Translational Imaging using Telemedical Modalities for 3D Printed Medical Devices

Team 3DMD

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Abstract

Clubfoot is the most common musculoskeletal birth defect in the world and is characterized by inwards rotation of the ankle in one or both feet. Once diagnosed at birth, infants require immediate treatment to correct the disorder. The current standard of care for clubfoot treatment is known as the Ponseti method, and involves the use of six to eight separate corrective casts worn for up to a week each. Few physicians are specialized enough to treat clubfoot, and the casting methods used are bulky and outdated. There is a need for a faster, more efficient method to produce personalized casts for treatment of this musculoskeletal defect. We plan to improve upon this method by developing a 3D-printed casting system that is fully customizable to a particular patient's physiological dimensions. In order to make this system widely available, we plan to transform an everyday mobile device into a 3D scanner used for clinical applications. This technology will allow cheaper and more widely available clubfoot treatment with efficacy comparable to current standards.

The three main objectives of this project are:

- To obtain a 3D simulation of an individual's appendage with accurate anatomical measurements specific to that patient.
- To design a 3D-printed, predictive cast model for clubfoot treatment based on a 3D-scan of the area of care.
- To generalize and expand our translational cell phone imaging technique to other orthopedic applications.

Introduction

Congenital talipes equinovarus, also known as clubfoot, is the most common musculoskeletal birth defect, occurring in 1.2 of every 1,000 newborns worldwide. Clubfoot is a congenital deformity characterized by inwards rotation of the ankle in one or both feet. The condition is composed of four distinct deformities of the foot that must all be corrected in order to prevent lifelong disability [1]. The treatment is relatively simple, requiring rotations of the foot and a series of casts to set the bone in a technique known as the Ponseti method.

Technology and Value Proposition

We propose a novel 3D-printed corrective brace system that will provide clubfoot realignment at efficacy comparable to Ponseti casting with improved convenience and simplified application. Images will be captured from multiple angles will be registered using MATLAB's Image Processing Toolbox. Key measurements of the foot will be used to modify a parametric CAD drawing of the brace to fit the patient. The cast design will then be altered to apply the needed adjustment to foot alignment. Patients will follow typical Ponseti Method timeline, but receive 3D-printed braces to be replaced at the same frequency as traditional casts. Current patents exist that aim to create custom casts for design and fabrication, but do not incorporate our 3D-printing aspect [2]. 3D camera cell phones have been developed, but have not yet been applied in medicine [3]. We plan to turn a smartphone into a mobile imaging device, and based our art searches, we have the freedom to operate and create our product.

To date, we have begun the process of translating a live, 3D model into a 3D image. Using Autodesk 123D Catch, we have successfully used a smartphone to scan a model of a baby foot and produce a 3D image. Our future work includes showing that we can take that 3D image and transfer it into AutoCAD or SolidWorks. Using this design program, we will create a specialized cast that corrects clubfoot by mirroring specific angle measurements as detailed in the Ponseti method. Finally, we plan to print out this cast and the end product will be a cast worn to correct clubfoot.

For both our family and physician customers, 3DMD seeks to increase efficiency and reduce the time it takes to receive corrective castings. Creating customized 3D-printed casts for newborns with clubfoot minimizes the workload of orthopedic surgeons and the time families spend in hospitals. In the United States, the average wait time to see a physician is 23 minutes, and identifying methods to reduce these delays are becoming increasingly important. With 3DMD, cell phone images of the foot may be sent from the nurse to the physician, and during routine cast changes, the physician may not even have to personally visit each patient. In addition, instead of travelling to specialized hospitals that are equipped to deliver corrective casting methods, families can visit their local primary care office for cell phone imaging. These images can then be sent to the specialized physician, who can order a cast to be printed and mail that cast directly to the family. Other advantages of our design is that it is breathable and less restrictive than traditional casts made of cotton padding and plaster.

The development and unification of these two technologies – a parametric predictive model for clubfoot treatment and a translational biometric smartphone imaging platform – is the first step in the realization of a low cost 3D-printed casting series for implementation of the Ponseti Method. By combining predictive treatment modeling and a translational smartphone imaging platform, our method would minimize the training required for traditional casting to correct clubfoot. Successful adaption of our innovation results in increased efficiency and reduced hospitalization periods. Eventually, our technology may be used in other applications where translating 2D images into 3D printed objects is useful. The smartphone image analysis software developed will be made open source and easily modifiable, so that others may explore new applications of translational parametric smartphone imaging.

Business Model and Market

The target market for implementation of this technology is health care professionals treating clubfoot and their patients. As previously mentioned, there is a need for a more efficient, timely, and cost effective method to develop personalized casts for the treatment of clubfoot. Although our software and cast design will eventually be implemented in a variety of orthopedic uses, we plan to target this niche market for our product launch.

Clearly, technology and society are now in a more advanced position than when plaster casts were first implemented. Traditional casts are outdated, bulky, and do not fulfill the customer's needs. Our 3D printed cast design will provide customers with a lightweight, minimalist brace that is still capable of generating the compressive forces needed to correct orthopedic problems. These features are especially advantageous in infants with clubfoot, as they will increase comfort and allow physicians to monitor the health of the skin and examine bone setting without removing the cast. Additionally, our design eliminates the need for the patient to see a specialist. An affiliated clinician or nurse can simply scan the patient and send the images to the clubfoot specialist, who can print the cast design and send it directly to the patient.

In order to successfully launch this product, we plan to market to and work closely with health care facilities and orthopedists who specialize in clubfoot treatment. Although parents of affected infants are our primary customers, as they are paying for the treatment, it will be more beneficial to market to physicians, because they will understand the clinical relevance of our design. The software and 3D printing supplies necessary to manufacture custom casts will be sold to hospitals and facilities that are staffed with these specialized orthopedists. We plan to sell primarily at medical conferences, trade shows, and through marketing representatives that will visit clients on-site. In order to use our product, physicians will need to be trained by our support specialists. These specialists will maintain a relationship with the customer to help with any questions and problems that may arise through the life of the device.

3DMD owns the rights to the use of a mobile device as a 3D scanner in a clinical setting. We plan to obtain a patent on this technology to ensure that it remains within our rights.

Team

We have assembled a team of 4th year undergraduate biomedical engineers, who each bring a variety of diverse backgrounds and interests to this project. Nathaniel Braman, practiced in parametrization and accomplished in his use of CAD software, will be managing development of the actual software for image translation. Attiyya Houston, experienced with coding and AutoCAD design, will be assisting in developing the program's algorithm. Melena Mendive functions as a project coordinator, cataloging meetings and task and managing deadlines. She and Simeng Miao handle formal correspondence with our advisors and any outside entities as well as assessment of the design's adherence to its clinical context. Team member Miao handles the website and keeps everything within that realm updated.

Our advisors are professionals who can guide us during this project. Dr. Jonathan Schoenecker (Vanderbilt University Medical Center, Nashville, TN) is a pediatric orthopedic surgeon who will ensure that our project maintains clinical relevancy. Another orthopedic surgeon, Dr. Jeffrey Willers (Elite Sports Medicine and Orthopaedic Center, Nashville, TN), will also provide us with medical experience. Dr. David Owens (Vanderbilt University Owen Graduate School of Management, Nashville, TN) is an entrepreneur who will contribute his extensive management expertise. Our project sponsor is Dr. Matthew Walker III (Vanderbilt University, Nashville, TN), associate professor of the practice of biomedical engineering.

Work Plan and Outcomes

Our timeline of milestones to complete is presented in Table 1. This project can be divided into three major constituent goals: (1) to develop a predictive model of clubfoot treatment from 3D models of clubfeet constructed throughout the Ponsetti casting process, (2) to create a versatile image processing tool that can turn a smartphone into a translational modality for clubfoot imaging, and (3) a unifying software that customizes the predictive correction software to each patient's specific deformity and treatment needs using biometrics extracted from smartphone images. Our successes will be measured by the major milestones we reach. Our first intention is to survey more potential customers, which include orthopedic surgeons who treat clubfoot cases and families affected by clubfoot. Success in our technology includes demonstrating that our software simulates cast design after scanning the foot. Once these images are scanned, we will be able to continue to the next step of our project, which is to print a physical prototype of the cast at each stage of correction. Finally, our long-term goal is to successfully correct a child's clubfoot using our innovative product.

Goal	Description	Estimated Completion Date
1. Obtain models of clubfoot	Realistic models that provide us with correct dimensionality and degree of clubfoot	October 2014
2. Generate 3D cell phone image of foot	Translate clubfoot models into 3D images using existing open-source scanning software (123D Sketch)	October - November 2014
3. Develop software which will transfer 3D images to a computer	Send the scanned images from the cell phone to a computer program that allows us to change dimensions of the foot and create a customized cast	November 2014 - January 2015
4. Acquire necessary measurements from 3D image	Calculate individualized measurements of foot length and curvature from scanned 3D images	January 2015
5. Calculate cast measurements using the Ponseti method	Identify the current curvature correction and apply these increments to our model	January - February 2015
6. Print first prototype	Using PLA, print the first prototype cast	February 2015
7. Prototype testing using phantom	Assess fit and viability of initial prototype printed	February 2015
8. Analyze and improve on prototype	Optimize pattern placement and test compressional strengths and mechanical properties	February 2015 - April 2015
9. Identify the best cast material to use	Based on desired material properties of casts, we will decide on material(s) that will be used to print the final product	March 2015
10. Design completed	Completed design to present on Design Day	April 20, 2015

Table 1. Estimated timeline for completion of product

Appendix

1. Budget Justification

1. *Personnel*: We currently have no plans of reimbursing our group members during the early stages of ideation and product design.
2. *Consultants*: Our advisors have volunteered and contributed their time to guide us.
3. *Equipment*: We are budgeting $500 to cover anticipated rental fees that will allow us to use more advanced 3D printers.
4. *Travel*: We do not yet anticipate requiring any reimbursement for travel.
5. *Supplies*: We expect that purchasing any needed 3D printing materials will required approximately $300.
6. *Consortium costs*: Our team will be fully responsible for all required project labor.

Total budget: Approximately $800

2. Supporting Images

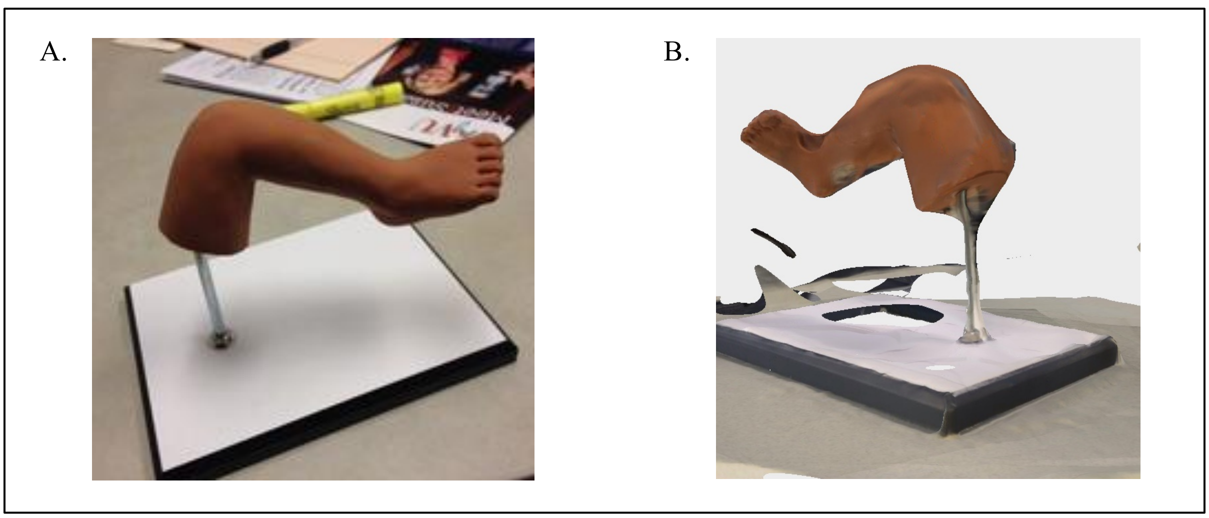

Figure 1. A The model leg obtained from Dr. Jonathan Schoenecker at the Vanderbilt University Medical Center, and **B** the first scanned leg image using 123D Catch.

References

1. M. B. Dobbs, C. A. Gurnett, Update on Clubfoot: Etiology and Treatment. *Clin. Orthop.*. **467**, 1146–1153 (2009).
2. Patent CA2740797 A1. Custom braces, casts, and devices for designing and fabricating
3. Patent CN103379215 A. 3D camera cell phone