
Medio-lateral axis	-8.89	Medial	-11	Medial
Long axis	-79.15	Inferior	-80.46	Inferior
C-Data collection				
	Trials (#)	**Steps (#)**	**Trials (#)**	**Steps (#)**
WA-L	2	62	2	57
WA-S	10	92	8	66
ST-A	5	45	5	46
ST-D	5	27	5	56
IN-A	6	66	6	62
IN-D	6	71	6	77

Table 2: Mean and one standard deviation, and differences of the temporal characteristics with both prostheses during activities of daily living.

	Cadence	Duration		
		Cycle	Support	Swing
	(strides/min)	(s)	(%GC)	(%GC)
PRO1 (C-leg, tube adapter, C-Walk)				
WA-L	53±1	1.123±0.050	59.08±1.13	40.93±1.13
WA-S	52±1	1.151±0.054	63.54±1.35	36.46±1.35
ST-A	43±3	1.372±0.105	55.83±2.11	44.17±2.11
ST-D	50±2	1.205±0.042	54.86±1.44	45.14±1.44
IN-A	50±1	1.195±0.042	65.09±1.32	34.91±1.32
IN-D	56±0	1.067±0.024	59.23±1.38	40.77±1.38
PRO2 (Total Knee, Total shock, tube adapter, Trustep)				
WA-L	50±0	1.189±0.031	58.18±1.33	41.82±1.33
WA-S	50±1	1.200±0.046	62.77±1.55	37.23±1.55
ST-A	42±2	1.424±0.089	56.17±2.30	43.83±2.30
ST-D	47±1	1.277±0.049	50.26±1.84	49.74±1.84
IN-A	47±1	1.286±0.041	63.86±1.83	36.14±1.83
IN-D	47±1	1.269±0.059	61.77±2.34	38.23±2.34
Difference [PRO2 - PRO1]				
WA-L	-3 *	0.066 *	-0.90 *	0.90 *
WA-S	-2 *	0.049 *	-0.77 *	0.77 *
ST-A	-2 NS	0.052 *	0.33 NS	-0.33 NS
ST-D	-3 *	0.072 *	-4.60 *	4.60 *
IN-A	-4 *	0.091 *	-1.23 *	1.23 *
IN-D	-9 *	0.202 *	2.54 *	-2.54 *

* Significantly different (p<.05), NS Not significantly different

Table 3: Mean and one standard deviation, and differences of onset and magnitude of the maximum force and moment along the antero-posterior (AP), medio-lateral (ML) and long (LG) axes of the residuum with both prostheses during activities of daily living.

	Onset						**Magnitude**					
	F_{AP} (%GC)	**F_{ML} (%GC)**	**F_{LG} (%GC)**	**M_{AP} (%GC)**	**M_{ML} (%GC)**	**M_{LG} (%GC)**	**F_{AP} (%BW)**	**F_{ML} (%BW)**	**F_{LG} (%BW)**	**M_{AP} (%BWm)**	**M_{ML} (%BWm)**	**M_{LG} (%BWm)**
PRO1 (C-leg, tube adapter, C-Walk)												
WA-L	46.43±1.36	42.40±1.46	40.59±1.77	7.16±1.16	61.59±1.91	18.19±2.55	12.82±0.54	10.79±0.37	82.29±2.22	0.94±0.17	-1.93±0.10	-0.51±0.11
WA-S	49.40±1.57	45.30±1.91	43.36±2.07	10.69±1.69	63.20±2.11	20.84±2.12	12.81±0.43	11.54±0.43	85.89±1.98	1.16±0.18	-2.20±0.15	-0.47±0.09
ST-A	45.65±2.56	43.88±2.44	21.40±2.11	51.56±2.19	77.59±2.26	22.76±7.69	7.87±1.13	9.35±0.72	99.65±3.88	-0.39±0.11	-1.09±0.10	-0.48±0.19
ST-D	40.82±2.39	21.64±4.08	22.57±2.56	4.65±2.24	37.84±2.70	43.38±6.72	-22.45±1.22	4.59±1.03	64.56±3.95	0.62±0.27	-4.56±0.33	0.29±0.17
IN-A	51.65±1.38	49.07±1.74	27.78±1.87	9.75±1.66	66.99±1.88	20.60±2.00	13.69±0.68	11.07±0.50	88.44±2.28	1.08±0.22	-2.07±0.12	-0.69±0.10
IN-D	43.76±1.43	33.52±1.66	33.49±1.83	9.49±1.21	46.05±1.53	51.08±2.50	-15.74±1.02	7.93±0.47	77.65±1.50	0.94±0.19	-6.05±0.24	0.34±0.08
PRO2 (Total Knee, Total shock, tube adapter, Trustep)												
WA-L	44.20±1.36	42.38±1.46	42.11±1.77	7.97±1.16	43.05±2.26	47.26±1.01	17.82±0.54	13.17±0.37	87.28±2.22	1.25±0.17	1.91±0.26	-0.46±0.07
WA-S	46.50±1.57	44.62±1.91	43.96±2.07	9.41±1.69	57.16±2.11	49.28±1.85	17.26±0.43	13.93±0.43	90.32±1.98	1.35±0.18	-1.98±0.15	-0.37±0.10
ST-A	46.36±2.56	44.03±2.44	22.45±2.11	51.28±2.19	78.06±2.26	28.68±7.69	9.25±1.13	10.11±0.72	100.63±3.88	-0.54±0.11	-0.98±0.10	-0.43±0.19
ST-D	18.68±2.39	34.82±2.16	26.46±2.56	35.63±7.57	25.20±2.70	27.90±7.38	-7.55±1.22	6.45±0.47	79.85±3.95	0.83±0.28	-1.36±0.33	-0.27±0.22
IN-A	48.05±1.38	46.50±1.74	45.55±1.51	9.72±1.66	45.19±2.25	22.63±2.00	17.77±0.68	12.41±0.50	89.67±2.14	1.40±0.22	2.62±0.27	-0.58±0.10
IN-D	48.76±1.43	46.67±1.36	24.61±1.50	11.48±1.21	23.26±2.31	49.04±2.50	14.46±1.02	9.74±0.59	87.59±2.25	1.28±0.19	-1.95±0.50	-0.38±0.08
Difference [PRO2 - PRO1]												
WA-L	-2.24 *	-0.01 NS	1.51 *	0.80 *	-18.54 *	29.07 *	5.00 *	2.38 *	4.99 *	0.31 *	3.83 *	0.05 *
WA-S	-2.89 *	-0.68 *	0.60 *	-1.28 *	-6.04 *	28.43 *	4.45 *	2.39 *	4.43 *	0.20 *	0.22 *	0.10 *
ST-A	0.71 NS	0.14 NS	1.05 *	-0.28 NS	0.47 NS	5.91 *	1.38 *	0.76 *	0.99 NS	-0.15 *	0.11 *	0.05 NS
ST-D	-22.14 *	13.19 *	3.90 *	30.98 *	-12.64 *	-15.48 *	14.90 *	1.86 *	15.28 *	0.21 *	3.21 *	-0.56 *
IN-A	-3.61 *	-2.57 *	17.77 *	-0.03 NS	-21.80 *	2.03 *	4.07 *	1.35 *	1.24 *	0.32 *	4.69 *	0.11 *
IN-D	5.01 *	13.15 *	-8.88 *	2.00 *	-22.79 *	-2.04 *	30.19 *	1.81 *	9.94 *	0.35 *	4.10 *	-0.72 *

* Significantly different (p<.05), NS Not significantly different

Table 4: Mean and one standard deviation, and differences of the slope of the forces and moments along the three axes of the residuum during initial and terminal loading with both prostheses during activities of daily living.

	Initial loading						**Terminal loading**					
	F_{AP} (deg)	**F_{ML} (deg)**	**F_{LG} (deg)**	**M_{AP} (deg)**	**M_{ML} (deg)**	**M_{LG} (deg)**	**F_{AP} (deg)**	**F_{ML} (deg)**	**F_{LG} (deg)**	**M_{AP} (deg)**	**M_{ML} (deg)**	**M_{LG} (deg)**
PRO1 (C-leg, tube adapter, C-Walk)												
WA-L	26.39±2.15	15.51±1.61	71.83±1.45	85.18±1.27	36.12±25.92	-76.19±3.54	-22.42±2.71	-32.26±1.94	-77.49±0.72	-78.69±3.95	-84.01±1.69	62.04±9.37
WA-S	26.53±2.33	14.75±1.44	70.56±1.86	84.33±1.30	12.38±27.78	-76.96±2.74	-24.12±2.34	-32.37±1.57	-77.05±0.95	-81.08±2.00	-83.77±1.40	62.88±11.35
ST-A	6.47±1.74	17.23±3.07	73.57±2.72	75.71±6.56	-33.31±27.48	-50.78±24.04	-28.31±4.19	-36.79±3.68	-81.02±0.69	-80.66±2.60	-69.76±6.01	76.52±13.95
ST-D	-24.06±2.35	9.40±3.46	68.92±5.22	84.94±2.93	-85.89±0.82	-49.69±44.81	54.93±2.81	-14.24±3.01	-64.34±2.21	-19.76±51.16	87.64±0.27	39.19±36.40
IN-A	18.48±1.88	16.17±1.36	70.05±1.28	83.84±1.94	-25.89±36.28	-79.28±4.07	-27.42±2.17	-34.24±2.15	-79.23±0.53	-51.92±27.17	-85.56±0.64	66.99±15.22
IN-D	-13.33±4.33	12.31±1.10	72.60±1.69	84.25±1.46	-85.95±0.34	-71.01±14.18	53.55±1.47	-31.38±2.56	-72.14±0.98	-78.53±9.40	88.42±0.19	-60.46±9.80
PRO2 (Total Knee, Total shock, tube adapter, Trustep)												
WA-L	34.58±1.36	15.85±0.99	71.56±0.93	85.58±0.86	82.54±1.21	-68.95±5.41	-34.26±1.83	-35.87±1.76	-78.81±0.46	-80.78±4.34	-88.02±0.22	69.15±4.39
WA-S	34.94±2.11	15.96±1.69	70.56±1.24	85.39±0.66	80.92±3.61	-70.30±12.19	-33.61±2.02	-35.83±1.55	-78.31±0.78	-82.20±5.92	-87.97±0.32	66.50±5.03
ST-A	8.32±1.69	16.82±2.77	72.65±1.86	70.51±32.36	51.06±21.31	-46.22±14.51	-33.10±5.72	-34.20±3.05	-79.77±0.65	-79.87±4.75	-76.09±2.17	79.16±3.40
ST-D	-9.51±3.52	11.13±3.01	70.44±3.34	83.14±4.55	-57.72±36.27	-47.74±12.34	14.43±2.32	-20.29±1.99	-76.60±1.03	-78.44±3.36	76.07±5.41	9.34±4.73
IN-A	25.28±2.30	16.17±1.85	70.77±2.14	84.75±1.36	82.72±0.98	-75.76±2.37	-35.63±2.32	-32.43±2.00	-77.92±1.23	-3.61±24.53	-87.74±0.53	73.60±2.62
IN-D	31.82±2.39	10.95±2.10	68.51±2.84	84.38±1.05	82.74±10.74	-64.54±8.61	-34.79±4.48	-30.36±3.03	-77.16±1.80	-84.60±1.48	-87.97±1.36	60.68±8.19
Difference [PRO2 - PRO1]												
WA-L	8.19 *	0.35 NS	-0.27 NS	0.40 *	46.43 *	7.24 *	-11.84 *	-3.61 *	-1.32 *	-2.08 *	-4.01 *	7.11 *
WA-S	8.41 *	1.20 *	0.00 NS	1.06 *	68.54 *	6.66 *	-9.50 *	-3.46 *	-1.26 *	-1.12 NS	-4.20 *	3.62 *
ST-A	1.85 *	-0.41 NS	-0.92 *	-5.20 NS	84.36 *	4.56 NS	-4.79 *	2.59 *	1.25 *	0.79 NS	-6.34 *	2.64 NS
ST-D	14.56 *	1.72 *	1.52 *	-1.80 *	28.17 *	1.94 NS	-40.50 *	-6.05 *	-12.25 *	-58.68 *	-11.57 *	-29.85 *
IN-A	6.80 *	0.00 NS	0.73 *	0.91 *	108.61 *	3.52 *	-8.21 *	1.81 *	1.31 *	48.31 *	-2.18 *	6.61 *
IN-D	45.15 *	-1.36 *	-4.09 *	0.13 NS	168.69 *	6.46 *	-88.34 *	1.03 *	-5.02 *	-6.07 *	-176.39 *	121.14 *

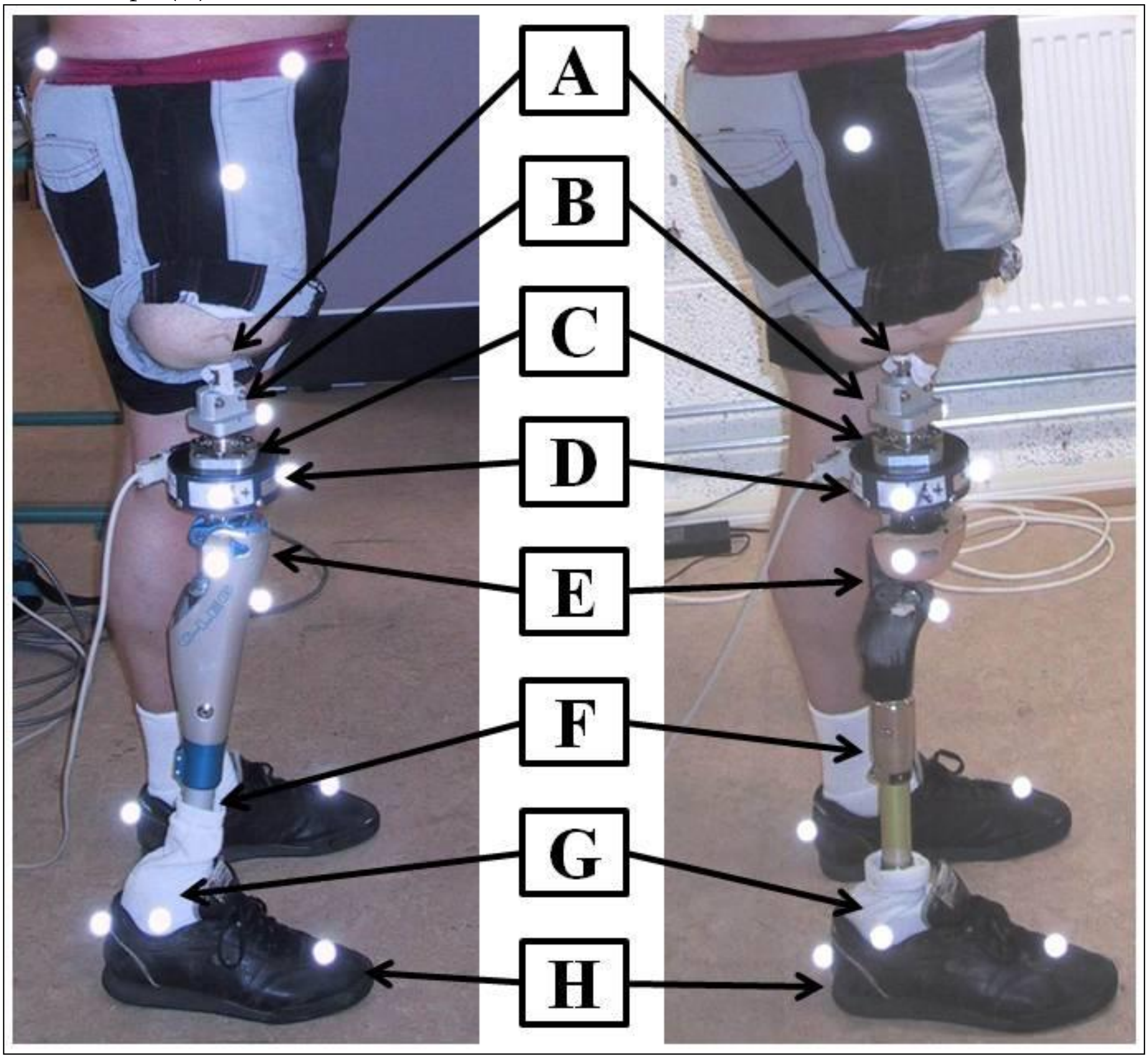
* Significantly different (p<.05), NS Not significantly different

Table 5: Mean and one standard deviation, and differences of the norm (N) of impulse and the component along the antero-posterior (AP), medio-lateral (ML) and long (LG) axes of the residuum with both prostheses during activities of daily living.

	I_{AP} (Ns)	**I_{ML} (Ns)**	**I_{LG} (Ns)**	**I_{N} (Ns)**
PRO1 (C-leg, tube adapter, C-Walk)				
WA-L	44.04±2.69	40.55±2.92	357.73±24.81	365.81±24.98
WA-S	47.36±2.26	45.93±3.58	398.14±25.00	406.94±25.17
ST-A	29.84±6.01	44.08±5.49	460.64±42.28	464.19±42.65
ST-D	79.77±5.28	16.10±3.07	260.61±21.30	274.18±20.88
IN-A	53.09±4.05	50.47±4.04	430.26±21.85	439.62±22.17
IN-D	54.29±2.88	26.12±1.85	294.94±8.13	302.17±8.26
PRO2 (Total Knee, Total shock, tube adapter, Trustep)				
WA-L	55.15±2.79	49.01±3.41	390.09±20.02	400.71±20.36
WA-S	57.66±3.64	53.28±3.91	422.40±20.48	433.57±20.85
ST-A	34.36±12.49	50.53±6.45	492.74±37.08	497.11±37.57
ST-D	26.09±5.13	23.19±3.10	319.07±21.39	321.51±21.60
IN-A	70.46±4.74	61.02±4.06	475.41±22.87	487.95±23.26
IN-D	51.90±5.21	42.60±5.99	433.32±33.96	441.66±34.77
Difference [PRO2 - PRO1]				
WA-L	11.11 *	8.46 *	32.36 *	34.90 *
WA-S	10.30 *	7.36 *	24.26 *	26.63 *
ST-A	4.53 *	6.45 *	32.10 *	32.92 *
ST-D	-53.68 *	7.08 *	58.46 *	47.33 *
IN-A	17.37 *	10.55 *	45.15 *	48.33 *
IN-D	-2.39 *	16.48 *	138.38 *	139.49 *

* Significantly different (p<.05), NS Not significantly different

Figure 1. Two prostheses used to measure the load applied to the bone-anchored fixation (A) of an individual with transfemoral amputation including an connector (B), 4-hole standard adapter and designed plate (C), a transducer^ (D), knee joint (E), foot (G) and footwear (H). The prosthesis on the left view included a C-Leg* (E), tube adapter* (F) and C-Walk* (G). The prosthesis on the right view included a Total Knee# (E), Total shock# (F), tube adapter# and TrustepO (G).



(Provider: ^Model 45E15A; JR3 Inc., Woodland, USA; *Otto Bock, Vienna, Austria; #Ossur, Reykjavik, Iceland; OCollege Park Industry, Detroit, USA)

Figure 2. Maximum value (Max) as well as mean and one standard deviation of forces and moments applied over a gait cycle along the antero-posterior, medio-lateral and long axes of the residuum during walking in long (WA-L) and short (WA-S) walkway. HC: mean heel contact, TO: mean toe-off

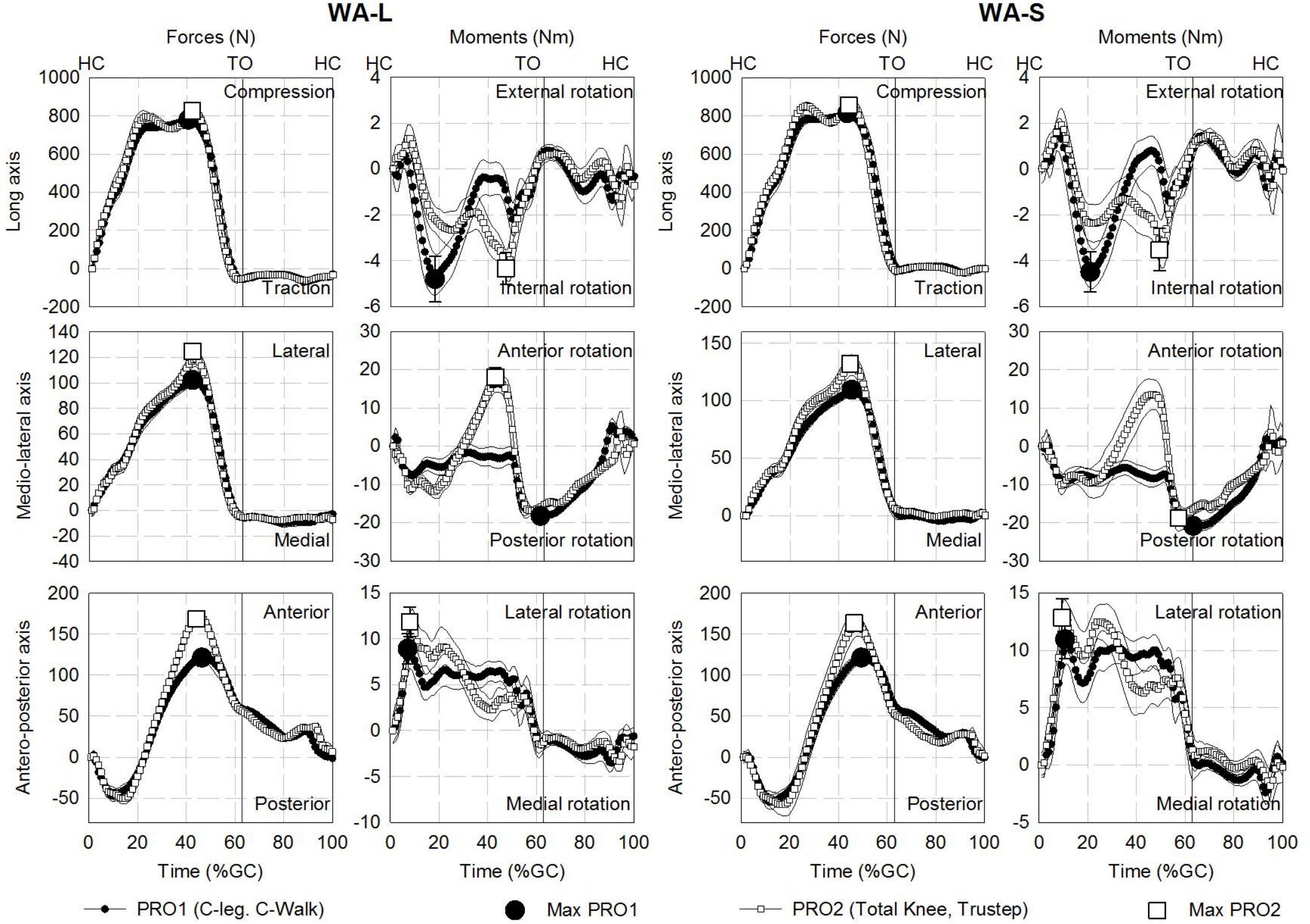


Figure 3. Maximum value (Max) as well as mean and one standard deviation of forces and moments applied over a gait cycle along the antero-posterior, medio-lateral and long axes of the residuum during stairs ascent (ST-A) and descent (ST-D). HC: mean heel contact, TO: mean toe-off

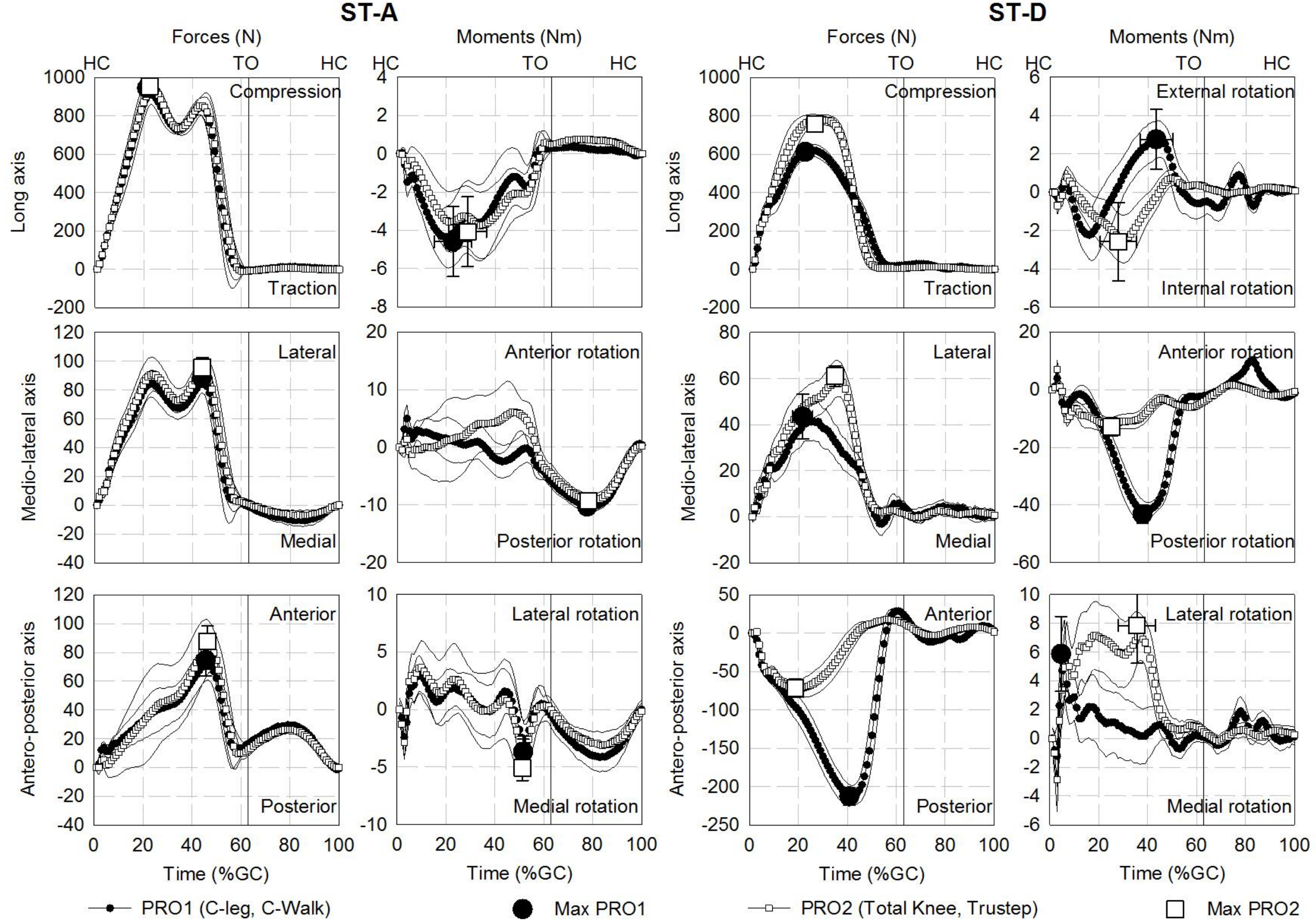


Figure 4. Maximum value (Max) as well as mean and one standard deviation of forces and moments applied over a gait cycle along the antero-posterior, medio-lateral and long axes of the residuum during incline ascent (IN-A) and descent (IN-D). HC: mean heel contact, TO: mean toe-off