Exercise Device for Child with Profound Weakness for use in a Wheelchair

BME 300/200

October 10, 2017

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Abstract

Type I spinal muscular atrophy (SMA) is the most common type among SMA patients, but is the most severe type with it being fatal early on in life. Since these patients have a mutation in the survival motor neuron gene, they do not produce the protein that is critical to the function of the nerves that control their muscles. Without the protein, their muscle cells die which leads to muscle weakness. With new treatments on the market for SMA, these patients need a way to exercise their muscles to promote muscle development. There are currently no devices on the market that attach to a Ki Mobility wheelchair that allow one with SMA to exercise. This team's goal is to create a device that effectively exercises the legs of a patient with type I SMA. The proposed design uses PVC for the frame and soft leg straps to hold the legs up. The device will be evaluated based on how it works for the patient and her family.

I. Introduction

Spinal muscular atrophy (SMA) is one of the most common neuromuscular disorders in the world that causes atrophy of ventral roots and weak muscular movements. In the general population, one in every 10,000 people have SMA[1]. SMA is an autosomal recessive disease [2], meaning that if both the parents are carriers of this gene, there is a 25% chance that their offspring will have the disease of SMA. There are four types of SMA having different symptoms and levels of severity respectively. Type I SMA, the focus of the project, is the most severe type and is usually diagnosed in the first six months of life. This type of SMA tends to be fatal soon after diagnosis[3]. About 60% of all SMA cases are type I [3].

Since type I SMA is the most common type among SMA patients, there should be an urgent need for effective therapies available in market. Current medicines like Spinraza and AveXis, focus on the gene alteration to change the splicing of survival motor neuron gene two to gene one[4]. Gene one is the gene that normal people have that give them the ability to use their muscles and do everyday activities[4]. In order to fully recover, patients can gain the muscles they need to do everyday activities through constant exercise. However, at first the strength of SMA patients is not enough to overcome their own gravity and cannot exercise by themselves, so exercise devices are needed. This project focuses on building a device that can help a SMA Type I patient exercise the muscles in their legs.

This device should help the patient move their legs on their own. The only way that is attainable for our patient, is for them to have their legs suspended in the air. Moreover, SMA Type I patients have very severe muscular dysfunction, requiring most patients to be in wheelchairs. There are many exercise devices available in the market currently, but these devices do not aim to help SMA Type I patients. This is due to none of the devices having the capability to attach to the wheelchair, giving patients the ability to exercise where they lay. Thus, the exercise device should be designed to exercise the legs of a patient with Type I SMA while they are lying in a wheelchair.

II. Background

Spinal Muscular Atrophy (SMA) is an awful disease that affects the victim's physical strength by affecting the motor nerve cells in the spinal cord. There are four types of SMA with type I SMA being the worst type.[1] Type I SMA affects almost every muscle in the body causing visible deformations of the human physique. Most victims will need a breathing tube considering they don’t have adequate neck and diaphragm muscles to do so. This also applies to swallowing, so a feeding tube is usually needed.[5] Most daily functions can’t be performed such as walking or even sitting up. Although the victim suffers from tremendous physical restrictions,

they still have full cognition.[5] SMA is caused by a mutation in the survival motor neuron gene 1(SMN1)[1]. Generally, this gene produces a protein that is critical to the function of the nerves that control muscles[1].

Client Information:

Karen Patterson received her Masters of Physical Therapy from the University of Indianapolis. Currently, she is the faculty associate for the University of Wisconsin Doctor of Physical Therapy Program. Karen continues to practice as a senior physical therapist and is involved with research in global health and pediatric neuromuscular diseases, including spinal muscular atrophy (SMA).

Design Specifications:

The product should be able to effectively exercise a patient with SMA Type I. The device should also be easy to use and fit the patient well while being used in a supine position. Next, the device should be positioned above the frame of the wheelchair and it should be able to attach and detach from the wheelchair in a timely manner. Finally, the device should be able to be used multiple times. The safety factor of the device is a top concern considering the patient is brittle and can feel everything she comes in contact with. Another top concern is comfortability of the device. Again, the patient can feel everything, so if the device is uncomfortable in anyway, the patient will not want to use the device.

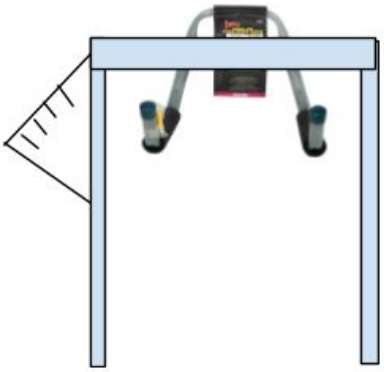
III. Preliminary Designs

Based upon the culmination of research performed and talking with the client and patient's family, the following designs were created. All the designs would use materials that were inexpensive and lightweight. The first three designs are meant to exercise the arms, while the last two designs are for the legs.

Wrist Spring

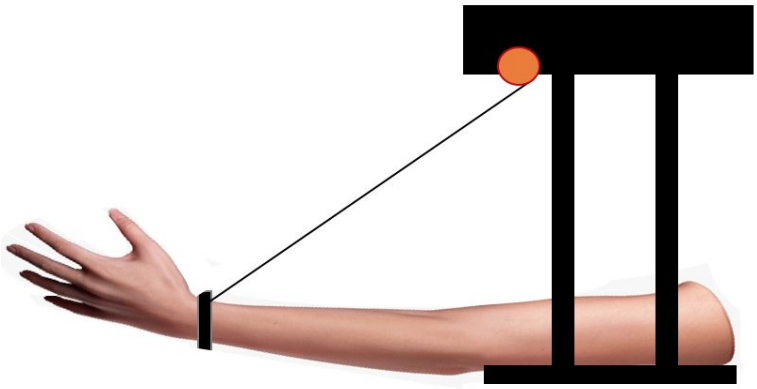
This design idea involves a very weak torsional spring to help a patient exercise their wrist. This mechanism would help the patient lift their hand and work similar to how a mouse trap works. However, unlike a mouse trap this design will have a much weaker torsional spring and would not hurt the patient. The torsional spring would be weak enough, so it wouldn't lift the patient's hand up all by itself, but yet be strong enough to make moving the patient's wrist easier. Finally, there would be a comfortable strap and hand rest to keep the patient's hand in place comfortably.

Finger Rockwell



This design is meant to exercise the wrist by slowing climbing the fingers up and down a mini rockwall. The device would attach to the side of the Ki Mobility chair and be positioned at a height that is comfortable for the patient. The patient's arm will then rest on the two foam holders. Attached to this device would be a mini rockwall/stair climber for the fingers. The patient can set their fingers on the first step and climb up the wall using their fingers. This will help the patient work on moving their wrist up and down as they climb the steps.

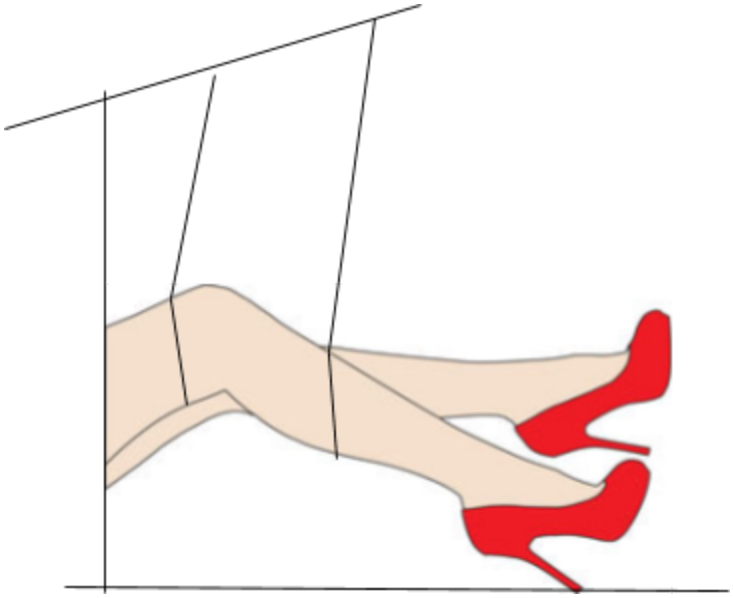
Retractable Arm Exerciser



The purpose of this device is to aid in adduction movement of the arm. To attain this movement the patient will have their arm rested so that the palm of their hand faces upward. The

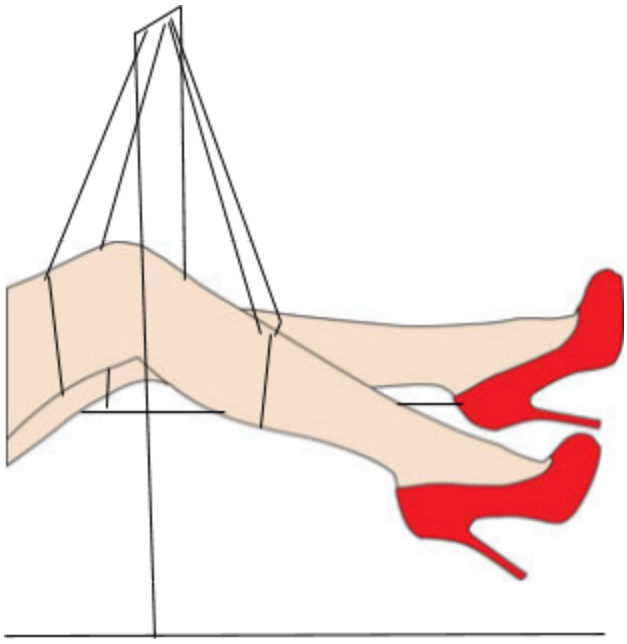
patient has minimal extremity movement and cannot hold up their arm on their own. This device will have a sling type mechanism to fully support the arm which will be positioned just behind the elbow extended to just in front of the shoulder. That sling will be supported by a frame directly above the patient's bicep which is attached to their wheelchair. Considering that the patient has minimal arm movement, full adduction of the bicep will be hard to attain. A second attachment will be positioned at the wrist which connects to the same frame above the bicep. The purpose of the second attachment is to maintain the progress of the bicep adduction. There will be a device that will allow the second attachment to retract in and lock into place. That will allow progress to be made and maintained when the patient gets tired. From there, a release mechanism will allow the arm to lay back at rest to repeat the process.

Single Leg Holder



This design involves an arm like structure that supports the weight of the patient’s leg made out of PVC pipe. Attached to the PVC arm two elastic band that extend to the patient's thigh and calf. The elastic bands are then attached to the two different spots on the patient's leg with comfy cloth straps. This design would also have the ability to swivel, giving the patient maximum sideways mobility with their leg. Finally, this structure is attached to the wheelchair with a screw clamp, which allows the device to be removed or attached whenever needed.

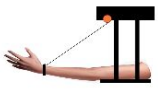
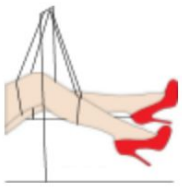
Double Leg Holder



This design will act as a frame which will fully support both of the patient's legs. The frame will be positioned above the patient's legs centered over the knee region. The frame will be one piece that attaches to the wheelchair on both sides. Hanging from the highest point on the frame will be two sets of two straps for the legs. The straps are going to be used to hold the patient's legs up to act as an antigravity mechanism. One strap will connect to her thigh just above her knee. The other strap will be positioned around her calf muscle just below the knee. PVC pipe will be the material for the frame that will attach to the wheelchair also with the capability to detach.

IV. Preliminary Design Evaluation

Design Matrix

Design / Criteria (weight)	Wrist Spring 		Finger Rockwall 		Retractable arm exerciser 		Single Leg holder 		Double Leg Holder 	
Ease of Use (20)	4/5	16	2/5	8	5/5	20	4/5	16	5/5	20
Comfortability (20)	2/5	8	5/5	20	4/5	16	4/5	16	4/5	16
Safety (20)	2/5	8	3/5	12	4/5	16	3/5	12	4/5	16
Ease of fabrication (15)	4/5	12	2/5	6	3/5	9	3/5	9	3/5	9
Durability (15)	4/5	12	3/5	9	4/5	12	3/5	9	4/5	12
Weight (5)	4/5	4	2/5	2	3/5	3	4/5	4	3/5	3
Cost (5)	4/5	4	3/5	3	3/5	3	5/5	5	4/5	4
Total (100)	**64**			**60**		**79**		**69**		**80**

* Scores are out of 5. Displayed as score | weighted scor

Table 1. The highlighted boxes indicate the highest scoring designs within each of the criteria.

Criteria:

Ease of Use: Ease of use is defined as how easy it is for the patient to use. The device needs to be easy to use for the patient the the person helping put the patient in the device. This is ranked as one of the highest because if the device is not easy to use, it will never get used. The point of making this device is so that it is easy to use and can be used to exercise the patient's arms or legs.

Comfortability: Comfortability refers to the comfort of the patient. Since the patient still has all feelings, the device needs to be comfortable to be in for a period of time. The device should be comfortable where it attaches to the arms or legs so the patient does not feel pain while exercising.

Safety: Safety is defined as the risk of danger presented to the user by performing an exercise on the device. This includes the risk of sharp edges and strength of device so that is does not collapse. Safety is weighted high because it is important that the user is safe and does not have any risk of getting hurt while using the device.

Ease of Fabrication: Ease of fabrication is defined as the level of knowledge and skill required to fabricate the model as well as replace any needed parts. This is not ranked as highly because the goal is for parts to be reusable and therefore fabrication and replacement should not occur often.

Durability: Durability is defined as the ability to withstand wear and pressure. The device should be strong enough to hold the patient's legs up and withstand adduction and abduction of the legs. The device should be able to last a significant amount of time if it is durable.

Weight: Weight refers to the weight of the device. The device should be lightweight since it has to attach above the Ki Mobility chair and be removable. Also, it needs to be lightweight so that it is easy to move and store, but strong enough to hold up the patient's legs.

Cost: Cost is defined as the combined price of initial fabrication components as well as any predicted replacement parts. Cost is ranked lowest because there is a not a set budget. This is because the device should be relatively cheap to make.

Scoring:

Wrist Spring: This design received a relatively high score for use because the device is simple to use. The patient's wrist is the only joint involved and only moves in a single plane. However, it scored low for comfortability because the device has very little support for the patient's arm and wrist.

The design received a low score for safety because of the potential pinch points and possibility the patient's hand could be forced into an awkward position. The device scored very high in the remaining categories of ease of fabrication, durability, weight, and cost.

It scored very high in these categories because the device would be easy to fabricate as the team would just need to find a torsional spring with a low spring constant. The wrist spring would also be cheap since there is not many parts that go into making it.

Overall, the wrist spring had the second to lowest final score since it would be uncomfortable for the patient, unsafe, and have little support for the patient's arm when using the device. Finally, the device would only be able to exercise the wrist in one plane of motion, limiting the effectiveness of the exercise.

Finger Rockwall: This design scored the lowest for ease of use because it is a little complicated to use. The hand must fit perfectly in the slot and then the fingers must be able to reach the steps in order to climb up the rock wall. However, it scored highest for comfortability because the arm rest on two foam covered bars and has nothing attached to the wrist or any straps that are attached to the patient.

The design received a middle score for safety because of the rock wall and the potential of getting the hand stuck in there once the fingers have climbed all the way up. The device scored lowest in the remaining categories of ease of fabrication, durability, weight, and cost.

It scored lowest in these categories because the rock wall would be hard to fabricate as the team would need to figure out the correct angle of the rock wall and the length of the steps. The rock wall could also be costly since it would have to be made out of a structural material but then be soft and comfortable for the patient.

Overall, it had the lowest final score since attachment to the Ki Mobility chair would be difficult and fabrication of the rock wall would be complicated. Finally, the device would be hard to use for the patient and would not give the patient the ability to exercise her entire range of motion of her wrist.

Retractable Arm Exerciser: This design scored highest for ease of use because there is only one range of motion that the patient will use. Also the device will fully support her arm which means that she will not have to worry about using additional muscles for stability. Ease of use also reflects on how easy it will be to get into the device. There are only two straps to connect and then the device is ready to use.

This device also scored highest for safety. There are very little areas where the patient would be in a situation to be hurt. The structure has very little room to collapse which means there are no concerns for the patient to have something land on her. The straps attached to her arm would be made out of a soft material. The only concern would be possible pinching if the attachment was not properly placed.

The score for comfort was also high. The only parts in contact with the patient are the two straps that attach to the arm. Those straps will be made out of a soft material that will provide nice comfort. Also the straps will fully suspend her arm in the air providing nice support.

Ease of fabrication is one aspect of concern for this device. The mechanism used to aid in lifting her arm that also stops in place when progress has been made will be hard to fabricate. A lot of problem solving would go into designing such a mechanism. Other than that mechanism, the rest of the device will be easy to fabricate.

Single Leg Holder: This design scored second highest for ease of use due to its high mobility and large range of leg movement. This structure can be easily attached and detached to and from the Ki Mobility chair, which makes it easy to use for the people putting the patient into the device.

This design also scored second highest for comfortability. This is because there are comfortable leg straps to hold the leg up. However, it did not receive the highest score because it is a single leg holder which might be uncomfortable to only have one leg hanging up.

It received a middle score for safety because the frame would only attach to one side of the Ki Mobility chair, making it unstable and more likely to fall over on top of her. It also gives the leg a wide range of motion, which could injure the patient if their leg was to swing too far out.

Ease of fabrication and durability received a lower score since it will be hard to fabricate the upper bar of this design due to the need for it to be adjustable and pivotable. Since the design only has a frame on one side of the chair, it makes it less durable.

This design scored highest in weight and cost because the design only has half the frame of the double leg holder it will weigh less and cost less.

Double Leg Holder: The double leg holder scored highest for ease of use mainly because the patients can exercise both of their legs at the same time. They do not have to detach the device and attach it again to the other side to exercise the other leg.

This design scored second highest for safety and durability because it has a stable frame that attaches to both sides of the Ki Mobility chair. This makes it more safe for the patient to suspend their legs in the device and more durable to handle the swinging of the patient's legs.

For ease of fabrication, cost, and weight, this device scored in the middle. This design will be harder to fabricate than the single leg holder because it requires a frame that attaches to both sides of the chair and a connector top bar that connects the two sides together. This design also requires more material making it weigh and cost more than the single leg holder.

Proposed Final Design:

Double Leg Holder: This device scored high in ease of use, safety, and durability because it is easy to use as the leg just hang in the leg straps, provides a stable frame to be structurally sound, durable, and safe. However, safety and durability only received a four out a five to to the fact that the team cannot guarantee the device is 100% safe and durable, but is more safe and durable than the other devices.

This design scored high in comfortability because there will be soft leg straps to hold the legs. Since there is two straps to hold each leg, the device will be even more comfortable for the patient as there is more support on each leg.

Ease of fabrication, weight and cost recieved middle scores because this design should be easy to fabricate since the frame has a simple design. However, the hard part about fabrication would be finding a way to connect the device to the Ki Mobility wheelchair. By using PVC piping as the material for the design allows for the structure to be lightweight and cheap. Being lightweight easily allows for the parents of the patient to attach and detach the device. PVC pipe is also rounded and softer than a steel type material, which is beneficial in the event the patient accidentally strikes the frame.

V. Future Work:

As the design process proceeds, more research will have to be done on the specific materials used for the exercising device. The design matrix lead us to the final design being the double leg holder idea. This design is relatively simple and should not be too complicated when looking for possible materials to use. The double leg holder idea primarily involves four distinct parts, being the bracket, PVC frame, leg straps, and leg holders. Research on these primary parts of the design need to be researched heavily if the team wants to make a well working design.

As of now the largest foreseeable difficulty is finding a way to attach and detach the device easily, while still maintaining the same structural integrity as if it was permanently attached. A mechanism that could possibly work for attaching the device to the wheelchair is a scaffolding double coupler (Figure 1). This type of bracket allows two different tubular shaped objects to be attached in a 90 degree angle. One of the tubes would be the bar on the side of the wheelchair, and the other would be the frame of the exercising device. This type of bracket would also make attaching and detaching of the device to be really easy with the simple turn of the tightening screw. Two of these brackets would be needed for both sides of the wheelchair to support the entire device. Another difficulty the team may run into is testing the device. Testing this device requires the team to go to the patient's house and attach the device to the wheelchair and the patient. Finding a good time to do this may be difficult as the patient lives a-half-hour drive away, and may not always be available to help us test the device due to scheduling issues. One way the team could resolve this problem is by setting specific dates far in advance, so the team can give the patient and family a good heads up. Planning will be a very important part going forward for the team to successfully meet deadlines and avoid leaving all of the work to the last few weeks of the semester.

Figure 1. Scaffolding double coupler [6]

Before fabricating begins, all of the materials need to be defined in order to get the idea of what the price of the device will be. If the team manages to keep the price of design low, the team's advisor agreed to cover the cost. If the price comes out to be relatively expensive, a proposal for money to the engineering department will be needed. If the project ends up to be on the expensive side, extensive research needs to be done on all of the materials to create a well defined and complete proposal. This task would be held accountable to the BPAG's.

The end goal of this project will be creating an exercise device that has the ability to give a patient with Type I Spinal muscular atrophy (SMA) a way to exercise. The difficulty of the exercise has to be applicable to a patient with Type I SMA. The patient has hopes of receiving a drug that will give her the ability to gain muscle like the average person. This exercising device would then play an integral role in helping her move in a way she has never had the ability to do before.

I. References

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[6] http://www.bfinternet.co.uk, "Scaffold Double Coupler (Drop Forged)", *Doughty-usa.com*, 2017. [Online]. Available: http://www.doughty-usa.com/cgi-bin/trolleyed_public.cgi?action=showprod_T24901.

Appendix

Product Design Specifications

Exercise device for child with profound weakness for use in a wheelchair
October 2, 2017
Advisor: Ed Bersu
Team Members:

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Function:

The device should be designed to help children with neuromuscular diseases such as Spinal Muscular Atrophy (SMA) find simple methods to exercise and gain or maintain their strength. The device should be compatible with the available Ki Mobility chair and will need to be capable of adjusting exercise intensity by different angles of flexion and extension.

Client Requirements:

- Device must exercise muscles in the legs, mainly focusing on abduction and adduction of the legs
- Device must be removable from the wheelchair.
- Device must be usable when the client is in a laying down position in Ki Mobility chair.
- Device needs to be positioned above the frame of Ki Mobility chair.
- Device needs to fit to the size of the client.
- Device should be lightweight

Design Requirements:

1. **Physical and Operational Characteristics:**

a. *Performance requirements:*

The device must effectively exercise a patient with SMA Type 1. This includes abduction and adduction of the legs. The patient must be able to fit easily into the device when in a laying down position. The device should also be attachable and detachable from the Ki Mobility wheelchair. Finally, the device should be reusable and have a consistent function.

b. *Safety:* Since the device serves child with SMA, the materials used must have no detrimental effects on patient's health. The device must have no sharp edges that might hurt the patient. The attachment to the patient must be comfortable since she still has full feelings in her body.

c. *Accuracy and Reliability:* The device should fit and have the capability to be used by a 10 year old with Type 1 SMA. The device should be reliable and able to withstand the movement of the legs after continuous use. The section of the model that attaches to the patient should fit properly while causing no pain to the patient. The device should have a uniformly smooth surface to prevent injury to the patient when using the device.

d. *Life in Service:* The device should last the lifetime of the patient, although parts may need to be adjusted as the patient grows.

e. *Shelf Life:* The device should be able to withstand multiple movements of the legs. The main apparatus of the device should last the lifetime of the patient, while some parts may need to be adjusted for the growth of the patient. The device should not be big and bulky and also easily stored.

f. *Operating Environment:* The model will mostly be used in a controlled, indoor environment. Under normal circumstances the device should not have to withstand extreme temperatures.

g. *Ergonomics:* The device should be able to handle movement of the legs while comfortably attaching to the patient.

h. *Size:* Since the device should last the lifetime of the patient, the length of the device should be adjustable so that it can fit the length of the legs at any point during the patient's life.

i. *Weight:* The device should be lightweight and should be light enough to transport and store with relative ease while having enough weight to support patients arms and legs.

j. *Materials:* Firstly, the device should be light enough so that SMA patients with profound weakness can use it to exercise effectively. Secondly, the material that may contact patient's skin should be antibacterial since the device is designed to last the lifetime of patients. Also,the material used should be affordable to common families.

k. *Aesthetics, Appearance, and Finish:* The device should be colorful as opposed to a bland color. Our patient has a personality in which they like things that are colorful. The texture should be smooth to minimize the risk of injury due to the fact that the device will be in direct contact with the patient.

2. Production Characteristics:

a. *Quantity: 1*

b. *Target Product Cost:* Less than 50 dollars

3. Miscellaneous:

a. *Standards and Specifications*: No regulatory requirements exist for this project at this time

b. *Customer:* The client wants a device that can be used to exercise the patient's legs and arms (universal)

c. *Patient-related concerns:* Needs to be comfortable for patient
d. *Competition*: The exercise device for patients of SMA type I is not common in market.