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DESIGN OF 3D ADDITIVE MANUFACTURED AND CUSTOMIZED DEVICES FOR BIOMEDICAL APPLICATIONS

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The State of the Art

1.1 Introduction

Additive Manufacturing (AM) technology, also known as three-dimensional printing (3D printing) or Rapid Prototyping (RP), was born more than 30 years ago and in recent years has generated a wide interest in various fields of applications (e. g. automotive, aerospace, building, etc.), as shown in Fig. 1.

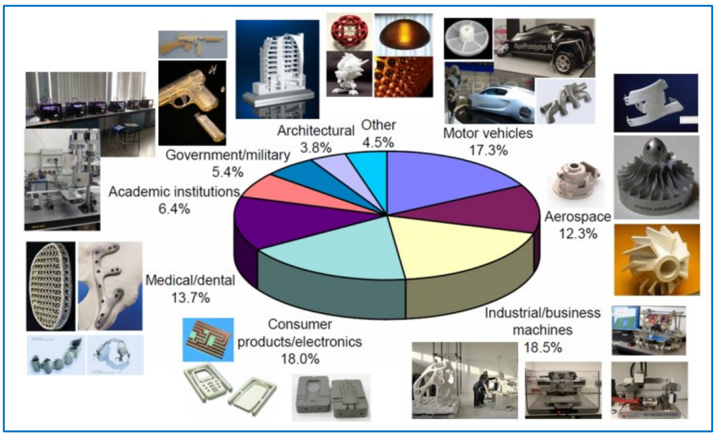


Figure 1 Principal fields of applications of AM techniques.

The growth of AM technologies is ascribable to the use of lower-cost printers to produce very complex objects. These technologies are expanding also in the biomedical field for manufacturing of different medical devices (e.g. surgical instruments, dental implants, anatomical models, etc.) and for tissue engineering applications (*Melchels et al., 2012*), as shown in Fig. 2.

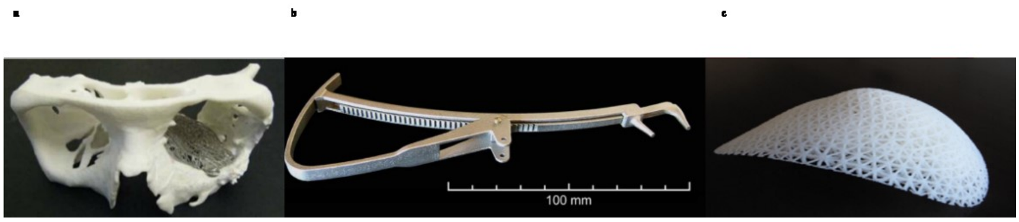


Figure 2 Medical applications of AM for (a) inert implants by Salmi et al. (*2012*), (b) surgical instrumentation by Mäkitie et al. (*2009*) and (c) tissue engineering by Tirella et al. (*2009*).

In recent years, a large interest about the application of these technologies in the field of rehabilitation therapy strategies is growing. In this particular area AM has the potential to offer solutions in order to overcome the common difficulties related to the production of orthoses and prostheses (*Lunsford et al., 2016*).

Orthoses (Fig. 3) and prostheses are medical devices to assist people with disabilities. In particular, orthoses or braces are designed to externally fit and apply force to the limbs, modifying structural and functional features, in order to restore the lost functionality. The characteristics of an orthosis should be listed as follows (*Jin et al., 2015*):

- to guarantee or correct segment alignment,
- to block the motion's limb,
- to distribute weiht-bearing forces,
- to give protection,
- to guarantee future motion,
- do not create deformities.

Figure 3 Traditional upper limb orthoses.

According to the *American Academy of Orthotists and Prosthetists Trends and Statistics*, the number of persons using orthoses and prostheses will be significantly increased over the next few years, hence, there is a growing interest in novel devices for this medical area.

In the field of rehabilitation, many works at the state of art concern the manufacturing by AM technologies of different kinds of lower limb devices, as ankle-foot orthoses (AFOs) or foot orthoses and upper limb devices, such as wrist orthoses, to overcome traditional problems linked to the application of the most common methods of orthoses manufacturing. A significant problem is, for example, that conventional processes can take many days.

Nevertheless, the effort is aimed to highlight how all these new technologies (Fig. 4) can serve to produce a complete customized orthosis in the shortest possible time, even if the time gained in production is often lost in obtaining insurance authorization.

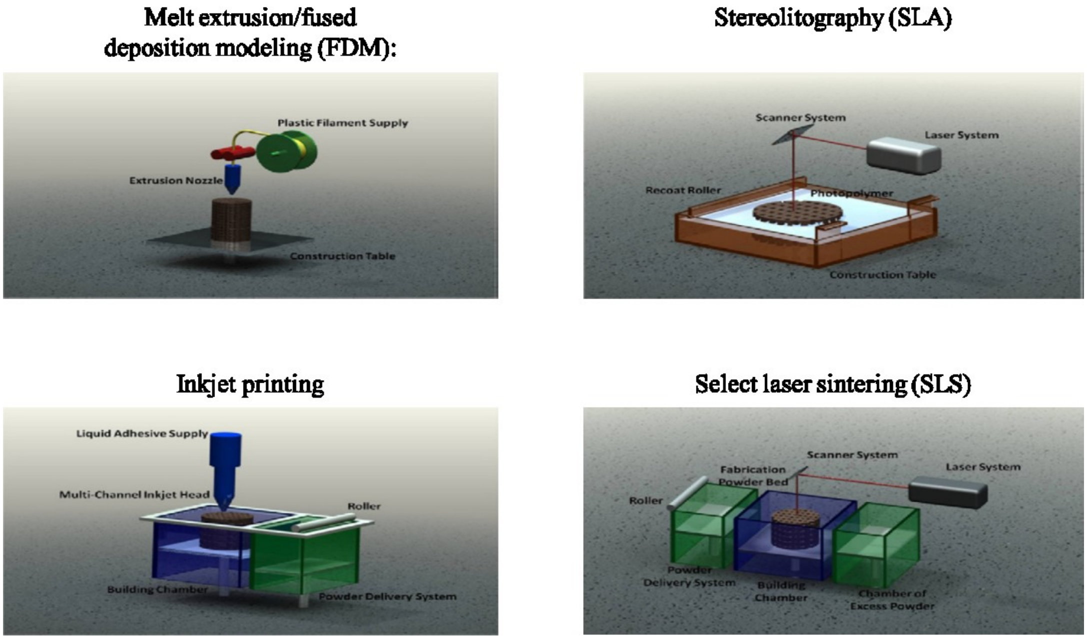


Figure 4 Some of commercially available AM techniques, as reported by Melchels et al. (*2012*).

In particular, the main advantages of these techniques are summarized as follows (*Bagaria et al., 2015*): customization, rapid manufacturing and cheapness.

Additive Manufacturing (AM) is an appropriate name to describe technologies to build tridimensional objects by adding material layer-upon-layer and, as mentioned above, covers a lot of proprietary name (e. g. 3D printing, Rapid Prototyping, Solid Freeform Fabrication, etc).

Over the years, many AM technologies have been developed, including Fused Deposition Modeling (FDM), 3D printing, ink-jet printing, stereolithography, selective laser sintering and different extrusion-based technologies, such as 3D Bioplotting.

3D printing incorporates a technology to eject a binder from a jet head that moves in accordance with the CAD cross-sectional data, onto a polymer powder surface. The binder dissolves and joins adjacent powder particles.

FDM employs a moving nozzle to extrude a fiber of polymer-based material and the physical model is built layer-by-layer. The pore sizes may be properly tailored to obtain adequate properties for specific applications. With regard to the ink-jet printing, the basic system consists of a build platform set on top of an elevator with a rolling cutter blade and two print jets.

In the stereolithography, the process involves the selective polymerization of a photocurable monomer by an ultraviolet laser beam. The UV beam is guided onto the liquid monomer surface according to the CAD cross-sectional data. With regard to selective laser sintering (SLS), the processing material is either a polymer or a polymer-coated ceramic powder. The powder bed on the platform is preheated to a temperature just below the glass transition temperature of the polymer to minimize the energy required in the subsequent fusing processing. In object building, the computer directs an appropriate laser to a raster on the polymer or the polymer-coated ceramic powder bed causing the powder particles to fuse.

3D Bioplotting is an extrusion-based technology similar to FDM. Such technology employs a pressurized nozzle to extrude the material in the form of fibers/filaments that solidify onto the platform. The Bioplotter system is a 3D plotter developed by the researchers at the University of Freiburg, and involves a moving extruder head (x-, y- and z axis control). The injector/extruder head can be suitably heated to process the material. The medium solidifies when it comes in contact with the substrate or previous layer.

Even if all these technologies are different for the type of processed materials, costs, etc., they have a similar basis (Fig. 5): a 3D model of an object is produced by a computer-aided design (CAD) software, that is then sliced in a two-dimensional geometry, which is digitally coded by a computer-aided manufacturing (CAM) software to manufacture the object layer-by-layer by the printer machine. A subsequent post-processing step is required to remove temporary supports or excessive materials trapped in the empty spaces.

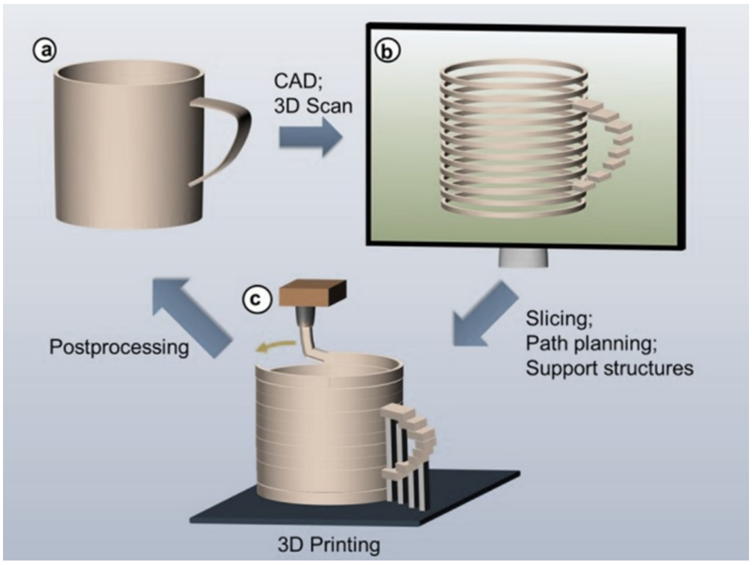


Figure 5 Basic principles of additive manufacturing (*Ligon et al., 2017*)

1.2 Additive Manufacturing : applications to rehabilitation field

1.2.1 Orthoses

One of the principal orthoses built by AM technologies have been created for the ankle-foot articulation; they are know as ankle-foot orthoses (AFOs) and are used to sustain muscles, correct deformities and improve ankle and foot functionalities.

Traditionally, the plaster molding process involves steps shown in the left side of Fig. 6.

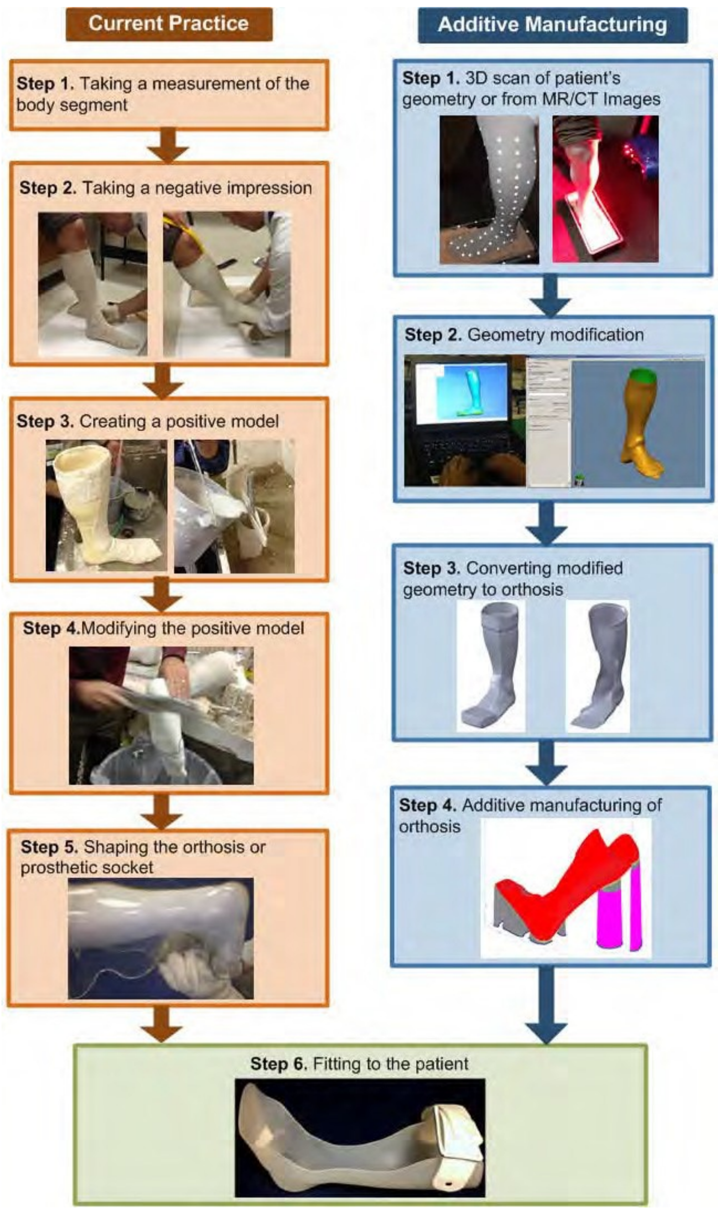


Figure 6 Current plaster molding and AM process in AFOs production (*Jin et al., 2015*).

The first step is the measure of dimensions, following by taking a negative impression with a plaster or fiber resin (step 2). In step 3, a liquid plaster is poured into the negative impression mold to obtain a positive model, rectificated with a mandrel embedded into. Successively (step 4), another plaster is added to apply additional forces and a thermoplastic sheet is precut in the step 5, heated to reach the plastic state and modelled around the plaster model. When it is completely cooled, the finished AFO (step 6) is fitted to the body. This process takes about two weeks.

AM process steps of an AFO building are shown on the right side of Fig. 6. 3D scanning of ankle, foot and plantar surface represent the first step of the process, followed by processing of scan data (step 2) and converting them to obtain the orthosis (step 3) by a dedicated software. In Step 4, AFO is fabricated by the use of an AM machine.

The idea of using AM for the fabrication of AFOs was reported by Milusheva et al. (*2005*) and developed by many authors (Fig. 7).

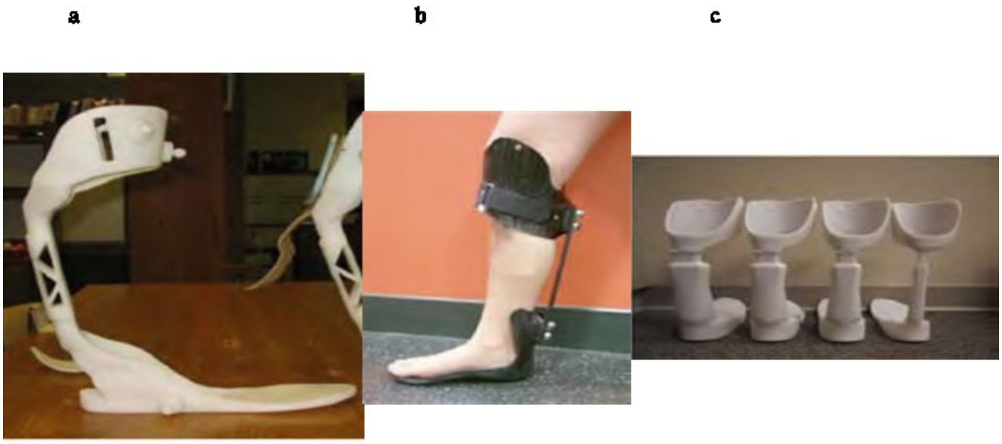


Figure 7 Examples of AM AFOs produced by (a) Faustini et al. (*2008*), (b) Schrank et al. (*2013*) and (c) Harper et al. (*2014*).

Faustini et al. (2008) compared biomechanical properties of three different materials (Rilsan D80, DuraForm PA, and DuraForm GF) to a control (carbon fiber) in order to produce a passive dynamic AFO by a powerd-bed fusion process. The study did not include participants and better properties have been noted in the Rilsan D80 case, but not improved upon the control. *Mavroidis et al.* (2011) also compared two kinds of material, in order to produce AFOs, including healthy participants tested by the gate-analysis, where hip, knee and ankle's kinematics and kinetics have been measured. Authors showed how the performance of 3D printed devices were vey closed to the commercially available ones.

Schrank and Stanhope (2011) developed a new customization process to improve dimensional accuracy of 3D printing process for fabricating a passive-dynamic AFO. Indeed, testing the process accuracy is very important because it was not properly established in old 3D printing processes (*Smith et al., 2001*).

Whereas the previous groups analyzed materials and processes for the manufacture of devices by AM technologies, others developed new orthosis through the same techniques. *Telfer et al.* (2012) studied a single case based on the use of an AFO with adjustable stiffness for different functional activities, submitting the patient to the gate analysis. *Harper et al.* (2014) studied 13 patients with various diagnoses requiring carbon fiber AFOs. They were treated by two different in stiffness AFOs and underwent gate analysis, demonstrating that stiffness did not involve a significant impact on gait.

Other studies analyzed 3D printed foot orthoses (FOs) that serve to correct deformities improving foot functionality by the correct distribution of body weight.

Depending on the problem, there are three possible FO: rigid, semi-rigid, and soft. Similarly to the AFOs case, traditional FOs are created by the initial negative impression of plantar surfaces, which serves as mold for plaster, while AM FOs are realized by a 3D scanner, dedicate software to process data and a 3D printing machine.

Telfer et al. (2013) studied 24 patients, each had 9 different FOs with incrementally increased rearfoot post angles, reporting a linear mechanical response by gate analysis. In another study, *Telfer et al.* (2014) treated 10 healthy participants with FO with embedded temperature sensors, monitoring their activities and developing a threshold-based algorithm to validate high activity by temperature values. *Pallari et al.* (2010) have enlisted 7 participants with rheumatoid arthritis, treated by traditional made and 3D printed orthoses (Fig. 8), evaluating gait parameters. Results did not show statistically different values between two kinds of orthoses. *Salles et al.* (2012) studied 26 runners with AM orthoses and generic control ones. Their gait analysis results demonstrated a decrease risk of injury when AM orthoses were applied. Dombroski et al. (*2013*) studied the scanning process and ABS FDM of a cheap custom FO and validated the practicability and efficiency in users.

Figure 8 Example of AM FOs produced by Pallari et al.(*2010*).

In recent years, some authors have been proposing solutions for upper extremity splinting by AM technologies (*Paterson, 2015*).

The difficulty in acquisition data related to the wrist and hand geometries have been often undervalued as reported by *Paterson et al.* (2010) who stated that an adapted method for detecting superficial topography of skin in the personalization of wrist splint has not been yet identified and standardized. For this reason they evaluated strengths and weaknesses of four different acquisition data methods: computerized tomography (CT), magnetic resonance imaging (MRI), anthropometry and 3d laser scanning, concluding that the last seems to be the most appropriate since it satisfies all needs (accuracy, resolution, patient safety and efficiency). In 2012 and 2015 (*Paterson et al., 2012 and Campbell et al., 2015*) the same group developed a custom 3D CAD approach for specialists in the splinting field to design custom splints and evaluated specific features guaranteed by the use of AM technologies (Fig. 9). Starting from the definition of a workflow, a software prototype was realized and developed with Microsoft Access® (2010) using Microsoft Virtual Basic for Applications® (2010).

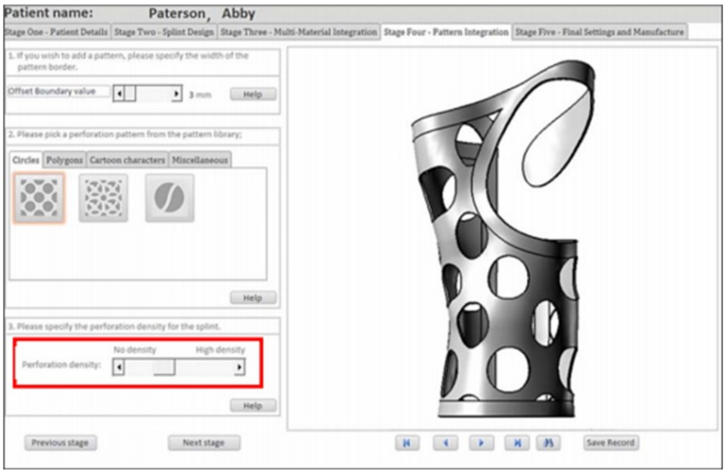


Figure9 Prototype interface example by Paterson et al. (*2012*).

Previously, the same group (*Paterson et al., 2010*) proposed multiple-material splints to prevent oedema and easy to put on and take off. Jin et al. (*2015*) reviewed AM of custom orthoses and prostheses comparing them to traditional plaster molding fabrication techniques, while Kelly et al. (*2015*) considered the particular case of wrist splint designs for Additive Manufacture.

Nowadays, there are many examples of wrist splints on the market produced by AM technologies (Fig. 10), but many of these are prototypes with no clinical validation. Moreover, in many cases, the importance of clinical data has been underestimated and CAD skills required to clinicians for the project of orthosis are taken for granted.

Figure 10 Examples of AM wrist orthoses by (a) Osteoid (*Karasahin*), (b, c) Connex, (d) Palousek et al., *2013*, (e) Cortex, (f) AmphibianSkinTM , (g) Paterson et al., *2015*, (h) Exovite.

One of the most widely used AM technology to produce wrist immobilization devices is Fused Deposition Modeling (FDM) where the object is manufactured by an ordered deposition of a melt polymeric material through a nozzle, usually provided in coils of wire of properly calibrated diameters (in various sizes).

Bush (*Royeen, 2015*), Zdravptint (*Zdravpint*), piuLab (*piuLab*) and WASP (*WASP*) used FDM to print flat splints modeled on the patient's wrist as happens in traditional casting process. Instead, AmphibianSkin (*3DMedScan*) allows the choice of color to patients and has a circumferential structure fabricated after scanning of the wrist. Open-Bionics (*Open-Bionics*) combined PLA (polylactic acid) and NinjaFlex (specially formulated thermoplastic elastomer) with a double extruder 3d printer. The choice of PLA, that covers the outer portion of orthosis, is in its strength, while the inner part is softer and realized by Ninjaflex, creating a model with a Voronoi pattern. In the HealX model (*HealX*) two sides of orthosis have been created, each attached to the sides of the fractured limb.

Also *Palousek et al.* (2013) realized a wrist orthosis with FDM. However, the device created is not breathable. Osteoid (*Karasahin*) and Exovite (*Exovite*) manufactured particular splints with AM technologies, combining them to some stimulators (ultrasound and electro) to accelerate the fracture healing process.

Another AM technology to realize wrist orthosis is the Selective Laser Sintering (SLS). With regard to SLS, the processing material is either a polymer or a polymer coated ceramic powder. The powder bed on the platform is preheated to a temperature just below the glass transition temperature of the polymer to minimize the energy required in the subsequent fusing processing. In object building, the computer directs an appropriate laser to a raster on the polymer or the polymer-coated ceramic powder bed causing the powder particles to fuse. Examples of wrist splints created by this technique are Cortex by Evill (*Evill*) and Splint+ (Fig. 11) (*3Ders*).

Figure11 Splint+ by *3Ders*.

One of the habits of friends and relatives of fractured patient is to write messages on the cast. With #Cast (*Fathom*) patient can customize the model in the phase of project with messages eventually released on cast by friends. Instead, *Paterson* (2015) realized some immobilization splints with a textile hinge by SLS; this component has been important for 6 patients suffering chronic pathologies as rheumatoid arthritis in order to facilitate the donning and doffing of splints. In addition, Material Jetting is an AM technology used to produce wrist orthosis, where an inkjet head deposits material into the 3D printer. It was used by *Paterson et al.* (2012) to manufacture orthosis easy to dress and remove with an integrated padding.

1.2.2 Prostheses

Since there are about 185,000 amputations every year in the United States (*Ziegler-Graham et al., 2008*) and the number of diabetics is steadily increasing, the cost associated with treating this type of problem is very high and about $8.3 billion (*Owings and Kozak, 1998*).

The particular treatment of this problematic state of health needs the application of prostheses or assistive devices in order to permit ordinary and comfortable activities for independent living. The prostheses are made of various components, as socket (Fig. 12), which is cause of discomfort for high contact pressure. In addition, the change of pressure and pressure points associated to the volume change of the limb is another annoying problematic.

Figure12 A tipical prosthetic socket.

It is known, in fact, that muscle atrophy decreases progressively. Some stocks are usually put inside the socket to compensate the reduce-in-volume of limb. According to the Center of Medicare and Medicaid *(CMS)* the need to apply these socks must be appropriately documented.

Traditionally, the design of a prosthesis starts with the detection of residual limb geometry by the use of plaster bandages and by taking note of eventual bony prominences. Subsequently, this cast is removed and filled with a plaster liquid. Plaster cast is destroyed when the slurry is set, leaving a positive mold of the residual limb.

A faster alternative to make a positive mold is by using an optical scanner (Fig. 13). Scan data of residual limb are converted into surface geometry and imported in a machine to obtain the object by milling of a foam block.

Figure13 Auto scanner by Infinity CAD systems.

Any method to create a positive mold involve modifications to add volume where bony prominences are presented and to reduce volume from pressure tolerant areas. The following step is to wrap the socket mold by a polymeric sheet or carbon fiber, which is vacuum formed.
This manufacture process is very laborious and wasteful of materials, being destroyed during manufacturing. Furthermore, the whole process could be repeated, since other sockets are necessary when volume limb changes, and depends a lot on the experience of prosthetists.
Hence, traditionally, in the manufacturing processes the geometry of the residual limb involve the use of plaster or fiberglass as casting materials (*Herbert et al., 2005, Hsu et al., 2010 and Goh et al., 2002*).
In the 90's Rovick et al. (*1992,1995*) created prosthetic sockets by AM at Northwestern University.
Another group presented a procedure to digitize the residual limb by the use of 3D laser scanner, the modification of geometry by a CAD software and SLS to manufacture the socket (*Rogers et al., 1991, Rogers et al., 1992, Stephens et al., 2000, Rogers et al., 2000, Rogers et al., 2001, Rogers et al., 2007*). Later, Hsu et al. (*2010*) compared traditional with CAD/CAM processes.
Since up to 95% of the amputees declared a lack of generic comfort (*Herbert et al., 2005*), researchers activity is aimed to evaluate how prosthetic devices and fabrication methods can be improved by AM technologies (Fig. 14).

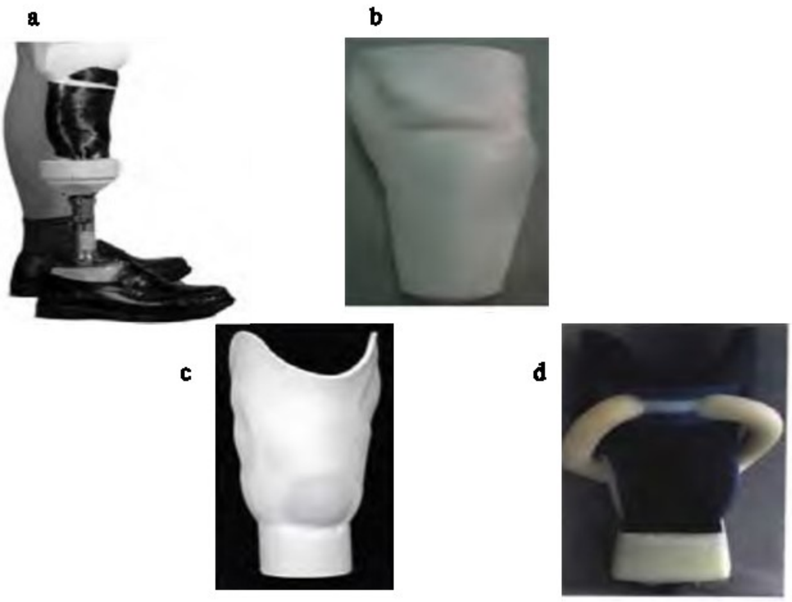


Figure14 AM prosthetic sockets, produced by (a) Herbert et al. (*2004*), (b) Hsu et al. (*2010*), (c) Rogers et al. (*2007*), and (d) Sengeh et al. (*2013*).

Herbert et al. (*2005*) realized 3D printed sockets for a transtibial and transradial amputee for a feasibility experiment, detailing the manufacturing process and demonstrating benefits of this new process, such as the possibility to store patient's limb data, not available with traditional plaster mold (*Smith and Burgess, 2001, Topper and Fernie, 1990, Torres-Moreno et al., 1991 and Torres-Moreno et al. 1992*).
More recently, Hsu et al. (*2010*) manufactured a resin-reinforced socket by 3D printing, demonstrating similar properties to that standard ones by analyzing pressure data during gait. In order to realize multimaterial prosthetic sockets, more advanced AM techniques were used by Sengeh and Herr (*2013*), reducing contact pressures to the bony prominences and increasing the walking speed.
Fey et al. (*2011*) analyzed the effect of varying keel and heel stiffness in different planes in the 3D printed prosthetic feet on gait mechanics in 12 participiants, while Laszczak et al. (*2015*) developed some sensors offering new ways to detect pressure data.
In addition, upper limb prostheses have been created by AM technologies. An example is the Robohand device, which design files are freely distributed online. Gretsch et al. (*2016*) studied the possibility to improve the Robohand design, since it shows some limits such as the requirement of functional wrist flexion and the simultaneous closing of all fingers. This study was conducted on one participant, a 13-year-old girl. Also Zuniga et al. (*2015*) produced a 3D printed prosthetic hand which was tested on 11 participants by anthropometric measurements.

1.2.3 Assistive Technology

Some researchers studied the possibility to develop new devices in the assistive technology field by AM techniques, to permit the maximum independence to the patients. For example, Brown et al. (*2012*) 3D printed particular tactile display for patients with visual problems (Fig. 15), which was well accepted. Instead, Medola et al. (*2012*) trialed new kinds of wheelchair push rim manufactured by 3D printing on 6 patients. Also this device was appreciate by most people especially for aesthetics.

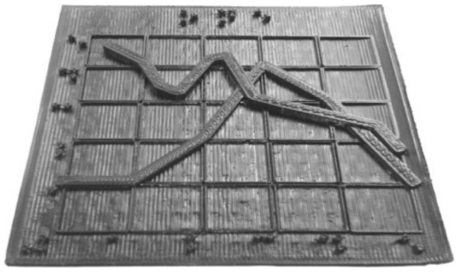


Figure 15 Three-dimensional printed Textile Graph for the visually impaired by Brown et al. (*2012*).

1.3 Discussion

1.3.1 General Advantages of Additive Manufacturing in rehabilitation field

America Makes (ex National Additive Manufacturing Innovation Institute), reports AM advantages: less material waste, low energy use, customization, etc. (*America Makes*). AM technologies also allow low-cost prototypes because, for example, molds typically used in injection molding techniques are not needed. Furthermore, even if subtractive techniques allow some customization, they are very wasteful. For this and other reasons, the Department of Energy consider AM technologies more convenient than subtractive ones, in terms of energy and material costs (*Chu, 2014*). Another method to reduce costs is to fill the inner volume by a lattice, reducing material amount and maintaining comparable mechanical properties. This method in not possible in the injection moulding and subtractive processes. One more advantage is the time needed to produce devices that is greatly reduced with 3D printing techniques respect to the current methods *(cascadedafo).*

A custom orthosis laboratory should be able to produce medical devices as soon as possible. Nevertheless, the entire production process depends on several parameters such as the type of material, the type of machine, and the resolution of the object.

Important challenges for AM technologies are related to different costs: 3D printer, software, training users, maintenance, etc. (*Smith et al., 2001*). It also notes how technology prices have come down due to the expiration of proprietary technology patents (*Mims, 2014 and Hornick, 2014*). Furthermore, CAD software require a high level of knowledge and expertise. *Paterson et al.* (2014) developed a

CAD software for therapists (Fig.16), but it remains obvious that such programs need an important training (*Mins, 2014 and Coppinger, 2014*).

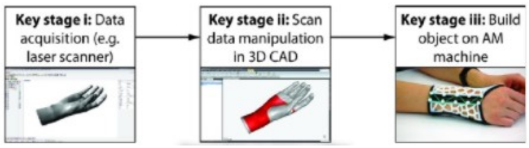


Figure16 Principal steps to produce orthoses through the use of a CAD software proposed by Paterson et al. (*2014*).

As mentioned above (*Harper et al., 2014 and Telfer et al., 2013*) scientists could be able to give some desired properties to manufactured devices using novel materials, processes and machines. Moreover, mass customization is possible since innovative software allows to quickly changing model design elements, offering the potential for cheap products (*Duray et al., 2000*).
Other 3DP techniques are under study, for example the Direct Metal Laser Sintering (DMLS) (*Frazier, 2014*). Even if this process is very expensive, customized metal devices can guarantee a lot of benefits in order to manufacture prosthetic pylons, sports equipment and wheelchairs.

1.3.2 Limits of Additive Manufacturing in rehabilitation field

The current state of art demonstrates a great potential impact of AM technologies in the production of orthoses and prostheses to rehabilitation applications. However, literature seems to be limited since both AM techniques and rehabilitation field are constantly evolving. Furthermore, many studies are often not supported by clinical trials. Anyway, many studies are aimed to show improvements over traditional manufacturing processes.

1.3.3 Implications of Additive Manufacturing for rehabilitation operators

The application of AM technologies in the rehabilitation field, born to overcome principal limitations of traditional methods is, hence, a very complex challenge. Some workers confirm that this is not a way to make better devices but a better way to make better devices and that there is the necessity to use an approach aimed to identify the process and products as separate aims, in order to better capture progresses and outcomes. Other improvements must be considered regard to study design, choosing the right cohort of patients and analysis instrument with high clinical impact.

Since this particular application area is new in the field of the rehabilitation field there is a great necessity to form clinicians and this could be done through the participation to organizational congresses or reviewing the abstracts from organizational conferences outside of their standard clinical practice.

Some medical centers are working to create inside their structures 3D printing labs, but if it can be beneficial is still under considering. Beyond the presence or absence of these centers, researchers can turn to service centers, where a print file is sent and the company processes it (Fig. 17) (*VACI and Shapeway*). Through this service, the purchase and maintenance costs of the machines are not efforded.

Figure17 Some of 3D printed models offered by *Shapeway*.

Clinical research, however, is aimed to analyze the actual costs of such a practice once the benefits of the process and its products have been demonstrated. The next step will be understanding rules for this products sale, quality control, risk management and responsibilities definition.

1.3.4 Future Research and Limitations

The future research on AM technology applied to the rehabilitation area should continue to focus on both processes and products optimization.

Attention should be paid to CAD / CAM techniques, material availability, cost of equipment, materials and software. Furthermore, there is the need to understand which specialists are really to engage. On the one hand, clinicians may help to understand what are the real medical needs while engineers will be interested in all the phases involved in the design and manufacturing of devices, responding technically to the various issues. Further studies could be aimed to improve aesthetics and optimize the quality control of process.

Long-term studies are also required to establish patients efficacy and efficacy, acceptance, degree of satisfaction and duration of the device.

1.4 Conclusion

This chapter summarized the traditional and AM methods to obtain custom foot, ankle-foot, wrist/hand orthoses and prosthetic sockets in the past 25 years. In limited clinical evaluations, authors had demonstrated the possibility to produce customized orthoses with good mechanical properties. However, some evidence also clearly shows that there are clinical, technological and financial barriers to consider before the AM technology can be implemented in a service system for custom-made devices.

Chapter 2

Additive Manufacturing

2.1 Introduction

Additive Manufacturing (AM) can be defined as the “process of joining materials to make objects from three-dimensional (3D) model data, usually layer upon layer, as opposed to subtractive manufacturing methodologies”, as reported by the ASTM F42 Technical Committee (*ASTM*). Rapid prototyping, rapid manufacturing, direct digital manufacturing, solid freeform fabrication are other terms to identify the class of AM technologies. Through the use of these manufacturing processes, investigated since the late 1980s, it is possible to produce a large variety of products, from prototypes to functional parts to serve to specific industrial and service applications. Furthermore, AM offers the possibility to control the whole architecture, to permit reproducibility and standardization (*Melchels et al., 2012*).

A lot of AM techniques have been developed, such as Stereolithography (SLA), Fused deposition modeling (FDM), Three Dimensional Printing (3DP), Selective Laser Sintering (SLS) and many materials have been used including photo-curable resin, acrylonitrile-butadiene-styrene (ABS), metals, ceramic and polymeric powders, etc. Briefly, through the use of AM techniques, 3D objects are manufactured from CAD models and produced by layer-by-layer material deposition (Fig. 18).

Figure18 AM process flow by *Deloitte Insights*.

In particular, an AM process starts with the creation of a computer model by a 3D CAD software or the importation from a 3D scanner (*Bartolo et al., 2004*). The acquisition of images data is possible through the use of many method, such as Computed Tomography (CT), Magnetic Resonance Imaging (MRI) (Fig. 19) and many others (*Edinger et al., 2002, McElroy et al., 2002 and Potter et al., 2004*). The CAD model is then converted in an STL file, which is successively sliced in thin layers.

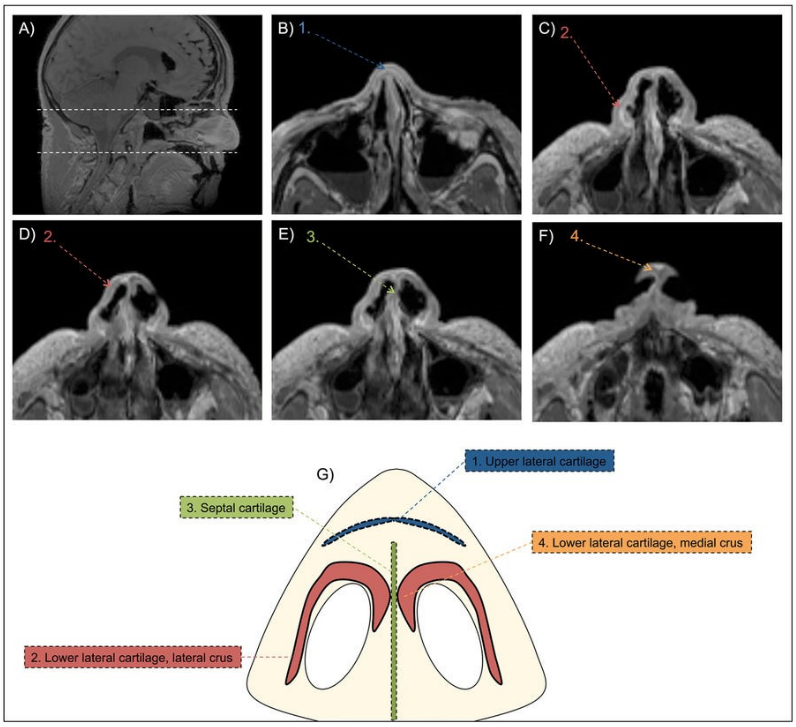


Figure19 Depiction of nasal cartilages on 3T MRI by *Visscher et al., 2017*.

AM techniques do not require the built part fixation as in subtractive processes and are cost-effective and production time is short (*Feygin and Hsieh, 1991*). With the developing of new AM technologies there has been an increase of their applications in a lot of fields as aerospace (*Thomas et al., 1996*), automative (*Song et al., 2002*), biomedical (*Giannatsis et al., 2009 and Sachlos E and Czernuszka, 2003*), etc.

Although all these technologies are in constant progression there are some challenges, as limited materials that can be processed, lack of standards and, for example, poor consistency of manufactured parts.

2.2 Design for AM

Design for manufacturing, also known by the acronym DFM, can be thought as a tool for designers to reduce manufacturing problems and costs (*Rosen, 2007*). For this reason, novel CAD and DFM processes are necessary to take advantages from AM abilities. Indeed, during a study of European researcher groups (*Rosen et al.,2004*), financially supported by U.S. government, the lack of valid CAD tool has been considered as a serious problem for the whole process in producing parts by AM technique with maximum performance.

Furthermore, a new concept of DFM can be proposed: DFM for Additive Manufacturing (DFMA). Typical DFMA processes or tools embraces topology optimization, mass customization, multiscale or multi-material design, etc. Many examples of DFAM applications can be reported, such as the helicopter engine composed by 16 parts instead of 900 by GE Aviation, so simplifying the whole structure (*Zelinski, 2017*).

DFMA methods can be listed as follow:

-Topology optimization (TO): a mathematical method used to maximize the performance of a system, optimizing material density for a specific set of loads and boundary conditions. This performance is evaluated by the finite element method (FEM). TO (Fig. 20) has applications in a lot of fields, such as civil engineering, aerospace, biochemical, etc.

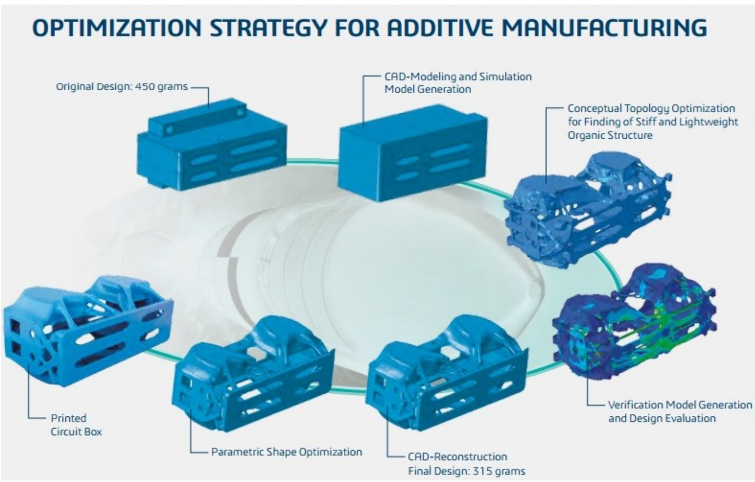


Figure 20 Topology optimization for a 3D printed circuit box. Rocket payload image credit NASA.

-Multiscale structure design: this approach consists in realizing structures wit multiscale complexities, starting with micro or mescoscales ones. For example, lattice parts manufactured by AM are used in the aerospace field for weight reduction (*Tang et al., 2015*) and it was demonstrated that lattice or cellular structures could enhance osseointegration (*Schmidt et al., 2011*).

-Multi-material design: additive manufacturing approach to obtain parts with multi-material distribution (Fig. 21). Different design and simulation processes has been proposed (*Zhang et al., Zhou and Wang, 2006 and Stanković et al., 2015*).

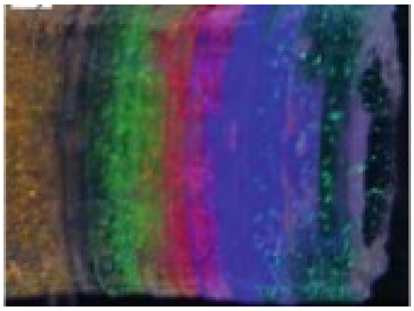


Figure 21 Side view of nerve guidance conduit fabricated using SL process from different materials by *Vaezi et al., 2013*.

-Design for mass customization: methods to produce customized parts (*Reeves et al., 2011*).

-Parts consolidation: the approach in which components are consolidated. It is advantageous since it reduces parts to be manufactured into the final structure with lowering of costs and increasing of speed and performance of production.

2.3 AM processes

Many industrial companies have introduced different AM processes (*Onuh and Yusuf, 1999*).
The first AM technology into the market was Stereolithography (SLA) (*Jacobs, 1992*). In this process (Fig. 22) a liquid photoresin is exposed to UV light that converts it into the solid state. This method starts by the creation of a CAD model followed by the UV scanning of each model's layer. The base runs down after one layer building.

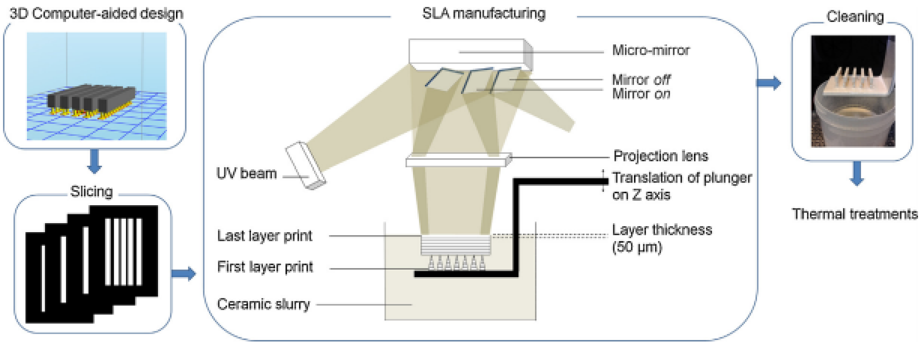


Figure 22 Sterolitography manufacturing process, as reported by *Dehurtevent et al., 2017*.

Over the years, various kind of SLA machines have been developed to produce ceramic and metal parts (*Brady and Halloran, 1997, Doreau et al. 2000, Chartier et al. 2002*). Digital micromirror device (DMD) and digital mask generators have been also presented to develop unconventional and cheaper processes to manufacture photo-curable polymeric structures (*Monneret et al., 1999, Sun et al., 2005*). This process is also faster than traditional ones.

Multi-Jet Modeling (MJM) (*Chua et al., 2010*) is a typical AM process to manufacture parts by the presence of multiple nozzles. Jets are generated in a linear manner and material deposition is layer by layer until the complete building of the part. Cheapness and short-time production are some of the advantages of MJM process.

Rapid Freeze Prototyping (RFP) is a novel but not yet commercialized AM process used to build ice parts by layer-by-layer deposition of ice droplets. In this process is important to keep temperature below the freezing point. It represents an environmental-friendly method since just water is necessary. Ith this technique is possible not only make full ice parts but also casting the object with ice patterns (*Liu et al., 2002*).

Fused deposition modeling (FDM) (*Crump, 1991*) was born in the late 1980s. A polymeric material is fused and deposited to the base by a nozzle. The material is heated at a temperature slightly above the melting point and cooled down to permit the solidification when is deposited to the base. Recent advances for this technology include the use of multi-nozzle system (*Jafari et al., 2000, Khalil, 2005 and Bellini et al., 2005*) to manufactured multi-material objects (Fig. 23).

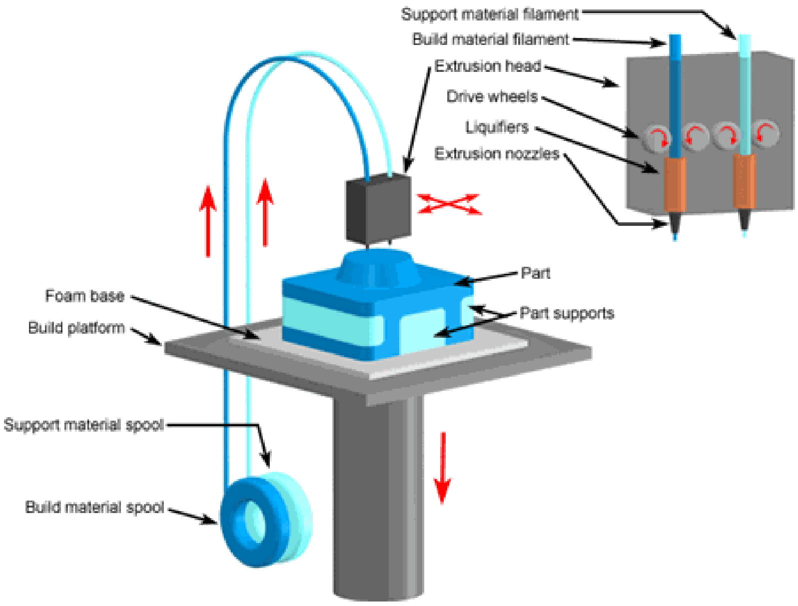


Figure 23 Fused deposition modeling (FDM) system by *CustomPartNet*.

Sandia National Laboratories developed Robocasting (*Robocasting and Russias et al., 2007*) in which ceramic paste are extruded.
Similar to Robocasting is Freeze-form Extrusion Fabrication (FEF) (*Mason et al., 2009, Huang et al., 2009 and Liu and Leu, 2009*) that was invented at the Missouri University of Science and Technology (*Missouri S&T*). In this process an aqueous paste is deposited and solidified by freezing (Fig. 24). This process is very cheap and environmental-friendly.

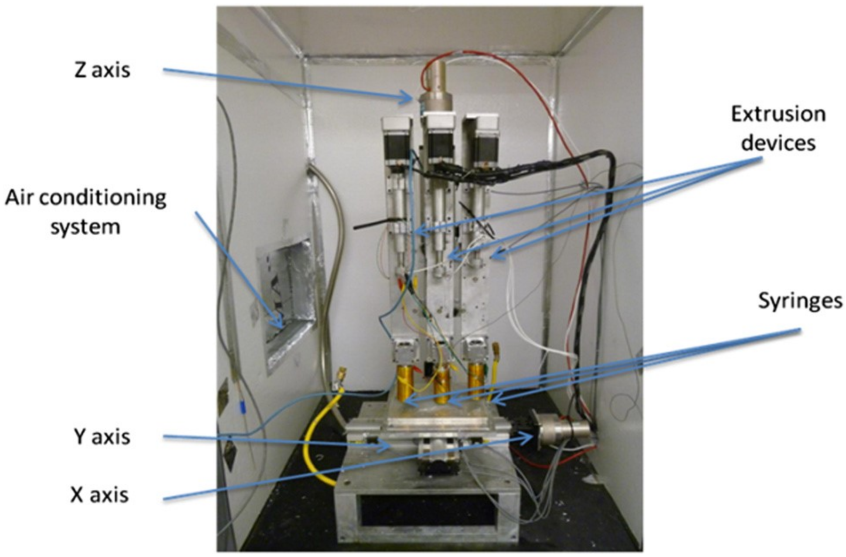


Figure 24 Experimental setup of the multi-extruder FEF machine as reported by *Leu and Garcia, 2014*.

There is another kind of AM process in which each layer is built by the exposition of a material in powder form to a heat source. Select Laser Sintering (SLS), for example, uses an emitting infrared radiation laser to keep the powder material above its melting point to sinter it in a layer that, after solidification is covered by a new layer by a mechanical roller (Fig. 25).

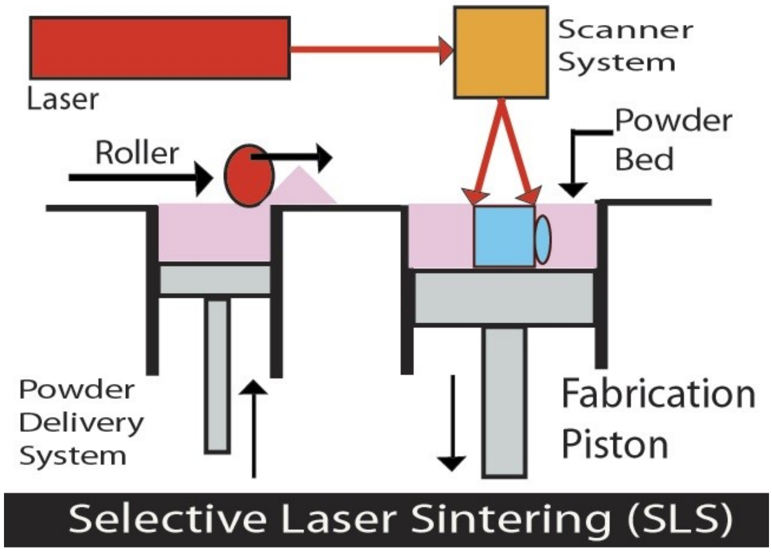


Figure 25 Selective Laser Sintering (SLS) process by JUST3D^{TM}.

By SLS a wide range of materials can be processed (metals, ceramics, polymers, composites, etc.) (*Pham et al., 1999, Das et al., 1998, Kruth et al., 2005a, 2005b, 2007, Kumar, 2003 and Levy, 2003*). This process is different from FDM and SLA since does not require supports to object in manufacturing procedure since the part is surrounded by unsintered powder.

Two variations to these techniques are Selective Laser Melting (SLM) and Electron Beam Melting (EBM).

SLM (*Kruth et al., 2004, Abe et l., 2001, Lu et al., 2000, Osakada and Shiomi, 2006*) derives from SLS, where a high-power laser beam is used to melt the metal powder and does not involve a post-processing phase. Some difficulties are presented in this process since the necessity to have a very high energy to melt metal and, for example the evenience of part deformation or residual stress (*Kruth et al., 2004*). Current materials involved in this manufacturing process are, for example, titanium or cobalt chromium.

In the EBM technology (*Cormier et al., 2004a, 2004b, Heinl et al., 2007, 2008, Rännar et al., 2007, Harrysson et al., 2008*), developed by Arcam in Sweden, an electron beam is the energy source to melt metal powder in order to build parts in a high vacuum chamber. The result is represented by an extremely strong part. The disvantage is that the surface part is not so perfect.

Laser Metal Deposition (LDM), showed in Fig. 26, is similar to SLM, since the need of a laser beam to melt the powder, without the necessity of a post-processing step (*Gasser et al., 2010, Balla et al., 2009, Lewis et al., 2000, Zhang et al., 2007, Lewis, 1995, Hofmeister et al., 2001*).

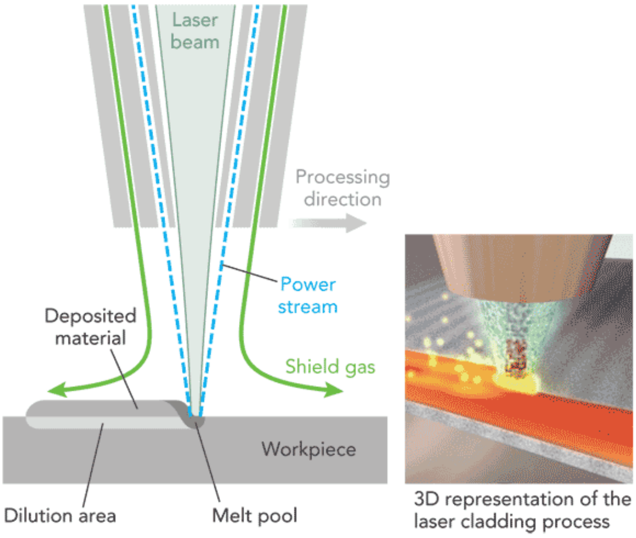


Figure 26 Laser metal deposition (LDM) process by INDUSTRIAL LASER SOLUTIONS FOR MANUFACTURING.

LDM is also known with other terms, as Laser Engineered Net Shaping (LENS), Laser cladding or Direct Metal Deposition (DMD). The most important difference between SLM and LDM is that while in the first case object is created in a powder bed, in the SLM case is provided by a coaxial or off-axial nozzle.

Also in the Three-Dimensional Printing (3DP) (*Sachs et al., 1993, Melican et al., 2001, Dimitrov et al., 2006, Lee et al., 2005, Butscher et al., 2012, Seitz et al., 2005*) the part is manufactured in a powder bed. The solid layer is formed by the use of a liquid binder sprayed on the powder bed to permit the solidification.

The major advantage of 3DP is the wide range of materials that can be processed as metal, ceramic, polymers. This process involves the necessity of a post-processing phase, as sintering or infiltration.

Laminated Object Manufacturing (LOM) is another AM process in which solid material is supplied in sheet form (*Mueller and Kochan, 1999, Prechtl et al., 2005, Park et al., 2000, Weisensel et al., 2004, Liao et al., 2006*).

2.4 AM materials

Originally, AM technology was used to produce polymeric prototypes. With increasing of developing of new teechiques, AM has become capable to produce functional parts also for the opportunity to process a large variety of materials as composites, ceramics and metals. In this section different materials processed by AM technologies are presented.

Polymers

A polymer is considered a large molecule constituted by the repetation of structural units, and it is possible to make a larger classification into natural or synthetic types. Through the major AM technologies (e. g. FDM, 3DP, SLS, etc.) a large variety of materials can be processed: nylon, ABS, resin, etc. Polyamide (PA) (*Caulfield et al., 2007, Zarringhalam et al., 2009*), for its better melting properties by laser, is one of the most widely investigated polymers in SLS process (*Kruth et al., 2007*). Instead, for example, ABS is very popular in FDM process (*Ahn et al., 2002*). For SLA process photocurable polymers are used, which cure after exposing to laser. Starch- based polymers (*Lam et al., 2002*) are instead used in 3DP process. There is another category of polymers for AM, represented by thermoplastic polymer (i.e. AS or nylon), that starting by a solid structures become a viscous fluid when heated to very high temperatures. Other thermosetting polymers are the photosensitive resins. In addition to aforementioned traditional polymers also poly-ε-caprolacton (PCL) and other biocompatibile polymers have been investigated by classical AM technologies (3DP, SLS, FDM) (*Lam et al., 2002, Schmidt et al., 2007, Leong et al., 2007, Ramanath, 2007-2008*) for tissue engineering applications.

Metals

AM technologies to produce metal parts can be classified in three categories: indirect or direct ways and rapid tooling. In the first category, a binder bonds metal particles and a phost-processing phase is necessary, while in the second one the final part is made by the fully melting of metal particles.

Metals-Indirect methods

In SLS method it is possible to partially melt the metal particles (*Kruth et al., 2007*) or to bond all metal particles by a low-melting point binder (*Agarwala, 1995a and 1995b*), such as a phenolic polymer, as a low-melting-point metal. A post-processing step is necessary for the complete remotion of the polymer binder and other processes to give a fully dense part. Also LOM, 3DP and SLA processes ca be used as indirect methods to produce metal parts. While in 3DP a liquid binder is sprayed to bond metal particles, in the SLA method after mixing metal particles with a liquid photo-curable resin, an UV light cures the suspension. In order to obtain desired properties post-processing phase is necessary (*Allen and Sachs, 2000*). In the LOM process metal sheets are joined by a layer-by-layer mode, even if in this process the critical point is the strength of the metal object in the direction perpendicular to the layers.

Metals-Direct methods

SLM, LMD and EBM can be used as direct methods to manufacture metal parts by fully melting (*Kruth 2005a, 2005b and 2007*). While in SLM and EBM a metal powder bed is used, in LMD process a high-power laser beam creates a melt pool of metal particles. Titanium, nickel, cobalt alloys are some examples of materials processed by AM technologies.

Metals-Rapid tooling

The combination of AM manufactured shell or cores and the casting with molten metal are another example of methods to produce metal parts (*Cheah et al., 2005*). These cores, usually made in ceramic materials, can be processed by SLA, SLS or 3DP (*Sachs et al., 1992*).

Ceramics

Aluminia, zirconia and silica are some examples of ceramic material, defined as solid, inorganic and non-metallic materials. These kind of materials are largely used in industrial applications for their chemical and termic resistance. Also for ceramic products, AM technologies can be used in direct and indirect ways and great advantages can be reached by the use of these processes.

Ceramics-Indirect methods

SLA, 3DP, FDM are some of AM technologies used to process biocompatible, industrial and advanced ceramics, that create a ceramic green part with a high amount of organic and inorganic binders. In the FDM process, for example, where a ceramic particle loaded thermoplastic filament is extruded, followed by the complete remotion of binder to obtain a fully dense part. Throug this technology advanced ceramics (*Allahverdi et al., 2001*) and Si_3N_4 and SiO_2 structural parts (*Rangarajan et al., 2000 and Agarwala et al., 1996*) have been manufactured. Another novel class of ceramic material, with advanced electrical and mechanical properties, is represented by Ti_3SiC_2, that is possible to process by 3DP spraying a liquid binder into the powder bed, followed by cold pressing and sintering (*Sun et al., 2002*). Ceramic parts also have been produced by SLS and SLA processes using different materials as alumina, silica or graphite.

Ceramics-Direct methods

High melting temperatures of ceramics make direct fabrication more challengelous than indirect type. Attemptions have been made, for example, by using SLM process to produce ceramic components starting by the complete mixing of zirconia and alumina (*Wilkes et al., 2013*), preheating the ceramic powder to a very high temperature (>1600°C) in order to obtain a fully dense part with a reduced thermal stress and without post-processing step. Also LENS process has been used in this category in order to produce, for example, alumina parts (*Balla et al., 2008*).

Composites

Composites are composed by two or more materials. This composition, at a macroscopic level, give superior properties to the material, respect to the case of singular materials. Composites materials can be classified in uniform and non-uniform composites depending on the type of mixing.
Different composites have been used in AM processes (3DP, SLS, SLM, etc.) such as metal, ceramic and polymeric matrix or reinforced composites (*Kumar and Kruth, 2010*). The most used composite is the fiber-reinforced composite, especially in FDM and LOM technologies, since there are some difficulties in SLS and 3DP processes when using these materials. Several attempts in SLS and SLM processes have been made in order to produce objects starting by metal-metal, metal-ceramic and ceramic-ceramic composites (*Kumar and Kruth, 2010*).

2.5 AM Applications

Different industrial applications have been largely proposed by the fabrication through AM technologies in many field, such as automotive, aerospace, biomedical and energy.
Since in the aerospace field components are composed by advanced materials (nickel and titanium alloys or special steels) and by complex geometries, AM technology represent a very suitable approach. For example LENS technology has been used in order to poduce components for helicopters or satellites (*Optomec*) and SLM for the fabrication of an engine housing (*Concept Laser*).
LENS can be also used to repair parts (rotors, steal, etc.) or geometrically complex components (*Mudge and Wald, 2007,Optomec, Hedges and Calder, 2006*).
Commercial applications in automotive industry have been also proposed in AM field (*Technology CRP, Optomec, Arcam, Concept Laser, Prometal R C T*) to produce, for example, components for motorsports, gearboxes, wheel suspensions, valve blocks, etc.

Chapter 3

Materials Analysis and Fabrication Methods

3.1. Materials and Manufacturing

3D additive manufactured and devices for biomedical applications were developed by reverse engineering approach and fused deposition modeling (FDM) starting from two Acrylonitrile-Butadiene-Styrene (ABS)-based thermoplastic polymers and a 3D printer (Zortrax S.A, Poland).
Two thermoplastic polymers (under the trade name Z-ABS and Z-UltraT) were selected in the form of filaments with a diameter of 1.75.
Some mechanical properties related to the Z-ABS material [Zortrax, «Material Data Sheet: Z-ABS»] Z-UltraT [Zortrax, «Material Data Sheet: Z-UltraT»] are reported in Table 1 and Table 2.

Mechanical Properties	***Test Method***	***Value***
Young's Modulus	*DIN EN ISO 527-2 (ASTM D638)*	*1.80 GPa*
Tensile Strength	*DIN EN ISO 527-2 (ASTM D638)*	*38 MPa*
Tensile elongation	*DIN EN ISO 527-2 (ASTM D638)*	*17 %*
Rockwell R hardness	*PN-EN ISO 2039-1 (ASTM D785)*	*109*

Table 1 Mechanical properties of Z-ABS.

Mechanical Properties	***Test Method***	***Value***
Young's Modulus	*DIN EN ISO 527-2 (ASTM D638)*	*1.95 GPa*
Tensile Strength	*DIN EN ISO 527-2 (ASTM D638)*	*42 MPa*
Tensile elongation	*DIN EN ISO 527-2 (ASTM D638)*	*21 %*
Rockwell R hardness	*PN-EN ISO 2039-1 (ASTM D785)*	*110*

Table 2 Mechanical properties of Z-UltraT.

3.2 Calorimetric analysis

Differential Scanning Calorimetry (DSC) and thermogravimetric analysis (TGA) were performed on Z-ABS and Z-UltraT at 10°C/min, according to the ASTM D3417 and ASTM D3418.

Such test method covers the determination of heat of fusion and heat of crystallization of polymers by DSC.

It can be applied to polymers in granular form or to any fabricated shape from which appropriate specimens can be cut.

In particular, this method consists of heating or cooling the material at a controlled rate in a specified purge gas at a controlled flow rate, then comparing the areas under the crystallization exotherm or fusion endotherm of the test material against the respective areas obtained by the similar treatment of a well-characterized standard.

Basically, DSC provides a rapid method for evaluating enthalpy changes accompanied by the first-order transitions of materials.

The heat of fusion, the heat of crystallization, and the effect of annealing may be generally evaluated in polymers that possess them. Differential scanning calorimetry may be used to assist in identifying specific polymers, blends, and certain polymer additives which exhibit thermal transitions.

This test method is useful for both process control and specification acceptance, as well for research purpose.

Results from DSC analysis performed on Z-ABS and Z-UltraT have been reported in terms of heat flow-temperature curves (Fig. 27 and Fig. 28).

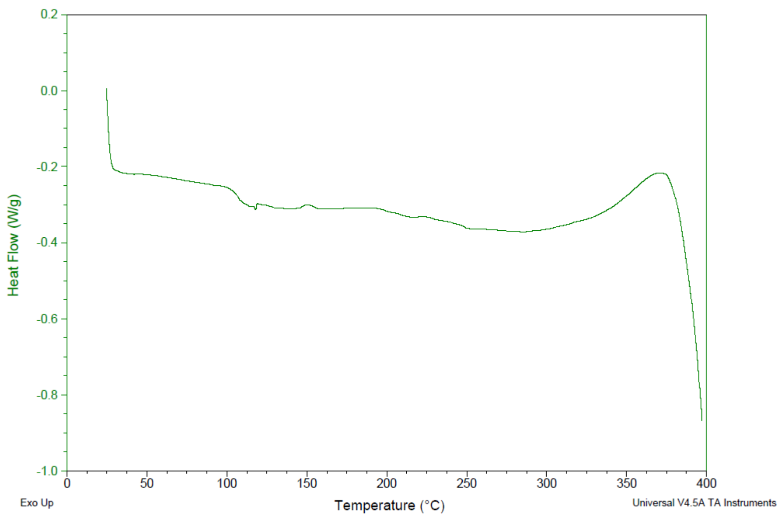


Figure 27 Results obtained from DSC analysis: typical curve of heat flow versus temperature for Z-ABS.

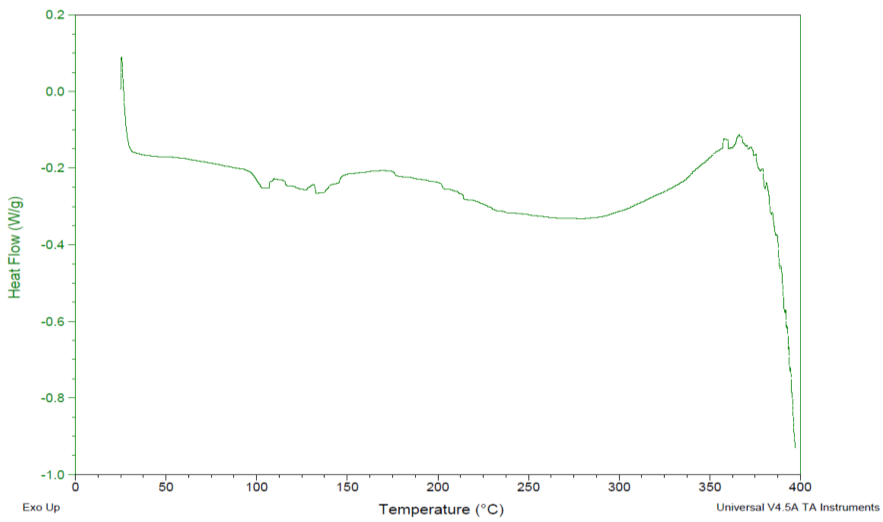


Figure 28 Results obtained from DSC analysis: typical curve of heat flow versus temperature for Z-UltraT.

Glass transition temperatures of about 125°C and 144°C were evaluated for Z-ABS and Z-UltraT, respectively.

On the other hand, thermogravimetric analysis (TGA) is a method of thermal analysis in which changes in chemical and physical properties of materials are evaluated as a function of increasing temperature at a constant heating rate, or as a function of time at a constant temperature and/or constant mass loss TGA may provide information about physical phenomena, such as second-order phase transitions, including absorption, adsorption, desorption, sublimation and vaporization.

TGA relies on a high degree of precision in three measurements: mass change, temperature, temperature change.

The basic instrumental requirements for TGA consist of a precision balance with a pan loaded with the sample, and a programmable furnace. The TGA apparatus continuously weighs a sample as it is heated to high temperatures.

As the temperature increases, several components of the sample can be decomposed. Thus, the weight percentage of each resulting mass change can be measured. Results are normally plotted with temperature on the X-axis and mass loss on the Y-axis.

The obtained results from TGA performed on Z-ABS and Z-UltraT have been reported in terms of weight-temperature curves (Fig. 29 and Fig. 30).

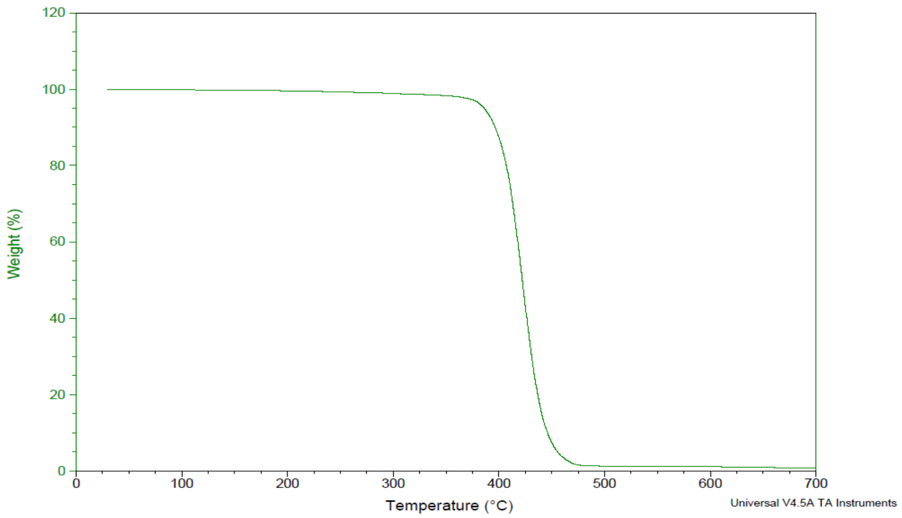


Figure 29 Results obtained from TGA: typical weight versus temperature curve for Z-ABS.

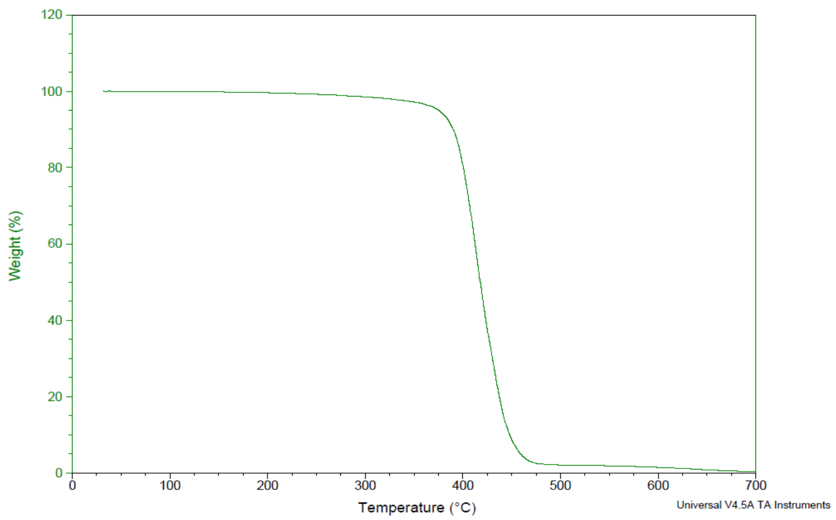


Figure 30 Results obtained from TGA: typical weight versus temperature curve for Z-UltraT.

Results from TGA have allowed to assess the thermal stability of the materials.
Accordingly, in a specific temperature range, if a species is thermally stable, no mass change is observed.
Negligible mass loss corresponds to little or no slope in the TGA trace. TGA provides the upper use temperature of a material and beyond this temperature the material begins to degrade, thus providing interesting information in terms of process parameters.

3.3 Mechanical Analysis: Flexural Tests

Three-point bending tests were carried out on the different kinds of printed “building blocks” made of Z-ABS and Z-UltraT, according to the ASTM D790. All the tests were performed using an INSTRON 5566 testing machine. The support span-to-depth ratio was 16 to 1 (Fig. 31 and Fig. 32).

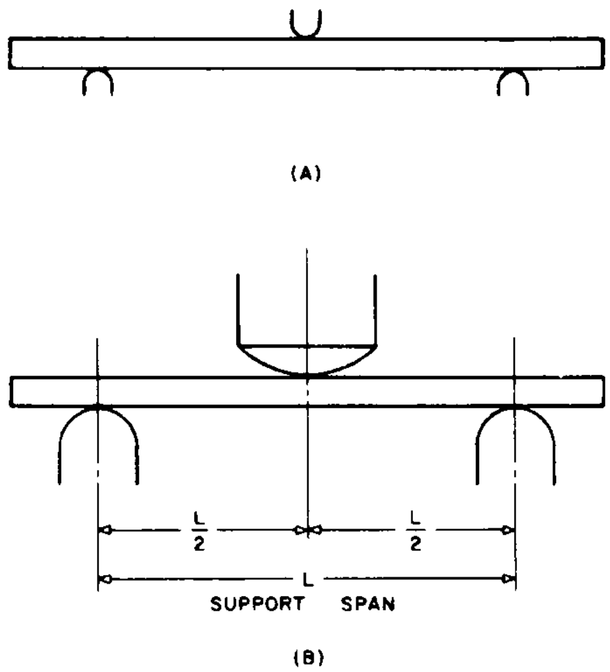


Figure 31 Schematic representation of three-point bending tests.

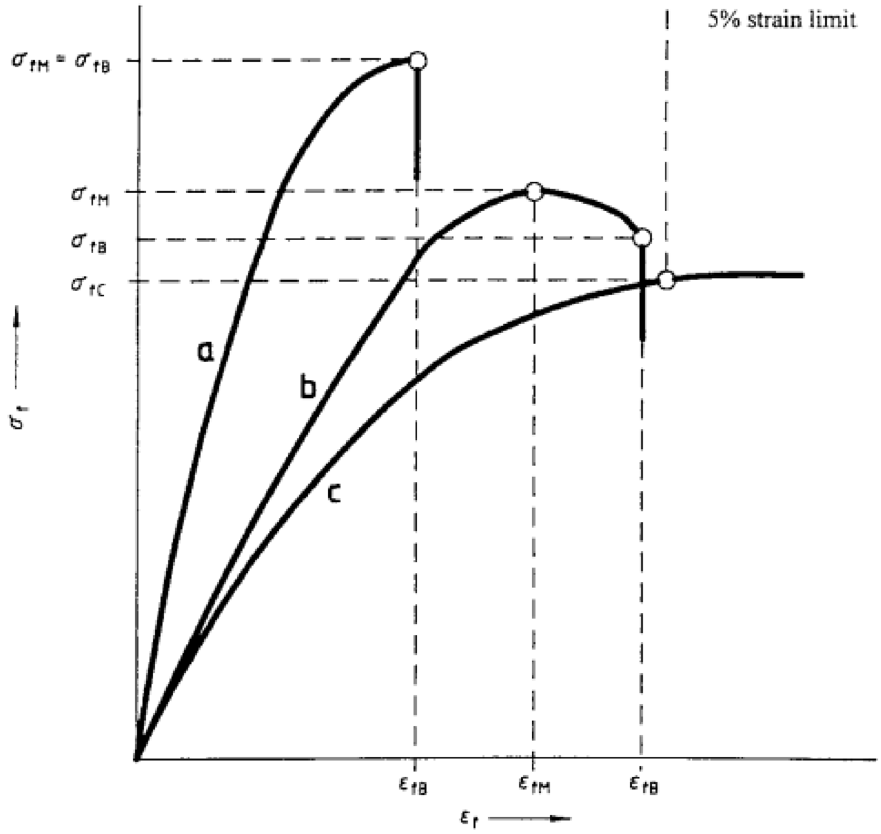
Stress (σ) and strain (ε) were evaluated as follows:

$$\sigma=\frac{3FL}{2bd^2} \qquad (3.1)$$

$$\varepsilon = \frac{6D_f d}{L^2} \tag{3.2}$$

where D_f is the deflection of the specimen at the middle of the support span, F is the load at a given point of the load-deflection curve, L is the support span, b and d are the sample width and depth, respectively.

Typical stress-strain curves usually obtained from three-point bending tests was reported in Fig. 32.



NOTE—Curve a: Specimen that breaks before yielding.
Curve b: Specimen that yields and then breaks before the 5 % strain limit.
Curve c: Specimen that neither yields nor breaks before the 5 % strain limit.

Figure 32 Typical curves of flexural stress versus flexural strain obtained from three-point bending tests, according to the ASTM D790.

Three-point bending tests on the two different kinds of printed "building blocks" made of Z-ABS and Z-UltraT evidenced similar stress-strain curves (Fig. 33).

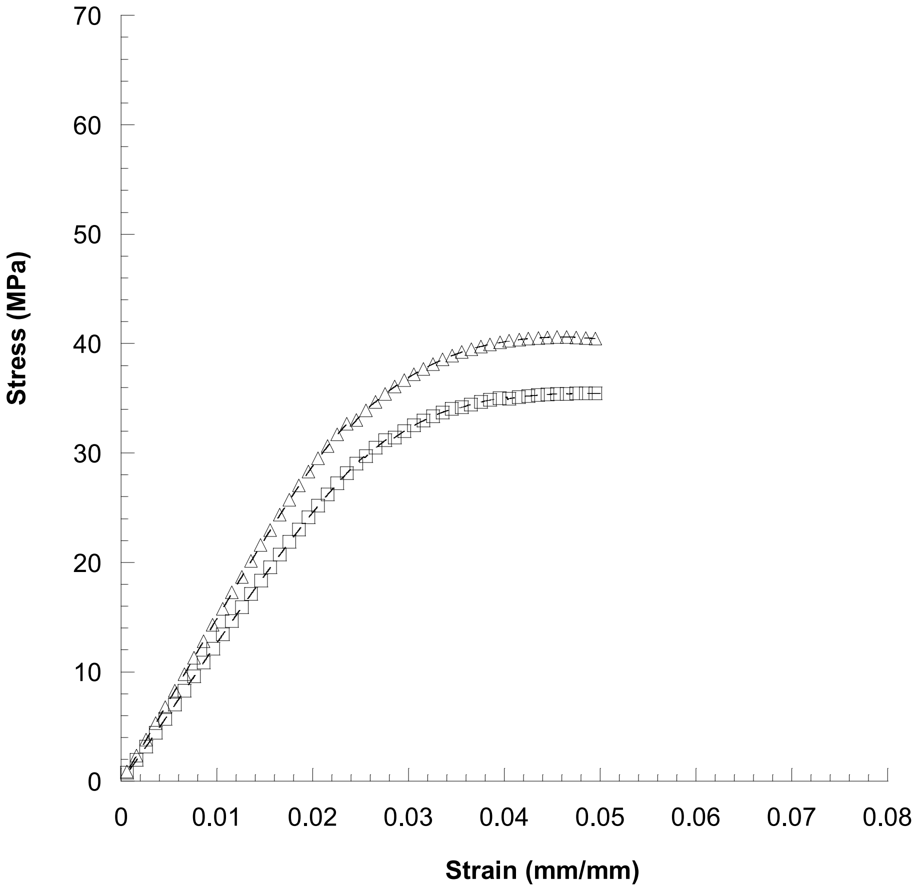


Figure 33 Typical stress-strain curves obtained from three-point bending tests on the two different kinds of printed "building blocks" made of Z-ABS (□) and Z- UltraT (Δ).

An initial linear region of the stress–strain curve was evident. Then, a decrease of the slope was observed.

Bending modulus (i.e., the slope of the linear region of the curve) and maximum stress were evaluated and reported as mean value ± standard deviation (Table 3).

Sample	***E*** ***(MPa)***	$\sigma_{max} = \sigma_{fc}$ ***(MPa)***
Z - ABS	*1217.3 ± 44.4*	*33.8 ± 0.6*
Z - ULTRA T	*1400.7 ± 47.7*	*39.2 ± 0.6*

Table 3 Results obtained from three-point bending: modulus (E) and maximum stress (σ_{max}) reported as mean value ± standard deviation.

According to the ASTM D790, as all the specimens neither yields nor break before the 5% limit, σ_{max} was equal to σ_{fc} (flexural stress at 5 % strain limit).

As reported in Table 3, Z-UltraT provided higher values of modulus and maximum stress than those obtained from Z-ABS.

Chapter 4

Development of 3D Additive Manufactured and Customized Devices for Biomedical Applications

4.1 Image Capture and Analysis

The treatment of particular bone fractures (i.e., wrist and arm), rheumatoid arthritis or post-surgical orthopedic rehabilitation require the prolonged immobilization of skeletal muscle system.

Many problems are usually related to traditional custom-made splints and supports, such as poor aesthetics, discomfort, excessive perspiration leading to odor issues, difficulties in cleaning, etc. To overcome the above mentioned problems and to improve the patients' compliance, in recent years the integration of Reverse Engineering (RE) and Additive Manufacturing (AM) has been proposed in the field of orthopedics and rehabilitation Reverse engineering and Additive Manufacturing may be suitably integrated to develop 3D customized devices for biomedical applications

Different physical models of orthosis devices were developed using the reverse engineering approach and the FDM technique. Benefiting from the Reverse Engineering approach, the information about the shape and size of the arms was obtained using laser scanning for image capture and then image analysis techniques.

The acquisition of 3D anatomical data with laser scanner generates a high resolution model.

The images were properly acquired and elaborated using graphic softwares (i.e., Aigisoft Photoscan Professional, Geomagic…) and all the models were further optimized.

An example of preliminary images are reported below (Fig. 34).

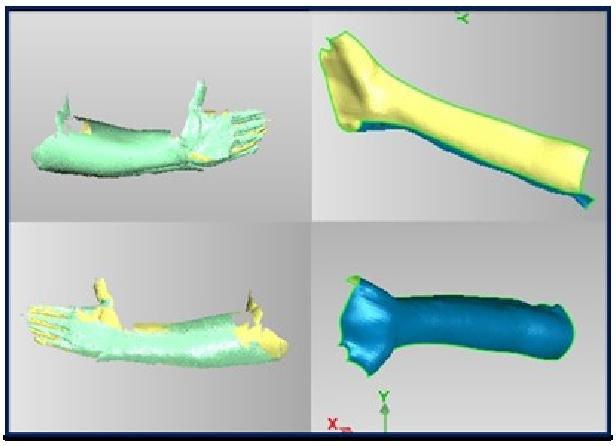


Figure 34 Acquisition of anatomical data through a 3D laser scanner.

4.2 Development of 3D additive manufactured and customized devices

Once all the features related to the virtual reconstruction have been done, different orthosis devices physical models were fabricated by FDM.

Benefiting from different approaches on topology optimization and finite element analysis, the proposed two-shell model with holes was properly optimized as holes with different geometries were initially considered (Fig. 35 and Fig. 36).

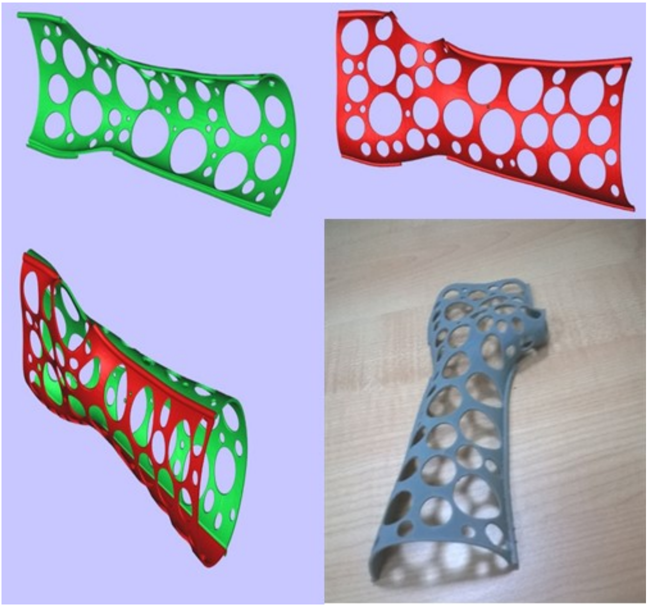


Figure 35 Images of a preliminary custom-made model obtained by integrating reverse engineering and additive manufacturing.

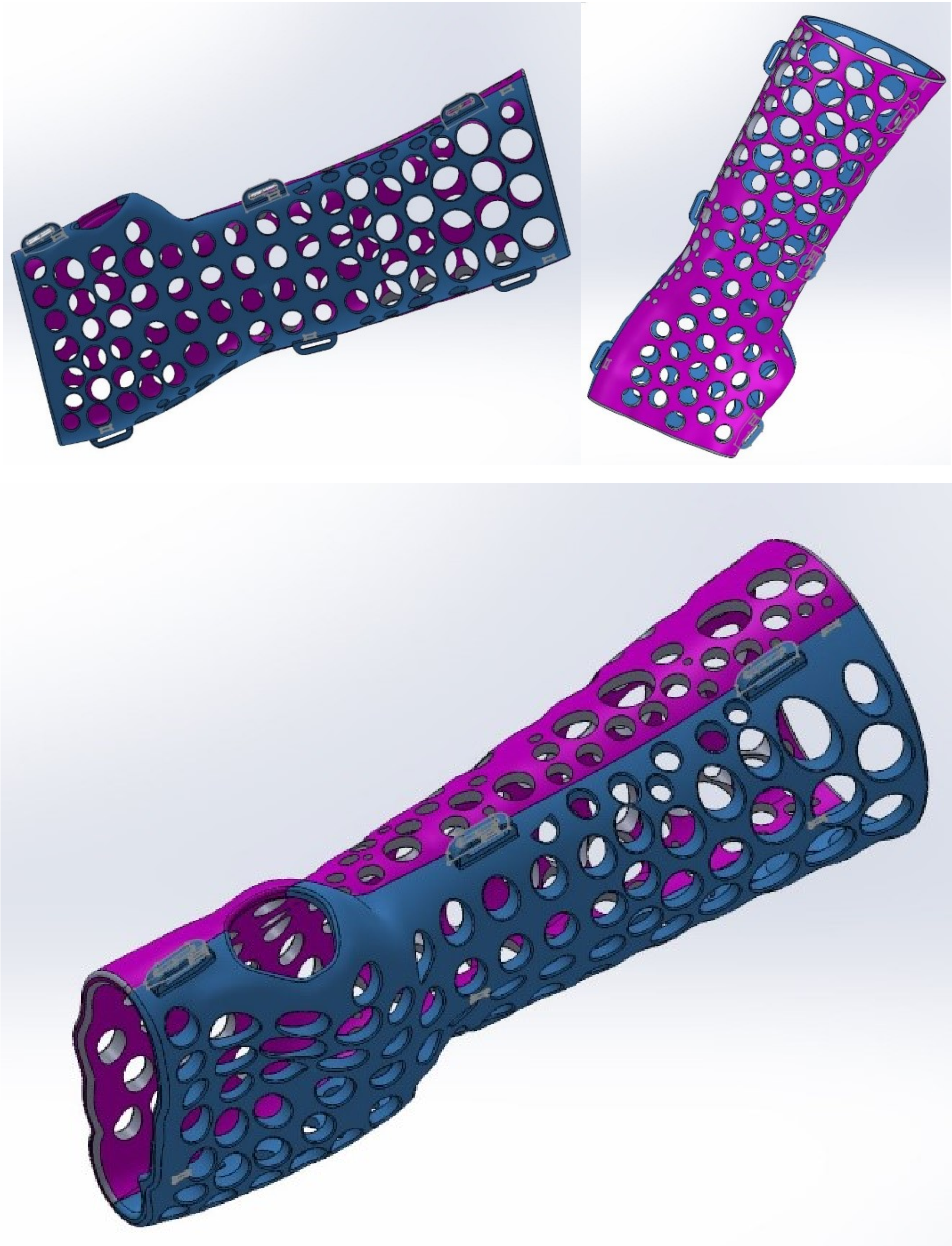


Figure 36 Images of the final customized model obtained by integrating Reverse Engineering and Additive Manufacturing.

Accordingly, different customized models were developed by Reverse Engineering and Additive Manufacturing (Fig. 37).

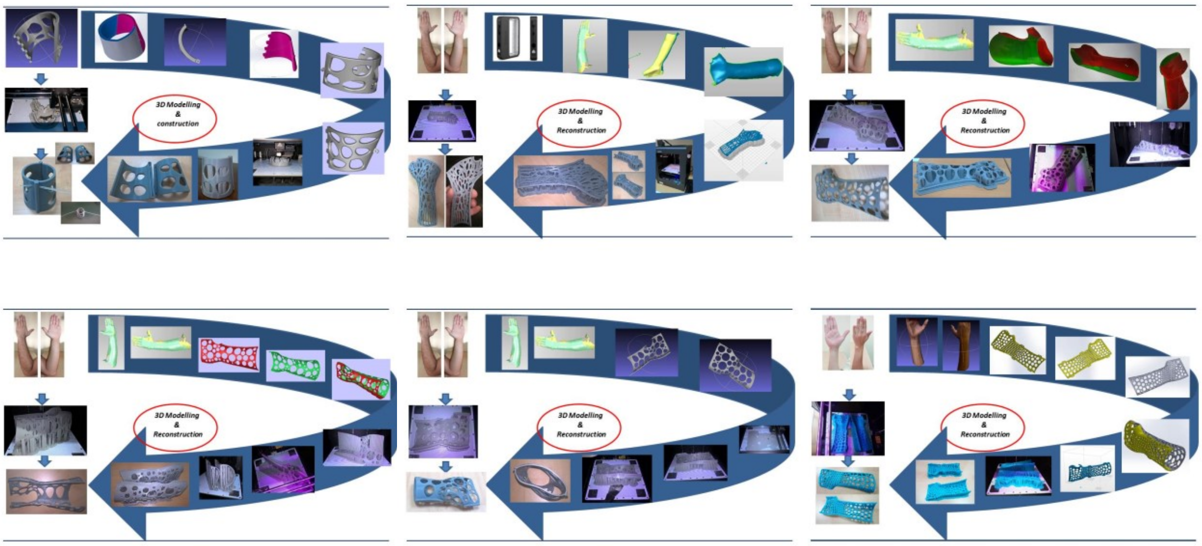


Figure 37 Design of a physical model integrating image capture and analysis techniques with FDM.

However, theoretical analyses (i.e., finite element analysis) were performed at different level of the process to optimize the design of the final device.

Accordingly, all of the developed were analysed by applying specific loads along the different directions to map von Mises stresses, displacements and safety factor (Fig. 38 – 40).

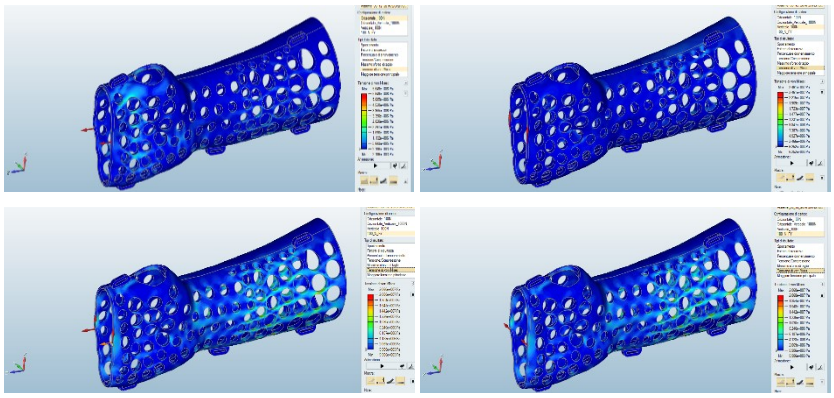


Figure 38 Theoretical analyses: von Mises stresses.

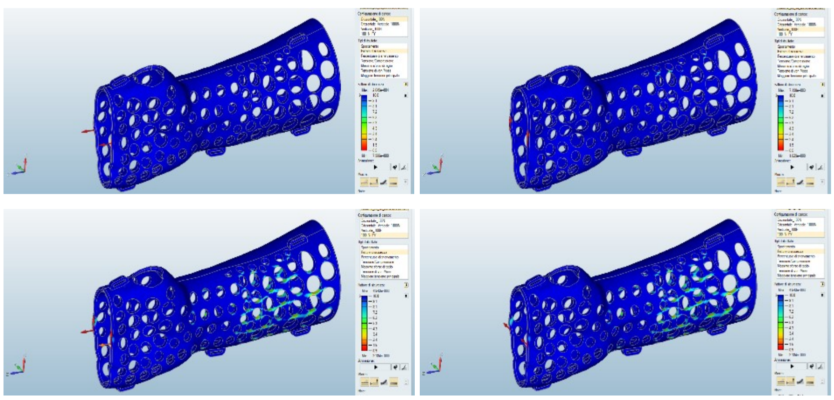


Figure 39 Theoretical analyses: safety factor.

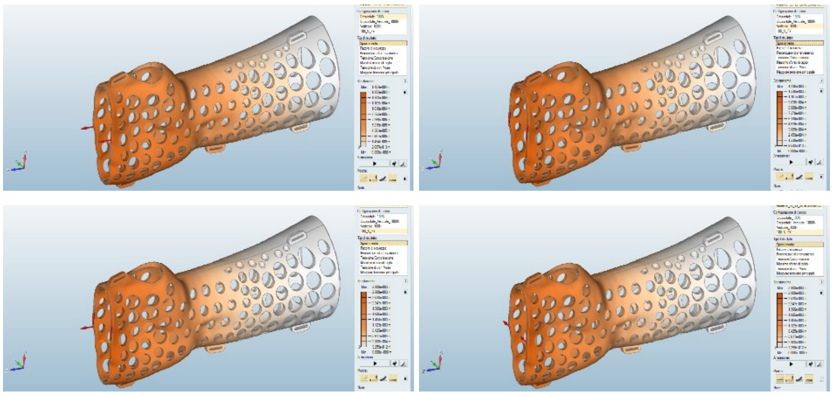


Figure 40 Theoretical analyses: displacements.

4.3 Conclusions and Future Trends

Customized orthosis devices were developed using the reverse engineering process and FDM technology combined with simulation/modeling process, topological optimization, analysis of material properties, to meet the mechanical/functional requirements. In addition, many reports and documents were also made concerning the ethical issues and several meetings involving the medical staff of local hospitals were attended. Clinical trials are still ongoing.

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