Revolutionizing Prosthetics 2009 Modular Prosthetic Limb–Body Interface: Overview of the Prosthetic Socket Development

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The Revolutionizing Prosthetics 2009 program is a Defense Advanced Research Projects Agency task targeted at developing a neurally controlled upper-extremity prosthetic limb for the wounded warrior population that would incorporate and emulate, from the shoulder joint through the fingertips, the full 22 degrees of freedom possessed by the biologic arm. This review will give a brief background of upper-limb prosthetics and the impact currently insufficient technology has on both the military and civilian sectors. It then highlights the most novel socket concepts, prototypes, and socket accessory tool designs developed to support the Revolutionizing Prosthetics 2009 Modular Prosthetic Limb and meet the body interface challenge unique to the Modular Prosthetic Limb. All of the technology developed also has potential to define directions of future prosthetic attachment and overall body interface standards in prosthetics as well as man–machine interface technology.

BACKGROUND

In 2008, more than 800 amputees returned from the Operation Iraqi Freedom/Operation Enduring Freedom conflicts. Of those, 20% were upper-limb amputees. The most recent statistics by the Army Medical Department reports in June 2011 indicate that there have been more than 1245 amputees from the "war on terror" operations, 237 (or 19%) of which are upper-limb amputees. Included in those numbers are the 470 amputees who have sustained amputation of more than one limb.[1] In the civilian sector, statistics are not as clear, and it is hard to get reliable numbers on how many upper-limb amputees there are at each level and what caused those amputations. According to a report of amputee statistics generated through a collaboration of the Amputee Coalition and the Johns Hopkins Bloomberg School of Public Health, there are approximately 185,000 amputations per year, but the study did not distinguish between upper-limb and lower-limb amputation sites. Several other studies assert that, each year, between 14% and 16% of total major amputations are upper-limb amputations. From the average of the data sets, we can assume that if 15% of amputations are upper-limb amputations, and if there are approximately 1.9 million people in the United States living with major amputations, then there are more than 266,000 upper-limb amputees in the United States.[2–4]

Each year, vascular insufficiency and increases in complications from diabetes drive increases in the number of lower-limb amputees and the amount of technology needed to serve them. At the same time, the technology to support upper-limb amputees historically lags. Prior to the start of the Defense Advanced Research Projects Agency (DARPA) Revolutionizing Prosthetics 2009 (RP2009) program, the best upper-limb prosthesis for shoulder-level amputees possessed anywhere from two to four actively controllable degrees of freedom. For example, the shoulder alone has three: internal/external rotation, flexion/extension, and adduction/abduction. If you break down taking a sip of your morning coffee, you will find that what is effortless with your own arm would be quite different if you had to think out each motion individually.

- Shoulder—forward
- Elbow—bend
- Forearm/wrist—rotate the thumb up
- Hand—open around the cup
- Hand—close slowly
- Wrist—abduct to keep cup level
- Elbow—lift without spilling
- Head—move forward to the cup
- Wrist—rotate closed hand downward to tilt cup to mouth
- Sip[5]

Because of the level of thought required to perform simple actions with readily available technology, single-side, upper-limb amputees often chose to not use a prosthesis and relearn common tasks with their remaining side, which is often their previously nondominant side. Studies show that 22–30% of all upper-limb amputees with upper-limb loss on one side, unilateral upper-limb loss, completely abandon use of the prosthesis.[6] The most frequent reasons for abandonment are:

- Lack of effective control
- Discomfort
- Weight
- Appearance

Use of the opposite hand and arm may not seem like a bad solution, but the result is overuse injury to the remaining, intact limb and inability to perform most bimanual tasks without additional aids. Leading up to the RP2009 project, manipulation of items with a prosthesis was most commonly performed using a pincher-style, gripping "hand" often called a terminal device or end controller. The terminal devices were controlled manually with

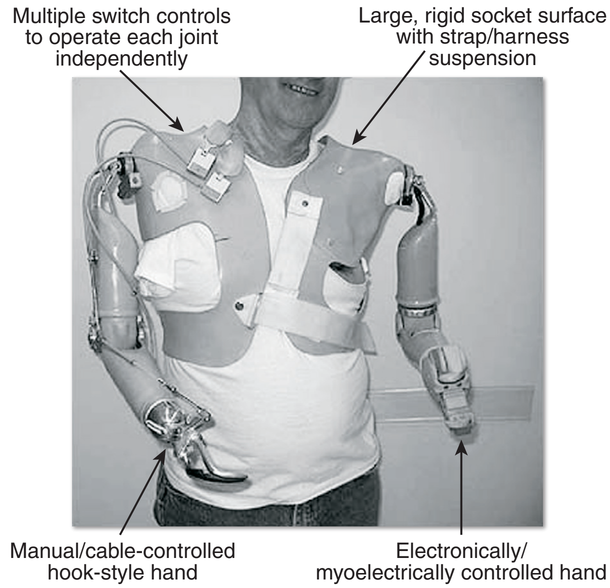

Figure 1. Industry-standard shoulder-level prosthetics with multiple control and device options.[7]

harness-driven, body-actuated cables or electronically with sensors on the surface of the skin over key muscle groups that picked up on electrical output from muscle contraction. Such electronic control is called myoelectric control, and the signals detected on the surface of the skin are called surface electromyography (EMG) signals. Sockets suspending the prosthesis were restrictive and covered a large surface of the remaining limb. Suspension of the socket with a harness system required tightening around the whole intact opposite shoulder area or forming the socket with tight, rigid extensions that pinched over the elbow and restricted forearm rotation. This harness system then resulted in a trade-off between control of the prosthesis and comfort. Softer, suction-

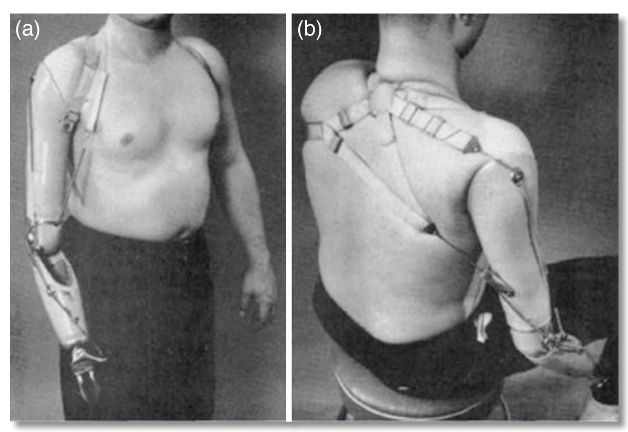

Figure 2. Common body-controlled upper-arm-level prosthesis with a harness providing manual cable control of the elbow, a pincher-hook-type controller/hand, and strap suspension of the total-coverage, rigid prosthetic socket. In panel b, note the harness tightness required to provide control and suspension.

Figure 3. Forearm-level silicone prosthesis with a flexible, passive-suction socket; a minimal, rigid frame; and a nonmoving, anthropomorphic hand. No active control of the hand is included in this device. Weight and appearance are traded for control.[8]

suspended sockets traded control for comfort and ease of putting on or taking off the device. Generally, desires for cosmetic appearance were traded for reduced function, whereas desires for increased function and control resulted in increased weight of the prosthesis, decreased comfort, and decreased cosmetic appearance. Examples of common prosthetic socket systems, controls, and joint components can be seen in Figs. 1–4. Hybrid body/myoelectric-powered prosthetic limbs at the shoulder amputation level are shown in Fig. 1. Figure 2 shows a body-powered upper-arm prosthesis with strap suspension and control and a pincher-hook-style hand or prehensor. Figure 3 represents a passive or nonfunctional forearm socket with a low profile, lightweight socket, and anthropomorphic appearance. Multiple industry standard end devices used as hands or task-specific manipulators are shown in Fig. 4.

Although these pictures by no means show all of the available interface options, they do give an idea of the current common technology. Hands with more joint motion have become available but are limited in what they can do and how they can be controlled. The dexterity of these devices has still fallen short of imitating the complexity of the human hand. At the same time, upper-limb socket fit and function have not been optimized to control more dexterous limbs and their associated forces comfortably.

INTRODUCTION

DARPA's requirements for the limb development targeted dramatic improvement to the most pressing issues in current technology—function, control, comfort, and appearance—by requiring that the RP2009 prosthesis have 22 degrees of freedom, the same as the native limb from fingertip to shoulder, and requiring that the limb be naturally controllable through neural signals from the wearer. The new limb would have to make common complex motions like taking a sip of coffee more natural and less taxing and enable more complex motions of daily living and advanced pursuits to be possible. Ultimately, the new limb would need to eliminate the need to make trades between function, comfort, control, and appearance because all are essential to returning to a fully independent lifestyle. The objectives of RP2009 were split into two phases: a 2-year Phase 1 that would focus on the advanced robotics of the limb itself and a 2-year Phase 2 that would focus on demonstrating real-time neural control of the limb and continued limb development. Socket development was part of the second phase of the program. Once the Modular Prosthetic Limb (MPL) was able to demonstrate the dexterity required and functionality based on neural signals, it became the goal of the Socket Development Team to enable this technology to be wearable and controllable by the amputee end user.

As stated earlier, the challenge of developing a comfortable prosthetic socket that also provided the wearer

Figure 4. Examples of common, but not all, industry standard wrist and hand components that enable degrees of freedom in prosthetic devices. Control of these is both manual and electronic but mostly operated in series. Clockwise from upper left: Hosmer split hook/body-powered terminal device; Otto Bock myoelectric sensor hand with electronic wrist rotator; Hosmer passive rotation quick-disconnect wrist (not electric); TRS Inc. voluntary closing terminal device.

intimate control of the attached prosthetic device was not a unique challenge but rather one shared across the field of prosthetics, especially for upper-limb amputees. The reason for the challenge is the socket, or body interface, of an external prosthetic device is more than just the point of attachment of the mechanical parts that are being worn to restore the function of a lost body part. Each level of amputation, forearm, upper arm, and shoulder, has different load bearing, suspension, comfort, and control challenges. Each level also has different directional forces and shear that are created by the attached prosthesis moving relative to the socket–body interface. Factors that the prosthetic socket design is specifically trying to control are suspension or secure attachment to the body, distribution of total weight, distribution and stabilization of dynamic forces, and heat dissipation. On top of those overarching factors, the condition, shape, and strength of the remaining limb of each individual amputee are always unique factors that are magnified in the blast injury amputees we were designing for as a preliminary target group.

Socket development in RP2009 was driven by project-specific requirements unique to the MPL, which included comfort allowing a full 8 hours of continuous wear time; stabilizing the larger number and magnitude of force vectors generated by the stronger, more dexterous limb; the weight of the MPL; and finally supporting sensor hardware for the various neural control strategies in targeted locations relative to the amputee's body. For example, surface electrodes need to stay in place against the skin without gapping or shear or the signal will be lost. The signal-receiving antenna for implantable electrodes must incorporate in the socket wall and be stabilized over the implanted electrode or the signal field will be interrupted and the signal lost. In meeting program requirements, socket development would ultimately help raise the standards of upper-limb socket design in upper-limb prosthetics as a whole.

Industry leaders in prosthetics were consulted throughout the project, but the Socket Development Team was assembled more specifically in Phase 2 and consisted of researchers, engineers, and clinicians from around the country and world, including the Rehabilitation Institute of Chicago, Orthocare Innovations, FlexSys Inc., and Martin Bionics (now part of Orthocare Innovations). The team was led by the team members at APL. Throughout the project, multiple amputees volunteered countless hours with engineers and clinicians at multiple locations to aid in the design of the prosthetic limb and limb systems. The evolution of the limb could not have happened without their input. For socket design specifically, continued support from clinical amputee volunteers Jesse Sullivan and Jon Kuniholm provided real-time feedback on practical wearability and use of the socket design concepts. Kuniholm was also a collaborating engineer on other limb subsystem design teams and was able to give invaluable input as both a wearer and engineering design member. These collaborations were essential to the usability of the socket design.

SOCKET DESIGN AND DEVELOPMENT

Socket design began with evaluation and down-selection of any technology that would meet the needs outlined by program requirements. Any ideas that involved surgical intervention such as osseointegration, the method of direct bony attachment of a prosthesis via a bone and skin implant, bone ostomy, bone fusing, procedures that involve surgical modification of a long bone to make an "L" shape at the end of the long bone to enhance socket suspension, or any designs that required bone-lengthening procedures were the first eliminated as options. All of these procedures were still deeply in the medical research stages and required further research to understand the high percentages of failure and skin infection rates relative to the successes, especially in the exit sites of the osseointegration procedure and particularly in upper-limb applications. Experimental, cutting-edge scanning methods that allowed for variable imaging of the hard and soft tissues and tissue densities of the residual limb were investigated as a way to automate and blend imaging and custom fabrication of the prosthetic socket. This concept was of particular interest because one of the biggest challenges in fitting a prosthetic limb and proper socket design is in shaping the socket to contour around the various tissue densities of the residual limb, bone, muscle, fatty tissue, and skin and to exploit pressure-tolerant areas while maintaining the tissue health of pressure-intolerant areas. Further research in multimodal imaging and custom bioarchitecture of body interface devices, and particularly prosthetics, for any area of the body was possibly one of the most compelling future research directions identified as a result of the down-selection of socket design pathways.

It was clear that each of these technologies had the highest possible potential for profound improvements to and impact on body interface and socket design, fit, and function, but the clinical risks and time constraints with each were beyond the scope of the socket development or the body interface strategy for this particular project. Next, one-size-fits-all adjustable concepts were eliminated. In blast injury and also many traumatic limb amputations, pervasive bony overgrowth and skin grafts made socket designs that were able to be customizable an essential feature. A project-specific consideration that impacted the socket design path and planning was the continued evolution of the limb and neural control system, which created a dynamic nature in the requirements driving socket design. A singular socket design might have resulted in a great prototype but not neces-

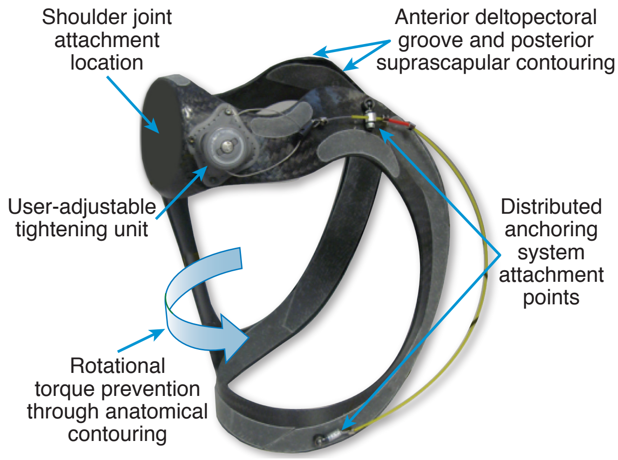

Figure 5. Shoulder-level microframe base socket.

sarily one that could keep up with the dynamic needs of the program and specifically the detailed evolution of the MPL functionality, which directly impacted socket design details. Any design strategies had to be adaptable to both variable patient conditions and levels of overall health as well as limb design variables.

A decision was made to have a modular socket development plan with three novel base socket designs that used available materials in new ways that enabled comfort, lightweight structural support, flexibility, and modularity for fitting many MPL and amputee wearer scenarios.

The following base socket concepts resulted and moved on to prototype-level development:

1. Shoulder microframe socket (Figs. 5 and 6)
2. Silicone upper-arm socket with embedded, flexible surface sensors (Fig. 7)
3. Forearm hybrid silicone and microframe socket, also adaptable for use on the upper arm (Fig. 8)

Each of these base socket designs met a challenge specific to a given level of upper-limb amputation.

At the shoulder level, a primary need is to minimize surface area contact to facilitate natural evaporative cooling and reduce pressure points without losing mechanical advantage and force transfer capabilities. Our solution was to use a lightweight shoulder-specific microframe structure that acts as the load-transferring and structural support as seen in Fig. 5. Unique to the shoulder-level socket was the use of elastic, breathable sport fabric as a full surface-bearing suspension system instead of a rigid, resin-based socket. In Fig. 6, the fabric is stretched over the microframe and a rotary system tightens a single arching cable that pulls the whole fabric structure tighter, keeping a wide distribution of forces and virtually no pressure points. The use of a minimal frame to support a fabric mesh socket wall allowed the skin to breathe and temperature to be regulated at the skin surface even though the overall support structure covered a larger surface area than traditional laminated sockets like the one in Fig. 1. The minimal or microframe shape could be adapted to various body shapes and shaped with projections on which to mount neural hardware without compromising comfort, support, and breathability.

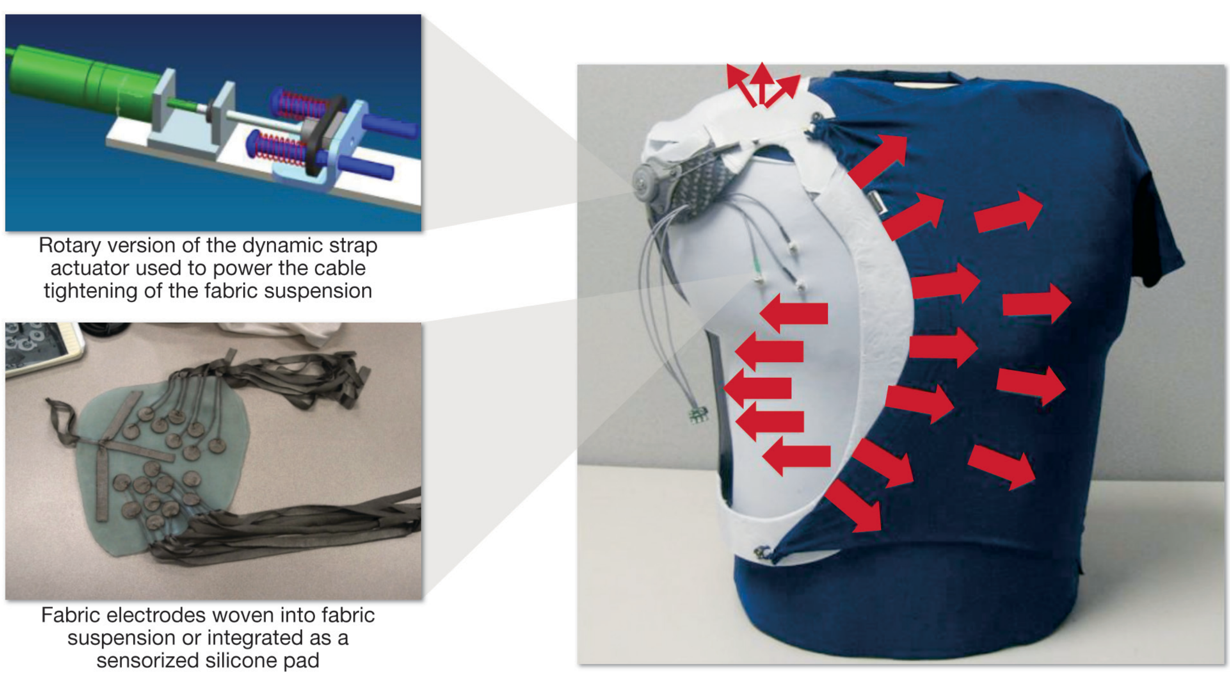

Figure 6. Shoulder-level base socket with full fabric suspension. Red arrows show the directions and distribution of forces produced by the total-surface, breathable fabric instead of individual straps. Exploded views point to where socket tools could be applied to enhance base socket features and functionality.

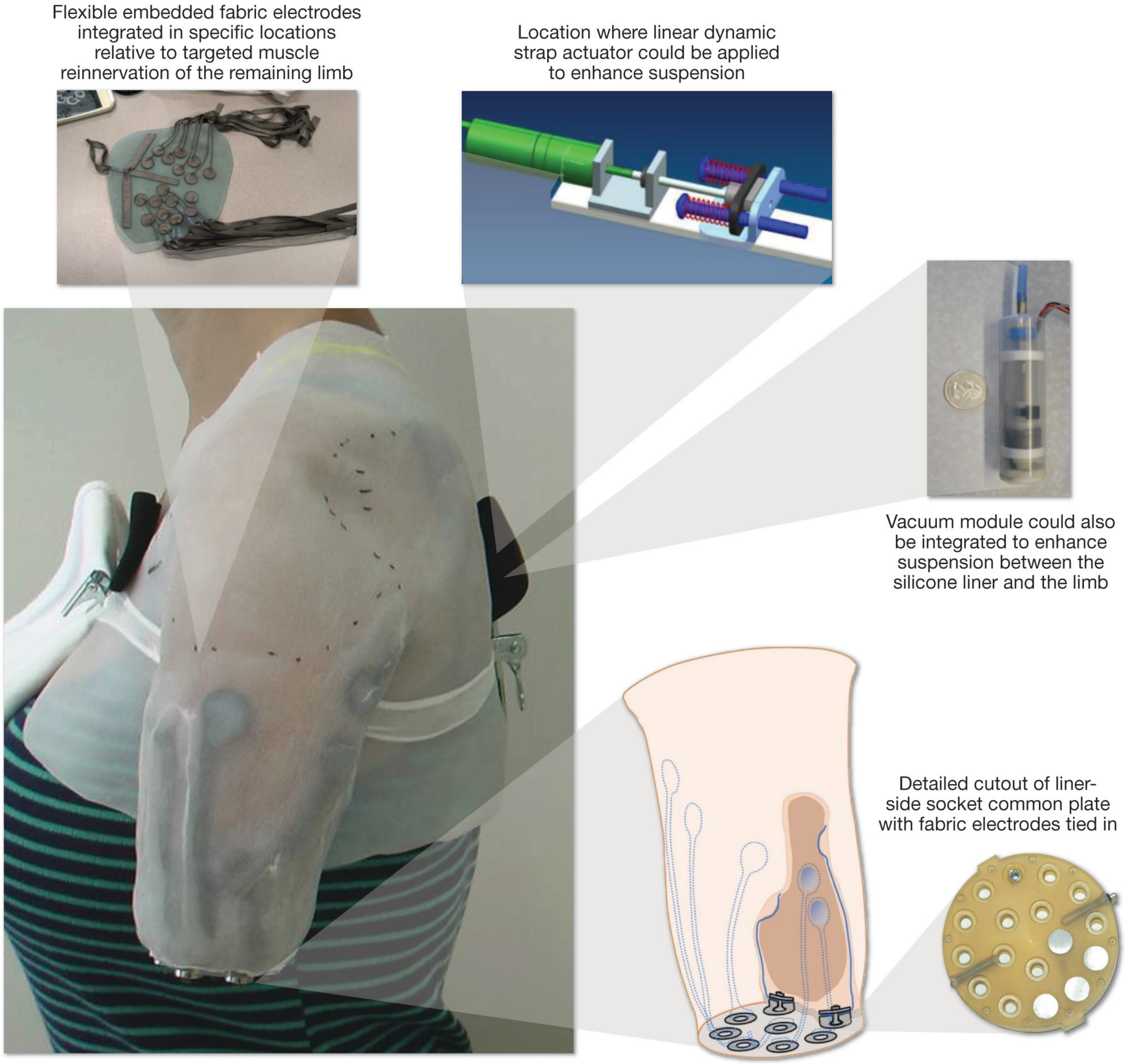

Figure 7. Upper-arm all-silicone base socket with embedded flexible fabric electrodes and a socket common connector plate. Areas of other socket tool use are also highlighted.

At the upper-arm level, the need was to find a way to support the high dynamic loads in axial and rotational directions based on the general cylindrical shape of the upper-arm residual amputated limb while allowing for full shoulder range of motion of the still-intact shoulder joint and comfortably integrating signal-receiving hardware. This was perhaps the most challenging level of amputation to design for because there was a lot of remaining anatomic joint motion at the shoulder that needed to be unencumbered and all but the shoulder joint and humeral rotator of the prosthetic limb to support and suspend. The shape of the residual upper arm also presents a challenge in its relatively uncontoured cylindrical profile and minimal total surface area. The integration of multiple sets of surface electrical muscle-control sites, known as EMG sensors, was especially challenging. Our solution, shown in Fig. 7, was an all-silicone, double-walled socket with integrated fabric electrodes with a common distal plate for wire-free EMG signal transmission from socket to limb. Traditionally, metal, domed electrodes were used for surface EMG reception and added to a silicone socket but in a way that required individual wiring of each electrode pair and a raised profile that became increasingly uncomfortable to the wearer as the number of electrode pairs increased. Also, the electrode connections were rigid and often broke from wear and tear as the prosthesis was taken on and off. The all-silicone socket concept provided a totally flexible socket to improve comfort and range of motion at the remaining shoulder, made maximal use

Figure 8. Hybrid base socket with microframe and silicone inner socket. Socket tools that could be used to enhance the base socket are shown above.

vous system control. In order to test the limb and socket system on patient volunteers and show practical application of the limb for a wide variety of users, improving surface electrode (EMG sensor) integration was a focus of socket development. The first part of improving surface electrode strategies beyond current technology was the use of flexible fabric as both the electrode body and wire.

The flexible embedded fabric electrodes tool is the result of using available materials in a novel application. Conductive fabric could be cut into any shape with a long wire "tail" and embedded in custom silicone liners or into pieces of silicone to form conformable conductive patches. This opened the door to a greater number of electrode

of available surface area, and supported the inclusion of multiple neural control strategies.

The forearm base socket concept was a hybrid of the first two designs with a flexible microframe and silicone socket material. The flexible microframe flexed to pass more comfortably over the elbow joint during application of the prosthesis and then was held secure by the silicone socket that folded over top. This enhanced comfort and stability but maintained surface area for inclusion of neural hardware. Figure 8 shows examples of this socket system and how it would look at the forearm level and, in Fig. 9, adapted to the upper-arm level.

At the same time that the base socket designs were being developed, the socket team developed a set of novel components that would serve to further enhance the base socket design and meet the full range of evolving program requirements. These accessory components were termed socket tools and included:

- Flexible embedded fabric electrodes
- Common socket connector
- Dynamic strap actuator
- Vacuum control module

Each tool was an individual component and could be added singularly or in multiples to any given base socket design to further enhance suspension, comfort, support, and control signal fidelity.

As stated above, the socket designs supported neural system development and neural control, from noninvasive strategies all the way up to fully invasive central ner-

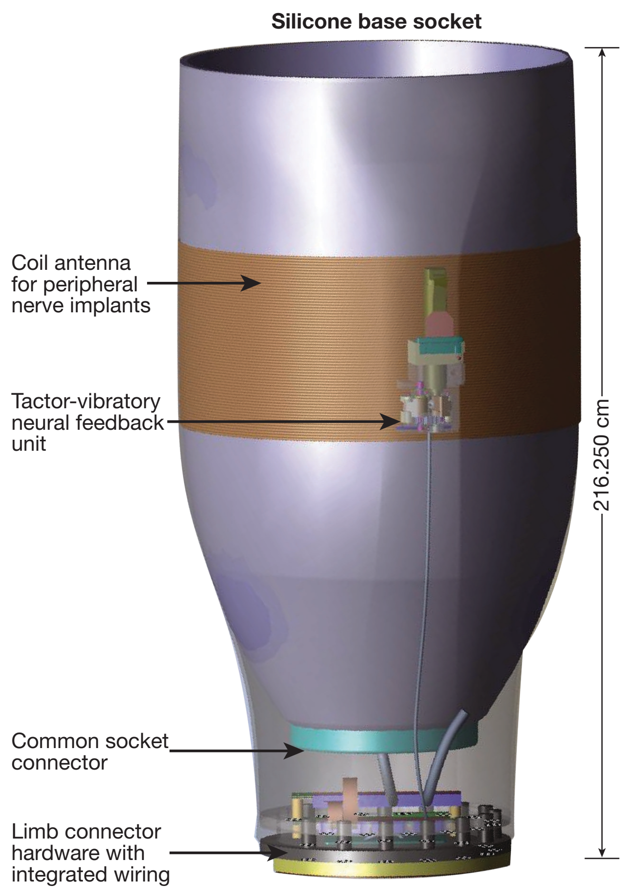

Figure 9. Integrated upper-arm base socket concept for higher-level neural hardware.

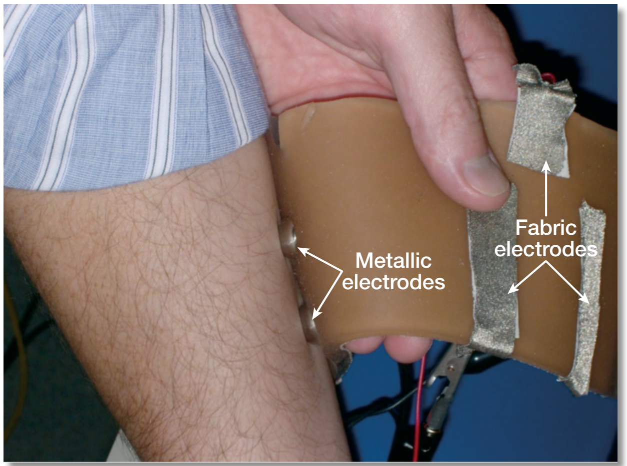

Figure 10. Comparison of standard metallic domed electrodes and novel use of embedded flat conductive fabric electrodes.

pairs per area, a flat, comfortable profile for the wearer, and full, long-term flexibility of the electrode wire junction during movement and application of the limb to the body. This alone was a huge advancement from rigid, domed electrodes with soldered wires that had to be connected individually, that often broke at the junction between electrode and wire, and that were often uncomfortable, especially when large numbers of electrodes were needed. Figure 10 shows the difference between the domed electrode profile and the flat fabric material. A full array of flexible embedded fabric electrodes and leads is shown in Fig. 11. The use of conductive fabric as a surface electrode strategy in prosthetic applications was shown to be feasible for integration in silicone as well as other materials and fabrics. This made it a key tool in enhancing all three levels of socket base design.

The next tool was the common socket connector. This component was a completely novel design developed at APL in order to have a single location for the entry and exit of EMG signal electronics from the limb to the socket. This tool was developed to support the flexible fabric electrodes used in the upper- and lower-arm amputation-level base sockets. It was a two-part system that locked together physically and electrically. The first half, shown in Fig. 12a, provided a common integration point or wire harness for all electrode fabric lead termination sites and was embedded in a flexible silicone liner that could be rolled onto the upper or lower residual limb. The second plate, shown in Fig. 12b, included a structural and electrical interface and was designed as part of a structural piece connected to the actual limb or base plate in the upper- or lower-limb socket end. The wearer would roll or pull on the first layer of the silicone socket with embedded electrodes and then slide into a second outer socket, locking the two plates together to complete the electrode circuit. The key to this design was the ability to pass the electrical signal without the need to physically connect or disconnect individual EMG leads.

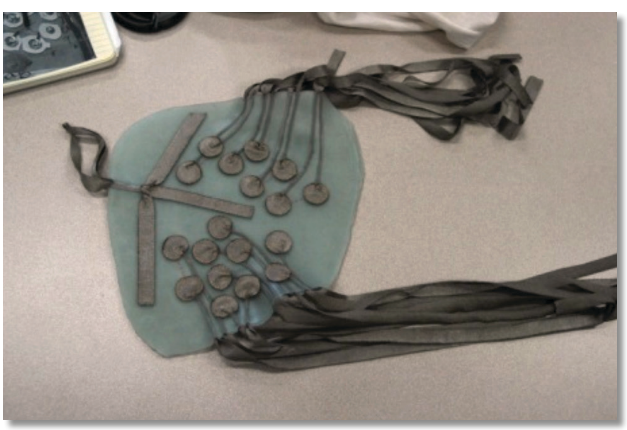

Figure 11. Conductive fabric electrodes with one-piece wire embedded in silicone gel. The fabric electrodes provide surface muscle signal pickup and are fully flexible, have no electrode wire junction, and have a flat profile.

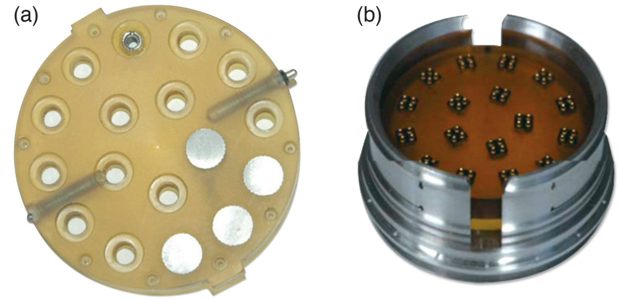

Figure 12. Two-part common socket connector tool to enhance upper-arm and lower-arm socket base designs. Each fabric electrode wire "tail" ties into the base conductive plate (a) at the end of a liner with embedded fabric electrodes. The liner side of the plate a locks to the socket side of the plate (b), and each conductive disk on plate (a) is paired to a spring pin receptor on the socket side of receptacle (b).

The third socket tool was the dynamic strap adaptor (see Fig. 13). The purpose of the dynamic strap tool was to provide additional suspension for the prosthesis, but only when needed because overly tight straps cause discomfort and tissue breakdown. The dynamic strap tool was designed to be integrated in-line with any linear strap type and to have an on-board load sensor that could sense a threshold strand value and tighten the corresponding strap temporarily in response until the load was released. The concept in Fig. 13 is shown as a linear device but was adaptable as a circular form factor with a pancake rotary motor. The exploded views in Fig. 6 point to where the dynamic strap actuator could tighten the fabric suspension system in the shoulder microframe socket in response to manipulating heavy items or performing high-force motions with the MPL. Because it was a standalone tool, the dynamic strap actuator could work with traditional prosthetic strap systems and has

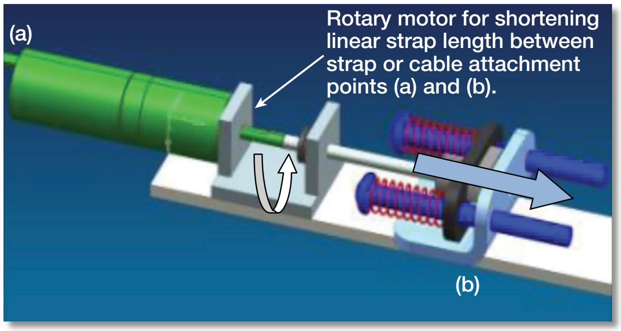

Figure 13. Dynamic strap socket tool for activity-dependent suspension augmentation. The device was conceptually designed in the linear package shown and a pancake motor disk shape package (not shown).

potential to be marketable as a standalone device used to enhance traditional prosthetic strap configurations.

Finally, the fourth accessory tool was the vacuum control module. A vacuum control tool specific to upper-extremity application was developed that could be applied to enhance suspension where silicone inner sockets were used. This tool primarily came into play for upper-arm and forearm socket concepts where the remaining limb is virtually cylindrical. The subatmospheric pressures are known to enhance suspension and improve soft tissue density and blood flow in lower-limb residual amputations, but existing vacuum control units were too large and not specific to the atmospheric pressure standards necessary for upper-limb prosthetic application. The vacuum prototype was designed to work by sensing pressure in the tissue–socket interface. When the negative pressure in the tissue–socket interface rises close to atmospheric pressure, a pump actively evacuates air, creating a greater negative pressure and improving suspension and fit between the biological limb and the prosthesis. Use of vacuum-assisted suspension in prosthetics improves fit, function, and feel between the wearer and the prosthetic limb. The prototype in Fig. 14 is an example of the form factor that could be integrated into the hollow areas of the prosthetic arm frame upper- and lower-limb base socket designs. Around each base socket design in Figs. 6–8, pictures of socket tools are shown in exploded views that point to where they are or could be integrated to fulfill the specific requirements of the MPL for each level of amputation and each individual wearer.

Beyond actual wearable prototypes, conceptual prototypes were developed to show how base socket designs could incorporate the neural hardware for more invasive peripheral and central nervous system signal-acquisition implants. An example of an upper-arm socket with hardware for peripheral nerve implants, a tactor for sensory feedback, and a limb connector that facilitates detachment of the prosthetic limb from the wearer both mechanically and electrically is shown in Fig. 9. Any of the base socket designs could embody aspects of this integration. An actual prototype would have cutouts between areas of embedded hardware to reduce weight and would include a variety of soft and rigid materials to enhance comfort.

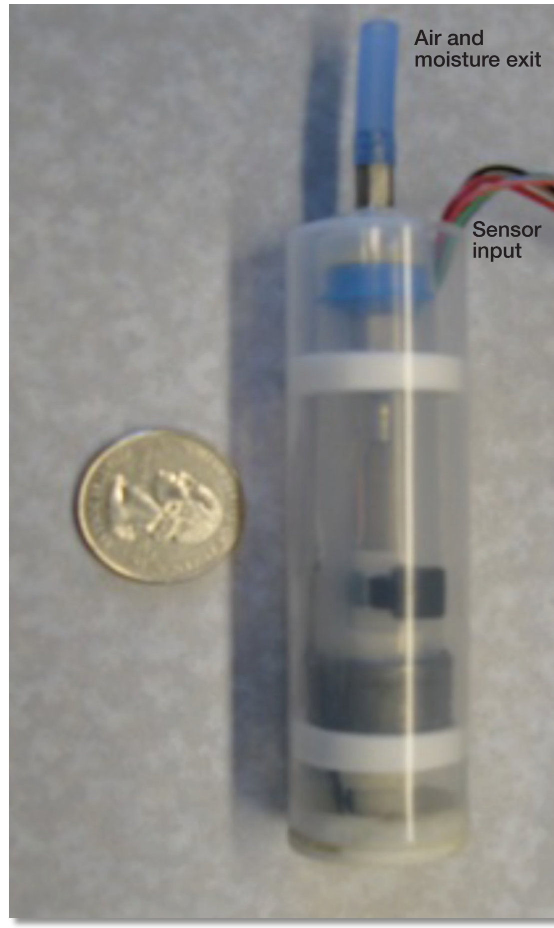

Figure 14. Vacuum control tool for generating negative pressure environments that enhance silicone base socket design suspension. The vacuum control tool was designed in a lightweight, compact, energy-efficient package to pull residual air from between the socket surface and skin surface, creating a suction or negative-pressure environment. This environment increases suspension, reduces sheer, and eliminates moisture. As air leaked into the socket interface, sensors in the system would cycle the pump to maintain set levels of negative pressure, resulting in consistent suspension and control.

SUMMARY

Ultimately, we were able to meet and even exceed the goals of developing and demonstrating via working prototypes a variety of modular socket strategies that could meet the needs of each level of amputation relative to the increased features of the MPL. The benefit of maintaining modularity in socket design concepts cannot be underestimated as a key development point, because it enables continued development of various components without a complete redesign. Additionally, it allowed for the most well-developed base sockets and tools to reach the patient population sooner and not stay locked in the conceptual phase. The shoulder microframe base socket with fabric suspension and the compact vacuum unit have both been introduced to the overarching prosthetic industry by socket team member Jay Martin and Orthocare Innovations. Fabric electrode applications and all-silicone base socket concepts continue to be studied at the Rehabilitation Institute of Chicago. Perhaps the most exciting part of the body interface work that went on in the Biomedicine Business Area during the prosthetic project was not just the great strides that were actually made but the potential for further development that was revealed.

All base socket designs were developed using currently available materials in novel ways, and each design has dramatic potential when paired with future smart material advancements. Conductive fabric can be manipulated to any shape with potential antenna characteristics, Faraday cage-type shielding, and complex sensor arrays if combined with advanced design of signal multiplexing hardware and software. The microframe designs would become more effective if reactive polymer technology could be applied so that they could remain wholly flexible until a certain load threshold is met. There are endless possibilities for the advancement of these initial designs.

The factors that will most influence body interface advances encompassing any man–machine interface, prosthetic, system, or body armor device are likely to be continued miniaturization of computing power, unique battery and power source technology, and smart materials science, specifically responsive materials that can stiffen and soften in response to applied load or current. RP2009 continues to advance its goals in direct neural control in conjunction with the Biomedicine Business Area in a third phase of the project. As those more intuitive control options become a reality, the gap between man and machine is narrowing, and body interface advances is a key part of that integrated system.

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