

ORIGINAL REPORT

FUNCTIONAL ADDED VALUE OF MICROPROCESSOR-CONTROLLED PROSTHETIC KNEE JOINTS IN DAILY LIFE PERFORMANCE OF MEDICARE FUNCTIONAL CLASSIFICATION LEVEL-2 AMPUTEES

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**Objective:** To assess the effects of using a microprocessor-controlled prosthetic knee joint on the functional performance of activities of daily living in persons with an above-knee leg amputation.

**Design:** Randomised cross-over trial.

**Subjects:** Forty-one persons with unilateral above-knee or knee disarticulation limb loss, classified as Medicare Functional Classification Level-2 (MFCL-2).

**Methods:** Participants were measured in 3 conditions, i.e. using a mechanically controlled knee joint and two types of microprocessor-controlled prosthetic knee joints. Functional performance level was assessed using a test in which participants performed 17 simulated activities of daily living (Assessment of Daily Activity Performance in Transfemoral amputees test). Performance time was measured and self-perceived level of difficulty was scored on a visual analogue scale for each activity.

**Results:** High levels of within-group variability in functional performance obscured detection of any effects of using a microprocessor-controlled prosthetic knee joint. Data analysis after stratification of the participants into 3 subgroups, i.e. participants with a “low”, “intermediate” and “high” functional mobility level, showed that the two higher functional subgroups performed significantly faster using microprocessor-controlled prosthetic knee joints.

**Conclusion:** MFCL-2 amputees constitute a heterogeneous patient group with large variation in functional performance levels. A substantial part of this group seems to benefit from using a microprocessor-controlled prosthetic knee joint when performing activities of daily living.

**Key words:** amputees; leg prosthesis; rehabilitation; classification; activity; mobility; knee joint.

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INTRODUCTION

The introduction of increasingly expensive prosthetic components, such as microprocessor-controlled prosthetic knee joints (MPKs), has led to greater demands for rehabilitation physicians and their teams to comprehensively justify prosthesis prescription to both health insurance companies and patients. Consequently, in-depth knowledge about the specific characteristics of MPKs and their potential effects on the patient’s functioning is essential. The effects of different types of MPK on the gait of amputees have been tested extensively, often focusing on the International Classification of Functioning, Disability and Health (ICF) level of “body functions and structures” (1), e.g. walking velocity, balance, energy consumption, cognitive load and gait symmetry (2–7). Although important, it is also necessary to assess the complex effects of the MPK at the ICF levels of activity and participation, e.g. assessing the effects on sitting down and standing up, climbing stairs, or going to the supermarket, because measures at these levels better relate to the patients’ daily life.

Currently, the assessment at the ICF activity and participation levels is often performed by using (self-report) questionnaires, resulting in subjective information on perceived performance, possibly obscuring information on actual performance. Theeven et al. (8) introduced a novel test concept called Assessment of Daily Activity Performance in Transfemoral amputees (ADAPT), in which participants perform a set of standardised simulated activities of daily living (ADL), which amputees have indicated as being difficult to carry out while using a leg prosthesis. Theeven et al. (8) showed that it was feasible to reliably and objectively assess the functional abilities of transfemoral amputees in performing ADL with ADAPT.

Several classification systems exist to assign specific codes to an amputee patient based on their functional status. The Mobis® mobility grades (9) (m°1 to m°4) and the Medicare Functional Classification Level (MFCL) index (10) (MFCL-0 to MFCL-4) are well-known classification systems intended

Table I. Medicare Functional Classification Level (MFCL) descriptions

Modifier	MFCL description
K0	MFCL-0 – Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance quality of life or mobility.
K1	MFCL-1 – Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
K2	MFCL-2 – Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
K3	MFCL-3 – Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
K4	MFCL-4 – Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete.

HCFA: Health Care Financing Administration.

for this purpose. A description of the MFCL grades is shown in Table I.

Most types of MPK are prescribed and reimbursed to amputees with a high functional level, i.e. MFCL-3 and MFCL-4, because the possibilities that an MPK offers are believed to better suit their functional abilities and prosthesis-related demands. However, as persons classified as MFCL-2 have had little or no access to MPKs, the possible benefit for this group of amputees remains unclear, thereby potentially denying them a suitable solution to their ambulation-related needs. Compared with persons classified as MFCL-3 or 4, persons classified as MFCL-2 are typically older, have a lower activity

level, have more comorbidities, have reduced muscle strength and coordination, and are more prone to falling.

In MFCL-3 and MFCL-4 amputees the use of an MPK has been shown to improve persons' ability to walk faster, to negotiate stairs and obstacles, to walk downhill, and to walk on uneven terrain. In addition, using an MPK seems to reduce the number of stumbles and falls (2, 4, 6, 11). It is hypothesised that those features of an MPK targeted at providing maximal safety and functionality may also improve the functioning of MFCL-2 amputees. This study aimed to assess the effects of using an MPK on the functional ability level of persons classified as MFCL-2 to perform common ADL.

Several limitations of the MFCL classification are reported in the literature and are important to the present study. A lack of objective tools to assess a person's functional performance has been reported to impact negatively on the accuracy of the MFCL grade assigned to that person (12, 13). Also, the broad definition of MFCL levels may lead to high levels of variability within each functional level (14). The clinical experience of rehabilitation physicians, prosthetists, physical therapists and occupational therapists further confirms these observations, particularly within the MFCL-2 population. In comparison with the groups with higher functional levels, the MFCL-2 population is often considered to be a heterogeneous group in which comorbidities and peripheral vascular disease are more prevalent. This group may also include former MFCL-3 amputees who, due to age or other causes, were assigned a lower MFCL grade after their physical function deteriorated. Therefore, large within-group variance regarding the functional performance is expected. Such a finding would be relevant, because the presence of large within-group variance may impede the detection of possible effects of using an MPK if only select users within the broad MFCL-2 population experience benefits from using it. Therefore, a further aim of this study is to examine within-group differences in an effort to explore this potential phenomenon further.

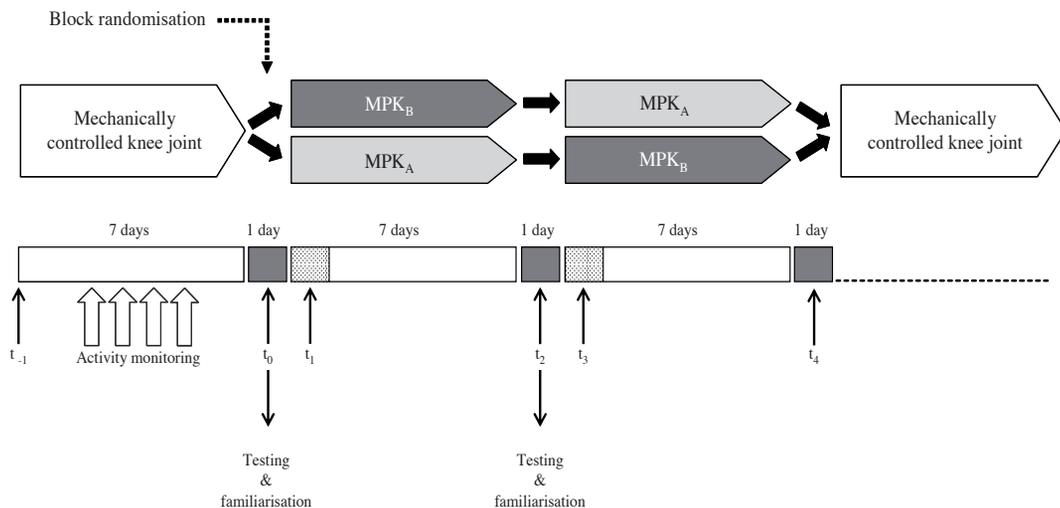


Fig. 1. Schematic overview of study design. MPK<sub>A</sub>: prosthetic knee joint featuring microprocessor-controlled stance and swing phase; MPK<sub>B</sub>: prosthetic knee joint featuring microprocessor-controlled stance phase and passive swing phase control.

## METHODS

*Participant recruitment*

Eligible participants were identified from rehabilitation centres, hospitals and local prosthetic and orthotic care centres in the southern region of the Netherlands and north-eastern region of Belgium. Participants were considered suitable for participation in the study if they had undergone a transfemoral amputation or knee disarticulation, were classified as MFCL-2, were over 18 years of age, used a leg prosthesis fitted with a mechanically controlled knee joint daily, had finished rehabilitation following their amputation for at least one year, were able to walk at least 500 m, and had no previous experience using an MPK. Persons were excluded in case of severe orthopaedic, rheumatological, neurological or cardiovascular disease, in addition to the amputation; severe perceptual or cognitive disorders; or momentary skin problems of the residual limb.

Participants were enrolled over a 3-year period. Approval was obtained from the medical ethics committee of the Rehabilitation Foundation Limburg, Hoensbroek, The Netherlands. Written informed consent was obtained from all persons prior to their participation.

*Study design*

Fig. 1 represents a schematic overview of the randomised crossover study design. Participants were tested in 3 different prosthetic knee joint conditions: (i) with their current mechanically controlled knee joint, i.e. 3R80, 3R106, 3R60, 3R92 (Otto Bock, Vienna, Austria), Acphapend (Proteval, Valenton, France), Ultimate (Ortho Europe, Oxfordshire, UK), Total Knee, Mauch Knee (Össur, Reykjavik, Iceland), Graph-Lite (Teh Lin Prosthetics & Orthopaedics, Kuala Lumpur, Malaysia) or manual locking knee; (ii) with a knee joint featuring a microprocessor-controlled stance and swing phase, i.e. MPK<sub>A</sub> (C-leg® (Otto Bock, Vienna, Austria)); and (iii) with a knee joint featuring a microprocessor-controlled stance phase, i.e. MPK<sub>B</sub> (C-leg® Compact).

Baseline data ( $t_0$ ) were always collected in the mechanically controlled knee joint condition. Participants' performance using either MPK was compared with that using their mechanically controlled knee. The mechanical knee joint condition was therefore chosen as the base of comparison in the subsequent data analyses.

The order in which the MPKs were assigned to the participants was done by block randomisation by a blinded assessor (block size = 4). Each MPK was fitted to the participant's existing socket and used by the participants for a one-week period in their free-living environment. Fitting and alignment was done by an experienced certified prosthetist followed by a 2-h "familiarisation session" with a skilled physical therapist to set the appropriate software settings of the MPK and to familiarise the participants with using the MPK. At the end of this session, the decision was made whether the participant was capable enough to use the prosthesis safely and effectively in his home environment. If so, the participant returned home with the new prosthesis. If not, the participant was not allowed to continue in the study.

Participants returned to the prosthetist one day after the fitting of the MPK for possible prosthetic adjustments regarding alignment and software settings ( $t_1$  and  $t_3$ ). Data were collected after each one-week period of home use, i.e. in the mechanical knee joint condition ( $t_0$ ) and in both MPK conditions ( $t_2$  and  $t_4$ ).

*Functional performance*

An ADAPT test circuit was composed, based on the concept developed by Theeven et al. (8), to objectively assess the functional performance of the participants. This new ADAPT test circuit consisted of 11 circuit stations, in which 17 simulated daily activities were performed by the participants. These activities were chosen from two previous ADAPT test versions (8), based on their psychometric properties. A description of the circuit stations is given in Table II.

For each activity the performance time was recorded and participants were asked to rate the perceived level of difficulty of all circuit stations

Table II. Description of the circuit stations of the Assessment of Daily Activity Performance in Transfemoral amputees test

Circuit station	Task description
1 Supermarket	"easy": 18 low weight (500 g), easy to handle objects have to be picked from shelves at different heights and placed into a shopping trolley. Seven objects are labelled with an "A", 6 objects with a "B" and 5 objects with a "C". "moderate": 4 moderate weight (2 and 5 kg) objects (labelled with a "D") have to be picked from the shelves at different heights and placed into a shopping trolley. "difficult": 2 large and heavy (6 kg) objects (labelled with an "E") have to be picked from the shelves at different heights and placed into a shopping trolley.
2 Shopping bags	The 18 "easy" objects (described in circuit station 1) have to be loaded into 3 shopping bags with corresponding labels "A", "B", "C", that are placed on a table.
3 Kitchen cabinets	Unload the shopping bags into the kitchen cabinets of a height-adjustable kitchen at different reaching heights. "easy": put the 18 low weight objects into the designated cabinets labelled "A", "B" and "C". Cabinets "A" and "C" are at eye level. Cabinet "B" is at knee level.
4 Hanging out laundry	Pick up the towels 1 by 1 (8 in total) from a tray on the ground together with two pins and hang them on the clothes line. The adjustable clothes line is set at wrist level when arms are fully extended and raised above the head.
5 Slalom	Slalom while holding a serving tray with 10 table tennis balls (approximately 32 m).
6 Get the remote control	Sit down, stand up, walk to the television set to pick up the remote control and sit down again. "easy": sit down on an armchair. "moderate": sit down in the middle of a low sofa without using the armrests.
7 Obstacle avoidance	Walk across the living room and avoid all the obstacles (e.g. toys) on the ground.
8 Car	Walk towards the car and get in at the passenger side (distance: 4 m). Get out and walk round the car once, get into and out of the car again and walk to the place where you started the task.
9 Theatre	Walk sideways between two rows of chairs while holding a cup of water. Sit down at the last chair, stand up and walk back to the start/finish line.
10 Stairs descent and climb	Walk down the stairs and then immediately up the stairs (2 flights of 9 threads connected by an intermediate landing). "easy": normal walking. "moderate": walking combined with a cognitive dual task.
11 Hill descent and climb	Walk up and down a sloped road twice (length 18 m; height 2.2 m). "easy": normal walking. "moderate": walking combined with a cognitive dual task.

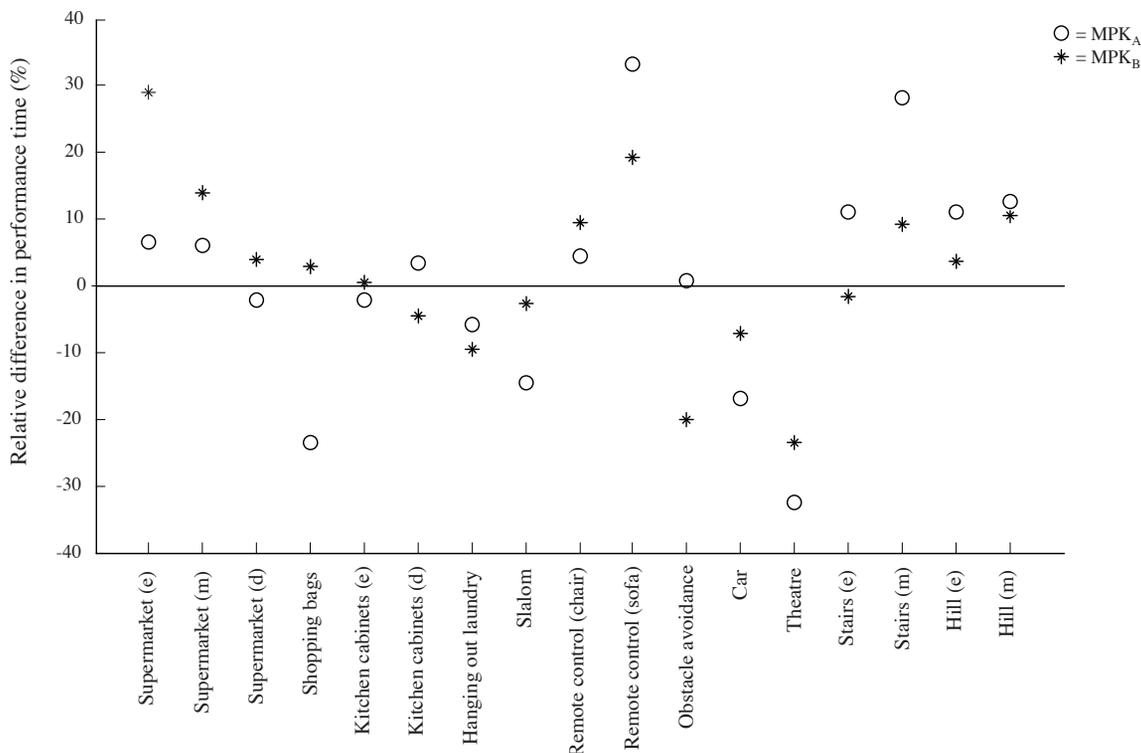


Fig. 2. Typical example of Assessment of Daily Activity Performance in Transfemoral amputees test results for one patient: overview of performance on mechanically controlled knee joint compared with two types of microprocessor-controlled knee joints (MPK<sub>A</sub> and MPK<sub>B</sub>). Performance on the mechanically controlled knee joint is set as the reference value to which the performance on the MPKs is compared (indicated by the horizontal line at 0% difference). Positive values illustrate a relative improvement in performance time while wearing an MPK compared with the performance with mechanically controlled prosthesis. Negative values indicate a relative deterioration in performance time on an MPK compared with the mechanically controlled prosthesis. MPK<sub>A</sub>: prosthetic knee joint featuring microprocessor-controlled stance and swing phase; MPK<sub>B</sub>: prosthetic knee joint featuring microprocessor-controlled stance phase and passive swing phase control.

on a visual analogue scale (VAS) from 0 mm (very easy) to 100 mm (very difficult). At the end of the study the participants were asked which type of knee joint they preferred in daily life.

An example of the ADAPT test results for one participant is given in Fig. 2. It shows a comparative overview of the differences in performance time on each of the ADAPT test activities for both MPK<sub>A</sub> and MPK<sub>B</sub> relative to the mechanically controlled prosthesis.

To be able to comprehensively interpret the results of the ADAPT test, the 17 activities were grouped into so-called activity subsets (AS). To determine the activity subsets, a statistical method called principal component analysis with varimax rotation (15) was used. This method identified 3 different “factors”. The corresponding ADAPT

test activities were then divided into 3 subsets based on the values of the “factor weights”. Each AS contains ADAPT test activities that share a certain underlying content similarity. The content similarity was identified as “Standing activities requiring an adequate degree of balance” (AS<sub>1</sub>), “Activities requiring sitting down and standing up” (AS<sub>2</sub>) and “Ambulation activities heavily depending on the patient’s prosthesis-related skills” (AS<sub>3</sub>). Table III gives an overview of the activities in each AS.

*Stratification*

As indicated, large within-group variability in functional performance was expected in the MFCL-2 cohort, which might impede detection

Table III. Three activity sets each representing content-similarity as indicated by factor weights in the principal component analysis of baseline data

AS <sub>1</sub> Standing activities requiring an adequate degree of balance	AS <sub>2</sub> Activities requiring sitting down and standing up	AS <sub>3</sub> Ambulation activities heavily depending on the patient’s prosthesis-related skills
Supermarket (easy)	Get the remote control (easy)	Kitchen cabinets (difficult)
Supermarket (moderate)	Get the remote control (moderate)	Slalom
Supermarket (difficult)	Car	Obstacle avoidance
Shopping bags	Theatre	Hill descent and climb
Kitchen cabinets (easy)		Hill descent and climb with cognitive dual task
Hanging out laundry		Stair descent and climb
		Stair descent and climb with cognitive dual task

AS: activity subset.

Table IV. Participant characteristics for the total group and for all 3 subgroups "high", "intermediate" and "low" MFCL-2

MFCL-2 subgroup	Gender (n) M/F	Age (years) Mean (SD)	Weight (kg) Mean (SD)	Post-amputation time (years) Mean (SD)	Amputation aetiology (n)			Walking velocity (km/h) Mean (SD)	Activity level (counts/day) Mean (SD)
					Trauma	Vascular	Tumour		
Total	22/8	59.1 (13.0)	76.9 (12.6)	21.5 (18.2)	23	6	1	3.4 (0.7)	120070 (57423)
Low	5/1	65.2 (12.6)	87.2 (3.2)	20.3 (19.6)	3	3	0	2.5 (0.4)	48292 (12236)
Intermediate	10/2	61.0 (10.0)	75.3 (14.0)	21.1 (19.1)	10	2	0	3.2 (0.4)	113945 (50304)
High	7/5	54.1 (14.9)	73.3 (12.0)	22.4 (18.1)	10	1	1	4.0 (0.5)	156102 (44826)

SD: standard deviation; MFCL-2: Medicare Functional Classification Level-2.

of possible effects of using an MPK. To reduce variance, participants were stratified into 3 subgroups, i.e. groups of MFCL-2 amputees with either a "low", "intermediate" or "high" functional level. Allocation to a particular subgroup was done by 3 independent experts (a physical therapist, a rehabilitation physician and a prosthetist) based on participants' daily activity level, mean comfortable walking speed, past medical history, psychosocial status and current physical condition. The participants' daily activity level was monitored during one week in the mechanical knee joint condition with a uniaxial accelerometer (Actigraph, Pensacola, FL, USA) worn around the waist. The activity level was expressed as the number of times an acceleration was recorded or "counts" per day. In addition, participants were asked to record their general daily activities in an activity diary. The activity diary provided descriptive information concerning the types of activity and daily routines in addition to the objective accelerometer data. Walking velocity was measured in the mechanically controlled knee joint condition using the two-min walk test on an even surface (16, 17). The participants' past medical history, psychosocial status and physical condition were obtained from the patients' medical records. As the MPK conditions were the experimental conditions, and the mechanically controlled knee joint condition was the reference condition, both activity level and walking speed were measured in the latter condition.

The stratification was performed in two steps. Participants were first allocated to one of the subgroups "high", "intermediate" or "low" based on their walking speed and activity level. Participants were assigned to subgroup "high" if their walking speed was equal to or more than 4 km/h and their activity level exceeded 100,000 counts/day. Participants were assigned to subgroup "low" if their walking speed was less than 3 km/h and their activity level was less than 65,000 counts/day. All other participants were allocated to subgroup "intermediate". In the second step, additional information about the participants (i.e. past medical history, psychosocial status, physical condition and information from the activity diary) was used to check and to further refine the primary stratification. In particular, participants with an activity level or walking speed close to the cut-off values were double-checked and if necessary reallocated to another subgroup if the clinical information strongly disagreed with the primary allocation ( $n=3$ ).

#### Statistical analysis

Data were assessed for both the total group of participants and for 3 subgroups of participants. Comparison of data between knee joint conditions included Friedman two-way analyses of variance by ranks test (18). Multiple comparison included Wilcoxon signed-rank tests for paired observations (18). In case of the multiple comparison tests a Bonferroni correction was applied (15).

Possible differences between subgroups of participants were tested using the nonparametric Kruskal-Wallis one-way analysis of variance tests (18). Multiple comparison included Mann-Whitney  $U$  tests (18).

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

## RESULTS

### Participants

From over 500 amputee patient records 103 eligible patients were identified. A total of 41 persons agreed to participate in the study. People of varying age, gender and physical condition declined the invitation to participate in this study for a number of reasons, such as having no interest in the study, travelling distance being too long, not getting the days off from work or no time to participate. Table IV shows an overview of the characteristics of the total group of participants and the assigned stratification (i.e. "low", "intermediate" or "high"). Characteristics of participants by subgroup are also presented in Table IV.

Twenty-eight of the 41 included participants completed the research protocol. In addition, two participants finished the tests using their mechanically controlled knee joint and only 1 of the two MPKs. The reasons these participants did not continue in the study were the onset of back pain ( $n=1$ ) and a high sense of insecurity using the MPK ( $n=1$ ). The other 11 participants dropped out at an earlier stage in the study, rendering an inadequate amount of data to include for further analysis. Reasons for dropping out of the study included: technical problems regarding the fit and alignment of the different knee joints ( $n=4$ ), inability to ambulate safely using the MPK after the familiarisation session ( $n=3$ ), physical problems due to overuse (e.g. skin disorders and muscle aching discomfort ( $n=2$ )), decease of a participant ( $n=1$ ) and the occurrence of a stroke ( $n=1$ ). Eight of the participants who dropped out had their amputations due to vascular problems and 3 participants were amputated due to trauma.

### Assessment of Daily Activity Performance in Transfemoral amputees test: performance times

Fig. 3 represents the performance times of the total group on the 3 ADAPT test activity subsets (i.e.  $AS_1$ ,  $AS_2$  and  $AS_3$ ) in all 3 knee joint conditions (i.e. mechanical,  $MPK_A$  and  $MPK_B$ ). Large variations were found regarding the performance times in the 3 activity subsets. A significant decrease in performance time was found in activities of  $AS_1$  for the MPK conditions  $MPK_A$  and  $MPK_B$  ( $p=0.0001$  and  $p=0.002$ ).

Comparing the results of the mechanical knee joint condition (baseline values) between the 3 subgroups of participants ("high", "intermediate" and "low") indicated that the  $AS_1$  activities were performed significantly faster by the participants

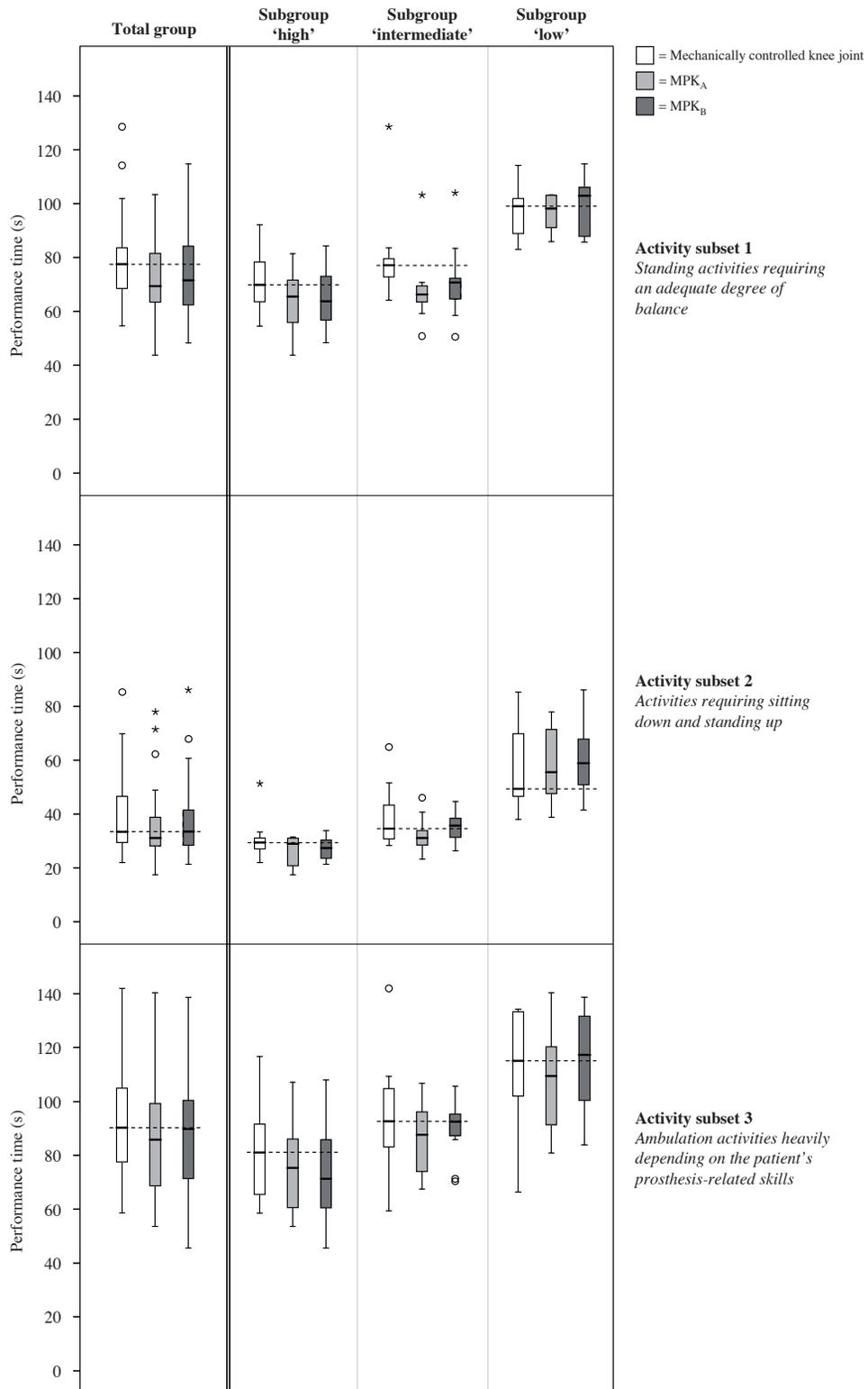


Fig. 3. Box-plots of the mean performance times for each activity subset of the total group of participants and of the participants from the subgroups “high”, “intermediate” and “low” for all knee joint conditions. The dotted horizontal lines in each of the 3 Assessment of Daily Activity Performance in Transfemoral amputees test activity subsets illustrate the median value at baseline; MPK<sub>A</sub>: prosthetic knee joint featuring microprocessor-controlled stance and swing phase; MPK<sub>B</sub>: prosthetic knee joint featuring microprocessor-controlled stance phase and passive swing phase control.

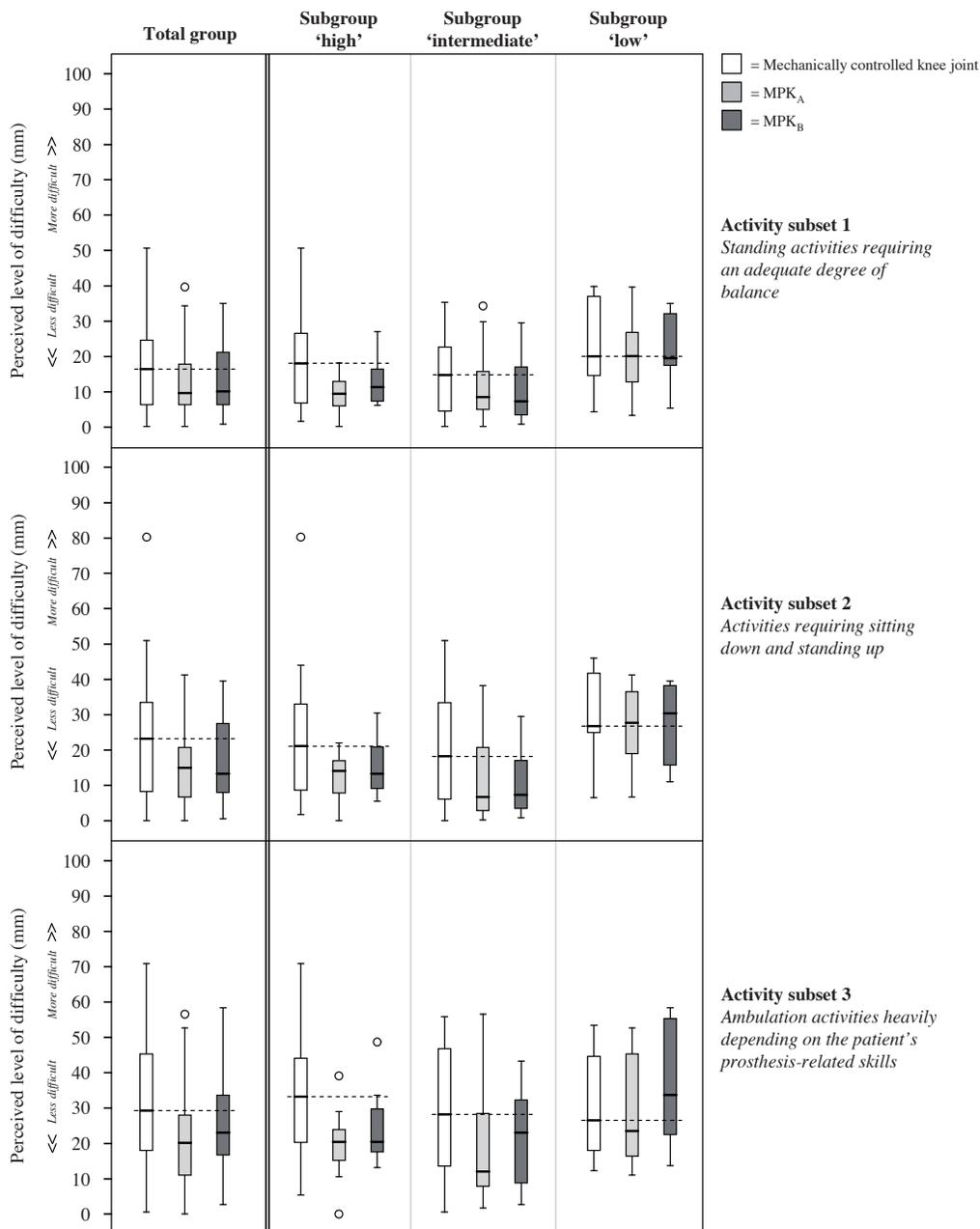


Fig. 4. Mean perceived level of difficulty scores (mm) for each of the activity subsets of the total group of participants and of the participants from the “high”, “intermediate” and “low” subgroups for all knee joint conditions. The dotted horizontal lines in each of the 3 Assessment of Daily Activity Performance in Transfemoral amputees test activity subsets illustrate the median value at baseline; MPK<sub>A</sub>, prosthetic knee joint featuring microprocessor-controlled stance and swing phase; MPK<sub>B</sub>, prosthetic knee joint featuring microprocessor-controlled stance phase and passive swing phase control.

in the subgroups “high” and “intermediate”, compared with the participants in the subgroup “low” ( $p=0.001$  and  $p=0.007$ , respectively). Performance times on the AS<sub>1</sub> activities did not differ between subgroups “high” and “intermediate”. The AS<sub>2</sub> activities were performed significantly faster by participants in the subgroups “high” and “intermediate” compared with participants assigned to subgroup “low” ( $p=0.003$  and  $p=0.015$ ). In addition, participants assigned to subgroup

“high” performed the AS<sub>2</sub> activities significantly faster than participants in subgroup “intermediate” ( $p=0.013$ ). The observed differences in performance time on the activities in AS<sub>3</sub> between the subgroups “high” and “low” just failed to attain significance after Bonferroni correction ( $p=0.025$ ). The observed differences between the subgroups “high” and “intermediate” and between the subgroups “intermediate” and “low” did not attain a statistical significance level.

The participants in the subgroup “high” performed the activities in AS<sub>1</sub> significantly faster in both the MPK<sub>A</sub> ( $p=0.010$ ) and the MPK<sub>B</sub> ( $p=0.019$ ) conditions compared with the mechanically controlled prosthesis condition. The performance times for the activities in AS<sub>2</sub> for subgroup “high” did not change in either the MPK<sub>A</sub> or the MPK<sub>B</sub> condition, compared with the mechanically controlled prosthesis condition. The observed difference in performance time for the activities in AS<sub>3</sub> between the mechanically controlled prosthesis condition and the MPK<sub>A</sub> prosthesis condition did not attain statistical significance. In contrast, the difference between the mechanically controlled and MPK<sub>B</sub> condition for the AS<sub>3</sub> activities was statistically significant ( $p=0.023$ ).

Participants in subgroup “intermediate” performed the activities in AS<sub>1</sub> significantly faster in both the MPK<sub>A</sub> and MPK<sub>B</sub> prosthesis conditions compared with the mechanically controlled prosthesis condition ( $p=0.004$  and  $p=0.008$ ). Participants from this subgroup also performed the AS<sub>2</sub> activities significantly faster on MPK<sub>A</sub>, compared with their mechanically controlled prosthesis for ( $p=0.016$ ). No difference in performance time was observed between the mechanically controlled prosthesis and MPK<sub>B</sub> conditions for activities in AS<sub>2</sub> in subgroup “intermediate”. Participants classified as “intermediate” showed no changes in performance times on the AS<sub>3</sub> activities between any prosthesis condition.

The performance times of the participants in subgroup “low” did not differ for any of the activity subsets between any prosthesis condition.

#### *Assessment of Daily Activity Performance in Transfemoral amputees test: perceived level of difficulty*

The mean VAS scores reflecting the perceived level of difficulty of the ADAPT test activities are presented in Fig. 4 for both total group of participants and the subgroups of participants (“high”, “intermediate”, and “low”). In the total group, the perceived level of difficulty for activities in AS<sub>2</sub> and AS<sub>3</sub> was significantly lower in the MPK<sub>A</sub> condition compared with the mechanical knee joint condition ( $p=0.023$  and  $p=0.008$ ). The perceived level of difficulty scores in the MPK<sub>B</sub> condition did not differ from the scores in the mechanical knee joint condition. The mean perceived level of difficulty scores per activity subset measured at  $t_0$  did not differ between the subgroups of participants.

For the subgroups “high” and “intermediate” there seems to be a trend, although not statistically significant, that the perceived level of difficulty in both MPK conditions is scored lower compared with the perceived level of difficulty in the mechanical knee joint condition for all activity subsets. The perceived level of difficulty scores of subgroup “low” showed no significant differences in any of the activity subsets between the mechanically controlled and either MPK<sub>A</sub> or MPK<sub>B</sub> condition.

Out of the 29 participants who completed the knee joint preference questionnaire at the end of the study, 21 participants (high=10, intermediate=7, low=4) indicated preferring MPK<sub>A</sub>, 7 participants (high=2, intermediate=3, low=2) preferred MPK<sub>B</sub>, and 1 participant (intermediate) preferred his own mechanically controlled prosthesis.

## DISCUSSION

The aim of this study was to assess the effects of using an MPK on the level of functional ability to perform ADL in persons classified as MFCL-2. MPK<sub>A</sub> and MPK<sub>B</sub> each seemed to improve the functional ability to perform standing activities that require adequate balance in the whole group of MFCL-2 amputees. Furthermore, the findings confirmed our expectations of large variation regarding the functional performance level within the group of MFCL-2 amputees. The stratification of persons with a comparable functional level within the MFCL-2 grade into 3 subgroups helped to refine the assessment of possible effects of using an MPK. Particularly the MFCL-2 amputees with either an “intermediate” or “high” functional level seemed to improve their ability to perform common daily activities using an MPK, while those amputees with a “low” functional level did not appear to do so.

Very few studies have focused on the MFCL-2 population and on the possible effects of an MPK on daily functioning. Hafner & Smith (12) have reported that MFCL-2 amputees may benefit equally from the use of MPK<sub>A</sub> to those persons classified as MFCL-3. They investigated a cohort of MFCL-2 amputees with similar characteristics to those of the participants of the current study. In addition, the findings of Hafner & Smith (12) and Kahle et al. (2) indicated that several persons who were initially classified as MFCL-2 advanced to MFCL-3 when they used MPK<sub>A</sub>. The results of the current study corroborate the findings of those previous investigations, but, additionally, allow for further differentiation of the effects of an MPK within this patient group. Because of the applied stratification of participants it has become clear that not all MFCL-2 amputees seem to benefit from using an MPK in daily life.

The MFCL classification is currently based on the subjective assessment by experienced clinicians of patient’s actual ability or potential ability to accomplish his expected post-rehabilitation daily function (19). Applying this definition inherently leads to considerable variability within each functional level. This observation is further corroborated by the findings of the current study. Three subgroups were identified within the MFCL-2 cohort by using a method that incorporates the use of objective measures to help clinicians to describe a person’s functional mobility level. At baseline, the 3 identified subgroups of patients showed significant differences in the level of functional ability to perform common daily activities, which may suggest the need for a more detailed classification system.

For the participants in the subgroups “intermediate” and “high”, both types of MPK led to significant improvements in their ability to perform activities, such as picking up objects from shelves at different heights and placing them in a shopping trolley, filling shopping bags with groceries, putting objects into kitchen cabinets and hanging out laundry on a clothes line (i.e. AS<sub>1</sub> activities). Performing this type of activities typically requires an adequate degree of both static and dynamic balance, which is known to be reduced in lower limb amputees (20). Often, amputees are less confident about their ability to maintain their balance when performing daily

activities (21), which, in turn, may have a strong effect on their level of mobility and participation (22). Kaufman et al. (3) previously reported MPK<sub>A</sub> to improve the level of balance and stability compared with using mechanically controlled knee joints in highly active amputees (MFCL-3 and MFCL-4). Our results suggest that the use of both MPK<sub>A</sub> and MPK<sub>B</sub> can also lead to increased performance in activities necessitating high balance levels in MFCL-2 amputees classified as either “intermediate” or “high”.

Activities that included sitting down and getting up from a chair in different settings, e.g. in a car, in a cinema, or in a living room (i.e. AS<sub>2</sub> activities), were performed significantly faster only by the participants in subgroup “intermediate”. The actively-controlled knee flexion damping available in both MPK<sub>A</sub> and MPK<sub>B</sub> should enable amputees to distribute their body weight more evenly over both legs when sitting down, reducing the load on the non-amputated leg and providing more stability. Participants in the subgroup “high” did not perform these activities faster on either type of MPK, most likely because they already performed these activities at a speed that is maximal for them in the mechanically controlled knee joint condition.

The activities from AS<sub>3</sub>, which include more demanding ambulation activities, such as walking stairs, hill negotiation, obstacle avoidance in a confined space and slalom while holding a tray, typically require adequate prosthesis-related skills and cognitive skills. Improvements in the performance of MFCL-2 amputees on some of the AS<sub>3</sub> activities when using MPK<sub>A</sub>, i.e. walking downhill and avoiding obstacles, have previously been reported by Hafner & Smith (12). Our results indicate that only the participants from the MFCL-2 subgroup “high” seem to benefit from using MPK<sub>B</sub> in performing this type of daily activities. It was expected that an improvement in the performance of the AS<sub>3</sub> activities would also occur in the other subgroups, given the active stance phase control of both types of MPK providing high levels of safety and efficiency in these types of challenging activities. Although, in general, the participants were able to apply newly learned performance strategies for the MPK, it remains unclear whether or not, after one week of use, they would also use these new strategies in more challenging conditions in which the full potential of the MPK would be required. Further research is required to investigate this.

The participants in the MFCL-2 subgroup “low” did not show an improvement in functional performance when using either type of MPK. However, neither the actual nor the perceived performance level during ADL did, on average, deteriorate in the members of subgroup “low” after transitioning from a mechanically controlled knee joint to an MPK. A more compromised overall physical condition, in combination with lower balance confidence levels in participants in subgroup “low” compared with the participants in the other subgroups may have contributed to this finding. Further research is necessary to assess whether an extended accommodation period on an MPK could lead to an improvement in the level of functional performance in amputees of subgroup “low”.

As it was also important to include the amputees’ opinion about the use of an MPK, a subjective assessment was solic-

ited (i.e. VAS questionnaire). However, in contrast to actual performance data, the level of variability of the participants’ perceived performance level did not seem to improve after stratification. One of the reasons for this may be that a VAS is sensitive to changes in the participants’ frame of reference, i.e. their perception of, for instance, the term “poor” may change over time to “moderate” because they have come to terms with a certain condition or state.

Although, statistically, no difference was found between both MPK conditions as to the level of functional performance, both types of MPK had different effects on the participants’ individual functional performance level. Some participants from the subgroup “high” did not improve their functional performance when using an MPK, whereas participants from subgroup “low” did improve their level of functional performance when using an MPK. Furthermore, some participants preferred MPK<sub>A</sub>, some participants preferred MPK<sub>B</sub> and one person preferred his mechanically controlled prosthesis. These different examples of between-subject variability underline the need of individual assessment when using the ADAPT test for prosthesis selection and prescription purposes. One should not try to find a singular best prosthesis for an entire group of amputees, but rather use tests, like the ADAPT test, to personalise the choice, because each individual responds differently to a specific prosthesis (4, 13).

#### Considerations

In the current study, persons who were classified as MFCL-2 participated. Approximately 20% of the research population acquired their amputation due to vascular reasons, which might not be fully representative for the total MFCL-2 population. Several vascular participants (designated to subgroup “low”) were not able to complete the study protocol due to their compromised physical condition. Cautious interpretation of the results of subgroup “low” is therefore warranted.

No clear consensus exists concerning the optimal accommodation time for a new prosthetic component. English et al. (23) reported that a one-week familiarisation period is adequate in clinical practice, but for research purposes, a familiarisation period of at least 3 weeks is recommended. Other studies report accommodation periods ranging from 1 to 33 weeks (2–5, 11, 12, 24, 25). Nonetheless, significant improvements in functional performance levels were found in the present study in the “intermediate” and “high” subgroups after one week of use. This indicates that using an MPK may lead to short-term effects related to an amputee’s functional performance level.

#### Future research

The circuit stations that constituted the current ADAPT test were tested in a previous proof-of-concept study (8). Given the nature of the ADAPT test, i.e. featuring representations of daily activities, the ecological validity of the test is considered promising. Part of our future research will be to further investigate and refine the psychometric properties of the ADAPT test. Also, research is planned to score the quality of performance, e.g. quantifying the amount of compensatory movements, accuracy,

efficiency and smoothness of motion during task performance, in addition to measuring performance time.

In conclusion, the use of prosthetic knee joints featuring microprocessor-controlled stance and/or swing phase control has beneficial effects on the level of functional ability to perform common daily activities in part of the MFCL-2 population. This patient population has shown to be heterogeneous as to the level of functional mobility, functional outcome and the way persons perceive their own functional performance. This population may be further divided into subgroups of MFCL-2 amputees. Persons classified as MFCL-2 with either intermediate to high prosthesis-related abilities seem to have a functional benefit from using an MPK to perform ADL.

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