Functional added-value of prostheses with an electronically controlled stance and/or swing phase for patients with a unilateral transfemoral amputation, a hip or a knee disarticulation
-
a clinical study

Final report

adelante
haal het beste uit jezelf

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Functional added-value of prostheses with an electronically controlled stance and/or swing phase for patients with a unilateral transfemoral amputation, a hip or a knee disarticulation
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1 Introduction

In the past decades many innovative developments have occurred in the field of upper leg prosthetics. As a result a wide range of prosthesis types is now available, all with different characteristics leading to possible advantages and disadvantages for the individual amputee. Nowadays, rehabilitation physicians and prosthetists have to meet the increasing demand to justify their prosthesis indications towards both patients and healthcare insurance companies. Therefore, it is very important to know the characteristics of prosthesis components and their effects on the functioning of the patient. The knee joint fitted in a leg prosthesis is essential for effective and safe ambulation (1, 2) and is therefore of special interest. All studies on prosthetic knee joints and their effects on gait have been performed by either the manufacturer or by independent research groups across the world. These studies typically focused on biomechanical and (neuro)physiological measures, i.e. measures at function level, to quantify any possible added-value of prosthetic knee joints (3-7). Although important, the effects of prosthetic components should not be assessed solely at function level, as this would disregard the problems that occur at activity and participation level. From the amputee's perspective, it is more important to be able to resume previous social roles, rather than to be able to, for example, walk 100 metres three seconds faster.
At present, no protocols describing the functional added-value or additional functional qualities of specific prosthesis are available. At Adelante rehabilitation centre in Hoensbroek, the Netherlands, a new test concept was therefore developed to objectively measure the performance of daily life activities in persons with a unilateral transfemoral amputation.

The aim of this study was to evaluate the possible functional added-value of two types of microprocessor controlled knee joints relative to conventional mechanically controlled knee joints in daily life for unilateral transfemoral amputees classified as Medicare Functional Classification Level-2 amputees (MFCL-2).

The main research questions for this study are the following:

1) Which of three types of prosthesis featuring a knee joint with either an electronic stance phase control, an electronic stance and swing phase control, or a non-electronic control best facilitates/improves basic ambulation functions and <u>actual</u> level of daily performance in patients with a unilateral above the knee amputation?

2) Which of three types of prosthesis featuring a knee joint with either an electronic stance phase control, an electronic stance and swing phase control, or a non-electronic control best improves <u>perceived</u> level of daily performance in patients with a unilateral above the knee amputation?

To be able to establish the participants' level of performance in daily life, measurements were performed in different areas of functioning according to ICF terminology:

- Participation level
- Activity level
- Function level

The initial phase of the study started in November 2006 and was aimed at setting up the equipment and readying all procedures. In February 2007 several test trials with transfemoral amputees were performed to fine-tune the procedures and address possible clinical issues. Participant testing took place between March 2007 and December 2009. A total of 103 eligible persons from different rehabilitation centres, hospitals and prosthetic businesses in parts of the Netherlands and Belgium were selected to participate. 41 persons were included into the study. Overall, each participant was tested on six full days during a three-week period, allowing for a maximum of two participants per week to be tested. Also, daily activity in the participant's home environment was measured during three consecutive weeks.

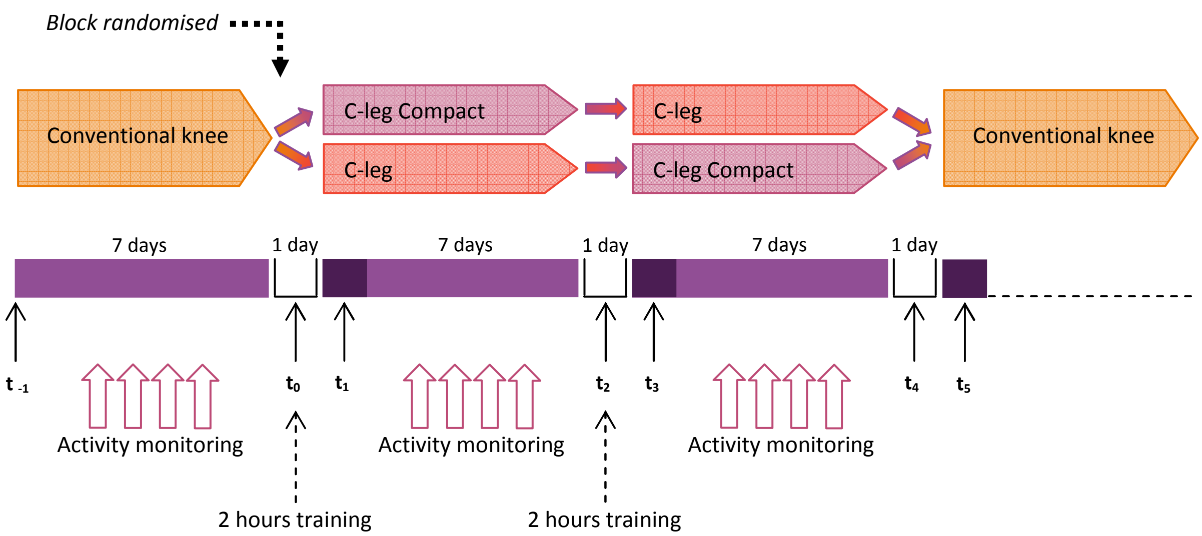
This report describes the participants that were measured, the methods and tests that were performed. It reports on the results regarding the individual tests. Overall conclusions concerning the abovementioned research questions are given, based on all test results. Furthermore, recommendations for future research are given.

2 Methods

2.1 Study design

The total time each participant was involved in the study was three weeks and four days (see figure 1). The participants started the study while using their own conventional prosthesis (**t_{-1}**). During the first week of the study the participants' activity level in their home environment was monitored by an accelerometer that was worn around the waist, and by keeping an activity diary.
At day 1 of the second week, the participants were tested for the first time at Adelante rehabilitation centre in Hoensbroek while wearing their own prosthesis fitted with a conventional knee joint (**t_0**).
After the measurements, the participant's prosthetic leg was fitted with either a C-leg or a C-leg Compact (assigned randomly) by a certified prosthetist, followed by a specialised two-hour physiotherapy training session. The purpose of the training was to make sure that the participants were able ambulate and function safely in their home environment. And the training was necessary to teach the participants to control the possibilities of their new prosthetic knee joint. After successful completion of the training, the participants went home and returned to the rehabilitation centre the next day (**t_1**), where the same tests were performed analogous to the day before.
Subsequently, the participants used the microprocessor controlled knee joint in their home environment for a period of seven days. During this period participants wore the same accelerometer in combination with a new (blank) activity diary similar to the procedures followed in week 1.
The participants performed the same measurements as before at the end of the seven-day period (**t_2**) and were then fitted with the second type of microprocessor controlled knee joint. After the training session, the participants went home and returned the next day to complete all the tests again (**t_3**).
During the third period of seven days, the participants could practice on this second type of prosthesis. Participants' activity levels were again measured during this week with the accelerometer in combination with the activity diary.
The participants were tested after this period (**t_4**). Subsequently, the prosthesis was refitted with their original conventional knee joint.
At the last day of the study, the same measurements were performed again on the conventional prosthesis (**t_5**). An overview of the study design is presented in figure 1.

Figure 1. Overview of study design



In total, each participant performed the same test battery six times, each time under different prosthesis conditions. These prosthesis conditions are coded as follows:

R1 = measurement at $\mathbf{t_0}$ with the participants' current mechanical prostheses.
R2 = measurement at $\mathbf{t_5}$ with the participants' current mechanical prostheses.
A1 = first measurement on C-leg after one day.
A2 = measurement on C-leg after one week of daily use.
B1 = first measurement on C-leg Compact after one day.
B2 = measurement on C-leg Compact after one week of daily use.

2.2 Measurements

The evaluation of the functional added-value of a microprocessor-controlled knee joint in daily life was performed on three distinct levels of functioning as described in the ICF, i.e. participation level, activity level and function level. Different measurements were performed for each ICF level.

2.2.1 Participation level

ADAPT-test
The ADAPT-test (Assessment of Daily Activities Performance in Transfemoral amputees) is a test circuit that consists of 17 common daily activities that are grouped into the following "stations":

1) Supermarket shopping.
   '*easy*': 18 low weight (500 g), easy to handle objects have to be picked from shelves at different heights and have to be placed into a shopping trolley.
   '*moderate*': 4 moderate weight (2 and 5 kg) objects have to be picked from the shelves and placed into the shopping trolley.
   '*difficult*': 2 large and heavy (6 kg) objects have to be picked from the shelves and then placed into the shopping trolley.
2) Putting 18 'easy' objects in the shopping bags.
3) Unloading the shopping bags into the kitchen cabinets at different reaching heights.
   '*easy*': put the 18 low weight objects in the designated cabinets.
   '*difficult*': put 5 objects from one cabinet onto another with the help of a kitchen step.
4) Picking up laundry from a tray on the ground and hanging it up.
5) Slaloming while holding a tray with table tennis balls.
6) Sitting down and standing up.
   '*easy*': sit down in high armchair, stand up, walk to the television to pick up remote control and sit down again.
   '*moderate*': sit down in low sofa, stand up, walk to the television to pick up the remote control and sit down again.
7) Walking across a room and avoid all the obstacles on the ground (toys).
8) Walking sideways between two rows of chairs while holding a cup of water (theatre).
9) Getting into and out of a car.
10) Going up and down stairs.
   '*easy*': normal walking.
   '*moderate*': with additional cognitive load.
11) Walking up and down a ramp with an angle of approximately 7°.
   '*easy*': normal walking.
   '*moderate*': with additional cognitive load.

For stations 10 and 11 the ADAPT-test was used in two different settings, i.e. in a single task paradigm and in a dual task paradigm.
Some examples of the common daily activities are shown in figures 2, 3, 4 and 5.

For all activities the performance time necessary to complete the task (in seconds) and the self-perceived level of difficulty (using a Visual Analogue Scale) were recorded.

Figure 2. Supermarket shopping

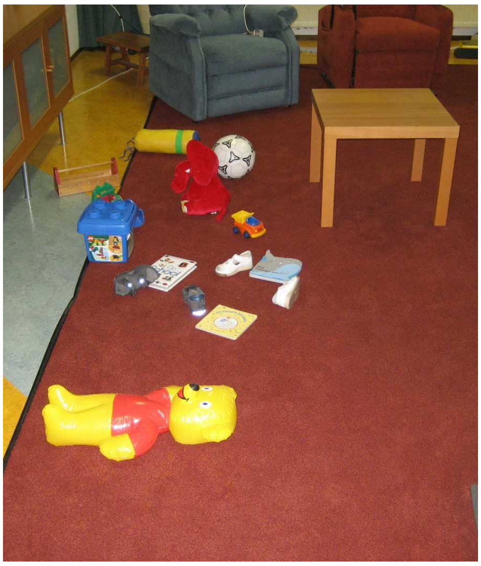


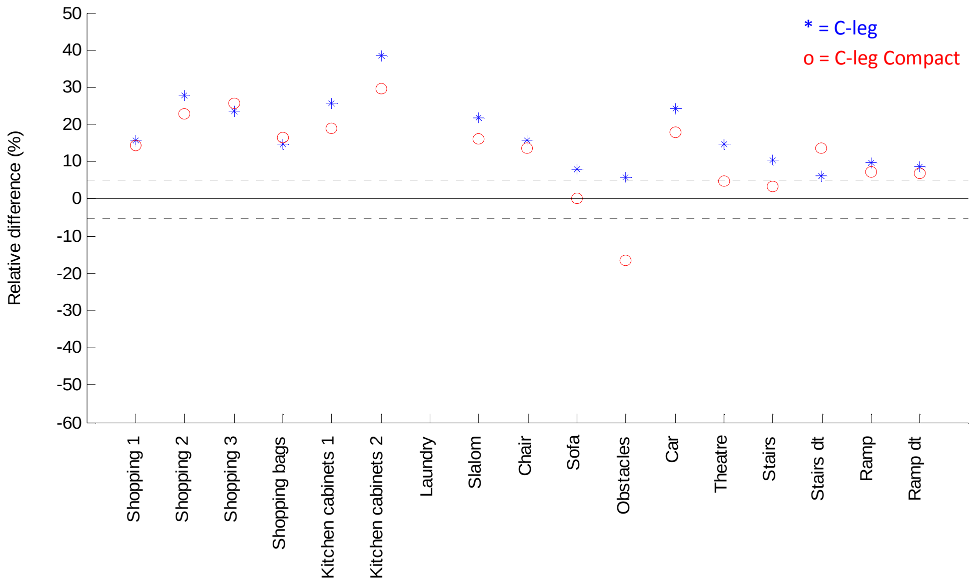
Figure 3. Obstacle avoidance

Figure 4. Walking sideways between two rows of chairs (theatre)

Figure 5. Getting into and out of a car

The results of the ADAPT-test can be used to, for example, create an individual patient profile providing easy-to-interpret information concerning possible benefits or detriments in performing daily activities from using a specific prosthetic components. To this end, differences in performance time can be calculated relative to a certain standard reference value for all ADAPT-test activities. Figure 6 shows an example of an individual patient profile of one typical participant in the current study. The horizontal line represents the participant's performance on his conventional prosthesis (standard reference value). A data point above this line indicates an improvement of performance on that particular activity when performing it on a different prosthesis type (in this case C-leg and C-leg Compact) relative to the performance on the conventional prosthesis. A data point below the line indicates a detriment of performance due to the alternative prosthesis type. A more extensive explanation concerning the calculations on which these figures are based can be found in section 2.3 of this report.

Figure 6. Example of an overview of the relative differences in performance time on all ADAPT-test activities for both C-leg (blue asterisk) and Compact (red circle) compared to the conventional prosthesis (0%) for one typical MFCL-2 amputee



Perturbation and stability tests

The protocol for the perturbation and stability tests is similar to the protocol used by Prof. Dr. Blumentritt and co-workers (personal communication dd. 08-03-2007). The protocol describes four different tests:

Tripping test: a line is attached to the prosthetic leg. During one of maximally 10 runs the line is briefly stopped giving the participants the impression that they tripped over something. The subjects do not know in advance when the trip will take place (see example in figure 7). Tripping is provoked during early swing phase.

Stop or Step test: the subjects walk towards the researcher who in turn can give them a hand signal indicating to them to stop immediately or to make a side step towards the unaffected side. Signalling was done when the participant's prosthetic leg is in early swing phase.

Obstacle test: three small blocks are placed along the walkway in such a way that the participant steps on them. The subjects are instructed to walk without focussing on the blocks. Several runs are often necessary to obtain a proper step onto the object(s).

During all tests the participants are secured by a safety harness attached to a ceiling mounted rail. All of these tests are recorded in standardised conditions using a digital camera. Independent professional therapists, blinded for knee joint condition of the participant, rated the quality of event recovery based on the video clips using a Likert scale from 1 to 10; 1 being very poor and 10 being excellent.

After each test the participants were asked to give a subjective opinion about:

- Their ability to perform the different perturbation and stability tests;
- Their sense of stability on the type of knee joint used during the different perturbation and stability tests;
- Their level of anxiety to fall experienced during these tests;
- Their overall sense of safety during the tests.

These opinions were scored using a Visual Analogue Scale (VAS) based questionnaire. Participants mark on a line, 100mm in length, the point that they feel represents their opinion best.

Figure 7. Example of a participant during the tripping test

Outdoor circuit

The outdoor circuit comprises of walking across a 58 meter outdoor circuit with different textures and obstacles. The test consisted of a tiled path (B), a 5,40 m slalom path (A), a 3,35 m path with 10x10 cm cobblestones (C), a 4,20 m path consisting of 0,75 cm grade gravel (D), two short ramps (length: 5,70 m (E) and 3,00m (F); inclination: 7.0° and 13.5°) and a short 5 step staircase (G) (rise: 14 cm; run: 30 cm). The outdoor circuit is presented in figure 8.

Figure 8 Overview of the outdoor circuit

2.2.2. Activity level

During the entire length of the testing period the participants' activity level was monitored using a uniaxial accelerometer (Actigraph, Pensacola (FL.), USA) that was worn at the waist. Activity level is measured as the number of accelerations per minute that exceed a predetermined threshold. From the data acquired from the accelerometer the mean total time the participant wore the accelerometer (=awake time) (min), the amount of time a participant was active during the awake time (%) and the activity level per minute for each knee joint condition. Figure 9 shows an example of the activity data for one week.

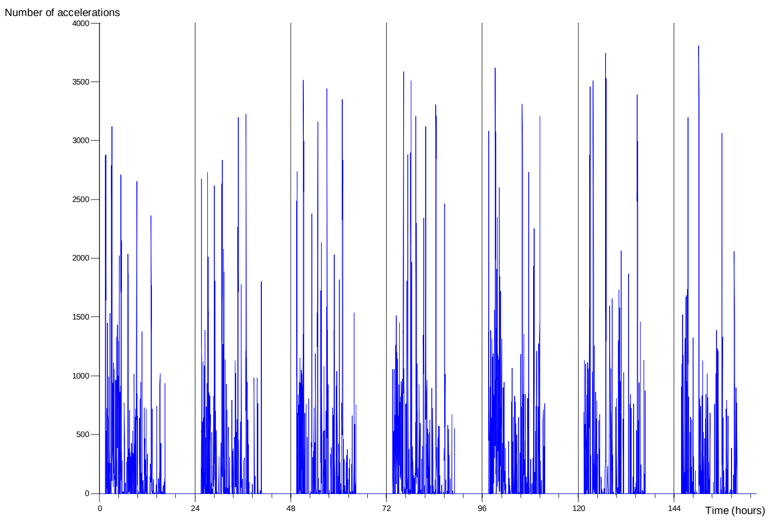


Figure 9. Example of raw activity monitor data (1 week)

2.2.3. Function level

2 Minute walking test

Participants were asked to walk at their comfortable walking velocity for a period of 2 minutes on even surface (indoors). The total distance travelled in this period was measured using a measuring wheel (Stanley Works Benelux, Mechelen, Belgium). The results of this test are a measure of endurance capacity and the results can be used to calculate average walking velocity.
To evaluate the gait automaticity of the participants, this test was performed a second time using a dual task paradigm. Participants were asked to walk at a comfortable walking velocity while simultaneously naming as many animals as possible. The difference in measured distance between the single task and dual task conditions is a indicator of automaticity.

Spatial-temporal gait parameters

The gait parameters step length (prosthetic leg and healthy leg), stance phase duration (prosthetic leg and healthy leg) and cadence were measured using the GAITRite© electronic walkway system (CIR systems Inc, Havertown (PA), USA).

2.3 Data analysis

Data reduction/grouping of participation circuit data

To give a more concise overview of the results on the participation circuit, all 17 activities were classified into 3 independent groups. These 3 groups were the result of a statistical data reduction method called principle component analysis (or factor analysis) using a Varimax rotation. This analysis was performed on the data acquired at $\mathbf{t_0}$ (first measurement on conventional prosthesis). This data set was specifically chosen because it represents the participants' performance time in situation they are most accustomed to, i.e. on their own conventional prosthesis. Each of the (orthogonal) factors identified by the principle component analysis represent underlying similarities of the 17 activities of the ADAPT-test. Varimax rotation was applied to optimise the fitting of factors across the data matrix of the 17 activities. This procedure resulted in 3 main factors. The ADAPT-test activities that had a high loading index in factor 1 were grouped. This was also done for factor 2 and 3, resulting in three independent groups of activities that share 'content-similarity'. These groups (1, 2 and 3) will be used in further analyses. The content-similarity has been identified as "physical multi-tasking activities" (group 1), "low to moderate intensity ambulation activities" (group 2) and "difficult ambulation activities heavily depending on patient's prosthesis-related skills" (group 3).
Table 1 gives an overview of the activities that were grouped, based on the factor analysis, and the description that was given to describe the factor-based content-similarity between activities.

Table 1. Three groups of activities each representing content-similarity as indicated by factor loading indices in the principle component analysis of t_0 data.

Group 1 *Physical multi-tasking activities*	**Group 2** *Low to moderate intensity ambulation activities*	**Group 3** *Difficult ambulation activities heavily depending on patients' prosthesis-related skills*
Supermarket shopping (easy)	Sitting down and standing up from a chair	Putting objects on top of kitchen cabinet using small kitchen step
Supermarket shopping (moderate)	Sitting down and standing up from low sofa	Slalom while holding a tray with table tennis balls
Supermarket shopping (difficult)	Getting into and out of a car	Obstacle avoidance in a living room setting
Filling of shopping bags	Walking sideways between two rows of chairs	Hill descent and ascent
Putting objects into kitchen cabinets		Hill descent and ascent with cognitive dual task
Picking up and hanging out laundry		Stair ascent and descent
		Stair ascent and descent with cognitive dual task

Per group of activities, one mean performance measure (=mean performance time) was calculated per subject, per prosthesis condition.

Statistical analysis

To detect possible differences in performance time between the knee conditions the nonparametric test for multiple correlated samples (Friedman two-way analysis of variance by ranks test) was used (8). Multiple comparison included Wilcoxon signed rank tests for paired observations.
Possible differences between subclasses of participants were tested using the nonparametric Kruskal-Wallis one-way analysis of variance test for multiple independent samples. Subsequently, multiple comparison included Mann-Whitney U tests. In case of the multiple comparison tests (Wilcoxon and Mann-Whitney U tests) the Bonferroni correction was used by dividing the significance threshold (α=0.05) by the number of comparisons (8).

Normalisation procedure for differences between prosthetic conditions

To gain more insight into the amount of change in performance between conditions the mean relative difference between the performance time on the conventional prosthesis and the performance time on both microprocessor controlled knee joints were calculated ($PT_{relative}$) for each group of activities (see table 1) and for each participant using the following formula:

$$PT_{relative} = \left(\frac{Performance_{electronical} - Performance_{conventional}}{Performance_{conventional}} \right) \times 100\%$$

This calculation expresses the percentage of improvement or deterioration of the participant's performance time when using either a C-leg or a C-leg Compact compared to the performance time on his of her own conventional leg prosthesis measured at t_0. A positive value indicates an improvement on a microprocessor-controlled knee joint compared to the conventional prosthesis. A negative value represents a decrease in performance time relative to the performance time when using a conventional prosthesis.

Data were statistically analysed using SPSS 16.0.1 (SPSS Inc, Chicago, Ill) and Matlab 7.2.0 (The MathWorks Inc, Natick, MA).

3 Results

3.1 Participants

Selection, inclusion and testing of patients occurred between January 2007 and December 2009. Figure 10 gives a schematic overview of this process.

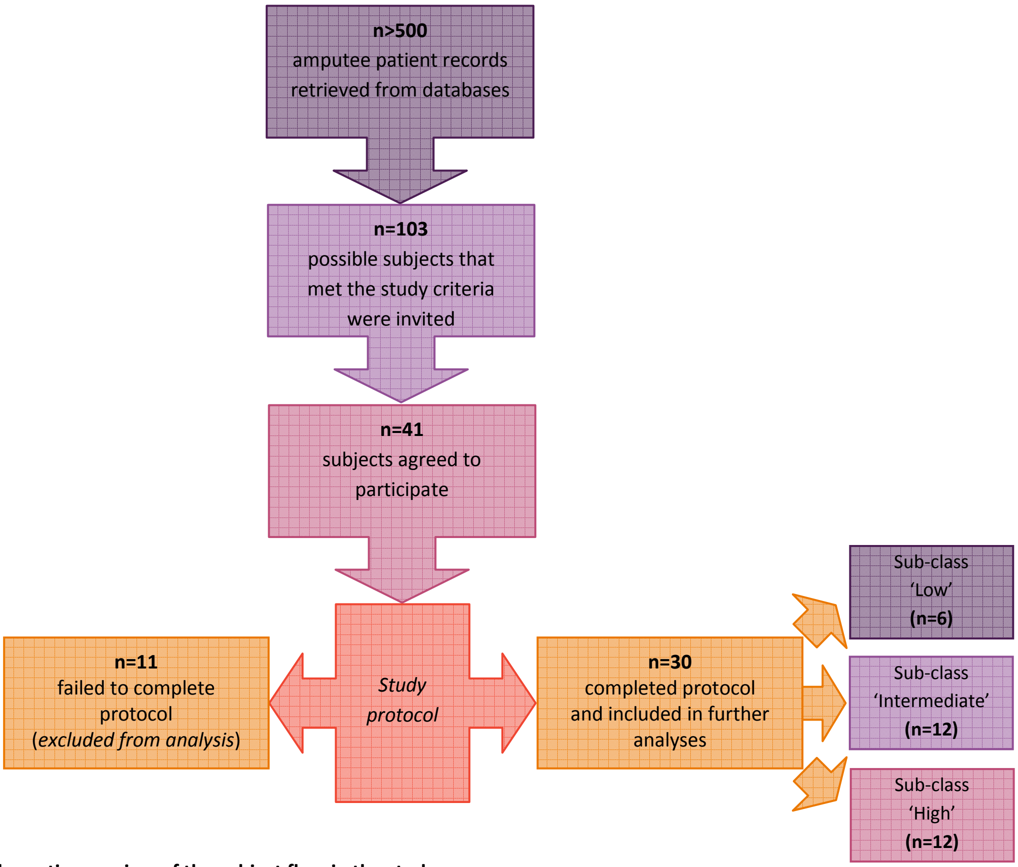


Figure 10. Schematic overview of the subject flow in the study

From over 500 (amputee) patient records 103 persons were retrieved that met the inclusion criteria. A total of 41 persons were included in the study. Table 2 gives an overview of the age and gender of these 41 participants.

Table 2. Participant characteristics of 41 included subjects

n	Gender		Age (years)
	Male	Female	Mean (SD)
41	31	10	59.5 (12.7)

Eleven of the included participants were not able to complete the entire protocol. The reasons for dropping out of the study were:

- General overuse, leading to physical complaints resulting in an inability to ambulate normally. The intensity of the measurements during the study was too high for those participants that were relatively inactive in daily life (n=1);
- Overuse of the stump during testing, leading to stump wounds (n=1);
- Inability of the participant to ambulate safely on the newly fitted microprocessor-controlled knee joint (n=3);
- Technical problems with prosthesis (e.g. impossible to fit different knee joint or poor fit of the socket at t_0) (n=4);
- Decease of participant (not related to participating in the study) (n=1);
- Co-morbidities: stroke (n=1).

The characteristics of the participants that dropped out are shown in table 3.

Table 3. Characteristics of the participants that did not complete the study protocol

Gender (n)		Age (years)	Aetiology for amputation (n)			Sub-class (n)		
Male	Female	Mean (SD)	Trauma	Vascular	Tumour	High	Intermediate	Low
9	2	61.4 (10.2)	3	8	-	-	2	9

Participant sub-classification

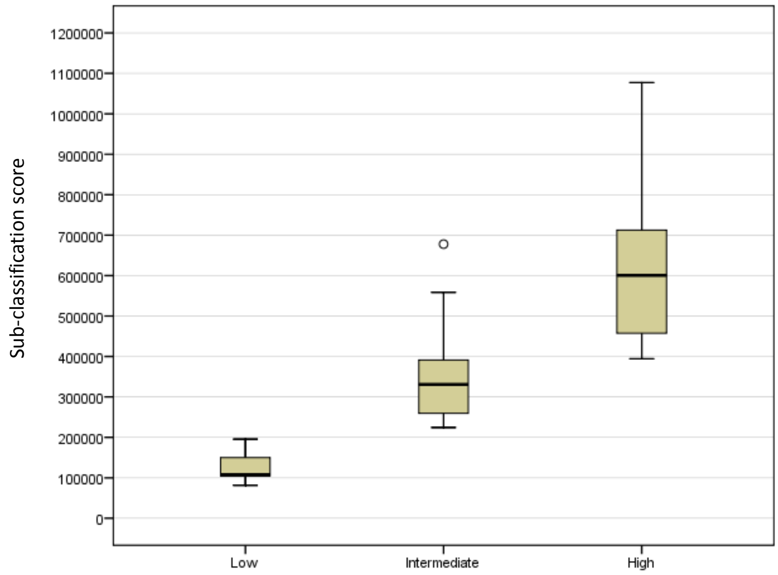
Clinical experience concerning the performance level of MFCL-2 amputees led to the assumption that this group is a heterogeneous group of patients. This assumption was also already suggested by other colleagues in this field of expertise across the Netherlands. Because large between-subject variability was expected in the MFCL-2 amputees due to the heterogeneous character of this patient population, the participants were categorized into 3 different subclasses: *'low', 'intermediate' and 'high'* MFCL-2 amputees. This classification was based on a combined measure of the participant's activity level in the home environment on the conventional prosthesis (measured with the accelerometer) and the average comfortable walking velocity on the conventional prosthesis (calculated from the 2 minutes walking test without a dual task). The combined measure used to categorise the participants is the product of activity level and walking velocity. After classification of the subjects using the combined measure the results were eventually assessed from a clinical point of view and knowledge about the patients to rule out possible mismatches. Using only walking velocity to classify the participants lead to 73.3% agreement with clinical classification of cases. Classification solely based on activity level was in agreement with clinical classification in 80% of the cases. The combined measure was able to accurately classify the participants in 93.3% of the cases. A description of the included participants after the final sub-classification is given in table 4.

Table 4. Participant characteristics for all 3 sub-classes

MFCL-2 subclass	**Gender**		**Age** (years)		**Weight** (kg)		**Post-amputation time** (years)		**Aetiology for amputation (n)**		
	♂	♀	Mean	SD	Mean	SD	Mean	SD	Trauma	Vascular	Tumour
Low	5	1	65.2	12.6	87.2	3.2	20.3	19.6	3	3	0
Intermediate	10	2	61.0	10.0	75.3	14.0	21.1	19.1	10	2	0
High	7	5	54.1	14.9	73.3	12.0	22.4	18.1	10	1	1

In figure 11 a visual representation of the sub-classification factors for the three sub-classes is presented. A clear distinction is visible between the three subclasses with the exception of a small overlap between the sub-classes ‘intermediate’ and ‘high’. This overlap represents the 6.7% (n=2) of the participants that were reclassified based on the discrepancy between the clinical expert assessment of the patient and the value of the calculated classification factor.

Figure 11. Overview of sub-classification scores of R1 for the ‘low’, ‘intermediate’ and ‘high’ sub-classes



3.2 Participation level

3.2.1 ADAPT-test

The relative difference in performance time (ΔPT) between the C-leg and the conventional prosthesis conditions and between the C-leg Compact and the conventional prosthesis conditions were calculated for every ADAPT-test activity. The performance time in the conventional knee joint condition was hereby set as the reference value (=0%). Subsequently, an average value of the relative differences in performance time (ΔPT) across all ADAPT-test activities was calculated for both the C-leg and the Compact conditions. The threshold for a clinically relevant change in performance time was set at 5% increase or decrease.
A general overview of the ADAPT-test results is given in table 5. It consists of the number of 'responders', 'non-responders' and 'double-responders' to a microprocessor-controlled knee joint. A 'responder' is defined as someone who meets both of the following criteria based on the abovementioned calculations:

1) The participant demonstrated an average improvement in performance time (across all 17 ADAPT-test activities) of more than 5%;
2) The participant demonstrated an improvement in performance time of >5% in the majority (>50%) of the ADAPT test activities.

A 'non-responder' is someone who does not meet the abovementioned criteria, whereas a 'double-responder' meets both these criteria when using either microprocessor-controlled knee joint.

Table 5. Overview of the number of 'responders', 'non-responders' and 'double-responders' to the C-leg and the C-leg Compact on the ADAPT test

	Responders		Non-responders		Double-responders
Subclass	C-leg	Compact	C-leg	Compact	
High	50.0%	50.0%	50.0%	50.0%	33.3%
Intermediate	81.8%	36.4%	18.2%	63.6%	36.4%
Low	33.3%	0%	66.7%	100%	0%
Total group	58.6%	34.5%	41.4%	65.5%	27.6%

Table 5 shows that 50% of the participants in subclass 'High' can be classified as a 'responder' to the C-leg, i.e. 50% of the participants classified as 'High' seem to have a benefit in performing common daily activities from using a C-leg. Furthermore, 50% 'responds' to the C-leg Compact and a third of the participants in subclass 'high' benefitted from both microprocessor-controlled knees. In the subclass 'Intermediate' 81.8% of the participants is a 'responder' using a C-leg in performing daily life activities. In the Compact condition 36.4% of the participants in the 'Intermediate' subclass could be classified as a 'responder', while 36.4% of the 'intermediate' subclass benefitted from both the C-leg and the Compact. From the participants in the 'low' subclass, 33.3% benefitted from using a C-leg and none of the participants from this subclass benefitted from using the Compact.
In total, 17 out of 29 participants (58.6%) were classified as a 'responder' to a C-leg. In the C-leg Compact condition this was the case for 10 out of 29 participants (34%). Moreover, in the Compact condition there were 4 participants who demonstrated an improvement in more than 50% of the ADAPT test activities but showed an average increase in performance that was less than 5%. One participant in the Compact condition had an average increase in performance of more than 5%, but did not improve on a majority of the ADAPT test activities.

Overall, 19 participants (65%) seem to benefit from at least one of the microprocessor-controlled knee joints:
9 out of these 19 participants (47%) benefitted only from the C-leg (2 high, 5 intermediate and 2 low); 2 participants (7%) benefitted only from the C-leg Compact (2 high); 8 participants (46%)

benefitted from both microprocessor-controlled knee joints, of which 5 participants (26%) benefitted more from the C-leg than from the Compact (3 high, 2 intermediate) and 3 participants (10%) benefitted more from the Compact than from the C-leg (1 high and 2 intermediate).

In the following section more detailed information concerning the ADAPT-test results are presented. The results will be presented for the three sub-classes 'high', 'intermediate' and 'low' MFCL-2 amputees.

Comparison of baseline performance times between subclasses on conventional prosthesis
Figures 12-14 show boxplots of the (median) performance times per knee joint condition (R1, R2, A1, A2, B1 and B2) on the 3 groups of activities of the ADAPT-test (grp1, grp2 and grp3). Each figure represents a different sub-class (high, intermediate and low). The large horizontal lines indicate the median values of the performance time at R1 for that specific group of activities.
A statistical comparison was made between the performance times at baseline (R1) between the 'high', 'intermediate' and 'low' sub-classes for groups 1, 2 and 3. Because three statistical tests were performed for each group, the statistical significance threshold was 0.05/3 = 0.017 (Bonferroni).
The activities in group 1 were performed significantly faster by the participants in the 'high' and 'intermediate' sub-classes compared to the participants in the 'low' sub-class (p=0.001 and p=0.007 respectively). The difference between sub-classes 'high' and 'intermediate' did not attain statistical significance for activities in group 1.
Group 2 activities were performed significantly faster in 'high' and 'intermediate' sub-classes compared to sub-class 'low' (p=0.003 and p=0.015). Sub-class 'high' performed the group 2 activities also faster than sub-class 'intermediate' (p=0.013).
The observed differences in performance time on the activities in group 3 between the sub-classes 'high' and 'low' just failed to attain significance (p=0.025). This is also the case for the differences between 'high' and 'intermediate' (p=0.094). The difference in performance time between sub-classes 'intermediate' and 'low' failed to attain statistical significance for the activities in group 3.

Figure 12. Boxplots of the performance times on the 3 groups of the ADAPT-test activities on all knee joint conditions for sub-class 'High'

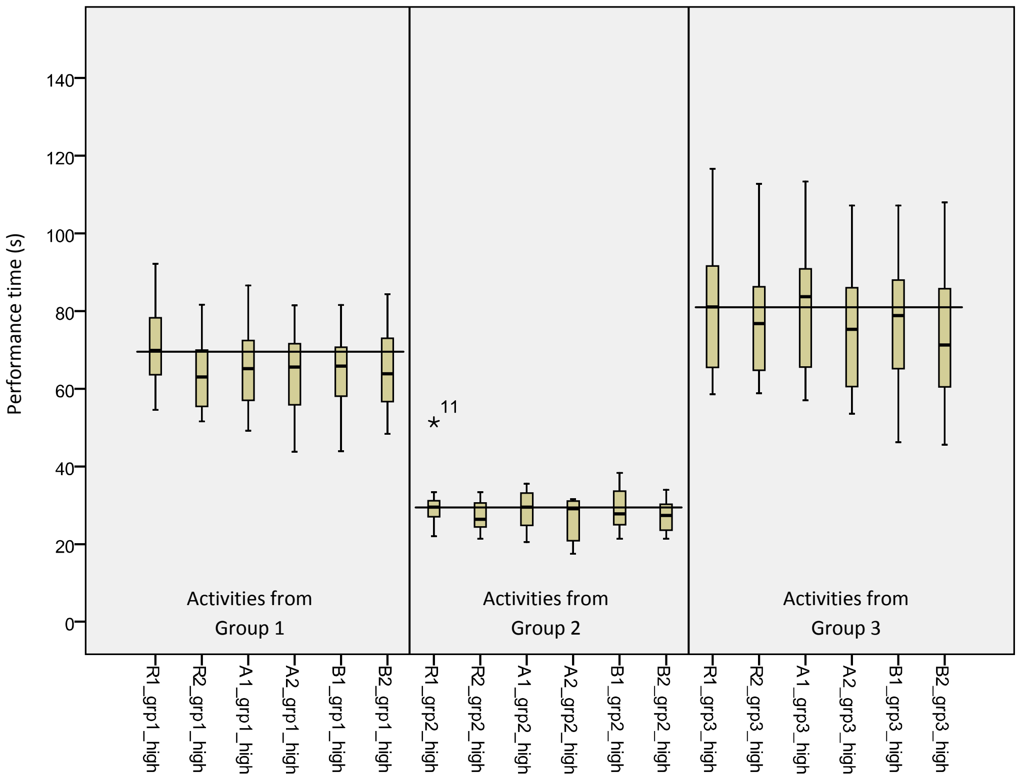


Figure 13. Boxplots of the performance times on the 3 groups of the ADAPT-test activities on all knee joint conditions for sub-class 'Intermediate'

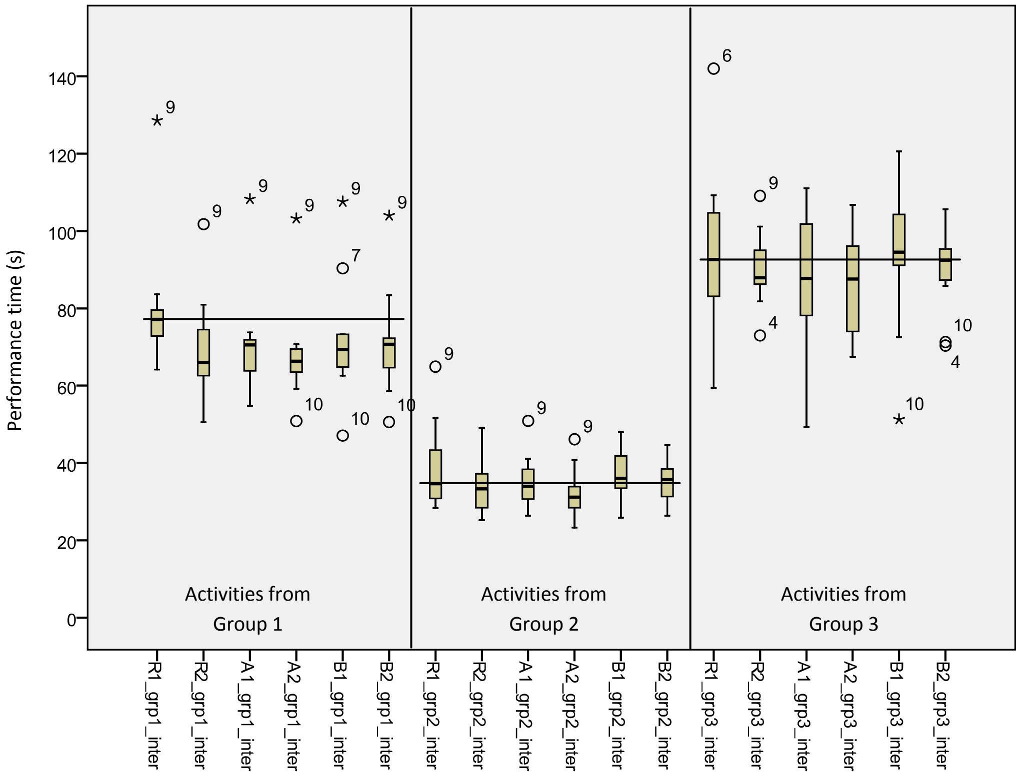
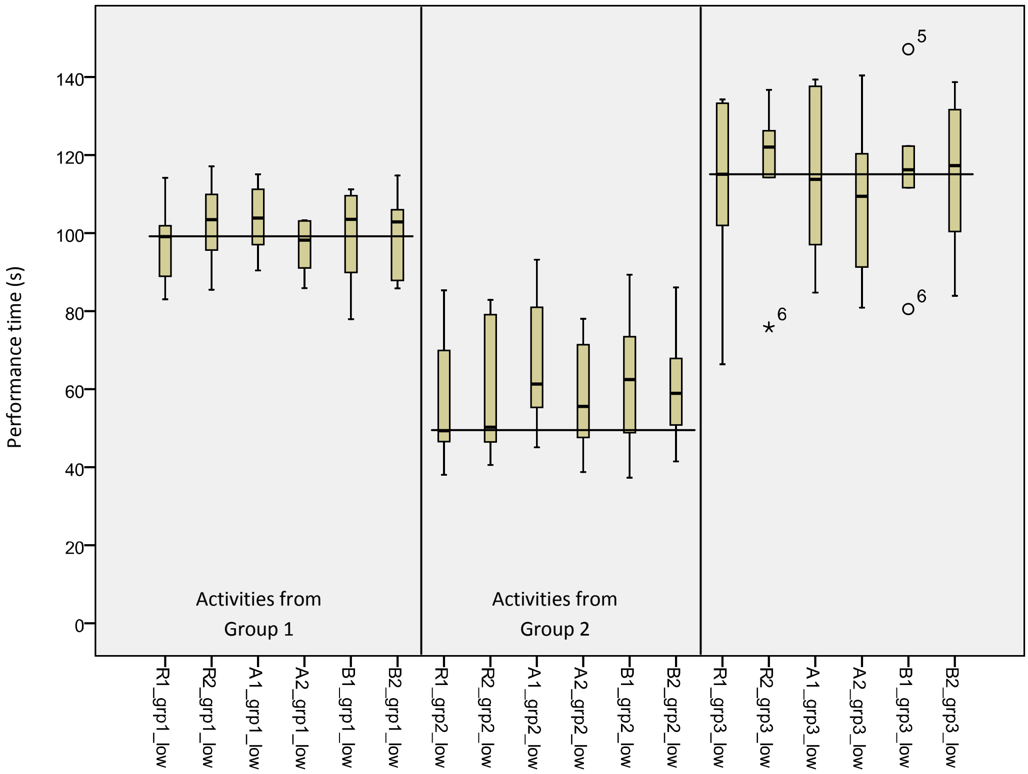


Figure 14. Boxplots of the performance times on the 3 groups of the ADAPT-test activities on all knee joint conditions for sub-class 'Low'



Comparison of performance times between knee joint conditions
The differences in performance times in the conventional prosthesis condition (R1) compared to both the C-leg condition after 1 week of home use (A2) and the C-leg Compact condition after one week of home use (B2) were evaluated within each sub-class. Per sub-class two statistical comparisons were performed (R1 vs A2 and R1 vs B2) resulting in a significance threshold of 0.05/2 = 0.025.

The results of sub-class 'high' (figure 12) show that the activities in group 1 were performed significantly faster on both the C-leg (p=0.010) and the C-leg Compact (p=0.019) after 1 week of home use.
The performance times of the activities in group 2 for sub-class 'high' did not differ significantly when performed on either a C-leg or a C-leg Compact compared to the conventional prosthesis.
The observed difference in group 3 activities between the performance times on the conventional prosthesis and the C-leg was not statistically significant. Group 3 activities were performed significantly faster on the C-leg Compact compared to the conventional prosthesis (p=0.023).

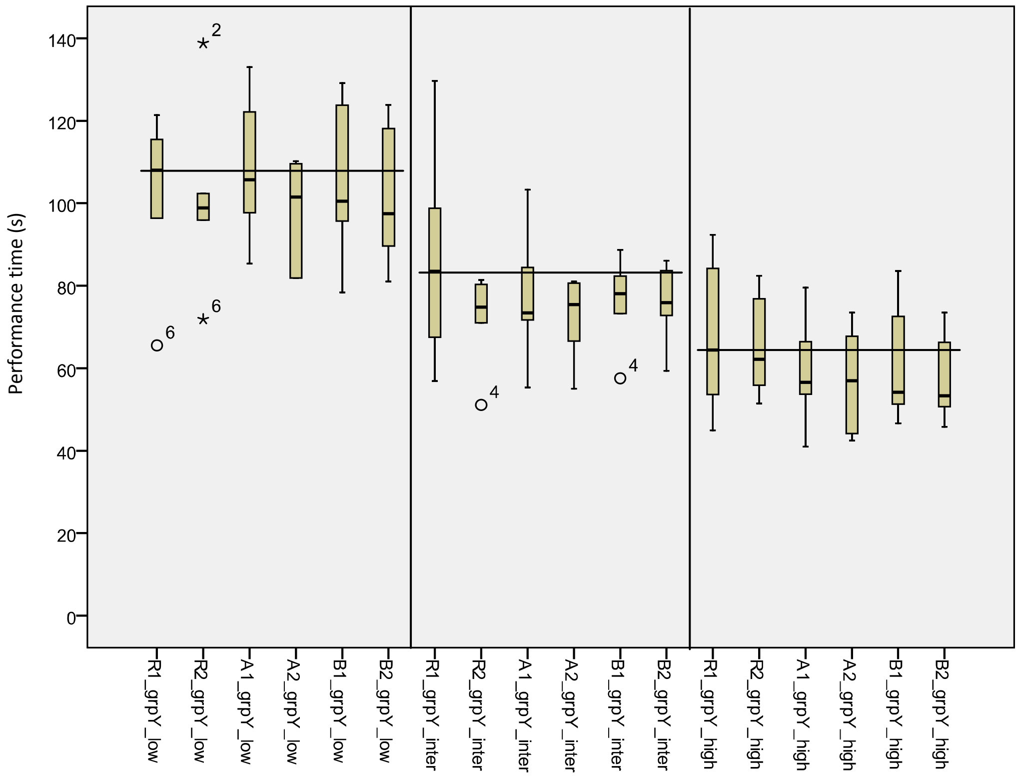
The participants in the 'intermediate' sub-class (figure 13) performed the activities in group 1 faster on both the C-leg and the C-leg compact compared to their conventional prosthesis (p=0.004 and p=0.008 respectively).
This sub-class also performed significantly faster on the C-leg compared to the conventional prosthesis for the group 2 activities (p=0.016). Performance did not differ between the conventional prosthesis and C-leg Compact for group 2 activities.
The difference in performance on activities in group 3 between the conventional and C-leg prosthesis conditions failed to attain significance. Participants from the 'intermediate' sub-class did not perform the activities in group 3 faster on a C-leg Compact compared to the conventional prosthesis.

The performance times of the 'low' sub-class participants (figure 14) in the conventional prosthesis (R1) condition compared to both the C-leg (A2) and C-leg Compact (B2) conditions did not differ for both group 1 and 3 activities according to the Friedman analysis.
The observed elongation of the performance times for group 2 activities in the C-leg and C-leg Compact conditions compared to the conventional knee joint condition did not prove to be statistically significant.

It was expected that the microprocessor-controlled knee joints would have an advantageous effect especially on the performance of group 3 activities (stairs negotiation, ramp descent and ascent, slalom, obstacle avoidance, placing objects on a high cabinet with a kitchen step). However, such an advantageous effect was only measured in the 'high' sub-class with the C-leg Compact for the group 3 activities.
Therefore, an extra analysis, focused on the effects of the microprocessor-controlled knee joints on these more difficult activities, was performed. A subset of group 3 activities was identified, consisting of activities related to a-cyclic manoeuvring in confined spaces. This new 'group Y' consisted of the activities obstacle avoidance, slalom and placing objects on a high cabinet with a kitchen step. These are all activities that are performed relatively often by persons within the MFCL-2 amputee group.

Boxplots of the performance times for this new group of ADAPT-test activities (group Y) for the three sub-classes is shown in figure 15. The performance times improved significantly on the C-leg in the 'intermediate' sub-class (p=0.010). Furthermore, a significant improvement was visible on the Compact in the 'high' sub-class (p=0.010). The observed difference in the 'high' sub-class on the C-leg just failed to attain significance (p=0.028).

Figure 15. Boxplots of the performance times on ADAPT-test activities in the new 'Group Y' on all knee joint conditions for all sub-classes 'low', 'intermediate' and 'high'



Self-perceived level of difficulty
The scores (in mm) given by the participants reflecting their perceived level of difficulty (PLOD) of the ADAPT activities are presented in figures 16-18. The figures each represent either the sub-class 'low', 'intermediate' or 'high'. The maximum score of 100 corresponds to the participants' opinion that the activity was 'very easy' to perform, while a score of 0 indicates that a task was considered 'very difficult' to perform. The three large horizontal lines in each of the 3 groups of ADAPT-test activities depict the median value of the PLOD-score in the conventional knee joint condition.

The PLOD scores for the three groups of activities were compared between the three sub-classes 'low', 'intermediate' and 'high' in the baseline (R1) condition. Participants from all three sub-classes showed no differences in PLOD scores at R1 for the 3 groups of ADAPT activities.

The PLOD scores were also compared between the knee joint conditions with a statistical significance threshold of 0.05/2 = 0.025. The participants in the 'high' and 'intermediate' subclasses show a tendency to indicate that the activities in all 3 ADAPT-test activities groups are easier to perform on both the C-leg and the C-leg Compact compared to the conventional prosthesis (R1) (see figure 16 and 17 respectively). However, these observed differences did not reach statistical significance.

The PLOD scores of the 'low' sub-class show no differences in self-perceived difficulty level in group 1 activities between the conventional and both microprocessor-controlled knee joint conditions (figure 18). For the groups 2 and 3 of ADAPT-test activities either no difference or a slight increase in perceived difficulty could be observed. However, these differences did not attain significance.

Figure 16. Self-perceived difficulty scores (mm) on the 3 groups of the ADAPT-test activities on all knee joint conditions for sub-class 'high'

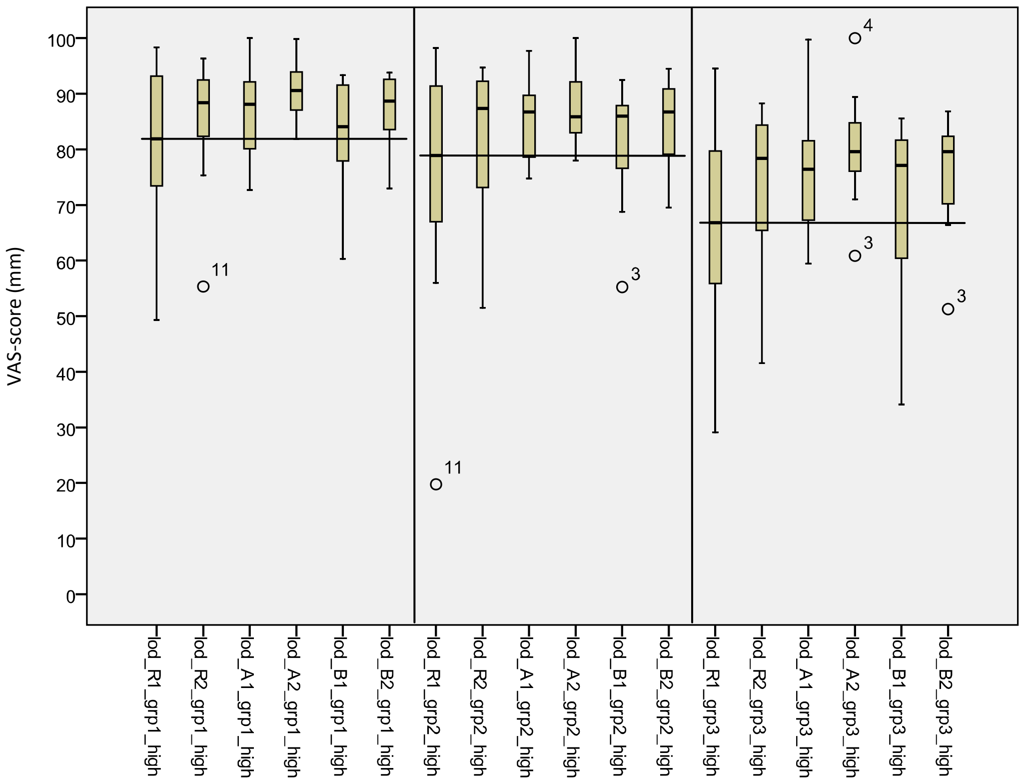


Figure 17. Self-perceived difficulty scores (mm) on the 3 groups of the ADAPT-test activities on all knee joint conditions for sub-class 'intermediate'

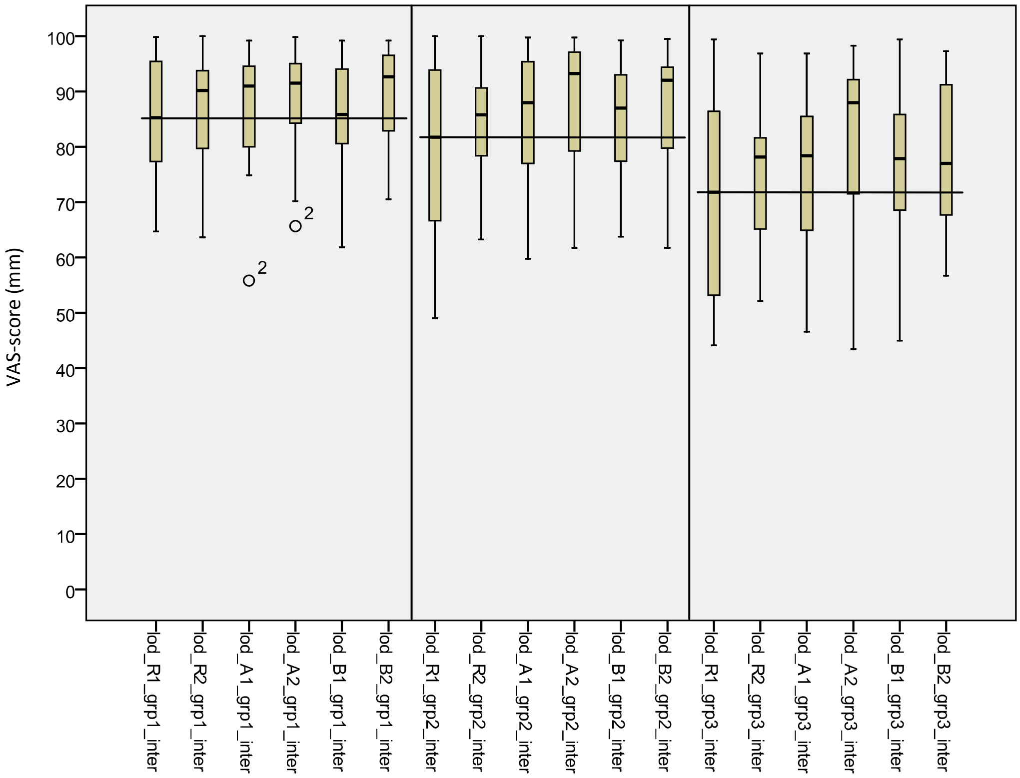
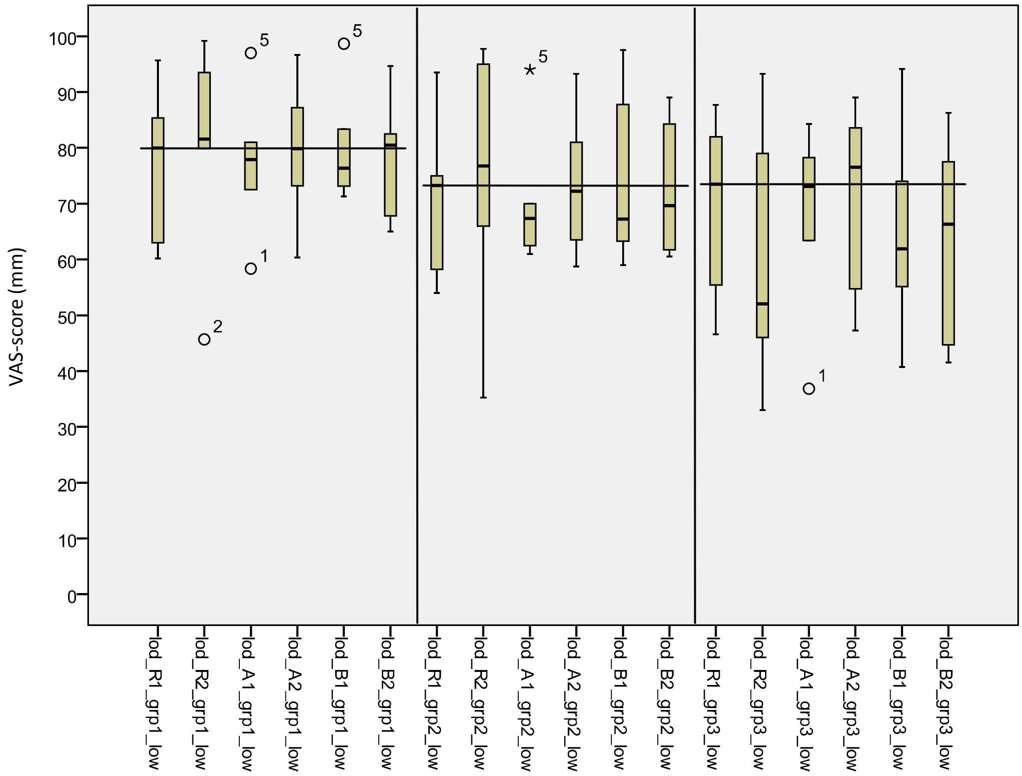
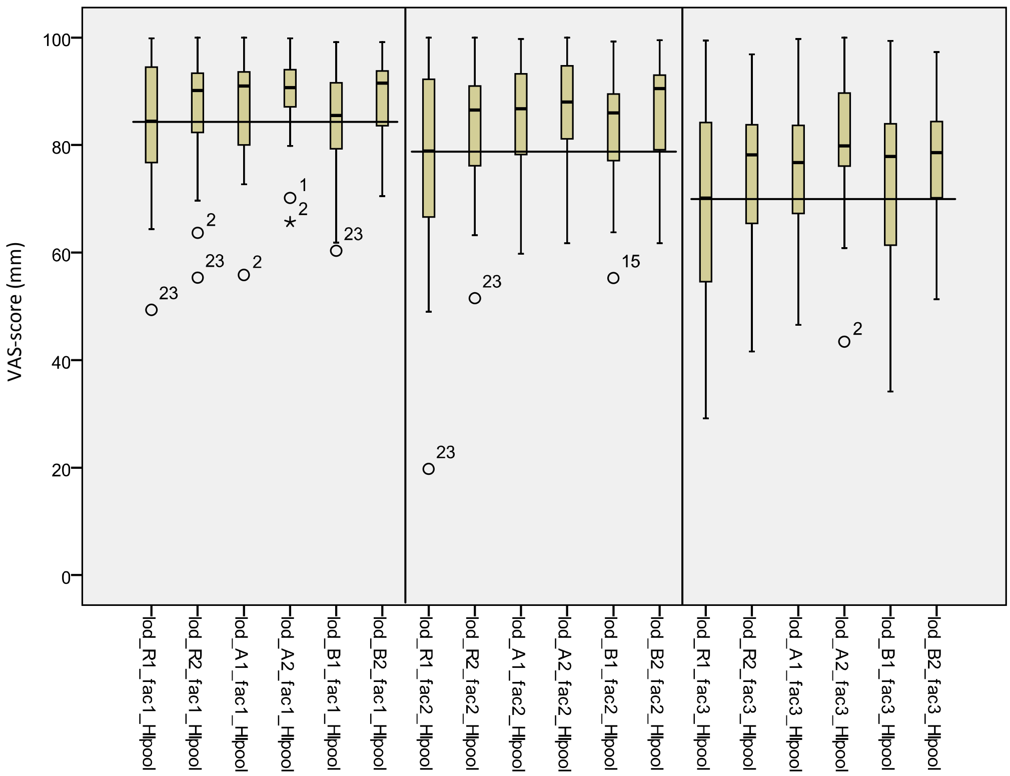


Figure 18. Self-perceived difficulty scores (mm) on the 3 groups of the ADAPT-test activities on all knee joint conditions for sub-class 'low'



In figures 16 and 17 a trend towards improvement of the PLOD scores in the ‘high’ and ‘intermediate’ sub-classes for all groups of ADAPT-test activities when performing the tests on the C-leg and the C-leg Compact seems to be visible. However, subsequent statistical testing (Kruskal-Wallis test) showed no differences between the PLOD scores of the ‘intermediate’ sub-class and the ‘high’ sub-class. Therefore, the data of these two sub-classes were pooled and were then analysed again with a significance threshold of 0.025.
In figure 19 an overview is given of the PLOD scores on the 3 groups of the ADAPT-test activities for the pooled data of sub-classes ‘intermediate’ and ‘high’, i.e. ‘H/I-pool’. This figure shows that the participants from the ‘high’ and ‘intermediate’ sub-classes together have significantly improved PLOD scores in the C-leg condition for the group 2 and 3 ADAPT-test activities (p=0.018 and p=0.006 respectively). The differences in PLOD scores between conventional knee joint condition and the C-leg condition just failed to attain significance in group 1 activities (p=0.031).

Figure 19. Boxplots of the pooled perceived level of difficulty scores of the ‘high’ and ‘intermediate’ sub-classes (‘H/I-pool’) for the three groups of ADAPT-test activities



The quality of the stairs and hill descent was scored using the Stairs Assessment Index (SAI) and Hill Assessment Index (HAI). Table 6 represents the mean values of the SAI and HAI scores for the three sub-classes of participants in the conventional knee joint condition (R1), the C-leg (A2) and the Compact condition (B2). The 'intermediate' and 'high' sub-classes show a statistically significant improvement in the quality of stairs negotiation on both the C-leg and the C-leg Compact.

No differences in the SAI scores were found between the conventional prosthesis condition and the C-leg or Compact conditions for the 'low' sub-class.
A small difference in the HAI scores is visible in the 'low' sub-class for both the C-leg and Compact conditions compared to the conventional knee joint condition. These differences are not statistically significant.

Table 6. Mean SAI and HAI scores for the sub-classes 'low', 'intermediate' and 'high' in the three knee joint conditions R1, A2 and B2

	Sub-class	Conventional (R1)	C-leg (A2)	C-leg Compact (B2)
SAI	Low	2.7	2.7	3.8
	Intermediate	3.2	8.7*	7.8*
	High	3.6	8.9*	8.8*
HAI	Low	4.3	6.0	6.7
	Intermediate	7.1	7.5	6.8
	High	8.5	8.2	7.9

*= statistically significant, p<0.025

3.2.2 Perturbation and stability

The performance on the four different tests of the perturbation protocol was scored by two independent raters. Scores were given between 1 and 10, where 1 is ‘very poor performance’ and 10 is ‘excellent performance’. The figures 20-23 represent the mean scores of the two raters on the four perturbations tests ‘induced trip’, ‘abrupt sidestep’, ‘abrupt halt’ and ‘obstacle negotiation’ for all knee conditions R1, R2, A1, A2, B1 and B2. The horizontal lines depict the median values at R1 per sub-class. Furthermore, in figures 24 and 25 a general overview is given on the perceived performance and perceived stability on the different perturbation tests in the conventional prosthesis (R1), C-leg (A2) and C-leg Compact (B2) conditions.

Scores based on video observation by experts

The scores at baseline (R1) of the performance of overcoming an induced trip, presented in figure 20, show that the ‘low’ sub-class participants tend to receive higher scores than the ‘intermediate’ sub-class. The ‘intermediate’ sub-class on the other end tends to score higher than the ‘high’ sub-class. These differences, however, are not statistically significant.

The baseline scores did not differ for the tests ‘abrupt sidestep’ and ‘abrupt halt’, represented in figures 21 and 22.

For the ‘obstacle negotiation’ test the results seem to be opposite to the findings of the ‘induced trip’ test. Here, ‘high’ sub-class get higher scores than ‘intermediate’ and ‘intermediate’ receive higher scores than ‘low’.

For all sub-classes no (statistically significant) differences were found when comparing R1 to A2 or B2.

Figure 20. Boxplots of the mean rater scores for the ‘Induced trip’ test on all 6 knee joint conditions displayed for all 3 sub-classes ‘low’, ‘intermediate’ and ‘high’

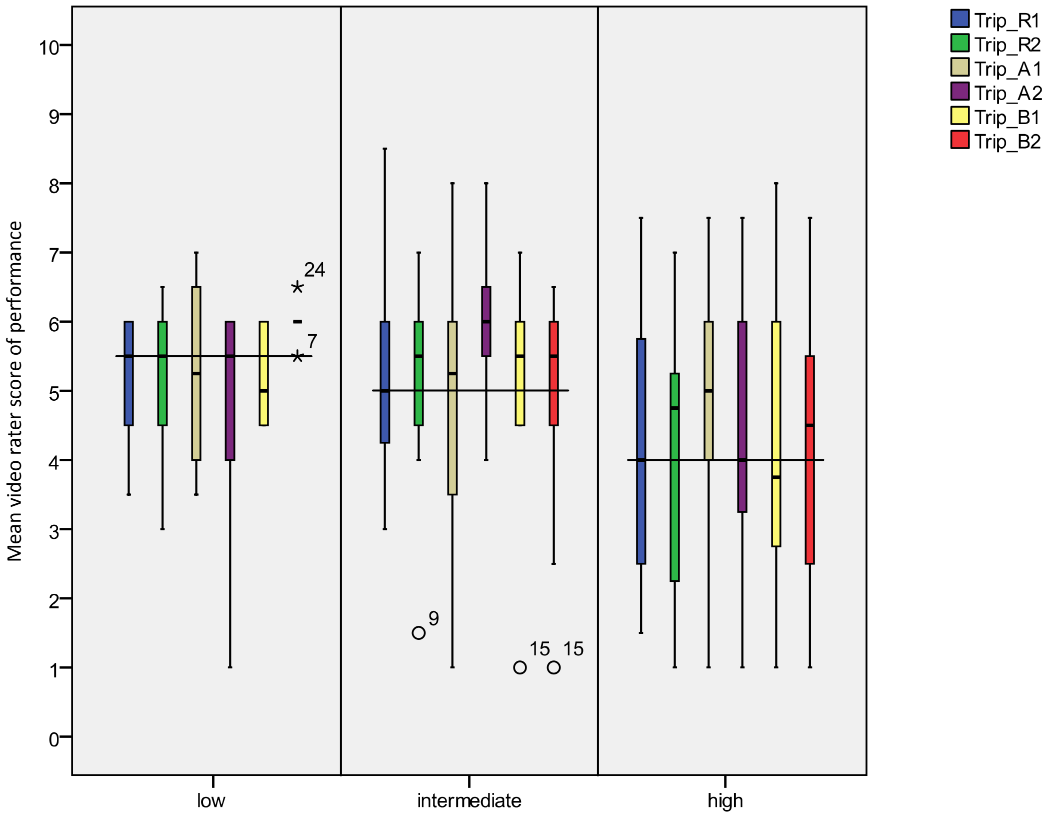


Figure 21. Boxplots of the mean rater scores for the 'Abrupt sidestep' test on all 6 knee joint conditions displayed for all 3 sub-classes 'low', 'intermediate' and 'high'

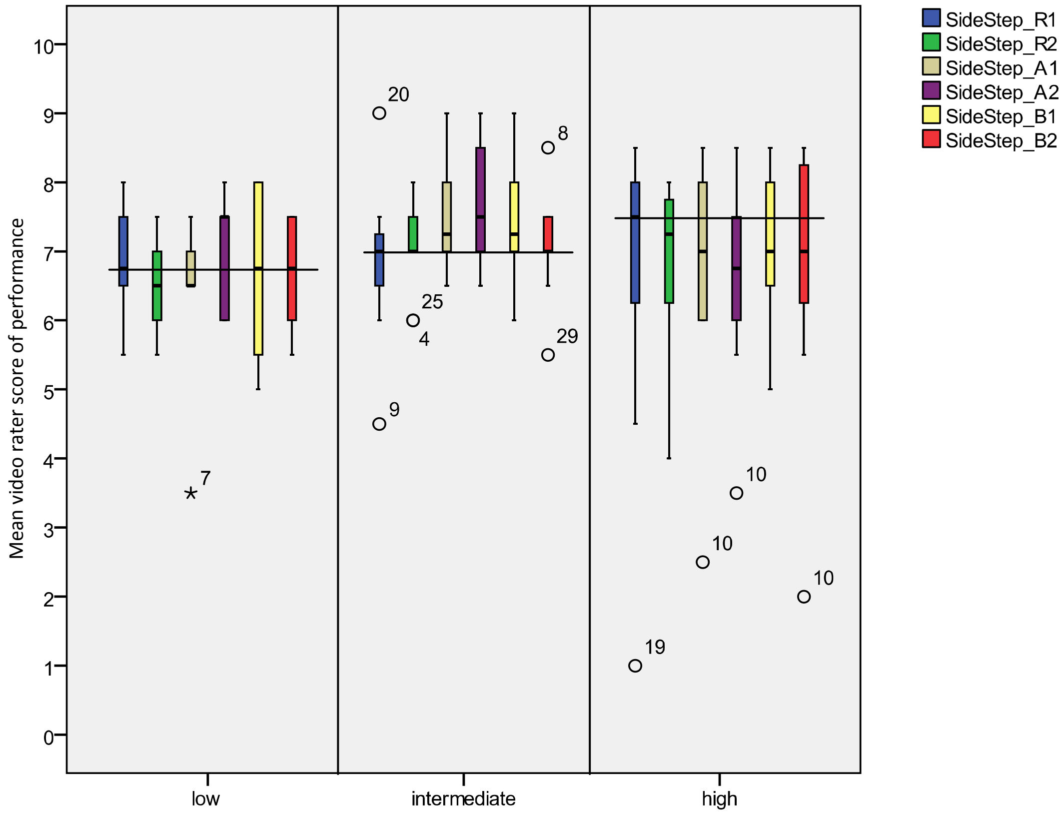


Figure 22. Boxplots of the mean rater scores for the 'Abrupt halt' test on all 6 knee joint conditions displayed for all 3 sub-classes 'low', 'intermediate' and 'high'

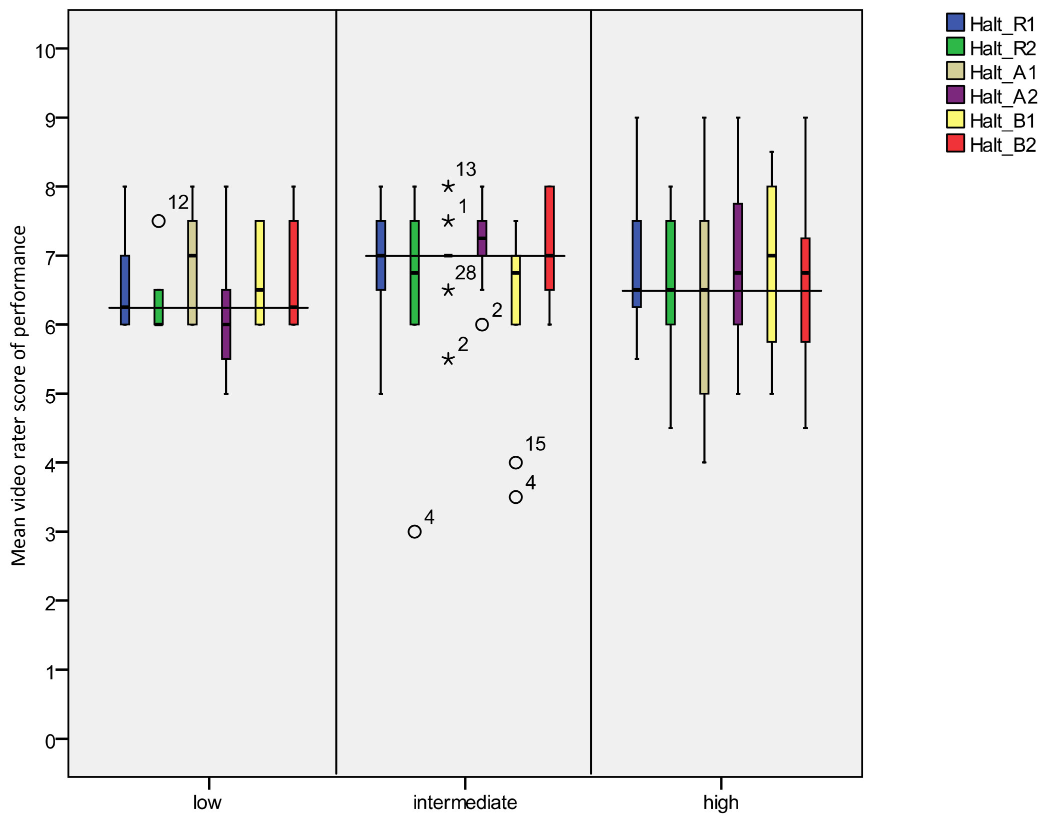
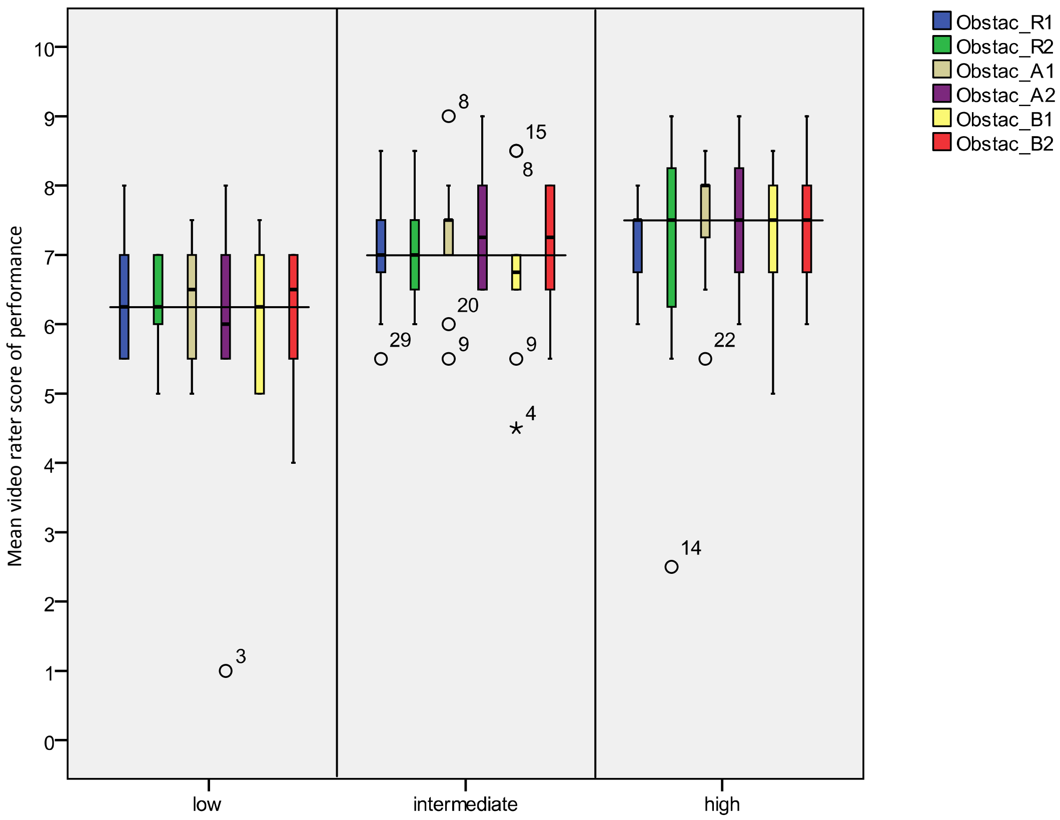


Figure 23. Boxplots of the mean rater scores for the 'Obstacle negotiation' test on all 6 knee joint conditions displayed for all 3 sub-classes 'low', 'intermediate' and 'high'



Scores based on patients' perception

In figure 24 the overall perceived performance scores on the conventional prosthesis (R1), the C-leg (A2) and the C-leg Compact (B2) are presented for the perturbation tests 'stumble', 'abrupt stop' and 'abrupt sidestep'. Performance ranges between 0 and 100, indicating 'very bad performance' to 'very good performance', respectively. There is a significant increase in the perception of the participants regarding the quality of performance on the different perturbation tests when they are performed on a C-leg compared to the conventional prosthesis. This is also the case for the C-leg Compact with the exception of the tripping test. Apparently, participants perceive no difference in performance during a stumble when performed on a Compact compared to their conventional prosthesis.

Table 7. Overview of the perceived performance scores on the different perturbation tests for the conventional, C-leg and C-leg Compact conditions

N=29	Conventional (R1)		C-leg (A2)			C-leg Compact (B2)		
	Mean (SD)	Median	Mean (SD)	Median	P-value	Mean (SD)	Median	P-value
Stumble	69.2 (17.1)	71	81.4 (13.2)	81.5	0.0005	74.7 (18.0)	77	0.113
Abrupt stop	75.6 (16.3)	80	83.4 (13.0)	86.5	0.005	82.9 (10.3)	86	0.010
Abrupt sidestep	72.6 (15.9)	75	82.9 (12.8)	84.5	0.002	81.0 (11.4)	81	0.009

Note: P-values relate to the comparison between either R1 and A2 conditions or between R1 and B2 conditions

Furthermore, table 8 represents the participants' perceived sense of stability during the perturbation tests with the conventional knee joint (R1), the C-leg (A2) and the C-leg Compact (B2). A significant increase in the level of perceived stability was observed in all perturbation tests when participants transitioned from their conventional prosthesis to the C-leg. On the C-leg Compact participants showed a significant improvement in all tests except for 'stumbling'.

Table 8. Overview of the perceived level of stability scores on the different perturbation tests for the conventional, C-leg and C-leg Compact conditions

N=29	Conventional (R1)		C-leg (A2)			C-leg Compact (B2)		
	Mean (SD)	Median	Mean (SD)	Median	P-value	Mean (SD)	Median	P-value
Stumble	71.5 (14.0)	73	81.5 (14.8)	82.5	0.002	77.0 (18.2)	81.5	0.039
Abrupt stop	73.4 (15.8)	74	84.2 (13.5)	88	0.0004	82.6 (10.5)	84	0.002
Abrupt sidestep	76.0 (15.1)	79	83.6 (12.7)	84.5	0.007	81.8 (12.2)	85	0.020
Obstacle clearance	70.3 (19.6)	78	83.6 (11.7)	85	0.001	81.0 (12.3)	83	0.009

Note: P-values relate to the comparison between either R1 and A2 conditions or between R1 and B2 conditions

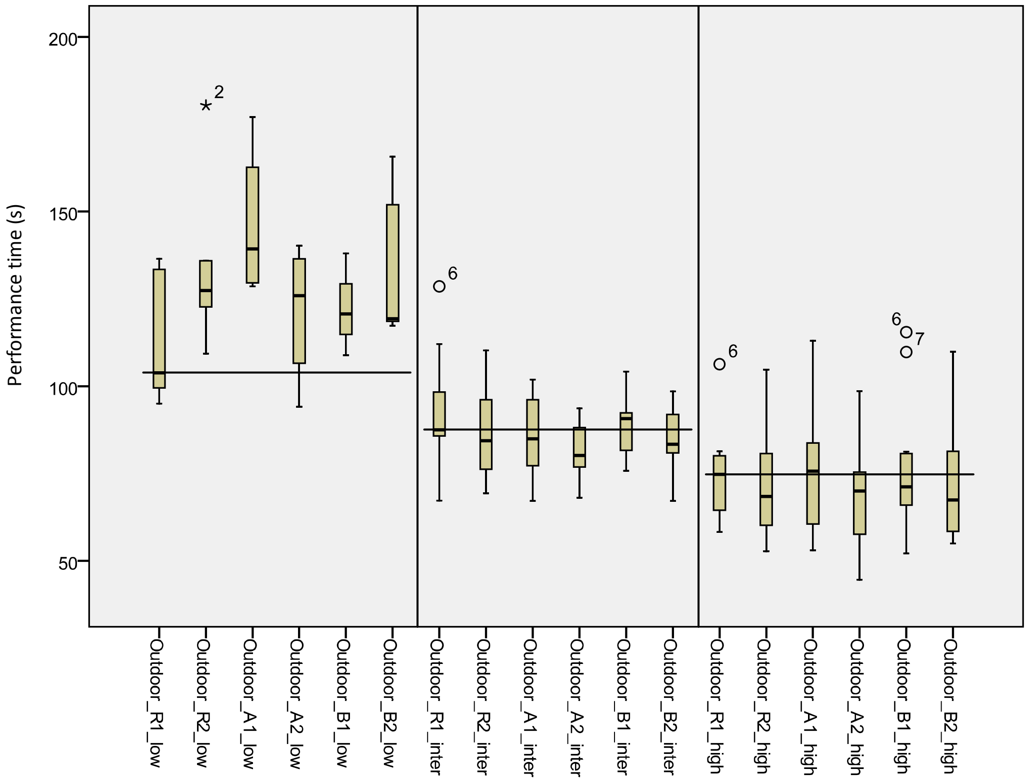
3.2.3 Outdoor circuit

Figure 24 represents the performance times (s) to complete the outdoor circuit in all 6 knee joint conditions for the 'low', 'intermediate' and 'high' sub-classes. The large horizontal lines depict the median values at R1 of the participants in the three sub-classes. A trend is visible concerning the differences in performance times between the participants from the 'low', 'intermediate' and 'high' sub-classes. The 'low' sub-class participants need more time to perform the outdoor circuit than the 'intermediate' and 'high' sub-class participants.

There is a difference in performance time found for R1 compared to the A2 or B2 conditions. The participants from the 'low' sub-class seem to need more time to perform the outdoor circuit when using a C-leg (A2) or C-leg Compact (B2) compared to the performance on the conventional knee joint (R1). However, these differences did not attain statistical significance.

The performance times on the outdoor circuit did not change significantly when adding a cognitive double task for neither knee joint conditions nor for participant sub-classes.

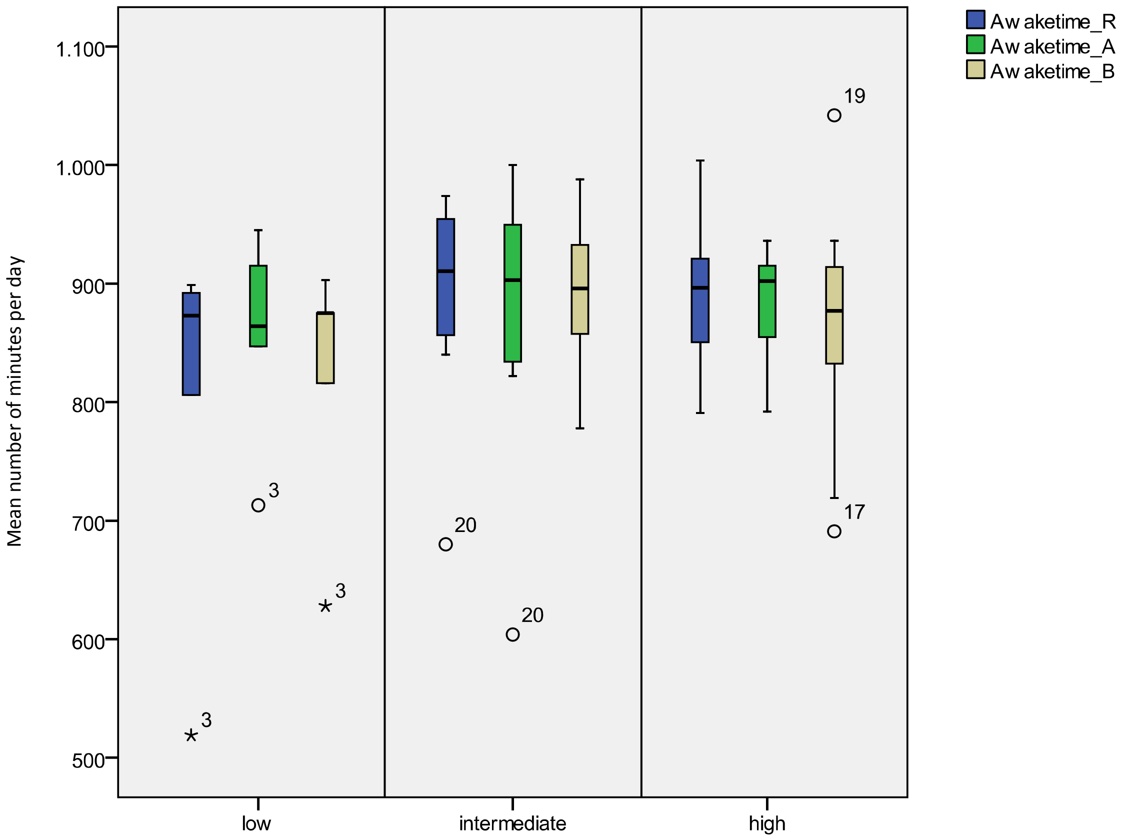
Figure 24. Boxplots of the performance times on the outdoor circuit (without cognitive double task) on all knee joint conditions for the sub-classes 'low', 'intermediate' and 'high'



3.3 Activity level

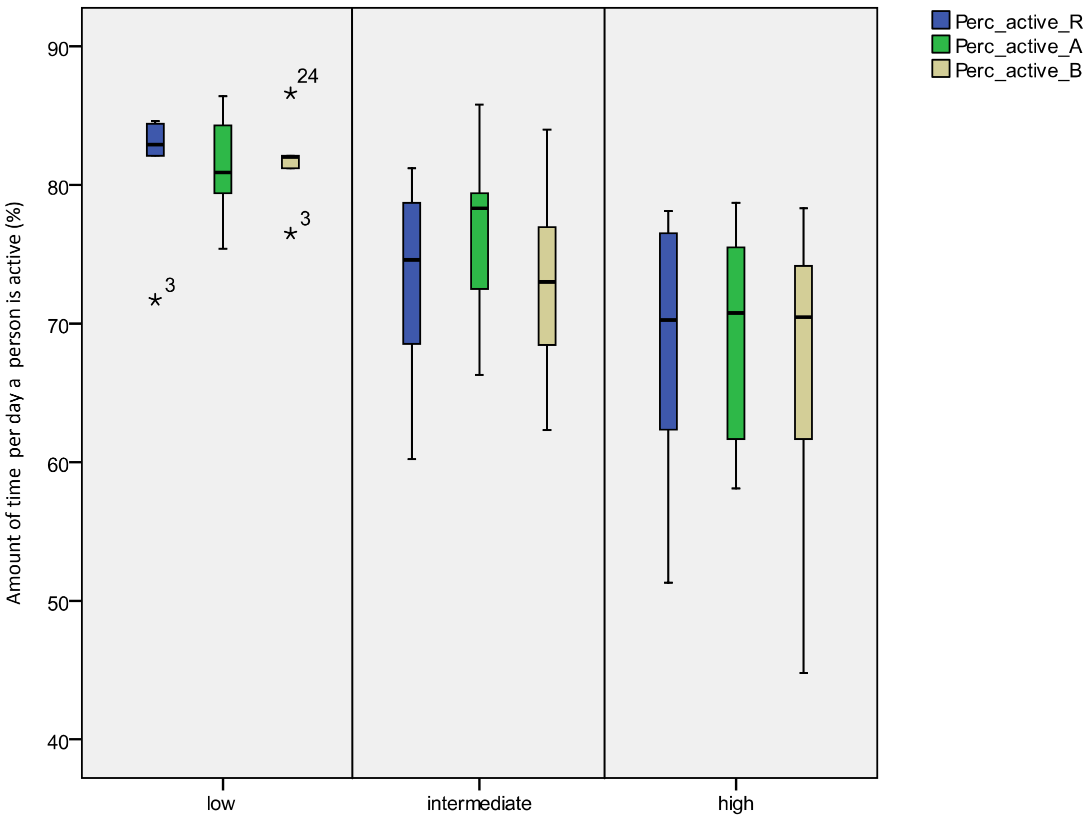
The first step in evaluating the activity levels of the participants from the three sub-classes 'low', 'intermediate' and 'high' for the three knee joint conditions (R1, A2 and B2) was to calculate the time that the participant wore the accelerometer (=awake time (min)). The awake time represents the period in which a person was awake and could be active. Figure 25 displays the number of minutes of the awake time for the three sub-classes in the three knee conditions.
The awake time did not differ between the sub-classes of participants or between knee joint conditions. This means that all participants have the same mean amount of time per day to perform activities or to be active. This does not change with knee type.

Figure 25. Mean number of minutes per day that a person is awake for the sub-classes 'low', 'intermediate' and 'high' in the conventional, C-leg and C-leg Compact conditions



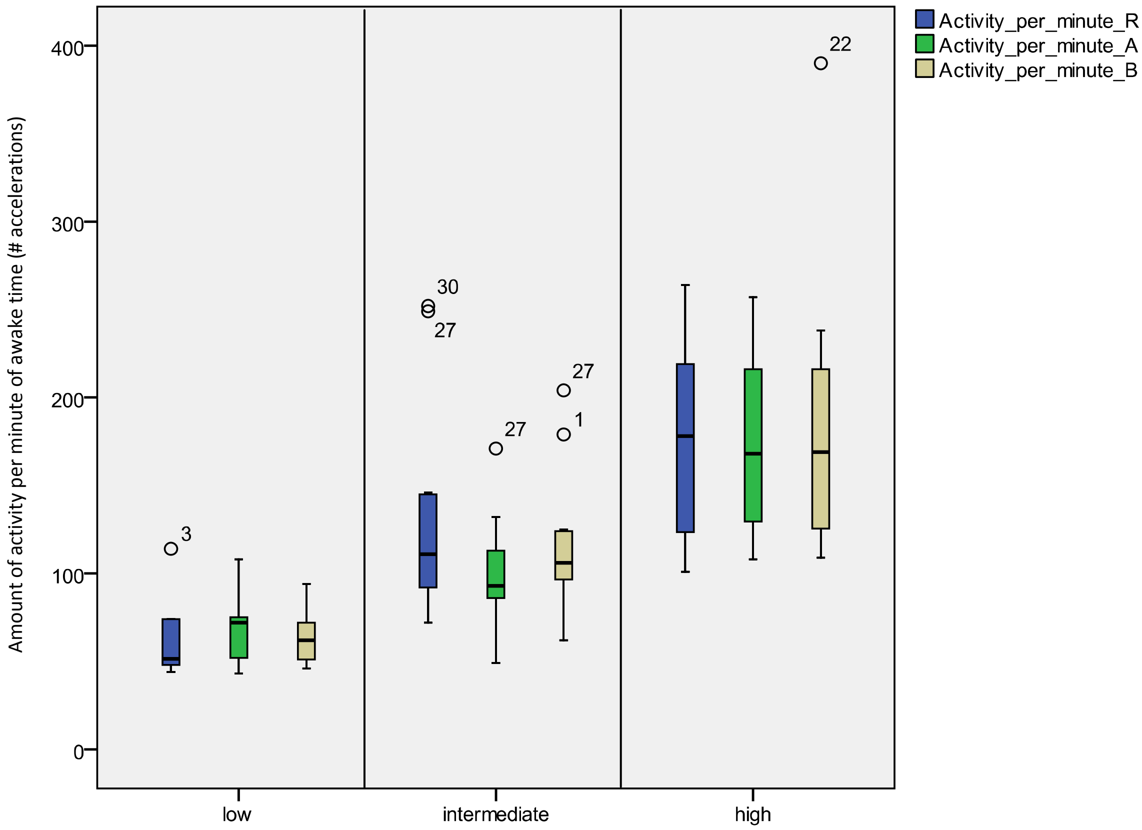
The next step in the analysis was to calculate the mean number of minutes per day in which the participant shows a level of activity above a certain threshold. The threshold value was set at 30 measured accelerations per minute. The introduction of this threshold minimises possible interference from minor movements during resting periods during the day, e.g. reaching for the remote control when watching television. Consequently, a more reliable overview of the amount of time a person is active or resting is acquired.
The percentage of activity per mean daily awake time for the three sub-classes on the three knee joint conditions is presented in figure 26.
The comparison between sub-classes was done with three statistical tests (low vs intermediate, low vs high and high vs intermediate) resulting in a significance threshold of 0.017. This figure shows that the participants from the 'low' sub-class are active during a longer part of their day (awake time) compared to 'intermediate' and 'high' participants (p=0.009 and p=0.003 respectively).

Figure 26. Overview of the amount of time per day that the participants show a certain level of activity (expressed as a percentage of awake time)



In figure 27 the mean amount of activity per minute of awake time is shown for the three sub-classes 'low', 'intermediate' and 'high' on all three knee conditions.
This figure shows that the participants from the 'low' sub-class exhibit less amount of activity per minute compared to 'intermediate' and 'high' in the R1 condition (p=0.008 and p=0.001 respectively). The difference in activity per minute between the 'intermediate' and 'high' sub-classes in the R1 condition just failed to attain significance (p=0.028).

Figure 27. Mean amount of activity per minute of awake time (number of accelerations)



3.4 Function level

2 minute walking test

In figure 28 the distance travelled (m) in a 2 minute period is presented for all three sub-classes ‘low’, ‘intermediate’ and ’high’ in all 6 knee joint conditions.

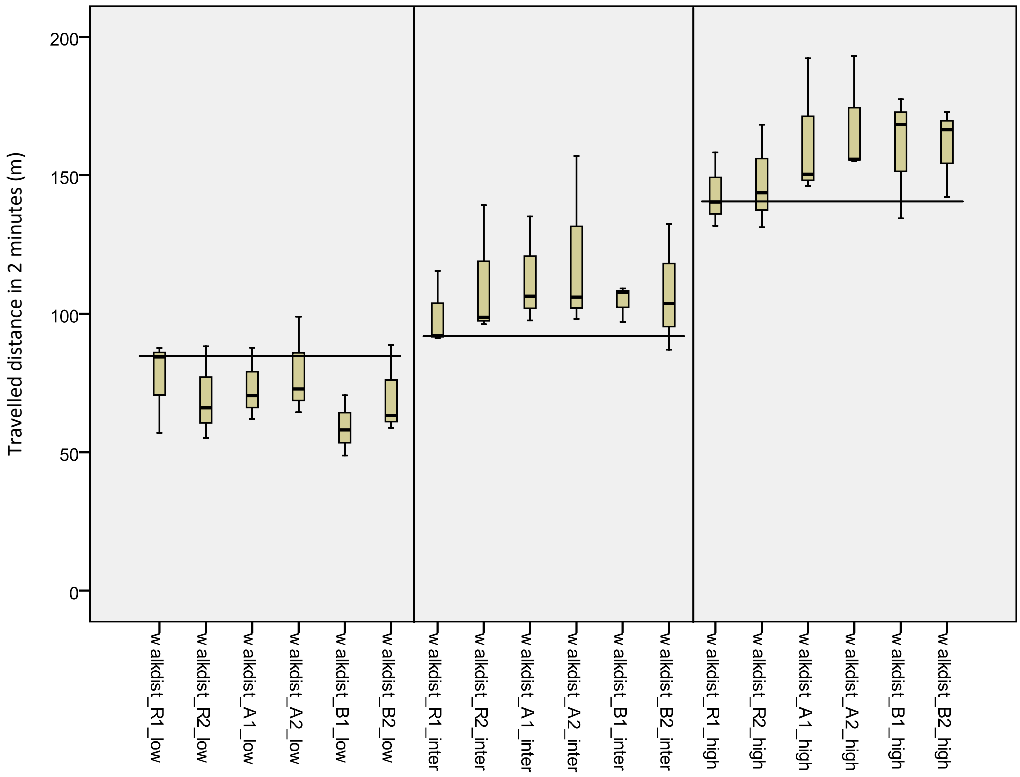
The two comparisons between the mechanical knee joint condition and both microprocessor-controlled knee joint conditions per sub-class resulted in a statistical significance threshold of 0.025.

The participants in the ‘high’ sub-class cover a longer distance in 2 minutes on the C-leg (A2) and the C-leg Compact (B2) compared to the conventional prosthesis condition (p=0.019 and p=0.023 respectively).

The participants in the ‘intermediate’ sub-class are also able to walk a longer distance in 2 minutes on the C-leg and the C-leg Compact (p=0.004 and p=0.023 respectively).

The participants from the ‘low’ sub-class tend to cover a smaller distance in 2 minutes when using a C-leg or C-leg Compact compared to the conventional prosthesis. These differences, however, are not statistically significant.

Figure 28. Distance covered in a period of 2 minutes for all three sub-classes in all 6 knee joint conditions



Spatial-temporal gait parameters

Cadence (steps/min), step length (cm) and stance phase duration (% of gait cycle) are the gait parameters that were measured during the gait analysis using the GAITRite.

Tables 9-11 show an overview of the mean values and standard deviations of these parameters. There were no differences found between the knee joint conditions for all gait parameters.

Table 9. Mean cadence and standard deviation (SD) for the sub-classes 'low', 'intermediate' and 'high' in the knee conditions R1, R2, A1, A2, B1 and B2

	Cadence (steps/min)	**R1**	**R2**	**A1**	**A2**	**B1**	**B2**
'Low'	Mean (SD)	84.8 (15.1)	82.9 (16.8)	81.3 (12.7)	84.7 (10.5)	82.9 (15.0)	82.1 (12.5)
'Intermediate'	Mean (SD)	87.9 (9.4)	87.8 (11.3)	89.6 (9.5)	89.9 (11.2)	87.5 (10.2)	88.4 (10.8)
'High'	Mean (SD)	96.6 (6.3)	97.3 (4.8)	96.4 (6.4)	99.3 (5.4)	97.9 (4.2)	98.5 (5.7)

Table 10. Mean step length and standard deviation (SD) of the healthy and the prosthetic leg for the sub-classes 'low', 'intermediate' and 'high' in the knee conditions R1, R2, A1, A2, B1 and B2

	Step length (cm)		**R1**	**R2**	**A1**	**A2**	**B1**	**B2**
'Low'	Mean (SD)	Healthy leg	41.4 (9.5)	39.8 (9.6)	41.4 (10.1)	40.7 (8.8)	40.9 (10.3)	42.2 (9.3)
		Prosthetic leg	46.9 (5.5)	46.5 (8.2)	47.1 (6.4)	47.3 (8.9)	45.5 (3.0)	44.1 (1.2)
'Intermediate'	Mean (SD)	Healthy leg	52.6 (13.3)	52.3 (7.2)	55.2 (6.8)	56.7 (7.5)	51.2 (10.8)	53.9 (8.9)
		Prosthetic leg	55.8 (8.3)	56.0 (8.3)	54.6 (8.8)	54.6 (8.6)	53.4 (7.9)	54.2 (6.6)
'High'	Mean (SD)	Healthy leg	60.6 (7.4)	61.0 (7.7)	61.6 (9.4)	62.8 (9.0)	62.2 (9.5)	63.5 (9.2)
		Prosthetic leg	62.4 (7.4)	59.8 (11.7)	57.9 (11.8)	60.9 (11.4)	60.8 (10.1)	60.8 (11.3)

Table 11. Mean stance phase duration as a percentage of the gait cycle (%) and standard deviation (SD) of the healthy and the prosthetic leg for the sub-classes 'low', 'intermediate' and 'high' on the knee conditions R1, R2, A1, A2, B1 and B2

	Stance phase duration (%)		R1	R2	A1	A2	B1	B2
'Low'	Mean (SD)	Healthy leg	73.1 (2.9)	74.5 (2.8)	74.5 (4.2)	73.8 (3.7)	74.4 (4.1)	74.0 (2.1)
		Prosthetic leg	61.8 (4.0)	61.7 (4.5)	63.0 (6.4)	62.2 (4.8)	62.2 (4.7)	64.7 (6.1)
'Intermediate'	Mean (SD)	Healthy leg	70.2 (3.0)	64.4 (20.3)	64.2 (20.3)	63.5 (20.0)	64.6 (20.4)	64.3 (20.3)
		Prosthetic leg	58.4 (2.3)	53.4 (17.2)	54.6 (17.3)	54.7 (17.3)	54.4 (17.2)	54.7 (17.4)
'High'	Mean (SD)	Healthy leg	68.3 (2.3)	68.9 (3.3)	68.1 (2.8)	67.9 (3.3)	68.6 (2.9)	67.7 (3.4)
		Prosthetic leg	59.0 (2.3)	58.6 (2.6)	59.9 (3.0)	59.0 (2.7)	58.7 (2.3)	59.1 (2.4)

3.5 Overall subjective measures

The participants have had the opportunity to experience to walk with a C-leg and a C-leg Compact. At the end of the study the participants were asked which type of knee joint they preferred in daily life, a C-leg, a C-leg Compact or their own conventional prosthesis.
From the 29 participants that filled out this questionnaire, 21 indicate that they prefer the C-leg, 7 preferred the C-leg Compact and 1 participant preferred his own conventional prosthesis.
After having completed the study 11 participants have filed a request for a C-leg to replace their conventional prosthetic knee joint.
Main reasons that were mentioned by the participants who preferred the C-leg Compact were:
"Provided more stability",
"I could walk faster with it",
"It is more pleasant to walk with",
"It did not have that extra moment of flexion (yielding) at heelstrike".

Main reasons for preferring the C-leg included:
"Provided more stability",
"Easier to walk with (smoother gait)",
"I have the ability to walk faster",
"It reduced the stress on my healthy leg and on my back",
"Increased sense of security and safety",
"Less tired at the end of the day".

4 Conclusions

4.1 General

- One of the most pronounced findings of the study is that the MFCL-2 group is not a homogeneous group. At least 3 MFCL-2 sub-classes may be identified, i.e. 'low',' intermediate' and 'high' MFCL-2 amputees.
- The accelerometer data show a clear difference in the activity levels between the 'low' MFCL-2 walkers and the 'intermediate' and 'high' MFCL-2 walkers. This was also the case for walking velocity. The sub-division of the MFCL-2 group into the low, intermediate and high sub-classes was further corroborated by the results found using the ADAPT test.
- Persons in the intermediate and high sub-classes seem to benefit from a microprocessor-controlled knee joint when performing physical multi-tasking activities (group 1) after 1 week of home use and two hours of training, relative to their own conventional prosthesis. Participants classified as low did not (yet) seem to benefit very much from using a C-leg or a Compact when performing common daily activities after one week of home use and two hours of training. Persons in the intermediate sub-class seem to benefit from a C-leg when performing low to moderate intensity ambulation activities (group 2) after 1 week of home use and two hours of training, relative to their own conventional prosthesis. Persons in the high sub-class seem to benefit from using a C-leg Compact when performing difficult (group 3) activities.
- Gender, conventional knee joint type used, cause of amputation, post-amputation time and self-perceived level of difficulty of the participation circuit activities do not seem to be major indicators of performance levels in MFCL-2 walkers. However, age and body weight do seem indicators of performance levels in MFCL-2 walkers.
- High as well as intermediate sub-class subjects walk significantly longer distances within 2 minutes when using the C-leg or the C-leg compact compared to the conventional prosthesis.
- From a practical point of view, the participation circuit offers clinicians an objective tool to assess the added-value of prosthetic components in performing home environmental activities in individual patients with a transfemoral unilateral amputation. At the moment, the ADAPT-test is being implemented in regular therapy. This implementation project is financed by health insurance companies. The ADAPT-test will be used as standard clinimetric system in the future.

4.2 Participation circuit

- Overall MFCL-2 results show that on a C-leg 70% and on a C-leg Compact 60% of all participants show an increase in performance of 5% or more when performing activities related to shopping and kitchen activities (activity group 1) as compared to their conventional prosthesis. During more difficult activities like getting in and out of a chair, sideways walking, stair negotiation or going up and down a ramp (activity group 2 and 3), the percentage of participants that seem to benefit from using a microprocessor controlled knee joint was somewhat smaller (±40%). The latter activities demand more from the participants with respect to using the full potential of the prosthetic knee joint.
- The intermediate and high MFCL-2 walkers benefit from both the C-leg and C-leg Compact during group 1 activities. As to group 2 activities only a significant improvement was found when using the C-leg knee joint in the intermediate sub-class, whereas for the C-Leg Compact no significant differences were found. For group 3 activities, a significant improvement was found when using the C-leg Compact relative to the use of participant's own conventional knee joint in the high sub-class.

- It was expected that the microprocessor-controlled knee joints would have resulted in more benefit in the performance of group 3 activities. Additional analysis concluded that use of a C-leg for the ‘intermediate’ sub-class and use of a C-leg Compact in the ‘high’ sub-class improves performance times in acyclic manoeuvring activities such as slalom, obstacle avoidance and kitchen activities (difficult).
- The ‘low’ MFCL-2 walkers do not seem to benefit from either a C-leg or a C-leg Compact as to their daily activities after only one week of home use.
- Overall, 19 participants (65%) seem to benefit from at least one of the microprocessor-controlled knee joints in performing common daily life activities, of which 47% of the participants only from the C-leg, 7% only from the Compact and 46% benefitted on both microprocessor-controlled knee joints.
- The participants in the ‘high’ and ‘intermediate’ subclasses pooled together indicate that the group 2 and 3 ADAPT-test activities are perceived to be significantly easier to perform on a C-leg than on their conventional prosthesis.
- Improvement in perceived level of difficulty scores for group 1, 2 or 3 ADAPT-test activities was not seen in the Compact condition.
- Quality of stairs descent was significantly improved in both the intermediate and high sub-classes in both the C-leg and the C-leg Compact conditions.
- The participation circuit may provide valuable additional information as to the possible benefit (or detriment) of the use of a microprocessor-controlled knee joint in certain daily activity conditions at a client-specific level, and thus may be used, in conjunction with other clinical measures, to make a well-founded, client-specific decision about the prescription of leg prostheses in upper leg amputees.

4.3 Outdoor circuit

No significant differences between prosthesis conditions were found.
Adding a cognitive task to the outdoor test performance did not lead to significant changes in performance time in any of the sub-classes nor between the knee joint conditions. This suggests that the achieved degree of gait automaticity of the patients in the study was high. This is not surprising considering the long post-amputation time of the participants. Apparently, the two hours training on a microprocessor-controlled knee joint was sufficient to maintain this level of walking automaticity.

4.4 Two minutes walking test

High as well as intermediate sub-class subjects walk significantly longer distances within 2 minutes when using the C-leg or the C-leg compact compared to the conventional prosthesis. This does not apply to the low sub-class subjects.

4.5 Perturbation and stability tests

No difference was observed in the quality of the way the participants overcame different types of gait perturbation between the conventional knee joint and a microprocessor-controlled knee joint. However, participants felt more capable to counteract the perturbations and also indicated a higher degree of perceived stability on both microprocessor-controlled knee joints. These changes in participants’ perception might lead to changes in actual performance after an extended period of using a microprocessor-controlled knee joint. However, this requires further investigation.

4.6 Activity monitoring

- Overall waking hours (=time between waking up in the morning and going to sleep at night) of subjects from the low, intermediate and high group was similar. Changing prosthesis conditions did not influence this awake time.
- Contra-intuitively, participants from the ‘low’ sub-class proved to be active during a longer part of their day (awake time) compared to ‘intermediate’ and ‘high’ participants. However, mean activity level per minute during waking hours is lower in the low sub-class relative to the intermediate and high sub-classes. Overall, activity level was lower in the low sub-class, relative to the intermediate and high sub-classes.
- The accelerometer data did show a clear difference in the activity levels between the ‘low’ MFCL-2 walkers and the ‘intermediate’ and ‘high’ MFCL-2 walkers. This difference is significant between ‘low’ MFCL-2 walkers and the ‘intermediate’/‘high’ MFCL-2 walkers. The activity levels just failed to attain significance between the ‘intermediate’ and ‘high’ MFCL-2 walkers. This indicates an important difference between subcategories that could also explain overall MFCL-2 group variance in other data domains.
- The analysis of the accelerometer data shows no significant changes in the level of activity per day between both microprocessor controlled knee joints and the conventional knee joint. Also, participants do not seem to become active for a longer period of time.

4.7 Gait cycle parameters

- For all three sub-classes of participants, no differences were observed between the knee joint conditions

4.8 Presentations and publications

The design and several preliminary participation circuit results were presented during the ECPRM congress in Bruges (Belgium) on 3-6 June 2008.

On 30-31 October 2008 preliminary results were presented at the 3rd Dutch-UK Rehabilitation meeting in Ermelo, the Netherlands.

The intermediate results were presented at the XXIInd. International Society Biomechanics Congress, Cape Town, South Africa in July 2009.

Article describing this study in the trade journal ‘Dialoog’. 2009, 4(7): 38-39.

Presentation at the Special Interest Group of Amputation Medicine (WAP), VRA, in Utrecht, the Netherlands, on the 27th January 2010.

Two presentations about the final results of this study were presented at the 13th World Conference ISPO, Leipzig, Germany in May 2010.

An article describing the ADAPT test was accepted for publication in the Journal of Rehabilitation Medicine and is available online.

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