Biomechanical Comparison of Novel Adaptive Swing-Phase Control Mechanical Knee Prostheses with 3R60 and 3R15 in Trans-Femoral Amputees

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ABSTRACT

Background: The knee joint must adapt to the changes in walking speed to stabilize the stance phase and provide fluency in the swing phase.

Objective: This study aimed to report a comparison of the gait patterns of transfemoral amputees using a novel mechanical prosthetic knee that can adapt automatically to different walking speeds with 3R60 and 3R15 knee prostheses.

Material and Methods: In this experimental study, biomechanical data were collected from six unilateral trans-femoral amputees walking with three knee prostheses. Gait data were gathered at slow, normal, and fast walking speeds across a 7-meter walkway using the Vicon motion system.

Results: The results revealed a significant difference in knee angular velocity during the swing phase between prosthetic knees across three walking speeds (P-value=0.002). Prosthetic knee flexion decreased significantly by increasing walking speed for the novel mechanical auto-adaptive prosthetic knee (P-value<0.001). A lower value of hip power during early swing was considered when amputees walked with novel knee prosthesis (P-value<0.00). The intact leg ankle plantar flexion angle or vaulting did not significantly change while walking speed increased in the novel knee prostheses compared to walking with the 3R60 and 3R15 knee prostheses (P-value=0.002 and P-value<0.06, respectively).

Conclusion: Based on the results, a novel mechanical auto-adaptive knee prosthesis has advantages compared to the other conventional designs for unilateral trans-femoral amputees walking at different speeds.

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Keywords

Adaptation; Amputees; Biomechanics; Kinematic; Gait; Prosthesis; Trans-femoral; Speed; Knee Prosthesis

Introduction

Approximately 600,000 people have been suffering from limb amputations in the United States (U.S.), and nearly half of them have a trans-femoral amputation (TFA) [1]. The global prevalence of TFA is about 20 to 30 times higher than the prevalence in the U.S. [2]. The loss of the natural knee joint in the trans-femoral amputees presents a challenge for the design and configuration of the prosthetic knee to restore mobility [3]. An optimal prosthetic knee and stabilization of the stance phase should provide fluency in the swing phase at the different walking speeds [4, 5]. An appropriate swing phase trajectory by increasing the speed of walking should prevent more swing knee flexion and also provide sufficient swing extension to start the following stance phase and timely placement of the foot on the ground [6, 7]. Biomechanical simulation of the intact leg requires automatic adjustment of the prosthetic knee joint at different speeds [8]. Adaptation to different speeds is one of the most important factors in improving the amputee's quality of life [9]. Most transfemoral amputees use non-microprocessor mechanical joints, including frictional mechanical joints, pneumatic joints, and hydraulic joints [10]. In these mechanical joints, the swing phase is controlled by dampers limiting the fluid passage valve and swing flexion, and extension damping is adjusted at self-selected speeds. However, these knee joints cannot be automatically adapted to changes in walking speed [11, 12]. In these joints, by increasing speed more than the self-selected speed, the swing peak knee flexion rises more; accordingly, the foot does not reach the ground at a proper instant to start the next step [7]. Conclusively, this lack of damping coordination with speed changes may cause problems, such as increased metabolic cost [13] and compensatory movements [14-16].

Microprocessors and active knee joints have been developed, including sensors to detect the knee joint's speed, angle, and a motor and drive system [6, 17-19]. These joints can reduce the peak knee swing flexion by increasing speed and subsequently reduce the swing extension time; accordingly, greater adaptability has been achieved [20-22]. Despite these advantages, compared to non-adaptive mechanical knee joints, these joints are large, heavy, and noisy with a higher maintenance cost. Moreover, these adaptive knee joints are not available to all amputees due to the high price [6, 10].

This study presents an alternative control algorithm for mechanical knee prostheses that enables the swing phase automatically to adapt to different walking speeds. In the present study, this knee prosthesis is the auto-adaptive knee, receiving the speed data from the hip joint using a pendulum affected by hip movements. This pendulum can change damping when the speed changes. Therefore, this study aimed to compare the biomechanics of three mechanical knee prostheses, the novel auto-adaptive, the 3R60 non-adaptive, and the conventional Knee without damper (3R15) across three speeds of slow, normal, and fast in above-knee amputees. In addition, we studied compensatory mechanisms associated with three prosthetic knee kinematics, such as vaulting and hip power generation during the early swing. Increased hip power generation may cause fatigue and secondary disability [11].

The study hypothesizes that the novel auto-adaptive mechanical knee prosthesis can adjust peak knee swing flexion, heel-rise, and swing extension time as the walking speed increases. Accordingly, it was hypothesized that the novel knee prosthesis decreases the hip power generation during the early swing of the prosthetic leg and the amount of vaulting compared to the 3R60 and the 3R15 knee prostheses.

Material and Methods

Mechanical design

In this experimental study, an auto-adaptive mechanical knee prosthesis was designed and compared with 3R60 and 3R15 mechanical knee prostheses (Figure 1). This novel mechanical knee included two hydraulic dampers that act unilaterally. One of the dampers controlled the knee flexion in the swing phase, in which the damping changes proportionally to different speeds via a pendulum attached to the damper valve (Figure 2a). These pendulum movements were affected by hip joint movements due to dynamic coupling interaction between the thigh and prosthetic knee.

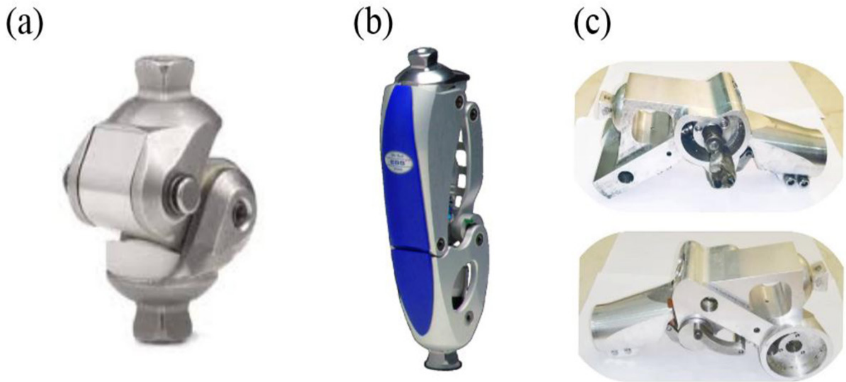

Figure 1: (**a**): 3R15, (**b**): 3R60, and (**c**): novel auto-adaptive knee prostheses

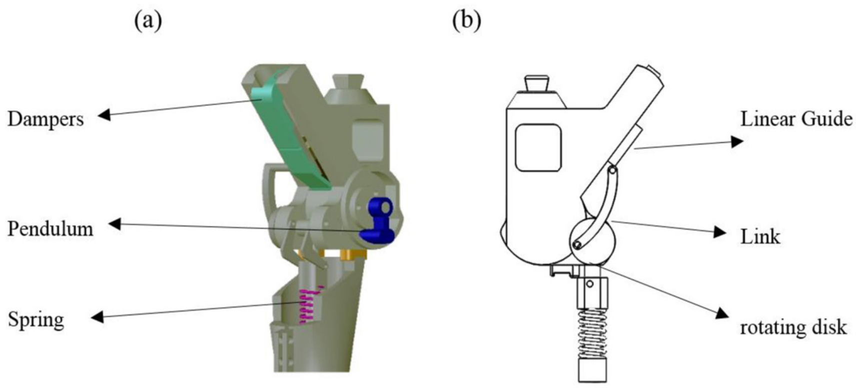

Figure 2: (**a**) The mechanical structure of the novel knee prosthesis, (**b**) the rotational force transform into the linear force via a link part

Forward acceleration of the hip joint caused the backward acceleration of the prosthetic shank and vice versa. The hip joint of amputees was considered the main engine source for the prosthetic knee [23].

Another damper acted in terminal extension to prevent terminal impact. A spring was used in the novel knee prosthesis to facilitate swing extension (Figure 2b). Stance phase stability was provided by creating intrinsic stability in the design [24, 25].

In normal walking, a higher walking speed leads to a greater angle of flexion and acceleration of the hip joint [26]. Swing flexion and extension damping in the prosthetic knee joint can be controlled based on the hip joint [27].

Participants

In this paper, six men with trans-femoral amputations were recruited (age: 45.93±5.55 years, weight: 75.87±10.62 kg, and height: 182.95±5.68 cm), as seen in Table 1. The inclusion criteria were at least three years post-amputation, functional level of K2 or higher, and individuals could walk without pain with a medium stump length. Neurological disorders and musculoskeletal problems influencing walking ability, stump problems or poor socket fitting, history of lower limb fracture or surgery exception of amputation were excluded. The participants were selected based on simple sampling among the amputees referred to the Iranian Red Crescent Society amputation

Table 1: Characteristics of participants

Variables	A person with an amputation (6)
Age (years)	45.93±5.55
Sex (male/female)	6/0
Height (cm)	182.95±5.68
Weight (kg)	75.87±10.62
Time since amputation (years)	5±2
Reason of amputation Stump length (cm)	Trauma (4), Osteosarcoma (1) Infection (1) 42±6

clinic in Tehran. The Ethics Committee of the Iran University of Medical Sciences approved this study. After recruiting participants, the procedures were explained clearly. All participants completed the consent forms.

All individuals were fitted with three prosthetic knees by the same prosthetist. Manufacturer recommendations were followed when aligning each knee prosthesis. In addition, each individual used the same prosthetic socket and prosthetic foot when testing each knee device. Participants were requested to wear comfortable walking shoes.

Data collection and processing

Data collection was performed at the Movaffaghian gait analysis center (Tehran, Iran). Spatiotemporal data collection was conducted using a ten-camera motion analyzer system (Vicon Motion Systems Ltd; Vicon MX T40-s and Vero v2.2 cameras at 100 Hz, Oxford Metrics, UK) integrated with two force plates (Kistler Instrument, DAQ system, Switzerland) for detecting heel contact and foot off. Before the assessments, each participant had approximately one hour for acclimatization to each knee prosthesis. Knee prostheses were covered with a cloth, and participants were blind to the types of the knee. Sixteen retro-reflective markers were placed on the anatomical landmarks according to the lower limb plug-in-gait marker set, with bilateral markers on the anterior and the posterior iliac spine, lateral condyles of the femur, lateral ankles, and head of the second metatarsus and behind the calcaneus. Tow markers were also placed on the lateral femoral and tibial segments to define the frontal plane [28]. Participants walked along with a 7-meter with three types of knee prostheses across three speeds: normal or self-selected walking speed, slower than normal, and faster than normal. Average walking speed was defined as the total displacement of the sacrum marker divided by time at a defined distance for each condition [29]. Three correct trials were recorded among several attempts.

Outcome measures included maximum sagittal hip power in the early swing, maximum flexion of prosthetic knee in swing, and the maximum height of heel marker in swing or heel rise. Knee flexion angle displacement was calculated to calculate the angular velocity of the prosthetic knee during a swing. The derivative of this displacement was then calculated as angular velocity. Hip joint power was also calculated using a motion analyzer system [30]. The vertical position of the heel marker during the static calibration trial was subtracted from the vertical position of the heel marker at the mid-stance to calculate the amount of vaulting in the intact leg during mid-stance, [28].

In this study, the motion capture marker data post-processing was performed in Vicon Nexus (Version 2.12, Plug-In-Gait) and then exported to MATLAB (version 9.7, Mathworks, Natick, MA).

Statistical analysis

Preliminary assumptions were tested to check for the normality by Kolmogorov Smirnov, outliers, and homogeneity of variance; no major violations were noted. Statistical analyses were conducted using SPSS software (version 26, SPSS Inc. Chicago, IL, USA). A two-way repeated measure ANOVA with a Bonferroni-adjusted posthoc test was conducted to compare the means at different knee prostheses and speed conditions. The significance level of all of the tests was *P*-value<0.05.

Results

The difference in prosthetic knee mechanics across the three prosthetic knees and three-speed conditions were characterized by statistically comparing the following parameters: maximum flexion of knee prostheses in swing, the maximum angular velocity of the prosthetic knee in swing, the maximum heel rise, maximum hip power in the early swing in the prosthetic leg, vaulting, and swing duration (Table 2).

Maximum angular velocity of knee prostheses: Statistically significant difference was considered in maximum angular velocity while walking with three different prostheses within walking speed conditions (*P*-value=0.002). Bonferroni test showed a statistically significant difference between the novel and 3R60 knee prosthesis (*P*-value=0.005) and between the novel knee and 3R15 knee prosthesis (*P*-value=0.04) as seen in Table 2.

Maximum flexion of knee prostheses in swing: Post hoc comparison using the Bonferroni test indicated that all types of

Table 2: The mean (standard deviation (M (S.D.)) and the results of ANOVA test (*P*-value) in different speed condition

Descriptive statistic					Multivariate tests		
		M(S.D.)			*P*-value		
	Type	Slow	Normal	Fast	Pairwise comparisons type	Pairwise comparisons speed	Within subject
Max. flex knee prostheses (degree)	Novel	56.06 (2.56)	51.21 (2.86)	48.13 (1.04)	Novel-3R60 (0.029)	Slow-normal (0.006)	Type (0.000)
	3R60	42.28 (4.18)	44.31 (4.05)	54.4 (5.18)	Novel-3R15 (0.001)	Slow-fast (0.000)	Speed (0.000)
	3R15	50.29 (2.15)	61.37 (3.41)	70.55 (2.29)	3R60-3R15 (0.001)	Normal-fast (0.030)	Type*speed (0.000)
Max knee angular velocity (degree/s)	Novel	212(16)	240(12)	286(15)	Novel-3R60 (0.005)	Slow-normal (0.002)	Type (0.000)
	3R60	154 (12)	158 (18)	164(12)	Novel-3R15 (0.04)	Slow-fast (0.000)	Speed (0.000)
	3R15	194 (11)	190 (18)	195(10)	3R60-3R15 (0.04)	Normal-fast (0.006)	Type*speed (0.000)
Max.Heel rise in peak swing flex (mm)	Novel	138.28 (5.70)	128.45 (3.13)	120.21 (7.97)	Novel-3R60 (0.063)	Slow-normal (1.000)	Type (0.000)
	3R60	117.21 (6.32)	118.13 (7.33)	137.05 (3.35)	Novel-3R15 (0.000)	Slow-fast (0.006)	Speed (0.000)
	3R15	207.57 (12.40)	222.83 (7.25)	292.95 (9.78)	3R60-3R15 (0.001)	Normal-fast (0.012)	Type*speed (0.000)
Vaulting (mm)	Novel	18.72 (1.41)	19.05 (0.80)	19.64 (0.70)	Novel-3R60 (0.002)	Slow-normal (0.14)	Type (0.001)
	3R60	26.69 (1.88)	28.15 (2.09)	29.59 (1.97)	Novel-3R15 (0.000)	Slow-fast (0.032)	Speed (0.007)
	3R15	25.15 (4.28)	32.24 (2.61)	36.74 (1.19)	3R60-3R15 (0.073)	Normal-fast (0.071)	Type*speed (0.018)
Hip power in early swing (w/kg)	Novel	0.62 (0.1)	0.71 (0.4)	0.74 (0.2)	Novel-3R60 (0.003)	Slow-normal (0.04)	Type (0.000)
	3R60	0.75 (0.2)	0.74 (0.2)	0.84 (0.3)	Novel-3R15 (0.000)	Slow-fast (0.000)	Speed (0.000)
	3R15	0.84 (0.3)	0.91 (0.2)	0.96 (0.5)	3R60-3R15 (0.000)	Normal-fast (0.03)	Type*speed (0.049)

M(S.D.): Standard deviation, *: Interaction effect between type and speed prostheses were significantly different (Novel-3R60 *P*-value=0.029, Novel-3R15 *P*-value=0.001, 3R60-3R15, *P*-value=0.001) (Table 2). A significant interaction was between the type of the prostheses and the speed of walking (*P*-value=0.007).

Maximum heel rise: A within-subjects tow-way repeated measure ANOVA test showed that there was a significant main effect for the prosthetic type (*P*-value<0.001). During different walking speed conditions, no difference was between the novel and 3R60 knee prostheses at slow and normal walking speed (*P*-value=0.06); however, at fast speed, this difference was significant (*P*-value=0.02). The significant difference was between the novel and 3R15 knee prostheses in all walking speed conditions (*P*-value<0.001, Table 2).

Hip power in early swing: Statistically significant difference was between all types of prostheses on hip power (*P*-value<0.001). Bonferroni test indicated the significant difference between the novel and 3R60 prostheses (*P*-value<0.001), novel and 3R15 prostheses (*P*-value<0.001), 3R60 and 3R15 prostheses (*P*-value=0.01).

Vaulting: Walking speed had a significant influence on the amount of vaulting in novel knee prosthetic types (*P*-value<0.001). The vertical displacement of intact leg heel marker in mid-stance was not significantly changed while walking speed increased in the novel knee prostheses compared to walking with the 3R60 and 3R15 knee prostheses (*P*-value=0.002 and *P*-value<0.06, respectively). Bonferroni test indicated no significant difference between 3R60 and 3R15 knee prostheses (*P*-value=0.07) (Table 2).

Swing duration: Statistically significant difference was between three tested prosthetic knees across different speed conditions (*P*-value=0.039). The swing duration for each of the three tested prostheses is shown in Figure 3. In the novel knee prosthesis, unlike the 3R15 knee prosthesis, the swing duration decreased as the walking speed increased. As shown in Figure 3 in the 3R60 knee prosthesis, the significant difference in swing duration was between normal to fast walking speed (*P*-value=0.024).

Discussion

This study aimed to compare three types of prosthetic knee joints across different walking speeds, and it was hypothesized the novel mechanical knee joint adjusted the amount of knee damping automatically by increasing the hip acceleration and consequently

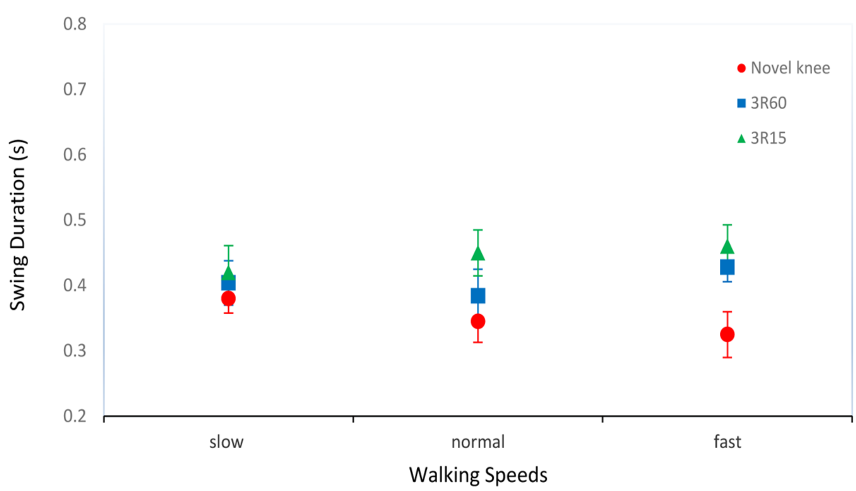

Figure 3: Mean (SD) of the duration of swing phase for the different walking speeds in different prosthetic knees

adjusted the speed of the swing phase according to the walking speed. Auto-adaptability of knee prostheses provided some potential benefits on gait; as followes:

Angular velocity: Compared to the novel mechanical auto-adaptive and non-adaptive damping (3R60) knees, peak knee angular velocity during the swing is significantly larger for the auto- adaptive knee prosthesis. Lenzi et al. reported similar findings in the automatic adaptive robotic knee joint that increasing walking speed resulted in higher angular velocity of the prosthetic knee [31].

Maximum swing knee flexion: The difference among the three knees was for peak swing knee flexion. The auto-adaptive knee had a significantly lower peak knee flexion angle compared to the 3R60 and 3R15 knees. The novel auto-adaptive knee demonstrated an increase in the amount of damping by increasing the walking speed and a decrease in the peak-swing knee flexion angle. However, the peak-swing knee flexion angle in the non-adaptive joints do not change significantly in slow and normal speeds, an excessive increase in high speed is observed. Yukogoshi et al. designed a knee joint, in which the swing phase resistance was automatically adjusted by the microprocessor while walking fast. Additionally, the peak knee flexion increased less than the 3R60 knee joint by increasing walking speed [32]. Since the 3R60 knee was adjusted at normal speed, it cannot provide reliable damping at high speeds; accordingly, the peak knee flexion angle increased significantly from slow to high speeds. However, the study by Prison et al. did not show any significant results between the peak knee flexion in the auto-adaptive and the non-adaptive knee joints [12].

Heel rise and swing duration: In the 3R15 knee joint (without damper), the peak swing knee flexion increased excessively as the walking speed increased. Increasing the knee flexion in this knee joint subsequently increased the heel rise and increased the swing time of the leg toward the extension [33]. Therefore, amputees have to push the leg forward by increasing the power of their hip joint and using compensatory movements, such as pelvic tilt and bending the trunk [34]. Conversely, by increasing walking speed, the heel-rise and the swing extension time is reduced in the novel mechanical joint. The other studies [20, 21, 35] confirmed these results. In the present study, in fast walking speed, the 3R60 knee has a longer swing time extension due to the higher heel rise. Therefore, the amputee will probably use compensatory movements to start the next step timely.

Hip power: However, hip power in the novel knee prostheses was less than non-adaptive knee prostheses, no statistically significant difference was observed between these two joints in slow and normal speed in early swing. Segal's study showed no significant difference in hip power at the early swing phase between the two C-leg joints with variable damping capability and the Mauch SNS knee joint with fixed damping [11]. In the present study, 3R60 knee had significantly higher values for peak hip power in the early swing in comparison with the novel knee, due to the unreliable damping of the 3R60 joint in the swing phase extension. As Johnson et al. demonstrated knee prostheses with variable damping had less power hip at the early swing phase [30]. Based on the results, the designed knee prostheses in the present study improved the biomechanical parameters of the prosthetic knee by increasing the walking speed.

Vaulting: By increasing the speed, this compensatory movement did not have any specific changes in the novel knee prosthesis. Because of higher damping in swing flexion from slow to fast speed, swing extension in the prosthetic leg and conclusively ankle plantar-flexion angle occur progressively earlier in the intact leg.

The current study had a few limitations as follows: 1) the number of subjects was relatively small, 2) the lack of a rehabilitation program was for retraining the amputees with these new prostheses. Further, the subjects had to learn to walk at three speeds slow, normal, and fast; this protocol was time-consuming.

This novel mechanical prototype prosthesis can be made in smaller dimensions and with less weight in the future. Furthermore, more intuition would be gained through some outcome measurements, such as recording the electromyography signals from the stamp or contralateral leg, energy consumption, or kinetics data.

Conclusion

The new algorithm of damping adjustment in the novel knee prosthetic offers better biomechanical parameters of the swing phase than a daily-use mechanical prosthesis across different walking speeds. Further, the novel knee reduces vaulting compared to the 3R60 and 3R15 knee prostheses at a fast speed.

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Authors' Contribution

R. Sheykhi-Dolagh, H. Saeedi, and B. Hajiaghaee conceived the idea. The introduction of the paper was written by R. Sheykhi-Dolagh, gathering the images and the related literature and also helping with the writing of the related works done by R. Sheykhi-Dolagh, H. Saeedi, and Z. Safaeepour. The method implementation was carried out by R. Sheykhi-Dolagh, H. Saeedi, B.Hajiaghaee. Results and analysis were conducted by R. Sheykhi-Dolagh, SH. Saneii, and Z. Safaeepour. All the authors read, modified, and approved the final version of the manuscript.

Ethical Approval

Ethics committee of Iran University of Medical Sciences approved all protocols (IR.IUMS.REC.1398.239).

Informed Consent

The participants signed the consent form to participate in this study.

Funding

There is no funding to report for this submission.

Conflict of Interest

None

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