Pediatric Arm Support

BME 402
University of Wisconsin-Madison
Department of Biomedical Engineering
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Team Members:
Team Leader: Camille Duan
Communicator & BWIG: James Tang
BPAG&BSAC: Maggie Zhou

Clients:
Ms. Megan Schiele
Advisor:
Tracy Jane Puccinelli, PhD

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ABSTRACT

Children with upper limb muscle weakness face difficulties in performing daily activities. Some typical causes of muscle weakness in children are neuromuscular diseases, such as muscular dystrophy or spinal muscular atrophy. Duchenne muscular dystrophy, one of the most common childhood-onset forms of muscular dystrophy affects 1 in every 3,500 live male births. [1] Spinal muscular atrophy (SMA) has generally been believed to affect as many as 10,000 to 25,00 children and adults in the United States. [2]. The muscular dystrophies as a whole are estimated to affect 250,000 individuals in the United States. [1] Occupational therapist, Megan Schiele, has approached us of designing an arm support system to help a 4-year-old girl with SMA symptoms. We came up with three preliminary design ideas and have chosen two proposed final designs. We hope to complete fabricating two prototypes by incorporating ideas from two preliminary designs. By rapid prototyping, we will decide on one final design to proceed. Finally, a more sophisticated testing method will be created to ensure the feasibility and safety of the design to help the little girl.

1. INTRODUCTION

1.1 Motivation

There exist several pediatric musculoskeletal diseases that are characterized by upper limb weakness with minimal or abnormal motor control and sensation. [3] Neuromuscular diseases, such as muscular dystrophy or spinal muscular atrophy (SMA), are individually rare. Yet, pediatric clinicians frequently encounter children with motor delay. [4] SMA has generally been believed to affect as many as 10,000 to 25,00 children and adults in the United States. One in 6000 to one in 10,000 children are born with this disease. [2] One in 40 to one in 50 people (approximately 6 million Americans) are carriers of the SMA gene. [2] A person with one of these neuromuscular disease conditions is usually not able to be independent and requires assistance to perform daily activities. Specifically, among other gross motor challenges, these patients often are too weak to overcome the weight of their arms for daily tasks including self-feeding. Thus, it is important to design a device to help strengthen upper limb muscles or help support upper limbs for children to perform daily activities.

1.2 Existing Devices & Current Methods

Several engineering devices designed to increase patient' independence by decreasing the power required to perform upper extremity tasks have been designed. Due to their high cost and complexity, most upper-limb exist today are used for rehabilitation only, not for daily assistance. In 1998, Hogan et al. designed a direct drive, a five-bar-linkage SCARA (Selective Compliance Assembly Robot Arm) called MIT-Manus to aid in stroke rehabilitation of the upper limb. [5] The device functions in a horizontal plane and works with visual feedback to assist users to perform predefined arm movements in therapy. In 2006, a group of researchers developed the mirror Image Movement Enabler (MIME) robotic device, to enable bilateral upper extremity rehabilitation for stroke patients. [6] The MIME had 6 degrees of freedom.[6] It involved bilateral upper extremity movement with the intent to promote neural changes within the brain to compensate for the affected hemisphere in controlling the paretic limb, and suggested the feasibility of this type of design and yielded therapeutic benefits.

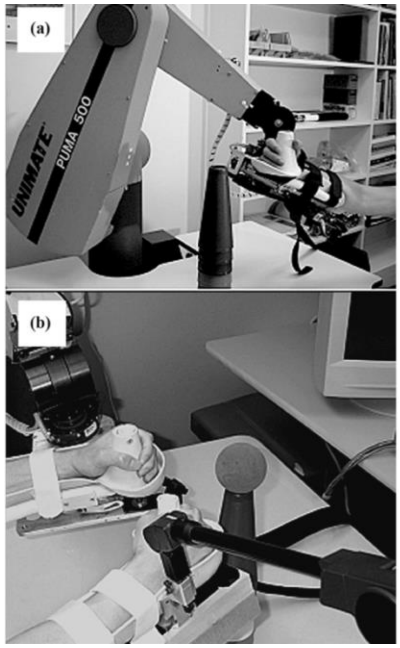


Figure 1. Subject performing (a) unilateral and (b) bilateral movements with MIME [6]

Another example is the WREX (Wilmington Robotic Exoskeleton), a currently commercialized passive, pediatric, upper-limb orthosis designed to assist children with upper limb weakness. The WREX has an anthropomorphic configuration and uses parallel mechanisms with zero rest-length springs for gravity balancing. However, it has limitations including lack of countering force to allow the child to pick up objects of significant weight and difficulties for the children to raise their arm above their head due to misalignment of joints between users and devices. [3]

Figure 2. Picture of a user in passive WREX. [3]

1.3 Problem Statement

Kids with upper limb muscle weakness have difficulty playing with their friends without the help of an adult because they do not have the adequate muscle strength to slide their arms. Our mission is to design an arm supportive device to help a 4- year- old girl who has similar symptoms with SMA (Spinal Muscular Atrophy) move her arm to pick up game pieces. The girl has great shoulder control that can rotate in three directions. The design needs to include straps to hold her arm and allow her arms to move in sagittal, transverse and frontal plane by moving her shoulders.

2. BACKGROUND

2.1 Spinal Muscle Atrophy (SMA)

Spinal Muscle Atrophy (SMA) is a disease that affects people's ability to walk, eat or breathe by affecting the motor neuron cell in the spinal cord. This genetic disease could lead to dysfunction in the central nervous system, peripheral nervous system, and voluntary muscle movement.[7] The cause of this disease is the mutation of survival motor neuron gene 1 (SMN 1), which produces a type of protein that affects the function of the motor nerve that controls the muscles in our body. Since the nerve cell would not be able to function normally, the result of this disease could be the debilitating of muscle and eventually death [7].

There are four types of SMA: Type 1 (severe) SMA, Type 2 (intermediate) SMA, Type 3 (mild) SMA and Type 4 (adult) SMA [8]. Type 1 SMA is the most severe and most rapidly developed SMA. Infants usually demonstrate symptoms either at birth or within the first six months. Symptoms include floppy limbs, weak trunk movement or difficulty swallowing. Infants with Type 1 SMA usually die within the age of 2 because of respiratory infection [8]. Type 2 SMA appears symptoms between 18 months to age 7 with a various developing rate. This type of SMA affects lower limbs more than upper limbs, thus the patients usually cannot stand. Life expectancy can range from early childhood to adulthood, depending on the severity of the patients' condition. Type 3 and Type 4 SMA have milder symptoms compared to the previous two types of SMA, both of these types' patients have life expectancy close to normal people [8].

2.2 Client Information

Our client, Ms. Megan Schiele, is a pediatric school occupational therapist working at Madison Metropolitan School District for grade K-12 kids. She graduated from Mount Mary University in 2011 with a master's degree in Occupational Therapy. She has been helping kids with injury or disability through the therapeutic use of everyday activities so that the patients could develop, recover or improve the skills needed for daily living and working.

2.3 Product Design Specification Summary

The goal of the design is to help the patient to support her elbow and wrist to move her arm to pick up game pieces. The client specified that the arm holding device should not interfere with the patient's arm movement in the sagittal, transverse and frontal planes. With the help of the device, the patient should be able to play with her friends either over the table or on the ground with the adult's constant help on the side. The device should be within 2 Ibs over the shoulder and 1 Ib over the arms and it should be able to lift 4-year-old kids' arms, which is about 6 Ibs.[9] Refer to Appendix 1 for the complete product design specification.

3. PRELIMINARY DESIGNS

3.1 Linear Rail Guide Arm Support System

The first design idea that the team came up with is the linear guide rail arm support system. One of the client requests is that the device is portable, therefore, the device needs to be light and can be easily carried around. The device as shown in figure 3 has three main components: PVC tube backbone structure, elastic band arm holders and a linear arm rail guide system. This design will be 0.5m wide and 0.5m in height. The metrics are based on the average height of a 4-year old girl.[9] The PVC tube backbone structure is designed to be placed on the floor and consists of 3 different pairs of PVC arms at various height locations. The top PVC arms are designed to hold 2 elastic band arm holders with one on each side. The middle part is directly connected to a linear arm guide rail. The bottom is used for stabilization on the floor.

The advantage of this design is that it is very easy to fabricate since the majority of materials are PVC tubes. This design also can be detachable, meaning that the linear arm guide rail could be detached when not needed so that the girl could play more freely. The linear guide rail allows her to have a stable arm support when painting or working on tablets. The elastic band arm holder allows her to move her arm in any degree possible, which fulfilled the client requirements of 3 directional movements. However, the elastic band arm holder requires another person's assistance for the arm placements. Additionally, the structure has the potential of falling over since PVC tubes are generally light and provide mediate support instead of strong support.

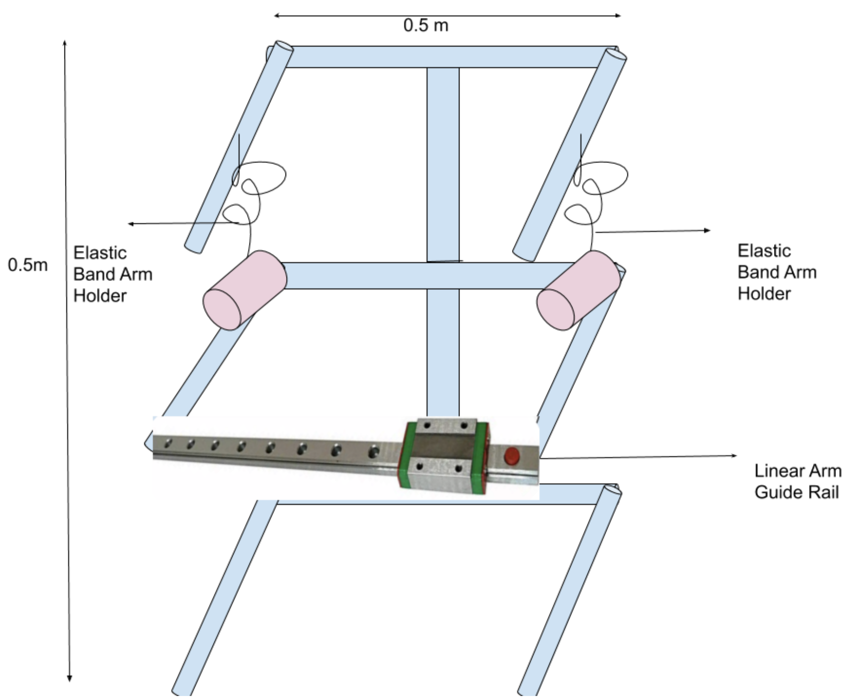


Figure 3. Linear Rail Guide Arm Supporting System with estimated dimensions

3.2 Arm Supporting Vest

The second design that the team developed is the Arm Supporting Vest. This design consists of a modified back straightened vest for kids and an addition of two hangers that will hold the both of the kid's arms. The vest will be based on the back straightened vest but we will cut loose some part of the shoulder and the waist so that the vest would not cause discomfort to the 4-year-old-girl. The vest is about 0.256 Ib and together with the PVC tubes, this design would not be an extra burden to the girl. The holder for the two hangers will be sewed over the vest to keep the hanger in the back. The hanger is made of PVC tubes and will be connected by 90 degree PVC elbow joints. Rubber bands will be attached on the tip of the tubes and an arm holder will be soldered to the tubes. For the estimated dimension please refer to Figure 4.

The advantage of this design is that the overall weight of the device will be less than 0.5 Ibs which will not cause any discomfort to the girl. In addition, this device is not fixed to either the table or the ground, so the girl can move in any direction or area she wants with the vest on. Whenever the girl needs to perform tasks such as picking up game pieces or drawing a few paintings she could just put this vest on with the help of an adult and be left with the device to help her arms up. No extra help will be needed from an adult for the rest of the actions after the arms are in the holders.

However, there are some associated disadvantages to this design. First, we are not sure yet if the girl is willing to put this vest on or if this vest will be too much for her muscle. Besides, since the arm holder is attached to the PVC tubes with rubber bands, we cannot determine which type of rubber bands have the best force that is not only strong enough to lift her arms but also not limits her movement in all directions. The material of the arm holder needed to be tested to see which one has the greatest comfortability and fits the arm best.

Figure 4. Arm Supporting Vest with estimated dimensions

3.3 Mind-**controlled Exoskeleton**

The third design that came up from the team is called Mind-controlled Exoskeleton. The mind-controlled exoskeleton is a powered arm and hand orthosis (brace) designed to help restore function to upper extremities paralyzed or weakened by neuromuscular and neurological disease or injury. The mind-controlled exoskeleton works by reading the faint nerve signals (myoelectric signals) from the surface of the skin (no implants) then activating small motors to move the limb as the user intends (no electrical stimulation).

The user is completely controlling their own hand, wrist, elbow, and arm; the robotic arm brace amplifies weak muscle signals to help move the upper limb. The dimension is designed specifically for a 4-year-old girl [10]. Its functioning process starts from the patient’s brain which decides the moves, and then it sends signals to the non-invasive sensing system. Afterward, the EMG signal processing system will read the signals sent from the brain and command the device to perform the move.

More importantly, the mind-controlled exoskeleton is a wearable robotic device on the market to help restore function for those who still have their arms and hands but are unable to use them.

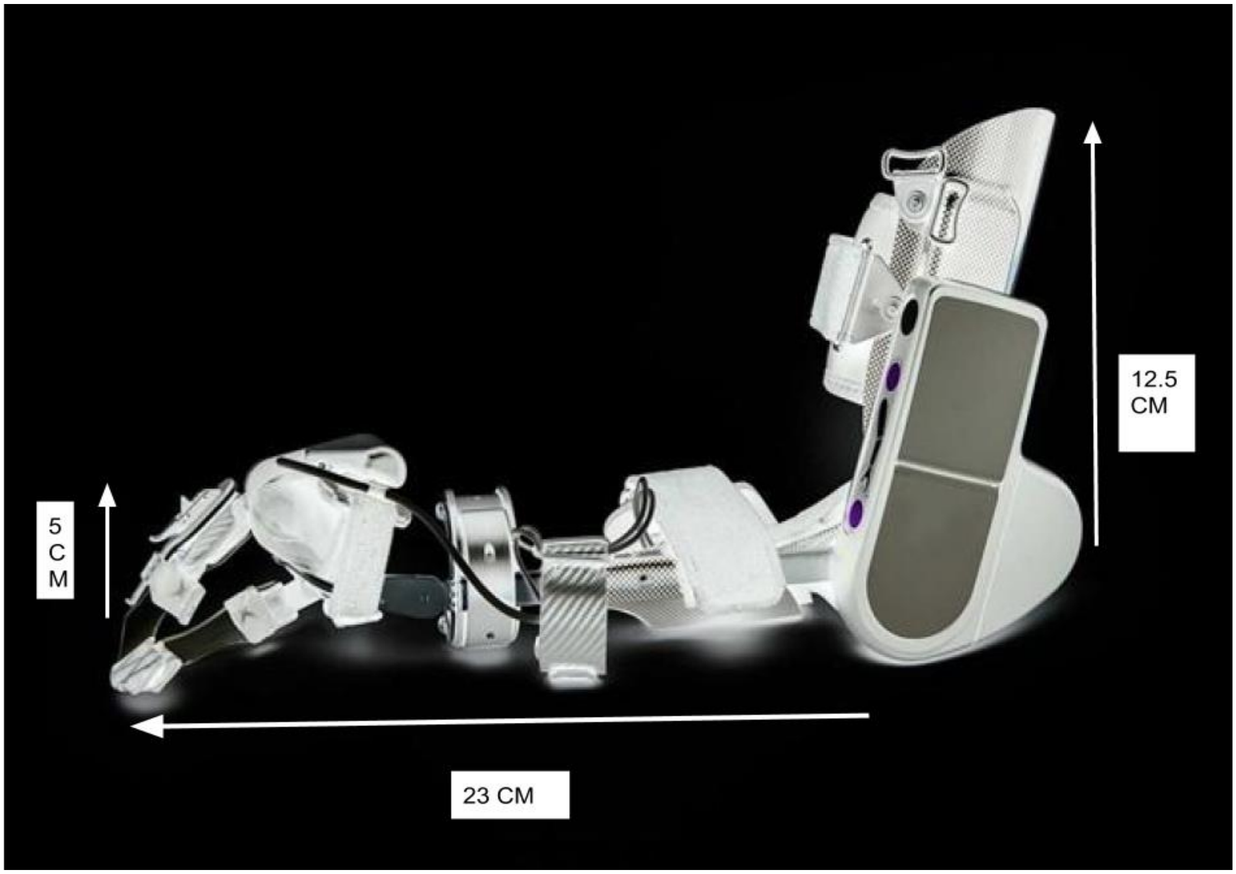


Figure 5. Mind-controlled Exoskeleton to support arm motion with signals sent from the brain. It consists of a non-invasive sensing system and an EMG signal processing system.

4. PRELIMINARY DESIGN EVALUATION

4.1 Design Matrix

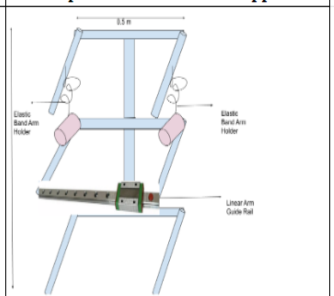
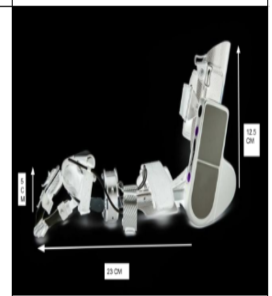
	Suspension Mobile Arm Support		Motor Elbow Lifting System		Mind-control Exoskeleton	
						
Mechanical Stability & Safety (25)	3/5	15	4/5	20	5/5	25
Patient Comfort (20)	4/5	16	4/5	16	3/5	12
Effectiveness (15)	3/5	9	4/5	12	5/5	15
Ease of Fabrication (15)	5/5	15	4/5	12	1/5	3
Cost (15)	5/5	15	4/5	12	1/5	3
Ease of Operation (10)	3/5	6	4/5	8	5/5	10
Total (100)	**76**		**80**		**68**	

Table 1. The design matrix with categories on the left, their weights in parentheses, and each design labeled in the first row. The pink cells represent the designs that won in each category and the red cell represents the design that won overall.

1. <u>Mechanical Stability & Safety</u>: Mind-controlled exoskeleton has the highest score for this criterion since it is a well-built machine and is supposed to be highly accurate and stable. Motor elbow lifting system design has the second-highest score since this design consists of a modified back straightened vest for kids and an addition of two hangers that will hold the kid's both arms. Suspension mobile arm support has the lowest score since its weight is small and the way of connection is not as reliable.
2. <u>Patient Comfort：</u> Motor elbow lifting system design has the highest score since the advantages of this design are that the overall weight of the device will be less than 0.5 Ibs

which will not cause any discomfort to the girl. Suspension mobile arm support also earns the same score since it is portable and the patient can easily carry it around.

3. Effectiveness: Mind-control exoskeleton received the highest score since ideally it is a perfectly designed robot controlled by the patient's brain. On another hand, the suspension mobile arm support or the motor elbow lifting system get lower scores because their components are manually attached.
4. Ease of fabrication: Suspension mobile arm support scores the highest since it has the least components which are basically multiple PVC pipes. Motor elbow lifting system design is ranked second since it also does not include complicated building techniques or calculations or advanced technologies to finish as the mind-controlled exoskeleton does.
5. Cost: Suspension mobile arm support received the highest score because it only requires multiple PVC pipes. Motor elbow lifting system design is similar, but the mind-controlled exoskeleton will definitely cost beyond the budget since it requires numerous highly cost components such as nerve-detector and the EMG signal processing system.
6. Ease of Operation: Mind-controlled exoskeleton scores the highest since it is completely automatic and controlled by the patient's brain and the robot system, so the patient does not need to take a lot of effort. Suspension mobile arm support receives the lowest score because its construction may not be reliable during use and it could be easily broken.

4.2 Proposed Final Design

The team proposed the Linear Rail Guide Arm Support System and the Arm Supporting Vest both to be our final designs because both designs are feasible and are within our budget, so we want to perform further testing. The Linear Rail Guide Arm Support System could provide the user a more stabilized support of the arm motion. It could also save a lot of strength for the users when using both arms. The Arm Supporting Vest is a lighter and more convenient design to be carried around, considering our user will be a 4-year-old girl. Both designs have strengths that we do not want to give up, so the team design that we are going to fabricate both designs to compare the actual usability.

5. FABRICATION/DEVELOPMENT PROCESS

5.1 Materials

Materials were chosen based on their weight and tensile strength. PVC tubes were considered for both designs since the tensile strength for 1’’ wide PVC tube is 581 lb and the weight density is 55 lb / 100 ft [11]. One inch PVC tube fittings and couplings to connect PVC tubes at 90-degree angles were also needed for both chosen preliminary designs. Additionally, a back supporting vest is purchased online that is suitable and comfortable for the kid to wear for the first design. For the second design, elastic bands that are 3’’ wide and a linear guide rail made from plastic are also required.

5.2 Methods

For fabrication of both proposed designs, we will be using machines and tools provided at the Makerspace. A hand saw or a miter saw will be used in order to cut through the 1’’ wide PVC tubes into the desired length. 1’’ tube fitting will be used to connect PVC tubes. In order to connect the linear guide rail to the PVC tubes, magnets left from last semester could potentially be used. Adding two more sliding guide rails on each side of the PVC tubes could also connect the linear arm guide rail system. We will conduct further testing to see which way works better. Additionally, industrial sewing machines would be used to fabricate the second design in order to attach PVC tubes through the back of the vest.

5.3 Final Prototype

The goal of the design is to help the patient to support her elbow and wrist to move her arm to pick up game pieces. With the help of the device, the patient should be able to play with her friends either over the table or on the ground with the adult’s constant help on the side. The device should be within 2 Ibs over the shoulder and 1 Ib over the arms and it should be able to lift 4-year-old kids’ arms, which is about 6 Ibs. The design is made up of a supporting system that can be clamped over the patient’s chair since the girl needs to sit in a supportive chair whenever she plays on the table or over the ground. The device will lift the patient’s both arms over the head to provide the necessary strength needed to pick up game pieces. Two plastic straps will not interfere with the little girl’s vision. Two cuffs around the wrists and the elbows could provide a better holding over the arms.

Figure 6. Final design

5.4 Testing

Testing will be performed on volunteer kids that the team recruited for testing purposes. Ideally, a testing population of fifteen kids will be organized to wear the device. One criterion is that healthy kids will be asked to try to not to use arm muscle to see if the arm holder is helping to lift the arms. The second criterion is whether the vest is causing discomfort to movement and body overall. Finally is if the vest is an extra burden when playing with game pieces or drawing in general. The most important criteria will be if the holder is lifting the arms since this is the whole purpose of this design project. Three criteria will be given a score and summed together to see if the device is helping to solve the client's problem. With the feedback, more modifications will be made.

6. RESULTS

Overall, our design should not interfere with the kids' normal actions. However, it might achieve some low score for the comfortness since the healthy kids would not want an extra device on them. The functionality score achieved a relatively high percentage compared to the comfortability. The device should help them lift their arms if they tried not to use their own arms to lift game pieces. Some kids did complain about the discomfort ability about the arm holders since they are not customized for each participant's arm size.

7. DISCUSSION

The design effectively lifted the kids' arm while they are playing pieces, multiple kids state that they feel the strength of support under their arms. Some kids say that they do not like the feeling the arm holders are too tight, and don't really fit. There are some sources of errors as well. The participants for our testing procedure are all healthy kids, so their arm strength will not be the same as the SMA kids. Testing population is not big enough to support the conclusion that the device is effective for all kids. More statistical testing is needed with the SMA kids in order to obtain more sophisticated testing results regarding whether the device is holding up the arms.

8. CONCLUSION

Our client, Ms. Megan Schiele is looking for a device that can help a 4-year-old girl with SMA muscle weakness symptoms to perform basic tasks and move her arms more easily. Overall, our proposed final design would be able to achieve the features that she has asked for. The design is portable meaning that it can be easily removed and attached on the chair that the girl is sitting on. The spring system is thin enough so that it would not block her vision compared with the current design she uses. This proposed design is also under 200-dollar budget. In the future, the team would like to continue the fabrication process with our proposed final design idea. The team would also conduct the proper testing based on the proposed testing protocol.

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10. APPENDIX

Appendix 1: Project Design Specifications

The Arm Support System for Kids with Upper Limb Disability
Project Design Specifications

Team: Camille Duan; pduan4@wisc.edu; Team leader
Maggie Zhou; zzhou269@wisc.edu; BPAG
James Tang; btang8@wisc.edu; Communicator

Date: February 14th, 2020

Function: Many kids with upper limb muscle weakness having difficulty playing with their friends without the help of an adult because they do not have adequate muscle strength to slide their arms. Our mission is to design an arm supportive device to help a 4- year- old girl who has similar symptoms with SMA (Spinal Muscular Atrophy) move her arm to pick up game pieces. The girl has great shoulder control that can rotate in three directions. The design needs to include straps to hold her arm and allow her arms to move in sagittal, transverse and frontal plane by moving her shoulders.

Design Requirements:

1. Performance Requirements: The device should be able to help the girl perform some basic movements such as writing and drawing on her own.
2. Safety: The device must meet the general safety standard for medical devices and try to minimize discomfort for patients. The materials used for the device must be sterile, and mechanically as well as chemically stable, such that additional harm to the patient is avoided.
3. Accuracy and Reliability: The device dimension should well fit the 4-year-old girl and the stripes on the device should not be too strong to potentially hurt the girl's arm.
4. Life in Service: The desired device should work at least for a year and not disband.
5. Shelf-Life: 3-5 years
6. Operating Environment: The device should be operated at multiple locations, either on the floor or at the table.
7. Ergonomics: The device aims to assist the girl achieve some easy tasks without others' assistance.
8. Size: A 4-year-girl fitting dimension.

9. Weight: Less than 2 lbs.
10. Materials: PVC pipes
11. Aesthetics: Children preferred color painting on the device.

Client Requirements:
- The device should allow the girl to freely move her arms up and down.
- The girl should be able to use the device on her own.
- The device should not lead the girl in any dangers.
- The cost of the device must be under $200.

Production Characteristics:
1. Quantity: Our client has requested for 1 specific design to help the 4-year-old girl, however, in the future there is potential for mass production of the device for muscle weakness rehabilitation exercises after successful testing. Following this, the quantity might be increased.
2. Target Product Cost: Our targeted budget will be limited to 200 dollars. The current competing designs cost around $500-10k.

Standards and Consumer Characteristics:
1. Standards and Specifications:
    a. This device will be used for rehabilitation of upper limb muscle weakness under the professional occupational therapist's guidance and is classified as a class III medical device according to FDA standards [1].
    b. FDA premarket approval is required before this device can be commercially distributed.
    c. Local regulations in regard to Human Subjects or Animal Studies with this medical device will require an IRB for further studies to validate the device.
    d. Phantoms and/or computational models can be an alternative to validify this device for its current stage of development.
    e. The device specifications will have to comply with the FDA's Federal Register, as well as the Code of Federal Regulations. The FDA also requires a number of approvals and clearances to ensure that a device is safe and effective before used on patients in hospitals. These include a 510(k) Premarketing Submission and Premarket Approval (PMA).
2. Customer: The product will be operated by trained occupational therapists and physical therapists. The product should be usable for children with upper limb muscle weakness for daily activities, play or rehabilitation purposes.
3. Patient or User-related Concerns: The device should be safe to use for both patient and operator. It should not create any discomfort for the patient. It should also have the ability

to help support the weights of both arms without falling over and help her perform desired training exercises or simply play.

4. Competition
    a. MIT-Manus [2]
        i. In 1998, Hogan et al. designed a direct drive, a five-bar-linkage SCARA (Selective Compliance Assembly Robot Arm) to aid in stroke rehabilitation of the upper limb. [2] The device functions in a horizontal plane and works with visual feedback to assist users to perform predefined arm movements in therapy.
    b. Mirror Image Movement Enabler (MIME) [3]
        i. In 2006, a group of researchers developed the device to enable bilateral upper extremity rehabilitation for stroke patients. The MIME had 6 degrees of freedom. It involved bilateral upper extremity movement with the intent to promote neural changes within the brain to compensate for the affected hemisphere in controlling the paretic limb, and suggested feasibility of this type of design and yielded therapeutic benefits.
    c. Wilmington Robotic Exoskeleton (The WREX) [4]
        i. A currently commercialized passive, pediatric, upper-limb orthosis designed to assist children with upper limb weakness. The WREX has an anthropomorphic configuration and uses parallel mechanisms with zero rest-length springs for gravity balancing. However, it has limitations including lack of countering force to allow the child to pick up objects of significant weight and difficulties for the children to raise their arm above their head due to misalignment of joints between user and devices.

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