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The influence of a user-adaptive prosthetic knee across varying walking speeds: A randomized cross-over trial



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ABSTRACT

Previously conducted trials comparing the gait pattern of individuals with a transfemoral amputation using a user-adaptive and a non-microprocessor-controlled prosthetic knee (NMPK) found mixed and conflicting results. Few trials, however, have compared user-adaptive to non-adaptive prosthetic knees across different walking speeds. Because of the ability of variable damping, the effect of user-adaptive knees might be more pronounced at lower or higher walking speeds. Our aim was to compare the Rheo Knee II (a microprocessor-controlled prosthetic knee) with NMPKs across varying walking speeds. In addition, we studied compensatory mechanisms associated with non-optimal prosthetic knee kinematics, such as intact ankle vaulting and vertical acceleration of the pelvis. Nine persons with a transfemoral amputation or knee disarticulation were included and measured with their own NMPK and with the Rheo Knee II. Measurements were performed at three walking speeds: preferred walking speed, 70% preferred walking speed and 115% preferred walking speed. No differences on peak prosthetic knee flexion during swing were found between prosthetic knee conditions. In addition, prosthetic knee flexion increased significantly with walking speed for both prosthetic knee conditions. At 70% preferred walking speed we found that vaulting of the intact ankle was significantly decreased while walking with the Rheo Knee II compared to the NMPK condition ($P=0.028$). We did not find differences in peak vertical acceleration of the pelvis during initial and mid-swing of the prosthetic leg. In conclusion, comparison of walking with the Rheo Knee II to walking with a NMPK across different walking speeds showed limited differences in gait parameters.

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1. Introduction

Developments in prosthetic knee design have led to the introduction of microprocessor-controlled prosthetic knees (MPKs), such as the Rheo Knee or C-Leg. User-adaptive prosthetic knees should, in contrast to non-microprocessor-controlled prosthetic knees (NMPKs), allow early stance prosthetic knee

flexion, ideal prosthetic knee kinematics during swing, and the ability to react to changes in walking speed. [1,2]

It is proposed that MPKs are beneficial for individuals with an amputation. Sawers and Hafner critically appraised the existing literature focusing on this proposition. [3] They found four trials [4–7] reporting an increase in preferred walking speed while using the MPK compared to a NMPK. They also found that comparison of other spatiotemporal variables were either inconsistent or not significant. Finally they found that the comparison of kinematic variables of walking with MPKs and NMPKs show “mixed and conflicting results”.

The above-presented findings indicate that there is a low level of evidence for an added value of MPKs on gait mechanics. One of the factors contributing to this might be that the majority of

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studies compared MPKs and NMPKs at preferred walking speed. Because NMPKs are usually set to have optimal knee damping at preferred walking speed, their biomechanical behavior might be not that different from MPKs at preferred walking speed. They, however, are less able to respond to an increase or decrease of walking speed, because they can only adapt knee damping within pre-set and limited parameters. The Rheo Knee II, the subject of our study, is able to adapt knee damping to a greater extent than NMPKs. To be able to do so, the Rheo Knee II incorporates a magnetorheological fluid, which is a carrier oil in which magnetic particles are dispersed. Based on the information from a knee angle, knee angular velocity, and a force sensor, an algorithm controls electromagnetics [1]. The magnetic particles in the carrier oil form torque-producing chains in response to the electromagnetic field [1]. By changing the magnetic field, the Rheo Knee II can constantly vary the amount of knee damping during the stance and swing phase with a frequency of 50 Hz [1]. It is thought that the control algorithm of Rheo Knee II leads to optimal knee damping irrespective of walking speed, whereas NMPKs have non-optimal knee damping at slower or faster walking speeds. This premise was tested by Herr and Wilkenfeld, who found that in two out of four subjects peak prosthetic knee flexion during swing while walking with the Rheo Knee remained around 70° (set target of the Rheo Knee during these measurements) irrespective of walking speed [1]. Contrastingly, knee flexion while walking with the NMPK increased with walking speed [1]. In the other subjects this was not visible, as they did not reach 70° of prosthetic knee flexion during swing [1].

Having more optimal prosthetic knee kinematics during swing can be beneficial for individuals with an amputation. Having too little prosthetic knee flexion might lead to problems with prosthetic foot clearance which, in turn, might lead to an premature ankle plantar flexion of the intact leg during mid-stance (vaulting) to assist with prosthetic foot clearance [8]. Having too much prosthetic knee flexion during swing might also be undesirable, as the prosthetic knee has to be extended at the beginning of the stance phase. A larger peak prosthetic knee flexion during swing means that a larger movement trajectory has to be completed. The mechanism by which the prosthetic knee is extended during swing is not well studied, but in children without an amputation velocity-related forces and muscle activity of predominantly the stance leg have been described [9]. During early and mid-stance, the hip abductors and extensors of the stance leg move the pelvis center of mass upwards [9]. This movement creates an external knee extension moment [9]. During slow walking stance limb muscle activity has shown to be the main contributor to knee extension during swing, while at faster walking the velocity-related forces are dominant [10]. Whether these mechanisms are seen in individuals with an amputation and whether they are influenced by a user-adaptive prosthetic knee is unknown.

The aim of this study is to compare walking with a NMPK to walking with the Rheo Knee II across different walking speeds. We hypothesized an increased preferred walking speed while walking with the Rheo Knee II. In addition, we hypothesized comparable peak prosthetic knee flexion during swing across all walking speeds while walking with the Rheo Knee II, while peak prosthetic knee flexion during swing would increase with walking speed in the NMPK condition. Finally, we hypothesized a reduced vaulting of the intact leg at lower walking speeds and reduced vertical pelvic acceleration during initial swing of the prosthetic leg while walking with the Rheo Knee II when compared to the use of a NMPK. To contribute to the existing body of knowledge, we also analyzed spatiotemporal and kinematic variables reported in existing literature.

2. Methods

2.1. Subjects

For this randomized cross-over trial we recruited persons with a transfemoral amputation or knee disarticulation from the Netherlands and Belgium. The inclusion criteria were: (i) at least one year post amputation; (ii) functional level from K2 (limited outdoor) or higher [11]; (iii) never previously fitted with a microprocessor-controlled knee. Exclusion criteria were: (i) other musculoskeletal problems influencing walking ability; (ii) stump problems/poor socket fitting; (iii) body weight >125 kg (maximum specification weight for the Rheo Knee II); (iv) knee centre-floor distance below 41 cm.

The Ethical Research Committee Twente, Enschede, the Netherlands approved the study protocol (NL 30112.044.09). All subjects provided written informed consent before the start of the measurements.

2.2. Prosthetic adjustments

We randomly assigned the subjects to start measurements with their own non-microprocessor controlled prosthetic knee or with the Rheo Knee II. In both prosthetic knee conditions, the LP Vari-Flex[®] with EVO[™] (Össur[®]) prosthetic foot was provided. After eight weeks of acclimatization the first set of measurements was performed after which subjects crossed over to the other prosthetic condition. After another eight weeks, the second set of measurements was performed and subjects left the research study. Full details regarding the process of prosthetic adjustments have been published before [12].

Participants did not undergo a gait training program while walking with the Rheo Knee II or their own NMPK to make the comparison as little affected by gait training factors as possible.

2.3. Protocol

Data were collected using the CAREN system (Motek Forcelink BV, Amsterdam, the Netherlands) at the Military Rehabilitation Centre 'Aardenburg', Doorn, the Netherlands. The CAREN system consists of an instrumented single-belt treadmill and a twelve infrared-camera Vicon motion capture system (Oxford Metrics Ltd., Oxford, UK).

We used the modified Helen-Hayes marker set, including 37 reflective markers, which were placed according to the Vicon full-body Plug-in-Gait model. In addition, we placed 2 markers on the rope connecting the safety harness to an overhead frame. During a preliminary trial, we asked subjects to place their full bodyweight on the safety harness. The distance between the two markers in this condition was used in the data-analysis to check if subjects made use of the safety harness. The sample rate of the Vicon system was set at 100 samples per second.

Trials were performed at preferred walking speed, 70% preferred walking speed +and 115% preferred walking speed We hypothesized that 70% preferred walking speed would be reflective of in-house ambulation. For reason of uniformity, we would ideally have studied walking at 130% preferred walking speed. We however, hypothesized that this might be too high for a proportion of our study population which would reduce the size of our study sample. We therefore felt that 115% preferred walking speed was a safer option. The treadmill speed was fixed. We determined preferred walking speed during a familiarization trial. In this trial, walking speed was gradually increased until participants indicated that the speed was comfortable. After this, the walking speed was increased with 0.1 m/s and the participant was asked whether this was more comfortable or uncomfortable. In case the walking speed

was uncomfortable, the earlier determined walking speed was used. In case the higher walking speed was more comfortable, the walking speed was further increased with steps of 0.1 m/s until it became uncomfortable.

The collected data were processed using Vicon Nexus 1.8 (Oxford Metrics Ltd., Oxford, UK). Initial contacts and toe-off were determined visually. Initial contact was defined as the moment the heel marker stopped moving downwards. The moment of toe-off was defined as the moment both the heel and toe marker trajectories changed from a backward to a forward movement. We loaded the processed data into customized Matlab 2010b software (The MathWorks, Inc, Natick, USA) for further analysis. We filtered the kinematic data using a zero-phase shift 2nd order Butterworth filter with a cut-off frequency of 10 Hz, meaning that the data were filtered twice with a 2nd order filter. We selected 15 representative strides from the kinematic data. We resampled the kinematic data of each stride to 101 data points (0–100% of stride cycle) to allow averaging over strides.

2.4. Outcome measures

We determined peak prosthetic knee flexion during swing. In addition, we calculated the amount of vaulting during the mid-stance of the intact leg. To do so, we subtracted the vertical position of the ankle joint center during the static calibration trial from the vertical position of the ankle joint center at the midpoint of the stance phase. Finally, we calculated the peak vertical acceleration of the pelvis during initial swing and mid swing of both the prosthetic and intact leg. To do so, we differentiated the position of the pelvic joint center, provided by the Vicon nexus software, twice in time intervals of 0.1 s.

Besides these outcome measures we calculated spatiotemporal and kinematic variables that have been previously reported in comparable trials to contribute to the existing body of knowledge.

2.5. Data analysis

Statistical analysis on the outcome variables were performed using IBM SPSS Statistics 22 software (IBM SPSS Statistics, Chicago, USA). All outcome variables were compared between conditions using the Mann-Whitney *U* test. In the evaluation of the effect of walking speed, each data point was used in two comparisons. To reduce the probability of a type II error due to multiple testing, we used the modified Holms-Bonferroni correction in the data analysis focusing on the effect of walking speed. In addition, we calculated the effect size by dividing the *Z* score, obtained from the Mann-Whitney *U* test, by the square root of the number of observations. The alpha level for all statistical comparisons was set to 0.05.

3. Results

A total of 61 participants were contacted of which 52 were potentially eligible based on the in- and exclusion criteria. Of these, 12 participants consented in participating. Three participants dropped out before the first measurements: one was not able to satisfactorily adjust to the Rheo Knee II, one because of stump problems, and one was not able to walk on a treadmill. The remaining nine participants completed both measurements. Characteristics of included participants and the non-microprocessor-controlled prosthetic knees with which they walked with are displayed in [Table 1](#).

3.1. Preferred walking speed

Results of preferred walking speed are presented in [Table 2](#). There was no significant difference in preferred walking speed between the Rheo Knee II and the NMPK condition.

3.2. Prosthetic knee flexion in swing

The results of the comparison of the NMPK and Rheo Knee II condition within a walking speed condition are shown in [Table 2](#) and [Figs. 1 and 2](#). The results of the comparison of the different walking speed conditions within a prosthetic knee condition are displayed in [Table 3](#).

There were no statistically significant differences in peak prosthetic knee flexion during swing while walking with the Rheo Knee II and the NMPK within a walking speed condition. When looking at the influence of walking speed, we found that in both the Rheo Knee II and NMPK condition peak prosthetic knee flexion during swing increased significantly with walking speed.

3.3. Vaulting and peak vertical acceleration of pelvic center of mass (CoM) in swing

Results are presented in [Tables 2 and 3](#) and the supplementary table.

We found that vaulting was significantly reduced while walking with the Rheo Knee II when compared to walking with the NMPK at 70% preferred walking speed. In the other two walking speeds conditions no differences were found between both prosthetic knee conditions. Walking speed had no significant influence on the amount of vaulting in both prosthetic knee conditions.

The peak vertical acceleration of the pelvic CoM during initial and mid-swing of the prosthetic leg was not significantly different between the Rheo Knee II and the NMPK condition in any of the walking speed conditions. Comparison of the peak vertical pelvic CoM acceleration during the swing phase of the prosthetic and

Table 1
Characteristics of participants.

Variables	Persons with an amputation (n = 9)
Age (years)	55 (23–67)
Sex (male/female)	5/4
Height (cm)	175 (158–189)
Weight (Kg)	72.1 (54.6–98.4)
Type of amputation (transfemoral amputation/knee disarticulation)	7/2
Time since amputation (years)	34 (1–41)
Reason for amputation	Trauma (6), Infection (2), Osteosarcoma (1)
Functional level	K2 (1), K3 (5), K4 (3)
Stump length (cm)	40 (32–60)
Non-microprocessor-controlled prosthetic knees	3R60 (4), 3R80 (1), 3R95 (1), Mauch SNS (1), Graph Lite (1), CaTech (1)

Age, Height, Weight, Time since amputation, and Stump length are presented as median (range). Sex, Reason for Amputation, Functional Level, and non-microprocessor-controlled prosthesis are presented as counts.

Table 2
Results of spatiotemporal and kinematic variables.

Variables	Results				Statistical comparison							
	NMPK		Rheo Knee II		NMPK		Rheo		NMPK vs Rheo			
	PL	IL	PL	IL	PL vs IL		PL vs IL		Prosthetic Leg		Intact Leg	
					P value	ES	P value	ES	P value	ES	P value	ES
70% preferred walking speed												
Walking Speed (m/s)	0.49 [0.35–0.50]		0.49 [0.34–0.72]		NA				0.167		0.326	
Peak knee flexion swing (degrees)	29.63 [15.77, 54.20]	57.14 [55.90, 62.87]	37.41 [24.06, 48.23]	56.37 [54.73, 58.98]	0.015	0.572	0.011	0.600	0.374	–0.889	0.515	0.154
Vaulting (mm)	NA		NA		NA		NA		NA		NA	
Peak vertical pelvic CoM acceleration in initial swing (m/s ²)	0.96 [0.74,1.40]	0.78 [0.44,0.88]	1.06 [0.80,1.41]	0.67 [0.47,1.11]	0.051	0.461	0.021	0.544	0.314	–1.007	0.859	0.042
Step Length (cm)	36.12 [25.61– 51.77]	35.60 [30.68– 46.37]	34.80 [27.54– 46.86]	37.37 [31.99– 42.97]	0.441	0.181	0.953	0.013	0.594	–0.533	0.859	0.042
Knee Yielding (degrees)	0.29 [0,3.46]	4.07 [1.73, 9.67]	0.05 [0,0.81]	5.25 [2.27, 8.23]	0.038	0.489	0.017	0.561	0.499	–0.676	0.953	0.225
Peak hip extension stance (degrees)	–8.50 [–11.00, –6.04]	–2.44 [–8.85, 0.41]	–7.95 [–9.88, –5.08]	–0.47 [–5.51, 1.70]	0.066	0.433	0.038	0.489	0.374	–0.889	0.594	0.140
100% preferred walking speed												
Walking Speed (m/s)	0.69 [0.50–0.71]		0.69 [0.49–0.83]		NA				0.167		0.326	
Peak knee flexion swing (degrees)	48.04 [18.72, 61.72]	60.79 [58.36, 66.61]	45.43 [30.12, 58.56]	60.86 [58.32, 64.25]	0.021	0.544	0.008	0.628	0.594	0.126	0.953	0.014
Vaulting (mm)	NA		NA		NA		NA		NA		NA	
Peak vertical pelvic CoM acceleration in initial swing (m/s ²)	1.61 [1.38,2.09]	1.43 [1.12,1.88]	1.69 [1.39,2.21]	1.29 [1.02,1.90]	0.173	0.321	0.110	0.377	0.767	0.070	0.441	0.181
Step Length (cm)	41.89 [30.06– 57.17]	41.14 [36.50– 50.28]	43.18 [31.61– 54.02]	43.35 [37.00– 50.86]	0.767	0.070	0.678	0.098	0.678	0.098	0.678	0.098
Knee Yielding (degrees)	0.03 [0,4.52]	6.20 [3.69, 13.49]	0.12 [0,1.06]	6.42 [4.61, 10.29]	0.021	0.544	0.015	0.573	0.310	0.239	0.515	0.154
Peak hip extension stance (degrees)	–10.10 [–12.73, –7.23]	–4.44 [–10.14, 1.94]	–9.26 [–10.32, –5.21]	–1.28 [–8.15, 1.91]	0.038	0.489	0.028	0.517	0.515	0.154	0.678	0.098
115% preferred walking speed												
Walking Speed (m/s)	0.80 [0.58–0.82]		0.80 [0.54–0.91]		NA				0.167		0.326	
Peak knee flexion swing (degrees)	57.23 [22.17, 65.82]	63.04 [59.50, 66.74]	48.38 [47.02, 59.78]	60.10 [59.71, 65.76]	0.038	0.489	0.008	0.628	0.767	0.070	0.859	0.042
Vaulting (mm)	NA		NA		NA		NA		NA		NA	
Peak vertical pelvic CoM acceleration in initial swing (m/s ²)	1.87 [1.59,2.67]	1.72 [1.41,2.15]	2.02 [1.58,2.53]	1.68 [1.09,2.05]	0.139	0.349	0.066	0.433	0.767	0.070	0.214	0.293
Step Length (cm)	47.17 [33.28– 63.23]	46.17 [39.65– 56.36]	47.02 [36.06– 56.80]	48.27 [42.13– 53.35]	0.953	0.014	0.678	0.098	0.515	0.154	0.953	0.014
Knee Yielding (degrees)	0.08 [0,4.80]	6.20 [3.02, 14.67]	0 [0,0.96]	8.15 [5.45, 12.16]	0.021	0.544	0.011	0.600	0.310	0.239	0.767	0.070
Peak hip extension stance (degrees)	–11.04 [–13.73, –7.55]	–5.64 [–12.70, –0.45]	–10.11 [–11.58, –5.92]	–2.86 [–8.26, 0.75]	0.086	0.405	0.038	0.489	0.515	0.154	0.594	0.126

Abbreviations: NMPK: NMPK: Non-microprocessor-controlled prosthetic knee; PL: prosthetic leg; IL: intact leg; RL: referent leg (leg of an able-bodied); ES: effect size; GC: gait cycle; NA: not applicable. All data are presented as mean (standard deviation). Bold figures indicate significant differences.

intact leg within a prosthetic knee showed one significant difference. In the Rheo Knee II condition a significantly higher peak vertical acceleration during the swing phase of the prosthetic leg at 70% preferred walking speed was found when compared to the swing phase of the intact leg. For the NMPK condition, the same comparison was on the borderline of significance. We found that

for both the Rheo Knee II and the NMPK peak acceleration of the pelvic center of mass significantly increased with walking speed. This was seen for both the prosthetic and intact leg. The only exception to this was the comparison of the intact leg at preferred walking speed and 115% preferred walking speed in the Rheo Knee II condition.

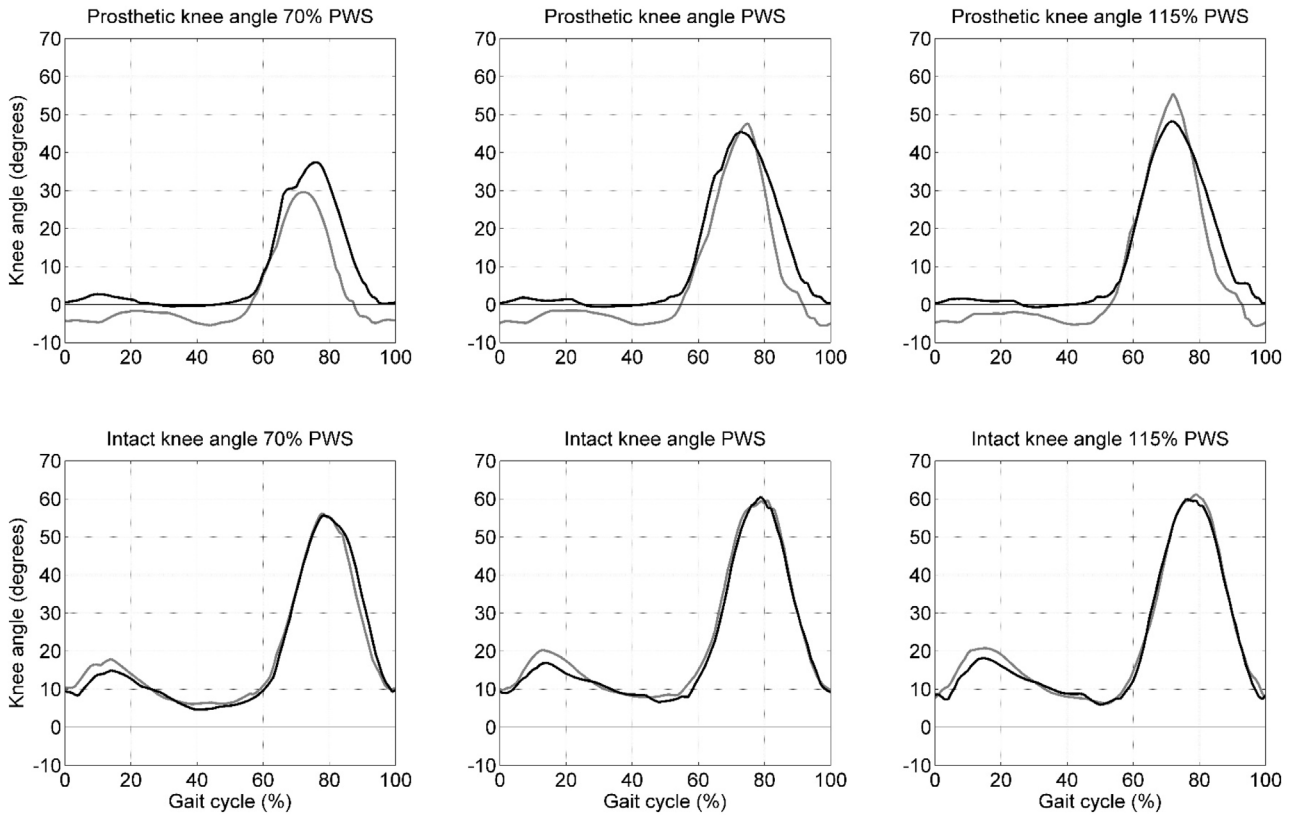


Fig. 1. Influence of walking speed on knee kinematics. This figure shows the median knee kinematics of both prosthetic knee conditions at the different walking speeds. The data of the Rheo Knee II condition are shown as a solid black line, the data of the non-microprocessor controlled prosthetic knee are shown as a solid grey line. Abbreviation: PWS: preferred walking speed.

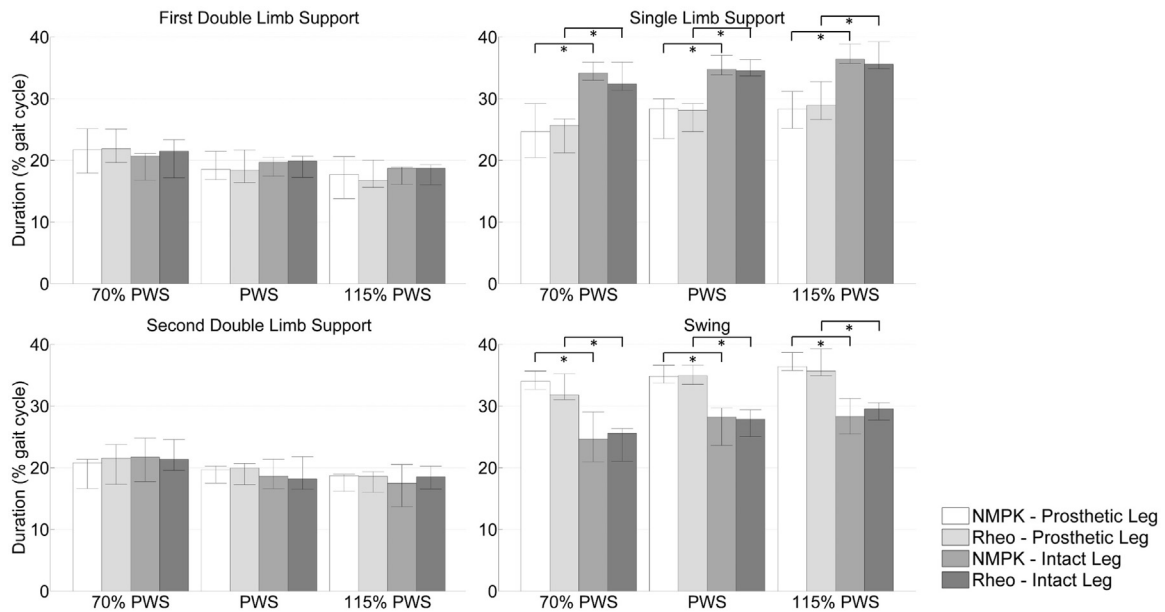


Fig. 2. Duration different gait phases for the different walking speeds. Graphical representation of the duration of the different gait phases. The bars show the median values, the error bar depicts the interquartile range. * Denotes a statistical significant difference ($P=0.008$). Abbreviations: PWS: preferred walking speed

Table 3
Influence of walking speed Prosthetic Leg.

	Non-microprocessor controlled prosthetic knee						Rheo Knee					
	70% PWS vs PWS		70% PWS vs 115% PWS		PWS vs 115% PWS		70% PWS vs PWS		70% PWS vs 115% PWS		PWS vs 115% PWS	
	Median difference	p-value; ES	Median difference	p-value; ES	Median difference	p-value; ES	Median difference	p-value; ES	Median difference	p-value; ES	Median difference	p-value; ES
Step length (cm)	−0.06 [−0.89,−0.01]	0.021 ; 0.544	−0.10 [−0.14,−0.08]	0.024 ; 0.628	−0.05 [−0.07,−0.03]	0.016 ; 0.628	−0.05 [−0.08,−0.04]	0.008 ; 0.628	−0.08 [−0.13,−0.06]	0.016 ; 0.628	−0.03 [−0.05,−0.03]	0.024 ; 0.628
First DSP (% GC)	2.29 [1.45,4.03]	0.028 ; 0.517	4.07 [3.26,5.11]	0.016 ; 0.628	1.65 [0.52,2.33]	0.024 ; 0.628	3.64 [1.68,5.28]	0.024 ; 0.628	5.35 [3.65,6.54]	0.016 ; 0.628	1.68 [1.03,2.01]	0.008 ; 0.628
SLS (% GC)	−2.20 [−3.16,−1.13]	0.024 ; 0.628	−3.32 [−4.25,−2.10]	0.016 ; 0.628	−0.86 [−1.63,−0.31]	0.021 ; 0.544	−3.15 [−3.89,−2.07]	0.024 ; 0.628	−4.44 [−5.30,−3.47]	0.016 ; 0.628	−1.35 [−1.83,−0.77]	0.008 ; 0.628
Second DSP (% GC)	0.71 [−0.76,0.99]	0.441; 0.181	2.07 [0.86,2.17]	0.022 ; 0.600	1.30 [0.80,1.69]	0.024 ; 0.628	1.36 [0.04,3.02]	0.028 ; 0.517	2.66 [1.53,3.56]	0.016 ; 0.628	1.29 [0.55,2.27]	0.024 ; 0.628
Swing (% GC)	−1.58 [−2.41,0.77]	0.260; 0.265	−3.30 [−3.45,−2.18]	0.008 ; 0.628	−1.73 [−2.84,−1.13]	0.016 ; 0.628	−1.43 [−3.46,−0.65]	0.016 ; 0.628	−3.91 [−4.73,−2.30]	0.024 ; 0.628	−1.65 [−2.60,−0.83]	0.008 ; 0.628
Peak vertical pelvic CoM acceleration in initial swing (m/s ²)	−0.65 [−0.80,−0.47]	0.024 ; 0.628	−0.95 [−1.35,−0.68]	0.016 ; 0.628	−0.26 [−0.44,−0.07]	0.011 ; 0.600	−0.54 [−0.80,−0.40]	0.016 ; 0.628	−1.01 [−1.27,−0.38]	0.024 ; 0.628	−0.29 [−0.62,0.01]	0.038 ; 0.489
Knee Yielding (degrees)	0.00 [−0.30,0.08]	1.000; 0.172	0.00 [−0.63,0.11]	0.686; 0.095	0.00 [−0.08,0.01]	1.000; 0.159	0.00 [−0.47,0.35]	0.753; 0.074	0.00 [−0.59,0.40]	1.000; 0.074	0.00 [−0.26,0.06]	1.000; 0.223
Peak knee flexion swing (degrees)	−4.94 [−12.48,−2.95]	0.024 ; 0.628	−10.78 [−18.91,−3.55]	0.022 ; 0.600	−5.34 [−7.52,−0.60]	0.011 ; 0.600	−5.43 [−10.33,−1.05]	0.021 ; 0.544	−8.85 [−11.58,−3.42]	0.022 ; 0.600	−2.72 [−3.47,−1.02]	0.024 ; 0.628
Peak hip extension stance (degrees)	1.26 [0.32,2.18]	0.030 ; 0.573	1.58 [0.81,3.21]	0.033 ; 0.600	0.70 [−0.12,1.35]	0.048 ; 0.461	0.45 [−0.58,3.06]	0.260; 0.265	1.10 [0.61,3.71]	0.024 ; 0.628	1.09 [0.63,1.37]	0.022 ; 0.600

All data are presented as median [interquartile range]. Abbreviations: PWS: preferred walking speed; ES: effect size; DSP: double support phase; GC: gait cycle. Bold figures indicate significant differences after the modified Holms-Bonferoni correction.

3.4. Previously reported outcome measures

For the results of the comparisons on the other outcome variables, see Tables 2 and 3, and the supplementary table. On previously reported outcome parameters no differences were found between the Rheo Knee II and the NMPK condition across all walking speeds. Walking speed had a significant influence on almost all outcome parameters for both prosthetic knee conditions.

4. Discussion

The aim of this study was to compare the use of a NMPK to the use of the Rheo Knee II across different walking speeds. The comparison of the NMPK and Rheo Knee II showed limited differences in gait parameters across all three evaluated walking speeds.

We hypothesized that patients would adopt a higher preferred walking speed while walking with Rheo Knee when compared to the NMPK. Our results disproved this hypothesis: we did not find a difference in preferred walking speed between the Rheo Knee II and NMPK condition. Differences in preferred walking speed between user-adaptive prosthetic knees and NMPKs have both been found to be significant (increased in user-adaptive knees) [5–7,13] and non-significant [4,14]. The reason for this ambiguity in results is unclear, but possible explanations include difference in study population, duration of acclimatization period and the presence/absence of a training protocol to get used to the user-adaptive prosthetic knee.

We further hypothesized that peak prosthetic knee flexion during swing while walking with the Rheo Knee II would be comparable in the three walking speed conditions, while prosthetic knee flexion would increase with walking speed while

walking with the NMPK. Although this pattern was visible in our results (see Fig. 1), these differences were not statistically significant within each of the walking speed conditions. In addition, when comparing peak prosthetic knee flexion during swing across walking speeds (see Table 3), we observed that prosthetic knee flexion significantly increased with walking speed in both prosthetic knee conditions. We were, thus, not able to confirm our hypothesis in our study population. One of the contributing factors might be that five subjects had a relatively low peak prosthetic knee flexion (<45° at preferred walking speed) during swing while walking with the NMPK and three had a relatively high peak prosthetic knee flexion in swing (>65° at preferred walking speed). The subjects with a low peak prosthetic knee flexion increased their peak prosthetic knee flexion during swing while walking with the Rheo Knee II, and the subjects with a high peak prosthetic knee flexion decreased it. In the non-parametric statistical analysis, this led to both positive and negative ranks leading to non-significant differences. The same pattern was visible at the faster and slower walking speeds.

We also looked at the compensatory movements on the intact leg, that might be associated with non-optimal prosthetic knee kinematics such as intact ankle vaulting and the peak vertical acceleration of the pelvis. We found that at 70% preferred walking speed, vaulting while walking with the Rheo Knee II was significantly decreased when compared to walking with the NMPK. This could be due to the fact that peak prosthetic knee flexion during swing was lower in the NMPK condition when compared to the Rheo Knee II condition (median difference [IQR]: −7.86 [−17.26, 2.83]). This difference, however, was not significant. The reduced peak knee flexion during swing while walking with the NMPK might have led to foot clearance problems, which may have increased vaulting of the intact leg to prevent toe drag of the prosthetic leg. We also looked at the peak vertical acceleration of

the pelvic CoM during the swing phase of the prosthetic leg and found no differences between prosthetic knees across walking speeds. We chose to look into this variable, because research in typically developing children the upward movement of the pelvis and velocity-related forces are the main contributors to the knee extension movement during swing. [9] However, we do not know if and how these findings are applicable on individuals with an amputation. This means that these results are exploratory of nature and should be interpreted with caution. Future research should elucidate the mechanism by which the prosthetic knee is extended during swing and if, and to what extent, a user-adaptive prosthetic knee could influence this mechanism.

Finally, we studied outcome parameters that have been reported in existing literature. We found no significant differences in these outcome parameters between prosthetic knees. Fig. 1 suggests that prosthetic knee flexion at initial contact was higher while walking with the Rheo Knee II when compared to the NMPK condition. We, however, believe that this is due to differences in alignment between prosthetic knees. As previously conducted trials show mixed and conflicting results on spatiotemporal and kinematic variables, our results are both in line and conflicting with previously conducted trials. If we look at knee yielding for instance, both trials reporting no differences in knee yielding [4,7,13] as an increase in knee yielding [1,15] are available (respectively 8 and 1°).

We think that a number of confounding factors may have contributed to the limited differences we found. At first, we had a small sample size, which affected statistical power and thereby the ability to detect significant differences. However, if marked differences between prosthetic knee conditions existed, these differences might have been identified. In addition, we provided eight weeks of acclimatization to the Rheo Knee II. This may have been too short for full acclimatization which might have affected the outcome of the studied variables. Thirdly, we chose to leave out a gait training because it is not common in the Netherlands to receive a gait training program after prescription of a microprocessor-controlled prosthetic knee. In addition, previous research has shown that gait re-education can influence the studied outcome parameters, even without altering the prosthetic components [16]. This means that in a research setting a gait training program always should be given to both prosthetic knee conditions which was practically not feasible due to the required time investment.

In conclusion, we found that walking with the Rheo Knee II lead to a reduced vaulting of the intact leg when compared to the NMPK condition at 70% preferred walking speed. On other gait parameters no differences were found.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.gaitpost.2016.11.015>.

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