The Missing Link - Design considerations for a 3D-printed pylon adapter in lower limb prostheses

Thesis

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Abstract

In the United States, an estimated 1.9 million individuals live with limb-loss, yet fewer than half of them receive prescriptions for prosthetic devices. This number is projected to double by 2050, indicating a proportional increase in amputees without access to prescribed prostheses. Countries lacking established prosthetists face even greater challenges in providing accessible medical devices and care. To address this critical issue, there is a need to develop an affordable and functional substitute for traditional prostheses that caters to individuals across various socioeconomic statuses. As Fused Deposition Modeling (FDM) printing technology has increased in accessibility and affordability, it has the potential to solve this issue and has been present in external research on 3-Dimensional (3D) printed prostheses. As such, this research aims to fill a gap in current studies on additive manufactured prosthetic devices by creating a 3D printed pylon for lower-limb prostheses. Using SolidWorks, I designed and simulated 3D models for FDM printed prosthetic pylons. These models underwent simulated compressive, torque, and bending tests, following ISO 10328 standards on testing lower limb prostheses. These simulations incorporated representative material properties for common FDM filaments such as polylactic acid (PLA), acrylonitrile butadiene styrene (ABS), polyamide 11 (PA11), and polyethylene terephthalate (PET), allowing for a comprehensive analysis of different material choices. Data analysis revealed that the

model designed after a traditional pylon consistently exhibited lower stress and strain compared to pylon models with varying cross-sections. ABS, with its favorable performance, accessibility, physical properties, and cost, was selected for printing. The cylindrical model was then printed in multiple replicants using Kodak white 2.85mm ABS filament on an Ultimaker 2+ FDM printer. These replicants will undergo compression testing following ISO 10328 standards, with the results contributing to this report. Successful completion of this research sets the stage for further work, aggregating results from this and similar studies to develop a fully functional below-knee prosthesis. Researchers can then conduct tests to confirm its ability to replace standard devices, providing a fully functional, accessible, and low-cost prosthesis option for patients lacking access to adequate medical care or coverage.

Acknowledgments

I wanted to begin by giving special thanks to Dylan Beam, and Dr. Goeran Fiedler for starting me on this project and helping me grow it from a generalized concept to a physical design. Their support and guidance have led me through this research and has proved influential in the overall design process.

Furthermore, I want to thank Dr. Sandra Metzler for her role as my research advisor and mentor throughout my time learning how to conduct research. Her expertise as an engineer helped me grow during my research and has shaped what this project has accomplished. Additionally, I wanted to thank Dr. Nocera Tanya for her role during my oral thesis defense. Her feedback and support aided me in the flow of my work and the strength of my research's purpose.

Finally, I wanted to thank The Ohio State University College of Engineering for believing in this work and providing me with a scholarship to help fund this endeavor. It is my hope that the work completed here will flourish into a means of addressing the global shortage of affordable and accessible prosthesis care.

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Introduction

Background

The loss of a limb can significantly impact an individual's mobility and dexterity, which also affects their quality of life and may restrict their ability to participate in day-to-day activities. Rehabilitation care can improve these outcomes but a large population of patients around the world have little to no access to proper prosthesis care. The World Health Organization estimates that the population of individuals with mobility reducing disabilities has increased by nearly 183 million from 2005-2015 (World Health Organization, 2017). Despite this, current systems do not exist in low-middle income countries that can meet current or future demands for rehabilitative care. Even in more prosperous countries, individuals without insurance or in remote areas can suffer from inaccessible care. Due to this gap in healthcare, patients' must rely on crutches, wheeled devices, or home-fashioned prosthetic devices that may not meet their needs.

In recent years, additive manufacturing and telehealth technologies have rapidly increased in both capability and accessibility. Leveraging these two emerging industries could allow for the expansion of medical services to regions that lack established systems (Edworthy, 2001) (Abbady, 2022). In these regions, trained personnel can be connected with patients across the globe and provide supplemental care. With the addition of 3D printing technologies, affordable, functional prosthetic devices can be fabricated local to patients or sent through common shipping methods (Merel van der Stelt, 2021). Current research has shown the capability for 3D-printed sockets and feet to be created that meet clinical standards while remaining affordable for low-income regions (Kim, Yalla, Shetty, & Rosenblatt, 2022). In some of these studies, patients even claimed higher degrees of comfort and usability with 3D printed prostheses than traditionally manufactured models (Yap & Renda, 2015).

However, there are some limitations to the use of 3D printed parts for prosthetic devices. The primary limitation is due to limited material options available for fabrication combined with an inability to recreate the entirety of a lower-limb prostheses with additive manufacturing. Because of this, any system implementing additive manufacturing would still require additional metal componentry that is not easily 3D printed, and which is not always readily obtainable. Some research has shown that low cost metal 3D printers as well as advanced 3D printable materials are possible that could allow for these components to be fabricated locally (Rosli, 2018) (Rogers, 2001). Yet, these methods generally remain a barrier to entry for many applications due to the expertise, maintenance, cost, or inaccessibility that these systems require. In summary, there is still a gap in current research that demonstrates the ability to create a fully functional 3D printed lower-limb prostheses.

3D Printing Overview

To understand the motivation for this research, a basic understanding of the field of 3-Dimensional printing is helpful. The definition of 3D printing is “an additive manufacturing method that creates a physical object from a digital model file. The technology works by adding layer upon layer of material to build up a complete object” (Durbin, 2023). Different printing methods will vary in how this is accomplished, with some common manufacturing methods utilizing raw materials in the form of filament, photocurable resin, or powder.

Filament based printing like Fused Deposition Modeling (FDM) or Fused Filament Fabrication (FFF), is a common printing practice for both hobbyists and industries. This manufacturing method takes a filament made of processed plastic, or in some cases metal, and pushes it through a heated nozzle that begins to melt the material. This nozzle is then moved through a 3D space in order to lay the material down in a generated toolpath that will create the desired object. A detailed figure for this process can be found below in Figure 1. The pros of FDM printing are that it is generally affordable, scalable, easy to maintain, and has access to a large variety of materials. This lends itself to being the most common first choice for beginners and companies alike. However, compared to some other printing methods FDM can lack in speed, precision, and strength.

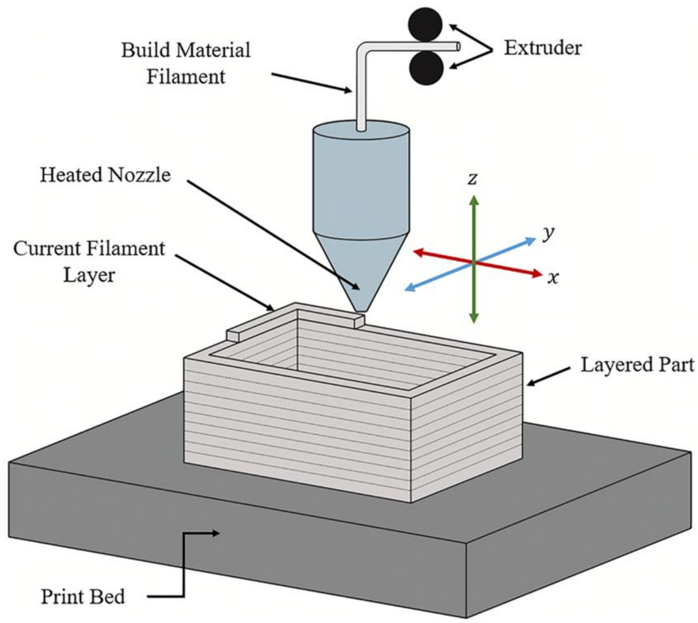


Figure 1: *FDM Printing Process* (Shah, Snider, & Clarke, 2019)

Stereolithography (SLA) is another form of 3D printing but uses photocurable resin in a tank that emits ultraviolet light to harden the material into the required shape. SLA printers work by focusing light on a single layer of resin in a discreet pattern, see Figure 2 for more detail. As such, the printer completes an entire layer during each exposure and will work through each layer of the object to create a full model. Generally, this means that SLA printers can create an object with greater precision and speed than FDM printing due to entire layers being completed at once. Moreover, SLA prints are homogeneous and can manufacturer geometry that is difficult or impossible to mimic on an FDM printer. However, the downside to SLA printers are quite substantial as they cost more, have limited material selection, require greater maintenance, and require postprocessing machines. These include a washing station that removes excess material and cleans up the surface of the print as well as a curing station that effectively seals the material properties of the resin and finishes the print as the printing process itself does not create a finalized product.

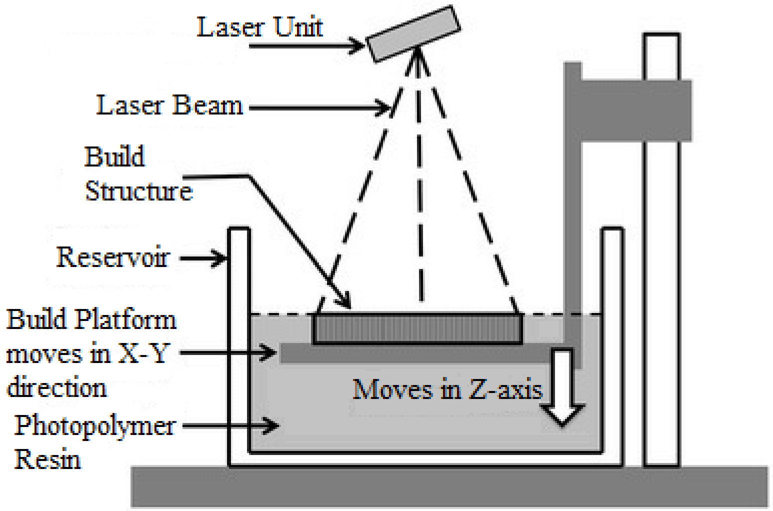


Figure 2: *SLA Printing Process* (Suresh, Reddy, & Kumar, 2019)

Finally, powder-based methods like Selective Laser Sintering (SLS) printing combine aspects of the previously reviewed methods. Overall, this method involves a layer of powdered material and a high-powered laser or heat source that effectively bonds together the powdered particles into the desired model. Figure 3 below illustrates this process. This is by far the most accurate and advanced of the reviewed methods and is used in cases ranging from automotive suppliers to aerospace applications. These printing methods can create objects that rival metal and injection molded parts in both accuracy and strength. However, this technology is prohibitively expensive to anyone but major researchers or businesses, features an extremely limited material range, and requires an abundance of maintenance and technical expertise.

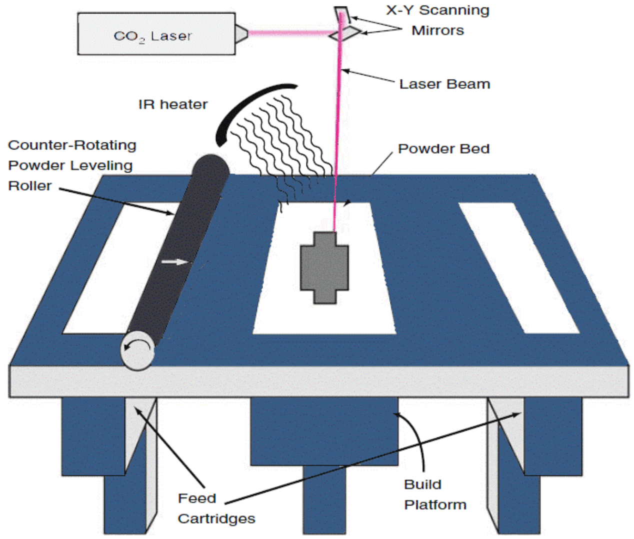


Figure 3: *SLS Printing Process* (Xometry, 2021)

It is important to note that this is not an exhaustive list of additive manufacturing methods and the specific methods used in different printing methods can vary greatly between manufacturers and models. Additionally, different printers and printer methods require specific software called "slicers" which are used to import object models and export toolpath code that is interpreted by a 3D printer. These slicers generally allow for users to manipulate printing parameters that will change how the machine behaves and how objects will be made. A parameter of interest in this study is object infill, which is the density of material inside of an object and greatly changes the weight, strength, and usability of a part. With that being said, this section is only to give a limited idea of the field of additive manufacturing to give background to readers that do not have knowledge in this growing field. As such, there is a plethora of information that is not covered to ensure brevity and to avoid overcomplications.

Lower-Limb Prostheses Overview

As this research focuses on lower-limb prostheses, it is helpful to understand the terminology associated with the different components and features of a prosthetic device. The following section provides a brief introduction into the anatomy of a lower-limb prostheses for the purposes of ensuring reader understanding throughout the remainder of this document. Beginning with the core portions of one of these prosthetic devices, there is the knee joint, socket, suspension system, pylon, pyramid adapters, and the foot. These segments can be seen in greater detail in Figure 4 below.

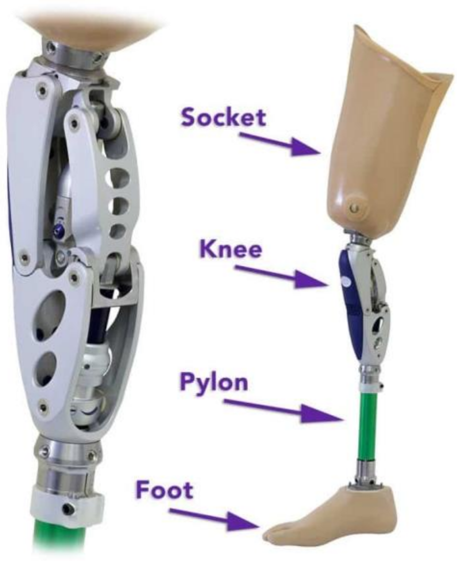


Figure 4: *Lower Limb Prosthesis Diagram* (Lyons, n.d.)

As stated in the Background section of this document, prior research has demonstrated the capabilities of 3D printed sockets, feet, as well as knees. The gap in research that is addressed by this work involves analyzing the suitability for using additive manufacturing to fabricate prosthetic pylons. This suitability will be determined through adapted testing requirements from the ISO 10328 standards for testing lower-limb prostheses. The ISO 10328 Standards Review section outlines the specifications of these standards as well as how they relate to the testing of the experimental model. The goal of the work presented here was to expand current knowledge into the feasibility of using 3D printed pylons as substitutes for traditional manufactured pylons. In order to determine the suitability of a 3D printed pylon in the use of a fully 3D printed lower-limb prostheses, as this has not been thoroughly studied or documented.

Purpose of Research

With the global issue of inaccessible prosthesis care growing (World Health Organization, 2017), the goal of this work is therefore to develop a pylon that can be created utilizing additive manufacturing methods in order to further the capability of printing a fully 3D printed lower-limb prosthesis. While there are limitations related to the material strength and range of materials available for use in 3D printing technologies, the adaptability and accessibility of these methods could be leveraged to achieve substitutive assistive devices in regions without access to established care.

Research Significance

The results of this work could provide insight into the feasibility of producing pylons through additive manufacturing. If feasible, the ability to print pylons would then increase the likelihood that an entire lower-limb prosthesis could be 3D printing. If the research indicates an ability for a pylon to be implemented, it could improve the availability and accessibility of lower limb prostheses in regions where they are currently unavailable.

Thesis Overview

This thesis describes the research that has been conducted regarding the feasibility of an FDM printed prosthetic pylon. The first section gives a brief understanding of the issue that is being addressed as well as background information that is relevant to this project. The next section, titled Methodology, will cover the design process of developing the current iteration pylon, the simulation setup that was used to gain preliminary understanding of model performance, as well as the physical testing procedure and standards. The third section, titled Results, discusses the selection behind the finalized pylon design tree, the simulation results of the model, as well as the current physical testing results. The Conclusion section summarizes the work presented in this thesis and discusses recommendations for future work, additional applications, and the importance of the findings of this research. Appendices are included at the end of the thesis which contain relevant information that was not suited for the main body of the thesis.

Methodology

This project utilized the 3D modeling software SolidWorks (2023) to document the detailed design path and to perform numerical simulations and analysis. A variety of model design paths were explored through the simulation add-on for SolidWorks. These paths allowed for the optimal pylon design to be narrowed down and selected for physical printing and testing. An overview of the initial design selection can be found in the Preliminary Design Trees section found below. Finally, commentary on the simulation and physical testing setup are provided to give greater detail on the means in which models were tested for performance.

Design Requirements and Objectives

This section details the specific design requirements that were used as criteria for model performance and success. As the goal for this thesis is to improve upon the capabilities of 3D printed prosthetic devices, accessibility, cost, and performance were major criteria for consideration. Table 1 below gives a breakdown of the criteria and rational that is expanded upon in this section.

Table 1: *Design Requirements*

ID	Requirement	Rationale	Verification	Acceptance Criteria
ID1	The pylon shall succeed the adapted static compression test from the ISO 10328 standards	To ensure pylon strength and durability for use in prosthetic device	Coaxial Compressive Load Test	Factory of safety >= 3
ID2	The pylon shall succeed the adapted torque test from the ISO 10328 standards	To ensure pylon strength and durability for use in prosthetic device	Upper Torque Load Test	Factory of safety >= 3
ID3	The pylon shall succeed the adapted bending test from the ISO 10328 standards	To ensure pylon strength and durability for use in prosthetic device	Bending Moment Test	Factory of safety >= 3
ID4	The pylon material will be accessible, reasonably affordable, and compatible with low end FDM printers	If the material is unable to be bought or used with affordable printers, then the pylon will not be accessible	Material vendor specifications	Total material cost =< $50
ID5	The pylon material must be able to withstand harsh UV rays, extreme hot or cold weather conditions, and variable humidity	The material must be able to withstand climates of varying conditions otherwise the possibility for premature failure grows	Material technical data sheet	>= 80 ºC Max operating temperature
ID6	The pylon must be functional between the total lengths of 150mm and 400mm	The pylon must be able to be adapted to compensate for different heights to ensure patient fit	Testing simulations	Passes requirements ID1-3 within this range length

The main testing components that were used to simulate model success were adapted from the ISO 10328 standards and are listed as ID1-3. These tests include compressive, torque, and bending loads that are used to determine model strength and functionality. If models are unable to pass these adapted tests, then it can be reasonably assumed that they will fail the ISO 10328 standards as well. Additionally, the materials that are to be used for 3D printing must be reasonably affordable and procurable to satisfy the accessibility requirements for the pylon for ID4. By ensuring this requirement, this keeps the pylon material from becoming an additional barrier in the ability to produce 3D printed prostheses. These materials must also demonstrate capable resistance to environmental factors such as heat, UV rays, and humidity to prevent premature pylon failure according to ID5. Lastly, the pylon must work for a range of lengths to ensure patients can receive the correct length required based on their residual limb to satisfy ID6. Without confirming the pylon works in this range, there is no evidence to support the capability of the pylon in these circumstances.

Preliminary Design Trees

This section describes the design process that was followed to develop and analyze several pylon geometries. The rationale behind the selection of each design and the acceptance criteria for acceptance is also described. This study began with evaluating two design alternatives with one being the common cylindrical pylon that is used in traditional prostheses, and the other mimicking the anatomical structure of the human leg. Preliminary static load testing demonstrated poor results for the anatomical design option which was therefore eliminated from future consideration due to ID1. The cylindrical pylon geometry was expanded to include four geometries with identical lengths and connections but different cross-section geometry. Each design measured a total length of 150 mm and had an outer diameter of 45 mm. The cross-sections for each design included the original cylindrical style, two designs with a cross-section broken up into six cylinders of equal or alternating diameters, and a fourth design that used four hexagons for its cross-section. Figure 5 and

Table **2** below show these cross-sections in greater detail and give key dimensions.

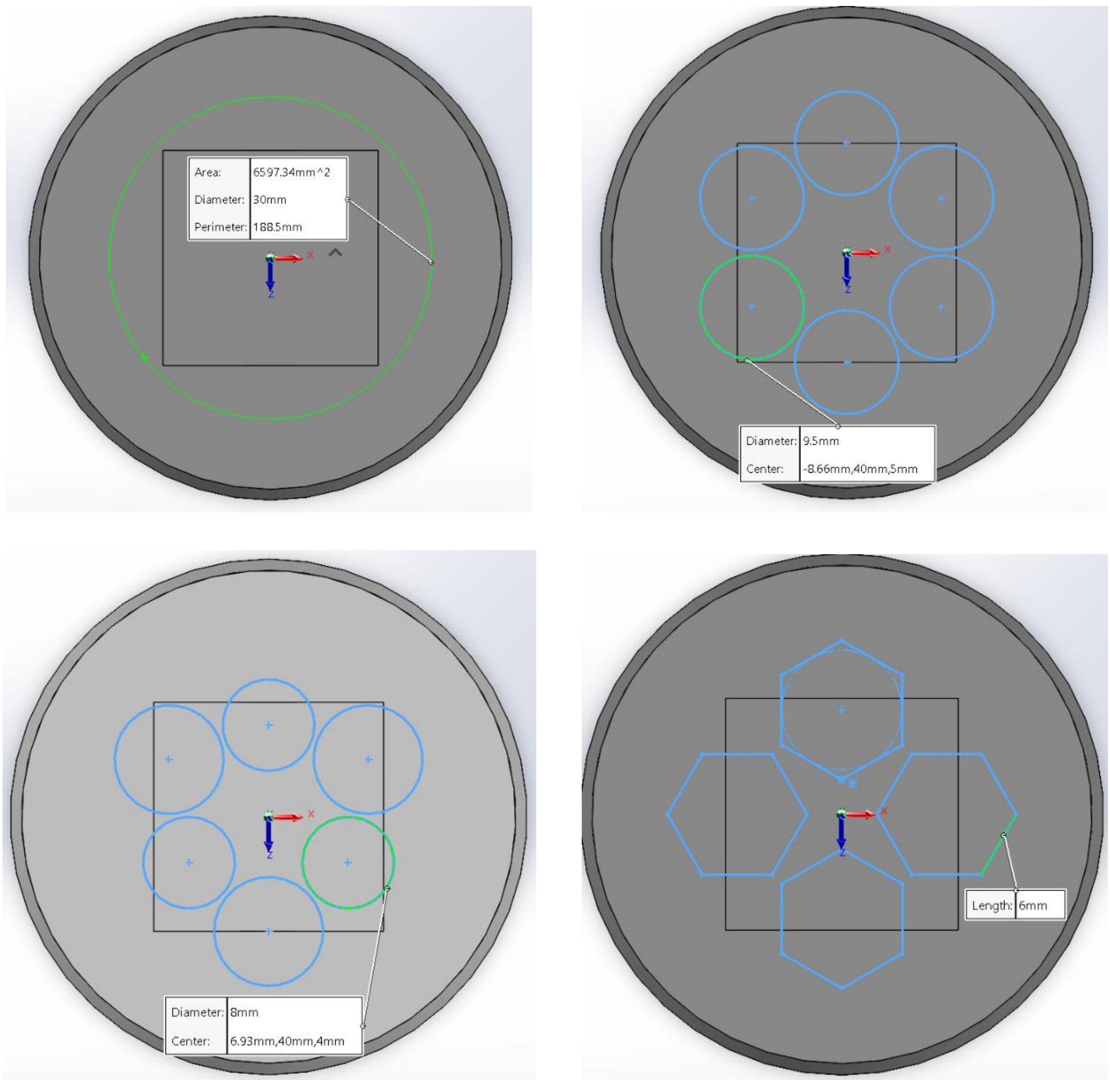


Figure 5: *Cross-Section Diagram*

Table 2: *Cross-Section Dimensions*

Geometry	Cylindrical	Equal Cylinder	Alternating Cylinder	Hexagonal
Segments	1	6	6	4
Key Dimension	Diameter = 30mm	Diameter = 9 mm	Diameter 1 = 9mm Diameter 2 = 8mm	Side Length = 6mm

In addition to these models, four material profiles were used to simulate common filament choices in FDM printing to determine the best choice for design requirements ID 4-5. These choices were polylactic acid (PLA), acrylonitrile butadiene styrene (ABS), polyethylene terephthalate (PET), and polyamide 11 (PA11). These materials underwent initial simulations with basic compressive loading characteristics to narrow down material selection for future simulations and printing. Each model then underwent a series of simulations for static, torque, and bending tests to satisfy design requirements ID1-3. These simulations were modeled with the ABS material type and an additional set of simulations were created at an increased total pylon height of 400 mm to meet design requirement ID6. The material properties that were used for the ABS simulation can be found in Table 3 below.

Table 3: *ABS Simulation Material Parameters*

Property	Value	Units
Elastic Modulus	2000000000	N/m^2
Poisson's Ratio	0.394	N/A
Sheer Modulus	318900000	N/m^2
Mass Density	1020	Kg/m^3
Tensile Strength	30000000	N/m^2
Thermal Conductivity	0.2256	W/(m*K)
Specific Heat	1386	(J/(kg*K)

ISO 10328 Standards Review

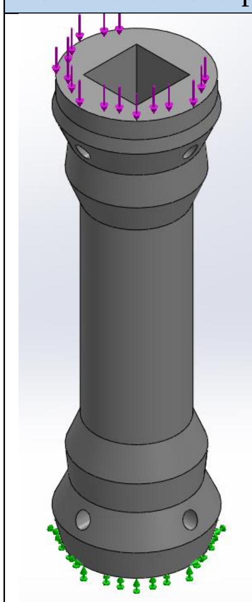
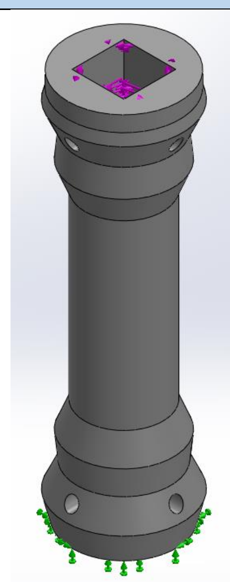
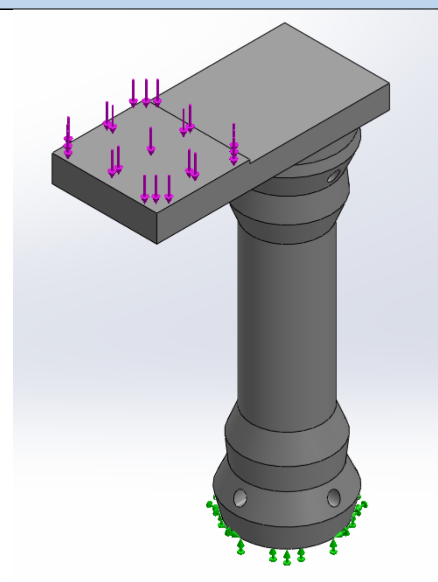
In short, the ISO 10328 standards are a set of guidelines that are to be used for physically testing lower-limb prosthetic components to determine if they are suitable for use with patients. The static tests from these standards include compression loading, torque loading, and bending. Cyclic loading is another important test included in the standards, but it was not a part of the work completed for this thesis. This is mainly due to time constraints and inexperience with setting up testing equipment for a cyclic load.

SolidWorks Simulation Finite Element Analysis

This section details the procedure of setting up the simulation in SolidWorks as well as their technical purpose for this work. SolidWorks simulation add-on allows for users to directly analyze the performance of their models in various loading scenarios. The software allows the user to apply different load conditions to the 3D mesh that is attached to the model, giving a simulated response to the amount and type of force, as well as the location where each force is applied.

Moving onto the process for each pylon model, the bottom connection for each design was treated as a fixed geometry throughout the tests. For the static load test, a 4500 N static force was applied coaxially at the top of the model. For the torque test, a 10 Nm torque was applied to the topmost portion of the design. For the bending test a load of 1500 N was placed at the end of a 50 mm plate attached to the top of each design to simulate a bending force. After each test, the design's stress profile and deformation were evaluated to gauge how changing the cross-section of the model affected these parameters. Table 4 below shows figures of the cylindrical pylon simulation setup for the static, torque, and bending load tests.

Table 4: *Simulation Setup Diagrams*

Static Load Simulation Setup	Torque Load Simulation Setup	Bending Load Simulation Setup
		

Two important factors to consider from these simulations are that SolidWorks assumes a homogenous solid structure that is not representative of what is produced from a 3D printer. The other factor is that these simulations are based on the ISO 10328 standards discussed earlier however, the simulations are simplified versions of the standard procedures. These standards encompass a large number of different cases and complexity, and completely simulating each of these scenarios was beyond the scope of this work. Therefore, the simulation models provided an initial assessment, but additional analysis would be necessary to fully assess compliance with these standards. Thorough physical testing would also need to be completed to confidently report model adherence and success, which is planned for future work.

Physical Test Setup

Two initial prints were made at 15% and 100% infill levels to determine the strength of the pylon at varying material density. The models were printed using Kodak white 2.85mm ABS filament on an Ultimaker 2+ FDM printer. These prints were then placed in an Instron 8501 Servo Hydraulic Machine that applied a coaxial compressive load to the topmost portion of the model until failure was detected. Figure 6 below displays this testing setup. Force vs Displacement graphs were acquired for each loading and will be used to determine maximum compressive load achieved for each model. Appendix A, and B, contain technical specifications sheets for the Instron 8501 machine, and the Ultimaker printer respectively. No data sheet could be found for the Kodak ABS filament, as such the material properties of this material were assumed to be similar in nature to the Ultimaker ABS filament (Ultimaker, 2022).

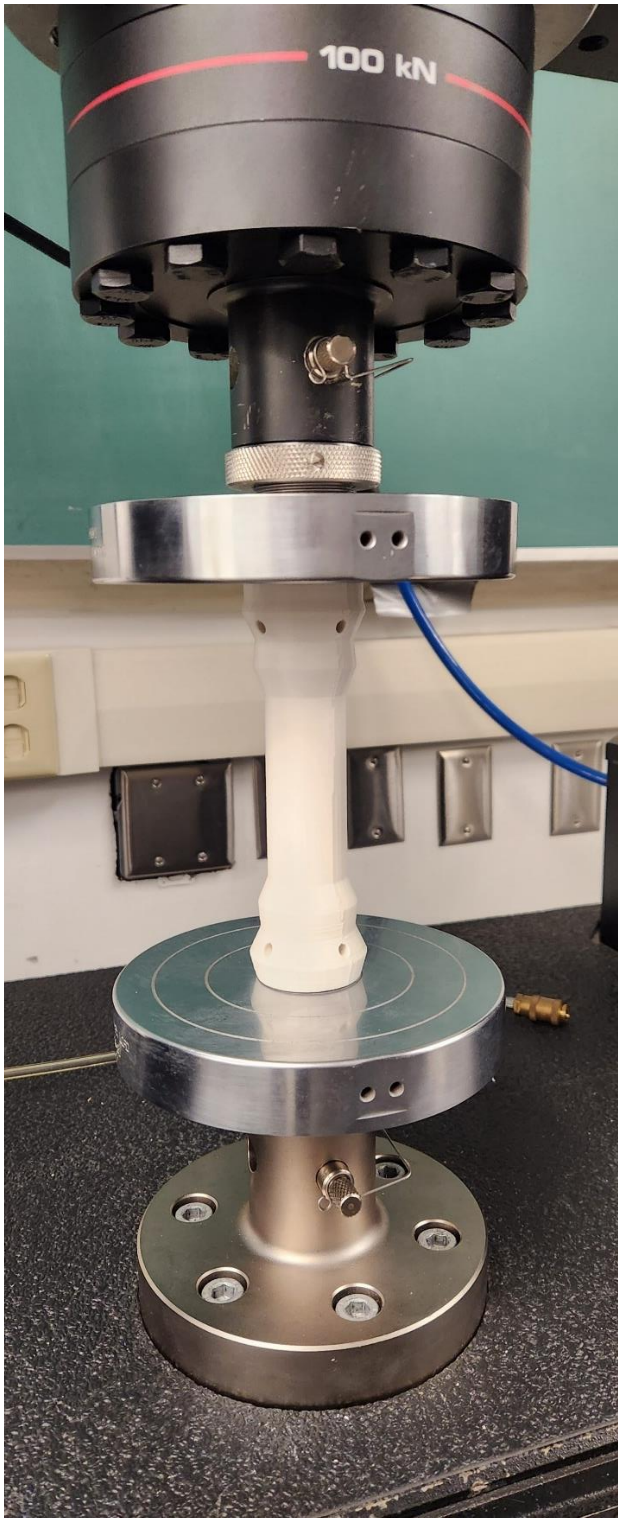


Figure 6: *Instron Compressive Testing Setup*

Results

SolidWorks Simulation Results

This section reports the results of the various SolidWorks simulations that were completed prior to physical model fabrication and testing. These simulations were used as a means of narrowing down design choices and preparing models for optimal strength and performance considerations. The subsequent thesis sections are organized according to the individual type of test that was performed and include the testing data as well as a brief explanation of results. For simplicity, green highlights mean the model has passed testing and meet acceptance criteria, orange highlights mean the model passed testing but did not meet the applicable acceptance criteria, and red highlights mean the modeled did not pass testing or the required acceptance criteria.

Additionally, ABS was chosen for these simulations as it showed high strength qualities in initial testing. ABS is also one of the most commonly produced FDM filaments and has high heat resistant properties and adequate UV resistance following design requirement ID5. All of this led to ABS being an appropriate choice for printing due to its accessibility, affordability, and reliability in line with criteria ID4.

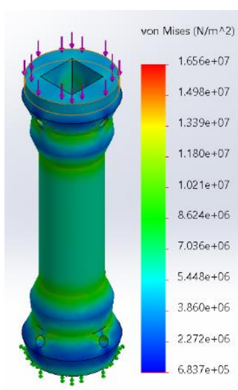
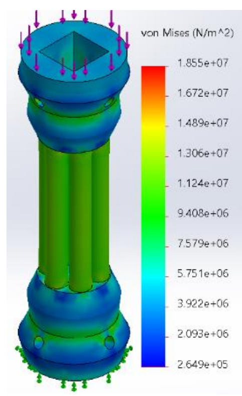
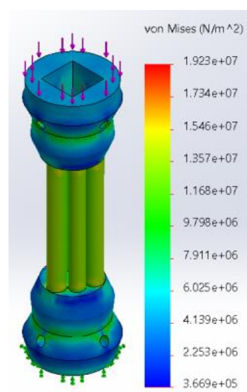
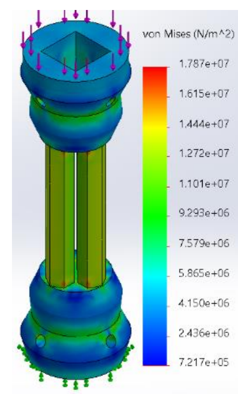
Static Load Stress and Deflection Profiles

- Based on these results, it is predicted that each design will pass the static load testing criteria ID1.

Table 5: *Static Load Results*

Model	Cylindrical	Equal	Alternating	Hexagon
Max Deformation (mm)	0.49	0.66	0.75	0.73
Max Stress (MPa)	16.6	18.6	19.2	17.9
Minimum Factory of Safety	4.44	3.97	3.84	4.12

Table 6: *Static Load Stress Profile*

Cyindrical	Equal	Alternating	Hexagon
			

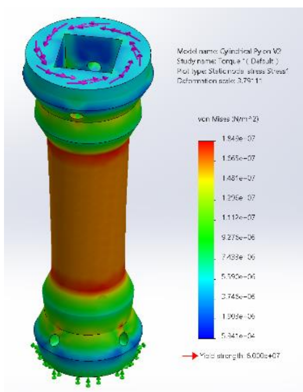
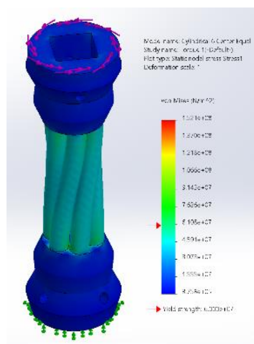
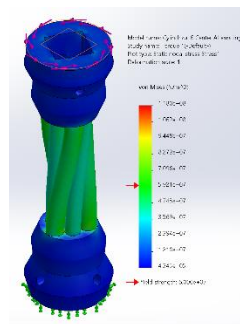
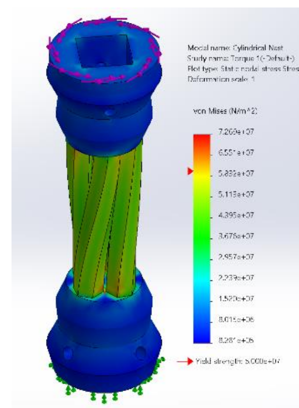
Torque Load Stress and Deflection Profiles

- Based on these results, it is predicted that the equal and alternating designs will fail the torque load testing as their minimum factors of safety are below 1. Additionally, the hexagon design did not meet the acceptance criteria of ID2 as its minimum factor of safety is only 1.56.

Table 7: *Torque Load Results*

Model	Cylindrical	Equal	Alternating	Hexagon
Max Deformation (mm)	0.82	7.1	9.2	6.6
Max Stress (MPa)	7.9	88.0	101.5	46.4
Minimum Factor of Safety	9.34	0.84	0.73	1.56

Table 8: *Torque Load Stress Profile*

Cyindrical	Equal	Alternating	Hexagon
			

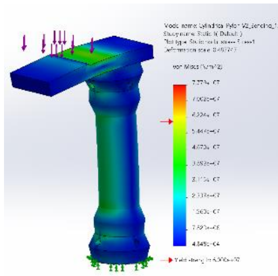
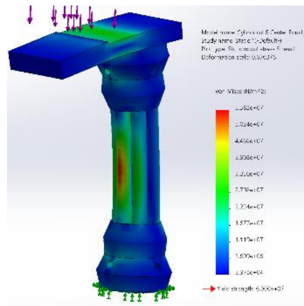
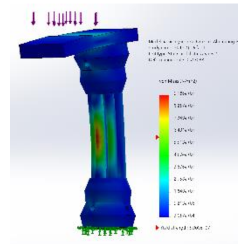
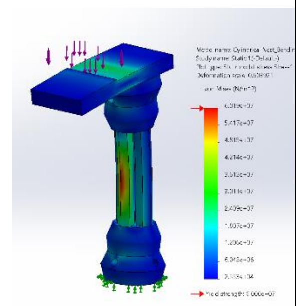
Bending Factor of Safety

- Based on these results, the cylindrical, equal, and hexagon models will pass the bending test but the alternating design will fail. However, only the cylindrical model passed the acceptance criteria of ID3.

Table 9: *Bending Load Results*

Model	Cylindrical	Equal	Alternating	Nest
Buckling Factor of Safety	3.6	1.24	0.98	1.28

Table 10: *Bending Load Stress Profile*

Cyindrical	Equal	Alternating	Hexagon
			

Additional Testing

The intention of this project was to develop initial understanding for the 3D printing of prosthetic pylons. The goal of this research was therefore to determine the likelihood of creating a usable pylon through FDM technology. Because of this, the model with the greatest likelihood to pass standards related tests was chosen for printing and physical testing. Similarly, the 150mm length class of pylons were focused upon as they showed a greater likelihood for passing physical testing. Similar simulation data for the 400mm length class can be found in Appendix C. 400mm Length Class Simulation Results

Final Design Selection

From the simulations that were conducted on the design paths of the 150mm length class, it was determined that the traditional cylindrical cross-section pylon will perform the best in physical testing. This is because it did not fail a single simulation and proved to have greater stress and deformation properties than the other cross-sections. As such, the 150mm length cylindrical pylon was chosen to be printed out of the selected Kodak white ABS filament.

Physical Testing Results

This section presents the results of physical testing of 2 different printed specimens under a compressive coaxial load. A load equaling 4500 N or 1100 lbs and above was considered to be passing according to criteria ID1 from the adapted standards. These specimens were printed from the cylindrical model design specified in the SolidWorks Simulation Results section. The subsequent sections address the loading and results of these three specimens respectively. Appendix D. Pylon Physical Testing Results, contains images of the pylons after testing.

15% Infill – Design 1

Figure X below shows the loading results for a static compression test on the 15% infill cylindrical pylon model. The maximum load achieved was 1062.6 kgf, equaling 10.4 kN or 2342.63 lbs. As such, the 15% infill model passed preliminary testing goals.

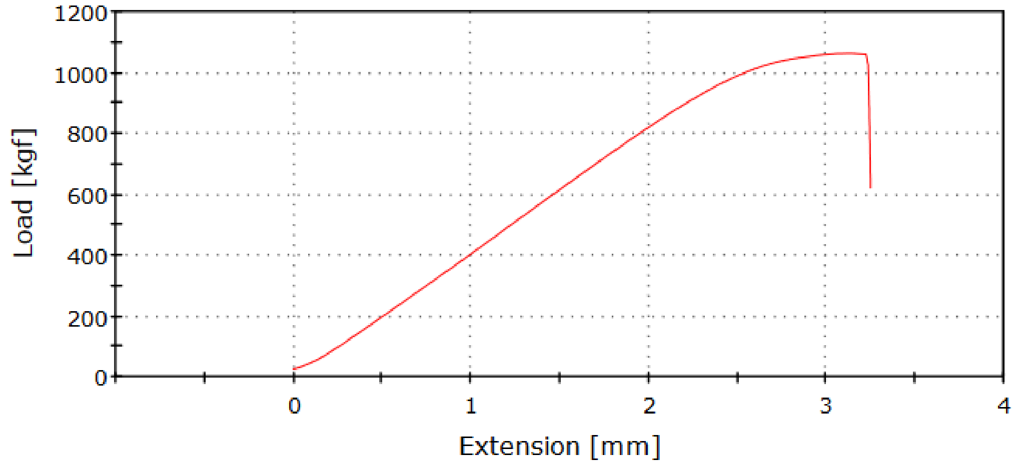


Figure 7: *15% Infill Model Compressive Loading Graph*

100% Infill – Design 1

Figure X below shows the loading results for a static compression test on the 100% infill cylindrical pylon model. The maximum load achieved was 3386.5 kgf, equaling 33.2 kN or 7466 lbs. As such, the 100% infill model passed preliminary testing goals. An important note is that at 100% infill, the printer has seemed to over extruded material through the printing process. This caused areas of the pylon to be bulbous in shape and reduced dimensional accuracy.

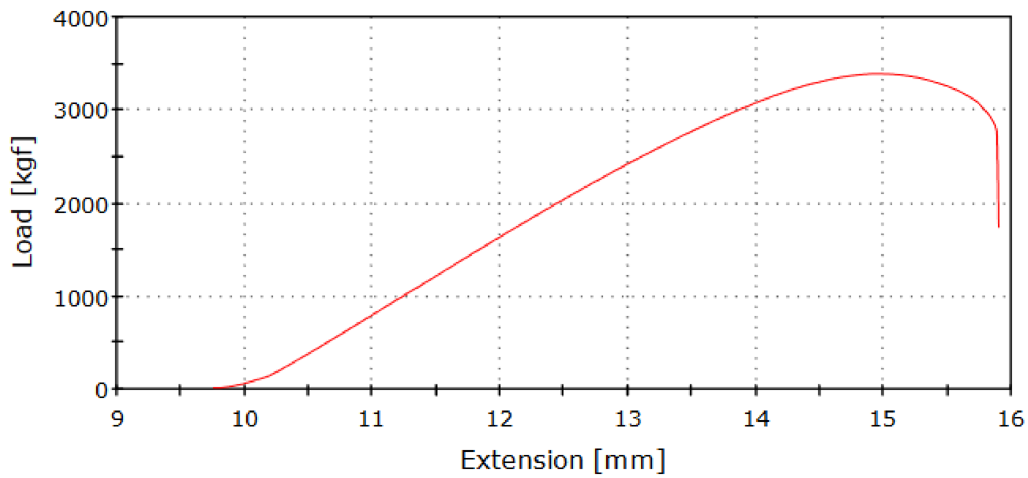


Figure 8: *100% Infill Model Compressive Loading Graph*

Conclusion

Summary

In this work, various pylon design geometries were evaluated in SolidWorks simulation manager to assess different cross-section geometries for their likelihood to pass the adapted ISO 10328 standards. These simulations also looked at material performance for common FDM filament to determine suitable material options based on the design requirements necessary for an accessible and affordable pylon. Once a material and cross-section had been selected, a variety of testing procedures were ran to determine if an FDM 3D printed prosthetic pylon was eligible to substitute a traditionally manufactured pylon. The goal behind this is to eliminate a gap in the current knowledge base for 3D printed prosthetic components. Preliminary results from these tests give strong evidence towards this eligibility. This can be further explored in future work to verify adherence to the traditional ISO 10328 standards.

Research Importance

The intention of this research is to provide information that can be utilized in the process of designing and fabricating 3D printed lower-limb prosthesis, in service of the overall goal of addressing the global concern of inaccessible rehabilitative healthcare in low-middle income countries. The results of this work indicate that creating a functional 3D printed prosthetic pylon is feasible. This provides further evidence that it is possible to create a fully 3D printed lower-limb prosthesis to address this concern discussed earlier.

Additional Applications

So far, this research has focused on providing a suitable alternative to traditional prostheses in regions that lack access to such devices. There is a need for affordable prosthetic devices and this research as well as future related work may result in a low-cost alternative to traditional lower-limb prostheses. Areas with reliable rehabilitative services could also benefit from this work as it could result in a greater population of patients being able to afford prosthetic devices.

Future Work

While significant, this research is only a single step to a larger goal. Future work would include more significant testing of this current model in order to determine ISO 10328 compliance. Doing so would likely require a dedicated test setup to match the conditions outlined in these standards. If this work determines that the design complies with the standards, then the continuation of this work with additional development could be used to create a fully functioning 3D printed lower-limb prosthesis. By doing this, the manufacturing process could rely solely on additive manufacturing which would allow for expanded prosthesis accessibility and aiding in mitigating the global lack of rehabilitative services.

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Appendix A. Instron 8501 Technical Specification Sheet (Frank Bacon)

Frank Bacon Machinery Sales Co.
21251 Ryan Road
Warren, MI 48091
586-756-4280 **www.frankbacon.com** **Email: sales@frankbacon.com**

Stock #	DESCRIPTION
12623-00	22KIP (100kN) Instron 8501 Fatigue Load Frame (1) USED 22 KIP (100 kN) Capacity Instron Model 8501 Two Column Top Mounted Actuator Material Fatigue Testing Load Frame.

Instron Model 8501
SPECIFICATIONS:

Model Number: OP1477-1013
Serial Number: 00284
Capacity (KIP): 22 (100 kN)
Number Of Columns: 2
Distance Between Columns: 22"
Test Specimen Max. Length: 48" (Less Load Cell & Tooling)
Table Size (W x D): 21" x 9.75"
Overall Dimensions (W x D x H): 36" x 48" x 99"-122"
Approximate Weight (lbs.): 2420

EQUIPPED WITH:

- Instron 22 KIP (100 kN) Dynamic Hydrostatic Actuator, Model A726-35A with 10" Stroke & LVDT S/N 992
- MOOG 760-714A Servo Valve S/N 194
- 22 KIP (100 kN) Dynamic Fatigue Rated Load Cell
- Hydraulic Crosshead Lifts and Hydraulic Locks

FOB Warren, MI
Reconditioned with 90 Day Parts and Labor Warranty
30 Day Satisfaction Guaranteed Return Privilege

Guarantee:

Unless otherwise specified, every machine is offered with the standard **MDNA** *(MACHINERY DEALERS NATIONAL ASSOCIATION)* Return privilege to ensure your complete satisfaction. If the machine is un-satisfactory it may be returned to our warehouse, freight prepaid and in the original condition within 30 Days of shipment for a full refund less the cost of SPECIALIZED EQUIPMENT, NEW ITEMS AND RE-CERTIFICATION COSTS, When applicable. Care is taken to provide accurate specifications. However, Critical areas should be verified by Inspection.

Appendix B. Ultimaker 2+ Technical Specification Sheet (Ultimaker, 2023)

SPECIFICATIONS

PRINTING	
Build volume L / W / H	223 x 223 x 205 mm / 8.77 x 8.77 x 8.07 inches
Layer resolution	200 micron – 20 micron
Postioning precision X / Y / Z	12.5 / 12.5 / 5 micron
Filament diameter	2.85 mm
Nozzle diameter	0.4 mm / 0.0157 inches
Print speed	30 mm/s – 300 mm/s
Travel speed	30 mm/s – 350 mm/s
Print surface	Heated glass bed
Filament types	PLA / ABS / CPE

PHYSICAL DIMENSIONS	
Desktop L / W / H	357 x 342 x 388 mm / 14.05 x 13.46 x 15.27 inches
Shipping box L / W / H	400 x 400 x 550 mm / 15.74 x 15.74 x 21.65 inches*
Weight	11.2 kg / 24.69 pounds
Shipping weight	18.0 kg / 39.68 pounds*

SOFTWARE	
Supplied software	Cura - Official Ultimaker Software
Supported OS	Windows / Mac / Linux
File types	STL / OBJ
File transfer	Stand alone SD card printing

TEMPERATURES	
Nozzle temperature	180 – 260 °C
Heated bed temperature	50 – 100 °C
Ambient operating temperature	15 – 32 °C
Storage temperature	0 – 32 °C

ELECTRICAL AND SOUND	
AC Input	100 – 240 V / 1.4 Amps / 50 – 60 Hz / 221 Watt Max
Average Operating noise	49 dBA

* Printers shipping from the USA have different shipping dimensions and a different shipping weight

WARRANTY

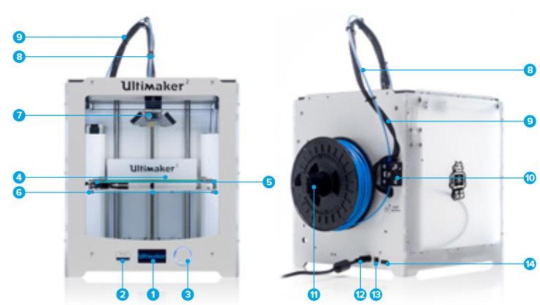
The Ultimaker 2 comes with a 1 year warranty (excluding the hot end) and free life-time support. This warranty gives users extra reassurance on their build quality and reliability.

Learn more about our services on the warranty page at www.ultimaker.com/en/support/view/16575-ultimaker-warranty.

CERTIFICATES

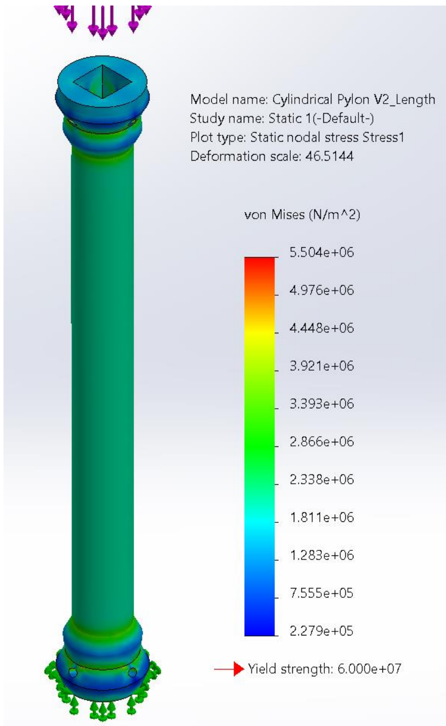
The Ultimaker 2 has CE marking and is therefore in compliance with the essential requirements of the Machinery Directive, Electromagnetic Compatibility Directive, RoHS, RoHS II and Reach.

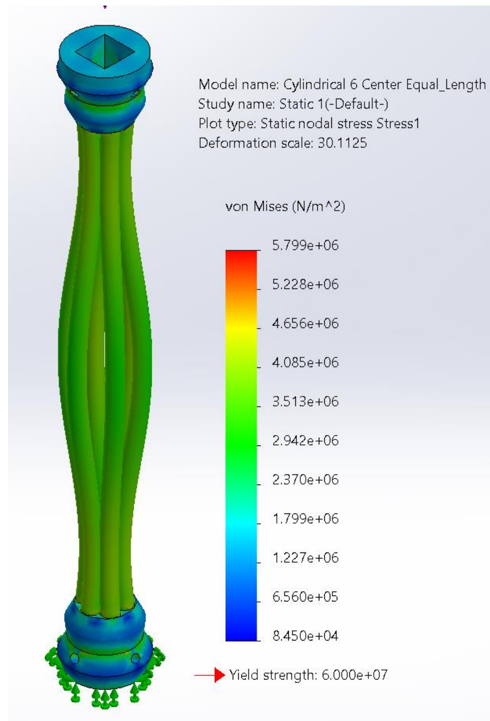
The official CE certificate can be downloaded here www.ultimaker.com/en/support/view/16482-safety-and-compliance.

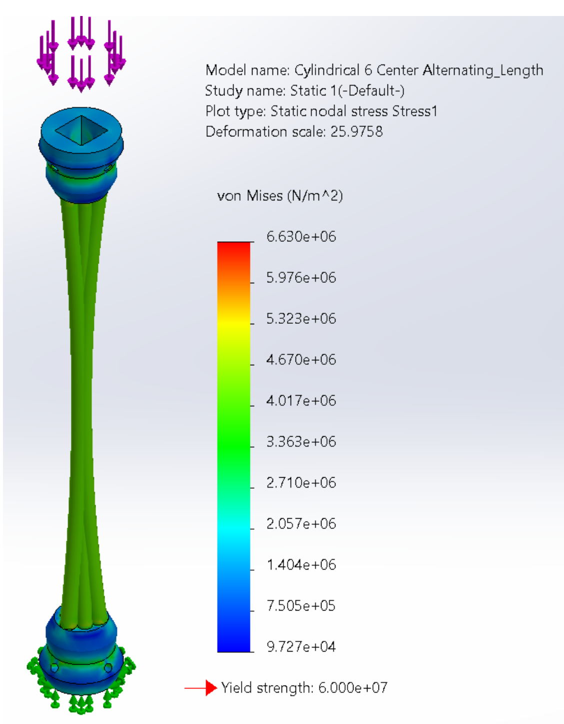


1 Display	4 Build plate	7 Print head	10 Feeder	13 USB socket
2 SD card slot	5 Build plate clamps	8 Bowden tube	11 Spool holder	14 Power switch
3 Push/rotate button	6 Build plate screws	9 Print head cable	12 Power socket	

Appendix C. 400mm Length Class Simulation Results



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Study name: Static 1(-Default-)
Plot type: Static nodal stress Stress1
Deformation scale: 25.9758
von Mises (N/m^2)
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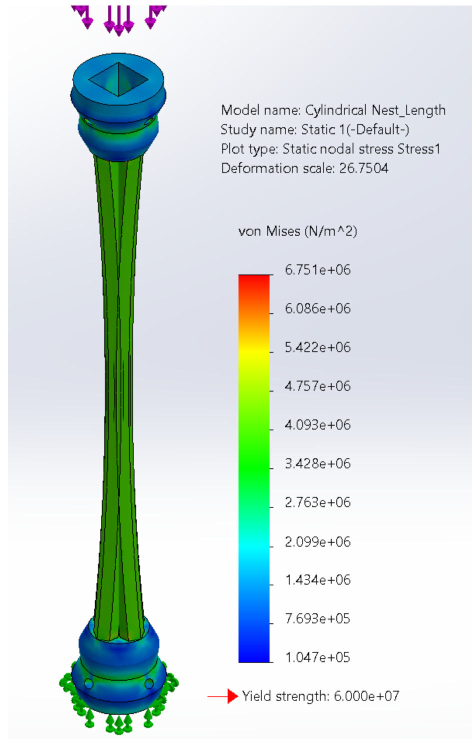
5.976e+06
5.323e+06
4.670e+06
4.017e+06
3.363e+06
2.710e+06
2.057e+06
1.404e+06
7.505e+05
9.727e+04
Yield strength: 6.000e+07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Study name: Static 1(-Default-)
Plot type: Static nodal stress Stress1
Deformation scale: 26.7504
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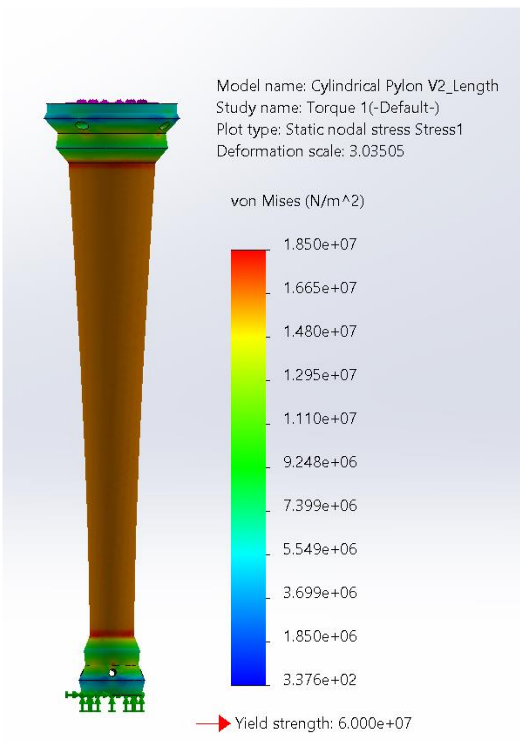
6.086e+06
5.422e+06
4.757e+06
4.093e+06
3.428e+06
2.763e+06
2.099e+06
1.434e+06
7.693e+05
1.047e+05
Yield strength: 6.000e+07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Study name: Torque 1(-Default-)
Plot type: Static nodal stress Stress1
Deformation scale: 3.03505
von Mises (N/m^2)
1.850e+07
1.665e+07
1.480e+07
1.295e+07
1.110e+07
9.248e+06
7.399e+06
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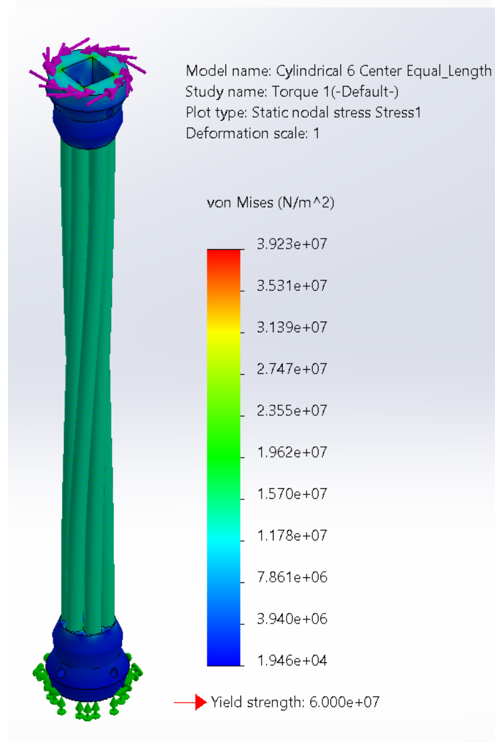
3.376e+02
Yield strength: 6.000e+07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Study name: Torque 1(-Default-)
Plot type: Static nodal stress Stress1
Deformation scale: 1
von Mises (N/m^2)
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3.531e+07
3.139e+07
2.747e+07
2.355e+07
1.962e+07
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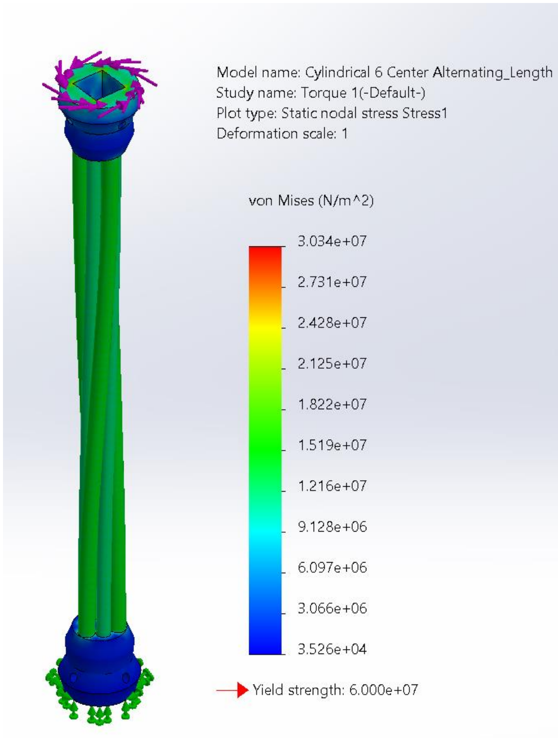
Yield strength: 6.000e+07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Study name: Torque 1(-Default-)
Plot type: Static nodal stress Stress1
Deformation scale: 1
von Mises (N/m^2)
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2.731e+07
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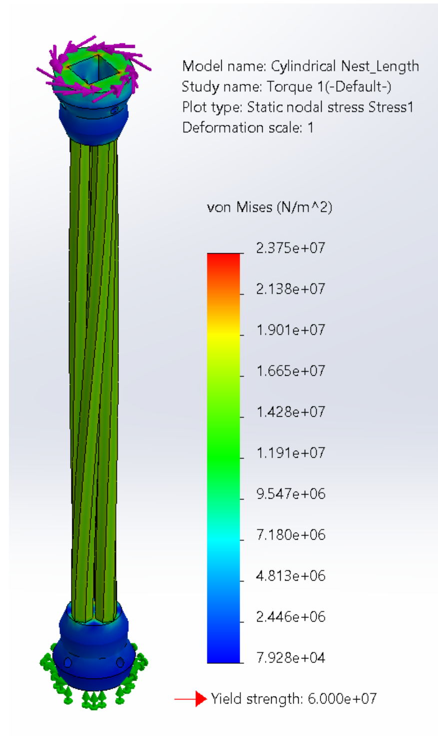
Yield strength: 6.000e+07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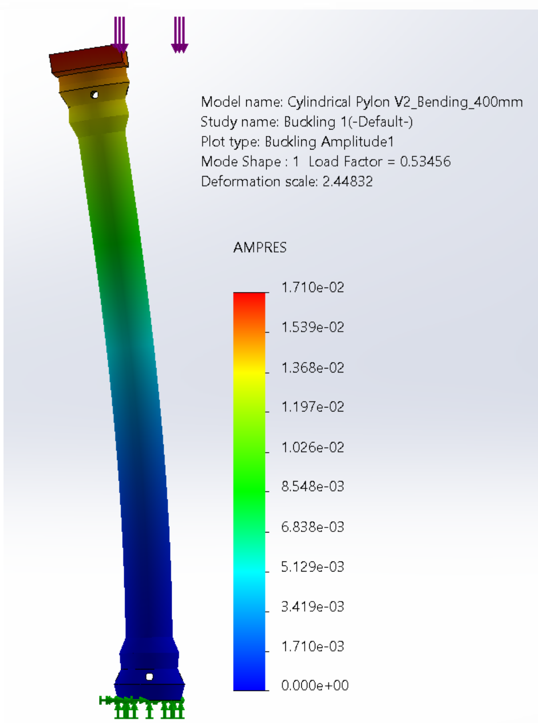
7.928e+04
Yield strength: 6.000e+07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Plot type: Buckling Amplitude1
Mode Shape : 1 Load Factor = 0.53456
Deformation scale: 2.44832
AMPRES
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1.539e-02
1.368e-02
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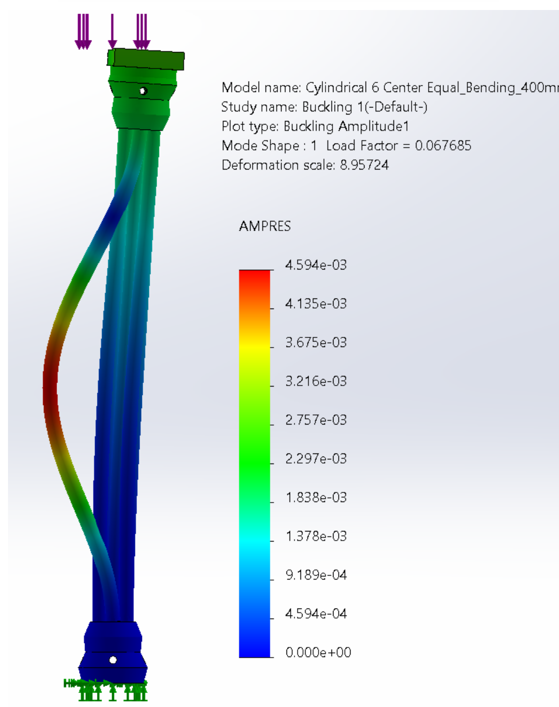
0.000e+00


Model name: Cylindrical 6 Center Equal_Bending_400mn
Study name: Buckling 1(-Default-)
Plot type: Buckling Amplitude1
Mode Shape : 1 Load Factor = 0.067685
Deformation scale: 8.95724
AMPRES
4.594e-03
4.135e-03
3.675e-03
3.216e-03
2.757e-03
2.297e-03
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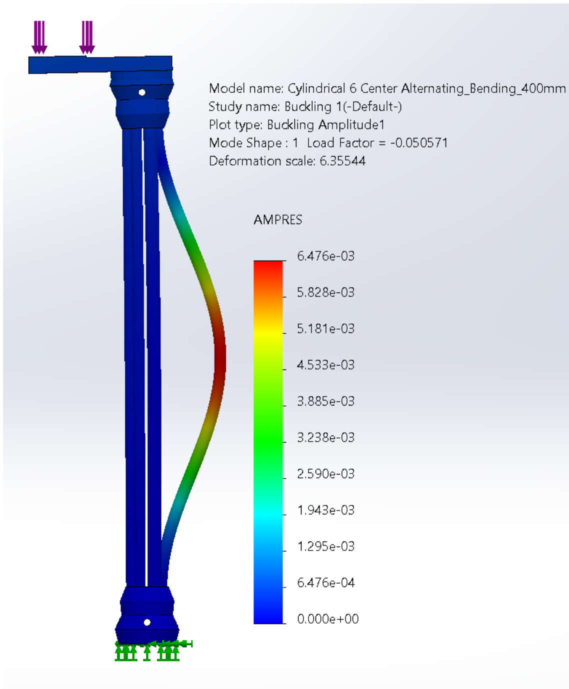
4.594e-04
0.000e+00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Study name: Buckling 1(-Default-)
Plot type: Buckling Amplitude1
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Deformation scale: 6.35544
AMPRES
6.476e-03
5.828e-03
5.181e-03
4.533e-03
3.885e-03
3.238e-03
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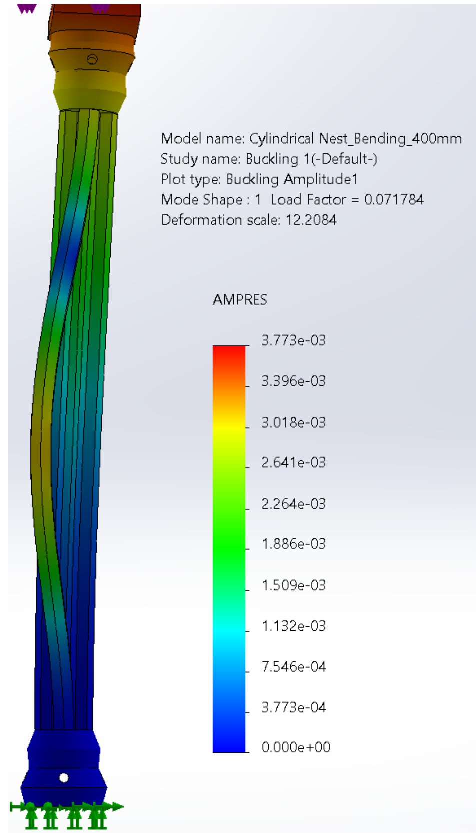
6.476e-04
0.000e+00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3.396e-03
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2.641e-03
2.264e-03
1.886e-03
1.509e-03
1.132e-03
7.546e-04
3.773e-04
0.000e+00

Appendix D. Pylon Physical Testing Results

15% Infill Model

100% Infill Model