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Ph.D. Thesis

Additive Manufacturing and Design Strategies for the Development of Advanced Biomedical Devices

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Table of Contents

Introduction

The study covers design methodologies for Additive Manufacturing (AM) applied to biomedical devices. In particular, the application of Triply Periodical Minimal Surfaces to implants plays a role in minimizing issues related to phenomena occurring at the bone-device interface. The capabilities of AM technologies have their foundation on enhancing shape, functional and material complexity leading to innovative applications. Many methodologies of DfAM are implemented at the state of the art and they include Light-weighting, Texturing and process Simulation. The light-weighting approaches are mostly represented by Topology Optimization and Lattice Structures. AM covers a wide range of materials ranging from polymers to metal and composites. The main technology for metal AM and biomedical devices is Selective Laser Melting (SLM). The AM process enables the customization of components resulting in patient-specific devices. Many applications have been carried out from cranioplasty to orthopedic implant. The material commonly used is Ti6Al4V which properties are appreciated in many fields and they are biocompatibility and corrosion resistance for biomedical applications.

The structure of the thesis is divided into four chapters. The first provides a general overview of the state of the art of Additive Manufacturing with focus on biomedical applications and methodologies applied to the next chapters. In Chapter II the investigation of a class of lattice structures, TPMS with variable thickness, is analyzed and mechanical properties coming from simulation are obtained. The work is completed by a case study of application of these structures on femoral hip stem. The third chapter presents the parametric design for customized Intervertebral Body Fusion Device manufactured in Metal AM with analyses and validation of the prototypes and the generation of a family of devices consisting in thirty-two configurations. Also, preliminary biological tests are performed to validate the full model. The last chapter presents the study of an interface for users with speech disorder and motor impairments.

Introduction

Chapter I - State of the Art of Additive Manufacturing

Chapter II - Investigating the domain of walled TPMS Lattice Structures through Homogenization approach for biomedical applications

Chapter III - Design strategies of Customized Intervertebral Body Fusion Devices via Additive Manufacturing Technologies with focus on manufacturability issues

Chapter IV - Development of interfaces for user with speech disorder and motor impairments

Chapter I

State of the Art of Additive Manufacturing

Table of Contents

Abbreviations

AM: Additive Manufacturing

DfAM: Design for Additive Manufacturing

EBM: Electron Beam Melting

FDM: Fused Deposition Modeling

HIP: Hot Isostatic Pressing

LBM: Laser Beam Melting

PBF: Powder Bed Fusion

SLM: Selective Laser Melting

SLS: Selective Laser Sintering

STL: Stereolitography

TO: Topology Optimization

1. Introduction

Additive Manufacturing is a term that represents a wide family of technology ranging from metal, polymeric and composite materials but not limited only to those materials. Additive Manufacturing differs from Rapid Prototyping due to its capability to produce final shape and total functional components with high production rates.

Capabilities of AM process for industry are:

- Shape complexity: the capability to generate complex shapes that are not replicable with other conventional manufacturing technology
- Functional complexity: the capability to generate a single component from assemblies or to collapse two components into one
- Material/Geometry complexity: the capability to tailor properties by the mean of geometry in order to obtain materials with target mechanical properties

A major advantage of AM given by its shape complexity and the use of computational design is to realize components with specific organic geometry that leads to patient-specific prosthesis for biomedical purposes.

The AM processes is carried out using the addition of slices by the building orientation that means that the CAD model is converted into a STL model, that represents the standard de-facto of AM technologies, and the model, subsequently, is divided into layers. By the mean of addition of materials in the form of filament or metallic powder the component is built, firstly, in a plane representing the single slice or layer and, secondly, is built another slice that adheres to the first one. The process goes on until the last slice is built and the final part is obtained.

In Tab. 1 the list of raw materials used for the major technologies of AM.

Technology	Raw Material
Selective Laser Melting	Powder: Ti6Al4V, SS316L, AlSi10Mg, Cobalt-Chromium
Electron Beam Melting	Powder: Ti6Al4V, SS316L, AlSi10Mg, Cobalt-Chromium
Fused Deposition Modeling	Filament: PLA, PEI, ABS, TPU, PET, PC
Stereolitography	Liquid: PC-like, ABS-like, PP-like
Selective Laser Sintering	Powder: PA11, PA12, TPU

Tab. 1 – Raw materials by AM technology

The knowledge of performances of lattice structures during their life-cycle are not fully covered by the state of the art. The design approach results to differ by applications and represents a core topic for the identification of the appropriateness of the model developed. Mechanical performances undergoing general loads and experimentation are focused mainly on axial loads while manufacturing issues still represents a wide topic for the understanding of the causes of failure for structures produced by AM technologies.

Design for Additive Manufacturing tools, procedures and approaches may include **Topology Optimization, Lattice Structures, Generative design, Texturing, Stress simulation, Heat Simulation, Build failure prediction, DfAM guidelines by technology, Part consolidation, Tailored properties**

Topology Optimization is a mathematical method aimed at optimizing the geometry of a component undergoing defined loads. In TO two main spaces are introduced: a design space and a non-design space. The non-design space represents a volume of the component not involved in the optimization process. The design space represents a volume of the component that is going to be fully optimized. The design space undergoing TO drastically modify its weight. TO, generally, uses Finite Element Method. Also, some TO approaches are based on Partial Differential Equation (PDE) formulation based on the elasticity problem.

The elasticity problem states:

$$div\ \sigma + f = 0\ in\ \Omega \qquad (1)$$

$$F = C\ \ u\ in\ \Omega \qquad (2)$$

$$\sigma \cdot n = T\ in\ \delta\Omega \qquad (3)$$

where f is a body force, T corresponds to tractions and Ω is the entire domain while $\delta\Omega$ is the frontier of the domain.

With applying constraints about density in the volume, the optimization problem is reduced to finding the minimum density per element

$$\min \int_{\Omega} f\ \cdot u\ (\chi) dx + \int_{\delta\Omega} T \cdot u\ (\chi)\ dS \qquad (4)$$

$$s.t. \int_{D} \chi(x)\ dx = \eta Vol(D) \qquad (5)$$

$$\chi(x) \in [0,1] \qquad (6)$$

A method that is classical used in TO problems is Solid Isotropic Material with Penalization (SIMP) Method developed by Bendsoe and Sigmud [1].

The objective function represents the quantity that is going to be minimized. Several approaches use the compliance of the structure as the quantity to be minimized while maintaining an objective of mass that is going to be the weight target of the optimized component.

While the density ranges in [0,1] allowing intermediate density, the interpolation with a power law diminishes the contribution of elements with intermediate density allowing a void-full structure.

Lattice Structures consist of a spatial repetition of unit cells along three directions. They are categorized by their mechanical response, as they are bending-dominated or stretch-dominated. Strut-based lattice structures (Fig. 1) have different topologies and are constituted by beams.

Strut topologies are characterized by Maxwell number by the mean of the following equation:

$$M = s - 3n + 6 \qquad (7)$$

where s are struts and n are nodes

If $M < 0$ the structure is bending-dominated

If $M \geq 0$ the structure is stretch-dominated

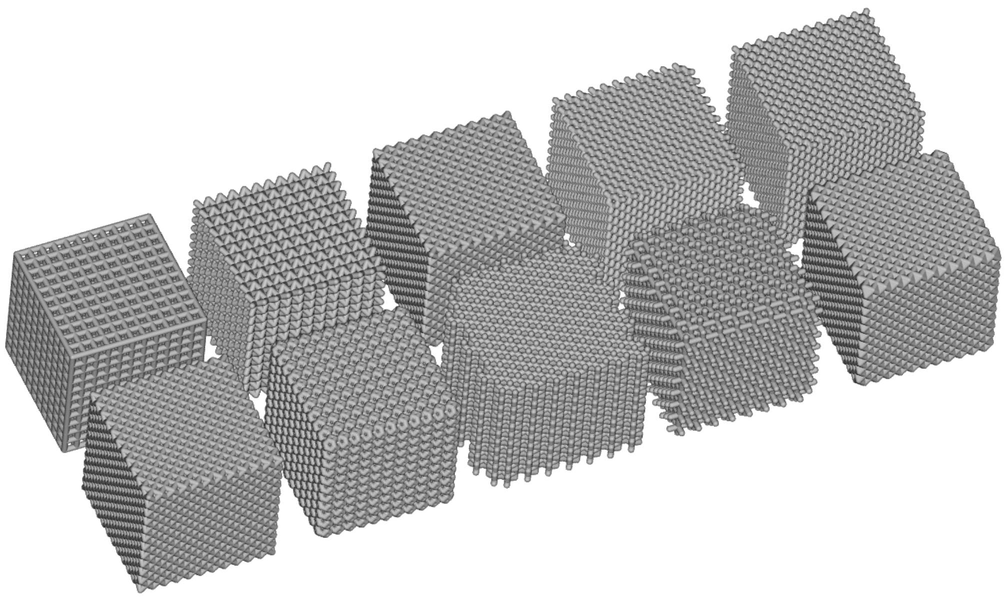

Fig. 1 – Strut-based lattice structures designed in nTopology

Triply Periodic Minimal Surface (TMPS) are structures based on mathematical equations and have a better manufacturability for AM technologies than strut-based lattices as the minimum beam section is replaced by the minimum wall thickness. These structures are better described in the Chap. II and III.

The properties of lattice structures determinates their application. The main advantages are lightweight and high strength-weight ratio which is appreciate in the aerospace field and automotive but are also crucial in the biomedical field due to the structural characteristics. Examples of biomedical applications including lattice structures are femoral stem incorporating lattice structures [2], orthopedic implants [3], scaffolding [4], graded lattice as biomaterials [5], bone implanting [6].

Heat simulation is a FEM tool that predict distortion and residual stresses in AM parts. Distortion may lead to a bad geometrical accuracy. Residual stresses may cause cracking of the part and, generally, reduces strength and fatigue life. Also, due to distortion other defects as pores may arise. Many tools are available in the AM software market, e.g. MSC Simufact Additive and Additive Works Amphyon are the leading software for this application.

A general Metal AM processes consists of Build Stage, Heat Treatment, Cooling, cutting from the substrate, Support Removal, Hot Isostatic Pressing. All these stages are investigated by the mean of thermo-mechanical simulation and, for each of these, a modification in the geometry may occur.

Due to the uncertainty of the values of parameters involved in AM process, a mechanical approach called inherent strain is used to simulate process equivalent loads. The method of inherent strains comprise the final strains excluded the elastic strain. To obtain these strains a calibration. By the calibration specimen the displacement after cutting the teeth is obtained and knowing the max height, the distortion is calculated.

In fig. 2 is showed the virtual testing of a lattice geometry undergoing heat loads caused by the process itself. The process, in this case, consists of build stage, cooling, cutting and support removal.

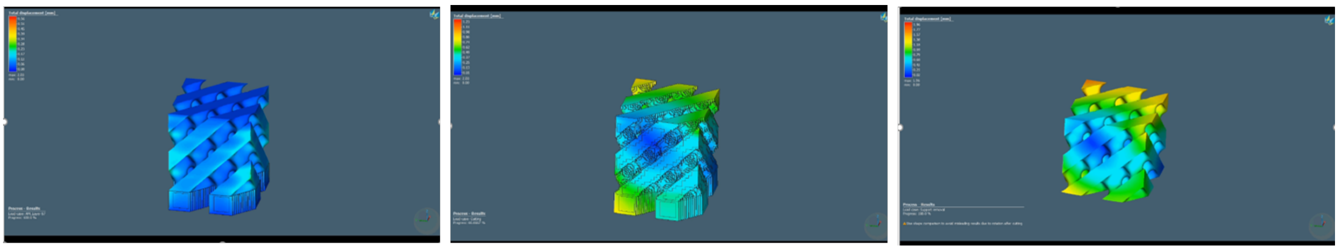

Fig. 2 - Virtual testing and process design for optimization of metal-based additive manufacturing of TPMS lattice structure using MSC Simufact Additive

In fig. 3 is showed the dimensional accuracy of a lattice produced from the counter-deformed shape obtained from MSC Simufact Additive.

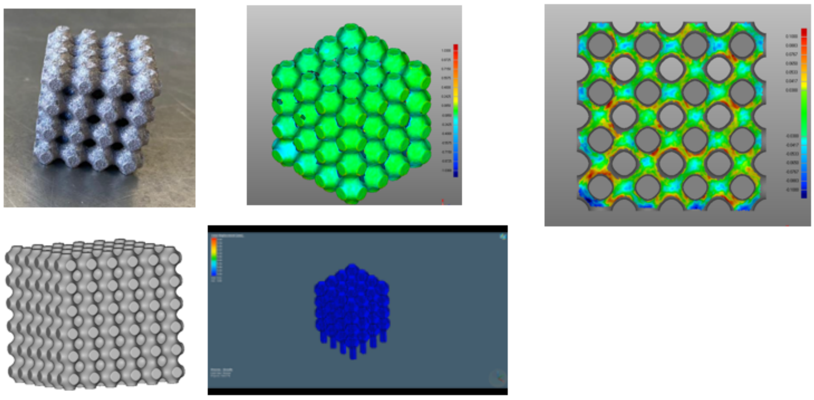

Fig. 3 – 3D printed Diamond Lattice Structure and distortion validation using a laser scanner

Reverse Engineering is "the act of creating a set of specifications for a piece of hardware by someone other than the original designers, based primarily on analyzing and dimensioning a specimen" [7]. RE is not only limited to the geometrical acquisition of the part, but also includes a redesign. The digital twin of an actual component may serve to investigate manufacturing issues occurred during a process. For biomedical applications, the approach to acquire a device is aimed at investigating the complexity of machine parameters in order to setup values as printing speed, extruded volume and material. By this approach it may be possible to control the shape, which modification leads to a reduction of mechanical performance or failure and, it represents an issue for those devices which requires tight tolerances.

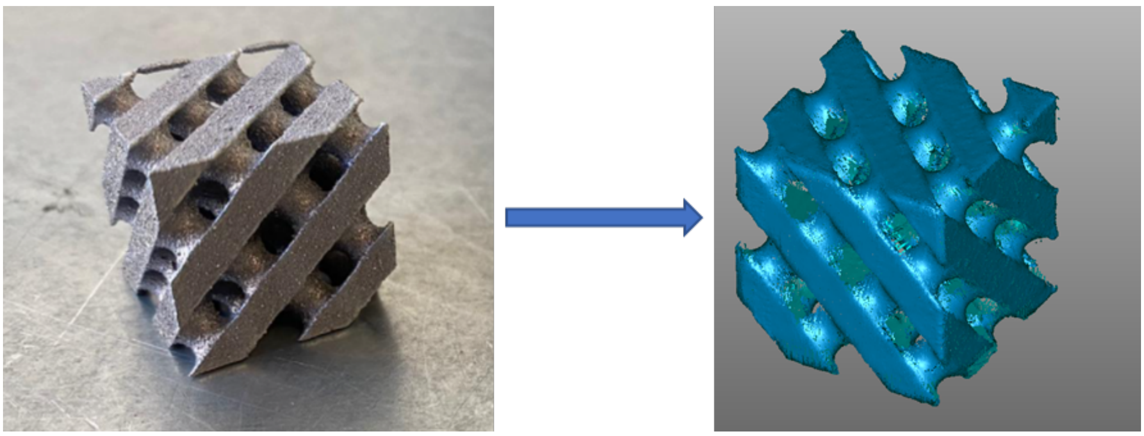

Fig. 4 – Laser scanning acquisition of a lattice structures

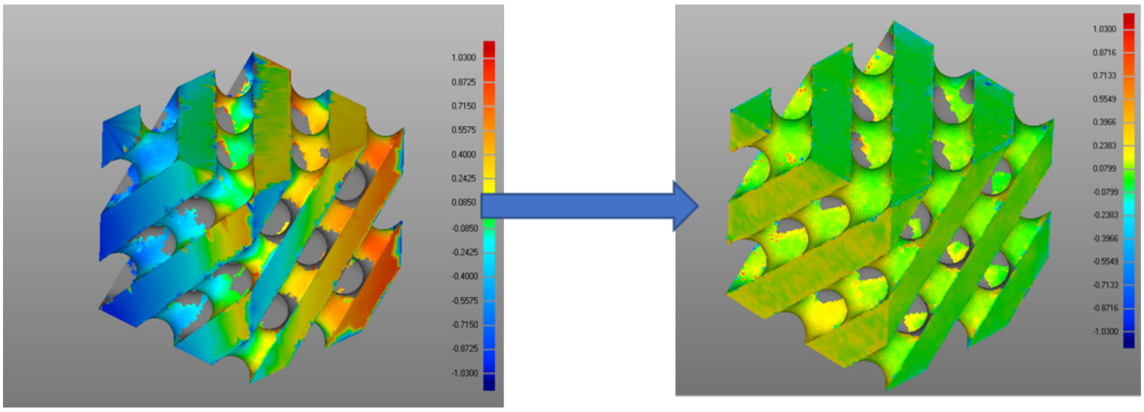

Fig. 5 – Acquisition of the lattice structures as-built (without shape correction) and acquisition of lattice structure with shape correction (counter-deformed shape)

2. Powder Bed Fusion

Applications of metal alloys in AM range from Aerospace, Medical, Energy, Automotive, Corrosion resistance, High Temperatures, Tools, Molds and Consumer Products. Powder Bed Fusion alloys and materials commonly used are Aluminium-based, Maraging steel, Stainless Steel, Titanium-based, Cobalt-Chrome, Nickel-based and precious metals. Even if the waste represents a small amount of materials, the quantity of materials in kilogram needed to fill the volume chamber may be appreciable. By this reason a reductor of chamber is needed for precious metals.

Metal AM is categorized into two main processes: Directed Energy Deposition (DED) and Powder Bed Fusion (PBF). The PBF are also divided into Electron Beam Melting (EBM) and SLM (Selective Laser Melting) depending on the heat source needed to melt the powders.

As-built SLM components may have a raw surface roughness. Post-processing methods as shot peening and sandblasting are used to achieve a better surface quality. Also, surface quality may be worst at the bottom of a part, lower boundary or starting layer usually known as down-skin, than in the upper-skin which may require a recoating. Roughness also depends on the orientation of the component.

Anyway, an issue in metal components, due to the heat exchange that occurs during the process which is the heating/cooling of powders when passing phase change and a melt pool is generated, leads to residual stresses. Residual stresses occur because of the thermal deformation when areas are constrained which means that some zones are unable to relax due to the rigidity of zones they are welded onto. Not only the spatial temperature gradient lead to residual stresses but also thermal expansion and plasticity and flow stress. [8]

SLM is a heat driven process. Numerical methods aimed at understanding the physics of melting powders by a laser source has been proposed. In [9] a mesoscopic model is proposed from which the authors found that the physics is driven by surface tension and its effect on the topology and heat conduction and introduces regime operations hypothesis which simplify the numerical model.

Fatigue behavior of metal AM still represents an issue. The fatigue strength of materials realized with AM technologies is lower than conventional materials leading to a premature failure at low loads. The behavior of Ti6Al4V, as showed in [10], is brittle at low strains. HIP treatment has many advantaged compared to the as-built component which is that it enables significant strain before failure and, also, enhance fatigue strength.

The layer in SLM, generally of 30 μm, 60 μm or 90 μm, is melted by the mean of a continuous or pulsed laser.

Fig. 6 – 3D Printed specimen in Ti6Al4V for fatigue testing according to ASTM-2207

Manufacturing differences in Laser Beam Melting and Electron Beam Melting show the importance to choose the right technology.

Laser Beam Melting has high temperature gradients, and it operates in inert Argon atmosphere. The build is pre-heated at approximatively at 180 °C but it can reach 250°C or even higher. The energy source is a Laser. At the state of the art, machines count four lasers which improves the production rate and enables a more industrialized production. Residual stresses still represent an issue of the technology, but stress-relief treatment is usually carried out to improve the mechanical performances. The roughness of as-built parts can range from 15 to 50 μm. Laser Beam Melting is also known as Selective Laser Melting meaning that during the process powder of raw material is selectively melted by the mean of a laser spot.

Electron Beam Melting operates in vacuum atmosphere. The process generates low stress and warping effects, and it has lower temperature gradients compared to LBM. Roughness is poorer than LBM, representing a good compromise for certain application, i.e., spinal implants which roughness improves the osteointegration. Dimensional accuracy is poorer than LBM resulting in issues for assembling to other components.

Mechanical performances vary along the planar and perpendicular directions. The variation of mechanical performances is an issue in AM because of the spurious and accidental loads that can lead to unexpected failure of the part.

The most used materials for biomedical applications are Titanium-based alloy, i.e., Ti6Al4V, Ti6Al4V ELI, Titanium Grade 2 and Stainless Steel, i.e., SS316L.

The effect of the microstructure and porosity on properties of Ti6Al4V, as shown in [11] is to lower tensile properties but the modification of process parameters would influence the microstructure and mechanical properties. Also, the location inside the platform plays a role in lowering mechanical properties.

An issue of metal materials used for biomedical applications is the Stress Shielding phenomenon. Stress shielding occurs due to the mismatch between stiffness of the implant and stiffness of the bone. At the interface the tension increases which can lead to failure of the implant.

3. SLM and biomedical applications

Clinical applications of AM are modelling of the anatomy, design and production of implants and tissue engineering. The use of Ti6Al4V in biomedical field includes: cranioplasty, knee replacement, hip prosthesis, interbody fusion cages, scapula prosthesis, dental implants and surgical guides.

A main application of SLM in the biomedical field is the 3D Printing of custom orthopedics implants. The most widely used materials are titanium-based alloy.

Titanium as a biocompatible material shows many advantages over other materials as it exhibits a high specific strength. Also, titanium has a low electrical conductivity which leads to the formation of titanium oxide which protects the surface against chemical corrosion.

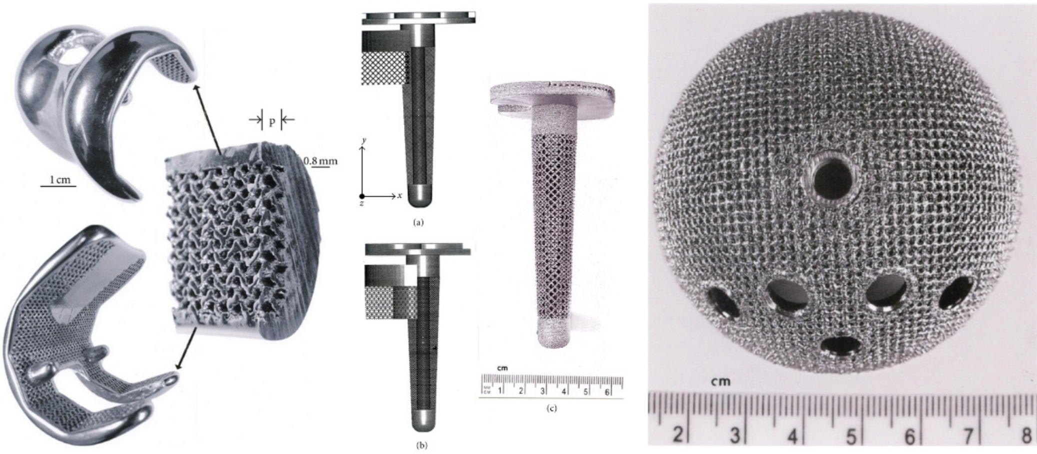

Fig. 7 – Knee prosthesis, femoral stem, acetabular cup with DfAM strategies [12]

Examples of orthopedics devices manufactured with AM technologies are showed in fig. 7 and better described in [12]. CAD models comprises cellular structures and porous structures that enhance osteointegration. The design strategies are fully implemented in the device (functional complexity) without any post-processing technique composing a monolith conceptual solution that leads to many advantages, mainly on manufacturability but also give a reliable product with low risk of disassembling and relative motion or without the use of other technology.

On the geometry sides, the control of the porosity is the first issue in attempting to reduce the stiffness. Change in porosity may be obtained by computational methods as introducing in the model trabecular or lattice structures. Also, manufacturing methods may be used to modify the porosity as heat treatments, hot isostatic pressing (HIP) and changing of laser parameters.

$$Porosity\% = \frac{Pore\ volume}{Total\ volume} x\ 100\ [\%] \qquad (8)$$

The porosity of 67% is recommended to obtain an optimal porosity compared to the bone [1].
A pore size between 400 μm and 600 μm [37] was recommended to enhance blood capillaries in bone formation.

The Gibson-Ashby model relates elastic modulus and stress to density. The formulae of the model are:

$$(1)\ \frac{E}{E_s} = C_1 \left(\frac{\rho}{\rho_s}\right)^{n_1} \qquad (9)$$

$$(2)\ \frac{\sigma_{pl}}{\sigma_s} = C_2 \left(\frac{\rho}{\rho_s}\right)^{n_2} \qquad (10)$$

Where:
E: Young's Modulus (GPa) of the porous structure

E_s: Young's Modulus of the material

σ_{pl}: plateu stress of the material

σ_s: yield strength of the material

$\frac{\rho}{\rho_s}$: ratio of density of the porous structure and the material

C_1, C_2, n_1, n_2: constants depending on the material

From experimental studies [13] a difference of Young's Modulus was found within experimental observation and FEM analysis. Irregularities of a manufactured component observed in microscopy caused by anisotropy in the process could make unpredictable the difference between simulation and experimentation and it is needed to consider the mechanical behavior of the material.

Triple Periodic Minimal Surface (TPMS) shows a better variation in design strategies as: pore size, pore geometry, internal connectivity and volume ration. For metal AM, TPMS shows also a better manufacturability when tailoring pore size with regards to strut-based cells.

Fig. 8 - A 3D printed metal scaffold generated from patient specific anatomy with Reverse Engineering and designed with software tools for AM. Pore size comprised between 350 μm - 400 μm

As an example, Fig. 8 shows a scaffold produced in SLM in Ti6Al4V with low pore size and a geometrical pattern of voids of strut-based type. The model has been generated starting from the model of a bone defect of patient obtained by a DICOM scan. Then, using a CAD modeler primitive subtractive geometry has been used to generate the porosity. With this approach the effort related to supporting local minimum in the manufacturing stage has been reduced leading to self-build component.

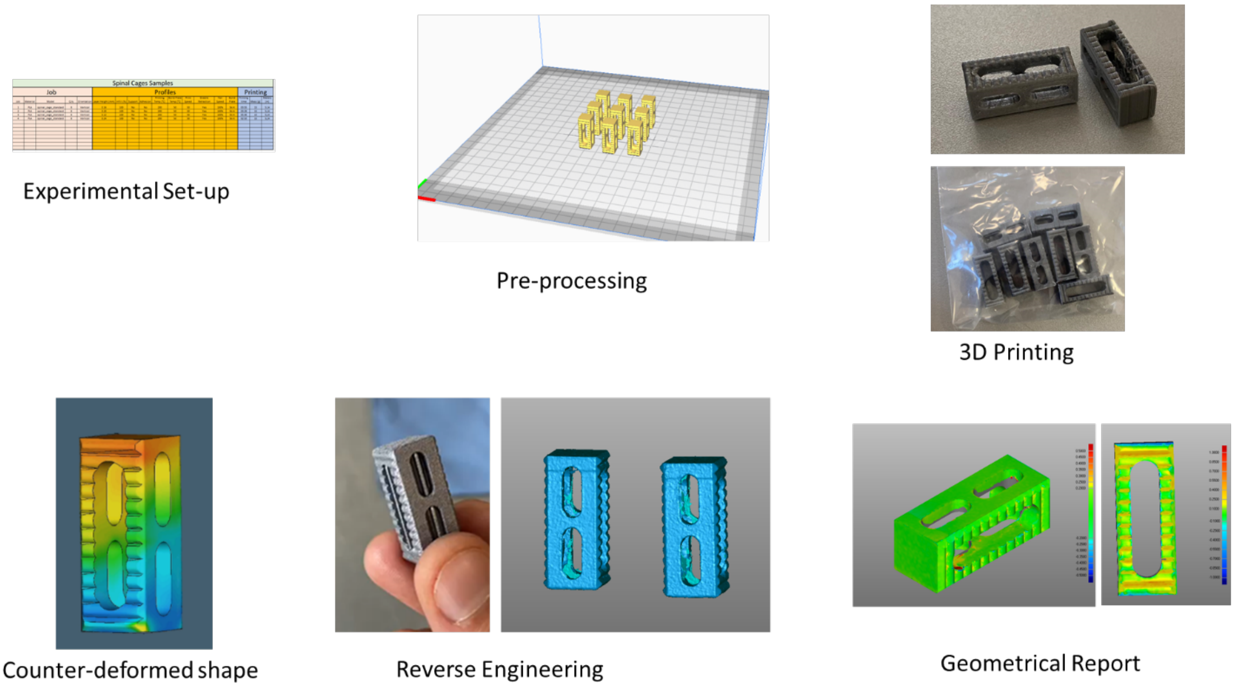

Fig. 9 – A general workflow for the tuning of machine parameters starting from an experimental setup, job creation, 3D printing of the parts, heat analysis and geometrical accuracy validation

In fig. 9 is shown a general workflow used to evaluate the variance of geometrical accuracy in polymer/metal 3d printing caused by process parameter. First, an experimental setup is required varying process parameter (for the polymers major parameters influencing the geometrical accuracy are raw material, printing speed, extrusion speed, chamber/bed temperature, extrusion temperature). Then, a software has the aim to slice the STL model and pre-processing the job. A software for thermomechanical analyses may be used to predict the deformation. Laser-scanner systems or CT-Scan are suggested for acquiring the geometry and provide a benchmark between the digital model, the actual model and deformed shape with statistical data that supports the study.

4. Ending notes

Additive Manufacturing has several advantages in the design of biomedical devices:

(1) Tailoring of mechanical properties by the mean of geometrical features enhance biomechanics-compatibility between hard tissues and bone leading, also, to a reduction in stiffness mismatch that reduces the effects related to stress shielding phenomenon

(2) The use of trabecular structures, i.e., lattice structures or infill with controlled porosity, leads to a better osteointegration

(3) The development of manufacturing parameters leads to products that are not far from commercialization whit a good geometrical accuracy and predictable mechanical performances

(4) The use of Reverse Engineering tools and methodologies has an advantage in the analysis of components produced via Additive Manufacturing technologies

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