Journal of Studies in Science and Engineering

EngiScience Publisher

Research Article

Design of Lower Prosthetic Limb Using Additive Manufacturing Processes

Muhammad Osama [1,*]

[1] Industrial and Manufacturing Department. NED University of Engineering & Technology ,Karachi , 75270, Pakistan

*Corresponding Author: Muhammad Osama, E-mail: muhammadosama1919@gmail.com

Article Info

Article History

Received Oct 23, 2021

Revised Nov 10, 2021

Accepted Nov 12, 2021

Keywords

Additive Manufacturing

Prosthetic limb

Stereolithography

FDM

Abstract

This paper presents an approach for designing a prosthetic limb using SolidWorks. The process of stereolithography helped manufacture the prosthetic limb due to the flexibility in the provided parameters. The designed leg weighs 4kg approx. The entire weight acts on the sole of the leg. The sole again underwent a SolidWorks simulation with the application of a 1200N load. The preferred material - TPU - was selected after considering all the factors. The manuscript proceeds with a financial analysis to get a price estimate for the manufacturing of each part of the limb, which is a crucial factor.

1. Introduction

Additive manufacturing (AM) is a process that produces three-dimensional (3D) objects layer by layer using specific materials. This process underwent revolutionization in the current period with the advent of various methods of additive manufacturing. Furthermore, these processes play a pivotal role in producing biomedical equipment like implants, devices, and scaffolds. In the present era, the term, Industry 4.0 describes the ongoing global fourth industrial revolution. It is primarily due to technologies, like the Internet of Things, used in the production process, leading to new industries and methodologies to develop products efficiently. Nine major industries are bringing a paradigm shift in this revolution. One of them that is of interest is additive manufacturing. It can produce parts faster, that too with more precision and greater flexibility. As a result, the consumer gets a product at a reduced cost but of extremely high quality. Additive manufacturing finds its application in multiple fields like aerospace, automotive, and medical products [1].

In the early 1980s, the rise of additive manufacturing technologies (AMTs) allowed the construction of 3D models. Hence, they are popularly known as 3D printing technologies in a manufacturing environment. Another reason lies in the introduction of the stereolithography technique. This technique finds its ground in the cure of photopolymer resin in thin layers with a UV laser. In the following years, the world saw other AMTs, such as fused deposition modeling (FDM), laminated object manufacturing (LOM), selective laser sintering (SLS), 3D printing, and variable rapid prototyping (Polyjet Technology), among others. The unique advantages of layer additive manufacturing pave the way for the design and development of multi-tasking functional tools. These tools offer a wide range of applications from dentistry to regenerative medicine and tissue engineering.

There have been numerous applications of 3D printing. An implant came into being using LASER by melting thin layers of titanium powder. In 2013, Oxford Performance Materials received FDA approval for a 3D-printed polyether ketone (PEKK) skull implant, first successfully implanted that year. 3D print titanium has also found its application in orthopedic maxillofacial, spinal, and dental implants. There are clear, removable, 3D-printed orthodontic braces that are custom-made and unique to each user. This product provides a well-suited example of how 3D printing can be applied efficiently and profitably to make customized and complex items.[8]

2. Literature Review

Medical applications for 3D printing are expanding rapidly and can revolutionize healthcare. Medical uses for 3D printing, both actual and potential, can be organized into several broad categories, including tissue and organ fabrication; creation of customized prosthetics, implants, and anatomical models; and pharmaceutical research regarding drug dosage forms, delivery, and discovery. The application of 3D printing in medicine can provide many benefits. These benefits include but are not limited to the customization and personalization of medical products, drugs, and equipment; and cost-effectiveness. Other benefits include increased productivity, the democratization of design and manufacturing, and enhanced collaboration [5].

However, despite recent significant and exciting medical advances involving 3D printing, notable scientific and regulatory challenges remain, and the most transformative applications for this technology will need time to evolve [6]. Patient-personalized implants have been proposed and developed with the advent of 3D printing techniques recently. 3D printing methods of leg implants can have manifold advantages over conventional manufacturing methods. For instance, Plaster of Paris is usually used to cover amputated legs to capture the surface of the patient that can tend to be less accurate, messy, and uncomfortable. Using topography scanners, a CAD designer can interpret the points and make a more precise and preferable model for the patient [10].

The design of patient-specific implants often complies with their medical 3D model, like 3D CT scan data and MRI data. On the other hand, 3D printing techniques can manufacture real-world components, including the screw placements, hence the customized implants for a selected patient. They can shorten the surgical time and improve the success of the surgery, which also are the most functions and advantages of 3D printing. Creating complex and intricate parts for vertebral implants, bone models, and prototypes is easy - a feat impossible through conventional methods. A wide range of materials can be used, from Titanium alloys, stainless steel mesh to biodegradable polymer resins to suit different medical requirements.

2.1. Experimental Methodologies

In FDM, the model gets created by extruding beads of semisolid material through a heated nozzle which gets hardened immediately upon removal or extrusion from the nozzle. The next step is that the part gets produced layer by layer. The material is in the form of a thermoplastic* filament. The nozzle is a heating filament that heats the material inside the nozzle to increase the flow capacity of the former, as it heats the material to its flow limit. The latter comes out of the nozzle and solidifies immediately. Stepper or servo motors help move the extrusion head and control the flow of the material. Extrusion is possible in horizontal and vertical positions [2]. It also refers to the extrusion-based rapid prototyping technique. It contains a nozzle that melts the material rapidly and extrudes the liquid according to the computer-provided design. It forms layer by layer structure. Keeping the temperature of the material below its melting point ensures good adhesion ability between layers. [2] It uses a heated nozzle. The process starts with feeding plastic filament into the heated nozzle, which undergoes extrusion onto the base in a layered manner and a decided path post-melting till the 3D product gets created. Creating complex shapes is possible with this method with ease. However, the process takes a long time and lacks a good surface finish and mechanical strength [2].

SLS is a relatively new technology used for rapid prototyping and low-volume production of components. It uses a laser beam to sinter metal or polymer powdered material. SLS is similar to direct metal laser sintering (DMLS). SLS is a kind of AM technique with a layer-wise mechanism. In this process, the powder undergoes spreading over a plate, sintering by a laser spot, and bounding together to build a complete part. A computer controls the scanning. [2] The source of heat energy for SLS is a laser. It forms the solid mass of the polymer powder for a specific area to form a 3D model. The procedure starts with heating fine polymer powder with a CO2 laser to form a solid mass. SLS is self-supporting, and building parts is possible over other and unused materials. SLS features are not much detailed and provide a rougher surface finish than SLA. SLS can be fruitful in bone tissue engineering, neurological surgery, oral maxillofacial, and tissue engineering applications [2].

Stereolithography finds its application in making objects layer by layer with a process called photo-polymerization. Usually, the materials used are liquid photopolymer and composites. Here optical light as the source of energy scans light-curable resin that makes the molecules join. Moving the vat floor downwards helps to increase the depth of the material. A support structure finds its application in providing stability to it. Excess resin gets washed off. Further, processes like exposure to UV light helps in improving the mechanical properties of the structure [3].

EBM uses an electron beam spot as the source to melt the powder. The building chamber undergoes evacuation to create a vacuum before the component gets manufactured. For EBM systems, the powder layer thickness is typically between 20 and 100μm, similar to SLM. Before manufacturing, the substrate plate must be heated to 700°C by the beam to decrease residual stresses between the plate and hence the as-produced component. Here the heat source is an electron beam in the vacuum that melts metal powder at a high temperature leading to final products possessing good mechanical properties. The process, carried out in a vacuum, enables us to use materials reactive to oxygen. The vacuum provides more benefits, such as good thermal insulation. Usually, materials used in EBM for medical purposes are titanium, Ti-6Al4V, stainless steel, Mg-alloys, Ni-alloys. EBM can be useful for medical implants [2].

Another method widely used to collect data points for prosthesis creation is 3D surface topography scanning. It is a labor-intensive process and has several advantages over surgical interventions. It is much better and advantageous over traditional prosthesis methods because of its accuracy and higher resolution. Moreover, it does not cause any discomfort to the patients throughout the process of prosthesis creation. Optical topography scanning is non-invasive, quick, and highly accurate. Moreover, it reduces the number of fitting and sculpting sessions [7]. Selective laser melting is the most widely used additive manufacturing process to create shape memory alloys. These alloys find their application as orthopedic implants in patients with scoliosis and the healing process of fractured bones. SMA has a large number of orthopedic applications, the spinal vertebra spacer being one. The insertion of this spacer between two vertebrae assures the local reinforcement of the spinal vertebrae, preventing any traumatic motion during the healing process. Using a shape memory spacer permits the application of a constant load regardless of the position of the patient, who preserves some degree of motion [9]. This device finds its application in the treatment of scoliosis [10]. The figure shows spinal vertebrae and a shape memory spacer. On the left side, the spacer is in the martensitic state, and on the right side, the spacer is in its original shape, recovered by the pseudoelastic phenomenon [11].

Sockets, part of 3D prosthetic legs, are also manufactured through additive manufacturing. Each socket is a tailor-made device designed to fit the unique geometry of the residual limb. The socket is seemingly the most important of the three components, for if it is uncomfortable, the patient may not wear the prosthesis [10].

A commonly used method to capture the leg for the generation of CAD model is when multiple 2D photographs undergo conversion into a single file, which goes through a rigorous design, and then fed into the 3D printer for desired prosthetic. The app used to convert 2D pictures to 3D models is called 123D, offered by Autodesk [11].

On another note, upper limb prosthetics get used when a significant portion of the leg has undergone amputation due to unavoidable circumstances. Knees that play a prominent role in movement and walking in human beings are not present in these patients. Therefore, a prosthetic that can simulate the actual gait movement finds its application. This prosthesis combines the concepts of electrical engineering (a brushless DC motor) and rapid manufacturing to satisfy the patient's needs [13].

2.2 Materials Used

Thermoplastics, having their application in FDM, include polylactic acid (PLA) and acrylonitrile butadiene styrene (ABS). They are relatively stiff, with Young's modulus on the order of a few gigapascals. They are best suited for 3D printing and prototyping. In contrast, flexible thermoplastics, such as thermoplastic polyurethane (TPU), with a lower Young's modulus, would be ideal for prosthesis applications because it allows a more comfort-able and forgiving fit to the amputee's remaining limb. Photocurable resins PPF (Polypropylene Fumarate) are un-saturated linear polyester that has carbon-carbon double bond cross-linkage. It is degradable by simple hydrolysis of the ester bonds, and its product is nontoxic. PPF gets mixed with DEF and BAPO as solvent and photo initiator, respectively. DEF stands for dimethyl fumarate, and BAPO is short for bis acyl phosphine oxide. These react with light photons used [4]. There are endless possibilities for the material types that can find their application, including metals, calcium, bio ceramic materials like Zirconia; Silica, etc. 3-D printing can also find its application in creating components from powdered materials, usually starch or gypsum [10].

Another considerable material is Micro Fibrillated Cellulose (MFC). It gets obtained from successive grinding. Moreover, the chemical treatment of wood has a very significant improvement in the tensile strength. Prosthetics made of MFC material showed a 30 wt. % improvement when juxtaposed with fossil-based thermoplastics. Fused deposition modeling (FDM) finds its application in MFC prototypes [12].

3. Model

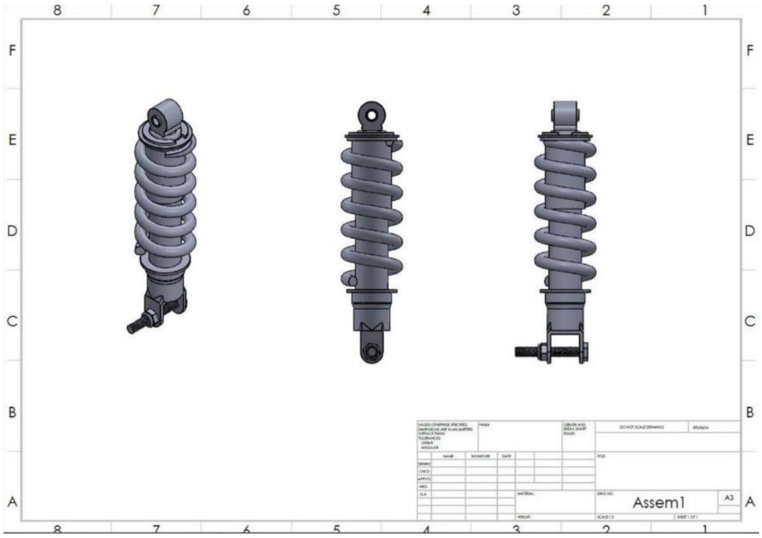

Figure 1. Damper Assembly

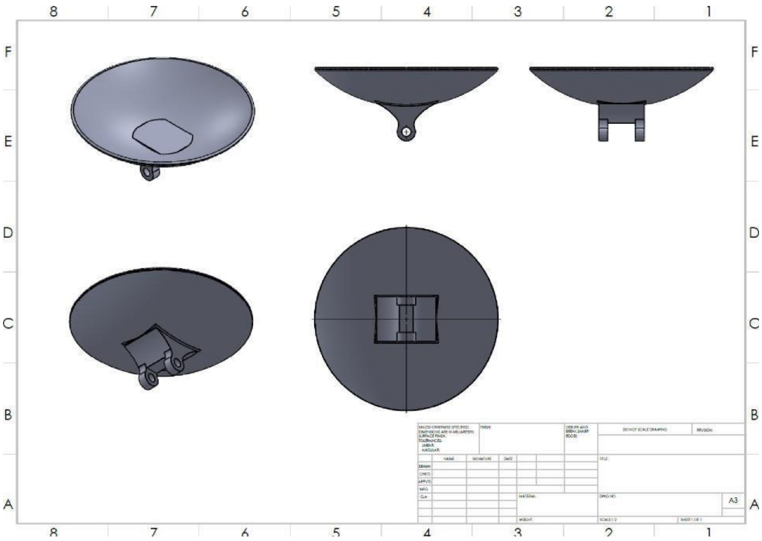

Figure 2. Socket View

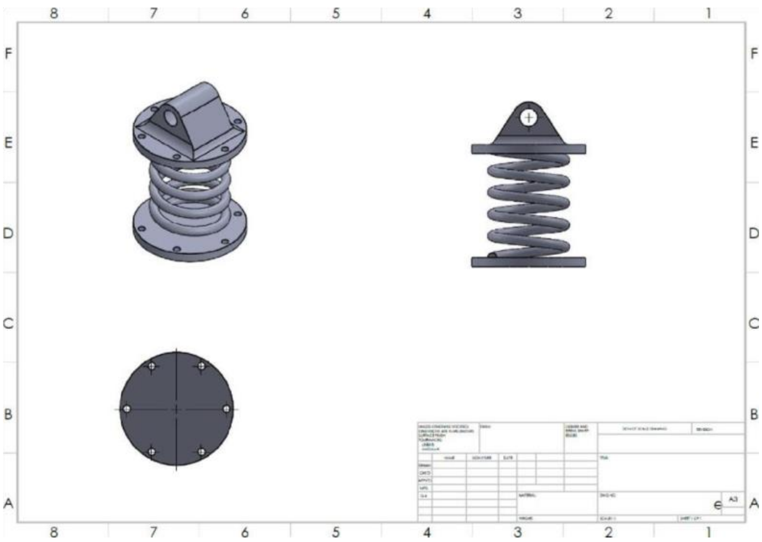

Figure 3. lower damper

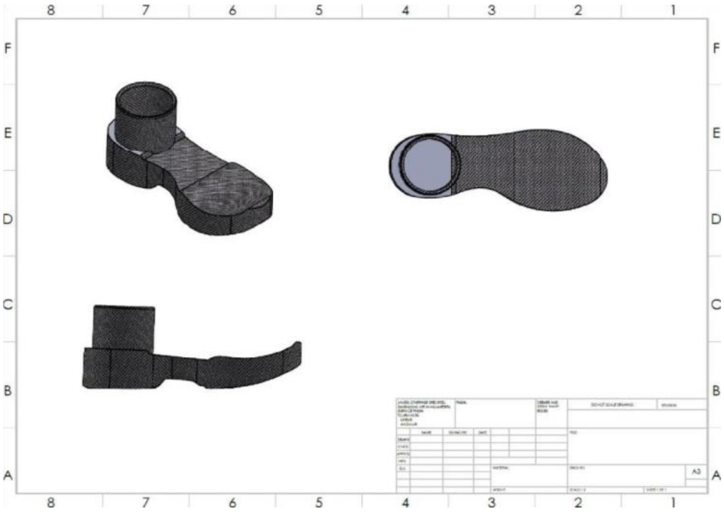

Figure 4. Sole view

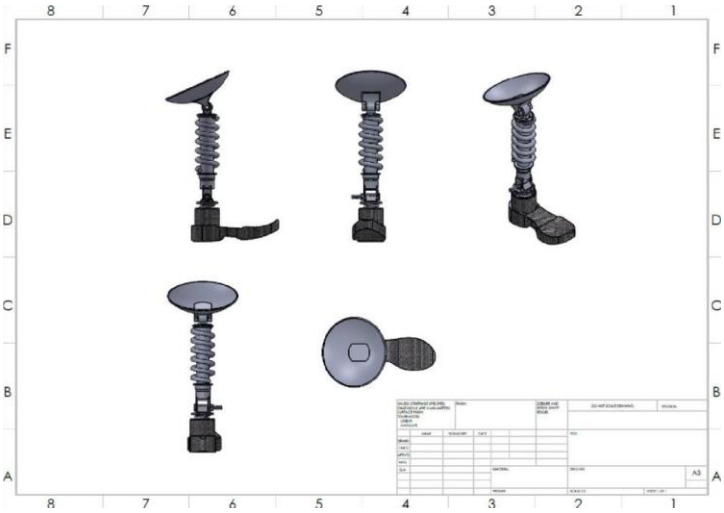

Figure 5. Posthetic limb Assembly

4. Financial Model

Table 1. Cost Analysis (Price Estimate)

Part	Material	Process	
		SLA	**FDM**
Sole	ABS	234940 pkr	12606 pkr
Upper Limb	ABS	6188 pkr	8022 pkr
Spring	Steel	1146 pkr	1146 pkr
Total		308288 pkr	32089 pkr
FDM Printer			91684 pkr
ABS Filament			900 kg
PU Filament			2999kg

As analyzed, we have compared the manufacturing cost of the prosthetic limb by the SLA and FDM process. The manufacturing cost in the FDM process is considerably cheaper. The initial capital of an FDM printer might be high, but for large-scale production, the preferred process is Fused Deposition Modeling.The price of a new prosthetic leg can cost anywhere from PKR 57,302 to PKR 2,292,105. But, even the most expensive prosthetic limbs withstand only three to five years of wear and tear, i.e., replacements occur throughout the lifetime, and they are not a one-time cost.Ten days after the Boston Marathon bombing, the most gravely injured victims are on the daunting road to recovery. At least 14 of those injured in the blasts had undergone amputation, and at least two people had multiple amputations.Each prosthetic limb must be custom fit to every patient, and costs can increment. Once they get fitted with the prosthesis, patients need to attend physical therapy for weeks or months.Depending on what components you get on it, the cost can vary greatly. They are probably in line with the price tag of a car. It implies that it can be a pricey thing.With physical therapy, amputees could start walking on their own within two to four weeks after receiving a prosthesis. Most patients will have one prosthesis for the first year but will likely need another to accommodate their changing physique.

5. Project Description

5.1. Procedure

- Creation of the design on SolidWorks.
- Conversion of the above files into STL format.
- The transfer of the STL file to Ultimaker cura - the software used for slicing products for layer additive manufacturing.
- The slicing was done by the hybrid slicing technique for each part.
- The 3D printer suggested is 3D systems polymer 7000SLA 3D printer. It shall take around 17-20 days, depending on the dimensions.
- Post the manufacturing part, the material needs to undergo drilling into the cup region of the patient. The cup should be compatible.
- The patient shall visit the doctor at least once every two months to check whether the body is compatible with the new implant.

- Immediate inspection of the swollen or infected region.

5.2 Description of the project

It is the manufactured leg of almost 4kg, ideal for an average 70kg man. It should undergo manufacturing using a stereolithography process which is the fastest and best for medical purposes. It gives a lot of flexibility in various parameters like customization, length, and width of the prototype. The material ranges can vary from aluminum, magnesium, steel, titanium, or copper.Now, the material selection depends on whether it is pure metal or alloy in nature. Titanium prosthetic is the costliest and requires time pores in it for airflow and biocompatibility reasons. Polymers, like polyoxymethylene along with pliable polyurethane, can be coated on the product for 3D printing.Hence, the cost factor plays a pivotal role in the choice of material. The flexibility of the leg should range from around 117 degrees to 10 degrees to provide the entire motion of the leg and thereby not restrict movement. The ischial containment socket also needs to be attached to the soccer of the knee joint. The ischial socket is used instead of the quadrilateral one.Firstly, it does not bear the entire weight and divides the weight in the whole leg, thereby not exerting too much pressure on the joint. Secondly, it gives exact volume determination. The creation of negative pressure helps fit the suction into the joint.We do not recommend using cuff straps and belting as it is an outdated method and does not provide proper fixing. Hence the above design is the proposal from our side on the prosthetic limb using 3D printing.

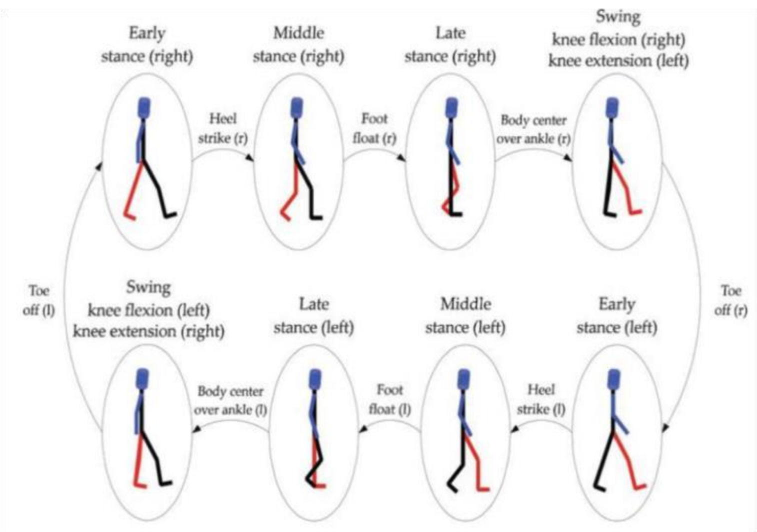

Figure 6. Leg movement for prosthetics

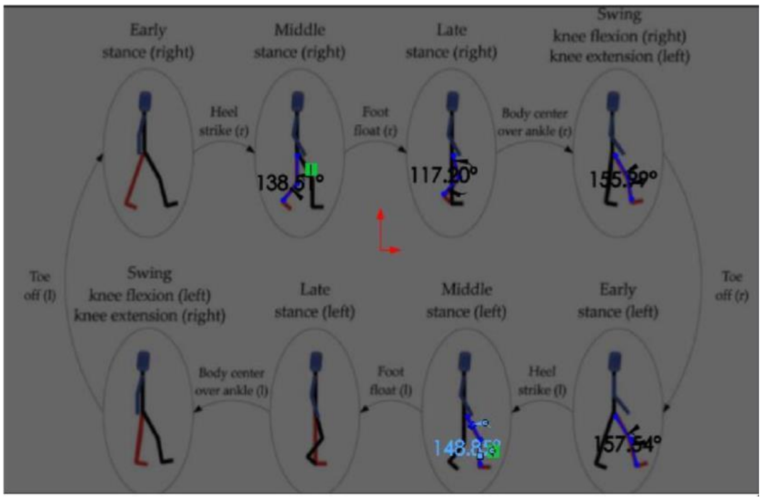

Figure 7. Angles for legs to walk

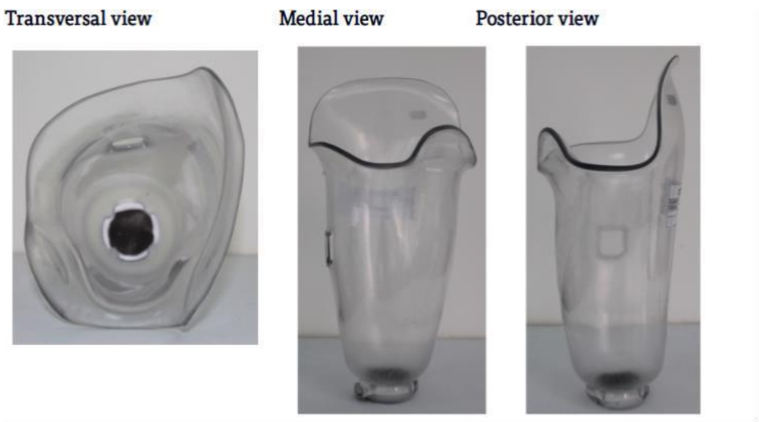

Figure 8. Socket views

6. Dimensions

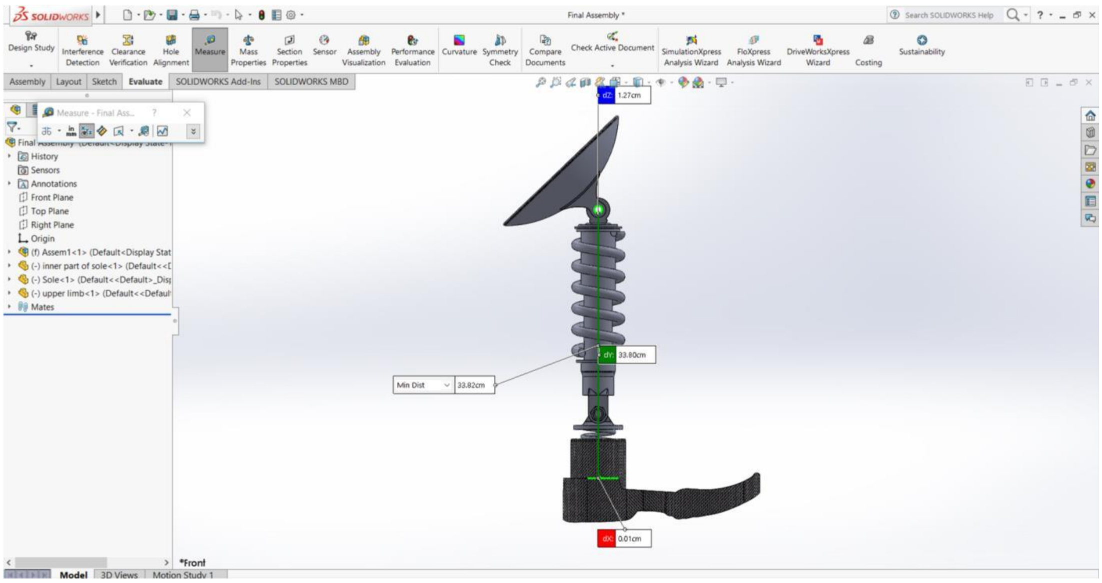

Figure 9. Height of Limbs

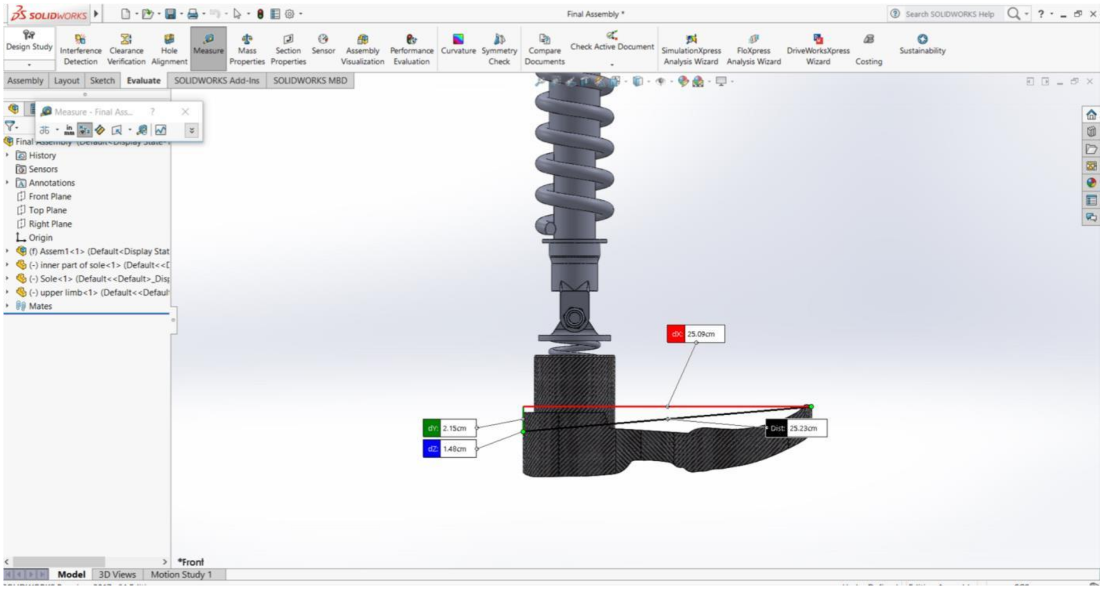

Figure 10. Length of Sole

7. Simulation Analysis

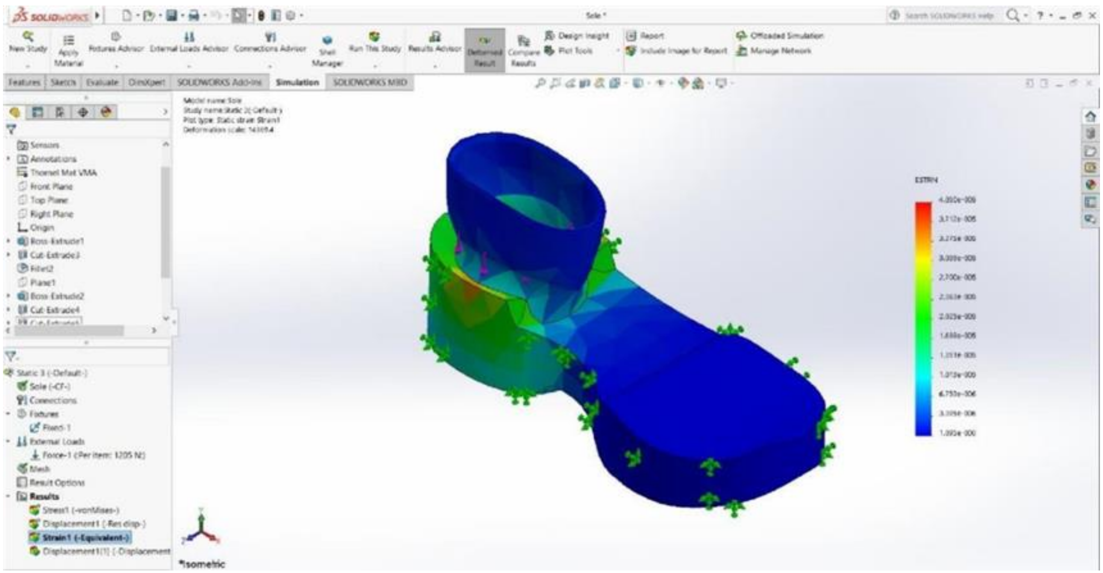

Figure 11. Total Strain

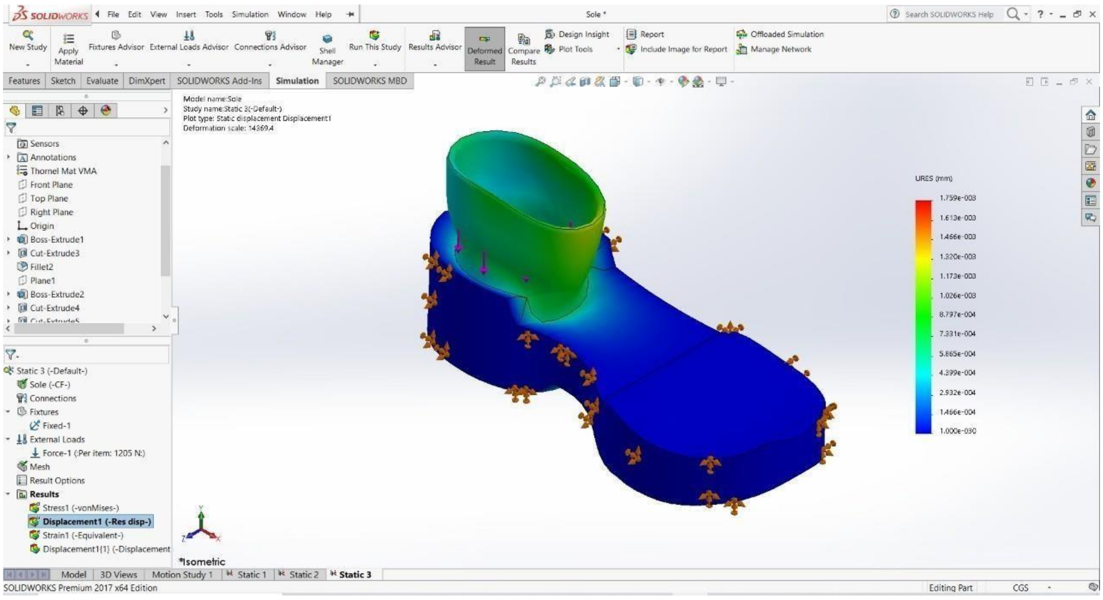

Figure 12. Total Displacement

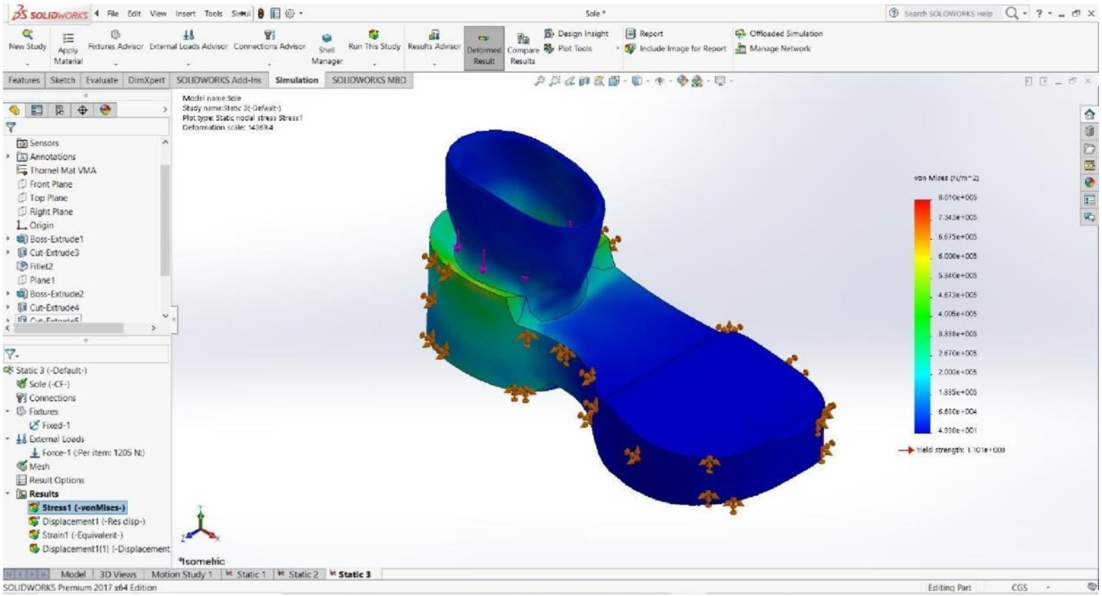

Figure 13. Total von-Mises stress

7.1 Procedure for Simulation

• The analysis shown was on the sole of the prosthetic limb since the weight is acting on the whole leg.

• The analysis type was static. The strain on displacement loading was visible.

• Fixed advisors are given.

• The material selected was Thermoplastic polyurethane (TPU).

• Applied load of 1204.5N.

• The process of meshing was done.

• Running the study and obtaining results.

8. Conclusion

We have presented an initial model for a prosthetic limb. This model can undergo manufacturing using additive manufacturing methods. However, numerous modifications are possible in the design and additive manufacturing processes, like selecting materials and the process. The material can be made more durable by adding metals or other polymers to increase the life span of the prosthetic leg. Design changes are possible based on the feedback received from analysis and user inputs.

9. Recommendation for Further Research

Material optimization and discovery of new materials are possible. Manufacturing processes, like 3D printing, can be used for customization, but economies of scale are unachievable. Hence for bulk production, a faster and quicker manufacturing process is needed. The design, as shown, produces low stresses. Therefore, those stresses demand improvement using higher quality material. While doing various optimizations, the load must be kept in the range of 1204N-1500N, depending on the person.

Acknowledgement: We extend our special thanks to Rafey Iqbal Rahman. He took out his precious time, despite his work commitments, and re-wrote the entire manuscript for us, keeping in view the editorial review, sentence structure, punctuation, spelling, and grammar errors in just a matter of three hours.

Declaration of Competing Interest: The author declare no conflict of interest.

References

[1] Zarrabeitia-Bilbao, E., Alvarez-Meaza, I., Río-Belver, R.M. and Garechana-Anacabe, G., 2019. Additive manufacturing technologies for biomedical engineering applications: Research trends and scientific impact. *Profesional de la Información*, *28*(2), pp. 121–139.

[2] Liu, Y., Wang, W. and Zhang, L.C., 2017. Additive manufacturing techniques and their biomedical applications. *Family Medicine and Community Health*, *5*(4), pp.286-298.

[3] Zaharin, H.A., Rani, A.M.A., Ginta, T.L. and Azam, F.I., 2018, March. Additive manufacturing technology for biomedical components: a review. In *IOP Conference Series: Materials Science and Engineering* (Vol. 328, No. 1, p. 012003). IOP Publishing.

[4] Schubert, C., Van Langeveld, M.C. and Donoso, L.A., 2014. Innovations in 3D printing: a 3D overview from optics to organs. *British Journal of Ophthalmology*, *98*(2), pp.159-161.

[5] Mertz, L., 2013. Dream it, design it, print it in 3-D: What can 3-D printing do for you?. *IEEE pulse*, *4*(6), pp.15-21.

[6] Klein, G.T., Lu, Y. and Wang, M.Y., 2013. 3D printing and neurosurgery--ready for prime time?. *World neurosurgery*, *80*(3-4), pp.233-235.

[7] Mohammed, M.I., Tatineni, J., Cadd, B., Peart, G. and Gibson, I., 2016. Applications of 3D topography scanning and multi-material additive manufacturing for facial prosthesis development and production. In *2016 International Solid Freeform Fabrication Symposium*. University of Texas at Austin, pp. 1695–1707.

[8] Ventola, C.L., 2014. Medical applications for 3D printing: current and projected uses. *Pharmacy and Therapeutics*, *39*(10), pp.704-711.

[9] Duerig, T.W., 2002. The use of superelasticity in modern medicine. *MRS bulletin*, *27*(2), pp.101-104.

[10] Herbert, N., Simpson, D., Spence, W.D. and Ion, W., 2005. A preliminary investigation into the development of 3-D printing of prosthetic sockets. *Journal of Rehabilitation Research & Development*, *42*(2), pp. 141-146.

[11] Summit, S., 2014. Additive manufacturing of a prosthetic limb. In *Rapid Prototyping of Biomaterials* (pp. 315-324). Woodhead Publishing.

[12] Stenvall, E., Flodberg, G., Pettersson, H., Hellberg, K., Hermansson, L., Wallin, M. and Yang, L., 2020. Additive manufacturing of prostheses using forest-based composites. *Bioengineering*, *7*(3), pp.1-18.

[13] Park, K., Ahn, H.J., Lee, K.H. and Lee, C.H., 2020. Development and performance verification of a motorized prosthetic leg for stair walking. *Applied bionics and biomechanics*, 2020, pp. 1-14.