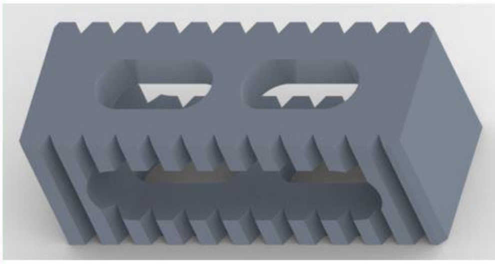

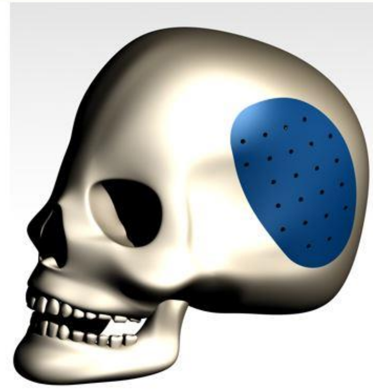

Rapid Design Through Manufacturing of Polymer Based Parts for Medical Applications

Authors:

Ibrahim Yousif — Iyousif@email.sc.edu

Alex Brasington — alexrb@email.sc.edu

Joshua Halbritter — halbritj@email.sc.edu

Teddy Tarekegne — theodros@email.sc.edu

Emails:

Academic advisor:

Dr. Clint Saidy — csaidy@mailbox.sc.edu

University of South Carolina

Table of Contents

1 Problem Statement

Healthcare is one industry in which 3D printing has made a lasting impact. In 2018, the medical 3D printing market was valued at $973 million and is expected to grow to almost $3.7 billion by 2026. Medical applications for 3D printing are vast and will change the industry forever [1]. Nowadays, many surgeons believe that 3D printing will be the future of the medical industry [2]. James Harrop, MD mentioned that he thinks 3D printing will have an expanding role in spine surgery in both the short and more importantly, in the long term. Peter Derman, MD mentioned that 3d printing is now implemented in the creation of spinal implants with unique structures and surfaces. Dr. Derman also mentioned the advantages of depending on the 3D printed cages specifically and other implants in general that each part will be tailored to a patient's anatomy and the desired correction.

3D printing is used to manufacture critical items in the medical industry such as surgical instruments, pedicle screws, cervical plating, spine cages, casting, and skull implants. 3D printing can also be used not only in instruments and implants manufacturing processes, but also can be implemented in the medical device's maintenance processes. This report will focus on using additive manufacturing in producing three items, spine cage, casting, and skull implant as shown in Figure 1. The spine cage is used as a space holder between the affected vertebrae to allow the bone to grow through it, eventually becoming a part of the patient's spine. Instead of using a one-size-fits-all implant that often does not fit all patients, 3d printing can help to create customized implants that would fit each patient's body anatomy. Casting like arm casting is used as a treatment for bone fractures and soft tissue injuries. The skull implant is used as a treatment for more serious medical conditions such as brain infections, brain tumors, stroke, and brain injuries. Each can lead to pressure on the brain due to occurring swelling inside it and if this pressure is not relieved immediately, it will lead to a severe problem that would need surgical interaction/entry by drilling a burr hole that allows blood to drain followed by removing a piece of skull bone to accommodate the swelling, followed by the skull implant to repair the defected area.

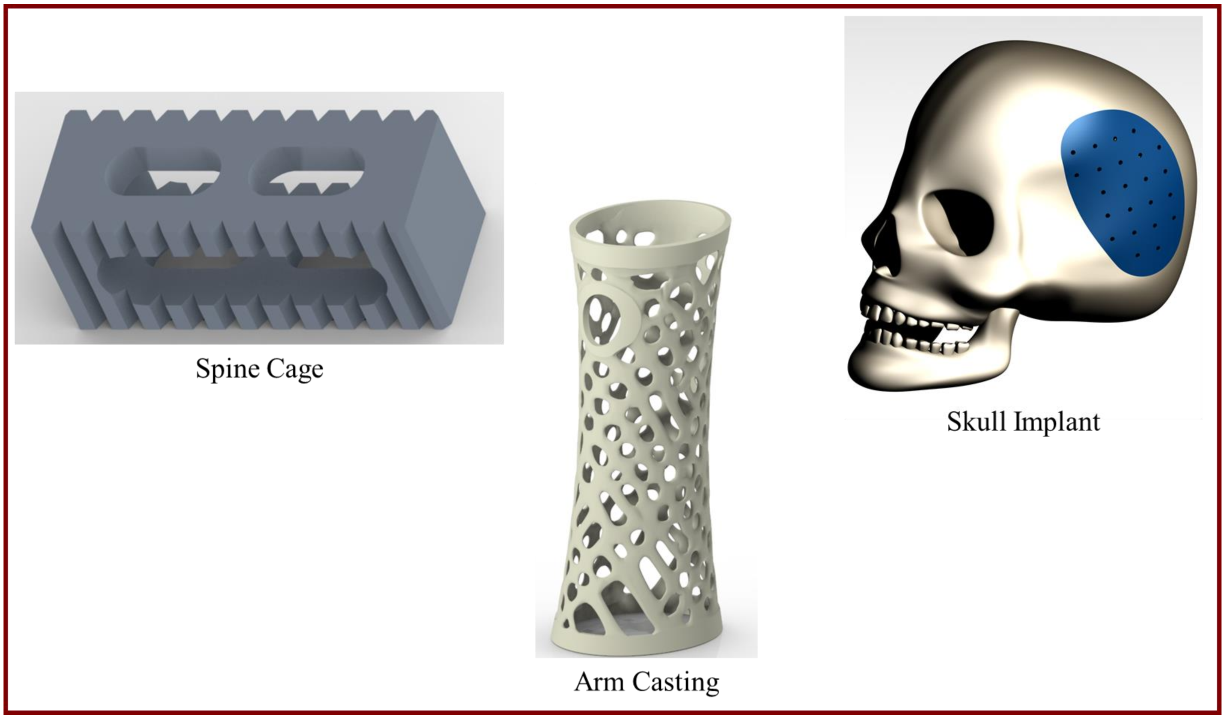

Figure 1: CAD representations of the designed parts

The worldwide supply chain continues to be affected by facing distinct types of unexpected pandemics like COVID-19 which freezes the world market logistics for more than twenty months and the world is not fully recovered from its sequence. When this pandemic started and the governments of most of the countries ordered to shut down the country and stop business for a few months including the manufacturing processes and the ports. This led to delays and disruption for all industries because of choked ports, out-of-place shipping containers, record freight rates, and other problems which might be acceptable for a few industries as it will be money/investment loss, but it is not acceptable at all in hospitals and pharmaceutical manufacturing as it includes patient safety and loss of lives. Another example is the events taking place in the Russian-Ukrainian War, which has an immediate and direct effect on Ukrainian healthcare, but it will also affect the U.S. healthcare in the long term as mentioned by Amanda Chawla, chief supply chain officer at Stanford. Issues such as ordering specific tools can be expensive and take a long time to arrive, and sometimes it can be impossible as right now in Ukraine. However, with leveraging additive manufacturing, the design of any surgical instrument or implant can be done remotely at any time, without presenting civilians like engineers and delivery people in high-risk war areas. With 3D printing, creating custom tools and parts can be created in a matter of hours, not weeks of delivery, with specialized tools for any job.

2 Functionality and Durability

The methodology of the presented technology is more of a complete process than a single manufactured part. With the utilization of digital manufacturing, further analysis as well as customization can be accomplished before use of the chosen medical part. Such customization is required for human rated parts since it is rare that any two people will require the same dimensions. Also, each part has been designed in a parametric way in which limited design changes are necessary to arrive at the resulting geometry. For example, the cast requires simple measurements of the arm to be input into the CAD model for generation. The combination of parametric design and 3D printing allows for rapid and optimized parts. For instance, a predefined load case can be applied to a model that updates its geometry based on the current design inputs. The resulting analysis can then be employed to make any final design changes before manufacturing.

The essential limiting factor in 3D printing medical grade parts is the process and its available materials. However, this has been overcome for the implementation of SLA since many parts can be qualified as medical grade while being manufactured with polymer resins. Providers of SLA printers also typically have medical grade polymers that can be purchased. Further, the SLA process allows for the use of materials with widely varying characteristics such as flexibility and polymer type. Certification of the process and its resulting parts will require a limited test campaign. Essentially, the parameters of a given machine and the resulting material characteristics will be investigated for a series of parts. The resulting quality will define the operating range for the printer.

3 Novelty and Utilization of Digital Manufacturing Processes and Materials

Additive manufacturing enables the production of complex parts with little domain knowledge, when compared against traditional subtractive technologies such as milling or lathing. Additionally, the complete automation of the process once printing has begun means that the operator of the printers is free to attend to other tasks while printing is underway. Also, when compared to traditional subtractive manufacturing technologies, additive manufacturing can create much more complex features within parts which would otherwise be prohibitively expensive or even impossible to manufacture. When combined with the concept of parametric modeling, which creates an intelligent CAD model where important aspects of the design are driven by a few critical dimensions, the required domain knowledge can be further reduced.

Many types of additive manufacturing can produce multiple parts in parallel as well, with little to no additional increase in printing time. For technologies such as SLA (example printers shown in Figure 2), these speedups can be achieved because a single mask is used to expose each layer of the print, and as a result, any additional features within an individual layer do not alter the mask exposure time. So, for items manufactured with SLA, the maximum number of layers for any single component during a print cycle is the driving factor for print time. The speedups for laser-based metal printing are less dramatic since the laser must trace the entire cross section of each layer during a print cycle. However, each of these printing techniques still enables the production of several complex structures in parallel within a single printer.

(a) (b)

Figure 2: Example SLA printers from (a) Formlabs [3] and (b) MakerBot [4]

By utilizing additive manufacturing and the benefits, such as the ability to create complex parts with no extra cost, it can help to reduce cost to produce medical equipment while simultaneously enabling the onsite manufacturing as demand for those parts arrive. In this way, additive manufacturing can directly simplify the supply chain, such that medical facilities would only need to keep the raw components available for manufacturing, instead of relying on the traditional external suppliers and manufacturers of medical equipment. Therefore, additive manufacturing can enable the creation of medical equipment in a way which is more resistant to supply chain disruptions, simply through the reduction of "links" from raw materials to usable products. For SLA or SLM, only supplies of resin or stainless-steel powder would need to be stocked.

4 Design Integration and Innovation

The presented process (see Figure 3) has the capability to revolutionize the current manufacturing process of surgical equipment and implants in terms of speed, customization, and reliability. Speed is increased by incorporating parametric design principles into the geometry of each part along with implementing fast printing methods such as SLA. Utilizing 3D printing also allows for extreme customization that is typically not possible with traditional techniques. Lastly, reliability is improved through enabling on-the-spot manufacturing of required applications. This allows entities such as hospitals to bypass the bottleneck of middleman manufacturing companies and directly create the required part.

The defined method can also be used in a prototyping stage or temporary fixes. Since the geometry will then be available in a CAD format, any traditional manufacturing methods can then be used. This supplies versatility to the user instead of limiting them to using the presented process. Also, rapid iterations can be performed to optimize a parts geometry before final manufacturing resulting in cost savings.

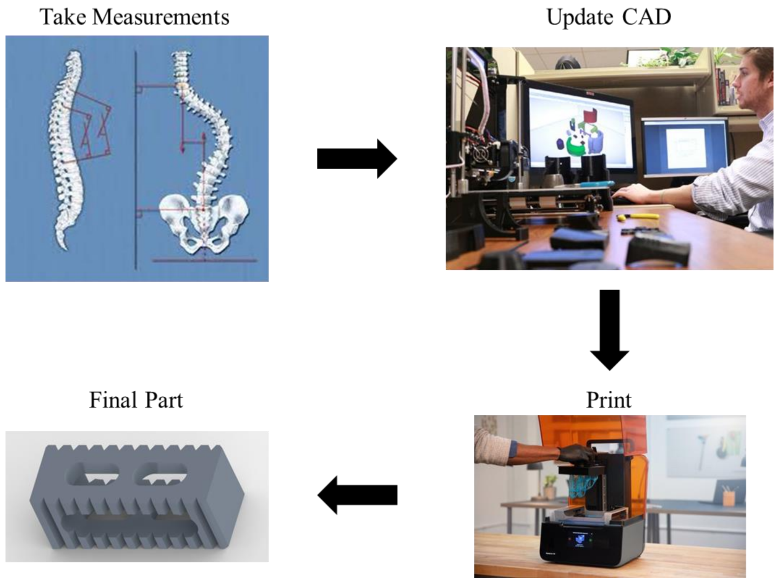

Figure 3: Flowchart of process from design to manufacturing

5 Digital and physical infrastructure

Surgeries are expensive around the world. For example, brain surgeries cost between $50,000 to $150,000 according to multiple health care centers [5]. One of the reasons that make these kinds of surgeries expensive is the cost of the instruments, implants, and devices that are used. The bulk/major part of the cost of these devices is not related to the materials that are used or the manufacturing processes only but also because of the extremely high expenses of the supply chain. Supply chain costs can be reduced by applying smart supply chain management. The same concept of the lean six sigma processes that are applied in the factories during the manufacturing process can be also applied in the supply chain management by defining the problem, measuring (quantifying the problem), analyze by identifying the cause of the problem, improve by design, implementing, and verify the solution, and control maintain the solution. This concept is known in lean six sigma as DMAIC (define, measure, analyze, improve, and control). Figure 4 below shows the supply chain management blocks by applying the DMAIC concept. Tn this process the authors started by defining the problem, which was the surgeries unaffordable prices, then quantified the problem by researching on why surgeries cost all of that, then it took the researchers to the analyze, and identifying the cause of the problem which in our case was the shipping, labor of moving these parts from country to another and from ware warehouse to another which also helped them to conclude the warehouses renting high prices, employees labors, utilities, and gas prices. Here came the role of digital manufacturing using additive manufacturing techniques to take place in improving the process. Implementing additive manufacturing in the facilities/hospitals would help to reduce a lot of expenses such as gas, trucks maintenance, warehouse renting and utilities fees, unneeded labor. The most important one it would play a significant role in is patient safety and saving lives, as many people who go to emergency rooms due to accidents might not found the closer hospital to them is qualified to do these kinds of surgeries because they do not have the necessary implant or one of the surgical instruments got broken earlier and they need to replace it. Replacement could take a few days and sometimes weeks to order and receive these implants and instruments which might lead to loss of lives or undesired sequences. Note that by mentioning these types of hospitals, the authors are not speaking about hospitals in the United States, but they are speaking about hospitals in other parts of the world such as Africa, European, and Asian countries. Eventually cutting out of the supply chain management of all these blocks as presented in the figure below would result in saving significant expenses and shipping time.

Implementation of digital, additive manufacturing in medical facilities will not only be helpful to reduce cost, time, and the carbon footprint around the world by a significant percentage, but also with the unexpected pandemics the world is facing these days from COVID-19 to the Russian-Ukrainian War it is impossible to ship products sometimes for several destinations. Therefore, eliminating the need to send civilians such as engineers, shipping personnel, and warehouse employees to remote army basis or high-risk areas to program the machines must be accomplished. Using digital manufacturing as presented here would solve this issue since the machine can be programmed from any place around the world with minimal effort.

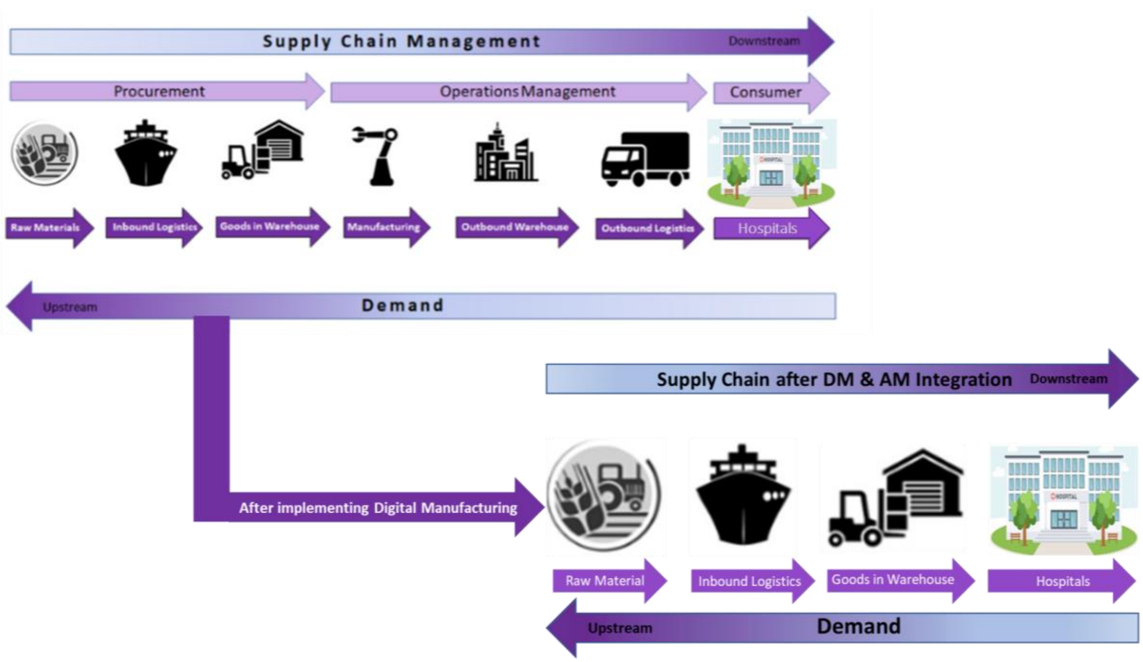

Figure 4: Diagram demonstrating supply chain logistics

6 Cost Analysis, Marketing, and Logistics

Conventional manufacturing techniques for producing biocompatible implants and devices are designed to be applicable to a wide variety of patients, and therefore are designed with modularity in mind. This allows for mass production of medical equipment at a low cost, as the cost is based on the amount of material required for manufacturing, rather than the complexity of the design process. A large disadvantage of this manufacturing approach, however, is the inability to modify equipment designs to create patient specific implants (PSI). Considering the costs and time necessary for creating a production line for manufacturing a new product, this approach is ineffective for producing one-off designs of products. 3D printing addresses this issue by allowing customization of designs to tend to patient specific needs. Rather than the bulk of the cost coming from material costs, the cost of 3D printed PSIs is generated from complexity of the design. For medical implants that require surgery, biocompatible surgical guides can be 3D printed based on acquired patient topology and can lessen the overall time the patient spends in surgery. As innovative technologies are developed, the cost burden of producing 3D printed parts should lessen as materials become cheaper and more available [6].

7 Social, Environmental, Health, Safety, and Regulatory Compliance

3D printing additive manufacturing has an advantage compared to conventional manufacturing processes when it comes to positive effects on the environment. Because only the necessary material needed to print the part is required, less material is required to construct the part. This leads to less overall waste produced through the manufacturing process. 3D printing material is also lighter than most biocompatible plastics. This can lead to lower distribution emissions during transportation of products. Moreover, the design of the 3D printed part can be sent as opposed to the part itself and can be produced in the facility itself rather than shipped from the factory. Compared to conventional manufacturing processes that produce pollution in aquatic, terrestrial, and atmospheric environments, 3D printing can be seen as a "greener" alternative.

The FDA is responsible for maintaining regulations regarding manufacturing of medical equipment and has released a document regarding 3D printing of medical devices to ensure safety of the public. The FDA recognizes the advantages offered by 3D printing in providing quick and personalized healthcare. The department assures that the control and effectiveness of medical devices are maintained to assure that product specifications are met. For this reason, the department advises that manufacturing techniques for medical equipment should have uniform specifications regardless of location, and that these facilities should have the requisite knowledge and expertise to effectively use these techniques.

8 References

[1] "3D Printing Healthcare Market by Component, Technology, Application, and End User: Global Opportunity Analysis and Industry Forecast, 2019–2026," August 2019. [Online]. Available: https://www.prnewswire.com/news-releases/the-global-3d-printing-healthcare-market-was-valued-at-973-million-in-2018--and-is-projected-to-reach-3-692-million-by-2026--growing-at-a-cagr-of-18-2-from-2019-to-2026--300925951.html. [Accessed 31 March 2022].

[2] C. Behm, *Will 3D printing take off in spine? What 15 surgeons predict*, Becker's Spine Review, 2021.

[3] "High Performance 3D Printers, Finally Within Reach," Formlabs, 2022. [Online]. Available: https://formlabs.com/. [Accessed 30 March 2022].

[4] "3D Printers for Educators & Professionals," MakerBot, [Online]. Available: https://www.makerbot.com/. [Accessed 30 March 2022].

[5] "Brain Surgery Cost: How Much Does Brain Surgery Cost?," CostHelper, [Online]. Available: https://health.costhelper.com/brain-surgery.html#extres1. [Accessed 31 March 2022].

[6] R. Mobbs, W. Parr, W. Choy, A. McEvoy, W. Walsh and K. Phan, "Anterior Lumbar Interbody Fusion Using a Personalized Approach: Is Custom the Future of Implants for Anterior Lumbar Interbody Fusion Surgery?," *World Neurosurgery*, vol. 124, pp. 452-458, 2019.