“3D Printed Prosthetics: Production and Opportunities”

By John Murphy

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22 Willow Drive
Chester NJ
December 11th, 2019

Vinit K. Asar, CEO of Hanger, inc.
Hanger Clinic Corporate Office
10910 Domain Drive
Austin, TX 78758

Dear Mr. Asar,

The Hanger Clinic's mission involves "assisting individuals with physical disabilities to experience life without a burden" (About The Hanger Foundation", n.d.). As the CEO of Hanger inc., your goals involve positively impacting the lives of those in need. The market for orthopaedics and prosthetics are predicted to reach $3.16 billion by 2024, by which global competitors such as Ottobock and Ossur could eventually surpass the Hanger Clinic in revenue (Bay, 2018). A limb prosthesis is an expensive option for children, who grow such that a brand-new prosthetic is often needed. This is a large cost burden on families. As such, prosthetic limbs need to be more cost-effective for amputees, and this can be done by utilizing 3D printing. With easily modified and reproducible components, a 3D printing business model offers a cost-effective and improved solution for individuals with disabilities.

The plan I will put forth strives to improve the already growing prosthetic market for the Hanger Clinic. Further, it encompasses a realistic opportunity for the Hanger Clinic to open its market to millions of amputees, and improve existing prosthetics. I hope after you go over this proposal, you believe that there is merit and value in 3D printed prosthetics. If you would like to give me your input on the issue please contact me at 973-407-0175. I look forward to hearing from you.

Sincerely,

3D Printed Prosthetics: Production and Opportunities

Submitted By:
John Murphy

Submitted To:
Vinit K. Asar, CEO of Hanger, inc.
Austin, Texas

Submitted On:
December 11th, 2019

Final Proposal for Scientific and Technical Writing
if found please return to:
English Department
Rutgers University

Abstract

Prosthetic limbs are life saving instruments that offer amputees a means to use lost limbs again. Problems with the current prosthetic market include lack of affordability, manufacturing efficiency, and comfortability. Current literature suggests that 3D printing offers an exponential growth in the prosthetic market with a plethora of technological advancements. Companies like E-nable suggest that 3D printing prosthetics can be inexpensively implemented in the current market. 3D printing technology has grown to the point that any material can be printed. For prosthetics, metal and polymers are required to make a durable and functional device. Key metals in traditional prosthetics such as non-toxic titanium can be utilized in 3D printing with new metal 3D printing technology. 3D printing tissue engineering introduces innovative ways to mimic trabecular bone structure in geometry and mechanical properties. With this information, a plan is proposed to fix all of these conditions through 3D printing a lower extremity below knee prosthetic that accurately mimics organic bone features. This proposal uses polymer and metal 3D printing technology to improve mechanics, manufacturing efficiency and comfortability at a decreased price. Furthermore, 3D printing reduces prosthetic production time by 86.2% and shows a reduction in cost by 88%.

Table of Contents

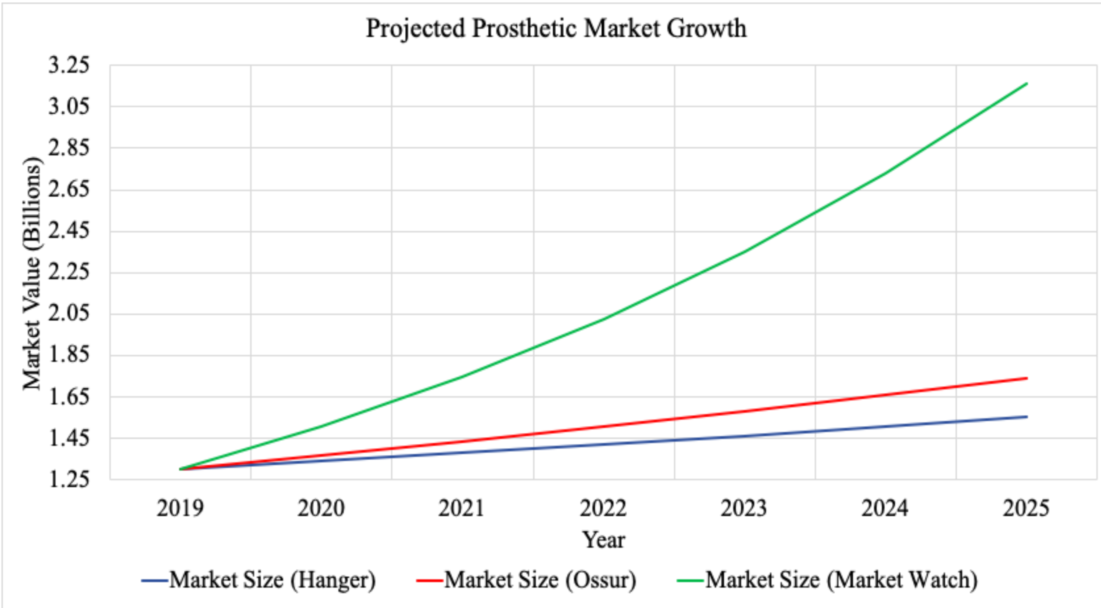
Illustrations

Introduction

The Jordan Thomas Foundation has done a cost analysis on children amputees. At a rate of one new prosthetic limb every two years until the age of 18, they have estimated a maximum and minimum cost - the minimum cost being $21,000, and the maximum being $300,000 for each limb (Sharington, 2017). A Hanger Clinic upper extremity myoelectric arm costs approximately $60,000 to $70,000 ("Life Care Plan Information for Upper Extremity Prosthetics", 2005). Moreover, the average maintenance cost for a typical repair is between 10% and 15% of the total price. In comparison, an average repair cost of the myoelectric system and cable operated system both are 50% of the total price. Keeping the prosthetic in good condition costs 115% of the total, costing the individual somewhere between $120,000 and $130,000 dollars. According to Hanger, every three to five years, the prosthetic must be replaced. With an increasing amputee population among low income Americans, this cost is realistically unattainable (Wachtel, 2005). A study done by Stanford scientists estimate that there is a total of 30 million amputees worldwide. In the United States alone, there are nearly two million people living with limb loss (Ephraim & Travison, 2008). Further, it is estimated that this number is projected to almost double to 3.6 million by 2050. This increase is due to medical conditions such as cancer, diabetes, and trauma. There are estimated to be around 185,000 amputations in the United States annually (US Census Bureau, 2019). 8.8% of Americans do not have health insurance to cover the cost of the prosthetic limb. The costs referenced above are not realistic for amputees that fall under the poverty line.

The process of constructing a prosthetic is also an issue with traditional prosthetics. Clinics usually take about 5 to 6 months to develop and fit an artificial limb ("Prosthetic FAQs for the New Amputee", 2015). This leaves the amputee without a limb for half a year. Studies have shown that 30% of people with limb loss experience depression or anxiety during that fitting period ("Limb Loss Statistics", n.d.). Consequently, the framework for an affordable, high-production prosthetic is dormant in the current competitive prosthesis market. The growth in amputees must be met or the global market can be lost to competitors. The predicted market size for the prosthetic market up until 2025 shows a polarizing view among professionals (see figure 1). The blue and red line represent Hangers prediction and Ossur's prediction respectfully. The green line is an expert analysts prediction for the market size. An observation is that both companies do not know their own potential for production. To produce a considerable shift in market size there must be a shift in technology and or production.

Figure 1: Projected Prosthetics Market Growth

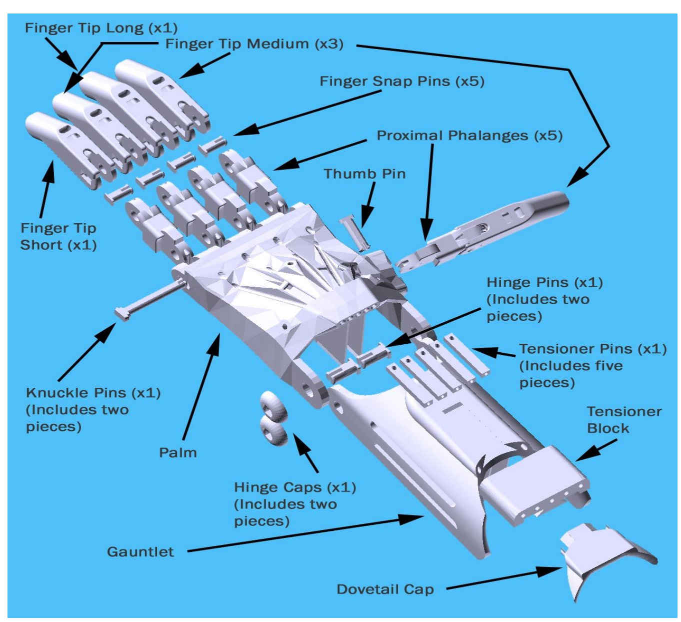


Lack of comfortability is an issue that amputees face when they are introduced to their artificial limb. The most common complaint amongst amputees is discomfort (Cuffari, 2017). This discomfort is traced to the prosthetic's socket. Traditional sockets are often made with a plaster cast of the amputees stump. A hard plastic, often polypropylene, is used to make a socket through injection molding. This method results in a stiff and uncomfortable plastic socket. Conditions such as osteoporosis, back pain, inflammation, dermal necrosis, and phantom limb pain all arise from an insufficient prosthetic (Cuffart, 2017).

Success Models

An affordable prosthesis is achievable through 3D printing technology. The International Data Corporation estimates that medical 3D printing will have a market share of 13% by 2020 (Reidel, 2019). The average price of a 3D printed arm and hand complex could be as cheap as $1050 (Dodziuk, 2016). This includes materials and assembly costs. Companies such as E-Nable specifically work with 3D printers to develop prosthetics. E-nable makes all of its parts with the

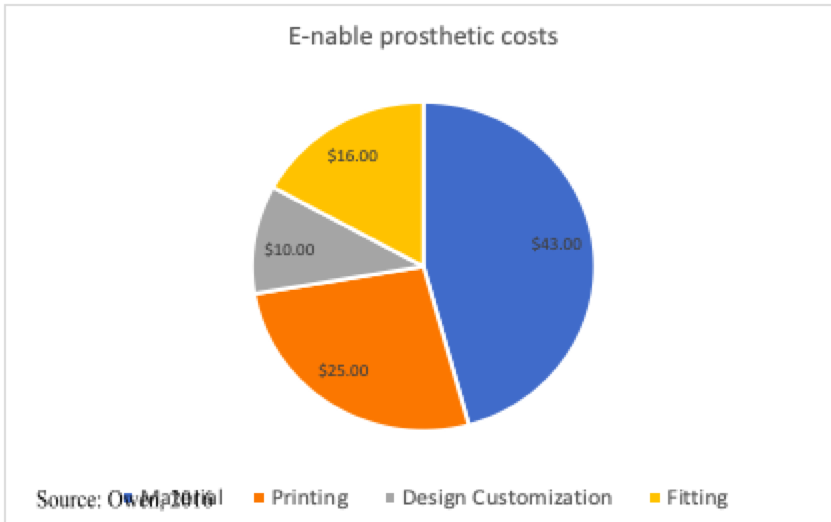
Figure 2: E-nable Design Diagram



3D printer according to their design diagram (see figure 2). E-Nable is an online global community of volunteers that use 3D printers to produce open-source designs of prosthetic hands and arms. Their creator, Ivan Owen, built a $500 prosthetic with 3D printing for a young girl who could not afford a recommended $80,000 artificial limb. They offer the computer aided design files free on their website. An E-nable prosthetic hand costs approximately $20 to $50 to fabricate and a prosthetic upper extremity arm costs approximately $50 to $150 (Owen, 2016) (See figure 3). The printing extrusion can take anywhere from 10 to 15 hours. E-nable recommends a FlashForge Creator Pro to print their prosthetics with. Along with E-Nable's success, they have had various problems in tandem. Durability is the main concern of consumers (Reidel, 2019). Moreover, volunteers are not licensed prosthetists, and the products are not FDA approved or tested. As a result, these products fracture more frequently than traditional prosthetics. E-Nable has since improved their practice with an engineer from the United Kingdom, Steve Wood, to produce a strong and flexible substitute. They used a material called FilaFlex, which is a thermoplastic elastomer with a polyurethane base. FilaFlex is printed using an extrusion method at approximately 80 mm/s and at 210℃ (Reidel, 2019). FilaFlex has a maximum tensile strength of 45 MPa, which is strong for a polymer. The prosthetic created with this material is around $2,000. When compared to traditional prosthetics, this is cost-effective.

Source: Owen, 2016

Figure 3: Cost E-nable Pi Chart



Developing countries suffer the most from lack of technology and production of prosthetics. In Guatemala, a hospital has successfully implemented 3D printing technology for amputee patients. The process allows the hospital to afford artificial limbs. 3D scanning and printing the object can reduce the costs down to as little as $4. (Peters, 2019). Brent Wright, prosthetist and orthotist, travels to Guatemala with a handheld 3D scanner, 3D printers, and materials for printing. The typical time for the process of constructing a prosthesis is significantly reduced. After scanning, a file is created and can be sent to the 3D printer then created. The file can be sent remotely, thus creating opportunities for surgeons to work remotely from their practice. This process also reduces the capital expenditures for outfitting a lab because a lab can cost upwards of $100,000. But a 3D printer costs approximately $1,000 to $3,000. Currently, the hospital only produces arms. According to Wright, a new printer, the HP Multijet Fusion, says it is technically possible to produce legs as well. Additionally, Wright says that materials are strong enough where it's long term durability equals that of a traditional prosthetic production (Peters, 2019).

Metal 3D printing

3D printing allows for various different materials to be used in the construction of prosthetics. Most 3D printing prosthetics use acrylonitrile butadiene styrene (ABS) plastic while traditional prosthetics use plastics such as polypropylene, polyethylene, acrylics, and polyurethane. (Hui & Kashani, 2018). Recent technology allows for biomaterials, such as lightweight titanium alloys, to be used in metal 3D printers (Cherdo, n.d.). 3D printed titanium is a lightweight, non-toxic biomaterial with strong mechanical properties that can resist up to 1077 MPa in compression (see figure 4). Titanium is printed using the direct metal laser sintering technique. A metal 3D printer prints the titanium at about 30 μm per second and has to be sintered at 1,600℃. An EOS M290 is the recommended printer to print titanium structures. A research group in Belgium was successful in 3D printing titanium for a jaw implant (Poukens, 2012). This was done by using titanium powder, which was heated then fused by a laser for each layer. Operations such as this provide a market for composite metal and plastic 3D printed prosthetics. Prosthetics made with composites including metal and plastic are more mechanically strong and durable compared to a prosthetic constructed of plastic alone (Hui & Kashani, 2018). A 3D certification license and class that educates employees to use biomaterials in 3D printing is $4,000. To draft prosthetic models online a CAD license is required, which is $1,610 per year (Buy AutoCAD 2020 Software, n.d.).

Figure 4: Titanium Mechanical Properties Table

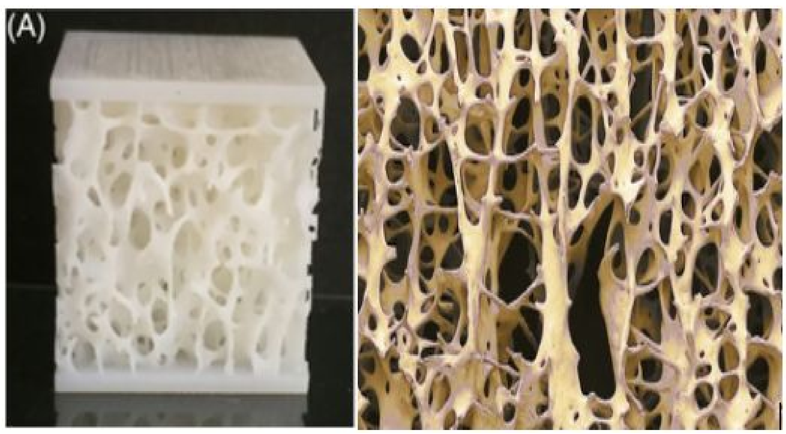
	Horizontal	Vertical
Ultimate tensile strength, Rm	1077 MPa	1065 MPa
Yield strength, Rp0.2	964 MPa	956 MPa
Elongation at break, A	13,0 %	13,3 %

Source: Hui & Kashini

Methods to Replicating Bone Structure

The mechanical properties of a bone should be reproduced when constructing a pylon for a prosthetic. Cortical bone and trabecular bone have elastic moduli of 20.85 GPa and 0.25 GPa respectively in compression (Alvarez & Nakajima, 2009). Advancements in biomedical engineering offer the option to 3D print a scaffold that accurately represents the mechanical properties of bone. A study included in the Journal of Biomedical demonstrates how scientists can mimic the microstructure of trabecular bone. A polyjet printer fabricated a trabecular bone scaffold using a VeroWhitePlus polymer at a 16 μm resolution (Amini & Pahr, 2019). This polymer was used because it has the same magnitude as the calcium phosphate structure in trabecular bone when treated properly. This scaffold has accurately mimicked a human trabecular bone in its weight bearing properties. When printed, the artificial scaffold and the organic scaffold are similar in geometry (see figure 3).

Figure 5: 3D Printed Scaffold vs. Human Trabecular Bone



Source: Amini & Pahr

Infinite Socket

Figure 6: Infinite Socket Fitting Methods

Source: OUR STORY, n.d.

The human technology interface, the socket, has held back the amputees movement for years. In response, LIM Innovations have developed an adjustable socket for maximum amputee comfort ("OUR STORY", n.d.). The Infinite Socket was developed to maximize amputee comfortability, and reduce harmful conditions such as back pain and osteoporosis. This modular socket was named the Infinite Socket, the first adjustable carbon fiber socket on the market. The Infinite Socket presents three modes of skin- prosthetic interface options: lanyard method, seal-in suction and pin suspension (see figure 6). LIM uses digital imaging to create a patient specific mold for the socket . Once the image is gathered, LIM uses 3D printing to create a carbon fiber strut that will encompass the patients stump. This process takes one week to process and fabricate. The price of the Infinite Socket is approximately $7,000.

Hanger's Method

Hanger's current practice involves two phases: the temporary prosthesis phase, and the final prosthesis phase ("Fitting Your Prosthesis", n.d.). The temporary phase starts after waiting four to six weeks for the swelling post amputation to subside. Next a socket is fitted for the patient and a temporary prosthesis is given. A final prosthesis for the patient can be issued months after surgery, and requires several visits to the clinic. This process could be improved for communities that can not commit to the expense and time intensive process offered by the Hanger Clinic. In addition, Hanger's product is only offered in the United States. There are Potential consumers all around the world that can be positively affected by Hanger's service and product.

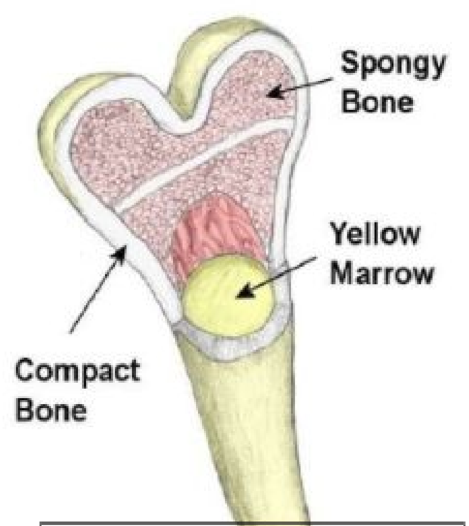
Proposal

The first step is to educate future and current employees on how to use a 3D printer. This is accomplished by having employees register and participate in a class that educates them on 3D printer operation. Once complete, the employees will obtain a license that will certify that they are competent with the system. A Computer Automated Design (CAD) license is also needed to draft a prosthetic STL file to send to the 3D printer.

The next step is to obtain the hardware needed to 3D print the proper materials. E-nable recommends the FlashForge creator Pro for printing polymers. The recommended metal 3D printer for titanium is the EOS M290. With these two printers, both biopolymers and biometals can be printed in tandem.

The fitting process comes next. Once the stump has stopped swelling, a 3D image file can be taken at the clinic and remotely sent to the production. This process is reminiscent of what Doctor Wright's team accomplished in Guatemala, and LIM Innovations technique of fabricating the Infinite Socket. Furthermore, the 3D image is sent to LIM Innovations to develop the patient specific Infinite Socket.

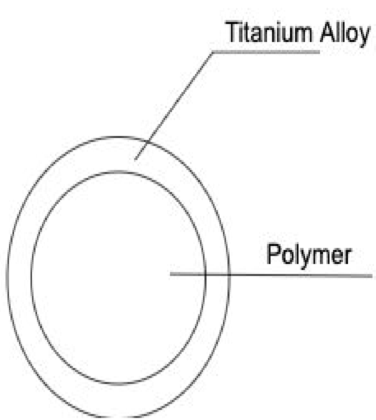
Figure 7: Cortical and Trabecular Bone - Femur



Source: https://www.researchgate.net/figure/Cortical-and-cancellous-bone

The final step is to produce a prosthetic that transcends traditional prosthetics in comfortability and strength. The focus will be producing a lower extremity prosthesis that mimics the lost limb's geometry and mechanical properties. The FlashForgeCreator Pro will use VeroWhitePlus to produce a scaffold that has the same geometry as trabecular (spongy) bone. The EOS M290 will print a hollow titanium pylon that will mimic the properties

Figure 8: Transverse View of Bone Pylon



of cortical (compact) bone (see figure 7). The FlashForge Pro will also print a FilaFlex exoskeleton to protect the inside and offer an aesthetic finish. The pylon will be fabricated such that the titanium will wrap around the outside of the polymer scaffold (see figure 8).

A time table is given in the form a Gantt chart to represent the printing and fabrication process (see figure 9). The production of the prosthetic starts right when the swelling has subsided in the patient's limb. This is done to get an accurate 3D image of the stump to send to LIM Innovations. First, the metal 3D printing for the pylon would take a week's time. In tandem with the metal, the polymer would only take two day to print. Once printed, the material is treated for any deformities that may have arisen during production. Once the Pylon is constructed, LIM Innovations work on the Infinite Socket for the specific patient. Lastly, when the socket is constructed and shipped, the product is assembled and tested for quality assurance. The fabrication process for the 3D printed limb takes only 3 weeks to complete.

Figure 9: Gantt Chart Production Time for 3D Printed Prosthetic

Budget

The budget is split into two segments: the equipment and the material cost. The equipment is a one time cost, while the materials have to reoccur for every new prosthesis constructed. The cost of producing the prosthesis includes no labor costs, because it is all done remotely with a 3D printer. The table below represents the material cost if the Hanger Clinic was to address every amputee in the United States annually.

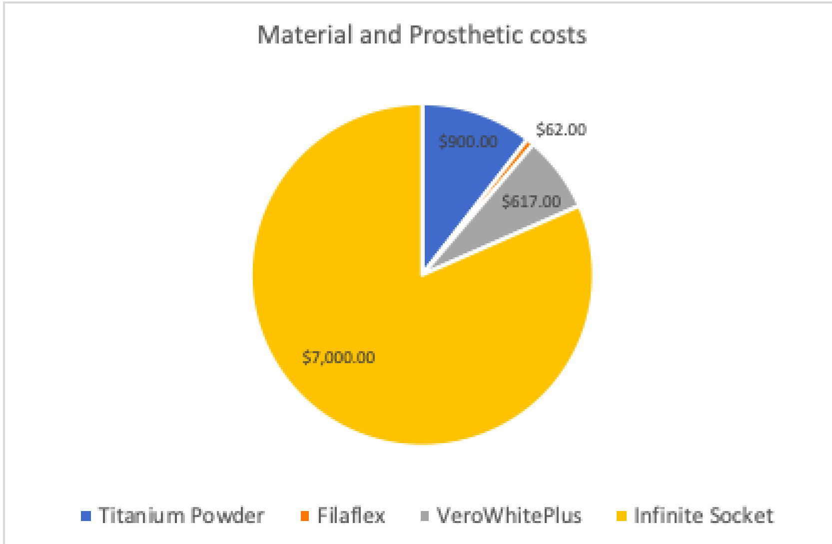
Equipment:

EOS M290 …………………………………………………………………………….....$700,000
(Maxey, n.d.)
FlashForge Creator Pro ………………………………………………………………….$800
(Dodziuk H, 2016)
3D printing certification ……………………………………………………………….$1,500
(Owen, 2016)
CAD license ……………………………………………………………………………...$1,610
(Buy AutoCAD 2020 Software, n.d.)

Total Equipment Cost…………………………………………………………………$703,910

Materials:

Figure 10: Material and Production Cost 3D Printed Prosthetic Pi Chart



Titanium Alloy Powder …………………………………………………………...….$900
(Advanced Ultrafine Spherical Titanium Alloy Powder Ti6al4v, n.d.)
FilaFlex (Black Dye) ………………………………………………………...……$62
(FILAFLEX BLACK, n.d.)
VeroWhitePlus ……………………………………………………………………..$617
(Amini & Pahr, 2019)
Adjustable Carbon Fiber Infinite Socket ……………………………………………...$7,000
(Dignan, 2014).

Total Prosthetic Cost (one limb)……………………………………………………..$8579

Total Cost of Plan
…………………………………………………...……………$712,489

Figure 11: Predicted Cost Table to Address Half of The Amputees in The U.S

Material	Cost (1 Prosthetic)	Cost (92500) prosthetics)
Titanium Powder	$ 900.00	$ 83,250,000.00
Filaflex	$ 62.00	$ 5,735,000.00
VeroWhitePlus	$ 617.00	$ 57,072,500.00
Infinite Socket	$ 7,000.00	$ 647,500,000.00
Total	$ 8,579.00	$ 793,557,500.00

Discussion

3D printed prosthetics offer an opportunity for the Hanger to increase their production and reduce their costs. A traditional prosthetic from Hanger today costs approximately $75,000, while a 3D printed prosthetic costs $8,579. This results in a cost reduction of 88%. The time to produce a traditional prosthetic is 182 days after swelling stops for traditional prosthetics ("Fitting Your Prosthesis", n.d.). The proposal put forward has a production time of 25 days. This results in an 86.2% reduction in production time. Using Hanger's 2018 revenue and the value from figure 11, Hanger can address half of the amputees in the United States with a 32.1% return on capital investment. As 3D printing becomes more integrated into the prosthetic field, Hanger could reach the predicted market value issued by market watch. This plan can be started immediately and will take at maximum one year to integrate the proper hardware and software into Hanger.

For future developments, Hanger can look into more tissue engineering practices to create an even more accurate scaffold for the pylon. Extensive gait analysis could be done to test the long term effects of a 3D printed prosthetic. Further, Hanger could move it's operation overseas due to the convenience of 3D printing operating remotely.

To address Hanger clinics mission 3D printing and additive technology should be utilized to address the disabled population. When this proposal is successfully implemented, Hanger's predicted 5-year revenue and mission can be achieved. Further, a more organic prosthesis can be developed to mimic anthropometric gait.

References

About The Hanger Foundation. (n.d.). Retrieved from http://hanger.com/doing/Pages/default.aspx.

Advanced Ultrafine Spherical Titanium Alloy Powder Ti6al4v Powder For 3d Printing - Buy Titanium Ti6al4v Powder,Titanium Powder Price,Titanium Powder Product on Alibaba.com. (n.d.). Retrieved from https://www.alibaba.com/product-detail/Advanced-Ultrafine-Spherical-Titanium-Alloy-Powder_60501544307.html?spm=a2700.7724857.normalList.2.2b6b4439JOYlGz&s=p.

Alvarez, K., & Nakajima, H. (2009). Metallic Scaffolds for Bone Regeneration. *Materials*, *2*(3), 790–832.

Amini, M., Reisinger, A., & Pahr, D. H. (2019). Influence of processing parameters on mechanical properties of a 3D‐printed trabecular bone microstructure. Journal of Biomedical Materials Research Part B: Applied Biomaterials, 108(1), 38–47.

Bay, J. (2018, October 15). Orthopaedic Prosthetics Market is Forecast to Cross US$ 3.0 Billion by 2024. Retrieved from https://www.marketwatch.com/press-release/orthopaedic-prosthetics-market-is-forecast-to-cross-us-30-billion-by-2024-2018-10-15.

Buy AutoCAD 2020 Software. (n.d.). Retrieved from https://www.autodesk.com/products/autocad/subscribe?plc=ACDIST&term=1-YEAR&support=ADVANCED&quantity=1.

Cherdo, L. (n.d.). The best metal 3D printers in 2019. Retrieved from https://www.aniwaa.com/best-of/3d-printers/best-metal-3d-printer/.

Cuffari, B. (2019, April 19). 3D Printing and Prosthetics: History and Current Advances. Retrieved from https://www.azom.com/article.aspx?ArticleID=14137.

Dignan, L. (2014, November 4). LIM Innovations: Multiple disciplines, amputee focus bolsters innovation. Retrieved from https://www.zdnet.com/article/lim-innovations-multiple-disciplines-amputee-focus-bolsters-innovation/.

Dodziuk H. (2016). Applications of 3D printing in healthcare. *Polish journal of cardio-thoracic surgery*, *13*, 283–293.

Ephraim, P. L., Travison, T. G., et al. (2008). Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050. *Archives of Physical Medicine and Rehabilitation*, *89*(3), 422–429.

FILAFLEX BLACK 1.75MM 250gr TPU FILAMENT. (n.d.). Retrieved from https://recreus.com/en/diameter-175/21-13-filaflexnegro175mm055lb-250gr-8435424800134.html.

Fitting Your Prosthesis. (n.d.). Retrieved from http://www.hangerclinic.com/limb-loss/resources/what-to-expect/fitting/Pages/default.aspx.

Hui T., Kashani, A., Imbalzano, G., Ngo, T. D., & Nguyen, K. (2018). Additive manufacturing (3D printing): A review of materials, methods, applications and challenges. *Composites Part B: Engineering*, *143*, 172–196.

J. Owen. (2016, March 29). e-NABLING Myo Band Arm Control Retrieved from https://enablingthefuture.org/2016/03/25/e-nabling-myo-band-arm-control-•-team-uw-bothel/.

Life Care Plan Information for Upper Extremity Prosthetics [PDF]. (2005). Retrieved from http://www.figeducation.com/nlcp/resources/section-4/Hanger%20Cost%20Estimate%20for%20UE%20Prosthesis.PDF

Limb Loss Statistics. (n.d.). Retrieved from https://www.amputee-coalition.org/limb-loss-resource-center/resources-filtered/resources-by-topic/limb-loss-statistics/limb-loss-statistics/.

Maxey, K. (n.d.). Metal Sintering Meets Industrial Needs with the EOS M 290. Retrieved from https://www.engineering.com/DesignerEdge/DesignerEdgeArticles/ArticleID/7829/Metal-Sintering-Meets-Industrial-Needs-with-the-EOS-M-290.aspx.

OUR STORY. (n.d.). Retrieved from https://www.liminnovations.com/our-story/.

Peters, A. (2019, July 24). How 3D printing is making prosthetics cheap and accessible Retrieved from https://www.fastcompany.com/90358495/how-3d-printing-is-making-prosthetics-cheap-and-accessible-even-in-remote-places.

Poukens , J. (2012, March 8). Transplant jaw made by 3D printer claimed as first. Retrieved from https://www.bbc.com/news/technology-16907104.

Prosthetic FAQs for the New Amputee. (2015, May 1). Retrieved from https://www.amputee-coalition.org/resources/prosthetic-faqs-for-the-new-amputee/.

Reidel, H. (2019, September 16). The Successes and Failures of 3D Printed Prosthetics. Retrieved from https://www.prescouter.com/2017/07/3d-printed-prosthetics/.

Sharington , G. (2017, June 29). The True Cost of Prosthetic Limbs: What it Means For Families. Retrieved from https://jordanthomasfoundation.org/true-cost-prosthetic-limbs/.

US Census Bureau. (2019, April 16). Health Insurance Coverage in the United States: 2017. Retrieved from https://www.census.gov/library/publications/2018/demo/p60-264.html.

Wachtel M. S. (2005). Family poverty accounts for differences in lower-extremity amputation rates of minorities 50 years old or more with diabetes. *Journal of the National Medical Association, 97(3)*, 334–338.