

Disability and Rehabilitation: Assistive Technology



ISSN: 1748-3107 (Print) 1748-3115 (Online) Journal homepage: http://www.tandfonline.com/loi/iidt20

Attrition and retention in upper limb prosthetics research: experience of the VA home study of the DEKA arm

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To cite this article: Linda Resnik & Shana Klinger (2017) Attrition and retention in upper limb prosthetics research: experience of the VA home study of the DEKA arm, Disability and Rehabilitation: Assistive Technology, 12:8, 816-821, DOI: 10.1080/17483107.2016.1269212

To link to this article: https://doi.org/10.1080/17483107.2016.1269212

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ORIGINAL RESEARCH

Attrition and retention in upper limb prosthetics research: experience of the VA home study of the DEKA arm

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ABSTRACT

Purpose: (1) Describe study attrition; (2) identify reasons for attrition, and (3) discuss implications for prosthetic prescription and design of future device studies.

Design and methodological procedures used: Completion phase (during in-laboratory training, after training, or home use) was identified for 42 participants. Qualitative data were analyzed to identify attrition reasons. Reasons were classified as related to the DEKA arm, or not.

Results: Study attrition was 57%, with 43% completing the full study. Attrition during the in-laboratory portion was 21%. Reasons for attrition were related to the DEKA arm entirely or in-part for 42%, 25%, respectively. Most common reasons were scheduling/personal (54%); device weight (29%); and dissatisfaction with device (25%). About 21% withdrew because of concerns about compliance with study protocol. **Conclusions:** This study had a high attrition rate with evidence of selective attrition due to device characteristics. Strategies to minimize attrition and the importance of tracking reasons for withdrawal are discussed. Given that retention could be an indicator of willingness to adopt the DEKA arm, findings suggest that it would be prudent to provide patients with the opportunity to train with the DEKA arm before a decision is made regarding the appropriateness of the device for the patient.

> IMPLICATIONS FOR REHABILITATION

- This study of a new upper limb prosthesis, the DEKA arm, had a 57% attrition rate with evidence of selective attrition due to characteristics of the DEKA arm.
- Findings point to the need for strategies to minimize attrition in future studies.
- Findings also illustrate the importance of tracking reasons for subject withdrawal in longitudinal prosthesis device studies.
- Because participant retention in longitudinal device studies may be an indicator of future willingness
 to adopt a device, our findings suggest that it would be prudent to provide patients with the opportunity to train with the DEKA arm before a final decision is made regarding the appropriateness of
 the device for the patient.

ARTICLE HISTORY

Received 8 November 2016 Accepted 2 December 2016

KEYWORDS

Amputation; upper limb; prosthetics; research design; attrition: DEKA arm

Introduction

In the past decade, there have been considerable advances in the development of new prosthetic devices for persons with upper limb amputation, with the introduction of multi-articulating prosthetic hands, and devices which enable more types of powered movements.[1–4] These types of devices promise greater functionality, but may come with an increased cost. Studies that evaluate the benefits of new types of devices and compare them to older technologies are needed to guide prescription and reimbursement decisions. Such studies must not only examine the benefits of new technologies in terms of restoring function and improving quality of life; but they must also examine users willingness to adopt the new technology.

Adoption and rejection is a particularly important outcome for studies of upper limb prosthetic devices, given that many persons with upper limb amputation refuse to use, or stop using, devices that have been prescribed to them. Studies have found that between 17% and 80% of persons with major upper limb amputation reject the use of a prosthesis entirely, with rejection rates typically the lowest for persons with transradial (TR) level

amputation, and highest for those with transhumeral (TH) level or shoulder level amputations.[5–9] Several studies have identified factors, such as female gender, and age (both adolescence and older age) that are associated with greater likelihood of prosthesis rejection.[9] However, various reports have documented consumers' desire for upper limb prostheses with greater functionality, lighter weight and more durability.[10,11] The expectation is that the availability of devices with greater functionality will ultimately lead to greater consumer satisfaction and hence a greater likelihood of prosthesis use. Research on adoption and rejection of new technologies is needed. However, prosthesis adoption is challenging to study, because it requires a longitudinal study design with prolonged subject engagement to identify rejection of a device and attitudes toward using the device over time.

Studies of prosthesis adoption must take subject attrition into account. Attrition occurs when subjects enrol in a research study, and subsequently drop-out without completing their participation.[12] Some attrition is expected in longitudinal studies, and reported rates range from 5% to 70%. However, it is generally desirable to keep attrition to a minimum (<20%),[13] because attrition is a potential threat to study internal validity if there are

systematic differences between those who are retained and those who withdraw from the study. This phenomenon is called attrition bias. If there are no systematic differences between those who withdraw and those who drop-out there is less likelihood of attrition bias.

However, studies of attrition report that one of the common reasons that individuals withdraw from a clinical study is if they perceive a lack of treatment efficacy.[14] Other reasons for attrition from research studies can be psychological, physical or economic [15] and include excessive burden of participating in the study; such as the need for extended periods of participation, the need to take time off from work to participate, and travel to a research site.[14] When attrition of subjects from longitudinal studies is selective, it can bias the study results, particularly if the reasons for attrition are associated with the ultimate outcome of interest. In the case of a device study, if subject attrition was related to perceived lack of device treatment efficacy (e.g. dissatisfaction with characteristics of the device itself) this would be considered selective attrition.

The VA Home Study of an Advanced Upper Limb Prosthesis (Home Study) was one of the largest home use studies of an advanced upper limb prosthesis conducted to date. Study participation involved extended in-laboratory training to use the device, and longitudinal follow-up while using the device at home for three months. To our knowledge it is the first longitudinal study evaluating new upper limb prosthetic technology adoption over time. However, participation in the was study involved a substantial time commitment, and for some participants, travel away from home, and time away from usual activities such as work.

Given the potential for attrition bias due to dissatisfaction with one or more aspects of the device, it was important to evaluate the extent of attrition during the study and to understand the reasons for attrition in order to inform interpretation of findings, particularly as they relate to device satisfaction and adoption. We believed that participant retention in the home use portion of the study could be used as a reasonable indicator of ultimate willingness to adopt the device. Therefore, the purposes of this paper are to: (1) describe patterns of attrition during the Home Study; (2) identify reasons for attrition at each study phase; and (3) discuss implications for prosthetic prescription and design of future studies of upper limb prostheses.

Methods

Study description

The VA Home Study of an Advanced Upper Limb Prosthesis (Home Study) was a multi-site clinical trial of the DEKA arm coordinated by the Providence VA Medical Center with data collected at three study sites: VA NY HHS, James Haley VA, and Center for the Intrepid (CFI). The Home Study consisted of two primary phases: Part A entailed fitting with the DEKA arm, on-site laboratory training to the point of readiness for home use, and performance testing with a DEKA arm. At the end of Part A, subjects who were deemed sufficiently skilled and behaviourally appropriate to continue to the home use portion of the study (Part B) were offered an opportunity to participate in this phase. Part B entailed unsupervised independent home use of the DEKA arm for a minimum of 9 of the 12 weeks, completion of daily diaries and weekly phone calls describing amount of use of the DEKA arm, biweekly self-report assessments by telephone, and in-person site visits for performance testing approximately every four weeks. During Part B participants were asked to wear the DEKA arm for a minimum of 2h per day during the first four weeks of home use, but thereafter were instructed that they could use the device as much or little as they wished.

Participants were fit with one of three levels of DEKA arm: RC (radial configuration for transradial amputees), HC (humeral configuration for transhumeral amputees), and SC (shoulder configuration for interscapular-thoracic, shoulder disarticulation, or very short transhumeral amputees). Users operated the DEKA arm movements by using IMUs (inertial movement units) located on the feet, conventional EMGs (not pattern recognition), pneumatic bladders, or manual switches alone or in combination, depending on the preferences and physical capabilities of the individual.

Participants

Participants were eligible for Part A if they were at least 18 years old, had an upper limb amputation at the TR, TH, shoulder disarticulation or scapulothoracic level (shoulder) and had sufficient control sites available to operate the DEKA arm, were able to tolerate wearing a prosthesis, and had no serious health conditions that might limit their participation. At the completion of Part A, the study Principal Investigator (PI) in consultation with the study staff, determined which subjects were eligible to continue to Part B, using a priori criteria. Eligible subjects were required to demonstrate independence in using the prosthesis in the clinical setting, and have at least fair functional performance and consistent safety awareness and good judgement when operating the prosthesis

Data collection

The analysis of reasons for attrition utilized qualitative data collected throughout the study that was recorded by audio and video during in-laboratory and testing sessions, and from written and recorded responses to open-ended survey questions and semi-guided interviews that were administered at the end of Parts A and B.

Data analyses

Phase of study completion or attrition was identified for the 42 participants who began fitting with a DEKA arm. Study participants were categorized into one of the following groups: began Part A and began fitting with a prosthesis but did not complete Part A (Incomplete A); Completed A - but did not proceed to Part B (Completed A, no B); began Part B but did not complete it (Incomplete B); or completed at least nine weeks of Part B and end of study data collection (Complete B). Qualitative data from openended comments by participants and observations by staff were analyzed and categorized into the reasons that the participant left the study without completing. Study attrition was first grouped into three overarching categories based on whether leaving the study was initiated by the participant, the study staff or both. Reasons were also grouped by whether or not the analytical staff believed that leaving the study was related or unrelated to the DEKA arm or its use. Coding of data was initially conducted by one author (SK) and then discussed with the second author (LR). An audit trail with supporting data was consulted to confirm the categorization.

To determine whether the burden of study participation during Part A differed for those participants who withdrew after completing Part A and those who withdrew during or after Part B, we counted days of study engagement beginning from the date of the first prosthetic fitting visit to the last visit for each group and compared them using t-tests. We also counted the number of prosthetic training visits used during Part A and compared the number of visits between groups.



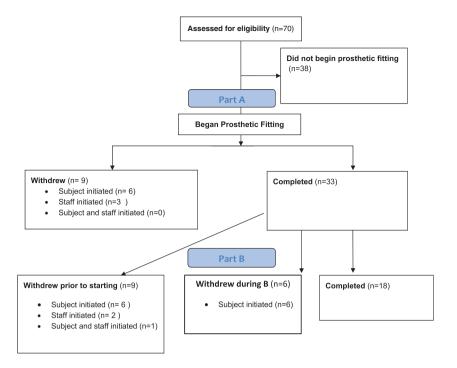


Figure 1. Flow diagram.

Table 1. Participant characteristics by completion status (N = 42).

	Before end of A $(N = 9)$ N $(\%)$	Completed A, No B (N = 9) N (%)	During B (<i>N</i> = 6) <i>N</i> (%)	All non-completers ($N = 24$) N (%)	Completed all (<i>N</i> = 18) <i>N</i> (%)
Gender					
Male	5 (55.6)	8 (88.9)	6 (100.0)	19 (79.2)	16 (89.9)
Female	4 (44.4)	1 (11.1)	0 (0.0)	5 (20.8)	2 (11.1)
Race					
White only	7 (77.8)	7 (77.8)	3 (50.0)	17 (70.8)	16 (88.9)
Black only	2 (22.2)	1 (11.1)	1 (16.7)	4 (16.7)	2 (11.1)
Mixed/other	0 (0.0)	1 (11.1)	2 (33.3)	3 (12.5)	0 (0.0)
Veteran status					
Non-veteran	4 (44.4)	4 (44.4)	2 (33.3)	10 (41.7)	7 (38.9)
Veteran	5 (55.6)	5 (55.6)	3 (50.0)	13 (54.2)	8 (44.4)
Active duty	0 (0.0)	0 (0.0)	1 (16.7)	1 (4.2)	3 (16.7)
Amputation level					
TR	4 (44.4)	3 (33.3)	4 (66.7)	11 (45.8)	10 (55.6)
TH short	2 (22.2)	3 (33.3)	2 (33.3)	7 (29.2)	2 (11.1)
TH long	2 (22.2)	0 (0.0)	0 (0.0)	2 (8.3)	5 (27.8)
Shoulder ^a	1 (11.1)	3 (33.3)	0 (0.0)	4 (16.7)	1 (5.6)
DEKA arm configu	ıration level				
RC	4 (44.4)	3 (33.3)	4 (66.7)	11 (45.8)	10 (55.6)
HC	2 (22.2)	2 (22.2)	0 (0.0)	4 (16.7)	6 (33.3)
SC	3 (33.3)	4 (44.4)	2 (33.3)	9 (37.5)	2 (11.1)

^aShoulder disarticulation/interscapular-thoracic.

Results

The flow of participants from screening through the end of Part B are shown in Figure 1. In summary, there were 24 of 42 participants (57%) who began prosthetic fitting but who did not complete all study activities: four never completed fitting in Part A; five left the study prior to completion of Part A; nine left after completion of Part A and before starting Part B; and six left during Part B (Table 1). Overall attrition rates were 54% for males and 71% for females. Eighteen participants (43%) completed at least nine weeks of Part B. Table 2 shows participants who completed the study and those who did not by the DEKA arm configuration level and amputation level. Nine of the 11 users of the SC configuration level (82%) did not complete all components of the study, as compared to 4/10 (40%) of users of an HC DEKA arm and 11/21 (52%) users of the RC DEKA arm.

Eighteen of the 24 (75%) non-completers initiated their study withdrawal; including 6 (67%) of those who withdrew Before A; 6 (67%) who withdrew at the end of A; and 6(100%) who withdrew during Part B. There was one participant who left at the end of Part A who initiated his withdrawal, but would have been discontinued by staff had he indicated an interest in continuing to Part B.

Overall, the three most common reasons for non-completion of the study were: scheduling or personal issues (54%); heaviness of the DEKA arm (29%); and other dissatisfaction with the DEKA arm (25%) (Table 3). Among the 13 non-completers whose reason for discontinuation was scheduling or personal reasons, scheduling/ personal reasons were the only reason for discontinuation for 8 (33%) of them, while 5 (21%) also had other reasons for discontinuing.



Table 2. Participants by configuration level and key characteristics.

	RC (N = 21)		HC (N = 10)		SC (N = 11)	
	Non-completers $(N = 11)$	Completers (N = 10)	Non-completers $(N=4)$	Completers $(N=6)$	Non-completers $(N=9)$	Completers $(N=2)$
Amp level						
TR	11 (100)	10 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TH short	0 (0.0)	0 (0.0)	2 (50.0)	1 (16.7)	5 (55.6)	1 (50.0)
TH long	0 (0.0)	0 (0.0)	2 (50.0)	5 (83.3)	0 (0.0)	0 (0.0)
Shouldera	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (24.4)	1 (50.0)

^aShoulder disarticulation/interscapular-thoracic.

Table 3. Reasons for non-completion by phase of study withdrawal.

		All $(N = 24)$	Before end of A $(N=9)$	Completed A, No B ($N = 9$)	During B $(N=6)$
Reasons for non-completion by phase		N (%)	N (%)	N (%)	N (%)
All reasons were unrelated to DEKA Arm		10 (42) (42)(42)	7 (78)	0 (0)	3 (50)
All reasons were related to DEKA Arm		8 (33)	1 (11)	5 (56)	2 (33)
Reasons were both related and unrelated to DEKA Arm		6 (25)	1 (11)	4 (44)	1 (17)
Specific reasons*	Related to DEKA arm				
Heaviness of DEKA arm	Yes	7 (29)	1 (11)	5 (56)	1 (17)
Dissatisfied with DEKA arm for reasons other than heaviness	Yes	6 (25)	0 (0)	5 (56)	1 (17)
Staff or participant concern about safety	Yes	4 (17)	0 (0)	4 (44)	0 (0)
Staff concern about behaviour	Yes	3 (13)	0 (0)	3 (33)	0 (0)
Prefers current prosthesis	Yes	2 (8)	0 (0)	2 (22)	0 (0)
Scheduling or personal – only reason given	No	8 (33)	6 (6)	0 (0)	2 (33)
Scheduling or personal – plus other reasons	No	5 (21)	0 (0)	3 (33)	2 (33)
Staff or participant concern about protocol compliance	No	5 (21)	0 (0)	4 (44)	1 (17)
Medical problem	Unclear	5 (21)	2 (22)	1 (11)	2 (33)
In pain	Unclear	4 (17)	2 (22)	0 (0)	2 (33)

^aParticipants could have multiple reasons.

Table 3 shows the reasons for non-completion categorized by whether or not the reason was classified as being related or unrelated to the DEKA arm. Sixteen of 24 participants (67%) discontinued participation for at least one reason that was not categorized as being related to the DEKA arm. For 10 of these participants (42%) their sole reason for withdrawal was unrelated to the DEKA arm, while for the other 6 (25%) there was also at least one other reason which was classified as being related to the DEKA arm. Seven of the 9 (78%) who withdrew before the end of Part A withdrew for reasons wholly unrelated to the DEKA arm. In contrast, 5 of the 9 (56%) participants who withdrew at the end of Part A withdrew for reasons related to the DFKA arm.

The most common reason for withdrawal related to the DEKA arm, 7/24 (29%), was classified as "heaviness", and was a reason for withdrawal of 5 SC users and 2 RC users (Table 4). Six participants' reasons for withdrawal were classified as "other dissatisfaction related to the DEKA" (4 RC, 1 HC, 1 SC). Data coded within this category included statements indicating that the participant didn't like the appearance; had concerns about reliability; that the arm was too hot; that the arm was a "hindrance" that slowed them down; that the arm needed "significant changes" before being ready for home use; and problems with donning/doffing and the control system (non-IMU set-up) for a lower extremity amputee.

The next most common reasons for withdrawal related to the DEKA arm were categorized as concerns about safety or behaviour. In 4 out of 24 participants (17%) either study staff or participants expressed concerns about safe use of the arm due to lack of skill, ability level, or understanding of how to independently use the DEKA arm. Examples include: an SC DEKA arm user who chose not to continue due to severe impairments of his sound hand and wrist which made him unable to use the manual release button for the SC arm and to don/doff independently; a SC user for whom staff had concerns about ability to troubleshoot and manage the unique aspects of the SC arm at home due to cognitive and emotional factors.

For 3 out of 24 participants (13%), staff had concerns about the participant's behaviour, specifically the participant's frustration level or poor motivation that could potentially impact safe use of the DEKA arm at home. There were five unique participants (3 SC; 1 HC; 1 RC) who were classified within these two categories of concerns about safety or behaviour, all of whom discontinued at the end of Part A. Two of these participants were deemed inappropriate to continue by study staff; 2 chose not to continue to Part B; and 1 chose not to continue, but would have been deemed inappropriate by the study staff had he wanted to continue.

The most common reason for withdrawal unrelated to the DEKA arm, noted in 5 out of 24 (21%) participants, was categorized as "concern about protocol compliance." Data coded within this category included statements made by participants or staff in audio tapes, video-tapes or written memos that indicated that the participant could not comply with protocol requirements of weekly communication with staff, written reporting, and in-lab testing appointments. There were four participants who did not proceed to Part B due to this concern. In addition there was one participant who began Part B and cited this as one of the reasons for his withdrawal.

Medical problems were a reason for withdrawal for 5 out of 24 participants (21%) and an episode of musculoskeletal pain was the reason for withdrawal in 4 out of 24 participants (17%). However, we were not able to definitively classify reasons for withdrawal due to medical problems or pain as being related to the DEKA arm in all cases. Three of the four participants who withdrew due to complaints of pain (1 RC; 1 HC; 2 SC) either selfreported or had medical documentation that suggested that using the DEKA arm had contributed to the onset or exacerbation of pain. Two participants experienced a new episode of or an

Table 4. Reasons for non-completion by level of DEKA arm.

	RC $(N = 11)$	HC (N=4)	SC(N=9)
Reasons for non-completion by configuration level ^a	N (%)	N (%)	N (%)
Heaviness of DEKA arm	2 (18)	0 (0)	5 (56)
Dissatisfied with DEKA arm for reasons other than heaviness	4 (36)	1 (25)	1 (11)
Staff or participant concern about safety	0 (0)	1 (25)	3 (33)
Staff concern about behaviour	1 (9)	1 (25)	1 (11)
Prefers current prosthesis	1 (9)	0 (0)	1 (11)
Scheduling or personal – only reason given	6 (54)	1 (25)	1 (11)
Scheduling or personal – plus other reasons	2 (18)	1 (25)	2 (22)
Staff or participant concern about protocol compliance	1 (9)	2 (50)	2 (21)
Medical problem	1 (9)	1 (25)	3 (33)
In pain	1 (9)	1 (25)	2 (22)

^aParticipants could have multiple reasons.

aggravation of preexisting back or neck pain, while the third participant developed new pain in the right ankle. The fourth participant discontinued due to low back pain, however it was unclear if use of the DEKA arm had contributed to onset.

We found that those participants who completed Part A, but did not proceed to B, had a longer period of participation (p=0.09) in Part A (mean 126.2, median 106) as compared to the 24 subjects who continued to Part B after completing Part A (mean 87.3; median 79 days). However, the number of training visits were similar for completers of Part A only and participants who proceeded to Part B (9.0 \pm 5.2, 8.9 \pm 3.5), respectively.

Discussion

This study quantified attrition in each phase of the VA Home Study of the DEKA arm, classified the reasons for attrition, and identified whether it was the participant or the study staff that initiated the study withdrawal. The results demonstrate an overall high retention rate for the in-laboratory portion of the study (Part A) with 79% of subjects who began fitting with the DEKA arm completing that phase. In contrast, only 43% of subjects who began fitting with the DEKA arm completed Part B, the home use portion of the study. We found that the majority of participants who withdrew during Part A withdrew for reasons entirely unrelated to the DEKA arm, while 100% of those who withdrew after completing Part A withdrew for at least one reason related to the DEKA arm. Given that we considered participant retention in Part B of the study as an indicator of their future willingness to adopt the device, this finding suggests that consumer willingness to adopt an upper limb prosthesis, like the DEKA arm, may be best determined after they have been fully trained to utilize the device. However, given the reimbursement structure for prosthetics and the lack of available "loaner" devices, patients rarely have the opportunity to try out different types of upper limb prosthetic devices and be trained in their usage before a prescription is made. Our findings suggest that better rates of adoption might result if patients had the opportunity to fully train with and evaluate a device before finalizing a prescription for them.

We found that attrition was more likely for participants who utilized an SC arm. While the SC DEKA arm holds great promise, given its 10 powered degrees of freedom and Endpoint control,[16] it is also heavy, complex and cognitively demanding to operate.[1] In our study there were six persons with transhumeral amputation who were fit with an SC DEKA arm because their residual limb length was considered too short for TH socket fitting, or their shoulder musculature was considered too weak to support an HC configuration device. This decision enabled participants to have a prosthesis that would restore maximal movement capabilities. However, there were clear drawbacks to

fitting an SC arm over an existing residuum, in that it created additional space for clearance of the residuum, making the profile of the device wider, and potentially interfering with the fit of usual clothing. Furthermore, the unique control mechanism and operating characteristics of the SC arm required that the user have greater safety awareness as compared to users of other configuration levels because they cannot use their own shoulder musculature to move the device away from the body or face or other targets.

Data on attrition rates from this study could be useful in planning future longitudinal studies of upper limb prosthesis effectiveness and adoption. These types of studies require recruitment of this relatively scarce population, intensive training to become proficient with a device, and substantial burden on the part of the participant. Thus, retention of study subjects is critical so that the final sample size is sufficient for statistical comparisons. Lessons learned in our study have implications for study design that could potentially improve interpretations of findings and retention of subjects in future work.

Twenty one percent of non-completers withdrew because of concerns about being able to comply with the requirements of the protocol. Although we cannot say with certainty if attrition could have been minimized with a less burdensome protocol, the literature suggests multiple strategies to minimize participation burden and reduce the risk of attrition.[14] Recommended strategies to enhance retention include provision of practical help with travel logistics, provision of transportation, as well as monetary incentives, plus involvement of stakeholders in the research design process.[14]

The Home Study protocol called for extensive testing and data collection. During Part A, testing and data collection took place during the course of regularly scheduled visits. However, during Part B the participant had to make three separate trips to the site for testing sessions and also had to participate in weekly scheduled phone calls, and daily diary keeping. The Home Study research assistants arranged travel and accommodations for subjects traveling from a distance, but transportation of participants who were local was not provided. Future study protocols might be best served by requiring less frequent intervals of performance testing, particularly during home use testing, to reduce the requirement of travel and time for the study and concerns about being able to comply with protocol requirements.

We did find an increased length of study participation for those who completed Part A but did not proceed to Part B (average of 39 days longer). This may have created a greater perceived burden of study participation. Given that the lengthier involvement with the study was not associated with a greater number of training visits, the longer period of study engagement was likely associated with, problems that those participants had in scheduling their visits to the study site. It is possible that for some

participants an extended period of participation in Part A created additional burden and diminished willingness to participate in Part B of the study, particularly for those whose views of the DEKA arm were not as positive.

Per-diem expenses were provided for travellers and a stipend for meals was provided for local participants who had study visits lasting longer than 4h, which occurred during some prosthetic fitting visits (e.g. when the participant was waiting for the socket to be fabricated) or when multiple training visits were scheduled in one day. While participant incentives during Part A were calculated based on a reasonable hourly compensation rate, the incentives for participation in Part B were much less, with small daily incentives, and no incentives for time spent in transit to and from the study site. It is possible that study participation during Part B might have been enhanced if the incentive structure for the home use portion of the study had been more generous.

Based on our analysis we suggest that future studies of prosthetic technologies carefully follow-up with study participants to assess their reasons for study withdrawal, and make efforts to classify those reasons as related to or unrelated to the intervention (the study prosthesis). This is particularly important to identify selective attrition due to dissatisfaction with the technology, as their attrition from the study has the potential to bias final outcomes (at the end of a study) related to participants interest in adopting a device and satisfaction with the device.

The findings from this analysis will be useful in the interpretation of ongoing analyses of Home Study data on satisfaction with and willingness to adopt a DEKA arm.

However, there are limitations to the transferability of our study results to studies of other types of upper limb prostheses which utilize different designs. We cannot say for certain if there would be a similar attrition rates if participants were to receive the study device at the study conclusion; or if they were training to use another type of device.

Conclusions

This paper reported on the attrition rates and patterns, as well as subjects' reasons for withdrawing from the VA Home Study of an Advanced Upper Limb Prosthesis. Only 43% of participants who began prosthetic fitting in this study completed all components of the study, meaning that the study had an overall 57% attrition rate. Yet, the attrition rate during the in-laboratory portion of this study (21%) was more modest. The remaining attrition occurred after completion of in-laboratory training, with participants either declining to participate in the home use portion of the study or withdrawing during their participation. In total, 42% of subjects withdrew from the study for reasons entirely unrelated to the DEKA arm, while in the remaining cases, at least one of the reasons for withdrawal related to some aspect of the DEKA arm. The study findings also have implications for the interpretation of results of the VA Home Study of the DEKA arm and for the design of future studies of advanced upper limb prostheses which should incorporate strategies to minimize attrition and clearly categorize reasons for attrition. Findings suggests that ultimate prosthetic rejection rates would be minimized if patients are given the opportunity to train with and evaluate an upper limb prosthesis, before a decision is made regarding the purchase of that device for that particular patient.

Acknowledgements

This research was supported by VA RR&D A9226-R. The information in this manuscript does not necessary reflect the position or policy of the government; no official endorsement should be inferred. The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of the U.S. Government.

Funding

The funding source for this paper is VA RR&D A9226-R.

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