

DETC2015-47385

**DESIGN OF MECHANISM AND PRELIMINARY FIELD VALIDATION OF LOW-COST,
PASSIVE PROSTHETIC KNEE FOR USERS WITH TRANSFEMORAL AMPUTATION
IN INDIA**

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ABSTRACT

An estimated 230,000 above-knee amputees in India are currently in need of prosthetic care, a majority of them facing severe socio-economic constraints. However, only few passive prosthetic knee devices in the market have been designed for facilitation of normative gait kinematics and for meeting the specific daily life needs of above-knee amputees in the developing world. Based on the results of our past studies, this paper establishes a framework for the design of a low-cost prosthetic knee device, which aims to facilitate able-bodied kinematics at a low metabolic cost. Based on an exhaustive set of functional requirements, we present a prototype mechanism design for the low-cost prosthetic knee. The mechanism is implemented using an early stance lock for stability and two friction dampers for achieving able-bodied kinematics and kinetics of walking. For early-stage validation of the prosthesis design, we carry out a preliminary field trial on four above-knee amputees in India and collect qualitative user feedback. Future iterations of the mechanism prototype will incorporate an additional spring component for enabling early stance flexion-extension.

BACKGROUND AND INTRODUCTION

This work is focused on designing low-cost, passive prosthetic knee that can facilitate normative gait and is appropriate for the daily life activities of above-knee amputees in developing countries.

It is estimated that there are currently 30 million people across the world in need of prosthetic and orthotic devices [1-3]. In India alone, we estimate the total number of above-knee amputees to be in excess of 230,000 [4]. Other studies have estimated a number of 6.7 million above-knee amputees in

Asia, with a majority living in developing countries of large population such as India and China [3]. According to an estimate by the World Health Organization, 90-95% of amputees in developing countries do not receive any prosthetic device [5] and only 20% of amputees are able to afford currently available prostheses in the market [6].

A majority of Indian amputees belong to economically poor families [7]. In a past study by Narang et al. [8], 47% of Indian amputees reported changing their occupation after amputation, as most of the amputees were earlier employed in jobs that demanded physical exertion such as agriculture and manual labor involving long hours of standing, walking and lifting heavy weights. In the interviews conducted as a part of our earlier work [4,9], amputees reported social discrimination in their families and communities because of their conspicuous disability and unnatural gait. The severe social consequences and stigma endured by people who undergo lower-limb amputation in the context of different cultures have been well documented [10-12]. Acute financial constraints coupled with socio-economic considerations project an urgent need for a low-cost product that can deliver high levels of functional performance.

Although a number of advanced prosthetic limbs and assistive devices have been designed in the developed world in the last few decades, very few of them have been suitable for large-scale use in developing countries due to vastly different and complex socio-economic considerations and resource-constrained settings. Prosthetic knee joints in the United States and Europe cost several thousand dollars to manufacture and distribute. Popular active above-knee prostheses that deliver very high performance can cost up to \$50,000 [13]. Even the

passive knee joints in developed countries are too expensive to meet the requirements of amputees in the developing world.

Current above-knee prostheses being distributed in developing countries are typically passive, low-cost and primitive in design [5]. Single-axis joints with and without manual locks have been found to be the most widely distributed across developing countries such as India [5]. These prostheses inhibit normative gait, and suffer frequent mechanical failures with low-user satisfaction [5]. The low-cost four-bar polycentric joint developed by D-Rev [3] has been adopted recently. It has shown better performance but still possesses the problems of impeding early stance flexion-extension and delaying late-stance flexion. The LCKnee designed by Andrysek et al [14] for developing countries has been shown to be a more promising technology. It uses single-axis architecture with an automated mechanical lock to enable early stance stability and late-stance flexion but cannot enable early stance flexion-extension and differential swing phase damping.

In this context, the overarching goal of our work is to design a low-cost, passive prosthetic knee joint that can facilitate able-bodied kinematics, minimize metabolic energy expenditure and meet the relevant socio-economic, cultural and aesthetic needs of users with transfemoral amputation in developing countries. Building upon our earlier work [4,9,15,16], this paper is focused on the following:

- 1) Classification of functional design requirements based on our user-needs survey and reported data in literature.
- 2) Conceptual design of mechanical architecture needed to meet the biomechanical goals and user-needs with the primary focus on minimal metabolic expenditure, stability and facilitation of able-bodied kinematics.
- 3) Preliminary field validation in India of an early prototype through user-trials and interviews for qualitative feedback.

FUNCTIONAL REQUIREMENTS

Biomechanical Requirements of Transfemoral Prosthesis

The Fundamental requirements of functional human walking have been well established in literature through theoretical biomechanical modeling and experimental gait data analysis [17-20]. For the purpose of our design, these requirements of able-bodied walking were grouped under the following three categories:

- 1) Kinematics: Movement of human body parts facilitating clearance in swing, adequate step length and smooth transitions between swing and stance.
- 2) Stability: Support of bodyweight both during single support and double support phases of gait. This is also the primary requirement of stable standing.
- 3) Energy Conservation: Achieving ideal kinematics and stability while minimizing energy expenditure.

The fundamental biomechanical objective of our transfemoral prosthesis design was to restore all the above three functions of able-bodied gait and stable standing at rest. Based on past studies of metabolic cost of walking, we postulate that by replicating able-bodied kinematics with adequate stability, it might be possible to minimize the mechanical work expenditure and thereby the metabolic cost of walking [21]. Meeting the first two requirements of walking listed above can also potentially aid in fulfilling the important third requirement of conserving energy and minimizing metabolic cost of walking with amputation.

Table 1. FUNCTIONAL REQUIREMENTS ESTABLISHED BASED ON BIOMECHANICAL CONSIDERATIONS AND USER-CENTRIC APPROACH [4,9].

Functional Requirements	
Biomechanical Requirements	<ul style="list-style-type: none"> •Able-bodied kinematics •Stability •Energy Conservation
Requirements articulated by users	<ul style="list-style-type: none"> •Ability to stand for long •Easy sit-stand transition •Ability to walk on wet mud •Ability to walk carrying heavy objects •Sitting cross-legged (important for Indian culture) •Ability to squat and climb stairs
Requirements articulated by stakeholders	<ul style="list-style-type: none"> •Cost per device < \$100 •Normal looking gait on flat ground •Stability on uneven terrain •ISO 10328 compliance •Mass-manufacturable •Ease of fitment, alignment and maintenance •Appropriate for amputees with long residual limbs •Aesthetically pleasing cosmesis

Determination of Functional Requirements through User-Centric Approach

In addition to the biomechanical requirements of walking and standing, a user-centric approach was used to establish design requirements based on activities of daily living, fitment, manufacturing, distribution, maintenance, and compliance to international standards (Tab. 1).

There were three important components to this approach:

- 1) Collaboration and interaction with Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS, also known as, the Jaipur Foot organization) based in Jaipur, India. BMVSS has distributed more than 400,000 low-cost prosthetic limbs in India and other developing countries since 1975 [22].
- 2) Interviews of Stakeholders: Technicians, engineers, physicians, professors and administrators at different prosthesis fitment clinics, rehabilitation hospitals, and academic institutions across India.
- 3) A structured user-needs survey of 19 transfemoral amputees in Jaipur, India to identify the specific

needs with respect to their common activities of daily living.

A wide range of functional requirements was established and ranked in order of importance based on quantitative and qualitative data, which served as the guidepost for further analysis and design of mechanism (Tab. 1) [4,9].

ANALYSIS AND DESIGN OF MECHANISM

Optimal mechanical component coefficients to achieve able-bodied Kinematics

Prosthetic knee designers have used components such as springs and dampers and optimized them with an aim of replicating ideal knee moment required for walking with able-bodied kinematics [Herr]. The work of Narang and Winter [4,9,15,16] theoretically established mechanical feasibility of achieving able-bodied kinematics by using low-cost passive mechanical components such as linear springs and friction dampers (Fig. 1). Their study also optimized the mechanical component coefficient values accounting for changes in inertial properties of prosthetic legs, which typically weigh lesser than physiological legs [16]. Their study concluded that using a single linear spring and two friction dampers, it is possible to accurately replicate the physiological knee moment (adjusted to the change in inertial properties of prosthetic components compared to able-bodied leg segments).

A mechanical embodiment of such a knee would need a mechanism to engage and disengage the spring and dampers at optimal points of time in the gait cycle. This study serves as the theoretical backbone for our design of low-cost prosthetic knee mechanism because linear springs and friction dampers are available widely and are relatively inexpensive. Secondly, by tuning the spring stiffness and damper friction coefficients to the prescribed values based on the weight of the person and weight of the prosthesis, it should be possible to closely replicate the desired knee-moment for able-bodied kinematics.

Challenge of achieving reliable stance control without compromising on able-bodied stance kinematics and kinetics

One of the fundamental design challenges in replicating able-bodied kinematics in a passive knee joint is achieving reliable stance control, which is important for stable locomotion and avoiding falls during early stance [23]. During early stance (Fig. 2), the Ground Reaction Force (GRF) acting at the Center of Pressure (COP) is posterior to the physiological location of knee axis and causes a large flexion moment at the knee. However, despite this large flexion moment, the physiological knee does not buckle as the extensor muscles in the leg provide an opposite internal extension moment and limit early stance flexion of the knee to a maximum of about 20 degrees (Fig. 1). Advanced electromechanical knee joints, counter this large flexion moment by either providing a counter extension torque using an active powered component or regulate the resistance of the joint based on electro-mechanical sensing of the center of

pressure [24, 25]. In a passive knee joint, which does not have any sensors or battery driven active component, stance control is a serious challenge.

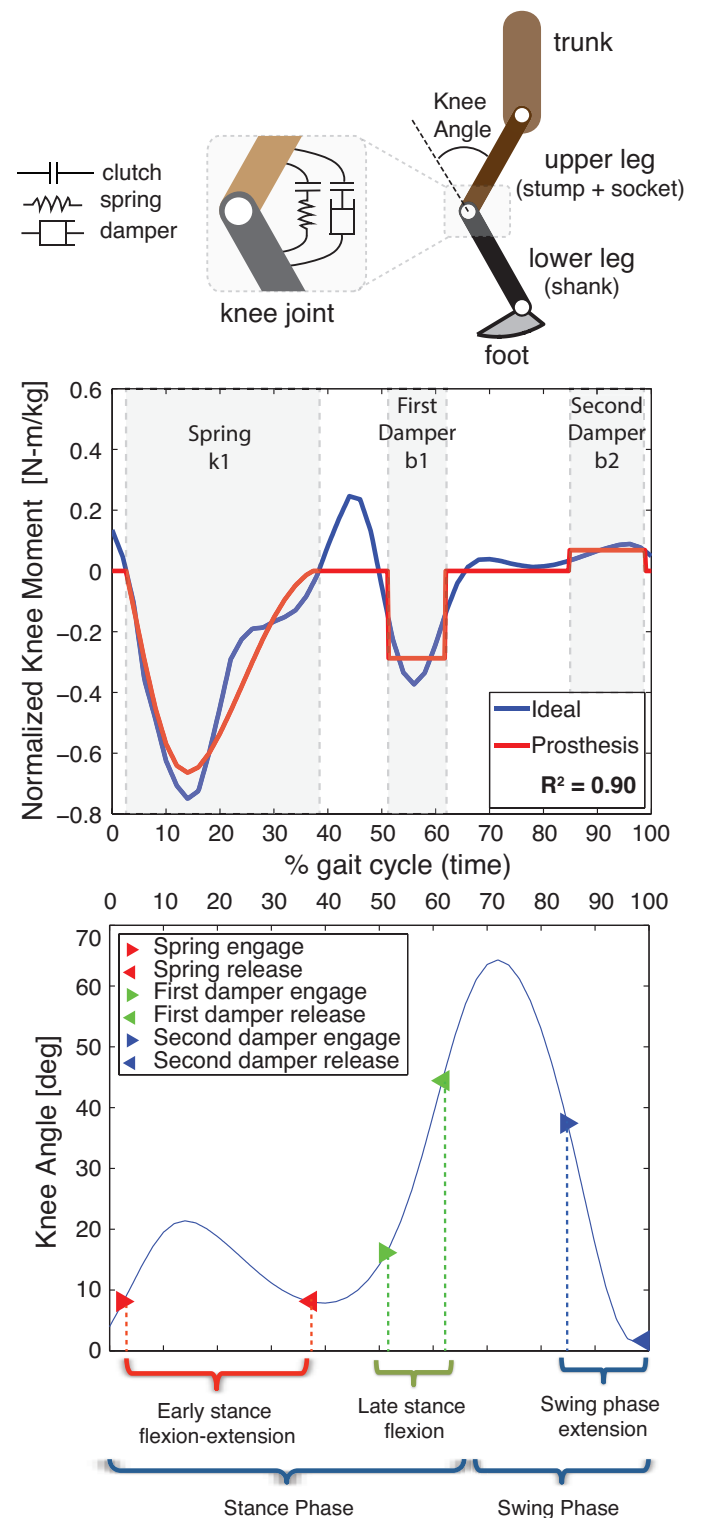


Figure 1. DETERMINATION OF OPTIMAL MECHANICAL COMPONENT COEFFICIENTS FOR REPLICATING ABLE-

BODIED KNEE MOMENT. Narang and Winter [4,9,15] used a rigid body model comprising foot, ankle joint, lower leg, knee joint, and upper leg (top). Using inverse dynamics, they predicted the spring stiffness (k_1) and frictional damping (b_1 and b_2) required for replicating able-bodied moment with $R^2=0.90$ (Middle). The engagement-disengagement points during each gait cycle were also established as a part of this analysis for one spring and two friction dampers (bottom). The knee angle is the relative angle measured between the upper leg and lower leg (top).

Different designs of passive prosthetic knees tackle this problem of stance control by compromising on early stance flexion through mechanical means well documented in literature [5]. For example, single axis knee joints rely on voluntary control of hip musculature to resist flexion during early stance. Single axis locking knee joints such as ICRC knee use a mechanical latch engaged by the user to provide extra stability, which leads to a stiff legged gait suited only for new amputees or low-activity elderly users who demand hyper-stability [5]. Polycentric mechanisms, using 4-bar mechanism or 6-bar mechanism rely on a moving instantaneous center of rotation to provide stability. The instantaneous center of rotation starts off posterior to the GRF vector at the beginning of stance and moves anterior to the GRF vector just before toe-off enabling some late stance flexion [23]. The LCKnee, recently developed by Andrysek et al [14], uses an automatic stance locking mechanism to lock the knee during early stance and unlocks it during late stance. A similar automatic stance locking mechanism was earlier developed by Farber and Jacobson [26].

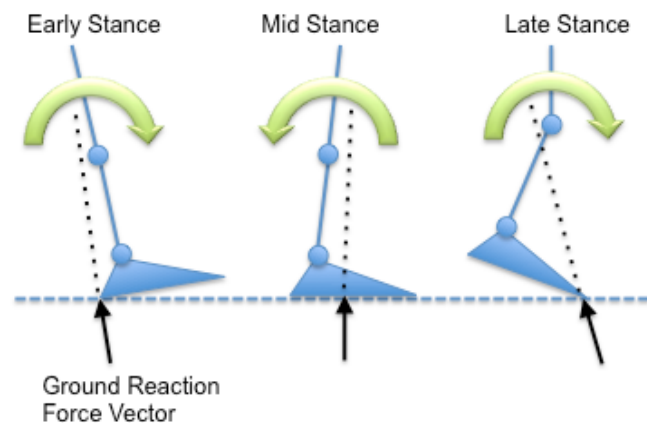


Figure 2. RELATIVE POSITION OF THE GROUND REACTION FORCE (GRF) VECTOR AND THE KNEE. The GRF vector is posterior in early stance and late stance causing a flexion moment at the knee. During mid-stance, the vector is anterior to the knee. Green arrow depicts the direction of the net moment at the knee during each stage because of the GRF vector, inertial forces and the hip moment. The moment exerted by hip muscles and the inertial forces are not shown.

Achieving correct kinematics and kinetics during stance involves early stance flexion (kinetic energy storage) followed

by extension (kinetic energy release). This early stance flexion-extension involves energy storage and energy release in nearly equal proportion [27]. A late stance flexion of up to 45-50 degrees with appropriate damping is also essential for a smooth transition into swing. However, most passive knee designs, as discussed above, do not facilitate appropriate early stance flexion-extension and appropriately timed late stance flexion. As discussed in the next section, our prototype aims to tackle this tradeoff between kinematics, kinetics and stability.

Architecture of the mechanism

The mechanism was designed with the following two functional modules (Fig. 3):

- 1) An automatic stance locking-unlocking mechanism, similar in function to the mechanism implemented by Andrysek [14] and Farber [26]. This feature was designed to provide stability to the user while the knee was locked from early stance to mid-stance. The locking axis was positioned anterior to the GRF vector but posterior to the knee axis to enable timely unlocking of the knee necessary for kinematics of late stance flexion. Compared to Andrysek's design, our prototype is simpler in architecture because of rear-locking feature which needs only one lever arm for actuation of the lock positioned posterior to the knee axis. Andrysek's knee architecture used two levers to engage the lock that was positioned anterior to the knee as a front-locking feature.
- 2) A differential damping system for appropriate late stance flexion and swing extension: As shown by Narang and Winter [4,9,15] the first friction damper to be actuated during late stance flexion is an order of magnitude higher than the second friction damper actuated during swing extension. This differential damping is realized in the mechanism by mounting the braking surface on a one-way rolling clutch which provides slipping friction during late-stance flexion and a much lower rolling resistance during swing extension. The preload on the braking surface is controlled by an adjustable screw mechanism (Fig. 3), this preload helps in controlling the normal force and thereby the slipping friction which is the product of the normal force and the coefficient of friction between the braking surface and the rotating module of the prosthesis.

The current version of the prototype (Fig. 3) does not permit elastic flexion-extension during early stance. The purpose of the prototype was to establish the feasibility of the proposed architecture with the above two modules. However, in the future iterations, we will be implementing a compliant latch member to provide early stance flexion-extension. In the current architecture, by making the locking member elastic in nature with a hard-stop, it should be possible to permit early stance flexion of up to 20 degrees (Fig. 1).

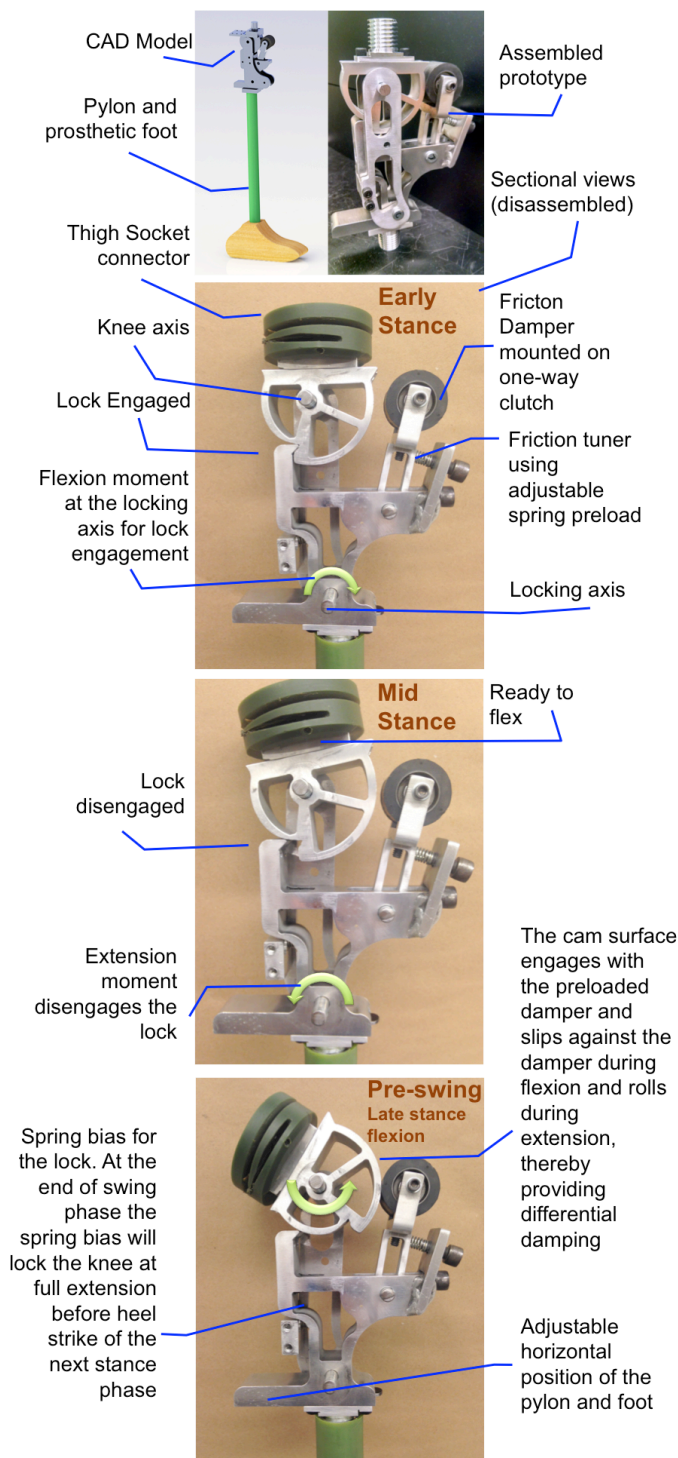


Figure 3. ARCHITECTURE AND FUNCTION OF THE PROTOTYPE MECHANISM. During early stance, GRF direction (see Fig. 2) causes flexion moment at the locking axis while the lock is engaged. During mid stance, the extension moment at the locking axis disengages the lock. During late stance, when the GRF vector passes posterior to the knee axis, late stance flexion at the unlocked knee joint can take place.

PRELIMINARY FIELD VALIDATION

Although the design of the prototype was only at an initial stage, early qualitative feedback of performance was sought from potential users for validation of the mechanism architecture. Four subjects with transfemoral amputation were fitted with the prototype with the help of trained prosthetists at the BMVSS clinic in Jaipur, India. The evaluation protocol included the 2-minute walk test [19], walking up and down on an incline of 25 degrees, climbing stairs and walking outdoors on dirt. At the end of evaluation, each subject was interviewed in his/her local language for qualitative feedback. Subjects were also asked to compare the performance of the prototype with the prosthetic device that they had been using. This field validation study was approved by the MIT Committee on the Use of Humans as Experimental Subjects.

All four subjects were able to walk comfortably in the 2-minute walk test after a period of acclimatization and learning to use the prototype knee. All of them were able to disengage the lock midway through stance and found the late stance flexion using the prototype to be more comfortable than the polycentric four bar knee they had been using (Fig. 4). Walking on an upward incline and climbing stairs was difficult for all four subjects. The engagement of the lock before stance was loud and was reported as an undesirable feature by each subject. None of the subjects felt the prosthesis to be heavy in comparison to their current prosthetic devices. These observations were recorded and mapped to strategies for further improvement in the next iteration of the prototype (see discussion).

DISCUSSION

Design Approach

The physiological knee is a net power dissipater over the gait cycle as compared to the physiological hip or the ankle [27], which are net power generators over the gait cycle. This implies that achieving able-bodied gait performance using a passive knee prosthesis is not restricted by a biomechanical limit. With the advent of electromechanical devices in the prosthetics industry over the last three decades, passive devices have not been optimized for enabling able-bodied gait, especially in the case of passive prostheses designed for the developing world. Though electromechanical devices have shown excellent results in terms of reducing metabolic cost of walking and enabling able-bodied gait, their high-cost remains a barrier for globally scaled adoption, particularly in developing countries. The approach presented in this work, therefore, can also benefit users in developed world markets as passive knees could potentially be used as lower-cost, high-performance alternatives to the more expensive, active prostheses.

Enabling able-bodied kinematics based on our theoretical analyses [4,9,15,16] was helpful in making design decisions for stance-control and swing-control in a quantitative manner. In our design of the early stance lock, it was possible to precisely position the locking axis (with respect to the knee

axis and the foot) by using center of pressure data and GRF data. By locating the locking axis in the correct horizontal position, we ensured that the lock disengages only after the early flexion-extension phase of stance but before the engagement of the damper during late stance flexion (Fig. 1). During field evaluation, this location accuracy for different subjects was achieved by horizontal adjustment of the pylon-foot assembly (Fig. 3).



Figure 4. PRELIMINARY FIELD EVALUATION. Fig. 4a. Subject 1 using the prototype for the 2-minute walk test. Fig. 4b. Subject 2 during the 2-minute walk test, late stance flexion of up to 40 degrees can be seen. Fig. 4c. Subject 2 walking outdoors on uneven terrain.

Based on the analysis of swing phase (Fig. 1), which requires two dampers of different coefficients of friction, we postulated that an extension assist spring was not necessary for accurate swing phase control. Extension assist springs have

been used widely in many passive above-knee prostheses [28] for achieving resistance-free extension during swing and high-resistance flexion during late stance and early swing. Use of extension springs without sufficient damping leads to a large terminal impact at the end of swing phase [28] and is also far from the ideal in terms of kinetics, as springs do not dissipate energy. Prosthetic knee designs with extension springs commonly use viscoelastic dampers to cushion the impact at the end of swing extension, further adding to the cost and functional complexity of the product. Basing our design on theoretical analysis, we used a differential damping system in our prototype with an aim of achieving resistance-free extension and negligible terminal impact.

Limitations of the study

The current prototype was found to have the following functional limitations as identified by comparison with our theoretical kinematic analysis (Fig. 1) and preliminary field evaluation:

- 1) Absence of early stance flexion-extension: There was no feature in the prototype to allow for energy storage and return during early stance, which is critical to meet the requirement of able-bodied gait during stance. By using a compliant latch of tunable stiffness, it should be possible to enable early stance flexion-extension. This feature is being incorporated for next iteration of the prototype.
- 2) The current design necessitates full extension of the knee at the end of swing phase to engage the lock before stance (Fig. 3). Failure to lock the knee before stance can lead to unstable stance and possible buckling of the knee and fall [5,14].
- 3) Use of braking elements in the device could lead to variable damping as reported in some of the earlier designs [5] due to wear, changes in humidity and exposure to outdoor dust and rain.
- 4) During field evaluation tests, subjects found it difficult to walk on steep inclines and climb stairs using the prototype due to the knee being locked at the beginning of stance. All subjects also deemed the loud clicking noise of the lock at the end of swing as undesirable.
- 5) Secondary user-needs of Indian transfemoral amputees such as squatting, cross-legged sitting were not met by this prototype.

Future work to develop this design further should take these limitations into account. Clinical gait data analysis of subjects using the prototype will be required for quantitative evaluation of our design as benchmarked against able-bodied kinematics and kinetics.

ACKNOWLEDGMENT

We would like to thank Yashraj S. Narang and Daniel S. Dorsch for their guidance and technical inputs. We would also like to acknowledge Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS, a.k.a., the Jaipur Foot organization) for their

partnership in our project to design a high-performance, low-cost prosthetic knee for the developing world. Funding for this research was provided by the Tata Center for Technology and Design at MIT.

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