THE COMPETITIVE ADVANTAGE OF USING 3D-PRINTING IN LOW-RESOURCE HEALTHCARE SETTINGS

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Abstract

Fabrication of medical devices using 3D-printing (3DP) technology can reduce the lack of adequate supply of medical devices in low-resource hospitals. Similar to Information and Communication Technologies (ICTs), 3DP facilities can be established with a low start-up cost and they can leverage the support of existent open-source community. This paper highlights how ICTs implementations have been successful in addressing information management issues in low-resource healthcare setting and from there argues how 3DP can offer similar advantages by providing low-cost medical devices. Three main case studies of 3DP applications are explained in-depth.

Keywords: Design for X (DfX), Biomedical design, Open Source Design, Complexity, Technology

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Please cite this paper as:
Surnames, Initials: *Title of paper*. In: Proceedings of the 20th International Conference on Engineering Design (ICED15), Vol. nn: Title of Volume, Milan, Italy, 27.-30.07.2015

1 INTRODUCTION

The existing world-wide manufacturing and supply chain systems need a significant amount of infrastructure, which can only be established and maintained by powerful economies such as the ones in North America and Europe. People in low-resource economies do not have the same access to the products that they need, because often they do not have the purchasing power to attract products that are made for the developed world. Product fabrication using 3D-printing (3DP) technology has the potential to allow individuals from variety of socio-economic circumstances to innovate and develop products to suit their personal needs; a process termed the "democratization of manufacturing" (Anderson 2014). The start-up costs and infrastructure needed to set-up a 3DP facility are significantly less than the costs necessary for mass-manufacturing industries (Birtchnell and Hoyle 2014). The lower cost barrier for setting up a 3DP facility mobilizes individuals and organizations in developing economies to make the products that they need, which in turn fosters innovation and growth within the economy (Anderson 2014). Hence, 3DP is appealing for international development practitioners who believe a bottom-up approach to development is essential for communities to exit the cycle of poverty (Birtchnell and Hoyle 2014). While it is clear that 3DP will not fully address the supply-chain problem, there are specific and critical product areas in which 3DP could make a significant contribution within certain communities, notably medical technologies. The supply-chain of medical devices in developing countries is particularly complex because of the lack of regulation of suppliers and donators. According to the World Health Organization (WHO), 50-80% of medical devices donated to low-resource hospitals are inoperable, which means that healthcare providers often do not have the necessary equipment to deliver essential care (Perry 2011 and Mullaly 2013). A possible solution to address this problem is to use 3DP technology to make medical devices on demand. Development of medical devices was one of the early application areas for 3DP technology. Benefits of 3DP, namely low-cost for design complexity, capability to customize and quick turn-around times, are highly valued in the medical device development field (Syam 2011). Currently, many biomedical device companies use 3DP to develop prototypes for testing their concepts. 3DP is also being used to manufacture products that are on the market and will be purchased by end-users (Syam 2011). The applications have ranged from low-cost prosthetics to scaffolds for tissue engineering and organ development (Syam 2011).

Application of 3DP technology to manufacture medical devices parallels how information and communication technologies (ICT) have been used to improve information and data management in healthcare systems. The Compendium of Innovative Health Technologies for Low-Resource Settings outlines a large number of innovative applications of ICT, also referred to as e- Health, m- Health or telemedicine (WHO 2014). All of these ICT-related solutions aim to address specific problems within the healthcare environment such that necessary medical information is accessible to users when they need it. Similarly, 3DP technology can fabricate certain medical devices when they are needed. While ICT can address lack of access to medical information, 3DP has the potential to address lack of access to medical devices. Both of these technologies offer two competitive advantages, namely low-cost infrastructure and open-source community support, for addressing different challenges in low-resource hospitals. With that in mind, the paper offers a comprehensive overview of the existing applications of 3DP for fabricating medical device and identifies the areas that have high potential for success based on the lessons learned from applications of information and communication technologies (ICT) within the healthcare sector in low-resource environments

2 LESSONS LEARNED FROM ICT APPLICATIONS IN HEALTHCARE

ICTs have an extensive range of applications within low-resource healthcare environments, such as electronic medical records (EMR), laboratory information management systems, patient registration, monitoring and evaluation, clinical decision support systems, and patient reminder systems (Blaya 2010). A case study of an EMR system in Kenyan hospital will be used to demonstrate the competitive advantages of using ICTs as a viable solution (Williams 2008). Similar advantages can also be leveraged for 3DP application for medical device production.

2.1 Case Study: Electronic Medical Record System at Kenyan Healthcare Center

In 2001, the Indiana University of School of Medicine and the Moi University School of Medicine collaborated to develop the Mosoriot Medical Record System (MMRS) for the Mosoriot Rural Health Center (MRHC) near Eldoret in Kenya. Prior to implementation of the MMRS, the healthcare practitioners recorded the patient data in logbooks and in each patient's booklet. The new MMRS included a paper encounter form, which was used in tandem with an MS-Access database (Rotich 2003). In the new system, the clinician would write the necessary prescription on the encounter form and then the patient would take it to a receptionist who would enter the information in the database. The patient would then take the paper encounter form with themselves. The system was powered by an uninterruptible power supply (UPS) and had several backup mechanisms including a solar battery, a gasoline-powered generator, and a paper backup system (Rotich 2003). After few design iterations in collaboration with MRHC, the system was implemented. Rotich and el. conducted formal time-motion studies to assess the change in workflow and found that the patient visits were 22% shorter. The patients spent 58% less time with the care provider and 38% less time waiting (Rotich, 2003). The MMRS model managed to successfully bring low-cost ICTs into a low-resource healthcare setting. The main competitive advantages of ICT as applied within the context of MMRS are the following:

- Low infrastructure cost: the cost of ICT has decreased significantly due to technological development and hence the system was affordable for the various stakeholders.
- Low power requirements: the MMRS energy requirements were such that back-up solutions such as solar battery could be sufficient if needed.
- Availability of low-cost software: the designers used low-cost and readily available software for development of MMRS.

The three main advantages of ICT application at MRHC were fully effective because the designers of the project provided the necessary ecosystem for successful implementation of MMRS.

2.2 Necessary Ecosystem for Successful Implementation of ICTs

Sustainable and effective implementation of ICTs within low-resource healthcare environment also depends on factors that are independent of advantages of the technology. The MMRS was successful because the designers collaborated closely with the healthcare workers for design of the system (Rotich 2003). For example, the designers initially thought that one person can get the encounter form and enter them; however, after initial implementation it was clear that a second computer was needed as this was not a task for a single personal. In the design process, the MRHC staff developed a sense of ownership for the system and also learned how to use the technology effectively (Rotich 2003). In addition, the project was completely supported by a strong collaboration between the Indiana University of School of Medicine and the Moi University School of medicine. The existence of these collaborations made it easier to acquire funding and support for this project. Use of human-centred design principles, existence of strong collaborations, and provision of training for the locals are the key elements of the ecosystem for successful implementation of MMRS. Importance of these elements is also echoed in other literature about applications of ICTs within low-resource healthcare environment (Blaya 2010, Qureshi 2013).

2.3 Parallels between ICTs and 3DP Technology

The MMRS case study highlighted the three main competitive advantages of ICT technology: low infrastructure cost, low power requirements and low-cost/open-source software. 3DP offers similar competitive advantage for development of medical devices in low-resource environments. Figure 1 highlights the parallels between the main competitive advantages of ICTs and 3DP when applied within a low-resource healthcare setting. ICT allows people to organize and communicate information effectively and efficiently. Similarly 3DP makes it easier to produce complex devices on-demand. Due to recent advancements, 3DP technology cost has decreased significantly and desktop 3D-printers can be purchased in the consumer market for less than $5000. This start-up cost is significantly less than setting up any type of manufacturing plant that can produce objects as complex in nature. In addition, the power requirement of a desktop 3D-printer is such that a solar panel can be used to power it (King 2014). Finally, 3DP technology has a strong open-source community which collaborate to create various 3D-printable designs, improve 3D-printer designs and also make 3DP accessible to general public. Setting up a 3D-printing facility at low-resource hospital is possible because of the low start-up cost and possibility of alternative sources of power. A 3DP facility can also be supported with strong online community. Therefore, the competitive advantages of 3DP can address the issue of lack of adequate medical devices in low-resource hospitals similar to how ICT can address the challenges with information management.

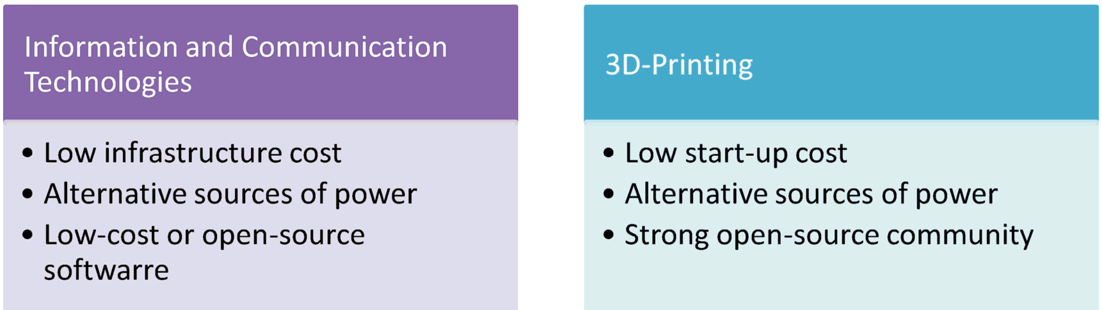

Figure 1. Parallels between ICT and 3DP

As indicated earlier, the applications of ICTs can only be successful and sustainable if the community is engaged in the process of the technology adoption. Similar parameters hold true for use of 3DP in low-resource environments. The lessons learned from ICT applications in global health is echoed by Birtchnell and Hoyle who highlight four key interventions to ensure that the advantages of the 3DP can be leveraged appropriately in developing countries (2014). These include the following:

- Open material – material is provided at low cost by taking advantage of recycling
- Open printing resources – an online platform exists that connects stakeholders
- Building local capacity and capability –training is provided to local users and entrepreneurs
- Trials of new models of distribution – manufacturers are encouraged to distribute 3D models of their parts

In conclusion, applications of ICTs have been successful in solving problems with information management in low-resource healthcare settings. 3DP has a similar set of advantages that could be leveraged for addressing challenges with lack of adequate medical devices. The following sections provide an overview of the applications of 3DP for fabricating medical devices and highlight three case studies where 3DP can be most useful considering the lessons learned from applications of ICTs within low-resource environments.

3 OVERVIEW OF APPLICATIONS OF 3DP WITHIN MEDICINE

The uses of 3DP within the field of medicine have ranged from prototyping conceptual models to making the end -user products. The following sections highlight the various applications currently being served by 3DP that could have particular value in low-resources settings.

3.1 Reconstructive surgery

Reconstructive surgeries are often complex in nature, and each patient presents with a unique set of conditions. 3DP has been used to fabricate appropriate reconstruction implants for orthopaedics, neurosurgery, oral and maxillofacial surgery, plastic and reconstructive surgery and periodontics (Honiball 2010). The general procedure of manufacturing a reconstruction prosthesis is depicted in the following figure:

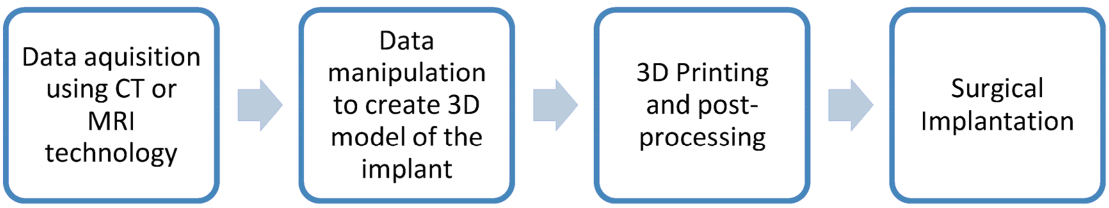

Figure 2. Procedure for Reconstruction Surgery Implant Fabrication

An example of this technique is the fabrication of a composite hemi-knee joint (Syam 2011). They used a CT scanner to take a image of an anatomical model and two image processing programs to develop a 3D model of the hemi-knee joint (Syam 2011). The joint was printed in Ti6Al4V using a stereolithography (SLA) technique (Syam 2011). The following figure is the image of the implant:

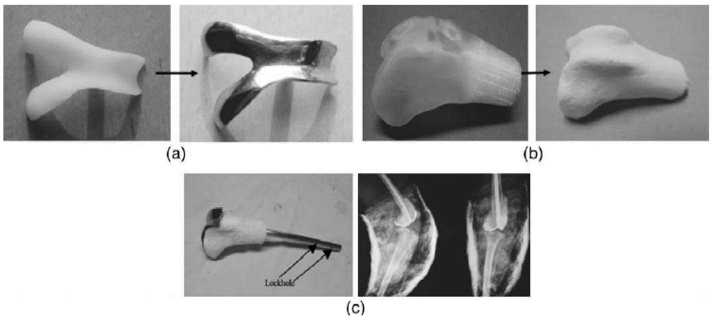

Figure 3. An example of printed knee implant (Syam 2011)

Currently, 3DP of reconstructive implants is not standard practice for surgeons even in developed countries; however, surgeons have used 3DPs to create patient-specific implants for research purposes. Several studies have shown that 3DP has the potential to offer significant cost saving as it shortens the operating room time for patients (Honiball 2010). However, there has been no accurate estimate for this cost saving. With more use of this technology and further development, the case for making 3DP a standard practice within well-resourced settings can be made (Honiball 2010).

3.2 Assistive devices

Another area in which personalized medical devices are often needed is assistive technology. Assistive devices are a natural application area for 3DP as it allows quick manufacturing of highly customized devices at low costs. Currently 3DP has been used to make hearing aids, prosthetic limbs, exoskeletons and wheelchair components.

Hearing aid shells are one of the most developed application areas of 3DP. Standard practice involves 10 steps, starting with a cast from an impression of the ear, and eventually using that cast to make the hearing shell (Cortez 2008). By using the combination of 3D scanning and 3D printing, the number of steps for making a hearing aid shell decreases from 10 to 4 steps. The following depicts the process that audiologists often use to develop hearing aid shells using 3DP:

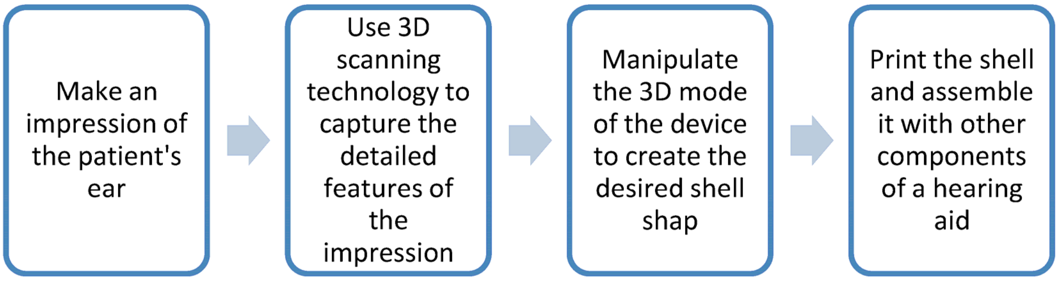

Figure 4. Procedure for Fabrication of Hearing Aid Shell

Audiologists and the patients who receive 3D-printed hearing aids have reported that they are satisfied with the ergonomics of the devices. However, it is important to note that the cost of the 3D-scanning equipment is significant, and it has limited the adoption rate of this technique for fabricating hearing aids.

Upper and lower limb prosthetics were one of the early application areas for 3DP, notably prosthetic hands. 3DP is used to make low-cost prosthetic limbs, and currently designs of these limbs are available on websites such as Thingiverse.com. The Robohand project (Robohand 2014) was one of the first prosthetic hand designs that was designed specifically for 3DP. This project addresses a significant need as existing prosthetic hands cost up to $20,000, a cost that is not affordable for many amputees and families, especially when their children will outgrow their prosthetics multiple times through their development. In addition, 3D-printing and 3D-scanning technologies are used to develop prosthetic limb sockets. Researchers at the Critical Making Lab at University of Toronto have developed a 3D-scanning and printing technology to develop low-cost residual limb sockets at the Kampala-based CoRSU (Comprehensive Rehabilitation Services in Uganda) hospital in Uganda.

Figure 5. 3D-Printed Hand (Left) and Exoskeleton (Right)

Exoskeletons are expensive and highly complex systems that are not easily accessible to people who need them. There are two reported cases of use of 3DP for fabricating exoskeletons. The first case was for a girl named Emma, who had a severe congenital musculoskeletal condition. Researchers from the Alfred I. duPont Hospital for Children in Philadelphia designed and developed a functional, custom, low-cost exoskeleton for her (Kaelin 2013). Another case was for a paralyzed skier who had 3D-printed custom parts created for her exoskeleton (Sorokanich 2014). It is critical that fitting components of exoskeletons are customized to the person because pressure points can cause severe injury, which can quickly lead to infections (Sorokanich 2014). Both of these cases showcase how 3DP can be used to lower the cost of exoskeletons and improve the quality of life for exoskeleton users.

3.3 Basic surgical instruments

3D printers have been used to manufacture basic surgical and medical instruments. In some low-resource regions, surgeons have limited access to even very common devices needed in general and orthopaedic interventions. Several studies have investigated the feasibility of printing basic surgical tools. A preliminary quality and economic analysis study of the 3DP of a surgical retractor was conducted at the University of Arizona and the researchers concluded that it was feasible to 3D-print surgical retractors in low-resource environment (Rankin 2014). Kondor et al. also printed a full surgical kit using 3DP and showed the feasibility of this application (Kondor 2013).

3.4 Surgical training models

3D printed training models of uncommon anatomical structures allow physicians to practice surgeries of rare cases in simulation, so that they can be more prepared during the actual surgery. The models are generally generated based on the MRI and CT scans of the patient (Giannatsis 2007, Rengier 2010, Syam 2011, Klein 2013). Currently, 3DP training models are being used in facilities where there is a close collaboration between biomedical engineering and medical faculties; however, it is still not an established practice for complex surgeries. The medical professionals who have used surgical training models prior to complicated surgeries have expressed that it helped them improve the quality of surgery and save time while the patient is under anaesthesia (Syam 2011, Negi 2014).

3.5 Biomedical device development

Biomedical device companies and academic institutions use 3DP to develop prototypes for various purposes. Recently, universities in developing countries have also begun using 3D-printers within their curricula. These 3DP facilities have stimulated innovation, fostered creativity and improved the educational experience (Malone 2007, Huang 2012, Fidan 2012, Krassenstein 2014).

As shown, the applications of 3DP are diverse in scope. The next sections will elaborate on some applications that have the potential to provide sustainable and effective solutions for several key problem areas in low-resource healthcare settings.

Applications of 3DP technology within medicine are extensive. The following section outlines three case studies where the application of 3DP has high potential of successfully addressing part of the access to medical devices problem in low-resource regions.

4 THREE CASE STUDIES: HIGH POTENTIAL APPLICATIONS OF 3DP FOR LOW-RESOURCE ENVIRONEMENTS

The following case studies highlight three applications of 3DP that can successfully address specific problems within low-resource healthcare systems. These projects were specifically chosen because they leverage the competitive advantages that 3DP has: low cost infrastructure and open-source community support. In addition, these projects were embedded within an ecosystem that sustainably supports it.

4.1 Low-cost Prosthetic Limbs: E-Nable Project

The E-Nable community was started by Jon Schull in 2013. He was inspired by the Robohand project, an open-source 3D-printed prosthetic hand that was built by a 3DP enthusiast in the U.S. for an amputee in South Africa (Robohand 2014). E-Nable is an online platform that brings together the users, families, designers, researchers, policymakers and 3DP enthusiasts to foster further innovation and development in the realm of low-cost 3D-printed prosthetic hands. In addition, the E-Nable group connects people who need a hand with people who have a 3D printer to manufacture the parts. The following figure illustrates how the E-Nable platform connects various stakeholders (E-Nable 2014).

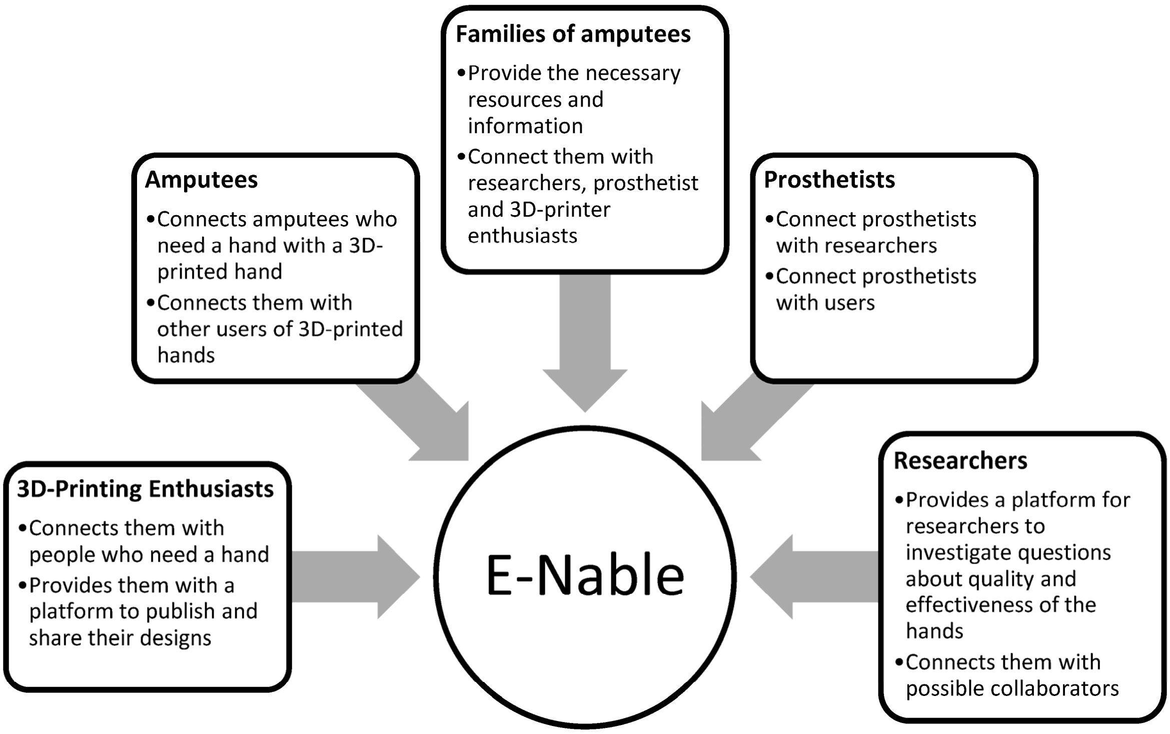

Figure 6. Illustration of the E-Nable Collaborative Platform

The group also encourages development of new prosthetic hand designs. Currently, their website (E-Nable 2014) features nine different designs, each with its own unique features. For example, the Raptor hand, is designed for ease of assembly and printing. All of the designs can be printed using a desktop-size fused deposition modelling 3D-printer. The cost of each prosthetic hand ranges from $50 to $350, which is significantly less expensive than existing commercial hand prostheses, which can cost up to $10,000.

Currently, there are no published studies on the quality of these prosthetic hands. However, researchers from Creighton University, who have developed the Cyborg design, are studying the mechanical integrity and muscle morphology of their contribution. The Cyborg hand is a mechanical low-cost prosthetic hand. From their initial studies, the hand has had a positive impact on the quality of life of the children who have received it. The E-Nable project has high potential for growth because the platform fosters a strong collaborative network between various stakeholders. In addition, the platform leverages on two competitive advantages of 3DP by establishing a strong open-source community and developing prosthetic hands that can be printed using desktop printers.

4.2 Basic Medical Surgical and Medical Devices: Low-cost Surgical Retractor

Currently hospitals at low-resource regions do not have access to basic surgical tools (WHO 2010, Mullally 2013). Therefore, when medical mission groups travel to low-resource hospitals, they take medical instruments that are donated by hospitals and companies in the western world. Fabrication of these basic instruments using 3DP can significantly reduce cost for the non-governmental organizations and also ensure that these low-resources settings have access to basic equipment when they need it.

To demonstrate the viability of this solution, Rankin et. al (2014) printed a surgical retractor using a MakerBot Replicator from Polylactic Acid (PLA). They concluded that the 3D-printed surgical retractors are comparable to the stainless steel surgical retractors. The PLA retractors can withstand an adequate amount of force and they were also tested to be sterile once printed. In addition, the cost of a PLA surgical retractor was shown to be one-tenth of the cost of a stainless steel retractor. Even though, the retractors have not been printed and used within a low-resource environment, from the preliminary investigation it can be concluded that this application could be valuable at low-resource hospitals because the cost of the retractors is significantly lower and the hospital can have the ability to provide basic equipment within a short time frame. The 3D-models of these basic instruments can be easily supported via an open-source platform.

4.3 Medical and Biomedical Engineering Education: Nairobi Fab Labs

In the developed world, 3DP facilities are available for students in medicine and engineering programs. Engineering students use these facilities to develop sophisticated prototypes for their design projects in a short amount of time, allowing them to develop more innovative and effective designs (Campbell 2007). 3D-printed medical models are used to train medical students (Syam 2011). Recently, some universities in developing countries such as University of Nairobi in Kenya have also established rapid prototyping facilities.

A Fab Lab was established at University of Nairobi in Kenya in 2009. Fab Lab is a component of the educational outreach program started by MIT's Center for Bits and Atoms. A Fab Lab is a rapid prototyping platform hosting a variety of digital technologies such as 3DP. Currently, there are 400 Fab Labs in 30 countries around the world (Fab Foundation 2013). Rapid prototyping platforms such as Fab Lab foster creativity and innovation (Malone 2007, Campbell 2011 and Anderson 2014). In the University of Nairobi Fab Lab, an engineering student developed a low-cost vein finder (Figure X) using a MakerBot 3D-printer to help physicians find veins in infants for administrating intravenous needles (Krassenstein 2014).

Facilities like the Fab Lab could also serve medical students. For instance, surgical residents can print different anatomical models, which they can use for improving their skills. The U.S. National Institutes of Health recently launched an open-source platform of 3D-printable bio-scientific models (Coakley 2014). This platform can be a great resource for healthcare professional at low-resource settings as it makes 3D-models of lab instruments and anatomical models (Figure X) accessible to them.

Figure 7. 3D-printed Vein Finder (left) and 3D Models from NIH (Right)

All of the three case studies showcase how the low start-up cost and open-source community can be leveraged to address issue of access to appropriate medical devices such as basic surgical tools or prosthetic hands. Also, the case studies showcase how competitive advantages that 3DP technology offers can spur innovation and economic growth.

5 DISCUSSION AND FUTURE WORK

Integrating 3DP facilities within low-resource healthcare settings is a complex problem. However, 3DP has the potential to address issues of lack of adequate medical devices, just like ICTs have addressed problems in the realm of information management within low-resource hospitals. ICTs and 3DP offer the same advantages for each of their problem spaces and if applied correctly they can offer sustainable solutions. Application of ICT showed the competitive advantages are low infrastructure cost and strong open-source support. The same competitive advantages apply to 3DP technologies. As discussed in this paper, preliminary development has leveraged these advantages and progress is being made in areas of low-cost prosthetics, basic surgical instruments and rapid prototyping facilities in educational settings.

There has still been a minimal research in how well a 3D-printer works within a low-resource environment and whether it would be possible to sustainably have such a technology present at a low-resource hospital in the long term. Long term field work based on one of the applications that were highlighted in the case studies could possibly be a direction for future research. In addition, future research could also focus on what type of medical or assistive technology is most suitable to be made from 3D-printers based on direct feedback from experienced clinicians. Finally, further research on how design of 3D-printers for low-resource environments is necessary. The road to solving the problem of access to appropriate medical devices is long; however, 3DP technology has inspired a range of promising solutions.

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ACKNOWLEDGMENTS

Funding from the UBC Biomedical Engineering Graduate Program “Engineers in Scrubs” (EiS) program and from Canada’s NSERC is gratefully acknowledged, as well as support from the Uganda Sustainable Trauma Orthopaedic Program (USTOP).