WIDE ANGLE

3D PRINTING AND PROSTHETICS: PROSPECTS AND CHALLENGES IN CONTEXTS WITH LIMITED RESOURCES

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Despite noticeable medical progress, the development of prosthetics[1] has not been deep enough to revolutionise the current system, creating increased and fairer access. Even though the life of amputees has certainly improved thanks to new materials and new scanning techniques, which allow them to become professional athletes as well as to hold a job in the artistic and technological field, these new technologies are still too expensive. Most of the time, a custom-made prosthesis requires an investment that is prohibitive not only for countries with insufficient resources, but also for those facing economic stagnation or recession. 3D printing is considered to be a real revolution in this sector, as new prospects allow a localised and distributed research system, more sustainable and open-source economic models, and a severe decrease in investments and maintenance. The implementation of this new technique is carefully followed by developing countries as well as in more developed regions that look for more accessible solutions at a lower cost. However, 3D printing needs to overcome some of the obstacles that still prevent it from becoming mainstream: high electrical consumption; ecological side-effects; and the continual technical support that is needed to make products more comfortable and healthier for the patient. These are some of the issues that need to be solved to transform the use of 3D printing in prosthetics as a solution of the future.

Keywords: Prosthetics, 3D printing, Medicine, Logistics, Disability, Resilience, Orthopaedics, Prosthesis, Innovation

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Origins and development of prosthetics

The first documented examples of prosthetics date back to around 1500 B.C. in Egypt.[2] Although the Egyptians prioritised psychological integrity over the physical functionality, a few prostheses resembling basic articular functions have been found on mummies in that period. For example, the so-called "Greville-Chester toe" was created in 600 B.C through the "Cartonnage" technique (papier-maché made of linen and soaked with animal glue, covered with painted plaster) and was also decorated with a false nail. This toe, which is considered to be one of the first working models of prosthesis, shows holes and signs indicating that it could have been attached to the foot, a sock or a sandal.[3]

Figure 1: The Greville Chester toe
Source: J L Finch, with the permission of the British Museum, London

The Greek and Roman antiquity was characterised by the invention of rehabilitation prosthetics, as there was a greater appreciation towards physical as well as psychological functionality.[4] While earlier designs had only a mechanical purpose (replacing a missing part of a limb), these models were able to imitate missing parts in their functionality, as well as in their appearance. They assumed more advanced roles as rehabilitating tools, aiming to benefit not only the capacity to move, but also the psychological and orthopaedic well being of the patient.

This is demonstrated by the remains of prostheses, dating back to 300 B.C., found by archaeologists in Capua, Italy (currently Santa Maria di Capua Vetere). In particular, a lower limb made of wood and bronze was discovered,[5] which was destroyed because of bombings on the Royal College of Surgeons in 1941 where it was stored. Its wooden nucleus was made empty to allow the insertion of a metal pivot or a foot, and it was most likely connected to the body through leather laces tied to a bronze belt. There are other proofs of metal hooks and wooden legs which are reported by Erodoto (424 B.C.) and Plinio il Vecchio (23-79 A.C.), but none of these reports have been proven.

Over the years there was steady and continuous improvement of prostheses, achieved through new medical knowledge and materials. But these were still quite simple until the Renaissance. In the late 16th century, Ambroise Paré, a barber and surgeon of the French Army (considered to be the founding father of the modern surgery and pre-cursor of the prosthetics design), launched modern amputation techniques (1529) and created innovative prosthesis models for the upper and lower limbs (1536). Most of his revolutionary observations and theories were developed in theatres of war and operating theatres rather than laboratories or offices. It is worthy of note that Paré defended the principle of humanity, often against the expectations of the time. According to Paré, the best solution was the one which could guarantee the best result for the patient's health, causing the least pain. The most widespread approach at that time imposed the acceptance of the standard medical principle, even if they proved to be ineffective or even damaging for the patient's health.

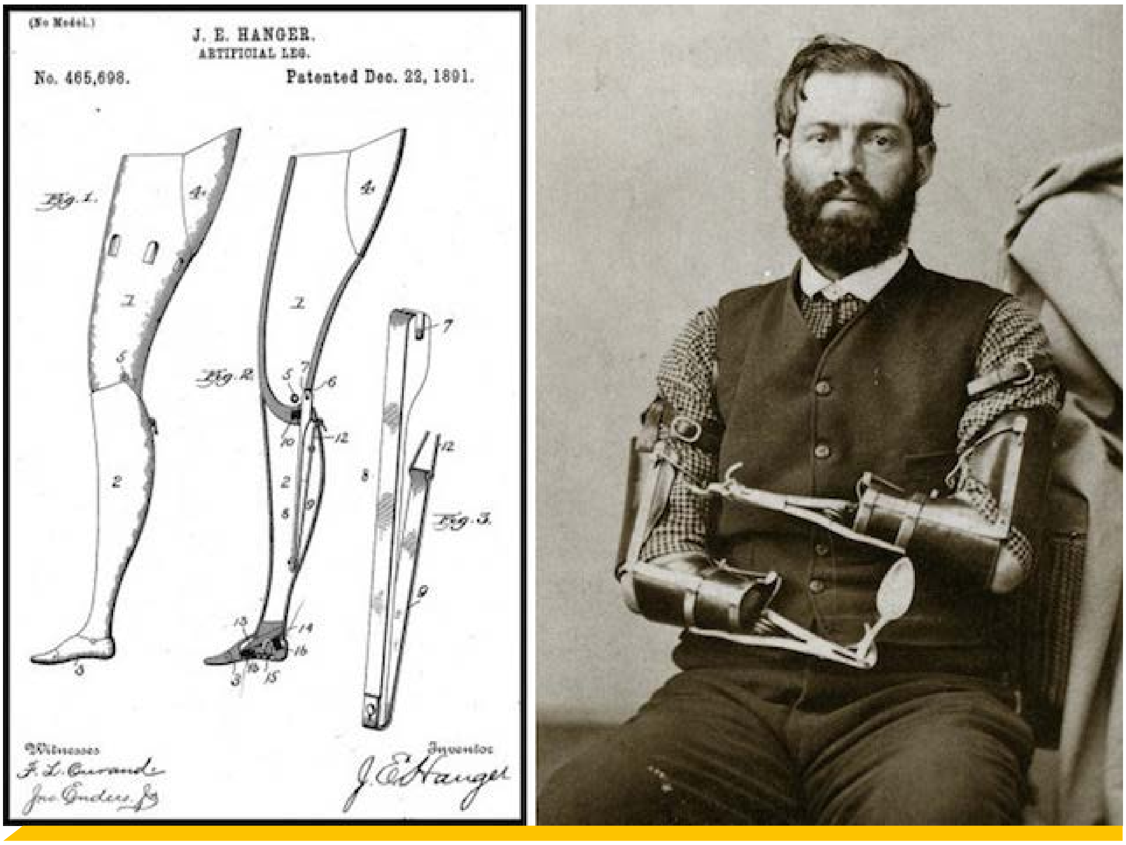

Figure 2: James Hanger's prosthetic sketchs (approx. 1891, on the left); On the right: Samuel Decker's mechanical arms.
Source: Collectors Weekly, http://www.collectorsweekly.com/articles/war-and-prosthetics/

The evolution of the artificial limb progressed together with amputation techniques until the American Civil War and the Second World War, when the high number of amputees provoked the creation of many public associations devoted to research on prostheses. In the U.S.A, James Hanger, one of the 60,000-70,000 amputees of the civil war, created the so-called "Hanger limb" made of staves in 1891.[6] The brand "Hanger" still produce orthopaedic and prosthetics items. It is very interesting to observe that one of the most important innovations in this sector came directly from a user who was looking for better and fairer solutions.

A system under examination

There have certainly been undeniable improvements in the quality and capability of modern prostheses, the result of new therapies, scanning processes, maintenance, personalisation and implantation. However, for communities living in poor areas, there are still concerns about access to orthotic and prosthetic material.

Even in regions that are not affected by conflicts, socioeconomic factors can strongly influence the amount of amputees. For example, a lack of adequate maternal health services can affect the development of the fetus, or result in complications during birthing. Poor nutritional support at birth can impact orthopedic development. Further, a lack of healthcare services can increase chances of infections or incidents leading to amputation.

Conflict also plays a decisive role in shaping how many people need access to prosthetic material. The introduction of new weaponry (rockets, grenades, missiles, cluster bombs, anti personnel mines, and improvised explosives) have extended the risks of mutilation to civilians. Consequently, while vascular diseases are the main cause for amputation in the U.S.A., 80-85% of amputees in countries such as Cambodia, Afghanistan, and Iran are the results of landmine explosions. Specifically, antipersonnel mines are responsible for 26,000 amputations per year and for nearly 300,000 amputees worldwide until 2006.[7] Furthermore, amputations are also triggered by industry or environmental accidents, terrorist attacks, diabetics, gangrene and infections.

The international community has unsuccessfully pursued the development of national sanitary systems related to the traditional orthopaedics services, which are often underestimated compared to other sectors such as maternity, paediatrics, surgery or first aid. This phenomenon is observable not only in developing countries but also in those belonging to the G8 group, where there is a little governmental participation in medical coverage, such as in the U.S.A. It is of no coincidence that the first 3D printed prostheses have been created by experts for their fellow citizens in the U.S.A., South Africa and Australia.[8] Moreover, the "distance" model, in which prostheses are developed with the newest technologies and lower prices by non-profit organisations and sent to users without the mediation of the local sanitary system, turned out to be ineffective. One of the most influential experts in this field, Dr. Albert Chi, stated that the use of certified technologies in laboratories is a good solution to offer an affordable prosthesis to American citizens who cannot afford to pay 30,000-50,000 USD.[9] Even in countries where the average price of a prosthesis ranges from 125 to 1,875 USD[10], most families cannot afford the maintenance and the consecutive therapies, since their yearly salary is about $300[11].

It is undoubtedly necessary to adapt development projects to our times for many reasons. Firstly, there is a decrease of many humanitarian budgets. Secondly, there is a lack of awareness of the impact of disabilities on local socioeconomic systems. According to research conducted in Afghanistan in 2001,[12] the economic damage deriving from fatal mine accidents is about 12,000 USD per person while for a non-fatal one the damage is 9,000 USD. Calculating one victim a year during 15 years, there would be a net economic loss of 69,000 USD in terms of production and welfare. This number would be obviously higher in a country with a stronger economy, but it still represents a serious problem for the local standards. This goes to show that amputees aren't just a moral and humanitarian problem. A whole economy is crippled when a relevant part of its population is in a state of handicap.

The high number of victims, caused by mines and explosive remains, is one of the most serious obstacles to the development of countries with a low income or in crisis. What is worse, this has a devastating effect on the economic stability of many families and communities. Very often, landmine victims were previously active contributor to their family's budget and the limited mobility of a member results in sudden dire economical hardships. Additionally, the structures that offer medical or prosthetic services are not accessible to everybody. Research has suggested that most of amputees in these regions receive a prosthesis only one year after their accident. During this time the potential user is forced to adopt alternative methods, which are often incompatible with the prosthesis and increase the risks for a rejection.[13] Furthermore, it is not easy for victims to receive psychological support, due to a lack of specified services, combined with increased likelihood of stigmatisation and discrimination because of their disability.

3D printing

3D printing consists of the creation of a three-dimensional objects. Known as additive manufacturing, a 3D printer deposits a binder material layer by layer from a digital model. The materials used for 3D printing are various, but the most common are natural, synthetic and plastic fibres, metal, cement and glass. 3D bioprinting uses a similar process but its aim is to create cell patterns preserving their functionality to create tissues and organs.[14] In the future 3D bio-printing will radically change the way we perceive prostheses, but currently it is still under development and is restricted to the creation of simple and small organs.[15] Consequently, this research pays more attention to 3D printing and on the changes provoked by its implementation - not only in more developed countries, but also those with fewer resources.

The first 3D printer was invented by Charles Hull in 1984. Hull, who worked for the 3D System Corporation, was a pioneer in the solid imaging process, known as stereolithography (the acronym STL is still used for the stereolithographic files for 3D printing) and his patent allowed him to create solid objects from the superimposition of layers of resin, which is sensitive to ultraviolet light. He is also responsible for the invention of the rapid prototyping, which is an alternative to the expensive traditional manufacturing processes that employ numerical control machines and a specific equipment for the object that needs to be produced.[16] Despite these theorical innovation, it is thought that the first solid object printed from a digital model was created by Hideo Kodama at the Nayoga Municipal Industrial Research Institute in Japan.

3D printing was initially limited to the research and experimentation field, due to the large expenses required to build and maintain equipment. Today however, printing is increasingly available for the general public thanks to the spread of new portable and simple models, characterised by open-source designs (made to be easier to reproduce with no need to buy specific patents or production rights). Many enthusiasts have supported projects based on free software and hardware that allowed the creation of open-source printers, which are covered by liberal patents such as GNU Public Licence, whose aim is to keep these products free and accessible to everyone in the future. Therefore, the 3D printer market has been enriched by the presence of different and often cheaper models, including those that are customisable, or can be bought as assembled items, according to creativity or need. Some of these printers (RepRap and Ultimaker) are self-replicating, which means that their main components can be infinitely 3D printed.

3D prosthetics

Both medicine and prosthetics have much to gain from 3D printing. However, the success that 3D printing has among individuals (rather than institutions) reflects an intense change of traditional healthcare sectors.

Due to the introduction of these new techniques and a collective approach to the creation of self-produced prosthesis, costs have been reduced and 3D printing is proving to be an efficient solution to substitute old or faulty prostheses as well as creating new ones for growing children. This approach is thought to have been successful because of its wider scope, taking into account the regular and numerous prostheses that a disabled person needs to use and change between during their entire life. For example, an adult would typically need 15-20 prostheses over a lifetime, whereas a 10-year-old child would need 25 artificial limbs. The rates in which prostheses need changing also varies according to growth. A child, from 4 to 16 years old, grows up 5-7 cm per year consequently, his/her prostheses should be renewed every 6-12 months as opposed to 3-5 years for an adult.[17]

A modern prosthesis is quite complex, typically consisting of three basic components: the socket, serving as an interface between the limb and the prosthesis, the modular section, that has the same length of the amputated limb and can include an articulation, and eventually the artificial foot/hand. Repairing a damaged prosthetic limb may cost more than buying a new one. This may force the user to live with a malfunctioning prosthesis or to adopt an unconventional solution that could affect its calibration, causing collateral damage. 3D printing could be very useful, as it encourages the creation of singular parts at a lower price (though, only if all the plastic materials are available).

The use of 3D printing in crisis contexts or with limited resources

Quick implementation is the main advantage of 3D printing. It takes only one day to print an artificial limb in 3D, and the more information is available on the patient, the faster this process can be in reprinting or updating the prosthesis.[18] This is in contrast to standard prostheses: the creation of a standard prosthesis may range from few weeks to several months depending on the medical structure and its accessibility. In many areas, especially those with limited resources, patients can often only reach orthopaedic laboratories after a long journey and considerable expense, as most of them are in larger cities. Many patients adopt alternative solutions between the first medical examination and the prosthesis' delivering, that might increase the risk of the body rejecting the prosthesis. This increased is essential when considering that research suggests that the possibility of a successful adaptation to a prosthesis decreases after 6 months from the amputation.[19]

Some researchers have argued that 3D printing could be a degrading solution that may detract attention and investment from the improvement of more traditional prostheses. Nevertheless, researchers have demonstrated that a prosthetic foot created with a 3D printer, which costs 12 USD for the purchase of the materials, has the same, or even better, performance of a SACH model,[20] that is commonly used in the developing countries.[21] This research is based on an artificial limb made of polylactic acid (or polylactide, PLA) printed with the Makerbot Replicator 2 (the RepRap advanced version, which is not considered a professional machine). This experimentation showed that this technique permits rapid interations that allows basic tests based on the autoethnographic method and the possibility to produce and modify the artificial limb in loco and adjust it to different needs. Subsequently, orthopaedic technicians would be able to adapt the prosthesis to the patient's necessities even in a context with limited resources.

Figure 3: #2 prosthetic prototype printed at the Swinburne University of Technology, compatible to the SACH model and analysed to wear a shoe.
Source: 3DPrint.com, available at: https://3dprint.com/84190/3d-printed-foot-prosthetics/

The comfort and adaptability of a prosthesis to a patient are important to consider. According to one piece of research, nearly 14.3% of amputees abandon their prostheses because they are uncomfortable or hard to wear, and these characteristics exceed the benefits. Indeed, it is estimated that most amputees feel uncomfortable wearing a prosthetic limb. Therefore, users have a particular interest in a wide range of factors that can affect how prosthesis feels, such as weight, shape, design, temperature, moisture regulation[22] and the reduction of friction.[23]

Despite great interest in 3D printing in developed countries, there is increasing evidence to suggest that the same holds true globally. For instance, the organisation "E-Nable" was founded by researchers of the Rochester Institute of Technology on the social media platform Google+, gathering more than 7000 members from all over the world. It has led to the creation of 2000 prosthetic limbs that have been donated to people living in more than 45 different countries.[24] Furthermore, the social, community and private laboratories focused on digital production and 3D printing (ILabs and Makers Space) are relatively widespread in every continent.

Reflection and conclusion

There has certainly been great improvement in both the design and delivery of prostheses over the years, offering innovative and customised solutions to people living with disabilities. While 3D prosthetics has great potential, there remains great structural and environmental barriers that limit its accessibility and feasibility for the future.

Research illustrates that 74% of people wearing prostheses have some form of cutaneous inflammation or fracture due to the artificial limb.[25] Further, inadequate hygiene or excessive friction or pressure of the prosthetic limb on the skin can provoke bladders, cysts and ulcers.[26] As it has been previously claimed, 3D printing can produce more comfortable prostheses, but only if there is a thorough scan of the implant zone. This particular stage requires highly qualified staff but "there is a lack of orthopaedic technicians and not of prosthesis", as an expert stated.[27] In fact, the World Health Organisation (WHO) estimates that nearly 40,000 orthopaedic technicians are needed in those countries with a mid-low income.[28] Most of the time, advanced diagnostic instruments, which would be necessary to choose the right combination of materials, are not available and this may have increased the inconvenience during the use of the artificial limb.

There have been been attempts to address these issues. The recent development of portable scanners for example, requiring less active presence by technicians, don't represent a valid solution for countries that are facing crisis or do not have enough resources yet. The distribution of an integrated kit for a project supported by the Comprehensive Rehabilitation Services (CoRSU), the University of Toronto and the NGO Blind Mission in Uganda, might have significant impact in a country that counts, especially in this country since it has only 12 orthopaedic technicians per 250,000 disabled child. The kit costs about 12,000 USD and it includes a laptop, a 3D scanner and a 3D printer, and it provides a basic orthopedic laboratory.[29]

Some experts argue that 3D printing isn't sustainable in rural areas characterised by a lack of technology and hardware. Open-source 3D printers have made the design phase more accessible, but it is still difficult to find materials such as pivots, screws and laces. The NGO Field Ready had to face this problem when it reached Haiti in 2010 after the tragic earthquake: in order to bypass the lack of an appropriate supply chain, it collaborated with another NGO Bold Machines to create a prosthesis that doesn't need screws, bolts or mounting tools.[30] Following its success, the organisations addressed the enthusiastic global prosthesis community, adopting an open license and sharing the original design of Jose Alves da Silva. Thanks to the support of Humanitarian Innovation Fund, Field Ready had the chance to cooperate with local groups, such as Haiti Communitere, Ti Kay Haiti, e MamaBaby Haiti whose aim is to transform the prosthesis in a disposable but recyclable item.

Figure 4: Prosthetic model entirely 3D printed.
Source: Bold Machines

There are also important issues concerning the environmental impact from a wider use of 3D printers. Compared to the traditional manufacturing process, 3D printing has many advantages: the artificial limb lasts longer because it is personalised to the intended user; it is more efficient; it reduces the level of equipment involved; and it can be used to produce prostheses only when it is necessary.[31] The NGO Field Ready is focused on 3D printing in crisis areas and has been experimenting with fibres that can be broken into small pieces, melted and reused for further printings, following the circular economy principles to make these materials more accessible.[32] Currently, this is the standard industrial method for some organisations, such as Perpetual Plastic Project, that recently started to recycle polyethylene terephthalate materials (PET) on a large scale. However, the University of Loughborough in England[33] produced research showing that 3D printers, which employ heat or laser to melt the fibres consume 50 or 100 times more electricity than the traditional injection moulding ones uses to create the same object. High consumption is particularly important to consider in those regions where electricity is rationed, expensive or irregular.

Similarly, traditional injection moulding printing uses the totality of the material needed for the process, whereas 3D printers, employing pulverised or liquified polymers, produce considerable plastic waste. Most of the time this refuse can't be recycled so it contributes to environmental pollution. Whilst in time new biodegradable plastic materials might substitute the older ones, this will most likely be a long process.

In conclusion, the use and development of prostheses still has many problems to solve before becoming a common option in areas with limited resources, where communities are dispersed or facing a crisis. It will take time and investment to find fair, efficient, sustainable and scalable solutions. However, 3D printing is certainly a promising option, offering portability, sustainability, and customisation to the user. The most promising option as it would be more portable, sustainable, impactful and In spite of all challenges still waiting to be solved, 3D printing remains a promising option offering portability, economic sustainability, and user customization. The collective innovative process that characterized the development of humanitarian 3D printing is a fascinating phenomenon by itself, raising hope that future solutions to humanitarian problems can result from crowdsourced and global efforts.

Endnotes

[1] The terms prosthetics (only when used in plural form) is the evaluation, fabrication, and custom fitting of artificial limbs, known as "prostheses." In the paper we mostly refer to this specific meaning, when not talking specifically about limbs or prostheses.

[2] A French newspaper reported of the finding of a woman's skeleton in Kazakhstan, dating back to 2300 B.C., who owned a n artificial foot, extracted from an animal's limb. We don't have this document to verify this news. (Mattogno F., Chiapparelli L., Pellegrini R., Borzi M. (2001). Manuale dispositivi ortopedici e classificazione ISO. ITOP - Officine Ortopediche. http://95.110.164.182/ecommerce/img/Protesi_a.pdf, last access: 5/30/2016);

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[9] Id.

[10] Strait (2006).

[11] Id.

[12] William A. Byrd and Bjorn Gildestad, The Socio-economic Impact of Mine Action in Afghanistan (SIMAA), World Bank/UNDP, 2001.

[13] Strait (2006).

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[16] Recently the team composed of researchers of the Università di Milano-Bicocca and the Imperial College di Londra developed a printing system, based on silicon and polymers, that can theoretically reproduce and substitute bones and cartilages, thanks to its flexible and auto-regenerating nature(http://www.lastampa.it/2016/05/13/scienza/benessere/creato-con-una-stampante-d-losso-artificiale-che-si-rigenera-4SKyQPCMQJeNZcnDlbu1CO/pagina.html, last access: 17 may 2016);

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[20] Strait (2006).

[21] For further regional models, please consult Strait (2006).

[22] Yap J. e Renda G. (2015).

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