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Case Report

Assessment of Performance Using an Advanced Upper Extremity Prosthesis: A Case Report

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Abstract

Background: As upper extremity prosthetic devices continue to advance, it is unclear if traditional outcome measures accurately assess their impact on function and quality of life. This case report describes the experiences of a military veteran with a transhumeral amputation utilizing the advanced DEKA prosthetic arm system.

Objective: Observe the performance of the DEKA Arm over one year; assess its impact on function using traditional outcome measures and subjective feedback from the subject.

Methods: Three previously validated assessment procedures on prosthetic hand control – viz., Box and Blocks Test (BBT), Southampton Hand Assessment Procedure (SHAP), and Assessment of Capacity for Myoelectric Control (ACMC) – were used as endpoints to compare the performance of the novel DEKA Arm System with that of the subject's body-powered prosthetic. First, with the body-powered prosthetic that the subject had used for over four decades, a baseline occasion of assessment was observed. Next, the subject was fitted and trained with the DEKA Arm System and repeated the tests at eight occasions over one year. Then, the longitudinal trends of the indexed scores for each of the three functional assessments were estimated using ordinary least squares linear regression. Finally, a qualitative assessment was conducted to understand the overall impact that the DEKA Arm System had on the subject's quality of life.

Results: Linear estimates of each of the three functional assessments suggested a gradual longitudinal improvement; however, the estimated effects were neither statistically nor clinically significant. Moreover, the subject's performance with the DEKA Arm system at the exit assessment did not surpass that with the body-powered prosthetic at baseline. In the qualitative assessment, the subject held that the DEKA Arm system simplified many of his routine tasks and improved his quality of life when compared to the body-powered prosthetic he had used for several decades.

Conclusion: This case report illustrates the likely disconnect between current upper-extremity prosthetic assessment tests and their ability to substantively capture a prosthetic's impact on quality of life, functional performance, and body mechanics.

ABBREVIATIONS

ACMC: Assessment of Capacity for Myoelectric Control; ADLs: Activities of Daily Living; BBT: Box and Blocks Test; BP: Body-powered (Prosthesis); FDA: Food and Drug Administration; HC: Humeral Configuration; IMU: Inertial Measurement Units; OPUS-UEFS: Orthotics Prosthetics User Survey - Upper Extremity Functional Status survey; SHAP: Southampton Hand Assessment Procedure

INTRODUCTION

The human upper extremity/hand enables tactile sensation, manipulation, expression and social interaction. Because of these vast functions, significant challenges exist in the development of prostheses that closely mimic functions lost after upper extremity amputation. Current prosthetic devices range from body-powered (circa Civil War technology) to advanced externally-powered myoelectric-controlled devices. However, overall rejection rates have been reported as high as 39% for transhumeral amputees and 16% for transradial amputees (16%) [1] due to general discomfort, lack of functionality, difficulty with prosthetic control, inability to perform fine motor tasks, limited grip strength from prosthetic hooks/hands, no haptic feedback (sensation), and the heavy weight of the devices [2].

The DEKA Arm, developed by DEKA Research & Development Corp. and commercialized as the LUKE arm by Mobius Bionics, LLC, is an advanced prosthesis designed to revolutionize functionality for patients with upper extremity amputations, and was the first device approved by the Food & Drug Administration (FDA) under the category of integrated prosthetic arms (Figure 1) [4,5]. This device provides up to ten powered degrees of freedom, including a two degree of freedom powered shoulder and wrist flexion/

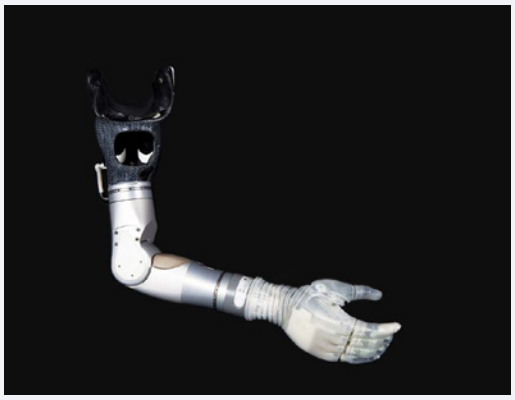

Figure 1 Transhumeral DEKA arm: This image shows the Humeral Configuration of the modular DEKA arm, similar to what was worn by the subject. The additional shoe-based IMUs, external battery, and toggle/switch computer system are not shown.

extension with integrated radial/ulnar deviation. Combined with multiple preprogrammed grip functions, this prosthesis offers more useful capabilities for completing daily activities with minimal negative ergonomic impact.

As advanced upper extremity prostheses, such as the DEKA Arm continue to develop, so too must our ability to accurately measure their impact on patient function and quality of life. Unfortunately, currently-available upper extremity prosthetic outcome assessments largely focus on the prostheses' ability to simulate anatomical function (e.g. mimicking hand grips), rather than accurately assessing patient-valued capabilities and the devices' impact on quality of life6 [7]. As a consequence, no single assessment adequately evaluates functional improvement or quality of life [8]. This knowledge gap makes it difficult for clinicians to quantify outcomes which is essential for effectively treating patients, identifying areas for improvement, and justifying future expenditures on further development of advanced prostheses that more approximate the complexity of the lost human arm/hand.

The purpose of this study was to evaluate the DEKA Arm longitudinally in a single subject, understand the functionality of an advanced prosthesis, and document any potential mismatch between the subject's observations and validated assessments.

METHODS

This case report focuses on one subject who was enrolled to complete the first year of this institutionally-approved study. The subject was a 72-year-old male (5'10", 172 lbs.) who sustained a left-transhumeral amputation and right-forearm injury while serving in the Vietnam War in 1968. Since then, he has continued to experience mild phantom limb pain and suffers from other comorbidities, including hypertension, glaucoma, bilateral sensorineural hearing loss, and distal biceps tendonitis in the intact (right) arm. He is considered an *expert user* of a body-powered (BP) prosthesis with voluntary-opening terminal hook device, having worn this system daily for over 40 years. Prior to this study, the participant had limited experience with prototypes of the DEKA Arm, having used them for multiple, week-long sessions throughout the most recent seven years of its development.

The research team used previously validated, upper-extremity prosthetic assessment procedures, which the current authors believed *a priori* were optimized to measure the functional capabilities of a given upper-arm prosthesis. In so doing, the authors hoped to observe the strengths and weaknesses of the most commonly utilized upper-arm prosthesis assessment procedures in terms of their ability to capture the functional performance and impact of a given prosthesis on the quality of life among upper-arm amputees. Details of these upper-extremity prosthetic assessment procedures are listed in Table 1.

After obtaining informed consent, the subject participated in a baseline assessment of the performance of his BP prosthesis as measured by three previously validated, upper-extremity prosthetic assessment procedures, namely, the BBT, SHAP and ACMC. The subject was then fitted with the humeral configuration (HC) DEKA™ (transhumeral) arm using a shoe-based control system called *Inertial Measurement Units* (IMUs), which are capable of capturing inversion/eversion (i.e., roll) and dorsal/pedal flexion (i.e., pitch) movements. One IMU operates wrist supination, pronation, flexion and extension, and a second operates hand open, close, and grip select. When the user presses a switch on his contralateral side, the same IMU controls also operate elbow flexion/extension and humeral rotation.

Upon initial fit and training, the subject took the DEKA Arm System home to experience it in his normal environmental conditions. The subject received additional, one-on-one training with the DEKA device twice during the first month and once per month for five subsequent months. The subject's performance with the DEKA Arm System was evaluated using the BBT, SHAP, and ACMC at seven occasions during the first six months and at an eighth occasion during the exit assessment at 12 months. Each occasion of assessment was completed in its entirety in a single session (i.e. no prolonged breaks or multiple testing days), in a quiet room or Occupational Health space (such as a test kitchen area). The longitudinal trend of the indexed scores for each of the three functional assessments were estimated using ordinary least squares linear regression. The subject's subjective observations regarding his overall impressions of the device were recorded at each occasion of assessment. All of the assessments were conducted and scored by the same members of the study team.

RESULTS

Linear estimates of each of the three functional assessments suggested a gradual longitudinal improvement in the functional performance of the DEKA Arm system; however, none of the estimated effects was statistically nor clinically significant: ACMC index score increased 0.02 points per month (95% CI -1.2 to 1.2); SHAP index score increased 0.64 points per month (95% CI -0.63 to 1.9); and the average of the three-trial BBT score increased 0.26 points per month (95% CI -0.40 to 0.93) (Figure 2). Inter-month variability in improvement was observed, and so it is likely that the true rate of increase was not linear.

The subject reported wearing the DEKA Arm routinely – that is, at least two days per week, sometimes as often as four days per week. He wore the device about ten hours each instance, and

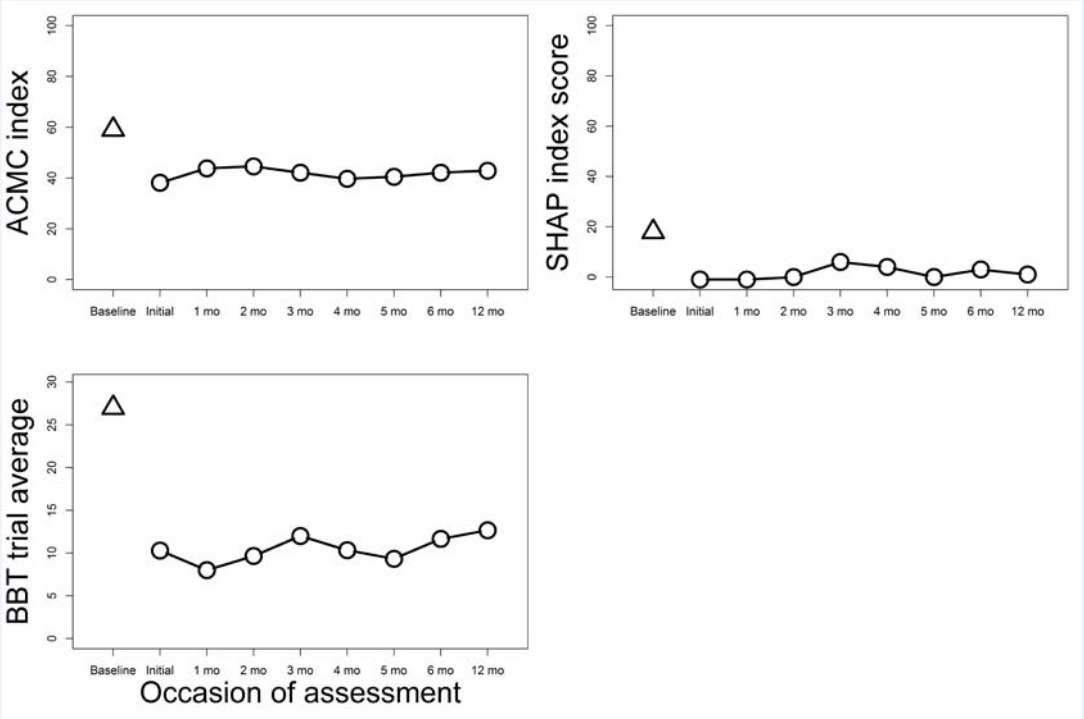

Figure 2 ACMC, SHAP and BBT performance over 12 months: The upper left panel features scores from the ACMC v.3.0. The upper right panel features index scores from the SHAP. Higher scores reflect shorter completion times. Of note, the subject scored a "-1" in both the Initial and Month 1 assessments when calculated using the standard SHAP calculator (http://www.shap.ecs.soton.ac.uk/about.php). The lower left panel features the average BBT score for three trials per assessment. "Initial" corresponds to the first assessment shortly after receipt of the DEKA arm.

Abbreviations

Δ: Baseline assessment with subject's personal body-powered prosthesis

○: Assessment performed with DEKA arm device

ACMC: Assessment of Capacity for Myoelectric Control; BBT: Box and Blocks Test; SHAP: Southampton Hand Assessment Procedure

Table 1: Assessments: These are the assessments used in this study. All are validated, clinically-relevant assessments routinely used for patients with upper extremity disabilities and those using upper extremity prostheses.

Assessment	Task	Grading Scale
Box and Blocks Test (BBT)	A basic test of gross dexterity that is simple to assemble and conduct [10]. The subject is tasked with picking up 1" square blocks one at a time and transferring them from one half of a divided tray to the other as quickly as possible in one minute.	0-150, with each successful move of a single blocks counting as "1." If more than one block is grasped in a transfer, a score of only "1" is given. Note that a subject of comparable age to our subject with an intact left-hand and no concomitant injury/illness is expected to be able to move approximately 64 blocks.
Southampton Hand Assessment Procedure (SHAP)	Designed to objectively measure prosthetic hand function and is available in a compact, mobile platform [11]. It utilizes abstract and functional tasks meant to mimic Activities of Daily Living (ADLs), emphasizing the use of six basic prehensile-grip patterns: spherical, lateral, tip, extension, power and tripod [12].	Time-based exam scored in seconds, maximum time allowed of 100 seconds. Scores are calculated by a pre-programmed, online calculator and are divided by prehensile grip pattern, as well as a summary net score. A "normal" individual with an intact limb is expected to score a 100. Scores may range from 0-100.
Assessment of Capacity for Myoelectric Control (ACMC), version 3.0	Considered one of the most comprehensive modern assessments for myoelectric prosthesis users that requires extensive training and knowledge from the therapist delivering the test [7], the ACMC is thought to quantify the user's ability to integrate their prosthesis into everyday activity, evaluating bimanual ability, various grips, repetitive grip motions, and use of the prosthesis without visual feedback. Note that our subject chose the "Packing a Suitcase" activity for all ACMC assessments.	The grader observes the subject and rates their performance from 0-3 (0 = not observed, 1 = sometimes capable, 2 = capable on request, 3 = spontaneously capable) in different categories (gripping – with/without support, adjustment of grip, timing, hand coordination, ability to use the prosthesis with/without visual feedback, etc.). An index score of the overall performance is calculated by the grader based on the raw score and converted into "ACMC units." A "normal" individual with intact limbs should score a 100 ACMC units (raw score 66).

Abbreviations: ACMC: Assessment of Capacity for Myoelectric Control; ADLs: Activities of Daily Living; BBT: Box and Blocks Test; SHAP: Southampton Hand Assessment Procedure

sometimes for a few hours at a time to complete activities that he felt he could perform better with the DEKA Arm than he could with the BP prosthesis, including cooking, working in the garage, and even cleaning firearms.

The subject also completed an Orthotics and Prosthetics User Survey - Upper Extremity Functional Status (OPUS-UEFS) for both devices. Of the 28 items, the subject stated "Easy" for all but eight activities with the DEKA Arm, and "Easy" for only six of the 28 activities for his BP. Of the eight activities the subject did not list as "Easy" or "Very Easy" with the DEKA Arm, he only rated 2 higher than the BP prosthesis ("Slightly Difficult" vs. "Cannot perform" and "Easy" vs. "Not applicable") (Table 2).

The subject reported the DEKA Arm had a positive impact on his daily life, noting that it allowed him to grasp items with a natural dexterity that could not be mimicked by his BP. In particular, he valued the wrist functions, reporting that "…my ability to hold things at different angles is something I couldn't do with the hook…", adding that the ability to flex and rotate the

Table 2: OPUS-UEFS Results: The OPUS-UEFS is a validated questionnaire specifically for upper extremity prosthesis and orthosis users that evaluates a patient's self-reported ability to complete various daily tasks in their home.

	Body-Powered Prosthesis						DEKA™ Arm					
Activity	**Very Easy**	**Easy**	**Slightly Difficult**	**Very Difficult**	**Cannot Perform Activity**	**Not Applicable**	**Very Easy**	**Easy**	**Slightly Difficult**	**Very Difficult**	**Cannot Perform Activity**	**Not Applicable**
Wash Face				X				X*				
Put tooth paste on brush and brush teeth		X						X				
Brush/comb hair		X						X				
Put on and remove t-shirt		X						X				
Button shirt with front buttons						X						X
Attach end of zipper and zip jacket			X					X*				
Put on socks						X						X
Tie shoe laces			X ǂ									X
Drink from a paper cup					X					X		
Use fork or spoon					X				X*			
Cut meat with knife and fork				X				X*				
Pour from a 12oz. Can				X				X*				
Write name legibly		X						X				
Use scissors						X					X	
Open door with a knob				X				X*				
Use a key in a lock					X			X*				
Carry laundry basket		X						X				
Dial a touch tone phone			X						X			
Use a hammer and nail			X					X*				
Fold bath towel				X				X*				
Open an envelop			X									
Stir in a bowl			X ǂ								X	
Put on and take off prosthesis or orthosis	X ǂ							X				
Open a bag of chips using both hands						X		X*				
Twist a lid off a small bottle			X					X*				
Sharpen a pencil			X					X*				
Peel potatoes(or fruit) with a knife/peeler								X*				
Take a bank note out of the walet			X			X		X*				

ǂ = BP prosthesis rated better than DEKA Arm
* = DEKA Arm rated better than BP
BP: Body-powered ™

DEKA™ wrist was "super," and "key" to his ability to complete tasks without contorting his body around the device. Examples he gave included the ability to reach zippers on shorter jackets than he could with his BP, drinking from a bottle or cup, replacing batteries in his hearing aid, and cleaning his firearms. While tasks could be performed with adaptive techniques that required contorting his body and intact arm around the BP, the DEKA Arm offered more seamless interaction with his intact arm.

Additionally, the subject noted that both his BP prosthesis and the DEKA Arm were important to his daily routine, stating "I want both…they each have their functional roles. The DEKA Arm increases my function and independence, but is not a cure-all. The hook is better for some things, and the robotic arm is better at others..." The subject insisted that the DEKA Arm was very helpful in daily tasks and was surprisingly "tough and rugged." It could grasp with greater strength and carry heavier objects than he could with his BP prosthesis. For example, the subject described an instance in which he went out to dinner and held a plate with the DEKA Arm and filled the plate with food, stating "I wouldn't dare do that with the hook."

DISCUSSION

Although linear estimates of each of the functional assessments from baseline to closeout at one year demonstrated longitudinal improvement in functional performance of the DEKA Arm system, the magnitude of the effects were not thought to be clinically meaningful nor were the estimates statistically significant.

Interestingly, the subject claimed the DEKA Arm System had a markedly positive impact on his quality of life, despite having performed better on the BBT, SHAP, and ACMC with the BP prosthesis than he did with the DEKA Arm System. This calls into question the clinical utility of these previously validated assessment procedures.

There are clinical observations that do not reflect the results of the clinical assessments. For example, the BBT reflects the ability to swiftly grasp and release a cube, which may be done relatively quickly with a BP prosthesis, compared to the DEKA Arm, which uses multiple gears; however, it was noted that the subject's shoulder and arm positioning was in a more natural position using the DEKA Arm than it was using the BP prosthesis, which was not captured in the score. Similarly, the SHAP assessment only reflects timing, and does not account for the accuracy of grips, proper posture, nor the achievement of otherwise natural body mechanics. In this regard, the SHAP penalizes the DEKA Arm because of its slower speed, while failing to capture the benefit of its superior ergonomics. Similar observations have been reported with other myoelectric devices [3].

The ACMC was designed for current-generation myoelectric users, and is one of the latest validated assessments developed [7]. Unlike other assessments, this test uses activities of daily living (ADL) (e.g. packing a suitcase, cooking, potting a plant), which are all bimanual and require coordinated use of the prosthesis and intact limb. The ACMC score does not include a time component, eliminating any potential bias against the slower, more precise DEKA Arm versus the BP prosthesis. When using this assessment, the subject still performed slightly better with the BP prosthesis (59.1) versus the DEKA Arm (44.6).

One of the fundamental limitations of comparing the functional performance of the DEKA Arm System obtained over one year's use to that of the subject's familiar BP prosthesis – with which the subject had more than 40 years of experience – is that functional ability of the familiar BP prosthesis was likely improved by the compensatory movements that one would develop over the decades of experience maneuvering routine tasks with the BP prosthesis. The current authors admit that 12 months may have been insufficient for the subject to have developed the fine motor skills associated with operating the DEKA Arm System, resulting in it being objectively competitive with his familiar BP prosthesis [8].

While the subject could use his BP prosthesis to grasp most objects, he noted that it could only be fully open or closed, with limited grip strength. Also, once engaged, he could no longer toggle his elbow to extend or flex, limiting his ability to transition objects with his BP. Conversely, the DEKA Arm allowed the subject to use visual feedback to change the magnitude of gripping force applied to objects, including pill bottles, a toothbrush, zippers, and clothing. The control scheme also allowed elbow and humeral control while maintaining grip.

- In addition to the subject's praise of the DEKA Arm, he recommended several areas for improvemeThe shoe-based IMUs, one of the available FDA-approved methods for controlling the DEKA Arm, was designed to function only when the subject was stationary and would automatically shut off when the subject was walking or his feet were not neutrally positioned. For example, our subject noted challenges when getting out of a car and walking, when his arm was still in the position most comfortable during driving. He also found difficulty using the device in any situations (ex. working in his garden) that involved positioning his feet in any position except neutral, triggering the auto-shut off feature. This necessitated that he adjust to a neutral, flat-footed position prior to using the arm, which diminished the fluidity of his transitions.

The DEKA Arm did not allow immediate changes in direction or movements (such as grasp and release) due to the control scheme, which required distinct and separate foot motions for each degree-of-freedom (e.g. dorsiflexion versus plantarflexion). Frequently, the user noted that the speed of action by the device versus his desire to complete activities in a smooth and natural manner were often mismatched, and he found himself sometimes moving slower than preferred. Reaction speed of the device was not unique to the DEKA Arm; many other myoelectric users have noted this [3].

Given that this was a longitudinal case study, caution should be taken when extrapolating results to the general amputee population. The findings presented in this case report corroborate that of previous research: the validated assessments used may not match the subject's self-reported improved functionality or quality of life [6,9]. This may be because such assessments were developed using older technology, and may be too naïve to detect user improvements when using a multi-degree-of-freedom, advanced device such as the DEKA Arm System.

CONCLUSION

The DEKA prosthesis represents a significant step forward

in technology for individuals with upper extremity amputation. This report features one subject's experience, which include the benefit of the DEKA Arm system on quality of life, while also highlighting potential limitations of previously validated, upper-extremity amputee assessment procedures.

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DISCLAIMER

The views and opinions expressed in this article are those of the authors and do not reflect the official policy or position of the Uniformed Services University of the Health Sciences, Walter Reed National Military Medical Center, the Department of Defense, or the U.S. Government.

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