FABRICATION OF CUSTOM DYNAMIC PEDORTHOSES FOR CLUBFOOT CORRECTION VIA ADDITIVE-BASED TECHNOLOGIES

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ABSTRACT

Additive technologies have created many opportunities to improve the quality of life for patients in a range of medical applications. This paper provides an overview of how several of these technologies were leveraged to transform custom pedorthosis designs into physical, end-use, custom pedorthoses for clubfoot patients. The pedorthoses that were produced are currently being tested on the respective patients for their improvement in mobility and degree of clubfoot correction, and will continue through early 2010. The advantage of this approach is the reduction in labor and the increase in degrees of design freedom available, compared to conventional methods of fabricating orthotic devices. Several new approaches for fabricating custom orthotic devices that were explored, and the related results, are discussed.

1. INTRODUCTION

Purpose

The purpose of this research was to determine the most-practical means of transforming computer-aided-design (CAD) models of custom clubfoot pedorthoses into functional pedorthoses for testing on patients in a clinical trial. The general pedorthosis design included two mating layers (one of variable thickness), each having specific mechanical properties required to achieve the desired pressure distribution across sole of the patient's foot. Precisely producing the variable-thickness regions is a significant challenge for conventional methods that use laminated foams and thermo-formed layers.

The goal of this paper is to convey the potential of the fabrication procedure used and lessons learned on this project to the rapid-prototyping and orthotic communities. To that end, the complete procedure and results-to-date are discussed herein.

Scope

The main challenge of this research was identifying the ideal method for reproducing the somewhat complex, variable-thickness pedorthosis geometry, using appropriate materials. The targeted goals were: fabricating a custom-fitting pedorthosis to aid in the correction of clubfoot;

using a stiff outer shell and low-stiffness inner layer for proper pressure distribution; and, producing a pedorthosis durable enough for daily use.

A number of options were considered, including direct additive manufacturing, a hybrid combination of a conventional approach and additive fabrication, and several other more-traditional material-removal approaches. The options explored are all described in the following "Background" section of this paper. Although the approach chosen is not considered the long-term optimal approach, it was the most practical within the timeframe of this project, and can achieve an outcome not obtainable by conventional orthosis-fabrication techniques. Timing and performance were the primary constraints driving the scope of this project.

Background

Conventionally, pedorthoses are created by an orthotist using a well-defined, widely accepted (standard) procedure to make a mold from the patient's leg, requiring several fiberglass and plaster castings and thermal-forming steps. The procedure begins by capturing the foot, ankle and calf in a fiberglass casting applied to the patient's skin. Upon curing, the "shell" is cut away from the patient[1], and re-closed using adhesive tape to form a mold. Next, plaster is poured into the fiberglass-shell mold, resulting in a reproduction of the patient's lower limb under a no-load condition. Once the plaster is cured, removed from the mold and smoothed, the required foam pads are held in place against the plaster as a heat-softened polypropylene (or polyethylene) sheet is wrapped around the entire setup and crimped shut. A vacuum is then used to pull the plastic against the plaster and foam pads to form the pedorthosis.

For clubfoot patients, these conventional pedorthoses are generally only intended to improve the comfort of the patients. Because the casting was conducted under no-load conditions, correction of clubfoot is ***not*** considered.

This work supports a collaboration between Dr. Robert Rizza of MSOE and Xue Cheng Liu, Ph.D, MD of Children's Hospital of Wisconsin & Medical College of Wisconsin, that is funded by the U.S. Department of Education under Grant No. H133G060142, to define a process of mapping a clubfoot patient's pressure distribution across the sole of their foot as they walk (loaded) and calculate the geometry of the pedorthosis required to correctly re-distribute the loads for a more normal gait.

These custom-designed clubfoot-corrective pedorthosis designs have several challenging features that conventional methods of orthosis production cannot accomplish; therefore, the relatively new technologies of 3-D scanning and rapid prototyping (RP) were identified as key enablers for this project. Unlike traditional material-removal fabrication techniques, such as computer-numerically-controlled (CNC) machining, rapid prototyping is an additive process, starting with an empty build platform, and adding material one layer at a time, on top of the build platform, to create a 3-D object (Figure 1). CAD data is used to define the exterior and interior surfaces of the solid 3-D object, making complex part geometries, as well as complex internal structures, possible and commonplace. RP is a subset of a broader group of layered manufacturing processes titled "Additive Fabrication."

[1] Special cutting tools are used to minimize the potential for harming the patient.

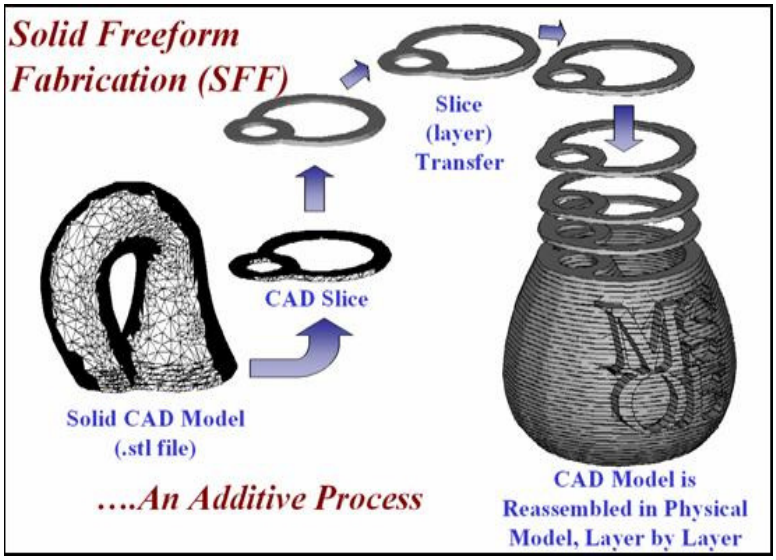


Figure 1: Conceptual image of Klein-bottle fabrication in layers, exemplifying the capability for directly fabricating complex geometries.

Additive manufacturing has made a tremendous impact in changing the methods used to produce many custom personal products, such as hearing aids and dentures. In a growing number of examples, "traditional manufacturing" methods are no longer competitive with this expanding technology for "growing" one-of-a-kind, end-use parts.

AM provides an ideal approach for generating the custom, end-use hard- and soft-layer patterns: each pedorthosis is truly unique; and, the soft layer has regions of variable thickness.

2. FABRICATION OPTIONS

The goal of the fabrication portion of this project was to construct a functional dynamic pedorthosis with a hard shell and a soft inner layer, based on designs generated by finite-element-analysis (FEA)-refined CAD models, to accommodate the specific functional requirements. The hard-shell region needed properties to provide strength and support, i.e. serve as the backbone of the pedorthosis, with equivalent or comparable properties to polypropylene or polyethylene currently used. The soft inner layer needed to have closed-cell-foam-like properties comparable to the ACOR® ethylene-vinyl-acetate foam product currently used for orthotic padding, with an effective elasticity of 128psi and durometer of 35 Shore A (1).

Unfortunately, the aforementioned materials used in conventional orthosis fabrication are not yet available for solid free-form fabrication; therefore, to fabricate the pedorthoses, several approaches were considered, including direct manufacturing, additive-based molding, laser cutting of foam and combinations of several of these approaches. The soft layer needed to be durable and provide a good recovery after being compressed for a length of time.

Direct manufacturing provides an ideal approach since the foam layer, represented by a fine lattice structure whose effective stiffness is lower than the constitutive material (“artificial foam”), and the hard shell could potentially be grown as one integrated part using a process such as 3D Systems’ Selective Laser Sintering® (SLS) or Objet’s PolyJet™ 3-D printing.

While 3D Systems does provide a polypropylene material (DuraForm® PP 100) (2), it has only been available for about one year, and only through their Preferred Service Providers (3). The testing required to determine the feasibility of directly manufacturing fine “artificial foam” structures is better done in-house. There is also some concern about the constitution of its blend with respect to prolonged skin contact. This material will be pursued further in future efforts.

Polyamide (nylon) is an option for SLS (DuraForm® PA) (4); however, there was significant reluctance on the part of several team members in using this nylon material for the immediate application, due to concerns over acceptance by the orthotic community.

Regarding PolyJet™ 3D-Printing, the materials are too stiff for the artificial foam (5). Functionally-graded solid materials are quite feasible, and may be used in future applications. Currently, there are no medical-grade materials available from the Polyjet® 3-D-printing technology.

Additive-manufacturing-based molding was another option for this project; and, several approaches were available including direct-mold and pattern-based. The first approach uses additive manufacturing to grow molds derived from the CAD of the desired part, accounting for shrinkage and de-molding challenges.

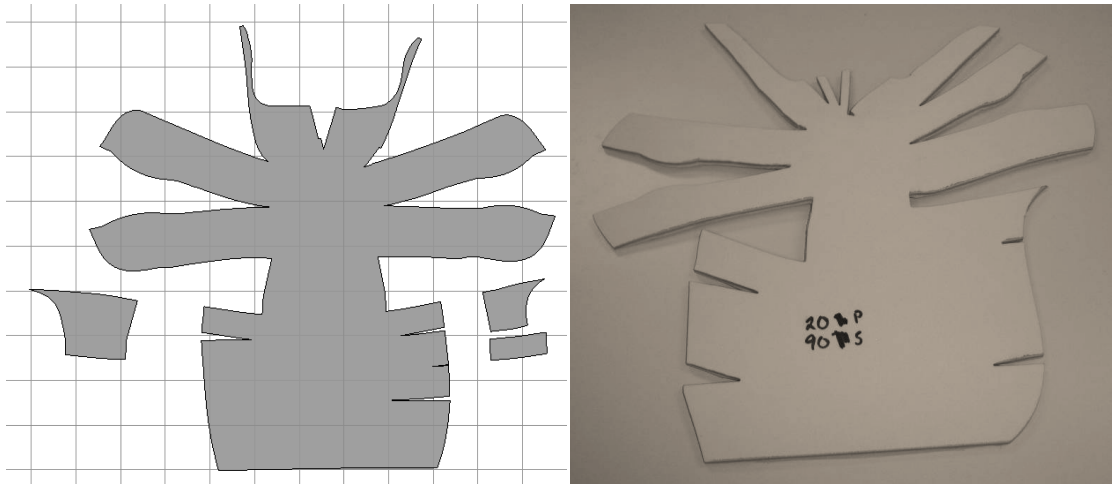
A pattern-based approach can also be used to create a mold, without the need for a respective CAD design. Room-temperature-vulcanizing (RTV) silicone resin can be cast around the positive pattern. By cutting into the cured silicone to remove the pattern, the mold parting surfaces are created. Venting and gating can then be added as needed.

For either case the final mold is filled with the desired casting material; and then, upon solidification, the mold is opened to reveal the final part. This approach is desirable because multiple parts can be made from one mold; and, a range of materials are available. Undesirable is the added labor of going from a final CAD model of the desired part to a molded part, and the time associated with the added steps.

For this project a pattern-based RTV-silicone molding process was used to produce the closed-cell polyurethane inner layer of the pedorthosis. If molds had been grown, the Z-corp 3-D-printing process in plaster would have been the preferred method due to the high speed, low cost, and applicable wax coating (that releases cast polyurethane readily).

Laser-cutting of the soft layer was another option that was explored. One prototype and one bi-lateral set of a patient’s orthoses were produced using this method. The soft-layer CAD model was “smashed” using McNeel’s Rhinoceros® 3-D NURBS modeling software (Figure 2, A) resulting in a CAD model that was flattened much like an unwrapped world map (6). The pattern was then laser-cut into a closed-cell ACOR® foam (Figure 2, B); and, the resulting foam

cut-out was laid-up and adhered to an SLS polyamide hard shell (Figure 3). These pedorthoses were functional; but, producing variable thicknesses was a significant challenge. Additionally, there was concern that the pedorthosis would deteriorate at the seams. For these reasons, this method was abandoned for this project.



A B

Figure 2: (A) Rhinoceros® 3-D CAD model of a smashed soft-layer pattern and (B) a laser-cut pattern in ACOR® foam.

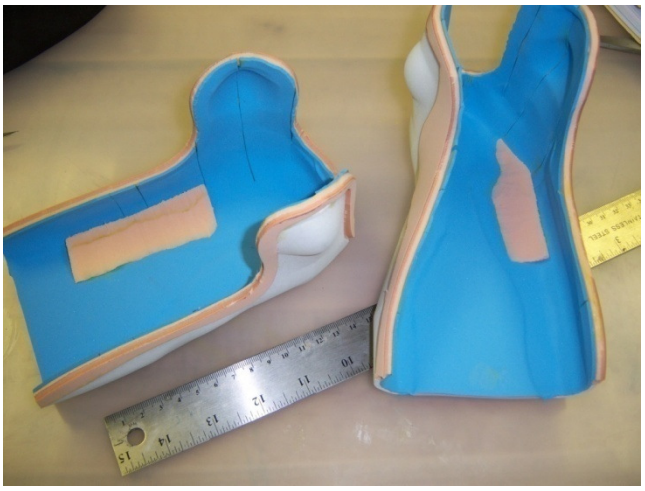


Figure 3: Laser-cut ACOR® foam folded and adhered to a hard SLS polyamide (nylon) shell. The blue foam is the thinner foam lining; and, the pink foam is thicker for corrective support and cushioning of the patient's foot.

3. SELECTED APPROACH

The approach used to fabricate all of the pedorthoses for the clinical trials was a combination of AM of the hard shell and additive-based molding of the soft layer as follows:

A. **Hard Shell:** The hard-shell layer was additively manufactured in the Milwaukee School of Engineering's (MSOE) Rapid Prototyping Center® using 3D-Systems®' Selective Laser Sintering™ (SLS) with DuraForm® PA (4).

Step 1. The CAD model was positioned to align the sole of the orthotic to the build direction (parallel to the build platform).
Step 2. The SLS laser settings were appropriately set to a power based on the glaze-test before the build to provide a tough, resilient part (Figure 4).

Figure 4: Hard shell of one custom pedorthosis produced in the Milwaukee School of Engineering's Rapid Prototyping Center® on a SLS machine.

Step 3. Upon completion of the orthotic, the part was cleared of loose nylon powder.
Step 4. Several sharp edges were filed or sanded off to reduce potential for foam wear and discomfort to the patient. These edges were not easily removable in the CAD model due to the complexity and size of the parametric file.

B. **Soft Inner Layer:** The soft layer was fabricated using a RTV-silicone mold to cast the polyurethane (PU) foam parts. The pattern was produced using MSOE's stereolithography apparatus (SLA).

Step 1. For the silicone and PU used, shrinkage was negligible; therefore, no shrinkage allowance was required in the CAD models. The ".stl" file of the soft layer was positioned for build on the SLA - chosen for its availability, accuracy, smoothness and part density (Figure 5).

Figure 5: Light-brown SLA soft-layer pattern, set inside white SLA hard-shell pattern.

Step 2. The SLA soft-layer pattern was then positioned in an acrylic mold box with several centimeters of clearance on all sides. The RTV-silicone (BlueStar Rhodorsil™ 3040A) was poured into the acrylic mold box, until the soft-layer pattern was several centimeters below the surface of the transparent resin (complete immersion). The entire mold box was degassed in a vacuum chamber and allowed to cure overnight, encapsulating the pattern.

Step 3. After curing, the mold box was disassembled; and, a razor knife was used to carefully cut through the silicone, along the profile of the pattern, forming a "parting-surface" that allowed for removal of the pattern. The pattern was then removed; and, venting and gating were added as needed. The empty mold (negative pattern) was injected with the desired castable material, in this case a polyurethane (PU) foam, (FlexFoam-iT®-X from SmoothOn™ with a density of 10lbs/ft^3). Once the foam cured, the mold was re-opened to reveal the solidified part (Figure 6). This approach was most desirable because multiple parts could be made from one mold; and, a range of material densities were available.

Step 4. Several fill paths and vents were cut into the silicone to allow for pouring of the castable PU foam into the mold and trapped air to escape, respectively.

Step 5. The mold was sprayed with a release agent,closed and positioned for filling with PU. The filling technique that resulted in the greatest success was to pour the mixed PU into the bottom of the mold and quickly, carefully close the mold as the PU begins to expand. The mold was bound with adhesive tape to prevent it from opening when the resin foams.

Step 6. After several hours of curing the PU was removed from the mold and the cast foam part was trimmed of flash and inspected for defects.

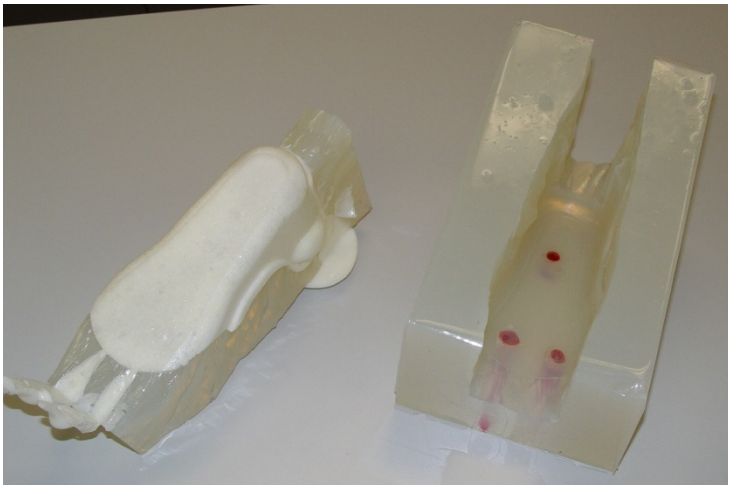


Figure 6: De-molding of custom, variable-thickness polyurethane foam layer. The mold is RTV silicone.

The resulting hard and soft layers were adjusted by the orthotist to fit the patient and finally adhered together using contact adhesive (Figure 7).

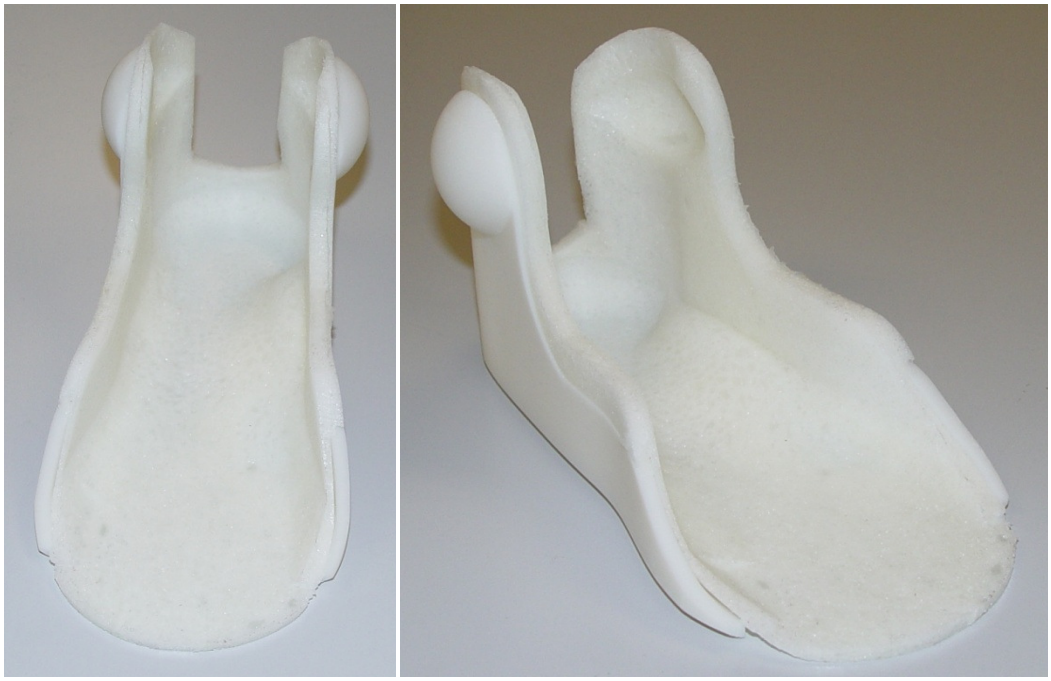


Figure 7: Mating of custom molded variable-thickness foam insert to stiff additively-manufactured polyamide (nylon) outer shell. The fit is nearly perfect due the accuracy of the fabrication processes involved.

4. RESULTS & DISCUSSION

The chosen approach of additively manufacturing the custom hard shell, and molding the polyurethane-foam insert, resulted in accurate, durable and effective pedorthoses. The time required for fabrication is 2-3 days, most of which is automated fabrication or material curing.

RTV silicone molding was a critical process used to produce the soft layer. This foam-molding process resulted in a good distribution of small cells in the foam. Two parts did develop some unacceptable bubbles; however, they were corrected in successive molds by simply cutting additional vents into the mold to prevent the growth of gas pockets. These pockets can be considered as very large foam cells having a stiffness much lower than the average cell, thereby compromising the performance of the insert.

Because of the accuracy of the RP processes, the final parts mated very well. In fitting the pedorthosis to the patient, the orthotist needed only to detail (sanding, filing, etc.) the hard shell to address "hot spots" (pressure points) before adhering the foam insert. Once fitted, the improvement in gait was dramatic. One patient decided to run down the hallway to show how his pedorthosis was helping him.

Five custom clubfoot pedorthoses were fabricated for the five patients (three bi-lateral) in the clinical trial. To date (over six months later), only one soft insert and one hard shell have required replacement. Because each custom insert has a unique, dedicated mold, replacement inserts can be molded in a matter of hours. The clinical testing of the produced pedorthoses will continue through early 2010.

Though additive manufacturing was not chosen to produce the entire dynamic pedorthosis, efforts to design and fabricate artificial foam continued in parallel with this research in anticipation of expanding material options. This development will continue in future work.

5. CONCLUSIONS

While the laser-cutting of foam sheets proved to be a feasible means of producing the soft inner layer, the durability was poor. Due to the time constraints of this project, the most practical fabrication approach was to mold the variable-thickness custom foam insert. Additive manufacturing of the hard shell & additive-based molding of the polyurethane foam insert resulted in accurate, durable and effective pedorthoses that fit well, and could be adjusted as needed. Replacement inserts can be molded in a matter of hours using this silicone-molding approach.

Five pedorthoses were successfully fabricated for four patients (one bi-lateral). During the first seven months of use, only one soft insert and one hard shell required replacement. Impact of the dynamic pedorthoses will be measured in late 2009 and early 2010.

Future work will further develop "artificial-foam" structures for additive manufacturing of the entire integrated pedorthosis.

6. ACKNOWLEDGEMENTS

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