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Major Goals: We propose to study the fusion of two advanced and promising technologies that can significantly improve quality of life in individuals with upper limb loss: (1) biologically-inspired, multi-degrees of freedom soft-robotics prosthetic hands, the SoftHand Pro (SHP), and (2) Neural-Enabled Prosthetic Hand (NEPH) technology that uses invasive peripheral neural interfaces to enable closed-loop control of terminal devices.

With regards to the SHP, our disruptive approach to prosthetics is based on the merger of the neuroscientific concept of postural synergies of the human hands with the new engineering technologies of soft robotics. The outcome of combining these two advances in an artificial hand led to the SHP, a prototype prosthesis characterized by human-like coordinated motion among all digits. The SHP can mold to a wide range of object shapes, is resistant to large impacts, and can be controlled in an intuitive way by activating only few input channels (e.g. two myoelectric signals in past work). The Arizona State University (ASU) team will (1) identify optimal training protocol to help users integrate haptic feedback in object manipulation tasks with behavioral studies in able-body subjects, and (2) improve control of grasp force in SHP by designing new myoelectric controller for SHP. With regards to the NEPH, the Florida International University (FIU) team has performed work with electrodes placed within peripheral nerve fascicles to stimulate sensory afferents to elicit naturalistic sensations of touch and hand posture. They will build on their current system to integrate SHP and NEPH systems to permit closed-loop operation of the myoelectric hand. Furthermore, they will (1) define optimal mapping of mechanical SHP-environment interaction sensing in grasp and manipulation tasks to electrical stimulation of the peripheral nerve fibers, and (2) conduct functional testing on transradial amputees using state-of-the-art clinical metrics as well as metrics obtained from literature on human grasping and dexterous manipulation. To accomplish these objectives, we have planned three Major Tasks

Major Task 1.0: Improve closed-loop force control of SHP (Target date: 10/30/17, actual completion date: 11/8/17). In this task we will optimize the performance of SHP during force control when users receive artificial force feedback through Clenching Upper-limb Force Feedback device (CUFF). The results will be used to improve the user experience in Phase II when amputees are tested with the NEPH-SHP system. ASU will develop refined mechanical mounting and software for testing able-bodied subjects to use SHP and CUFF. ASU will construct sensorized objects, as well as objects with different sizes and compliance, for the functional grasping tasks. There are two Minor Tasks which aim to evaluate the effectiveness of alternative training protocols and alternative EMG-to-force control laws.

Minor Task 1.1 (Target date: 10/30/17, actual completion date: 11/8/17): ASU will collect data using the improved myoelectric controller for SHP. ASU will examine two different training protocols to help user to integrate force feedback from CUFF to interact with objects. Data will be analyzed and interpreted to compare the efficacy of the two training protocols. The obtained result will be shared with FIU team.

Minor Task 1.2 (Target date: 6/30/17, actual completion date: 6/30/17): ASU will develop an alternative new myoelectric controller for SHP to improve the control of grasp forces. ASU team will collect data using validated experimental protocol and setup. Data will be analyzed and interpreted to compare the performance of the original and new SHP myoelectric controllers. The obtained result will be shared with FIU team.

Major Task 2.0 (Target date: 7/31/17, actual completion date: 1/1/18): Integrate SHP with NEP-H10S device and assess the impact of sensory feedback on prosthesis control and functional performance. We will interface the NEP-H10S device with the SHP to create the NEPH-SHP. This system will enable investigations of the ability of amputees to utilize the neural enabled multi-channel sensory feedback to better control the SHP. This task will be accomplished by first developing the hardware and firmware required to interface the SHP with the NEP-H10S device and the subsequently obtaining regulatory approvals to test the system in a laboratory environment. FIU will work with the team at ASU to first come up with system level requirements for the NEPH-SHP for laboratory testing which will then be translated into detailed hardware and firmware requirements in collaboration with qbrobotics and the prosthetists (OrthoPro). Preliminary hazard analysis will be conducted and corresponding mitigation options will be incorporated into design requirements. Traceability matrix will be developed to link hazard and mitigation options.

Major Task 3.0 was an option in the original contract, and it has been cancelled without funding. The original objectives are listed below

Major Task 3.0 (Target date: 7/31/18, actual progress 10%): FIU team will interface, for the first time, artificial feedback arising from force and motion sensors on the SHP with the neural stimulation system to deliver feedback associated with reach-to-grasp and manipulation, and quantify the gains in performance arising from sensory feedback. There are two Minor Tasks for accomplishing this goal.

Minor Task 3.1 (Target date: 10/31/17, actual progress 20%): FIU will prepare and submit a supplement to the original IDE for the NEPH-SHP system. Simultaneously, the current human study protocol will be updated to include experiments with the NEPH-SHP and submitted to local IRB and DoD for approval.

Minor Task 3.2 (Target date: 7/31/18, actual progress 0%): FIU will conduct experiments to assess the impact of sensory feedback on sensorimotor function and utility of the NEPH-SHP. A series of experimental tests will be completed to document system performance and the benefits that might be afforded to the amputee subjects in terms of motor control capabilities and hand function. Two transradial amputee subjects who have already received the implanted components of the ANS-NEPH system will be fitted with the sensorized SHP and the associated IHI and then will participate in the experiments.

Accomplishments: In the whole project period, we have accomplished the following major activities (The technical details and figures can be found in the supplemental materials uploaded as a PDF document).
Major Task 1.0: We successfully completed MT 1.0. We successfully set up the SoftHand Pro (SHP) and Clenching Upper-limb Force Feedback Device (CUFF) to be used as a prosthetic system with a gravity compensation system to allow long period of testing for able-body subjects at ASU (Supplement Fig. 1). However, we changed the order of the planned project activities and we completed MT 1.2 first followed by MT 1.1.
Minor Task 1.2: We designed, implemented, and validated a new myoelectric controller for the SHP to improve its force control. The existing onboard controller of SHP is a simple single gain (SG) differential EMG velocity controller. It takes the EMG difference between the extensor and flexor, and uses it to control the velocity of the reference position of the single motor that drives all fingers. The EMG-velocity gain was set to be relatively high such that the response from the SHP motor (i.e., open/close) to EMG signal is fast and accurate. However, this controller exhibits sub-optimal behavior when the grasping force needs to be controlled smoothly and precisely. The grasping force was generated when the internal control of the SHP motor tries to move to the reference position but stopped by the object in hand. Therefore, the grasping force would change very rapidly due to high gains in the EMG-velocity mapping. This makes it very difficult for the user to generate desired force and/or small changes in force due to the inherent delay in the human sensorimotor loop. To overcome this challenge, we designed a new hybrid gain (HG) controller (Supplement Fig. 2) that changes control gains depending on the state of the SHP. A high EMG-velocity gain is used when the SHP is in free motion, whereas a low gain is used when the SHP starts grasping objects. The state change is determined by both the EMG signals and the motor current of the

SHP (see supplemental material).

To validate the new HG controller, we developed multiple experimental tasks to compare the performance between the SG and HG controllers (Supplement Fig. 3). These tasks mainly consist of repetitive pick-and-place of objects with different size, weight, and fragility between two target zones. The major findings are:

1. The performance of object pick-and-place tasks was measured as the number of successful repetitions for a given object in 45 seconds. A successful pick-and-place requires subjects to not drop the object and not 'crush' the object. Depending on the pre-defined threshold, 'fragile' objects need to be handled with much less grasp force than the 'solid' objects. HG group performed significantly better (i.e., more repetitions) than the SG group in all 'fragile' object conditions, regardless of object size and weight (Supplement Fig. 4). HG group also performed better than SG group in half of the 'solid' object conditions, and equally well in other conditions.
2. We also measured grasp forces during successful pick-and-place executions using sensors embedded in the objects. We found that HG group used significantly smaller grasp forces in most of the 'Solid' object conditions which did not require a small grasp force (Supplement Fig. 5). Most importantly, the HG group showed qualitatively similar pattern of grasp force modulation to object weights as those found in native hands.
3. We recorded EMG during pick-and-place tasks and found little difference between the mean EMG amplitude between HG and SG groups. This suggests that HG group achieved better performance without changing motor effort used during these tasks.

Overall, these results suggested that, a context-dependent myoelectric controller could enable users to control grasp force in a more natural and precise fashion. This is achieved by flexible switching of controller gains to match the context.

Minor Task 1.1: After validating the improved myoelectric controller developed in the previous reporting period, we tested two different approaches for training user to integrate force feedback through non-invasive devices. Specifically, we tested a) ipsilateral training in which subjects map CUFF pressure levels to a visual representation through SHP myoelectric control, and b) contralateral training in which subjects map CUFF pressure levels to the haptic perception of the left hand (Supplement Fig. 6). The effect of these two protocols on perception-action coupling with the SHP-CUFF system was compared based on subjects' performance using a force matching task, subjects had to reproduce different levels of grasp forces without vision using SHP, and they can only rely on the feedback from the CUFF. Eighteen healthy subjects were assigned to two groups: EMG-Haptic group and Native-Haptic group. These two groups were trained with different proportions of the two training protocols. The EMG-Haptic group was trained with large number of Ipsilateral training, whereas the Native-Haptic group used large number of contralateral training (Supplement Fig. 7). Subjects' performance on force matching was assessed with their own hands and SHP. We report the major findings below:

1. At the end of training, the EMG-Haptic group was better at controlling the SHP to produce desired grasp force level (Supplement Fig. 8). However, EMG-Haptic group also spent more time in the training session because Ipsilateral training is more time consuming.
2. Two training protocols did not give advantage in the speed of force matching task to neither groups (Supplement Fig. 8). Additionally, the 7 N level took the longest time to match in SHP session, but not in Native hand session.
3. Measured using absolute matching error, subjects tended to perform the best in 7 N condition with their native right hand, but worst with the SHP/CUFF system. Furthermore, two training protocols did not lead to differences in the magnitude of matching errors (Supplement Fig. 9).
4. Measured using relative matching error, we found that the Native-Haptic group generated matching performance in SHP matching qualitatively similar to native hand matching, especially in 7 N conditions. The EMG-Haptic group, in contrast, had significant positive bias for SHP matching in 7 N conditions (Supplement Fig. 9).

Overall, these results suggested that, when training users to integrate novel haptic feedback into their control of hand prosthesis, it would be better to consider mapping the novel feedback to users' native sensory channels. This would greatly help improve the perception-action coupling.

Major Task 2.0: FIU obtained the SHP later than we have planned due to delays in the contract process. But we were able to complete the development of a NEPH - Soft Hand Prosthesis interface system based on python-ARM board (Supplement Fig. 10-13). We assembled a prototype unit for in-lab use. Briefly, we completed the following tasks: (1) Updated SP12 and PyBoard firmware and hardware to demonstrate end-end communication between the Soft Hand Prosthesis and the NEPH system. NEPH-SHP system acquires the sensor data from SHP to modulate the sensory stimulation while simultaneously saving the sensor data into the SD card on the PyBoard. (2) Completed testing the prototype unit to demonstrate full functionality – SHP-NEPH system communication and Sensor data storage.

Major Task 3.0: Although MT 3.0 was not funded as an option, we nevertheless completed hazard analysis per ISO-14971 standard. We identified that the risk profile of the NEPH-SHP system is similar to that of the current IDE-approved device. This analysis indicates that these changes should fall under the FDA's '5-day notice' category for changes to an IDE, which means that we should be able to test the NEPH-SHP system without prior approval from the FDA and then provide them with notification of the changes within 5-days of deployment.

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Results Dissemination: Nothing to Report

Honors and Awards: Nothing to Report

Protocol Activity Status:

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Supplemental materials

Definitions

SHP: SoftHand Pro, a synergy-based soft prosthetic hand. The design of the SHP represents a disruptive approach to prosthetics that is based on merging the neuroscientific concept of postural synergies of the human hand with the new engineering technologies of soft robotics. The outcome of combining these two advances has led to the SHP, a prototype prosthesis characterized by human-like coordinated motion among all digits. The SHP can mold to a wide range of object shapes, is resistant to large impacts, and can be controlled in an intuitive way by activating only two myoelectric signals.

CUFF: Clenching Upper-limb Force Feedback device. Used for providing non-invasive force feedback by generating pressure through elastic belt on user's arm. The pressure is driven by two motors and its value is proportional to the grasp force estimated from the SHP motor.

NEP-H: Neural-Enabled Prosthetic Hand technology, a method that uses invasive peripheral neural interfaces to provide haptic feedback in prosthetic systems. It delivers stimulation via electrodes placed within peripheral nerve fascicles to elicit naturalistic sensations of touch and hand posture.

sEMG: Surface electromyography.

Major Task 1

- We have setup customized programs for SHP/CUFF control, training and data collection (EMG, grasp force, motor current and position).
- We have built the hardware for testing able bodied individuals (Fig. 1), which includes:
    - Harness with quick wrist connector for wearing SHP at different wrist angles
    - Gravity compensation system to offload the weight of SHP and harness to prevent fatigue caused by long period testing.

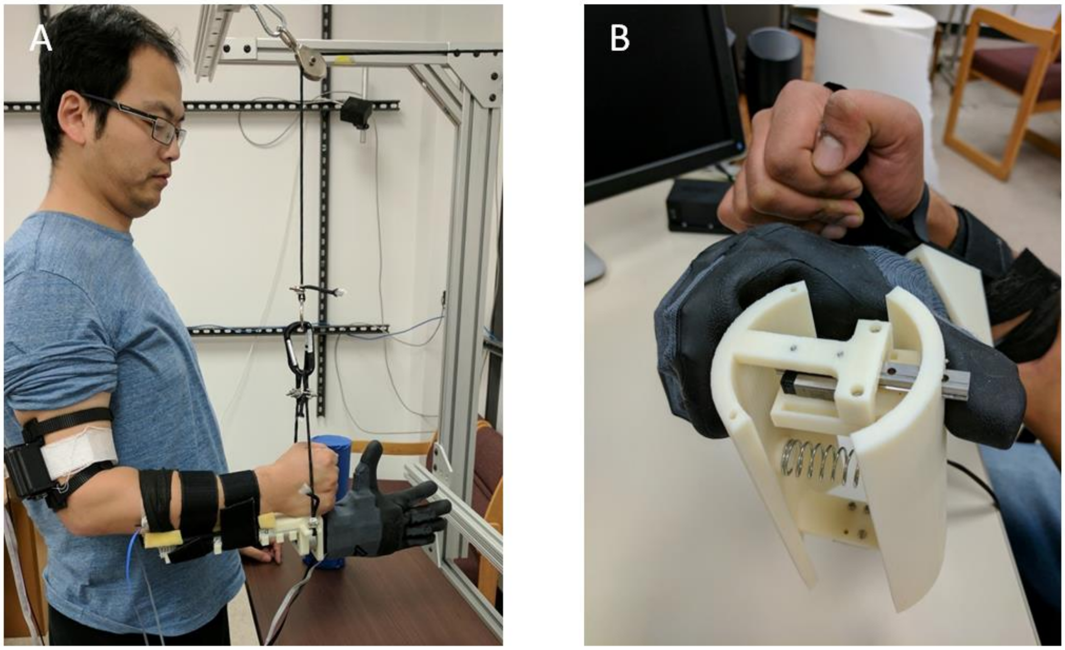

Figure 1. Hardware setup for testing SHP and CUFF at ASU. Panel A illustrates an able-bodied user wearing SHP on the forearm with harness and gravity compensation, as well as CUFF on the upper arm. Panel B shows SHP grasping a variable stiffness object.

Minor Task 1.2

- Designed and implemented a myoelectric controller that switches control gains depending on the state of the SHP (e.g., in motion or in contact).
    - The SHP has an internal PID position controller to track a reference motor position. For myoelectric control, the SHP reads surface EMG (sEMG) signals from two 13E200 Myobock electrodes (Ottobock) placed over flexor digitorum superficialis (FDS) and extensor digitorum

communis (EDC), with standard amplification and filtering. The difference between the sEMG magnitude measured from flexor and extensor muscles is used to drive the change of the reference motor position for the SHP (Fig. 2A). That is, the greater the difference between EMG activity from the flexor than extensor muscles, the faster the SHP closes. Note that there is only one gain ('speed' block) that maps the sEMG difference to the velocity of reference position. We implemented this method as the standard '**single gain (SG) controller**' with only one modification: Instead of a fixed reference position limit, we used an adaptive limit that prevents the increase of reference position if the motor current is close to the max capacity. This prevents the reference position 'closing into' the object too much, thus allowing consistent opening motion from objects with any size.

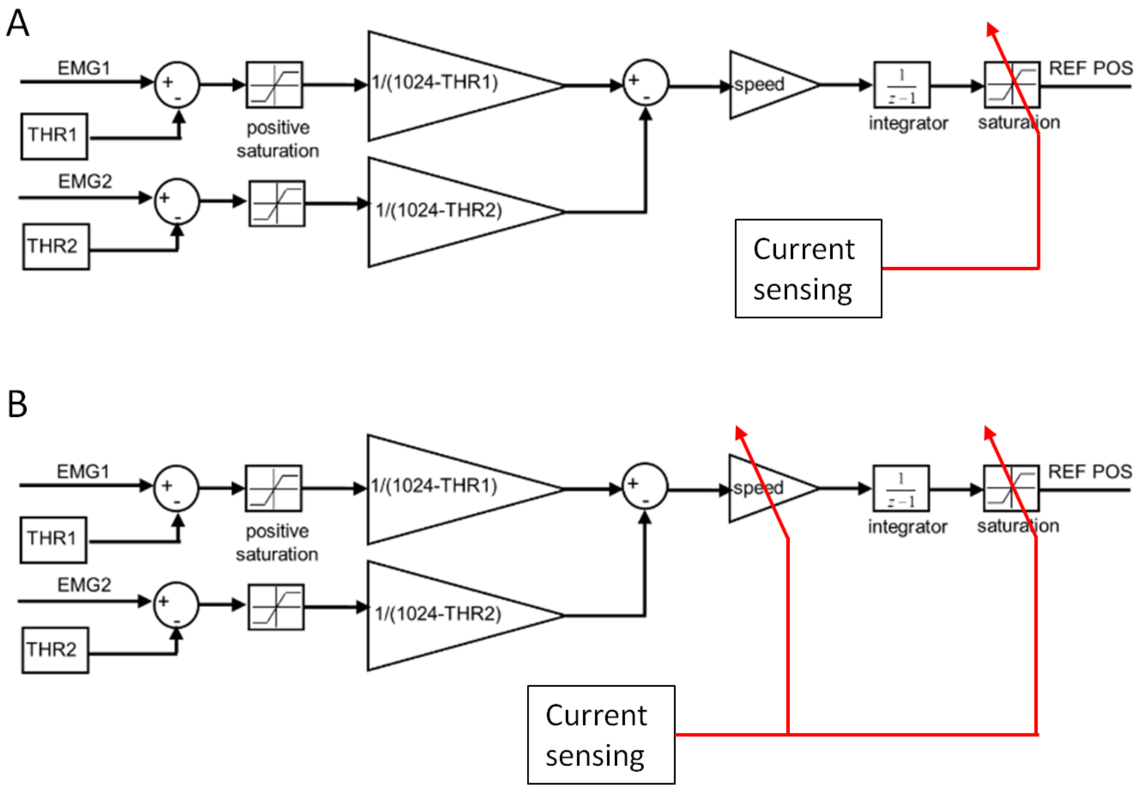

Figure 2. A. Schematic diagram for standard SG control. B. Schematic diagram for HG control.

- However, we found that the main drawback of the standard SG controller is that a single gain cannot control **both** SHP motion and grasp force very well. The internal PID control of the SHP was quite stiff and the motor current (and therefore grasp force) ramps up quickly to the maximum after making contact with the object, if the reference position changes too quickly. To overcome this problem, we created a '**hybrid gain (HG) controller**' that changes control gains depending on the state of the SHP (Fig. 1B). The SHP uses '**residual current'** to estimate the grasping force, which is calculated by subtracting kinematics-dependent current component from the total motor current. Therefore, we can use the residual current to define the state of the SHP (e.g., in motion, or in contact). Specifically, this controller is similar to the SG controller when the fingers are in free motion. However, the gain that maps sEMG difference to the velocity of the reference position switches to a lower one if two criteria are met: 1) the residual current of SHP is above a threshold (i.e., contacts with object are made) and 2) extensor activity does not exceed flexor activity by more than 10% (i.e., no intention of fast opening).The first criterion ensures higher resolution of grasping force control, whereas the second criterion helps to open the hand quickly if needed.

- To quantify the performance of hand prostheses during interactions with objects. We developed the following three **Experimental Tasks** inspired by commonly used clinical hand function assessment tools (e.g., SHAP, block and box test, etc.), with the focus on the ability of fine control of grasp forces.
    - *Large object pick and place*. Subjects have to pick and place a cylindrical object (Fig. 3A) with power grasp (all fingers) repetitively. The object is equipped with a Nano25 F/T sensor that records the grasp forces, and motion capture marker that record the motion. There are two target regions separated by 30 cm with a 5 cm high obstacle located on the mid-line between the two target regions (Fig. 3B), which is aligned with subject's right shoulder. The proximal end of the obstacle is 30 cm away from the right shoulder, and it is defined as the starting region. Subjects were asked to place their hands in the start region in the beginning of a trial, while the experimenter places the object in the right target region. On an auditory 'GO' signal, subjects have to grasp the object and transport it to the other target region and move their hand back to the start region, and repeat as many successful times as possible within 45 seconds. The weight of the object can be modified by inserting mass into the base of the object. There are two object weights: Medium (420 g) and Heavy (820 g). Most importantly, a successful transport is recorded if the object is not dropped or 'crushed'. The fragility of the object is rendered by giving 'glass breaking' sound when the grasping force exceeds a pre-defined threshold. There are two types of fragility. The Solid type has a 'crushing threshold' of 80 N which is beyond the force capability of the SHP, therefore subjects do not need to be careful about crushing the object. The Fragile type has 'crushing threshold' defined based on the object weight, such that the threshold is ~3 N above the minimum grip force required to prevent slipping. Since the object is made by plastic and a glove is always worn on the operating hand, the coefficient of friction is estimated to be 0.5. Therefore, the fragile 'crushing threshold' for the Medium and Heavy objects are 6 N and 9 N, respectively.

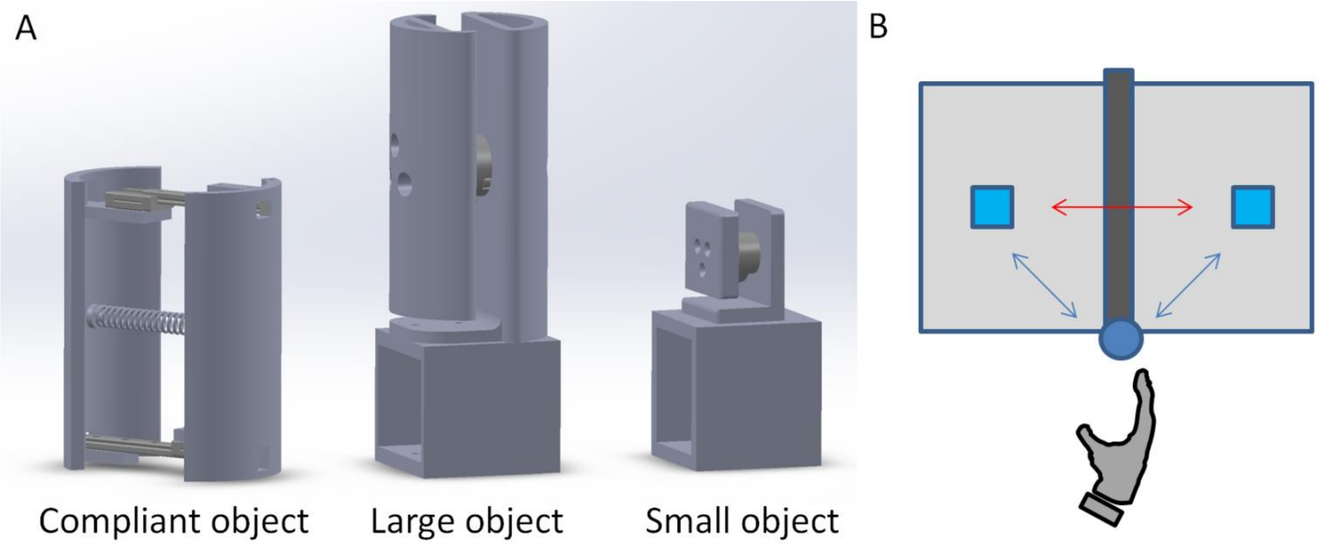

Figure 3. A. Test objects designed to assess user's ability to manipulate objects using fine force control. B. Experimental setup for object pick and place tasks.

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    - *Small object pick and place*. This task is similar to the "Large object pick and place" task, the only difference being that the object is smaller (Fig. 3A). Specifically, there are two small grasp surfaces and subjects have to use a three-digit grasp (thumb, index and middle finger). Therefore, this object requires a higher precision in reach-to-grasp in order to place the thumb accurately on the grasp surface. Two object weights are used: Light (220 g) and Medium (420 g), and the fragile 'crushing threshold' for the Light and Medium objects are 4 N and 6 N, respectively.
    - *Compliant object squeeze*. Subjects have to repetitively squeeze a compliant object (Fig. 3A) with power grasp. The compliance of the object is determined by the stiffness of the spring between the two grasp surfaces. There are two types of compliance: Soft (0.33 N/mm) and Hard (0.54 N/mm). Visual feedback about the deformation of the object is given to the user by

tracking the two grasp surfaces of the object. There are two levels of target deformation 0.8 cm, and 1.8 cm with an error margin of 0.2 cm. For one squeeze action, subjects have to start from 0.8 cm and deform the object into 1.8 cm, then release the squeeze back to 0.8 cm level. Each level has to be maintained for 1 second continuously to proceed to the next level. Each trial contains 5 squeeze actions.

- In addition to the Experimental Tasks, we also developed a two-step simple **Training Scheme** that helps subjects to familiarize with myoelectric control.
    - *Motion control training*. The objective of this training is to learn the EMG-to-motion mapping of the SHP. No CUFF feedback is given. There are three training trials. 5 target levels of hand open/close positions are defined as the SHP motor rotation (0 is fully open): 30, 60, 90, 120, 150. Each trial consists of eight ‘close and open’ actions that always start from 30 and move to one of the other positions, then move back to 30. Subjects are provided with visual feedback of actual and reference open/close positions. The reference position level will automatically advance to the next if the actual position stays within an error margin of 5 for 1 second.
    - *CUFF training*. The objective of this training is to learn the haptic feedback given by the CUFF (Casini et al., 2015). The SHP uses residual current to estimate the grasp force. Therefore, the CUFF could use two motors driving a belt to apply pressure on subjects’ upper arm based on such grasp force estimation. The pressure is calibrated for each subject’s arm size, such that the maximum and minimum pressure is mapped to the maximum and minimum (0) residual current of the SHP. There are 5 training trials. Two target levels of grasp force are defined: 6 N and 12 N. For each trial, subjects have to reach and grasp the large object and generate grasp force first to 6 N, then to 12 N (both with an error margin of 1N) and release, with total of five repetitions.

- Experimental procedures for validating the new myoelectric controller are described below:
    - Subjects are evaluated with the Edinburgh handedness questionnaire.
    - Attach the CUFF and sEMG electrodes to subjects’ arm with medical tapes and Velcro straps.
    - A simple calibration procedure is performed by adjust the amplifier gain of the electrodes such that the MVC of the muscles corresponds to the maximum output voltage (5V) of the electrode.
    - Subjects perform the Experimental Tasks with the native right hand wearing the same glove worn on the SHP. Specifically, one ‘pick and place’ trial is performed for each condition (2 weight types, both with fragile and rigid settings) and for each object size. Before ‘Fragile’ trial starts, subjects are asked to squeeze on the objects without lifting to learn about the ‘crushing threshold’. Additionally, one compliant object trial for each stiffness is performed.
    - Assign experimental groups (SG vs. HG)
    - Training SHP motion control.
    - Training CUFF.
    - Subjects perform the Experimental Tasks with SHP. Specifically, three ‘pick and place’ trials are performed for each condition (2 weight type, both with fragile and rigid settings) and for each object size. Additionally, three compliant object trials for each stiffness are performed.

- 16 right-handed subjects (9 females and 7 males, ages 19–34 years) with normal or corrected-to-normal vision took part in the experiments. They had no history of musculoskeletal or neurological disorders. All subjects were naive to the experimental purpose of the study and gave informed consent to participate in the experiment. The experimental procedures were approved by the Institutional Review Board at Arizona State University and were in accordance with the Declaration of Helsinki. They were randomly assigned to two controller groups. One subject in the SG control group was excluded from the data analysis because he was not able to finish training within an acceptable performance range, and did not participate the experimental task with SHP.

- To demonstrate the superior performance of the HG controller, we performed the following analyses on the ‘pick and place’ task:
    - *Native hand performance*. We quantify performance by number of successful transport within 45 seconds, using three-way mixed ANOVA (Group, Weight, and Fragility) per object size. For both Large and Small object pick-and-place tasks, two groups performed equally well (Fig. 4A,

B). However, as expected subjects handled the fragile objects with more caution, therefore we found that the number of successful transport for fragile objects is significantly smaller than the solid ones (only main effect of Fragility for both Large and Small object $p < 0.001$).

- *SHP performance*. Since each subject performed three trials for every condition, we computed the average number of the three trials for comparison. For the Large object, we found significant Fragility × Group ($p = 0.003$) and Fragility × Weight interactions ($p = 0.023$). Further t-tests suggested that the HG group performed significantly better than the SG group in Heavy-Fragile, Medium-Solid, and Medium-Fragile conditions ($p < 0.05$; Fig. 4C). The two controller groups performed equally well in the Heavy-Solid condition. For the Small object, we found a significant Fragility × Group interaction ($p = 0.035$). Further t-test suggested that HG group performed significantly better than SG group in Heavy-Fragile, Medium-Solid, and Medium-Fragile conditions ($p < 0.05$; Fig. 4D), but not in Heavy-Solid condition.

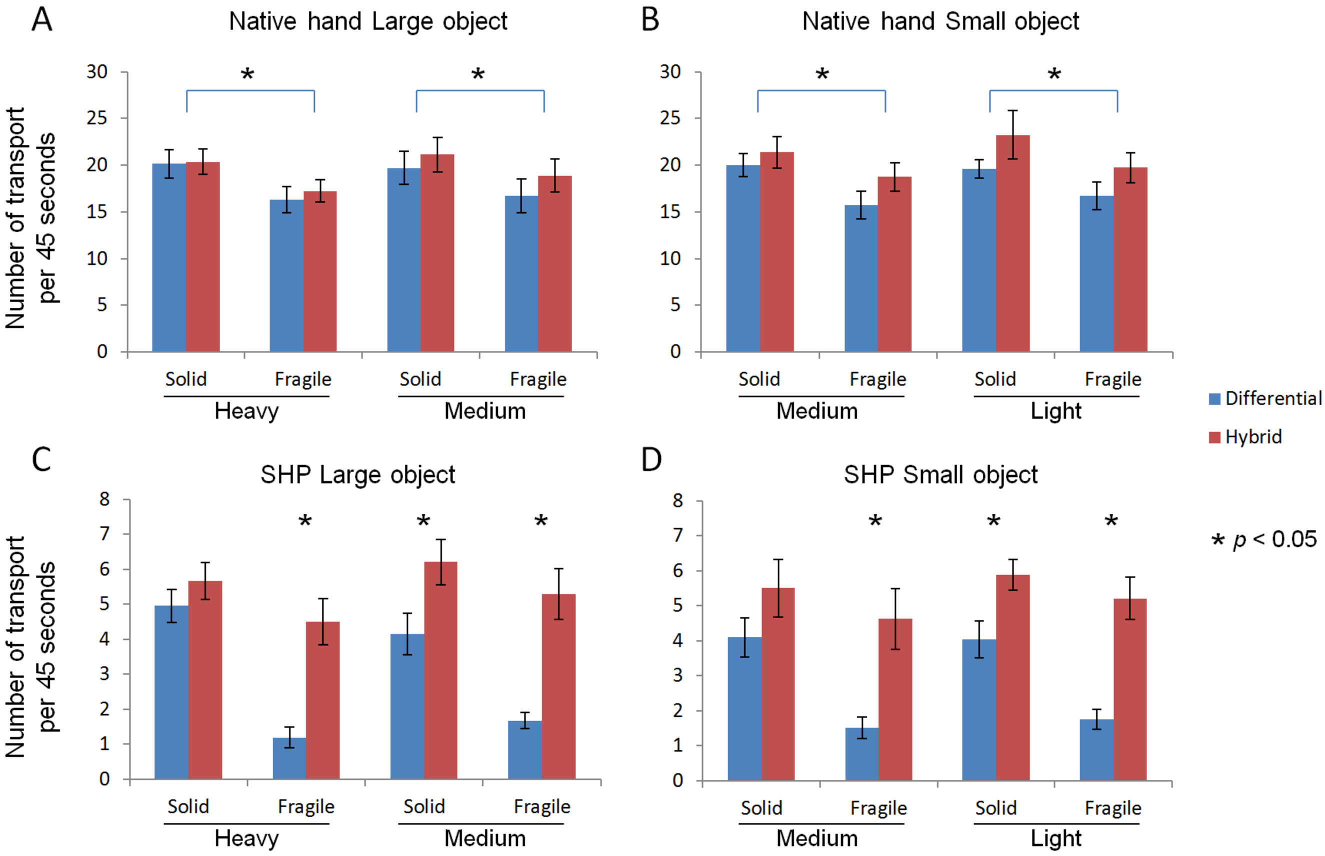

Figure 4. Pick-and-place task performance in all conditions. Panel A and B are Native hand performance. Panel C and D are SHP performance. Data is shown as means and S.E.s.

- *Native hand grasp force*. In addition to performance, we also measured grasp force when the object was moving over the center metal bar during successful trials. It was found that subjects grasp force scaled to object weight and fragility in both object size conditions (Fig. 5A, B). Specifically, for Large object, we found significant main effect of both Weight ($p = 0.003$) and Fragility ($p < 0.001$). For Small object, similarly, we found significant main effect of both Weight ($p < 0.001$) and Fragility ($p < 0.001$).
- *SHP grasp force*. For Large object, we found a main effect of Weight ($p < 0.001$), and a significant Fragility × Group interaction ($p = 0.024$). Further t-test showed that HG group used significantly smaller grasp force than the SG group in Medium-Solid condition ($p < 0.05$; Fig. 5C). Similarly, for Small object, we also found a main effect of Weight ($p = 0.003$), and significant Fragility × Group interaction ($p < 0.001$). T-test showed that HG group used significantly smaller grasp force than the SG group in both Medium-Solid and Light-Solid conditions ($p < 0.05$; Fig. 5D).

- In sum, we demonstrated that a) the HG controller significantly improved subjects' ability to perform fine force control on fragile objects (Fig. 3), and b) HG controller significantly reduced grasp forces in most of the solid object transport movements, except for the heavy object (Fig. 5).

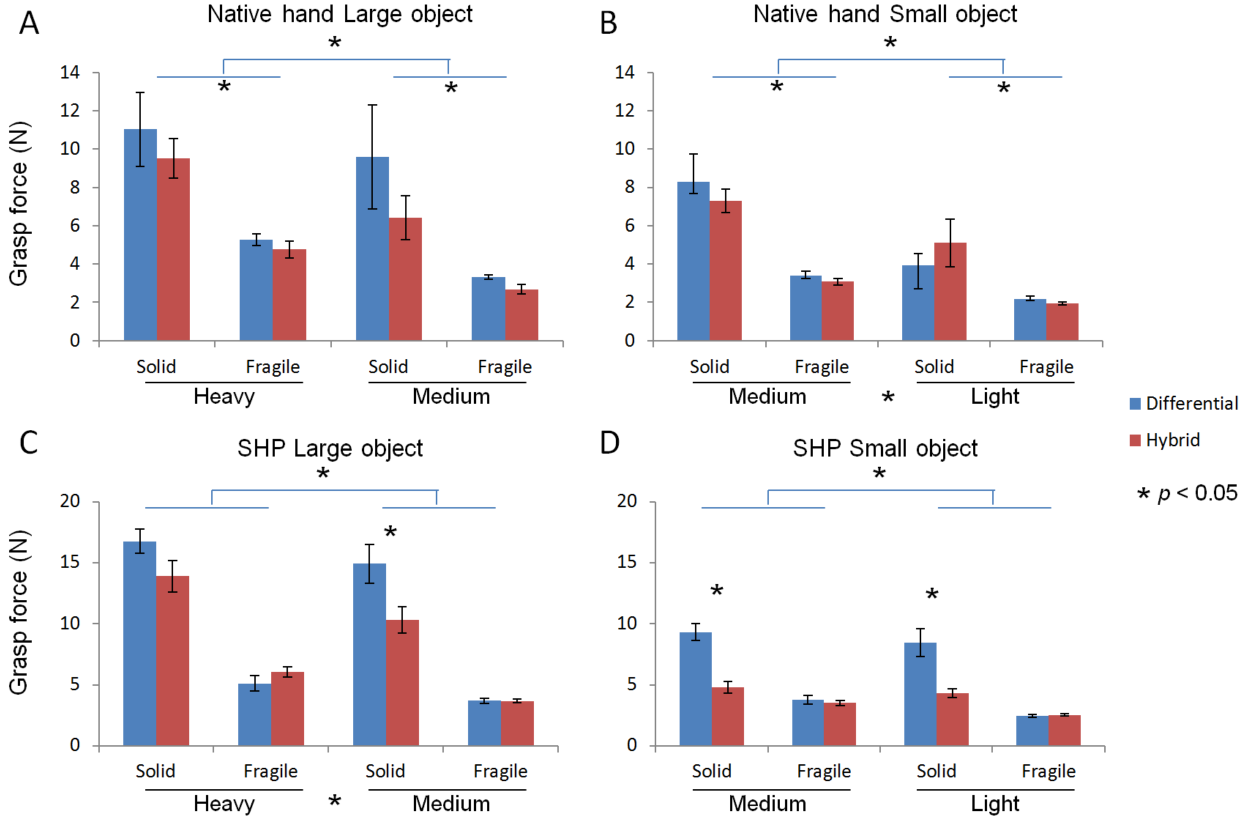

Figure 5. Pick-and-place task grasp forces in all conditions. Panel A and B are Native hand grasp forces. Panel C and D are SHP grasp forces. Data is shown as means and S.E.s.

- We performed the additional analysis listed below.
  - <u>EMG motion control training performance</u>. We quantify the performance by the average duration to complete each target actions (i.e., 'close' and 'open'). With three-way mixed ANOVA (Group, Trial, and Target), we found only a significant effect of Target for both 'close' and 'open' actions ($p = 0.001$ and $p < 0.001$, respectively). This suggests that subjects did not improve over short training sessions. A similar trend was found when examining only the duration it took for subject to move the motor to the desired position. Furthermore, we performed another three-way mixed ANOVA after averaging across trials (Group, Target and Action). We found a significant Target × Action interaction ($p = 0.015$). Post-hoc T-test showed that 30˚ close took significantly shorter time than the other three closing actions, whereas 120 ˚ open took significantly longer than the other three opening actions ($p < 0.05$).
  - <u>EMG force control training performance</u>. The protocol of force training required subjects to generate force by squeezing on the large object with SHP. We found that both subject groups improved over five training trials, but the HG group consistently outperformed the SG group with HG controller. Specifically, two-way ANOVA (Trial and Group) found significant effect of both Trial ($p < 0.001$) and Group ($p = 0.048$).
  - <u>EMG force control training EMG.</u> We examined the average EMG used in force control training with two-way mixed ANOVA (Group and Trial). For both flexor and extensor muscle, we found HG controller group used significant larger activity than the SG group across training trials (main effect of Group $p < 0.001$ and $p = 0.01$; no effect of Trial). This result, in combination with the performance advantage of the HG controller, suggests that the HG controller allows better control of grasping force but requires greater effort/energy.
  - <u>Large object pick-and-place Task EMG</u>. For the large object, we found no difference in the flexor EMG magnitude between the two controller groups (only main effect of Weight and

    Fragility, *p* = 0.035 and *p* < 0.001, respectively). Furthermore, we found no difference in the extensor EMG magnitude between the two controller groups (only main effect of Fragility *p* = 0.002). Lastly, we found no difference in the co-contraction of the muscles between two groups.
  - <u>Small object pick-and-place Task EMG.</u> Similar to the large object, we examined the EMG in the small object tasks. For the flexor muscle, we found a main effect of Fragility (*p* = 0.009), as well as a Group × Weight interaction (*p* = 0.038). Post-hoc comparison showed that subjects in the HG controller group used less EMG for light weight than for the medium weight, but the SG group did not show difference between weights. For the extensor muscle, we found no difference between the two controller groups (only main effect of Fragility *p* = 0.005). Lastly, we again found no difference in the co-contraction of the muscles between two groups.
  - <u>Compliant object Task performance</u>. In addition to object pick-and-place tasks, subject performed compliant object task in which they had to deform a compliant object with either their native hand or the SHP. There were two type of compliance that were set by the stiffness of the spring inside the object. We found that SG and the HG controller performed similarly in this task, and both were much slower than their native hands. Three-way mixed ANOVA (Group, Hand, and Compliance) showed a significant effect of Hand (*p* < 0.001, native hand vs. SHP), as well as a significant Group × Compliance interaction (*p* = 0.006). However, post-hoc comparison between two compliance levels did not reveal significant differences.
  - <u>Compliant object Task EMG</u>. We compared the average EMG between the two controller groups with two-way mixed ANOVA (Group and Compliance). For the flexor muscle, we found that subjects used significant larger activity in the HG group (only main effect of Group, *p* = 0.011). For the extensor muscle, no significant difference was found between the two groups.

- The SHP factory package operates with Ottobock electrodes, which requires careful attachment to the skin. As an alternative, we also implemented the improved HG controller on a low cost EMG sensor array (Myo Armband). This sensor array has eight electrodes embedded in an elastic band. Therefore it allows quick setup and calibration with more robust performance. We successfully demonstrated it at DARPA family day event (Arlington, VA; July 28, 2017).

Minor Task 1.1

- We used the hybrid gain controller developed and validated in Minor Task 1.2.
- We used a motion training protocol similar to the one used in Minor Task 1.2. The objective of this training is to familiarize participants with the EMG-to-motion mapping of the SHP. No CUFF feedback was given. Four target levels of hand open/close positions were defined as the SHP motor rotation (0 is fully open): 30, 60, 90, 120. There were only one training trial which consisted of nine ‘close and open’ actions that always start from 30 and move to one of the other three positions, then move back to 30. Subjects are provided with visual feedback of actual and reference open/close positions. The reference position level will automatically advance to the next if the actual position stays within an error margin of 5 for one accumulated second.
- There were two types of feedback training methods focusing on different aspects of the sensorimotor loop between the user, SHP and CUFF.
  - <u>*Ipsilateral EMG sensorimotor training*</u>: This training focused on the sensorimotor mapping between the EMG signal and CUFF feedback of the grasp force (Fig. 6C). The SHP was positioned next to the cylindrical object (Fig. 6B) for its fingers to close on. The grasping force was displayed on a monitor in real-time as a vertical rising bar. Subject were required to control the SHP grasp force such that the bar follows a series of force targets (0 N, 4 N, 6 N, 8 N, and 10 N) with an error margin of ± 1N. Each force target must be maintained for 1 second to advance to the next one in ascending order until 10 N and the sequence were repeated from 0 N. All targets were repeated five times for one trial. Grasp force was also estimated from SHP motor current and delivered by the CUFF. Subjects were told that the CUFF pressure is equal to the SHP grasping force.

  - *Contralateral haptic mapping training*: This training focused on the haptic mapping between CUFF pressure and subjects' native haptic channels from the contralateral hand (Fig. 6D). Specifically, the right hand with the SHP was positioned out of view, whereas the left hand was positioned next to a second sensorized object with a power grasp without reaching. The grasp force of the left hand was displayed in real-time on a monitor as a vertical rising bar. The visual feedback and target force levels were exactly the same as the ipsilateral training. We carefully calibrated the CUFF and SHP such that the CUFF pressure was consistently mapped to the grasp force measured from the cylindrical objects in both training.
  - Each of the above two training approaches essentially covered part of the force matching task where left hand force has to be recreated by the SHP and CUFF on the right side. Note that the left hand force was not connect to the CUFF during force matching task, but only during contralateral haptic training

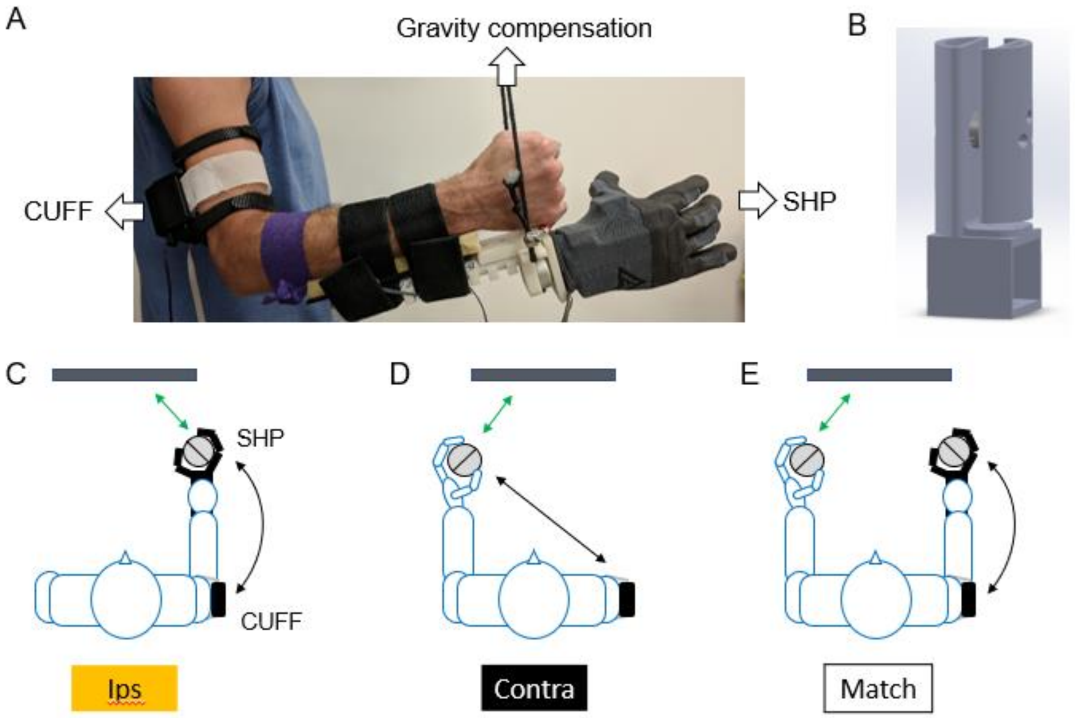

Figure 6. A. Prosthetic system setup. B. Object used to measure grasp force. C. Setup for Ipsilateral EMG sensorimotor training. D. Setup for Contralateral haptic mapping training. E. Setup for force matching.

- To test user's ability to use Haptic feedback from the CUFF, we developed the following force matching task (Fig. 6E). Note that the same task can be performed with either subjects' native right hand or SHP as the matching hand. Subjects had to first produce grasp force with their left hand (contralateral to SHP) on a cylindrical object (Fig. 6B) following visual feedback on the monitor to maintain a target level for 6 seconds within the error margin (±10% of the target). The object is equipped with a Nano25 F/T sensor that measures the grasp forces. The visual feedback does not provide force magnitude information, and only shows the percentage of subjects' grasp force with respect to the target force. Immediately after left hand force production, subjects were instructed to relax the left hand and reproduce the same force level on a second object with eyes closed using SHP and CUFF (or their right hands). When they feel the force is correct, they had to verbally inform the experimenter to record the matching force level. We examined three force levels (4 N, 7 N, and 10 N) evenly and randomly distributed within 24 trials of one testing session.

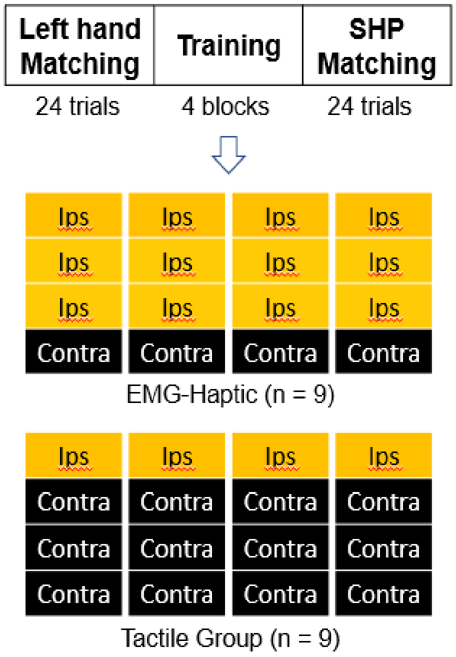

Figure 7. Experiment procedure

- The overall experimental design started with baseline force matching task performed by subjects' native hands, followed by motion control training. Then total of sixteen training trials were given in alternating order between the above two training approaches. There were two subject groups (n = 9 each) which were differentiated by the proportion of the two training approaches. The EMG-haptic group used 12 ipsilateral EMG sensorimotor training and 4 contralateral haptic mapping training, whereas the native-haptic group used the opposite trial composition (Fig. 7). After completing the training trials, subjects were tested with the force matching tasks again with SHP and CUFF.
- Data analysis revealed the following results
  - <u>Feedback training</u>. The total training time was significantly shorter for the HM group than the SM group. This was because the HM group had more contralateral training trials, which took less time to perform due to the use of left hand instead of SHP (Fig. 8A). We found that completion time of the two groups were similar for the first Ipsilateral training trial, but EMG-Haptic group was significantly faster for the last Ipsilateral training trial. Furthermore, the training did not improve the performance in neither groups, as force production with subjects' own left hands was intuitive. Overall, these results indicate that EMG-Haptic group was better at producing target grasp forces with SHP than the Native-Haptic group at the end of force control training session.

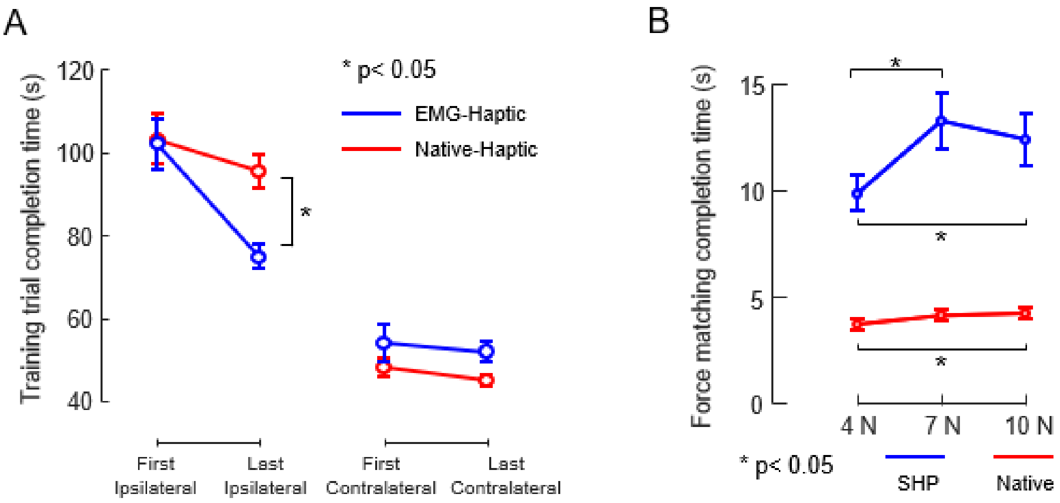

Figure 8. A. Training time comparison. B. Matching time comparison.

  - <u>Matching time</u>. We first assessed whether there was a general learning effect in matching speed, i.e., if subjects spent less time to match their left hands as they progress through the trials. This was accomplished by averaging the matching time across three force levels for each of the eight trials. We performed two-way mixed ANOVA (Trial × Group) for both the native hand matching and SHP matching sessions, and found no significant effect of neither factors. Therefore, we decided to assess the interaction between training protocols and force levels using two-way mixed ANOVA (Group × Force) after averaging all matching time from eight trials for each force level. For the native hand session, we found no difference between groups but a significant main effect of Force (F(2,32) = 6.53, p = 0.014). Post-hoc comparison suggested that subjects used significantly less time for matching the 4 N force (3.73 ± 0.24 sec.) than 10 N force (4.25 ± 0.25 sec.) across two groups, whereas 7N matching time was not significantly different from the other two levels (4.13 ± 0.27 sec.; Fig. 3B). For the SHP session, we also found a main effect of Force (F(2,32) = 6.05, p = 0.007). However, Post-hoc comparison suggested that subjects used significantly less time for matching the 4 N force (9.89 ± 0.84 sec.) than both the 7 N and 10 N force levels (13.25 ± 1.32 sec. and 12.40 ± 1.20 sec., respectively) across two groups (Fig. 8B). Overall, these results indicate that two training protocols did not give advantage in the speed of force matching task to neither groups. Additionally, the 7 N level took the longest time to match in SHP session, but not in Native hand session.

- <u>Matching performance: absolute error.</u> To determine which trials should be used to evaluate the matching accuracy, we first assessed whether there was a general learning effect through multiple trials. This was again accomplished by averaging the absolute errors across three force levels for each of the eight trials. We performed two-way mixed ANOVA (Trial × Group) for both the native hand matching and SHP matching sessions, and both sessions showed significant main effect of Trial (native hand: F(7,112) = 6.25, p < 0.001; SHP: F(7,112) = 5.94, p < 0.001). After visual inspection of the trend (Fig. 9A), we decided to assess the interaction between training protocols and force levels (Group × Force) by averaging the last five trials which showed performance plateau. For the native hand, we found significant effect of Force (F(2,32) = 7.59, p = 0.003). Post-hoc comparison revealed that subjects were less accurate in 10 N condition (1.67 ± 0.14 N) than 4 N and 7 N conditions (1.12 ± 0.15 N and 1.07 ± 0.11 N, respectively; Fig. 9B). For the SHP, neither Group nor Force effect was significant (1.60 ± 0.14 N, 2.13 ± 0.18 N, and 1.69 ± 0.17 N for 4 N, 7 N, and 10N conditions, respectively). Overall, these results suggested that subjects tended to perform the best in 7 N condition with their native right hand, but worst with the SHP/CUFF system. Furthermore, two training protocols did not lead to differences in the magnitude of matching errors.
- <u>Matching performance: relative error.</u> We also averaged the relative errors across the last five trials per force level based on the results from the previous section. Two-way mixed ANOVA (Group × Force) was performed for the native hand matching and SHP matching sessions separately. For the native hand, we found only effect of Force (F(2,32) = 34.93, p < 0.001). One sample T-tests suggested that subjects had positive error in 4 N conditions (0.77 ± 0.19 N), neutral errors in 7 N conditions (0.14 ± 0.21 N), and negative errors in 10 N conditions (-1.06 ± 0.30 N; Fig. 9C). For the SHP, we found significant effect of both Force (F(2,32) = 7.81, p = 0.002) and Group (F(1,16) = 4.84, p = 0.043). One sample T-tests revealed that subjects in the EMG-Haptic group had positive error in both 4 N and 7 N conditions (1.25 ± 0.25 N and 1.36 ± 0

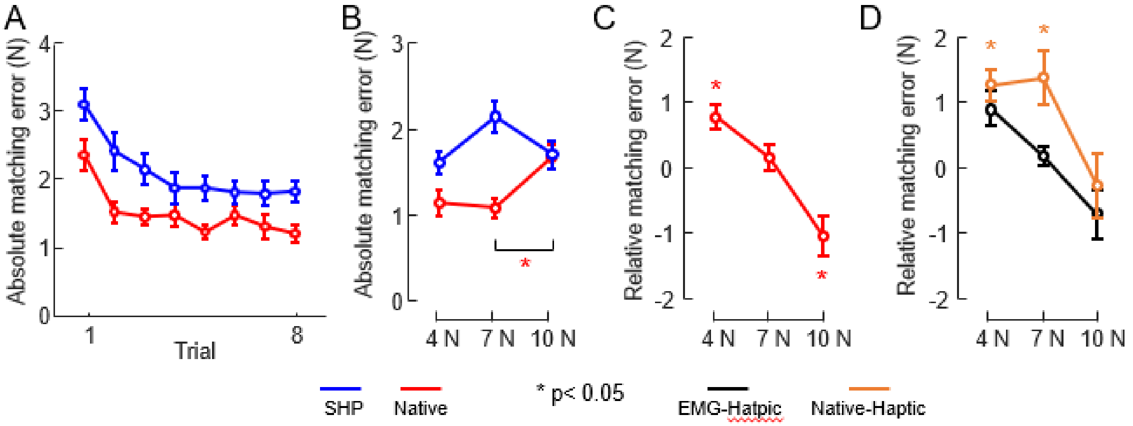

Figure 9. Matching performance

ral errors in 10 N conditions (-0.29 ± 0.50 N). In contrast, the Native-Haptic group had neutral error in all three force conditions (0.70 ± 0.34 N, 0.07 ± 0.36 N, and -0.48 ± 0.30 N for 4 N, 7 N, and 10 N, respectively; Fig. 9D). In summary, we found that the Native-Haptic training helped subjects to generate matching performance in SHP matching qualitatively similar to native hand matching , especially in 7 N conditions. The EMG-Haptic training, however, lead to significant positive bias for SHP matching in 7 N conditions.

Major Task 2.0

Minor Task 2.1

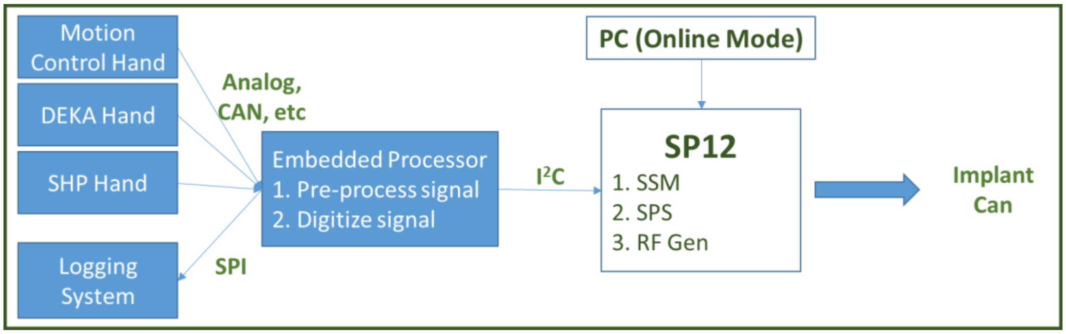

Figure 10: Preliminary approach towards a single peripheral interface solution that can be used for DEKA, SHP, motion Control, and Home Use Monitoring (usage logging + activity monitor).

We have completed development of a NEPH - Soft Hand Prosthesis interface system based on python-ARM board. We combined the different sub-blocks to complete the full system shown in Fig. 10 and assembled a prototype unit for in-lab use. Briefly, we completed the following tasks:

- We updated SP12 and PyBoard firmware and hardware to demonstrate end-end communication between the Soft Hand Prosthesis and the NEPH system. NEPH-SHP system (Fig. 11) acquires the sensor data from SHP to modulate the sensory stimulation while simultaneously saving the sensor data into the SD card on the PyBoard.

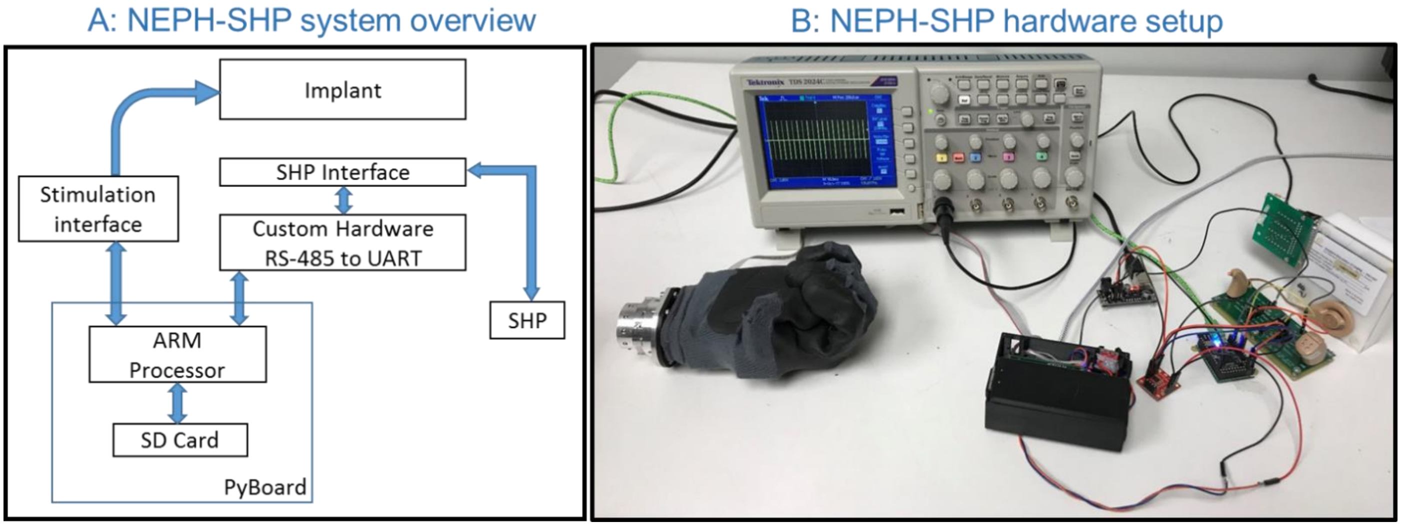

Figure 11: Block diagram (A) and the hardware setup (B) linking the SoftHand Prosthesis (SHP) and NEPH system to the PyBoard. Firmware running on PyBoard is designed to get sensor information from the SHP, log it to memory and simultaneously provide the sensor data to the NEPH system

stimulation interface. Stimulation pulses for a given hand closing position is displayed on the oscilloscope (B).

- We developed working prototype and enclosed in the box.

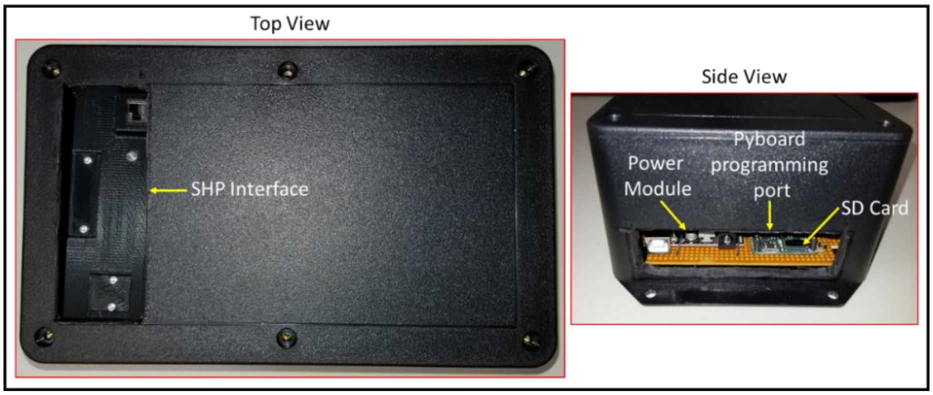

Figure 12: Prototype enclosed in a box with necessary outlets.

- We completed testing the prototype unit to demonstrate full functionality – (1) SHP-NEPH system communication and (2) Sensor data storage. Plots of position and force sensor data retrieved from the SD card are shown in Fig. 13A and 13B. NEPH-SHP communication is demonstrated in Fig. 13C which shows the stimulation output of the NEPH system (as visualized on an oscilloscope) being modulated by hand position.

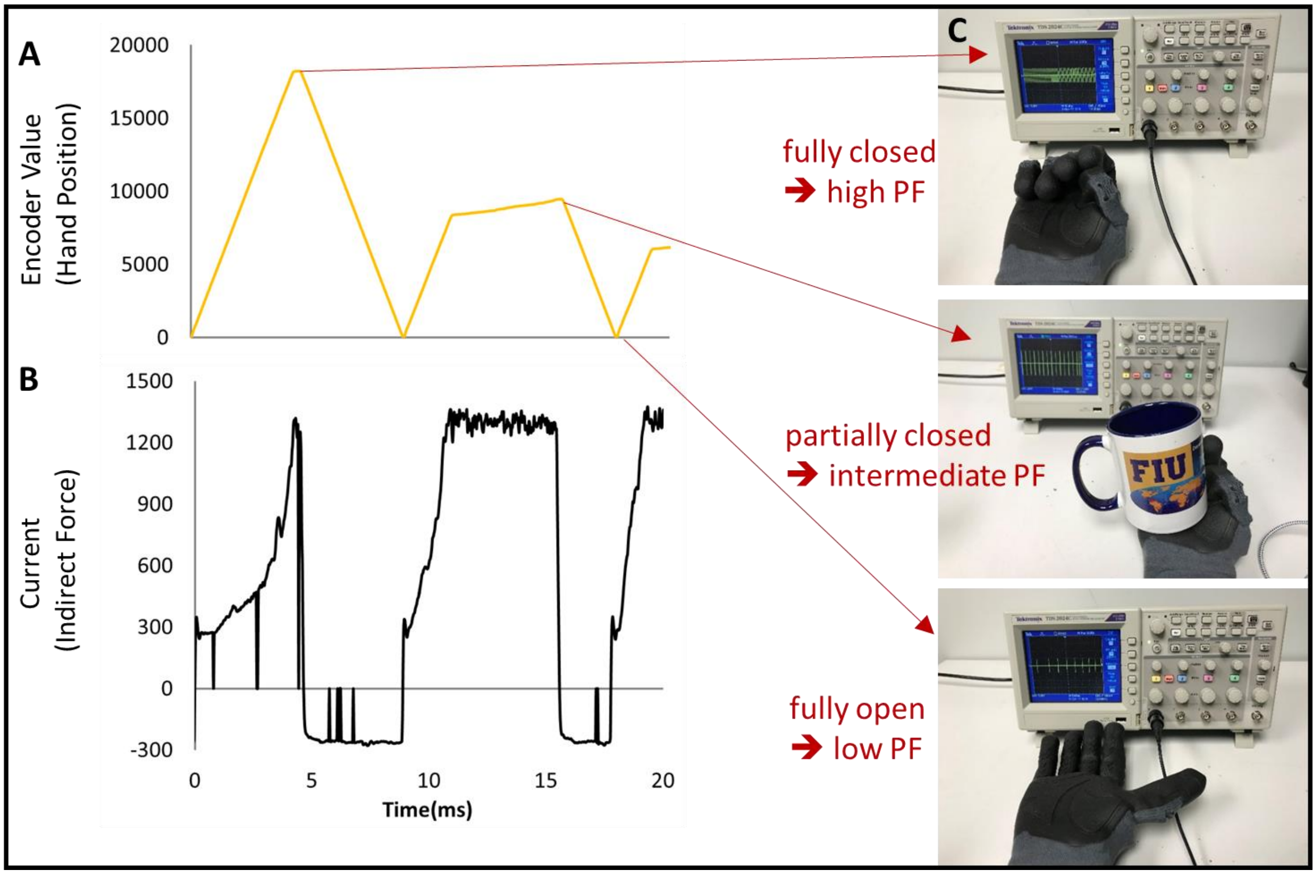

Figure 13: Demonstration of SHP-NEPH communication system and data storage. (A) Encoder data indicating hand position, (B) motor current as an indirect measure of the force exerted during holding an object. (C) Pulse frequencies generated for different hand opening positions as shown on the oscilloscope

Major Task 3.0

Minor Task 3.1

Obtain regulatory approval for laboratory-based testing of the NEPH-SHP system

Hazard analysis has been completed for the NEPH-SHP system. Hazard analysis was conducted as per *ISO-14971: Medial devices -- Application of risk management to medical devices consensus* standard.

Hazard Analysis Process Details

Hazard Analysis was conducted based on the guidelines listed in ISO14971. A qualitative approach was adopted to estimate the hazards associated with design change to the NEPH system for use with SHP hand.

First a list of hazardous situations were identified based on different use cases for the NEPH system. For each hazardous situation, a severity level and probability of occurrence of harm was evaluated based on the definitions in Table 1 and Table 2. An estimate of probability of occurrence of harm was arrived at by considering the probability of the hazardous situation occurring and the probability of harm to the subject if they were to be exposed to the hazardous situation.

Table 1: Potential consequences or severity level used in risk assessment

Severity Levels	Description
Major	The hazard has potential of resulting in death or serious injury
Moderate	The hazard has potential of resulting in permanent injury
Minor	The hazard has potential of resulting in temporary injury
Negligible	No potential safety hazard

Table 2: Different probability levels used in risk assessment

Probability Levels	Description
High	Likely to happen, often and frequently
Medium	Can happen, but not frequently
Low	Unlikely to happen, rare and remote

Each hazardous situation was assigned a risk level based on the severity level of harm and the probability of occurrence of harm. The risk could be intolerable, as low as reasonably practical (ALARP), or a low and broadly acceptable risk (LBAR). A matrix explaining the identified risks is shown in Table 3.

Table 3: Risk classification matrix

Probability	Severity Level

Levels				
	MAJOR	**MODERATE**	**MINOR**	**NEGLIGIBLE**
High	Intolerable Risk	Intolerable Risk	ALARP	ALARP
Medium	Intolerable Risk	ALARP	ALARP	LBAR
Low	ALARP	ALARP	LBAR	LBAR

Table 4 provides a short description of the various risk classes and how the risk is interpreted. In addition to the risk class, the worksheet also lists the risk controls adopted for each risk class.

Table 4: Interpretation of Risk classes

Risk Classes	**(Refer to Annex D 3.1, D4 in ISO 14971 document)**
Intolerable Risk	Unacceptable - Should be controlled or mitigated to lower risk level
As low as reasonably practical **(ALARP)**	Acceptable to use device with practical controls/mitigations
Low Broadly Acceptable Risk **(LBAR)**	Acceptable risk (similar to this associated with day-day activities) to use device with/without controls

Summary of Hazard Analysis

The following hazard categories were identified for the external components of the NEPH-SHP system.

- Electrostatic Discharge (ESD)
- Electromagnetic Interference (EMI)
- Firmware failure on the external components of the NEPH-SHP system
- Hardware failure on the external components of the NEPH-SHP system

A summary of the total number of hazards from all hazard categories for each risk class is listed in Table 6 for the external components of the NEPH-SHP system.

Risk Classes	**Number of hazardous situations**
Intolerable Risk	0
As low as reasonably practical **(ALARP)**	1

Low Broadly Acceptable Risk **(LBAR)**	12

The hazard analysis concluded that the risk profile of the NEPH-SHP system is similar to that of the current IDE-approved device. This analysis indicates that these changes should fall under the FDA's '5-day notice' category for changes to an IDE, which means that we should be able to test the NEPH-SHP system without prior approval from the FDA and then provide them with notification of the changes within 5-days of deployment.

Based on the outcome of the hazard analysis, we have prepared a Q-submission: Pre-Submission request to the FDA to confirm that our regulatory strategy is agreeable to the FDA and that we can use the NEPH-SHP system without prior approval (with a 5-day notice).