AWARD NUMBER: W81XWH-15-1-0149

TITLE: Tactile Sensing Reflexes for Advanced Prosthetic Hands

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REPORT DATE: OCT 2018

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
OCT 2018	Annual	30 Sept 2017 – 29 Sept 2018

AND SUBTITLE
Tactile Sensing Reflexes for Advanced Prosthetic Hands

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-15-1-0149

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

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

16. SECURITY CLASSIFICATION OF: Unclassified			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
Unclassified	Unclassified	Unclassified	Unclassified	33	USAMRMC

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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 dexterity when grasping fragile objects. This technology is expected to improve the reliability and confidence when grasping fragile objects, thereby reducing the cognitive load associated with these difficult tasks. The battery life of the prosthesis is also anticipated to benefit 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 in able bodied subjects, and second, to test the product in the field with amputee 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:

What were the major goals of the project?

1. **Design and build a compliant and sensitive tactile sensor that meets the identified commercial requirements and specifications**
    a. Milestone: First NumaTac Prototypes. Target date 3/31/2016, Completed 3/31/2016
    b. Milestone: Selection of NumaTac design for study. Target date 6/30/2016, Completed 9/30/2017
2. **Design, build, and test prosthetic hand system to be used in clinical studies**
    a. Milestone: Completion of prosthetic hand system. Target date 1/31/2017, Completed 6/11/2018
3. **Design and validate novel outcome measures for evaluating fragile grasping and cognitive load**
    a. Critical Step: IRB and Military 2nd level IRB approval or exemption for outcome measure validation. Target date 12/31/2016, Completed 6/29/2016
    b. Milestone: Outcome measures for fragile grasping and cognitive load developed and validated. Target date 3/31/2017, Completed 1/23/17
4. **Conduct in-office and in-the-field clinical studies**
    a. Critical Step: IRB and Military 2nd level IRB approval. Target date 9/30/2017, Completed 4/27/2018
    b. Milestone: Clinical studies completed. Target date 4/30/2019, 50% complete
5. **Organize results for publication and documentation**
    a. Academic publications, 2 of 3 planned, 1 of 3 completed

b. Milestone: Final documentation released. Target date 9/30/2019, 0% complete

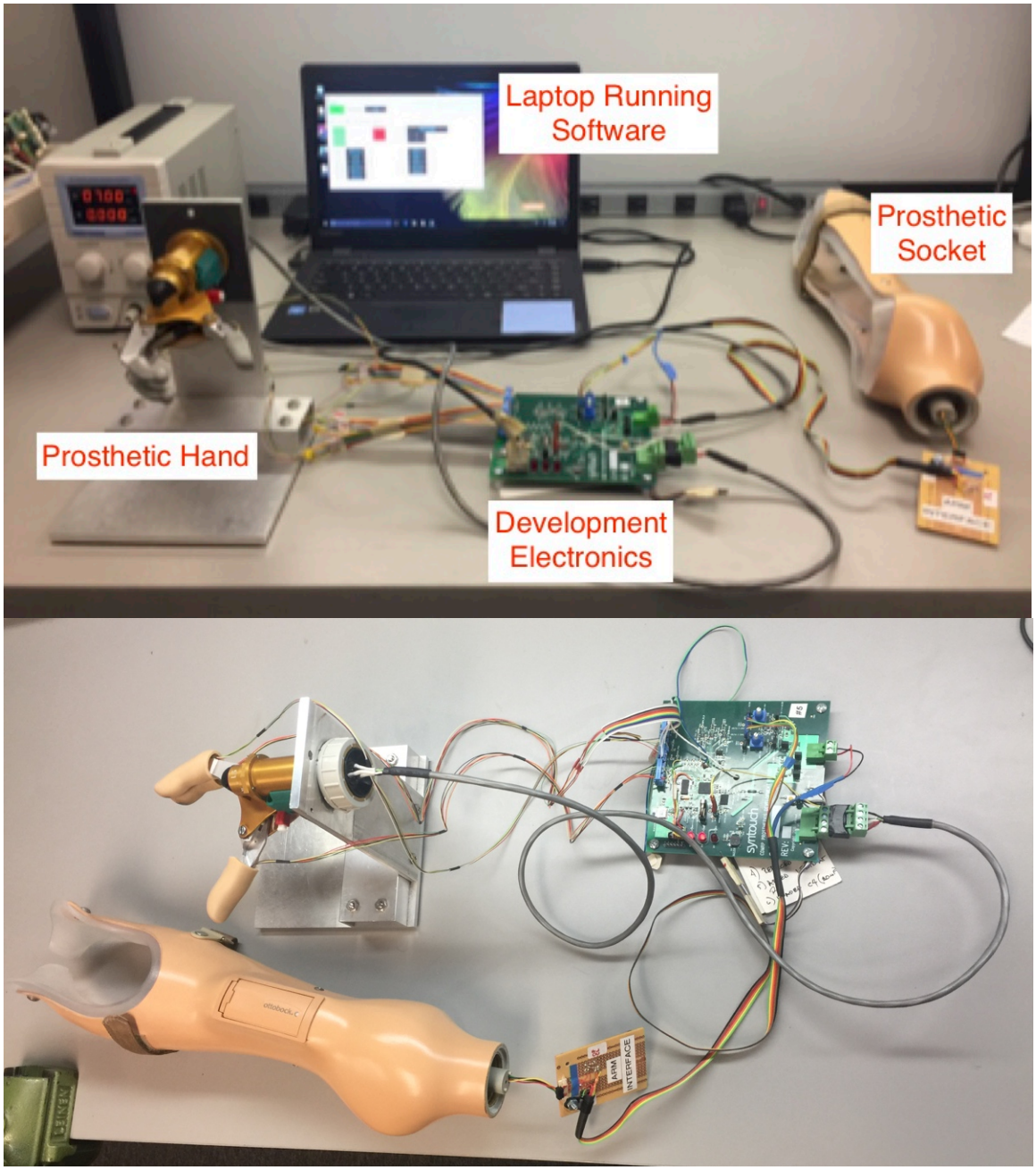
What was accomplished under these goals?

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

Final Prosthetic Hand Design Sent to Production
In the conclusion of year-2 we demonstrated final design decisions to build the final prosthetic hand, sensors, controllers and flexible circuits. A substantial portion of effort in year 3 has been focused on the final engineering to permit for the production of all components, which we are pleased to report is complete. More details relating to specific components in this design are discussed below.

Robustness Field Testing Completed
As an additional measure of robustness testing, prior to starting clinical studies, we took a prosthetic hand that had our sensors installed (without electronics or reflex) for in-field robustness testing. The hand was worn for 2 months straight by Vikram Pandit (key personnel on this project, who is also an amputee) and was instructed to use as a normal prosthetic hand and encouraged to even be a little rough with it. Without the reflex enabled the sensors would be exposed to greater forces and wear over this period. After 2 months, the hand was inspected for any damage and connected electrically to our testbed system to evaluate performance and we are pleased to report that the sensors did not see any damage or loss of function in this testing, further solidifying our confidence in the robustness of this design.

Reflex False-Triggering Investigated and Strategies to Mitigate Put in Place
As the number of available components for the completed system increased we continued performance testing on our testbed with these systems, which includes a prosthetic hand, sensors, electronics and all components in a benchtop configuration (pictured below)



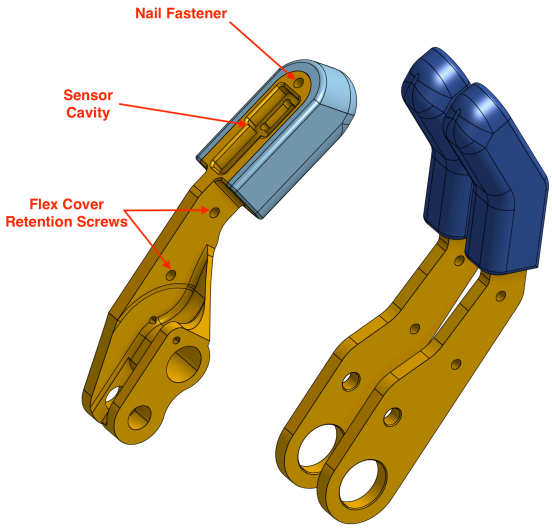
Reflex Testbed

In this continued testing, we also evaluated a hand with a full cosmesis on and noticed some anomalies and false-triggering of the reflex at medium speeds indicating that contact had happened when it had not. This was not observed before as we have never had an unmodified cosmesis fully assembled, but since this is how the final system was configured it was cause for concern. In our continued evaluation we developed two possible causes of the false triggering, either A) the pressure inside the cosmetic glove (now fully sealed) was increasing with the motion of the cosmesis or B) the fingertips, now undergoing the strain of the glove when moving, were tugging on the sensors and being misclassified as contact. On a

deeper inspection we had concluded that both were playing a role. To rectify for pressure increases in the glove, we have included a reference sensor to measure total glove pressure that can be used to cancel out pressure increases in the glove. To rectify strain from the cosmesis, we have modified our sensors to permit for a nail-like fixturing screw to hold the cosmesis in place at the fingertip. *As discussed below, we ultimately discovered that the source was due to pressure increases inside the glove and we have made corrections in firmware to mitigate the anomaly and achieve satisfactory performance.*

Sensor Engineering Completed & Sent to Production

As the previous report solidified design concepts of the sensors and materials to be used, progress in this report consisted of final engineering of the devices for production. Several improvements were made to the design to address issues with false-triggering and general production improvements to make the attachment of the pressure sensor and circuit more robust. CAD drawings of the sensors with notes are shown below:



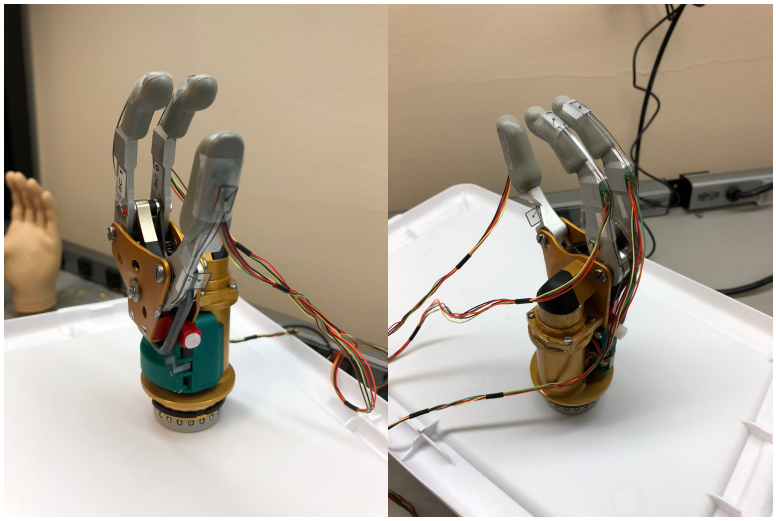
Final Sensor Designs, Thumb (left) and Fingers (right)

Of the design features, we have included a nail fastener screw that serves several functions, as follows: 1) It permits the cores (gold parts) to be fastened into the foam molding cavity firmly to minimize flashing in the over-molding process, 2) It allows for a fixture point when bonding the pressure sensor in place to ensure a tight seal while the epoxy cures, and 3) it serves as a fail-safe if our efforts in minimizing false-triggering as discussed above and allows the skin to be pinned down to the sensor without movement.

These final designs have been sent out to our partners at Foam Molders who specialize in foam overmolding and are currently in the process of being quoted for production.

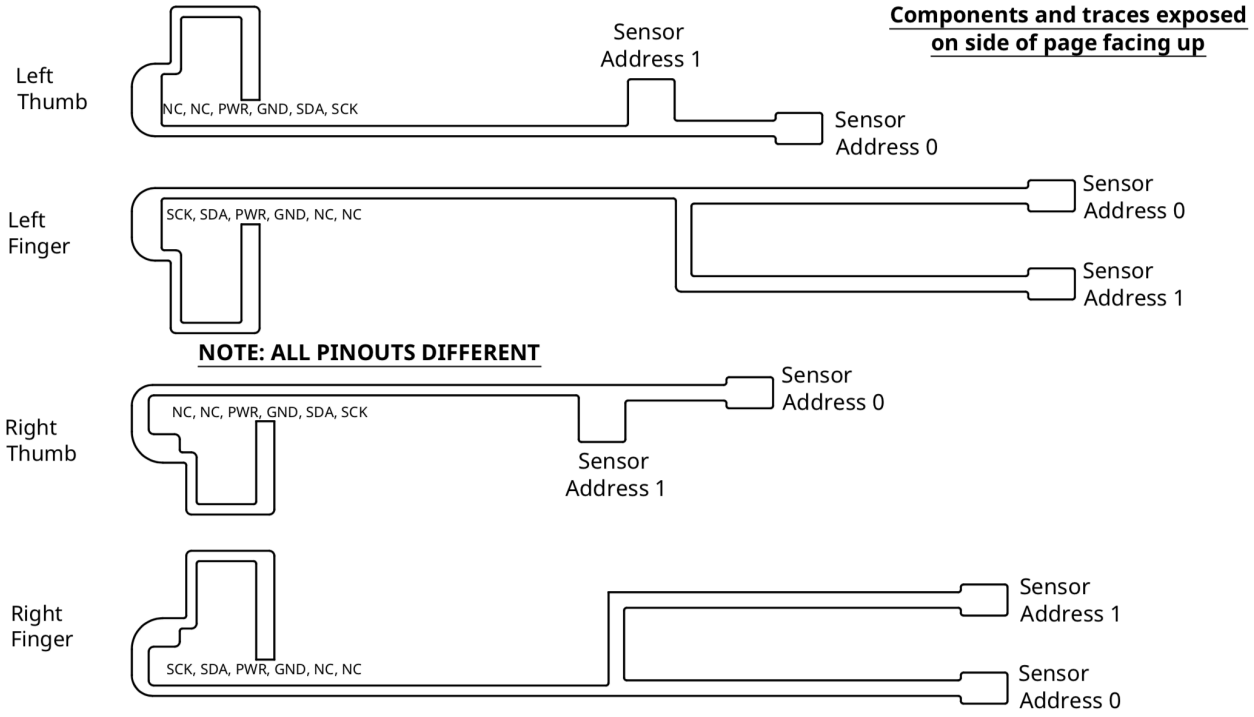
Firmware Revision to Support SPI to I2C Conversion on Sensor Data
As the development of flexible circuits were underway (discussed below), we realized that we needed to make a change from a 6-lead SPI configuration for the pressure sensors to a 4-lead I2C configuration to resolve complications with flexible cable routing. This was done to match the existing 4-lead flexible circuits designed for passage through the gears in the Ottobock hands, which have been demonstrated to work in the field for this product. Not wanting additional risk to the success of this circuit, a decision was made to convert to I2C protocol. Fortunately, this was a very minimal effort change do to good modular coding practices in our firmware development and only required a new module for I2C communication to implement and minimal electronics changes to re-route the SPI and I2C lines on the controller. As part of this, the memory module which was previously on the I2C line of our controller was converted to an SPI module to use the now freed SPI line. All changes were implemented in the electronics and firmware simultaneously and worked on the first attempt. As part of the validation the reflex performance and datalogging were also validated and worked without issue.

Flex Circuit Engineering Completed & Sent to Production
Designs were made for the I2C circuits for the finger and thumbs for both left-hand and right-hand configurations. This was an iterative process that involved many measurements, printing those shapes on transparency film and carefully cutting out with a scalpel for assembly and testing as pictured below:



Flex Circuit Prototyping

Final dimensional drawings were made for production flexible circuits:



Production Circuits

Several design features were incorporated into these circuits. The first, to conserve board space on the final controller, these circuits were configured to go into the same connector, one facing up and one facing down. Separate I2C lines were needed for the fingers and thumbs, but power was shared. The pads where the sensors sit have a small 2mm edge that permits for adequate bonding to the core. These final designs were tested for many cycles without issues. They have since been sent for fabrication and as discussed below the final parts worked as designed.

Data-Logging Functions Completed & Verified

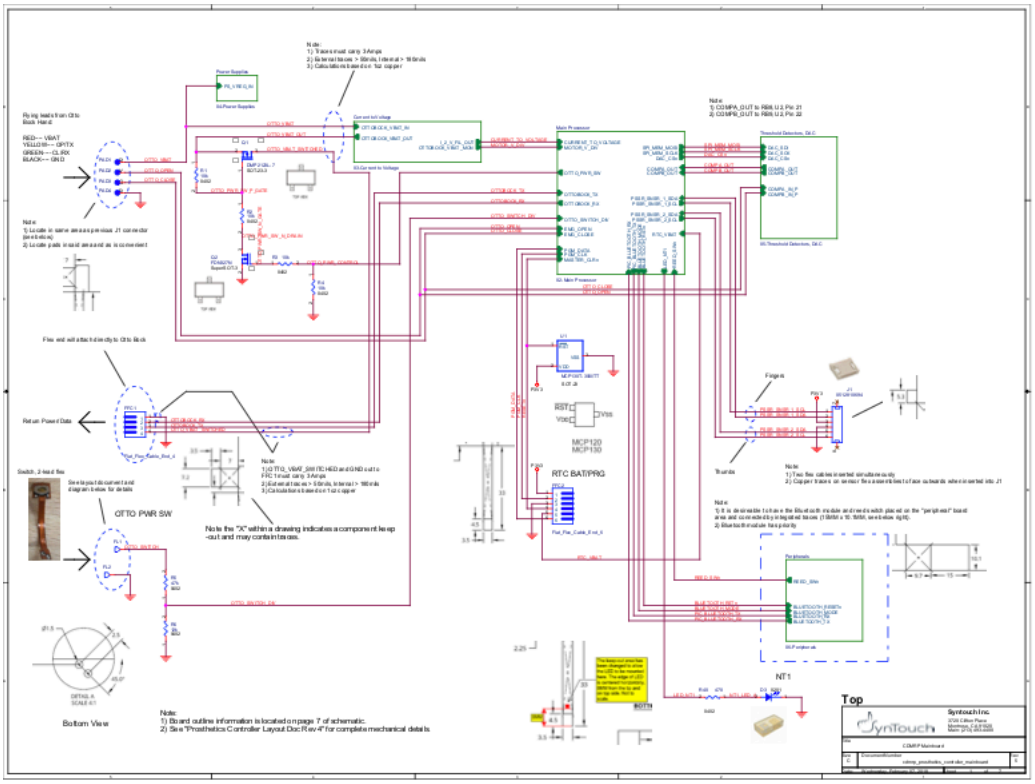
As part of the design specification, the controller is to log the following data:

- 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)

These have all been tested and validated in the firmware of our development electronics before sending to final production. Additionally, the storage structure of this information was optimized to ensure maximum compression. The memory also was upgraded from 16MB to 32MB to support up to 4 months of continuous logging under normal usage (the maximum anticipated for future clinical studies). Additional features included a dual-pointer addressing informing the controller of where the next write should be. This is toggled between two memory locations as a fail-safe in case of power-loss and corruption of the write data as well as the pointer. This has been stress tested and found to be reliable for sudden power loss.

Final Electronic Circuit Design Signed Off On

The above-described changes and others were incorporated into the final flexible circuit schematic (below) which was reviewed by four of our engineers in detail including the ones working on electronics layout, firmware development, sensor design and testing, and the PI. This signed off circuit has been prepared with the layout document (discussed below) and sent to production.

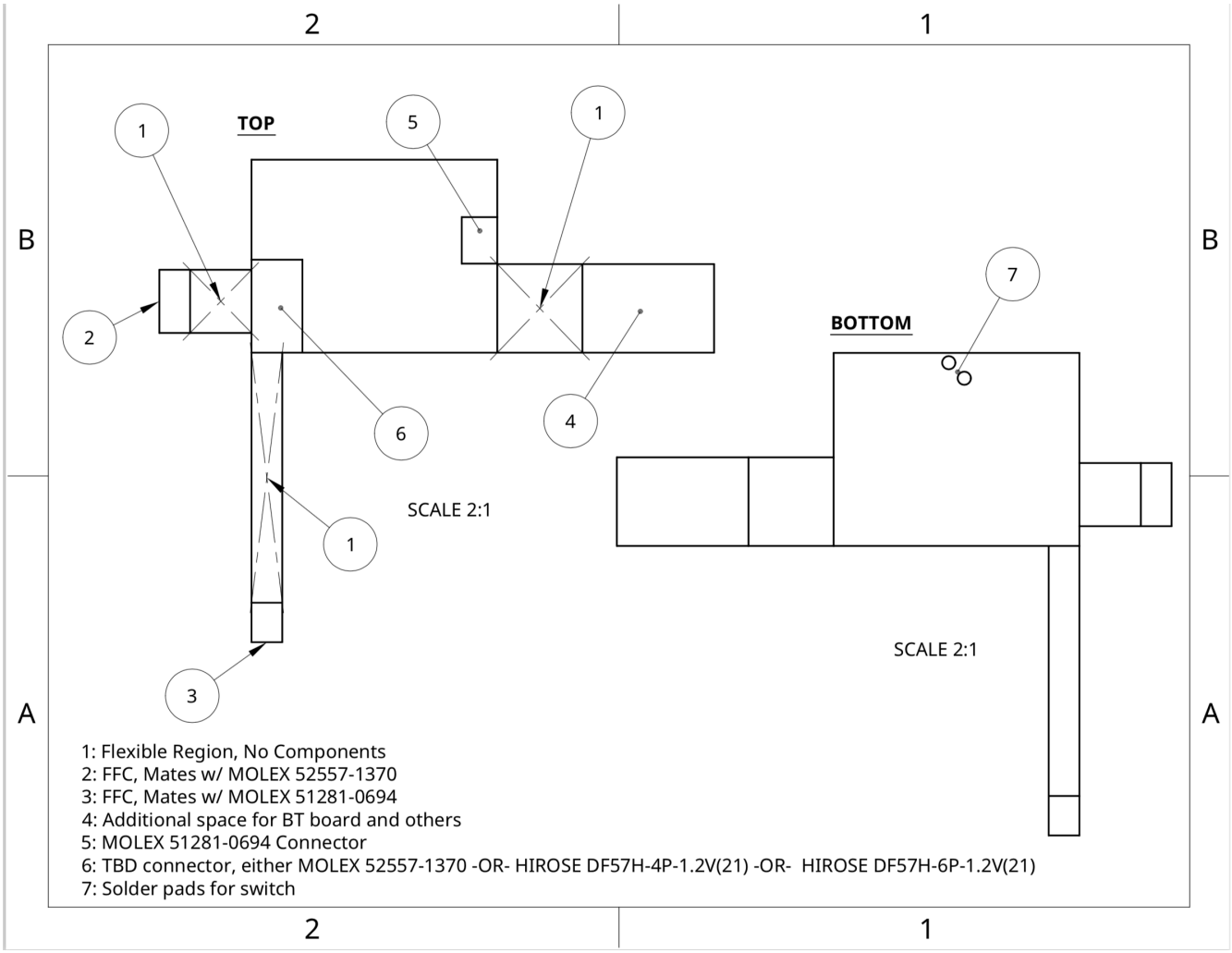


Final schematic overview

Controller Layout Finalized & Sent to Production

During this reporting period we needed to make a major change to the architecture of the electronics circuit from PCB with connectors to an all-flex design without connectors. This was done as all of the components could not fit into the final controller housing and the connectors needed to be removed. While this introduces

additional costs, it permits for reduced costs of redesigning the housing, which has been proven to be robust in the field. Several design iterations were made and several variants of this circuitry were considered before settling on the final layout as shown below.



Final all-flex circuit layout for the controller.

Several features were included in this design to minimize the number of connectors. The first is the flexible circuit power-data out that connects directly into the ZIF of the Ottobock hand with no additional cabling, connectors and wiring (bullet 2 above). The second is a flexible battery connector that exits the housing and routes along the backside to the location of where we are attaching the battery. This will be inserted into a small PCB to which the battery is connected (bullet 3 above). The next is an overflow region (bullet 4 above) for additional components that is folded up on the main controller inside the housing, this is where the Bluetooth communication module and reed switch to enable the Bluetooth will reside. The switch of the Ottobock hand was also routed to our controller (bullet 7 above) to allow the controller to go into standby mode and conserve power, this is directly

soldered on our controller. As the sole connector (bullet 5 above), the dual I2C lines will connect to the finger and thumb sensors.

These finalized layout designs along with schematics and BOM have been sent to production for final layout, manufacturing and assembly.

Bluetooth Bootloader Development
As we have already established Bluetooth communication for datastreaming, the development of a full Bluetooth bootloader was seen as low risk addition with a lot of potential upside, permitting firmware upgrades without completely disassembling the hands and will be a good fail-safe for resolving any issues encountered in the field. The design was implemented and tested comprehensively and has been verified to work as designed.

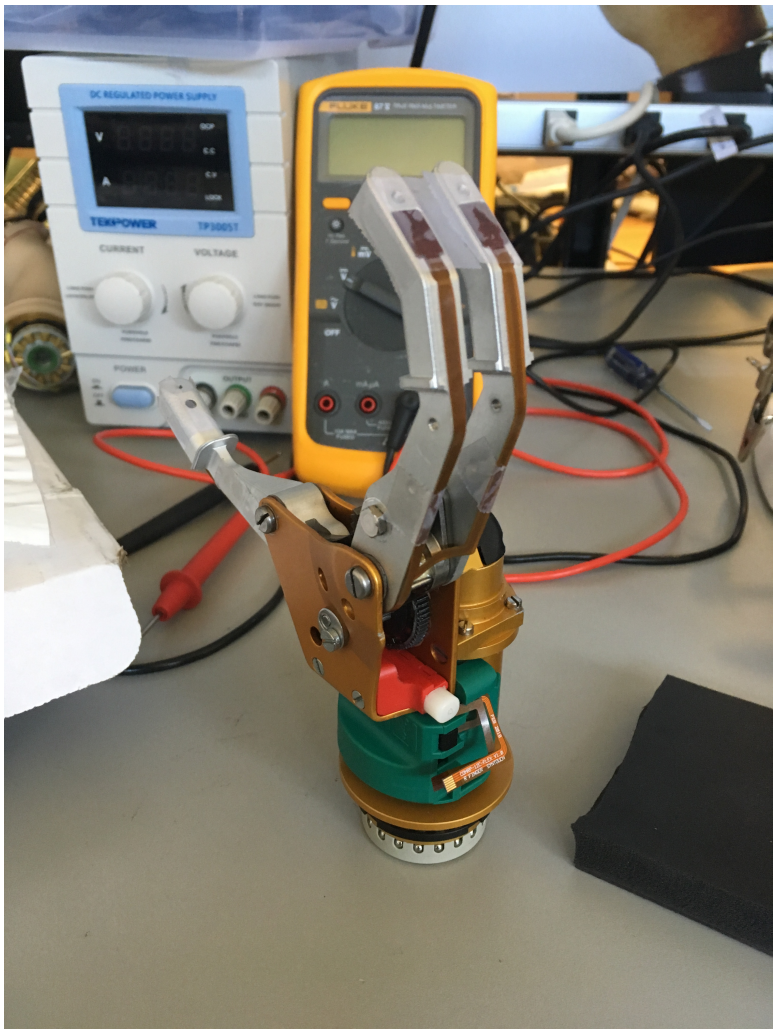
Final Prosthetic Hand Design Reviews with Vendors
As part of the effort to finalize electronics, changes to the main board design included the addition of an auxiliary board to connect the battery and programming pins in an accessible location at the backside of the controller housing. This was measured and prototyped with mechanical components to ensure fit and specify appropriate tolerances. Final auxiliary boards were designed and electronics layout was completed then sent to production over the course of 1 week to ensure schedule and receipt of the final product is expected to align with the receipt of the main controller boards.

The main controller boards had many design iterations between our engineer working on the layout and the fabrication house. Due to tight space requirements we had to iterate from a rigid board to a flexible circuit to minimize the use of connectors and accommodate production capabilities. This was a demanding design but we are pleased to report that we have sent for production and anticipate a successful build that fits within the tight space inside the existing prosthetic controller housing.

Evaluating of Received Components
We have received prosthetic hands and cores of the fingers as well as flexible circuits from vendors and have assembled the devices to confirm the complete mechanical function and fit of the device, including the complex routing of flexible circuits and are pleased to report that everything has worked mechanically as designed. Electrically, there was a minor issue with the I2C communication between the pressure sensors of the flexible circuit, but this was quickly identified and resolved with a just-in-time change of the loading resistor on the main controller board in production. We anticipate no further complications with the remaining non-mechanical components.

Of the received components including sensor cores, flexible circuits and prosthetic hands we were able to verify mechanical fit and that the routing of the flexible circuits worked as design passing through the center of the hand and gearing

systems without getting damaged. We anticipate no remaining mechanical issues with the final system.



Final mechanical assembly demonstrating fit of the sensor cores and flexible circuits through the gear housing

On receipt of the flexible circuits electrical function was tested and a loading issue with the I2C lines was observed on the flexible circuits on the finger side of the hand. This was identified and debugged and the loading resistor on the final controller was changed and observed to work on our development electronics. We were able to make this change just-in-time without production delays of the electronics which were in production while the issue was identified and resolved.

Final Prosthetic Hand Hardware Completed and Validated

We are very pleased to report that the final prosthetic hand with all integrated features was completed in this reporting period. The detailed design and review effort put forth by the project's engineers led to a well-made system that worked on the first design iteration. In summary, this design effort consisted of:

- Custom NumaTac foam sensors that meet robustness and performance requirements outlined in the project objective.
- Custom flexible cabling from the sensors to controller that route through the prosthetic hand's gearing system without damage.
- Protective covers for the flexible circuits on the dorsal surface of the fingertips.
- A customized electronics controller to collect data from the sensors and power/EMG inputs from the prosthetic socket to perform the reflex algorithm, communicate with a computer via Bluetooth once the cosmesis is installed, as well as a number of logging functions as outlined in the project objective.
- Firmware to implement the desired functions with customizable parameters to fine-tune the reflex and performance, to store usage data in a log that can be downloaded via Bluetooth, and a Bluetooth bootloader allowing for firmware updates without needing to remove the cosmesis.
- Miniaturization of the customized electronics controller to fit inside the original housing of and with the existing prosthetic hand controller.
- Various customized covers for to protect components including the electronics housing, accessory battery, and auxiliary board.

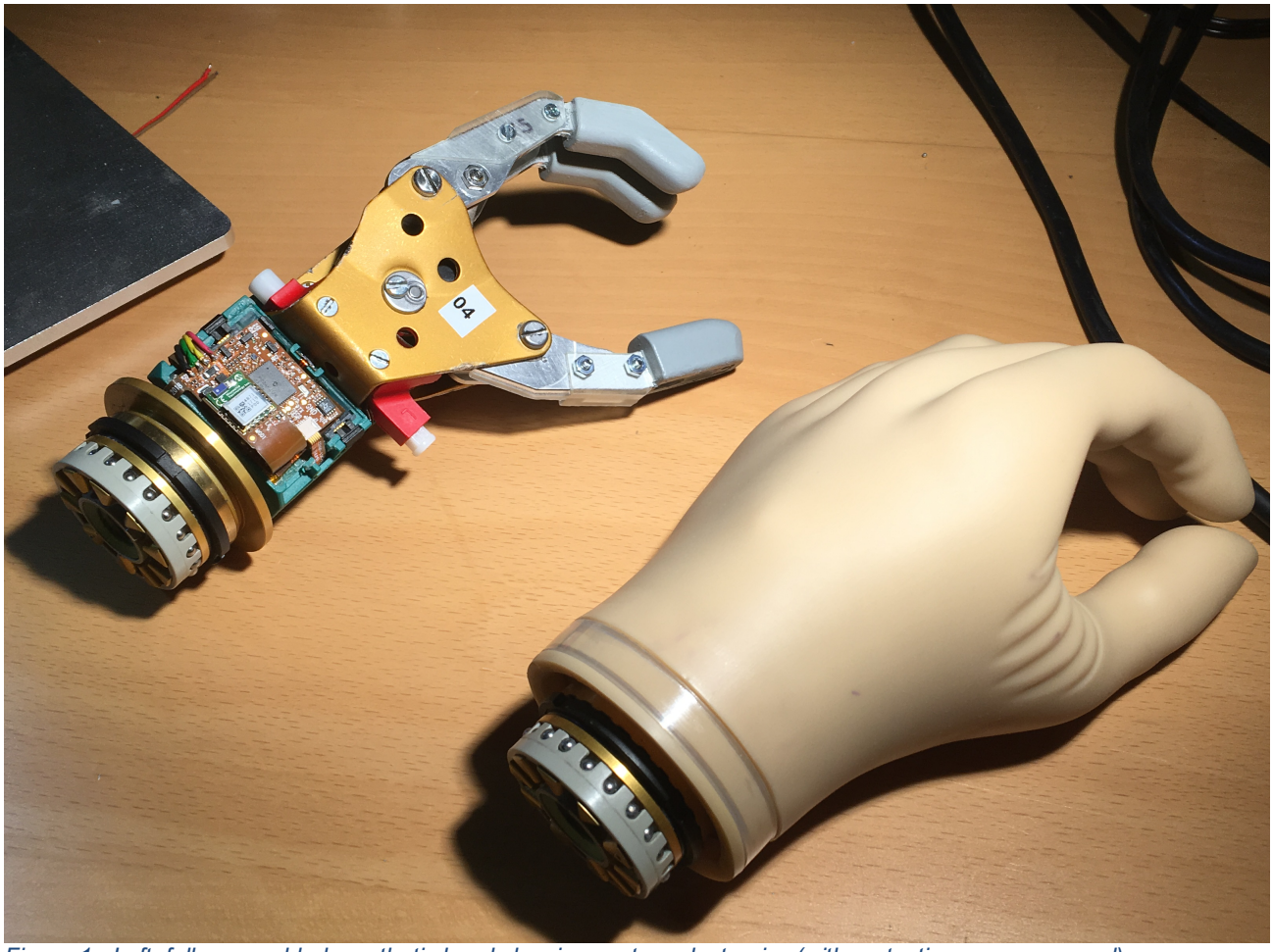


Figure 1 - Left: fully assembled prosthetic hand showing custom electronics (with protective cover removed), sensors, cable covers and wiring. Right: A second fully assembled prosthetic hand with the cosmesis installed.

The entire system has been tested for 2 weeks of usage for burn-in with no major problems identified and was released for use in clinical studies. As of this reporting period, we have built 5 prosthetic hands **and are pleased to report the design components of this major task and specific aim complete**.

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

IRB & HRPO Approval

During year 3, the clinical study, "Validation of Reflex Enabled Myoelectric Hand for Improved Fragile Grasping," (which was previously reviewed and approved by Heartland IRB) was reviewed by HRPO. HRPO requested additional information to continue with the review, which was provided. HRPO then competed the initial administration review and consolidated the necessary documents and alterations to the protocol. These changes included a HIPAA authorization form, device determination from the primary IRB, and changes to the protocol and consent form. Changes to the submission documents were made and a dialogue took place

between HRPO, SynTouch, and the IRB in order to determine the process, schedule, and requirements for a device determination. A summary and supplemental documents were provided to the IRB for review and a full board convened, determining that the device in question is a non-significant risk device that does not need an IDE application prior to beginning the study. Final approval of this study took much longer than expected due to long communication delays and many back and forth meetings with IRB and HRPO related to device safety. However, we ultimately received full approval by both IRB and HRPO to proceed in Y3 Q3.

Team Preparation for Clinical Studies
In preparation for clinical studies and just before HRPO approval, we started bi-weekly meetings to ensure alignment of deliverables between our clinical partner Gary Berke and SynTouch engineers. Topics of these meetings include hardware progress and outstanding issues, IRB/HRPO approval status, coordinating logistics for patient outreach once approval is received, finalizing details of clinical studies, and discussing progress of the publications under development and related new research.

Final Engineering/Clinical Team Review of Clinical Studies & Critical Risks
Prior to the start of the clinical studies we arranged for a final engineering and clinical team review to go over the entire project's progress and identify any potential issues. We were fortunate enough to involve all employees whom have ever worked on this project, including three who played major roles on this project, but were no longer primarily employed with SynTouch (Kelsey Muller, Vikram Pandit and Blaine Matulevich) for a very productive project review. Several potential improvements to the software and firmware as well as strategies to implementing the clinical protocol were identified in these meetings.
during in-office and take-home studies.

Initial Subject Outreach
Through initial outreach efforts, Clinical Investigator Gary Berke managed to connect with five subjects interested in participating in the study and have been provided with consent forms and materials to review.

<u>Major Task 4-2: Conduct clinical studies</u>

Clinical Studies Started
We are also pleased to report that our clinical studies have begun with our first subject beginning testing on 6/25/2018 and 4 other subjects in the pipeline. At the moment our plan is to first take these 5 subjects through the entire clinical study process before starting a second tranche of 5 subjects to better manage scheduling and team bandwidth.

<u>Major Task 5-1: Prepare academic submissions and documentation</u>

A conference proceedings to ICRA was submitted on preliminary findings based on the technology developed and studied in this project and also included pilot clinical studies done in a previous project with NIH. The full publication is included in the attachments and the abstract can be found below:

> Myoelectric prosthetic hand users have difficulty grasping fragile objects with their prosthesis and tend to avoid these objects altogether. The objective of this study was to implement tactile sensors into a myoelectric prosthetic hand and evaluate a reflex that inhibits the closing of the hand when contact is detected. The tactile sensors were made from a robust open-cell self-skinning polyurethane foam further sealed with an elastomer coating. When the sensor is touched, increases in air pressure inside the foam can be detected by a transducer and processed by the reflex controller. This design allowed for the compliant and sensitive measurement of contact as well as an improved rejection of vibration noise from the motors. Four unilateral myoelectric prosthesis users completed five trials of three different timed grasping tasks with fragile and rigid items. Subjects performed each task in each of three scenarios: with their sound side limb, their current myoelectric hand, and the modified prosthesis. Findings demonstrated that grasping performance with fragile objects was significantly enhanced using the modified prosthesis, even nearing the performance of subject's sound side limb. Results suggest that this approach can substantially improve the speed and success of grasping fragile items, leading to improved use patterns, decreased cognitive effort, and improved user confidence.

Our initial plans were to also submit a separate study on the clinical outcome measures developed in this project, but after a thoughtful team review, we concluded it would be best to combine this outcome measures study with the final clinical study in a more comprehensive and impactful journal article.

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 opportunities.

How were the results disseminated to communities of interest?

The following publications were submitted for peer review covering various aspects of technology developed and research conducted under this project:

- J.A. Fishel, B. Matulevich, K.A. Muller, G.M. Berke, "The (Sensorized) Hand is Quicker than the Eye: Restoring Grasping Speed and Confidence for Amputees with Tactile Reflexes, Submitted to the International Conference on Robotics and Automation (ICRA) for 2019.

A number of lectures and conference presentations were given covering various aspects of this research and development:

- October 25, 2018, "Tactile Sensing for Robotic Dexterity", J.A. Fishel, Accepted Talk, Collaborative Robotics, Advanced Vision, and AI (CRAV.ai), Santa Clara, CA
- August 23, 2018, Updates on Project Status to Ottobock Healthcare (video conference)
- April 22, 2018, "Getting a Feel for Grasping", J.A. Fishel, Guest Lecture, California State University, Chico, CA
- February 6, 2018, "Shaking Hands with the Future: Synthetic Touch in Bionics", J.A. Fishel, Invited Keynote, Medical Devices & Manufacturing (MD&M), Anaheim, CA
- Berke, et al., "Contact Reflex Improves Fragile Grasping while Blindfolded," American Academy of Orthotists & Prosthetists 2017.
- July 15, 2017, "Applications in Touch: Dexterity and Perception", J.A. Fishel, Invited Talk, Robotics: Science and Systems (RSS), Cambridge, MA
- June 6, 2017, "The Future of Machine Touch", J.A. Fishel, Guest Seminar, Georgia Tech, Atlanta, GA
- May 9, 2017, "Development of a Prosthetic Hand Outcome Measure, Fragile Grasping with Cognitive Distraction", G.M. Berke, Accepted Talk, International Society of Prosthetics and Orthotics, International Symposium (ISPO), Cape Town, South Africa
- March 2, 2017, "Does Contact Detection Reflex Improve Fragile Grasping While Blindfolded", G.M. Berke, Accepted Talk, American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium (AAOP), Chicago IL
- October 17, 2016, "Advanced Tactile Sensing Technology for Robotic Hands", Invited Seminar, National Institute of Standards and Technology, Gaithersburg, MD
- August 21, 2016, "Tactile Sensing and Collision Management in Robotic Grasping", J.A. Fishel, Invited Talk, Conference on Automation, Science and Engineering (CASE), Workshop on Robotic Hand Technologies and Performance, Fort Worth, TX
- April 8, 2016, "Tactile Sensing Reflex Reduces Need for Visual Feedback when Grasping Fragile Objects with a Prosthetic Hand," K.A. Muller, Haptics Symposium 2016.
- March 10, 2016, "Contact Detection Reflex to Improve Fragile Item Grasp in Myoelectric Prostheses: A Novel Technology", G.M. Berke, Accepted Talk, American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium (AAOP), Orlando FL

The technology was demonstrated to the public at the following events:

- October 13-14, 2018, WIRED Magazine's 25th Anniversary, Robotic Petting Zoo, San Francisco, CA
- August 24, 2017, SynTouch Open House, Montrose, CA
- April 8-11, 2016, Haptics 2016, Philadelphia, PA

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

Over the remaining year, efforts will be spent to accomplish the following remaining goals:

1. Complete recruitment targets (Gary Berke). To reach the target of 10 subjects we will advertise and promote this study on various online groups, and reaching out to clinicians in neighboring communities. Through the entire project, clinical investigator, Gary Berke has maintained contact with the VA to push the approval of this study through their organization, and this may soon be approved as an additional recruitment source.
2. Manufacture, test, monitor and repair all clinical hands to be used in this study. Hands are individually customized for each subject and go through an extensive testing and validation process before they are deployed in a study. At each office visit the hand is inspected for damage and evaluated.
3. Continue conducting clinical trials through the end of the study.
4. Analyze results and prepare journal article outlining the study's findings
5. Prepare technical material and documentation to education manufacturers and clinicians of the new technology.

4. 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.
- 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.

- Finally, the development of an integrated controller with logging functions on long-term usage statistics will be a critical tool for completion of this study and could potentially benefit others in the same discipline who may want to use this hardware in their own studies.

What was the impact on other disciplines?

- Methods and approaches used to achieve rapid, reliable and fragile grasping in prosthetic hands as developed under this project, have potential to translate generally to the field of robotics as a whole and could benefit collaborative robots.

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. We are currently in mid-level talks with Ottobock, the leading prosthetic hand manufacturer as well as introductory talks with their leading competitor Ossur.
- It is anticipated that if the distraction method outcome measures are demonstrated to be effective in a clinical setting with amputees that 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.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

The following minor changes in approach from the stated project plan were made:

- Rather than paying an outside agency for performing the ACMC evaluations for clinical studies as planned, we decided to repurpose this budget towards the ACMC certification of Clinical Investigator, Gary Berke, so that he could perform

these evaluations himself. This allowed our team to have a greater understanding of this outcome measure and improved confidence in efficiently conducting these evaluation metrics in a clinical setting. This minor change in budget category was discussed and approved with Grants Officer Troy Turner.

- After planned reviews of final clinical studies as outlined in the statement of work, we ultimately decided to not include the SHAP testing metric in clinical studies in the interest of reducing the total length of office visits. After being evaluated by our clinical investigator, Gary Berke, and discussing with other clinicians, we determined that the ACMC was a better measurement of activities of daily living and held in higher regard by the academic and research community. The remaining budget for the 2nd SHAP system was repurposed to general materials and supplies. This was discussed and approved with Grants Officer Troy Turner.
- After discussions with our clinical investigator and discussions with other clinicians, it was decided that it would be best to use naturally occurring objects (such as crackers) for fragile grasping tasks, rather than using a "mechanical egg" as originally planned. It was proposed that the visual and cognitive associations subjects have with object strength would be critical in achieving performance. The remaining budget for these components were repurposed to general materials and supplies. This was discussed and approved with Grants Officer Troy Turner.

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

- There was an unanticipated delay throughout the study in the manufacturing of the integrated prosthetic hand, which did not take into consideration ample design iterations to achieve performance and better understand the requirements for final system development. To get the best development effort with available time, we decided to work backwards and determine when the hands were needed and what milestones needed to be hit and at what schedule to meet those deadlines. To ensure proper alignment with budget and progress in the presence of longer-than-expected lead times, the development effort was distributed over an extra year beyond what was planned, which was determined to be suitable to meet deliverables. This was discussed and approved with Grants Officer Troy Turner.
- For budgetary reasons, it became more practical to recruit subjects then order and build an appropriately sized hand for them, rather than the original plan of building hands, then recruiting subjects. This was due to the fact that both left and right hands exist in small/medium/large sizes, so to minimize inventory and cost, hands were ordered and built on demand.

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.

6. PRODUCTS:

Publications, conference papers, and presentations

Journal publications:

- J.A. Fishel, B. Matulevich, K.A. Muller, G.M. Berke, "The (Sensorized) Hand is Quicker than the Eye: Restoring Grasping Speed and Confidence for Amputees with Tactile Reflexes, Submitted to the International Conference on Robotics and Automation (ICRA) for 2019. In Review. Federal support acknowledged.

Other publications, conference papers, and presentations.

- October 25, 2018, "Tactile Sensing for Robotic Dexterity", J.A. Fishel, Accepted Talk, Collaborative Robotics, Advanced Vision, and AI (CRAV.ai), Santa Clara, CA
- August 23, 2018, Updates on Project Status to Ottobock Healthcare (video conference)
- April 22, 2018, "Getting a Feel for Grasping", J.A. Fishel, Guest Lecture, California State University, Chico, CA
- February 6, 2018, "Shaking Hands with the Future: Synthetic Touch in Bionics", J.A. Fishel, Invited Keynote, Medical Devices & Manufacturing (MD&M), Anaheim, CA
- Berke, et al., "Contact Reflex Improves Fragile Grasping while Blindfolded," American Academy of Orthotists & Prosthetists 2017.
- July 15, 2017, "Applications in Touch: Dexterity and Perception", J.A. Fishel, Invited Talk, Robotics: Science and Systems (RSS), Cambridge, MA
- June 6, 2017, "The Future of Machine Touch", J.A. Fishel, Guest Seminar, Georgia Tech, Atlanta, GA

- May 9, 2017, “Development of a Prosthetic Hand Outcome Measure, Fragile Grasping with Cognitive Distraction”, G.M. Berke, Accepted Talk, International Society of Prosthetics and Orthotics, International Symposium (ISPO), Cape Town, South Africa
- March 2, 2017, “Does Contact Detection Reflex Improve Fragile Grasping While Blindfolded”, G.M. Berke, Accepted Talk, American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium (AAOP), Chicago IL
- October 17, 2016, “Advanced Tactile Sensing Technology for Robotic Hands”, Invited Seminar, National Institute of Standards and Technology, Gaithersburg, MD
- August 21, 2016, “Tactile Sensing and Collision Management in Robotic Grasping”, J.A. Fishel, Invited Talk, Conference on Automation, Science and Engineering (CASE), Workshop on Robotic Hand Technologies and Performance, Fort Worth, TX
- April 8, 2016, “Tactile Sensing Reflex Reduces Need for Visual Feedback when Grasping Fragile Objects with a Prosthetic Hand,” K.A. Muller, Haptics Symposium 2016. *
- March 10, 2016, “Contact Detection Reflex to Improve Fragile Item Grasp in Myoelectric Prostheses: A Novel Technology”, G.M. Berke, Accepted Talk, American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium (AAOP), Orlando FL

** Produced a manuscript*

Website(s) or other Internet site(s)

- http://research.syntouchinc.com/ - website used for recruitment materials or forms.

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.

6. 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: 6.5
Contribution to Project: Dr. Fishel has coordinated all design review and project planning meetings to complete specific aims and worked alongside team to ensure progress and took the lead on engineering and production of prosthetic hands to be used in the study.

Name: Gary Berke
Project Role: CI
Nearest person month worked: 2.8
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: Vijay Anandani
Project Role: R&D Engineer
Nearest person month worked: 4.9
Contribution to Project: Mr. Anandani has worked on the durability testing and sensor fabrication and analysis of results and assisted with electronics layout and validation.

Name: Neil Ragsdale
Project Role: Electronics Engineer
Nearest person month worked: 1.5
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: 1.3
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.

Name: Kelsey Muller
Project Role: R&D Consultant
Nearest person month worked: 0.3

Contribution to Project:	Ms. Muller consulted on IRB/HRPO and clinical studies submissions and requirements.
Name:	Blaine Matulevich
Project Role:	R&D Consultant
Nearest person month worked:	0.05
Contribution to Project:	While no longer currently employed with SynTouch, Mr. Matulevich joined the clinical and technical teams for a final kick-off meeting before starting clinical studies, which involved all parties whom have worked on this project to review potential risks and threats to the project's success.
Name:	Vikram Pandit
Project Role:	R&D Consultant
Nearest person month worked:	0.05
Contribution to Project:	While no longer currently employed with SynTouch, Mr. Pandit joined the clinical and technical teams for a final kick-off meeting before starting clinical studies, which involved all parties whom have worked on this project to review potential risks and threats to the project's success.

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

- Blaine Matulevich is no longer employed with SynTouch. This leaves PI Jeremy Fishel and CI Gary Berke as the only two senior personnel remaining on this project since the project's start. All senior personnel whom have departed the project have done so on good terms and are still consulted periodically.

What other organizations were involved as partners?

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

- **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.

8. SPECIAL REPORTING REQUIREMENTS:

Collaborative Awards: None

Quad Charts: Attached

9. APPENDICES:

- J.A. Fishel, B. Matulevich, K.A. Muller, G.M. Berke, "The (Sensorized) Hand is Quicker than the Eye: Restoring Grasping Speed and Confidence for Amputees with Tactile Reflexes, Submitted to the International Conference on Robotics and Automation (ICRA) for 2019. In Review. Federal support acknowledged.

The (Sensorized) Hand is Quicker than the Eye: Restoring Grasping Speed and Confidence for Amputees with Tactile Reflexes *

Jeremy A. Fishel, *Member, IEEE*, Blaine Matulevich, Kelsey A. Muller, and Gary M. Berke

***Abstract*— Myoelectric prosthetic hand users have difficulty grasping fragile objects with their prosthesis and tend to avoid these objects altogether. The objective of this study was to implement tactile sensors into a myoelectric prosthetic hand and evaluate a reflex that inhibits the closing of the hand when contact is detected. The tactile sensors were made from a robust open-cell self-skinning polyurethane foam further sealed with an elastomer coating. When the sensor is touched, increases in air pressure inside the foam can be detected by a transducer and processed by the reflex controller. This design allowed for the compliant and sensitive measurement of contact as well as an improved rejection of vibration noise from the motors. Four unilateral myoelectric prosthesis users completed five trials of three different timed grasping tasks with fragile and rigid items. Subjects performed each task in each of three scenarios: with their sound side limb, their current myoelectric hand, and the modified prosthesis. Findings demonstrated that grasping performance with fragile objects was significantly enhanced using the modified prosthesis, even nearing the performance of subject's sound side limb. Results suggest that this approach can substantially improve the speed and success of grasping fragile items, leading to improved use patterns, decreased cognitive effort, and improved user confidence.**

I. Introduction

While myoelectric prosthetic hands have been in clinical use for decades, users of these devices still struggle with many activities of daily living that are trivial for non-disabled individuals, such as quickly, reliably, and confidently grasping fragile objects. The surface electromyography (EMG) [1] input signals that are used to open and close a myoelectric prosthesis [2] tend to be noisy and difficult to control so high grip forces often occur unintentionally, damaging fragile objects and limiting the usability of a myoelectric hand. Since EMG signal strength customarily determines both the closing velocity and resulting stall force of myoelectric hands [3], there is no simple way for users to close their prosthesis quickly and delicately grasp a fragile object. As a result, myoelectric users must rely on visual feedback to grasp fragile objects, requiring them to slow down the task and use a lot of attention to determine the precise timing of when to stop EMG signals to avoid breaking fragile objects. These challenges force the user to question whether a given object can be grasped safely with their prosthesis, a step that is distracting, furthers a lack of trust in, and increases disembodiment with, their prosthesis. Thus, most stop using their prosthesis for fragile or semi-fragile grasping tasks entirely, resulting in less useful myoelectric devices [4][5].

Tactile feedback facilitates fragile grasping in human hands [6][7] and would be expected to do the same in prosthetic hands. There have been several attempts to implement tactile sensing in prosthetic and robotic hands in an academic setting [8-11], but with the exception of [12], these have not yielded commercial solutions in prosthetic technologies due to challenges in robustness and cost that such devices must meet. In previous research by the authors, liquid-filled tactile sensors have been demonstrated to dramatically improve grasping performance through implementation of an inhibitory reflex loop [13]. However, these sensors were also not economically viable or robust enough for prosthetic applications, so the authors developed a more robust and low-cost foam-based tactile sensor [14]. In this study, we evaluate the grasping performance of fragile objects with four subjects in a clinical setting using these low-cost tactile sensors and reflex.

II. Methods

A. Tactile Sensors

Custom foam-based tactile sensors were installed on the index, middle, and thumb digits and under the cosmesis of a standard, commercially available, myoelectric prosthetic hand (VariPlus Speed, Ottobock) (Figure 1). The tactile sensor (NumaTac, Figure 2) is made from an open-cell foam with a

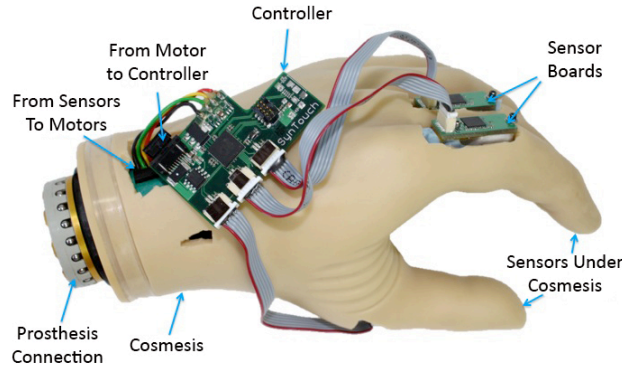


Figure 1. The assembled prosthesis used in this study incorporating an external reflex controller and internal tactile sensors.

*Research supported in part by the Eunice Kennedy Shriver National Institute of Child Health & Human Development of the National Institutes of Health SBIR Grant R43HD081861, and the Office of the Assistant Secretary of Defense for Health Affairs through the Clinical and Rehabilitative Medicine Research Program under Award No. W81XWH-15-1-0149. The content, opinions, interpretations, conclusions, and recommendations are solely the responsibility of the authors and do not necessarily represent the official views of, or are endorsed by, the of the National Institutes of Health or the Department of Defense.

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G. M. Berke is with Berke Prosthetics, San Mateo, CA 94404 (email gberke@berkeprosthetics.com).

self-sealing skin molded over a rigid core with the outer surface of the foam further sealed with an elastomeric coating. When the NumaTac collides with an object, the internal air pressure increases, which is measured by a pressure transducer contained within. The design results in a highly compliant tactile sensor that is sensitive to contact over its entire surface. The lattice structure of the open-cell foam also serves to improve signal isolation from the prosthetic motor's mechanical vibrations, permitting a lowered sensor threshold when determining sensor contact than the liquid-filled sensor used in [13].

The foam density and sealing characteristics of the NumaTac can be modified to change the sensitivity and robustness. In general, lower-density foams and thinner skins result in a more sensitive but less robust sensor and vice versa (for further technical details see [14]. The NumaTacs used in this study consisted of rigid aluminum cores with the same geometry of the replaced fingers and thumb and were over-molded with a low-density polyurethane foam mixture (fms74100-6 85b/15a, Foam Molders, Cerritos, CA) then airbrushed with a fluoropolymer coating to seal. Signals measured by the pressure transducer (MS1471, TE Connectivity) were amplified to optimize the resolution of the 12-bit data acquisition, with all electronics and sensors residing on the same printed circuit board. Custom firmware and SPI communication protocols were developed to permit sampling on demand of these sensors by a separate controller board.

B. Tactile Reflex Prosthesis

Figure 3 illustrates a functional diagram of the complete Tactile Reflex prosthesis. A Custom Reflex Controller and firmware were developed to collect measurements from the NumaTac tactile sensing fingertips, measure the user's analog EMG open and close signals from their prosthesis socket, and then communicate directly with the prosthetic hand's motor controller. The prosthesis motor controller had two communication modes: analog mode (used in normal operation when connected directly to the socket) and serial communication mode. We chose to adopt the serial communication mode to improve responsiveness and bypass redundancies in EMG filtering already implemented in the custom reflex controller. However, to simplify the comparison between EMG inputs to the controller and EMG outputs from the custom reflex controller, we refer to the equivalent EMG output in voltages in this manuscript.

The custom reflex controller was designed to implement a grasping reflex by modifying EMG close signals that were made by the user in the prosthetic socket before they get delivered to the prosthetic hand. The controller operates in two states when the user is sending EMG close commands: pre-contact, and post-contact. In the pre-contact state, the EMG close output mirrors the input with unity gain, allowing the hand to move quickly with fingertip speeds up to 300mm/s proportional to EMG signal [15]. After detecting contact, a linear piecewise function (Figure 4) defines the reduction of the EMG close input. The post-contact outputs provide a more significant reduction in low-to-medium EMG close input ranges (the "squeeze" range) but still permit the EMG close output to reach peak voltages at higher inputs (the "crush" range) resulting in the standard maximum of 100N of grip

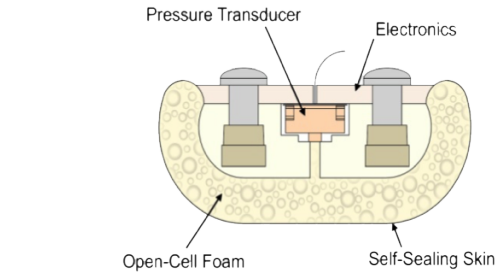

Figure 2. A conceptual schematic that demonstrates the function of the NumaTac sensor. The use of an open cell foam with a self-sealing skin allows air to move freely through the sensor. When the NumaTac makes contact with an object anywhere on its surface air pressure inside the foam increases where it can be detected by the pressure transducer and associated signal condition and A2D electronics.

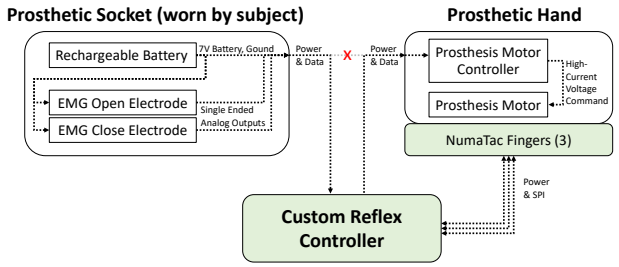

Figure 3. A diagram of the complete Tactile Reflex prosthetic hand system. Amputee subjects use a fitted prosthetic socket that houses a rechargeable battery and pair of EMG-sensing electrodes (open and close) that provide amplified, rectified, and filtered analog outputs proportional to muscle activation for these two muscle groups. In a traditional myoelectric prosthesis, a 4-wire standardized connector carries power and data signals directly from the socket to the prosthetic hand. However, for the Tactile Reflex prosthesis (component additions in light green), these 4-wire power and data signals are re-routed through a custom reflex controller that also communicates with the three NumaTac tactile sensing fingers over SPI and is capable of modifying the data signals delivered to the prosthetic hand.

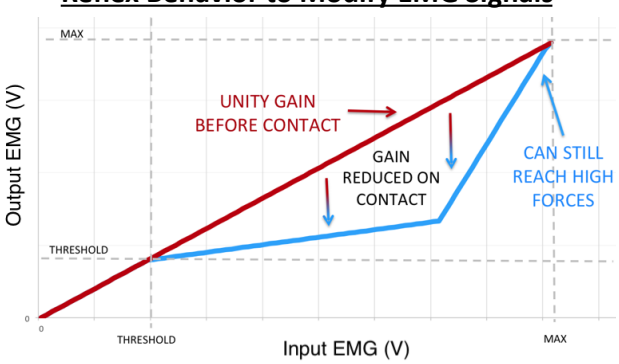

Figure 4. A graphical representation showing the programmed behavior of the reflex before and after contact. Before contact, input and output EMG are identical with unity gain, permitting the hand to move at high speeds. When contact is detected the EMG gain is reduced causing the hand to significantly slow at medium EMG inputs, yet still reach maximum values at higher EMG inputs.

force the hand can provide. Only the EMG close signal was programmed to adopt this behavior; the EMG open signal always had unity gain between input and output. After the operator sends any EMG open command over a predefined threshold or after 1 second of inactivity, or any opening or closing signals above that threshold, the contact state of the controller would be reset to pre-contact.

At the lowest of EMG close inputs, just above the threshold, the hand initially moves slowly (approximately 10mm/s), and on contact this reduction of gain causes the motor to stall at extremely light grasping forces (~2N). At higher closing EMG inputs the velocity of the fingers and the compliance of the sensors play a critical role in proportionately controlling the resulting grasping force. This behavior is due to the increased momentum of the fingertips at contact, the higher command signals to power the motor into the stall, and communication latencies all contributing to the compliant sensors advancing further into the grasped object at higher closing EMG inputs. If the sensors were rigid, the collision force would increase rapidly, losing the dynamic range of grasping forces. Instead, the compliance (~10N/mm) passively turns variation in position overshoots into a useful open-loop force control.

Contact thresholds for individual sensors were established as twice the noise levels observed from mechanical noise when rapidly opening and closing the hand, as well as inertial noise from waiving the hand around aggressively. Grasping contact was established when contact was detected by opposing tactile sensors during a closing grasp (either the thumb and index or the thumb and middle).

The piecewise function that defines the relationship between EMG input and EMG output was programmable in the reflex controller's firmware to allow for customization to individual subjects. As part of this configuration, both the opening and closing EMG input signal thresholds would be set to a voltage higher than the background EMG noise when the subject is was not intentionally sending any signals. The subject would then be asked to send a strong open and close signal to determine the maximum EMG input value for these signals. The closing EMG input inflection point voltage between the "squeeze" and "crush" ranges was set to the voltage observed when the subjects were asked to make a gentle squeeze. The output of the inflection point was set to be a fixed 25% of the closing EMG output, which was determined anecdotally to deliver a decent response by test subjects.

C. Clinical Studies Protocol

Inclusion criteria for the clinical study were candidates at least 18 years old, with unilateral limb-loss/failure-of-formation of the upper extremity below the elbow, a history of sustained use of a myoelectric prosthesis (more than one year), and that were otherwise healthy. A total of four subjects (two male and two female) meeting these criteria responded to our recruitment outreach and consented to participate.

Upon arriving for testing all subjects filled out an entry survey where they reported that their prosthesis (both the prosthetic socket and personal prosthetic hand) was behaving normally and that they were comfortable using it for daily living activities as well as throughout the testing process. The prosthetic socket remained on the subject's residual limb throughout the entire testing period, and only the prosthetic hand terminal device was changed for the study.

The authors researched several standard prosthetic hand outcome measures and evaluations to identify those incorporating fragile objects or fragile grasping [16][17], none were found so a new fragile grasping task was developed involving timed grasping tasks of fragile and non-fragile objects. The task involved moving 10 of a given object from one location to another two feet away. Objects were selected to have a range of fragile and non-fragile properties, as follows:

- 10 RITZ® crackers (weight 3g, break force ~5N) that were individually handed to the subject by the experimenter and needed to be dropped into a cup two feet away (Task 1).
- 10 hollowed egg shells (weight 6g, break force ~25N) to be moved one-by-one from one egg carton to another two feet away (Task 2).
- 10 unopened soda cans (weight 385g, break force exceeding prosthesis power, >100N) to be moved from one location to another two feet away. The inclusion of the rigid object was done to evaluate whether or not the reflex behavior had detrimental effects on grasping heavier non-fragile objects.

Subjects performed all tasks with a single hand and were timed to determine how long each task took to complete. The timer started when the first object was touched and stopped when the last object was released. Broken or dropped objects were recorded and did not count towards the total. Each task was repeated for five trials. Subjects then repeated this in three scenarios, using each their sound side hand, their personal prosthetic hand, and the Tactile Reflex prosthetic hand. Additionally, subjects were permitted to sit or stand in each task, but all found the tasks easier to perform while standing.

After being given time to practice until becoming comfortable with each task in each scenario, participants completed 5 trials of that task in that scenario. Testing order was first with their sound side hand, then with their personal prosthetic hand, and finally with the Tactile Reflex prosthetic hand. Before starting the studies with the Tactile Reflex hand, the experimenter explained the operation and behavior of the device and the gains and configuration were optimized until the control scheme felt natural to the participant. Upon completion subjects were given an exit survey regarding their perception of the Tactile Reflex prosthesis.

An Institutional Review Board (IRB) evaluated the final clinical research protocol and determined the study exempt from IRB review with minimal risk to subjects (Heartland IRB, approval number: 141126-25).

III. Results

A. Entry Questionnaire

Questions and responses to the entry surveys are provided in Table I (for conciseness, all testing-related questions such as those about the subject's prosthesis fit, battery charge, and other criteria to perform the studies are not presented). By coincidence, all subjects that arrived for the study happened to use either the SensorHand Speed or VariPlus Speed hand by

TABLE I. ENTRY QUESTIONNAIRE RESULTS

	Sub. 1	*Sub. 2*	*Sub. 3*	*Sub. 4*
What is your current myoelectric prosthesis model?[1]	VPS	SHS	SHS	VPS
For how many years have you been using a myoelectric prosthesis?	22	20	27	3
On average, how many days per week do you wear a:				
Myoelectric prosthesis?	7	0	5	5
Body-powered prosthesis?	4	0	5	0
Cosmetic prosthesis?	0	4	0	0
On average, how many hours per day do you wear a:				
Myoelectric prosthesis?	15	0	7	3
Body-powered prosthesis?	2	0	3	0
Cosmetic prosthesis?	0	2	0	0
Please rate your confidence in performing the following tasks with your prosthetic hand. Please use one of the following descriptors (NEVER, RARELY, SOMETIMES, OFTEN). Place a * next to each task that you feel would be important to improve.				
Picking up a fragile object such as an egg, chip or cracker	Rarely *	Never	Rarely *	Never*
Shaking hands with another person	Never	Some-times	Never	Never
Picking up a piece of fruit, vegetable or other soft food	Often	Rarely	Rarely	Rarely
Holding a drink	Often	Rarely (if open)	Some-times	Some-times
Holding a drink in a deformable cup (such as a plastic or paper cup)	Rarely *	Rarely (if open)	Rarely *	Some-times*
Holding a piece of food while cutting it	Often	Often	Some-times*	Often
Please rate each of the following statements on a scale of 0 through 10 (0=Strongly Disagree, 5=Neutral, 10=Strongly Agree). Place a * next to each statement that you feel would be important to improve.				
I have confidence when grasping delicate objects with my prosthesis.	6*	3	0*	3
I need to pay close attention when grasping delicate objects with my prosthesis.	7*	9	10*	10*
I only grasp objects with my prosthesis when it is necessary.	5	4	10*	10*
I often attempt to grasp delicate or fragile objects with my prosthesis.	6*	5	0*	3
I avoid grasping delicate or fragile objects with my prosthesis.	6*	5	10*	8*

1: Subject's current myoelectric prosthetic hand model was determined with help of the clinician (VPS=Ottobock VariPlus Speed, SHS=Ottobock SensorHand Speed

Ottobock. This happened to be the same hand that was modified in this study to be the Tactile Reflex hand as their personal prosthetic hand (with the exception of the fingertips, which are replaced in the Tactile Reflex hand, the SensorHand Speed and VariPlus Speed are identical). This was not entirely surprising as the these are both popular devices. However, the coincidence was worth reporting as it had the unplanned benefits of ensuring the subjects were all familiar with the performance and characteristics of the device and removed one more variable, allowing a more direct comparison between their personal prosthesis and the Tactile Reflex prosthesis.

FRAGILE E CRACKER

	Sound Side			Personal Prosthesis			Reflex Hand Prosthesis		
	Time (s)		Fails	Time (s)		Fails	Time (s)		Fails
Subject	Average	St. Dev.	Average	Average	St. Dev.	Average	Average	St. Dev.	Average
1	12.73	1.22	0.00	24.65	3.53	1.60	14.14	2.62	0.80
2	8.72	1.17	0.00	57.13	6.69	10.80	13.02	2.29	1.20
3	9.76	0.71	0.00	35.56	5.46	5.60	21.81	3.19	1.40
4	9.88	0.51	0.00	37.36	6.44	4.00	17.66	2.71	1.40
Average	**10.27**	**0.90**	**0.00**	**38.67**	**5.53**	**5.50**	**16.66**	**2.71**	**1.20**

HOLLOW EGG

	Sound Side			Personal Prosthesis			Reflex Hand Prosthesis		
	Time (s)		Fails	Time (s)		Fails	Time (s)		Fails
Subject	Average	St. Dev.	Average	Average	St. Dev.	Average	Average	St. Dev.	Average
1	11.91	0.92	0.00	22.18	3.74	0.40	14.90	2.33	0.00
2	7.72	1.04	0.00	22.84	5.83	0.60	13.95	3.06	0.20
3	10.61	0.73	0.00	26.44	1.68	0.60	19.15	1.61	0.00
4	10.73	0.56	0.00	27.31	2.10	0.00	19.63	0.78	0.00
Average	**10.24**	**0.81**	**0.00**	**24.69**	**3.34**	**0.40**	**16.91**	**1.94**	**0.05**

UNOPENED SODA CAN

	Sound Side			Personal Prosthesis			Reflex Hand Prosthesis		
	Time (s)		Fails	Time (s)		Fails	Time (s)		Fails
Subject	Average	St. Dev.	Average	Average	St. Dev.	Average	Average	St. Dev.	Average
1	12.29	0.49	0.00	19.42	2.26	0.00	16.22	1.58	0.00
2	8.45	0.41	0.00	16.12	1.01	0.00	16.85	2.13	0.00
3	9.92	0.74	0.00	20.49	2.09	0.00	16.62	0.74	0.00
4	10.73	0.46	0.00	24.06	2.90	0.00	24.02	2.71	0.00
Average	**10.34**	**0.53**	**0.00**	**20.03**	**2.06**	**0.00**	**18.43**	**1.79**	**0.00**

Figure 5. Each sub-table shows summary statistics for each subject including average time to complete each task across all five trials, standard deviation across those trials, and the average number of fails (dropped or broken object) during those trials. Average performance across all subjects is also presented for these metrics. The outer tables compare the tasks (fragile cracker, hollow egg, and unopened soda can) and scenarios (sound side hand, personal prosthesis, and Tactile Reflex prosthesis). A significant improvement in task performance time as well as a reduction in standard deviation is demonstrated for the Tactile Reflex Prosthesis over the Personal Prosthesis when grasping fragile objects for all subjects individually as well as averaged across all subjects. No degradation in performance for the non-fragile rigid soda can was observed.

As shown in Table I, most subjects reported having substantial history using myoelectric hands and/or used them frequently. Responses indicated that most subjects desired improvement in picking up fragile objects with their prosthesis and tended to avoid these objects with their current prosthesis.

B. Evaluation of Grasping Performance

The Tactile Reflex prosthesis allowed all subjects to grasp fragile objects (crackers and eggs) faster than their personal prostheses (Figure 5). This improvement was statistically significant using a one-tailed t-test (used for all statistical analyses in this paragraph) for each subject's repeated trials in the cracker and egg tasks ($p<0.01$). For the task involving rigid unopened soda cans, the performance of the Tactile Reflex prosthesis was never worse than the performance of the subject's personal prosthesis with statistical significance ($p>0.05$), and for subjects 1 and 3, performance improved with the Tactile Reflex prosthesis ($p<0.05$). Furthermore, in Subject 1, the performance of the Tactile Reflex prosthesis was even close enough to the performance of the subject's sound side hand that the five trials collected were not enough data to even reject the null hypothesis that the performance of the sound side hand was statistically better ($p=0.15$).

Figure 6 presents a graphical representation of average subject performance across all tasks in each scenario. Several

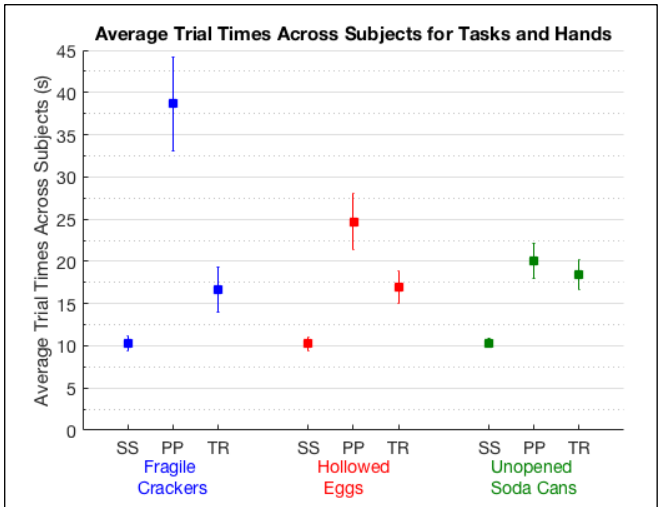

Figure 6. Average task performance times for all subjects for each of the three tasks (fragile crackers = blue, hollow eggs = red, unopened soda cans = green) of all subjects using each hand type scenario (SS = Sound Side Hand, PP = unmodified Personal Prosthetic hand, TR = Tactile Reflex hand with reflex and contact sensors). Error bars at each data point represent the average of each individual subject's standard deviation for the given task and scenario.

significant trends can be observed. First, for the subject's sound side hand, it took roughly 10 seconds to move ten objects two feet, regardless of how fragile those objects were and performance was precise as indicated by the small error bars. Additionally, for the subject's personal prosthesis, the more fragile the objects were, the longer it took to perform the task and the higher the variability in performing those tasks. The Tactile Reflex prosthesis exhibited characteristics that were more like that of the sound side hand, with a consistent performance across tasks (roughly 15-20 seconds to complete each task, regardless of how fragile those objects were), and a consistent, but less precise, variability.

Similar patterns emerge when analyzing the subjects as a population, using a Repeated Measures ANOVA and Holm t-test, and the Tactile Reflex prosthesis demonstrated a significant improvement over the personal prosthesis on both grasping tasks involving fragile objects ($p<0.05$), and no significant difference on the grasping task with the rigid object ($p>0.05$).

C. *Exit Surveys*

A summary of the exit survey results comparing the prostheses is provided in Table II. Subjects all unanimously responded "Yes" to the following questions: "*Do you see a benefit to the technology used in the experimental prosthesis?*", "*Would you consider using a prosthetic hand using this technology?*", "*Would this technology prompt you to wear a myoelectric prosthesis more?*", "*Would this technology prompt you to use a myoelectric prosthesis to grasp objects more often?*", "*Would this technology give you more confidence in using a myoelectric prosthesis?*", and "*Are you interested in participating in future studies evaluating this technology?*"

In the free-writing section subjects also reported enthusiasm for using the prosthesis to grab and carry cups, opening water bottles, cooking/baking, and opening their wallet.

TABLE II. EXIT QUESTIONNAIRE RESULTS

	Sub. 1	***Sub. 2***	***Sub. 3***	***Sub. 4***
Please indicate which device you would score more favorably in the following categories: [choices include BOTH, EXP=Experimental (i.e. Tactile Reflex prosthesis), PER=Personal Prosthesis]				
Weight	BOTH	BOTH	EXP	BOTH
Grasping Speed	BOTH	EXP	BOTH	EXP
Comfort	BOTH	EXP	BOTH	BOTH
Ease of use for grasping rigid objects	BOTH	BOTH	EXP	BOTH
Ease of use for grasping fragile obejcts	EXP	EXP	EXP	EXP
Confidence in grasping fragile objects	EXP	EXP	EXP	EXP
Required less concentration on grasping	EXP	EXP	EXP	EXP
Intuitive to control	BOTH	EXP	EXP	BOTH
Overall, I would choose to wear:	EXP	EXP	EXP	EXP

IV. DISCUSSION

The incorporation of the contact-detection reflex with compliant and sensitive tactile sensors in the Tactile Reflex prosthesis provided dramatic improvements in the speed of grasping the most fragile objects (crackers). Subjects recovered an average of more than 75% of their handicap with the Tactile Reflex prosthesis (represented by the additional time required for commercially available prostheses to grasp fragile objects compared to their sound side hand). While this result was indeed impactful and significant, through observing the performance of the subjects it seemed that the confidence they had developed in such short time to perform these tasks with the Tactile Reflex prosthesis was even more remarkable than the speed. In the exit surveys, one subject reported that "It was amazing to not have to look at the object I was trying to grab and just trust that it would be fine." This confidence was developed in just 45 minutes of time with the prosthesis.

We hypothesize that the lowered standard of deviation subjects see in performing multiple trials of the same task relates to this confidence. This reduction in standard deviation between trials was observed in all subjects for all fragile items (crackers and eggs) when switching to the Tactile Reflex prosthesis. By definition, the reduced standard deviation indicates a more repeatable and predictable performance, which is a sensible explanation for this increased confidence. We further hypothesize that traditional myoelectric prosthetic hand users do not avoid grasping fragile objects because they are difficult to grasp, indeed this study has shown that even grasping fragile crackers can be done with a reasonably low degree of failure and in a reasonable amount of time. Instead, we propose that users avoid these objects because of the risk and unpredictability associated with grasping them and the high degree of visual concentration required to overcome those risks, something the tactile reflex proposed offers exceptional promise over.

The topic of visual attention is also of great interest to the authors. Industrial robotic systems frequently make use of vision systems for planning and execution of tasks, yet tactile

feedback is virtually absent. While vision is well-established as the primary sense for movement planning in both humans and robotic systems, when dealing with uncertainty in object manipulation, humans use both touch and vision as feedback mechanisms. Studies of the relative contributions of touch and vision in dexterous tasks have demonstrated that for some tasks, the sense of touch becomes more important than the sense of vision [18]. In a separate pilot study using the Tactile Reflex prosthesis with a blindfolded subject, we were able to evaluate performance for a modified version of the cracker passing task (where the subject passed the cracker from their sound side to prosthesis, then to the cup). We then compared the performance to a non-blindfolded subject with their personal prosthesis to compare "touch without vision to "vision without touch." Preliminary findings were quite promising as the "touch without vision" performance in this task were approximately 25% faster as shown in the supplemental video. We are presently designing more formal studies in a properly controlled environment to explore the role of visual and cognitive distraction in grasping and whether tactile reflexes can help overcome them.

V. Conclusion

Myoelectric prostheses incorporating a biomimetic contact detection reflex have been demonstrated to improve the speed and confidence in grasping fragile objects when compared to commercially available prostheses without these capabilities. The addition of contact detection and a biomimetic reflex did not affect the ability to produce large grip forces or otherwise accomplish non-fragile grasping tasks. In addition to demonstrating performance improvements, all subjects reported in the exit evaluation an overall preference for the "experimental prosthesis" (i.e. Tactile Reflex hand) and reported that they believed this technology would prompt them to increase the amount of time they would use their prosthesis, expand their capabilities in grasping objects, and improve their confidence while using their prosthesis.

Additional studies are being planned to validate these reported claims as well as to explore the role of cognitive and visual distraction when grasping objects with and without the contact detection reflex. A long-term trial with additional participants and a “take-home” version of the Tactile Reflex prosthesis that includes data logging capabilities will be conducted to determine if usage patterns improve in a take-home setting. Prior to developing the prosthesis for long-term take-home studies, the foam density of the NumaTac will need a more systematic exploration to determine the optimal density to achieve both a satisfactory sensitivity and robustness.

From the results in this experiment, we predict that contact detection in myoelectric hands will enable users to accomplish a broader range of fragile grasping tasks - increasing confidence, improving daily function, and improving outcomes in their activities of living.

Acknowledgment

The authors would like to thank the government agencies that have supported this research, Ottobock for their assistance in the integration process, and most importantly the teams at SynTouch and Berke Prosthetics/Orthotics that helped make this research possible, including Vikram Pandit, Gary Lin, Raymond Peck, Matthew Borzage, Gerald Loeb, and Taylor Wolzen. This work would not have been possible without your contributions and expertise.

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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.

Two customized prosthetic hands fully integrated with sensors and electronics, 1 with and 1 without cosmetic glove.

Major Accomplishments: 1) Final customized prosthetic hand built and tested. 2) Clinical studies started. 3) Publication on technical function submitted.

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: June 30, 2018 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
☑ Start Clinical Studies

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

Comments/Challenges/Issues/Concerns

Project back on schedule and clinical studies started following initial hardware delays.

Budget Expenditure to Date

Projected Expenditure: $1,666,488, Actual Expenditure: $1,511,087