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42-401: Foundations of Biomedical Engineering Design
Department of Biomedical Engineering
Carnegie Mellon University

# NOVEL METHODOLOGY TO ACQUIRE GRIP FORCE DURING FUNCTIONAL TASKS

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# Contents

# 1 Background

## 1.1 Clinical Problem

### 1.1.1 Observation and Problem Identification

| Process | Description |
| --- | --- |
| Set up Observations | Either perform phone interviews with researchers, or meet them in person. Obtain permission to watch/observe a patient - therapist sessions. Identify issues patients are having with current techniques, including their grip. Ask the clinicians to compare the results they received from the existing tests to real-life examples. Ask patients about problems they are having in real life with objects. |
| Prepare for observations | Research current methods that assess grip force in rehabilitation treatments. |
| Conduct observations | Talk to occupational therapists, clinicians, and researchers involved with motor control therapy and research. These could be individuals at the University of Pittsburgh Rehabilitation Center, as well as the Carnegie Mellon Quality of Life Technology Center. Plan to observe patients utilizing existing techniques, as well as interviewing patients about use-cases where they have issues utilizing objects. |
| Document observations | The grip force data in current methods for assessment are poorly correlated with the actual grip force required in functional tasks. Observations will be recorded via Google Docs, recordings, and if allowed, pictures and videos. |
| Name the problem | Existing tools to measure grip force are inadequate for assessing the grip force necessary for functional tasks. |
| Test and refine problem statement | Determine how existing measures are inadequate. Figure what the trade-offs are between possible solutions, and establish stakeholder priorities. How expensive is the product? Will it be able to be easily distributed/used by clinicians in a simplified setting? How can this integrate with other measurements of motion/pressure. How easy is this for individuals to use at home? |

### 1.1.2 Need Statement Development

| Process | Description |
| --- | --- |
| Translate problem into need statement | Need statement= A method to measure grip force in such a way that it will be strongly correlated with that of functional tasks. |
| Verify accuracy of need statement against problem | Will this be useful to patients and clinicians? Does the statement infer anything about obtaining grip force? Do we have observations from patients, researchers, and clinicians that support this claim? |
| Confirm that need is solution independent | Are we implying any particular solution in our needs statement? Do we specify an approach or technologies in the statement? Can we back our statement with direct observations? Are there any other constraints we placed on ourselves in the need statement? |
| Validate that scope of the need is appropriate | Are there any differences between force measurements for neurological diseases versus other diseases? Can this be applied to a variety of force limitations, or will it be relevant to grip only? Is it relevant for a very general population or for a more specific group? Why are functional tasks relevant? |
| Define need criteria and classify need | Is there a target market/location for this solution? Is it reasonable for all practices to have one, or is it only applicable for certain facilities? Are there certain disease prerequisites that need to be met in order for this measurement to be applicable? Are there any patient prerequisites? Who is the target user and what is the user's expectations? |

## 1.2 Scope of Problem

Our project assignment seeks to develop techniques for assessing grip force in patients with musculoskeletal or neurological impairments. Thus, our assessment of fundamentals of pathology and treatment options focuses on the loss of function in patients with impairments. We focus on current technologies for assessing efficacy of treatments irrespective of the disease state rather than treatment of the diseases that engender functional loss.

### 1.2.1 Disease State Fundamentals

**Anatomy and Physiology** In normal anatomy and physiology of the human nervous system, the brain signals other systems within the body to perform their necessary, respective functions. Through electrochemical control, the nervous system produces articulation of joints and physical movement of the musculoskeletal system. For example, in order to lift an object, the brain signals appropriate muscle groups, causing them to contract and pull on the bones in the desired direction, which results in desired movement of the object. With a myriad of muscles, tendons, and forms of neural control, there are many forms of disfunction that may lead to loss of musculoskeletal mobility and coordination.

**Pathophysiology** Loss of grip strength can be attributed to many causes. Some examples include old age, arthritis, carpal tunnel syndrome, nerve injury, tendon injury, neuromuscular disorders, and stroke, which is the leading cause of disability in the United States. For this reason, we have selected assessment of stroke victims as our primary goal. During stroke, reduced blood flow to the brain can cause temporary ischemia, a state where nutrient supply is insufficient for supporting normal metabolic activity. As a result, tissue death may occur, leading to loss of brain function and temporary or permanent impairment of stroke survivors. According to one study, hemiparesis, or weakness on one side of the body, affects 50% of stroke survivors; as a result of the loss of strength, patients may face complications in normal function and daily life. In the same study, 30% of stroke survivors were unable to walk without assistance and 26% were no longer able to independently perform daily activities.

**Clinical Presentation** During a typical clinical examination, the grip strength of an individual's affected hand is significantly weaker than that of able-bodied individuals. Lab tests conducted with force measuring instruments, such as a dynamometer, a device that measures grip strength through measurements of grip force and pinch force, may be performed to help quantify these differences in grip strength over the course of patients' treatments. Other methods of measuring grip force and muscle activity include sensor gloves, force scanners, electromyography, 3-dimensional imaging technology, and others. Ideally, one should be able to quantify efficacy of rehabilitative treatments through measurement of grip, pinch, and muscle activity. Additionally, grip testing of healthy and diseased patients should be able to help researchers better understand salient factors that define the disease state.

**Clinical Outcome** Patients with significant reduction in grip strength commonly struggle with performing everyday tasks which might result in decreased quality of life. Strong correlations exist between individuals' grip strength and ability to live independently. More specifically, frailty and loss of muscle mass and strength, or sarcopaenia, has been associated with reduced health-related quality of life. Grip strength may also predict functional limitations during old age, frailty, and mortality, as a high level of grip strength earlier in life may provide a larger margin of safety against injury and disability later on in life. With respect to stroke, both the morbidity and mortality of the disease are high. Stroke has not only been identified as the leading cause of serious long-term disability in the United States, but also as the fourth leading cause of death in the country.

**Epidemiology** Though the exact incidence and prevalence of individuals who suffer from impaired grip strength is unknown, similar numbers may be taken from data on patients with arthritis, stroke, diabetic neuropathy, and spinal cord injury in order to visualize the number of people who are affected. 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. 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. The National Spinal Cord Injury Database indicates that there are approximately 273,000 patients with spinal cord injuries. 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. The prevalence of these diseases and their effects on patients' quality of life provides motivation for further research to aid recovery.

**Economic Impact** 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 United States $127.8 billion.
- In 2009, stroke accounted for $38.6 billion.
- In 2004, diabetic neuropathy costs totaled $16.8 billion in America.
- Spinal cord injury costs amounted to $14.47 million.

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, care takers may be required or patients' family and friends may have to take time away from work to care for them. John Hancock's 2013 Cost of Care Survey indicates that the average cost for a assisted living facility is $41,124 annually.

## 1.3 Current Treatment Methods

### 1.3.1 Fundamentals of Functional Assessment

#### Types of Techniques to Assess Patient Rehabilitation

- Testing by Geometry - It may be of interest to measure the range of joint angles that patients are capable of achieving over their course of treatment. Increased range of motion may be a significant indicator of treatment efficacy.
- Testing by Force - We have previously described loss of grip force as a potential consequence of morbidities that patients may encounter. Whether this reduction in strength is due to neurological impairment, nerve injury, muscle injury, tendon injury, carpal tunnel syndrome, or arthritis, we hypothesize that ability to measure grip force will be an essential for assessing efficacy of patient rehabilitation.

- Testing by Competency - Since the ultimate goal of treatment is to help patients increase functional independence, another possible method of interest would be to create a set of functional tests requiring a representative dexterity and force needed to perform usual daily activities. Measuring patients' ability to perform functional tasks may be a more sensitive indicator than generic tests which only measure grip strength and not manner in which the force is utilized.

**Current Methods and Technologies**

- Hand and Pinch Dynamometers - These are devices that isometrically measure the hand grip or pinch force of the user. Users are instructed to grip or pinch the device. After peak force has been achieved, an evaluator can read the force measurement from the device. This product is durable, easy to use, and has no associated operating costs. A generic grip dynamometer costs approximately $200 on Amazon Marketplace. Averaging the cost over many uses, the dynamometer is a relatively cheap device. It however does not measure grip force very naturally. Studies have shown that correlations between grip strength, as measured by hand dynamometers, and individuals functional ability are weak to moderate.

Figure 1: Hand Dynamometer

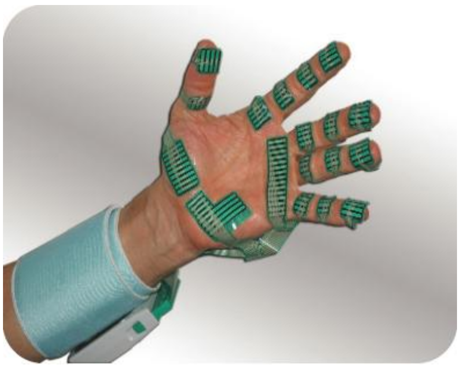
www.hymanhealth.com/website/images/re-55701500%20Dynamometer%202.jpg

Figure 2: Pinch Dynamometer


www.ssl.cdn.ncmedical.com/items/fullsize/2009_05_12_11_45_36__6_NC70143_05A_LG.jpg

- Pressure Sensors - Tekscan is a company that utilizes pressure sensors arrays of various types and geometry to ergonomic testing. We envision that their technology could also be applied to occupational therapy for grip testing. We hypothesize that it will be able to generate abundant amounts of useful data. For an occupational therapy application however, having to attach multiple sensors to patients would be a time-consuming, impractical method to test their grip.

Figure 3: Pressure Sensors Applied to a Hand



www.measol.com/Accessories/TekScan/TekScan_Grip.JPG

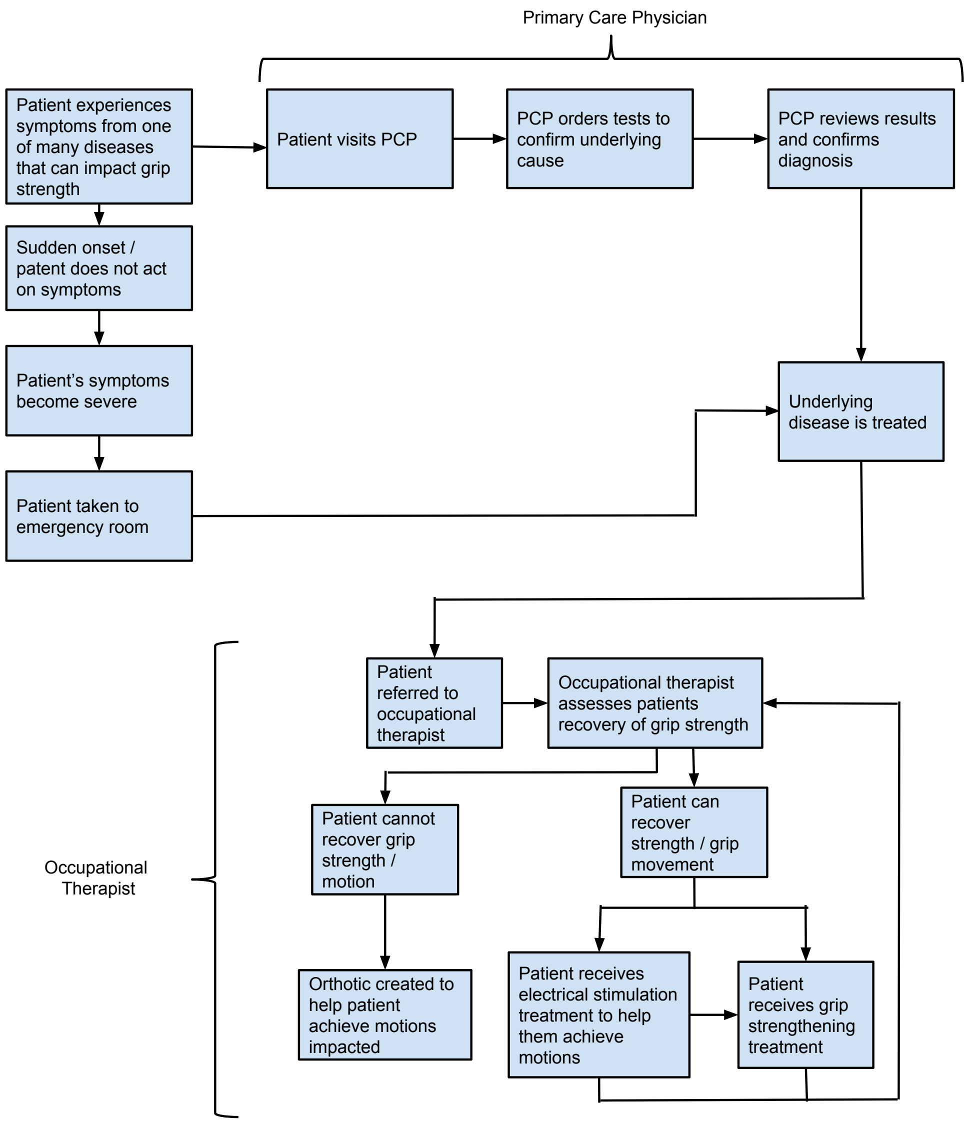
**Summary of Product Opportunity Gap** Through observation of current technologies that are used to assess or could be used to assess improvement of patients with impairments that reduce functionality and quality of life, we have discovered a lack techniques and devices that effectively integrate all of the assessment fundamentals we identified in section 2.2.1.

There exists an opportunity to create a device or method that captures functional measures of dexterity and force. We hypothesize that functional measure will be more representative of what is required to perform typical daily activities. We further hypothesize that such a device or technique will allow researchers to better assess the differences between disease states and healthy states and also allowing therapists to identify the most effective treatments for the diseases that impair musculoskeletal movement.

# 2 Cycle of Care and Stakeholder Analysis

## 2.1 Cycle of Care

The cycle of care was developed taking into account both the originating disease that could cause a loss of grip force as well as rehabilitation for such a disease. The initial portion listed under the Primary Care Physician (PCP) was generalized to apply to both chronic diseases with slow development, e.g. arthritis, or sudden onset conditions, e.g. a stroke. After the treatment of the underlying condition, occupation therapy is started to assist with the patient's recovery of their daily living and work skills. In this occupational therapy, the patient is constantly assessed and treated according to their current recovery level. Eventually, the patient either reaches a point that is deemed to be sufficient for resuming normal activity without therapy, or the patient is unable to recover a particular skill and they supplement their living conditions to account for their inability to perform that skill. Grip strength follows this general pattern, with our primary area of concern focused around the assessment portion for grip strength.



### 2.2 Stakeholder Analysis

Stakeholders were identified through the cycle of care. Additional stakeholders were also identified by taking money flow into consideration. The effects of our innovation were categorized into benefits and costs for each of the stakeholder groups. An assessment of net impact was then made for each group and designated as positive, neutral, or negative. In the figure above, it can be seen that the majority of net impact assessments suggest benefits for their respective stakeholder groups. Two groups, funding sources and manufacturers, face costs that will result from our innovation. However, given the large amount of power and control held by the other groups (patients, researchers, therapists, facilities), we believe support can be garnered from all stakeholder groups. The primary costs of funding sources and manufacturers also appear to be relatively short term in comparison to the primary benefits.

| | Primary Benefits | Primary Costs | Assessment of Net Impact |
|---|---|---|---|
| Patients | The device will help physicians improve the treatment | May increase cost of treatment. Could require a more in-depth assessment | Positive: Improved efficacy of the treatment |
| Researchers | New, more precise methods to perform various tests. Can help to improve existing and create new rehabilitation methods | Need to determine the applicability / translation to rehabilitation methods. May have to adapt existing measures to accommodate different results | Positive: Will allow researchers to develop better rehabilitation methods that correspond to functional recovery |
| Occupational Therapists | Better assessments of patient health. Can better assign rehabilitation treatments to patients | Need to learn how to use new implements. Will have to include it in their current practice | Positive: Improved efficacy of the treatment |
| Funding Sources | Improves quality of care for patients | Need to pay for new assessment devices | Negative: Assessments will be more expensive. New devices will have to be purchased in order to perform these assessments |
| Institutions & Facilities | Expansion of more effective treatments to patients who could benefit from it | Increased costs for new devices. Need to train therapists on how to use devices | Positive: More accurate results will allow for better treatments that can improve the reputation of the hospital. |

# 3 Needs Filtering

## 3.1 Needs Statement

We have identified the need for a method, device, or system to measure grip force that accurately represents patients' capabilities to perform functional tasks.

## 3.2 The Problem

Current methods of measuring impaired grip strength and coordination do not correlate with the ability to perform functional tasks. For example, the grip force measured with a hand-held dynamometer is not representative of one's ability to perform functional daily tasks. Other existing methods to measure grip force including pressure sensors, goniometers, sensor gloves, electromyography,and 3-dimensional imaging technology also lack correlation with functionality.

## 3.3 Needs Criteria

1. **Location**: Device is usable at homes and in clinics/hospitals.
2. **Efficacy**: Device measurements of grip force correlate to patient's ability to perform functional tasks. Measurements from our product should correlate strongly (at least 95%) with patients' functionality, as indicated by their ability to perform grip related tasks required in everyday life (e.g. turning door handles, opening jars, holding a bag of groceries, etc.).
3. **Value**: Device life span must be competitive to similar medical devices. An ideal goal is to make the product as robust as a dynamometer. Implementation of the device should be as minimally complicated as possible. Addition of diagnostic capabilities should be modular.
4. **Comparative pricing**: The cost should be comparable to that of similar technologies, this includes both the cost of the device itself and all other relevant costs for treatment. Ideally, it should be approximately equal or less than the price of a hand dynamometer ($200).
5. **Ease of use (for the patient)**: Under supervision of the physician/therapist, solution should allow patients of all backgrounds and ages to complete the diagnostic exercise. The product should be as easy to use as gripping objects encountered in everyday life.
6. **Perception to patients**: Solution should enable patients to perceive the gripping task as they would perceive the functional gripping task in real life.
7. **Safety/complications**: Diagnostic methodology should be safe and non-invasive at all points for the patient.
8. **Procedure Time**: If procedure time for solution exceeds that of current devices, the additional time should be as insignificant as possible.
9. **Sensation**: Tactile effects should interfere as little as possible with user grip force or familiarity with the gripped object.
10. **Integration into current practices**: Solution should be usable while presenting minimal disruption to current procedure/protocol used by researchers and clinicians.

# 4 Proposed Solution to Address Needs

## 4.1 CAD Illustration

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## 4.2 Description of Prototype Operation

**Form Factor and Appearance** The Suitcase consists of several objects, representative of objects encountered in daily life, each designed to test a specific type of grip, including cylindrical, spherical, hook, pinch, and lumbrical grips. Each object is to be made from a uniform material, such as metal or plastic, with embedded force sensors exposed on its surface. The sensors will cover the intended surface area which patients will grip. In this manner, an evaluator using this tool may obtain the gripping force of the patient as well as the distribution of force.

**Intended Use for Patients** The shapes of the object will be reflect the five different types of grip that evaluators may want to evaluate. We intend to create shapes that mimic the shape and feel of everyday objects. For example, the grip force measurement object for a cylindrical grip may have a similar shape, form factor, and color of a soda can, with force sensors around its outer surface. During testing, the patient will be asked to perform certain motions utilizing one of the objects, to test for his/her ability to perform similar tasks involving the same kind of grip force. In a test, the soda can-shaped object would be placed on a table while the patient, sitting in a chair in front of the object, would be asked to grasp it, retrieve it, and deliver it to himself as if he were to drink soda from a can.

**Data Acquisition** While the test object is being handled by the patient, the embedded sensors will continuously register the force that is being applied. This data will be sent to a computer either via a cable or wirelessly, and then recorded and analyzed. During analysis, the data collected from all sensors on the surface of the test object can be used to create a two dimensional heat map of forces being applied to the surface of the object, both at specific times during the task or integrated over the entire time period. This data can then be compared to one that is pre-recorded by a healthy individual and be used to determine the efficacy of the patients rehabilitation.

## 4.3 Fulfillment of Needs Criteria

**Primary Objective** The Suitcase meets the primary need of measuring grip force that is correlated to functional tasks through the use of five representative objects. Using objects representative of everyday life will fulfill the criteria of perception, which will psychologically aid the user in gripping in a manner that is similar to functional tasks. While gripping these objects, measuring the force during movements reminiscent of functional tasks will be more strongly correlated than those of current solutions. The portability of the Suitcase will render it usable in various settings such as research facilities, hospitals, and homes.

**Secondary Objectives** Given the common look of the Suitcases objects, use should be intuitive for patients, thus making the testing simple for therapists and physicians.The Suitcase will also be easily incorporated into current related practices. Instead of gripping a dynamometer, the patient will grip any number of representative objects 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 objects into other tests, such as the Fugyl Meyer motor recovery test.

# 5 Outline of Tasks and Spring Semester Schedule

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