Original Article

A Comparison of Gait Analysis and Amputee Satisfaction and Acceptability between the CU Polycentric Knee Unit and the Four-Bar Linkage Knee Unit in Transfemoral Amputees: A Pilot Randomized Crossover Study

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ABSTRACT

Objectives: To compare the spatiotemporal gait parameters and satisfaction of transfemoral amputees using a prosthesis with Chulalongkorn University (CU) polycentric and four-bar linkage knee units.

Study design: A pilot randomized, crossover design.

Setting: Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital, Thailand.

Subjects: Transfemoral amputees using a prosthesis in daily life

Methods: Participants were randomly allocated by block randomization into 2 groups. The knee unit of prostheses used in both groups was changed to the CU polycentric and four-bar linkage knee units but in different sequences. Gait parameters were analyzed by using gait analysis when walking at a comfortable speed.

Results: Of the 10 participants, 80 percent were classified as K3 level of functional classification. The mean duration of amputation was 24 years (SD 16) years and mean daily prosthesis use was 6.8 (SD 2.1) hours. There was not a significant difference in gait speed, step length, and cadence of prosthesis side and contralateral side ($p > 0.05$) between the two knee units. However, double limb support time when using the CU polycentric knee unit was statistically significant longer than using the four-bar linkage knee unit (mean difference 0.05 second, 95%CI 0.003-0.100, $p = 0.04$). Amputee satisfaction level and perception of knee stability showed no significant difference between knee units.

Conclusion: Using the CU polycentric knee unit seems feasible and acceptable for K2-K3 transfemoral amputees. However, further development and testing are required before use in clinical practice.

Keywords: gait analysis, amputees, artificial limbs, knee prosthesis

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Introduction

Major components of transfemoral prostheses consist of a socket, a suspension, a knee unit, a pylon and an ankle/foot assembly.[1] The prosthetic knee joint is an essential component to improve transfemoral amputees' mobility functions during stance to prevent the knee buckling and to control the knee motion during the swing phase of a gait cycle.[2] According to prosthetic technological advancement, there are more than two hundred designs of prosthetic knees, ranging from a simple mechanical-controlled single-axis knee unit to a complex microprocessor-controlled knee unit. However, most transfemoral amputees still have gait abnormality because of a lack of active torque generation, loss of somatosensory feedback and limb position awareness, mobile interface between an amputee's stumps and prostheses, pain, contralateral limb problems, and a limit to prosthetic components that fit for the amputee's gait performance.[3]

In Thailand, four-bar linkage polycentric knee units are commonly used due to several advantages including good knee stability, desirable appearance especially while bending the knee, and more foot clearance during swinging when compared with the single-axis knee unit.[4] Their costs are high which limits their usage. Therefore, to lower the cost, the Department of Mechanical Engineering, Faculty of Engineering, Chulalongkorn University (CU) has developed a new knee unit for transfemoral amputees called the "CU polycentric knee unit" (Figure 1), which costs one-half times less than an imported knee unit.[5]

The CU Polycentric knee unit is a prismatic two linkage joint designed from natural knee motion analysis. It can create the same degree of freedom like the 4-bar linkage knee unit does but has fewer components. Knee stability is achieved by setting its alignment to facilitate ground reaction force to be posteriorly to the knee axis. Its adjustable friction ability is comparable with other available knee unit designs.[5] Moreover, assembly and maintenance is easy to perform.[5] For this reason, the CU polycentric knee unit could be a new optimal choice for transfemoral amputees in Thailand.

Since safety is the most important concern for new medical devices, the CU polycentric knee unit passed the stress

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Figure 1. The Chulalongkorn University (CU) polycentric knee unit

test by finite element methods before it was finished,[6] and received ISO 10328, which is a standard structural test of lower-limb prostheses. The strength and endurance of prostheses was tested by a hydraulic simulator that was equivalent to three million strides with a one hundred- and twenty-kilogram load during the heel strike and toe off phase of the gait cycle. Thus, it has adequate knee stability theoretically and mechanically, and is durable for use in transfemoral prosthesis. However, it has had no clinical data to support it in practice; therefore, the objective of this study was to investigate gait parameters and transfemoral amputees' satisfaction when using a prosthesis with the CU polycentric knee unit and comparing it with a 4-bar linkage knee unit.

Method

This was a pilot study of a randomized crossover design which was approved by Faculty of Medicine, Chulalongkorn University Review Board. (Approval number 249-60).

Participants

Amputees with unilateral transfemoral amputation who used a transfemoral prosthesis were recruited and were asked for informed consent. The inclusion criteria consisted of participants had to be aged more than 18 years, have used a prosthesis with a four-bar linkage knee unit at least five hours/day for more than 1 year, have a lower limb prostheses Medicare functional classification level K2 - K4,7 have independent community ambulation without gait aid and be able to complete the study.

Exclusion criteria were inappropriate stumps including a wound, infection, inflammation, the length of stump was too short or too long, a body weight more than 120 kilograms and any underlying problems that obviously affected their walking ability e.g., osteoarthritis of knee, hemiplegia, balance instability, etc.

Materials

Participants' prostheses with standard 4-bar linkage knee units and the CU polycentric knee unit invented and manufactured by the Department of Mechanical Engineering, Faculty of Engineering, Chulalongkorn University, were used during the gait motion analyses. The analyses were performed at the Center of Excellence in Gait & Motion Analysis, King Chulalongkorn Memorial Hospital, by using a Qualisys Motion Capture System (Qualisys AB, Sweden), 6 Oqus cameras, 45 reflective markers capture frequency 120 Hz, Qualisys Track Manager, Visual-3D basic/RT version 3.99.25.6, and Bertec Force Plate.

Procedure

After receiving informed consent, participants' demographics, cause and duration of amputation, duration of prosthesis usage, components of prosthesis and the lower limb prosthesis Medicare Functional Classification level (K-level), were recorded by interviewing and reviewing their medical records.

Using block randomization, the recruited participants were divided into two groups based on sequences of knee unit used for gait motion analysis. Group 1 used the CU polycentric knee unit followed by the 4-bar linkage knee unit and group 2 used the opposite sequence (Figure 2).

All participants were informed to walk at a comfortable speed for 6 trails for each knee unit for gait motion analysis and to stand still on the force plate while eyes opened for 30 seconds and closed for another 30 seconds to record center of pressure (COP) path length for checking stability.

One certified prosthetist-orthotist (CPO) was assigned to change only the knee unit of the participants' prosthesis and maintain the same prosthetic length and alignment by using a prosthetic alignment device. Knee friction adjustment was permitted to achieve participants' familiarization with their prosthesis and walking pattern. After achieving the participants' most comfortable walking ability, they were allowed to have 1-2 days for better familiarization with the changed knee unit before gait motion analysis.

Following the gait motion analyses, they rated their overall satisfaction with the knee units and their feeling of knee stability with a five-point Likert scale of very satisfied, satisfied, neutral, unsatisfied, and very unsatisfied before lastly rating their preference.

Outcome measures

The primary outcomes were spatiotemporal gait parameters including gait speed, step length and cadence, double limb support time and percentage, and center of pressure (COP) path length; and participants' satisfaction with the CU polycentric knee unit and feeling of stability while walking.

The secondary outcomes were other lower limb kinematic and kinetic parameters, and participants' preference.

Statistical analysis

Gait parameters from motion analysis of both groups were gathered and combined according to types of the knee units, the CU polycentric and the 4-bar linkage knee units. The quantitative data were showed in means and standard

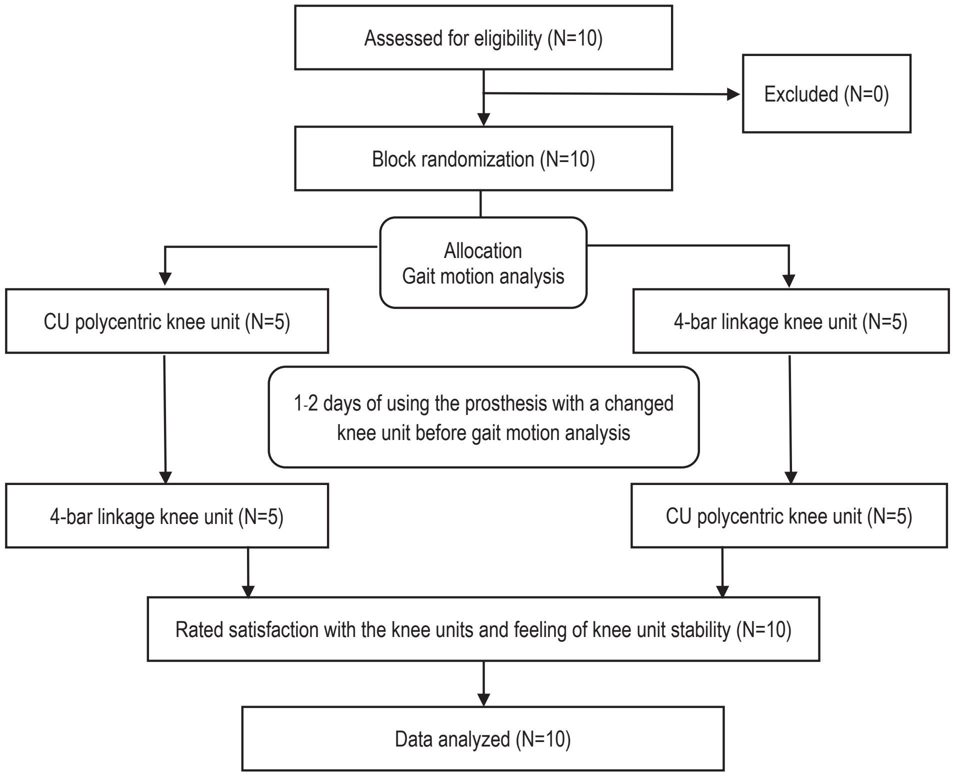

Figure 2. Schematic flow diagram of the study

deviations. The qualitative data were showed in frequencies and percentages. The SPSS version 22 was used for statistical analysis. Mean differences of recorded gait parameters between groups values were analyzed using a paired t-test for parametric data and a Wilcoxon signed-ranks test for paired ordinal data with a confidence limit of $p < 0.05$. The satisfaction score was analyzed using a Chi-square test.

Results

All ten participants completed the study (Figure 2). All participants in the study were males with a mean age of 55 years and a mean duration of amputation of 24 years. Traffic accidents were the causes of amputation. Seven participants used prostheses with a SACH foot and others with a single-axis ankle and foot assembly. The mean duration of current prostheses used was 1.6 years and the daily use of prosthesis was 6.8 hours per day. Eight were classified as K3 level. Some reported underlying diseases such as hypertension and dyslipidemia (Table 1).

A comparison of the spatiotemporal gait parameters between walking with the CU polycentric and the 4-bar linkage knee units is presented in Table 2. There were no statistical differences in gait speed, step length and cadence of the prosthetic leg and sound leg, as well as the COP path length when standing with eyes closed and eyes open for 30 second between the two knee units. Double limb support time was the only parameter that showed a statistically significant difference between the two knee units. The CU Polycentric had a longer double limb support time than the four-bar linkage knee unit had (mean difference = 0.05 seconds or 2.74% of gait cycle, $p = 0.04$).

Table 3 shows a comparison of kinematic parameters while walking between the two knee units. There was signifi-

Table 1. Demographic, medical, amputation-related and prosthetic-related data of the 10 participants

	Mean (SD)	N
Demographic data		
Age (years)	55 (12)	
Gender (male/female)		10 / 0
Underlying diseases		
- Hypertension		3
- Dyslipidemia		3
Amputation-related data		
Cause of amputation, traffic accident		10
Duration of amputation (years)	24 (16)	
Stump length (percentage)	69 (11)	
Prosthetic-related data		
Ankle/foot assembly		
- SACH foot		7
- Single axis		3
Duration of current prosthesis used (years)	1.6 (1.0)	
Duration of daily prosthesis used (hour)	6.8 (2.1)	
K-level		
- K2		2
- K3		8
- K4		0

SACH, solid ankle cushion heel; K-level, the lower limb prosthesis Medicare Functional Classification level

Table 2. Comparison of spatiotemporal gait parameters between the two knee units

Spatiotemporal parameter	CU polycentric	4-bar linkage	Mean difference	95%CI	*p*-value
Gait speed (m/s)	0.70 (0.18)	0.76 (0.20)	-0.06	-0.16 to 0.04	0.22
Step length (m)					
Prosthetic leg	0.57 (0.10)	0.60 (0.09)	-0.03	-0.07 to 0.01	0.11
Sound leg	0.47 (0.11)	0.50 (0.11)	-0.03	-0.08 to 0.01	0.13
Cadence (step/min)					
Prosthetic leg	71.49 (11.48)	74.09 (10.35)	-2.60	-8.27 to 3.07	0.33
Sound leg	90.85 (13.32)	90.19 (12.29)	0.67	-4.4 to 5.76	0.77
Double limb support (s)	0.47 (0.19)	0.42 (0.16)	0.05	0.003 to 0.10	0.04
Double limb support (%)	29.75 (7.87)	27.04 (7.06)	2.71	0.16 to 5.45	0.04
COP path length (m)					
Open eyes	2.615 (0.309)	2.628 (0.372)	-0.013	-0.103 to 0.077	0.75
Close eyes	2.723 (0.386)	2.751 (0.373)	-0.028	-0.128 to 0.072	0.54

Mean (SD); CU, Chulalongkorn University; m, meter; s, second; min, minute; COP, center of pressure

Table 3. Comparison of kinematic parameters while walking between the two knee units

	CU polycentric	4-bar linkage	Mean difference	95%CI	*p*-value
Peak hip flexion (degree)					
Prosthetic leg	30.73 (9.32)	31.05 (9.87)	-0.32	-4.43 to 3.79	0.86
Sound leg	34.99 (9.40	32.82 (7.73)	2.16	-1.89 to 6.21	0.26
Peak hip extension (degree)					
Prosthetic leg	7.76 (7.65)	6.83 (6.21)	0.93	-1.80 to 3.65	0.46
Sound leg	6.69 (3.12)	6.57 (6.19)	0.12	-4.4 to 4.77	0.96
Peak knee flexion (degree)					
Prosthetic leg	40.04 (21.85)	57.17 (21.56)	-17.13	-30.27 to -3.99	0.02*
Sound leg	59.08 (9.84)	60.38 (5.59)	-1.30	-8.83 to 6.24	0.71
Minimum toe clearance (cm)					
Prosthetic leg	3.82 (1.83)	4.27 (2.02)	-0.45	-1.21 to 0.31	0.21
Sound leg	4.89 (1.04)	4.78 (1.98)	0.10	-1.00 to 1.21	0.83

Mean (SD); CU, Chulalongkorn University; cm, centimeter

Table 4. Comparison of kinematic parameters while walking between the two knee units

	CU polycentric	4-bar linkage	Mean difference	95%CI	*p*-value
Peak hip extension moment (Nm/kg)					
Prosthetic leg	0.17 (0.14)	0.18 (0.14)	-0.01	-0.18 to 0.15	0.85
Sound leg	0.50 (0.28)	0.32 (0.09)	0.18	-0.02 to 0.37	0.07
Peak hip flexion moment (Nm/kg)					
Prosthetic leg	0.30 (0.15)	0.35 (0.16)	-0.06	-0.17 to 0.05	0.25
Sound leg	0.25 (0.21)	0.25 (0.15)	0.01	-0.09 to 0.10	0.89
Peak knee extension moment (Nm/kg)					
Prosthetic leg	0.17 (0.14)	0.18 (0.14)	-0.01	-0.18 to 0.15	0.85
Sound leg	0.50 (0.28)	0.32 (0.09)	0.18	-0.02 to 0.37	0.07
Peak knee flexion moment (Nm/kg)					
Prosthetic leg	0.30 (0.15)	0.35 (0.16)	-0.06	-0.17 to 0.05	0.25
Sound leg	0.25 (0.21)	0.25 (0.15)	0.01	-0.09 to 0.10	0.89

Mean (SD); CU, Chulalongkorn University; Nm, Newton-meter; kg, kilogram

cant difference of peak knee flexion angle during the swing phase of the prosthetic leg. The CU-Polycentric knee unit had a lower peak knee flexion angle during the swing phase than the four-bar linkage knee unit [40.04 (SD 21.85) vs 57.17 (SD 21.56) degrees, mean difference 17.13, *p* = 0.02]. Other kinetic parameters including peak hip flexion angle, peak hip extension angle and minimum toe clearance were not significantly different between the two knee units (Table 4). Figure 3 and Figure 4 demonstrate the average of the hip and knee angles and moments from all participants comparing the CU polycentric and the 4-bar linkage knee units. Table 5 reveals that there were no statistical differences of participants' overall satisfaction and feeling of knee stability while walking between the two knee units. Regarding participants' preference based on overall satisfaction, 5 preferred the 4-bar linkage knee unit, 2 preferred the CU-polycentric knee unit, and 3 preferred both equally; finally, based on knee stability, only 1 preferred the former but 5 preferred the latter and the rest preferred both equally.

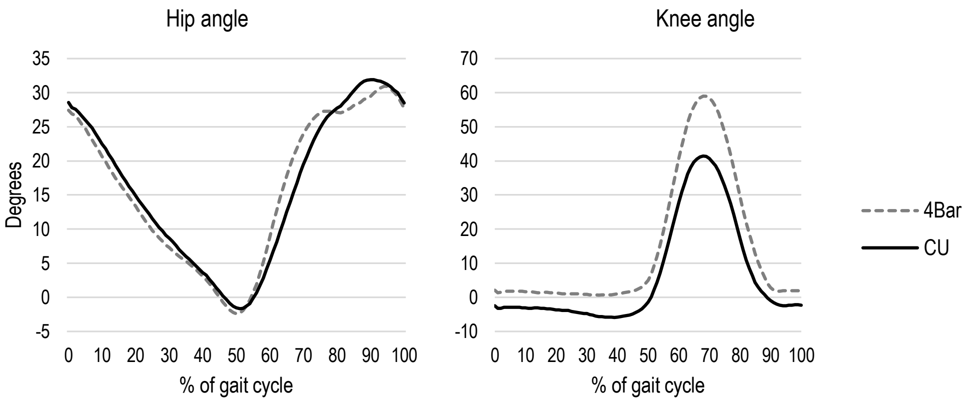

Figure 3. Average hip and knee angles during the gait cycle of the CU polycentric and 4-bar linkage knee units

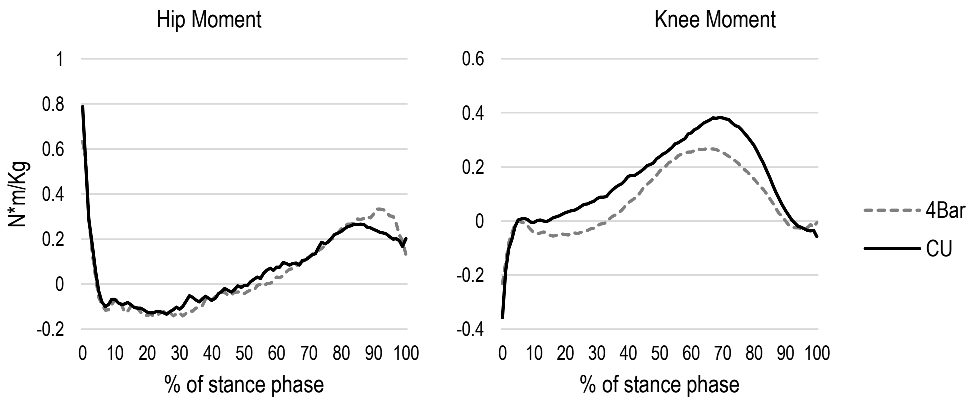

Figure 4. Average hip and knee moments during the gait cycle of the CU polycentric and 4-bar linkage knee units

Table 5. Comparison of the overall satisfaction and feeling of knee stability while walking between the two knee units

	CU Polycentric	4-bar Linkage	*p*-value
Overall satisfaction			0.161
Very satisfied	1	3	
Satisfied	3	3	
Neutral	5	4	
Unsatisfied	0	0	
Very unsatisfied	1	0	
Feeling of knee stability			0.084
Very satisfied	1	4	
Satisfied	3	2	
Neutral	5	4	
Unsatisfied	0	0	
Very unsatisfied	1	0	

Number: Wilcoxon signed-ranks test; CU, Chulalongkorn University

Discussion

This is the first report on comprehensive biomechanical evaluation with spatiotemporal, kinetic and kinematic data in amputees with transfemoral amputation who have experience with the new CU polycentric knee unit. All participants were experienced prosthesis users. In this study, we gave priority to participants' walking ability, thus knee friction and extension assist properties could be adjusted during the fitting process to maximize their walking ability and satisfaction. According to previous studies, a higher gait speed is associated with greater functional independence[8] whereas a comfortable speed is a gait speed that amputees consume with a minimum energy per walking distance,[9] and in the gait analytic study, gait speed is the first parameter that should be concerned not only because of energy expenditure but also kinematic and kinetic gait parameters deviations.[10]

In this study, all participants were used to a transfemoral prosthesis with a 4-bar linkage knee unit and their mean gait speed was 0.76 m/s while walking comfortably. When using the CU polycentric knee unit, the mean gait speed was 0.70 m/s, which was slower. However, according to a prior systematic review, minimal clinically important differences of gait speed ranged from 0.1 to 0.17 m/s.[11] Therefore, a slower gait speed of 0.06 m/s was not clinically significant. Most of transfemoral amputees have gait deviations with decreased self-selected gait speed, short intact limb step length and decrease cadence.[12] These spatiotemporal gait parameters deviations were demonstrated in both groups, the CU Polycentric and the four-bar linkage knee units, without a significant difference. The shorter double limb support time in gait cycles is caused by better stability and less balance concern during walking.[8] Although the CU polycentric had a statistically significant longer double limb support time than the four-bar linkage, the mean difference of 0.05 seconds was clinically insignificant. In addition, COP path length had a difference of less than 2 cm between the two knee units, which did not reach a level of statistical significance. The self-reported feeling of prosthetic/knee stability showed statistically insignificance but there was a trend that the 4-bar linkage knee unit was preferable to the CU polycentric.

The peak knee flexion angle during the swing phase is caused by a ground reaction force while toe-off generated the knee flexion moment, and the knee flexion motion from this force is controlled by proper friction of the knee unit.[3] In this study, the CU polycentric had a smaller peak knee flexion angle during the mid-swing phase than the 4-bar linkage had, as shown in Figure 1. This might be a result of the CU Polycentric knee unit having a different path of instantaneous center of rotation whereas the 4-bar linkage might enhance the apparent ankle dorsiflexion and shank shortening translation.[13] Hence, the CU Polycentric showed a smaller peak knee flexion angle during the swing phase while the minimum toe clearance was not significantly different. However, the assumptions should be further investigated in a mechanical study.

This study had some limitations. Firstly, it was a pilot cross-over study with 10 participants. The results of analytic statistics should be interpreted cautiously due to the small sample size. Secondly, this study focused on comparing the knee units, not correcting participants' gait deviation. We allowed them to have 1-2 days for familiarization with the new knee unit due to ethical reasons, which might not be long enough. We believed that experienced prosthesis users could easily adapt to the new knee unit to the point that waiting for another week or month would not change the walking parameter significantly. Additionally, we used the cross-over design in which both knee units were used first or second equally during the gait analysis. Thirdly, all participants were male, active, and amputated by reason of accident. Recruitment of amputees with different characteristics should be considered. Lastly, there were no clinical data such as complications as gait analysis was done in a short period of time and we did not expect any complications during such. Further study should be done with a larger sample size, a longer training period of at least three weeks[15] and adding a physical therapy program to maximize long-term outcomes. In addition, further study is needed to explore clinical outcomes over the long-term use of the CU polycentric knee unit.

In conclusion, this is the first pilot study comparing the CU Polycentric and the 4-bar linkage knee units, there were no significant differences of gait parameters in terms of gait speed, step length, cadence, peak hip extension and flexion angle, minimum toe clearance, hip extension and flexion moment, overall satisfaction and feeling of stability. Nevertheless, the CU Polycentric knee had a 0.05 second longer double limb support time (2.71% of gait cycle) and a smaller peak knee flexion angle in the prosthesis leg than the 4-bar linkage knee unit had. Further research is needed for further development of the CU polycentric knee unit before use in clinical practice.

Disclosure

The authors certify that there is no conflict of interest with any financial organization regarding the materials discussed in the manuscript.

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References

1. Lovegreen W, Murphy DP, Smith WK. Lower limb amputation and gait. In: Cifu DX, editor. Braddom's Physical medicine and rehabilitation. 5th ed. Philadelphia: Elsevier Health Sciences; 2015. p. 191-224.
2. Walsh NE, Bosker G, Maria DS. Upper and lower extremity prosthetics. In: Frontera WR, DeLisa JA, editors. DeLisa's Physical medicine & rehabilitation: principles and practice. 5th ed. Philadelphia: Wolters Kluwer/Lippincott Williams & Wilkins Health, 2010. p. 2017-50
3. Wilken JM, Marin R. Gait analysis and training of people with limb loss. In: Pasquina P, Cooper RA, editors. Care of the combat amputee. Washington, DC: Office of the Surgeon General at TMM Publications, Borden Institute, Walter Reed National Military Medical Center; 2009. p. 535-52.
4. Gard SA, Childress DS, Uellendahl JE. The influence of four-bar linkage knees on prosthetic swing-phase floor clearance. J Prosthet Orthot. 1996;8:34-40.
5. Charoenboonvivat S. Design of knee joint mechanism for leg prosthesis [dissertation/ MSc]. Bangkok: Chulalongkorn University; 2010.
6. Lapapong S, Sucharitpwatskul S, Pitaksapsin N, Srisurangkul C, Lerspalungsanti S, Naewngerndee R, et al. Finite element modeling and validation of a four-bar linkage prosthetic knee under static and cyclic strength tests. J Assistive Rehabil Ther Technol. 2014;2:23211.
7. United States Health Care Financing Administration. Healthcare common procedure coding system. In: US Department of Health and Human Services, editor. Washington DC: 2001.
8. Barr JB, Wutzke CJ, Threlkeld AJ. Longitudinal gait analysis of a person with a transfemoral amputation using three different prosthetic knee/foot pairs. Physiother Theory Pract. 2012;28:407-11.
9. Esquenazi A.Gait analysis in lower-limb amputation and prosthetic rehabilitation. Phys Med Rehabil Clin N Am. 2014;25:153-67.
10. Kaufman KR, Frittoli S, Frigo CA.Gait asymmetry of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees. Clin Biomech. 2012;27:460-5.
11. Bohannon RW, Glenney SS. Minimal clinically important difference for change in comfortable gait speed of adults with pathology: a systematic review. J Eval Clin Pract. 2014;20:295-300.
12. Highsmith MJ, Andrews CR, Millman C, Fuller A, Kahle JT, Klenow TD, et al. Gait training interventions for lower extremity amputees: a systematic literature review. Technol Innov. 2016;18:99.
13. Sensinger JW, Intawachirarat N, Gard SA.Contribution of prosthetic knee and ankle mechanisms to swing-phase foot clearance. IEEE Trans Neural Syst Rehabil Eng. 2012;21:74-80.
14. Noble JW, Prentice SD. Adaptation to unilateral change in lower limb mechanical properties during human walking. Exp Brain Res. 2006;169:482-95.
15. English RD, Hubbard WA, McElroy GK.Establishment of consistent gait after fitting of new components. J Rehabil Res Dev. 1995; 32:32-5.