3D Printed Tooling for Thermoforming of Medical Devices

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ABSTRACT

Purpose: The purpose of this paper is to evaluate the performance of 3D printed materials for use as rapid tooling molds in low volume thermoforming processes such as in manufacturing custom prosthetics and orthotics.

Design/methodology/approach: 3D printed specimens of different materials were produced using the Z-Corp process. The parts were post processed using both standard and alternative methods. Material properties relevant of the 3D printed parts such as pneumatic permeability, flexural strength and wear rate were measured and compared to standard plaster compositions commonly used.

Findings: 3D printing can replicate the performance of the plaster materials traditionally used in prosthetic/orthotic applications by using modified post process techniques. The resulting 3D printed molds can still be modified and adjusted using traditional methods. The results show that 3D printed molds are feasible for thermoforming prosthetic and orthotic devices such as prosthetic sockets while providing new flexibility.

Originality/value: The proposed method for rapid tooling of a mold for prosthetic/orthotic manufacturing provides great flexibility in the manufacturing and fitting process while maintaining proven materials in the final device provided to patients. This flexibility increases the value of digital medical records and efforts to develop model-based approaches to prosthetic/orthotic device design by providing a readily available process for recreating molds. Depending on the needs of the practitioners and patients, 3D printing can be incorporated at a variety of points in the manufacturing process.

Keywords: 3D printing, flexural strength, orthotics, pneumatic permeability, prosthetic sockets, rapid tooling

Paper type: Research paper.

1. INTRODUCTION

Currently, many medical devices, particularly prosthetic sockets and orthotic interfaces, are manufactured by thermoforming plastic sheets over positive plaster molds. (Seymour 2002) Traditionally these parts are manufactured by creating a cast (or impression) of the relevant anatomy from which a positive plaster mold is created. This plaster mold is then modified by hand to achieve the desired fit and then used as a tool for forming the desired medical aid (prosthetic socket, orthotic interface, etc.). This final part may be made by thermoforming a plastic sheet over the mold and/or laying up thermosetting laminates. In many cases, both processes are used as a polymer liner is first

formed over the mold and then a composite structural socket is fabricated around the liner. Other components of the artificial limb are assembled to the socket to provide functionality and cosmetic appearance (Ng, P. 2002). The expertise and trial and error required for a good fit increases the cost of care. While several forming operations may be done on the mold as the fit is adjusted, typically just one finished part will be manufactured on the mold.

Freeform fabrication increases manufacturing flexibility by eliminating the need for part-specific tools. It can be used to directly manufacture parts (Rapid Manufacturing - RM) or to make the tooling for parts (Rapid tooling - RT) (Cooper 2001). In prosthetic/orthotic applications, a rapid manufacturing (RM) or rapid tooling (RT) process could facilitate better record keeping, streamlined processing, and improved access to expert care for people in remote locations. A digital process would likely start with 3D scanning of the relevant geometry. Modifications could then be made electronically rather than physically. Efforts are underway to develop a more scientific basis for device fit by studying the relationships between patient anatomy, device fit, and device performance for prosthetic sockets (Lee, Zhang 2007, Goh 2005, Peery 2005, Shuxian, Wanhua & Bingheng 2005). Recent developments have shown the feasibility of direct manufacturing of orthotic devices via additive manufacturing (Gervasi, V. 2009, Faustini, M. 2006). Using central fabrication facilities to produce the medical devices can alleviate the prosthetists' workload. As a result, prosthetists would be able to fit more patients and reduce waiting time inside clinics (Sanders, Joan E. 2007).

Implementation of RM/RT techniques requires a method for direct manufacture of the socket (RM) or tooling (RT). Rapid manufacturing of the medical device using freeform fabrication techniques such as fused deposition modeling (Goh, Lee & Ng 2002, Hsu, L. H. 2008, Tan, K.C. 1998, Tay, Manna & Liu 2002), and 3D printing (3DP)(Herbert 2005) , and Selective Laser Sintering (SLS) (Rogers, W. 1991, Montgomery, J. 2009, Faustini, M. 2001, Faustini, M. 2003) has been explored, but this approach requires the development and validation of new materials. Clinicians may be wary of new materials because of the potential for patient injury. Alternatively, freeform fabrication processes could be used to produce the *mold (RT)* so that the actual medical device is made using traditional materials and methods. Mold modifications and traditional cast molds could be documented by 3D scanning knowing that a process was available to recreate the geometry if it were needed. If a new device were required, it could be produced from the scan using the rapid tooling process—increasing the value of digital medical records. Some specialized equipment is currently available to carve molds from foam blanks. However, this equipment tends to be specialized and the blanks very expensive.

This purpose of this work is to assess the suitability of 3DP molds produced using a commercial ZCorp printer for thermoforming of medical appliances. Three-dimensional printing (3DP) is a low cost freeform fabrication process that builds parts from layers of fused powder. (Sachs et al. 1992, Sachs et al. 1993) A material that replicates the key properties of traditional plaster molds can be more readily accepted by medical professionals. While plaster molds are commonly used for both thermoforming and lay-up of fiber composites, this work will focus on the thermoforming process as the thermoforming material requirements are more challenging. The pneumatic permeability, flexural strength, and wear rates of commercial 3DP materials with standard and custom post processing is compared to standard plaster/vermiculite materials.

2. MATERIALS

Three dimensional printing (3DP) produces inherently porous prototypes and commercial Zcorp 3DP materials are very similar to the traditional plaster molds used in prosthetic and orthotic applications. Two different commercial powders (Zp130, Zp140) were analyzed during this work. Zp 130 parts disintegrate in water without post processing and lack sufficient handling strength to be used directly as thermoforming molds. Typically, the Zp 130 parts are infiltrated with epoxy or cyanoacrylate (CA) adhesive to increase the strength and make them water resistant. However, these treatments seal the pores. For this work, alternative post processing methods using diluted CA and steam were evaluated to increase strength while maintaining a porous surface suitable for thermoforming. Zbond CA infiltrant was diluted with acetone (1:4, 1:8 ratios). Parts were infiltrated with the mixture until saturation. The evaporating acetone leaves open pores in the part surface. Alternatively, some parts were placed in a closed container for 2-3 minutes with a steady flow of steam from a commercial steam generator used to remove wrinkles from clothing. Special care was taken to avoid direct contact of the Zp 130 printed parts with condensed water.

Additional test components were also produced using the ZCorp Zp 140 powder designed for water curing. Water was applied to the Zp 140 specimens by dipping the specimens in water or misting the surface with a spray until the surface was thoroughly moistened. The parts were permitted to dry thoroughly after treatment. Epoxy post processing was not tested. In addition to clogging the pores, the high strength of epoxy-treated parts would make it difficult to modify post-processed parts by hand as is traditionally done in many medical device manufacturing processes.

The Zcorp printed parts with different post processing treatments were compared to the traditional mold material-plaster of paris (calcium sulfate hemihydrate). As is common in practice, the plaster of paris was mixed with varying quantities of vermiculite (0%, 30%, 50%, 70%) to increase porosity, decrease mold weight, speed curing and facilitate hand modification.

Table 1: Material and post-treatments tested.

Material	Post-treatment	Reference
Plaster of Paris	None	100% Plaster
Plaster of Paris 30% vermiculite	None	70% Plaster
Plaster of Paris 50% vermiculite	None	50% Plaster
Plaster of Paris 70% vermiculite	None	30% Plaster
zp 130	None	zp 130 untreated
zp 130	Infiltrated with pure CA	zp 130-CA
zp 130	infiltrated with Acetone:CA (4:1 ratio)	zp 130-CA (4:1)
zp 130	infiltrated with Acetone:CA (8:1 ratio)	zp 130-CA (8:1)
zp 130	Steamed surface	zp 130-V
zp 140	None	zp 140 untreated
zp 140	Misted with water	zp 140-M
zp 140	Dipped in water	zp 140-D

3. EXPERIMENTAL METHODS

In thermoforming, a thermoplastic sheet is softened by heating and then formed over a mold. Typical thermoforming molds have holes so that when a negative pressure is applied to the mold the polymer sheet is drawn into and around the mold (Groover 2006). The essential material requirements for thermoforming molds are (1) free airflow through the mold to prevent the formation of air pockets between the plastic and the mold and (2) sufficient mechanical strength for handling and forming. The current trial and error fitting process also requires (3) suitability for manual modification techniques such as sanding, filing, and building up sparse areas. To assess the suitability of 3DP materials to replace standard plaster/vermiculite mold materials for thermoforming of custom medical appliances, the pneumatic permeability, flexural strength, and wear rate of each were measured. Adhesion of plaster buildups was evaluated qualitatively. Experimental procedures for each test are summarized below.

Pneumatic Permeability - Thermoforming requires effective removal of the air between the plastic and the mold to ensure good feature replications. As plaster molds rely on inherent porosity to achieve air removal, this was assessed by comparing the pneumatic permeability of post processed 3DP materials to traditional plaster. Pneumatic permeability is the ratio of volumetric flow through a specimen to the resultant pressure drop across it at steady state. The apparatus set up, specimen preparation, measurements and testing procedures were supported from ASTM Standard D6539-00. The pneumatic permeability (K_p) is given by

$$K_p = \frac{Q_{av} L}{\Delta P A} \mu \cdot 1.013 \times 10^{12} \qquad (1)$$

where, Q_{av} is the volumetric flow at specimen average pressure and test temperature (m^3/s), ΔP is the specimen pressure drop (Pa), L is the specimen length (m), A is the specimen cross-sectional area (m^2), and μ is the viscosity of air at the test temperature (Pa·s).

$$Q_{av} = Q \frac{P_B}{P_I + P_B - \frac{\Delta P}{2}} \qquad (2)$$

where, Q is the flow of air out of specimen (m^3/s), P_B is the test barometric pressure (Pa), and P_I is the specimen inlet gage pressure (Pa).

Cylindrical specimens (5.08 cm ∅ x 7.62 cm) were used. Plaster specimens were produced by pouring the desired mixture of Plaster-water-vermiculite into a PVC pipe with the desired dimensions. Specimens were cured two days at room temperature before testing. The 3DP parts are printed in the Zcorp 310 3D printer and post processed using one of the methods described above. After the rapid prototyped specimens were post treated, they were dip coated in Plasti Dip™ rubber coating. This treatment seals the circumference to assure that the air flows through the specimen rather than around

it. Cured specimens were inserted into PVC pipe and the specimen/pipe gap sealed with silicone caulking. The entire assembly was checked for leaks before each test. The experimental apparatus (Figure 1) used a differential pressure gage (PX26-030DV, Omega) to measure the pressure drop along the specimens. The volumetric flow rate was calculated using a bubble meter technique (Levy 1964) in which a container with a fixed volumetric capacity (1 liter) and a stopwatch to measure the time needed to displace the water with the air that passed through the specimens. The pneumatic permeability was calculated from the average of flow rate measurements at four different pressures.

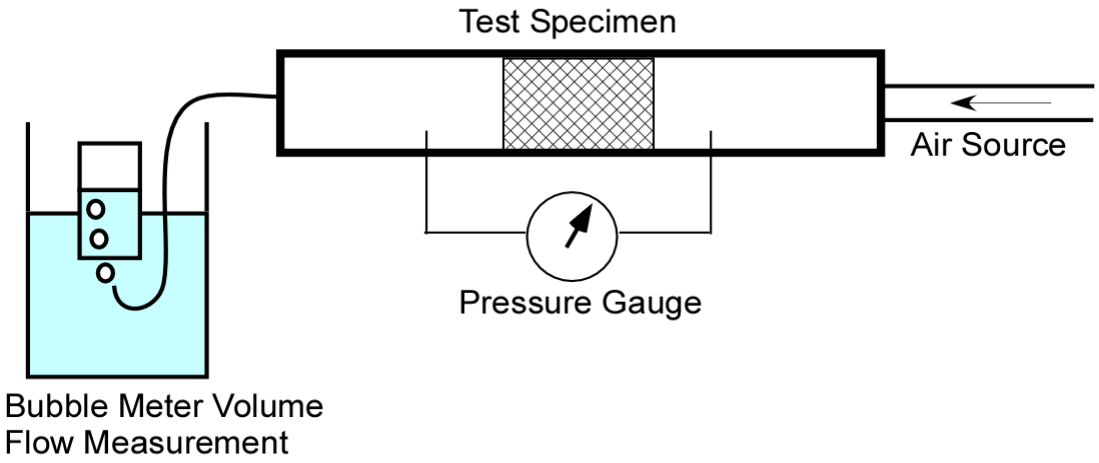

Figure 1: Schematic of pneumatic permeability measurements.

Flexural Strength - Flexural strength was measured by a three-point bending test. Flexural strength of plaster and 3DP specimens were measured according to ASTM Standard D790-03. Where the flexural strength (σ_f) is given by

$$\sigma_f = \frac{3PL}{2bd^2} \qquad (3)$$

where b and d are the width and depth of beam respectively, P is the peak load, and L is the support span. Test specimens were bars 15.24 cm x 3.81 cm x 0.89 cm with a 13.34 cm span and a loading rate of 0.032 cm/s. Testing was completed using an MTS 858 Universal Testing Machine.

Plaster and plaster/vermiculite specimens were fabricated by casting into a silicone mold of the desired dimensions. After filling the mold, the excess of material is removed using a straight edge to achieve a uniform top surface. The specimens were allowed to cure at least 2 days before testing. The rapid prototyped specimens were printed in a ZCorp printer using default parameters with the long direction of the bars in the fast axis of the printer and post processed as described previously. Actual specimen dimensions were used for calculating the flexural strength.

Wear testing - Wear testing was performed with the broken flexural strength specimens. Figure 2 shows in detail the apparatus and experimental set up that was used for these tests. The pin joint and specimen wear location were maintained at the same height to assure that the friction force (F_f) acted through the pin joint. Under this condition, the normal force (F_N) is independent of the frictional force. To further minimize any error, the sand paper was always moved away from the pin joint during testing. Mass was added to the arm until the normal force (F_N) was 4.81 N. The sandpaper was then moved under the specimens at a rate of 5.1 cm/s for 8 passes each of 20.3 cm length. Every pass was made on an unused region of 3M 332U 60 coarse grain sand paper. Wear was assessed by the area of the worn edge as measured by image analysis of an optical scan of the worn corner of the bar.

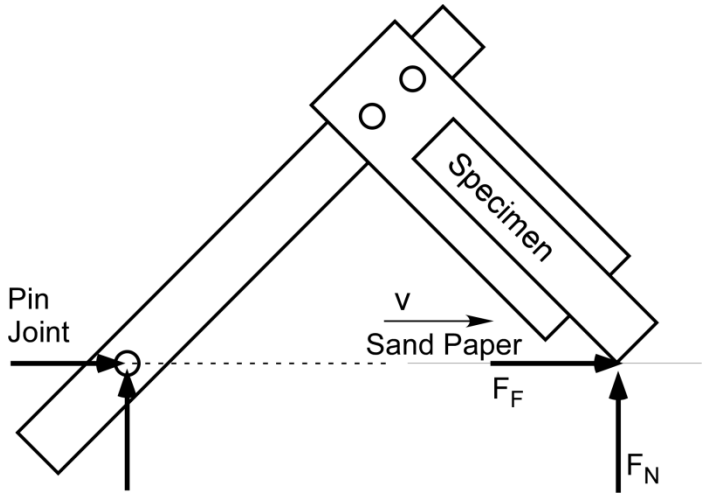

Figure 2: Free body diagram of wear test setup.

4. RESULTS

Thermoforming Suitability

The performance of the Zcorp materials were analyzed and compared to traditional plaster- based materials in the areas of flexural strength, permeability, and wear rate. The results are summarized below.

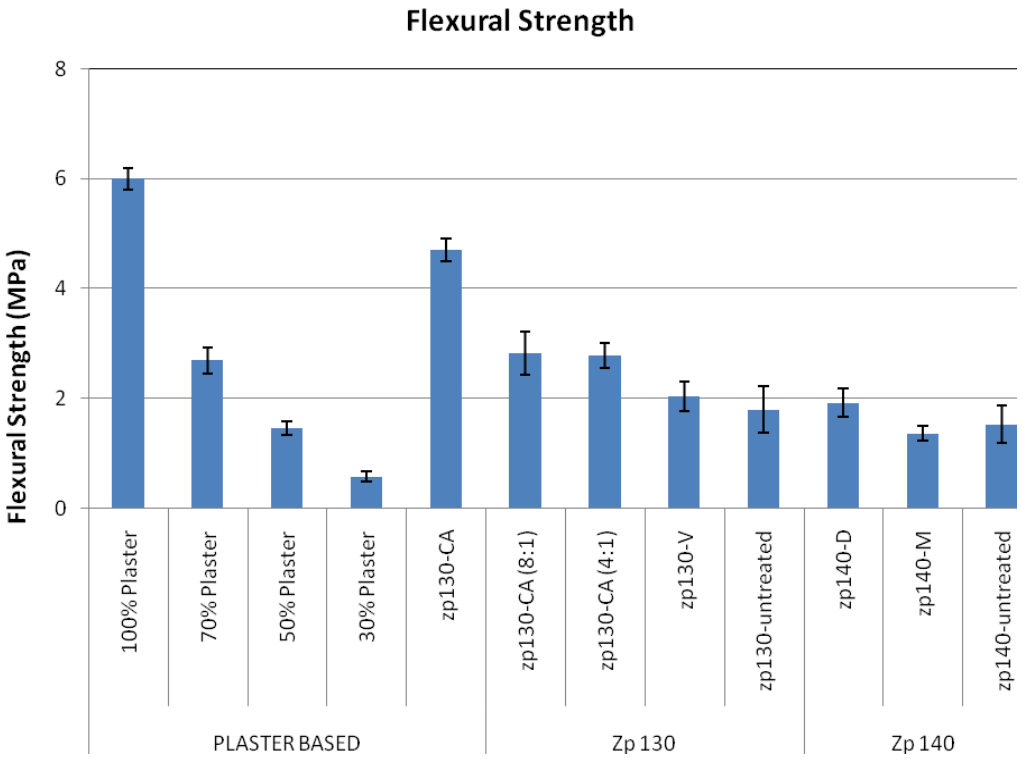

Figure 3: Flexural strength of the different material configurations. Error bars represent one standard deviation in the measurements.

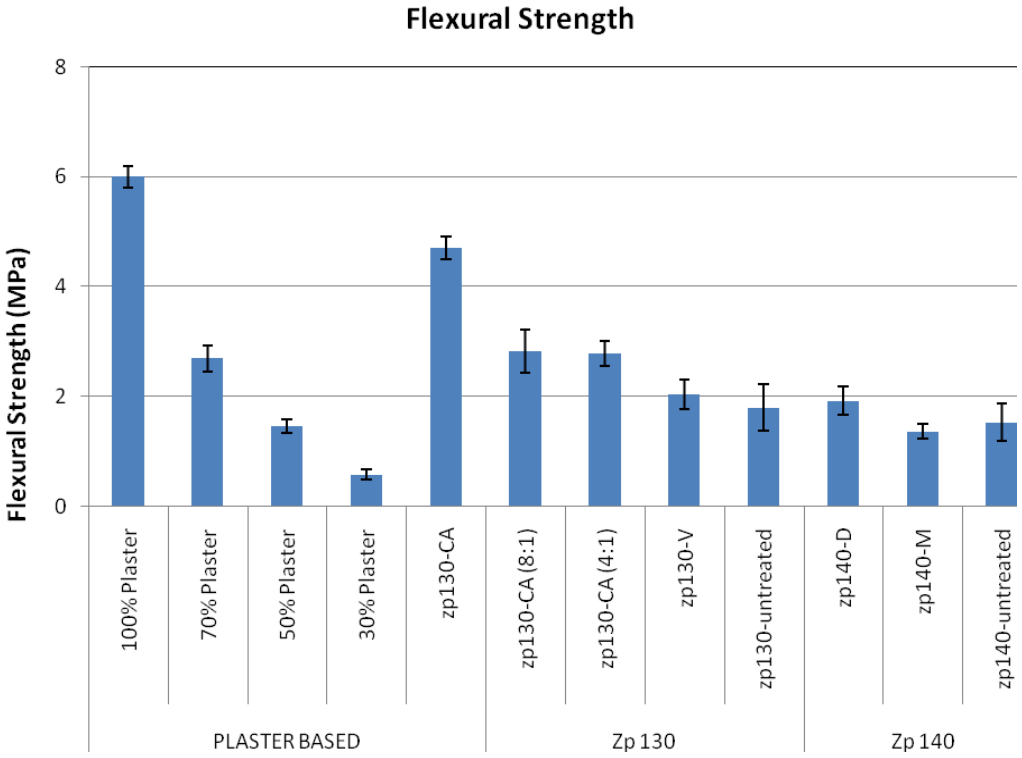

Figure 3 compares the flexural strength of the plaster and 3DP materials. The data show that there is a wide range of strengths for the traditional materials depending on how much vermiculite is added to the plaster. As all of these appear to meet the clinicians' strength requirements, the strength of all 3D Printing materials is judged to be adequate. While untreated parts have comparable strength to 50% plaster bars, these parts abrade easily and may not maintain adequate dimensional stability during handling and processing. Zp 130 infiltrated with pure CA has the highest flexural strength of all the tested 3DP materials, but is left out of subsequent testing since it has no pneumatic permeability. The remaining materials have flexural strengths comparable to 50-70% plaster molds.

Figure 4 compares the pneumatic permeability of the different sample materials. The 4:1 CA and dipped Zp 140 specimens come closest to matching the plaster permeability, but the rapid prototyping materials are much more permeable than traditional plaster-based materials. To evaluate whether the increased permeability would affect the thermoforming, a polypropylene sheet was formed over untreated Zp 130 specimens (highest permeability) by an experienced clinician. No differences in thermoforming performance were observed between the rapid prototyped specimen and traditional plaster specimens.

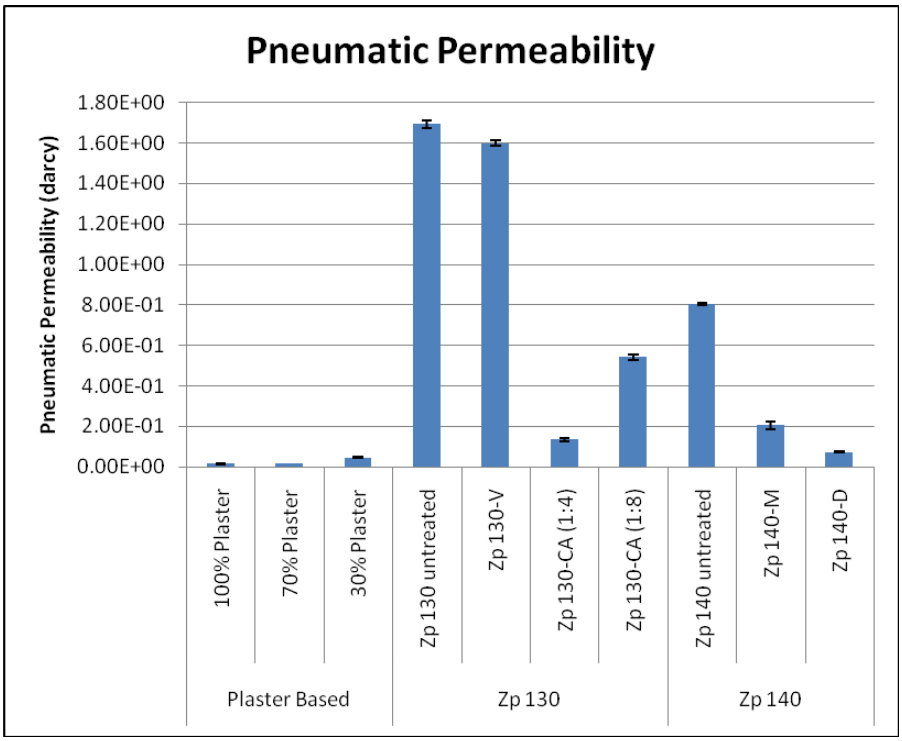

Figure 4: Pneumatic permeability of different materials and post processing treatments. Error bars represent one standard deviation of the measured data.

Suitability for Manual Modification

Often, the fit of a prosthetic or orthotic device must be adjusted through removing or adding material to the mold. Easy material removal reduces the time and physical effort required for making the modifications. The abrasion rate of the 3DP materials were compared to the traditional plaster materials using the wear test described above.

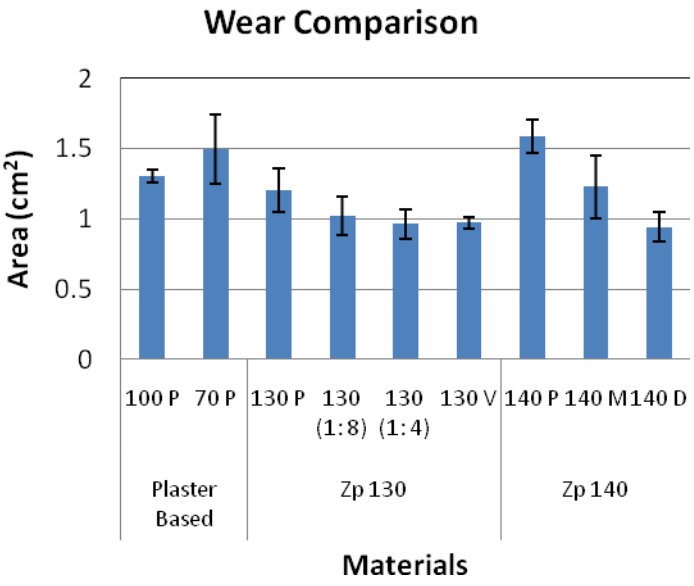

Figure 5 Worn area of different materials and post processing treatments. Error bars show one standard deviation in the data.

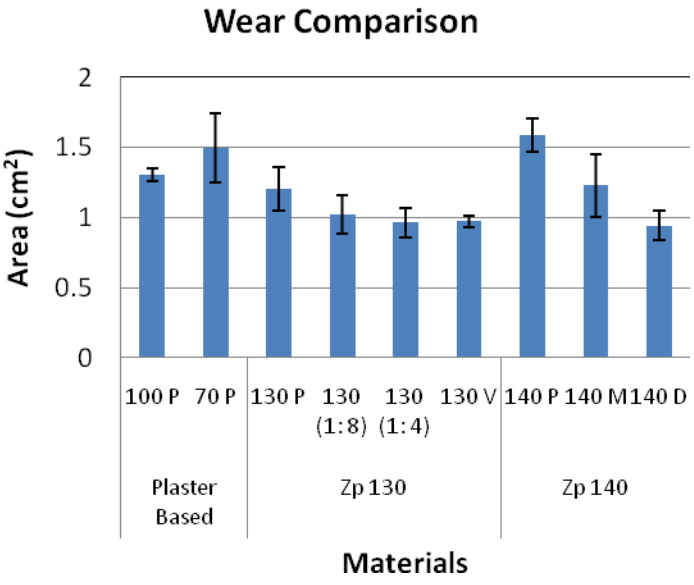

Figure 5 summarizes the worn area of the different materials and post treatments. High areas correspond to more easily modified materials. The worn areas are typically smaller for the 3DP

materials than the 100% plaster materials. Most clinicians prefer to work with mixtures containing vermiculite due to the easier wear. The untreated and misted Zp140 wear is most comparable to the 70% plaster materials.

Sometimes material must also be added to the mold. Due to the similar composition of the 3DP powders and the plaster, a buildup of plaster may be placed on existing 3DP parts after treatment. The adhesive strength of a plaster buildup was tested by adding plaster to the tension side of a 3-point bend bar prepared by 3DP and post treated with the various treatments. The adhesion of the buildup was evaluated by observing the failure location of the specimen. The CA-treated bars failed at the interface between the buildup and the original bar with little increase in strength due to poor adhesion. However, the remaining specimens had sufficient adhesive strength so that the plaster interface did not fail. The buildup significantly increased the maximum bending load in the Zp 140 specimens and in the untreated Zp130 specimen. Further improvements in the bonding could be achieved by roughening the surface before applying the buildup as is commonly done in clinical modifications of plaster. These results confirm that the Zp 140 (untreated, misted, dipped) and untreated Zp 130 samples can be manually modified by adding material.

5. DISCUSSION OF RESULTS

The material testing shows that commercial 3DP processes are amenable to use in thermoforming of medical devices. Both the standard Zp140 powder with water post treatments and the Zp130 powder with diluted CA adhesives or vapor post treatment have comparable strength and wear rate as the plaster materials typically used by professionals in the field. The Zp140 materials most closely approximated the plaster performance in the wear tests and had the highest strength in the buildup tests. While the pneumatic permeability is much higher than traditional plaster molds, no negative impact on the thermoforming process has been observed.

While the 3DP materials are more expensive than traditional plaster materials, it has the lowest material cost and one of the fastest build rates of the commercial freeform fabrication methods. The costs and manufacturing time can be substantially reduced by printing a shell with the desired external geometry. The center can then be filled with a plaster or plaster/vermiculite mixture. This will also reduce the total mold permeability to levels comparable to a plaster/vermiculite mold. One potential obstacle is the limited build size of commercial 3DP machines. For example, molds for a lower limb prosthetic socket might not fit in the available build space. This can be addressed by dividing large parts into multiple segments that are joined after assembly. A sample hollow mold produced in one and two pieces is shown in Figure 6.

Due to the similarity of the 3DP materials to traditional clinical materials they can be readily integrated into current practices described in the introduction. In fact, 3D scanning of patients is growing more common. 3D Printing could be used to recreate a previous mold when a modified device is required. If the initial fit is not adequate, the mold can be modified by hand rather than waiting for the manufacture of a new mold. Digital history can be preserved by scanning the final modified mold. This hybrid approach could be particularly valuable in a transition to increasingly digital mold design. These scans

can provide a record of patient changes over time. A key advantage of the 3DP approach to producing the molds is that the materials and equipment are not specific to this application. Thus, medical professionals have the option of using commercial 3DP fabrication services. The flexibility of this method may also aid as a bridge to fully digital design and modification.

In contrast, direct fabrication of the socket as done previously (Goh, Lee & Ng 2002, Tay, Manna & Liu 2002,Herbert 2005) requires introduction of new materials into the actual socket. Additionally, if the initial fit is inadequate, then the entire socket must be manufactured anew. In the present approach, the mold can be modified and a new socket quickly fabricated—reducing fitting time and cost. Machinining of molds from foam blanks avoids the material substitution problem, but typically requires customized equipment and does not support modification as readily as the 3DP molds presented here. (Smith 2001)

Figure 6 One piece and two piece socket molds created by 3D printing.

6. CONCLUSION

This paper has considered the use of commercial 3D printed components as molds for thermoforming medical devices such as prosthetic sockets and orthotic interfaces. 3D Printed parts have the necessary strength and permeability to replicate the performance of the current plaster/vermiculite materials currently used. Additionally, these materials are amenable to modification including material removal and buildup as required in current forming processes. While all of the post processing techniques have sufficient strength and permeability, the Zp140 parts and the vapor treated ZP130 parts demonstrated superior adhesion to plaster buildup material. Due to the similarity of the 3D printed materials and the traditional materials, the 3D printed molds are easily integrated into current processing procedures.

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