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User and clinician perspectives on DEKA Arm: Results of VA study to optimize DEKA Arm

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Abstract—This article summarizes feedback from Department of Veterans Affairs (VA) subjects and clinicians gathered during the VA optimization study of the DEKA Arm. VA subjects and clinicians tested two DEKA Arm prototypes (second-generation [gen 2] and third-generation [gen 3]). Features of the prototypes in three configurations are described. DEKA used feedback from the VA optimization study and from their own subjects to refine the gen 2 prototype. Thirty-three unique subjects participated in the VA evaluation; 26 participated in the gen 2 evaluation (1 subject participated twice), 13 participated in the gen 3 evaluation, and 5 participated in both gen 2 and gen 3 evaluations. Subject data were gathered through structured and open-ended surveys, interviews, and audio- and videotaped sessions. Study prosthetists and therapists provided ongoing feedback and completed surveys at the end of each subject's protocol. Eleven categories of feedback were identified: weight, cosmesis, hand grips, wrist design, elbow design, end-point control, foot controls, batteries and chargers, visual notifications, tactor, and socket features. Final feedback on the gen 3 was generally positive, particularly regarding improvements in wrist design, visual notifications, foot controls, end-point control, and cosmesis. Additional refinements to make the device lighter in weight, eliminate external wires and cables, and eliminate the external battery may further enhance its perceived usability and acceptability.

Key words: amputation, assistive technology, DEKA Arm, optimization, prosthetics, qualitative, satisfaction, upper limb, usability, Veterans.

INTRODUCTION

Background

The development of the DEKA Arm was funded by the Defense Advanced Research Projects Agency's (DARPA's) Revolutionizing Prosthetics program in 2006 [1]. By 2008, DEKA had built and tested the first-generation DEKA Arm and developed the second-generation (gen 2) prototype. Because the gen 2 DEKA Arm was designed as an experimental platform, it included many test features that had not yet been finalized or miniaturized. Before moving to the next prototype, the Department of Veterans Affairs (VA)

Abbreviations: ACI = arm control interface, CFI = Center for the Intrepid, DARPA = Defense Advanced Research Projects Agency, DSC = dynamic socket controller, EMG = myoelectrode, FSR = force sensitive resistor, gen 2 = second-generation DEKA Arm, gen 3 = third-generation DEKA Arm, HC = humeral configuration, IMU = inertial measurement unit, LED = light-emitting diode, LUI = Luke User Interface, MCM = master control module, NYHHS = New York Harbor Healthcare System, PI = principal investigator, PVAMC = Providence Department of Veterans Affairs Medical Center, RC = radial configuration, ROM = range of motion, SC = shoulder configuration, TH = transhumeral, VA = Department of Veterans Affairs.

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examine the ease of use and perceived attributes of the device within a clinical setting [2]. DEKA used feedback from both the VA study and from studies of their own subjects to refine the prosthetic prototype and made numerous iterative changes to features and software. Major hardware and design changes were introduced in the third-generation (gen 3) DEKA Arm prototype. An earlier article resulting from the VA optimization study reported that the majority of study participants viewed the DEKA Arm favorably, could do new activities using the DEKA Arm that they were unable to do with their current prostheses, and wanted to receive a DEKA Arm when it becomes available in the future [3]. That said, most participants also had concerns about using the device at home and made recommendations that they hoped would be incorporated in the optimization of the device [3]. This article describes the qualitative usability feedback from VA subjects and clinicians that was generated during the VA optimization study. Quantitative study results reporting on dexterity and activity performance and a separate detailed qualitative study reporting on users' experiences using the foot controls to operate the device will be reported elsewhere.

DEKA Arm

The DEKA Arm (both gen 2 and gen 3) is available in three configurations: radial configuration (RC), humeral configuration (HC), and shoulder configuration (SC) (see Figure 1 in Resnik and Borgia in this issue for gen 2 and gen 3 SC prototypes [4]). The SC has 10 powered degrees of freedom and additional passive degrees of freedom [5–6] (**Table 1**). A full description is available elsewhere [7].

Table 1.
Powered movements of DEKA Arm.

Joint	Movement
Shoulder	Flexion, Extension, Abduction, Adduction
Humeral Rotator*	Internal Rotation, External Rotation
Elbow	Flexion, Extension
Forearm	Pronation, Supination
Wrist	Flexion,† Extension†
Thumb	Flexion, Extension, Abduction, Adduction
Index Finger	Flexion, Extension
Fingers 3–5	Flexion, Extension

*Humeral rotation occurs proximal to elbow joint.
†Third-generation DEKA Arm wrist has compound movement of flexion-ulnar deviation and extension-radial deviation.

A major change in gen 3 was the compound wrist, which combined movements of ulnar radial deviation with wrist flexion and movements of ulnar deviation with wrist extension. Both prototypes had six preprogrammed grips: power, tool, chuck, lateral pinch, fine pinch open, and fine pinch closed.

All configuration levels used control inputs for the hand and wrist. The HC and SC control schemes had dual modes enabling the user to switch between "hand mode" of operation and "arm mode." In gen 3, up to three movements of the hand and or wrist were potentially available in arm mode if sufficient inputs were available. The SC employed end-point control to enable simultaneous, coordinated movement to bring the terminal device (the end point) to a desired position in space. During the VA optimization study, there were three different versions of end-point control, each with differences in movement trajectories and features.

Users controlled movements with a combination of foot controls, myoelectrodes (EMGs), pneumatic bladders, and/or manual switches. Three iterations of foot controls (see Figure 2 in Resnik and Borgia in this issue [4]) were used: force sensitive resistors (FSRs); inertial measurement units (IMUs) during gen 2 (IMU-1); and a refined version of the IMU in gen 3 (IMU-2) that did not require an external arm control interface (ACI) unit worn on the ankles and had new features, including the ability to detect walking motion and to automatically put the arm into standby (called Walk Detect).

The DEKA Arm was powered by a rechargeable external battery worn on a belt or harness. The gen 3 HC and SC DEKA Arms had the potential to include an internal battery. All gen 2 DEKA Arms had a master control module (MCM) unit that was also worn externally. In gen 3, this was internalized in the wrist as the master ACI unit. The DEKA Arm made a variety of sounds to notify users of events such as powering on and off, low battery, and system faults. In addition, an audible, vibratory tactor "buzzed" to indicate changing between hand and arm modes, moving into or out of standby mode, changing grips, and changing grip pressure. The Luke User Interface (LUI) introduced in gen 2 displayed information about grip, mode, power, battery charge, and system faults (see Figure 3 in Resnik and Borgia in this issue [4]). In gen 3, the LUI was replaced with an embedded wrist display (see Figure 3 in Resnik and Borgia in this issue [4]) that had light-emitting diode (LED) displays for grip, low battery, mode notification, and system faults, as well as indicators for Walk Detect and over-angle limit detect.

DEKA designed inflatable bladders to be used inside transhumeral (TH) sockets to increase skeletal stabilization or for use inside X-frames to provide pressure relief [8]. During the gen 3 phase, DEKA introduced a dynamic socket controller (DSC) that could be used to regulate socket bladder inflation through independent pneumatic channels using the touch of one or more buttons.

METHODS

This was an iterative optimization study using a multiple case study design [9–10]. Participating sites included the Providence VA Medical Center (PVAMC), VA New York Harbor Healthcare System (NYHHS), James A. Haley Veterans' Hospital, VA Long Beach Healthcare System, and Center for the Intrepid (CFI). The study was approved by each site's institutional review board. Subjects had unilateral or bilateral amputation at the transradial, TH, shoulder disarticulation, or forequarter level and were recruited through clinical staff, advertisements, and press releases.

After socket fitting and control setup, subjects were oriented to device features and controls through an interactive virtual reality environment software program [5]. They were then trained in the use of the device in 10 or 15 2-hour training sessions, depending on amputation level. Training progressed from simple grasp and release activities to more complex functional activities and daily tasks in a clinical environment. Subjects used the DEKA Arm under supervision of the study staff at all times.

Data Collection

Surveys containing both structured and open-ended questions were administered after prosthetic fitting, after 10 h of training, and at the end of training. The questions asked about overall impressions and the ease of use of the DEKA Arm. Gen 2 subjects were asked how the system could be improved. Questions were modified both during gen 2 and at the start of gen 3 to address iterative changes. Because further optimization was not foreseen, subjects in gen 3 were not asked to suggest general improvements. Instead, they were asked to comment on gen 3 changes to the IMU controls, wrist display, battery life and charger, user notification system, and end-point control. They were also asked to talk about device weight and whether or not they had experienced any changes in "wearability" since beginning the study. After the last training visit, semistructured interviews were used to elicit comments on areas not addressed in surveys. Users who participated in both the gen 2 and gen 3 portions of the study were queried about differences and improvements in the DEKA Arm.

Study prosthetists and therapists provided ongoing feedback through audiotaped and written study notes and surveys at the end of each subject's protocol. Clinician survey questions were modified to address changes to the DEKA Arm as it was optimized. Digital handheld recorders were used to record additional subject and clinician comments before, during, and/or after study visits. All study training and testing sessions were videotaped.

Data Analysis

Each case was assigned to a primary data analyst who was responsible for tracking the subject and his or her progress through the study. Videotaped sessions were viewed by data analysts who took notes on the subject's and clinician's key comments and concerns. The study principal investigator (PI) also viewed videotaped segments and read study transcripts. After each subject completed study activities, all data sources were analyzed. Data analysts coded the subject responses to open-ended surveys, transcribed semiguided interviews, audiotaped comments from subjects and clinicians, created memos of videotaped study sessions, and organized clinician study notes by theme.

Themes were synthesized into a detailed case study that contained a synopsis of all usability concerns and an overview of the subject perspective on using the DEKA Arm [10]. The PI and analyst then met to discuss the coding and categorization of themes within the case study and discussed any instances where their opinions differed. The source data was consulted to obtain additional information to support coding categories. The coding and thematic grouping were discussed until consensus was achieved. The usability synopsis was then sent to the site clinicians for member checking. Clinicians provided their feedback and any additional clarification regarding their observations and comments on usability. The usability section was then refined by the PI using this feedback. After case study completion, the synopsis of usability concerns and subject perspective were extracted from the case and shared with DEKA.

To address the specific purposes of this article, we first classified 11 key areas of subject feedback from the case studies. Two data analysts then constructed a cross-case

analysis to identify whether or not there were patterns of responses for subjects by device prototype and configuration level. The cross-case analysis was facilitated by extracting data from the case studies, survey responses, and subject transcripts using NVivo software (QSR International; Melbourne, Australia) and then constructing a comparison matrix of subject responses about key aspects of the DEKA Arm by prototype and amputation level. The data analysts worked together to reach consensus on categorization. Comparison matrices are an analytic tool used to visually display data in a systematic way [11]. Our analytical matrices contained key exemplars from the qualitative data and responses to specific closed-ended questions. The two analysts verified all comparison matrices against the data to confirm the quantified numbers, coding, and interpretation of findings. Clinician feedback, extracted from the usability analyses of the case studies, clinical notes, and clinician specific surveys, were also grouped by the 11 key categories and the results analyzed by prototype. The PI then audited the cross-case analyses of subject and clinician feedback.

Accuracy of the analysis was enhanced by prolonged engagement with and persistent observation of subjects; triangulation of multiple data sources, including video, audio, and written data, in construction of the case studies; comparison matrices; careful review and debriefing of the analytical thought process; an audit trail of methodological and analytic decisions; and thick description.

RESULTS

Participants

Thirty-three unique subjects participated in evaluation of the DEKA Arm. Of these subjects, 26 participated in the gen 2 evaluation (1 participated twice with different types of controls) and 13 participated in the gen 3 evaluation (5 also had participated in gen 2) (**Table 2**). Of the 14 subjects using an SC DEKA Arm, 8 completed extended training (15 sessions). **Table 3** shows the number of subjects who used each major design feature and prototype.

Data from all subjects were included in this analysis. Although five subjects terminated their study participation without finishing all training or testing activities, we found that there was robust qualitative data from all subjects because it was collected throughout the protocol. That said, there were occasions when responses to entire surveys or specific survey questions were missing. Study clinicians included one or two prosthetists and one or two occupational therapists at each of the four study sites. All clinicians were experienced with upper-limb amputation and had been trained by the study team in use of the DEKA Arm and its features.

Qualitative Feedback on Prototype Features

We categorized subject and clinician feedback into 11 key areas: weight, cosmesis, hand grips, wrist design, elbow design, end-point control, foot controls, batteries and chargers, visual notifications, tactor, and socket features (**Table 4**). User and clinician perspectives on these areas are described next.

Weight

Sixteen (62%) gen 2 users suggested making the DEKA Arm lighter. Six (75%) HC, six (75%) RC, and four (40%) SC users in gen 2 made this recommendation. Similarly, 11 (85%) gen 3 users (3 [75%] SC, 5 [100%] HC, and 3 [75%] RC) said the DEKA Arm was heavy or the weight was what they liked least about it (**Figure**). The weight, they said, made them tired, required them to "take breaks," and/or required them to doff the DEKA Arm after a few hours use. An HC user observed, "It's heavier than any one of my other arms." Weight seemed more problematic for smaller-sized users. For instance, a very petite female SC user said, "Some days I'd wear it for a couple hours and my shoulder muscles would get strained, and I really needed to take it off." In contrast, a tall, large, male SC user stated, "The way it is harnessed to me allows for such an even distribution of the weight that you don't feel the weight of the arm." It was also problematic for HC users with long residual limbs, particularly when the DEKA Arm was fully extended away from the body.

Clinical staff repeatedly recommended that the device be made lighter, commenting on subject fatigue, difficulties with donning and doffing, and the added challenges of socket fit with a heavy device. They also commented that they believed that the center of mass was located more distally than was common in other prosthetic devices, creating a longer lever arm and thus requiring greater strength to move the limb through space.

Most users adjusted to the weight and gained strength and stamina. Ten (77%) gen 3 users indicated that they had "grown accustomed to" wearing the DEKA Arm system and were "getting stronger" with training. Even after

Table 2.
Characteristics of all screened subjects.

Characteristic	Gen 2* (*n* = 26)	Gen 3† (*n* = 13)	Screened But Not Enrolled (*n* = 36)
Age (yr)			
Mean ± SD	45.4 ± 16.7	46.4 ± 16.4	43.1 ± 14.6
Range	19.7–82.8	23.1–70.8	19.9–79.4
Training Visits (*n*)			
Mean ± SD	9.8 ± 3.0	10.7 ± 3.5	—
Range	2–15	5–15	—
DEKA Arm Fit Level (*n*)			
Radial Configuration	8	4	—
Humeral Configuration	8	5	—
Shoulder Configuration	10	4	—
Sex, *n* (%)			
Male	22 (84.6)	12 (92.3)	33 (91.7)
Female	4 (15.4)	1 (7.7)	3 (8.3)
Race, *n* (%)			
White	23 (88.5)	13 (100.0)	29 (80.6)
Other	3 (11.5)	0 (0.0)	7 (19.4)
Veteran, *n* (%)			
Nonveteran	8 (30.8)	5 (38.5)	7 (19.4)
Veteran	13 (50.0)	5 (38.5)	24 (66.7)
Active Duty	5 (19.2)	3 (23.1)	5 (13.9)
Prosthetic User (active device only), *n* (%)			
Not Current User	3 (11.5)	2 (15.4)	7 (19.4)
Full-Time	14 (53.9)	6 (46.2)	21 (58.3)
Part-Time	9 (34.6)	5 (38.5)	8 (22.2)
Participant in Gen 2* Study, *n* (%)	26 (100.0)	5 (38.5)	—
Prosthetic Experience (includes cosmetic), *n* (%)			
Very New User (<3 mo)	1 (4.4)	0 (0.0)	—
New User (3 mo–1 yr)	4 (17.4)	3 (27.3)	—
Experienced (1–5 yr)	3 (13.0)	5 (45.5)	—
Very Experienced (>5 yr)	15 (65.2)	3 (27.3)	—

*Second-generation DEKA Arm.
†Third-generation DEKA Arm.
SD = standard deviation.

acclimation, however, one participant commented, "The load will never be light enough."

Cosmesis

Sixteen (62%) gen 2 users, including all four female subjects, suggested improvements in appearance or size. Some females recommended that the DEKA Arm be made more feminine looking, while users of both sexes suggested making it smaller, less bulky, more natural, or skin-colored. Subjects noted that there were too many dangling cables and wires. Clinicians suggested that the gen 2 would be more appealing and would be easier to don and doff independently if more components were integrated into the DEKA Arm and there was less external wiring. Two (20%) gen 2 SC users recommended that the shoulder motor noise be reduced.

Nine (69%) gen 3 users stated that they would be comfortable wearing the DEKA Arm in public. However, eight (62%) gen 3 users made negative comments about wires, cables, and belts, suggesting that DEKA should "clean the wires up so they're not all on the outside." Five (38%) thought that the robotic look of the DEKA Arm was "cool," reminding them of the Terminator or Robocop. Two (15%) indicated that they would prefer a more natural skin-like covering for the hand.

Table 3.
Number of subjects who used each major design feature by level of DEKA Arm.

Feature	Configuration Level			Total Subjects
	RC	HC	SC	
No. of Subjects	12	13	14	39
Foot Control				
FSR	2	1	3	6
IMU-1	6	7	7	20
IMU-2	4	5	4	13
Battery				
External Only	12	12	13	37
External and Internal	0	1	1	2
User Notification				
Auditory Only	3	1	5	9
Auditory and LUI	5	7	5	17
Auditory and Wrist Display	4	5	4	13
Control for SC				
Direct Control	NA	NA	1	1
End-Point Version 1	NA	NA	2	2
End-Point Version 2	NA	NA	2	2
End-Point Version 3	NA	NA	9	9
Socket Bladder				
Manual Inflation	NA	13	11	24
Dynamic Socket Controller	NA	3	3	6

FSR = force sensitive resistor, HC = humeral configuration, IMU = inertial measurement unit, LUI = Luke User Interface, NA = not applicable, RC = radial configuration, SC = shoulder configuration.

The DEKA Arm was available in a single size. Clinicians requested that smaller-sized components be available. Of 14 SC users, 7 (50%) (4 [40%] gen 2 and 3 [75%] gen 3) commented on the disproportionate width or "conspicuous" size of the shoulder and the difficulty they had wearing a shirt over it. Clinicians gave positive feedback about the smaller gen 3 components and the overall sleeker design and remarked that the shoulder was quieter. They suggested making the hand smaller to "allow for easier manipulation of small objects within small spaces." Clinicians frequently mentioned the need to reduce the number of gen 3 wires and cables and requested shorter length cables.

Hand Grips

Although users had generally favorable opinions about the increased functionality afforded by the six hand grips, 16 (62%) gen 2 users suggested improvements to increase grip force or speed or improve finger alignment. Clinicians recommended that finger tips be longer and the thumb shorter, because it sometimes projected too far in lateral pinch. When gen 3 users were asked whether grip strength was adequate, 11 (85%) responded affirmatively for lateral pinch, 10 (77%) for tool and power grips, and 8 (62%) for pinch grips. Six (46%) responded affirmatively for chuck grip. Clinicians suggested that finger tips be made slightly longer and have a tackier pad covering.

Wrist Design

All but one gen 2 user recommended wrist changes: either adding radial-ulnar deviation or increasing extension range of motion (ROM). Clinicians strongly urged that radial and ulnar deviation be added and that greater extension ROM be available. After major gen 3 design changes were introduced, 10 (77%) gen 3 subjects said that they liked the new wrist, although 3 (23%) made negative comments about the compound feature, saying it was "confusing" and "awkward." Even with the new design, four (31%) gen 3 users expressed a desire for greater ROM, noting that wrist extension was more limited than wrist flexion. Two (15%) gen 3 users who had existing prostheses with 360° of wrist rotation commented that they would like this feature. Clinicians agreed that this added motion would assist in completing certain tasks.

Four (80%) of the five subjects that used both a gen 2 and gen 3 DEKA Arm stated they liked the gen 3 wrist better, saying that it was "a lot easier to use" or was a "100 percent improvement." Clinicians agreed that the gen 3 wrist was beneficial and "a bit more natural and intuitive." Therapists thought it made certain activities easier, such as placing items on a lower shelf or surface without compensatory movements, placing items at overhead reach level, and picking up items off the floor.

Elbow Design

Of 13 HC users, 5 (38%) (1 [13%] gen 2 and 4 [80%] gen 3 users) reported that elbow-flexion ROM was insufficient, affecting their ability to reach their hand to mouth or head. For at least three users, however, excessive length of the prosthesis caused by long residual-limb length was a contributing factor. Clinicians also recommended that elbow ROM be increased in both gen 2 and gen 3. In several instances, prosthetists remarked that flexion ROM was "insufficient," limiting such activities as eating and drinking. Two (15%) users suggested that the elbow be made to swing freely when walking (instead of staying in a static position) to provide a more natural appearance.

Table 4.
Key categories of subject and clinician feedback on second-generation (gen 2) and third-generation (gen 3) DEKA Arm.

Category	Example of Feedback
Weight	Greater perceived weight for smaller users.
	Many reported increased acclimation to weight over time.
	Weight became problematic for TH users with long residual limbs when arm was extended.
Cosmesis	Majority suggested improved looks: make it smaller, less bulky, more natural, and skin-colored with fewer externals such as dangling wires and belts.
	Some liked "cool" robotic look.
	Many SD users commented on its disproportionate size.
Hand Grips	Most were favorable about functionality afforded by 6 hand grips.
	Gen 2 users suggested increased grip force, increased speed, or improved finger alignment.
	Gen 3 users said 5 out of 6 grips had sufficient strength.
Wrist Design	Gen 2 users wanted radial-ulnar deviation.
	Most gen 3 users with compound wrist (radial-ulnar deviation) liked it.
	Extension ROM was limited in both gen 2 and gen 3 users.
Elbow Design	Limited elbow flexion for some decreased ability to do activities near face.
	A few wanted elbow to swing freely (not be static).
End-Point Control	Importance of training to learn movement trajectories, which varied with starting position and angle of shoulder and elbow.
	Users acclimated but were still cautious with use near face and head.
	Gen 2 users disliked frequency of faults and arm becoming stuck.
Foot Controls	Early FSRs not well accepted.
	IMU-1 users disliked ankle units and putting arm into standby for walking.
	IMU-2 users were most satisfied.
Batteries/Chargers	Most frequent negative feedback: "cumbersome" size, weight, and wires of external battery and MCM.
	External battery charger was simple to use.
	Warning signal for low battery needed improvement.
Visual Notifications	LUI (gen 2) users liked it but wanted it smaller or embedded in prosthesis.
	Embedded wrist display (gen 3) users all found it useful, but wrist display was not visible when wrist was rotated.
Tactor	Operated inconsistently in both gen 2 and gen 3 users.
	Wide range of perceived usefulness: "very important" to "didn't pay attention to it."
	Mixed responses about acceptability of sound and vibration levels.
Socket Features	Early users wanted automatic, not manual, inflation of bladders.
	Dynamic socket controller had limited trial, technical difficulties.

FSR = force sensitive resistor, IMU = inertial measurement unit, LUI = Luke User Interface, MCM = master control module, ROM = range of motion, SD = shoulder disarticulation, TH = transhumeral.

End-Point Control

End-point control was a major and novel feature of the SC prosthesis and was used by all but the first gen 2 SC subject. SC users learned to use end-point control to perform many functional activities without serious adverse incident. However, it was obvious that proficient use required training and extensive practice. Four (44%) of the nine gen 2 end-point control users commented on the unpredictability of end-point motion, which varied with starting position and angle of the elbow and shoulder. One other user commented on the "weird" trajectory of the up and down movement (which was particularly evident in end-point version 2) and the need to correct this trajectory midway through the movement in order to avoid contact with the head or body. A gen 2 SC user, who hit himself accidentally in the head (with no injury) when first learning to use the DEKA Arm, expressed "tentativeness" when using the DEKA Arm near his face, even at the end of his

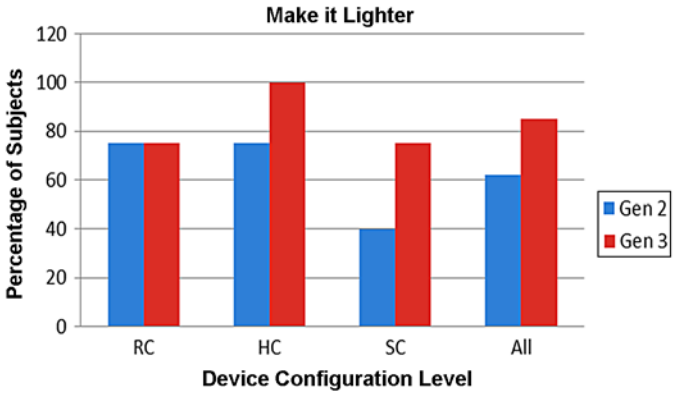

Figure.
User perceptions on weight of second-generation (gen 2) and third-generation (gen 3) DEKA Arm by prototype and configuration level. HC = humeral configuration, RC = radial configuration, SC = shoulder configuration.

protocol. Clinicians agreed that end-point control could be confusing for subjects and suggested making changes to enable the DEKA Arm to follow an identical path through space with repetitive motions.

At the end of 15 training sessions, gen 3 SC users were asked whether they were comfortable using the DEKA Arm near their head or face. One remarked, "It got more and more comfortable as I adapted . . . [but] you have to be cognizant of what your arm is doing at all times." Users were particularly careful when handling sharp objects, saying things like, "I'm not super confident with a sharp object or anything near my face, basically because sometimes the arm gets jerky."

All four gen 3 SC end-point control users were generally favorable about it, with one remarking, "It was my favorite thing." Like gen 2 users, 3 (75%) gen 3 users commented that they had to learn to keep the DEKA Arm away from their head and body, particularly when commanding it to move up or down. Several noted that they had gradually learned to avoid moving the DEKA Arm to the end of its functional envelope, where it would sometimes freeze because of preprogrammed stops designed to protect the hardware.

One SC user who had tried two versions of end-point control noted how the revised version had improved saying, "It runs much smoother, especially if I'm trying to drink from a cup or something. I can bring it directly across my body and up instead of having to go out, over and up." He said, "This arm is operating a little bit more like a regular arm would. It's getting a little bit more natural."

Gen 2 users commented on the frequency of faults and freezing that occurred at the end of the shoulder's programmed ROM. Clinicians complained that the process of manually adjusting the gen 2 DEKA Arm to release when "stuck" involved multiple steps, required a laptop, and took several minutes. They were concerned that users would be unable to manually release the device themselves and suggested that a quick release button be added to release the DEKA Arm and also open the hand, if needed. After this feature was added in the gen 3 DEKA Arm, clinicians thought it was an improvement but commented that it was awkward to hold down the button continuously while manipulating the DEKA Arm. Because it was located on the dorsum of the hand, they didn't think users would be able to reach and hold the button themselves if the DEKA Arm was outstretched when frozen. Lastly, they noted, the button only functioned when the DEKA Arm was powered on and would not operate in the event of a dead battery.

Foot Controls

The FSRs were not well accepted by subjects or clinicians who found them difficult to configure. Five (83%) of the six subjects who used the FSRs suggested improvements. IMU-1 users were more positive, although 18 (90%) of 20 expressed a desire for an improvement or an alternative control method, in part due to the large size of the accompanying ACI unit worn on the ankles, the need to put the DEKA Arm into standby while walking, and the lag time of the wireless communication protocol. Ten (77%) of thirteen IMU-2 users were positive or very positive about them, although seven (54%) wanted them to be further miniaturized.

Clinicians provided similar feedback. They were very dissatisfied with the FSRs; had many recommendations to improve the IMU-1; and were more positive about the IMU-2, noting its faster response time and smaller size. However, they also expressed concerns about how users would charge or reset the IMU-2 if away from a charging pad and recommended that DEKA design an alternative resetting method.

Batteries and Chargers

Five (19%) gen 2 users complained about wearing the external battery and the MCM units, calling them "cumbersome" or "too big and heavy." Two (8%) worried that

cables and wires might get snagged during activities. Two (8%) commented, and clinicians confirmed, that the gen 2 DEKA Arm became "sluggish" or had more faults as the battery charge decreased. Four (15%) commented that the time between the low battery alarm and the DEKA Arm running out of power was insufficient. Battery life was a particular concern for SC users, whose devices required more power.

While the MCM was internalized in gen 3, eight (62%) users expressed concern about the size, comfort, weight, or wiring of the gen 3 external battery. Nine (69%) gen 3 users thought that the external main battery life was sufficient to meet their needs, "as long as it comes with two batteries." Eleven (85%) reported that charging and changing the external battery was "simple" and "easy to use." However, the single gen 3 participant with bilateral upper-limb loss stated that the battery charger was difficult for him to use. Clinicians observed that the gen 3 batteries had longer life, were smaller, and were easier to charge and replace. Yet several wished that the external battery would last for a full day, be smaller, or be eliminated entirely and replaced with an internal battery.

Visual Notifications

Fourteen (82%) of the seventeen subjects who used a LUI felt positively about it, finding it useful and "almost indispensable." The most frequently suggested improvements were to make it smaller, make it wireless, incorporate it into the DEKA Arm, and minimize redundancy of display information (which included lights, letters, and numbers). Clinicians echoed subjects' suggestions but added that the LUI helped them in troubleshooting because it displayed error codes.

All 13 gen 3 users provided positive feedback about the embedded wrist display, saying that it was "easy to understand," "self-explanatory," and "easy to learn." However, 12 (92%) also commented that they were unable to see it when the wrist was rotated away. Clinicians made similar comments, recommending that it be made visible as the wrist rotated. They also thought it should be easier to see in sunlight, that the grip LEDs should be illuminated in both hand and arm mode (instead of hand mode only if no hand controls were configured in arm mode), and that different color LEDs be used for low battery, system fault, Walk Detect, etc., so that the user could clearly identify which event was occurring. Participants who had used both the gen 2 LUI and the gen 3 wrist display expressed a preference for the gen 3 visual notification system.

Tactor

Feedback on the tactor was mixed. The tactor was initially tried with all subjects; however, it worked intermittently or malfunctioned in at least seven cases (2 gen 2 and 5 gen 3 users) and in four other gen 2 cases was working only for mode notification, not grip change notification or grip pressure indication. One third of all subjects, 10 (38%) gen 2 and 3 (23%) gen 3 users, commented negatively about its sound and/or vibration, stating it was "annoying," "distracting," too "intense," or loud. One gen 3 user requested that it be disabled at first use because he found it so unpleasant. However, about a quarter of all subjects, eight (31%) gen 2 users and two (15%) gen 3 users couldn't hear or feel it well and suggested that it be more "definitive."

In contrast, at least four (15%) gen 2 and two (15%) gen 3 users were enthusiastic about the tactor, saying it was "very important" or commented that it was helpful in notifying them that mode or grip change was occurring. Because vibrations and sounds were similar for changes in mode and grip, tactor notifications were sometimes perceived as "ambiguous and not that informative." Eight (31%) gen 2 and two (15%) gen 3 users stated that they "didn't pay attention to it," did not know what function it provided, or didn't want it. Two stated that it was more helpful at the start of training than later. One gen 2 user commented that the tactor was "moot" because the LUI provided the same information.

The most common suggestions to improve the tactor were to differentiate between the vibrations and sounds for changes in mode and grip (6 [23%] gen 2 and 3 [23%] gen 3 users) and to allow the user to turn its vibrations and sounds off or on (2 [8%] gen 2 and 3 [23%] gen 3 users). In addition, two (8%) gen 2 and four (31%) gen 3 users wanted the tactor placed inside the DEKA Arm or socket rather than having it externally mounted on the skin with accompanying wires, something that could have been tried in the VA optimization study, but was not.

Socket Features

Improvements to the inflatable bladders or their inflation process were suggested by four gen 2 users (3 HC and 1 SC user). These users wanted automatic, rather than manual, inflation to enable easier pressure control and/or to avoid soreness and/or bruising from too much pressure.

Clinicians thought the bladders worked well but were "too much maintenance" and "seemed to leak quite a bit." They sometimes had to manually inflate them multiple times during a 2-hour session because leaking caused the socket to loosen.

Among the six gen 3 subjects (3 HC and 3 SC) who tried the DSC, one HC user and one SC user discontinued it during the first session because of technical problems, and the remaining four used it between three and six sessions. Comments by those who wore the DSC four or more sessions included that, "It didn't work nearly as well as it was projected it would," and "I am beeping all over the place" (referring to the DSC sounds).

Clinicians commented that the DSC allowed subjects to control bladder inflation independently, provided additional stability, and provided feedback on the socket fit by monitoring pressure. They suggested making the manifold easier to remove, miniaturizing and/or embedding it, making it quieter, and enabling individual bladder inflation control (instead of grouped bladder control). Clinicians observed that DSC bladders occasionally inflated in response to muscle action used to produce EMG signals, thus making the socket tighter when that was not desired.

DISCUSSION

Optimization Results

VA subjects and clinicians tested DEKA Arm prototypes during their development stage and provided usability feedback. DEKA used this feedback to inform iterative changes to the device and its software. DEKA made early changes to the gen 2 device in response to VA recommendations, such as adding a wrist display (the LUI) to provide visual notifications and replacing the FSRs with an alternative foot control method (the IMU-1). These innovations were tested and further user feedback informed subsequent advances in design, leading to the well-regarded embedded wrist display and the much improved IMU-2. Early VA feedback was used to inform the iterations of end-point control software. User and clinician feedback confirmed that the final versions of end-point control were highly functional but required extensive training to become proficient. Some VA recommendations to alter the wrist design and make the shoulder motor quieter could not be addressed without hardware changes; thus, major changes were introduced by DEKA with the gen 3 prototype.

The gen 3 DEKA Arm built upon the successful aspects of the gen 2 device. It had the same modularity, the same powered degrees of freedom, and similar control options. Our subject and clinician feedback was that the gen 3 was superior in some regards. That said, user feedback on the gen 3 indicated that further refinement would be desirable to optimize this device to make it most usable and acceptable to people with upper-limb amputation.

Areas for Continued Improvement

The most desired improvements mentioned by our study participants and clinicians were to decrease the device weight and to internalize or eliminate the wires and cables. A related need is the production of smaller-sized components to accommodate smaller-sized users, including women. Further miniaturization of internal components may be needed to make these smaller arms available. A smaller-sized device should also be lighter in weight. Shorter-length components, particularly for HC users with long residual limbs, may be beneficial. Other features that are promising but need further refinement prior to launching a commercial product include the tactor, socket bladders, and DSC.

The gen 2 prototype was not intended to be optimized for production-like cable routing; thus, the comments about wiring and cabling in the gen 2 are not unexpected. Although the gen 3 design altered the cabling and wiring requirements somewhat, many were still external. It is possible that efforts could be made to reduce or hide the number of external cables required for the current gen 3 design if prosthetists were to manufacture socket covers. This would make some of the wires and cables less visible. Our study prosthetists indicated that doing so would be a time-consuming task and that they did not have the time to do so during the VA optimization study. Even with such socket covers, however, some external cabling would be necessary if an external battery was required. Total elimination of the external battery may not be possible until smaller, lighter, more powerful batteries are available and could be internalized within the device itself. The trade-off is that an internal battery adds to the weight of the device, which is already a concern.

Our study gathered extensive usability feedback from subjects and clinicians. Both were asked to provide constructive criticism about the DEKA Arm in order to maximize optimization efforts. The synopsis feedback presented in this article needs to be appreciated within the context of

the study and triangulated with other data sources and analyses reported elsewhere. The analyses presented here were part of a much larger effort to obtain a broad array of feedback. In the VA optimization study, subjects were also asked to comment on the perceived functional benefits of the DEKA Arm, to compare it to their current prostheses (if they used one), and to state whether or not they would desire to receive a DEKA Arm in the future. These results are reported elsewhere [3]. Despite the concerns and suggested improvements reported in the current article, the majority of subjects viewed the arm favorably. Of the subjects, 79 percent of gen 2 and 85 percent of gen 3 users indicated that either they wanted to receive or might want to receive a DEKA Arm in the future. Over 90 percent of subjects who used gen 2 and gen 3 reported that the DEKA Arm enabled them to perform activities that they were unable to do with their existing prostheses [3]. Thus, it is clear that most subjects with upper-limb amputation in our study valued the DEKA Arm and appreciated its benefits, even though they suggested improvements.

We believe that the understanding of user and clinician attitudes toward the DEKA Arm described in this article may help inform designs of other upper-limb prostheses. Generally speaking, we believe that users of a complex device with multiple functions and grip types will want to have some type of visual user notification system to inform them about the state of the device. We also believe that auditory or vibratory notifications, while useful for some, are insufficient in and of themselves because they are transient, not always noticed by users, and easy to forget or ignore. Prosthetic designers might also consider incorporating some of the control strategies used for the DEKA Arm, such as end-point control and foot controls. These strategies, once refined, were generally well regarded by users.

Study Limitations

Subjects in the VA optimization study were purposefully sampled to provide a diverse range of users at each of three device levels, include subjects with bilateral and unilateral amputation as well as subjects of both sexes. Subjects were not selected from a representative population. It is possible that subjects who had the time to participate in the VA optimization study were different from the general population with upper-limb amputation, and that these differences may have influenced the type of feedback obtained in our study. Unfortunately, no national statistics exist on the characteristics of adults with upper-limb amputation; thus we are unable to compare our sample to the overall population. We do not believe that this is a particular cause for concern because our sample was large for a usability study [12], and feedback was robust and represented a wide range of usability concerns.

CONCLUSIONS

A large VA usability study provided user and clinician feedback to inform optimization of a new advanced upper-limb prosthesis, the DEKA Arm. Final feedback about the refined prototype (gen 3) was generally positive, particularly regarding improvements in wrist design, visual notifications, foot controls, end-point control, and cosmesis. Additional refinements to make the device lighter-weight and eliminate external wires and cables and the external battery may further enhance the perceived usability and acceptability of the device. Other suggested refinements would address the visibility of the embedded wrist display and improve the tactor, socket bladders, and DSC.

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