EMG Arm Orthosis for Assistance and Rehabilitation

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Executive Summary

Hemiparesis affects about 80% of stroke patients each year [1]. It is characterized by paralysis or weakness on one half of the body. If left untreated, hemiparesis makes it difficult for patients to live independently by interrupting daily activities such as eating, dressing, and using the restroom. Current treatment options include postural control and balance, scapular mobilization, weight-bearing exercises, drug injections, and neural stimulation, which can be very time-consuming, painful, and require professional assistance. Therefore, reducing the amount of time patients must spend in rehabilitation in order to fully recover is in high demand. Currently the best method to improve the rate of rehabilitation is continued use and exercise of the weakened limb following a typical physical therapy regimen. In order to address this problem, we have designed an orthotic device that not only assists the patient in everyday, load-bearing activities, but also encourages the patient to actively use their weakened limbs as a supplement to their regular therapy regimen through EMG progress tracking and ease of use.

Clinical Need

There already exist many types of orthotics that help with hemiparesis rehabilitation. However, almost none are purely mechanical, and hence, considerably more expensive. This orthosis is more affordable, helps the patient use their limbs, and will also encourage the patient to use their arm more often due to the inexpensive EMG LCD screen.

Description of market

795,000 people suffer from stroke each year. Roughly 82% of stroke sufferers survive. Of this group, 50% suffer from mild to severe side effects ranging from paralysis to complete loss of memory and cognition [1]. Hemiparesis affects 80% of these patients [1]. According to the American Heart Association, stroke costs the United States about 43 billion dollars each year [2]. 43% of that is initial hospitalization, 16% is rehabilitation, 14% is physician costs, 14% is hospital readmission, and 13% is the cost of medication [2].

Novelty

This device is novel because it incorporates only mechanical components to assist patients in daily activities, which makes it affordable and easy to use. In addition, an EMG display provides a cheap and simple way to keep track of patient progress.

Description of design

We've created a device that provides both assistance and physical therapy for at-home and prolonged use. Our goal is to provide a force that pulls the forearm up, imitating bicep contraction, which will assist the user during load bearing activities. This will also encourage the user to continue to use their weakened limb rather than letting the arm hang limp, thus helping them to continue to utilize it for faster recovery. To help encourage the user, an LCD screen displaying EMG data will also be attached to the orthosis so the user can observe his or her progress in rehabilitation. In order to accomplish this goal, the force will be provided through a constant force spring attached to an ergonomic orthosis that secures to the arm. The orthosis also contains a joint placed by the user's elbow that will allow the user to rotate the arm in one direction, extension or contraction, through a dual ratcheting mechanism. The ratcheting mechanism will allow for contraction in one configuration and extension in the other.

Figure 1: CAD model (left) and final prototype (right) of the design

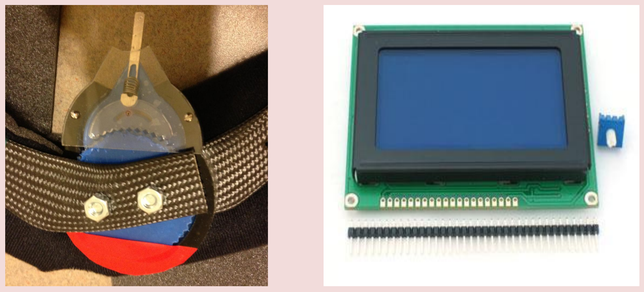

Figure 2: Ratcheting (left) and LCD screen (right)

The EMG portion is comprised of three components: the EMG Sensor, the Arduino board, and the LCD Screen. The EMG sensor receives and processes the EMG data into smoothed rectified waves, and sends it to the programmed Arduino board. The Arduino is wired to the LCD screen and continuously graphs the last several EMG points with respect to time.

Estimated Product Cost

Component/Subassembly	Process	Estimated Manufacturing Cost Per Part
Sleeve components	Purchased direct	$20.00
Carbon fiber beams	Shaped and set by hand	$15.00
Constant-force spring	Purchased direct	$7.56
Spring mounts	Machined from aluminum	$2.16
Ratcheting mechanism	Laser cut from acrylic	$19.84
EMG Components (LCD & Sensor)	Purchased direct	$70.00
	Total	**$134.56**

After additional cost considerations such as quality assurance testing and assembly labor, a markup from manufacturing cost of approximately 200% is estimated for the consumer.

Cost to Consumer: ~ $400.00

Regulatory Pathway

If we would like to commercialize our product, we will need FDA approval for safety and effectiveness. Specifically, our device would need to pass the assessment of the Center for Devices and Radiological Health (CDRH). Our product, based on its nature, falls under the category, *Division of General, Restorative, and Neurological Devices*. 510(K) will conduct pre-market notification for our device because our device should have low risk and substantial equivalence (the market has many orthotic devices of rehabilitation despite different specifications).

Acknowledgements

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References

1) **"Stroke-Spinal Cord Injury - Paralysis Research Center." Christopher Reeve Spinal Cord Injury and Paralysis Foundation. N.p., n.d. Web. 10 Nov. 2012. <http://www.christopherreeve.org/site/c.mtKZKgMWKwG/b.4453405/k.CD2C/Stroke.htm>.**

2) **"Stroke Statistics | Internet Stroke Center." Internet Stroke Center. N.p., n.d. Web. 10 Nov. 2012. <http://www.strokecenter.org/patients/about-stroke/stroke-statistics/>.**