SPECIAL COMMUNICATION

Advanced Upper Limb Prosthetic Devices: Implications for Upper Limb Prosthetic Rehabilitation

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The number of catastrophic injuries caused by improvised explosive devices in the Afghanistan and Iraq Wars has increased public, legislative, and research attention to upper limb amputation. The Department of Veterans Affairs (VA) has partnered with the Defense Advanced Research Projects Agency and DEKA Integrated Solutions to optimize the function of an advanced prosthetic arm system that will enable greater independence and function. In this special communication, we examine current practices in prosthetic rehabilitation including trends in adoption and use of prosthetic devices, financial considerations, and the role of rehabilitation team members in light of our experiences with a prototype advanced upper limb prosthesis during a VA study to optimize the device. We discuss key challenges in the adoption of advanced prosthetic technology and make recommendations for service provision and use of advanced upper limb prosthetics. Rates of prosthetic rejection are high among upper limb amputees. However, these rates may be reduced with sufficient training by a highly specialized, multidisciplinary team of clinicians, and a focus on patient education and empowerment throughout the rehabilitation process. There are significant challenges emerging that are unique to implementing the use of advanced upper limb prosthetic technology, and a lack of evidence to establish clinical guidelines regarding prosthetic prescription and treatment. Finally, we make recommendations for future research to aid in the identification of best practices and development of policy decisions regarding insurance coverage of prosthetic rehabilitation.

Key Words: Allied health personnel; Amputation; Health policy; Insurance; Occupational therapy; Patient care team; Prosthesis; Rehabilitation.

THERE ARE MORE THAN 1.7 million persons with major limb loss in the United States, approximately 1 in 200 persons, 80% of whom have lower limb loss caused by dysvascular disease.[1] In contrast, upper limb amputation is relatively rare, impacting approximately 41,000 persons, or about 3% of the U.S. amputee population.[2] Most amputees (68.6%) who have lost limbs to traumatic injuries have lost an upper limb.[1,2] Traumatic amputation is the major reason for upper limb loss in the military. As of July 1, 2011, there were 1286 major limb amputations from Operation Enduring Freedom and Operation Iraqi Freedom treated in all U.S. military facilities. Two hundred seventy had major upper extremity involvement (21%) (P. Pasquina, MD, U.S. Army Medical Director, Amputee Program, unpublished data, July 2011), and 250 additional persons lost part of a hand, fingers, or thumbs (as of January 31, 2011) (R. LeMacks, Administrator, Amputee Service, Military Advanced Training Center, Walter Reed Army Medical Center, written communication, February 1, 2011).

To meet the needs of military amputees, the Defense Advanced Research Projects Agency (DARPA) funded development of 2 advanced upper limb prosthetic solutions through the Revolutionizing Prosthetics program. One of the technologies uses neural control, while the other, the DEKA Arm,[a] developed with funding awarded to DEKA Integrated Solutions, uses a "strap and go" system that can be controlled by noninvasive methods. The Department of Veterans Affairs (VA) has partnered with DARPA and DEKA Integrated Solutions since 2008 by conducting research studies to assist in optimization efforts of the DEKA Arm prototype. The ultimate goal of these efforts is to produce a prosthetic arm system that will become commercially available, not require invasive neurosurgery to operate, and be desired and accepted by consumers. In concert with our optimization study, we developed a training protocol for users and participated with DEKA Integrated Solutions in training of more than a dozen clinical personnel, including physiatrists, prosthetists, and occupational therapists.

In this article, we reflect on our experience working with the DEKA Arm at 4 clinical sites during the VA Study to Optimize

List of Abbreviations

ACT	Amputation Care Teams
ADLs	activities of daily living
APOC	Amputation Points of Contact
ASoC	Amputation System of Care
DARPA	Defense Advanced Research Projects Agency
DoD	Department of Defense
FSR	force-sensitive resistor
IMU	inertial measurement unit
OT	occupational therapy
PANS	Polytrauma/Amputation Network Site
PT	physical therapy
RAC	Regional Amputation Center
VA	Department of Veterans Affairs

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the DEKA Arm. We discuss the need for better upper limb prosthetic technology; ramifications of current practices in, and payment for, prosthetic rehabilitation; and describe the VA system of amputee care. Lastly, we make key recommendations to ensure that the potential for improvement in advanced upper limb prostheses, stimulated by the Revolutionizing Prosthetics program, is realized by a broad spectrum of upper limb amputees.

WHY IS NEW TECHNOLOGY NEEDED? UPPER LIMB PROSTHETIC USE AND REJECTION

Many studies show that upper limb amputees are not satisfied with available technology. Many abandon their prostheses or reject using a prosthesis altogether.[3,4] Numerous factors are related to rejection and abandonment such as proximal level of amputation, type of device, poor training, late fitting, limited usefulness of devices, and cost of repairs.[4-10] Rates of abandonment are higher for those with more proximal levels of limb loss.[3] Transradial users are reported to have the lowest rate of rejection (6%), followed by transhumeral users (57%).[4] Persons with shoulder disarticulation report the highest rate (60%).[4] Other factors related to rejection include poor fit/comfort, weight, repeated mechanical failure, unnatural look, and lack of tactile sensation.[6,9,11] Rates of rejection vary for different types of prostheses,[3] with rejection rates of 39%, 53%, and 50% for myoelectric hands, passive hands, and body-powered hooks, respectively.[12] Psychological and psychosocial factors related to rejection include negative reactions of other people, low self-esteem, lack of acceptance of disability, unrealistically high expectations regarding prosthetic function, and poor initial prosthetic experience.[6,7,10,11,13,14]

Despite a high rate of dissatisfaction with prostheses, there are many advantages of prosthetic use such as improved activities of daily living (ADLs) performance in hygiene, grooming, and dressing, as compared with the use of passive prosthetic devices and nonuse.[15] Prosthetic rejection is associated with the development of one-handedness, the presence of residual limb and phantom pain, and limitations in strength, flexibility, endurance, and/or mobility.[6-10] Regular prosthetic use may help amputees avoid future cumulative trauma disorders in the sound-side limb, as well as back and neck pain related to poor compensatory strategies, which are commonly reported in this population.[16,17]

One study[5] reported that most amputees (68%) who have abandoned or rejected prosthetic use may be willing to reconsider using a prosthesis if improvements in technology were made at a reasonable cost. Advances made through the Revolutionizing Prosthetics program have the potential to benefit prosthetic and nonprosthetic users.

ROLE OF REHABILITATION

Several studies[18,19] suggest that prosthetic training, early fitting and functional training, an experienced team, and patient education are critical in increasing the likelihood of prosthetic acceptance. Prosthetic training may double the likelihood of long-term, full-time use,[13] and receipt of early (within 3mo of amputation) and specialized prosthetic training appears to be more effective than nonspecialized or delayed specialized prosthetic training.[20] There is some evidence that persons who are fit and trained with temporary prostheses within 30 days of their amputation have greater rehabilitation success, earlier return to work, and report less amputation-related pain.[11,21] Patients who are fit with a prosthesis within 30 days are less likely to adopt a one-handed habit.[7,20,22,23] One year after rehabilitation, 96% of an immediate specialized therapy group were daily prosthetic users compared with 56% from a delayed therapy group, who averaged 4 months from discharge to the start of specialized rehabilitation.[20]

Our experience with the Gen 2 DEKA Arm suggests that clinicians require extensive specialized training and may need to modify aspects of their approach to address the needs of users of advanced prosthetic devices, like the DEKA Arm. During our study, we had several nonprosthetic users who had been amputees for a long time, who decided to adopt a prosthesis after receiving extensive training in our study. Based on these results, as well as subject feedback, we believe that quality training with an experienced team may be more influential than early training, in eventual prosthetic adoption.

THE REHABILITATION PROCESS

Rehabilitation after traumatic limb amputation can be separated into 4 phases: acute postsurgical, subacute preprosthetic training, basic prosthetic training, and advanced long-term rehabilitation.[18,24] The length of basic prosthetic training depends on amputation level, prosthesis complexity, functional needs, learning ability, and motivation.[7,20] There is no clear consensus on the amount of prosthetic training upper limb amputees should have. The VA and Department of Defense (DoD) share similar guidelines in the treatment/rehabilitation for lower limb amputees[25]; however, there are no official policies on frequency and timeline of upper limb amputee rehabilitation. The DoD recently developed and published a plan for occupational therapy (OT) for the polytrauma casualty that addresses specific issues for upper limb amputees, goals and treatments unique to unilateral and bilateral amputees at each level, but does not make recommendations for duration or frequency of training.[26]

Existing recommendations for duration, frequency, and intensity of training vary. Atkins[18] suggested daily 1- to 2-hour sessions to learn to use a body-powered prosthesis, estimating that transradial amputees require 5 hours; transhumeral, 10 hours; amputees with shoulder disarticulation, 12 hours; and bilateral upper limb amputees, 20 hours. Dakpa and Heger[7] reported that a transradial amputee can learn to use a body-powered device in 2 to 4 weeks, with 3 to 5 weeks needed for a unilateral transhumeral amputee, but they did not specify training intensity. Others report that duration and intensity of training vary with patient and functional goals. Persons who have sustained multiple and/or catastrophic injury, or have complex problems may require 4 to 6 hours of daily therapy over prolonged periods.[20] At Walter Reed Army Medical Center/National Naval Center, the average time in rehabilitation before going home or back to active duty is 6 to 18 months, involving 3 to 6 weeks of inpatient treatment before daily outpatient treatment.[27]

When we began our study, only a few subjects had used the DEKA Arm. Those subjects were part of early research and development work by the engineering team, were introduced to the Arm system over a long period during development activities, and had extended periods of practice. Thus, when designing our protocol, we made an educated guess about the amount of training needed. Our initial protocol called for 20 hours of training, divided into ten 2-hour sessions. Training sessions were delivered at least 3 times per week, with some subjects receiving more than 1 session per day. We soon discovered that 20 hours of training was insufficient for some powered shoulder users, and added an additional 10 hours of training for these subjects. Our experience affirms that the amount of training needs to be customized for each amputee, and may be longer or more intensive for older persons and those with cognitive impairments. Our multidisciplinary research study team in-

cluded physiatrists, prosthetists, and occupational therapists and was led by a physical therapist.

THE REHABILITATION TEAM

A well-coordinated, multidisciplinary approach to improving functional outcomes and enhancing emotional adjustment of patients with amputations is well recognized.[7-9,11,13,20,23,24,27-31] Ideally, the team approach centers on the patient who is engaged in development of treatment goals and care decisions. If possible, the rehabilitation team, including the prosthetist, are included in determining the type of surgery and the overall length of the residual limb, and delivering presurgical therapy.[32-34] That said, there is rarely the opportunity to "plan" ahead, because most upper limb amputations occur secondary to trauma.

After initial surgery, amputee care is typically managed by a physiatrist, who coordinates referral to therapy and prosthetics.[28] Within the VA system, the amputee clinic team is a physician-led, interdisciplinary group that may include a prosthetist, podiatrist, physical therapist, occupational therapist, kinesiotherapist, Preservation Amputation Care and Treatment coordinator, and other specialists as required.[35] The amputee clinic team, together with the patient, develop a comprehensive rehabilitation treatment plan to address problems and identify realistic treatment goals.

Therapists play an important role in preparing the patient for fitting and optimal use of a prosthesis. Interventions may include testing for appropriate myosites and training muscles needed for effective myoelectric control and/or body motions used to operate the prosthesis, instruction in the prosthetic componentry and controls, donning and doffing, developing a wearing schedule, and ADL training. OT or physical therapy (PT) treatment may be provided, if indicated, before the prescription of the prosthesis. Although the roles of the OT and PT vary depending on the type of amputation and the patient, therapy always includes residual limb care and preparation, therapeutic exercise, range-of-motion techniques, and instruction in care and use of a prosthetic device. Therapy focuses on skills needed for a return to the highest level of function possible.[9,11,28,36] Some specialized interventions include instruction in ADLs, introduction of adaptive equipment, change of dominance training (if applicable), integrating the prosthesis into more complex activities (eg, cooking, driving, and recreation activities), community reintegration, and vocational rehabilitation if needed.[36]

When possible, therapists and prosthetists work together to maximize outcomes. The prosthetist is most knowledgeable about prosthetic options, and often knows the most about sources of funding, because prosthetic companies typically deal directly with third-party payers.[9] Ideally, therapists are involved in prosthetic prescription, and communicate with the prosthetist regarding the patient's functional and personal preferences.[20] Both professionals should be involved in the assessment of prosthetic fit and function.[7] This type of teamwork, greatly facilitated when the 2 professions are located under 1 roof,[10,28] improves evaluation of the patient-prosthetic interface, component choice and use, and efficiency in solving any therapeutic issues.[11]

Other potential team members include professionals from nursing, social work, psychology, pharmacy, and dietary services who work together to contribute to the management of residual limb and phantom pain, encourage healing after trauma and surgery, and attend to the patient's psychological and social needs. Interdisciplinary communication is facilitated by regularly scheduled meetings. In the inpatient rehabilitation setting team, these meetings are often scheduled weekly.[24,30] After outpatient therapy ends, patients typically follow-up with their physician, prosthetist, and therapist at regular intervals.[13] After fitting of a definitive prosthesis and training has been completed, reevaluations are scheduled at least annually, or as needed to check on the patient's fit and function.

WHO PAYS FOR PROSTHETIC REHABILITATION?

The VA has developed a unique Amputation System of Care (ASoC) to provide consistent and specialized care for veterans with amputations. The ASoC classifies each facility in the VA system into 1 of 4 designations based on the level of services provided at the facility. The facility classification levels are as follows: level I, Regional Amputation Centers (RACs); level II, Polytrauma/Amputation Network Site (PANS); level III, Amputation Care Teams (ACTs); and level IV, Amputation Points of Contact (APOC). The VA has 7 facilities designated as RACs that have the greatest expertise in amputation care. The 15 VA facilities designated as PANSs provide inpatient and outpatient amputation rehabilitation programs as well as orthotic and prosthetic laboratories closer to a veteran's home. VA ACTs provide outpatient amputation care using an interdisciplinary approach. APOCs do not have amputation rehabilitation services available, but have a designated point of contact who can help access appropriate care. As long as a veteran is enrolled in VA services and has a designation of service-connected disability, the VA reimburses for all costs of prosthetics care. This level and type of coverage are paralleled by the DoD, but generally unavailable through other private or public health coverage.

Our study was fully funded by VA Research and Development, and the arm system was provided as part of the DARPA-funded efforts at DEKA Integrated Solutions; thus the costs of the precommercial Gen 2 DEKA Arm prosthesis and all clinical services were covered as part of the research endeavor. When an advanced prosthetic device, like the DEKA Arm, is introduced commercially, adequate reimbursement will be important to support the device and services needed for fitting, setup, training, and maintenance. Without third-party coverage, the costs of the new technology may be a barrier to its widespread use.

For many amputees, the coverage restrictions of third-party payers impact prosthetic rehabilitation. Some insurance policies limit coverage by classifying prostheses as durable medical equipment, subject to the same annual cap as those items. Medicare coverage will pay for 80% of the cost for external prostheses and prosthetic device benefit supplies and equipment, with a 20% patient copay obligation.[14] Generally, Medicare pays for prostheses that are reasonable and necessary to restore "normal" function in day-to-day activities, and to get back to work, but not technology for sports, recreation, or to enhance cosmesis.[14] Costs for myoelectric and microprocessor prosthetic devices are substantially higher than those for body-powered devices (table 1). While exact prices vary with regional Medicare reimbursement rates and the precise components selected at each level, a transfemoral prosthesis including microprocessor knee such as the C-Leg or Rheo Knee costs between $45,000 and $50,000, whereas a knee with a simple locking mechanism costs approximately $15,000. In comparison, a body-powered upper limb prosthesis costs approximately $7000. Myoelectrically controlled devices that use 1 of the advanced hands that have recently been introduced to the market, such as the BeBionic hand or the I-Limb Pulse, cost approximately $40,000. An above-the-elbow, myoelectrically controlled prosthesis may cost nearly $100,000, more than twice the cost of a body-powered, above-the-elbow device.

Table 1: Comparison of Costs for Body-Powered and Externally Powered Prostheses*

Type of Device	Type of Control	
Upper limb prostheses	Body powered	Externally powered
Transhumeral	$5,000–$10,000	$50,000–$75,000
Transradial	$4,000–$8,000	$25,000–$50,000
Lower limb prostheses	Nonpowered (no microprocessors)	Microprocessor controlled
Transfemoral	$15,000–$25,000	$50,000–$100,000+
Transtibial	$5,000–$15,000	$40,000–$100,000

*Estimates based on New York region Centers for Medicare and Medicaid Services 2011 fee schedule.

Reports from a recent survey of 20 major insurers indicated that all had financial caps on prosthetic coverage.[37] Annual prosthetic service caps in private health plans vary, but typically range from $500 to $3000.[37] Lifetime restrictions range from $10,000 to 1 prosthetic device during a person's lifetime. Payer limits and required patient copays can place a high burden on prosthetic users paying out-of-pocket.

Cost can be a barrier to successful prosthetic use when there are insufficient financial sources for maintenance, repair, and replacement, or a need for multiple devices to effectively perform different tasks.[7,9] Lifetime costs of prosthetic care are high, particularly in the newest group of combat veterans who use more technologically advanced devices and own more prosthetic devices.[38] Blough et al[38] reported that lifetime prosthetic costs ranged from $103,442 to more than $877,039 for unilateral upper limb amputees, and $227,874 to more than $1,992,782 for bilateral upper limb amputees.

Amputees require periodic device and socket replacements, repairs, and modifications, although statistics on frequency of replacement and new prescription are sparse. Some report that amputees receive a new prosthetic limb once every 1 to 2 years and see their prosthetist between 4 and 9 times per year.[39] Others suggest that a new prosthesis is needed every 4 to 5 years.[7] Some insurers cover an initial prosthesis but no repairs beyond the warranty, or they may place a dollar limit on repairs. Some policies will only pay for 1 prosthesis per lifetime,[40] or stipulate that an extended period must pass before getting a new one, regardless of change in function or need for more than 1 prosthesis to accomplish specific tasks. Additionally, many private insurers have preexisting health condition exclusions that would preclude amputees from having coverage for prosthetic services.[40] Coverage limits by third-party payers may limit access to the best prosthetic care.[41]

Insurance may limit the number of visits patients can make to a prosthetist, and therefore may be related to whether fit problems with the prosthesis are sufficiently resolved.[42] While those in the military and the VA have access to the resources to fabricate as many test sockets as necessary, civilian insurance may only pay for 2 test sockets before fabrication of the final laminated socket.[31] Ideally, patients should be given the opportunity to try several types of sockets, harnesses, prostheses, and terminal devices before choosing their permanent device.[23]

While coverage of prostheses is largely unregulated, some states have parity laws requiring coverage comparable to Medicare.[43] Eighteen states have parity legislation, while 19 others are in the process of passing this type of legislation. State parity laws do not mandate coverage for health plans that are exempt from state regulations, such as those 40% to 50% of health plans that are federally regulated by the Employee Retirement Income Security Act.[44]

Receipt of prosthetic rehabilitation services is critical to successful device adoption. Yet, third-party payers may also limit the type and amount of rehabilitation services. Medicare, for example, has a therapy "cap" for nonhospital outpatient therapy. Today, this cap allows combined annual expenses of $1870 for PT and speech language pathology, and a separate $1870 cap for OT.[45] Some exceptions to the Medicare cap can be made if services meet specified diagnostic and clinical criteria. If exceptions to the cap are not made, Medicare patients who need further therapy must pay out-of-pocket or discontinue therapy. Many other health plans provide coverage for PT and OT sessions; however, most have a cap on number of visits. Given these types of limits, it is not surprising that 20% of upper limb amputees report an unmet need for rehabilitation services, largely because of costs.[46]

Rehabilitation services may be limited during the acute care period as well. Inpatient care offers advantages in enhanced wound care and increased access to therapy and support services. Yet, length of inpatient hospital stays for amputees declined over 40% between 1979 and 1993, and was related to payer source.[22] Medicare and Medicaid patients spent 1.5 to 3 days longer in acute care than private-pay patients.[22] Intensive rehabilitation, offered through inpatient rehabilitation programs, is not typically offered to traumatic amputees, with only 3% to 4% of upper limb amputees discharged from acute care to rehabilitation settings.[22]

Although we are unaware of national statistics on VA inpatient usage for upper limb amputees, the VA does admit upper limb amputees as inpatients for intensive inpatient rehabilitation in Commission on the Accreditation of Rehabilitation Facilities–accredited inpatient units at RACs or PANSs. Additionally, some VA Medical Centers have hotel services that allow veterans to stay on the hospital premises as guests, to facilitate extended participation in outpatient therapy.

PROSTHETIC REHABILITATION USING THE DEKA ARM

Our experience with the VA Study to Optimize the DEKA Arm affirmed the need for close therapist-prosthetist collaboration. It also pointed to the need for expansion of clinical roles and receipt of specialized clinical training in the use of advanced technology. The Gen 2 DEKA Arm system that we tested incorporated multiple degrees of powered movement and endpoint control of movement (at the shoulder configuration level), and was set up via a sophisticated computer interface.

The Gen 2 system included interactive virtual reality environment software and involved multiple control options, including force-sensitive resistors (FSRs), electromyography, pull switches, and inertial measurement units (IMUs) that were customized for each amputee. More information about the features of the Gen 2 Arm are provided in an earlier article.[47] For most users, the control scheme involved some version of foot controls, either in the form of FSRs placed beneath the foot in the shoe or IMUs placed on top of the foot. Thus, our research teams were training subjects to use a device with enhanced technical capabilities, operated with a novel control scheme. The full DEKA Arm, used for persons with shoulder disarticulation, forequarter amputation, or extremely short transhumeral amputation, has 10° of powered movement and uses endpoint control. In endpoint control, the entire Arm is moved to achieve an endpoint position of the terminal device.[48] DEKA Arms at the transhumeral and transradial level use sequential joint control. An example of the control scheme used for 1 of our subjects with forequarter amputation is shown in table 2.

We encountered many challenges in working with a prototype device, unfamiliar and evolving advanced technology, and

Table 2: Example of Control Scheme Used by One of the VA Subjects With Shoulder Disarticulation

Type of Control	Mechanism	Function in Hand Mode	Function in Arm Mode*
Left foot			
Movement (toe up)	IMU	Wrist extension	Arm moves backward
Movement (toe down)	IMU	Wrist flexion	Arm moves forward
Movement (roll inside/pronation)	IMU	Forearm pronation	Arm moves right
Movement (roll outside/supination)	IMU	Forearm supination	Arm moves left
Right foot			
Movement (toe up)	IMU	Hand close	Arm moves down
Movement (toe down)	IMU	Hand open	Arm moves up
Movement (roll inside/pronation)	IMU	Activates grip selection (backwards cycle); sequence of 6 grips	None
Movement (roll outside/supination)	IMU	Activates grip selection (forward cycle); sequence of 6 grips	None
Other			
Mode	Air bladder	Switches to arm mode	Switches to hand mode
Activate/deactivate	Air bladder (extended pressure)	Turns arm off	Turns arm off

*This version of the DEKA Arm used endpoint control (used in arm mode) where the entire Arm is moved to achieve an endpoint position of the terminal device.

foot-controlled upper limb movement. Some of these challenges are described below.

Control Setup

Control setup or modification of settings for an advanced prosthesis is typically the responsibility of the prosthetist, while prosthetic training in functional activity performance is typically delegated to therapists. In our study, it became clear that to be effective trainers, occupational therapists had to understand the control scheme individualized for each subject, and needed to acquire skills in using the computer interface so that they could assist in control setup and modifications during therapy. Study prosthetists took an active role in ensuring that the occupational therapist understood the control setup and device functions. This was facilitated by prosthetists observing portions of therapy training. This direct involvement helped prosthetists make more informed choices in control setup and modification, and enhanced training sessions by providing another perspective on formulating strategies to accomplish certain tasks. It also provided an opportunity for prosthetists to observe issues during functional activities, which may be difficult to reproduce in a prosthetics office, and provide input into functional training with the device.

Thus, in future deployment of advanced technologies, such as the DEKA Arm, we recommend that the occupational therapist be present and play an active role during control setup, and that the prosthetist be present for several therapy sessions. This involvement ensures an effective transition from control setup to training, providing continuity in discussions about control preferences and future options for refining controls.

Our experience leads us to conclude that prosthetists and therapists who work with this type of advanced technology need specialized training to understand the uniqueness of the device, to be most effective. Although we had developed an initial prosthetic training protocol, like the Gen 2 device itself, our protocol evolved through experience and reflection. Some of the challenges that we encountered with training subjects to use the DEKA Arm are common in training upper limb amputees to use any new prosthesis. These challenges included problems obtaining ideal socket fit, comfort, and suspension; fatigue in the affected limb; acclimation to the weight of the socket and prosthesis; and lack of familiarity with electromyography use or difficulty isolating electromyography contractions. Other training challenges were inherent in mastery of the complex control scheme required to operate many powered degrees of freedom of the DEKA Arm.

Maximizing Learning

To maximize outcomes during its short duration, our study emphasized continuity of training and incorporation of multiple learning strategies. Clinicians needed to be sensitive to cognitive burden when training subjects to use complex devices, and to incorporate adult learning theory to progress learning activities appropriately without overwhelming or fatiguing subjects.

When controls were initially configured, the clinical staff provided the subject with a visual depiction of the controls (“cheat sheet”) that they could study at home. Any changes made to controls on that cheat sheet were documented as they occurred. Therapists reinforced the need for the subject to review controls at home between sessions, so that they could get comfortable and quick at recalling them.

Mastery of the DEKA Arm controls was a cognitive challenge for some subjects. These subjects were visibly fatigued or expressed mental fatigue after training sessions. Therefore, clinical staff were urged to avoid double sessions (4 hours in 1d) if they appeared to tire the subject, either physically or cognitively. In addition, clinical teams tried to avoid breaks longer than 4 days between training sessions. Users of the powered shoulder had the most demanding control scheme to master, and had to be more cognizant of commands meant to move the hand away from the face or body. Control at the shoulder level could include up to 16 distinct control actions associated with about half as many control sites, many of which were assigned 2 separate movements, 1 while the Arm is in “arm” mode and 1 while in “hand” mode.

As done in traditional therapy protocols, and to keep the process standardized, therapists sequenced the difficulty and content of sessions so that early training visits focused on basic drills/instruction while introducing problem solving in later visits. During introductory visits, subjects were coached on grip and positioning strategies to use with varying shaped and sized objects. Later in training, when complex movements were required, therapists had each subject verbalize strategies,

grips, and controls needed to perform the activity in an attempt to bring the thought process into conscious awareness.

The team recommended that every session begin by reviewing controls and integrating multiple learning modalities (subject demonstrations of movement using sound side, subject verbalization of controls, subject follows instructions, mix order of review and movements). Control reviews were performed in both sitting and standing, since activation of foot controls often varied in difficulty and sensation depending on position. In early sessions, the occupational therapist directed the control review, while in later sessions, subjects directed the review. The complexity of control reviews progressed to include combinations of movements.

Prosthetic training was made personally meaningful to each patient by using real-life activities, such as cooking, doing laundry, working with money, or eating. Training sessions also included as many subject-desired activities as possible. When subjects did not request activities, the staff probed for preferred activities and experimented with those that could be attempted in the clinic.

Teaching Novel Movement Trajectories

The DEKA Arm powered shoulder uses a feature called endpoint control. In endpoint control, the movement trajectory initiated by a given control site varies depending on the position of the endpoint in space in relationship to the shoulder joint, and can involve movement of multiple joints simultaneously. For safety reasons and for effective patient training, clinicians needed a thorough understanding of this concept with an appreciation of how the Arm moves through the full range of endpoint control. Thus, we recommend that clinicians obtain direct experience with endpoint control, and suggest that clinicians be required to demonstrate a minimal proficiency before training patients. When therapists are training the subject in use of endpoint control, they must, for the sake of safety, include frequent drills on the control sequences that are needed to move the Arm away from the body.

Using the Feet to Control the Upper Extremity

We found that using the feet to control a prosthetic arm requires training and awareness to avoid inadvertent and potentially unsafe movements. In the Gen 2 DEKA Arm system, each control input could have dual functions, depending on the "mode" the system is in. For example, the shoulder and humeral configurations of the DEKA Arm have 3 modes: "standby" mode, "arm" mode, and "hand" mode. Each input, like the foot controls for example, may be assigned to 1 movement in hand mode and another in arm mode. Therefore, it was especially important for users to maintain an awareness of mode to select the designated movement and avoid any unintended movements. Additionally, when using foot controls, subjects needed to learn to minimize unconscious movements of the feet, and Gen 2 users were advised to place the Gen 2 DEKA Arm in standby when walking.

Based on our study experience, we recommend that clinical staff have personal experience using foot controls to appreciate the sensitivity and awareness needed to operate them, the subtle differences between operation in sitting and standing positions, and the delay times in resulting movement. When clinicians had controls set up for their own use, they were more likely to appreciate the individuality of user preferences for control setup, as well as the need to make modifications as training progressed.

NEED FOR FUTURE RESEARCH

Our experience highlights the need for future research to ensure that this technology is deployed appropriately. As new prosthetic technologies are introduced, it is crucial to conduct comparative effectiveness studies to support clinical deployment and reimbursement. Such studies should examine rates of abandonment, as well as functional benefits and impact on the user's quality of life. This research is needed to aid in the development of policy decisions that promote consistent coverage of prosthetic rehabilitation.[43]

Further study is needed on the impact of specialized treatment provided by knowledgeable teams. This type of treatment is seldom available because few facilities/organizations have the resources to implement it. Further study is needed to determine the optimal frequency and intensity of rehabilitative training, particularly for advanced technologies like the DEKA Arm, which differs from conventional devices in capabilities, and type and number of controls. Similarly, studies are needed to understand whether and how location, type, and number of controls are associated with the cognitive load needed to operate the device.

Studies are also needed to determine which amputees are appropriate candidates for advanced prosthetic devices. Clinical prescription guidelines need to be developed to help discriminate appropriate from inappropriate candidates for use of a particular system, and to ensure that resources are used judiciously. Such guidelines, informed by research efforts, might consider neuropsychological assessments to judge whether subjects have sufficient information processing speed and executive functioning to operate a device safely.

Further study is needed to understand the optimal point in the rehabilitation process for introducing an advanced prosthetic device. Typically, a basic body-powered device is the first type of prosthesis introduced, with more complex devices introduced at a later time. It is not known how the timing of technology introduction affects ultimate acceptance or rejection of an upper limb prosthesis.

CONCLUSIONS

The U.S. government has made a major investment in developing technologically advanced upper limb prosthetic devices through the Revolutionizing Prosthetics program. Much work is needed to ensure that this investment will benefit persons with amputations. Implementation of advanced prosthetic technology requires a coordinated approach offered by a specialized, colocated rehabilitation team. Integrated health systems, such as the VA and military treatment facilities, are ideally suited to offer this type of comprehensive amputee rehabilitation, and many, in fact, already offer similar models.

Ultimately, successful implementation of advanced prostheses will be largely contingent on the availability of highly specialized and trained clinical personnel to fit and train amputees, and resources to pay for these services. While the VA and DoD offer comprehensive coverage of prosthetic devices and rehabilitative services, this broad coverage is not generally available elsewhere. Third-party reimbursement for advanced upper limb prosthetic devices and prosthetic rehabilitation services associated with their deployment is needed for the benefits of this technology to extend to amputees outside of the VA and DoD systems of care. Additional research funding is needed to examine the benefits of advanced prosthetic technologies and further delineate the ideal candidates for the technology. Data from well-designed studies can help inform payment policy.

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