

Upper and Lower Limb Robotic Prostheses

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Learning objectives

Upon reading this chapter, you will be able to:

1. Describe the challenges and benefits of rehabilitation robots that are directly mounted to the human body in the case of limb amputation to assist them in their daily life.
2. List the different components of upper and lower limb prosthetic devices, describe how these components are integrated with the human body to form a functional unit, and explain how user intent is used to direct the motion of prosthetic limbs.
3. Explain how prosthetic devices are used in clinical practice, including insights into user acceptance and embodiment, and measures used to assess prosthesis use.
4. Demonstrate a high-level understanding of next-generation prosthetic technologies that are not yet seeing regular clinical application. These include advanced control paradigms, robotic devices with numerous controllable joints and actuators, novel brain-body-machine interfaces for

prosthetic control, and new surgical innovations to more effectively merge prosthetic devices with the human body.

Introduction

Robotic technology helps persons undergoing rehabilitation to recover lost abilities. Robotic technology also has an important, persistent role in replacing lost abilities that cannot be recovered, or mitigating the impact of that loss on a long-term basis. One special example of a rehabilitation robot that replaces lost function is the *robotic prosthesis*: a robotic device that is attached to a patient's body throughout daily life to replace the functions of the patient's missing limb (Figures 4-1 and 4-2). Robotic prostheses consist of battery-powered, motorized components with movements that are user initiated, typically by way of muscle signals (termed myoelectric control) but also in some cases by external switches. This is in contrast to traditional body-powered hook-and-cable harness prostheses that mechanically couple proximal motion of the body (ie. shoulder or chest) to the excursion of a cable that physically "pulls" or actuates the motion of a prosthetic joint. Advanced robotic prostheses tend to be more anthropomorphic in appearance, often simulating motions and common grip patterns of the human hand.

<FIGURE 4-1 HERE>

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Robotic prostheses differ from other assistive rehabilitation robots in the way that they directly interact with the human body and the way that they must interpret user intent. To greater or lesser degrees, robotic prostheses must become the body part they intend to replace. This physical, long-term connection between a human and their robotic device is a

challenging setting for technical development, and a powerful area for improving the lives of people who have lost limbs due to injury, illness, or other complications. Robotic prostheses currently see regular clinical prescription and daily use, and there are a large number of prosthesis manufacturers world wide producing robotic prostheses. At the same time, new robotic prostheses are being developed that may be able to closely approximate and some day even exceed the abilities of a patient's lost biological limb.

Principles

The ultimate goal of a robotic prosthesis is to completely and seamlessly replace the form, function, and abilities lost due to limb amputation (Zuo and Olson 2014; Childress 1985; Castellini 2014; Williams 2011). In other words, the objective of a robotic prosthesis is commonly considered to be returning the user to the same condition as they were in prior to losing their limb. Importantly, this restoration must be done without creating additional burden or inconvenience to the user above what they would have had in using their non-amputated limb (Williams 2011). No current prosthesis achieves this grand goal, but progress is being made toward restoring individual aspects or functions of a lost limb, and reducing the mental and physical effort that devices require of their users. In particular, a significant amount of research and development has been done to improve the *form* and *functionality* of prostheses, the ease of *control* for prosthetic users, and more recently the quality of *feedback* that can be delivered from the device to its user (Peerdeman 2011; Scheme 2011; Williams 2011; Castellini 2014). These three principles of function, control, and feedback come together to support the user in incorporating a prosthesis as part of their daily life, and ideally as part of their own body— termed *user embodiment* (Longo 2008).

The following four subsections will describe these core principles and how they come together to create useful prosthetic technology.

Form and Function

Form and function are often the first aspects that spring to mind when discussing a prosthetic device. *Form* includes how the different parts of the device are configured, how they relate to each other, the material used in the construction of the prosthesis, and the cosmetic appearance of these parts (such as color and texture.) For example, a prosthesis could be formed from a fiberglass or plastic base that is painted to match the color of the user's skin, with metal parts concealed under cosmetic rubber liners to simulate the look of regular human tissue. Alternately, a device might be fabricated from black carbon-fiber with visible motors and some exposed metal parts or highlighted technology. Some prostheses are painted with custom artwork. Others are sculpted to exactly match the shape and appearance of a user's non-amputated limb. While form may vary greatly, it is dictated in a large part by the functional and social needs of the user.

Often, there is a tradeoff between appearance and usability. The most functional terminal device is often still regarded to be hook-shape in form, due to the provision of clear lines of sight to the user and ability to provide fine motor pinch, compared to the more anthropomorphic appearing powered hands. With the advent of newer multi-grip powered hands with multiple grasp patterns, the functional gap is closing, but none-the-less the vast majority of hands have a mechanical robotic appearance rather than a cosmetic one. For this reason, some patients may prefer a passive device with better cosmesis over one with robotic appearance and function. Form also includes the quality of movement, for example

the smoothness or rate of change of a device's moving parts; it is considered desirable for a prosthesis to not move in mechanical or unnatural ways (Childress 1992; Weir 2004).

Function describes what the device can accomplish: the abilities that the device is able to confer, or the different degrees of control that it affords for the user. Simple examples of function include the number of joints or powered actuators used in a device, the maximum strength of any of these actuators, and the length of time a device can be used without replacing or recharging its battery. More general examples of function include the number of grasp types available to a user of a robotic hand, the capacity of the robotic hand to hold a cup of coffee without it slipping from the user's grasp, or the ability of the robotic ankle of a lower-limb prosthesis to flex appropriately while walking up stairs. The functionality of a prosthesis is governed by design, and chosen based on the needs of the user and the recommendations of the clinical practitioners prescribing their device.

For lower limb prostheses, the clear functional goal is stable weight-bearing and propulsion for mobility. Over basic level surfaces, this can be achieved with the simplest of prosthetic devices, but the degree to which the prosthesis can accommodate for the challenges of daily mobility can vary dramatically. Robotic lower limb prostheses strive to replace functionality over the widest range of conditions, allowing stability and mobility over a variety of terrains including inclines, declines, uneven ground, and for ascending and descending stairs. For upper limb function, the end goals are much more diverse and dependent on each user. In the absence of ability to completely replace the function and form of a normal human hand and arm, users must prioritize between features such as durability, grasp function, cosmesis, and weight. For example, only a small portion of

powered upper (and lower) limb devices are waterproof, so working in wet environments would preclude many component choices in comparison to working in an office setting.

As one example of functional needs, users of forearm prostheses reported a desire for their device to have multiple selectable wrist movements and grasping patterns to suit common situations of daily life (Peerdeman 2011). Further, they desired the simultaneous control of more than one of these functions at any given time—for example, the ability to both bend their wrist and close their hand in a pinching motion to pick up a small object. Finally, users and clinicians recommended that devices have no noticeable delay between the time when a user intends to execute a motion through muscle contraction, and the time that the user sees the effect of the prosthetic joint motion. While initial reports have suggested that a delay of 300ms may be acceptable to users, more recent reports suggest an ideal delay of as low 100ms to 125ms (Peerdeman 2011).

Because of the weight and power demands of each powered actuator deployed within a robotic prosthesis, function is also limited by factors like the type and nature of the user's amputation, the length and shape of their residual limb, how the prosthesis may be secured to the user's body, and other physical properties. As described in the section that follows, the functionality of a prosthesis is also intimately connected to how its user will be controlling the various functions of their device.

Control

Control is defined here as the aspect of a prosthesis that links user intent to the motion and operation of prosthetic functions. User intent cannot in practice be recorded directly (or in many cases even clearly defined). However, it is possible to record a number

of signals from the human body that, taken together, form a first approximation of how a user intends to use their prosthesis or how they wish their prosthesis to behave. These signals can take the form of electrical activity recorded from the muscles of the residual limb, contact forces in a socket, manual or mechanical switches, or other biometric recordings. In addition to signals actively delivered to the prosthesis by the user, a prosthesis may also passively record signals relating to the user, the prosthesis, and their environment. Control of a robotic prosthesis can therefore be thought of as the process of mapping recorded signals to the motion of one or more prosthetic actuators or functions. Depending on the nature and number of signals that can be recorded and the number of functions the user wishes to control, control can be straightforward, or in other cases can be extremely challenging for both users and prosthetic designers (Parker 2006; Scheme and Englehart 2011; Micera 2010). A user's capacity to generate control commands is often a major limiting factor in directing the form and function of their prosthesis.

In many cases, especially in upper limb prostheses, the number of prosthetic functions that are possible to implement within a device are much greater in number than the number of clear, unique signals that can be recorded from the user's body. For example, with an amputation in the upper arm or at the shoulder, it may only be possible to record different muscle command signals from one or two regions of a user's residual limb. At the same time, it would be desirable to give the user control over a robotic elbow, a wrist that flexes and rotates, and a hand with multiple grasp patterns. The more biological function a user has lost, the more function is required from their robotic device (Parker 2006; Williams 2011; Scheme and Englehart 2011). However, due to the nature of the amputation,

the user often does not have the ability to provide clear information about their control intent to their prosthetic device, leading to frustration and abandonment (Parker 2006; Castellini 2014; Biddiss and Chau 2007a, 2007b).

As core principles of effective prosthetic control, it is therefore important that:

- The functions of a prosthetic device are readily accessible to the user;
- The burden of control does not outweigh the benefits of the implemented form and function, and does not negatively impair other user abilities;
- Shifting between the multiple capabilities of a device is swift and seamless for the user;
- There be minimal delays between a user sending a command to the device and having the device respond to their command;
- Use of the device as a whole is as intuitive and natural as possible.

These principles are evident in the usability requirements noted by patients, clinicians, and rehabilitation staff in a number of classical surveys (e.g., Oskoei and Hu 2007; Peerdeman 2011; Childress 1992; Weir 2004; Biddiss and Chau 2007a, 2007b). In addition, autonomy of some basic functions has been noted as a further desirable property of a prosthetic control approach. For example, in a task like grasping an object, it may be desirable for a user to initiate the action, but to have the prosthesis complete or maintain the movement or position without the direct attention of the user (Peerdeman 2011). Current systems that automatically detect and prevent objects slipping from a user's grasp are one example of this paradigm. Artificial reflexes, as reviewed by Weir (2004), are another example of additional autonomy on the part of the control system, as are recent

demonstrations of control interface reorganization (i.e., a prosthesis adaptively changing how the user selects functions), semi-autonomous grasp selection, and grasp pre-shaping (i.e., a prosthesis selecting hands postures and their apertures for the user) (Castellini 2014). Simultaneous control of multiple functions is considered to be an important objective for effective control approaches. It has also been argued that, to be intuitive, control should mirror a user's original neuromuscular control as closely as possible in terms of the arrangement of control channels and the timing of signals flowing between the user and their device (Peerdeman 2011).

Feedback

The flow of signals from a prosthetic user to their device allows a device to perform motions that enact the intent of the user. However, as in conventional control systems in machines of all kinds, the use of a robotic prosthesis is very challenging or impossible for a user without a complementary channel of information flowing from the device back to the user. This information to the user, termed *feedback*, is a critical part of effective prosthesis control.

In its simplest form, feedback is provided to the user as a byproduct of the form and regular operation of the robotic prosthesis. Users are able to see and hear how their limb is moving and interacting with other objects. Vibration, torque, or impact forces to the limb are transmitted through the chassis of the device to the interface with the user's body. These mechanical sensations are well known to be an important way for users to interpret the operation of their prosthetic device, even when they are not looking at it. Similarly, the sound, vibration, and movement of all the actuators within a limb are conveyed to the user

through the chassis and have been reported to be one of the most important components of feedback for users of commercially available limb systems (Lundborg 2001). At present, the majority of available prosthetic technologies use intrinsic signals from the device to the user as their only form of feedback—sensation is not explicitly recorded and transmitted from a robotic prosthesis to the user. For lower-limb robotic prostheses, vibrations, sounds, and impacts often provide a significant percentage of the information that a user needs to skillfully locomote; for upper-limb prostheses, users often desire more information about what their prosthesis is feeling and how it is operating.

One limitation of the simple forms of feedback noted above is that they do not capture the full range of sensations that might be accessible to a biological limb, and thus the type of feedback signals that help provide dexterous, natural control of an artificial arm and hand is missing. For example, in many cases it would be desirable for users to receive feedback about temperature, texture, the motion or position of their limb in space (proprioception and kinesthesia) and even damage or pain. These modalities are not typically present in commercially available devices, but are the subject of significant research and development. Communicating the full range of perceptual information from a device back to the human is considered to be a significant remaining challenge for closing the loop between a user and a robotic prosthesis.

Some approaches to closing this loop aim to link actual actions of the device to specific sensations delivered to the user's body that are perceived by a user in the same way as the information that was recorded by the robot—e.g., the user perceives the robot's contact with other objects as touch, or its proximity to a flame as heat. This feedback can be

provided in ways that are matched or non-matched in form and physiology (Antfolk 2013; Schofield 2014). True physiologically matched sensations would have the patient perceive the sensation on the robot arm as the exact same sensation on their now-amputated biological limb—i.e., the patient perceives pressure on the robot's index finger as pressure on their missing index finger. An alternative approach that leverages the body and brain's ability to adapt is substitution, which delivers sensation to the body in forms other than the way they were recorded (non-physiologically matched sensations). For example, force of contact with an object may be reported to the user by vibration in the socket of their limb or at another location on their body. In either case, physiologically matched or unmatched feedback, the intent is for the user to understand aspects of the operation of their device not otherwise readily perceivable through their direct physical attachment to the device. The device is actively, as opposed to passively, transmitting information to the user.

Because a robotic prosthesis has internal information relating to its actuators, power system, sensors, and control system, devices may also provide a user feedback about things not directly relating to the prosthesis's physical interactions with environment. It is important to communicate information to the user about the operation of the prosthesis itself, for example, communicating to the user which functions or modes they are currently operating, or signaling to the user that the battery is getting low. These forms of information must be communicated in a way that the user immediately knows what they mean, and in a way that is not distracting or irritating during constant use. Wireless links to external devices such as a smart phone or tablet are also possible ways for users to receive different forms of information about their prosthesis, its operation, and the kinds of signals it is

perceiving from the user's body (e.g., plots of the muscle activity signals being recorded in the socket, or a schematic of the configuration of grasps that the user can currently select during their use of the device).

With these examples in mind, we can readily identify that the core principles of feedback and control of robotic prostheses are in fact similar to those of human-to-human communication, and also to those of machine-to-machine communication—e.g., information theory, communication theory, classical cybernetics, and a large body of work dating back to researchers like Harry Nyquist, Ralph Hartley, Claude Shannon, Norbert Wiener, and Alan Turing. Signals should be clear, interpretable, contain an amount of information that is appropriate to their complexity, and readily preserve the intent of the sender upon its interpretation by the receiver. Moreover, different signals need to be distinguishable as unique in order for the control system to understand that each signal has a different meaning (as well described in a mathematical sense by Shannon, 1948).

Practically, this means that the feedback delivered from a robotic prosthesis should:

- Not be too detailed or complex for the user to understand, and be presented in a way that it can indeed be understood (clarity and interpretability);
- Be delivered at a rate that is appropriate for the physical interface with the user (frequency, timing, and timeliness);
- Capture the most useful or important aspects of the information being recorded by the prosthesis (saliency);

- Optimize how the modes of sensation recorded from the robot are matched to the perceptual information perceived by the human body (perceptual alignment or matching)

Embodiment

The sense of ownership of the different parts of one's body is essential for navigating the world around us and for successful interactions with other objects and people. Embodiment is a term used to describe awareness of what makes up our own body. Interestingly, we can be tricked into thinking that an external object, such as an artificial hand, is our own hand. Similarly, when we use a tool, we sense that it becomes a part or an extension of our body. In both of these cases, we can say that the object becomes "embodied". Limb ownership in healthy populations can be manipulated through illusory embodiment of a rubber hand. A landmark study by Botvinick and Cohen (1998) first demonstrated the Rubber Hand Illusion. In this protocol, the subject's arm is hidden from view behind a screen and a rubber model of the same arm is placed on the table in front of them. The subject is instructed to fixate on the rubber limb, while two small paintbrushes simultaneously stroke the rubber hand and subject's hidden hand. Within minutes, subjects report that they feel the touch on the rubber hand, not their hidden hand, as if their arm has embodied the rubber arm (Botvinick 2004).

Hallmarks of embodiment include a sense of *ownership*, *location*, and *agency* of the rubber hand as rated by questionnaires, an autonomic arousal to threat when measuring skin conductance response, and proprioceptive drift where the participant's own hand is felt to disappear and be physically located in the position of the rubber hand (Armel and

Ramachandran 2003; Longo 2008), suggesting that the rubber hand actively displaces the actual hand, rather than merely being mistaken for it.

This embodiment phenomenon is of great interest for those that have lost a limb. It has been suggested that usage of a prosthesis after limb amputation may be most related to the integration of the prosthesis into the individual's body schema (Gallagher 1986), and embodiment is generally considered to be a central factor in how well a user accepts their device. Clearly, form and function will impact how the user perceives their prosthetic limb, and be influenced by how closely the operation of the limb matches their intent. Control impacts how swiftly and accurately the user's intent is communicated to the prosthesis and brought to life. Feedback further closes the loop, and allows the user to feel sensations and situations encountered by their robotic prosthesis. Taken together, these aspects lay the groundwork for embodiment. To have a user fully embody their prosthetic device as their own limb is perhaps the most important goal of prosthetic design, regardless of the level of complexity or functionality provided by the device. As such, a core principle of robotic prosthesis design is to make choices in form, function, control, and feedback that support a user's successful embodiment of their device.

Evidence from Botvinick and Cohen (1998), Armel and Ramachandran (2003), Ehrsson et al. (2004), Tsakiris and Haggard (2005), Longo et al. (2008) suggest that the sense of body self-identification or body schema is intrinsically linked with cutaneous touch. Studies of embodiment after limb amputation have supported the contention that this illusion can be robustly applied using prosthetic limbs. The embodiment illusion was demonstrated in transradial (lower-arm) amputees with cutaneous mapping (Ehrsson

2008), in which questionnaires, skin conductance response and temperature regulation all shifted towards the artificial hand. Marasco et al. (2011) measured embodiment using questionnaires and physiological temperature measurements to show that a prosthetic device that provided a physiologically appropriate sense of cutaneous touch could drive a shift in perception towards incorporation of the device into the self-image of the amputee. They created an artificial sense of touch for a prosthetic limb by coupling a pressure sensor on the hand through a robotic simulator to surgically redirected cutaneous sensory nerves that once served the lost limb. The results suggested that providing physiological and anatomically appropriate direct sensory feedback for a prosthetic limb created a more vivid illusion of embodiment, enough to elicit an involuntary physiological change in temperature regulation. Other studies using a sensory substitution paradigm with vibrotactile stimulation to induce the rubber hand illusion (D'Alonzo 2015) have also shown strong embodiment responses. Results from these studies give insight into how to improve the embodiment of robotic limbs for amputees by incorporating active feedback, which might lead to greater acceptance of the robotic prosthesis.

Critical review of the technology available

Robotic prostheses have been in development for decades and have to date seen extensive use in the daily life of people with amputations (Childress 1992; Zuo and Olson 2014). There are numerous companies world-wide supplying prosthetic components and complete prosthetic solutions for individual patients. These devices are therefore considered to be at the highest Technology Readiness Level (TRL 9), as defined in Chapter 1. Historically, these prosthetic components have tended to be “one-size fits all” based on

ideal engineering specifications. As a result, modern prostheses are modular in nature—they are formed from a range of possible technological components that must be skillfully combined to address the needs of a specific person. As such, the sub-sections below present a high-level overview of the main components of a prosthetic robot: actuators, chassis, and power; the socket; signal acquisition; and the control and interface system (Figures 4-1, 4-2, and 4-3). Each sub-section presents the currently available technology that relates to the described component, and details how the technology interacts with the other components of a prosthetic limb.

<FIGURE 4-3 HERE>

The pace of commercial development of robotic prostheses is very rapid. Prosthetic systems are highly modular, and new solutions are constantly being developed to the point of prescription for patients. Therefore, where possible, we will avoid reference to specific commercial products or models. Information on robotic modules, specifications, and components is readily available from the catalogues of prosthetic manufacturers. However, exceptions will be made from this policy when an emerging technology is only available from a single source, or when mentioning a supplier or manufacturer is required for clarity. The intent of this section is to give the reader a clear understanding of the modern technological components of a robotic prosthesis—i.e., commercially available products and solutions (defined as TRL 8-9)—and a comprehension of how these components can be combined into a unified whole to support the needs of patients with amputations during their daily life. For the interested reader, emerging technologies (defined as TRL 7 and below) will primarily be discussed below.

Actuators, chassis, and power

The physical parts of prostheses can be broken down into electrical, mechanical, and electromechanical components. The main mechanical component of the prosthesis is the chassis: the shell that encloses the moving parts, the power system, the control electronics, and the computing hardware. In most prostheses, the chassis is a rigid exterior that is mostly hollow inside to provide areas to secure electromechanical components (Figure 4-3a). The chassis is also the main point of contact for the *socket*—the part of the prosthesis that affixes to the body of a user with an amputation (described below). For most upper and lower limb prostheses, the chassis also encloses the *actuators*: the motors that move parts of the chassis with respect to the user's body.

In many cases that involve more proximal amputations (those closer to the body's center), the chassis of a robotic prosthesis is also modular, such that a user or their prosthetist can remove more distal components (those farther from the body's center) in a straightforward way. For example, with an upper-limb arm and hand system, the prosthetic hand, wrist, and elbow are potentially independent modules, and connect together at the wrist by way of a locking mechanism. Power and information are shared between these connected components via electrical contacts present in mating ends of any interlocking parts. For example, metal contacts on the surface of a standard electrical and mechanical locking mechanism at the proximal end of a robotic hand chassis mate with a similar arrangement of metal contacts on the distal end of a robotic elbow and forearm chassis (Figure 4-3b,d). The exact design of the interface between chassis modules is typically

specific to each manufacturer, though efforts have been made to standardize interfaces for physical and electrical connection of components (Sutton 2011).

Actuators provide the forces needed to move the different parts of the robotic prosthesis (Figure 4-3a,c). They must be robust, generate forces that allow the user to be able to perform daily life tasks, and be efficient in their use of power. Depending on the joint that is being powered by an actuator, the size and type of motor varies. Actuation of individual fingers in a prosthetic hand is readily done by a series of small actuators at the base of a finger or in the palm of the hand (Figure 4-1 and Figure 4-3c). Larger actuators are used in joints such as the knee, elbow or wrist (Figure 4-3a). For the most part, DC motors remain the standard source of actuation, as well reviewed with technical clarity by Weir (2004). Specifically with regard to prosthetic hands, models are now available that allow more than two dozen different grasp patterns through actuators for each finger, with either a manually moveable thumb or powered thumb opposition (Belter 2013).

The chassis further provides a housing for the batteries that power the actuators and control hardware (Figure 4-3a). These batteries can be removable, such that they can be interchanged during extended periods of use, or they can be permanently mounted within the chassis such that a prosthesis must be directly connected to charging electronics via a plug on its exterior surface (Weir 2004). Batteries range in type, but in recent years older nickel-cadmium (Ni-Cad) and nickel-metal hydride (Ni-MH) models have been replaced with lithium (Li) and lithium polymer (Li-Po) equivalents that have better charging properties, smaller size and weight, and more charge-carrying capacity (Weir 2004).

Important considerations when designing the chassis and its internal components are robustness during daily use, and weight. These two considerations are often in opposition: stronger and more durable chassis are heavier and more bulky for a user. To be accepted by users, a chassis with all power and actuators installed should be significantly lighter than a biological arm, as the lack of direct skeletal attachment makes the prosthesis feel heavier due to soft tissue motion between the socket and limb. Importantly, as the number of actuators within a prosthesis increases, so too does the battery demand and the weight of the device. As such, a great amount of design has gone into the shape, size, and materials of prosthetic chassis.

Efforts are ongoing to reduce the size and weight of prescribed prostheses while not compromising the functionality of these systems. Commercially available chassis and actuator configurations are designed to be worn by children, and many new robotic hands come in both a small and a large size to better suit a range of individuals.

Sockets, harnessing, and attachment to the body

The socket is the foundation of the prosthesis and acts as the main structural interface between the prosthetic components and the remaining bone and soft tissue (Figure 4-3a). Generally, a poor fitting socket will almost universally lead to rejection of the device, regardless of the potential functionality of the components and control system. The standard clinical method of attaching a prosthetic device to the user requires a socket and interface between the residual limb and the prosthetic components, with some form of suspension to hold the prosthesis in place either through socket design or by adding harnessing and straps. The socket is typically a rigid laminated material that is custom molded to the body, with an

interface against the skin such as a flexible thermoplastic material or various types of liners that distribute forces across the soft tissue, reduce friction and in some cases provide suspension (for example pelite, or gel liners such as silicone, urethane, or thermoplastic elastomer). As a general principle, areas of the residual limb that can withstand pressure (muscle and soft tissue) are loaded or compressed to ensure secure suspension of the prosthesis and reduce excess movement between the socket and the user's residual limb. Areas that cannot withstand pressure, such as bony prominences, scar tissue and neuromas are relieved to avoid pain and skin breakdown.

The secondary role of the socket as the main communication transmitter between the user and the terminal components should not be overlooked. In the upper limb, the electrodes for the muscle control signals are encased in the socket, and must maintain adequate and consistent contact over the muscle sites. In addition, in both upper and lower limb sockets, indirect feedback clues as to the state of the prosthesis are provided through vibration and torque felt on the residual limb, based on the activity and position of the prosthesis. The more intimate the fit of the prosthetic socket, the more likely the user will incorporate these feedback clues into their awareness of the function of the prosthesis.

Lower limb sockets must be fashioned to transmit the load of the entire body during gait, and are designed to accomplish this through reliance on weight bearing occurring through specific load tolerant areas (i.e. the patellar tendon and tibial flares for amputation below the knee, and the ischial tuberosity for amputation above the knee). With newer materials such as polyurethane and elastomer liners, the traditional designs have been able to move more towards a "total weight bearing" approach in which the forces are transmitted

hydrostatically throughout the entire residual limb. Suspension is often provided through suction, sleeves, or a locking pin in the end of the liner to avoid the need for belts and cuffs, which were historically required prior to suction methods of suspension using newer materials. The more proximal the limb loss, the more extensive the socket and suspension system generally must be in order to secure the weight of the prosthesis to the body and allow adequate control.

In the upper limb, bearing axial loads are less of a concern as the major challenge becomes one of maintaining suspension or preventing slippage of the socket when carrying loads or moving the arm. In addition, the socket must be designed with consideration to not restrict the available degrees of movement of the more proximal joints. For below elbow levels of amputation, bony prominences can often be used for suspension by contouring around the elbow, but for more proximal levels in the upper arm, harnessing and strapping across the contralateral shoulder and trunk is almost universally required. Newer designs such as high compression or hi-low alternating compression (Alley 2011), and adjustable sockets using pneumatic inflation air bladders have been described (Resnik 2013) to try to avoid the requirement for harnessing.

In even the most advanced socket designs, as the bony residuum is not directly secured to the prosthesis, rotation and movement of the limb in relationship to the socket typically occurs to some degree. Problems with loss of socket fit and poor suspension can be magnified with limb atrophy, changes in limb volume throughout the day, or physical load on the limb. Importantly, this loss of suspension or a loose socket often leads to the patient reporting “heaviness” of the device, when in fact if motion is eliminated and better

suspension achieved the weight of the device will feel less. In the upper limb myoelectric device, slipping of the prosthesis or lack of contact will create poor control not only due to poor mechanical coupling of the device to the limb, but also due to shifting of muscle electrodes creating inconsistent contact of the control sensors to the muscle sites.

In summary, advances in materials such as gel liners have significantly improved socket comfort, skin condition, and offered additional suspension methods. Newer socket designs that focus on stabilizing the limb for effective transmission of forces are an improvement on traditional sock and harness fittings. However, ongoing work to improve these factors is required as the socket remains the key to comfort, wear time, control, and acceptability for advanced prosthetic users.

Signal acquisition and myoelectric recording

How user intent is communicated to their robotic prosthesis is important, and a key element informing the design of the robot. As was discussed above, user intent is approximated by the signals that are recorded from the user, and state information that is maintained within the control system of the device. These signals can take many forms—mechanical, electrical, or combinations of the two—and can be recorded in a variety of ways. As a simple example, manual switches touch pads, linear transducers, and buttons are commonly used to change control options or inform the movement of prostheses. However, the dominant method for reading a user's intent during the control of a robotic prostheses is a technique called *electromyographic recording* (EMG): the sampling of electrical signals generated by muscle tissue in the user's residual limb or adjacent regions (Parker 2006;

Micera 2010; Scheme and Englehart 2011; Oskoei and Hu 2007). This process of using these signals in the control of a robotic prosthesis is called *myoelectric control*.

Myoelectric recording for the control of prostheses has been pursued since as early as the 1940's (Childress 1985), and has matured to the point of widespread use in commercial prostheses (TRL 9). Sampling of EMG signals is typically done at the *surface* of the skin (denoted sEMG), and specifically through contact between the skin of the residual limb and a series of metal electrodes embedded within the socket of the prosthesis. These electrodes measure small changes in electrical potential generated by the muscle tissue located directly beneath them in the socket. As small units of muscle tissue, termed motor units, are recruited during muscle contraction, they contribute to consistent changes in the electrical properties of a specific muscle group or part of a muscle (Micera 2010; Parker 2006). Muscle contractions can be detected through the increased amplitude and differing frequency components of electrical signals recorded at the skin above the muscle. Electrodes are thus placed and oriented within a socket so as to best acquire clear signals from relevant muscle groups while minimizing the amount of cross-talk received from neighboring muscles (as described in detail by Micera 2010; Parker 2006, Weir 2004; Oskoei and Hu 2007; and others).

In practical application, there is limited real-estate within a prosthetic socket for recording, and the exact location and type of electrodes placed within the socket has to be carefully considered so as to maximize the number of clear channels of information that can be recorded from the user. To aide in this placement process, electrodes are sold in different shapes and sizes that can be mounted to socket liners or to the hard wall of a socket.

Furthermore, electrodes can be positioned side-by-side in a single hard case, or arranged remotely at the end of short leads that form differential pairs with a dedicated reference electrode, single points with a common electrode for reference, or a range of alternate configurations to suit specific circumstances (Micera 2010). For example, in the case of a user with a transhumeral (upper-arm) amputation and the desire to control a prosthetic elbow actuator, EMG electrodes might be placed in differential pairs over the biceps and triceps of the user's residual limb; this could take the form of two small metal domes protruding from the inside of the socket. For the case of a transradial (lower-arm) amputation, electrodes are placed around the interior of the socket to make contact at the flexor and extensor muscles of the user's residual forearm.

Sampled myoelectric signals are amplified, filtered, and processed by the electronics housed within the prosthetic chassis, such that they can be readily used to inform prosthesis control (as will be described in more detail below). Some electrodes conduct this amplification and filtering at the point of recording, so as to better reduce the amount of noise in the signals, while others rely primarily on amplification and filtering by electrical components at another point in the prosthetic chassis. Recorded signals may be rectified and conditioned, or left unfiltered depending on the needs of a particular manufacturer's actuators and control systems. Electrodes are connected to other electrical hardware within the chassis via shielded electrical cables.

In summary, myoelectric recording is an effective, widely used method for reading user control intent from voluntary contractions of their muscle tissue. EMG recording technology is designed and deployed so as to maximize the number of distinct myoelectric

signals that can be sampled from a user's residual limb. Prosthetists configure the socket, chassis, number of actuators, and internal hardware of a robotic prosthesis to best utilize the information contained in these myoelectric signals. However, there remains room for improvement in myoelectric recording, as evidenced by a large body of ongoing work in industry and academia. Examples include new electrodes with different conduction properties and sockets with dense arrays of recording electrodes (Daley 2012; Tkach 2012) that promise to greatly enhance the effectiveness and resiliency of myoelectric control once they see widespread clinical deployment.

Control systems and interfaces

The control system is the principal means of linking signals recorded from the user to the control actions to be performed by their robotic device (Figure 4-4). As reviewed by Parker et al. (2006), Micera et al. (2010), and more recently by Scheme and Engelhart (2011), there are a range of methods and approaches for developing a control system to transform the signals provided by a user into precise motor commands for a robotic limb (Figure 4-4). In practical application, these range from simple routines in hardware and software that map input signals to output commands using straightforward mathematical relationships, to approaches that use machine learning and advanced statistical techniques to map a series of complex myoelectric patterns onto a range of discrete motions. This section will focus on upper limb applications, as practically speaking, no current available systems provide myoelectric powered control for the lower limb outside of the research laboratory. Most current commercial lower-limb prostheses (eg. Figure 4-2) are indirectly, passively controlled by alignment with respect to the ground-reaction force, and momentum

through proximal joint motion (hip or knee). The most advanced lower-limb prostheses use internal torque and accelerometer sensors with a computer control algorithm to control stance phase resistance and passive prosthetic joint motion. A few more recent powered components also provide active powered motion, controlled based on motion, position and velocity sensors rather than direct muscle signals (Sup 2011).

<FIGURE 4-4 HERE>

For upper limb robotic devices, in the simplest case each commercial robotic module or actuator accepts one or more myoelectric signals as input (via wires that connect the module to the electrodes mounted in the user's socket) and proportionally or discretely maps these analog signals in a pre-defined way to the movement of the module's respective joints. A prosthetist is able to manually change the amplification of the signals to match with the quality and intensity of signals that can be provided by the user, or configure the other internal control parameters of the device itself. In more recent systems, a robotic prosthesis will provide a wireless or wired interface to a mobile device or computer that gives access to some or all of its control parameters such that they can be tuned by a user or a prosthetist. In practice, the initial calibration and tuning of the control system for a robotic prosthesis is done by a prosthetist trained in the setup of a given prosthetic component. The user is then trained on the use of their new control approach and related robotic technology through sessions with occupational and physical therapists. This training is crucial for a number of reasons, but, as it relates to control, it helps the user provide myoelectric signals that can more readily be interpreted by the control system of the prosthesis. As such, there

is often an iterative in-clinic process of training and calibration focused on improving control for the user (Resnik 2012).

As a user-centered example, some modern multifunction robotic hands allow the user to connect to the device with their smart phone and modify the way that they select grasp patterns, and even customize the grips available during daily use. However, in all commercial cases, the low-level control of actuators and the related parameters are not presented to the user, and control typically relies on hardware and software that is proprietary to the manufacturer of each prosthetic component.

More advanced control options have only very recently become available to prosthetic users, in the form of *pattern recognition* (TRL 8-9). In contrast to the approach described above, where a series of electrodes are mapped by the prosthetist in a fixed way to the input control channels of prosthetic components, pattern recognition uses statistical machine learning approaches to automatically form a mapping from input signals to output motion on a robotic prosthesis (Scheme and Englehart 2011; Micera 2010). In essence, a control system is tasked with perceiving the pattern of signals being recorded from a set of electrodes at any given movement, and learning how to match this pattern with a user-specified movement of the attached robotic actuators. Then, when a user later presents one of the learned patterns of myoelectric activity, the control system is able to detect the pattern and generate the appropriate movement. This mapping can be formed using machine learning algorithms such as linear discriminant analysis, support vector machines, or other well-established classification methods (Castellini 2014). A significant amount of research has been conducted to determine the correct way to train such a classifier, and how

best to provide myoelectric information the classifier in the form of processed time, frequency, and time-space features (Scheme 2011; Micera 2010; Castellini 2014).

The only currently commercially available example of pattern recognition is Complete Control (Coapt LLC); in this control solution, all electrodes in a socket are fed into a single pattern recognition module, which then provides output signals to a set of down-stream actuators. The pattern recognition hardware and software forms an intermediary between the electrodes and actuators of a number of other manufacturers. To use the system, the user presses a training button mounted on the chassis of their prosthesis. Under the control of the pattern recognition module, the prosthesis then automatically generates a set of motions that the user must copy by flexing their residual muscles in the way they think is most appropriate for the given motion. The pattern recognition system records a set of training examples wherein each motion is linked to multiple examples of the corresponding myoelectric patterns as provided by the user, and computes a mapping from EMG input signals to output control signals. After training, control is returned to the user. Multiple movements can be learned and effected in this way, without detailed calibration by a prosthetist, and the user is in control of retraining their control system in response to day-by-day and moment-by-moment changes in their myoelectric signals. Training of the pattern recognition systems is straightforward and brief. In Figure 3, the training of the pattern recognition system can be thought of as changing the mapping block from input signals to output control actions.

Recent machine learning-based control approaches represent an important paradigm shift in technology for robotic prostheses—prosthetic control systems are now able to play

an active role in adapting to their user and the way a person's signals and patterns of use change outside of the clinic (Castellini 2014; Pilarski 2013a). In particular, advanced control approaches like pattern recognition are decreasing the time that it takes for users to be able to control a new robotic prosthesis, and increasing the number of accessible prosthetic functions available to a user. However, in upper-limb prostheses, whether with conventional control or pattern recognition, users are presently still limited to controlling a single actuator or motion at a time, or in promising cases performing two simultaneous movements. A significant amount of work is required and ongoing to provide users with fluid, natural, and simultaneous control of large numbers of actuators (Castellini 2014).

Critical review of the available utilization protocols

The goal of prescribing a robotic prosthesis is to provide a functional replacement for the lost limb that the user wears on a daily basis. Lower limb prosthetic users typically don their prosthesis every morning as part of their dressing routine, wear throughout the day, with occasional breaks for comfort or to adjust socket fit as limb volume can change throughout the day. At night they must clean and air the limb and the prosthetic interface to maintain hygiene and skin condition. Externally powered components often must be charged throughout the night. For the upper limb, constant use for a full day is less common, as patients can manage with one-handed function at home, so typically the prosthesis is used when out of the house or for specific tasks that require bimanual function.

Choosing the right prosthesis requires that the clinician understand the needs and goals of the patient, the environment in which the prosthesis will be used, and the required tasks. In addition, psychological adjustment to amputation includes learning to incorporate

the prosthesis into their body image as well as function, so appearance is an important factor for some. For the lower limb, a patient must have a minimum level of strength and ability to weight bear in the remaining limb to allow adequate prosthetic function, as well as proximal joint (hip or knee) range and strength to drive the prosthesis. For the upper limb, shoulder and contralateral arm function are important factors to evaluate, as well as condition of the residual limb. Most limb anomalies such as scarring, grafted skin tissue, and bony prominences can be adequately managed with today's technology and advanced interfaces, but daily inspection of the residual limb and meticulous skin care is essential to maintain limb health, and must be incorporated into the daily routine.

Training to use a prosthesis is an essential factor in success, as prosthetic provision alone does not equate to restoration of function (Dawson 2011). Gait training typically progresses through graduated weight bearing and reduction of gait aids as the user learns to trust the prosthesis and the limb accommodates to the new forces being transmitted through the socket, which must be guided by a therapist experienced in lower limb prosthetics. This is particularly true for advanced microprocessor and powered robotic components, which act and respond in very different ways than traditional prostheses. For the upper limb, training for myoelectric control can often start prior to provision of the prosthesis, through teaching the user to activate and strengthen existing muscle signal control signals. This can be as simple as visualization techniques where the user imagines phantom limb movements and voluntarily activates remaining muscles, or can use virtual reality or table mounted robotic arms to practice myoelectric control using affixed EMG electrodes (Dawson 2011). During this process, the prosthetist establishes the location of the most efficient and

separable control signals, and manufactures the socket with the electrodes placed in the optimal locations on the interior of the socket. Once the socket is fit to the user, control training using the robotic prosthesis continues, starting with simple tasks (hand open/close control) progressing to more complex multi-joint tasks, and eventually to coordinated bimanual tasks simulating performance of activities of daily living. The user is also encouraged to try new tasks at home and then problem solve any difficulties encountered with their therapist. This process can take several weeks to months to achieve expert control of the system, and is typically directed by the occupational therapist. Close coordination between an interdisciplinary team (prosthetist, therapist, physiatrist) is ideal throughout prosthetic fitting and training to ensure all potential issues are being addressed to maximize function and create a successful outcome for the patient.

Upper-limb robotic prostheses

Myoelectric prostheses have a long history of development, but generally have been available for widespread clinical use since the late 1970's (Childress 1985). There are no definitive criteria for which devices to fit to which patient, but in general several factors are considered for each individual such as function, comfort, cosmesis, reliability, and cost. Myoelectric devices are more expensive, heavier, and require more maintenance than body powered prostheses, however have the advantages of requiring less harnessing allowing greater range of motion and functional range of the terminal device, having a more natural control scheme, and better cosmetic appearance.

Over the years several studies have shown varying rates of rejection of electrically powered prostheses, from 25% (Biddiss 2007a) up to 50% in some studies (Silcox 1993;

Wright 1995). Heavy weight, low durability, slow response, and lack of sensory feedback are often stated as limiting factors (Biddiss 2007b). However some studies, such as one in injured workers, showed 83% acceptance of electrically powered prostheses (Millstein 1986), and that many workers used more than one type of prosthesis to meet all their functional needs.

With the more recent advances in multi-function grip hands, patterns of usage may be changing. As more options are available for hands to provide more functional grasp patterns, users can use the myoelectric prostheses for a wider range of activities. In the clinic, the sooner the amputee is fit with a prosthesis, the better the long term acceptance of the device. Usage patterns and acceptance in general are highest for transradial amputation levels versus higher levels of amputation, as the complexity of the system increases with multiple components. Often hybrid prostheses with a combination of body powered and myoelectric components are prescribed for higher-level amputations to minimize weight, cost and complexity of operation. A critical factor for acceptance often is the ease of donning and doffing the prosthesis, and the robustness and reliability of control. For this reason, recent advancements such as interface liners with embedded electrodes and pattern recognition with on board calibration may improve long term acceptance due to greater reliability and less effort to don and adjust myoelectric sites.

Lower-limb robotic prostheses

Lower limb prostheses are more commonly accepted and used for greater hours during the day due to the need to restore functional ambulation. Prescription of prosthetic components is typically based on assessment of an individual's functional ambulatory

potential. For example, an individual expected to only be ambulatory in the household or over level surfaces using gait aids at one cadence is not expected to benefit from a cadence responsive hydraulic knee, and in fact the increased weight may be a detriment. As functional ability increases to the point of community ambulation at varying cadences, the advantages of advanced components become more evident. Of particular importance is the ability of most microprocessor controlled knees to provide resistance to involuntary stance phase knee flexion by altering resistance based on real-time input, which is thought to reduce risk of falls. Reported advantages of advanced prosthetic knees include improved balance and more normalized gait pattern (Kaufman 2007), and subjective impression of improved ability to navigate uneven terrain, slopes and inclines, and possibly less cognitive load required during ambulation (Williams 2006).

Powered lower-limb robotic prostheses are unique in that they are designed to generate powered movements rather than rely on passive variable dampening of microprocessor knees. This provides a specific advantage in movements such as from sit to stand and stair ascent (Lawson 2013). This is hoped to reduce the requirements of the proximal joints and contralateral limb to generate the additional power required to compensate for the loss of anatomic knee power, thereby normalizing biomechanics of gait (Goldfarb 2013). The major barrier to accessing this technology is cost and acceptance of funding agencies. Ongoing work is required to document the potential benefits of these advanced technologies through appropriate metrics and economic analyses.

Review of user studies, outcomes, clinical evidence

Acceptance, use cases, and clinical successes

Upper-limb

Development of advanced upper limb technology has been dramatic in the last decade, but parallel improvements in clinical usage and success have not been thoroughly documented as of yet. As noted above, rates of abandonment in the past have been reported from 25-50% (Biddiss and Chau 2007a, 2007b), with concerns over poor control, limited dexterity, discomfort, poor durability, weight, cost, and limited sensory feedback commonly cited as reasons for rejection (Atkins 2007; Biddiss and Chau 2007a, 2007b). It is presumed that those that continue to use their prosthesis do so because they have attained a level of control that improves their function, although cosmesis may also play a role. In general this is an understudied area, and the rates of acceptance may change with more recent technological advances. This has led to increasing focus on a “user-centered” approach to design and development (Resnik 2011). Usability research has only recently incorporated end-users into the device development stages in an attempt to overcome barriers to clinical usage and meet the needs of consumers. From an ergonomic human factors approach, this would seem an essential component in the deployment of robotic prostheses where usability hinges on acceptable human interaction with the device.

An additional challenge is lack of agreement on the best methods of measuring clinical success in the application of robotic technology. Substantial work has been done by the working group on Upper Limb Prosthetic Outcome Measures (ULPOM) (Hill 2009). They recommended the use of the World Health Organization’s International Classification of Functioning, Disability, and Health (ICF) as a framework for selection of outcome measures. However, a clear limitation of existing metrics is that no one measure covers the

range of potential outcomes of interest, and therefore a range of metrics covering the elements of the ICF are advised, including measurement of body structure and function (performance of the prosthesis), activity (carrying out tasks), and participation (use of the prosthesis in real-life situations). In addition, standard metrics were developed for standard technology and basic function, and do not always take into account the types of improvement expected with advanced robotic devices that add dexterity and feedback. The measurement of higher cognitive functions such as embodiment and cognitive load/visual attention are not traditionally considered as prosthetic outcomes, but need to be incorporated into future assessments of effectiveness of robotic devices from a human-machine interaction perspective. This will be especially important as strides are made in neural machine interfacing, improved communication protocols, and other advances in limb attachment (detailed below) that improve the function of advanced devices past research settings into the clinical environment.

Lower-limb

Similar concerns over lower limb functional outcome metrics exists, with many standard mobility tests focusing on assessment of basic levels of function. A comprehensive review of lower limb prosthetic outcomes was published by Condie in 2006, updated and catalogued according to ICF elements in 2009 (Hebert 2009; Deathe 2009), and most recently reviewed from a clinical perspective (Heinemann in 2014). In general, most metrics evaluate basic mobility and have significant ceiling effects, inadequately addressing potential advantages of more complex advanced prostheses. More advanced metrics for

higher level function have been introduced with less functional ceiling effect (Gailey 2013), but to truly discern the differences with advanced components most researchers rely on detailed biomechanical / gait analysis evaluations vs. global mobility metrics. The most advanced microprocessor and power knees claim to have significant beneficial effects on improving stability and ability to navigate uneven terrain and stairs, reducing compensatory gait strategies and lessening cognitive load in having to control the prosthesis, however existing metrics do not capture these mostly qualitative findings (Orendurff 2013). It is clear that more sensitive metrics will need to be developed to detect these more subtle effects of advanced components.

Remaining barriers to patient acceptance

As reviewed in a number of recent publications, and noted above, there are remaining barriers to the acceptance and consistent use of prescribed myoelectric prostheses (Peerdeman 2011; Scheme and Englehart 2011; Micera 2010; Atkins 1996; Micera 2010; Biddiss and Chau 2007; Resnik 2013). Coarsely grouped, these barriers have been found to relate to the functionality of the robotic prosthesis, the amount of feedback users receive from their device, the complexity of the control interface, comfort, durability, and the appearance of their device.

By way of examples from a study by Peerdeman et al. of forearm prosthesis users (2011), grasp execution time for hand prostheses remains too slow for many users (~1s); while force-based control and velocity-based control, as opposed to positional control, have been listed as desirable control properties, their execution for precise user manipulation in practice is still lacking. Further, users report that their devices often do not have the right

number or type of functions (e.g., lack of a movable wrist on a forearm prosthesis, or lack of individual finger control); they desire more actuation. However, when multiple functions are supplied, they are at present not always easy for users to access. In many cases where multiple functions are present, users often disregard or cannot access already present functionality due to complexity of the control interface. Commercially available pattern recognition should help alleviate some of these concerns. However, active feedback, as opposed to inherent feedback via the chassis of the prosthesis, is in all practical senses missing from deployed systems.

An additional concern with the majority of modern upper-limb robotic prostheses is the requirement for a user to maintain their visual and cognitive attention on their robotic prosthesis during operation (noted by Atkins 1996; Bongers 2012). Prosthetic hands lack meaningful sensory feedback and must be carefully watched at all times to perform even simple tasks. Visual attention demands are an area where improved sensory feedback may play an important role, and feedback systems are thus a major area of development (Antfolk 2013; Schofield 2014). Other remaining concerns include prostheses being generally too large or heavy for most of their users due to the engineering requirements for actuation and robustness (Atkins 1996; Sensinger 2014), and that users cannot always reliably use their devices in protracted or vigorous activities of daily life (Atkins 1996). As described in the next section, these difficulties are being addressed by a significant body of ongoing industrial, clinical, and fundamental research.

In the lower limb, barriers to use mainly relate to socket comfort (Dillingham 2001; Pezzin 2004), although dissatisfaction with cosmesis may also play a role to a greater

degree than previously appreciated, based on recent surveys in which patients listed concerns with respect to shape of the prosthesis matching the cosmesis to the sound limb, free prosthetic joint movement underneath the cosmesis and natural fit of clothing over the cosmesis (Cairns 2014). Interestingly, gait deviation has been reported as unimportant to the amputee, with self-reported functional ability and attitudes toward the prosthesis having the strongest correlation to satisfaction following lower-limb amputation (Kark 2011).

Future directions

The intent of this section is to briefly introduce a range of frontier directions for improving the outcomes of patients with amputations. A focus is placed on breadth as opposed to depth, such that a wide range of topics can be covered ranging from the conceptual (TRL 1 -5) to those nearing practical use (TRL 5-8). Specifically, this section will address ongoing work that aims to further close the loop between a person and their robotic prosthesis, the deployment of implantable technologies, the use of machine learning and machine intelligence for advanced control, and ground-breaking new robotic prostheses that significantly extend the function of currently available devices.

Bidirectional control and feedback

Targeted motor and sensory reinnervation

Surgical reconstruction of the amputation limb plays an essential role in maximizing outcomes for prosthetic applications. In addition to advances in bone management, residual muscle management, and skin coverage, advanced nerve procedures have been developed to improve the ability to extract the rich control signals that are lost after upper limb

amputation. Targeted Reinnervation (TR) surgically redirects the amputated nerve endings that used to innervate the hand and wrist muscles to new muscle sites, to provide physiologically natural motor command signals for myoelectric control (Kuiken 2013). The surgically redirected nerves reinnervate purposely denervated remaining muscles, which then act as biological amplifiers for the neural signals that are still under voluntary (brain) control. These muscle responses, which are intuitively activated, are then linked to the action of the prosthesis. After reinnervation, patients are able to operate multiple degrees of freedom of advanced prosthetic devices with increased ease. Combining newer surface EMG recording techniques (such as pattern recognition) with TR, may allow even more signals to be extracted for prosthetic control. Recently, in subjects with upper limb amputation having undergone TR, simultaneous pattern recognition control was found to be superior in preference and performance to both sequential pattern recognition and conventional myoelectric control (Young 2013).

In addition to improved motor control, targeted reinnervation provides a potential avenue for sensory feedback. Redirection of the amputated sensory nerves to denervated skin restores the sensation of the hand and fingers on the new target area of skin (Marasco 2009; Hebert 2014a). This ‘transfer sensation’ from reinnervation of the sensory afferents is a possible access point to provide physiologically natural and appropriate avenues of cutaneous touch and proprioceptive feedback through robotic devices (Hebert 2014b). Ongoing research in this area is linking haptic feedback to tactor devices that stimulate the skin and muscle in proportion to sensors on the prosthesis, thereby providing real time bidirectional feedback in a non-invasive socket system.

Non-invasive recording alternatives

While sEMG from a small number of recording sites has become the dominant approach to controlling robotic prostheses, a number of alternatives have been proposed to help increase a prosthesis's view into the intent of its user. As reviewed in Castellini et al. (2014), and Founger et al. (2012), there have been promising demonstrations of prosthesis control using ultrasound, high-density EMG arrays, topographic force mapping within the socket, acceleration measurement, mechanomyography (the measurement at the skin of muscle-contraction-related mechanical disturbances), and others. Each method has its own benefits in terms of the features of a user's upstream control intent that it provides. Each method also has specific implementation challenges that potentially limit deployment in take-home settings. Considered as a whole, the move to more diverse and more detailed recording of user intent—novel non-invasive recording modalities coupled with conventional sEMG technology—promises to alleviate significant failure modes of sEMG and increase the robustness of next-generation systems (Casellini 2014).

Implantable technology

Osseointegration

Osseointegration refers to the direct structural and functional connection between living bone and the surface of an artificial metal implant. Worldwide, osseointegration is used in joint replacement, dental implants, craniofacial deficiencies, maxillofacial reconstruction, orbital prostheses, and bone anchored hearing aids. The technique for prosthetic attachment using a transdermal implant for limb amputation has been an

accepted clinical treatment technique in Europe since the 1990's (Hagberg 2009), but only recently has been approved for investigational device exemption in the US. The primary advantage of osseointegration is that the weight and functional leverage of the prosthetic limb is transferred directly to the skeleton, eliminating the need for a prosthetic socket. A titanium fixture is placed in the center of the amputated limb bone, with a replaceable titanium abutment extending through a skin opening. The end of the abutment serves as the mounting point for the prosthetic limb. The skin adheres to the bone at the junction where the percutaneous abutment traverses the skin, to minimize communication with the underlying structures. The main persisting complication is that of intermittent superficial skin infections that can occur at the percutaneous junction. Published results from a recent protocol indicate 92% implant survival (Branemark 2014) with a 55% rate of superficial infection. Techniques of management of the skin-implant interface continue to evolve in attempts to reduce this relatively high rate of infection. Reports on the functional and quality of life benefits of osseointegration in general indicate improved prosthetic use, mobility, physical function, and global improvement in quality of life for both transfemoral and transhumeral levels of amputation (Lundberg 2011; Jönsson 2011; van de Meent 2013; Branemark 2014). In addition to benefits of greater range of motion and control due to lack of requirement for a socket, there is a phenomenon of "osseoperception" described, whereby the individual feels tactile and proprioceptive feedback through vibrations transmitted directly to the skeleton.

New techniques of osseointegration have shortened the rehabilitation time and in some cases combined osseointegrated limb attachments with joint replacement, in order to

address the most challenging cases of prosthetic application (Khemka 2015). Recent exciting advances combine neural machine interfaces with osseointegration for proximal upper limb loss, which promises a “plug and play” system where the individual is functionally, structurally connected to their robotic prosthesis through a single abutment attachment (Ortiz-Catalan 2014).

Implantable muscle recording

Surface recording of EMG signals for prosthetic control is limited by the variability of the interface between the electrode and the skin, and imprecision of the recorded signal due to cross-talk and other artifacts. To address these limitations and improve the precision of myoelectric recording for prosthesis control, the Alfred Mann Foundation developed and deployed implantable and fully wireless EMG electrodes (Pasquina 2014; Merrill 2011). These Implantable Myoelectric Sensors (IMES®), are cylindrical devices with a very small footprint (2.5mm by 16mm) that, when implanted inside muscle tissue, can accurately sample multiple channels of EMG and report the resulting values over a wireless link to receivers outside the body (Pasquina 2014). Epimysial electrodes are another type of muscle sensing electrode implanted on the surface of the muscle belly (sewn to the muscle casing) and have been widely used in humans, commonly for functional electrical stimulation and more recently for neuroprosthetic control (Ortiz-Catalan 2012, 2014).

The IMES system has seen active development and recently a first-in-human demonstration, wherein eight IMES units were implanted in eight different muscles of the residual forearm of a subject with trans-radial amputation. The subject reported satisfaction

with the system and a number of qualitative gains over his previous myoelectric control; he further reported the ability to effectively and intuitively use IMES to perform a number of functional tasks with his robotic prosthesis (Pasquina 2014). This demonstration shows great promise, and, while preliminary, suggests a number of fruitful combinations with other innovations such as targeted reinnervation (described above) and advanced pattern recognition approaches (described below). The estimated lifespan of IMES units is suggested to be upwards of 80 years (Merrill 2011). If successful in long-term deployment, IMES paves the way for significant gains in both the usability and functionality of robotic prostheses, including easy donning and doffing of prostheses, simultaneous control of multiple joints and greater dexterity in the control of individual actuators.

Peripheral nerve recording and stimulation

Direct communication with the peripheral nervous system has been investigated through the use of implanted intra-neural electrodes and nerve cuff approaches. Studies in amputee subjects using longitudinal intrafascicular electrodes (LIFE) (Rossini 2010), transverse intrafascicular multichannel electrodes (TIME) (Raspopovic 2014), the Utah Slant Array (which penetrates the nerve fibers bundles) and the Flat Interface Nerve Electrode (FINE) have all shown ability to use sensory input feedback with simultaneous motor control in amputee subjects. Research is ongoing to demonstrate long-term viability of the implants but some have been in place as long as 2 years. These investigations are exciting advances that will likely lead to significant changes in the approach to sensory

motor restoration in the future through the ability to directly tap in to neural control and feedback signals.

Advanced control paradigms

Pattern Recognition

Pattern recognition, an approach to classifying a user's intended motions based on learned patterns of myoelectric activity, has seen recent commercial availability. However, there is significant ongoing work underway to improve the interpretation of myoelectric patterns from users (Castellini 2014; Micera 2010). Recent work includes approaches to the simultaneous pattern recognition control of multiple functions and to increase the robustness of pattern recognition to the rigors of daily life—for example, decreasing the sensitivity of classifiers to the position of the residual limb, other simultaneous bodily activities, or to ongoing fatigue (Scheme and Englehart 2011; Scheme 2013; Hargrove 2013a, 2013b). Another very active area of ongoing research is supervised adaptation (by way of pre-specified or intermittent re-training of a pattern recognition system) and unsupervised adaptation (automatic re-training or updating of a pattern recognition system, without the need for specific training periods) to allow a device to modify its operation to new users or new situations (Sensing 2009; Tommasi 2013). Continual, real-time adaptation of pattern recognition is considered to be a major area of clinical interest (Scheme and Englehart 2011), as are ways to better structure the training of pattern recognition systems. For the interested reader, Castellini et al. (2014) provide a comprehensive review

of ways in which pattern recognition is being enhanced to better leverage sEMG for more precise and user-friendly pattern recognition.

Machine learning, intelligent systems, and shared control

Pattern recognition represents one form of autonomy and machine learning on the part of a robotic prosthesis (Oskoei and Hu 2007). The prosthetic control system is observing complex patterns from the user and making moment-by-moment decisions as to which of the many functions on their device the user will control. In this case, the control system's choices are based on learned predictions of a user's motor intent. Pattern recognition and other forms of autonomy have been demonstrated to be desirable for the users of robotic prostheses (Castellini 2014). One simple example of autonomy now deployed in commercial systems is slip detection for grasping, such that a system will hold on to an object even when a user is not attending to their grasp. These examples suggest how even modest intelligence on the part of an assistive technology can help support the user of that technology. More advanced examples include research into ways that a prosthetic hand could automatically pre-shape its grip to accommodate specific objects in an environment (as reviewed in Castellini 2014), or how a robotic system may in fact build up knowledge about the user in the form of predictions and control policies to better inform the simultaneous control of multiple movements or functions (Pulliam 2011; Pilarski 2013a; Pilarski 2013b; Edwards 2015).

Taken as whole, there is a growing body of evidence to suggest that intelligence and agency on the part of a robotic prosthesis will extend the potential abilities of a prosthetic

user (e.g., the idea of a prosthesis-human partnership developing shared *communicative capital* through ongoing interactions, as proposed by Pilarski, 2015). More specifically, increased and more general machine intelligence in the control systems of robotic prostheses is expected to greatly increase the robustness, adaptability, and situational awareness of current systems to better meet the needs of users (Castellini 2014). This hypothesis remains to be rigorously proved or disproved.

Next-generation robotic prostheses

New physical and computational interfaces will form a keystone for improving the life of the next generation of prosthetic users. One principal reason to expect improvement is a corresponding surge in advanced robotic prostheses that vastly exceed the functionality of their predecessors but are not yet at the point of commercial readiness (TRL 7 and below). The intent of this section is to briefly describe the capabilities and highlights of some of the most notable advanced bionic limbs. While the summary is by no means complete, the reader will gain an understanding of the potential for future improvements in form, function, control, and feedback that evolves from game-changing new technology.

As one recent example, researchers from the University of New Brunswick and the Rehabilitation Institute of Chicago (RIC) have demonstrated the RIC Arm: a small, lightweight, modular prosthetic arm and hand solution with multiple actuators (TRL 7-8) (Sensinger 2014). By incorporating custom motors tuned to the requirements of daily life, the RIC Arm is designed to be suitable for use by a 25th percentile female, as opposed to the 75th percentile male population that is the target of most prostheses. This provides the first multi-function prosthesis of hopefully many alternatives, to further increase the

opportunities for prostheses that are personalized in all aspects to their different users—a major change from one-size-fits-all solutions of previous decades.

A representative example of one of the most advanced engineered limbs is the Modular Prosthetic Limb (MPL) developed by the Applied Physics Laboratory of Johns Hopkins University as part of the Defense Advanced Research Projects Agency (DARPA) Revolutionizing Prosthetics Program (Johannes 2011; Bridges 2011; Ravitz 2013). Now in its third generation, the MPL limb is arguably the most dexterous upper-limb prosthesis developed to date. The hand of the MPL is actuated using small motors placed within the palm and fingers, and involves multiple contact sensors, thermal, capacitive sensors, and other sensors (>100 sensors in total) located throughout the fingers, hand, and arm; the hand of the MPL also features computing hardware and embedded control electronics for the entire arm (Johannes 2011; Ravitz 2013). This configuration enables independent finger flexion and extension, finger deviations from their midline, thumb flexion and rotation. A third-generation MPL is shown in Figure 4-1d and Figure 4-5. In addition, the MPL features three-degree-of-freedom wrist actuation, elbow flexion and extension, humeral rotation, and two axes of shoulder motion. As such, it provides a first approximation to the degrees of actuation in a biological limb, and a viable recording source for a diverse set of sensory feedback modalities.

<FIGURE 4-5 HERE>

Another powerful new DARPA limb technology is the DEKA Arm (Resnik 2013). This system provides a number of actuators that greatly exceeds those of commercially deployed prostheses, and, while featuring less actuation than the MPL, it is

an example of a robust system that is suitable for use in deployed end-user environments; it has been through aggressive testing in military and civilian applications (TRL 8-9). The DEKA Arm recently saw Food and Drug Administration (FDA) approval in the United States. As such, it is one example of an advanced upper-limb device that is nearing the point of clinical translation to widespread use, though testing is still needed to determine the most effective control modalities for all settings, and other factors affecting user acceptance.

With respect to the lower limb, recent work has demonstrated powered knee and ankle robots with and without TMR pattern recognition control that promise to greatly extend locomotion abilities (Ingraham 2016; Hargrove 2013b; Schultz 2015), and in a high-profile example allowed one subject to climb more than 100 flights of stairs to summit the Chicago Willis Tower. Significant high-profile work on powered lower-limb robots is also being conducted by the team led by Hugh Herr at the Massachusetts Institute of Technology, giving subjects with lower-limb amputations the power to run, to climb, and even return to precise and graceful activities like ballroom dance (e.g., Rouse 2015; Eilenberg 2010).

Advanced robotic prostheses currently in development represent the future of limb replacement—a future where the function, strength, speed, and dexterity of a replaced limb equals or even exceeds that of a lost biological limb. With the advent of non-physiological prostheses (artificial limbs that do not mirror the look or operation of a biological limb), and also supernumerary limbs for users without amputations (Parietti 2014; Llorens-Bonilla 2014), the potential for prosthetic technology to improve lives is vast. As a remaining

challenge to unlocking the power of these system, it will be important to continue to accelerate the state-of-the-art in control and interface technology to keep pace with the potential power of available robotic hardware, and rigorously develop robotic prostheses such that they can be brought to effective function in the daily life of users (TRL 9).

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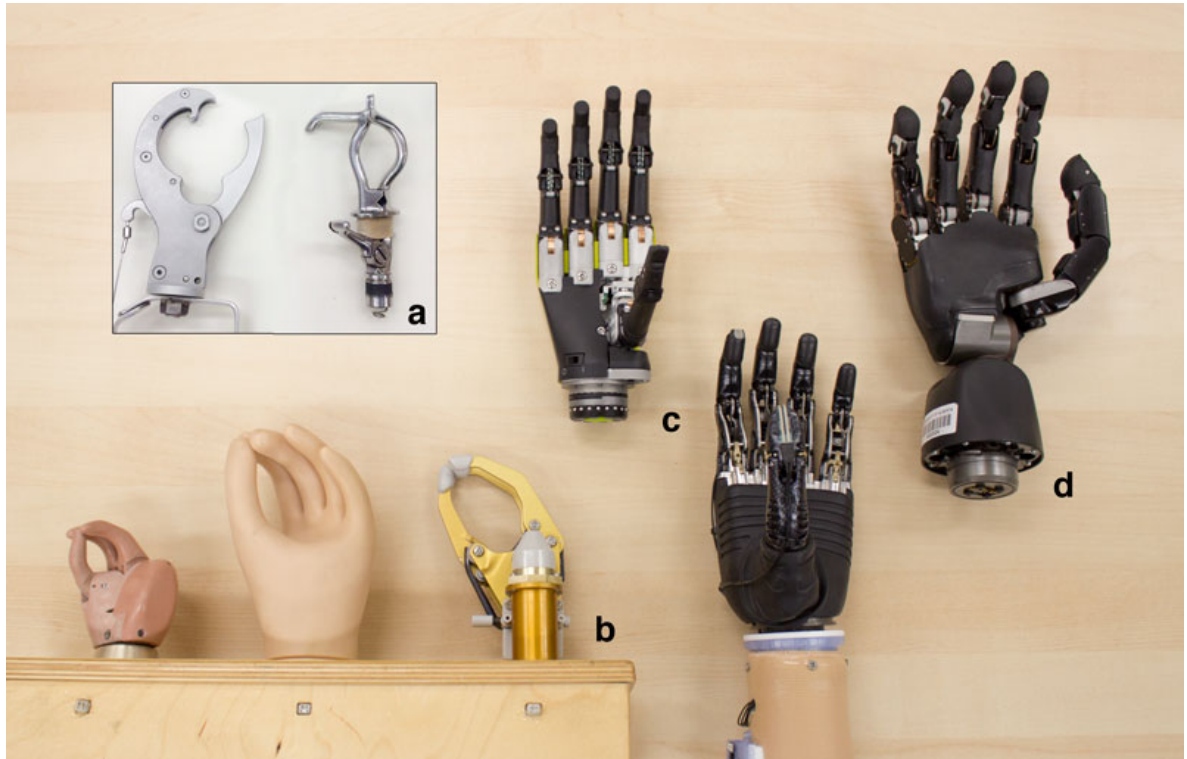


Figure 4-1: An example of electromechanical and mechanical prosthetic hands, including a) common non-robotic, body-powered grippers; b) clinically available single-actuator robotic grippers; c) clinically available robotic grippers with multiple grasp patterns and fingers that can flex and extend independently; d) research prosthetic hand and wrist with diverse sensor systems, three-axis wrist motion, and dexterous finger and thumb actuation (Modular Prosthetic Limb v3.0).

ALT-TEXT: “Powered prosthetic hands differ in form, function, and capacity, and represent significant potential improvements over purely mechanical prostheses.”



Figure 4-2: An example of lower-limb electromechanical and mechanical prostheses, including a) disassembled microprocessor-controlled robotic prosthetic leg, and a clinical prosthetics workbench demonstrating b) an assembled prosthetic knee and ankle robot; c) an assembled knee-only prosthesis; and d) a purely mechanical, non-robotic prosthetic foot.

ALT-TEXT: “Powered lower-limb prostheses for persons with an above-knee amputation are typically comprised of a powered knee with a fixed or mechanically actuated ankle, though some systems also provide powered ankle movement.”

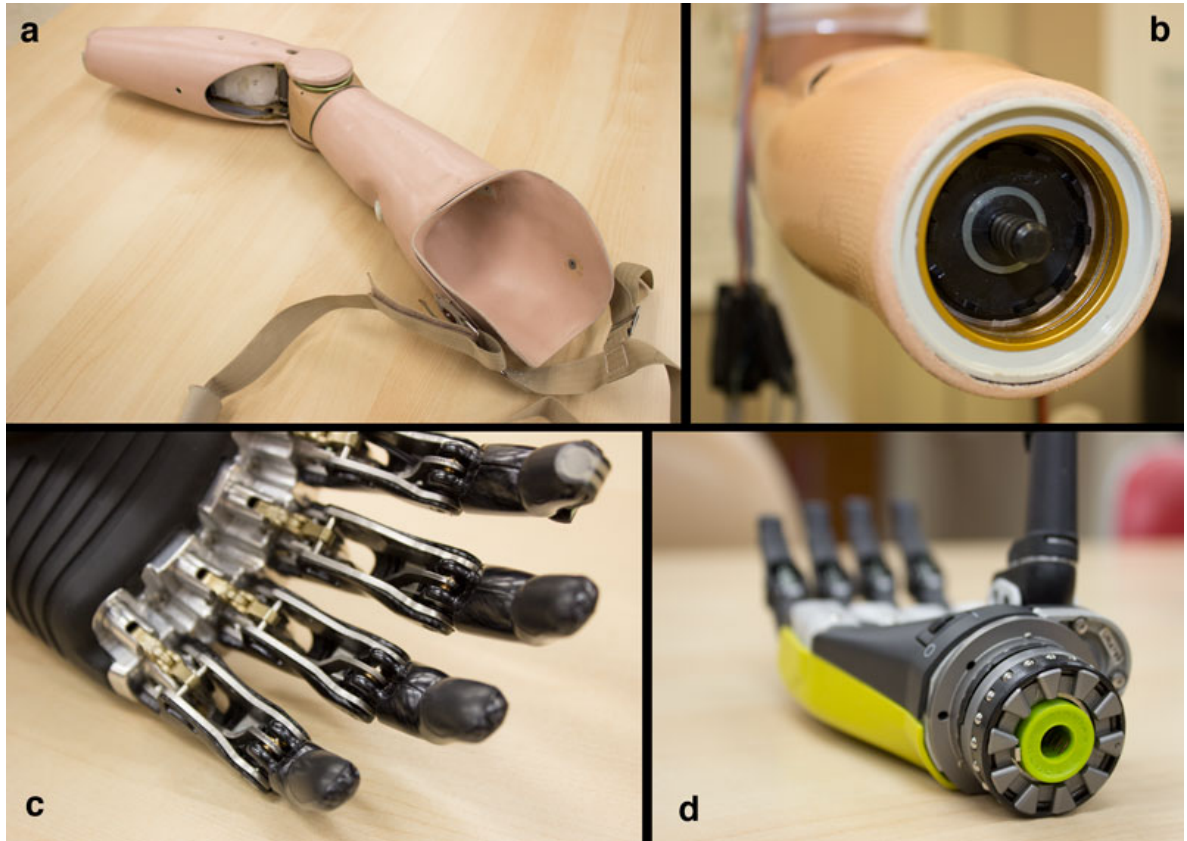


Figure 4-3: Examples of prosthetic chassis, actuators, interconnects, power, and socket systems. a) Assembled prosthesis with a powered elbow attached to a socket and harness; power system and battery are visible in the hollow to the left of the actuator. b) Interconnect system at the terminal end of the prosthesis's forearm, connecting power and control signals to a robotic hand. c) Small actuators and linkages that move the individual fingers of a robotic hand to provide multiple grasp patterns for the user. d) A different robotic hand, also capable of multiple grasp patterns; interconnect on the displayed end mates with interconnect shown in b).

ALT-TEXT: “Prosthetic robots are modular in nature, and rely on a series of interconnected mechanisms and subsystems that must be assembled into a complete system that can attach to, interface with, and extend the abilities of the human body.”

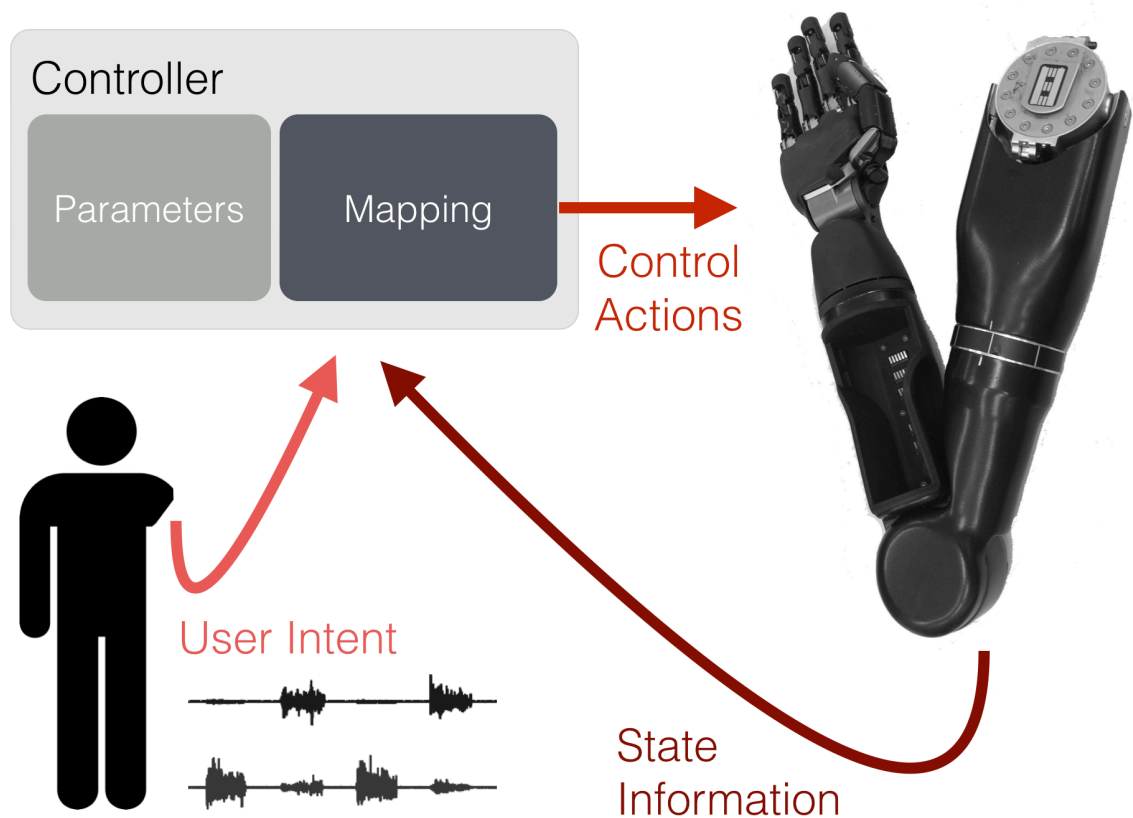


Figure 4-4: Control interactions between a user and their prosthetic device. User intent is measured from the body, for example using myoelectric recording (labeled “user intent”). These signals are passed to a control system, in many cases along with information from the robot’s actuators and state (labeled “state information”). Informed by electrical and software parameter settings and calibration values, the control system forms a mapping from these input signals to control actions for the robotic limb.

ALT-TEXT: “Control of a robotic prosthesis involves interactions between robot actuators, a control system, and a user, where user intent is interpreted by the control system, along with feedback from the actuators, and mapped to produce new control commands for all actuators as modulated by a set of fixed or variable control parameters.”



Figure 4-5: Third generation modular prosthetic limb (HDT Global), with battery compartment in forearm and showing the following actuators: shoulder (two actuators), humeral rotator in the middle of the upper arm, elbow, wrist (three actuators), and dexterous hand (independent finger and thumb actuation). This system, as shown, would be connected to the harness technology for someone with a shoulder disarticulation, but can also be broken down into modules for other levels of amputation and socket integration.

ALT-TEXT: “Next-generation prosthetic limbs promise to provide many if not all of the motor functions of a biological human limb, and also provide a diverse set of sensations that could be communicated to the user.”