INVESTIGATION AND DESIGN OF AN ACTIVELY ACTUATED LOWER-LEG PROSTHETIC SOCKET

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Abstract

A prosthetic socket worn by an amputee must serve a wide variety of functions, from stationary support to the transfer of forces necessary to move. Fit and comfort are important factors in determining the therapeutic effectiveness of a socket. A socket that does not fit the subject well will cause movement problems and potentially long-term health issues. Because a subject's residual limb changes volume throughout the day, it is desirable that the socket adapt to accommodate volume changes to maintain fit and comfort. This paper presents research to manufacture adaptive sockets using selective laser sintering (SLS). This additive manufacturing process allows freedom to design a socket that has both compliant areas that can adapt to changes to the residual limb, as well as rigid regions to provide necessary support for the limb. A variety of concepts are discussed that are intended for manufacture by SLS, and that feature flexible inner membranes in various configurations. For each concept the membrane will be inflated or deflated to match the limb's change in volume. and the paper also presents a study to determine SLS machine parameters for optimal build results, as well as results from initial pressure-deflection experiments.

Introduction

The prosthetic socket is the portion of the prosthetic leg that attaches to the residual limb. We have all experienced the phenomenon of feet swelling after standing and walking for long periods of time. Shoes are commonly made from flexible material like cloth or soft leather, so this swelling can be accommodated. The same phenomenon occurs for an amputee's residual limb. However, prosthetic sockets are generally stiff and have little to no compliance. Studies have shown residual limb volume can vary -11% to 7% in a single day due to changing activity level or weight. However, volume changes of only 3% to 5% can cause users to have difficulty putting on their prosthetic sockets [1]. The improper fit that results can cause problems with gait and health problems. Many existing volume compensation methods are cumbersome, rely on the amputee to maintain the appropriate pressure level, or allow only for a decrease in limb volume. Automatic compensation for volume gain and loss is therefore needed; however, the complexity of designing such sockets renders traditional fabrication methods cost prohibitive or technically infeasible.

Selective Laser Sintering (SLS), an additive manufacturing (AM) technology, addresses both of these concerns. SLS is a layer-based AM technology that relies on a high power laser to fuse powder particles into a solid object. SLS fabricates parts directly from a 3D CAD model and provides virtually unlimited geometric freedom in the design of parts. Previous researched has demonstrated the manufacture of prosthetic sockets with passive compliant regions using SLS [2]. Based on this SLS AM technique, steps toward developing a transtibial nylon prosthetic socket that automatically adapts to volumetric changes in a residual limb will be described.

Objectives

The objective of this research is to design, develop, and manufacture a prosthetic socket that is actuated by inflation of an inner membrane. Inflation based designs are attractive for the potential they offer in design and implementation of all subsystems. The inflated membranes can be tailored in size, location and deflection characteristics. Additionally, inflation of such a bladder could be powered by energy harvested from a patient's gait. The target manufacturing technology is SLS. The socket must meet the following three performance criteria:

- The socket allow for a ± 10% volume change globally. This feature is the current focus of the project.
- The socket must have the capability for localized change.
- The socket must be capable of responding with a time constant of no more than 1 second.

Methodology

The first stage of the research involved concept development using various concept generation techniques, such as brainstorming and mindmaps [3]. However, for a generated concept to be viable, the mechanical properties of the SLS materials need to be well quantified. Of particular importance for any inflation based concept are density (to maintain a proper seal) and modulus of elasticity (to provide a flexible working area). Finally, once the material properties are determined, the relationship between membrane inflation pressure and applied pressure will need to be developed.

Concept Generation

Since SLS is a freeform process, we are free to develop concepts that are not subject to the restrictions of traditional manufacturing techniques. The design space available is therefore much larger. However, designing with SLS also requires careful design of the material properties as well since they are based on build parameters.

Our concept generation to date has focused on inflatable bladders, as described above. The concepts can be grouped into "single bladder" and "multiple bladders" categories. All of the concepts use a flexible inner membrane surrounded by a stiff outer shell. The stiff outer shell is equivalent to the socket wall on more traditional sockets. The membrane therefore expands inward toward the limb in place of (or in addition to) a normal liner. Implementation of the inner membrane differentiates the concepts.

The first and most basic concept is the Single Uniform Bladder concept (Figure 1). This concept features a thin membrane that is a simple offset of the outer socket wall. The membrane inflates and deflates uniformly and globally. Volume changes in lower-limb patients, however, are rarely uniform, so the remaining concepts provide ways to focus the inflation.

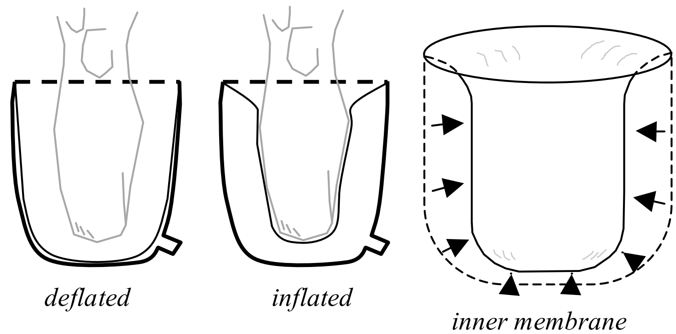

Figure 1: Single Uniform Bladder Concept

Still using a uniform global membrane, the Multiple Linked Bladders concept (Figure 2a) has fixed ribs that allow deflection only in areas that need it (as determined by the prosthetist). An inverse of this concept is the Inflating Plates concept (Figure 2b). This concept has inflexible plates joined by flexible membranes. Inflating this concept moves the plates and theoretically provides better force transfer between the patient and the prosthesis. Additionally, since the plates are stiff, they are capable of accommodating localized deflection mechanisms (such as those developed at The University of Texas at Austin [2]).

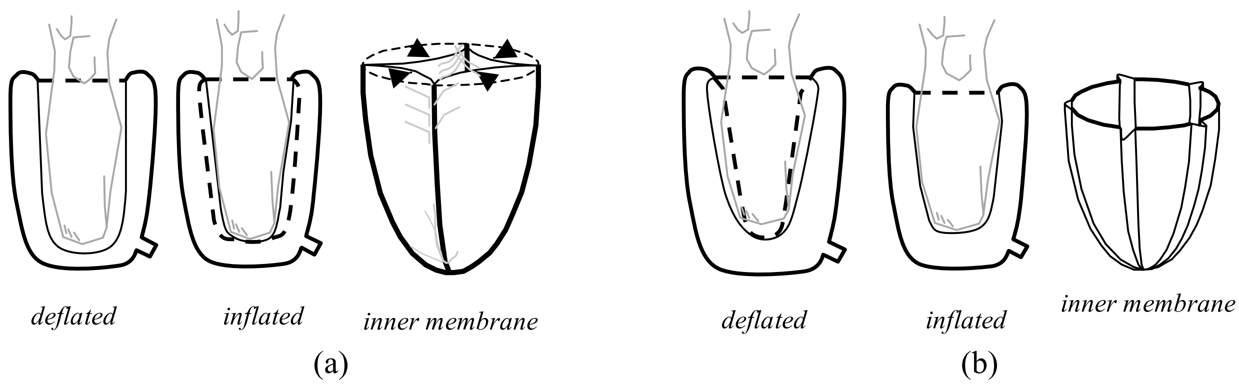

Figure 2: Multiple Linked Bladders Concept (a) & Inflating Plates Concept (b)

The final concept eschews global changes for a series of multiple independent bladders (Figure 3). Each bladder has a separate pressure source and control scheme. This design holds the most promise because it allows the prosthetist and the designer the most control over the socket's deflection characteristics.

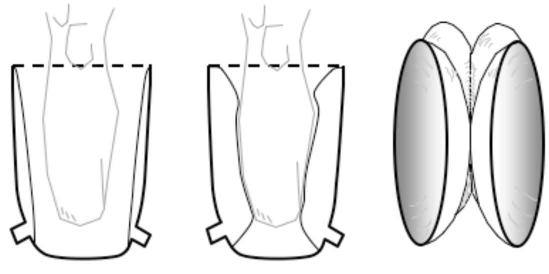

Figure 3: Multiple Independent Bladders Concept

Build Parameter Characterization

An important task for this research was determining the appropriate SLS process parameters for this application. For a concept to be successfully inflated, the bladders need to meet several material-based performance characteristics. The first is extremely low porosity (high density). Whether using air, water or another inflation media, the bladder will need to be impermeable to the fluid while containing the pressure. Secondly, the flexible membrane portions will need to be highly flexible (low modulus of elasticity), while the outer shell will need to be rigid with little to no deflection under pressure. Both parameters (density & modulus of elasticity) are highly affected by energy input into the part during the sintering process. The Andrew Number (AN), shown below, is a quantification of energy concentration [4].

$$AN = \frac{LP}{SS \cdot SSP}$$

The Andrew Number is a function of Laser Power (LP), Scanning Speed (SSP) and Scan Spacing (SS), typically measured in J/cm^2.

The University of Texas at Austin Mechanical Engineering Department operates a 3D Systems Vanguard HiQ Sinterstation, which was selected for use on this project. The Vanguard is used primarily with nylon powders. For this research, we focused on manufacturing sockets from Nylon 11 and Nylon 12. The operating software for the Vanguard allows a large variety of parameters to be modified. Thus, ANs were determined for both powders produce the required material properties for prototyping.

The Design of Experiments (DOE) method was used to find the Andrew Number. The control parameters selected were Laser Power, Scan Spacing and Part Bed Temperature (PBT). Laser Power and Scan Spacing are two parameters in the Andrew Number. Scan Spacing, however, is a fixed parameter in the software and could not be manipulated. Part Bed Temperature was varied because, while it does not figure into AN, it greatly affects both the energy flux for the part and the overall build quality. Issues such as curl, yellowing, and orange peel are all affected by PBT. A sealable, flexible part without geometric quality is unacceptable. PBT is a build parameter, meaning that it is set at a single value for the entire build. LP and SS can be set on a part-by-part basis.

With these three variables, the DOE was constructed for two builds for each powder. Each build was performed at a separate PBT with combinations of the LP and SS selected. Shown below in Figure 4 are the Nylon 11 DOE build parameters. The parts selected for the DOE were a combination of tensile dog bones, flexure check pieces and density check pieces. Additional parts were included in the build to evaluate general part quality and eliminate problems such as curl and loss of part detail. Figure 5 shows a sample build.

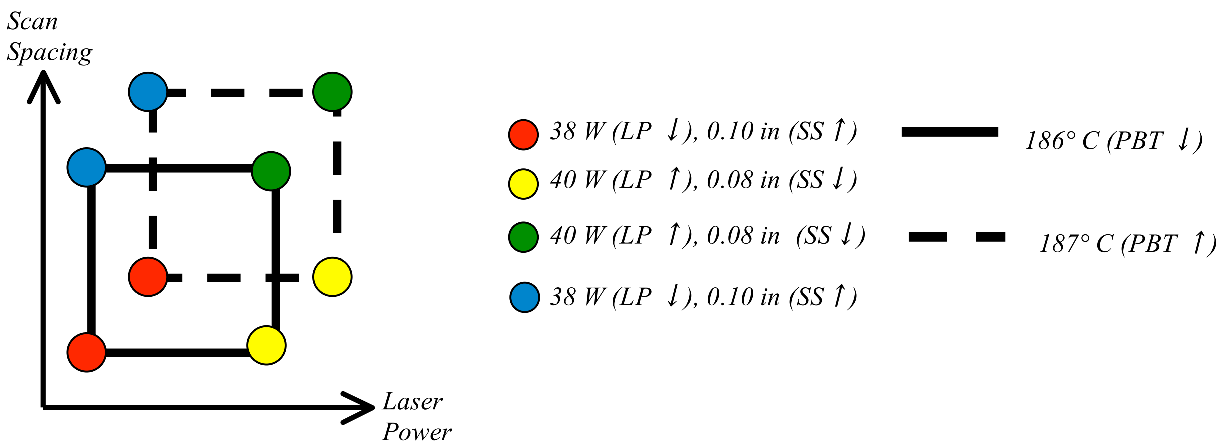

Figure 4: Nylon 11 Design of Experiments Setup

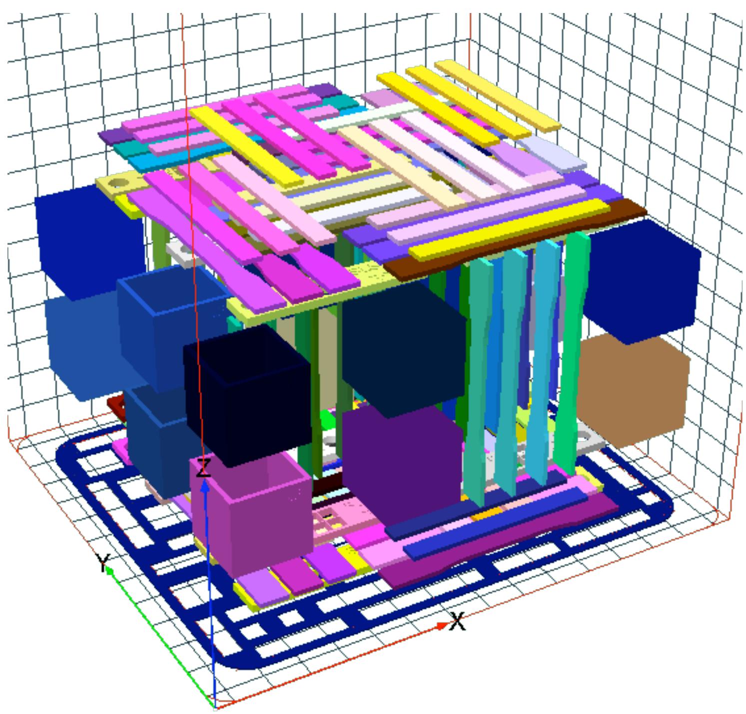

Figure 5: Sample Test Build

The tensile dog bones were pulled on an Instron 3300 Tensile Tester to determine the modulus of elasticity. The density check pieces were thin rectangular pieces that were precisely measured in length, width and thickness, and then weighed to get average density.

The Nylon 12 DOE was completed first. The Andrew Numbers investigated were between 1.16 and 2.71 J/cm^2. The results show that density, in the area of investigation, is lightly related to AN, increasing with more energy input (Figure 6). The density, however, was still lower overall than expected. The theoretical density of Nylon 12 is 1.00 g/cc [5] and the best average density that was achieved was 0.91 g/cc.

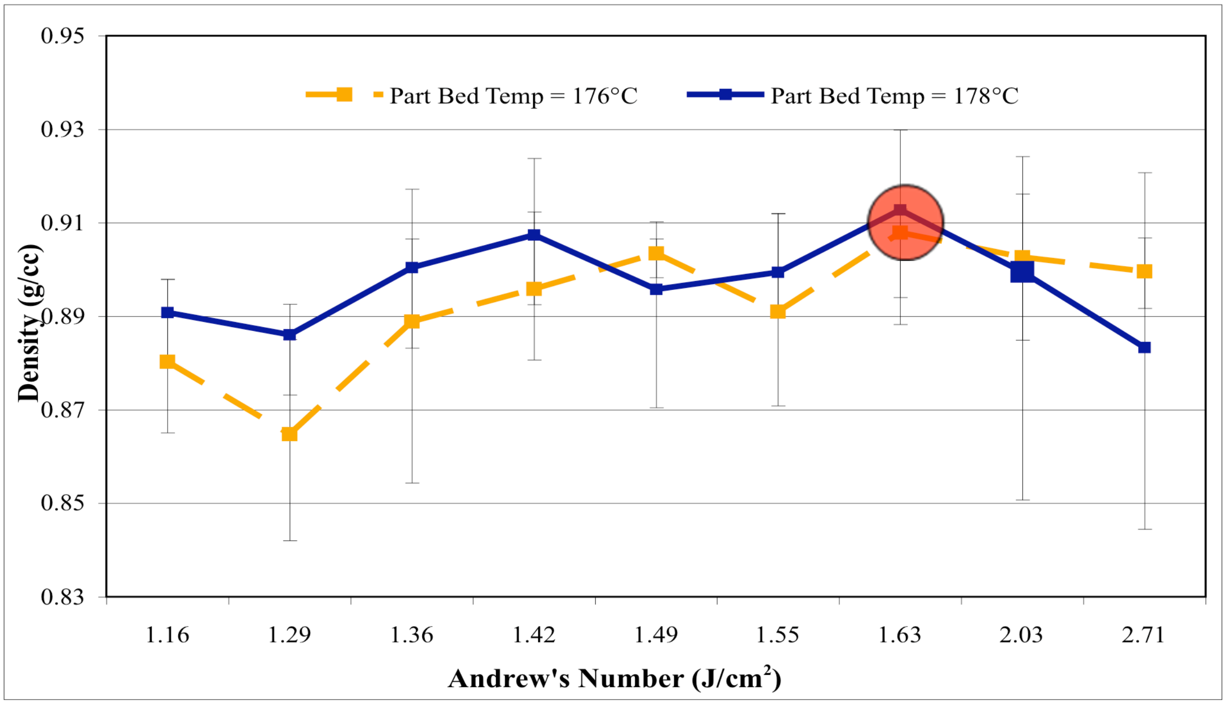

Figure 6: Nylon 12 Density vs. Andrew Number Results

The Nylon 12 modulus results show similar light relation to AN, but with a severe drop off in the lower AN range (Figure 7).

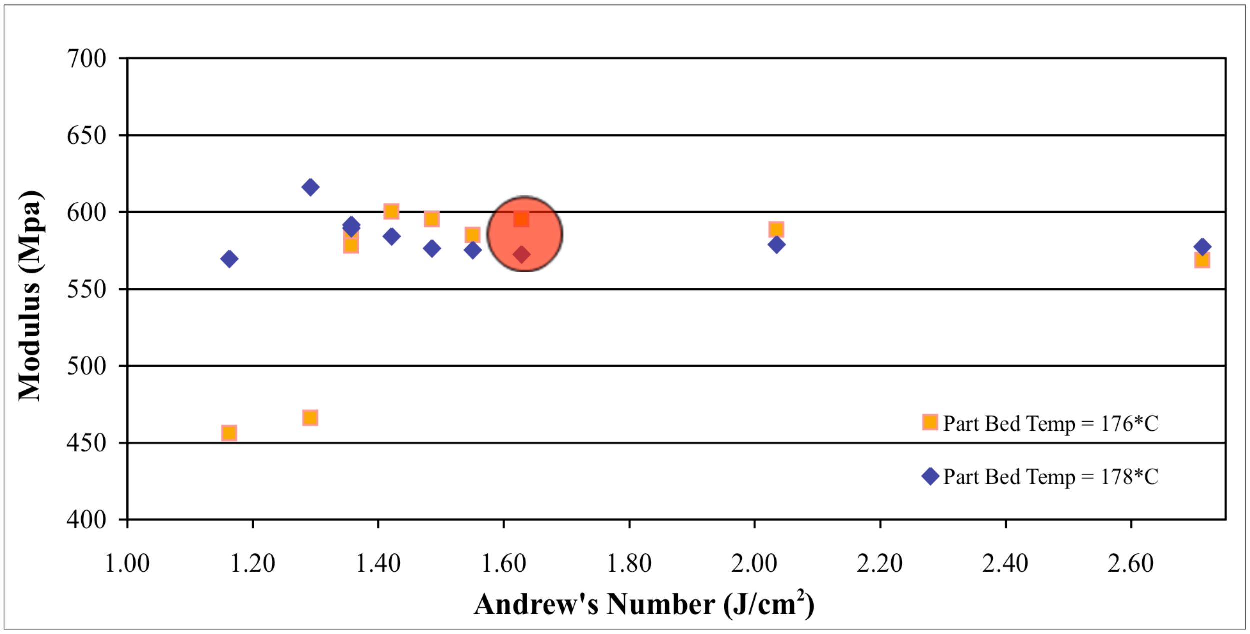

Figure 7: Nylon 12 Modulus of Elasticity vs. Andrew Number Results

Based on the results of both the density and modulus of elasticity tests, we selected 1.63 J/cm^2 as the optimal AN for Nylon 12. The Nylon 11 results showed similar trends and the selected AN was 1.47 J/cm^2.

Pressurization Results for Flat Specimen

The next research task focused on characterizing the performance at each material at the selected build parameters for the inflation application. A small test piece was used to judge each powder's ability to contain pressure and to deflect elastically in the desired range. The test piece (Figure 8) was a flat membrane 7.62 mm (3 in.) in diameter that was built with varying thicknesses (1.0 mm, 1.3 mm, 1.8 mm). It was designed to be inflated pneumatically and equipped with a QuickConnect pressure coupling for use with pressurized air lines.

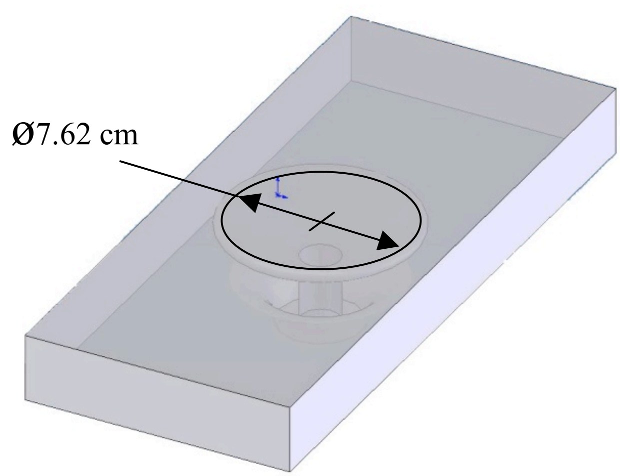

Figure 8: Pressure Test Specimen

The specimens were each attached to a test rig that included a pressure regulator for applying pressure, a pressure gauge for measuring applied pressure, and a dial indicator to measure membrane deflection. The complete test setup is shown below in Figure 9.

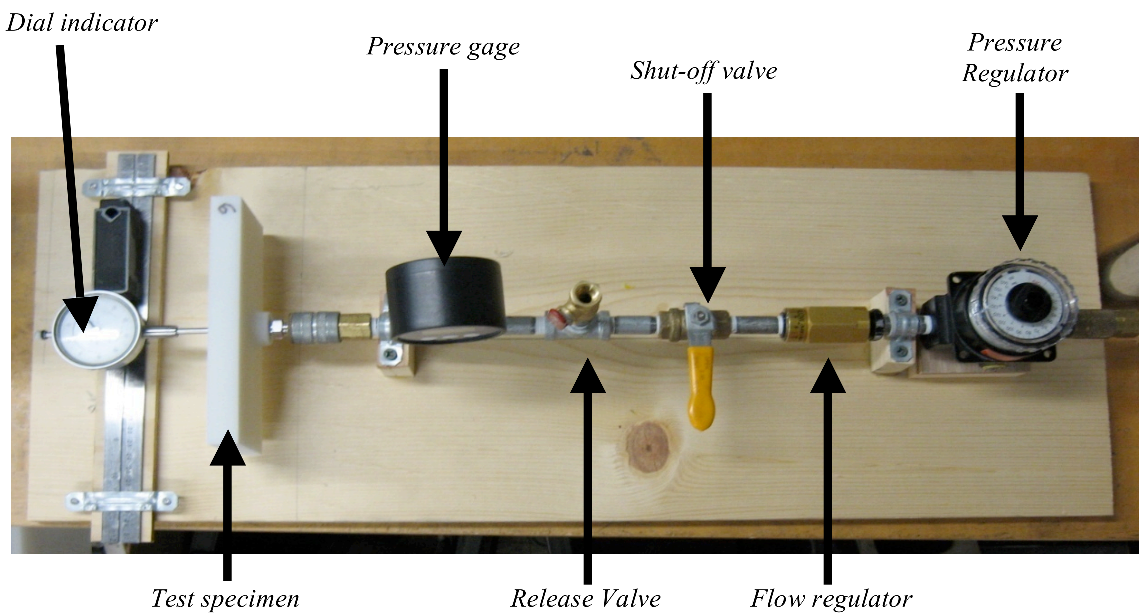

Figure 9: Experimental Test Setup

The specimens were inflated using shop compressed air. Two test schemes were employed. The first was designed to evaluate plastic deformation. With this protocol, 5 psi was added incrementally, the deflection measured, and then the pressure was released. The residual deflection was measured before the sample was re-inflated to the pressure before release. The second test protocol was designed to test deflection based on continuous inflation. Five psi was added incrementally until a maximum pressure was obtained. The deflection was recorded for each pressure increment.

It became immediately obvious that the Nylon 12 specimen leaked and would require application of sealant. A constant air supply was necessary for the test specimen to hold pressure. The Nylon 11 specimens held pressure to a much greater degree, but still leaked at high pressures, though at a significantly slower rate.

The Nylon 11 test specimens were built using Arkema D80 Naturelle powder, 50% virgin, 50% overflow. Only the two thinner thicknesses (1.0 and 1.3mm) were built (Figure 10). The maximum deflection achieved was 3.38 mm at 0.340 MPa on the 1.0mm thick membrane. The test pieces had negligible plastic deformation, but they took a long time to return to their original shape.

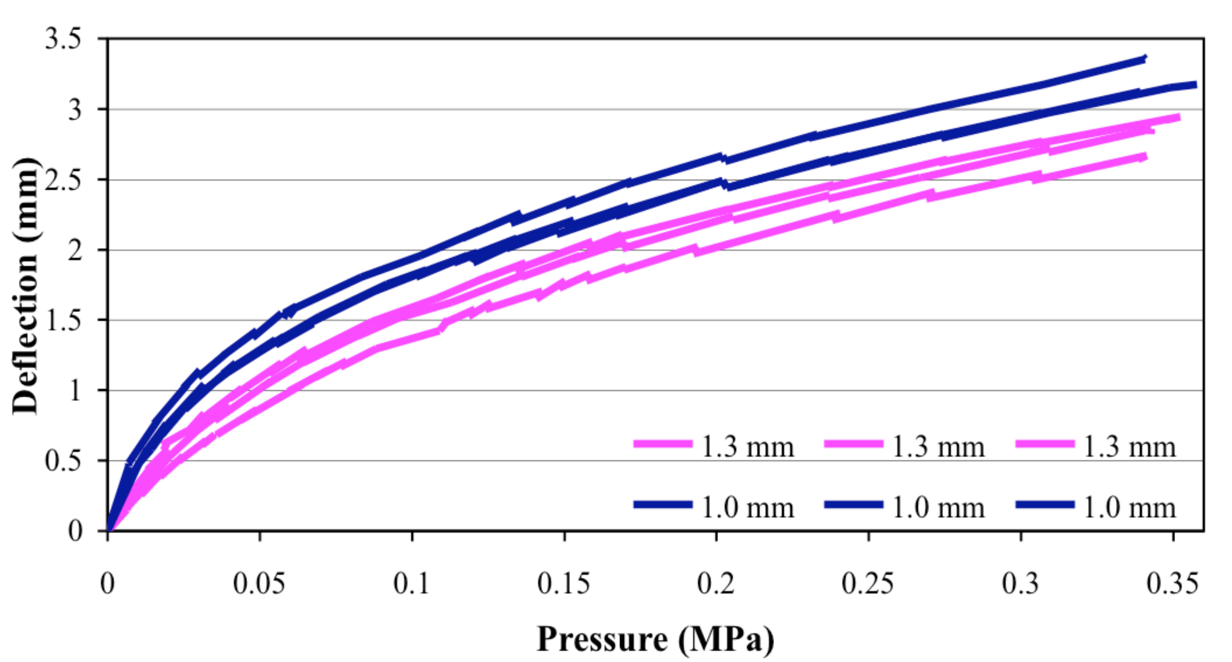

Figure 10: Flat Specimen Nylon 11 Inflation vs. Pressure Results

The Nylon 12 test specimens were built using ALM powder, a mixture of 50% virgin powder, 25% overflow and 25% part cake. All three sample thicknesses were built. The maximum deflection was 2.13mm at 0.145 MPa for the 1.3 mm thick membrane. The 1.0mm thick membranes experienced severe plastic deformation and the 1.3 had minor plastic deformation (0.10 mm on average). Similar to the Nylon 11 specimen, the Nylon 12 specimen was very slow to return to original shape.

The posterior distal tibia socket end of the residual limb will need the greatest deflection. A 6% volume change over a 10.9 cm diameter region (as recommended by a prosthetist) requires 6.1mm of deflection. Because the largest deflection for either powder (2.13mm for Nylon 12 and 3.38 mm for Nylon 11) does not meet this specification, a flat plate single bladder will likely not suffice for this application.

Pressurization Results for Redesigned Curved Specimen

A curved design, one that more closely resembles an actual socket wall, has much different response characteristics that the flat design. Using the prosthetist's example of a 10.9 cm diameter area and a needed 6.1 mm deflection as a starting point, the above test specimen was refined in size and layout. A half-scale model was constructed (Figure 10). The deflection necessary was 6.1mm, or at half-scale, 3.05mm. That 3.05mm was split between the two sides of the neutral plane. The specimen therefore was built with a concave shape similar to the organic shape of the socket wall. The thickness was kept at 1mm, which was shown to be the thinnest that could be built without problems. Additionally, the large stiff flanges were removed since they were no longer needed for clamping the specimen to the test rig.

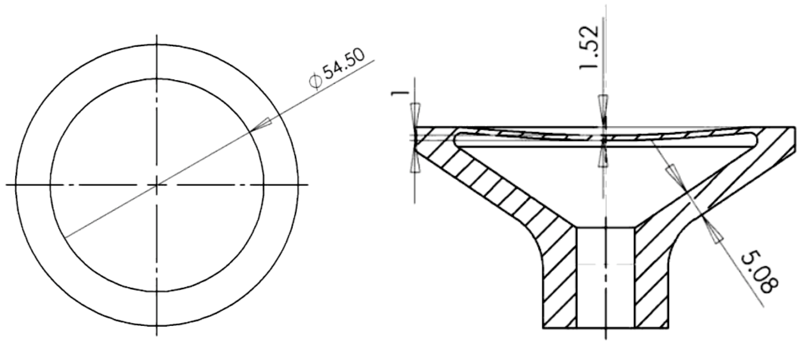

Figure 11: Redesigned Curved Specimen

The new curved specimens were built using Arkema Nylon 11 (D80 Naturelle, 50% virgin, 50% overflow), since that powder showed the best results in the previous test. Six identical specimens were built and tested using compressed air (Figure 12). The results at low levels of pressurization are markedly different. The range between 0 and 2.5mm of deflection showed rapid expansion as the initial concave shape popped out. Once the membrane popped out, the expansion from that point on is very similar to that observed earlier with the flat specimens. The maximum deflection achieved was 7.67 mm with a pressure of 0.714MPa. Even at half-scale and with the same thickness the test piece exceeded the 6.1mm needed. However, 0.714 MPa is a very high pressure and is unlikely to be actually used in practice. The actual working range necessary for the specimen is a much lower pressure range (0 to 41.02 kPa (average)), as highlighted in Figure 12.

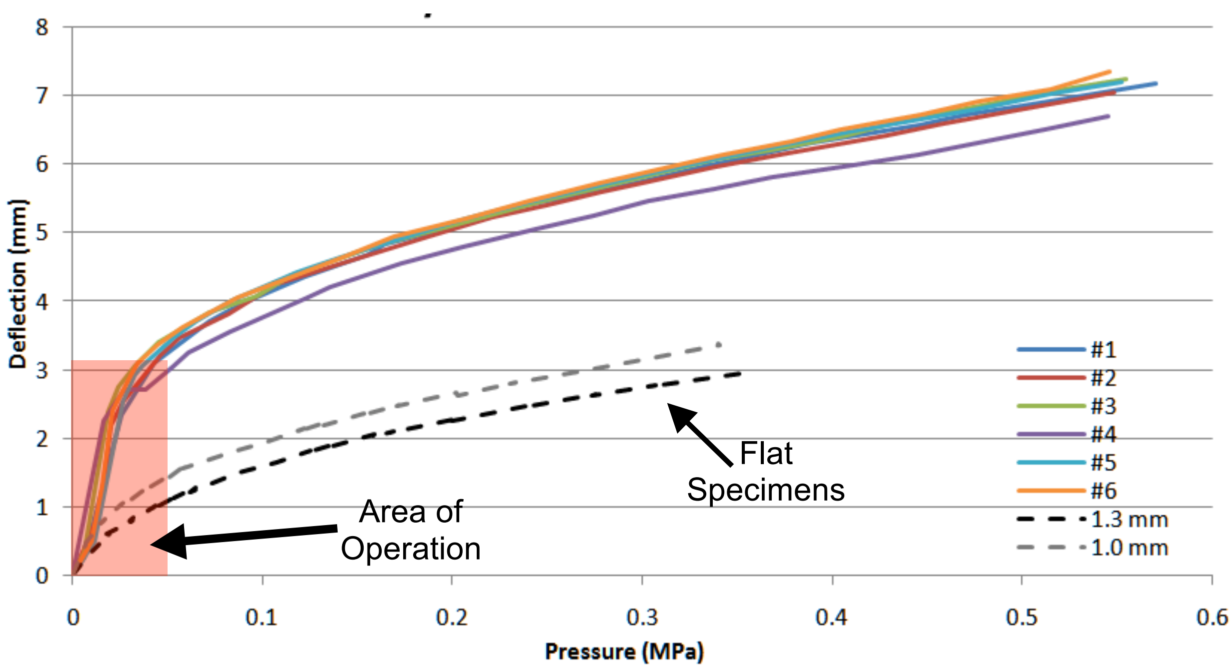

Figure 12: Curved Specimen Inflation vs. Pressure Results

The specimens were inflated to the maximum pressure and then all of the pressure was released. The specimens deflated to a convex shape that was nearly the inverse of the initial concave shape. The typical residual deflection was between 3.05mm to 3.81mm. This deflection was not permanent, however, and the application of hand pressure snapped the membrane back to its original shape with negligible (less than 0.1mm) deflection.

Since the results from the curved specimens were so promising, one specimen was selected and repeatedly inflated and deflated to test for plastic deformation or kinetic hardening (Figure 13). The results show that the material actually softens upon repeated cycling and takes less pressure to inflate in the low pressure range. Additionally, at high pressures, there is not a large decrease in maximum deflection. This test is obviously preliminary and more sustained fatigue testing will be needed before any such bladder could be used with confidence on a patient.

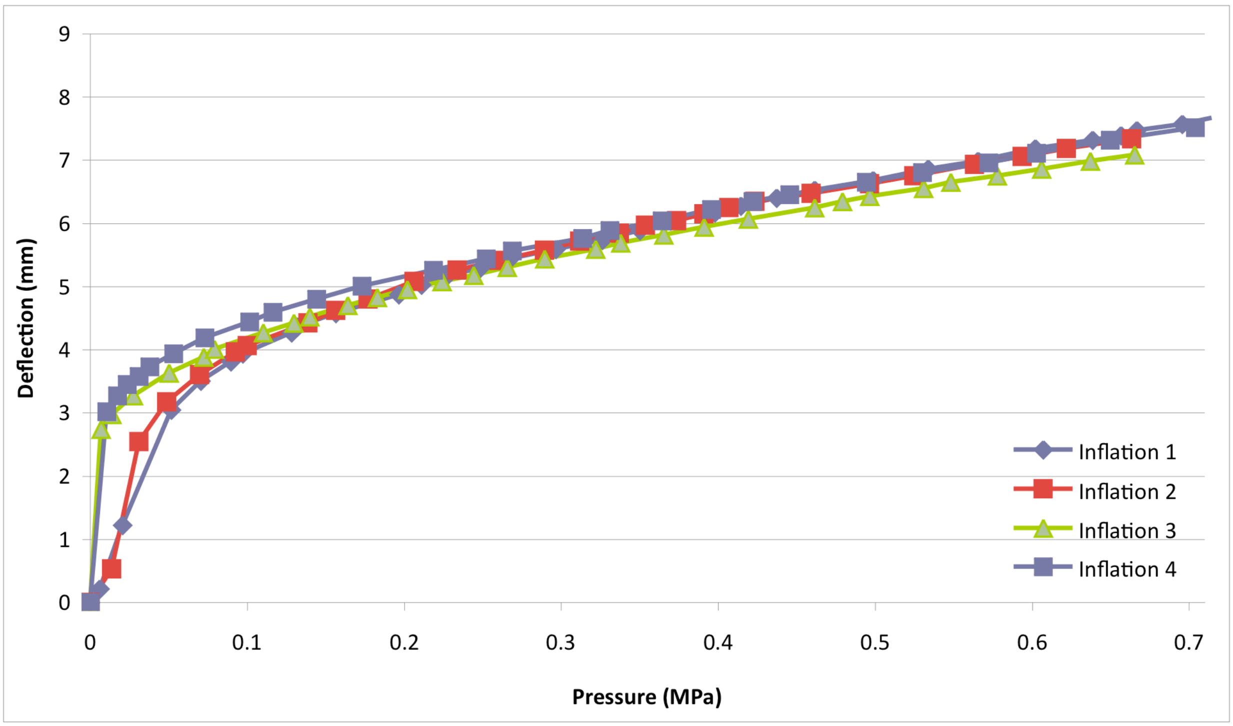

Figure 13: Repeated Inflation Cycling of Curved Specimen

Conclusions & Future Work

At this point, the flat test specimens lack the necessary deflection range and require too pressure to actuate. The redesigned curved specimen, however, shows promise in both of these areas. Additionally, the softening of the material from repeated cycling makes the expected performance of the specimen even more appealing.

Future work on the inflatable prosthetic socket concept will include a full-scale test specimen of the prosthetist's recommended case. Additionally, new work will have to be undertaken to quantify the effect of various thicknesses on deflection of curved membranes. While finite element analysis (FEA) has been completed for the flat membrane specimens, the curved membrane FEA needs further development. Once individual membranes can be designed with confidence, they will need to be integrated into an overall socket before subject trials can begin.

Not discussed in this paper is the actuation system necessary to operate the socket. Work continues on this subsystem, including development of pneumatics sources and associated control schemes. As all these areas are developed, pilot studies and subject trials can begin.

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