A Solution for Transfemoral Amputees: Stability, Function, and Access

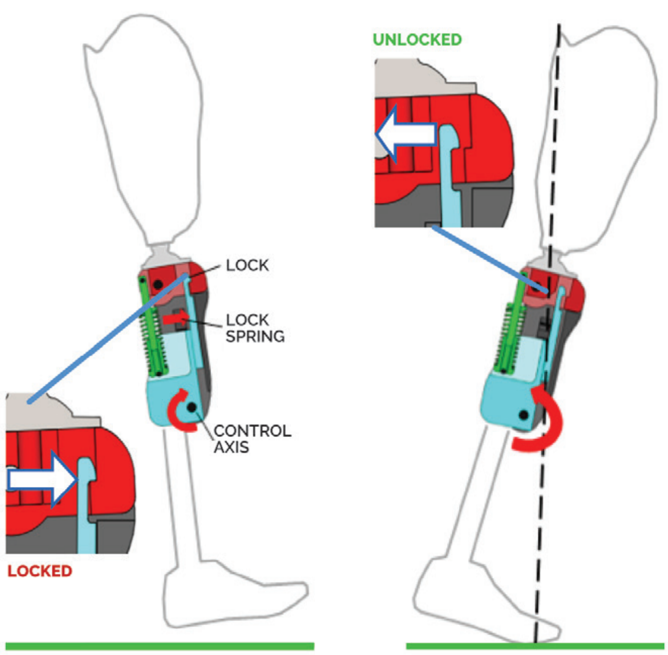
Patient A is a community ambulator and small-business owner without health insurance. The geometric locking knee in his prosthesis had lost function after 15 years of use. This limited his mobility, both in leisure activities and in his daily work cleaning commercial buildings. His goal was to resume normal activities, which included playing basketball with his children. Unfortunately, the only financially acceptable choices for him were K2-rated friction swing-control devices. Patient B is a car mechanic with the potential for unlimited community ambulation who experienced several falls while using a weight-activated stance-control knee joint. As a result, he reported experiencing anxiety related to a fear of falling during prosthetic use and remained a single-cadence ambulator.

A significant challenge for many amputees is access to prosthetic care and appropriate devices. High-deductible/high-coinsurance plans effectively block access to rehabilitative care for people of limited financial resources.[1] Limits may also be placed on the number of visits to a clinician and number of repairs to a device.[2] When adding the barrier of highly restrictive annual and lifetime caps on prosthetic coverage, durability and affordability of servicing assume greater importance when considering device design. Utilization of nonfluid-based means of variable cadence control would address a greater range of mobility needs while eliminating issues sometimes found in hydraulic devices, such as leakage. An additional factor that can inform product development is the need for reliable stability. Falls continue to be prevalent for people with lower-limb amputations from post-amputation to community living in ensuing years.[3] For individuals with lower-limb amputations, the incidence of fall-related injuries severe enough to require medical care is higher than in other at-risk populations.[4] Inclusion of a simple and highly effective stance-phase controller would meet the stability needs of K2–K4 users.

Innovative Technology

In 2007, Jan Andrysek, PhD, PEng, MASc, associate professor and associate director, professional programs, at the University of Toronto Institute of Biomaterials and Biomedical Engineering, set out to design a simple, high-functioning knee joint that would provide a high level of durability and stability while withstanding harsh environments.[5] The device, called the All-Terrain Knee, utilizes patented

FIGURE 1. AUTOLOCK TECHNOLOGY



AutoLock Technology, which is the only positive locking mechanism that automatically engages at full swing-phase extension. The knee remains securely locked until forefoot loading in stance phase, at which point the lock disengages (Figure 1). Execution of a hip flexion moment then freely initiates knee flexion. Premature unweighting of the prosthetic side will prevent the lock from disengaging, which provides biofeedback to the amputee during the acclimation phase of prosthetic use while ensuring stability upon subsequent heel strike. Energy-inefficient gait deviations such as vaulting and hip hiking can thus be eliminated or greatly reduced. With a hip flexion moment, traditional polycentric knee designs may buckle at heel strike or during the midstance phase, whereas the aforementioned conditions for release of the locking mechanism result in the device being less prone to collapse when navigating slopes and turns or when carrying heavy loads.

Prototype models of a pediatric knee utilizing the same locking mechanism as the current AutoLock Technology were manufactured for a quantitative evaluation of the stance-phase controller compared to a conventional geometric locking polycentric pediatric knee joint. Six children with a mean age of 10.8 years participated in the study. The median number of monthly occurrences of knee buckling were 30 and one for the conventional and prototype knees, respectively ($p<0.03$). The children with the prototype knee also reported minimal anxiety about falling during walking, scoring (0.5/5) versus (3.5/5) for the conventional knee joint.[6] A prospective study involving ten adults ages 16–26 years with unilateral above-knee amputations compared biomechanical and functional aspects of an automatic stance-phase lock (ASPL), now referred to as Auto-Lock technology, and a weight-activated stance-control knee. Physiological Cost Index scores were found to be lower by 40 percent on average for the ASPL knee joint after 12 months of use ($p<0.05$). Pelvic obliquity and anterior pelvic tilt were each reduced by 16 percent compared to the weight-activated stance-control knee ($p<0.05$)[7]. Developed in 2013, the Variable Cadence Controller (VCC) provides a smooth and quiet gait by reducing terminal impact and heel rise. This is achieved through a combination of two mechanisms: non-uniform braking, which increases friction resistance in late swing phase to slow the shank and limit terminal impact; and an optimized extension bias spring, which increases resistance and energy return at higher flexion angles, corresponding to faster walking speeds. Performance of the VCC was assessed through a combination of computational modeling (gait model) and empirical testing. The results demonstrated significantly lower flexion angles of the knee at slow, medium, and fast walking speeds. Unlike other spring and friction combinations, the VCC limited terminal impact velocity at fast walking speeds.[8]

A Solution

LegWorks developed the All-Terrain Knee collection, which brings to market four models of knees that utilize both Auto-Lock technology and the Variable Cadence Controller and are rated for activity levels K2–K4. The All-Terrain Knee and All-Terrain Knee with Stance Flexion are freshwater proof (lake immersion, shower) with a 275-lb. weight limit. The All-Terrain Knee Premium and All-Terrain Knee Premium with Stance Flexion are corrosion resistant (saltwater immersion) with a 330-lb. weight limit. All versions feature a simple, integrated anterior twist knob that easily engages a manual lock for situational use.

Patient A, referenced earlier in this article, was fit with the All-Terrain Knee. He nearly eliminated previously established gait deviations characterized by long prosthetic steps and vaulting due to the powerful extension-assist spring, which provided cadence-responsive swing-phase extension. He also reported high confidence in the stability of the prosthesis, which allowed him to resume engagement in sports activities with his children. The lower cost of the knee compared to fluid-based swing-control knees allowed him access to a device that supports his K3-level activity needs.

Patient B, a limited community ambulator, switched from his weight-activated stance control knee to the All-Terrain Knee. He reported greatly reduced anxiety when using his prosthesis and strongly preferred the mechanical lock of the All-Terrain Knee to the friction braking method utilized in his previous device. Furthermore, his prosthetist documented an increase in activity level from K2 to K3 a year after initial fitting, an outcome partly attributable to the VCC. This allowed Patient B access to a microprocessor knee, while retaining the All-Terrain Knee as part of a highly functional secondary prosthesis for situational use (activities that involve water, sand, or mud).

While there is an increasing emphasis on prosthetics research and development, the primary focus is placed upon expensive, state-of-the-art technologies. There remains a large unmet need for economical yet high-performing prosthetic devices. The All-Terrain Knee collection helps fill this gap by providing optimal stability and promoting an increase in mobility while meeting the functional and economic needs of moderate and highly active amputees. The goal of LegWorks is to continue to serve this unmet demand by developing more prosthetic devices that are high functioning and accessible to amputees globally.

References are available at www.oandp.org/page/ATcurrent.

Nicolas Vogel, CP
LegWorks
nick@legworks.com

Paul E. Leimkuehler ONLINE LEARNING CENTER

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