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Title

Soft Robotic Wearable Device to Assist Upper Extremity Movement in Infants with Motor Impairments

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Abstract

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1. INTRODUCTION

1.1 Background

Around 42,121 - 64,882 children are affected by some form of muscle weakness in the United States. The families of these children can spend \$36.6B - 56.4B in medical costs in a lifetime. In California alone, 5,114 - 7,877 children are affected by some form of muscle weakness and end up spending \$4.4B - 6.8B in medical costs in a lifetime. Narrowing down the data to Riverside County, 322 - 496 children are affected by muscle weakness and end up spending \$280M - 431M in medical costs in a lifetime.

Muscle weakness can alter the course of typical development in children. Exploration and interactions with surroundings help children with the development of social, motor and cognitive skills. During typical development, infants exhibit reaching behaviors around three to four months of age. With the onset of reaching, infants start to frequently use bimanual strategies with the arms in synchronized and symmetric trajectories. The ability to switch between uni- or bimanual reaches based on different object properties gets progressively refined, and asymmetrical bimanual manipulation of objects becomes prominent at later ages. Furthermore, at four months of age, reaching results in grasping of the objects and object-oriented arm movements become increasingly smooth. During subsequent months, reaching trajectories become more smooth and fluent. There is an increase in movement velocity and a decrease in the number of trajectory corrections. From six months onwards, development of reaching continues at a slower pace with a gradual increase of the straightness of the reaching path. Additionally, the orientation of the hand during reaching gets increasingly adapted to the orientation and size of the object. This phenomenon is known as anticipatory control. However, children suffering from

neuromuscular diseases and genetic disorders struggle with arm movements as they often lack anticipatory control.

As a result of upper extremity weakness, it becomes increasingly difficult for children to independently perform motor actions unless provided with some external assistance. With so many diseases causing muscle weakness and subsequent motor impairments in infants, it becomes increasingly important to make assistive exoskeletons commercially available so that these infants can benefit in the development of their social, motor and cognitive skills. The goal of this project was to design and develop a prototype exoskeleton that provides arm assistance in infants with various motor impairments. In order to understand the urgency of the need for the proposed device, data on disease prevalence (Section 1.2) and currently available assistive technology for ages 0-2 years (Section 1.3) were gathered from research to arrive at some pressing numbers.

1.2 Diagnoses Leading to Motor Impairments

1.2.1 Cerebral Palsy

Cerebral Palsy (CP) is the most common developmental disorder among children in the United States with approximately 8,000 – 10,000 infants developing CP each year [1]. A 2011-2012 National Survey of Children’s Health and a 2011-2013 National Health Interview Survey reported prevalence of CP as 2.6 and 2.9 per 1000 children respectively [10]. The average lifetime costs for a person suffering from CP is estimated to be \$921,000 [1].

CP, the most prevalent cause of motor function impairment, is a persistent neurological brain disorder of movement and posture that is caused as a result of a non-progressive brain injury or malformation that occurs while the child’s brain is under development [1,30,21,24,26]. The primary effect of CP is on body movement, muscle control, muscle coordination, muscle tone, reflex, posture and balance [1,30,24]. Associative conditions, such as sensory impairment,

seizures, and learning disabilities, also occur frequently with CP. The earliest sign of CP is a developmental delay in reaching key growth milestones including rolling over, sitting, crawling and walking [1]. Some of the risk factors for developing CP include low birth weight or preterm birth, multiple gestations, infertility treatments, infections and fever during pregnancy, incompatible blood factor between mother and fetus, exposure to toxic chemicals, maternal medical conditions such as thyroid, and jaundice and seizures in infants [24,22,12].

The type of CP and extent of impairment help in determining the appropriate treatments [1]. Preventing CP can be carried out on various levels such as Primary, Secondary, and Tertiary [30]. Primary prevention involves preventing abnormalities in the growing brain, however such genetic inferences are not known [30]. Secondary prevention involves decreasing the susceptibility of the neonatal central nervous system to noxious influences such as hypoxia [30]. Finally, tertiary prevention includes therapy such as acupuncture, behavioral therapy, massage therapy, and play therapy [1,30]. Furthermore, tertiary prevention also involves adaptive equipment such as braces, crutches, stroller, and wheelchair [1,30].

1.2.2 Arthrogryposis Multiplex Congenita

Arthrogryposis Multiplex Congenita (AMC) affects 1 in 2-3000 live births with an approximately equal gender ratio [2, 15]. AMC is a condition that results in the development of multiple joint contractures affecting two or more areas of the body prior to birth [2,15,18]. A contracture appears as a result of a joint becoming permanently fixed in a bent or straight position that can further impact the function and range of the joint's motion and can lead to muscle atrophy [2]. AMC signs and symptoms are related to shoulder (internal rotation), elbow (extension and pronation), wrist (volar and ulnar), hand (fingers in fixed flexion and thumb in palm), hip (flexed, abducted and externally rotated, often dislocated), knee (flexion), and foot

(clubfoot) [15]. In some cases, only a small number of joints are affected and have an almost full range of motion but in the most severe cases, nearly every joint is involved. Further signs and symptoms may involve congenital anomalies of the organs such as scoliosis, lung hypoplasia, respiratory problems, growth retardation, midfacial hemangioma, facial and jaw variations as well as abdominal hernias, congenital heart defects, tracheoesophageal fistulas, and ophthalmologic abnormalities [15].

AMC can be treated with the help of standard physical therapy, which can improve joint motion and avoid muscle atrophy in the newborn, and in some cases surgery to increase the range of motion in joints such as the elbows or wrists [3]. A comprehensive approach to treatment is based on a triad of tools: first, rehabilitation including physiotherapy, manipulation of contractures, and social and occupational rehabilitation; secondly, individually tailored orthotic management, whether for maintenance or correction of joint mobility, and for prevention of recurrent deformities; thirdly, surgical techniques for correction of musculoskeletal deformities, typically found in congenital contractures [18].

1.2.3 Congenital Muscular Dystrophy

The prevalence of Congenital Muscular Dystrophy (CMD) was found to be between 19.8 and 25.1 per 100,000 births in the U.K. [29]. Myotonic dystrophy (0.5-18.1 per 100,000), Duchenne muscular dystrophy (1.7-4.2 per 100,000) and facioscapulohumeral muscular dystrophy (3.2-4.6 per 100,000) were found to be the most common types of disorder [29].

CMD refers to a group of genetic, degenerative muscular dystrophies that become apparent at or near birth affecting voluntary muscles [4,11,13]. Children with CMD exhibit progressive muscle weakness, identified as hypotonia, or lack of muscle tone and can appear floppy [4]. Later in life, infants and toddlers are slow in meeting motor milestones such as rolling

over, sitting up or walking, or may not even meet some milestones at all [4]. Although muscle weakness may improve or stabilize in the short term, typically weakness and its complications worsen with time leading to feeding difficulties, joint contractures, spinal deformities, respiratory compromise, and cardiac involvement. In some subtypes, eye, central nervous system, and connective tissue may also be involved in complications [14]. Increased risks of acquiring CMD are seen in siblings and offsprings of a proband (the affected individual) [27]. Increased risk of passing on the pathogenic variant is also seen in parents of the affected child who are obligate heterozygotes carrying a single copy of the pathogenic variant [27].

Physiotherapy treatments for CMD are advisable for preventing joint deformities, muscle retractions and scoliosis [13]. Furthermore, supportive treatment with non-invasive respiratory support in case of respiratory distress, correction of gastroesophageal reflux, support in cardiac failure, treatment of respiratory infections, and nutritional treatment must be frequently carried out [13].

1.2.4 Spinal Muscular Atrophy

It has been estimated that Spinal Muscular Atrophy (SMA) genotype prevalence at birth can range from 8.5–10.3 per 100,000 live births, with a mid-range estimate of 9.4 per 100,000. Among infants born with an SMA genotype, it is further reported that 58% will develop SMA Type I, 29% will develop Type II, and 13% will develop Type III, respectively [19]. In other words, it has been estimated that 8,526–10,333 individuals with SMA Types I, II, and III were living in the United States in 2016 [19]. Approximately 1455–1764 of these people have SMA Type I, 3567–4322 have SMA Type II, and 3504–4247 have SMA Type III [19].

SMA refers to a group of genetic disorders that are all characterized by the degeneration of anterior horn cells (spinal motor neuron loss) and subsequent muscle atrophy and weakness

[23,17,8]. SMA type 0 is used to describe neonates who present with severe weakness and hypotonia. Infants with type 0 may have areflexia, facial diplegia, atrial septal defects, joint contractures and respiratory failure [17]. Infants with type 1 SMA, also known as Werdnig-Hoffman disease, present with hypotonia, poor head control and reduced or absent tendon reflexes prior to 6 months of age. They also never achieve the ability to sit unassisted [17]. Moreover, children with type 2 SMA are able to sit unassisted at some point during their development, however they are not able to walk independently because of progressive proximal leg weakness that is greater than weakness in the arms [17]. A family history of SMA in an immediate family member (such as brother or sister) is a risk factor for this disorder [7].

Various treatments and therapies are often employed to treat SMA in infants. Respiratory treatment, orthopedic management of scoliosis and other deformities, and nutritional support have made a difference in clinical outcome [5]. Therapeutic strategies such as improving functional protein expression and increasing protein levels have been integrated in promising clinical trials [5]. Exercises and equipment such as braces are also available to help with movement and breathing [23].

1.2.5 Down Syndrome

Down Syndrome (DS) remains the most common chromosomal condition diagnosed in the United States [25]. In the United States, 6000 babies are born each year with DS which means that it occurs in about 1 out of every 700 babies [25].

DS is a birth defect caused by trisomy of whole or part of chromosome 21 and is associated with deleterious phenotypes, such as learning disability, heart defects, early-onset Alzheimer's disease and childhood leukemia [5,16,9,31]. DS is coupled with mental retardation, gastrointestinal anomalies, physical challenges due to weak neuromuscular tone and loose joints,

dysmorphic features of the head, neck and airways, audiovestibular and visual impairment, characteristic facial and physical features, hematopoietic disorders and a higher incidence of other medical disorders [16,9]. Women, 35 years or older, have a higher risk of a pregnancy being affected by DS than women who become pregnant at a younger age [5].

Treatments for children with DS include early medical support and developmental interventions during childhood [16,31]. They can also receive a variety of therapies such as speech therapy, physical therapy, and work-related therapy [16,31]. Recently, therapy has also focused on pharmacological treatment in order to enhance cognition [31].

1.3 Available Technology to Assist with Arm Movement

Our search revealed only two recently developed devices to assist infants with motor impairments from 0-2 years of age.

1.3.1 Pediatric Wilmington Robotic Exoskeleton

The Pediatric Wilmington Robotic Exoskeleton (P-WREX) was the first device that was developed for this age range. The P-WREX is a passive exoskeleton that supports the arm in a new resting position based on the properties of the elastic bands. It consists of 3D-printed plastic supportive parts with elastic bands to provide torque about the shoulder and elbow joints to support flexion against gravity.

P-WREX was tested on an infant with arthrogryposis [20]. Intervention consisted of daily activities in sitting to promote general arm movement, reaching, object exploration, and elbow flexion for three months. The infant also received physical therapy and occupational therapy each 1 hour per week throughout the study. Object interaction abilities with and without the P-WREX were assessed. Results from this study showed that within sessions, the P-WREX was most effective at improving reaching ability when the infant reached for objects at hip and chest

level. In addition, the infant showed improved unimanual and bimanual contact with objects presented in midline at chest level when wearing the P-WREX. Lastly, the infant also showed improved visual attention for objects when wearing the P-WREX. These results show that the device was feasible and effective for this infant.

1.3.2 Playskin Lift

Playskin Lift is a novel exoskeletal garment that assists infants to perform arm movements against gravity. It was developed as a tool to improve function in young children with weakness and poor motor control [32,33]. The inspiration behind this device came from the same research team after reviews from users who had discontinued the use of P-WREX due to concerns arising from temperature regulation, bulkiness, and safety and movement limitations [20]. Hence, the goal was to build a device that was wearable and did not hinder every day activities.

For the design, an inter-disciplinary, user-focused design process was used. A Functional, Expressive and Aesthetic Consumer Needs Model was used to guide the design process [32]. This model emphasizes on clothing and devices for users that focus on fashion and functional needs. The Playskin Lift is a onesie made of 4-way stretch blended fabric (87% polyester, 13% spandex). This particular fabric is comfortable and fits closely to support and properly align the mechanical components. Channels were created using narrow strips of vinyl casings to hold the mechanical inserts that would assist with the lifting of the arms. Two mechanical inserts for each arm were built using carbon steel music wire. These wires were covered in rubber heat-shrink tubing. These wires are able to provide sufficient moment to lift the weight of the arms and place them at a flexed equilibrium position [32,33].

The device was tested on one infant suffering from AMC. While wearing the device, the child was able to contact objects more often, to look at toys more while contacting them, and to perform more complex interactions with toys. The parents also gave the device high ratings in the range of 4-5 out of a 5 scale in areas such as ease of use, comfort and attractiveness [33].

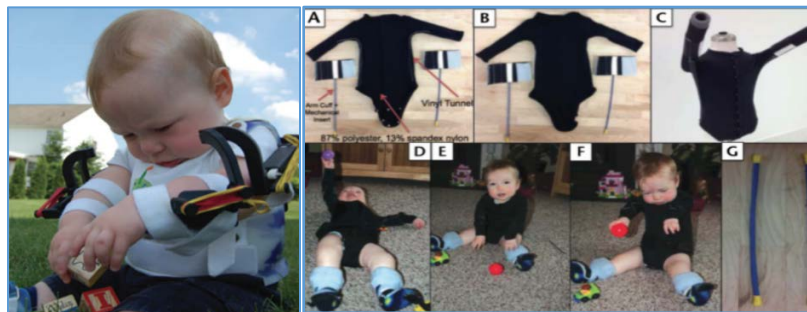


Figure 1. Infant using the P-WREX (left) and Playskin Lift (right).

1.4 Limitations of Current Technology and Proposed Solution

Both devices have certain limitations. Parents that used the P-WREX reported concerns on various aspects [20]. For example, the device restricted floor mobility, poorly assisted elbow flexion, and was bulky (difficult to carry and incompatible with devices like car seats and strollers). Since it utilizes rubber bands to provide assistance at the joints, it was also reported as being unattractive. Other key challenges consisted of problems related to accessibility and affordability - about \$10,000 per pair. There is typically an extended waiting period to receive the device and children require replacements regularly due to continued growth [20].

Although the PlaySkin lift overcomes the problem of aesthetics by integrating its mechanical inserts with a wearable onesie, it has its own functional limitations as reported by the research team [33]. It fails to provide assistance at multiple joints and only assists with the shoulder joint. A thinner and softer fabric can replace the material used for the onesie. Aesthetics and expressiveness can be worked on by adding more fabric color, texture and embellishments.

Lastly, both devices share a common limitation. These are both passive assistive devices, meaning there is no actuation to assist with arm movement.

Our proposed solution is to create an exoskeletal device that is able to address the aforementioned issues by using soft robotic materials to provide assistance at both the elbow and the shoulder joint. Also, the goal is to keep the building costs in less than \$300. The average lifetime medical cost per person suffering from CP, AMC and MD is \$921,000, \$771,062 and \$771,062 respectively. Hence, the device may significantly reduce the medical costs making motor intervention affordable and accessible.

2. METHODS

2.1 Prototype Development

2.1.1 Components

Our prototype consists of different components to sense and actuate movement with an estimated cost of \$269.68, which is within our proposed price range. Figure 2 shows all the components that were selected.

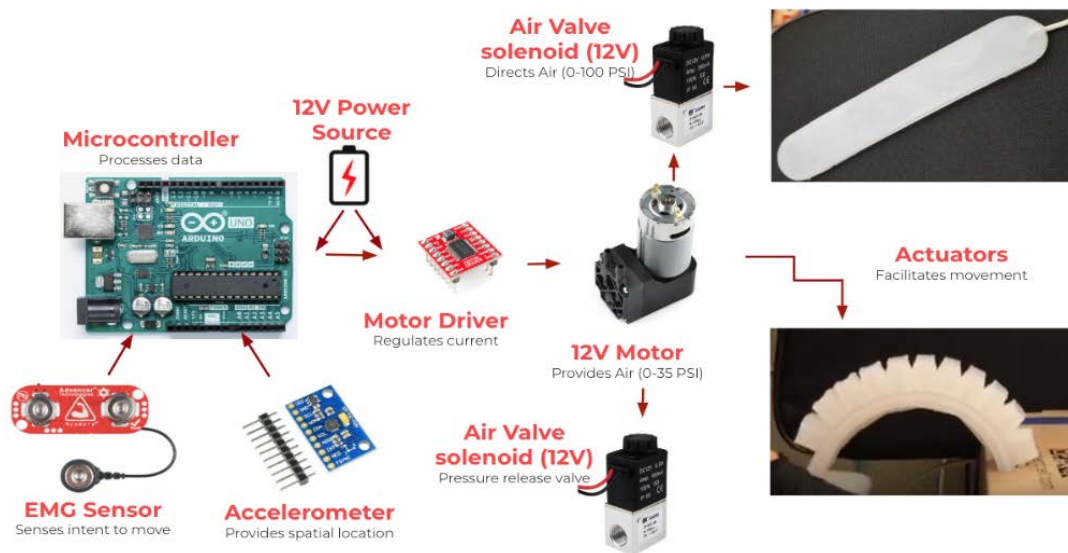


Figure 2. The different components of the prototype.

Pneumatic Actuators. These are used to move the elbow and the shoulder. They help with movement as a result of pressurization and depressurization of hollow chambers as air flows through them. Research was performed on several different actuators on the SoftRobotics Toolkit website and the PneuNets bending actuator was chosen since it is able to provide one-directional motion (Figure 3). The bottom layer of this actuator cannot stretch. As a result, when the air chamber is pressurized, the actuator bends around the bottom layer with a full 180 degrees. It also provides less air resistance and needs simple printing and molding.

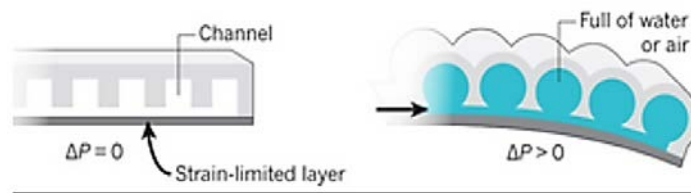


Figure 3. *PneuNets bending actuator.*

The development process was started using 3D printing but was later switched to casting. For the first 3D-printed design, Solidworks files were downloaded and manipulated to print bending actuators using a flexible thermoplastic elastomer, NinjaFlex (McMaster-Carr). Multiple designs were tested but ultimately the actuators were unable to hold air due to air leaks. Figure 4 (left) shows how the actuator bends when 30 PSI is applied into the air chamber. The actuator is expected to bend at a full 180 degrees, but only bends at approximately 45 degrees. Because of air leaks (shown in Figure 4 right), continuous air flow was not possible to hold the positioning of the actuator. Patching was attempted with material such as plastidip and a flexible patching compound, but due to the shape of the actuators, it was difficult to achieve a 100% sealed actuator. In addition, the actuators were stiffer than expected.



Figure 4. Response of Pneunets bending actuator to 30psi air input (left). Air leaks in the 3d printed actuator (right).

Following attempts at 3D printing, casting was attempted with a silicone rubber material called Dragon Skin (McMaster-Carr). These actuators require a pressure of up to 35 psi in order to perform the necessary motor movements. The elbow actuator was downloaded from the SoftRobotics toolkit, while the shoulder actuator design was made from scratch. Once the molds were printed, Dragon Skin was poured into the molds and was given 16 hours to cure. Each actuator took approximately 2-3 days to put together as the individual parts had to be casted separately and then pieced together (Figure 5).

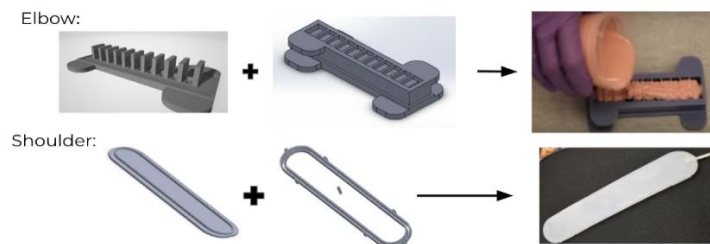


Figure 5. Design and casting of elbow and shoulder actuator.

Air Pump. The chosen air pump is used as an air source to provide the air needed to pressurize and depressurize the pneumatic actuators.

Sensors. We used electromyography (EMG) sensors and accelerometers. The EMG sensors (SparkFun) sense the arm's intent to move. These sensors are coupled as one is placed on the bicep and the other on the tricep muscles. As the user moves his/her arm, these sensors receive signals in the form of a waveform function. The relationship of the two sensors will

determine the intended movement by the child, extension or flexion. The accelerometers sense angular/linear acceleration in order to provide spatial information about the arm's movement.

Microcontroller. This is an Arduino Uno board. It utilizes computer codes to assist with the functioning of sensors by analyzing and processing data from sensor inputs and outputs. This is essential for the automation that the device intended to provide.

Battery. A rechargeable 12V lithium battery was used to power the prototype device.

2.1.2 Component Integration

All components were integrated and placed on a wooden mannequin that was built based on the circumference of forearm, upper arm and elbow of a 2-year old infant. The dimensions were obtained from anthropometric data collected from different sources. As Figure 6 shows, the prototype was mounted specifically on one limb of the mannequin with the goal of flexing the arm as air passes through the actuators. The process starts with the EMG sensing and sending signal to the Arduino controller and in turn, the controller sends signal to the motor driver. Using the 12V battery, the motor driver is able to adjust the amount of current being sent to the pump. As the pump turns on, air starts to flow to the elbow actuator. This causes the accelerometer to rise since it is attached to the wrist. This opens the solenoid to let air flow to the shoulder actuator. Once again using the accelerometer, the shoulder reaches a certain angle after which the pump stops.

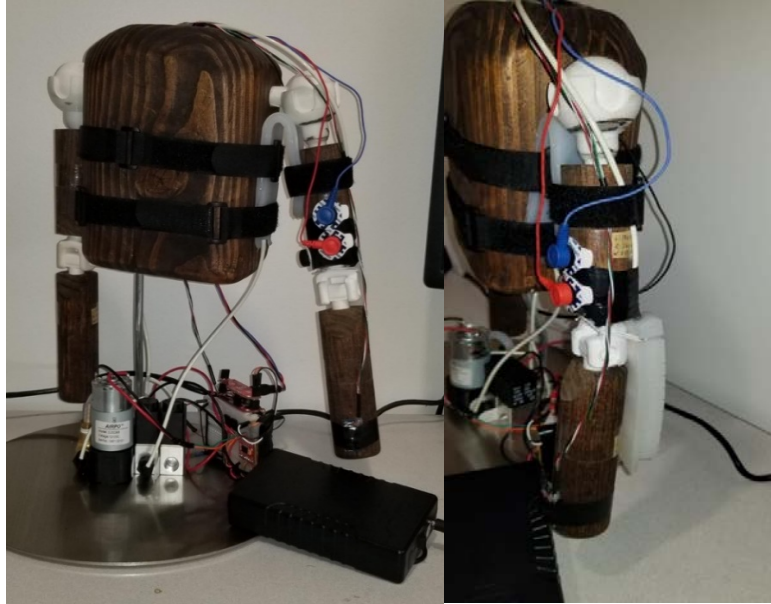


Figure 6. Integration of all components on a wooded mannequin on the size of an infant's body.

2.2 Prototype Testing

The first prototype was tested on the mannequin to ensure it is safe and functions properly before it would be tested with an infant. We assessed the prototype's ability to (i) properly read EMG signal from an adult human's arm muscles, (ii) use the EMG signal to effectively actuate an elbow flexion of the mannequin arm, and (iii) read data from the accelerometer about a human arm's position during elbow flexion.

For this preliminary testing, we had an adult perform a series of elbow flexions and read the signal from his bicep muscle using the EMG sensors. After connecting the sensors to the Arduino and a computer and attaching electrode pads to the muscles, several iterations were performed in order to determine if the EMG was able to read signals as a result of muscle activity. It was hypothesized that a consistent pattern of waveform signal depicting the muscle's activity during the flexions would be obtained.

With respect to actuation, although four different actuators were casted (Figure 7), we only tested one (100% size) since this one has a more spacious hollow chamber that would not create a lot of pressure build up. We assessed the actuator by using a load sensor to create pressure vs. load profiles and see the change in amount of force produced as the pressure changed over time and also by looking at the range of motion of the mannequin's arm. It was hypothesized that this actuator would provide adequate force needed to flex the elbow joint.

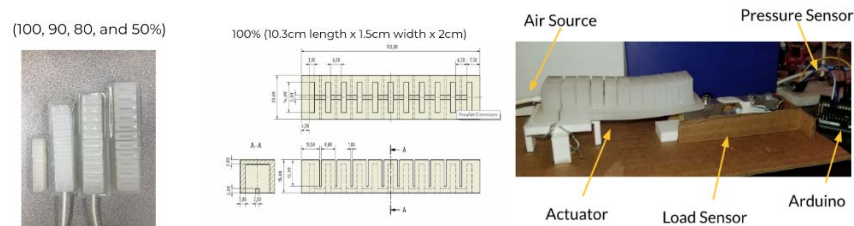


Figure 7. The different actuator sizes casted (left) and the size of the actuator used for testing (middle and right).

Testing was also performed on the accelerometer to make sure it was working properly. After connecting the accelerometer to the Arduino and the computer, the code was run, and different values of acceleration were analyzed. It was hypothesized that three different acceleration values would be obtained in the x, y, and z directions.

3. RESULTS

In Figure 8 below, each of the peaks represents flexion, hence indicating that the EMG was appropriately monitoring signals from the biceps. The x-axis represents the amount of iterations performed. This means that the iterations correspond to the amount of time the graph was running for. Y-axis represents the voltage. When starting iterations, the graph begins at 0 on the x-axis and continues to increase as it goes on. If the EMG was not monitoring properly, we wouldn't have expected to see any one of these peaks.

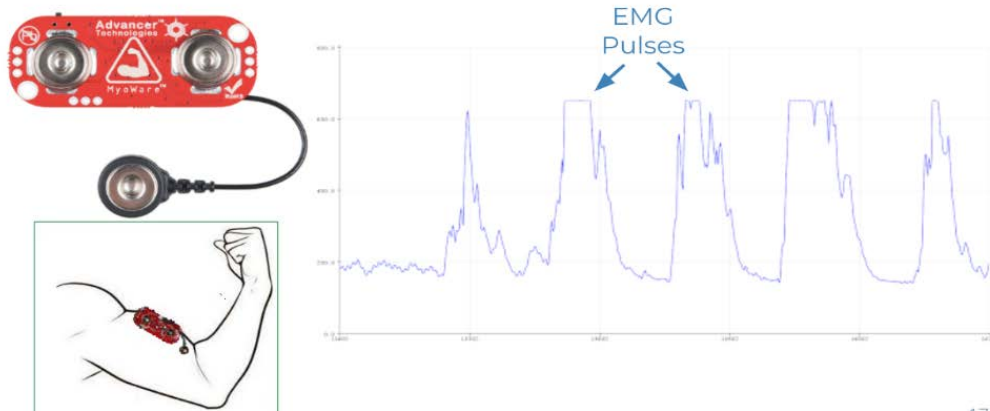


Figure 8. EMG signal gathered from the EMG sensor while the adult performed elbow flexions.

Figure 9 shows the pressure vs. load profile of the chosen actuator during testing with the load cell. This actuator seems appropriate as it provides an adequate amount of force at low PSI (0.275 lbs is enough to lift the forearm of an average 6-month-old based on anthropometric data). The pump only provides 36 PSI, and this is with no load on the arm.

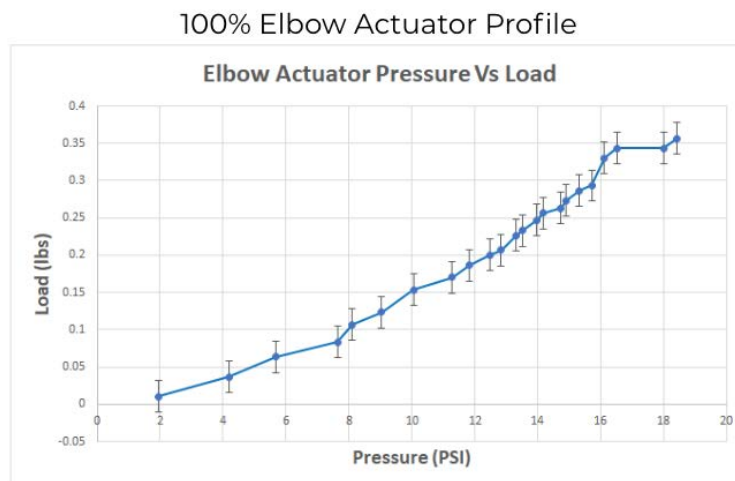


Figure 9. Pressure vs. Load profile of the 100% casted actuator.

With respect to the mannequin's testing with both the shoulder and the elbow actuators, the arm moved up sideways against gravity up to an angle of 90 degrees. Once the entire arm was lifted up with the help of the shoulder actuator, the elbow actuator started working. As a result of the actuation of the elbow actuator, the elbow flexed forward up to an angle of 90

degrees. Further testing would need to be performed in order to determine how different actuation pressures lead to different arm movements.

With respect to the accelerometer's performance, we were able to obtain data that confirmed the proper functioning of the sensor. Figure 10 shows sample data collected during accelerometer testing. Three different acceleration values were indeed obtained corresponding to the three different directions.

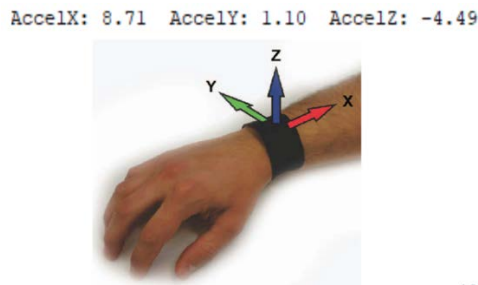


Figure 10. Example of accelerometer placement and collected data.

4. DISCUSSION

While some movement results were obtained with the mannequin, further testing would need to be performed in order to find out the extent and range of motion that the device can provide with respect to arm movement. Different amounts of air would have to be supplied through the actuators to study how the actuation changes and how this, in turn, leads to different degrees of motion. Further, only four different actuator sizes were explored. It is possible to look into several more different sizes and study their pressure vs. load profiles in order to determine an even better actuator.

The device provides an edge over existing research technologies as it attempts to provide movement assistance at both the elbow and the shoulder. Attempts were made to design a wearable suit for the device, however problems were encountered. The sewed in pockets at the elbow joints prevented the actuator from fully bending. In the future, a more innovative design

for the wearable suit will have to be considered so that the device can look compact. The pumps utilized for the device make a lot of noise as they operate. This is not suitable, especially for infants from 0-2 years of age. In order to improve the device, it is best to look into pumps that are quieter. The accelerometer that was used for the device also comes with a gyroscope and magnetometer. Since a lot of issues were faced with troubleshooting codes for these components, they could not be incorporated in the device. For future use, these components can be added for better and more accurate data collection.

5. CONCLUSION

If the device is successfully manufactured and makes it out to the market, it is anticipated that it will have a positive impact on the user by helping them improve their social, motor and cognitive skills. With continued assistance at the elbow and shoulder joint, the infants can improve their upper extremity reaching movements and eventually be able to perform such actions unassisted. If, in the future, an innovative suit can successfully be created, the users would be more willing to wear the device for its comfort and aesthetic looks.

The customers would also be more willing to buy the device because of its soft, comfortable and pleasing looks. One of the biggest reasons why the customers would be interested in the device is certainly the cost. Using the device significantly brings down the medical costs for the user that encourages the customers to buy the device. There would also be a profitable impact on the market. Since a positive impact on the users and the customers is anticipated, the demand for the device will stay high.

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I helped the team by performing background research for our project, performing observations at the UCR Early Childhood Services to understand normal development in infants, researching and implementing the air distribution system in our device, casting actuators, troubleshooting accelerometer codes for testing purposes and attempting to build a wearable suit for the device. Kristina Rodriguez contributed by helping me perform observations, researching background information and power sources for our device, troubleshooting and testing actuators and helping with the suit design. Melanie Beltran contributed by researching background information and different sensors for our device, 3D printing and moulding actuators, troubleshooting and testing the EMG sensor and putting all components together to make the device work as a whole. Mark Estafanous contributed by building the wooden mannequin, building actuator designs on solidworks, 3D printing and moulding actuators, troubleshooting sensors and putting together all the components together. David Creighton contributed by researching background information, researching different actuators, helping with 3D printing,

moulding and testing actuators, troubleshooting sensors and assembling together all the components.

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