Stasia Mculsky

BME 8

Project Revision Proposal

4/18/18

**Patient-tailored orthotics treating Neurodegenerative and Trauma Injuries**

**Abstract**

There are many children suffering from neurodegenerative diseases, along with trauma, which then lead to other issues such as issues in the legs and feet that then need orthotics. These diseases include but are not limited to brachiosephaly, scoliosis, spinibifida, multiple sclerosis, lyme disease, connective tissue disorder, cerebal palsy, trisomy 12. In addition to diseases, strokes, trauma and anything really leading to a loss of oxygen in the brain cause issues often in the leg and foot area, needing to be treated with orthotics. Orthotics are often thought to be preventative, but due to the fact that I will be working in pediatric orthotics, these braces can also be corrective. Orthotics that have to ability to decrease the negative effects of these diseases are greatly necessary to increase quality of life for these children and decrease the negative future possibilities if their diseases are left untreated. Orthotics are a non-invasive, non-surgical, topical means of gradually treating the issues that arise with these diseases. Current treatments involve physical therapy, chiropracters, and other methods. The long term goal for this project is to develop orthotics that treat the patient, i.e. reshape the head in the case of brachiosephaly or lessen the planter-flex of an ankle of a patient suffering from spinibifida. The proposed study will create several different types of orthotics, being helmets or AFOs that significantly decrease the effects of the given disease. I plan to test the success of my devices by utilizes the normal measurement ranges dictated by the charts attached at the end of this paper as well as durability of materials, and comfort of orthotic.

**Intended Goal:**

My goal for this project is to understand the diseases being treated in the clinic such as cephalic diseases. Once I understand the diseases and gain proficiency in the anatomy and diagnoses, I want to dissect current treatments. I want to gain the skills of creating orthotics from being able to utilize the scanner and clean the image in CAD, to creating the mold, to cooking and shaping the polymer onto the mold and finally adjusting the pressure points so that the reshaping of the skull is successful. Once I have these skills down, I eventually want to do a little bit of polymer study to try and find a material that does not crack as easily or deform over time. I also intend on doing some research on prosthetics this summer and possibly incorporating that into my project. Long term, I want to design and build orthotics and prosthetics that are light weight, durable, corrective for the disease my patient suffers from and or successful replacements of the limb in the case of amputees.

**Introduction to Cephalic Diseases:**

Cephalic disorders, in relation to what I will be working on, are congenital conditions stemming from abnormal development of the skull. These disorders are present at or possibly before birth. The root of these disorders are relatively unknown due to the multitude of factors that play into them. Hereditary or genetic conditions are stated as a possible factor as well as environmental exposures during the mother’s pregnancy. These environmental exposures can include possible infection of the mother, radiation exposure, and medication ingestion. Cephalic disorders stem from several main issues in development such as the premature fusion of cranial sutures or disturbances in the fetal nervous system. While there is a large variety of the types of cephalic disease, in my work, I will focus predominately on Brachycephaly. This disease is defined as the result of “the coronal suture fus[ing] prematurely, causing a shortened front-to-back diameter of the skull. The coronal suture is the fibrous joint that unites the frontal bone with the two parietal bones of the skull. The parietal bones form the top and sides of the skull.” 5 Another type of cephalic disease is Plagiocephaly which is defined as the flattening of one side of the head, resulting in asymmetry and sometimes bulging of the forehead on the flat side of the skull. These are very common diseases in infants, quantified as about 1 in 5 babies.6

**ENGINEERING DESIGN ELEMENTS:**

The objectives are as follows:

1. Achieve a tailored orthotic that will treat a patient suffering from brachiocephaly/scoliosis by specifically applying pressure to certain points on their spine/skull (specific to patient). We chose this objective –that a device could specifically apply pressure because clinical research has shown at a young age a child’s skull is very malleable and can be manipulated to the correct shape with constant pressure/alignment techniques.
2. Achieve values in the range of normal, symmetrical skull range after typically around 9-12 months depending on the patient. If this objective is not met, then we will return to objective 1. Often times, if there is too much room in the helmet, it’s too tight, it rubs in the wrong way, certain parts need to be shaved down, etc it needs to be adjusted and refit.
3. Explore new polymer systems. This is because each polymer offers it’s own pros and cons and I want to focus on finding the best fit for certain orthotics.

I note that while the primary application if for patients with brachiocephaly and scoliosis, the techniques explored here represent a general platform that may also apply to patients with congenital deformities.

· ***What system, component, or process is to be designed? TOM***

I will have the ability to be building, molding, modifying orthotics addressing anything from scoliosis to deformities at birth.

· ***What need does it fulfill (clinical, research, etc.)?***

This will fulfill a clinical need of treating children who suffer from brachiocephaly, scoliosis and other diseases that inhibit their movement typically.

· ***What scientific, math, and/or engineering methods will be applied?***

I will be using a lot of force balancing in regards to creating the braces. I will also be using anatomy/kinesiology to understand how the body should move/versus how it moves with the disease currently. Lastly, I will be using some mechanical engineering in regards to physically building the orthotics.

· ***What realistic constraints (cost, safety, reliability, aesthetics, ethics and social impact, etc.) are to be considered.***  
Cost is always an issue in the healthcare system we have. In addition, the use of specific polymers is important because for orthotics you need pliable materials so that you can fit and mold them to the body part but not too malleable because they will lose shape over time. Aesthetics are also important because you want the child to feel confident enough to wear it otherwise compliance goes down and the effectiveness of the orthotic decreases.

· ***What alternative solutions or changes to the plan will be considered?***

I will look into different types of polymers for the materials. I will also look into ways to make the most supportive brace but the least restrictive.

· ***What are the planned tests and what are the quantitative milestones that will demonstrate achievement of the objectives?***

Having real life human patients makes this a very important, very hands on data experience. Patients are scheduled typically for bi-weekly reviews depending on the severity of the orthotic treatment. They come back in and get scanned and you can compare their scans. More specifically, in regards to brachiocephaly, we have charts that dictate measurements that fall under levels of severity. This is one concrete measurement to quantify success. (Will attach charts in paper).

· ***Competition: what else is going on in the field that would compete with the project plans?***

There are many different ways to create orthotics to help fix things such as scoliosis and other birth defects. For example, there are different materials used, different force balanced options (I.e. to fix toe balancing you push down on the calf rather than up on the toe). Other options for brachiocephalic include therapy and chiropractic care but the helmets I will be designing have been proven to be most successful. There is also one product currently on the market that has lower compliance due to the need to be cast but sleeker design which is the doc band. There is also the torticollis collar but it is very invasive.

**Specific Aims**

**Specific Aim #2: Develop helmet capable of reshaping a skull to normal range**

My hypothesis is that if we exert a force on the protruding part of the skull over a certain range of time, depending on the severity of the brachiocephaly/plagiocephaly that the skull will eventually be reshaped to normal dimensions. The expected outcome of this study is a helmet capable of fixing the deformity that does not cause irritation or pain and is lightweight enough for a baby’s neck to support. The way I propose treating this is by designing a helmet that will utilize force balancing. The intention is applying a pressure force on the extruding section of skull while concaving the helmet to allow alleviation of pressure on the flatter sections of the skull, enabling room for growth. This treatment must be done while the infant is still young, i.e. typically around the age of 4 months is ideal. The reason early treatment is necessary is this is when the skull is still malleable and therefore this helmet can actually reshape the skull, i.e. corrective. Depending on the severity of the skull deformation, the time of wear will vary, but we can assume it will be anywhere from 20-23 hours a day.

**Specific Aim #3: Assess material capabilities and try new types in the design process**

My hypothesis is that if I try different polymers in my design of the orthotics that they will provide more stability, less deformity over time and less chance of cracking. The expected outcome of this study is possibly a new standard of polymer used in standard orthotics practice. Currently, I intend to use aliplast for the foam insert in the helmet. A possible downside of this are there are some patients that suffer from aliplast allergies. In that case, I intend to use moleskin or a cotton liner instead. In the future, I might be able to discover a hydrogel that does not stick as much as moleskin (in turn easier to clean). PETG is another alternative for materials but it is very brittle so if the helmet were to be dropped it would crack. Another material alternative is copolymer. This is a good material to use because it is very durable. The downside of it is that it is difficult to open the helmet when made of this material. A method for making this easier to use is by adding a hinge to the helmet. The other con of this material is due to its stiffness, it can be sharp if not fully buffed by the orthotist. Lastly, I want to explore the use of polypropelene and in the future maybe silk.

**Technical Background**

**Studies Conducted:**

There is slight controversy over whether or not the cranial reshaping helmets are successful. The American Academy of Orthotists and Prosthetists released an article on the effectiveness of remolding helmets recently. The study was conducted on 128 infants with 62 receiving treatment (helmet) and 66 with no helmet intervention. In the helmet group, the babies were treated at 6 months old with a 10 month follow up while the non-treated babies were checked on after 18 months. The control group was allowed more time to see if natural correction of the skull shape would occur. The length of treatment should also be noted as the helmet group had a significantly faster treatment time, i.e. one third of the time for the non-helmet group. The authors of the paper stated “all infants showed a significant reduction of their plagiocephaly. Although children with helmet had more severe asymmetry initially, they showed significantly better improvement (68% vs 31%)…Despite concerns against helmet therapy (comfort, finances), it should be the treatment of choice for moderate to severe cases.”8 More recently, another study was conducted on a larger patient group of 4,378 children. Of the 1,531 patients who were treated with a helmet, 95 % of the infants experienced complete correction.9 “Complete correction was defined as a cephalic index below .85 and a diagonal difference (cranial vault asymmetry) of less than 5 mm. These journal articles along with hands on experience from the orthotists at Boston O&P make a compelling case of the efficacy of these helmets.

**Design Process:**

**Risk assessment**

|  |  |  |
| --- | --- | --- |
| Item Number | Risk | Mitigation |
| 1 | Orthotic may cause blisters due to excessive rubbing in bony, non cushioned parts of the foot | Utilize plaster bandages to create buildups over section of the foot where rubbing occurs, then use dental molding plaster to even the orthotic out, then rebuild orthotic using new mold with more space in the problem location. |
| 2 | Material used may lead to skin irritation | Materials such as the fiberglass wrap used to reinforce the prosthetic can cause irritation of the skin. We can prevent this by creating a lining in the brace that prevents interaction with the skin. We can also add moleskin or another substitute material that does not irritate the skin as much. |
| 3 | Materials deforming over time | Copolymer used for the frame of the brace will deform over time. We can fix this by remolding it or using a different polymer that has better resistance to deformity. |
| 4 | Orthotic may not place enough pressure to fix, for example, a misshapen head | We can go back and measure where the indentation is on the patient and then add either foam layers into the helmet to put pressure on the right spot and force the bump to go away. |
| 5 | Material, say in the toe plate, may crack | Sole flex firm can be added to strengthen it. Also sulcus pads can be added to lift the toes and decrease the pressure on the material. Lastly, we can test other materials to see if there is a more flexible option that doesn’t lose shape. |

**Timeline**

**September:**

Literature review on doc bands/other less bulky options, materials study (with professor Yi)

**October:**

Incorporate more materials into design (possibly silk) and build smaller helmets, maybe try to 3D print skull mold

**November:**

Conduct trials on success, comfort and validation tests

**December:**

Get patient feedback, cost assessments, FDA approval

Future Tasks

-downsize bulkiness and weight of helmet

-integrate different materials into helmet mold

-decrease irritation of helmet

References

1. “US9072340B2 - Lower Limb Orthosis.” *Google Patents*, Google, patents.google.com/patent/US9072340B2/en.
2. Parsons, F. G. “The Brachycephalic Skull.” *The Journal of the Royal Anthropological Institute of Great Britain and Ireland*, vol. 54, 1924, p. 166., doi:10.2307/2843666.
3. Marín-Padilla, Miguel. “Cephalic Axial Skeletal-Neural Dysraphic Disorders: Embryology and Pathology.” *Canadian Journal of Neurological Sciences / Journal Canadien Des Sciences Neurologiques*, vol. 18, no. 02, 1991, pp. 153–169., doi:10.1017/s0317167100031632.
4. Gianotti, Raffaele, et al. “Benign Cephalic Histiocytosis.” *The American Journal of Dermatopathology*, vol. 15, no. 4, 1993, pp. 315–319., doi:10.1097/00000372-199308000-00004.
5. “Cephalic Disorders Fact Sheet.” *National Institute of Neurological Disorders and Stroke*, U.S. Department of Health and Human Services, www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Cephalic-Disorders-Fact-Sheet.
6. *NHS Choices*, NHS, www.nhs.uk/conditions/plagiocephaly-brachycephaly/.
7. “Plagiocephaly Helmets.” *Technology In Motion*, www.technologyinmotion.com/plagiocephaly-helmets/.
8. Kluba, S., Kraut, W., Calgeer, B., Reinert, S., & Krimmel, M. (2014). Treatment of positional plagiocephaly – Helmet or no helmet? *Journal of Cranio-Maxillofacial Surgery,* *42*(5), 683-688. doi:10.1016/j.jcms.2013.09.015
9. Sestokas, L., Rawlani, R., Rawlani, V., Connor, C., & Vicari, F. (2012). Treatment Efficacy of Deformational Plagiocephaly and Brachiocephaly. *Plastic and Reconstructive Surgery,* *130*, 17. doi:10.1097/01.prs.0000421717.28128.4b