Comparison of outcomes between the DEKA Arm and conventional prosthesis – *an in depth review study of measures and evaluation techniques*

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1. INTRODUCTION

The **ability to measure and evaluate** [1] is a major exercise in the daily lives of health professionals, regardless of their speciality, may they be physiotherapists, nurses, doctors, prosthetist and orthotisc and of biomedical engineers, who assist in the whole process of gathering the data and analysing it. This exercise must be realized in a professional, responsible and economic manner and ultimately based on backed-up evidence. Therefore it is of extreme importance to focus on a correct and accurate measurement system and be able to properly evaluate a persons's illness or disability. To understand the results of the study case that was reviewed [2], it becomes important to understand two important and different definitions: **outcome** and **outcome measure**. A database of a few of the measures available can be consulted online. [3] [4]

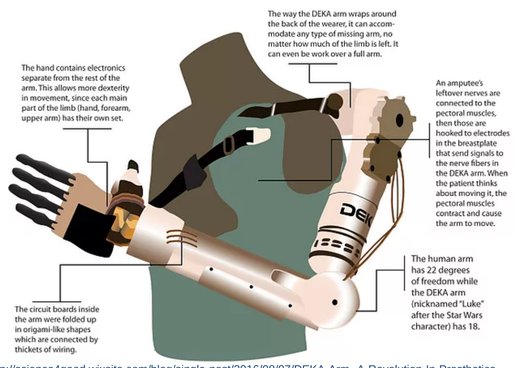
- An **outcome** is a "*measurable individual, family, or community state, behavior or perception that is measured along a continuum and is responsive to clinical interventions*" [5].
- An **outcome measure** is a set of items that are used to create scores that are "*intended to quantify a patient's performance or health status based on standardized evaluation protocols or closed ended questions*". [5]

It is therefore important to make sure that these patient characteristics are measured using **standardized outcome instruments** so that they can be adequately stored in electronic records, allowing for its use by clinical bodies, to facilitate in the identification of signal or symptoms of any healthy condition, making the diagnostic and call for action easier, all the while contributing to the development of clinical knowledge and professional education. [6] More detailed information about outcome measurements can be consulted in [7].

2. OBJECTIVES

The **main objectives** of this work are **three-fold**:

- **Compare** DARPA's DEKA Arm with conventional prosthesis, in terms of self-reported function, dexterity, activity performance, quality of life and community integration;
- **Examine differences** in outcomes by conventional prosthesis type, terminal device type and by DEKA arm configuration level;
- **Provide a review** of the measurement and evaluation techniques involved in the study [2].



http://science4good.wixsite.com/blog/single-post/2016/08/07/DEKA-Arm--A-Revolution-In-Prosthetics

Fig.1. The nicknamed "Luke Arm"

3. THE DEKA ARM

The DEKA Arm, now renamed "**LUKE**" arm (Life Under Kinetic Evolution) [8], by medical device Maker Mobius Bionics, in homage to the StarWars franchise, is the next generation in prosthetic arms. IT was developed under USA **DARPA**'s (Defense Advanced Research Projects Agency), Revolutionizing Prosthetics program by **DEKA** Research & Development Corp. Having received its approval from the U.S. **FDA** (Food and Drug Administration) in 2014 and is now available for medical providers and as a promise to service members and veterans who are rehabilitating after suffering upper-limb loss.

- o +10 years of research [9];
- o +10000 hours of testing in nearly 100 amputees;
- o Electromyogram (EMG) electrodes pick up electrical signals;
- o 10 powered degrees of freedom;
- o Increased mobility;
- o Increased outcome measures and improved performance;
- o 3 configurations: radial configuration (RC), humeral configuration (HC) and shoulder configuration;
- o Controled primarily with inertial measurement units (IMUs);
- o Powered wrist allows flexion and extension, powered wrist propanation and supination and 6 programmable hand grip patterns;

4. METHODS

The study in which this work is based was a **two-part study**:

IN-LABORATORY TRAINING → **PART A** → **PART B** → HOME USE

- **23** protheses users completed **Part A**
- **Mean age** = 45 ± 16
- 87% male
- Fit and trained to use the DEKA Arm

- **15** protheses users - that completed **Part A** moved on to **PART B**
- **Mean age** = 45 ± 18
- 87% male
- Used the DEKA Arm at home for up to 12 weeks. Returned for re-evaluation on-site every 4 weeks.

Outcomes including *self-report* and *performance measures*, were collected at Baseline using participants' personal prosthesis and at the end of Parts A and B, scores were compared using paired **t-tests**.

Wilcoxon signed-rank tests were used to compare outcomes for the full sample and for the sample stratified by device and terminal device type.

Analysis of outcomes by configuration level was performed graphically.

5. STANDARDIZED MEASURES

At **Baseline** (refer to the participant's personal prosthesis) and at the **end of Parts A and B**, the study occupational therapists (OTs), administered a set of standardized measures to participants. A broad range of (**23**) measures were selected to assess important constructs for upper limb amputees. On **point 6** we describe some of them objectively. Below an explanation of the outcome measures.

Table.1. Outcome measures

Measure	Construct	Brief description	Response	Higher scores indicate. . .
Dexterity				
Jebsen-Taylor Hand Function Test (JTHF)	Dexterity	7 tests of hand function	Performance speed; items.sec	better performance
Activity				
Activities Measure for Upper-Limb Amputees (AM-ULA)	Activity performance	18-everyday tasks	Task completion: speed, movement quality, skill and independence	better performance
University of New Brunswick Test of Prosthetic Function (UNB): Skill	Prosthetic skill	10 components of daily tasks requiring bimanual engagement	Skillfulness of terminal device use.	better performance
University of New Brunswick Test of Prosthetic Function (UNB): Spontaneity	Prosthetic spontaneity	10 components of daily tasks requiring bimanual engagement	Spontaneity of engaging the prosthesis in activities	better performance
Timed Measure of Activity Performance (T-MAP)	Activity performance	5 activities of daily living	Task completion: speed	Worse performance
Brief Activity Measure for Upper Limb Amputees (BAM-ULA)	Activity performance	10 items of functional task performance	Task completion: Unable to complete; Can complete	better performance
Self-Reported Function				
Disabilities of the Arm, Shoulder and Hand Score (QuickDASH)	Disability	Self-reported functional difficulty (8 items) 3 items about sleep, sensation and pain	Performance difficulty and impairment severity	greater disability
Upper-Extremity Functional Scale (UEFS)	Activity performance	Self-reported difficulty performing 23 everyday activities	Difficulty in performance	greater difficulty
Upper-Extremity Functional Scale (Use)	Use of prosthesis	Self-reported use of the prosthesis during everyday activities	Prosthesis use	more activities done with prosthesis
Patient-Specific Functional Scale (PSFS)	Difficulty performing activities	5 self-selected activities difficult to do because of the amputation	Difficulty in performance	less difficulty
Other Measures				
Wong-Baker FACES Pain Rating Scale	Pain	Six faces showing levels of pain severity	Pain intensity	more pain
Quality of Life (QOL)	Quality of life	16 question items about quality of life	Satisfaction with quality of life	better QOL
The Community Reintegration of Service Members Computer Adaptive test (CRIS-CAT)		Computer adaptive testing measuring participation in life roles		better community integration
CRIS-CAT Extent of Participation	Extent of participation		Frequency and amount	
CRIS-CAT Perceived Limitations	Perceived difficulty		Perceived limitations	
CRIS-CAT Satisfaction with Participation	Satisfaction		Satisfaction scale	
Trinity Amputation and Prosthesis Experience Scales (TAPES)	Prosthetic satisfaction	10 items satisfaction with prosthesis	Satisfaction	greater satisfaction

6. MEASURES – definitions [2]

- **Modified Jebsen-Taylor Hand Function (JTHFT):** measure of dexterity and simple functional activities. It has 7 subtasks.
- **Activities Measure for Upper-Limb Amputees (AM-ULA):** measure of activity performance for prosthesis users. The test has 18 items.
- **University of New Brunswick test of prosthetic function (UNB):** measure of prosthetic skill and spontaneity that is appropriate for unilateral amputees.
- **Timed Measure of Activity Performance (T-MAP):** timed based measure of common activity performance developed for upper limb amputees. Consists of 5 items.
- **Brief Measure of Activity performance (BAM-ULA):** observational measure of activity performance. It has 10 items.
- **QuickDASH:** it is an 11-item disability scale, a shorter version of the Disabilities of the Arm and Shoulder (DASH) measure, which has been validated for use in upper limb amputation It includes 8 items.
- **The Upper-Extremity Functional Scale (UEFS):** one of the scales of the Orthotics and Prosthetics Users Survey (OPUS). It is the only self-report measure of activity performance developed specifically for adults with upper limb amputation.
- **The Patient Specific Functional Scale (PSFS):** it is a patient-specific outcome measure that assesses functional status.
- **The Wong-Baker FACES:** it is a self-report measure of pain, which has a 6-point pain scale that utilizes faces to indicate different levels of pain intensity. Patients are asked to choose the face that best describes how he/she is feeling.
- **The Community Reintegration of Service Members Computer Adaptive test (CRIS-CAT):** it is a computer adaptive test version of the CRIS measure. It has 3 sub-scales.
- **Trinity Amputations and Prosthetics Experience Scale (TAPES) Satisfaction Scale:** it is a condition-specific instrument that assesses the psychosocial processes involved in adjusting to a prosthesis, the specific demands of wearing a prosthesis and the potential sources of maladjustment.

7. RESULTS & DISCUSSION*

There is a vast amount of information generated by the chosen study [2]. Below, on **table 2**, we have one of them, representing the scores for all measures by **testing period**. Similar tables and figures were produced by **device type** (body powered, myoelectric), **degrees of freedom**, **DEKA Arm configuration level** and **self-report levels**.

DATA ANALYSIS

Effect sizes differences (EZ- quantitative measure of the magnitude of a phenomenon), was calculated for the full sample to quantify the magnitude of differences for those tests that were found to be statistically different.

The Benjamini-Hochberg method was used to maintain a false discovery rate (FDR) of 0.10 within each category of tests.

Table.2. Outcomes across assessment time points

		Baseline	End of A	T test		Baseline	End of B	W S-R
	N	Mn (sd)	Mn (sd)	P	N	Mn (sd)	Mn (sd)	P
Dexterity								
Jebsen-Taylor Hand Function (JTHFT)								
JTHFT: Writing items/sec	23	0.33 (0.23)	0.34 (0.14)	0.9284	15	0.35 (0.25)	0.45 (0.20)	0.1354
JTHFT: Page Turning items/sec	23	0.07 (0.07)	0.06 (0.04)	0.2496	14	0.10 (0.07)	0.11 (0.07)	1.0000
JTHFT: Small items items/sec	23	0.07 (0.08)	0.08 (0.08)	0.3730	14	0.08 (0.09)	0.09 (0.07)	0.6698
JTHFT: Feeding / Eating items/sec	23	0.10 (0.08)	0.07 (0.05)	0.1164	14	0.12 (0.08)	0.08 (0.08)	0.0785
JTHFT: Checkers items/sec	23	0.09 (0.08)	0.08 (0.07)	0.6318	14	0.09 (0.08)	0.11 (0.08)	0.1937
JTHFT: Light Cans items/sec	23	0.20 (0.13)	0.20 (0.16)	0.7603	14	0.22 (0.14)	0.26 (0.18)	0.2958
JTHFT: Heavy Cans items/sec	23	0.22 (0.14)	0.21 (0.17)	0.9105	14	0.24 (0.14)	0.29 (0.16)	0.3575
Activity								
AM-ULA	23	16.7 (5.4)	17.1 (4.8)	0.5851	13	16.5 (4.8)	19.8 (4.5)	***0.0024**
UNB: Spontaneity	22	3.1 (0.5)	3.1 (0.5)	0.9610	13	3.1 (0.4)	3.3 (0.4)	0.1943
UNB: Skill	22	2.9 (0.5)	2.9 (0.5)	0.9038	13	3.0 (0.5)	3.2 (0.4)	0.1138
T-MAP	20	533.8(228.5)	786.6(413.1)	***0.0008**	11	508.6 (264.2)	676.6 (469.6)	0.3203
BAM-ULA summary (new)	16	6.9 (3.0)	7.5 (1.7)	0.3002	10	7.7 (2.2)	8.3 (1.5)	0.6563
Self-reported function								
QuickDASH	23	28.3 (13.0)	21.9 (10.3)	***0.0108**	15	26.5 (11.3)	20.8 (12.0)	***0.0313**
Upper Extremity Functional Scale (UEFS)	14	44.4 (6.0)	44.2 (4.5)	0.8810	10	43.0 (5.4)	38.6 (9.3)	0.2754
UEFS use	23	0.4 (0.2)	0.7 (0.3)	***0.0060**	14	0.5 (0.2)	0.7 (0.2)	***0.0105**
Patient Specific Functional Scale (PSFS)	23	2.6 (1.4)	5.3 (1.8)	***0.0001**	15	2.6 (1.3)	6.2 (2.0)	***0.0001**
Quality of life etc.								
Wong-Baker Pain Scale	23	0.8 (1.0)	0.9 (1.1)	0.7040	15	0.5 (0.7)	0.9 (1.0)	**0.0313**
Quality of Life (QOL) Scale	23	5.7 (0.6)	5.7 (0.7)	0.9201	15	5.7 (0.6)	5.8 (0.8)	0.5526
Community integration								
CRIS-CAT Extent of Limitations	22	54.4(9.2)	54.9 (8.5)	0.7853	15	54.5 (9.2)	57.6 (10.1)	0.2378
CRIS-CAT Perceived Limitations	22	55.9 (14.6)	51.5 (9.4)	0.2001	15	57.5 (17.0)	60.3 (19.2)	0.4810
CRIS-CAT Satisfaction with Participation	22	53.4 (12.3)	50.7 (5.9)	0.2182	15	54.9 (14.0)	56.0 (13.9)	0.6721
TAPES Satisfaction Scale	23	3.5 (0.6)	3.5 (0.7)	0.8222	15	3.6 (0.6)	3.7 (0.9)	0.5151

* significant after Benjamini-Hochberg adjustment with false discovery rate = 0.1.

- After in-laboratory training, activity performance of the DEKA Arm and conventional prosthesis was equivalent, however after home use, AM-ULA scores using the DEKA Arm surpassed conventional prosthesis scores.
- **DEKA Arm was slower at end of PART A** to conventional prosthesis, but **equivalent after Part B**.
- DEKA users listed new activities that they could not perform with conventional prosthesis;

** For an extensive analysis of the results obtained please consult the original article* [2]

8. STUDY LIMITATIONS

- Comparisons between the DEKA Arm and the myoelectric device required far larger samples at both End of A and End of B;
- The sample size, while relatively large for a study of a new upper limb prosthesis, was still very small, limiting statistical comparisons;
- The analysis of outcomes by configuration level (not shown on on this poster) was performed graphically and needs to be interpreted cautiously;
- Some subjects may not have fully acclimated to the DEKA Arm, being conceivable that the results at end of PART A &/or B would continue to improve.

9. CONCLUSIONS

- Participants using the **DEKA Arm** had **less perceived disability** and **more engagement** of the prosthesis in everyday tasks at the end of Part A (although their performance activity was slower);
- After home use experience (**PART B**), **perceived disability was lower**, **prosthesis engagement higher**, **activity performance** was **improved** and **activity speed equivalent to using conventional prosthesis**;
- No differences (for the full group) were observed in measures of dexterity, prosthetic skill, spontaneity, pain, community integration or quality of life between the DEKA Arm and conventional prosthesis.

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