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Impresión 3D como alternativa de Prótesis Humanas. Artículo de Revisión

3D Printing as an Alternative for Human Prostheses. Review Article

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RESUMEN

La tecnología de impresión 3D ha encontrado aplicaciones innovadoras en el campo de la medicina, especialmente en el desarrollo de prótesis humanas por su adaptabilidad a las necesidades de los pacientes. Muchas personas de todo el mundo necesitan prótesis y sólo el 0,5% puede conseguir una. Las prótesis fabricadas en una impresora 3D pueden costar hasta un 50% menos que una prótesis normal. Las prótesis de impresión 3D surgieron como una alternativa para las personas que habían sufrido una amputación o una enfermedad. A pesar de todas las grandes ventajas de la fabricación aditiva, existen limitaciones en la producción de prótesis mediante impresión 3D: el tamaño del objeto impreso depende del tamaño de la impresora y, además, la gama de materiales potenciales a utilizar es bastante limitada. Este trabajo pretende revisar los artículos científicos que documentan el uso de la impresión 3D como alternativa para el desarrollo de prótesis de bajo costo. Este artículo se centra en las prótesis de manos, pies, orejas, ojos y mandíbulas, y describe los materiales (alcohol polivinílico y ácido poli láctico) y las técnicas (chorro de aglutinante, deposición de energía dirigida, extrusión, fusión de lecho de polvo y laminación de láminas) que se suelen emplear para su fabricación. Los polímeros utilizados en este tipo de prótesis impresas pueden ser sustituidos rápidamente y a menor costo, y son adaptables a las necesidades del paciente. Los niños son los más beneficiados por las prótesis de manos y brazos impresas en 3D, ya que con frecuencia necesitan sustituir sus prótesis a medida que crecen. Aunque el tiempo de fabricación de las prótesis impresas en 3D es inferior al del proceso habitual, la calidad del material y las técnicas de fabricación específicas garantizan una prótesis de alta calidad.

Palabras clave: tecnología de impresión 3D, prótesis de manos, prótesis de ojos, manufactura aditiva, diseño asistido por computadora.

Abstract

3D printing technology has found innovative applications in the medical field, especially in the human prosthesis development because of its adaptability to the patients´ needs. A lot of people around the world need prosthesis and only 0.5 % is able to get one. Prostheses made in a 3D printer can cost up to 50% less than a normal prosthesis. The 3D printing prosthesis emerged as an alternative for people that had suffered an amputation or a disease. Despite all the great advantages of the additive manufacturing, there are limitations in the prostheses production using 3D printing: the size of the printed object depends on the size of the printer and, additionally, the range of potential materials to be used is quite limited. This work aims to review scientific articles, that document the use of 3D printing as an alternative for the development of low-cost prostheses. This article focused on prosthetic of hands, feet, ears, eyes, and jaws, it also describes the materials (polyvinyl alcohol and poly lactic acid) and techniques (binder jetting, directed energy deposition, extrusion, powder bed fusion, and sheet lamination) that are typically employed for its fabrication. The polymers used in those kinds of printed prostheses could be replaced quickly and at a lower cost, and they are adaptable to the patient needs. The kids are the most benefited by 3D printed hands and arms prostheses because they frequently need to replace their prostheses as they grow. Although the fabrication time of prosthetics 3D printing is lower than the regular process, the quality of the material and the specific manufacturing techniques, guarantee a high-quality prosthesis.

Keywords: tridimensional technology printing, hands prosthetics, ocular prosthetics, additive manufacturing, computer-aided design.

INTRODUCTION

Prostheses are artificial objects that replace a part of the human body, which have different focuses according to the people's specific requirements of individuals (Gómez, 2019).

0.5% of the people worldwide need at least one type of prosthesis, which represents 35-40 million people, and only between 5 to 15% of the population of each country can get it. It is estimated that 90% of the people who need a prosthesis, will not have access to one, because they are not affordable or available (OMS, 2017)

In 2005, around 1.6 million people were living without a limb, 38% of them had a secondary amputation cause by dysvascular disease (diseases that in one way or another generate amputation). By 2050 it is expected that the population living without a limb will be more than double (3.6 million approximately) (Ziegler-Graham *et al.*, 2008).

Medical advances have been increasing thanks to technology. The 3D printing industry is contributing in different ways in the prosthesis field. One of the most remarkable examples are the specific shape, size, and color prostheses manufacturing. (Ventola, 2014).

3D printing started in 1983 when Charles Hull invented “Stereolithography”, which is a process of resin hardening that can join materials for the purpose of making an object from a digital model, putting a material layer on top of another one (Francolí & Díaz, 2014).

The 3D printing industry growth has been around 26% overall its history, as the number using 3D printers is increasing day to day because of the great variety of uses that these machines have (De Jong & De Bruijin, 2012).

Prostheses made in a 3D printer can cost up to 50% less than a normal prosthesis; that is an important factor especially for children because they often need to replace their prostheses as they grow (Ten Kate *et al*., 2017).

Orthopedic prostheses have been developed using 3D printing such as hands (Wu *et al.*, 2018), and mandibular (Xiao *et al.*, 2020), as well as aesthetic prostheses such as ears (Mohammed *et al.*, 2017), and facial prosthesis (Mohammed *et al.*, 2018).

A successful case was the application of additive manufacturing (3D printing) in human prostheses for an 8-year-old boy who lost his hand because of a trauma caused by a mincing machine that injured of his arm at the level his right wrist; the boy was able to satisfactory perform activities of daily living, such as writing, eating, and self-dressing (Xu *et al*., 2017).

The object gripping task with hand was improved using 3D printing working together with 3D scanning in clinical cases of amniotic band syndrome (prosthetic hand), which is common in each 1 per 1000 children (Tong *et al*., 2019).

3D printed pieces for prosthesis for shoulders that are sophisticated were made throughout computer-aided designs (CAD). The novel 3D printed titanium alloy shoulder prosthesis was able to make the patient's shoulder perform the movements that his daily routine requires (Zou *et al*., 2018).

This work aims to review scientific articles in indexed journals, which document the use of 3D printing as an alternative for the development of low-cost prostheses. It is intended to be a brief review of characteristics that are necessary to develop a 3D printed prosthesis to help people to know alternatives of prosthesis according to their specific needs.

DEVELOPMENT

Techniques

The medical field is an area where 3D printing technology has been implemented (César-Juárez et al., 2018), it has taken advantage of its benefits to create several types of prostheses with different materials, depending on the needs of the customer. This technology can manufacture objects from a geometrical representation then setting the data in the machine that will print this object (Shahrubudin et al., 2019) and this one will be generated using various materials in the form of binder and powder (Gabor P-ța Eftimie Murgu nr et al., 2017)

As mentioned before, compared with some manufacturing techniques, additive manufacturing (3D printing) has several advantages, some of these are (Ten Kate et al., 2017):

- Personalized Designs.
- It can design complex geometries.
- Assembly is no needed, so it is viable to manufacture the product in just part.
- Cost-effective manufacturing for high productivity (Gabor P-ța Eftimie Murgu nr et al., 2017)
- Skin can be retorted with its same structure.
- Additive manufacturing can create cartilage and bone to replace any cavity.
- Can improve the tissue’s function.
- This technology is useful for practicing surgical techniques, improving its accuracy. (Shahrubudin et al., 2019)

Even though the adoption of this technology has increased in several field thanks to the advantages mentioned, there are several disadvantages, as the following ones (Ten Kate et al., 2017):

- The size of the printer limits the size of the object; objects cannot be too big.
- The strength of the object manufactured will depend on the fabrication methods.
- 3D printers work with the limited number of materials.
- Several protheses printed are performed by trial and error because there are no specific design guidelines.

There are varieties of AM (Additive Manufacturing) technologies for different performance, but only some of them can be used in the medical field; in order to acquire high quality medical devices, the technique must have a specific fabrication process and raw materials (Fan et al., 2020).

According to ASTM Standard F2792, 3D printing technologies are listed in several clusters, some of them are binder jetting, directed energy deposition, material extrusion, powder bed fusion, and sheet lamination (Shahrubudin et al., 2019).

Binder jetting

This 3D printing process mixes powder particles with a liquid binding agent. It can be printed in many materials as metals, polymers, sands, and ceramics. Binder jetting technology is characterized by printing products of considerable size (Shahrubudin et al., 2019)

Directed energy deposition

Printing process which is mainly adopted to fix or add material to components that already exist. This process can manufacture an object of excellent quality. It can be used with polymers, ceramics, metals, and metal-based hybrids (Shahrubudin et al., 2019).

Materials extrusion

Material extrusion is adopted to print multi-materials and colour printing of food, plastics or living cells. This process besides of having low costs, can manufacture sections of the products that will be functional. One example of material extrusion is FDM, fused deposition modelling; this process uses polymer as its main material (Shahrubudin et al., 2019). One advantage of this type of printing is that the hydrogels of extrusion-based printing can create products with high cell density (Fan et al., 2020).

Powder bed fusion

This process includes diverse techniques as EBM /electron beam melting), SLS (selective laser sintering) and SHS (selective heat sintering). It uses this technique to melt or merge the material powder. This melting process causes that object has fully dense parts without any other treatment (Fan et al., 2020). Some examples of materials adopted for powder bed fusion are metals, ceramics, polymers, composite, and hybrid material (Shahrubudin et al., 2019).

Sheet lamination

In this process some pieces of materials are merged to create a section of an object. Some examples of this technology are LOM (laminated object manufacturing) and UAM (ultrasound additive manufacturing). This process can print in full color, is unexpensive and the overage material can be recycled (Shahrubudin et al., 2019).

As previously described, medical devices obtained from 3D printing must have high quality materials. The material selected for the object will depend on which technique will be used. One of the most used materials for printing protheses are polymers which have a significant part in biomaterials. This material has the advantage of manufacture functional objects with a difficult structure. There are three polymers commonly adopted for medical purposes (Shahrubudin et al., 2019).

Materials

Polyvinyl Alcohol (PVA)

PVA is thermoplastic synthetic polymer that is soluble in water and insoluble in several organic solvents. Its main production route proceeds from the partial hydrolysis of polyvinyl acetate through the elimination of acetate groups. The melting point of this polymer depends on its hydrolysis degree; this property oscillates between 180 °C and 220 °C. The hydrolysis factor also establishes the viscosity degree of the polymer. PVA is considered non-toxic due to its poor gastrointestinal absorption and its biodegradable (Konta et al., 2017).

Poly (Lactic Acid) (PLA)

PLA has the same biodegradable characteristics as polyvinyl alcohol. It has a lot of applications in medical field. Its properties depend on the quantity of isomers, its crystallinity, and its molecular weight. The melting point goes from 150 °C to 175 °C. PLA is soluble in diverse chemical substances as chloroform, dioxane, and acetonitrile. Its solubility depends on the temperature of the solvents. It is insoluble in water and many alcohols. As PVA, polylactic acid is a non-toxic polymer. PLA has been adopted in the medical field for manufacturing many devices (Konta et al., 2017).

Poly (Caprolactone) (PCL)

This polymer is also biodegradable, even though its process of degradation takes more time than PLA does. It is a semi-crystalline hydrophobic polymer. Its property of crystallinity depends on how much reduces its molecular weight. It cannot be soluble in many acetones, alcohol, and petroleum ether. Contrariwise is soluble in many chemical substances as benzene, dichloromethane, and chloroform (Konta et al., 2017).

Hand prosthetics

Hand prostheses history started with an iron hook after a Roman general lost his hand in war in 200 before Christ (LeBlanc, 1988). Even though that technology emerged a long time ago, it is still an option for people living without a limb (Belter *et al*., 2014).

The people who have lived the amputation experience have consequences in the society like economic (Mckechnie *et al*., 2014), social (Cabibihan *et al*., 2021), and psychological (Rodríguez *et al*., 2018). The statistics around the world show that 10 million people have suffered an amputation, of which 30% are amputations of hands and arms. Approximately 2,300 amputations of the wrist and hands are performed in Mexico each year, which most of them occurring people between 20-39 years old (Vazquez-Vela, 2015).

The technology of 3D printing has influenced the commercialization of hand prosthetics because they provide the ability of elaborating prototypes in a shorter time and decrease the cost of the protheses (Vujaklija *et al*., 2019). Requirements for operating 3D printed prostheses are comfort, lifting and gripping capacity (Hernandez *et al*., S.F.), weight and size (Dally *et al*., 2015), and the ability of learning how to use it (Sánchez *et al*., 2019).

The methodology of how to build a prosthesis begins with an interview to know the patient's needs, after taking the measurements of the arm, the CAD design begins. When the prototype is finished it is 3D printed and the proof of the prosthetic function starts prosthetic (Sánchez *et al*., 2019). 3D printing hands prosthetics are functional devices for children because their application is easy for their comprehension. One advantage of using tridimensional technology is that if a piece breaks out, it can be printed again (Dally et al., 2015).

One application of hand prostheses is for the use of a computer keyboard. This design improved the movement of the people who had worn the 3D printing prosthesis and solves the high price problem of the normal prostheses. The prototype uses the material of acrylonitrile butadiene styrene (ABS) because of its low weight and an Arduino mega board for its electrical function (Lopez *et al*., 2019).

Leg Prosthetics

People with lower-limb amputations had many complications because they often favor and stress their lower limb, are more prone to degenerative changes such as osteoarthritis of the hip joints or the knee. This is caused by insufficient load through the long bones of the lower limb, which can be corrected with the use of a suitable prosthesis that manages to distribute the forces correctly through the limbs that they have intact (Gailey et al., 2008).

As a new technology have emerged, it has become possible to use 3D scanning to manufacture custom foot molds, as well as custom-made orthotic components. Therefore, 3D printing is a more efficient way of making prostheses since they can be designed with excellent precision in terms of their dimensions, and additionally, their performance is comparable to that of prostheses made with plaster or foam (Dombroski et al., 2014).

Ocular Prosthetics

Millions of people around the world suffer from sight problems because of retinal diseases or corneal pathologies. In 2012, there were around 185 000 corneal transplants, but only 1 cornea was available for 70 people that needed it. Almost 53% of the people in the world do not have access to a cornea transplant (Gain et al., 2016).

An ocular prosthesis is a piece made according to the specifications of the patient, and it is a cosmetic solution for people who had suffered the loss of their eyes. The creation of these prostheses consumes a lot of time, and it also involves the work of artists that draw the eyes, to make sure look natural. One of the biggest challenges in 3D printing in medicine is that the materials must be compatible and safe to use in the body; the biomaterials are an important innovation in the medical field, but because of their nature, they are viscous and must be used at a certain temperature to be able to 3D print an ocular prosthesis (Ko et al., 2019).

Bioprinting is a 3D printing innovation, in which materials that incorporate living cells are used, that are also called, biopolymers. In this case, there are researchers using hydrogels to create ocular prostheses, that are not dangerous for the patients (Vijayavenkataraman et al., 2017). Collagen is also a popular material for 3D printing corneas, it is derived from fish scales, which are scraps in the fishing industry (Ludwig et al., 2018).

There are also different ocular techniques of 3D printing. The inkjet printing technique has efficiency in the use of material during the production, but it also has the disadvantage that is complicated in the use of biomaterials that include living cells. The laser-assisted printing technique has a high-rate production cost, and it also takes a lot of time to 3D print one piece. The micro-extrusion printing technique is cheap and fast in the production of prostheses. Selecting the appropriate technique depends on the needs of the prostheses and the characteristics of the materials used in their fabrication (Lorber, 2016).

The dye sublimation transfer technique has been used to print specific parts of the eye, with the objective of creating realistic prostheses. The material used has been successfully proved and shows that it does not cause any adverse effects to the patients. This is an efficient and consistent option for providing an accessible ocular prosthesis to people (Ko et al., 2019).

In Spain, the Biomedical Research Institute of La Paz Hospital (IdiPAZ), a group of researchers are working on developing a 3D printing prosthesis that can be used as a substitute for a human cornea. They are using the cells of each patient to create corneas that satisfy their needs (Saunders ,2017).

In London, a company focused on research and design, has been developing 3D printed prosthetic eyes, using an additive manufacturing technique, having a high production rate and reduced costs compared to normal ocular prostheses. The 3D printer that the company uses allows them to create a prosthesis in less than 10 hours, reducing the production time compared with a handmade prosthesis (Vijayavenkataraman et al., 2017).

Ear Prosthetics.

According to the idea of 3D printing with functional electronics systems, it could be possible to have a bionic organ that increases functionalities to the humans with many defects that may be congenital, or also like a traumatic biology origin (Saadi & Lighthall, 2017). By this kind of prosthesis is focus in the middle or inner ear´s practicality (Suaste-Gómez et al., 2016).

For the humans, having a proper sense of hearing is basic and important for speaking normally, and identifying directionality; so the point of ear prostheses is to give that function to the patient, and by this reason it needs to prove sensory stimulation as pressure, and temperatures (Suaste-Gómez et al., 2016).

As an example, there is a bionic ear made by a composed cell-seeded hydrogel through the use of nanotechnology via additive manufacturing and using on its biological material know as chondrocytes (Mannoor et al., 2013). Other materials that have been used to complete the creation of the ear, are polycaprolactone (PCL), polyethylene glycol (PEG), and sodium salt of alginate acid (Lee *et al.,* 2014). Also, other ear prostheses are made from polyvinylidene fluoride (PVDF), that is known as a smart material, because it has as piezoelectric, ferroelectric and photopyroelectric properties (Suaste-Gómez et al., 2016).

Building or regenerating a bionic ear is difficult because of its complex pattern and composition (Lee et al., 2014). For this simple reason there are many patients who do not agree with the idea of 3D printing, because it implies a reconstruction in stages (Saadi & Lighthall, 2017).

Mandibular Prosthetics

The oral cavity area has the same fragility as other body parts, a lot of the damage in area can be inflicted by punches, diseases, and a great list of affections These damages can put in danger the health and life of the people if they are not treated on time (Xiao et al., 2020). The mandible is a main part of the face, not only for the esthetic, but also because os the vital functions that it carries out, such as the capacity of talking and eating (Garibaldi et al., 2017).

If dental prostheses are in a bad state or the user had very poor hygiene, with time this can lead to the appearance of buccal lesions (Alpízar & Valladares, 2012) and in the case of the maxillary prosthesis, a bad installation, or an error with the prosthesis in the moment of his creation, can lead in the formation of osteoporosis (Xiao et al., 2020).

3D printing helps many odontologists, because, with the use of all this technology, the designs that are obtained (and therefore prothesis) are more exact than those produced by the traditional methods. Thanks to this technology, the process has become easier and less painful (Suárez et al., 2019).

The method for creating a dental prosthesis is very simple and can be explained in three steps, the first is scanning, where the teeth are scanned with the purpose of having a 3D model of the teeth; design, the 3D model is edited to have the better prosthesis possible; and fabrication, with the help of a 3D printer, the model is printed in plastic or meltable wax (Suárez et al., 2019).

CONCLUSION

According to the reviewed literature, the performance of 3D printed prostheses still needs to be further studied and improved, but it has proved to be an efficient alternative for making hands, legs, eyes, ears, and jaws, which makes possible to improve the people´s life quality. The polymers used in those kinds of prostheses could be replaced quickly and at a lower cost, and they are adaptable to the patient needs. The children are the most benefited in 3D printing hands and arms prostheses. The fabrication time in 3D printing prosthetics is lower than the regular prosthetics.

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