Additive Manufacturing Systems for Medical Applications: Case Studies

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1 Introduction

Additive manufacturing is a bioinspired layer-by-layer fabrication technique that emerged in the mid of 1980s, and since then is growing very fast. Currently, additive manufacturing is being used in several fields such as aerospace, aeronautics, consumer goods, construction and medicine (Verhoef et al. 2018). It is a key technology for the implementation of smart, efficient and minimal waste strategies for mass personalization. The use of additive manufacturing in the medical field is expanding very fast due to the ability to produce complex, low weight and personalized medical devices in a wide range of biocompatible, degradable and nondegradable materials such as polymers, metals, ceramics and composites (Tibbitt et al. 2015). It also allows printing biological materials such as cells. In this field, additive manufacturing is being used to produce passive devices for repairing and restore applications and active devices for repairing, restoring, and regeneration (Ligon et al. 2017). This chapter introduces the main additive manufacturing techniques being used in the medical field, discusses main process steps and presents several case studies including the development of a hand-wrist-forearm orthosis, personalized insoles and bone composite scaffolds for regenerative medicine.

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2 Overview of Additive Manufacturing Systems in Biomedical Applications

Additive manufacturing is defined as the process of joining materials in order to make objects from 3D digital models in a layer-by-layer way, as opposed to either subtractive or shape forming manufacturing technologies (Chua and Leong 2014). The main features of additive manufacturing are its ability to produce parts of virtually any shape and high complexity in one process step, with less material and energy, reducing assembly requirements by consolidating parts into a single component. It disrupts the traditional supply chain, allowing for goods to be produced closer to the point of use at the time of need and dramatically shrinking the time between design creation and prototyping (Gibson et al. 2015). It is also the ideal technology to create lightweight structures without requiring expensive tooling. It is also possible to process a wide range of materials such as polymers, ceramics, metals, composites and biological materials (e.g. cells and growth factors). Multi-material objects, geometric or material functionally gradient structures can also be produced at multiple scales. Main limitations of additive manufacturing processes are related to the slow build rates, production costs resulting from the slow build rate and material costs (metal powder and photopolymers), component anisotropy, poor surface finish and dimensional accuracy. Additive manufacturing processes for medical applications comprise the following techniques (Almeida and Correia 2016; Gibson et al. 2015):

- Vat Photopolymerization—an additive manufacturing process in which a liquid photopolymer in a vat is selectively cured by light-activated polymerization.
- Powder bed Fusion—an additive manufacturing process in which thermal energy selectively fuses regions of a powder bed.
- Material Extrusion—an additive manufacturing process in which material is selectively dispensed through a nozzle.
- Binder Jetting—an additive manufacturing process in which a liquid bonding agent is selectively deposited to join powder materials.
- Material Jetting—an additive manufacturing process in which droplets of build material are selectively deposited.

The information chain applied to additive manufacturing processes for medical applications comprises the following steps as illustrated in Fig. 1:

More specifically, Fig. 2 provides a general overview of the necessary steps to produce passive/non-biological and active/biological structures for medical applications using additive manufacturing. The first step is the generation of the corresponding computer solid model through one of the currently available medical imaging techniques, such as computed tomography (CT) or magnetic resonance imaging. These imaging methods produce continuous volumetric data (voxel-based data), that provides the input data for the digital model generation (Almeida and Bártolo 2013). If the external geometric body data is necessary, common 3D scanning systems may be used. Depending on the type of product, two different routes can be considered. The fabrication of passive products usually requires the use of nondegradable materials

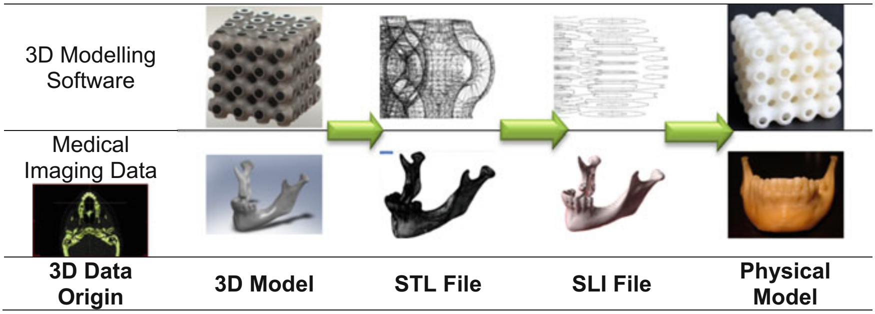

Fig. 1 Flowchart of digital information to produce physical models

and the fabrication process follows the steps commonly used to produce any kind of products using additive manufacturing. Active products usually require the use of cells. They can be directly printed embedded in hydrogels or seeded on biodegradable 3D structures. In most cases, constructs are pre-cultured before implantation.

2.1 Vat Photopolymerization Processes

Vat photopolymerization has been used by the Texas Cardiac Arrhythmia Institute to produce accurate patients' hearts models based on CT data for surgery planning. This technique is also being extensively used for dental applications (Fig. 3), hearing aids and lattice structures and biodegradable scaffolds for tissue engineering.

2.2 Powder Bed Fusion

Powder bed fusion processes have been explored by Ekso Bionics (Northern California, USA) to produce customized, lightweight parts for a bionic suit for a patient confined to a wheelchair as a result of an accident (Fig. 4). This additive manufacturing technique has been also used to produce personalized medical devices such as ankle/foot orthosis with improved material and design characteristics preventing, for example, excessive sweating (Fig. 5) and lightweight orthopaedic titanium implants and dental cobalt implants (Fig. 6). The EBM technique has been used to produce a wide range of implants such as sculpt plates and acetabular cups (Fig. 7) and knee implants with density gradients representing the high-end trabecular region (approx. 0.8 g/cm^3) and the low-end cortical bone region (approx. 1.5 g/cm^3) (Murr et al. 2010).

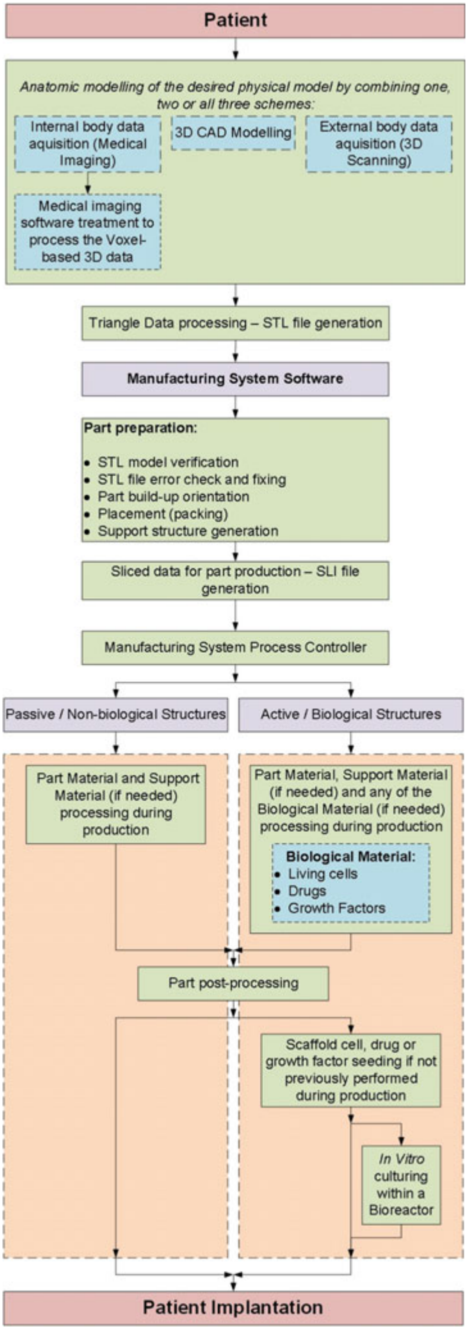

Fig. 2 Process flowchart for the production of passive/non-biological and active/biological structures for medical applications using additive manufacturing

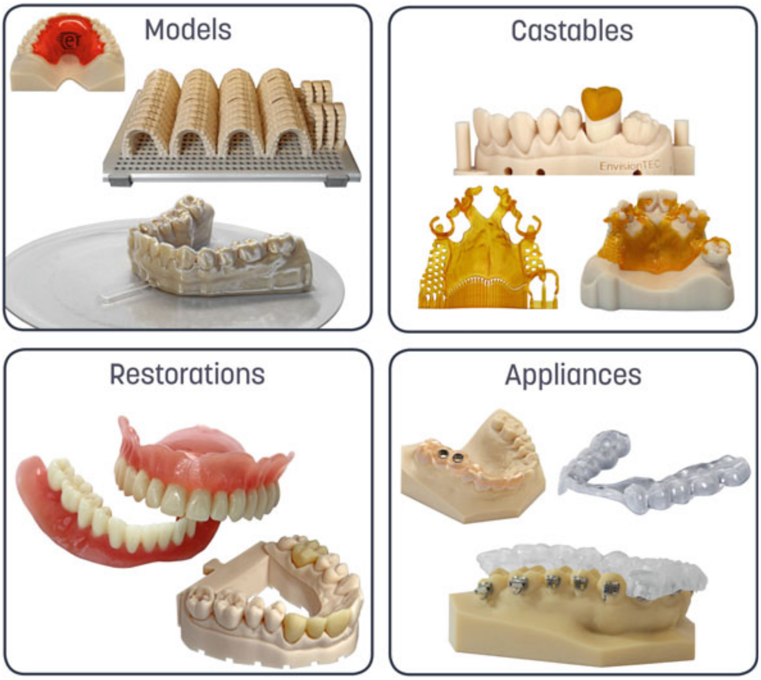

Fig. 3 Dental applications of vat photopolymerisation (EnvisionTEC 2017)

Fig. 4 Ekso Bionics suit (3D Systems 2017)

2.3 *Material Extrusion*

For tissue engineering applications and to process biological materials, new systems have been developed. An example is the BioScaffolder from Gesim, a biomanufac-

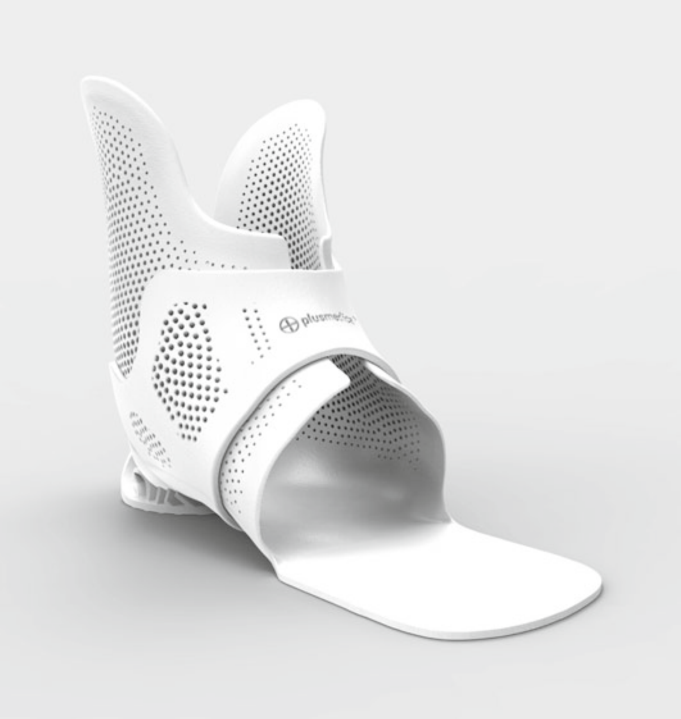

Fig. 5 Ankle/foot polymer orthosis (EOS 2017)

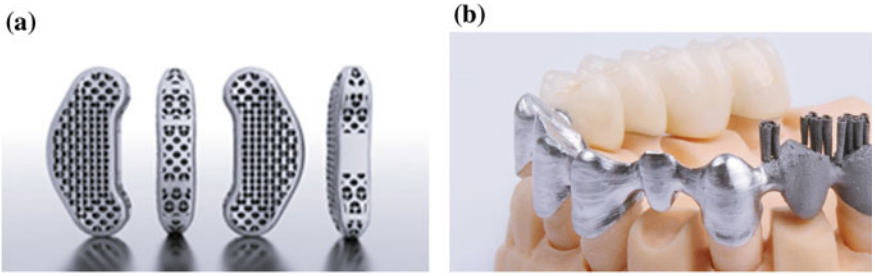

Fig. 6 **a** Orthopaedic titanium implants **b** Dental cobalt implants (EOS GmbH 2017)

turing extrusion-based system able to process synthetic polymers, polymer/ceramics and soft materials such as hydrogels including biomolecular signals such as growth factors (Fig. 8) (Gesim 2017).

Another example is the 3D-Bioplotter from EnvisionTEC capable of producing a wide range of soft and hard scaffolds using single or multiple materials (Fig. 9) (EnvisionTEC 2017).

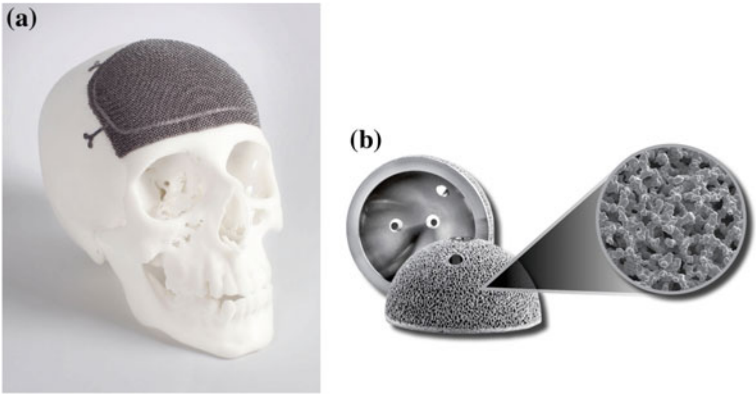

Fig. 7 **a** Custom sculpt implant **b** Acetabular cups with integrated lattice structures for improved osseointegration (Arcam EBM 2017)

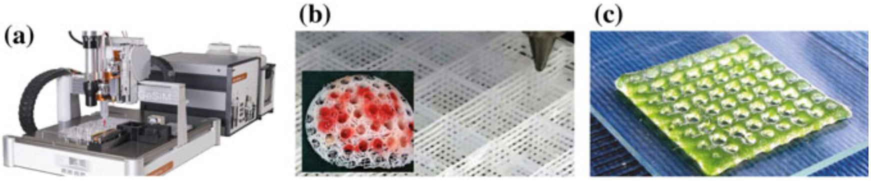

Fig. 8 **a** BioScaffolder 3.1 system **b** medical-grade PCL scaffold to reconstruct the shape and volume of a female breast after mastectomy **c** human cells printed onto an alginate/hydrogel scaffold (Gesim 2017)

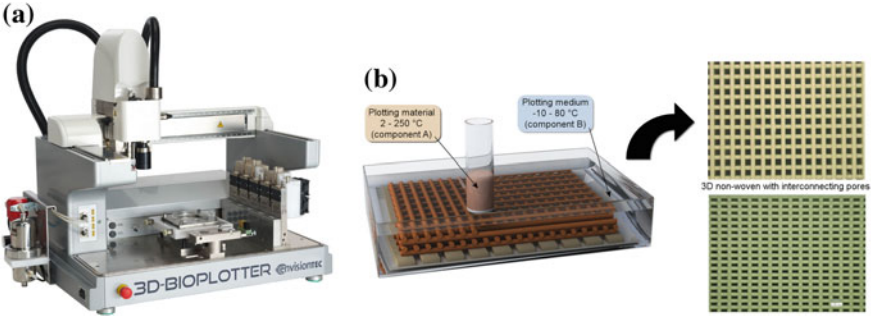

Fig. 9 **a** Fourth generation 3D Bioplotter manufacturer series **b** with a schematic of the building platform (EnvisionTEC 2017)

Extrusion processes have been extensively used in the medical field, for example, to develop a more realistic airway trainer (Fig. 10a), for the fabrication of customized moulds for the pressing of a thin titanium sheet that will act as an orbital floor implant (Fig. 10b), for the fabrication of bone bio-models for in-depth assessment and pre-surgical rehearsal resulting in a smoother operation process in which implants

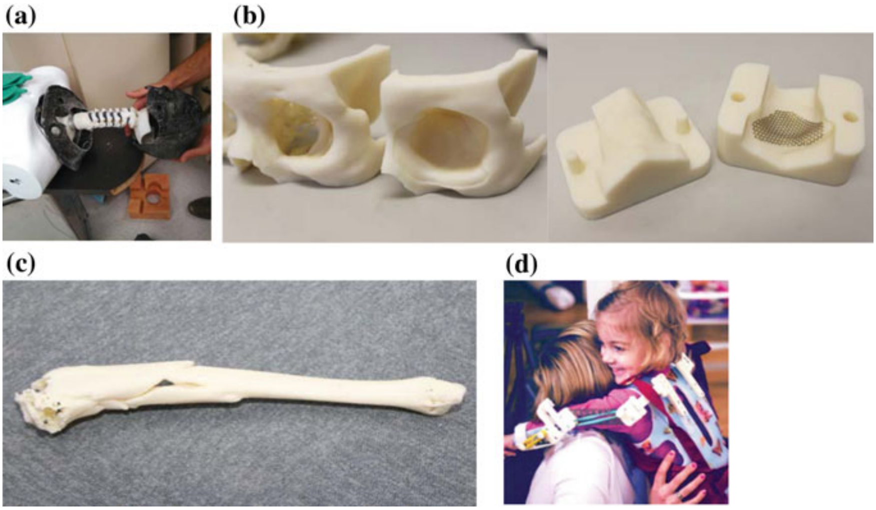

Fig. 10 **a** Technician assembling a prototype airway trainer. **b** Patient's missing orbital floor (left) versus original shape before impact (right) and the customized mould for titanium sheet pressing. **c** Corrective osteotomy (realignment of bone from deformity) to complex bone fractures. **d** Custom orthopaedic exoskeleton

are more accurately fitted to the curvature of the patient's bone (Fig. 10c) and the fabrication of exoskeletons (Figs. 10d) (Stratasys 2017).

2.4 Inkjet Printing Processes

Inkjet printing has been used to produce vascular tissue samples and other types of tissue constructs for bone, cartilage and nerve regeneration (Cyfuse 2017; Itoh et al. 2015). Other examples include middle ear prostheses and realistic anatomic models (Fig. 11).

3 Case Studies of Additive Manufacturing in Healthcare

Additive manufacturing is considered a groundbreaking technology mainly because of its potential to be used in areas like healthcare. Figure 12 shows many possibilities of additive manufacturing to be used in the healthcare ranging from specific devices to research protocols. One key element is the integration of CT scanner dataset to the additive manufacturing machines by means of medical image processing tool associated to CAD and CAE tools to directly or indirectly produce such solutions.

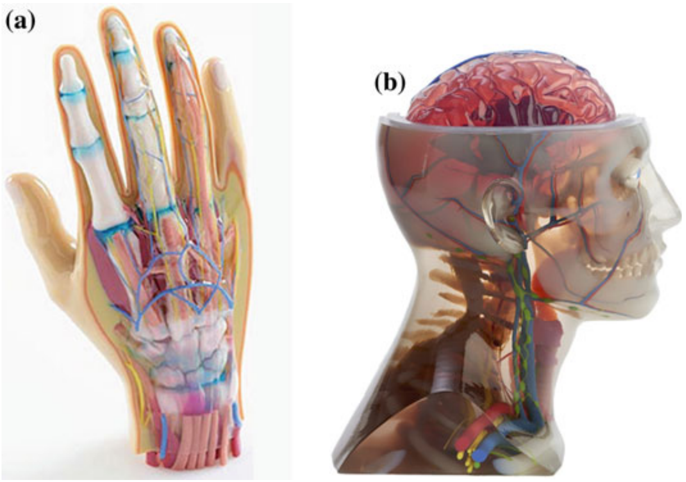

Fig. 11 Realistic anatomic presentations models of the **a** hand and the **b** head illustrating all existing tissues (Stratasys Polyjet 2017)

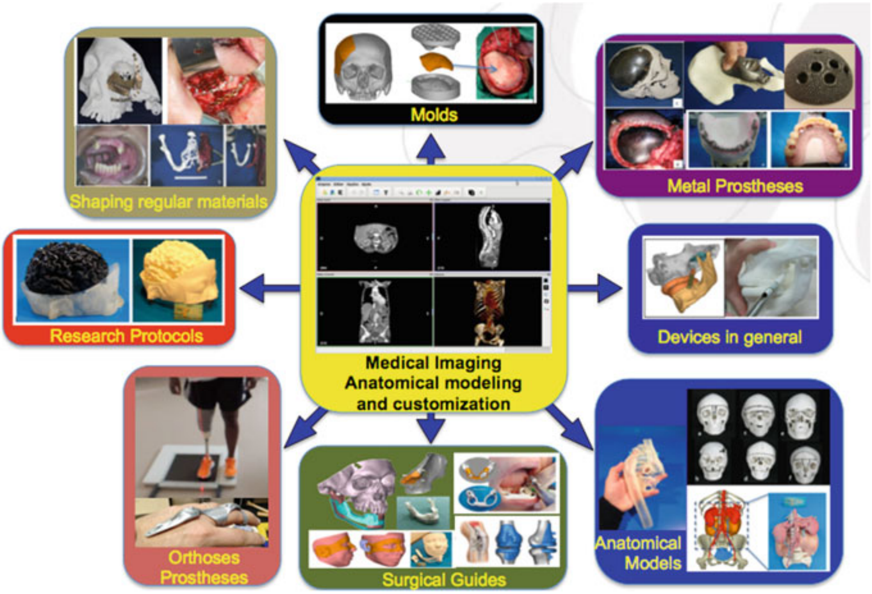

Fig. 12 The use of additive manufacturing to improve healthcare solutions

Next sections will provide some real case studies of using additive manufacturing as new healthcare technologies.

Fig. 13 3D digital scanning procedure

3.1 Hand-Wrist-Forearm Orthosis

An orthosis is an external component applied to the body in order to facilitate the execution of a task, to compensate for any deformities, reinforcing treatment of disease or even prevent diseases in the trunk and limbs. There is a great diversity of orthoses for the trunk, with different characteristics and different purposes which can be classified into Cervical Orthoses; Cervical Thoracic Orthoses; Cervico-Thoraco-Lumbo-Sacral Orthoses; Thoraco-Lumbo-Sacral Orthoses; Lumbo-Sacral Orthoses; Sacroiliac Orthoses and Hand-Wrist-Forearm Orthoses (Matos et al. 2017). Commercially available orthoses are not personalized and all have a negative aesthetical impact during the time prescribed to use. Combining digital scanning and additive manufacturing systems into the production of this particular family of products increases both the functionality of the products as well as its aesthetics and appealing design towards the customers. For a better understanding of the steps involved in a medical application, a case study of a hand-wrist-forearm orthosis is presented. The case study will follow the process flowchart presented in Fig. 2. The first main step consists in obtaining the CAD data of the outer shape of the patient's hand-wrist-forearm in order to design the orthosis. In this case, a 3D digital scanning system (GOM ATOS CORE) with a scanning volume of 300 cm^3, was used as illustrated in Fig. 13. The scanned data is then processed (removal of noise data, filtering geometric data, filling of gaps and wholes, point cloud matching) to create a corresponding CAD model. Figure 14 shows the completed hand-wrist-forearm CAD model (light grey) with an initial solid design of the orthosis (dark grey).

Finally, the optimized design was produced in polyamide (PA 12) using the inkjet HP Jet Fusion 3D 4200 Printing system. In this case, the CAD model is manipulated using the machine building manager software (SmartStream 3D Build Manager) and positioned in the printing platform in three different positions, namely laying down, lateral and upright (Fig. 15) in order to determine building time. In the laying down position, the two halves of the orthosis occupy 1.78% of the building chamber that corresponds to a maximum building height of 63.05 mm and a building time of 3 h

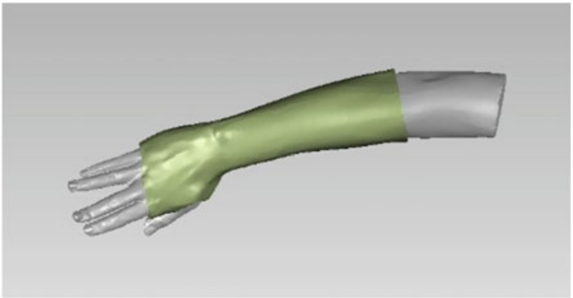

Fig. 14 Hand-wrist-forearm CAD model (light grey) and orthosis (dark grey)

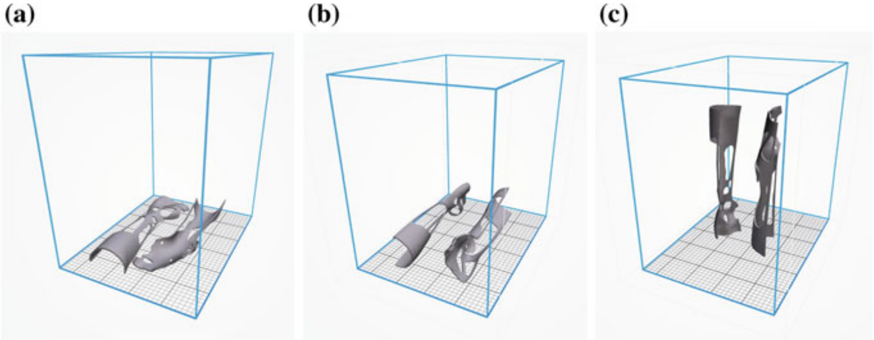

Fig. 15 **a** Laying down, **b** lateral and **c** upright position of the orthosis parts for production

59 min 10 s. In the lateral position, both parts occupy 1.3% of the building chamber that corresponds to a maximum building height of 86.54 mm and a building time of 4 h 54 min 09 s. Finally, in the upright position, the two halves of the orthosis occupy 0.36% of the building chamber that corresponds to a maximum building height of 310.02 mm and a building time of 13 h 37 min 30 s. As the staircase effect was not significant in any of the trees considered orientations, the laying down position was selected due to the lowest building time. After printing, the models were submitted to a series of post-processing steps, namely, excess powder removal, and then air jetting for the removal of the unprocessed powder on the part (Figs. 16 and 17) and finally tested (Fig. 18).

3.2 *Finger Orthosis*

Another case of orthosis production using additive manufacturing is a device to attach on fingers to keep them opened by means of strings. The patient is a pianist and conductor, one of the most important world interpreters of Bach compositions. Due to

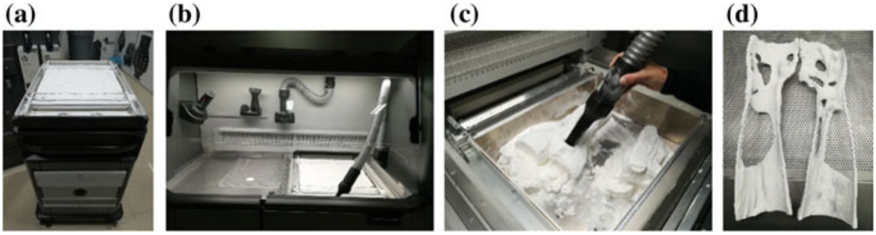

Fig. 16 **a** Building chamber removal from printer **b** building chamber insertion into the processing station **c** vacuum to remove of the excess powder and **d** parts with excess powder

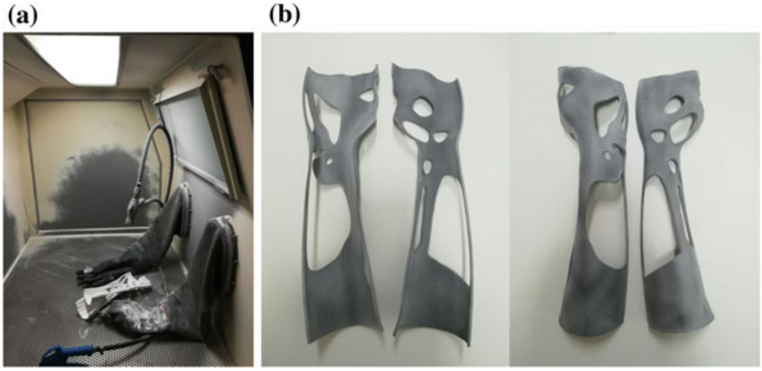

Fig. 17 **a** Air jetting chamber for excess powder removal and **b** final parts of the orthosis

Fig. 18 Patient testing the orthosis

the advanced age and genetic predisposition, the patient suffers from a neurological disease that makes it difficult to control opening some fingers, and consequently not permitting a good piano performance. Together with his physiotherapist, engineers developed an experimental device that could not occupy space between fingers guarantying free relative movements. Figure 19 shows the process utilized to produce the experimental orthotic device. His hand was digitized opened using a laser scanner (Creaform HandScan 3D) and generating a 3D mesh. The 3D model of the hand

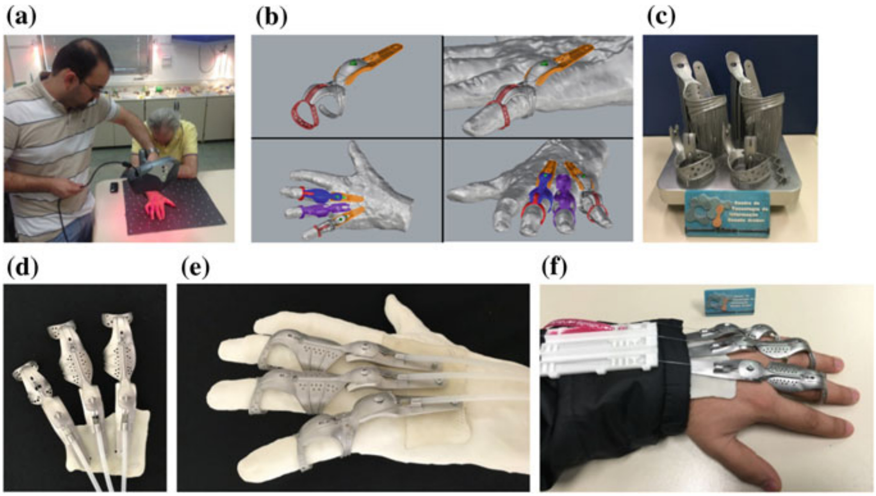

Fig. 19 Personalized finger orthotic device for a patient with neurological disease that affects finger opening. **a** scanning the patient's hand **b** CAD Design based on 3D model of the hand **c** orthotic parts printed in Cr–Co metal additive manufacturing, after structural optimization using FEM **d** orthotic device assembled **e** orthotic device mounted on the Polyamide model of the hand, and **f** device mounted on a real hand (not the patient's hand)

was used for the device design and Finite Element Method (FEM) simulation, considering metal material printed in a Selective Laser Melting machine (ConcepLaser MLab 100). The 3D model of the hand was also printed in a Selective Laser Sintering machine (3D Systems HiQ) using Polyamide 12 for fitting tests before sending it to the patient for evaluation. The FEM simulation permitted to design thinner structures of about 0.5 mm. Three versions of the device were produced and tested by the patient, always with physiotherapist assistance. All versions took into account some premises like the good stiffness properties of the metal material used (Co–Cr), complex geometries and monolithic structures with relative movement, obtained using additive manufacturing advantages. The design took into account usability, easy to wear, and facility to calibrate the forces of the strings to keep fingers opened with the right forces to permit open–close movement under patient control.

3.3 Mandibular Reconstruction Using Autologous Bone and Cutting Guides

Figure 20 shows a patient with a severe anomaly in the low jaw in need of reconstruction and the doctor's decision was to use an autologous bone harvested from tibia to remodel the mandible in a more anatomic shape with possibility to fix dental implants after healing in the future. A series of CT scan images were taken from the

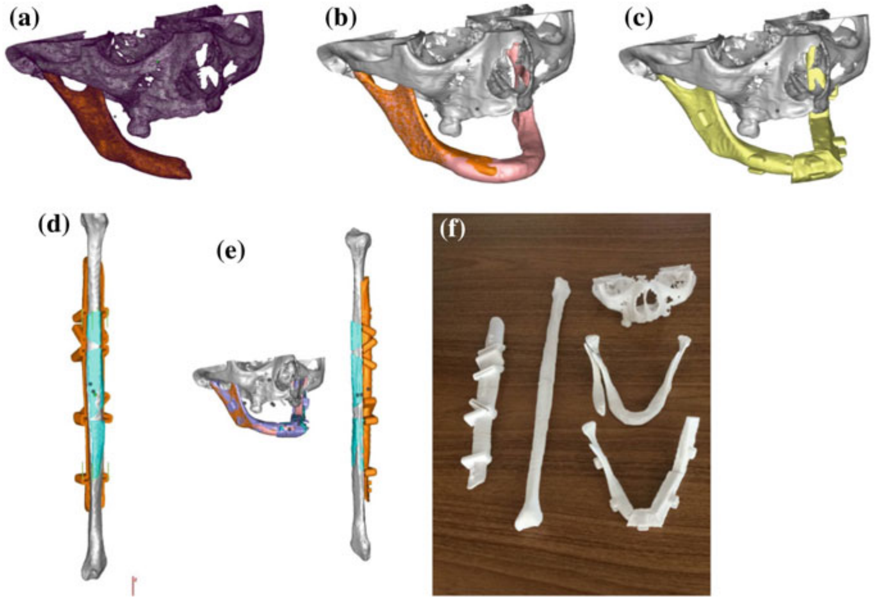

Fig. 20 A surgical planning for mandible reconstruction with autologous bone **a** STL file of the patient's maxilla and mandible obtained from image processing on CT dataset **b** mirroring mandible to start virtual reconstruction **c** virtual reconstruction of mandible using tibia's bone **d** and **e** virtual model of tibia and cutting guides designed to optimize harvesting time and amount of bone and **f** virtual planning and anatomical models of the maxilla, mandible and tibia printed in Polyamide 12 (3D Systems—HiQ)

head of patient and tibia. The CT images were segmented and a STL file generated using specific open-source software (CTI Renato Archer—InVesalius) for medical image processing, both from mandible and tibia. The patient mandible was mirrored in STL manipulator software (Materialize—Magics) in order to reconstruct missing regions of the mandible bone. The tibia's bone was measured to complete the missing bones of reconstructed mandible and cutting guides were designed to cut the tibia in many small parts for the mandible graft. The whole process focused on reducing surgery time and costs, besides risks for the patient with less morbidity due to the second surgery for bone harvesting in the tibia. All virtual models of the anatomies, guides and virtual planning were printed in Polyamide 12 to be sterilized and used in intra surgery. The guides were used for precise bone cutting.

3.4 Customized Cranial Prostheses

Cranioplasty is a very common procedure to repair cranial defects due to many kinds of accidents that can lead to a cranial bone loss, many times due to a cranial decom-

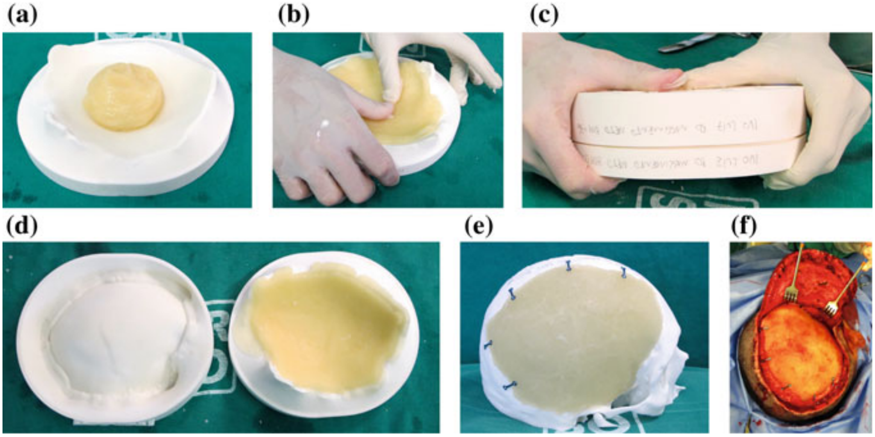

Fig. 21 Customized cranial plates produced in PMMA **a** Mould produced in additive manufacturing in Polyamide 12 **b** Spreading the PMMA mix inside the mould **c** closing the mould **d** opening the mould to reveal the customized cranial plate after cooling down the PMMA **e** fitting tests in a skull biomodel, and **f** placing PMMA cranial plate in the patient

pression to relief intracranial pressure. Materials and surgical techniques are still in development and the use of medical imaging associated with additive manufacturing can bring great potential to solve elegantly this problem. A patient with need for cranioplasty presents drawbacks not only socially because of his/her appearance but also the psychological ones. Biological materials like autografts and xenograft from many different regions of the body are still in use but can cause higher morbidity. Synthetic materials as metal alloys, polymers, and ceramics are also options. In the polymer's domain, the Poly(methyl methacrylate) (PMMA) is a thermosetting material that has been used for bone repair and devices for bone attachment for more than 60 years and is also known as bone cement. PMMA is an ordinary product in the medical market, very easy to manipulate and shape, can incorporate drugs, and cost-effective. One of the most important drawbacks of PMMA is its exothermic polymerization reaction when the two components are mixed before hardening, that can cause burns to the patient's tissue. Figure 21 presents a cranial reconstruction technique that uses medical imaging, CAD design and additive manufacturing to produce moulds for customized cranial plates production. This kind of device can be sterilized and brought to the surgery. During surgery, a mix of the two components of PMMA is produced and moulded. After moulding the cranial plate, it can be fit tested in the patient's skull biomodel for eventual adjustments and implanted in patient with a high degree of customization without the drawbacks abovementioned. Different from metal alloy plates for cranioplasty, the PMMA can be calculated to behave like bone in the case of a second, rare but possible accident. In this case, the rest of the bone will not be impacted due to the energy dissipation breaking the PMMA and not the bone itself.

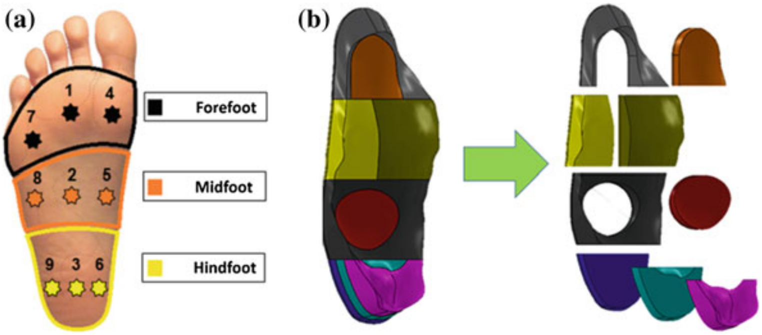

Fig. 22 **a** Foot plantar regions and sensor positions outline; **b** Insole design

3.5 *Personalized Insoles*

Insoles have been widely investigated in order to reduce the impact forces in the plantar pressure of the feet, as a method to treat medical diseases such as diabetic foot or knee osteoarthritis and to provide comfort to the end user. Currently, customized insoles are produced using labour intensive manual manufacturing processes characterized by high production times and costs, making its use restricted to critical patients and specific applications. Additive manufacturing plays a key role in the development of a novel strategy to develop customized made insoles. This strategy allows designing zonal regions in the insole with different stiffness regions defined according to the information obtained from a pressure distribution analysis of the foot.

Plantar pedal pressures and specific forces were determined in an individual who had no known history of foot problems and no pathological gate. Two different tests were employed. First, a pressure distribution mapping during both static pose and walking was performed with the individual barefoot. Second, force sensors were used to determine specific forces and nine different points in the foot (Fig. 22a) with the individual using casual shoes. The measurements were taken on both feet.

From the first test, a pressure distribution map was obtained from the static analysis (Fig. 23) and a force versus time variation was obtained from the dynamic analysis (Fig. 24a). From the second tests, force variation with time was obtained from a number of steps taken and the obtained data analysed to produce mean results for the analysis. For the insole design, both individual's feet were scanned using commercial handy scan 3D Exsys Scan System. The insole was divided into nine parts (Fig. 22b), allowing to modify each part's mechanical characteristics by changing material or fabrication parameters. In the case reported here, only silicon is considered. Insoles were produced using the EnvisionTEC 3D Bioplotter system. The produced insole was then tested by the patient and a second force versus time variation was obtained from the dynamic analysis (Fig. 24b). As illustrated in Fig. 24, the patient produced much less force versus time variation during the gait analysis of the left foot. The

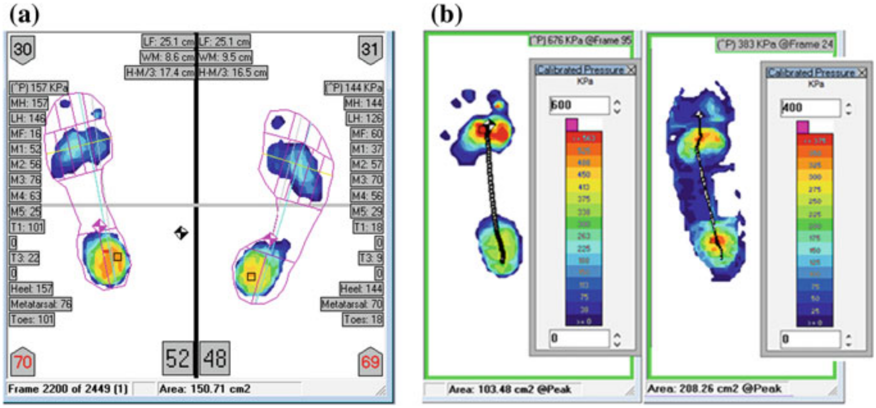

Fig. 23 **a** Static pressure distribution mapping example; **b** Left plantar pressure distribution mapping from walking analysis without insole (left) and with the produced insole (right)

force values reduced from pick values of 227.17 lb and 268.73 lb to 90.16 lb and 93.41 lb. A reduction of 39.69% and 34.76%, respectively was achieved.

3.6 Bone Composite Scaffolds for Regenerative Medicine

Scaffolds are 3D porous structures that provide the right environment for cell attachment, proliferation and differentiation. They must be biocompatible, biodegradable, with adequate mechanical performance that depends on the target tissue. A wide range of both organic and inorganic materials and composites have been explored for the fabrication of scaffolds for different tissues such as bone, cartilage, skin, nerve and muscle. The development of these scaffolds requires the following:

- The design of the scaffold using a CAD system;
- Material and fabrication process selection;
- Generation of G-Code instructions for scaffold fabrication;
- Characterisation: morphological; mechanical; degradation and biological (in vitro cell studies and in vivo studies.

This case study corresponds to a composite scaffold for bone regeneration. The scaffold was made using polycaprolactone/carbon nanotube (PCL/CNT) blends containing different amounts of carbon nanotubes. Blends were prepared using a melt blending process. Scaffolds were produced using an extrusion-based screw-assisted system (3D Discovery, Regenhu) (Fig. 25) considering a 0o/90o lay-down pattern (Fig. 26) to obtain pores with a regular square geometry, maintain a constant filament distance of 730 μm. All the scaffolds were produced using a screw rotation velocity of 22rev/m, a feed rate or deposition velocity of 22 mm/s and a layer thickness of

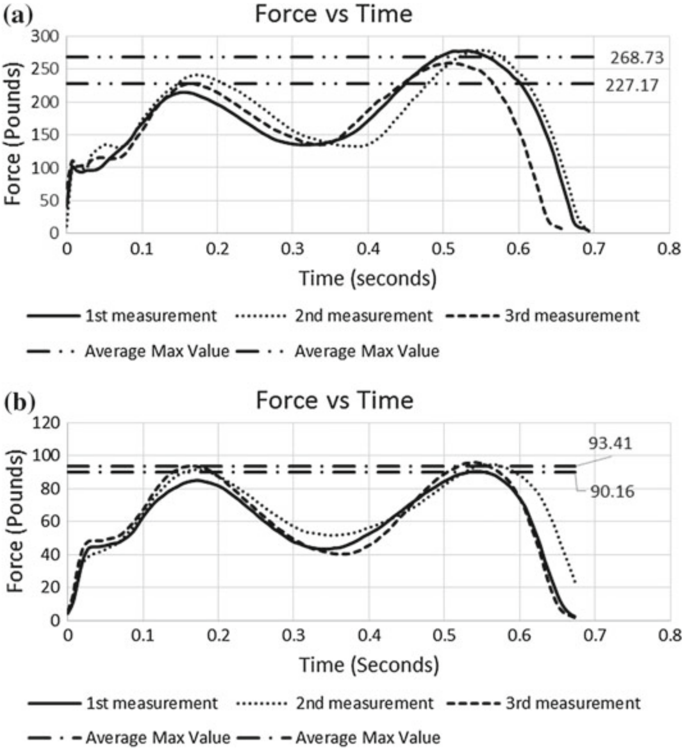

Fig. 24 **a** Force versus time curve for left foot walking analysis without insole; **b** Force versus time curve for left foot walking analysis with produced insole

0.22 mm. The needle diameter used was 0.33 mm with an air pressure of 6 bar and a processing temperature of 90 °C.

Carbon nanotubes are considered in order to improve mechanical properties and to induce some electrical characteristics to the polymeric scaffolds allowing their use for cell electrical stimulation. Scaffolds were morphologically accessed using scanning electron microscopy, mechanical tested under compression and biologically characterized. Produced scaffolds present uniform pore distribution and well-defined internal geometry. Adipose-derived human mesenchymal stem cells were used (Fig. 27). Cell attachment/proliferation was accessed using the Alarmar blue assay and cell differentiation accessed using the Alkaline Phosphatase (ALP) assay.

4 Conclusions

Additive manufacturing is a growing technology and has become part of mankind's daily life, namely, at a technological, economic and social level. It is a main topic of

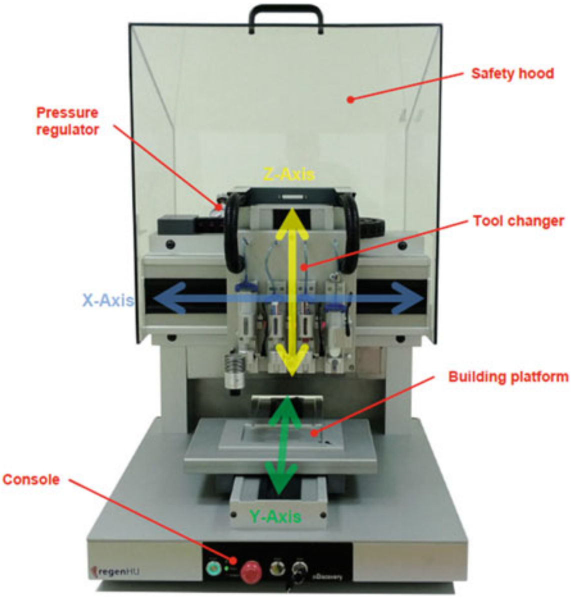

Fig. 25 3D discovery system from RegenHU

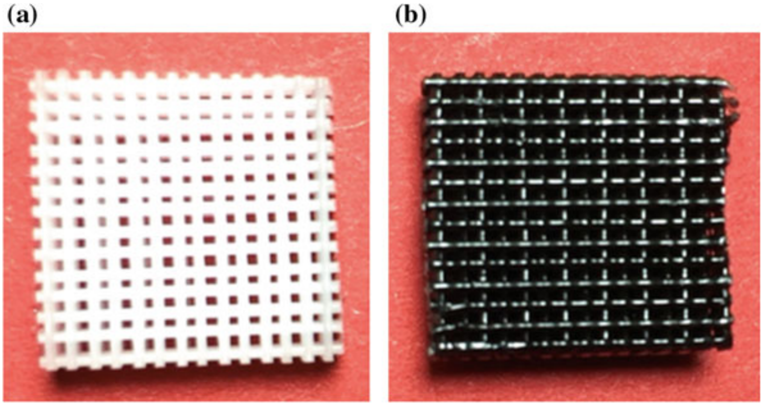

Fig. 26 **a** PCL and **b** PCL/CNT scaffolds

university lectures worldwide and it is applied by every industrial sector; in particular, it has been promoted in the medical field where its impact has increased and more and more systems are being acquired and developed for healthcare applications. Due to its capability to produce complex geometric parts directly from medical imaging data using biocompatible materials, additive manufacturing is a key technology for the fabrication of external (e.g. exoskeletons, or orthoses) and internal (permanent or temporary tissue implants) medical devices.

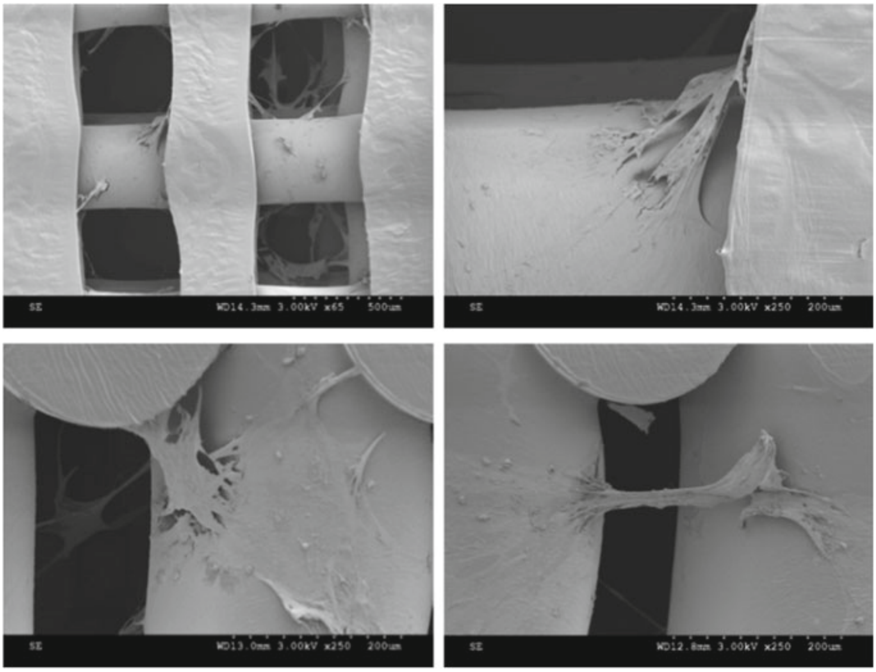

Fig. 27 Cell attachment and cell spreading on PCL scaffold with 0.2% CNT

This chapter presents an overview of additive manufacturing systems and how they have been used in the medical field for the production of medical devices. The main additive manufacturing techniques used are presented, main process steps detailed and several case studies such as the development of a hand-wrist-forearm and finger orthosis, mandibular reconstruction, cranial prostheses, personalized insoles and bone composite scaffolds for tissue engineering. In spite of the potential of additive manufacturing in the medical field, there are still many challenges to overcome. Some of these challenges include the need to produce functionality gradient structures; the need for more sophisticated systems (e.g. hybrid systems) able to create structures mimicking the biological ones (e.g. highly hierarchical and multi-material structures); novel in situ bioprinting strategies; and the improvement of mechanical properties in the fatigue behaviour. Standards are also required for the future developments of the field.

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External Resources: School of Technology and Management is currently the largest higher education institution in the district of Leiria. It provides undergraduate and master's degree, in the areas of engineering, technology, management, public administration and science. In addition to the aforementioned training courses, ESTG also promotes continuous training, service provision, scientific research and technology transfer, in both national and international levels. https://www.ipleiria.pt/estg.

The 3D EVER is a Certified Reseller of HP in Portugal, dedicated to representing their 3D printing technology named Multi Jet Fusion. This technology enables to print plastic parts in voxel-by-voxel fashion with printing agents. http://3d-ever.pt/en/inicial.

The Manchester Biomanufacturing Centre is a world leading research centre in the field of biomanufacturing. It integrates a group of multidisciplinary researchers and state-of-the-art equipment. The research program focus, among other topics, on computer-aided design and manufacturing of medical devices, biomaterials, design and fabrication of tissue scaffolds, tissue constructs and drug delivery systems, cell printing and organ printing. http://www.mace.manchester.ac.uk/our-research/centres-institutes/mbc/.

Renato Archer Information Technology Center–CTI, is one of the many R&D institutions from the Brazilian Science, Technology, Innovations and communications Ministry–MCTIC. CTI is located in Campinas, Brazil, the most advanced technological and research region of Latin America. The Three-Dimensional Technologies Research Group–NT3D was established in 1997 and since then is reference in the area of additive manufacturing, working closely with companies and hundreds of hospitals and universities in interdisciplinary researches. One of the most known research results of NT3D is the software InVesalius that is being used in 150 countries as an open-source platform for medial imaging. https://www.cti.gov.br/en.