Advanced Robotic Arm Projects

Brian Schulz, PhD

Scientific Program Manager for Rehabilitation Engineering and Prosthetics/Orthotics

Rehabilitation Research and Development Service

VA Office of Research and Development

Veterans Health Administration

Research & Development

Improving Veterans' Lives — www.research.va.gov

VA's UE prosthetics research efforts are comprised of several separate studies:

- **Completed & ongoing**
  - DEKA arm optimization studies
  - DEKA arm take-home study
  - Future plans for arms used in study
- **Starting up now**
  - Transhumeral osseointegration
  - Dextrous manipulation of hands
  - Alternative control systems

VA Studies of the DEKA Arm

PI: Linda Resnik, PT, PhD

VA RR&D A6780
VA RR&D A6780I
VA RR&D A9226-R

DEKA's support of the VA optimization studies was sponsored by the Defense Advanced Research Projects Agency and the U.S. Army Research Office

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History of VA Studies of DEKA Arm

2005 DARPA launched Revolutionizing Prosthetics Program 2-year contract awarded to DEKA 2006-2008

2008 DEKA completed first 2-year contract: developed the Gen 2 Arm

2008 VA began planning optimization studies

2010 Completed testing of Gen 2 Arm

2011 Testing of Gen 3 Arm

2012 June, 30th Completion of Optimization study

2012- Home Study of the DEKA Arm began

The DEKA Arm

- The DEKA Arm is designed for users with amputations at the forequarter, shoulder disarticulation, transhumeral or transradial level

- There are three versions available:
  - Shoulder Configuration (SC)
  - Humeral Configuration (HC)
  - Radial Configuration (RC)

SC Arm: 10 Powered Degrees of Freedom

- ARM
  - Shoulder Abduction
  - Shoulder Flexion/Extension
  - Humeral Rotation
  - Elbow Flexion/Extension
  - Wrist Pronation/Supination
  - Wrist Flexion/Extension
- Hand
  - 2nd digit Flexion/Extension
  - 3rd, 4th and 5th Digit Flexion/Extension
  - Thumb flexion/Extension
  - Thumb Ab/Adduction

Controlling the Arm

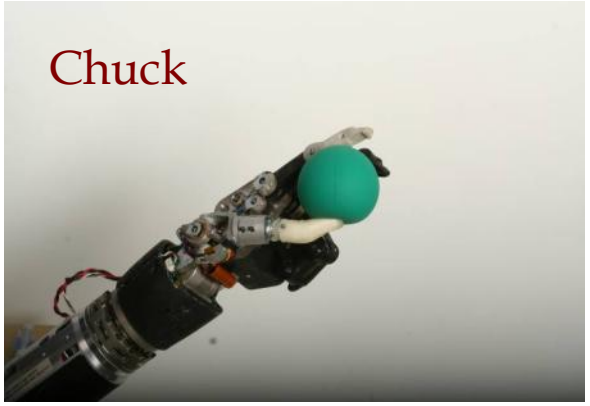
- Each user has their own unique control scheme based on preference and ability:
  - Myoelectric (muscles)
  - Control switches
    - Triggered by motion
  - Foot control(s)
    - Inertial Measurement Units (IMU)
  - Pneumatic bladder controls

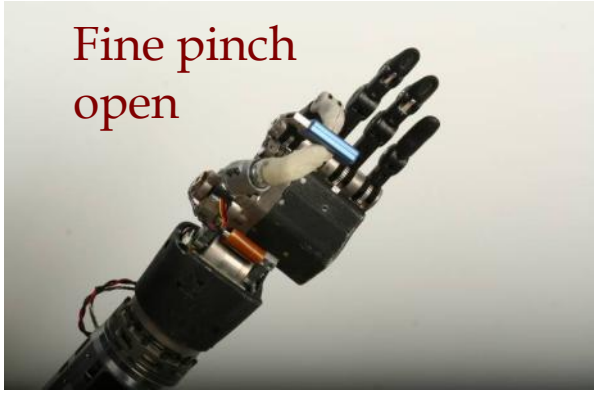
Modes of Operation

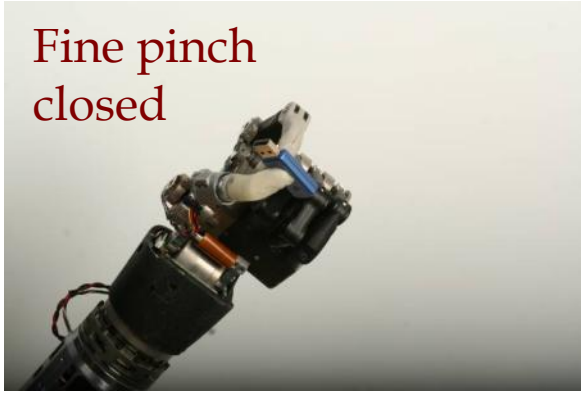
- Single control sites can have multiple functions depending upon the “mode” of operation:
  - Arm Mode
  - Hand Mode

- Mode selection switches – can be customized to each user

Six Grip Patterns



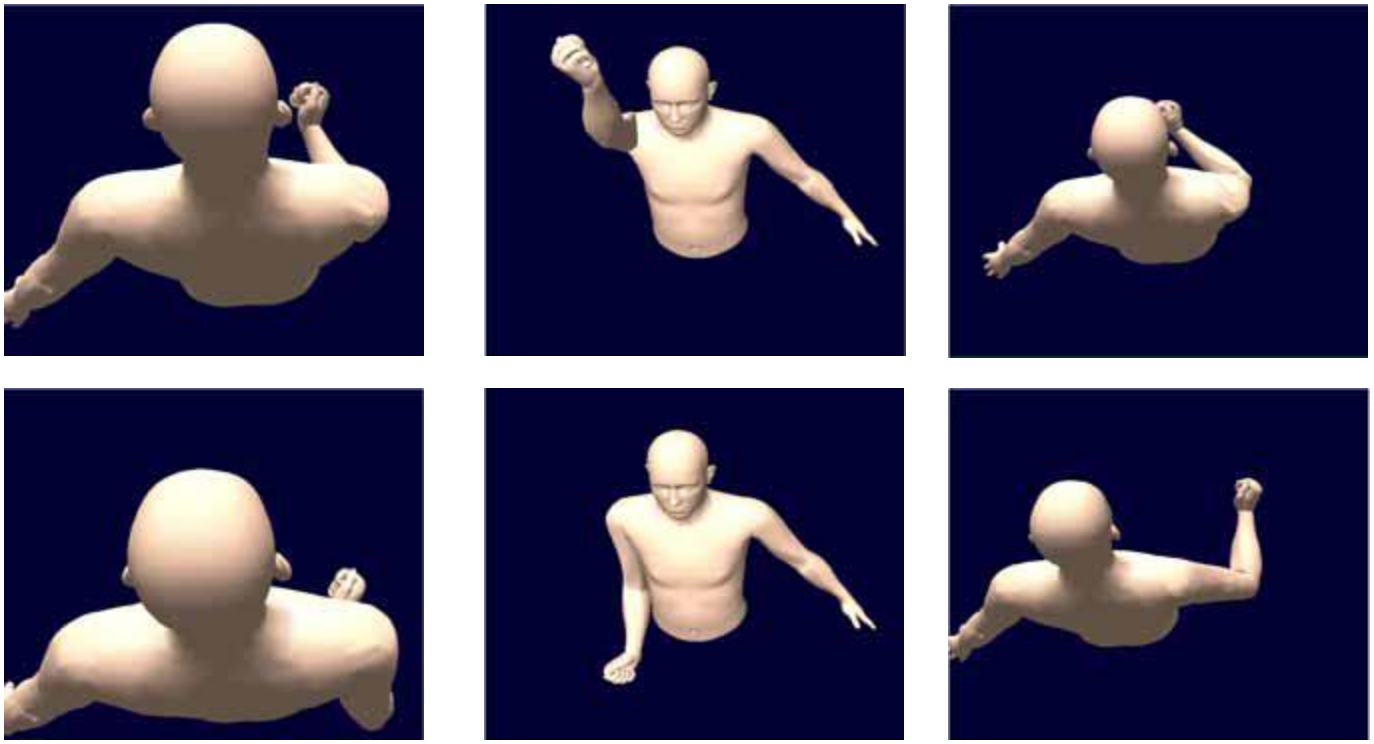




Choosing a Grip

- Toggle through full six grip patterns
  - Forward sequence
  - Backward sequence
- Direct selection of grip
  - Limits to four grip patterns

Endpoint Control



Forward/Back Up/Down Left/Right

Endpoint features

- Design of the shoulder prevents movement in the upper spatial quadrant (beyond 90 degrees of shoulder abduction)
  - “Functional window” of operation
  - Built-in software stops

- Endpoint has slow-down zones near the area of the head that reduced the speed of motions toward the head and face

VA STUDY TO OPTIMIZE THE DEKA ARM

VA RR&D A6780

VA RR&D A6780I

DEKA's support of the VA optimization studies was sponsored by the Defense Advanced Research Projects Agency and the U.S. Army Research Office

Purposes:

1. Summarize recommendations to improve second-generation (Gen 2) DEKA Arm
2. Examine satisfaction & usability ratings of DEKA Arms
3. Quantify outcomes including dexterity, performance of daily activities, and prosthetic skill and spontaneity of DEKA Arm users
4. Compare outcomes when using DEKA Arm versus existing prosthesis

METHODS

Study Sites

- Providence VA - Coordinating Center
- VA New York Harbor Healthcare System (NYHHS)
- Tampa VA
- Long Beach VA
- Center for the Intrepid, Brooke Army Medical Center

Enrollment: Optimization Study

- Eligibility:
  - Unilateral or bilateral amputees
  - Transradial, transhumeral, shoulder disarticulation or forequarter amputation

- 75 Screened
- 39 participated
  - 26 Gen 2
  - 13 Gen 3
    - 33 unique subjects
      - 5 subjects participated in both Gen 2 and Gen 3
      - 1 subject participated in Gen 2 twice (different controls)

Study Procedures

Visit 1	Screening Visit/baseline testing
Visit 2	Retesting
Visits 3-8	Prosthetic fitting and controls set-up
Visit 9	Initial testing with DEKA arm
Visits 10-14	Training (5 sessions)
Visit 15	Retesting with DEKA arm
Visits 16-20	Training (5 sessions)
Visit 21	Retesting with DEKA arm
Visit 21-26	Training (5 sessions)
Visit 27	Retesting with DEKA arm

Methods

- Data gathered through:
  - Structured and open-ended surveys
  - Repeat administration of standardized outcome measures
  - Audio- and videotaped sessions
  - Study prosthetists and therapists provided ongoing feedback and completed surveys at end of each subject's protocol

Data Analyses

- Feedback and communication with sites and DEKA throughout trials
- Video, audio and written data analyzed as each subject completed participation
- Regular, informal interaction and feedback with DEKA engineers
- Usability synopses sent to DEKA
- Service and repair data tracked

Data Analyses

- Qualitative analysis to understand user and clinician experiences
- Usability and satisfaction ratings evaluated
  - Prototypes compared
    - Results stratified by DEKA Arm configuration level
- Examined outcomes by configuration levels
- Compared outcomes using existing prostheses with DEKA Arm

RESULTS

Results: Optimization Needs

- 11 categories of user feedback were identified:
  - Weight
  - Cosmesis
  - Hand grips
  - Wrist design
  - Elbow design
  - End-point control
  - Foot controls
  - Batteries and chargers
  - Visual notifications
  - Tactor
  - Socket features

Optimization Results

Gen 3	Gen 2

Gen 3 New Features

- Sleeker contours
- New shoulder design
- Improved foot controls
- New wrist design
- Wrist indicator
- Improved grips
- Internal battery (SC & HC)
- Hand open button

Improved Foot controls

a. FSR footpad wired to ACI

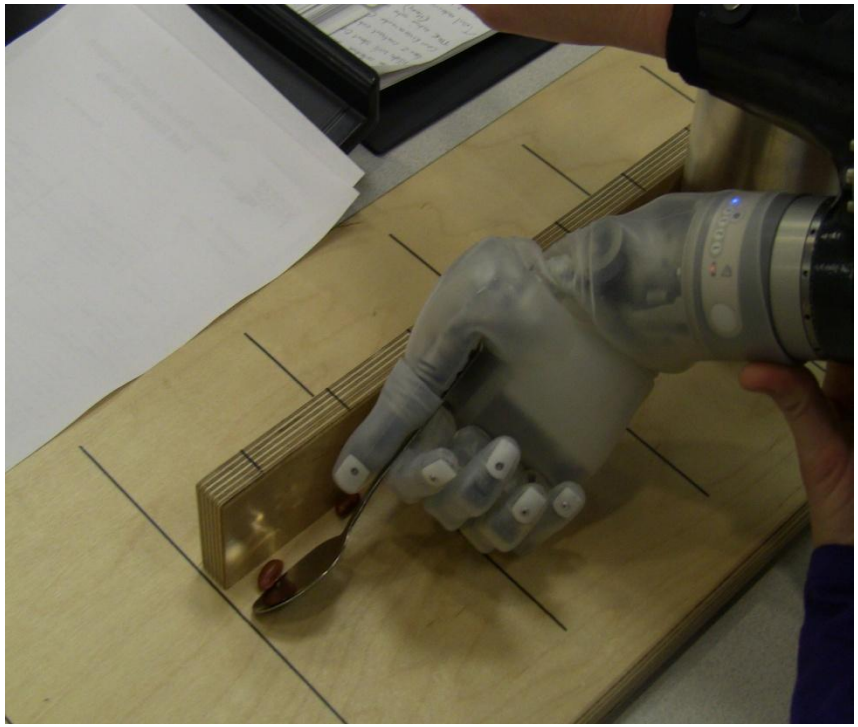
b. IMU-1 and ACI unit

c. IMU-2 worn on laces

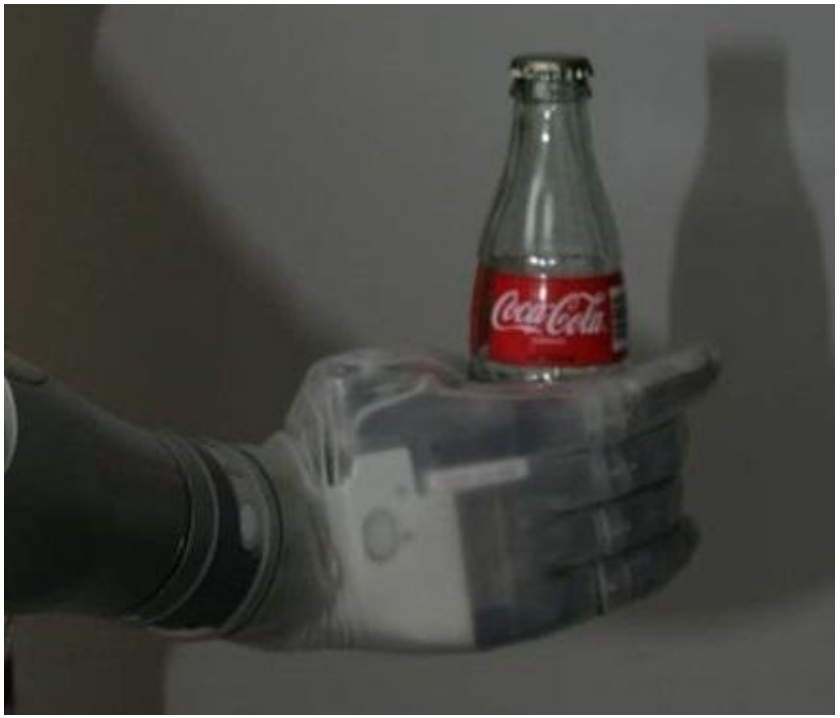
Figure 2. Three iterations of Foot Controls: a. FSRs, b. IMU-1 and c. IMU-2

Compound Wrist

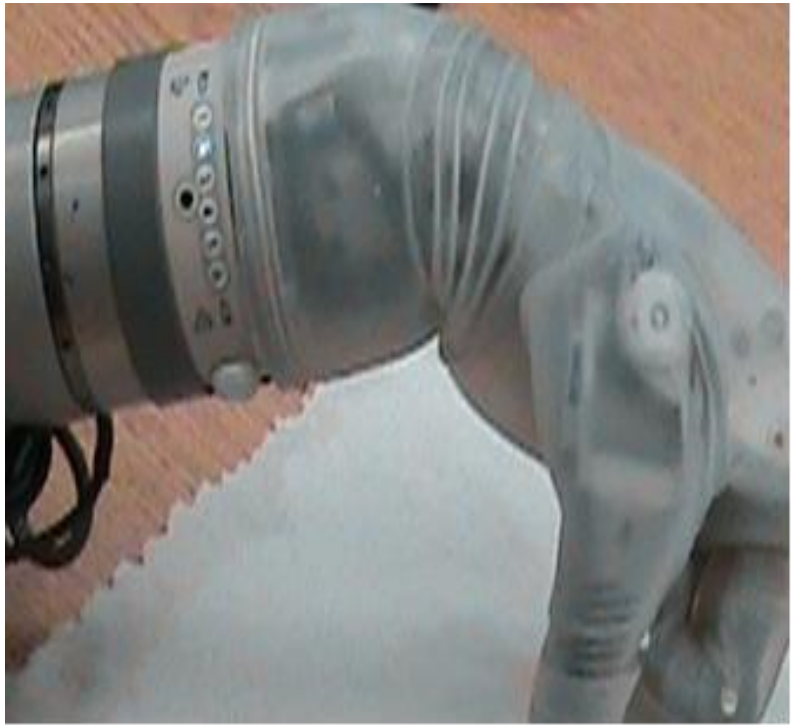
Down and in
(flexion/ulnar deviation)



Up and out
(extension/radial deviation)



Wrist indicator

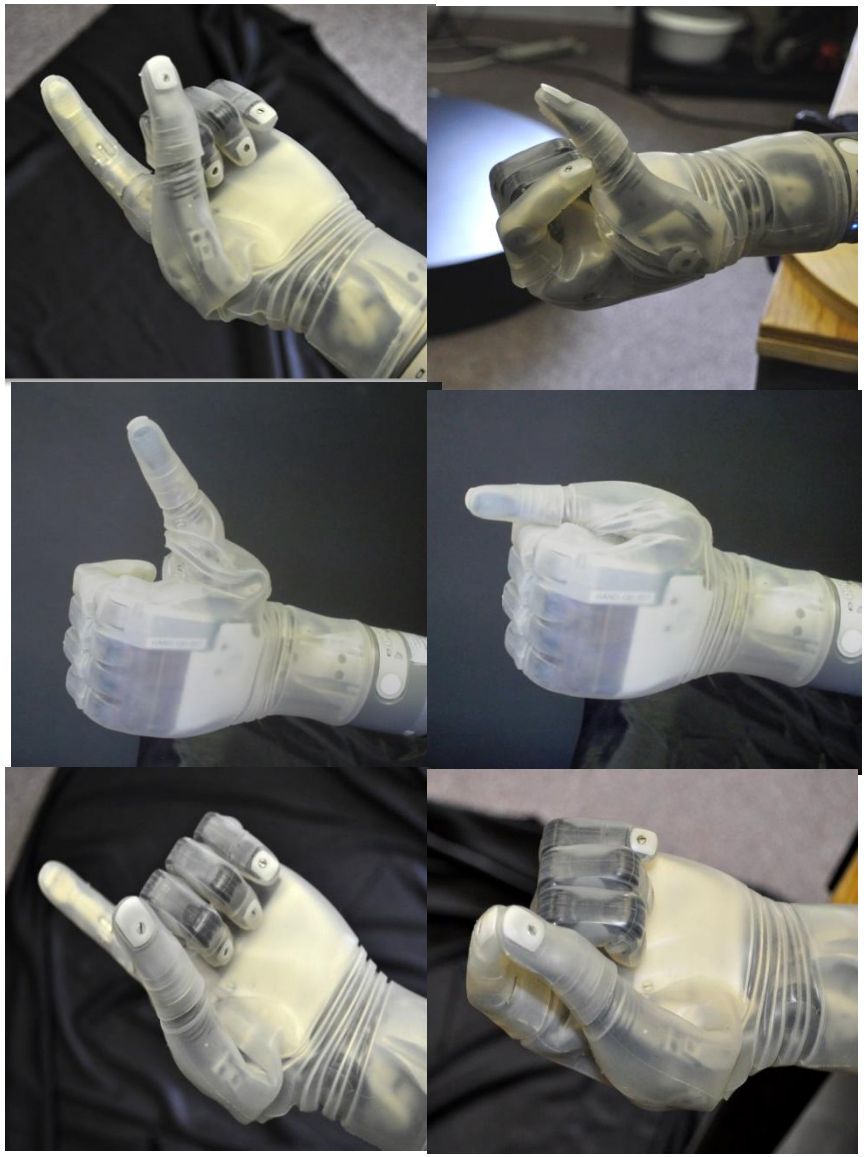


- Grip selection
- Battery charge
- Mode

Grip Detents

- Separates positioning/stabilizing and grasping aspects from the precision aspects
- Present in tool grip, lateral pinch, and fine pinch closed
  - Two consecutive signals to fully open or full close
    - User activates the hand signal to the first detent position, ceases the command, and then repeats the command to complete the action

Detents

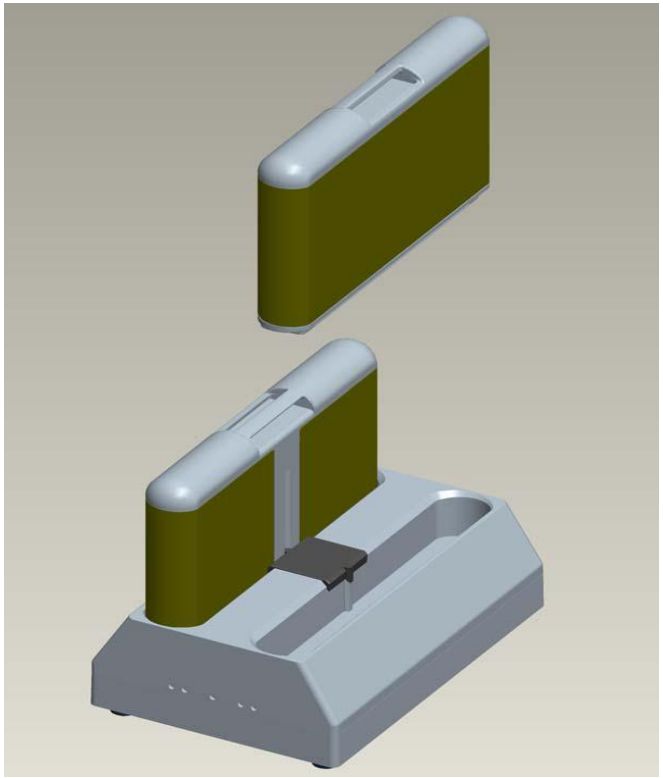


Tool grip

Lateral pinch

Fine pinch closed

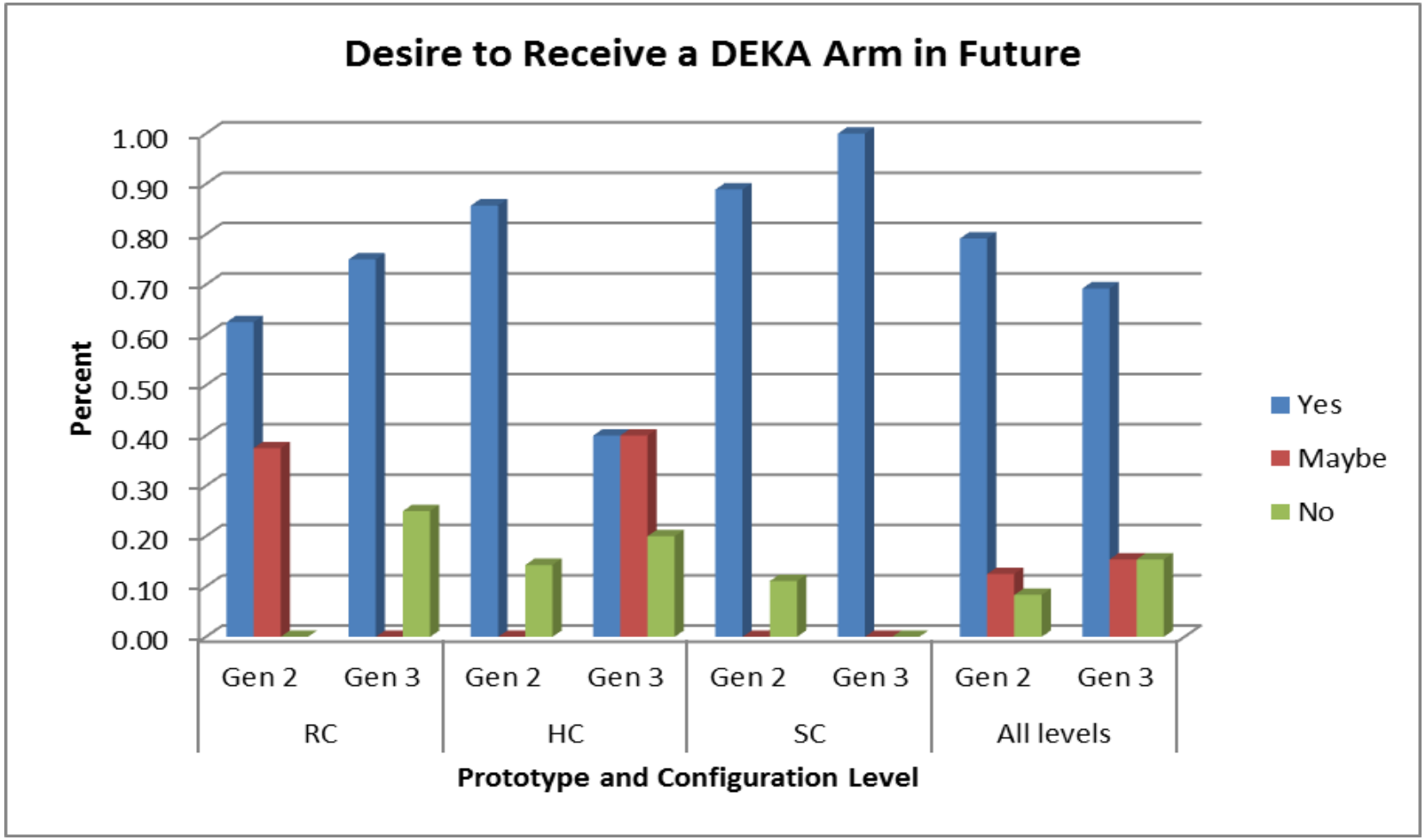
Easier Battery Charging



Satisfaction and Usability Ratings

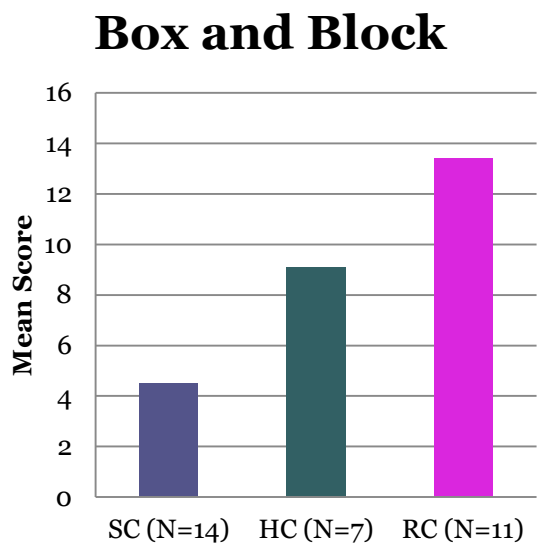
- Aesthetic satisfaction was higher for Gen 3 users than Gen 2
  - Greater satisfaction with the appearance of the device.
- Gen 3 users were more satisfied with:
  - Grips.
  - Doffing
- Scores for the overall usability scale were higher for Gen 3 users
  - Gen 3 users said using the arm was “easy”
  - Gen 2 users said that it was “neither easy nor difficult”

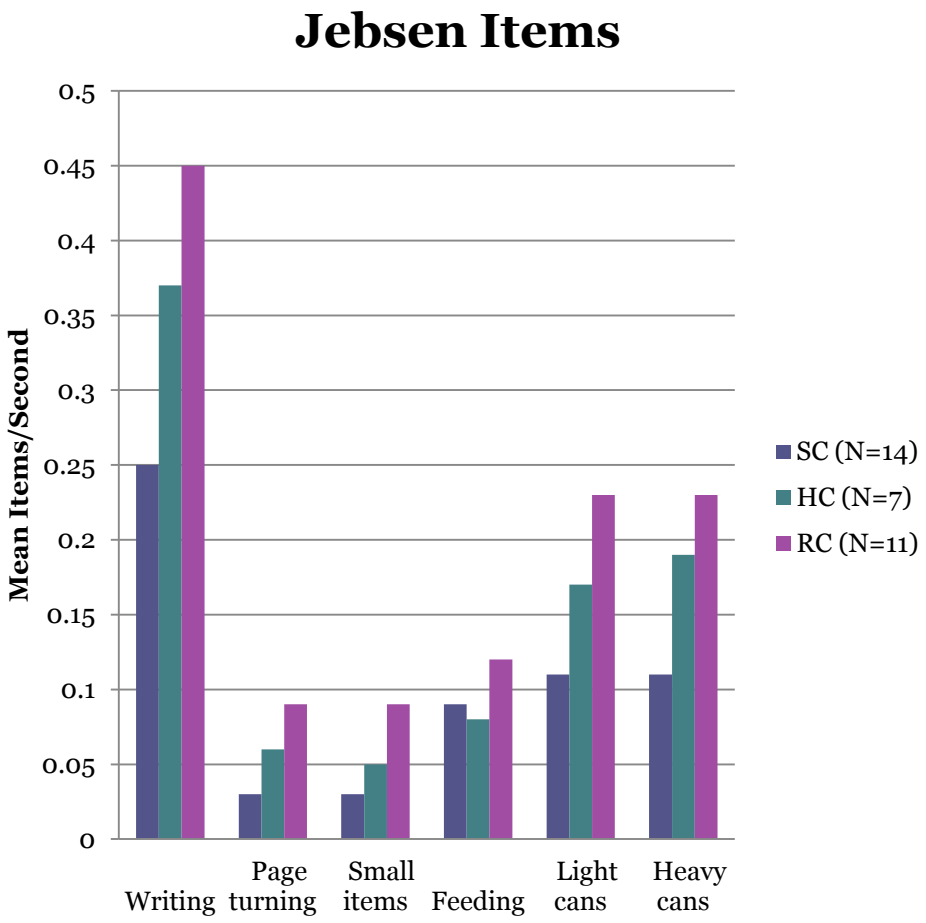
Did Users Want a DEKA Arm?



Functional Outcomes with DEKA Arm

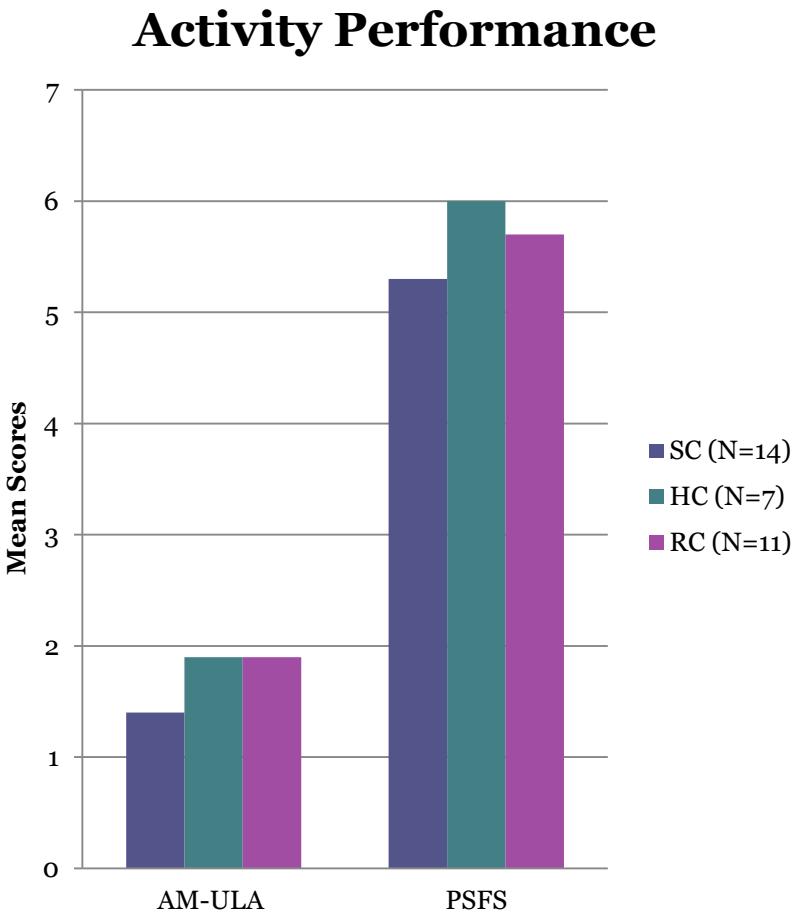
- **Dexterity**
  - Better for RC users as compared to HC and SC users





Functional Outcomes with DEKA Arm

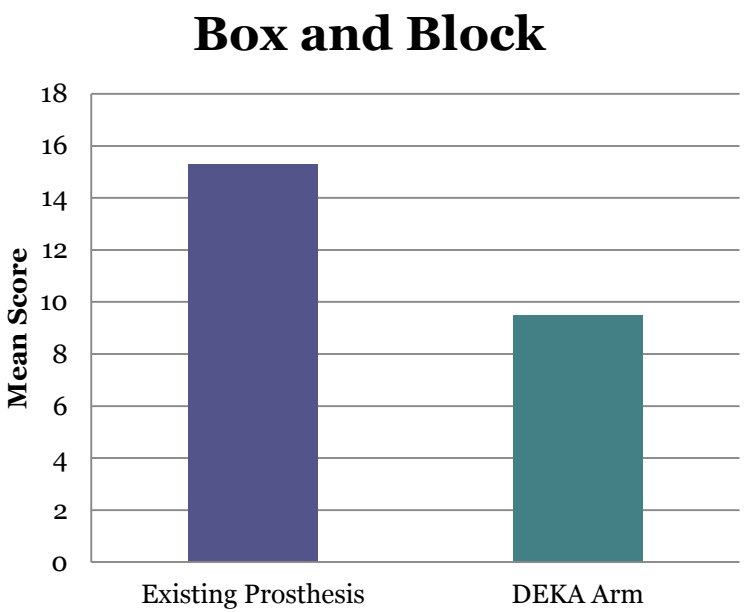
- **Activity performance**
  - Better for RC and HC compared to SC users

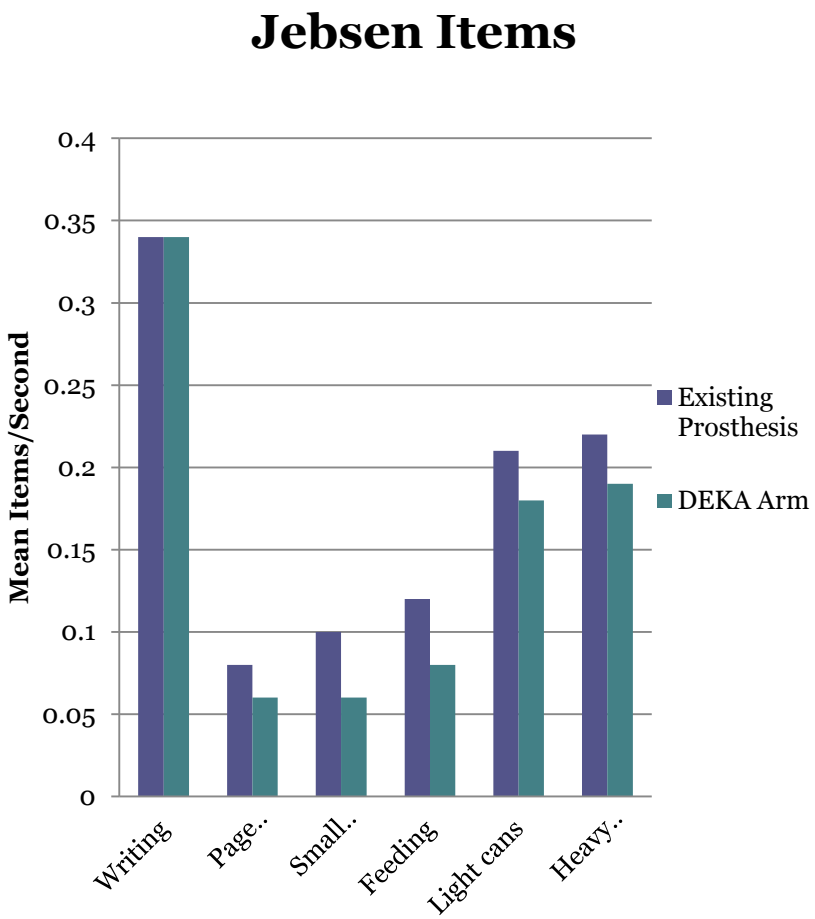


DEKA compared to existing prostheses

26 Prosthetic Users

- **Dexterity**
  - Better with existing prosthesis (RC, HC)





DEKA compared to existing prostheses

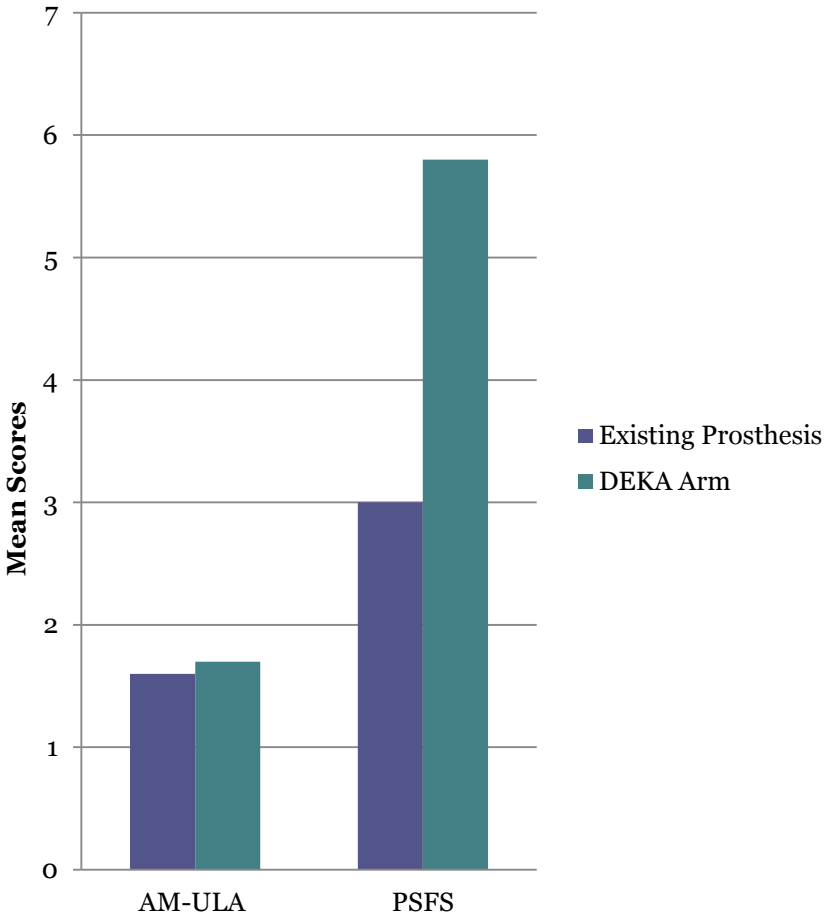
26 Prosthetic Users

- **Dexterity varied by level**
  - **RC Users**
    - Worse on 2 tests
    - Equivalent on 5 tests
  - **HC Users**
    - Worse on 1 test
    - Better on 2 tests
    - Equivalent on 4 tests
  - **SC Users**
    - Better on 1 test
    - Equivalent on 6 tests

DEKA compared to existing prostheses

26 Prosthetic Users

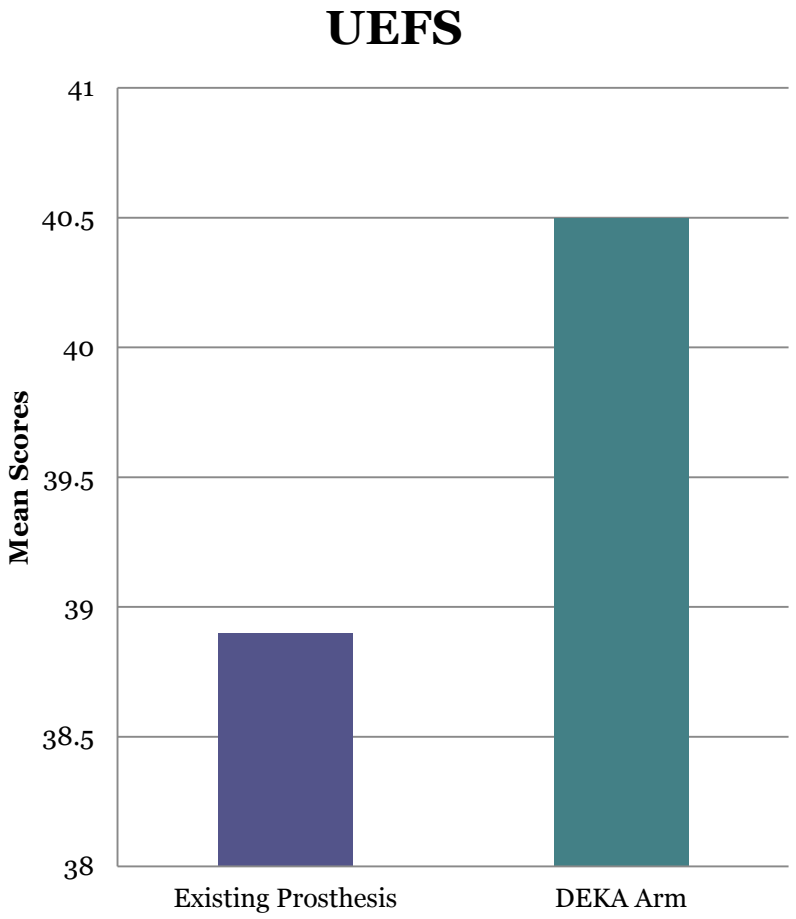
- **Activity Performance (AM-ULA)**
  - No difference
  - Varied by level
    - Better for SC users
- **Performing self-selected tasks** (PSFS)
    - Better with DEKA



DEKA compared to existing prostheses

26 Prosthetic Users

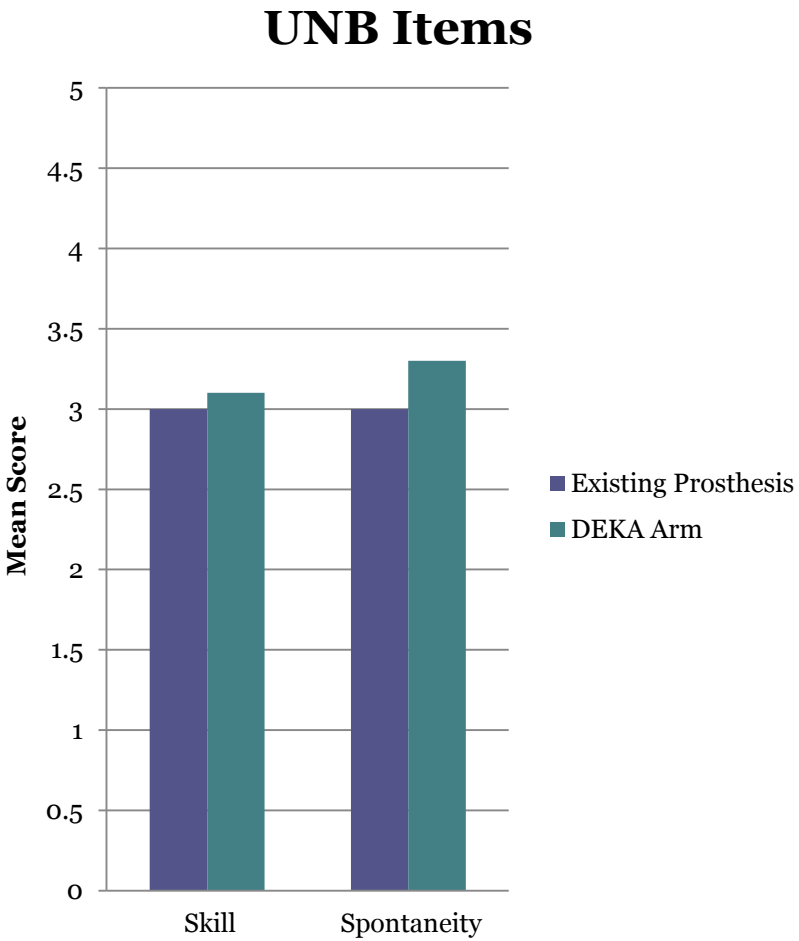
- **Self-Reported Use of prosthesis to perform activities (UEFS)**
  - Better for DEKA Arm



DEKA compared to existing prostheses

26 Prosthetic Users

- **Spontaneity and skillfulness of use (UNB)**
  - No difference
  - Varied by Level
    - Spontaneity better for SC users



Conclusion

- Final feedback on Gen 3 was generally positive, particularly regarding improvements in wrist design, visual notifications, foot controls, end-point control, and cosmesis

- Data suggests that DEKA's optimization efforts were successful.

Conclusions

- Dexterity and activity performance
  - Better for lower level amputees than upper level
- Speed of using DEKA Arm vs. other prosthesis
  - Not as fast as existing prostheses at RC level
  - Equivalent for HC
  - Maybe slightly better for SC
- Activity performance vs. other prosthesis
  - Same for RC, HC
  - Better for SC
- Self-reported activity difficulty vs. other prosthesis
  - Better with DEKA
- Spontaneity of use vs. other prosthesis
  - Better for SC

ARMY

Implications of Research

- VA data was used in DEKA's FDA application
- FDA approved DEKA Arm for marketing, May 9, 2014

- DEKA Arm **is NOT** yet available for clinical use, a commercial partner has not been announced.

Ongoing Efforts: VA Home Study

- VA currently conducting a home study of the DEKA Arm
- VA NYHHS, Tampa VA and CFI are study sites.

Home Study Objectives

1. Identify and describe upper limb amputees who would be appropriate candidates for home use as well as those who would not be appropriate
2. Compare the extent of use of the existing prosthesis to that of the DEKA Arm
3. Quantify the impact of home use of the DEKA arm on device satisfaction, performance of functional activities and QOL
4. Quantify the amount and type of technical support and repairs needed during the study, and estimate the number of home study days lost due to service/repair

Take Home Study Design

- Part A: In-clinic supervised training (1-3 months)
- Part B: Take-home trial (13 weeks)
  - Biweekly check-ups

Part A: Training Overview

- Screening
- Neuropsychological testing
- Baseline testing and retesting with current device
- 2 weeks of device use monitoring (current device)
- Prosthetic fitting and set-up
- Supervised training
- Testing with the DEKA Arm
- Advanced training: community outings
- Final Testing
- Determination of Home Study Appropriateness

Part A Training

- Training amount determined by therapist
  - 5 sessions minimum
  - Maximum allowable number of training visits:
    - 20 (40 hours of training) for TR/TH users
    - 25 visits (50 hours of training) for SD users

- A minimum of 3 community outings

Part A: Required Community Outings

Eating a meal in public

Riding in a car (as a passenger) or riding on public transportation

Shopping -selecting, carrying purchases and paying for items

Part A: Advanced Training

- Home use preparedness
  - Review of safety
  - Review of troubleshooting
  - Battery care and charging
  - Storing the arm
  - Packing the arm for shipment

- Demonstration of independence
  - Subject performs 10 minutes of complex activity without ANY cueing (except as needed for safety)
    - Goal is to have the subject demonstrate ability to problem solve

PART B ACTIVITIES	WEEKS												
	Home Visit	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Home Visit	■												
Take Home Diary		■	■	■	■	■	■	■	■	■	■	■	■
Weekly Phone Call or Visit (non-visit weeks)		■		■		■		■		■		■	
On-Site or by Video			■				■				■		■
On-Site Visits					■				■				■
SELF-REPORT MEASURES			■		■		■		■		■		■
PERFORMANCE MEASURES					■				■				■
Video Logs					■				■				■
Surveys					■				■				■
Semi-guided Interview													■

Enrollment: Home Studies

	Screened	Completed
Home study		
Part A (in-lab)	41	21
Part B (12 weeks at home)		9

Future Plans for Arms Used in Take-Home Study

- VA purchased 22 arms in various configurations (RC, HC, & SC) to ensure adequate stock to complete take-home study
- These are research arms that can't be given to patients (as per FDA)
- Some may be used in other VA research studies
- At the conclusion of study, these arms will be used for pre-testing, training (for patients & trainers/therapists), fitting, and demonstration purposes in VA clinics

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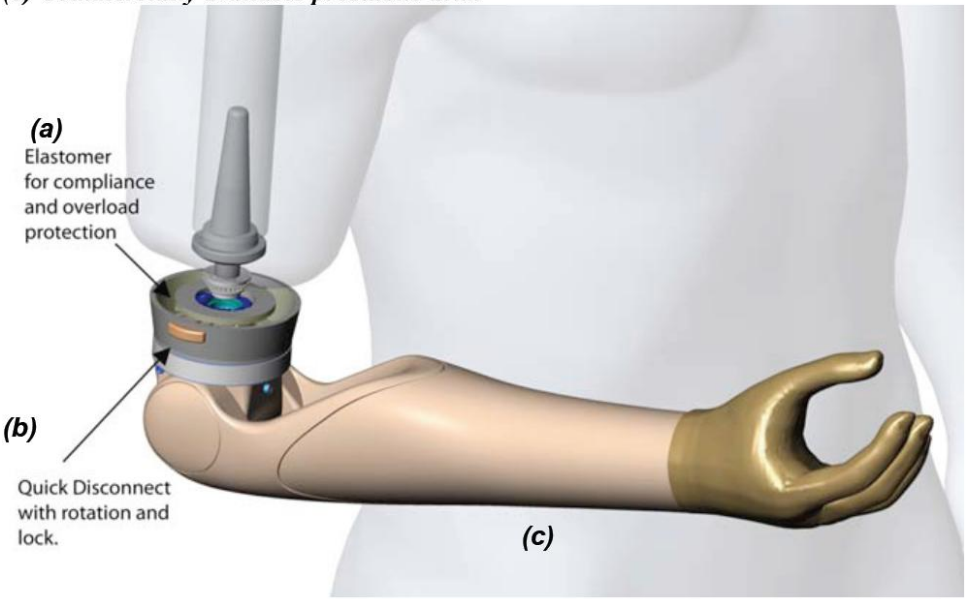
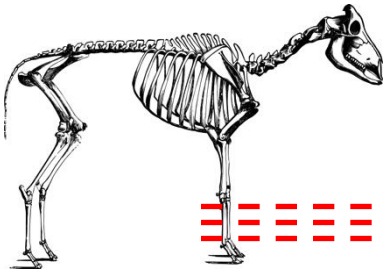
Percutaneous Osseointegrated Docking System for Above Elbow Amputees (PI- Kent Bachus, PhD)

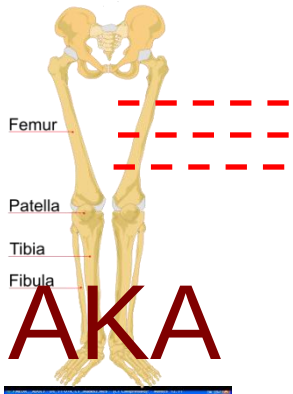
- Starting safety study of transfemoral OI implant
- Applying same methods to transhumeral implant
  - Statistical shape modeling from cadaver CT data
  - Implant design
  - Virtual implantation & evaluation
  - Human studies?

Figure 15: (a) Rendering of compliant connection for dampening of impact loading. (b) Rendering of quick disconnect with rotation and locking capabilities. (c) Commercially available prosthetic arm.

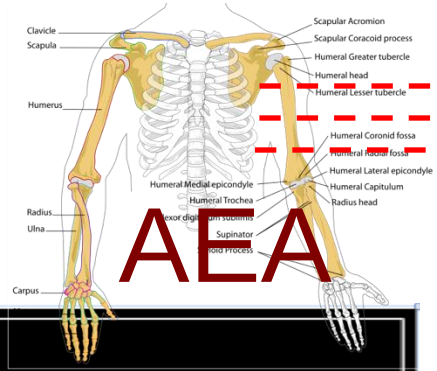




Sheep



AKA



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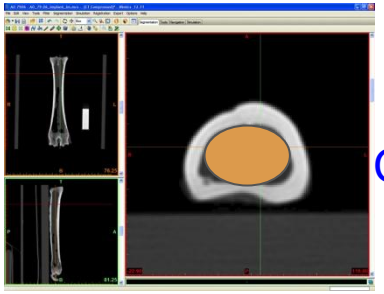
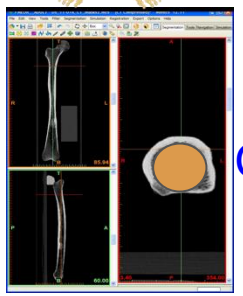
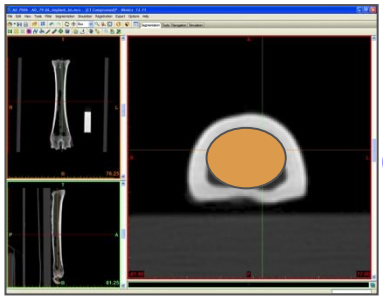


Oval



Circular

Oval With Rotation



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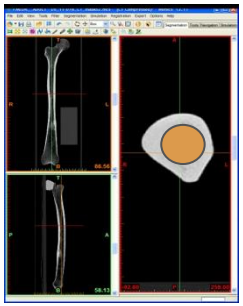

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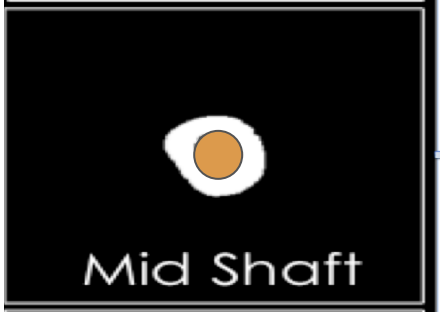

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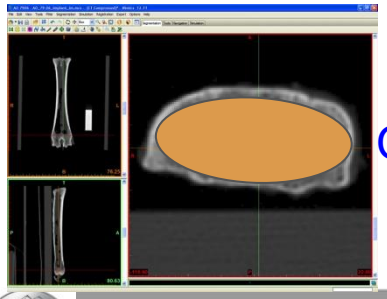
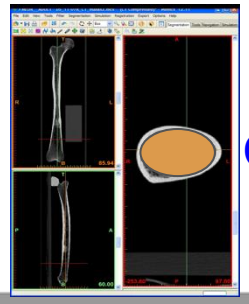


Oval



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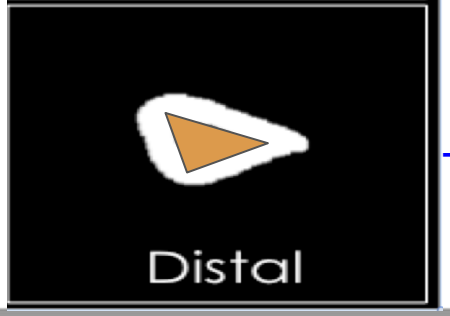
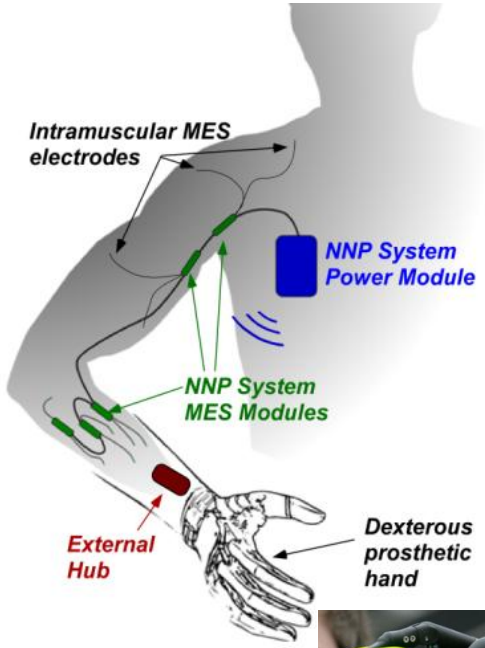


Triangular

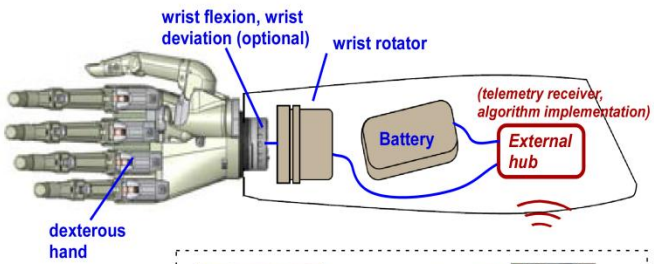
Implanted MES system and multi-DOF simultaneous prosthesis control

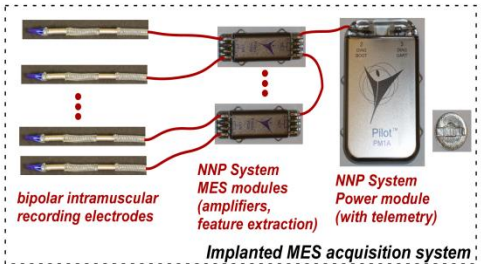
Robert F. Kirsch, Ph.D.
Center of Excellence on Functional Electrical Stimulation
Louis Stokes Cleveland VA Medical Center

Concept

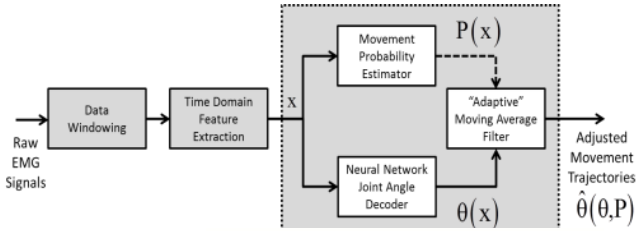


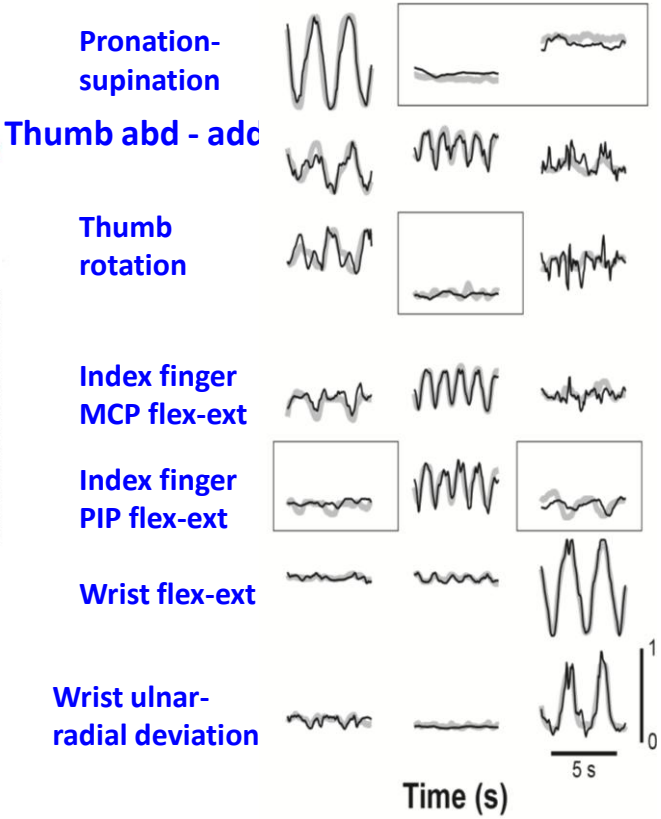
Implementation



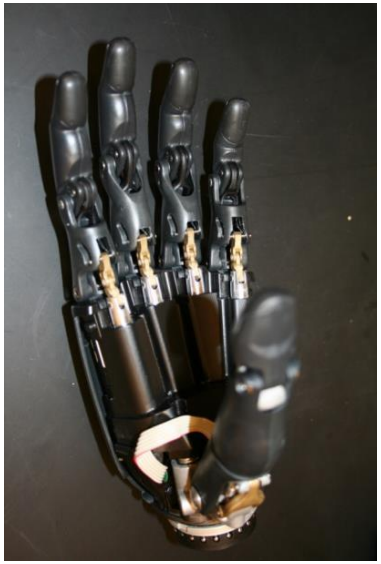


Multi-DOF algorithm



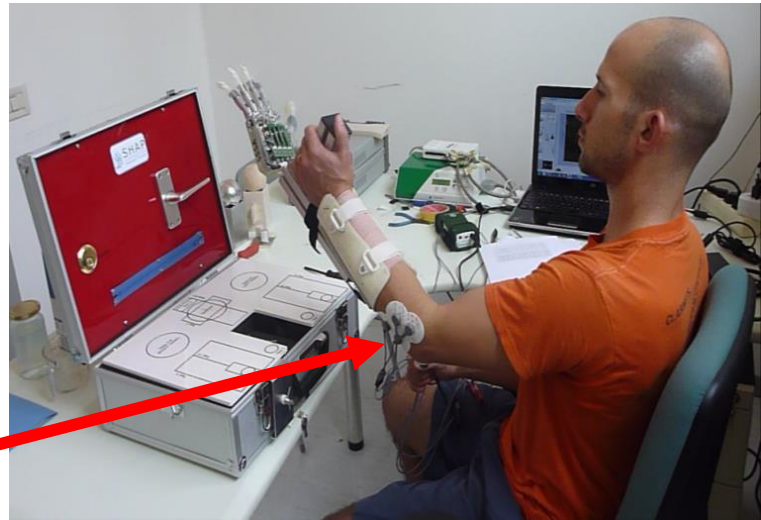


A Postural Control Paradigm for EMG Control of Advanced Prosthetic Hands (PI- Richard Weir, PhD)

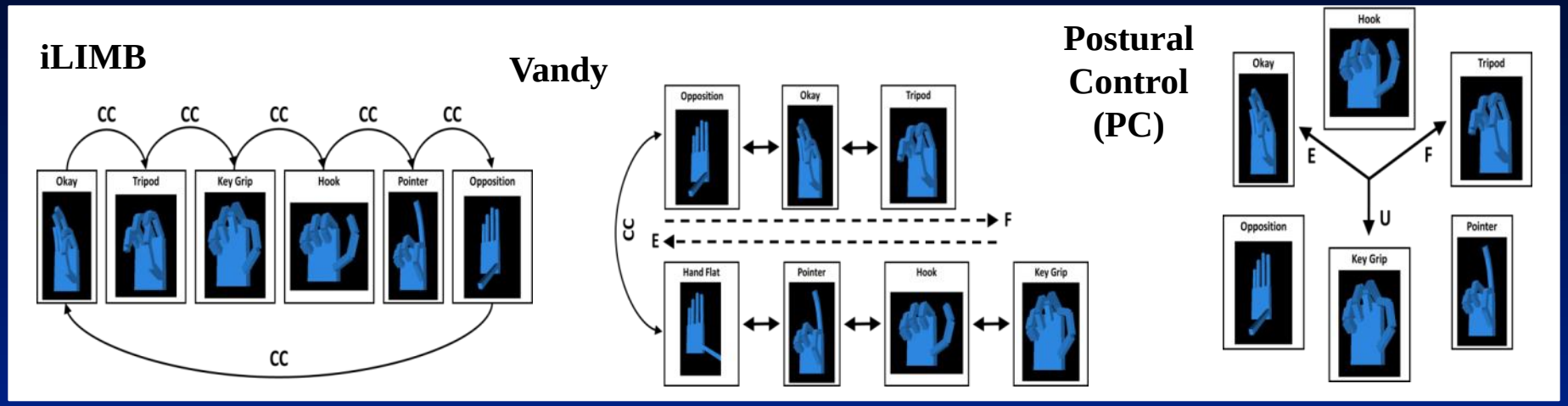


- Modified Bebionic hand to add thumb ab/adduction
- Comparing 2 exiting myoelectric controllers (iLimb & Vanderbilt state machines) to new postural controller
- 7 able-bodied subjects using hand on splint
- 2 experimental sessions
  - SHAP test
    26 activities of daily living
  - Virtual hand matching task
    Match 7 functional grasps

3-site EMG surface electrodes



Myoelectric Controllers Tested



-Wrist Flexion (F) -Wrist Extension (E) -Ulnar Deviation (U) -Co-contraction (CC)

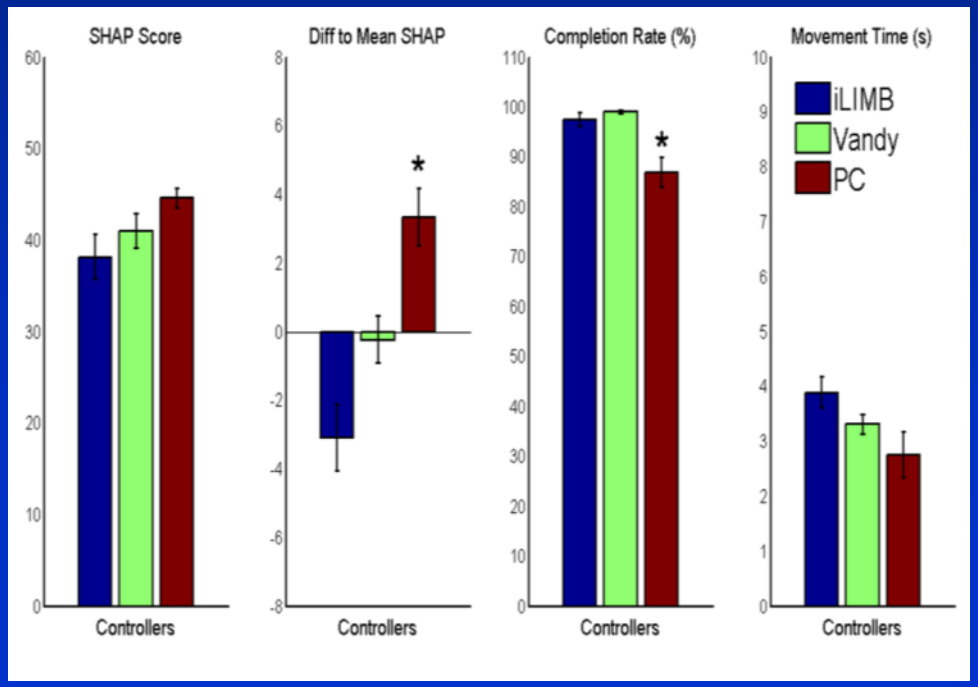
Results

SHAP Test (26 ADLs):

- PC has greatest SHAP score
- Diff to Mean (normalized) SHAP score is significantly greater for PC

Virtual Hand Matching Test:

- Completion rate for PC significantly lower
- PC tends to have lowest movement time



Thank-you

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