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Design and Preliminary Field Validation of a Fully Passive Prosthetic Knee Mechanism for Users With Transfemoral Amputation in India

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An estimated 230,000 above-knee amputees in India are currently in need of prosthetic devices, a majority of them facing severe socio-economic constraints. However, only a 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 designing a potentially low-cost, fully passive prosthetic knee device, which aims to facilitate able-bodied kinematics at a low metabolic cost. Based on a comprehensive set of functional requirements and biomechanical analysis from our past work, we present an early prototype mechanism for the prosthetic knee joint that is primarily focused on enabling able-bodied kinematics. The mechanism is implemented using two functional modules: an automatic early stance lock for stability and a differential friction damping system for late stance and swing control. For preliminary, qualitative validation of the knee mechanism, we carried out a field trial on four above-knee amputees in India, which showed satisfactory performance of the early stance lock. The prototype enabled smooth stance-to-swing transition by timely initiation of late stance flexion. Possible methods of incorporating an additional spring module for further refinement of the design are also discussed, which can enable flexion-extension during the early-stance phase of the gait cycle and potentially reduce the metabolic energy expenditure of the user further. [DOI: 10.1115/1.4039222]

Keywords: bio inspired designs, dynamics, mechanism design, prosthetics

1 Introduction

This work is focused on designing a 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 India and China [3]. According to an estimate by the World Health Organization, Geneva, Switzerland 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 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], 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 [9–11]. 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 for the developed world in the last few decades (Fig. 1), 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 U.S. and Europe cost several thousand dollars to manufacture and distribute. Popular active above-knee prostheses that deliver very high performance can cost more than \$50,000 [12]. Even the passive knee joints in developed countries are too expensive to meet the requirements of amputees in the developing world.

In biomechanical terms, the cyclic motion of walking is defined as the “gait cycle.” Qualitatively, the gait cycle is often divided into phases based on whether the specified leg is in contact with the ground. “Stance” is when the foot of a specified leg is in contact with the ground, and “swing” is when the foot of the leg is off the ground. Stance and swing of one leg alternate with those of the other with a short overlap of “double support” phase when both the feet are on the ground.

Current above-knee prostheses being distributed in developing countries are typically passive, low-cost, and simple in design [5] (Fig. 1). Single-axis joints with and without manual locks have

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Fig. 1 Different Prosthetic knees available in the developing and developed world markets and their selling prices: (a) BMVSS (Jaipur-foot) manual-locking knee, shown fully extended and at full flexion [22]. (b) The International Committee of the Red Cross manual locking, single-axis knee, (c) Jaipur-Stanford four-bar knee joint, also used by BMVSS [3,22], (d) LCKnee designed by Andrysek et al. [13], with an automatic locking mechanism, and (e) the popular Ottobock range of quasi-passive and active, microprocessor-controlled prosthetic knees: C-leg and Genium Microprocessor-controlled knees have been widely adopted in the developed world markets and they can enable a wide range of activities and motions [12].

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 single-axis joints with manual locks constrain the user to a peg-leg gait, which necessitates circumduction to enable ground clearance during the swing phase and hip hiking during stance phase. The single-axis joints without manual locks lead to hyper-stable gait, wherein the transition from stance phase to swing phase (through knee flexion) is delayed. If not aligned correctly, they can lead to buckling of the knee joint during early stance causing the user to stumble or fall. The low-cost four-bar polycentric joint developed by D-Rev [3] has been adopted recently in India and other developing countries (Fig. 1). It has shown better performance but still possesses the problems of impeding early stance flexion (ESF)–extension at the knee and delaying late-stance flexion. The four-bar knee, as the name suggests, uses a four-bar mechanism to generate a moving instantaneous center of rotation for the knee joint to achieve early stance stability and delay late stance flexion.

A comprehensive review of the recent developing-world knee technologies has been compiled by Andrysek [5]. An innovative technology, developed by Andrysek himself, is the LCKnee [13]. The knee locks at the end of swing and unlocks in late stance, mitigating the delayed initiation of late stance flexion, which is often the problem in alignment-stabilized single-axis knees, braking knees, and four-bar knees (Fig. 1). It uses a single-axis architecture with an automated mechanical lock to enable early stance stability and late-stance flexion. Currently, fully passive prosthetic knees designed for the developing world do not enable early stance flexion and accurate swing phase damping. More importantly, most designs have been adaptations of existing designs in the developed world and have not been designed with a strategy to best replicate the kinematics of each phase of the gait cycle, without compromising on stability [5]. The specific design limitations associated with the kinematics versus stability trade-off are discussed in further detail in this paper.

In this context, the overarching goal of our research is to design a low-cost, passive prosthetic knee joint that can facilitate able-bodied kinematics (thereby minimizing the total metabolic energy expenditure) and meet the relevant socio-economic, cultural, and

aesthetic needs of users with transfemoral amputation in developing countries. In this paper, we present an early mechanism design and prototype of the prosthetic knee, which is specifically focused on the following:

- (1) Mechanical architecture with the potential to meet the biomechanical goals and user-needs of able-bodied walking. The primary focus of the prototype was on stability and facilitation of able-bodied kinematics.
- (2) Preliminary field validation of an early prototype in India through user-trials and interviews for qualitative feedback.

We build upon our earlier work, which was focused on theoretical biomechanical analysis of able-bodied walking, inertial factors, and mechanical components affecting amputee gait [14–16], and determining the user-needs of above-knee amputees in India [4].

2 Background

2.1 Biomechanical Requirements of a Transfemoral Prosthesis. The fundamental requirements of functional human walking have been well established in the 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, during both the 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 walking gait and stable standing at rest. Based on past studies of metabolic cost of walking, we postulate that by

Table 1 Functional requirements established based on biomechanical considerations and a user-centric approach [4]

| Functional requirements | |
|--|--|
| Biomechanical requirements | Able-bodied kinematics Stability Energy conservation |
| Requirements articulated by users | 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 in Indian culture) Ability to squat and climb stairs |
| Requirements articulated by stakeholders | Cost per device within \$100–\$150 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 |

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 the metabolic cost of walking with a prosthetic limb.

2.2 Determination of Functional Requirements Through a User-Centric Approach. As part of our earlier work [4], in addition to the biomechanical requirements of walking and standing, a user-centric approach was used to establish the design requirements based on activities of daily living, fitment, manufacturing, distribution, maintenance, and compliance to international standards (Table 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 and is currently the largest organization in the world manufacturing and distributing low-cost prosthetic limbs [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 the prosthetic knee mechanism (Table 1) [4].

2.3 Primary Functional Requirement for Early Stage Design and Validation. As discussed, we lay out a multitude of functional requirements important for meeting most needs of transfemoral amputees in developing countries, specifically in India. For the purpose of this study, the most critical functional requirement of the design was identified as enabling able-bodied kinematics and stability for walking at normal cadence. The biomechanical reason for enabling stability and able-bodied kinematics during normal cadence is well documented in literature [17,23,24] and was also articulated repeatedly by the Indian users

in our survey, albeit not for biomechanical reasons [4]. Most users explicitly expressed the need for the prosthesis to help them look able-bodied. Past studies of amputees in both developing and developed countries have also reported the need to rehabilitate amputees with the aim of making the effects of their amputation as inconspicuous as possible [9–11]. Users in India also wanted the prosthesis to look aesthetically as close to their biological limbs as possible [3,4].

Although the primary focus of the design was to enable stability and able-bodied gait, many constraints were imposed on the design to make future enhancements possible. These future additions would have to be practical, low-cost, and amenable to adoption in the developing world. The most important constraint, relevant to the prototype presented in this paper, was to use only passive elements to keep the design robust and to reduce the eventual manufacturing cost.

3 Analysis and Design of the Mechanism

3.1 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 [25]. The work of Narang et al. theoretically established mechanical feasibility of achieving able-bodied kinematics by using low-cost passive mechanical components such as linear springs and friction dampers (Fig. 2) [14,16]. Their study also optimized the mechanical component coefficient values accounting for changes in inertial properties of prosthetic legs, which typically weigh significantly lesser than physiological legs [15]. Their study concluded that using a single linear spring and two friction dampers of appropriate mechanical component coefficients, 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. These studies [14–16] serve as the theoretical foundation for our design of a low-cost prosthetic knee mechanism because linear springs and friction dampers are available widely and are relatively inexpensive. 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.

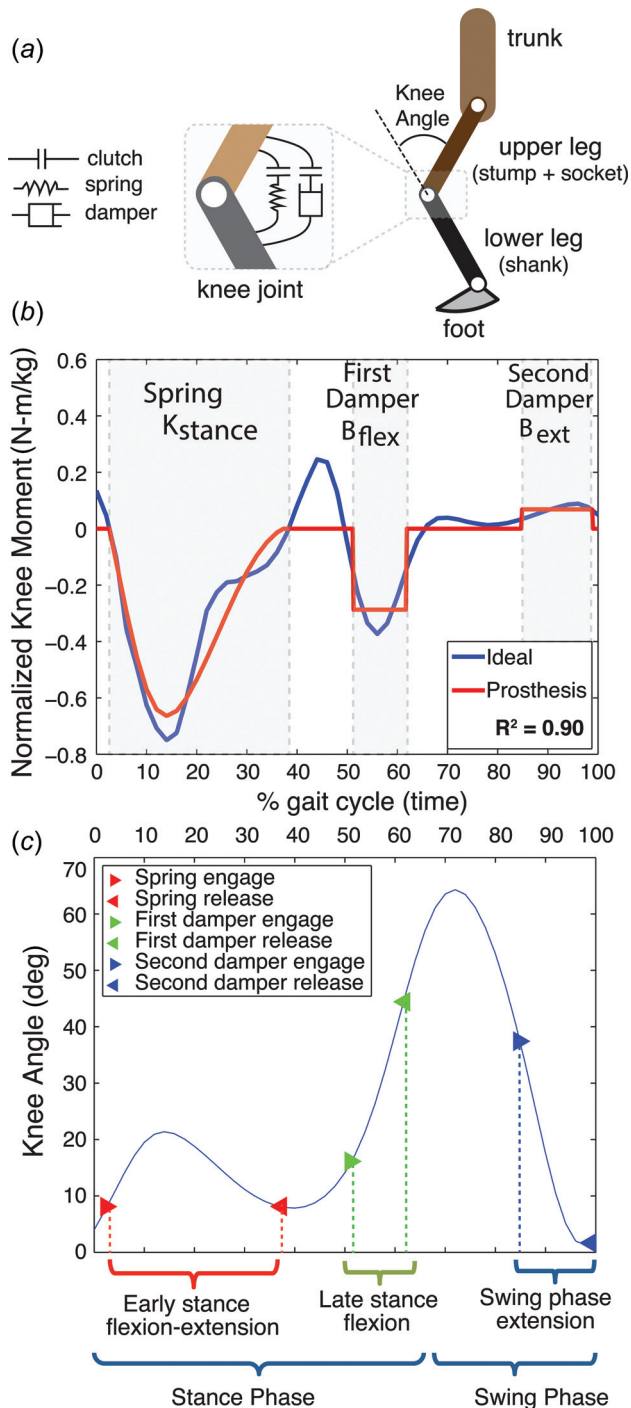


Fig. 2 Determination of optimal mechanical component coefficients for replicating able-bodied knee moment: (a) Narang et al. [15] used a rigid body model comprising the foot, ankle joint, lower leg, knee joint, and upper leg, (b) Using inverse dynamics, they predicted the spring stiffness coefficient (K_{stance}) and the frictional damping coefficients (B_{flex} and B_{ext}) required at the knee joint for replicating able-bodied moment with $R^2 = 0.90$ [14], and (c) the engagement-disengagement points during each gait cycle were also established as a part of this analysis for one spring and two friction dampers. Increase in the positive value of the knee angle denotes flexion (and decreasing positive value denotes extension).

3.2 Achieving Reliable Stance Control With Able-Bodied Stance Kinematics. 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

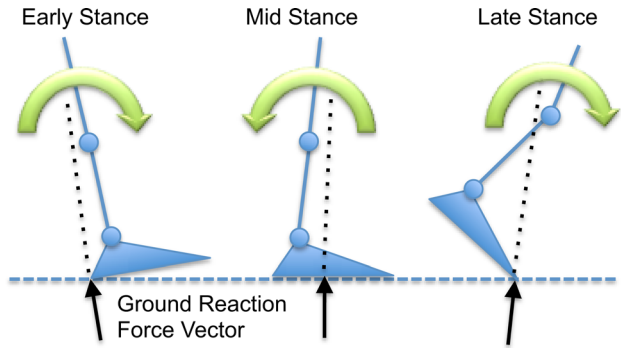


Fig. 3 Relative position of the GRF vector and the knee. The GRF vector is posterior in early stance and late stance causing a flexion moment at the knee (clockwise direction, with respect to the upper leg frame). During mid-stance, the vector is anterior to the knee. The curved arrow depicts the direction of the net resultant 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.

locomotion and avoiding falls during early stance [23]. During early stance (Fig. 3), 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 physiological leg provide an opposite internal extension moment and limit early stance flexion of the knee to a maximum of about 20 deg (Fig. 2). This initial 15–20 deg flexion is also important because it ensures that the center of mass of the body transitions smoothly from swing phase into the stance phase at the beginning of gait cycle [20]. Advanced electromechanical knee joints (Fig. 1) 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 electromechanical sensing of the center of pressure [25,26]. In a passive knee joint, which does not have any sensors or battery driven active component, stance control is a serious challenge (Fig. 3).

Different designs of passive prosthetic knees (Fig. 1) tackle this problem of stance control by compromising on early stance flexion through mechanical means, which have been well documented in literature and practiced widely by clinicians and prosthetists [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 International Committee of the Red Cross 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 [5,23]. Polycentric mechanisms, using a four-bar mechanism or six-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. [13], uses an automatic stance locking mechanism to lock the knee during early stance and unlocks it during late stance to enable late-stance flexion for transition into swing. A similar automatic stance locking mechanism was earlier developed by Farber and Jacobson [27].

Achieving correct kinematics and kinetics during stance involves early stance flexion (kinetic energy storage) followed by extension (kinetic energy release) (Fig. 2). This early stance flexion–extension involves energy storage and energy release in nearly equal proportion [24]. A late stance flexion of up to 45–50 deg 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. Our prototype aims to tackle this trade-off between kinematics, kinetics, and stability. However, the mechanism presented in Sec. 3.3 only enables late-stance flexion. Possible methods to incorporate an additional early stance flexion–extension within the presented architecture are discussed later.

3.3 Architecture of the Mechanism. The mechanism was designed with two major functional modules in the prototype: the automatic locking–unlocking mechanism using a mechanical latching element (referred to as the lock) and a friction-based differential damping system using brake material mounted on a one-way roller clutch. Figure 4 illustrates the functioning of the prototype through each phase of the gait cycle.

The automatic stance locking–unlocking mechanism in the prototype is similar in function to the mechanism implemented in the LCKnee by Andrysek et al. [13] and Farber and Jacobson [27]. 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 the earlier designs by Andrysek and Farber, our prototype is simpler in architecture because of the rear-locking feature, which needs only one lever arm for actuation of the lock, which is positioned posterior to the knee axis. In comparison, the LCKnee architecture used two levers to engage the lock, which was positioned anterior to the knee (front-locking feature intended to leave room for flexion of more than 90 deg after unlocking [13]). However, by laying out the latch with a much longer length (along the length of the leg) in the posterior position, the rear-locking feature in our prototype was implemented to maintain flexibility of more than 90 deg flexion. A similar rear-locking feature was also recently implemented by Wyss [28]. Using a single element as a lock is also advantageous as it can be much simpler to design the latch member to be compliant in compression (with a normalized torsional stiffness coefficient $K_{\text{stance}} = 2.86 \text{ N}\cdot\text{m}/\text{kg}/\text{rad}$ [14]). As the latch locks the knee during early stance, the compliance offered by the latch can enable elastic, early stance flexion–extension of up to 20 deg (Fig. 2), while keeping the knee secure from accidental flexion, which may result in loss of control and possible fall. The prototype presented in this paper (Fig. 4) does not incorporate this elastic flexion–extension module. However, our ongoing work has been focused on adding this module to the design, as described in the discussion section.

The second module in the prototype is the differential damping system for appropriate late stance flexion and swing extension. As shown by Narang et al. [14,15], the magnitude of damping (with normalized, zero-order rotational damping coefficient, $B_{\text{flex}} = 0.29 \text{ N}\cdot\text{m}/\text{kg}$) needed during late stance flexion is an order of magnitude higher than the damping required during swing extension ($B_{\text{ext}} = 0.069 \text{ N}\cdot\text{m}/\text{kg}$). 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 much lower rolling resistance during swing extension. The braking surface used in the prototype is the common brake lining used in automotive applications with a high coefficient of friction (0.4–0.5 between the braking surface and Aluminum 6061 alloy). The preload on the braking surface is controlled by an adjustable screw mechanism (Fig. 4); 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 brake lining and the rotating aluminum module of the prosthesis. The differential damping system implemented in the prototype, however, can be improved further, so that the exact values of damping required during late stance flexion and swing extension could be dialed-in. The current

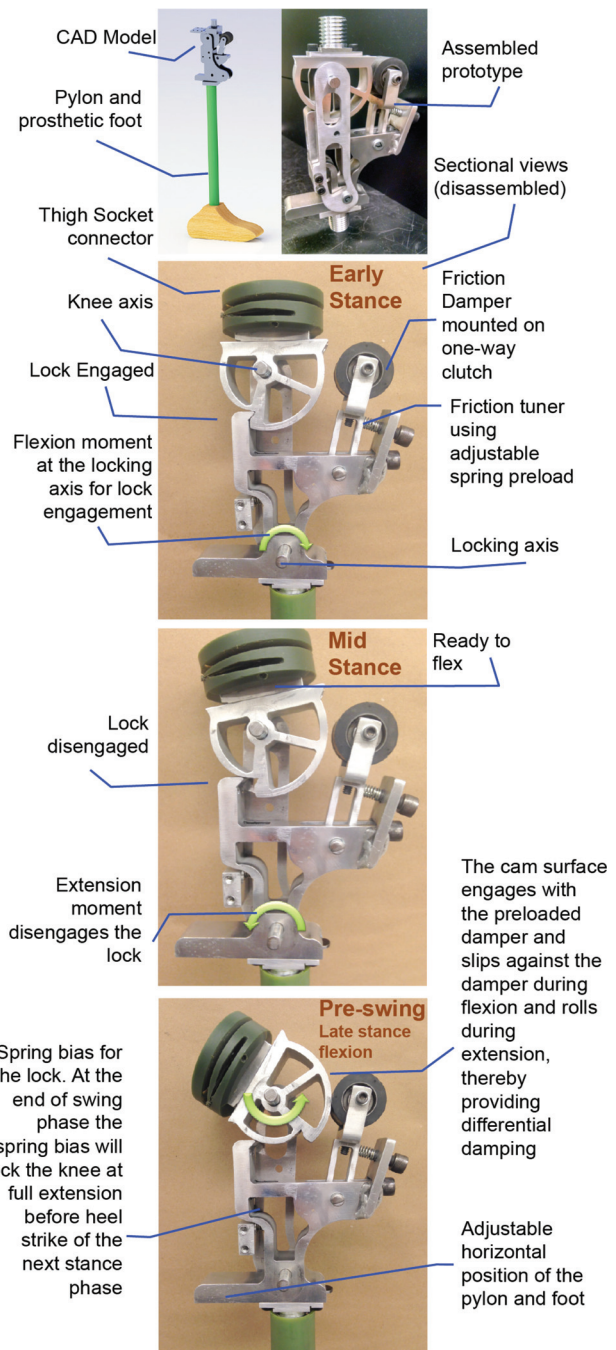


Fig. 4 Architecture and function of the prototype mechanism. During early stance, GRF direction (Fig. 3) causes a flexion moment at the locking axis while the lock is engaged. During mid-stance, the extension moment at the locking axis disengages the lock (as the locking element and rest of the lower leg assembly is mounted about the locking axis). During late stance, when the GRF vector passes posterior to the knee axis, late stance flexion at the unlocked knee joint can take place. During late stance flexion and early swing phase, the cam surface of the knee rotates about the knee axis and slips against the stationary brake lining, resulting in large damping torque (B_{flex}). During late swing extension, the brake, which is mounted on a one-way roller-clutch, also rotates along with the cam surface and provides a much lesser damping torque (B_{ext}).

prototype only provides an approximately accurate damping force during flexion but future iterations would implement a different embodiment of the similar concept to provide hermetically sealed, accurate, and repeatable damping in both directions [29].



Fig. 5 Preliminary field evaluation: (a) subject 1 using the prototype for the 2 min walk test, (b) subject 2 during the 2 min walk test, late stance flexion of up to 40deg can be seen, and (c) subject 2 walking comfortably outdoors on a relatively flat, muddy terrain

4 Preliminary Field Validation

Although the physical design of the prototype was only at a preliminary stage, early qualitative feedback of performance was sought from potential users for validation of the mechanism architecture and basic functionality of the two modules discussed in Sec. 3.3. Four subjects with transfemoral amputation were fitted with the prototype with the help of trained prosthetists at the BMVSS clinic in Jaipur, India [22]. Three out of the four selected subjects previously used the Jaipur-Stanford four-bar polycentric knee joint [3] for more than two years. The fourth subject was using the single-axis knee joint for more than three years [22]. All four subjects were males and less than 35 years of age.

The evaluation protocol included the 2 min walk test [20], walking up and down on an incline of 25 deg, 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. The

MIT committee on the use of humans as experimental subjects approved this field validation study.

All four subjects were able to walk in the 2 min walk test after a period of acclimatization and learning to use the prototype knee. As articulated by the clinicians at BMVSS and the subjects themselves, the gait with the prototype was deemed “relatively comfortable.” All four subjects 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. 5). Walking on an upward incline and climbing stairs was difficult for all four subjects. The engagement of the lock before stance was found to be loud. Each subject reported this as an undesirable feature. The subjects also voiced their concern regarding the lack of aesthetically pleasant appearance of the prototype. None of the subjects felt the prosthesis to be heavy in comparison with their current prosthetic devices. These observations were recorded and mapped to strategies for further improvement in the next iteration of the prototype as described in the following discussion section.

5 Discussion

5.1 Design Strategy. For normative, level-ground walking gait, the physiological knee is a net power dissipater over the gait cycle as compared to the physiological hip or the ankle [24], which are net power generators over the gait cycle. This implies that achieving able-bodied gait performance using passive knee prosthesis is not restricted by any theoretical biomechanical limitation. 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 prosthetics 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 [4,14,15] 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 (Fig. 6). 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. 2). During field evaluation, this locational accuracy for different subjects was achieved by horizontal adjustment of the pylon-foot assembly (Fig. 4).

Extending this approach to enable early stance flexion–extension (Fig. 2), an improved concept of the knee can be designed that implements an “ESF axis” (Fig. 7) [29], which is positioned posterior to the knee axis and about which, the knee can elastically flex up to 20 deg (even when the knee is locked during early stance). This is possible because the ESF axis is positioned in space such that the GRF vector causes flexion about the ESF axis during early stance and engages the spring mounted at a specific lever length to provide a normalized torsional stiffness coefficient, $K_{stance} = 2.86 \text{ N-m/kg/rad}$ [14]. As the COP moves anterior during early stance phase of the gait, the GRF vector moves anterior to the ESF axis and results in elastic extension of the mechanism about the ESF axis back to 0 deg (Fig. 7). An alternative approach is to make the locking member compliant in compression during early stance with the precise stiffness coefficient (K_{stance}). Our ongoing work is also exploring the design of a compliant locking member in compression, which can potentially

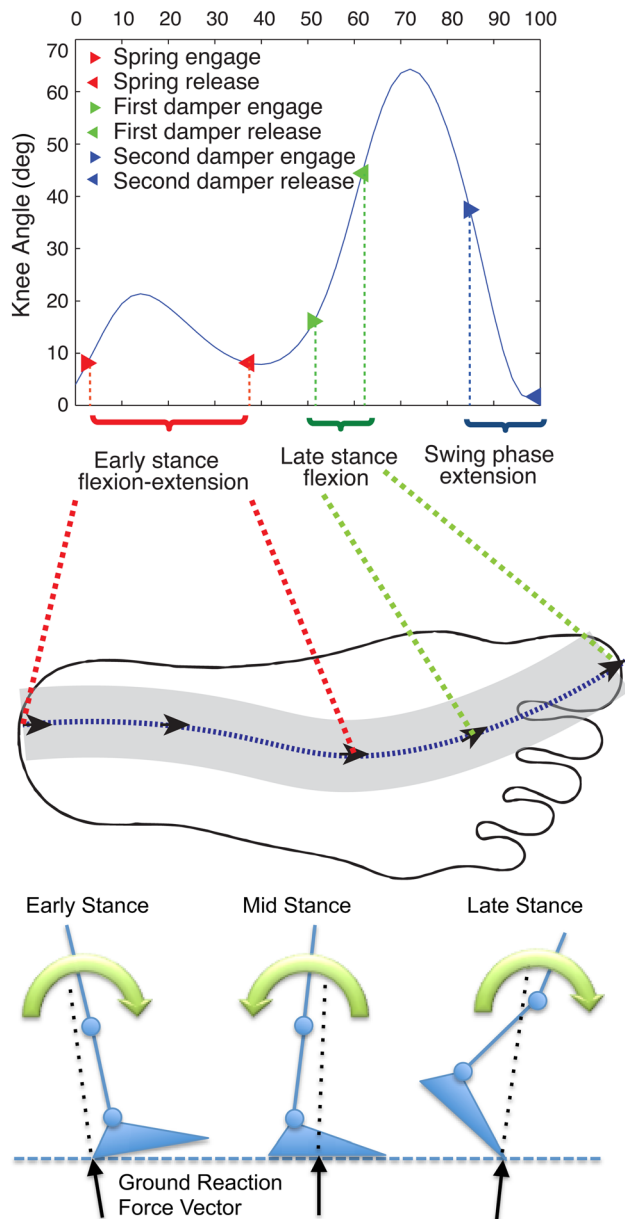


Fig. 6 The movement of the COP on the foot during stance phase of gait (as a function of time) has been determined in past studies [24]. The magnitude and direction of the GRF vector are also known through the stance phase [24]. This provides complete information about the physical location of the GRF vector as a function of time during stance phase of gait. The positioning of the locking axis (Fig. 4) is optimized in 2D space (the sagittal plane) to achieve the following: the GRF vector originating from the COP is posterior to the locking axis during early stance, keeping the knee locked. During mid-stance, the COP advances, moving the GRF vector anterior to the knee and locking axis, releasing the latch. During late stance just before toe off, the latch remains disengaged (Fig. 4), as the GRF vector moves posterior to the knee axis. This strategy can also be potentially used to enable ESF and extension.

replace the concept with an additional ESF axis and a large stiff spring (Fig. 7).

Based on the analysis of swing phase (Fig. 2), 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 [30] for achieving resistance-free extension during swing and high-resistance flexion

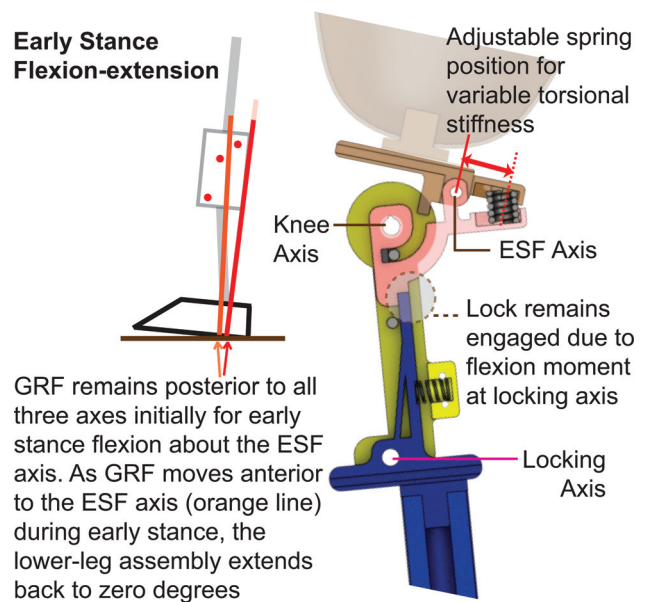


Fig. 7 By incorporating an ESF axis, about which a spring is mounted for elastic early stance flexion-extension (Fig. 2), an additional module could be added to the proposed architecture of the prosthetic knee mechanism (Fig. 4). Illustration adapted with permission [29].

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 [30] 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 more controlled, resistance-free extension with negligible terminal impact.

5.2 Limitations of the Study. The current prototype was found to have the following functional limitations as identified by comparison with theoretical biomechanical analysis (Fig. 2) and preliminary field evaluation:

- (1) The 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. This feature is being incorporated for next iteration of the prototype as discussed previously [29].
- (2) The current design necessitates full extension of the knee at the end of swing phase to engage the lock before stance (Fig. 4). Failure to lock the knee before stance can lead to unstable stance and possible buckling of the knee and fall [5,13].
- (3) The 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 and cross-legged sitting were not met by this prototype.

Future work to develop this design further should take these limitations into account. Our ongoing work is focused on clinical gait data analysis of subjects using the prototype required for quantitative evaluation of our design, as benchmarked against able-bodied kinematics and kinetics of walking. Biomechanical testing of the prototype will highlight the exact deviant phases of amputee gait, which might necessitate changes in the prosthetic knee design. Experimental testing in a clinical gait lab will also establish the best use case for the prototype, which can provide an insight into the best training practices for users in developing countries. Additionally, a comprehensive cost reduction analysis needs to be done to ascertain the price of the potential product that can use a similar mechanism. For example, the preliminary prototype discussed in this paper was primarily fabricated using aluminum 6061 alloy, which is expensive but could easily be replaced by appropriately engineered components using cheaper plastics such as Delrin, a common material used in existing passive knee prostheses in the developing world [3]. A comprehensive commercialization strategy, which accounts for selection of appropriate local manufacturing resources, design-for-manufacturing analysis, and design-for-assembly analysis, would also be crucial in further reducing the cost of the future product using the mechanism discussed in this paper.

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