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RESEARCH ARTICLE

HOW INFILL PERCENTAGE AFFECTS THE ULTIMATE STRENGTH OF 3D-PRINTED TRANSTIBIAL SOCKETS DURING INITIAL CONTACT

Campbell L¹, Lau A^{1*}, Pousett B²

¹ Prosthetics and Orthotics, School of Health Sciences, British Columbia Institute of Technology (BCIT), Burnaby, British Columbia, Canada.

² Barber Prosthetics, Vancouver, British Columbia, Canada.

ABSTRACT

BACKGROUND: The strength requirements for upper extremity prostheses are not as high as the strength requirements for lower extremity prostheses. Therefore, strength testing on 3D-printed lower extremity sockets is one of the first steps that needs to be conducted to ensure patient safety.

PURPOSE: Our study tests how changing the infill percentage (the percentage of material between the internal and external socket wall) affects the strength of 3D-printed transtibial sockets.

METHODS: A Fused Deposition Modelling (FDM) printer was used to print a total of nine transtibial (TT) sockets (three sockets at 30% infill, three sockets at 40% infill, and three sockets at 50%) using polylactic acid (PLA). A strength-testing apparatus measured, in Newtons (N), the maximum load the 3D-printed transtibial sockets could withstand at initial contact of the gait cycle.

RESULTS: Based on the specific criteria outlined in our research project, all nine sockets exceeded the 4480N threshold set by ISO Standard 10328. Eight out of nine sockets failed at approximately double the force required with one socket (socket #2) failing at 5360N. Seven out of nine sockets failed at the medial popliteal region and two out of nine sockets failed at lateral mid socket region. Differences in infill percentage from 30%, 40%, 50% did not appear to influence strength of sockets.

CONCLUSION: Strength of 3D-printed TT sockets needs rigorous testing to be deemed safe for patient use. More definitive research and a higher number of samples are required to investigate how a larger range of infill percentage can affect strength. Until all the requirements of ISO Standard 10328 are satisfied, the safety of using 3D-printed TT sockets in clinical practice are uncertain.

*CORRESPONDING AUTHOR

Adriel Lau, Prosthetics and Orthotics, School of Health Sciences, British Columbia Institute of Technology (BCIT), 3700 Willingdon Avenue, Burnaby, British Columbia, Canada.

Email: lau.adriel@gmail.com

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Prosthetic socket, Transtibial, 3D Printing, Infill percentage, Strength testing, Fused deposition modeling, Polylactic acid.

ABBREVIATIONS

FDM (Fused Deposition Modeling); Fmax (Maximum force); Fset (Settling test force); Fsp (Static proof test force); PLA (Polylactic Acid); TIJ (Thermal Inkjet Printing); SLS (Selective Laser Sintering)

INTRODUCTION

3D printing has been around for 30 years, but recently it has been making significant strides in the field of prosthetics. 3D printing allows for increased cost efficiency and enhanced productivity (1). Because of this, 3D-printed prosthetic sockets are becoming an alternative option to traditional methods. However, 3D-printed sockets used for weight bearing need to be tested rigorously and like all lower limb conventional prostheses, will need to satisfy ISO standards to ensure patient safety.

Ventola (2014) states that the three most common types of 3D printers used in medical applications are selective laser sintering (SLS), thermal inkjet (TIJ) printing, and fused deposition modeling (FDM) (1). During SLS printing, a laser draws the shape of the object in powder which fuses it together. TIJ printing “uses thermal, electromagnetic, or piezoelectric technology to deposit tiny droplets of ‘ink’ onto a substrate according to digital instructions” (1). FDM printers lay down layers of heated beads of plastic and these build the object layer by layer. FDM printers are less expensive and more common than the SLS type printers (1). For this reason, they are likely the type of printer that prosthetics and orthotics clinics will have in their clinics (1).

The technology of 3D printing is advancing, but many of these designers are becoming more involved with the idea of creating prostheses when they have little to no concept of the intricacies of creating a prosthetic device nor the treatment planning involved. For example, Chhaya et al (2015) discuss several online groups that provide open-source files available for printing upper extremity devices (3). As both prosthetists and healthcare professionals, we believe there is a need to become more involved in the process of designing and testing safe 3D-printed sockets.

Before additive manufacturing technology can be fully implemented in the prosthetics and orthotics field, there are barriers that must be addressed and resolved (Chen, 2016) (4).

Some prosthetics and orthotics clinics have begun to use the technology in their practice due to the decrease in cost of 3D printers as well as the development of 3D scanning technology to efficiently capture the shape of a patient’s limb (5).

Strength Testing

To ensure that weight bearing 3D-printed sockets are safe for patient use, it must adhere to the strength standards for lower extremity prostheses. ISO Standard 10328 is the international standard for the structural testing of lower limb prostheses and it outlines test methods (6).

The ISO 10328 outlines the procedures for testing lower limb prostheses both statically and cyclically (6). The static test is a one-time, single-event test to determine the performance of a structure under a specific load. The cyclic test consists of a specific load applied to a structure multiple times or for many cycles. This simulates conditions of normal walking (6).

Lower extremity prostheses must be tested to satisfy ISO 10328 standards loading condition I and II. Condition I loading “the instant of maximum loading occurring early in the stance phase of walking” (6). Condition II loading “the instant of maximum loading occurring late in the stance phase of walking” (6).

There are three loading levels that can be tested in ISO 10328. P5 is the greatest loading condition where the body mass of an amputee is less than 100 kg. P4 condition is for an amputee whose body mass is less than 80kg, and finally P3 condition is less than 60 kg (6).

A literature search for the strength testing of 3D printed lower extremity prostheses did not produce any results. Other studies have used ISO standards

to test the strength of non-3D printed lower extremity prostheses.

Gerschutz et al., (2012) conducted a study examining static failure loads on traditional sockets (7). In their study, mechanical testing on three different types of sockets was performed (check, copolymer and definitive laminated) for a total of $n = 98$ sockets. They were assessed for passing brittle failure = 4,426N and ductile failure = 3,421 N. This quantitative study evaluated socket strength to provide an understanding of the materials used for prosthetic sockets.

Goh et al., (2002) tested complete prostheses using both cyclic and static procedures (8). The researchers conducted the static test procedure by subjecting the prosthesis to sinusoidal loads ranging from 50N to F_{max} ($F_{max}=1330N$ for condition I and $F_{max}=1200N$ for condition II). The force was maintained for 30s and if permanent deformation of 15mm or the prosthesis failed, the prosthesis was not found to be adhered to ISO 10328 standards (8). If the prosthesis did not fail, it proceeded to the failure test. The article found that the polypropylene sockets passed the static load test with only minimal deformation and passed cyclic test of 250000 cycles with no failure.

Infill percentage

3D printing can change different parameters such as infill percentage. Infill percentage is the density of the plastic between the inner and outer walls and is “specified in percentage altering the density of the pattern” (2). Increasing the infill percentage on a 3D-printed transtibial (TT) socket made from polylactic acid (PLA) should influence the ultimate strength of the socket. Johansson (2016) states that low infill is weaker and more prone to cracking. Whereas, printing at 100% can increase printing time and cost and may not necessarily increase strength (2). It is valuable for the prosthetics and orthotics profession to determine at what infill percentage has adequate strength, but

at the same time, does not take an excessive time to print.

The purpose of this study was to test how changing the infill percentage affects the strength of a 3D-printed TT socket during initial contact. We hypothesized that greater infill percentage could correspond to a greater socket strength. This project collaborated with a research facility to investigate this concept and hope to be a part of a much bigger picture in progressing 3D printing as a tool to help the field of prosthetics.

METHODS

Settings

This experimental study printed nine identical Total Surface Bearing (TSB) transtibial sockets. To maintain consistency, the sockets were all printed from the same data file supplied by the company Additive O&P in Charlotte, N.C. and the clinic Barber Prosthetics in Vancouver, B.C.

The sockets were printed from a FDM printer located at Barber Prosthetics. The FDM printer uses a nozzle head that extrudes melted plastic layer by layer to create a three-dimensional structure¹. It took an average of 8-9 hours to print each socket. The sockets were all printed using a white PLA filament and were all reinforced with scotch cast. At the distal end, each socket was equipped with a 5R1 wood block which served as the attachment point for the pylon in the strength testing apparatus. A registered prosthetic technician oversaw the production and finished each 3D-printed transtibial socket as can be seen in Figure 1.

Considering the various 3D printer parameters that were available to be evaluated, the authors finalized researching infill percentage as a parameter because this variable was hypothesized to have a direct relationship with strength and print time. Three different infill percentages were chosen that would best represent realistic categories that clinicians may decide to print: Three sockets were printed at 30% infill, three sockets at 40% infill, and three sockets at 50% infill. Table 1 describes the properties of each socket.



Figure 1. 3D-Printed TT Socket

Table 1. Characteristics of the 3D-Printed Sockets

Socket #	Infill %	Length (cm)	Weight - Unfinished (gr)	Finished (gr)
1	30	20.8	291	531
2	30	20.8	304	543
3	30	20.8	304	543
4	40	20.8	297	527
5	40	20.8	296	538
6	40	21	302	543
7	50	20.8	325	564
8	50	20.9	324	574
9	50	20.5	326	575

Componentry

This project worked closely with the Centre for Applied Research Institute (CARI) in Burnaby, BC to fabricate components that held our 3D-

printed socket in the proper orientation for strength testing as can be seen in Figure 2. The components included an upper plate and bottom plate made from one-inch thick steel. The superior part of the upper plate and the inferior part of the lower plate contain a concave surface that articulated with two hitch balls which was attached to the strength testing apparatus. Firstly, this ensured a pure vertical force is generated as accurately and consistently as possible. Secondly, this allowed the plates to be oriented in the correct alignment for our project. Our experiment focused on initial contact of the gait cycle as ISO standards state that during this phase, the socket experiences the largest loading force. Lastly, the plates can be placed in different orientations to test for multiple weight classes which are specified as P3, P4, and P5. Our study focused on P5 condition which represents a body mass that is less than 100 kilograms.

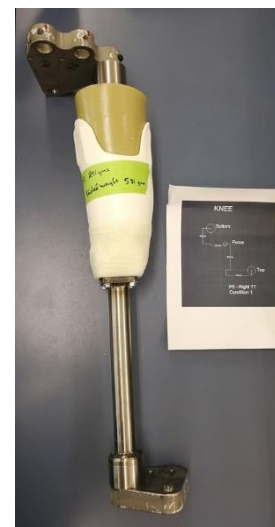


Figure 2. Componentry Attached to 3D-Printed Socket

To simulate a residual limb, a high-density urethane mold was fabricated as seen in Figure 3. The model was created from the same data file which created an intimate fit thus simulating an appropriate fit with the TSB socket. The urethane mold and the upper plate were connected by a 5/8

bolt which allowed the load generated by the strength testing apparatus to be distributed throughout the entire socket.

The bottom plate articulated with the socket through a solid piece of welded steel that acted as the pylon. Since existing prosthetic componentry such as the pylon, tube clamp adaptors and pyramids have already been tested to ISO standards, attempting to eliminate them from the equation is most logical to isolate the strength of the socket. Therefore, a 311 mm solid piece of steel was fabricated to satisfy these requirements. This piece of steel also contained a welded pyramid adaptor which allowed it to be attached to the wood block.



Figure 3. High-Density Urethane Residual Limb Model.

Strength Testing Apparatus

Strength testing was performed on a Tinius Olsen Universal testing machine as seen in Figure 4 (Left) and focused solely on static testing. It was found that cyclic loading requires 3 million cycles which would take approximately one year of continuous testing. Due to time and cost constraints, we decided to forego cyclic testing.

The sockets were tested for ultimate strength. Ultimate strength is defined as static load representing a gross single event, which can be sustained by the prosthetic device/structure but which could render it unusable (ISO, 2006). The static load will be applied for testing condition I which is described as evaluating the instant of

maximum loading during early stance phase or initial contact of the gait cycle. Each socket was tested to ISO standards where the force measurement data was gathered in Newtons (N). The force measurement data we wish to exceed is 4480N which was found in the ISO standard. Furthermore, if the sockets surpassed the threshold, they were subjected to further testing and compressed to failure to determine how much force is required before breaking the socket.

The procedure for principal static ultimate strength test is outlined as follows:

A force is steadily increased at a constant rate between 100 N/s and 250 N/s to 2240 N and held for 10-30 seconds (Values are recorded). The force is removed and the socket rests at zero load for one minute.

The force is again steadily increased at a constant rate between 100 N/s and 250 N/s to 4480 N and held for 30 seconds (Values are recorded). If socket hasn't failed, compression continues and the load is increased until failure is reached. Figure 4 (Right) provides a visual representation of the 3D-printed socket attached to all the componentry.



Figure 4. Left: Tinius Olsen Universal Testing Apparatus; Right: Completed set-up.

RESULTS

Force at Socket Failure

The results of the strength testing procedure were recorded in Table 2. These recordings include the settling test force (Fset), the amount of time each socket spent at Fset, the amount of time the socket spent with no force between Fset and the static proof test (Fsp), the actual force at Fsp, the time the socket spent at Fsp, the force that the socket ultimately failed at, and whether the socket passed the minimum force dictated in the ISO Standard 10328.

Table 2. Results of Loading Procedure (Note: Fset = Settling test force, Fsp = Static proof test force).

Socket #	Infill %	Fset (N)	Fset time (s)	Total rest time (s)	Fsp (N)	Fsp time (s)	Force at failure (N)	Pass Minimum (4480 N)
1	30	1079	15	60	2630	30	11854	Y
2	30	1074	10	60	2438	30	5360	Y
3	30	1070	10	60	2303	30	12841	Y
4	40	1114	10	60	2314	30	9009	Y
5	40	1147	10	60	2425	30	10345	Y
6	40	1216	10	60	2266	30	11383	Y
7	50	1252	10	60	3457	30	11965	Y
8	50	1115	10	60	2371	30	12243	Y
9	50	1177	10	60	2491	30	9847	Y

Both the Fset and Fsp forces listed in table 2 are different for each socket due to the setting capabilities of the strength testing apparatus. The apparatus was controlled via a dial so a specific set point for both Fset and Fsp was not possible. The accuracy of these points depended solely on the operator of the strength testing apparatus pausing the loading at a force close to the intended forces (laid out in the methods) of Fset = 1024 N and Fsp= 2240 N.

Figure 5 shows the force at failure of all 3D-printed sockets. The black threshold line indicates the minimum threshold (4480 N) that the ISO standards dictates for condition I, weight class P5. As shown in Figure 6, all the sockets surpassed the

threshold and all sockets (with the exception of socket number 2) failed at approximately double the force required by ISO standards

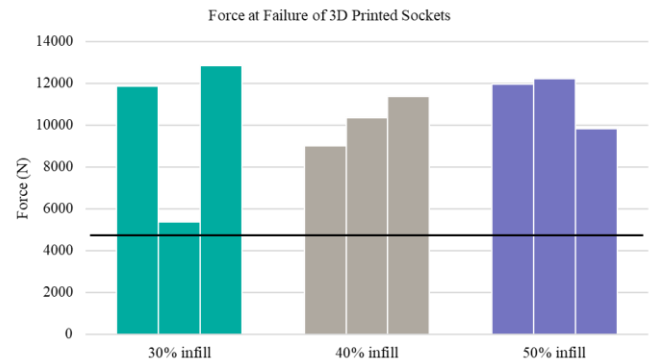


Figure 5. Graph showing the force of failure of 3D Printed transtibial sockets.

Visual Analysis of Socket Failure

Table 3 shows the area that the sockets failed at as well as the type of socket failure. Most sockets failed in the medial popliteal region (seven of nine sockets) and two of the nine sockets failed in the lateral mid socket region. An example of a medial popliteal area socket failure is shown in Figure 6 (left). Figure 6 (right) shows an example of a socket failing in the lateral mid socket.

Table 3. Area of Socket Failure and Failure Type

Socket #	Infill %	Failure point	Failure Type
1	30	medial popliteal	crack
2	30	lateral mid socket	crack
3	30	medial popliteal	complete
4	40	medial popliteal	crack
5	40	lateral mid socket	crack
6	40	medial popliteal	crack
7	50	medial popliteal	complete
8	50	medial popliteal	crack
9	50	medial popliteal	crack

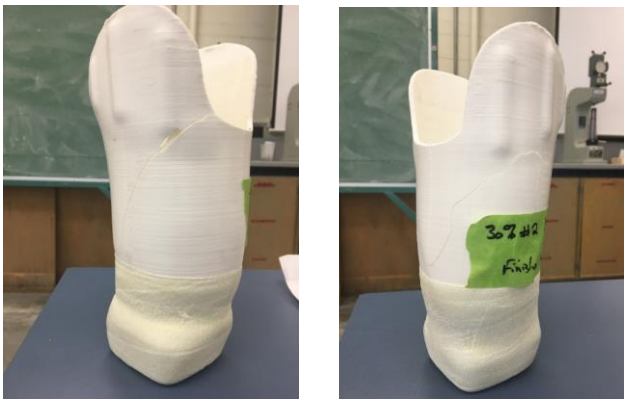


Figure 6. Left: Socket broken in the medial popliteal area; Right: Socket broken in the middle lateral area.

Table 3 shows that the primary method for socket failure was a crack in the socket (seven of the nine sockets). A crack failure type was defined as a failure in which the proximal and distal aspects of the socket remained attached. Figure 6 shows examples of a crack failure. Figure 7 shows an example of a complete failure of the socket. In this case, the proximal and distal aspects of the socket are completely separated from each other. Two of the nine sockets failed in this manner.



Figure 7: Complete Socket Failure

DISCUSSION

The purpose of this research project was to evaluate how changing infill percentage would affect the ultimate strength of a 3D-printed TT socket. To safely use these sockets in either a diagnostic or a definitive phase, the efficacy and

effectiveness of these devices must be clearly shown (9). 3D-printed sockets will need to satisfy the same requirements as lower limb conventional prostheses as stated in ISO Standards 10328. Based on the results, the sockets in this study exceeded the threshold of 4480 N. However, it is important to note that the sockets were evaluated with a specific set of criteria. The conditions of static testing, initial contact (condition I) and P5 weight class were implemented and only under these conditions did all of the sockets exceed the threshold. To fully deem a 3D-printed socket safe for patient use, the other criteria explained in ISO standard 10328 will also need to be satisfied. For example, cyclic testing needs to be performed where the socket is continuously compressed through a low load, long duration setting. This will better simulate a socket when completing activities of daily living. Furthermore, it has been seen in clinical practice that sockets often fail during terminal stance in the gait cycle. Testing in this specific phase of the gait cycle in addition to initial contact, will provide a more encompassing picture as an individual ambulates. Testing each of these conditions in all the weight classes (P3, P4 and P5) will also need to be completed to fully satisfy safety requirements.

The infill percentage did not appear to influence the ultimate strength of the sockets. It was hypothesized that a greater infill percentage would require a greater force for a socket to fail. However, the results show that all the sockets failed at approximately twice the required force (except for socket #2). Perhaps the range of infill percentage was not large enough to see a difference in ultimate strength. In the future, choosing a larger gap in infill percentage may show difference in the force values required for a socket to fail. Another possible explanation for this result is that the other parameters used for the sockets were structurally weaker so the infill percentage was not the factor that influenced failure.



The failure points occurred in different areas of the socket during the experiment; however, it was observed that all the failure points occurred above the reinforced scotch cast. With a diagnostic socket, it is more advantageous that reinforcement methods be done to create additional strength and stability. With the breaks occurring above this area, this suggests that the reinforced area is successful in delegating the force to an area that is less strong. Knowing this, removing the reinforced scotch cast in might have shown different results when evaluating for ultimate strength. As mentioned earlier, the sockets broke in different areas with seven of the nine sockets failing on the medial popliteal area and two of the nine sockets failing at the middle, lateral area of socket. Two of the sockets also experienced complete failure where the socket was broken into two separate pieces. There was no predictability and no trend was seen as to how a socket broke compared to its failure values.

Limitations

The limitations of this study included the small sample size of sockets. Due to cost and time constraints, only nine sockets were printed as this was a logical way to compare sockets printed at different infill percentages. Because of the small sample size, we were unable to comment on any significant differences and can only comment on general trends. Future studies should focus on printing a larger number of sockets encompassing a wider variety of infill percentages which could enable the generation of a statistical analysis.

In general, more testing is needed to be done on the strength of 3D-printed sockets. The settings of 3D printing can be optimized and customized to the user or practitioner's preferences. As a result, evaluating how individual parameters affect the strength of a socket would be beneficial. This study focused on infill percentage as an attempt to isolate its effects and how changing this setting would ultimately affect its strength.

No articles were found regarding the evaluation of the ultimate strength of a 3D-printed TT socket. 3D printing is a relatively new technology in the field; therefore, there is not enough data currently to perform meta-analysis. There are also no randomized control trials to investigate the efficacy of these sockets which created a challenge in narrowing down the testing procedures and methodology process. With 3D printing technology advancing at an impressive rate, future directions should consider investigating how different printers, different materials and how different methods of printing can affect the strength of a socket.

CONCLUSION

3D printing technology is currently being used in many different industries. The field of prosthetics and orthotics needs to embrace this technology and demonstrate how it can be successfully used in clinical practice. A logical first step is testing the strength of 3D-printed prosthetic sockets to determine if it is safe for patient use. This research project demonstrated that the amount of force required for a socket to fail exceeded the 4480N threshold set by ISO Standard 10328. Furthermore, infill percentages ranging from 30% to 50% did not seem to affect the ultimate strength of the sockets. However, it should be noted that the sockets were tested to specific and limited criteria (static testing, initial contact and P5 weight class). This project is a stepping stone to much more extensive research and as such, further work is recommended to investigate how different parameters can influence the strength of socket. Moreover, additional conditions outlined by the ISO standards need to also be satisfied to determine if 3D-printed prosthetic sockets are safe and suitable for patients.

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DECLARATION OF CONFLICTING INTERESTS

Barber Prosthetics donated the use of their 3D printer and the PLA used to print the sockets. The researchers did not receive any financial compensation for this project.

ETHICAL APPROVAL

Not required

AUTHOR CONTRIBUTION

Leah Campbell: Conceptualization, formal analysis, investigation, methodology, visualization, writing original, review & editing.

Adriel Lau: Conceptualization, formal analysis, investigation, methodology, visualization, writing original, review & editing.

Brittany Pousett: Conceptualization, investigation, visualization, supervision, review & editing.

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