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The Design, Prototype, and Testing of a Robotic Prosthetic Leg

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The Design, Prototype, and Testing of a Robotic Prosthetic Leg

by

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To my wife and lifelong friend,

Karen

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CONTENT

FIGURES

TABLES

Tables Page

ABBREVIATIONS

AK	Above-knee amputation level (as defined by AMA, JCAHO, Tabers Medical Dictionary, and Stedman's medical dictionary). Equivalent to TF (for trans-femoral) used in academia.
a-MPK	Active Microprocessor Knee
APxA	Articulated Prosthetic Ankle
BK	Below-knee amputation level (as defined by AMA, JCAHO, Tabers Medical Dictionary, and Stedman's medical dictionary). Equivalent to TF (for trans-femoral) used in academia.
CC	Carbon composite
CoM	Center of mass
GRF	Ground reaction force
IMU	Inertial Measurement Unit
K1	Medicare classification activity level 1
K2	Medicare classification activity level 2
K3	Medicare classification activity level 3
K4	Medicare classification activity level 4
KD	Knee disarticulation amputation level also called through-knee (TK) amputation
MFCL	Medicare Functional Classification Level (“K-level”)
MPK	Microprocessor-controlled knee
p-MPA	Powered Microprocessor-controlled Ankle
p-MPK	Powered Microprocessor-controlled Knee

PWLL	Person with limb loss
RPL	Robotic Prosthetic Leg
sa-MPK	Semi-active Microprocessor Knee
sa-MPA	Semi-active Microprocessor Ankle
SACH	Solid ankle cushion heel
SAFE	Stationary attachment flexible endoskeletal
5xSTS	Five time sit-to-stand
TF	Transfemoral amputation level (ISPO, ISO, IEEE)
TK	Through knee amputation level, also called knee disarticulation (KD)
TKA	Trochanter knee ankle – an alignment reference
TT	Transtibial amputation level (ISPO, ISO, IEEE), also called below-knee (BK) amputation level

DEFINITIONS OF TERMS

Above-knee – An amputation level above the knee. Sometimes better defined as transfemoral (TF), it can be confused with knee disarticulation (through knee) amputation level as it can be technically below the knee. It is abbreviated as AK.

Active Prosthesis – A prosthesis that relies on an external power source. The power source may contribute to positive work (powered prosthesis) or may only actively resist motion (semi-active or quasi-passive).

Below-knee – An amputation level below the knee, sometimes defined as trans-tibial (TT). It is abbreviated as BK.

Componentry – Not a real word, but an overused industry slang term meaning components.

Double Limb Support – An event in locomotion that describes when the body's weight is supported on both lower extremities. It is essential in standing and during gait. It occurs twice in a single stride length of normal gait.

Dynamic Elastic Response – A prosthetic foot, sometimes called an "energy-storing foot," can be confusing. It is abbreviated as DER.

Four-bar knee – A prosthetic knee comprised of four connected links with their unique center of rotation. The composite motion of all four links creates the instantaneous center of rotation. Most four-bar-knees place the ICOR posteriorly and proximally to the anatomical knee center, allowing the user involuntary knee stability in stance. These knees also have improved swing phase dynamics and improved sitting cosmesis.

Ground Reaction Force Vector – A composite reaction force vector generated from collision forces from the body reacting with the ground surface during locomotion. Sometimes also referred to as the floor reaction force. It is abbreviated as GRFv.

Human-machine Interface – An interface that couples a person with a mechanical or electrical system and be physical (i.e., a button) or cognitive (i.e., biosignal). It can also be called a human-robot interface (HRI).

Initial Contact – The first of 8 subphases of gait, sometimes referred to as heel strike and a component of double limb support.

Initial Swing – An event in gait and the sixth of eight subphases is the beginning of the swing phase for the limb under scrutiny.

Knee disarticulation – an amputation level through the knee joint capsule. It is synonymous with the term through knee amputation, and this level is often included in above-knee amputation level definitions. It is distinctly different from a transfemoral amputation level as it generally retains all thigh musculature and femoral length. Additionally, this level has the advantage of distal weight-bearing, and therefore, the dynamics kinetics of this level is significantly different from transfemoral levels and therefore defined separately.

Loading Response – The second subphase of the gait cycle is when the foot becomes flat, and the extremity under scrutiny fully accepts full body weight and is generally considered an event of shock absorption. A part of double limb support.

Medicare functional classification level 0 - does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance their quality of life or mobility. A prosthesis is not eligible for this level. Often called K0

Medicare classification activity level 1 - amputees with potential only for standing, transferring, and/or a small amount of household ambulation. These patients are eligible for lower-level functioning components (no dynamic response feet or fluid adjustable knees). They are often called K1.

Medicare classification activity level 2 - amputees who have potential only for household or community ambulation at a single cadence and enduring low-level environmental barriers (curbs, stairs, or uneven surfaces). These patients are eligible for lower-level functioning components (no dynamic response feet or adjustable fluid control knees). Single-axis and multi-axial feet may be appropriate. They are often called K2.

Medicare classification activity level 3 - amputees who have the potential to community ambulate at variable cadences and have the potential to endure most environmental barriers. They may have vocational, therapeutic, or exercise activities that demand prosthetic utilization beyond simple locomotion. These patients are eligible for prostheses with dynamic response feet and adjustable fluid control knees. They are often called K3.

Medicare classification activity level 4 - amputees who have the potential for high levels of activities with the prosthesis, high impact, stress, or energy levels. Typical of the prosthetic demands of a child, active adult, or athlete. These patients are eligible for all levels of functional components. They are often called K4.

Microprocessor Controlled Knee – A device that uses a microprocessor (or microcontroller) as an onboard embedded control mechanism.

Midstance – The third of 8 subphases of gait that signifies all the body weight is on the leg of scrutiny, with the weight line and GRFv passing through the center of the leg. This period of gait is in single-limb support.

Midswing – the seventh of 8 subphases of gait, the limb under scrutiny. The ankle is at 90 to the level ground in normal gait and has sufficient toe clearance to avoid tripping. Abbreviated as MSw

Passive Prosthesis – A type of device that utilizes passive dynamics as a means of locomotion, meaning only the user's residual limb strength initiates the swing phase, and in the case of AK prosthesis, the pendular motion of the swing extends the knee unit and in stance phase, relies on the passive geometric alignment of the device to provide knee and ankle stability.

A person with limb loss – An individual who has had at least one limb amputated. Sometimes referred to as an amputee, a person with limb loss may be a preferred term and can be abbreviated as PWLL.

Powered – A prosthetic device that is not only electrically active but uses an external power supply to contribute work energetics to the production of activities such as locomotion, standing, sitting, and stair ascent/descent.

Pre-swing – The fifth of eight subphases of gait, where the reference limb prepares for the swing phase and transfers body weight to the opposite limb. It is abbreviated as PSw.

Prosthesis – an external device engineered to replace an amputated or otherwise missing extremity. They are sometimes referred to as exoprosthesis to differentiate from a surgically implantable device.

Push-off – A phase in locomotion studies to describe the plantarflexing ankle prior to the swing phase of gait. Although a misleading term, it is commonly used in literature to describe Pre-swing (PSw).

Semi-active Prosthesis – Implies that although the prosthesis uses a battery or external power supply, the device does contribute power to the locomotive process. The actuators only dampen or resist motions and may store powers but do generate them.

Single Limb Support - An event in locomotion that describes when the weight of the body is supported on the single extremity under scrutiny.

Solid Ankle Cushion Heel – A prosthetic foot developed at UC Biomechanics Lab in the 1950s and was a clinical standard for 40 years. Today serves as a reference point to compare all other prosthetic feet. Abbreviated as SACH

Stance Phase – Phase of gait, where the extremity under scrutiny is in contact with the ground

Swing Phase – Phase of gait where the extremity under scrutiny is in a non-weight bearing state and in an aerial phase, not in contact with the ground.

Terminal Stance – Phase of gait where the body prepares to transfer body mass to the contralateral limb.

Terminal swing – the final phase of the gait cycle as the limb under scrutiny prepares to make initial contact with the ground.

Through knee amputation – an amputation level through the knee joint capsule. It is synonymous with the term knee disarticulation. This level is often included in above-knee amputation level definitions. It is distinctly different from a transfemoral amputation level as it generally retains all thigh musculature and femoral length. Additionally, this level has the advantage of distal weight-bearing, and therefore, the dynamics kinetics of this level is significantly different from transfemoral levels and therefore defined separately.

Transfemoral amputation - An amputation level above the knee. Sometimes identified as an above-knee (AK) amputation, abbreviated as TF.

Transtibial amputation - An amputation level below the knee. Sometimes identified as a below-knee (BK) amputation, abbreviated as TT.

Trochanter Knee Ankle – a reference line used in the static assessment of the alignment of lower limb prosthetic components. This line assists the clinical prosthetist in making predictive outcomes of dynamic joint motions. It is abbreviated as TKA.

ABSTRACT

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Since antiquity, health professionals have sought ways to provide and improve prosthetic devices to ease the suffering of those living with limb loss. Mid-century modern engineering techniques, in part, developed and funded by the American industrial war effort, led to numerous innovations and standardization of mass-customized products. Followed by the Digital Revolution, we are now experiencing the roboticization of prosthetic limbs. As innovations have come and gone, some essential technologies have been forgotten or ignored. Many successful products have been commercialized, but unfortunately, they are often rationed to those who need them most. Here we present a prototype device based on many prior discoveries, utilizing commercially available parts when possible. This device has the potential to reduce the overall costs of powered robotic prosthetics, making them accessible to those with knee instability or the fear of falling. Additional benefits of this device are that it is designed to improve the kinematic and kinetic symmetry of the lower extremities, including the hips.

We will design, prototype, and test this robotic prosthetic leg for feasibility and safe performance.

KEYWORDS: ENGINEERING, LIMB LOSS, FEAR OF FALLING, POWERED ROBOTIC PROSTHETIC LEG, PROTOTYPE

CHAPTER ONE

INTRODUCTION

An estimated 2 million persons are living with limb loss in the United States due to the 147,000 amputation surgeries performed annually [1]. The loss of the leg and subsequent loss of the function of the knee poses several complications for the individual in terms of weight-bearing, gait kinematics, and social well-being. There is the loss of passive support of the distal extremity. Still, there is also the loss of the kinesthetic feedback and the loss of the contractile function of the absent muscles [2]. Additionally, there is evidence that limb loss is associated with pain, fatigue, anxiety [3], poor social health [4], disturbances to sleep [3], slower walking [5], balance impairment [6], increased cognitive demand while walking [7], increased plantar pressures [8], greater risk of falls [9], more injuries from falls [10, 11] and possibly muscle atrophy of the non-amputated leg [12].

Background

Robert L. Horner, Richard G. Rincoe, and Marlin B. Hull developed a prosthetic robotic knee in 1992, which is later described [13]. This robotic knee joint, controlled in many ways including myoelectrically, was powered by a conventional self-contained power source (battery). This invention comprised a linear actuator and provided rotary motion through a uniquely designed epicyclic cam which affords low torque, high speed in walking, and high torque, low speed when sitting. Ankle motion occurred when used with a specially-designed prosthetic ankle [14], which provided restrained tibial progression in stance, but swing-assist dorsiflexion in swing. Unlike those evaluated in

the literature, this robotic knee is non-backdrivable. When not under power, the knee locks and cannot flex or extend passively, providing a unique solution for stance control.

Hypothesis

The primary hypothesis of this study is that a prototype robotic prosthetic leg (RPL) will improve the dynamics of standing and sitting in persons with unilateral limb loss. A secondary hypothesis is that the RPL will decrease stress levels, increase confidence during standing and sitting activities, and elicit a metabolic response measurable by a change in heart rate.

REVIEW OF LITERATURE

There are an estimated 2 million persons with limb loss (PWLL) in the United States, with an estimated 185,000 new amputations per year, and it is estimated that there are 42 million PWLL globally [15]. The number of PWLL is estimated to double by 2050 [16], and this population is getting younger [17]. Limb loss has several implications for the patient, the patient's family, and our society. In a study of PWLL in the United Kingdom, it was reported that 58% of persons with unilateral limb loss reported at least one fall in the last 12 months [18]. During 2012 in the United States, diabetes had an incidence and prevalence of 7.1/100 and 8.3/100, respectively, with diabetes as the leading cause of amputation [16]. Although there are many innovations to treat the loss of a leg and return the PWLL with the ability to walk again, these biomedical systems still leave patients with multiple mobility impairments. Most interventions today still rely on passive dynamics and body-powered kinematics to facilitate the PWLL to ambulate. Loss of a leg above the knee (AK) results in the loss of

passive support in the stance phase, the loss of the contractile ability of the remaining muscles, and the loss of the kinesthetic sensation resulting from the missing limb [2]. Amputees fitted with a typical passive prosthesis suffer from increased hip flexion activity in early stance to initiate the swing phase and clear the foot in the stance phase. This increases the vertical displacement of the center of mass (CoM) and increases gluteal activity to advance the limb.

Consequently, there will be a 50% decrease in metabolic energy efficiency when walking [19]. Many have proposed powered robotic devices to improve locomotion and safety, augmenting the lower-limb loss [20-33]. It has been suggested that these technologies can make the user safer by reducing the incidence of falls.

The attempts to resolve these issues include various innovative iterations of semi-active knees [30, 31, 34, 35], active knees [20, 24, 32, 36, 37], and active ankles [38, 39]. Some of these innovations have even been commercialized and are available to patients through their prosthetists. Although these robotic technologies have good performance outcomes, current commercially available semi-active knees cost $31,571 [40] - $32,163 [41], the current commercially available semi-active ankle costs approximately $22,000 [42]. The current available powered knee is $46,540 [43]. With a median household income of $67,521[44], these devices are out of most consumers' reach, so they must rely on the policies of third-party health insurance to gain access to these technologies. Typically, they are reserved for the wounded warrior, veteran, or who can demonstrate a level K3 or higher ambulation potential.

In contrast, those with balance dysfunction, single-speed cadence in gait, or an inability to negotiate ramps or stairs are deemed ineligible for the very technology needed

to assist those conditions [45]. These policies exclude most persons with limb loss who are the least able to pay for their care, the most at-risk for falling, and the most in need of these advanced technologies. Finally, these technologies do not fully consider the full potential of assisted standing and sitting.

Historical Perspectives

One of the earliest known prosthetic limbs was a leg prosthesis discovered in Capua, Italy, estimated to be from 300 BC [46, 47]. Modern attempts to recreate the device through 3D modeling and 3D printing lead some to conclude that the knee could flex, possibly allowing the user a more natural gait [48]. The prosthesis, made of bronze and wood, was assumed to have been suspended by leather belts and straps. In 1863, a patented knee design was an improvement made to prosthetic legs by Uriah Smith [49], an American theologian, Seventh-day Adventist minister, and an amputee himself. This improvement allowed him (the user) to kneel for prayer, as it featured a flexible knee and ankle [50] and then locked when he stood. Smith recognized the need for a functional prosthetic leg to perform beyond just walking. In 1846, a New York Prosthetist created, after his name, the A. A. Marks Corporation to provide prosthetic limbs for PWLL. Marks praised kinetoscopic photography for quantifying gait [51], as prosthetists had otherwise lacked an empirical measure to quantify the performance of prosthetic legs otherwise. By analyzing kinetoscopic photographs of subjects while walking, he divided the gait cycle into eight distinct subphases, which is the basis for the subphases described today in contemporary gait analysis.

At the conclusion of World War II, Howard Eberhart directed a cooperative project between the Department of Engineering at the University of

California (UC) Berkeley and the School of Medicine at UC San Francisco, evaluating prosthetic devices. Known as the UC Biomechanics Lab (UC-BL), the team included Verne Inman, Charles Radcliff, John Bertrand deCusance Morant Saunders, and James Foort [52]. Advances such as the UC-BL solid ankle cushion heel (SACH) foot, suction sockets, quadrilateral sockets, and the UC-BL four-bar knees were engineered and extensively tested [53]. Afterward, Marks' eight phases of gait were revised and later clarified and published as a clinical standard by Verne Inman [54, 55] to better analyze and describe amputee gait. These works are remarkable because Inman and his associates later recognized the complex ankle axis [56-58] and its role in energy-efficient gait and developed the so-called six determinants [55, 59, 60]. Later, Jacquelin Perry (a medical resident at UCSF) saw the value of gait analysis [61] and further refined the works of Inman, better describing all types of pathomechanic gait patterns into a unified nomenclature [62-64] that we use today (see table 1). Perry's terminology is beneficial because it adequately describes the gait of other pathologies (e.g., stroke) and is still accurate in analyzing amputee gait. Perry's naming convention improves our understanding of amputee gait, as passive limbs with fixed ankles cannot "push-off." Perry and others recommended prosthetic foot designs that incorporate mechanisms to promote an early loading response (foot flat) without compromising limb stability [65].

<table>
<tr><td colspan="5">Stance phase: 62% of the gait cycle</td><td colspan="3">Swing phase: 38% of the gait cycle</td></tr>
<tr><td>Heel strike</td><td>Foot flat</td><td>Midstance</td><td>Terminal stance</td><td>Push-off</td><td>Initial swing</td><td>Mid-swing</td><td>Terminal swing</td></tr>
<tr><td>Initial contact</td><td>Loading response</td><td>Midstance</td><td>Terminal stance</td><td>Pre-swing</td><td>Initial swing</td><td>Mid-swing</td><td>Terminal swing</td></tr>
<tr><td colspan="2">Weight acceptance</td><td colspan="2">Single limb support</td><td colspan="4">Swing limb advancement</td></tr>
</table>

Table 1: Summary of the phases of gait adapted from [51, 55, 61, 66-69].

Early prosthetists already recognized this need but lacked a unified method to manufacture and design feet consistently. Instead, the prosthetists of the time relied on artisanal talents to fabricate prosthetic feet. These designs lacked repeatability. James Foort, a Canadian chemical engineer, joined the UC-BL and brought his prototype SACH foot. Foort and Radcliffe developed the first production prototypes of the SACH Foot in 1956 (figure 1). This development allowed prosthetists to order a size-specific prefabricated commercial off-the-shelf (COTS) foot from the many orthopedic product suppliers. This improved delivery times and provided patients with a consistent product.

Figure 1 SACH foot (left) and SAFE foot (right) give prosthetists and patients COTS

An orthotist and member of the UC-BL, John Campbell develops a unique and important ankle-foot orthosis that replicates the oblique axis of the talocrural and subtalar joints [56, 70]. Fabricating the external orthotic joints was complex [71] and the finished design was bulky. But the concept was sound and seemed that it could be easily incorporated internally into a prosthetic foot/ankle system. Campbell later teamed with

Charles Childs, and together they developed the stationary attachment flexible endoskeletal (SAFE) foot [72] (figure 1). In a study by Wirta [73], PWLL subjectively preferred the SAFE over the SACH. Although the SAFE foot was simple in design, it did not incorporate all the biomechanical features of the UC-BL dual-axis AFO.

Prosthetic foot/ankle designs do not consider these findings, and this topic deserves more research and attention. Figure 2 illustrates the oblique and sometimes subtle axis in relationship to the line of progression and the floor [74].

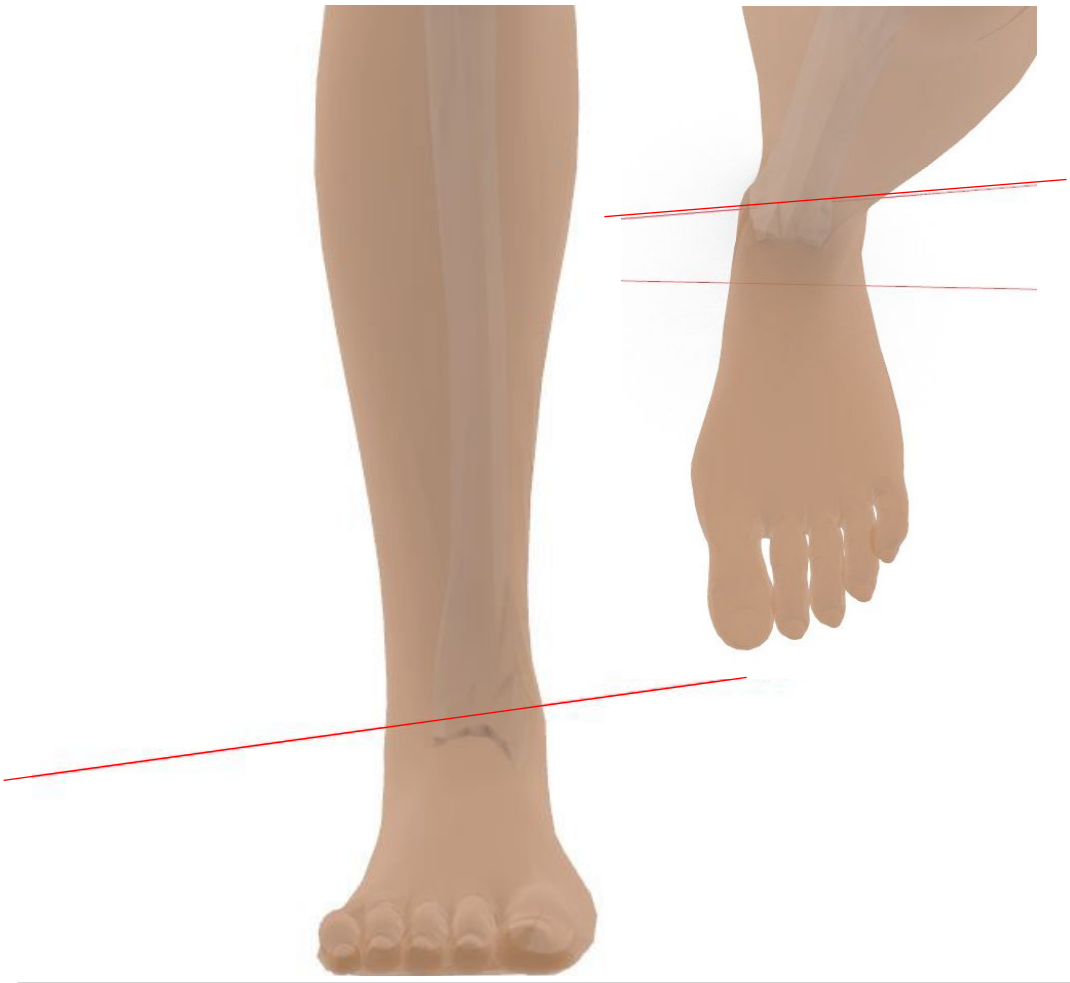

Figure 2 Talocrural axis in two planes of both legs. In the coronal view (left) for a right leg the axis is 8° roll to the floor and in the transverse view (right), the axis is 8° yaw to the line of progression.

The UC-BL team made a considerable contribution in their attempts to unify AK alignment techniques by comparing the "American" and the "German" alignment methods of the time [62, 63, 75]. The spatial location of the socket to the knee, ankle and foot is referred to as the alignment. Proper alignment is essential for balancing efficiency with knee stability by optimally directing ground reaction forces through the prosthesis. The alignment process typically goes through three iterations (bench, static, and dynamic alignments). Because of the design of wooden exoskeleton prostheses, alignment changes were not easily performed. This led Foort to develop a "modular system" of COTS adapters, so prosthetists could easily make alignment changes during the dynamic analysis optimizing the patient's gait in real-time [76, 77]. These COTS feet opened up many opportunities for novel COTS parts and adapters, and prosthetists could quickly assemble complex assemblies unique to their patient's needs and requests. Examples of COTS adapters can be seen in figure 3 and afford easy alignment changes to optimize the patient's gait during the dynamic alignment process.

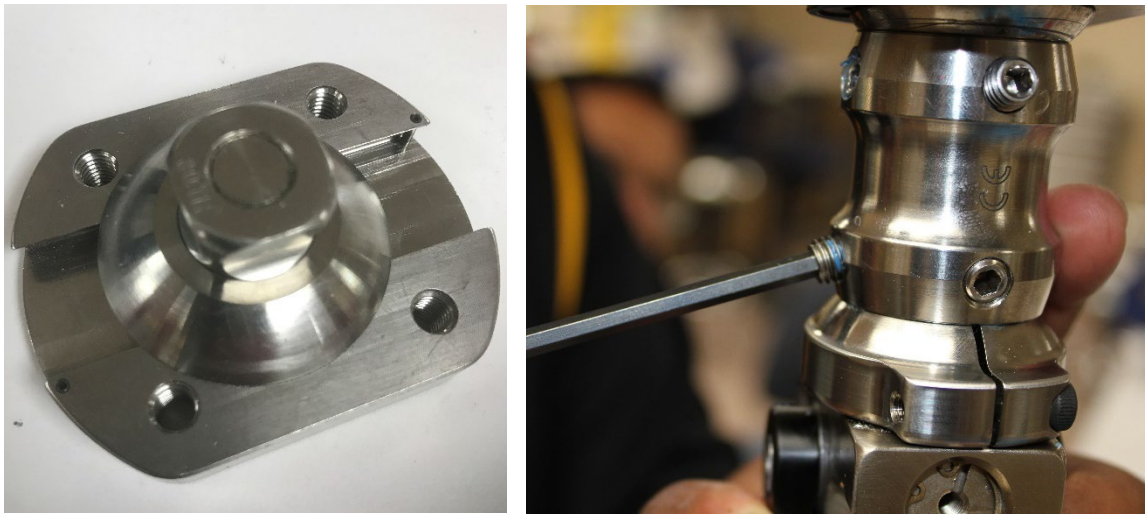

Figure 3 Examples of COTS adapters that allow for easy assembly of prosthetic components and allow the prosthetist to tune the alignment of the prosthesis easily and accurately.

However, “normal gait” is more of a goal. So many prosthetists and patients settle for a "good enough gait" that can account for comfort, patient preferences, and performance [78]. Through education and experience, the prosthetist determines the alignment using the best judgment, paired with some objective measures, and finally with observational gait analysis [79, 80] augmented with patient feedback. It was not until the 1990s that Blumentritt described a method and portable tool to assess the alignment of PWWL while using prosthetic devices objectively. This tool, the LASAR Posture®, is a force plate coupled with a stepper motor and geared belt to drive a laser module tracking the user's static vertical ground reactions. The laser casts a visible red line onto the subject. The prosthetist can evaluate the results on the patient before and after making alignment changes in the static and dynamic alignment stages (figure 4).

Figure 4 LASAR Posture®. Laser line, represents vertical ground reaction in relationship to the trochanter, knee, and ankle (TKA)

Even with systematic adherence to nominally align the prosthesis, extension and varus moments will remain dominant during the stance phase [81]. Accurate and repeatable alignment is essential to the prosthetist and the patient. However, performance and patient preference may differ, so this is still a personalized process [82]. Shepherd and associates report that PWLL reliably preferred a mean of 7.8◦ (SD: 4.8◦) dorsiflexion during ramp ascent and 5.3◦ (SD: 3.8◦) plantarflexion during ramp descent [83].

One vital component was the development of passive articulated ankle in single-axis and multi-axis designs. These designs used springs, rubber bumpers, or even hydraulics. In comparing the SACH to the Greissinger multi-axis ankle, PWLL with TT had significant improvements in the hip and ankle's spatial and temporal parameters and hip symmetry [84]. Hydraulic ankles (HA) provided reliable shock absorption in early stance and restrained tibial progression in late stance. A study of PWLL with both unilateral transtibial (TT) amputation and transfemoral (TF) amputation found that providing subjects with an HA can improve the health and longevity of the remaining limb by reducing the peak plantar pressures acting upon it [85]. Alexander and associates found that PWLL-TF, using an HA versus rigid ankle joint component, experienced reduced mean joint flexion (48%) and extension (92%) at the hip joint of the residual limb while walking on level ground, inclines, and declines [86]. Criticisms of HAs are that they are heavy and can be prone to an increase in mechanical failure. However, in a study of 19 amputee subjects, Su and others [87] found that the increased ankle sagittal plane motion (6°-7°) from a flexion unit increased positive ankle power (about 0.17 watt/kg) while adding a torsion unit, transverse plane ankle range of motion increased by 1°-2°. Responses indicated that 14 of the 19 subjects preferred the prosthetic

configuration that included both the flexion and torsion units. Furthermore, the subjects perceived that the combination provided stability on uneven terrain.

Early prosthetic knees were typically a single-axis constant friction design, which relied on a fixed ankle. Through a stable alignment, voluntary knee control was provided through hamstring contraction. Figure 5 illustrates an example of one of these early designs.

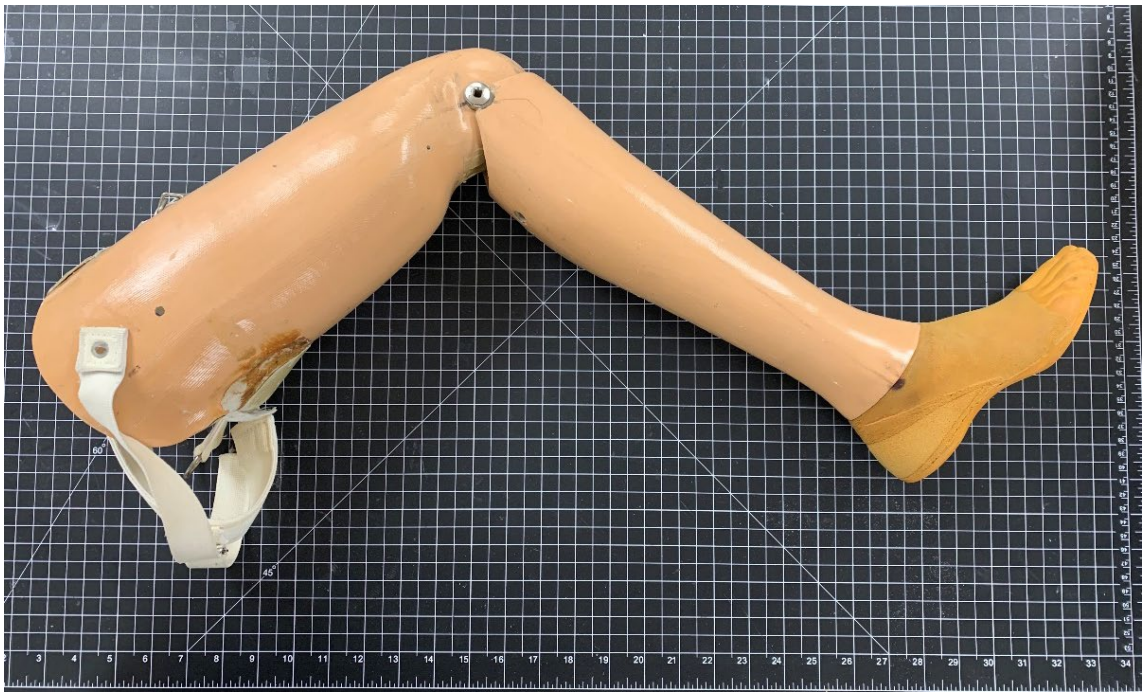

Figure 5 Non-modular type prosthesis with single-axis, constant friction knee and SACH foot.

If a knee required a locking mechanism (i.e., K1 or K2 ambulator), that lock was manually controlled. The user would walk with a circumducted gait until they needed to sit. At that time, they manually unlocked the knee. The unit was automatically locked upon standing again and remained in this position. Attempts to make clutchable weight-activated locking knees (sometimes called "Safety Knees") were made, but they did not perform well.

In 1934, German inventor Georg Greissinger filed a French patent [88] describing a polycentric knee mechanism utilizing a four-bar linkage. Later at the UC-BL, Inman and Radcliffe described a four-bar linkage [63, 64, 89, 90] that provided stance phase stability through geometric locking of the linkage and unlocking for the swing phase.

Four-bar knees (figure 6) benefit from increased toe clearance compared to single axis-knees [79, 80]. The hip-to-toe length shortens in the swing phase as the dynamic geometry effectively shortens the leg. Furthermore, four-bar knee units can increase knee stability through involuntary stance phase control [62-64, 79, 91, 92]. Five-bar mechanisms were a natural evolution and had been described as having the added benefit of individualized fine-tuning [93].

Figure 6 Example of a four-bar geometric locking prosthetic knee.

The Total Knee® by (Össur Grjóthálsi 1-3, 110 Reykjavík, Iceland) is a commercially available polycentric knee with a six-bar linkage and is seen in figure 7. Although more complex than four or five-bar linkages, the six-bar has improved ankle trajectories in swing, stability in stance, and control adjustments [94]. There is solid quantitative evidence that the six-bar knee improves stance phase stability. Most users prefer six-bar knees as they feel more stable and provide more confidence when walking on the Total Knee® than on the 3R80 0 [95]. A crossover experiment of 10 subjects with TF, Sensinger, Intawachirarat, and Gard concluded that four-bar knees provide greater foot clearance in the swing phase than single-axis knees. Still, ankle mechanisms that dorsiflex provide substantially more toe clearance [80].

Figure 7 Össur Total Knee® six-bar component on LASAR Posture® device.

From July 1948 - June 1958, the Stewart-Vickers knee, later marketed as the hydra-cadence knee by the United States Manufacturing Company [96] (figure 8), was tested in 100 subjects with TF or Hip Disarticulation [97]. The Hydra-cadence was a novel design that coupled ankle dorsiflexion with knee flexion and independent plantarflexion to facilitate toe clearance in swing and shock absorption in early stance. However, this innovative design did not increase knee stability in the stance phase [97], relying instead on the user's ability to control the knee voluntarily.

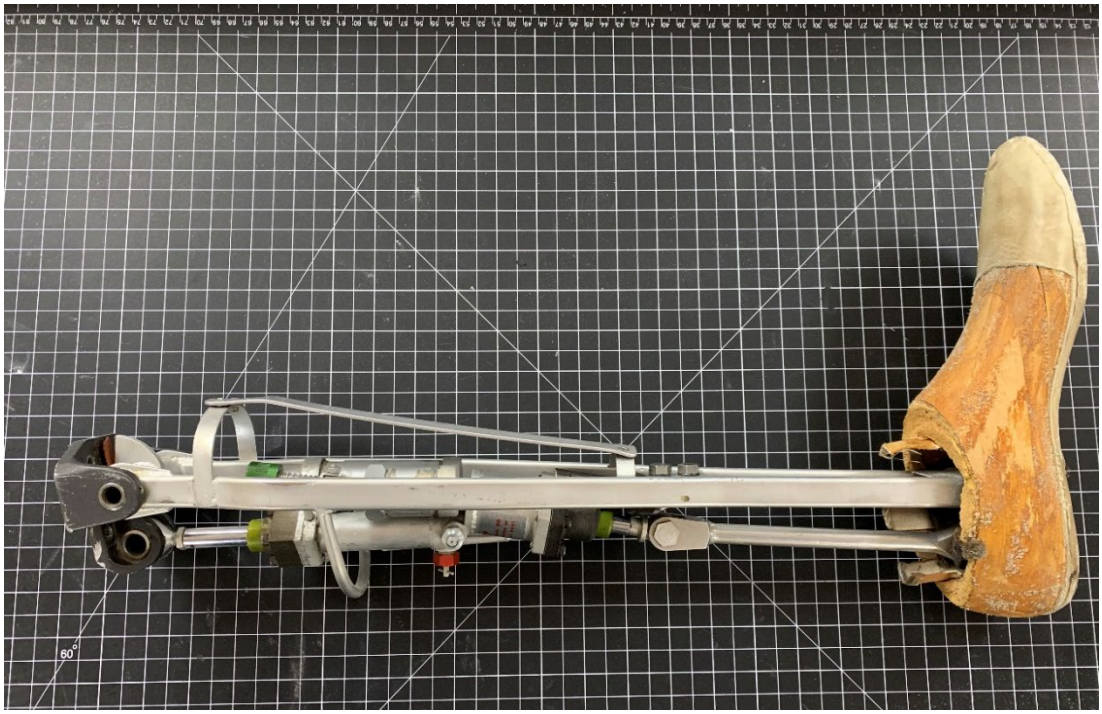

Figure 8 Stewart-Vickers, Hydra-cadence hydraulic knee and ankle system.

In 1948, a significant change in prosthetic knee technology evolved [98] as part of post-war research, called the Henschke-Mauch SNS hydraulic knee. The hydraulic cylinder of the device allowed for stance phase locking of the knee and a slow yield of knee flexion [99]. By the 1980s, the Mauch SNS had become a gold standard in above-knee prosthetics, particularly among active amputees [100]. Volatile et al., [101] evaluated 61 PWLL and reported that users of the Mauch SNS had a smoother gait, could vary their cadence and had increased activity level and stability in the stance phase, experienced fewer falls, and had less fatigue. While Murray et al., [102], in a seven-subject evaluation of the Mauch SNS. vs. a single-axis constant friction knee, showed a wider range of walking speeds, an improvement in the equality of the durations of successive swing and stance phases, and greater uniformity of forward progression for

Figure 9 Ottobock 3R80

users of the Mauch SNS. One limitation of the SNS is that the stance control can inadvertently disengages on some uneven surfaces and in stair descent [103].

The 3R80 knee (Ottobock SE & Co. KGaA, Duderstadt, Germany) is an example of a modernized version of a hydraulic single-axis knee unit (figure 9).

It is important to note that all aforementioned technologies were reasonably successful, given the technological limitations of the time. Still, all relied on proper alignment and passive dynamics for control and function.

Microprocessor Controlled Devices

In 1967, a significant breakthrough occurred when a microcontroller orthosis was described [104], using electromyography (EMG signals) to operate the device. Collaborative work at UCLA was also being done at this time [105] with a microcontroller elbow prosthesis based on the "Rancho Los Amigos Arm" [106] and was successfully demonstrated to operate and control an upper extremity prosthetic device. Two years later, at the Massachusetts Institute of Technology (MIT), a microprocessor-controlled prosthetic knee was demonstrated to be functional and utilized an electro-hydraulic servo mechanism that could be interfaced with bioelectric signals [107], allowing the user semi-active (SA) control of the device. This device was required to be tethered to an external power source and a computer for operation and was not self-contained. Soon after that, another innovation from MIT [108] demonstrated a self-contained SA microcontroller swing-phase dampening of a pneumatic knee. Later in the 1990s, a group of researchers at the University of Paris described a method of using an

SA microcontroller with an Intel 8051 chipset for swing phase control of a pneumatic four-bar prosthetic knee [109].

In 1993, Rincoe, Hall, and Horner developed a non-backdrivable self-contained, actively powered MPK (p-MPK) [13, 110, 111], using an Intel 8051 chipset. This device's unique epicyclic-geared cam transmission (figure 10), similar to the passive Habermann polycentric knee joint [112], had a motion path similar to a four-bar knee mechanism, thus changing the power to speed ratio as the knee rotates.

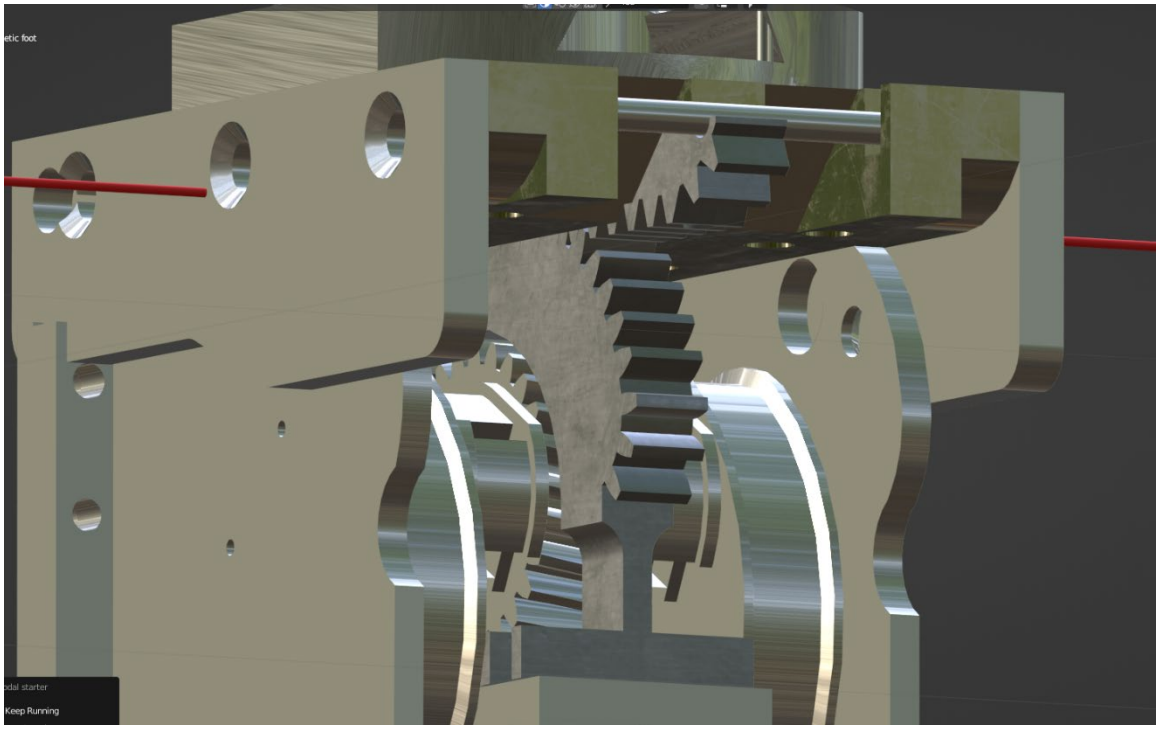

Figure 10 Curved rack and elliptical pinion of the actuated knee

The Rincoe knee was successfully demonstrated on several users using a hand-controlled human-machine interface (HMI) by the investigator. At least one user successfully navigated slopes and stairs [113]. The device was intended for an EMG HMI for volitional knee control, but that design was never realized, and the findings of

the trials were never published for peer review. This device was significant because it provided a net power gain to the user's gait and did not require passive dynamics for stance control or swing phase control of the knee. The knee was coupled with a passive articulating ankle that provided substantial dorsiflexion (~15 degrees) in swing phase to function correctly [14]. Marketed as the R-Hab ankle, it was to be coupled with a commercial SACH foot (figure 11) and weighed 1.03 kg with the foot. The ankle was high maintenance and prone to failure, and newly developed and commercially available carbon-composite (CC) feet quickly replaced the UC-BL SACH foot, rendering the R-Hab ankle obsolete, as it did not couple with a CC.

Figure 11 R-Hab ankle with SACH foot.

An innovation first filed in 1987 and patented in 1989, marketed as the Flex-Foot®, was developed by Philips [114] and was considered the first CC foot. Other designs followed and quickly went to market, but all are evolutions of this J-shape design and now use COTS adapters to tune the alignment and provide multiple configurations of components. These design iterations and market competitors include the Vari-Flex®, Vari-Flex® low-profile, and the Freedom Innovations, LLC (Irvine, CA, USA) Renegade® (pictured in figure 12). Studies showed that these CC feet outperformed other passive feet in the performance of PWLL with TT amputations [65, 115] and TF amputations [116, 117]. In a study comparing CC against the SACH and a single-axis ankle, Rao et al., concluded that future designs should provide improved ankle mobility that mimics the dynamic characteristics of early stance [118].

Figure 12 Examples of COTS CC Feet, left to right Össur Vari-Flex®, Össur Pro-Flex® with VSP, Össur LP Vari-Flex®, Freedom Innovations Renegade®, Freedom Innovations Pathfinder®.

In a study by Zmitrewicz and others, PWLL walking with CC feet paired with an articulating ankle joint generated a significantly greater propulsive impulse with the residual leg, as compared to without an ankle joint, and with or without SACH foot, and with or without an ankle joint [119], which improved propulsive symmetry between the residual and intact legs. This leaves opportunities for future designs.

One of the more significant innovations in prosthetics was the C3100 ("C-Leg®") by Ottobock (figure 13). This SA microprocessor-controlled knee (sa-MPK), which initially relied on a PIC16 chipset, and was first described in 1998 [120] and again in

Figure 13 First generation Ottobock C-Leg® sa-MPK – image courtesy of Loma Linda University Health.

2000 [121]. Beyond the hype of being the first commercially available “bionic” leg component, there is substantial support in the literature validating the effectiveness of the C-Leg®, including ramp and slope safety and decreased hip torque in early stance [122]. Although intended for MFCL K3 and K4 ambulators, the C-Leg® has even been shown to benefit MFCL K2 subjects with improved gait and ramp safety [123].

The C-Leg® functions by providing users with computerized SA swing phase control and SA variable impedance (resistance) in the stance phase. This impedance to knee flexion allowed users to improve safety in the descent of ramps and stairs [124, 125] as strain gauges in the pylon inform the microcontroller of the state of ground reaction forces (GRFs) in the system and operate through a finite state machine (FSM) algorithm to determine the behavior of the knee. Although technically an active prosthesis, sa-MPKs like the C-Leg® do not provide any positive power to walk energetically, so the term SA is preferred. In other words, it did not provide active knee extension to allow stair ascent, walking up slopes, or standing from a seated position. Some have suggested naming or classifying these devices as quasi-passive knees instead of SA. Both terms are used in literature to describe these devices.

Perry et al., [126] showed that a person with bilateral limb loss using the C-Leg® ambulated farther and faster, with lower oxygen consumption and metabolic costs than walking with so-called "stubbies" and passive leg prostheses. There was a reduction in oxygen consumption compared to the passive hydraulic knees. However, another study [102] tested the hypothesis that sa-MPKs improve gait efficiency in AK amputees in a prospective randomized crossover trial compared to passive knees with the Mauch SNS in eight subjects. Dietl and associates found that in some subjects, the cost savings was

substantial. However, in other subjects, it was not significant. A later study [127] evaluated 12 AK PWLL using the C-Leg® compared to a passive hydraulic knee (Mauch SNS). Compared with the passive hydraulic knee, the C-Leg® demonstrated increased symmetry between limbs, increased velocity, and decreased vertical ground reaction forces (GRF). The C-Leg® has since evolved into the commercially available X2 and X3 sa-MPKs, which provide improved stair ascent by increasing the ability to use a step-over-step gait pattern and increased prosthetic side peak knee flexion and increased swing duration [128].

Microprocessor technology soon led to the commercial development of a SA microprocessor ankle (sa-MPA). This ankle, the Proprio® by Össur (figure 14), improved

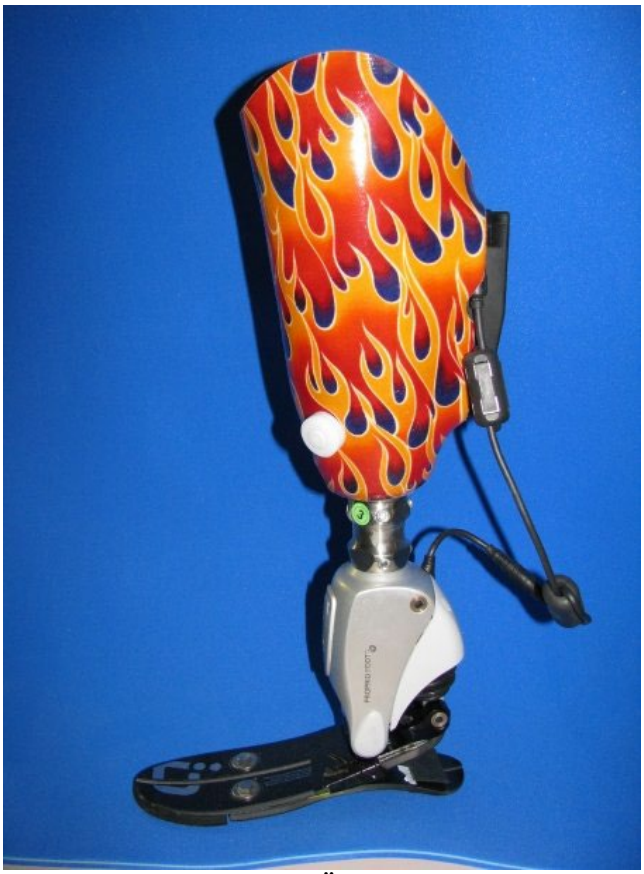

Figure 14 First generation Össur Proprio® sa-MPK foot/ankle on a BK prosthesis

ramp and stair mobility [129], and provided enhanced chair exit. Because it does not generate positive power, it is an sa-MPA.

Blatchford Group (Basingstoke, Hampshire, UK) has developed a sa-MPK with HA and is marketed as the Elan® (figure 15) and may reduce contralateral loading on ramps [130].

Figure 15 Elan® sa-MPK with HA, by Blatchford Group

At MIT, Herr described a magnetorheological sa-MPK with a user-adaptive control scheme [131, 132]. Based on the Motorola 68HC11 chipset, this sa-MPK was later marketed as the Rheo Knee® and sold by Össur Corporation, giving prosthetists and patients market choice of commercially available sa-MPK. In a comparison study of a passive hydraulic knee (Mauch SNS) and the sa-MPKs C-Leg®, and Rheo Knee® [133],

the investigators found that the Rheo Knee® and the C-Leg® perform better than the passive device by 2 and 3%, respectively, in terms of energy conservation [133]. The Rheo Knee® sa-MPK was important as it was the first commercial leg device to utilize an embedded artificial intelligence (AI) to accommodate user walking potential changes [132]. Compared to C-Leg®, the Rheo Knee® may not provide reliable knee control when the users is walking backwards [134].

Freedom Innovations also entered into the market with the Plie®, this first waterproof MPK. Thiele et al., demonstrated that all three MPKs (figure 16) offer reliable detection of stance and swing phase and respond with knee impedance to prevent

Figure 16 Examples of sa-MPK with CC feet. Left to right, C-Leg®, Rheo®, and Plie®.

knee buckle [135]. In a study of the C-Leg®, Rheo®, and Plie® (figure 16), Campbell, Stevens, and Wurdeman [136], found no significant differences in functional mobility and user satisfaction.

A human-robot interface (HRi) can be described as a hardware and software link between two dissimilar systems, such as a human and a robotic prosthesis [137]. Pons further reported that the interface is linked informationally, mechanically, or electronically to support human-robot interactions. A well-implemented HRi should be able to realize user-intended control; that is, when the system should adapt accordingly to when the user intends to stand, walk, and sit. In 1972, the first description of an electromyography (EMG) controlled AK prosthesis was made [138], and a decade later, a pattern recognition algorithm was developed [139] in an attempt to isolate user intention and differentiate the movements of the hip and knee. This was then implemented into a myoelectrically-controlled pneumatic prosthesis [140], and although the device was tethered, it demonstrated that the user could voluntarily adjust the damping characteristics of the prosthetic knee in the swing phase through an implementable HRi. Mobile phones can be thought of as HRi or, better stated, HMI. These technologies can be used to collect gait data [141-143] historically available only through expensive gait labs. These technologies revealed the power of wearable dataloggers to collect anthropomorphic movements of individuals in environments outside of the gait lab. Today, a trained researcher can tap into the power of the onboard inertial measurement units (IMU) comprised of accelerometers, magnetometers, and gyroscopic sensors on the phone to collect gait parameters of users of a powered prosthesis, passive prosthesis, and those without mobility impairment.

Powered Prosthetics

The first commercially available powered microprocessor knee (p-MPK) was developed by Össur (figure 17) and, through a linear actuator using echo-control, provides net power to ambulation, chair exit, and, most notably, stair ascent. Creylman et al., [122] described these devices (commercially known as the Power Knee™) and, in a four-subject investigation, compared the device to an sa-MPK, commercially known as the Rheo Knee®. Results showed an induced knee flexion during stance, hip torque was diminished, and increased stance phase duration. Creylman also found that subjects had decreased biological hip torque in early stance with increased prosthetic knee flexion. In another study, Haffner and Askew [144] found that the Power Knee™ significantly improves timed up and go (TUG) tests, ramp times, and increased balance confidence compared to passive devices in MFCL K4s. A 2013 study by Wolf et al., [145] found that p-MPK subjects generated more knee power in gait than sa-MPK among wounded

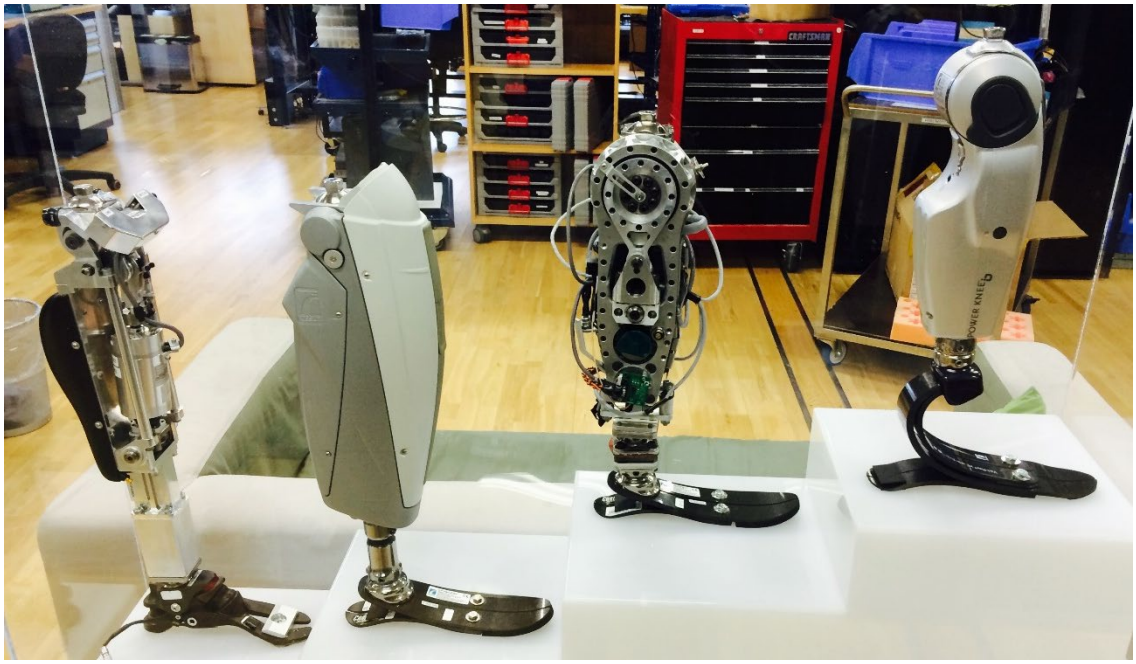

Figure 17 First and second generation Össur Power Knee® p-MPKs – image produced by author

soldiers (MFCL K4). They also found that in sit-to-stand (STS) transitions, the p-MPK showed more symmetrical knee power and decreased GRFs for the intact limb. They did not describe the type of foot/ankle used.

In 2007, at the University of Arizona, Hitt and others, and principal investigator (PI) Sugar developed the Spring Ankle with Regenerative Kinetics (SPARKy) [146]. This device coupled in series a DC motor with a helically wound spring to create an artificial Achilles tendon.

The above series elastic actuator (SEA) was similar in concept to work being done at MIT, during the same period, with Au and associates in the MIT Media Lab lead by Hugh Herr [23, 38, 147-150]. In a study of 3 PWLL, researchers found that their device decreased the metabolic CoT by 14% compared to the physician prescribed device (RxPx), even though the powered ankle was more than twofold heavier than the prescribed devices. The works of Herr et al., have branched off into a commercially available powered ankle called the BiOM® (figure 18) and later known as the Empower and sold by Ottobock.

In a study of 11 PWLL and 11 matched able-bodied controls [151], Ferris and associates found that at preswing, the users' CC feet generated 40% less peak ankle power than control and intact limbs, while the BiOM® generated significantly greater peak ankle power than control (35%) and CC feet (125%) and walking velocities

Figure 18 First generation BiOM® powered ankle being programmatically tuned by the prosthetist using an HMI mobile device

improved. The increased ankle power resulted in a peak flexor moment that was significantly greater (25%) during terminal stance. In a study of seven subjects with amputation and seven matched controls, Herr and Grabowski found that using the BiOM® on average decreased metabolic cost (8%), increased prosthetic leg mechanical work (57%), and decreased leading biological leg mechanical work (10%). Subjects increased their self-selected walking speeds by 23% [152]. Another study by Grabowski and D'Andrea [153] evaluated seven subjects with amputation and seven matched controls, comparing peak ground reaction forces using the BiOM® and their RxPx. They found that BiOM® significantly decreased resultant ground reaction forces in the contralateral limb by 2-11%. However, a controlled clinical

trial of 10 TT subjects did not experience improvements in metabolic costs of self-selected walking speeds [154]. Using clutchable series-elastic actuators (CSEAs), researchers at MIT have developed several iterations of knees [155, 156], ankles, and knee-ankle combinations [21].

At Osaka University, Li et al., developed a prototype prosthetic ankle-foot that used a DC motor and worm gear to adjust the balanced position of the prosthetic ankle-foot while walking on slopes [157]. Since it was only powered during the swing phase, the energy consumption was smaller than competing devices.

At Peking University, Zhu, Wang, and Wang proposed and developed an ankle using dual SEA with an MTP joint. They hypothesized that toe joint articulation could decrease ankle torque [158, 159]. In a single subject study [159] evaluating this device, called the PANTOE, joint angles and vertical ground reaction forces of both prosthetic and sound sides of the PWLL had improved symmetry.

At Beijing University, Wang and researchers described a powered ankle prosthesis driven by an Electro-Hydraulic Actuator [160] and demonstrated a device with similar weight, volume, and mechanical properties as the human biological ankle.

At Vanderbilt University, in Michael Goldfarb's laboratory, Sup describes a powered microprocessor ankle (p-MPA) prosthesis used independently or in conjunction with a p-MPK [161]. The Vanderbilt p-MPA incorporates a Maxon EC60 BLDC motor, coupled with a 116:1 through a 3-stage belt/chain/chain transmission producing peak ankle joint torque of 100 Nm with a 116:1 reduction

[162, 163]. In a single-subject study evaluating the device with a developed control scheme [164], Culver concluded that the powered ankle provides at least some desirable characteristics on stairs compared to the users' passive RxPx. Other works evaluate the design on uneven terrain [165]. In a study by Ledoux and Goldfarb [166] et al., evaluating the p-MPK/p-MPA combination, subjects experienced a 24% reduction in oxygen consumption and a 30% reduction in stair ascent time. This device was commercially licensed to Freedom Innovations [167], but is not yet on the market. The p-MPK/p-MPA combination device, sometimes called the Vanderbilt prosthesis, is developed, described by, and extensively tested by Sup [28, 161, 168-171], Lawson [27, 172-180], Varol [181-185], and Goldfarb [186]. Simon and associates looked at SiStSi on MFCL K3 and K4 among seven subjects and found 28% less asymmetry when compared to the users' prescribed prosthesis [187].

At the University of Michigan, Rouse and others have open-sourced their mechanical design, so that others can contribute to new control schemes [26, 188, 189]. This platform uses a Raspberry Pi for a microcontroller further making this open-source collaborative accessible to a new generation of developers that can focus on the controller and not waste time, effort, and resources on developing a mechanical platform.

At the University of Texas, Elery and others have developed a low-speed, high torque actuator with single-stage stepped-planet compound planetary gear transmission [190-192]. This design has several advantages including a lower operating noise level.

At the University of Alabama, Wu and associates made a powered ankle [193-196] and a powered knee and ankle. This case study describes a sit-to-stand stand-to-sit (SiStSi) controller for a p-MPK/p-MPA. Although it improved body symmetry, the study was limited to data (joint angles and torque) only from sensors embedded in the prosthesis.

At the University of Utah, Tran and associates described a p-MPK/p-MPA that provides 125 Nm of repetitive peak torque and weighs 1.6 kg [197]. In a single-subject evaluation, the total mass of the device with the ankle was 2.6 kg.

At the Vrije Universiteit Brussel, a new AK-type prosthesis called The CYBERnetic LowEr-Limb CoGnitive Ortho-prosthesis describes an Alpha-prosthesis [198] and a Beta-prosthesis [36]. These tethered devices had been tested, and like other p-MPK/p-MPA combinations, the sample size in these studies is small.

Summary of the Literature

In the United States, 147,000 amputations per year are performed [1], contributing to the estimated 2 million individuals living with limb loss. The loss of the leg and subsequent loss of the function of the knee poses several complications for the individual in terms of weight-bearing, gait kinematics, and social well-being. There is the loss of passive support of the distal extremity, but there is also a loss of kinesthetic feedback and a loss of contractile function of the absent muscles [2] needed to prevent a passive prosthesis from buckling. Knee buckling is the sudden loss of postural support across the knee during weight-bearing activities [199] and typically occurs during the initial 40 % of the gait cycle among transfemoral amputees. Uncontrolled knee buckle is a precursor to

a fall. In addition, more than half of PWLLs experience falls at least once a year after completing a rehabilitation program [200]. PWLLs with a limited walking ability (i.e., K1 and K2) are at higher risk for all-cause falls and injury than PWLLs with community walking ability (i.e., K3 and K4) [10]. There is evidence that limb loss is also associated with pain, fatigue, social health, anxiety, and disturbances to sleep [3]. Several researchers and developers at leading universities have engineered electro-mechanical (or robotic) solutions to augment the missing leg to address these limitations. Robert L. Horner, Richard G. Rincoe, and Marlin B. Hull developed a prosthetic robotic knee in 1992. This robotic knee was non-backdrivable, meaning that when not under power, the knee locks and cannot flex (buckle) or extend passively, unlike other semi-active and active powered devices. We know that those using p-MPK generate more knee power, have fewer GRFvs on the sound side, and demonstrate more whole-body standing symmetry than those with sa-MPK during sitting and standing. Although users continue to favor the amputated side, there is improved limb loading with the p-MPK compared to the sa-MPK. Subjects using a p-MPK/p-MPA combination device (Vanderbilt 2.0) were significantly more symmetrical in peak GRF in sit-to-stand transitions than their RxPx. The general problem is that these studies have a small sample size, are not representative of the general amputee population (typically K3 and K4), and rarely control for the type of ankle-foot used. Studies with larger samples of passive and sa-MPKs have been performed, but these devices do not store and/or dissipate energy, and these devices do not generate net power during locomotion, so users continue to have gait asymmetries. Additionally, these passive knees and sa-MPKs still expend up to 60% more metabolic energy than normal and exert three times the affected-side hip power and torque during

walking on level surfaces. Furthermore, most studies of these devices have focused on walking, ramps and stair navigation, and uneven terrain, but there is limited research on robotic augmentation of sit-to-stand and stand-to-sit transitions. Wu, Haque, and Shen [194] demonstrated that their p-MPK/p-MPA device successfully improved body symmetry, but these findings are limited to a single subject, and the collected data (joint angles and torque) were only from sensors embedded in the prosthesis. The specific problem is even with evidence provided by Hafner and Smith [201], where they found that SA control of the knee allowed 50% of MFCL-K2 subjects and 33% of MFCL-K3 subjects to transition to a higher activity level, policy limits the access to MFCL-K2. Also, we do not know how these devices affect sitting and standing transitions on large samples and may further justify these technologies for the MCL-K2 populations. Therefore, the purpose of this study is to test that the RPL with a coupled knee and ankle is feasible, can provide stance phase stability with passive ankle compliance while improving symmetry, efficiency, and metabolic function during sit-to-stand and stand-to-sit transitions among those who have above the knee amputation (AKA).

PROTOTYPE OF ROBOTIC PROSTHETIC LEG

Currently, a powered prosthetic solutiondoes not exist for AK limb-loss (KD and TF) that incorporates the passive shock-absorbing and swing phase properties of devices like the hydra-cadence and while providing resisted knee flexion of a manually locking knee or Össur Total Knee®, we developed a robotic prosthetic leg (RPL) to provide these features. This design consists of a modified version of the powered knee of Rincoe, Hall, and Horner to address the technological gaps of knee stability. To improve stance phase

dynamics and symmetries, we developed a passive articulating ankle prosthesis (APxA) [202] and it is coupled to the knee using standard COTS adapters. Powered by a pair of lithium-polymer secondary batteries, controlled through a programmable logic controller (PLC) interfaced with a motor controller, and operated through a handheld human-machine interface (HMI), the control and power system are off-human in a tethered backpack worn by the researcher. Figure 19 shows the configuration, and a more detailed discussion is presented in chapter two.

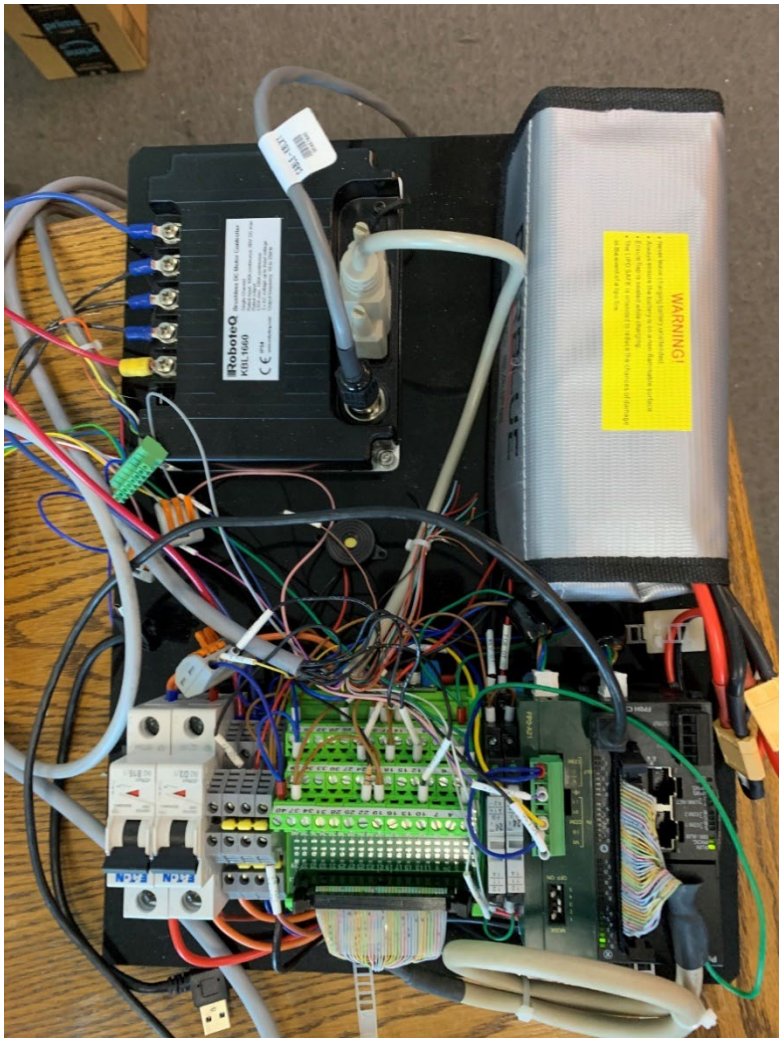

Figure 19 PLC, robot controller, fuses, and lithium-polymer batteries

A COTS prosthetic foot connects to the ankle also using COTS prosthetic adapters. This allows for a customizable alignment configuration with a build height of 24cm. We configured the RPL with a 22cm Össur LP Vari-Flex® Foot for initial testing and instrumented it with an IMU (figure 20).

Figure 20 CC foot instrumented with BNO550 IMU.

The knee is involuntarily locked until the user commands the device to flex through a button push. The device is timed to the user's ambulation potential (K-Level) to flex and automatically extend the knee. Although this programmatically simple control scheme may add to the cognitive demand of the user to initiate a step, it may lower the cognitive demand needed to maintain the knee in extension to prevent buckle.

In addition to providing control of the knee position and speed, the PLC monitors and stores data collected (battery performance, step count, etc.). Naming conventions

will adhere to ISO standards [203, 204], and system alignment will follow the ISO standard 10328:2016(E) [205] and the parameters described by Muller [206]. To preserve the transverse rotational moments [59], we will establish joint angles near mean [70, 74]. Alignment procedures will be performed and verified with the process described by Blumentritt [207, 208] by a certified prosthetist/orthotist (CPO) and personalized to each subject, as needed. Finalized design is in figures 21 and 22, summarized in table 2 and finished protoype picured in figures 23 and 24.

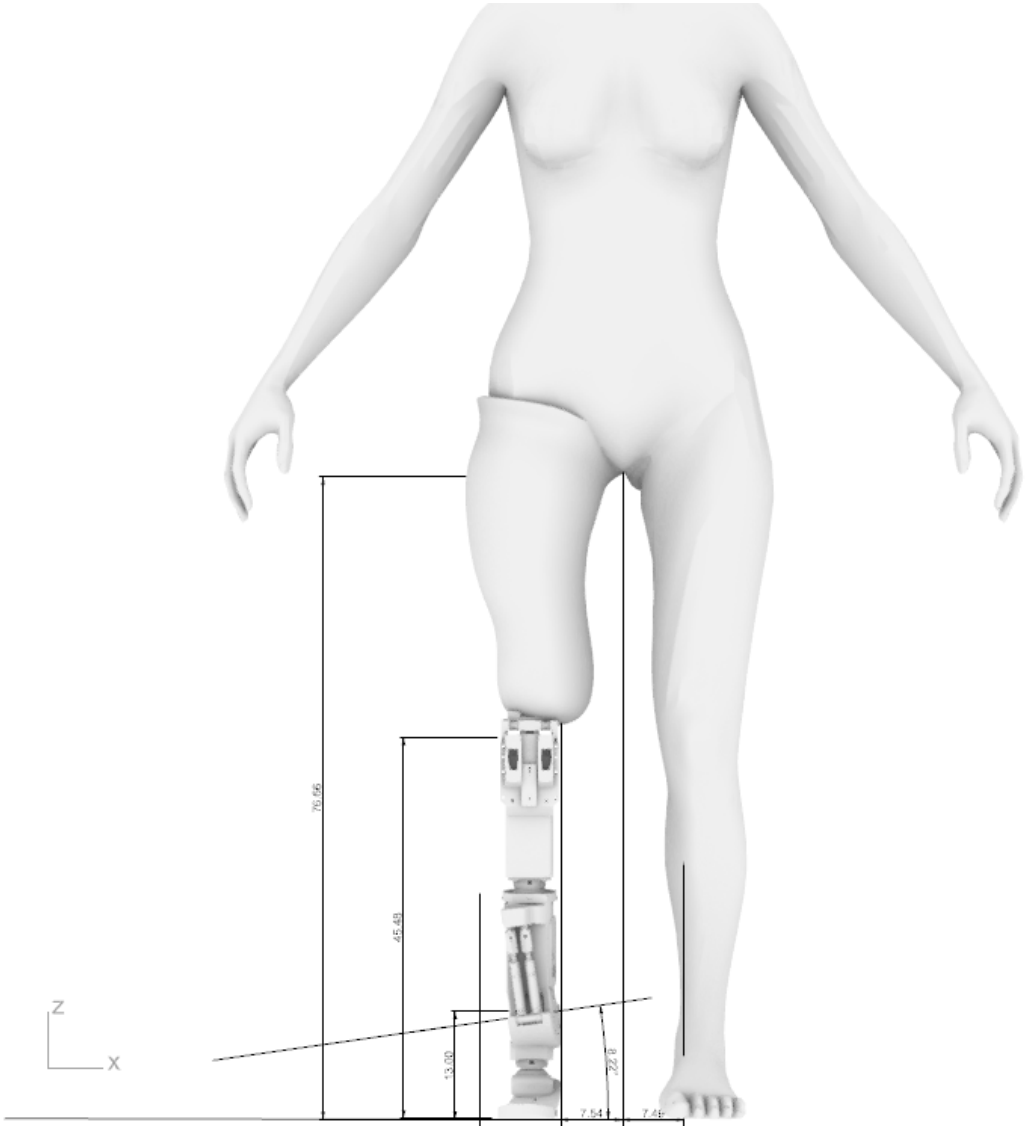

Figure 21 Modeled RPL configure for a 5'4" female.

Computational estimates are based on known parameters of the device and an assumed male subject and are outlined in table 2.

Parameter	Value	Comments
Height	≥ 0.46 m	Knee, ankle, foot. Excludes socket
Mass	5.140 kg	Excludes subject
Operating voltage	21.1 v	Lithium-polymer batteries x 2
MCU voltage	12 v	Regulated
Motor Controller	12 v	Roboteq KBL1660
Knee Actuator	Maxon EC40	Brushless DC Maxon corporation
Ankle actuator	Pneumatic Assist	Passive
Sensors	Absolute IMUs x2	Direction, pitch, roll, accelerations
Foot mechanism	CC	Össur LP Vari-flex®
CoM	200mm distal to kc	Assumes a 6-foot tall, 180 lb. male
Radius of gyration	141*mm*	
Moment of inertia	0.0656 $kg \cdot m^2$	$I_0 = M\rho 2_0$
Moment of inertia of knee	0.1976 $kg \cdot m^2$	$I = +\ Mass\ of\ Px(\ I_0\ (10^{-3})^2$
Dynamic Torque	136 N	
Stall Torque	400 N	
Gear Reduction	360	
Input Gear Teeth	13	
Output Gear Teeth	373	
Gear Ratio	373:1	= input Gear Teeth/output Gear Teeth
Mechanical Advantage	27.69	Teeth/input Gear Teeth = output Gear
Input Speed	10300 rpm	= 10300;
Output Speed	371.94 rpm	= input Rot. Speed/Mechanical Advantage
Torque Of Knee		= Dynamic Torque * Mechanical Advantage
Flexion Of Knee	100º	
Extension Of Knee	0 º	
Dampener_01	729.51 N	dorsi-flexion (resist) force
Dampener_02	729.51 N	dorsi-flexion (resist) force
Dampener_03	177.93 N	dorsi-flexion (assist) force

Table 2 Computation Parameters of the RPL

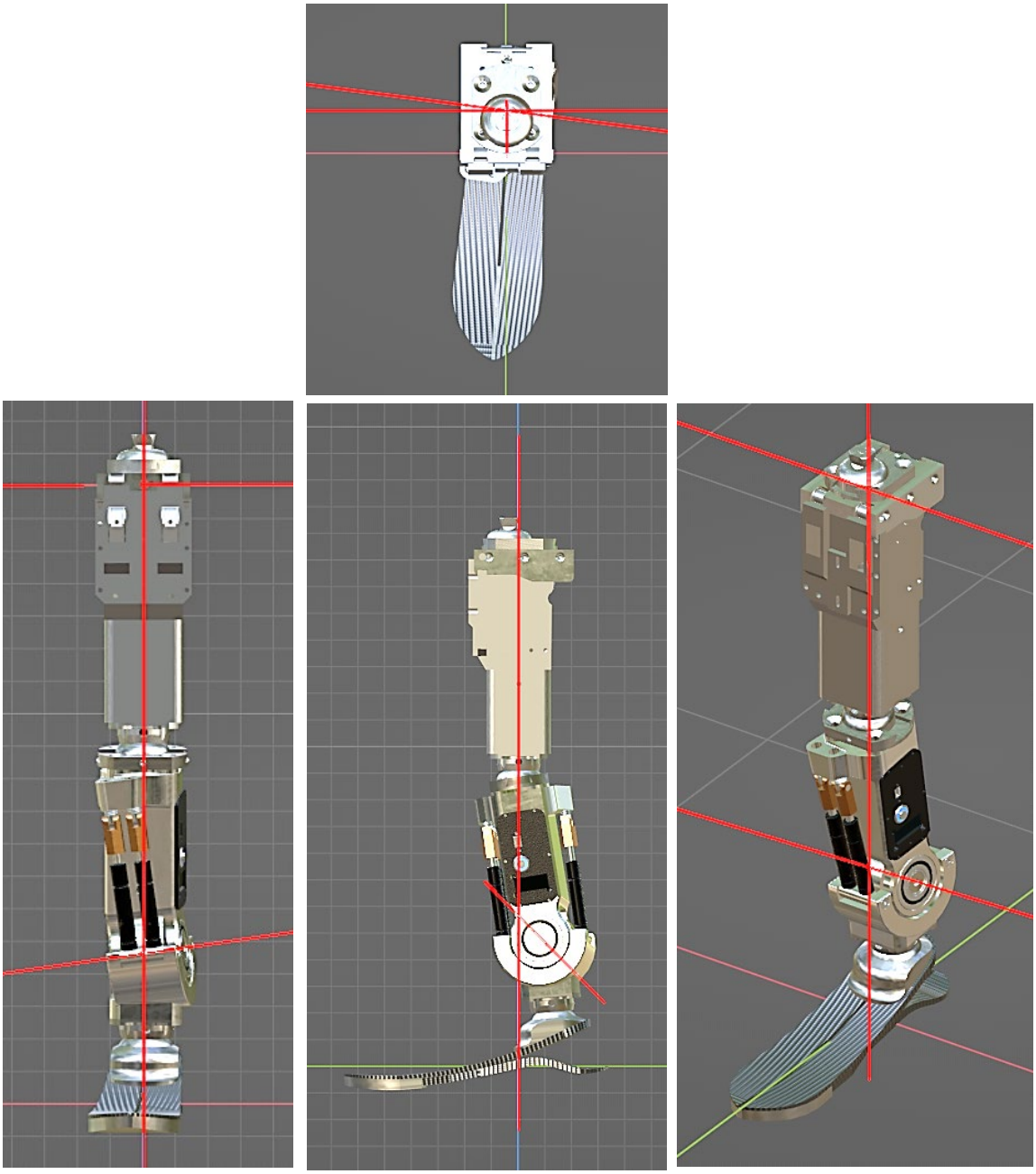

Figure 22 Knee axis, and ankle axis, (red) in relation to vertical weight line (red) and forward line of progression (green) in the transverse plane, (top), coronal plane, (left). sagittal plane, (middle), and oblique view (right).

Figure 23 Completed RPL

Purpose of the Study

This study aimed to test whether a specially designed robotic prosthetic leg (RPL) is feasible, safe, and improves symmetry, efficiency, and metabolic function during walking tasks and sit-to-stand and stand-to-sit transitions of users of prosthetic legs while improving their balance confidence.

The Need for the Study

In the United States, current medical policy limits access computerized semi-powered and powered robotic knees and ankles to those with a Medicare Classification activity level 3 (K3) or higher [45, 209]. We argue that those in most need of powered augmentation (K2 and even K1) are the individuals excluded from access to advanced technologies. Furthermore, little evidence sufficiently evaluates these devices during sit-to-stand and stand-to-sit transitions.

Research Questions

Can we design and prototype a feasible robotic prosthetic leg (RPL)? Can the RPL perform safely? Does the RPL improve the function of individuals in standing and sitting? Does the RPL have a physiological distress/eustress response measurable through a change in heart rate? Do users of the RPL report, through questionnaire, improved confidence in standing and locomotion activities?

CONCLUSION

There have been several attempts to provide powered augmentation of the missing lower extremity through robotic prosthetic limbs. We have developed a unique design that provides stance control through a powered non-backdrivable knee, passively compliant ankle, biologically accurate joint angles, and through use of COTS components, alienable to meet the personalized needs of each subject. We fabricated and bench-tested the designed device, and it is now ready for feasibility testing.

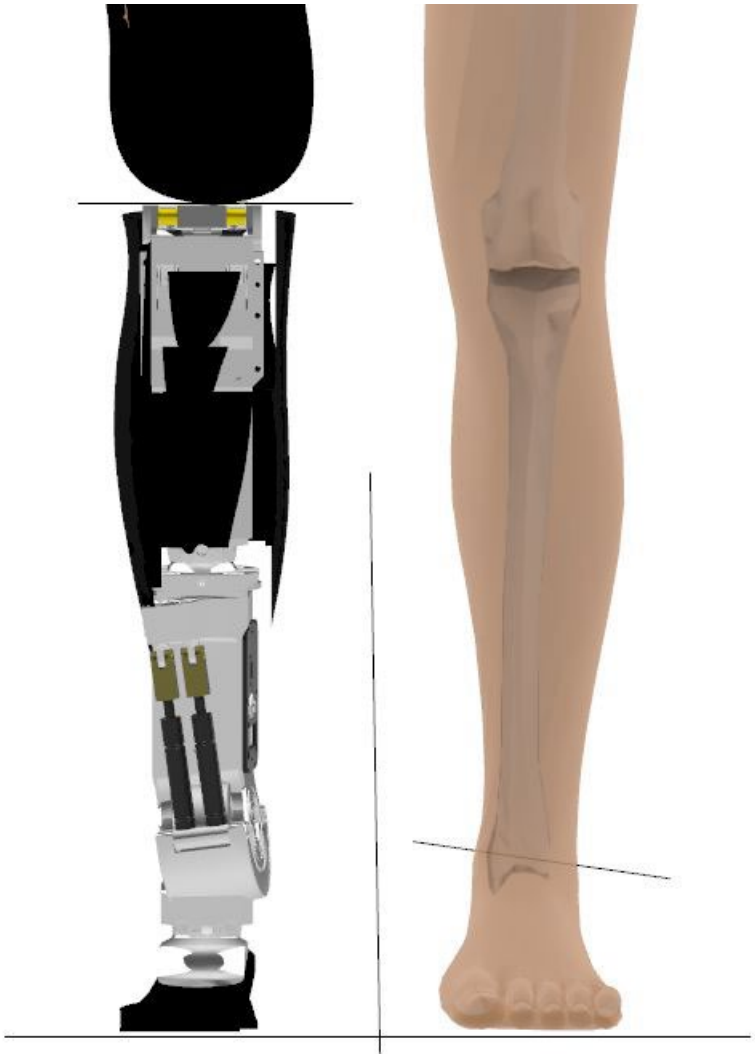

Figure 24 Modeled RPL, suitable for a person 5'4" tall with 3D printed protective calf

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CHAPTER TWO

Manuscript One

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DESIGN, PROTOTYPING, AND TESTING OF A ROBOTIC PROSTHETIC LEG PRELIMINARY RESULTS

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ABSTRACT

We report on our design and initial evaluation of a prototype robotic prosthetic leg (RPL) with a powered non-backdrivable knee and a hydro-pneumatic passive-resistive ankle. Our design was intended to increase health providers' opportunities when offering their patients greater options, expanding the accessibility of advanced technology to those with lower functional levels of ambulation while decreasing the overall costs of care. The purpose of this biomedical device was to improve stance stability, increase balance confidence, and through powered-knee extension, reduce the contralateral limb's kinetic stresses in gait, sitting, and standing. This device was designed to provide K2 and above ambulators a more adaptive, safe, and enhanced lower limb prosthesis. The prototype was assessed on a healthy subject while performing multiple 10-meter walk tests (10MWT) and six-minute walk tests (6MWT) on level-ground, inclines, and declines. We report walking velocity, the frequency of steps, cadence, falls, stumbles, toe-drags, battery consumption, and estimated torque of the knee actuator. We found the device safe on an able-bodied subject and feasible for future use on persons with limb loss.

Keywords: robotic prosthetic leg, biomedical device, gait, 10MWT, 6MWT, stance, balance, symmetry

1. INTRODUCTION

In the United States, there are approximately 185,000 amputation surgeries performed annually [1]. It has been estimated that by 2050, there could be as many as 3.6 million persons with limb loss (PWLL) [2]. Diabetes is the leading cause of amputation, and the costs associated with caring for these individuals are over $4.3 billion per year [3]. Persons with transfemoral (TF) amputation achieve less household and community ambulation [4] as compared to their non-disabled peers. These individuals also experience decreased balance, [5] reduced balance confidence [5, 6], increased energy expenditure while walking [7], decreased walking velocities [8], greater gait asymmetries [9], and an increased frequency of stumbles and falls [6, 10-12]. To address these needs, semi-active microprocessor-controlled prosthetic knees became commercially available in 1998 [13]. Although they do not provide net power to advance the limb, the literature validates the effectiveness of these devices in users who have a Medicare functional classification level (MFCL) [14] of K3 and K4 (see Table 1) in improving gait [15 - 21] and enhancing safety through fall prevention [22]. Further, there is growing evidence these technologies might also be effective in the prevention of falls in those with a K2 functional level [23]. Powered robotic prosthetic legs (RPLs) have been developed and tested on people with MCFL K3 and K4 [24 - 33]. These advanced technologies are not currently available to the general public. The "POWER KNEE™" (Össur, Reykjavik, Iceland) is the only commercially available RPL and has been shown to provide improved symmetry in gait [34 - 36] and standing on K4 ambulators [37, 38]. In the literature, RPLs have been shown to provide users with K3 and K4 potential with net power in ambulation [35], chair exit [37 - 40], and improve gait dynamics [41 - 44] but have not yet been adequately tested on K2 ambulators. There appears to exist a gap in the available technology that provides K2 ambulators a safe, stable and powered knee control.

Additionally, there is a need for an articulating ankle with a biologically correct axis that assists with ambulation, slopes, and chair exit efficiency. Thus, the purpose of this research study is to test that a specifically designed and novel RPL is feasible and safe for use on a non-amputee subject. We report on multiple 10MWT and 6MWT on level-ground, inclines and declines. We recorded walking velocity, step frequency, cadence, falls, stumbles, toe-drags, and battery consumption.

Medicare Functional Classification Levels	
K0:	The user does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance their quality of life or mobility.
K1:	The user has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at a fixed cadence – typical of the limited and unlimited household ambulator.
K2:	The user has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces - typical of the limited community ambulator.
K3:	The user has the ability or potential for ambulation with variable cadence - typical of the community ambulator with the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
K4:	Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels - typical of the prosthetic demands of the child, active adult, or athlete.

TABLE 1: MFCL DEFINITIONS AND SUMMARY [14]

2. MATERIALS AND METHODS

The prototype was developed utilizing commercial off-the-shelf (COTS) material and was tested on a single healthy subject without amputation to validate the design. This research protocol was approved by Loma Linda University Office of Sponsored Research Institutional Review Board (#HS5200345).

2.1 Human Subject

The investigator (a healthy subject without amputation, 183 cm tall, and 86 kg) applied the RPL to himself with a custom-made bent-knee adaptive socket (Figure 1) which affords non-disabled individuals to simulate walking in a prosthesis by keeping their leg in a flexed position while weight-bearing through the prosthetic device. This socket was fabricated from a custom plaster cast of his right thigh, typical of a shape capture procedure used in the prosthetics industry. Using four layers of bi-axial carbon fiber (Paceline, 12K Carbon Sleeve) and an epoxy-acrylic resin (Paceline, EAR1) to create a lightweight and rigid laminate typical of a standard prosthetic socket. A proximal flexible brim was fabricated using Northvane, a compliant polymer (North Sea Plastics Ltd, Glasgow), to provide comfortable ischial weight-bearing and ramus relief during use. A custom aluminum prong adapter with a standard 4-hole pattern was fabricated to allow for a secure yet adjustable distal attachment to the knee unit. As Muller [45] described, an initial bench alignment was utilized in the design and fabrication of the device (Table 2).

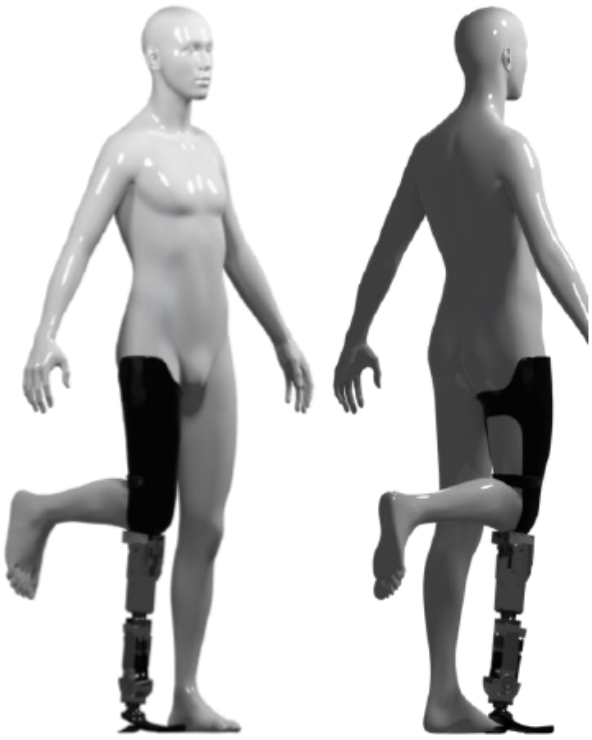

FIGURE 1: ADAPTIVE SOCKET INTERFACE FOR NON-AMPUTEE SUBJECT USE

2.2 Knee

The knee design (Figure 2) is a modified iteration of the works performed by Rincoe and Hull [46]. Our iteration of the knee unit features a series of proximal mounting holes to allow for various attachment configurations of the socket. This knee unit is actuated by a brushless DC motor (Maxon EC40) with a Hall sensor. Directly to the motor shaft, we integrated a two-channel optical incremental encoder (Avago Technologies HEDB-9000) with a resolution of 100 counts per revolution, providing precise and accurate position and speed control of the knee. A custom-built gearbox with elliptical gearing provides a 360:1 reduction to meet the walking and standing power requirements of the typical K2/K3 ambulator. The knee unit chassis is fabricated from 2024 T3 aluminum and coupled with an ankle unit using commercial prosthetic rotatable pyramid adapters (Össur A-245300 and A-235100), allowing for multiple alignment options. This economical knee design affords the K2 and above ambulator with stance phase stability.

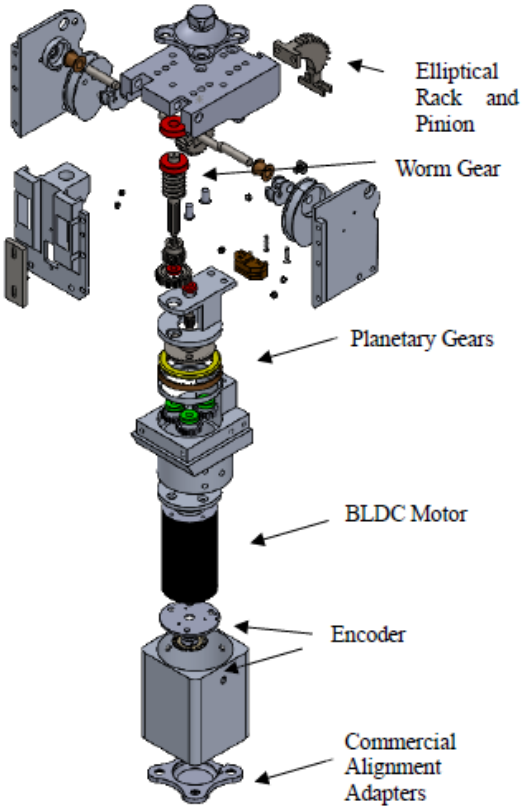

FIGURE 2: EXPLODED VIEW OF THE KNEE UNIT

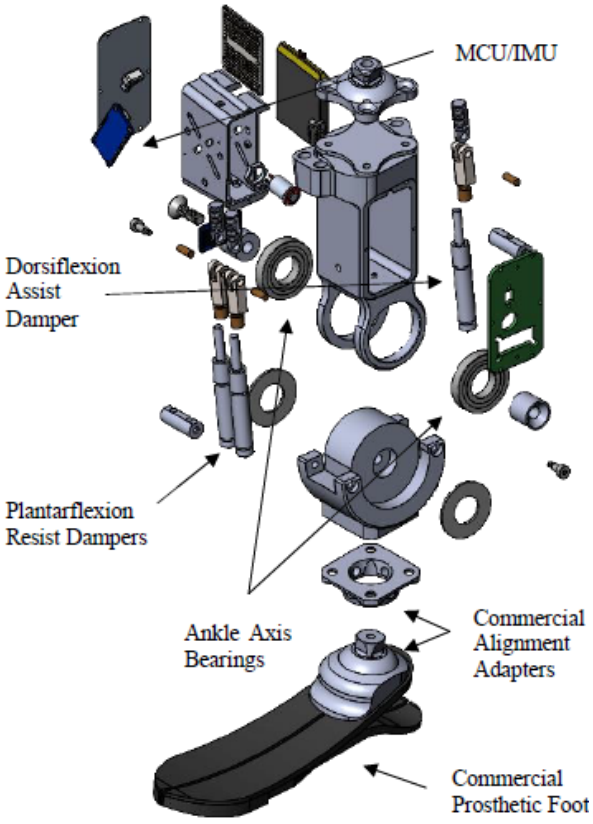

FIGURE 3: EXPLODED VIEW OF THE ANKLE UNIT WITH COMMERCIAL PROSTHETIC FOOT

2.3 Ankle

The developed ankle [47] (Figure 3) incorporates three passive hydro-pneumatic dampers (Kaller CU4), which provide tunable plantarflexion resistance and dorsiflexion assistance/resistance. While in loading response, the ankle has resisted plantar flexion. In late stance, the dampers provide resisted dorsiflexion, and in swing phase, the foot returns to neutral through dorsiflexion assistance. The chassis of the ankle is machined from 6061 aluminum and incorporates shielded ball bearings (Timken 16004-2Z) to minimize frictional losses at the joint axis. Table 2 also summarizes the initial bench alignment of the ankle axis, which is 8° of external rotation (yaw) and 8° of eversion (lateral pitch) to match the talo-crual axis as defined by [48]. The ankle uses a commercial prosthetic rotatable pyramid adapter (Össur A-245300 and A-235100) to attach the foot. This allows for the attachment of many commercially available feet and for the transverse rotation of the prosthetic foot (independent of ankle and knee axis rotations) to match biological limb alignment. For this trial, the ankle unit was mounted to a 26 cm manufactured foot (Össur LP Vari-flex). Both foot and ankle are instrumented with two inertial measurement units (IMUs (Bosch BNO055)). A 32-bit microcontroller (Adalogger, Adafruit Industries) collects and stores inertial, positional, and acceleration data for later analysis. This ankle design provides a more natural alignment than current designs and provides enhanced ankle motion necessary for chair exit and walking on level ground and slopes. Further, this design will allow clinical prosthetists custom tunability in alignment that is not afforded in other commercially available products.

2.4 Controller

A programmable logic controller (PLC (Panasonic)) was used to provide modularity and scalability for future demands. With a RISC architecture CPU, the PLC has a processing speed of 10ns per step, more than sufficient to meet the needs of the system. Interfaced with a motor controller (Roboteq KBL1660), the PLC gives precise and responsive motion control.

	Bench Alignment	Tuned Alignment
Socket Flexion (pitch)	5°	0°
Socket Adduction (roll)	5°	5°
Socket Rotation (yaw)	5°	5°
Knee Flexion (pitch)	0°	8°
Knee Adduction (roll)	0°	0°
Knee Rotation (yaw)	5°	5°
Ankle (pitch)	8°	8°
Ankle Eversion (roll)	8°	8°
Ankle Rotation (yaw)	8°	8°
Foot flexion (pitch)	0°	0°
Foot Inversion (roll)	0°	0°
Foot Rotation (yaw)	7°	7°

TABLE 2. ALIGNMENT PARAMETERS OF THE RPL

A handheld human-machine interface (HMI) enables the user to manually position the knee and change the speed of knee motion. An automatic mode was provided to initiate a complete step with a button push. A "live-man" switch provides a safety mechanism to instantaneously stop the motion of the leg in the event of an emergency. A secondary HMI (Maple Systems 5040b) was provided with a touch screen (Figure 4) housed in a 3-D printed case to provide the researcher or future clinician additional monitoring and control of the system. A computer interface was written using FPWIN Pro7 (Panasonic, Kadoma, Osaka, Japan) and EasyBuilder Pro (Weintek, New Taipei City 23586, Taiwan) to interface directly with the PLC. This small program included

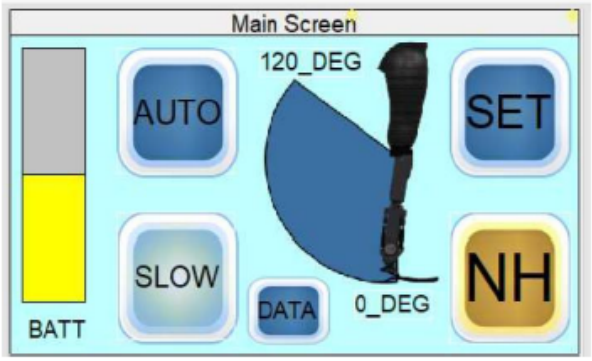

FIGURE 4: SECONDARY HMI WITH TOUCHSCREEN

1894 steps at a size of 400kb, and there is sufficient processing power, memory, and I/O ports to allow for future expansion and development of this system using IMU and other input data (Figure 5).

2.5 Battery

The system was powered by two 5000mAh, 11.1V lithium-polymer (LiPoly) batteries (VENOM 35C 3S). The complete control system, secondary HMI, and battery supply were housed in a tethered backpack.

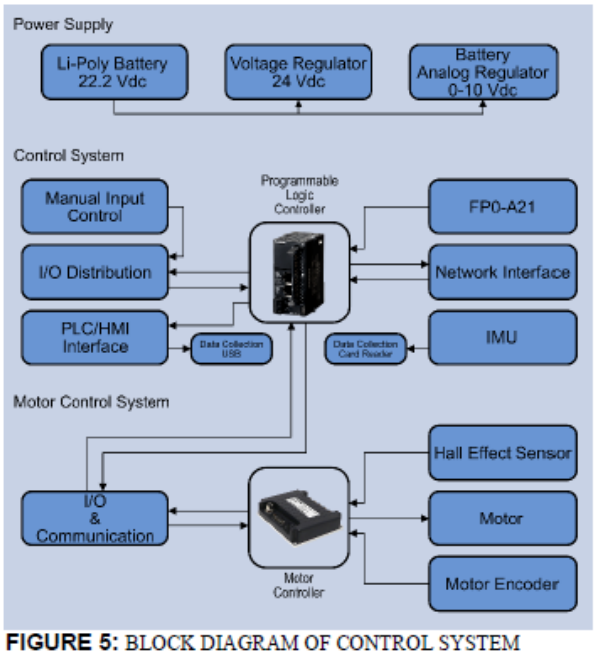

FIGURE 5: BLOCK DIAGRAM OF CONTROL SYSTEM

2.6 Methods

Testing was conducted at Loma Linda University Medical Center, Outpatient Rehabilitation Center in the Orthotics & Prosthetics Lab. The investigator applied the RPL to himself and using a force plate (LASAR-Posture, Otto Bock) with a laser marker, minor adjustments were made to optimally tune the alignment in the sagittal and coronal planes to optimize weight-bearing forces and match the biological limb alignment (Figure 6). Transverse plane alignment was assessed, but no additional tuning was required. Dynamic alignment was then evaluated, and adjustments were made as necessary. The final alignment was confirmed, documented, and all adjustment screws were torqued (14.5 N·m.), and thread locker (Loctite 242) was applied to ensure the alignment could not change during use. The subject then demonstrated the RPL with various cadences and velocities on level-ground and ramps. In total, the subject participation was for about 1 hour 3 times a week for one month.

The subject walked along a 10-m indoor walkway, and time was recorded using a stopwatch, and six trials were performed at a self-selected walking speed. The average of the six trials was reported. The subject walked for six minutes indoors, and distance was recorded. Three trials were performed,

FIGURE 6: COMPLETED PROSTHESIS ON NON-AMPUTEE HUMAN SUBJECT WITH TUNED BIOLOGICALLY CORRECT ALIGNMENT

and results were averaged. The subject walked on a ramp (10 meters in length) in both directions (incline, decline). Three trials in each direction were performed, and results were averaged.

3. RESULTS AND DISCUSSION

The subject was able to walk on level ground at a varied cadence with an average velocity of 0.46 m/s, a minimum of 0.39 m/s, and a maximum velocity of 0.59 m/s meeting the velocity demands of many K2 (0.38 m/s) and K3 (0.63 m/s) ambulators [49]. Mean incline and decline velocities were 0.41 and 0.37 m/s, respectively. In one of the 6MWT, the subject achieved a walking distance of 190.8 meters with 173 steps. To achieve K3 velocity requirements, the motor's recommended speed of 10,300 rpm was increased to 15,000 rpm. Even at these higher speeds, the battery consumption was sufficient to supply the device for the entirety of the testing on a single charge. The actuator and battery temperature change were negligible. Backlash in the knee's worm gear was present but did not give the user a sense of instability. Final parameters of the protype are summarized in Table 3.

There were an estimated 1400 steps taken over a cumulative distance of 1 km in total. Although 18 toe-drags were recorded, there were no stumbles or falls. This prototype functioned correctly and demonstrated the viability of the engineering design. A limitation of this study is that these results may differ when this technology is used with persons with limb loss. Future testing on amputee subjects is required. These works will explore this technology against currently available commercial products to catalog performances for patients and providers to make informed healthcare decisions about their rehabilitation options. Specifically, kinematic and kinetic testing of this device on persons with limb loss will be conducted to optimize the RPL performance parameters. This optimization will be tested for improved metabolic function, leg kinetics, and limb load symmetry during the timed-up and go test and the five times sit-to-stand test as compared to the user's prescribed device. Future development will also include developing a non-tethered (embedded) controller and power supply with a more advanced and sophisticated control scheme.

Specification	Value
Mass of prosthesis	5.140 kg
Knee Range of Motion	0-100°
Ankle Range of Motion	-20° – 30° plantarflexion
Estimated Torque of Knee	19 N·m
Height	50 cm
Batteries (2)	11.1V 5000mAh
Maximum Motor Speed	15,000 rpm
Maximum Walking Velocity	0.59 m/s
Minimum Walking Velocity	0.39 m/s
Mean Walking Velocity	0.46 m/s

TABLE 3: SUMMARY OF RPL PARAMETERS

4. CONCLUSION

The prototype functioned correctly and demonstrated the viability of the device. These preliminary results demonstrate that the RPL is safe for use on a healthy, non-disabled subject and is feasible for future testing on persons with limb loss with MFCL K2 and above.

DISCLOSURE

The author, Michael Davidson, is the primary inventor of the patent application claiming technology used in this study, which is the intellectual property of Loma Linda University Health. This work was internally funded by Loma Linda University Medical Center Rehabilitation Services.

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CHAPTER THREE

Manuscript Two

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TESTING OF AN ARTICULATED PROSTHETIC ANKLE

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ABSTRACT

This paper presents our initial evaluation of a prototype ankle prosthesis with a one degree-of-freedom joint-axis featuring a biologically correct joint-axis alignment with hydro-pneumatic passive-resistance. The purpose of this biomedical device is to improve stance stability, increase balance confidence, and reduce the contralateral limb's kinetic stresses in gait, sitting, and standing. The objective of this case study was to test the safety and feasibility of the device on an active single-limb male amputee. A single subject with a trans-tibial amputation was fitted with the prototype ankle prosthesis and tested against his prescribed daily use prosthesis. In addition to extended walking on level ground, kinematic and kinetic measures were taken in an 18-camera motion capture lab with two in-floor force platforms. These measures assessed body symmetry in the timed-up and go (TUG) test and five times the sit-to-stand (5xSTS) test while the subject used this prototype device. Balance confidence was assessed using the activities-based balance confidence (ABC) questionnaire. While performing the 10MWT, the subject was able to ambulate at a maximum velocity of 1.34 m/s and an average of 1.32 m/s. In the six-minute walk test (6MWT), the subject was able to walk a distance of 416.84 meters (a velocity of 1.16m/s). Although kinetic symmetry did not improve, kinematic symmetry of both lower extremities did improve in sitting and standing. In total, the subject walked with the device for 2 km. We found the device safe on a single amputee subject in a controlled environment and feasible for future testing on ramps and lower level ambulators.

Keywords: robotic prosthetic leg, biomedical device, gait, 10MWT, 6MWT, TUG, 5xSTS, ABC, balance, symmetry

NOMENCLATURE

5xSTS	Five times, sit to stand
6MWT	Six-minute walk test
10MWT	Ten-meter walk test
ABC	Activities-based balance confidence
APxA	Articulated prosthetic ankle
CC	Carbon composite
CoM	Center of Mass
GRF	Ground reaction force
IMU	Inertial measurement unit
K1	Can stand, pivot, transfer, and take a few steps
K2	Walks at a single cadence
K3	Walks with variable cadence and on ramps.
K4	Athletic capabilities
MFCL	Medicare Functional Classification Level
MPCA	Microprocessor controlled ankle
PWLL	Person with limb loss
RxPx	Subject's physician-prescribed prosthesis
SACH	Solid ankle cushion heel
TT	Transtibial amputation
TUG	Timed up and go
VSP	Vertical Shock Pylon

1. INTRODUCTION

Two million people live with limb loss in the United States [1] due to approximately 147,000 amputations each year [2], and

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this population is getting younger [3]. Caring for these persons costs $4.3 billion per year [4], and the perioperative mortality of this population can be as high as 42.3% [5]. Standard clinical practice provides these individuals with only essential components clinically appropriate for their estimated ambulation potential (Medicare Functional Classification Level (K-Level)) [6]. Higher functioning components are accessible to those with higher ambulation potential. Commercially available prosthetic feet with fixed or solid ankles and cushion heels (SACH) are manufactured from wood and rubber (K1 and K2) or carbon-composite (CC) laminates (K3 and K4), which rely on the materials' deformation to store and return energy during gait. Neither SACH nor CC feet effectively adapt to slopes or chair exit. These passive, non-articulating limbs, although practical, still require increased muscle activity to lift the prosthetic foot and initiate the swing phase of gait [7]. They result in limited knee flexion, which requires hip hiking, vaulting, or circumduction of the prosthetic limb to clear the foot, and large vertical displacements of the center of mass (CoM) [7], causing an increase in energy expenditures [7, 8]. Additionally, these persons experience more falls and are at increased risk of injury [9-11].

Prosthetic ankles with passive hydraulic dampers have been found to improve toe clearance [12], gait symmetry [13], and reduce contralateral peak plantar pressures [14].

Microprocessor-controlled ankles (MPCA), with hydraulic dampers, are a recent market development. The OttoBock Meridian and the OttoBock Empower (Otto Bock HealthCare, Duderstadt, Germany), and the Össur Proprio (Össur HF, Reykjavik, Iceland) are commercial examples of these developments. MPCAs have been shown to outperform SACH and CC feet [15, 16], but these complex technologies are strictly reserved for those amputees that can demonstrate walking on uneven terrain (K3) or perform sports activities (K4). Another challenge is that these advanced ankles have batteries that require daily recharging, and each device can cost up to US $40,000 per unit. Since healthcare is a limited resource, rehabilitation professionals are challenged as these emerging technologies are not accessible to the populations that need advanced functioning prosthetic components.

Several standardized tests and measures are available that the clinician or researcher can easily administer to assess the rehabilitative outcomes of persons with limb loss (PWLL) [17]. These tests are valuable tools in evaluating fall risk, balance, and walking and include the ABC [18], TUG [19], 5xSTS [20], 10MWT [21], and 6MWT [21].

This study evaluates a passive hydro-pneumatic articulating prosthetic ankle (APxA) design using the 5xSTS, 10MWT, 6MWT, ABC, kinetic, and kinematic motion capture. The APxA was developed at Loma Linda University Health and uses three hydro-pneumatic gas dampers under pressure to produce dampening assistive/resistive dorsiflexion forces. With this design comes the challenges of using durable non-linear moving parts that provide a smooth roll-over throughout ambulation in a compact design. Therefore, this ankle design has exploited the placement and configuration of the pneumatic dampers to provide dorsiflexion resistance and plantarflexion assistance on level and sloped terrain. The design incorporates a biologically correct talocrural axis, not found in competing designs. Unlike MPCAs, this design does not need to be recharged and may be more cost-effective. We developed a prototype and tested it on a non-disabled subject [22]. The device feasibly performed safely and reliably. Thus, the purpose of this research study was to determine the feasibility of the APxA on a subject with leg amputation and test if the APxA improves performance while walking, sitting, and standing as compared to the subject's physician-prescribed prosthesis (RxPx).

We hypothesized that a subject using the APxA would experience improved symmetry during gait on level ground and while sitting and standing as compared to their RxPx. We also hypothesized that the subject wearing the APxA would not experience a decrease in balance confidence as compared to his RxPx.

2. MATERIALS AND METHODS

2.1 Human Subject

We recruited a single (n=1) male subject with a right trans-tibial amputation. The subject was 1.83 meters tall, with a mass of 121 kg. This protocol was approved by Loma Linda University's Institutional Review Board, and the subject gave informed consent before testing. Exclusion criteria included MFCL K2 or below, compromised skin on the residual limb (stump), or those who have uncontrolled edema. The subject uses a physician-prescribed prosthesis (RxPx) for daily mobility needs. The RxPx is configured with a silicone-suspension liner with a pin-lock suspension mechanism, total-surface bearing type socket, an Össur Vari-flex brand prosthetic foot/ankle with a VSP.

2.2 Prosthetic Device

The developed ankle incorporates three passive hydro-pneumatic dampers (Kaller CU4), which provide tunable plantarflexion resistance and dorsiflexion assistance/resistance. While in loading response, the ankle has resisted plantar flexion. In late stance, the dampers provide resisted dorsiflexion, and in swing phase, the foot returns to neutral through dorsiflexion assistance. The chassis of the ankle is machined from 6061 aluminum alloy and incorporates shielded ball bearings (Timken 16004-2Z) to minimize frictional losses at the joint axis. The alignment of the ankle axis is 8° of external rotation (yaw) and 8° of eversion (lateral pitch) to match the talocrural axis as defined by [23]. The ankle uses a commercial prosthetic rotatable pyramid adapter (Össur A-245300 and A-235100) to attach to the prosthetic foot. This adapter allows for the attachment of many commercially available feet. This configuration allows individualized tunning of the transverse rotation of the prosthetic foot (independent of ankle and knee axis rotations) to match biological limb alignment. We mounted the ankle unit to a 26 cm manufactured foot (Össur LP Vari-flex). A standard heel wedge was needed to stiffen the heel lever to match the subject's mass

and activity level. The ankle has an onboard inertial measurement unit (IMU (Bosch BNO055)), and we added an IMU to the toe of the prosthetic foot. A 32-bit microcontroller (Adalogger, Adafruit Industries, New York, NY) collects and stores inertial, positional, and acceleration data. Figure 1 illustrates the assembly of the device.

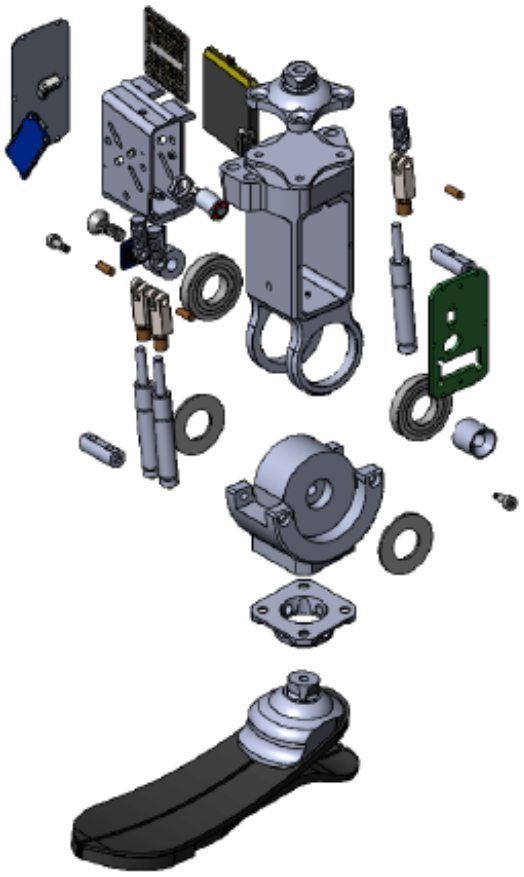


FIGURE 1: EXPLODED VIEW OF ANKLE PROTOYPE

2.3 Over-ground Walking

The first testing phase was conducted at Loma Linda University Medical Center, Outpatient Rehabilitation Center in the Orthotics & Prosthetics Lab. For each trial, the VSP and foot/ankle system were removed by a certified prosthetist, and care was taken to ensure that the original alignment of the device was preserved. The prototype ankle with an appropriately sized and category Össur LP Vari-flex foot was attached to the subject's socket and suspension system.

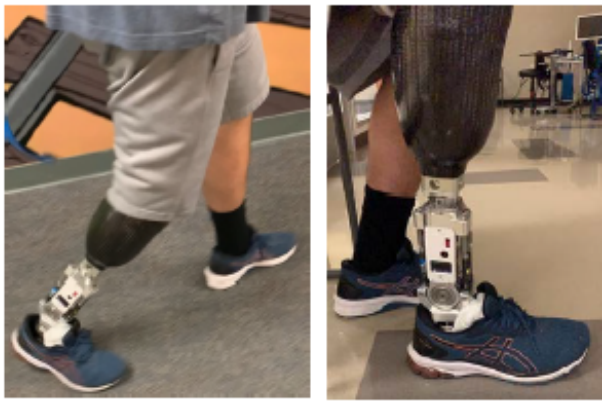
This configuration was used for the testing prosthesis (APxA). The alignment configuration was tuned using an Ottobock LASAR Posture™ alignment plate to optimally direct ground-reaction forces through the subject's residual limb, and alignment parameters were recorded (table 1).

TABLE 1: SUMMARY OF ALIGNMENT PARAMETERS

	Bench Alignment	Tuned Alignment
Socket Flexion (pitch)	5°	8°
Socket Adduction (roll)	5°	5°
Socket Rotation (yaw)	5°	5°
Ankle (pitch)	8°	8°
Ankle Eversion (roll)	8°	8°
Ankle Rotation (yaw)	8°	8°
Foot Flexion (pitch)	0°	0°
Foot Inversion (roll)	0°	0°
Foot Rotation (yaw)	7°	7°

All adjustment screws were torqued to 14.5 N·m prior to testing. The total mass of the user's prescribed prosthesis and test prosthesis was 2.05 kg and 2.91 kg, respectively.

The subject was provided with an ABC scale, a one-page questionnaire used to determine fall potential and balance confidence and helps assess PWLL [24-26]. The subject was outfitted with a modified belt to house a mobile phone over the



FIGURES 2 AND 3: ANKLE MOTION WHILE WALKING AND WHILE STANDING UP

posterior sacral spine on the first visit. The phone's IMU recorded the pelvis's acceleration, tilt, and positional data. Data was collected using the MATLAB™ mobile app (Mathworks, Natick, MA.). The subject then walked in parallel bars 10 times to acclimate to the dynamic function of the ankle. When confident, the subject walked out of the parallel bars without assistance at a self-selected speed. The subject then performed a series of 10MWT and a single 6MWT (figure 2). The 10MWT and 6MWT effectively assess the walking velocity of PWLL while using prosthetic devices [24]. The subject then performed the 5xSTS three times. The 5xSTS (figure 3) assesses the patients' ability to transition safely and efficiently and how they use movement strategies to complete these tasks. It is safe to

administer, reliable [25, 27], and has been used by others to assess the performance of prosthetic devices on PWLL [25, 28]. The subject then answered a series of open-ended questions about the experience, and the responses were audio recorded. At the conclusion of the visit, the prosthetist reattached the VSP and Vari-flex foot to the socket, original alignment was verified, and adjustment fasteners were retorqued and secured with an appropriate thread locking fluid (Loctite 242).

2.4 Kinematic and Kinetic Testing

Three weeks later, the subject returned for motion analysis at Loma Linda University's Motion Capture Lab in the School of Allied Health Professions. The prototype was attached to the subject's socket identically as described. Clusters of motion capture body markers were applied to the subject in a modified Helen Hayes pattern described by Davis and Associates [29]. These 32 retroreflective markers were attached bilaterally to the participants' iliac crest, anterior superior iliac spine, and posterior superior iliac spine. For the left, non-amputated lower extremity, markers were placed on the medial and lateral femoral epicondyles, medial and lateral malleoli, calcaneus, and base of the first and fifth metatarsals. The markers on the right (amputated) leg were applied to the prosthesis and anatomical equivalent locations were estimated by the prosthetist and the biomechanist to match the left leg, as shown in figure 4. A series of TUG tests were performed with both the RxPx and APxA. Additionally, a series of sit-to-stand tests with two-second resting periods between the stand and the sit was performed with the RxPx and APxA. An 18-camera Qualisys Motion Capture System (Gothenburg, Sweden) was used to record three-dimensional marker position data using a capture rate of 120 Hz. Marker position data were smoothed using a fourth-order, low pass recursive Butterworth filter with a frequency cutoff of 6Hz. Visual 3D motion analysis software (C-Motion, Inc., Rockville, MD) was used to calculate joint angles from marker position data. All joint angles were modeled as the motion of the distal segment relative to the proximal using Euler/Cardan angles (x-y-z rotation sequence). Two in-floor tri-axial force platforms (AMTI, Inc, Watertown, MA) placed in series were used to collect kinetic data at a rate of 1200 Hz. The subject performed a series of TUG tests and a sit-to-stand, stand-to-sit activity while kinetic and kinematic data were recorded. Data was analyzed and plots created using MATLAB™ R2021a. At the conclusion of the study, the subject completed the ABC questionnaire again.

FIGURE 4: RETROREFLECTIVE MARKER PLACEMENT

3. RESULTS AND DISCUSSION

3.1 Static Assessment

The mass of the subject's prescribed prosthesis and test prosthesis were 2.05 kg and 2.91 kg, respectively. Bilaterally, the trochanters to the floor were 36.5 inches, and the knees were 22 inches. We confirmed that the subject has an ambulation potential of K3. After the subject was fitted with the APxA, alignment was verified using a LASAR Posture™ system (figures 5 and 6). The parameters are summarized in table 2.

3.2 Dynamic Assessment

While wearing the APxA and performing the TUG three times an average of 9.42 seconds was demonstrated within normal limits. Barry and Associates [30] reported that a TUG score of 13.5 seconds or longer was predictive of fall risk, suggesting the ankle motion of the APxA did not increase the subject's perceived risk of fall or imbalance.

While wearing the APxA, the subject performed the 10MWT three times, averaging 8.29 seconds. In the single 6MWT, the subject walked 417 meters (1367.6 feet), demonstrating a velocity of 1.16 m/s. These times and distances are typical of a K3 ambulator.

As expected, unfiltered IMU data shows transverse plane rotational movement (yaw) between the prosthetic toe and prosthetic talus. Additionally, IMU data demonstrates expected movements in the coronal and sagittal planes.

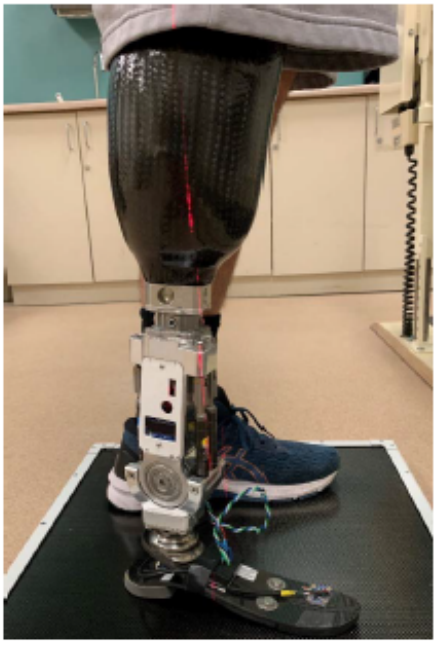


FIGURE 5: TUNED ALIGNMENT IN THE SAGITTAL PLANE

FIGURE 6: TUNED ALIGNMENT IN THE CORONAL PLANE

Unfiltered mobile phone acceleration data of the pelvis indicates a favoring of the left leg (table 2) but demonstrated a clear sinusoid pattern. Pelvic orientation also favors the left leg, but quickly detects changes in direction (table 2).

TABLE 2: SUMMARY OF MOBILE PHONE INERTIAL DATA AT PELVIS

	X	Y	Z
Min Acceleration (m/s^2)	-3.98	7.30	-1.29
Mean Acceleration (m/s^2)	0.37	9.76	1.11
Max Acceleration (m/s^2)	2.98	14.01	4.28
Min Orientation (°)	-179.9	-89.89	-144.95
Mean Orientation (°)	-27.56	-82.91	-18.04
Max Orientation (°)	179.85	-70.10	173.32
Min Velocity (m/s)	-0.53	-2.47	-0.58
Mean Velocity (m/s)	0.0024	-0.17	-0.03
Max Velocity (m/s)	0.67	1.80	0.38

3.3 Motion Capture Lab

Force-plate data showed that there was a slight decrease in ground reaction force symmetry through the APxA (68%) as compared to the RxPx (71%) during standing and sitting tasks (figures 7 and 8). This data does not support our hypothesis that GRF symmetry would improve. This could result from a training effect as the subject only had about 2 hours to be accustomed to the APxA, and it provides an opportunity for further study.

FIGURE 7: SITTING TO STANDING

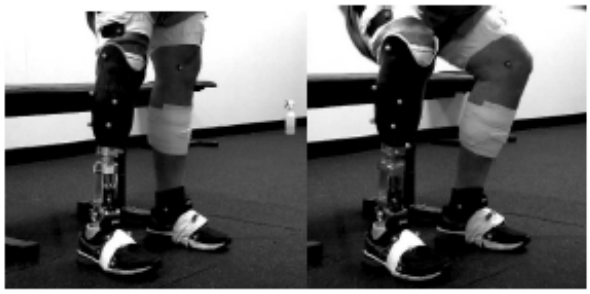


FIGURE 8: STANDING TO SITTING

A 3D motion-capture camera system recorded kinematic performance during the sit-to-stand tasks (figures 9 and 10) and TUG (figures 12 and 13). Using kinematic data described by [31] as an initial target for joint motions of the hip, knee, and ankle, the performance goals of the APxA was established.

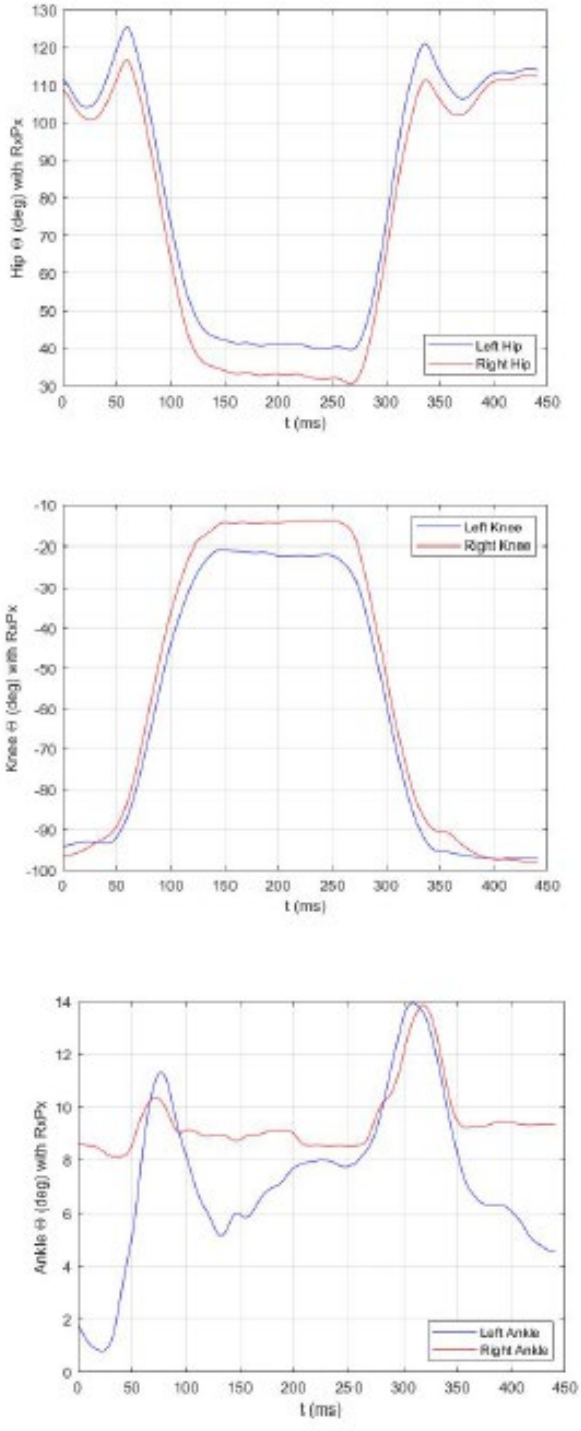


FIGURE 9: JOINT MOTIONS FROM REFLECTIVE MARKERS DURING STANDING AND SITTING WITH RxPx

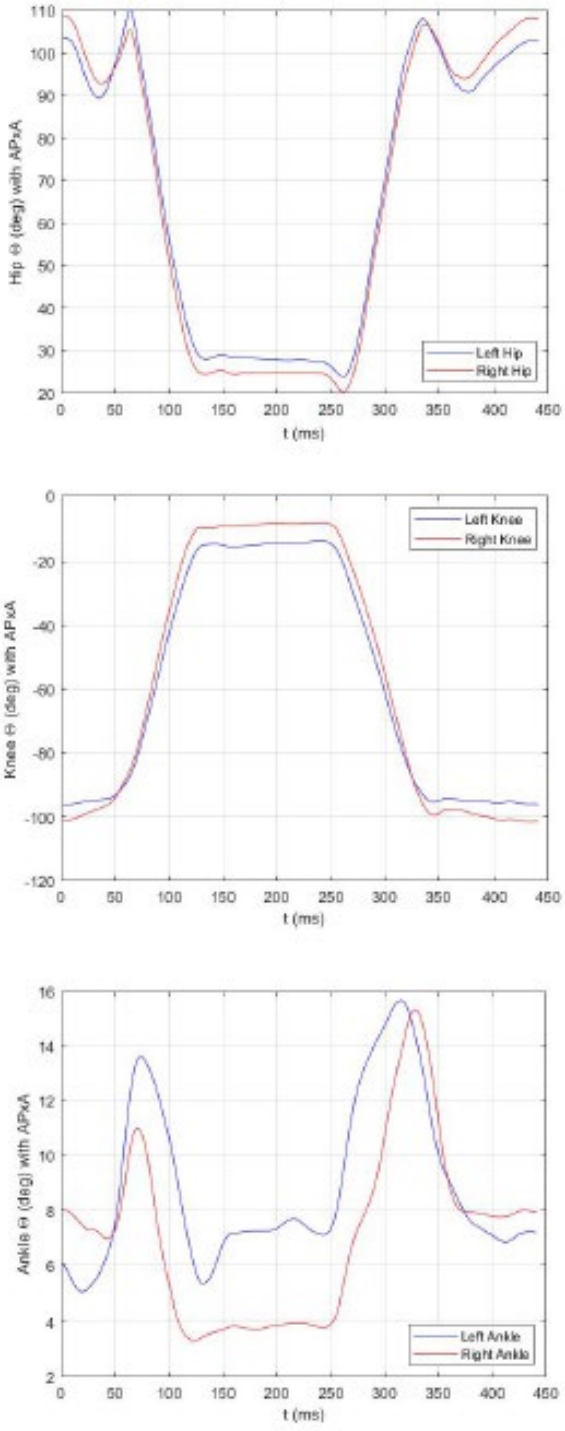


FIGURE 10: JOINT MOTIONS FROM REFLECTIVE MARKERS DURING STANDING AND SITTING WITH APxA.

While performing the TUG test (figure 12), at loading response (10-20% gait cycle) the vertical GRFs demonstrated improved symmetry (figure 11), but became less symmetrical in terminal stance to preswing (40-60% gait cycle). While using the RxPx, there was an excessive motion of the hip and knee of the amputated side. As expected, the motion of the manufactured prosthetic ankle was noticeably less than the left intact leg. When the user used the APxA, the hip and knee motions decreased, and ankle motion increased (figure 13). It appears to improve the overall kinematic symmetry of both extremities and partially supporting our hypothesis that kinematics would improve.

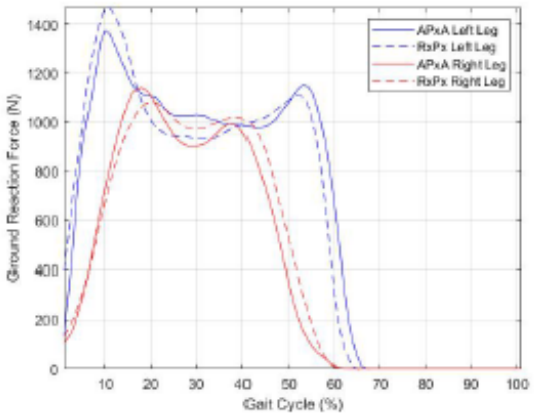


FIGURE 11: VERTICAL GRF DURING TUG TEST

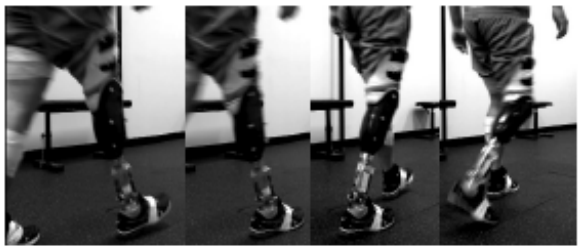


FIGURE 12: ANKLE MOTION DURING TUG TEST WHILE USING APxA

In the open-ended post-experience questions, the subject reported that the APxA felt "lighter" in mass than his RxPx, surprising, as it weighed 0.87 kg more. Given that the APxA represents a 45% increase in weight of the RxPx, the results (along with the subject's feedback) validate the engineering of the passive hydro-pneumatic configuration. The subject also mentioned the increased ankle motion as a positive attribute but stated that "it made it harder to stand up". In the ABC scale test, the subject initially reported a score of 1100 and a final score of 1270. The self-reported assessment and subjective feedback should be viewed with caution; it could serve as a useful tool in future randomized trials with large sample sizes where subjects use the device for several weeks or months between the pre-and post-intervention surveys.

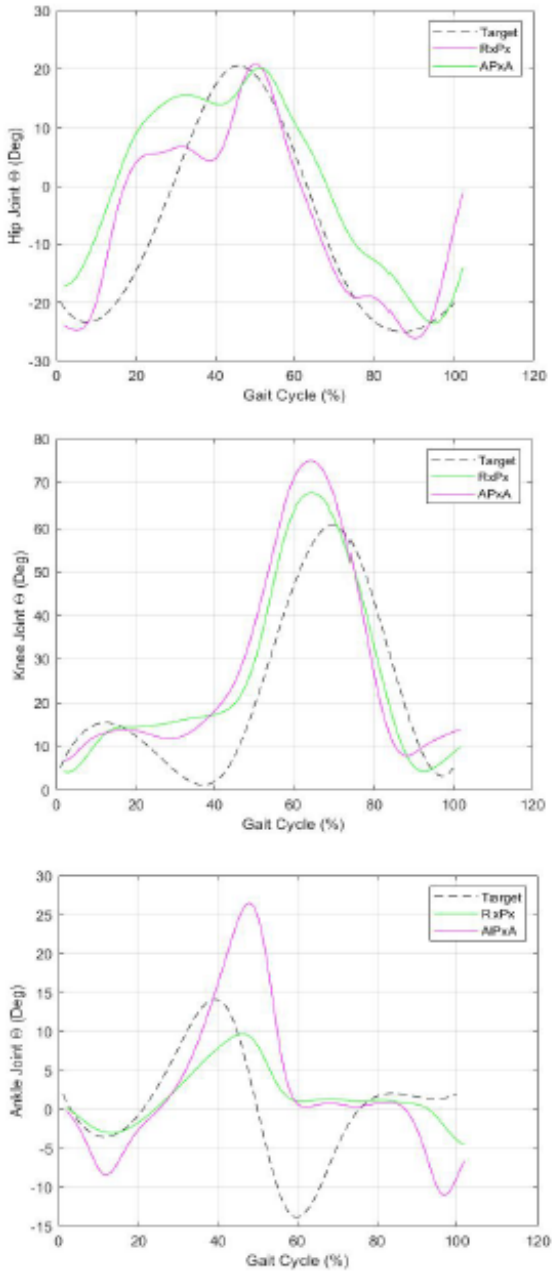


FIGURE 13: HIP, KNEE, ANKLE MOTIONS APPEAR TO IMPROVE IN THE TUG TEST WHILE USING THE APXA, BUT STILL DO NOT ACHIEVE TARGET.

This study has some limitations. We conducted a single-subject evaluation, and a more extensive pilot study or clinical trial is warranted to thoroughly evaluate the performance of the APxA against commercial products. As with most protocols assessing the performance of prosthetic devices, it is not possible to blind the subject to the intervention. The mere novelty of a new device has the potential to induce bias in the results, so this preliminary data should be viewed carefully.

4. CONCLUSION

The subject ambulated an estimated 2km on this prototype device. This study showed that the prototype functioned correctly and demonstrated the device's viability. It also showed increased movement at the ankle in gait, improved kinematic symmetry in standing and sitting tasks, and did not cause the subject to experience a decrease in balance confidence. These preliminary results demonstrate that the APxA is safe for use on a single K3 TT subject in a controlled environment. It is feasible for future testing on ramps and stairs and lower level ambulators (K2) on level ground.

DISCLOSURE

The author, Michael Davidson, is the primary inventor of the patent application claiming the technology used in this study, which is the intellectual property of Loma Linda University Health.

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CHAPTER FOUR

Manuscript Three

The following manuscript has been submitted to the ASME IMECE 2022 conference proceedings.

Proceedings of the ASME 2022
International Mechanical Engineering Congress and Exposition
IMECE2022
October 30 to November 03, 2022, Columbus, OH

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TESTING OF A ROBOTIC PROSTHETIC LEG

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ABSTRACT

We report on our evaluation of a prototype robotic prosthetic leg on a subject with leg amputation. This biomedical device aimed to improve stance stability, increase balance confidence, and reduce the contralateral limb's kinetic stresses in gait. The objective of this study was to test the safety and feasibility of the device on an active person with leg amputation. A single female subject with a knee disarticulation (KD) is fitted with the prototype prosthesis and tested against her prescribed daily use prosthesis. In addition to extended walking on level ground, kinematic and kinetic measures were taken in an 18-camera motion capture lab with two in-floor force platforms to assess body symmetry while the subject used this prototype device. We assessed balance confidence using the activities-based balance confidence questionnaire. While performing the 10MWT, the subject could ambulate at a maximum velocity of 0.77 m/s and an average of 0.61 m/s. In the six-minute walk test (6MWT), the subject walked a distance of 206 meters with a velocity of 0.57 m/s. Kinematic symmetry of both lower extremities improved in walking tasks. However, kinetic symmetry was inconclusive. In total, the subject walked on the device for 2 km. We found the device safe on a single amputee and is feasible for future clinical testing in a larger population.

Keywords: robotic prosthetic leg, biomedical device, gait, 10MWT, 6MWT, balance, symmetry

NOMENCLATURE

6MWT	Six-minute walk test
10MWT	Ten-meter walk test
ABC	Activities-based balance confidence
AKA	Above-knee amputation
APxA	Articulated prosthetic ankle
GRF	Ground reaction force
IMU	Inertial measurement unit
K1	Can stand, pivot, transfer, and take a few steps
K2	Walks at a single cadence
K3	Walks with variable cadence and walks on ramps, stairs, and uneven terrain
K4	Athletic capabilities
KD	Knee disarticulation
MFCL	Medicare Functional Classification Level
ML	Narrow Mediolateral
PWLL	Person with limb loss
RPL	Robotic prosthetic leg
RxPx	Subject's physician-prescribed prosthesis
TF	Transfemoral

1. INTRODUCTION

In the United States, 147,000 major limb amputations are performed each year [1]. Over the last decade, non-traumatic major limb amputations have increased in frequency, this population is getting younger [2], and the perioperative mortality can be as high as 42.3% [3]. In 2013, there were more than

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twenty-two thousand transfemoral (TF) amputations in the US. [4]. These individuals achieve less household or community ambulation than those with trans-tibial (TT) amputation [5]. They have an increased frequency of back, knee, and hip pain [6], obesity [7], and osteoarthritis [8]. They also have decreased balance [9] and balance confidence [10, 11]. Moreover, they have increased metabolic energy expenditure while walking [12, 13], decreased walking speed [13-15], and pronounced gait asymmetries [16-18]. They experience a higher frequency of stumbles and falls [19], [15] and have difficulty negotiating uneven terrain, hills, and stairs [16], [20]. Locomotion tasks require a higher cognitive demand [21], and they are more likely to suffer from fatigue, sleep disturbance, anxiety, and depression [22].

Standard clinical practice provides these individuals with only basic components matched to their estimated ambulation potential (K-Level) [23]. Those with more potential are eligible for higher functioning components, even though Chihuri and associates found that persons with limb loss (PWLL) who had limited walking ability experienced increased falls and injury [15]. Commercially available prosthetic knees with manual locks or mechanical clutches (K1 and K2) can be clumsy and difficult to use. Passive fluid control knees (K3 and K4) rely on hamstring and, to some extent, gluteus maximus contraction to maintain the knee in a stable alignment. Passive microprocessor limbs significantly improve some of the deficiencies of mechanical and fluid control knee as they adapt to slopes improving the safety of the individual but are strictly limited through policy for the K3 or K4 ambulator. These passive limbs, although practical, require a fixed ankle to maintain passive alignment and, therefore, stance control. Additionally, the increased muscle activity to lift the prosthetic leg and initiate swing [6] results in increased energy expenditures. Strategies such as hip hiking, vaulting, or circumduction of the prosthetic limb are used to clear the floor, and large vertical displacements of the center of mass (CoM), result from maintaining the prosthetic knee in extension in early stance contribute to the metabolic costs [24].

In a study by Fanciullacci and associates [25], PWWL with TF, sometimes called above-knee amputations (AKA), who used passive limbs, ranked knee stability as an overall priority in their "ideal" prosthesis. Users of microprocessor knee (MPK) technologies reported significantly greater functional autonomy, satisfaction, and a sense of ownership of the technology than non-MPK users. PWLL who have limited community walking ability have the highest risk of falls and injury [15], and those with a lower household income have higher rates of major lower limb amputation [26].

Best practice healthcare is a limited resource, so we are challenged as rehabilitation professionals to pair our patients with the technologies they need and to restore gait, mitigate falls, and improve balance confidence while decreasing the cognitive demand for safe and efficient locomotion.

This study continues our evaluation of an RPL which includes a powered non-backdrivable knee and a passive hydro-pneumatic articulating prosthetic ankle (APKA) on a person with limb-loss, using the 10MWT, 6MWT, ABC questionnaire, in addition to HR, kinetic, and kinematic motion capture. The APKA was developed at Loma Linda University Health and used three hydro-pneumatic gas dampers under pressure to produce dampening assistive/resistive dorsiflexion forces. Combined with a non-backdrivable powered knee, we believe this design configuration is appropriate for low-level ambulators (K2) and as a rehabilitation tool for new patients of all ambulation potential to relearn walking patterns while reducing their fear of falling.

We hypothesized that a subject using the RPL would experience improved symmetry during gait on level ground compared to their RxPx. We also hypothesized that the subject wearing the RPL would not experience a decrease in balance confidence compared to their RxPx. Conversely, we also hypothesized that using the technology would increase heart rate.

2. MATERIALS AND METHODS

2.1 Human Subject

We recruited a single (n=1) female subject with a right knee disarticulation. The subject was 162 cm (5'4") tall, with a mass of 68 kg (150 lbs), 28 years old, and had a Medicare Classification Functional Level (MCFL) of K3. The exclusion criteria included MFCL K2 or below, compromised skin on the residual limb (stump), or uncontrolled edema. This protocol was approved by Loma Linda University's Institutional Review Board, and written informed consent was obtained before testing. The subject is an experienced user of passive and MPK prosthetic devices. For her daily ambulation tasks, she uses a physician-prescribed passive prosthesis (RxPx). The RxPx is configured with a silicone-suspension liner with a supracondylar suspension, narrow-mediolateral (ML) transfemoral (TF) type carbo-acrylic socket with a flexible proximal brim, an Össur Total knee 2100, an Össur Vari-flex brand prosthetic foot/ankle, and custom cosmetic cover.

2.2 Prosthetic Device

For this case study, we configured the RPL to match the subject's lower leg height (45 cm) and shoe size (22 cm). This powered knee unit uses a brushless DC motor (Maxon EC40) with a Hall sensor and a two-channel optical incremental encoder. The custom-built gearbox with elliptical gearing provides a 360:1 reduction to meet the walking and standing power requirements of a K2 or K3 ambulator. This non-backdrivable knee was coupled with an articulating prosthetic ankle (APKA) that incorporates a passive-dynamic ankle described and tested in an earlier study [27]. While in loading response, the ankle has resisted plantar flexion. In late stance, the dampers provide resisted dorsiflexion, and in swing phase, the foot returns to neutral (8° dorsiflexion) through dorsiflexion assistance. The initial bench alignment of the ankle axis was 8° of external rotation (yaw) and 8° of eversion (lateral pitch) to match the average talocrural axis as defined by Elftman [28].

We used commercial prosthetic rotatable pyramid adapters (Össur (Reykjavik, IS) A-245300 and A-235100) to attach a custom fabricated carbon-fiber foot to the ankle and the knee. These adapters allow for the angular and transverse

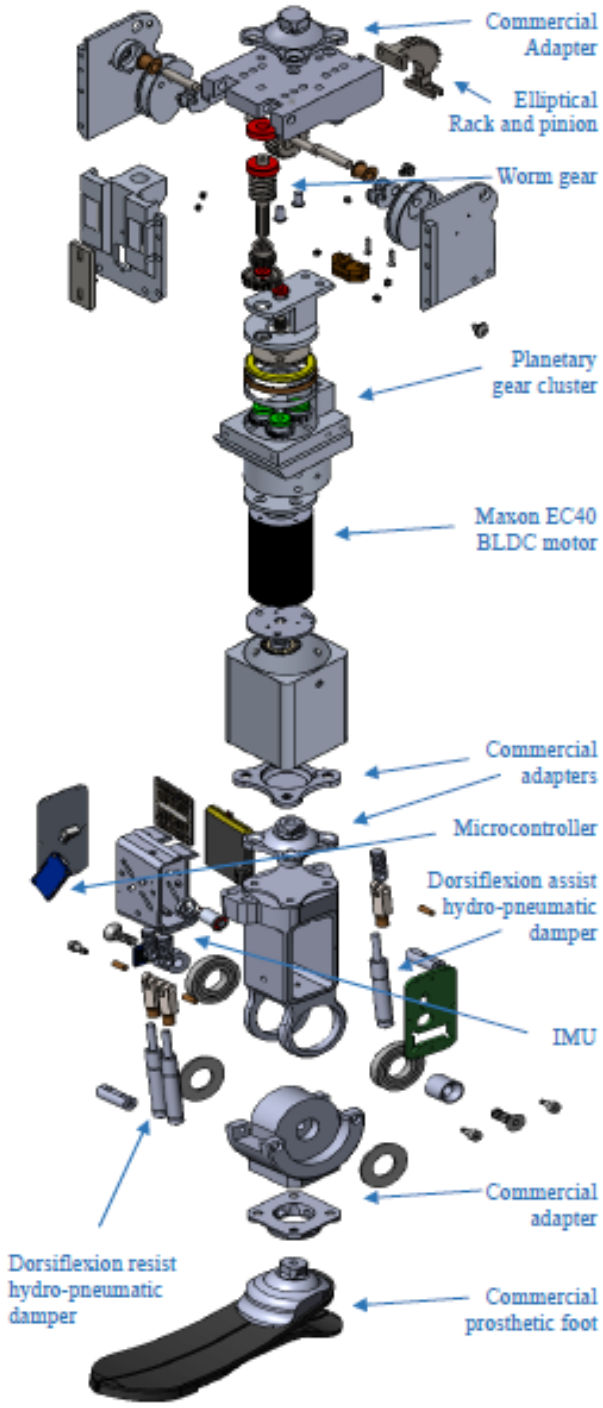

FIGURE 1: EXPLODED VIEW OF THE RPL PROTOYPE

rotation of the prosthetic foot, ankle, and knee axis to be independent of each other to match biological limb alignment. Both foot and ankle were instrumented with two inertial measurement units (IMUs (Bosch BNO055)). A 32-bit microcontroller (Adalogger, Adafruit Industries, New York, NY) collected and stored inertial, positional, and acceleration data. Figure 1 illustrates the assembly of the device. The subject used a handheld human-machine interface (HMI) to control the motion of the knee. An automatic mode was provided to initiate a complete step with a push of a button. The non-backdrivable knee provides stance control. When the subject presses the button, the knee automatically flexes, then extends the leg. The clinician sets the timing of the flexion and extension to match the subject's preferred walking speed. The total mass of the RPL in this configuration was 4.1 kg. A secondary HMI was equipped with a touch screen, providing the researcher or clinician additional monitoring and control of the system and data collection. The complete control system, secondary HMI, and battery supply are housed in a tethered backpack worn by a researcher and weighs 5.3 kgs. To protect the knee mechanism, the electronics, and to safely guide the tether, we fabricated a protective fairing using an optical scanner (Creaform, Levis, Canada) to 3D image the subject's contralateral leg and derived a mirrored NURBS model (Rhino 7, Robert McNeel & Associates, Seattle WA) with a boolean difference of the RPL mesh derived from a solid-model (SolidWorks, Dassault Systèmes, Vélizy-Villacoublay, FR). The fairing was fabricated using a 3Dprinter (Makerbot Z-18, New York, NY) using tough PLA, and the completed device is shown in figure 2.

FIGURE 2: CONFIGURED PROTOYPE WITH 3D PRINTED COSMETIC PROTECTIVE FAIRING

2.3 Over-ground Walking

We conducted the first testing session at Loma Linda University Medical Center, Outpatient Rehabilitation Center in the Orthotics & Prosthetics Lab. The subject responded to an activities-based balance confidence (ABC) scale; a one-page questionnaire used to assess fall potential and balance confidence [7, 11-13]. Then, using an Otto Bock LASAR™ Posture alignment plate, a certified prosthetist attached the RPL to a replicated socket and suspension system used by the subject's RxPx. The RPL alignment was tuned to match the non-amputated leg of the subject, optimally directing ground-reaction forces through the subject's residual limb and prosthesis as described by Blumentritt [29] and summarized in figure 3. Thread locking fluid (Loctite 242) was applied prior to testing.

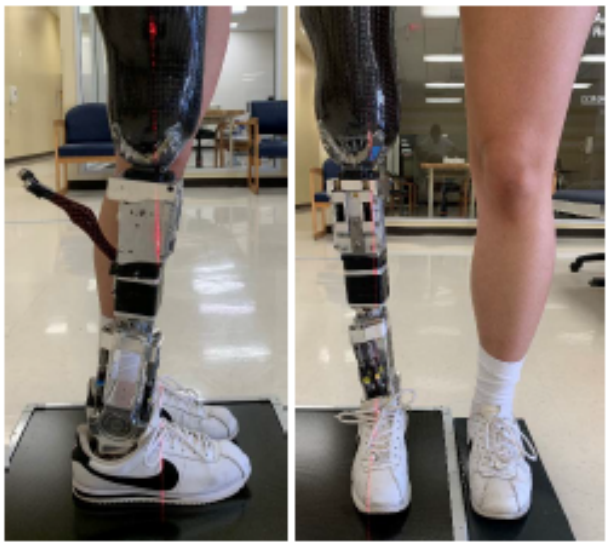

FIGURE 3: SAGITTAL AND CORONAL VIEWS OF CONFIGURED STATIC ALIGNMENT

The subject was fitted with a heart rate monitor (HRM (Polar H10, Kempele, FN)) and a modified belt to house a mobile phone over the posterior sacral spine. The phone's inertial measurement unit (IMU) recorded the pelvis's acceleration, tilt, and positional data. The subject walked a length of about 10 meters with a handrail ten times to acclimate to the dynamic function of the RPL and gain familiarity with the handheld HMI (figure 4).

Once comfortable with the operation of the RPL, the subject was then asked to walk at a selected speed without assistance to gain additional familiarity with the device. The researcher walked alongside, carrying the PLC backpack, and guiding the tether to prevent tripping (figure 5).

FIGURE 4: HANDHELD HMI

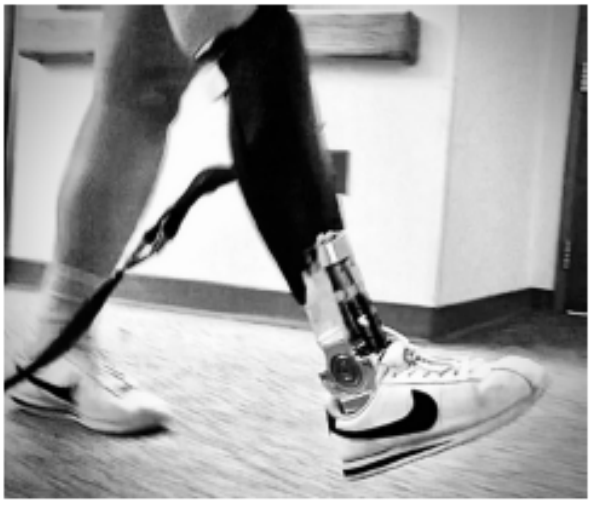

FIGURE 5: SUBJECT USING RPL AND TETHER SAFELY MANAGED BY RESEARCHER

The subject then performed a series of 10MWT and 6MWT at a self-selected speed. We recorded the number of steps, toe-drags, stumbles, and falls.

2.4 Subject Feedback

After the study, the subject answered a series of open-ended questions about the experience, and the responses were audio recorded. The questions included:

1. Tell me how you are feeling/what are you thinking?
2. How would you describe the experience of standing?
3. How would you describe the experience of walking (ease, balance, speed, etc.)?
4. Tell me about the qualities of this device that are beyond its basic function of standing/walking/sitting.
5. What do you think about its appearance?
6. What do you think about its sounds?

2.5 Kinematic and Kinetic Testing

The subject returned for motion analysis at Loma Linda University's Motion Capture Lab in the School of Allied Health Professions two weeks later. The subject utilized both the RxPx and the RPL for testing. Clusters of motion capture body markers were applied to the subject in a modified Helen Hayes pattern described by Davis and Associates [30]. These 32 retroreflective markers were attached bilaterally to the subject's iliac crest, anterior superior iliac spine, and posterior superior iliac spine. For the left, non-amputated lower extremity, markers were placed on the medial and lateral femoral epicondyles, medial and lateral malleoli, calcaneus, and base of the first and fifth metatarsals. The markers on the right (amputated) leg were applied to the prosthesis, and both the biomechanist and the prosthetist placed markers to approximate the axes of rotation to match the left leg shown in figure 6.

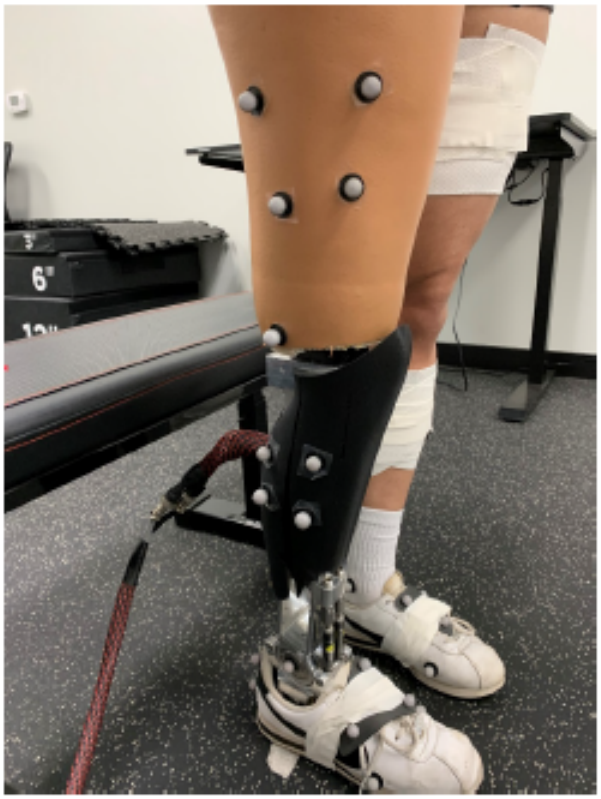

FIGURE 6: RETROREFLECTIVE MARKER PLACEMENT

An 18-camera Qualisys Motion Capture System (Gothenburg, Sweden) was used to record three-dimensional marker position data using a capture rate of 120 Hz. Marker position data were smoothed using a fourth-order, low pass recursive Butterworth filter with a frequency cutoff of 6Hz. Visual 3D motion analysis software (C-Motion, Inc., Rockville, MD) calculated joint angles from maker position data. All joint angles were modeled as the motion of the distal segment relative to the proximal using Euler/Cardan angles (x-y-z rotation sequence). Two in-floor tri-axial force platforms (AMTI, Inc, Watertown, MA, USA) placed in series were used to collect kinetic data at 1200 Hz. The subject performed a series of walking tests in both the RxPx and the RPL while kinetic and kinematic data were recorded. We Analyzed the data using MATLAB™ 2021b (MathWorks, Inc., Natick, MA) and plotted the results. As the study concluded, the subject completed the ABC questionnaire again.

3. RESULTS AND DISCUSSION

3.1 Static Assessment

The mass of the subject's RxPx and RPL were 3.74 kg and 4.11 kg, respectively. Bilaterally, the trochanters to the floor were 82.5 cm (32.5) inches, and the knees were 47cm (18.5 inches). We confirmed through 10MWT that the subject has an ambulation potential of K3. After the subject was fitted with the RPL, alignment was verified using a LASAR™ Posture system to match the alignment of her RxPx.

3.2 Dynamic Assessment

While wearing the RPL, the subject performed the 10MWT nine times (mean velocity 0.61 m/s (SD 0.1)), averaging 8.29 seconds. In the 6MWT, the subject walked 206 meters, demonstrating a velocity of 0.57 m/s, typical of a K3 ambulator as the subject was performing the 6MWT. We recorded one toe drag. As she became more confident with the device, we observed five stumbles due to the timing of the knee swing in late stance. In all observations, the subject safely recovered from the stumbles, there were no falls, and the results are summarized in table 1.

Unfiltered IMU data shows transverse plane rotational movement (yaw) between the prosthetic toe and prosthetic talus. Additionally, IMU data demonstrates expected movements in the coronal and sagittal planes. HR data showed that while walking with the RPL, heart rate was 88.34 (SD 11.5) compared to the RxPx, which was 83.72 (SD 7.5). These results support our hypothesis that HR would increase while using the RPL.

TABLE 1: SUMMARY OF RESULTS FROM OVER-GROUND WALKING TESTS

	RxPx	RPL
Mass of prosthesis (kg)	3.74	4.11
Mass of backpack PLC (kg)	n/a	5.3
Height of prosthesis (cm)	47	47
Velocity (10MWT) in m/s	1.32	0.61
Distance (6MWT) meters	372	206
ABC score	930	1020
Heart rate (bpm)	83.7	88.3
Frequency of Toe drags	0	1
Frequency of Stumbles	0	5
Frequency of Falls	0	0

3.3 Motion Capture Lab

Force plate data shows peak ground reaction occurs later in stance for the RPL as compared to the RxPx (figure 7). There might be an opportunity for design iteration, or this could result from a training effect as the subject only had about 2 hours to be accustomed to the APxA. The 3D motion-capture camera system recorded kinematic performance while walking and we plotted the results (figures 8 through 10), and supports our interpretation of GRF data and the need to allow more training or consider using a stronger dorsiflexion resist.

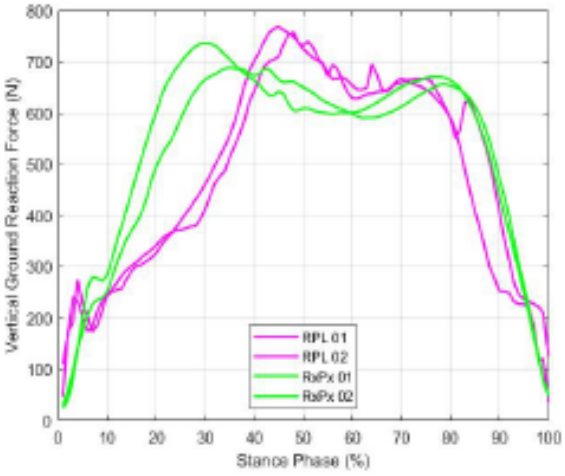

FIGURE 7: GROUND REACTION FORCES OF RxPx vs RPL IN TWO TRIALS

While using the RxPx, there was an excessive motion of the hip and knee on the amputated side, and, as expected, the motion of the manufactured rigid prosthetic ankle was noticeably less than the left leg. The hip and knee motions decreased when the user used the RPL, ankle motion increased, and overall kinematic symmetry of both extremities improved. Further tests will need to be performed to determine if the excessive stance phase dorsiflexion will decrease with practice or if a stiffer damper is required.

In the open-ended post-experience questions, the subject stated, *"I felt like I could put more weight on it* [RPL as compared to RxPx]*…even though the ankle had movement, I felt stable"* The subject also stated, *"I felt comfortable, stable… and I was confident"*.

In the ABC scale test, the subject initially reported a score of 930 and a final score of 1020. Although this anecdotal feedback should be viewed with caution, it could serve as a valuable tool in future randomized trials with large sample sizes where subjects use the device for several weeks or months between the pre- and post-intervention.

This study has several limitations. As it was a single-subject evaluation, a more extensive pilot study is warranted to evaluate the performance of the RPL against commercial products

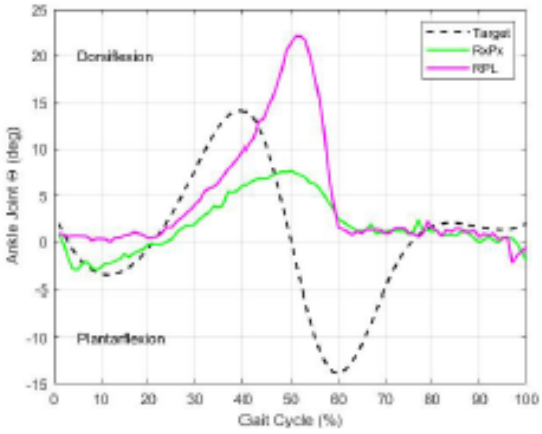

FIGURE 8: ANKLE JOINT MOTIONS

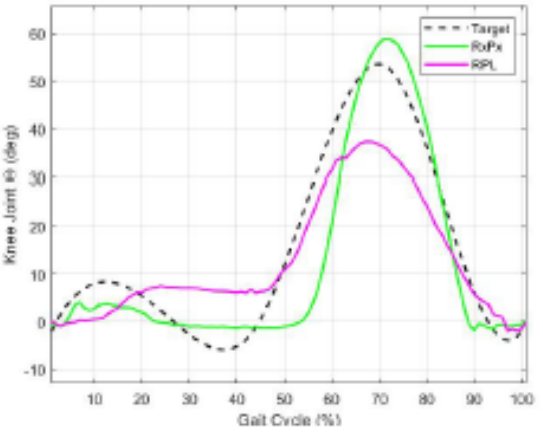

FIGURE 9: KNEE JOINT MOTIONS

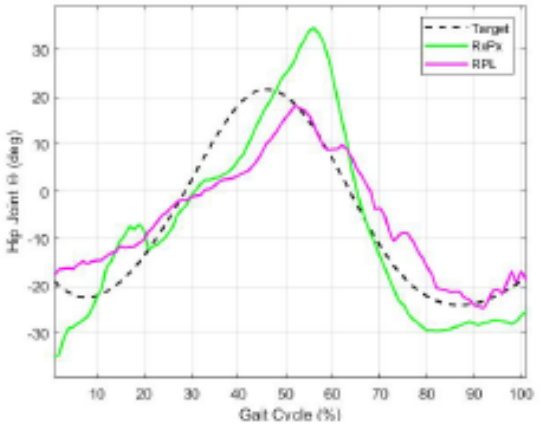

FIGURE 10: HIP JOINT MOTIONS

thoroughly. As with most protocols assessing the performance of prosthetic devices, it is not possible to blind the subject to the intervention. The mere novelty of a new device has the potential to induce bias in the results, so this preliminary data should be viewed carefully. Finally, our observations are that there is likely a training bias to this type of technology. As the subject continued to use the RPL, we observed the subject's heart rate decrease as velocity increased, indicating that the subject became more comfortable with the technology with time. Future protocols should consider allowing several hours or days to acclimate to the technology before testing.

4. CONCLUSION

The subject ambulated an estimated 2km on this prototype device. This study showed that the prototype functioned correctly and demonstrated the device's viability. We demonstrated the RPL to be safe and feasible in ambulation tasks on a female with a KD amputation. These results demonstrate that this prosthetic device operated safely in a controlled environment on a single K3 ambulator and is feasible for further testing among larger populations of persons with limb loss.

DISCLOSURE

The author, Michael Davidson, is the primary inventor of the patent application claiming the technology used in this study is the intellectual property of Loma Linda University Health.

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CHAPTER FIVE

DISCUSSION

In this chapter we summarize our key findings with the stated aims and questions by discussing their contribution to the fields of prosthetics and amputation rehabilitation. This chapter also provides an in-depth discussion of the limitations of the conducted studies. These limitations create opportunities to frame our proposed trajectory for continued research. A power analysis is provided to justify the sample size needed to achieve appropriate statistical power.

INTRODUCTION

We developed a robotic prosthetic leg (RPL) with a passive articulated prosthetic ankle (APxA). The APxA can be used independently of the RPL for those with below the knee (BK) amputations at the transtibial (TT) level. The RPL with APxA can be used for those with limb loss above the knee (AK) which includes both knee-disarticulation (KD) and transfemoral (TF) amputation levels. The unique passive compliance of the APxA allows the user to adapt to slopes, sitting, and standing tasks bilaterally. The non-backdrivability of the RPL provides stance stability, without compromise, to balance confidence on level ground and slopes (figure 1). A study by McGrath and others [1], assessing five subjects with a transfemoral amputation, found that combining a hydraulic articulated ankle and a knee with standing support achieved near-normal biomechanics - congruent with our early findings.

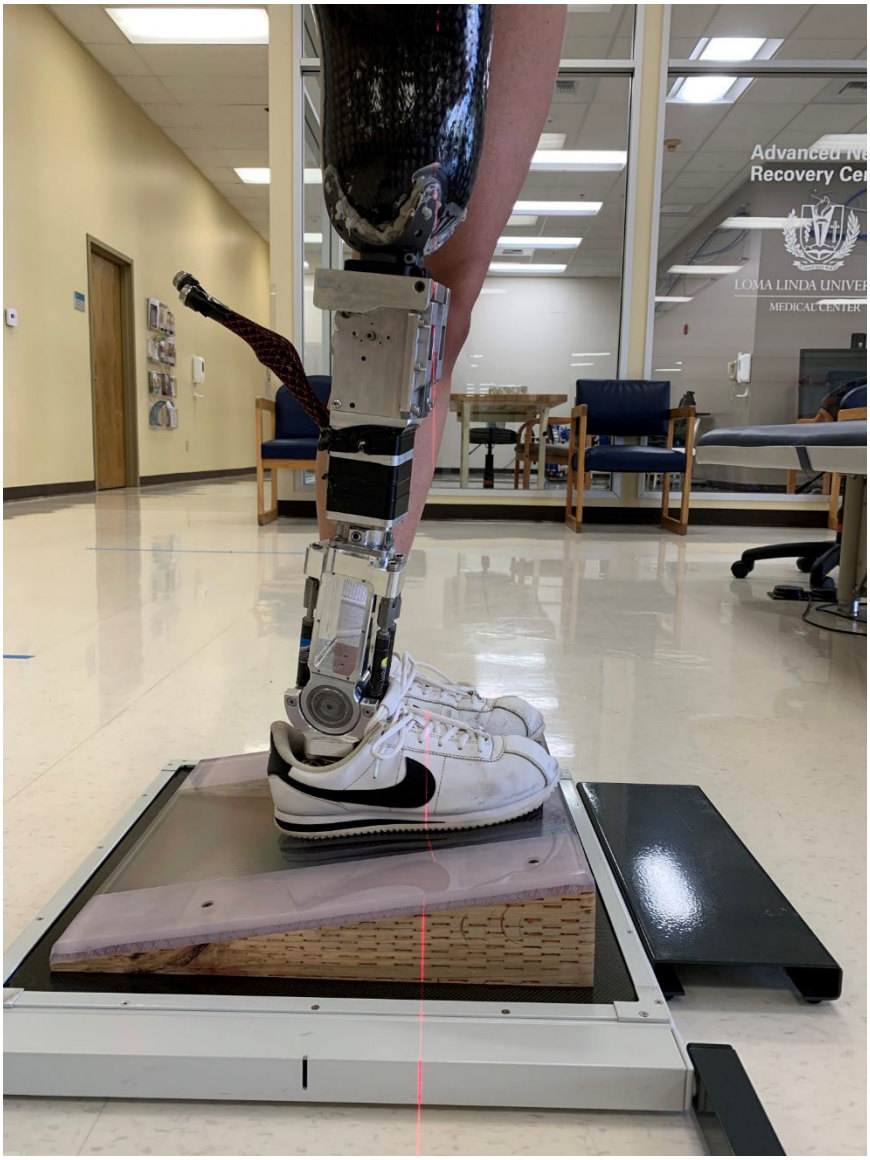

Figure 25 RPL with APxA demonstrates knee and ankle stability on a 10^{o} incline. The laser line demonstrates the true center of gravity symmetrically passing through both extremities

CONTRIBUTIONS

This study aimed to investigate the feasibility and safety of the RPL while testing its performance in walking, sitting, and standing. We specifically examined symmetry and balance confidence in subjects using the RPL and the APxA. The results suggest that unilateral joint trajectories improved at the ankle, knee, and hip compared to the user's physician-prescribed prosthesis (RxPx) in two amputee subjects. Furthermore, our findings show that while using the APxA, hip motions appear to be more symmetrical. Of particular interest was the observed improvement of hip symmetry in the transtibial subject using the APxA while performing sitting and standing tasks. Of the two amputee subjects, neither reported an increased fear of falling, nor reported concern with the added weight of the devices. Subject 2 self-reported that the device felt lighter in weight, when it was heavier.

This study's findings show that the articulated passive ankle motion, both independently and with powered, non-backdrivable knee motion, is feasible and trends towards safety under the conditions tested. It did not reduce the subjects' balance confidence or increase their fear of falling. Battery power was sufficient for the duration of testing, and thermal buildup was negligible at the batteries and the actuator. There were no falls in either RxPx or APxA.

LIMITATIONS

This study had several limitations. First, we relied on a convenience sample of subjects recruited through word of mouth from our clinic. The subjects had an ambulation

potential of K3 and did not represent other ambulation levels. Further testing is required on those levels. Additionally, this research, a series of case studies, cannot be used to make broad inferences on the efficacy of the RPL or the APxA, nor can these results infer the safety of these devices in unsupervised outdoor environments or in unsupervised sloped conditions. However, based on our assessment of an able-bodied subject, PWLL will be able to feasibly perform supervised ramp and slope conditions using these devices in an approved and structured protocol. The insufficient sample size primarily limits our findings, and repeated measures on larger samples are needed to address the low-resolution and strengthen our analysis in phase three of the research study.

Another limitation is that both subjects were observed altering their gait to place their foot entirely on the force plate in the kinetic testing. Future studies may look at means to conceal the force plates or have more plates so that participants do not attempt to help with the collection process. Another strategy might be to use an instrumented walkway to measure several stride lengths to assess step symmetry.

In the kinematic testing, we took great care to ensure marker placement was consistent with the RxPx and the intervention prosthesis (APxA or RPL). Nonetheless, some differences may have occurred possibly in the order of centimeters.

There was also the practical limitation of funding. Direct costs associated with the development of the RPL and APxA were $30,000 and $26,000, respectively. Additional modifications and repairs were made to the RPL for $6000.

Patient blinding is not possible in these types of studies as the subject can see and sense the intervention.

Finally, the student researcher is the primary inventor of the APxA, and although Loma Linda University Health owns the claimed technology, an inherent bias could exist in our findings. Future studies should include independent assessors to collect quantitative data to ensure best practice and clinically relevant data is collected using validated methods to reduce the bias of competing interests.

FUTURE RESEARCH

We propose a series of three additional protocols to fully evaluate the APxA on BK populations. Once completed, we suggest repeating the three studies using the RPL and the APxA on AK populations.

The first study should look at the balance performance and coordination on ramps (inclines and declines). Through computational analysis of simulated powered vs. passive articulated prosthetic ankles, Pickel and associates' postulate that energetic measures may come at the expense of dynamic balance, which is essential for avoiding falls [2], and that prosthetic ankles differ negatively from able-bodied gait in terms of segmental coordination of balance. Clites and others found that six of seven TT subjects preferred a lower foot/ankle stiffness self-selected walking velocity which maximized kinematic symmetry in both prosthetic and contralateral joints [3]. This may be congruent with our early findings but needs further exploration through dynamic balance assessment and performance assessment on ramps (inclines and declines).

The second study should consider the performance of the APxA in sitting and standing and during the timed-up and go (TUG) tests. The TUG test has excellent intrarater and interrater reliability [4, 5], but may suffer from a ceiling effect in advanced

users (i.e., K4) [6], but it is associated with a lower frequency of falls [7]. Although there seems to be a lack of evidence of the reliability and validity of the 5xSTS in those with lower-limb loss [8], it, in conjunction with the TUG test, may augment the performance assessment of the APxA in sitting and standing tasks.

The third study should further examine the added mass of the APxA. The two subjects reported that the devices are considerably heavier than their RxPx, even though in prior works by Fanciullacci and others [9], amputee subjects ranked a low overall mass to be a high priority of the ideal prosthesis. However, Meikle and others report that when adding mass to the distal shank of a prosthesis, six of ten TF subjects preferred the added mass condition over a placebo mass and did not have any significant decrease in walking velocity [10]. This conflicts with the works of Hekmatfard and associates [11], where 8 of 10 TF subjects preferred a no-added mass prostheses compared to two mass added conditions. Interestingly in that study, the authors concluded that adding mass to a prosthesis has no significant effect on the spatiotemporal gait characteristics but did improve spatiotemporal gait symmetry. Future works should explore this further, evaluating subjects' preferences against their performance and determining if the non-compliant nature of a fixed ankle gives the perception of added mass to the prosthesis. We should continue to monitor heart rate in these tests to see if there is a metabolic change due to the intervention. As stated before, once completed on a BK population, we can repeat the testing protocols on AK subjects.

The studies mentioned above will need a sufficient sample size to make firm conclusions about subjects' performance using the technologies. To ensure these three studies will have an adequate sample size, we performed a Power Analysis using

G*Power 3.1.9.7. [12]. Assuming an alpha level of 0.05, a moderate effect size of 0.6, a 10% dropout rate, and a power of 0.8, we determined that a sample of 26 subjects is needed. The moderate effect size was chosen because there is inadequate literature to substantiate precedence for effect size. Results are plotted in figure 26.

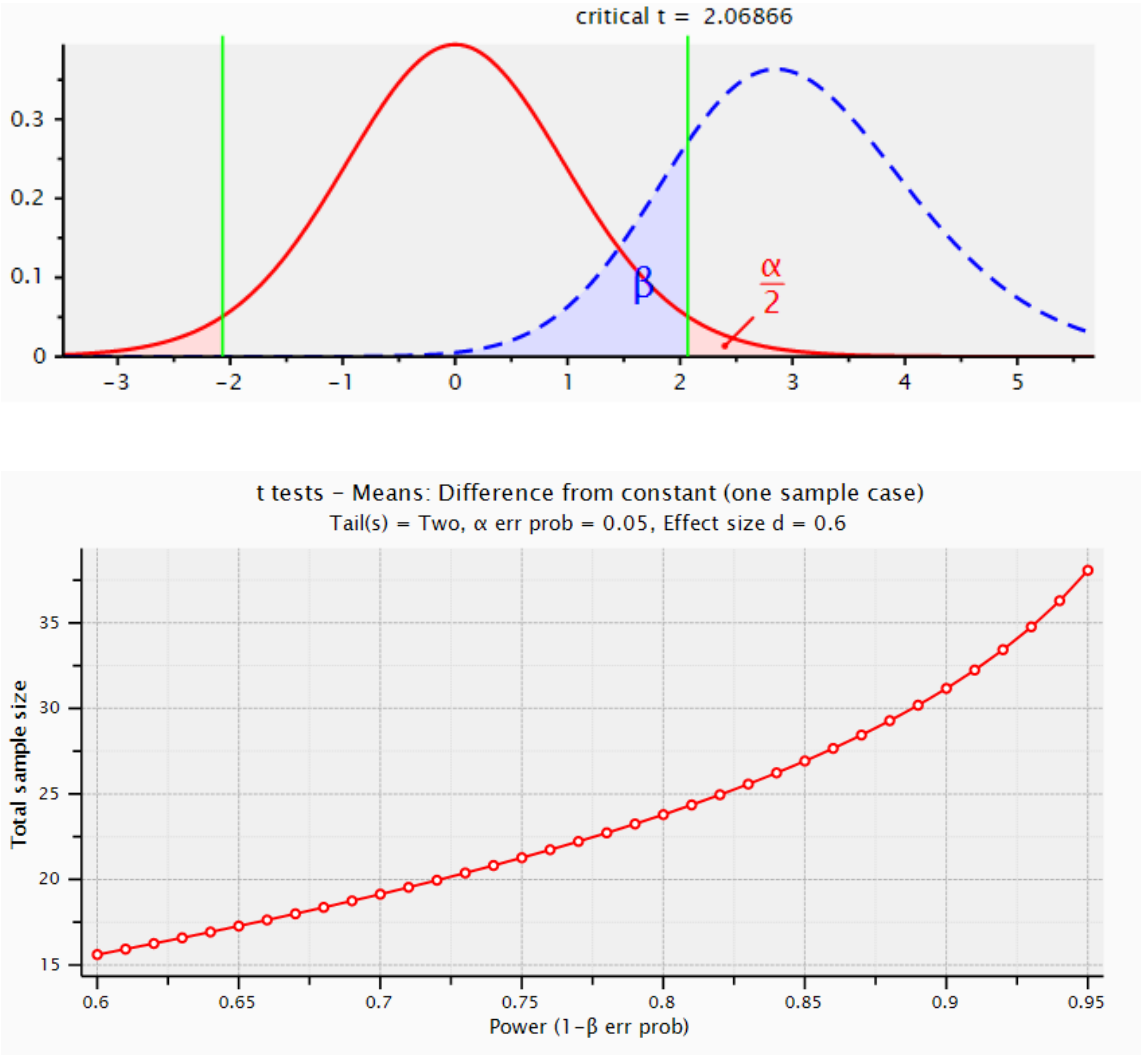

Figure 26 Power Estimates for Future Studies

STUDY ONE - We have proposed a future research study to test if the APxA improves performance while walking, sitting, standing, and during balance tasks compared to the subject's RxPx. We hypothesize that subjects using the APxA will experience improved symmetry during gait while on level ground and ramps and improve subjects' speed while sitting and standing. Conversely, we hypothesize that subjects wearing the APxA will not decrease balance performance but will have an increase in heart rate. We will recruit up to 26 males and females 18 to 75 years of age with trans-tibial (TT) limb loss. The subjects must be able to ambulate with a variable cadence (MFCL K3 or K4).

Additionally, they must use a prosthesis daily for ambulation or sports activities and have the ability to sit and stand from a chair independently. Males or females who have a Medicare functional classification level (MFCL) of K2 or below, foot amputations at the ankle, use assistive devices for ambulation, have compromised skin on the residual limb (stump) or foot, or have uncontrolled edema, or have had an amputation within 90 days or less will be excluded from participating in this study. Following is the list of tests that will be used in this study:

Activities-based balance confidence (ABC) scale will be administered at the beginning of the study.

The ten-meter walk test (10MWT) will be administered on level surfaces as well as ramps, with the subject walking down the incline (descent) and up the incline (ascent).

The six-minute walk test (6MWT) will be administered. This test measures the distance walked in six minutes to assess the subject's physical endurance.

An instrumented walkway (GAITRite®) will be used for the 6MWT and all 10MWT to record step time, step length, and cadence.

Five times sit-to-stand (5XSTS) test will be administered with the subject's prescribed prosthesis and with the APxA.

Subjects will stand on the SMART Balance Master® force plate system and perform the following tests in the following order while secured in a safety harness:

Weight-bearing squat (WBS) test – examines a subject's ability to perform squats with the knee flexed at 0, 30, 60, and 90º while maintaining equal weight on both legs.

The unilateral stance (US) test is a performance test that assesses a subject's ability to maintain postural stability while standing on one leg at a time and having eyes open and closed.

The sensory organization test (SOT) – evaluates a subject's performance of their vestibular, visual, and proprioceptive systems of balance control.

Limits of stability (LOS) test – This assessment quantifies impairments in the subject's stability limits without losing balance when their center of gravity (COG) is intentionally displaced.

STUDY ONE DATA COLLECTION

Ambulation velocity (max, min, average m/s), Step time (s), step length (m), and cadence (s) (GAITRite® data) on level ground and on ramps will be collected. Additionally, we will collect inertial vectors (direction (º), yaw (º), pitch (º), roll (º),

inertia (g), and altitude (m)) of the pelvis (mobile phone data), and the prosthetic ankle of the APxA. Balance confidence will be assessed using the ABC-16 Likert score and sitting and standing will be evaluated using the 5xSTS (time). Balance performance will be evaluated with WBS, US, SOT, and LOS scores.

STUDY ONE DATA ANALYSIS

Mean± standard deviation (SD) will be computed to compare symmetry (SMART Balance Master®, GAITRite®, iPhone ™, Velocity (6MWT), and time (10MWT, 5xSTS) between APxA and prescribed prosthesis.

STUDY TWO - Inclusion criteria: We will recruit 26 males and females 18 to 65 with unilateral limb loss from transtibial amputation. They must be able to ambulate with single or variable cadence (MFCL K2 and above), use a prosthesis for ambulation daily, and can follow one-step commands. Exclusion criteria: Males or females who have an MFCL K1 or below ambulation potential, compromised skin on the residual limb (stump), or uncontrolled edema will be excluded from participating in this study.

Using a 3D, 18-camera motion capture (MoCap) system, kinematic data will be recorded, and data will be collected for later analysis for the 5XSTS (phases 2 and 3) and TUGT (phase 2). Using two in-floor force platforms, ground reaction force vectors (GRFv) of each subject's biological leg and prosthetic leg will be recorded. Data will be collected for later analysis for the 5XSTS and TUGT (phases 2 and 3). Activities-based

balance confidence (ABC) scale will be administered at the beginning and the end of the study.

STUDY TWO DATA COLLECTION

Kinematic symmetry (mm), Kinetic symmetry (N), Heart Rate (bpm), 5 x STS, Inertial vectors (direction (º), yaw (º), pitch (º), roll (º), inertia (g), altitude (m)) of the robotic foot and tibia, and ABC score.

STUDY TWO DATA ANALYSIS

Repeated-measures analysis of variance to compare mean symmetry (MoCap, Ground Reaction, iPhone™), metabolic efficiency (HR), and time (5xSTS) among three interventions (APxA, RxPx, and no prosthesis (NoPx)).

STUDY THREE

A yet-to-be-determined protocol will be developed once a reliable tool can be identified to measure subjects' attitudes and perceptions of their prosthesis mass. In the studies of prosthetic technologies, it is generally impossible to blind interventions to the users, and they can see, feel, and perceive their RxPx and will undoubtedly be aware of any new device that is applied to them. Even though Clark and Fiedler found that blinding may not be necessary [13], the inconsistency of patient preference with performance necessitates an attempt to eliminate this bias in assessing the overall mass of the APxA and the RPL. Kinematic and temporal gait measures will be made as above and heart rate.

CONCLUSION

The RPL and APxA operated as designed and demonstrated safety in the conditions tested. Although larger future studies will be required to demonstrate a statistically significant difference in safety, the RPL is feasible to continue evaluating these technologies of K2 and above PWLL in sitting, standing, and level-ground walking. It is feasible to continue evaluating these devices on ramps (inclines and declines) and testing dynamic balance in PWLLs who are K3 and above.

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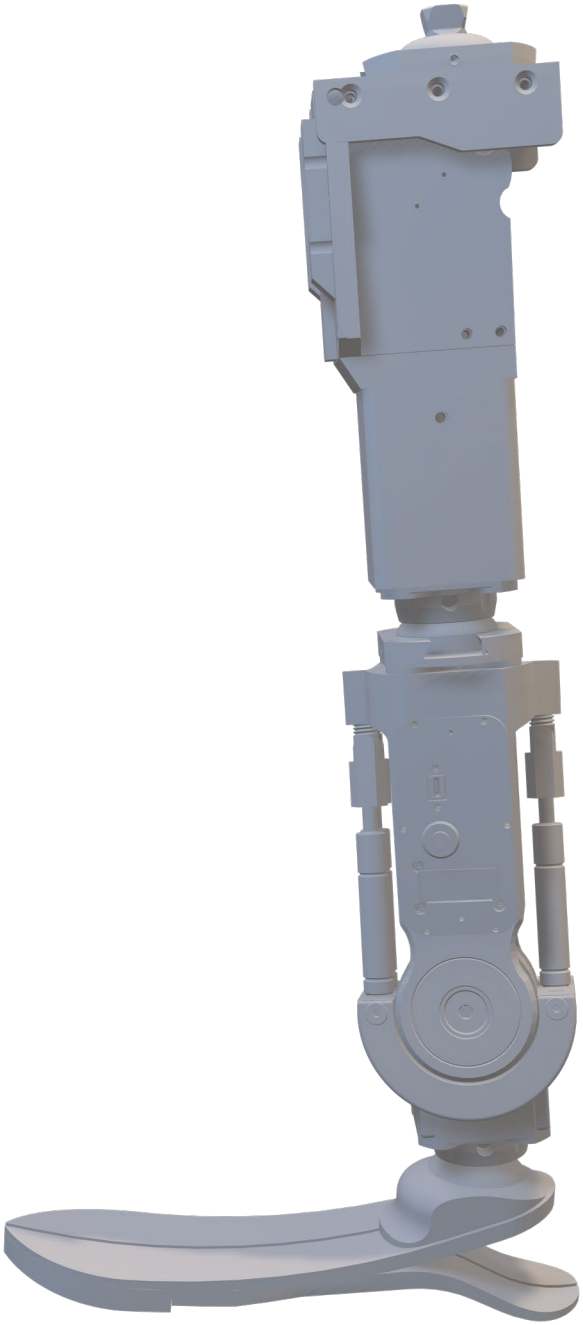
APPENDICES

Appendix A

Loma Linda University Health, Robotic Prosthetic Leg

User Manual

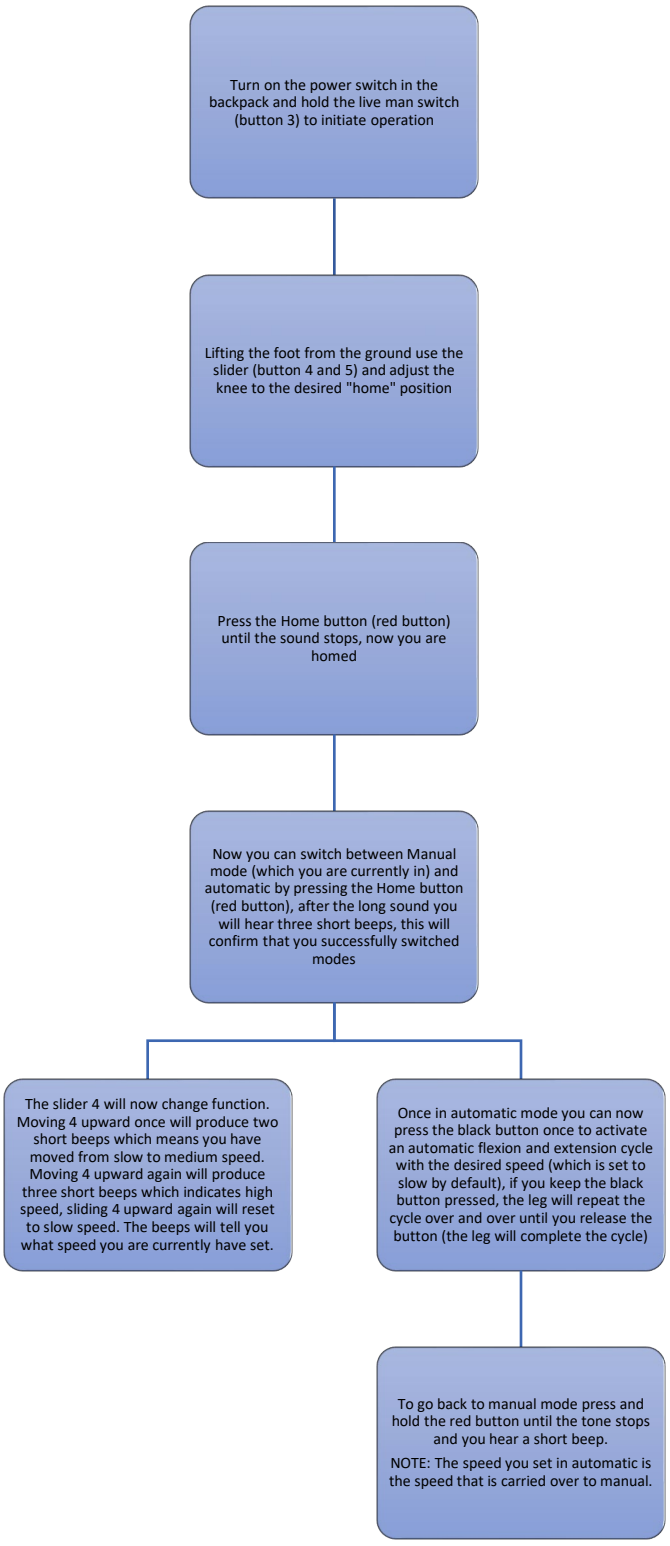


The Loma Linda Leg pHMI

The LLUH-RPL is equipped with a patient human-machine-interface (pHMI), which is a handheld controller that provides user-intent motion of the knee for walking, standing, and sitting tasks. The device is equipped with a "live-man" switch which must be activated for the device to operate. If the pHMI is not held in the hand, the live-man switch will immediately turn off the power to the controller board and motor. This provides an extra level of safety to "kill" the device, in the event of a fall or other sentinel event. The pHMI has two momentary switches as well as a sliding potentiometer to give precise movement control to the patient.

1) Automatic Cycle Button
2) Home/Function Button
3) Live man switch*
4) Slider up function
5) Slider down function

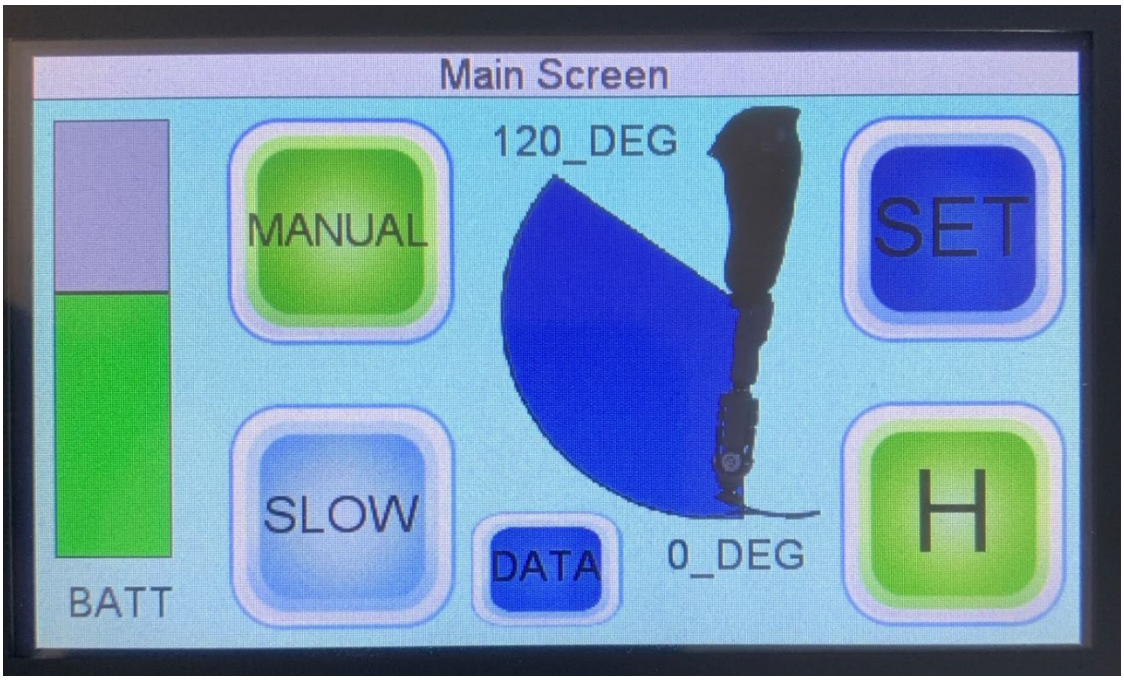
*To input any command or initiate motion the live man switch must be pressed; if released while in motion, the knee will freeze instantly and will finish any previously inputted command once the switch is pressed again.

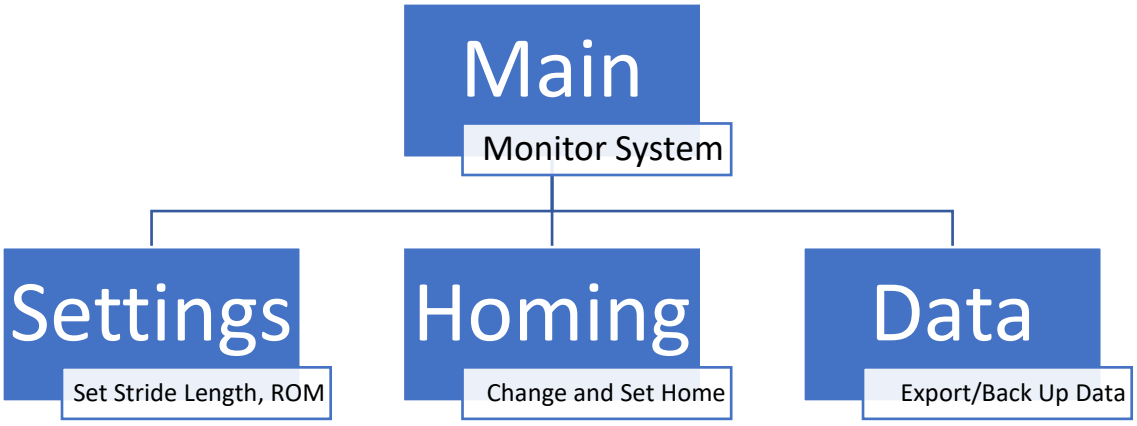


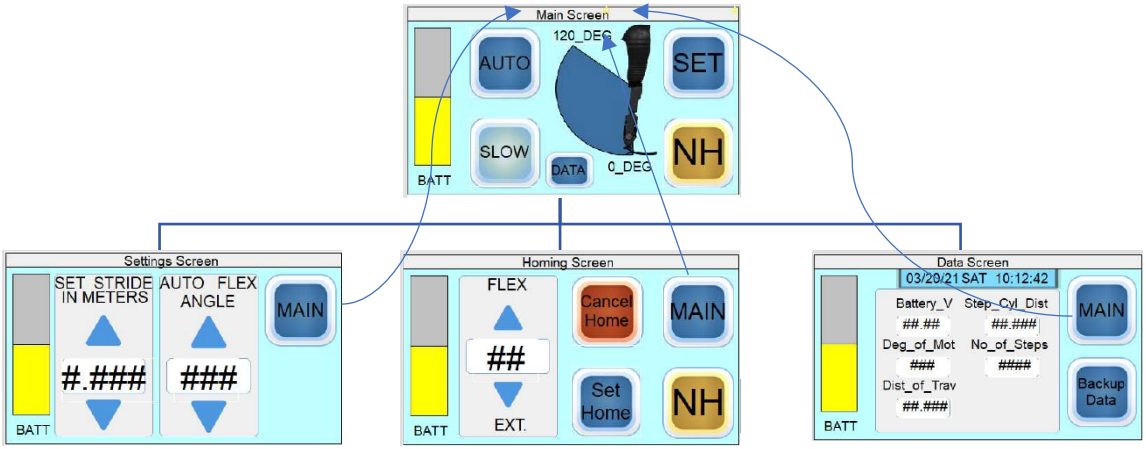
If you do not know what part of the procedure you are in, it is advisable to power cycle the system to avoid errors.

The LLUH RPL Clinical Human Machine Interface (cHMI)

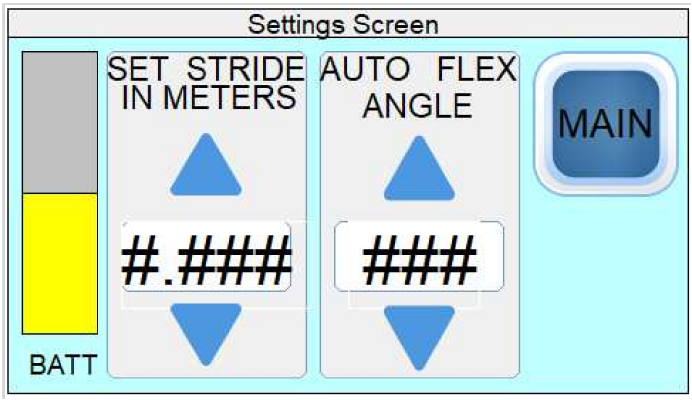
The LLU-RPL is equipped with a clinician human-machine-interface (cHMI) which includes a touchscreen and user interface with a *Home Screen* and three utility screens. This interface affords the clinician the ability to change parameters such as speed and knee range-of-motion, as well as monitor battery life and the number of steps taken. There is an export function to transfer data to a flash-drive device.



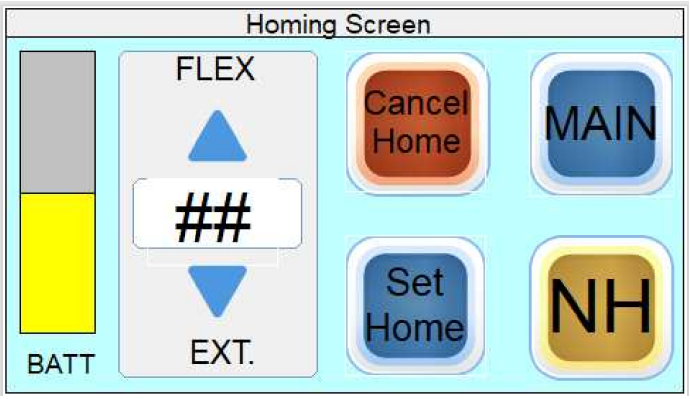

Main
Monitor System
Settings
Set Stride Length, ROM
Homing
Change and Set Home
Data
Export/Back Up Data


Main Screen
120_DEG
AUTO
SET
SLOW
DATA
0_DEG
NH
BATT
Settings Screen
SET STRIDE IN METERS
AUTO FLEX ANGLE
MAIN
#.###
###
BATT
Homing Screen
FLEX
Cancel Home
MAIN
##
Set Home
NH
EXT.
BATT
Data Screen
03/20/21 SAT 10:12:42
Battery_V
Step_Cyl_Dist
##.##
##.###
Deg_of_Mot
No_of_Steps
###
####
Dist_of_Trav
##.###
MAIN
Backup Data
BATT

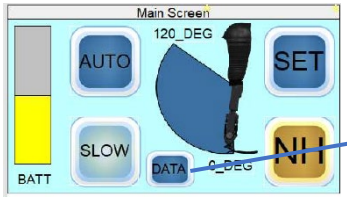
To go to the Settings Screen

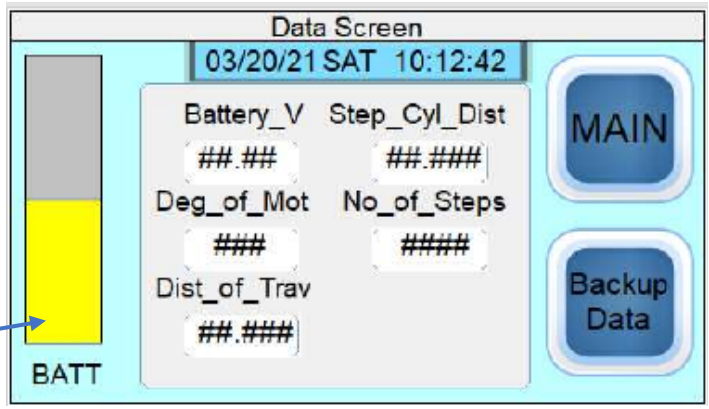


To go to the Homing Screen



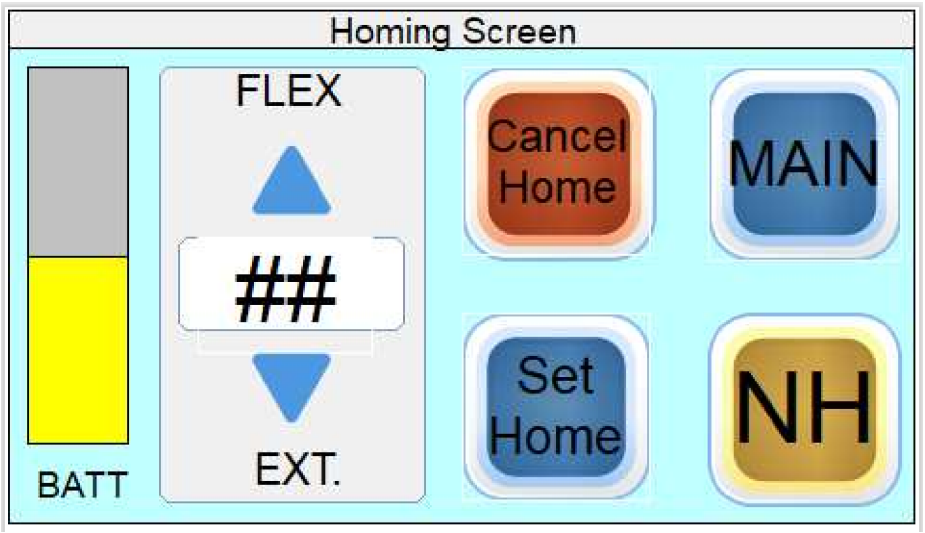
To go to the Data Screen



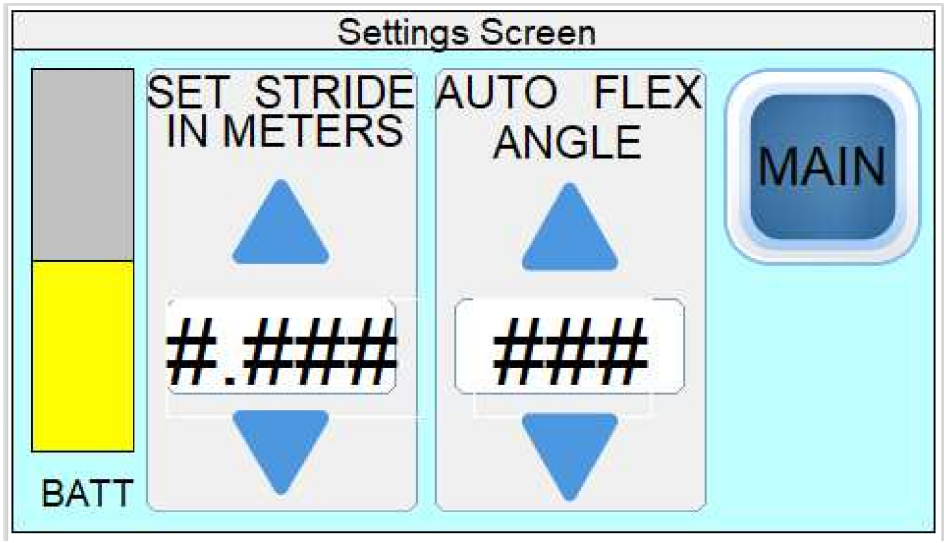


The battery level can be monitored from any screen. A green status bar indicates that the batteries are ≤ 75% of capacity. A yellow status bar indicates that the batteries are below 75% capacity and a red status bar indicates the batteries are below 10% capacity and are near critical. The device should be immediately shut down and recharged before further use. If the critical battery level is reached, the system will not be able to operate, and a red screen will be displayed on the cHMI. This protects the LiPoly batteries from damage.

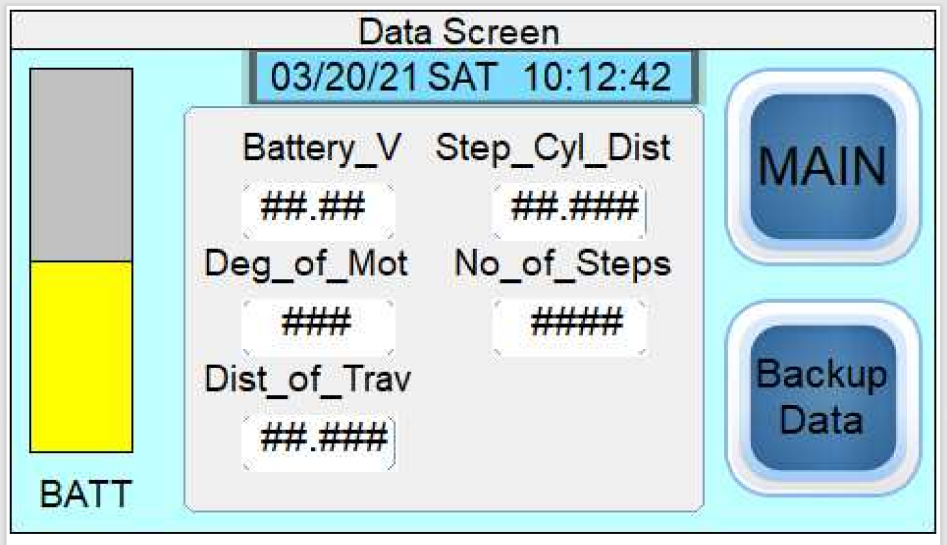
To reach the *Homing Screen*, press the **NH** (or **H**) button *Main Screen*. From the *Homing Screen*, the home position can be set. An indicator informs the operator if the system is not homed (**NH**) or homed (**H**). Use the toggle arrows to move the knee into position. It is suggested that this position should be 0-5°. Using the Set *Home button*, the position is now set, and the **NH** indicator will change to **H**. It is important to note the home position must be set before the auto function can be used. Auto function is achieved from the pHMI by holding the homing button (red) for 3 seconds or until the audible beep stops. A **Cancel Home** button provides the operator the ability to reset the home position by canceling it. The reset home procedure must be done before proceeding. The **MAIN** button returns the operator to the *Main Screen*.



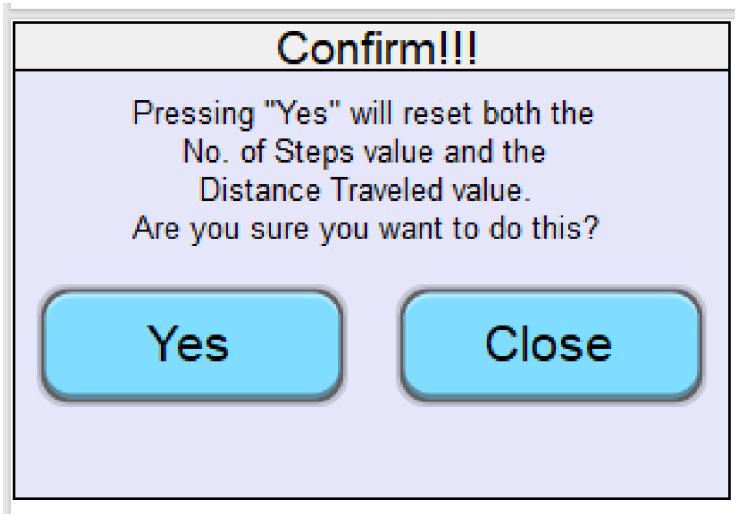
It is recommended the operator determines each patient's stride length prior to using the LLU-RPL. Using the toggle arrows, enter the stride length in meters. If this is not known, enter 1.341 for a 50th percentile female or 1.520 for a 50th percentile male. Then determine the amount of desired knee flexion to achieve sufficient heel rise in early swing. Consider 30 degrees as a minimum, but 80 degrees may result in too much delay of swing phase extension. Once the desired parameters are set, use the **MAIN** button to return to the *Main Screen*.



To access the *Data Screen* from the *Main Screen*, press the **DATA** button. Once in the *Data Screen*, you can monitor battery voltage, degrees of knee motion, distance traveled, distance of step cycle, and number of steps taken.



To export data, use the **Backup Data** button. A USB drive must be inserted into the cHMI. A port is located on the bottom of the unit. Once Backup Data is pressed, a pop-up will ask the operator if data should be reset, press **Yes** to confirm or **Close** to continue to back up and not reset the data.



Use the **MAIN** button to return to the *Main Screen*.

APPENDIX B

IMU Code

```
/*
 *  Program created By Karen J Davidson MPH
 *  along with help from  Jesus Adrian Gutierrez and Ryan Philcox
 *
 *  Rehabilitation Institute, Loma Linda University
 *
 *  This program uses adalogger feather M0, multiple IMUs(BNo055), and an OLED screen.
 *  The purpose is to record inertial data from IMUs and save the data onto
 *  SD memory card while simultaneously displaying data onto serial monitor
 *
 *  Motion tracking wearable unit
 */



// Libraries necessary to gather/interpret data from IMU BNo055



#include <Wire.h>
#include <Adafruit_Sensor.h>
#include <Adafruit_BNO055.h>

// Libraries necessary to Display on OLED 164x32 I2C, setup
#include <Adafruit_SSD1306.h>
#define OLED_RESET    6 // Reset pin # used on OLED
Adafruit_SSD1306 display(OLED_RESET);

// Libraries necessary to write data onto SD memory card
#include <SPI.h>
#include <SD.h>

File logfile;
```

```
uint8_t i=0;
const int chipSelect = 4;   // Data pin that will be used to write onto SD card


 // Countdown timer Function to display on OLED display. Counting down from int "start"
void CountDown(int start){
 int starter = start;

 for (int i = starter; i > 0; i--){
  display.clearDisplay();
  display.setTextSize(4);
  display.setTextColor(WHITE);
  display.setCursor(55,0);
  display.println(String(i));
  display.display();
  delay(1000);
 }
 display.clearDisplay();
}

  // The two BNo055 modules, bnoB has the ADR pin wired to 3.3v to change its I2C address
  // Both are wired: SCL to analog 5, SDA to analog 4, GRN to ground
  // IMU A is on Main board (5v Vin pin)
 Adafruit_BNO055 bnoA = Adafruit_BNO055(-1, BNO055_ADDRESS_A);
  // IMU B is on smaller separate unit (3.3v ADR pin)
 Adafruit_BNO055 bnoB = Adafruit_BNO055(-1, BNO055_ADDRESS_B);


void setup() {


 Serial.begin(115200);
 delay(3000); // give user time to open serial port before displaying data on it
 Serial.print("Initializing...");
```

```
  // Begin OLED display
display.begin(SSD1306_SWITCHCAPVCC, 0x3C); // // Address 0x3C for 128x32 SCREEN
display.clearDisplay();
display.setTextSize(1);
display.setTextColor(WHITE);
display.setCursor(0,0);
display.println("Initializing...");
display.display();


  // Check components are plugged in (IMUA,IMUB,OLED)
if(!bnoA.begin()) {
   /* There was a problem detecting the BNO055 ... check your connections */
   Serial.print("Ooops, BNO055(A) not detected");
   display.clearDisplay();
   display.setTextSize(1);
   display.setTextColor(WHITE);
   display.setCursor(0,0);
   display.println("Ooops, BNO055(A) not detected");
   display.display();
   // don't do anything more:
   while(1);
}
 bnoA.setExtCrystalUse(true);

if(!bnoB.begin()) {
    Serial.print("Ooops, BNO055(B) not detected");
    display.clearDisplay();
    display.setTextSize(1);
    display.setTextColor(WHITE);
    display.setCursor(0,0);
    display.println("Ooops, BNO055(B) not detected");
    display.display();
    // don't do anything more:
```

```
    while(1);
  }
  bnoB.setExtCrystalUse(true);

 if (!SD.begin(chipSelect)) {
   Serial.println("Card failed, or not present");
    display.clearDisplay();
    display.setTextSize(1);
    display.setTextColor(WHITE);
    display.setCursor(0,0);
    display.println("Card failed, or not     present");
    display.display();
  // don't do anything more:
  while (1);
 }

  // Open file on SD card to start wrting data on it
 File logfile = SD.open("Data_KNEE.txt", FILE_WRITE);

 Serial.println(" SD card initialized ... ");

  // Write header of file
 Serial.println("       Main IMU A, Rotation Quat | Linear Acceleration (m/s^2) ||   Secondary IMU B, Rotation Quat | Linear Acceleration ");
 Serial.println(" A    qW    qX    qY    qZ    |    X     Y     Z    ||  B   qW    qX    qY    qZ    |    X     Y     Z");

 logfile.println("       Main IMU A, Rotation Quat | Linear Acceleration (m/s^2) ||   Secondary IMU B, Rotation Quat | Linear Acceleration ");
 logfile.println(" A    qW    qX    qY    qZ    |    X     Y     Z    ||  B   qW    qX    qY    qZ    |    X     Y     Z");
 logfile.println(" ");
 logfile.flush();

 int start = 5;
 CountDown(start);
```

```
}

 // end condition state variable
int endCondition = 1;

void loop() {

 display.clearDisplay();
 display.setTextSize(1);
 display.setTextColor(WHITE);
 display.setCursor(0,0);
 display.println("Recording Data");
 display.println(" ");
 display.println("   ... in progress");
 display.display();


 // Get Orientation and Accelerations from IMU's

   // Get a new sensor event for true orientation
 sensors_event_t eventA;
 sensors_event_t eventB;
bnoA.getEvent(&eventA);
bnoB.getEvent(&eventB);
   // Retrivieing linear accelerations vectors (m/s^2)
imu::Vector<3> linaccA = bnoA.getVector(Adafruit_BNO055::VECTOR_LINEARACCEL);
imu::Vector<3> linaccB = bnoB.getVector(Adafruit_BNO055::VECTOR_LINEARACCEL);
   // Retrieving Quaternion rotation for more accurate data manipulation
//imu::Quaternion quatA = bnoA.getQuat();
//imu::Quaternion quatB = bnoB.getQuat();


 // Display Orientation data onto serial monitor
```

```
   //IMU A orienatation(Euler Angle) & linear acceleration (m/s^2)
Serial.print("  ");
Serial.print(eventA.orientation.x, 3);
Serial.print("  ");
Serial.print(eventA.orientation.y, 3);
Serial.print("  ");
Serial.print(eventA.orientation.z, 3);
Serial.print("  |  ");
Serial.print(linaccA.x(), 3);
Serial.print("  ");
Serial.print(linaccA.y(), 3);
Serial.print("  ");
Serial.print(linaccA.z(), 3);
   //IMU B orienatation(Euler Angle) & linear acceleration (m/s^2)
Serial.print("  |  ");
Serial.print(eventB.orientation.x, 3);
Serial.print("  ");
Serial.print(eventB.orientation.y, 3);
Serial.print("  ");
Serial.print(eventB.orientation.z, 3);
Serial.print("  |  ");
Serial.print(linaccB.x(), 3);
Serial.print("  ");
Serial.print(linaccB.y(), 3);
Serial.print("  ");
Serial.print(linaccB.z(), 3);


Serial.print("\n");


File logfile = SD.open("Data_KNEE.txt", FILE_WRITE);



  // Write data onto SD card file
//logfile.print(String(quatA.w(),4));
logfile.print("  ");
```

```
 //logfile.print(String(quatA.x(),4));   // Need to convert data to string data type for SD.print()
 logfile.print("  ");
 //logfile.print(String(quatA.y(), 4));
 logfile.print("  ");
// logfile.print(String(quatA.z(), 4));
 logfile.print("  ");
 logfile.print(String(linaccA.x(), 4));
 logfile.print("  ");
 logfile.print(String(linaccA.y(), 4));
 logfile.print("  ");
 logfile.print(String(linaccA.z(), 4));
 logfile.print("  ");

 logfile.flush();                    // Data will only be written onto sd card after flush function

 //logfile.print(String(quatB.w(),4));
 logfile.print("  ");
// logfile.print(String(quatB.x(),4));
 logfile.print("  ");
// logfile.print(String(quatB.y(), 4));
 logfile.print("  ");
// logfile.print(String(quatB.z(), 4));
 logfile.print("  ");
 logfile.print(String(linaccB.x(), 4));
 logfile.print("  ");
 logfile.print(String(linaccB.y(), 4));
 logfile.print("  ");
 logfile.println(String(linaccB.z(), 4));

 logfile.flush();



 // When end condition is met, close SD card stop recording data
 // End condition is met after certain number of of data point are recorded
```

```
 if ( endCondition >= 500){
   //Close & store data
  logfile.close();

   // Display OLED
  display.clearDisplay();
  display.setTextSize(4);
  display.setCursor(25,0);
  display.println("DONE");
  //display.println(" ");
  //display.println("Data Recording Terminated ");
  display.display();
  delay(4000);

   // DONE Serial communication
  Serial.println("Task complete - LLUMCRPL");
  while(1){
   logfile.close();
   delay(1000);


     // Display OLED
//   display.clearDisplay();
//   display.setTextSize(2);
//   display.setCursor(0,0);
//   display.println("Standby..");
//   display.display();
   }
 }

endCondition++;

delay(10);    // Change delay time according to how frequent you need to record data points
```

APPENDIX C

Curriculum Vitae

Michael J. Davidson Ph.D. MSE, MPH, CPO
Loma Linda University Health
mdavidson@llu.edu
michael.j.davidson@ieee.org

|Education|

PHD | 2022 | LOMA LINDA UNIVERSITY
School of Allied Health Professions
Major: Rehabilitation Sciences
Research Topic: Design, prototyping, and testing of a robotic prosthetic leg

MASTER OF SCIENCE IN ENGINEERING | 2018 | UNIVERSITY OF CALIFORNIA RIVERSIDE
Bourns College of Engineering
Major: Bioengineering

MASTER OF PUBLIC HEALTH | 2001 | LOMA LINDA UNIVERSITY
School of Public Health
Major: Health Administration

BACHELOR OF SCIENCE | 1992 | CALIFORNIA STATE UNIVERSITY – DOMINGUEZ HILLS
Major: Orthotics & Prosthetics

|Certifications and Licenses|

American Board for Certification (ABC): Certified prosthetist and orthotist (CPO 01263)
American Heart Association: Basic Life Support (CPR) life safety certification
Federal Communications Commission (FCC) Amateur Radio License – Technician Class, KD6NBM

|Employment and Positions Held|

CLINICAL MANAGER | LOMA LINDA UNIVERSITY MEDICAL CENTER | 2002-CURRENT

ASSISTANT PROFESSOR | LOMA LINDA UNIVERSITY SCHOOL OF MEDICINE | 2001-PRESENT

ASSISTANT PROFESSOR | LOMA LINDA UNIVERSITY SCHOOL OF ALLIED HEALTH | 2009-PRESENT

ORTHOTIST & PROSTHETIST | LOMA LINDA UNIVERSITY MEDICAL CENTER | 1989-2002

O&P STUDENT PRECEPTOR | HEMET ORTHOTICS & PROSTHETICS GROUP | 1991

O&P TECHNICIAN | LOMA LINDA UNIVERSITY MEDICAL CENTER | 1989-1991

O&P TECHNICIAN | REDLANDS PROSTHETICS & ORTHOTICS GROUP | 1988-1990

|Publications, Inventions, and other Scholarly Activities|

Author, **Michael Davidson**, Noha Daher, Thomas Fryer, Johannes Schaepper, Duc Tran, "Design, Prototyping, and Testing of a Robotic Prosthetic Leg Preliminary Results", Proc of the ASME, IMECE 2021. Volume 5: Biomedical and Biotechnology. Published 2022
https://doi.org/10.1115/IMECE2021-68786

Principal Investigator & Contributing Author, Katie Swafford, Heather Orosco, David Ojeda, Chelsie Rodgers, Benjamin Becerra, Gurinder Bains, **Michael Davidson**, "The Effects of Variable Time Domain of Thermoforming Polypropylene", JPO-Journal of Prosthetics & Orthotics, 2022
https://doi.org/10.1097/jpo.0000000000000428

Inventor, **Michael Davidson**. Spencer Cutting, "ANATOMICALLY ALIGNED PROSTHETIC ANKLE"
U.S. Provisional Application No. 62/888,587, Filed: August 19, 2019

Principal Investigator & Contributing Author, Tobin Abraham, Tuan Duong, Alec Friedrich, Brandon Wagner, **Michael Davidson**, Gurinder Bains, Noha Daher; "A Comparative Study of Functional Grasp and Efficiency Between a 3D Printed and Commercial Myoelectric Trans-Radial Prosthesis Using Able-Bodied Subjects: A Pilot Study"; JOURNAL OF PROSTHETICS AND ORTHOTICS; July 2017
https://doi.org/10.1097/jpo.0000000000000130

Author, pre-market notification (510k number - K023572) LLUMC Cranial Remolding Helmet, FDA class II device clearance for a cranial remolding orthosis - 2003.

Author, Lundsford, Thomas, **Davidson, Michael**, and Lundsford, Brenda; "A Comparison of Four Contemporary Cervical Orthoses"; JOURNAL OF PROSTHETICS AND ORTHOTICS; Winter 1994. https://doi.org/10.1097/00008526-199406040-00002

|Peer-Reviewed Scientific and Professional Presentations|

Author, **Michael Davidson**, Noha Daher, Thomas Fryer, Johannes Schaepper, Duc Tran, "Design, Prototyping, and Testing of a Robotic Prosthetic Leg Preliminary Results", accepted to the American Society of Mechanical Engineers (ASME), IMECE November 2021

Principal Investigator & Contributing Author, Katie Swafford, Heather Orosco, David Ojeda, Chelsie Rodgers, Benjamin Becerra, Gurinder Bains, **Michael Davidson**, "The Effects of Variable Time Domain of Thermoforming Polypropylene", poster-presentation, National Assembly – American Orthotic & Prosthetic Association, San Diego CA., Sept 25-28, 2019

|Funded/In Review Grant Activity|

Co-PI, **Michael Davidson**, Lisa Zidek, "The performance of an Articulating Prosthetic Ankle in Gait and Balance Tasks in Individuals with Transtibial Amputation" 2021 – Loma Linda University GRASP-MC
Awarded $75,000

Co-PI, **Michael Davidson**, Lisa Zidek, "A Comparison of Conventional Physical Therapy, Powered Exoskeleton, and Hybrid Physical Therapy with Exoskeleton in the Treatment of Individuals with Sub-acute and Chronic Stroke" – Loma Linda University Medical Center – Internally funded
Awarded $15,000

Student Investigator – The Design and Prototype of an Anatomically Aligned Prosthetic Ankle"
Internally funded by Loma Linda University Medical Center Rehabilitation Services
Awarded $30,000

|Current/Active Research Activity|

Inventor – Chelsie Rodgers, Abraham Castillo, **Michael Davidson** DEVICES AND METHODS TO HARVEST ELECTRICAL ENERGY FROM ELECTROMOTIVE FORCE, Patent Application LLU 20-013 (105781.01227 U.S. Provisional Patent Application Serial No. 63/063, 477, filed August 10, 2020

Inventor, **Michael Davidson**. Spencer Cutting, "Anatomically Aligned Prosthetic Ankle" U.S. Provisional Application No. 62/888,587, Filed: August 19, 2019

Clinical Trial - A Comparison of Conventional Physical Therapy, Powered Exoskeleton, and Hybrid Physical Therapy with Exoskeleton Clinical Trial – Recruiting https://clinicaltrials.gov/ct2/show/NCT04648878

Clinical Trial – Design, Prototyping, and Testing of a Robotic Prosthetic Leg – Recruiting
https://clinicaltrials.gov/ct2/show/NCT04616378

|Additional Information: Research Support and/or Scholastic Performance |

2011-2012: Lead Orthotist-Prosthetist for Loma Linda University Medical Center, Nationwide multicenter research project, "Randomized Trial of the Innovative Neurotronics Walk Aide Compared to Conventional Ankle-Foot Orthosis (AFO) in Stroke Patients." Loma Linda University Medical Center, Outpatient Neurological Department, CA.

2013-2021: I have served as a Principal Investigator in 15 completed human studies through LLU's Office of Sponsored Research and am currently involved in 4 active protocols until 2022.

|Societies and Memberships|

Institute of Electrical and Electronics Engineers – IEEE Engineering in Medicine and Biology Society 04/2012 – present

Engineering in Medicine and Biology Society 04/2012 – present

American Society of Mechanical Engineers – ASME 04/2019 – present

|Awards and Accomplishments|

OUTSTANDING DOCTORAL RESEARCH AWARD - 2022, recognized by Loma Linda University, School of Allied Health Professions Office of Research Affairs. In recognition of commitment to scholarship and professional development through research.

ALUMNUS OF THE YEAR – 2016, recognized by the Monterey Bay Academy Alumni Association in recognition of education to transforming the lives of others and the commitment to “Make Man Whole”.

GRADUATE WHOLENESS PORTFOLIO AWARD – 2015, recognized by Loma Linda University Faculty for innovation, contribution, self-care, and community involvement as a graduate student.

GOOD SAMARITAN IN LEADERSHIP AWARD – 2009, recognized by senior leadership at Loma Linda University Medical Center, nominated and voted by management peers for “walking the talk” in leadership by living the core values of Loma Linda University Medical Center.

APPENDIX D

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Michael J Davidson Ph.D., MSE, MPH, CPO

eRA COMMONS USERNAME (credential, e.g., agency login):

POSITION TITLE: Assistant Professor – School of Medicine; Assistant Professor – School of Allied Health; Clinical Manager – Therapy Services

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows, as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
California State University, Dominguez Hills	Bachelor of Science	12/1992	Orthotics & Prosthetics
Loma Linda University School of Public Health	Master of Public Health	6/2001	Health Administration
University of California, Riverside	Master of Science in Engineering	9/2018	Bioengineering
Loma Linda University School of Allied Health	PhD	6/2022	Rehabilitation Sciences

A. Personal Statement

I have dedicated my career to learning and teaching others how to incorporate technological advances (i.e., Bionics) into clinical practice to rehabilitate those with physical disabilities. These innovations include orthotic devices for neuromuscular conditions such as brain injury and cerebral vascular disease (stroke) and robotic prosthetic devices for those who live with amputation. Physical rehabilitation is a crucial element of regaining wholeness, and technology uniquely advances that wholeness for those living with a disability. Blending spirituality and science is a unique offering that we have at Loma Linda University Health and offer to our brain injury program.

B. Positions and Honors

- Clinical Manager | Loma Linda University Medical Center | 2002-Current
- Assistant Professor | Loma Linda University School of Medicine | 2001 – Present
- Assistant Professor | Loma Linda University School of Allied Health | 2009 – Present
- Orthotist & Prosthetist | Loma Linda University Medical Center | 1989 – 2002
- American Board for Certification (ABC): Certified Prosthetist and Orthotist (CPO 01263)
- American Heart Association: Basic Life Support (CPR) Life Safety Certification (2018 – 2023)
- Outstanding Doctoral Research Award – 2022, recognized by Loma Linda University, School of Allied Health Professions Office of Research Affairs. In recognition of commitment to scholarship and professional development through research.
- Alumnus of the Year – 2016; Recognized by the Monterey Bay Academy Alumni Association in Recognition of Education to Transforming the Lives of Others and the Commitment to "Make Man Whole."
- Graduate Wholeness Portfolio Award – 2015, recognized by Loma Linda University Faculty for innovation, contribution, self-care, and community involvement as a graduate student.
- Good Samaritan in Leadership Award – 2009, recognized by senior leadership at Loma Linda University Medical Center, nominated and voted by management peers for "walking the talk" in leadership by living the core values of Loma Linda University Medical Center.

C. Contributions to Science

Peer-Reviewed Publications:
Principal Investigator & Contributing Author, David Ojeda Sersun, Katie Swafford, Heather Orosco, Chelsie Rodgers, **Michael Davidson,** Gurinder Bains, Ben Becerra, The Effects of Cooling Time on the Dimensional Stability of Thermoforming Polypropylene, Journal of Prosthetics and Orthotics: March 10, 2022 - Volume - Issue - doi:10.1097/JPO.0000000000000428

Author, **Michael Davidson,** Noha Daher, Thomas Fryer, Johannes Schaepper, Duc Tran. "Design, Prototyping, and Testing of a Robotic Prosthetic Leg Preliminary Results." *Proceedings of the ASME 2021 International Mechanical Engineering Congress and Exposition*. *Volume 5: Biomedical and Biotechnology*. 2022. V005T05A062. ASME. doi.org/10.1115/IMECE2021-68786

Principal Investigator & Contributing Author, Tobin Abraham, Tuan Duong, Alec Friedrich, Brandon Wagner, **Michael Davidson**, Gurinder Bains, Noha Daher; "A Comparative Study of Functional Grasp and Efficiency Between a 3D Printed and Commercial Myoelectric Trans-Radial Prosthesis Using Able-Bodied Subjects: A

Pilot Study"; Journal of Prosthetics and Orthotics; July 2017 DOI:10.1097/JPO.0000000000000130

Author, Thomas Lundsford, **Michael Davidson,** and Brenda Lundsford; "The Effectiveness of Four Contemporary Cervical Orthoses in Restricting Cervical Motion"; Journal of Prosthetics and Orthotics; Winter 1994. DOI:10.1097/00008526-199406040-00002

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Principal Investigator & Contributing Author, Katie Swafford, Heather Orosco, David Ojeda, Chelsie Rodgers, Benjamin Becerra, Gurinder Bains, **Michael Davidson**, "The Effects of Variable Time Domain of Thermoforming Polypropylene," poster-presentation, National Assembly – American Orthotic & Prosthetic Association, San Diego, CA.,
Sept 25-28, 2019

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Awarded $75,000

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internally funded by Loma Linda University Medical Center Rehabilitation Services
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Inventor - Chelsie Rodgers, Abraham Castillo, **Michael Davidson** DEVICES AND METHODS TO HARVEST ELECTRICAL ENERGY FROM ELECTROMOTIVE FORCE; Patent Application LLU 20-013 (105781.0122.7U.S. Provisional Patent Application Serial No. 63/063,477, filed August 10, 2020

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https://clinicaltrials.gov/ct2/show/NCT04648878

Clinical Trial – Design, Prototyping, and Testing of a Robotic Prosthetic Leg - Recruiting
https://clinicaltrials.gov/ct2/show/NCT04616378

Membership in Scientific/Professional Organizations:
Institute of Electrical and Electronics Engineers (IEEE) Robotics and Automation Society 04/2012 - present

Institute of Electrical and Electronics Engineers (IEEE) Engineering in Medicine and Biology Society 04/2012 - present

American Society of Mechanical Engineers (ASME) 04/2019 - present

D. Additional Information: Research Support and/or Scholastic Performance

2011-2012: Lead Orthotist-Prosthetist for Loma Linda University Medical Center, Nationwide multicenter research project, "Randomized Trial of the Innovative Neurotronics Walk Aide Compared to Conventional Ankle-Foot Orthosis (AFO) in Stroke Patients." Loma Linda University Medical Center, Outpatient Neurological Department, CA.

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