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ORIGINAL REPORT

INFLUENCE OF ADVANCED PROSTHETIC KNEE JOINTS ON PERCEIVED PERFORMANCE AND EVERYDAY LIFE ACTIVITY LEVEL OF LOW-FUNCTIONAL PERSONS WITH A TRANSFEMORAL AMPUTATION OR KNEE DISARTICULATION

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Objective: To assess the effects of two types of microprocessor-controlled prosthetic knee joints (MPKs) on perceived performance and everyday life activity level.

Design: Randomized cross-over trial.

Subjects: Thirty persons with a unilateral above-knee amputation or knee disarticulation classified as Medicare Functional Classification Level-2.

Methods: Participants were measured in 3 conditions, i.e. using a mechanically controlled prosthesis, an MPK featuring a microprocessor-controlled stance and swing phase (MPK_A), and an MPK featuring a microprocessor-controlled stance phase (MPK_B). Subjects' perceived performance regarding prosthesis use was measured with the Prosthesis Evaluation Questionnaire. Subjects' activity level was quantified using accelerometry. As high within-group variability regarding subjects' functional performance was expected to impede detection of possible effects of an MPK, data were analysed for the total group and for 3 subgroups of participants.

Results: Participants' perception regarding ambulation, residual limb health, utility, and satisfaction with walking were significantly higher in the MPK_A condition compared with the mechanical knee joint condition. Participants' activity level was similar in all knee joint conditions.

Conclusion: Although Medicare Functional Classification Level-2 amputees report benefitting in terms of their performance from using an MPK, this is not reflected in their actual daily activity level after one week of using an MPK.

Key words: accelerometer; activity; amputee; knee; microprocessor-controlled; participation; prosthesis; rehabilitation.

J Rehabil Med 2012; 44: 454–461

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Submitted June 16, 2011; accepted January 4, 2012

INTRODUCTION

Ambulating with a prosthetic limb is known to be a demanding task, both physically and mentally. Persons with a transfemoral

amputation are less efficient ambulators in comparison with able-bodied persons, demonstrating a 27–49% increased energy expenditure when walking at self-selected velocities. Moreover, the self-selected walking velocities of persons with an amputation are considerably lower (1, 2). The loss of motor control at the ankle and knee makes maintaining balance more difficult, which may reduce persons' sense of stability, safety and balance confidence (3, 4). In addition, due to the absence of somatosensory feedback from the amputated leg, persons with an above-knee amputation have to rely on other stimuli (e.g. vision) to control the prosthesis during ambulation, which may interfere with their ability to concentrate on concurrent tasks (5). In an attempt to decrease the physical or mental strain, persons with a leg amputation may alter, reduce, or avoid the performance of strenuous activities such as walking (6, 7). This eventually affects their level of participation in daily life (3, 8–10). This poses a problem, because activity avoidance may lead to further deterioration of a person's physical condition and eventually to additional loss of mobility (9).

Manufacturers of microprocessor-controlled prosthetic knee joints (MPKs) generally claim that the continuous active control of the stance and/or swing phase featured in the MPK may help reduce the physical and mental load of walking with a prosthesis, thus enhancing the functional mobility of persons with an amputation. Much research has been performed to assess the effects of MPKs on persons' level of functioning. Many of the studies performed focused on the level of "body function and structures", defined by the International Classification of Functioning, Disability, and Health (ICF) (11). Only little is known about the effects of using an MPK at the ICF levels of activity and participation. Moreover, as outcome measures at the ICF level of body functions and structures typically measure actual performance, outcome measures at the ICF levels of activity and participation often have to rely on patients' perceived performance. The findings of studies that focused on actual performance, such as gait symmetry (12–14), the level of energy efficiency of walking (15–19), or the daily activity level (20–22), are not always in agreement with findings concerning the perceived performance of persons who transitioned from

a mechanically controlled knee joint to an MPK. They report increased ease of walking with the MPK (23).

MPKs have been specially developed for persons with a high functional mobility level, i.e. persons who have been classified as Medicare Functional Classification Level-3 or -4 (MFCL-3 or MFCL-4) (24) or Mobis® grade 3 or 4 (K3 or K4) (25). Those persons have the ability or potential to ambulate with variable cadence and have the ability or potential to be involved in activities that demand prosthetic utilization beyond simple locomotion (24). Very little is known about the effects of using an MPK in individuals with a lower functional mobility level (MFCL-2 or K2). These persons have the ability or potential to ambulate indoors and are able to overcome low-level environmental barriers (e.g. kerbs, stairs, or uneven surfaces) (24).

The MFCL-2 population is seen by clinicians involved in amputation and prosthetics as being more heterogeneous regarding functional performance in comparison with persons with a higher functional level. This heterogeneity has recently been confirmed in a study by Theeven et al. (26). Persons classified as MFCL-2 typically are older, have a more proximal level of amputation, have reduced muscle strength and coordination, have more comorbidities and are often amputated due to peripheral vascular disease. This group also includes individuals who were formerly classified as MFCL-3, but who, due to age or other medical causes, lost specific ambulation and prosthetic utilization skills, and hence were given a lower MFCL grade.

In 2004 an MPK with a microprocessor-controlled stance phase (C-leg® Compact, Otto Bock HealthCare, Vienna, Austria) was introduced particularly for individuals classified as MFCL-2. This MPK aimed to offer a high level of security to its user. The results of previous studies suggest that most persons with an amputation classified as MFCL-2 who use a prosthesis fitted with an MPK instead of a mechanically controlled knee joint show an increased level of functional ability to perform daily activities, fall less and may experience a higher sense of safety and stability in critical situations (26–28). Although those findings suggest that an MPK may reduce the physical and mental strain of ambulating with a prosthesis in persons classified as MFCL-2, it is not known whether these advantageous effects will actually lead to these persons becoming more active in everyday life. In addition, it is important to take the perspective of persons with a leg amputation regarding prosthesis use into account when evaluating prosthetic components. Prosthesis use may be greatly influenced by the level of satisfaction with the prosthesis (29).

The aim of this study was to investigate possible changes in perceived performance of persons classified as MFCL-2 who transition from a mechanically controlled prosthetic knee joint to an MPK. This study also assessed whether such a transition between prosthetic knee joints affects their everyday activity level. It is hypothesized that an MPK will reduce the physical and mental strain of ambulating with a prosthesis (as perceived by the participants), which in turn will encourage subjects to perform more activities during the day.

METHODS

Participants

Eligible individuals ($n=103$) were identified from patient records of rehabilitation centres, hospitals and prosthetic and orthotic care centres in the southern region of the Netherlands and north-eastern region of Belgium. Each person was screened by a panel of experts, including a rehabilitation physician, a senior physiotherapist, and a senior prosthetist, to determine the person's MFCL level. Factors such as age, cause of amputation, physical condition, comorbidities, pain, and fear of falling were taken into account during classification. Inclusion criteria were: unanimously diagnosed by the screening panel as MFCL-2; over 18 years of age; having a transfemoral amputation or knee disarticulation; daily use of a leg prosthesis fitted with a mechanically controlled knee joint; finished rehabilitation for at least one year; able to walk at least 500 m per day; no previous experience using an MPK. Exclusion criteria were: severe orthopaedic, rheumatological, neurological or cardiovascular disease in addition to the amputation that might impede performance; severe perceptual or cognitive disorders; and/or skin problems of the stump.

Approval was obtained from the institutional medical ethics committee of the Rehabilitation Foundation Limburg (currently: Adelante Rehabilitation Centre), Hoensbroek, The Netherlands. Written informed consent was obtained from all subjects prior to their participation.

Design

A double crossover study design was used, in which participants were measured in 3 different prosthetic knee joint conditions, i.e. a mechanical knee joint condition and 2 different types of MPK conditions.

In the mechanical knee joint condition, participants used their current, mechanically controlled knee joint (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.

The MPK conditions involved a knee joint with a microprocessor-controlled stance and swing phase (C-leg®, Otto Bock) and a knee joint with a microprocessor-controlled stance phase (C-leg® Compact, Otto Bock). The MPK conditions are abbreviated as MPK_A (C-leg) and MPK_B (C-leg Compact), respectively.

The participants were assessed in each knee joint condition during a 1-week period in the participants' home and community environment. At the end of each week (at t_0 , t_2 , and t_4), participants' perceived performance and satisfaction with the prosthesis was assessed. The study design is illustrated in Fig. 1.

Both types of MPK were fitted to the participant's existing socket by an experienced certified prosthetist and were aligned using the L.A.S.A.R. posture device (Otto Bock). Participants started the study on their mechanically controlled prosthesis (t_0) and the order in which the MPKs were subsequently assigned was determined by a computer-generated block randomization (block size=4). After fitting of the MPK (t_0 and t_2) a skilled physical therapist gave a 2-h "familiarisation session" in which the appropriate software settings of the MPK were set and the participants were familiarized with using the MPK. At the end of this session the therapist assessed whether the participants were able to use the MPK safely in their home environment. If this was the case the participant returned home, fitted with his adapted prosthesis. If safe use was not possible, the participant was not allowed to continue in the study. Participants returned 1 day after fitting of the MPK for possible prosthetic adjustments regarding alignment and software settings (t_1 and t_3). At t_4 the participant's prosthesis was returned to its original configuration.

Measurements

At the end of each test week the participants' perception about the use of an MPK in daily life was assessed using 6 out of the 9 validated, independent subscales of the Prosthesis Evaluation Questionnaire

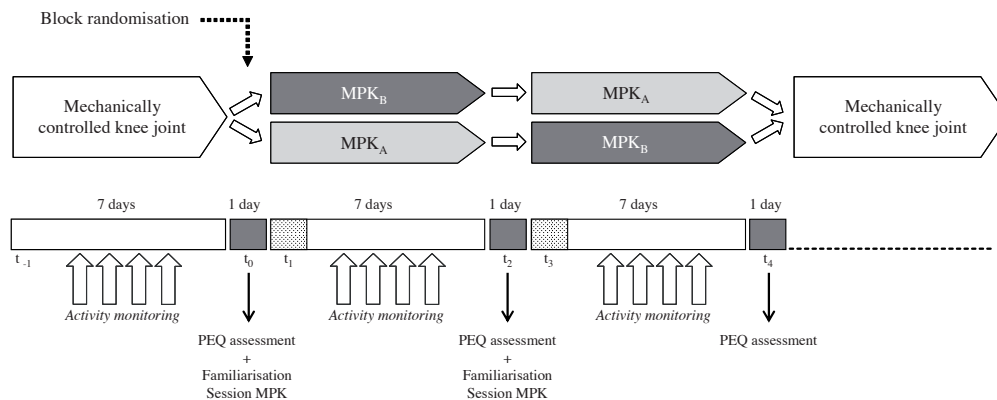


Fig. 1. Overview of the study design. MPK_A: prosthetic knee joint featuring microprocessor-controlled stance and swing phase; MPK_B: prosthetic knee joint featuring microprocessor-controlled stance phase and passive swing phase control; PEQ: Prosthesis Evaluation Questionnaire.

(PEQ) (30), i.e. Ambulation (AM), Appearance (AP), Residual Limb health (RL), Sounds (SO), Utility (UT) and Well-being (WB). These subscales have shown moderate to strong levels of test-retest reliability (ICC ranges 0.79–0.90) and validity (30). The 3 other subscales of the PEQ (Frustration, Perceived Response and Social Burden) did not fit the scope of this study and were therefore not used. Furthermore, two additional individual questions of the PEQ concerning the participants' satisfaction about the prosthesis (SA_{satpro}) and the participants' satisfaction about walking with the prosthesis (SA_{satwalk}) were included. All questions were answered on a visual analogue scale from 0 to 100 mm. A higher score corresponds with a more positive response.

The participants' activity level was recorded with a uniaxial accelerometer (GT1M, Actigraph, Pensacola, FL, USA) (dimensions: 38 mm × 37 mm × 18 mm) during 3 1-week periods. This type of accelerometer has shown adequate validity and sensitivity for use with both young and older persons (31, 32). The accelerometer was worn firmly around the waist on an adjustable belt during waking hours. The GT1M records accelerations ranging in magnitude from approximately 0.05 to 2.5 G. The analogue acceleration signal is subsequently digitized by a 12-bit converter at a rate of 30 Hz and band-limited to a frequency range that best detects human motion (0.25–2.5 Hz). The digitized acceleration values were summed over a 1-min period and are expressed as so-called "counts", which incorporate both the amount of accelerations and the magnitude of the accelerations. Participants also kept a small activity diary in which they recorded their general activities performed during the day.

Data analysis

Activity data were downloaded from the accelerometer at the end of each week with Actigraph software. The raw data were then processed using Matlab software (version 7.2.0, The MathWorks Inc, Natick, MA, USA). Bouts of activity were identified for each day in the 3 prosthesis conditions. A bout of activity was defined as the number of min between the moment that the accelerometer signal exceeded a

predetermined threshold value of 30 counts per min to the moment that the signal dropped below that threshold value. This threshold value was chosen after inspecting the accelerometer signal during periods of rest, as was indicated by the participants in the activity diary (e.g. watching television in the evening). Small levels of activity recorded during these periods were likely to represent non-pertinent activities, such as repositioning oneself on the sofa.

Everyday life activity was assessed using the following outcome measures: (i) "up-time", i.e. the amount of time per day (minutes) that the participant wore the accelerometer; (ii) "active-time", i.e. the portion of the up-time (%) during which the participant performed bouts of activity; (iii) the total level of activity during the up-time (in so-called "counts"); (iv) the mean number of bouts of activity during the up-time.

Theeven and co-workers (26) have shown large between-subject variability in functional performance among persons classified as MFCL-2. As large variance may impede detection of possible effects of using an MPK, subjects were stratified into 3 subgroups, i.e. "low", "intermediate" and "high" MFCL-2 subjects, based on persons' self-selected walking speed (2-min walk test) and total activity level (accelerometry) in combination with additional clinical information about the participants (e.g. past medical history, psychosocial status and current physical condition) analogous to the procedure described in more detail by Theeven et al. (26). The data of the current study were analysed both for the total group of participants and for the 3 MFCL-2 subgroups.

Statistics

The level of activity in the mechanically controlled knee joint condition and both microprocessor-controlled knee joints conditions were compared using non-parametric statistics with alpha set at 0.05. Multiple comparisons for related samples were performed using Wilcoxon signed-rank tests with Bonferroni correction (33, 34). Differences between MFCL-2 subgroups were assessed using Kruskal-Wallis tests

Table I. Characteristics of participants in the subgroups "high", "intermediate" and "low"

MFCL-2 subgroup	Gender		Age, years Mean (SD)	Weight, kg Mean (SD)	Type of amputation		Post-amputation time, years Mean (SD)	Amputation aetiology			Self-selected walking velocity, km/h Mean (SD)	Activity level "Counts"/day Mean (SD)
	M/F	n			TA	KD		Trauma	Vascular	Tumour		
Total	22/8		59.1 (13.0)	76.9 (12.6)	24	6	21.5 (18.2)	23	6	1	3.4 (0.7)	117,852 (57,982)
Low	5/1		65.2 (12.6)	87.2 (3.2)	5	1	20.3 (19.6)	3	3	0	2.5 (0.4)	48,322 (10,926)
Intermediate	10/2		61.0 (10.0)	75.3 (14.0)	9	3	21.1 (19.1)	10	2	0	3.2 (0.4)	114,165 (50,309)
High	7/5		54.1 (14.9)	73.3 (12.0)	10	2	22.4 (18.1)	10	1	1	4.0 (0.5)	156,304 (44,869)

TA: transfemoral amputation; KD: knee disarticulation; SD: standard deviation; MFCL-2: Medicare Functional Classification Level-2.

and Mann-Whitney *U* tests. Data were statistically analysed using SPSS 16.0.1 (SPSS Inc., Chicago, IL, USA).

RESULTS

Participants

Of the 103 eligible subjects who were invited to participate in the study, 41 entered the study. Persons of various age, gender and with different causes for amputation declined the invitation for various reasons, such as, travelling distance being too long, no interest in participating in the study, not getting the time off work or having no time to participate.

For 11 of the 41 participants insufficient data were collected to include in the final analyses, because they discontinued the study protocol at an early stage for one of the following reasons: the participant's existing socket could not accommodate the MPK due to an incompatible attachment fitting (*n*=4), the participant was not capable of safely ambulating using the MPK after the 2-h familiarisation session (*n*=3), the participant experienced physical discomfort after prolonged use of the prosthesis (e.g. skin lesions and extreme muscle ache) (*n*=2), the participant had a stroke (*n*=1), or the participant deceased from reasons unrelated to participating in the study (*n*=1).

The data of 30 participants were included in the final analyses. The characteristics of the total group of participants and of the 3 MCFL-2 subgroups are presented in Table I.

In two of the participants the accelerometer data for one of the MPK conditions were not available as these subjects did not complete the study protocol due to the occurrence of back pain (*n*=1) or a high sense of insecurity using the MPK (*n*=1). For one participant the accelerometer data of the two MPK prosthesis conditions were lost due to a technical error, but this subject's PEQ results were included in the analysis. One other participant did not complete the PEQ in the baseline condition and for that reason was not included in the PEQ analysis. However, his data was included in the analysis of the accelerometer data.

Perceived performance

The results on the different PEQ subscales are presented in Table II.

The scores of the total group on PEQ subscales AM, RL, UT and SA_{satwalk} were significantly higher in the MPK_A condition compared with the mechanically controlled knee joint condition. The scores on PEQ subscales RL and UT were significantly higher in the MPK_B condition compared with the scores in the mechanically controlled knee joint condition.

The scores in MCFL-2 subgroup "low" showed no statistically significant differences in PEQ subscale scores between knee joint conditions.

Table II. Overview of the Prosthesis Evaluation Questionnaire (PEQ) results on 6 subscales and 2 satisfaction-related questions

PEQ subscale	Mechanical		MPK _A		MPK _B		p-value		p-value		p-value		p-value high
	Mean (SD)		Mean (SD)		Mean (SD)		total		low		inter.		
	group	High	group	High	group	High	total	low	inter.	low	inter.	high	
AM	68.0 (15.8)	61.2 (12.6)	71.1 (16.5)	68.5 (16.7)	75.8 (17.8)	58.2 (25.0)	79.1 (16.2)	80.3 (11.6)	0.01	0.69	0.009	0.06	0.06
AP	71.2 (16.8)	72.1 (17.5)	77.1 (13.0)	65.4 (18.9)	73.1 (18.0)	72.1 (14.6)	78.6 (14.1)	69.0 (22.1)	0.55	0.92	0.88	0.58	0.56
RL	57.6 (18.4)	60.5 (13.0)	63.1 (17.2)	51.2 (21.0)	66.8 (17.1)	66.2 (11.2)	69.5 (18.6)	65.0 (19.1)	0.003	0.25	0.29	0.01	0.006
SO	75.8 (28.3)	66.3 (30.3)	80.5 (31.6)	76.2 (25.2)	83.6 (23.4)	82.3 (22.6)	90.3 (15.0)	78.8 (29.4)	0.52	0.46	0.81	0.91	0.56
UT	67.9 (13.8)	68.4 (19.7)	67.9 (13.2)	74.1 (12.2)	75.9 (17.8)	69.3 (24.6)	79.5 (16.3)	76.3 (15.7)	0.006	0.92	0.02	0.04	0.02
WB	72.8 (20.8)	62.7 (21.3)	76.9 (18.2)	74.1 (22.8)	76.8 (18.7)	70.7 (21.0)	81.9 (15.3)	75.6 (20.5)	0.30	0.69	0.68	0.45	0.81
SA _{satwalk}	68.4 (21.2)	68.5 (21.9)	66.9 (24.1)	69.7 (19.8)	78.8 (19.5)	73.0 (27.3)	82.3 (13.7)	78.8 (20.2)	0.05	0.69	0.11	0.15	0.35
SA _{satwalk}	64.2 (22.6)	65.7 (16.7)	56.4 (24.6)	70.7 (22.7)	79.4 (19.8)	67.0 (29.7)	84.5 (13.6)	81.3 (17.3)	0.003	0.92	0.007	0.04	0.84

p-values relate to the comparison between the mechanically controlled knee joint and MPK_A, and between the mechanically controlled knee joint and MPK_B, respectively. These comparisons were performed using the Wilcoxon signed ranked test. AM: Ambulation; AP: Appearance; RL: Residual Limb health; SO: Sounds; UT: Utility; WB: Well-being; SA_{satwalk}: Satisfaction with prostheses; SA_{satwalk}: Satisfaction with walking; MPK_A: microprocessor controlled prosthetic knee joints; MPK_B: MPK featuring microprocessor-controlled stance and swing phase (C-leg®); MPK_C: MPK featuring microprocessor-controlled stance phase and passive swing phase control (C-leg® Compact); inter.: intermediate; SD: standard deviation.

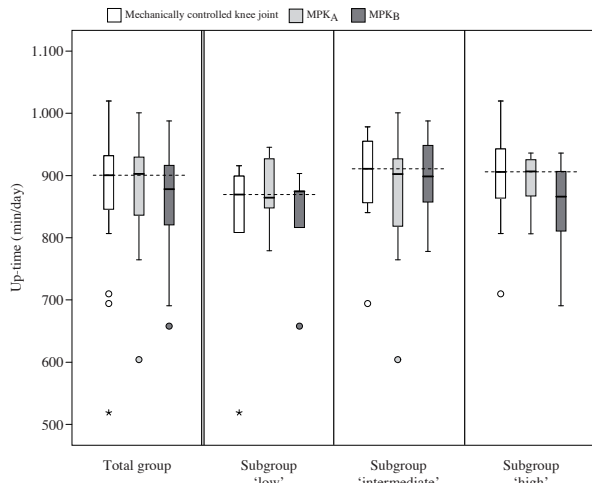


Fig. 2. Boxplots of the mean daily up-time in all prosthetic knee joint conditions for both the total group and the 3 subgroups of participants. Up-time is the amount of time per day (min) that the participant wore the accelerometer. The dotted horizontal lines illustrate the median value of the mechanically controlled prosthesis condition (t_0) for the particular group or subgroup; MPK_A: prosthetic knee joint featuring microprocessor-controlled stance and swing phase; MPK_B: prosthetic knee joint featuring microprocessor-controlled stance phase and passive swing phase control.

The scores on PEQ subscales AM, UT and SA_{satwalk} were significantly higher ($p \leq 0.025$) in the MPK_A condition compared with the mechanically controlled knee joint condition for participants from the subgroup “intermediate”, but were not significantly different for the MPK_B condition compared with the mechanically controlled knee condition. Participants in

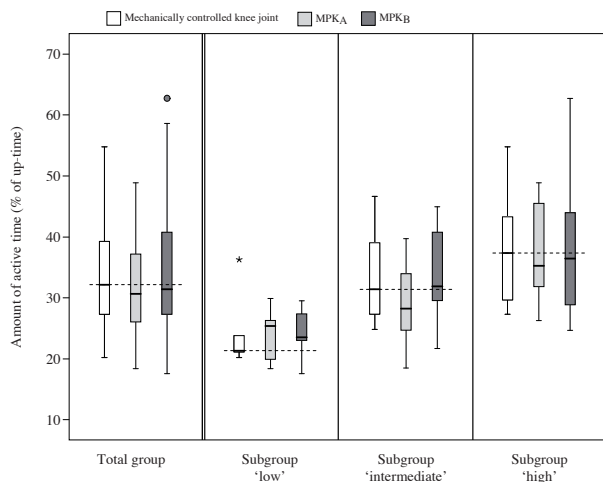


Fig. 3. Mean amount of time (%) that participants were active during their up-time. Active-time is the portion of the up-time (%) during which the participant performed bouts of activity. The dotted horizontal lines illustrate the median value of the mechanically controlled prosthesis condition (t_0) for the particular group or subgroup; MPK_A: prosthetic knee joint featuring microprocessor-controlled stance and swing phase; MPK_B: prosthetic knee joint featuring microprocessor-controlled stance phase and passive swing phase control.

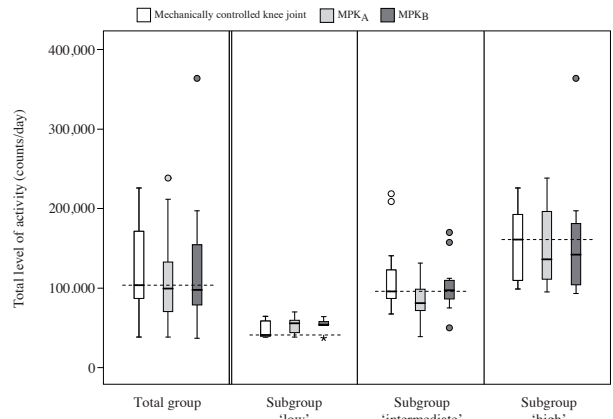


Fig. 4. The level of total activity per day (counts/day). The dotted horizontal lines illustrate the median value of the mechanically controlled prosthesis condition (t_0) for the particular group or subgroup; MPK_A: prosthetic knee joint featuring microprocessor-controlled stance and swing phase; MPK_B: prosthetic knee joint featuring microprocessor-controlled stance phase and passive swing phase control.

subgroup “high” showed increased PEQ subscale scores in the MPK_A condition compared with the mechanically controlled knee joint condition on scale RL and in the MPK_B condition vs the mechanically controlled knee on scales RL and UT.

Activity level

The up-time results for all conditions and subgroups are presented in Fig. 2. The differences in up-time between prosthetic knee joint conditions and the differences in up-time between subgroups did not reach statistical significance.

Fig. 3 shows boxplots of the “active time” for the total group of participants and for the subgroups “low”, “intermediate” and “high”. The differences in active time between the prosthetic knee joint conditions did not reach statistical significance levels in either the total group or in any of the subgroups. Active time in subgroup “low” was less than the active time in subgroup “high” ($p=0.008$) in the mechanically controlled prosthesis condition. The difference in active time between the subgroups “low” and “intermediate” showed a trend in favour of the subgroup “intermediate”, but just failed to attain significance after Bonferroni correction ($p=0.020$). No statistically significant difference was found between subgroups “intermediate” and “high” ($p=0.184$).

Fig. 4 shows the results of the total level of activity per day. The total level of activity measured during the up-time in the mechanically controlled knee joint condition differed ($p \leq 0.017$) between the participants of all 3 subgroups. The level of activity of the total group of participants did not differ between prosthetic knee joint conditions. Participants in subgroup “intermediate” showed a reduction in the number of counts of activity per day (activity level) in the MPK_A condition compared with the mechanically controlled knee joint condition ($p=0.013$). No differences were found between knee joint conditions for participants in the other subgroups.

The mean number of bouts of activity per day for the whole group as well as for the 3 subgroups is shown in Fig. 5. The

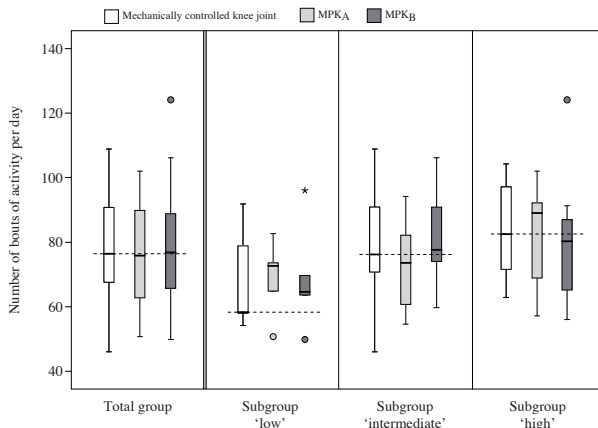


Fig. 5. Mean number of bouts of activity per day. A bout of activity is the time between the moment that the accelerometer signal exceeded a predetermined threshold value of 30 counts per min to the moment that the signal dropped below that threshold value. The dotted horizontal lines illustrate the median value of the mechanically controlled prosthesis condition (t_0) for the particular group or subgroup; MPK_A: prosthetic knee joint featuring microprocessor-controlled stance and swing phase; MPK_B: prosthetic knee joint featuring microprocessor-controlled stance phase and passive swing phase control.

differences in the number of bouts of activity per day between prosthetic knee joint conditions and between the subgroups of participants did not reach statistically significant levels.

DISCUSSION

The purpose of this study was to investigate the effects of using a leg prosthesis featuring an advanced prosthetic knee joint on both the self-assessed performance and the (actual) daily activity level of persons with a leg amputation who are classified as MFCL-2. The results of the current study suggest that these persons perceive considerable improvements concerning their ability to ambulate with the prosthesis, their quality of walking, the condition of their residual limb, and the utility of the prosthesis, when they use a prosthesis fitted with an MPK (particularly an MPK that actively controls both the stance and swing phase) in comparison with a mechanically controlled prosthetic knee. Despite these self-assessed improvements their daily activity level remained unchanged after 1 week of use.

Only 3 studies (26, 27, 35) were found in the literature that investigated the effects of an MPK explicitly in persons classified as MFCL-2. In an additional study by Kahle et al. (36) a mixed group of individuals classified as MFCL-2 and MFCL-3 were investigated, but only total group data were reported. The characteristics of the MFCL-2 research population that was assessed in the current study were comparable to those reported by Hafner & Smith (27) in terms of age, post-amputation time, male to female ratio, and the ratio of amputations due to trauma and vascular disease. Compared with the MFCL-2 cohort studied by Wetz et al. (35), the persons in our research population were slightly younger (59.1 vs 66.0 years) and included relatively

more amputations due to trauma. Overall, the MFCL-2 population investigated in both the present study and in our previous work (26) is considerably larger than in both other studies.

The PEQ results confirmed our hypothesis that subjects are more satisfied about their performance using the MPK compared with using their mechanically controlled knee. This is partly in agreement with the findings of Hafner & Smith. (27) who found improved PEQ scores in the MPK condition for their MFCL-2 population. However, those differences failed to attain statistical significance in all of the PEQ subscales, possibly due to the small sample size ($n=8$).

Contrary to persons' perceived performance, the activity level of the total group of persons classified as MFCL-2 does not seem to be affected by the use of the MPK. Apparently, increasing the persons' potential to ambulate by fitting their prosthesis with an MPK, does not automatically stimulate them to be more active in daily life. It becomes increasingly clear in rehabilitation that actual performance and perceived performance are different constructs that are not necessarily related. Persons with a leg amputation have adapted their lifestyle in order to manage the functional limitations that come with the loss of a limb. Changing one's lifestyle instantaneously is difficult to accomplish. Regarding our research, an important factor that may have played a role here is that the subjects were not explicitly encouraged to perform more activities in daily life. For example, no cognitive behavioural training techniques have been used to stimulate persons to become more active. Introducing such an additional intervention would have obscured the design of the study. If subjects had been stimulated to perform at their maximal level, it is possible that more distinct differences between prosthesis conditions might have been found. However, the added value of measuring people in their everyday life would then have been lost.

Also, it should be considered that 2 h of accommodation time and 1 week of home use might have been too short for the subjects to familiarize themselves with the adapted prosthesis. Perhaps a longer accommodation period led to different results, as subjects might be more able to use the MPKs to their full potential after a longer period of use. However, in addition, in studies with considerably longer periods of accommodation time for the MPK no change in activity level (step count) was measured (21, 22), whereas results of the study by Kaufman et al. (20) suggest otherwise. They reported significantly increased activity-related energy expenditure levels and concluded that persons with a transfemoral amputation using an MPK increased their daily physical activity level. Although in literature an average accommodation period of between 12 and 18 weeks is reported (14, 19–21, 27, 36, 37), no consensus exists on what the most optimal accommodation period should be. In the present study it has been shown that 2 h of actively familiarizing the person with the newly fitted prosthetic knee joint proved to be adequate for most individuals to attain safe use of the prosthesis.

It is not uncommon in prosthesis research to stratify a group of subjects into subgroups. Legro et al. stratified subjects based on gender, age, presence or absence of comorbidities, level

of amputation, and years since the amputation to test whether the PEQ could differentiate between those groups (30). In the current study data were analysed for both the total group of included participants and 3 MFCL-2 subgroups. This approach was chosen in an attempt to reduce the large variability in activity level among the total group. As large variability may obscure possible effects of using an MPK, the group of participants was stratified into 3 subgroups. A similar approach has been used in a previous study, which showed large variability in the level of functional ability of persons classified as MFCL-2 (26). Although, the classification of participants into smaller subgroups indeed reduced the degree of dispersion regarding the subjects' activity level in the present study, a considerable amount of variability still remained. This indicates that not only between subgroups, but also within each subgroup the MPK seems to have diverse effects on the participants. This further supports our hypothesis that the group of persons classified as MFCL-2, as opposed to the MFCL-3 and MFCL-4 populations, is a more heterogeneous population. This also means that it is more difficult to make generalized statements about the effects of an MPK on the functioning of the "typical" MFCL-2 patient. Therefore, determining whether a person classified as MFCL-2 may benefit from using an MPK in daily life should perhaps be done at the individual patient level.

Study limitations

It is noted that the perceived performance data might have been influenced by the expectations of the subjects about the benefits they would have when wearing an MPK. Although methodologically, blinding the subjects for prosthesis condition would have eliminated this issue, this was practically not possible. Participants would immediately notice the difference between their mechanically controlled prosthesis and an MPK (e.g. the MPK has to be recharged).

The accelerometer measured the accelerations of the participants' centre of mass. Although this merely quantifies the amount and intensity of the movements made, it does not provide information about the type of movements or about the quality with which the activities were performed. Perhaps, participants performed different types of activity that they were not able to do with their mechanically controlled prosthesis.

All subjects were tested with the accelerometer during 3 consecutive 1-week periods. Because the persons did not perform a fixed or predefined set of activities during each week of testing, it should be taken into account that other factors, apart from changing the prosthetic knee joint, may have influenced the activity level of the participants. To control for possible deviations within each weekly routine, a mean value of the accelerometer data over the 7-day period was calculated. To control for the occurrence of deviations between weekly routines is considered virtually impossible. Unfortunately, this is inherent to testing people in their home environment, i.e. outside the standardized laboratory setting.

Classification of the total group of participants into 3 subgroups reduced within-group variance, but resulted in fairly small numbers of participants per subgroup. The results of the

study should therefore be interpreted with care. Nevertheless, even with the current number of participants in each of the subgroups, this study is one of the largest studies to compare the effects of using an MPK with the effects of using a mechanically controlled knee joint (15–20).

Future research

Advanced activity monitors, able to detect the specific nature of the performed bouts of activity (such as level walking, walking stairs, sitting, or bicycling), may provide more detailed information about changes in persons' quality of the performed activities in their free-living environment. This may provide more insight in the type of activities persons with a leg amputation tend to avoid in daily life and how the prosthesis configuration may affect that performance. In addition, a randomized controlled trial with prolonged follow-up measurements is necessary to investigate the long-term effects of using an MPK on activity level in persons classified as MFCL-2.

Conclusion

Persons with a transfemoral amputation or knee disarticulation, classified as MFCL-2, perceive an improved ability to ambulate, are more satisfied with how they walk, experience an improved condition of the stump, and report increased utility when they use a prosthesis featuring an MPK compared with a mechanically controlled knee joint. However, these perceived benefits do not encourage these persons to increase their everyday activity level in the short term.

ACKNOWLEDGEMENTS

The authors would like to thank Guido Meys and Sven Balk of Adelante Rehabilitation Centre, Hoensbroek, The Netherlands, for supporting the participants during the accommodation sessions and familiarizing them to use the MPKs. The authors also thank the work of Frans Rings and his fellow prosthetists at Livit Ortopedie BV, Hoensbroek, The Netherlands, with fitting and aligning the prosthetic knee joints.

Funding/support: This study was supported by a grant provided by Otto Bock Healthcare GmbH, Vienna, Austria. Prior to the start of the investigation that has led to the current publication, it was contractually agreed between Adelante and the grant provider, that Adelante has the full and unrestricted right regarding: (i) the establishing of results of the investigation leading to scientifically corroborated conclusions; and (ii) the presentation of any result or conclusion resulting from the investigation, independent of any other party or grant provider.

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