

## Article

# Development and Evaluation of a Passive Mechanism for a Transfemoral Prosthetic Knee That Prevents Falls during Running Stance

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**Abstract:** Existing prosthetic knees used by transfemoral amputees have function almost akin to non-friction hinge joints during the running stance phase. Therefore, transfemoral amputees who wish to run need sufficient strength in their hip extension muscles and appropriate prosthetic leg swing motion to avoid falling due to unintended prosthetic knee flexion. This requires much training and practice. The present study aimed to develop a passive mechanism for a transfemoral prosthetic knee to prevent unintended prosthetic knee flexion during the running stance phase. The proposed mechanism restricts only flexion during the prosthetic stance phase with a load on the prosthetic knee regardless of the joint angle of the prosthetic knee. The load on the prosthetic knee required to maintain locked flexion was analyzed. We developed a rough prototype and conducted an evaluation experiment with an intact participant attached to a simulated prosthetic limb and the prototype. The results of level walking showed that the proposed mechanism limits knee flexion, as designed. The results of the preliminary trial suggest that the proposed mechanism functions appropriately during running, where the load on the prosthetic knee is larger than that during walking.

**Keywords:** transfemoral amputee; running; prosthetic knee; passive mechanism



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## 1. Introduction

In recent years, lower-extremity amputees have been able to choose prosthetic leg parts to fit their individual lives and abilities due to the technological advancement of healthcare and engineering. Transfemoral amputees who are amputated at the thigh segment between the knee and hip joints attach a prosthetic knee to recover the knee function. Passive prosthetic knees are widely used for transfemoral amputees [1]. However, a previous study stated that 52.4% of transfemoral amputees reported falling in the past year, whereas 49.2% reported a fear of falling [2]. Existing prosthetic knees cannot support the body when the flexion moment acts on the knee joint by external forces, such as the ground reaction force, during the stance phase. Subsequently, the prosthetic knee is unintentionally flexed, causing a fall.

Importantly, transfemoral prosthetic runners must use a passive prosthetic knee to participate in official para-sport competitions. Existing prosthetic knees for running usually have few functions such as a simple hinge joint in the stance phase. Hence, running prosthetic knees induce a higher risk of falling than daily prosthetic knees. Moreover, the supply of running prosthetic knees is low. Currently, transfemoral amputees use almost the same prosthetic knee, regardless of their running abilities or skills. For this reason, for intact and transtibial amputee runners, they can contact the ground with their leg with its knee flexed, but transfemoral prosthetic runners require full extension of the prosthetic knee to run safely during the prosthetic stance [1,3,4]. Several studies have

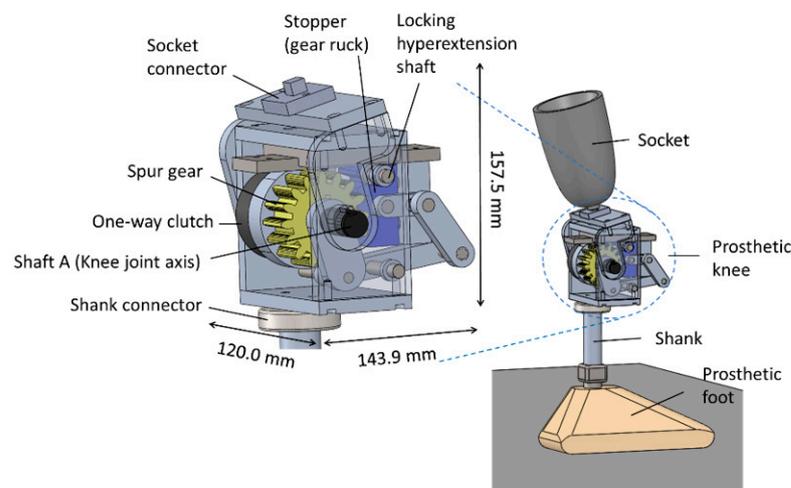
shown that hip extensor muscles play a major role in the process to keep the prosthetic knee fully extended during the prosthetic stance [5,6]. In addition, transfemoral amputees who run have to acquire skills to strike their prosthetic leg on the ground with the knee extended after the swing phase. It takes a certain amount of time to acquire these skills, thus, beginner-level runners have a high incidence of unintended knee flexion during weight-bearing on the prosthetic side. If a new running prosthetic knee has the function of knee flexion lock during the stance phase, even beginners who are not sufficiently trained can run safely. Transfemoral amputees can also choose a non-articulating prosthesis to remove the risk of falls with knee flexion. However, a non-articulating knee results in a stiff-legged gait, which requires compensatory motions that significantly increase the heart rate and oxygen consumption during walking [7]. Similarly, Highsmith et al. [8] suggested that an articulating-knee prosthesis reduces the ambulatory energy costs of transfemoral prosthetic runners when compared to using a non-articulating knee prosthesis. As noted above, prosthetic knees have several advantages. Therefore, a new prosthetic knee that mechanically controls knee flexion only in the stance phase is necessary to address these situations. The purpose of the present study was to develop a prosthetic knee mechanism to prevent unintended prosthetic knee flexion during the running stance phase and hence, for transfemoral amputees to run safely.

## 2. Mechanisms of the Proposed Prosthetic Knee

The main function of the proposed mechanism is to limit flexion during the stance phase to prevent unintended knee flexion. Extension during the stance phase allows the amputee to move forward easily even if the prosthetic leg contacts the ground with its knee flexed. No interference occurs with the flexion and extension during the swing phase.

### 2.1. Structural Design

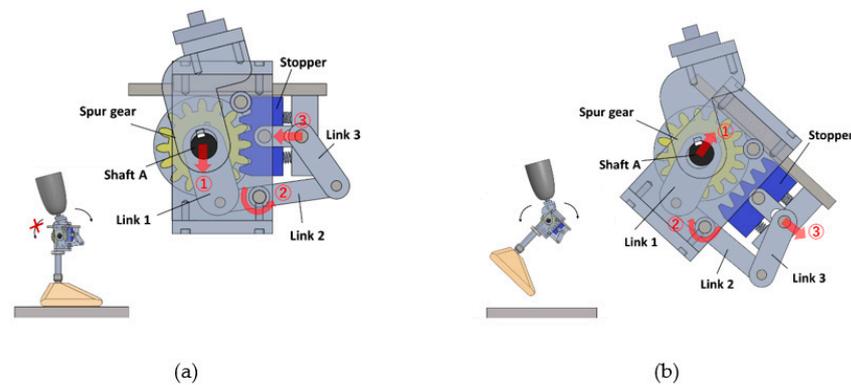
The CAD models of the transfemoral prosthesis assembly and the proposed prosthetic knee are shown in Figure 1 [9]. The dimensions are length 143.9 mm, width 120.0 mm, and height 157.5 mm. The weight of the proposed prosthetic knee is 5.44 kg. The proposed mechanism has a single axis (shaft A) for the flexion and extension of the knee joint axis. Shaft A, which is fixed to the thigh socket via a socket connector, can move in the slit of the housing along the long axis of the shank part. A spur gear was placed on Shaft A. The stopper (gear ruck) was moved along the linear guide mounted on the housing. The stopper moves orthogonally to the long axis of the shank part through several links in accordance the motion of Shaft A. In the present design, when shaft A moves downward by 3.00 mm, the total movement distance of the stopper is 14.36 mm.



**Figure 1.** CAD models of the transfemoral prosthesis assembly and the proposed prosthetic knee.

## 2.2. Flexion Lock Mechanism

As the prosthesis contacts the ground where the compressive force (load) acts on the proposed prosthetic knee along the long axis of the shank part, Shaft A moves downward. Simultaneously, the stopper moves through three links (links 1, 2, and 3 in Figure 2), and contacts the spur gear on shaft A to limit the rotation of the prosthetic knee joint (Figure 2a). This mechanism prevents unintended knee flexion during the stance phase, even if the prosthetic knee joint is not fully extended.



**Figure 2.** Mechanism of the proposed prosthetic knee. (a) Stance phase; (b) swing phase.

Shaft A and the spur gear are attached to the inner ring side and outer ring side of the one-way clutch, respectively. The one-way clutch transmits torque in only one direction between the rings. Therefore, even when the spur gear and stopper teeth are engaged, the mechanism only limits flexion and allows extension.

As the prosthesis is off the ground, its lower leg moves downward relative to the thigh because of its weight. In other words, shaft A is located at the top of the slit during the swing phase. The stopper then separates from the spur gear. Therefore, flexion and extension are not restricted (Figure 2b).

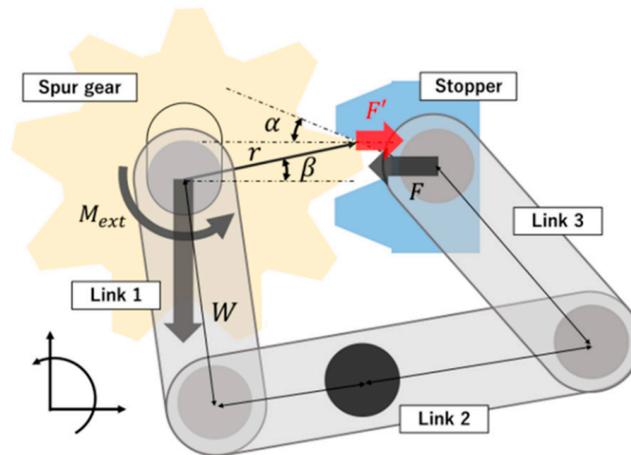
## 2.3. Mechanical Analysis

When the gear and stopper are engaged during the stance phase and when an external flexion moment is generated around the knee joint axis (Shaft A), the gear pushes the stopper back, owing to the tooth angles of the gear and stopper. If the external flexion moment increases, the force of the gear pushing the stopper back also increases. When the pushback force exceeds the maximum static friction between the teeth of the gear and stopper, the gear starts to slip on the stopper. The stopper then separates from the gear and the flexion lock is released. For this reason, the forces on the mechanism were analyzed statically.

When the load pushing shaft A ( $W$ ) down acts on the prosthetic knee during the stance phase, the force ( $F$ ) that pushes the stopper into the gear arises (Figure 3).  $F$  is calculated from the principle of virtual work and shown in Equation (1).

$$F = W \frac{dy}{dx}, \quad (1)$$

where  $dx$  is the microscopic displacement of the stopper in the direction perpendicular to the long axis of the shank part, and  $dy$  is the microscopic displacement of the spur gear in the longitudinal direction of the shank part.



**Figure 3.** Forces and moments acting on the gear and stopper.

Figure 3 illustrates the forces and moments acting on the gear and stopper when the stopper is engaged with the gear. First, when the flexion moment by the external forces ( $M_{ext}$ ) acts around the knee joint axis, the force in the direction orthogonal to the long axis of the shank part exerted by the gears on the stopper ( $F'$ ) is calculated as

$$F' = \frac{M_{ext}(\sin \alpha - \mu \cos \alpha)}{r\{\cos(\alpha + \beta) + \mu \sin(\alpha + \beta)\}} \tag{2}$$

where  $\alpha$  is the pressure angle of the stopper,  $\beta$  is the angle between the line perpendicular to the long axis of the shank part and the line from the center of the gear to the contact point between the gear and stopper,  $\mu$  is the coefficient of static friction between the gear and stopper, and  $r$  is the distance from the center of the gear to the contact point.

The condition for the stopper to remain in the gear is given by Equation (3).

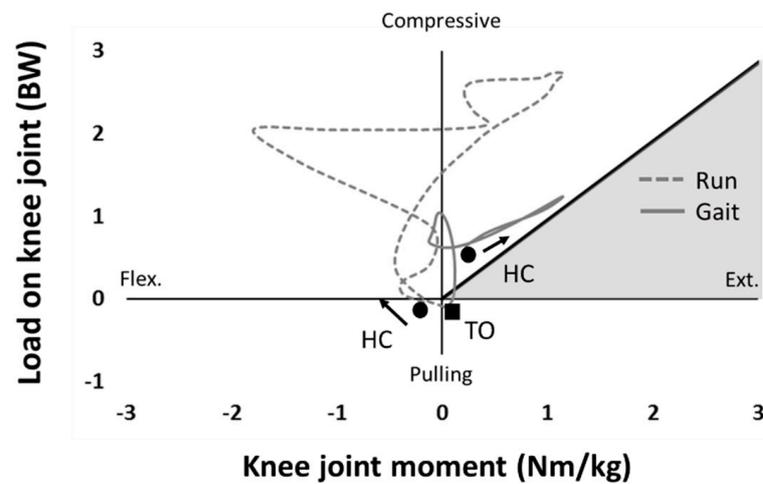
$$F' \leq F \tag{3}$$

therefore, if the load ( $W$ ) is sufficiently large, the condition of Equation (3) is maintained, and slip does not occur. The load ( $W$ ) required for the stopper to remain on the gear is given by Equation (4), derived from Equations (1)–(3).

$$W \geq \frac{M_{ext}(\sin \alpha - \mu \cos \alpha)}{r\{\cos(\alpha + \beta) + \mu \sin(\alpha + \beta)\}} \frac{dx}{dy} \tag{4}$$

as the running speed is slower, the joint reaction force (equivalent of  $W$ ) is smaller [10]. It is assumed that  $W$  at any running speed is larger than that during normal walking [10,11]. In order to restrict flexion at all running speeds, we set that the relationship between  $W$  and  $M_{ext}$  during walking as the maximum requirement. Preliminary experiments were therefore conducted to investigate the relationship between  $W$  and  $M_{ext}$  during walking and running. Figure 4 shows pilot intact subject data (sex: male, age: 21 years, weight: 63 kg, height: 1.70 m) of joint reaction force (equivalent of  $W$ ) and muscle moment (equivalent of  $M_{ext}$ ) during the stance phase of level walking (1.50 m/s) and running (3.29 m/s) on a 10 m straight walkway.  $\alpha$ ,  $\beta$ ,  $\mu$ ,  $r$ , and  $dx/dy$  ( $\alpha = 20^\circ$ ,  $\beta = 8^\circ$ ,  $\mu = 0.3$ ,  $r = 0.032$  m, and  $dx/dy = 5.087$ ) in Equation (4) were set with reference to this preliminary experiment.  $dx/dy$  depends on the link lengths (links 1, 2, and 3). The relationship between  $W$  and  $M_{ext}$  of Equation (4) is also shown in Figure 4. If the relationship between  $W$  and  $M_{ext}$  is in the gray shaded area, the stopper moves on the gear and the stopper eventually separates from the gear. If the same value of  $M_{ext}$  is obtained with the proposed prosthetic knee, the maximum stress acting on the stopper tooth will be 24.88 MPa. However, the kinetics and kinematics of prosthetic legs during walking and running are different from those of able-

bodied and intact legs, owing to prosthetic mechanical properties [5,6,12–17]. Subsequent measurements by amputees wearing the proposed prosthetic knee are necessary.



**Figure 4.** The load on the knee joint required for the stopper to remain at rest on the gear when the flexion moment acts around the knee joint axis. The load was normalized with body weight (BW). Positive moments indicate knee extension moment (Ext.). Positive forces indicate compressive force. ● is the heel contact, and ■ is the toe off.

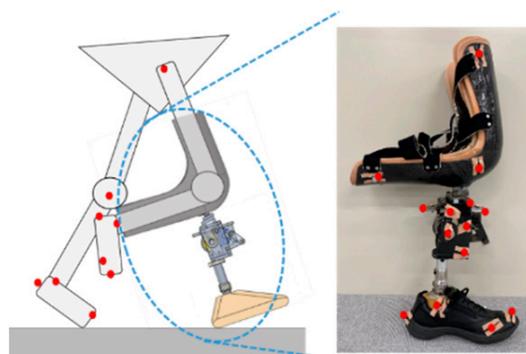
### 3. Evaluation Experiment

The purpose of the evaluation experiment in the present study was to confirm the functions of the stance phase. We developed a rough prototype of the proposed mechanism, and a pilot evaluation experiment was conducted with an intact participant using a simulated thigh socket. Since this evaluation experiment was a trial with an inexperienced subject, only the gait measurements were conducted to ensure safety.

#### 3.1. Methods

##### 3.1.1. Experimental Procedure and Data Collection

One intact person (sex: male, age: 21 years, weight: 63 kg, height: 1.70 m) who obtained informed consent performed level walking on a 10 m straight walkway. The participant attached a simulated thigh socket and the prototype of the proposed prosthetic knee (on the right limb). The ankle joint of the prosthesis was fixed, and a 1D10 (OttoBock) was used for the foot. A total of 71 retro-reflective markers were attached to the bony landmarks and the prosthetic leg (Figure 5). After the practice session, five successful trials each prosthetic leg and intact leg were recorded.



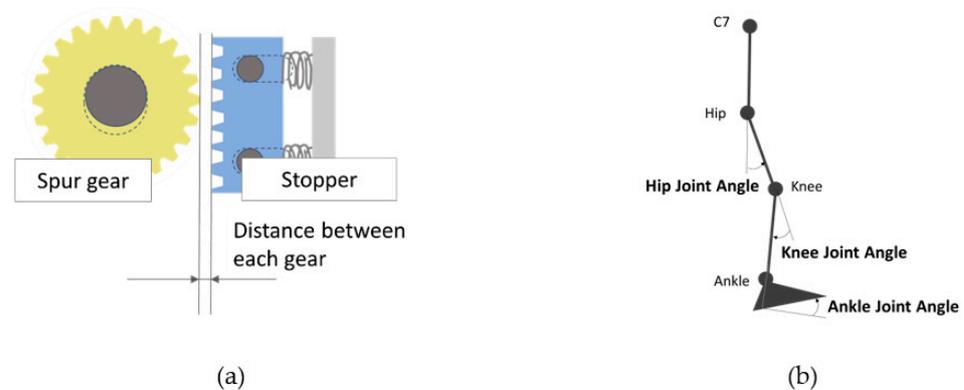
**Figure 5.** Marker placement on the body and prosthetic knee.

Kinematic data were obtained using a three-dimensional motion system (MAC3D, Motion Analysis) with 10 high speed cameras (200 Hz). Ground reaction forces (GRFs) were recorded with three force plates (AMTI) sampled at 2000 Hz.

### 3.1.2. Data Analysis

The marker position and force data were filtered with a fourth-order, zero-lag low-pass Butterworth filter with cut-off frequencies of 6 and 20 Hz, respectively. Then, the ground reaction force data were down-sampled to 200 Hz to correspond to the kinematic data.

The kinematics of the prosthetic knee was determined based on the marker positions. Figure 6 illustrates the definition of the distance between each tip of the spur gear and stopper in the proposed mechanism and joint angles of the lower limb. When the value of the distance is negative, the mechanism locks flexion (fully interlocked by less than approximately  $-5$  mm). Kinetic data were computed from inverse dynamics using kinematic data and measured GRFs.



**Figure 6.** Definition of the kinematics data. (a) Distance between each tip of the gear and stopper. (b) Joint angles of the hip, knee, and ankle.

Inverse dynamic analysis was performed on the intact leg side using AnyBody (AnyBody Technology) [18]. The body was modeled with upper body (head, trunk) and intact leg side (thigh, lower leg, foot) segments. Subsequently, 192 Hill-type muscle models were added to the lower limbs. The hip joint was defined as a spherical joint. The knee and ankle joints were defined as hinge joints. The mass, length, moment of inertia, and muscle anatomy of the body segments were calculated using a template model [19]. Kinematic and kinetic data were calculated from the measured GRFs and body coordinate data, respectively. An optimization method that minimizes the sum of squares of muscle activity was used to estimate the muscle forces. The muscles were grouped according to their function, as shown in Table 1 [14]. Joint moments and muscle forces were normalized to body weight.

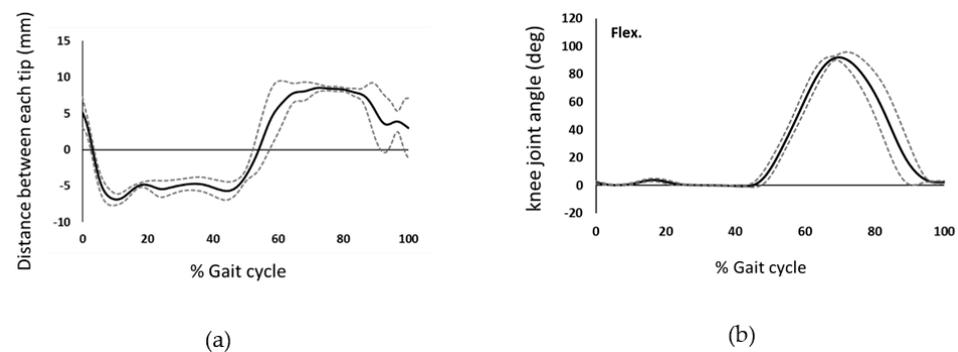
**Table 1.** Intact leg muscles included in the analysis.

Muscles	Muscle Group
Gluteus maximus	GMAX
Gluteus medius	GMED
Biceps femoris, Semitendinosus, Semimembraneus	HAM
Iliacus, Psoas	IL
Vastus lateralis, Vastus medialis, Vastus intermedius	VAS
Rectus femoris	RF
Soleus	SOL
Gastrocnemius	GAS
Tibialis anterior	TA

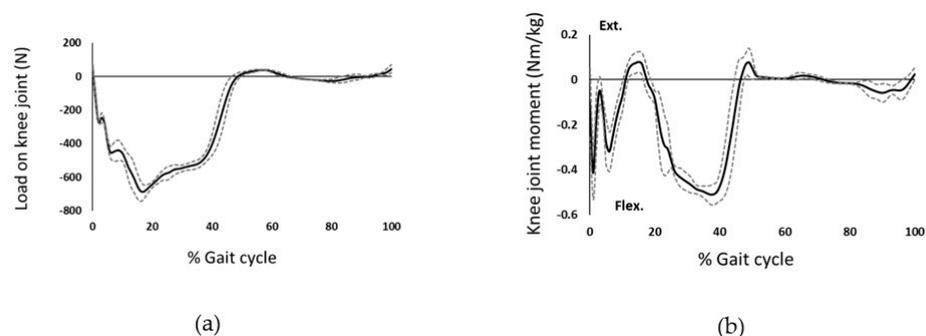
Five successful trials of level walking were collected. All results were normalized to the gait cycle of the prosthetic leg. A foot contact and next foot contact of the prosthetic leg was defined as the beginning (0% GC) and end (100% GC) of a gait cycle, respectively.

### 3.2. Results

The gate speed was  $1.05 \pm 0.03$  m/s, and the stance phase of the prosthetic side was 51% GC. Figure 7a illustrates the distance between the spur gear and stopper. As the prosthetic leg contacts away from the ground, the distance between the gear and stopper rapidly decreases, and the gear and stopper began to mesh at approximately 4% GC. The distance data indicated that the teeth were fully interlocked from 10 to 45% GC. Subsequently, the teeth were separated from each other, and the gear was able to rotate freely. The prosthetic knee joint angle began to flex at 45% GC (Figure 7b). The load on the prosthetic knee ( $W$ ) was compressive (minus values in Figure 8a) from 10 to 45% GC, synchronizing with the distance between the gear and stopper. The flexion moment was generated almost throughout the stance phase, except for 12–16% GC (Figure 8b).

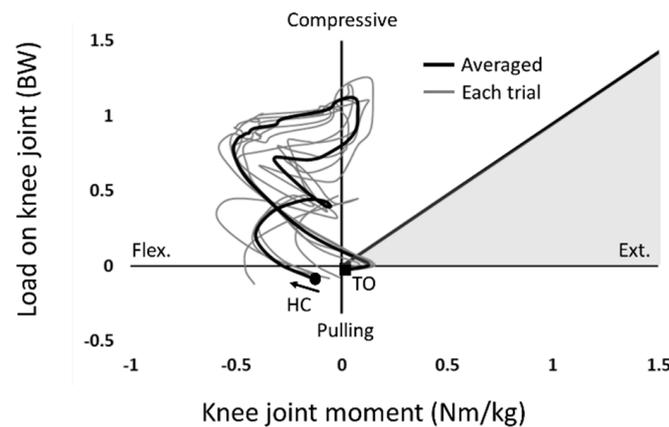


**Figure 7.** Kinematic data while walking. (a) Distance between each tip of the gear and stopper. The negative values indicate that the stopper contacts the gear to limit the rotation of the prosthetic knee joint, and the positive values indicate that the stopper is separated from the gear. (b) Knee joint angle. Positive angles indicate knee flexion (Flex.). The solid and dashed lines indicate the mean values and standard deviations, respectively.



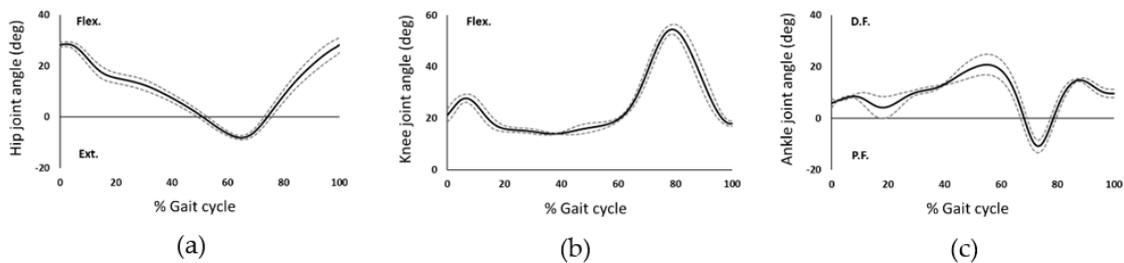
**Figure 8.** Kinetic data of the prosthetic side while walking. (a) Load ( $W$ ). Positive and negative values indicate the pulling and compressive forces, respectively. (b) Knee joint moment of the prosthesis side. Positive value indicates knee extension moment (Ext.). The solid and dashed lines indicate the mean values and standard deviations, respectively.

The curved lines in Figure 9 indicate the relationship between the load on the prosthetic knee ( $W$ ) and the moment (equivalent to  $M_{ext}$ ) during the stance phase. The gray shaded area shows the condition that does not satisfy Equation (4). The curved lines were almost out of the area, except at the end of the stance phase.

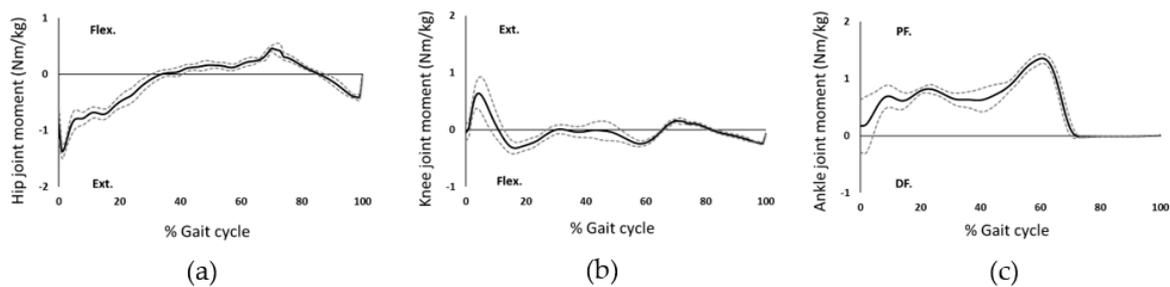


**Figure 9.** Relationship between the moment and the load on the prosthetic knee in the stance phase. Positive and negative values in the moment indicate extension (Ext.) and flexion moments (Flex.). Positive and negative values in the force indicate compressive and pulling forces, respectively. ● is the heel contact (HC), and ■ is the toe off (TO).

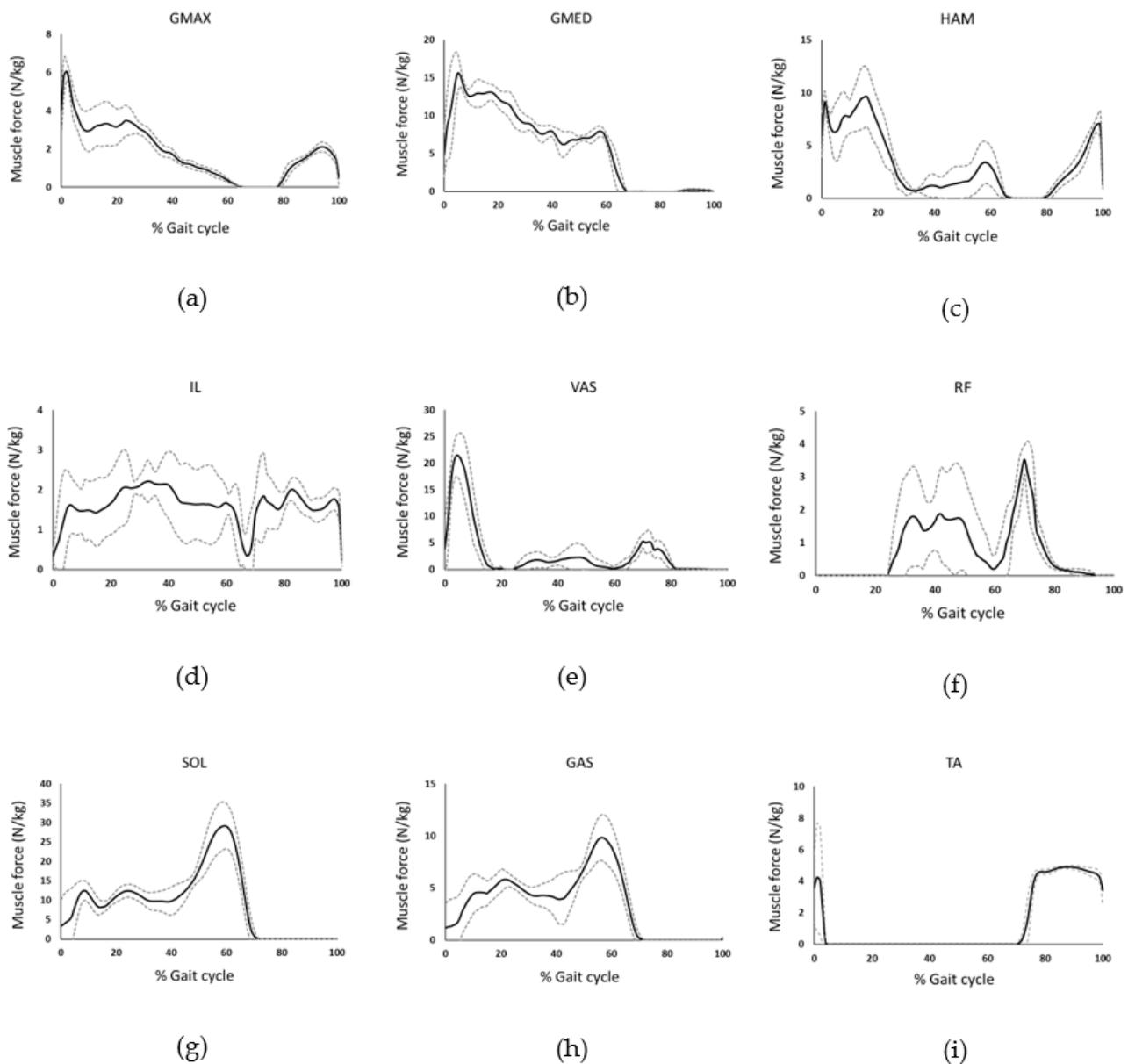
Figures 10–12 illustrate the joint angles, joint moments, and forces of the muscles in the intact leg, respectively. The GC was set with the intact side and started with heel (0% GC) contact and ended with toe off (100% GC) of the intact side. The stance phase of the intact leg was 72% CG. The hip joint generated an extension moment in the first half of the stance phase. The GAMX, GMED, and HAM generated greater forces during this period. The magnitude of the GMED was greater than that of the GMAX and HAM (Figure 12a–c). The knee joint flexed slightly during the loading response (0–7%). The VAS generated greater forces in the loading response, which resulted in the knee joint extension moment (Figures 11b and 12e). The ankle joint was in dorsal flexion during the terminal stance (Figure 10c). The GAS and SOL generated greater forces at this time (Figure 12g,h), which resulted in the ankle joint plantar flexion moment (Figure 11c).



**Figure 10.** Joint angles of the (a) hip, (b) knee, and (c) ankle in the intact legs. The solid and dashed lines indicate the mean values and standard deviations, respectively. Positive angles indicate hip extension (Ext.), knee flexion (Flex.), and ankle dorsal flexion (D.F.).



**Figure 11.** Moments of the (a) hip, (b) knee, and (c) ankle joint of the intact leg. The solid and dashed lines indicate the mean values and standard deviations, respectively. Positive values in the moments indicate hip flexion moment (Flex.), knee extension (Ext.), and ankle plantar flexion moment (P.F.).



**Figure 12.** Forces of muscles in the intact legs. (a) Gluteus maximus (GMAX); (b) Gluteus medius (GMED); (c) Biceps femoris, Semitendinosus, Semimembraneous (HAM); (d) Iliacus, Psoas (IL); (e) Vastus lateralis, Vastus medialis, Vastus intermedius (VAS); (f) Rectus femoris (RF); (g) Soleus (SOL); (h) Gastrocnemius (GAS); (i) Tibialis anterior (TA). The solid and dashed lines indicate the mean values and standard deviations, respectively.

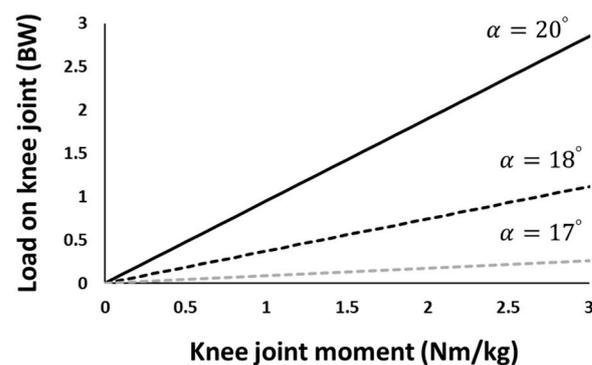
#### 4. Discussion

The present study aimed to propose and analyze a prosthetic knee mechanism to prevent flexion during the prosthetic stance phase in transfemoral amputees. We developed a rough prototype of the mechanism and conducted an evaluation experiment.

The prototype of the proposed mechanism is completely passive and theoretically has no friction; therefore, the moment about the prosthetic knee must have been generated by structural restriction. The flexion moment, which was the reaction to the extension moment by external forces, was induced by the restriction of hyperextension. An extension moment of approximately 15% GC (Figure 8b) was induced by the proposed mechanism. A previous study stated that unintended knee flexion during weight bearing on the prosthetic side occurs, in particular, during the initial 40% of the gait cycle in transfemoral

amputees [20]. The extension moment in the present study indicated that the designed mechanism functioned appropriately and prevented unintended prosthetic knee flexion. The slight flexion at approximately 15% GC (Figure 7b) is attributed to backlash between the gear and stopper. The rough prototype in the present study can theoretically flex a maximum of  $15^\circ$  even when the teeth are fully meshed. Although we could not evaluate the running conditions, the proposed mechanism would have appropriately functioned. A greater load acts on the prosthetic knee during running than during walking. The flexion–lock condition (Equation (4)) may be easier to maintain.

As shown in Figure 9, the gait data were in the gray shaded area immediately before toe-off, indicating a risk of falling. However, the body weight had already shifted to the intact side in this terminal prosthetic stance phase, therefore, the participant would be able to continue walking without falling. If it is necessary to mechanically reduce the risk of falls, a possible solution would be to change the pressure angle ( $\alpha$ ) of the stopper. The prototype in the present study was set up with the pilot data of an intact subject. If  $\alpha$  changes from  $20^\circ$  to  $18^\circ$  or  $17^\circ$ , the load on the prosthetic knee required for the stopper to remain at rest on the gear will be significantly reduced (Figure 13). The maximum stress will be 1.61–1.97 MPa at the tooth root of the stopper of the present prototype. Theoretically,  $\alpha = 0$  is the best for maintaining locked flexion, but a larger pressure angle is ideal for smooth meshing and releasing of the teeth.



**Figure 13.** Change of the load on the prosthetic knee required for the stopper to remain at rest on the gear versus pressure angle ( $\alpha$ ). The black solid indicates  $\alpha = 20^\circ$ . The black and gray dashed lines indicate  $\alpha = 18^\circ$  and  $\alpha = 17^\circ$ , respectively.

The gait patterns of the intact and prosthetic limbs were asymmetric. The proportion of the stance phase in the gait cycle was greater on the intact side. In addition, the knee flexion angles of the intact limb during the stance phase were larger than those of the prosthetic legs (Figure 8b). These temporal and kinematic results agree with those of previous studies that analyzed the gait of unilateral transfemoral amputees by using passive knees [14,16,21]. However, the result of the knee moment in the intact leg disagrees with that of a previous study [22]. As shown in Figure 11b, an extension moment occurred in the knee joint in the loading response (1–11%). Subsequently, a flexion moment was observed until the swing phase was reached. This pattern is more similar to that of intact subjects than that of amputees in a previous study. The difference between the present and previous studies may be due to the muscles around the knee. The present study showed that the VAS generated greater forces in the loading response, which resulted in the knee joint extension moment. Subsequently, the VAS force decreased, and the HAM generated a flexion moment. In contrast, a previous study showed that the HAM generated greater forces in the loading response, which resulted in the knee joint flexion moment. Subsequently, VAS and RF caused an extension moment until the swing phase. These differences may have been induced by the prosthetic knee function. Further research with a larger sample size is required.

In our future work, we will develop a polished prototype with a swing control function in which the dimensions and material must be modified to reduce the mass and downscale

the size of the prosthetic knee. In addition, an evaluation experiment on running with actual amputees is necessary.

## 5. Conclusions

We designed a passive mechanism for a transfemoral prosthetic knee that prevents falls during the running stance phase. The mechanism locks flexion while the prosthetic knee is under load and always allows extension using a one-way clutch. Mechanical analysis of the mechanism revealed the condition required to maintain locked flexion. A greater external force on the prosthetic knee increases resistance to the moment about the prosthetic knee. A rough prototype was developed, and the parameters of the mechanism were set with reference to the intact subject's gait and running parameters to avoid unintentional flexion-lock release during stance. The evaluation experiment showed that the proposed mechanism worked as designed during walking and that the condition for flexion lock was, in general, maintained throughout the stance; therefore, unintended flexion was prevented. These results suggest that the mechanism will function appropriately under normal running conditions.

**Author Contributions:** Conceptualization, K.I. and M.M.; methodology, M.M. and K.I.; software, M.M. and T.M.; validation, M.M., T.M. and K.I.; formal analysis, M.M. and T.M.; investigation, M.M.; resources, K.I.; data curation, K.I.; writing—original draft preparation, M.M.; writing—review and editing, K.I.; visualization, M.M., T.M. and K.I.; supervision, K.I.; project administration, K.I.; funding acquisition, K.I. All authors have read and agreed to the published version of the manuscript.

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**Informed Consent Statement:** Informed consent was obtained from all subjects involved in the study.

**Data Availability Statement:** Not applicable.

**Conflicts of Interest:** The authors declare no conflict of interest.

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