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Designs and performance of three new microprocessor-controlled knee joints

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Abstract: A crossover design study with a small group of subjects was used to evaluate the performance of three microprocessor-controlled exoprosthetic knee joints (MPKs): C-Leg 4, Plié 3 and Rheo Knee 3. Given that the mechanical designs and control algorithms of the joints determine the user outcome, the influence of these inherent differences on the functional characteristics was investigated in this study. The knee joints were evaluated during level-ground walking at different velocities in a motion analysis laboratory. Additionally, technical analyses using patents, technical documentations and X-ray computed tomography (CT) for each knee joint were performed. The technical analyses showed that only C-Leg 4 and Rheo Knee 3 allow microprocessor-controlled adaptation of the joint resistances for different gait velocities. Furthermore, Plié 3 is not able to provide stance extension damping. The biomechanical results showed that only if a knee joint adapts flexion and extension resistances by the microprocessor all known advantages of MPKs can become apparent. But not all users may benefit from the examined functions: e.g. a good accommodation to fast walking speeds or comfortable stance phase flexion. Hence, a detailed comparison of user demands and performance of the designated knee joint is mandatory to ensure a maximum in user outcome.

Keywords: amputee; knee joint; level walking; microprocessor-control; prosthesis; transfemoral.

Introduction

Since the introduction of the first microprocessor-controlled exoprosthetic knee joint (MPK) in the 1990s,

numerous MPKs have been developed and introduced to the market. All of these medical devices feature unique combinations of sensors, actuators and control strategies. The complex interaction of these components directly affects movement and safety outcomes for amputees [1–3]. Consequently, prosthetic practitioners are faced with the challenge of choosing the appropriate MPK for the particular needs of a user. Therefore, comparative analyses that demonstrate the functional characteristics of knee joints are essential to support the selection process. In the literature, microprocessor control is mainly compared with passive mechanical control of prosthetic knee joints [5, 7, 8, 11, 12, 16–18, 20, 25–27]. The outcome measures are usually limited to self-reports, interviews and different standardized questionnaires, if bigger cohorts are examined or multicentered study designs are applied [5, 8, 27]. The results indicate benefits concerning the assessed scores and psychosocial effects while using MPKs. Biomechanical measures often focus on easily assessable parameters, e.g. number of steps per day, comfortable gait velocity, gait symmetry and duration of different tasks [11, 12, 16–18, 20, 25, 26]. Extensive biomechanical measures are limited to smaller groups of subjects and involve posturography, whole-body kinematics, ground reaction forces and energy expenditure, likewise with better outcome for MPKs [7, 17, 18, 20, 25]. The spectrum of methods used for evaluating the probability of stumbles and falls reaches from self reports [11, 12, 16, 27] to forced falling situations in the laboratory [7]. All studies indicate a higher level of safety when using MPKs that could be linked to the reported increase in multitasking ability. Other biomechanical parameters only show a slight tendency to better outcomes with MPKs but no statistically significant differences, e.g. energy expenditure [20]. It underlines that despite the obvious differences between microprocessor control and passive mechanical control, large cohorts are necessary to compensate individual preconditions and day-to-day variability during biomechanical measures. Therefore, a comprehensive comparison of different MPKs may be very extensive. Another approach was presented in a prior study [28] in which only a small group of subjects took part in a comparative biomechanical analysis featuring four MPKs [C-Leg (Otto Bock HealthCare, Duderstadt, Germany), Plié2.0 (Freedom Innovations, Irvine, CA, USA), Orion (Chas A Blatchford

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and Sons, Basingstoke, UK) and REL-K (Rizzoli Ortopedia S.p.A, Budrio, Italy)]. During level walking, significant differences were found in stance and swing phase control. The subsequent technological analysis identified the reasons for the findings in the designs of the MPKs and underlined that these conclusions are not limited to the investigated group of subjects. With every update of a product previous comparative analyses have to be revised as slight design changes or software updates can significantly improve or diminish the biomechanical characteristics of an MPK. The present study uses this basis to investigate three new MPKs C-Leg 4 (Otto Bock Health-Care, Duderstadt, Germany), Plié 3 (Freedom Innovations, Irvine, CA, USA), and Rheo Knee 3 (Össur, Reykjavik, Iceland) focusing on the interrelation of technological designs and user outcomes. The aim of the present study was to show that only if a knee joint adapts flexion and extension resistances by the microprocessor, then all the mentioned benefits of MPKs can become apparent.

Preliminary technological analysis

As a first step, a comparison of the technological designs of the three new knee joints and their previous versions appeared necessary. Six computed tomographies (CTs) were performed to examine the mechanical designs of the knee joints without the need for disassembling the units. The tomographic system was equipped with a 450 kV X-ray source and a 1-MP flat-panel X-ray detector resulting in a resolution of 0.5 mm. Patents, instructions for use and other information published by the manufacturers were also included in the analysis [9, 10, 15, 21, 22, 24, 29]. While the functional principles of the three knee joints remained the same, changes in the mechanical design were found for each joint.

C-Leg 4 generates knee joint resistances hydraulically with two separate microprocessor-controlled, motorized valves. This enables continuous variations in the hydraulic resistance to be set for both movement directions (Figure 1, top). A compensation reservoir B stores energy during flexion using a steel spring, which supports the subsequent extension movement. The progressive characteristics of the hydraulics 5 and a progressive spring 6 provide a smooth extension stop. An important modification compared to the previous version enables a complete occlusion of the extension flow via valve 2. Therefore, very high extension resistances can be set which could be necessary if the user walks with stance phase flexion.

Plié 3 generates knee joint resistances hydraulically with two manually adjustable valves and pneumatically with a

Figure 1: Top: C-Leg 4 scheme of hydraulics (blue: flow during extension, red: flow during flexion); middle: Plié 3 scheme of hydraulics and pneumatics (blue: flow during extension, red: flow during flexion), computed tomography of the Plié 3, a small cross-section of switching valve 5 (left), manually adjustable valve 1 and a large cross-section of check valve 4c (right); Bottom: Rheo Knee 3 functional principle (left, blue arrows: magnetic flux) with a magnetorheological clutch (top right, red: magnetic particles, orange: particle chains) and computed tomography of the torsion steel spring for extension assistance (bottom right).

manually adjustable air spring system, which also provides extension assistance (Figure 1, middle). A microprocessor-controlled spool valve 5 allows switching between two basic flexion resistances for stance and swing phase. Hence, the control algorithm cannot alter the two flexion resistances. This function is achieved by using passive check valve 4b with pressure-dependent hydraulic resistance (Figure 1, middle; illustrated by valve 6). The extension resistance can only be set manually, as spool valve 5 is unable to influence the flow resistance during extension due to the considerably larger cross-section of the parallel check valve 4c shown in the CT (Figure 1, middle). Therefore, the extension resistance has to be set to a suitable value for swing phase extension with comfortable walking speed. Comparing the CT data of Plié 3 and its previous version, the geometry of valve 2 was reengineered, but this does not change the functional principle of the knee joint.

Rheo Knee 3 generates knee joint resistances with a microprocessor-controlled, magnetorheological clutch which enables continuous variation of knee joint resistances in both movement directions (Figure 1, bottom). An electric current sent through a coil induces a magnetic flux through the stacked plates of the clutch. The coil is wrapped around the knee axis and the plates are connected to the thigh and shank sections of the knee in an alternating fashion. The flux causes the magnetic particles in the fluid volume of the clutch to form particle chains between the plates. The amount of current determines the viscosity of the fluid. Therefore, an adaptable friction moment is generated for both flexion and extension movements at the same time. A torsion steel spring provides extension assistance (Figure 1, bottom right) and elastomer elements are used for damping of the extension

stop. Comparing the CT data of Rheo Knee 3 and its previous version, a manual lock can be found. With the lock enabled, the Rheo Knee can be used as a “locked knee” prosthesis when the battery runs out of power.

The analysis showed that all knee joints provide microprocessor-controlled switching between stance and swing phase (Table 1). With C-Leg 4 and Rheo Knee 3 the microprocessor adapts the flexion resistance to different movement patterns and walking velocities. As the Plié 3 employs passive hydraulic elements, it can only provide two basic flexion resistances. Hence, we expect fluctuating flexion angles with varying walking velocities during gait analysis with Plié 3. The generation of extension resistances also shows significant differences between the MPKs. With C-Leg 4 and Rheo Knee 3 the extension resistance for both swing and stance phase is adapted by microprocessor control. Plié 3 only provides one manually preset value for swing extension and no separate stance extension resistance. As a result, we expect inadequately low stance extension damping for Plié 3 after stance phase flexion.

Materials and methods

Four male subjects with transfemoral amputation (Table 2) and a Medicare Functional Classification Level of K3 participated in the comparative evaluations. Approval KR_02_20151118 was granted by the Ethics Committee of the Berlin University of Technology. No additional orthopedic impairments, neurologic conditions or cardiovascular disease were reported and this resulted in an above-average mobility for the group. All subjects entered the study as users of a Genium MPK (Otto Bock HealthCare, Duderstadt, Germany) and had experience performing motion analysis tests with previous versions of the tested MPKs. For all test conditions, the prosthetic foot 1C60

Table 1: Overview of the three knee joints, microprocessor-controlled elements marked gray.

	C-Leg 4	Plié 3	Rheo Knee 3
Microprocessor-controlled elements	2 Hydraulic motor valves	1 Hydraulic spool valve (switching open/close)	Magnetorheological clutch
Switching between stance and swing phase	Controlled	Controlled	Controlled
Stance phase flexion resistance	Controlled hydraulic motor valve	Manually adjustable hydraulic valve (spool valve is closed)	Controlled magnetorheological clutch
Swing phase flexion resistance		Pressure-dependent hydraulic valve and manually adjustable air spring (spool valve is open)	
Stance phase extension resistance	Controlled hydraulic motor valve	Same setting as swing phase extension	
Swing phase extension resistance		Manually adjustable hydraulic valve	
Extension assistance	Helical steel spring	Air spring	Torsion steel spring

Table 2: Subject demographics and static prosthesis alignment.

Subject	A	B	C	D
Age (years)	42	30	48	59
Height (cm)	183	175	178	172
Weight (kg)	93	84	76	103
BMI, Body mass index (kg/m ²)	28	27	24	35
Residual limb length (cm)	21	27	16.5	25
Time since amputation (years)	31	15	25	40
Time with a MPK (years)	13	8	15	12
Static prosthesis alignment: distance between knee axis and load line				
C-Leg 4 (mm)	30	29	30	–
Plié 3 (mm)	28	31	30	–
Rheo Knee 3 (mm)	28	31	–	30

(Otto Bock HealthCare, Duderstadt, Germany) and existing ischial containment socket from each subject were used.

The motion analysis lab used for biomechanical evaluations was equipped with a 12-m instrumented walkway with a VICON (Vicon Motion Systems, Oxford, UK) optoelectronic 12 camera system and two Kistler (Kistler Instrumente, Winterthur, Switzerland) force plates embedded in the floor. Tracking markers were attached to the metatarsophalangeal joint V, lateral malleolus/ankle adapter screw on the prosthetic side, knee center defined by Nietert [19]/knee axis on the prosthetic side, trochanter major, acromion, lateral humeral epicondyle and ulnar styloid process. Joint angles were calculated directly using the marker positions. In preparation for each test procedure, an identical prosthetic alignment that met all manufacturer's specifications was performed with the LASAR

Assembly (Otto Bock HealthCare, Duderstadt, Germany). Afterward, the static alignment (Table 2) was optimized according to recommendations by Blumentritt [23]. A certified prosthetist individually adapted the knee joint settings according to the manufacturer's recommendation to achieve a secure and uniform gait for all gait velocities. For each MPK there was an accommodation time of minimum 3 h which involved supervised walking in the lab. If knee joint settings had to be changed meanwhile, the time was extended resulting in a maximum of 4 h. Finally, the accommodation was terminated at the discretion of the subjects and then the testing series was commenced. Eight to 10 repetitions of level-ground walking at self-selected slow, comfortable and fast velocities were recorded. The subjects were also told to walk at a self-selected speed with conscious stance phase flexion. Automatic step recognition was

Table 3: Results of the biomechanical evaluations.

	Gait velocities (m/s)			Count of steps with complete swing extension		
	Slow	Comfortable	Fast	Slow	Comfortable	Fast
C-Leg 4	0.96±0.03	1.26±0.13	1.79±0.11	3/3	15/15	16/16
Plié 3	0.95±0.03	1.28±0.1	1.82±0.15	6/8	16/16	11/13
Rheo Knee 3	0.96±0.03	1.16±0.14	1.54±0.04	5/7	7/20	4/16
Parameter	Group 1	Group 2	Lower boundary	Est. mean difference	Upper boundary conf. interval	p-Value
Results of the multiple comparison procedures						
Gait velocity	C-Leg 4	Plié 3	–0.07 m/s	0.00 m/s	0.07 m/s	1
	C-Leg 4	Rheo Knee 3	0.07 m/s	0.15 m/s	0.22 m/s	1.43E–06
	Plié 3	Rheo Knee 3	0.07 m/s	0.15 m/s	0.22 m/s	6.26E–07
Maximum knee angle stance phase	C-Leg 4	Plié 3	1.02°	2.99°	4.96°	0.0004
	C-Leg 4	Rheo Knee 3	1.80°	3.61°	5.42°	9.10E–06
	Plié 3	Rheo Knee 3	–1.19°	0.62°	2.42°	0.969
Knee angular acceleration stance ext.	C-Leg 4	Plié 3	–2079°/s²	–1759°/s²	–1439°/s²	6.18E–15
	C-Leg 4	Rheo Knee 3	–558°/s ²	–264°/s ²	30°/s ²	0.0412
	Plié 3	Rheo Knee 3	1202°/s²	1495°/s²	1788°/s²	3.88E–14

Top left: walking velocities (m/s), mean value and standard deviation; top right: count of steps with complete swing extension (zero crossing of the knee angular velocity before heel strike) compared to all recorded steps for the three velocities; bottom: results of the multiple comparison procedure: estimated mean differences, upper and lower boundaries of the confidence intervals and p-values for the group comparisons (significance level 2%, $p < 0.02$ marked bold).

[Correction added after online publication on February 21, 2018: Mistakenly this article was already published ahead of print with a composition error in the Table 3.]

used during recording of the trials. Incompletely recorded steps and steps with a walking velocity <0.9 m/s were excluded from further analyses. Steps with a slower velocity showed a high variation in gait pattern and would have masked the measured differences between the MPKs. Smoothing was used for the derivative calculation of the knee angle and this slightly shifted maxima and minima. Biomechanical parameters were evaluated using Kolmogorov-Smirnov tests, n-way analyses of variance and multiple comparison procedures with Bonferroni adjustments [14]. This approach enables to check for interaction effects resulting from single subjects or the non-controlled walking velocity. Due to the low number of subjects, the results did not comply with a normal distribution for several parameters within the group comparisons (Table 3). Hence, the significance level was set relatively low (2%). Mean values with standard deviations for biomechanical parameters are displayed in the table. A linear regression model was used for correlation testing. All mean curves were calculated using a dynamic time warping algorithm [4] which slightly shifts maxima and minima to achieve uniform curve characteristics. Mean curves are displayed together with an underlying area that represents the range of dispersion, given by the 25% and 75% quartiles.

Results

For a general analysis of the results concerning the biomechanical evaluation, time-distance parameters were

assessed first. While gait velocities were not controlled during the trials, differences were found between subjects and knee joints. The mean values for self-selected and fast velocity were significantly lower with Rheo Knee 3 than C-Leg 4 and Plié 3 (Table 3, $p < 0.001$).

As expected from the state-of-the-art MPKs, there were no incidents of sudden knee flexion during the stance phase while walking on level ground and no stumbling situations could be observed during measurements. Nevertheless, differences could be found during the test series with self-selected walking speed and conscious stance phase flexion (Figure 2). With C-Leg 4 ($11.4 \pm 2^\circ$) the highest flexion angles were reached with significant differences to Plié 3 ($8.4 \pm 0.9^\circ$) and Rheo Knee 3 ($7.8 \pm 1.3^\circ$) (Table 3, $p < 0.001$). Compared to the contralateral side ($20.8 \pm 4.8^\circ$), the flexion angle maxima for all MPKs were significantly smaller (Table 3, $p < 0.001$). Furthermore, the damping characteristic of the stance phase extension was calculated. A smooth curve characteristic of the knee angle (Figure 2, top left) indicates a smooth damping characteristic. The curvature of the knee angle was quantified by the maximum of the angular acceleration (Figure 2, top middle). C-Leg 4 ($505 \pm 125^\circ/\text{s}^2$) and Rheo Knee 3 ($783 \pm 100^\circ/\text{s}^2$) show the smoothest extension damping.

Figure 2: Top: mean knee angle (°) for stance phase (top left) and mean knee angle acceleration (°/s²) for stance extension (top middle) over the gait cycle (%), steps with conscious stance phase flexion; maximum knee angle (°) over walking velocity (m/s) for all valid steps (top right) and linear regression line over all velocities, amputated side for the single knee joints and contralateral side for all joints; bottom: mean knee angle (°) over gait cycle (%) at the end of swing phase extension for three self-selected velocities.

With Plié 3 ($2280 \pm 410^\circ/\text{s}^2$) an abrupt extension stop occurs. This is confirmed by significant differences in the data (Table 3, $p < 0.001$).

At the end of the stance phase, the MPKs are in an extended position and swing phase initiation begins. At first the MPKs control swing flexion resistance to enable appropriate toe clearance irrespective of walking velocity. Hence, the linear correlation between maximum knee flexion angle and gait velocity should be low (Figure 2, top right). This is illustrated by the nearly flat slope of the regression line for the contralateral side. The slope was similar for all tested knee joints with a mean of $3.02^\circ/\text{m/s}$ ($R^2 = 0.02$). The swing flexion behavior of the C-Leg 4 is similar to the contralateral side with a mean slope of $2.01^\circ/\text{m/s}$ ($R^2 = 0.26$). Rheo Knee 3 with $17.04^\circ/\text{m/s}$ ($R^2 = 0.53$) shows a stronger correlation between knee flexion angle maximum and walking velocity. With Plié 3 the strongest correlation of $23.55^\circ/\text{m/s}$ ($R^2 = 0.9$) could be found.

Also, during swing extension significant differences were observed between the MPKs. A well-designed swing extension behavior (Figure 2, bottom) ensures that the knee joint reaches its specific extended position reproducibly before initial contact to support correct foot positioning. Even if slight flexion remains at the specific extended position with some MPKs, a zero crossing of the angular velocity can be measured prior to heel strike with completed knee extension. In this fashion, the number of steps with complete extension was examined for all trials (Table 3). With C-Leg 4 the extension stop was reached for all recorded steps. For Plié 3 only single steps at slow and fast walking speeds missed the extension stop. Rheo Knee 3 reached the extended position in fewer cases and this was especially seen during self-selected and fast walking speeds. Additionally, the percentiles of the knee angle curve show a remarkably higher spread before heel strike with Rheo Knee 3 for all velocities (Figure 2, bottom).

Discussion

For a reliable comparison, a well-executed prosthetic alignment, a reasonable adaptation of the knee joint settings and a comparable and sufficient adaptation time for the subjects are essential. While the prosthetic alignment can easily be measured, the setting of the knee joint parameters requires several trials to find a good compromise for all velocities and gait situations. As the certified prosthetist and all subjects were experienced in test fittings for gait laboratory tests, a good compromise was easily

achieved during test preparation. The accommodation time could be kept short because all subjects were experienced MPK users and were fitted with previous versions of all tested MPKs before. To minimize the bias from the testing situation, the three requested walking velocities were not controlled and showed significant differences between the MPKs. As the walking velocity influences other gait parameters, its effect was always considered in the subsequent analysis by examining the different velocity classes and eliminating parameters with a strong velocity bias from the analysis.

For example, the impact after heel strike is velocity-dependent and requires an adequate damping of the loading response. On the contralateral side, stance phase knee flexion reduces peak loads and the modulation of the center of gravity. Additionally, a reduced time interval between heel strike and stable foot flat was shown for stance phase flexion with a prosthesis [6]. All investigated MPKs allow stance phase flexion and ensure sufficient flexion resistance during stance. The highest flexion angles are reached with C-Leg 4 and also when compared to the previous version of the C-Leg. There are still noticeable differences to the movements of the contralateral knee. Nevertheless, among the tested knee joints, the stance phase flexion maximum of C-Leg 4 is closer to the natural knee function. This can be additionally confirmed by the stance phase extension damping which is measured by the minimum of the angular acceleration and that indicates abrupt movement transitions. C-Leg 4 and Rheo Knee 3 show the smoothest damping characteristics. In contrast, Plié 3 does not meet the demands for adequate stance phase extension damping. The technical analysis confirmed that the extension resistance cannot be influenced by the microprocessor with Plié 3 and only meets the requirements for swing phase extension.

One of the most important advantages of microprocessor-controlled knee joint systems is the controlled damping of the swing phase. It enables users to walk at different velocities without the need to change their gait pattern. Inadequate knee flexion angles can result in tripping during mid-swing or incomplete extension at heel contact when changing walking speed. Furthermore, the lack of dorsiflexion during swing phase of most prosthetic feet reduces toe clearance. On the contralateral side, the maximum knee flexion angle during walking changes only slightly with the walking velocity and this has been shown in several studies with able bodied subjects [13, 30]. C-Leg 4 performs in a similar fashion and therefore enables the most natural knee function for swing phase flexion. The correlation between maximum

knee flexion angle and gait velocity with Rheo Knee 3 is comparable to other MPKs [2, 28]. Plié 3 exceeds the values of other knee joints within this group and does not comply with the requirement for natural swing phase behavior. The technical analysis showed that only Plié 3 does not provide microprocessor-controlled adaptation of swing flexion resistance. Although the extension resistance of Plié 3 is not microprocessor controlled, the knee reaches its extended position with almost all steps. C-Leg 4 showed a reproducible extended position before heel strike for every step and this eases foot positioning. Only Rheo Knee 3 shows incomplete extension movements which could be observed frequently for self-selected and fast velocities. This could be related to the measured walking velocities that were significantly slower for those two groups. The higher weight of the Rheo Knee 3 (Rheo Knee 3: 1.6 kg, C-Leg 4: 1.2 kg and Plié 3: 1.2 kg), which results from a large accumulator, could be a reason for this result. Its low position in the artificial thigh additionally increases the moment of inertia which may complicate controlling the prosthesis during swing. The remarkably higher range of the percentiles for the knee angle confirms that with Rheo Knee 3 the reproducibility of swing extension is lower. Nevertheless, the slight differences may only be relevant in challenging gait situations, which require more accurate foot positioning than level walking.

Limitations

The technical analysis revealed differences in the generation of knee joint resistances that might also be relevant with respect to safety issues. During the measurements that involved walking on level ground, no stumbling or falling situations were observed. Further research is needed to evaluate the functional characteristic of the MPKs concerning safety.

A major limitation of this study is the low number of subjects who participated and that the subjects do not represent the entire population of transfemoral amputees as typical comorbidities are not apparent. The high mobility of the subjects puts high demands on the functional characteristics of the knee joints. On the one hand, this enables a comprehensive comparison. On the other hand, users of lower functional levels may not benefit from some examined functions: a good accommodation to fast walking speeds or comfortable stance phase flexion. If the demands of a user are not evident, test fittings with different knee joints should be performed to determine if

there might be a functional benefit resulting from a higher functional quality of one knee joint.

Conclusion

The C-Leg 4, Plié 3 and Rheo Knee 3 offer a reliable detection of stance and swing phase and the generation of joint resistances to avoid uncontrolled flexion of the knee joint. As shown in the technical analysis, only C-Leg 4 and Rheo Knee 3 allow for microprocessor-controlled adaptation of resistances to different movements and situational requirements. The Plié 3 has manually adjustable elements that generate the resistances. This directly affects the outcome of the biomechanical analysis which examined level walking at different walking velocities. C-Leg 4 showed the most natural knee function when compared to the contralateral side and this was followed by Rheo Knee 3.

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