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User ratings of prosthetic usability and satisfaction in VA study to optimize DEKA Arm

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Abstract—The Department of Veterans Affairs study to optimize the DEKA Arm provided feedback to inform optimization of the gen 2 (second-generation) prototype and evaluate the gen 3 (third-generation) prototype. This article summarizes recommendations to improve gen 2 and reports satisfaction and usability ratings of gen 2 and gen 3. Data were collected from 39 subjects; 37 subjects were included in this analysis. Of the subjects, 24 were fit with gen 2 (8 radial configuration [RC], 6 humeral configuration [HC], and 10 shoulder configuration [SC]), 13 were fit with gen 3 (4 RC, 5 HC, and 4 SC), and 5 were fit with both. Usability and satisfaction were evaluated using the Trinity Amputation and Prosthesis Experience Scale (TAPES) and study-specific usability and satisfaction scales. Descriptive statistics were examined and prototypes compared using Wilcoxon rank-sum. Results were stratified by configuration level and outcomes compared by prototype. Satisfaction and usability were greater for gen 3 than gen 2. Overall TAPES scores were similar; however, scores of the TAPES aesthetic satisfaction subscale were higher for gen 3. Compared with gen 2 users, gen 3 users were more satisfied with appearance, grips, and doffing and rated overall usability higher. Features of gen 3, including weight, external cables and wires, hand covering, and fingernails, would benefit from further optimization.

Key words: amputation, assistive technology, DEKA Arm, optimization, outcome assessment, prosthesis, satisfaction, upper limb, usability, Veterans.

INTRODUCTION

Commercially available upper-limb prostheses can be controlled through one of two means. They can be body-powered, using a harnessing cable operated through shoulder motion, or they can be controlled by myoelectric recordings from the residual muscles. Hybrid devices use a combination of body-powered and myoelectric controls. These controls can be used to operate one prosthetic movement at a time. Currently available prostheses are also limited in the types of motions that they can perform. None include powered wrist flexion or extension, powered humeral rotation, or powered shoulder movement. Furthermore, there are no devices on the market that allow multiple simultaneous joint movements.

A recent Inspector General report found that only 70 percent of new combat Veterans were satisfied with their current upper-limb prosthesis [1]. This report builds upon ample evidence that suggests that people with

Abbreviations: CFI = Center for the Intrepid, DARPA = Defense Advanced Research Projects Agency, EMG = myoelectrode, gen 2 = second-generation DEKA Arm, gen 3 = third-generation DEKA Arm, HC = humeral configuration, IMU = inertial measurement unit, LUI = Luke User Interface, NYHHS = New York Harbor Healthcare System, RC = radial configuration, RR&D = Rehabilitation Research and Development, SC = shoulder configuration, SD = shoulder disarticulation, TAPES = Trinity Amputation and Prosthesis Experience Scale, TH = transhumeral, TR = transradial, VA = Department of Veterans Affairs.

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upper-limb amputation are not satisfied with available technology. As a result, many reject using a prosthesis altogether [2–3]. Rates of abandonment are higher for those with more proximal levels of limb loss, with persons with transradial (TR) amputation having the lowest rates (6%), and persons with transhumeral (TH) amputation and shoulder disarticulation (SD) reporting rates of 57 and 60 percent, respectively [2–3]. There are many reasons for dissatisfaction with currently available devices [4–9]. Development of new and better upper-limb prosthetic technology was identified as a high priority by the participants at the 2006 State-of-the-Science Meeting in Prosthetics and Orthotics [10]. Improving care for people with upper-limb amputation has been a strong priority for the Department of Defense and the Department of Veterans Affairs (VA) for the past decade.

The development of the prototype of the DEKA prosthetic arm system was funded by the Defense Advanced Research Projects Agency's (DARPA's) Revolutionizing Prosthetics program in 2006 [11] with a goal of drastically improving the state of the art in upper-limb prosthetics. Two years later, DEKA had built and tested the first-generation DEKA Arm (gen 1) and had developed the initial gen 2 (second-generation) prototype. The gen 2 DEKA Arm was designed as an experimental platform, and as such, it included many test features that had not yet been finalized or miniaturized. In 2008, the VA and DARPA entered into a Memorandum of Agreement to collaborate on a study to optimize the DEKA Arm. Subsequently, VA Rehabilitation Research and Development (RR&D) funded the multisite VA study to optimize the gen 2 DEKA Arm (Optimization Study). VA subject and clinician feedback about gen 2 was analyzed on an ongoing basis and shared with DEKA. This feedback was used in refining the gen 2 prototype and finalizing the gen 3 (third-generation) prototype, which had major hardware, software, and design changes. VA subject and clinician feedback about the gen 3 DEKA Arm was gathered in the next phase of the Optimization Study, which began in 2011.

The gen 2 and gen 3 DEKA Arm prototypes are described in detail elsewhere [12]. Briefly, the DEKA Arm (both gen 2 and gen 3) is available in three configurations: the radial configuration (RC), for people with TR amputation; the humeral configuration (HC), for people with TH amputation; and the shoulder configuration (SC), for people with very short TH amputation or amputation at the SD and scapulothoracic level. **Figure 1** shows gen 2 and gen 3 SC prototypes.

The SC DEKA Arm has 10 powered degrees of freedom (20 movements) and additional passive degrees of freedom [13–14]. A major change in the gen 3 was the inclusion of a compound wrist that combined the movements of radial deviation with wrist flexion and the movements of ulnar deviation with wrist extension. Both prototypes supported the use of up to six preprogrammed grip patterns: power grip, tool grip, chuck grip, lateral pinch, fine pinch open, and fine pinch closed. Users selected the desired grip directly or by toggling through the grips. Three grips were modified in gen 3 by adding a new feature, called a detent, that allowed users to separate the positioning and/or stabilizing and grasping aspects of grip from the precision portion.

All levels of the DEKA Arm used control inputs for the hand and wrist. At the HC and SC levels, the control scheme had dual modes enabling the user to switch between a "hand mode" of operation (to control movements of the hand and wrist) and an "arm mode" of operation. In gen 3, changes were made to enable up to three movements of the hand and/or wrist to also be available in arm mode if sufficient control inputs were available.

The SC DEKA Arm employed end-point control to enable simultaneous, coordinated movement of the prosthesis to bring the terminal device (the end point) to a desired position in space. During the Optimization Study, there were three different versions of end-point control, each with some differences in movement trajectories and features.

Users controlled prosthetic movements with a combination of foot controls, myoelectrodes (EMGs), pneumatic bladders, or manual switches. Three iterations of foot controls (**Figure 2**) were used: force sensitive resistors; inertial measurement units (IMUs) during gen 2 (IMU-1); and a refined version of the IMU in gen 3 (IMU-2) that had new features, including the ability to detect walking motion and automatically put the arm into standby (called walk detect).

The DEKA Arm was battery-powered by a rechargeable battery typically worn on a holster on a belt around the waist or on the back. The gen 3 for HC and SC had the potential to include an internal battery. The DEKA Arm made a variety of beeping sounds to notify users of powering on and off, low battery, and system faults. In addition, an audible tone and a vibratory tactor "buzzed" to indicate changes between hand and arm mode, moving

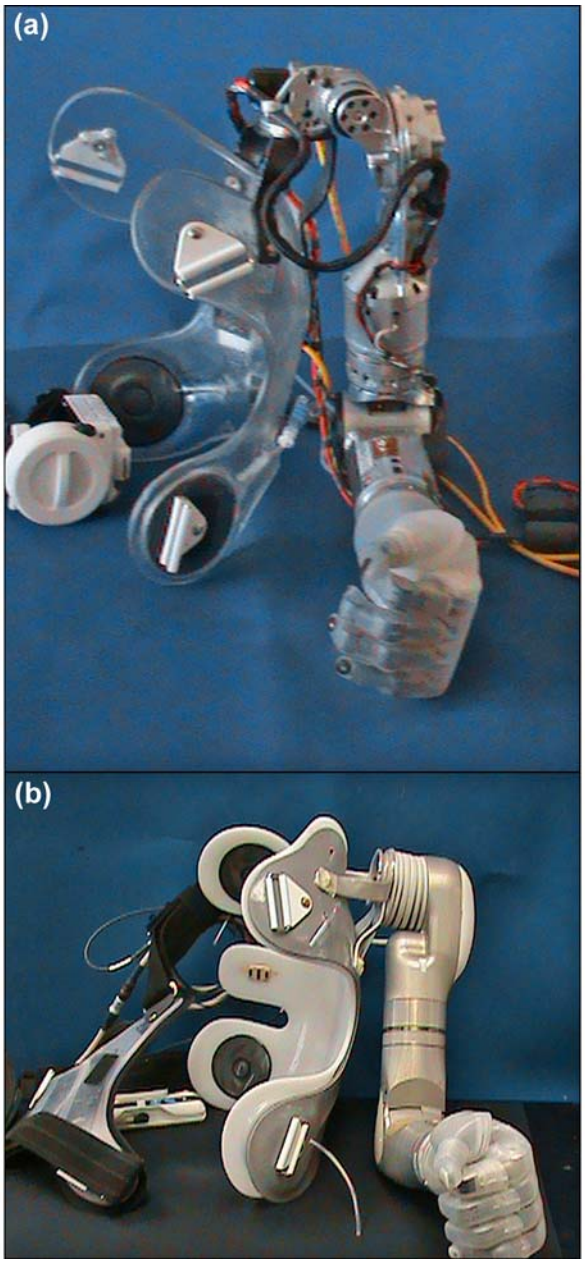

Figure 1.
(a) Second-generation DEKA Arm shoulder configuration (SC) on socket. **(b)** Third-generation DEKA Arm SC on socket.

into or out of standby, changing grip, and changing grip pressure. The Luke User Interface (LUI) introduced during the gen 2 studies displayed information to the user about grip, mode, power, battery charge, and system faults (**Figure 3**). The gen 3 replaced the LUI with a wrist display embedded on the dorsal wrist (**Figure 3**) that had light-emitting diode displays for grip, low battery, mode

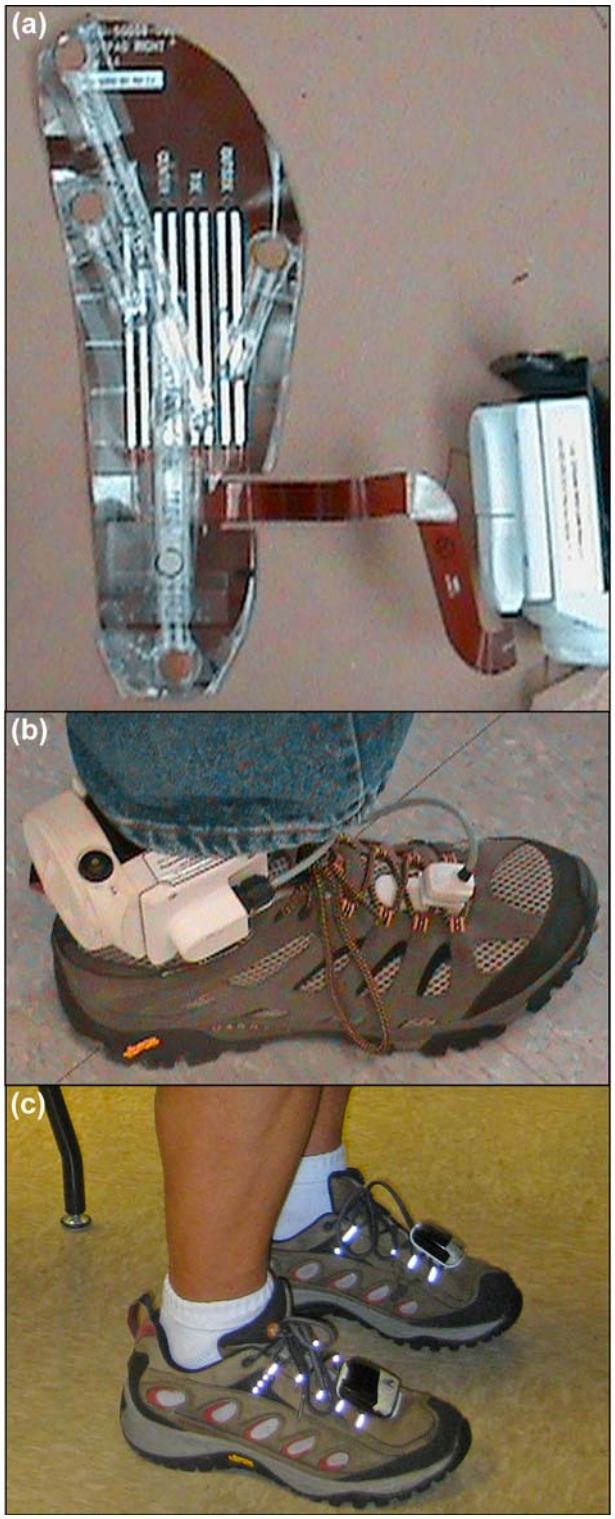

Figure 2.
Three iterations of foot controls. **(a)** Force sensitive resistor footpad wired to arm control interface (ACI). **(b)** Inertial measurement unit (IMU)-1 and ACI unit. **(c)** IMU-2 worn on shoelaces.

notification, and system faults, as well as indicators for walk detect and detection of over-angle limits for the IMU (that temporarily disabled the IMU-2).

DEKA designed inflatable socket bladders or actuators to be embedded inside TH sockets using a special design aimed at increasing skeletal stabilization [15] or to be used inside X-frame sockets to provide pressure relief and greater stability. During the gen 3 phase, DEKA introduced a dynamic socket controller that could regulate inflation of the socket bladders through independent pneumatic channels using the touch of one or more buttons.

The VA study collected both qualitative and quantitative data on subject and clinician attitudes and opinions about the usability of the DEKA Arm. This article summarizes the major subject and clinician recommendations to improve the gen 2 device and reports on subjects' satisfaction and usability ratings for the gen 2 and gen 3 prototypes. Detailed qualitative feedback on subject perceptions about the DEKA Arm and its controls are reported in separate articles.

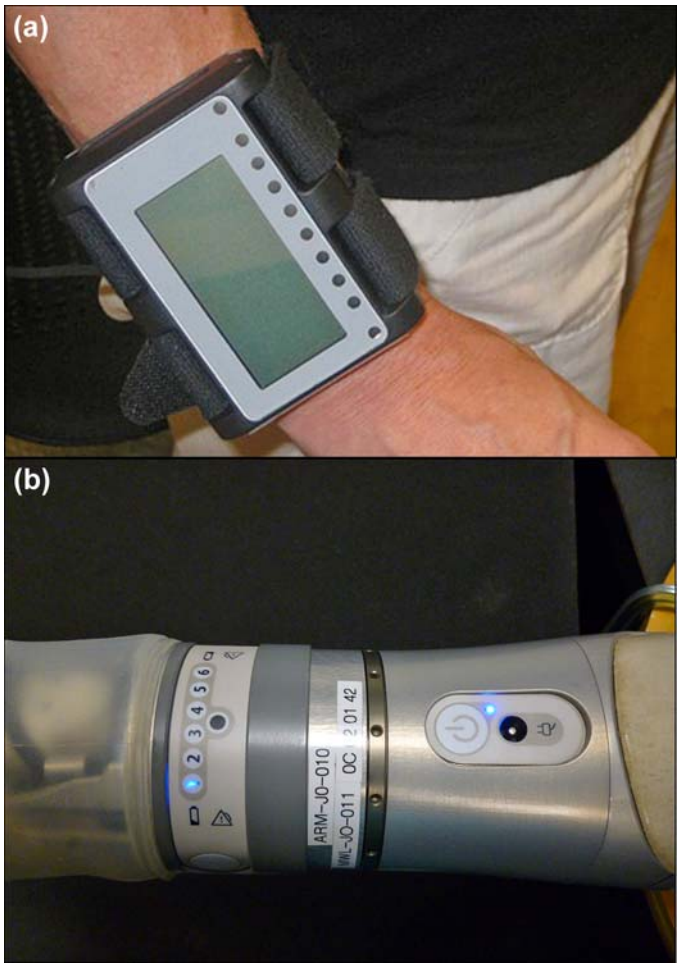

Figure 3.
Visual notification system. **(a)** Luke User Interface worn on wrist (second-generation DEKA Arm). **(b)** Wrist display embedded into third-generation DEKA Arm wrist.

METHODS

Five sites participated in this study between 2009 and 2012: Providence VA Medical Center, Providence, Rhode Island; VA New York Harbor Healthcare System (NYHHS), Brooklyn, New York; James A. Haley Veterans' Hospital, Tampa, Florida; VA Long Beach Healthcare System, Long Beach, California; and the Center for the Intrepid (CFI), San Antonio, Texas. The protocol was approved by the institutional review boards at each site. Subjects met the following inclusion criteria: at least 18 yr old and single or bilateral upper-limb amputation at the TR, TH, SD, or scapulathoracic level. All subjects were required to have active control over one or both ankles or have an appropriate number of myoelectric and/or other control sites to enable adequate prosthetic control configuration for the DEKA Arm (as determined by the study prosthetist). Subjects were excluded if they had significant uncorrectable visual deficits; major communication or neurocognitive deficits; skin conditions that prevented prosthetic wear; an electrically controlled medical device; or any significant comorbidity, cognitive deficit, or mental health problem that would limit their ability to participate fully.

Subjects were recruited through clinical staff, flyers and brochures, email lists, and press releases. All subjects provided their written consent before entering the study.

After DEKA Arm controls were set up, subjects were familiarized with controls and arm features by using the virtual reality environment, an interactive computer software program [13]. Subjects were then trained in use of the device over the course of 10 or 15 two hour training sessions, depending on level of amputation. Prosthetic use training began with reinforcement of prosthetic control patterns of motions, proceeded to simple grasp and release activities, and progressed to more complex functional tasks. The training protocol for SC subjects was extended from 10 visits to 15 visits partway through the study, after a need for additional training for users at this level was recognized.

Data Collection

Recommendations for Improvements

Subject and clinician recommendations for improvements to the DEKA Arm were gathered using several methods. First, all study sessions were videotaped, and subject and clinician feedback was made during study sessions, videos were viewed by study analysts, and key recommendations were extracted from the sessions. Subjects and clinicians also had use of digital audio recorders that they could use after study sessions to make comments about their experiences and the DEKA Arm and suggestions for how it could be optimized. Audiotapes were transcribed verbatim and analyzed for recommendations. In addition, structured surveys containing both structured and open-ended questions eliciting critical feedback and recommendations for improvement were administered after fitting the DEKA Arm, after 10 h of training, and at the end of training. At the end of the study, semistructured interviews were administered to elicit comments on areas not addressed in the end of study survey. Study prosthetists and therapists provided ongoing feedback and answered survey questions at the end of each subject's protocol.

Standardized Tests and Measures

The Trinity Amputation and Prosthesis Experience Scale (TAPES) satisfaction scale [16], the DEKA Arm satisfaction scale, and the DEKA Arm usability scale scores were collected at the end of the study. The TAPES was scored as overall composite and as three separate subscales: aesthetic satisfaction, weight satisfaction, and functional satisfaction [16]. Three DEKA Arm satisfaction scales and three DEKA Arm usability scales were developed to address the unique features of the DEKA Arm. Detailed information on the development and content of these measures is provided in the **Appendix** (available online only).

Briefly, the gen 2-gen 3 satisfaction scale is a 25-item scale, with an alpha of 0.89, that was administered to both gen 2 and gen 3 subjects. Two additional items, also administered to both gen 2 and gen 3 subjects, that did not fit well with the overall scale were examined individually. A gen 2 satisfaction scale, with an alpha of 0.63, was constructed from three items that were asked only in the gen 2 portion of the study. A 15-item gen 3 satisfaction scale, with an alpha of 0.87, was used in the gen 3 portion of the study. Five additional items that did not fit well with the gen 3 satisfaction score were evaluated individually. In all satisfaction scales developed for this study, subjects were asked to rate satisfaction with specific aspects of the DEKA Arm's function on a 7-point scale (where 1 = very unhappy, 2 = unhappy, 3 = mostly dissatisfied, 4 = mixed, 5 = mostly satisfied, 6 = happy, and 7 = very happy).

The 17-item gen 2-gen 3 usability scale, with alpha of 0.89, was administered to subjects in the gen 2 and gen 3 portions of the study. Six items that did not fit well with the overall scale were not included in the summary score and were examined individually. The gen 2 usability scale included three items, with an alpha of 0.54, that were asked to gen 2 users only. Two items that did not fit well with the overall scale were examined individually. The gen 3 usability scale, with alpha of 0.85, contained five items that were asked only to gen 3 users. Four additional items that did not fit well with the overall scale were examined individually. All usability scales used a 6-point scale (where 1 = unable to do, 2 = very difficult, 3 = difficult, 4 = neither easy nor difficult, 5 = easy, and 6 = very easy).

Data Analysis

At the conclusion of each subject's participation in the study, all recommendations for optimizing the DEKA Arm were identified from data sources including video, audio, surveys, and semiguided interviews; they were then grouped by theme. A written synopsis of usability concerns and recommendations was then sent to the study site for verification by clinicians. After verification, and refinement as needed, the usability report with recommended improvements was forwarded to DEKA. At the conclusion of the study, themes from all usability reports were compiled by investigators and the VA research team evaluated whether or not study recommendations identified in gen 2 usability reports had been addressed in whole or in part in the gen 3 design.

Users' perspectives on usability and satisfaction with the gen 2 and gen 3 prototypes were evaluated using the TAPES and the usability and satisfaction scales and items developed for this study. Descriptive statistics for all scales and individual items were examined and results compared by prototype using nonparametric Wilcoxon rank-sum tests. Results for summary scores were stratified by level of DEKA Arm and outcomes compared by prototype using Kruskal-Wallis analysis of ranks tests.

RESULTS

Thirty-nine subjects participated in the study: 26 in the gen 2 phase and 13 in the gen 3 phase. Of the 13 gen 3 subjects, 5 had participated in the gen 2 phase. Two subjects from gen 2 did not complete the end of study survey questions because they terminated the study unexpectedly. **Table 1** shows detailed characteristics of the 37 subjects who provided end of study survey data and are included in this analysis. Of these gen 2 subjects, 8 were fit with an RC, 6 with an HC, and 10 with an SC. Of the gen 3 subjects, 4 were fit with an RC, 5 with an HC, and 4 with an SC. There were four female subjects in the gen 2 group and one in the gen 3 group.

Table 1.
Characteristics of subjects included in analysis of second-generation (gen 2) and third-generation (gen 3) DEKA Arms.

Characteristic	Gen 2 (*n* = 24)	Gen 3 (*n* = 13)
Age (yr)		
Mean ± SD	44.8 ± 17.0	46.4 ± 16.4
Range	19.7–82.8	23.1–70.8
Training Visits (*n*)		
Mean ± SD	10.3 ± 3.0	10.7 ± 3.5
Range	5–15	5–15
DEKA Arm Fit Level, *n* (%)		
Radial Configuration	8 (33.3)	4 (30.8)
Humeral Configuration	6 (25.0)	5 (38.5)
Shoulder Configuration	10 (41.7)	4 (30.8)
Sex, *n* (%)		
Male	20 (83.3)	12 (92.3)
Female	4 (16.7)	1 (7.7)
Race, *n* (%)		
White	21 (87.5)	13 (100.0)
Other	3 (12.5)	0 (0.0)
Veteran, *n* (%)		
Nonveteran	7 (29.7)	5 (38.5)
Veteran	12 (50.0)	5 (38.5)
Active Duty	5 (20.8)	3 (23.1)
Prosthetic User (active device only), *n* (%)		
Not Current User	2 (8.3)	2 (15.4)
Full-Time	13 (54.2)	6 (46.2)
Part-Time	9 (37.5)	5 (38.5)
Participant in Gen 2 Study, *n* (%)	24 (100.0)	5 (38.5)
Prosthetic Experience (includes cosmetic), *n* (%)		
Not Prosthetic User	2 (8.3)	2 (15.4)
Very New (<3 mo)	1 (4.5)	0 (0.0)
New (3 mo–1 yr)	4 (18.2)	3 (27.3)
Experienced (1–5 yr)	3 (13.6)	5 (45.5)
Very Experienced (≥5 yr)	14 (63.6)	3 (27.3)

SD = standard deviation.

Summary of Gen 2 and Gen 3 Recommendations for Improvement

Table 2 summarizes the major user and clinician suggestions for improvements to gen 2 and indicates whether or not the research team believed that these suggestions were addressed in the gen 3 design. With few exceptions, the areas of improvement recommended by gen 2 users and clinicians were addressed to some degree in gen 3. Clinicians also provided detailed feedback about the computer software used to configure the controls. This feedback was shared with DEKA on an ongoing basis but is not detailed in **Table 2** or in this article.

Overall Satisfaction and Perceived Usability

Quantitative analyses suggest that satisfaction and perceived usability of the DEKA Arm was greater for gen 3 than for gen 2. Overall TAPES scores were similar for gen 2 and gen 3 (**Table 3**); however, scores of the TAPES aesthetic satisfaction subscale were higher for

Table 2.
Summary of recommended improvements (second-generation DEKA Arm [gen 2]) and changes to third-generation DEKA Arm (gen 3).

Recommendation	Gen 2		Addressed in Gen 3?
	User	Clinician	
Size/Weight			
Make lighter in weight.	×	×	No
Make arm/hand smaller/less bulky.	×	×	Yes
Comfort/Public Use			
Reduce components/wires (number and size).			
Reduce external components.	×	×	Yes
Reduce wires.	×	×	Yes
Internalize battery.		×	Yes*
Make wireless or internalize wires.	×	×	Yes
Improve cosmesis.	×		Yes
Make less noisy.	×		Yes
Waterproof.	×		Yes
Improve inflatable socket bladders.	×		Yes
Controls/User Interface			
Improve foot controls.	×	×	Yes
Improve EMG system.	×	×	Yes
Improve user notification system.	×	×	Yes
Make process of correcting faults easier.	×	×	Yes
Improve tactor.	×	×	No
Improve battery life (main/IMU).		×	Yes
Mechanics/Movements			
Wrist: Add radial-ulnar deviation/increase tension.	×	×	Yes
Improve grip force/finger alignment/grip speed.	×		Yes
Improve end-point control.		×	Yes
Reliability			
Improve overall reliability.	×	×	Yes
Improve reliability of hand and fingers.	×	×	Yes
Reduce faults and unexplained stoppages.	×	×	Yes

*For humeral and shoulder configurations.
EMG = myoelectrode, IMU = inertial measurement unit.

Table 3.
Satisfaction and usability ratings (mean ± standard deviation) by second-generation (gen 2) and third-generation (gen 3) DEKA Arm prototype at end of study.

Measure	Gen 2 (n = 21)	Gen 3 (n = 11)	p-Value
TAPES	3.3 ± 0.8	3.6 ± 0.4	0.45
Aesthetic	3.2 ± 0.8	3.9 ± 0.6	0.04*
Weight	2.4 ± 1.2	2.4 ± 1.4	0.71
Function	3.7 ± 0.9	3.6 ± 0.6	0.70
Scale	**Gen 2 (n = 24)**	**Gen 3 (n = 13)**	**p-Value**
Gen 2-Gen 3 Satisfaction	5.3 ± 0.8	5.6 ± 0.7	0.18
Gen 2-Gen 3 Usability	4.8 ± 0.7	5.3 ± 0.5	0.02*

*Statistical significance at $p < 0.05$.
TAPES = Trinity Amputation and Prosthesis Experience Scale.

gen 3 (p = 0.04), indicating greater satisfaction with the appearance of the device. No statistically significant differences were observed in TAPES scores for overall scale or subscales when stratified by DEKA Arm level (results not shown).

Scores of the gen 2-gen 3 satisfaction scale were higher for gen 3, but differences were not statistically significant. No statistically significant differences were observed in DEKA Arm satisfaction scores when stratified by DEKA Arm level (results not shown). Scores of individual satisfaction items that were significantly higher for gen 3 subjects than for gen 2 subjects related to satisfaction with device doffing, grip switching, elbow movement, and humeral rotation (**Table 4**). Among all items asked of gen 3 subjects, those with the lowest mean satisfaction scores (3 = mostly dissatisfied) were satisfaction with wires and cables, rated as 3.3, followed by weight of the arm, rated as 3.5. The three highest rated items (6 = happy) were battery charger, rated at 6.5; shoulder appearance, rated at 6.3; and EMG speed, rated at 6.2.

Scores for the gen 2-gen 3 usability scale were higher for gen 3, indicating better overall perceived usability for the gen 3 prototype (p = 0.02). No statistically significant differences were observed in these scores when stratified by DEKA Arm level (results not shown). Scores of individual usability items showed higher rankings for the following items in Gen 3: socket and harness doffing, chuck grip, tool grip, pinch grip, lateral pinch, power grip, and grip switching ($p < 0.05$) (**Table 5**).

The mean score of the 3-item satisfaction scale asked only in gen 2 was 5.4 and the mean score for the 3-item gen 2 usability scale was 5.3 (**Table 6**). The mean score of the gen 3 satisfaction scale was 4.8 and the mean score for the gen 3 usability scale was 4.7. The lowest ranked usability items asked only to gen 3 subjects were related to fingernails, rated as 4.2, followed by hand covering, rated as 4.3, and the DEKA Arm system as a whole, rated as 4.3 (**Table 6**). The highest ratings were for the battery charger, rated at 5.7; tactor for mode, rated at 5.8; and tactor for grip, rated at 5.8.

DISCUSSION

This article summarized subjects' and clinicians' key recommendations to improve the gen 2 DEKA Arm, and presented subjects' ratings of satisfaction and usability. Subjects' ratings of satisfaction and usability were compared by DEKA Arm prototype using standardized measures. Our findings indicate that subjects rated aspects of satisfaction and usability higher for the gen 3 than for the gen 2 prototype. Data suggests that DEKA's optimization efforts were successful, although there are features of the gen 3, such as its weight, external cables and wires, reliability, hand covering, and fingernails, that would benefit from further optimization efforts.

Satisfaction with the gen 3 appearance, as measured by the TAPES, was rated higher than that of the gen 2. Considerable efforts were made to enhance the appearance of the gen 3 prototype by altering the contours and arm covering, miniaturizing the IMUs, eliminating the ankle straps, and embedding the wrist display.

Users of both prototypes rated their satisfaction with the DEKA Arm as "mostly satisfied" on the gen 2-gen 3 satisfaction scale developed for this study. Comparison of individual items from the scale revealed that gen 3 users were more satisfied with doffing, grip switching, and

Table 4.
Comparison (mean ± standard deviation) of satisfaction items asked of second-generation (gen 2) and third-generation (gen 3) DEKA Arm users.

Item	Gen 2 (n = 24)	Gen 3 (n = 13)	p-Value
Overall Function	5.1 ± 1.6	5.2 ± 1.6	0.91
Inertial Measurement Units	4.8 ± 1.1	5.2 ± 1.7	0.40
Other Controls	5.2 ± 1.6	5.8 ± 1.3	0.61
Tactor for Grip Pressure	4.6 ± 1.7	4.9 ± 1.7	0.57
Virtual Reality Environment	5.4 ± 1.2	5.0 ± 1.5	0.47
Donning	4.3 ± 2.0	5.2 ± 1.5	0.20
Doffing	4.5 ± 2.0	5.8 ± 1.3	0.03*
Hand Operation	5.9 ± 1.4	5.9 ± 1.0	0.79
Chuck Grip	5.3 ± 1.5	5.2 ± 1.4	0.69
Tool Grip	5.3 ± 1.3	5.8 ± 1.1	0.20
Pinch Grip	5.6 ± 1.1	6.1 ± 1.4	0.08
Lateral Pinch	5.9 ± 1.1	5.5 ± 1.1	0.25
Power Grip	5.7 ± 1.3	6.3 ± 0.8	0.20
Switching Grips	4.9 ± 1.7	5.9 ± 1.8	0.03*
Forearm Rotation	5.5 ± 1.5	6.3 ± 1.0	0.10
Wrist Movement	5.2 ± 1.5	5.8 ± 1.3	0.22
Elbow Movement	5.3 ± 1.2	6.3 ± 0.9	0.05*
Humeral Rotation	5.3 ± 1.1	6.3 ± 1.1	0.04*
Socket Comfort	5.3 ± 1.7	5.5 ± 1.1	0.15
Harnessing	5.0 ± 1.8	4.8 ± 1.2	0.57
Bladders	5.1 ± 1.5	5.6 ± 1.3	0.39
Socket Stability	5.5 ± 1.4	6.0 ± 0.9	0.45
Grip Indicator	5.6 ± 1.2	5.3 ± 1.5	0.69
Mode Indicator	5.6 ± 1.4	5.9 ± 1.2	0.63
Battery Indicator	5.3 ± 1.4	6.2 ± 1.1	0.11
Not Included in Summary Score			
Myoelctrodes	4.9 ± 1.5	5.4 ± 1.0	0.32
Error Indicator		6.0 ± 1.3	0.41

*Statistical significance at $p < 0.05$.

movements of the elbow and upper arm than gen 2 users. Greater satisfaction with switching grips may have been associated with the gen 3 wrist display, which provides user notification of current handgrip.

Overall usability ratings were higher for gen 3 users who indicated that using the arm was "easy" as compared with gen 2 users who indicated that it was "neither easy nor difficult." All of the grips were rated as more usable by gen 3 users than gen 2 users. This may be because the grip trajectory and finger shapes were changed in gen 3. Gen 3 users also rated the elbow and humeral movements as more usable than did gen 2 users.

The findings reported in this article can be triangulated with the findings from the qualitative analysis that will be reported elsewhere, which provides further insights into why users may have rated satisfaction and usability the way that they did.

To our knowledge, ours is largest evaluation study of any new upper-limb prosthetic technology ever conducted. We worked with the device developer (DEKA) throughout the gen 3 development phase to provide feedback on specific device features. We then evaluated subject feedback on the resulting gen 3 design. Our findings can be used to further refine the gen 3 prototype and prepare it for commercialization. The integration of findings from usability research into the product development process should result in a better final product. Moreover, our findings can be used by other device developers who want to understand user perspectives on specific device features and functions.

Table 5.
Comparison (mean ± standard deviation) of usability items asked of second-generation (gen 2) and third-generation (gen 3) DEKA Arm users.

Item	Gen 2 (*n* = 24)	Gen 3 (*n* = 13)	*p*-Value
Overall Function	4.8 ± 1.0	5.1 ± 1.0	0.37
Inertial Measurement Units	4.6 ± 0.9	5.2 ± 1.0	0.13
Other Controls	4.7 ± 1.6	5.3 ± 1.0	0.70
Tactor for Grip Pressure	4.8 ± 1.2	5.3 ± 1.0	0.21
Donning	3.9 ± 1.7	4.5 ± 1.7	0.15
Doffing	4.0 ± 1.5	5.0 ± 1.8	0.02*
Chuck Grip	5.0 ± 0.8	5.5 ± 0.7	0.03*
Tool Grip	5.0 ± 0.7	5.6 ± 0.5	0.02*
Pinch Grip	5.1 ± 0.7	5.8 ± 0.4	<0.01*
Lateral Pinch	5.1 ± 0.8	5.7 ± 0.5	0.01*
Power Grip	5.1 ± 0.8	5.7 ± 0.5	0.02*
Switching Grips	4.6 ± 1.1	5.4 ± 1.0	0.02*
Forearm Rotation	5.2 ± 0.9	5.3 ± 0.9	0.48
Wrist Movement	5.0 ± 0.9	5.4 ± 0.9	0.15
Elbow Movement	4.8 ± 0.9	5.4 ± 0.5	0.06
Humeral Rotation	4.9 ± 0.7	5.6 ± 0.5	0.05*
Harnessing	4.1 ± 1.7	4.3 ± 1.9	0.68
Not Included in Summary Score			
Myoelectrodes	5.0 ± 1.0	4.8 ± 1.1	0.58
Virtual Reality Environment		5.1 ± 0.8	0.34
Bladders	4.8 ± 1.3	4.9 ± 1.8	0.68
Grip Indicator		5.5 ± 0.7	0.74
Mode Indicator	5.5 ± 1.0	5.4 ± 0.7	0.51
Battery Indicator		5.5 ± 0.7	0.85

*Statistical significance at $p < 0.05$.

Although we compared mean scores for some scales and some items by prototype, we recognize that our results need to be interpreted cautiously for several reasons. We tested two groups of subjects: those who participated in gen 2 and those who participated in gen 3. These two groups may have differed from each other in ways that could have influenced the satisfaction and usability ratings. The few individuals who participated in both the gen 2 and gen 3 portions of the study were in the best position to evaluate improvements in the prototypes. Therefore, we examined summary scores for the five subjects who participated in both the gen 2 and gen 3 portions of the study and found that their ratings of satisfaction and usability were higher in gen 3 for all scales, although only statistically different for the TAPES aesthetic satisfaction scale.

Furthermore, our analyses are limited by the small sample size. Because we lacked the statistical power to detect differences in groups, we were at risk of making a type II statistical effort, meaning that we may have failed to detect a true difference in scores when one did indeed exist. This might explain why several of the key improvements made in the gen 3 (such as changes to the IMUs and indicators) were rated more highly, but differences in scores were not statistically significant. We conducted a post hoc power analysis and found that we would have needed two equal size samples of 23 persons in each to be 80 percent confident that we could detect a large effect size. Such a sample size was not feasible given the limitations of funding and the time line of DEKA's optimization efforts.

CONCLUSIONS

Data suggest that DEKA's optimization efforts were successful. Compared with gen 2 users, gen 3 users were more satisfied with appearance, grips, elbow movement,

Table 6.
Items and scales utilized in second-generation (gen 2) or third-generation (gen 3) DEKA Arms only.

Satisfaction	*n**	Mean ± SD
Gen 2 Only		
Force Sensitive Resistors	6	4.5 ± 1.6
Air Bladder Controls	19	5.8 ± 1.1
Dynamic Straps	6	5.0 ± 1.8
Summary Score	21	5.4 ± 1.4
Gen 3 Only		
Arm Appearance	13	5.5 ± 1.0
Hand Shape	13	5.5 ± 1.1
Hand Size	13	5.1 ± 1.7
Hand Covering	12	5.2 ± 1.2
Arm System	13	3.8 ± 1.9
Hardware Reliability	13	4.6 ± 1.4
Hand Cover Durability	13	4.8 ± 1.3
Hand Cover Material	13	4.6 ± 1.1
Fingernails	13	4.5 ± 1.6
Inertial Measurement Unit Speed	13	5.7 ± 1.3
Tactor for Mode	9	5.7 ± 0.7
Tactor for Grip Change	10	5.7 ± 0.7
Weight	13	3.5 ± 1.7
Wires and Cables	13	3.3 ± 1.8
Waterproofing	8	5.4 ± 1.3
Summary Score	13	4.8 ± 0.8
Items Not Used in Gen 3 Summary Score		
Shoulder Appearance	4	6.3 ± 1.0
Myoelectrode Speed	9	6.2 ± 0.4
End-Point Control	4	6.0 ± 0.8
Dynamic Socket Controller	6	5.7 ± 1.0
Battery Charger	11	6.5 ± 0.5
Usability	***n***	**Mean ± SD**
Gen 2 Only		
Hand Operation Use	24	5.4 ± 0.9
Air Bladder Controls	19	5.4 ± 0.6
Dynamic Straps	6	4.7 ± 1.2
Summary Score	24	5.3 ± 0.9
Items Not Used in Gen 2 Summary Score		
Force Sensitive Resistors	6	4.3 ± 1.2
Socket Stability	23	4.9 ± 1.2
Gen 3 Only		
Hand Covering	9	4.3 ± 0.9
Hand Cover Material	12	4.5 ± 1.1
Fingernails	13	4.2 ± 1.3
Dynamic Socket Controller	6	5.3 ± 0.8
Battery Charger	11	5.7 ± 0.5
Summary Score	13	4.7 ± 0.7
Items Not Used in Gen 3 Summary Score		
Arm System	12	4.3 ± 0.9
Tactor for Mode	9	5.8 ± 0.4
Tactor for Grip Change	10	5.8 ± 0.4
End-Point Control	4	5.3 ± 0.5

*Number of respondents who completed item. Not all items were applicable to all subjects.
SD = standard deviation.

and doffing and rated overall usability higher. There are still features of the gen 3, including weight and external cables and wires, that would benefit from further optimization efforts.

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Drafting of manuscript: L. Resnik, M. Borgia.

Critical revision of manuscript for important intellectual content: L. Resnik, M. Borgia.

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