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14. ABSTRACT
The purpose of this research is to develop and clinically validate a novel tactile sensing technology and control algorithm to improve grasping performance in amputee users of myoelectic prosthetic hands. The planned scope of research for this reporting period was to: 1) evaluate and finalize the sensor to be used in a prosthetic hand, 2) validate, finalize, and miniaturize the controller to be used in these prosthetic hands, 3) conduct outcome measure studies and analyze findings, and 4) design and submit to IRB for a clinical study to assess the functional use of the prosthetic hand. Major findings during this reporting period include 1) the modification and selection of the prosthetic hand sensor, 2) verification and miniaturization of the controller board, 3) the successful completion of outcome measure studies to evaluate visual and cognitive distraction while grasping, and 4) the design and submission to IRB of a clinical study to use the previously verified outcome measure, and other measures for functional assessment of the developed prosthetic hand.

15. SUBJECT TERMS
tactile sensing, prosthetic hands, grasping, reflexes, clinical study, distraction measures, electronics board, functional validation

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1. INTRODUCTION:

The purpose of this research is to equip a myoelectric prosthetic hand with contact detecting sensors and a custom controller that enables a biomimetic reflex to improve the speed and ability to perform fragile grasping tasks for amputees. This hand would reduce the variability in grasping performance with delicate object thereby reducing the cognitive load associated with these difficult tasks. The battery life of the prosthesis would be conserved by applying appropriately low forces when needed without an effect on the maximum force and performance capabilities of the hand. In this research, the outlined technology will be developed and assembled including customized sensors, firmware, and a controller board. Clinical studies will be performed in order to first, develop baseline outcome measures of fragile grasping and second, to test the product in the field with myoelectric prosthesis users to ensure that user-benefit objectives have been met.

2. KEYWORDS:

Myoelectric Prosthesis, Outcome Measure, Volunteer Study, Fragile Grasp, Cognitive Load, Low Force, Sensors, Firmware, Controller, Amputee

3. ACCOMPLISHMENTS:

Summary of work done this reporting period:

Specific Aim 1: Design and build a compliant and sensitive tactile sensor that meets the identified commercial requirements and specifications - COMPLETED

Major Task 1.1 Design and fabricate NumaTac prototypes - COMPLETED

- Order PCBs and components and assemble 25 electronics prototypes (2-4 mos.) 100%
- Assemble first batch of NumaTac prototypes (6 mos.) 100%

Major Task 1.2 Verify commercial requirements and performance specifications and select final design - COMPLETED

- Design reviews and evaluations (as needed) (7-8 mos.) 100% (ongoing)
- Select the candidate foam material and process that meets commercial requirements that has best performance in sensitivity and compliance (9 mos.) 100%

Specific Aim 2. Design, build, and test prosthetic hand system to be used in BP clinical studies

Major Task 2.1 Build, assemble, and test prosthetic hand with NumaTac sensors and controller

- Design/order/build electronics boards and electrical wiring (8-10 mos.) 100%
- Manufacture two NumaTac sensors for medium-sized VariPlus Speed fingertips (10-11 mos.) 100%
- Program controller to perform contact detection reflex (11-13 mos.) 100%

- Program controller to perform software functions for clinical studies (12-13 mos.) 100%
- Evaluate software functions for clinical studies in bench testing (13-15 mos.) 100% (ongoing with software updates)
- Evaluate performance in fragile grasping in bench testing (13-15 mos.) 100%
- Evaluate software functions for clinical studies in bench testing (13-14 mos.) 80% (ongoing with software updates)
- Debug software (as needed) (11-16 mos.) 90% (ongoing with software updates)
- Manufacture prostheses for each subject in clinical studies (as needed) (24-36 mos.) 5%
- Design reviews and evaluations (as needed) (9-48 mos.) 40%
- Provide technical support (as needed) (16-48 mos.) 50%

Specific Aim 3. Design and validate novel outcome measures for evaluating BP fragile grasping and cognitive load - COMPLETED

Major Task 3.1 Develop protocol for evaluating grasping and perform studies to validate these outcome measures

- Recruit 30 normal volunteers and perform studies (16-17 mos.) 100%
- Analyze all outcome measure candidates to determine their reliability between tests and retests, and between raters (17 mos.) 100%
- Select outcome measures to be used in clinical studies (18 mos.) 100%

Specific Aim 4. Conduct in-office and in-the-field clinical studies

Major Task 4.1 Finalize experimental and research protocol, prepare regulatory documents, and recruit subjects for clinical studies

- Develop final schedule and tests to be performed at each site visit (18 mos.) 100%
- Coordinate with sites for protocol review, CRADA submission (18 mos.) 80%
- Refine eligibility criteria, exclusion criteria, and screening protocol (18 mos.) 100%
- Finalize consent form and human subjects protocol (18 mos.) 100%
- Submit documentation for IRB review (19-21 mos.) 100%
- Submit Military 2nd level IRB review (22-24 mos.) 100%

Major Task 4.2 Conduct clinical studies

- Not yet started, awaiting IRB approval and completion of hardware

Specific Aim 5. Organize results for publication and documentation

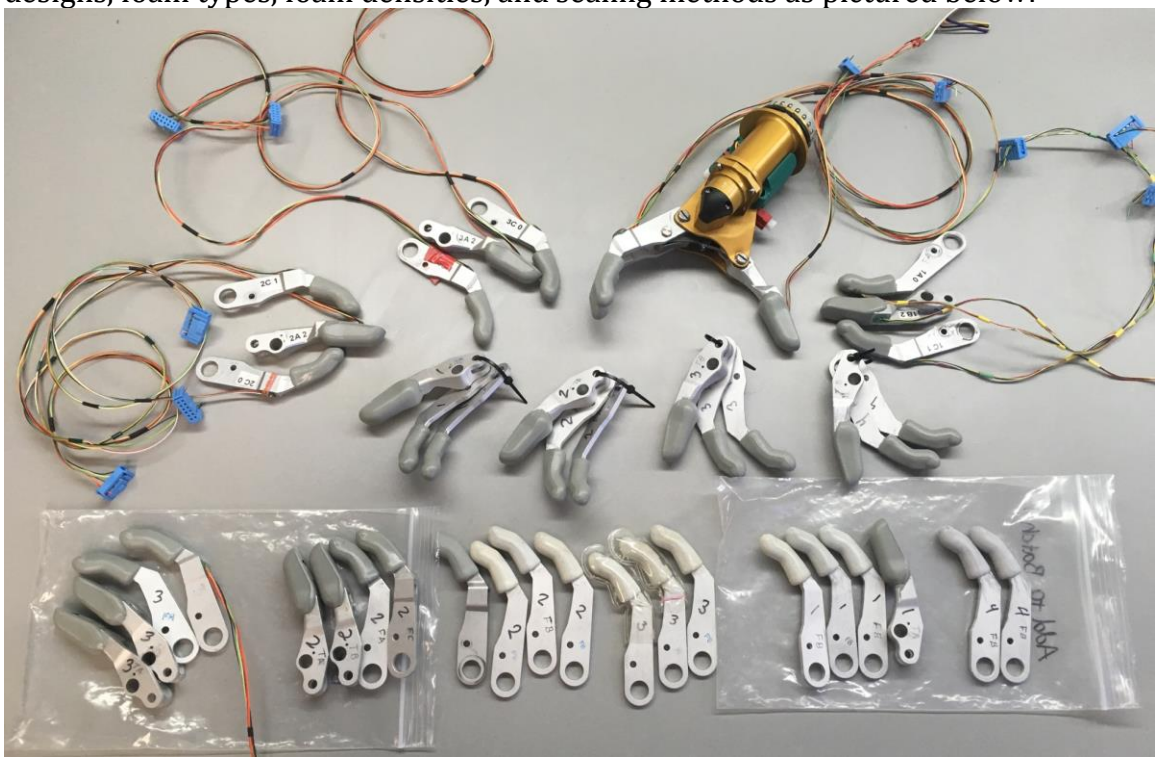
5.1 Prepare academic submissions and documentation

- Prepare academic submission on technical function (16-17 mos.) 15%
- Analyze results and prepare academic submission on novel outcome measures (24-34 mos.) 50%

What was accomplished under these goals?

Major Task 1-1: Design and fabricate NumaTac Prototypes

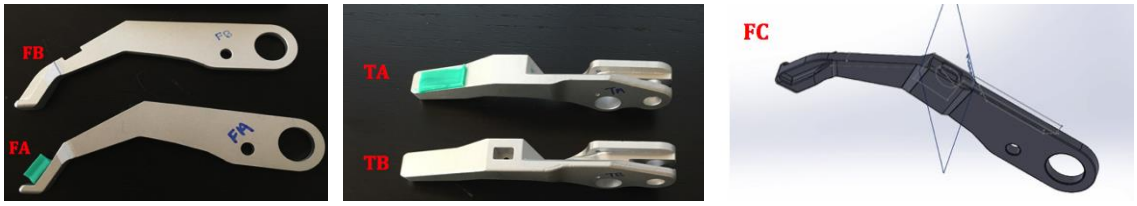
A total of 45 foam over-molded aluminum core prototypes were produced for evaluation. This included 13 different thumbs and 32 fingers of varying core designs, foam types, foam densities, and sealing methods as pictured below:



Caption: Sensor prototypes manufactured for evaluation.

The following parameters were varied through the prototype samples:

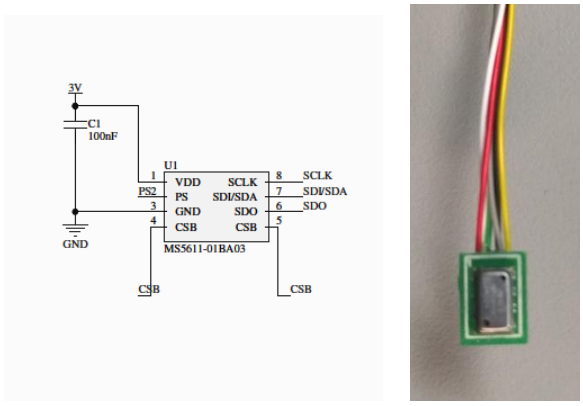
- Foam Density:
  - 1: Original polyurethane mixture (fms74100-6; ratio: 85b/15a; fingers: 1.0-1.2g, thumb: 1.4-1.6g)
  - 2: Denser polyurethane mixture (fms74100-6; ratio 80b/20a; fingers: 1.0-1.2g, thumb: 1.4-1.6g)
  - 3: New composition foam material proposed by foam molders for this application (fms7390-3 0.5; ratio 58b/42a; fingers: 1.0-1.2g, thumb: 1.4-1.6g)
  - 4: High density foam (fms310021; ratio 70b/30a; fingers: 1.0-1.2g, thumb: 1.4-1.6g)
- Sensor Positioning (see below figure):
  - TA/FA: Sensor embedded in foam
  - FB: Sensor offset from foam
  - TB/FC: sensor connected to foam through a pilot hole
- Sealing:
  - Standard polyurethane spray-coat sealing
  - Experimental sleeve sealing on uncoated sensors



Caption: Sensor positioning designs on unmolded sensors

The foam type was found to be the most significant variable to sensitivity and robustness and included a standard polyurethane density, 2x this density of the same material, a low density foam blend, and a high density foamed material. Prior to foam molding, some core designs (TA and FA) required custom manufactured silicone inserts to prevent the foam from entering the space of future sensory electronics. Molds were designed for these and manufactured at SynTouch as was the molds for these parts. After molding, these inserts were excavated from the part.

As part of the effort to get all sensory components and electronics under the prosthetic cosmesis, a smaller pressure sensing board was created to measure the pressure increase in the finger foam. The pressure sensor is soldered on one end with components on the other so that different methods can be explored for sealing the board to the finger with a clean surface. While final designs will include a flexible circuit, for prototype evaluation, flexible wires connect the board and data acquisition system used with both the cyclic load and static load testing platforms developed in year 1. During this year 2 period, these sensing boards were designed, ordered, populated tested, approved, and implemented for prototype and full hand testing. 30 have been created and soldered for testing of the prototype fingers. Some sealing methods such as those that include silicone or gaskets allowed the electronics to be removed and re-used. Completed sensors with wiring can also be seen in the picture on the previous page. The connections, layout and board can be seen below:



Caption: Pressure Sensor Electronics

During prototyping a high percentage of TA and FA sensors with the excavated silicone pieces were damaged in the excavation process and required a great deal of

repair work to get a proper seal. We were able to make a few successful prototypes with this method, but it did have noticeably poor yield although at times good sensitivity (with more variability part-to-part). The best yields were achieved with the TB and FC designs.

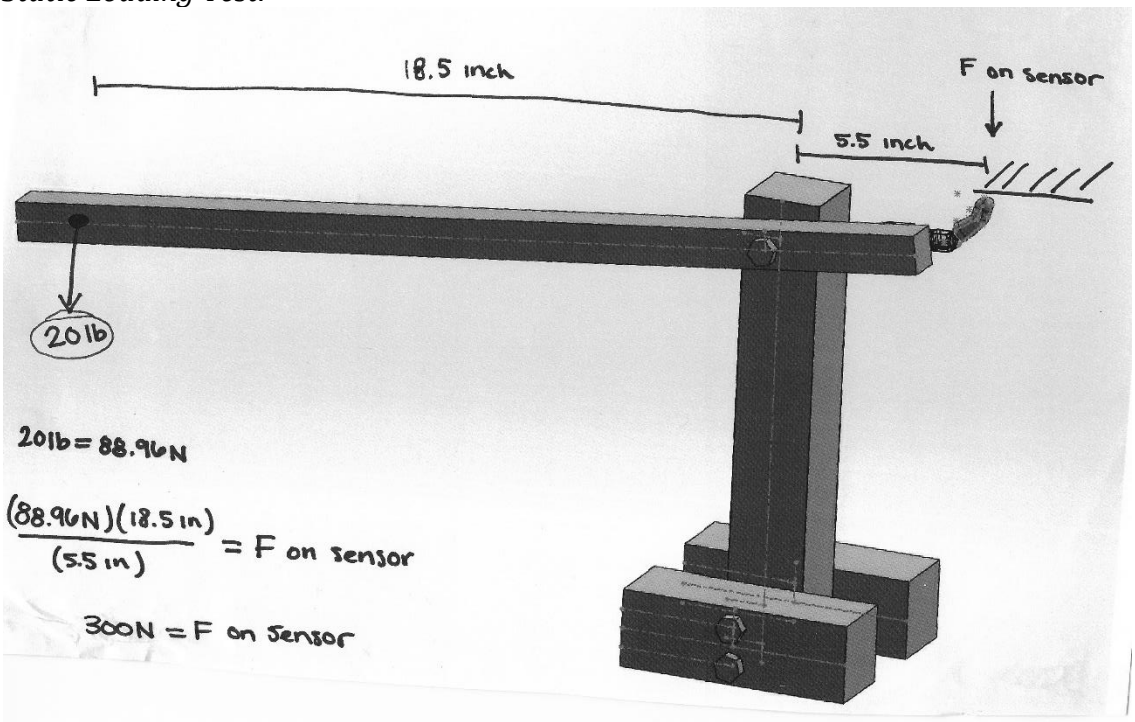
Major Task 1-2: Verify commercial requirements and performance specifications and select final design

Our commercial partner proposed the following requirements of a viable system:

- Low power consumption of less than 1mA per sensor (verified in previous reports)
- Cost of less than $50/sensor in quantities of 1,000 or more (verified in previous reports)
- Sensors able to withstand passive forces of 300N
- Sensors capable of withstanding more than 500,000 cycles of loading at 50N at 0.5s/cycle (after discussion with them, we were able to get approval at a cycle time of 3x faster)

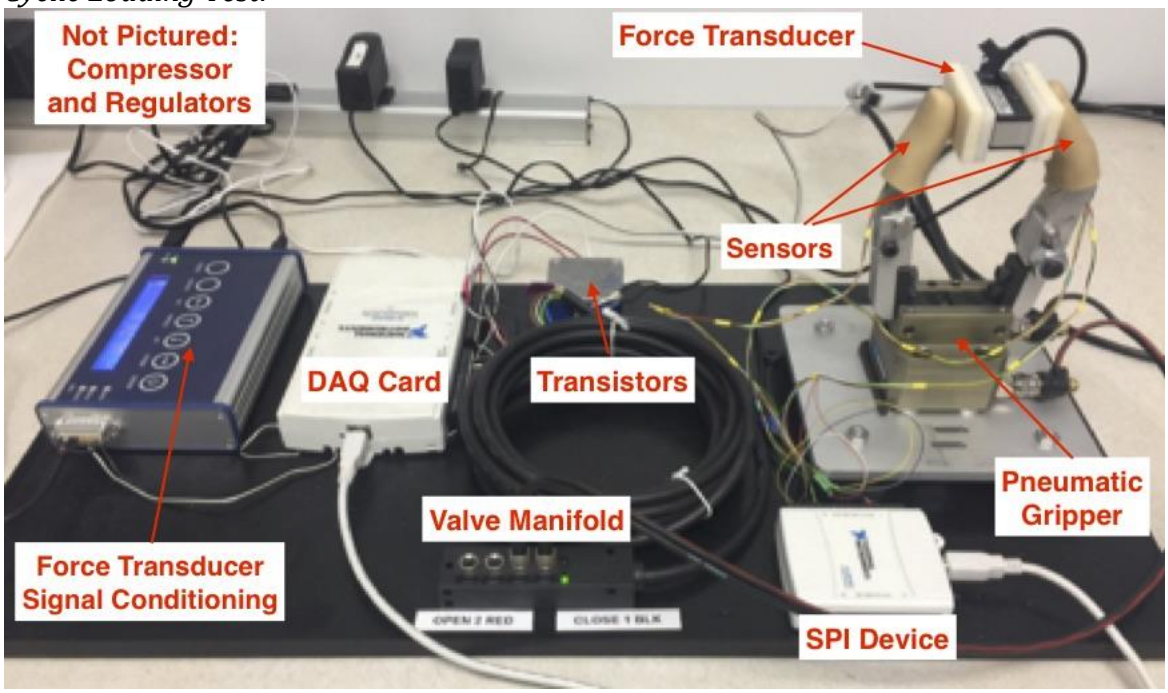
In order to test the durability of the prototype fingers two tests were developed the static loading test and the cyclic loading test and all sensors went through these testing processes

Static Loading Test:



Caption: Static loading test consisted of a lever system that would produce the required 300N of force on the individual fingers or thumbs by attaching a 20lb weight.

Cyclic Loading Test:



Caption: Cyclic loading test for fatigue

To test fatigue and wear over 500,000 cycles at 50N an instrumented testbed was designed, fabricated, and assembled incorporating a pneumatic Schunk angular gripper to apply this loading to the sensors. A pneumatic gripper was selected specifically due to the ability to handle many cycles (the lifecycle of the prosthetic hands to be used in this study is also approximately 500,000 cycles). A program in LabVIEW was designed to control the opening and closing of the hand, measure the signals from the sensors and force transducer and log the data over 500,000 cycles. Every 100 cycles a measurement was taken so performance over time could be observed and to identify any failures. To calibrate the grip force a force transducer and its signal conditioning were added to the system that provided an analog output proportional to the force that was measured by the DAQ card and processed by the software; the air pressure to the gripper could be regulated up and down until the 50N force was set. The DAQ card also provided digital signals to open and close the two valves to the pneumatic gripper. These needed to be stepped up from 5V to 24V with transistors. The data from the sensors was read by a separate SPI device.

Applying the 500,000 cycles would take approximately 24 hours and was not done consecutively as the testing was frequently paused during working hours to minimize the audible nuisance of the pneumatic valves to co-workers. The duty cycle needed to be tuned to ensure that the fingers broke lose on each cycle but the gripper did not slowly drift open. We found that a duty cycle of 65% accomplished this well.

For each of the sensors sensitivity and performance on the prosthetic system was checked before and after we applied the 300N load and subjected them to the 500,000 cycle duty testing. In instances where adequate performance could not be obtained BEFORE the durability tests, those durability tests were not performed. For instance, it was found that the experimental sleeve sealing designs on uncoated sensors (pictured below) failed to produce a reliably adequate sensitivity in any formulation with a wide range of sealing fabrics, furthermore those sensors that did work did not survive robustness testing so these methods were abandoned (which included more than half of the prototypes).

All of the foam formulations (batch 1-4) with the standard sealing method survived durability testing without significant degradation, although sensor designs FA had some failures in some of these batches. In general across all formulations the following was observed in designs:

- Finger Designs:
    - FA: Sensitive, but periodic failures in durability testing (3 of 5)
    - FC: Sensitive and no failures
- Thumbs
    - TA: Most sensitive, no failures
    - TB: Least sensitive, no failures

From this we concluded that the optimal designs were FC and TB.

Evaluation of foam performance indicated that while all formulations survived testing, Batch 2 had the best performance before and after testing (discussed in more detail below on whole system development and testing).

Final conclusions are to proceed with product of fingers FC and TB with batch 2 foam formulation for clinical studies.

<u>Major Task 2-1: Build, assemble, and test prosthetic hand with NumaTac sensors and controller</u>

Electronics and Firmware Development

We have completed the development electronics and firmware and have validated that the following capabilities per our design specification have been met:

- When initially powered on (connected to battery), SynTouch Controller sends initialization sequence to put the Prosthetic Hand's Motor Controller into serial communication mode to support high-speed reflex control mode.
- When system is idle (no EMG activity) SynTouch controller puts prosthetic controller to sleep to conserve power, upon EMG activity resuming SynTouch controller re-initializes prosthetic controller.

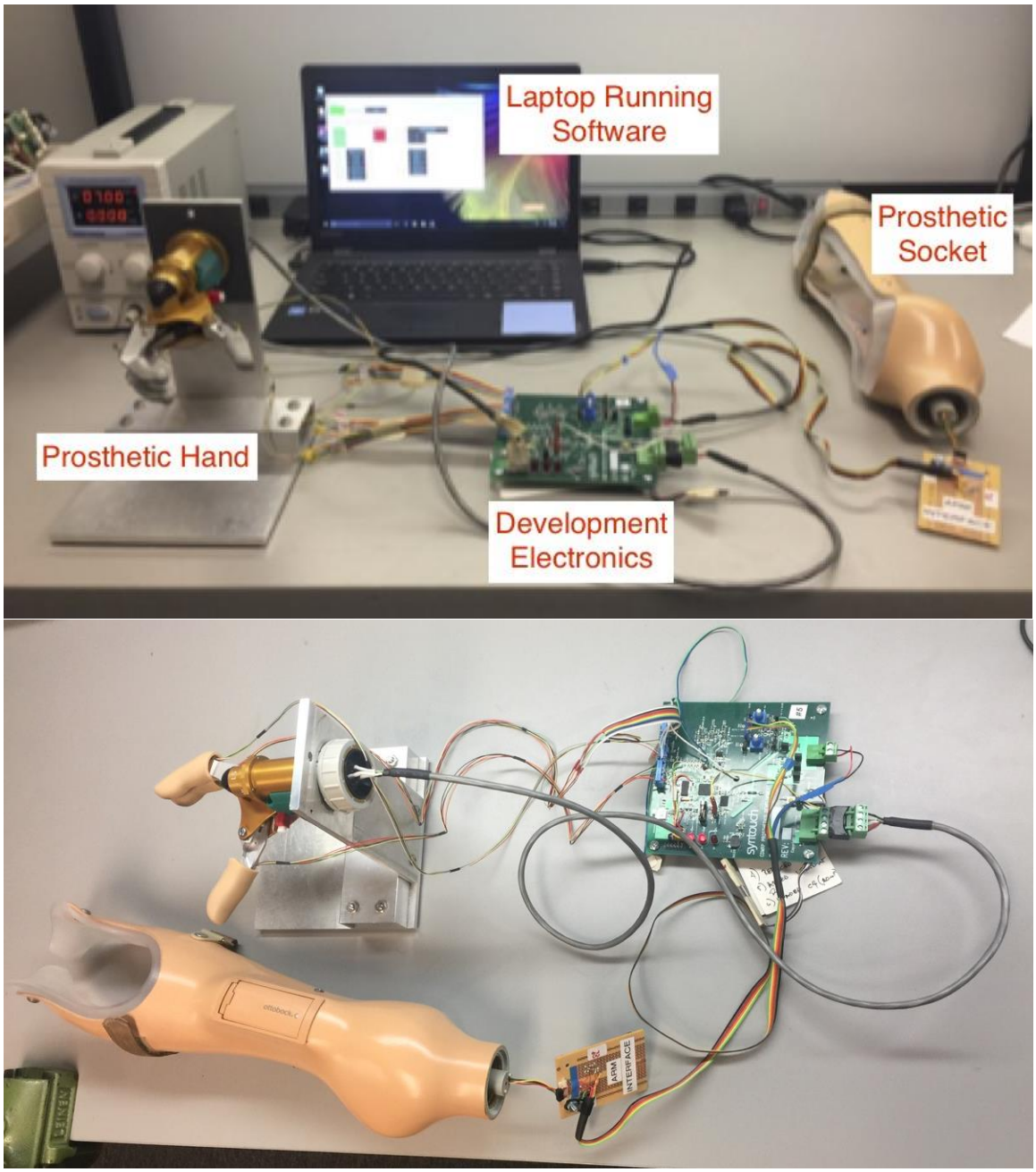
- Collect data from the three pressure sensors using the SPI communication protocol for the sensor.
- Analyze pressure sensor data and determine when values have crossed a programmable threshold value.
- Read 2 EMG inputs (EMG_open and EMG_close) from electrodes (analog 0-5V).
- Filter EMG inputs in firmware (coefficients as a hardcoded parameter)
- Calculate the proper motor control signal based on EMG inputs, pressure sensor data and mapping parameters from functions defined by SynTouch engineers.
- Output motor control signals to Motor Controller via serial communication using Ottobock's serial protocol.
- Keep a running clock (10ms precision or better) with ability to write a timestamp to memory.
- Microcontroller should reset when the hand is power cycled or on timeout/crash. This is typically done when the hand is physically disconnected and reconnected to the socket.
- Record the following analytic/diagnostic information in non-volatile memory. Memory should not become corrupted in the event of power loss.
    - Timestamp when hand is powered on and off (i.e. connected or disconnected to battery) (OK if power off not saved every time)
    - Timestamp when a close (EMG_close > programmable threshold) occurs
    - Timestamp when contact signals occur in opposing fingers during one close ("grasp")
    - Timestamp when a close finishes (EMG_close falls back below threshold)
    - Timestamp when an open (EMG_open > programmable threshold) occurs
    - Peak close signal (EMG_close) after each grasp (between "grasp" and close finished)
    - Integer count of number of contacts (pressure > threshold) on each of the three Pressure sensors
    - Power consumption during "closes" (while EMG_close is above threshold)
- Controller shall be able to communicate with outside world using near-field-communication (NFC) or similar wireless communication (i.e Bluetooth). Wireless communication should be able to make controller execute diagnostic and/or other subroutines, including the ability to read/write parameters used in the normal controller function. Wireless communication shall also be simple to implement on the computer side with pre-existing software/drivers/etc. and basic UART communication.
- If enabled in microcontroller via a wireless communication command, record the next 30 seconds of EMG and pressure data in volatile memory. This data

from shall then be accessible via wireless communication serial protocol as described below.

- If enabled via a parameter setting, control 3 LEDs that reflect whether the sensors are in contact. The LEDs will be labeled as NT1, NT2, NT3.
- Easily change the programmable threshold parameters for pressure sensor contact and for EMG closing/opening voltages and other parameters via wireless communication that supports simple serial communication.
- Easily change the parameters of the transformation from input EMG signals to motor signal out via wireless communication (Bluetooth).
- Every two months, allow clinician to easily retrieve data and reset analytic/diagnostic information via wireless communication that supports simple serial communication. Controller should support up to 6 months of data logging under typical usage patterns .
- Housekeeping function to safely finish saving data OR to safely cancel saving data without corrupting anything, if battery drops out / hand is unplugged – whichever is simpler to implement, i.e. there is no preference on whether data being acquired during power drop is saved or not, but it is essential that a power drop does not corrupt data. Must be able to save timestamp of when power is disconnected however.
- Incorporate a reed switch that can be used with a magnet to switch the controller into wireless communication mode.
- Implement: Use wireless communication to update firmware on microcontroller with a bootloader if possible and simple to implement.
- Power Consumption while Idle – While the controller is idle (EMG_Close and EMG_Open both below threshold), its power consumption should be less than 2mA on average. Typical usage in this mode – sample EMG_Close, EMG_Open, and Hall Sensor with 25Hz frequency. Less than 2mA is required, less than 0.5mA is desired if simple to implement.

The above functions were derived from a 29 page design document that has been refined over the entire project period to enable effective assembly and quality control of the hands, configuration in the clinical settings, and to collect diagnostic data in the long-term take home studies with the hands. Initial developments of firmware and electronics were done in a larger development system. Now that all functions have been verified, the miniaturization of the final electronics have started.

A picture of the developed electronics development board, firmware and software is shown below:



Caption: Full development system running

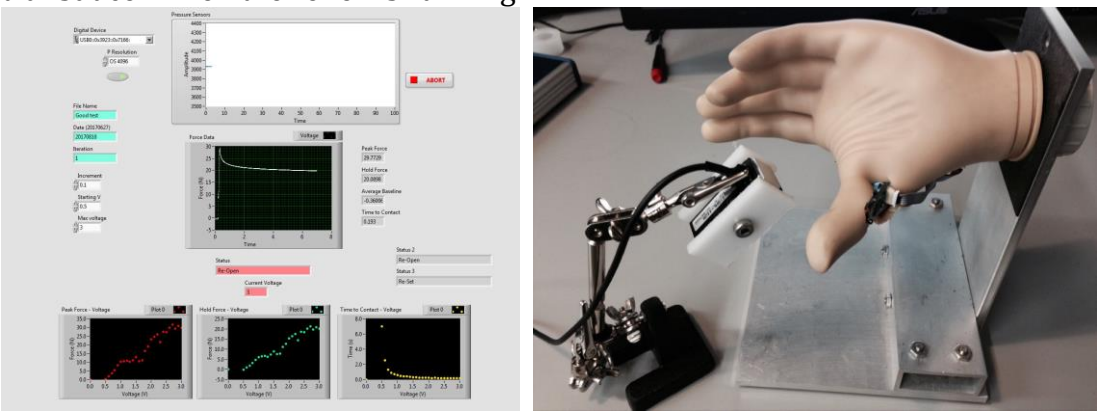
We are awaiting the layout and manufacturing of a miniaturized board that allows fit within the existing OttoBock controller housing space. Preliminary investigation has determined this is feasible.

Software and performance testing has verified all data logging features and the wireless data communication has been fine-tuned. Testing will continue and likely be modified when the miniaturized board, hand, and final prosthetic fingers are installed together. Additional customizations may be made on a case-by-case basis when hands are manufactured for clinical study participants.

The large scale development board has been installed and verified with the full hand, new fingers, pressure sensors, software and firmware. The system can be seen here:

System Evaluation

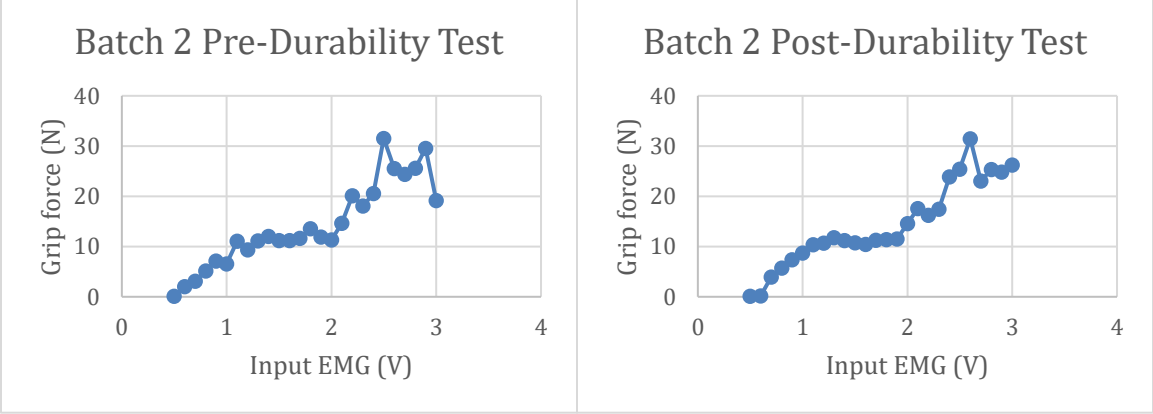
A LabVIEW program was made to apply varying grip forces to produce hand movements (fragile and firm) to test function and clinical study data collection (similar to previous work of Matulevich et. al. 2013 & 2014). This program applies different levels of closing EMG values and measures the grasping force with a force transducer when the reflex is running.



Caption: Left: LabVIEW program that measures activity. Right: Test system with cosmesis and sensors and force plate.

In this program, peak and residual forces are measured as a function of EMG closing value. The reflex was configured to completely stop on contact (as opposed to traditional operation where the reflex is configured to reduce commands on contact) to effectively determine the peak performance. Due to inertia and communication delays the contact force can never be zero, so these characterizations demonstrate optimal performance.

An example of this performance for Batch 2 foam before and after durability testing is shown below:



Caption: Sensitivity performance of final sensors selected for production

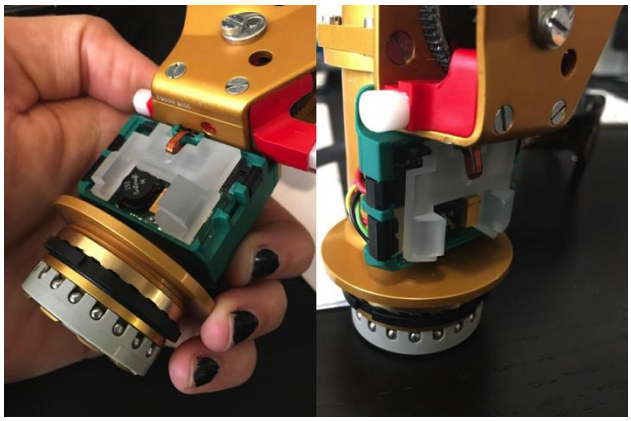
As can be seen at very slow closing speeds (0.5-1V Input EMG) there is a nice linear progression from 0-10N of closing force, this corresponds to light effort. In the medium ranges of 1-2V Input EMG, peak sensitivity levels around 10N and then increases up to 30N at maximum EMG inputs. At low closing speeds the sensitivity of the sensors dominate the peak grip force, at medium speeds the combined increased sensitivity at higher impacts counteracts the faster closing hand to have this stable region and at higher closing speeds the inertia of the hand and latencies of control signals begin to dominate (however the compliance and sensitivity of the sensor help mitigate this). Alternative foam formulations saw peak closing forces closer to 40-50N, so batch 2, as previously stated was determined to be optimal.

The performance seen here is similar to previous work on fragile grasping (in fact slightly better) so we are optimistic of the progress in also being able to identify a design and formulation to meet the robustness and cost requirements of this technology.

Final Integration Design (Electronics)

Next steps will be to miniaturize the electronics into the cosmesis and this activity will take place over the next 3-6 months.

In early design reviews it was determined that the best approach was to use the standard OttoBock hand controller (referred to as “prosthetic controller”) with a custom made electronics interface board (referred to as “SynTouch controller” or just “controller”) to implement the reflex performance and log data for clinical studies. Attempts were made to fit the SynTouch controller in the same housing of the prosthetic controller (pictured below). A Solid Works model of the available internal space was created and a 3D printed part was created to confirm the availiable space. The physical prototype of this internal space (off-white), situated in the final location is seen here:

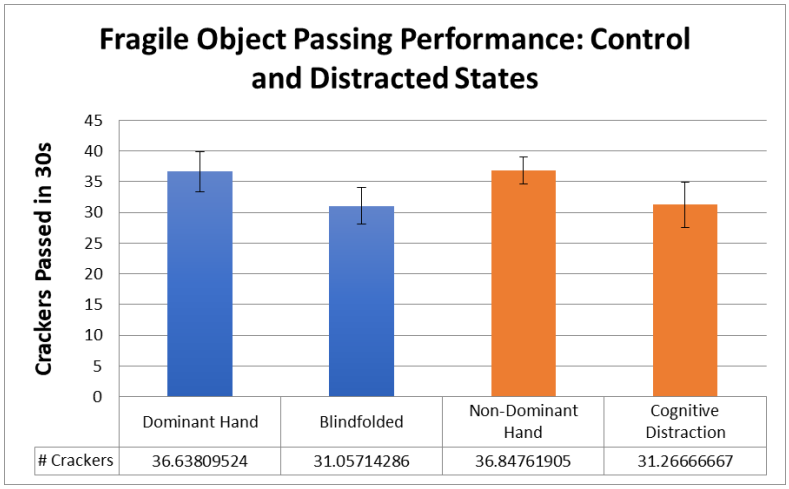


In addition to the modeled space, R&D efforts have been made to design flexible leads to connect the prosthetic fingers and our miniaturized controller board. These flexible leads will be designed to integrate with the existing Otto Bock hand, movements, and capabilities through thickness, material, geometry, slack loops, and trace order, with the existing Otto Bock design and capabilities. Prototyping efforts have been made and the method and location of connection on the controller board has been determined and documented.

Major Task 3-1: Develop protocol for evaluating grasping and perform studies to validate these outcome measures

30 able-bodied volunteers were recruited to perform the IRB-approved study to validate novel developed outcome measures of visual and cognitive distraction. This study evaluated the number of crackers that could be passed from one location to the other with and without visual distraction (passing objects behind a curtain) and with and without cognitive distraction (passing objects while recalling a story). 21 subjects completed the full study and 9 subjects completed a sub-study that compared the difference between bimanual and unimanual passing without distraction. In the sub-study we validated that subjects were able to complete the task faster with two hands instead of one (substantiating the rationale that this task is best performed bimanually).

In the main study, data analysis was completed to determine candidate reliability and performance between test and retests using a two-way ANOVA with repeated measures test as well as Tukey's multiple comparisons test. It was found that our methods for visual and cognitive distractions significantly affected speed and distracted participants whether starting with their dominant or non-dominant hand (see graph below). For the subgroup, we found that bimanual passing was significantly faster than unimanual passing with either the dominant or non-dominant hand and therefore can reasonably assume that in a speed testing scenario, an individual would normally choose a bimanual method (now implemented in the clinical study protocol).



Caption: Final results of outcome measure studies

These results have informed our protocol decisions and validated our outcome measures. We have selected to use the following procedure to compare fragile grasping prosthetic hand use in our future clinical study.

Participants will receive a fragile cracker with their dominant hand, pass to their non-dominant prosthetic had, and transfer it to a cup as fast as possible without breaking any. The number of successful cracker transfers in 30 seconds will be recorded. This will be done under three conditions: while passing behind a visual barrier, while cognitively distracted and continuously talking, and with no distractions. Performance under these three conditions will be recorded while using their personal prosthetic hand, our modified sensorized hand, and again with our sensorized hand with the contact detecting reflex disabled. If performance is statistically better using one hand over another, it can be determined that the functionality and ease of use of that hand for fragile grasping tasks is superior to the other hands.

These results are currently being prepared for academic submission.

<u>Major Task 4-1: Finalize experimental and research protocol, prepare regulatory documents, and recruit subjects for clinical studies</u>

A final study protocol, schedule, eligibility criteria, exclusion criteria, and screening protocol were created and agreed upon by the clinical investigator, principal investigator, and study manager. All materials associated with the study were drafted and finalized including consent forms, entry and exit questionnaires, prosthetic hand ordering forms for the study duration, an electronic safety letter, and a recruitment document and flyer. A full board IRB submission was drafted and submitted to the Heartland IRB. The IRB was approved with no modification requests. The 2nd level Military IRB documents were drafted and the study has been submitted for 2nd level military review and we are awaiting approval. The full IRB

clinical study submission, including all supplementary documents, is submitted as an appendix (Appendix A) and followed by the letter of approval by Heartland IRB (Appendix B).

Gary Berke has been in correspondence with the VA in order to draft an approach to study recruitment and expected participant populations. After discussions, it was decided to begin recruitment from Berke Prosthetics and the general population following IRB approval, and if additional numbers are required, we will re-visit our relationship with the Palo Alto VA and attain approval for the added recruitment method from the Heartland IRB. This approach was decided upon in order to simplify the study approval process and verify recruitment numbers and collaborative needs prior to VA involvement.

Major Task 4-2: Conduct clinical studies

Not yet started, awaiting 2nd level military IRB approval.

Major Task 5-1: Prepare academic submissions and documentation

Data and figures from the concluded outcome measure study were reported and presented at ISPO (International Society for Prosthetics and Orthotics) World Congress 2017 in Cape Town, South Africa by our clinical investigator, Gary Berke.

An academic journal article is being drafted to document the outcome measure study and findings.

4) Other Accomplishments

What opportunities for training and professional development has the project provided?

- Nothing to report – the project was not intended to provide training and professional development apart from topic related conference attendance.

How were the results disseminated to communities of interest?

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

Nothing to Report

IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

- The principal discipline of this project is related to the development of more advanced and useful prosthetic hands, improved contact detecting sensors, and outcome measures for the comparison of prosthetic hand utility. With this project,

final findings on the effects of visual and cognitive distractions have been presented to the public at the ISPO World Congress in South Africa.

- Distraction methods have been shown to affect fragile grasping performance in able-bodied individuals. We are therefore able to compare grasping performance of prosthesis users to able-bodied individuals in order to show how different types of prosthetic hands enable fragile grasping performance compared to the biological human hand. This comparison can be made without distracting stimuli and with visual or cognitive distractions in order to demonstrate the visual or cognitive focus someone may need to operate a particular type of prosthetic hand. This will be applied as a new measure to determine how useful a particular prosthetic hand is in a more comprehensive way by comparing how much attention is needed to operate the hand.
- In addition to the aforementioned outcome measure development, this study is developing a smart prosthetic hand that includes contact detecting sensors in the fingers to improve fragile grasping abilities. It is anticipated and shown in preliminary studies that this prosthetic hand improves fragile grasping abilities for amputees and decreases the need for visual and cognitive attention compared to a standard prosthetic hand without sensors. It does not affect the ability to apply maximum force grasps. It is anticipated that this technology will improve the standard of prosthetic hands.

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

It is likely that the integration of sensing technology in prosthetic hands will prove effective enough that existing prosthetic hand companies will integrate the technology into their products. Additionally, it is anticipated that if the distraction method outcome measures are fully proven, they will be adopted as a new standard for the analysis of prosthetic hand utility by associated groups such as hand manufacturers, researchers, and prosthetists.

What was the impact on society beyond science and technology?

It is anticipated that the prosthetic hand technology that is being developed in this study will improve the fragile grasping abilities of upper limb amputees. They will be able to perform a wide variety of tasks that are otherwise very difficult. They will be able to perform these tasks with relatively low visual and cognitive focus, similarly to able-bodied individuals. This technology is anticipated to enable amputees and improve their confidence using their prosthetic hand.

CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them

There has been an unanticipated delay throughout the study in the manufacturing of the integrated prosthetic hand. The component parts of the hand have needed to be designed and updated in parallel, and as such, progress is made in each area (sensors, flex leads, electronics, software, firmware, redesigns) however finishing one step before the others, as outlined in the original statement of work, is not likely. Additionally, the manufacturing of integrated prosthetic hands for use during clinical studies could not be done before the study was submitted, approved, and participants were recruited. This is because each hand is sized and custom made for the volunteers.

The final creation of the miniaturized controller board is slightly delayed. This is because modifications are being made to the large scale controller board, software, and firmware. It is easier and much more economically strategic to change a modifiable system prior to the creation of a miniature version. All testing and software/firmware updates are being made to the large scale system connected to the hand and computer. When this setup is finalized and functionality is verified for use during clinical studies, the miniaturization process will be a quick step because miniature components have already been chosen and a layout created to ensure proper fit in the wrist compartment.

The above has caused modest delays, but we feel that total project schedule will not be inhibited.

Changes that had a significant impact on expenditures

We chose to assemble and manufacture the prosthetic hands to be used in clinical studies following the recruitment of a volunteer. This will minimize the expenditures by purchasing components and creating hands that are customized for each volunteer rather than having products on the shelf that may or may not be used by the completion of the study.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report.

Significant changes in use or care of human subjects

Nothing to Report.

Significant changes in use or care of vertebrate animals.

Nothing to Report.

Significant changes in use of biohazards and/or select agents

Nothing to Report.

PRODUCTS:

Publications, conference papers, and presentations

Journal publications.

Nothing to Report.

Books or other non-periodical, one-time publications.

- Muller, et al., "Tactile Sensing Reflex Reduces Need for Visual Feedback when Grasping Fragile Objects with a Prosthetic Hand," Haptics Symposium 2016.
    - Accepted symposium abstract. Federal support acknowledged.
- Berke, et al., "Contact Reflex Improves Fragile Grasping while Blindfolded," American Academy of Orthotists & Prosthetists 2017.

Other publications, conference papers, and presentations.

Nothing to Report.

Website(s) or other Internet site(s)

Nothing to Report.

Technologies or techniques

Nothing to Report.

Inventions, patent applications, and/or licenses

Nothing to Report.

Other Products

- Prosthetic hand contact-detecting sensors for improvement in fragile object grasping and reduced cognitive load while being used by amputee.
- Development and testing of a clinical outcome measure for analysis of prosthetic hand utility with and without distractions has been done.

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

(1) Project Directors (PDs)/PIs

Name:	Jeremy Fishel
Project Role:	PI
Nearest person month worked:	6.7
Contribution to Project:	Dr. Fishel has coordinated all design review and project planning meetings to complete specific aims and worked alongside staff to ensure progress.

Name:	Gary Berke
Project Role:	CI
Nearest person month worked:	3.6
Contribution to Project:	Gary Berke has performed work planning future clinical studies, advising on outcome measure development, collecting data in

outcome measure validation, and advising on the entire project.

(2) Other Personnel (working more than 1 person month in reporting period)

Name: Blaine Matulevich
Project Role: R&D Manager
Nearest person month worked: 1.55
Contribution to Project: Mr. Matulevich has advised on the development and evaluation of outcome measures and improvements to the mechanical and electrical design of the NumaTac sensors as well as the design of the controller electronics.

Name: Vikram Pandit
Project Role: Technician
Nearest person month worked: 0.5
Contribution to Project: Mr. Pandit consulted on evaluating outcome measures to be developed and used in clinical studies. As an amputee himself he has provided critical feedback on the value of such tests in everyday prosthetic hand usage.

Name: Raymond Peck
Project Role: Mechanical Engineer
Nearest person month worked: 0.75
Contribution to Project: Mr. Peck has advised on work related to the mechanical design and fabrication processes of the NumaTac sensors.

Name: Kelsey Muller
Project Role: R&D Engineer
Nearest person month worked: 4.6
Contribution to Project: Ms. Muller has performed work in developing and submitting IRB protocol for both studies, coordinating sensor evaluation and constructing test equipment, and conducting outcome measure evaluation studies and analysis.

Name: Vijay Anandani
Project Role: R&D Engineer
Nearest person month worked: 3.6
Contribution to Project: Mr. Anandani has worked on the durability testing and sensor fabrication and analysis of results.

Name: Neil Ragsdale
Project Role: Electronics Engineer
Nearest person month worked: 2.0
Contribution to Project: Mr. Ragsdale has worked on developing sensor and controller

	electronics for the entire development system and has consulted on a number of electronics matters.
Name:	Christopher Kepner
Project Role:	Firmware Engineer
Nearest person month worked:	1.5
Contribution to Project:	Mr. Kepner has worked on developing firmware and software to achieve the required reflex performance and data logging for the development system and has advised on electronics component selections and testing.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report.

What other organizations were involved as partners?

Organization Name: Berke Prosthetics
Location of Organization: Redwood City, California, USA
Partner's contribution to the project

Financial support;
In-kind support: Partner advises on and conducts clinical studies. Partner also advises on outcome measure development
Facilities The partner's facilities are used for clinical study conduction.
Collaboration partner and partner's staff work on project.
Personnel exchanges SynTouch project staff may use the partner's facilities to aid with clinical study conduction.

SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: None

QUAD CHARTS: Attached

APPENDICES: Attached

Appendix A

Heartland Institutional Review Board Submission

Validation of Reflex Enabled Myoelectric Hand for Improved Fragile Grasping

Date: September 18, 2017

Submitted By: Kelsey Muller | kelsey.muller@syntouchinc.com

Funded by: CDMRP

Protocol Review

Payment Information

Review fee: $___850_____ (per fee for services quote)

Bill to Purchase Order No. _____ or

Check made payable to "Heartland IRB" _____ (ck #), in the amount of $_____ mailed on _____.

Department of Health and Human Services regulations require review and approval of all research involving human subjects. Approval of Heartland Institutional Review Board must be obtained **PRIOR** to the involvement of any human subjects. HIRB will not review protocols for projects if projects were initiated prior to submission of forms to HIRB for review.

PROJECT TITLE

VALIDATION OF REFLEX ENABLED MYOELECTRIC HAND FOR IMPROVED FRAGILE GRASPING

PRINCIPAL INVESTIGATOR

First Name: Jeremy A.		Last Name: Fishel	
Street Address: 3720 Clifton Place	City: Montrose	State: CA	ZIP: 91020
Phone Number: (213) 493-4400		E-mail: Jeremy.Fishel@SynTouchINC.com	

CO-RESEARCHER(S)

First Name: Gary		Last Name: Berke	
Street Address: 2001 Winward Way, Suite 100	City: San Mateo	State: CA	ZIP: 94404
Phone Number: (650) 570-5861		E-mail: GBerke@BerkeProsthetics.com	

SPONSOR CONTACT (If research is being sponsored or funded by a third party.)

First Name:		Last Name:	
Street Address:	City:	State:	ZIP:
Phone Number:		E-mail:	

If the study will be funded by a grant, indicate the name of the funding agency.

CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)

DOCUMENT DISTRIBUTION: Please identify individuals below to whom you authorize access to documents related to this application. HIRB will send an email notification to the individuals below when a document is posted on the portal.

Name	Email address
Jeremy Fishel	**Jeremy.fishel@syntouchinc.com**
Kelsey Muller	**Kelsey.muller@syntouchinc.com**

How did you learn of HIRB?

_X_Have previously been a client

__ Sponsor/CRO recommendation

__ Tradeshow

__ Industry Publication

__ Internet/Website

__ Other:

SCREENING TOOL

Directions: Please, review each item and answer each by placing an "X" in the appropriate box to the right. Use "N/A" for any item that is "not applicable" to your proposed research study. Then follow the directions at the bottom of this page.	**YES**	**NO**	**N/A**
1) Is this research designed to study typical educational practices (e.g., instruction, classroom management)?		x	
2) If so, will the research occur in an established educational setting?			x
3) Will the research consist <u>solely</u> of standardized tests, surveys, interviews, or tracking public behavior?	x		
4) Will subjects have anonymity? (If participant names appear on consent forms, if research involves interviews, or if the investigator can link a number with a name then subjects will not have anonymity.)	x		
5) If information about subjects is disclosed, can you ensure they will not be at risk for damage to their financial standing, employability, or reputation?	x		
6) Will you collect or study existing data, documents, records, pathological or diagnostic specimens from publicly available sources?		x	
7) Will you collect or study existing data, documents, records, pathological or diagnostic specimens so that data cannot be linked to identifiable subjects?		x	
8) Will the study use deception (i.e., withholding information or giving false or misleading information to subjects)?		x	
9) Will procedures cause any degree of discomfort, harassment, invasion of privacy, risk of physical injury, threaten the dignity, or otherwise potentially harm subjects?		x	
10) Has another IRB declined to review or approve this protocol?		x	
11) Has another IRB terminated this research?		x	
12) Will subjects be drawn from any of the categories listed below?	x		
a) Minors (individuals not of age under State law to consent) b) Prisoners or persons who are under criminal sanctions c) Persons with diminished mental capacity (retardation, neurological, psychiatric, or related disability) d) Persons in a residential program (hospital, developmental center, group home, nursing home, etc.) e) Clients of a human service program (e.g., counseling center, clinic, etc.) f) Children who are wards of State g) Non-English speaking h) Adults who do not read or write i) Educationally disadvantaged j) Economically disadvantaged k) Employees or family members of the Principal Investigator or Sponsor l) Students of the university or the Principal Investigator participating in this research			

Directions:

- **If you answered "yes" to <u>any</u> of the questions 1 through 7 and "no" to <u>all</u> the questions 8 through 12, complete the <u>Basic Review Form</u>.**

- **If you answered "yes" to <u>any</u> of the questions 8 through 12, complete the <u>Advanced Review Form.</u>**

- **ADVANCED PROTOCOL REVIEW**

Directions: Answer each question below. Your responses should be concise and, as non-technical as possible. If a question does not apply to your research, answer "N/A" for "Not Applicable."

---

1. Describe the purpose of the study.

   The objective of the study is to observe, record, and compare how upper limb amputees use each of three different myoelectric prosthetic hands. This is evaluated using timed fragile grasping tasks, recorded use patterns during at-home wear, ACMC evaluated performance during a task of daily living, and surveys. The purpose of this is to determine and quantify the comparative benefit of a prosthetic hand that is equipped with contact detecting sensors and a biologically inspired reflex for fragile grasping tasks. The final results will indicate whether this technology proves to be beneficial to upper limb amputees and in what ways.

2. Describe your potential subject pool and what determines final choice of subjects.

   The potential subject pool includes transradial, unilateral amputees that have experience using a myoelectric prosthesis. These individuals will be at least 6 months post-amputation with a healthy sensate residual limb, no medical issues, and otherwise neurologically intact and able to consent and participate in the study.

3. Will any of the below vulnerable populations be in the subject pool? If so, justify allowing these populations into this study and describe additional safeguards to protect their rights and welfare.

   - Minors (individuals not of age under State law to consent)
   - Prisoners or persons under criminal sanctions
   - Persons with diminished mental capacity (retardation, neurological or psychiatric disability, etc.)
   - Persons in a residential program (hospital, developmental center, group home, nursing home, etc.)
   - Clients of a human service program (counseling center, clinic, etc.)
   - Children who are wards of State
   - Non-English speakers
   - Adults who do not read or write
   - Educationally disadvantaged
   - Economically disadvantaged
   - Employees or family members of the Principal Investigator or Sponsor
   - Students of the institution or the Principal Investigator participating in this research

   The subject pool for this study will include clients of a human service program, specifically clients of a prosthetics clinic (Berke Prosthetics) as well as individuals who are part of a collaborating site such as the Palo Alto Veterans Administration and may include other Veterans Administrations if additional volunteers are needed. Prior to the study, adult individuals identified as potential candidates will be provided

with relevant information about the study procedure, risks, and benefits involved in the study as well as consent forms in order to make an educated decision about their choice whether to participate or not. In no way will the choice to or not to participate, consent, or end participation at any point during the study impact an individual's relationship with the clinic or administration, level of care, or relationship with involved parties in any way.

4. How will potential subjects' names be obtained (specific lists, telephone directories, etc.) and how you will have access to these sources?

   Subjects names will be obtained from a list of clinic clients (in the case of Berke Prosthetics) and VA members (in the case that recruitment efforts need to be expanded) who fit the inclusion criteria of the study. These individuals will be provided with study recruitment information by their healthcare organization with the option to volunteer. Only if they choose to volunteer will SynTouch have access to potential subjects' names for the purpose of providing additional information, answering questions, or coordinating office visits.

5. How will subjects be recruited (mail, email, phone, presentation, personal contacts, ads), and by whom?

   Participants that are recruited will already be under the care of our clinical investigator, Gary Berke of Berke Prosthetics, or a potential collaborating site. These subjects will be made aware of the study in person or through media sources (mail, flyers, info packets) by the clinical team at the associated location (Appendix #3-4). If additional participants are required, print or electronic ads may be locally or nationally distributed to potential subjects through orthotic & prosthetic periodicals, websites, organizations, etc.

6. If you are associated with the subjects (your students, employees, clients, patients), explain the association and how a third party will solicit participation.

   SynTouch, Inc is not directly associated with any subjects. All subjects are associated Berke Prosthetics, a collaborating site, or are publicly recruited. Gary Berke is the clinical investigator and will recruit from Berke Prosthetics and accept and coordinate visits with any volunteers referred by the VA or who volunteer after viewing any advertising material.

7. How much time (minutes or hours per day or week) will typically be required for an individual subject's participation?

   It is anticipated that each subject will participate in 3 office visits and two take-home sessions with a prosthetic hand. The take home sessions will last 1 month each, consisting of regular use of a prosthetic hand provided during an office visit. The first office visit will be 2 hours and the two subsequent visits will be approximately 1.5 hours. During the take home sessions, a subject will be instructed to use their myoelectric hand as desired and at their discretion to complete tasks of daily living typically done with a prosthetic hand, which is estimated to be a maximum of 8 hours of intermittent use.

8. How many subjects will be involved in the study?

The goal is to recruit 10 subjects. If a sufficient number of subjects cannot be recruited from Berke Prosthetics, support from a collaborating site like the Palo Alto VA, or public recruitment efforts will be pursued.

9. How many subjects will be in each study group?

   All 10 subjects will complete the same clinical study.

10. Will any group receive less than standard practice?

    No

11. Give the approximate dates research subjects will be contacted and when involvement will end.

    From the time of contact to the start of the study will depend on the availability of each subject and lead time to develop a custom prosthetic hand for them to use. It is expected that when a study begins it will take each person approximately 2.5 months to complete. The projected total timeline for all 10 subjects is 2 years starting January 1, 2018.

12. Exactly where will research be conducted (classroom, office, residence, via mail, email, phone, etc.)? What resources are available at this site to support successful completion of the study?

    Research will be conducted at a prosthetics clinic, Berke Prosthetics. This office regularly receives and works with upper limb amputee patients and has all resources needed for the conduction of the in-office performance study, data collection, and prosthetic hand fitting and adjustments. A portion of the study is take-home and participants will be using a prosthetic hand as part of their daily routine, to be provided and fit at Berke Prosthetics before 1 months of use. If participants are recruited from the general public and live outside the local region, an executive suite or suitable office space will be rented in that location and Gary Berke will travel to, set up, and conduct the study protocol with the participant for each office visit.

13. If research will be in a classroom or service delivery setting, will it require any activity that is not part of the normal class or service delivery?

    Fitting patients with prosthetics and observing and documenting performance are regular services of Berke Prosthetics and prosthetist, Gary Berke. This location does not commonly conduct clinical studies for the sole purpose of research, however the associated requirements are not outside the realm of normal service delivery. At rented office spaces, Gary Berke will be present with all standard items needed to conduct the clinical protocol.

14. Will the project use facilities or interact with personnel at another institution or business? (If so, a letter of permission on the institution's letterhead must be sent to HIRB prior to beginning your study.)

    The project will use Berke Prosthetics as the main site for clinical investigation. If additional participants are needed agreements and compliance with the Palo Alto, VA requirements and standards will be needed. Is possible that temporary, private office space will be used for remote participants.

15. What will subjects be asked to do?

The subjects will be asked to participate in a study that involves a number of different commonly encountered physical tasks involving both fragile grasping and the conduction of daily tasks. The main in-office task will involve the timed movement of fragile crackers in three separate scenarios: unobstructed, with a visual barrier, and while cognitively distracted. Participants will also be observed while performing a daily task of their choice (folding clothes, preparing a meal, assembling a puzzle, etc.) with their hands and scored using the Assessment of Capacity for Myoelectric Control, ACMC. The last major task will be a take-home prosthetic hand use portion in which a participant will be given one of two terminal prosthetic hands and asked to use it for a month as they would their personal prosthetic hand. During this time, the hand is programmed to record use patterns and the data will be downloaded during the following office visit.

16. Describe the procedures that the researcher will use with the subjects.

When a subject is recruited and has provided prosthetic hand customization info, orientation, overview, and filled out consent forms, they will perform the following tasks, outlined briefly here and in greater detail in Appendix #1.

Visit 1

#1: complete a written questionnaire about media they have seen, read, etc. as well a survey about their prosthetic hand use.

#2: perform an every-day task for a researcher to review using the ACMC assessment tool. This will be done using their personal prosthetic hand.

#3: take a break to recover, eat, etc.

#4: Grasp a fragile object in various conditions that are encountered in daily life including both visually and cognitively distracted states (CDI: cognitive distraction impact & VDI: visual distraction impact). Their task ability and speed will be monitored and timed. This measure will be done using the participant's personal prosthetic hand and again while using the SynTouch reflex enabled hand.

#5: A SynTouch prosthetic hand will be configured and personalized for the participant in preparation for a 1-month take-home session. During this session, the hand will record use patterns and the reflex will be disabled.

Visit 2

#1: Complete a survey about their prosthetic hand use during the at-home session.

#2: Perform an every-day task for a researcher to review using the ACMC assessment tool. This will be done using the SynTouch prosthetic hand with the reflex disabled.

#3: Perform the CDI and VDI measures using the SynTouch prosthetic hand with the reflex disabled.

#4: Data from the SynTouch prosthetic hand will be downloaded and the hand will be configured in preparation for the second 1-month take-home session. During this session, the hand will record use patterns and the reflex will be enabled.

Visit 3

#1: Complete a survey about their prosthetic hand use during the at-home session.

#2: Perform an every-day task for a researcher to review using the ACMC assessment tool. This will be done using the SynTouch prosthetic hand with the reflex enabled.

#3: Perform the CDI and VDI measures using the SynTouch prosthetic hand with the reflex enabled.

#4: Data from the SynTouch prosthetic hand will be downloaded and the hand will be configured for the participant to keep the hand if desired.

17. Describe any physical, psychological, social, economic, legal or other risks to the subject. (Subjects should be protected against injury and invasion of their privacy, and their dignity should be preserved.)

    The study is a low risk study that asks volunteers to perform the same types of tasks they perform at home and in daily life, but to do so both at home and in a clinical environment where performance can be monitored and recorded. The tasks chosen (like moving a fragile cracker) are chosen so that even in case of total failure, the individual will remain safe. Distraction methods are chosen in a way that any person can endure them with no stress or anxiety and volunteers can end or skip any testing scenario if they desire. The prosthetic hands that will be used are terminal devices to their personal prosthetic arm socket, prescribed by their prosthetist.

    The privacy of the volunteers will be maintained via standard practices of coding their personal information and not distributing physical copies.

18. Describe steps that will be taken to minimize risk, including how subjects will be informed of any risks.

    Risks are minimized by asking subjects only to perform tasks that would be or are encountered during daily life. Additionally the exclusion criteria includes those at risk of excess fatigue or inability to perform such tasks in a minimally risky way. Subjects will be informed of risks verbally and in writing while undergoing an informed consent process. The prosthetic devices used are terminal devices to their personal socket and introduce risks no greater than prescribed by their doctor and prosthetist. See Appendix #2 for the informed consent documentation.

19. If subjects will face more than minimal risk (obtaining blood, information on sensitive issues such as illegal drug use, drug treatment, psychological manipulation, more than moderate exercise, etc.), describe procedures in detail, including qualifications/certification of data collectors.

All research is low risk. Modifications in prosthetic hand style are localized to a participant's prosthetic terminal device and safety has been validated by electrical engineering specialist, Neil Ragsdale and attached (Appendix #8).

20. Describe your plan for providing emergency medical treatment or psychological support for incidents that may occur during research, and provide the distance from the research site to a facility that can treat medical or psychological emergencies.

    In the event of an emergency, the research is occurring within a facility designed to treat a variety of issues related to problems a subject performing grasping tasks may experience. In the event of an emergency that takes place at a rented office space offsite from Berke Prosthetics, the location will be located in a populated town or city that is within reasonable and safe distance from a medical treatment facility.

21. Describe any electrical equipment to be connected to subjects. (You will need to attach a signed and dated letter from the individual who checked the equipment for electrical safety, including their qualifications and the types and results of the checks.)

    Subjects will be using a myoelectric prosthetic hand, which is the terminal device of their custom prosthetic socket. The subject's personal socket is the portion that they have direct contact with and it will not be modified in any way. The terminal device to be used will rotate between two different prosthetic hands, the subject's personal prosthetic hand and a prosthetic hand that has physically been modified to include custom contact detecting fingers and a controller that initiates a reflex and records use data. This hand uses the existing socket for power and does not exceed the maximum forces of an off-the-shelf prosthetic hand.

22. Describe the need for any audio/video recording of subjects, where recordings will be stored, the specific intended uses of the recordings, the person(s) who will have access to the recordings, and when or if recordings will be destroyed or erased.

    Audio and video recordings of subjects will be needed to record performance of both an outcome measure and ACMC tests during all office visits. ACMC requires both video and audio for test assessment by a trained ACMC administrator. The outcome measure study observes and records performance of individuals completing a fragile grasping task under the influence of different distraction methods. Video and audio recordings are needed to ensure that the subject performs a task according to directions and in order to verify that recorded performance matches actual performance.

23. Describe the nature of any deception used in the study, why it is necessary, and how subjects will be debriefed. Include any feedback – educational or otherwise – subjects will receive.

    No deception will be used.

24. How will subjects indicate consent? (A copy of the consent form or, in the case of a mailed survey, a cover letter explaining the project, must be offered to each subject. HIRB requirements for consent forms are available on the HIRB Web site.) If you are requesting a waiver of the written/signed consent, what other method will be used to obtain consent?

Subjects will be provided with documents where they will provide written consent (Appendix #2). They will also provide recoded verbal consent prior to beginning a video/audio recorded ACMC or fragile object grasping/passing session.

25. Indicate any state or local laws that require additional information in the consent form.

    None.

26. Will you obtain consent from anyone other than the participant?

    No.

27. Who will present consent documents and/or conduct consent interviews with potential participant?

    Gary Berke – Clinical Investigator

28. What steps will you take to minimize the possibility of coercion or undue influence?

    Coercion or undue influence in our study can be mitigated using standard techniques:

    #1 When visiting in person or between office visits, potential volunteers will have the ability to refuse to participate or end participation at any time. They also have this ability during an initial inquiry (whether phone, email, fax, etc.), during which they will be provided with a study overview and the option to receive and review informed consent materials.

    #2 Only nominal financial compensation for the volunteer's time will be given.

    #3 Volunteers who show initial interest in study participation will be encouraged to review the informed consent materials at home or with others before consenting.

    #4 Volunteers will be given the option to keep the custom prosthetic hand at the end of the study and provide periodic feedback about how it works and any problems or programming errors. Servicing of this device will only be provided for the duration of the CDMRP project. To avoid coercion, this will only be disclosed to participants at the end of the study with feedback being optional.

29. Will prospective participants be allowed to take consent documents away from the site to discuss with their family members, legal counsel, doctors or others?

    Yes. Consent documents will be optionally provided in person or by electronic distribution (email, fax, etc).

30. Describe desired timeframe between approaching prospective participants and obtaining consent.

    A prospective volunteer would be identified and provided with recruitment documents outlining the study or will observe a recruitment ad in a media form (magazine, website, etc). A prospective volunteer would contact principal investigator, Gary Berke if interested in participating in the study. They would be provided with informed consent materials and asked to complete a form with their prosthetic hand information (size, hand, cosmesis color, etc) for custom hand ordering and manufacturing (Appendix #9). They will be contacted to schedule the

primary visit, ideally between 2-4 weeks from the time of initial contact; this time is needed to create the custom prosthetic hand that they will be using during the first office visit.

31. Who will assist the Investigator in ensuring consent is appropriately obtained and documented?

    Gary Berke will obtain and document consent. SynTouch employee and project principal investigator Jeremy Fishel will review all consent documentation.

32. What language(s) are spoken by those obtaining consent and prospective participants?

    English

33. In your state, what is the legal age to consent to this research?

    18

34. In your state, are both parents required to consent on behalf of the child?

    No children are included.

35. Other than parents, who is legally authorized in your state to consent on behalf of a child?

    NA

36. Describe community attitudes (religious, ethnic, etc.) about your research that may affect the study.

    The study will assess and quantify the benefits of a sensorized prosthetic hand to myoelectric prosthesis users. In comparison to a standard, unsensorized prosthetic hand, we dill determine how effective it is in improving ease and frequency of use during daily life. This study will support the development of an improved prosthetic hand and the general community supports this future direction, as it is based on improving prosthetics, therefore we do not anticipate any community concerns.

37. What specific aspects of this study may be most sensitive to this community?

    The general community may falsely believe that our advanced prosthetic hands for research are currently being sold commercially. This has only happened infrequently in the past and is addressed by explaining that the work is currently research, not commercially available.

38. How will/have you obtained permission to access existing/secondary data. (A letter of permission must also be attached. See required attachment checklist at the end of this form.)

    NA. We will not require existing or secondary data.

39. Where are the existing/secondary data files kept and who will gather the information?

    NA. We will not require existing or secondary data.

40. Do the subjects (and/or their parents or guardians) know that these files will be read? If not, explain.

    NA. We will not require existing or secondary data.

41. Will you access subjects' protected health information?

    No.

42. What processes will ensure that persons assisting in the study are adequately informed about the protocol/study plan, and their study related duties and functions?

    Documentation from the PI will be provided to people assisting in the study to describe their duties and functions. These people will retain one copy, and sign and return a second copy to document their understanding of their duties.

43. How will you ensure anonymity or confidentiality during and after the study? (Substituting numbers for names, locking or password-protecting data files, confidentiality contracts with staff, not identifying individuals in reports, etc.) **NOTE:** Social Security numbers may NOT be used.

    All data sent to SynTouch will be coded with a randomized identifier number. Gary Berke will retain a key that indicates the identity corresponding to each randomized identifier number that will be destroyed after the study is complete. Confidentiality protocols of potential supporting groups (used for subject recruitment) such as the Palo Alto VA will also be followed.

44. If you use a code numbers linked to identifying names…
    - Will you keep the code listing and data in separate and secure locations?
    - Will you destroy the code list when the study is complete?
    - Who will have access to the code list and data?

    Gary Berke will have access to the code list; all other study personnel have access to study data, except this code list and any other volunteer details. The code list will be destroyed upon the completion of the study.

45. Will results be disseminated to subjects (and/or their parents or guardians)? If so, explain the qualifications of the person(s) interpreting the results.

    Yes. The performance on the tasks will be available to participants in the study following the completion of the study, if they wish to see their performance data. Results will be provided by PI, Gary Berke.

46. What will you do with the data collected (publish data, present paper)?

    The collected data will be used to compare in-office and at-home use and performance patterns of different prosthetic hands. We aim to determine how a sensor and reflex enabled prosthetic hand affects an amputee's fragile grasping abilities and at-home use patterns. We will use the data to support scholarly activities: publication of papers, presentations to the academic community, and submission of grants.

47. Is a follow-up anticipated, and if so, for what reason?

No mandatory follow-up after the study completion will be required. An optional extended period is possible where a subject is given the option to keep the experimental prosthetic hand. The hand will not be logging data and SynTouch may periodically request feedback about the participants experience with the hand to see if they are happy and if any problems have occurred. This is important to document unanticipated issues associated with daily or long term use. This way, programming and design improvements can be made so that the best possible technology can be provided to the prosthetic community in the future.

48. Will subjects receive any compensation (money, grade, extra credit, etc.)?

    Yes. Participants will be compensated a total of $600 for their time and reimbursed for travel, without being an undue inducement to participate in the study. In the case that SynTouch receives interest outside of a local radius, transportation arrangements will be made in advance (ie. Train, bus, etc) while those outside of CA will have the option to participate at a rented office/clinical site in their city where CI Gary Berke will travel to.

49. If participants will be paid, indicate how they will be paid in the table below. (Add lines if needed.)

Visit Number/Type	Amount to be paid
1. Initial Visit	**$200**
2. Second Visit	**$100**
3. Third Visit	**$100**
4. Completed Take-Home 1	**$100**
5. Completed Take-Home 2	**$100**

50. When should participants expect payment? (At each visit, at final visit, upon completion of study, etc.)

    Participants will expect payment at the end of each office visit.

51. Will an end-of-study bonus be offered to participants, and if so, what will be the amount?

    No, though they will have the option to keep the reflex-enabled prosthetic hand that was used by them during the study, if they desire, however this option will not be made known at the beginning of the study in an effort to avoid coercion. The option to keep the prosthetic hand will not be accompanied with any formal repairs or support beyond the CDMRP project duration and SynTouch will request optional feedback on their experience in the form of periodic surveys.

52. What is the maximum total potential compensation for completion of protocol/study plan requirements?

    $600

53. If extra credit or a grade is given, how will students who choose not to participate get other chances to receive extra credit or an equivalent grade?

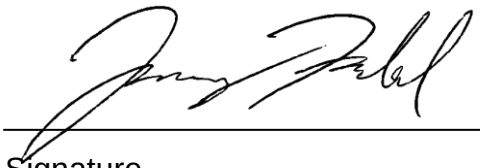
NA. No extra credit or a grade is to be given.

CERTIFICATION STATEMENT and SIGNATURE

I certify that the information provided within this report is true and accurate, and represents my intent to pursue review of this research by Heartland Institutional Review Board. My signature below indicates that I understand that it is my obligation to review the reporting responsibilities, as provided on the Heartland Institutional Review Board website and to me in printed form. I understand I may contact Heartland Institutional Review Board at any time with questions or concerns about these requirements. I understand that failure to comply with the above requirements may result in regulatory action by Heartland Institutional Review Board. By signing this agreement, I grant Heartland Institutional Review Board the authority to approve and oversee the above referenced research investigation.

Jeremy A. Fishel

Printed Name of Investigator (Single Site PI submissions)



Signature

09/18/17

Date

Procedures Referred to in Protocol

ACMC (Assessment of Capacity for Myoelectric Control)

a) Volunteer will be given an every-day bimanual task to perform while observed by an ACMC trained assessor. The task will be something common such as folding laundry, assembling a product, putting photos in an album, etc. They will have the option to practice the task if they desire. When they indicate they are ready, they will be recorded while performing the daily task. The recording of this task will be assessed using ACMC (Assessment of Capacity for Myoelectric Control). The individual may be stopped and asked to repeat the task if any events occur that would inhibit the ability to properly assess the recorded task.

Bimanual Passing Task Performed During CDI, VDI, or No Impact

b) Volunteer is standing facing a table with a centerline directly in front of them, a line 18" to their left, and a line 18" to their right.
c) Volunteer indicates when they are ready to begin the timed portion.
d) Researcher presents two trays of crackers for the volunteer to receive from at one line, on the volunteer's left if they have an able-left hand or to their right if they have an able-right hand. The volunteer will remove crackers from the tray with their able hand. They cannot move on to the next tray until the previous is finished. The researcher will replace the empty tray when the volunteer has moved on to the next.
e) Volunteer starts with two hands on the table. When the timer starts, it will beep, indicating that they can grasp the first cracker with their able hand.
f) Volunteer passes object to their prosthetic hand over the midline.
g) Volunteer moves cracker with their prosthetic hand to the cup, located on the 18" line opposite the receiving line, without breaking or dropping it.
h) Volunteer releases the object in the cup. It is important that the person attempts to drop the cracker in the cup but perfection is not necessary.
i) Steps c-f are repeated until 30 seconds have elapsed. No additional crackers can count towards the total after 30 seconds have elapsed.
j) The number of intact objects that were placed in the predetermined location is recorded.
k) Volunteer is allowed to rest until they indicate they are ready to begin again.
l) Researcher may re-instruct the volunteer on the protocol if performed improperly.

VDI (Visual Distraction Impact)

a) The individual has a blindfold curtain in front of them while standing at the table.
b) The individual performs the Bimanual Passing Task and transfers the cracker to their prosthetic hand behind the curtain. They may not see the transfer. Touching the curtain is allowed as long as this does not allow them to see their hands. They may see the cracker when grasping it and when dropping it in the cup.

CDI (Cognitive Distraction Impact)

a) Presenter will say the name of one media source written or chosen by the volunteer on the entry media survey. It is dictated that the goal is to talk about the movie and convey the plot using full sentences without pausing or repeating the movie title (i.e. “The movie Shrek is about...”). The volunteer will begin speaking when the timer starts upon the start of the Bimanual Passing Task and can stop when the timer stops upon the completion of each trial of the Bimanual Passing Task. They cannot pause or delay dictation for more than 2 seconds. A unique media title is used for each trial and if there is a mistake during the trial, a new media title needs to be used. Tell the person to avoid just saying single words or pausing, they should try to speak continuously even if they’re giving their opinion about the movie or talking about just one scene.

b)

NI (No Impact)

a) Volunteer will follow the Bimanual Passing Task procedure with no visual or cognitive distractions.

Clinical Protocol

Visit 1A

a) Volunteer arrives at office for testing
b) Office obtains a signed consent form if not already on file
c) Volunteer is given a list of movies and instructed to indicate which, if any, they are familiar enough with to verbally summarize for a span of about 30 seconds. Volunteer is also given a blank list to fill in with additional movies if they could not mark 30 on the previous list.
d) Audio and video recording device is started and the experimenter states the participant’s ID number, date, dominant hand, and time of recording. They then ask the participant “are you aware you are being audio and video recorded during this session? Do we have your permission to record and video this session?”
e) Volunteer is given a brief verbal overview of the background and purpose of the entire study followed by an overview of the visit procedure. This will include the fact that we’re observing the use of their existing personal prosthetic hand during an every-day task of their choice, which was decided upon by the volunteer prior to arrival, so that it could be prepared by the clinical investigator.
f) The volunteer will perform the ACMC testing procedure with their personal prosthesis.
g) The volunteer will take a break for a duration of their choosing to relax.

Visit 1B

h) Volunteer is given a brief introduction to the VDI and CDI procedures and allowed to practice if desired.
i) The participant will alternate between the CDI, VDI, and NI until 5 trials of each have been completed using their personal prosthetic hand.
j) The participant will alternate between the CDI, VDI, and NI until 5 trials of each have been completed using the SynTouch reflex enabled hand.
k) Clinical Investigator and prosthetist will configure the SynTouch hand and personalize the EMG thresholds for the participant to use for 1 month of home use. This hand will have the reflex disabled for the entire take home session. The participant is instructed to use the hand for the entire month as frequently as they see fit. During this time, the hand will be internally recording use patterns such as grip forces and frequency of use.
l) Volunteer be given an exit survey about their experience if necessary.
m) Audio and video recording is stopped.

Visit 2

a) Volunteer arrives at office for testing.
b) Data from the SynTouch hand will be downloaded by the clinical investigator.
c) Volunteer will complete a survey about their prosthetic hand use during the at-home session.
d) Audio and video recording device is started and the experimenter states the participant's ID number, date, dominant hand, and time of recording. They then ask the participant "are you aware you are being audio and video recorded during this session? Do we have your permission to record and video this session?"
e) The volunteer will perform the ACMC testing procedure with the SynTouch prosthetic hand and the reflex disabled.
f) Volunteer is given a brief review of the VDI, CDI, and NI procedures and allowed to practice if desired.
g) The participant will alternate between the CDI, VDI, and NI until 5 trials of each have been completed using the SynTouch prosthetic hand and the reflex disabled.
h) Clinical Investigator and prosthetist will configure the SynTouch hand and personalize the EMG thresholds for the participant to use for 1 month of home use. This hand will have the reflex enabled for the entire take home session. The participant is instructed to use the hand for the entire month as frequently as they see fit. During this time, the hand will be internally recording use patterns such as grip forces and frequency of use.
i) Volunteer be given an exit survey about their experience if necessary.
j) Audio and video recording is stopped.

Visit 3

a) Volunteer arrives at office for testing.
b) Data from the SynTouch hand will be downloaded by the clinical investigator.
c) Volunteer will complete a survey about their prosthetic hand use during the at-home session.
d) Audio and video recording device is started and the experimenter states the participant's ID number, date, dominant hand, and time of recording. They then ask the participant "are you aware you are being audio and video recorded during this session? Do we have your permission to record and video this session?"
e) The volunteer will perform the ACMC testing procedure with the SynTouch prosthetic hand and the reflex enabled.
f) Volunteer is given a brief review of the CDI, VDI, and NI procedures and allowed to practice if desired.
g) The participant will alternate between the CDI, VDI, and NI until 5 trials of each have been completed using the SynTouch prosthetic hand and the reflex enabled.
h) Volunteer be given an exit survey about their experience if necessary.
i) Audio and video recording is stopped.

Dear Potential Volunteer,

You are invited to participate in our research to evaluate how a novel prosthetic hand, equipped with contact detecting sensors, compares to existing prosthetic technology, especially during fragile grasping tasks. The results of this study will be used to influence next-generation prosthetic hand technology and the technology used has the potential to be directly beneficial to you.

Please review the attached document carefully. It outlines both the benefits to society and risks to you if you choose to participate in this research. Please know that if you agree to participate, or do not agree to participate it will not alter or affect your relationship with SynTouch, Berke Prosthetics, the US Department of Veterans Affairs, or any other entity involved in this study. Also please know if you agree to participate, you may change your mind or withdraw from the study at any point prior to or during the research without penalty. Additionally, there is a video and audio recording component of this study used for data analysis. Information gathered from the recordings may be used in printed research such as articles and confidentiality will be preserved.

If after reviewing the description of the research study you have any questions, please contact the researchers directly using the contact information provided below.

Thank you for your consideration of this request for participation.

Sincerely,

Jeremy A. Fishel
Principal Investigator
SynTouch, LLC
office: (213) 493-4400
email: Jeremy.Fishel@SynTouchINC.com

Gary Berke
Clinical Investigator
Berke Prosthetics
office: (650) 365-5861
email: GBerke@BerkeProsthetics.com

PROSTHETIC HAND USE STUDY

INFORMATION AND CONSENT FORM

Introduction:
You are invited to participate in our research to evaluate how a novel prosthetic hand, equipped with contact detecting sensors, compares to existing prosthetic technology, especially during fragile grasping tasks. The results of this study will be used to influence next-generation prosthetic hand technology. This DOD funded study is being conducted by Jeremy Fishel of SynTouch, INC and Gary Berke at Berke Prosthetics in Redwood City, CA. You have been selected as a possible participant in this research because you are a healthy unilateral amputee and myoelectric prosthesis user. Please read this form and ask questions before you agree to participate in the study, which can be directed to either Jeremy Fishel or Gary Berke (contact information below).

Background Information:
The purpose of this study is to compare your speed and accuracy performance using various prosthetic hands when grasping fragile objects with and without a visual or cognitive distraction. There is also a take-home portion to understand your daily prosthesis use patterns as well as an in-office observation of prosthesis hand technique patterns during a common task of your choosing. Ten people are expected to participate in this research study.

Procedures:
If you decide to participate, you will be asked to participate in three 1-2 hour office sessions and two take-home sessions when you will use a provided prosthetic hand for 1 month of normal use. Each office visit will consist of different combinations of some of the following tasks:

1) You will complete a questionnaire asking you to indicate what media sources you are familiar with and able to describe (movies, TV shows, books, etc.) or write down alternative titles from such sources (5 minutes).
2) You will complete a questionnaire asking you to reflect upon your 1 month hand use take-home session, if applicable (5 minutes).
3) You will be informed of the testing procedures of the tasks and allowed to practice these tasks. You will be asked if you consent to the test being video and audio recorded (5 minutes).
4) Bimanual Passing Procedure: Each task will be completed and timed before moving on to the next task. You will cycle through the 3 tasks several times. You will be allowed to rest in between each trial if desired (25-45 minutes total). You will use your personal prosthesis or a prosthetic hand provided by the researcher, depending on the office visit.
    a. Task 1: While standing, the researcher will present trays of fragile objects for you to grasp with one, pass to your other hand, and drop in a predetermined location. The total amount of unbroken objects passed in 30 seconds will be recorded.
    b. Task 2: The same as Task 1, but without the ability to see your hands.
    c. Task 3: The same as Task 1, but while summarizing a form of media (movie, book, etc.).
5) ACMC (Assessment of Capacity for Myoelectric Control): You will be asked to perform an untimed, daily bimanual task (folding laundry, assembling sandwich, etc) while your use patterns and hand technique are observed by a researcher (25 minutes).
6) You will fill out an exit questionnaire about your experience.

The audio and video recording component of this study is done to aid in data analysis, which may be reported in print research.

Risks and Benefits of being in the study:
The study has minimal risks. First, you may experience fatigue however, the likelihood of this risk is low if you do not experience this type of fatigue while using your hands for periods over 60 minutes. Second, while we will make every effort to ensure your participation in the study is kept confidential as required by protocol, there is always a risk that it may be accidentally disclosed unintentionally. Recordings will only be used by researchers and destroyed following the analysis of data. If you have any concerns with these risks it is advised that you discuss with the researchers before signing this consent form or participating in the study. If at any point during the study you appear to be in discomfort or unable to safely conduct the remainder of the study, the researchers will end the study.

There will be no direct benefits to you for participating in this research. Your participation is completely voluntary and if you decide not to participate, your relationships with Berke Prosthetics, SynTouch Inc, or any other entity involved in this study will not change in any way.

Compensation:
If you participate in this study, we will compensate you for your time $200 for the first visit, $100 per subsequent office visit and completed take-home session, and reimbursed for travel. Depending on your location, you may be required to travel to Redwood City, CA, provided with airfare/train/bus in advance to travel to Redwood City, CA, or required to travel to a temporary office space within reasonable distance from you.

In the event that your participation in this research activity results in an injury, we will be unable to provide any compensation. Any medical care for research-related injuries should be paid by you or your insurance company. If you think you have suffered a research-related injury, please, inform the researchers as soon as possible so they can notify appropriate safety review boards.

Confidentiality:
Any information obtained in connection with this research study that can be identified with you will be disclosed only with your permission; your individual results will be kept confidential. In any media, written reports or publications, no one will be identified or identifiable and only group data will be presented.

The researchers will maintain all research results and records in locked file cabinets at offices of SynTouch and Berke Prosthetics. Only the researchers at these institutions will have access to the records while analyses of results are performed for this research project. The department of defense (DOD) or Federal representatives may access research records for the purpose of protecting human subjects.

Voluntary nature of the study:
Participation in this research study is voluntary. Your decision whether or not to participate will not affect your future relations with Berke Prosthetics, SynTouch, or any other entity involved in this study in any way. If you decide to participate, you are free to stop at any time without affecting these relationships.

Contacts and questions:
If you have any questions, please feel free to contact the researchers:
Gary Berke, Berke Prosthetics – GBerke@BerkeProsthetics.com, phone: 650-365-5861.
Jeremy Fishel, SynTouch – email: Jeremy.Fishel@SynTouchLLC.com, phone: 213-493-4400

You may ask questions now, or if you have any additional questions later, the researchers will be happy to answer them. If you are interested in participating, please notify the above researchers for additional information.

This project has been reviewed and approved by the Heartland Institutional Review Board. Questions concerning your rights as a participant in this research may be addressed to the Executive Director at Heartland IRB. Office: (866) 618-HIRB; Fax: (866) 300-0679; or by emailing director@heartlandirb.org.

Please, keep one copy of this letter and consent form for your records and return the other signed copy to the researcher/s.

Thank you,

Jeremy Fishel
213-493-4400

Gary Berke
650-365-5861

Statement of Consent

You are making a decision whether or not to participate.
Select whether you agree to participate or choose not to participate.
Your signature indicates that you have read this information and your questions have been answered.
Even after signing this form, please know that you may withdraw from the study at any time.

___ I consent to participate in the study.

___ I do NOT consent to participate in this study.

_____
Participant name (please, print)

_____
Signature of Participant Date

Video and Recording Consent

You are making a decision whether or not to give permission for the video and audio recording of this experiment.

Select whether you agree to be videoed and recorded in this experiment.
Even after signing this form, please know that you may withdraw from the study at any time.

___ I agree to have my session video and audio recorded and understand that I may withdraw my consent at any time without penalty.

___ I do NOT agree to have my session video or audio recorded

_____

Signature of Participant Date

English:

This project has been reviewed and approved by the Heartland Institutional Review Board. Questions concerning your rights as a participant in this research may be addressed to the Executive Director at Heartland IRB. Office: (866) 618-HIRB; Fax: (866) 300-0679; or by emailing director@heartlandirb.org.

Spanish:

Este proyecto ha sido revisado y aprobado por Heartland Institutional Review Board. Preguntas sobre sus derechos como participante en esta investigación pueden dirigirse al Directo Ejecutivo de Heartland IRB. Oficina: (866) 618-HIRB; Fax: (866) 300-0679; o por correo electrónico: director@heartlandirb.org.

September 18, 17

IRB APPROVED RESEARCH PROJECT, NEED SUBJECTS

SynTouch is recruiting subjects for a study to evaluate how a novel prosthetic hand, equipped with contact detecting sensors, compares to existing prosthetic technology, especially during fragile grasping tasks. This is part of a grant from the Congressionally Directed Medical Research Programs (CDMRP). The results of this study will be used to influence next-generation prosthetic hand technology. The study will involve three 1-2 hour office visits, two take-home sessions with prosthetic hand use, and volunteers will be compensated for their time.

In order to participate in this research you must:

- Be 18+ years old
- Be unilateral, transradial amputee
- Have experience using a myoelectric prosthesis
- Be 6+ months post amputation

If you are interested in participating in this study and would like more information, please contact Gary Berke below.

Upon contact, you will have the option to receive an introduction letter as well an "Information and Consent Form" containing the details of the study, activity, and compensation for participation.

If you or someone you know are a potential candidate, please feel free to contact me with questions or for more information. I am happy to discuss this project with anyone interested.

Best,

Gary M. Berke MS, CP, FAAOP
GBerke@BerkeProsthetics.com
650-365-5861

English: This project has been reviewed and approved by the Heartland Institutional Review Board. Questions concerning your rights as a participant in this research may be addressed to the Executive Director at Heartland IRB. Office: (866) 618-HIRB [4472]; Fax: (866) 414-0517; or by emailing director@heartlandirb.org.

Spanish: Este proyecto ha sido revisado y aprobado por Heartland Institutional Review Board. Preguntas sobre sus derechos como participante en esta investigación pueden dirigirse al Directo Ejecutivo de Heartland IRB. Oficina: (866) 618-HIRB [4472]; Fax: (866) 414-0517; o por correo electrónico: director@heartlandirb.org.

SUBJECTS NEEDED

IRB approved research funded by the
Congressionally Directed Medical Research Programs (CDMRP)

Qualifying candidates are:

- 18+ years of age
- Unilateral transradial amputee
- Have experience using a myoelectric prosthesis
- Be 6+ months post amputation

Your participation in this minimal risk, will consist of three 1-2 hour office visits, 2 take-home sessions with a prosthetic hand, and help will influence the development of next generation prosthetic hands.

Volunteers will be compensated for their participation.

Contact

Gary Berke
(650) 365-5861
Gberke@BerkeProsthetics.com

Indicate 20 of the following titles that you would be able to summarize or talk about for 30 seconds:

Movies 1970s:

- ☐ Apocalypse Now
- ☐ Clockwork Orange
- ☐ Star Wars (any)
- ☐ Jaws
- ☐ Rocky
- ☐ Monty Python & the Holy Grail
- ☐ Grease
- ☐ Halloween
- ☐ Willy Wonka & Choc. Factory
- ☐ Alien
- ☐ Blazing Saddles
- ☐ Carrie

Movies 1980s:

- ☐ ET
- ☐ Raiders of the Lost Ark
- ☐ The Terminator
- ☐ Die Hard
- ☐ The Princess Bride
- ☐ Fast Times at Ridgemont High
- ☐ Gremlins
- ☐ Back to the Future
- ☐ Rain Man
- ☐ Karate Kid
- ☐ The Little Mermaid
- ☐ Top Gun
- ☐ Field of Dreams
- ☐ Ghostbusters
- ☐ The Breakfast Club
- ☐ Caddyshack
- ☐ Ferris Bueller's Day Off

Movies of 1990s:

- ☐ Titanic
- ☐ The Lion King
- ☐ Jurassic Park
- ☐ Forrest Gump
- ☐ Independence Day
- ☐ The Sixth Sense
- ☐ Home Alone
- ☐ Men in Black
- ☐ Toy Story
- ☐ Mrs. Doubtfire
- ☐ Beauty and the Beast
- ☐ Aladdin
- ☐ Austin Powers
- ☐ Dances with Wolves
- ☐ Pretty Woman
- ☐ The Matrix
- ☐ Big Daddy
- ☐ The Mummy
- ☐ Batman
- ☐ Pocahontas
- ☐ Doctor Doolittle
- ☐ Rush Hour
- ☐ Stuart Little
- ☐ Good Will Hunting
- ☐ The Green Mile
- ☐ 101 Dalmatians
- ☐ Dumb and Dumber
- ☐ The Truman Show
- ☐ Wild Wild West

Movies of the 2000s:

- ☐ The Lord of the Rings
- ☐ Batman
- ☐ Bourne Identity
- ☐ Almost Famous
- ☐ Finding Nemo
- ☐ There Will Be Blood
- ☐ Gladiator
- ☐ Up
- ☐ Shrek
- ☐ The Incredibles
- ☐ Avatar
- ☐ Spider Man
- ☐ Super Troopers
- ☐ The Aviator
- ☐ X-Men
- ☐ Blood Diamond
- ☐ Zoolander
- ☐ The Prestige
- ☐ The Notebook
- ☐ Mean Girls
- ☐ Pirates of the Caribbean
- ☐ Pride and Prejudice
- ☐ Harry Potter
- ☐ Monsters, Inc.
- ☐ Idiocracy
- ☐ My Big Fat Greek Wedding
- ☐ Juno

Movies of the 2010's:

- ☐ Deadpool
- ☐ The Martian
- ☐ Sing!
- ☐ The Wolf of Wall Street
- ☐ Interstellar
- ☐ La La Land
- ☐ Jurassic World
- ☐ Pitch Perfect
- ☐ Bridesmaids
- ☐ Frozen
- ☐ Guardians of the Galaxy

Books:

- ☐ Treasure Island (R. L. Stevenson)
- ☐ Lord of the Flies (William Golding)
- ☐ The Call of the Wild (Jack London)
- ☐ Charlotte's Web (E.B. White)
- ☐ Oliver Twist (Charles Dickens)
- ☐ A Tale of Two Cities (Charles Dickens)
- ☐ Don Quixote (Cervantes)
- ☐ Alice's Adventures in Wonderland (Lewis Carroll)
- ☐ Nineteen-Eighty Four (George Orwell)
- ☐ To Kill a Mockingbird (Harper Lee)
- ☐ Of Mice and Men (John Steinbeck)
- ☐ The Lion the Witch and the Wardrobe (C.S. Lewis)
- ☐ Moby Dick (Herman Melville)
- ☐ Harry Potter (J.K. Rowling)
- ☐ The Hunger Games (Suzanne Collins)
- ☐ Romeo and Juliet (Shakespeare)
- ☐ A Christmas Carol (Charles Dickens)

TV Shows:

- ☐ Full House
- ☐ House of Cards
- ☐ The Walking Dead
- ☐ Game of Thrones
- ☐ Arrow
- ☐ The Big Bang Theory
- ☐ Supernatural
- ☐ The Blacklist
- ☐ Breaking Bad
- ☐ Stranger Things
- ☐ Downton Abbey
- ☐ Orange is the New Black
- ☐ Modern Family
- ☐ Sherlock
- ☐ New Girl
- ☐ Law and Order
- ☐ Castle
- ☐ The Office
- ☐ House M.D.
- ☐ Doctor Who
- ☐ One Tree Hill
- ☐ The Sopranos
- ☐ Friday Night Lights
- ☐ Nashville
- ☐ The Wire

If you are unfamiliar with the above titles, list movies, books, or TV shows that you would be able to summarize or talk about for 30 seconds:

1.
2.
3.
4.
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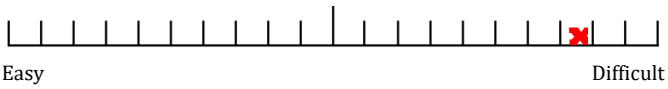
19.
20.

Exit Questionnaire

Please indicate how you felt you performed in each of the following categories by filling in the appropriate box. Optional comments can be written to the right.

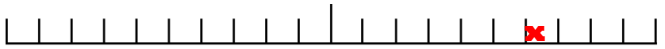
Example: How easy was it to pass the object to yourself?

Nothing:



Easy Difficult

Blindfolded:

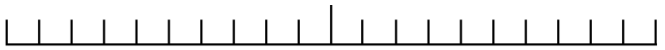


Easy Difficult

Didn't notice a huge difference

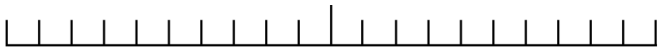
1. How difficult was it to accomplish the task?

Nothing:



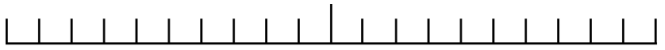
Easy Difficult

Blindfolded:



Easy Difficult

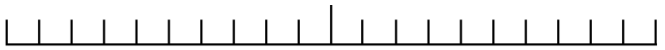
Talking:



Easy Difficult

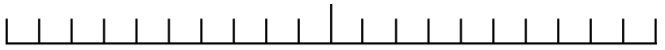
2. How distracted were you during the task?

Nothing:



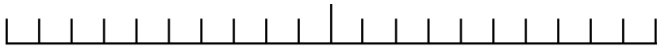
Not Distracted Very Distracted

Blindfolded:



Not Distracted Very Distracted

Talking:



Not Distracted Very Distracted

English: This project has been reviewed and approved by the Heartland Institutional Review Board. Questions concerning your rights as a participant in this research may be addressed to the Executive Director at Heartland IRB. Office: (866) 618-HIRB [4472]; Fax: (866) 414-0517; or by emailing director@heartlandirb.org.

Spanish: Este proyecto ha sido revisado y aprobado por Heartland Institutional Review Board. Preguntas sobre sus derechos como participante en esta investigación pueden dirigirse al Directo Ejecutivo de Heartland IRB. Oficina: (866) 618-HIRB [4472]; Fax: (866) 414-0517; o por correo electrónico: director@heartlandirb.org.

Take Home Hand Use Questionnaire

Please complete this questionnaire about your experience during the at-home prosthetic hand use session.

For the following questions, please indicate which hand ranked higher if any, and comment if desired.

	SynTouch	Personal	Same	Notes:
1. Which hand do you prefer?	_____	_____	_____	
2. Do you trust one hand over the other?	_____	_____	_____	
3. Which hand was faster to use?	_____	_____	_____	
4. Which hand requires less concentration?	_____	_____	_____	
5. Is it easier to multitask with one hand?	_____	_____	_____	
6. Which hand is easiest to use while grasping fragile objects?	_____	_____	_____	

1. **How do you compare your use of the SynTouch hand during the take-home session to your personal prosthesis before the study? Did you use it more, less, or the same amount?**

2. **Were particular tasks easier or harder with the SynTouch hand? Which ones?**

3. **What did you like about the hand? What did you dislike or find frustrating/difficult?**

4. **Please give general feedback about the hand, including improvements or changes you would like to see.**

Heartland Institutional Review Board

4226 Woodfield Place

Suite 100

Belleville, IL 62226

To Whom It May Concern,

As the lead hardware engineer (senior) I hereby attest that the prosthetic hand and associated electronics do not pose any electrical shock hazard to the end user. This applies to both operation and maintenance of the device.

The maximum applied voltage to the system is less than 8 Volts of direct current. A resistance of between 1.5kΩ and 1kΩ is used as an acceptable human reference value and would produce a current of between 5.3mA and 8mA. This current may be perceptible but would not produce a current flow that would induce a muscle reaction.

Thus, the device may be considered electrically safe.

Sincerely,

Neil Ragsdale
Senior Hardware Engineer

HAND ORDERING FORM & PRE-VISIT CHECKLIST

INFORMATION FOR HAND ORDERING

During this study, we will be creating a custom, experimental prosthetic hand for you to use during office visits and 1-month take-home sessions. This hand is a modified Otto Bock VPS hand and will be made at no expense to you. In order to make sure it is created correctly for you, please fill out the following table.

Note: it may be necessary to contact your prosthetist to obtain specific data. Please keep in mind all information provided is confidential and is used for the sole purpose of creating a prosthetic hand for you to use for the duration of the study.

Volunteer Name	
Prosthetic Hand Manufacturer	
Prosthetic Hand Model	
Prosthetic Hand Size	
Cosmesis Color Code	
Handedness (L/R)	

PRE-VISIT CHECKLIST

- ☐ Review study information and consent form
- ☐ Contact Jeremy Fishel or Gary Berke for questions, scheduling, directions, and arrival information
- ☐ Provide above information for hand ordering to Jeremy Fishel or Gary Berke via email, fax, phone, or mail as soon as possible for hand ordering
- ☐ Complete media questionnaire

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Appendix B

TO: Jeremy A. Fishel, PhD (SynTouch, LLC) & Gary M. Berke, MS, CP, FAAOP (Berke Prosthetics)
FROM: S. J. Maberry, Director
DATE: September 22, 2017
SUBJECT: VALIDATION OF REFLEX ENABLED MYOELECTRIC HAND FOR IMPROVED FRAGILE GRASPING
RE: Protocol review and approval of project designated HIRB No. 170921-168b

The Heartland Institutional Review Board (HIRB) is in receipt of all required documentation (dated September 19, 2017 and on digital file at the HIRB main office) and has completed the review process of the project: **VALIDATION OF REFLEX ENABLED MYOELECTRIC HAND FOR IMPROVED FRAGILE GRASPING**, research study, HIRB No. 170921-168b. This project has been funded by Congressionally Directed Medical Research Programs (CDMRP). The objective of the study is to observe, record, and compare how upper limb amputees use each of three different myoelectric prosthetic hands. Documentation provided meets the DHHS policy guidelines of CFR §46.116. As submitted, this research study has been approved and classified as follows:

[X] There is no more than minimal risk to the subjects. [ ] There is greater than minimal risk to the subjects.

This approval applies only to the proposal currently on file for a period of one year from date of approval as indicated by the date of this letter. If this study is to extend past said date, please complete an extension form available online from our website and submit no less than 30 days in advance of the one year deadline. Any changes in the study or protocol(s) that affect human subjects (the participants) must be reviewed and approved by HIRB prior to implementation. Injuries or any unanticipated events involving risk to human subjects (participants) or to others involved with the project must be reported within 10 calendar days to the HIRB Director in writing using the appropriate form available on the HIRB website. Also, note that all researchers/investigators involved in this research study/program evaluation must have on file with Heartland IRB either the Heartland IRB Human Subjects Assessment Certificate offered through the HIRB website or a HIRB-approved training completion certificate prior to engaging in this study. Use only the Heartland IRB approved protocols, consent/assent forms, and instruments for this research study.

Continue to include the HIRB approval statement (see below use either English or Spanish as needed) to Statement of Consent page of the Information and Consent Form as well as recruitment letter, recruitment flyer, media questionnaire and exit questionnaire:

a. English: This project has been reviewed and approved by the Heartland Institutional Review Board. Questions concerning your rights as a participant in this research may be addressed to the Executive Director at Heartland IRB. Office: (866) 618-HIRB [4472]; Fax: (866) 414-0517; or by emailing director@heartlandirb.org.

b. Spanish: Este proyecto ha sido revisado y aprobado por Heartland Institutional Review Board. Preguntas sobre sus derechos como participante en esta investigación pueden dirigirse al Directo Ejecutivo de Heartland IRB. Oficina: (866) 618-HIRB [4472]; Fax: (866) 414-0517; o por correo electrónico: director@heartlandirb.org.

Also, prior to the involvement of any human subjects (participants), properly executed consent/assent forms must be obtained from each subject and/or authorized representative following the HIRB-approved protocol. Such documentation of informed consent/assent must be kept on file and made available at any time to authorized HIRB representatives performing an on-site audit. Each participant must also be provided a copy of all consent/assent forms and project information materials for their own personal records.

Best wishes on the success of your research study.

Cordially,

S. J. Maberry
Director, Heartland IRB
director@heartlandirb.org

Tactile Sensing Reflexes for Advanced Prosthetic Hands

MR140094
W81XWH-15-1-0149

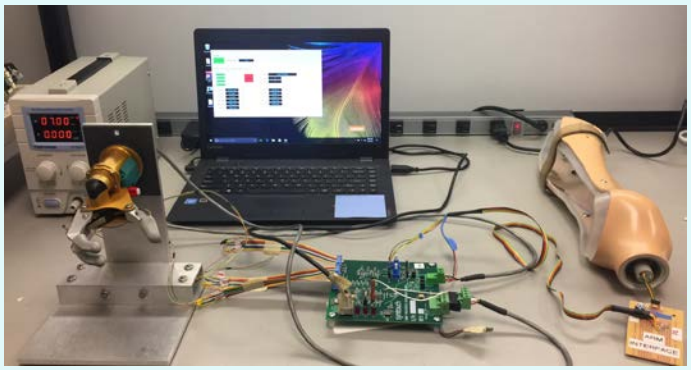
PI: Jeremy A. Fishel, PhD **Org:** SynTouch, LLC **Award Amount:** $1,865,449

Study/Product Aim(s)

- Build NumaTac Sensors that meet Commercial Requirements
- Build integrated prosthetic hand system for clinical studies
- Design outcome measures to evaluate clinical benefit
- Conduct in-office and in-the-field clinical studies
- Organize results for publication and documentation

Approach

Pilot studies have demonstrated that both compliance and contact sensitivity are critical to enabling prosthetic hands to grasp fragile objects. We have developed a tactile sensor which is low-cost and compliant. We will use this sensor to produce intelligent tactile reflexes that make grasping of fragile objects both reliable and intuitive. We will test these results by equipping military amputees with modified hands, performing clinical assessment, and monitoring performance at home.



Development board, hand, sensors, software and firmware connected and working as a cohesive unit.

Accomplishments: 1) Finish testing all prototype prosthetic fingers & identify ideal design, 2) Finalize electronics and verify miniaturization design, 3) Finalize clinical study submission documents, submit to and approved by IRB and 2nd level military IRB.

Timeline and Cost

Activities CY	15	16	17	18	19
Design, Build & Verify Sensors					
Build & Test Prosthetic Hands					
Design & Validate Outcome Meas					
Perform Clinical Studies					
Document and Publish Results					
Estimated Budget ($K)	**179**	**688**	**539**	**310**	**149**

Updated: Oct 29, 2017

Notes: Dashed lines indicate start/end, blue is current date. Budget shown for four year project over 5 calendar years.

Goals/Milestones

CY15 Goal – Hardware Prototype Development
- ☑ *Identify alternatives for outcome measures*
- ☑ *Explore sensor design parameters*

CY16 Goals – Complete Design of Equipment and Outcome Measures
- ☑ First NumaTac prototypes
- ☑ Final candidate outcome measures identified
- ☑ Final NumaTac design determined

CY17 Goal – Manufacture Equipment, Validate Measures, Start Clinical Studies
- ☐ Completion of prosthetic hand system
- ☑ Validation of outcome measures
- ☑ Clinical studies begun

CY18 Goal – Perform Clinical Studies
- ☐ Perform Clinical Studies

CY19 Goal – Complete Clinical Studies, Documentation
- ☐ Clinical studies completed
- ☐ Final documentation

Comments/Challenges/Issues/Concerns

Schedule to build and test prosthetic hands slightly behind, extended to EOY 2017 before we run into delays, can still work on IRB approval and recruitig.

Budget Expenditure to Date

Projected Expenditure: $1,320,040, Actual Expenditure: $1,082,745