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Biomechanical and clinical evaluation of a newly designed polycentric knee of transfemoral prosthesis

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Abstract—We have designed a new polycentric knee adopting a hydraulic unit and an intelligent mechanism. The biomechanical parameters of this prototype, such as the stance duration, peak knee flexion angle in stance and swing, peak hip flexion angle, and peak hip extension moments were analyzed at three different cadences (88, 96, 104 steps/min) in three amputees, and then compared to those of polycentric hydraulic knees currently in use. The same parameters were also measured for 10 healthy volunteers and subsequently analyzed. In the prototype, almost all the values of the parameters showed no significant variety in individuals at the different cadences. The situation was the same with the healthy volunteers. However, the values of the parameter for the conventional knee varied significantly with the individual at the different cadences. The prototype may be of practical use, contributing to a stable walk even at different cadences.

Key words: biomechanics, hydraulic, knee joint, pneumatic, polycentric, prototype, transfemoral prosthesis.

INTRODUCTION

Losing a leg is one of the most difficult things to cope with, and every amputee expects an ideal prosthesis that enables him or her to walk the same way he or she did before the loss of limb. The knees of transfemoral prostheses currently in use contain excellent control mechanisms, which work during either the stance phase or the swing phase or both, allowing amputees to walk naturally and maintain balance while adapting to various road conditions [1]. Among these, computer-controlled prostheses are now available and contribute greatly to a better life for amputees. The C-Leg (Otto Bock Orthopedic Industry, Inc., Minneapolis, MN) is one of them [2]. Much advertising exists in the media for this new model, but little can be found in the literature about its clinical and biomechanical data [3–7].

We have designed a new polycentric knee for experimental use, which can produce a stable stance knee flexion and easy swing corresponding to a change in walking speed. The prototype has a 4-bar linkage with a pair of intermediate links, a hydraulic unit working during the stance phase, and a pneumatic unit controlled by a microprocessor working during the swing phase (the intelligent knee). This study compared the biomechanical gait parameters for transfemoral amputees at different cadences with those for healthy volunteers and examined the functional performance and subjective evaluation of the prototype compared to those for the prosthetic knees currently being used.

Abbreviation: EBS = ergonomically balanced stride.

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METHODS

Subjects

Three unilateral transfemoral amputees, who had been using prosthesis for more than 3 years, participated in this study. All subjects were males with amputations at the midthigh level, and whose amputations were caused by trauma. The side of the amputated leg was right in two and left in the one. The mean age, body weight, and height were 28.0 ± 1.5 years, 61.0 ± 9.0 kg, and 172.0 ± 1.5 cm, respectively. Ten male healthy volunteers participated in the collection of normal biomechanical data for comparison with those of the amputees. Their mean age, body weight, and height were 22.0 ± 1.5 years, 71.0 ± 8.9 kg, and 175.0 ± 5.8 cm, respectively.

Newly Designed Polycentric Knee

The prototype has a polycentric knee joint and two different control units (**Figures 1** and **2**). One is a hydraulic unit (A2M20, Taiyo-Tekko Ltd., Osaka, Japan) used during a weight-activated flexion stance, and the other is a pneumatic unit controlled by a microprocessor (TC32X48RC, Nabco Ltd., Kobe, Japan) allowing an easy swing responding to different walking speeds [8]. The polycentric knee consists of a 4-bar linkage with a pair of intermediate links. The intermediate links keep the knee in a lock-on position and prevent knee collapse. The hydraulic unit supports the load transferred through the knee and allows a stance knee flexion to aid in weight acceptance. When the load starts to diminish at the beginning of the second double-limb support, the intermediate links are no longer blocked on the stoppers. The links then shift the knee to a lock-off condition and allow the knee to flex further and prepare for the swing (**Figure 3**). A pneumatic unit controlled by a microprocessor allows an easy swing responding to different walking speeds. The basic design and performance are listed in **Table 1**.

Experimental Setup

Prior to the testing session, the subjects and healthy volunteers read and signed informed consents in accordance with our institutional guidelines. The 3R60 (Otto Bock Orthopedic Industry, Inc., Minneapolis, MN) was chosen for comparison with the prototype in this study, because it is a polycentric hydraulic knee with an ergonomically balanced stride (EBS) widely used in moderately active adults [9], and because all the subjects had currently been using it.

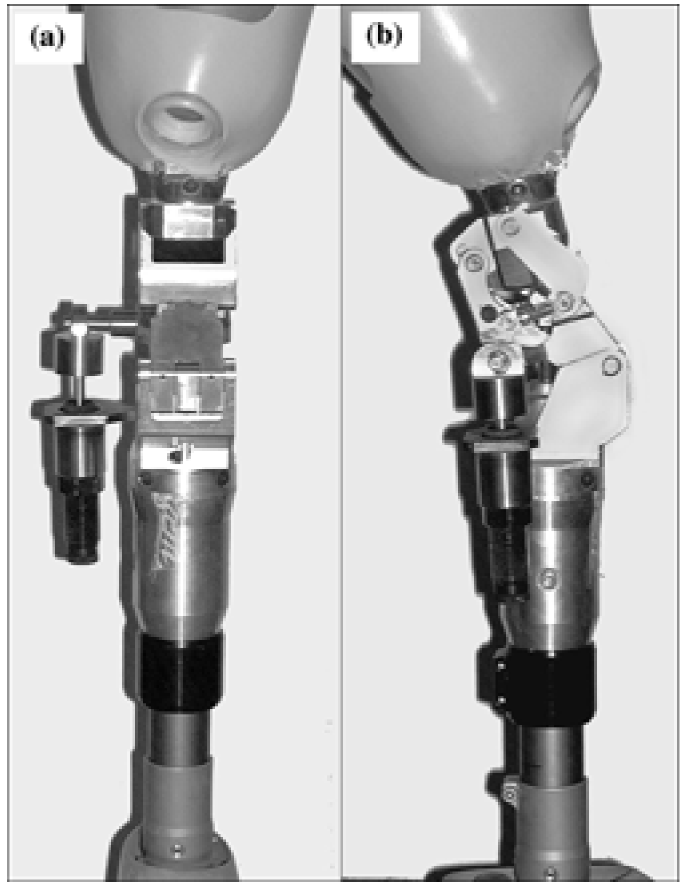

Figure 1.
Prototype overview: **(a)** front view and **(b)** lateral view. A hydraulic unit is built-out and a pneumatic unit is built-in.

They alternately wore the test prostheses, or an identical ischial-ramal containment socket and energy storage foot. The test prostheses were fitted and aligned properly by one of the authors (Nosaka T, CPO, PhD), an experienced prosthetist. The subjects were trained indoors for 30 min to familiarize themselves with the test prosthesis. They were instructed to walk on a platform containing two force plates (9286A, Kistler Instrument Corp., Amherst, NY) set 40 cm apart in a column. Gait analysis was performed more than three times on each subject and the healthy volunteers at three different cadences (88, 96, 104 steps/min), keeping time with an electrical metronome. Each force plate recorded the ground reaction force of the fourth and fifth prosthetic steps. Kinematic data were collected using a 3-D (three-dimensional) motion analyzer (VICON140, Oxford Metrix Ltd., London, UK) with a four-camera unit surrounding the platform. The infrared light-emitting diodes markers were fixed firmly to the skin over both sides of the acromion, major

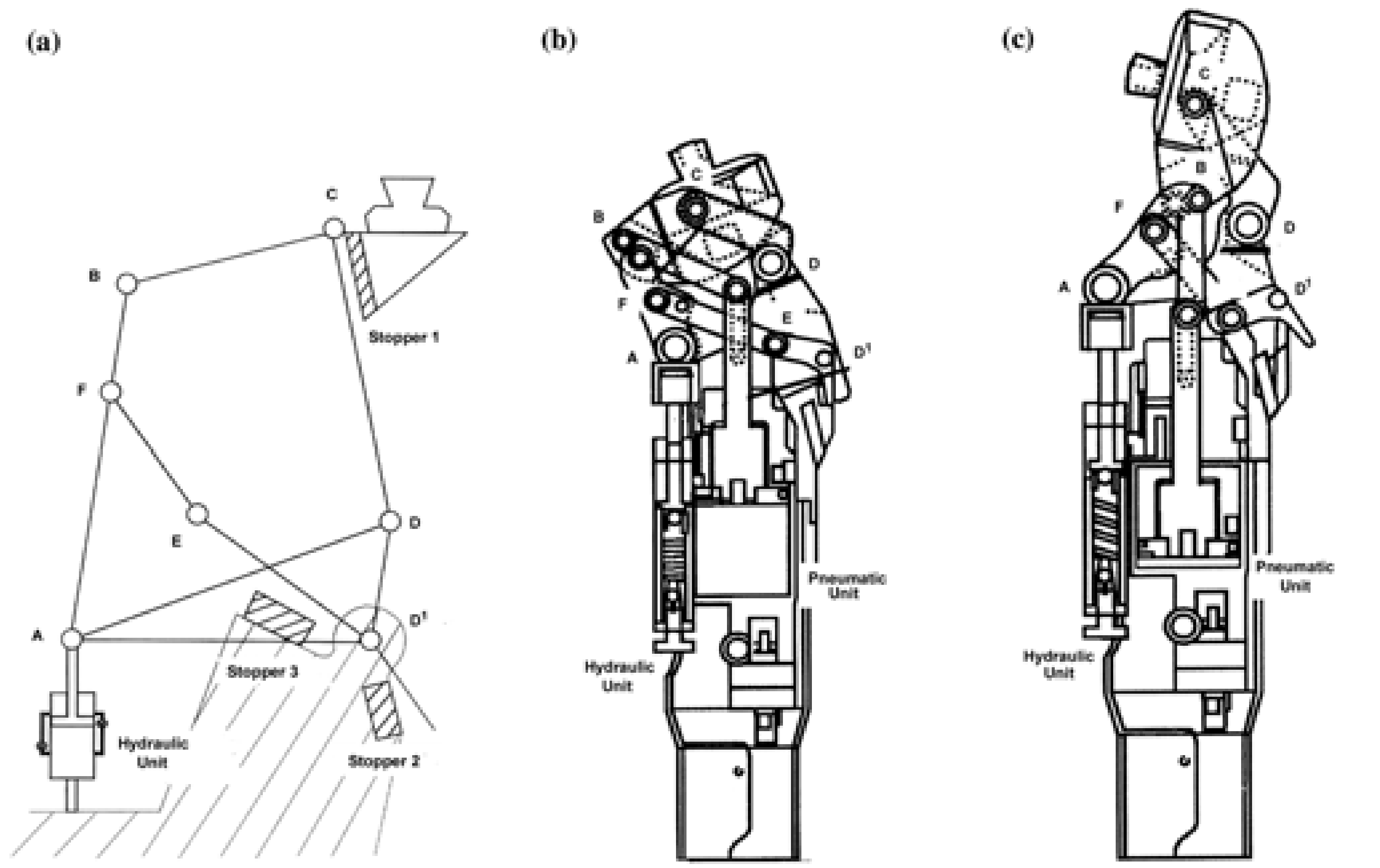

Figure 2.
Diagram of prototype basic structure: **(a)** A 4-bar linkage (AB, BC, CD, and ADD[1]) with a pair of intermediate links (EF, D^1E) and three stoppers installed near links. Link BC is fixed to the thigh. One end of intermediate links connects with link AB at F, and other end connects with a shank at D^1. **(b)** The hydraulic unit works during stance phase to produce a weight-activated flexed stance. **(c)** A microprocessor-controlled pneumatic unit works during swing phase to produce an easy swing in response to different walking speeds.

trochanter of the hip, lateral condylus of the knee joint, fibular malleolus of the ankle, and proximal base of the fifth metatalus. Markers were fixed on the corresponding sites of the skeleton of the test prosthesis in the same way as the sound limb. The force plate and 3-D kinematic data were converted simultaneously and recorded as digital data in a personal computer (Gateway Performance 700, Gateway Companies, Inc., Poway, CA). The sampling frequency was 60 Hz and the cutoff frequency was 6 Hz. Joint angles and moments were calculated using the technique described by Winter et al. [10,11].

This study focused on how the biomechanical data of the prosthetic gait varied with changing speed. The optimal outdoor walking speed for the subjects ranged from a cadence of 90 to 100, so three different cadences (88, 96, 104 steps/min) were adopted.

Data Analysis

The stance to compare duration, the peak knee flexion angle at the early stance and during the swing phase, the peak hip flexion angle, and the peak hip extension moment were measured the two prosthetic knees at the different cadences. We analyzed the data with the Kruskal Wallis test statistical analysis software (SPSS, 7.5J for Windows). A p-value of <0.05 was taken as significant.

RESULTS

Biomechanical Parameters for Healthy Volunteers

The stance duration, the peak knee flexion angle at the early stance and during the swing phase, and the peak hip flexion angle in the healthy volunteers showed no

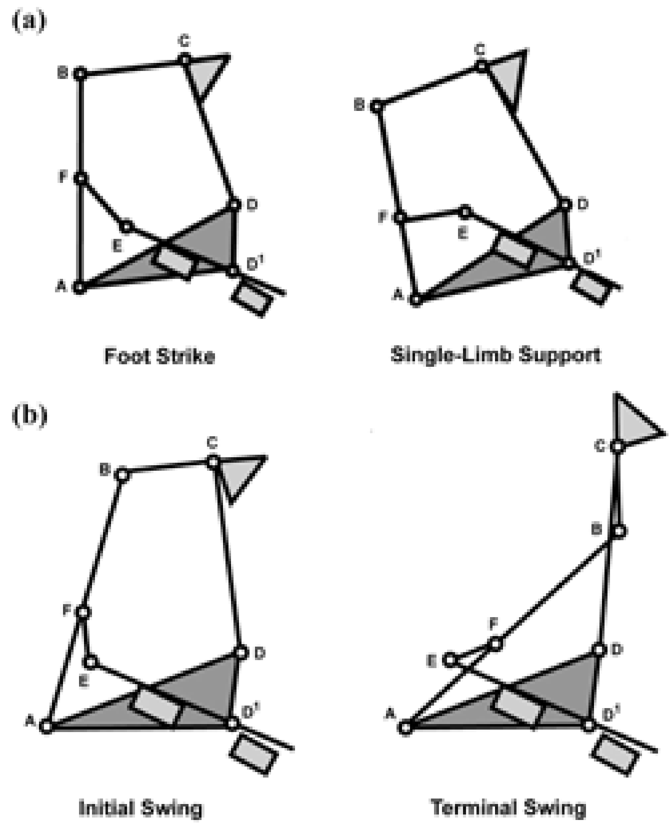

Figure 3.
Diagram of prototype joint mechanism: **(a)** Intermediate links and three stoppers installed near links alter configuration of 4-bar linkage indirectly during stance phase. A hydraulic cylinder supports the load transferred through pivot A and allows a stance knee flexion to aid in weight acceptance. In the meantime, an extended part of link D^1E is blocked by the third stopper. Intermediate links then keep knee in a lock-on position and prevent knee collapse. **(b)** At beginning of the second double-limb support, the load starts to diminish and intermediate links are no longer blocked on the stoppers. They then shift knee to a lock-off condition, allowing knee to flex further and prepare for swing. A pneumatic cylinder controlled by a microprocessor attached to pivot B controls swing in response to walking speed.

significant variations values at the different cadences. On the other hand, the peak hip extension moment increased corresponding to the increase in cadence (**Table 2**).

Biomechanical Parameters for Amputees

The values of the biomechanical parameters for the transfemoral amputees were different from those for the healthy volunteers. The stance duration, the peak knee flexion angle at the early stance and during the swing phase, and the peak hip flexion angle tended to be smaller than those of the healthy volunteers. The peak hip extension moments in the amputees were bigger than those in the healthy volunteers (**Tables 2, 3,** and **4**).

Prototype

Comparing the data for the individual at the different cadences, almost all parameters showed no significant variation of the values in the prototype. Only one case (Subject C) showed a statistically significant change in the peak knee flexion angle during the swing phase. One of the three subjects (Subject B) showed a difference of peak hip extension moment at the different cadences (**Table 3**).

The 3R60

All parameters at the different cadences showed statistically significant variation in the values in at least one of three subjects (**Table 4**).

Subjective Evaluation of Two Different Knees

All subjects recognized an increased stability and ease of swing in the prototype. They also felt that the weight of the prototype was lighter than that of the 3R60, despite the fact that the prototype was 0.24 kg heavier. All subjects felt uncomfortable at the slow cadence and an unreliable resistance at the rapid cadence during the swing phase in the 3R60. One of them (Subject B) voiced a concern about possible knee collapse during the stance phase at the slow cadence in the 3R60.

DISCUSSION

The rhythmic stage of human walking and the patterns of movements of the body during free speedwalking are remarkably consistent between individuals. The average walking cycle consists of 62 percent stance phase and 38 percent swing phase. Leg muscles work in a precise, orchestrated fashion to keep the walking cycle constant by inducing proper changes of the joint moments [12–14]. In this study, the stance duration, the peak knee flexion angle at the early stance and during the swing phase, and the peak hip flexion angle in the healthy volunteers showed no significant variation at the different cadences. On the other hand, the peak hip extension moment increased corresponding to the increase in the cadence. This is an anticipated result, which does not contradict the previous report [12–15].

Table 1.
Basic design of prototype and 3R60.

Property	Prototype	3R60
Weight (kg)	1.2	0.96
Maximum Stance Knee Flexion*	11.2	15.0
Maximum Swing Knee Flexion*	155.0	140.0
Stance Control	Hydraulic Unit	Rubber Bumper
Swing Control	Pneumatic Unit*	Hydraulic Unit

*Controlled by a microprocessor

Table 2.
Biomechanical parameters for healthy volunteers.

Parameter	Cadence 88 (Mean ± SD)	Cadence 96 (Mean ± SD)	Cadence 104 (Mean ± SD)	χ^2 Value
Stance Duration (%)	62.2 ± 0.8	62.8 ± 0.8	63.9 ± 1.1	3.31
Peak Knee Flexion Angle at Early Stance*	12.0 ± 3.5	14.5 ± 2.6	15.2 ± 4.8	1.99
Peak Knee Flexion Angle During Swing*	63.6 ± 4.5	64.1 ± 3.4	62.1 ± 2.8	0.62
Peak Hip Flexion Angle*	24.0 ± 3.2	25.1 ± 3.7	24.0 ± 4.8	0.42
Peak Hip Extension Moment (N/m)	4.1 ± 0.7	5.4 ± 1.0	5.8 ± 1.2	6.15*

*One-factorial analysis of variance, $p < 0.05$ SD = standard deviation

Table 3.
Biomechanical parameters for amputees using prototype.

Parameter	Subject	Cadence 88 (Mean ± SD)	Cadence 96 (Mean ± SD)	Cadence 104 (Mean ± SD)	*F*-Value
Stance Duration (%)	A	57.2 ± 0.8	56.0 ± 1.0	54.7 ± 0.8	5.41
	B	60.3 ± 0.6	60.7 ± 0.6	60.2 ± 0.8	1.28
	C	60.0 ± 1.0	62.0 ± 1.0	59.0 ± 1.0	5.6
Peak Knee Flexion Angle at Early Stance*	A	3.2 ± 0.4	3.3 ± 0.4	3.4 ± 0.5	0.04
	B	4.2 ± 0.4	5.0 ± 0.4	4.6 ± 0.6	0.24
	C	10.1 ± 0.6	9.1 ± 0.5	9.6 ± 0.6	2.19
Peak Knee Flexion Angle During Swing*	A	45.0 ± 2.5	46.0 ± 2.7	47.9 ± 3.5	0.77
	B	60.0 ± 3.5	58.3 ± 3.4	60.4 ± 3.6	0.46
	C	41.5 ± 3.7	52.4 ± 3.6	44.6 ± 4.3	6.29
Peak Hip Flexion Angle*	A	20.3 ± 2.7	19.3 ± 2.6	20.1 ± 2.7	0.13
	B	18.1 ± 3.2	23.7 ± 3.1	22.0 ± 3.6	2.29
	C	19.3 ± 3.4	21.7 ± 2.7	20.7 ± 3.2	0.47
Peak Hip Extension Moment (N/m)	A	39.3 ± 8.5	37.1 ± 8.6	39.5 ± 8.2	0.07
	B	17.7 ± 7.5	26.0 ± 6.8	37.5 ± 8.4	5.15
	C	40.6 ± 7.6	47.0 ± 8.5	51.3 ± 9.5	1.17

*Two-factorial analysis of variance, $p < 0.05$ SD = standard deviation

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Table 4.
Biomechanical parameters for amputees using 3R60.

Parameter	Subject	Cadence 88 (Mean ± SD)	Cadence 96 (Mean ± SD)	Cadence 104 (Mean ± SD)	*F*-Value
Stance Duration (%)	A	59.3 ± 0.6	59.3 ± 0.6	59.0 ± 1.0	0.33
	B	68.0 ± 3.3	63.0 ± 0.5	62.0 ± 1.0	6.32*
	C	60.7 ± 1.5	53.0 ± 1.0	54.0 ± 1.0	6.18*
Peak Knee Flexion Angle at Early Stance*	A	6.2 ± 0.5	5.7 ± 0.6	6.1 ± 0.8	0.48
	B	3.6 ± 0.6	3.9 ± 0.6	5.7 ± 0.7	10.35*
	C	10.4 ± 0.5	10.1 ± 0.5	11.1 ± 0.7	2.43
Peak Knee Flexion Angle During Swing*	A	32.6 ± 4.2	40.7 ± 3.5	45.7 ± 4.2	8.31*
	B	53.4 ± 3.9	68.1 ± 3.7	70.5 ± 4.8	14.79†
	C	53.8 ± 4.8	74.7 ± 4.7	80.8 ± 5.2	12.13†
Peak Hip Flexion Angle*	A	22.3 ± 3.2	24.7 ± 3.6	31.5 ± 3.7	0.02
	B	21.0 ± 3.1	21.6 ± 3.5	21.3 ± 3.3	5.55*
	C	29.9 ± 3.6	29.5 ± 3.2	38.8 ± 4.2	6.05*
Peak Hip Extension Moment (N/m)	A	40.8 ± 7.5	34.6 ± 9.5	55.7 ± 10.5	4.10
	B	22.9 ± 6.8	24.2 ± 8.6	39.2 ± 9.7	3.44
	C	36.8 ± 11.4	69.2 ± 13.5	56.2 ± 10.5	5.69*

*Two-factorial analysis of variance, $p < 0.05$ †$p < 0.01$ SD = standard deviation

When transfemoral amputees walk at different speeds, they have to compensate for the pendulum action of the prosthesis by altering their stride length or step rate by tilting the pelvis, or by using other maneuvers, which leads to an abnormal gait and requires extra concentration and physical effort [14]. Because of the lack of most leg muscle function, the values of the biomechanical parameters for the transfemoral amputees were different, as was predicted, from those for the healthy volunteers.

Transfemoral prostheses work best when aiding the amputees in keeping the walk cycle within the range of normal walking speeds. This problem has been resolved and developed in various knee mechanisms by means of a hydraulic or pneumatic unit incorporated within polycentric knee joints. Among these, the 3R60 is a unique polycentric knee with geometric locking using a 5-bar linkage mechanism. This modular knee offers an EBS with a rubber bumper, which contributes to the production of a stable flexion stance, and provides an automatic swing control with a hydraulic unit [9]. In this study, the biomechanical evaluation focused on the functional performance of the two different knees in maintaining the consistency of the prosthetic walking cycle at the different cadences. Com-parison of the data for individuals at the different cadences using the prototype showed no significant variation in the values of almost all the parameters. The healthy volunteers demonstrated similar results. On the contrary, all parameters showed statistically significant variations in values for individuals at the different cadences in the 3R60.

The prototype used a 4-bar linkage with a pair of intermediate links, a hydraulic unit, and a pneumatic unit controlled by a microprocessor. The linkage, with the hydraulic unit that worked during the stance phase, could produce an accurate movement of the instantaneous center of knee rotation and then deliver a stable and comfortable flexion stance up to 11.2°. The pneumatic unit controlled by a microprocessor, known as “the intelligent knee,” could alter the knee extension level automatically corresponding to walking speed. The amputees perceived improvements in walking at different speeds, walking further, and reduction of energy consumption [3–7] with the prototype. The biomechanical results in this study suggest that the prototype can achieve a comfortable walk and remove the burden of compensation even at different cadences. The subjects' perceptions of the prototype were, on the whole, favorable as well.

Additional studies collecting data under various conditions are needed to elucidate how this prototype could assist amputees who are not satisfied with conventional prostheses. One of the weak points in this study is that the subjects enrolled in it were fit and active, so the results may not be directly transferable to other amputees. In addition, the number of markers for the motion analysis might be too few and consequently exclude the influence of motion of the trunk and pelvis on change of walking strategy according to the different walking speeds. However, the data presented here can serve as objective information about biomechanical investigations of transfemoral prostheses.

CONCLUSION

We have designed a new polycentric knee for experimental use. The prototype has a hydraulic and microprocessor-controlled pneumatic unit and a 4-bar linkage with intermediate links. Most of the values of the prosthetic gait parameters with the prototype showed no significant variation in individuals in the different cadences, as were also demonstrated in the healthy volunteers. Although the prototype needs further improvement for practical use, recent mechanical and microelectronic technology could address this practical issue and produce an easy-to-operate prosthesis for amputees at a reasonable price.

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