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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 myoelectric 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 was to equip a myoelectric prosthetic hand with contact detecting sensors and a custom controller that enables a biomimetic contact-detection reflex to improve the speed and dexterity when grasping fragile objects. This technology was 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 was 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 was developed and assembled including customized sensors, firmware, and a controller board. Clinical studies were 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. While significant challenges were encountered through multi-site and multi-organization IRB and HIRB protocol synchronization and approval as well as the detrimental impact the COVID-19 pandemic had on clinical studies planning, we were able to obtain insights into the performance of this approach in limited clinical studies and challenges this technology would need to resolve before reduction to practice.

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: Completion 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, Initial Review Completed 4/27/2018, Final Protocol Approved 2/20/2020, Revised COVID Amendments Completed: 7/23/2020.
   b. Milestone: Clinical studies completed. Target date 4/30/2019, Completed 12/22/2020.
5. **Organize results for publication and documentation**
   a. Academic publications, 1 of 3 completed, 2 of 3 planned for future dissemination.
   b. Milestone: Final documentation released. Target date 9/30/2019, Planned for future dissemination.

What was accomplished under these goals?

Major Task 1-1: Design and fabricate NumaTac Prototypes

YEAR 1

Initial and follow-on review meetings took place with technical team and collaborators to identify designs, materials, and modifications that should be researched for NumaTac designs. Meetings were held with Foam Molders (Cerritos, CA), to identify viable material and manufacturing options for the foam-based tactile sensor. In parallel, options for creating an air-tight seal around the sensor including ripstop fabrics, glues, coatings, and elastomers were identified, ordered, and tested in bench top tests. It was determined that a thin polyurethane film sleeve, heat sealable ripstop nylon, and manufactured silicone skin were the three most viable, air tight and durable options for the foam sensor to allow for a viable pressure signal to be measured when the sensor is compressed. A manufacturer for the polyurethane sleeve was identified and a design was developed and manufactured for final sensor testing.

An initial batch of finger sensor aluminum cores were designed and manufactured. It was determined after receiving testing information from commercial partner and prosthetic hand manufacturer (Ottobock) that the finger core would need to have a more bulbous tip to prevent the thumb and finger from sliding past one another and damaging the sensors. After this, three new finger and thumb cores were designed to address this problem and interface with the hand, cosmetic glove, and current foam molding practices. These core designs include pressure sensor pockets within the foam and one with the sensor pocket outside of the foam. These core candidates were designed, ordered, and had custom relief holes laser drilled. A custom flexible component board that held the pressure sensor was made for an integrated design that improved sensitivity for use during testing. Aluminum cores overmolded with 4 candidate foam materials that vary in durability and deformability and were identified as viable candidates according to specifications. Among these foams are also different treatments for creating airtight seals including spray sealing, RF sealed polyurethane sleeves, and silicone finger skins were investigated.

YEAR 2

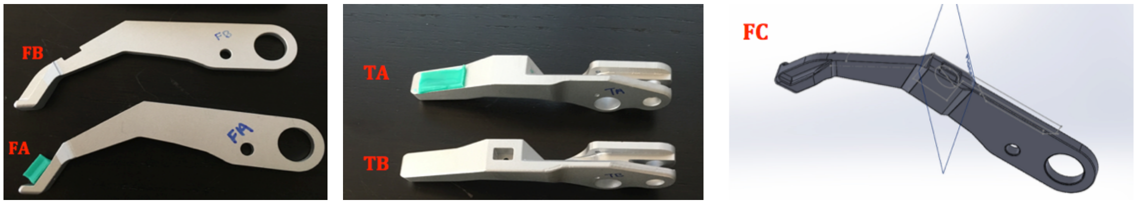
A total of 45 foam over-molded aluminum core prototypes were produced for evaluation. This included 13 different thumbs and 32 fingers of varying core designs, foam types, foam densities, and sealing methods as pictured below:

Sensor prototypes manufactured for evaluation.

The following parameters were systematically 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

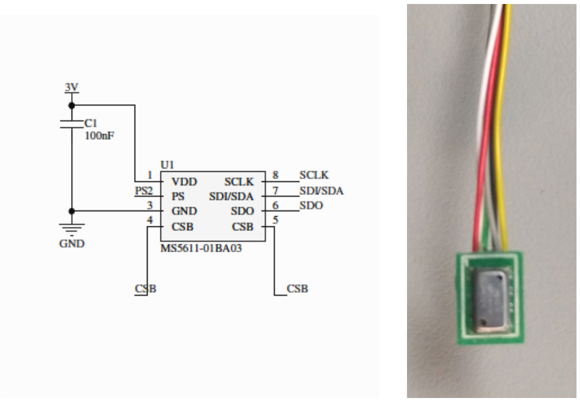
    - FB: Sensor offset from foam
    - TB/FC: sensor connected to foam through a pilot hole
- Sealing:
    - Standard polyurethane spray-coat sealing
    - Experimental sleeve sealing on uncoated sensors



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).

Successful yields were achieved with the TB and FC designs, which were ultimately the final design implemented through this project.

<u>Major Task 1-2: Verify commercial requirements and performance specifications and select final design</u>

<u>YEAR 1</u>

At the onset of our study, 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)

The development and analysis of a NumaTac simulation has allowed us to identify key parameters to optimize to improve the performance of our sensor and control its sensitivity threshold, namely the general reduction of sensor volume outside of the contact region, the increase of sensor volume inside the contact region as well as the reduction of membrane stiffness. While the reduction of membrane stiffness was also seen to be in contradiction to our desire for a robust sensor, this could be adequately compensated for by optimization of sensor volume.

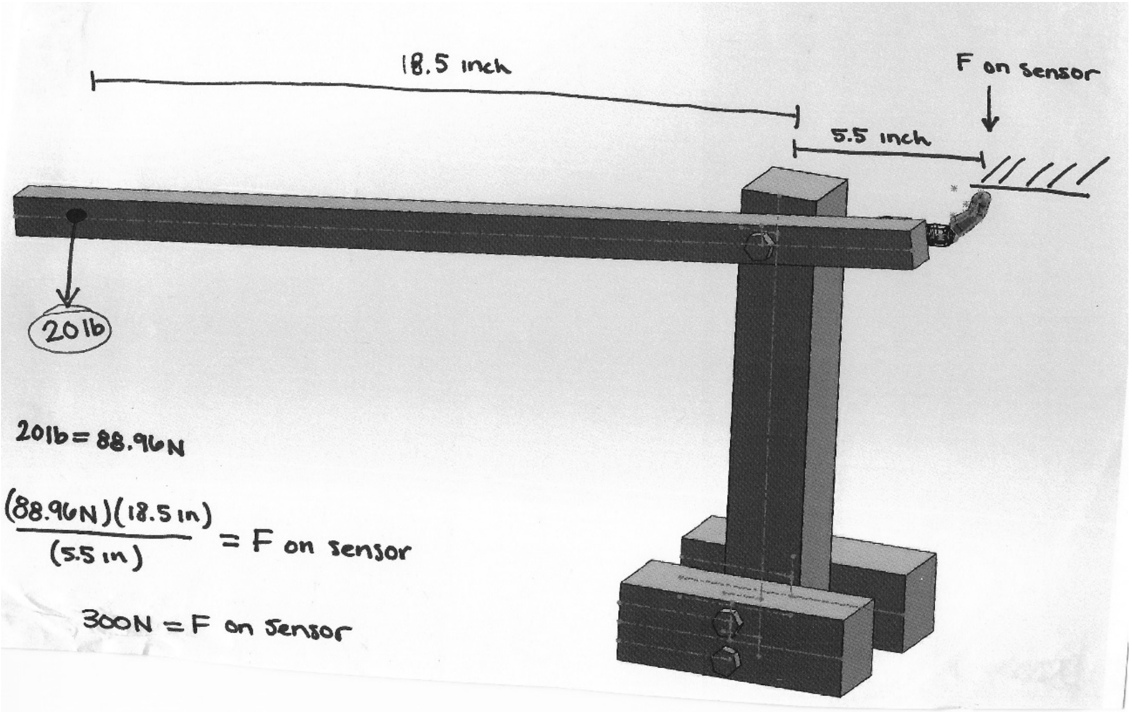
Static and cyclic loading requirements of the hand and sensors were verified. Testing equipment for the evaluation of sensor durability under static and cyclic loads was designed, sourced, assembled, and tested. Cyclic loading was planned to be applied using a pneumatic gripper producing 100N of force on the sensors for 500,000 grasps, which is consistent with the prosthetic hand warranty. Software was developed to control the behavior of the gripper including force, rate, and number of grasps. The static loader was designed to apply 300N of force to the end of the finger sensor. New hands were ordered for additional testing.

Requirements for power consumption were identified and verified. It is required that each sensor draws <1mA. The evaluation of the sensor and associated electronics to be used verified that we should expect 0.02mA power consumption for each sensor. This is based on a safe estimate of 500 grasps/day and an average usage time of 8 hours/day.

YEAR 2

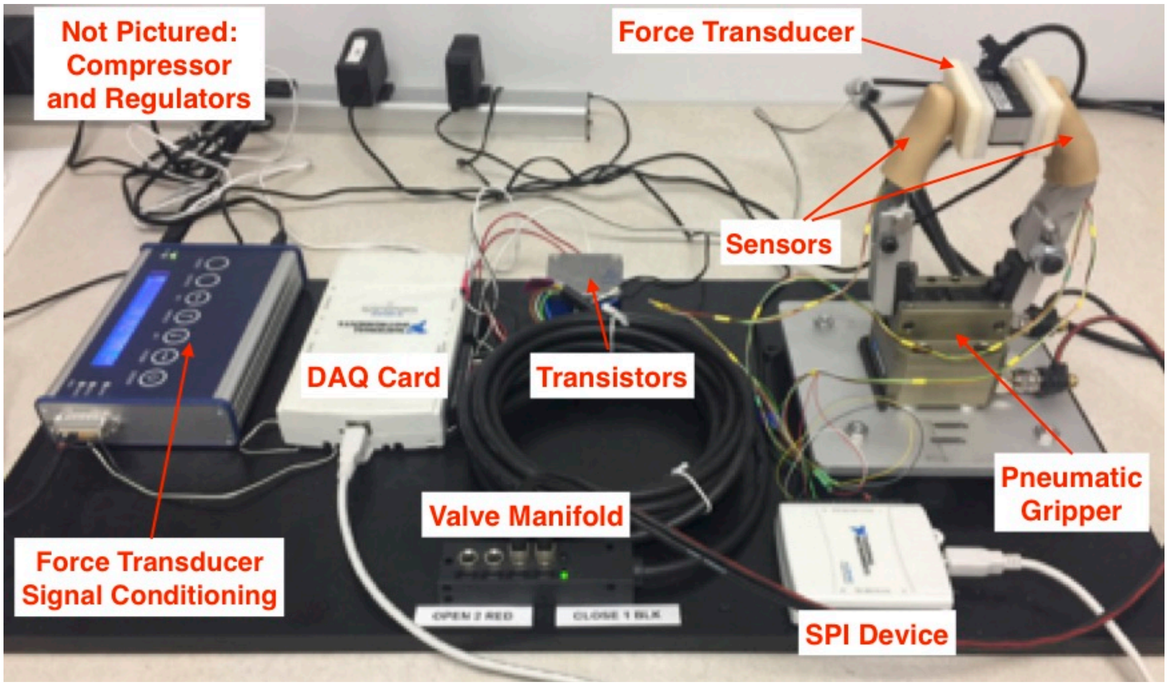
In order to test the durability of the prototype fingers two tests were developed the static loading test and the cyclic loading test and all sensors went through these testing processes

Static Loading Test:



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:



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 loose 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 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.

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

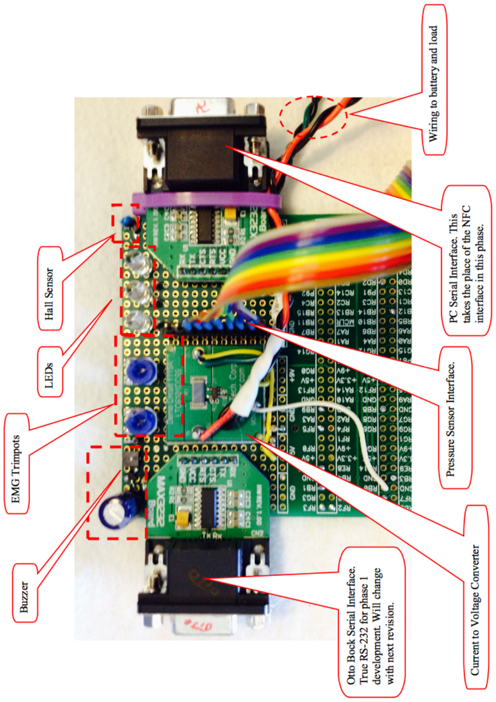
YEAR 1

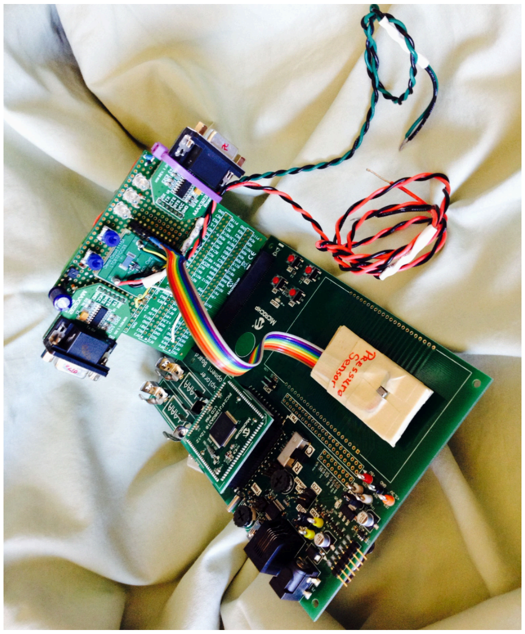
Electronics and Controller Development:

An ideal pressure sensor was sourced and ordered to optimize sensitivity, size, and cost.

Comprehensive documentation was developed on the requirements for the prosthetic hand controller and associated electronic components. A layout and breadboard version of the controller has been designed and developed to verify that functional, power, and storage specifications are met. This breadboard electronic circuit validates the proposed electronics circuitry between the EMG electrodes (input), hand motor (output), and contact event information from the sensors. A schematic for the controller can be found in Appendix A.

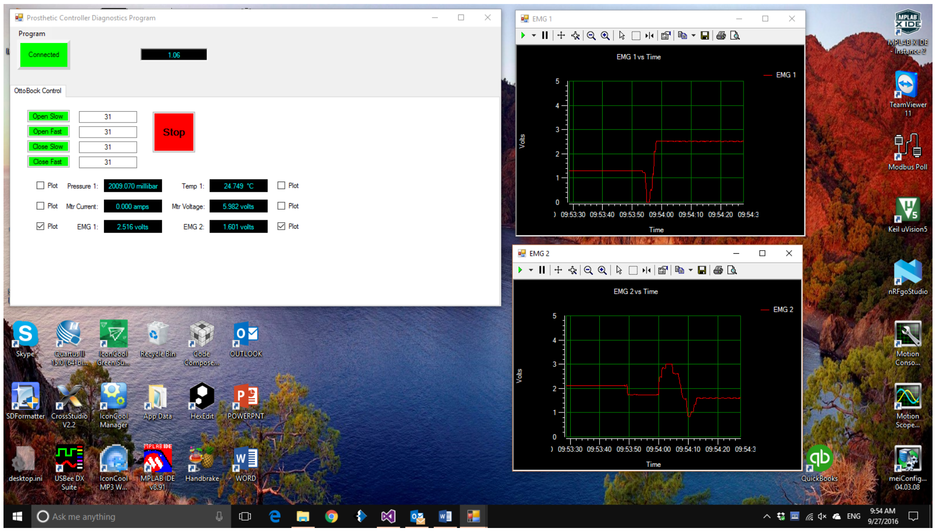
After the breadboard circuit development, revisions and improvements were made including a 5V interface and regulator and a change to the power supply. This final design has been tested and current consumption using all three sensors is consistent with our specifications. The components, circuitry, and geometry of this development board are now in the final format and in production. Documentation and a bill of materials have been created for this final format of the prosthetics hand controller. Photos of the completed, custom-developed, breadboard are below:





Firmware Development:

A list of requirements for the firmware associated with the prosthetics controller have been developed. These requirements include directions for operating the hand, reading sensor data, implementing reflex behavior, recording diagnostic behavior, downloading data, and communicating via BTLE to change parameters. Two firmware experts were identified and Chris Kepner was chosen to produce firmware, which has been completed and tested with the prosthetics controller hardware. The development board is now successfully executing code, communicating with analog inputs and the DMA controller, and talking to the pressure sensor chip through the SPI bus. The pressure and temperature sensors are being read, the processor is communicating to the PC using the UART-USB bridge chip and a PC diagnostics program has been written for control of the prosthetic hand and viewing of the sensor analog inputs. Overall, the firmware is in final stages and successfully integrating with the electronics circuitry. A screenshot of the functioning firmware displaying EMG and a sensor pressure signal are found here:


Prosthetic Controller Diagnostics Program

Connected 1.06

Open Slow 31
Open Fast 31
Close Slow 31
Close Fast 31

☐ Plot Pressure 1: 2009.070 millibar
Temp 1: 24.749 °C ☐ Plot
☐ Plot Mtr Current: 0.000 amps
Mtr Voltage: 5.982 volts ☐ Plot
☑ Plot EMG 1: 2.516 volts
EMG 2: 1.601 volts ☑ Plot

YEAR 2

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.

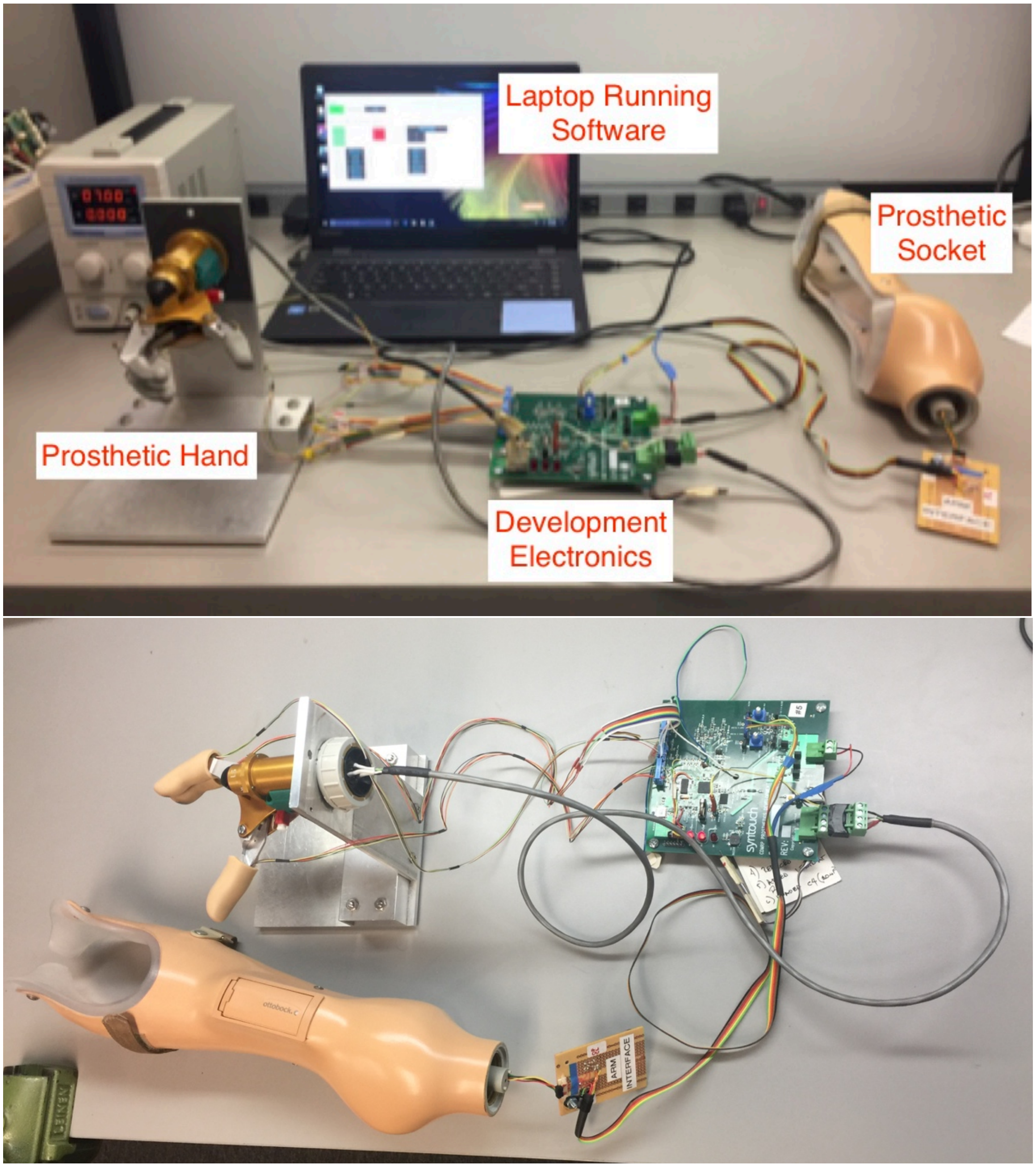
- Collect data from the three pressure sensors using the SPI communication protocol for the sensor.
- Analyze pressure sensor data and determine when values have crossed a programmable threshold value.
- Read 2 EMG inputs (EMG_open and EMG_close) from electrodes (analog 0-5V).
- Filter EMG inputs in 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:



Full development system running

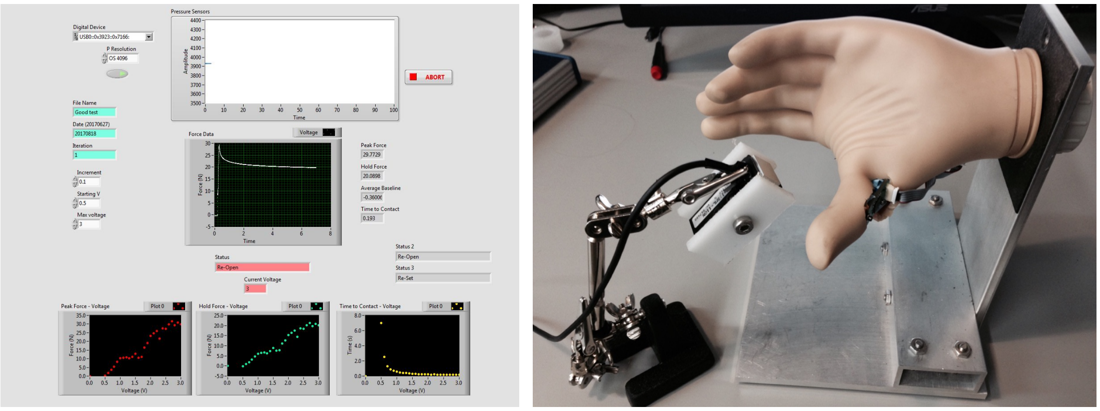
In awaiting the layout and manufacturing of a miniaturized board that allows fit within the existing OttoBock controller housing space, preliminary investigation determined this was feasible.

Software and performance testing 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 was installed and verified with the full hand, new fingers, pressure sensors, software and firmware.

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.

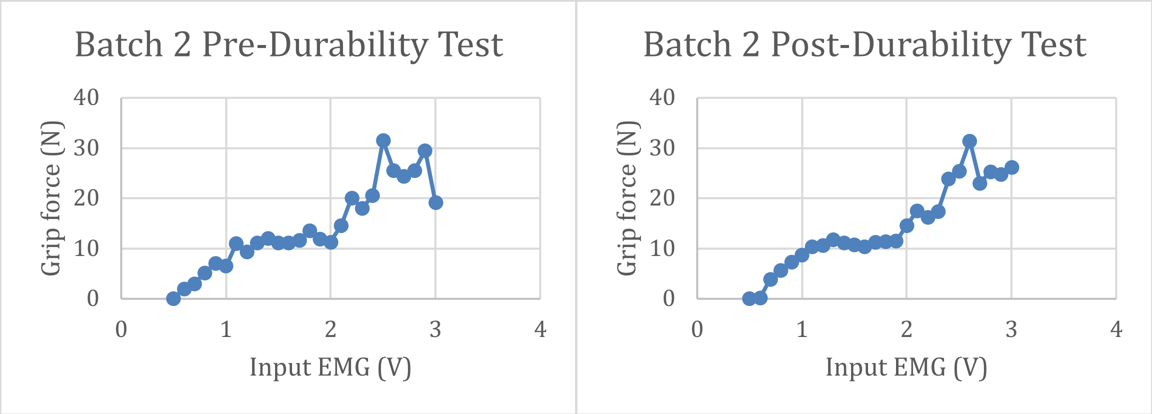


Digital Device: USB0::0x3923::0x7166:
P Resolution: OS 4096
File Name: Good test
Date (20170627): 20170818
Iteration: 1
Increment: 0.1
Starting V: 0.5
Max voltage: 3
Peak Force: 29.7729
Hold Force: 20.0898
Average Baseline: -0.36006
Time to Contact: 0.193
Status: Re-Open
Current Voltage: 3
Status 2: Re-Open
Status 3: Re-Set

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:



Sensitivity performance of final sensors selected for production

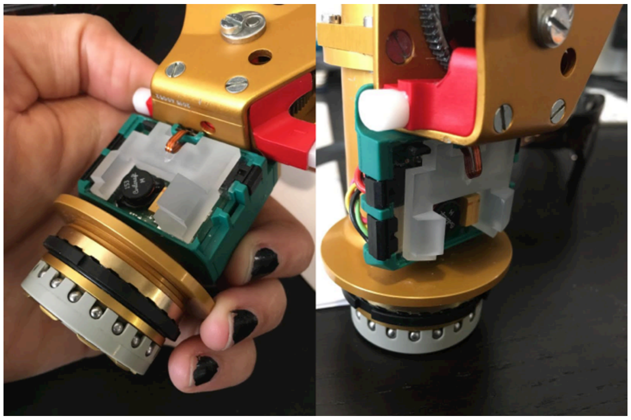
As can be seen at very slow closing speeds (0.5-1V Input EMG) there is a nice linear progression from 0-10N of closing force, this corresponds to light effort. In the medium ranges of 1-2V Input EMG, peak sensitivity levels around 10N and then increases up to 30N at maximum EMG inputs. At low closing 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)

A plan was made to miniaturize the electronics into the cosmesis and this activity 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 were 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.

YEAR 3

Final Prosthetic Hand Design Sent to Production

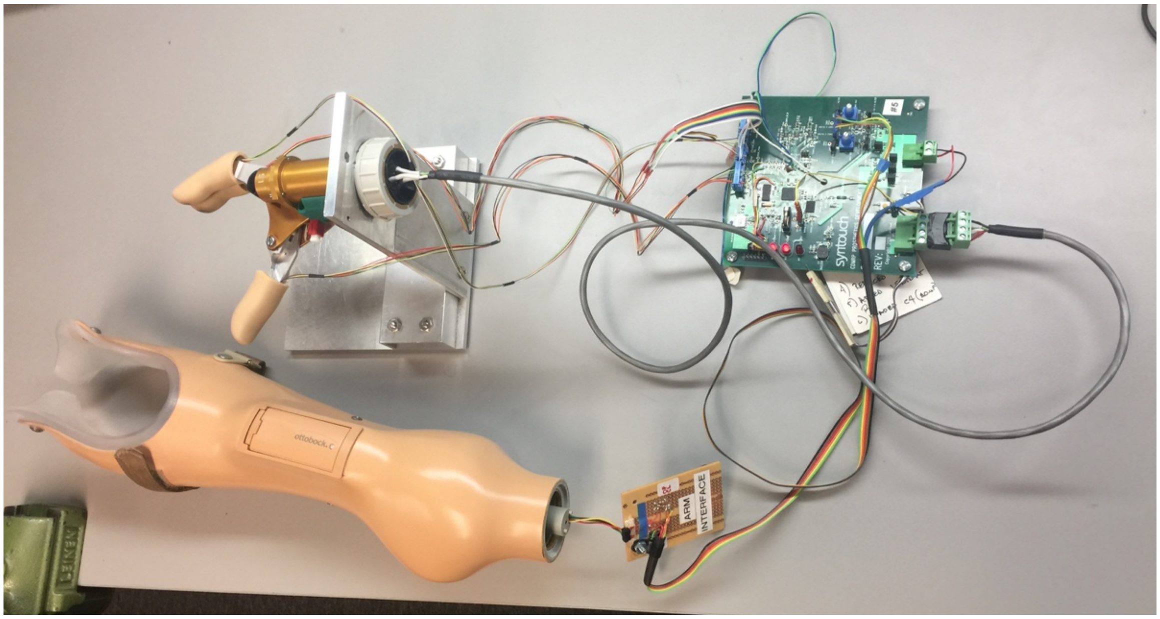
In the conclusion of year-2 we demonstrated final design decisions to build the final prosthetic hand, sensors, controllers and flexible circuits. A substantial portion of effort in year 3 has been focused on the final engineering to permit for the production of all components, which we are pleased to 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)

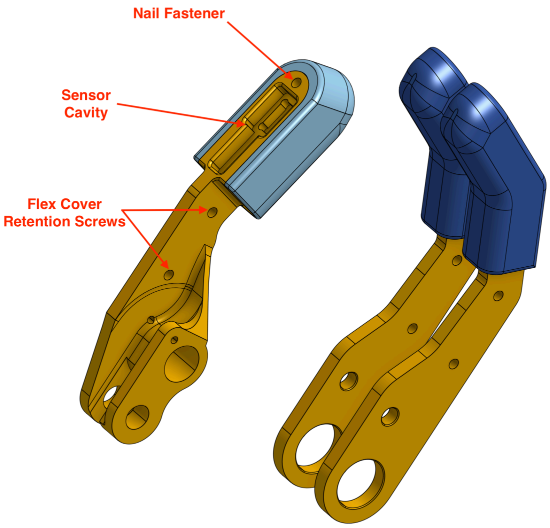


Reflex Testbed

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.

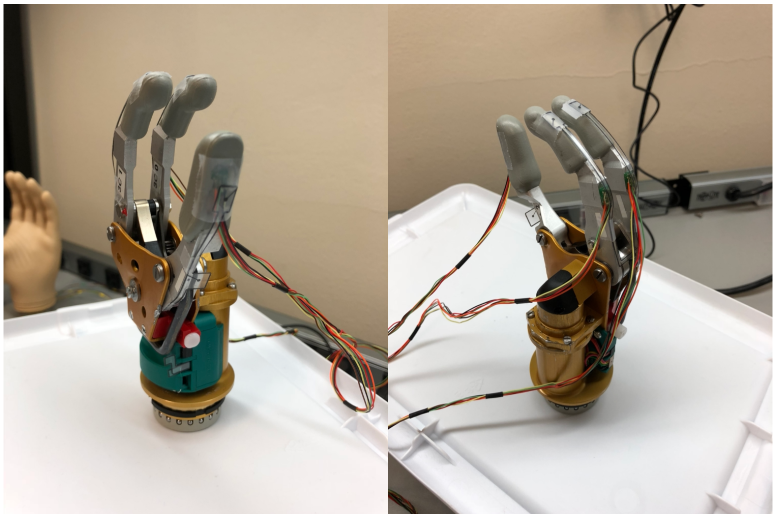
These final designs have been sent out to our partners at Foam Molders who specialize in foam overmolding and are currently in the process of being quoted for production.

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.

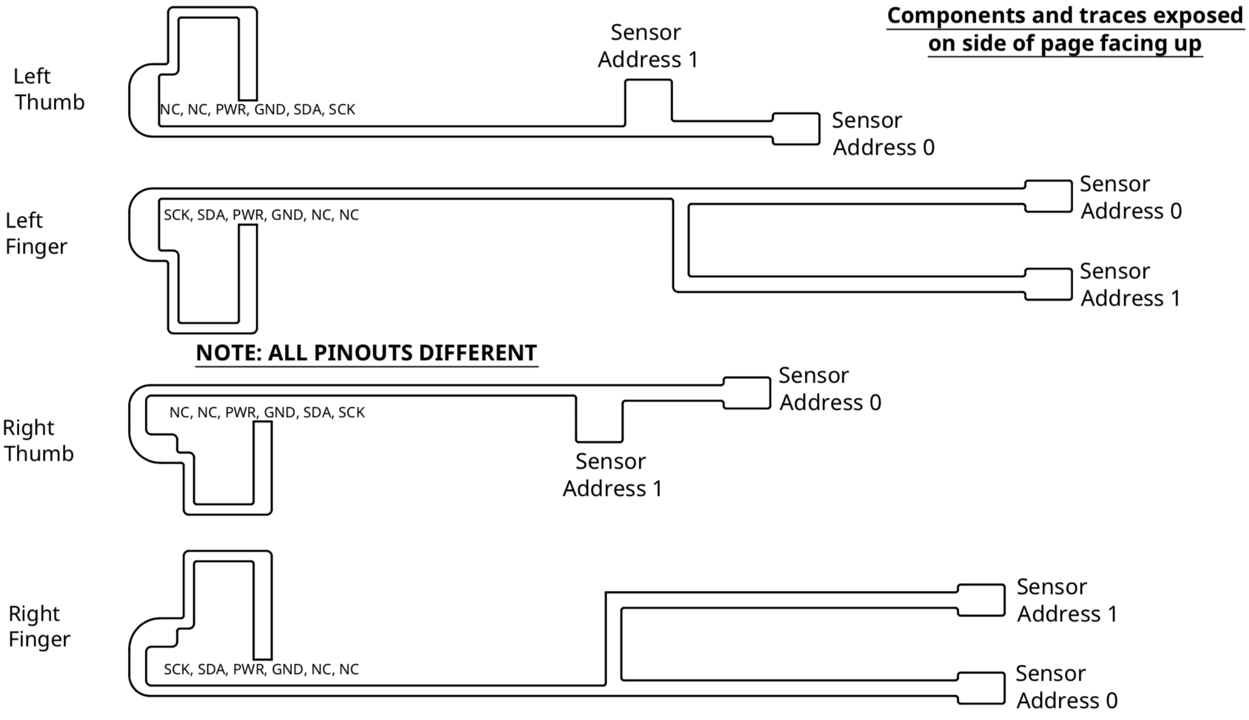
Flex Circuit Engineering Completed & Sent to Production

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 Flex Circuit Layout

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

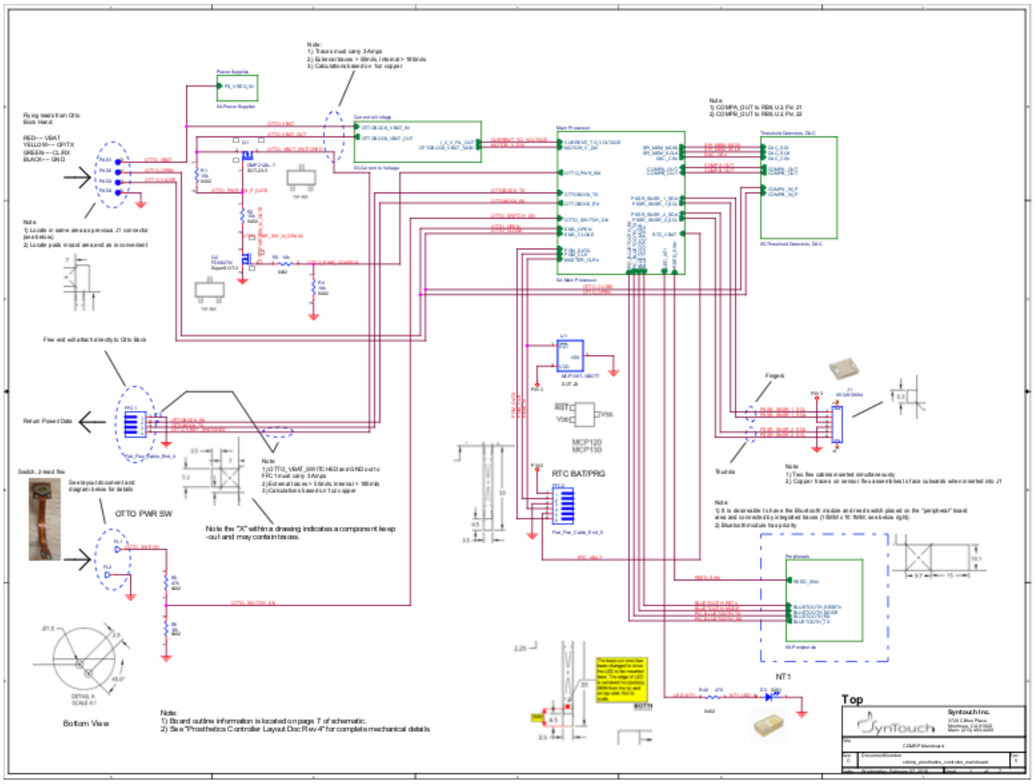
As part of the design specification, the controller is to log the following data:

- 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

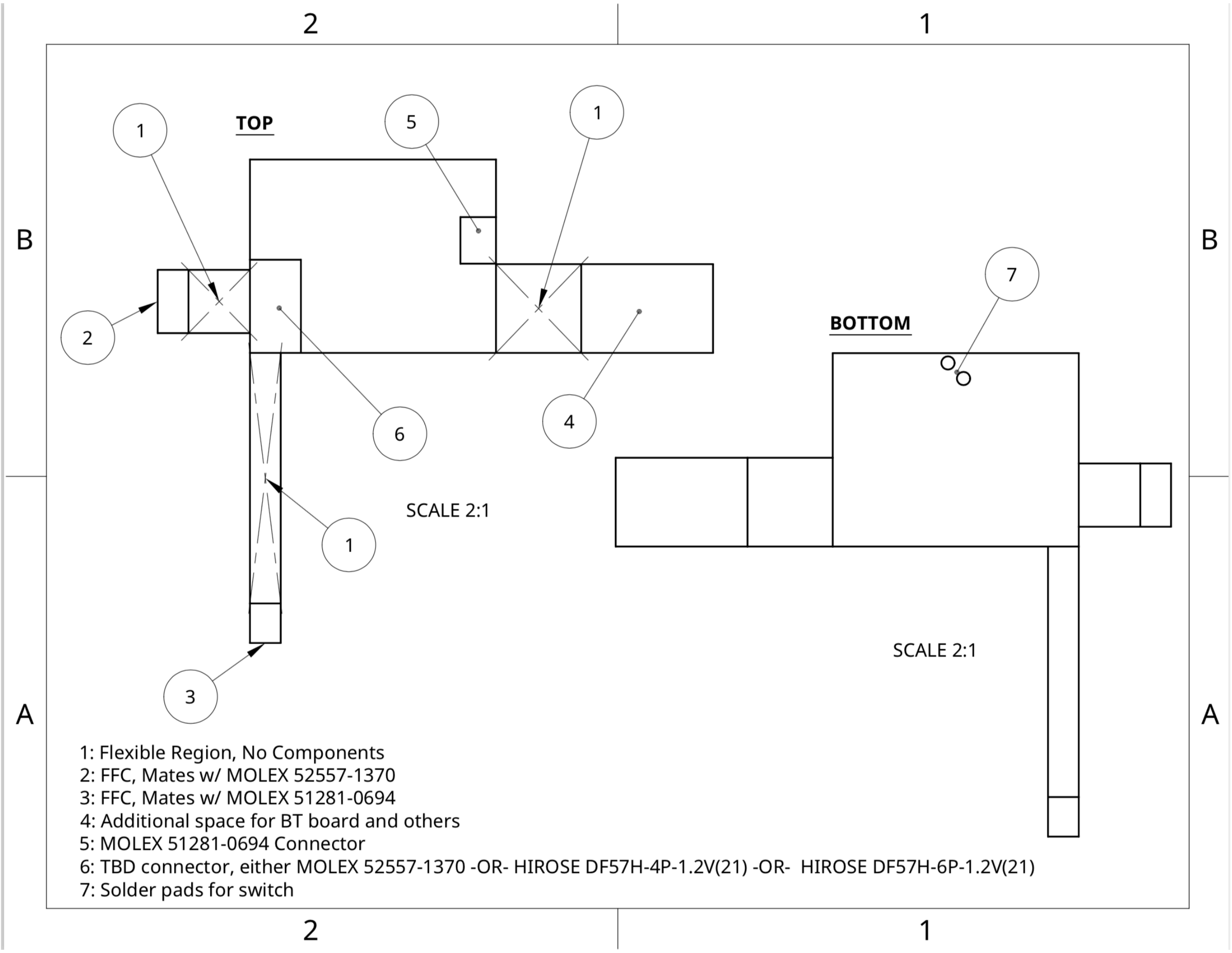
The above-described changes and others were incorporated into the final flexible circuit schematic (below) which was reviewed by four of our engineers in detail including the ones working on electronics layout, firmware development, sensor design and testing, and the PI. This signed off circuit has been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



1: Flexible Region, No Components
2: FFC, Mates w/ MOLEX 52557-1370
3: FFC, Mates w/ MOLEX 51281-0694
4: Additional space for BT board and others
5: MOLEX 51281-0694 Connector
6: TBD connector, either MOLEX 52557-1370 -OR- HIROSE DF57H-4P-1.2V(21) -OR- HIROSE DF57H-6P-1.2V(21)
7: Solder pads for switch

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

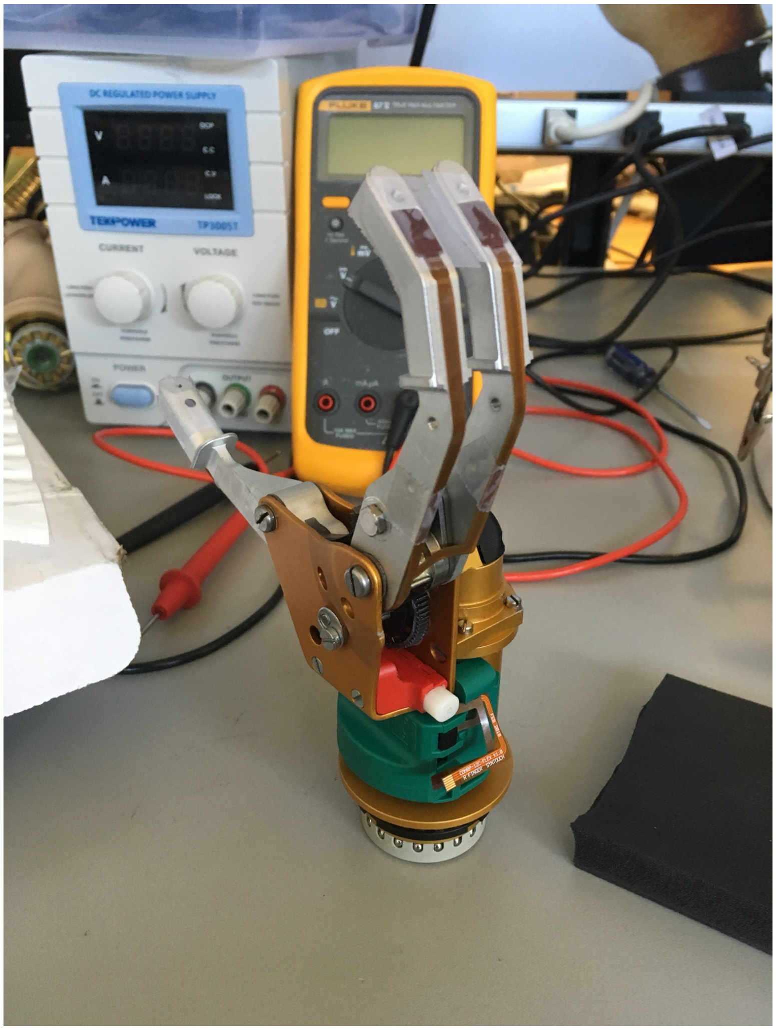
As part of the effort to finalize electronics, changes to the main board design included the addition of an auxiliary board to connect the battery and programming pins in an accessible location at the backside of the controller housing. This was measured and prototyped with mechanical components to ensure 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

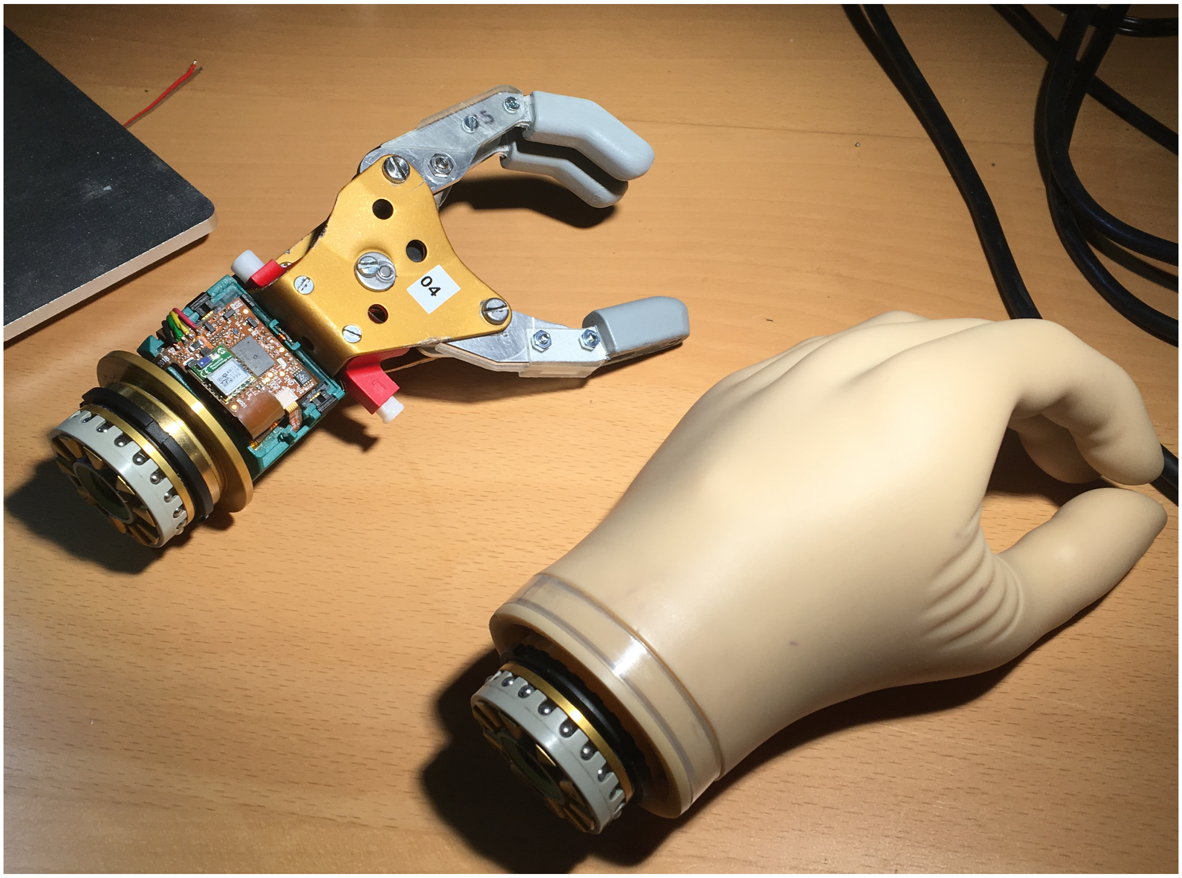
On receipt of the flexible circuits electrical function was tested and a loading issue with the I2C lines was observed on the flexible circuits on the finger side of the hand. This was identified and debugged and the loading resistor on the final controller was changed and observed to work on our development 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.



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**.

YEAR 4

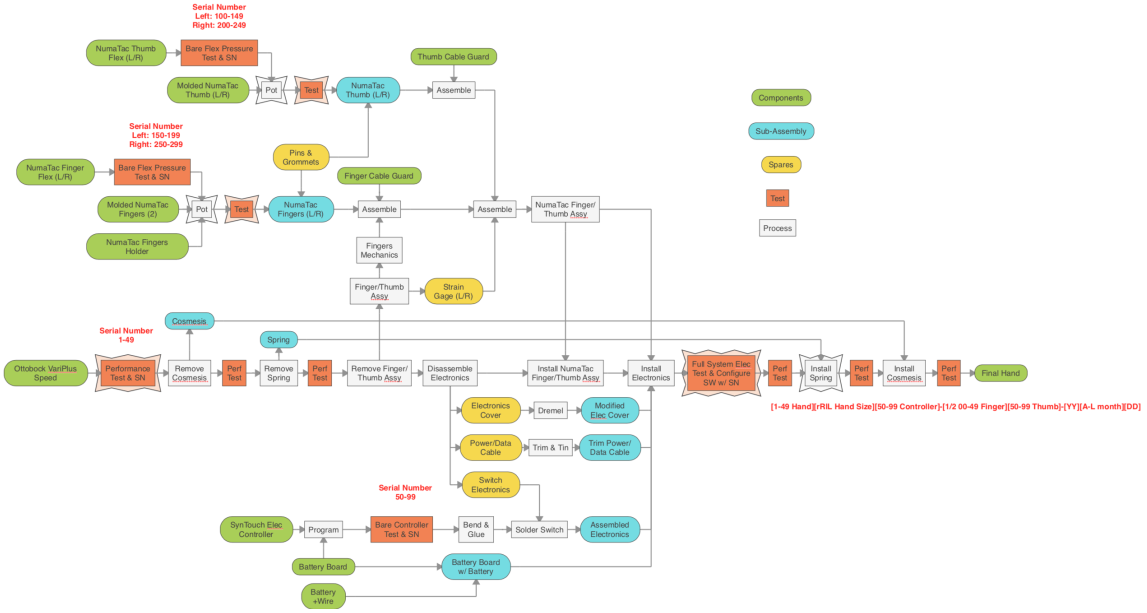
Clinical Studies Technical Support

After consultation with our clinical investigator a number of software features and improvements have been implemented to simplify programming and output of data. We have also developed a physical controller to make it easier to open and close the prosthetic hand when not installed on a socket as well as other equipment to aid in the clinical testing protocol.

Prosthetic Hand Manufacturing and Documentation

A total of 5 prosthetic hands have been built and tested thus far. We have presented our progress to Ottobock over web conference and they were very pleased with the progress and donated several spare parts to aid with the manufacturing and repair processes.

In addition to this, to ensure knowledge was not lost in the lengthy delays of IRB/HRPO approval (as discussed below), several steps were made to document the manufacturing and testing processes (SOP) and implement a serialization scheme for the sensors, hands, and electronics. Exerpts from this documentation are provided below.



Hand Manufacturing, Serializing, and Testing Flowchart

Assembly Notes on Hand Manufacture

YEARS 5 & 6

Prosthetic Hand Manufacturing, Maintenance, Organization, Usability and Documentation

Our study had a very long and unfortunate sequence of IRB approvals due to needing to first expand our recruitment sites, then to adapt protocols to the coronavirus pandemic (COVID-19), these are detailed below. Throughout this, there have been periodic design reviews and improvements to the hardware and software to maintain familiarity with the technology while awaiting the start of clinical studies. During this period, we took the time to do a complete calibration and testing of all sensors so that the best of the lot could be built into the final prosthesis. We also implemented several improvements to the sealing and coatings of the final NumaTac sensors and improved the routing of the flexible circuits through the prosthetic motor gearing as well as strengthened their protective covers. This included introducing a nail-like top to improve the sealing of the sensors and protect the top edges from small tears that were discovered on some units.

3D printed parts of improved finger covers (left) and final assembly of left/right fingers and thumbs (right)

Subject Prostheses Configuration and Manufactured to Spec

We have completed the manufacture of the three prostheses configured for our three subjects in the clinical studies, including a spare hand and spare parts for quick replacements.

Final hands (with cosmeses removed) that were ultimately sent to subjects, plus spare parts retained for any necessary repairs.

Software and Firmware Reconfiguration for Remote Studies

Through preparations of the final prostheses described above, a few minor complications relating to the mechatronics and firmware were discovered. The most notable of these was an issue discovered once the hands were finally sealed up that the pressure inside the cosmesis rose when the hand closed, creating a false "contact" signal at the fingertips that interfered with the contact-detection reflex we have been designing and testing. Fortunately, this problem was anticipated as a possible failure in the early stages of design, and as a fail-safe, a reference pressure sensor was incorporated to compensate for such an error. Implementing this improvement, however, required a rather extensive overhaul of firmware architecture, which also required additional testing to properly validate. Through re-working the contact detection algorithm and timing we were able to resolve the issue so relative pressure was detected between each fingertip and the reference pressure sensor, mitigating the interference from cosmesis internal pressure. This unfortunately had a slight impact on performance due to the increased sampling and calculation time in the microprocessor as well as doubling the noise of the measurement by combining two sensors. Nonetheless, the improvements were significant enough to warrant implementing into the final builds.

Related to the above firmware architecture changes, we also took the opportunity to improve the Bluetooth bootloader to be more robust given that subjects would no longer be coming in to office visits during the pandemic. Now if the firmware becomes corrupted the hand will constantly be on the lookout for a Bluetooth bootloader command from our software to reconfigure and reset it with any updates that we have configured to software to send. We do not anticipate needing to perform this operation, but it will be useful since our subjects would not be able to open the hand and access the programming lines as we designed for our own team to do if needed in the office. We also improved the usability of the software in case subjects needed to interact with it directly, although the current plan is for us to control the software through screen sharing on their computer through a video-conferencing software such as Zoom.

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

YEAR 1

Experimentation was conducted in order to evaluate fragile grasping candidate objects based on strength and deformation. The final object, saltines, stood out as the best choice because they are fragile and break in a distinct way, leaving little room for subjectivity on the part of those conducting studies. It was decided that an every-day object like this is the best for evaluating fragile grasping because the task is both realistic and grip forces are easy for the subjects to estimate; therefore, the idea of a "mechanical egg" or force measuring object was rejected in favor of this common cracker.

A comprehensive bench top study was conducted in order to identify effective outcome measures for the evaluation of fragile grasping for myoelectric prosthesis users. Methods of visual and cognitive distractions that were evaluated for their effect on grasping performance of an amputee included but were not limited to visual occlusion (full, partial, augmented) mathematical calculations, question answering, spelling and word associations, decision making, etc. The best distraction methods were identified as visual occlusion and parallel story summarization. An amputee, Vikram Pandit, performed timed preliminary experiments both bimanually and unimanually. A summary of experiments performed can be found below and the downfalls of the experiment are shown with "X's", while promising results are shown with checks.

Outcome Measures Summary:

1. Visual Distractions

    a. Visual Impairment Goggles

- Two different types of visual impairment goggles were used, one that blurs vision, and one that warps vision. A unimanual cracker passing task was conducted where the subject is presented with a cracker and transfers it to a cup. This was done without wearing goggles and while wearing a pair of goggles.

× *With goggles, the subject was significantly slower with their sound hand (52%) and VPS (32%) hand than with the NT hand (14%). The sound hand is the "easiest hand to use" however performance decreases more with the sound side than NT hand. This is a problem – we cannot correlate % speed decrease to how difficult it is to use a given prosthesis using this measure.*

× *The subject felt sick wearing the goggles for too long. It is evident that they distort vision so much that when the subject closed their eyes to avoid looking through the goggles, they actually performed better. The goggles are too difficult to use and may actually make subjects sick.*

    b. Visual Barrier

- The subject is instructed to grasp a cracker with the sound hand, pass it to the prosthetic hand behind a large barrier that obstructs view, and transfer that cracker to a cup using the prosthetic hand.

× *With a relatively rapid task, the barrier tended to obstruct the movement of the subject often enough that task time was affected.*

✓ *Speed dropped more with VPS (21%) than the NT (13%)*

× *More dramatic numbers were measured when vision was occluded completely with a blindfold and therefore we decided that the barrier is too much of a hassle and the process can be simplified with better results by removing vision completely.*

c. Unimanual Blindfolded Passing

- The subject is instructed to grasp a cracker with the prosthetic hand and transfer that cracker to a cup. This was done with the subject wearing a blindfold.
- × *It was difficult for the subject to grasp a cracker with the prosthesis if they are not holding it. They have no way to know where it is.*
- ✓ *It is possible to compare performance to the sound side.*

d. Bimanual Blindfolded Passing

- The subject is instructed to grasp a cracker with their sound hand, pass to their prosthetic hand, and transfer that cracker to a cup. This was done with the subject wearing a blindfold.
- ✓ *Performance speed decreased significantly more when using the VPS (80%) than the NT (16%) or sound side hands (21%).*
- ✓ *The task is very simple.*
- × *It is a little difficult for the subject to find the initial cracker, therefore it needs to be placed in the same spot every time it is presented.*
- × *We cannot compare to the subject's sound side, therefore we will need to compare to able-bodied individual's performance.*

2. Cognitive Distractions

A one-to-one task is a series of tasks with one occurring with each cracker pass. A parallel task is a single task that spans for the duration of the experiment.

a. Math Problems & Odd/Even Sum (one-to-one)

- The subject is presented with two random single digit numbers at the same time that they are presented with a cracker. They are instructed to add the two numbers and dictate whether the sum is odd or even before dropping the cracker into the cup, upon which they will be presented with two new numbers. This is a unimanual passing task. This is repeated 10 times, once for each cracker that is grasped. Time, cracker breaks, and addition failures are recorded.
- × *The cognitive portion of this task slowed the subject's passing speed when using the sound hand, Vari-Plus Speed (VPS) hand, or the NumaTac hand (NT). There was no significant difference in worsening percentage (WP) between the VPS or NT hands and therefore is not a good method to compare difficulty of use between the two hands.*
- × *Addition introduces performance anxiety, which may affect a person's performance and comfort level with the task.*

- × *Each person has different mathematical backgrounds and mathematical processing speeds so it is likely that this experiment would have a large amount of variability among subjects.*
- × *The subject quickly started to use memory and different strategies that decreased the need for cognitive processing.*

b. Word Association (one-to-one)

- The subject is presented with a random word at the same time that they are presented with a cracker. They are instructed to say a word that is associated with the word they were presented with and do so before dropping the cracker into the cup. This is repeated 10 times, once for each cracker that is grasped. Time and cracker breaks are recorded. This same process was repeated but instead of open word association, the subject had to listen to the presented word and say the name of an animal beginning with the last letter of the presented word.
- × *During the task, the subject is slowed by the same amount of time for both the NT and VPS hands.*
- × *It is too easy for the subject to delay until the passing motion to say an associated word. This allows them to grasp the cracker and think at different times. It is such a quick task that delaying briefly until the grasp is over does not affect the speed.*
- × *The presenter uses time saying the word, which affects the experiment because the time it takes to say the word is sometimes longer than the time it takes to move from dropping the cracker in the cup to grasping the next cracker. This skews the 1:1 ratio of words to cracker passes.*
- × *With themed word association (animal names) the subject tends to repeat animals and learns how to use as little thought as possible. After this learning has happened, comparisons among trials that happened during the training period cannot be compared.*

c. Solve Short Definitions (one-to-one)

- The presenter says a two-word definition before the cracker is presented. The subject has to think of the term that the two words define and say it before dropping the next cracker in the cup (king’s hat → crown). This is repeated 10 times, once for each cracker that is grasped. Time and cracker breaks are recorded.
- × *There was very little delay in time due to the cognitive task.*
- × *Again, there was the issue of the presenter delaying the task while speaking and the 1:1 ratio of definition to cracker pass tended to get skewed after 5 crackers because of this delay.*
- × *It is difficult to force the subject to think while grasping the cracker. They tend to grasp the cracker and then think and complete the task during the transfer period between grasp and drop.*

- ✓ *The benefit of this method is that there is no strictly right or wrong answer. This facilitates thought without the same potential for performance anxiety that math problems may pose.*

d. Change Tense of Sentence (one-to-one)

- The presenter says a three word sentence before the cracker is presented. The subject has to change the tense of the sentence to past tense. The presented sentence can be in any tense, including past tense to start with. This is repeated 10 times, once for each cracker that is grasped. Time and cracker breaks are recorded.
- ✓ *There was a higher delay percentage with the distraction when using the VPS hand than NT hand.*
- × *Again, there was the issue of the presenter delaying the task while speaking and the 1:1 ratio of definition to cracker pass tended to get skewed after 5 crackers because of this delay.*
- × *Repeated verbs allow the subject to work off of memory instead of thought.*
- × *It is difficult to force the subject to think while grasping the cracker. They tend to grasp the cracker and then think and complete the task during the transfer period between grasp and drop.*

e. Finger Tapping Rhythm (parallel)

- ✓ The subject performs the traditional unimanual cracker passing task with their prosthesis. During this task, they are instructed to continuously pinch their sound side thumb with each free finger, one after another, in a loop pattern starting with the pointer and ending with the pinky.
- × *Though the subject has to continuously think about which finger to tap, this is not a purely cognitive task – it is physical multi tasking.*
- × *This task did not significantly slow the subject with either prosthesis.*

f. Listen For Words in Story (parallel)

- During the traditional unimanual cracker passing task, the subject listens to a recorded story and is instructed to listen for a specific word (they, was, etc) and count the number of times it is repeated.
- × The subject found this task very difficult because once they got lost in the story or thought they missed one word, they gave up knowing they had already failed the task. This was deemed to be too difficult due to the fact that missing one word threw the subject off greatly.
- × The final number of words counted cannot be used as a metric for performance. Even if the person is listening intently, it is possible to over or under count. It is also possible for the person to make up a number at the end to avoid the task.

- ✓ A parallel task that does not involve a delay from the presenter dictating seems to be a good option. This kind of task requires constant attention whether grasping, transferring, or dropping the cracker.

g. Parallel Addition (parallel)

- During the traditional unimanual cracker passing task, the subject listens to a list of numbers that are dictated at regular intervals throughout the task. The numbers are small and are either positive or negative. The task is to add the numbers as they are presented throughout the passing task.
- × The subject found it difficult to continue once they became overwhelmed or missed a number.
- × This task could be very difficult for someone who processes numbers slowly. It could also be very easy for someone who does this quickly and therefore the level of distraction is subjective.
- ✓ It was concluded that although a parallel task has its benefits, the task should not have a definitive answer at the end (no counting or math) because this leads to frustration.

h. Summarize Story (parallel)

- Throughout the unimanual grasping task, the subject summarizes a movie. This movie title is given to the subject just before the task starts and they are instructed to explain the plot as best possible using full sentences without pausing. No movie title is repeated.
- ✓ *Performance data showed that the subject did not get significantly worse using the NT hand during the distraction, however they did get significantly worse when using the VPS hand. The NT and sound side data was well correlated however it was obvious that the VPS hand took more effort.*
- ✓ *Due to the nature of "reliving" or recounting the plot of a story, it seems like the subject commits to the summary more than most verbal or mathematical tasks. The subject's interest in this type of task will keep them engaged and thinking.*
- ✓ *There is no right or wrong answer at the end of the task so it is easy for the subject to continue with little frustration.*
- ✓ *Any subject can complete this regardless of verbal or mathematical knowledge as long as they are provided with media titles they are familiar with.*
- ✓ *This encourages the person to think throughout the task without the ability to avoid thinking during the grasping phase.*
- × *The quality of the summary varies among subjects, therefore their mental engagement in the task also varies.*
- × *Able-bodied subjects may need a more difficult task to perform in a clinical setting in order to see a larger difference between the distracted and not distracted cases.*

Outcome Measure Study Conduction:

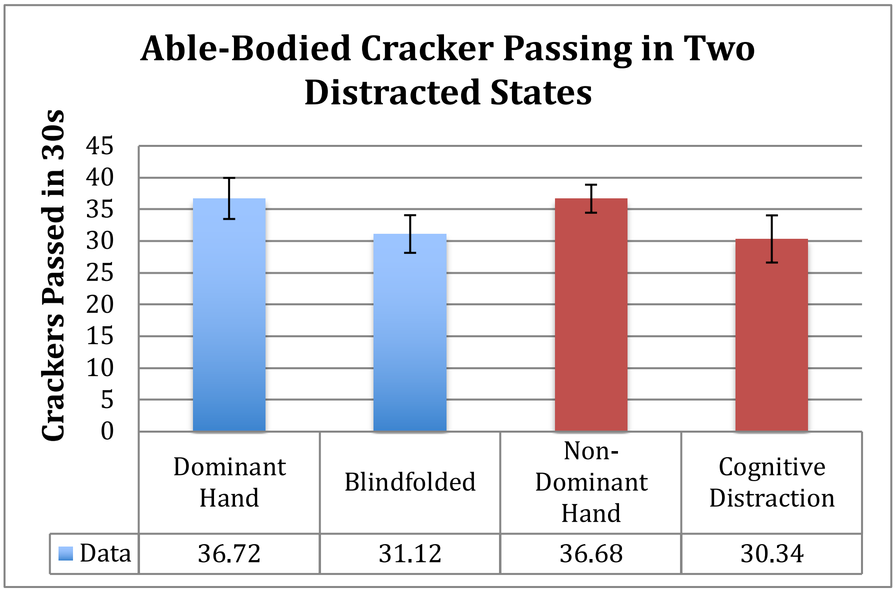
The final distraction methods were chosen and they are visual occlusion and cognitive distraction using story summarization. The outcome measure study procedure was refined, drafted, and tested. Documents for IRB protocol submission were created, submitted, and the study for evaluation with able-bodied individuals was approved as a minimal risk study. This includes the full procedure (Appendix B), modified procedure for a small subset of individuals to assess single and double handed performance (Appendix C), the study consent form and cover letter (Appendix D), and an exit questionnaire (Appendix E). This was then submitted for 2nd level military IRB and approved. Clinical protocol refinements were made in collaboration with CI Gary Berke and were approved by both IRB organizations. The conduction of the study has begun and 10/30 volunteers have performed the refined protocol. Preliminary data has been analyzed. It can be concluded with statistical significance ($P<0.05$) that both distracted states are significantly slower than the corresponding non-distracted state. See data here:

Preliminary Outcome Measure Study Findings (10/30 Volunteers)

Four volunteers have performed the primary clinical study, which looks at the effect of both visual and cognitive distraction on fragile grasping performance in able-bodied subjects. The two distraction methods are performed using a bimanual grasping strategy. The visual distraction has the person perform the bimanual task, however they transfer the object between hands behind a curtain so the person cannot see. The cognitive distraction has the person summarizing a story as they perform the normal bimanual task. The volunteers also perform the bimanual tasks without any distraction so that we can compare to a baseline.

A two-way ANOVA test with repeated measures was implemented and it was found that both the testing condition (method of distraction) and trial-to-trial performance of individuals demonstrated significant differences ($P<0.05$). A post-hoc multiple comparisons test was performed via Tukey's multiple comparisons test to determine what conditions differed significantly. It was found that for the dominant hand, the blindfold and non-blindfolded cases differed significantly. It was also found that for the non-dominant hand, the distracted and non-distracted cases differed significantly. Additionally, the dominant non-blindfolded and non-dominant distracted cases differ significantly.

This study will continue until performance from 30 volunteers has been observed and analyzed.



Additional Work:

An abstract and demonstration were submitted and included in the Haptics 2016 symposium, Philadelphia (Appendix F). The submission topic was about contact detecting sensors used on prosthetic hands and the contribution of this technology to fragile grasping tasks. This used data from visual occlusion outcome measure preliminary tests, which showed that the prosthetic hands with contact detecting sensors perform more similarly to able-bodied individuals than prosthetic hands without in both distracted and non-distracted states.

An abstract has been submitted to AAOP 2017 (American Academy of Orthotists & Prosthetists) about our pre-study findings comparing bimanual fragile grasping of a myoelectric prosthesis user with and without the use of contact detecting sensors. The data is compared to that of able-bodied individuals performing the same task. The abstract is attached and is called "Contact Reflex Improves Fragile Grasping while Blindfolded" (Appendix F).

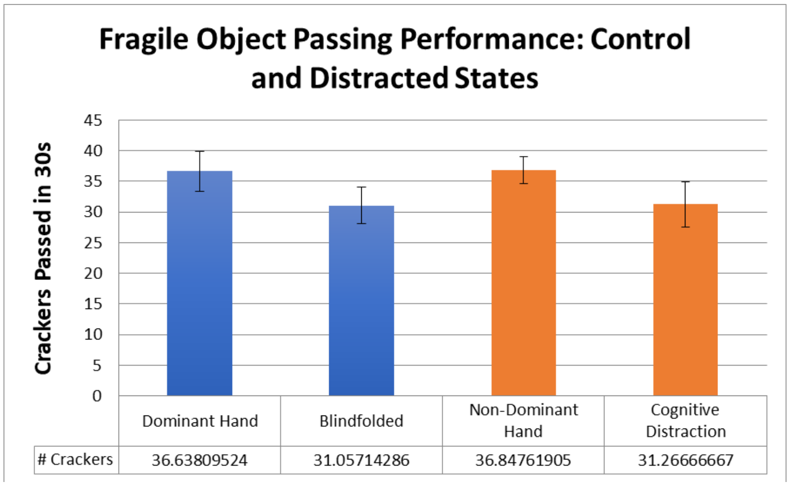
Steps have been made to prepare for the clinical study. SHAP (Southampton Hand Assessment Procedure) was ordered, evaluated, and determined not to be a useful outcome measure for use in clinical studies. CI Gary Berke finished ACMC training and some tasks have been tested using this assessment measure for inclusion in clinical studies. The Palo Alto VA has agreed to collaborate for the clinical study.

<u>YEAR 2</u>

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).



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.

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

YEAR 2

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.

YEAR 3

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. 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 and a minor change in protocol were submitted to the HRPO for review.

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.

As outlined below, what should have been a very minor protocol change submitted to and approved by HRPO, allowing us to complete this study with the 5 interested subjects at this moment in time resulted in a very unfortunate and unpredictable sequence of events (ultimately culminating in the COVID-19 pandemic) which was damaging to the quality of the final study. While this could not have been predicted and much of what followed could only be described as "bad luck", there is significant regret by the PI for taking this approach as the quality of this study would have been much better if we had proceeded with the original protocol with the subjects available at this moment in time.

<u>*YEAR 4*</u>

Overview of Recruitment Challenges Stemming from IRB/HRPO Delays

We have encountered a great number of challenges with recruitment and IRB/HRPO approvals which can only be described as a perfect storm of bad luck. While our original plan as submitted in the proposal was to include the VA Palo Alto as a second site, their long approvals made it more attractive to pursue the study with Berke Prosthetics as a single site since we had 5 subjects interested in participating (this was discussed and approved by Troy Turner, our original PM). Our IRB protocol was submitted to Heartland IRB on 9/18/2017 and was expeditiously reviewed and approved on 9/22/2017 and we immediately submitted to HRPO also on 9/22/2017. This process with HRPO and IRB took more than 7 months to sort out, and we did not receive approval until 4/27/2018 and over that time all 5 of our interested subjects were no longer in town or available to commit to the study, leaving us with no test subjects. After a series of recruitment attempts (discussed below), we decided to revert to the original plan of including the VA as a second site as they had additional subjects available, this started in October of 2018 and due to many delays (discussed below) was not approved by the Stanford IRB (which serves the Palo Alto VA) until 12/6/2019 and is still awaiting HRPO final approval. We have filed and received a no-cost extension as a result of these delays. This became a critical risk which we contacted our PM to help to resolve.

Clinical Studies Outreach to Improve Recruitment Numbers

As discussed above, the entire original team for this project met to discuss priorities in year 4. An outcome of this meeting was a decision to focus on recruitment and the following action plan was outlined:

- Continue working with the VA to get the study approved.
- Continue working with Hangar Prosthetics to gain access to their network.
- Reach out to colleagues in neighboring cities (Bay Area, Southern California, Seattle, Portland, and Denver) for recommendations.
- Reach out to our commercial partner at Ottobock to ask for recommendations and assistance.

In parallel to collaborating with the VA Palo Alto as a second recruitment site (discussed below in greater detail), many efforts were made to increase our recruitment.

Clinical Investigator, Gary Berke, reached out to a number of his colleagues in the field including Hangar Prosthetics and started paperwork and attending meetings to open up their network of patients to the study. Ultimately the costs they required to prioritize this work on their agenda was found to be cost prohibitive and out of our budget.

In an attempt to improve public outreach we also created a research website at http://research.syntouchinc.com with information on the study including eligibility criteria, recruitment letter, consent forms and other standard materials that would be provided to interested parties. This website was also circulated to colleagues in the field. We also attempted a Facebook advertising campaign but it did not yield results. We have concluded that making fellow clinicians aware of the study is perhaps our best approach. As of this report we have halted our outreach to this community and will restart once we have HRPO approval for the complete study.

IRB & HRPO Approval with VA Palo Alto as a 2nd Site

At the commencement of year 3, a new strategy was developed to improve recruitment yield. The Veterans Association of Palo Alto (VA) were re-identified as a collaborating group and initial steps were made to set up the VA Palo Alto as a secondary clinical site. At the beginning of Year 4, Clinical Investigator, Gary Berke, reached out to a number of colleagues in the field including Hangar Prosthetics in an effort to open up their network of patients to the study. Hangar Prosthetics was interested in aiding with recruitment, but ultimately the amount of costs they required to prioritize this work was out of the budget of the study. In an attempt to improve public outreach, we created a research website at http://research.syntouchinc.com with information on the study including eligibility criteria, recruitment letter, consent forms and other standard materials for interested parties. This website was also circulated to colleagues in the field. With little forward movement from non-VA contacts in regards to recruitment promise, we decided to proceed with only the Palo Alto VA as a secondary clinical site.

There are 4 sets of approvals that were required in order to include the VA as a collaborating site:

1. Study approval by the VA's IRB, Stanford IRB
2. VA organization internal study approval
3. Study approval by SynTouch/Gary Berke's IRB, Heartland IRB
4. HRPO overarching study approval

Relevant documents were modified including the consent form and cover letter, protocol, flyer, and Heartland IRB submission overview in order to reflect the addition of the VA as a collaborator and secondary site. In Q4 of Year 3, the VA submitted the clinical plan and supporting documents to Stanford IRB and received approval in the same quarter. With the Stanford IRB approval letter included, the modified documents that reflected the inclusion of a secondary clinical site and secondary IRB were submitted to Heartland IRB for review in 2/12/2019 and approved on 2/22/2019. **This completed the final approval of the current study design by Heartland IRB.**

Upon review of the dual IRB approved study by the VA's internal review board, modifications to the wording and structure of the proposed proceedings were requested, fulfilled by the VA, and approved by the VA's internal review in June, 2019. At this time, submission of the modified study and approval letters from both clinical sites to HRPO were complete (March, 2019) and awaiting review. In early June, we were made aware that our reviewer was no longer working at HRPO at the time of submission and our submission was assigned a new reviewer in June. HRPO requested various documents including human subjects protection training, conflict of interest statements, form FDA 1572, etc. from the VA. These documents were then provided and submitted to the reviewer on July 8, 2019.

On August 16, 2019 we were notified that our reviewer from HRPO had changed again and upon review by this third reviewer, a list of requests were made for the VA. Specifically, HRPO wanted confirmation that Stanford IRB supported the device determination made by Heartland IRB. When this request was presented to Stanford IRB, it was realized that a clerical error was present and the study had been miscategorized as “greater than minimal risk” and Stanford IRB required a resubmission of materials by the VA. This was received and approved in October, after which the VA’s internal review requested a third modification. **This was provided and approved by the VA organization in late October, 2019, completing their request for modifications** and these changes were submitted to Stanford IRB, and **final approval of all modifications by Stanford IRB was received on December 6, 2019.**

The final Stanford IRB approval and stated support for the Heartland IRB device determination were submitted to HRPO on December 6, 2019 and are currently awaiting final review. Following this approval, all 4 reviewing groups will have approved the current, final study design.

Team Preparation for Clinical Studies

When clerical and categorical issues were identified at Stanford IRB, weekly meetings were set up between HRPO, SynTouch, and Stanford IRB to identify the source of discrepancies between the two IRB reviews. It was identified that the Stanford IRB was mis-categorizing the clinical study as greater than minimal risk solely due to the fact that this is a DoD funded study. With the aid of HRPO, Stanford IRB was educated on the interpretation of regulations regarding approval of DoD funded studies, and review concluded. At the end of Quarter 4, we began preparation for a whole team kickoff meeting to review the clinical protocol and procedure for accepting and coordinating participant office visits.

YEAR 5

Overview of IRB/HRPO, Recruitment Sites, and Pandemic Challenges

As discussed in the previous annual report, we have had a great number of challenges with recruitment in this study that did not improve this year. To briefly summarize:

- In September of 2017 we were ready to begin testing with 5 subjects interested at the Berke Prosthetics site, however HRPO took 7 months to approve and at that time all 5 of our interested subjects were no longer in town or available to commit to the study.

- After trying for a few months to find more subjects, we started the process of adding the VA Palo Alto as a second site in October of 2018, which due to many unfortunate delays (discussed in our last report) was not approved until December 2019.
- We then had the study sent and approved by HRPO for all sites in February 2020 and started recruiting subjects, and then the world was hit with the COVID-19 pandemic, which effectively put a halt on any research collaboration with the VA Palo Alto.
- After waiting to see what would happen with the COVID-19 pandemic and recognizing that it was not going away anytime soon, we worked to reconfigure our studies for remote subject testing over video conferencing. This new testing mechanism allowed us to recruit 3 of the original 5 subjects from September 2017 to participate in our research.

This series of unfortunate luck was a painfully inefficient process and in retrospect we should have been more vigilant in moving the process forward, however, not much of the above, particularly the pandemic could have been foreseen.

Complications and Adaptations for COVID-19 Contingency Planning

In response to the COVID-19 outbreak and subsequent shelter-in-place orders issued in the Bay Area and eventually by California Governor Gavin Newsom statewide on March 19 our teams met to discuss contingency plans. The VA Palo Alto has placed an administrative hold on non-critical, in-person interactions with human research subjects, including our own until further notice, so recruitment of the three interested subjects and further outreach has been put on hold for that site. Berke Prosthetics have implemented similar policies for non-emergency care during this period, however, they are able to still communicate with interested participants and have three subjects interested in participating in the study when protective measures relating to COVID-19 are lifted. In the early months of the pandemic we focused our efforts on building the prosthetic hands for these subjects and waited to see how the pandemic would change.

As it became apparent that the pandemic would outlast our study we began planning for modified clinical trials that would include subjects performing the same tests, but at their homes over videoconferencing for health and wellbeing of all involved. This involved testing several scenarios of how the subjects might be able to set up and perform the experiments without an experimenter present and instead guiding them over video conferencing. Improvements such as incorporating a lighted timer on the subject's side allows for time to be kept precisely without worry of videoconferencing delay and the operators to observe (over video) when the 30 seconds for each experiment has lapsed. We also were able to find additional silver linings in these modified tests such as allowing subjects to perform the "activities of daily living" in the ACMC task with activities they actually use in their daily life.

Effective June 29, 2020 all protocols were submitted and approved by IRB and HRPO under special exception for improving safety in COVID allowing us to proceed with our study in the less-than-ideal remote testing environment.

Major Task 4-2: Conduct clinical studies

YEAR 3

Initial Clinical Studies (Planned)

Plans went in place to start 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. This was interrupted by the lengthy HRPO approval discussed above.

YEAR 4

Clinical Studies Awaiting Approval

During Q3 Year 3, we had to discontinue recruitment and scheduling efforts while study modifications were submitted for approval by the VA. The duration of time and iterative nature of the requests and resubmissions caused unanticipated and lengthy delays. Final approval by HRPO, was expected before the conclusion of 2019 after which recruitment and clinical study conduction would resume.

To ensure knowledge was not lost through these delays, the clinical team coordinated regular meetings at a minimum of every 2 months.

YEAR 5

Recruitment of subjects

After final approval of clinical studies by HRPO, then changes to the study to adapt to COVID-19 which were fortunately approved rapidly under special exception for improving safety in the pandemic we were able to successfully recruit three subjects for the study. It should be noted that these were three of the five original subjects we had in summer of 2018, but had moved away, therefore causing us to add the VA as a second site and the string of bad luck that had followed.

Preparation of kits

Given the restrictions of in-office testing due to COVID, we modified our study protocol to allow for remote testing over video conferencing. This included designing a template and standardized items to ship to all subjects to perform the experiments. Each subject was shipped a laptop, hand, and a complete kit of items to perform the cracker-passing task from tray to bowl, with and without visual or cognitive distraction. Both the SynTouch site and the Berke Prosthetics site maintained a spare kit for design and testing of the experimental protocol (which was completed before shipping to subjects) and as a backup.

Kits sent to each subject, which include a wide-angle web-camera with gooseneck stand, the towel and stand for no-vision tests, a flashing timer, a template sheet, a bowl for the crackers to be passed to, charger and Bluetooth card for the laptop, the laptop, and the prosthetic hand. Not pictured is the tray that goes on top and the crackers that were shipped separately.

At the end of Year 5, all kits were shipped to the three participants.

<u>YEAR 6</u>

In the final quarter of the project we conducted remote Zoom clinical studies according to the modified clinical protocol approved by IRB and HRPO. Subjects met for either three or four virtual meetings according to protocol performing ACMC evaluations and all variants of the fragile passing task (no distraction, visual distraction with obstructed vision, and cognitive distraction through storytelling). These tests were performed with the subject's personal prosthesis, the modified prosthesis with the reflex off, and the modified prosthesis with the reflex on.

The protocol as planned was to go from personal prosthesis -> reflex-off -> reflex on -> reflex off, with three multi-week take-home studies in between. After the first take-home study indicated issues with the first subject's hardware, and in consideration of the remaining timeframe, the take-home tests were aborted for subjects 2 and 3, and partially aborted for subject 1. Other hardware issues were encountered as described below.

Preliminary Analysis of Findings and Evaluation of Hardware

It is with great disappointment that after the significant challenges of: 1) removing the VA as a site due to lengthy IRB delays, 2) needing to add the VA as a again as a site after losing interested subjects waiting on lengthy HRPO approval, 3) waiting more than a year on the VA/IRB/HRPO approval and finally getting all approvals only a few weeks before the COVID-19 pandemic, 5) the VA pulling out of all non-essential research through the pandemic, and 6) scrambling to modify protocol for remote clinical studies, that after all of the above our studies had a disappointing outcome that could have been resolved if we had more time or proceeded with the approved protocol in 2018. In particular, all three subjects experienced electrical anomalies issues with their hardware in the field that were not identical and indicated that the electronics were not sufficiently robust for take-home testing. While no issues for any hands were observed in the hands when tested on the lab bench, each of the three hands to the three subjects (as well as a fourth hand sent to one of the subjects) experienced different, but infrequent issues, as follows:

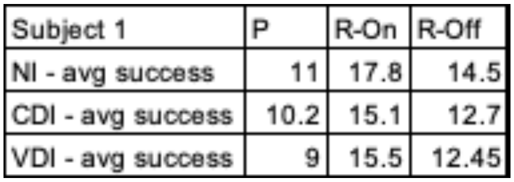
- Subject 1, first hand (SN 15L55): Reflex was inconsistent and at times during clinical studies and sometimes would not work at all (essentially behaving like a normal prosthetic hand without the reflex). Upon bringing the hand back for postmortem evaluation, this was observed to be true for the first evaluation, but the hand returned to normal function for the remaining evaluations. Disassembly of the hand showed no damage to electronics or sensors. It was hypothesized that the pressure of the cosmesis on the electronics controller could have contributed to the issue, but we were unable to confirm this.
- Subject 1, second hand (SN 12L70): The hand worked perfectly fine, with the reflex, but would occasionally stop working all together unless reset. This made the hand unusable for clinical studies and we reverted back to the first hand for the remainder of the studies. Upon observing the hand in the laboratory we were unable to see the same symptoms.
- Subject 2 (SN 24r53): The hand was sensitive, but also had occasional instances of the reflex going offline that seemed to be related to the orientation of the hand, bringing suspicion that perhaps there was a manufacturing defect or another issue with the controller board. Upon reviewing visual data from the subject and reading the log files from the data controller we can see clear alignment on the reflex failure and the breaking of crackers.

- Subject 3 (SN 24r53): The data logging function of the hand was damaged and we were unable to collect detailed data for analysis. At times the hand would “false trigger” which means that it would stop moving and engage the reflex without making contact. Adjusting the sensitivity of the sensors did not resolve this, which seems to suggest that the data logging inability of the controller could have been locking up the processor and slowing down the hand.

In all cases, the sensors, which had been designed to be robust, held up well through the clinical studies, which is certainly a positive outcome. However, it appears the electronics controller, which was extensively tested and validated on the lab bench, did not fare well in the field studies. Further investigation into sources of electrical or mechanical interferences will need to be conducted to understand the root cause of these issues.

Summary of Performance

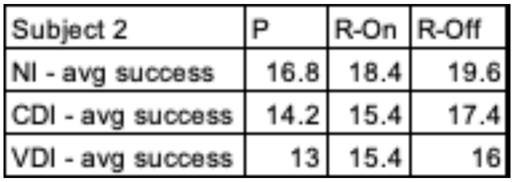
A summary of all subject performance can be seen in the tables below.



Subject 1	P	R-On	R-Off
NI - avg success	11	17.8	14.5
CDI - avg success	10.2	15.1	12.7
VDI - avg success	9	15.5	12.45

Subject 1 summary data. NI=No Intervention/Distraction, CDI=Cognitive Distraction Intervention, VDI=Visual Distraction Intervention, P=Personal Prosthesis, R-On=Study Prosthesis with Reflex On, R-Off=Study Prosthesis with the Reflex Off. Numbers indicate the number of non-broken crackers successfully passed in 30 seconds.

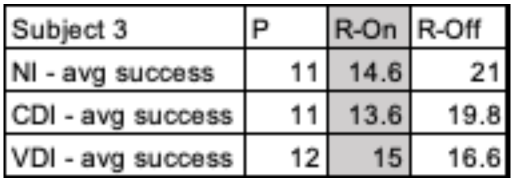
Subject 1 did significantly better with the reflex version of the hand compared to their personal prosthesis (62% improved under normal no-distraction testing, 48% better when cognitively distracted, and 72% better when visually distracted), this subject also did slightly better than the same hand with the reflex disabled (23% improved under normal no-distraction testing, 19% better when cognitively distracted, and 24% better when visually distracted), this reduced improvement has been interpreted to mean that the compliance of the fingertips alone contributes to some portion of this performance even without the reflex. The subject scored a 76.7 on the ACMC task with their personal prosthesis, a 100 with the reflex on, and a 67.6 with the reflex off, indicating that the functioning prosthesis with the reflex on did lead to improved performance.



Subject 2	P	R-On	R-Off
NI - avg success	16.8	18.4	19.6
CDI - avg success	14.2	15.4	17.4
VDI - avg success	13	15.4	16

Subject 2 summary data. NI=No Intervention/Distraction, CDI=Cognitive Distraction Intervention, VDI=Visual Distraction Intervention, P=Personal Prosthesis, R-On=Study Prosthesis with Reflex On, R-Off=Study Prosthesis with the Reflex Off. Numbers indicate the number of non-broken crackers successfully passed in 30 seconds.

Subject 2 only did slightly better with the reflex version of the hand compared to their personal prosthesis (10% improved under normal no-distraction testing, 108% better when cognitively distracted, and 118% better when visually distracted), and a similar performance was observed when the reflex was on or off, indicating the reflex was not reliably contributing to performance. The subject scored a 93.2 on all ACMC tasks for all versions of the hand, indicating no significant improvement or difference as a result of the prosthesis.



Subject 3	P	R-On	R-Off
NI - avg success	11	14.6	21
CDI - avg success	11	13.6	19.8
VDI - avg success	12	15	16.6

Subject 3 summary data. NI=No Intervention/Distraction, CDI=Cognitive Distraction Intervention, VDI=Visual Distraction Intervention, P=Personal Prosthesis, R-On=Study Prosthesis with Reflex On, R-Off=Study Prosthesis with the Reflex Off. Numbers indicate the number of non-broken crackers successfully passed in 30 seconds.

While subject 3 did perform better with the reflex version of the hand compared to their personal prosthesis, they performed even better when the reflex was off, which we have contributed to issues with the electronics, with the subject reporting that the hand felt "sluggish" when the reflex was enabled. We have attributed this to the same electronics error that has interfered with the ability to write to the data log, which has made it difficult to diagnose further. Otherwise, this subject had outstanding performance on the ACMC tasks, with a perfect 100 with their personal prosthesis and with the reflex off, and a reduced score of 93.2 when the reflex was on due to the sluggishness.

Video Analysis of Failed Reflex Issues

A MATLAB script was written to graphically represent the log files, each open and close grasp and whether or not contact was detected and the reflex was enabled. Another script was created to stream the data as a video that could be played alongside the actual Zoom video of the clinical studies. Analysis of these videos side-by-side was highly illuminating to the issues at hand. Through this, we could see that the reflex was failing maybe 10% of the time (although sometimes it came in bursts), and each and every time the reflex failed a cracker would be broken (many times this was audible in the video too). This was seen in subjects 1 and 2, however, as we could not download subject three's log files it could not be confirmed.

Summary and Final Conclusions from Clinical Studies

It appears obvious that the electronic controllers were not robust enough to survive field use for the clinical studies, although they held up well on the laboratory bench before and even after field use. In retrospect, additional field testing should have been planned in the original research plan. This was further impacted by the reduced time window of the studies and pandemic making it difficult to coordinate rapid repairs or evaluation without great inconvenience. Earlier HRPO approval would have permitted earlier studies and perhaps these issues could have been identified and resolved, but unfortunately there was not time or budget to address this. Nonetheless, while we failed to deliver a viable solution in such short time frame with little field testing, there were indeed interesting scientific findings. Particularly that the reflex worked to successfully grasp crackers rapidly when it engaged, and that nearly 100% of the time the reflex failing to engage caused a failed cracker pass. There is an important lesson to be learned here in confidence the users place in their prosthesis and if we are to develop technology to improve their performance, it better work all of the time, else it fails catastrophically. Alternatively, without such technology, subjects approached the cracker pass with caution and while fewer crackers were passed, there were fewer breaks as well.

Additional research and technology improvements will be needed to continue these studies and properly demonstrate or evaluate the potential of a tactile reflexes for advanced prosthetic hands.

Major Task 5-1: Prepare academic submissions and documentation

YEAR 2

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.

YEAR 3

A conference proceeding 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

YEAR 4

The above-described paper was accepted and presented at the International Conference on Robotics and Automation (ICRA), titled: "The (Sensorized) Hand is Quicker than the Eye" covering pilot work exploring the capabilities of the prosthetic hand in Montreal Canada.

YEAR 5 & 6

Further dissemination of findings from this study are planned but were unable to be completed during the project due to timing. In particular the development of novel outcome measures and the findings of necessity of reflex reliability to achieve significant performance were noteworthy and are planned to be shared with the academic community.

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

- Nothing to Report.

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.

Over the course of this project, a number of lectures and conference presentations were given covering various aspects of this research and development, in reverse chronological order:

- December 9, 2020, “Haptics in Robotic Manipulation”, Invited Presentation, Smart Haptics, Online.
- February 24, 2020, “Prosthetic Hands and Tactile Sensing”, Guest Lecture, California State University, Chico, CA.
- May 22, 2019, “The (Sensorized) Hand is Quicker than the Eye”, International Conference on Robotics and Automation (ICRA), Montreal, Canada
- October 25, 2018, “Tactile Sensing for Robotic Dexterity”, J.A. Fishel, Collaborative Robotics, Advanced Vision, and AI (CRAV.ai), Santa Clara, CA
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- 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, those within this reporting period are highlighted:

- 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?

- Nothing to Report.

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 more comprehensively by comparing how much attention is needed to operate the hand, which has been a deficiency in existing outcome measures.
- 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 to safely interact with their surroundings.

What was the impact on technology transfer?

- While our findings were inconclusive due to several challenges discussed above, we remain confident 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.
- 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 has been 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.
- Due to the restrictions imposed by the State of California and nation-wide as a result of the COVID-19 pandemic, changes were required to our clinical studies to be performed remotely over video conference. This required modifications to testing procedures and additional attention to technology robustness as repairs would not be feasible throughout the study. This was discussed and approved with Grants Officer Tracy Behrsing.
- Due to significant delays in HIRB approval and site coordination, impact of the COVID-19 pandemic, and challenges in recruiting that ensued our study population was reduced from 10 as planned to 3 in order to complete the project on schedule and budget. While not ideal, this was discussed and approved with Grants Officer Tracy Behrsing.

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 planning overlooked the necessary number of 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.
- This study was plagued by a very unfortunate sequence of bad luck related to subject recruitment. In year 3, it became apparent that the recruitment goal of 10 participants could not be fulfilled through recruitment at Berke Prosthetics alone, which at the time had only five participants available for recruitment – ironically, two years later and after great expense and effort the study would conclude with

three subjects, and poorly. In the year 3 all-hands review, after determining that the second VA site would be required to meet recruitment goals our team also decided to make improvements to clinical protocols and submit alongside the multi-site IRB. Significant delays were introduced during the addition of the VA as a collaborator, including Stanford IRB, VA internal approval, and HRPO which ultimately took more than 18 months to approve due the approval process and delivery of appropriate and complete materials by the VA to Stanford IRB as well as this IRB's understanding of DoD funded study regulations caused the need for multiple re-submissions and outside intervention. In parallel, there was turnover of reviewers at HRPO on two separate occasions that delayed the process further. This required three separate people to review a single submission before approval would be made. After all of these troubles, after finally receiving approval for all sites, we were hit with the global COVID-19 pandemic, causing the VA to suspend all non-emergency research, including our study. After a final modification of protocols to adapt to remote clinical studies over Zoom meetings at Berke prosthetics only, we were able to secure funding, resources, and participants for only 3 subjects with only a few months remaining in this study. Unfortunately, at this time we had noticed technical issues with the hands that were only seed in the field setting and not in office testing and there was no time to resolve them. While the unusually long delays and COVID-19 pandemic could not have been predicted, in retrospect, there are regrets about not proceeding with the 5 subjects we had in year 3 as this would have allowed time to discover and resolve technical issues in the hands when deployed in the field.

Changes that had a significant impact on expenditures

- Rather than creating significant inventory, due to the number of variations in sizing and handedness of prosthetic hands, we chose to assemble and manufacture the prosthetic hands to be used in clinical studies following the recruitment of a volunteer. This minimized 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.
- The significant and unfortunate sequence of clinical approvals through IRB and site coordination, some within and some outside of our control, had consumed a significant amount of time and effort consuming budget resources. After significant delays and when final approval was granted our study was paralyzed by the global COVID-19 pandemic forcing additional resources to redesign the protocol to be effectively conducted remotely. This consumed far more resources and ability to conduct studies than could have been expected and as a result, the number of subjects were reduced from 10 to three.

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

- Nothing to Report.

6. PRODUCTS:

Publications, conference papers, and presentations

Journal and conference 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, International Conference on Robotics and Automation (ICRA) for 2019. Federal support acknowledged.

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

- Nothing to report.

Other publications, papers, and presentations.

- December 9, 2020, "Haptics in Robotic Manipulation", Invited Presentation, Smart Haptics, Online.
- February 24, 2020, "Prosthetic Hands and Tactile Sensing", Guest Lecture, California State University, Chico, CA.
- May 22, 2019, "The (Sensorized) Hand is Quicker than the Eye", International Conference on Robotics and Automation (ICRA), Montreal, Canada*
- October 25, 2018, "Tactile Sensing for Robotic Dexterity", J.A. Fishel, Accepted Talk, Collaborative Robotics, Advanced Vision, and AI (CRAV.ai), Santa Clara, CA
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- 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
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- 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,

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- 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
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- 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

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.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:

(1) Project Directors (PDs)/PIs

Name:	Jeremy Fishel
Project Role:	PI (Entire Project)
Nearest person month worked:	34
Contribution to Project:	Dr. Fishel has coordinated all design review and project planning meetings to complete specific aims throughout the project. He worked alongside team to ensure progress and took the lead on engineering and production of prosthetic hands to be used in the study and ensuring knowledge and plans were maintained throughout the project and lengthy IRB/HRPO approval process.

Name: Gary Berke
Project Role: CI (Entire Project)
Nearest person month worked: 11
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: Kelsey Muller
Project Role: R&D Engineer (years 1-2), R&D Consultant (years 3-5)
Nearest person month worked: 16
Contribution to Project: Ms. Muller has performed work in developing and submitting IRB protocol and coordinating sensor evaluation and constructing test equipment. In later years she has consulted on IRB/HRPO and clinical studies submissions and requirements coordinating sites, IRB, and HRPO offices.

Name: Blaine Matulevich
Project Role: R&D Manager (Years 1-2), R&D Consultant Year 3
Nearest person month worked: 11
Contribution to Project: Mr. Matulevich has managed 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 in early years of the project. In year 3 Mr. Matulevich joined the clinical and technical teams for a final kick-off meeting before starting clinical studies to review potential risks and threats to the project's success.

Name: Vijay Anandani
Project Role: R&D Engineer (Years 2-3)
Nearest person month worked: 8
Contribution to Project: Mr. Anandani has worked on the durability testing and sensor fabrication and analysis of results and assisted with the electronics layout and validation.

Name: Raymond Peck
Project Role: Mechanical Engineer (Year 1)
Nearest person month worked: 8
Contribution to Project: Mr. Peck has performed work related to the mechanical design and fabrication processes of the NumaTac sensors in first year of the project.

Name: Vikram Pandit
Project Role: Technician (Years 1-2), R&D Consultant Year 3
Nearest person month worked: 4

Contribution to Project: Mr. Pandit has performed work in evaluating possible outcome measures to be developed and used in clinical studies in early years of the project. In year 3 Mr. Pandit joined the clinical and technical teams for a final kick-off meeting before starting clinical studies to review potential risks and threats to the project’s success.

Name: Neil Ragsdale
Project Role: Electronics Engineer (Years 2-3)
Nearest person month worked: 3
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: Chris Kepner
Project Role: Firmware Engineering Consultant (Years 2-5)
Nearest person month worked: 3
Contribution to Project: Mr. Kepner has worked on developing firmware and software to achieve the required reflex performance and data logging for development and production electronics and in later years adapted this software to work in a remote setting for COVID-19 clinical studies.

Name: Rahman Davoodi
Project Role: Software and Firmware Engineer Advisor (Year 1)
Nearest person month worked: 2
Contribution to Project: Dr. Davoodi has provided strategic advice on software and firmware for controller development in the early stages of the project.

Name: Peter Botticelli
Project Role: Production Engineer (Year 1)
Nearest person month worked: 2
Contribution to Project: Mr. Botticelli has provided advisement on electronics design and manufacturing for the sensors and controller in the early stages of the project. He has also assisted with the development of testing equipment and had designed and manufactured electronics for this equipment.

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

- With the exception of the PI (Fishel) and CI (Berke), all key and senior personnel have changed throughout this multi-year project due to changes in employment. We have been fortunate that all personnel have departed on good terms and have been accessible for occasional project reviews and brainstorming throughout the term of the project.

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:

- **Quad Charts:** Attached

9. APPENDICES:

- K.A. Muller, V. Pandit, B. Matulevich, J.A. Fishel, "Tactile Sensing Reflex Reduces Need for Visual Feedback when Grasping Fragile Objects with a Prosthetic Hand," Haptics Conference, 2016. Federal support acknowledged.
- 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, International Conference on Robotics and Automation (ICRA), 2019. Federal support acknowledged.

Tactile Sensing Reflex Reduces Need for Visual Feedback when Grasping Fragile Objects with a Prosthetic Hand

Kelsey A. Muller, Vikram Pandit, Blaine Matulevich, Jeremy A. Fishel, *Member, IEEE*

Abstract— **Able-bodied individuals can perform complex manipulation tasks without looking because of their ability to feel. Amputees utilizing a myoelectric prosthetic hand without the ability to feel need to compensate with visual feedback to help control grasping forces. In this study, a standard myoelectric prosthetic hand is equipped with compliant tactile sensors and an autonomous contact detection reflex to simplify grasping and reduce the user's reliance on vision. A single unilateral amputee and prosthesis user's performance was evaluated in a fragile grasping task between this modified prosthesis and an unmodified prosthesis. This was done with and without visual occlusion. Additionally, performance with and without visual occlusion is evaluated for three able-bodied subjects. In all scenarios, it was found that the occlusion of vision slowed the performance of the test subject, however, performance with the modified prosthesis was only slightly degraded (16.1%) with vision occluded, similar to able-bodied subjects (21.2%), but significantly hindered with the unmodified prosthesis (80.1%). Furthermore, it was found that the amputee subject could perform the grasping task faster without vision using the modified prosthesis than using the unmodified prosthesis unobstructed. This technology is expected to improve a user's confidence and decrease the visual attention needed when using a myoelectric prosthetic hand.**

I. INTRODUCTION

In the human hand, tactile feedback plays a critical role in object grasping and manipulation [1]. This allows able-bodied individuals to divert visual attention when grasping, which facilitates multitasking and grasping without visual focus (e.g. putting on clothes or picking up a glass while reading). For a myoelectric prosthesis user, surface electromyography (EMG) signals are recorded from the residual limb to provide control signals to a prosthetic hand, typically driven by DC electric motors. When these hands close on an object, the motors stall, typically producing large grasping forces unless visual feedback is used to control the closing speed and stopping time of the hand. Reducing the visual attention required to operate a myoelectric prosthesis would greatly improve the utility of these devices.

One approach to this utilizes a tactile grasping reflex that detects when the prosthetic fingers close on an object and adjusts the control of the prosthesis [2]. In this work, a highly sensitive and compliant tactile sensor (the NumaTac, SynTouch, Los Angeles) was integrated into a prosthetic hand (Figure 1). Mechanical integration was achieved by replacing an original finger with the NumaTac finger, and electronic integration by intercepting communication between the EMG electrodes and prosthetic hand motors and modifying these signals based on sensor data. When contact is detected by the sensor during a grasp, the gain of the controlling EMG signals is reduced, a process similar to a natural spinal inhibitory reflex. This has been demonstrated to greatly improve speed and accuracy when grasping fragile objects.

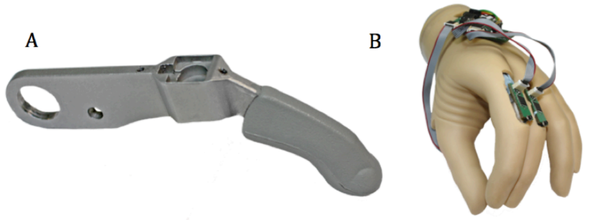

Figure 1. A) Custom NumaTac prosthetic fingertip sensor core and foam; B) Ottobock VariPlus Speed hand installed with two NumaTac fingers, a thumb, and electronics.

The more difficult a dexterous task, the more visual attention is required; therefore, it is expected that hand performance without visual feedback is reflective of the utility of the hand [3, 4]. In this study we observed speed and accuracy during bimanual fragile grasping tasks in two situations: full vision and while blindfolded to simulate visual occlusion (Figure 2). The NumaTac-sensorized VariPlus Speed hand (NT) performance is compared to that of the same hand without contact detecting reflexes (VPS).

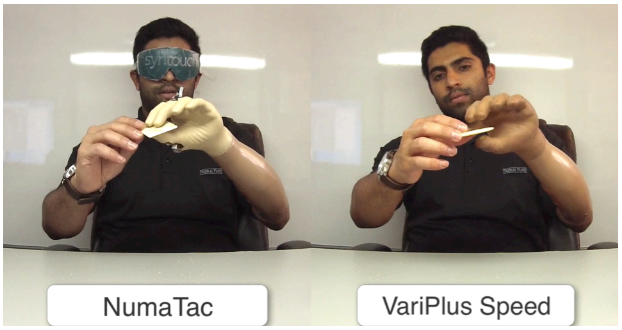

Figure 2. Two examples of the fragile cracker grasping task using 1) the NumaTac sensorized hand while blindfolded and 2) the unsensorized VariPlus Speed Hand with full vision.

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* This work was supported by 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. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.

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B. Matulevich is with SynTouch LLC, Los Angeles, CA (e-mail: blaine.matulevich@syntouchllc.com).

J. A. Fishel is with SynTouch LLC, Los Angeles, CA (e-mail: jeremy.fishel@syntouchllc.com).

Performance is also compared to able-bodied individuals as a baseline to understand the role of vision in this task.

II. METHODS

As a fragile grasping task, the amputee subject (second author VP) was asked to pick up a fragile object (saltine cracker) from the table top with their sound-side hand, pass it to their prosthetic hand (Figure 2) without breaking the object, and place it into a cup. This was repeated ten times as quickly as possible, with broken objects being replaced. Five trials were recorded to find average task speed and the experiment was repeated under two test conditions:

1. *Full vision – subject had no visual obstruction.*
2. *No vision – subject was completely blindfolded.*

Performance was tested with one subject, a 23-year-old male, congenital, unilateral, transradial amputee and regular myoelectric prosthesis user. Each scenario was performed using an unmodified Ottobock VariPlus Speed (VPS) and an Ottobock VariPlus Speed hand equipped with NumaTacs and a contact detection reflex (NT). As a control, three able-bodied individuals between the ages of 25-27 followed the aforementioned protocol using both sound hands. Data were averaged to obtain task speed and accuracy of bimanual passing between able-bodied subjects (AB) for each visual condition. Control and test subjects were allowed to practice under each condition until steady performance was achieved.

III. RESULTS

In all scenarios for the prosthesis user, bimanual passing with the NT hand was found to be significantly faster and showed fewer grasping failures than with the unmodified VPS hand (Table 1). In addition, the blindfold hampered the VPS task speed significantly more than either the NT or AB hands (Figure 3). The blindfold slowed AB speed by an average of 2.2 seconds, NT by 2.7 seconds, and VPS by 18.2 seconds.

TABLE I. DATA SUMMARY

	Able-Bodied	**NumaTac**	**VPS**
Vision			
Time (s)	10.4	16.8	22.5
Breaks	0	0.2	1
Blindfold			
Time (s)	12.6	19.5	40.7
Breaks	0	0.2	0.4
Comparison			
Delay due to Blindfold	2.2	2.7	18.2
% Worse with Blindfold	21.2%	16.1%	80.1 %

IV. DISCUSSION

Myoelectric prostheses with contact detecting sensors and biomimetic reflexes have been demonstrated to improve the speed and accuracy of bimanual, fragile grasping tasks when compared to the same hand without this technology. Gratifyingly, fragile grasping with the NT hand was so efficient that the subject could perform the task faster without vision with this hand than with vision and the unsensorized prosthesis.

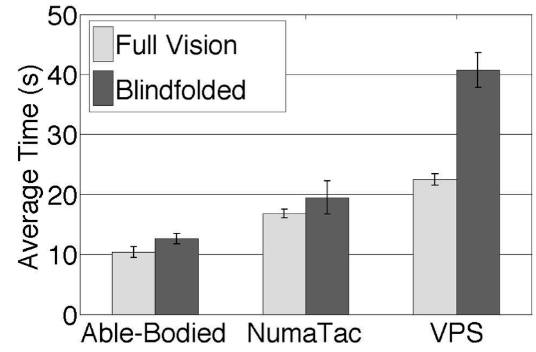

Figure 3. Average bimanual task performance speeds for each hand with full vision and while blindfolded. Hand types include able-bodied (AB), NumaTac sensorized (NT), and unsensorized VariPlus Speed Hand (VPS).

When vision is removed, the NT hand showed a delay in speed similar to able-bodied subjects, indicating that the reflexive behavior restores some of the capability and autonomy of natural hands while grasping fragile objects. Meanwhile, the task speed with the VPS hand is substantially more degraded when vision is removed. This makes it apparent that use of the unsensorized hand relies heavily on visual feedback. With contact detection, grasping is quicker and more natural because, just like with a sound hand, vision can be averted without greatly compromising performance. This is desired when using a prosthesis for functional, every-day tasks. This is because a prosthesis user predominantly uses their prosthesis during bimanual tasks and they appoint visual attention to the sound-side hand, which is used to perform the more complex portion of the task.

Contact-detecting sensors are a simple yet effective advancement in prosthetic research. It is found that contact detection and automated adjustments that mimic natural reflexes have the ability to increase myoelectric hand speed and control of low grip forces with or without visual attention. Visual attention will continue to be a topic of study as well as the contribution of cognitive distraction to fragile grasping performance. Future research will be aimed at validating this as an outcome measure and the conduction of a large clinical study with people who vary in their skills and experience with myoelectric prostheses. It is expected that this technology will improve the user's confidence with fragile grasping tasks, and through utility, increase the amount of tasks they can perform.

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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

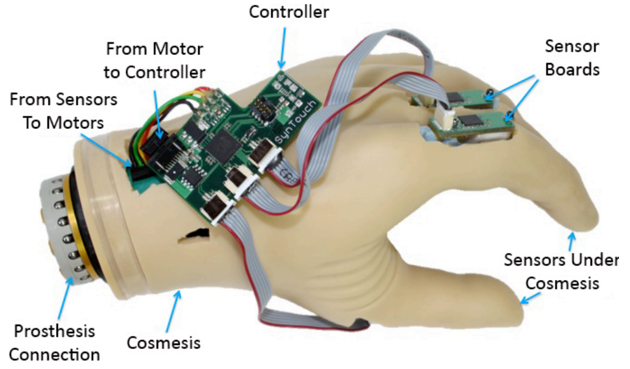

Figure 1. The assembled prosthesis used in this study incorporating an external reflex controller and internal tactile sensors.

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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

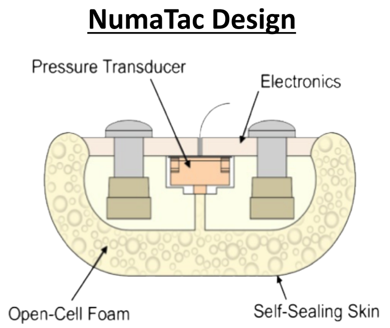

Figure 2. A conceptual schematic that demonstrates the function of the NumaTac sensor. The use of an open cell foam with a self-sealing skin allows air to move freely through the sensor. When the NumaTac makes contact with an object anywhere on its surface air pressure inside the foam increases where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

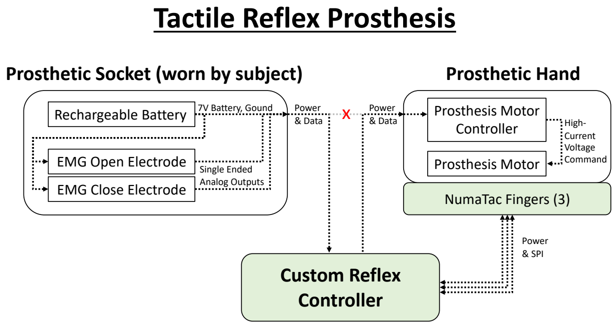

Figure 3. A diagram of the complete Tactile Reflex prosthetic hand system. Amputee subjects use a fitted prosthetic socket that houses a rechargeable battery and pair of EMG-sensing electrodes (open and close) that provide amplified, rectified, and filtered analog outputs proportional to muscle activation 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.

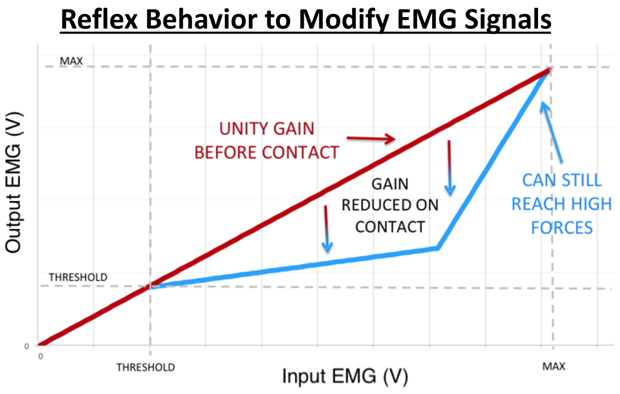

Figure 4. A graphical representation showing the programmed behavior of the reflex before and after contact. Before contact, input and output EMG are identical with unity gain, permitting the hand to move at high speeds. When contact is detected the EMG gain is reduced causing the hand to significantly 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	Sometimes	Never	Never
Picking up a piece of fruit, vegetable or other soft food	Often	Rarely	Rarely	Rarely
Holding a drink	Often	Rarely (if open)	Sometimes	Sometimes
Holding a drink in a deformable cup (such as a plastic or paper cup)	Rarely *	Rarely (if open)	Rarely *	Sometimes*
Holding a piece of food while cutting it	Often	Often	Sometimes*	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.

		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
FRAGILE CRACKER	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**

		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
HOLLOW EGG	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**

		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
UNOPENED SODA CAN	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

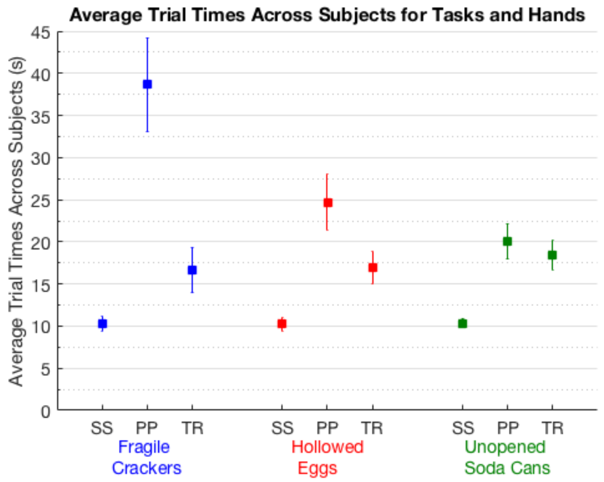

Figure 6. Average task performance times for all subjects for each of the three tasks (fragile crackers = blue, hollow eggs = red, unopened soda cans = green) of all subjects using each hand type scenario (SS = Sound Side Hand, PP = unmodified Personal Prosthetic hand, TR = Tactile Reflex hand with reflex 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.

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