Topic: Study of Hand Rehabilitation System Effectiveness and Design of Revised System

Goal: To get clinical engineering and IRB approval on a clinical study for a hand rehabilitation device, to design and fabricate an improved version of the device based on study feedback, and to get preliminary study feedback for the revised version.

Team Member(s): Jacob Carducci

Mentor: Kevin Olds

Importance: Patients that have been affected by stroke improve most in motor skills when treatment is administered within the first couple months after the incident. By introducing a user-friendly, portable, and relatively low-cost device that can record and process small forces from the fingers that are typically characteristic of severe stroke cases, early intervention and treatment of stroke becomes more practical and feasible for a larger demographic of patients.

Technical Summary: Patients will have their hand of focus fitted into an adjustable wrist brace that locks into the base of the rehab tool. The fingers of the patient will fit into up to five adjustable silicon retention cups. The base of each cup structure will contain a strain-gauge force-sensor array that can detect pressing, lifting, and lateral pressures from the patient at a high sensitivity to account for the potential weakness of the patient. The signal changes from the sensor arrays are sent to a controller board inside the tool and then to a connected computer, which processes the signal fluctuations into useful information that can be used in higher-level applications or games.

Key Deliverables and Tasks:

Minimum Deliverables and Tasks	Expected Date
Send the existing prototype to the clinical engineering team (CES) within the Johns Hopkins hospital system and get an approval stamp	03/06/2017
Get IRB approval for a clinical study of the prototype	03/17/2017

Design a revised prototype on paper and in CAD software • Easily removable arm brace • Appropriate design for thumb force sensor • Snap-on mechanism for finger retention cup adapter • PCBs for microcontroller and signal processing to support 5 fingers	03/17/2017
Get feedback from at least 5 individuals affected by stroke of various degrees	04/07/2017
Expected Deliverables and Tasks	Expected Date
Fabricate the revised prototype to implement features developed from patient feedback and other considerations • All designed components from revision design • Sensitivity / calibration testing of components & soldering PCB parts	04/14/2017
Maximum Deliverables and Tasks	Expected Date
Send the revised prototype to clinical engineering and get the approval stamp	04/21/2017
Get feedback again from at least 5 stroke-affected patients for revised design	05/05/2017

Dependencies with Plan of Resolve:

Dependency	Status	Plan of Resolve
Hardware from outside vendors (PCBs, printed & machined parts, etc.)	Unresolved (Estimated Resolve Date: 03/20/2017)	None of these parts require a specific vendor, and the vendor can be changed if there are any issues.
CES and IRB approval	Unresolved (Estimated Resolve Date: 03/17/2017)	If intractable delays in CES and IRB approval come up (unlikely since similar projects and devices from the same group have been approved in the past), the project will shift to focus more on technical development of the new prototype.

Patient recruiting	Unresolved (Estimated Resolve Date: 04/07/2017)	Even with CES and IRB approval, there can be delays in recruiting patients to participate in the study. If this occurs, many aspects of the design can be tested with healthy subjects, which are much easier to recruit.

Management Plan & Responsibilities:

- There will be at least a weekly meeting with Kevin to keep the project on track.
- Jacob would be responsible for assisting in creating documentation for submission to clinical engineering and to the IRB for study approval, collecting data from patients during the study, and designing and fabricating the revised prototype of the device.
- Mentor (Kevin Olds) would be responsible for connecting Jacob with all necessary resources at the School of Medicine, supervision of all documents and designs, providing access to fabrication facilities, and purchasing components from outside vendors.

Reading List:

[1] K. Nagata, "Fingertip-mounted six-axis force sensor". US Patent 6622575 B1, 7 July 1999.

[2] J. Xu, A. Haith, J. Krakauer, "Motor control of the hand before and after stroke," *Clinical Systems Neuroscience,* Ed. K. Kansaku et al. Springer Japan, 2015.

[3] J. Xu, N. Ejaz, B. Hertler, M. Branscheildt, M. Widmer, A. Faria, M. Harran, J. Cortes, N. Kim, P. Celnik, T. Kitago, A. Luft, J. Krakauer and J. Diedrichsen, "Recovery of hand function after stroke: separable systems for finger strength and control," *bioRxiv,* 2016.

[4] R. Pozos and J. Agraz, "Force measuring device and method". US Patent 6673026 B2, 27 March 2000.

[5] S. Ito, H. Kawasaki, Y. Ishigure, Y. Nishimoto, T. Aoki, T. Mouri, H. Sakaeda and M. Abe, "Development of a Hand Motion Assist Robot for Rehabilitation Therapy by Patient Self-Motion Control," in *Proceedings of the 2007 IEEE 10th International Conference on Rehabilitation Robotics*, Noordwijk, Netherlands, 2007.