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GRIP IT GOOD
Methodology to Acquire Functional Grip Force

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1 Executive Summary

Stroke, the leading cause of disability in the United States, affects approximately 795,000 patients each year [1]. Roughly one half of stroke-patients suffer from hemiparesis resulting in functional disabilities like loss of motor skills [1]. Occupational therapists are striving to develop more detailed quantitative methods to assess rehabilitation of patients with functional disabilities due to stroke and other ailments such as disease or physical injuries. In order to identify the most effective means of treatment, a precise, standardized metric that accurately represents patients' functional ability is required.

Currently, the gold standard for assessing patients' ability is their grip strength. Hand dynamometers are commonly used to measure patients' grip strength but studies suggest that functional ability and measured grip strength are poorly correlated. It is hypothesized that the lack of correlation is due to flaws within the current assessment technique [2, 3, 4]. Hand dynamometers are difficult to use and are not representative of the gripping required for common everyday tasks.

Our team aims to create measurement tools that improve assessment of patients' functionality using grip force. Instead of using hand dynamometers, we propose the use of force sensors that mimic the appearance and feel of common objects that patients encounter in their daily lives. By more accurately simulating the perception of interacting with common, everyday objects, we postulate that quantitative measurements of how patients grip these objects and how much force they use to grip them will allow occupational therapists and researchers to determine patients' functional ability and assess the efficacy of treatments. With subsequent research using the proposed devices, we believe that occupational therapists will be able to use relevant data to improve the rehabilitation of patients with functional disabilities.

Our approach to simulate commonly encountered objects is to embed pressure sensing equipment within a series of objects that are normally gripped with commonly used gripping types. This semester, we have focused on creating a device to quantify patients' ability to perform a cylindrical grip. Our device takes the form of a standard 355 milliliter aluminum soda can. Force sensing matrix arrays embedded in the device measure the grip force applied to the object as well as the spatial distribution of gripping force.

Talk about initial testing and results using the Coke Can force sensing device.

Our semester goal was to create a prototype that demonstrates the proof-of-concept. For future work, additional devices can be created to measure the force and spatial distribution of different types of grip. Eventually, we envision a suite of objects that, together, can be used to determine patients' functional abilities in different facets of daily life.

2 Problem and Clinical Needs Description

- For **patients,** the device will help physicians improve the treatment.
- For **researchers,** the device will provide a new, more precise method to perform various tests. It can also help to improve existing methods and create new rehabilitation methods.
- For **occupational therapists,** the device can provide better assessments of patient health, thus allowing occupational therapists to better assign rehabilitation treatments to patients.
- For **funding sources,** the quality of care for patients can be improved.
- For **institutions** and **facilities,** the device will facilitate the expansion of more effective treatments to patients who could benefit from it.

Our device meets the primary need of measuring grip force that is correlated to functional tasks through the use a representative object. Using an object representative of everyday life will fulll the criteria of perception, which will psychologically aid the user in gripping in a manner that is similar to functional tasks. Thus, the force recorded while gripping these objects will be more strongly correlated than that of current solutions. Furthermore, our device is highly portable, rendering it usable in a variety of settings such as research facilities, hospitals, and homes.

As a result of the familiar look of our device, use should be intuitive for patients, thus making the testing simple for therapists and physicians. Our device will also be easily incorporated into current related practices. Instead of gripping a dynamometer, the patient will grip the representative object as deemed appropriate by the supervisor. In research applications, subjects can grip and move the objects to quantify grip strength alongside other relevant measurable grip parameters. An occupational therapist would be able to integrate the device into other tests, such as the Fugl Meyer motor recovery test, a widely used assessment of motor recovery after a stroke, in which the stroke patient attempts to hold or pull various objects away from the occupational therapist.

We believe that our device will allow researchers to better assess the differences between disease states and healthy states and also allow therapists to identify the most effective treatments for the diseases that impair musculoskeletal movement.

3 Description of Design

3.1 Design Overview

To obtain patients' cylindrical grip force and distribution, our design utilizes force sensing equipment contained inside a standard 355 milliliter soda can. A chassis constructed from high-density polyethylene houses the required electronic components, provides structural support against users' gripping forces, and acts as a hard surface on which sensors can be mounted. The soda can shell covers the internal force sensing components, accurately simulating the appearance and feel of a familiar object.

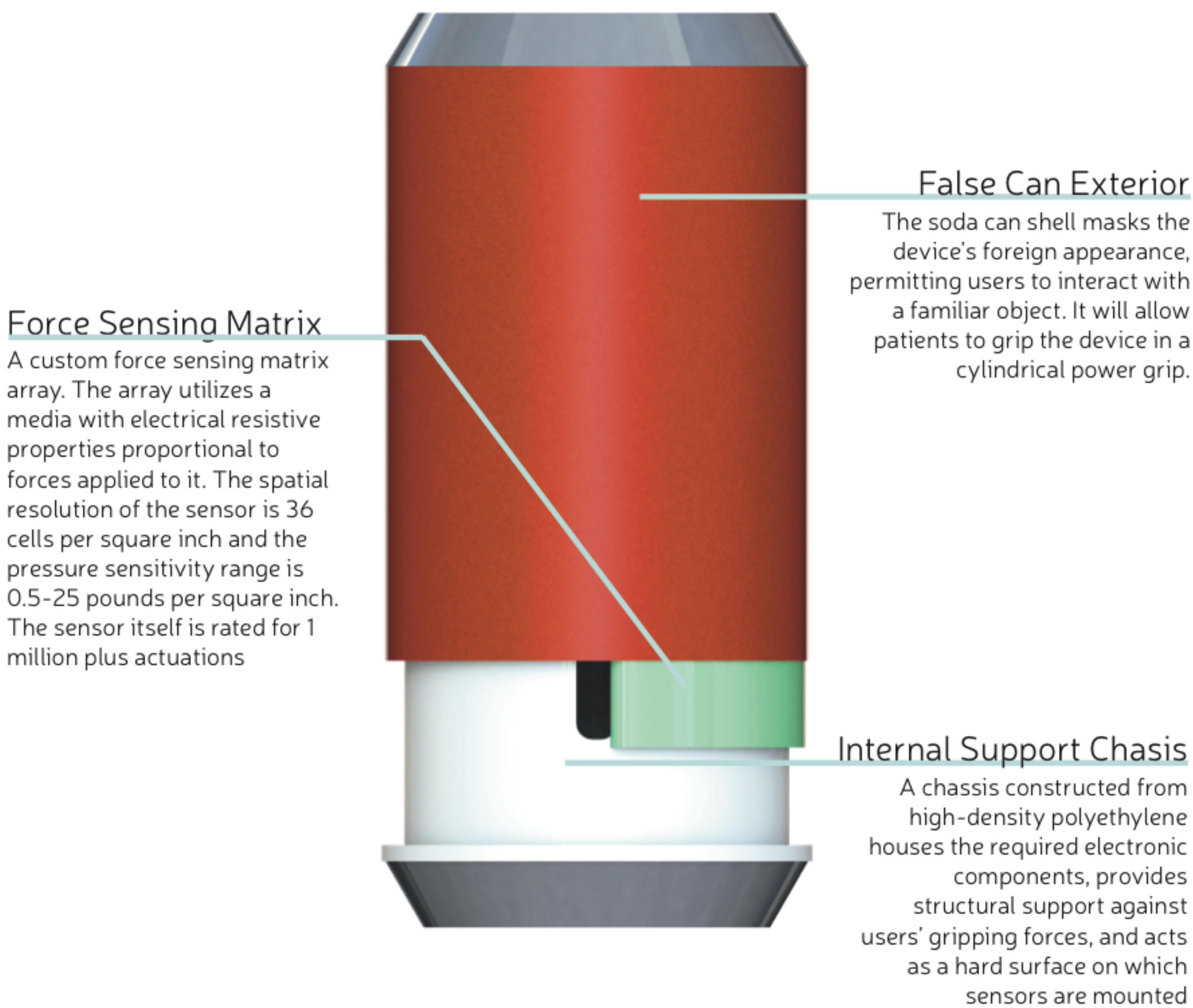

Figure 1: Device Components

3.2 Sensor Details

In order to capture both gripping force and the distribution of the force, the design utilizes a custom force sensing matrix array, the ThruMode matrix array, developed with Sensitronics LLC. The array is composed of cells which consist of dielectric media sandwiched between two electrical conducting surfaces. The electrical resistance of each cell is inversely proportional to the amount of force applied to it. The spatial resolution of the sensor is 36 cells per square inch and the pressure sensitivity range is 0.5-25 pounds per square inch. The sensor itself is rated for 1 million plus actuations.

3.3 Device Use and Data Acquisition

The device is opened and closed by sliding the chassis and its associated components axially into the soda can shell. In the open configuration, users are able to replace batteries and electrical components as necessary. Grip force data is collected by an Arduino chip that is programmed to read through the rows and columns of the sensing array by gathering the voltage of each cell. This data is transmitted via a Bluetooth module to a Matlab graphical user interface running on an external computing device. The data can be saved and analyzed by users to quantify patients' gripping characteristics.

4 Prototype of Final Design

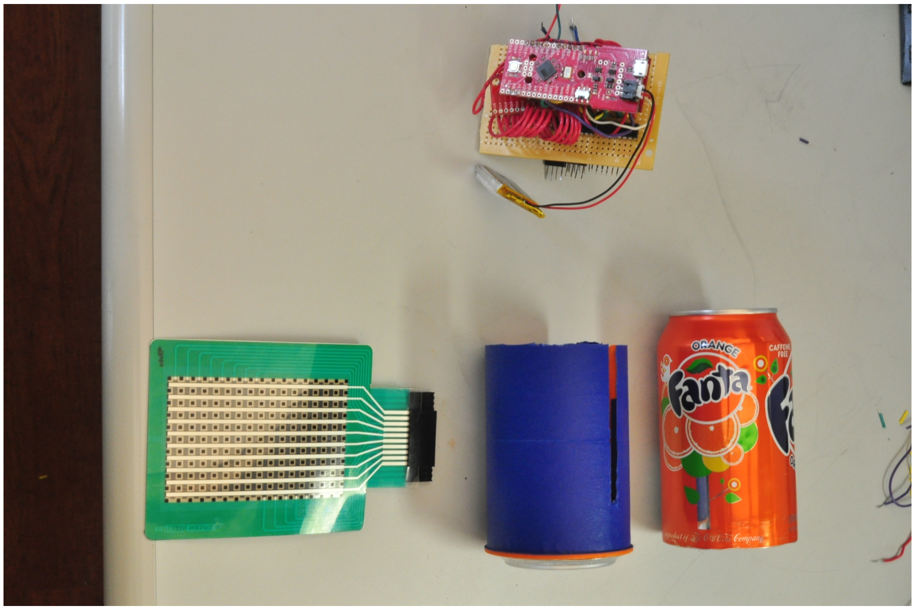

Figure 2: *top: electronics, left: sensor, middle: chassis, right: can shell*

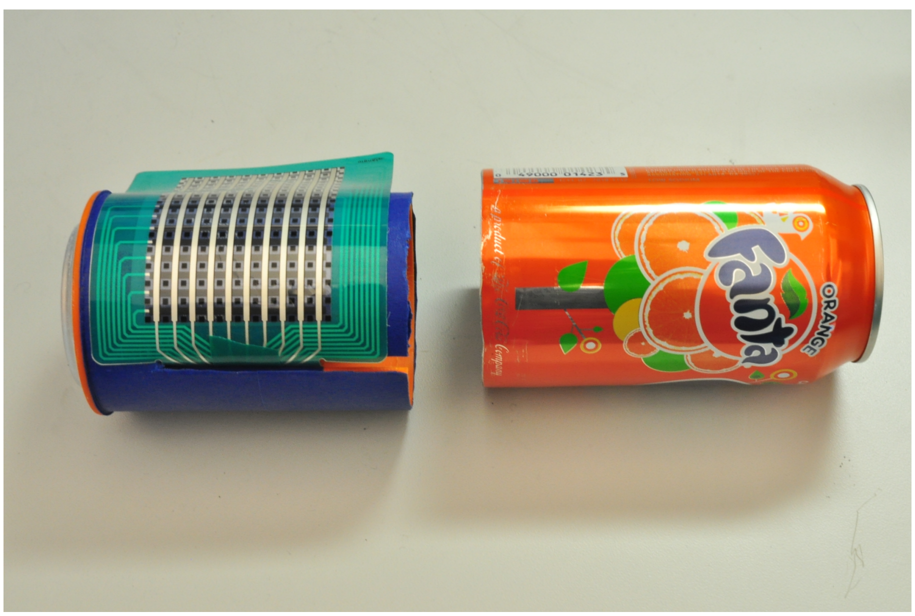

Figure 3: *left: sensor attached to chassis, right: can shell*

4.1 Features

The proof-of-concept prototype consists of an acrylonitrile butadiene styrene chassis for housing electronic components, providing structural rigidity, and for mounting force sensors. To reduce prototyping costs, grip force is measured with a sample sensor of Sensitronics' ThruMode matrix cell array. The sensor has a resolution of 16 cells per square inch, a pressure sensitivity range of 0.5-25 pounds per square inch, and a lifecycle of 1 million plus actuations.

4.2 Fabrication Methods

The prototype chassis was fabricated using a Dimension 3D printer. The chassis was post-machined on a lathe to achieve tolerances for correct sensor fitment inside a soda can. The soda can shell was created by puncturing the can on the bottom side to drain the liquid contents, as to not affect the visible appearance of the can to users. The bottom part of the can was then separated from the top portion by grinding down the bottom edge until the bottom cap could be separated manually.

5 Novelty

Our approach is novel when considering methods that are currently conventional as well as those that are in development. Hand and pinch dynamometers are the most widely used grip strength measuring devices today. These devices isometrically measure force applied by the user. Once peak force is achieved, evaluators can read the measurements from the device. Grip strength as measured by such devices and the user's functional ability, however, have poor correlations. This is likely due to perception and sensation being overlooked in such an approach.

User perception and sensation are important aspects of Grip It Good because occupational therapists have stated that the unrealistic nature of conventional grip measurement devices contributes to the poor correlation to functional tasks. Resemblance to an everyday object such as a soda can is novel and will make Grip it Good superior to current devices.

Our conceptualized method also considers multiple types of grip. Each device will measure grip strength that corresponds to a particular grip type. A few patents do address multi-functional grip assessment, such as US Patent 8,601,869 [5]. However, in a similar fashion to the current conventional methods, perception was not taken into consideration in these patented approaches. Furthermore, our device will consider the actual distribution of force. By using an array of force sensors, therapists will not only accurately determine the amount of force, but also the locations on which force is applied. This will give grip assessment greater depth as compared to devices like the hand or pinch dynamometer which only register a maximum force reading.

Our approach is novel for prioritizing the look and feel of the devices to mimic items found in everyday life. This will properly correlate measurements to actual functional tasks in a novel manner. Additionally, the device is capable of mapping applied force by location. By incorporating the aspects of perception, sensation, and location-mapping, proper relevance to therapy through our device's measurements can be achieved in a way that has not been utilized before.

6 Regulatory Pathway

The intended use of our device is equivalent to other grip assessment devices such as dynamometers. Both our device and dynamometers measure the force with which users grip them. There exists two types of dynamometers classified by the FDA: alternating current (AC) powered and non-powered dynamometers. The AC-powered ones are Class II, while the non-powered dynamometers are Class I [6]. Our device more closely resembles the non-powered dynamometers (Grip It Good is not AC powered, but battery powered and charged with a USB). Thus, it is proposed to be classified as Class I. Furthermore, because non-powered dynamometers are exempt from premarket notification (510(k)), it is expected that Grip It Good will not require the notification either. Our product should additionally be classified as Class I due to the low weight, lack of invasiveness, and nonexistent exposure to electronic components. A majority of Class I devices are exempt from premarket notification.

If Grip It Good is classified as a Class I device without exemption or as a Class II device, a 510(k) will then be needed, with substantial equivalence being shown. This is demonstrated when the new device has an intended use and technological characteristics identical to that of an existing, legally marketed device. Grip it Good possesses equivalent intended uses as digital hand and pinch dynamometers which already have existing 510(k) approval. These devices also have predicate devices listed, thereby showing the numerous substantially equivalent products available.

Clinical testing may be required along with a 510(k) [7]. An investigational device exemption (IDE) will allow the device to be better supported in the 510(k). An application will be sent to the FDA for their approval, as well as an investigational plan to the Institutional Review Board (IRB) for review of the location in which clinical testing will occur.

After receiving approval for IDE, clinical studies will be conducted with consenting patients and the appropriate investigational monitoring and recordkeeping measures as required by the FDA.

These include proper labeling of the device and reports to the FDA and IRB.

7 Estimated Costs of Grip it Good

The total estimated cost of our product is $66.42. A hydraulic hand dynamometer, commonly used in muscle force studies, costs $363.55 [8, 9].

Table 1: Estimated Product Cost

Component	**Supplier**	**Cost**
Arduino	Sparkfun	$14.95
Bluetooth	Digikey	$18.32
Sensor	Sensitronics	$30.00
Electronics	Digikey	$2.24
Chassis	Protolabs	$0.87
Shell	Ball	$0.04
Total		**$66.42**

The costs of this product are based on a production run of 10,000 units. The cost of aluminum cans was obtained from Ball [10]. The cost of the chassis was estimated using the CUSTOM-PART.NET injection molding cost estimating tool [11] and verified with ProtoLabs [12]. The cost of the sensor was obtained from Sensitronics LLC [13].

8 Market Description

The Center for Disease Control estimates that 50 million Americans suffer from arthritis, a number that is expected to increase to 67 million by 2030 [14]. The National Stroke Association indicates that there are approximately 7 million stroke survivors in America, 40% of which experience moderate to severe impairments requiring special care [1]. The National Spinal Cord Injury Database indicates that there are approximately 273,000 patients with spinal cord injuries [15]. The American Diabetes Association estimates there 25.8 million Americans with diabetes, 60% to 70% of which have mild to severe forms of nervous system damage [16]. The prevalence of these diseases and their effects on patients quality of life provides motivation for further research to aid recovery. The loss of grip strength can be attributed to many causes, the estimated costs of which are listed:

- In 2003, arthritis and other rheumatic conditions (AORC) cost the US $127.8 billion [14].
- In 2009, stroke accounted for $38.6 billion [17].
- In 2004, diabetic neuropathy costs totaled $16.8 billion in America [16].
- Spinal cord injury costs amounted to $14.47 million [15].

The loss of grip strength itself means that affected individuals are have reduced ability to care for themselves and further costs are incurred. When a patient has reduced functional grip, caretakers may be required or patients family and friends may have to take time away from work to care for them. John Hancocks 2013 Cost of Care Survey indicates that the average cost for a assisted living facility is $41,124 annually [18].

The competitive landscape of the device includes the currently used dynamometer as well as other pressure sensing devices developed by companies such as Tekscan or Sensitronics.

In order to plan a successful reimbursement strategy, three necessary elements must be considered: coverage, coding, and payment. Ideally, the device will have universal coverage from all insurers and for all patients, unambiguous coding, and sufficient payment to the institution and physician. To receive coverage, FDA clearance must be obtained, and the product must be deemed medically necessary, appropriate for the patient in the treatment setting, and not experimental or investigational; in other words, the device must have adequate evidence supporting its efficacy in improving a patient's health. For this purpose, unbiased clinical trials of the device would be run. For coding, if possible, an existing CPT code that adequately describes the device should be used, such as the code for a dynamometer. However, if the code is not applicable or no such code exists, a new Current Procedural Terminology (CPT) code must be obtained from the American Medical Association (AMA). Finally, payment provided to the healthcare professionals who use the device, such as physicians or occupational therapists, must be determined. For all three elements, the policies of the Centers for Medicare & Medicaid Services (CMS) and various private payers (Blue Cross/Blue Shield, United Healthcare, etc) must be taken into consideration [19].

9 Letter of Support

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May 7, 2014

BMEStart Competition,
Carnegie Mellon University,
Biomedical Engineering Design Team,

Dear Committee Members,

I am writing this letter in support of the design team who have developed the Grip it Good. During the past few months I have had the pleasure of advising the design team as they developed a novel prototype to measure grip strength during daily tasks. I am an Occupational Therapist, and recognize the importance to measure grip strength in older adults and individuals with disabilities.

The team consists of Luke Auyeung, Tomas Dardet, Cheryl Deng, Nathan Hahn, Ethan Ungchusri, and Ting Xu. Throughout the last two semesters the team has diligently worked to develop an initial prototype of the product. The team not only created an attractive design but also implemented wireless application of the product.

They worked as a team to conduct a thorough research of the alternative products on the market and also contacted several vendors to inquire about the appropriate sensors to be used in the product. I strongly feel that this product has potential to be a viable product. I would like to see further development of this product.

Please do not hesitate to contact me if you have any further questions.

Sincerely,

Amit Sethi, PhD, OTR/L.

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