

Archives of Rehabilitation Research and Clinical Translation

Archives of Rehabilitation Research and Clinical Translation 2021;3:100148 Available online at www.sciencedirect.com



Check for updates

Original Research

Understanding the Relationship Between Patient-Reported Function and Actual Function in the Upper Limb Prosthesis User Population: A Preliminary Study

Xuyuan Zhang, PhD ^{a,b}, Kerstin S. Baun, MPH, OTR/L ^c, Lauren Trent, MOT, OTR/L ^c, John Miguelez, CP ^c, Kimberly Kontson, PhD ^a

^a Center for Devices and Radiological Health, Office of Science and Engineering Labs, United

States Food and Drug Administration, Silver Spring, MD

^b School of Public Health, University of Maryland, College Park, MD

^c Clinical Services, Advanced Arm Dynamics, Redondo Beach, CA

List of abbreviations: ADL, activities of daily living; BBT, Box and Blocks Test; CAPPFUL, Capacity Assessment of Prosthesis Performance for the Upper Limb; DASH, Disabilities of the Arm, Shoulder, and Hand questionnaire; PRO, patient-reported outcome.

Supported in part by base funding from the Division of Biomedical Physics in the Office of Science and Engineering Labs within the United States Food and Drug Administration. The mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as an actual or implied endorsement of such products by Department of Health and Human Services. This article reflects the views of the authors and should not be construed to represent the United States Food and Drug Administration's views or policies. Disclosures: None.

Cite this article as: Arch Rehabil Res Clin Transl. 2021;3:100148

https://doi.org/10.1016/j.arrct.2021.100148

2590-1095/Published by Elsevier Inc. on behalf of American Congress of Rehabilitation Medicine. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

interval [CI], -0.015 to 0.001; P=.0937) and CAPPFUL (B=-0.083, 95% CI, -0.374 to 0.208; P=.5623)). In both models, individuals with elbow, transhumeral (above elbow), and shoulder disarticulation showed a significant negative association with the dependent variable (CAPPFUL or logBBT). In the CAPPFUL model, there was a significant negative association with individuals using a hybrid prosthesis (B=-20.252; 95% CI, -36.562 to -3.942; P=.0170). In the logBBT model, there was a significant positive association with individuals using body-powered prostheses (B=0.430; 95% CI, 0.089-0.771; P=.0157).

Conclusions: Although additional data and analyses are needed to more completely assess the association between self-reported measures and performance-based measures of functional abilities, these preliminary results indicate that patient-reported outcomes alone may not provide a complete assessment of an upper limb prosthesis users' functional ability and should be accompanied by population-specific performance-based measures.

Published by Elsevier Inc. on behalf of American Congress of Rehabilitation Medicine. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Individuals with upper limb loss typically use prosthetic rehabilitation intervention and/or assistive technology to restore their functional abilities to the greatest extent possible. To assess efficacy of these approaches in restoring function, clinicians can use patient-reported outcomes (PROs) and/or performance-based outcome measures. PROs are commonly used in many different clinical populations because they enable patient-centered care through the evaluation of intervention efficacy as measured from the patient's perspective.¹ These measures are often relied upon to support clinical care management and prescriptive decisions related to patient care. They may also be used as endpoints in clinical studies to support effectiveness of therapeutic or assistive technology interventions. In the population that uses upper limb prostheses, there are few PROs that query individuals' abilities to perform specific activities of daily living (ADL).²

There are many benefits of evaluating perceived functional ability through PROs because they are generally quick to administer, do not require certified raters or observers, and provide an indication of an individual's ability to operate independently.³ However, PROs reflect a self-report of functional abilities with no direct observation, which could lead to an inaccurate reflection of an individual's actual level of function.⁴ To address these inherent limitations, performance-based outcome measures could be used in conjunction with PROs. However, there is a gap in our understanding of how perceived function relates to actual function at specific stages in the rehabilitation process for this unique population.

This need to understand the relationship between PROs of function and actual function can be seen for other clinical populations as well.⁵⁻⁸ Findings reveal implications regarding the type of outcome measures to use as well as the timing of administration when assessing changes in function in the studied clinical populations. Investigations into the association between perceived and actual function in the upper limb prosthesis user population are scarce. Ostlie et al⁹ examined the association between joint motion, arm strength, and patient-reported function through a series of multiple linear regressions and found significant positive associations between joint motion without a prosthesis on the amputated side and PRO scores. However, this study did not assess actual function in terms of ADL. Resnik et al¹⁰ also

conducted a study to determine the association between prosthesis configuration (primary prosthesis and terminal device type) and PROs of function, but this study did not incorporate performance-based metrics and focused exclusively on the veteran amputee population.

To address the research gaps for the upper limb prosthesis user population, the goal of this study is to investigate the association between a commonly used PRO of perceived function and actual functional abilities as measured through administration of standardized performance measures based on ADL that incorporate multiple planes of movement and grips. Using PRO and performance-based outcome measure data from the population of interest, multiple linear regression models were developed that controlled for relevant independent variables that may have an effect on the perceived function. Addressing this knowledge gap would improve interpretation of outcome measure results and inform the best types of measures to use for assessing a patient's functional progress or effectiveness of a prosthesis. By defining the most appropriate outcome measures to use during patient assessments, care can be streamlined such that patient/clinician burden is reduced and more universal methods for evaluating patient progress are adopted by the field. Results from this preliminary analysis can also provide insight into the advantages and limitations of PROs and performance-based outcome measures at a specific stage in the rehabilitation process.

Methods

Participants

A representative sample of 61 individuals with upper limb loss participated in this study (mean age, $43.0\pm12.8y$; 51 male/10 female). The study was approved by the Western Institutional Review Board and conforms to the Declaration of Helsinki. Research began in July 2018 and concluded in March 2019. For the data analyzed in this study, participants had to meet the following inclusion criteria: have an upper limb amputation at any level, be at the definitive stage of the prosthesis fitting process, have any type of prosthesis (passive, body-powered, electric, hybrid, activity specific), present with any type of

Table 1	Independent	Variables
---------	-------------	-----------

Characteristics	Total Samp	le N=61
Sex, n (%)		
Male	51	83.61
Female	10	16.39
Age (y), mean \pm SD	42.98±12.8	30
Amputation level, n (%)		
Digit(s)/finger(s)	9	14.75
Partial hand	14	22.95
Wrist disarticulation	8	13.11
Transradial (below elbow)	15	24.59
Elbow disarticulation	8	13.11
Transhumeral (above elbow)	4	6.56
Shoulder disarticulation	3	4.92
Prosthesis, n (%)		
Body-powered	17	27.87
Electric	26	42.62
Hybrid	4	6.56
Passive	11	18.03
Passive positionable	3	4.92

amputation/limb loss (disease, trauma, congenital), be able to understand study directions and content, and be between the ages of 18 and 95. The definitive stage of prosthesis fitting is the point at which the materials and design of the prosthesis are finalized. All participants provided informed consent prior to participation. Independent variables of amputation level, prosthesis type, age, and sex are reported for all included participants (table 1).

Data collection

To assess the relationship between perceived and actual function, participants completed a PRO measure, the Disabilities of the Arm, Shoulder, and Hand questionnaire $(DASH)^{2,11,12}$ and 1 or both of 2 performance-based outcome measures: the Capacity Assessment of Prosthesis Performance for the Upper Limb $(CAPPFUL)^{13}$ and the Box and Blocks Test (BBT).^{14,15}

The first 30 questions of the DASH were used to calculate a single disability/symptom score based on instructions within the survey. Most questions asked participants to rate their ability to perform a number of activities within the last week using a scale from 1 (*no difficulty*) to 5 (*unable to complete*). A few of the DASH questions inquire about the extent to which the participant's arm, shoulder, or hand problem interfered with social and work activities; the severity of pain/weakness in the arm; and confidence, which were also included in the final scoring to be consistent with the recommended scoring approach for the DASH. The DASH has been extensively used in the upper limb prosthesis user population^{2,9,10,12,16} and validated in the partial hand/finger amputee population.¹⁷

The CAPPFUL consists of 11 tasks representative of ADL, with each scored on multiple domains: prosthesis control skills, component utilization, adaptive compensatory movement, maladaptive compensatory movement, and task completion. The CAPPFUL has been previously validated in the upper limb prosthesis user population.¹³ It provides a single percentage score indicating return of function compared with a sound upper limb as well as percentage scores in the domains noted above.

Participants were also asked to perform 3 trials of the BBT. The rounded average of the 3 BBT trials were used as the final score for this measure. The BBT has also been validated for use in the upper limb prosthesis user population.¹⁴

The patient-reported and performance-based measures were collected at the same time point in their care for each participant (ie, definitive stage of prosthesis fitting).

Data analysis

Data were analyzed using SAS v9.4.^a Descriptive analysis statistics for independent variables included in the models were generated. These items included amputation level and primary prosthesis type because the authors' expert opinions indicated that these factors would be most influential in evaluation of function. Age and sex were also included as independent variables. The occurrence of possible multicollinearity between all independent variables was assessed using the Pearson correlation coefficient. We also examined the variance inflation factor and tolerance for each of the CAPPFUL and logBBT models.^{18,19} No high correlation coefficients between independent variables were observed; a moderate correlation between amputation level and prosthesis type was observed (r=0.59). The minimum tolerance and maximum variance inflation factor for the CAPPFUL model were 0.30 and 3.34, respectively. The minimum tolerance and maximum variance inflation factor for the logBBT model were 0.23 and 4.17, respectively. These values indicate that there is no multicollinearity between independent variables, thus satisfying the assumption of multiple linear regression analyses. DASH, CAPPFUL, BBT scores, and age were treated as continuous variables and mean values for each item were calculated (table 2). To estimate the unadjusted association between actual function and perceived function of the selected independent variables, we first conducted simple linear regression analyses. CAPPFUL score or BBT score, representing the actual function, was respectively treated as the dependent variable in the simple linear regression analyses. In these analyses, a number of categories were collapsed within an independent variable to make the results more interpretable and to account for low sample size in a given category. Categories within the amputation level were grouped as follows: amputation level 1 includes digit(s)/fingers and partial hand amputations, amputation level 2 includes wrist disarticulation and transradial (below elbow), and amputation level 3 includes elbow disarticulation, transhumeral (above elbow), and shoulder disarticulation. Categories within prosthesis type were grouped as follows: type 1 includes electrically powered; type 2 includes body-powered; type 3 includes hybrid; and type 4 includes passive and passive positionable. Only variables significantly associated with change in CAPPFUL or logBBT scores in the simple regression analyses were used in the multiple linear regression analysis.

Two separate multiple linear regression analyses were then conducted to examine the adjusted association between CAPPFUL or BBT and DASH, amputation level, and prosthesis type. The same collapsed independent variables

Tuble 2 Mea	n, 50, 52, and 75/0		indubited				
Variable	Minimum	Maximum	Mean	SD	SE	95% CI	n
Age	19.00	67.00	42.98	12.80	1.64	(39.70-46.26)	61
DASH	0.83	65.83	24.33	16.50	2.41	(19.48-29.17)	47
CAPPFULL	42.61	98.86	74.83	14.93	2.20	(70.40-79.27)	46
BBT	9.00	56.00	24.79	12.44	2.02	(20.70-28.88)	38
logBBT	2.20	4.03	3.09	0.51	0.08	(2.92-3.25)	38

Table 2 Mean, SD, SE, and 95%CI of Continuous Variables

described previously were also used here. To avoid violation of linear regression assumptions, BBT scores were log transformed and residual analyses were applied.

A total of 61 participants were included in this study, but not all participants completed every outcome measure. In the linear regression analyses, participants without complete information for dependent variables and independent variables were excluded from the models. Details of the number of participants in the subgroup (n) can be found in the regression analysis (tables 3-6).

Results

Our sample of unilateral amputees scored similar to previously reported DASH scores from another sample of upper limb prosthesis users with a mean DASH score of 24.3 ± 16.5 (95% confidence interval [CI], 19.48-29.17) compared with a mean DASH score of 22.1 (95% CI, 19.8-24.5).⁹ Similar outcomes were seen in our sample of transradial (below elbow) prosthesis users for the BBT (mean score, 18.9 ± 7.6) compared with a previous report (mean score, 19.9 ± 10).¹⁴ These similarities in scores to other samples reported in previous studies provide confidence that our sample was representative of the unilateral amputee population. Results are presented in the next sections for the CAPPFUL and BBT linear regression models.

CAPPFUL model

In the simple linear regression analysis with CAPPFUL as the dependent variable, the significance level α was set to .05. DASH (B=-0.363; 95% CI, -0.677 to -0.050; P=.0247); amputation level 2 including wrist disarticulation and transradial (B=-12.154; 95% CI, -19.671 to -4.637; P=.0022); amputation level 3 including elbow, transhumeral (above elbow), and shoulder disarticulation (B=-27.068; 95% CI. -36.398 to -17.738; P<.0001); prosthesis type 2 including body-powered (B=9.561; 95% CI, 0.619-18.502; P=0.0367); and prosthesis type 4 including passive and passive positionable (B=19.441; 95% CI, 9.169-29.712; P=.0004) were significantly associated with CAPPFUL (table 3). Because age and sex were not found to be significantly associated with change in CAPPFUL score in our sample, and to limit the inconsistency and instability of results that can be found in regression analyses with high numbers of predictor variables and lower sample sizes,²⁰ age and sex were omitted from the multiple linear regression analysis.

In multiple linear regression analysis, the significance level α was set to .05. In the multiple linear regression model with

CAPPFUL as the dependent variable and DASH, amputation level, and prosthesis as the independent variables, amputation level 3 including elbow, transhumeral (above elbow), and shoulder disarticulation (B=-22.650; 95% CI, -36.383 to -8.916; P=.0023) and prosthesis type 3 including hybrid (B=-20.252; 95% CI, -36.562 to -3.942; P=.0170) were significantly associated with CAPPFUL (table 4). The R^2 value of the model was 0.63. Based on the analysis of residuals, regression assumptions were not violated.

BBT model

In simple linear regression analysis with logBBT as the dependent variable, the significance level α was set to .05. DASH (B=-0.019; 95% CI, -0.026 to -0.011; P<.0001); amputation level 2 including wrist disarticulation and transradial (B=-0.699; 95% CI, -0.958 to -0.440; P<.0001); amputation level 3 including elbow, transhumeral (above elbow), and shoulder disarticulation (B=-0.907; 95% CI, -1.240 to -0.575; P<.0001); prosthesis type 2 including body-powered (B=0.630; 95% CI, 0.342-0.917; P<.0001); prosthesis type 3 including hybrid (B=0.560; 95% CI, 0.162-0.958; P=.0072); and prosthesis type 4 including passive and passive positionable (B=0.943; 95% CI, 0.635-1.252; P<.0001) were significantly associated with logBBT (table 5). Because age and sex were not found to be significantly associated with change in CAPPFUL score in our sample, and to limit the inconsistency and instability of results that can be found in regression analyses with high numbers of predictor variables and lower sample sizes,²⁰ age and sex were omitted from the multiple linear regression analysis.

In the multiple linear regression model with logBBT as the dependent variable and DASH, amputation level, and prosthesis as the independent variables, amputation level 3 including elbow, transhumeral (above elbow), and shoulder disarticulation (B=-0.620; 95% CI, -1.014 to -0.225; P=.0035) and prosthesis type 2 including body-powered (B=0.430; 95% CI, 0.089-0.771; P=.0157) were significantly associated with logBBT score (table 6). The R^2 value of the model was 0.75. As with the previous model, the plot of jackknife residuals vs predicted values scattered randomly around zero. Based on this analysis of residuals, regression assumptions were not violated.

Discussion

The association between perceived and actual function as measured by ADL was not well established for the upper limb prosthesis user population in the literature. The goal of

Table 3	Simple Linear Regression Models With CAPPFUL as Dependent Vari	iable

Independent Variable		Simple Linear Regression Analysis								
	n	В	SE	t Value	P Value		95% CI			
DASH	32	-0.363	0.154	-2.360	.0247	-0.677	-0.050			
Age	46	0.028	0.176	0.160	.8759	-0.327	0.382			
Sex										
Male	39	6.315	6.123	1.030	.3080	-6.026	18.655			
Female	7									
Amputation*										
Level 2	19	-12.154	3.727	-3.260	.0022	-19.671	-4.637			
Level 3	9	-27.068	4.626	-5.850	<.0001	-36.398	-17.738			
Level 1	18									
Prosthesis [†]										
Туре 2	14	9.561	4.430	2.160	.0367	0.619	18.502			
Туре 3	4	-8.957	6.920	-1.290	.2026	-22.922	5.008			
Type 4	9	19.441	5.090	3.820	.0004	9.169	29.712			
Туре 1	19									

* Amputation level 1 includes digit(s)/fingers and partial hand; amputation level 2 includes wrist and transradial (below elbow) disarticulation; amputation level 3 includes elbow, transhumeral (above elbow), and shoulder disarticulation.

[†] Type 1: electrically powered, type 2: body-powered, type 3: hybrid, type 4: passive and passive positionable.

Independent Variable	Multiple Analysis							
	n	В	SE	t Value	P Value	Q	95% CI	
DASH	32	-0.083	0.141	-0.590	.5623	-0.374	0.208	
Amputation*								
Level 2	14	-9.994	6.496	-1.540	.1365	-23.372	3.384	
Level 3	7	-22.650	6.668	-3.400	.0023	-36.383	-8.916	
Level 1	11							
Prosthesis [†]								
Type 2	10	3.045	5.491	0.550	.5842	-8.265	14.355	
Type 3	3	-20.252	7.919	-2.560	.0170	-36.562	-3.942	
Type 4	6	5.077	8.400	0.600	.5510	-12.224	22.378	
Type 1	13							

Table 4	Multiple Linear	Regression Models With CAPPFUL	. as the Dependent Variable (n=32	2)
---------	-----------------	--------------------------------	-----------------------------------	----

* Amputation level 1 includes digit(s)/fingers and partial hand; amputation level 2 includes wrist and transradial (below elbow) disarticulation; amputation level 3 includes elbow, transhumeral (above elbow), and shoulder disarticulation.

[†] Type 1: electrically powered, type 2: body-powered, type 3: hybrid, type 4: passive and passive positionable.

this study was to understand the relationship between perceived function and actual function. The multiple linear regression models, which controlled for prosthesis type and amputation level, did not show evidence that changes in the independent variable (DASH) are associated with changes in the dependent variables (BBT and CAPPFUL). Prosthesis type and amputation level were significantly associated with each performance-based outcome measure. This result is consistent with previous reports in other clinical populations. Clinical and regulatory implications of these preliminary analyses are discussed below.

In the upper limb prosthesis rehabilitation field, a standardized approach to assess and track functional improvements over time has not been implemented²¹; the use of outcome measures is rare and, if completed, typically composed of brief PRO type measures. This results in limited and incomplete data on outcomes. Time and resource constraints may contribute to provider reluctance in incorporating outcome measures as a part of standard care.²² Of those that do capture outcome measure data, PROs may be the measure of choice owing to the ease of use and the fact they typically do not require a certified, professional therapist for administration.²² Even fewer patient care programs use performance outcome measures and vanishingly few administer both PRO and performance measures. The preliminary results presented in this study support the notion that a performance-based outcome measure should be used in conjunction with PROs, similar to the DASH, when evaluating function in the upper limb prosthesis user population.

One unique aspect of this work in determining the association between perceived and actual function was the use of performance-based outcome measures that assess an individual's ability to perform ADL. The 2 performance-based measures differed in their end goals, however, because the CAPPFUL is a population-specific measure whereas the BBT is used to assess

Independent Variable	Simple Linear Regression Analysis							
	n	В	SE	t Value	P Value	9	5% CI	
DASH	31	-0.019	0.004	-5.210	<.0001	-0.026	-0.011	
Age	38	0.003	0.007	0.460	.6465	-0.010	0.017	
Sex								
Male	34	0.189	0.273	0.690	.4930	-0.364	0.742	
Female	4							
Amputation*								
Level 2	17	-0.699	0.128	-5.470	<.0001	-0.958	-0.440	
Level 3	7	-0.907	0.164	-5.540	<.0001	-1.240	-0.575	
Level 1	14							
Prosthesis [†]								
Type 2	10	0.630	0.141	4.460	<.0001	0.342	0.917	
Type 3	4	0.560	0.196	2.860	.0072	0.162	0.958	
Type 4	8	0.943	0.152	6.210	<.0001	0.635	1.252	
Type 1	16							

 Table 5
 Simple Linear Regression Models With logBBT as the Dependent Variable

* Amputation level 1 includes digit(s)/fingers and partial hand; amputation level 2 includes wrist and transradial (below elbow) disarticulation; amputation level 3 includes elbow, transhumeral (above elbow), and shoulder disarticulation.

[†] Type 1: electrically powered, type 2: body-powered, type 3: hybrid, type 4: passive and passive positionable.

			<u> </u>	<u> </u>	· · /				
Independent Variable	Multiple Analysis								
	n	В	SE	t Value	P Value	(95% CI		
DASH	31	-0.007	0.004	-1.750	.0937	-0.015	0.001		
Amputation*									
Level 2	15	-0.339	0.196	-1.720	.0975	-0.744	0.067		
Level 3	7	-0.620	0.191	-3.240	0.0035	-1.014	-0.225		
Level 1	9								
Prosthesis [†]									
Type 2	9	0.430	0.165	2.600	.0157	0.089	0.771		
Туре 3	3	0.135	0.222	0.610	.5492	-0.323	0.592		
Type 4	5	0.307	0.244	1.260	.2200	-0.196	0.811		
Type 1	14								

Table 6 Multiple Linear Regression Models With logBBT as the Dependent Variable (n=31)

* Amputation level 1 includes digit(s)/fingers and partial hand; amputation level 2 includes wrist and transradial (below elbow) disarticulation; amputation level 3 includes elbow, transhumeral (above elbow), and shoulder disarticulation.

[†] Type 1: electrically powered, type 2: body-powered, type 3: hybrid, type 4: passive and passive positionable.

a broader clinical population. The BBT is a measure of gross manual dexterity that evaluates repeated motions and speed, whereas the CAPPFUL assesses common activities such as zipping a jacket, turning a knob, or cutting with a knife and fork. Although both measures are classified as performance based, the CAPPFUL evaluates many facets of specific tasks, which gives a more complete picture of the current functional level of the patient compared with a sound upper limb. Even with these differences, our preliminary results in this sample of prosthesis users indicate changes in DASH scores are not associated with changes in either performance-based outcome measure at the definitive stage of prosthesis fitting.

There were some differences in the significant associations of prosthesis type across the 2 types of performancebased outcome measures. Given that prosthesis type also affects performance differently owing to their unique benefits and limitations, the results seen here are not unexpected. For the CAPPFUL model, the hybrid prosthesis (type 3) was found to be negatively associated with increases in the CAPPFUL score (B=-20.252; 95% CI, -36.562 to -3.942; P=.0170). This indicates that individuals using hybrid prostheses have poorer performance as measured by the CAPP-FUL. Hybrid prostheses, although an option at almost any level of amputation, are often selected for transhumerallevel amputations to decrease weight and complexity of a device. A hybrid transhumeral prosthesis consists of multiple types of prosthetic controls used together, which may affect compensatory movement and range of motion. These factors together would result in lower compensatory movement scores on the CAPPFUL and possibly affect other facets of this measure including control skill, component utilization, and task completion. Therefore, lower scores (ie, poorer performance) on CAPPFUL for this prosthesis type are to be expected. For the logBBT model, body-powered devices were significantly associated with higher performance (B=0.430; 95% CI, 0.089-0.771; P=.0157). Given that these devices are intuitive to use and have a clear line of sight to the terminal device enabling improved control,²³ better

performance on a simple repetitive task such as moving blocks is to be expected. The limitations of decreased efficiency (ie, power required to operate) and lack of strength (of most body-powered terminal devices) do not affect outcomes for this type of measure.

Scientists and researchers continue to push the boundaries of what we know to be possible to deliver promising advancements in upper limb prosthetic technology that provide more robust control of robotic prosthetic devices and incorporate sensory feedback.²⁴⁻²⁶ Such technological advancements are at the doorstep of the United States Food and Drug Administration, as research groups are pursuing and receiving investigational device exemptions to conduct early feasibility studies of their advanced technology in take-home trials.²⁷ Our preliminary analysis indicates that PROs alone may not accurately reflect the functional capabilities of individuals using prosthetic devices to perform ADL and thus could fall short in providing a complete assessment of potential benefit of a new prosthetic device. Although additional research is needed on the topic, these results imply that appropriate performancebased measures may also be needed in the development and evaluation of next-generation prosthetic devices.

Study limitations

The low sample size of this study may affect the generalizability of the results to the upper limb prosthesis user population. However, given the paucity of studies investigating the association between PROs and performance-based outcome measures, this preliminary analysis still provides value insights that can inform future studies. The study is also limited in that only a single PRO of perceived function was used. Although the DASH is commonly used to assess perceived function in the upper limb prosthesis user population, it is not an upper limb loss -specific measure. Therefore, it does not query about use of a prosthesis but rather asks the user to rank their abilities regardless of how a task is performed. Other outcome measures specific to the population of interest should be assessed to determine their association to actual function. It may also be of interest to use a combined PRO and performance-based outcome measure that assesses the individual's perceived and actual function for the same tasks. A more robust analysis of how an individual's perception of their abilities relates to their capacity to perform a task could be done.

Conclusions

Although additional data and analyses are needed to more completely assess the association between self-reported measures and performance-based measures of functional abilities, these preliminary results provide some insight into the types of measures to select for evaluation of function in the upper limb prosthesis user population as well as guidance and limitations on the interpretation of these measures.

Supplier

a. SAS v9.4; SAS Institute Inc.

Corresponding author

Kimberly Kontson, PhD, US Food and Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Labs, 10903 New Hampshire Ave, Silver Spring, MD 20993. *E-mail address*: kimberly.kontson@fda. hhs.gov.

Acknowledgment

We thank Wei Wang, PhD, (US Food and Drug Administration) for his review of the article and insight into the statistical methods applied.

References

- Kingsley C, Patel S. Patient-reported outcome measures and patient-reported experience measures. BJA Educ 2017;17:137-44.
- Wright V. Prosthetic outcome measures for use with upper limb amputees: a systematic review of the peer-reviewed literature, 1970 to 2009. J Prosthet Orthot 2009;21(Suppl):P3.
- Finch E, Walsh M, Thomas SG, Woodhouse LJ. Functional ability perceived by individuals following total knee arthroplasty compared to age-matched individuals without knee disability. J Orthop Sports Phys Ther 1998;27:255-63.
- American Physical Therapy Association. Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function (PF), PROMIS PF. Available at: https://www.apta.org/ patient-care/evidence-based-practice-resources/test-measures/patient-reported-outcomes-measurement-informationsystem-promis-physical-function-pf-promis-pf. Accessed January 12, 2021.
- Mizner RL, Petterson SC, Clements KE, Zeni Jr JA, Irrgang JJ, Snyder-Mackler L. Measuring functional improvement after total knee arthroplasty requires both performance-based and patient-report assessments: a longitudinal analysis of outcomes. J Arthroplast 2011;26:728-37.
- Dayton MR, Judd DL, Hogan CA, Stevens-Lapsley JE. Performance-based versus self-reported outcomes using the hip disability and osteoarthritis outcome score after total hip arthroplasty. Am J Phys Med Rehabil 2016;95:132-8.
- Stratford PW, Kennedy DM. Performance measures were necessary to obtain a complete picture of osteoarthritic patients. J Clin Epidemiol 2006;59:160-7.
- Stratford PW, Kennedy DM, Woodhouse LJ. Performance measures provide assessments of pain and function in people with advanced osteoarthritis of the hip or knee. Phys Ther 2006;86:1489-96.
- **9.** Ostlie K, Franklin RJ, Skjeldal OH, Skrondal A, Magnus P. Assessing physical function in adult acquired major upper-limb amputees by combining the Disabilities of the Arm, Shoulder and Hand (DASH) outcome questionnaire and clinical examination. Arch Phys Med Rehabil 2011;92:1636-45.
- Resnik L, Borgia M, Clark M. Function and quality of life of unilateral major upper limb amputees: effect of prosthesis use and type. Arch Phys Med Rehabil 2020;101:1396-406.
- Armijo-Olivo S, Woodhouse LJ, Steenstra IA, Gross DP. Predictive value of the DASH tool for predicting return to work of injured workers with musculoskeletal disorders of the upper extremity. Occup Environ Med 2016;73:807-15.
- Davidson J. A comparison of upper limb amputees and patients with upper limb injuries using the Disability of the Arm, Shoulder and Hand (DASH). Disabil Rehabil 2004;26:917-23.
- Kearns NT, Peterson JK, Smurr Walters L, Jackson WT, Miguelez JM, Ryan T. Development and psychometric validation of

Capacity Assessment of Prosthetic Performance for the Upper Limb (CAPPFUL). Arch Phys Med Rehabil 2018;99:1789-97.

- 14. Resnik L, Borgia M. Reliability and validity of outcome measures for upper limb amputation. J Prosthet Orthot 2012;24:192.
- Mathiowetz V, Volland G, Kashman N, Weber K. Adult norms for the Box and Block Test of manual dexterity. Am J Occup Ther 1985;39:386-91.
- Resnik L, Ekerholm S, Borgia M, Clark MA. A national study of veterans with major upper limb amputation: survey methods, participants, and summary findings. PLOS ONE 2019;14:e0213578.
- **17.** Yoon AP, Kaur S, Chou C-H, Chung KC. Franchise Group. Reliability and validity of upper extremity patient-reported outcome measures in assessing traumatic finger amputation management. Plast Reconstr Surg 2020;145:94e-105e.
- Joshi H. Multicollinearity diagnostics in statistical modeling & remedies to deal with it using SAS. Paper presented at: Pharmaceutical Users Software Exchange. October 14–17, 2012; Budapest, Hungary.
- Schreiber-Gregory DN, Jackson HM. Multicollinearity: what is it, why should we care, and how can it be controlled? In: Brinkley J, editors. SouthEast SAS Users Group Conference; 2017 Nov 5-7; Cary, North Carolina. p 1-12.
- 20. Prescott PA. Multiple regression analysis with small samples: cautions and suggestions. Nurs Res 1987;36:130-3.
- Department of Veterans Affairs, Department of Defense. Clinical practice guideline for the management of upper extremity amputation rehabiliation. Available at: https://www.healthquality.va.

gov/guidelines/rehab/uear/index.asp. Accessed August 17, 2021.

- 22. Hafner BJ, Spaulding SE, Salem R, Morgan SJ, Gaunaurd I, Gailey R. Prosthetists' perceptions and use of outcome measures in clinical practice: long-term effects of focused continuing education. Prosthet Orthot Int 2017;41:266-73.
- Biddiss EA, Chau TT. Upper limb prosthesis use and abandonment: a survey of the last 25 years. Prosthet Orthot Int 2007;31:236-57.
- Mastinu E, Doguet P, Botquin Y, Hakansson B, Ortiz-Catalan M. Embedded system for prosthetic control using implanted neuromuscular interfaces accessed via an osseointegrated implant. IEEE Trans Biomed Circuits Syst 2017;11:867-77.
- 25. Dhawan AS, Mukherjee B, Patwardhan S, et al. Proprioceptive sonomyographic control: a novel method for intuitive and proportional control of multiple degrees-of-freedom for individuals with upper extremity limb loss. Sci Rep 2019;9:9499.
- Emondi A. Hand proprioception and touch interfaces (HAPTIX). Available at: https://www.darpa.mil/program/hand-proprioception-and-touch-interfaces. Accessed January 24, 2021.
- 27. Stone E. FDA approves an EFS-IDE study at the University of Utah for the DARPA HAPTIX Bionic (Prosthetic) Arm System. Center for Neural Interfaces—University of Utah. Available at: https://cni.bme.utah.edu/2020/07/29/fda-approves-an-efside-study-at-the-university-of-utah-for-the-darpa-haptixbionic-prosthetic-arm-system/. Accessed January 24, 2021.