4 Overview of the Components Used in Active and Passive Lower-Limb Prosthetic Devices

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Abbreviations

CESR	Controlled energy storage and return
DC	Direct current
IC	Ischial containment
ICEROSS	Icelandic roll-on silicone socket
KBM	Kondylen Bein Muenster
PTB	Patellar-tendon-bearing
PTS	Patellar-tendon-supracondylar
SACH	Solid ankle cushion heel
TSB	Total surface bearing

Introduction

Over recent decades, many advances have been made to restore function lost due to lower-limb amputation, leveraging novel mechanical design, dynamic energy exchange (passive and active), and intelligent control to approximate insofar as possible the function of the human leg. The purpose of this chapter is to review the components currently used in active and passive lower-limb prosthetic devices. This overview spans socket systems for above- and below-knee amputees and the components available to restore function at the foot, ankle, and knee. Considerations include conventional componentry, design solutions, and emerging technologies currently being advanced to expand the performance capability of lower-limb prosthetic devices and improve overall quality of life for those with lower-limb amputations.

The Socket Interface

The fundamental component of lower-limb prosthetic devices is the socket. Serving as the interface between the amputee as user and the prosthesis as device, the socket is responsible for both load transmission to the amputee during weight-bearing support and suspension of the prosthesis when ground forces are absent (e.g., during the swing phase of gait). The specific configuration for the socket depends upon a number of factors including the level of amputation, the anatomy of the residual limb, and the activity level of the amputee. Here we will begin with an overview of socket technology currently used in clinical practice. Due to differences in functional

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requirements dependent upon amputation level, socket technologies for below-knee and above-knee prosthetic devices will be addressed separately. This will be followed by a presentation of some of the advanced research and commercial technologies currently under investigation to improve the fit of the prosthetic device and the comfort and health of the amputee's residual limb.

Below-Knee Socket Systems

Sockets for transtibial amputees can be categorized based on the mechanisms for weight bearing and suspension. Generally there are two approaches for load transmission during weight-bearing support. The first is to concentrate loading at specific weight-bearing surfaces on the residual limb. In this case, the most common example is the patellar-tendon-bearing (PTB) socket [1]. As the name implies, the PTB socket transmits weight-bearing loads to the patellar tendon of the amputee using a bar or protrusion in the socket wall at the middle of the tendon. It should be noted that other anatomical features contribute to the load bearing of the PTB socket. In particular, the tibial condyles and surrounding tissue serve as important weight-bearing structures and, in conjunction with the posterior surface of the socket, help to stabilize the residual limb against the posteriorly directed loads of the patellar tendon bar. The medial and lateral regions of the socket serve to contain the soft tissue of the residual limb and help to prevent the prosthesis from rotating about the residual limb.

The second approach for load transmission is uniform loading over the entire surface area of the residuum. For example, total surface bearing (TSB) socket designs distribute weight-bearing loads uniformly over the residual limb [2, 3]. TSB sockets are custom shaped to contain the residual limb in its nominal volume, leveraging hydrostatic principles to transfer loads uniformly to the surface of the residual limb. Note that TSB sockets typically incorporate a flexible liner between the rigid outer socket and residual limb to stabilize the volume of the residual limb under loading and thereby facilitate uniform distribution of the transmitted loads. The load-bearing functions of both TSB and PTB sockets are typically realized using thermoplastics or carbon composites (infused or pre-impregnated) molded into a rigid structure that fully encloses the relevant residual-limb anatomy.

There are several approaches to suspend the transtibial prosthesis on the residual limb. Mechanical means for suspending the prosthesis include a waist-belt suspension, a thigh-corset suspension, and a knee cuff strapped around the distal thigh, all of which entail additional componentry attached to the proximal end of the socket that is then anchored to anatomical features proximal to the residual limb. Alternative approaches integrate limb suspension directly within the socket. The patellar-tendon-supracondylar (PTS) method extends the medial, lateral, and anterior walls of the socket to completely enclose the patellar tendon and femoral condyles [4]. The PTS method enables additional suspension of the socket at the quadriceps tendon, but with the potential for increased discomfort when kneeling (due to complete enclosure of the patella). Similar to the PTS suspension, the Kondylen Bein Muenster (KBM) suspension technique fully encloses the knee joint through extension of the medial and lateral walls of the socket [5]. However, the anterior wall of the socket is left low, which keeps the patella exposed. The KBM suspension improves ease of kneeling at the expense of somewhat degraded suspension due to the absence of suspension at the quadriceps tendon.

Elastic sleeves that fit over the amputee's thigh and encapsulate the proximal outer socket wall provide additional suspension options. The elastic sleeve achieves suspension through a combination of negative pressure created in the sealed volume during swing and the tensile elasticity of the sleeve under axial loads. Such sleeves can be used as the sole means of suspension or as an auxiliary suspension when combined with one of the supracondylar suspensions. Drawbacks to elastic sleeve suspension include the possibility of sleeve rupture and perspiration-induced hygiene and skin-irritation issues.

The flexible sleeves commonly used in the TSB socket also support suspension of the prosthetic limb. The concept was first realized in the form of the Icelandic roll-on silicone socket (ICEROSS) [2, 3]. During the donning process, a silicone sleeve is turned inside out and then rolled over the residual limb from the distal end. The sleeve is then secured to a rigid outer socket using a shuttle-lock pin (Fig. 4.1) or hypobaric sealing membrane (consisting of a single ring or series of concentric rings that provide a seal between the silicone and rigid sockets). The stretched liner radially constricts the residual limb and displaces the residual-limb tissue in the distal direction. The resulting interface provides enhanced bidirectional resistance to axial displacement of the residual limb. The silicone acts as a suction socket when suspending the prosthesis and serves to minimize pistoning of the residual limb within the socket when cycling between weight-bearing support and prosthetic-limb suspension. Note that although their use originated in the process of developing TSB sockets, flexible sleeve socket suspensions can also be used in combination with PTB designs. These liners are available in a range of sizes and materials (including silicone, polyurethane, thermoplastic elastomers, and elastomer gels).

Fig. 4.1 The Alpha Hybrid transtibial socket liner (Image courtesy of WillowWood)

A number of clinical studies have assessed the functional outcomes of different transtibial socket designs. With PTB sockets, weight-bearing loads are concentrated at specific locations on the residual limb. Thus, without sufficient pre-stretching of soft tissue at the weight-bearing surfaces when donning the prosthesis, PTB sockets may allow significant tibial movement [6]. While TSB sockets address such issues to some extent, difficulties with donning the socket and the increased potential for hygiene-related issues (due to the requisite liner) are among the potential drawbacks [7, 8]. Comparative studies of PTB and TSB sockets have produced mixed results. A comparison of TSB sockets with ICEROSS suspension systems, and PTB sockets with knee cuff suspensions, found that the TSB socket provided improved suspension and tibial stability [9]. Another comparative study showed the TSB socket enhanced suspension and improved amputee balance [10]. More recently, a comparison of silicone-lined TSB and PTB sockets revealed no significant differences for user satisfaction, performance in gait, and other mobility-related functions [11]. As is evident from clinical evaluations, no single solution is appropriate for all below-knee amputees. Reaching a satisfactory solution requires careful consideration of weight bearing and prosthesis suspension in the context of the state of the individual's unique residual-limb presentation.

Above-Knee Socket Systems

Analogous to below-knee sockets, design considerations for above-knee socket systems revolve around weight bearing and prosthesis suspension. With regard to weight-bearing load transmission, the two common approaches used in above-knee sockets are the quadrilateral and ischial containment socket designs. The origins of the quadrilateral socket date back to the 1950s [12]; the design derives its name from the anterior/posterior and medial/lateral walls evident in a transverse cross-section of the socket. In general, these sockets have narrow anterior-posterior dimensions and wide medial-lateral dimensions. The quadrilateral socket imposes weight-bearing loads on the ischial tuberosity and gluteal musculature that rest on top of the posterior wall of the socket. The anterior wall of the socket provides counter-support to stabilize the ischium and gluteal muscle tissue on the proximal wall. The lateral wall provides adduction and lateral support of the femur during stance, with the medial wall containing the remainder of the residual limb but with little to no weight-bearing function.

The primary alternative approach to the quadrilateral socket is ischial containment [13]. Ischial containment (IC) sockets enclose, to varying extents, the ischial tuberosity and ischial ramus (medially and posteriorly); IC sockets were developed in part to address the tendency for abduction of the prosthetic-side limb during stance when using quadrilateral socket designs [14]. In contrast to quadrilateral sockets, where medial loads are borne by adductor musculature and surrounding soft tissue, IC sockets additionally recruit the skeletal structure of the ischial ramus to augment the load-bearing function provided by the more distal soft tissue. The resulting oblique slope of the medial brim of the IC socket biases the ischial ramus toward lateral and downward displacements within the socket, necessitating a tighter fit on the lateral side of the socket for adequate ramus stabilization. Somewhat analogous to the TSB below-knee sockets, the IC socket seeks to distribute loads uniformly along the length of the femur. However, the degree to which this objective is realized remains largely uncharacterized. As is the case with quadrilateral sockets, vertical loads in IC sockets are borne primarily by the ischial tuberosity augmented by gluteal musculature. Thus, the primary differences between quadrilateral and IC sockets stem from the IC socket's recruitment of the ischial ramus for load bearing in the medial direction (and the changes in socket shape at other locations to accommodate the ischial containment). These sockets are typically fabricated with resin-hardened carbon fiber; they either fully contain the residual limb or, when used in combination with a flexible inner socket, are designed as open-section frames. The benefits of the composite frame and flexible inner socket shown in Fig. 4.2 include the reduced constraints on hip motion (due to the inherent flexibility of the inner socket brim) and accommodation of muscle expansion

Fig. 4.2 ComfortFlex™ Socket System (Image courtesy of Hanger Inc.)

and contraction during ambulation (due to select removal of regions of the outer socket wall).

Suspension options for above-knee socket designs include direct suction on the tissue of the residual limb (silicone suspension socket as previously discussed) or mechanical suspension via auxiliary components strapped to anatomy proximal to the amputated limb. Socket designs that incorporate direct suction on the residual limb achieve limb suspension through a combination of negative pressure, surface tension, and contractile activity of the residual-limb musculature. Such designs typically incorporate a one-way expulsion valve in the distal socket wall to facilitate donning and maintain a seal with the residual limb. Direct suction eliminates mechanical losses between the residual limb and prosthesis, enhancing proprioception through the socket interface. Suction sockets are best suited to users with moderate to long residual limbs that are free of significant volume fluctuations, excess scarring, and redundant tissue.

Silicone suspension sockets extend the benefits of suction sockets to amputees with residual limbs otherwise unsuitable for suspension that requires direct suction. Silicone sockets contain an inner socket that attaches to a rigid outer socket using a pin and shuttle lock or hypobaric seal. Like their transtibial counterparts, silicone liners for transfemoral amputees are available in standard sizes or can be custom molded. Relative to direct suction alternatives, silicone suspension sockets are more tolerant of fluctuations in residual-limb volume; they allow the use of socks and gel pads to compensate for moderate amounts of residual-limb volume loss.

Options for mechanical suspension of the limb include a Silesian belt, a hip joint and pelvic belt, and a total elastic suspension. These designs generally incorporate some form of waste belt that provides for suspension of the socket at anatomical features proximal to the residual limb. Belt systems can be used as the primary suspension mechanism or as an auxiliary suspension option when combined with the suction or silicone suspension systems (during high activity levels or when fitting short residual limbs). Mechanical suspensions can provide enhanced rotational and mediolateral stability and control but require increased componentry that may introduce additional bulk and discomfort.

Socket Augmentation Componentry and Advanced Socket Solutions

A number of commercial systems are available for enhancing suction on the residual limb via vacuum-assisted suction suspension systems, and these systems are available in both passive and microprocessor-controlled varieties. The Harmony® Vacuum Management System (Ottobock Healthcare), shown in Fig. 4.3a, offers mechanical and microprocessor-controlled variations. The mechanical system uses a mechanical pump actuated with each step to provide additional negative pressure to enhance limb suspension. The electronic option expands this functionality, offering four preset vacuum levels with integrated sensing for active regulation of the vacuum pressure. The LimbLogic system (Ohio Willow Wood) shown in Fig. 4.3b provides similar active vacuum regulation with a user-selectable desired vacuum level. In a study involving transtibial amputees, the presence of regulated vacuum pressure during walking resulted in an increase in residual-limb volume, versus volume loss in the absence of the vacuum [15]. A subsequent investigation found that vacuum-assisted sockets reduce positive pressure on the residual limb during stance and increase negative pressure during swing [16]. Shifting of the residual-limb pressure in the negative direction is thought to reduce fluid loss during stance and increase fluid gain during swing, resulting in an overall reduction in volume loss or even volume gain in the residual

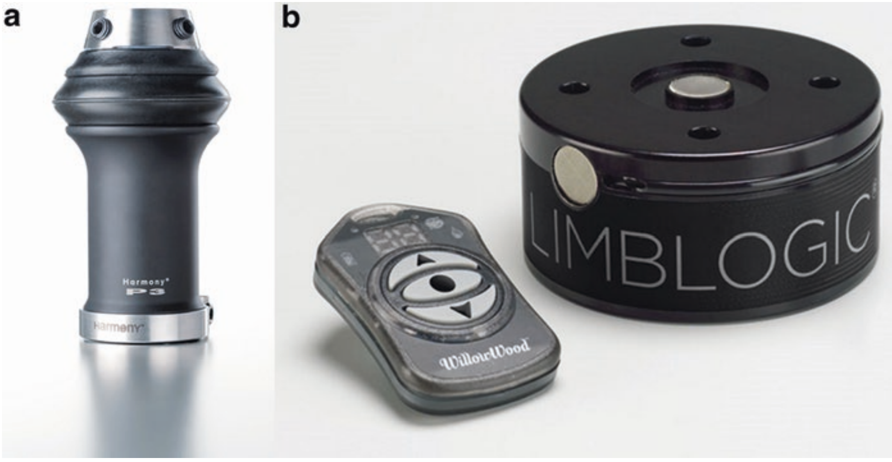

Fig. 4.3 Vacuum-assisted suspension system: (**a**) the Harmony® P3 pump (Image courtesy of Ottobock Healthcare) and (**b**) the LimbLogic system (Image courtesy of WillowWood)

Fig. 4.4 The Active Contact System™ volume accommodation socket (Image courtesy of Simbex LLC)

limb. A more recent study based on bioimpedance measurements on the residual limb found similar benefits of vacuum-assisted systems but noted that a number of other factors (e.g., subject health, size and shape of the residual limb, time of day for data collection) also contribute to the observed volume fluctuations [17].

Fluctuations in the volume and shape of the residual limb can significantly affect the fit and comfort of the socket. Common approaches to the accommodation of volume fluctuation include the insertion of socks of uniform thickness and pads within the socket. These strategies offer discrete levels of accommodation best suited for longer time-scale volume fluctuations. Less common alternative options include the use of pneumatic (air-filled) or hydraulic (fluid-filled) inserts within the inner socket to vary the shape and volume of the inner socket in response to fluctuations in residual-limb volume. Pneumatic systems available in the commercial market include the Air Contact System (Ottobock Healthcare, Duderstadt, Germany), the Pneu-Fit™ (Little Rock Prosthetics, Inc., Little Rock, AR), and the Pump It Up!™ socket (Amputee Treatment Center, Batavia, NY). While providing a means to alter volume within the socket, the inherent compliance of the inserts coupled with the relatively high pressures needed to support the residual limb result in large bladder thicknesses, which in turn cause localized high pressures that may cause discomfort or even damage to the underlying tissue [18].

In lieu of using a compressible fluid, the Active Contact System™ (Simbex LLC, Lebanon, NH) uses fluid inserts to accommodate volume fluctuations of the residual limb (Fig. 4.4) [19]. This system leverages the natural pumping action between the residual limb and a suction socket to draw fluid from a reservoir into the bladder system (during the suction loads of swing) and distribute it among the bladders (during the compressive loads of stance). Fluid control is accomplished with a purely mechanical fluid-control circuit comprising check valves, pressure regulators, and a flow resistor. The hydraulic system offers the ability to modulate pressures and shear stresses within the socket interface, but the clinical significance of such capability to prosthetic outcomes remains unclear [20]. Current research efforts include the development of an actively controlled bladder system that adjusts bladder pressures in real time with the objective of minimizing high-pressure loading of the residual limb and improving the overall fit and comfort of the socket [21].

In contrast to efforts focused on adaptively containing the soft tissue of the residual limb, osseointegration offers the potential to anchor the prosthetic limb directly to the skeletal system, thereby avoiding many of the difficulties associated with the fit and comfort of standard socket systems [22]. Osseointegration involves a two-part surgical procedure in which (1) a titanium fixture is implanted in the distal end of the residual bone and (2) a transcutaneous abutment protruding from the distal end of the residual limb is affixed to the implanted fixture. The prosthetic limb is then attached directly to the titanium abutment as shown for the transfemoral prosthesis in Fig. 4.5, eliminating altogether the need for traditional socket containment of the residual limb. Benefits include reduced risk of skin irritation or breakdown, improved range of motion, improved sitting comfort, stable suspension of the prosthesis, improved proprioception, and fewer alignment issues. Despite these benefits, limb attachment based on the principles of osseointegration does raise some issues. The surgical procedure requires a lengthy recovery and rehabilitation period as the implant stabilizes prior to realizing its full weight-bearing function. Furthermore, patients face the risk of infection at both the skin-implant interface and the implant-bone interface. Such infections are primarily staph infections of the superficial and deep tissue surrounding the implant [23]. Osseointegrated implants may also suffer mechanical failure between the residual limb and prostheses (necessitating abutment replacement) or loosening within the residual bone (necessitating implant removal and replacement). Nonetheless, provided an appropriate rehabilitation protocol is followed in preparation for unrestricted limb use [22], the principles of osseointegration offer a potentially viable alternative to conventional socket systems.

Fig. 4.5 Osseointegrated transfemoral prosthesis (Image courtesy of Sahlgrenska I.C.)

Despite the current state of the art in lower-limb socket technology and ongoing advances, solutions are still needed to manage temperature and moisture within the socket interface, accommodation of daily and longer-term volume fluctuations of the residual limb, and enhancement of load transmission between the amputee and prosthetic limb. Increased functionality provided by emerging technology introduces increased component weight that, in turn, must be adequately supported through the socket suspension. Additionally, the increased functionality of the prosthesis will likely result in increased levels of moderate and high activity and increased load transmission at the socket interface. Continued socket advancement will be needed to sustain greater loads while maintaining the comfort and health of the residual limb.

Passive Components in Foot-Ankle Systems

Components distal to the socket provide varying degrees of capacity to restore function. While recent developments have resulted in the emergence of externally powered anthropomorphic lower-limb systems with greatly expanded capability, the component landscape in lower-limb prostheses remains largely dominated by passive systems optimized for specific functionalities. Beginning with foot-ankle components relevant to above-knee and below-knee prosthetic limbs, this discussion focuses first on mechanical and microprocessor-controlled passive systems. Following a similar examination of passive knee systems, we consider a number of advanced bionic designs that demonstrate further narrowing of the performance gap between lower-extremity prosthetic limbs and their physiologic counterparts.

The SACH Foot and Single-Axis Foot

The most basic prosthetic foot available is the solid ankle cushion heel (SACH) foot with a solid keel (composed of wood or aluminum) and a cushioned heel wedge, all contained within a molded external cosmesis. The SACH foot is a non-articulating design that provides no significant movement about the ankle either in plantarflexion/dorsiflexion or inversion/eversion. In the absence of ankle plantarflexion at heel strike, the SACH foot instead uses the cushioned heel wedge to dissipate energy in early stance. Forefoot dorsiflexion is approximated with flexible toes positioned distal to the rigid keel. The flexible toes are molded into the cosmesis, providing compliance in the forefoot when transitioning from stance to swing. The SACH foot has no moving parts and provides good shock absorption for up to moderate activity levels. Heel wedges are available in different heights and densities, allowing limited ability to customize the foot to a user's specific needs. Drawbacks to the design include the potential for deterioration of the heel wedge over time and subsequent degradation in performance. Additionally, the rigid keel provides no shock absorption functionality that would otherwise be beneficial during high activity levels.

Fig. 4.6 Basic single-axis foot (Image courtesy of WillowWood)

The single-axis foot shown in Fig. 4.6 expands upon SACH foot functionality with allowance for limited plantarflexion and dorsiflexion of the ankle about its neutral position. Single-axis designs typically incorporate anterior and posterior rubber bumpers of varying durometers to control the ankle's resistance to plantarflexor and dorsiflexor loads. The forefoot compliance of the SACH foot cosmesis is preserved in single-axis feet, but shock absorption at heel contact is realized via ankle plantarflexion into the posterior bumper in lieu of heel cushioning. Single-axis feet enable users to reach foot flat quicker than SACH feet, providing enhanced stability in stance. Though of limited utility for transtibial amputees [24], the stabilizing functions of the single-axis foot make it well suited to low-mobility transfemoral amputees who may benefit from enhanced weight-bearing stability [25].

Energy Return Foot-Ankle Systems

In contrast to the basic SACH and single-axis feet, foot-ankle systems with energy return are designed to absorb and return energy to the user during various segments of the stance phase of locomotion for improved gait efficiency. The VA Seattle Foot, which combines a cushioned heel with a monolithic cantilevered keel composed of an acetal homopolymer (Delrin®), was one of the early pioneering examples of energy-storage foot design and development [26]. Its cantilevered keel progressively stores energy as the foot is loaded through mid-stance and then releases that stored energy as the foot is unloaded in the transition to toe-off. More contemporary designs expand upon the VA Seattle Foot's cantilevered spring configuration by integrating carbon fiber composites to enable tuned compliance in both the keel and heel. Deformation at the heel provides energy absorption at heel strike, which is then released in the transition to mid-stance, augmenting the energy-storage functions of the keel from mid-stance to toe-off.

Additional variations in energy-return foot-ankle systems include designs that offer inversion/eversion compliance and/or vertical compliance. Split-toe keel designs, such as the Esprit foot from Endolite USA, provide multi-axis flexibility with the addition of inversion and eversion compliance to the foot-ankle complex. Multi-axis flexibility offers improved adaptability to uneven and time-varying terrains. Vertical compliance is realized using either compliance of the composite structure or axial spring systems integrated at the proximal termination of the ankle. A feature of the axial spring system is its ability to achieve vertical compression and axial rotation, which modulates the vertical forces and axial moments transmitted to the residual limb. Specialized energy-return foot-ankle systems such as Freedom Innovations' Catapult (Fig. 4.7) designed for medium and high impact recreational and sporting activities are also available on the commercial market. Compliance in such designs is optimized to maximize energy storage and return for jogging, running, and/or sprinting gaits.

Fig. 4.7 The Catapult ™ running foot (Image courtesy of Freedom Innovations, LLC)

The main benefits on walking gait can largely be attributed to flexibility in the keel [27]. Compliance in the foot results in increased step length of the sound-side limb, decreased impact force at sound-side heel strike, and reduced gait asymmetry (for unilateral transtibial amputees). Additional reported benefits of energy-return feet include increased self-selected walking speed, cadence, and prosthetic-side propulsive force. While these improvements often lack strong statistical significance, the trends combined with users' subjective perceptions suggest that energy-return foot-ankle systems do offer benefits of clinical significance for certain users and activities.

Hydraulic Foot-Ankle Systems

Hydraulic foot-ankle systems expand upon composite energy-return designs with the addition of hydraulic componentry to enable tuning of ankle resistance in plantarflexion and dorsiflexion. Higher resistance promotes increased loading and energy return from the heel and keel, whereas lower resistance enables increased ankle movement and improved terrain adaptation. Plantarflexion resistance controls damping and the amount of ankle plantarflexion at heel strike, with dorsiflexion resistance controlling the speed at which the user advances over the foot in transition to swing. Designs such as Endolite's echelon foot and Freedom Innovations' Kinterra™ foot (Fig. 4.8) combine a hydraulic ankle with carbon composite foot springs and allow independent control of plantarflexion and dorsiflexion resistance at the ankle. The hydraulic ankle smoothly adapts to varying terrains and provides more comfortable ankle positions when sitting. The Kinterra™ also incorporates a mechanical spring to provide dorsiflexion assistance during swing for improved toe clearance. Relative to standard energy-return designs, the echelon foot has been shown to provide decreased peak internal stresses and rates of loading on the residual limb as well as improved protection of the distal residual-limb tissue [28]. Additionally, a study of transtibial and transfemoral amputees found the echelon foot provided enhanced user satisfaction and self-reported improvement in gait, indicative of the user-perceived benefits of hydraulic ankles [29].

Fig. 4.8 The Kinterra™ hydraulic foot/ankle (Image courtesy of Freedom Innovations, LLC)

Microprocessor Foot-Ankle Systems

Microprocessor control offers further capability in expanding the performance of passive foot-ankle systems; this has been successfully leveraged in research and commercial foot-ankle systems. Intelligent control of features such as ankle position, plantarflexion/dorsiflexion resistance, and energy storage/release enables the microprocessor-controlled ankle to be optimized to the individual's specific gait and allows it to adapt in real time to variations in gait and terrain. The Össur PROPRIO FOOT® (Fig. 4.9a) is the earliest commercial microprocessor foot-ankle system; it combines a carbon composite foot with a stepper-motor actuated ankle joint. The system does not provide power assist but is instead used to adapt ankle angle to the underlying terrain and to increase swing-phase dorsiflexion for improved ground clearance. The PROPRIO FOOT® incorporates instrumentation for real-time sensing of acceleration and ankle angle and determines appropriate ankle settings depending upon the sensed terrain or activity level. Clinical evaluations of the PROPRIO FOOT® with unilateral transtibial amputees for stair and incline walking yielded socket interface pressures that were closer to those of level walking [30]. Furthermore, increased dorsiflexion during ramp ascent resulted in more physiologic kinetics and kinematics in the prosthetic-side and contralateral limb [31]. While similar results were not realized during ramp descent, users subjectively reported the perception of improved safety in the slopeadapted configuration (i.e., increased plantarflexion relative to neutral).

More recent commercial systems such as the Endolite élan foot, the Hosmer Raize™ Ankle/Foot System, and the Ottobock Triton smart ankle combine carbon composite feet with microprocessor-controlled hydraulic ankles. The élan foot expands upon the hydraulic design of the echelon foot by including microprocessor control of hydraulic resistance for enhanced response to changes in gait speed and terrain. During incline ascent, the élan foot exhibits large plantarflexion resistance for improved energy return at the heel while reducing dorsiflexion resistance to foster rollover progression. In descent, the microprocessor-controlled ankle resistance decreases in plantarflexion (for improved stability) and increases in dorsiflexion (for improved late-stance weight support). The Raize™ (Fig. 4.9b) provides user-adjustable plantar/dorsiflexion range of motion, heel height, and ankle resistance. It offers terrain accommodation modes for improved stability on slopes and a remote ankle lock for activities such as driving or donning shoes and socks. The Triton smart ankle also uses a microprocessor-controlled hydraulic ankle to enable gait and terrain adaptation. The Triton incorporates proximally located sensing technology to measure forces and moments transmitted to the residual limb at the socket interface. The ankle is dynamically controlled, in part to improve the socket reaction loads during gait. An additional feature of the Triton is mobile app-based connectivity, which facilitates clinician interaction for assessing device performance and user interaction for custom configuration of the device.

As an alternative to energy storage and return via a carbon composite foot, the controlled energy storage and return (CESR) foot (Intelligent Prosthetic Systems, LLC) uses microprocessor-controlled release of energy stored in mechanical springs [32]. The CESR foot incorporates two low-power motors; one actuates a one-way clutch to release the mechanical spring, while the other is used to reset the device following toe-off. Energy captured in the mechanical spring at heel contact is stored until sufficient load is detected in the forefoot, at which point the spring is released to return energy as the forefoot is unloaded prior to toe-off. Clinical evaluations of the CESR foot in transtibial amputees showed increased energy storage in early stance, increased prosthetic-side peak push-off power and work, and decreased sound-side collision work relative to a conventional energy-storage foot and the user's prescribed daily-use foot [33]. However, despite the energetic benefits, the study

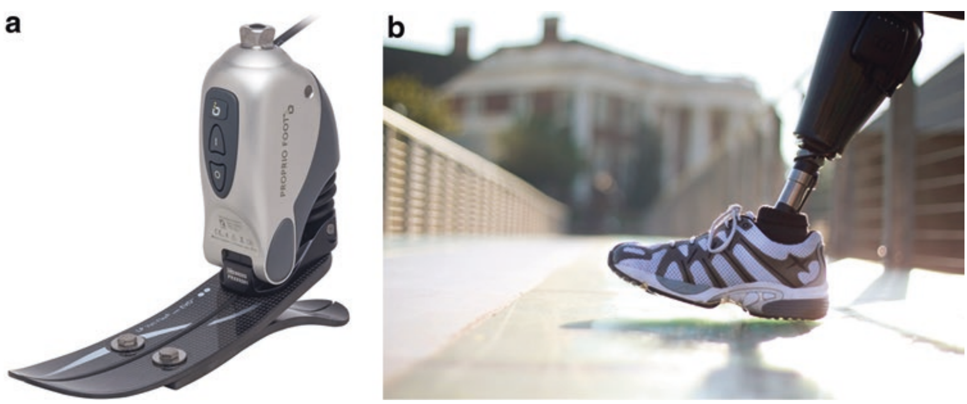

Fig. 4.9 Microprocessor foot-ankle systems: (**a**) the motor-actuated PROPRIO FOOT® (Image courtesy of Össur, Inc.) and (**b**) the hydraulic-based Raize™ Ankle/Foot System (Image courtesy of Hosmer Dorrance Corp.)

found no net change in metabolic cost when compared with the conventional foot and increased metabolic cost when compared with the prescribed foot. While a number of factors other than the CESR likely contribute to the measured metabolic expenditures, the rate of energy release from the CESR foot and the need for increased muscle activity to handle its increased energy release may have adversely affected the metabolic cost of its use.

Passive Components in Knee Systems

The functional requirements of prosthetic knees alter the approaches taken in their design as compared with passive foot-ankle systems. Rather than focus on energy storage and release, the primary design objectives of passive prosthetic knees are stance-phase stability and swing-phase control. As with foot-ankle systems, passive prosthetic knees range from simple mechanical designs to complex microprocessor-controlled variants. Passive prosthetic knees can be divided into three classes: mechanical single axis, polycentric, and microprocessor, each of which is considered here in the context of mechanisms for stance-phase stability and swing-phase control.

Single-Axis Knee Systems

Single-axis knees represent the most basic prosthetic knee design and consist of a single revolute joint at the knee center. Stability is maintained during stance with a combination of prosthetic alignment and user voluntary muscle contractions. By aligning the prosthesis such that the user's center of mass in stance lies anterior to the knee center, knee stability is passively achieved with little voluntary control. This passive or involuntary stability is augmented with voluntary muscle contractions (e.g., hip extensors) that provide additional extensor moments about the knee. The basic single-axis knee provides free or unrestrained motion in swing, limited by the friction in the knee joint. The benefits of single-axis knees include their ease of maintenance and functional simplicity, attained at the cost of reduced mechanical stability in stance. Variations of the nominal design for improved stability include a manual lock to enable a locked-knee configuration, a weight-activated friction brake that is engaged during weight-bearing support (Fig. 4.10), and hydraulic stance assistance. For swing-phase assistance, additional components are available such as hydraulic damping for resistance control in swing, mechanical spring-based swing assist (Fig. 4.10), and pneumatic swing assist.

Fig. 4.10 The 3R90 single-axis knee with weight-activated friction brake and mechanical spring swing assistance (Image courtesy of Ottobock Healthcare)

Polycentric Knee Systems

Polycentric knee designs incorporate a multi-bar linkage rather than a single revolute joint. This design aspect offers features beneficial to both stance-phase and swing-phase performance. The inclusion of a multi-bar linkage results in a changing instant center of rotation as the knee moves through its range of motion. The variation in instant center of rotation enables variable knee stability throughout the gait cycle; small changes in linkage geometry significantly affect the evolution of the instantaneous center as the knee flexes [34]. To provide enhanced weight-bearing stability during stance, the instantaneous center of rotation is located anterior to the vertical component of the ground reaction force. As the knee flexes, the changing instantaneous center of rotation can then be used to foster knee flexion at the transition to swing or, in the case of users who need enhanced stability, to maintain a locked-knee configuration throughout stance. An additional benefit is enhanced ground clearance during swing [35]. As the knee flexes, the change in instantaneous center of rotation effectively shortens the limb during swing, as measured by the distance from hip to toe. Thus, relative to single-axis designs, polycentric knees provide increased toe clearance at smaller knee flexion angles. When the user is sitting, the effective shortening of the limb in flexion also lends itself to improved cosmetic appearance and requires less hip flexion with the prosthetic knee fully flexed [36]. The enhanced stability of polycentric knee designs makes them well suited for transfemoral amputees with short residual limbs. Additionally, due to the effective shortening of the shank with increased knee flexion, polycentric knees are also well suited for knee-disarticulation amputees or transfemoral amputees with long residual limbs. Options beyond the basic linkage design include pneumatic swing control, hydraulic swing and stance control, and friction-based swing control. An example of a linkage design with pneumatic swing control is shown in Fig. 4.11.

Fig. 4.11 The 3R106 Modular Knee Joint with pneumatic swing-phase control (Image courtesy of Ottobock Healthcare)

Microprocessor Knee Systems

The most advanced passive knee systems also incorporate microprocessor control for enhanced performance and stability. Though technically single-axis systems, microprocessor knees are addressed separately here due to the expanded capability achieved by intelligent microprocessor control. Like their foot-ankle counterparts, microprocessor knees actively control resistance in the knee for improved functionality. They can provide weight-bearing support in fully extended and flexed-knee positions, expanding the range of configurations for which the prosthesis provides stable load-bearing functionality.

Furthermore, the swing-phase resistances can actively adapt to changes in gait and/or terrain for improved comfort and performance.

The RHEO KNEE® (Össur, Inc.) incorporates a damper based on magnetorheological fluid, the viscosity of which varies as a function of an applied electromagnetic field. The RHEO KNEE® controls damping in the knee based on measured knee angle, sensed axial force, and sagittal-plane torque exerted on the frame, providing controlled support in stance and controlled transition into swing. Alternatively, designs such as the Freedom Innovations Plié 2.0 (Fig. 4.12a) and the Ottobock C-leg leverage microprocessor control of a closed hydraulic system to modulate knee dissipation. The C-Leg and Plié 2.0 merge hydraulic swing and stance control with controlled stumble recovery, based on sensed knee angle and axial loads. The Orion2 knee (Endolite USA) pictured in Fig. 4.12b is a hybrid microprocessor knee, combining hydraulic stance control with pneumatic swing control.

Though components and control designs vary from one device to another, they all share the common objectives of enhanced multifunction stance-phase stability and adaptive variable-cadence swing-phase control. While some studies show decreased metabolic energy consumption when using microprocessor knees [37, 38], such findings are not universal [39]. The benefits of microprocessor knees may instead be more attributable to their ability to accommodate multiple terrains and gait speeds with increased user comfort and security [40]. Intelligent microprocessor control of knee resistance relieves the user of cognitive burden related to maintaining stability and limb control, providing enhanced safety [41] and the potential for increased levels of physical activity [39].

The Ottobock Genium knee (Fig. 4.13) expands the performance capability of microprocessor knees through complex sensing and intel-

a b

Fig. 4.12 Microprocessor knees: (**a**) Plié 2.0 (Image courtesy of Freedom Innovations, LLC) and (**b**) Orion2 knee (Image courtesy of Endolite USA)

Fig. 4.13 The Genium microprocessor knee (Image courtesy of Ottobock HealthCare)

ligent mode switching, providing enhanced flexed-knee support that can be used to ascend stairs step over step and better traverse obstacles [42]. Enhanced multifunction control of joint resistance is implemented based on feedback from a gyroscope, accelerometer, and sensors that measure knee and ankle moment, knee angle, and axial load. The Genium is not capable of active power generation, but its ability to prevent knee flexion under load enables the user to utilize extension of the residual limb, e.g., to raise the body's center of mass without also needing to stabilize the knee from collapse. The resulting gait provides a good approximation to the stair-ascent movement patterns of able-bodied subjects, though without any net power generation from the prosthesis. Subjective evaluations comparing the Genium and C-Leg show the Genium improves perception of stability and perceived difficulty, particularly in social and mobility-related activities [43]. Building upon the Genium's performance capabilities, the Ottobock X3 knee additionally provides the ability to detect walk-to-run transitions, at which point swing flexion angles automatically increase. The X3 comes in a ruggedized and fully waterproofed package designed in collaboration with the US military for the express purpose of returning above-knee amputee service members to normal activity levels and, if desired, to active duty. It represents the current state of the art in microprocessor-controlled passive knee systems.

Active Components in Lower-Limb Prosthetic Devices

Mechanical and microprocessor-controlled passive components provide a host of functional capabilities that enable significant restoration of lower-limb function. Despite these capabilities, the ultimate functionality of energetically passive solutions is constrained by the absence of net-positive power generation at the knee and ankle. While energy storage and return at the ankle assists forward progression, the inability to generate net power prevents passive foot-ankle systems from restoring the full functionality of the human ankle. Likewise, the similar absence of net power generation in passive knee systems limits their ability to replicate fully the function of the human knee. Increased metabolic energy expenditures are required for many locomotor functions that are at best approximations. To address functional gaps in performance, a number of recent advances have been made in the design of active, externally powered knee, ankle, and knee-ankle systems to expand the energetic performance of lower-limb prosthetic systems. Such advances primarily build upon electromechanical actuation powered by lithium-polymer battery packs.

Active Ankle Systems

A powered foot-ankle prosthesis developed at the Massachusetts Institute of Technology [44] and commercialized as the BiOM® Ankle System (Fig. 4.14a) provides programmable ankle stiffness control and power assist. The device leverages a series-elastic actuator, consisting of a direct current (DC) motor and ballscrew transmission in series with a mechanical spring, augmented with a unidirectional parallel spring. This feature enables ankle impedance modulation and the output of human-scale torque and power. Feedback control is effected based on joint torque (measured with position sensing integrated in the series-elastic actuator), ankle position (measured with an integrated encoder), and state of foot contact (measured with capacitive transducers integrated at the heel and toe). The combination of impedance control with powered propulsion at the ankle provides decreased metabolic consumption (rel-

Fig. 4.14 Actively powered foot-ankle systems: (**a**) the BiOM® Ankle System (Image courtesy of BiOM) and (**b**) the Odyssey ankle (Image courtesy of SpringActive, Inc.)

ative to conventional energy-return foot-ankle systems) in unilateral transtibial amputees walking at self-selected speed, an achievement made despite the increased weight of the powered foot-ankle [44]. Additional benefits of the powered foot-ankle in level walking include reduced loading in the unaffected limb, which may reduce the risk of comorbidities such as knee osteoarthritis in the unaffected limb [45]. The metabolic energy costs, self-selected walking speeds, and gait patterns enabled by the BiOM® Ankle System are comparable to normative measures in individuals without amputation [46].

Another powered foot-ankle prosthesis developed at Arizona State University [47] is now being commercialized as the Odyssey (Fig. 4.14b) through a partnership between SpringActive, Inc. and Össur. The device uses a spring ankle comprising a DC motor, leadscrew transmission, and helical spring. The helical spring stores stance-phase kinetic energy supplemented with additional motor energy that is then released during toe-off to provide powered plantarflexion of the foot-ankle assembly. Incorporation of the helical spring serves to reduce the overall power requirements of the DC motor. The resulting motor-actuated spring ankle provides power and kinematics comparable to those seen in the gait of non-amputees. Building upon the successes of the Odyssey, a revised design that incorporates dual-motor actuation, dual springs, and component reinforcement is currently under development as a running prosthesis for transtibial amputees [48]. Preliminary results with a single subject with unilateral transtibial amputation demonstrate sustained running at 3.6 m/s (8 mph) from the dual-motor actuation system. Future efforts are focused on reduction of system weight and inertial properties.

Active Above-Knee Systems

The emergence of energetically active solutions for above-knee prosthetic systems began with the Össur POWER KNEE™ (Fig. 4.15a), a motor-driven single-axis knee capable of producing physiologic torque and power outputs. The

POWER KNEE™ incorporates accelerometers, gyroscopes, a torque sensor, and a load cell to monitor the position and orientation of the knee and the external loads being applied to it. These measurements are used to determine the activity and intent of the user and the appropriate knee response. The POWER KNEE™ provides active control of dissipation for activities such as ramp and stair descent. It also provides stance-flexion cushioning at heel contact and propulsive power outputs during level walking and ascent of ramps and stairs. Though clinical evaluations of the effectiveness of the POWER KNEE™ have been limited, a case study involving a single subject performing stand-to-sit transitions showed increased symmetry in hip moment (relative to the C-Leg) between the prosthetic-side and unaffected limbs [49]. More recently, the POWER KNEE™ was shown to provide increased power, increased symmetry of power, and reduced peak ground reaction forces on the unaffected limb (relative to the C-Leg) for sit-to-stand tasks [50]. It should be noted, however, that the study found no significant reduction in power generation of the intact knee, indicative of the users' continued reliance on power generation at the unaffected limb.

A two-degree-of-actuation above-knee prosthesis (Fig. 4.15b) originally developed at Vanderbilt University and currently being commercialized by Freedom Innovations, LLC combines actively powered knee and ankle joints within a single, self-contained design [51]. Each joint is actuated with a brushless DC motor, and the prosthesis is designed to provide physiologic torque and power generation at both the knee and ankle. The current limb prototype includes an axial load sensor in the shank, angle sensors in both the knee and ankle joints, and a 6-axis inertial measurement unit. Experimental evaluations of the limb with a single subject with unilateral transfemoral amputation demonstrate the ability to provide gait kinematics similar to that of non-amputee subjects for level walking [51], incline ascent [52], and stair ascent/descent [53]. The actively powered knee and ankle prosthesis offers the ability to realize powered knee extension, powered ankle plantarflexion, and knee flexion at heel strike, the combination of which is other-

Fig. 4.15 Actively powered above-knee prosthetic systems: (**a**) the POWER KNEE™ (Image courtesy of Össur, Inc.) and (**b**) the Vanderbilt Leg (Image courtesy of the Center for Intelligent Mechatronics, Vanderbilt University)

wise not possible in above-knee prosthetic-limb systems.

Despite the functionality already demonstrated by the emerging bionic limb technology, continued development is still needed. DC motor technology offers improvements in actuator power density but at torques and speeds mismatched to the needs of ankle and knee systems. As such, the development of compact and efficient transmissions persists as a need in lower-extremity prosthetic limbs. Additionally, while lithium-polymer batteries provide power sources of reasonable energy density, efficient exploitation of energy generation and exchange remains a critical requirement for expanding the operation longevity in active limb systems. Related to the issues of power and energy density are the overall weight and build height of actively powered prosthetic devices. For such solutions to be universally applicable, reductions in size and weight must be made for the limbs to fit an expanded range of residual-limb anatomies. Furthermore, the increased functionality afforded by such actively powered designs places increased burden on the weight-bearing and suspension functions of the socket interface. This necessitates continued advances in socket interface technology. The foundations have been laid for general accessibility to advanced lower-limb prosthetic systems, but a number of hurdles still exist with respect to how the enhanced functional capabilities of our most advanced technologies can be made useful and effective for those who will wear them.

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