3D Printing Innovation in Healthcare

A Research Paper submitted to the Department of Engineering and Society

Presented to the Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree

Bachelor of Science, School of Engineering

Trent Jerome Levy

Spring 2021

On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

Advisor

Sean M. Ferguson, Department of Engineering and Society

The Emergence of 3D Printing

3D printing (3DP) has become increasingly accessible to a large portion of the global population. In the early 2000's, only Fortune 500 companies and major research universities had access to 3D printers which cost up to $300,000 in the 1980s; however, today people are able to purchase 3D printers for as little as $49 (*The Evolution of 3D Printing*, 2016). There are clear cost benefits for adoption of 3DP as it can help companies reduce dependence on shipping and inventory as well as allow consumers to save up to 99% of commercial pricing for products (Pearce et al., 2020). In addition to low cost of entry benefits, there has been an increase in the democratization of 3DP technology facilitated by the creation of Hackerspaces, Makerspaces, and Fab Labs which serve as locations that draw hobbyist maker communities together, create political interventions, and serve as start-up incubators (Savvides, 2019).

The growth of both adoption and accessibility for 3DP has led to an enabling environment for those previously isolated from traditionally expensive manufacturing and prototyping techniques. "The global hackerspace movement has helped proliferate a 'maker culture' that revolves around both technological and social practices of creative play, peer production, and commitment to open source principles" which is critical in order to empower more members of the global community (Ames et al., 2014). Actor Network Theory (ANT) can be applied as a framework in analyzing how there has been a disruption in the traditional network of device production and how many new actors acting in their own self-interest to create innovations have started to change the 3DP network to become more accessible to spread innovation. Examples of these changes can be explored from the creation of forum resources, physical resources, and design resources (*How to Mend the 3D Printing Digital Divide | 3DPrinterOS*, n.d.). Forum resources such as "Thingiverse" or "YouMagine" not only provide a community where individuals can share designs and models but also provide a community where advice and troubleshooting occur. In these online forums, models can be uploaded and downloaded by anyone with access to the internet and subsequently printed using their own respective 3D printers. Physical resources such as “Makerspaces”, provide communal resources such as 3D printers, filament, and post-manufacturing tools. Design resources such as computer aided design (CAD) are increasing in number and allow for individuals to create, model, and test products all on personal computers before production. Cloud and web-based CAD also enable designers to be collaborative. Utilizing CAD, designers are able to work on models simultaneously having access to modify and even 3D print from different locations (Maguire, 2017). These developing resources have built a stable, wide network of 3DP, and a sociotechnical ecosystem has emerged that has impacted healthcare in meaningful ways. There now exists a revolutionary infrastructure in which people are able to share physical designs and have them be produced anywhere in the world with 3DP. The objectives of my analysis are to explore the emergence of 3DP in healthcare, evaluate an opportunity space for 3DP to potentially integrate within healthcare, and provide advice and requirements for 3DP to reach its maximum potential in improving healthcare. Although 3DP has been integrated into the healthcare industry to some extent, there is a nascent opportunity to further integrate 3DP to aid in solving significant healthcare issues.

Introduction to the Benefits of 3D Printing in Healthcare

The integration of 3DP technology can augment the experience of patients and physicians by improving personalized healthcare while decreasing cost with the enabling resource of rapid, customized, and cheap prototyping (Aquino et al., 2018). One example of 3DP improving personalized healthcare is the growing interest in the creation of patient-specific pills that could allow individualized dosages and unique combinations of medication (outsourcing-pharma.com, n.d.). Another case of personalized healthcare innovation are the potential of 3D printed casts which offer a unique customized fit for patients whereas traditional casts and braces are made to accommodate a general anatomical shape (*4 Ways 3D Printing Is Changing Orthopedic Casts And Braces*, n.d.). 3DP also has the potential to significantly reduce costs of healthcare. For demographics who grow at a rapid rate, like children, constant exchange and fitting of prosthetics is expensive. As a result, innovation has been made in prosthetic sockets for below-the-knee prosthetic limbs to create custom sockets that will fit specifically tailored to their recipient made with lower cost (*3D Printed Prosthetic Socket | University of Toronto Scientific Instruments Collection*, n.d.). 3DP also offers a method for physicians to prepare for complex, unique surgeries in which traditional expected anatomy is not present. In order to prepare for operations such as conjoined twins where survival and functionality of the patients is prioritized, better preparation and planning for the best strategy of separation is critical for success. In Kenya, 3D printing technology is being used to generate physical models of unique anatomy deformities in order to prepare surgeons for successful surgery strategy. In this instance, 3DP technology has been provided pro bono in order to “give patients access to the cutting edge technology and not make it a distant cry of something they hear of or see on television” (CGTN Africa, 2019). The effect of allowing healthcare to be more customized to the patient as well as being more affordable aids in expanding healthcare access while improving patient outcomes and should be explored further.

3DP designs can easily be created in one country and subsequently shared across the globe for use elsewhere. This easy distribution of files for 3DP provides a great advantage to those isolated from robust healthcare infrastructures lacking certain access to devices or products. Powered by the shareable network of 3D printed designs, individuals with access to the internet are equipped with the ability to create devices and tools that can be made on-site at any location. The use of this far-reaching digital infrastructure has made a considerable impact on societal health struggles in water management and disease control. For example, in order to aid in preventing water-borne bacterial infections which result in more than 2,000 deaths per day, open source 3D printed microscopes have been produced in remote areas to identify unsafe water before it is consumed. These microscopes provide a simpler, faster, and cheaper method for getting more tests done in a shorter amount of time (*Four Ways 3D Printing Is Improving Healthcare in Developing Countries | ManufacturingTomorrow*, n.d.). Disease identification has also been improved in areas lacking hospitals or dedicated laboratories through innovations in blood and saliva tests. One example that emerged from the 2014 Ebola Outbreak was FieldLab, a solar powered partially 3D printed "lab in a box" developed by Rhodes University in South Africa that could be used to carry out DNA analysis. Another test kit made by PandemicTech also emerged which was made to combat the rise of leishmaniasis using 3D printed test tubes and caps (*Four Ways 3D Printing Is Improving Healthcare in Developing Countries | ManufacturingTomorrow*, n.d.). These 3DP enabled innovations have brought improved healthcare technology to those who otherwise would be at greater risk of water contamination or rampant unmonitored disease spread. The benefit of the 3DP network to spread ideas of innovation has also been experienced during the COVID-19 pandemic. 3DP offers a rapid response to emergencies, can accommodate disruptions in supply chains, and has been used in order to share mask designs and other medical equipment designs (Choong et al., 2020). 3DP has been used in order to aid in accommodating shortages in personal protective equipment (PPE) as demonstrated in the partnership of MITRE and the University of Virginia to produce face-shields during periods of scarcity to effectively produce “enough face shields to protect its front-line workers” (*3D Printing Accelerates Face Shield Supply Chain at UVA*, 2020). Collaborative and rapid responses such as this partnership makes 3DP a disruptive and beneficial asset for actors in the healthcare industry. As demonstrated from the current applications of 3DP in healthcare, 3DP is being utilized in order to solve critical issues such as improvement of personalized healthcare, cost, patient outcomes, and public health.

A Problematic Relationship

Although 3DP technology is spreading throughout the world and being implemented to create better healthcare for the global community, problems still exist that 3DP can help solve. Currently, there exists an established network between high-resource nations and low-resource nations in which medical equipment is donated to low-resource countries. Specifically, high resource countries will often aid low-resource countries by donating up to 80% of their utilized medical equipment; however, the World Health Organization (WHO) along with other sources have stated that up to 40-70% of equipment is out of service while only one percent of equipment in high-resource countries is out of service (*Medical Equipment Graveyards*, 2019)(Marks et al., 2019)(Malkin, 2007). The result of these dysfunctional medical equipment items in low-resource nations are the creation of “medical equipment graveyards” where broken donated equipment is amassed in hospitals in low-income and middle-income countries (Marks et al., 2019). This problem stems from four major points of failure: donors shipping inappropriate or broken equipment, poor access to supplies and parts, lack of expertise in the donated country to maintain and repair the equipment, and challenges with coordinating among donors to finance the cost of operating the equipment (*Medical Equipment Graveyards*, 2019).

The donation and shipping of inappropriate or broken equipment is a major issue that contains two major contributing factors: a power imbalance in the donor-recipient relationship and medical device design tailored to high-resource nations. The donation of medical equipment from high-resource nations to low-resource nations currently exists with a donor-recipient power disparity where "an 'anything is better than nothing' attitude" encourages the donation of poor-quality donations (Marks et al., 2019). Oftentimes, recipients might be pressured to withhold sentiments about donors' efforts and accept donations regardless. Additionally, recipients might find it culturally inappropriate to decline a gift (*CHA Medical Surplus Donation Study: How Effective Surplus Donation Can Relieve Human Suffering*, n.d.). The compounding of a lack of resistance to accepting donations with an attitude that anything is better than nothing creates a surplus of donations even when the donations are of poor quality. Medical device companies also prioritize development of their devices for use in developed nations with robust healthcare programs. For medical device companies in developing nations, "market penetration is close to zero" (Malkin, 2007). This prioritization where "health technologies are overwhelmingly designed for [high-income countries]" can lead to unoptimized design for medical equipment to function in low-income countries with less resources (Marks et al., 2019). The impact of prioritization of medical device design for the developed nation market is significant as devices are designed and expected to be supplied with reliable power and water resources. Assumed available resources for medical devices can cause failure of operation when used in healthcare infrastructures incapable of supporting the equipment with sufficient resources. Considering the fact that over 95% of medical equipment for public hospitals in developing nations is imported, failure of devices to operate in a different setting can lead to amassing of nonfunctional equipment in medical equipment graveyards (Malkin, 2007). This failure to operate imported equipment manifests in manners where 95% of imported medical equipment does not function after five years while 39% never work at any point.

Poor access to supplies and parts is another major contributing factor to the problematic creation of medical equipment graveyards. In terms of the barriers faced for medical devices in the developing world, “the most important design barrier is the lack of spare parts in the target countries” (Malkin, 2007). For donated medical devices, the equipment likely only lasts as soon as the first replacement part is required. This shortcoming of the life cycle of medical devices in the developing world is caused by a lack of available spare parts, a ceasing of the production of the part, or a requirement of payment with a credit card which few people in the developing world own (Malkin, 2007). The lack of spare parts available to extend the life

cycle of a medical device contributes to the rapid accumulation of obsolete medical equipment and subsequent creation of medical equipment graveyards.

Lack of expertise is a third contributing factor to the creation of medical equipment graveyards. Beyond the simple functioning of the physical equipment, there also needs to be staff with sufficient training expertise to utilize advanced donated technology. However, there are obstacles such as “brain drain” where qualified staff in developing nations are trained and subsequently emigrate leaving their developing nation with a decreasing number of qualified staff to operate equipment (Malkin, 2007). This drawback makes stakeholders such as medical device companies reluctant to invest funds into training staff in developing nations to operate their equipment and further entrenches the focus of medical device companies to focus their design for developed nations. An additional confounding variable is that the operation of a “mishmash of equipment in nearly impossible for resource-strapped healthcare providers” (*Medical Equipment Graveyards*, 2019). The draining of talent to operate equipment and the complexity of various models of equipment being present in one hospital system creates an environment where medical equipment is not able to be utilized or is possibly incompatible with other equipment. In this instance, donated medical equipment could be deemed dysfunctional not due to internal failure of the equipment, but rather due to external failures of the recipient system of a developing nation.

Challenges with coordinating among donors to finance the cost of operating the equipment is a fourth contributing factor to the problematic creation of medical equipment graveyards. Unfortunately, in certain instances "donated equipment can sit in a warehouse in the US for years and never make it to [a] recipient" due to a lack of a coordinated donation plan (*Medical Equipment Graveyards*, 2019). Beyond this initial complication, donors do not know the manner in which their donations are benefitting the recipients which can discourage future donations. Additionally, beyond the donation of medical equipment, there currently is little incentive to fund costs of replacement parts and other supplies to continue the operation of the donated equipment from donors. This lack of incentive for funding repair and maintenance of donated equipment prevents equipment from being repaired and further exacerbates the creation of medical equipment graveyards.

These four contributing factors to medical equipment graveyards are significant and deserve attention in order to solve the issue of donated medical equipment not being utilized to its maximal potential in developing nations. However, although this issue has persisted, there exists an opportunity to solve this issue harnessing the intrinsic advantages of 3DP.

The 3D Printing Solution

3DP offers advantages for the healthcare industry which could be directly involved in solving the misuse of donated equipment in the developing world. Specifically, 3DP can serve as a helpful intervention in repairing broken equipment and thereby prolong the life cycle of donated medical equipment.

First, 3DP can be utilized in order to create accessibility to parts and supplies. With forum resources such as “Thingiverse” and “YouMagine”, repair parts can be uploaded to databases to house model files for future download and printing for those who need them in any part of the world with access to the internet. Whereas previously medical equipment would be thrown away once a repair was needed, 3DP can further the longevity of medical equipment by providing repair parts easily and cheaply to be made on-site at the facility in need.

Second, 3DP can be utilized in order to reduce costs in healthcare. Specifically, if medical equipment requires disposable supplies that are easily accessible in developed nations yet inaccessible in developing nations, 3DP could aid in production of these supplies in a similar manner in which PPE has been produced cheaply in mass during the COVID-19 pandemic. Not only would this aid medical equipment functioning for a longer period, but it would also be less costly than importing scarce supplies with transportation costs. Instead of large medical equipment being shipped from donor nations to recipient nations through physical transportation, essential parts could be physically shipped while 3D printable parts could be manufactured on site for later assembly after arrival of shipped material. By taking advantage of 3DP’s ability to “overcome supply chain challenges”, we can drive down costs of transportation and healthcare overall (Corsini et al., 2020). By decreasing costs, low-resource healthcare systems could afford medical equipment and become less reliant on donated medical equipment. By decreasing dependency on donations from other nations, issues intrinsic of the donated medical equipment process can pose less of a disrupting effect.

Third, 3DP could be used in order to encourage and develop technology in developing nations to improve autonomy of those nations' healthcare systems. 3DP production allows nations to "respond quickly to unpredictable events under significant resource constraints" (Corsini et al., 2020). By having a 3DP network in place, healthcare systems can have a means of responding rapidly to shortages in certain supplies and thereby increase their ability to handle stresses of public health phenomena such as disease outbreaks. Additionally, not only does an established 3DP network in developing nations' hospitals enable them to be resilient to unpredictable events, it also fosters local production and a 3DP-trained community. Overall, this "democratizing [of] technology is just as important as developing it" (*How to Mend the 3D Printing Digital Divide | 3DPrinterOS*, n.d.). Increased democratization and exposure to 3DP technology will allow members of disadvantaged communities to develop innovations with a direct and knowledgeable perspective of the issues faced. Not only will this democratization create innovations for developing nations, but it will create innovation for developed nations to adopt from developing nations as well thereby changing a previously unidirectional relationship to a bidirectional network. By improving the power imbalance experienced by high-resource and low-resource nations, 3DP can improve autonomy, decrease dependency on donations, and avoid the complications of donated equipment from other nations creating medical equipment graveyards.

3DP can be used effectively in order to solve the issue of medical equipment graveyards in healthcare. By effectively creating access to repair parts, creating lower costs of supplies, and creating an environment of autonomy and innovation in developing nations, 3DP could be used in order to diminish issues of donated medical equipment being wasted and not used to their utmost potential.

Limitations and Obstacles to Overcome

Although the potential for 3DP has been proposed as a solution to a major issue in healthcare, there are still significant obstacles to be overcome in order for the revolutionary potential of 3DP to become realizable.

Currently, it is becoming "increasingly difficult for consumers to fix a wide range of electronics…including medical devices" (*Why It's so Hard for a Hospital in Tanzania to Fix Broken Incubators*, 2021). Barriers such as restricting access to spare parts, imposing prohibitive warranties, and using software locks have been utilized in order for companies to control the use of their devices. These restrictive tactics from companies can cause significant obstacles for those who desire to repair a certain product. Attention was drawn to the adverse effects of these restrictions during the COVID-19 pandemic when repair of ventilators was obstructed by these restrictions (*Why It's so Hard for a Hospital in Tanzania to Fix Broken Incubators*, 2021). In order to counter these obstructive protections intentionally designed to make repairs and upgrades difficult, there has been a growing interest in "right to repair" legislation which ensures that consumers are safe, prevents products from being open to hacking, and does not limit innovation (*Legislation*, n.d.). This "right to repair" legislation would "lift barriers that prevent healthcare providers from maintaining and repairing their medical equipment they desperately need" (Arena, 2020). In the medical device industry, protections such as patents and copyrights are extensive. These additional regulations exacerbate the common restrictions aforementioned and make repair of medical devices extremely difficult.

In the case of countries such as Tanzania which rely on second hand electronics imported from other countries, obstacles such as password-protected software require expenses to be paid for official repair to be conducted by the manufacturing company (*Why It's so Hard for a Hospital in Tanzania to Fix Broken Incubators*, 2021). These official repairs are often delayed and costly, leading to healthcare administrators avoiding the process when repairs are required for medical equipment. Instead of having cheap easy access to repair parts for medical equipment, patents, copyrights, and other restrictive measures prevent many medical devices from being repaired. Without greater accessibility for consumers to access repair from manufacturers, we will most likely continue to experience issues such as medical equipment graveyards as in Tanzania where "warmers and incubators [are] all just shoved in corners, broken, [and] dismantled…because they don't have the right piece for it" (*Why It's so Hard for a Hospital in Tanzania to Fix Broken Incubators*, 2021).

The ability for 3DP to make a considerable impact on solving issues as medical equipment graveyards is substantive; however, without destabilization of current restrictive measures especially in the medical device industry, significant change will not occur and we will continue to experience issues. By making repair accessible and allowing repairs to be conducted locally and easily, we could reap the full potential that 3DP offers to healthcare beyond its current benefits today.

Works Cited:

3D printed prosthetic socket | University of Toronto Scientific Instruments Collection. (n.d.). Retrieved November 2, 2020, from https://utsic.utoronto.ca/wpm_instrument/3d-printed-prosthetic-socket/

3D Printing Accelerates Face Shield Supply Chain at UVA. (2020). https://www.mitre.org/publications/project-stories/3d-printing-accelerates-face-shield-supply-chain-at-uva

4 Ways 3D Printing Is Changing Orthopedic Casts And Braces. (n.d.). Covering the Specialized Field of Orthopedic Product Development and Manufacturing. Retrieved November 1, 2020, from https://www.odtmag.com/contents/view_online-exclusives/2019-05-29/4-ways-3d-printing-is-changing-orthopedic-casts-and-braces/

Ames, M. G., Bardzell, J., Bardzell, S., Lindtner, S., Mellis, D. A., & Rosner, D. K. (2014). Making cultures: Empowerment, participation, and democracy - or not? *CHI '14 Extended Abstracts on Human Factors in Computing Systems*, 1087–1092. https://doi.org/10.1145/2559206.2579405

Aquino, R. P., Barile, S., Grasso, A., & Saviano, M. (2018). Envisioning smart and sustainable healthcare: 3D Printing technologies for personalized medication. *Futures*, *103*, 35–50. https://doi.org/10.1016/j.futures.2018.03.002

Arena, K. (2020, October 15). *Medical Device Repair Act: The Right to Repair*. InterMed Group. https://intermed1.com/medical-device-right-to-repair-act/

CGTN Africa. (2019, July 1). *Kenyan doctors turn to 3D printing to improve healthcare*. https://www.youtube.com/watch?v=f9wIFQsNrhE

CHA Medical Surplus Donation Study: How Effective Surplus Donation Can Relieve Human Suffering. (n.d.). Retrieved May 1, 2021, from https://www.chausa.org/store/products/product?id=2296

Choong, Y. Y. C., Tan, H. W., Patel, D. C., Choong, W. T. N., Chen, C.-H., Low, H. Y., Tan, M. J., Patel, C. D., & Chua, C. K. (2020). The global rise of 3D printing during the COVID-19 pandemic. *Nature Reviews Materials*, *5*(9), 637–639. https://doi.org/10.1038/s41578-020-00234-3

Corsini, L., Aranda-Jan, C. B., & Moultrie, J. (2020). The impact of 3D printing on the humanitarian supply chain. *Production Planning & Control*, *0*(0), 1–13. https://doi.org/10.1080/09537287.2020.1834130

Four Ways 3D Printing Is Improving Healthcare in Developing Countries | ManufacturingTomorrow. (n.d.). Retrieved November 2, 2020, from https://manufacturingtomorrow.com/news/2018/09/07/four-ways-3d-printing-is-improving-healthcare-in-developing-countries/12111/

How to Mend the 3D Printing Digital Divide | 3DPrinterOS. (n.d.). Retrieved April 18, 2021, from https://www.3dprinteros.com/john-dogru-how-to-mend-the-3d-printing-digital-divide/

Legislation. (n.d.). The Repair Association. Retrieved May 1, 2021, from https://www.repair.org/legislation

Maguire, R. (2017, April 13). *Shaping the Future of CAD*. IndustryWeek. https://www.industryweek.com/cloud-computing/article/22012768/shaping-the-future-of-cad

Malkin, R. A. (2007). Barriers for medical devices for the developing world. *Expert Review of Medical Devices*, *4*(6), 759–763. https://doi.org/10.1586/17434440.4.6.759

Marks, I. H., Thomas, H., Bakhet, M., & Fitzgerald, E. (2019). Medical equipment donation in low-resource settings: A review of the literature and guidelines for surgery and anaesthesia in low-income and middle-income countries. *BMJ Global Health*, *4*(5), e001785. https://doi.org/10.1136/bmjgh-2019-001785

Medical Equipment Graveyards: Three Causes of the Problem – And How Blockchain Can Help. (2019, March 26). NextBillion. https://nextbillion.net/medical-equipment-problem-blockchain/

outsourcing-pharma.com. (n.d.). *Next step in personalized medicine enabled by 3D printing*. Outsourcing-Pharma.Com. Retrieved November 2, 2020, from https://www.outsourcing-pharma.com/Article/2019/02/01/Personalized-medicine-enabled-by-3D-printing

Pearce, J. M., Pearce, J. M., & Pearce, J. M. (2020, April 27). *The 3D printing revolution is finally here*. Fast Company. https://www.fastcompany.com/90497468/the-3d-printing-revolution-is-finally-here

Savvides, L. (2019). *3D Printing: Politics, Material Hacking And Grassroots* [Thesis, University of Leicester]. /articles/thesis/3D_Printing_Politics_Material_Hacking_And_Grassroots/10211555/1

The Evolution of 3D Printing: Past, Present and Future. (2016, August 1). 3D Printing Industry. https://3dprintingindustry.com/news/evolution-3d-printing-past-present-future-90605/

Why it's so hard for a hospital in Tanzania to fix broken incubators. (2021, March 10). Rest of World. https://restofworld.org/2021/why-its-so-hard-for-a-hospital-in-tanzania-to-fix-broken-baby-incubators/