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Unlimited Distribution.

13. SUPPLEMENTARY NOTES

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

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

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1. INTRODUCTION:

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

2. KEYWORDS:

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

3. ACCOMPLISHMENTS:

What were the major goals of the project?

1. **Design and build a compliant and sensitive tactile sensor that meets the identified commercial requirements and specifications**
    a. Milestone: First NumaTac Prototypes. Target date 3/31/2016, Completed 3/31/2016
    b. Milestone: 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, Modified Review Expected to be Completed by 12/31/2019, 90% complete.
    b. Milestone: Clinical studies completed. Target date 4/30/2019, 25% complete
5. **Organize results for publication and documentation**

a. Academic publications, 2 of 3 planned, 1 of 3 completed
b. Milestone: Final documentation released. Target date 9/30/2019, 15% complete

What was accomplished under these goals?

Overall Project

Original Team Project Review
In conjunction with our third-year annual report, our team took the opportunity to do a detailed project review and planning in our final year to identify which objectives need the most attention and set forth a plan to address those needs. In this meeting we decided that developing documentation on manufacturing and testing procedures as well as an extra effort in outreach to improve clinical studies recruitment were the priorities (progress on these are discussed in more detail below). We were fortunate to have Blaine Matulevich and Vikram Pandit join us for this review and planning meeting as they were both key personnel on the project and active in years 1 and 2, but no longer with the SynTouch in years 3 and 4. Their input was invaluable in setting priorities.

No-Cost Extension Filed and Approved
As a result of lengthy IRB/HRPO approval delays, a no-cost extension of 1 year was filed and granted to permit additional time to complete our clinical studies once the HRPO approval is granted.

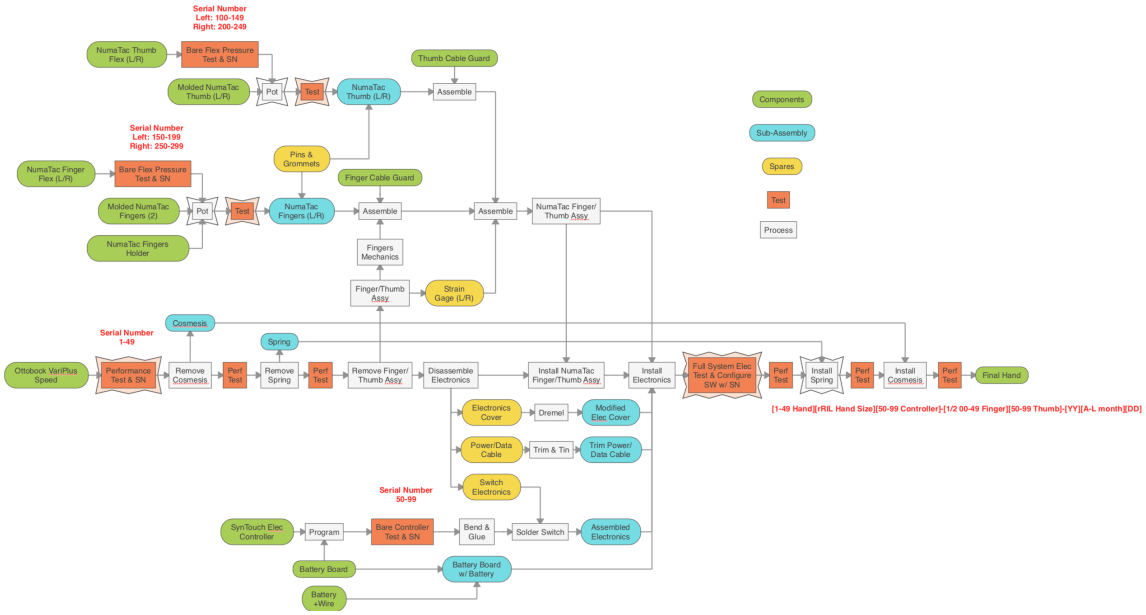
Major Task 2-1: Build, assemble, and test prosthetic hand with NumaTac sensors and controller

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

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

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 remains a critical risk and we ask any assistance that can be given to expedite the processing at HRPO so this significantly delayed study can proceed**.

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.

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

Clinical Studies Started
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. Upon final approval by HRPO, expected before the conclusion of 2019, recruitment and clinical study conduction will resume.

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

Major Task 5-1: Prepare academic submissions and documentation
A conference paper was submitted to the International Conference on Robotics and Automation (ICRA) highlighting 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 with, and frequently avoid, grasping fragile objects with their prosthesis. While the sense of touch is known to be critical for human hand dexterity, it has been virtually absent in prosthetic hands. In this study, a standard myoelectric prosthetic hand was modified with tactile sensors and a simple tactile reflex to inhibit excessive forces on contact. The tactile sensors were made from an open-cell self-skinning polyurethane foam that produced a detectable increase in air pressure inside the foam when contacted. This contact signal was then used by an inhibitory reflex controller which served to reduce the gain of weaker closing signals after contact but allow stronger closing signals to pass through. Four unilateral myoelectric prosthesis users completed five trials of three different timed grasping tasks with fragile and rigid items. Subjects performed each task in three different scenarios: with their sound side limb, their current myoelectric hand, and the modified prosthesis with tactile reflex. 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.

This work was also 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.

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

- Nothing to report – the project was not intended to provide training and professional development opportunities.

How were the results disseminated to communities of interest?

We published and presented our hardware design and pilot study work at the International Conference on Robotics and Automation (ICRA), titled: "The (Sensorized) Hand is Quicker than the Eye" covering pre-clinical trial pilot work exploring the

capabilities of the prosthetic hand in Montreal, Canada.

A number of lectures and conference presentations were given covering various aspects of this research and development, those within this reporting period are highlighted:

- 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
- August 23, 2018, Updates on Project Status to Ottobock Healthcare (video conference)
- April 22, 2018, "Getting a Feel for Grasping", J.A. Fishel, Guest Lecture, California State University, Chico, CA
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- Berke, et al., "Contact Reflex Improves Fragile Grasping while Blindfolded," American Academy of Orthotists & Prosthetists 2017.
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- 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?

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

1. Final HRPO approval of IRB reviews from Stanford (VA Palo Alto), and Heartland (Berke Prosthetics) so recruitment of the final clinical study can proceed. This has been substantially delayed through long response times from Stanford IRB and HRPO as outlined above and resulted in the need for a no-cost extension. Once this is complete the roadblock to completing this research will be removed.
2. Complete recruitment targets. To reach the target of 10 subjects we will recruit from existing populations at Berke Prosthetics and the VA and once HRPO approval is granted, we do not expect major barriers.
3. Schedule and complete participant office visits and full procedure in order to gather data and performance metrics for 10 participants through the end of the study.
4. Manufacture, test, monitor and repair all clinical hands to be used in this study. Hands are individually customized for each subject and go through an extensive testing and validation process before they are deployed in a study. At each office visit the hand is inspected for damage and evaluated.
5. Analyze results and create journal article outlining the study's findings, we intend to submit one publication on the final hardware design and another publication on the clinical studies and results.
6. Prepare technical material and documentation to educate manufacturers and clinicians of the new technology.

4. IMPACT:

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

- The principal discipline of this project is related to the development of more advanced and useful prosthetic hands, improved contact detecting sensors, and outcome measures for the comparison of prosthetic hand utility.
- Distraction methods have been shown to affect fragile grasping performance in able-bodied individuals. We are therefore able to compare grasping performance of prosthesis users to able-bodied individuals in order to show how different types of prosthetic hands enable fragile grasping performance compared to the biological human hand. This comparison can be made without distracting stimuli and with visual or cognitive distractions in order to demonstrate the visual or

cognitive focus someone may need to operate a particular type of prosthetic hand. This will be applied as a new measure to determine how useful a particular prosthetic hand 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.

What was the impact on technology transfer?

- It is likely that the integration of sensing technology in prosthetic hands will prove effective enough that existing prosthetic hand companies will integrate the technology into their products. We are currently in mid-level talks with Ottobock, the leading prosthetic hand manufacturer as well as introductory talks with their leading competitor Ossur.
- It is anticipated that if the distraction method outcome measures are demonstrated to be effective in a clinical setting with amputees that they will be adopted as a new standard for the analysis of prosthetic hand utility by associated groups such as hand manufacturers, researchers, and prosthetists.

What was the impact on society beyond science and technology?

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

focus, similarly to able-bodied individuals. This technology is anticipated to enable amputees and improve their confidence using their prosthetic hand.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

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

- Rather than paying an outside agency for performing the ACMC evaluations for clinical studies as planned, we decided to repurpose this budget towards the ACMC certification of Clinical Investigator, Gary Berke, so that he could perform these evaluations himself. This allowed our team to have a greater understanding of this outcome measure and improved confidence in efficiently conducting these evaluation metrics in a clinical setting. This minor change in budget category was discussed and approved with Grants Officer Troy Turner.
- After planned reviews of final clinical studies as outlined in the statement of work, we ultimately decided to not include the SHAP testing metric in clinical studies in the interest of reducing the total length of office visits. After being evaluated by our clinical investigator, Gary Berke, and discussing with other clinicians, we determined that the ACMC was a better measurement of activities of daily living and held in higher regard by the academic and research community. The remaining budget for the 2nd SHAP system was repurposed to general materials and supplies. This was discussed and approved with Grants Officer Troy Turner.
- After discussions with our clinical investigator and discussions with other clinicians, it was decided that it would be best to use naturally occurring objects (such as crackers) for fragile grasping tasks, rather than using a "mechanical egg" as originally planned. It was proposed that the visual and cognitive associations subjects have with object strength would be critical in achieving performance. The remaining budget for these components were repurposed to general materials and supplies. This was discussed and approved with Grants Officer Troy Turner.

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

- There was an unanticipated delay throughout the study in the manufacturing of the integrated prosthetic hand, which did not take into consideration enough 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.

- It became apparent that the recruitment goal of 10 participants could not be fulfilled through recruitment at Berke Prosthetics alone. Efforts were made to recruit from the general public, however we decided that collaboration with the VA provided the best chance to economically, and reliably reach recruitment numbers.
- Significant delays were introduced during the addition of the VA as a collaborator across all approval steps: Stanford IRB, VA internal approval, and HRPO. 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. This required three separate people to review a single submission before approval would be made (this is still in progress, was the direct cause of our need for a no-cost extension, and remains the greatest threat to completing this project on schedule).
- To deal with the length and unexpected delays of Stanford IRB and HRPO to the total project, it became necessary to organize regular review meetings with the clinical team on clinical studies status and plan as well as regular reviews of the hardware and manufacturing plan to ensure knowledge was not lost during the waiting period.

Changes that had a significant impact on expenditures

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

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

- Nothing to Report.

Significant changes in use or care of human subjects

- Nothing to Report.

Significant changes in use or care of vertebrate animals.

- Nothing to Report.

Significant changes in use of biohazards and/or select agents

- Nothing to Report.

6. PRODUCTS:

Publications, conference papers, and presentations

Journal 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.

Other publications, papers, and presentations.

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

Website(s) or other Internet site(s)

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

Technologies or techniques

- Nothing to Report.

Inventions, patent applications, and/or licenses

- Nothing to Report.

Other Products

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

6. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:

(1) Project Directors (PDs)/PIs

Name:	Jeremy Fishel
Project Role:	PI
Nearest person month worked:	4.4
Contribution to Project:	Dr. Fishel has coordinated all design review and project planning meetings to complete specific aims and worked alongside team to ensure progress and took the lead on engineering and production of prosthetic hands to be used in the study and ensuring knowledge and plans were maintained during the lengthy IRB/HRPO approval process.
Name:	Gary Berke
Project Role:	CI

Nearest person month worked:	1.2
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 Consultant
Nearest person month worked:	0.4
Contribution to Project:	Ms. Muller consulted on IRB/HRPO and clinical studies submissions and requirements coordinating with the VA site, Stanford IRB, Heartland IRB, and HRPO offices.

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

No.

What other organizations were involved as partners?

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

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

8. SPECIAL REPORTING REQUIREMENTS:

Collaborative Awards: None

Quad Charts: Attached

9. APPENDICES:

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

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

Jeremy A. Fishel[1], *Senior Member, IEEE*, Blaine Matulevich[1], Kelsey A. Muller[1], and Gary M. Berke[2]

***Abstract*— Myoelectric prosthetic hand users have difficulty with, and frequently avoid, grasping fragile objects with their prosthesis. While the sense of touch is known to be critical for human hand dexterity, it has been virtually absent in prosthetic hands. In this study, a standard myoelectric prosthetic hand was modified with tactile sensors and a simple tactile reflex to inhibit excessive forces on contact. The tactile sensors were made from an open-cell self-skinning polyurethane foam that produced a detectable increase in air pressure inside the foam when contacted. This contact signal was then used by an inhibitory reflex controller which served to reduce the gain of weaker closing signals after contact but allow stronger closing signals to pass through. Four unilateral myoelectric prosthesis users completed five trials of three different timed grasping tasks with fragile and rigid items. Subjects performed each task in three different scenarios: with their sound side limb, their current myoelectric hand, and the modified prosthesis with tactile reflex. 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 at the same time. As a result, myoelectric users must rely on visual feedback to grasp fragile objects, requiring them to move slowly and concentrate 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 [8-15], 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 [16]. 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 of a standard commercially available myoelectric prosthetic hand (VariPlus Speed, Ottobock) (Figure 1). The design principle of the tactile sensors (NumaTac, Figure 2, [16]) consisted of an open-cell self-skinning foam that would produce a detectable increase in air pressure when contacted.

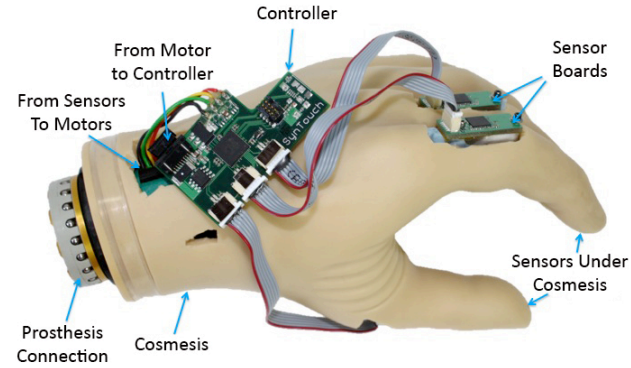

Figure 1. The assembled prosthesis used in this study incorporating an external reflex controller and internal tactile sensors.

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

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The NumaTacs used in this study were built from aluminum cores with the same geometry of the replaced fingers and thumb that were then over-molded with a low-density self-skinning polyurethane foam mixture (fms74100-6 85b/15a, Foam Molders). The open-cells allowed air to flow freely within the foam while the self-skinning process resulted in smaller cells near the boundary of the mold resulting in a seal that kept the air trapped inside. This seal was further improved with an additional fluoropolymer coating. After drilling a small hole through the seal, a pressure transducer (MS1471, TE Connectivity) could be connected to measure the pressure inside the foam. Signals measured by the pressure transducer were amplified to optimize the resolution of the 12-bit data acquisition using an identical circuit to [18]. Custom firmware and SPI communication protocols were developed similar to [19] to permit sampling on demand of these sensors by a separate controller board discussed below. The design resulted in a highly compliant tactile sensor that is sensitive to contact over its entire surface. While the foam structure damped signals from contact to about half of what was seen in the liquid bladder sensor from [13], it also reduced sensitivity to motor vibrations and inertia by a factor of 10, resulting in an overall 5x improvement in signal-to-noise.

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 [17]. 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 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 the contact state of the controller would be reset to pre-contact.

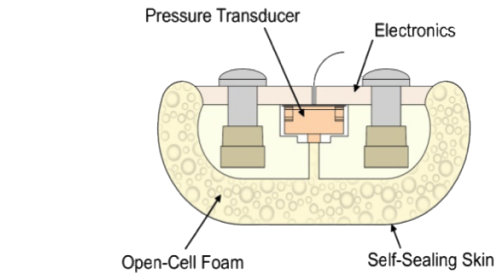

Figure 2. A conceptual schematic that demonstrates the function of the NumaTac sensor. The use of an open cell foam with a self-sealing skin allows air to move freely through the sensor. When the NumaTac makes contact with an object anywhere on its surface air pressure inside the foam increases where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

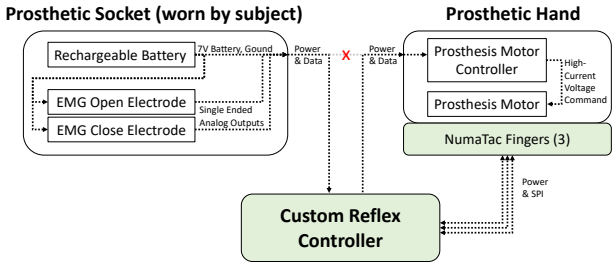

Figure 3. A diagram of the complete Tactile Reflex prosthetic hand system. Amputee subjects use a fitted prosthetic socket that houses a rechargeable battery and pair of EMG-sensing electrodes (open and close) that provide amplified, rectified, and filtered analog outputs proportional to muscle activation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

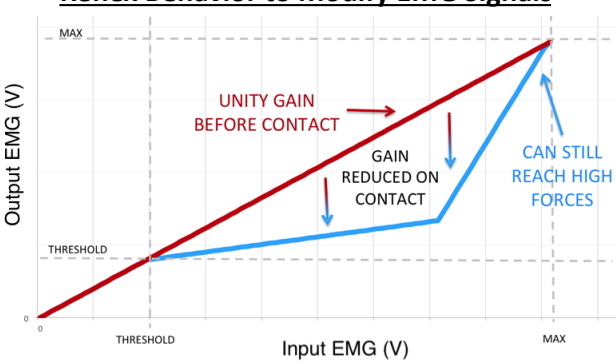

Figure 4. A graphical representation showing the programmed behavior of the reflex before and after contact. Before contact, input and output EMG are identical with unity gain, permitting the hand to move at high speeds. When contact is detected the EMG gain is reduced causing the hand to significantly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

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. All subjects had a prosthetic socket fitted by their personal clinician with reliable opening and closing EMG signals configured by their clinician for their limb.

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.

Several standard prosthetic hand outcome measures and evaluations were researched to identify those incorporating fragile objects or fragile grasping [20][21], none were found so a new fragile grasping task was developed. 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 as much time as desired in each scenario and task to practice, participants would then complete five trials of that task. 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 as no subjects reported any issues). By coincidence, all subjects that arrived for the study happened to use either the SensorHand Speed (SHS) or VariPlus Speed (VPS) hand by Ottobock. While this is not entirely surprising as these are popular models, this was fortunate as the Tactile Reflex hand was the same architecture as these two hands, allowing for a more direct comparison of performance between their personal prosthesis and the Tactile Reflex hand.

TABLE I. ENTRY QUESTIONNAIRE RESULTS

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

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

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 as was expected.

FRAGILE CRACKER

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

HOLLOW EGG

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

UNOPENED SODA CAN

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

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

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 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

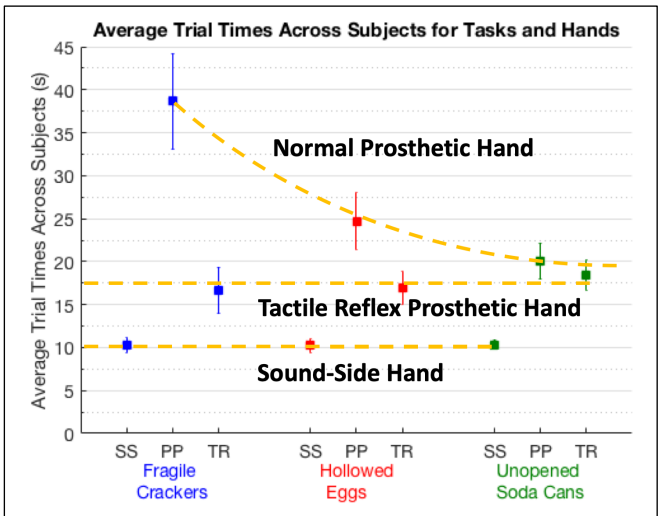

Figure 6. Average task performance times for all subjects for each of the three tasks (fragile crackers = blue, hollow eggs = red, unopened soda cans = green) of all subjects using each hand type scenario (SS = Sound Side hand, PP = unmodified Personal Prosthetic hand, TR = Tactile Reflex prosthesis 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. Trends are presented with dashed lines. As indicated, the Tactile Reflex prosthetic hand shares characteristics with the Sound Side hand in that it faster performance and lower variability regardless of object fragility, whereas the unmodified Personal Prosthetic hand sees performance and variability suffer with fragile objects.

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?*
- *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 after only using the Tactile Reflex prosthesis 45 minutes.

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 prosthesis 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 [22]. 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 was approximately 25% faster than "vision without touch" 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 restrict 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 prosthesis) 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.

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

Acknowledgment

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Tactile Sensing Reflexes for Advanced Prosthetic Hands

MR140094
W81XWH-15-1-0149

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

Study/Product Aim(s)

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

Approach

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

New testing site to meet recruitment targets (in proc)

VA PAHCS
Veterans Affairs Palo Alto Health Care System

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

Jeremy A. Fishel[1], *Senior Member, IEEE*, Blaine Matulevich[1], Kelsey A. Muller[1], and Gary M. Berke[2]

Publication in International Conference on Robotics and Automation

Major Accomplishments: 1) ICRA Submission accepted and presented in Motnreal, 2) VA Added as a Testing Site and Recruiting Subjects (complete, HIRB still in process)

Timeline and Cost

Active ◆ Complete ◇ Planned ▭ Scheduled

Activities CY	15	16	17	18	19	20
Design/Build/Verify Sensors						
Build/Test Prosthetic Hands						
Dsgn/Val Outcome Meas						
Perform Clinical Studies						
Document/Publish Results						
Estimated Budget ($K)	**179**	**688**	**539**	**310**	**149**	

Updated: Sept 30, 2019

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

Goals/Milestones

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

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

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

~~CY18~~ CY19 Goal – Perform Clinical Studies (delayed)
- ☑ Start Clinical Studies

~~CY19~~ CY20 Goal – Complete Clinical Studies, Documentation (delayed)
- ☐ Clinical studies completed
- ☐ Final documentation

Comments/Challenges/Issues/Concerns

Progress on recruitment issues and VA being added as a testing site.

Budget Expenditure to Date

Projected Expenditure: $1,865,449, Actual Expenditure: $1,643,004