REVEAL: AN AUTOMATED TACTILE ASSESSMENT DEVICE

by

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To my parents, Gene and Mary Gonzales

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by

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THESIS

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REVEAL: AN AUTOMATED TACTILE ASSESSMENT DEVICE

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Stroke is one of the leading causes of disability and often causes chronic somatosensory loss. Reliable measurement of the sensory function is critical for the development of therapies to improve recovery post-stroke. In this study, we developed a tactile stimulation device to allow a simple and rapid assessment of digits and the hand's tactile function. We measured the sensation of motion using the tactile stimulation device in a post-stroke participant with severe sensory loss and neurologically intact participants. We found that the tactile stimulation device could be useful to provide an assessment of tactile functionality in physical units over time in post-stroke patients. These findings indicate that this device represents a reliable system for longitudinal evaluation of the hand and digits post-stroke and may allow for further developments of somatosensory recovery.

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CHAPTER 1

INTRODUCTION

Stroke is a global leading cause of long-term disability(Virani et al. 2020). There are currently 80 million stroke survivors (Gorelick 2019) living with a reduced quality of life as a result of a permanent neurological disability. Methods to improve the diagnosis and treatment for poststroke neurological losses is a present and significant clinical need that needs to be filled.

While both motor and somatosensory function are often impaired after stroke, the majority of assessments and therapeutic interventions only target restoration of motor function. Unlike motor deficits, the degree of somatosensory loss is easily obscured and therefore, challenging to identify and diagnose. Currently, simple but effective, implementations of Semmes-Weinstein monofilaments (SWM) are used to measure light touch and pain perceived by the patient. Even though both SWMs and Von Frey filaments have been widely adopted and often show significant differences between pre/post-treatment and treated/nontreated groups (Darrow et al. 2020; Kilgard et al. 2018; Darrow et al. 2021; Byl et al. 2003; Lee et al. 2003; Bell-Krotoski and Tomancik 1987) there remain numerous nervous system deficits left unnoticed by these methods as they only take a single measure of somatosensation and do not describe the full range of somatosensory function lost. When investigating qualitative aspects of sensory function SWMs have been used to determine the presence of hypo-sensibility or hyper-sensibility. While the SWMs screenings do allow for the clinicians to perform rapid assessments of the possible presence of impaired sensory function there is no information obtained in regards to the severity of the sensory impairment (Olaleye, Perkins, and Bril 2001; Perkins et al. 2001). In addition to the filaments, the Erasmus modified Nottingham Sensory Assessment (NSA) contains both somatosensory (tactile) and stereognosis (ability to identify the shape and form of a three-dimensional object with tactile manipulation of the object in the absence of visual and auditory stimuli)(Schermann and Tadi 2021) assessments for evaluating the impairments in the upper limb of adults with stroke with most resulting in only 3 levels of impairment absent, altered, and normal.

In the present study, we sought to create a device that could combine multiple fields of somatosensory assessments to rapidly and effectively quantify the degree of somatosensory loss of stroke survivors. To do so, we created the ReVeal system. The Reveal system is comprised of a rotating textured cylinder enclosed within a case. An accompanying software application controls the rotation of the cylinder and provides a graphical user interface for data input. During use, participants place their digit in contact with the cylinder and report whether they detected movement of the cylinder across a range of rational speeds and directions. Testing a range of speeds allows for a more diverse set of data points from a single device. Below, we describe the system and report initial findings from testing under simulated conditions and in a participant with sensory loss after stroke.

CHAPTER 2

SYSTEM DESIGN

During the development of the tactile stimulation device (TSD), we focused mainly on the user's thumb on their right hand as the stimulation region (SR) with long-term goals of being used for any region of the hand. This allowed the tactile stimulation region to be kept small for quick iterations of the device. Our system (ReVeal), as well as the majority of its components, were designed using the CAD program SolidWorks (Dassault Systèmes) and created with the F270 3D printer (Stratasys). ReVeal consists of two main devices, the TSD and an Android Tablet (AT) (Samsung Galaxy Tab S4: SM-T830). The TSD was designed to deliver highly salient tactile stimulation (STS) to the user and to detect the amount of pressure (load) the user was applying to the SR during use.

1.1 Hardware

Overall, the TSD has a cylindrical shape which can be held at extended periods without causing discomfort (Fig. 2). The selection of components added was constrained by the size of the cylinder, driven by the size of the average hand, with a circumference of 5.6 cm. The TSD can be placed on a table, mounted via the common ¼” bottom screw mount, or resting in the lap of the user. A stepper motor (SM) (Lin Engineering: WO-4418L-36) was selected with the following size (4.24cm), weight (0.39kg), speed (peak: 1200 Revolutions/Minute (RPMs)), torque (peak: 0.65Nm, holding: 0.7Nm) and accuracy (1.8°/step). A stepper driver/controller (SDC) (Trinamic Motion Control: TMC5130) was selected to utilize StallGuard2^{TM} (SG), a feature that allows for high precision sensor-less motor load detection. SDC also allows for increased SM accuracy as the 1.8°/step can be reduced down to $\frac{1.8^\circ}{256}$ per step. A custom printed circuit board (PCB) was designed to facilitate a safe and robust connection to the SM, SDC, power supply in addition to a microcontroller (μC) (ItsyBitsy M4 Express) which is used to manipulate the hardware and communicate, via serial line, with the AT. The AT provides means to communicate with the user/clinician in tandem with prescription (Rx) ingestion/formulation combined with saving gathered data for ad hoc analyses.

1.2 Software

An Android companion application (CApp) was created to facilitate both goals of diagnostic and therapy functionalities of the ReVeal system. A sweep across all usable speeds or a dynamic speed test can be used for the assessment, (Fig. 4). The CApp's therapy function utilizes passive tactile retraining therapy (PTRT) and ingests Rxs, JSON files, created by the clinician using a custom Python program or by editing an existing Rx file pre-loaded into the AT.

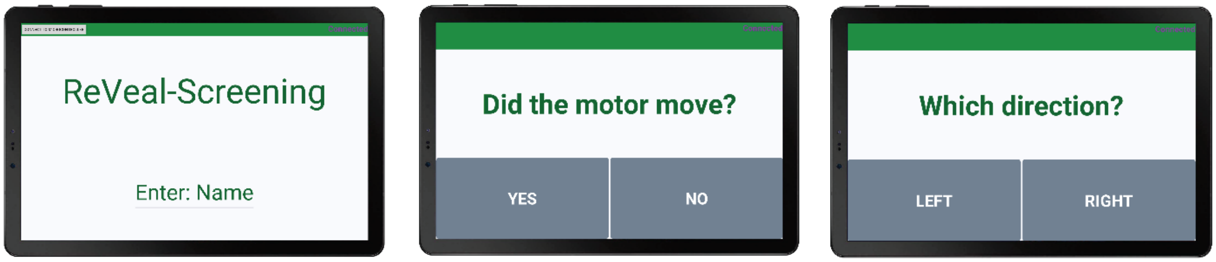

Figure 1: Android tablet pages in order of appearance

1.3 Hardware Integration

To properly transfer rotational motion to perceived translational motion the stimulation barrel (SB), shown in red in (Fig. 2a), is designed with a surface similar to those in the Carey et al.(Carey, Matyas, and Oke 1993) study. Unlike the Carey study, which uses several different surfaces, the

SB has one continuous surface containing 20 fixed ridges with a spatial period of 6.60mm. Movement mechanics of the TSD allows us to vary the perceived frequency of each ridge by varying the rate at which the SB rotates. The SB is connected to the motor by way of two embedded shaft couplers fixed to a rotary shaft (McMaster-Carr) guided by a set of ball bearings, to constrain any axial movement (e.g., the user applying force to the SB), and a shaft coupler seated in a 3D printed adapter housing. To select the SR, guards are used to select the amount of the user's hand exposed to the SB. This adaptable design allows the user/clinician to test multiple regions of the hand with a single device using interchangeable parts.

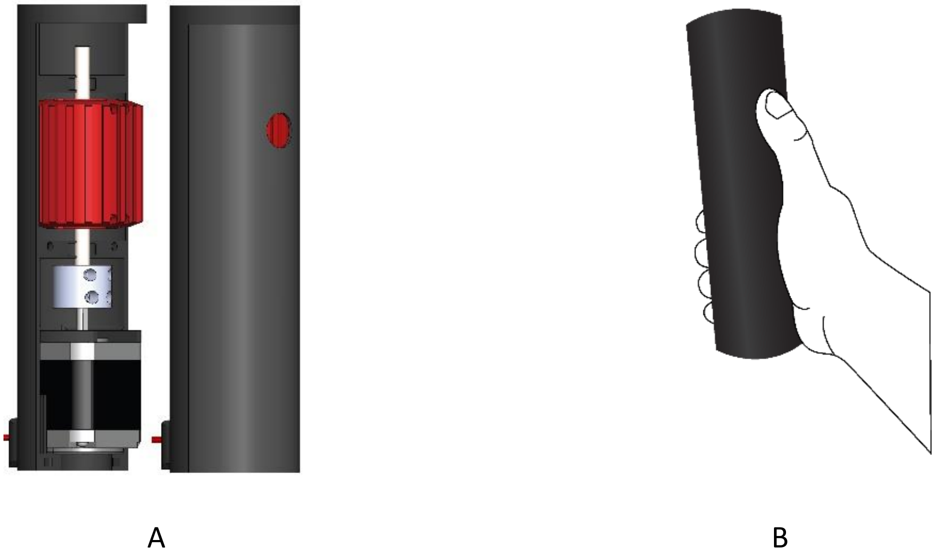

Figure 2: Showing the inside, the profiles of the rotating stimulation applicator, and the ways the region of stimulation can be easily changed (a). Device being used to test the thumb (b).

1.4 Electromechanical Applications

SG captures the load applied on the motor by resolving the SM's back electromagnetic field (BEMF) into SG values with a 10-bit resolution. It is these SG values in which the TSD can detect the amount of load the user is applying to the motor. This form of load detection will be used to ensure the user's finger, or SR is in contact with the SB such that they are receiving the STS the TSD is administering. Fig. 3 shows the SDC’s readout of the SG values and the delivered motor current when dynamic loads are applied. The red horizontal line demonstrates that the SM is attempting to rotate at a constant velocity during the entirety of the demonstration. SG values, represented in blue, are inversely related to the amount of applied load on the SM. A higher reading indicates less mechanical load, while a lower reading indicates a higher load. Therefore, we can see that at the beginning of the test the values start high as there is little to no load on the SM. However, once the two light loads (light touches) are followed by 3 heavy loads (heavy touches) the SG values drop accordingly. These loads are followed by an ever-increasing load until the SM stalls for roughly 1 second resulting in erratic SG values followed by a split second of the motor returning to its being speed as the load is removed. Based on these SG values any SM can be fully characterized to report dynamic loads it experiences. During this test, a rotary encoder (US Digital, E8T-400-250) was attached to the rotary shaft and showed no change in the shaft's rate of rotation during the light and heavy loads. These findings demonstrate that the TSD, using the SG functionality, can reliably detect a minimum of three categories; one, a light load is applied to the motor, two, there is a significant, heavy, load on the motor and lastly, it is possible to detect if the motor stalls and therefore SG can be used as the sole form of finger detection.

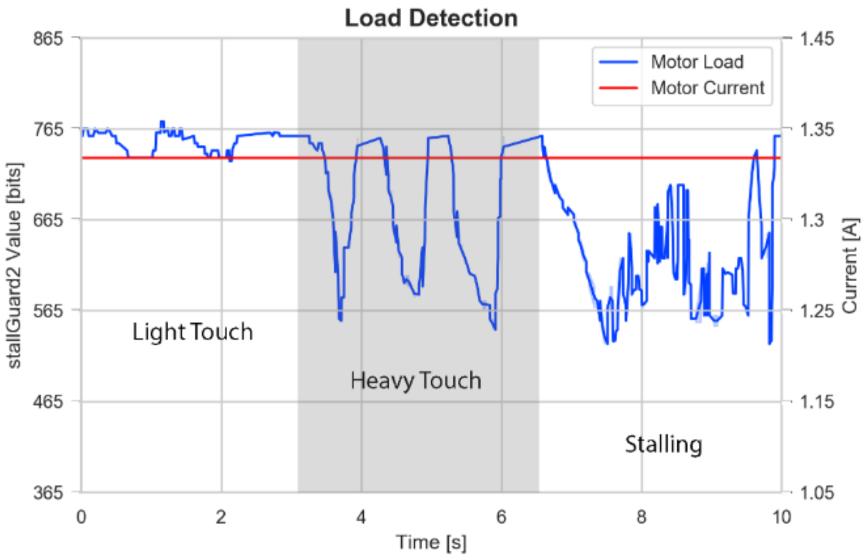

Figure 3:Shows the signals from the motor driver. The stallGuard2 values (blue) and the current being delivered to the motor (red).

CHAPTER 3

METHODS

During development, the TSD was tested on neurologically intact individuals. As the intact subjects have two healthy hands the TSD was tested solely on the right hand with and without the simulated impaired somatosensation conditions (SISC). The SISC was created to emulate somatosensory loss by fitting the individual with a 1.15 mm – 2mm leather glove two sizes larger than necessary (e.g., if one wears a medium glove, they would be fitted with an extra-large glove). For the control trial, the motor was energized in only one direction at randomized RPMs (10-30 RPM) with each speed being delivered/sampled 4 times. The task for this trial is to find the speeds required to ensure the STS delivered by the TSD would be detected. As the responses of the task resulted in binary answers, yes and no, the percentage detected is calculated to show the average total number of times the subjects indicated that the SB was moving at the given speeds.

Using the control trial's outcome, the speeds were adjusted to ensure that the speed ranges delivering the STS would yield interpretable data. The participant who completed this trial suffered from a stroke > 6 months before testing, has one unimpaired hand (right) and one severely impaired hand (left). Therefore, the data shown in Fig. 5 is gathered from both hands respectively. This test trial's STS is randomized in both the direction and speed of rotation. Prompting two questions; 1, if they detected any motor movement; 2, if yes what direction did the motor rotate (Fig. 1). Each direction and speed coupling were sampled five times and the percent correct was calculated, similarly to the percent detected in the control trial, to show the average of the total number of times the subject correctly indicated the direction at the given speed.

CHAPTER 4

RESULTS

We sought to determine the ability of the device to detect the reduction of somatosensory function. To do so, we tested neurologically intact individuals under control and SISC. Participants were asked to detect the movement of the device over a range of rotational speeds. Under the SISC, somatosensory detection was significantly reduced compared to control conditions, (Fig. 4), (linear regression, showing p-values < 0.01 between all groups to be statistically significant; hand impairment: 2.206e-44, Speeds: 4.384e-26, interaction of Speed and hand group: 1.8843-19. Paired t-test between the mean bin values for healthy and impaired % Detection result in: test-stat = 4.828 and p-value = 0.0013). Participants could detect rotational speeds of approximately 18 RPM with an accuracy of 50% under control conditions. Alternatively, under SISC, the same speed of 18 RPM detected an accuracy of only 15%. This confirms that the device can show differences in tactile perception in simulated impairment conditions.

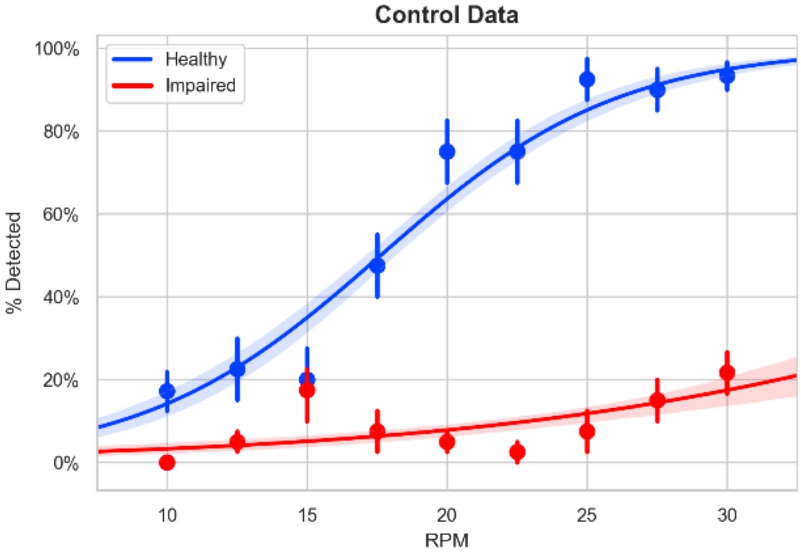

Figure 4: The data we expect to see simulated in a controlled environment. Each point indicates the mean of each bin, error bars indicate variance within the bins of every 2.5 RPMs, river indicate (mean ± SEM), data fit to a sigmoidal function.

Next, we sought to determine if we could resolve somatosensory deficits in individuals with stroke. To do so, we assessed detection using the task described above in an individual with stroke. We observed a deficit in sensory detection in the stroke-affected hand compared to the unaffected hand, (Fig. 5) (linear regression, showing p-values < 0.01 between all groups to be statistically significant; hand impairment: 5.939e-198, Speeds: 2.901e-319, interaction of Speed and hand group: 2.155e-7. Paired t-test between the mean bin values for healthy and impaired % Correct result in: test-stat = 4.603 and p-value = 0.0017). With the stroke-affected hand preforming lower than chance (25%) these preliminary findings indicate that the device can provide a means to assess sensory dysfunction in individuals with stroke.

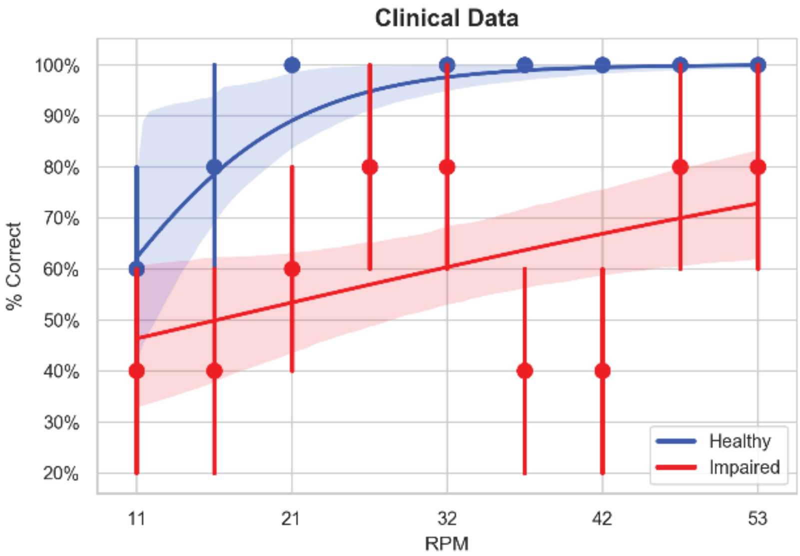

Figure 5: Showing a stroke participant who has one healthy (non-affected hand) and one severely impaired hand. Percent Correct is calculated by dividing the number of correct responses by the total number of tactile stimulations at the given speed. Each point indicates the mean of each bin, error bars indicate variance within the bins of roughly 10 RPMs, river indicate (mean ± SEM), data fit to a sigmoidal function.

CHAPTER 5

DISCUSSION

In this study, we characterized Reveal, a novel tactile stimulation device, to measure hand somatosensory function after stroke. The system consists of the tactile stimulation device paired with the android tablet to quantify tactile perception on any given stimulation region of the hand. The stimulation region allows for the tactile stimulation device to isolate regions of the hand that are being tested thus allowing for a granular approach when fully characterizing the user's loss of somatosensory function. During the control trials, the tactile stimulation device provided clear differences between the healthy and simulated impaired somatosensory condition assessments of detecting any motor movement (Fig. 4). The divergence of the healthy and impaired hand was present in the post-stroke participant's trials where they were asked if movement was detected and if so, what direction was the stimulation (Fig. 5). Showing that the tactile stimulation device's automation of somatosensory assessment is capable of identifying a healthy hand from one that suffers from somatosensory loss. Automation allows for reliable, repeatable, and rapid measurements longitudinally and from patient to patient without the need for extensive training required by established assessment methods (e.g., NSA). Each assessment taken with our system consisted of 3 – 6 minutes, depending on the response time of the user, to capture 90 data points with 5 at each speed.

Individuals who suffer from stroke often see going to the clinic or doctor's office as a difficult task. The system's automation allows for the tactile function to be measured anywhere, such as at home. Leading to the system's functionality of being used as a PTRT device in the home environment. PTRT has been shown to recover the deficits in stroke surviving patients with somatosensory loss by leveraging principles of neuroplasticity (Byl et al. 2003). Allowing the user to take the system home to perform PTRT can drastically increase their amount of therapy and therefore recovery. Even when the system is off-site, it can still be accessed for data acquisition or over-the-air updates to the Rx based on the user's performance. However, increasing therapy time is not the only avenue that can be explored. By incorporating the AT into the system, Vagus Nerve Stimulation (VNS) can be paired with PTRT to further improve somatosensory recovery. VNS has already been shown to increase recovery in post-stroke patients using traditional methods of assessments (SWM & NSA) and treatments (PTRT) in both rodents and humans (Byl et al. 2003; Carey, Matyas, and Oke 1993; Darrow et al. 2020; Sivaji et al. 2019). Utilizing an implantable pulse generator with the accompanying system, ReStore's wireless VNS integrated into our system could increase somatosensory recovery significantly (Sivaji et al. 2019). To ensure that any unnecessary stimulations were being administered, the load detection of the TSD can be used to identify if the user is properly holding the device. Paired with the AT, the user can be given positive reinforcement or prompted that the therapy will be paused until the device detects the TSD is being used properly.

Further testing in individuals who suffer from somatosensory loss is needed to fully characterize the TSD. Additionally, the system would benefit from further sound dampening to reduce the amount of noise. Currently, the system uses a wall mount adapter (Digi-Key: 364-1286-ND) to supply the TSD with 24V @ 1.5A needed to run the SM and a secondary wall adapter (provided by the manufacture) to charge the AT. While not a major concern, it would be beneficial for further development of the PCB's power management subsystem such that the entire system only requiring a single power supply that would be able to power the SM and the AT. It was found that the current SM provided more power that could be used in this application due to safety reasons. Reducing the size of the SM would allow the TSD to shed excess weight as well as require less power.

CHAPTER 6

CONCLUSION

In this study, we developed the ReVeal system, an automated system to evaluate the somatosensory function of the hand. We report that the TSD is capable to assay tactile detection in its users. These results indicate that the system has the potential to be a reliable system for longitudinal assessment of hand somatosensation function after stroke and may provide a framework to assess the efficacy of strategies aimed at improving recovery of hand function.

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BIOGRAPHICAL SKETCH

Phillip Andrew Gonzales was born in San Antonio, Texas, in 1994 to Gene and Mary Gonzales. He graduated with a Bachelor of Science Degree in Biomedical Engineering from The University of Texas at Dallas in 2019. During his first semester in his undergraduate program, he volunteered in Dr. Christa McIntyre’s neurobiology of memory lab where he used his attention to detail and engineering skills to help design various preclinical testing devices and protocols to extinguish fear caused by PTSD. Currently, he is working toward his Master’s in Biomedical Engineering with a focus on medical device development to diagnose and treat neurological deficits brought on by stroke.

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