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Projects for BME 7 & BME 8 [Biomedical Engineering Senior Design I & II]
AY 2017-2018

PROJECT TITLE: Patient-tailored orthotics treating asymmetrical brachiocephali and scoliosis and patient-tailored lower limb prosthetics treating above and below knee amputations and hip distarticulations.

STUDENT(S): Stasia Mculsky

OTHER TEAM MEMBER(S): none

PROJECT TEAM LEADER: James Wynne and John Warren

PROJECT DESCRIPTION:
[This should be a paragraph that describes the ENGINEERING DESIGN aspects of your project.]

I will be working at Boston O&P in the lab at the Peabody and Boston Children's Hospital locations and MCOP in Allston. My goal will be to design several patient tailored orthotics that will reshape the heads and spines of patients suffering from brachiocephalic and scoliosis. I will also be designing several patient tailored prosthetics treating belowknee (BK), above knee (AK) and hip-disarticulation amputations. I will achieve this goal first by developing proficiency in the following areas: I will learn how to conduct scans of children's spines and other body parts to characterize the deformity, I will learn how to deisgn an orthotic based on those images and finally how to build an orthotic that places pressure in specific parts to realign or attempt to straighten out spines/skulls inflicted with scoliosis and brachiocephali. To achieve the latter goal, I will learn how to cast and produce molds from my patients residual limb, build a socket from the mold and then build the rest of the leg utilizing mechanical engineering and physics. To measure success for my orthotics, I will utilize skull measurements and the normal ranges to base my success off of. Typically, these orthotics will be checked every few weeks with full success hoping to be achieved in 9-12 months. To check the success of my prosthetics, I will analyze the gait gate of my patient, check pressure spots, modify my sockets and adjust alignments of the legs. I will work closely with my mentor on all clinical aspects of this project including fitting the device to the patient and monitoring recovery and those clinical feedbacks will drive future device designs.

ENGINEERING DESIGN ELEMENTS:
[1-2 sentences in response to each question below should specify the engineering design components of each project]

- ***What are the objectives of the project and the criteria for selecting them?***

The objectives are as follows:

1. Achieve a tailored orthotic that will treat a patient suffering from brachiocephalic/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.
4. Achieve a tailored prosthetic that will treat a patient post amputation/congenital limb loss by creating a socket that is comfortable, does not cause soft tissue damage and can handle body weight applied.
5. Achieve a hip/knee/ankle prosthetic that allows a normal gate, prevents whip, is durable, water proof, and serves as a functioning replacement of the limb lost.
6. Explore new materials used in the creation of the prosthetics. Certain materials are common place but we want to focus on new innovative materials to decrease weight of the socket, increase durability, make it more cost effective. Seems to overlap with Point #3

Clarify which condition this is for

How to assess over course of fall term

It would help to define different polymer systems here

I note that while the primary application if for patients with brachiocephali 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 prosthetics addressing anything from scoliosis, deformities at birth, and all lower limb amputations.

Some more detail about How you tailor the orthotic to the patient would be helpful here

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

This will fulfill a clinical need of treating children who suffer from brachiocephalic, scoliosis and other diseases that inhibit their movement typically. In addition, many veterans, trauma patients, cancer survivors, and congenital limb loss patients are in need of prosthetics to allow them to walk, drive, and fulfill daily basic tasks.

How do you measure forces?

- ***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/prosthetics. 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 and prosthetics and chemical engineering in my materials studies.

- ***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. Certain materials used in government labs treating veterans are not accessible in private practice. This will drive my search for strong, cost effective, low weight materials to use in my prosthetics. 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/amputee to feel confident enough to wear it otherwise compliance goes down and the effectiveness of the orthotic/prosthetic decreases. Lastly, in relation to the prosthetics safety is a big focus. In the case of lower limb amputations, when designing the prosthetics we must add some safety features such as lock systems so that the leg does not buckle under the patient and cause a fall risk.

Do insurance companies place any constraints? (I really don't know answer to this)

- ***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. There are several joint options to consider for the prosthetics, including hydraulic systems.

Can you suggest a design change?

- ***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 monthly reviews depending on the severity of the orthotic treatment and biweekly for the prosthetics. They come back in and get scanned and you can compare their scans. More specifically, in regards to brachiocephali, 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). For the prosthetics, socket fit is crucial. Making sure the soft tissue is not degrading or being pulled off the bone is key. Analyzing the gate of the patient,

gait

making sure there is no whip, checking the alignment and assessing patient comfort are all tests needed to be done to ensure the best product.

- ***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. In the case of prosthetics, there are so many options for lower limb amputations. I plan on analyzing skin fit sockets, pin and lock systems, liner fits and other options to determine how my final products compares and what I can pull from each system to make mine the strongest alternative.

Are there any commercial products upon which you would improve?