Title: Wearable Pediatric Sensory Transfer Devices for Improved Neuromotor Control of Impaired Limbs after Spinal Cord Injuries

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Budget Request: $299,609 over two years

Motivation: Sensory feedback is crucial to the development of neuromotor skills in children. The loss of haptic sensation or proprioception in the extremities due to neurological diseases or physical trauma can significantly diminish a child's ability to achieve fine, dexterous motor control in their affected limbs, or to control any prostheses or orthoses prescribed for rehabilitation. These sensory challenges often result in the disuse of the affected limbs or the rejection of assistive devices, which can subsequently lead to the overuse of contralateral limbs and other physical or psychological problems that may persist or, in some cases, worsen as a child develops. There exist surgical means of restoring sensory capabilities that involve relocating healthy nerves to sensory-impaired areas (nerve transposition), but these methods are expensive and invasive. Alternative approaches that are less invasive and more amenable to pediatric use are desperately needed.

Our Solution: We propose the development of a ***wearable pediatric sensory transfer device*** that acquires haptic and proprioceptive sensory information from (1) a powered prosthesis or orthosis or (2) regions of child's body desensitized by disease or trauma, and noninvasively displays that information to areas of the body still having intact sensory capability. The sensory transfer display will apply cutaneous vibrotactile and mechanotactile stimuli to the skin to convey encoded information about the state of sensory-impaired regions of the child's body (e.g. hands or feet), or the activity of an assistive device being used, with the intent of improving neuromotor learning and limb control. These sensory transfer displays will have the advantages of (1) being noninvasive and inexpensive in comparison to conventional nerve transposition surgeries and (2) being easily reconfigurable so that the method of sensory information encoding and the physical dimensions of the device can be modified to accommodate the growth of pediatric patients, changes in their conditions, or the type of assistive device being used.

Our **central hypothesis** is that the provision of transferred sensory information will facilitate the establishment of new feedback pathways that enable (1) greater recovery of natural limb motor skills lost due to pediatric sensory impairments and/or (2) dexterous control of pediatric powered prostheses or orthoses. The restored sensory capabilities availed by the proposed device will impact children with a variety of diseases and impairments including the following:

- **Peripheral neuropathy and Guillain-Barré syndrome**: restoration of tactile sensation on the hands and feet, as well as proprioception of ankles and fingers during walking or manipulation
- **Cerebral palsy**: improving grasp control and object perception/discrimination
- **Upper or lower extremity amputation or congenital limb differences**: enabling fine motor control of powered prostheses or orthoses by providing tactile sensation and proprioception

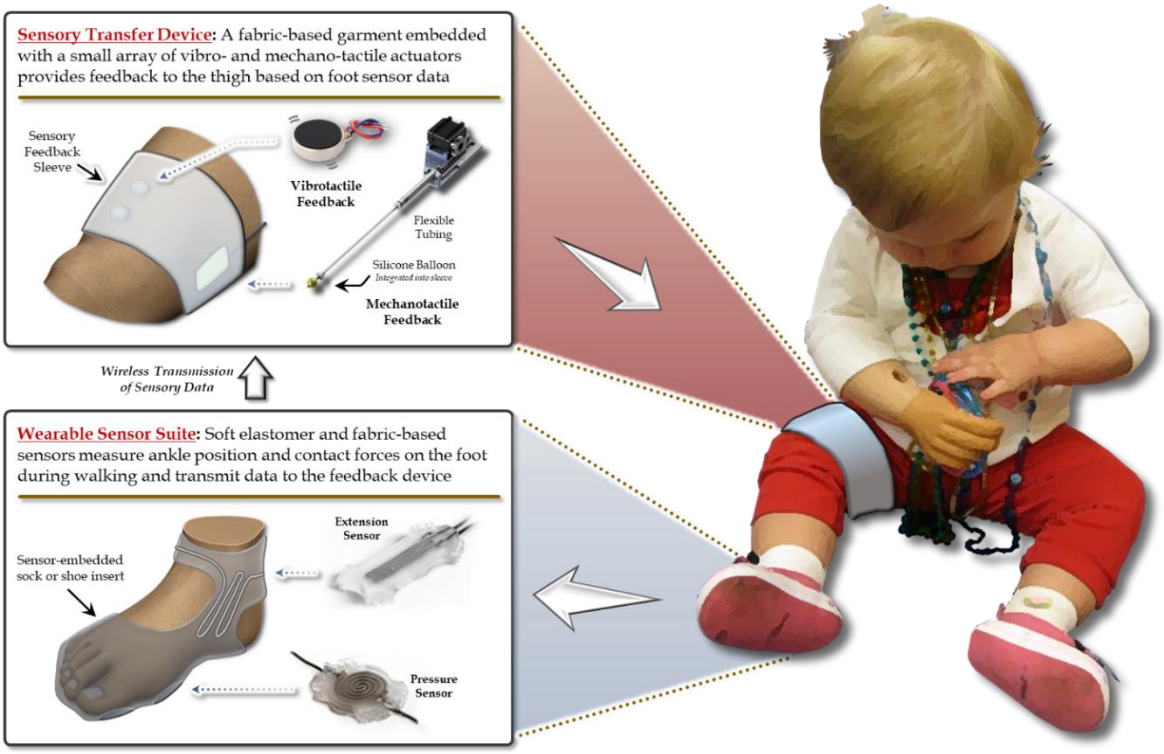

Figure. Concept of a wearable sensory transfer device for lower extremity peripheral neuropathy

Our **objective** in this research is to ***restore peripheral tactile and proprioceptive sensitive for pediatric patients with spinal cord injuries*** (**SCI**). We will develop a sensory transfer device for SCI-related hand impairments and evaluate its effect on a group of five human subjects. The results of this study will provide scientific and engineering bases upon which to extend the use of the wearable sensory transfer device to other conditions that cause sensory impairment in children.

Specific Aims: We will test our central hypothesis via the following Aims:

Aim 1: ***Develop a prototype wearable pediatric sensory transfer device for a specific sensory impairment condition (Engineering Design)*.** The prototype will display encoded sensory information via a combination of localized vibrations (vibrotactile stimulation) and small pressures (mechanotactile stimulation) applied to the skin. The initial prototype system will be designed as a soft band to be worn on the subject's arm or leg. The band will stimulate the underlying skin in proportion to physical events such as contact forces, temperatures, strains, or changes in the activity or state of a natural limb (e.g. joint motion), which are acquired by a suite of wearable wireless sensors (to be developed by Co-PI Yeo) placed on the human body.

Wireless sensor array development: Co-PI Yeo's group has matured technologies, proven by the prior works (Mishra 2020; Kwon 2020; Mahmoud 2019; Kim 2019), to develop various types of nanomembrane, wireless electronic sensors, including pressure, strain, temperature, and motions. Data will be wirelessly transmitted via Bluetooth over 10 meters. An additive nanomanufacturing based on aerosol jet printing will be used to fabricate both sensors and electronics. The key innovation of this technology is in the miniaturization of the entire sensor package by using stretchable nanomembranes as well as the soft material packaging to avoid rigid, bulky electronics.

Evaluation: The sensory device will first be evaluated in-lab using mechanical testers to verify that vibrotactile and mechanotactile feedback are accurately generated in proportion to sensor signals received from a remote wearable sensor suite. The device will then be tested on human subjects to determine the placements and output settings (i.e. signal frequency and magnitude) for the sensory feedback elements that allow subjects to perceive feedback without causing physical discomfort or cognitive burden.

Aim 2: ***Experimentally assess the efficacy of sensory transfer*** by conducting a preliminary study with five subjects having a sensory impairment. The sensory transfer tests will involve instrumenting either the sensor-impaired regions of a subject's body with tactile and joint motion sensors. Joint angles and contact force information from the sensors or the hand or foot (depending on the subject) will be displayed on a subject's skin using the sensory transfer device. The location of the display will be selected based on a sensitivity and perception data from Aim 1.

Evaluation: The study will measure, among several outcomes, the subjects' abilities to discern the contact forces and joint angles of the limbs, with and without vision, using the sensory transfer device. The impact of sensory transfer to manipulation capabilities or walking gait (depending on the subject) will be quantified using standardized clinical assessment methods. Cognitive loading (NASA TLX) and user experience surveys will be conducted and analyzed along with the quantitative experimental data.

Long-Term Impact: The results of this work have broad implications not only for pediatric patients with sensory impairment, but also for the following applications:

- Adults with sensory impairments due to diabetes-related peripheral neuropathy
- Providing sensory feedback for myoelectric adult prostheses
- Use of the wearable sensory transfer device to diagnose sensory impairments

Research Method

Task 1: Development of the Wearable Pediatric Sensory Transfer System

The objective of this task is to ***design and prototype a wearable pediatric sensory transfer device for the treatment of sensory-impaired hands***. This proposed system will sense the motions and contact events at a user's hands during object grasping and manipulation, and provide cutaneous mechanical stimuli, representing those manual grasp data, elsewhere on the body. The device will be comprised of two components, ***a three-finger sensor glove*** and ***wearable feedback display***, which will be developed and evaluated independently before integration as a complete system.

The sensor glove will employ flexible wireless circuits on the thumb, index, and middle fingers to sense the shape of the user's hand (Fig. 1), as well as the pressures and temperatures on the finger tip pads during manual object manipulation. The feedback display will comprise a fabric-based sleeve containing an array of vibrotactile and mechatactile cells that mechanically stimulate the wearer's skin based on data acquired by the sensing glove, and will be designed for use on the upper and lower arm. The feedback display cells will be controlled by a portable, wireless communication-enabled microcontroller (MCU).

Successful completion of this task will include (1) ***fully functional prototypes*** of the sensor glove and feedback display, (2) an ***IRB protocol*** for evaluating the sensory transfer system in a human subject study, and (3) ***experimental data*** characterizing the reliability of the display output (from benchmarking tests) and the efficacy of the device (from the clinical trial).

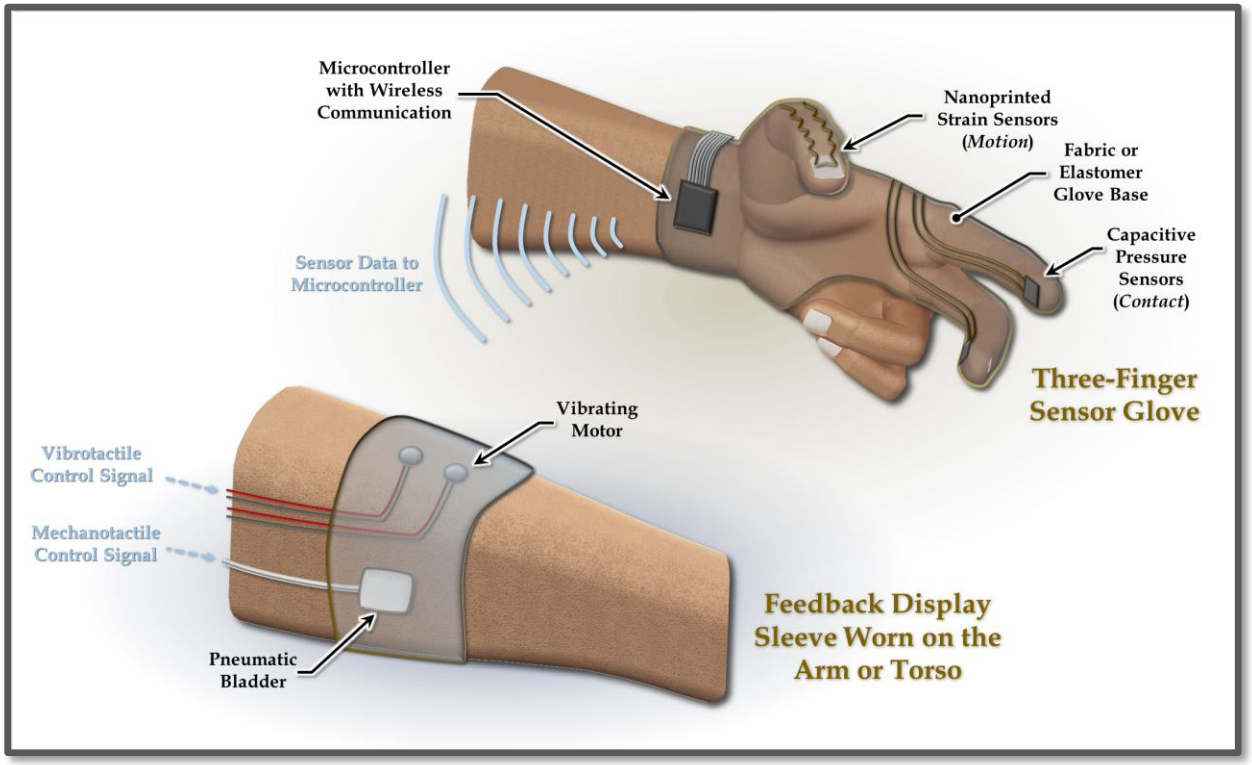

Figure 1. Illustration of the wearable sensory transfer system showing the two primary subsystems: the sensor glove and the feedback display (power source, controller, and temperature sensors not shown)

Task 1.1: Development of the Wearable Sensory Feedback Display (PI Hammond)

Subtask 1.1.1: Literature review on feedback displays and sensory transfer (Mo. 1)

The team will survey literature on wearable haptic feedback displays for healthcare and human-machine interfacing, with a focus on the modes of feedback used to convey certain physical quantities, and the metrics used to assess the efficacy of the various sensory feedback approaches. The team will also review different system/device design approaches taken in recent rehabilitation and human augmentation research. The students will draft a formal survey document providing a chronological overview of clinically-focused sensory research, identifying the key challenges facing current sensory feedback researchers, and highlighting new technologies (including those in the PI Hammond's and PI Yeo's labs) that are being leveraged to advance the field.

- **Deliverables:** A literature review in the form of a journal manuscript, citing 50+ archival journal paper and peer-reviewed conference proceedings.
- **Metrics for Success**: Publication in a reputed archival journal on wearable, haptically enabled medical devices or powered prostheses and orthoses.
- **Expected Outcomes, Challenges, and Mitigation Plans**: It may be challenging to synthesize a comphrensive survey in sensory feedback given the vast number of fields that comprise it (e.g. neuroscience, psychology, materials science, mechanical engineering, machine learning). The team will focus the survey on a domain-specific topic relevant to this project to yield a more rigorous and informative survey (i.e. balancing technical depth and breadth).

Subtask 1.1.2: Develop wearable mechatactile and vibrotactile displays (Mos. 1-6)

In this subtask, PI Hammond's lab will design and manufacture independent mechotactile (skin stretch) and vibrotactile displays for experimental evaluation of human sensitivity to different signal types and interfacing approaches. These displays will be designed as separate fabric-based sleeves for the arm, and will be refined and later integrated into a bimodal feedback display based upon the results of the experimental evaluations.

Mechanotactile Feedback: Two approaches will be explored for mechanotactile feedback: (1) ***skin stretch*** by applying shear forces to the arm with small motors and (2) ***localized normal pressures*** using pneumatic bladders. The skin stretch approach will use servos with soft, elastomer contact pads to rotate small patches of skin in proportion in feedback signal strength. The amount of skin stretch required to safely provide this feedback will be determined by a combination of experimental investigation and literature on human skin sensitivity to mechanical inputs.

Figure 2. Proposed cutaneous feedback display components.

The localized normal pressure mechanotactile feedback approach involves the use of elastic pneumatic pouches (Fig. 2), made of either rubber or heat-sealed thermoplastic sheets, actuated by a motor-driven syringe pump. This approach will leverage recent advancements in pneumatically-actuated wearable devices designed and PI Hammond's lab, and will be miniaturized to accommodate the anatomy of children from 5-18 years of age.

Vibrotactile Feedback: Vibrotactile displays will be created using off-the-shelf (OTS) button cell DC motors. A mechatronic system will be designed to facilitate control of the mechanical stimuli to within the human sensitivity limits noted in literature. These displays will include wireless communication capabilities required interface with the wireless sensor suite developed in **Subtask 1.2**. This task will leverage the PI's previous work on wearable sensory feedback displays used for prosthetic device control (Lee, 2017; Lee, 2018; Choi, 2018).

- **Deliverables:** Prototypes of the two feedback display devices and data from benchmarking tests. Benchmarking tests involve attaching the feedback displays to phantom limbs, with human-like mechanical properties, to confirm the controllability and repeatability of their mechanical output on compliant surfaces.
- **Metrics for Success**: Data confirmaing that the output magnitude and frequency of vibratory stimuli, and the pressure or twist-base skin stretch created by mechanotactile stimuli, are repeatable to within 5% of the targeted response.
- **Expected Outcomes, Challenges, and Mitigation Plans**: The feedback displays may exhibit different mechanical output behaviors when coupled to materials of different stiffness and damping (simulating different amounts of adipose tissue) and may need calibration to provide consistent mechanical stimuli to users of various anatomical size and body composition.

Subtask 1.1.3: Experimental evaluation of human subject response to feedback (Mos. 4-6)

This substask lab will involve a study of human sensitivity to mechanotactile and vibrotactile feedback provided by the wearable displays. Human subjects will be recruited to participate in trials where cutaneous stimuli are provided in different patterns (e.g. frequencies, pressures, etc.) and on different regions of the upper body recommended by literature and Shriner's clinicians, while performing tasks. These tasks will include motor activites such as object pick-and-place and cognitive tasks such as perceiving visual or mechanical events.

The ability of subjects to perceive changes in cutaneous stimuli under different conditions will be measured quantitatively by percentage accuracies in perception, and the cognitive loading induced by the proposed forms of feedback will be assessed using NASA TLX surveys.

Study protocol will be developed to evaluate feedback display sensitivity on adult subjects without sensory impairment, but will be designed to consider a range of anatomical sizes appropriate for pediatric SCI patients in future studies.

- **Deliverables:** Prototypes of the two individual feedback display devices (one mechanotactile and one vibrotactile) and data from benchmarking tests. Benchmarking tests will involve attaching the feedback displays to phantom limbs, with human-like mechanical properties, to confirm the controllability and repeatability of their mechanical output.
- **Metrics for Success**: Data showing that the output magnitude and frequency of vibratory stimuli, and the pressure or twist-based skin stretch created by mechanotactile stimuli, are repeatable to within 5% of the targeted response.
- **Expected Outcomes, Challenges, and Mitigation Plans**: The feedback displays may exhibit different mechanical output behaviors when coupled to materials of different stiffness and damping (simulating different amounts of adipose tissue) and may need calibration to provide consistent mechanical stimuli to users of various anatomical size and body composition.

Subtask 1.1.4: Development of a bimodal feedback display for upper extremities (Mos. 6-15)
This substask lab will involve the electromechanical integration of the mechanotactile and vibrotactile feedback displays, and evaluation of this bimodal system in a human subject study. Adult subjects without sensory impairment will be recruited to wear this bimodal feedback display while performing a variety of manual manipulation tasks. During the completion these tasks, the ability of the subjects to perceive the mechanotactile and vibrotactile feedback in the presence of other external stimuli will be assessed. Human subject perception performance will be used to improve the placement of the vibrotactile and mechanotactile cells and the coordination of feedback signals to mitigate any sensory interference or confusion caused by the two input types.

- **Deliverables:** Two prototypes of the bimodal feedback display device, data from benchmarking tests, and perception accuracy data from human subject studies.
- **Metrics for Success**: Assessment methods include the NASA TLX survey, quantitative data on the accuracy of subject perception (i.e. confusion matrices), and physiological data (e.g. pupillometry, heart rate, and galvanic skin response).
- **Expected Outcomes, Challenges, and Mitigation Plans**: The biomodal feedback displays may induce sensory confusion when both feedback types are delivered simultaneously or in close proximity to one another. Feedback display component placement and the timing and frequency of the stimuli will be modified to reduce these effects.

Task 1.2: Develop Flexible Circuits for Motion, Contact and Temperature Sensing (PI Yeo)
In this task, PI Yeo's lab will leverage its expertise in flexible circuit design and nanomaterial printing-based technologies to create a three-finger wearable sensor glove (Fig. 3). This glove will measure the motion of the wearer's hand while sensing the fingertip forces and temperatures associated with the manual manipulation of objects.

Matured technologies, proven by the prior works (Mishra 2020; Kwon 2020; Mahmoud 2019; Kim 2019), will be used to develop various types of nanomembrane, wireless electronic sensors, including pressure, strain, temperature, and motions. Data will be wirelessly transmitted via Bluetooth over 10 meters. An additive nanomanufacturing based on aerosol jet printing will be used to fabricate both sensors and electronics. The key innovation of this technology is in the miniaturization of the entire sensor package by using stretchable nanomembranes as well as the soft material packaging to avoid rigid, bulky electronics.

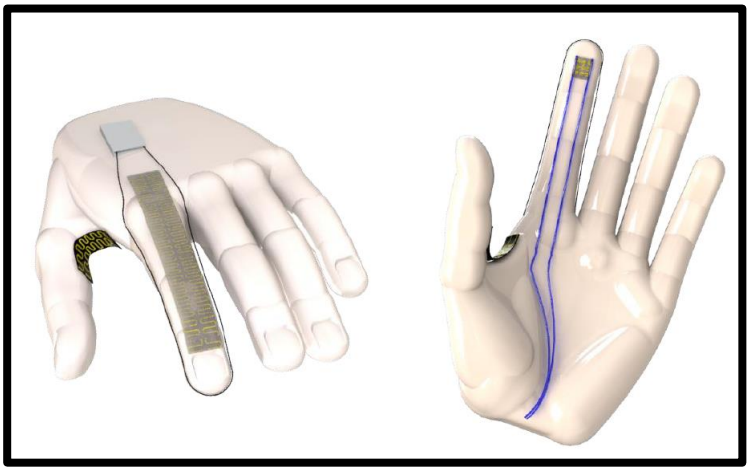

Figure 3.Sensor glove illustration with pressure and strain sensors

Subtask 1.2.1: Pressure sensor development for grasp force estimation (Mos. 1-6)

This subtask will focus on the development of nanoprinted capacitive sensors to measure contact pressure on the fingertip pads during manual object manipulation. Previous work has demonstrated the sensitivity of wearable nanoparticle printed pressure sensors (Fig. 4). This work will focus on designing these capacitive sensors in form factors small enough for use with pediatric patients, while facilitating the acquisition of accurate, repeatable data over hundreds of individual contact events.

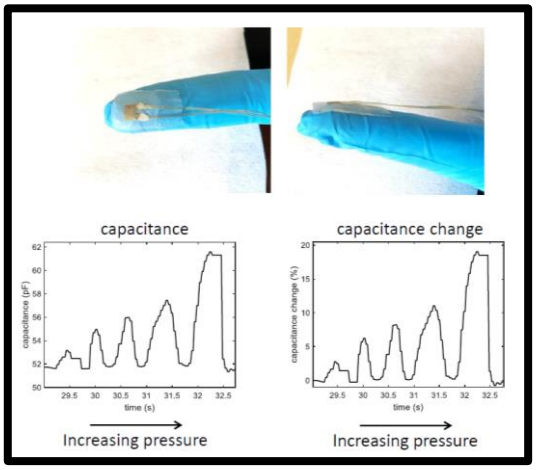

Figure 4. Capacitive pressure sensor prototype.

Subtask 1.2.2: Strain sensor development for hand configuration estimation (Mos. 1-6)

This subtask will focus on the development of nanoprinted strain sensors to measure finger posture. Finger posture can be estimated by monitoring length deformations that occur as a finger flexes or extends. Prior work has shows the sensitivity of strain sensors to finger articulation (Fig. 5). This work will focus on designing four strain sensors to measure flexion-extension of the thumb, index, and middle fingers, as well as abduction-adduction.

Subtask 1.2.3: Temperature sensor development (Mos. 4-9)

Task 1.3: Sensory Transfer Device Integration and Evaluation (Hammond and Yeo)

After independent evaluation of the sensor glove and bimodal feedback display, the two subsystems will be integrated to form the pediatric sensory transfer device. The integrated system will be evaluated based on the following criteria:

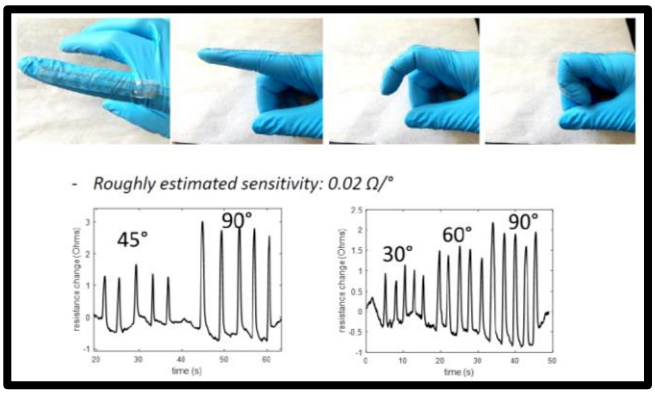

Figure 5. Strain sensors for finger posture estimation.

Task 2: Experimental Assessment of Sensory Transfer

This task will focus on designing, prototyping and evaluating a wearable pediatric sensory feedback display capable of providing multiple, cutaneous mechanical stimuli to the wearer. Researchers will design the feedback display as a flexible sleeve for the upper extremity containing an array of vibrotactile and mechatactile cells which are actuated by a portable, wireless communication-enabled microcontroller. Successful completion of this task will include (1) fully functional prototypes of the sensory feedback display for clinical evaluation, (2) an IRB protocol for evaluating the display in a human subject study, and (3) experimental data

characterizing the reliability of the display output (from benchmarking tests) and the clinical efficacy of the device (from the clinical trial).

Project Schedule

Project Task Name	Performance Period - 24 Months							
	1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24
Task 1: Pediatric Sensory Transfer Device Design								
Subtask 1.1: Development of a Wearable Sensory Feedback Display								
Subtask 1.2: Flexible Wireless Circuits for Contact and Temperature Sensing								
Subtask 1.3: Wireless Integration of the Feedback Display and Flexible Sensors								
Task 2: Experimental Assessment of Sensory Transfer Efficacy								
Subtask 2.1: Assessment of Human Sensitivity to Feedback Display Stimuli								
Subtask 2.2: Conduct Clinical Trial on Pediatric Grasp Performance w/ Device								
Bi-monthly and Annual Reporting								
Project Management and Meetings								
Clinical Translation Planning								

Key Project Personnel	Affiliation	Technical Expertise
Dr. Frank L. Hammond III (PI)	Georgia Tech	Soft actuators and wearable robotics
Dr. Scott Kozin (PI)	Shriners Hospitals	Pediatric orthropaedic surgery
Dr. Woon-Hong Yeo (Co-PI)	Georgia Tech	Stretchable sensors and bioelectronics
Alicia Molina (MS student)	Georgia Tech	Soft actuators and wearable robotics
Carl Demolder (MS student)	Georgia Tech	Stretchable sensors and bioelectronics
Dr. Praveen Samuel (clinician)	Shriners Hospitals	Pediatric orthopedic surgery

Project Management

Georgia Tech internal team meetings: The PIs at Georgia Tech will hold bi-weekly meetings where researchers will report on progress toward milestones, discuss challenges and proposed solutions, and set milestones/goals for the next meeting. These meetings will be held remotely, via BlueJeans or some other conferencing application, until in-person meetings are permitted in campus. After each meeting, meeting minutes will be sent to the GA Tech team by a designated notetaker(s), and a log of meeting minutes will be stored in the group's Box account.

Georgia Tech- Shriners Hospital group meetings: The PIs at Georgia Tech and Shriners Hospitals will hold monthly meetings where technical progress is presented to the clinicians for discussion. These meetings will also be held remotely, via BlueJeans or some other conferencing application. When deemed necessary, an in-person meeting may be held to review device prototypes or plan a clinical trial. After each meeting, meeting minutes will be sent to the entire project team by a designated notetaker(s), and a log of meeting minutes will be stored in the group's Box account.

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