LUKE Arm
Outcome Assessment and Program Evaluation

A. OUTCOME METRICS

A.1 Domains
A battery of assessments that address the following domains will be obtained and monitored:
  A. Activity limitation
      a. Self-reported
      b. Performance based
  B. Pain
  C. Prosthesis use
  D. Prosthesis satisfaction
  E. Satisfaction with prosthetic services.

A2. Description of Measures

A. 2 a Measures of Activity Limitation

A.2a1 Self-report measures

QuickDASH The QuickDASH is a shorter version of the DASH consisting of 11 items that measure physical function and symptoms in musculoskeletal disorders of the upper limb. The QuickDASH includes two optional scales to assess a patient's function with work activities as well as sports or playing an instrument. The QuickDASH is scored in two components: the 11 item disability/section sections where each item is scored 1-5, and the optional work and sport/music modules (4 items, scored 1-5), Respondents indicate the amount of difficulty they have performing the items (1=no difficulty, 6=unable). Scores are summed and averaged and the value is transformed to a score out of 100 by subtracting one and multiplying by 25. A higher score indicates greater disability. The QuickDASH was used in the VA OIG report that examined psychosocial adjustments and activity limitations of OEF/OIF/OND veterans with amputations. The only study that we found which reported on the QuickDASH's reliability in our target patient populated evaluated patients with upper-limb musculoskeletal disorders and reported a test-retest ICC of 0.91; the corresponding MDC90 was 12.85.[1]

Several studies show that the QuickDASH was very strongly correlated with the DASH (r-0.96-0.98).[1,2] QuickDASH change scores were correlated with change in the DASH (r=0.92) and the Global Rating of Change Scale (r=0.71). Costantino reported a significant correlation between the QuickDASH and Constant score (r=-0.60) among patients with humeral fractures treated with a locking plate. Moderate correlations were reported between the QuickDASH and the Patient Activation Measure, a measure of patient participation in healthcare, at first visit to orthopedic surgeon (r=-0.3), follow-up (r=-0.41) and between change scores (r=-0.23).[3]

QuickDASH initial, final and change scores were also moderately or strongly correlated with the Patient Health Questionnaire-2 and Pain Self-Efficacy Questionnaire.[3] Finally, Bear-Lehman reported that among patients with arm or hand injuries, the QuickDASH was correlated with measures of psychosocial functioning including the Impact of Events Scale-Revised (IES-R) total score (r=0.51), and intrusion (r= 0.57) and hyperarousal (r=0.45) subscales.[4]

Several studies support QuickDASH responsiveness. Franchignoni used both distribution-based (SEM=5.5) and anchor-based (AUC=0.86) methods and reported a MCID of 5.9.[1] No floor/ceiling effect analyses were reported.

PSFS The Patient-Specific Functional Scale (PSFS) is a patient specific measure that asks persons to identify up to five activities that they have difficulty performing due to their condition and then rate the amount of limitation they have in performing these activities on a scale of 0 to 10, with "0" being unable to perform the activity and "10" being able to perform the activity with no problem. Individual items are scored separately. One study reported a significant difference across levels of amputation with the lowest scores amongst transradial amputees using conventional prostheses.[5] However, in a separate study, no differences level of device configuration (radial, humeral or shoulder) in users of the DEKA Arm[6] However, subjects scored better with the DEKA arm as compared to their conventional prostheses. An effect size of 1.59 after completion of prosthetic training sessions with the DEKA Arm.[7] No floor or ceiling effects were observed when the PSFS score distribution was examined. No data on reliability of the PSFS was found.

A.2a2   Performance measures

JTHFT The modified Jebsen-Taylor Test of Hand Function Test (JTHFT) was created to minimize administration time of the original test by capping the maximum allowable time to complete each sub-test to 2 minutes.[5] The JTHFT assesses fine and manual finger dexterity through the use of seven timed subtests related to functional tasks. Tasks include: 1) printing a 24-letter sentence, 2) simulated page turning, 3) picking up small common objects and placing them in a container, 4) stacking checkers, 5) simulated feeding, 6) moving light cans, and 7) moving 1 lb. cans. In the modified JTHFT, the score is the number of items completed per second for each task. Reliability and validity of the modified Jebsen tasks were reported in a sample of patients with upper limb amputations.[5] Test-retest reliability was excellent (ICC: 0.82-0.92) for 4 tests. ICC for the light cans and small item were good (ICC=0.73, 0.79 respectively); while ICC for the checkers was less than acceptable for use with individual patients (ICC=0.68). Corresponding MDC90 and MDC95 values ranged from 0.09-0.18 and 0.10-0.21 respectively. Significantly worse scores were reported for subjects with more distal amputation levels.[5] Significant differences in scores were reported by DEKA Arm configuration level for all subtests except checkers. Writing, checkers, light cans, and heavy cans showed no signs of floor or ceiling effects, however page turning, feeding, and small items showed evidence of a floor effect.

Correlations between the JTHFT and the AM-ULA, were reported as follows: page turning (r=0.52), small items (r=0.55), checkers (r=0.42), feeding (r=0.61), light cans (r=0.69) and heavy

cans (r=0.60).[5] The writing score was not significantly correlated with the AM-ULA.[5] Correlation of JTHFT and UNB subscales of Prosthetic Skill ranged from r=0.36-0.47 while correlations of UNB Skill subscale ranged from r=0.32-0.39.[8]

JTHFT responsiveness was reported in a sample of subjects who were trained to use the DEKA Arm.[7] Statistically significant effect sizes were reported for the light cans (ES=0.65) and heavy cans (ES=0.64).[7]

AM-ULA The Activities Measure for Upper Limb Amputees (AM-ULA) is a performance based measure of functional activities for upper limb amputees.[5] The 18 items include a variety of household and self-care tasks ranging from brushing hair, eating with a knife, to zippering a jacket. Scoring takes task completion, speed, movement quality, skillfulness of prosthetic use and independence into consideration. The test takes about 30 minutes to administer. Internal consistency (alpha) of the AM-ULA was 0.89 to 0.91, test-retest reliability (ICC) was 0.88-0.91, and ICC for interrater reliability was 0.84 - 0.85.[5] MDC95 was reported as 4.4 points. Persons with more distal levels of limb loss had higher AM-ULA scores than those with more proximal levels.[5] AM-ULA scores were significantly correlated with the BBT (r=0.63), several JTHF items (r=0.42-0.69) and self-reported activity limitations (UEFS) (r=-0.44).[5] AM-ULA was used in a study quantifying outcomes for DEKA Arm users and significant differences were reported by configuration level users.[7] No significant differences were noted between scores of those using a current prosthesis and scores using the DEKA Arm except in persons using a shoulder configuration where scores were higher. No floor or ceiling effects were observed. Responsiveness was examined in upper limb amputees who used the DEKA Arm and the effect size calculated after 20 hours of training was 1.33.[7]

A.2b. Pain

Wong-Baker FACES Pain Rating Scale (FACES)[9]: The FACES is a commonly used 6-point pain scale that utilizes faces to indicate the intensity of pain. The subject is asked to choose the face that best describes how he/she is feeling relative to their pain. Pain should be scored in the following areas; residual limb, phantom limb, neck, back and shoulders.

A2c. Prosthesis use

Prosthesis use will be assessed using simple patient self-report questionnaires and data logs downloaded from the LUKE Arm. LUKE data logs are cumulative and can provide information on hours that the prosthesis has been powered on in a given amount of time. Data logs will be monitored on a routine basis including at each of the follow-up intervals as noted below.

A2d. Prosthesis satisfaction

Trinity Amputations and Prosthetics Experience Scale (TAPES): The TAPES assesses three primary areas: psychosocial adjustment, activity restriction and satisfaction with the prosthesis. We recommend the 10 item scale related to prosthetic satisfaction which includes

questions about extent of satisfaction regarding functional characteristics of the artificial limb: reliability, comfort, fit, and overall satisfaction, contentment with cosmetic characteristics of the device.[10] Each item is rated on a 5-point scale from very dissatisfied to very satisfied. Cronbach alpha (internal consistency) for the prosthetic satisfaction scale for upper limb amputees has been reported as 0.94.[10]

A2e. Quality of care

Quality of care will be assessed by a validated metric, the Orthotics and Prosthetics Users Survey (OPUS) Follow-up Evaluation of Services and Device Scale. [1011] The OPUS Evaluation of Services and Device Scale is an 11-item scale with evidence of construct validity and internal consistency of 0.74. [1011] The OPUS was recommended as a VA performance measurement tool.[1112] For tool see: http://www.ric.org/research/research-centers--programs/cror/publications/opus/ For scoring guide see p. 11 of OPUS scoring guide.

The VA Amputee Clinic Standardized Clinic Satisfaction Tool will also be utilized to collect and analyze the quality of care provided.

A.3 Assessment Time Points

	Baseline	Pre-discharge	6 month	1 Month	Annually
A. Activity limitation	X	X	X	X	X
Self-report					
QuickDASH					
PSFS					
Performance	X	X	X	X	X
JTHF					
AM-ULA					
B. Pain	X	X	X	X	X
C. Prosthesis use	X		X	X	X
D. Prosthesis satisfaction	X		X	X	X
E. Quality of care		X	X	X	X

B. PROGRAM EVALUATION SUCCESS MILESTONES

AT DISCHARGE
1. Satisfaction with the LUKE Arm, as measured by the TAPES in patients accepting the prosthesis, will be rated "satisfied" or "very satisfied" by 75% of patients
2. Satisfaction with services will be rated positively by 85% of patients

AT ONE MONTH

1. 75% of patients will be using the prosthesis
2. Satisfaction with services will be rated positively by 85% of patients

AT ONE YEAR

1. 75% of patients fit with the LUKE Arm will be using the prosthesis at 1 year
2. Satisfaction with the LUKE Arm, as measured by the TAPES will be rated "satisfied" or "very satisfied" by 75% of patients
3. Satisfaction with services will be rated positively by 85% of patients

References

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