



Designing an Adjustable Below Knee Prosthetic for Children

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BACKGROUND

Current prosthetics pose several problems for children including weight, comfort, durability, and fit. Most importantly, they do not grow with the child as the healthy leg bones grow. This causes families to have to replace the prosthetics approximately every two years [1]. With below knee prosthetics cost ranging from approximately \$6,400 to well over \$46,000, continually replacing prosthetics becomes a financially stressful task for the average family [2]. Creating an adjustable prosthetic will address the need of having to replace prosthetics as well as provide the opportunity to analyze other problems. A lightweight prosthetic with a socket that properly fits the child's stump will be critical to improving the comfort and minimizing the amount of the socket wounds the child will experience. Not compromising functionality and durability for cost will be crucial in creating a realistic prosthetic that will not only withstand, but also assist a child in their daily activities of playing, running, walking, and standing. The goal of this project is to reinstate a child's physical independence while satisfying the ultimate prosthetic function of replacing an unhealthy tibia to the highest accuracy possible. In order to classify a child's leg size, the ASTM D6458-12 size standards were used. Child sizes were chosen to be ASTM size 8 through 20 (Table 1). All testing was done in comparison to these sizes [3]. Functional comparison was made in accordance with the US Health Care Financing Administration MFCL system [4].

Table 1: Summary of adjustability requirements of ASTM size characteristics 8 through 20 [3]

ASTM Size	Height (in.)	Average Weight (lb)	Calf Girth (in.)
8	52	65	10.5/8
20	69	140	14

OBJECTIVES

The prototype goals were:

1. To create a prosthetic which will fit ASTM sizes 8 through 20

* The socket to be able to grow approximately 1.07 inches in diameter and the pylon to be able to grow approximately 2.83 inches in height

2. To design a K4/Level 7 functioning prosthetic [4]

* The pylon be able to support at least 438 lb of force with a safety factor greater than 3

3. To be cost effective

* To have a total prototype manufacturing cost under \$500

4. To design a comfortable prosthetic

* Reduce all socket shear stress to under 0.58 psi

The prosthetic was designed and tested using Solidworks CAD software. The prototype socket was 3D printed from a Stratasys Connex 500 printer while the pylon was manufactured using aluminum.

PROTOTYPE SOCKET

The socket attaches to the stump through four methods:

1. Two supports run up the medial and lateral sides of the tibia, knee, and femur connecting the socket to a strap that goes around the femur
2. Two bladders are then wrapped around the stump prior to putting it inside the socket (Figure 1, 4).
3. The stump is connected to a piece of Velcro inside the socket (Figure 2)
4. A strap is then wrapped around the socket just below the knee (Figure 3)

In having several contact points throughout the stump, knee, and femur, it is theorized the socket will move more directly with the femur and tibia bone. This will then minimize the shear stress induced on the stump further reducing the skin damage caused by a prosthetic.

The lateral and medial supports of the socket are locked at a 90 degree, to the socket, simulating a true extension of an amputee's tibia allowing the bottom of the stump to be loaded directly on the bottom of the socket, which has 1 inch of high density memory foam as well as a 0.25 inch gel loading pad to minimize load impact from jumping or running. The rest of the socket is lined with 0.25 inches of slow recovery polyurethane foam and 0.125 inches of polyester-PVC foam mesh covered with a fabric lining helping reduce possible shear stress.



Figure 3: Picture of the prototype socket

The socket is adjustable at four locations (Figure 3, 4):

1. The bladder has two easily accessible pumps and release valves allowing for finite adjustment inside the socket
2. Two straps, one each on the tibia and femur, can adjust to custom girth
3. Interchangeable backbone supports can adjust to custom height
4. The two lateral and medial supports can adjust laterally 2 inches



Figure 1: Air bladder inside a fabric cover which will wrap around the stump



Figure 2: Top view of the socket, where a piece of Velcro attaches to the bottom of the stump



Figure 4: A top view of the bladder. A valve decreases the air volume while an attachable hand held pump can increase the air volume

PROTOTYPE PYLON



Figure 5: The pylon top piece fitting overtop of the bottom piece

The pylon is composed of two pieces both made of aluminum. The "top" piece comfortably fits over the "bottom piece" (Figure 5). Slot options are listed in growing height with Slot A connecting the top piece to the shortest pin hole, in the bottom piece, and Slot I connecting the top piece to the tallest pin hole, in the bottom piece (Figure 6).

The prototype is able to successful adjust between ASTM sizes 4 through 18 through 9 slot options (A, B, C, D, E, F, G, H, I). It easily supports the predicted max jumping forces, which were modeled as:

$$3.0 * (\text{maximum body weight of ASTM size}) [5]$$

During FEA, the highest Von Mises stress the pylon experienced was just under 4,300 psi, which is much smaller than aluminum's yield strength of approximately 35,000 psi (Table 2). Additionally, it was concluded the max deformation values in the X or Y axis directions will not produce any visible deformation to the structure.

Table 2: Summary of the FEA results of the aluminum pylon for Slot A (the shortest pylon height) and Slot I (the tallest pylon height)

Slot	Height (in.)	Max Force Imposed Jumping (lb)	Max Von Mises Stress (psi)	Max Deformation X Axis (in.)	Max Deformation Y Axis (in.)	Factor of Safety
A	7.06	129	1367.2	2.41e-5	-1.79e-5	29.2
I	11.06	405	4297.2	1.02e-4	-6.23e-5	9.3



Figure 6: Images of the pylon prototype at its shortest height, slot A (left), and its tallest height, slot I (right)

CONCLUSION

Overall, the socket itself can comfortably fit ASTM sizes 6 through 18. The pylon can adjust to fit ASTM sizes 4 through 18. Together, the prosthetic can fit ASTM sizes 6 through 18, almost satisfying Objective 1. The prosthetic can easily withstand the approximate forces of a child user jumping, satisfying Objective 2. The entire prototype prosthetic cost under \$500 for materials and manufacturing, satisfying Objective 3. Lastly, the entire prosthetic weighs under 2 kg, without the foot.

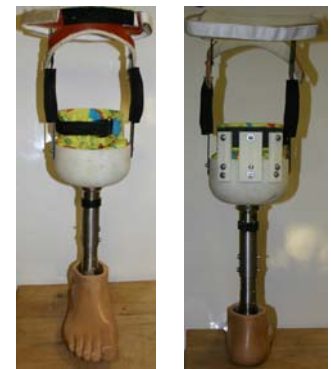


Figure 7: (Left) A front view and a (Right) back view of the prototype adjustable below knee prosthetic

FURTHER WORK

The next step for the project is to work towards quantitatively satisfying Objective 4. This will be done by approximating the shear stress in various areas of the socket through experimental trials and finite element analysis in order to eliminate possible high pressure points leading to skin tissue damage. Additionally, conducting user surveys in regarding comfort including breathability, weight, and aesthetics. Lastly, the entire prosthetic's induced gait will be analyzed.

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