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Master's degree in biomedical engineering

Study and evaluation of additive manufacturing technologies applied to build medical devices like customized orthopaedic insoles

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I. Summary

II. List of figures

III. List of tables

Abstract

The work carried out in this thesis takes place within the corporate context of Duna S.r.l. and arises from the company's need to renew business processes through the introduction of additive manufacturing technologies in the production of custom-made orthopaedic insoles. Additive manufacturing, or 3D printing, is taking hold in numerous sectors, including the footwear sector and the biomedical sector, and it is precisely in this context that custom-made orthopaedic insoles fit in. The method used in this thesis requires that selection criteria for materials and technologies are first established. Subsequently, simulations and comparative analyses are carried out and prototypes are developed. In the case study, the previously described method is applied to the specific case of employing additive manufacturing to custom-made orthopaedic insoles. In particular, 4 selection criteria are applied to the material: flexibility, Shore A hardness, durability, biocompatibility. 4 selection criteria are applied to the technologies: a construction volume that can accommodate at least one insole, production times and costs that are, at most, 150% of the traditional ones, production volumes that equal or higher than the traditional ones. From the simulations, information emerge regarding additive manufacturing which, inserted into the process, gives the possibility of evaluating 3D printing technologies in terms of costs and times, both for the entire batch and for the single insole. Subsequently, the information obtained from the simulations is used to carry out two types of comparative analysis: (1) comparing additive manufacturing technologies; (2) comparing subtractive manufacturing and additive manufacturing technologies, placing traditional manufacturing as a threshold. Finally, the development of the prototypes is carried out using the technology which, considering the previous steps, appears to have the best performances. Compliance with the geometries and weight of these prototypes are evaluated.

The results that emerge in this thesis identify TPU and TPU-like resins as the most appropriate materials, as they are flexible, with a hardness of 55-95 Shore A and the biocompatibility which must be tested on the individual sample.

From here, 4 technologies emerge: FDM, SLA, DLP, SLS, which are subjected to simulation, and from which information is obtained regarding the batch, the cost of the material, the printing time and post-processing. By inserting this data into the processes, the times and costs of the batches and individual insoles are obtained. The comparative analysis between 3D printing technologies highlights that the shortest times concern SLA and DLP, while the lowest costs belong to FDM and SLA. The second comparative analysis, between SM and AM, highlights SLA as the only technology comparable to traditional manufacturing in terms of costs and times. For this reason, SLA is used for the development of prototypes, which perfectly reflect the designed geometries, but have a higher weight than the traditional insole.

From a future perspective, it is conceivable to combine this study with those regarding the design of custom-made 3D printed insoles and create prototypes that can be tested on patients.

Il lavoro portato avanti in questa tesi si svolge all'interno del contesto aziendale di Duna S.r.l. e nasce dall'esigenza dell'azienda di rinnovare i processi aziendali attraverso l'introduzione di tecnologie di manifattura additiva nella produzione di plantari ortopedici su misura. La manifattura additiva, o stampa 3D, sta prendendo campo in numerosi settori, tra cui il settore calzaturiero e il settore biomedicale, e proprio in questo contesto si inseriscono i plantari ortopedici su misura. Il metodo utilizzato in questa tesi prevede che in primo luogo vengano stabiliti dei criteri di selezione per i materiali e per le tecnologie. Successivamente, si svolgono delle simulazioni, delle analisi comparative e si sviluppano dei prototipi. Nel caso studio, il metodo precedentemente descritto viene applicato al caso specifico dell'applicazione della manifattura additiva ai plantari ortopedici su misura. In particolare, al materiale verranno applicati 4 criteri di selezione: flessibilità, durezza di scala Shore A, durabilità, biocompatibilità. Alle tecnologie vengono applicati 4 criteri di selezione: un volume di costruzione che possa ospitare almeno un plantare, tempi e costi di produzione che siano, al massimo, il 150% di quelli tradizionali, volumi di produzione che siano uguali o superiori rispetto a quelli tradizionali. Dalle simulazioni emergeranno delle informazioni riguardo la manifattura additiva che, inserite all'interno del processo, danno la possibilità di valutare le tecnologie di stampa 3D in termini di costi e tempi, sia per l'intero lotto che per il singolo plantare. Successivamente, le informazioni ottenute dalle simulazioni vengono utilizzate per svolgere due tipologie di analisi comparativa: (1) comparando le tecnologie di manifattura additiva; (2) comparando la manifattura sottrattiva e le tecnologie di manifattura additiva, ponendo la manifattura tradizionale come soglia. Infine, lo sviluppo dei prototipi viene portato avanti utilizzando la tecnologia che, considerando gli step precedenti, risulta essere la migliore. Di questi prototipi viene valutato il rispetto delle geometrie e il peso.

I risultati che emergono in questa tesi individuano il TPU e le resine simil-TPU come i materiali più appropriati, in quanto flessibili, con una durezza di 55-95 Shore A e la biocompatibilità che va testata sul singolo campione.

Da qui, emergono 4 tecnologie: FDM, SLA, DLP, SLS, che sono sottoposte a simulazione, e da cui si ottengono informazioni riguardanti il lotto, il costo del materiale, il tempo di stampa e il post-processing. Inserendo questi dati all'interno dei processi si ricavano tempi e costi dei lotti e dei singoli plantari. L'analisi comparativa tra tecnologie di stampa 3D evidenzia che le tempistiche più corte riguardano SLA e DLP, mentre i costi più bassi FDM e SLA. La seconda analisi comparativa, tra SM e AM, evidenzia la SLA come unica tecnologia comparabile alla manifattura tradizionale in termini di costi e tempi. Per questo motivo, la SLA viene utilizzata per lo sviluppo dei prototipi, che rispecchiano perfettamente le geometrie progettate, ma hanno un peso superiore rispetto al plantare tradizionale.

In un'ottica futura è pensabile combinare questo studio con quelli riguardanti il design dei plantari su misura stampati 3D e creare dei prototipi che possano essere testati sui pazienti.

1 Introduction

Additive manufacturing, commonly called 3D printing, builds physical 3D geometries by successive addition of material [2], starting from the digital model of the object. There are seven process categories: binder jetting, direct energy deposition, material extrusion, material jetting, powder bed fusion, sheet lamination and vat photopolymerization. Each of them can print one or more types of material, including metals, polymers, ceramics and composites. 3D printing is applied to numerous fields, such as the automotive, aerospace, construction, fashion and medical industries.

In particular, as regards the footwear sector, numerous studies have been carried out on the additive manufacturing of soles, insoles, uppers and lasts, experimenting with different technologies and materials, based on specific needs.

The work presented in this thesis takes place within the corporate context of Duna S.r.l. and was born from the company's need to renew business processes through the introduction of additive manufacturing technologies in the production of custom-made orthopaedic insoles. These latter combine the needs of the footwear sector and, being medical devices, those of the biomedical sector.

The method used in this thesis requires that, firstly, selection criteria for materials and technologies are established. There are four material selection criteria:

- Flexibility;
- Softness;
- Durability;
- Biocompatibility.

And four technology selection criteria:

- Building volume of the printer;
- Costs;
- Times;
- Production volumes.

Once these criteria are established, a variety of materials and technologies emerge and are subsequently analysed according to three methodologies.

The first examination method is the simulation which, by analysing the production process, allows us to obtain information on costs and times. Through the latter data, two types of comparative analysis are carried out and prototypes are developed, whose geometries and weight are evaluated.

In the case study, the previously described method is applied to the specific case of additive manufacturing of custom-made orthopaedic insoles.

In particular, the four selection criteria will be applied to the material: flexibility, Shore A hardness, durability, biocompatibility. The four technology selection criteria are: a construction volume that can accommodate at least one insole, production times and costs that are, at most, 150% of the traditional ones, production volumes that are equal or higher than the traditional ones.

From the simulations, information regarding additive manufacturing emerge, and they are inserted into the manufacturing process, with the individual declinations for each of the technologies. The study of the manufacturing process gives the possibility of evaluating 3D printing technologies in terms of costs and times, both for the entire batch and for the single insole. Subsequently, the information obtained from the simulations is used to carry out two types of comparative analysis:

- Comparison between additive manufacturing technologies, normalizing the data with respect to the maximum values of times and costs;
- Comparison between subtractive manufacturing and additive manufacturing technologies, normalizing the data with respect to the time and cost values of subtractive manufacturing and placing traditional manufacturing as the threshold.

Finally, the phase of prototypes development is carried out employing the technology which, considering the previous steps, seems to have the best characteristics and complies with the established selection criteria.

The respect of the geometries, which must match those designed, and the weight, which must not exceed 150% of the weight of the traditional insole, are evaluated for these prototypes.

The results that emerge in this thesis identify the TPU filament, TPU-like resins and TPU powder as the most appropriate materials, as they are flexible, with a hardness of 55-95 Shore A and the biocompatibility which must be tested on the individual sample.

From here, 4 printing technologies emerge that can be evaluated: FDM, SLA, DLP, SLS, which are subjected to simulation, and from which information is obtained regarding the batch, the cost of the material, the printing time and post-processing.

By inserting this data into the processes, the times and costs of the batches and individual insoles are obtained, and the comparative analysis between 3D printing technologies highlights that the shortest times concern SLA and DLP, while the lowest costs are FDM and SLA. The second comparative analysis, between SM and AM, highlights SLA as the only technology comparable to traditional manufacturing in terms of both costs and time. For this reason, SLA is used for the development of prototypes, which perfectly reflect the designed geometries, but have a higher weight than the traditional insole and compared to the threshold value imposed in the method presented in this thesis.

From a future perspective, it is conceivable to combine this study with those regarding the design of custom-made 3D printed insoles and create prototypes that can be tested on patients.

2 State of the art

Additive manufacturing (AM), commonly called 3D printing, is a manufacturing process that allows the realisation of physical objects starting from a digital model. With this procedure, a three-dimensional object is built up by superimposing material layers using different manufacturing techniques, having advances in technology and cost reduction, which allows very complex objects to be manufactured in short time and at a competitive cost [1].

2.1 Additive Manufacturing VS Subtractive Manufacturing

Additive manufacturing contrasts with subtractive manufacturing; in fact, AM consists in the superimposition of layers of material, while, with SM, objects are constructed by successively cutting material away from a solid block of material using a CNC machine [1] (Figure 2.1).

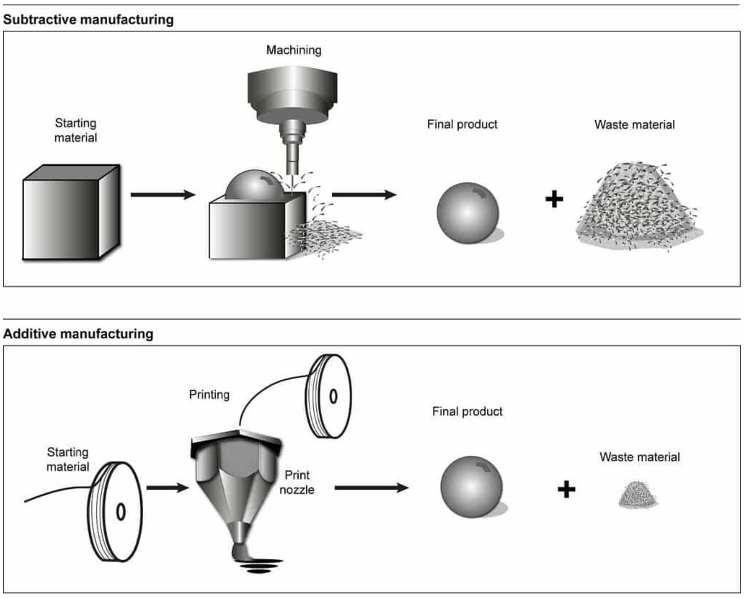

Figure 2.1 Additive Manufacturing VS Subtractive Manufacturing

This latter manufacturing process is based on removing material through cutting, drilling or milling to achieve the desired volume, but it brings with it several disadvantages, like the waste of materials, the lack of flexibility to alternate materials in different areas of the object and the impossibility of having access to the internal parts of the object. All these issues are overtaken by additive manufacturing.

Differences between AM and SM are reported in Table 2.1.

Table 2.1 Characteristics of AM and SM

	Additive Manufacturing	**Subtractive Manufacturing**
Material options	Metal, polymer, ceramic, composite	Wider range of materials, including stone, glass, wood
Material waste	Almost no waste	A lot of material waste
Achievable complexity	Complex and intricate design	Simple geometry
Accuracy	Less accurate than SM	More accurate than AM
Properties of finished parts	Layering can compromise some properties, causing weaknesses	Excellent resistance and structurally sound
Speed	Faster and less costly for prototyping and small batch production	Faster and less costly for large parts and large batch production

In particular, from a first comparison between subtractive manufacturing and additive manufacturing, AM appears to be advantageous in terms of material consumption, complexity of geometry and design, speed and production costs in the case of small batch productions. On the contrary, SM is more convenient when a wider range of materials, greater accuracy and part strength are needed.

Certainly, with the evolution of technology, the problems of accuracy and strength of 3D printed parts have been fine-tuned and overcome. This is the reason why AM is making its way into many fields of application, giving the possibility of obtaining pieces of equal or superior quality compared to what can be obtained with traditional manufacturing.

2.2 3D printing technologies

The standard ISO/ASTM 52900:2015 [2] is the International Standard that establishes and defines the terminology used in AM, together with its general principles. This will be the guideline for the explanation of technologies and materials used in additive manufacturing.

As reported in [2], 3D printing techniques are classified into seven categories, reported below and in Figure 2.2:

- Binder Jetting
- Direct Energy Deposition
- Material Extrusion
- Material Jetting
- Powder Bed Diffusion
- Sheet Lamination
- Vat Photopolymerization

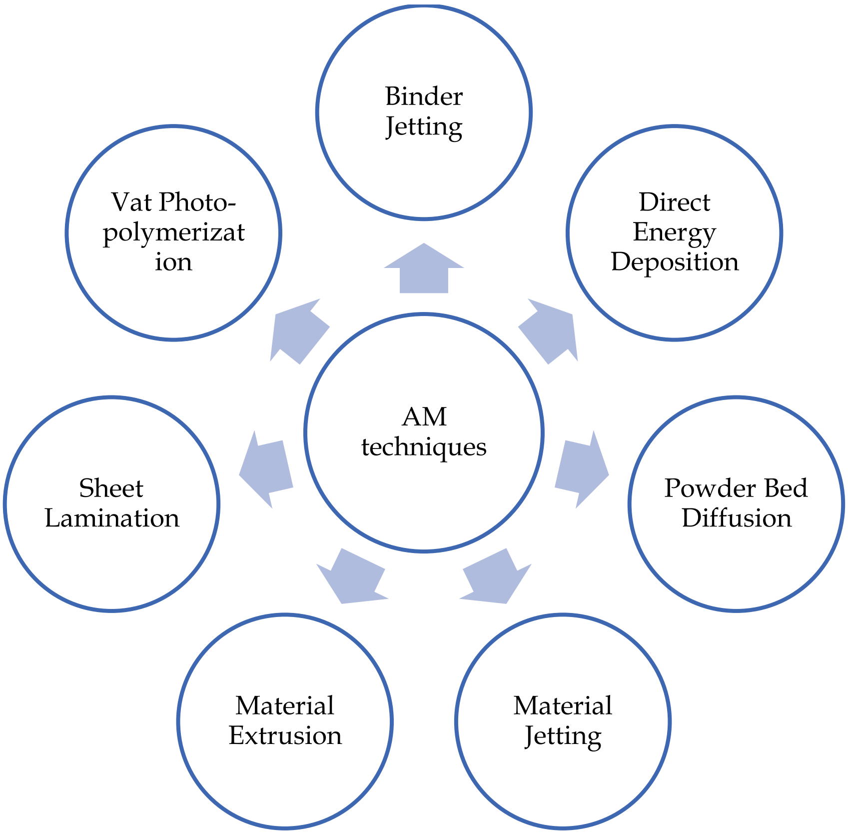

Figure 2.2 3D printing techniques

Depending on the printing process, additive manufacturing can have different applications, such as industry, medical, pharmaceutical, food, fashion, household and miscellaneous fields [3]; and, depending on the printing mechanism together with the chosen material, different final products can be achieved.

According to the standard ISO/ASTM 52900:2015 [2] there are basically two different categories of AM processes:

- Single-step processes (also called "direct" processes), in which parts are fabricated in a single operation where the basic geometric shape and basic material properties of the intended product are achieved simultaneously. Direct processes involve the fusion of similar material, using metallic, polymer and ceramic, or the adhesion of dissimilar materials, using composites;

- Multi-step processes (also called "indirect" processes), in which parts are fabricated in two or more operations where the first typically provides the basic geometric shape and the following consolidates the part to the fundamental properties of the intended material. Indirect processes involve secondary processing such as sintering and/or infiltration, using metallic, ceramic and composite.

In both cases, the removal of the support structure and cleaning may be necessary, but they are not considered as a separate process, even if they are time-consuming procedures, which must be considered when quantifying the overall process.

2.2.1 Binder Jetting

The binder jetting process provides that a liquid bonding agent is selectively deposited to join powder materials [2]. This technique makes use of two materials: a powder-based material and a binder, usually in liquid form (such as polymer in solvent or aqueous solution). The printing process with this technology is shown in Figure 2.3, and it consists of spraying a liquid binder onto a bed of powder, solidifying the cross section of the piece, layer by layer.

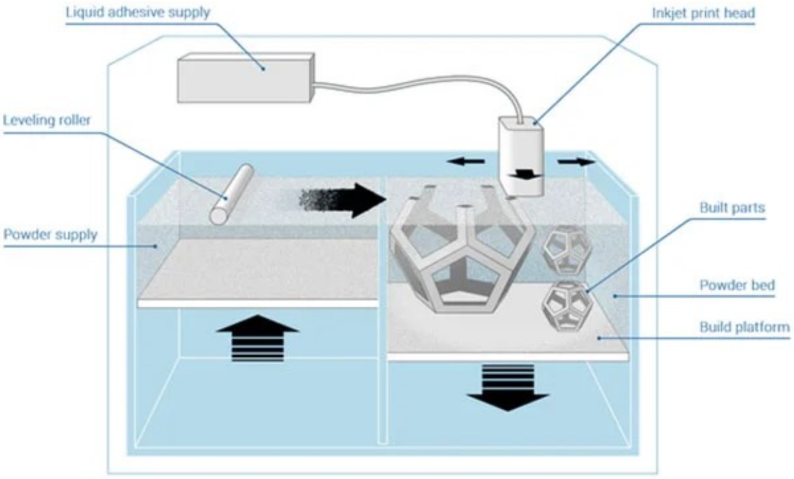

Figure 2.3 Binder jetting

Once the printing step is complete, some binder jet technologies require a post-cure to dry the binder and give the printed powder its green strength [6]. The printing process of a binder jetting system is usually faster than other AM methods, since it operates at lower temperatures and multiple nozzles can print simultaneously [10]; despite this, additional post-processing is always needed and can add significant time to the overall process, resulting in a technique that is slower with respect to the other AM techniques.

Binder jetting has multiple advantages, like wide range of colours, multiple materials supported, free of support, design freedom, large build volume, high speed and relatively low cost. At the same time, it is not always suitable for structural parts and the cleaning of the 3D-printing result needs time and increases the time of the procedure.

Materials typically used with binder jetting are stainless steel, polymers and ceramics.

2.2.2 Direct Energy Deposition

Direct Energy Deposition (DED) focuses thermal energy and is used to fuse materials by melting as they are being deposited [2]. Generally, a highly powerful laser is used to melt the metal powders and the quantity of metal powder deposited for DED process has a direct influence on the resolution of the printed part [8]. Metals are the only materials that can be used with this technology, and they typically are cobalt chrome and titanium.

DED-AM, as shown in Figure 2.4, is a complicated process in which heat transfer, fluid flow, solidification, and phase transformation occur simultaneously [7].

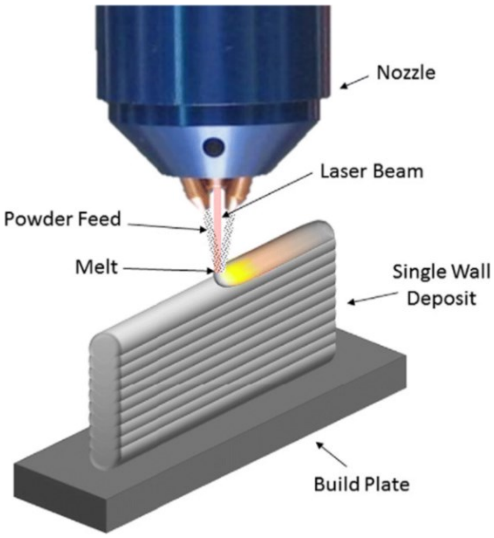

Figure 2.4 Direct Energy Deposition

Pros of DED are high control of grain structure, high-quality dependent on speed, high accuracy dependent on accuracy, fast built with rapid material deposition, fully dense parts (no need for supports) and best process for part repair.

On the contrary, main limitations are limited range of materials, poor surface quality and wire process is less accurate.

2.2.3 Material Extrusion

In Material Extrusion, material is selectively dispensed through a nozzle or orifice [2] and deposited layer by layer. The nozzle, that heats and extrudes the material at a constant pressure, can move horizontally, while the printing platform moves vertically when a new layer is deposited. The material deposits at a constant speed and bind with the previous layer of material as it is in the melted state. There can be the need of support structures basing on the geometry of the object, and they have to be removed during the post-processing.

This technology is known as Fused Deposition Modelling (FDM) or Fused Filament Fabrication (FFF), and involves materials like plastics and polymers, most commonly ABS, nylon, PC and AB.

The process is shown in Figure 2.5.

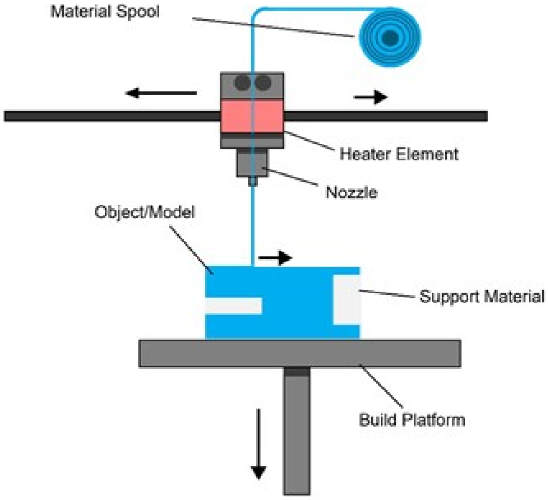

Figure 2.5 Material Extrusion

Material extrusion is the most inexpensive and widespread AM technology, but, depending on the characteristics of the nozzle, it can lack of resolution, precision and speed.

2.2.4 Material Jetting

Material Jetting process involves droplets of build material that are selectively deposited [2] in the working platform to partially soften the previous layer of material and solidify as one piece during the material jetting process [8]. In practice, as shown in Figure 2.6, this process is based on photo-polymerization and the printer jets the material from a tiny nozzle onto a build surface, and, as it passes, it instantly solidifies with UV energy, building up the 3D object layer by layer.

MJ allows the multi-material and polychrome printing, as the print head has multiple nozzles able to spray different materials simultaneously. These materials are typically plastics and polymers.

Post-processing is needed to remove eventual support material.

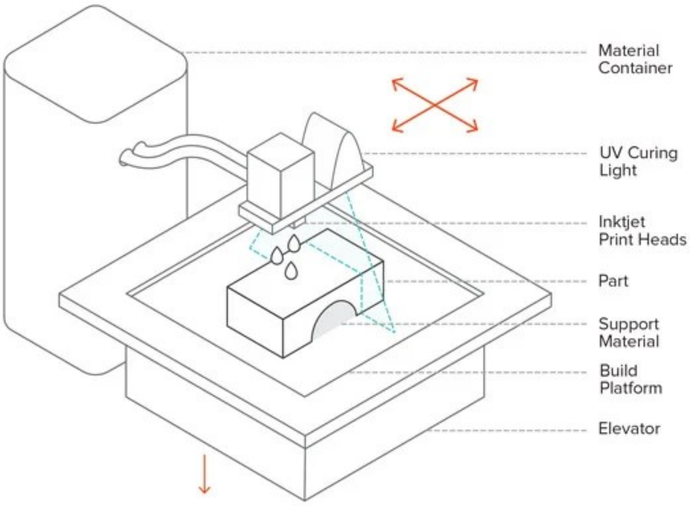

Figure 2.6 Material Jetting

Pros of this AM technology are high accuracy, low waste, multiple material parts and colours in one process. At the same time, support materials are required and there is a limited choice of materials.

2.2.5 Powder Bed Fusion

Powder Bed Fusion is the technology in which thermal energy selectively fuses regions of a powder bed [2]. The first layer of, typically, 0.1mm thick is spread all over the build platform and then all the other layers are fused above it, until the entire model is created. Laser or electron beam is used in this process to fuse the material, partially or fully. We consider sintering as the partial melting process and melting as the full melting process.

In these processes, laser power is usually in the range of 100-1000 W depending on the manufacturer. The thickness of each build layer of laser-based PBF can be as small as 20 µm, which shows the advantage in terms of resolution over other AM processes [10].

We can also have the solid-state sintering, in which the particles fuse at the surface only that result in inherent porosity of the part while in liquid-state melting, all particles fully melt and fuse together that give a fully dense part with almost zero porosity [8].

Based on the thermal energy source, it can be distinguished into Selective Laser Sintering (SLS), using lasers, and Electron Beam Melting (EBM), using electron beams. SLS laser scans the powder surface point by point, making the process slower but more precise. In contrast, EBM electron beam heats the powder in multiple places simultaneously, reducing time and precision.

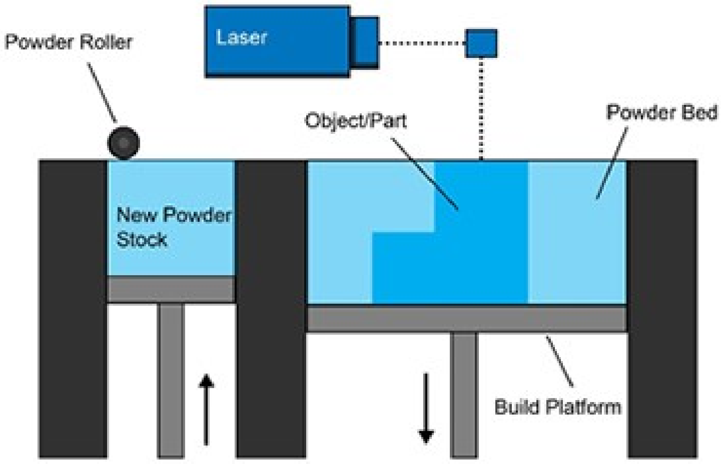

Figure 2.7 Powder Bed Fusion

The process, illustrated in Figure 2.7, uses polymers, metals and ceramics, having the advantage of being able to choose from a wide range of materials.

Disadvantages are low speed, limited size and dependence on powder grain size.

2.2.6 Sheet Lamination

Sheet lamination involves the use of sheets of material that are bonded to form a part [2]. Bonding is made using ultrasonic welding or adhesive materials and each material sheet can be considered as one of the cross-sectional layers of the solid object [8]. Everything starts in the cutting bed, where the first layer of material is positioned and all the others are bonded over the previous one. The required shape is cut from the layer using laser or knife. An additional CNC machine is required to remove the unbound material.

During this process (Figure 2.8), the temperature of the consolidated region increases due to frictional heat at the bonded interfaces. In order to avoid thermal residual stress, there is a short period of cooling between the manufacturing of each layer. After building all of the layers, the product is cut from the base plate and then polished for better surface finishing [10].

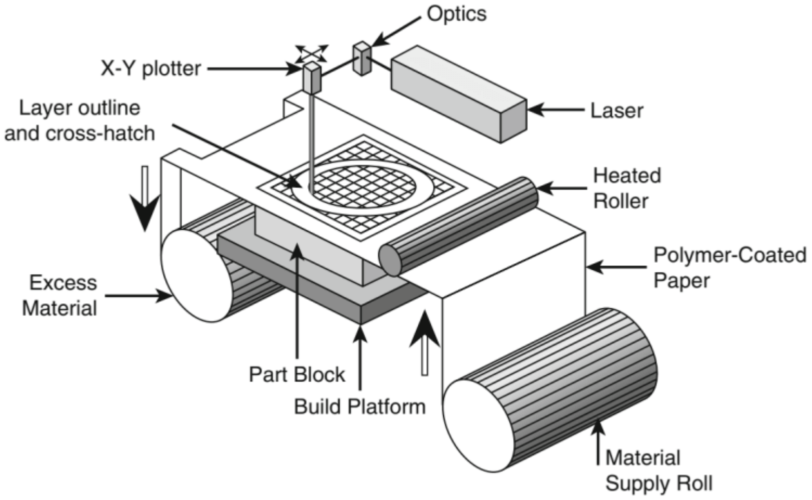

Figure 2.8 Sheet Lamination

Sheet lamination distinguishes into Laminated Object Manufacturing (LOM) and Ultrasonic Consolidation (UC). LOM uses sheet of adhesive-coated materials, while UC uses ultrasonic vibration under high pressure to make the layers of material adhere.

This process involves paper, plastic and metals; it is fast, inexpensive and the material handling is easy. On the contrary, disadvantages are the waste of material and the need of post-processing.

2.2.7 Vat Photo-Polymerization

The Vat Photo-Polymerization process makes use of a liquid photopolymer in a vat that is selectively cured by light-activated polymerization [2]. In fact, UV light is used to turn the material from liquid into solid.

During this procedure (Figure 2.9), the building platform moves vertically from upwards to downwards by the layer thickness and the UV light cures the resin layer by layer. Sometimes it's possible to use a blade between layers in order to smoothen the resin base to build the next layer on. One the procedure is complete, the vat is drained and the object is removed. This kind of process needs post-processing adjustments, such as the removal of any excess resin. At the end, objects can be dried naturally or using an air hose.

Two technologies can be identified: Stereolithography (SLA) and Digital Light Processing (DLP). They involve the same process, with the difference that the light source for SLA is a laser that moves along the horizontal axis and solidifies the material layer by layer. DLP uses a projector as light source and does not work point by point, but layer by layer, making it faster with respect to SLA.

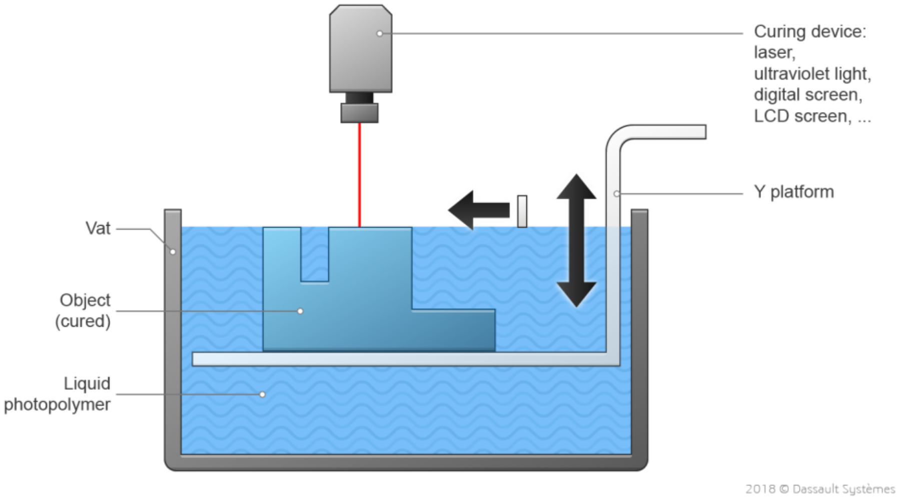

Figure 2.9 Vat Photo-Polymerization

Vat photo-polymerization uses photopolymer resins as the only possible material to use, giving high resolution, accuracy, complexity and smooth finish to the printed part. The printer typically has large build areas. On the other hand, this technology lacks in strength and durability, it is expensive and the final object is still affected by UV light after printing.

2.3 3D printing materials

Additive manufacturing uses three types of materials: metals, polymers and ceramics. They can be compared analysing some core characteristics, reported in Figure 2.10, which are quantified on a scale from 1 to 4, where 1 corresponds to bad, 2 corresponds to low, 3 corresponds to good, 4 corresponds to high.

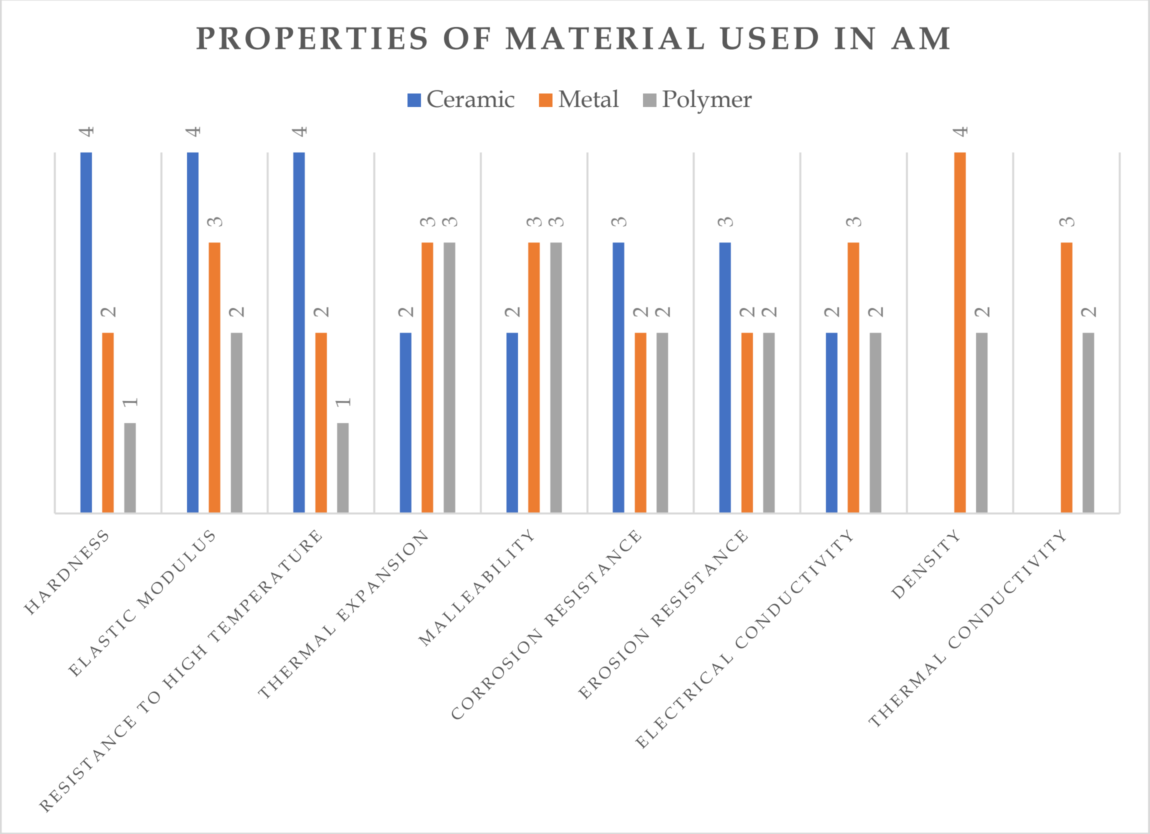

Figure 2.10 Properties of materials used in AM. 1 = bad; 2 = low; 3 = good; 4 = high

As we can see in the graph, polymers are those that exhibit worst properties, while metals and ceramics have better characteristics. Obviously, materials have to be chosen based on the end use of the object produced with AM. In order to enhance the properties of a certain material it is possible to use fibres; materials reinforced with fibres are called composites.

2.3.1 Metals

Metallic materials find application in aerospace, automotive, medical and energy fields. They can be printed with binder jetting, direct energy deposition, powder bed diffusion and sheet lamination technologies.

The most commonly used are [9]:

- Aluminium, when machinability, weldability and consumer products are needed. It offers good chemical resistance, lightness, and one of the best strength-to-weight ratios of any metal;
- Stainless steel, when machinability, weldability, corrosion resistance, high temperature, tools and molds are needed. Parts printed with stainless steel can have the same or even greater strength than parts created using traditional manufacturing methods;
- Titanium, when machinability, weldability, corrosion resistance, high temperature are needed. Titanium and its alloys have high mechanical strength and they also offer better corrosion resistance than stainless steel;
- Cobalt chrome, when corrosion resistance in needed. It is a superalloy comprised primarily of cobalt and chromium. Its high tensile strength and resistance to creep and corrosion makes it a good material choice for aerospace components and medical instrumentation;
- Nickel superalloys, when machinability, weldability, corrosion resistance and high temperature are needed. Nickel-based superalloy that offers high strength and can retain its strength over a wide temperature range. Due to its excellent corrosion and oxidation resistance, it is considered ideal for corrosive environments.

2.3.2 Polymers

Polymers are a class of materials used in all the seven techniques of AM. They are used in [11]: biomedical applications, including tissue engineering and bioprinting, drug delivery, tissue phantoms, and soft surgical models (PDO); electronics industry, using, for example, carbon black and silicone rubber to build flexible and stretchable parts; aerospace applications, requiring lower weights and high strength; textile industries, aiming to reproduce the characteristics of softness, strength, flexibility, and porosity, typical of that application.

PLA, ABS, nylon and TPU are the three most used materials in additive manufacturing. They can also be used on desktop 3D printers and with low costs. In particular:

- ABS polymer is an opaque thermoplastic, made of three monomers, acrylonitrile, butadiene and styrene. It's typically used in AM by FDM or FFF printers and the material is in filament form. It is used for mechanical purposes thanks to its good properties of impact resistance, tensile strength and stiffness and heat deflection temperature. Objects made of ABS presents like rigid and opaque objects, white coloured that with oxidation can lead to a yellowing colour. On the other hand, disadvantages can be the low melting point, that makes the material not suitable to be adopted to high heat situations, poor weathering resistance and poor resistance to solvent;
- PLA is a thermoplastic easy to use, with a resistance and rigidity higher than those of ABS and nylon. Its properties of low melting point and minimum deformation makes it very easy to be used in AM, but these features disappear when the material is exposed to temperatures higher than 50°C. For this reason, PLA is almost exclusively intended for non-professional use;

- Nylon is a plastic material which has characteristics of flexibility and hardness, but at the same time is less resistant and rigid than ABS and PLA. It is also more malleable, giving greater toughness and greater impact resistance to the nylon printed parts. It also exhibits good chemical resistance. This material, together with ABS, requires attention during the printing process; in fact, it must be extruded at high temperatures and, because of its tendency to absorb humidity, it must be conserved inside a dryer;
- TPU is an elastomer that combines the properties of thermoplastic materials and rubbers. It is characterized by good flexibility and resistance and has advantages like elevated resistance to impact, usury, abrasion and cuts. Moreover, the good adhesion between layers gives it an excellent mechanical homogeneity. The biggest limitation of this kind of material is that it does not withstand high temperatures and its properties are better kept at low temperatures. TPU can be found in powder form, used with SLS technology, or as filament, used with FDM technology. In particular, the TPU powder for SLS printing offers a balanced property profile with good flexibility, shock absorption and the possibility to print very fine structures with a high level of detail [13].

2.3.3 Ceramics

Additive manufacturing makes also use of ceramic materials, in particular technical ceramics. This kind of material is used in automotive and aerospace applications for those parts that require resistance to both high temperature and usury. It can also have application in the dentistry field. Ceramics are 3D printed with SLS and FDM/FFF techniques.

In the post-processing of SLA, heat treatment is needed, in order to enhance the final density, microstructure and surface quality of the final piece. Ideally, we would have fully dense ceramic parts, with fine microstructure and low surface roughness.

Indeed, these three properties directly affect the overall performance of ceramic components and in particular their mechanical properties [14]. These latter are improved when the final density is increased, and the grain size is reduced. Furthermore, a high surface roughness is also undesirable, first for aesthetic reasons, and second because surface features may initiate the formation of cracks under mechanical load, thus resulting in significantly lower elastic modulus, flexural strength and hardness [14].

Typical ceramics used in additive manufacturing are:

- Alumina Al2O3: technical ceramic oxide. It presents high degree of hardness, thermal stability, good resistance to high temperature and abrasion. It is suitable for wide variety of applications;
- Zirconia ZrO2: zirconium oxide. It is characterized by high rupture strength, comparable thermal expansion to cast iron, high flexural and tensile strength, high resistance to wear and abrasion, low thermal conductivity and excellent tribological properties;
- Silican carbide SiC: properties depend on the type of carbide used, that can be dense or porous. In general, it shows very high strength at high temperatures, resistance to wear, corrosion, oxidation, and thermal impacts. They are also electrical semiconductors;
- Silicon nitride Si3N4: it has a unique combination of properties. In fact, it is extremely hard, highly resistant to thermal impacts, chemical products and wear. It also presents features of low coefficient of thermal expansion, in combination with average thermal conductivity.

2.3.4 Composites

Composite materials are product of the combination of two materials, a matrix and a reinforcement. Typical matrices are polymeric materials, such as PLA, ABS and nylon, whose characteristics are improved by the presence of the reinforcement. In particular, composite materials are used to produce lightweight parts, having better mechanical properties than parts produced with only matrix. This kind of material is usually fabricated with FDM, SLS, DED and SLA processes [16].

Composites printed with FDM make use of two types of reinforcement:

- Short fibres, having a length up to 1 mm and united with traditional thermoplastic materials. This kind reinforcement confers rigidity and resistance, without increasing the weight of the extruded filament. The quantity of fibres allows to obtain filaments of different strengths;
- Continuous fibres, giving the best performances. Parts containing continuous fibres are much more difficult to produce but at the same time give such a strength that you can compare the composite with metal.

The most commonly used reinforcements are carbon fibre, glass fibre and Kevlar. Carbon fibre is the most popular among these three; glass fibre is a cheap material that is able to give more strength to plastic; Kevlar has a high impact resistance, as it bends instead of breaking.

SLS process is used for fabricating particulate-reinforced polymers by mixing the powder and then sintering the mixture using a laser source. In this context, one of the challenges is to have a uniform mixture between the matrix and the reinforcement [16].

The DED process is similar to the SLS process except that it is a powder-fed process while SLS is a powder-bed process. The use of DED process in composites fabrication allows more flexibility in reinforcement distribution. The SLA can be used to fabricate composites but with less mechanical properties [16].

Furthermore, typical matrices can be also metal or ceramic materials. In the first case, the metal matrix provides ductility and thermal stability for the composite at elevated temperatures, while the fibre may increase the strength, the stiffness, enhance the resistance to creep or abrasion, and improve the thermal conductivity [17].

Metal matrices are mainly Cu, Fe and Ti, and typical reinforcement are SiC, Al2O3 and TiC. Reinforcing elements are blended into the molten alloys to produce metal matrix composites with dispersion of particles and short fibres [18]. Moreover, Behera et al. [18] have observed that conventional manufacturing methods fall short of achieving the controlled dispersion and the full benefits of the metal matrix composites; while, AM methods are better alternatives for processing this kind of material.

At last, the fabrication of ceramic matrix composite is difficult by using conventional techniques [17], and this problem is overcome by AM techniques like SLS, SLA and direct inkjet printing.

Typical ceramic materials used to fabricate CMCs are alumina, silicon carbide, aluminium nitride and zirconia, and they can be reinforced with [19]:

- Zirconia or alumina particles, that are popular candidates to improve the properties of advanced ceramics. Indeed, particulates can deflect cracks, obstruct crack propagation and promote the densification process;
- Carbon-based nano reinforcement, such as carbon nanotube, enhancing mechanical properties and physical properties like electrical or thermal performance, and graphene, offering exceptional mechanical, optical, electrical and thermal properties. In particular, graphene, coupled with bioactive ceramics, improves the bioactivity yielding greater proliferation and adhesion of bone cells;

- Fibre-based reinforcement, using short or continuous fibres, including sic and carbon fibres. Mechanical properties can be enhanced if the three following issues are overcome: uniform dispersion of matrix and reinforcement; degradation of fibres at high processing temperatures; optimization of the fibre/matrix interfacial bonding. In addition, continuous fibre typically exhibit non-catastrophic failure and exceptional damage tolerance if compared to short fibre.

2.4 3D printing process

The productive process of a 3D prototype is slightly different between types of AM, but, in principle, it makes use of the following six generic steps (Figure 2.11):

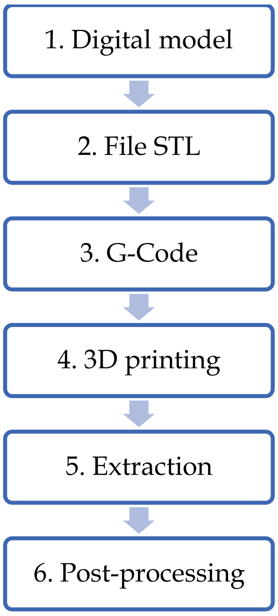

Figure 2.11 Productive process of AM

There are three different ways to obtain the digital model [4]:

- Process the model using a CAD software;
- Get the geometry of the model through a 3D scanner or Reverse Engineering;
- Download the model from an online repository or contact an expert.

Once the 3D digital model is obtained, it must be converted into the STL format. STL stands for "Standard triangle language" and uses little triangles to recreate the surface of the solid model. Sometimes, problems during the conversion can arise, and they are solved in the succeeding step, in which the model is analysed in several aspects (like structure, holes, angles, stability, ecc…), the support structures are inserted, the infill is chosen, the model is placed on the print bed and the G-Code is generated. Figure 2.12 shows the process from the digital 3D model to the 3D printing.

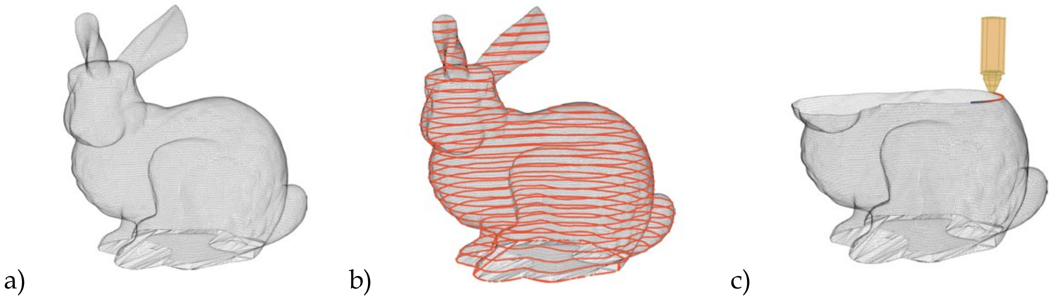

Figure 2.12 a) 3D model b) slicing c) 3D printing

In particular, the G-Code is a file containing the instructions for the printer, consisting of the combination of printing parameters related to the machine. The operation is called slicing and consists in dividing the model in layers and defining their height and thickness, together with temperature and velocity of printing, density of infill and other parameters. The result of the slicing phase generates the G-Code and it is possible to start printing. The 3D printer manufactures the object by starting at the base layer and building a series of layers on top until the object is built using the raw materials that are needed for its composition [5].

Once the printing is complete, the object is extracted from the machine with procedures that depend on the type of printing, and, at the end, the piece is subjected to finishing and post-processing processes.

2.5 3D printing for footwear

Nowadays, additive manufacturing involves almost all industrial sectors, including the footwear industry, integrated in all the process chain, from the design to the development and final production of shoe components, like soles, insoles, uppers, heels and shapes.

Conventional production methods are costly, time intensive, work intensive, and unpractical in this context of a constant need to refresh product ranges and extend the number of fashion seasons. Automation and digitalization of production processes are two ways to address these changes [20].

In this context, Nike, Adidas and New Balance have been the first industries to enter the market with sports shoes manufactured with 3D printing (Figure 2.13).

Figure 2.13 3D printed shoes

Nike brought 3D printing in footwear industry in 2013, starting with the plate of the cleat of football shoes, by using a proprietary material and the SLS technology. Over the years, they started to 3D print uppers of running shoes and custom-made running shoes, by using TPU and FDM technology [21].

Previously, footwear manufacturers only used 3D printing for prototyping purposes, but they can now use it for other purposes, including the mass-customization of insoles, midsoles, and sandals, the production of unique luxury items, agile prototyping and moulding processes, and increased design freedom, all of which are major benefits for traditional shoemaking [20].

Elastomeric, rubber-like and flexible materials have been used and the most used is TPU, capable of producing light, resistant and flexible parts. TPU can be found as filament, resin and powder, exploiting, respectively, FDM, SLA and SLS technologies. The same technologies can be used with different materials, like ABS or nylon, in order to reproduce those parts that need to be hard and inflexible.

Danko et al. [22] conducted a study on 3D printed individual running insoles, using a procedure which involves the development of the CAD model of the customized insole and its subsequent 3D printing. An FDM 3D printer and the TPU filament, as flexible material, have been employed for this purpose. The printing process is shown in Figure 2.14.

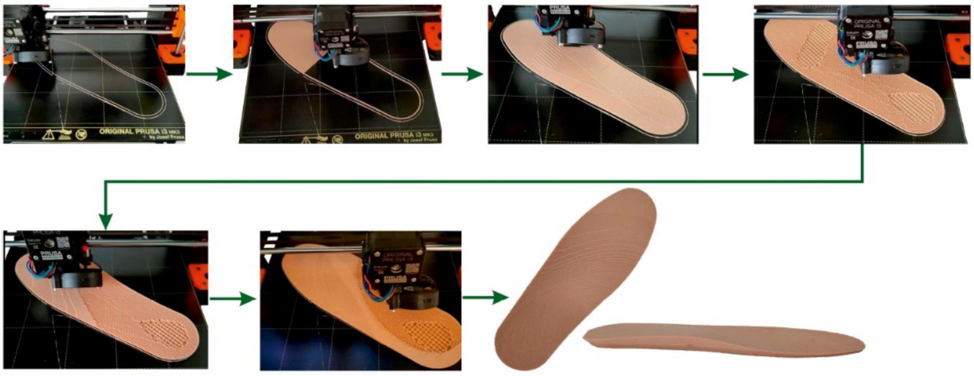

Figure 2.14 3D printing process of CMI [22]

The study concludes that a customized internal structure with corrective elements in the form of springing around the metatarsals bar and heel, with the support of the longitudinal arch, can redistribute pressure and increase the feeling of comfort.

In the field of orthopaedic footwear, the study is even more challenging, since orthopaedic shoes must alleviate or compensate for certain pathologies suffered by the patient. In this context, most studies are focused on soles and insoles.

Zolfagharian et al. [23], selected TPU as the proper material for shoe sole production with 3D printing and studied different lattice design, such as hexagonal, elliptical and circular, at different scenarios.

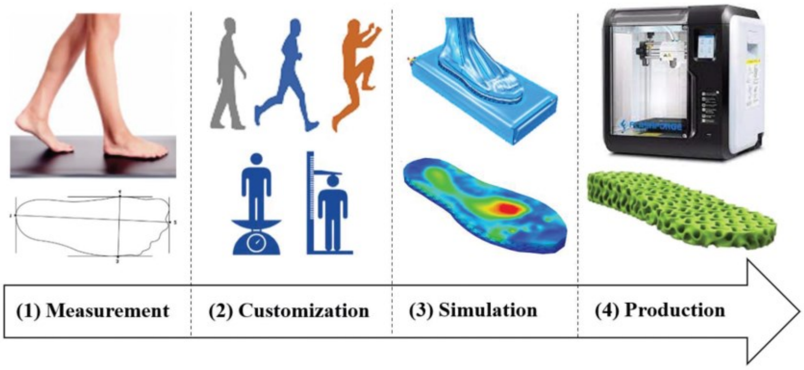

Figure 2.15 Workflow of custom 3D-printed midsole production [23]

The workflow followed by [23], shown in Figure 2.15, starts with the foot shape of the patient, using scan or even the shoe size. Then the lattice of different shapes is designed and generated in CAD and a simulation is carried out to reflect the stress distribution on the midsole surface. Finally, the desired lattice providing less stress compatible to the user application, that is, walking or running, are suggested for 3D printing.

The results of this study provide scope of using combination of lattice structure to increase the energy absorption capacity or elasticity, or providing more local support and comfort as per individual requirements, such as diabetic injuries or sports.

Insoles are even more delicate to be manufactured, since they are in direct contact with the foot, being in between the foot and the shoe sole. Davia-Aracil et al. [1] proposed FDM technology, combined with TPU, for insoles production, proving that shock absorption properties can be modified along with internal structure incorporated into the insole. This study is also comparative between traditional manufacturing and 3D printing, demonstrating that AM is actually cost-effective and feasible at industrial level. Moreover, 3D printing allows to achieve a high level of customization, which is an essential feature of custom-made insoles.

Over the years, other studies have also been able to confirm that customized 3D printed insoles are more effective than prefabricated insoles.

In particular, Xu et al. [24] conducted a study on 80 patients suffering from bilateral flat feet for 8 weeks. The foot has been divided into 10 areas: the big toe (T1), toes 2–5 (T2–T5), the 1st to 5th metatarsal (M1, M2, M3, M4, and M5), medial heel (H1), lateral heel (H2), and mid-foot (MF); and 3 parameters, peak pressure, peak contact area, and peak force, has been measured in the 10 areas, at week 0 and at week 8.

In terms of biomechanical performances, the study highlighted that customized 3D printed insoles reduced the load of the metatarsals and distributed the load to the mid-foot area to reduce lesions of the foot in patients with symptomatic flatfoot. Customized 3D printed insoles performed better than the prefabricated insole and showed better comfort improvement.

3D printed insoles have also been studied and developed for another pathology, the diabetic foot. In this case [25], the insole was manufactured by creating regions of different stiffness, to redistribute the plantar pressure peaks with the aim to avoid the formation of ulcers.

Finally, the combination of FDM and TPU has been used by Yarwindran et al. [26], with the objective to study the internal structure of 3D printed insoles and their effectiveness. The infill pattern (Figure 2.16) can be expressed as percentage and characterizes the hardness and weight of the insole, together with the speed of the process. In fact, harness increases with the percentage of infill, and, on the contrary, with low percentage of infill, the insole becomes lighter, and the process becomes faster.

Figure 2.16 Example of Hexagonal Infill patterns and printed insole [26]

Another application of AM in the field of footwear has been studied by Amza et al [27]. This study regards the 3D printing of custom-made shoe last, with the aim of optimizing low weight and material consumption.

In fact, the process involves the digitization of the model, optimizing the geometry, and the manufacturing of the piece using FDM printing with ABS, PETG and PLA filaments. Then, 3D printed samples have been fabricated, inserted into the manufacturing process and tested.

During the tests, the shoe lasts were subjected to typical process loads and to high temperatures, highlighting that ABS is the most suitable for the manufacturing process, while PETG and PLA suffer from catastrophic flaws during the process.

As can be seen in the literature, 3D printing has numerous applications in the footwear and orthopaedic footwear industry.

All the references of the state of the art on 3D printing for footwear are reported in Table 2.2, together with the material, technology and application proposed in those works.

Table 2.2 State of the art of 3D printing for footwear

Reference	Material	Technology	Application
[21]	Property material	SLS	Cleat of football shoes
[21]	TPU	FDM	Upper and CM running shoes
[22]	TPU	FDM	Individual running insoles
[23]	TPU	FDM	Shoe soles
[1]	TPU	FDM	Insoles
[24]	-	-	Insoles
[25]	EPU41 (TPU-like)	SLA	Insoles
[26]	TPU	FDM	Insoles
[27]	ABS, PETG, PLA	FDM	Shoe last

3 Scientific background

3.1 The foot

The foot is the distal segment of each lower limb of our body, which guarantees stability in the upright position and allows walking. It is a fundamental organ, as internal muscular forces and external environmental forces, due to contact with the ground, act on it.

Each foot has 26 bones, over 30 joints and more than 100 muscles, ligaments and tendons. It is traditionally divided into 3 regions (Figure 3.1) [46]:

- Hindfoot: between the ankle joint and the transverse tarsal joint. The bones of the hindfoot are the talus and the calcaneus;
- Midfoot: between the transverse tarsal joint and the tarsometatarsal joint. These joints have limited mobility and the five bones of the midfoot comprise the navicular, cuboid, and the three cuneiforms (medial, middle, and lateral);
- Forefoot: composed of five metatarsals, fourteen phalanges, and two sesamoids.

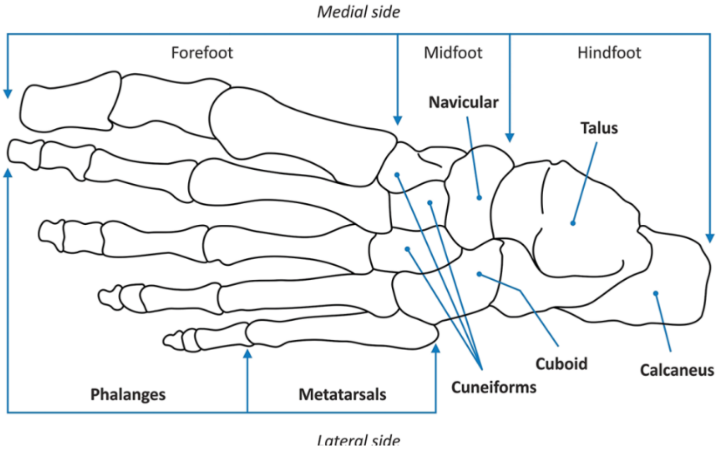

Figure 3.1 The foot

The ankle and foot joints are responsible for the biomechanics of the foot. In fact, as illustrated in Figure 3.2, the foot can perform 3 main movements along 3 axes of rotation, and their respective movement planes:

- Ab-adduction movements, along the vertical axis of rotation and the horizontal plane of movement;
- Plantar flexion and dorsiflexion movements, along the medio-lateral axis of rotation and sagittal plane of movement;
- Inversion and eversion rotations, along the antero-posterior axis of rotation and frontal plane of movement.

Pronation and supination are added to the 3 principal movements, being a combination of them, along an oblique axis that varies depending on the joint. Pronation occurs inward, while supination occurs outward.

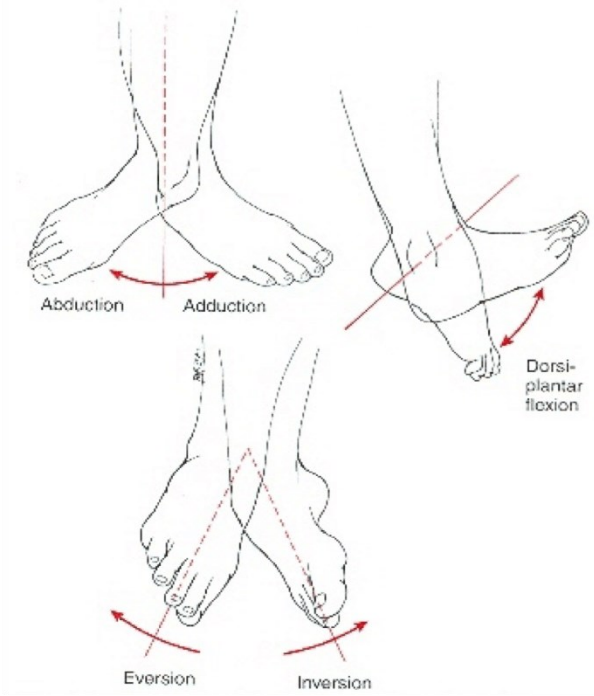

Figure 3.2 Rotations of the foot

Moreover, the foot is in contact with the ground in 3 points:

- Head of the first metatarsal bone (A);
- Head of the fifth metatarsal bone (B);

- Calcaneal tuberosity (C).

Between these 3 points, 3 plantar arches develop: the front longitudinal arch is stretched between the two front support points (A and B); the lateral arch is stretched between the two external support points (B and C); while the internal support points (C and A) the medial arch (the longest and highest of the three) is stretched.

In a normal conformation of the foot, the plantar arches must be balanced to guarantee correct morphology of the foot, and consequently, a correct upright position and correct walking.

The imbalance of these arches leads to flat foot, in which the plantar arch collapses partially or totally, or hollow foot, in which the plantar arch is excessively accentuated (Figure 3.3).

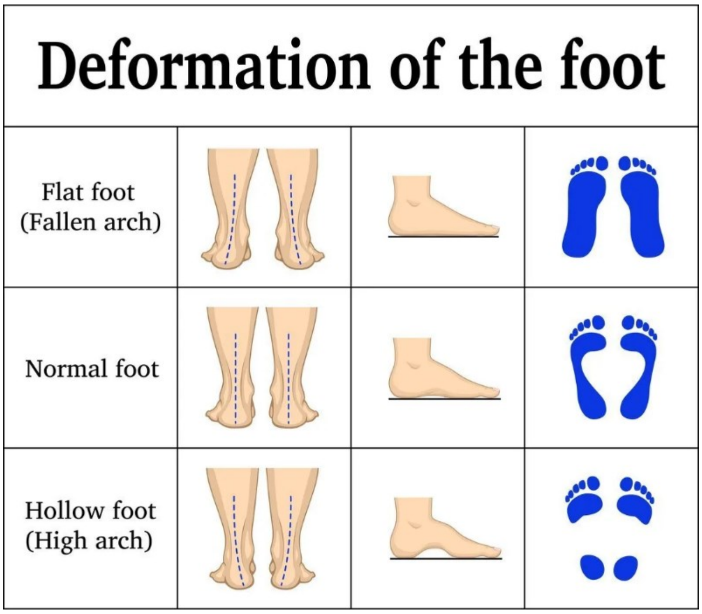

Figure 3.3 Deformation of the foot

These are two deformations of the morphology of the foot which, together with other foot defects or pathologies, affect the distribution of plantar pressure.

3.1.1 Plantar pressure distribution

During standing and walking, the foot and the ground come into contact, developing an impact force with the ground and a distribution of plantar pressure, which may be normal or abnormal. Consequently, the study of the PPD can help in the evaluation of pathologies or abnormalities.

PPD can be evaluated both in standing position and during gait. Asmi et al. [28] conducted an experimental investigation on the plantar distribution of the human foot during standing. In particular, five factors that influence foot behaviour were considered: body mass index, gender, type of arch, diabetes and progressive foot deformity.

The measurements were made with sensors placed in correspondence with the big toe, metatarsal 1, metatarsal 2, metatarsal 3 and heel.

The results of this study reveal that body mass increases the overall plantar pressure; regarding gender, there are no significant differences in contact area between men and women; the type of arch leads to different locations of the plantar peaks. Finally, in healthy subjects the highest peak and mean plantar pressures were found at the second and third metatarsal heads in healthy subjects. For the diabetic factor, pressures will distribute more to the metatarsals and heel area where the ulcers are usually developing.

Also Ang et al [29] studied the plantar pressure distribution during free standing, in a population of 24 healthy young adults. Sensors have been placed in 6 regions of the foot: hallux (HA); medial forefoot (MF); central forefoot (CF); lateral forefoot (LF); lateral midfoot (LM); hindfoot (HF).

PPD was measured from the flat plane to 25° of inclination, revealing that, in the case of flat plane, hindfoot exerts the greatest pressure (32%), then MF (19%), CF (18%), LF (17%), HA (10%), LM (4%).

As the inclination increases, the subject shifts the greater plantar peak from hindfoot to forefoot regions. Deviations from these values could indicate pathological conditions or abnormalities.

Studies on the distribution of plantar pressure can also be conducted during the gait, and are useful in distinguishing normal and pathological subjects.

Rai et al [30] studied a population of 66 subjects (46 males and 20 females), of which 56 had a normal gait, while 8 had a pathological gait. Plantar pressure distribution has been investigated during the stance phase of gait, from heel strike to toe off. Normal subjects follow a set pattern of rollover of the centre of pressure from heel to toe and in the 88% of normal subjects, it was found that maximum peak pressure was in the 2nd and 3rd metatarsal region. The maximum peak pressure of the forefoot was observed during 70 to 82% of the stance phase.

For what concern the pathological group, the plantar pressure distribution was entirely different than that in normal subjects. No definite roll over process like that in normal subjects from heel to toes was observed in pathological subjects and the maximum peak pressure was observed in the midfoot, rather than in the metatarsal region.

3.2 Custom-made insoles

Orthopaedic insoles are medical devices realised to prevent, compensate or correct postural or foot dysfunctions or pathologies. Foot orthotics can be divided into two categories: prefabricated, which are less expensive, easily made and generally shaped, and custom-made, which take longer time to design and manufacture and are more expensive but, definitely, more effective and patient-appropriate [31].

Compared to prefabricated insoles, customized insoles tend to improve the biomechanics of the soles and even the lower extremities. By optimizing the traditional support structure, it can be more suitable for the patient's plantar structure, thereby reducing damage and improving comfort [24].

In particular, custom-made insoles are realised according to medical prescription, for the exclusive use of a specific patient.

They can improve a variety of medical conditions, such as arthritis, foot or ankle injuries, plantar fasciitis, flat feet or diabetic feet, back pain and incorrect posture. These kinds of devices are not able to cure the problematic, but it is able to compensate it, giving relief to the symptoms.

Custom-made insole is generally made up of two parts: the base and the covering material. Shock-absorbing materials are used to manufacture the base, with the aim to alleviate certain areas of the foot, relieving the areas of greatest pressure. While, the covering material comes into direct contact with the foot and it is biocompatible, hypoallergenic and breathable.

3.2.1 Material

The material currently used for insoles is EVA (Ethylene-Vinyl Acetate), which is an elastomeric polymer, copolymer of ethylene and vinyl acetate, that can be compared to rubber in terms of softness, flexibility and elasticity. It is particularly useful because of its excellent properties, including good energy-absorber and high fracture toughness relative to other polymers [32]. EVA is widely used in many fields such as electrical insulation, cable jacketing and repair, component encapsulation and water proofing, corrosion protection, packaging of components and the shoe industry, which directly highlight the extent of its industrial importance [33].

EVA foam in sports application is typically layered with harder polymers such as polycarbonate or a composite laminate to provide an excellent performance in dumping property [32]; while, in the orthopaedic footwear field, it is useful because it manages to provide comfort, lightness and good performance in relation to the needs of the insole.

On the other hand, machining of EVA foam as orthotic insoles is a challenging process from the point of machinability because the material has anisotropic and non-homogeneous properties [32].

EVA blocks of the following dimensions are used for the manufacturing of insoles:

- 350x260x30 mm;
- 350x260x40 mm;

- 350x300x30 mm;
- 350x300x40 mm;

Sometimes, when a greater thickness is necessary, two blocks can be coupled together.

Two of the most important features of EVA are density and hardness. The very low density of the material, having values between 0.11 and 0.40 g/cm^3, confers lightweight to the piece; while low values of hardness, measured on scale Shore A, gives flexibility to the insole. Hardness varies from 20 Shore A to 70 Shore A, but the most frequently used are those that varies from 30 Shore A to 50 Shore A. The latter mentioned can be compared in terms of density, compression and shrinkage, as reported in Figure 3.4, 3.5 and 3.6. As it can be seen, density values increase with hardness, and the same happens for shrinkage percentage. On the contrary, values of compression, in terms of percentage of deformation, decreases as the hardness increases.

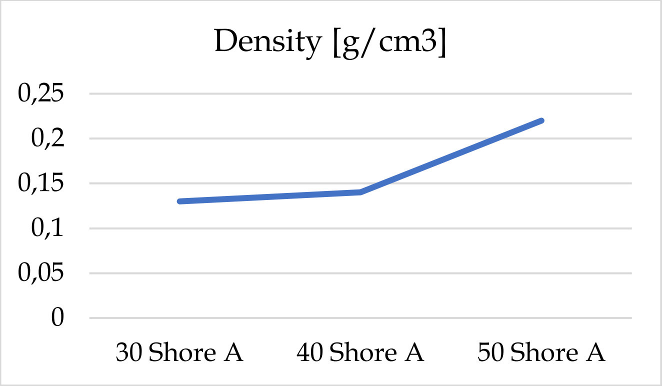

Figure 3.4 Relationship between hardness and density

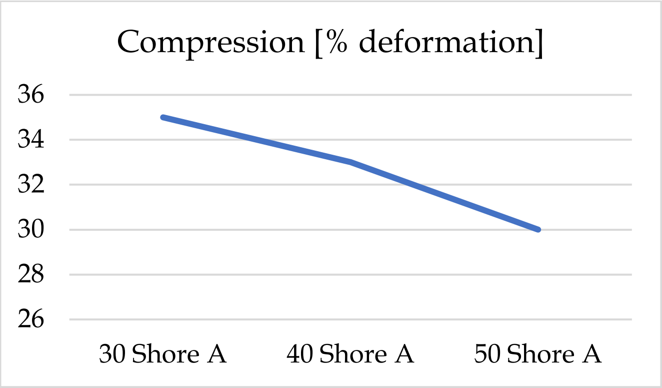

Figure 3.5 Relationship between hardness and compression

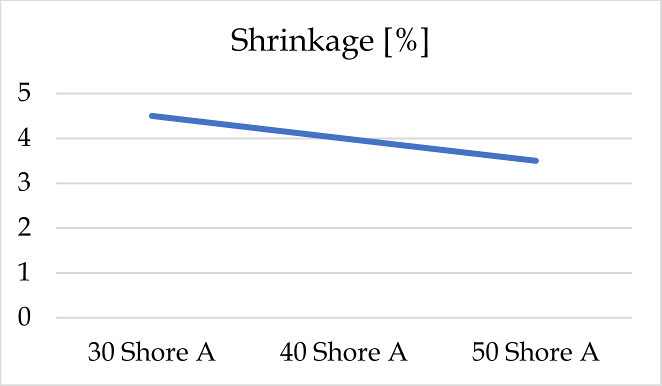

Figure 3.6 Relationship between hardness and shrinkage

In terms of safety, in normal conditions, EVA is harmless to the mankind and environment, combustion risk arise only in presence of ignition sources and it floats in water. At room temperature the product is not toxic; only in case of combustion, the gases from combustion could cause breathing problems and the exposure to the melt product could cause burns.

Moreover, the covering material is generally made of EVA, with a thickness and hardness that depend on the individual need. The peculiarity of this layer, unlike the base, is that it comes into direct contact with the foot, and therefore with the skin. For this reason it is essential that the coverage meets the following characteristics. It should be:

- Free from toxicological and carcinogenic risks;
- Disinfected ;
- Compatible with skin.

All these characteristics must be tested and certified.

3.2.2 Process analysis

The production process of custom-made insoles manufactured with subtractive techniques is divided into five main phases:

1. The first phase, in the technical office, includes receiving the order, creating the processing note and managing the progress. It takes 15 minutes.

2. The second phase consists in preparing the material in the warehouse, taking 5 minutes.
3. The third phase, or design phase, involves CAD design, generation of the CAM path and cutting of the roofing materials. With this procedure the digital model of the insole is created and it takes 40 minutes.
4. The fourth phase is preparation of the pantograph, milling and finishing. It is the longest and more consistent phase, taking about 60 minutes.
5. The fifth and final phase develops in the warehouse and administration, consisting in 10 minutes.

All these steps are shown in Figure 3.7.

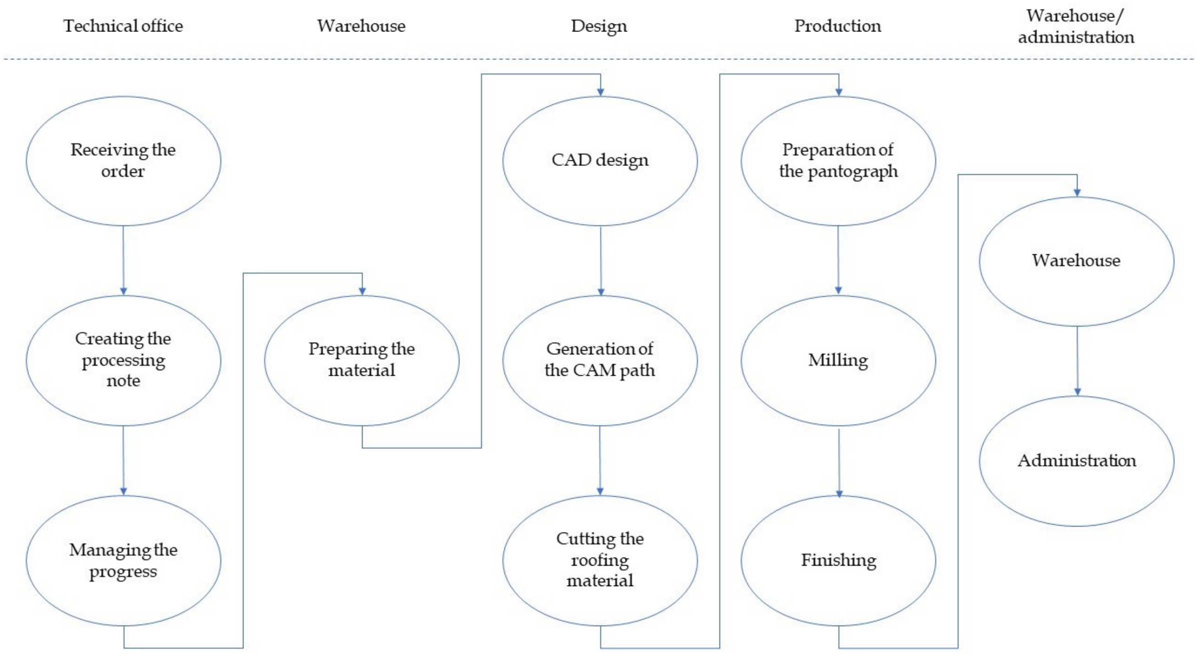

Figure 3.7 Productive process of custom-made insoles

The timing of each production phase is shown in Table 3.1. It refers to a pair of insoles.

Table 3.1 Working phase of SM of CMI

Working phase – SM	Timing
Receiving order	5 min
Processing note	5 min
Managing of progress	5 min
Preparing the material	5 min
CAD design	30 min
CAM path	5 min
Cutting of the roofing materials	5 min
Preparation of the pantograph	5 min
Milling	35 min
Finishing	20 min
Warehouse	5 min
Administration	5 min
Total	2 h 10 min

3.2.3 *Insole design*

The design procedure of a custom-made orthopaedic insole determines the geometry and the choice of material, starting from some measurements, and defines the milling path. This is almost entirely computerized, and involves the four steps shown in the figure.

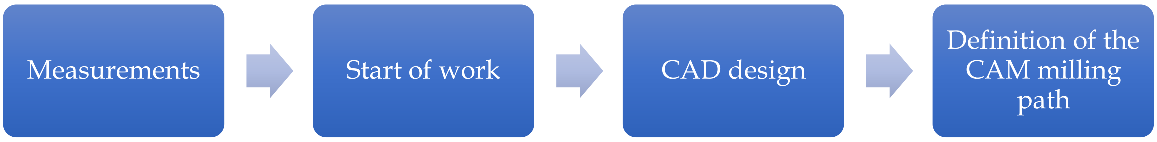

Figure 3.8 Insole design phases

The first step consists in the diagnosis of the foot, carried out by the specialist doctor, and the 3D scan of the foot. Sometimes, when scanning is not possible, footprint are taken in a foam box.

The scans and the processing document are viewed by the designer in the second design phase. Based on this information, the CAD design of the customized insole begins. In this third step, first a starting shape is chosen, onto which the scan of the foot is superimposed, verifying that the shape is suitable for the project. After that, the insole geometry is defined, in particular:

- The section curves of the foot are extracted, defining whether to flatten the forefoot part
- The medial/lateral profile curves of the insole are drawn
- The guiding curves of the insole are created and possibly modified, together with the internal support curve and the shape of the heel cup
- The final surface of the insole is created and any defects are corrected

An example of a CMI CAD design is shown in Figure.

The fourth and final phase involves the generation of the CAM path, that is the set of cutting parameters necessary for processing the insole with the milling machine.

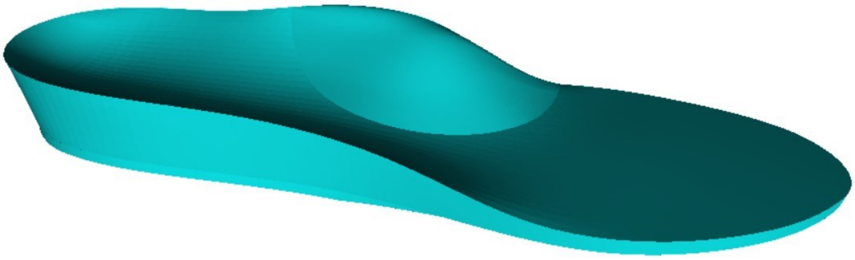

Figure 3.9 CAD design of a insole

Once the base of the insole has been milled and finished, the covering material is applied, which has a functional task.

3.2.4 *Insole comfort*

The comfort of an insole does not only concern the alleviation of symptoms and pressure relief, but also the maintenance of a certain temperature and degree of humidity inside the shoe. The latter, in fact, are risk factors for the onset of dermatological problems, such as ulcers, in the case of diabetic feet, or fungi.

For patients with diabetic feet, high skin temperature has been recognized as a risk factor of skin degradation [34], together with excessive moisture, that will lead to severe damage to feet and is very harmful for diabetic patients [35].

Sasagawa's study [36] involved 420 patients, categorized into non-tinea, tinea pedis, or tinea anguium groups, and external climate conditions and temperature, humidity, and dew point inside the patient's shoe were recorded. The results of this study demonstrated that the combination of high temperature and high humidity inside the shoe are factors that contribute to the development of the fungus. Moreover, there are three factors that can be considered necessary for the development of tinea: an environment with high temperature and high humidity, sufficient adhesion time and fine cracks on the skin or nails.

Going deeper into studies, Ning et al [34] examined a population of 21 female participants (age: 25.5 ± 4.5 years old, 161.5 ± 6.5 cm, and 52.5 ± 12.5 kg). Their shoe size ranges from EU36 to 40 and the exclusion criteria are any foot disease or lower limb injury. Participants wore four types of orthotics made of different materials during a 30-minute walk on a treadmill. The insole samples are made of: PU insole, TPU insole (3D-printed), textile-fabricated insole made of knitted spacer fabric with silicon tubes inlay, and leather insole. At the end of the trials, perceived comfort towards heat and moisture and the thermal comfort of the insoles were measured.

The study outcome provides new information for the design of footwear with a particular focus on insole materials. In particular, no significant difference can be found between the traditional PU, 3D printed TPU, and leather insoles in maintaining foot skin temperature. Despite the popularity of custom-made 3D printed insoles, its performance in sweat absorption is less desirable as compared to the textile-fabricated insole.

4 Method

This chapter illustrates the practical method carried out in this thesis for the evaluation of the additive manufacturing of custom-made insoles, and used in the subsequent case study. The workflow is shown in Figure 4.1.

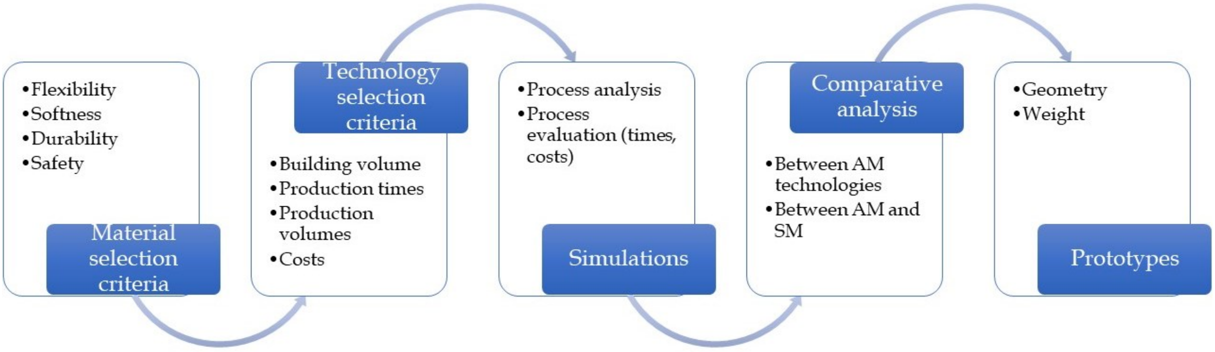

Figure 4.1 Workflow of the method

4.1 Material selection criteria

As illustrated in Figure 4.1, the first selection criteria concern the material. In fact, in order for the material used in 3D printing to be applicable to an insole, it must respect certain characteristics of:

- Flexibility;
- Softness;
- Durability;
- Safety.

From a mechanical point of view, primarily the material must be flexible, since during walking the sole of the foot flexes, and with it also the insole.

Therefore it is inadvisable to use a rigid material, which would compromise the functionality and comfort of the insole during the gait.

Additionally, mechanical properties such as resilience and compressive stiffness are important characteristics in the choice of material. In particular, resilience is linked to the durability of the material, and consequently the durability of the insole, while the compression stiffness is proportional to the physical characteristics of the material, such as density and hardness. In fact, Lo et al. [37] studied that compression stress behaviour of typical material used for the manufacturing of insoles, and demonstrated that both density and hardness show a positive slope, which indicates a positive relationship with compression stress; a denser or harder insole material shows more resistance to compression force.

Furthermore, the material should be soft, so as to provide a cushioning effect, absorb shocks and reduce peaks of plantar pressure, which are the main functions for which custom-made insoles are used. This characteristic is connected to the hardness, physical property of the material.

Finally, in case the insole comes into contact with the skin, the selected material must be declared biocompatible and certified according to the ISO 10993, or at least non-toxic and not dangerous for humans. If it is not biocompatible, you can consider using the same layer of covering material used for traditional insoles, which is declared compatible with the skin, free from toxicological and carcinogenic risks and disinfected. If a covering layer is placed between the insole and the foot, there is no need for the base material of the insole to be certified with ISO 10993.

From the imposition of these material choice criteria, the material(s) will emerge that can be considered suitable for application to the 3D printing of custom-made insoles.

4.2 Technology selection criteria

Once the suitable material has been chosen, the printing techniques are derived. In order to select the technologies that can be applied in the specific case, it is necessary to impose some selection criteria also on the printing techniques. These allow the evaluation of 3D printing to be carried out at 360 degrees, considering the entire manufacturing process.

4.2.1 Building volume of the printer

The building volume of the printer is the first exclusion criteria, as it must be large enough to be able to contain at least an entire insole. This is a characteristic that varies depending on the specific printer, and it represents the maximum size of an object that 3D printer is capable of producing. It is generally defined by Cartesian coordinates system of X, Y and Z dimensions in millimetres [mm].

There are some important benefits of having a large print volume, including:

- The ability to print the model in one piece. In fact, having a smaller print volume may result in the need to print the parts in two pieces, to be joined together after printing;
- The possibility of producing multiple products in the same batch, avoiding to start the print several times;
- The opportunity to grow and start printing for different applications.

4.2.2 Production times

Production times are essential when choosing a 3D printing technology. There are several factors that determine the time to print a part, including the size, height, complexity and technology used.

More specifically, the factors that influence printing speed are:

- Size: the bigger the part, the longer it takes to print;

- Geometry/complexity: the more complex the geometry of the part, the longer it takes to print;
- Quantity of parts, also in relation to the chosen technology;
- Infill pattern of the internal structure: increasing the internal density of the part, material consumption and production time increase;
- Layer height: thinner layers provide smoother finish and better quality, but at the same time, it takes longer to produce;
- Post-processing: each technology has its own post-processing, which can take from a few minutes to a few hours.

Regarding the entire additive manufacturing process, printing time and the time spent in the labour phases must be taken into consideration.

4.2.3 Production volumes

At the moment, with traditional manufacturing, one pair of insoles is produced at a time. From a future perspective, with additive manufacturing technologies it is conceivable to be able to produce more than two insoles at a time, depending on the printing volume and compatibly with acceptable production costs and times.

4.2.4 Costs

From an industrial point of view, costs are a determining factor in the acquisition of new technologies. Considering the entire manufacturing process, the cost calculation is based on the following data:

- Cost of material;
- Labour cost.

In particular, the cost of the material depends on the size of the object and its filling percentage. The more material used, the higher the cost. While the labour cost depends exclusively on the processing phases carried out by the personnel.

4.3 Simulation

The method proposed in this thesis requires that the materials and technologies that emerge are subjected to simulation. Through the process analysis, data emerging from the simulations are inserted into the manufacturing process for the evaluation of costs and times necessary for 3D printing.

4.3.1 Process analysis

The process analysis is carried out starting from the traditional manufacturing process. By evaluating the individual phases of the process, it is possible to identify which of these can be:

- Left, if it is the same between the old and new process;
- Modified, if it changes in some way between the old and new process;
- Discarded, if it is not foreseen in the new process;
- Added, if it is not foreseen in the old process, but necessary in the new one.

In this analysis it is also necessary to specify, for each of the phases, whether they are carried out by personnel or by machine.

4.3.2 Process evaluation

By introducing the simulation results into the previously analysed process, it is possible to carry out an overall evaluation of the process, in terms of:

- Costs, which include material costs and labour costs;
- Times, which include printing times and labour times.

The evaluation of the process can be carried out considering both the batch and the single object produced.

4.4 Comparative analysis

The comparative analysis involves the comparison between the data obtained from the previous simulation phase. In particular, this analysis involves two comparison methods:

1. The first involves the comparison between additive manufacturing techniques, so as to be able to identify which are the most convenient;
2. The second involves the comparison between subtractive manufacturing and additive manufacturing techniques, assuming traditional manufacturing as the threshold value.

Both comparison methods involve the use of time and cost data that emerge from the previous phase.

4.5 Prototype

The last step of this method involves the development of prototypes using the material and technology which, from the previous steps, appear to be the most suitable for the application of 3D printing to the production of customized insoles. In particular, respect for the geometry of the insole and its weight are evaluated.

4.5.1 Geometry

Since the custom-made insole is a medical device and must be of assistance and support for the patient during walking, it is essential that the 3D printed insole faithfully reflects the technical requests that accompany the order. Therefore, it is necessary that additive manufacturing is able to respect, for all intents and purposes, the geometries of the three-dimensional design of the customized insole.

4.5.2 Weight

The weight of the insole is a factor that significantly affects the quality of the product. In fact, since the orthopaedic insole is used by patients suffering from problems or pathologies, the insole should be as light as possible, so as not to weigh on the overall weight of the orthopaedic shoe.

Most of the time patients have locomotion problems, which can be aggravated by excessive weight of the shoe. Moreover, prolonged use of heavy shoes can strain joints and back. It can also inhibit your movement as the feet become somewhat restricted due to the lack of flexibility [38].

For this reason, it is essential that the insole is characterized by an adequate weight, to allow maximum comfort inside the shoe, giving natural lightness to the foot.

5 Case study

Having knowledge of the sources of the previous chapters and the method adopted in this thesis, the real work of investigation and experimentation of 3D printing applied to custom-made insoles begins here.

In fact, in this chapter the previously explained method is applied to the real case, retracing the selection criteria of materials and technologies, simulations, comparative analysis and prototypes.

5.1 Material selection criteria

The first requirement that the material must meet in order to be applied to the 3D printing of customized insoles is flexibility, so the first research will take place among flexible materials. In terms of the physical characteristics of the material, its hardness must fall within values included in the Shore A scale, which is the scale most used in measuring the hardness of medium-soft rubbers, plastics and elastomers. While the Shore D scale is discarded in this thesis, as it is used for medium hard plastics and rubbers. Finally, as regards the biocompatibility of the material, if the sample has already been tested according to ISO 10993 it can be assumed that the foot is directly in contact with the insole, otherwise the same certified covering materials also used in manufacturing can be used of traditional insoles. The material selection criteria are summarized in Table 5.1.

Table 5.1 Material selection criteria

Flexibility	Hardness	Biocompatibility
Flexible material	Shore A scale	Tested (ISO 10993) → contact with skin Not tested → covering material

5.2 Technology selection criteria

From the material selection criteria, one or more materials will emerge that can be considered suitable for the 3D printing of customized insoles, and from these materials it will be possible to derive the additive manufacturing technologies that can be evaluated in this specific context. Some selection criteria are also applied to technologies.

5.2.1 Building volume

With 3D printing it is possible to orient the object to be printed in any way within the print volume. For this reason, for the 3D printing of custom-made insoles it is necessary that at least one of the 3 dimensions of the printing volume is large enough to contain the length of the insole. In particular it is necessary that one of the 3 dimensions is approximately 300 mm, in order to be able to print insoles up to number 45, which corresponds to 290 mm in length. In this way we are able to satisfy the majority of patient requests.

5.2.2 Production times

The production times of the customized insole made through additive manufacturing should reflect those of traditional manufacturing, or at most 150% of the current time needed can be allowed, in favour of larger production volumes and/or lower costs. Shorter times are obviously allowed.

5.2.3 Production volumes

The production volumes of the customized insole made through additive manufacturing should reflect those of traditional manufacturing, therefore 2 insoles for each process. Printing one insole at a time is allowed only in favour of lower times and costs compared to traditional manufacturing. The printing of more than two insoles at a time is allowed if times and costs of the single insole are comparable to those of SM.

5.2.4 Costs

The production times of the customized insole made through additive manufacturing should reflect those of traditional manufacturing, or at most 150% of the current costs can be allowed, in favour of larger production volumes and/or lower times. Lower costs are obviously allowed.

5.3 Simulations

The simulations presented in this thesis has been performed using the simulation software of specific printers, loading the STL file of an insole, previously designed in CAD (Figure 5.1) and lightened using an internal honeycomb structure.

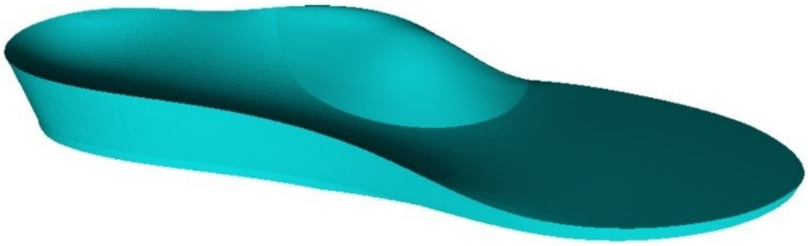

Figure 5.1 3D model of the insole

The following data is obtained from the simulations:

- Material cost per insole;
- Printing time per batch;
- Batch, intended as the maximum number of insoles that can be made with one print;
- Post processing time.

By contextualizing this data in the overall 3D printing process of customized insoles, it is possible to obtain the related costs and times of manufacturing, first of the batch, and then of the single insole.

5.3.1 Process analysis

The analysis of the additive manufacturing process of customized insoles is based on highlighting similarities and differences between the steps involved in SM and AM. The method, applied on the real case, is shown in Table 5.2.

Table 5.2 Process analysis, SM vs AM

Process – SM	SM vs AM	Labour
Receiving order	Leave	Personnel
Processing note	Leave	Personnel
Managing of progress	Leave	Personnel
Preparing the material	Leave	Personnel
CAD design	Leave	Personnel
CAM path	Modify	Personnel
Cutting of roofing materials	Discard	Personnel
Preparation of the pantograph	Modify	Machine
Milling	Modify	Personnel and machine
Finishing	Modify	Personnel
Covering material	Added	Personnel
Warehouse	Leave	Personnel
Administration	Leave	Personnel

These two processes are similar to each other and, in particular, there are only four phases that differentiate the two processes, one discarded and none added.

Moreover, for each phase, Table 5.2 indicates whether it is carried out by personnel or by the machine. This influences the subsequent evaluation of times and costs.

The detailed analysis of the process allows to subsequently quantify the costs and production times of customized insoles, remembering that these change depending on the type of technology used.

5.3.2 Process evaluation

The evaluation of the process is carried out by inserting the data of each simulation within the process, so as to be able to obtain information relating to the costs and times of the process of each technology investigated.

In particular, the quantification of the overall timing of the additive manufacturing of customized insoles is based on the time necessary to carry out the individual phases. For the common phases between AM and SM, the same timings as for SM can be considered, while the other timings emerge from the simulations.

As regards the cost of additive manufacturing of custom-made insoles, it is based on the cost of the individual phases and on the cost of the material, which emerges from the printing simulation.

Each simulation refers to the batch, therefore to the maximum productivity of the single print. With the aim to obtain the production time and cost of the single insole, it is necessary to divide the time and cost of the entire process by the number of insoles obtained from the batch.

5.4 Comparative analysis

The first method of comparative analysis requires that the results emerging from the evaluation of the additive manufacturing processes of custom-made insoles are normalized with respect to the maximum values, so as to be able to identify the longest, shortest, most expensive and cheapest processes. The results of this first analysis are reported in a radar graph.

The second comparative analysis method requires the simulation results to be normalized with respect to subtractive manufacturing, in order to compare traditional manufacturing with 3D printing technologies. The results of this analysis are reported in a histogram graph, highlighting the subtractive manufacturing values as threshold values.

5.5 Prototype

The creation of the prototypes uses the same CAD project of the insole with which the simulations were made and lightened using an internal honeycomb structure. The render of the 3D model of the insole is shown in Figure 5.2.

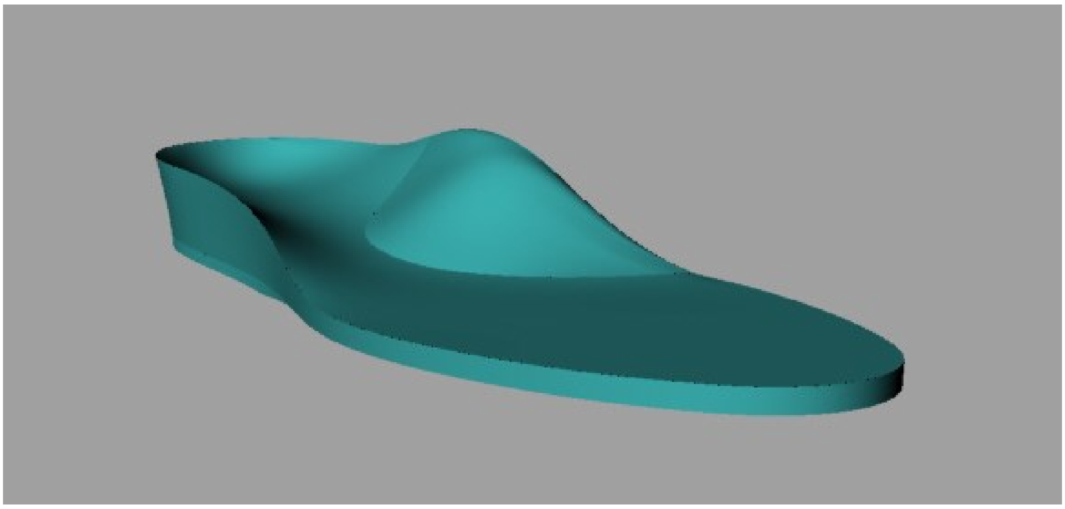

Figure 5.2 Render of the 3D model of the insole

The evaluation of the prototypes is based on the verification of the geometries and weight. In particular, the measurements corresponding to the 3D design of the insole are shown in figure 5.3 and figure 5.4, and must also be respected by the 3D printed insole.

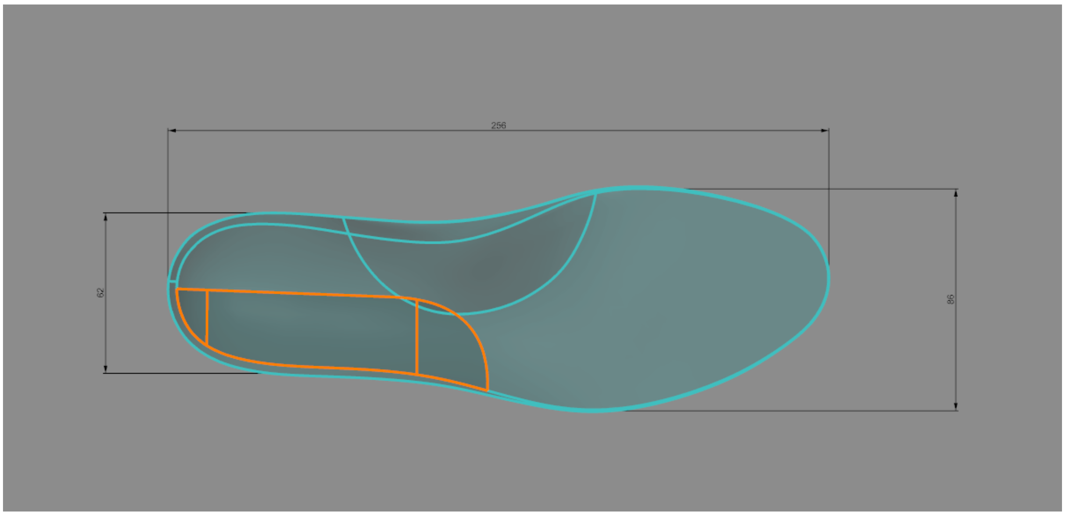

Figure 5.3 Measures of the 3D model along X and Y axes

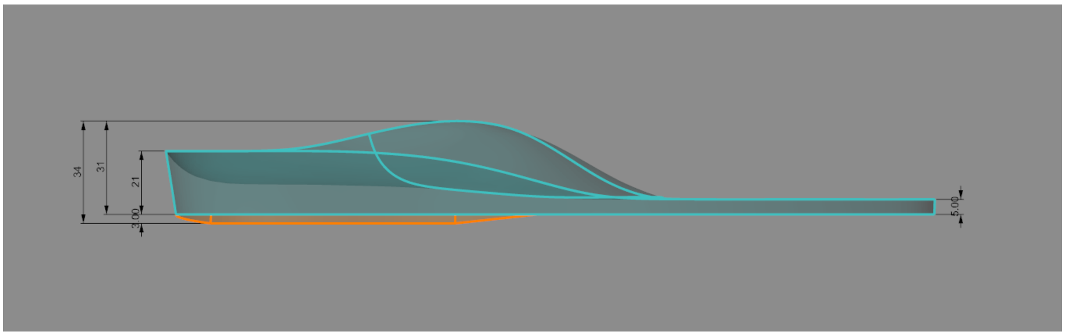

Figure 5.4 Measures of the 3D model along Z axes

These measurements are also shown in table 5.3:

Table 5.3 Measures of the 3D model of the insole

Length along X-axis [mm]	Length along Y-axis [mm]	Length along Z-axis [mm]	Weight [g]
- Rear width: 62 mm - Front width: 86 mm	- Insole length: 256 mm	- Arch height: 31 mm - Rear height: 21 mm - Floor height: 3 mm - Front height: 5 mm	- Insole weight: 20

For what concern the weight of the insole, this should not exceed 150% of the weight of the traditional insole.

6 Results and discussion

This chapter illustrates all the results obtained in this work, following the method and case study illustrated previously. The results obtained concern the material and technologies identified as suitable for the 3D printing of customized insoles. Subsequently the results of the simulations and the prototypes are reported.

6.1 Results

The results chapter is divided into four sections: the first concerns the analysis of TPU (Thermoplastic Polyurethane), together with its fatigue properties and its biocompatibility; the second section identifies the technologies with which it is possible to print TPU and presents the results of their simulations; the third section regards the comparative analysis; the fourth and final section illustrates the prototypes.

6.1.1 TPU (Thermoplastic Polyurethane)

Thermoplastic Polyurethane (TPU) is a thermoplastic elastomer, composed of soft segments and hard segments. The soft segment is generally a flexible segment consisting of methylene, ester, or ether groups, and the hard segment is commonly a rigid segment consisting of aryl, urethane, or urea groups [39].

TPU is developing very fast and used for 3D printing of elastic or flexible parts. It is characterized by its high resistance to abrasion, wear, tear, oxygen, ozone and low temperatures [13]. Thermoplastic polyurethane offers the mechanical performance characteristics of rubber but can be processed as thermoplastics [40], and all these features make the material particularly useful in engineering applications.

The advantages of the TPU include [13]:

- Ultra-soft and flexible;

- Lightweight;
- Excellent physical and mechanical properties, such as good grip and excellent abrasion resistance;
- Shock absorption.

On the other hand, TPU is subject to time, temperature and UV aging, that must be taken in consideration when using thermoplastic polyurethane for some applications.

Boubakri et al [41] investigated the effects of time and temperature on the mechanical properties of TPU, by immerging TPU samples in distilled water at 25, 70 and 90°C at different durations. The study proved that higher is the aging temperature more important is the mechanical degradation, in terms of stress-strain relationship.

In another study, Boubakri et al [42] examined how UV-exposure impact on the properties of TPU. During the aging experiments, the samples were subjected to a UV lamp with temperature variations between 65 and 70°C, for exposure times of 3, 6, 12, 72 and 144 h.

TPU material, which initially has a colourless appearance, yellower in the first stage of aging (after 6 h), and then turn to brown (after 72 h) and therefore remained almost unchanged. SEM photographs have shown the formation of microcracks on UV-exposed surfaces, especially at long exposure duration. From DSC analysis, the thermal properties of the studied TPU were affected. The glass transition temperature (Tg) decreased in the beginning and then increased with UV-exposure time. Similarly, the mechanical properties, elastic modulus and stress at 200% of strain, initially decreased and then increased progressively revealing an increase in crosslink density. On the other hand, the wear resistance of the material surface decreased, and this degradation became more important with UV exposure time.

Taking in consideration all these advantages and disadvantages, TPU can be considered as the most suitable material to be used for 3D printing of insoles.

Traditional TPU for additive manufacturing can be found in the form of filament and powder, used with FDM and SLS technologies respectively. It can be found with hardness varying between 80 and 95 Shore A, which is much higher than the hardness that characterizes insoles.

For this reason, it is necessary to modulate the internal structure of the piece, so as to lighten it and make it more flexible. Both [26] and [43] studied variable internal geometry, observing that the variation of the infill density progressively varies the final elasticity of the product.

Traditional TPU cannot be used with resin 3D printing technologies, but research has developed new flexible resins that are able to simulate the properties of TPU. These resins are called TPU-like and they are used with SLA and DLP technologies.

6.1.1.1 Fatigue properties of TPU

Traditional insoles have a durability of approximately six months, and in this period of time they are subjected to continuous stress and, mainly, vertical compressions. Therefore, it is essential to investigate the behaviour of TPU when subjected to fatigue cycles.

The composition of the TPU, made of hard and soft segments, makes it vulnerable. In fact, the hard and soft segments are usually incompatible in thermodynamics, and hydrogen bonds can form between TPU molecules, generating microphase regions and microphase separation [39].

Wang et al [39] subjected the material to a load-controlled tensile test, in a range of 10^3 to 10^7 cycles at room temperature, using a sinusoidal load and a stress ratio of 0.1 with a frequency of 5 Hz. the S-N curve of TPU material shows a downward trend before reaching the fatigue limit (10.25 MPa), and the energy is continuously consumed during the cyclic creep process and undergoes three stages of the hard segment and the soft segment changes.

The infrared spectrum study shows that the increase in fatigue life will lead to more physical crosslinking, resulting in the reduction of hydrogen bond content, and the increase in microphase separation, leading to the occurrence of fatigue fracture.

In addition, the scanning electron microscope and three-dimensional confocal analysis showed that the crack originated from the aggregation of micropores on the surface of the material and was accompanied by the slip of the molecular chain, the crack propagation direction was at an angle of about 45°.

The study conducted by Scetta et al [44] uses a pure shear geometry to investigate how a crack propagates in a typical commercial soft TPU submitted to a cyclic loading.

Results showed that, when TPUs are cyclically loaded up to the same value of maximum stretch, their stress-stretch curve changes with the number of applied cycles, but eventually achieves a steady-state. Moreover, they demonstrated that TPUs possess typical values of fracture toughness and a cyclic fatigue threshold almost one order of magnitude larger than those of filled SBR rubbers with similar values of small strain modulus.

This implies that TPUs may either resist for more cycles than classical rubbers when similar energy release rates are applied, or may sustain larger strains with only moderate crack growth when rubbers would fail in a single cycle. This result confirms that TPUs possess the combination of high fatigue threshold and low stiffness.

6.1.1.2 Compatibility of TPU

Custom-made orthopaedic insoles, being medical devices, must be subjected to biological risk assessment. This procedure is identified by ISO 10993, which is the standard used for the evaluation of the biocompatibility of medical devices and materials. In particular, the biocompatibility of TPU, like any other material, refers to the specific formulation of the material and can be found already tested by the manufacturer.

In the specific case of custom-made orthopaedic insoles, if the material has already been tested and assessed as biocompatible, the insole without covering material can be envisaged. On the contrary, if the material has not been tested, it is necessary to insert covering material, which is biocompatible.

6.1.2 Process analysis

The additive manufacturing production process of custom-made orthopaedic insoles is shown in Table 6.1. As reported, for each of the phases of the process it is indicated whether it is carried out by personnel or by the machine, so as to be able to differentiate the times and costs of the personnel and those of the machine. In particular:

- Personnel: receiving order, processing note, managing of progress, preparing the material, CAD design, G-Code generation, preparation of the printer, post-processing, covering material, warehouse, administration;
- Machine: printing, post-processing.

Table 6.1 Process analysis, AM

Process – AM	Labour
Receiving order	Personnel
Processing note	Personnel
Managing of progress	Personnel
Preparing the material	Personnel
CAD design	Personnel
G-Code generation	Personnel
Preparation of the printer	Personnel
Printing	Machine
Post-processing	Personnel and machine
Covering material	Personnel
Warehouse	Personnel
Administration	Personnel

It is important to remember that the phases carried out by the machine, and therefore printing and post-processing, depend on the type of technology examined.

6.1.3 Simulations

As regards the 3D printing of customized insoles, the most suitable materials turn to be TPU and TPU-like resins, capable of giving them lightness and flexibility. Starting from these materials, 4 different types of printing can be identified and used for the simulations:

- FDM (Fused Deposition Modelling);
- SLA (Stereolithography);
- DLP (Digital Light Processing);
- SLS (Selective Laser Sintering).

This results section reports the simulations and subsequent evaluations of the four technologies mentioned above, in terms of process analysis, costs and time. These last two data are reported both for the entire batch, at maximum productivity, and for the production of the single insole.

To quantify process times, reference is made to the printing time and the sum of the times of the labour phases. The formula is as follows (Eq. 1):

Eq. 1 $$time_{batch} = time_{print} + \sum time_{labour}$$

Using the formula described above, the time necessary for the entire process is obtained, which must be divided by the number of insoles printed in a batch with the aim of obtaining the time necessary for the single insole (Eq. 2):

Eq. 2 $$\mathrm{time_{insole}} = \frac{\mathrm{time_{batch}}}{\mathrm{n^\circ\ insoles}}$$

Similarly, to calculate the costs of the process it is necessary to add the cost of the material and that of the individual labour phases (Eq. 3):

Eq. 3 $$\mathrm{cost_{batch}} = \mathrm{cost_{material}} + \sum \mathrm{cost_{labour}}$$

In particular, as regards labour costs, reference is made to 25,00 € per hour for the design phase and 20,00 € per hour for all other labour phases.

With the aim to obtain the cost of the single insole you need to divide the cost of the lot by the number of insoles (Eq. 4):

Eq. 4
$$\mathrm{cost}_{\mathrm{insole}} = \frac{\mathrm{cost}_{\mathrm{batch}}}{\mathrm{n°\ insoles}}$$

Figure 6.1, Figure 6.2 and Figure 6.3 show how the insoles are arranged inside the print volume, for FDM, DLP and SLS respectively. The printing simulations has been done using the printer manufacturers' software, which can be downloaded from their website.

SLA technology exploits the vertical printing of the insoles, but for confidentiality reasons it is not possible to include the image of the printing simulation in this thesis.

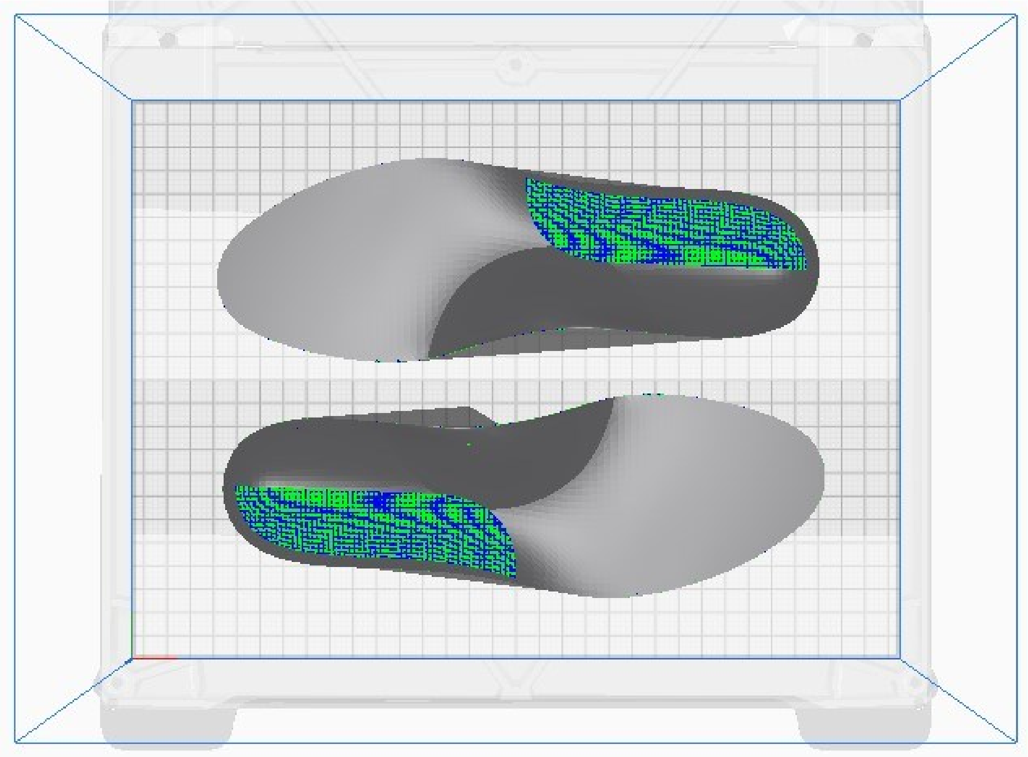

Figure 6.1 FDM printing simulation

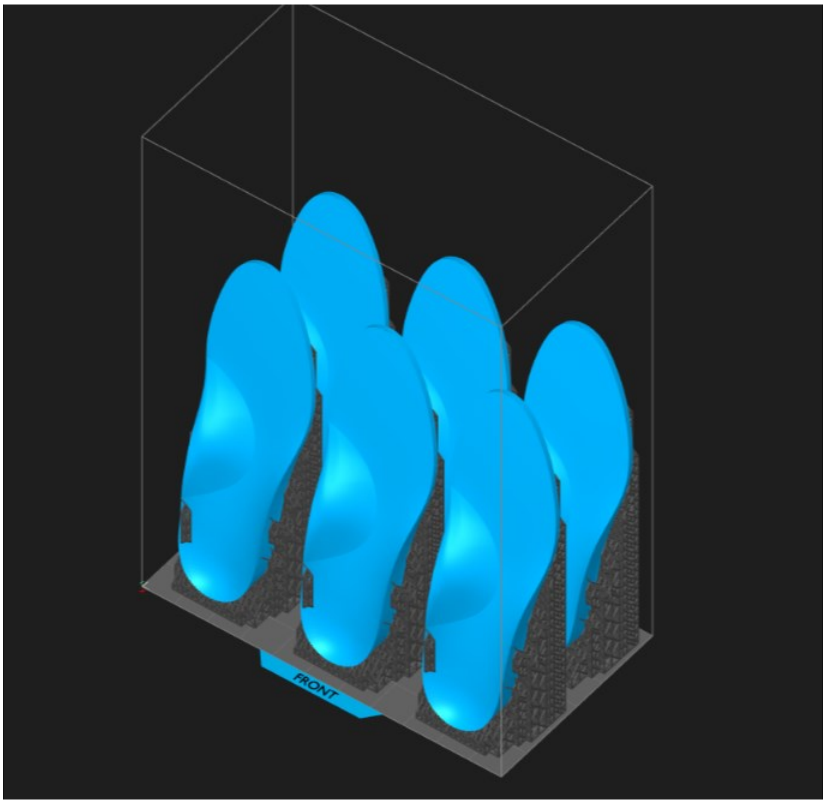

Figure 6.2 DLP printing simulation

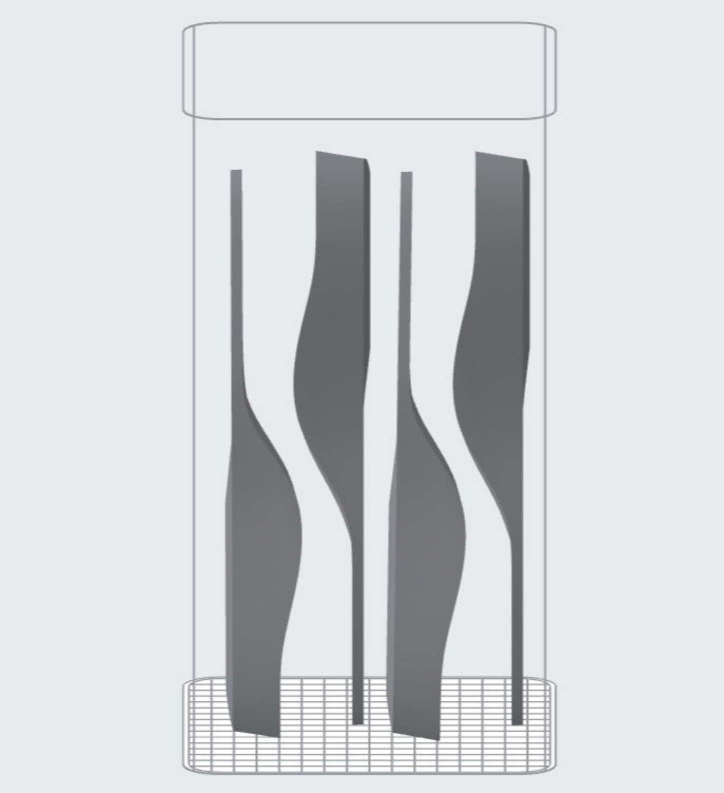

Figure 6.3 SLS printing simulation

6.1.3.1 FDM technology, TPU filament

The first simulation concerns FDM technology, working with a TPU filament. The details of the material are shown in Table 6.2:

Table 6.2 FDM material details

Material	
Type of material	TPU filament
Hardness	Shore 95A
Compatibility	Not tested

Table 6.3 shows the details of the technology:

Table 6.3 FDM technology details

Printer	
Building volume	330 x 240 x 300 mm
Filament diameter	2.85 mm
XYZ resolution	6.9, 6.9, 2.5 micron
Nozzle diameter	0.25, 0.4, 0.6, 0.8 mm
Nozzle temperature	180-280 °C
Operating ambient temperature	15-32 °C

The following results were obtained:

- Batch: 2 insole per print;
- Material cost: 22,00 € per print;
- Printing time: 24 hours per print;
- Post-processing time: not necessary.

Table 6.4 shows times and costs of the entire process. In this case we do not find the post-processing phase, because it is not foreseen.

The time of the printing phase considers the 24 hours necessary for printing, carried out solely by the printer. While the printing cost refers only to the cost of the material. As regards the application phase of the covering material, the times refer to the labour of the staff, while the costs refer to the cost of labour and the cost of the material.

Table 6.4 Simulation of FDM process

Working phase – FDM	Times	Costs
Receiving order	5 min	1,67 €
Processing note	5 min	1,67 €
Managing of progress	5 min	1,67 €
Preparing the material	5 min	1,67 €
CAD design	30 min	12,50 €
G-Code generation	5 min	1,67 €
Preparation of the printer	5 min	1,67 €
Printing	24 hours	22 €
Covering material	10 min	4,93 €
Warehouse	5 min	1,67 €
Administration	5 min	1,67 €
Total	25 h 20 min	52,79 €

In this case the batch production times and costs are the same for the single insole, therefore:

- Time per insole: 12 h 40 min;
- Cost per insole: 26,40 €.

6.1.3.2 SLA technology, TPU-like resin

In this second simulation, SLA technology uses a TPU resin. The details of the material are shown in Table 6.5:

Table 6.5 SLA material details

Material	
Type of material	TPU-like resin
Hardness	Shore 75A
Compatibility	Not tested

Table 6.6 reports the details of the printer:

Table 6.6 SLA technology details

Printer	
Building volume	300 x 300 x 500 mm
Slice thickness	10-100 micron
Operating temperature and humidity	20-25 °C / 60%

The following results were obtained:

- Batch: 12 insoles per print;
- Material cost: 245,00 € per print;
- Printing time: 20 hours per print;
- Post processing time: 5 hours. It consists of washing and curing for the finished part. Post-processing is made by other machineries, therefore it is possible to hypothesize parallel processing between the post-processing and the subsequent printing. For this reason only 10 minutes of labour is taken into account in this phase.

Table 6.5 shows times and costs of the entire process. The time of the printing phase considers the 12 hours necessary for printing, carried out solely by the printer. While the printing cost refers only to the cost of the material. As regards the application phase of the covering material, the times refer to the labour of the staff, while the costs refer to the cost of labour and the cost of the material.

Table 6.7 Simulation of SLA process

Working phase – SLA	Times	Costs
Receiving order	5 min	1,67 €
Processing note	5 min	1,67 €
Managing of progress	5 min	1,67 €
Preparing the material	5 min	1,67 €
CAD design	30 min	12,50 €
G-Code generation	5 min	1,67 €
Preparation of the printer	5 min	1,67 €
Printing	12 hours	245 €
Post-processing	10 min	3,33 €
Covering material	60 min	29,60 €
Warehouse	5 min	1,67 €
Administration	5 min	1,67 €
Total	14 h 30 min	307,12 €

From the results of costs and times for the batch, costs and times relating to the single insole can be obtained:

- Time per insole: 1 h 12 min;
- Cost per insole: 25,60 €.

6.1.3.3 DLP technology, TPU-like resin

The third simulation involves the use of a DLP technology 3D printer and a TPU-like resin. The details of the material are shown in Table 6.8:

Table 6.8 DLP material details

Material	
Type of material	TPU-like resin
Hardness	Shore 55A
Compatibility	Not tested

Table 6.9 reports the details of the printer:

Table 6.9 DLP technology details

Printer	
Building volume	274 x 155 x 400 mm
Max resolution	4K
Wavelength	405 µm
Slice thickness	10-100 micron
Operating temperature and humidity	20-25 °C / below 70%

This resin is not dangerous after polymerization, but before this process it is irritating to the skin, eyes and respiratory system, therefore care must be taken when handling it as a liquid. Furthermore, it is important to check that, if the resin remains inside the insole (due to poor design of the lightening cells or inaccurate washing), it does not leak out during the use of the insole.

The simulation results are as follows:

- Batch: 6 insoles per print;
- Material cost: 270,00 € per print;
- Printing time: 5 hours and 17 minutes per print;
- Post processing time: 45-60 min. It consists of washing and curing for the finished part. Post-processing is made by other machineries, therefore it is

possible to hypothesize parallel processing between the post-processing and the subsequent printing. For this reason only 10 minutes of labour is taken into account in this phase.

Table 6.10 shows times and costs of the entire process. The time of the printing phase considers the 5 hours and 15 minutes necessary for printing, carried out solely by the printer. While the printing cost refers only to the cost of the material. As regards the application phase of the covering material, the times refer to the labour of the staff, while the costs refer to the cost of labour and the cost of the material.

Table 6.10 Simulation of DLP process

Working phase – DLP	Times	Costs
Receiving order	5 min	1,67 €
Processing note	5 min	1,67 €
Managing of progress	5 min	1,67 €
Preparing the material	5 min	1,67 €
CAD design	30 min	12,50 €
G-Code generation	5 min	1,67 €
Preparation of the printer	5 min	1,67 €
Printing	5 h 15 min	270 €
Post-processing	10 min	3,33 €
Covering material	30 min	14,80 €
Warehouse	5 min	1,67 €
Administration	5 min	1,67 €
Total	7 h 7 min	313,99 €

From the results of costs and times for the batch, costs and times relating to the single insole can be obtained:

- Time per insole: 1 h 11 min;
- Cost per insole: 52,33 €.

6.1.3.4 SLS technology, TPU powder

The fourth and final simulation concerns SLS technology, together with TPU powder. The details of the material and the printer are shown in Table 6.11:

Table 6.11 SLS material details

Material	
Type of material	TPU powder
Hardness	Shore 90A
Compatibility	Biocompatibility verified

In this case a 90 Shore A hardness TPU powder has been used, which was evaluated in accordance with ISO 10993-1:2018, and passed the requirements for biocompatibility risks, resulting non-cytotoxic, non-irritant, non-sensitizer.

Table 6.11 reports the details of the printer:

Table 6.12 SLS technology details

Printer	
Building volume	165 × 165 × 300 mm
Layer thickness	110 micron
Operating temperature and humidity	18-28 °C / below 50%
Internal temperature	200 °C

The simulation results are as follows:

- Batch: 4 insoles per print;
- Material cost: 140,00 € per print;
- Printing time: 20 hours per print;
- Post processing time: 20 hours. It consists of cooling the powder tank, extracting the pieces, cleaning the excess powder from them and recycling the powder. Of these 20 hours of post-processing, only one hour is carried out by the staff, the remaining time is necessary to cool the powder tank. For this

reason, one hour of labour will be considered for the timing, and 20 € of labour for the costs.

Table 6.13 shows times and costs of the entire process. The time of the printing phase considers the 5 hours and 15 minutes necessary for printing, carried out solely by the printer. While the printing cost refers only to the cost of the material. As regards the application phase of the covering material, the times refer to the labour of the staff, while the costs refer to the cost of labour and the cost of the material.

Table 6.13 Simulation of SLS process

Working phase – SLS	Times	Costs
Receiving order	5 min	1,67 €
Processing note	5 min	1,67 €
Managing of progress	5 min	1,67 €
Preparing the material	5 min	1,67 €
CAD design	30 min	12,50 €
G-Code generation	5 min	1,67 €
Preparation of the printer	5 min	1,67 €
Printing	20 h	140 €
Post-processing	1 h	20 €
Warehouse	5 min	1,67 €
Administration	5 min	1,67 €
Total	22 h 10 min	189,19 €

From the results of costs and times for the batch, costs and times relating to the single insole can be obtained:

- Time per insole: 5 h 32 min;
- Cost per insole: 47,30 €.

6.1.4 Comparative analysis

The results of the first analysis are presented through a normalization of them with respect to the highest values, and using Equation 5 and Equation 6:

Eq. 5 $$cost\_norm_i = \frac{cost_i * 100}{cost_{max}}$$

Eq. 6 $$time\_norm_i = \frac{time_i * 100}{time_{max}}$$

Results of this first comparative analysis are shown in Figure 6.4:

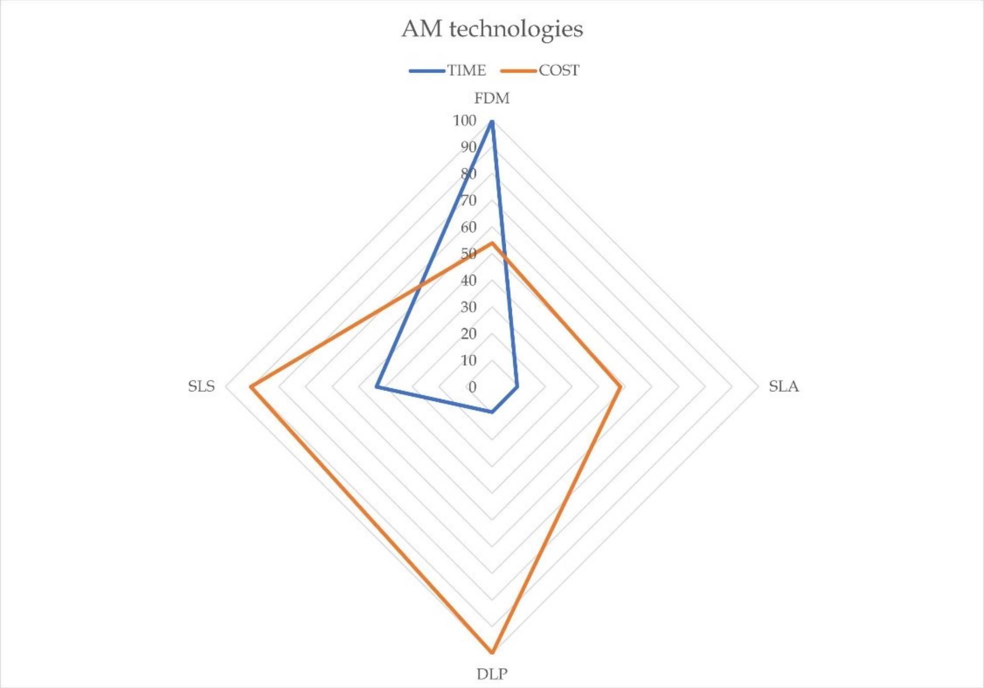

Figure 6.4 Comparative analysis, method 1. Values are normalized with respect to the maximum values

The second analysis uses traditional manufacturing process data as the baseline, and the 3D printing data is normalized to the baseline. Equation 7 and Equation 8 are used:

Eq. 7 $$cost\_norm_i = \frac{cost_i * 100}{cost_{trad}}$$

Eq. 8 $$time\_norm_i = \frac{time_i * 100}{time_{trad}}$$

Results of the second comparative analysis are shown in Figure 6.5, where the red line is the threshold represented by the time and cost values of the subtractive manufacturing of custom-made orthopaedic insoles.

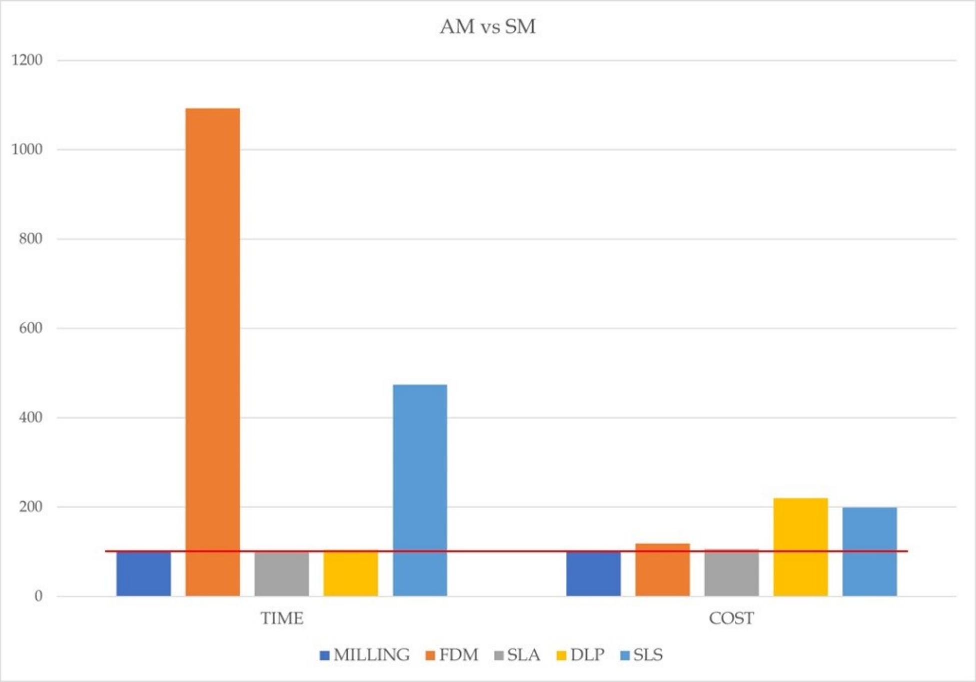

Figure 6.5 Comparative analysis, method 2. Values are normalized with respect to traditional manufacturing values

6.1.5 Prototypes

Prototypes has been developed using the same design file used in the simulations and lightened using an internal honeycomb structure. Figure 6.6 shows the render of the 3D project of the insole, developed in CAD.

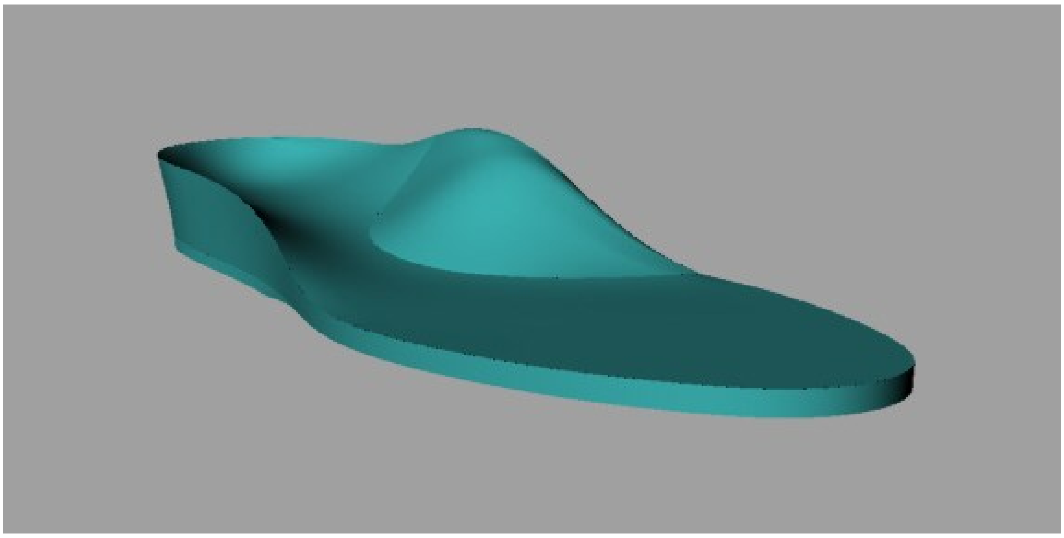

Figure 6.6 Render of the 3D model of the insole

The results regarding the prototypes are shown in Figure 6.7, Figure 6.8 and Table 6.14, where the numerical values of the measurements carried out on the geometries of the 3D printed insole and its weight are reported.

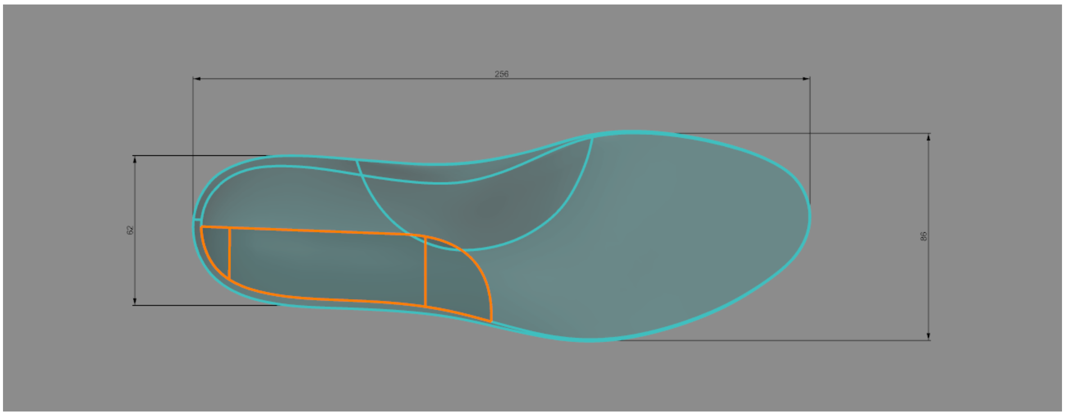

Figure 6.7 Measures of the 3D model along X and Y axes

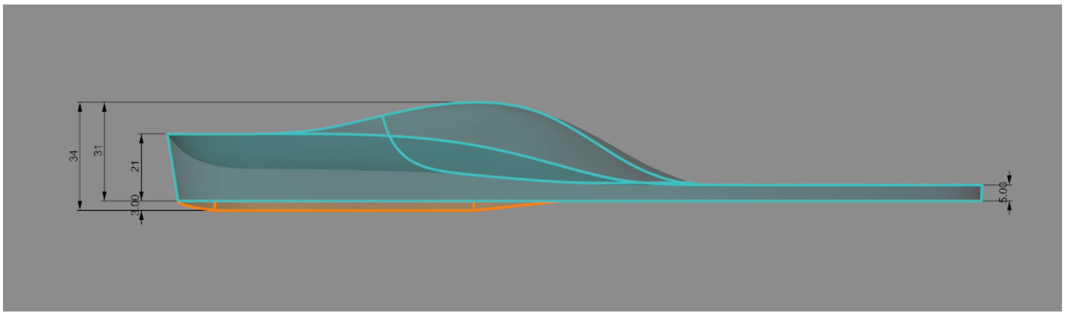

Figure 6.8 Measures of the 3D model along the Z axis

Table 6.14 Prototype measurements

Measure	Project	Prototype
Rear width	62 mm	61 mm
Front width	86 mm	86 mm
Insole length	256 mm	256 mm
Arch height	31 mm	31 mm
Rear height	21 mm	21 mm
Inclined plane height	3 mm	3 mm
Front height	5 mm	5 mm
Insole weight	20 g	100 g

The images of some measurements are shown from Figure 6.9 to Figure 6.14.

Figure 6.9 Rear width

Figure 6.10 Front width

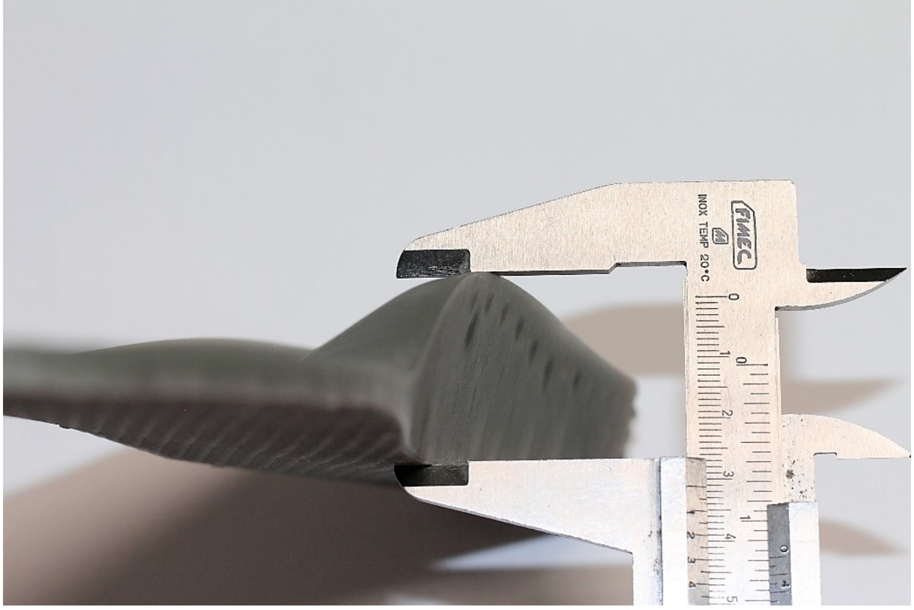

Figure 6.11 Arch height

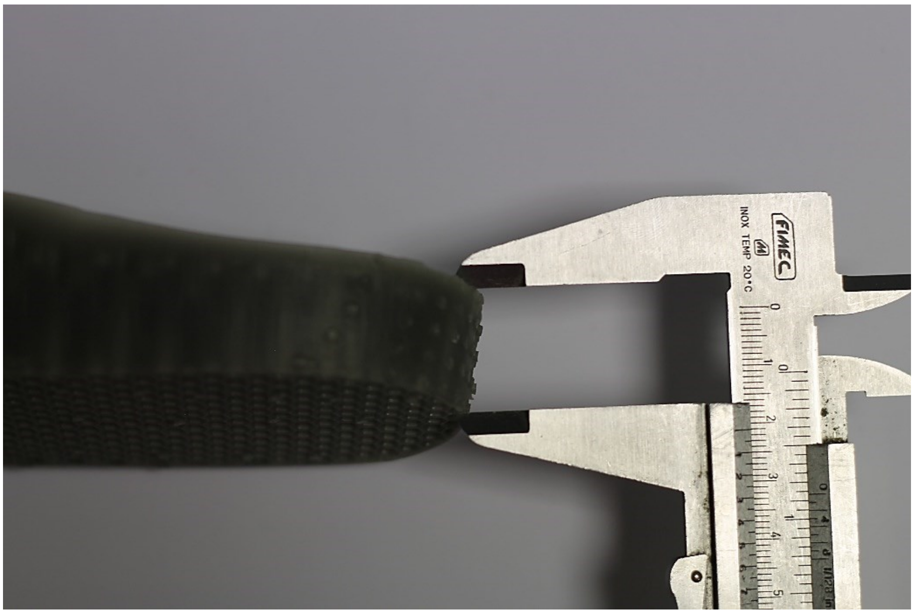

Figure 6.12 Rear height

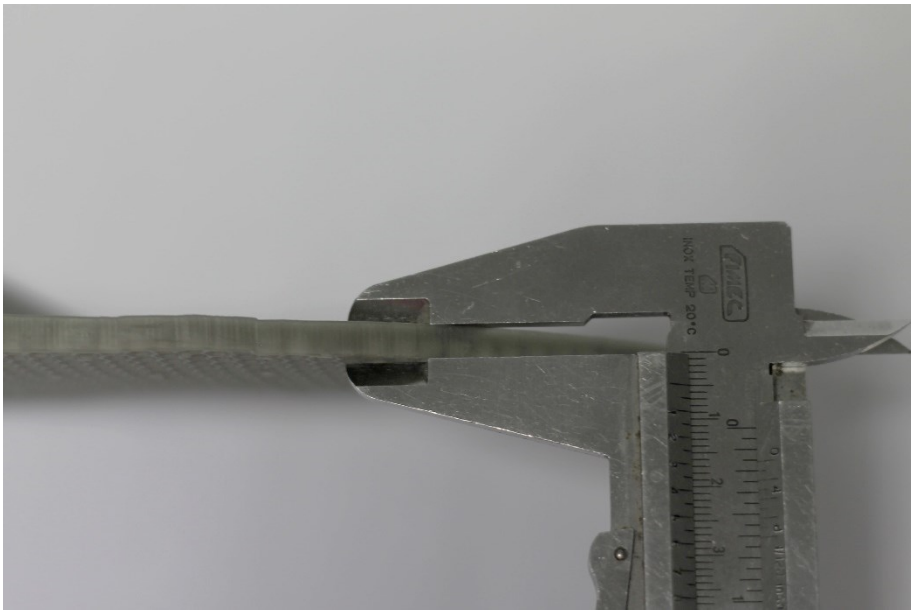

Figure 6.13 Front height

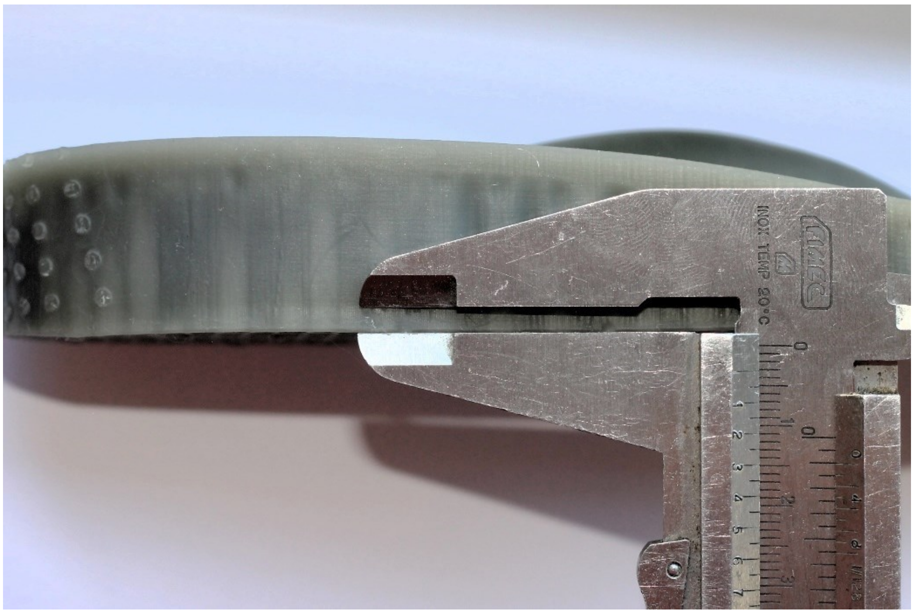

Figure 6.14 Inclined plane height

From Figure 6.15 to Figure 6.17 the images relating to the developed prototype are reported from all perspective. In particular, Figure 6.15 shows the lateral view of the prototype, from both left and right sides; Figure 6.16 shows the inferior and superior views of the 3D printed insole; Figure 6.16 shows the rear view, where the inclined plane and the points where the supports are placed can be appreciated, and a focus on the honeycomb cells.

Figure 6.15 a) left lateral view b) right lateral view

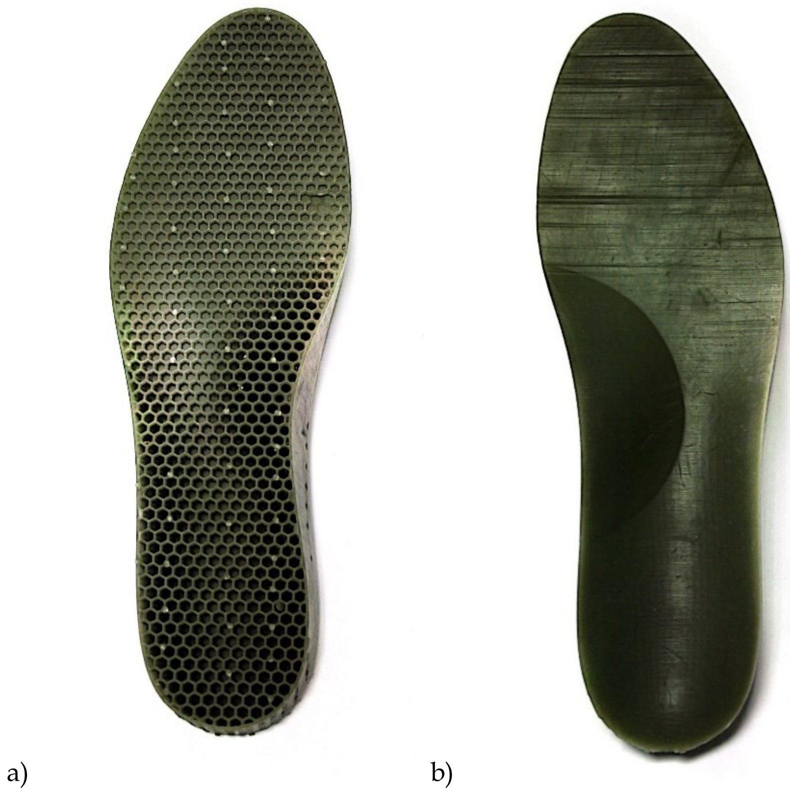

Figure 6.16 a) inferior view b) superior view

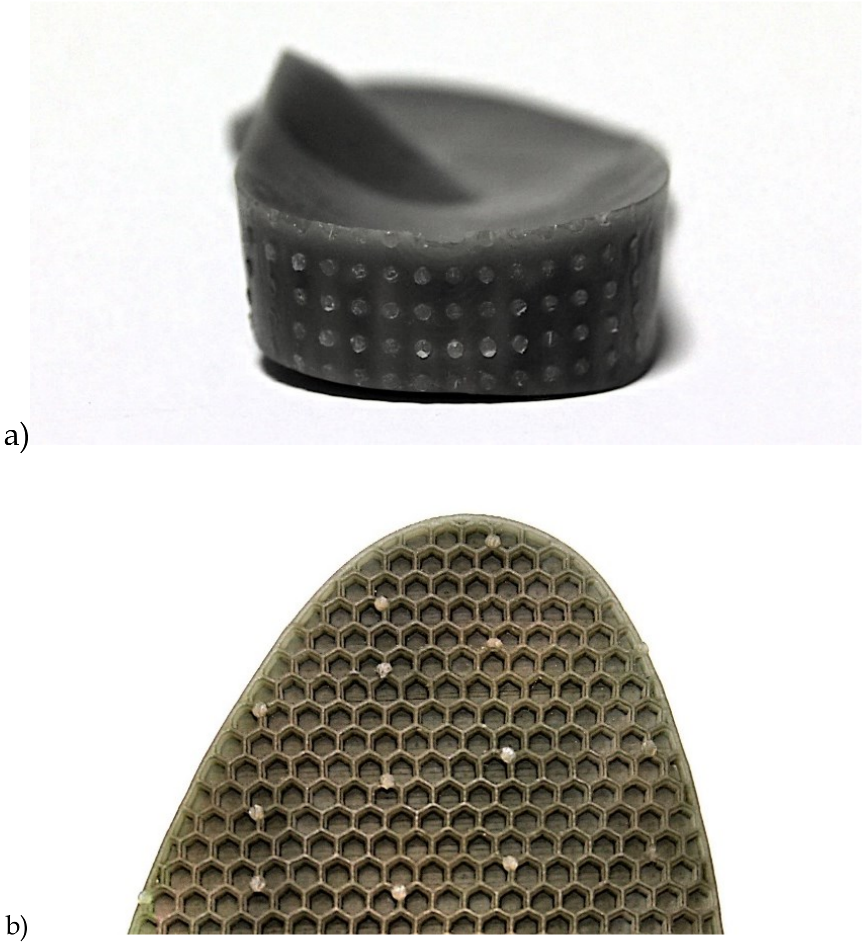

Figure 6.17 a) rear view b) honeycomb cells

6.2 Discussion

From the results presented in the previous section of this thesis, Thermoplastic Polyurethane can be seen as a possible material to be used in the 3D printing of custom-made orthopaedic insoles. TPU can be printed in the form of filament, TPU-like resin and powder, respectively with FDM, SLA and DLP, and SLS technologies. This kind of material is particularly suitable for this application as it is flexible, soft, durable and, in one case, without biocompatibility problems, respecting all the selection criteria imposed to the material, since they are crucial characteristics that the insole material must possess.

Subsequently, analysing the entire manufacturing process of 3D printing of insoles, it is possible to see how it is very similar to the traditional process, except for the phases that concern printing rather than milling. However, it is important to highlight that the post-processing phase differs depending on the type of technology used.

In the work carried out in this thesis, data from simulations are inserted into the overall additive manufacturing process of custom-made insoles, from which, taking into consideration the single insole, times and costs can be resumed as follows (Table 6.15):

Table 6.15 Summary of times and costs per insole

Technology	Times	Costs
FDM	12 h 40 min	26,40 €
SLA	1 h 12 min	25,60 €
DLP	1 h 11 min	52,33 €
SLS	5 h 32 min	47,30 €

Going deeper into the comparative analysis, it can be seen that:

- FDM technology requires the longest production times both compared to other AM technologies and compared to SM. As regards costs, they are among the lowest compared to other AM technologies and comparable to those of SM;
- SLA technology provides the lowest time values together with DLP and cost values that are the lowest among AM techniques. Both of these data are comparable to those of SM;
- DLP technology provides the lowest production times and comparable to both SLA and SM, but costs that are the highest among AM technologies and double those of SM;

- SLS technology has shorter times than FDM, but still higher than the MS threshold, and costs slightly lower than DLP, but still higher than the threshold value.

From these results, SLA technology can be identified as the one that respects all the constraints imposed by the limiting conditions on the material and technology, and it is also the only AM technology that is comparable to traditional manufacturing in terms of costs and production times. For these reasons, SLA technology is used for prototype development. From this latest analysis it is possible to see that the 3D printing in question managed to respect all the previously designed geometries, however encountering some problems:

- The upper surface of the insole is not perfectly smooth, on the contrary, there are lines and printing defects;
- Some support residues are visible on the rear part of the insole.

Despite this, these problems do not appear to be limiting, as more attention would be enough when removing the supports and the defects would not be visible if we consider the covering layer of the insole.

The only limitation presented by this prototype is its weight, which is 5 times higher than the weight of the corresponding traditional insole, and therefore does not respect the last limit condition imposed in this study.

7 Conclusions

The work presented in this thesis, and carried out in collaboration with Duna S.r.l., has the objective of evaluating additive manufacturing techniques that can be applied to the production of custom-made orthopaedic insoles. The method applied to this context involves the imposition of selection criteria on both the material and the technologies. In particular, the material selection criteria bring out the most appropriate material for the application in question, from which the technologies to be examined are then derived. FDM technology with TPU filament, SLA technology with TPU-like resin, DLP technology with TPU-like resin and SLS technology with TPU powder stand out.

These four combinations of material and technology were first examined through process analysis and simulations, from which information emerged regarding the batch, the cost of material, the printing time and the type and time of post-processing. By contextualising this information to the additive manufacturing process of customized insoles, it was possible to calculate the costs and times of the entire process and of the individual insole, which are subsequently used to carry out the two types of comparative analysis.

In particular, the combination of TPU-like resin and SLA technology appears to be the only one to respect all the limit conditions previously imposed for 3D printing, and at the same time also respects the threshold values of traditional manufacturing. For this reason it is chosen for the development of the prototype, which respects the designed geometries.

Up to this point of the work, every initial objective has been achieved, having found a technology and material pair that, in terms of material and technology characteristics, times, costs and precision of the printing geometries meets all the requirements.

The problem that emerges and cannot be solved in this work concerns the weight of the prototype, which, as explained in the previous chapters, is a factor of crucial importance for a custom-made orthopaedic insole, as a too heavy insole can aggravate the patient's situation rather than alleviate it.

With the aim to solve the problem of the excessive weight of the 3D printed insole, a possible solution to implement is to design an internal structure that can reduce the filling density, and consequently reduce the quantity of material used and the overall weight.

In conclusion, to improve these results and looking towards the future, it is possible to continue the research in the following ways:

- Combining the research carried out in this thesis with that concerning the study and design of internal structures capable of guaranteeing the right performance and lightness of the insole, thus overcoming the only problem that emerged during the course of this work;
- Once the evaluation of the technologies in combination with the study of the design of the insole have been completed, it is possible to produce wearable prototypes, so as to be able to evaluate their performance and comfort directly on people, both healthy and diseased.

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