Smart Grip Enhancement Device (SGED)

Product Design Specification

BME 200/300

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Function

The client, a hemiplegic stroke survivor, has requested the fabrication of a grip-strength mechanism that improves the grip function of their paralyzed hand. Grip strength is defined as the power generated by the hand and forearm muscles, impacting one's ability to hold, pull, or lift objects [1]. The device will stimulate the hand to promote grip strength by forcing the hand into grip position and by providing real-time biofeedback of the measured grip strength. It must be adjustable allowing for gripping of various sized objects and must allow extension of the hand to release the object. The mechanism must be easily sanitized and should be used with minimal assistance. Following usage of the device, a hand dynamometer will measure the clients improved grip strength [2].

Client requirements

- The device must be easily attached and detached on the user's hand without the need of additional support or involving lots of fastening procedures.
- The product must be applicable for both physical training sessions and common daily-life applications outside of sessions.
- The device must adequately stimulate initial support for the hand to open or close to desired angles for accomplishing specific tasks such as holding onto training instruments.
- Specific device intended for one client participating in the UW Adapted Fitness program, but later on could be applicable for usage to others with similar needs.
- Continuous in-person interactions with the specific client during their training session to further analyze and discuss the mechanism and development of the prototype.
- Must be easily sanitized for daily usage, even for domestic, personal purposes.

Design requirements

1. **Physical and Operational Characteristics**
    a. **Performance requirements:**
        i. The main performance requirement of this device is to improve user's grip strength by providing assistance on physical movements of hand's flexion and extension. This device is meant to effectively recover the grip power of the patient after they have experienced a stroke.
        ii. The device should consist of elastic materials for easy self attachment capability along with consistent physical support and real-time biofeedback of measured grip strength that is easily transmittable for further analysis.
        iii. The target goal for improving user's grip strength is to reach above 26 kg which is the standard for weak grip strength [2]
    b. **Safety:**
        i. The smart grip mechanism must allow for rapid hand extension if the gripped object needs to be dropped in an emergency.
        ii. The device must be fabricated from a biomaterial that does not irritate the skin when exposed to sweat.
        iii. All electronic components of the device must be properly stored and labeled, following ISO Standard 10218 [3].
    c. **Accuracy and Reliability:**

i. The device must allow the client to grip varying sized objects consistently. The grip strength of the device will be measured to ensure it is functioning properly.
ii. All biosensors and electronic aspects of the device must report accurate biofeedback and provide guidance on next stages of training sequences.

d. **Life in Service:**
i. The device will be used weekly during the client's hour-long adapted fitness sessions. The device must withstand all workouts and must be easily cleaned. At a minimum, the device must last for an entire semester, spanning 5 months.
ii. Ideally, the device will remain functional for several years. If parts of the device wear down over time, it should be easily replaced.
iii. If biosensors or electronic components are used, the device will need to be charged from an external power source.

e. **Shelf Life:**
i. The device should be stored in a cool and dark place away from any UV light, ozone, moisture, or heat [3]. Competing medical gloves can be safely stored for 3-5 years [2].
ii. Any internal batteries should be stored separately and follow ISO Standard 10218 [4].

f. **Operating Environmen**t:
i. The device will be mostly used in indoor environments under standard air conditioned room temperature (68-72 ℉) [5].
ii. The device must be easily sanitized using medical-grade disinfectant in between usage and should be water and erosion-proof.
iii. The device will be stored at the Adapted Fitness training facility and should be easily accessible for client's usage for weekly training sessions.

g. **Ergonomics:**
i. The device should be conveniently and automatically equipped to the hand for grip improvement without much use of physical involvement directly related to hand and wrist. In general, the user must not apply more than 15-20% of their maximal strength to avoid excessive fatigue and injury risk. [6].
ii. Turning and twisting motions such as opening a jar should also require minimal torque to prevent strain on the forearm, wrist, and hand muscles. A similar mechanism from mobile blood pressure cuff can be applied to achieve this objective with an instrumental application with direct command inputs for grasping and releasing actions on the hand.

h. **Size:**
i. The device will be adjusted in size to fit the client's hand. It should cover the fingers and palm in which the gripping motions are involved.
ii. The average glove size for adult males is 8.5 to 9.5 inches, measured around the palm of the dominant hand [7].
iii. Competing devices range in size, with a large glove fitting wrists sizes of 7.1 in to 8.7 in and the distance from the wrist to the tip of the middle finger being 7.7 in to 11.0 in [8].

i. **Weight**
i. The device will be made for a survivor of a stroke with limited mobility on the side of the body of which the device will be on so the device will need to be light enough as to not weigh down or affect the mobility of the client's arm. Further discussion with the client will be done in order to determine a specific weight that works best for the client's situation.

j. **Materials**
i. The device will be made with a comfortable fabric which will go onto the client's hand. The fabric will need to be comfortable to wear for an extended period of time and will also need to

have a strap made with velcro or something similar in order for the device to stay comfortably in place throughout the ranges of motion that the device will go through during use.

ii. The device will also need important hardware on the top of the hand in order for the device to operate. Some of this hardware could include wires, motors, pressure sensors, batteries, or other needed components.

k. **Aesthetics, Appearance, and Finish**

i. The device needs to be safe and comfortable to wear for extended periods of time. The hardware on top of the hand needs to be well organized and concealed so that the hardware stays protected, does not affect the use of the device, and looks organized and appealing to the eye. Since the device is initially intended for an individual client, further customizations on the appearance can be added at the request of the client.

2. **Production Characteristics**

a. **Quantity:**

i. This particular device is being custom designed for the client, therefore one final device will be produced.

ii. In the future, the device should be mass-produced using parameters specific to each individual. Regardless of dimensions, the same principles will be assigned to each glove to allow users to open and close their hands, and grasp objects of varying sizes firmly.

b. **Target Product Cost:**

i. The budget for the design is currently unknown, therefore costs will be kept to a minimum until funding is received.

1. Similar devices range in price from $70-$300. The mechanism should be within this range to make the product competitive [8].

ii. The project will be funded through the College of Engineering, by virtue of Mike and Ginny Conwary, the namesakes of the Conway Adapted Fitness space at the Bakke Recreation & Wellbeing Center.

3. **Miscellaneous**

a. **Standards and Specifications**

i. The device must be fabricated with a biomaterial that is easily disinfected and sanitized, following ASTM Standard E1837-96 [9].

ii. All robotic elements of the smart grip enhancement device must adhere to ISO Standard 10218 [4].

iii. When quantifying the grip-strength of the glove-like mechanism, the measurements must comply with ASTM Standard F2961-24 [10].

b. **Customer**

i. The intended customer for the grip-strength mechanism is a hemiplegic stroke survivor. The customer desires a product that improves the extension and gripping capabilities of paralyzed hand muscles.

1. The device should be user friendly, as the customer requires assistance when exercising and gripping objects.
2. The mechanism must be lightweight to ensure the customer can lift the product.

ii. The smart grip enhancement device will be designed specifically for the customer, meaning it must be adjustable to their hand and forearm measurements.

c. **Patient-related concerns**

i. The customer's medical history will be shared with the product design team. Their medical history must remain confidential and all team members will undergo proper HIPAA training.

ii. The device must be easily sanitized using Lysol disinfectant spray when used in the Adapted Fitness facility.

d. **Competition**

i. Competing designs include the General Purpose Gripping Aid, manufactured by the company Active Hands. The glove-like design forces the hand into a fist shape, allowing for gripping of various sized items [8].

1. The gripping aid is fabricated from tough webbing and neoprene, making it machine washable.
2. The device has adjustable straps to accommodate the gripping diameter of the object. Since it fastens the user's palm to the gripped item, the object could not be easily released in an emergency situation.
3. The gripping aid costs between $70.00 and $100.00, depending on the size and color.

ii. The Exo Glove, developed by Kyujin Cho at Seoul National University, is a wearable robotic glove that allows paralyzed users to grasp and pinch objects. The device consists of a wearable three-finger glove and a tendon actuation system that is motor controlled.

1. The robotic glove is fabricated from silicone, making it waterproof and easily sanitized.
2. The electronic components of the device measure the wrist's angle during motion, including finger movement.
3. The device has a pinch force of 20N and a grasp force of 40N [11].

iii. The Gripping System, Apparatus, and Methods Patent, US8192296B2, describes a two-member mechanism that provides users with weakened hand strength a tighter grip around everyday objects. The mechanism consists of a mating glove that fastens to compatible material on the object to be gripped [12].

1. The device is fabricated from hook-and-loop fastener material that mates with retrofit tape wrapped around the graspable surface.The device must be fastened to both the user's hand and the gripped object, which might require assistance to use.

4. References

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[12] P. Pinkart, "Gripping system, apparatus, and methods," United States Patent 8192296B2, June 5, 2012.